

Atellica® Solution

Operator's Guide

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1 Legal Information

Legal Information

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The information in the printed customer documentation was correct at the time of issue. Access the Document Library for current information (Page 25 *Accessing Product Information in the Document Library*). Siemens Healthineers continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

THE CUSTOMER DOCUMENTATION INCLUDES INFORMATION ON THE SAFETY HAZARDS ASSOCIATED WITH USE OF THE SYSTEM AND PRECAUTIONS TO BE TAKEN TO AVOID SUCH HAZARDS. FAILURE TO OBSERVE WARNINGS OR USE OF THE SYSTEM IN A MANNER DIFFERENT FROM THAT SPECIFIED BY SIEMENS HEALTHINEERS MAY RESULT IN INJURY TO THE OPERATOR OR OTHER PERSONS. SEE WARNING AND HAZARD STATEMENTS.

2 Intended Use

Atellica Solution Intended Use

The Atellica® Solution is a multi-component system for *in vitro* diagnostic testing of clinical specimens. The system is intended for the qualitative and quantitative analysis of various body fluids, using photometric, turbidimetric, chemiluminescent, and integrated ion selective electrode technology for clinical use.

Atellica Sample Handler Intended Use

The Atellica® Sample Handler (SH) is intended for identifying samples, moving samples, storing calibrator and control samples, and tracking onboard samples for the Atellica Solution.

Atellica CH Analyzer Intended Use

The Atellica® CH Analyzer is an automated, clinical chemistry analyzer designed to perform *in vitro* diagnostic tests on clinical specimens. The system's chemical and immunochemical assay applications utilize photometric, turbidimetric and ion-selective electrode technology for clinical use.

Atellica IM Analyzer Intended Use

The Atellica® IM Analyzer is an automated, immunoassay analyzer designed to perform *in vitro* diagnostic tests on clinical specimens. The system's assay applications utilize chemiluminescent technology for clinical use.

3 Customer Documentation

Customer Documentation

The Atellica Solution is an automated system for professional use. The operator's guide provides information for the following clinical laboratory professionals who use the system:

- System operators who perform daily operating tasks such as preparing the system, processing samples, reviewing results, and performing maintenance
- System key operators who perform daily and other tasks such as reviewing control data, managing data files, and modifying system parameters

For more detailed information about the system features, refer to the system online help (Page 703 *Accessing Online Help*).

Analyzer and System Configuration

Certain features and procedures in the customer documentation are dependent on the analyzer and system configuration and may not be available.

Conventions

Customer documentation uses the following symbol and text conventions.

Symbol and text conventions

Convention	Description
BIOHAZARD	Biohazard statements alert the operator to potentially biohazardous conditions.
WARNING	Warning statements alert the operator to conditions that may cause severe personal injury or loss of life if operating procedures and practices are not strictly observed.
CAUTION	Caution statements alert the operator to conditions that may cause minor or moderate injury to the operator or patient, the possibility of damage to the system, or loss of data, if operating procedures and practices are not strictly observed.

Convention	Description
Note	Note statements alert the operator to important information that requires attention.
Bold	Bold type indicates commands on the user interface, keys, or the exact text that an operator needs to type.
Italic	Italic type refers to the title of a document or a section title in the customer documentation . If the title is not preceded by a page number, search for the title in the system online help.

Terminology

The following table describes the terminology in the customer documentation and the specific actions to perform when indicated.

Terminology and Actions

Term	Description
Select	Select an item using the touchscreen monitor or the pointing device.
Enter	Type the information using the keyboard and select **Enter**.
Scan	Move the external barcode scanner over a barcode to enter the information.
Navigate to	Move to the indicated screen to perform the task. Screen names are listed on the Navigator ().

Term	Description
Atellica® Solution	General reference to the Atellica product line or to an installed Atellica system.
Standalone system	A system with a sample handling subsystem that routes samples to a single analyzer.

Product Information

About Document Library

The Laboratory Diagnostics Document Library includes all customer-facing product information related to assays, consumables, reagents, calibrators, symbols, and the system.

From a web browser on a standalone computer or tablet, enter **www.siemens-healthineers.com/eIFU**.

If no Internet access, contact the local technical support provider.

Accessing Product Information in the Document Library

If no Internet access, contact the local technical support provider.

1. From a browser, such as Internet Explorer, on a standalone computer or tablet, enter **www.siemens-healthineers.com/eIFU**.
2. In the top-right corner, select **Login/Register > Login**.

   NOTE: If this is the first time entering the site, register (Page 26 *Registering for Online Services*).

   If Laboratory Diagnostics Document Library was selected during registration, this area displays after logging in. If not, select that service.
3. To filter documents by language, ensure preference is selected.
4. To filter search:

   a. In Products, select **Atellica Solution > Atellica Platform** or a specific Atellica product name.

   b. In Document types, select **System and Software Information**.

   c. In search bar, enter 1 or more words then select **ENTER**.

   NOTE: Suggested keywords include operator, release notes, quick guide, online help, LIS, LAS, or a specific assay name.

5. Select the appropriate documentation.
6. Select **Download** to print or save.

Registering for Online Services

If no Internet access, contact the local technical support provider.

1. From a web browser on a standalone computer or tablet, enter **www.siemens-healthineers.com/eIFU**.
2. In the top-right corner, select **Login/Register > Register**.
3. Select the appropriate services.

   NOTE: To locate Operator's Guides (OG) and Release Notes (RN), ensure that Laboratory Diagnostics Document Library is selected.
4. Enter all Personal Information and Business Contact in the mandatory fields.
5. Review all information and select **Submit**.
6. Select **Continue**.
7. Select **Submit**.
8. Wait for email confirmation and select the link to activate the account.
9. Enter a new password and select **Save new password**.
10. Select **Login/Register > Login**.
11. Enter email address and new password.

    NOTE: The services from step 3 display.
12. Select **Go to service**.
13. Enter a product, document name, document type, product code, or lot number, and select **ENTER**.

    NOTE: If appropriate, locate any additional documentation (Page 28 *Downloading Software Release Notes*) or (Page 703 *Accessing Online Help*).

Subscribing to Document Library Email Notifications

Subscribe to receive weekly email notifications for technical document updates in the selected Product groups. If no Internet access is available, contact the local technical support provider.

NOTE: The operator must be registered to subscribe to these notifications (Page 26 *Registering for Online Services*).

1. From a web browser on a standalone computer or tablet, enter **www.siemens-healthineers.com/eIFU.**.
2. In the top-right corner, select **Login/Register > Login**.
3. Select the appropriate Product groups.
4. Under Email Notifications, select **Subscribe**.

Configuring Document Library Favorites

Configure favorites to locate technical documents in the selected Product groups. If no Internet access, contact the local technical support provider.

1. From a web browser on a standalone computer or tablet, enter **www.siemens-healthineers.com/eIFU.**.
2. In the top-right corner, select **Login/Register > Login**.
3. From the top menu, select **Favorites > Create new favorites list**.
4. Enter a title for the list and select **Save list**.
5. From the top menu, select **Home** and then select the document category.
6. To search for documents, use the filter (Page 28 *Accessing the CH Operator-defined Assays Operator's Guide Supplement*) (Page 25 *Accessing Product Information in the Document Library*).
7. Select the check box next to the document to add to the favorite list.
8. Select **Add to Favorites**.
9. Select the list and select **Add to list > Done**.
10. To add more favorites, repeat steps 6–9.

Configuring Document Library My Products

Configure My Products to group technical documents by selected products. Email notifications for Laboratory Diagnostics & Point-of-Care are filtered based on the configured product selection.

If no Internet access, contact the local technical support provider.

1. From a web browser on a standalone computer or tablet, enter www.siemens.com/eIFU.
2. In the top-right corner, select **Login/Register > Login**.
3. From the top menu, select **My Products**.
4. Select **Laboratory Diagnostics & Point-of-Care**.
5. To display products, select the appropriate product line.

6. To add products under product line, select each appropriate product.
7. Repeat steps 5–6 for each additional product line.
8. To remove a product after configuration, select in the appropriate product row.

Accessing the CH Operator-defined Assays Operator's Guide Supplement

If no Internet access, contact the local technical support provider.

1. From a web browser on a standalone computer or tablet, enter **www.siemens-healthineers.com/eIFU**.
2. In the top-right corner, select **Login/Register > Login**.

   NOTE: If this is the first time entering the site, register (Page 26 *Registering for Online Services*).

   If Laboratory Diagnostics Document Library was selected during registration, this area displays after logging in. If not, select that service.
3. To filter documents by language, ensure the appropriate language is selected.
4. In Products, select **Atellica Solution > Atellica Platform**.
5. In the search bar, enter **CH Operator-Defined**, then select **ENTER**.
6. Select the appropriate guide.
7. Select **Download** to print or save the guide.

Downloading Software Release Notes

If no Internet access, contact the local technical support provider.

1. From a browser, such as Internet Explorer, on a standalone computer or tablet, enter **www.siemens-healthineers.com/eIFU**.
2. Select the country or region from the drop-down menu.
3. Select the language from the drop-down menu then select **Apply**.
4. In the top-right corner, select **Login/Register > Login**.

   NOTE: If this is the first time entering the site, register (Page 26 *Registering for Online Services*).

   If Laboratory Diagnostics Document Library was selected during registration, this area displays after logging in. If not, select that service.
5. To filter documents by language, ensure the appropriate langauge is selected.
6. In Products, select **Atellica Solution > Atellica Platform**.

7. In Document types, select **Instrument and Software Information > Release Notes**.
8. Select appropriate software version.
9. Select **Download** to print or save the release notes (RN).
10. To understand any known issues, software enhancements, or bug fixes, consult the RN.

Security Whitepaper

See the Atellica Solution Product Security Whitepaper for additional information about specifications for software, hardware, network characteristics, and security controls. This technical information is not part of the instructions for use and is intended for the information technology or security professional.

Customer Deliverables for Atellica Solution Configurations

A variety of information is available to ensure the safe and effective setup and operation of Atellica Solution configurations. The following table provides the name of the document as it displays on the Document Library (Page 25 *About Document Library*), www.siemens-healthineers.com/eifu, for the appropriate system configurations.

NOTE: The Atellica Solution Online Help Installer is a software package that Smart Remote Services (SRS) delivers to the system and is not available on the Document Library. After delivery, the operator installs it on the system.

Customer Deliverable	CH Analyzer + DL	IM Analyzer + DL	SH Configurations
Atellica Solution Online Help Installer	•	•	•
Atellica Solution Online Help (PDF or EPUB)	•	•	•
Atellica Solution Operator's Guide	•	•	•
Atellica Solution Software Release Notes	•	•	•
Atellica® Solution with Sample Handler Quick Guide	—	—	•
Atellica® Solution with Direct Load Quick Guide	•	•	—
Atellica CH Analyzer Operator-Defined Supplement	•	—	CH Analyzer only

Customer Deliverable	CH Analyzer + DL	IM Analyzer + DL	SH Configurations
Atellica CH TDef Enhancement Customer Information	•	—	CH Analyzer only
Atellica CH Assay Chart	•	—	CH Analyzer only
Atellica IM TDef Enhancement Customer Information	—	•	IM Analyzer only
Atellica IM Assay Chart	—	•	IM Analyzer only
Atellica Sample Handler Calibrator-QC Storage and Stability	—	—	•
Atellica Solution Product Security Whitepaper	•	•	•
Atellica Solution LIS Interface Guide	•	•	•
Atellica® CH Analyzer LOINC Customer Information	•	—	CH Analyzer only
Atellica® IM Analyzer LOINC Customer Information	—	•	IM Analyzer only
Atellica Solution LAS Interface Guide	—	—	•
CH System Fluids - Atellica CH	•	—	CH Analyzer only
IMT System Fluids - Atellica CH	•	—	CH Analyzer only
IM System Fluids - Atellica IM	—	•	IM Analyzer only

NOTE: Assay instructions for use, including traceability and uncertainty information, are available from the Document Library under each individual assay.

Contact Siemens Healthineers directly for the following documents:

- Atellica Solution Spec Sheets
- Atellica Solution Maintenance Guide
- Atellica Solution Assay Overview Charts
- Atellica Solution Carryover Study White Paper

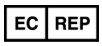
4 Symbols

Symbols

The symbols on the system identify the location of certain components, product information, and display warnings for proper operation.

This table provides information, including the Standards Development Organizations (SDOs) reference numbers and sources, for the symbols that may appear on the interior or exterior of the system or on the system packaging. For more information about an SDO symbol, consult the source information provided. Siemens Healthineers developed the proprietary symbols.

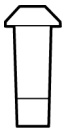
For symbols on the assay packaging, refer to the assay IFU.

Symbol	Symbol title	Source
Product Identification		
	Manufacturer	5.1.1[a]
	Authorized representative in the European Community/ European Union	5.1.2[a]
	Authorized representative in Switzerland	Proprietary
	Date of manufacture	5.1.3[a]
	Use-by date	5.1.4[a]
	Batch code	5.1.5[a]
	Catalog number	5.1.6[a]
	Serial number	5.1.7[a]
	Contains sufficient for <n> tests	5.5.5[a]
	Unique Device Identifier	5.7.10[a]

Symbol	Symbol title	Source
Compliance		
	Consult instructions for use	5.4.3[a]
	Consult instructions for use	5.4.3[a]
	Consult electronic instructions for use	5.4.3[a]
	*In vitro* diagnostic medical device	5.5.1[a]
RxOnly	Prescription device (US Only)	FDA[d]
	CE Mark	EC IVDR[f]
	Eurasian Conformity Mark	Eurasian Customs Union[g]
	Ukrainian Conformity Mark	Ukrainian Cabinet of Ministers[h]
	Ukrainian Conformity Mark with notified body ID number	Ukrainian Cabinet of Ministers[h]
	NRTL TÜV SÜD Mark	TUV[i]
	Environmentally Friendly Use Period	People's Republic of China RoHS[j]
	WEEE Recycle	EC WEEE[k]
	UK Conformity Assessment Mark	Great Britain[n, o, p]
Package Markings		
	Keep away from sunlight	5.3.2[a]

Symbol	Symbol title	Source
	Fragile, handle with care	5.3.1[a]
	Keep dry	5.3.4[a]
	Temperature Limit	5.3.7[a]
	Lower limit of temperature	5.3.5[a]
	Upper limit of temperature	5.3.6[a]
	Do not freeze	Proprietary
	Measure Humidity	0224[b]
	This way up	0623[b]
	Do not stack	2402[b]
	Stacking limit by number	2403[b]
	Center of gravity	0627[b]
	Do not use a forklift	Proprietary
	Use no forks	2406[b]
	Do not use a hook	Proprietary
	Use no hooks	0622[b]

Symbol	Symbol title	Source
	First in First Out: Use oldest inventory first	Proprietary
	Do not re-use	5.4.2[a]
Rev.	Revision	Proprietary
	General symbol for recovery/recyclable	1135[b]
	RESY: Recycling material	RESY[e]
	A-LYTE® IMT Standard B + Salt Bridge	Proprietary
	A-LYTE® IMT Standard A	Proprietary
	A-LYTE® IMT Diluent	Proprietary
	CH Diluent	Proprietary
	CH Wash	Proprietary
	CH Conditioner	Proprietary
	CH Cleaner	Proprietary
	IM Wash	Proprietary
	IM Cleaner	Proprietary
	IM Acid	Proprietary
	IM Base	Proprietary
	CH dilution segments	Proprietary

Symbol	Symbol title	Source
	CH reaction segments	Proprietary
	IM cuvettes: Quantity indicators display adjacent to the symbol	Proprietary
	IM sample tips: Quantity indicators display adjacent to the symbol	Proprietary
	Atellica Solution Tube-Top Sample Cups • 1 mL for use with 13-mm diameter sample tubes • 2 mL for use with 16-mm diameter sample tubes	Proprietary
	Do not use with 16-mm diameter sample tubes	Proprietary
	Mixing of substances	5657[l]
	Ensure sample tips are not damaged before loading	Proprietary
	Sample tip tray is secured on all 4 tip tray hooks	Proprietary
	Sample tip tray is not secure on all 4 hooks	Proprietary
Warnings		
	Warning; Biological hazard	W009[m]
	Biological risks	5.4.1[a]

Symbol	Symbol title	Source
	Caution	5.4.4[a]
	Warning; Electricity	W012[m]
	Entanglement hazard: Moving parts can cause entrapment and serious injury	Proprietary
	Warning; Sharp element	W022[m]
	Warning; Moving belt hazard	Proprietary
	Warning; Pinch hazard	Proprietary
	Warning; Hot surface	W017[m]
	Warning; Ultraviolet (UV) light hazard	Proprietary
	Warning; Magnetic field	W006[a]
	Warning; Impact hazard	Proprietary
	Corrosion	GHS05[c]
	Environment	GHS09[c]
	Exclamation mark	GHS07[c]
	Health hazard	GHS08[c]

Symbol	Symbol title	Source
	Flame	GHS02[c]
	Flame over circle	GHS03[c]
	Skull and crossbones	GHS06[c]
	No pacemakers: Strong magnetic fields are dangerous to pacemakers and other medical implants	Proprietary
	No access for people with active implanted cardiac devices	P007[m]
Electrical		
	Alternating current	5032[l]
	Direct current	5033[l]
	Protective earth; protective ground	5019[l]
	Frame or chassis connection	5020[l]
	"ON" (power)	5007[l]
	"OFF" (power)	5008[l]

[a] International Standard Organization (ISO). ISO 15223-1:2020-04. Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.

[b] International Standard Organization (ISO). ISO 7000: 2019. Graphical Symbols for use on equipment — Registered symbols.

[c] Globally Harmonized System of Classification and Labeling of Chemicals (GHS). *Official Journal of the European Union*, 31.12.2008, REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008:325–328.

[d] Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.

[e] RESY Organisation für Wertstoffent-sorgung GmbH. Available at: www.resy.de. Accessed January 26, 2017.

[f] In-Vitro Diagnostic Regulation (IVDR), EU 2017/746.

[g]On Common Mark of Products Circulation in the Market of the Eurasian Economic Union Member-States and its Application Procedure (as amended by March 17, 2016) Decision of the Customs Union Commission No.711 as of July 15, 2011.

[h]Decrees of the Ukrainian Cabinet of Ministers of 02/10/2013 No. 753 (MDs) and No. 754 (IVD Devices and Reagents).

[i]TÜV SÜD Certification Marks. Available at: https://www.tuev-sued.de/product-testing/-services/markets_and_competition/quality_and_test_marks/download_center.

[j] People's Republic of China SJIT 11364-2014, *Marking for the Restriction of the Use of Hazardous Substances in the Electrical and Electronic Product*.

[k] European Commission Directive 2012/19/EU. Waste Electrical and Electronic Equipment Directive (WEEE).

[l] International Electrotechnical Commission (IEC). IEC 60417-1:2002 Graphical symbols for use on equipment - Part 1: Overview and Application.

[m] International Standard Organization (ISO). ISO 7010:2002-06 Graphical symbols - Safety colors and safety signs - Registered safety signs.

[n] Supply of Machinery (Safety) Regulations 2008: Great Britain.

[o] Electromagnetic Compatibility Regulations 2016: Great Britain.

[p] Electrical Equipment (Safety) Regulations 2016: Great Britain.

5 Safety

Safety

This chapter provides information about the following hazards:

- Biohazards
- LEDs
- Mechanical hazards
- Electrical hazards
- Hot surfaces

This summary is based on the guidelines developed by the Centers for Disease Control, the Clinical and Laboratory Standards Institute Document M29-A4, *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline*–4th edition, and the Occupational Safety and Health Administration's Bloodborne Pathogens Standard.[1–3]

Dispose of hazardous or biologically contaminated materials according to the practices of the laboratory. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Biohazard Safety

This summary is for general information only. This information does not replace or change laboratory or hospital biohazard control procedures.[1–3]

A biohazardous condition is any situation involving infectious, biological agents, such as the hepatitis B virus, the human immunodeficiency virus, and the tuberculosis bacterium. These infectious agents may be present in human blood, blood products, and other bodily fluids.

The following are the major sources of contamination when handling potentially infectious agents:

- Needlesticks
- Hand-to-mouth contact
- Hand-to-eye contact
- Direct contact with superficial cuts, open wounds, and other skin conditions that may permit absorption into subcutaneous skin layers
- Splashes or aerosol contact with skin and eyes

To prevent accidental contamination in a clinical laboratory, adhere to the following procedures:

- Wear gloves while servicing parts of the system that have contact with body fluids such as serum, plasma, urine, whole blood, or cerebral spinal fluid.
- Wash hands before going from a contaminated area to a noncontaminated area, or when removing or changing gloves.
- Perform procedures carefully to minimize aerosol formation.
- Wear facial protection when splatter or aerosol formation is possible.
- Wear personal protective equipment such as safety glasses, gloves, laboratory coats, and aprons when working with possible biohazard contaminants.
- Keep hands away from face.
- Cover all cuts and wounds before starting any work.
- Dispose of contaminated materials according to the laboratory's biohazard control procedures.
- Use a 10% bleach solution to disinfect tools and other items that have been near any part of the system sample path or waste area.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses while in the laboratory.
- Do not mouth pipette any liquid, including water.
- Do not place tools or any other items in mouth.
- Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands.

To prevent needle stick injuries, do not recap, bend, cut, break, or remove needles from disposable syringes or otherwise manipulate needles by hand.

Biohazard Safety References

1. CDC Update: universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in health-care settings. *MMWR*, 1988; 37:377–382, 387, 388.
2. Clinical and Laboratory Standards Institute (formerly NCCLS). *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline*—4th ed. CLSI Document M29-A4. [ISBN 1-56238-961-0]. Wayne, PA: Clinical and Laboratory Standards Institute, 2014).
3. Federal Occupational Safety and Health Administration. Bloodborne Pathogens Standard. 29 e-CFR 1910. 1030.

LED Classification

IEC 62471 classifies the LEDs in this system as exempt.[1,2] The Exempt group classification states the lamps and LEDs do not pose any photobiological hazard.

LED Classification References

1. IEC 61010-2-101:2015. Safety requirements for electrical equipment for IEC measurement, control, and laboratory use. Part 2-101: Particular requirements for in-vitro diagnostic (IVD) medical equipment. Geneva, Switzerland.
2. IEC 62471:2006 Photobiological safety of lamps and lamp systems, Geneva, Switzerland.

About Electrical Safety



ELECTRICAL HAZARD

Do not operate modules without a protective grounding connection that prevents electrical shock. Electrical shock can cause equipment damage and bodily harm. Use caution when working around these locations or contact a local technical support provider for more information about using a protective grounding connection and avoiding electrical shock hazards.



CAUTION

Do not perform system maintenance procedures that require the power off without powering off the system. Performing these procedures with the system powered on can result in exposure to shock hazards or system damage.



CAUTION

Do not place any objects that interfere with access to the power connection. Interference can damage the electrical cord or provide intermittent power to the system and prevent access to the system's main power disconnect.

Sufficient space must be around the system to access all panels and doors. The operator must have clear access to the power connection. The power connection is the safety disconnect for the system in case of emergency.

About System Installation and Relocation

CAUTION

Do not move or install the system. Unauthorized movement or installation can either damage the system or affect its alignment and void the warranty and service contract. A local technical support provider must move or install the system.

Contact a local technical support provider to install or to relocate the system within the laboratory.

About Cleaning Materials

CAUTION

Do not use any decontamination or cleaning agents unless approved by Siemens Healthineers. Using unapproved agents can result in equipment damage.

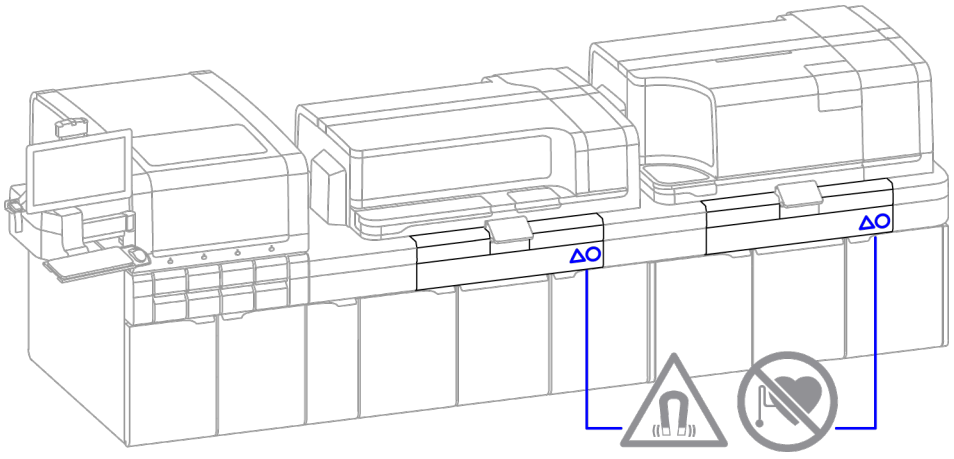
The system cleaning procedures require the cleaning materials listed in each procedure. Siemens Healthineers has approved these cleaning materials for use on the system. Operators should only use the cleaning materials specified in the system cleaning procedures.

Location of Safety Hazard Symbols on the System Exterior

Symbols on the exterior of the SH and the Atellica Magline® Transport indicate possible safety hazards the operator may encounter while operating the system.

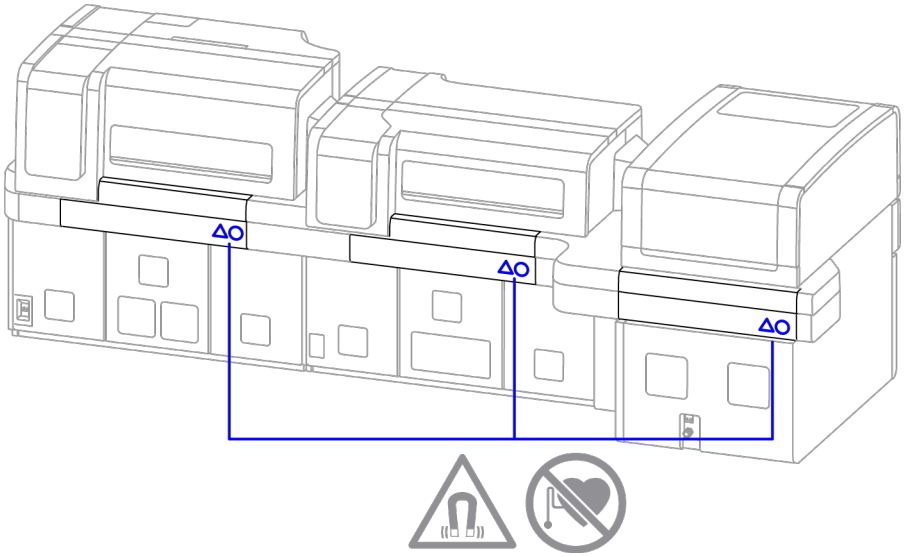
The following figures show the locations of these safety hazard symbols.

Symbols on the system exterior (front view)



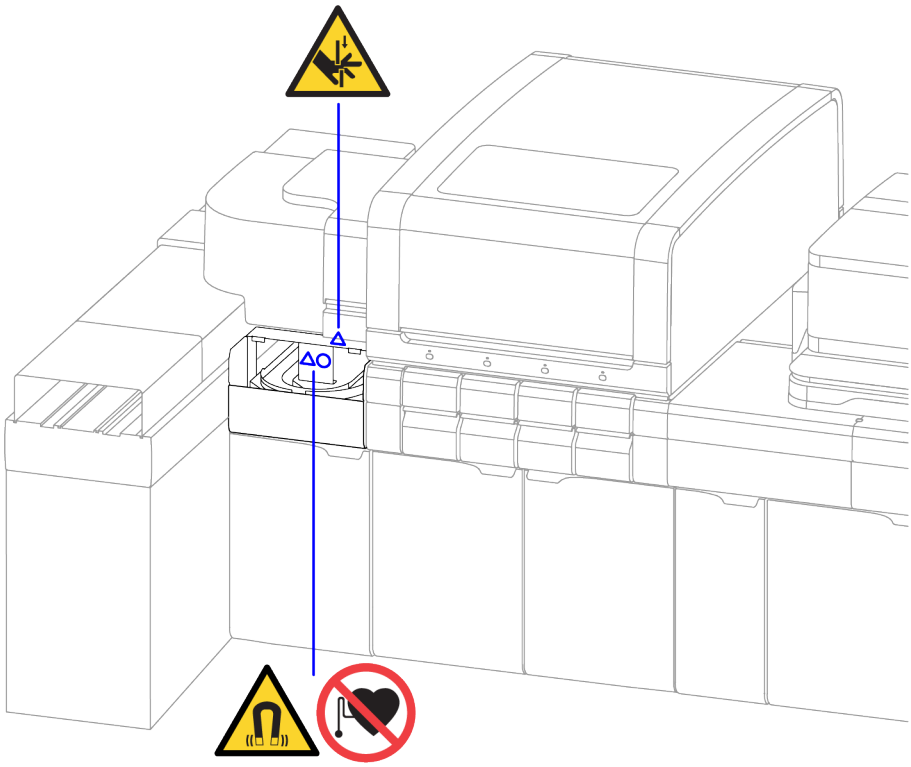
Safety symbol	Hazard description
	Warning; Magnetic field / No pacemakers (Page 87 *Safety Hazards*)

Symbols on the system exterior (back view)



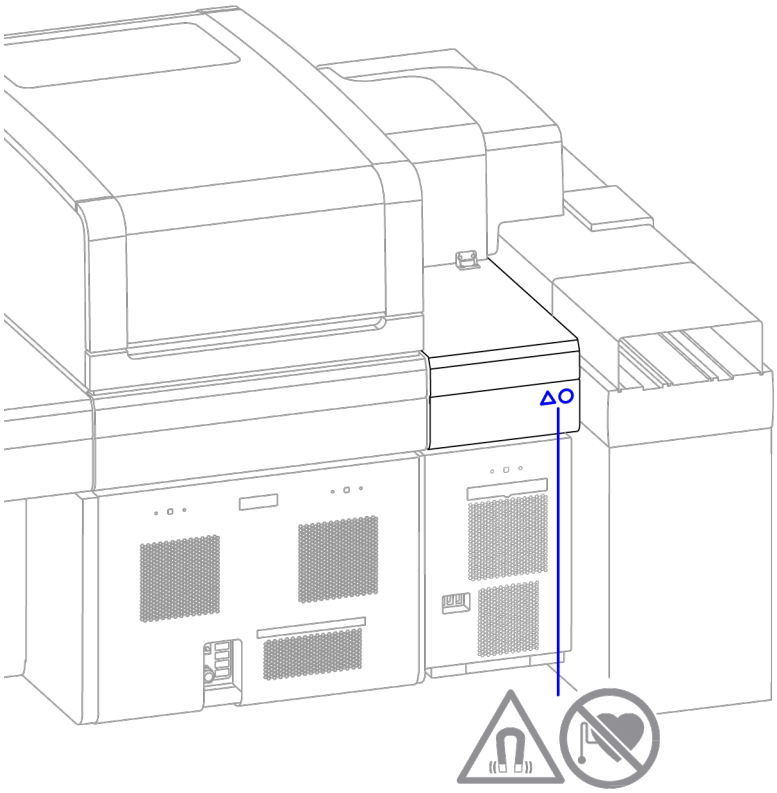
Safety symbol	Hazard description
	Warning; Magnetic field / No pacemakers (Page 87 *Safety Hazards*)

Symbols on the SHC (front view)



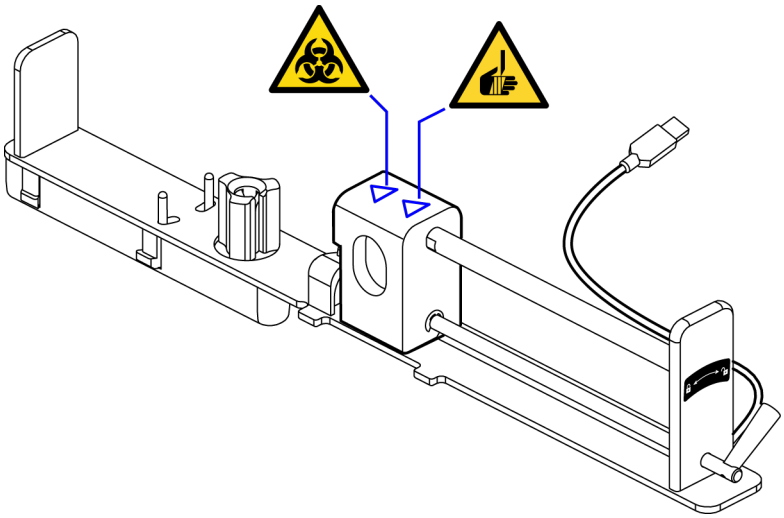
Safety symbol	Hazard description
	Warning; Pinch hazard (Page 87 *Safety Hazards*)
	Warning; Magnetic field / No pacemakers (Page 87 *Safety Hazards*)

Symbols on the SHC (back view)



Safety symbol	Hazard description
	Warning; Magnetic field / No pacemakers (Page 87 *Safety Hazards*)

Symbols on the ESL carrier



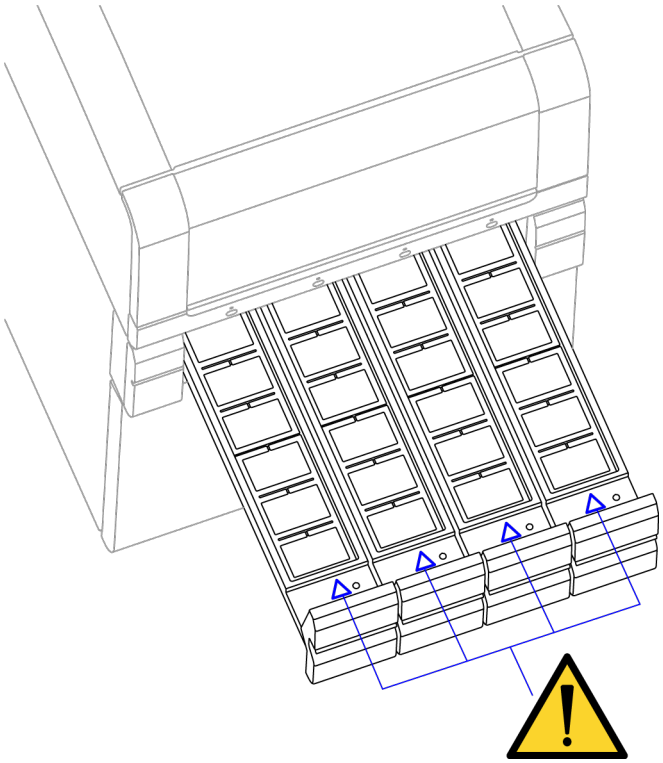
Safety symbol	Hazard description
	Biohazard (Page 87 *Safety Hazards*)
	Warning; Sharp element hazard (Page 87 *Safety Hazards*)

Location of Safety Hazard Symbols on the SH, SHC, and Atellica Magline Transport Interior

Symbols on the interior of the SH, SHC, and Atellica Magline Transport indicate possible safety hazards the operator may encounter while operating and maintaining the system.

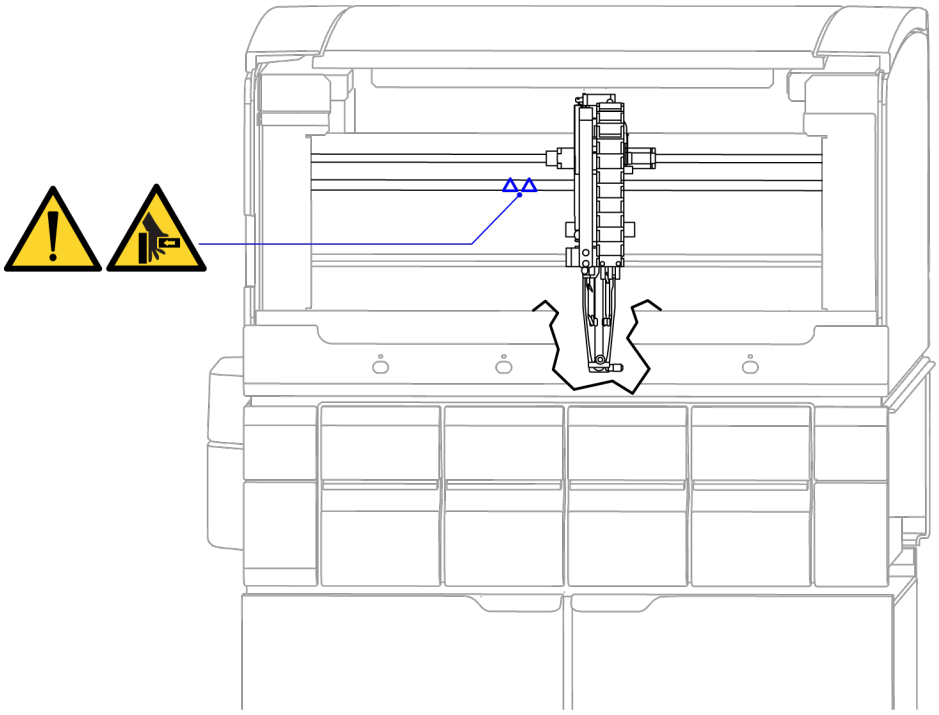
The following figures show the locations of these safety hazard symbols.

Symbols on the SH drawers



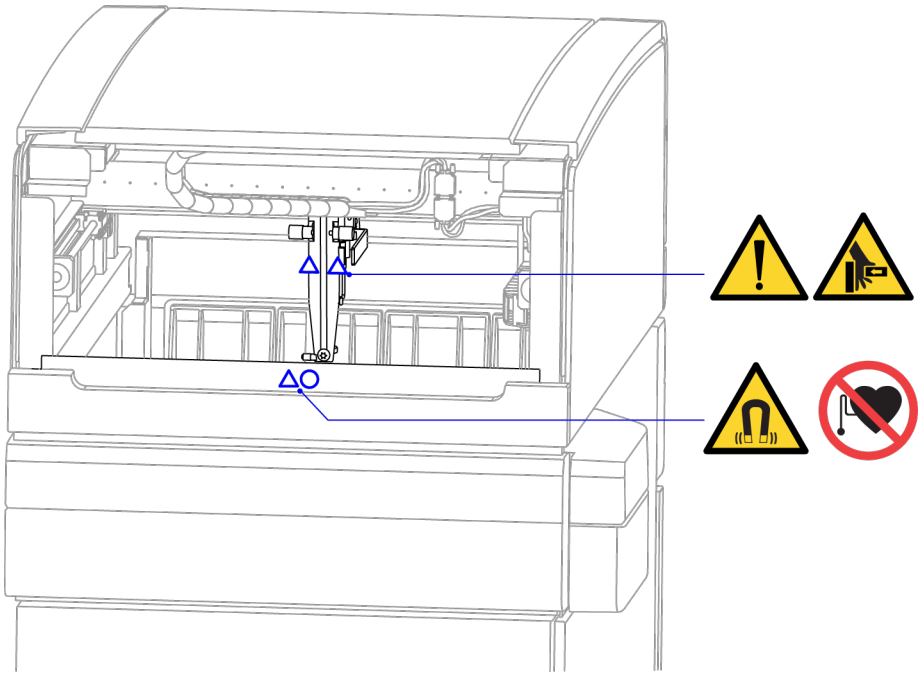
Safety symbol	Hazard description
⚠	Caution (Page 87 *Safety Hazards*)

Symbols on the robot



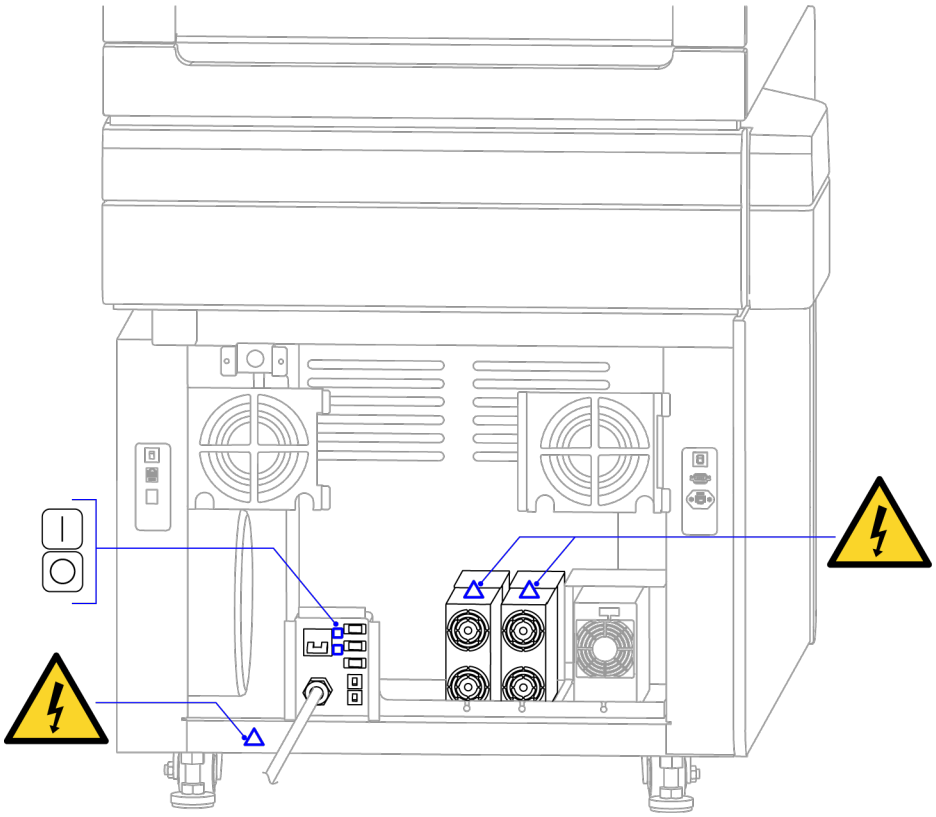
Safety symbol	Hazard description
	SH Robot Impact Hazard (Page 87 *Safety Hazards*)

Symbols on the SH (back top view)



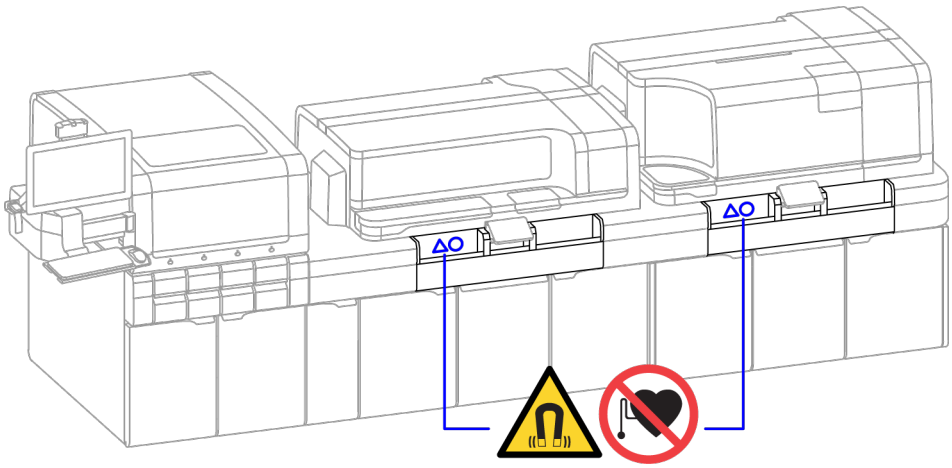
Safety symbol	Hazard description
	SH Robot Impact Hazard (Page 87 *Safety Hazards*)
	Warning; Magnetic Field / No Pacemakers (Page 87 *Safety Hazards*)

Symbols on the SH (back bottom view)



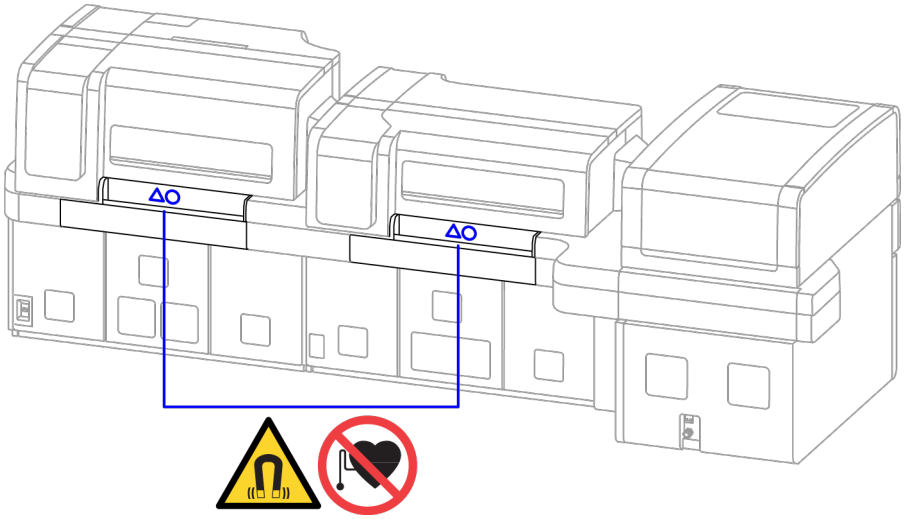
Safety symbol	Hazard description
	Electric Shock Hazard (Page 87 *Safety Hazards*)

Symbols on the Atellica Magline Transport (front view)



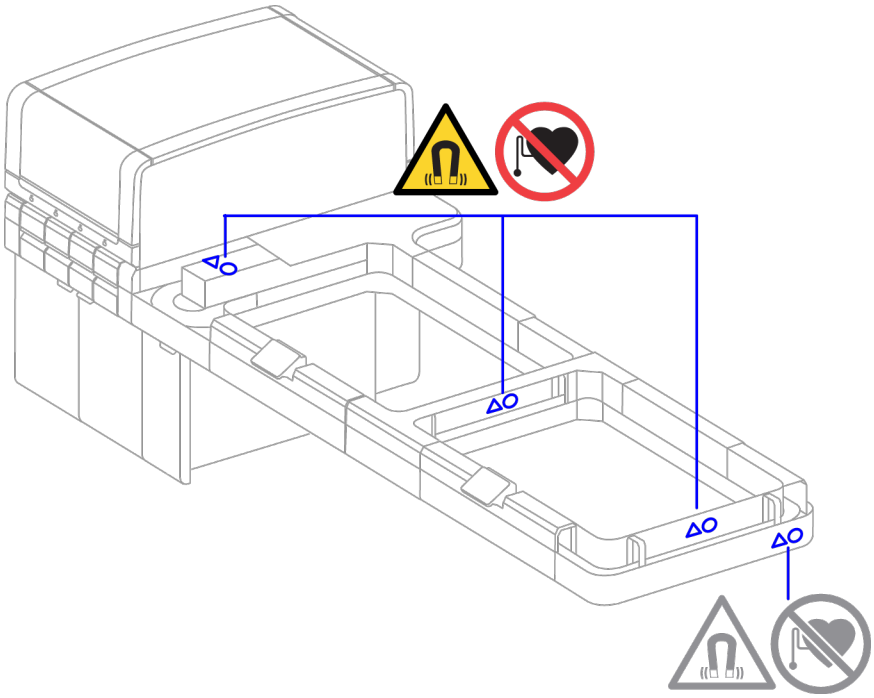
Safety symbol	Hazard description
	Warning; Magnetic Field / No Pacemakers (Page 87 *Safety Hazards*)

Symbols on the Atellica Magline Transport (back view)



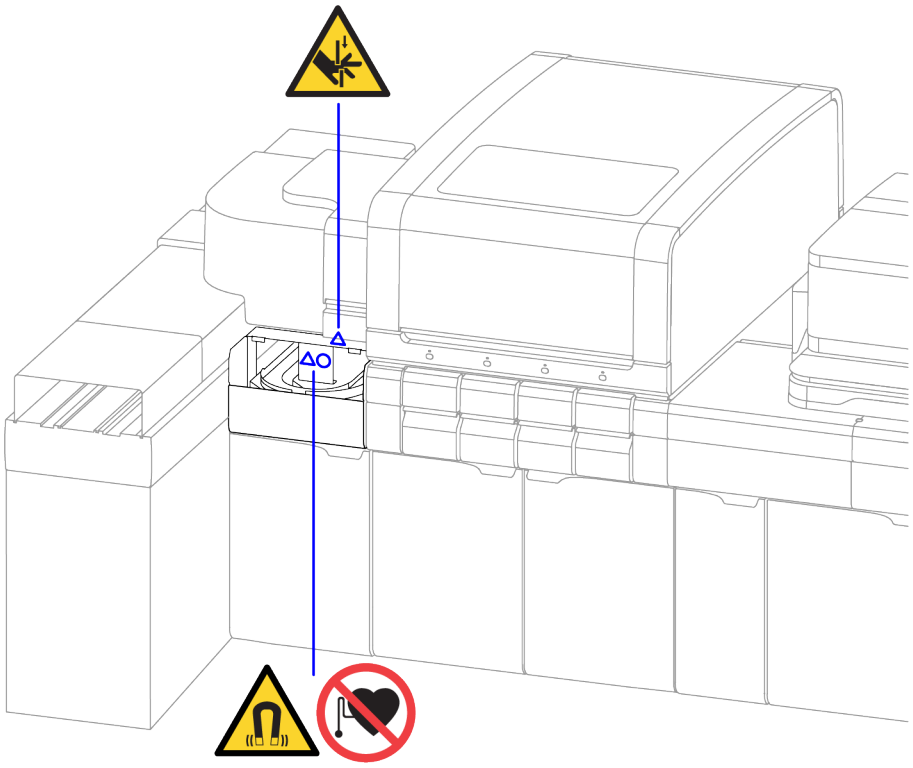
Safety symbol	Hazard description
	Warning; Magnetic Field / No Pacemakers (Page 87 *Safety Hazards*)

Symbols on the Atellica Magline Transport (side view)



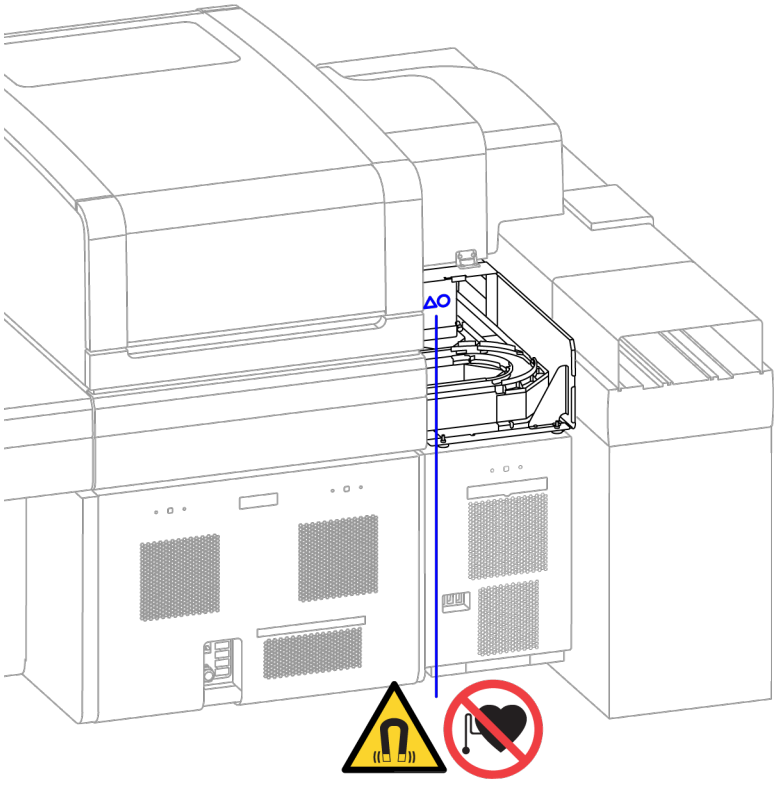
Safety symbol	Hazard description
	Warning; Magnetic Field / No Pacemakers (Page 87 *Safety Hazards*)

Symbols on the SHC (front view)



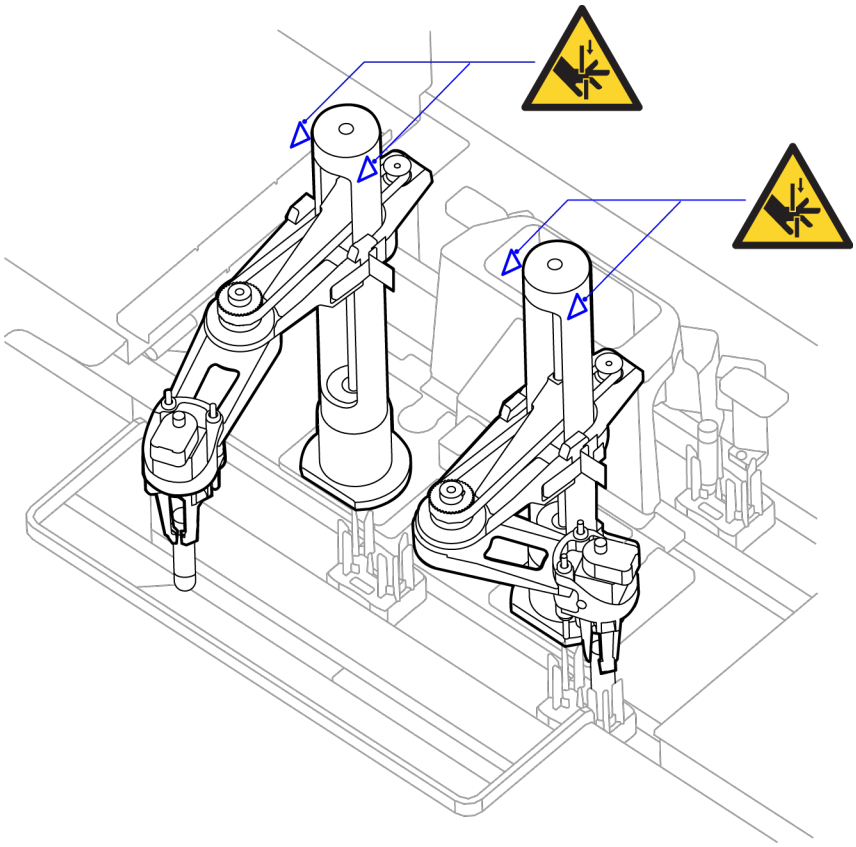
Safety symbol	Hazard description
	Warning; Pinch hazard (Page 87 *Safety Hazards*)
	Warning; Magnetic Field / No Pacemakers (Page 87 *Safety Hazards*)

Symbols on the SHC (back view)



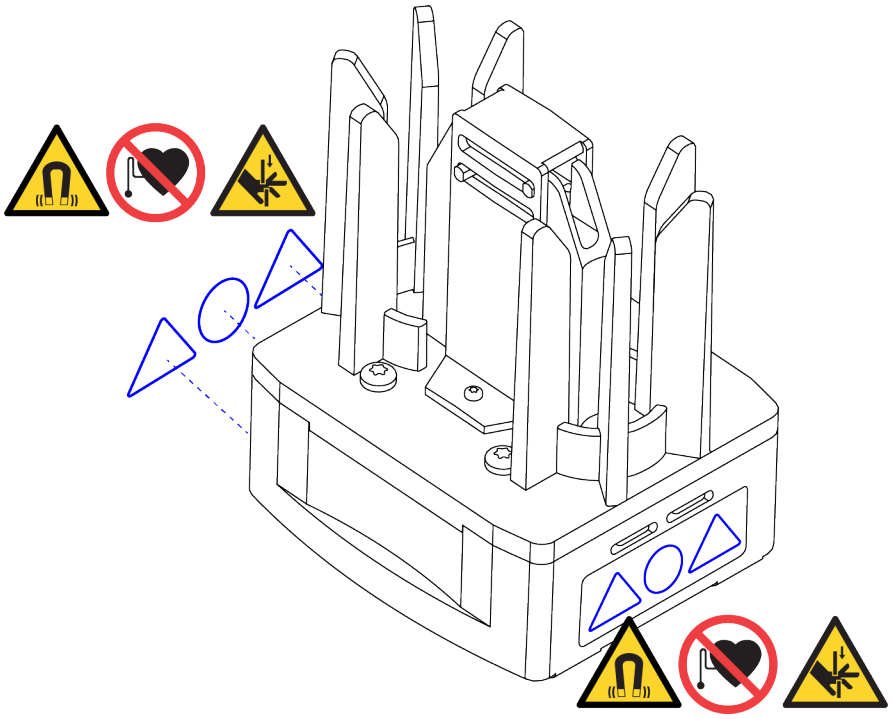
Safety symbol	Hazard description
	Warning; Magnetic Field / No Pacemakers (Page 87 *Safety Hazards*)

Symbols on the SHC robots



Safety symbol	Hazard description
	Warning; Pinch hazard (Page 87 *Safety Hazards*)

Symbols on the carrier



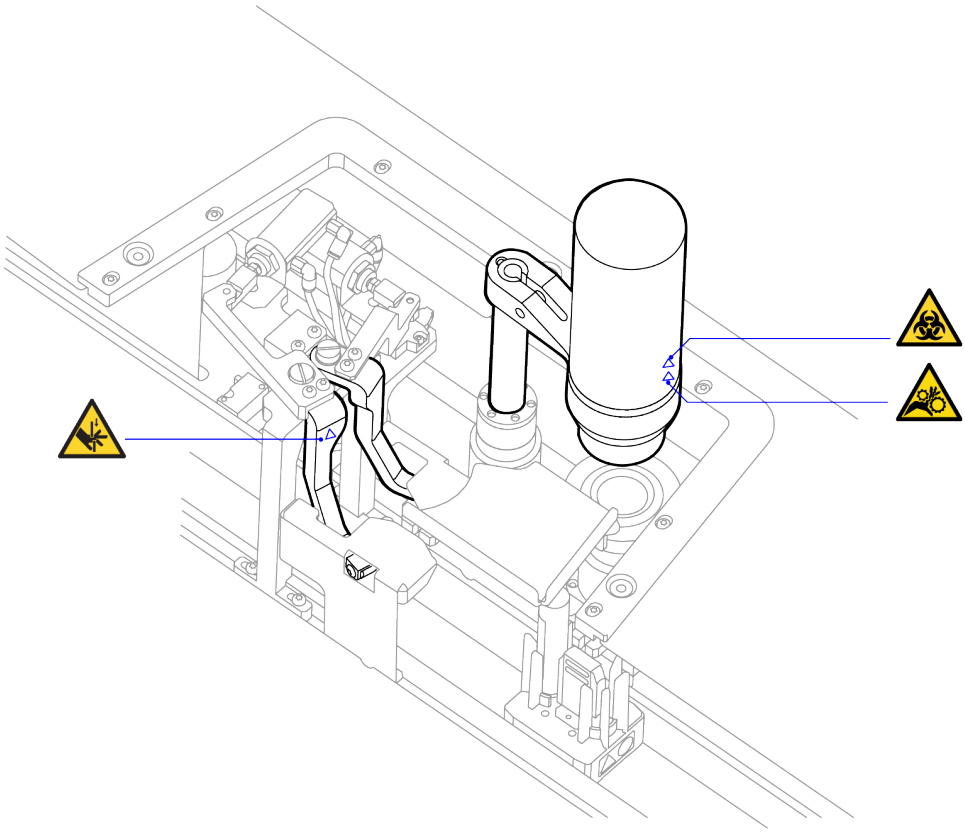
Safety symbol	Hazard description
	Warning; Magnetic Field / No Pacemakers / Carrier Pinch Hazard (Page 87 *Safety Hazards*)

Location of Safety Hazard Symbols on the Decapper Interior

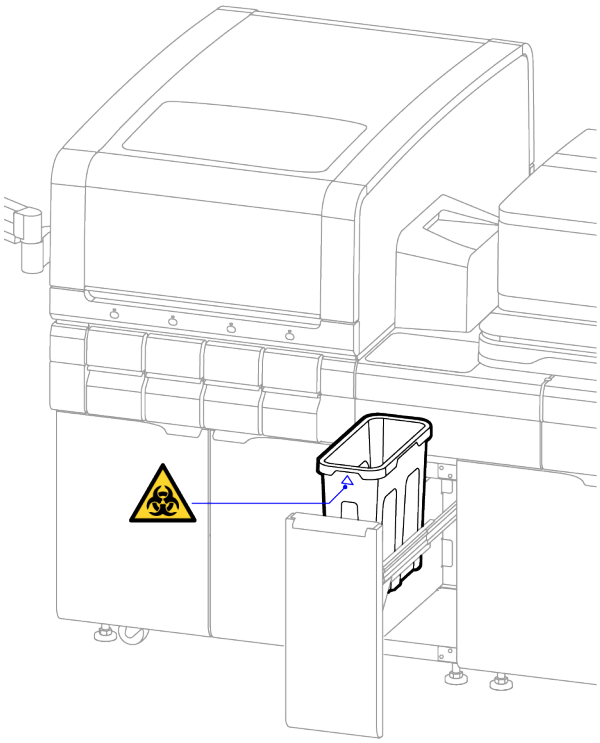
Symbols on the interior of the Decapper indicate possible safety hazards the operator may encounter while operating and maintaining the module.

The following figures show the locations of these safety hazard symbols. For descriptions of the symbols, see (Page 31 *Symbols*).

Decapper open cover



Decapper chute waste drawer open

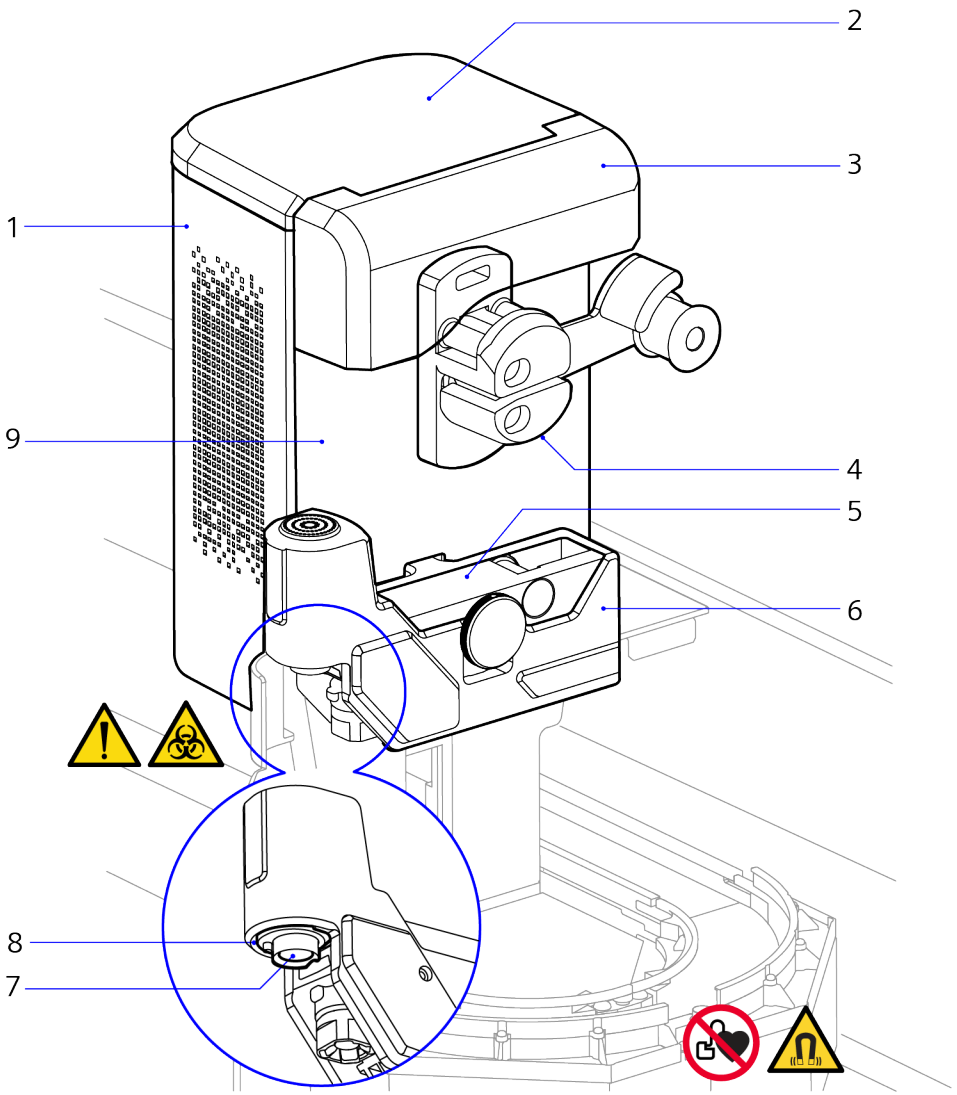


Safety Symbol	Hazard Description
	Biohazard (Page 87 *Safety Hazards*)
	Warning; Pinch hazard (Page 87 *Safety Hazards*)
	Entanglement hazard: Moving parts can cause entrapment and serious injury (Page 31 *Symbols*).

Location of Safety Hazard Symbols on the Sealer

Symbols on the Sealer indicate possible safety hazards the operator may encounter while operating and maintaining the module.

The descriptions of the symbols are also available (Page 31 *Symbols*).



1	Side cover	6	Foil feed carriage
2	Top cover	7	Plunger
3	Foil roll cover	8	Primary crimper
4	Spindle	9	Front cover
5	Foil feed cover		

Safety Symbol	Hazard Description
	Biohazard (Page 87 *Safety Hazards*)
	Caution (Page 87 *Safety Hazards*)

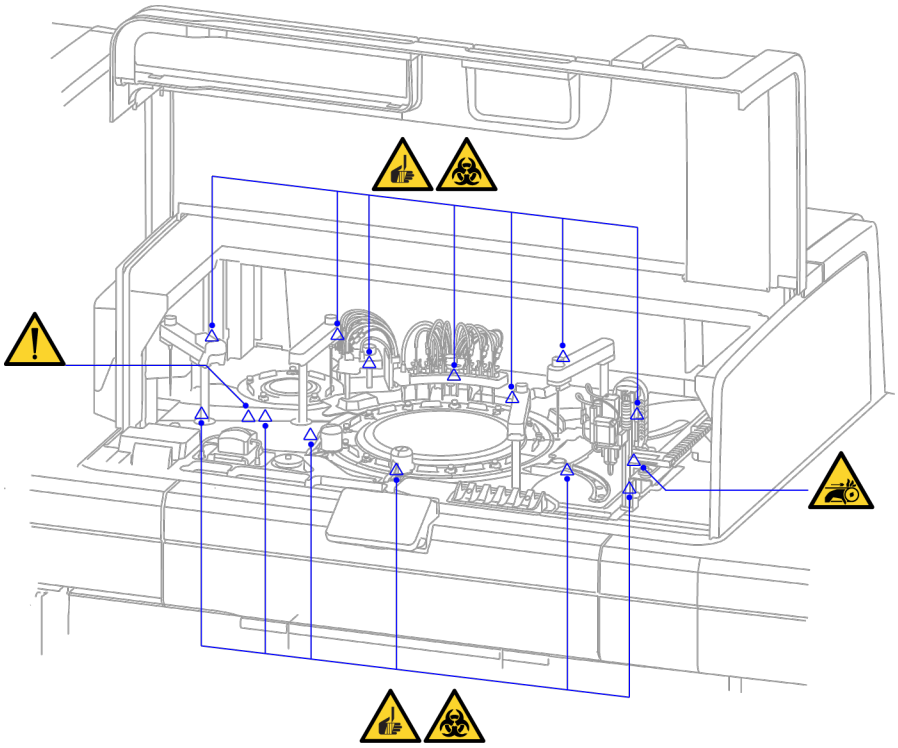
Safety Symbol	Hazard Description
 (Atellica Magline Transport)	Warning; Magnetic Field / No Pacemakers (Page 87 *Safety Hazards*)

Location of Safety Hazard Symbols on the CH Analyzer Interior

Symbols on the interior of the CH Analyzer indicate possible safety hazards the operator may encounter while operating and maintaining the analyzer.

The following figures show the locations of these safety hazard symbols. For descriptions of the symbols, see System Symbols (Page 31 *Symbols*).

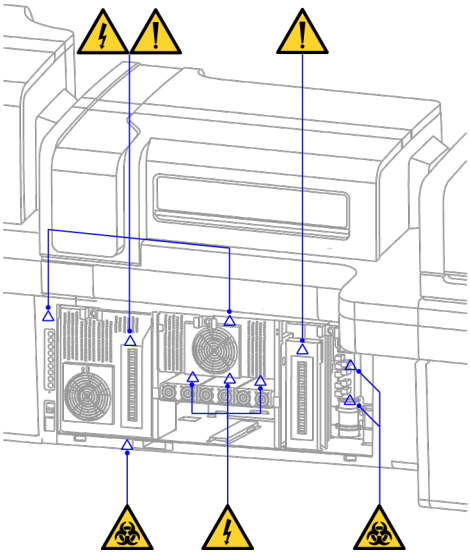
CH Analyzer open front cover



Safety Symbol	Hazard Description
	Warning; Biological hazard (Page 87 *Safety Hazards*)
	Warning; Sharp element (Page 87 *Safety Hazards*)

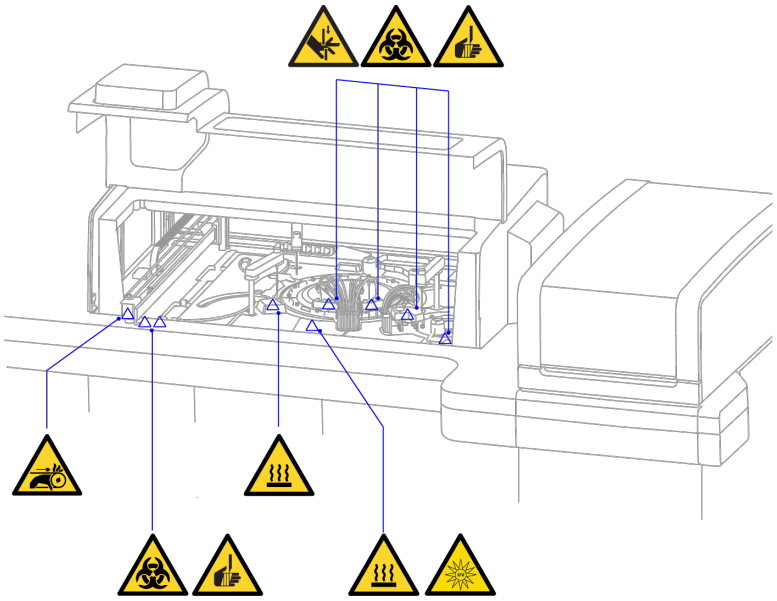
Safety Symbol	Hazard Description
	Caution: Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device (Page 31 *Symbols*).
	Warning; Moving belt hazard (Page 31 *Symbols*)

CH Analyzer back panels off



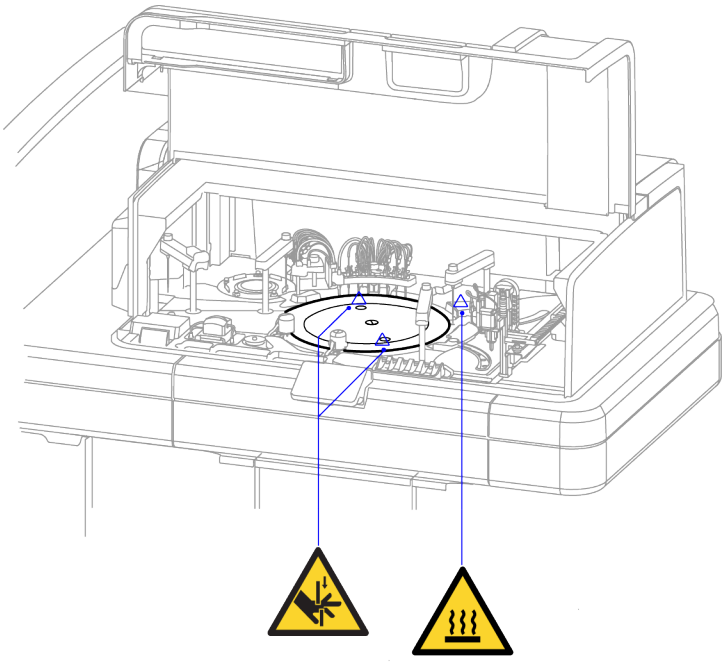
Safety Symbol	Hazard Description
	Warning; Biological hazard (Page 87 *Safety Hazards*)
	Caution: Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device (Page 31 *Symbols*).
	Electric shock hazard (Page 87 *Safety Hazards*)

CH Analyzer open back cover



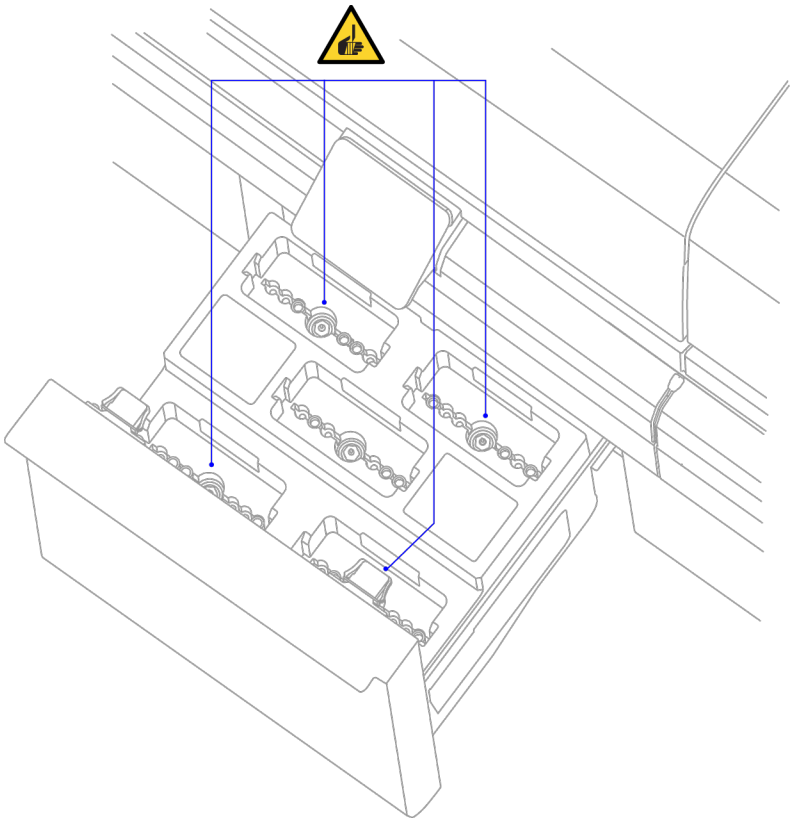
Safety Symbol	Hazard Description
	Warning; Biological hazard (Page 87 *Safety Hazards*)
	Warning; Puncture hazard (Page 87 *Safety Hazards*)
	Caution: Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device (Page 31 *Symbols*).
	Warning; Moving belt hazard (Page 31 *Symbols*)
	Warning; Pinch hazard (Page 87 *Safety Hazards*)
	Warning; Hot surface (Page 87 *Safety Hazards*)
	Ultraviolet (UV) light hazard (Page 87 *Safety Hazards*)

Under the CH Analyzer reaction ring cover



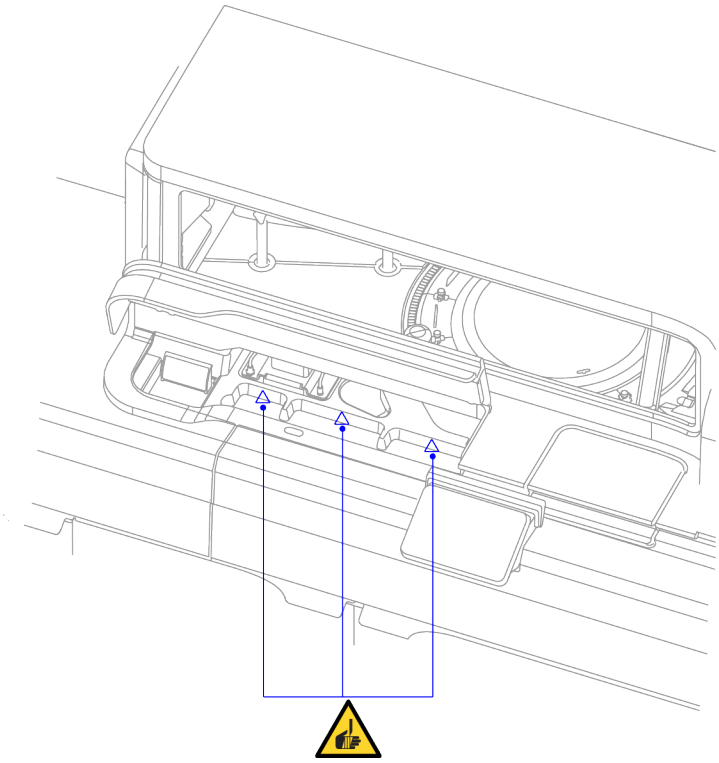
Safety Symbol	Hazard Description
	Warning; Pinch hazard (Page 87 *Safety Hazards*)
	Warning; Hot surface (Page 87 *Safety Hazards*)

CH Analyzer system fluids drawer



Safety Symbol	Hazard Description
	Warning; Sharp element (Page 87 *Safety Hazards*)

IMT fluids



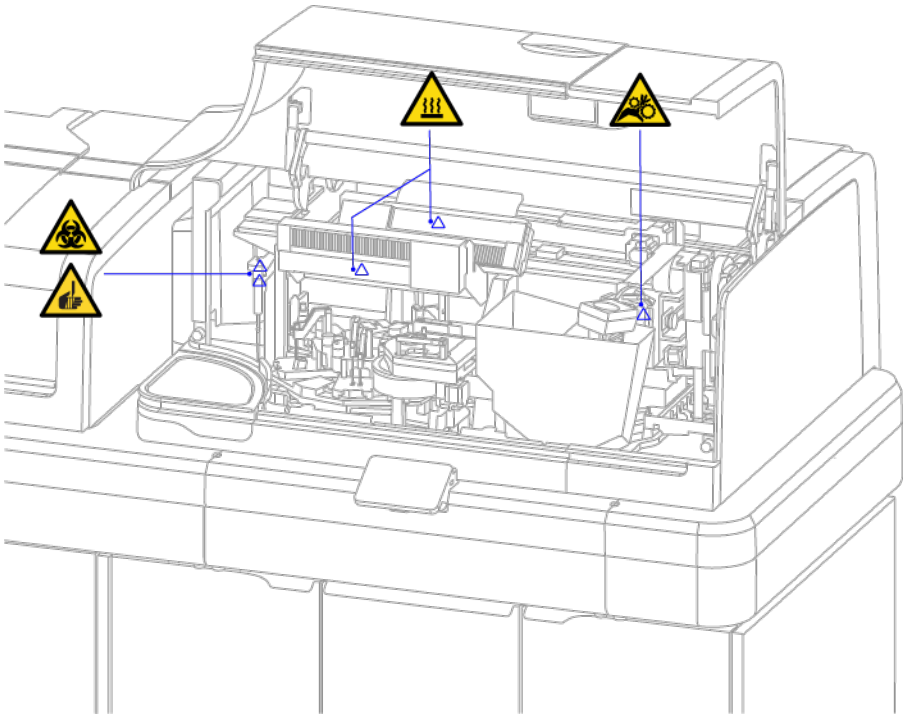
Safety Symbol	Hazard Description
	Warning; Sharp element (Page 87 *Safety Hazards*)

Location of Safety Hazard Symbols on the IM Analyzer Interior

Symbols displayed on the interior of the IM Analyzer indicate safety hazards and warnings for proper operation of the system.

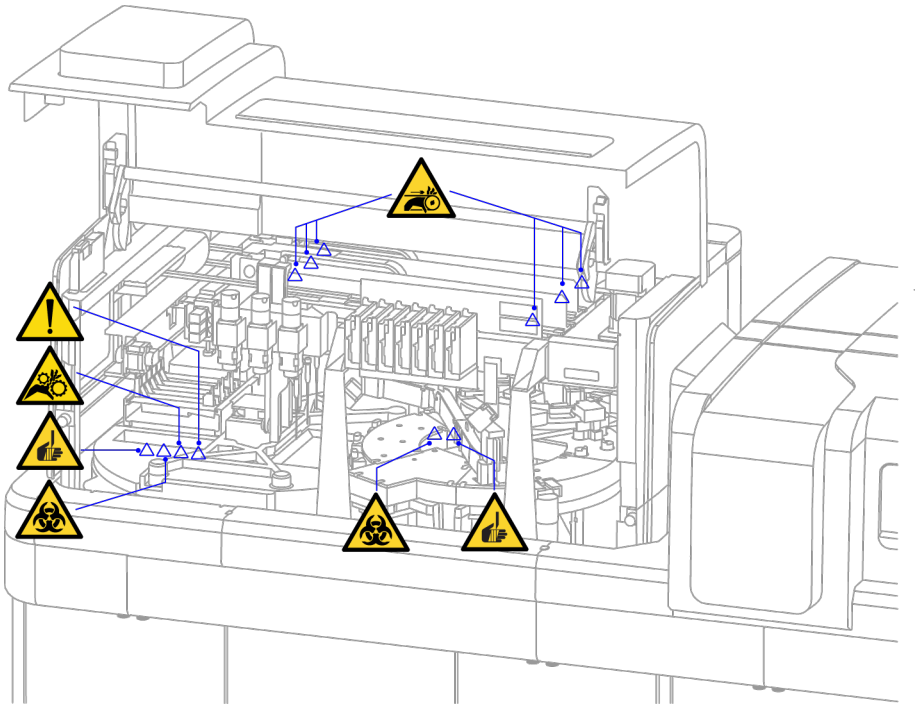
For more information, see System Symbols (Page 31 *Symbols*).

IM front cover open



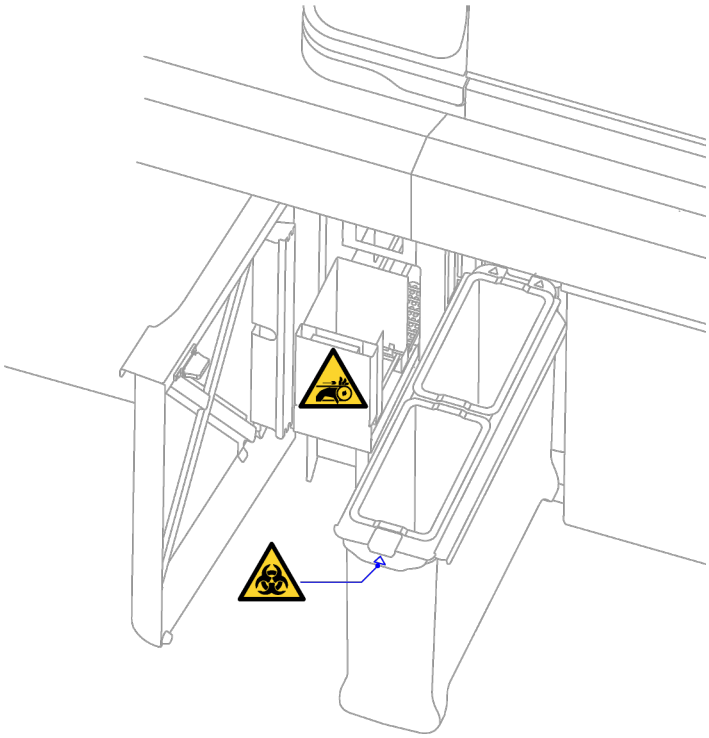
Safety symbol	Hazard description
	Warning; Sharp element (Page 87 *Safety Hazards*)
	Biohazard (Page 87 *Safety Hazards*)
	Warning; Hot surface (Page 31 *Symbols*)
	Entanglement hazard: Moving parts can cause entrapment and serious injury (Page 31 *Symbols*).

IM back cover open



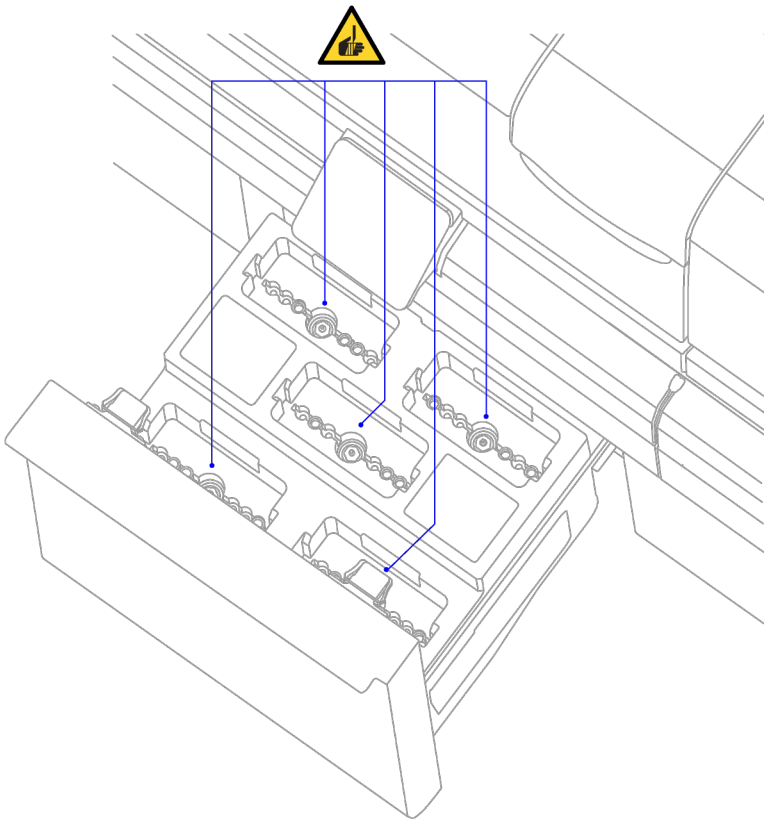
Safety symbol	Hazard description
	Biohazard (Page 87 *Safety Hazards*)
	Warning; Sharp element (Page 87 *Safety Hazards*)
	Entanglement hazard: Moving parts can cause entrapment and serious injury (Page 31 *Symbols*).
	Caution: Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device (Page 31 *Symbols*).
	Warning; Moving belt hazard (Page 31 *Symbols*)

IM solid waste



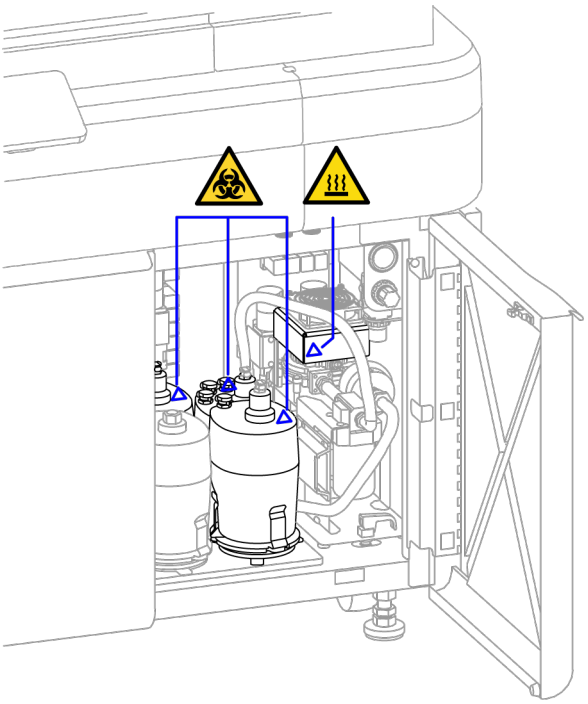
Safety symbol	Hazard description
	Biohazard (Page 87 *Safety Hazards*)
	Warning; Moving belt hazard (Page 31 *Symbols*)

IM system fluids drawer



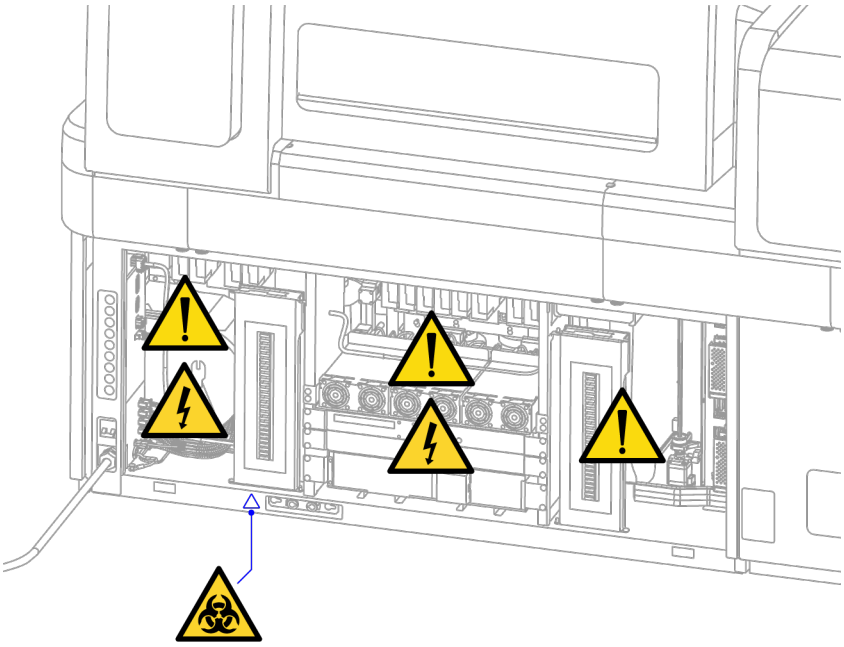
Safety symbol	Hazard description
	Warning; Sharp element (Page 87 *Safety Hazards*)

IM water and liquid waste



Safety symbol	Hazard description
	Biohazard (Page 87 *Safety Hazards*)
	Warning; Hot surface (Page 31 *Symbols*)

IM back panels off



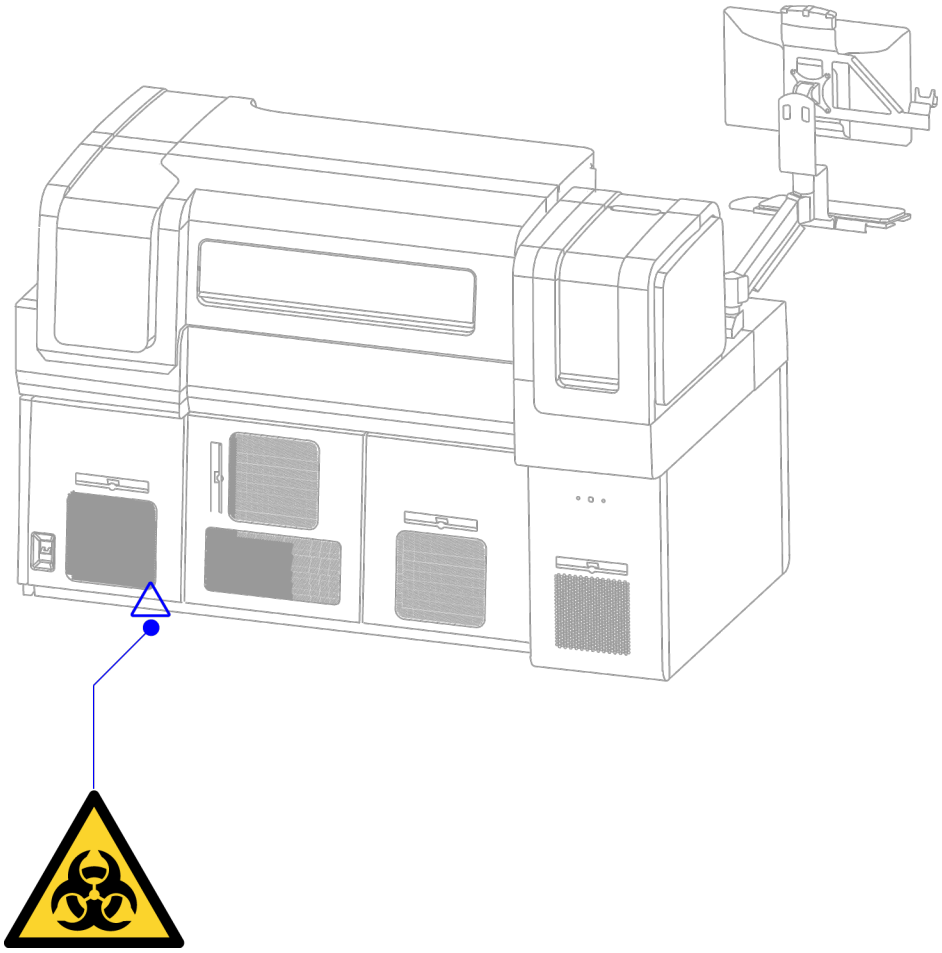
Safety symbol	Hazard description
	Biohazard (Page 87 *Safety Hazards*)
	Electric Shock Hazard (Page 87 *Safety Hazards*)
	Caution: Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device (Page 31 *Symbols*).

Location of Safety Hazard Symbols on the CH DL Exterior

Symbols on the exterior of the CH DL indicate possible safety hazards the operator may encounter while operating and maintaining the analyzer.

The following figures show the locations of these safety hazard symbols. For descriptions of the symbols, see System Symbols (Page 31 *Symbols*).

CH DL exterior back view



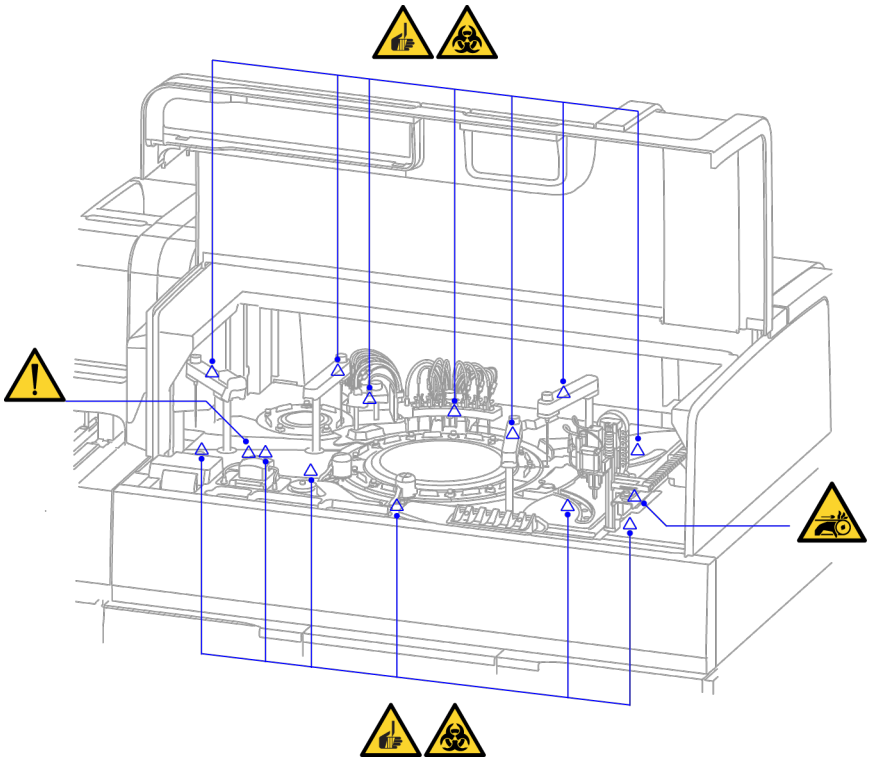
Safety Symbol	Hazard Description
	Biohazard (Page 87 *Safety Hazards*)

Location of Safety Hazard Symbols on the CH DL Interior

Symbols displayed on the interior of CH DL indicate safety hazards and warnings for proper operation of the analyzer. The locations of the symbols on the interior of the analyzer are shown in the following figures.

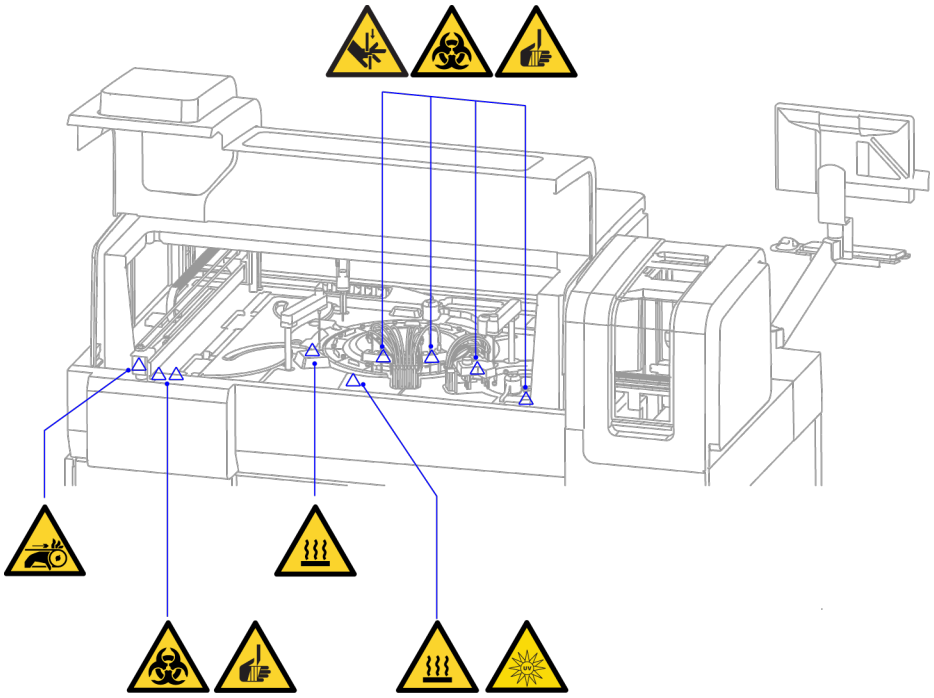
For more information on safety hazard symbols, see System Symbols (Page 31 *Symbols*).

CH DL front (cover open)



Safety Symbol	Hazard Description
	Warning; Biological hazard (Page 87 *Safety Hazards*)
	Warning; Sharp element (Page 87 *Safety Hazards*)
	Caution: Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device (Page 31 *Symbols*).
	Warning; Moving belt hazard (Page 31 *Symbols*)

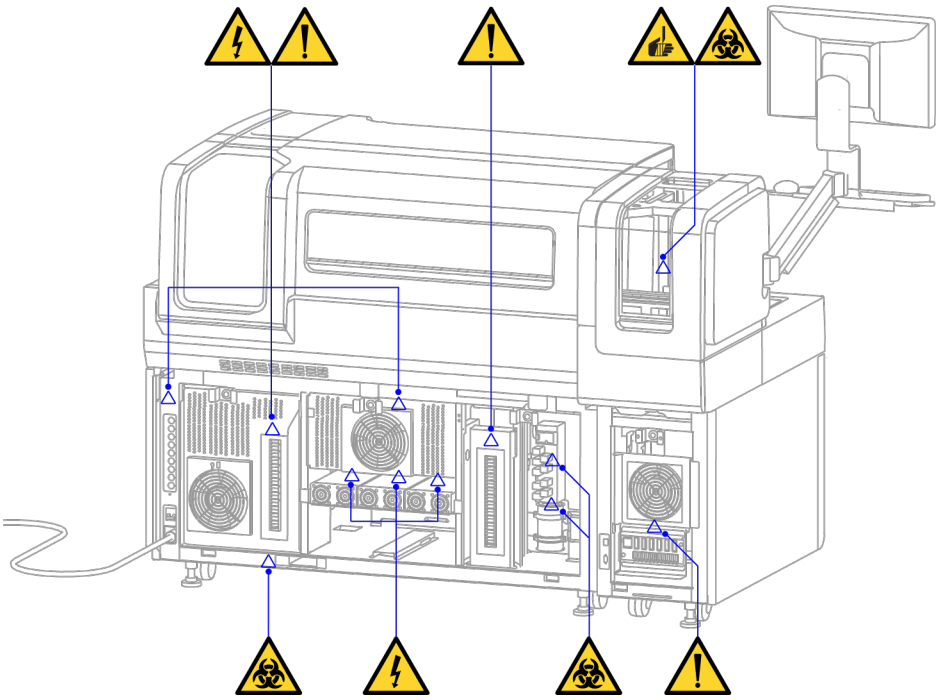
CH DL back (cover open)



Safety Symbol	Hazard Description
	Warning; Biological hazard (Page 87 *Safety Hazards*)
	Warning; Sharp element (Page 87 *Safety Hazards*)
	Caution: Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device (Page 31 *Symbols*).
	Warning; Moving belt hazard (Page 31 *Symbols*)
	Warning; Pinch hazard (Page 87 *Safety Hazards*)

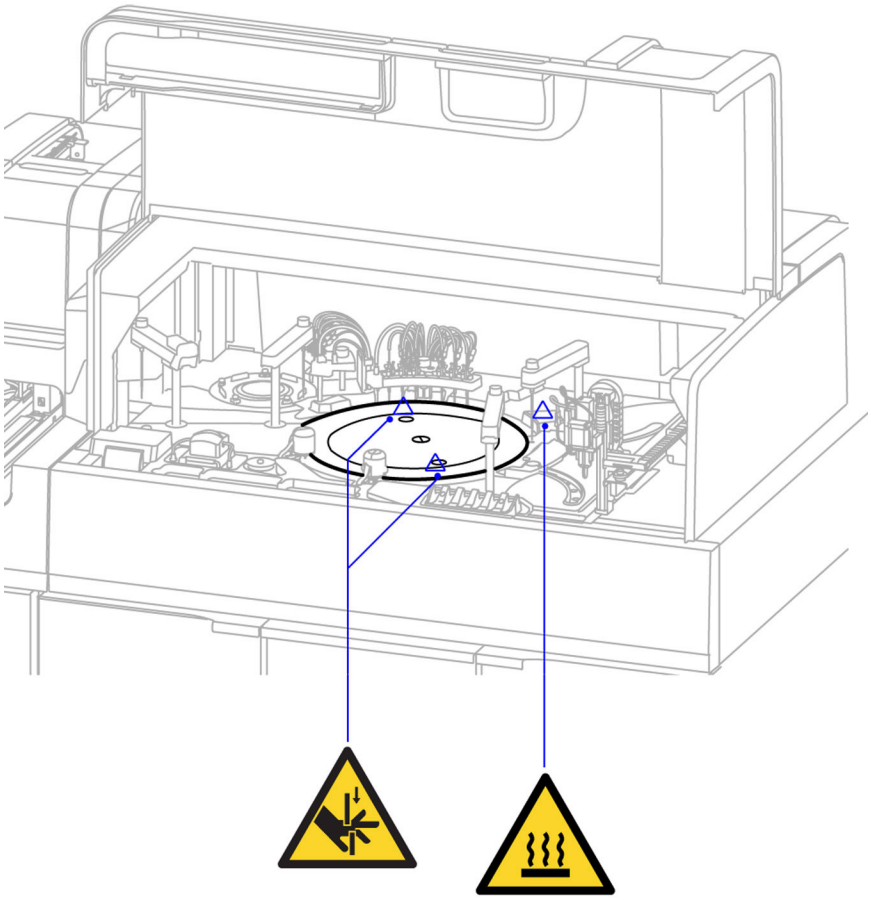
Safety Symbol	Hazard Description
	Warning; Hot surface (Page 87 *Safety Hazards*)
	Warning; Ultraviolet (UV) light hazard (Page 87 *Safety Hazards*)

CH DL behind the back panels



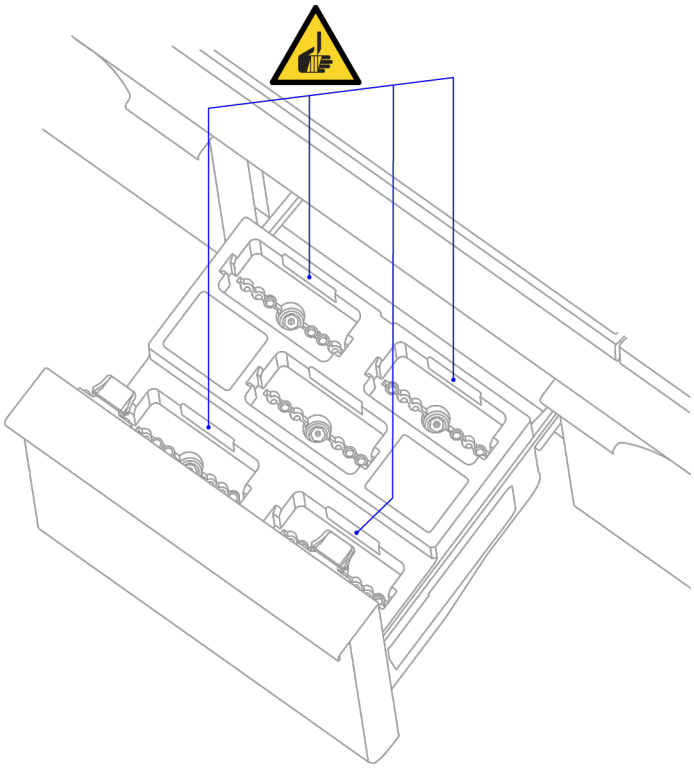
Safety Symbol	Hazard Description
	Warning; Biological hazard (Page 87 *Safety Hazards*)
	Caution: Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device (Page 31 *Symbols*).
	Warning; Electric shock hazard (Page 87 *Safety Hazards*)

Under the CH DL reaction ring cover



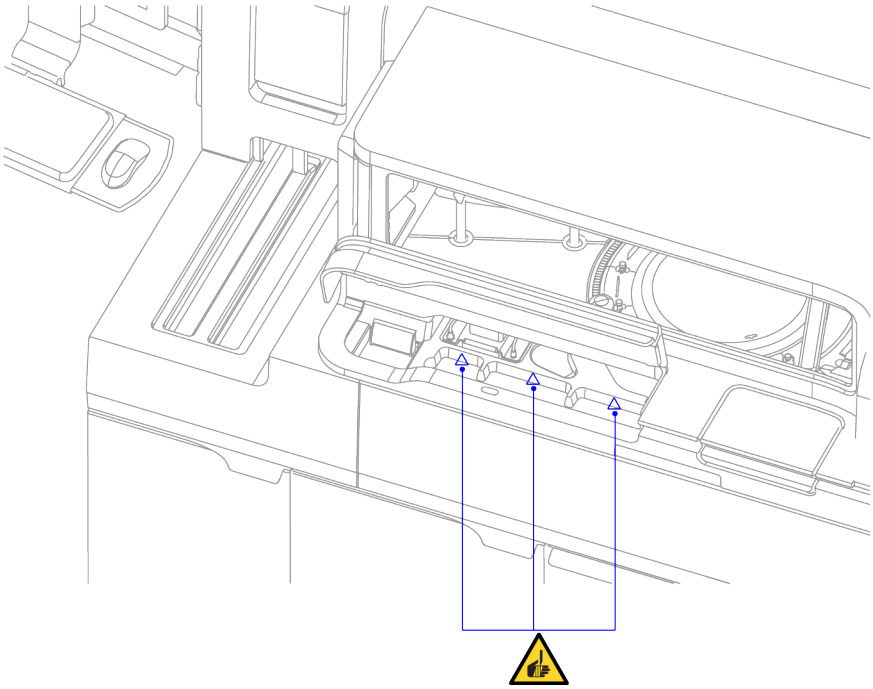
Safety Symbol	Hazard Description
	Warning; Pinch hazard (Page 87 *Safety Hazards*)
	Warning; Hot surface (Page 87 *Safety Hazards*)

CH DL system fluids drawer



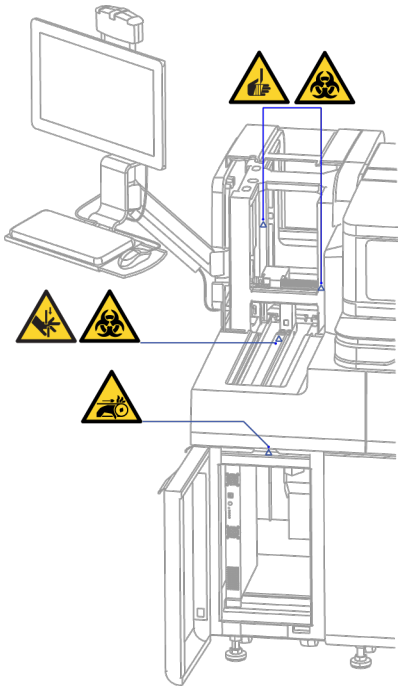
Safety Symbol	Hazard Description
	Warning; Sharp element (Page 87 *Safety Hazards*)

IMT fluids



Safety Symbol	Hazard Description
	Warning; Sharp element (Page 87 *Safety Hazards*)

CH DL entry and exit queues and computer door



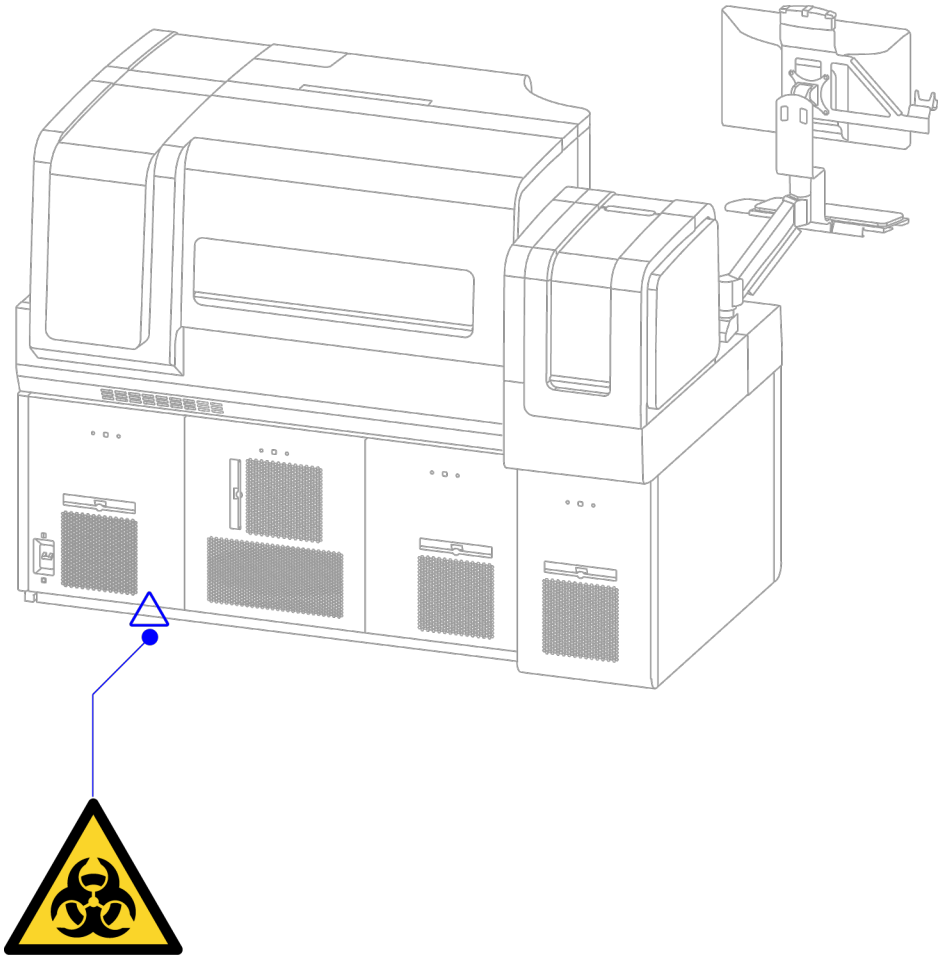
Safety Symbol	Hazard Description
	Warning; Biological hazard (Page 87 *Safety Hazards*)
	Warning; Sharp element (Page 87 *Safety Hazards*)
	Warning; Moving belt hazard (Page 31 *Symbols*)
	Warning; Pinch hazard (Page 87 *Safety Hazards*)

Location of Safety Hazard Symbols on the IM DL Exterior

Symbols displayed on the IM Analyzer exterior indicate safety hazards and warnings for proper operation of the analyzer.

For more information, refer to System Symbols (Page 31 *Symbols*).

IM DL exterior back view



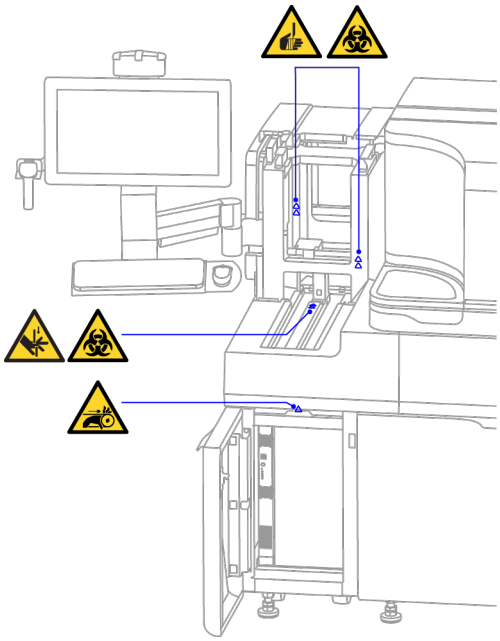
Safety Symbol	Hazard Description
	Biohazard (Page 87 *Safety Hazards*)

Location of Safety Hazard Symbols on the IM DL Interior

Symbols displayed on the interior of the system indicate safety hazards and warnings for proper operation of the system.

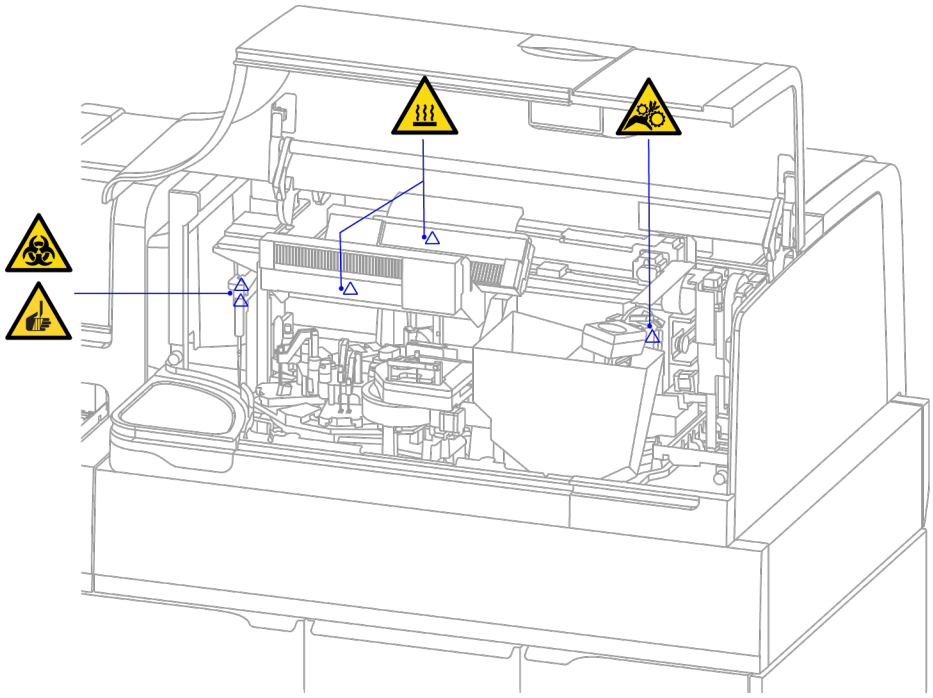
For more information, refer to System Symbols (Page 31 *Symbols*).

IM DL entry and exit queues and computer door



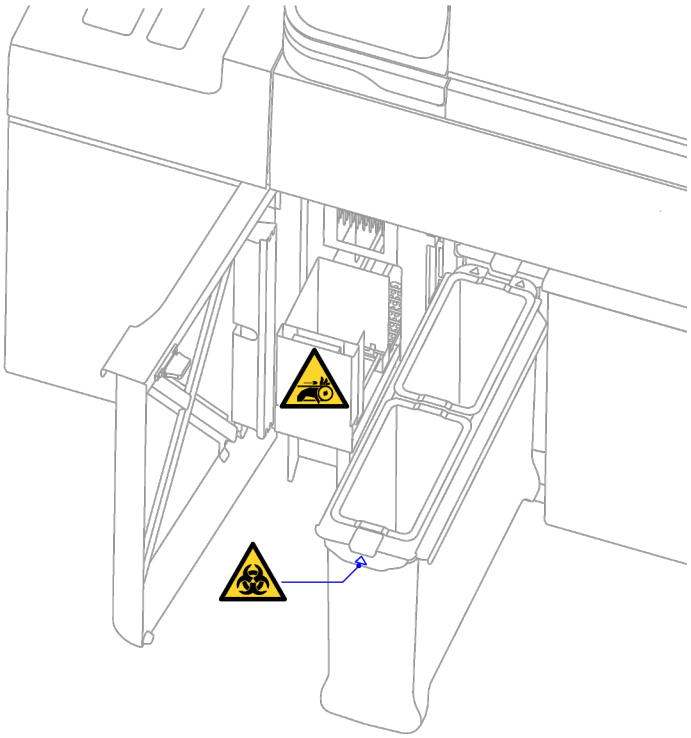
Safety symbol	Hazard description
	Warning; Moving belt hazard
	Warning; Pinch hazard (Page 87 *Safety Hazards*)
	Warning; Biological hazard (Page 87 *Safety Hazards*)
	Warning; Sharp element (Page 87 *Safety Hazards*)

IM DL front cover open



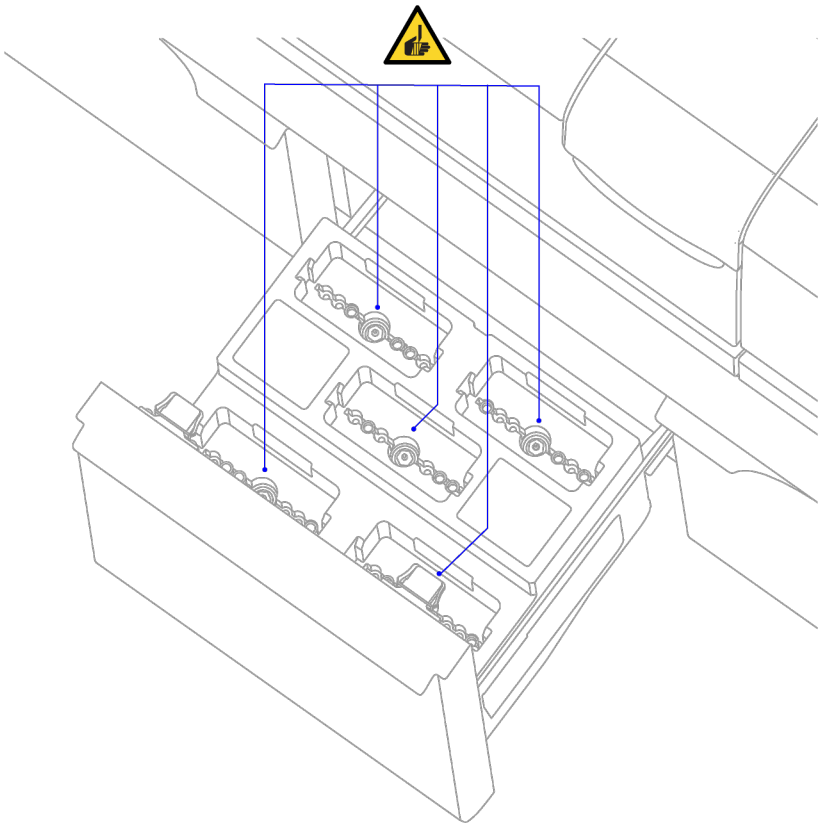
Safety symbol	Hazard description
	Warning; Sharp element (Page 87 *Safety Hazards*)
	Warning; Biological hazard (Page 87 *Safety Hazards*)
	Entanglement hazard: Moving parts can cause entrapment and serious injury (Page 31 *Symbols*).
	Warning; Hot surface (Page 31 *Symbols*)

IM DL solid waste



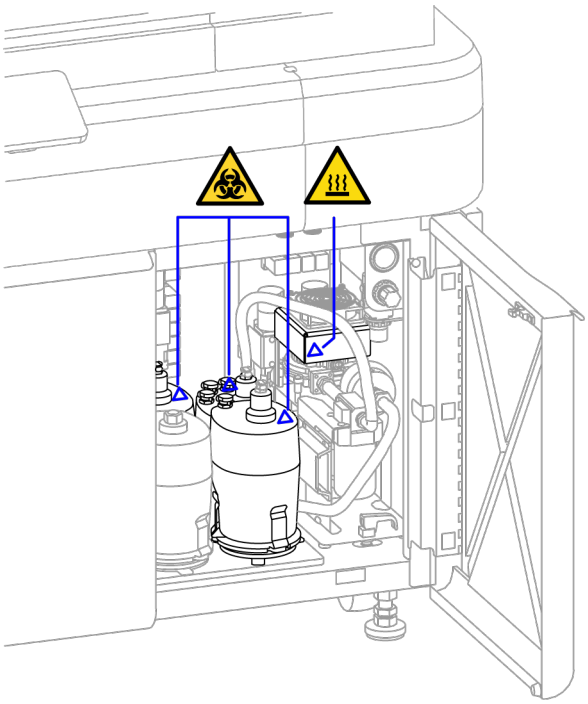
Safety symbol	Hazard description
	Warning; Biological hazard (Page 87 *Safety Hazards*)
	Warning; Moving belt hazard (Page 31 *Symbols*).

IM DL liquid waste



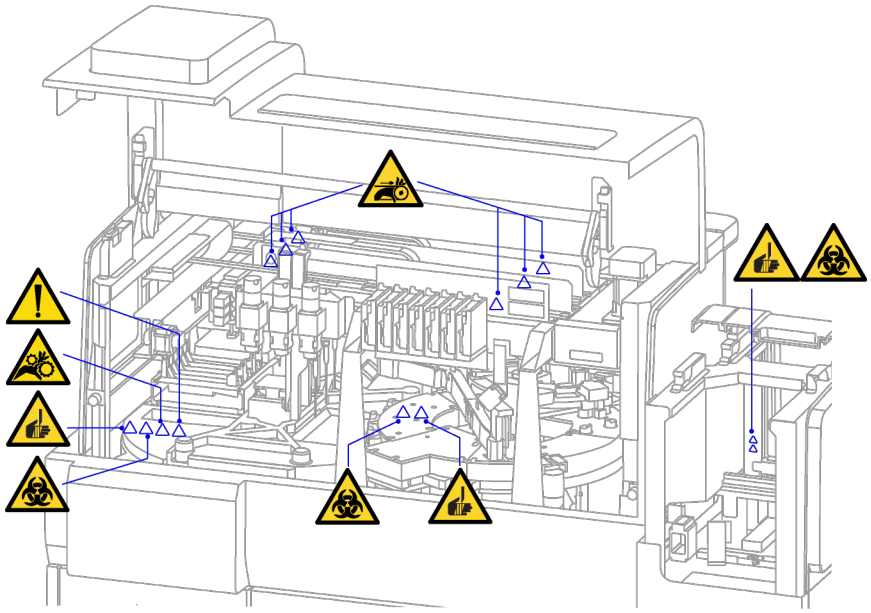
Safety symbol	Hazard description
	Warning; Sharp element (Page 87 *Safety Hazards*)

IM water and liquid waste



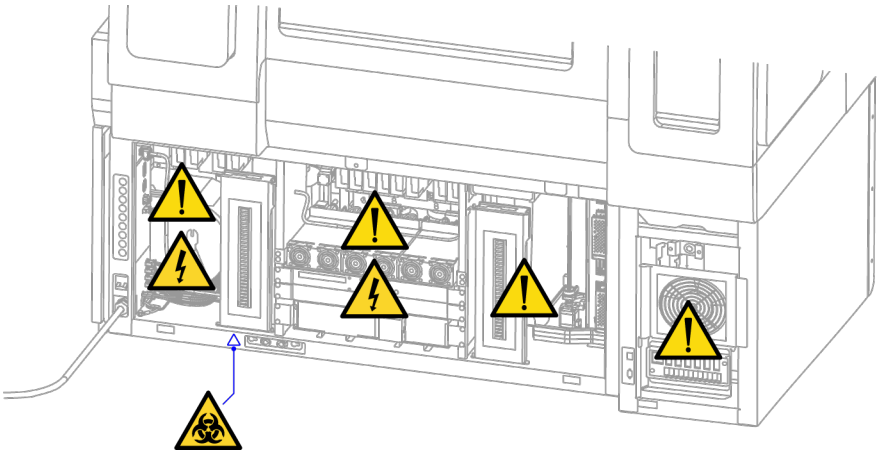
Safety symbol	Hazard description
	Warning; Biological hazard (Page 87 *Safety Hazards*)
	Warning; Hot surface (Page 31 *Symbols*)

IM DL back cover open



Safety symbol	Hazard description
	Warning; Biological hazard (Page 87 *Safety Hazards*)
	Warning; Puncture hazard (Page 87 *Safety Hazards*)
	Entanglement hazard: Moving parts can cause entrapment and serious injury (Page 31 *Symbols*).
	Caution: Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device (Page 31 *Symbols*).
	Warning; Moving belt hazard (Page 31 *Symbols*)

IM DL back panels off



Safety symbol	Hazard description
	Warning; Biological hazard (Page 87 *Safety Hazards*)
	Warning; Electric shock hazard (Page 87 *Safety Hazards*)
	Caution: Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device (Page 31 *Symbols*).

Safety Hazards

The operator may encounter the following safety hazards while operating the system. For the location of the safety hazard labels, refer to the following sections:

- (Page 42 *Location of Safety Hazard Symbols on the System Exterior*)
- (Page 46 *Location of Safety Hazard Symbols on the SH, SHC, and Atellica Magline Transport Interior*)
- (Page 60 *Location of Safety Hazard Symbols on the CH Analyzer Interior*)
- (Page 65 *Location of Safety Hazard Symbols on the IM Analyzer Interior*)
- (Page 71 *Location of Safety Hazard Symbols on the CH DL Exterior*)
- (Page 72 *Location of Safety Hazard Symbols on the CH DL Interior*)

- (Page 79 *Location of Safety Hazard Symbols on the IM DL Exterior*)
- (Page 80 *Location of Safety Hazard Symbols on the IM DL Interior*)

Biohazard



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

Carrier Pinch Hazard



CAUTION

Do not remove the carriers from the Atellica Magline Transport. The carriers have strong magnets in the base and handling them in close proximity to metal objects can result in a body part being pinched between the carrier and the metal object. Only authorized service personnel should handle carriers.

Electric Shock Hazard



ELECTRICAL HAZARD

Do not operate modules without a protective grounding connection that prevents electrical shock. Electrical shock can cause equipment damage and bodily harm. Use caution when working around these locations or contact a local technical support provider for more information about using a protective grounding connection and avoiding electrical shock hazards.

Hot Surface Warning



CAUTION

Do not touch the lamp housing. The lamp housing becomes hot with use and can cause burns. Allow the lamp to cool for approximately 5 minutes before touching any components.

Pinch Hazard



CAUTION

Be careful when working on parts that can move. Moving parts create pinch hazards and can cause bodily harm.

Pinch Hazard



CAUTION

Do not work or open the SHC front cover without caution. The SHC front cover is heavy and can result in injury if a body part is caught between the cover and the SHC frame.

Puncture Hazard



CAUTION

Keep hands clear of analyzer module sample probes when installing or removing the ESL carrier. The sample probes can puncture skin, resulting in personal injury.



WARNING

Do not touch the probe tip when working with the probes. The probe tip is sharp and can cause bodily harm.



WARNING

Do not touch the cannulas in the keyed areas at the bottom of the system fluids drawer. The cannulas can puncture skin.

SH Robot Impact Hazard



WARNING

Do not reach into the SH when sample drawers are open. The SH robot moves with high speed and force and can cause severe bodily harm.

Strong Magnetic Field / No Pacemakers Warning



WARNING

Do not position pacemakers or other implanted medical devices closer than 7.5 cm (3 inches) from the base of a carrier on the Atellica Magline Transport. Magnets in the carrier base generate magnetic fields that can interfere with cardiac medical implants.

UV Lamp Warning



CAUTION

Do not look directly at the CH UV light in the source lamp assembly or at its reflection from a shiny surface. The UV light can cause eye damage. Only trained local technical support providers should perform procedures related to the CH UV lamp assembly.

Location of SH Safety Latches

The SH employs safety latches on the front and back covers and on the sample drawers to prevent injury to operators during system operation.

The SH front and back covers lock during normal operation. To open the front or back cover, the operator requests the cover to unlock from the system display or the operator tablet. After the operator unlocks and opens the cover, the system removes power from the SH robot so it cannot move. The system resumes normal operation after the operator closes and locks the cover.

A cover inside the SH, accessible through the SH back cover, protects the operator from moving sample carriers on the Atellica Magline Transport. The internal Atellica Magline Transport cover has an interlock switch. When the operator removes the cover, the system disables the Atellica Magline Transport so carriers do not move through the SH. The Atellica Magline Transport resumes normal operation when the operator reinstalls the cover.

Sample drawers lock when the robot accesses sample racks in that drawer and any time the Drawer Vision System (DVS) downloads images. The drawers are unlocked at all other times. An LED and button located above each drawer indicates if the drawer is locked or unlocked and allows the operator to request the system to unlock a currently locked drawer.

Feature	Access to
SH front cover	Robot and racks in closed sample drawers
SH back cover	Robot, TCS, Cal-QC storage area, and the internal Atellica Magline Transport cover

Feature	Access to
SH internal Atellica Magline Transport cover	Portions of the Atellica Magline Transport
SH sample drawers	Sample racks
Lower-frame panels*	SH electronics assemblies

NOTE: * indicates no safety latches.

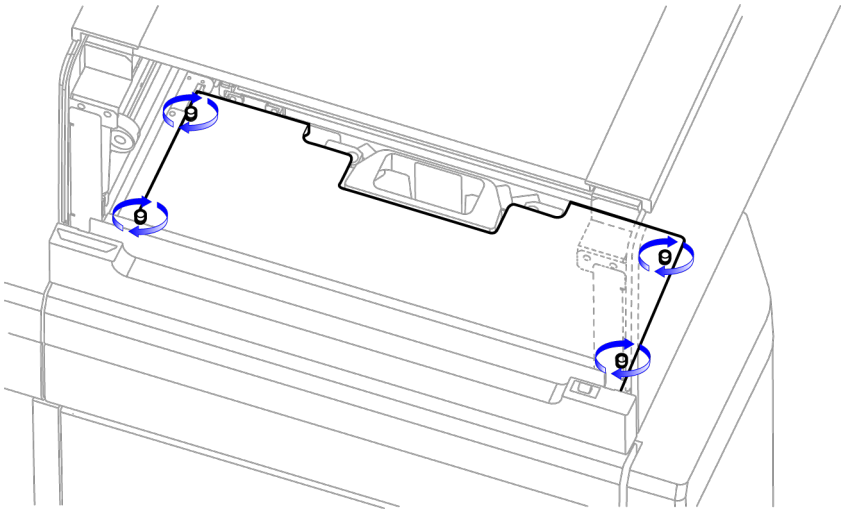
Locking SH Covers

> **CAUTION**
>
> Do not hold the SH robot grippers or push the robot down when moving the robot manually. Holding the grippers to move the robot may damage the crash sensor. Moving the robot down may cause the robot grippers to impact another object, possibly resulting in damage to the robot gripper or sample container breakage. Only move the robot by holding the robot body, and keep the robot grippers clear of all obstacles.

1. If the SH internal Atellica Magline Transport cover is not in position, manually move the SH robot to a position where it does not block access to the cover location.

> **CAUTION**
>
> Do not touch the TCS when removing or installing the SH internal Atellica Magline Transport cover. Touching the TCS may misalign the cameras and the SH would be unable to scan sample containers. If the TCS cameras are misaligned, contact the local technical support provider to realign the cameras. Use care when removing or installing the internal Atellica Magline Transport cover.

2. If appropriate, install the internal Atellica Magline Transport cover:

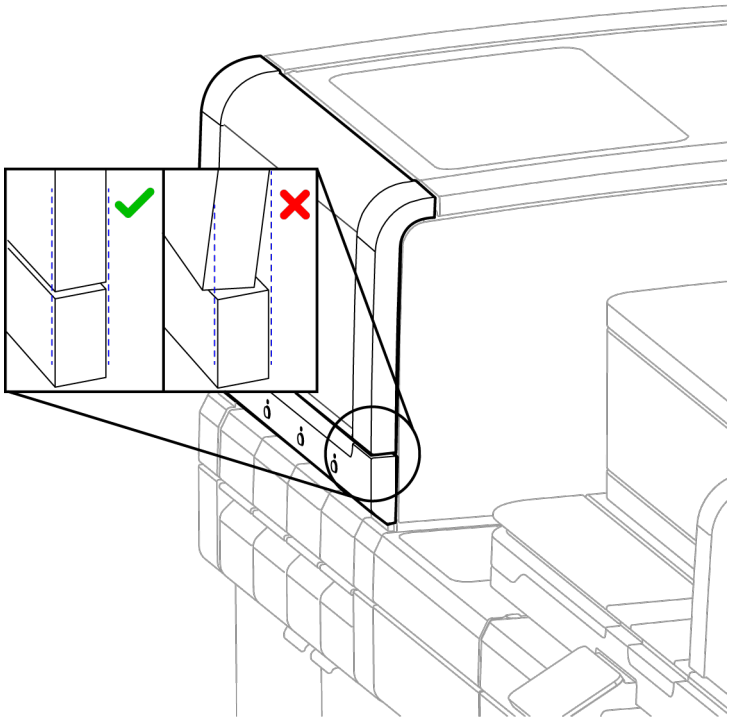


   a. Place the cover in position inside the SH.

   b. Tighten the 4 captive screws located in the corners of the cover.

3. Close the SH cover by pushing down on the center of the cover. Ensure the lower corners of the cover are flush with the panel below the cover.

   NOTE: If the SH cover is not flush with the panel below the cover, the SH cover may not properly latch.



4. On the system status map, select the SH.
5. Select for Front Cover or Back Cover, as appropriate.
6. Wait for to change to .
7. To restart the SH, select ▶.

Unlocking SH Covers

1. On the system status map, select the SH.
2. Select ■.

   NOTE: The SH must be stopped before the operator can unlock the SH cover.

   – Selecting **Stop** enables the system to complete all tests currently in process.

   – Selecting **Stop Immediately** cancels all tests in process.

3. Select **Stop** or **Stop Immediately**.
4. Select for Front Cover or Back Cover, as appropriate.
5. Wait for to change to .

   NOTE: If an error occurs while unlocking the cover, changes to and a message displays under Alert Description.
6. Open the cover within 30 seconds of unlocking it.

   NOTE: If the operator does not open the cover within 30 seconds, the cover automatically locks and changes back to .
7. If there is an issue unlocking the covers, perform a reset (Page 704 *Resetting the SH Front and Back Covers in Operator Diagnostics*).

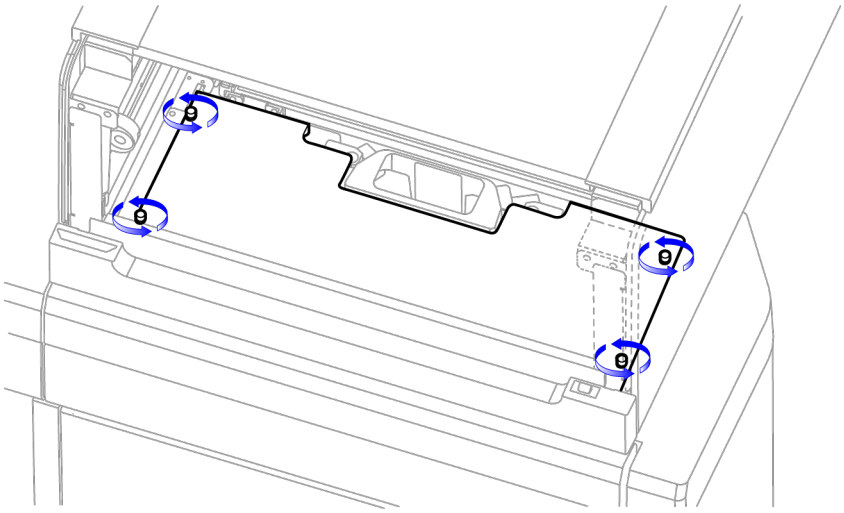
   CAUTION

   Do not hold the SH robot grippers or push the robot down when moving the robot manually. Holding the grippers to move the robot may damage the crash sensor. Moving the robot down may cause the robot grippers to impact another object, possibly resulting in damage to the robot gripper or sample container breakage. Only move the robot by holding the robot body, and keep the robot grippers clear of all obstacles.
8. If appropriate, manually move the SH robot to a position where it does not block access to SH internal components.

CAUTION

Do not touch the TCS when removing or installing the SH internal Atellica Magline Transport cover. Touching the TCS may misalign the cameras and the SH would be unable to scan sample containers. If the TCS cameras are misaligned, contact the local technical support provider to realign the cameras. Use care when removing or installing the internal Atellica Magline Transport cover.

9. If appropriate, remove the SH internal Atellica Magline Transport cover:



   a. Loosen the 4 captive screws located in the corners of the cover.
   b. Lift the cover.
   c. Remove the cover from the SH.

Location of Atellica Magline Transport Safety Interlocks

The Atellica Magline Transport employs safety interlocks on each Atellica Magline Transport cover to prevent injury to operators during system operation and help maintain chain of custody.

The Atellica Magline Transport covers allow access to the Atellica Magline Transport and its carriers. The cover interlock detects when the operator removes the cover. When the operator removes a cover, the system removes power from that section of the Atellica Magline Transport to prevent sample carriers from moving through that area. After the operator replaces the cover, Atellica Magline Transport resumes normal operation.

Location of Decapper Safety Interlocks

The Decapper employs safety interlocks on its cover to prevent injury to operators during system operation and help maintain chain of custody.

The Decapper cover allows operator access to the tube gripper, cap remover, and cap waste chute. The cover interlock detects when the operator removes the cover, and the module stops. After the operator replaces the cover, the Decapper resumes normal operation.

Location of SHC Safety Latches

The SHC employs safety latches on the SHC cover to prevent injury to operators during system operation.

The SHC cover locks during normal operation. To open the cover, the operator requests to unlock the cover from the primary user interface. After the operator unlocks and opens the cover, the system removes power from the SHC robots so they cannot move. After the operator closes and locks the cover, the system resumes normal operation.

Feature	Access to
SHC cover	Robots, portions of the Atellica Magline Transport and LAS, carriers, and the SHC TCS
Lower-frame panels*	SHC electronics assemblies

NOTE: * indicates no safety latches.

Unlocking the SHC Cover

1. Stop the SHC (Page 137 *Changing the Module Status*).

   NOTE: The SHC must be paused or stopped before the operator can unlock the SHC cover.

   – Pausing the SHC allows the system to return all SHC samples currently on the Atellica Magline Transport to the SHC for transfer to the LAS before it enters the Paused state.

   – Stopping the SHC stops the SHC immediately, potentially leaving SHC samples on the Atellica Magline Transport.

2. Unlock SHC front cover (Page 93 *Unlocking SH Covers*).

3. Wait for cover to unlock.
4. Open the cover within 30 seconds of disabling the cover lock.

   NOTE: If the operator does not open the cover within 30 seconds, the cover automatically locks and the 🔓 changes back to 🔒.

Locking the SHC Cover

1. If the operator removes the SHC front Atellica Magline Transport cover, install the cover (Page 631 *Installing Atellica Magline Transport Covers*).
2. Close the SHC cover.
3. Unlock the SHC cover (Page 93 *Unlocking SH Covers*).
4. Wait for 🔓 to change to 🔒.
5. To resume the SHC, select ▶.

Location of CH Safety Latches

The CH Analyzer employs safety latches on the covers to prevent injury during operation. Use caution when opening the covers during operation.

The front and back covers contain 2 tinted polycarbonate windows. Each cover is hinged across the center of the analyzer.

CH Analyzer Feature	Access to
Front cover	Reaction cuvettes, the IMT system, and the reagent compartment
Back cover	Sample dilution cuvettes
System fluids drawer*	System fluids
Panels*	Interior of the analyzer

NOTE: * indicates no safety latches.

Location of IM Safety Latches

The IM Analyzer employs safety latches on the front and back covers to prevent injury during operation. Use caution when opening the covers during operation.

The front and back covers are structural foam panels containing tinted polycarbonate windows. Each panel is hinged left to right across the top of the module.

IM Analyzer Feature	Access to
Front cover	Cuvette bin, luminometer, sample tip loader, and wash ring
Back cover	Incubation rings, reagent compartment, reagent probes, and sample probe
System fluids drawer*	System fluids
Lower doors and panels*	Lower interior of the analyzer

NOTE: * indicates no safety latches.

Locking or Unlocking Analyzer Covers

1. In System Status area, select the appropriate analyzer.
2. Ensure the analyzer is in the stopped state (Page 137 *Changing the Module Status*).

   NOTE: The operator must stop the analyzer before unlocking the cover.
3. To unlock the cover, select **Front Cover** or **Back Cover** as appropriate.
4. Wait for the lock icon to indicate the appropriate state.

   NOTE: The lock icon indicates whether the cover is locked or unlocked. When unlocked, the cover automatically relocks unless the operator opens or removes the cover within 30 seconds.
5. To relock the cover, close or replace the cover.

   NOTE: The lock stays open but armed until the operator replaces the cover. When the operator replaces cover, it relocks. The operator must manually restart the analyzer.
6. To restart the analyzer, select ▶.

Location of DL Safety Latches

The DL employs safety latches to prevent injury during operation. Use caution when opening the covers during operation. To unlock or lock the DL, see (Page 99 *Locking and Unlocking DL Covers*).

The front and back covers are structural plastic panels with foam backing containing smoked polycarbonate windows. Each cover is recessed down into receptacles that hold the cover in place (Page 664 *Removing the DL Front Cover*) (Page 666 *Reinstalling the DL Front Cover*).

Feature	Access to
Front cover	Entry and exit queue lanes
Back cover	Sensors
Panels	All sides of the module

Locking and Unlocking DL Covers

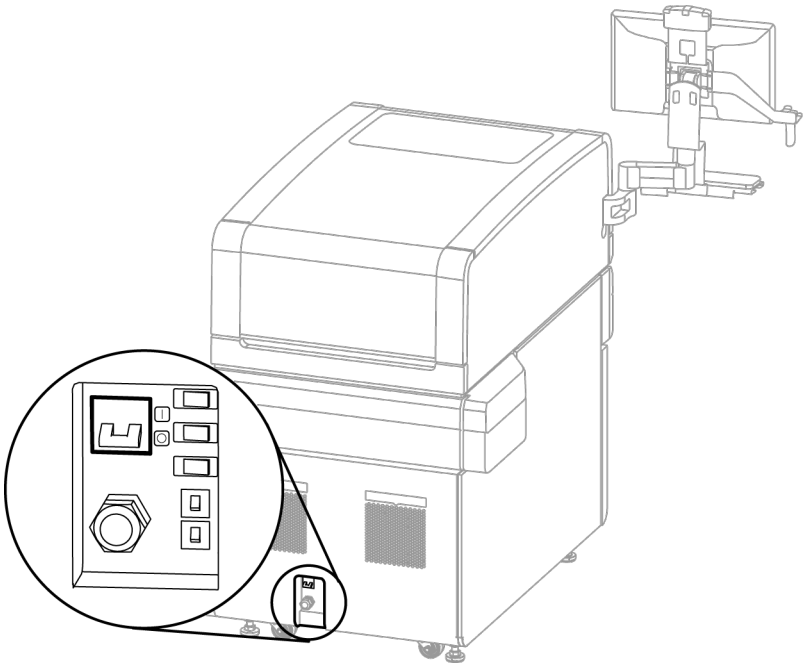
1. In the **System Status** area, select the DL module.
2. Select ■ and select the appropriate stop process.
3. Wait for process to complete.
4. To open the DL covers, select  and wait until  displays.

   NOTE: If the software is preventing the covers from unlocking, an emergency lock override is located on each of the covers. Insert hex tool and turn to unlock. Once the cover is no longer securely seated, the DL cover area becomes yellow to indicate that the system cannot process samples.

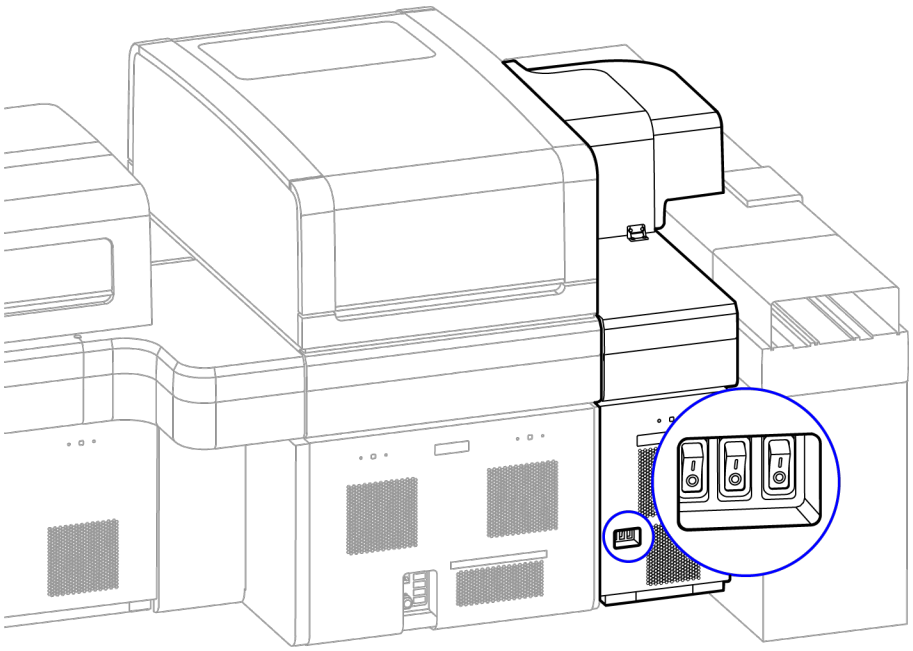
Location of the System Main Power Switches

The main power switch is located at the back of each SH, the SHC, and each analyzer.

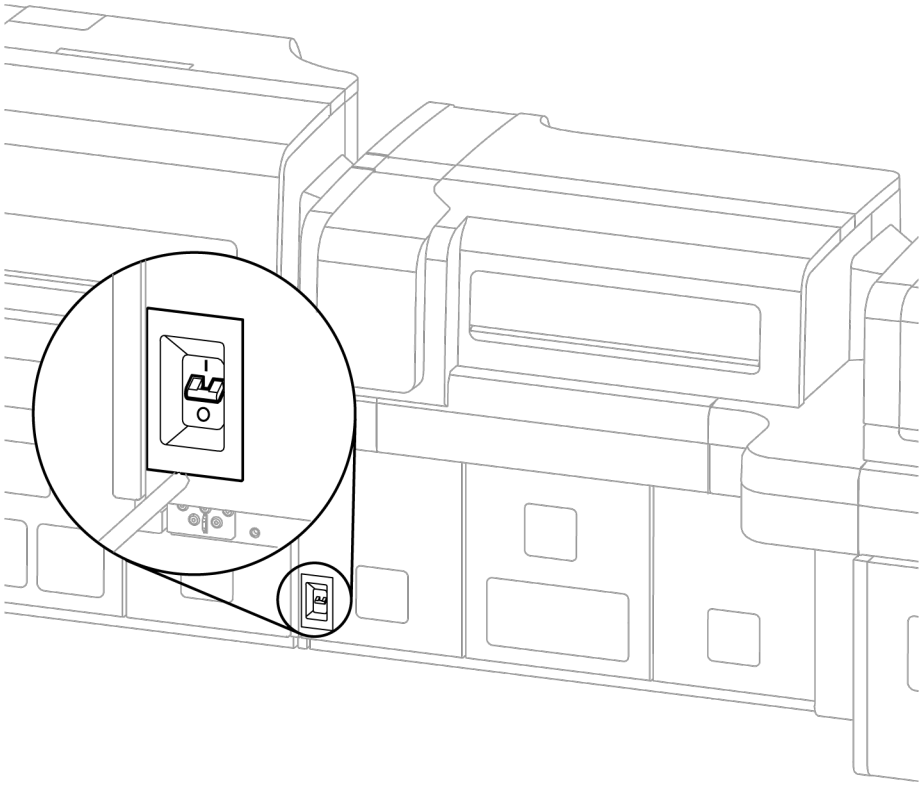
SH main power switch



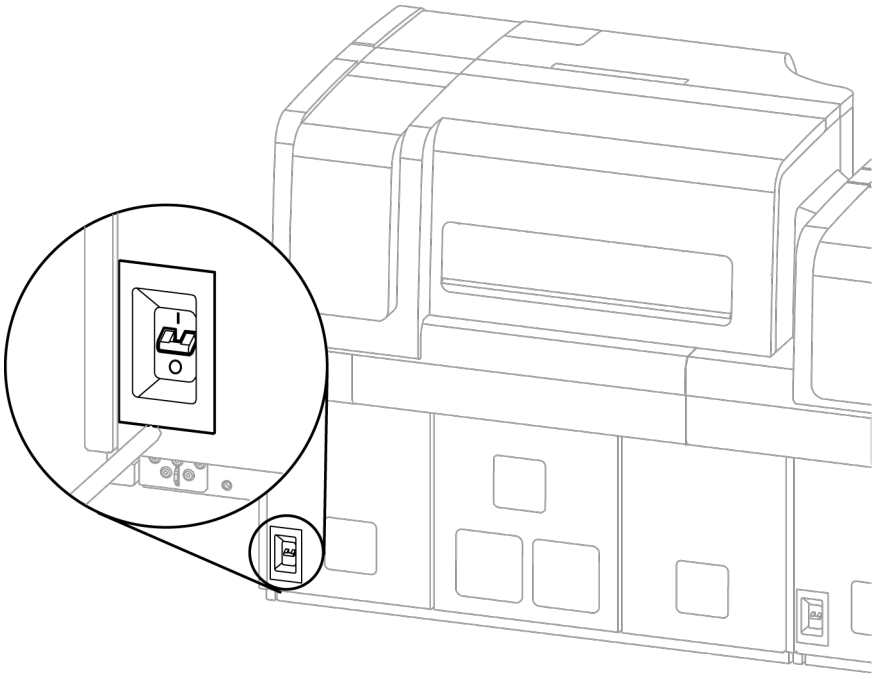
SHC main power switches



CH Analyzer main power switch

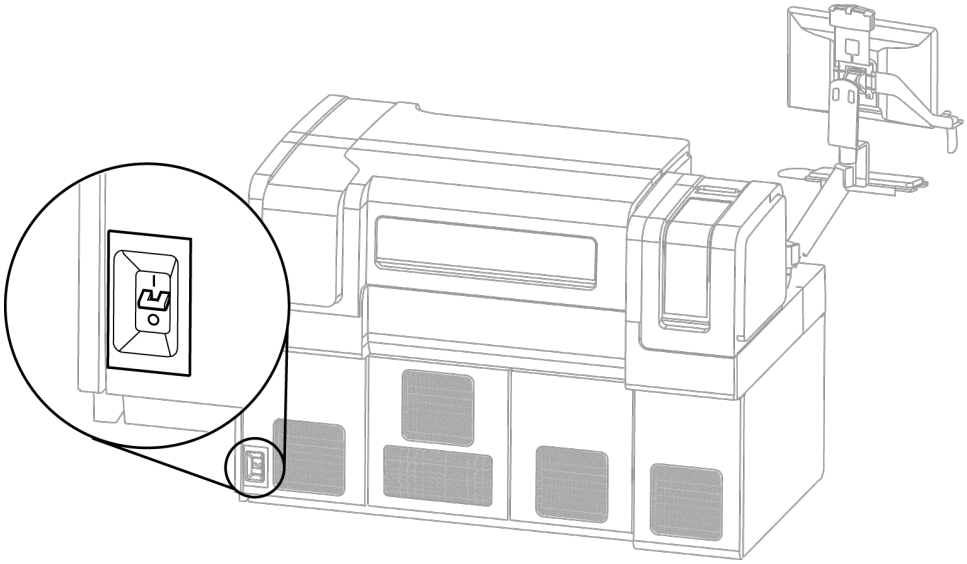


IM Analyzer main power switch



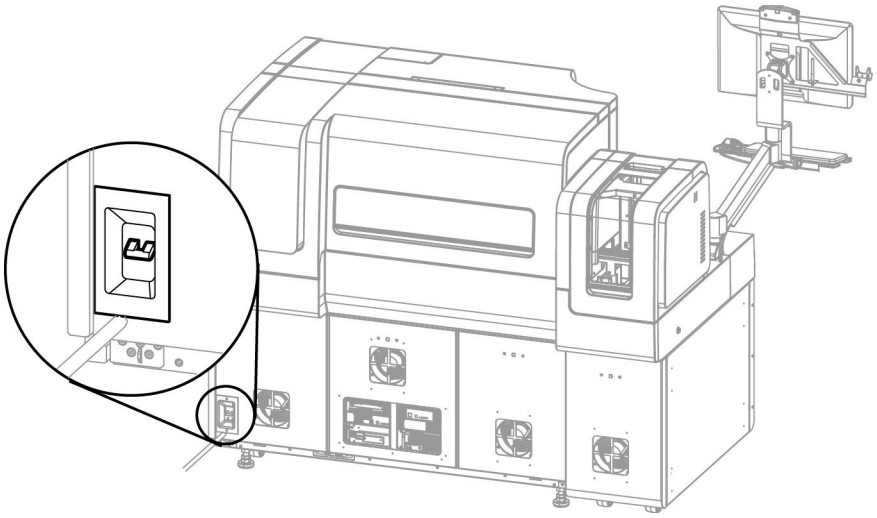
Location of Main Power Switch on the CH DL

The main power switch is located at the back of the CH DL.



Location of Main Power Switch on the IM DL

The main power switch is located at the back of the system.



6 Key Features and Principles

SH Key Features

The SH has features for enhancing laboratory operations. These features are based on a system configuration that includes 1 SH, 1 CH Analyzer, and 1 IM Analyzer.

Feature	Notes
High capacity	Load up to 440 samples through the front-loading drawers.
Optimal productivity	Maximum throughput of up to 500 samples per hour when front-loading samples.
Onboard refrigeration	The refrigerated Cal-QC storage area stores calibration and QC materials onboard the system.
System status indicators	Colored LEDs provide a visible indication of system status.

Decapper Key Features

The Decapper has the following features for enhancing laboratory operations:

Feature	Notes
Integrated tube decapping	Feature allows decapping of a majority of accepted tube types integrated into the system.
Optimal productivity	Between SH and first analyzer: 300 tubes per hour. Between any 2 analyzers or at the end of configuration: 500 tubes per hour.
Walkaway time	Up to 5 hours.

Feature	Notes
Flexible configuration	Up to 3 customizable configurations.
High capacity	Waste bin has capacity of up to 2000 sample caps and supports a bagged biohazard removal.

Sealer Key Features

The Sealer has the following features for enhancing laboratory operations:

Feature	Notes
Integrated tube sealing	Feature allows sealing of a majority of accepted tube types integrated into the system.
Optimal productivity	Up to 480 tubes an hour.
Walkaway time	20000 seals.

CH Analyzer Key Features

The CH Analyzer has the following features for enhancing laboratory operations:

Feature	Notes
Optimal productivity	Maximum throughput of 1800 tests/hour, consisting of 1200 photometric tests/hour and 600 IMT tests/hour.
Onboard refrigeration	The refrigerated reagent compartment stores reagents onboard the system.
Direct plumbing	The analyzer connects to external special reagent water and waste lines.
Automated maintenance	The operator can set the system to automatically schedule daily and weekly maintenance procedures and can configure the time to complete.

Feature	Notes
Internal system temperature management	The system maintains an interior temperature of 37 °C when the system covers are closed.
No-pause reloading	The operator can load samples, reagents, and supplies while the system processes samples.

IM Analyzer Key Features

The IM Analyzer has the following features for enhancing laboratory operations:

Feature	Notes
Optimal productivity	Atellica IM 1600 Analyzer maximum throughput of up to 440 tests/hour. Atellica IM 1300 Analyzer Maximum throughput of up to 220 tests/hour.
Onboard refrigeration	The refrigerated reagent compartment stores and mixes reagents onboard the system.
Direct plumbing	The analyzer connects to external special reagent water and waste lines.
Automated maintenance	The operator can set the system to automatically schedule daily and weekly maintenance procedures and can configure the time to complete.
Internal system temperature management	The system maintains an interior temperature of 33 °C when the system covers are closed.
No-pause reloading	The operator can load samples, reagents, and supplies while the system processes samples.

About CH Technology

The system uses both photometry and integrated multisensor technology (IMT) to process samples.

About CH Photometric Measurements

The analyzer uses photometric technology to measure the light absorbance of samples. These absorbances convert to qualitative, quantitative, and semi-quantitative test results that the analyzer reports.

Photometric assays process samples in reaction cuvettes that are at a constant temperature (37 °C) on the reaction ring. The analyzer measures the absorbances of the cuvettes prior to use and washes them after each use.

The following sequence summarizes a 2-reagent photometric measurement:

Step	Photometric measurements (2 reagents)
1	The dilution probe aspirates a sample from a sample container, and then dispenses and dilutes the sample into a dilution cuvette on the dilution ring.
2	The dilution mixer mixes the diluted sample.
3	The reagent probe aspirates the first reagent from the reagent pack and dispenses the reagent into a reaction cuvette on the reaction ring.
4	The sample probe aspirates the required amount of diluted sample and dispenses it into the reaction cuvette containing the first reagent. The remaining diluted sample in the dilution cuvette is available for additional tests on an order.
5	The sample mixer mixes the first reagent and the diluted sample.
6	The reagent probe aspirates the second reagent from the reagent pack and dispenses the reagent into the reaction cuvette containing the first reagent and the diluted sample. The analyzer adds the second reagent approximately 5 minutes after adding the sample to allow for reaction time between the sample and the first reagent.
7	The reagent mixer mixes the diluted sample and both reagents.

Step	Photometric measurements (2 reagents)
8	The reaction takes place for the amount of time the analyzer designates for the assay. The analyzer allots approximately 10 minutes of incubation time from the start of sample addition.
9	The photometer reads the absorbance data approximately once every 9 seconds.

About CH Results Calculation

The analyzer measures 2 types of assays:

- Photometric
- IMT

For photometric assays, the analyzer calculates absorbance measurements each time a reaction cuvette passes by the photometer and reports in milliabsorbance units (Absorbance x 10^{-3}). The analyzer collects the absorbance measurements every few seconds between the first reagent dispense up to 5 minutes after the second reagent dispense (if applicable). Absorbance measures at 11 wavelengths (340nm, 410nm, 451nm, 478nm, 505 nm, 545nm, 571nm, 596nm, 658nm, 694nm, and 805nm). Most photometric assays use a bichromatic technique. This technique has a main wavelength that is positioned near the chromogen's peak absorbance and a secondary wavelength positioned away from the chromogen's peak absorbance. The secondary wavelength is useful to minimize photometric noise and minimize the impact of interferences.

The analyzer calculates photometric assays as follows:

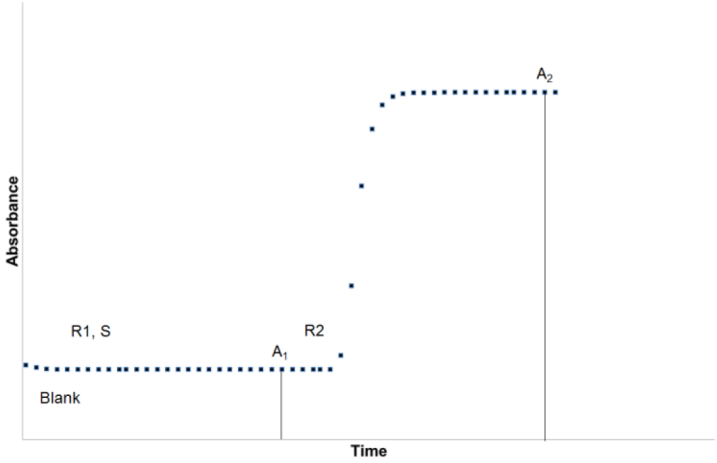
- Endpoint (Page 110 *About CH Endpoint Assay Calculation*)
- Rate (Page 111 *About CH Rate Assay Calculation*)
- 2-point (Page 111 *About CH 2-point Assay Calculation*)

For IMT assays, the analyzer measures the concentration of sodium (Na), potassium (K), and chloride (Cl) ions in patient samples through potentiometry. The dilution probe presents a diluted sample (1:10 with IMT Diluent) to a flow-through sensor cartridge. This cartridge encloses a reference electrode and 3 ion-selective electrodes: Na+, K+, and Cl-.

The electrical potential generated on a sample is compared to the electrical potential generated on a standard solution, and the concentration of the desired ions is calculated by use of the Nernst equation.

About CH Endpoint Assay Calculation

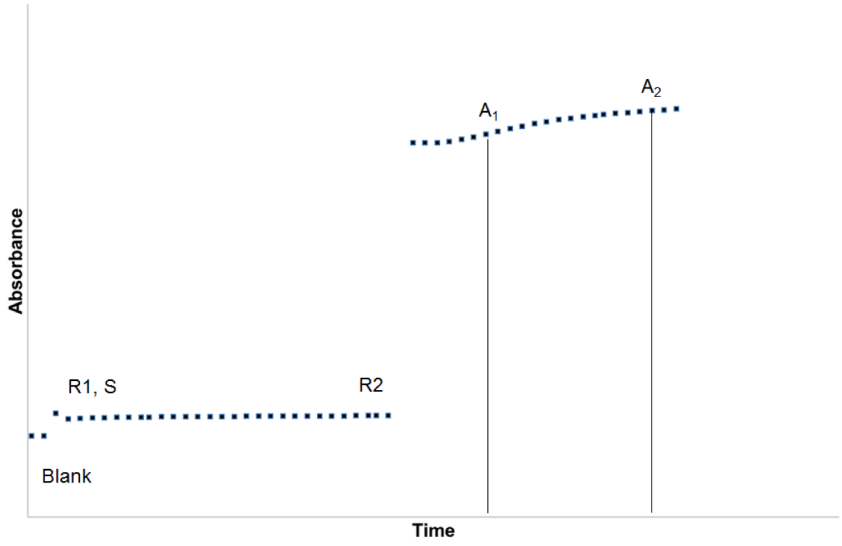
The endpoint assay measures absorbance after the reaction or color formation completes. For most endpoint assays, the analyzer collects 3 absorbance measurements and uses the median measurement in the calculated signal. This format can use a sample blank correction by measuring absorbance prior to the second reagent probe dispense (if applicable). A volume correction factor applies to the sample blank absorbance to account for the differential reaction volume before and after the reagent addition. The blank measurement adjusts the endpoint absorbance measurements. The analyzer collects the blank measurement during the reaction cuvette cleaning process when the cuvette contains water, prior to the start of every new assay test. The calculated signal converts to an assay concentration by mapping to a calibration curve.



- Blank: cuvette water blank
- R1: first reagent addition
- S: sample addition
- R2: second reagent addition (if applicable)
- A1: first absorbance time point (sample blank)
- A2: second absorbance time point (endpoint)

About CH 2-point Assay Calculation

The 2-point assay measures absorbance as the reaction proceeds. Assays with first-order reaction kinetics use the 2-point assay format. Absorbance measurements at 2 time points calculate the rate of absorbance versus time. The 2-point assay format uses a sample blank correction by measuring absorbance prior to the second reagent probe dispense (if applicable). A volume correction factor applies to the sample blank absorbance to account for the differential reaction volume before and after the reagent addition. The calculated signal converts to an assay concentration by mapping to a calibration curve.

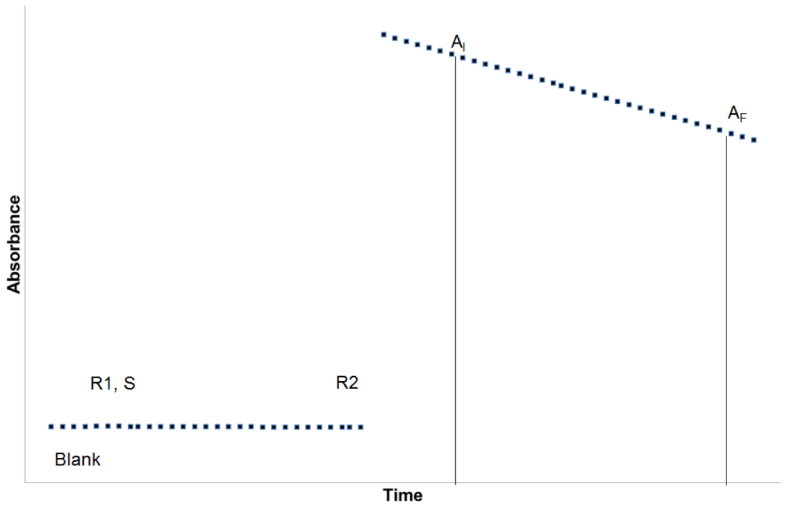


- Blank: cuvette water blank
- R1: first reagent addition
- S: sample addition
- R2: second reagent addition (if applicable)
- A1: first absorbance time point
- A2: second absorbance time point

About CH Rate Assay Calculation

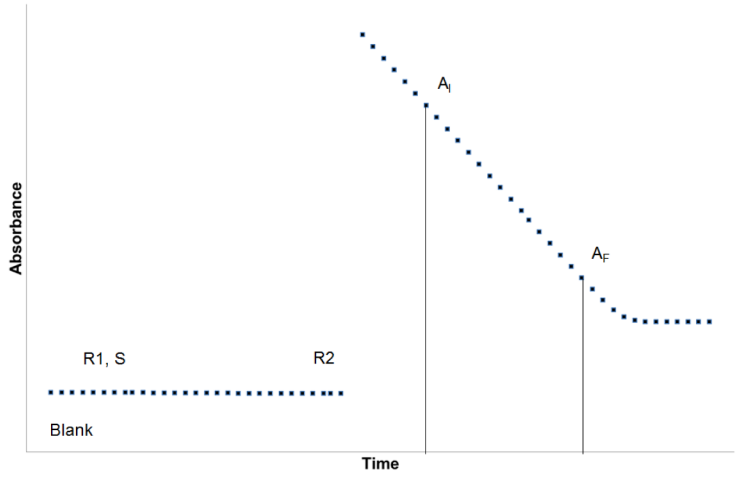
The rate assay measures absorbance as the reaction proceeds. The linear, zero-order reaction kinetics calculate the rate of absorbance versus time using a least-squares linear regression fit. The rate assay format can use a sample blank correction by measuring the change in absorbance versus time prior to the reagent probe second dispense (if applicable). A volume correction factor applies to the sample blank to account for the differential reaction volume before and after the reagent addition. The calculated signal converts to an assay concentration by mapping to a calibration curve.

Some rate assays perform a check to confirm the linear portion of the reaction rate is used in the signal calculation. The default measuring window is assessed for non-linearity and the measuring window is truncated to effectively capture only the linear portion of the reaction rate.



- Blank: cuvette water blank
- R1: first reagent addition
- S: sample addition
- R2: second reagent addition (if applicable)
- A1: initial absorbance time point
- A2: final absorbance time point

Some rate assays perform a check to confirm the linear portion of the reaction rate is in the signal calculation. The analyzer assesses the default measuring window for non-linearity and truncates the measuring window to effectively capture only the linear portion of the reaction rate.



About IM Chemiluminescence Technology

Chemiluminescence is a chemical reaction that emits energy in the form of light.[1–5] In combination with immunoassay technology, the light the reaction produces indicates the amount of analyte in a sample.

The analyzer applies the immunoassay binding principles of antibodies using the following formats:

- Sandwich
- Competitive
- Antibody-capture

The immunoassays use acridinium ester (AE) as the chemiluminescent label.[6]

Immunoassay Technology References

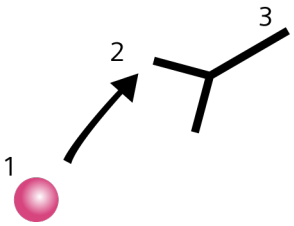
1. Whitehead TP, Kricka LJ, Carter JN, Thorpe G. Analytical luminescence: its potential in the clinical laboratory. *Clin Chem*. 1979;25(9):1531–1546.
2. Woodhead JS, Campbell AK, McCapra F, Beheshti I, Weeks I. Acridinium esters as high-specific-activity labels in immunoassays. *Clin Chem*. 1983;29(8):1474–1479.
3. Weeks I, Woodhead JS. Chemiluminescence immunoassays. *J. Clin Immunoassay*. 1984;7(1):82–89.
4. Patel A, Morton MS, Woodhead JS, Ryall MET, McCapra F, Campbell AK. A new chemiluminescent label for use in immunoassay. *Biochem Soc Trans*. 1982;10:224–225.

5. Tietz NW. *Fundamentals of clinical chemistry*, 3rd ed. Philadelphia, PA: W.B. Saunders Company; 1987:1010.
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About Antibody Binding Principles

Antibodies are proteins the immune system produces in response to an antigen. Antibodies can bind to specific antigens. In immunoassays, the antigen is the analyte that the system measures.

Antibody binding



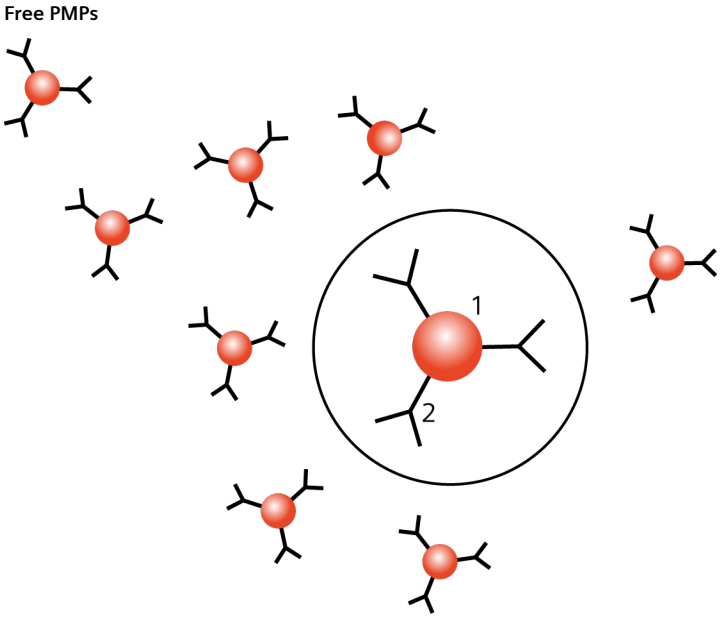
1	Antigen
2	Binding site
3	Antibody

To measure antigen, IM assays use antibodies that are covalently bound to AE without altering the ability of the antibody to bind to an antigen.

About IM Assays Paramagnetic Particles and Magnetic Separation

Paramagnetic particles (PMP) are iron oxide crystals.[1] PMPs coated with antibody or antigen make up the Solid Phase of IM assay primary reagent.[1]

During incubation, coated PMPs in the cuvette bind to the target antigen or antibody. The system exposes the cuvette to a magnetic field and draws the antigen or antibody-bound PMPs toward the magnets. While the magnets hold the PMPs in place, the system washes away unbound sample and reagent.



1	PMP
2	Antibody

Immunoassay Technology References

1. Dudley R. *The Immunoassay handbook*, 1st ed. New York: Stockton Press, 1994; 161–164.

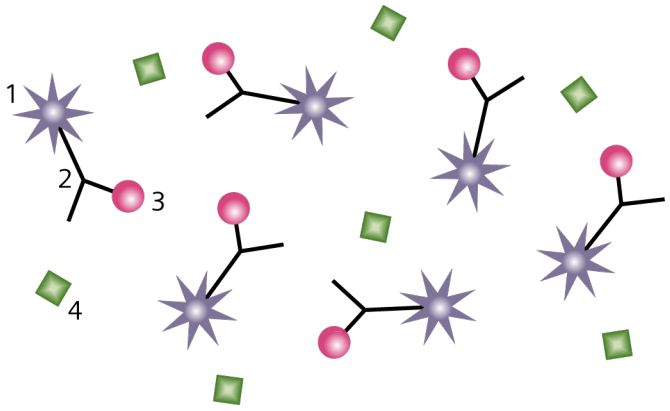
About IM Assays Sandwich Assay Complex Format

The IM Analyzer adds the following to the sample:

- Lite Reagent, containing AE-labeled antibody
- Solid Phase, containing antibody-labeled PMP

The system adds Lite Reagent, containing AE-labeled antibody, to the sample. The AE-labeled antibody binds specifically to the analyte-specific antigen in the sample.

Sandwich complex assay format

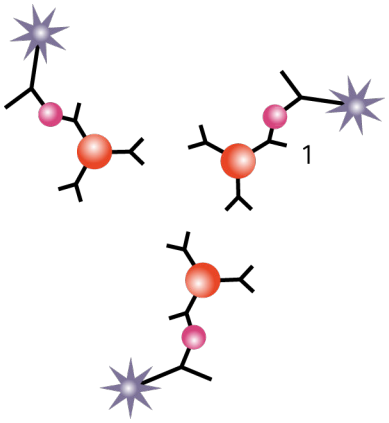


1	Acridinium ester (AE)
2	Antibody
3	Analyte-specific antigen in the sample
4	Other antigens

The system adds Solid Phase containing antibody-coated paramagnetic particles (PMP) that are specific for the antigen in the sample.

The system incubates the cuvette at 37°C (98.6°F). The PMPs bind to the antigens that bind to the AE-labeled antibody.

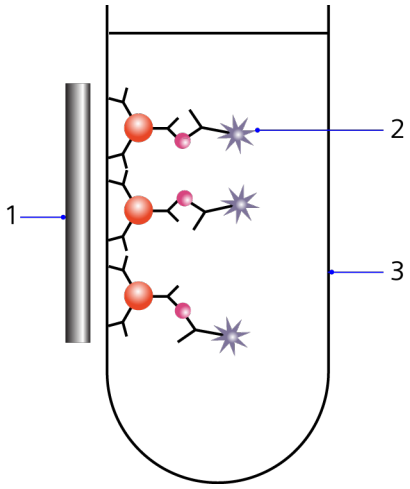
Sandwich complex assay format with Solid Phase



1	PMP-Antibody-Antigen-Antibody-AE complex

The IM Analyzer exposes the cuvette to a magnetic field and draws the antigen or antibody-bound PMPs toward the magnets. While the magnets hold the PMPs in place, the system washes away unbound sample and reagent. The sandwich complex made of PMP-Antibody-Antigen-Antibody-AE remains in the cuvette.

Sandwich format assay in the cuvette

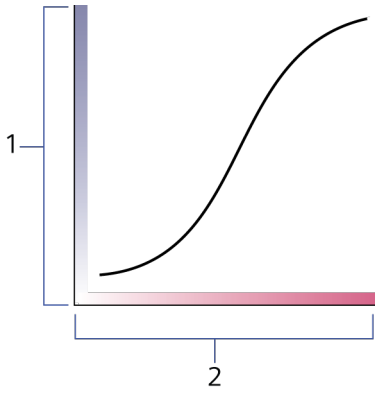


1	Magnets
2	PMP-Antibody-Antigen-Antibody-AE complex
3	Cuvette

The system adds acid and base to initiate the chemiluminescent reaction and measures the emission of light in relative light units (RLUs). The system quantitates the light the oxidation of AE produces and calculates the concentration of antigen.

In a sandwich complex format, the analyte-specific antigen concentration in the sample and the light emission in RLUs have a direct relationship. If more analyte-specific antigen molecules are present in the sample, more AE is present and the light emission is greater.

Sandwich complex assay format result analysis



1	Light emissions (RLUs)
2	Analyte concentration

About IM Assays Competitive Format

Competitive formats include:

- AE-labeled antigen in the Lite Reagent
- AE-labeled antibody in the Lite Reagent

About IM Assays AE-labeled Antigen

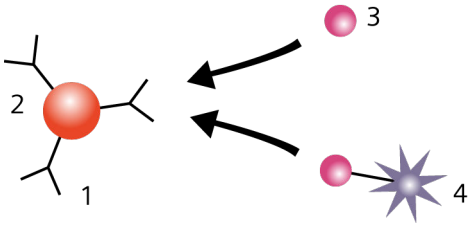
The IM Analyzer adds the following to the sample:

- Lite Reagent, containing AE-labeled antigen
- Solid Phase, containing antibody-labeled PMPs

The analyzer incubates the cuvette at 37 °C (98.6 °F). The AE-labeled antigen competes with analyte-specific antigen in the sample for limited binding sites on the antibody-bound PMPs.

If more analyte-specific antigen is present in the sample, less AE-labeled antigen binds to the antibody. Alternatively, if less analyte-specific antigen in the sample is present, more AE-labeled antigen binds to the antibody.

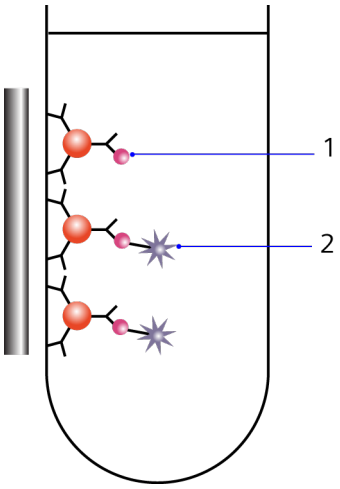
AE-labeled antigen



1	Antibody
2	PMP
3	Analyte-specific antigen in the sample
4	AE-labeled antigen

The IM Analyzer exposes the cuvette to a magnetic field and draws the AE-labeled antigen-antibody-bound PMPs toward the magnets. While the magnets hold the PMPs in place, the system washes away unbound sample and reagent. The PMP-antibody-analyte-specific antigen from the sample-AE-labeled antigen complex and the PMP-antibody-analyte-specific antigen from the sample complex remain in the cuvette.

AE-labeled antigen in the cuvette



1 PMP-Antibody-Antigen complex
2 PMP-Antibody-Antigen-AE complex

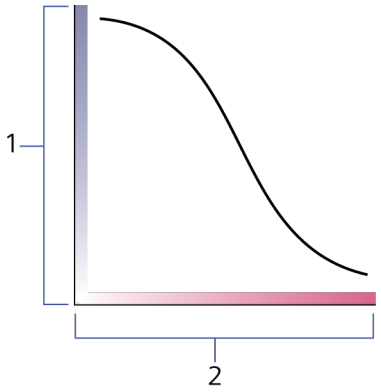
The IM Analyzer adds IM Acid and IM Base to initiate the chemiluminescent reaction and measures the emission of light in RLUs. The system quantitates the light the oxidation of AE produces and calculates the concentration of the analyte.

If the sample has a low concentration of analyte-specific antigen, AE-labeled antigen binds to more sites on the antibody-labeled PMP. This causes an elevated reading of RLUs.

If the sample has a high concentration of analyte-specific antigen, AE-labeled antigen binds to less sites on the antibody-labeled PMP. This causes a lower reading of RLUs.

In a competitive assay with AE-labeled antigen, the concentration of antigen in the sample and the light emission in RLUs have an inverse relationship.

AE-labeled format result analysis



1	Light emissions (RLUs)
2	Analyte concentration

About IM Assays AE-labeled Antibody

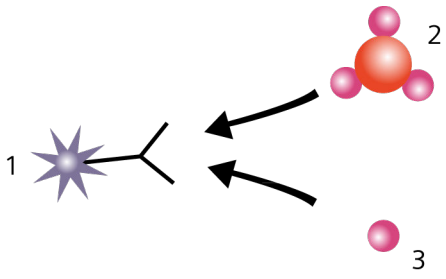
The IM Analyzer adds the following to the sample:

- Lite Reagent, containing AE-labeled antibody
- Solid Phase, containing antigen-labeled PMP

The system incubates the cuvette at 37 °C (98.6 °F). Antigen-bound PMPs compete with analyte-specific antigen in the sample for limited binding sites on AE-labeled antibody.

If more analyte-specific antigen is present in the sample, less PMP-labeled antigen binds to the AE-labeled antibody. Alternatively, if less analyte-specific antigen in the sample is present, more PMP-labeled antigen binds to the AE-labeled antibody.

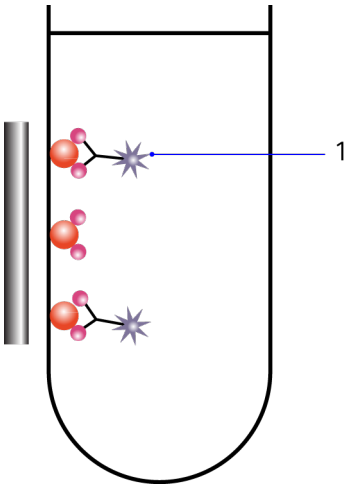
AE-labeled antibody



1	AE-labeled antibody
2	PMP-labeled antigen
3	Analyte-specific antigen in the sample

The IM Analyzer exposes the cuvette to a magnetic field and draws the AE-labeled antibody-antigen-bound PMPs complex toward the magnets. While the magnets hold the PMPs in place, the system washes away unbound sample and reagent. The PMP-analyte-specific antigen from the sample-AE-labeled antibody complex remains in the cuvette.

PMP-antigen-antibody-AE Complex in the cuvette



1	PMP-Antigen-Antibody-AE complex

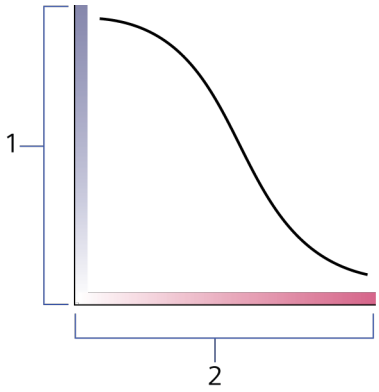
The system adds IM Acid and IM Base to initiate the chemiluminescent reaction and measures the emission of light in RLUs. The system quantitates the light the oxidation of AE produces and calculates the concentration of analyte.

If the sample has a low concentration of analyte-specific antigen, the PMP-labeled antigen binds to more sites on the AE-labeled antibody. This causes an elevated reading of RLUs.

If the sample has a high concentration of analyte-specific antigen, the PMP-labeled antigen binds to less sites on the AE-labeled antibody. This causes a lower reading of RLUs.

In a competitive assay with AE-labeled antibody, the concentration of analyte in the sample and the light emission in RLUs have an inverse relationship.

AE-labeled format result analysis



1	Light emissions (RLUs)
2	Analyte concentration

About IM Assays Antibody-capture Format

Antibody-capture assays detect specific IgG antibody or IgM antibody in patient samples. The IM assay reagent contains an additional antibody that can attach to the antibody in the sample.

The analyzer adds the following to the sample:

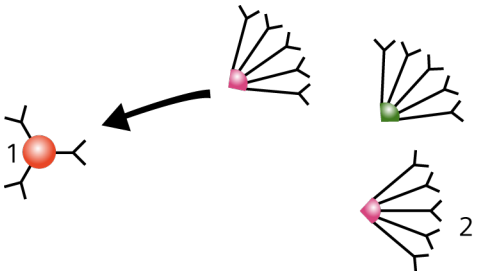
- Lite Reagent, containing AE-labeled antigen
- Solid Phase, containing anti-human IgG antibody or IgM antibody-labeled PMPs

Antibody-capture formats require 2 cycles of incubation and wash. The first incubation and wash removes excess interfering substances in the sample. The second incubation and wash prepares the antibody and AE-labeled antigen complex.

The following example is an antibody-capture assay that detects human IgM antibody in a patient sample:

The system adds Solid Phase, containing anti-human IgM antibody-bound PMPs, to the sample.

Antibody-capture assay format

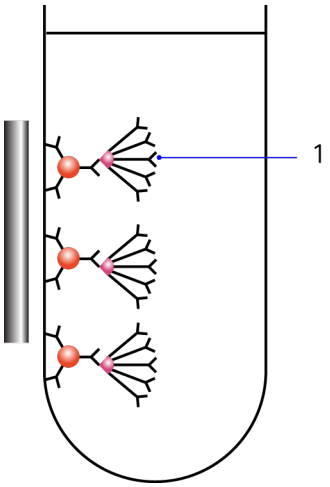


1	Anti-human IgM Antibody bound to PMP
2	Human IgM Antibody in sample

The system exposes the cuvette to a magnetic field that draws PMP toward the magnets.

While the magnets hold PMP in place, the system washes away sample and reagent not bound to PMP. The cuvette now contains the PMP-Anti-lgM Antibody-IgM from the sample complex.

Antibody-capture Assay Format in the Cuvette

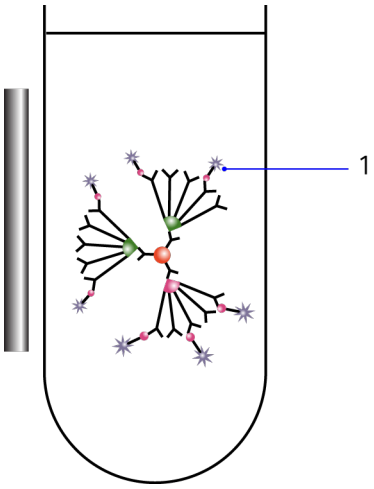


1	PMP-Anti-lgM Antibody-IgM complex

The system adds Lite Reagent, containing AE-labeled antigen, to the cuvette and incubates at 37 °C (98.6 °F).

The AE-labeled antigen binds to the sample IgM antibody in the sample.

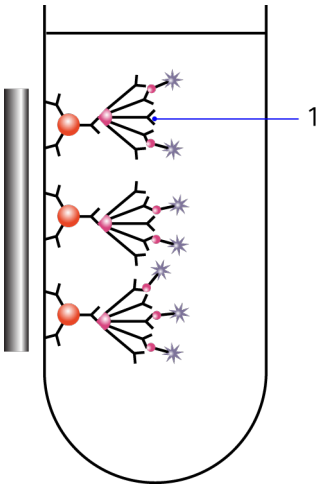
Antibody-capture assay format in the cuvette



1	AE-labeled antigen

The analyzer exposes the cuvette to a magnetic field and draws the antigen or antibody-bound PMPs toward the magnets. While the magnets hold the PMPs in place, the system washes away unbound sample and reagent. The antibody-capture complex made of PMP-Anti-IgM Antibody-analyte-specific IgM antibody from the sample-AE-labeled antigen remains in the cuvette.

Antibody-capture assay format in the cuvette



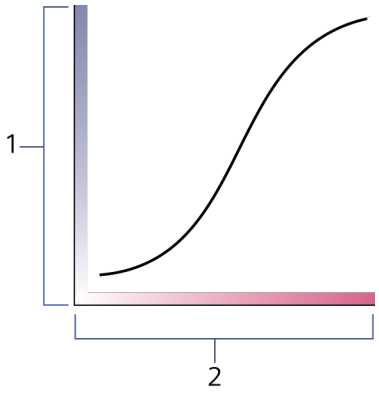
1	PMP-Anti-IgM Antibody-IgM-AE-labeled antigen complex

The system adds IM Acid and IM Base to initiate the chemiluminescent reaction.

The system measures the emission of light in RLUs. The system quantitates light the oxidation of the AE produces and calculates the concentration of the analyte.

In this example of an antibody-capture assay, the sample concentration and the light emission have a direct relationship. If more sample IgM antibody is present, more AE is present and therefore the light emission is higher.

Antibody-capture assay format result analysis



1	Light emissions (RLUs)
2	Analyte concentration

About IM Assay Result Calculation Formulas

The assay test definition determines the type of formula the IM Analyzer uses to calculate IM assay results.

The analyzer utilizes the following result calculation formulas:

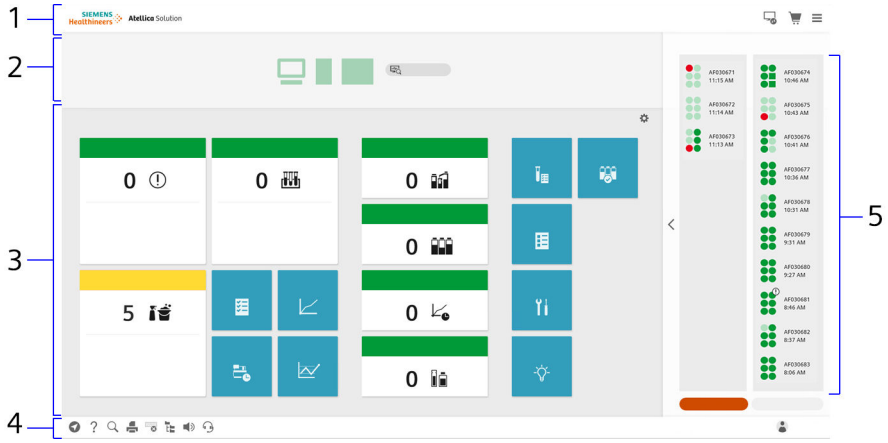
- Four parameter logistic (Four PL)
- Four parameter logistic weighted (Four PLW)
- Five parameter logistic (Five PL)
- Five parameter logistic weighted (Five PLW)
- Spline
- Single point
- Multicomponent

7 Software

Software Overview

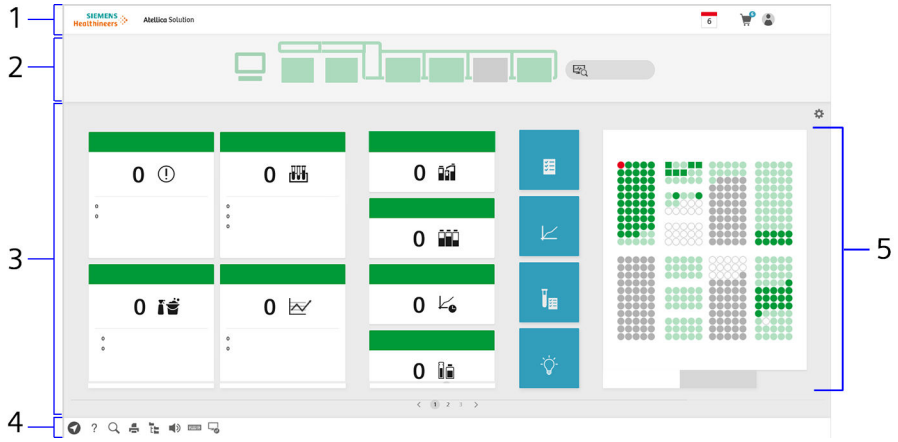
The Home screen displays system functions and information.

Standalone Configuration



1	Access bar
2	System Status
3	Dashboard
4	Tool bar
5	Samples

Sample Handler Configuration



1	Access bar
2	System Status
3	Dashboard
4	Tool bar
5	Samples

The Access bar displays at the top of every window and contains system information, system status icons, and operator controls.

The System Status area consists of the System Status Map and access to troubleshooting functions.

The Dashboard consists of dynamic tiles that display activity statuses, samples information, system needs requiring operator attention, and static shortcut tiles to the most commonly used screens.

The Dashboard is configurable. The operator can add or remove certain tiles from the Dashboard but others, like Samples, are mandatory.

The Tool bar contains system utility functions.

The area for Samples displays rack information and sample statuses.

About the Access Bar

The Access bar displays at the top of every Atellica® Solution window and contains system information, system status icons, and operator controls. Some items do not display on the Home screen.

Access bar	Notes
	Previous screen. Available when operator navigates away from Home screen.
	Home. Available when operator navigates away from Home screen.
Product name	Name of the system.
Navigation path	The screen hierarchy that displays in the Navigator when the operator navigates away from the Home screen.
Screen title	Name of the current screen except on the Home screen.
System Status map	Current status of all modules on the system: • Green: The module is able to process samples. • Green with red triangle in corner: The analyzer has partial capability and cannot process samples. • Gray: The module is disconnected or stopped. • Yellow: The module is in maintenance. • Red: The module has stopped because of a failure and cannot process samples. The count of alerts displays.

Access bar	Notes
	Notifications. The count indicates the number of red and yellow Dashboard tiles plus the number of unacknowledged alerts (error and warning messages that do not otherwise display as system status or dynamic tile alerts). The count updates dynamically as conditions on the system change. The color changes to match the highest severity alert in Notifications. The icon is animated when the system adds: • A new alert and the operator is not viewing the Home screen. • A new alert that is not related to any displayed Dashboard tiles and the operator is viewing the Home Screen.
	Cart List. The number of items currently in the cart displays and updates dynamically.
	User menu containing Help, About, and Sign Out.

About Notifications

Notifications consists of:

- Error and warning messages outside of system status or dynamic tile alerts. These messages initially display as alert popups that close automatically after 5 seconds. The list of messages displays all errors followed by all warnings, sorted with the most recent first.
- The dynamic tiles on the Dashboard that display red or yellow alert conditions.

  NOTE: Alerts for tiles the operator removes from the Dashboard using Dashboard setup do not display in Notifications.

The tile count increments as the system adds a message because of new alert conditions or dynamic tiles change from green to red or yellow.

The tile count decrements as the operator acknowledges messages or a dynamic tile changes to green. Acknowledged messages remain in Notifications until the operator resolves the alerting condition.

Control	Notes
	Acknowledges alert. Selecting unbolds message text and decrements icon count by 1.
Acknowledge All	Acknowledges all unacknowledged alerts. Unbolds all message text. Decrements icon count by the number of acknowledged alerts. The icon count matches the number of dynamic tiles in Notifications.
Troubleshooting	Displays the Troubleshooting screen with the Operator Event Log and Online Help filtered to information related to the alert condition.
Dynamic tile	Displays the screen that contains the alerts without navigating to the Home screen first.

Reviewing Notifications

1. On the Access bar, select 5.
2. To acknowledge a new alert message, select next to the appropriate message.
3. To acknowledge all new alert messages, select **Acknowledge All**.
4. To view alerts for a dynamic tile, select the appropriate tile.
5. To access troubleshooting information for a specific alert, select **Troubleshooting** for the appropriate alert message.

About Software Information and System Information

The operator locates the system software version before contacting the local technical support provider. The system software version is located in the following areas:

- Lower right corner
- Navigate to **General > About**

Software Information displays the software and other tools the system uses with its corresponding versions (Page 132 *Atellica® Solution Software Copyright Information*).

System Information displays the hardware information about the modules included in the system.

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Immunoassay Analyzer (IM)

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Locking the Screen

1. Select  .
2. Select  .
3. Select  .
4. To sign back in as the current operator:
   a. Select **Unlock**.
   b. Enter the appropriate password.
   c. Select **Unlock**.
5. To sign in as another operator:
   a. Select **Change Operator**.
   b. Enter the appropriate Operator ID.
   c. Enter the appropriate password.
   d. Select **Sign In**.

Unlocking the Screen

1. To sign back in as the current operator:
   a. Select **Unlock**.
   b. Enter the appropriate password.
   c. Select **Unlock**.
2. To sign in as another operator:
   a. Select **Change Operator**.
   b. Enter the appropriate Operator ID.
   c. Enter the appropriate password.
   d. Select **Sign In**.

About the System Status Area

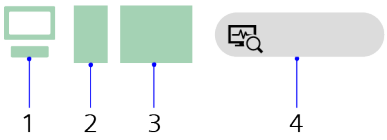
The area for System Status provides access to the status of all system modules and Troubleshooting functions.

The map for System Status is a graphical representation of the system. It displays the status of each module and automatically refreshes when changes occur on the system. The name of each module displays below it.

Selecting **Troubleshooting** displays the following:

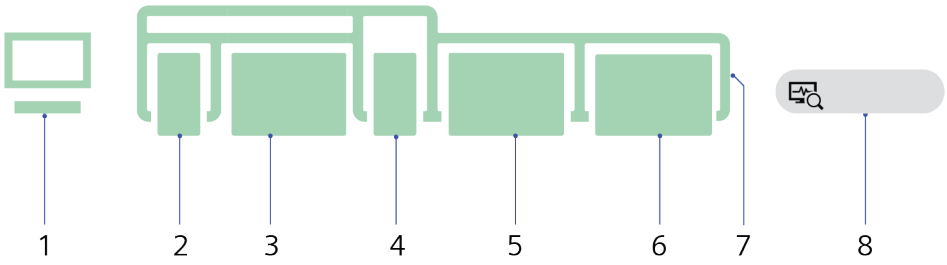
- Online Help
- Diagnostics
- Service Support Request

System Status map - Standalone Configuration



1	PCC
2	Sample loading module
3	Analyzer
4	Troubleshooting

System Status map - SH Configuration



1	PCC	5	Analyzer
2	Sample Handler Connect	6	Analyzer
3	Sample Handler	7	Atellica Magline Transport
4	Decapper	8	Troubleshooting

NOTE: The map for SH System Status displays in linear form even when the system is configured as L- or U-shaped. Turns display as track segments in the linear form. The displayed modules vary with the installed configuration.

The following colors indicate the status of each module:

Color	Description
Green	Module is processing without any issues.
Green with red corner	Module is partially processing but cannot process samples.
Yellow	Module is in maintenance mode. Selecting a module displays the maintenance activities inprocess.
Red	Module has stopped because of a failure and cannot process samples. The count of alerts displays. If errors or alerts occur anywhere on the track when the Atellica Magline Transport is in Ready, Standby, or Processing, displays in the top right corner of the track. When selecting anywhere on the track, the exact sections with errors highlight in red and errors display.
Red with or	Module is in diagnostic state.

Color	Description
Gray	Module is in stopped state with no errors.
Gray with ⟳	Module is in startup.
Gray with ⏻	Module is in off state.

Reviewing Module Status

1. In System Status, select the appropriate module.
2. Review module status and resolve any issues.

Changing the Module Status

1. In the area for System Status, select the appropriate module.
2. Change the module state by selecting:
   - ⏻ to shut down the module
   - ■ to stop processing

     NOTE: If the system is processing samples, select the option to wait for processing to stop or stop immediately.
   - ▶ to resume sample processing
3. Select **Yes**.

About the Atellica Magline Transport Status

The Atellica Magline Transport status provides the following information and controls:

- Name and type of module
- Activity or transition state
- Communication status
- If not connected to the PCC, the date and time of the last connection to the PCC
- Module controls
- Timespan until a state transition completes
- Atellica Magline Transport diagram
- Alerts specific to the Atellica Magline Transport with the category and time for each

About the SH Status

The SH status provides the following information and controls:

- Name and type of module
- Activity or transition state
- Communication status
- If not connected to the PCC, the date and time of the last connection to the PCC
- Module controls
- Timespan until a state transition completes
- Controls that allow the operator to perform the following functions:
  - Confirm Cal-QC Storage contents
  - Unlock and lock the Front Cover
  - Unlock and lock the Back Cover
- Alerts specific to the SH with the category and time for each

About the SHC Status

The SHC status provides the following information and controls:

- Name and type of module
- Activity or transition state
- Communication status
- Module controls
- If not connected to the PCC, the date and time of the last connection to the PCC
- Timespan until a state transition completes
- Controls that allow the operator to perform the following functions:
  - Diagnostics
  - Unlock and lock the Front Cover
- Alerts specific to the SHC with the category and time for each
- Information regarding LAS connectivity

About the Decapper Status

The Decapper status displays the following in the System Health area:

- Name of module.
- Color of the Decapper icon represents its current state:
  - Grey: Off
  - Green: No alerts
  - Yellow: Operator or system initiated maintenance
  - Red: 1 or more system-level alerts
- Icons indicating inprogress () and error ().
- Communication status: Connected to PCC or Not connected to PCC.
- Module control icons: Power off, stop, and resume the Decapper hardware and software.
- Timespan until a state transition completes.
- General module Alerts including description and Time.
- When a Decapper is in maintenance mode, the system displays the maintenance activities inprogress.

About the Sealer Status

The Sealer status provides the following information and controls:

- Name
- Activity or transition state
- Communication status
- If not connected to the PCC, the date and time of the last connection to the PCC
- Module controls
- Timespan until a state transition completes
- Alerts specific to the Sealer with the category and time for each

About the CH Analyzer Status

The CH Analyzer status displays the following in the System Health area:

- Name of analyzer.
- Color of analyzer icon represents its current state:
  - Grey: Off
  - Green: No alerts
  - Green with red triangle in corner of icon: Partial capability
  - Yellow: Operator or system initiated maintenance
  - Red: 1 or more system-level alerts
- Icons indicating inprogress () and error ().
- Communication status: Connected to PCC or Not connected to PCC.
- Analyzer control icons: Power off, stop, and resume the analyzer hardware and software.
- Timespan until the state transition completes.
- General analyzer Alerts including description and Time.
- When an analyzer is in maintenance mode, the system displays the maintenance activities inprogress.
- Controls that allow the operator to lock and unlock the following covers:
  - Front Cover Locked () or Front Cover Unlocked ()
  - Back Cover Locked () or Back Cover Unlocked ()

  When the cover is closed and the module is resumed, the system automatically locks the cover.
- Patient Sample Processing check box must be selected to process patient samples.

About the IM Analyzer Status

The IM Analyzer status displays the following in the System Health area:

- Name of analyzer.
- Color of analyzer icon represents its current state:
  - Grey: Off
  - Green: No alerts
  - Green with red triangle in corner of icon: Partial capability
  - Yellow: Operator or system initiated maintenance
  - Red: 1 or more system-level alerts
- Icons indicating inprogress () and error ().
- Communication status: Connected to PCC or Not connected to PCC.
- Analyzer control icons: Power off, stop, and resume the analyzer hardware and software.
- Timespan until the state transition completes.
- General analyzer Alerts including description and Time.
- When an analyzer is in maintenance mode, the system displays the maintenance activities inprogress.
- Controls that allow the operator to lock and unlock the following covers:
  - Front Cover Locked () or Front Cover Unlocked ()
  - Back Cover Locked () or Back Cover Unlocked ()

  When the cover is closed and the module is resumed, the system automatically locks the cover.
- Patient Sample Processing check box must be selected to process patient samples.

Disabling Patient Sample Processing

1. In System Status, select the appropriate module.
2. Deselect the check box for Patient Sample Processing.
3. Select **Yes**.

About the DL Status

The DL status displays the following in the System Health area:

- DL module name.
- Color of DL icon represents its current state:
  - Grey: Off
  - Green: No alerts
  - Yellow: Operator or system initiated maintenance
  - Red: 1 or more system-level alerts
- Icons indicating inprogress () and error ().
- Communication status: Connected to PCC or Not connected to PCC.
- Module control icons: Power off, stop, and resume the DL hardware and software.
- Timespan until the state transition completes.
- General module Alerts including description and Time.
- When the DL is in maintenance mode, the system displays the maintenance activities inprogress.
- Controls that allow the operator to lock and unlock the cover:
  - DL Cover Closed ()
  - DL Cover Open ()

  When the cover is closed and the module is resumed, the system automatically locks the cover.
- Patient Sample Processing check box must be selected to process patient samples.

About System Alerts

The system displays all Alerts that may affect system processing in the system status area. The icon of each module or analyzer that has an alert displays red or yellow to assist the operator in locating the source of the alert. The operator selects the appropriate icon to view the text of the Alerts and access the Troubleshooting for each alert. The icon continues to display red or yellow until the laboratory has resolved the alert.

In addition, the titles of the tile in the Dashboard display red, yellow, or green to indicate the status of the feature:

Status light	Description
Solid green	The feature is operating normally.
Solid yellow	One or more warning conditions exist.
Solid red	One or more critical conditions exist that may cause the system to stop processing samples. The system requires immediate attention.

The laboratory can suppress specific Alerts in the tab for Configure Alerts in Alert Settings so that the Alerts are no longer visible to the operator.

NOTE: The system response to suppressed alert conditions remains the same and operators must continue to resolve any conditions that arise. If an alert is suppressed and the system stops new tests from processing, the system does not allow new tests to start until the operator resolves the alert condition, even if the alert is suppressed and does not display. The light pole does not indicate suppressed alerts. Appropriate security privileges are required to suppress alerts.

Viewing Alerts

1. In System Status, select the system or a module icon.

   NOTE: Suppressed Alerts do not display.
2. To sort the Alerts, select the appropriate column heading.
3. Select the appropriate alert.
4. Select **Troubleshooting**.
5. In Operator Event Log, select the appropriate alert and review the details.

About the Dashboard

The Dashboard consists of a configurable, tile-based layout with the following default functional groups:

- Current Status: Consists of sample and maintenance activity status tiles and predefined shortcut tiles.
- Day Needs: Consists of consumable status tiles.
- Tools: Consists of predefined shortcut tiles.

NOTE: Because the Dashboard is configurable, references to group names, Dashboard layout, and tile location within groups refer to their default configuration.

View Mode

Tiles that display a status color dynamically update the displayed information and are resizable. Single-color tiles are predefined or operator-defined shortcut tiles, static, and cannot be resized.

Tile Status Colors



1 Critical alerts exist.
2 Maintenance is in process or an activity is due within the warning threshold.
3 No issues require immediate attention.

Dashboard	Notes
	Dashboard setup mode.
STAT Samples	Summary information about STAT samples on the system. The tile title displays 1 of 2 colors: • Red: At least 1 STAT sample requires intervention. • Green: No STAT samples require intervention. The tile body displays: • The count of STAT samples that require intervention and the count of STAT samples inprocess.

Dashboard	Notes
Sample Interventions	Summary information about patient, calibration, and QC samples on the system that require intervention. The tile title displays 1 of 2 colors: • Red: At least 1 patient, Cal, or QC sample requires intervention. • Green: No samples require intervention. The tile body displays: • The total number of patient, Cal, and QC samples that require intervention.
Maintenance	Summary information about the maintenance activities for the operator-defined day. The tile title displays 1 of 3 colors: • Red: Immediate operator intervention required. One or more maintenance activities failed for the day. The title remains red until these activities successfully complete or the operator reschedules them to a new day. • Yellow: One or more Inprocess or Due activities exist within the configured maintenance activity reminder time. • Green: No Failed, Inprocess, or Due maintenance activities exist to automatically start within the configured maintenance activity reminder time.

Dashboard	Notes
	The tile body displays: • Number of current calendar day's Maintenance activities not completed and Due. • Number of current calendar day's Maintenance activities completed with a failed status. • Modules that are starting maintenance. • Modules where maintenance is in progress.
QC Statistics	A summary count that represents the total number of QC Errors and Warnings currently on the system. The tile title displays 1 of 2 colors: • Green: No QC errors exist. • Red: 1 or more QC errors exist on the system. The tile body displays: • Number of errors • Number of warnings The operator selects the tile to open QC Statistics when the QC interface is enabled for the system.

Dashboard	Notes
Supply Needs	Summary information about the supply needs. The tile title displays 1 of 2 colors: • Red: If 1 or more supply or waste alert conditions exist: – The consumable usable remaining volume is 0. – The onboard stability expires within the operator-defined threshold. – The count is less than the sample warning level. – Waste status is above the operator-defined threshold. • Green: No supply or waste alert conditions exist. The tile body displays the count of required supplies.
Reagent Needs	Summary information about the reagent needs for the operator-defined day. The tile title displays 1 of 2 colors: • Red: One or more of the reagent alert conditions exist. • Green: No reagent alert conditions exist. The tile body displays the total number of reagent needs required to complete testing for the day.

Dashboard	Notes
Calibrations Due	Summary information for assay reagents onboard the system and associated calibrations. The tile title displays 1 of 2 colors: • Red: At least 1 calibration is due Today within the threshold configured in Calibration Due Warning (hours) and requires 1 or more of the following: – Calibration order. – Calibrator Material is not defined, inactive, or expired. – Calibrator Material not onboard. – QC material is not defined or onboard when Perform QC with Calibration is enabled, based on the QC Master List. • Green: No calibrations due Today within the threshold configured in Calibration Due Warning (hours) that require operator intervention. Today is the period before midnight of the current day. The tile body displays the number of calibrations due on the current day before midnight that require intervention. In Calibrations Due, the calibrations that display include the calibrations that are due before midnight of the next day and require intervention.

Dashboard	Notes
QC Needs	Summary information about the QC Needs for the operator-defined day. The title displays 1 of 2 colors: • Green: No alert conditions exist. • Red: An order is placed and there is: – No QC onboard. – QC is onboard but the control material is unusable due to insufficient sample volume or stability expired errors. The tile body displays: • The total number of alert conditions. • The tile size can be small or medium and the same information displays on both.
Worklist	The operator selects to open WorkList.
Calibration Results	The operator selects to open Calibration Results.
Lab Evaluations	The operator selects to open Lab Evaluations . The following Lab Evaluations are available: • QC Parallel • Reagent Comparison • Automatic Measuring Interval Verification • Manual Measuring Interval Verification • Simple Precision
Orders	The operator selects to open Orders.

Dashboard	Notes
Assay Status	The operator selects to open Assay Status.
Guided Workflows	The operator selects to display predefined workflows. The following workflows are available: • Assay Setup • QC Settings and Master List • HIL Setup • Monthly Approvals and Lab Metrics • Start of the Shift • System Configurations • Software Updates
QC Scheduler	The operator selects to open QC Scheduler.
Utilities	The operator selects to open Utilities. The following utilities are available: • Data Restore • Copy Configuration • Directories • Audit Trail Log • Kinetics • Lab Metrics
Samples	The status of all sample container positions for all racks on the system. Information dynamically updates as statuses change. Selecting a rack displays Samples Overview (Page 152 *About Samples*).
	This image displays when more than 1 Dashboard page exists.

Edit Mode

When the Dashboard is in edit mode, the layouts, group names, available tiles, and tile sizes are configurable. To edit the Dashboard, the operator selects ⚙.

Edit Home Screen Layout	Notes
	Displays tile resize options.
	A smaller black X inside a white circle removes a tile or group from the Dashboard. Removing a group removes all tiles in the group.
	A larger grey X deletes a group name. Group names can be blank. The operator must select the group tile to display the grey X.
	Moves groups around the Dashboard when the operator selects and drags this control.
	Deletes the currently viewed page from the Dashboard.
Add or Remove Tiles	Displays the Add Tiles to Home window.
Add New Group	Adds an empty group to the Dashboard with a default name. Drag and drop tiles to add them to the group. Selecting Group Name makes it editable.
Restore Default	Restores the Dashboard to the default layout and exits edit mode.

Edit Home Screen Layout	Notes
Save	Saves the current Dashboard configuration.
Cancel	Cancels any changes made to the current Dashboard configuration.

About Dashboard Setup

The operator can customize the Dashboard by selecting the Edit Home icon . From the screen for Edit Home, the operator can:

- Add or remove tiles, groups, and pages
- Resize tiles
- Create new groups
- Add tiles to groups
- Modify the dashboard layout

About Samples

Samples displays the status of all sample container positions for all racks on the system. Information dynamically updates as statuses change. Selecting a rack displays Samples Overview for SH systems and Rack Overview for standalone systems (Page 362 *About SH Samples Overview and Standalone Rack Overview*). Samples cannot be relocated or removed from the Dashboard on either SH or standalone systems.

Each tube position displays an icon indicating its current processing status:

Sample container position icon	Notes
Circle	Patient sample.
Square	Cal-QC sample.
	The position is empty.
	An unidentified container. The DVS has scanned the position and a container is present but the TCS has not yet scanned the barcode.

Sample container position icon	Notes
	The position is unusable.
	The sample status is Waiting or Started.
	The operator configured the calibration or QC container to store in Cal-QC storage, but the storage area is full, the temperature is out of range, or the container has unconfirmed content. The sample status is Overflow. The sample returns to the storage area when the condition is resolved. The system returns the container to an output rack in a sample drawer. The operator must remove the container from the system and properly store the container or make room in Cal-QC storage.
	The operator did not configure the calibration or the QC container to store in Cal-QC storage and the sample status is Waiting or Started, but aspiration is not complete.
	The sample status is Aspirated.
	The sample status is Aspirated and the operator did not configure the container to store in Cal-QC storage.
 	The sample status is Complete.

Sample container position icon	Notes
	The sample container has no orders. The operator must check for orders. If no orders exist, the operator can manually enter an order or remove the container from the system.
	The system detected the material in the calibrator or QC container is partially expired. The operator must determine which parts of the material are still usable.
	The operator loaded a calibrator or QC container and the system has no orders for the material. The operator must check for orders. If no orders exist, the operator can manually enter an order or remove the container from the system.
	Sample error.

SH Configuration

Samples on SH systems displays statuses of all racks in the selected SH. For multi-SH systems, a tab displays for each SH. Selecting anywhere on the displayed SH tab displays all SHs on one screen. Selecting a rack displays Samples Overview. If an archive rack is unusable, all rack positions display  and  is superimposed on the entire rack.

Standalone Configuration

Samples on standalone systems displays the statuses of all Inprocess Racks and up to the last 10 Processed Racks.

Samples Panel	Notes
Inprocess Racks	Racks in the rack shuttle or rack positioner inside the analyzer sorted by Scanned Time. The sample statuses update automatically when changes occur on the system.
Processed Racks	The last 10 racks the analyzer processed sorted by Scanned Time. These racks reside in the output queue or an operator-designated location.
 (Left-hand side of Samples)	Displays Rack Overview with sample statuses for all samples in the selected rack. Select a rack from Inprocess Racks.
Clear All Racks	The system removes all racks from Processed Racks. **NOTE:** The system may remove a rack from Processed Racks but still be physically in the output queue.
	The system deletes the selected rack from Processed Racks.
	Superimposed on another status icon to indicate a STAT sample.

Deleting Racks from Standalone Processed Racks

1. In **Home** > **Samples** > **Processed Racks**, select a rack.
2. Select  .
3. To delete all racks, select **Clear All Racks**.

About the Tool Bar

The Tool bar on the bottom of the screen contains icons for quick access to functions.

Tool Bar Icon	Notes
	Accesses Search and Navigator functions. The Navigator displays the site map of all software screens.
	Displays online help.
	Searches for a specific Sample ID, Patient ID, Patient Name, or Rack ID.
	Accesses print options for the current screen.
	Accesses folders containing archives, back-ups, and exports, and manages data transfer to USB.
	Adjusts the volume of the system alerts.
	Indicates muted system volume.
	Displays an on-screen keyboard for text input.
	Indicates the on-screen keyboard is deactivated.
	Launches Teamviewer to allow the service provider remote access to the system.
	Displays when 1 or more troubleshooting windows are minimized without completing them. Selecting displays thumbnails with the window title.
	Displays when 1 or more Guided Workflows workflow windows are minimized without completing them. Selecting displays thumbnails with the window title.

Tool Bar Icon	Notes
	Creates a shortcut of the currently-viewed screen, including any active filters, and adds it to the Dashboard.
	Indicates the system is communicating and sending updates to the APM.
	Indicates the operator at the APM is remotely connected and controlling the system.
	Displays or changes the current status of the LIS connection and performs diagnostics.
	Indicates the LIS is connected.
	Indicates the LIS is disconnected.
	Indicates the system is attempting to connect to the LIS.
	SRS is enabled in Informatics Connection settings. Selecting  opens the Create a Service Support Request window.
	Indicates an error with the ticketing interface.
	Indicates a request error exists.

About Navigator

Navigator lists all screen titles on the system. The titles are hyperlinked for direct navigation.

Navigator	Notes
Search	Filters the listed screens. Typing a string in Search highlights the screens with that string in their name.
Update Dashboard Tiles	Displays a check box next to all screen titles. Checked screens have a tile on Dashboard.

About the System Search

The 🔍 on the Tool bar displays System Search and allows the operator to search for sample and patient information from any screen. The operator can select 🔍 and specify a sample ID, rack ID, patient ID, or patient name to search in the active or historical database. Alternately, the operator can scan barcodes, if available. The active database contains current orders not yet in historical. The historical database contains past records that cannot be changed.

NOTE: The active database contains current orders not yet in historical. The historical database contains past records that cannot be changed.

The operator can also specify whether to include the events in the System Search.

About LIS Communication Status

The LIS Communication window allows the operator to connect or disconnect from the LIS and respond to LIS connectivity messages.

About Guided Workflows

Related tasks require the appropriate security level.

Guided workflows allow the operator to complete a multistep process without navigating to multiple windows. These workflows display in the main navigator window.

The operator can:

- Complete 1 or multiple parts of a guided workflow.
- Exit the guided workflow at any point, then save or discard changes.
- Save pending changes during the workflow by selecting **Save**, if available.
- Cancel saved changes during the workflow by selecting **Restore Default**, if available.

About Communications

The communications message on the module status indicates if the module is connected to the PCC.

Cybersecurity

The system protects data integrity and patient confidentiality through the following:

- Operator ID authentication and identification (Page 161 *About Protecting the System from Unauthorized Operators*)
- Timed operator sessions (Page 161 *About Operator Sessions*)
- Encryption of protected health information (PHI) data (Page 163 *About the PHI Key*)

An anti-virus solution and application whitelisting protects the system from malicious attacks (Page 160 *About Protecting the System from Viruses and Malware*).

WARNING

Do not delay installing security updates on the system. A delay may permit cyber attacks against the system and potentially cause operator and patient harm. Install approved security updates in a timely manner.

Cybersecurity Icons

Icons alert the operator to a required action or more information.

Icon	Notes
	Sorts a column in the descending direction
	Sorts a column in the ascending direction
	Indicates additional fields are available to the operator
	Closes or removes the selection or feature
	Indicates that the operator has applied a filter

Icon	Notes
	Indicates that the filter is clear
	Searches in the ascending direction
	Searches in the descending direction
	Sets the date and time
	Indicates a warning condition is present
	Indicates that online help is available for the window
	Signs in or signs out the operator

About Protecting the System from Viruses and Malware

An anti-virus solution protects the system from viruses and malware.



CAUTION

Do not use a system infected by a virus or malware. Using a system infected with a virus or malware can cause erroneous results or compromise other data. Discard all results from an infected system, and contact the local technical support provider.

The operator should immediately report any suspected malicious activity to the local technical support provider (Page 695 *Contacting the Local Technical Support Provider*). The local technical support provider collects forensic evidence and initiates an Incident Handling and Vulnerability Handling process to protect the system and data.

The system also limits access to the operating system and prevents automatic executables from initiating.

NOTE: Application whitelisting software contains a list of safe applications and blocks any application from launching that is not on this list.

About Protecting the System from Unauthorized Operators

Access to the system requires a valid Operator ID and password. The system software authenticates the credentials of the operator and authorizes the operator's access in the application.

The Audit Trail Log provides a chronological record of each time an operator accesses the system (Page 710 *About the Audit Trail Log*).

About Operator Sessions

An operator session is the total time that the operator is signed in to the system. Each operator sign-in starts a session that is active until 1 of the following occurs:

- A new operator signs in after the system automatically locked the screen because of inactivity (Page 846 *About the Automatic Screen Lock*).
- The operator signs out of the system.
- The operator shuts down the system.
- The operator restarts the system.

The operator should always Sign Out of the system or lock the screen before leaving the system unattended (Page 643 *Signing out of the System*) (Page 135 *Unlocking the Screen*).

NOTE: The system posts an entry to the Audit Trail Log each time an operator signs in, signs out, or unlocks the system. The system also posts an entry each time the software signs out an operator because another operator signs in to the system (Page 710 *About the Audit Trail Log*).

About Manually Locking the Screen

The operator can manually lock the screen if leaving the system unattended. After the operator locks the screen, the window for Lock displays to prevent unauthorized access to the system.

Lock has the following options:

Option	Notes
Unlock	Enables the operator who locked the screen to sign back in and continue the current operator session (Page 135 *Unlocking the Screen*).
Change Operator	Enables a different operator to sign in to the system. The current operator session ends and a new session begins (Page 162 *Changing the Operator of Locked Screens*). **NOTE:** The system discards any unsaved data before the new session begins (Page 161 *About Operator Sessions*).

Changing the Operator of Locked Screens

1. In Lock, select **Change Operator**.
2. Select **Yes**.

   NOTE: Changing the operator discards any unsaved changes from the previous operator session.
3. Enter the Operator ID and Password.
4. Select **Sign In**.

About Protecting Patient Information

The system uses a protected health information (PHI) key to encrypt confidential patient information in the system database and to export files. Only authorized operators have access to the PHI key and can view and access patient information (Page 163 *About the PHI Key*).

Confidential information includes:

- Patient name
- Patient ID (PID)
- Patient date of birth (DOB)
- Location of patient in a medical setting

About the PHI Key

CAUTION

Do not misplace the PHI key. If the key is misplaced, the laboratory cannot access encrypted data. No one can restore encrypted data without the key. Store the PHI key in a secure location.

The laboratory must create a PHI key before using the system in the laboratory. The PHI key must meet the following criteria:

- Contain 8–20 characters
- Include 1 of the following special characters: !, $, #, and %
- Does not contain spaces

NOTE: The system prompts the operator to enter the PHI key on the first sign-in of the system in the laboratory. The operator must be in the G1 Group to enter the PHI key (Page 840 *About Groups*).

The PHI key hides patient information in the following windows, logs, and databases:

Location	Notes
Patient sample and order details, LIS Logs, and the Audit Trail Log	The system does not display patient names, patient IDs (PIDs), and patient date of birth (DOB) unless the matching PHI key is present.
System Message Log	The system encrypts patient names and PIDs during the export process.
Database backups	The system encrypts patient names and PIDs during database backups.

Creating the PHI Key on Initial Sign-in

An operator in the G1 Group must configure the PHI Key when signing into the system for the first time. No other operators can sign into the system until the PHI Key is configured.

1. In Operator ID, enter **Labmanager**.
2. In Password, enter the temporary password for the account.

   NOTE: The local technical support provider provides the temporary password during installation of the system.
3. Select **OK**.
4. In Old password, enter the temporary password for the account.
5. In New password, enter a New password.

6. In Confirm new password, enter the New password again.
7. From the drop-down menu for Question 1, select 1 of the following:
   - An existing question
   - The option to **Enter a new security question or choose a question from the menu.** and enter a new question.

     NOTE: The operator can enter a new question in the Question 1 text box.
8. In Answer 1, enter the answer to the new or existing Question 1.
9. From the drop-down menu for Question 2, select 1 of the following:
   - An existing question
   - The option to **Enter a new security question or choose a question from the menu.** and enter a new question.

     NOTE: The operator can enter a new question in the Question 2 text box.

   NOTE: Question 2 must be different from Question 1.
10. In PHI Key, enter the encryption key.

    NOTE: The PHI Key must comply with the currently set password policies for this system.
11. In Confirm PHI Key, enter the key again.
12. Select **Save**.

About Changing the PHI Key

CAUTION

Do not unnecessarily change the PHI key. Changing the PHI key makes the LIS log, patient names, and patient IDs for previous orders unavailable. Delta checks on previous results are also unavailable.

CAUTION

Do not unnecessarily change the PHI key. Changing the PHI key can make data in the database have more than 1 key.

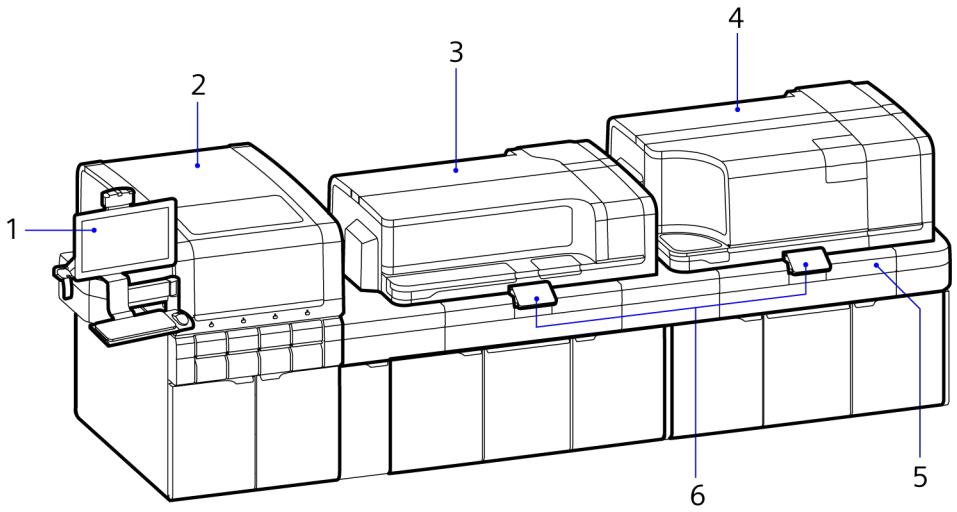
The system enables operators in the G1 Group to change the PHI key (Page 840 *About Groups*).

The system posts an entry to the Audit Trail Log if an operator changes the PHI key.

8 Hardware

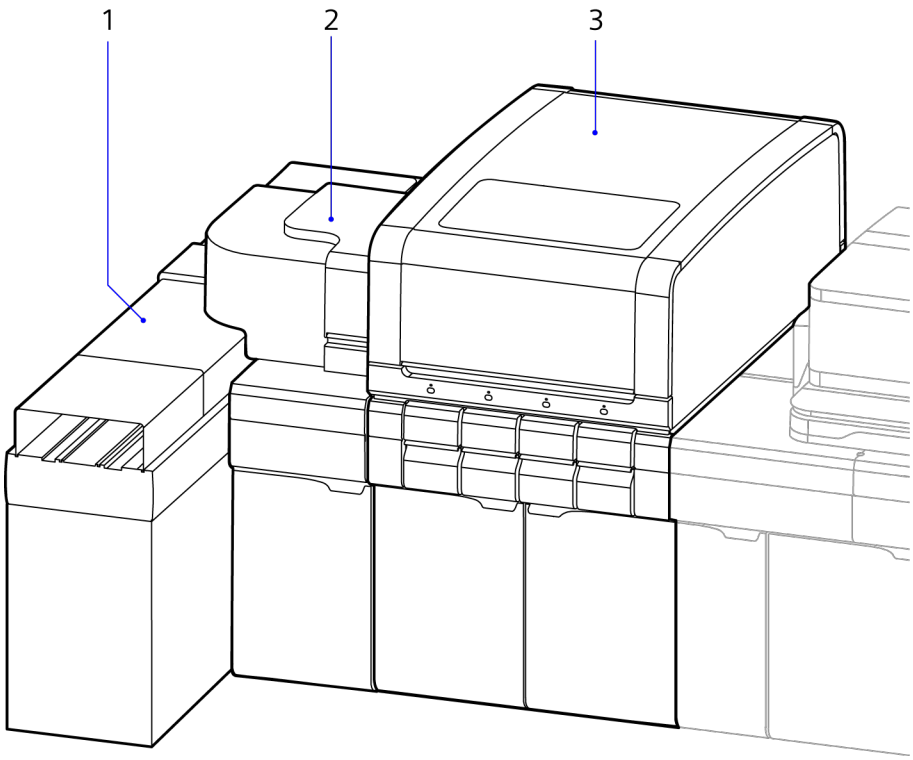
About the Atellica Solution with Sample Handler

The Atellica® Solution with Atellica® Sample Handler is an automated modular system with different configurations combining Sample Handler (SH), Atellica IM Analyzer (IM Analyzer), Atellica CH Analyzer (CH Analyzer), and Atellica Magline Transport.



1	Primary user interface	4	IM Analyzer
2	SH	5	Atellica Magline Transport
3	CH Analyzer	6	Module display

The Atellica® Sample Handler Connect (SHC) connects the Atellica Solution to a Laboratory Automation System (LAS) and moves samples to and from the Atellica Magline Transport.



1 LAS
2 SHC
3 SH

Feature	Notes
Atellica Magline Transport	Patented bi-directional, variable speed magnetic transport technology 10 times faster than conventional conveyors (part of Atellica SH).
Multi-camera vision system and intelligent sample routing	System that controls every sample from routines to STATs.
Automatic QC and calibration	Configuration that reduces operator task load.

Feature	Notes
Scalable module configuration	Up to 10 components connected by Atellica Magline Transport and more than 300 customizable configurations. Configurations may include a maximum of 7 analyzers and 3 SH modules with the following limitations: • Up to 4 IM Analyzers. • Up to 6 CH Analyzers. The operator can use this as a standalone system or connect it to Aptio® Automation or FLEXLAB Automation with up to 1 SHC.
Sample types	More than 30 sample container types, including tube-top sample cups, pediatric tubes, and special containers.
Reagents and consumables	Same reagents and consumables across analyzer configurations.
Assays	Broad and expanding assay menu with proven detection technologies.
Operator tablet	The Operator can the tablet to perform system maintenance and troubleshooting. It connects directly or wirelessly to the system and includes the following features: • Remote Assistance to access live troubleshooting help through Smart Remote Services (SRS) • Camera
Emergency Sample Load (ESL)	Mode that allows the operator to continue processing samples directly on an analyzer if a failure condition of the Atellica Magline Transport prevents automated processing.

Feature	Notes
Smart Remote Services (SRS)	Service that allows operator to obtain remote troubleshooting help.
Flexible installation	Available in linear, "L", and "U" designs.

*Dependent upon test mix.

About the Primary User Interface

The primary user interface provides the primary means for the operator to interact with the system. It consists of the following components:

- Touchscreen
- Keyboard
- Pointing device
- Handheld barcode scanner

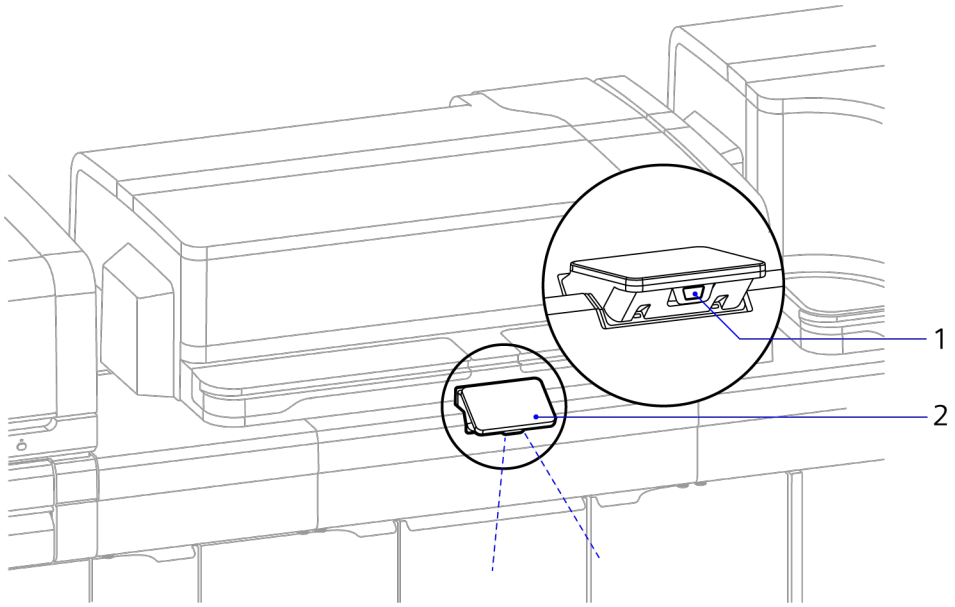
When equipped with more than 1 SH, only the SH Prime has a primary user interface.

About Module Displays

Each analyzer in a system configuration with an SH includes an affixed module display. The module display allows the operator to perform analyzer-specific functions directly at the analyzer without having to use the primary user interface. The functions available to the operator include:

- View and change the analyzer state
- Lock and unlock analyzer covers
- Check system fluids, supplies, waste (IM Analyzer), IMT supplies (CH Analyzer), and reagent loader status
- Load system fluids
- Load reagents and view scanned pack details
- Process samples using the optional Emergency Sample Load tool

Each module display includes a built-in barcode reader to scan system supplies and fluids and a USB port that allows the operator to connect the Emergency Sample Load (ESL) carrier barcode reader to scan samples during ESL operation (Page 660 *About Emergency Sample Load Mode*).



1	Barcode reader
2	Module display

About the Operator Tablet

The operator tablet allows the operator to perform certain tasks without being physically present at the system display, including:

- Viewing the system status
- Creating orders
- Viewing sample results
- Performing system maintenance or troubleshooting
- Submitting service support request tickets or conducting live service support sessions

  NOTE: Service support is only available if the tablet is connected and registered with Smart Remote Services (SRS).

The operator uses the tablet as a hand-held device or with the tablet docking station and keyboard. When the operator docks the tablet, the docking station charges the tablet battery.

The operator tablet includes the following features:

- Touch screen interface
- Video camera capable of taking video and still-images for service support request tickets
- Microphone and speaker for service support chat sessions or video recording

NOTE:

Refer to the operator tablet manufacturer's IFU to learn about standard features and functions of the tablet, including:

- Controls and indicators
- Docking and undocking the tablet
- Using the keyboard
- Powering the tablet on and off
- Taking photos and video

The operator tablet connects to the system using a Wi-Fi or wired-Ethernet connection. The system supports the connection of multiple operator tablets. An operator can sign in to each tablet and system display simultaneously with different or the same credentials.

NOTE: The maximum distance the operator can be from the system depends on the effective range of the system Wi-Fi signal.

About Carriers

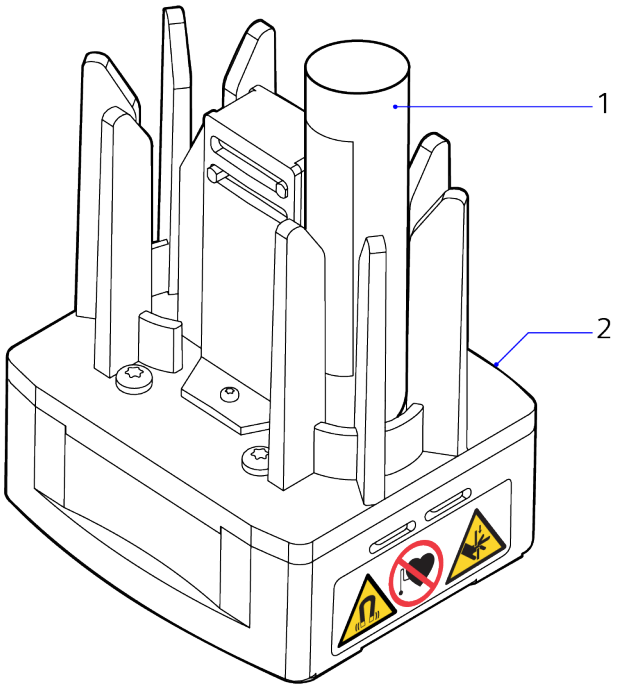
The system uses carriers to transport patient samples, calibrators, and QC materials between the SH and the analyzers on the Atellica Magline Transport.

Each carrier has 2 positions to hold sample containers. The system uses only 1 position to transport 1 sample at a time. The system leaves the other position empty so the SH robot can place the next sample container in the carrier before removing the completed sample container. This allows the system to maximize throughput by minimizing the number of robot moves in order to load and unload samples.

During system installation, the customer can specify the number of carriers to reserve for STAT samples. The default system configuration reserves 2 STAT carriers.

NOTE: Only the local technical support provider can change the number of reserved STAT carriers.

The following figure shows a carrier with 1 sample container:



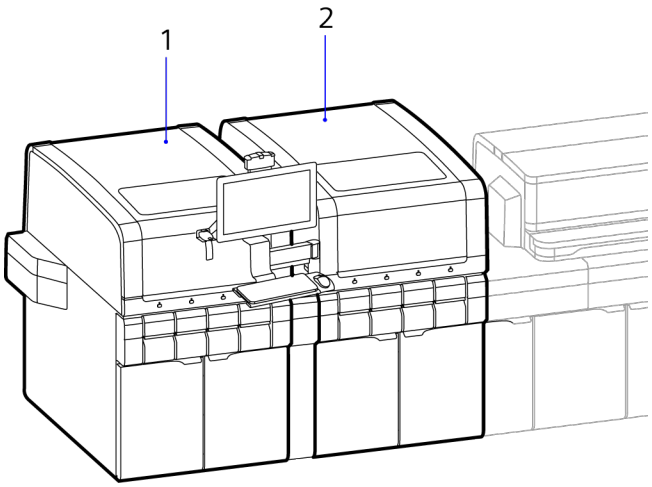
1	Sample container
2	Carrier

About the Atellica SH

The SH is the primary way the operator interfaces with the system. It allows the operator to load and unload routine patient samples, STAT samples, and calibrator and QC (Cal-QC) materials.

Each system can have up to 3 SH modules with each SH capable of processing up to 500 samples per hour.

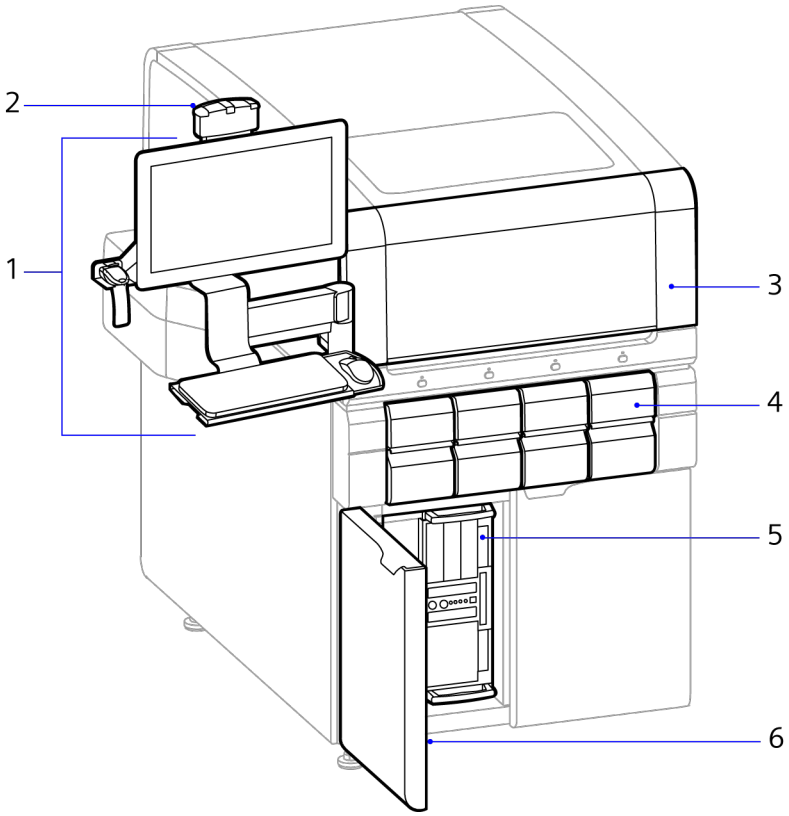
When a system is equipped with 1 SH, that SH is referred to as SH Prime and includes the Process Center Computer (PCC) and system display. When equipped with more than 1 SH, the SH with the PCC and system display is the SH Prime and any other SH is an SH Additional.



1 SH Additional
2 SH Prime

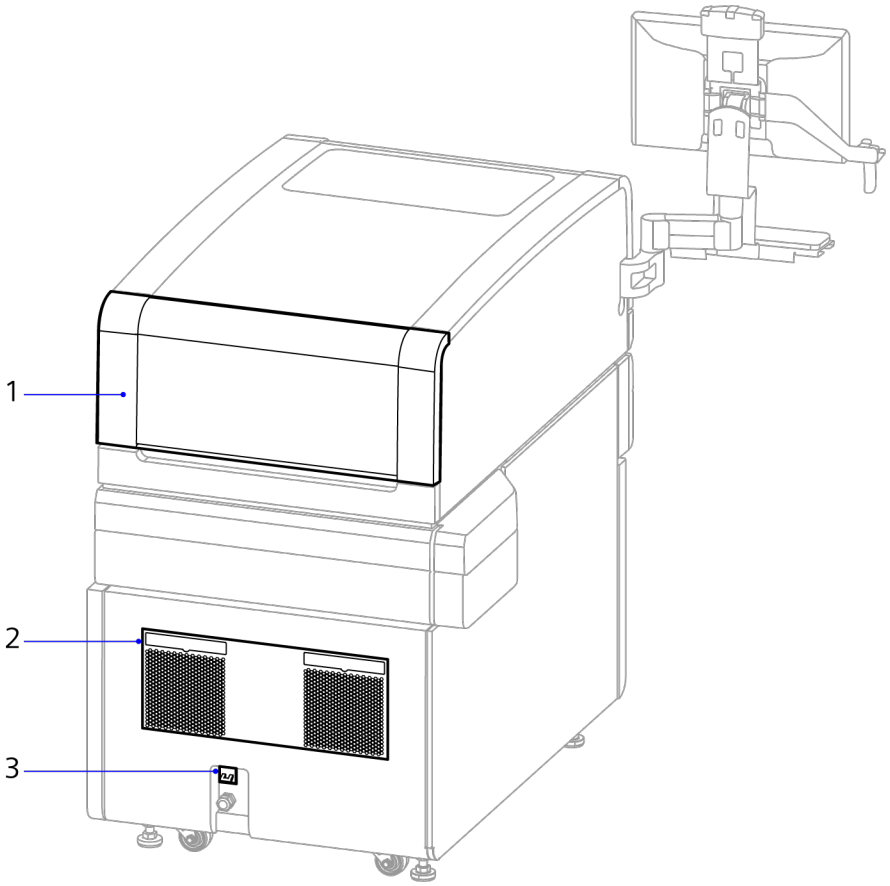
The SH front and back covers lock during normal operation. To open the front or back cover, the operator requests to unlock the cover from the system display or operator tablet. After the operator unlocks and opens the cover, the system removes power from the SH robot so it cannot move. After the operator closes and locks the cover, the system resumes normal operation.

SH (front view)



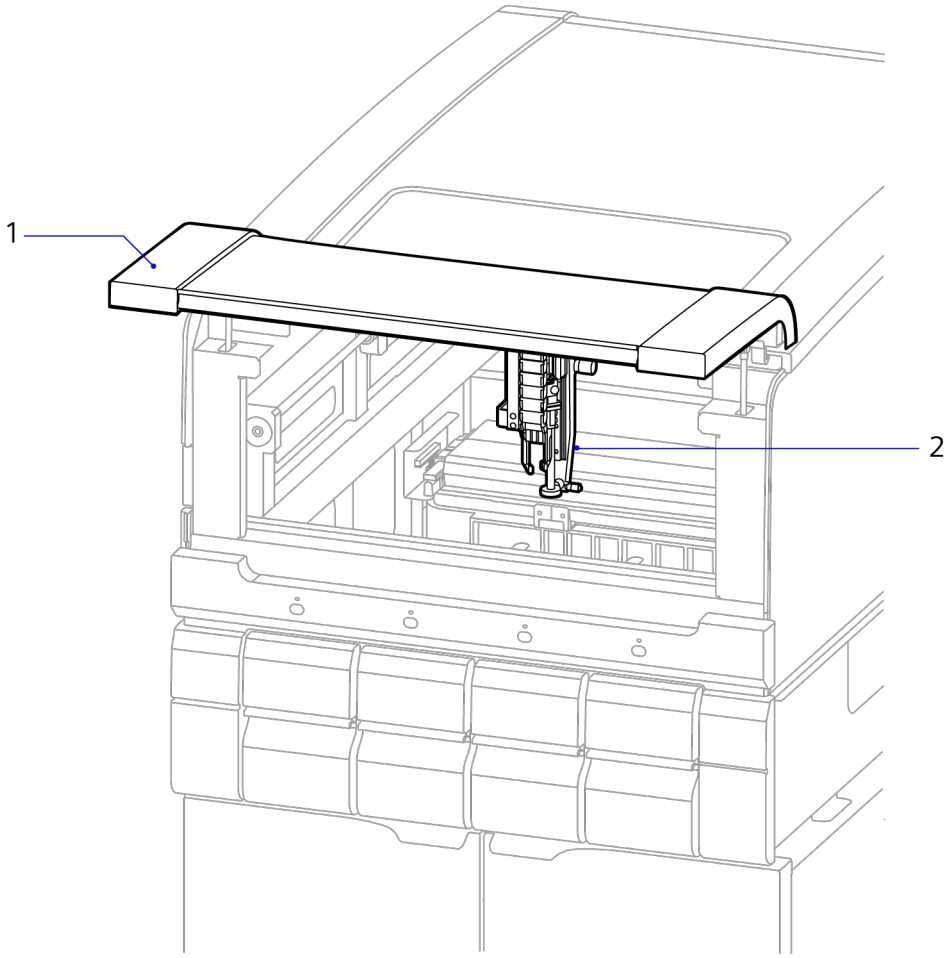
1	System display	4	Sample drawers
2	Visible status light	5	PCC
3	Front cover	6	PCC door

SH (back view)



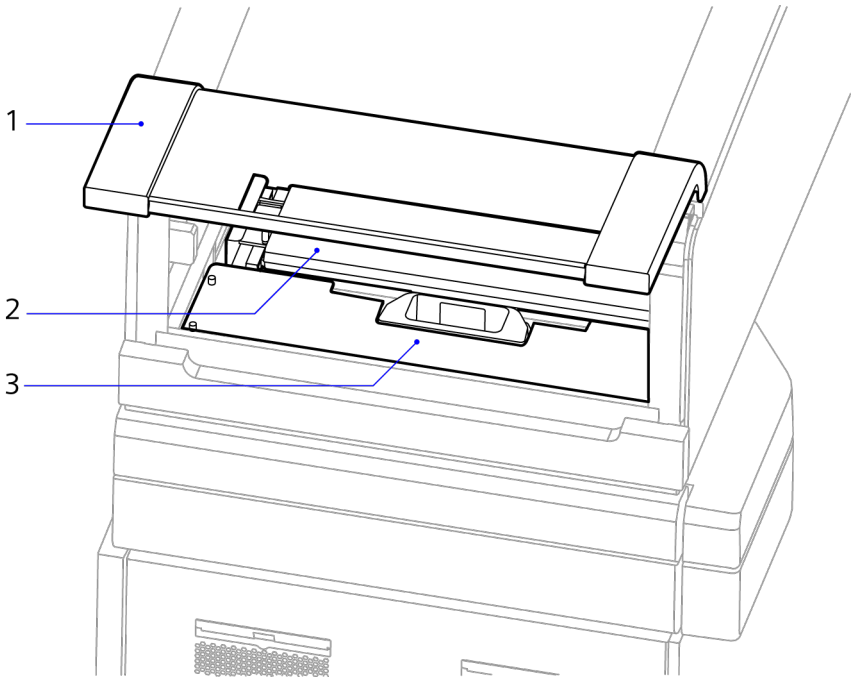
1	Back cover
2	Air vents
3	Main power switch

SH (inside front view)



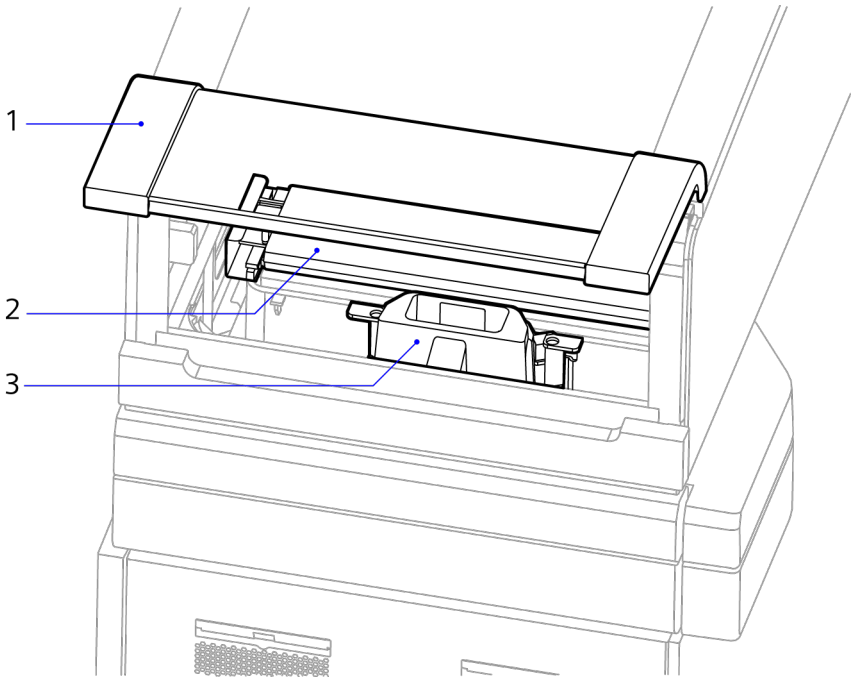
1	Front cover
2	Robot

SH (inside back view)



1	Back cover
2	Cal-QC storage area
3	SH internal Atellica Magline Transport cover

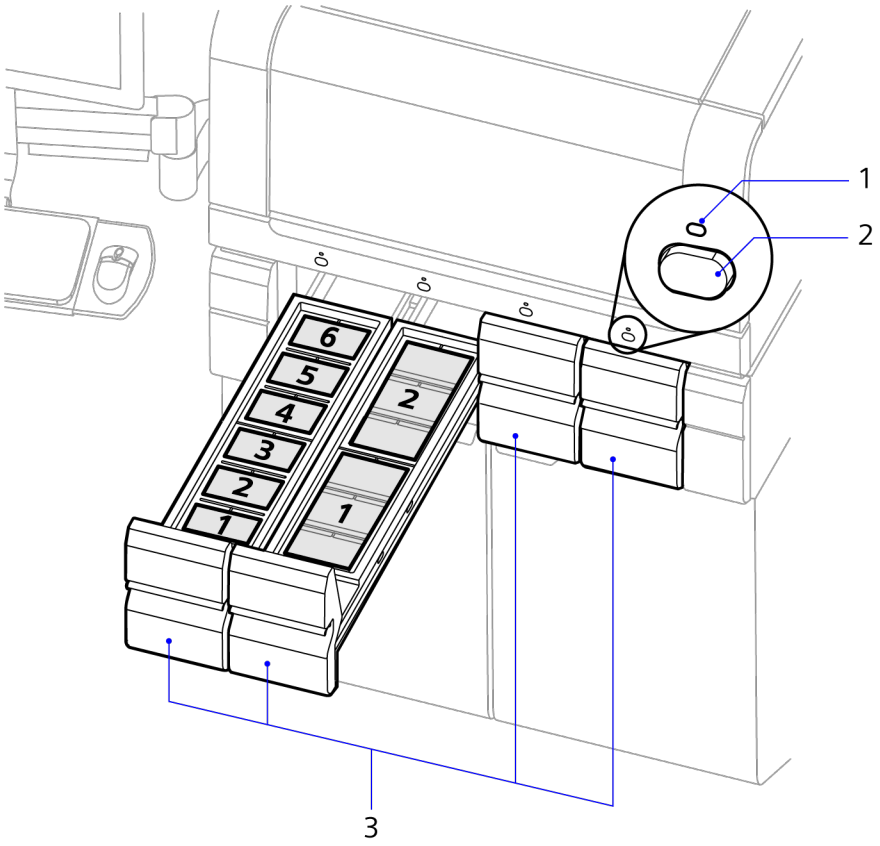
SH (inside back view–Atellica Magline Transport cover removed)



1	Back cover
2	Cal-QC storage area
3	Tube Characterization Station (TCS)

About Sample Drawers

Each SH has 4 sample drawers. Each drawer can store up to 90 or 110 sample containers, depending on the type of sample racks the operator loads in the drawer. The operator can load up to 6 15-position racks or 2 55-position racks in any appropriate location within a single drawer.



1	Drawer LED
2	Drawer unlock button
3	Sample drawers

Sample drawers are locked when the robot is accessing the sample racks in that drawer and any time the Drawer Vision System (DVS) is downloading images. The drawers are unlocked at all other times. An LED and button located above each drawer indicates the drawer locked/unlocked status and allows the operator to request the system to unlock a currently locked drawer.

The following table describes the drawer LED status:

Drawer LED status	Notes
On	The drawer is locked.
Off	The drawer is unlocked.
Blinking	The system is unlocking a locked drawer or the drawer is automatically cycling between the locked and unlocked state as the robot accesses sample racks.

About Sample Racks

The operator uses sample racks to load sample containers into and unload sample containers from the SH.

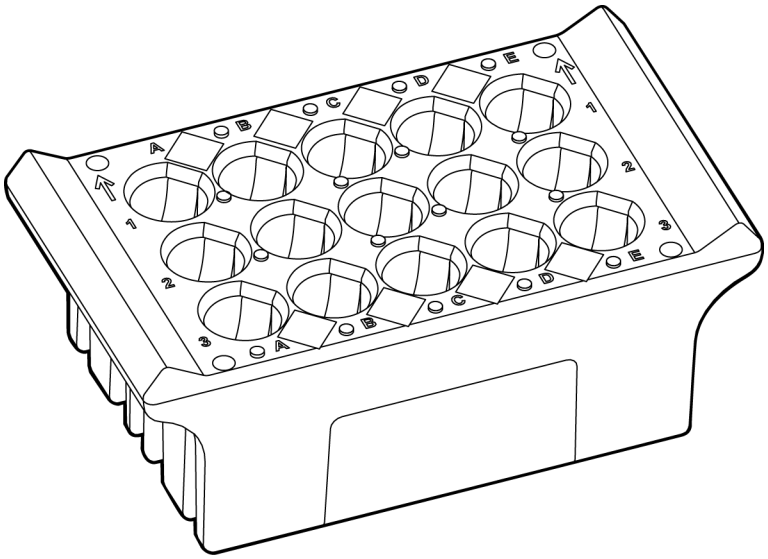
The system supports the following types of sample racks:

- Routine 15-position racks
- Routine 55-position racks
- STAT 15-position racks
- Special 15-position racks
- Special 55-position racks
- Special STAT 15-position racks

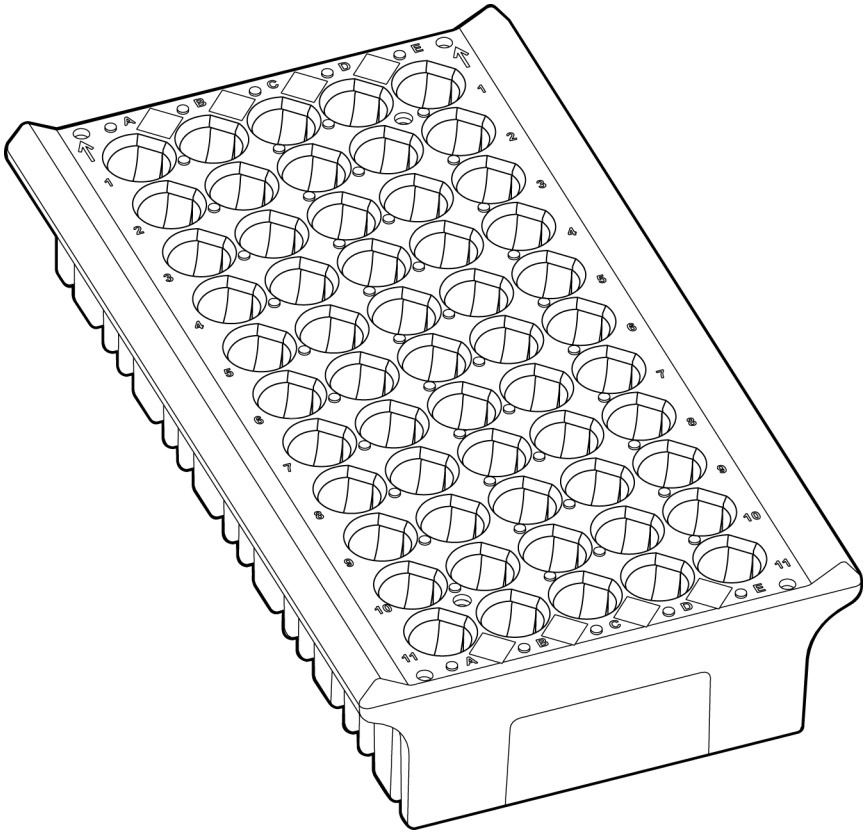
NOTE: If the operator places a routine 15 or 55-position rack in an Archive zone, the system uses the rack as a sample archive rack. These can be used in addition to, or instead of, dedicated archive racks (Page 181 *About Archive Racks*).

NOTE: Use special racks when processing false-bottom sample containers.

15-position rack



55-position rack



Each rack has barcodes and localization marks that enable the Drawer Vision System (DVS) to:

- Identify a rack
- Identify the row and column of each occupied position
- Locate the center of the sample container within each occupied position

STAT and special racks have color-coded labels on the front and sides to identify the rack type:

- Magenta: STAT rack
- Blue: Special rack
- Magenta and blue: Special STAT rack

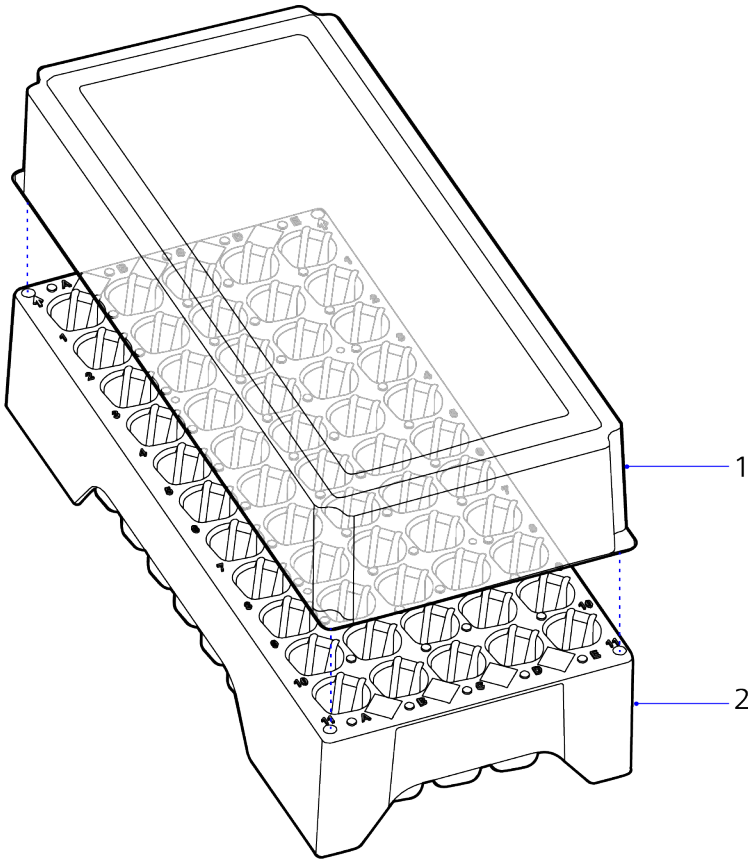
About Archive Racks

The system uses dedicated archive racks solely as output racks for archiving samples. The system can also use routine 55 and 15 position racks as archive racks when an Archive zone is assigned to their drawer position. (Page 179 *About Sample Racks*). When the operator loads an archive rack in an SH drawer and the DVS scans the rack, the rack barcode identifies the rack and the system automatically recognizes it as a dedicated archive rack. After sample processing is complete, the system transfers the appropriate samples to an available archive rack. The system retains the location of the sample within the rack and the rack ID.

NOTE: The system automatically recognizes dedicated archive racks when at least 1 Archive zone is assigned to an SH drawer anywhere on the system. The operator can place a dedicated archive rack in any drawer output location without having to define the specific zone as an Archive zone.

The operator can place an optional cover over the samples in a dedicated archive rack after removing the rack from the SH. The optional cover is also compatible with routine 55-position racks.

Archive 55-position rack



1	Archive rack cover
2	Archive rack

About the SH Drawer Vision System

The Drawer Vision System (DVS) is a series of 8 cameras with built-in illumination. Two cameras are located above each sample drawer. The cameras image each rack and rack position in the drawer as the operator closes the drawer.

After capturing images, the SH analyzes them to determine the rack characteristics, including whether the rack is a routine rack or STAT rack, and sample container characteristics. The barcodes and localization marks on each rack determine the rack characteristics, including:

- Sample container presence
- Sample container cap or cup presence
- Sample container height and diameter (mm)
- Sample container X and Y offsets from center

The SH robot uses this information to transport sample containers between the racks and the carriers.

About the SH Robot

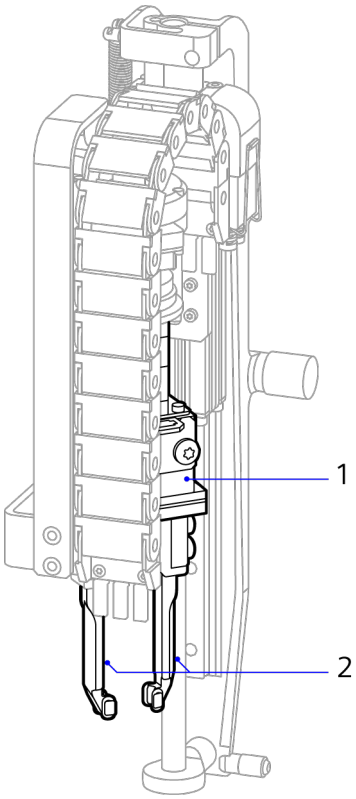
The SH robot is an automated 3-axis robot that transports sample containers (patient samples and calibrator or QC materials) between racks in the sample drawers, Cal-QC tube storage area, and the carriers on the Atellica Magline Transport inside the SH.

After the operator loads the racks and closes the sample drawer, the robot receives the information decoded from the DVS images and begins selecting sample containers from the rack according to STAT or routine status and loading order. The system moves each sample container to an open carrier position in the Tube Characterization Station (TCS) for the system to read the barcode. If a sample container is in the other carrier position, the robot retrieves that container and returns it to the Cal-QC tube storage area or to an open rack position in a sample drawer, depending on sample type.

After the system reads the barcode on the sample container in the carrier, the system determines the associated orders (if any) and transports the sample to the appropriate location.

After the system completes all available orders for the sample, the carrier returns to the SH where the robot moves the sample container from the carrier back to the Cal-QC storage area or to an open rack position in a sample drawer.

The following figure shows the major sections of the SH robot:



1	Robot body
2	Robot grippers

About the Cal-QC Storage Area

The Cal-QC storage area, located between the sample loading area and the TCS, provides a space that maintains the temperature between 2 °C (35 °F) and 8 °C (46 °F). This refrigerated space allows for prolonged storage for up to 60 sample containers containing calibrator or QC material for up to 7 days or the maximum listed on the material IFU. The system constantly monitors the temperature to ensure proper refrigeration is maintained.

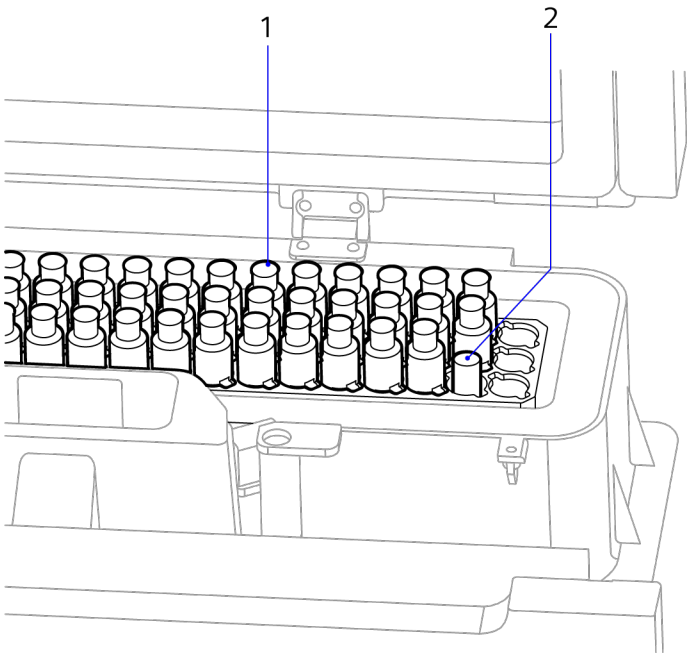
The operator loads calibrator and QC materials in the sample drawers in the same manner as patient sample containers. The SH robot retrieves a Cal-QC sample container and places it in a carrier for the TCS to read the barcode. After the TCS reads the barcode and identifies the material as requiring onboard storage, the system releases the carrier onto the Atellica Magline Transport.

After releasing the carrier, the system takes 1 of the following actions:

- If the calibrator or QC material has open work orders, the system routes the carrier to the appropriate analyzer and performs the required tests. After testing is complete, the system returns the carrier to the SH.
- If the calibrator or QC material has no open work orders, the system returns the carrier to the SH.

After the carrier returns to the SH, the SH robot loads the container into the Cal-QC storage area.

Cal-QC storage area (back view)



1	Tube covers
2	Cal-QC sample container

By default, the far-right column positions of the Cal-QC storage area are empty. The remaining positions have tube covers and may have sample containers.

After the SH stores the calibrator or QC material, the robot retrieves the appropriate calibrator or QC material from the Cal-QC storage area when the system requires it. Operators do not access the Cal-QC tube storage area except in the event of a system failure or power outage that prevents the SH robot from removing the materials.

About the Tube Characterization Station

The Tube Characterization Station (TCS) acts as the SH Pick-and-Place Station (PPS) and is an integrated system of 3 cameras that reads the barcodes on the sample containers. The center camera also performs image analysis of the sample containers.

The cameras are in a triangular arrangement, which provides 360° imaging of sample containers in the carrier. This pattern enables the system to read barcode labels without requiring the operator to align the barcodes when loading samples.

The images obtained by the cameras determine the following information:

- Carrier ID (2D barcode—Data Matrix only)
- Sample container ID (1D barcode)
- Sample container height and width (mm)
- Sample container cap, cup, or capillary collection container presence
- Center of the sample container top along the axis of the Atellica Magline Transport

After the TCS acquires the barcode and determines all tube characteristics, the system routes the carrier to the appropriate analyzer.

About the Barcode Printer

A barcode printer prints the labels that the operator can affix to the calibrator, QC, and patient sample containers.

NOTE:

Refer to the barcode printer manufacturer's IFU to learn about standard features and functions of the printer, including:

- Controls and indicators
- Powering the printer on and off
- Loading labels
- Replacing the thermal ribbon

The system supports barcode printers and labels that meet the following specifications:

Specification	Notes
Printing method	Thermal transfer
Head density (resolution)	12 dots/mm (300 dpi)

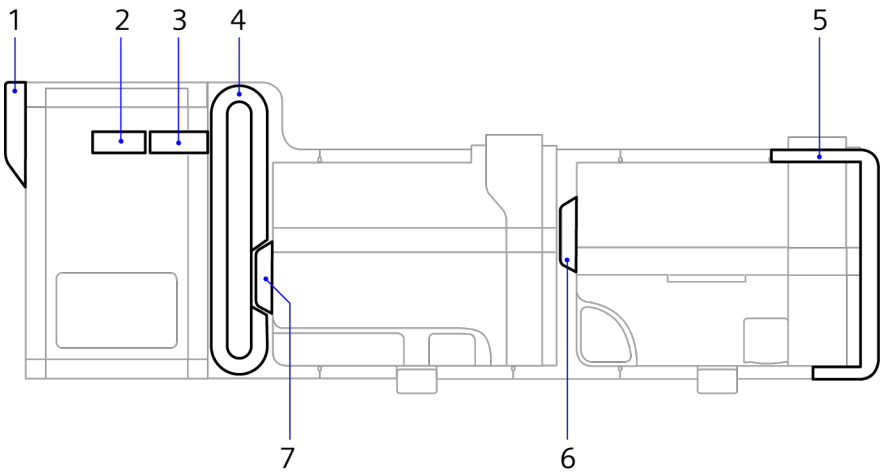
Specification	Notes
Effective print area	56 mm (2.2 inches) x 400 mm (15.75 inches)
Acceptable media type	Paper or polypropylene **NOTE:** For containers the system stores in the Cal-QC storage area, only use polypropylene barcode labels (such as SMN 10734465 when using the optional SATO CG212 barcode printer). Paper labels may not properly adhere to the container or the system may damage the paper labels during handling.
Minimum bar width	6.66 MIL (0.00666 inches)
Barcode support	Code 128 (recommended), Code 39, InterLeaved 2 of 5, Codabar (NW7)
Programming language	Zebra Printer Language II (ZPL II)
Interface	Ethernet

About the Atellica Magline Transport

The automated Atellica Magline Transport moves samples, calibrators, and QC materials between the SH and the analyzers using carriers (Page 170 *About Carriers*).

The Atellica Magline Transport covers ensure sample chain of custody and protect the operator from moving sample carriers. Each cover connects securely to the Atellica Magline Transport using latches and thumbscrews and includes an interlock switch that detects when the operator removes a cover. If the operator removes a cover, the system removes power from that section of the Atellica Magline Transport to prevent sample carriers from moving through that area. After the operator replaces the cover, the Atellica Magline Transport resumes normal operation.

The following figure shows the major sections of the Atellica Magline Transport:



1	SH entry queue	5	Waiting queue
2	TCS	6	IM Analyzer aspiration station
3	SH exit queue	7	CH Analyzer aspiration station
4	Loop		

The SH robot retrieves a sample container from a rack in the sample drawer and places it in a carrier in the TCS. After the TCS acquires the sample container barcode and determines all relevant characteristics, the Atellica Magline Transport routes the carrier through the SH exit queue to the appropriate analyzer. When the carrier enters the analyzer's inprocess queue, the analyzer takes control of the carrier and moves it to the aspiration station.

After the system completes aspirating the tests on the analyzer, the Atellica Magline Transport assumes control of the carrier and routes it to the next analyzer or back to the SH. When the system returns the carrier to the SH and additional samples require processing, the robot places the next sample container in the carrier and removes the completed sample, returning it to a rack in a sample drawer or to the Cal-QC storage area.

The process repeats as long as unprocessed samples or orders marked for repeat processing remain.

NOTE: The system performs repeat processing automatically as long as the sample remains in the SH.

If an analyzer's inprocess queue is full and the system sends additional samples to the analyzer, the Atellica Magline Transport routes the carrier to the waiting queue until space is available.

If the operator loads a STAT sample into the SH, the system routes the carrier containing the STAT sample to the appropriate analyzer. The system moves any carriers currently in the analyzer's inprocess queue out of the queue to make room for the STAT sample carrier.

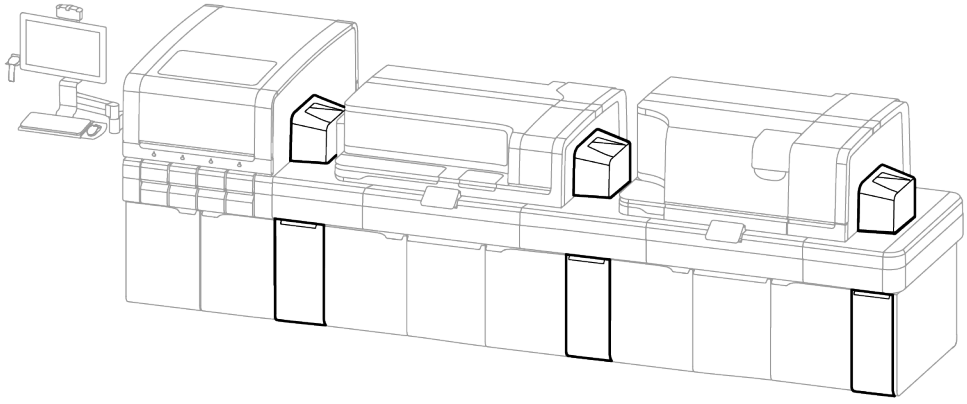
After the STAT sample carrier enters the analyzer's inprocess queue, the analyzer assumes control of the carrier and takes 1 of the following actions:

- If no carrier is currently in the aspiration station, the system immediately moves the STAT sample carrier to the aspiration station.
- If a carrier is currently in the aspiration station, the analyzer holds the STAT sample carrier in the inprocess queue until the system completes aspirating the test on the current sample. After aspiration is complete, the system moves the carrier out of the aspiration station and moves the STAT sample carrier to the aspiration station. After the system completes aspirating the tests on the STAT sample and moves the STAT sample carrier out of the aspiration station, the system takes 1 of the following actions:
  - If test remain on the routine sample the system moved to process the STAT sample, the system moves that routine sample carrier back to the aspiration station to complete aspirating the remaining tests.
  - If the system completes all aspirations on the sample the system moved to process the STAT sample, the system moves the next carrier in the inprocess queue to the aspiration station to resume normal sample processing.

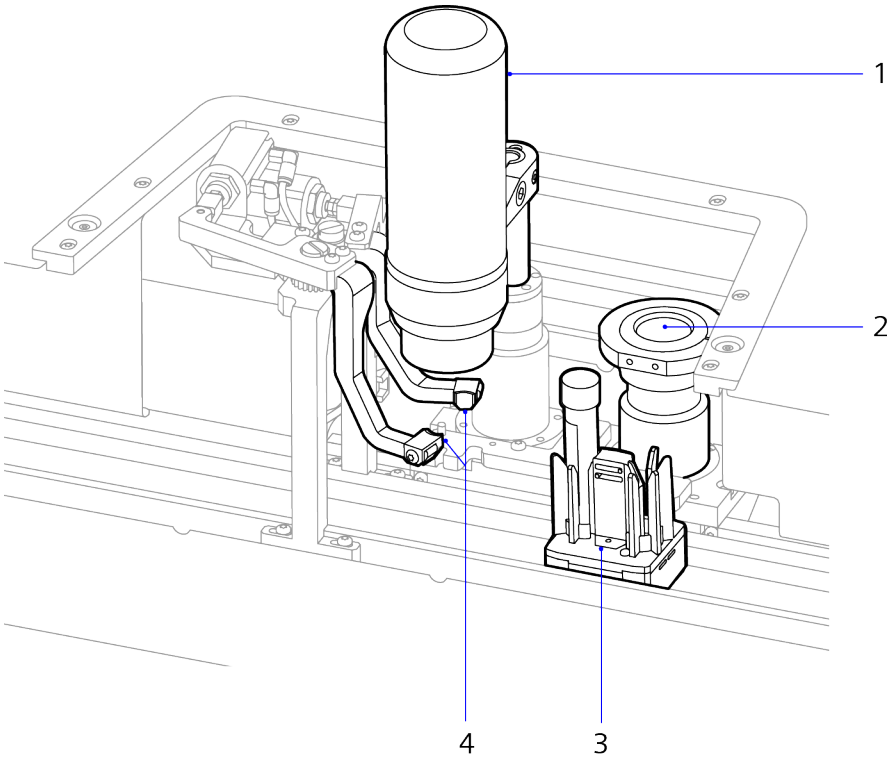
About the Decapper Module

The Decapper module removes and discards caps from all approved sample containers (Page 907 *About Supported Sample Containers*).

The location of the Decapper within a system has 3 possible configurations.

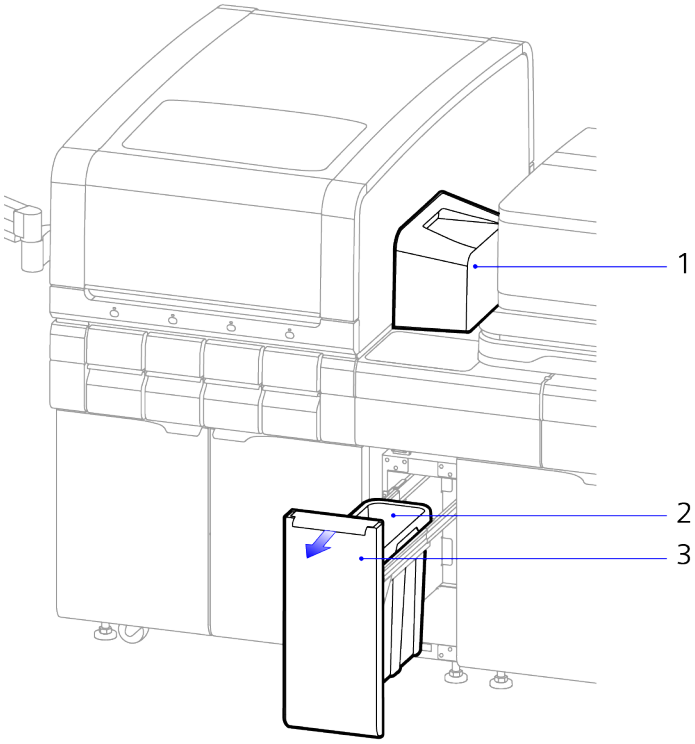


The sample carrier approaches the Decapper and stops. Sample tubes that do not require decapping are diverted and bypass the Decapper. If the sample tube requires decapping, the diverter opens and the carrier moves to the Decapper module.

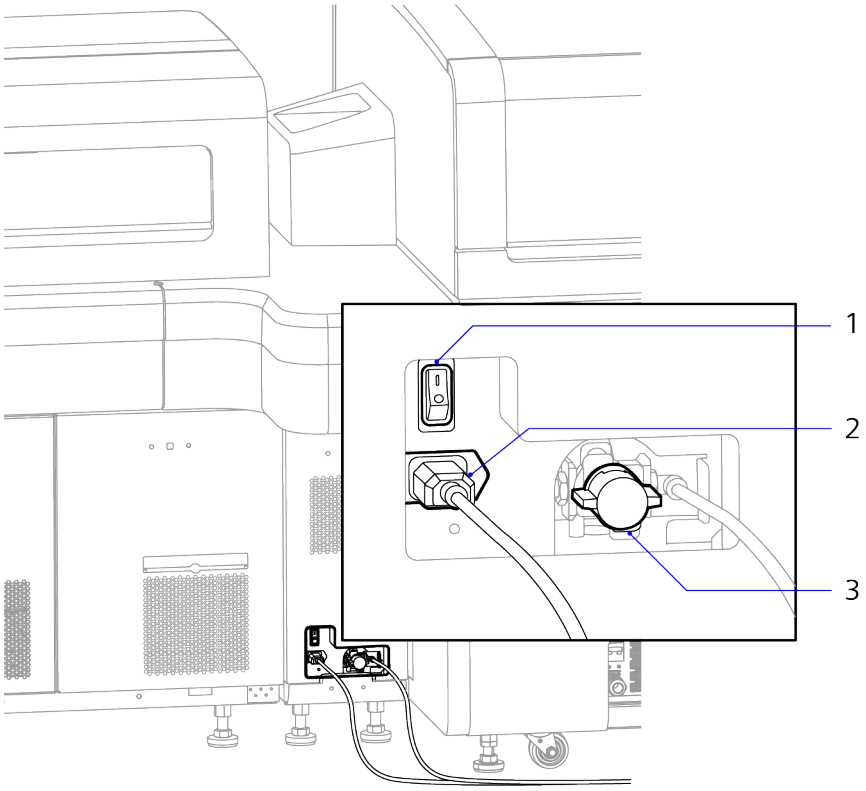


1	Cap remover
2	Cap waste chute
3	Sample tube in carrier
4	Tube gripper

The tube gripper holds the sample tube in the decapping position. The head lowers and grips the sample tube cap. To remove the cap, the head lifts, then rotates over the cap waste chute and drops the cap. The tube gripper releases the decapped tube for additional processing.



1	Cover
2	Cap waste bin
3	Cap waste drawer

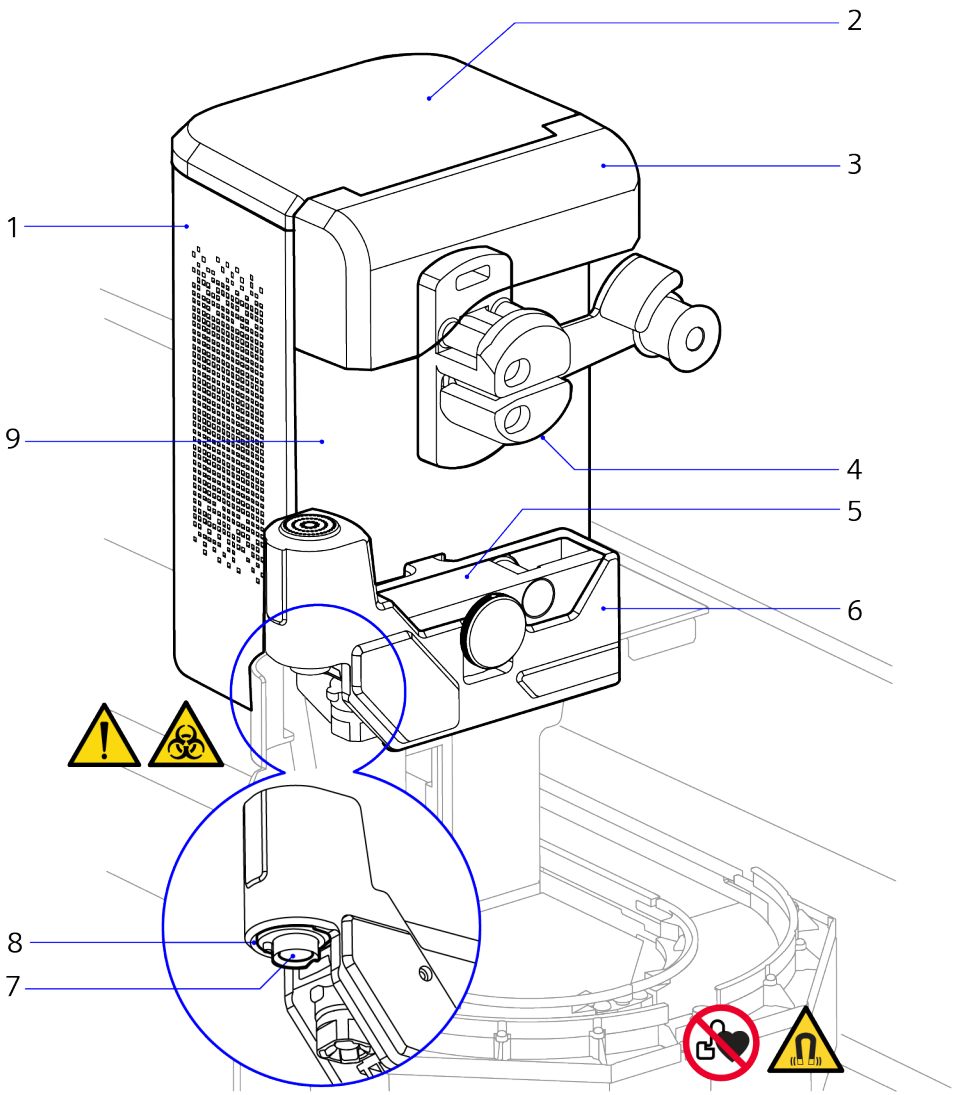


1 Power switch
2 Power cord
3 Pressure valve

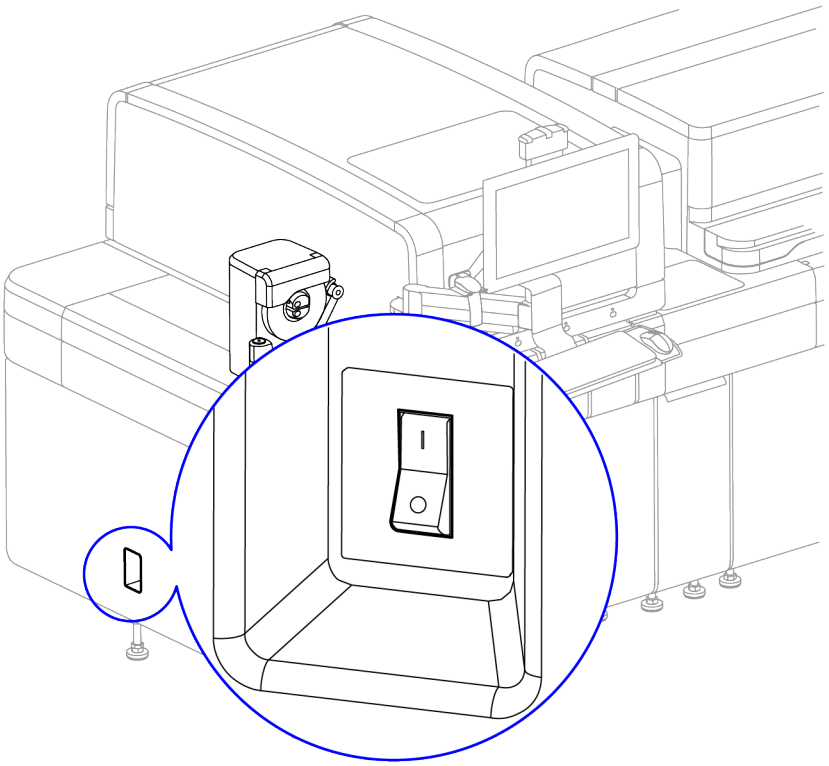
NOTE: Manually recapped sample tubes must be manually decapped. Sealed tubes must be manually unsealed.

About the Atellica® Sealer

The Atellica Sealer module seals all approved sample containers with foil (Page 907 *About Supported Sample Containers*). It delivers the foil by unrolling a small section of aluminum foil, cutting it to a square, and heat sealing it to adhere to the top of the sample containers.



1	Side cover	6	Foil feed carriage
2	Top cover	7	Plunger
3	Foil roll cover	8	Primary crimper
4	Spindle	9	Front cover
5	Foil feed cover		



Power switch

About the Atellica SHC

The Atellica SHC is a sample transfer unit that provides the hardware for transferring routine and STAT samples between a connected Lab Automation System (LAS) and the system at a rate of up to 1200 samples per hour (depending on LAS and system configuration and order composition).

During operation, the operator can simultaneously load and unload samples from the SH sample drawers while the system processes samples from the LAS. The SHC returns all LAS-routed samples back to the LAS. The operator removes all operator-loaded samples from the system through the SH racks and drawers.

If equipped, the SHC is connected to the side of the SH Prime and receives all power and communications from the SH.

The SHC cover locks during normal operation. To open the cover, the operator requests to unlock the cover from the primary user interface. After the operator unlocks and opens the cover, the system removes power from the SHC robots so they cannot move. After the operator closes and locks the cover, the operator can resume normal system operation.

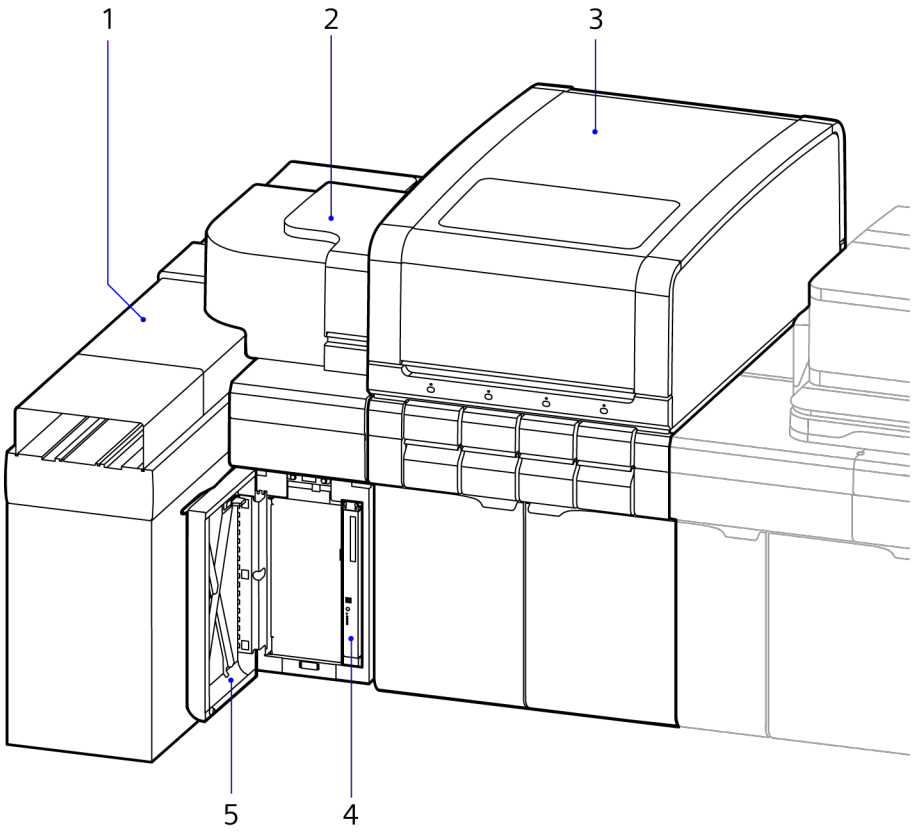
CAUTION

Do not work or open the SHC front cover without caution. The SHC front cover is heavy and can result in injury if a body part is caught between the cover and the SHC frame.

New SHC front covers are reinforced with a steel frame to provide more rigidity to the cover. The reinforced cover is a heavy object with 2 pneumatic pistons supporting the cover motion. The cover may cause injury if any of the pneumatic pistons fail and the cover falls.

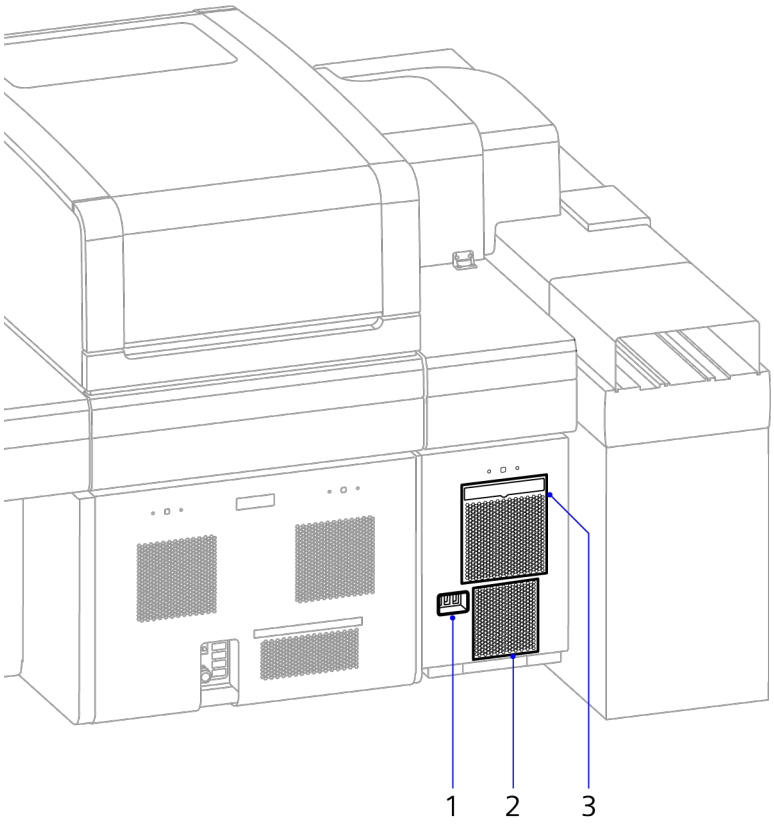
NOTE: The new SHC front covers are available on new systems and on existing systems with a replaced cover.

SHC (front view)



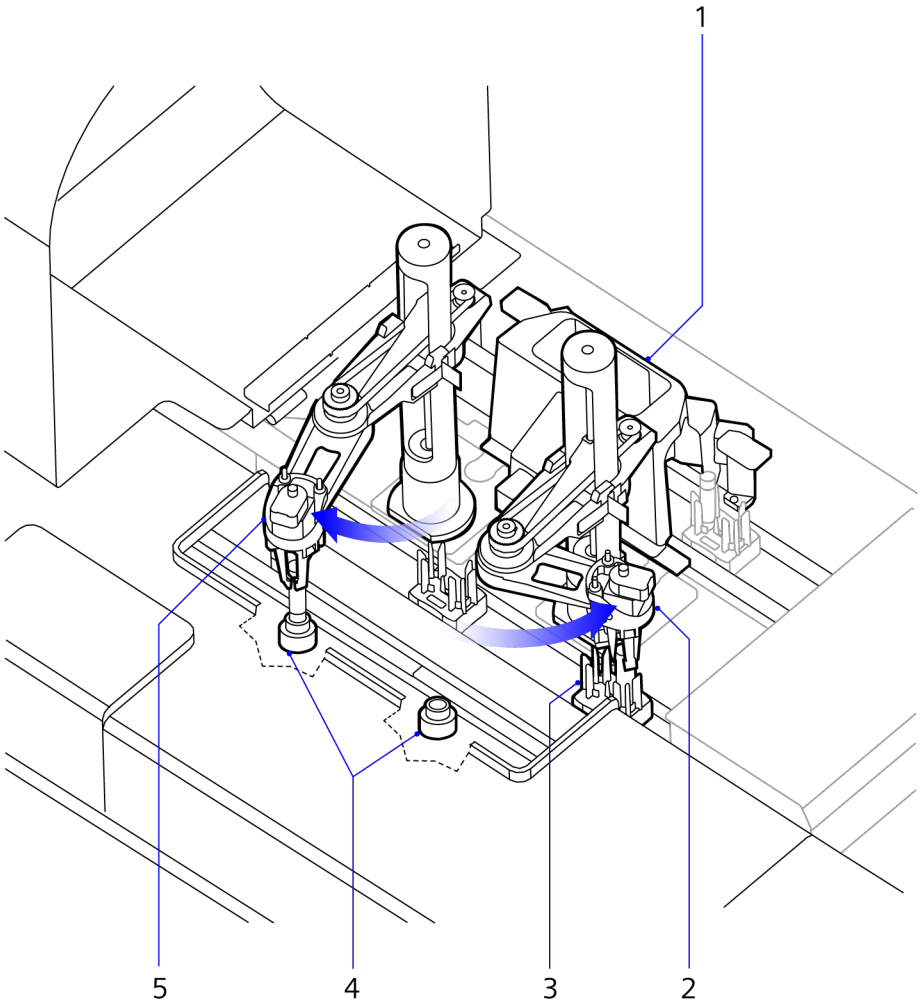
1	LAS track
2	SHC
3	SH (primary user interface not shown)
4	SHC computer
5	SHC computer access door

SHC (back view)



1	Main power switches
2	Air vent
3	Fan filter

SHC (inside view)

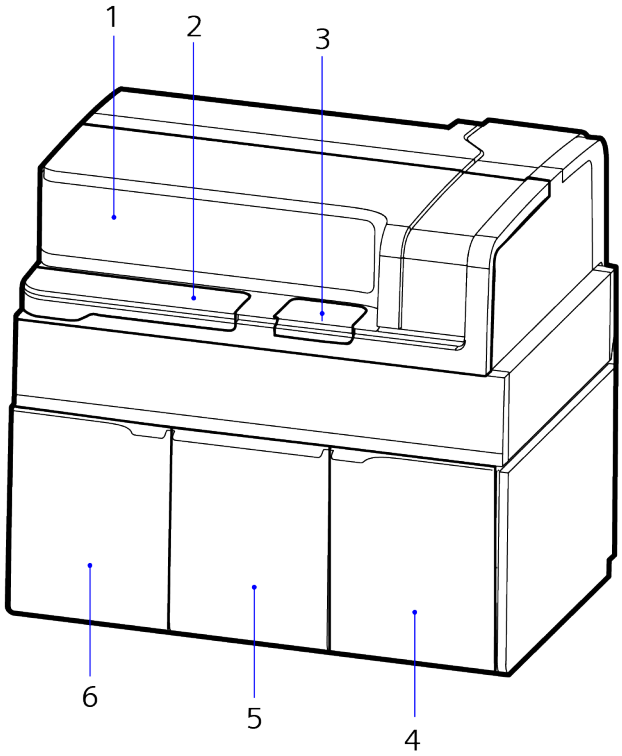


1	SHC TCS
2	Robot 1 (input robot)
3	Atellica Magline Transport carrier
4	LAS puck
5	Robot 2 (output robot)

About the CH Analyzer

The automated CH Analyzer contains all the necessary hardware, electronics, and software to process samples and generate results, including sample and reagent dispensing, mixing, and incubating.

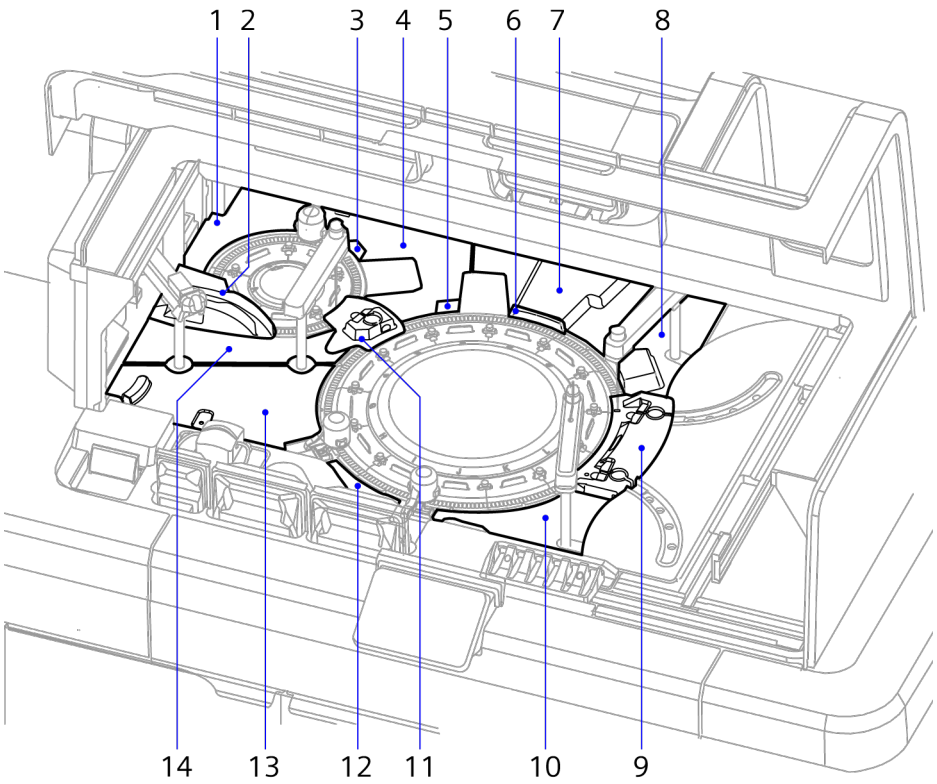
CH front with covers closed



1	Front cover	4	Fluidics compartment door
2	IMT fluids lid	5	System fluids drawer
3	Reagent manual load station lid	6	Left front door

The analyzer plates, shields, and guards cover the individual subsystems and reduce dust collection on the components. For identification purposes, the plate title is embossed on the underside of each plate. The 3 probe shields and guards do not have this identification.

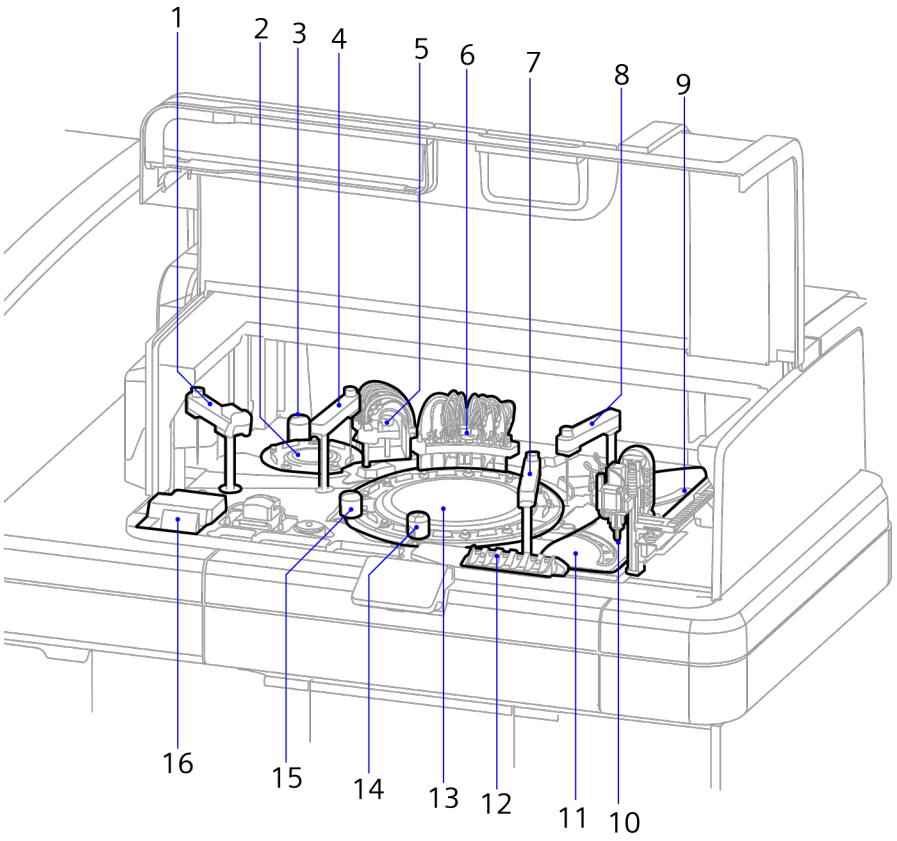
CH plates from front with cover open



1	D1	8	R3
2	Dilution probe guard	9	Reagent probe guard
3	Shield dilution wash probe	10	R4
4	D2	11	Sample probe guard
5	Shield reaction wash probe LS	12	R2
6	Shield reaction wash probe RS	13	R1
7	Bulb access	14	D3

The exterior covers, doors, drawers, and lids provide access for checking and replacing fluids.

CH front with cover open



1	Dilution arm	9	Reagent compartment 1
2	Dilution ring	10	Reagent loader
3	Dilution mixer	11	Reagent compartment 2
4	Sample arm	12	Reagent manual load station
5	Dilution washer	13	Reaction ring
6	Reaction washer	14	Sample mixer
7	Reagent arm 2	15	Reagent mixer
8	Reagent arm 1	16	IMT system

About CH Reagent Pumps

The CH reagent pumps provide the mechanism that enables the reagent probes to aspirate reagent from reagent packs in the reagent compartments and dispense it into the reaction cuvettes. The high pressure pumps also sends special reagent water through the inside of the probes during probe washing.

About the CH Reaction Ring Bath

The analyzer suspends cuvettes in an incubation fluid maintained at a constant 37°C ± 0.3°C. This bath maintains the reaction volume at the target temperature and provides a consistent thermal profile.

The incubation fluid is special reagent water with an additive containing surfactant (inhibits bubble formation) and a preservative (inhibits microbial growth).

NOTE: Reagent probe 2 aspirates the water bath additive (WBA) from a reagent pack and adds it to the incubation fluid as part of the automated maintenance for the analyzer.

About CH IMT Measurements

The IMT system on the analyzer uses potentiometry to determine the concentration of sodium (Na), potassium (K), and chloride (Cl) ions in patient samples. The dilution probe presents samples to a flow-through sensor cartridge. This cartridge encloses a reference electrode and 3 ion-selective electrodes: Na^+, K^+, and Cl^-. The analyzer amplifies the potential of the Na, K, and Cl electrodes and measures the potential against the reference electrode and then converts it to ion concentrations.

The following sequence summarizes an IMT measurement on serum samples, using IMT Standard A:

Step	IMT measurement
1	The analyzer pulls Standard A through the IMT cartridge.
2	The analyzer measures the potential difference between each of the 3 analytes in the Standard A solution.
3	The IMT system pulls in air and fluidic segments of Standard A to clean and prepare the sensor chip for sample measurement.
4	The IMT diluent pump dispenses 75 µL of IMT diluent into the IMT sample port.
5	The dilution probe aspirates 25 µL of sample from a sample container.
6	The dilution probe dispenses the sample and 150 µL of special reagent water into the IMT port. As the dilution probe dispenses the sample, it mixes the sample, diluent, and water.

Step	IMT measurement
7	The dilution probe returns to its wash station for rinsing and cleaning.
8	The analyzer pulls the mixed sample through the IMT cartridge.
9	The system measures the potential difference between each of the 3 analytes in the sample and the reference electrode.
10	The drift correction completes when the analyzer pulls a second Standard A sequence through the IMT cartridge comparing this reading to reading in step 2.
11	The system converts the potential differences into ion concentrations and reports this value.

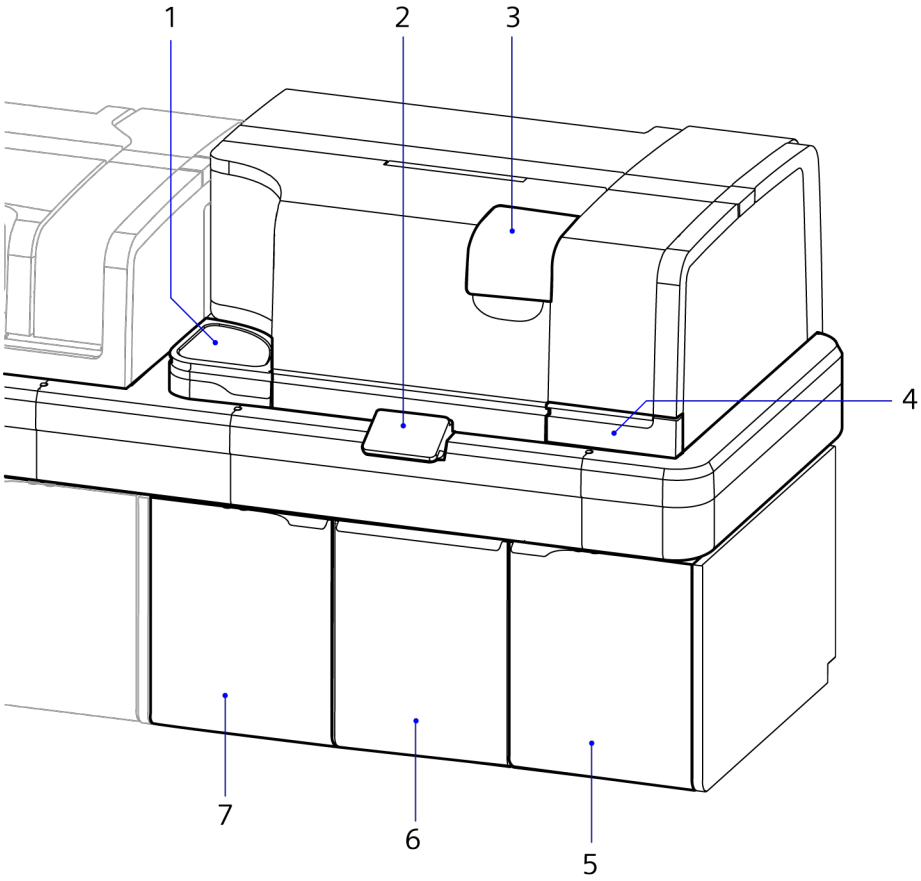
NOTE: This sequence assumes the inactivity of the IMT system for greater than 2 minutes. This sequence is slightly different on an active IMT system.

IMT measurements on serum samples are an 18-second process. IMT measurements on urine samples are a 21-second process and use both Standard A and Standard B.

About the IM Analyzer

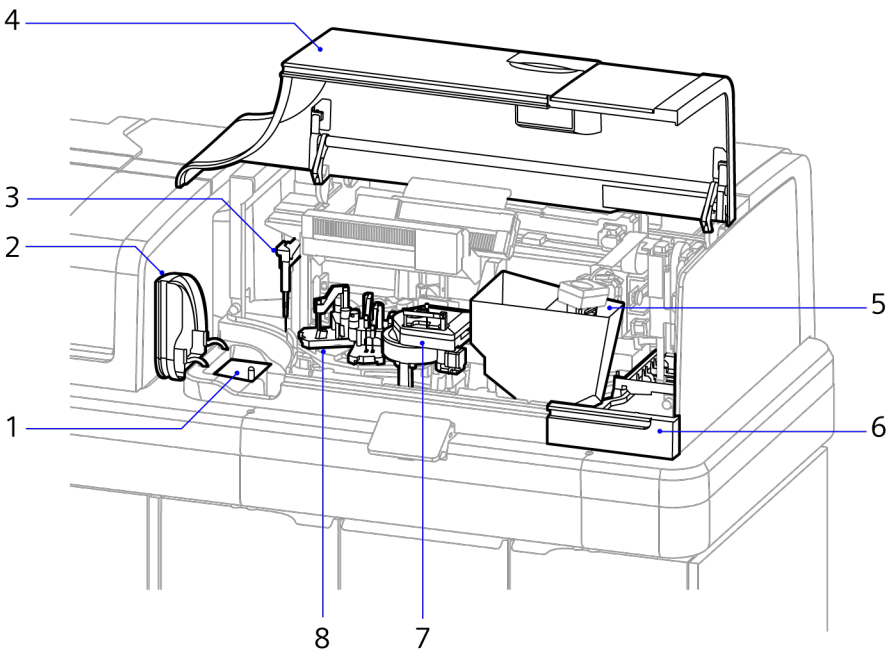
The automated IM Analyzer contains all the necessary hardware, electronics, and software to process samples and generate results, including sample and reagent dispensing, mixing, and incubating.

IM front view with covers closed



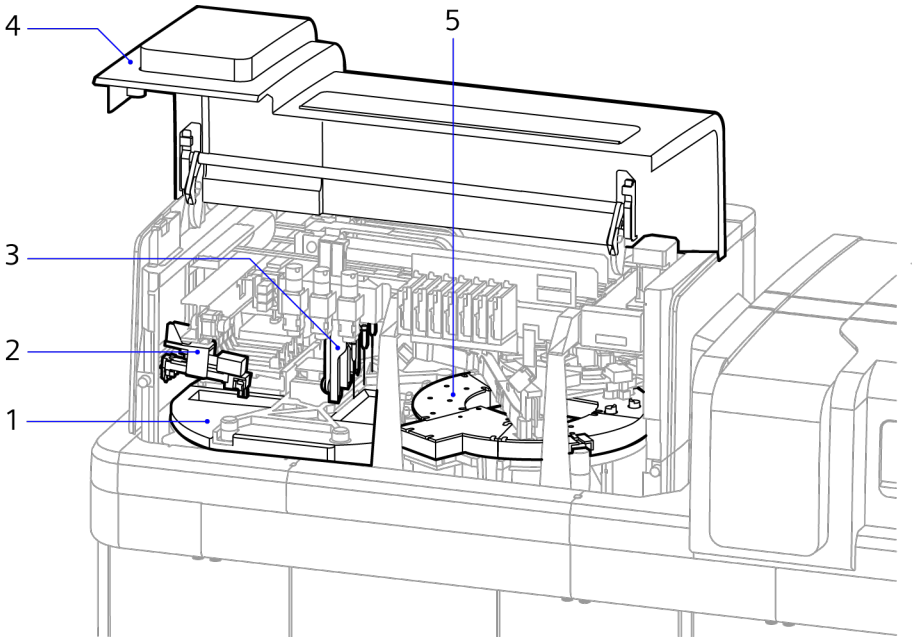
1	Sample tip loading lid	5	Water and liquid waste door
2	Module display	6	System fluids drawer
3	Cuvette bin lid	7	Solid waste door
4	Reagent drawer		

IM front view with cover open



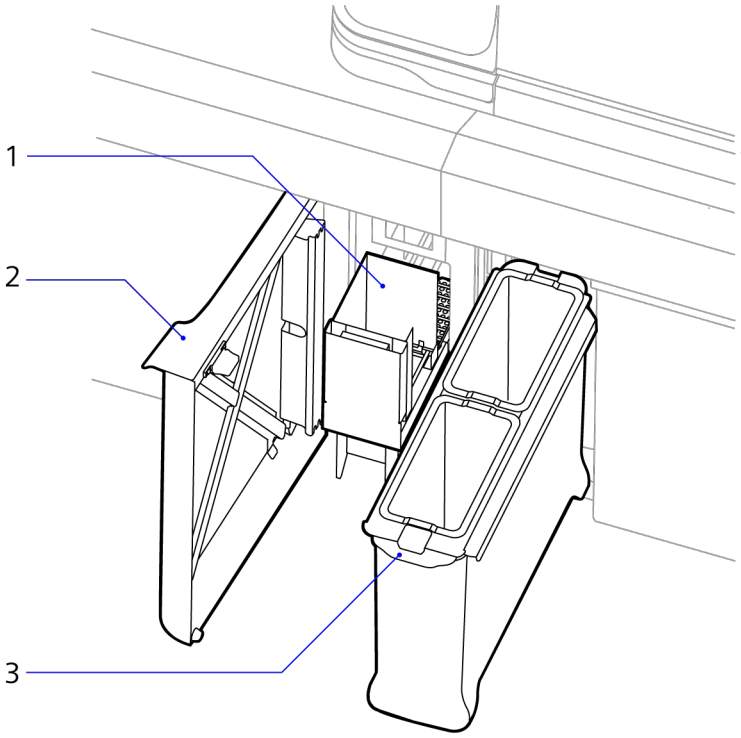
1	Sample tip loader	5	Cuvette bin
2	Sample tip loading lid	6	Reagent drawer
3	Sample probe	7	Luminometer
4	Front system cover	8	Wash ring

IM back view with cover open



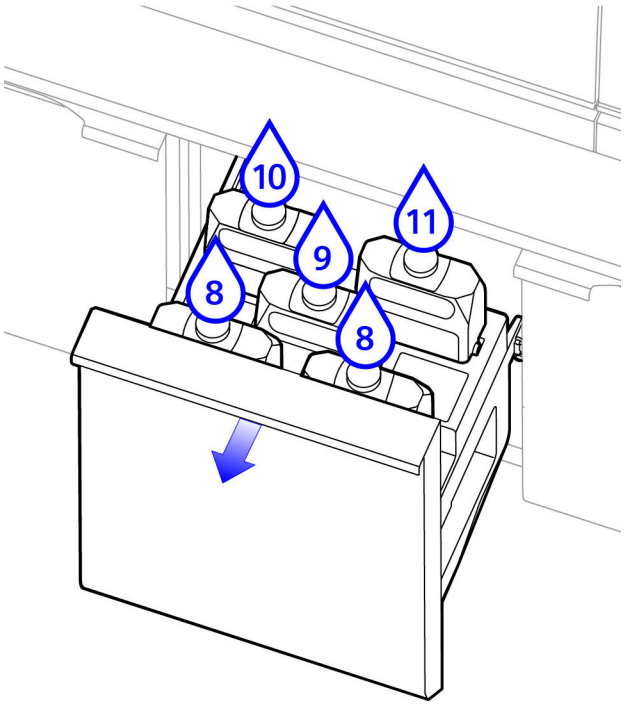
1	Reagent compartment
2	Reagent loader
3	Reagent probes
4	Back system cover
5	Incubation ring

IM Solid Waste



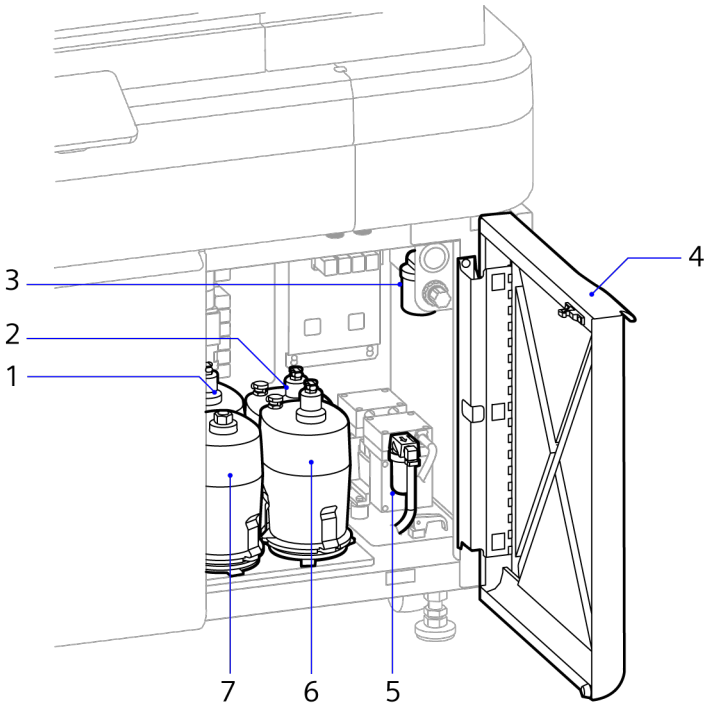
1	Sample tip tray waste drawer
2	Solid waste door
3	Solid waste bin drawer (cuvette and sample tip waste)

IM system fluids drawer



Symbol	System Fluid
8	IM Wash
9	IM Cleaner
10	IM Acid
11	IM Base

IM water and liquid waste

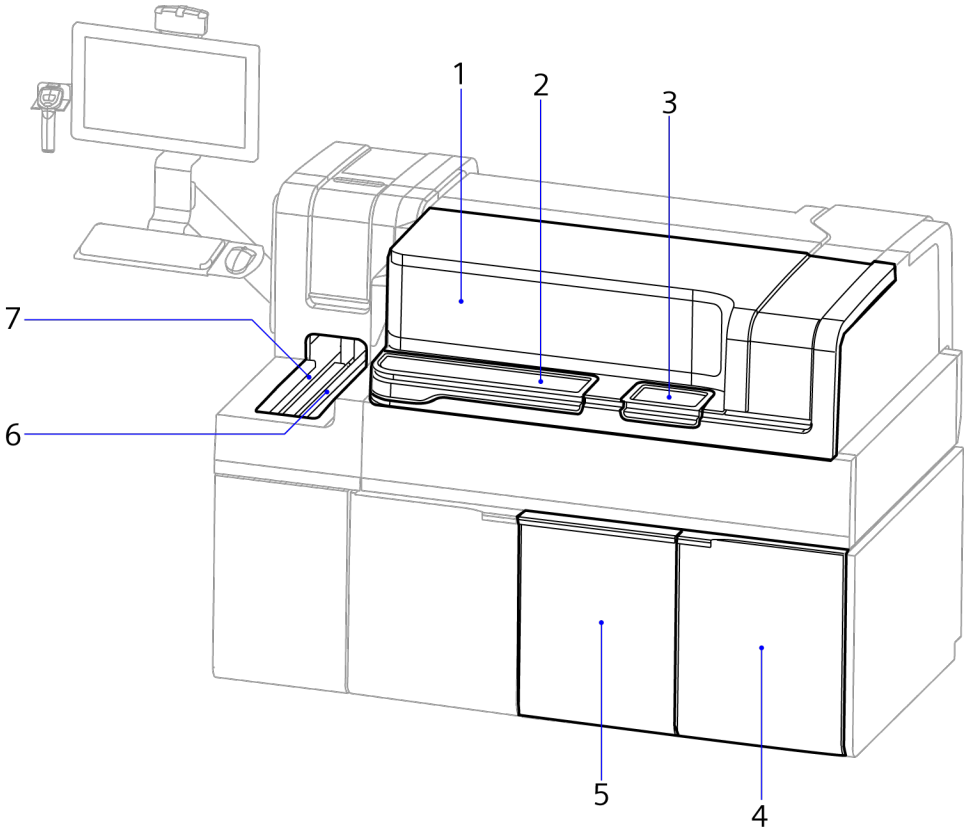


1	Liquid waste	5	Dryer
2	Liquid waste	6	Liquid waste
3	Water trap	7	Special reagent water
4	Water and liquid waste door		

About CH DL

The automated CH DL contains all the necessary hardware, electronics, and software to process samples and generate results, including sample and reagent dispensing, mixing, and incubating.

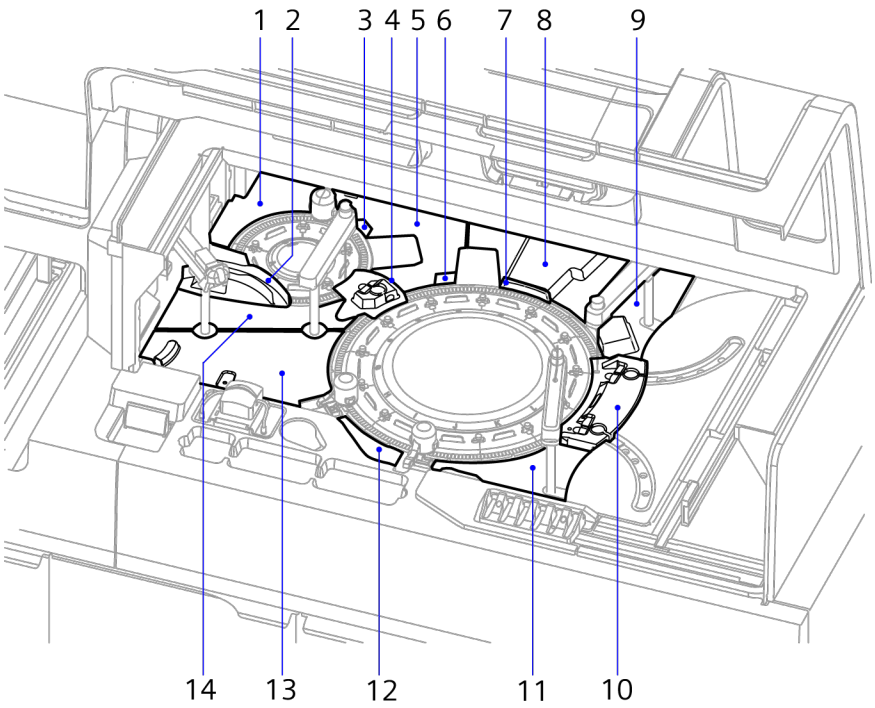
CH DL with covers closed



1	Front cover	5	System fluids drawer
2	IMT fluids lid	6	Exit queue
3	Reagent tray lid	7	Entry queue
4	Water and liquid waste door		

The analyzer plates and shields cover the individual subsystems and reduce dust collection on the components. For identification purposes, the plate title is embossed on the underside of each plate. The 3 probe shields do not have this identification.

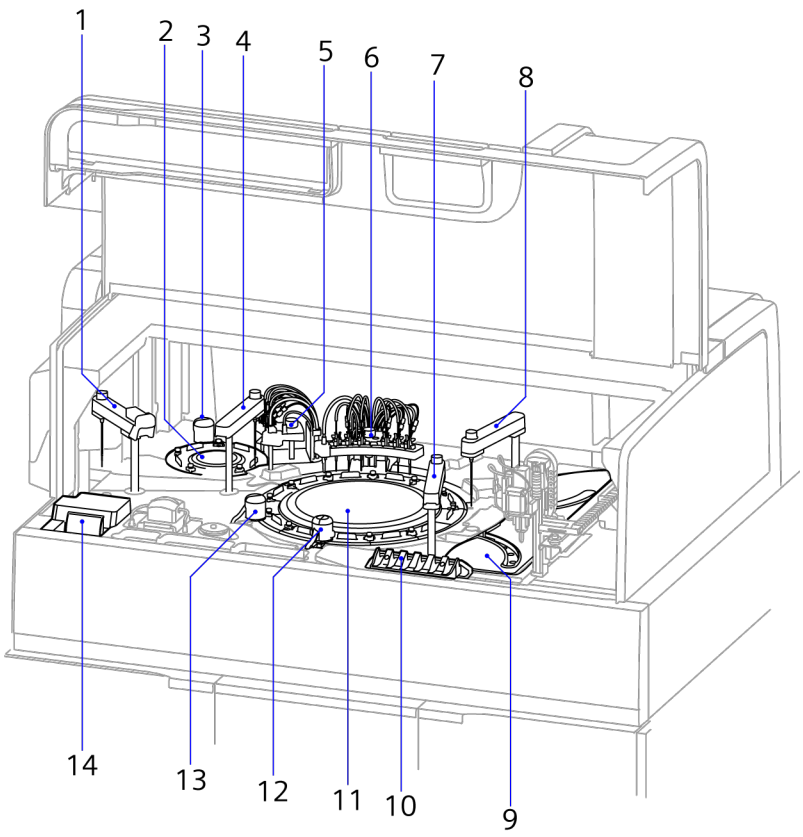
CH interior plates and probe shields



1	D1	8	Bulb access
2	Dilution probe guard	9	R3
3	Dilution probe shield	10	Reagent probe guard
4	Sample probe guard	11	R4
5	D2	12	R2
6	Left reaction probe shield	13	R1
7	Right reaction probe shield	14	D3

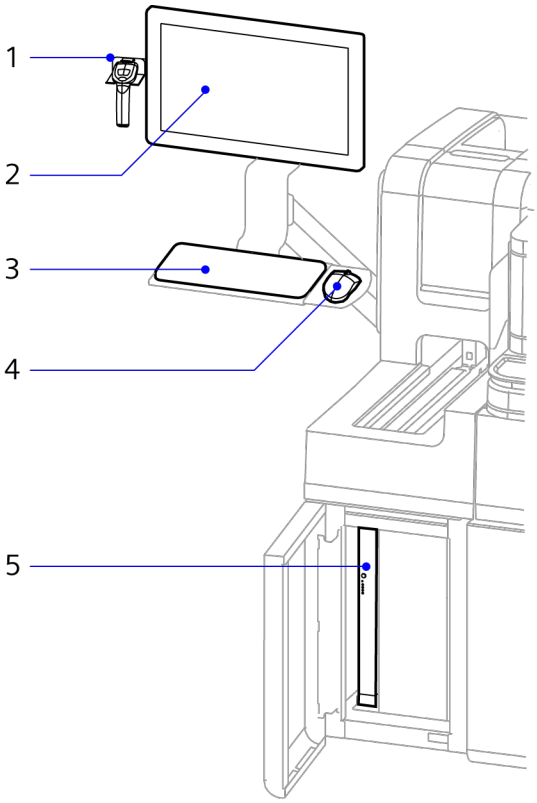
The exterior covers, doors, drawers, and lids provide access for checking and replacing fluids. The entry and exit queues load, unload, identify, and present samples to the analyzer for processing.

Front view of CH DL with cover open



1	Dilution arm	8	Reagent arm 1
2	Dilution ring	9	Reagent compartment
3	Dilution mixer	10	Reagent tray
4	Sample arm	11	Reaction ring
5	Dilution washer	12	Sample mixer
6	Reaction washer	13	Reagent mixer
7	Reagent arm 2	14	IMT system

CH DL workstation

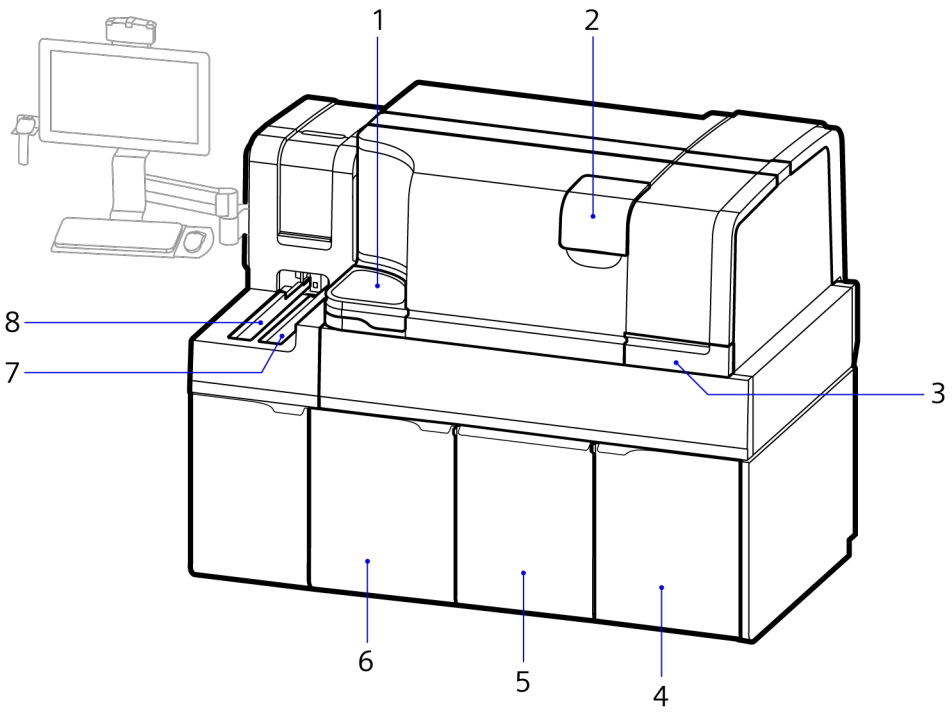


1	Barcode reader
2	Monitor
3	Keyboard
4	Pointing device
5	Computer

About the IM DL

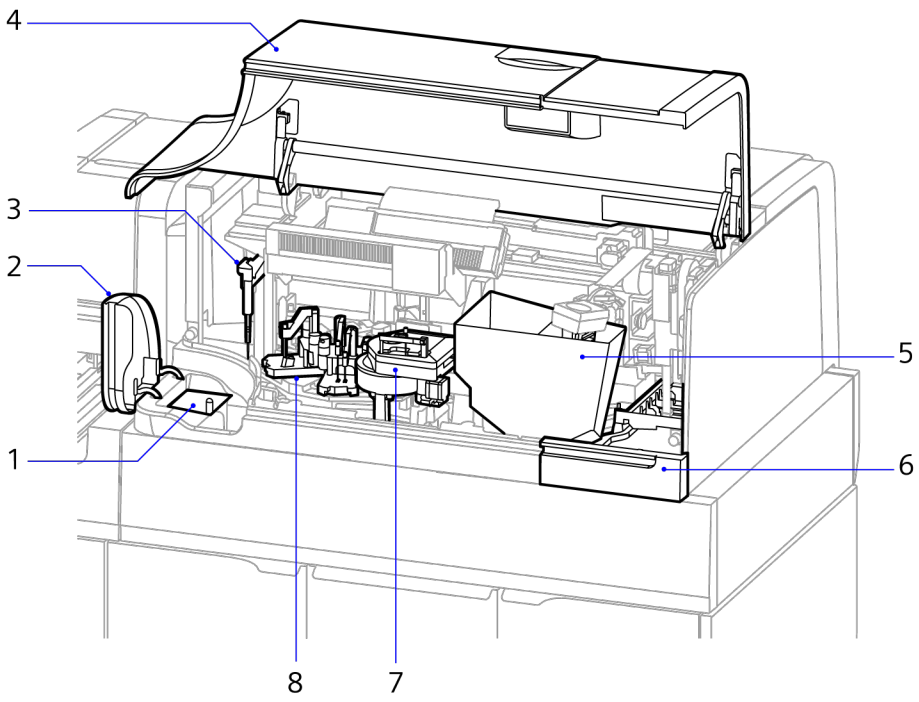
The automated IM DL contains all the necessary hardware, electronics, and software to process samples and generate results, including sample and reagent dispensing, mixing, and incubating.

Full system with covers closed



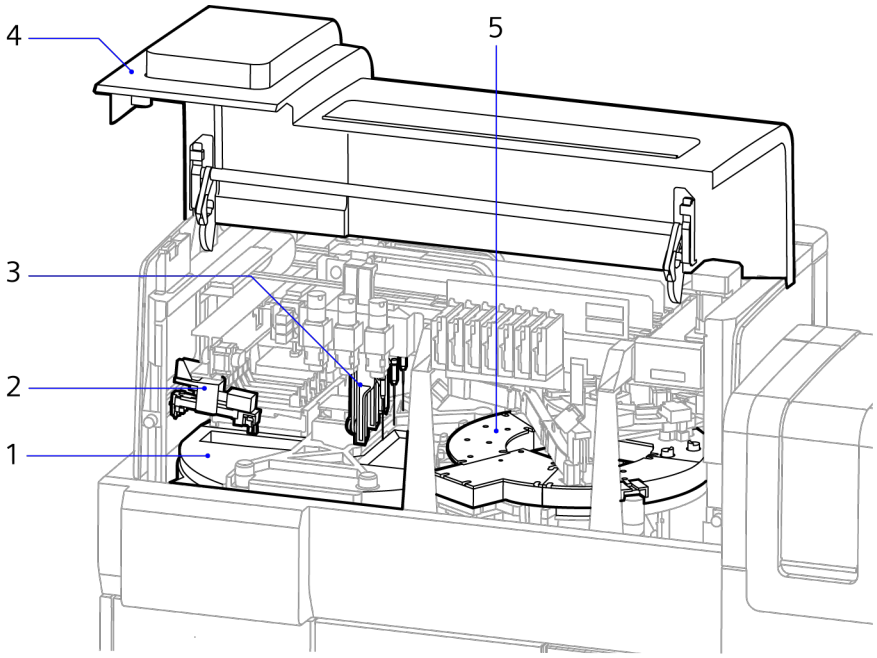
1	Sample tip loading lid	5	System fluids drawer
2	Cuvette bin lid	6	Solid waste door
3	Reagent drawer	7	Exit queue
4	Water and liquid waste door	8	Entry queue

Front view of the system with cover open



1	Sample tip loader	5	Cuvette bin
2	Sample tip loading lid	6	Reagent drawer
3	Sample probe	7	Luminometer
4	Front system cover	8	Wash ring

Back view of the system with cover open



1	Reagent compartment
2	Reagent loader
3	Reagent probes
4	Back system cover
5	Incubation ring

About the Direct Load

The Direct Load (DL) is an optional sample handling subsystem that allows each analyzer to operate as a standalone system.

Feature	Notes
DL	Provides a mechanism to present patient samples, calibrators, and control materials to a connected analyzer. The DL supports a variety of tube types as well as a smaller volume tube top cup.
Sample rack	Provides 6 positions for sample tubes on a rack (45 mm x 60 mm x 90 mm) for DL input. Adapters allow sample tubes with a smaller diameter than the 16mm rack opening to fit securely in the rack. The adapters also aid in level sensing smaller tubes.

Feature	Notes
Sample rack lanes: entry and exit queue	Consists of an entry queue with a maximum capacity of 10 sample racks, for a total of 60 sample tubes. The exit queue is next to the entry queue and also holds a maximum of 10 racks. A magnetic conveyor system controls the movement of the racks on the queues. An optical sensor at the front of the entry queue initiates an automatic loading sequence when the operator loads a rack. A sensor on the exit queue detects the unloading of racks and enables racks at the back of exit queue to move forward.
Rack shuttle	Transfers sample racks from the entry queue into the rack positioner. The shuttle also presents the sample racks to the vision system for sample identification. A sensor detects the rack before it goes into the shuttle, and another sensor detects successful entry into the rack positioner. The shuttle carriage has an L-shaped design on both sides to push sample racks along the baseplate, perpendicular to the entry and exit queues.
Vision cameras and rack image processing	Identifies rack ID barcodes, tube ID barcodes, adapter type E-code, sample cups in tubes, and sample tubes without caps. The shuttle carriage exposes both sides of the sample racks so that the 2 cameras on the back of the unit can process each position on the rack. Each camera processes the images for 1 side of the rack.
Rack positioner and sampling	Moves the sample rack to the analyzer sampling points. The analyzer has 2 sampling points for the 2 rows of sample positions on the rack. After the analyzer processes all 6 positions of the rack, the rack positioner moves the rack under the shuttle carrier toward the exit queue. The rack goes through a gate, and moves forward as the operator unloads any racks in front of it on the exit queue.

About the Barcode Printer

A barcode printer prints the labels that the operator can affix to the calibrator, QC, and patient sample containers.

NOTE:

Refer to the barcode printer manufacturer's IFU to learn about standard features and functions of the printer, including:

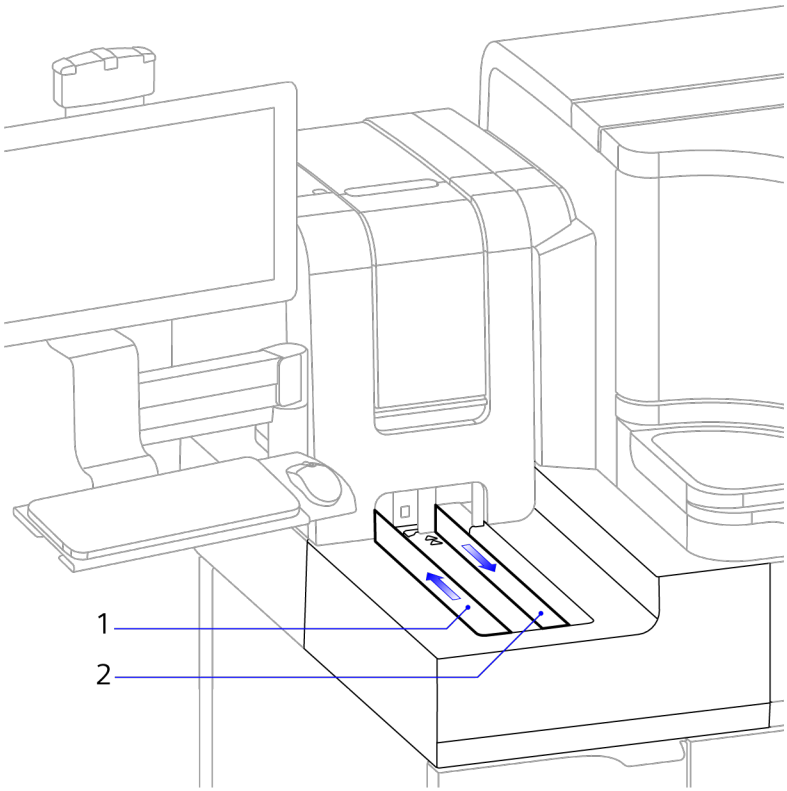
- Controls and indicators
- Powering the printer on and off
- Loading labels
- Replacing the thermal ribbon

The system supports barcode printers and labels that meet the following specifications:

Specification	Notes
Printing method	Thermal transfer
Head density (resolution)	12 dots/mm (300 dpi)
Effective print area	56 mm (2.2 inches) x 400 mm (15.75 inches)
Acceptable media type	Paper or polypropylene **NOTE:** For containers the system stores in the Cal-QC storage area, only use polypropylene barcode labels (such as SMN 10734465 when using the optional SATO CG212 barcode printer). Paper labels may not properly adhere to the container or the system may damage the paper labels during handling.
Minimum bar width	6.66 MIL (0.00666 inches)
Barcode support	Code 128 (recommended), Code 39, InterLeaved 2 of 5, Codabar (NW7)
Programming language	Zebra Printer Language II (ZPL II)
Interface	Ethernet

About DL Entry and Exit Queues

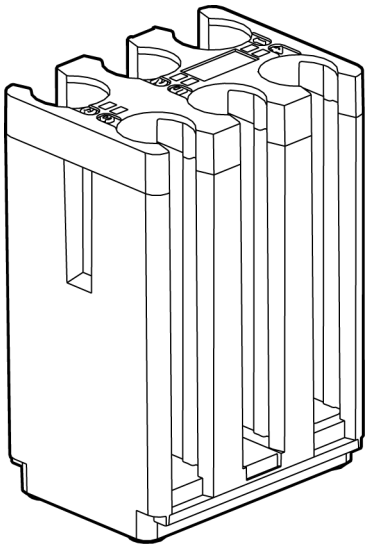
The entry and exit queues provide a means of loading and unloading, identifying, and presenting samples to the system for aspiration.



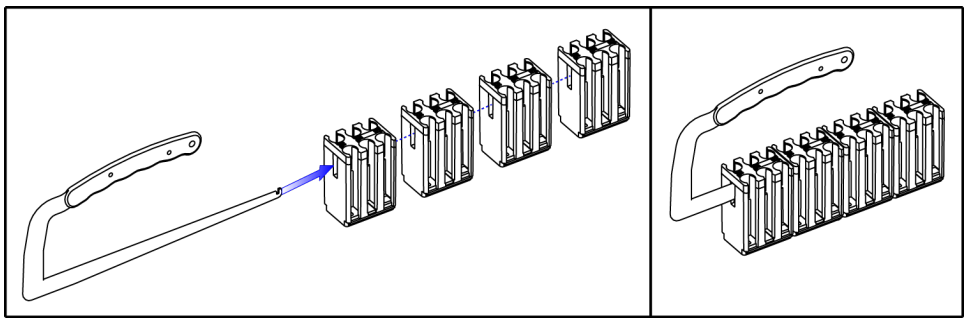
1	Entry queue
2	Exit queue

About Sample Racks and Adapters for Standalone Analyzers

Standalone analyzers introduce patient samples to the sample loading module in sample tubes or Tube Top Sample Cups (TTSC) seated in sample tubes. The operator can only use unstoppered 3.5–10 mL primary tubes in sample loading module racks. Sample racks hold 6 barcoded samples and each position has a number to communicate the location of a sample. The capacity of the exit queue is 10 sample racks.



The sample rack carrier holds up to 5 racks at a time. The operator inserts the carrier blade through openings in the racks to transport multiple racks from the preparation to the system.



If the operator uses an unspecified sample container, the operator must configure an open-tube rack. The operator configures a single rack color and the tube bottom offset. It is the operator's responsibility to place acceptable sample tubes in the designated open-tube sample racks.

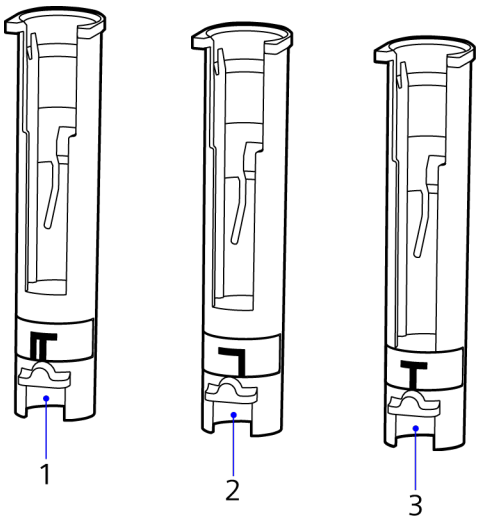
The following constraints apply when using open-tube racks:

- Tube diameter and length must fit the sample rack insert.
- Sample container must have a valid barcode.
- No stoppers or caps allowed.

NOTE: The system uses false-bottom tubes as a secondary pour-off tube for barcoding on automated analyzers. The tube length does not equal the specimen depth.

About Sample Adapters for Standalone Analyzers

The 12-mm and 13-mm sample containers require an adapter. The operator can only use the 3 adapters that come with the sample loading module. The operator must use these adapters because they have specific codes that identify them to the sample loading module.



1	Grey
2	Teal
3	Brown

Sample Container	Adapter Type	Adapter Color	Adapter Code	Diameter	Length
5-mL tube	5-mL	Teal		13 mm	75 mm
7-mL tube	7-mL	Brown		13 mm	100 mm
		Grey		12 mm	75 mm
10-mL tube	None	None	None	15 mm	92 mm

9 Routine Operations

General Safety

Follow safety precautions when operating the system. For more information about protection against hazards, see the *Safety* chapter in this guide.

Daily System Operation Workflow



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

The following workflow list is an example of daily operations:

- Sign in to system (Page 643 *Signing in to the System*).
- Respond to system alerts (Page 143 *Viewing Alerts*).
- Ensure required maintenance is complete (Page 551 *Responding to Maintenance Alerts in System Status Area*).
- Check CH andIMT system fluids status (Page 274 *Checking System and IMT Fluids on the CH Analyzer*).
- Check IM fluids, supplies, and waste status (Page 292 *Checking IM System Fluids, Supplies, and Waste*).
- Check reagent status in Reagent Needs (Page 268 *Reviewing Reagent Needs*).
- Check assay reagent calibration status in Calibrations Due or Calibration Needs (Page 271 *Reviewing Calibrator Needs*).
- Review assay reagent QC status in QC Needs (Page 270 *Reviewing QC Needs*).
- Order routine and STAT samples (Page 320 *Ordering Patient Tests Workflow*).
- Load samples on:
  - System (Page 386 *Loading Samples into SH Racks*) and (Page 388 *Loading Racks into Sample Drawers*).
  - CH DL or IM DL (Page 391 *Loading Sample Racks on a Standalone Sample Handling Subsystem*).
- Review results (Page 354 *Reviewing Patient Results in Worklist*).

- Remove samples from SH drawers (Page 390 *Unloading Racks from Sample Drawers*).
- Remove samples from CH DL or IM DL (Page 391 *Unloading Sample Racks from the Standalone Sample Handling Subsystem*)
- Sign out (Page 643 *Signing out of the System*).

10 Inventory

Inventory

This chapter provides information about managing consumable supplies and waste products on the system.

About Reagent Overview

Reagent Overview provides information about the status of the onboard reagent packs that includes:

- OBS (onboard stability)
- Cal Status
- Reagent Details

NOTE: The operator cannot perform any action in Reagent Overview on the Atellica Asa™ Application.

Reagent Overview updates immediately.

Reagent Overview	Notes
Select a Module:	Operator selects to filter reagents by analyzer. Default is All.
Selector column	Operator selects global check box for all reagents or appropriate reagents. If 1 reagent is selected, the Reagent Details display. **NOTE:** The check box does not display on the Atellica Asa Application.
Analyzer	Reagent resides on this analyzer.

Reagent Overview	Notes
Reagent	Short name for the assay or ancillary material associated with the reagent pack. The reagent highlights in red when the reagent pack has any of the following status conditions: • Invalid Barcode or Bad Read • Unknown product (IM only) • Unknown lot (IM only) • All Tests Disabled • Missing Paired Pack (CH only) • Use for Inventory TDef Missing (IM only) • Mixing Required (IM only)
Inventory	Number of tests remaining for the primary reagent packs. Volume remaining in mL for: • IM primary and ancillary probe wash • IM ancillary reagent • IM diluent packs

Reagent Overview	Notes
OBS	Count down timer in days and hours before the stability of the reagent expires. This time is based on the OBS or lot expiration. The column is empty if the pack or well has no established OBS. OBS starts when: • The operator initially loads the IM reagent pack onto an analyzer. • The operator initially loads the IM primary wash onto an analyzer. • The IM Analyzer pierces the ancillary pack. • IM ancillary reagent and diluent are based on the IM test definition configuration. • The CH Analyzer pierces a pack well.
Sequence	For CH packs, 5-digit pack identification portion of the barcode. The Sequence highlights in red when there is a paired pack and the pair is not loaded. For IM packs, 6-digit pack identification portion of the barcode.

Reagent Overview	Notes
Cal Status	Not all assays require reagent calibration. Blank when no calibration required. An icon displays when a calibration is required for the pack or reagent lot: •  : Valid calibration exists. •  : Reagent is shared among multiple assays and not all have a valid calibration. • Highlights in red when the pack calibration status is Expired, Invalid, or Rejected. •  : One or more of the following applies: – Error or expired lot. – Expired OBS. – Expired calibration interval. – Invalid or rejected calibration result. – Assay does not have a valid calibration status.
Cal Exp	Count down timer in days and hours for the next calibration event required for that pack or CH well. Count down measures the shorter value between the lot expiration and Cal Interval. **NOTE:** When a valid calibration expires, the system considers a reagent pack empty if insufficient tests remain in the pack to produce a calibration or the combinationf of a calibration, QC, and 1 patient result.

Reagent Overview	Notes
Cal Type In Use	The current type or category of calibration for the selected pack that the system uses to generate patient results. The field is blank if an active calibration does not exist on the system.
QC Status	No icon is present for the following: IM and CH • QC Required, QC on Pack Change and QC Statistics violation settings are disabled. IM • Reagent is IM probe wash, ancillary reagent or diluent. • Reagent pack has an unrecoverable error. • The operator performed QC due to QC on Pack Change configuration. CH • New or unpierced reagent pack. • Both wells of a pack have unrecoverable errors. • The operator performed QC due to QC on Pack Change configuration.  : A reagent pack can be used for patient processing. • QC Required or QC Statistics violation configurations are enabled, but no conditions exist that are blocking patient processing.  : A reagent pack cannot be used for patient processing.

Reagent Overview	Notes
	• 1 or more conditions exist that prevent patient processing. Conditions can include QC on Pack Change not performed, QC Statistics violations or QC Required timeframe expired.
Lot	Lot of the reagent, ancillary or wash packs.
Cal Eligibility	Lot and pack eligibility status for reagents eligible for calibration: • Lot and Pack: The operator can order a Lot or Pack calibration. It is recommended that the operator orders a lot calibration if it is available to have the best efficiency. • Pack: The reagent is too old to perform a lot calibration and the operator orders a pack calibration. The operator loads a new pack if a lot calibration is needed.
Group by reagent	A global selection check box to list all packs for the same reagent together. **NOTE:** Selecting this check box on the Atellica Asa Application groups the reagents by lot.
Disable Reagent Pack	The operator selects to disable a reagent pack to: • Manage inventory. • Ensure the lot is qualified by the laboratory before they place it into use. • Troubleshoot assay issues.

Reagent Overview	Notes
Disable Reagent Lot	An operator selects to disable a reagent lot to: • Manage inventory • Ensure the lot is qualified by the laboratory before they place it into use. • Troubleshoot assay issues.
Unload	The operator selects to remove packs after Inprocess tests have completed.
Unload Immediately	Displays when IM Analyzer is selected in Select a Module:. The operator selects to stop processing and cancel tests associated with the selected IM reagent packs.

CH Reagent Details	Notes
Reagent Details	Additional reagent pack information displays when the operator selects a Reagent check box.
Name	Short name for the assay associated with the reagent pack.
Paired Pack	5-digit pack identification portion of the CH paired reagent barcode located in Reagent Details.
Lot	Lot of the reagent packs.
Count Remaining	Number of tests remaining in the reagent pack.
Pack Location	Where the pack resides in the analyzer reagent compartment.
Onboard Stability	Count down timer in days and hours for the remaining OBS. The reagent lot expiration and analyzer vent time affect the OBS.
Position	Position of the reagent pack in the reagent compartment or loader.

CH Reagent Details	Notes
Lot Expiration	Date and time the reagent lot expires.
Status	A reagent pack error status including the following: • Expired: The pack reagent lot or OBS is expired and unusable. Unload and discard the pack. • Temperature Error: The pack is exposed to an out-of-range temperature for a significant period of time. Unload and discard the pack. • Contaminated: Another reagent compromised the pack contents, rendering it unusable. Unload and discard the pack. • Volume Check Error: The pack has insufficient fluid volume and is no longer usable. Unload and discard the pack. The operator reloads a pack to potentially clear the error and make it usable. • Duplicate Reagent Pack: The pack label duplicates an existing label, rendering the pack unusable. Unload and enter a unique label manually or unload and discard onboard pack. • Invalid Barcode: The pack has a readable barcode label that does not conform to a known, acceptable value. Unload and discard the pack. • Bad Read: The pack has an unreadable barcode label. Manually enter barcode data. • Invalid Analyzer Type for test {0}.: The analyzer type is incorrect for the assay.

CH Reagent Details	Notes
	Recoverable reagent pack statuses highlighted in red include the following: • Empty: No reagent in the pack. Unload and discard the pack. • Below Threshold ({0}): Reagent pack volume is below the Alert Threshold configured in Reagent Thresholds. • Reagent Pack Inactive: The operator disabled the pack and is unusable. Enable the pack or unload and discard the pack. • Lot Inactive: The operator disabled the pack reagent lot and is unusable. Enable the pack reagent lot or unload and discard the pack. • Processing: The pack is processing tests. If the system requests an unload, the analyzer waits for scheduled tests to complete processing. • Unload: The pack is queued for unload after all associated tests scheduled complete. Wait for processing to complete and pack to unload.  displays to the left of the status until loading completes. • Removable: The pack is in removable state, waiting to be removed. • Invalid Barcode: The pack has a readable barcode label that does not conform to a known, acceptable value. Unload and discard the pack. • All Tests Disabled: The pack is disabled and cannot be processed. • Missing Paired Pack: The associated paired pack is not onboard. Load pack. Usable reagent pack status: • Idle: The pack is usable and not processing tests. If unloaded, the pack does not have to wait for test processing to complete.

CH Reagent Details	Notes
	CH reagent pack well statuses include the following: • Sealed: The Well is not pierced. • Punctured: The Well is pierced. • Ready: The Well is ready to use. • Processing: The pack is processing tests. If the system requests an unload, the analyzer waits for scheduled tests to complete processing. • Empty: No reagent in the pack. Unload and discard the pack. • Expired: The pack reagent lot or OBS is expired and unusable. Unload and discard the pack. • Error: The pack produces a processing error. Unload and visually inspect the pack. The operator reloads the pack to potentially reset it and use the remaining tests.
Calibration Expiration	The calibration expiration time in date and time format.
Sequence Number	5-digit pack identification portion of the barcode.
Well 1	Test Count, Status, and Time Punctured for Well 1 of reagent pack.
Time Punctured	The date and time the analyzer pierces the pack for Well 1 and Well 2.
Well 2	Test Count, Status, and Time Punctured for Well 2 of reagent pack.
Calibrate Lot	Button enabled after a specific CH Analyzer is selected and a CH reagent pack or well is eligible for a lot calibration. Creates a calibration order for the selected pack or well. Edit this order if it is not in process.

CH Reagent Details	Notes
Calibrate Pack	Button enabled after a specific CH Analyzer is selected and a reagent pack or CH well is eligible for a pack calibration.
Disable Well 1/ Enable Well 1	This task requires the appropriate security level. The operator selects to disable Well 1.

IM Reagent Details	Notes
Reagent Details	Additional reagent pack information displays when the operator selects a Reagent check box.
Name	Short name for the assay associated with the reagent pack.
Lot ID	Lot of the reagent, ancillary, or humidity packs.
Pack Location	Analyzer reagent compartment where the reagent pack resides.
Position	Position of the reagent pack in the reagent compartment.
Status	A reagent pack error status including the following: • Expired: The pack reagent lot or OBS is expired and unusable. Unload and discard the pack. • Temperature Error: The pack is exposed to an out of range temperature for a significant period of time. Unload and discard the pack. • Contaminated: Another reagent compromised the pack contents rendering it unusable. Unload and discard the pack. • Volume Check Error: The pack has insufficient fluid volume and is no longer usable. Unload and discard the pack. The operator reloads a pack to potentially clear the error and make it usable. • Incompatible Lot: The reagent Lot is incompatible.

IM Reagent Details	Notes
	• Duplicate Reagent Pack: The pack label duplicates an existing label so the pack is unusable. Unload and enter a unique label manually or unload and discard onboard pack. • Invalid Barcode: The pack has a readable barcode label that does not conform to a known, acceptable value. Unload and discard the pack. • Bad Read: The pack has an unreadable barcode label. Manually enter barcode data. • Invalid Analyzer Type for test {0}.: The analyzer type is incorrect for the assay. Recoverable reagent pack statuses highlighted in red include the following: • Empty: No reagent in the pack. Unload and discard the pack. • Below Threshold ({0}): Reagent pack volume is below the Alert Threshold configured in Reagent Thresholds. • Reagent Pack Inactive: The operator disabled the pack and is unusable. Enable the pack or unload and discard the pack. • Lot Inactive: The operator disabled the pack reagent lot and is unusable. Enable the pack reagent lot or unload and discard the pack. • Processing: The pack is processing tests. If the system requests an unload, the analyzer waits for scheduled tests to complete processing. • Unload: The pack is queued for unload after all associated tests scheduled complete. Wait for processing to complete and pack to unload.  displays to the left of the status until loading completes. • Removable: The pack is in removable state, waiting to be removed.

IM Reagent Details	Notes
	• Invalid Barcode: The pack has a readable barcode label that does not conform to a known, acceptable value. Unload and discard the pack. • Unknown: The pack is unusable because it references an unknown reagent product code or reagent lot. If appropriate, scan the corresponding Master Curve or Test definition card. • Test Disabled: The pack is disabled and cannot be processed. • Use for Inventory TDef Missing: The pack is unusable because no IM Test Definitions are defined. • Mixing Required: The pack requires mixing. Wait until mixing is complete. • Mixing in Progress: The pack is unusable because it is insufficiently mixed. Wait until mixing is complete.
Sequence Number	5-digit pack identification portion of the barcode.
Count Remaining	Remaining tests in reagent pack. The analyzer updates the Count when the minimum change threshold is 10 tests until 10 tests remain. Then the inventory updates with every performed test.
Onboard Stability	Count down timer in days and hours for the remaining OBS. OBS starts when: • The operator initially loads the primary IM reagent or humidity pack onto an analyzer. • The operator initially loads the IM primary wash onto an analyzer. • The IM Analyzer pierces the ancillary wash pack. • IM ancillary reagent and diluent are based on the IM test definition configuration.
Lot Expiration	Date and time the reagent, ancillary, or humidity pack lot expires.
Calibration Expiration	The calibration expiration time in date and time format.

IM Reagent Details	Notes
Refresh	Reagent Details updates with current count and status.
Edit	The operator edits Count and OBS.

About Reagent Icons

An icon alerts the operator to a required action or more information. The assay short name and position number displays on the assay icons. Undefined displays for CH Analyzer operator-defined assays.

Reagent icon	Icon description
Red highlight	Unusable supply or reagent pack error. If any of the following errors exist, the Reagent is highlighted in red: • Depleted • Reagent expired • Onboard stability (OBS) expired • Permanent temperature error • Loader issue when the reagent loader mishandles a reagent pack • Excessive reagent volume check (RVC) errors • Incompatible with test definition • Duplicate pack • Contaminated pack
	Reagent pack transfer, mixing, or venting is in process.
	Batch code.
	Use-by date. Use by the designated date.

Reagent Loading CH pack icon	Icon description
	Empty position.
	Depleted or expired, unassigned operator-defined pack, bad barcode or barcode read error.
	Ready for use.

Reagent Loading IM pack icon	Icon description
	Empty position, depleted or expired, bad barcode or barcode read error.
	Ready for use.
	Low or expiring soon.
	Primary reagent pack in the drawer for > 30 minutes and requires re-mixing.
	Reagent drawer locked.
	Reagent drawer unlocked.

Reagent Overview Cal-QC status icon	Icon description
	The assay lot or pack has a successful calibration.
	The assay lot or pack has no calibration or a failed, rejected, or expired calibration.
	Some of the assays are calibrated.
	The reagent pack can be used for patient processing.
	The reagent pack is disabled for patient processing.

About Filtering Reagent Overview

The Reagent Overview filter allows the operator to narrow down the reagent list so only those reagents that match the filter criteria display. The filter automatically revises the results as choices are made.

Reagent Overview Filter	Notes
Clear	The operator selects to clear previous filter options.
Reagent Type	The operator selects from the following: • IM Primary Reagents: Displays IM primary reagent pack status and issues. • IM Ancillary Reagents: Displays IM ancillary reagent pack status and issues. • CH Reagents: Displays CH reagent pack status and issues.

Reagent Overview Filter	Notes
Pack Status	The operator selects **Packs with issues** to display those reagent packs with an immediate need. This does not include pack calibration or QC alerts.
All	The operator selects **All** to open the by module options. The operator can select all or filter by module.

About Reagent Loading

Reagent Loading displays the status of the following:

- Loader Status: Reagent loader lid (CH) and drawer (IM)
- Loader door Unlock (IM only)
- Reagent Inventory in the loader

If appropriate, review (Page 240 *About CH Reagent Loader*) or (Page 244 *About the IM Reagent Loading*).

About CH Reagent Management

The system stores reagents packs in the reagent compartment, which has 2 refrigerated reagent compartments. Each reagent compartment has an inner ring and an outer ring. The inner ring holds 24 packs and the outer ring holds 46 packs. The positions on the inner ring are numbered 0–23 and the positions on the outer ring are numbered 24–69. Each reagent compartment holds a total of 70 packs for photometric, Reagent Probe Cleaner (RPC), and Water Bath Additive (WBA). Both compartments combined hold a total of 140 packs.

Reagent compartment	Pack
1	P1
2	P2

The system loads 2-reagent assays as a paired pack, placing one on each reagent compartment. P1 and P2 always have 2 wells. For 3-reagent assays, P1 contains reagents 1 and 3 and P2 contains reagent 2.

The reagent loader:

1. Picks up the pack from the reagent tray.
2. Identifies the pack with the reagent barcode reader.
3. Places the pack in the designated position on reagent compartment 1 or reagent compartment 2.
4. Unloads empty or expired packs from the compartments.

The reagent compartments operate on a 3-second cycle with approximately 1 second for motion and 2 seconds for the respective reagent probe to access the compartment.

The reagent aspiration volume is 10–100 µL per assay.

About CH Reagent Loader

The status of the scanned CH reagent positions displays in Reagent Loader. The color and icon associated with a pack displays the pack status. When the operator empties the reagent loader and closes the lid, the loader is rescanned, returning the positions back to empty.

CH reagent pack icon	Icon description
	Empty position.
	Depleted or expired, unassigned operator-defined pack, bad barcode or barcode read error.
	Ready for use.

The following displays in Loader Status:

- Status of the reagent loader arm (Idle, Transfer inprocess, Scanning inprocess, or a loader error description)
- Status of reagent loader lid (Reagent loader lid is closed or Reagent loader lid is open)

Reagent Inventory displays 2 charts with the total number of packs and empty positions in each reagent compartment. Each chart indicates the number of the following packs in each reagent compartment:

- In Use
- Removable
- Empty Position

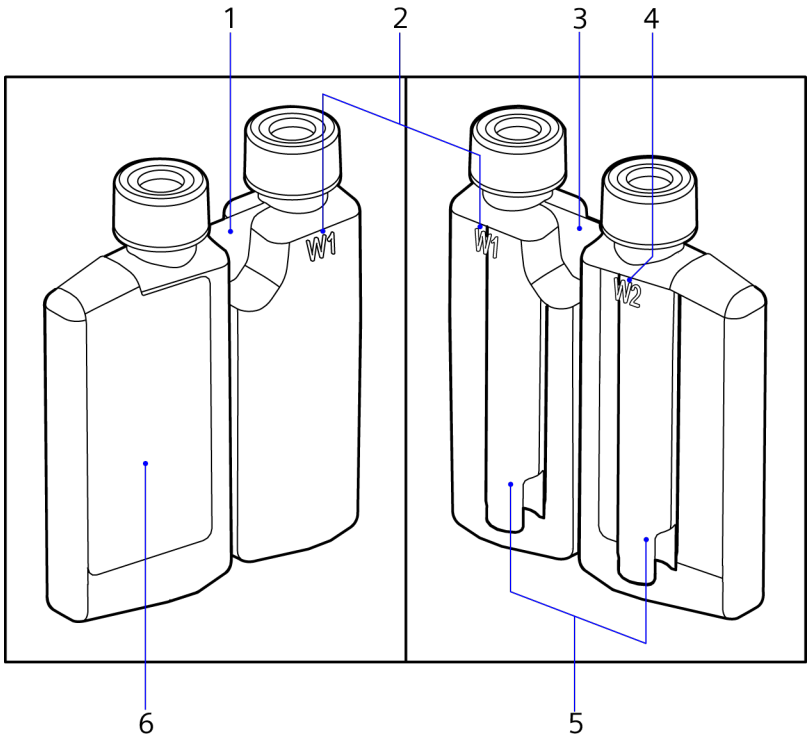
P1 Reagents are on reagent compartment 1. P2 Reagents are on reagent compartment 2.

The operator selects:

- **Manual Entry** if there an issue exists with the scan of the barcode
- **Assign** if the operator loads an operator-defined pack

About CH Reagent Packs

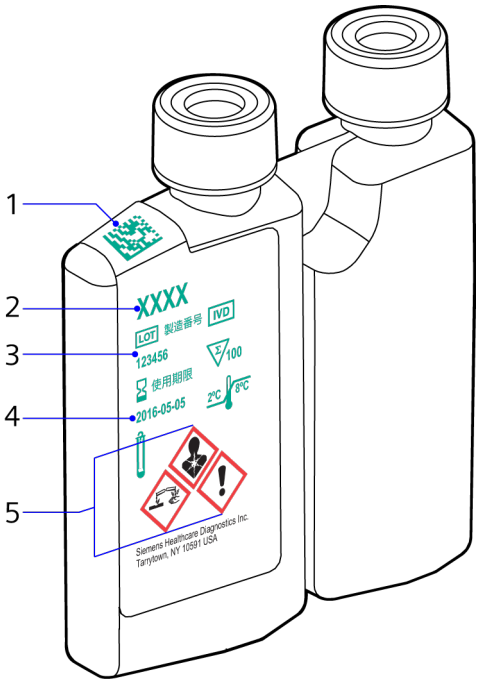
Reagent packs are double-well packs. A well contains up to 25 mL of reagent. In most cases, the double well allows for longer onboard stability because the second well in the pack is not opened until the analyzer needs reagent. For some assays, both wells are opened at the same time. Some of these packs contain a chimney to minimize absorption of CO_2 into the reagents.



1	CH reagent pack, without chimney	4	Well 2
2	Well 1	5	Chimney inside reagent pack
3	CH reagent pack with chimney	6	Reagent pack barcode label

A barcode label on the reagent pack identifies the assay, lot, expiration date, maximum number of tests for the pack, and compartment location.

CH reagent pack label



1	2D barcode
2	Assay short name
3	Lot
4	Expiration date
5	Safety hazards

Manually prepare and mix certain reagent packs before loading them on the system. Refer to the assay IFU for preparation instructions. All material for manual preparation of the reagent are in the same package.

Assay reagents are available as single or paired packs. The system loads assays containing packs with a single color cap as single packs.

The system loads paired packs with the same lot as a set. Paired reagent packs have caps of different colors.

About IM Reagent Management

The IM reagent compartment stores primary and ancillary reagent packs in the rotary tray. The tray holds up to 42 primary and 35 ancillary reagent packs. The tray holds 7 humidity packs initially and up to 3 additional humidity packs. If all 10 humidity packs are loaded, the tray holds up to 32 ancillary reagent packs. A barcode reader in the reagent compartment reads the reagent and humidity pack barcodes during startup. The reagent compartment maintains a temperature of 4–8 °C and 70–100% humidity. The rotary tray motion mixes the reagent packs.

The reagent loader picks up the reagent pack from the reagent tray at the front of the analyzer and places the pack in a position on the rotary tray. A barcode reader in the reagent loader reads the reagent pack barcode. The reagent loader also unloads packs when they become unuseable.

The reagent compartment has a manual access door that allows the operator to extract packs from the rotary tray in case of power failure.

The IM Analyzer uses reagent probes with onboard washing to reduce reagent carryover. The analyzer performs onboard washing for all reagent probes after each reagent aspiration and dispense cycle. When performing specific test combinations together, the system utilizes additional washes using special wash packs. The individual assay Test Definition controls the wash protocols and materials. More information about assays requiring special washes is available in the *Materials Required but not Provided* section of the appropriate assay IFU.

About the IM Reagent Loading

The status of the IM reagent pack displays in Reagent Loading. The color and icon associated with a pack displays the pack status. When the operator empties the reagent loader and closes the drawer, the drawer locks, the loader re-scans, and the pack status of each position updates.

IM pack icon	Icon description
	Depleted or expired, bad barcode or barcode read error
	Primary pack ready for use
	Ancillary pack ready for use
	Empty position
	Reagent loader hardware error
	Reagent drawer locked
	Reagent drawer unlocked

The following reagent drawer statuses display in Loader Status:

- Reagent Drawer locked: To unlock the IM reagent drawer, the operator selects **Unlock**.
- Reagent Drawer unlocked and opened.

Reagent Inventory displays the number of Primary Reagents and Ancillary Reagents in 2 charts. Each chart indicates the number of the following packs in each reagent compartment:

- In Use
- Removable
- Empty Position

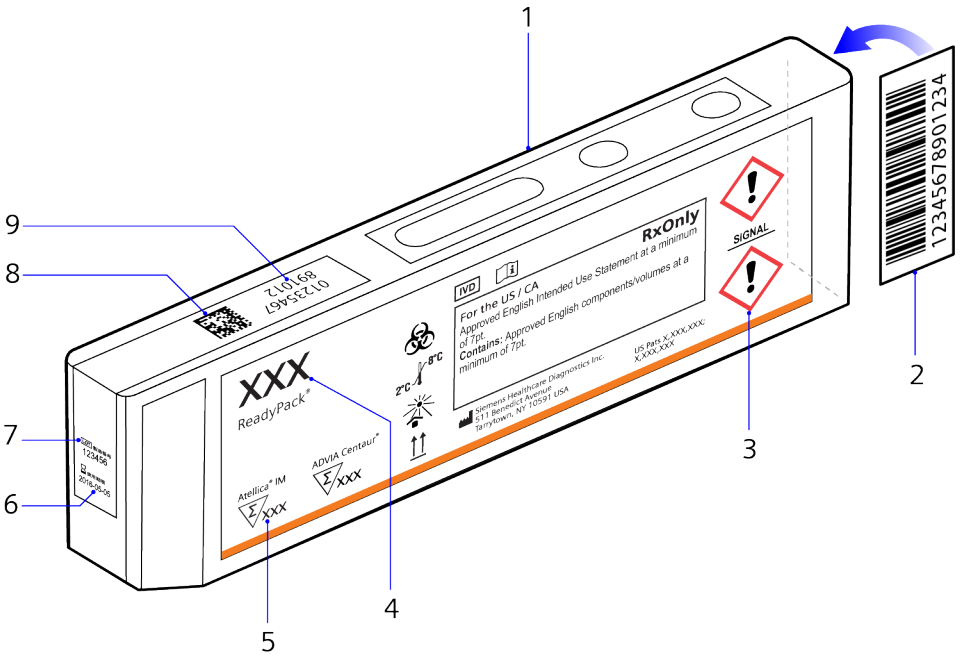
The operator selects **Manual Entry** if an issue exists with the scan of the barcode.

> **CAUTION**
>
> Do not select **Resume Work** before clearing obstructions. Damage to the loader and possible contamination of all reagents in the compartment can occur.

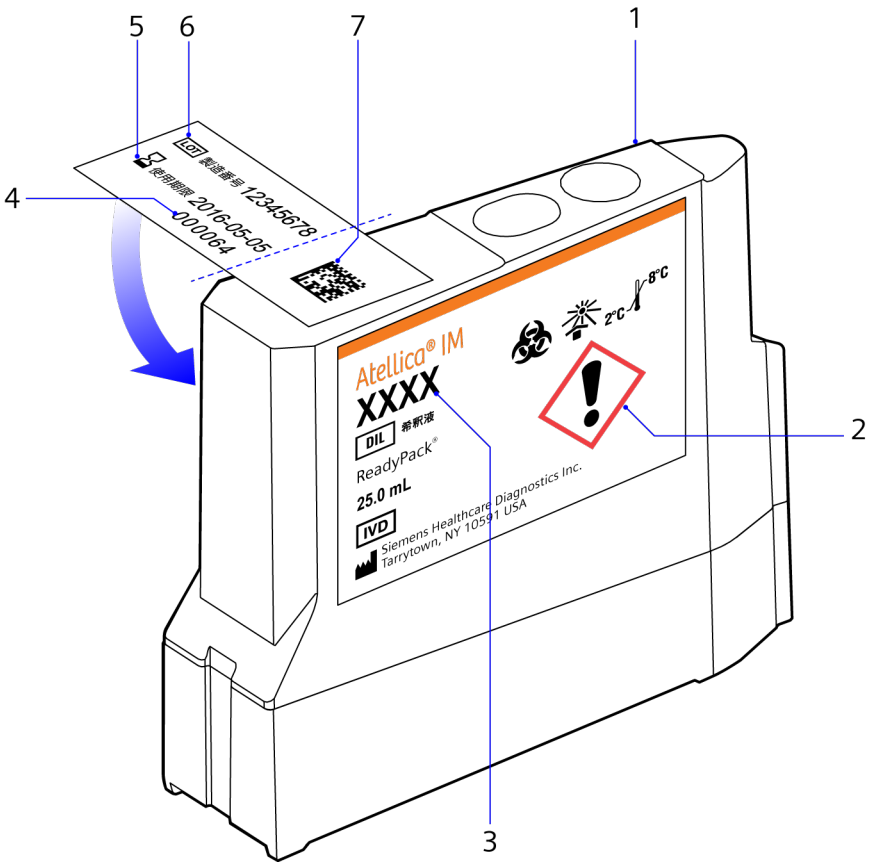
To clear a IM reagent compartment obstruction alert or event and reset the autoloader, the operator selects **Resume Work** after removing all obstructions.

About IM Reagent Packs

The system uses primary and ancillary reagent packs.

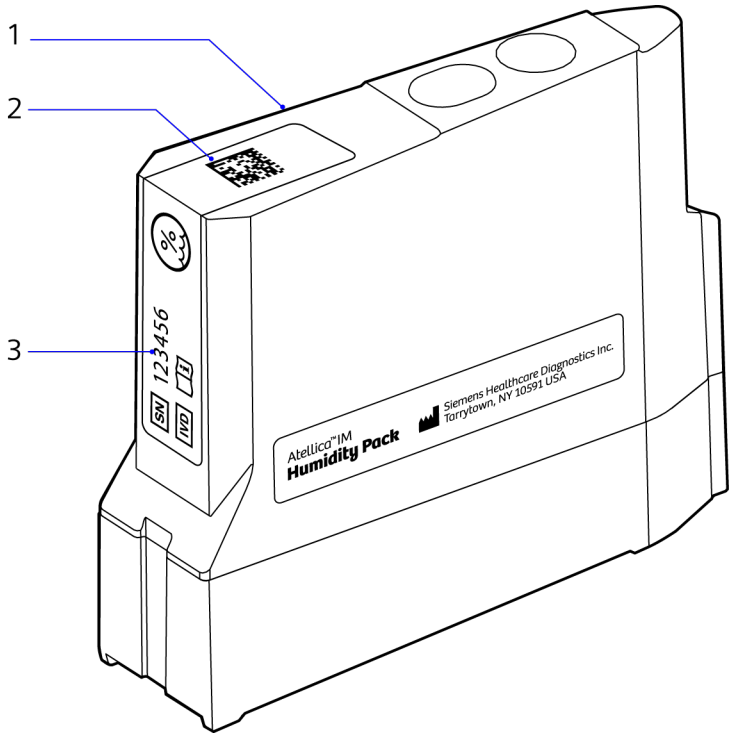


1	IM primary reagent pack	5	Atellica number of tests
2	Linear barcode and barcode number	6	Expiration date
3	Safety hazards	7	Lot
4	Assay short name	8	Atellica 2D barcode
		9	Atellica 2D barcode number



1	IM ancillary reagent pack	5	Expiration date
2	Safety hazards	6	Lot
3	Assay short name	7	2D barcode
4	Serial number		

If appropriate, consult the online help for more information about handling IM reagent packs (Page 250 *Handling IM Reagent Packs*).



1	IM ancillary humidity pack
2	2D barcode
3	Serial number

About IM Humidity Packs

Humidity packs maintain reagent compartment humidity between 70–100%. The operator loads 7 empty humidity packs initially. The system automatically fills the packs with water during the daily maintenance procedure. The system monitors humidity in the reagent compartment and, if the humidity falls below 70%, may require up to 3 additional humidity packs for a total of 10.

Loading IM Reagent Packs

1. Ensure the system is in the Ready or Processing state.
2. Manually mix primary reagent packs (Page 249 *Manually Mixing IM Reagents*).
3. Open the reagent drawer.
4. Insert up to 5 primary or ancillary reagent packs.

5. Close the reagent drawer.

   NOTE: When the reagent drawer closes, the drawer locks and the gripper scans the packs and automatically loads valid packs. If the operator unlocks the reagent drawer when packs are loading, the Inprocess pack loads, the remaining packs cancel, and the drawer unlocks.

6. Review Reagent Loader and resolve any issues.

Manually Mixing IM Reagents



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.



CAUTION

Do not load an IM reagent on the system without manually mixing the pack. Failure to manually mix an IM reagent pack prior to loading on the system may adversely impact assay results.

1. If the reagent pack is pierced, gently press on the self-sealing laboratory film that covers the pierced film area while mixing to prevent leakage.
2. With the film side up, loosely hold the reagent pack at each end.
3. Raise 1 end of the pack 90° to its vertical position.
4. Return the pack to a horizontal position.
5. Raise the other end of the pack 90° again to its vertical position.
6. Return the pack to a horizontal position.
7. Repeat steps 2–5 a minimum of 20 times or until any visible clumps, settled particles, or particles adhering to the reagent pack wall are resuspended.

   NOTE: If foam appears inside the pack, use a slower mixing speed.

8. Mix 5–10 times more to ensure complete mixing.
9. If the reagent pack is pierced, remove the self-sealing laboratory film.
10. Load the reagent pack onto the appropriate IM Analyzer (Page 248 *Loading IM Reagent Packs*).

Loading IM Humidity Packs

1. Open the reagent drawer.
2. Insert 5 empty humidity packs.

3. Close the reagent drawer.
4. To load 2 more packs, repeat steps 1–3 after the system finishes loading the first 5 humidity packs.

Unloading IM Reagent Packs Immediately

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

NOTE: Use Unload Immediately to stop processing and cancel tests associated with the selected reagent packs. To remove packs after Inprocess tests have completed, see.

1. Navigate to **Reagent Overview**.
2. Select the appropriate .
3. Select the appropriate reagent packs.
4. If tests are processing, select **Unload > Unload Immediately**.

   NOTE: The reagent status changes to "Operator requested immediate pack removal." in Reagent Details.

   Unload Immediately is not an option if tests are not Inprocess. To confirm unloading of the reagent pack, select **Yes**.
5. In Reagent Loading, ensure Loader Status is .
6. Open the reagent drawer.
7. Remove the reagent packs from the reagent tray.
8. If the reagent pack is pierced and intended for reuse, cover the pierced film area of the reagent pack with self-sealing laboratory film.
9. Store useable reagent packs according to the assay IFU.

Handling IM Reagent Packs

NOTE: During off-system storage, solid phase particles settle as a pellet at the bottom of the primary reagent pack.

If shutting down the analyzer reagent compartment refrigeration for longer than 2 hours or in case of a power outage for longer than 30 minutes, remove and store all reagent packs.

If shutting down the analyzer reagent compartment mixing for 30 minutes or longer, remove and store all primary reagent packs and manually mix before resuming normal operations.

1. Cover the pierced film area of the reagent pack with self-sealing laboratory film.
2. Store any off-system reagent packs at 2–8 °C (35.6–46.4 °F).
3. Before loading primary reagent packs onto the system, manually mix the packs to resuspend the particles homogeneously (Page 249 *Manually Mixing IM Reagents*).
4. Return the reagent packs to the system when the reagent compartment temperature is 2–8 °C (35.6–46.4 °F).
5. Verify reagent performance based on acceptable QC results (Page 471 *Performing Quality Control in an SH Configuration*) or laboratory criteria.

   NOTE: If the reagent compartment is out of temperature range for greater than 60 minutes, the system will flag results using those reagents as Reagent Compartment Temperature.

Handling IM Ancillary Reagent Packs at Altitudes > 350 m (1148 ft)

NOTE: If the laboratory is located at an altitude of > 350 m (1148 feet) above sea level, the operator must perform this procedure prior to loading ancillary reagent packs.

BIOHAZARD

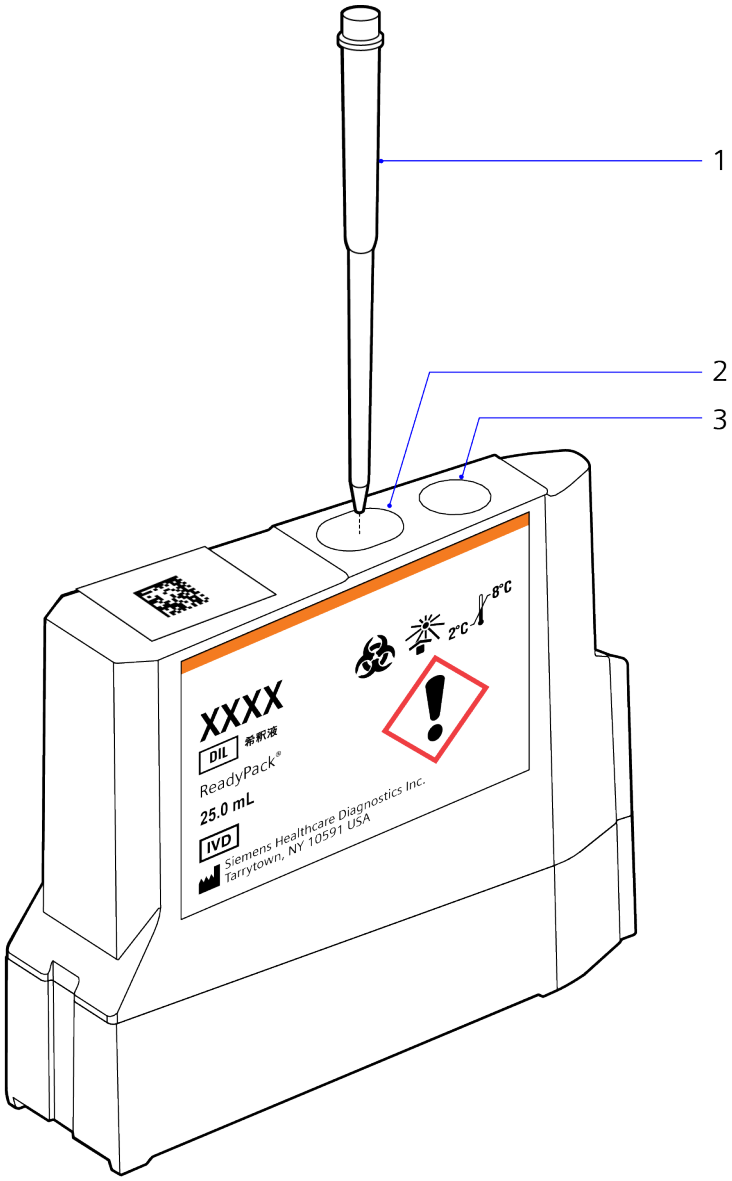
Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

1. Place the appropriate IM ancillary reagent pack on a flat surface.

CAUTION

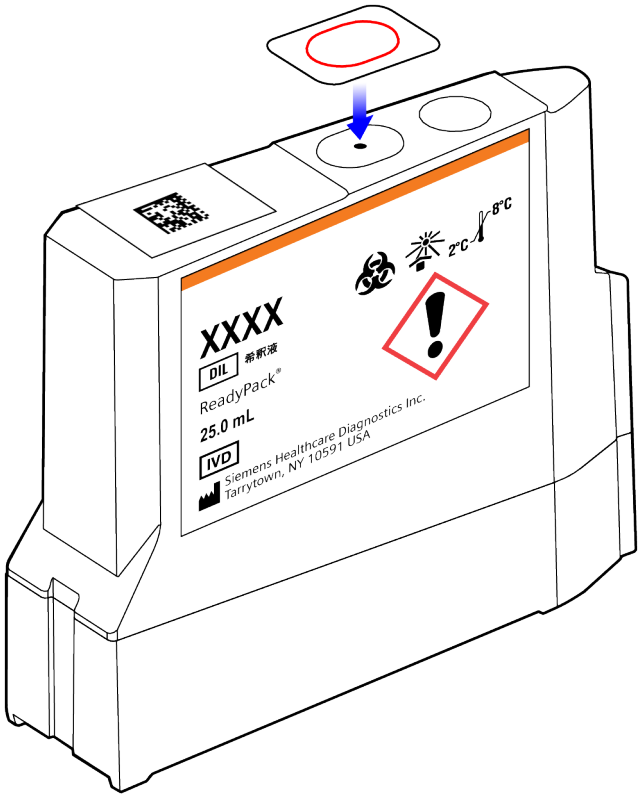
Do not puncture the IM ancillary reagent aspiration port. If the aspiration port is punctured instead of the fill port, reagent may expel from the port due to the pressure. Only the system can puncture the aspiration port.

2. Locate any unused disposable sample tip and then puncture only the fill port seal.



1	Any unused sample tip
2	Fill port
3	Aspiration port: Do not puncture

3. Place a replacement seal (SMN 11208742) over the punctured fill port hole.



4. Verify reagent performance based on acceptable QC results or laboratory criteria.

About the Cart List

The Cart List provides the operator with the following:

- Consumables, system fluids, supplies, reagent, and other materials required for the system that day.
- The option to create and print a list to retrieve the items from storage.
- Custom supply option to add an item to the cart that is not listed in the needs tiles.

Items in the list include the following:

- Reagents: Added through Reagent Needs
- Supplies: Added through Supply Needs
- Calibrators: Added through Calibrator Needs

- Quality Control: Added through QC Needs
- Other: Only displays when the operator adds items manually from Cart List

The workflow for using the Cart List is as follows:

1. The operator adds materials from 1 of the 4 needs screens.
2. When all needs are added, the operator selects  from the Access bar and reviews the complete set of required needs.
3. If appropriate, the operator selects **Add Item** to add a customized item not in the system to the list and enters a description and quantity.
4. To print out the complete Cart List, the operator selects  from the Tool bar.
5. The operator takes the list to obtain the needs from the supply locations and manually checks off the list.
6. When all the required needs are gathered collected, the operator selects **Clear Cart**.
7. The operator then replaces all required needs.

Reagents	Notes
Reagent Name	The name of the required reagent
Packs Needed	The total number of packs added to the cart for the specified reagent lot
Module	The name of the module for the required reagent

Supplies	Notes
Supply Name	The name of the supply
Quantity	The total amount of the supply added to the cart
Lot	The lot of the supply
Module	The name of the module for the required supply

Calibration	Notes
Calibrator Name	The name of the calibrator material
Calibrator Lot	The appropriate calibrator material lot
Assay	The assay associated with the calibrator material

Quality Control	Notes
Material Name	The name of the QC material
Lot	The appropriate QC material lot
Level	The appropriate QC material level
Required Volume	The required volume in mL
Assay	The assay associated with the QC material

To remove all items from the Cart List, the operator selects **Remove**.

To add a custom item to the Cart List, the operator selects **Add Item**.

To clear all the items from the Cart List, the operator selects **Clear Cart**.

Reviewing the Cart List

1. On the Title bar, select .
2. To expand a table, select its title.
3. To sort the information, select a column heading.

   NOTE: Selecting the same column heading a second time reverses the sort order.
4. To remove items from the cart, perform 1 of the following:
   - To remove an item from the cart, select **Remove** in that row.
   - To remove all items from the cart, select **Clear Cart**.

About Supply Needs

Supply Needs provides information about the status of the onboard supplies:

- CH Analyzer: System fluids, IMT supplies, reagent supplies (RPC1, RPC2, RPC4, and WBA), and other supplies (Pretreatment and cuvette status).
- IM Analyzer: System fluids, other supplies (tips, cuvettes, humidity packs, and water supply), and waste (solid and liquid).

The Supply Needs tile displays the total number of alerts in View Alerts Only.

Supply Needs tile title color	Notes
Green	No supply or waste alert conditions exists.
Red	If 1 or more supply or waste alert conditions exist: • The consumable usable remaining volume is 0. • The onboard stability expires within the expiration period. • The count is less than the sample warning level. • Waste status is not OK.

These alert levels are configured in Supplies Alert Threshold Configuration.

Supply Needs	Notes
Module	The Supply Needs is separated by analyzers.
Alert Time	The time the alert was generated.
Supply	The supply name.
Position	For system fluids only. The system fluids bottle number or location in system fluid drawer.

Supply Needs	Notes
Status	Status of the remaining volume: • Counts remaining by supply • Empty: Supply empty • OK • Almost empty: Container empty, reservoir full • Expiring in {0} hours: Hours remaining until Lot or OBS expires for the container • Full: Container full IM Analyzer Status only: • Tips: Identifies which tray is in use, count remaining, or Empty • Humidity packs
Replace Item	The operator selects to start the replacement process.
	Operator selects to add each supply to the Cart List.

To view the status of all supplies for all modules, select **View All Supplies**.

View All Supplies	Notes
View All Supplies	Operator selects to see all system fluids, IMT fluids, A-LYTE Multisensor, and Other Supplies on all analyzers.
System Fluids	System fluids list by system.
IMT Supplies	IMT fluids and A-LYTE Multisensor on a CH Analyzer.
	The remaining number of counts per system fluids and IMT fluids.

View All Supplies	Notes
Volume	The remaining volume on the analyzer displayed in %.
Onboard Stability (OBS)	Count down timer in days and hours for the remaining supply onboard stability. OBS starts when the operator initially loads the supply onto an analyzer. OBS expiration date and time = date and time the consumable is loaded + OBS interval for consumable. OBS remaining = OBS expiration date and time – current date and time.
Lot Expiration	Date and time the system fluids or IMT fluids lot expires. This date and time expires at the end of the supply expiration date. An event is generated when the consumable expires.
Lot	Lot of the supply.
Replace Item	The operator selects to start the replacement process.
	Operator selects to add the supply to the Cart List.

View All Supplies	Notes
Other Supplies	CH Analyzer consumables include: • Cuvettes • View Cuvette Status • RPC4, RPC2, and RPC1 • WBA IM Analyzer consumables include: • Tips • Cuvettes • Water • Humidity packs Sealer consumable includes Sealer Foil
Status	Status of the remaining volume: • View Cuvette Status: Displays the CH Cuvette State Information for the reaction and dilution cuvettes onboard. • Counts remaining (drop with number icon) • Empty: Supply empty • Reserve empty: • OK • Almost empty: Container empty, reservoir full • Expires Soon: < 2 days remaining until Lot or OBS expires for the container • Full: Container full

View All Supplies	Notes
	IM Analyzer Status only: • Tips: Identifies which tray is in use, count remaining, or Empty. • Cuvettes: Operator selects **Prime Cuvettes** after filling.
Cuvette State Information (CH only)	Operator selects to view the CH cuvette status definitions: • Clean (blue): Wash is complete. The cuvette is ready for use. • Need Replacement (Red): Cannot use the cuvette. Cuvette QC, washing, and cleaning failed too often. Replace all the cuvettes in the ring. • Disabled (white): Cannot use the cuvette. The cuvette was disabled by service in Diagnostics. • Waiting for acceptable QC (yellow): Only applicable to Reaction cuvettes. Cannot use until the cuvette is washed and checked again. The cuvette failed the last Cuvette QC check. If greater than 35 cuvettes require replacement, an alert is generated in Operator Event Log.

View All Supplies	Notes
Pretreatment (CH only)	Only displays if the A1C assay is enabled. Status includes: • Inventory Remaining (Pretreatment): The remaining Pretreatment in test counts. • Inventory Remaining (A1C): The remaining A1C reagent test counts. • Onboard Stability (OBS): Count down timer in days and hours for the remaining supply onboard stability. OBS starts when the operator initially loads the supply onto the CH Analyzer. • Lot Expiration: The date and time the system fluids or IMT fluids lot expires. • Lot: Lot of pretreatment.
Waste (IM only)	The IM waste includes: • Cuvette and Tip Waste • Tip Tray Waste: to replace, the operator selects **Open Tip Tray Waste Drawer**. • Liquid Waste
View All Supplies	Operator selects to review all supplies.
View Alerts Only	Operator selects to review only supplies with an alert.
Expand All	Operator selects to open all module views.
Collapse All	Operator selects to close all module views.
Add All to Cart	Operator selects to add all supply needs to the Cart List.

Reviewing CH Cuvette Status in Supply Needs

The operator investigates Cuvette Status and, if appropriate, replaces all the CH dilution or reaction cuvettes.

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

1. Navigate to **Supply Needs > View All Supplies**.
2. Navigate to the appropriate CH Analyzer area then select **Other Supplies**.
3. In Other Supplies and Cuvettes, select **View Cuvette Status**.

   NOTE: There is a tab for Reaction Cuvettes and Dilution Cuvettes. The status of the each cuvette displays under each tab.
4. To display the description of each status, select Cuvette State Information:
   - Blue: Usable
   - Red: Need Replacement
   - Gray: Disabled
   - Yellow: Waiting for acceptable QC
5. If appropriate, replace the dilution or reaction cuvettes.

   NOTE: Replace all dilution or reaction cuvettes at the same time and every 4 months.

Checking Decapper Waste

BIOHAZARD

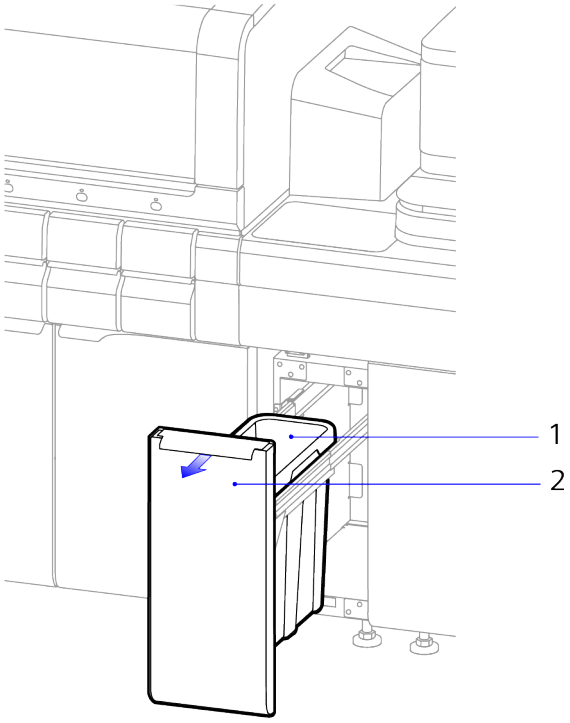
Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

WARNING

Do not lift the biohazard bag without being able to lift 6.8 kg (15 pounds). Lifting the biohazard bag without proper care risks personal injury.

1. Navigate to **Supply Needs** then select **View All Supplies**.
2. Select the Decapper module row.

3. If appropriate, identify and select Decapper waste alert to empty.
4. Open the cap waste drawer.



1	Cap waste bin
2	Cap waste drawer

5. Remove the biohazard bag and discard according to laboratory protocol.
6. Insert a new biohazard bag into the cap waste bin, tucking the bag over bin and under the flange.

   NOTE: To allow the caps to drop freely into the cap waste bin, the new biohazard bag must be fully opened and fit snugly in the bin.
7. Ensure the cap waste drawer is out >10 seconds to automatically reset the waste counter.
8. Manually remove any caps dropped in the chassis before closing the drawer.
9. Push the drawer until firmly against the back wall to ensure that it is in the correct position.

Emptying Decapper Waste

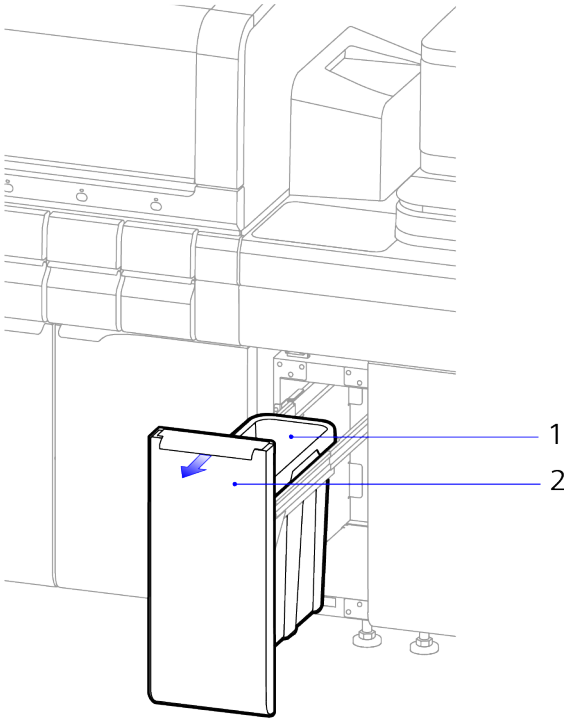
BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

WARNING

Do not lift the biohazard bag without being able to lift 6.8 kg (15 pounds). Lifting the biohazard bag without proper care risks personal injury.

It may be necessary to perform this procedure more than daily, depending on the laboratory workload.



1	Cap waste bin
2	Cap waste drawer

1. Pull the cap waste drawer away from the system.
2. Remove the biohazard bag and discard according to laboratory protocol.

3. Insert a new biohazard bag into the cap waste bin, tucking the bag over bin and under the flange.

   NOTE: To allow the caps to drop freely into the cap waste bin, the new biohazard bag must be fully opened and fit snugly in the bin.

4. Ensure the cap waste drawer is out for more than 10 seconds to automatically reset the waste counter.

   NOTE: If the drawer is opened for less than 10 seconds, the system does not reset the waste counter.

5. Manually remove any caps dropped in the chassis before closing the drawer.

6. Push the drawer until firmly against the back wall to ensure that it is in the correct position.

About CH Cuvette Status in Supply Needs

The Cuvette Status in Supply Needs provides information about the quality status of the CH cuvettes. Additional checks for CH cuvette quality are implemented in the CH Daily Maintenance and CH Weekly Maintenance.

The operator selects **View Cuvette Status** to review the definitions for each of the following cuvette states:

View Cuvette Status	Notes
Usable	Wash is complete. The cuvette is ready for use.
Need Replacement	Cannot use the cuvette. Cuvette QC, washing, and cleaning failed too often. Replace all the cuvettes in the ring.
Disabled	Cannot use the cuvette. The cuvette was disabled by service in Diagnostics.
Waiting for acceptable QC	Cannot use until the cuvette is washed and checked again. The cuvette failed the last Cuvette QC check.

About Reagent Needs

In Reagent Needs, the operator views current inventory that fall below the configured threshold. Only enabled reagents display. The operator configures this threshold in Reagent Thresholds. Reagent Needs updates every 3 minutes.

The number on the Reagent Needs tile is the total number of reagent needs. This number equals the total rows in Reagent Needs.

Reagent Needs tile title color	Notes
Green	No reagent alert conditions exist.
Red	One or more of the reagent alert conditions exist.

If an alert occurs or packs are loaded, the data updates to reflect the change. The remaining columns refresh every 1–5 minutes.

Reagent Needs	Notes
Reagent Name	Short name for the assay, cleaning solution, or ancillary material associated with the reagent pack. The operator selects the arrow to sort the column contents in ascending or descending alphanumeric order.
Packs to Load	The number of reagent packs required until the operator-defined day ends. System calculates as Tests Remaining ÷ tests per pack from the appropriate IFU.
Module	The analyzer where pack is located.
Inventory	The current inventory for the specified analyzer remaining for that reagent: • Primary reagents: Tests remaining. • Ancillary reagents: Amount remaining in mL.

Reagent Needs	Notes
Reason	• No Available Reagent: Reagent is unavailable (Empty, error, expired OBS or lot). • Below Threshold ({0}): The reagent inventory level has reached the red alert threshold the operator defined in Reagent Thresholds.
	The operator selects to add an individual reagent to the cart.
Add All to Cart	Operator selects to add all reagents listed to the cart.
	Operator selects to navigate to Reagent Thresholds.

Reviewing Reagent Needs

1. Select **Reagent Needs**.
2. If appropriate, place the reagents in the cart:
   a. Select  in the appropriate reagent row.
   b. Select  for each additional reagent.

   NOTE: The number in  located on the Access bar increases as the operator adds items to the cart.
3. Load the CH reagent or IM reagent (Page 248 *Loading IM Reagent Packs*) onto the analyzer.

About QC Needs

The operator reviews the required QC materials to load to perform current or scheduled QC orders in QC Needs. If appropriate, the operator adds the required materials to the Cart List then prints the required barcode labels.

QC Needs is created for a QC material based on:

- Tests the QC scheduler sets to perform before midnight of the defined day.
- Any pending QC orders in Worklist.
- The required control material is expired, low, or not onboard.

QC Needs resets at midnight for the next day.

The number displayed on the QC Needs tile is the number of alert conditions.

QC Needs tile title color	Notes
Green	No alert conditions exists.
Red	An order is placed and there is: • No QC onboard. • QC is onboard but the control material is insufficient (low volume or expired).

If an alert occurs or QC materials are loaded, the data updates to reflect the change. The remaining columns refresh every 1–5 minutes.

QC Needs	Notes
Material Name	The name of the control material from QC Definitions QC Material.
Level	The concentration level of the control material.
Lot	The lot of the control material.
QC ID	A unique identifier for the control from QC Definitions QC Material ID.
Volume Needed (mL)	The volume of the control required for the day.
Store Onboard	Whether the control material is onboard and available (not expired or depleted).
Reason	Whether the control is Scheduled or Ordered.
	The operator selects to add an individual control material to the cart.
Add All to Cart	Operator selects to add all QC needs to the Cart List.

Reviewing QC Needs

1. Navigate to **QC Needs**.
2. To group control material by Name, select **Group by QC Material**.
3. To sort control material that is onboard, select **All**.
4. Locate appropriate control.
5. Determine the control need and replace, as appropriate.

About Calibrator Needs

In Calibrator Needs, the operator:

- Reviews the calibrator materials required to perform current or scheduled Calibration orders.
- If appropriate, adds required materials to the Cart List then prints required barcode labels.
- Filters for materials based on alerts (immediate need) or forecasted needs for the current day. Calibrations scheduled highlight as an immediate need when the scheduled time is within the warning threshold configured in Calibration Setup.
- Configures Calibrations to automatically order at a scheduled time. The orders due in that calendar day display as Scheduled at midnight until they are automatically ordered.
- Selects a calibration to manually order at a scheduled time. These display as Scheduled.

The system creates a forecast for the appropriate calibrator materials. The system determines the Calibrator Needs information based on the following:

- Pack calibration intervals expiring before operator-defined day ends.
- Lot calibration intervals expiring before operator-defined day ends.
- If no fresh packs are available, No eligible pack onboard for lot cal displays.

No need displays for C0 adjustments.

Calibrator Needs resets at midnight for the next day.

Calibrator Needs tile title color	Notes
Green	No calibrator material required.
Red	The calibrator material expires within the configured Calibration Due Warning (hours).

If an alert occurs or calibrator materials are loaded, the data updates to reflect the change. The remaining columns refresh every 1–5 minutes.

Calibrator Needs	Notes
Selector column	Operator selects global check box for all or the appropriate calibrators to add to the cart.
Calibrator Material	Name of the calibrator material.
Levels	The level of the calibrator material.
Calibrator Lot	Calibrator material lot.
Assay	Assays impacted by the calibrator need. The material must be loaded because the calibration on assays is required.
Store onboard	Calibrator material stored Onboard or Not Onboard the system.
Reason	Calibrations statuses are: • Scheduled: The analyzer orders the calibration at that time then updates to Ordered. Scheduled calibrations highlight as an immediate need when the scheduled time is within the configured Calibration Due Warning (hours) in Calibration Setup. • Ordered: Immediate need and highlighted red.
	The operator selects to add an individual calibrator material to the cart.
Print Barcode	The operator selects to print the barcode label for the selected calibrator material.
Add All to Cart	The operator selects to add all the calibrator material to the cart.

Reviewing Calibrator Needs

1. Navigate to **Calibrator Needs**.
2. To select all the calibrators listed, select the global check box for all.

3. To add calibrator material to the cart, select .
4. To sort the calibrator information, select any calibrator column header.

   NOTE: Select the same column header a second time to reverse the sort order.

About CH Fluids Management

CAUTION

Do not load the same system fluids container multiple times. Removing and reloading a system fluids container can cause the punctured membrane to leak. Load only new and unused containers on the analyzer.

The Analyzer stores the following CH fluids:

- System Fluids
- Pretreatment
- IMT Fluids
- Lamp coolant

Replace or replenish all fluids without shutting down the analyzer. To access the Pretreatment pack or lamp coolant, pause analyzer, and unlock the CH front cover.

About CH System Fluids

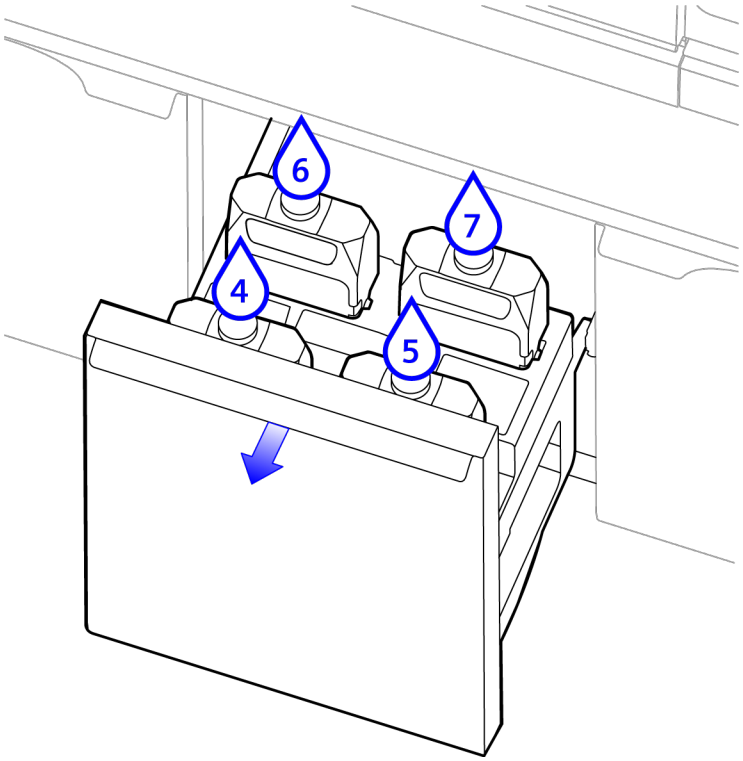
CAUTION

Do not replenish a system fluids container. Replenishing a container can cause contamination. Remove the container from the system fluids drawer and install a new container. Dispose of the old container according to laboratory protocol.

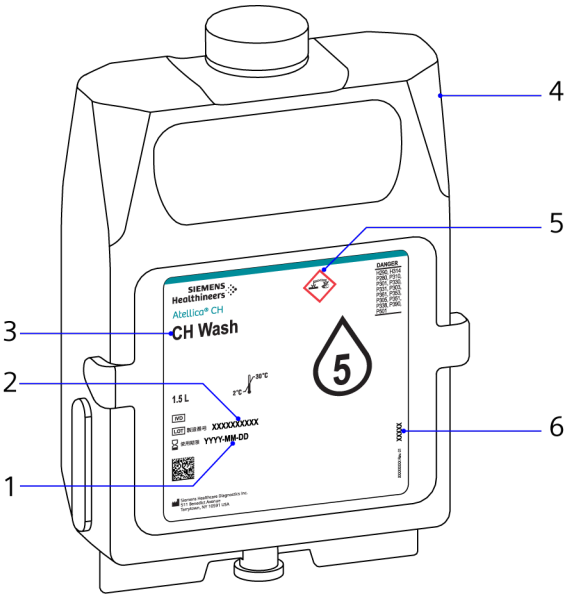
CAUTION

Do not load the same system fluids container multiple times. Removing and reloading a system fluids container can cause the punctured membrane to leak. Load only new and unused containers on the analyzer.

The CH system fluids are located on a sliding drawer in the center of analyzer. The analyzer uses 4 CH system fluids.



Symbol	System fluid
4	CH Diluent
5	CH Wash
6	CH Conditioner
7	CH Cleaner



1	Expiration date	4	CH fluid container
2	Lot	5	Warning symbol
3	System fluid name	6	Sequence number

The CH system fluids IFU provides additional information about CH system fluids.

Checking System and IMT Fluids on the CH Analyzer

1. Navigate to **Supply Needs** then select .
2. Identify system fluid alerts.
3. If appropriate, replace the system fluids (Page 274 *Replacing System Fluids on the CH Analyzer*), Pretreatment pack (Page 283 *Replacing the Pretreatment Pack on the CH Analyzer*), or IMT fluids (Page 280 *Replacing IMT Fluids on the CH Analyzer*).

Replacing System Fluids on the CH Analyzer

WARNING

Do not handle cleaner solution without wearing protective equipment, including gloves, laboratory coat, and safety glasses or a protective face shield. Cleaner solution can cause eye and skin irritation.

NOTE: The operator must wait until the IMT completes calibrating before selecting Replace IMT Supplies. Selecting Replace IMT Supplies while IMT calibration is in process displays a status that the IMT is pausing until the calibration is complete.

A window displays if the IMT Advanced Clean is required. The analyzer pauses the IMT when the operator selects **Replace IMT Supplies** to replace the A-LYTE multisensor from this window.

1. Navigate to **Supply Needs** then select .
2. Identify system fluid alerts.
3. If appropriate, add the system fluids to the Cart List:
   a. Select next to the system fluids need.
   b. Repeat step a until all system fluids with alerts are in the Cart List.
4. Select **Replace Item**.
5. Open the fluids drawer.
6. Tighten the system fluid container cap.
7. Discard the container per laboratory protocol.
8. Hold the new system fluids container 150 mm (6 inches) at a 45° angle under the barcode reader.
9. Ensure the analyzer displays the correct Lot and Expiration under the appropriate fluid.
10. Select **Save**.

WARNING

Do not touch the cannulas in the keyed areas at the bottom of the system fluids drawer. The cannulas can puncture skin.

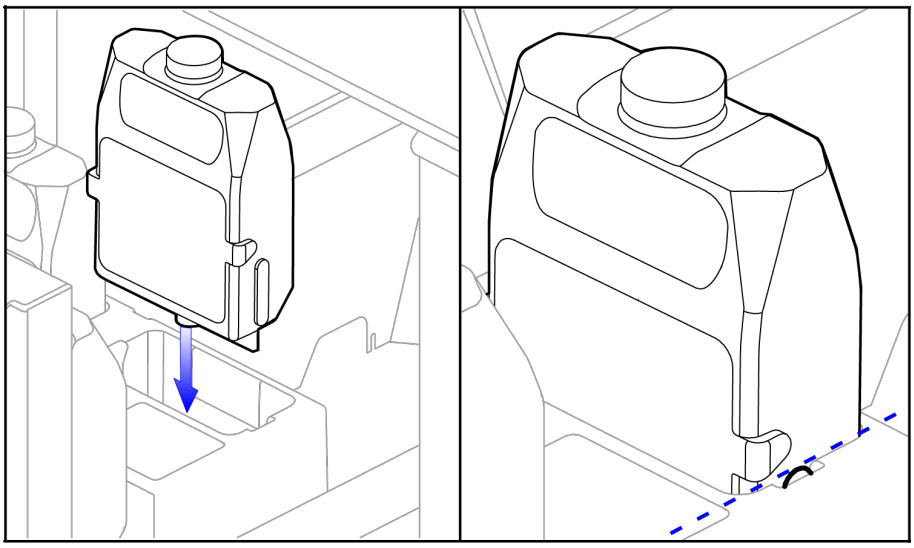
CAUTION

Do not load the same system fluids container multiple times. Removing and reloading a system fluids container can cause the punctured membrane to leak. Load only new and unused containers on the analyzer.

CAUTION

Do not insert the container at an angle. Inserting the container at an angle can cause a system fluids leak. Insert the new container vertically.

11. Hold the new container vertically with the septum facing down, firmly insert the container straight down into the drawer with label away from the analyzer.



NOTE: The container only delivers fluid when the operator fully seats it into the designated location. Refer to the fluid chart within the drawer for correct container placement.

12. Ensure the container is securely seated with the tabs on both sides of the container even with the drawer surface.

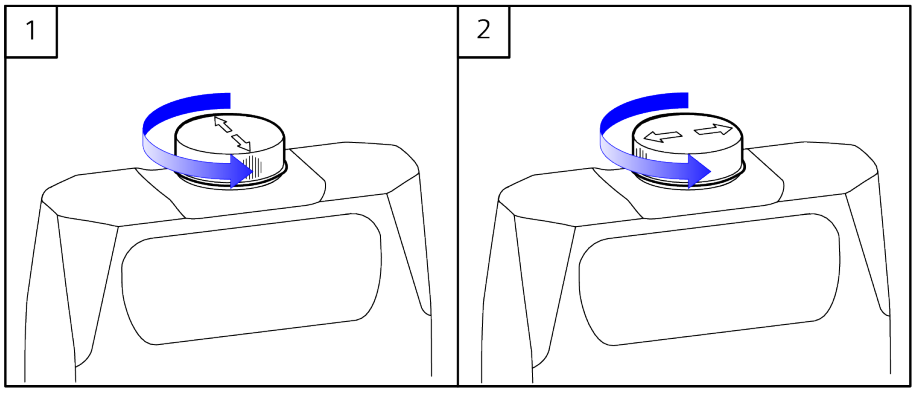
    NOTE: To prevent system fluid leaks or a vacuum forming inside the container causing the analyzer to stop processing, each cap must be vented.

    The squeeze lock cap has 2 stops:

    – Stop 1 occurs at approximately a 1/4 counterclockwise turn and prevents the cap from closing after vented.

    – Stop 2 occurs at approximately a 3/4 counterclockwise turn and prevents the cap from falling off into the drawer.

13. To vent the squeeze lock cap:



    a. Squeeze the cap at the arrows and twist the cap slightly more than a 1/4 counterclockwise turn past the first stop (figure 1).

    b. Release and twist the cap counterclockwise until the arrows on the cap match figure 2.

14. To replace each additional system fluid, repeat steps 3–8.

15. Close the fluids drawer.

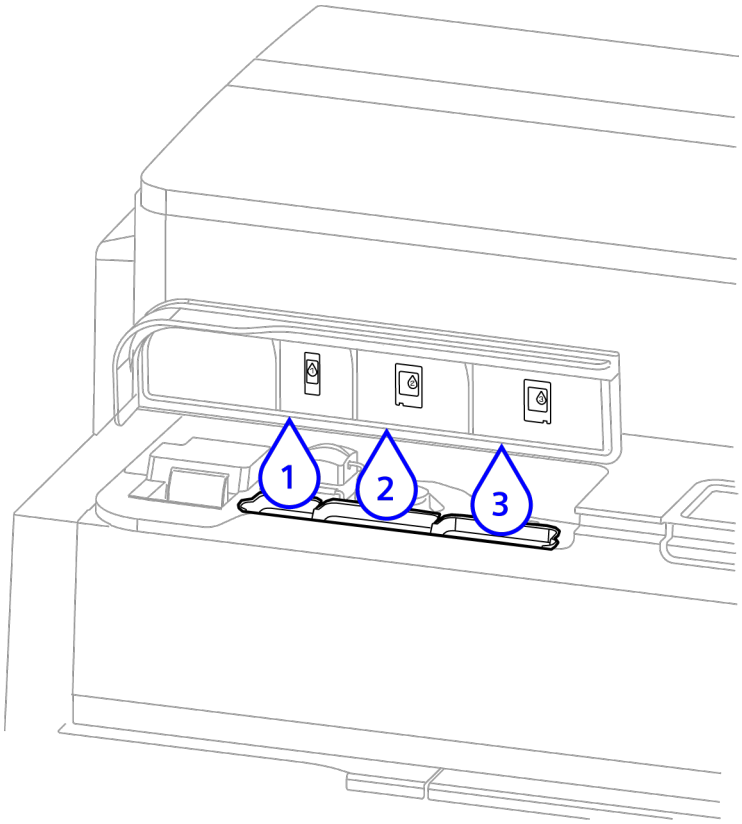
16. If appropriate, order the replacement catalog numbers (Page 888 *CH Supplies*).

About IMT Fluids

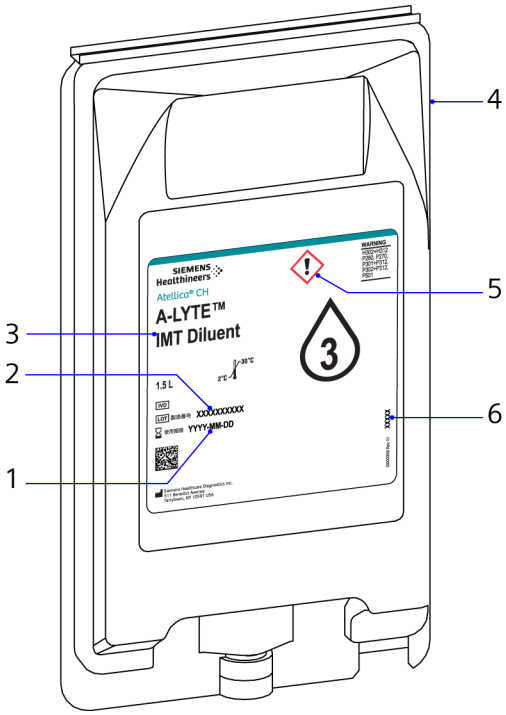
The IMT fluids are located in the front of the CH Analyzer on the top left. The location of each IMT fluid is inside the IMT fluids lid.

NOTE: The operator must wait until the IMT completes calibrating before selecting Replace IMT Supplies. Selecting Replace IMT Supplies while IMT calibration is in process displays a status that the IMT is pausing until the calibration is complete.

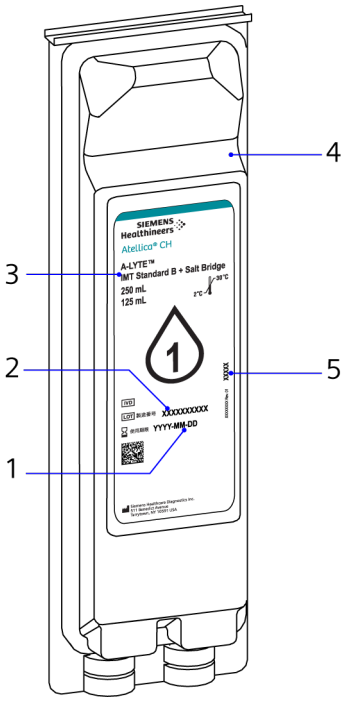
A window displays if the IMT Advanced Clean is required. The analyzer pauses the IMT when the operator selects **Replace IMT Supplies** to replace the A-LYTE multisensor from this window.



Symbol	IMT fluid
1	IMT Standard B + Salt Bridge
2	IMT Standard A
3	IMT Diluent



1	Expiration date	4	IMT fluid container
2	Lot	5	Warning symbol
3	IMT fluid	6	Sequence number



1 Expiration date
2 Lot
3 IMT fluid
4 IMT fluid container
5 Sequence number

The IMT fluid IFU provides additional information about IMT fluids.

Replacing IMT Fluids on the CH Analyzer

WARNING

Do not handle IMT Diluent without wearing protective equipment, including gloves, laboratory coat, and safety glasses or a protective face shield. IMT Diluent can cause eye and skin irritation.

1. Ensure analyzer is in Ready, Processing, or Standby state (Page 137 *Changing the Module Status*).
2. Navigate to **Supply Needs > View All Supplies**.

3. Select the appropriate and identify IMT system fluid alerts.

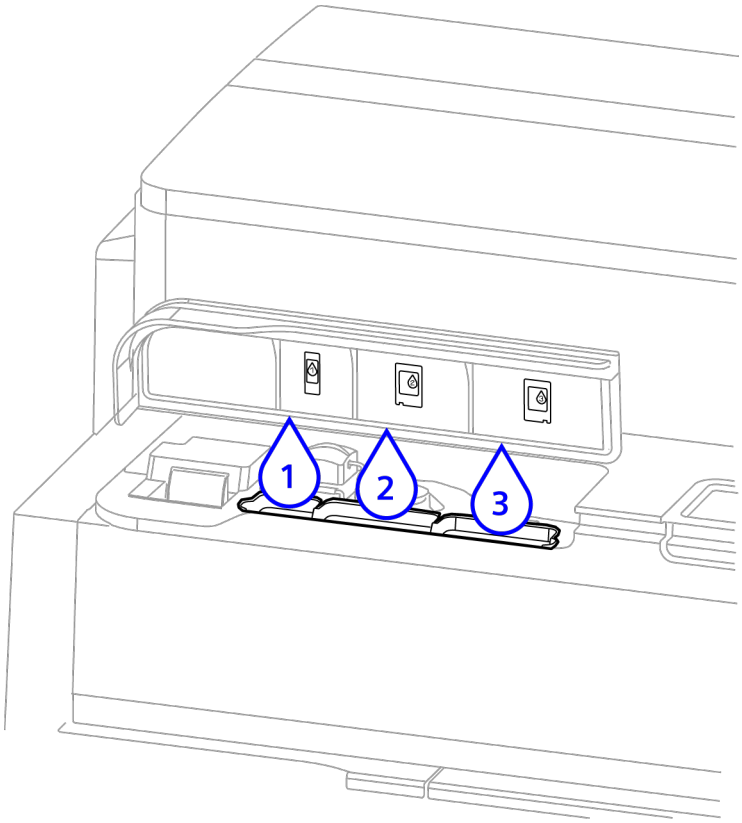
   NOTE:

   If an IMT Advanced Clean is required at the next A-LYTE® multisensor replacement, a window displays with 2 options:

   a. To begin the IMT Advanced Clean before replacing the A-LYTE multisensor, select **Perform IMT Advanced Clean**.

   b. To replace IMT fluids directly without performing the IMT Advanced Clean, select **Replace IMT Supplies**.

4. Open the IMT fluids lid.



1	A-LYTE IMT Standard B + Salt Bridge
2	A-LYTE IMT Standard A
3	A-LYTE IMT Diluent

5. Select **Replace Item** and wait for the IMT pause process to complete.

6. Locate and remove the appropriate IMT fluid container.

> **CAUTION**
>
> Remove the container from the IMT fluids area and install a new container. Dispose of the old container according to proper laboratory protocol.

7. Discard the IMT fluid container per laboratory protocol.
8. To scan new IMT fluid:
   - If an analyzer with DL, use the handheld barcode reader.
   - If included in a system configuration, use the module display barcode reader.
9. Hold the IMT fluid container 150 mm (6 inches) at a 45° angle under the barcode reader.
10. Ensure the analyzer displays the Lot and Expiration under the appropriate fluid.

> **WARNING**
>
> Do not touch the cannulas in the keyed areas at the bottom of the system fluids drawer. The cannulas can puncture skin.

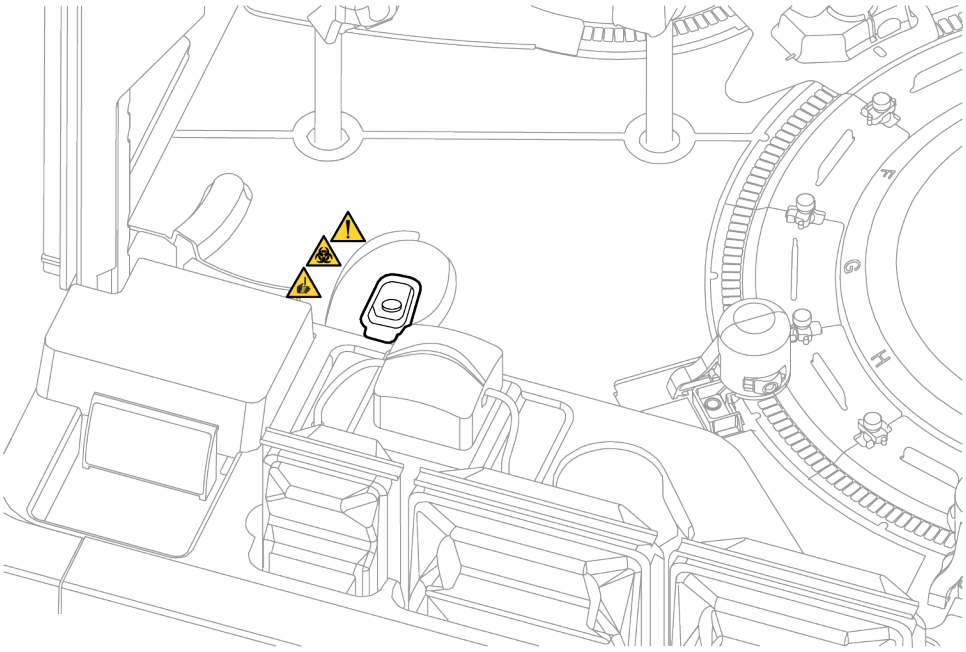
11. Holding the new IMT fluid container vertically with the septum facing down, insert the new container into position.

    NOTE: The IMT fluid containers only fit in the designated position when the cannulas punctures the septum.
12. To replace each additional IMT fluid, repeat steps 5–11.
13. Close the IMT fluids lid.
14. Select **Save**.
15. If appropriate, order a replacement catalog number (Page 888 *CH Supplies*).

About the CH Pretreatment Pack

The CH Analyzer uses a Pretreatment pack to dilute and lyse red blood cells in whole blood samples.

The reagent pack for the Pretreatment is located behind the IMT multisensor.



Replacing the Pretreatment Pack on the CH Analyzer

BIOHAZARD

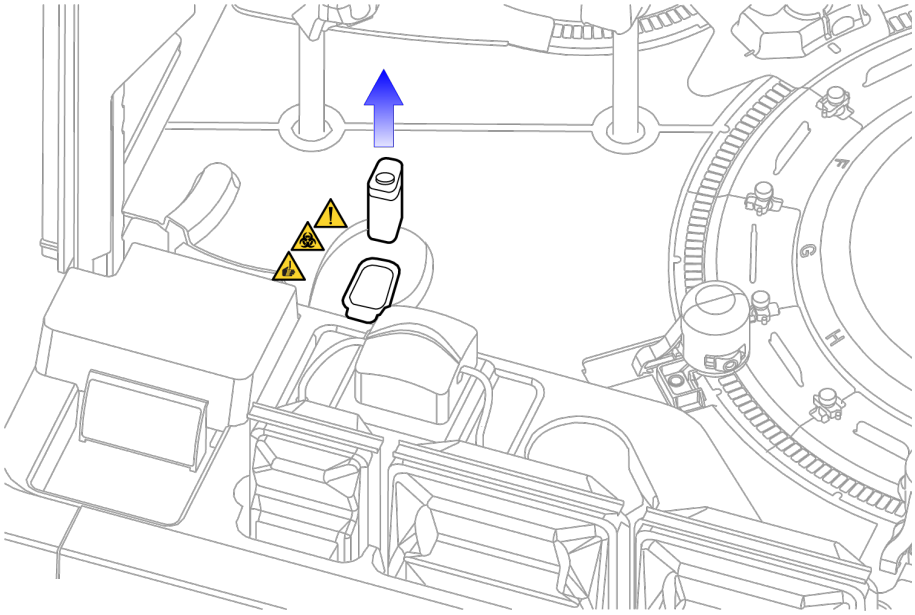
Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

WARNING

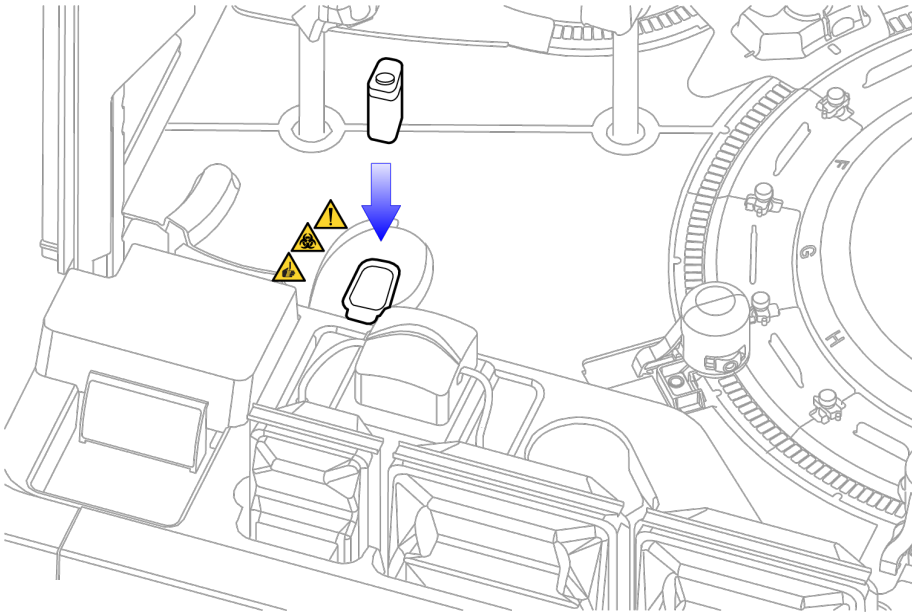
Do not turn on the system mechanics while near subassemblies that can move. When the analyzer is powered on, moving subassemblies can cause injury.

1. Navigate to **Supply Needs > View All Supplies**.
2. Locate the appropriate analyzer Pretreatment area and select **Replace Item**.
3. If analyzer is not stopped, select **Stop > Yes**.
4. Wait for analyzer to stop.
5. Select **Unlock > OK**.

6. Locate the Pretreatment pack.



7. Grasp the pack and pull up and out.
8. Discard the pack per laboratory protocol.
9. Scan the new pack.



10. Insert the new pack.
11. Remove the pack cap and discard.
12. Close the cover and select **Save**.

13. To resume the analyzer, select **Yes**.
14. If appropriate, order a replacement catalog number (Page 888 *CH Supplies*).

About CH Lamp Coolant

The CH lamp coolant is located in a refillable reservoir to the right of the IMT fluid containers. The CH Analyzer uses the lamp coolant to cool the photometer system.

Refilling Lamp Coolant on the CH Analyzer

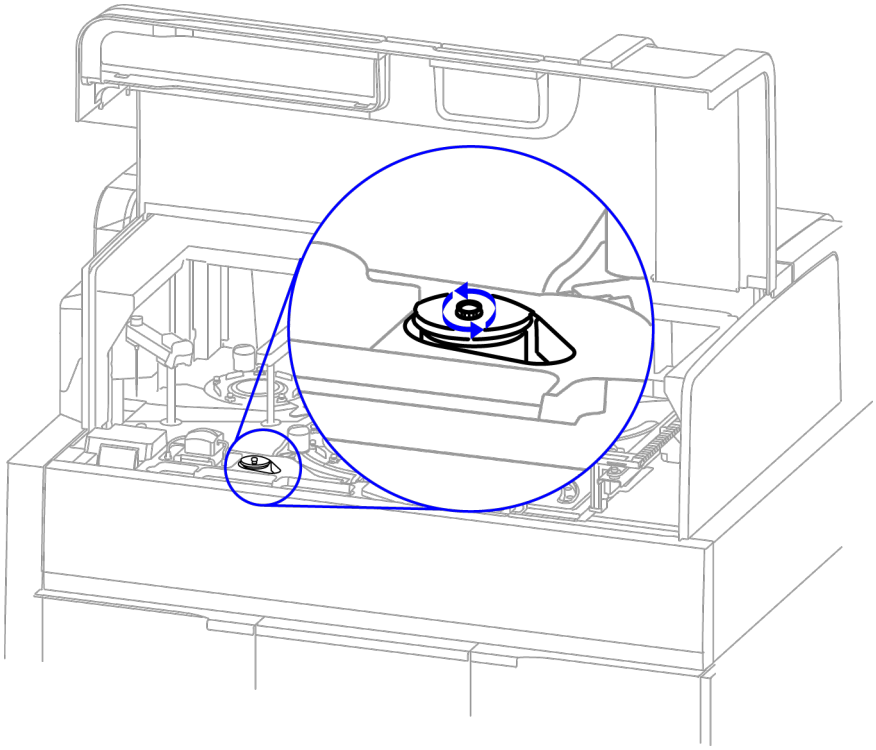


BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

1. Enter diagnostics and open front covers (Page 704 *Enter Diagnostics State in CH Operator Diagnostics*).
2. Select **Subsystems > Lamp**.
3. Select **Checking the Lamp Coolant**.
4. Select **Perform > Yes**.

5. Locate the lamp coolant reservoir directly behind the IMT fluid containers.



> **CAUTION**
>
> Do not unscrew the large lamp coolant lid. Unscrewing the large lamp coolant lid may turn the entire reservoir, resulting in a lamp coolant leak inside the analyzer.

6. Unscrew the small screw cap at the top of the reservoir and set aside.
7. Using the spout on the lamp coolant bottle, replenish the lamp coolant until the fluid level is approximately 1–2 cm from the lamp coolant reservoir cover (Page 285 *Refilling Lamp Coolant on the CH Analyzer*).
8. Replace the small screw cap.
9. Close the front cover.
10. To resume the analyzer from System Status area, select the appropriate CH Analyzer then ▶.
11. If appropriate, order a replacement catalog number (Page 888 *CH Supplies*).

About IM System Fluids

CAUTION

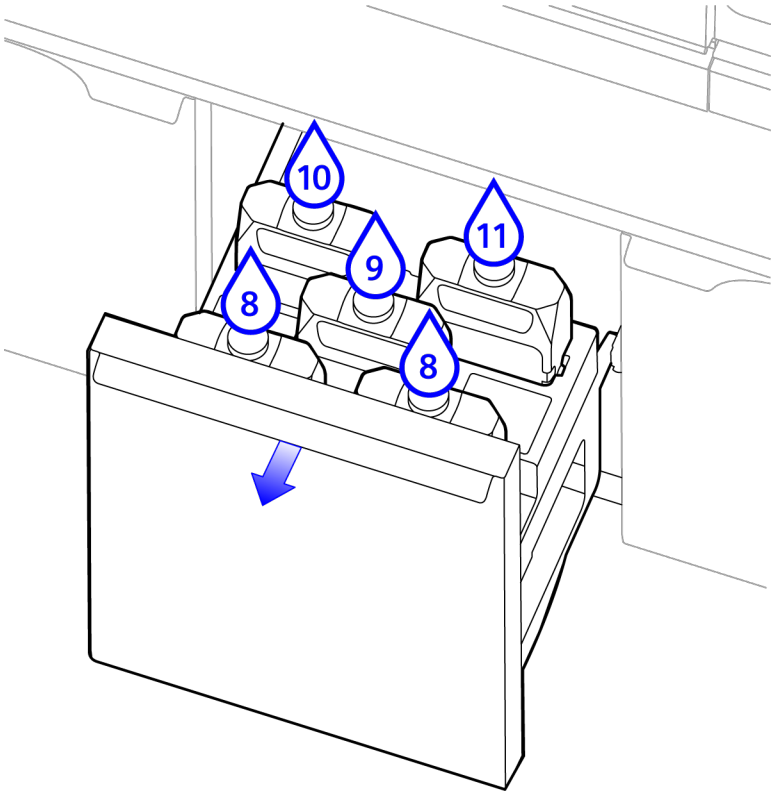
Do not replenish a system fluids container. Replenishing a container can cause contamination. Remove the container from the system fluids drawer and install a new container. Dispose of the old container according to laboratory protocol.

CAUTION

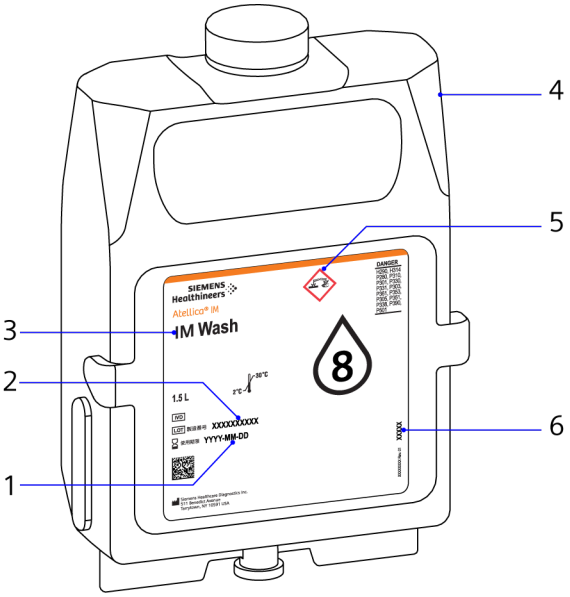
Do not load the same system fluids container multiple times. Removing and reloading a system fluids container can cause the punctured membrane to leak. Load only new and unused containers on the analyzer.

The IM System Fluids are located on a sliding drawer in the center of IM Analyzer. The IM Analyzer uses 4 types of System Fluids.

IM System Fluids **fluids drawer**



Symbol	System fluid
8	IM Wash
9	IM Cleaner
10	IM Acid
11	IM Base



1	Expiration date	4	IM fluid container
2	Lot	5	Warning symbol
3	System fluid name	6	Sequence number

The System Fluids IFU provides additional information about IM System Fluids.

Replacing IM System Fluids

WARNING

Do not handle cleaner solution without wearing protective equipment, including gloves, laboratory coat, and safety glasses or a protective face shield. Cleaner solution can cause eye and skin irritation.

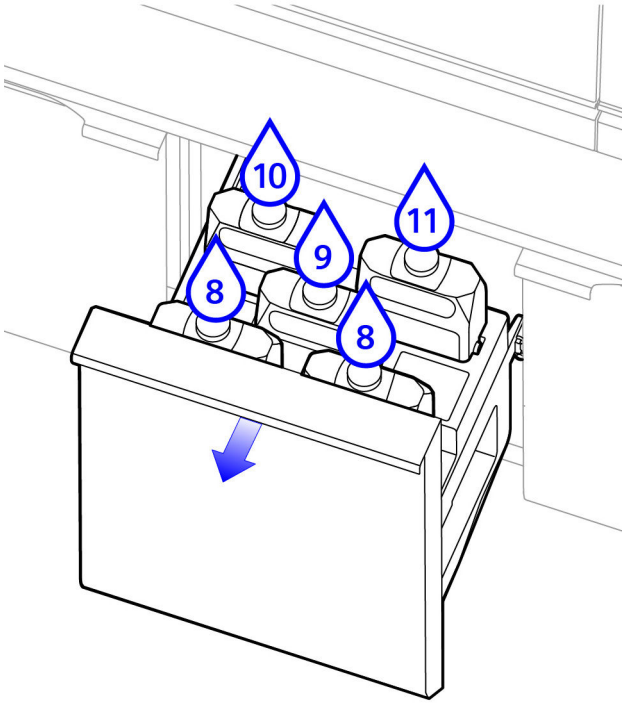
CAUTION

Do not replenish a system fluids container. Replenishing a container can cause contamination. Remove the container from the system fluids drawer and install a new container. Dispose of the old container according to laboratory protocol.

CAUTION

Do not load the same system fluids container multiple times. Removing and reloading a system fluids container can cause the punctured membrane to leak. Load only new and unused containers on the analyzer.

1. Navigate to **Supply Needs > View All Supplies**.
2. Locate the appropriate IM Analyzer.
3. Determine the system fluids that require replacement and select **Replace Item**.
4. Open the system fluids drawer.



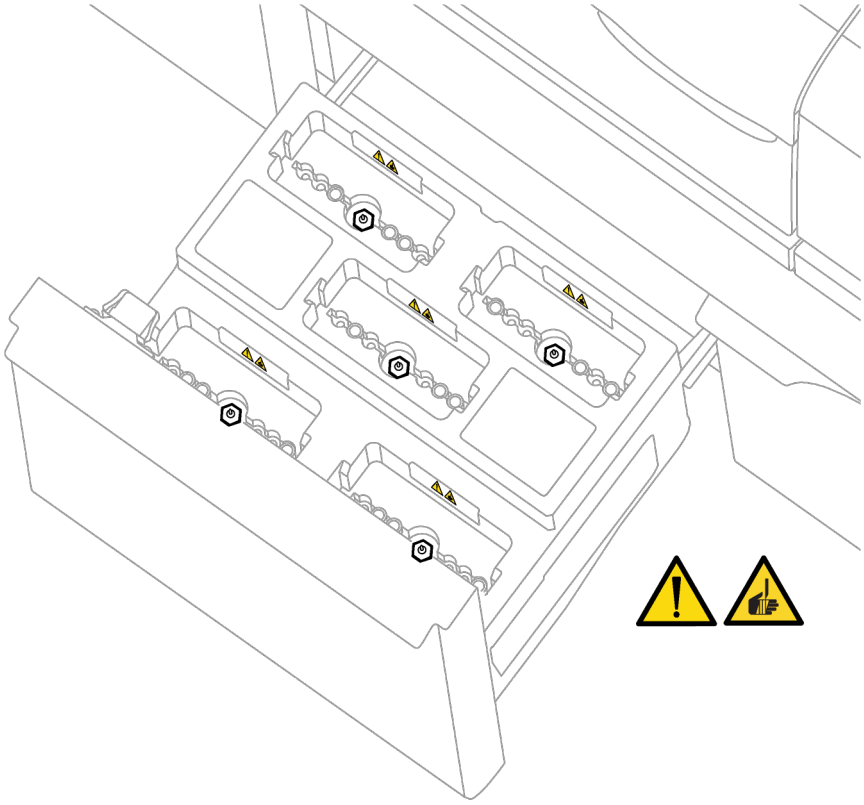
Symbol	System Fluid
	IM Wash
	IM Cleaner
	IM Acid
	IM Base

5. Tighten the cap of the system fluids container to be removed.
6. Remove the appropriate system fluids container.
7. Discard the system fluids container according to laboratory protocol.
8. Scan the new fluids container.
9. Ensure the analyzer displays the correct Expiration, Lot Number, and Sequence Number under the appropriate fluid.
10. Select **Save**.

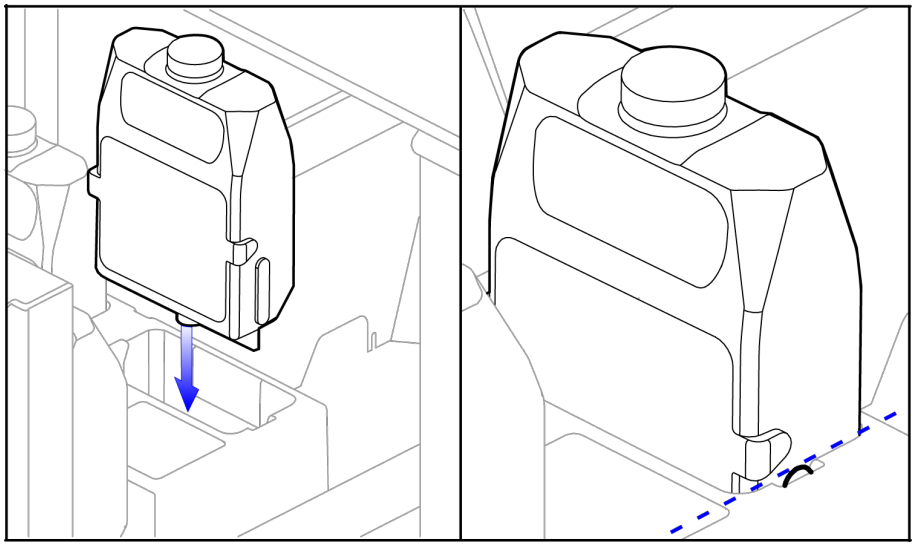


WARNING

Do not touch the cannulas in the keyed areas at the bottom of the system fluids drawer. The cannulas can puncture skin.



11. Holding the new system fluid container vertically with the septum facing down, insert the container straight down into the drawer with label away from analyzer.



NOTE: The container only delivers fluid when the operator fully seats it into the designated location. Refer to the fluid chart within the drawer for correct container placement.

12. Ensure the container is securely seated with the tabs on both sides of the container even with the drawer surface.

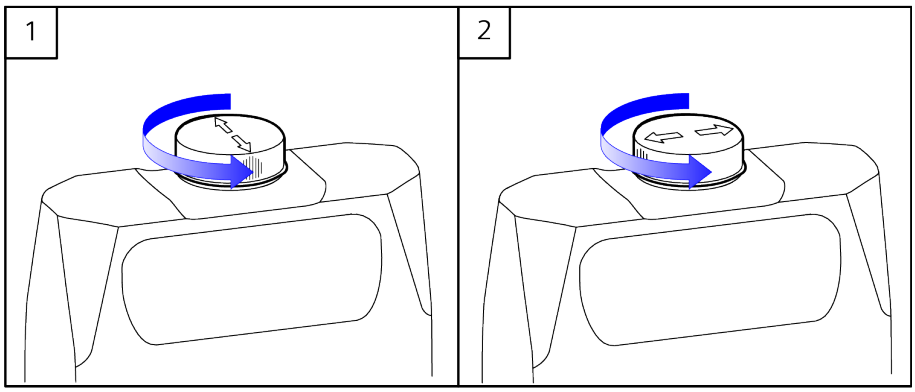
    NOTE: To prevent system fluid leaks or a vacuum forming inside the container causing the analyzer to stop processing, each cap must be vented.

    The squeeze lock cap has 2 stops:

    – Stop 1 occurs at approximately a 1/4 counterclockwise turn and prevents the cap from closing after vented.

    – Stop 2 occurs at approximately a 3/4 counterclockwise turn and prevents the cap from falling off into the drawer.

13. To vent the squeeze lock cap:



    a. Squeeze the cap at the arrows and twist the cap slightly more than a 1/4 counterclockwise turn past the first stop (figure 1).

    b. Release and twist the cap counterclockwise until the arrows on the cap match figure 2.

14. To replace each additional system fluid, repeat steps 3–13.

15. Close the fluids drawer.

    NOTE: To locate replacement catalog number, see (Page 891 *IM Supplies*)

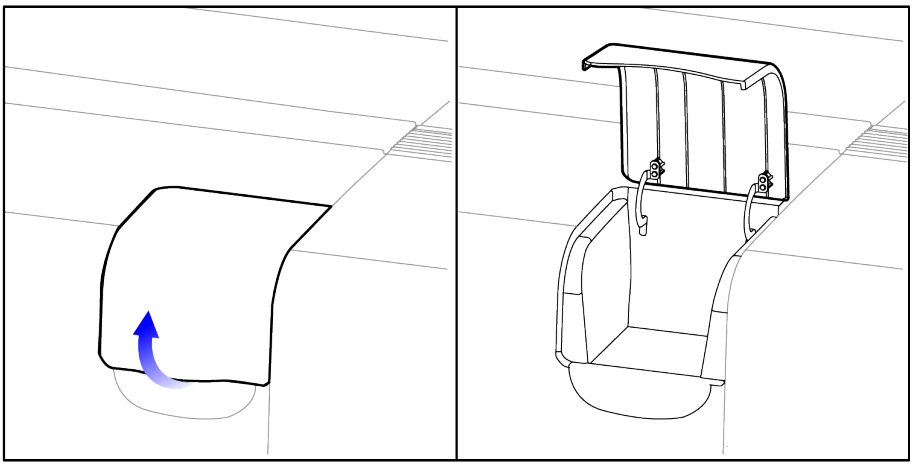
Checking IM System Fluids, Supplies, and Waste

1. Navigate to **Supply Needs**.
2. Select the appropriate analyzer.

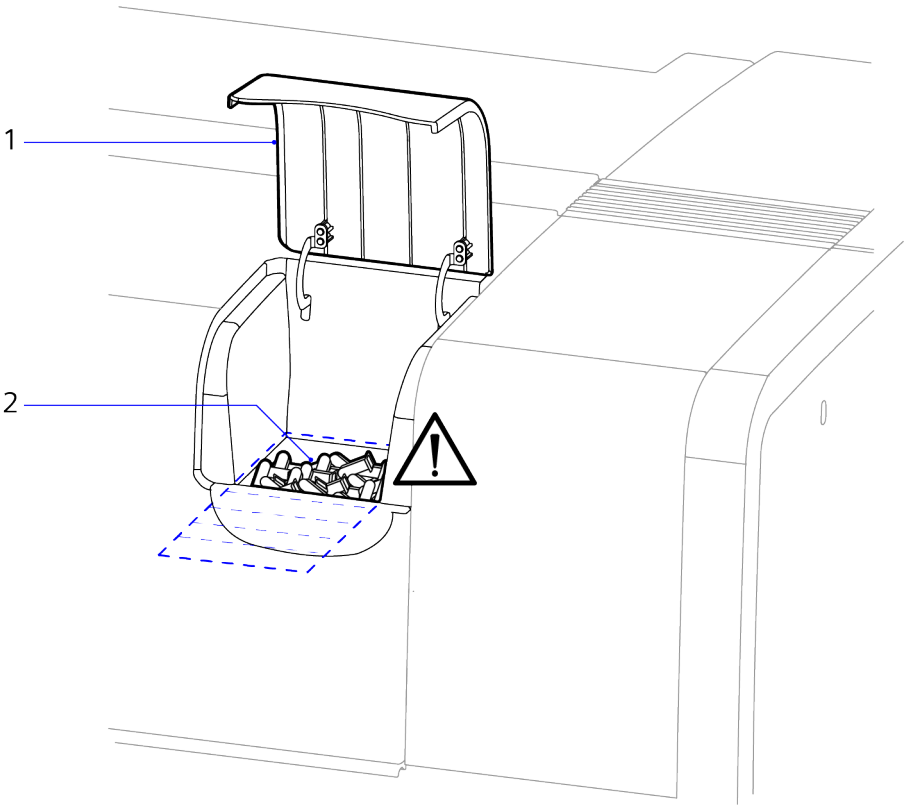
3. Check the status of the following:
   - System Fluids
   - Supplies
   - Waste
4. If appropriate, replace system fluids or supplies or empty the waste.

Replacing IM Cuvettes

1. Open the lid.



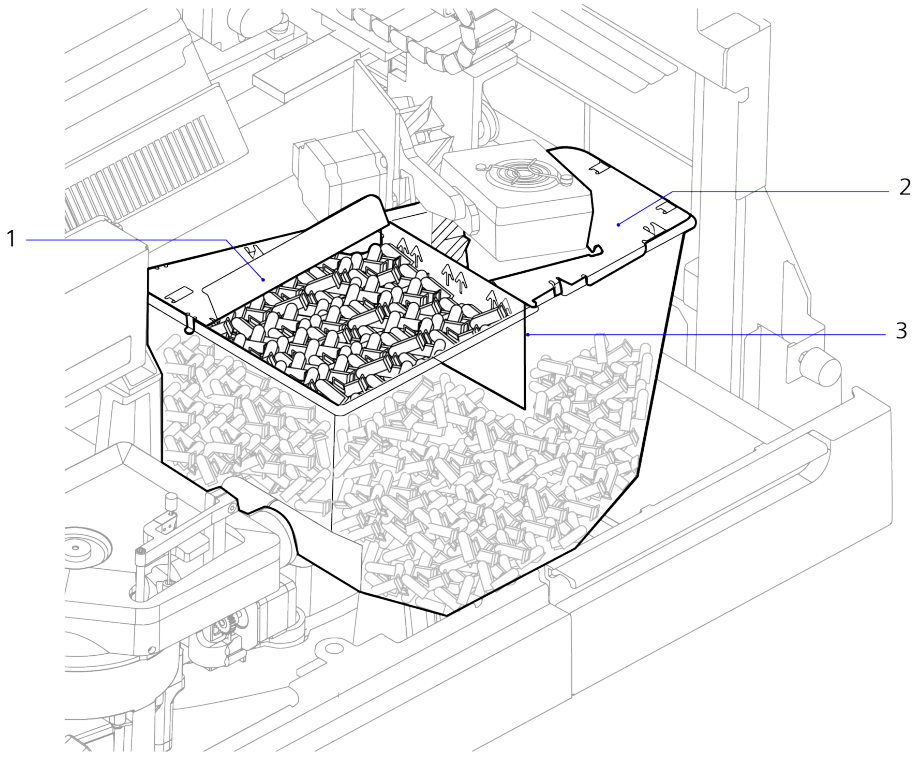
2. To open the cuvette packaging, use scissors to ensure that plastic bag fragments do not drop into the cuvette bin that could cause jams.



1	Cuvette bin lid
2	Cuvette bin

> **CAUTION**
>
> Do not push down the cuvettes, remove the plastic divider, push cuvettes to the right side of the bin, or overfill the bin enough to prevent the cuvette lid from fully closing. Performing any of these can cause a cuvette jam.

3. Pour cuvettes up to the brim in the left side of the cuvette bin.



1	Left side of the cuvette bin
2	Right side of the cuvette bin
3	Plastic divider

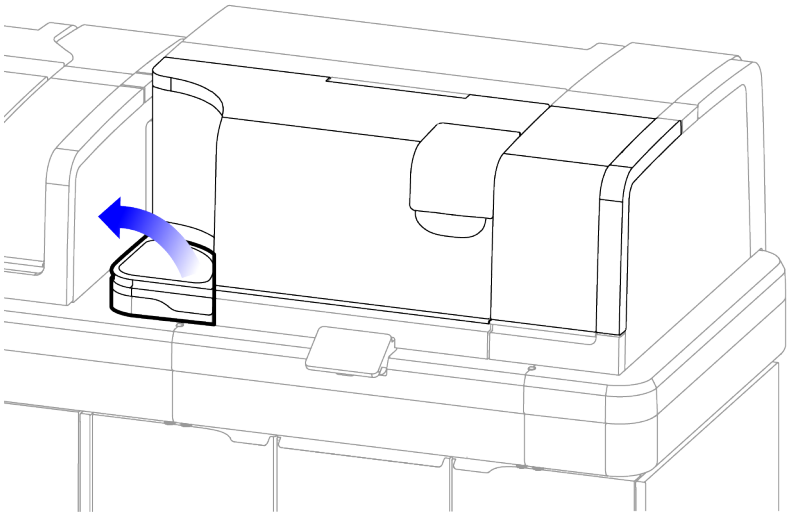
4. Close the cuvette bin lid and ensure the lid completely closes.

   NOTE: To locate the replacement catalog number, see (Page 891 *IM Supplies*) .

Replacing IM Sample Tips

> **CAUTION**
>
> Do not handle sample tips without wearing new, uncontaminated gloves. Handling sample tips without wearing new gloves can cause cross contamination.

1. Open the sample tip loading lid.

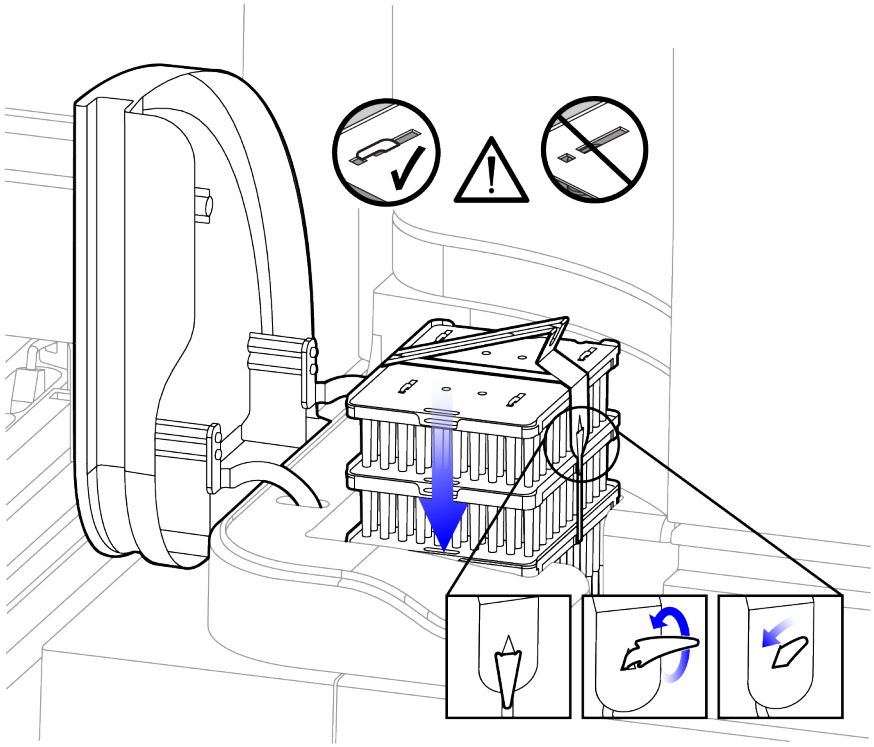


2. Refer to the instructions on the sample tip tray bundle to remove the protective cover.
3. Inspect the bottom tray for damage or defects.

> **CAUTION**
>
> Do not use a tip tray with damage or defects. Using damaged or defective tip trays can cause system errors. If tips are damaged, contact the local technical support provider with the lot number.

4. Slide the tip tray bundle on to the 4 tip tray hooks.

5. Install the sample tip trays ensuring that the tab is facing the opening on the right and the rounded notches in the trays are facing the back of the system.



6. Twist then pull the tab down and out to release the strap from the trays.
7. Pull the strap out to remove it from the bundle.

   NOTE: Leave the top on the upper tip tray.
8. After the analyzer lowers the bundle into the tip tray storage area, close the sample tip loading lid.

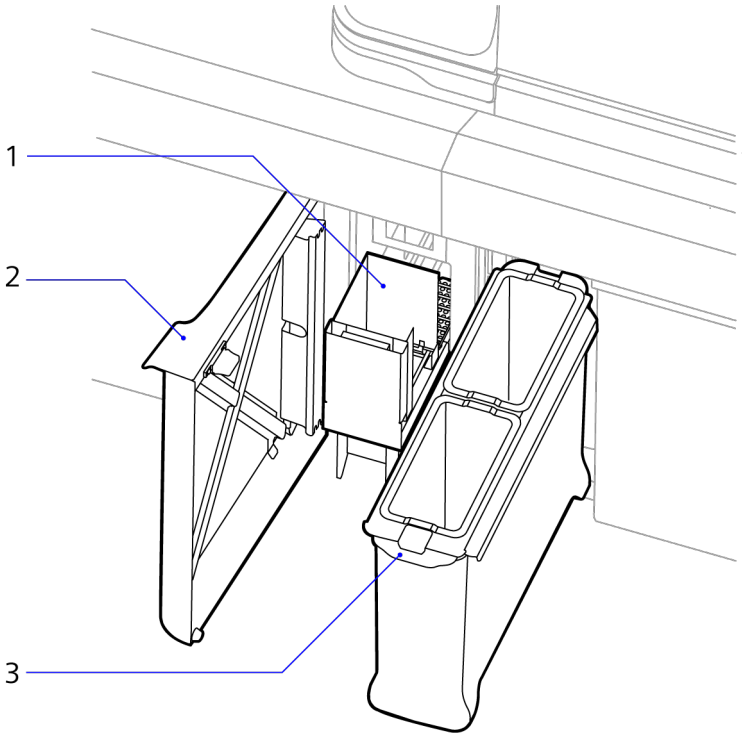
   NOTE: To locate the replacement catalog number, see (Page 891 *IM Supplies*) .

Emptying the IM Sample Tip Tray Waste

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

1. Navigate to **Supply Needs > View All Supplies**.
2. Locate the appropriate IM Analyzer.



1	Sample tip tray waste drawer
2	Solid waste door
3	Solid waste bin drawer (cuvette and sample tip waste)

3. Open the solid waste door.
4. Pull out the sample tip tray waste drawer.
5. Remove the empty sample tip trays.
6. Close the sample tip tray waste drawer.
7. Confirm Tip Tray Waste Status is Empty.

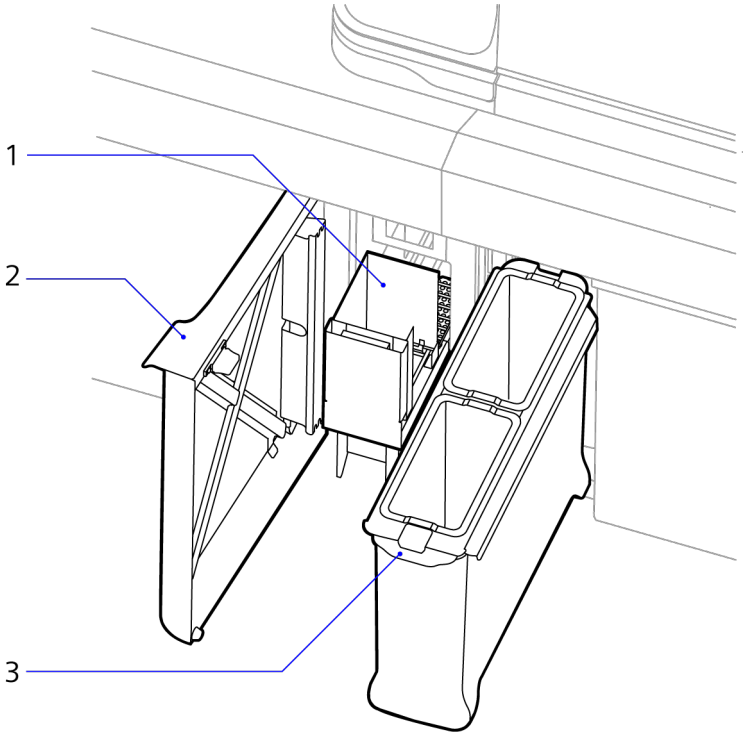
Emptying the IM Solid Waste - Cuvettes and Sample Tips

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

1. Navigate to **Supply Needs > View All Supplies**.
2. Locate the appropriate IM Cuvette and Tip Waste Status.

3. Open the solid waste door.



1	Sample tip tray waste drawer
2	Solid waste door
3	Solid waste bin drawer (cuvette and sample tip waste)

4. Pull out the solid waste drawer and remove the solid waste bins.

   NOTE: To facilitate solid waste bin removal, grasp the bin with both hands and shake slightly.

5. Empty the contents of the solid waste bins into a laboratory-approved container for biohazardous waste.
6. Return the bins to the solid waste drawer.
7. Push the drawer in.
8. Close the door.
9. Confirm Cuvette and Tip Waste Status is Empty.

About the Cal-QC Storage Inventory

The Cal-QC Storage Inventory provides details about the individual calibrator and QC tubes in the Cal-QC storage area of all SH modules or on the Atellica Magline Transport.

The Cal-QC Storage Inventory has 4 areas:

- Capacity (does not display in Atellica Asa Application)
- Filter
- No Filter
- Assay Details

About Capacity in Cal-QC Storage Inventory

The Capacity area provides information on the total number of available and unusable Cal-QC storage positions.

Capacity	Notes
Available	The total number of Cal-QC storage positions available (positions with tube covers) for additional Cal or QC materials from all SH modules.  displays if the number of available positions is 0.
Unusable	The total number of Cal-QC storage positions from all SH modules that the system identifies as being unusable due to a hardware-related error condition. The system does not include empty or expired materials in the unusable capacity.  displays if the number of unusable positions is >10% of the total capacity. **NOTE:** When the number of unusable positions equals 0, Unusable does not display and no alert icon displays.

About Cal-QC Storage Inventory Filter

The operator filters Cal-QC Storage Inventory using the following options:

Cal-QC Storage Inventory Filter	Notes
Search Inventory	The operator enters appropriate text to search the inventory list or Cal-QC samples.
Search	The operator enters appropriate text to search for a particular assay.
Status	The operator selects the appropriate statuses: • OK • Insufficient Volume • Expired • Partially Expired
Type	The operator selects the appropriate material: • QC • Cal
Location	The operator selects the appropriate SH location.

The operator can select  to clear the current filter options.

About Cal-QC Inventory Cal-QC Sample Details Area

The Cal-QC Sample Details provide information for each calibrator or QC tube available.

Functions are also available to display assay details for calibrators or QCs or to unload selected tubes from the Cal-QC storage area.

Cal-QC Sample Details	Notes
Type	The material type: Cal or QC.
Material	The Cal or QC material product name.
Lot	The lot of the material.
Sequence	A unique number (from the barcode sequence) that identifies the specific container of a Cal-QC material.

Cal-QC Sample Details	Notes
Status	The material status: • OK: Material is acceptable to use. No status indicator displays. • Insufficient volume: The total volume of Cal-QC material is less than the low volume threshold. The text displays with a yellow background. • Partially Expired: The material is usable for some assays but has exceeded the onboard stability for use with at least 1 assay. The text displays with a yellow background. • Expired: The onboard expiration date for the material expires. The text displays with a red background.
Vol (µL)	The total usable volume for the material in the tube. For approximated volume values, the number contains a prefix of "~".
Location	The location of the tube: SH name or In Use (on the Atellica Magline Transport).
Expiration	The manufacturer's expiration date for the lot of materials.

About the Cal-QC Storage Inventory Assay Details

The Cal-QC Storage Inventory Assay Details provides a list of the assays that use the selected Cal-QC material and expiration information for the assay.

Assay Details	Notes
Assay	The assays that uses the selected Cal-QC material.
Expiration	The onboard stability date of each assay defined by the Cal-QC material or Expired with a red background for expired assays.

About Assay Status

Assay Status is a summary that displays the following:

- A list of individual assay names with each specimen type the laboratory has Enabled or is in Troubleshooting mode on at least 1 analyzer.
- Current availability of each assay with a status indicating why an assay is not performing.

To refresh the view, the operator must navigate away from then navigate back to Assay Status.

Assay Status	Notes
Assay grouping	Assays are grouped by CH Assays and IM Assays with number of rows matching the filter criteria selected. The operator selects to display assays then selects again to close that list.
Assay	The Enabled or in Troubleshooting mode assay short name.
Sample Type	The defined Sample Type configured in TDEF for the assay. Each Sample Type displays as a separate line item for the assay.
Analyzer	Friendly name of the analyzer where the assay resides. Each analyzer has its own column for each Assay row. The status for the assay and sample type displays in this column. The operator selects the row for more status details.

When the operator selects an Assay row, that assay lot details displays.

Lot Details Display	Notes
Analyzer	Friendly name of the analyzer where the assay resides. Each analyzer has its own column for each Assay lot details row.
Lot	The reagent lot that has 1 or more reagent packs onboard the selected analyzer for the selected assay. The reagent Lot information displays for all onboard reagent packs regardless of their Active or Inactive status. If no reagent packs are onboard for any reagent Lot, "Reagent packs are not loaded for the assay on the analyzer." displays. **NOTE:** The reagent Lot information does not display for IMT assays.
Lot Calibration	The system identifies if a current valid calibration exists for that reagent Lot on that analyzer: • Yes: Valid calibration exists. • Needed: Lot calibration is required.

Lot Details Display	Notes
Packs/Wells Loaded	The status of the individual primary reagent packs currently loaded for that reagent lot on that analyzer with details on each well for multi-well packs: CH assays display the lot, sequence, and well number: • Blank: No reagent available. • Unusable Reagent: The well is empty, expired, or an error exists. IM assays display the lot and sequence: • Blank: No reagent available. • Unusable Reagent: The pack is not in Idle or Processing state.
Pack Calibration	The system identifies whether a Pack Calibration is required for the lot: • N/A: Pack Calibration is not applicable. • Yes: Valid Pack Calibration exists. • Needed: Pack Calibration is required.
QC Valid	The system identifies whether QC is currently in an acceptable state for that reagent lot on that analyzer: • Yes: QC is valid. • No: QC violation exists.

Reviewing Assay Status

1. Navigate to **Assay Status**.
2. Filter the list, if appropriate (Page 307 *Filtering Assay Status*).
3. To expand assay list by assay type, select **CH Assays** or **IM Assays**.
4. To collapse the list, select **CH Assays** or **IM Assays** again.

5. Review the statuses under the analyzer column.
6. Select the appropriate Assay row.
7. Resolve all issues.
8. To refresh the list, exit and navigate back to **Assay Status**.

About Assay Status Filter

The operator filters Assay Status summary to review the following:

- One or more specific assays based on the entered assay name.
- Assays related to 1 or more specific specimen types.
- Assays with a specific status.

The operator uses < and > to collapse or expand the filter.

Assay Status Filter	Notes
Clear	The operator selects to clear previous filter options.
Status	The operator selects 1 or more of the following statuses: • All: Default and includes all statuses. • Disabled: The assay and specimen type combination are Disabled for the analyzer. • Troubleshooting: The assay and specimen type is currently in Troubleshooting mode on that analyzer. • Missing Reagent: No primary reagent packs for that assay are loaded on the analyzer. The operator must load the appropriate reagents. • Unusable Reagent: Onboard reagent is empty, expired, or not mixed (IM only).

Assay Status Filter	Notes
	• Calibration Need: Usable primary reagent packs are onboard the analyzer but all require a calibration. • QC Needed: At least 1 usable and calibrated reagent pack is onboard but but all require QC to process and complete. • OK: Reagent the operator can use for patient processing. Default option is All.
Sample Type	The operator selects 1 or more configured sample types. Default option is all types.
Search	The operator enters any portion of the assay short name. This is a partial string and case-insensitive search.
Assay list	The operator selects 1 or more of the assays listed.

Filtering Assay Status

1. Navigate to **Assay Status**.
2. To filter by Status, select all appropriate statuses from the drop-down menu.
3. To filter by Sample Type, select all appropriate types from the drop-down menu.
4. To search for the appropriate assay:
   - Enter the assay short name and select **Search**.
   - Select the assays from the assay list that displays.

About Supplies Alert Threshold Configuration

This task requires the appropriate security level.

In Supplies Alert Threshold Configuration, the operator configures thresholds to trigger alerts that display in Supply Needs for the following:

- Fluids: System fluids, IMT system fluids, A-LYTE multisensor, and Pretreatment
- Onboard stability and lot expiration
- Other supplies: (IM) tips and waste and (CH) RPC1, RPC2, RPC4, and WBA

The operator sets the threshold for each supply to allow enough time to replace the supply without interrupting test processing.

Supplies Alert Threshold Configuration	Notes
Fluids	System fluids, IMT system fluids, A-LYTE multisensor, and Pretreatment thresholds.
System Fluid Volume Threshold (%)	The analyzer alerts the operator when the remaining system fluids level drops below the operator-configured threshold. The default is 5% and the range is 0%–50%.
IMT Fluid Volume Threshold (%)	The analyzer alerts the operator when the remaining IMT system fluids level drops below the operator-configured threshold. The default is 5% and the range is 5%–50%.
A-LYTE Multisensor Threshold (Counts)	The analyzer alerts the operator when the actual test counts remaining drops below the operator-configured threshold. When initially loaded, the multisensor can process up to 5000 samples. The default is 250 and the range is 1–2500.

Supplies Alert Threshold Configuration	Notes
Pretreatment Volume Threshold (Counts)	The analyzer alerts the operator when the actual number of tests remaining for the Pretreatment pack (40-mL) or 180-mL bottle meets the operator-configured threshold. The default is 5 and the range is 5–50.
OBS and Lot Expiration	Onboard stability and Lot expiration.
Onboard Stability Threshold (Hours)	The analyzer alerts the operator when the number of hours until the onboard stability for a consumable meets the operator-configured threshold. At that time, the opened container or pack is no longer stable on the system. The displayed OBS remaining is rounded down to the next whole hour. The default is 2 hours and the range is 1–48 hours.
Lot Expiration Threshold (Hours)	The analyzer alerts the operator when the number of hours until the lot expiration for a consumable meets the operator-configured threshold. The default is 36 hours and the range is 1–48 hours.
Other Supplies	IM tips and waste with CH reagent probe cleaners and WBA.
Tips Remaining	The analyzer alerts the operator when total number of IM sample tips remaining meets the operator-configured threshold. The default is 120 tips and the range is 1–120.

Supplies Alert Threshold Configuration	Notes
Waste Bin Level (%)	The analyzer alerts the operator when the percent of waste capacity remaining meets the operator-configured threshold. This only displays when the following is on the system: • IM tips and cuvettes • IM tip tray • Decapper cap
Reagent Supplies RPC1 & RPC2 Volume Threshold (Inventory)	The analyzer alerts the operator when the CH RPC1 and RPC2 supplies count thresholds trigger based on the sum of all the reagent packs loaded for each supply rather than each individual reagent pack. The default is 20 test counts and the range is 10–50.
Reagent Supplies RPC4 & WBA Volume Threshold (Inventory)	The analyzer alerts the operator when the CH RPC4 and WBA supplies count thresholds trigger based on the sum of all the reagent packs loaded for that supply rather than each individual reagent pack. The default is 10 test counts. **NOTE:** For example, if the daily and weekly automated CH maintenance performs Friday through Sunday, the operator configures the threshold trigger to 35 or 40 to allow for usage over that time period.
Restore Defaults	The operator selects to restore all the operator-configured thresholds to the default values.

Supplies Alert Threshold Configuration	Notes
Save	The operator selects to save the changes to the operator-configured thresholds.
Cancel	The operator selects to cancel the changes to the operator-configured thresholds.

About Lot Log

When the operator loads consumables, the Lot Log stores all consumable and supply lot information, including the date and module:

- The system automatically adds the consumables with barcodes to the log.
- The operator manually adds the consumables without barcodes to the log.
- The system adds QC and calibrator materials to the log after first use.
- During the first Daily Maintenance of each month, the system automatically performs Database: Archiving and Deleting on Lot Log data that expired more than 2 years ago in the previous month.

The Lot Log has options to add an entry or comment and edit comments. All records display in reverse chronological order based on the Date First Loaded.

Lot Log is located in Utilities.

The operator exports up to 50,000 entries to store files off-system in a Tab Separated Values (*.tsv) or XML Data (*.xml) file format.

NOTE: To store files off-system within the system security protocols and certificates, set the path to **F: > USERROOT > FTP > Export**. The files securely transfer to the laboratory FTP server. These files then route to the desired location according to the IT administrator.

The operator can filter the Lot Log to change the attributes that display. By default, the Lot Log automatically refreshes when the filter applies.

Lot Log Filter	Notes
	The operator selects to clear previous filter options.
Inventory Type	A drop-down menu for the known consumables for the configured module types. The operator selects a consumable or inventory type from the drop-down menu: • All • A-LYTE IMT Cleaner • A-LYTE Multisensor • Calibrator • CH Cuvettes • IM Tips and IM Cuvettes • IMT Dilution Check • IMT Fluids • Manually Added • Pretreatment • QC • Reagent Packs • Sealer Foil • System Fluids
Search Name	The operator enters a consumable or inventory name.
Search Lot	The operator enters a lot.
Module	The operator selects the module from the drop-down menu.
Date Range	The operator selects the date range. Default date range is 90 days.
Apply	The operator selects to initiate filtering.

To clear the current filter options, select  .

To collapse the filter view, select < next to Filter.

To open filter view, select > above Filter.

Lot Log	Notes
Add New	The operator selects to manually add a new lot.
Name	The name of the consumable or supply.
Lot	The lot of the consumable or supply.
Inventory Type	The system displays the known consumables for the configured module types: • A-LYTE IMT Cleaner • A-LYTE Multisensor • Calibrator • CH Cuvettes • IM Cuvettes • IM Tips • IMT Dilution Check • IMT Fluids • In Add New, the Name the operator enters as Custom • Pretreatment • QC • Reagent Packs • Sealer Foil • System Fluids

Lot Log	Notes
Date First Loaded	The date and time the lot is introduced to the module. The date and time is based on the Inventory Type: • Scanned consumables: Date and time the operator successfully loads the consumable on the module. • Calibrator or QC material: Date and time the new material lot first aspirated on the analyzer. • Custom consumable: Date and time the operator manually added the consumable in Add New.
Lot Expiration	The date that the lot expires.
Module	The module where the consumable or supply is located.
Comments	The operator adds up to 3 comments that include the time and date. The operator selects the row then  to add a comment. If a comment exists, the operator selects  to review or edit that comment.
Export	The operator selects to export up to 50,000 entries in a Tab Separated Values (*.tsv) or XML Data (*.xml) file format. **NOTE:** To store files off-system within the system security protocols and certificates, set the path to **F: > USERROOT > FTP > Export**. The files securely transfer to the laboratory FTP server. These files then route to the desired location according to the IT administrator.

Lot Log	Notes
View All Supplies	The operator selects to review all onboard supplies.
Reagent Overview	The operator selects to review all onboard reagents.
Cal-QC Inventory	The operator selects to review all onboard calibrator and QC materials. Does not display on a standalone system.

The operator can navigate between Lot Log pages by selecting the number of the page or < or >.

Add New	Notes
Inventory Type	The operator selects the following inventory types from a drop-down menu: • Custom: The operator enters the consumable or inventory type and name. • A-LYTE IMT Cleaner. • IMT Dilution Check. • IM Cuvettes • IM Tips • CH Cuvettes. • Sealer Foil.
Name	The Name defaults as the selected Inventory Type. For Custom consumables or supplies, the operator enters the name of the consumable or supply.
Lot	The operator enters the lot of the consumable or supply.
Lot Expiration	The operator enters the expiration date of the consumable or supply.

Add New	Notes
Module	The system defaults to a specific module depending on the system configuration and inventory type. For Custom, the operator selects the module where the consumable or supply is onboard from a drop-down menu.
Comments	The operator enters a text comment. Manually Added is the default.
Add	The operator manually enters a new consumable lot.
Cancel	The operator discards the new consumable.

11 Patient Orders

About Patient Orders

Patient orders require a sample ID, specimen type, and test information. The operator can add a rack ID and sample or patient information such as patient demographics, physician sample collection times, or comments to display as sample details (Page 370 *Viewing Sample Details*).

Sample Information	Notes
Sample ID	The identification code for the sample. This field allows all uppercase and lowercase letters, numbers, and the following symbols: - . $ / + % =* : \. This field is not case-sensitive. For example, abc1 and ABC1 are identical SIDs.
Rack ID	The identification number of the rack. The second field designates which section of the rack holds the sample tube.
Specimen Type	The type of fluid in the sample container. The specimen type restricts orderable tests. Acceptable specimen types are viewable in Test Definitions.
Manual Dilution	The manual dilution factor the operator performs on the sample off-system. The software applies the manual dilution factor before reporting the results to the system.

Sample Information	Notes
Priority	The order in which the system processes the samples. Routine is the default. The system processes STAT samples first. The priority for whole blood samples is always STAT and cannot be changed.
For Study	When enabled, results do not transmit to the LIS automatically. The operator can manually transmit results marked For Study to the LIS from Worklist.

Add Assays	Notes
Assay Type	One of Chemistry, Immunoassay, or All. This field is optional and functions only to filter the test selection options.
Selected Tests	Tests that are currently in the order.
Tests	A list displaying the Tests available for that Specimen Type and Assay Type. The operator can modify the test display order in Assay List - Display Order.
Test Panels	A list displaying the Test Panels available for that Specimen Type and Assay Type (Page 776 *About Adding Test Panels*).
Dilution Panels	A list displaying the Dilution Panels available for that Specimen Type and Assay Type (Page 774 *About Dilution Panel Definition*).

Orders	Notes
Test	The selected test or tests. The operator can select + next to each test to add multiple instances of the same test to the order (Page 319 *About Replicate, Multiple, and Repeat Tests*). Selecting × next to a test deletes that test from the order.
Dilution	The dilution factors available to the assay as defined in the test definition that the analyzer performs as defined by the test definition.
Replicates	The number of times to perform the test (IM assays only). IM assays use replicates to determine the mean test result (Page 319 *About Replicate, Multiple, and Repeat Tests*).
System Test Options	The option to change the reagent lot and analyzer associated with this test.

About Replicate, Multiple, and Repeat Tests

The system can process tests as replicates, multiples, or repeats.

Replicate tests process simultaneously with the same specified dilution. The system uses replicate test results to obtain a statistical mean result. Some IM tests require a minimum number of replicates, as the test definition specifies. The operator can order additional replicate tests using the Replicates feature when creating a patient order. The system reports the mean replicate result on the Worklist.

NOTE: CH assays do not accept replicate tests on patient orders.

When creating a patient order, the operator can add multiple instances of the same test for the same sample. Multiple tests also process simultaneously with the same specified dilution. With multiple tests, the system reports each test result separately. The system does not automatically report a mean result for multiple tests.

Repeat tests use the same specified dilution and process in sequence. The system performs repeat testing when the initial result triggers a rule defined under Ranges or Repeat Conditions. The operator can configure the system to automatically order repeat tests in Setup or manually order repeat tests by creating separate orders for the same sample. The system reports each repeat test result separately on the Worklist.

Ordering Patient Tests Workflow

1. Add sample information.
2. Add patient demographics.
3. Add tests.
4. Submit the order.

Adding Sample Information

1. Navigate to **Patient Orders**.

   NOTE: To print the sample barcode, select **Print Barcode** at any time while the order window is open.

2. In Order By, select **Sample ID**.

   NOTE: Selecting Rack ID in Order By makes Rack ID required.

3. Scan the sample tube barcode or manually enter a Sample ID.

   NOTE: Barcode scans automatically activate the entry fields.

4. To advance to any field for additional information, select the field or select **Tab** on the keyboard.
5. To specify the Rack ID, scan the sample rack barcode or manually enter a Rack ID and enter the tube position in the second field.
6. Select a Specimen Type.
7. For a sample that is manually diluted, enter the manual dilution factor.
8. Select **STAT**, **ASAP**, or **Routine**.

   NOTE: Routine is the default Priority except for whole blood samples which have STAT priority.

9. To mark the patient order as for study, select **For Study**.
10. To add more information about the sample, including collection and receipt date and sample comments, select **Additional Information** in Sample Information.

Adding Patient Demographics

1. If appropriate, enter a Patient ID.
2. Select Q.

   NOTE: Selecting Q fills the patient demographic information.
3. Add patient first name.
4. Add patient middle name.
5. Add patient last name.
6. Add patient Date of Birth.
7. To add more details about the patient, including Patient Status, select **Additional Demographics** in Patient Demographics.

Adding Tests

1. Select **Add Tests**.

   NOTE: The operator can only select tests that support the specified Specimen type.
2. Select 1 or more Tests.

   NOTE: Selecting a test a second time removes that test from the order.
3. Select **Add Tests**.
4. To add multiples of an ordered test, select + next to that test.
5. To remove a test from the order, select × next to that test.
6. To specify analyzer, reagent lot, or primary pack, select **Edit Test Options** next to the appropriate test.

Submitting the Order

1. Select **Place Order**.
2. If Confirm Run ID on Create Patient Orders Screen is active, select **OK** in Run ID Settings and the Information screen.
3. To print the sample barcode for the order, select **Print Barcode**.
4. Select **OK**.

About Batch Orders

The Batch Orders feature is a template that allows the operator to create orders for a group of samples of the same specimen type undergoing the same tests.

About Batch Orders - Order by Rack ID

Selecting Rack ID in Order By allows the operator to order the same tests for samples in specific racks. Any time a rack with this Rack ID enters the system, the system applies the associated batch order.

NOTE: Only Batch Orders ordered by Rack ID display in View Batch Orders.

Sample Information	Notes
Batch Name	A unique name for the batch.
Specimen Type	The type of fluid in the sample container.
Manual Dilution	The manual dilution factor the operator performs on the sample off-system. The software applies the manual dilution factor before reporting the results to the system.
Rack IDs	The rack or racks holding the samples in the batch. Add or Edit Rack IDs allows the operator to add, edit, or delete Rack IDs.
Comment 1, Comment 2, Comment 3	Comments the operator enters or selects from the drop-down menu.

Add Assays	Notes
Assay Type	The assay type of the batch tests, either Chemistry, Immunoassay, or All. This is an optional field for filtering the Tests selections.
Selected Tests	Tests that are currently in the order.
Tests	A list displaying the Tests available for that Specimen Type and, if selected, Assay Type.

Add Assays	Notes
Test Panels	A list displaying the Test Panels available for that Specimen Type and, if selected, Assay Type (Page 776 *About Adding Test Panels*).
Dilution Panels	A list displaying the Dilution Panels available for that Specimen Type and, if selected, Assay Type (Page 774 *About Dilution Panel Definition*).

Orders	Notes
Test	The selected Tests. The operator can select + next to each test to add multiple instances of the same test to the order (Page 319 *About Replicate, Multiple, and Repeat Tests*). Selecting × next to a test deletes that test from the order.
Dilution	The dilution factors available to the assay that the analyzer performs as defined in the test definition.
Replicates	The number of times to perform the test (IM assays only). IM assays use replicates to determine the mean test result (Page 319 *About Replicate, Multiple, and Repeat Tests*).
System Test Options	The option to change the reagent lot and analyzer associated with this test.

Creating Batch Orders by Rack ID Workflow

1. Add batch information.
2. Add tests and submit the order.

Adding Batch Information

1. Navigate to **Batch Orders**.
2. In Order By, select **Rack ID**.
3. Enter a Batch Name.
4. Select a Specimen Type from the drop-down menu.
5. For a sample that is manually diluted, enter the Manual Dilution factor.
6. To enter the rack ID, select **Add or Edit Rack IDs**.

   NOTE: The operator can use the handheld barcode reader to input rack IDs for multiple racks.
7. Select up to 3 comments from the drop-down menus or enter a unique comment.

Adding Tests and Submitting the Order

1. Select **Add Tests**.
2. Select 1 or more tests.

   NOTE: Selecting a test a second time removes that test from the order.
3. Select **Add Tests**.
4. To add multiples of an ordered test, select + next to that test.
5. To remove a test from the order, select × next to that test.
6. To specify analyzer, reagent lot, or primary pack, select **Edit Test Options** next to the appropriate test.
7. Select **Place Order > OK**.

   NOTE: The system creates Batch Orders as active. Batch Orders remain active until deleted.

About Batch Orders - Order By Sample ID

Selecting Sample ID in Order By allows the operator to create orders using the same assays for a range of sample IDs.

NOTE: Batch Orders ordered by Sample ID do not display in View Batch Orders. Instead, they are displayed in Worklist once the order is placed.

When creating batch orders by SID, the following criteria applies:

- The starting and last IDs cannot match any sample IDs the system defined previously in active and pending batch orders until that batch closes.
- The operator can load samples in any order between the starting and ending samples.

Range of Orders	Notes
Sample ID	The first sample ID in the batch. The Sample ID must end in a number
Specify Range By	The operator can specify the range of samples in the batch by the Number of Samples or the Last Sample ID.

Sample Information	Notes
Specimen Type	The type of fluid in the sample container.
Manual Dilution	The manual dilution factor the operator performs on the sample off-system. The software applies the manual dilution factor before reporting the results to the system.
For Study	For Study results only transmit to the LIS if the operator manually transmits them.
Priority	The order in which the system processes the samples. Routine is the default. The system processes STAT samples first.
Additional Information	Optional sample information.

Add Assays	Notes
Assay Type	The assay type of the batch tests, either Chemistry, Immunoassay, or All. This is an optional field for filtering the Tests selections.
Selected Tests	Tests that are currently in the order.
Tests	A list displaying the Tests available for that Specimen Type and, if selected, Assay Type.

Add Assays	Notes
Test Panels	A list displaying the Test Panels available for that Specimen Type and, if selected, Assay Type (Page 776 *About Adding Test Panels*).
Dilution Panels	A list displaying the Dilution Panels available for that Specimen Type and, if selected, Assay Type (Page 774 *About Dilution Panel Definition*).

Orders	Notes
Test	The selected Tests. The operator can select + next to each test to add multiple instances of the same test to the order (Page 319 *About Replicate, Multiple, and Repeat Tests*). Selecting × next to a test deletes that test from the order.
Dilution	The dilution factors available to the assay that the analyzer performs as defined in the test definition.
Replicates	The number of times to perform the test (IM assays only). IM assays use replicates to determine the mean test result (Page 319 *About Replicate, Multiple, and Repeat Tests*).
System Test Options	The option to change the reagent lot and analyzer associated with this test.

Creating Batch Orders by SID Workflow

1. Add batch information.
2. Add tests.
3. Submit the order.

Adding Batch Information

1. Navigate to **Batch Orders**.
2. In Order By, select **Sample ID**.
3. Enter the Sample ID for the first sample in the batch.

   NOTE: The Sample ID must end with a number.
4. To define the batch by a specific number of samples:
   a. Select **Number of Samples** from the drop-down menu.
   b. Enter a Number of Samples.
5. To define the batch by the beginning and ending sample ID:
   a. Select **Last Sample ID** from the drop-down menu.
   b. Enter the Sample ID of the final sample in the batch.
6. Select a Specimen Type type from the drop-down menu.
7. For a sample that is manually diluted, enter the Manual Dilution factor.
8. Select a STAT, ASAP, or Routine Priority.

   NOTE: Routine is the default Priority.
9. To add more information about the sample, including collection and receipt date and sample comments, select **Additional Information** in Sample Information.

Adding Tests

1. Select **Add Tests**.
2. Select 1 or more tests.

   NOTE: Selecting a test a second time removes that test from the order.
3. Select **Add Tests**.
4. To add multiples of an ordered test, select + next to that test.
5. To remove a test from the order, select × next to that test.
6. To specify analyzer, reagent lot, or primary pack, select **Edit Test Options** next to the appropriate test.

Submitting the Order

1. Select **Place Order**.
2. To print the sample barcode for the order, select **Print Barcode**.

   NOTE: The operator can print the barcode at any time.
3. Select **OK**.

12 Worklists

About Worklist

Worklist displays information about the Sample, patient demographics, results, and associated tests.

In Worklist, the operator can interact with orders and tests and filter displayed results.

The operator can expand the Filter pane by selecting > or collapse the Filter pane by selecting <. Collapsing the Filter pane displays an additional column.

Column content can be configured by selecting ⚙.

NOTE: Selecting Samples or Tests in the View By area changes the layout of the Worklist Display columns. In Samples view, Test results and associated flags are not visible unless the test list is expanded.

The following table is an alphabetical list of all potential content for the Worklist display.

Column Content	Notes
Analyzer	The friendly name of the analyzer.
Aspiration Date Time	—
Flags	Flag icons or text associated with the test. The operator can select the Flag to display additional information.
Interpretation	The test result is Positive, Negative, Equivocal (unclear), or, depending on the assay, Reactive, or Nonreactive (Page 767 *About Interpretation Ranges*).
Name	The selection displays as: Patient / Control / Calibrator Name.
None	—
Order Time	The time the system received the order.
Patient Location	—

Column Content	Notes
PID / Lot	The selection displays as: Patient ID, Control / Calibrator Lot.
Priority	Displays the following order priority: • Blank for Routine • ✱ for ASAP **NOTE:** ASAP is the default priority for QC and Repeat tests but they do not display ✱. • ⓘ for STAT
Rack ID	Operator-entered or scanned Rack ID.
Reagent Lot	—
Result	The selection displays as: Concentration / Index. Displays the result value for concentration or index.
Result Time	—
RLU/ABS	The selection displays as: RLU / Absorbance. For Immunoassay tests, displays the relative light units (RLU) that the luminometer measures. For Chemistry tests, displays the absorbance (ABS) that the photometer measures.
Run ID	An optional identifier applied to orders. The operator can configure Run ID when creating an order or importing worklists . The system can configure Run ID in Lab Evaluations.
Sample Status	Selecting the status icon displays a list of possible sample statuses.
Sample Type	Patient, Control, or Calibrator.

Column Content	Notes
Scanned Time	—
SID	The sample identifier.
Specimen Type	The type of fluid in the sample container.
Test	The test display name as configured in the test definition.

Except where noted, the following functions are available with View By set to Samples or Tests:

Function	Notes
Edit/View	Opens the Sample Details.
Add Test to Order	Opens Order Details. Only available for 1 Sample or Test selection at a time.
Move to Historical	Moves the Order from the Active Database to the Historical Database. Archiving orders in the Historical Database allows reuse of the associated SID. **NOTE:** Only available in Samples view.
Repeat	Repeats all eligible tests in the selected order or any individually selected eligible tests. Provides access to Repeat Options. The system can only repeat patient tests. Eligible Tests must have active results and must not be in the Historical Database.

Function	Notes
Accept	Accepts the results of all eligible Tests associated with the selected order or any individually selected eligible Tests. Eligible Tests must have active results and be in the Hold test state.
Transmit	Manually transmits to the LIS the results of all eligible Tests associated with the selected order or any individually selected eligible Tests. Eligible Tests must be in the Complete, Transmit Failed, or Transmitted test states.
Cancel	Cancels the Order for the selected sample or any individually selected eligible Tests.
Delete	Deletes the Order for the selected Sample including all associated tests or any individually selected eligible Tests.
Print Barcode	Prints the barcode associated with the selected order.

The following functions are available for Worklist:

Function	Notes
Query LIS	Provides the option to manually request worklists from the LIS.
Import worklist	Provides the option to import a list of orders from a USB or file.
Statistics	Opens Result Reports Selection and provides the option to export Worklist Statistics.
Export	Provides the option to export test results.

Worklist Flags

The system displays a flag when the status of a sample result or test requires additional attention. The system may display 1 or more of the following flags.

Result Type represents the value, if any, the system returns with the flag.

Yes in the To LIS column means the flag is transmitted to the LIS.

Flag	Analyzer	Result Type	To LIS	Notes
< Manufacturer Limit	CH	Alphanumeric	Yes	The result was below the manufacturer's defined low value for the measuring interval. This flag only displays if the laboratory configures a custom measuring interval below the manufacturer's defined low value for the measuring interval.
< Measuring Interval	CH/IM	Alphanumeric	Yes	The result was below the low value for the concentration or index calculation.
> Dilution Point	IM	Alphanumeric	Yes	The result was above the dilution setpoint in the test definition.
> Manufacturer Limit	CH	Alphanumeric	Yes	The result was above the manufacturer's defined high value for the measuring interval. This flag only displays if the laboratory configures a custom measuring interval above the manufacturer's defined high value for the measuring interval.
> Measuring Interval	CH/IM	Alphanumeric	Yes	The result was above the high value for the concentration or index calculation.

Flag	Analyzer	Result Type	To LIS	Notes
A1c < Measuring Interval	CH	Error	Yes	The A1c component result value was below the low limit of the configured A1c component range.
A1c > Measuring Interval	CH	Error	Yes	The A1c component result value was above the high limit of the configured A1c component range.
Abnormal Assay	CH	Alphanumeric	Yes	Results monitoring detected an abnormal assay.
Abnormal Reaction	CH	Alphanumeric	Yes	A foam error occurred.
Above Check	IM	Alphanumeric	Yes	The result was above a check range in the test definition range setup.
Above Linearity	IM	Alphanumeric	Yes	The result was above the linearity in the test definition.
Absorbance Error	CH	Error	Yes	The photometer is outside the measuring range.
Autorepeat	CH/IM	Alphanumeric	Yes	The system automatically orders this assay as a repeat as the test definition specifies.
Below Check	IM	Alphanumeric	Yes	The result is below the check range as the test definition range setup defines.
Below Linearity	IM	Alphanumeric	Yes	The result is below the linearity in the test definition.
Bubble Detected	CH/IM	None	Yes	The system detected a sample integrity or insufficient sample error.
Cal Accepted	IM	Alphanumeric	Yes	The system obtained the result using an operator-accepted calibration.

Flag	Analyzer	Result Type	To LIS	Notes
Cal Expired	CH/IM	Calibration	Yes	The active calibration expired.
Cal Extended	IM	Alphanumeric	Yes	The operator extended the active calibration.
Cal Invalid	IM	None	No	The operator did not perform the calibration or the calibration failed.
Cal None	CH/IM	None	No	The calibration has failed, expired, or not run.
Cal Required	CH/IM	None	Yes	A valid calibration is not available for the reagent lot.
Calculated Result	CH/IM	Alphanumeric	Yes	The result is for a ratio test.
Canceled	CH/IM	None	Yes	The system canceled the test.
Check Component Flag	CH/IM	Alphanumeric	Yes	One of the ratio components has a flag that may have impacted the calculated result.
Check DL State	CH/IM	None	Yes	The system cannot process tests because of a DL error.
Check QC	CH/IM	None	Yes	The system cannot process the test due to an outstanding QC violation or no open control bracket. Run QC or open a QC bracket to start processing patient tests.
Check SH State	CH/IM	None	Yes	The system cannot process tests because the Sample Handler is not in the correct state or the covers are open.
Check Stability	IM	None	Yes	The result aspiration exceeded the Analyte Stability or First Aspiration Time Out in the test definition.

Flag	Analyzer	Result Type	To LIS	Notes
Check Variable	IM	Error	Yes	A portion of the calculated equation was divided by 0.
Clog	IM	None	Yes	The system detected a probe clog.
Conf N/A	IM	Error	Yes	The system cannot calculate a result for a confirmatory assay.
Contaminated	CH/IM	None	Yes	The reagent probe was contaminated.
Control Bracketed	IM	None	Yes	The operator must run QC before and after this test or series of tests before the result is displayed.
Correlated	CH/IM	Alphanumeric	Yes	The system produced the result by correlation coefficients.
Critical High	CH/IM	Alphanumeric	Yes	The result is above the critical high value from the assay's test reference range definition.
Critical Low	CH/IM	Alphanumeric	Yes	The result is below the critical low value from the assay's test reference range definition.
Cuvette Loader Error	IM	None	Yes	The system was unable to complete the test because the cuvette jammed or did not load.
Cuvette Temperature Out of Range	IM	None	Yes	The cuvette ring temperature was out of range.
Delta Check Range Conflict	IM	Alphanumeric	Yes	The system generated Exceeded Delta Check and Within Delta from the matching ranges.

Flag	Analyzer	Result Type	To LIS	Notes
Diluted	IM	Alphanumeric	Yes	The result was calculated using a system or manual dilution.
Dilution Expired	CH/IM	None	Yes	The analyzer was not able to use an existing dilution to repeat a test. The operator should reload the sample.
Dilution Options	CH/IM	Alphanumeric	No	Test option flag. The test has manual or system dilutions.
Dilution Panel	CH/IM	Alphanumeric	No	The dilution factors selected for this dilution panel. It is a single test with multiple dilutions.
Discarded	CH	None	Yes	The system discarded the Control Bracketed test results because the closing QC bracket failed.
Exceeded Delta Check	IM	Alphanumeric	Yes	The difference between the current result and the previous result of the same test on the same patient exceeded the limit.
Final Optical Density	CH	Error	Yes	The final optical density (OD) is greater than the photometer's linear range.
Final Result Rule	IM	Alphanumeric	Yes	The system obtained the result using the Final Result Rule option. The result is considered the final result.
General TDef Error	IM	Error	Yes	The module software was unable to interpret new error type.
Has Comments	CH/IM	Alphanumeric	Yes	The system added comments based on range checking.

Flag	Analyzer	Result Type	To LIS	Notes
Has Operator-specified Reagents	CH/IM	Alphanumeric	Yes	The operator has selected specific reagent lots or packs for this test request.
Hemolyzed	CH/IM	Alphanumeric	Yes	The hemolytic result is greater than or equal to the threshold in the test definition.
High	CH/IM	Alphanumeric	Yes	The patient result is above the high value for the result reference range or the control result is above the high value in the control definition.
High CV	IM	Alphanumeric	Yes	The measured coefficient of variation (CV) for the test replicates is above the Acceptable CV in the test definition for the assay.
Icteric	CH/IM	Alphanumeric	Yes	The icteric result is greater than or equal to the threshold in the test definition.
IM Acid Error	IM	None	Yes	The system detected insufficient IM Acid to perform the test.
IM Base Error	IM	None	Yes	The system detected insufficient IM Base to perform the test.
Incomplete Set	IM	None	Yes	A required calibrator level is not on the system.
Incubation Ring Error	IM	None	Yes	The system detected an error during incubation.
Incubation Temperature is Out of Range.	CH	Alphanumeric	Yes	The reaction ring bath temperature is outside the predefined range.

Flag	Analyzer	Result Type	To LIS	Notes
Incubation Temperature is Out of Range.	IM	None	Yes	The reaction ring compartment temperature is outside the predefined range.
Initial Optical Density	CH	None	Yes	The Initial Optical Density (OD) is greater than the photometer's linear range.
Insufficient Reagent	CH/IM	None	Yes	The reagent volume is not sufficient for the ordered test.
Insufficient Sample	CH/IM	None	Yes	The sample volume is not sufficient for the ordered test.
Internal Error	IM	None	No	The scheduler lost control of this test. The system is unable to continue with this test for safety reasons.
Invalid Test	CH	None	Yes	The test definition for this assay does not exist or the IMT subsystem is not on.
Investigational	CH/IM	Alphanumeric	Yes	The test is defined as Investigational in the test definition. If the system flags 1 or more ratio components as Investigational, it also flags the ratio result as Investigational. The system changes the result to the Hold test state.
Less than Zero	CH	Alphanumeric	Yes	The system returned a negative number as a result.
Lipemic	CH/IM	Alphanumeric	Yes	The lipemic result is greater than or equal to the threshold in the test definition.
Lot Expired	IM	QC	Yes	A QC material expired prior to download to the analyzer.

Flag	Analyzer	Result Type	To LIS	Notes
Low	CH/IM	Alphanumeric	Yes	The patient result is below the low value for the result reference range or the control result is below the low value in the control definition.
Low IM Acid	IM	None	No	The system detected insufficient IM Acid to perform the test.
Low IM Base	IM	None	No	The system detected insufficient IM Base to perform the test.
Low IM Wash	IM	None	No	The system detected insufficient IM Wash to perform the test.
Low Probe Wash	IM	None	No	The system detected insufficient probe wash to perform the test.
Low Tips	IM	None	No	The system could not perform the test because of insufficient tips.
Low Water	IM	None	No	The system could not perform the test because of insufficient water.
Luminometer Error	IM	Alphanumeric	Yes	The system obtained the result while the PMT was out of temperature range.
Manually Added	CH/IM	Alphanumeric	Yes	The operator added the result.
Manually Canceled	IM	None	Yes	The operator canceled the test.
Manually Diluted	CH/IM	Alphanumeric	Yes	A manual dilution value is defined and not equal to 1. The system does not apply a flag to a result for a manually entered test result.

Flag	Analyzer	Result Type	To LIS	Notes
Max Absorbance (K)	CH	Alphanumeric	Yes	The result exceeded the maximum absorbance limit.
Meaned Result	IM	Alphanumeric	No	The reported result is an average of 2 or more replicate results.
Measurement Error	CH	Error	Yes	The detector did not generate a reading or the assay parameter detected an issue.
Mechanism down	CH	None	Yes	Mechanical errors on the analyzer prevented the system from processing this test request.
Missing Consumable	IM	None	No	System fluids are not available on the analyzer. Replace system fluids and reload the sample.
Missing Reading	CH	Error	Yes	The system could not use 1 or more readings to calculate the result. If this occurred on more than 1 test, troubleshoot the photometer. For a single test, rerun the test.
Module Unavailable	CH/IM	None	Yes	The system cannot perform the test because a subsystem is offline.
Multiple Results	IM	Alphanumeric	No	The system reported more than 1 result for this test.
Multiple Results With Critical Result	IM	Alphanumeric	No	The system reported more than 1 result and 1 or more results were critical.
No Ancillary	IM	None	No	The test requires an ancillary reagent.

Flag	Analyzer	Result Type	To LIS	Notes
No Calculation	CH	Error	Yes	The result is greater than the MaxResultValueLimit configured in the test definition or a result calculation attempted to divide by zero. If the result is for a ratio test and an incorrect math calculation causes the error, the system does not send the flag to the LIS.
No Diluent	IM	None	No	The system scheduled an automatic dilution and did not load a diluent for this test.
No Dilution Allowed	CH	None	No	No system dilutions are available.
No Interpretation	IM	Alphanumeric	Yes	The system was unable to provide an interpretation because the Final Result Rule (FRR) could not get 2/3 interpretations when running multiples.
No Lot Match	CH/IM	None	No	The test requires a specific primary reagent and ancillary reagent lot combination.
No Primary	CH	None	No	Primary reagent is disabled, unusable, or not loaded for this test.
Omitted Rep	IM	Alphanumeric	No	The system excluded 1 or more replicates in the calculation of the meaned test result.

Flag	Analyzer	Result Type	To LIS	Notes
Operator-defined Assay	CH	Alphanumeric	Yes	The operator created the assay using Operator-defined. The laboratory is responsible for validating any modifications they make to the instructions, systems, reagents, or software provided by Siemens Healthineers.
Operator-defined Dilution	CH	Alphanumeric	Yes	The operator set the dilution to a level other than that defined by the manufacturer. The laboratory is responsible for validating any modifications they make to the instructions, systems, reagents, or software provided by Siemens Healthineers.
Operator Interpretation (uses Range Setup)	CH/IM	Alphanumeric	Yes	Operator defined interpretations that are added to the result. These may be in addition to manufacturer predefined interpretations. The laboratory is responsible for validating any modifications they make to the instructions, systems, reagents, or software provided by Siemens Healthineers.
Overdiluted	CH/IM	Alphanumeric/ Error	Yes	The system did not obtain a result because the diluted sample result is below the overdilution point in the test definition for this assay.
PMT Temperature	IM	Alphanumeric	Yes	PMT temperature was out of range.

Flag	Analyzer	Result Type	To LIS	Notes
Predefined: Confirmed	IM	Alphanumeric	No	Range Checking: manufacturer-defined interpretations.
Predefined: Equivocal	IM	Alphanumeric	No	Range Checking: manufacturer-defined interpretations.
Predefined: Moderate	IM	Alphanumeric	No	Range Checking: manufacturer-defined interpretations.
Predefined: Negative	IM	Alphanumeric	No	Range Checking: manufacturer-defined interpretations.
Predefined: None To Mild	IM	Alphanumeric	No	Range Checking: manufacturer-defined interpretations.
Predefined: Non-Reactive	IM	Alphanumeric	No	Range Checking: manufacturer-defined interpretations.
Predefined: Not Confirmed	IM	Alphanumeric	No	Range Checking: manufacturer-defined interpretations.
Predefined: Positive	IM	Alphanumeric	No	Range Checking: manufacturer-defined interpretations.
Predefined: Reactive	IM	Alphanumeric	No	Range Checking: manufacturer-defined interpretations.
Predefined: Severe	CH	Alphanumeric	No	Range Checking: manufacturer-defined interpretations.
Priming	CH	None	No	The system cannot perform the test because the system needs to schedule priming for a probe or a pump.

Flag	Analyzer	Result Type	To LIS	Notes
QC Expired	CH/IM	QC	Yes	A QC material expired prior to download to the analyzer.
QC Fail	CH/IM	Alphanumeric	Yes	An operator-specified QC event occurred on this test prior to the patient test.
QC Stability Expired	CH/IM	QC	Yes	A QC material expired prior to download to the analyzer.
Rack ID Conflict	CH/IM	None	No	The system determined that orders created with an SID and Rack ID were not where the system expected them to be within a rack. The system suspends these orders out of safety. The operator can restart the orders with unsuspend.
Rack ID Timeout	CH/IM	None	No	Orders created with just a Rack ID that are not matched to a tube within 4 hours. The system suspends these orders and awaits the operator intervention to unsuspend after careful review.
Reagent Compartment Error	IM	None	Yes	The system is unable to dispense reagents due to mechanical error or packs in unexpected places.
Reagent Compartment Humidity	IM	None	Yes	The reagent compartment humidity had exceeded or fallen below operating range.
Reagent Compartment Temperature	IM	None	Yes	The system obtained the result using primary or ancillary reagents it received during a reagent compartment temperature warning condition.

Flag	Analyzer	Result Type	To LIS	Notes
Reagent Loader Error	CH/IM	None	Yes	The system is unable to load reagents to the compartment for this test.
Reagent Lot Expired	CH/IM	None	Yes	The reagent lot expired.
Reagent Probe1 Error	IM	None	Yes	The system was unable to dispense reagent.
Reagent Probe 2 Error	IM	None	Yes	The system was unable to dispense reagent.
Reagent Probe 3 Error	IM	None	Yes	The system was unable to dispense reagent.
Reagent Ring Temperature is Out of Range.	IM	Alphanumeric	Yes	The system detected a reagent ring temperature that was out of range.
Reagent Ring Temperature Warning	IM	Alphanumeric	Yes	The system detected a reagent ring temperature that was out of range.
Reagent Stability Expired	IM	None	Yes	The system was unable to use a reagent because the onboard stability had expired.
Re-analysis	CH/IM	Alphanumeric	Yes	The test was repeated.
Redilute	CH/IM	Alphanumeric	Yes	The operator must dilute and repeat this test.
Reference Interval Conflict	CH/IM	Alphanumeric	Yes	The result matched opposite ending reference intervals or opposite delta check intervals. For example, this flag could indicate a result that matches a critical high and critical low in the same range. The system added this flag for safety and the operator must review the ranges setup.

Flag	Analyzer	Result Type	To LIS	Notes
Reflexed	CH/IM	Alphanumeric	Yes	The system automatically ordered this test because of another assay's result as the test definition specifies.
Repeat	CH	Alphanumeric	Yes	The operator has requested a Repeat test. Autorepeat and Repeat flags are mutually exclusive.
Requires Centrifugation	IM	None	No	The operator must centrifuge the sample before repeating the test. After reloading the sample, the system proceeds as if the operator centrifuged the sample. This flag can only appear if the operator sets Centrifuge before Repeating in the IM test definition.
Result Reused	IM	Alphanumeric	Yes	The system used an existing result from the same worklist for a component when calculating ratio test result.
Retained Result	IM	None	No	The system waits for the closing control bracket before releasing the result.
Sample Integrity	CH/IM	None	Yes	The system detected an irregular sample aspiration. The test result is Error.
Sample Probe Error	IM	None	Yes	The system was unable to complete the scheduled test because the sample probe was unavailable.
Sample Tip Loader Error	IM	None	Yes	The system is unable to load a sample tip.

Flag	Analyzer	Result Type	To LIS	Notes
Signal shape error	IM	Error	No	The system did not obtain a result because a signal shape error occurred.
Signal shape error: Failed or abnormal shape	IM	Error	No	The system did not obtain a result because the signal shape was abnormal.
Signal shape error: High average dark count	IM	Error	No	The system did not obtain a result because the signal had a high average dark count.
Signal shape error: No signal	IM	Error	No	The system did not obtain a result because there was no signal.
Signal shape error: Pre-light ratio test failed	IM	Error	No	The system did not obtain a result because there was too much light.
Signal shape error: Signal too low	IM	Error	No	The system did not obtain a result because the signal was low.
Signal shape error: Spike occurred	IM	Error	No	The system did not obtain a result because of an erratic signal.
Software Error	CH/IM	None	Yes	A database or software corruption of the result caused an error. This flag indicates a serious problem. Stop the system and check the results.
Sort Test	CH/IM	Alphanumeric	No	The system uses Sort Test to handle sample output. Sort Test is non-resulting test.
STAT Test	CH/IM	Alphanumeric	Yes	The test has the highest priority.

Flag	Analyzer	Result Type	To LIS	Notes
Study	IM	Alphanumeric	Yes	The system performed a non-reportable test, such as a Precision Study. The system changes the result to the Hold test state.
System Error	CH/IM	None	No	Test request encountered more than 1 mechanical error. Check your capabilities for this analyzer.
Test Canceled	CH/IM	None	Yes	The operator manually canceled the test.
Test order Option not met	CH/IM	None	No	The analyzer did not perform the test as requested
tHb < Measuring Interval	CH	Error	Yes	The tHb component result value was below the low limit of the configured tHb component range.
tHb > Measuring Interval	CH	Error	Yes	The tHb component result value was above the high limit of the configured tHb component range.
Time Exceeded	CH/IM	None	Yes	The component test results of a ratio or multicomponent test exceeds the Result Time Limit setting in the IM test definition. The system presets the CH Result Time Limit.
Unable to process LYTES	CH	None	Yes	The CH Analyzer was unable to process NA, K, and CL tests.
Unable to wash cuvettes	CH	None	Yes	The system was unable to wash cuvettes due to a lack of system fluids or a mechanical error.

Flag	Analyzer	Result Type	To LIS	Notes
Unknown Error	CH	None	Yes	The system detected an error in the methpar.
Waiting for HIL	CH/IM	Alphanumeric	Yes	The result is pending the results of the serum indices: hemolysis, icterus, or lipemia.
Waiting for H	CH/IM	Alphanumeric	No	The result is pending the results of the hemolysis serum index.
Waiting for I	CH/IM	Alphanumeric	No	The result is pending the results of the icterus serum index.
Waiting for L	CH/IM	Alphanumeric	No	The result is pending the results of the lipemia serum index.
Wash Ring Error	IM	None	Yes	The analyzer cannot perform the test because the wash ring subsystem is Offline. Check your capabilities.
Waste Full	IM	None	No	The system cannot perform the test because the cuvette bin, sample tip bin, tip tray bin, or the waste reservoir is full.
Water Pressure Error	CH/IM	None	Yes	The analyzer cannot perform the test because water pressure is out of tolerance.
Whole Blood Sample Expired	CH/IM	None	Yes	Whole blood samples must be loaded in a STAT tray and aspirated within 10 minutes of loading on the system. The 10 minute time was exceeded.
Within Check	CH/IM	Alphanumeric	Yes	The result is within the check range in the test definition.

Flag	Analyzer	Result Type	To LIS	Notes
Within Delta	CH/IM	Alphanumeric	Yes	The difference in results between the current result and the previous result of the same test on the same patient is within the limits. To get this flag, the operator must configure the Delta Check Range in the test definition.
Wrong Pack ID	CH/IM	None	No	The operator did not load the primary or ancillary reagent with the specified pack serial number for this test.

About Configuring the Worklist Display

The following headers are available in the Worklist display.

NOTE: Selecting ⚙ opens the configuration screen.

Selecting **Restore Defaults** changes the column content to those labeled as (Default) in the following table:

Column Content for Sample View
Priority (No header)
SID (Default) Run ID
Sample Type
Order Time (Default) Scanned Time Result Time
Name (Default) PID / Lot Rack ID
Sample Status

Column Content for Sample View
Analyzer (Default)
Aspiration Date and Time
SID
Run ID
Name
PID / Lot
Rack ID
Order Time
Scanned Time
Result Time
Sample Type
Specimen Type
Patient Location
None
NOTE: This column is only visible when the filter pane is collapsed.
Analyzer
Aspiration Date and Time
SID
Run ID
Name
PID / Lot
Rack ID
Order Time
Scanned Time
Result Time
Sample Type
Specimen Type (Default)
Patient Location
None
Comments (No header)

Column Content for Test View
Priority (No header)
NOTE: This column is only visible when the filter pane is collapsed. Order Time (Default) Scanned Time Result Time
SID (Default) Run ID
Name (Default) PID / Lot Rack ID Reagent Lot
Test
Status (No header)
Conc/Index (Default) RLU/ABS
Interpretation
Flags
NOTE: This column is only visible when the filter pane is collapsed. Analyzer (Default) Aspiration Date and Time SID Run ID Name PID / Lot Rack ID Order Time Scanned Time Result Time

Column Content for Test View
Sample Type
Specimen Type
Patient Location
None
Comments (No header)

Reviewing Patient Results in Worklist

1. Navigate to **Worklist**.
2. Perform 1 of the following:
   - To view options related to Samples, select **Samples** in View By.
   - To view options related to Tests, select **Tests** in View By.
3. To configure the Worklist columns, select ⚙.
4. To narrow the displayed Samples or Tests, filter the list.
5. To sort the Worklist, select an option from the drop-down menu for Sort By or select a column header.

   NOTE: Selecting the same column header a second time reverses the sort order.

About the Patient Order Worklist Format

The operator can create patient order worklists using any plain text editor or spreadsheet program that can generate a CSV format file. If using a spreadsheet program, the operator must save the file in CSV format. Depending on the country, the spreadsheet program may save the file using decimals instead of commas as delimiters. Without commas as delimiters, the system will fail to import the worklist.

Acceptable Specimen types are:

- Amniotic Fluid
- Buffer-based Solutions
- Buffered Fecal Matter
- CSF
- Oral Fluids
- Other

- Plasma
- RBC Hemolysate
- Saliva
- Serum
- Urine
- Whole Blood

The following examples show the valid formats for the patient order worklist data. The CSV text file examples shows the format of the file that the system accepts as input for worklist import. The spreadsheet program examples indicate the order that the cells must appear, from left to right in the worklist. Worklists can contain multiple rows, 1 row for each sample. The system reads the first row of Carryover Study (COS) worklists as header information.

The following is an example of a worklist (Non-COS) CSV text file:

100,,,CA125,10,903,20,Serum,1-1-1-1-1-1

1001,,,COR,,125,10,Serum,2-2-2-2-2-2

1002,1000,A,COR,5,307,50,Plasma,

The following is the same example in a spreadsheet program.

worklist format (Non-COS)

(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)
100	—	—	CA125	10	903	20	Serum	1-1-1-1-1-1
1001	—	—	COR	—	125	10	Serum	2-2-2-2-2-2
1002	1000	A	COR	5	307	50	PlasmaPlasma	—

NOTE: Worklists (Non-COS) have order data in the first row. The system does not allow header data in non-COS worklists.

For more information on patient orders format requirements, see (Page 317 *About Patient Orders*).

Column	Notes	Example
A	Sample ID.	1002
B	Rack number. This cell can remain blank.	1000
C	Tube position if the worklist contains a rack number in Column B. If Column B does not contain a rack number, this cell remains blank.	A
D	Requested test for the sample in Column A. The cell contains only the test name. The cell cannot contain the display name, LIS code, or print name. Panel or ratio tests are invalid. The system lists the available test names in **CH Test Definition > Test Name/ID** and **IM Test Definition > Test Name/ID**.	COR
E	Replicates for the requested test in Column D. Must be 1 or more. Must be 1 for CH tests. For more information about replicates and multiples, see (Page 319 *About Replicate, Multiple, and Repeat Tests*).	5
F	Reagent lot number for the specified test in Column D. This cell can remain blank.	307

Column	Notes	Example
G	Dilution for the specified test in Column D. If the same sample and test have multiple dilutions, the operator must add each dilution in a new row. The operator must enter 0 for no dilution.	50
H	Specimen type for the specified sample in Column A (case sensitive).	Plasma
I	Serial number of the analyzer performing the requested test in Column D (case sensitive). This cell can remain blank. **NOTE:** If creating the worklist in a spreadsheet program, this cell must contain at least a blank space or the system rejects the worklist. With a blank space in this cell, the system schedules an assay on any available analyzer configured for that assay.	F3F847474

The following is an example of a COS worklist CSV text file:

Sample ID,Rack Number,Tube Position,Specimen Type,Analyzer Serial,Test

100,,,Serum,1-1-1-1-1-1 ,CA125

1001,,,Serum,2-2-2-2-2-2,COR,CA125,COR,CA125

1002,1000,A,Serum,3-3-3-3-3-3,COR,COR,COR

The following is the same example in a spreadsheet program.

COS worklist format

(A)	(B)	(C)	(D)	(E)	(F)			
Sample ID	Rack Number	Tube Position	Specimen Type	Analyzer Serial	Test			
100	—	—	Serum	1-1-1-1-1-1	CA125	—	—	—
1001	—	—	Serum	2-2-2-2-2-2	COR	CA125	COR	CA125
1002	1000	A	Serum	3-3-3-3-3-3	COR	COR	COR	—

NOTE: COS worklist must have the specified header information in the first row. The system does not import any order information from the first row of a COS worklist.

For more information on patient orders format requirements, see (Page 317 *About Patient Orders*).

Column	Notes	Example
A	Sample ID.	1002
B	Rack number. This cell can remain blank.	1000
C	Tube position if the worklist contains a rack number in Column B. If Column B does not contain a rack number, this cell remains blank.	A
D	Specimen type for the sample in Column A (case sensitive).	Plasma
E	Serial number of the analyzer performing the requested test in Column F (case sensitive). This cell can remain blank.	F3F847474
F	Requested test for sample in A. The cell contains only the test name. It cannot contain the display name, LIS code, or print name. Panel or ratio tests are invalid. The system lists the available test names in **CH Test Definition > Test Name/ID** and **IM Test Definition > Test Name/ID**.	COR

13 Samples

Samples

This chapter provides information about sample management.

About Sample Integrity

The system uses liquid level and pressure sensing to check for the following conditions before and during sample aspiration:

- Clogs
- Bubbles
- Short sampling
- Probe crashes

The system checks for the following interfering indices:

- Hemolysis
- Icterus
- Lipemia

NOTE: The IM Analyzer requires connection to a CH Analyzer to measure HIL indices (Page 723 *About HIL Absorbance Measurements*).

About Probe Level Sensing

The CH Analyzer and IM Analyzer perform level sensing when a probe approaches the aspirating liquid. Level sensing occurs with the sample, dilution, and reagent probes to ensure that the probe is contacting the liquid. It allows the probe to minimize the depth the tip enters into the liquid, as the CH Analyzer only cleans the tip of the probe.

The analyzer probes that include this feature include the following:

- Dilution probe (CH Analyzer only): The analyzer performs level sensing when aspirating out of the primary sample container.
- Sample probe: The level detect confirms the presence of liquid.

  The CH Analyzer monitors the available volume in the dilution cuvette then the sample probe moves to that height.

  The IM Analyzer monitors the available volume in the sample container then the sample probe moves to that height.
- Reagent probes: The analyzer requires level sensing when aspirating from a reagent pack.

About Probe Crash Detection

The CH Analyzer and IM Analyzer probes are equipped with crash detection:

- Sample probe
- Dilution probe (CH Analyzer only)
- Reagent probes

Crash detection allows the probe to detect when it hits an obstruction during its downward motion. When the probe encounters an obstacle, the probe immediately stops its motion to protect itself from damage. Following a probe crash, the analyzer automatically recovers, reschedules any interrupted tests, and continues with the remaining test workload.

About Probe Pressure Sensing

All analyzer probes have a pressure sensor. The analyzer monitors and records probe pressures during all aspirations. Pressure sensing monitors for probe clogs, short aspirations, and other abnormal aspirations.

About SH Samples Overview and Standalone Rack Overview

SH Samples Overview and standalone Rack Overview provide detailed sample information.

SH Configuration

The left side of the screen displays information about all the tube positions for the selected drawer location (1 55-position rack or 3 15-position racks) in Racks (Page 366 *About Racks*).

The system displays 1 of the following icons next to each rack:

Rack type icon	Description
No icon	Standard rack
	STAT rack
	Special rack
	Special STAT rack

The following sample information displays:

- Detailed sample status icon
- Patient name
- Sample ID
- Sample processing status

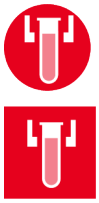
Selecting a sample displays Sample Details on the right side of the screen. (Page 369 *About Sample Details*)

Standalone Configuration

The left side of the screen displays information about all the tube positions for the selected rack in Samples and the Sample Details for the selected sample. The sample information that displays is the same as the SH configuration.

Detailed Sample Status Icon	Description
Circle	Patient sample.
Square	Cal-QC sample.

Detailed Sample Status Icon	Description
	The system cannot identify the container because of a barcode read error. The operator must remove the container from the system to clean, reposition, or replace the barcode label. The operator may then place the container back in the system.
	The system detected a container with the same sample ID as another container currently on the system. The operator must remove the duplicate container from the system. The operator may return the container to the system after resolving the duplicate ID.
	The system does not include a Decapper and detected a cap on a container. The operator must remove the container from the system and remove the cap, then return the container to the system.
	The system detected an error while decapping a supported container. The operator must remove the container from the system. The operator may remove the cap from the container then return the container to the system, or return the capped container to the system after resolving the decapping error.
	The system detected a container the system does not support. The operator must remove the container from the system, transfer the contents to a container the system supports, and return the new container to the system.

Detailed Sample Status Icon	Description
	The system detected an error while transferring the container from one point to another. The operator must remove the container from the system and inspect the rack position to determine if the problem is with the rack position or the container.
	The system detected a sample container with an HIL error flag. The operator must view the sample details to determine the error type (H, I, or L). After determining the error type, the operator must reference the IFU for each assay to investigate the error and perform the appropriate action.
	An aspiration-related error occurred. The operator must remove the container from the system and address the error. The operator may return the container to the system after resolving the error.
	The operator must manually retrieve the sample container.
	The system identified a container and is waiting to sort the container.
	The system cannot perform 1 or more tests on the sample because of a problem with an assay. The operator must review the alerts and resolve the assay problem.

Detailed Sample Status Icon	Description
	The sample requires intervention.
	A calibrator or QC is not usable because of the following conditions: • Operator marked unusable • Lot expired • Stability expired • Unrefrigerated time expired • Insufficient material The operator must remove the container from the system and discard the material.
	Superimposed on another status icon to indicate a STAT sample.
	This icon is superimposed on another patient sample icon and indicates that the sample originated from the LAS.

About Racks

Racks displays icons that indicate rack type, drawers status, and rack zone configuration, in addition to the sample status information in Samples.

The system displays 1 of the following icons next to each rack:

Rack type icon	Description
No icon	Standard rack
	STAT rack

Rack type icon	Description
	Special STAT rack
	Special rack

The system displays 1 of the following icons below each drawer position:

Drawer status icon	Description
	The sample drawer is open. The operator must close the drawer to continue processing samples from the drawer.
	The sample drawer is closed. The operator must open the drawer fully to ensure the DVS performs a complete scan of the drawer, then close the drawer.
	The system detected a drawer hardware error.
	The system detected a drawer DVS error.
No icon displays	The DVS scan of the drawer contents completes and the system proceeds with processing samples from the drawer.

The system displays 1 of the following icons below each rack zone (Page 813 *About Sample Processing Configuration Profiles*):

Rack zone icons	Description
	Input Only The system uses a rack in the zone for sample processing input only. The system takes samples from a rack in an input zone for processing.
	Output Normal The system uses a rack in the zone for sample processing output. The system returns samples to a rack in an output zone and places them in the first available rack position.
	Output Sort The system uses a rack in the zone for sample processing output. The system returns samples to a rack in an output zone according to the sort groups the operator assigns to the zone . Each rack shows the list of assigned sort groups.
	Holding Area The system places samples in a rack in the zone before moving them to their final destination.
	Archive The system uses a rack in the zone for sample archiving.
	Combined The system uses a rack in the zone for sample processing input and output.

When the operator defines sort groups, the system displays a line between each sort group type in each rack position the operator defines as Output Sort. When the operator selects an Output Sort rack, the system displays the sort group information in the left area of Samples Overview.

The system displays a colored icon for each sample container position in every rack in the sample drawers. The shape and color of the icon describes the status of the sample container position (Page 366 *About Racks*).

About Sample Details

Sample Details provides additional details for the selected sample.

Sample Details displays the following sample information:

Sample detail	Notes
Name	Patient name or product name for Cal-QC samples.
Sample ID	The barcode ID for the sample.
Lot/Patient ID	The following displays: • Cal samples: Lot ID from Calibrator Definitions • QC samples: QC Lot from QC Definitions • Patient samples: Patient ID
Priority	The sample priority, such as Routine or STAT.
Status	The sample status if no errors are associated with the sample. The statuses include: Pending, Started, Aspirated, and Complete. If an error is associated with the sample, the status describes the type of error.
Sample Type	The sample type. The types include: Patient, QC, and Cal.
Sample Container Type	The general type of tube containing the sample. The types include: • Small Diameter Short Tube • Small Diameter Tall Tube • Large Diameter Short Tube • Large Diameter Tall Tube
Scanned	Date and time the TCS scans the sample.

Sample detail	Notes
Location	SH: The position of the sample in the rack. DL/RH: Rack ID and position number.
Aspirated	Date and time the system aspirates the sample.
Sample Attributes	The sample container special attributes. The attributes include: • Tube Top Cup • Capillary • Capped • False Bottom • None (no special attributes)
Problems Associated	The errors associated with the sample. If no errors are associated, the system displays None.

Sample Details displays the following functions:

Function	Description
Print Barcode	Prints a barcode for the selected sample
View/Edit	Displays the appropriate sample detail screen

Viewing SH Rack Details

1. Navigate to **Samples Overview** and select **Racks**.
2. In a multi-SH system, select the appropriate SH tab then select **Racks**.
3. Select a rack.

Viewing Sample Details

1. Navigate to **Samples Overview** and select **Racks**.
2. In a multi-SH system, select the appropriate SH tab.

3. Select the rack containing the sample.
4. In the left-hand area, select the sample.

About Sample Loading and Unloading

The system uses the following criteria to determine which sample to transfer from an SH drawer to the Atellica Magline Transport, and the output rack to return the sample to after processing is complete:

- Rack status
- Rack load time
- Tube status
- Tube load time
- Processing rules for selecting tubes to transfer to the Atellica Magline Transport
- Processing rules for selecting output racks to transfer tubes from the Atellica Magline Transport

About Rack Status

The system assigns a status to a rack after the operator loads the rack in a sample drawer. The rack status helps determine the tube status and tube load time.

The following table describes each status the system may assign to a rack:

Rack status	Notes
New: Rack previously empty	The system assigns a status of New to a rack when the operator removes an empty rack from a sample drawer, loads tubes into the rack, and reloads the rack into a sample drawer.
New: No tubes	The system assigns a status of New to a rack when the SH identifies the rack is empty.
New: New rack	The system assigns a status of New to a rack when the SH detects a rack that was not present the last time the operator closed the drawer.

Rack status	Notes
New: New location	The system assigns a status of New to a rack when the SH detects the rack was in a different drawer location the last time the operator closed the drawer.
New: All previous tubes removed	The system assigns a status of New to a rack when it meets the following conditions after the operator closes the sample drawer: • The rack was in the same location in the drawer the last time the operator closed the drawer. • The rack has the same rack ID. • All formerly occupied positions in the rack are now empty.
Old: Routine rack remaining occupied in same position	The system assigns a status of Old to a routine Input Only or Input/Output rack when it meets the following conditions after the operator closes the sample drawer: • The rack was in the same location in the drawer the last time the operator closed the drawer. • The rack has the same rack ID. • The rack was not previously empty. • At least 1 position in the rack that was previously occupied by a tube is still occupied.

Rack status	Notes
Old: Output racks with samples	The system assigns a status of Old to an Output rack when it meets the following conditions after the operator closes the sample drawer: • The rack type is Output Normal or Output Sort. • The rack was in the same location in the drawer the last time the operator closed the drawer. • The rack has the same rack ID. • The rack was not previously empty. • At least 1 position in the rack that was previously occupied by a tube is still occupied.
Pending verification: STAT racks	The system assigns a status of Pending Verification to a STAT rack when it meets the following conditions after the operator closes the sample drawer: • The rack was in the same location in the drawer the last time the operator closed the drawer. • The rack has the same rack ID. • The rack was not previously empty. • At least 1 position in the rack that was previously occupied by an identified tube is still occupied.

About Rack Load Time

The system determines the load time of a rack based on the rack status. The system uses the rack load time for selecting a rack for processing and determining the tube load time.

The following table describes each rack load time scenario:

Rack status	Notes
New	The system sets the load time of a rack with a status of New to the time the operator closes the sample drawer.
Old	The system does not change the load time for a rack with a status of Old. Racks with a status of Old have the highest processing priority.
Pending verification	The system does not change the load time for a rack with a status of Pending Verification.

About Tube Status

The system assigns a status to a tube after the operator loads the rack in a sample drawer. The tube status helps determine the tube load time.

The following table describes each status the system may assign to a tube:

Tube status	Notes
New tube: New rack	The system assigns a status of New to every tube in a rack when the system sets the rack status to New.
New tube: Operator inserts new tube in the rack	The system assigns a status of New to a tube in a rack when the operator closes the sample drawer and the SH detects the tube in a position that was previously empty.
New tube: Tube with different characteristics	The system assigns a status of New to a tube in a rack when the operator closes the sample drawer and the SH determines the cup or cap characteristics of a tube in a previously occupied position have changed.

Tube status	Notes
Old tube: Old rack	The system assigns a status of Old to every tube in a rack position that remains occupied when the system sets the rack status to Old. **NOTE:** If the SH determines the cup or cap characteristics of a tube in a previously occupied position have changed, the system assigns a status of New to that tube.
Old tube: Pending verification rack	The system assigns a status of Old to every tube in a rack position that remains occupied when the system sets the rack status to Pending Verification. **NOTE:** If the SH determines the cup or cap characteristics of a tube in a previously occupied position have changed, the system assigns a status of New to that tube.

About Tube Load Times

The system determines the load time of a tube based on the tube status. The system uses the tube load time for selecting a tube to transfer to the Atellica Magline Transport.

The following table describes each tube load time scenario:

Tube status	Notes
New	The system sets the load time of a tube with a status of New to the time the operator closes the sample drawer.
Old	The system does not change the load time for a tube with a status of Old. Tubes with a status of Old have the highest processing priority.

About Sample IDs

The system assigns a sample ID to a tube after the system sets the tube status.

The following table describes each sample ID scenario:

Tube status	Notes
New	The system sets the sample ID for each tube with a status of New to Unknown. The system re-identifies tubes with a sample ID of Unknown.
Old	The system does not change the sample ID for a tube with a status of Old. Tubes with a status of Old have the highest processing priority.

About Rules for Selecting Tubes for Processing

The following table describes the rules the system uses for selecting tubes to transfer from racks in sample drawers to the Atellica Magline Transport for processing:

Rule	Notes
Complete image analysis before beginning tube processing	Image analysis for a tube must be complete before the system selects a tube for processing. The system requires the tube information and position within the rack before tube processing can begin.
Selecting STAT samples for processing	The system uses the following hierarchy when selecting a STAT tube for processing: 1. The system selects the oldest STAT tube with an Unknown sample ID across all sample drawers. 2. The system selects the oldest STAT tube with a known sample ID and a status of Old from a STAT rack with a status of Pending Verification. STAT tubes have a higher priority over routine tubes. The system processes the oldest STAT tube first.
Selecting STAT samples among equal STAT samples	When all STAT samples have the same load time, the system selects STAT samples starting from the back, left-most rack and working from left to right and back to front.
Selecting the oldest routine tube	When there are no STAT tubes for processing, the system selects the oldest routine tube with an Unknown sample ID across all drawers.

Rule	Notes
Selecting routine tubes among equal routine tubes	When all routine samples have the same load time, the system selects routine samples starting from the back, left-most rack and working from left to right and back to front.
Scheduler-initiated loading	The system prioritizes Scheduler-initiated sample load requests over loading new samples, assuming equal sample priority.

About Rules for Selecting Output Racks

The following table describes the rules the system uses for selecting output racks to transfer tubes from the Atellica Magline Transport after processing:

Rule	Notes
Returning a STAT sample	The system returns STAT samples to a STAT rack unless it routes the sample based on sample sorting criteria.
Returning a routine sample	The system returns routine samples to a routine rack unless it routes the sample based on sample sorting criteria.

Rule	Notes
Selecting output racks	The system selects the output rack based on the following criteria: • The rack matches the required type of unload region. • The rack has empty positions. • The rack matches the sorting criteria. • The rack is the oldest rack. • The sample drawer is closed. The system attempts to fill an output rack before unloading samples to another output rack, and attempts to fill the oldest rack first.
Selecting output racks among equal output racks	When all output racks have the same load time, the system selects output racks starting from the back, left-most rack and working from left to right and back to front.

About Rules for Sealing Sample Containers

The operator can only seal patient samples in tubes on the approved sample container list (Page 907 *About Supported Sample Containers*).

These samples route to the Sealer, when available, under the following conditions:

- For archiving samples, the following criteria must be met:
  - Archive Rack Management is enabled.
  - At least 1 SH drawer zone is configured as Archive (Page 813 *About Sample Processing Configuration Profiles*).
  - Seal Archiving Samples is enabled in **Sample Workflow > Sealer Settings**.
  - The tests configured in **Sample Workflow > Wait for Results Workflow** have results, the configured tests are not applicable for the sample, or **Wait for Results Workflow** is disabled.

- For test sort samples, the following criteria must be met:
  - Seal Sample Tubes is enabled in **Test Sort Groups**.
  - The tests configured in **Sample Workflow > Sealer Settings** have results, the configured tests are not applicable for the sample, or the **Wait for Results Workflow** is disabled.
- For samples with no on-system tests (samples are loaded in racks for direct archiving using Input to Archive Racks), the following criteria must be met:
  - Archive Rack Management is enabled.
  - At least 1 SH drawer zone is configured as Archive (Page 813 *About Sample Processing Configuration Profiles*).
  - At least 1 rack is configured for direct archiving.
  - In order to be sealed and archived, the operator must load samples with no on-system tests into a rack configured for direct archiving.
  - Seal Archiving Samples is enabled in **Sample Workflow > Sealer Settings**.
  - The sample has no error conditions.

About the Sample List

Sample List provides access to the current sample status details for all samples on the system.

Filter allows the operator to sort the sample list according to Load Type, Sample Type, Sample Priority, Sample Issues, and Sample Progress or to search for specific samples.

Sample Details displays the following sample information:

Sample detail	Notes
Summary information	The following displays: • Sample icon (Page 362 *About SH Samples Overview and Standalone Rack Overview*). • Patient or product name • Sample ID

Sample detail	Notes
Lot/Patient ID	The following displays: • Cal samples: Lot ID from Calibrator Definitions • QC samples: Parent Lot from QC Definitions • Patient samples: Patient ID
Priority	The sample priority, such as Routine or STAT.
Status	The sample status if no errors are associated with the sample. The statuses include: Pending, Started, Aspirated, Complete, and Overflow (Page 152 *About Samples*). If an error is associated with the sample, the status describes the type of error.
Cap Status	The sample container cap status. The statuses include: Unknown, No Cap, Capped, Decap Pending, Decapped, and Decap Error. **NOTE:** This field only displays if the system is configured with a Decapper.
Sample Type	The sample type. The types include: Patient, QC, and Cal.
Sample Container Type	The general type of tube containing the sample. The types include: • Small Diameter Short Tube • Small Diameter Tall Tube • Large Diameter Short Tube • Large Diameter Tall Tube Tube Top Cup displays when present.

Sample detail	Notes
Location (SH systems)	The current location of the sample. The locations include: the position of the sample in the rack with the rack location and barcode displaying, in the Cal-QC storage area, or on the Atellica Magline Transport.
Source (DL/RH systems)	Rack ID and position number.
Scanned Time	The time the system scans the sample barcode at the TCS (SH systems) or barcode reader (DL/RH systems).
Unloaded Time	Date and time the operator unloads the sample from the system.
Aspirated	Date and time the system aspirates the sample.
Sample Attributes	The sample container special attributes. The attributes include: Tube Top Cup, Capillary, Capped, False Bottom, or None (no special attributes).
Problems Associated	The errors associated with the sample. If no errors are associated, the system displays None.

Sample Details displays the following functions:

Function	Description
Recall	Returns the sample to the SH drawer from anywhere on the system
View/Edit	Displays the appropriate sample detail screen
Locate Sample	Displays SH Samples Overview or standalone Rack Overview with the selected sample and its rack location.

Reviewing the Samples List

1. Navigate to **Samples List**.
2. To narrow the sample list or search for a specific sample, use the options in Filter. Alternatively, scan a sample barcode.
3. To clear filter criteria, select .
4. To sort the Samples List, select a column header.

   NOTE: Select the same column header a second time to reverse the sort order.
5. Select the appropriate sample.

About STAT Samples

STAT Samples provides details of the current status for all STAT samples on the system:

- STAT Samples Needing Intervention
- STAT Samples Inprocess

STAT Samples	Notes
Time of Error	The exact time when the first error for the sample occurred.
Sample ID	The code that identifies a sample. Selecting Sample ID displays Patient Sample Details.
Tests	The tests related to the Sample ID.
Description	The error description displays if 1 test or all tests have the same error. If more than 1 error occurs, Multiple errors displays and the operator can expand the row to view the error for each test.
Impacted Tests	The tests that require intervention.
Time to Completion	The number of minutes until results complete for a sample or an individual test.

STAT Samples	Notes
Time On System	The amount of time since the system read the sample barcode at the TCS.
Location	The last known location of the sample is 1 of the following: • The rack position of the sample: – SH Systems: SH Name/Drawer Number/(Back/Front)/Rack ID/ Rack Position – DL/RH Systems: Rack ID and Position • On the Atellica Magline Transport

The following functions are available for eligible tests:

Function	Notes
Ignore	Ignores any errors for the appropriate sample. The button changes to Undo. Selecting **Ignore** for all rows changes the tile color to green, removes the tile from Notifications, and decrements the count on Notifications.
Undo	Reverses the actions of Ignore.

Reviewing STAT Samples

1. Navigate to **STAT Samples**.
2. To expand a table, select its title.
3. To sort the information, select a column heading.

   NOTE: Selecting the same column heading a second time reverses the sort order.

4. To view the errors for a sample with multiple errors, select ❯ in the appropriate row.
5. To view the status for an inprocess sample with multiple tests, select ❯ in the appropriate row.

6. To force the system to ignore any errors for a specific sample, select **Ignore** for the appropriate sample.
7. To force the system to ignore errors for all samples needing intervention, select **Ignore** for all rows.

   NOTE: Ignoring all errors changes the STAT Samples tile to green status.

About Sample Interventions

Sample Interventions provides the status of onboard samples for which an issue has been detected and requires operator action to resolve.

Sample Interventions displays the following types of samples:

- Patient (non-STAT)
- Calibrations
- QC

Sample Interventions	Notes
Time of Error	The exact time when the first error for the sample occurred.
Sample ID	The code that identifies a patient sample. Selecting **Sample ID** displays Patient Sample Details.
Description	The error description displays if 1 test or all tests have the same error. If more than 1 error occurs, Multiple errors displays and the operator can expand the row to view the error for each test.
Impacted Tests	The tests that require intervention.
Time On System	The amount of time since the system read the sample barcode at the TCS.
Analyzer	Friendly name of affected analyzer.
Assay	Impacted assay.
Material Name	Calibrator or QC material name.
Material Lot	Lot ID from Calibrator Definitions

Sample Interventions	Notes
Location	The last known location of the sample is 1 of the following: • The rack position of the sample: – SH Systems: SH Name/Drawer Number/(Back or Front)/Rack ID/ Rack Position – DL/RH Systems: Rack ID and Position • On the Atellica Magline Transport

Reviewing Sample Interventions

1. Navigate to **Sample Interventions**.
2. To expand a table, select its title.
3. To sort the information, select a column heading.

   NOTE: Selecting the same column heading a second time reverses the sort order.

4. To view the errors for a sample with multiple errors, select ❯ in the appropriate row.

Loading Samples into SH Racks



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling biohazardous materials can cause bodily harm.



CAUTION

Do not fill sample containers past the maximum recommended level of 1 container diameter below the top of the container (for example, the maximum fluid height for a 16 mm diameter container is 16 mm from the top of the container). Overfilling sample containers may cause splashing while the container moves in the SH or on the Atellica Magline® Transport. Fill sample containers to no more than the maximum recommended level.

NOTE: If the system does not include a Decapper, remove caps from sample containers before loading the containers in racks.

1. Place 1 or more sample containers in the appropriate type of rack.
   - For immediate processing, place STAT samples in a STAT rack.
   - Place routine samples in a routine rack.
   - Place false-bottom tubes in a special False-Bottom Tube rack.

   CAUTION

   Do not load false-bottom sample containers in any rack other than a specifically designated special rack for false-bottom sample container use. Placing the sample containers in a rack other than the special rack may result in damage to the system if the probe impacts the sample container bottom.

2. Ensure all sample containers are fully seated to the bottom of the rack.

   CAUTION

   Do not open or close the sample drawer without using caution. Opening or closing the sample drawer too quickly or forcefully can damage the drawer self-closing mechanism or cause splashing of the samples. Open or close the sample drawer slowly. Contact the local technical support provider if the self-closing mechanism is damaged.

3. Load the appropriate racks in a sample drawer (Page 388 *Loading Racks into Sample Drawers*):
   a. Load the rack with patient samples in the appropriate sample drawer position.
   b. Load 1 or more empty routine racks in an appropriate output area or sort area in a sample drawer.

Opening Sample Drawers

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling biohazardous materials can cause bodily harm.

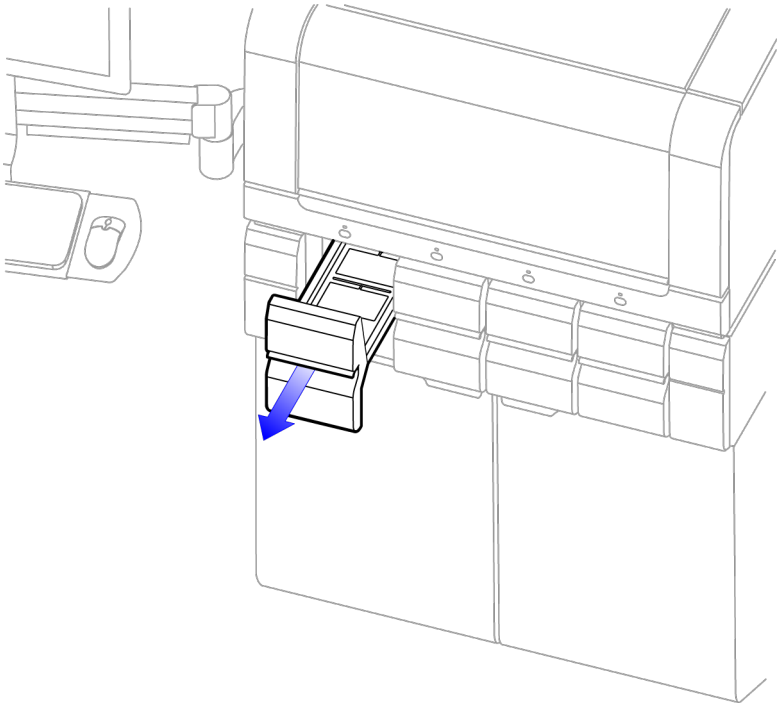
WARNING

Do not reach into the SH when sample drawers are open. The SH robot moves with high speed and force and can cause severe bodily harm.

CAUTION

Do not open or close the sample drawer without using caution. Opening or closing the sample drawer too quickly or forcefully can damage the drawer self-closing mechanism or cause splashing of the samples. Open or close the sample drawer slowly. Contact the local technical support provider if the self-closing mechanism is damaged.

1. To open an unlocked sample drawer (the LED above the drawer is not lit), grasp the drawer handle and pull the drawer fully open.



2. To open a locked sample drawer (the LED above the drawer is lit):
   a. Press the button above the sample drawer.
   b. Wait for the LED above the drawer to stop blinking and remain off.
   c. Grasp the drawer handle and pull the drawer fully open.

Loading Racks into Sample Drawers

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling biohazardous materials can cause bodily harm.

WARNING

Do not reach into the SH when sample drawers are open. The SH robot moves with high speed and force and can cause severe bodily harm.

CAUTION

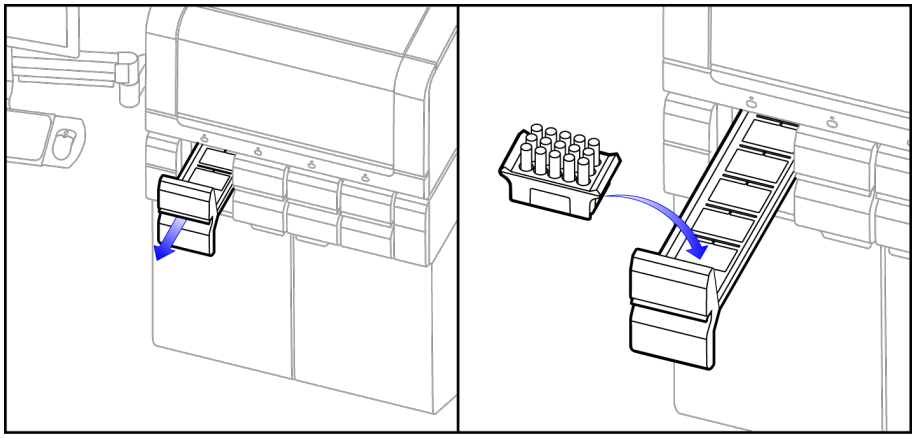
Do not open or close the sample drawer without using caution. Opening or closing the sample drawer too quickly or forcefully can damage the drawer self-closing mechanism or cause splashing of the samples. Open or close the sample drawer slowly. Contact the local technical support provider if the self-closing mechanism is damaged.

When archiving samples, configure at least 1 Archive zone before loading racks into the sample drawers. Configuring a Holding Area is optional but recommended (Page 813 *About Sample Processing Configuration Profiles*).

CAUTION

Do not partially open sample drawer. If the drawer is not fully open, the DVS may not properly scan the racks when the drawer is closed. Ensure the sample drawer is fully open.

1. Open the sample drawer (Page 387 *Opening Sample Drawers*).



NOTE: If loading a dedicated archive or routine rack into an Archive zone, ensure the rack is empty.

2. Ensure the arrow on the rack is pointed in, towards the SH.
3. Seat the rack so it clicks securely into the guides in the appropriate location within the drawer.

CAUTION

Do not force the drawer closed. If a rack is not fully seated in the drawer, the drawer may not close. Ensure the rack is fully seated in the drawer.

4. Close the sample drawer.

   NOTE: If loading a specialty rack, a prompt to confirm the rack is empty displays.

5. Select **Yes.**

Unloading Racks from Sample Drawers

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling biohazardous materials can cause bodily harm.

WARNING

Do not reach into the SH when sample drawers are open. The SH robot moves with high speed and force and can cause severe bodily harm.

CAUTION

Do not open or close the sample drawer without using caution. Opening or closing the sample drawer too quickly or forcefully can damage the drawer self-closing mechanism or cause splashing of the samples. Open or close the sample drawer slowly. Contact the local technical support provider if the self-closing mechanism is damaged.

1. Open the sample drawer (Page 387 *Opening Sample Drawers*).
2. Lift the rack from the sample drawer.
3. Close the sample drawer.
4. If the rack contains samples for archiving:
   a. If appropriate, cover the samples in the rack.
   b. Store the rack and samples in the appropriate archive location.

Loading Sample Racks on a Standalone Sample Handling Subsystem



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.



CAUTION

Do not fill sample containers past the maximum recommended level. Overfilling sample containers may cause splashing while the container moves in the entry and exit queues. Fill pour-off tubes no more than 1 container diameter below the top of the container or sample containers to the manufacturer-recommended max fill level.

1. Before loading sample tubes in a rack, verify that any rack insert is fully seated in the rack (Page 220 *About Sample Adapters for Standalone Analyzers*).
2. Place sample tubes in the appropriate sample rack and positions.
3. Load the sample rack in the entry queue.
4. Select **Load STAT Rack** to load STAT racks on the system (Page 391 *Loading STAT Racks on a Standalone System*).

Unloading Sample Racks from the Standalone Sample Handling Subsystem



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling biohazardous materials can cause bodily harm.

1. Wait for samples to finish processing.



CAUTION

Do not allow the exit queue to reach its capacity of 10 racks. This causes the exit queue to become obstructed. Remove sample racks as the system processes the racks.

2. Remove sample racks after the racks enter the exit queue.

Loading STAT Racks on a Standalone System

1. Ensure the entry and exit queues are not full and the exit queue has room to add the STAT rack. If appropriate, remove up to 4 racks.
2. Select **Load STAT Rack > Yes**.
3. Load the STAT rack at the back of the exit queue. Ensure no other racks are present between the STAT rack and the back analyzer cover.
4. Select **Continue**.
5. To load another STAT rack, select **Continue**:
    a. If a STAT rack is still inprocess, select **OK** on the message that displays the remaining time on the first STAT sample.
    b. Wait until the STAT sampling completes, then load the new STAT rack.
6. Select **Cancel**.

Sample Volume Requirements

System sample volume requirements depend on assay requirements, specific unusable volumes by analyzer and container type.

About Determining the Minimum CH Assay Sample Volume

The primary sample volume for CH assays is 4–50 µL. For most assays, the CH Analyzer completes 1 of the following depending on the sample type:

- Serum, plasma, or urine sample: Aspirates 50 µL of the primary sample then dilutes it with 200 µL CH Diluent.
- Whole blood sample for A1c_E: Aspirates 4 µL of primary sample then dilutes it with 150 µL CH Pretreatment.
- For IMT assays: The analyzer pumps 75 µL IMT Diluent into the IMT sample port. The dilution probe aspirates 25 µL of the primary sample and dispenses this sample and 150 µL of special reagent water into the sample port.

The analyzer retains this diluted sample for up to 20 minutes in a dilution cuvette and holds it for automatic retesting for analyzer sample errors.

Primary sample volume	Test yield
50 µL	Approximately 15 photometric assays
25 µL	3 electrolytes (IMT) assays
75 µL	Approximately 15 photometric plus 3 electrolyte assays

The assay IFU includes:

- Sample volume: The analyzer delivers pre-diluted sample to the reaction cuvette.
- Primary sample dilution by sample type located in the Assay Procedure section.

About CH Sample Volume Requirements

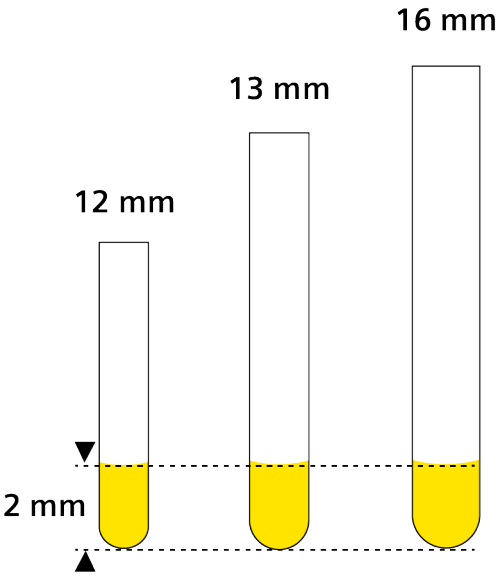
For CH assays, the minimum required sample volume for a reportable result depends on the following factors:

- Primary sample volume for the CH assays.
- Volume of unusable sample for the sample container.
- Minimum volume required for a sample height so the dilution probe can sample from the container. This height and volume varies per container type.

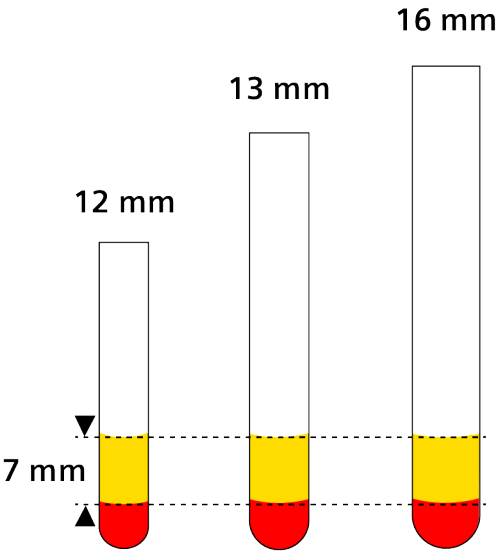
About CH Minimum Sample Height

The minimum sample height volume is the amount of sample required for the dilution probe to sample from the container. This height and volume varies per container type.

2 mm sample height required for round bottom containers without a gel layer (tube size indicates diameter width)



7 mm sample height required for round bottom containers with a gel or cell layer (tube size indicates diameter width)



CH Sample Container Volume Requirements

The CH Analyzer uses multiple sample containers (Page 907 *About Supported Sample Containers*).

The operator uses the following table to calculate CH sample volume requirements:

Sample container type	Sample container unusable volume	Minimum sample volume for sample height	Usable volume with minimum sample height volume
Atellica Solution Tube-Top Sample Cups (TTSC) (1 mL) blue	10 µL	35 µL	25 µL
Atellica Solution Tube-Top Sample Cups (TTSC) (2 mL) green	25 µL	50 µL	25 µL
False-Bottom - Sarstedt Pour-off Tube 12X75	50 µL	75 µL	25 µL
12 mm tube Non-separator or gel	200 µL	430 µL (2 mm sample height)	230 µL
13 mm tube Non-separator or gel	200 µL	470 µL (2 mm sample height)	270 µL
16 mm tube Non-separator or gel	200 µL	600 µL (2 mm sample height)	400 µL
12 mm tube with separator or gel	200 µL	1000 µL (7 mm above separator gel)	800 µL
13 mm tube with separator or gel	200 µL	1130 µL (7 mm above separator gel)	930 µL
16 mm tube with separator or gel	200 µL	1600 µL (7 mm above separator gel)	1400 µL

Volume Required to Meet Minimum Sampling Height for Capillary Tubes

Before centrifugation, the operator must fill a capillary tube according to the manufacturer's required minimum. For capillary tubes centrifuged in a swing bucket adaptor, the minimum required volume (MRV) is > 100 µL above the gel. Capillary tubes spun at a slant risk the sample probe entering the gel separator.

The following is an example of the workflow for an acceptable sample in a capillary tube on the system for only CH testing:

Step	Capillary tube workflow
1	The operator loads the patient capillary tube sample with CH tests on the SH.
2	The TCS reads the sample barcode for the SID and determines the CH test orders.
3	The system determines the CH test orders that require 100 µL of sample volume.
4	The capillary tube routes to the IM Analyzer for the required volume check.
5	The system determines sufficient volume and the capillary tube routes to the CH Analyzer for aspiration.
6	The operator tracks the Inprocess sample status and test order completion in **Worklist > Samples**.

The following is an example of the workflow for an acceptable sample in a capillary tube on the system that includes CH and IM testing:

Step	Capillary tube workflow
1	The operator loads the patient capillary tube sample with CH and IM tests on the SH.
2	The TCS reads the sample barcode for the SID and determines the CH and IM test orders.
3	The system determines the CH test orders that require 100 µL of sample volume.
4	The capillary tube routes to the IM Analyzer for the IM testing aspiration.
5	The IM Analyzer performs the required volume check for the CH tests.

Step	Capillary tube workflow
6	The system determines sufficient volume and the capillary tube routes to the CH Analyzer for aspiration.
7	The operator tracks the Inprocess sample status and test order completion in **Worklist > Samples**.

About Determining Minimum CH Assay Sample Volume

The following equations calculate the CH minimum required volume (MRV) for a reportable result. See About CH Primary Sample Volume (Page 392 *About Determining the Minimum CH Assay Sample Volume*) for primary sample volume requirements and the CH Sample Container Volume Requirements (Page 394 *CH Sample Container Volume Requirements*) for the unusable volume and minimum height volume requirements for specific tube types.

The operator uses the greater of the 2 following results for the MRV:

- The primary sample volume + unusable volume
- Volume required for minimum sample height requirements

For example: 16 CH assays plus 3 electrolyte (IMT) assays in a 1 mL TTSC container:

1. Primary sample volume for 16 chemistries (2*50 µL) + 3 IMT (25 µL) +unusable volume for 1 mL TTSC (10 µL)

   (2*50) µL +25 µL + 10µL= 135 µL

2. Volume for the required for minimum height for 1 mL TTSC = 35 µL total volume required

   Use the greater value (135 µL) for the minimum required volume 135 µL > 35 µL

   MRV= 135 µL

For example: 5 CH assays plus 3 electrolyte (IMT) assays in a 16 mm tube with separator gel:

1. Primary sample volume for 5 CH assays (50 µL)+ 3 IMT (25 µL) + unusable volume 16 mm tube (200 µL)

   50 µL +25 µL + 200 µL= 275 µL

2. Volume required for minimum height for 16 mm tube with separator gel (7 mm above the gel) = 1600 µL total volume required.

   Use the greater value (1600 µL) for the minimum required volume

   1600 µL > 275 µL MRV = 1600 µL (7 mm above the separator gel)

NOTE: For the round-bottom sample containers with and without a gel layer, the volume for minimum height sample requirement exceeds the primary sample volume + the unusable volume. Therefore, the minimum height requirement ensures adequate sample volume for these containers.

About IM Minimum Required Sample Volume

For IM assays, the minimum required sample volume for a reportable result depends on the following factors:

- Sample volume for the assay
- Sample volume to prime the sample tip
- Volume of unusable sample for the sample container

NOTE: The minimum to maximum sample volume range for IM assays is 10–100 µL.

IM Sample Container Volume Requirements

The IM Analyzer can use multiple sample containers (Page 907 *About Supported Sample Containers*).

Use the following table to calculate IM sample volume requirements:

Pour-off tubes

Sample Container Type	Sample Volume	Sample Tip Prime Volume	Sample Container Unusable Volume
Transfer tube 12 mm diameter	< 50 µL	10 µL	100 µL
Transfer tube 12 mm diameter	> 50 µL	15 µL	100 µL
Transfer tube 13–16 mm diameter	< 50 µL	10 µL	300 µL
Transfer tube 13–16 mm diameter	> 50 µL	15 µL	300 µL

Sample Container Type	Sample Volume	Sample Tip Prime Volume	Sample Container Unusable Volume
False bottom Sarstedt 62.612 15.3 mm by 92 mm	< 50 µL	10 µL	100 µL
False bottom Sarstedt 62.612 15.3 mm by 92 mm	> 50 µL	15 µL	100 µL

SH sample cups

Sample container type	Sample volume	Sample tip prime volume	Sample container unusable volume
Atellica Solution Tube-Top Sample Cups 1 mL	≤ 50 µL	10 µL	50 µL
Atellica Solution Tube-Top Sample Cups 1 mL	> 50 µL	15 µL	50 µL
Atellica Solution Tube-Top Sample Cups 2 mL	≤ 50 µL	10 µL	50 µL
Atellica Solution Tube-Top Sample Cups 2 mL	> 50 µL	15 µL	50 µL

About Determining Minimum IM Assay Sample Volume

The following equations calculate the IM minimum required volume (MRV) for a reportable result. The assay IFU specifies the sample volume for each assay. The Sample Volume Requirements table includes the tip prime volume and the unusable volume for the specific tube type and sample volume (Page 398 *IM Sample Container Volume Requirements*).

- For a single replicate of 1 test:

  ```
  Sample Volume + Tip Prime Volume + Unusable Volume =
  MRV
  ```

- For multiple replicates of 1 test:

  ```
  (Sample Volume + Tip Prime Volume) x Number of
  Replicates + Unusable Volume = MRV
  ```

- For multiple tests scheduled for a sample:

  ```
  Sum of (Sample Volume + Tip Prime Volume) for all
  replicates for all tests + Unusable Volume = MRV
  ```

14 Calibration

Calibrating CH Assay Reagent Workflow



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling biohazardous materials can cause bodily harm.



CAUTION

Do not reuse calibrator tubes after removing them from the Cal-QC storage area in an SH configuration and storing them offline. Reusing removed calibrator tubes results in a false onboard stability that may cause unwarranted calibration troubleshooting if a calibration fails.

1. Ensure the following items are on the system:
   - Assay test definitions
   - Calibrator definitions
   - QC definitions: When Perform QC with Calibration is enabled
   - Assay reagents
2. Confirm the system is in 1 of the following states:
   - Ready
   - Standby
   - Processing
3. Prepare the calibrator samples according to the calibrator IFU.
4. When Perform QC with Calibration is enabled, prepare QC materials according to the QC IFU.
5. Create a calibration order.
6. Print the calibrator sample barcodes.
7. When Perform QC with Calibration is enabled, print the QC material barcodes.
8. Place the barcode labels on the appropriate calibrator sample tubes.

9. Load the calibrator samples on the system.
   - For a standalone analyzer, load the calibrator samples in a rack and place the rack in the entry queue.

     NOTE: The operator must load each set of calibrator material in the same rack. If Perform QC with Calibration is enabled, they must load all QC material associated with the calibrator material in the same rack.
   - For an SH configuration, load the calibrator samples in a rack and place the rack in an SH sample drawer.

   NOTE: To process immediately, load calibrator samples in a STAT rack.

   NOTE: Some CH calibrator material is not eligible for onboard storage in the Cal-QC area in an SH configuration. The operator cannot select Store Onboard and save a calibrator definition that includes an assay that is not eligible for onboard storage.

   Load calibrator samples directly into the SH drawer for processing.
10. Review the calibration results.

Calibrating IM Assay Reagent Workflow



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.



CAUTION

Do not reuse calibrator material remaining in the sample tubes or refill calibrator sample tubes after use. If an operator reuses the calibrator material, errors occur. Always dispense fresh calibrators.



CAUTION

Do not reuse calibrator tubes after removing them from the Cal-QC storage area and storing them offline. Reusing removed calibrator tubes results in a false onboard stability that may cause unwarranted calibration troubleshooting if a calibration fails.

1. Ensure the following items are on the system:
   - Assay master curves and test definitions
   - Calibrator definitions
   - Assay reagents
2. Confirm the system is in 1 of the following states:
   - Ready
   - Standby
   - Processing
3. Prepare the calibrator samples according to the calibrator IFU.
4. Create a calibration order.
5. Print the calibrator sample barcodes.
6. Place the barcode labels on the appropriate calibrator sample tubes.
7. Load the calibrator samples on the system.
   - For an IM DL, load the calibrator samples in a rack and place the rack in the entry queue.
   - For an Atellica Solution, load the calibrator samples in a rack and place the rack in an SH sample drawer.

   NOTE: To process immediately, load calibrator samples in a STAT rack.

   NOTE: IM calibrator material and some IM control material are not eligible for storage in the Cal-QC area. The operator cannot select Store Onboard and save a calibrator definition that includes an assay that is not eligible for onboard storage.
8. Review the calibration results.

About Calibrations Due

Calibrations Due provides information for assay reagents onboard the system and associated calibrations. The operator performs the following functions in Calibrations Due based on settings configured in Calibration Setup:

- (Page 271 *Reviewing Calibrator Needs*)
- (Page 473 *About QC Definitions*)
- (Page 270 *Reviewing QC Needs*)
- (Page 223 *About Reagent Overview*)

The number that displays on the Calibrations Due tile is the number of calibrations due on the current day before midnight that require intervention. In Calibrations Due, the calibrations that display include the calibrations that are due before midnight of the next day and require intervention.

Calibrations Due tile title color	Notes
Green	No calibrations due Today within the threshold configured in Calibration Due Warning (hours) that require operator intervention. Today is the period before midnight of the current day.
Red	At least 1 calibration is due Today within the threshold configured in Calibration Due Warning (hours) and requires 1 or more of the following: • Calibration order. • Calibrator Material is not defined, inactive, or expired. • Calibrator Material not onboard. • QC material is not defined or onboard when Perform QC with Calibration is enabled, based on the QC Master List. Today is the period before midnight of the current day. The operator configures Calibration Due Warning (hours) in Calibration Setup.

Calibrations Due feature displays the following information for Calibrations Required With Needs, Calibrations Required Without Needs, and Extended Calibrations:

Calibrations Due status area	Notes
Timeframe	Today and Tomorrow: Displays the calibrations required by midnight of the next day.
	Displays information that is configured in Calibration Setup: • Calibration Order Settings: The configuration options for ordering automatic calibrations and QC for pack and lot calibrations. • Schedule: The time at which calibrations perform daily if scheduled for assays with calibration intervals of ≥ 48 hours. • Calibration Warning: The number of hours prior to a scheduled calibration or expiration time that triggers a warning. For assays with calibration intervals of < 48 hours, the system uses the configured Calibration Warning threshold as the auto calibration order time prior to calibration expiration. The system filters calibrations by the Timeframe of Today and Tomorrow and includes the calibrations required by midnight of the next day.
	Enables the operator to navigate directly to Calibration Setup.

Calibrations Due displays the calibrations required and associated information within 1 of the following 2 areas, as appropriate:

Calibrations required*	Notes
Calibrations Required With Needs	Displays the onboard reagents that require operator intervention to perform a calibration Today and Tomorrow. Red highlights indicate: • Calibration order time is within the operator configured Calibration Warning threshold in Calibration Setup. NOTE: For calibrations manually ordered, this will be the warning time before the expiration. • An issue exists in Order Status or Material Status. Includes a count of the number of usable onboard reagent packs with a Due or Expired calibration that require intervention in order to perform a new calibration. If Calibrations Required With Needs are not present, None Needed displays.
Calibrations Required Without Needs	Displays the onboard reagent packs with calibrations due or expiring Today and Tomorrow that do not require operator intervention to perform a new calibration. Includes a count of the number of usable onboard reagent packs with a Due or Expired calibration that do not require intervention in order to run a new calibration. When no calibrations meet the criteria, this does not display.

Calibrations Required With Needs and Calibrations Required Without Needs includes the following information:

Calibrations required*	Notes
Global check box	A global selection check box to select or deselect all rows.
Analyzer	The specific analyzer with the reagent onboard.
Assay	The assay name for reagent packs with a calibration due. If a reagent is shared by multiple assays, each assay uses a separate row.
Reagent Lot - Pack ID	The lot of reagent and pack ID. Includes the well number for CH.
Inventory	The remaining test count in the reagent pack or well.
Pack OBS	The time until the onboard stability expires for the pack or well.
Order Status	The calibration order status. Displays as 1 of the following: • Ordered: The calibration is ordered. • Scheduled: The calibration is scheduled to be ordered automatically at Order Time. • Place Order: The calibration is not scheduled and not ordered. The operator must order the calibration manually.

Calibrations required*	Notes
Order Time	The time or date when the next calibration is due. Order Time displays as 1 of the following: • Time: The calibration is due Today. • Date: The calibration is due tomorrow. • The calibration scheduled time: The Order Status is Scheduled. Note: For assays with calibration intervals < 48 hours, the schedule time is the configured warning time before expiration. For other scheduled calibrations, the schedule time is the configured schedule time in Calibration Setup. • The calibration expiration time: The Order Status is Place Order and the calibration is not expired. • Now: The Order Status is Place Order and the calibration is expired, or the Order Status is Ordered.
Material Status	Displays the status of calibrator and QC materials onboard. When the Order Status is Scheduled or Place Order, the Material Status is 1 of the following: • Onboard: The required calibration and QC materials are onboard the analyzer. • Load Cal: Calibrator Material is required. • Missing: The current defined material has expired or an active lot is not defined for the assay.

Calibrations required*	Notes
	• Load QC: QC material is required. • Need QC Def: Perform QC with Calibration is configured in Calibration Setup and the QC levels in the QC Master List required for the calibration are not defined or had expired. The Material Status highlights in red when: • When the material is not onboard. • The Order Status is Scheduled and the hours until the scheduled date and time are within the configured Calibration Due Warning (hours). • The Order Status is Place Order and the hours until the Calibration Expiration are within the threshold configured in Calibration Due Warning (hours). • The Order Status is Ordered, regardless of the Calibration Due Warning (hours) configuration.
Calibration Expiration	The hours remaining until the calibration interval expires.

* To sort the column contents in ascending or descending alphanumeric order, select the column header. Selecting the column header a second time reverses the sort order.

The operator selects single or multiple rows to perform the following operations in Calibrations Required With Needs and Calibrations Required Without Needs:

Operations	Notes
Order	Orders the Calibrations Due for the selected rows with an Order Status of Scheduled or Place Order. **NOTE:** If more than 1 lot of calibrator material is Active, the system automatically selects the compatible Active calibrator lot that expires first. To order a calibration on a specific calibrator material lot, order the calibration in Calibration Orders.
Schedule	Option not available for Calibrations Required Without Needs. Adds calibration to the next configured time for the selected rows with an Order Status of Place Order.
Print Barcode	Prints the calibrator material barcodes. Prints QC material barcodes when applicable. Option not available for Calibrations Required Without Needs.
Ignore	Removes the calibrations from Calibrations Due consideration until the next day.
Extend	Extends the lot calibration expiration dates. Extending is limited to calibrations in Due or Expired status. **NOTE:** This feature requires the appropriate security level.

Extended Calibrations displays:

- Non-expired calibrations that have an extended expiration date.
- A count of usable onboard reagent packs for reagent lots with Extended Calibrations. The count does not display when no calibration meets the criteria.

Extended Calibrations*	Notes
Global check box	A global selection check box to select or deselect all rows.
Analyzer	The specific analyzer with the reagent onboard. Option not available for a standalone configuration.
Assay	The assay name for this reagent lot.
Calibration Expiration	Days and hours remaining until the extended lot calibration expires.
Reagent Lot	Displays the Reagent Lot, Pack ID, and the CH Well number (CH only).
Reagent Lot Expiration	The expiration date of the Reagent Lot.
Calibrator Material	The name of the Calibrator Material.

* To sort the column contents in ascending or descending alphanumeric order, select the column header. Selecting the column header a second time reverses the sort order.

The operator selects single or multiple rows to perform the following operations in Extended Calibrations:

Operations	Notes
Order	Orders the Calibrations Due for the selected rows when an eligible pack- to perform a lot calibration for the selected rows exists. The entries remain in Extended Calibrations as the system continues to extend the calibrations until replacement, expiration, or the operator selects **Undo Extend**.
Print Barcode	Prints the operator-selected calibrator material barcodes. Prints QC material barcodes when appropriate.
Undo Extend	Removes the extended time from an extended calibration expiration. The calibration expiration returns to the original value. The system removes the calibration from Extended Calibrations and adds it to the required calibrations, as appropriate (Page 414 *About Extending Calibrations*). This feature requires the appropriate security level.

Calibrations required for New Packs displays:

- The analyzer, assay, reagent lot combinations that require a calibration for a new CH or IM pack.
- A count of reagent lots requiring calibration for newly loaded and punctured packs.

Calibrations required for New Packs	Notes
Analyzer	The name of the analyzer where the new reagent pack that requires calibration will reside. Does not display for a CH DL or IM DL.
Assay	The assay name for the reagent pack that requires calibration.
Reagent Lot	The reagent lot number for the new pack associated with an assay or reagent lot that requires calibration.

About Ordering Calibrations in Calibrations Due

In Calibrations Due, the operator selects **Order** to order a Lot or Pack calibration when the appropriate resources are available.

NOTE: If more than 1 lot of calibration material is Active, the system automatically selects the compatible Active calibrator lot that expires first. To order a calibration on a specific calibrator material lot, order the calibration in Calibration Orders.

To order a calibration, the Order Status must be 1 of the following:

- Scheduled
- Place Order

When the operator orders the calibration, the Order Status updates to Ordered. The order remains in Calibrations Required With Needs if any immediate needs are required.

Order is disabled if the Order Status of all selected rows is Ordered or missing the Calibrator Definitions.

About Scheduling Calibrations in Calibrations Due

The operator schedules a calibration to perform at the next configured time in Calibration Setup. In Calibrations Due, the operator selects **Schedule** to schedule a calibration for the selected rows..

To schedule a calibration, the Order Status must be Place Order.

The Order Status changes to Scheduled and the Order Time updates to the scheduled date and time.

About Ignoring Calibrations in Calibrations Due

In Calibrations Due, the operator selects **Ignore** to postpone the selected Calibrations Due until the next day.

The system removes the entries from the appropriate panels in Calibrations Due until the following day.

About Extending Calibrations

> **CAUTION**
>
> Do not extend a calibration unnecessarily. Extending calibrations may cause erroneous results. The laboratory is responsible for monitoring calibration stability after extending a calibration interval beyond the calibration interval in the assay IFU. Perform QC to verify the calibration remains acceptable. If the calibration interval for an assay reagent lot is extended and the QC falls outside the laboratory limits, investigate immediately and recalibrate the assay reagent lot as appropriate.

This feature requires the appropriate security level.

A calibration for an assay reagent lot may expire while the system processes orders that include the test. To enable the system to finish processing samples and report results after the calibration is expired, the operator can extend the lot calibration. The system uses the extended calibration to calculate results and then flags the results as Extended. Extending a calibration is available for lot calibrations but not available for pack calibrations.

NOTE: The system cannot report results for samples that process after a calibration expires or before the operator extends the calibration. The system removes the entries from Extended Calibrations the following day.

This feature extends lot calibration intervals for all CH assays or only specific IM assays. The IM test definition contains the setting options for extending IM assay calibrations.

The original calibration is extended to 180 days, to not exceed the lot expiration.

NOTE: Perform a calibration for the assay reagent lot as soon as possible following a calibration extension.

Assay Reagent Calibration Order Status Icons

The system displays calibration order status icons in the Order Status column.

Calibration Order Status Icon	Notes
	Ordered
	Valid
	Processing
	Intervention Needed
	Error

About CH Assay Reagent Calibrations

Calibration establishes the relationship between the system response (absorbance values) and reported results (concentration). The relationship is unique for each assay. The system determines the relationship by measuring the absorbance of a material with known concentrations (or levels) of the analytes for the assay.

The system uses linear and nonlinear calibration models when converting the system response to concentrations.

About Linear CH Assay Reagent Calibration Models

Linear calibrations generate a calibration curve by using 2 to 3 calibrator levels that span the analyte measurement range.

About Nonlinear CH Assay Reagent Calibrations

Nonlinear calibrations generate a complex calibration curve by using up to 6 multiple calibrator levels that span the analyte measurement range.

Nonlinear calibrations use 1 of 2 different types of calibrator kits:

- Multiple calibrators
- Single calibrator

The multiple calibrators kit contains vials of increasing analyte concentration. Level 1, or blank, contains the lowest concentration of analyte in the kit. Levels 2–6 increase in concentration. The level 1 can be 1 of the following:

- CH Diluent (reagent blank)
- Calibrator material

NOTE: Calibrator kits can contain concentrations of several analytes and can calibrate more than 1 assay.

Single level calibrator kits contain 1 vial of concentrated analyte. For multilevel calibrations using a single calibrator, the system dilutes the concentrated calibrator with CH Diluent to make multilevel calibrator samples. If the assay calibration requires a blank, the system uses CH diluent or an assay-specific material the calibrator lot-specific value sheet specifies.

About IM Assay Reagent Calibrations

Calibration establishes the relationship between the system response in relative light units (RLU) and reported concentration results. The relationship is unique for each assay. The system determines the relationship by measuring the RLU of a material with known concentrations, or levels of the analytes for the assay.

The system uses a Master Curve and a 2-point calibration to calibrate qualitative and quantitative tests.

About Quantitative and Qualitative IM Assay Reagent Calibrations

The system calculates and reports IM quantitative assay results to indicate the concentration of the analyte and qualitative assay results to indicate the presence or absence of the analyte.

The system performs an IM quantitative assay calibration using 2 calibrator levels of known concentration. If the calibrator results meet defined validity criteria, the system compares the average RLUs for each calibrator to the Master Curve and determines an analyzer-specific formula. The system then adjusts the observed RLUs to the Master Curve according to the following formula:

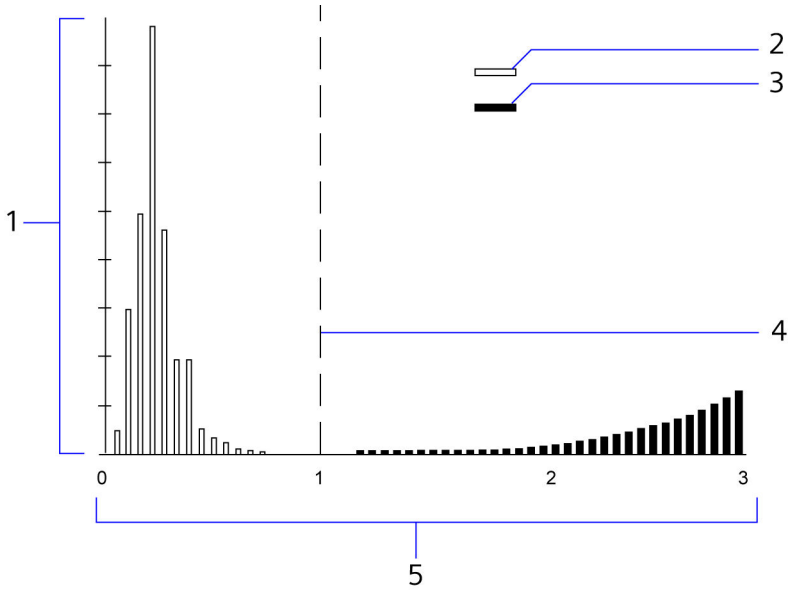
```
adjusted RLUs = observed RLUs × defined slope +
defined intercept
```

When processing patient samples or quality control samples for a quantitative assay, the system matches the adjusted RLU value to the corresponding analyte concentration using the Master Curve.

Qualitative assays have a cut-off point that remains constant for each lot of assay reagent. The manufacturer establishes the cut-off during product development and bases the cut-off on extensive population studies. The manufacturer assigns the analyte concentration associated with the cut-off as, for example, an index value of 1.0. Refer to the assay IFU for the assay cut-off value.

The RLU relative to the cut-off is the basis for a Master Curve consisting of 6–10 standards. A specific level on the Master Curve represents the qualitative assay cut-off point or index value.

Qualitative assay cut-off point



1	Frequency
2	Nonreactive
3	Reactive
4	Cut-off
5	Index

The system performs a qualitative assay calibration using 2 calibrator levels of known concentration. If the calibration meets defined validity criteria, the system compares the calibrator RLUs to the Master Curve and determines a system-specific correction formula. When the system processes patient or quality control samples, the system adjusts the measured RLUs using the system-specific correction formula. The system compares the sample RLUs to the calibration curve, and determines the RLU associated index value.

For the interpretation of the results rule for the assay, see the assay IFU. For example, the assay may have the following interpretation of results:

- If the index value is greater than or equal to 1.0, the system interprets the sample as Reactive to indicate the analyte is present.
- If the index value is less than 1.0, the system interprets the sample as Nonreactive to indicate the system does not detect the analyte.

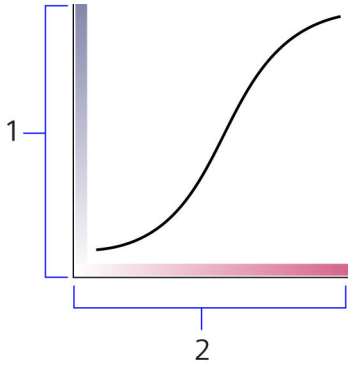
About IM Assay Master Curves

Measuring the relative light unit (RLU) response at multiple concentration levels establishes a specific master curve for assay reagent lots. The standard concentrations and corrected RLUs define the shape of the curve for a particular assay reagent lot.

The manufacturing process uses reagents from a specific lot to generate a master curve by performing the test on standards of varying concentrations on multiple systems over several days. The ensuing standard curve determines the relationship between the defined analyte levels and the measured RLUs. The lot-specific Master Curve exists in a 2D barcode on the Master Curve and Test Definition sheet.

The Master Curve for a sandwich or direct test format, has a positive slope, indicating that the analyte concentration is directly proportional to the light emission in RLUs.

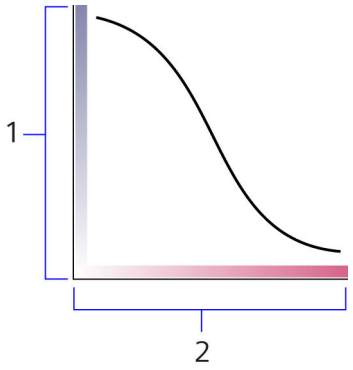
Master curve for a sandwich test



1 RLUs
2 Analyte concentration

The Master Curve for a competitive test has a negative slope, indicating that the analyte concentration is inversely proportional to the light emission in RLUs.

Master curve for a competitive test



1 RLUs
2 Analyte concentration

About Calibration Orders

The system performs automatic and manual calibrations. The Calibration Orders window provides the following functions for placing manual calibration orders:

- Select analyzer
- Select assays and calibrator material
- Select reagent pack
- Edit calibration orders
- Place 1 or more orders

NOTE: If multiple calibrator definitions exist for the selected assay, the definitions display in the Select Calibrator Material area. If only 1 active calibrator definition exists for the selected assay, the calibrator displays in the area for Select Reagents.

The operator can view information and create calibration orders from Calibration Orders.

The tables that display in the right panel depend on which Select By option is selected.

Select Calibrator Material	Notes
Material Name	Name of the calibrator material
Material Status	Whether the calibrator is stored onboard
Lot	Calibrator lot number
Lot Expiration	Expiration date of the calibrator lot
Assays	The assays associated with the calibrator

Select Reagents	Notes
Assay	Name of the assay.
Reagent Pack ID	Primary reagent pack ID.
Inventory	Total number of usable tests remaining on the analyzer for multiple packs of the same assay reagent lot.
Cal Expiration In Use	The amount of time left on the pack or well calibration.

Select Reagents	Notes
Type to Run	• The system automatically selects the type, but the operator can manually change the selection • Lot: For IM, available if the reagent pack has been on the system for less than 24 hours. • Lot: For CH, available if the reagent pack or well is unpierced or pierced for less than 24 hours • Pack: Always available • C0 Adjust: Available when appropriate for the assay
Lot Cal Expiration	The amount of time left on the lot calibration
Edit Pack Options	For IM assays, the operator can edit the order to assign IDs for the following packs: • Ancillary 1 Pack • Ancillary 2 Pack • Diluent Pack

NOTE: To replace a valid lot or pack calibration with recalibration results, the operator must edit the new calibration order and select the appropriate type of calibration.

Depending on how long the pack is on the system, the system may override the lot calibration designation and save the results as a pack calibration (Page 425 *About CH Lot and Pack Assay Reagent Calibrations*) (Page 421 *About IM Lot and Pack Calibrations*). To ensure the system performs a lot calibration, the operator must select the unpierced well of the pack in Edit Cal Order or load a new pack.

Calibration Types

Calibration type	Notes
Lot Calibration	A reagent lot calibration is valid for an entire lot until the lot calibration interval expires.
Pack Calibration	A reagent pack calibration is valid for an individual pack only until the pack calibration interval expires (Page 421 *About IM Lot and Pack Calibrations*) (Page 423 *About CH Assay Pack Calibrations*).

About IM Lot and Pack Calibrations

The system performs reagent lot and reagent pack calibrations. A lot calibration is valid for all of the reagent packs of the same reagent lot. A pack calibration is valid for an individual reagent pack only.

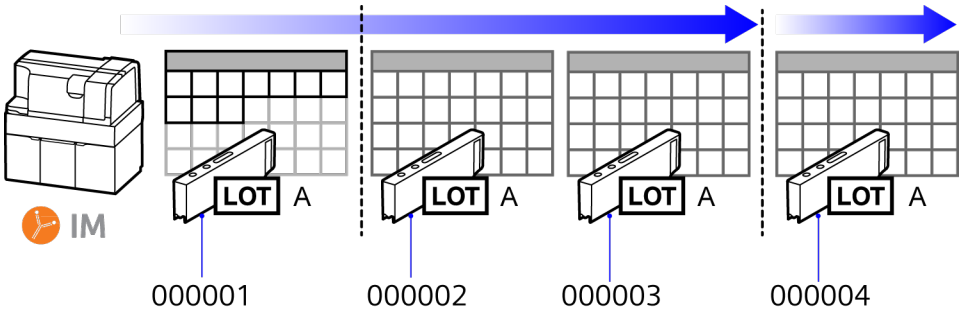
To establish a lot calibration, the operator must calibrate a new assay reagent pack shortly after loading a pack of that lot on the system. The time limit to establish a lot calibration is 24 hours. When the system opens subsequent reagent packs of the same lot, the system uses the lot calibration to calculate test results until the lot calibration interval expires. A lot calibration interval is the time period in days or hours between required assay reagent lot calibrations.

Reagent packs that remain on the system over a designated period of time require recalibration to ensure continued use on the system. A pack calibration interval is the time period in days or hours when the system requires the next pack calibration.

The assay test definition contains the assay-specific lot and pack calibration interval information. The system tracks lot and pack calibrations and displays reminders when calibration or recalibration of an assay reagent lot or pack is due.

The following is a sequential description of lot calibration and pack calibration life cycles. For this example, the assay reagent lot calibration interval is 28 days. The assay reagent pack calibration interval is 10 days.

Lot calibration and pack calibration life-cycle sequence



Sequence order	Calibration life cycle
Day 1	The operator loads Lot A, Pack 000001 and the system establishes the lot calibration. The calibration is valid for all newly loaded packs from Lot A until the lot calibration interval expires.
Day 10	The Pack 000001 requires a pack calibration, because the pack has been on the system for 10 days. The system performs a pack calibration of 000001 and ensures continued use of the pack. The calibration is valid only for Pack 000001 until the pack calibration interval expires.
Day 15	The operator loads Lot A, Pack 000002, which does not require calibration because the lot calibration for Lot A is still valid for another 13 days.
Day 20	The operator loads Lot A, Pack 000003, which does not require calibration because the lot calibration is still valid.
Day 25	Pack 000002 requires a pack calibration, because the pack has been on the system for 10 days.

Sequence order	Calibration life cycle
Day 28	The lot calibration interval for Lot A expires. The system determines that Pack 000003 is open beyond the designated period of time for a lot calibration and cannot use the recalibration of Pack 000003 to establish a new lot calibration for Lot A. The operator loads Lot A, Pack 000004 and the system establishes a new lot calibration for Lot A. The calibration is valid for all newly loaded packs from Lot A until the lot calibration interval expires. If the system establishes a new lot calibration before performing a pack calibration for Pack 000003, Pack 000003 inherits the lot calibration for 2 days before requiring a pack calibration.
Day 30	The Pack 000003 requires a pack calibration, because the pack has been on the system for 10 days. The system performs a pack calibration of 000003 and ensures continued use of the pack. The calibration is valid only for Pack 000003 until the pack calibration interval expires.
Day 38	Pack 000004 requires a pack calibration, because the pack has been on the system for 10 days.

The operator must continue to calibrate an assay reagent lot and pack until the assay reagent lot expires, assay reagent pack onboard stability expires, or the pack depletes.

About CH Assay Pack Calibrations

The analyzer supports 2 types of pack calibrations:

- Full
- C0 Adjust

The system uses all defined calibrator levels for a full pack calibration but only CH Diluent for C0 Adjust pack calibrations.

The system determines if a pack or well is eligible for C0 Adjust pack calibration.

The operator orders a Pack Calibration for a C0 Adjust-configured assay but does not need to load calibrator samples because the system automatically uses CH Diluent.

NOTE: If the operator orders a Lot Calibration on a pierced reagent pack that is onboard the system for over 24 hours and selects **C0 Adjust**, the system performs a pack calibration.

The operator must ensure the appropriate calibrator level samples are available (Page 425 *About CH Lot and Pack Assay Reagent Calibrations*).

NOTE: If a Lot Calibration does not exist, the system overrides a C0 Adjust calibration order and performs a Full pack calibration.

About Automatic Calibration Orders

The system automatically creates a calibration order when the following conditions apply:

- At least 1 automatic calibration trigger selection exists in Calibration Setup.
- An active calibrator definition exists for the calibrator.
- No open calibration orders for the test, reagent lot, or calibrator lot exist.
- The operator enables the assay in the Assays Configuration tab in Setup.
- Current calibration for the reagent lot is Expired, Due, or Not Calibrated.
- For IM assays with control bracketing, the IM reagent lot is not associated with any open control brackets with retained results.

The system automatically performs the created calibration order when the required calibrators and reagent packs are onboard the system and calibrators meet the following criteria:

NOTE: For calibrators with Perform QC with Calibration setup, QC material is required.

- Calibrator lot is not expired.
- Calibrators belong to the same lot.
- Calibrator is within its onboard stability date.

CH reagent packs and IM primary and ancillary reagent packs must meet the following criteria:

- Reagent lot is not expired.
- Reagent pack and lot are Active.
- Reagent pack onboard stability is not expired.
- Reagent pack contains sufficient material to perform all the required calibration replicates and QC replicates, if required.

About Assay Reagent Calibration Frequency

The operator must perform assay reagent calibration according to the following:

- Expired assay reagent calibration
- New assay reagent lot or bottle values
- Replacement of major system components or service
- Troubleshooting quality control results
- Government regulations
- Laboratory quality control programs and procedures

The system performs the following types of calibrations:

- Reagent lot (Page 425 *About CH Lot and Pack Assay Reagent Calibrations*) (Page 421 *About IM Lot and Pack Calibrations*)
- Reagent pack

About CH Lot and Pack Assay Reagent Calibrations

The system performs reagent lot and reagent pack calibrations. A lot calibration is valid for an entire assay reagent lot. A pack calibration is valid for an individual reagent pack well.

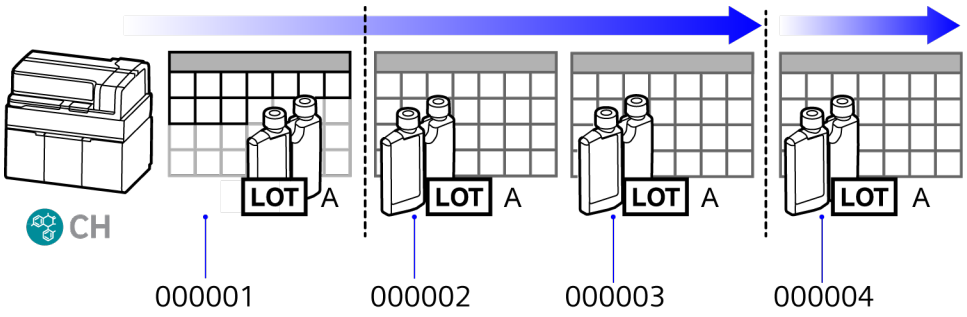
To establish a lot calibration, calibrate a new assay reagent pack within 24 hours after loading the first pack of the lot on the system. When the system opens subsequent reagent packs or wells of the same lot, the system uses the lot calibration to calculate test results until the lot calibration interval expires. A lot calibration interval is the time period in days or hours between required assay reagent lot calibrations.

The open wells of reagent packs that remain on the system over a designated period of time require recalibration to ensure continued use on the system. A pack calibration interval is the time period in days or hours when the system requires the next pack well calibration. With rare exceptions, a reagent pack well calibration interval has a shorter duration than a reagent lot calibration interval. CH assays use 2 pack calibration types (Page 423 *About CH Assay Pack Calibrations*).

The assay test definition contains the assay-specific lot and pack calibration interval information. The system tracks lot and pack calibrations and displays reminders when calibration or recalibration of an assay reagent lot or pack well is due.

The following is a sequential description of lot calibration and pack calibration life cycles. For this example, the assay reagent lot calibration interval is 28 days. The assay reagent pack well calibration interval is 10 days.

Lot calibration and pack calibration life-cycle sequence



Sequence order	Calibration life cycle
Lot A, Pack 000001	Day 1: The calibration of Lot A, Pack 000001 establishes the lot calibration. The calibration is valid for all packs from Lot A until the lot calibration interval expires. Day 10: Pack 000001, Well 1 calibration interval expires. The system performs a pack calibration of 000001, Well 1 and ensures continued use of the pack. The calibration is valid only for Pack 000001, Well 1 until the pack calibration interval expires.
Lot A, Pack 000002	Day 15: Pack 000002 does not require calibration because the lot calibration for Lot A is still valid.

Sequence order	Calibration life cycle
Lot A, Pack 000003	Day 20: Pack 000003 does not require calibration because the lot calibration is still valid. Day 28: Lot calibration interval for Lot A expires. The system determines that Pack 000003, Well 2 is open longer than 24 hours for a lot calibration and cannot use the recalibration of Pack 000003, Well 2 to establish a new lot calibration for Lot A. The system performs a pack calibration of 000003, Well 2 and ensures continued use of the pack. The calibration is valid only for Pack 000003, Well 2 until the pack calibration interval expires.
Lot A, Pack 000004	Day 1: The calibration of Pack 000004 establishes a new lot calibration for Lot A. The calibration is valid for all packs from Lot A until the lot calibration interval expires.

Continue to calibrate an assay reagent lot and pack until the assay reagent lot expires, assay reagent pack onboard stability expires, or the pack depletes.

About Calibrator and QC Sample Transportation and Aspiration

Calibration and QC material contain known concentrations for 1 or more assays. The system transports the calibrator and QC material samples from the Cal-QC Storage Area to the analyzers for aspiration.

The transportation and aspiration workflow for calibrator or QC samples containing a single assay consists of the following:

1. The Atellica Magline Transport moves the samples from the Cal-QC Storage Area to the appropriate analyzer.
2. The analyzer aspirates all the replicates for each calibrator or QC level.
3. The Atellica Magline Transport returns the samples to the Cal-QC Storage Area.

The transportation and aspiration workflow for calibrator or QC samples containing multiple assays consists of the following:

1. The Atellica Magline Transport moves the samples from the Cal-QC Storage Area to the appropriate analyzer.
2. The analyzer aspirates all the replicates for 1 assay for each calibrator or QC level.
3. The Atellica Magline Transport returns the samples to the Cal-QC Storage Area.
4. The Atellica Magline Transport moves the samples from the Cal-QC Storage Area to the appropriate analyzer.
5. The analyzer aspirates all the replicates for the second assay for each calibrator or QC level.
6. The Atellica Magline Transport returns the samples to the Cal-QC Storage Area.
7. The system repeats this process until the analyzer completes aspirating all of the assays associated with the calibrator or QC material.

About Calibration Results

Calibration Results provides calibration results data for each assay.

The system retains calibration data for a minimum of 2 years from when the calibration was last performed. The operator configures Calibration Results to automatically print a report to a printer or file when a calibration completes in Reports Setup.

In the screen for Calibration Results, the operator can View By Current or Assay and perform the following:

- View the Details of the calibration result
- Export the calibration result
- Delete calibration order
- Invalidate an active calibration
- Print calibration results

Red highlights in Calibration Results indicate:

- Critical and impending warning calibration events
- Calibration has expired
- Calibration is rejected
- Calibration is invalid

Calibration Results Filter limits the number of calibrations that display. The operator can filter results by:

- Analyzer
- Calibration Status
- Assay
- Reagent Lot
- Reagent Pack ID

Calibration Results	Notes
Global check box	A global selection check box to select or deselect all rows.
Assay	The assay associated with the calibration.
Analyzer	The specific analyzer that performs the calibration, when available.
Cal Lot	The calibrator lot for the calibration.
Result Date	The date the calibration completed. Displays "--" if the calibration has no result.
Cal Status	The status of the calibration. A status with an alert displays with a red highlight (Page 431 *Calibration Results Status*).
Cal Expiration	The expiration date for this calibration. A calibration with a status of Awaiting Acceptance, Invalid, Inprocess, or Ordered displays as "--".
Type	A lot, a pack or C0 adjust calibration (Page 421 *Calibration Types*).
Reagent Lot	The reagent lot for the calibration.

Calibration Results	Notes
Reagent Pack ID	Reagent pack ID for the calibration. • For CH assays, the reagent pack and well ID. • For IM assays, the primary reagent pack ID.
Flags	When the Cal Status is Ordered, the operator selects a flag link to display more information (Page 433 *About Flags in Calibration Results*).
Comments	The operator adds Comments in Details. When Filter is expanded and Comments exist,  displays.
Details	Information and data for the calibration (Page 445 *About Details in Calibration Results*).
Export	The operator selects to obtain a data export of selected calibration results.
Delete Order	The operator selects to delete the selected calibration order.
Invalidate	The operator selects to permanently Invalidate an active calibration. Invalidate is enabled when 1 calibration result is selected and the Calibration Status is Active.

Calibration Results Status

Cal Status	Notes
	The calibration currently in use to calculate patient and QC results for the reagent lot, pack or well.
Awaiting Acceptance	Automatic Acceptance in Calibration Setup could not be applied to this calibration because the option is Disabled or the calibration does not qualify. The operator accepts or rejects the calibration.
Expired	The lot or pack calibration is expired and no longer available for use. An event message generates for an IM pack calibration expiration.
Extended	The operator has extended the calibration expiration to enable the system to finish processing samples and report results with an expired calibration. The system uses the extended calibration to calculate results and then flags the results as Extended. Extending a calibration is available for lot calibrations but not available for pack calibrations. The operator extends calibrations in Calibrations Due. (Page 414 *About Extending Calibrations*)
Inprocess	All necessary calibrator and QC materials are present, scanned, and the calibration is processing.

Cal Status	Notes
Invalid	A calibration is Invalid when: • The operator invalidates an active lot or pack calibration to remove the calibration from use. • The system cannot calculate an IM calibration result. The system reverts to using the previous valid calibration to process test results (Page 444 *About Invalidating a Calibration in Calibration Results*).
Ordered	The calibration is ordered and pending. The order automatically transmits to the system when: • All calibrators associated with the order are available to the appropriate analyzer. • Perform QC with Calibration is enabled and at least 1 Active QC level on the Master QC list is available. • At least 1 eligible reagent pack with sufficient inventory is loaded on the appropriate analyzer.
Rejected	The system or operator rejected the calculated calibration result.

Cal Status	Notes
Valid	The system automatically changes the calibration status to Valid and places the calibration in use if: • Automatic Acceptance is enabled. • The calibration results meet all predefined acceptance criteria, including QC Results Must Be Within Ranges when enabled. • When the operator manually accepts a calibration with a status of Awaiting Acceptance, the calibration status changes to Valid.

About Flags in Calibration Results

The system displays calibration result flags when the status of a calibrator result is Ordered and requires additional attention. Calibration orders display a flag in Sample Interventions and alert the operator with a red banner. Each flag is a hyperlink that the operator can hover over to open a new window with a link for more information about that flag.

The system may display 1 or more of the following Calibration Results flags.

Flag	Type	Notes
Abnormal Reaction	CH	A foam error occurred. Repeat the calibration.
Absorbance Error	CH	The photometer was outside the measuring range. Repeat the calibration.
Absorbance Limit (D)*	CH	Lamp energy was low during cell blank measurement check. Repeat the calibration.
Analyzer Rejected	CH/IM	The analyzer rejected the order. Reorder the calibration.

Flag	Type	Notes
Atellica Magline error	CH/IM	The Atellica Magline Transport cannot deliver samples to the analyzer due to errors.
Bubble Detected	CH/IM	The system detected a sample integrity error.
Calibrator OBS Expired	CH	A previously loaded calibrator sample is no longer usable. The Onboard Stability expired for the calibrator sample. Load new calibrator samples to complete the calibration.
Canceled	CH/IM	The system canceled the test. Repeat the calibration.
Check Atellica Magline State	CH/IM	The system could not process tests because the Atellica Magline Transport is not in the correct state or covers are open. Resolve any issues in System Status.
Check SH State	CH/IM	The system could not process tests because the SH is not in the correct state or the covers are open. Resolve any issues in System Status.
Clog	IM	The system detected a sample probe clog. Check the sample and repeat the test.

Flag	Type	Notes
Contaminated	IM	The reagent probe was contaminated. Repeat calibration.
Crash (G)*	CH	The system detected a probe crash. Resolve any hardware issues in Troubleshooting and repeat the calibration.
Cuvette Loader Error	IM	The system was unable to complete the test because the cuvette jammed or did not load. Resolve any Cuvette Loader issues and repeat the calibration.
Cuvette Temperature Out of Range	IM	The incubation ring temperature was out of range. Resolve any Cuvette Temperature issues and repeat the calibration.
Final Optical Density	CH	The final optical density (OD) was greater than the photometer's linear range.
General TDef Error	IM	The module software was unable to interpret new error type.
IM Acid Error	IM	The system was unable to deliver IM Acid due to a mechanical or electrical failure. Troubleshoot and resolve any pump or heater issues.

Flag	Type	Notes
IM Base Error	IM	The system was unable to deliver IM Base due to a mechanical or electrical failure. Troubleshoot and resolve any pump or heater issues.
Incomplete Set	IM	A required calibrator level was not on the system.
Incubation Ring Error	IM	The system detected an error during incubation.
Incubation Temperature is Out of Range.	CH/IM	The reaction ring bath (CH) or reaction ring compartment (IM) temperature was outside the predefined range.
Initial Optical Density	CH	The Initial Optical Density (OD) was greater than the photometer's linear range.
Insufficient Points (n)*	CH	The number (n) of valid data points was not sufficient for the ordered calibration.
Insufficient Reagent	CH/IM	The reagent volume was not sufficient for the ordered test.
Insufficient Sample	CH/IM	The sample volume was not sufficient for the ordered test.

Flag	Type	Notes
Internal Error	IM	The scheduler lost control of this test. The system was unable to continue with this test for safety reasons.
Invalid Test	CH	The test definition for this assay did not exist or the IMT subsystem was offline.
Investigational	CH/IM	The test was defined as Investigational in the test definition. If the system flagged 1 or more ratio components as Investigational, it would also flag the ratio result as Investigational. The system changed the result to the Hold test state.
Irregular Aspiration	CH/IM	The system detected a problem with the reagent fluid during aspiration. Check the reagent pack for irregular fluid or low fluid levels.
Liquid Level Sensor Error (Q)*	CH	The system detected an error with the liquid level sensor.
Low IM Acid	IM	The system detected insufficient IM Acid to perform the test.
Low IM Base	IM	The system detected insufficient IM Base to perform the test.

Flag	Type	Notes
Low IM Wash	IM	The system detected insufficient IM Wash to perform the test.
Low Probe Wash	IM	The system detected insufficient probe wash to perform the test.
Low Ratio	IM	The pre-light test failed or the signal was poor.
Low Tips	IM	The system could not perform the test because of insufficient tips.
Low Water	IM	The system could not perform the test because of insufficient water.
Luminometer Error	IM	The system obtained the result while the PMT was out of temperature range.
Manually Canceled	IM	The operator canceled the test.
Measurement Error	CH	The detector did not generate a reading or the assay parameter detected an issue.
Mechanism down	CH	Mechanical errors on the analyzer prevented the system from processing this test request.
Missing Module Capability	CH/IM	The system could not process tests because 1 or more system capabilities were not available.

Flag	Type	Notes
Missing Consumable	IM	One or more system consumables were not available on the analyzer. Replenish the appropriate system consumables and reload the sample.
Missing Reading	CH	The system could not use 1 or more readings to calculate the result. If this occurred on more than 1 test, troubleshoot the photometer. For a single test, repeat the test.
Mix Error (M)*	CH	The system detected a mixer motion error.
Module Unavailable	CH/IM	The system could not perform the test because a subsystem is offline.
No Ancillary	IM	The test required an ancillary reagent.
No Diluent	IM	The test requires an automatic dilution and the diluent is not onboard.
No Lot Match	IM	The test required a specific primary reagent and ancillary reagent lot combination.
No Primary	CH/IM	Primary reagent was disabled, unusable, or not loaded for this test.

Flag	Type	Notes
No Prior Lot Cal	CH/IM	The system could not perform a pack calibration because a prior lot calibration does not exist.
Patient Processing Disabled	CH/IM	The system could not Perform QC with Calibration because Patient Sample Processing is disabled.
PMT Temperature	IM	PMT temperature was out of range.
Priming	CH	The system could not perform the test because the system needs to schedule priming for a probe or a pump.
Rack ID Conflict	CH/IM	The system determined that orders created with an SID were not in the expected location within a rack. The system suspends these orders for safety. The operator can restart the orders with unsuspend.
Rack ID Timeout	CH/IM	Orders were created with a Rack ID only that were not matched to a tube within 4 hours. The system suspends these orders and awaits the operator intervention to unsuspend after careful review.

Flag	Type	Notes
Reagent Compartment Error	IM	The system was unable to dispense reagents due to a mechanical error or packs in unexpected places.
Reagent Compartment Humidity	IM	The reagent compartment humidity had exceeded or fallen below operating range.
Reagent Compartment Temperature	IM	The system obtained the result using primary or ancillary reagents it received during a reagent compartment temperature warning condition.
Reagent Loader Error	CH/IM	The system was unable to load reagents to the compartment for this test.
Reagent Lot Expired	CH/IM	The reagent lot expired.
Reagent Prep in Progress	IM	The system could not process tests because reagent mixing is inprocess.
Reagent Probe1 Error	IM	The system was unable to dispense reagent.
Reagent Probe 2 Error	IM	The system was unable to dispense reagent.
Reagent Probe 3 Error	IM	The system was unable to dispense reagent.
Reagent Ring Temperature is Out of Range.	IM	The system detected a reagent ring temperature that was out of range.

Flag	Type	Notes
Reagent Ring Temperature Warning	IM	The system detected a reagent ring temperature that was out of range.
Reagent Stability Expired	IM	The system was unable to use a reagent because the onboard stability had expired.
Released for Calibration or Control Bracket	CH/IM	Release of the Hold for Review Calibration or QC results is required before reporting patient results.
Safety (S)*	CH/IM	A system error occurred.
Sample Error	CH/IM	1 or more required calibrator or QC samples associated with the order have errors.
Sample Integrity	CH/IM	The system detected an irregular sample aspiration. The test result is Error.
Sample Probe Error	IM	The system was unable to complete the scheduled test because the sample probe was unavailable.
Sample Short (s)*	CH	The system detected insufficient amount of sample for the scheduled test.
Sample Tip Loader Error	IM	The system was unable to load a sample tip.
Sample Unloaded	CH/IM	The sample was no longer on the system.

Flag	Type	Notes
Software Error	CH/IM	A database or software corruption of the result caused an error. This flag indicates a serious problem. Stop the system and check the results.
System Error	CH/IM	The system encountered more than 1 mechanical errors before processing the order. Check the capabilities for the analyzer.
Temperature Error (F)*	CH	The reaction ring bath temperature was outside the specification range.
Test Canceled	CH/IM	The operator manually canceled the test.
Thermistor (T)*	CH	The system detected an abnormal thermistor.
Unable to process LYTES	CH	The CH Analyzer was unable to process NA, K, and CL tests.
Unable to wash cuvettes	CH	The system was unable to wash cuvettes due to a lack of system fluids or a mechanical error.
Waiting for Calibrator Samples	CH/IM	The required calibration samples were not onboard.
Waiting for QC Samples	CH/IM	The assay configuration included Perform QC with Calibration but the QC samples were not onboard.

Flag	Type	Notes
Wash Ring Error	IM	The analyzer could not perform the test because the wash ring subsystem was offline. Check system capabilities.
Waste Full	IM	The system could not perform the test because the cuvette bin, sample tip bin, or waste reservoir was full.
Water Pressure Error	CH/IM	The analyzer could not perform the test because the water pressure was out of tolerance.
Wrong Pack ID	CH/IM	The operator did not load the primary or ancillary reagent with the specified pack serial number for this test.

* The system replaces the letter or symbol in the parenthesis with a specific value.

About Invalidating a Calibration in Calibration Results

This task requires the appropriate security level.

The operator can invalidate a current active lot or pack calibration to remove the calibration from use. The system reverts to using a previous valid calibration to process test results or may require a new calibration.

The operator invalidates an active lot or pack calibration:

- One calibration at a time
- In any system state
- After all inprocess tests requiring the calibration complete with results

NOTE: If the operator invalidates the only active calibration available to generate results for inprocess tests, the system flags test results with Cal Required.

Invalidating a calibration removes the calibration from use permanently and cannot be reversed.

About Details in Calibration Results

Details in Calibration Results includes the following:

- Information (Page 445 *About Information Details in Calibration Results*)
- Coefficients (CH only) (Page 445 *About Information Details in Calibration Results*)
- Data (Page 448 *About Calibration Results Data*)
- QC Performed with Calibration
- Acceptance Criteria (Page 450 *About CH Assay Reagent Calibration Data Evaluation Values*), (Page 452 *About IM Assay Reagent Calibration Data Evaluation Values*)
- Comments
- Graph (CH only)

The following are functions of Details in Calibration Results:

- Print
- Accept
- Reject

About Information Details in Calibration Results

Details in Calibration Results provides a summary of the calibrator order information from the test definition, reagent pack barcode data, or operator-defined entries.

Information	Notes
Activity	Calibration type (Page 421 *Calibration Types*).
Assay	Calibrated assay reagent name.
Units	Assay result units.

Information	Notes
Calculation Type	A specific standard curve the system uses to calculate the analyte concentration.
Ordered Date	Date and time the system or operator placed the calibration order.
Completed Date	Date and time of the calibration result.
Accepted By	Operator ID for manual calibration acceptance or the system for automatic acceptance.
Analyzer Name	Analyzer that processes the calibration.
Analyzer Serial Number	Analyzer serial number.
Reagent Lot	Calibrated assay reagent lot. For IM: Lot of the Primary reagent.
Pack/Well	Calibrated IM assay primary reagent pack identification. Calibrated CH assay reagent pack and well identification.
Ancillary 1	IM only: Calibrated assay that requires ancillary 1 reagent pack.
Ancillary 1 Lot/Pack	IM only: Ancillary reagent 1 lot and pack identification.
Ancillary 2	IM only: Calibrated assay that requires an ancillary 2 reagent pack.
Ancillary 2 Lot/Pack	IM only: Ancillary reagent 2 lot and pack identification.
Calibrator Name	Calibrator material name.
Calibrator Lot	Calibrator material lot.
Calibration Status	Calibration status.

Information	Notes
Acceptance Criteria	CH calibration acceptance criteria (Page 450 *About CH Assay Reagent Calibration Data Evaluation Values*). IM calibration acceptance criteria (Page 452 *About IM Assay Reagent Calibration Data Evaluation Values*).
Acceptance Mode	Acceptance mode includes: • Automatic: The system accepts results when configured in Calibration Setup. • Manual: The operator accepts results.
Trigger Mode	Manually-created calibration orders display Operator Initiated. Automatic calibration orders display Automatic. Automatic calibration triggers are assay-specific according to the CH and IM test definition settings and may include the following: • New reagent lot • Lot calibration interval expired • Pack calibration interval expired • Calibrator IFU changed • New assay TDef version
Calibration Expiration	Date and time the calibration expires.

About CH Coefficients in Calibration Results

The system calculates the CH Coefficients values from the associated curve fitting algorithm. The calculated values display with 2 decimal places and include a coefficient label and the associated coefficient value (C0–C9).

About Calibration Results Data

The Calibration Results Details displays information about the Analyte concentration and the measured Signal values for multiple calibrator replicates.

Details Data provides data for the following:

- Up to 6 CH calibrator levels
- IM low and high calibrator levels

Data	Notes
Replicate	Recovered replicate results and calculations
Include	Options for excluding or including replicate results
Analyte	Concentration for this replicate of the calibrator level
Signal values	Measured signal value from the detector
Flags	A list of any result Flags
Mean	Average of the replicate results
Median	Middle value between the highest and lowest replicate result values
SD	Standard deviation or the amount of variation for the recovered result values
Target %CV	Acceptable Coefficient of Variance for the IM calibrator levels
Observed %CV	Precision of the recovered results

About Assay QC Results in Calibration Results Details

When the system performs QC with a calibration, a summary of results displays in the QC Performed with Calibration in Calibration Results Details.

The system automatically performs QC with a calibration when the operator enables Perform QC with Calibration in Calibration Setup.

If a QC check fails, the operator must perform 1 of the following:

- Accept the calibration with failed QC
- Reject the calibration

NOTE: The system compares the QC results with the defined control material ranges before automatically accepting a calibration.

QC Performed with Calibration includes the QC results for calibration acceptance. This includes a row for each QC Level and is blank if the system does not perform QC.

QC Performed with Calibration	Notes
QC	The QC name and level.
QC Limits	The acceptable range of results for this QC level. QC results must be within QC limits as defined in the quality control product value sheet.
New Observed	The QC result for this level calculated from the new calibration adjustment.
Old Observed	The QC result for this level calculated from the previous Calibration adjustment.

About Accepting Calibrations in Calibration Results Details

The system compares calibration results to the assay acceptance criteria and determines 1 of the 4 following result outcomes:

- Valid
- Rejected
- Awaiting Acceptance
- Invalid

The Acceptance Criteria parameters display with a determination of a Pass or Fail calibration result.

Acceptance Criteria	Notes
Criteria	Acceptance criteria in the assay test definition
Result	An indication of passed or failed calibration results. Calibrations that did not pass have a red highlight.
Value	Recovered or measured result
Expected	Range of expected calibrator values
Observed	Range of observed calibrator values

Automatic and manual acceptance of assay calibrations depends on system configuration settings (Page 454 *About Accepting CH Assay Calibrations*) (Page 454 *About Accepting IM Assay Calibrations*).

About CH Assay Reagent Calibration Data Evaluation Values

The system reviews the following test definition calibration data evaluation criteria when determining a calibration result. If any of the acceptance criterion fails, the system cannot automatically accept the calibration and the operator must intervene.

Calibration evaluation data criteria	Notes
Percent Bias	Bias is the difference between the recovered calibration values and the expected calibrator values for all levels: `%Bias = ((Recovered value-Expected value)/Expected value)) * 100`
Slope	Linear comparison of the recovered calibrator values versus the expected values.
Intercept	The Y-intercept of the plot of the recovered calibrator values versus the expected values.
Correlation Coefficient Range	Measure of the linear relationship between the recovered calibrator values versus the expected values.

Calibration evaluation data criteria	Notes
Percent Deviation	Measure of how closely the calibrator level results fit the expected calibrator values. Similar to %Bias, except that the system calculates the absolute value to ensure that a high bias in a 1 level does not cancel a low bias in another level.
Percent Deviation Excluding Low Level	Measures how closely the calibrator levels fit the expected calibrator levels. The system excludes the low level.
QC Results Must Be Within Ranges	If selected, the system performs QC with the calibration. QC results must be within defined QC limits.

Accuracy measures how closely the recovered calibration results match the expected calibrator values.

Calibrator level accuracy evaluation data	Notes
Average Recovered Bottle Values	Averages of the recovered values
Recovery Percent Bias	Difference between the recovered value and the expected calibrator value for each calibrator level

Precision measures the variability between the replicate results for a calibrator level.

Calibrator level precision evaluation data	Notes
SD	Amount of variation of the calibration results
Recovery level %CV	Precision of the recovered results
Delta System Response	Delta system response between paired calibrator levels for each level pair: 1–2, 2–3, 3–4, 4–5 and is configured for all CH assays. When the operator compares the 1 and 2 values, they should review the configuration for level 2 to determine the delta absorbance for the delta system response.

The CH assay calibration feature includes 2 non-editable acceptance criteria.

System acceptance criteria	Notes
No flags	The system checks for process or measurement errors: • If no flags are present, this criterion is accepted. • If flags are present, the calibration fails.
No auto-excluded replicates	If the system auto-excludes a calibration replicate, the calibration fails.

About IM Assay Reagent Calibration Data Evaluation Values

The system reviews the following test definition calibration data evaluation values when determining a calibration result:

Calibration evaluation data value	Notes
Signal Slope	Comparison of high and low calibrator RLUs to the Master Curve (Page 455 *About IM Calibration Signal Slope*).
Signal Ratio	Comparison of low and high calibrator RLUs (Page 456 *About IM Calibration Signal Ratio*).
Level Deviation	Measure of how close the high and the low calibrator RLUs fit the master curve. The values are a relative measure of the deviation of the average RLUs of the low calibrator and the high calibrator from the master curve (Page 456 *About IM Calibration Allowed Level Deviation*).
Minimum replicates	Minimum number of calibrator samples the system aspirates for each calibrator level. The assay test definition contains the settings for the minimum required replicates for a calibration (Page 745 *About the Calibration Parameters in IM Test Definition*). This is the first criterion that the system checks after performing a calibration.
Low Level %CV	Precision of the low level calibrator replicates based on RLUs. Maximum CV allowed for a valid calibration. The CV of the individual calibrator replicates cannot exceed a defined acceptable value.
High Level %CV	Precision of the high level calibrator replicates based on RLUs. Maximum CV allowed for a valid calibration. The CV of the individual calibrator replicates cannot exceed a defined acceptable value.

Calibration evaluation data value	Notes
Critical Precision	Master Curve definition value that the system uses to determine whether an outlier is too far out for the system to autoexclude.
Minimum % neutralization	An acceptance criteria for Hbs confirmatory (CONF) calibrations. The minimum acceptable value is 50% neutralization.

About Accepting CH Assay Calibrations

Automatic acceptance of CH assay calibrations depends on system configuration settings.

If Automatic Acceptance is enabled in the CH test definition and the calibration results meet the evaluation acceptance criteria, the system automatically accepts the CH calibrations. The system sets the accepted calibration status to Valid. When the calibration results do not meet the evaluation of the acceptance criteria, the system sets the calibration status to Awaiting Acceptance. If the system cannot compute a calibration result, the calibration status is Invalid.

If Automatic Acceptance is disabled in the CH test definition and calibration acceptance criteria are within or outside the assay test definition specifications, the system sets the CH calibration to Awaiting Acceptance. The operator reviews the calibration data and accepts or rejects the calibration. If the operator accepts the calibration, the system sets the calibration status to Valid. If the operator rejects the calibration, the system sets the calibration status to Rejected.

About Accepting IM Assay Calibrations

The IM Analyzer automatically accepts calibrations under specific conditions. When calibration results meet all the acceptance criteria, the system sets the calibration status to Valid. When calibration results do not meet all the acceptance criteria, the system sets the calibration status to Rejected.

The operator has the option to configure the system to manually accept or reject calibrations for each assay.

If Accept Cal is enabled in the IM test definition and the calibration results meet the evaluation acceptance criteria, the system sets the calibration status to Valid. When the calibration results are in a manual acceptance range, the system sets the calibration status to Awaiting Acceptance. The operator reviews the calibration data and accepts or rejects the calibration. If the operator accepts the calibration, the system sets the calibration status to Valid. If the operator rejects the calibration, the system sets the calibration status to Rejected.

If the system cannot compute a calibration result, the calibration status is Invalid.

About IM Assay Reagent Calibration Data Evaluation

The system evaluates a calibration using values from the scanned MC TDEF 2D barcode for a reagent lot. The master curve definition includes the standard concentrations, related RLUs, and target values the system uses to evaluate calibration data. The system defines target value ranges for acceptable %CV, ratio, slope, and calibrator deviation. A calibration is valid if the calibration results are within the defined and observed ranges the system calculates.

About Acceptance Criteria for IM Assay Reagent Calibrations

The assay test definition contains the calibration acceptance criteria settings. Evaluate the calibration acceptance criteria to manually accept a calibration result. If configured , the system automatically accepts calibration results if the acceptance criteria passes.

Acceptance Criteria	Notes
Criteria	Acceptance criteria in the assay test definition
Result	An indication of passed or failed calibration results
Value	Recovered or measured result
Expected	Range of expected calibrator values
Observed	Range of expected calibrator values

About IM Calibration Signal Slope

The system reviews the calibration acceptance criteria including the Signal Slope. Signal Slope is a comparison of high and low calibrator RLUs to the Master Curve:

```
Slope = (High Cal Expected RLU - Low Cal Expected RLU)
/(High Cal Measured RLU - Low Cal Measured RLU)
```

About IM Calibration Signal Ratio

Signal Ratio is a comparison of low and high calibrator RLUs.

For sandwich assays, the ratio value is the difference between the mean RLU value of the high calibrator and the mean RLU value of the low calibrator divided by the mean RLU value of the low calibrator:

```
Ratio = (High Cal Mean RLU - Low Cal Mean RLU)/ Low Cal
Mean RLU
```

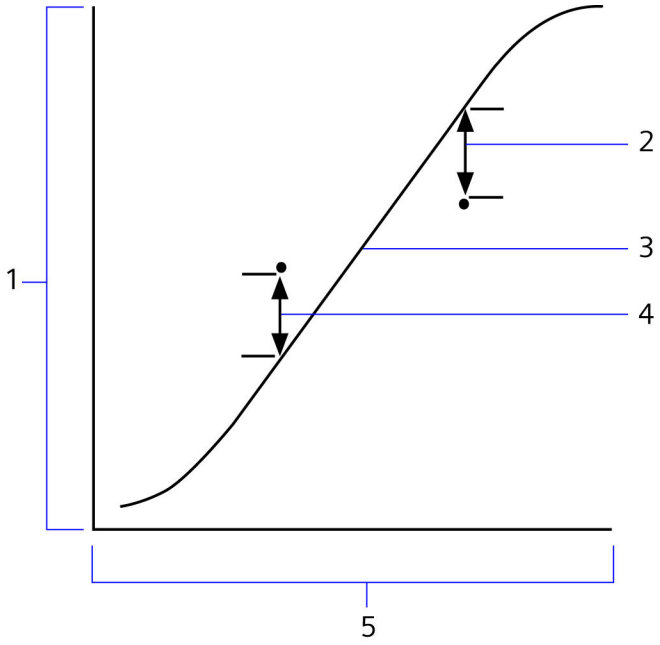
For competitive assays, the ratio value is the difference between the mean RLU value of the low calibrator and the mean RLU value of the high calibrator divided by the mean RLU value of the high calibrator:

```
Ratio = (Low Cal Mean RLU - High Cal Mean RLU)/ High Cal
Mean RLU.
```

About IM Calibration Allowed Level Deviation

The Level Deviation measures how well the high and the low calibrator RLUs fit the master curve. The values are a relative measure of the deviation of the average RLUs of the low calibrator and the high calibrator from the master curve.

Master curve with low and high deviations



1	RLUs
2	High calibrator deviation
3	Master curve
4	Low calibrator deviation
5	Concentration

About IM Calibration Results and Coefficient of Variation

Percent coefficient of variation (%CV) is the precision of the calibrator replicates for each level based on RLUs.

Acceptable %CV is the maximum %CV acceptable for a valid calibration. The %CV of the individual calibrator replicates cannot exceed a defined acceptable value. This is the first criterion that the system checks after performing a calibration.

The critical precision is a value in the Master Curve definition that the system uses to determine whether an outlier is too far out to exclude.

About Defined IM Assay Reagent Calibration Ranges

The Master Curve and Test Definition (MC TDEF) 2D barcode includes the defined ranges for Slope, Ratio, Allowed Low Level Deviation, and Allowed High Level Deviation for the assay reagent lot. The system uses these values to evaluate calibration results.

About Observed IM Assay Reagent Calibration Ranges

After performing 4 valid calibrations for a new reagent lot and calibrator lot combination, the system calculates observed ranges for Slope, Ratio, Allowed Low Level Deviation, and Allowed High Level Deviation. The system compares results from subsequent calibrations using the same reagent lot and calibrator lot combination to the defined ranges from the Master Curve definition and to the observed ranges the system calculates. The system recalculates observed ranges with each valid calibration.

The system establishes new ranges for the following events:

- New reagent lot
- New calibrator lot

Observed ranges are specific for the system and are narrower than the defined ranges.

About Excluding and Including Calibration Replicate Results

The assay test definition defines the minimum number of replicates the system requires to obtain a valid calibration. Outliers can cause a calibrations to fail. If specific criteria are met, excluding an outlier may correct an Invalid or Awaiting Acceptance calibration result. The system can autoexclude IM qualified outliers. The operator can manually exclude CH or IM calibration replicate results. After excluding an outlier replicate result, the system recalculates the calibration data and rechecks the calibration criteria.

The system autoexcludes IMoutlier calibration replicate results under the following conditions:

- The IM assay test definition setting for Autoexclude Cal Replicates is enabled.
- The calibration replicate result is an outlier.
- The minimum number of replicates the system requires for a valid calibration remain after the exclusion of the replicate.

The operator may manually exclude outlier calibration replicate results under the following conditions:

- The IM assay test definition setting for Autoexclude Cal Replicates is not enabled.
- The minimum number of replicates the system requires for a valid calibration remain after the exclusion of the replicate.

About IM Master Curve Data in Calibration Results

IM assays use an identical format for the Master Curve Data (Page 417 *About IM Assay Master Curves*). The curve points that display are the lot specific values from IM Test Definition Lots.

Master Curve Data	Notes
Concentration	The system uses data pairs to calculate a concentration value from an RLU value.
RLU	Relative Light Units is a unit of measure.
Critical Precision	Master Curve definition value that the system uses to determine if an outlier is too far outside to autoexclude.

About IM Trending on Calibrator Reagent Lot Pair in Calibration Results

About Trending on Calibrator Reagent Lot Pair displays the Initial and Last calibration results. The operator compares this data to the current result. The Initial value is the first accepted calibration. The Last value updates with the most recent calibration results. Last is blank when the system has only performed a calibration for a calibrator and reagent pair once.

Trending on Calibrator Reagent Lot Pair	Notes
Initial	The first calibration result the system performed on a reagent calibrator lot pair.
Last	The most recently accepted calibration result.
Low RLU	Mean signal from low calibrator.
High RLU	Mean signal from high calibrator.
Slope	Linear comparison of the recovered calibrator values versus the expected values. $\text{Slope} = \frac{\text{RLU}_{\text{High Cal Expected}} - \text{RLU}_{\text{Low Cal Expected}}}{\text{RLU}_{\text{Low Cal Measured}} - \text{RLU}_{\text{Low Cal Measured}}}$

Trending on Calibrator Reagent Lot Pair	Notes
Ratios	Comparison of the low and high calibrator RLUs. $\text{Ratio}_{\text{sandwich}} = \frac{\text{RLU}_{\text{High Cal Measured}} - \text{RLU}_{\text{Low Cal Measured}}}{\text{RLU}_{\text{Low Cal Measured}}}$ $\text{Ratio}_{\text{competitive}} = \frac{\text{RLU}_{\text{Low Cal Measured}} - \text{RLU}_{\text{High Cal Measured}}}{\text{RLU}_{\text{Low Cal Measured}}}$
Low Cal Dev	The acceptable deviation for the low level calibrator. $\text{Intercept} = \text{RLU}_{\text{Low Cal Expected}} - \text{slope} * \text{RLU}_{\text{Low Cal Measured}}$ $\text{Dev Low} = \frac{(1 - \text{Slope} - \text{Intercept}/\text{RLU}_{\text{Low Cal Measured}})}{(1 + \text{Slope}^2)^{1/2}}$ The calibration meets the acceptance criteria when the calculated Low Cal Dev is within the acceptable defined range.
High Cal Dev	The acceptable deviation for the high level calibrator. $\text{Intercept} = \text{RLU}_{\text{Low Cal Expected}} - \text{slope} * \text{RLU}_{\text{Low Cal Measured}}$ $\text{Dev High} = \frac{(1 - \text{Slope} - \text{Intercept}/\text{RLU}_{\text{High Cal Measured}})}{(1 + \text{Slope}^2)^{1/2}}$ The calibration meets the acceptance criteria when the calculated High Cal Dev is within the acceptable defined range.

About Calibrator Definitions

Calibrator Definitions provides the following functions for creating calibrator definitions:

- Add new calibrator material definitions (Page 461 *About Installing Calibrator Definitions*)
- Edit calibrator material definitions
- Delete calibrator material definitions
- Print calibrator material definition barcodes

The Filter area provides the following filter options:

- Material Name
- Status
- Assay Type
- Assays

▼ and ▲ sort the column contents in ascending or descending alphanumeric order, respectively.

Column header	Notes
Material Name	Name of the calibrator material definition.
Lot ID	Lot for the calibrator.
Material ID	Calibrator material product ID.
Expiration Date	Calibrator expiration date and time.
Assays	The calibrator material contains known concentrations of analyte for 1 or more assays.

About Installing Calibrator Definitions

Install calibrator definitions using 1 of the following methods:

- Scanning the barcode on the calibrator lot-specific value sheet.
- Manually entering the required information from the calibrator lot-specific value sheet.

Manually Adding CH Calibrator Definitions

1. Navigate to **Calibrator Definitions**.
2. Select **Add Manually**.
3. From the Assay Type drop-down menu, select **Chemistry**.
4. In Material Name, enter a name for the calibrator definition.
5. In Material ID, enter the ID from the calibrator lot-specific value sheet.

   NOTE: The Material ID is an optional field that contains 1 or 2 alphanumeric characters. The calibrator lot-specific value sheet specifies the Material ID.
6. In Lot ID, enter the calibrator lot.

7. In Expiration Date, select the calibrator material expiration date from the drop-down calendar.
8. In Revision, enter the revision number from the calibrator lot-specific value sheet.
9. If storing the calibrator in the Cal-QC storage area, select **Store Onboard**.

   NOTE: Some CH calibrator material is not eligible for onboard storage in the Cal-QC area in an SH configuration. The operator cannot select Store Onboard and save a calibrator definition that includes an assay that is not eligible for onboard storage.

   Load calibrator samples directly into the SH drawer for processing.
10. To enable the calibrator material for calibration, select **Active**.
11. Select 1 or more assays associated with the calibrator material.
12. Enter the concentration values for each level from the calibrator lot-specific value sheet.

    NOTE: The operator must enter CH calibrator values in the report unit configured in the CH Test Definition. If changing units in the CH Test Definition for an assay, the operator should change units prior to creating CH calibrator definitions.
13. Select **Save**.

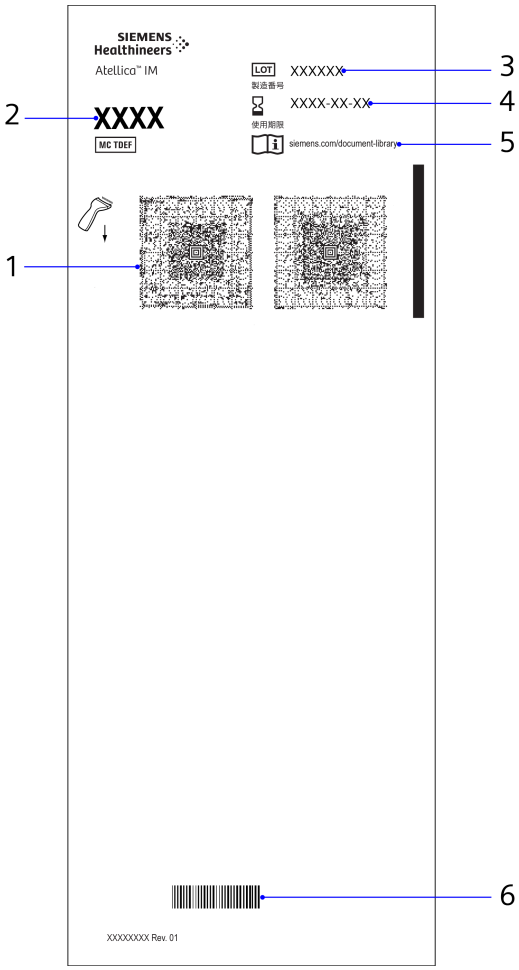
    NOTE: Some assays require calibrator material levels with a different Material ID, Lot ID, or Expiration Date.

About IM Master Curve and Test Definition 2D Barcodes

Each IM assay reagent kit includes a Master Curve and Test Definition (MC TDEF) 2D barcode.

The manufacturer encodes a collection of data on a set of MC TDEF 2D barcodes that are specific to an individual assay reagent lot and test definition version. The system uses the encoded values to calibrate, process, and calculate results. The MC TDEF insert can have 1 or more 2D barcodes.

MC TDef 2D barcode



1	2D barcode	5	Laboratory Diagnostics Document Library URL
2	Assay name		
3	Lot	6	Linear barcode for manufacturer use only
4	Expiration date		

About Calibrator Sample Barcode Format

To manually create calibrator sample barcodes offline, include the following information in sequence:

Barcode Information	Length	Content
Unique identifier for calibrator samples	2 characters	:%
Material ID	2 characters	Enter the Material ID from the calibrator definition or if a Material ID does not exist, 2 spaces.
Lot ID	2–9 characters	Enter the Lot ID from the calibrator definition.
Calibrator level ID	1 character	For a 2 level calibrator, enter the following: • **A** for the low calibrator level. • **B** for the high calibrator level. For a CH calibrator using up to 6 levels, enter **A**–**F** as appropriate. For a single IM calibrator, enter **A**. For manual measuring interval verifications, enter number IDs from **1** up to **9**.
Operator-defined tube tracking number	6 digits	Enter a unique 6 digit number from 000000–999999.

The Lot ID must match the calibrator definition information.

The following is an example of a low and high level calibrator sample barcode where the Material ID is XY and the Lot ID is C111:

:%XYC111A000001

:%XYC111B000002

NOTE: Printing the barcode requires a 300 DPI printer and 6.66 MIL.

About CH Calibrator Definition Value Sheet Barcodes

A lot-specific value sheet accompanies the calibrator material. The 2D barcodes on the value sheet contain the following information:

- Material ID
- Lot ID
- Expiration Date
- Revision
- Assays associated with the calibrator material
- Calibrator material level values

About IM Calibrator Definition Value Sheet Barcodes

A lot-specific value sheet accompanies the calibrator material. The set of linear barcodes on the value sheet contain the following information:

- Material ID
- Lot ID
- Expiration Date
- Revision
- Checksum
- Assays associated with the calibrator material
- Calibrator material level values

About CH IMT Calibrations

NOTE: The operator must wait until the IMT completes calibrating before selecting Replace IMT Supplies. Selecting Replace IMT Supplies while IMT calibration is in process displays a status that the IMT is pausing until the calibration is complete.

A window displays if the IMT Advanced Clean is required. The analyzer pauses the IMT when the operator selects **Replace IMT Supplies** to replace the A-LYTE multisensor from this window.

The system uses 2-point calibration to automatically calibrate the IMT system after the following situations:

- 4-hour intervals.
- 250 IMT tests complete since the last calibration.
- Temperature changes more than ±2°C.

- NA, K, CL ion SD unstable errors or Drift Errors cycle ion drift.
- Standard air or liquid detect error.
- System startup.
- Reset from a paused or stopped state.
- Routine cleaning procedure.
- Exiting diagnostics and maintenance.
- IMT successful error recovery.
- A-LYTE multisensor, Standard A, or Standard B replacement.
- Either Standard A, Standard B, or Salt Bridge are primed via Prime All or individually. No calibration is required if only the IMT Sample Diluent is primed.

If the IMT calibration fails 3 times in succession, the IMT system generates an error. The operator must intervene and resolve any issues before performing any additional calibrations.

During an IMT calibration, the analyzer does not process IMT tests.

IMT Calibration	Notes
Module selector	When available, the operator selects the appropriate analyzer to view IMT calibrations.
IMT Calibration Status	When IMT testing is enabled, the last completed IMT Calibration Status including the date and time of completion displays. When IMT testing is enabled, the IMT Calibration Status displays as 1 of the following: • Valid: Calibration criteria was met and displays as ✔. • Invalid: Calibration completed, at least 1 ion tested is out of range, and displays as ⚠. • Inprocess: Currently processing the IMT calibration and displays as ⟳. Error: The system did not perform an IMT Calibration and displays as ⚠. When IMT testing is disabled, the system displays IMT Tests are disabled for this analyzer.
IMT Status	The status of an IMT system activity.
Status	The status for each individually performed IMT test and includes 1 of the following: • Pass • Fail

IMT Calibration	Notes
Ion	Displays the following calibration tests: • Na+: The values from the Na+ sensor. • K+: The values from the K+ sensor. • Cl-: The values from the Cl-sensor. • Air Reading: The values of the air readings during calibration for STD A and STD B. • Liquid Reading: The values of the fluid readings during calibration for STD A and STD B. • IMT Pumping Rate: The value of the peristaltic pump alignment test. Compensates for any variations in pumping efficiency.
STD A	The results for STD A calibration tests.
STD B	The results for STD B calibration tests. Does not display values for IMT Pumping Rate.
Slope	The slope of the measured values compared to the slope limits. Does not display values for Air Reading, Liquid Reading, and IMT Pumping Rate.
Slope Ranges	The range of the slope. Does not display values for Air Reading, Liquid Reading, and IMT Pumping Rate.

IMT Calibration	Notes
Errors	The associated error messages for First STD A Measurement, STD B, and Second STD A Measurement. Does not display if no errors are associated with the last calibration.
Calibrate IMT	The operator selects to initiate an IMT calibration. This button is disabled when 1 of the following occurs: • The IMT calibration is Inprocess. • The IMT system is disabled. • The system is stopped because of an error.

About IMT Calibration Status Icons

Icons alert the operator to information or a required action.

IMT calibration status icons	Notes
	Valid
	Error
	Inprocess

Reviewing IMT Calibrations

1. Navigate to **IMT Calibration**.
2. Review results.
3. Troubleshoot any existing errors.
4. To print the IMT calibration, select from the Tool bar.

15 Quality Control

Quality Control

This content provides information about adding quality control (QC) definitions, performing quality control, and reviewing statistics.

Use the quality control material in accordance with the quality control instructions for use. Follow laboratory procedures, accreditation requirements, and government regulations for quality control frequency. In addition, perform quality control:

- Following a valid calibration
- With use of a new lot of reagent
- When troubleshooting test results that do not match clinical conditions or symptoms

Follow the laboratory's quality control procedures if obtained results do not fall within acceptable limits.

Performing Quality Control in an SH Configuration



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.



CAUTION

Do not use barcode labels from 1 lot of QC material for another lot of QC material. QC barcode labels are lot specific. If an operator uses the wrong lot specific QC barcode labels, errors occur.



CAUTION

Do not reuse IM QC material remaining in the sample tubes or refill QC sample tubes after use. If an operator reuses the QC material, errors occur. Always dispense fresh QC material.

1. To perform QC for an assay, ensure the following items are configured on the system:
   - Assay master curve (IM only)
   - Test definition
   - Assay calibration
   - Control definition
   - Assay reagent
2. Import or manually enter the QC definitions for all required levels (Page 477 *Manually Adding QC Definitions*).
3. Create a QC order.
4. Print the QC material barcodes.
5. Affix the barcode labels to the QC tubes.

   NOTE: Orient the barcode label characters vertically.
6. Add sufficient volume of fresh QC material to the labeled tubes.

   NOTE: Optimum quality control reproducibility requires consistent QC material sample processing. For a given QC material, consistently process cold QC material samples directly from the Cal-QC storage area or the Sample Handler drawer at ambient temperature.
7. Place the QC material samples in a sample rack and place the rack in the sample drawer.
8. To process the QC material samples immediately, place the tubes in a STAT rack.
9. Review the QC results.

Monitoring QC Results

1. Create QC Orders.
2. Schedule QC (Page 497 *About the QC Scheduler*).
3. Review in-process QC orders (Page 354 *Reviewing Patient Results in Worklist*).
4. Analyze QC Results.
5. View QC Statistics data and charts.
6. Create QC Reports.
7. Maintain the QC database.

About QC Definitions

The operator can import QC Definitions from an XML file or manually add them in Add New QC Definition. A QC definition can contain from 1–9 Levels, where the ranges are defined separately for each level of the QC Material ID. When manually adding new QC Definitions, the operator must define the control details then the associated tests.

The operator can export QC Definitions from an existing Atellica Solution configuration and import them to the same or another Atellica Solution configuration using the Export and Import features in QC Definitions. When importing a new QC definition, the system overwrites existing settings using the new settings defined in the imported QC definition. The operator can then edit the settings, if appropriate.

Assays which have a separate control card for Negative and Positive controls have a separate XML file for each level. Neg or Pos is in the file name.

Quantitative assays reported in conventional or SI units have an XML file available for each reporting unit type. Unit type is specified in the file name. Select the document with the appropriate reporting unit type.

File Name by Unit Type	Example
SI units type has SI in the file name	cPSA QC – SI – Atellica IM – Lot 051662 – QC Def – Exp. 2022-06-15.xml
Conventional units type does not have SI in name	cPSA QC – Atellica IM – Lot 051662 – QC Def – Exp. 2022-06-15.xml

About Add New QC Definitions

QC Details	Notes
QC Material	The name of the QC material as defined by the customer or imported from the QC Definitions XML file. Displays as Material Name. **NOTE:** QC Material applies to all lots of a specific QC material.
Parent Lot	The lot number that designates all levels of the QC Material.

QC Details	Notes
Specimen	The Specimen type associated with the tests that the QC Material supports. **NOTE:** The operator must select the **Serum/Plasma** specimen type for QC materials associated with tests for Serum, Plasma, or both. This specimen type applies to QC samples only.
QC Type	The type of QC Material: • Routine QC materials are independent from the reagent kits and do not require a checksum. • Kit QC materials are part of the reagent and require a checksum. Kit QC materials may be lot-locked or control-bracketed. **NOTE:** For Kit QC materials, the operator must create a separate QC definition for each Level.
Usage	The Usage drop-down menu specifies the purpose of the QC Material for system and assay performance: • Primary: Primary QC materials produce QC results that determine Patient QC Flagging in QC Statistics. • Alternate: The operator performs Alternate QC Material lots for additional QC flagging and statistical data.

QC Details	Notes
	• Parallel: The operator can perform QC on new QC Material lots in parallel with primary QC Material lots for QC Statistics. Parallel QC results generate observed ranges but do not generate violations or flags for test evaluations (Page 482 *About Observed Ranges*). • Not In Use: The QC Material lot is expired or unavailable.
Store onboard	The system can store some QC Material onboard. This option applies to SH configurations only.
Level check boxes	The operator can select the QC Material levels to be grouped together in the QC definition.

Select Assays	Notes
Assay Type	The operator can filter the assay list according to CH or IM assay type.
Search Assay	The operator enters the assay name to select and add to the Level Details.

Level Details	Notes
QC Material ID	An identifier for the QC Level as defined by the customer or imported from the QC Definitions XML file. Displays in the Sample ID column of the Worklist.
QC Lot	The bottle lot number of the QC Material.
QC Lot Expiration	The date the QC Material expires.
Test Name	Tests associated with the QC Material.

Level Details	Notes
Units	Units of concentration, obtained from the QC Material packaging.
RiliBÄK Setting	The operator can select B1 or Non-B1. **NOTE:** Configurable when RiliBÄK Feature is On in QC Settings.
SD	The standard deviation the system uses to calculate the range. The system uses SD to calculate the Low and High values of the range when the operator enters values for Mean and +/- Range. The system uses SD to calculate the Mean and +/- Range when the operator enters Low and High values for the range. **NOTE:** The operator can select **N/A** for no range.
Low	The low range value for QC flagging (enter if the +/- Range is not available). Low value determines when to flag QC Results on the Worklist.
High	The high range value for QC flagging (enter if the +/- Range is not available). High value determines when to flag QC Results on the Worklist.
Mean	The mean value of the range for QC flagging.
+/- Range	The range above and below the mean.
Result	The possible QC result for a Qualitative Assay. **NOTE:** The Result column is applicable when QUAL is selected for SD.

Level Details	Notes
Open Stability Days	The number of days the QC Material remains stable after loading.
Open Stability Hours	The number of hours the QC Material remains stable after loading.
Clear All Ranges	The system clears the ranges entered for all tests in Level Details for the current Level tab.
Observed Ranges	When selected, the system uses the ranges calculated from data obtained from QC Statistics.

Manually Adding QC Definitions

1. Navigate to **QC Definitions**.
2. Select **Add New**.
3. Add Control Details (Page 478 *Adding Control Details*).
4. Add Level Details (Page 478 *Adding Level Details*).
5. Select **Save**.

Adding Control Details

1. In QC Details, enter the following information:
   - QC Material
   - Parent Lot
   - Specimen
   - QC Type
   - Usage

   NOTE: Select Specimen type **Serum/Plasma** for controls that support tests for Serum or Plasma.
2. If the system stores the controls onboard, select the check box for Store onboard.

   NOTE: When performing QC with onboard controls, the system retrieves the control sample automatically as part of the QC order.
3. Select the appropriate check boxes for Level to be included in the QC definition.

   NOTE: Kit QC materials can have only 1 Level per QC definition.

Adding Level Details

1. For each level, enter the following information:
   - QC Material ID
   - QC Lot
   - QC Lot Expiration
2. In Select Assays, select the appropriate tests.

   NOTE: When selecting tests, filter the list using the Assay Type drop down.
3. Enter the SD for each assay.
4. Define ranges by 1 of the following methods for each assay:
   - Specify Low and High.
   - Specify Mean and +/- Range.

   NOTE: When defining ranges, select **Observed Ranges** to update the target control ranges with QC data the lab obtains.
5. Enter 1 of the following for each assay:
   - Open Stability Days
   - Open Stability Hours

About Import QC Definition

Import QC Definition	Notes
QC Material	The name of the QC material as imported from the QC Definitions XML file. Displays as Material Name. **NOTE:** QC Material applies to all lots of a specific QC material.
Parent Lot	The lot number that designates all levels of the QC Material.
QC Lot	The bottle lot number of the QC Material.
QC Material ID	An identifier for the QC Level as imported from the QC Definitions XML file. Displays in the Sample ID column of the Worklist.
QC Lot Expiration	The date the QC Material expires.
Usage	The Usage drop-down menu specifies the purpose of the QC materials for system and assay performance: • Primary: Primary QC materials produce QC results that determine Patient QC Flagging in QC Statistics. • Alternate: The operator performs Alternate QC Material lots for additional QC flagging and statistical data.

Import QC Definition	Notes
	• Parallel: The operator can perform QC on new QC Material lots in parallel with primary QC Material lots for QC Statistics. Parallel QC results generate observed ranges but do not generate violations or flags for test evaluations (Page 482 *About Observed Ranges*). • Not In Use: The QC Material lot is expired or unavailable.
QC Type	Whether the QC Material is part of the reagent: • Routine QC materials are independent from the reagent kits and do not require a checksum. • Kit QC materials are part of the reagent and require a checksum. Kit QC materials may be lot-locked or control-bracketed. **NOTE:** For Kit QC materials, the operator must create a separate QC definition for each Level.
Checksum	An 8-digit hexadecimal value generated by the control product manufacturer and used to verify the correctness and completeness of the QC definition data for Kit QC Material types.
Specimen	The Specimen type associated with the tests that the QC material supports. **NOTE:** The operator must select the **Serum/Plasma** specimen type for QC materials associated with tests for Serum, Plasma, or both. This specimen type applies to QC samples only.

Import QC Definition	Notes
Store onboard	The system can store some QC Material onboard. This option applies to SH configurations only.
Test Name	Tests associated with the QC Material.
Units	Units of concentration, obtained from the QC Material packaging.
RiliBÄK Setting	Displays when RiliBÄK Feature is On in QC Settings.
SD	The standard deviation the system uses to derive the range. **NOTE:** The operator can select **N/A** for no range.
Low	The low range value for QC flagging (enter if the +/- Range is not available). Low value determines when to flag QC Results on the Worklist.
High	The high range value for QC flagging (enter if the +/- Range is not available). High value determines when to flag QC Results on the Worklist.
Mean	The mean value of the range for QC flagging.
+/- Range	The range above and below the mean.
Result	The possible QC result for a Qualitative Assay. **NOTE:** The Result column is applicable when QUAL is selected for SD.

Import QC Definition	Notes
Open Stability Days	The number of days the QC Material remains stable after loading.
Open Stability Hours	The number of hours the QC Material remains stable after loading.

About Importing QC Definitions from XML Files

The control material supplier provides the QC Definitions information. If the QC Definitions is available in an XML file, the operator can import the QC Definitions directly to the system. To obtain the XML file from the supplier, the operator must follow the supplier instructions. The operator can obtain XML files from the Siemens Healthineers Document Library (Page 25 *Accessing Product Information in the Document Library*).

In addition, the system can import an XML file exported from an Atellica Solution configuration. The operator can transfer XML files to the system using local media such as a USB drive.

NOTE: If using a USB to transfer the XML file, the operator must remove the USB prior to restarting the system. If the USB is in the system during a restart, the system attempts to restart from the USB drive.

If the system is connected to a local network, the operator can transfer the xml file to the system from the network. The operator should follow laboratory protocol for transferring the XML file.

The operator must follow the supplier instructions for material use and laboratory protocol for supplied ranges use. The system warns the operator that the import file replaces the QC Definitions low and high limits for the selected assays. The operator can select to continue with the import and update QC limits. Using this feature, the laboratory can cascade low and high QC limits from laboratory observations or for reagent lot dependent controls on systems with an existing QC definition.

About Observed Ranges

The operator can update the target control ranges in the QC Definitions with QC data the lab obtains, such as during parallel testing. Follow laboratory protocol for the amount of data necessary to establish observed ranges.

About QC Sample Barcode Formats

To manually create routine QC sample barcodes offline, include the following information in sequence:

Barcode Information	Length	Content
Unique identifier for QC samples	2 characters	Enter :&
Operator-defined QC Material ID	1–11 characters	Enter the Operator-defined QC Material ID from the QC definition
Operator-defined tube tracking number	6 digits	Enter a unique 6 digit number from 000000–999999

The QC Material ID must match the QC Material ID in the QC definition.

The following is an example of a routine QC sample barcode where the operator-defined QC Material ID is QC1:

:&QCLow000001

:&QCHigh000001

NOTE: Printing the barcode requires a 300 DPI printer and 6.66 MIL.

About Kitted QC Sample Barcode Formats

To manually create kitted QC sample barcodes offline, include the following information in sequence:

Barcode Information	Length	Content
Unique identifier for QC samples	2 characters	:&
Operator-defined QC Material ID	1–11 characters	Enter the Operator-defined QC Material ID from the control definition.
Operator-defined tube tracking number	6 digits	Enter a unique 6 digit number from 000000–999999.

The QC Material ID must match the QC Material ID in the lot-locked control definition and includes K and the last 4 digits of the control lot.

The following are examples of kitted QC sample barcodes:

Control level	Name	Control lot	Control ID	Sample barcode
1	XXX-NEG031	311061	K1061	:&K1061000001
2	XXX-POS032	311062	K1062	:&K1062000002
3	XXX-POS033	311063	K1063	:&K1063000003
4	XXX-POS034	311064	K1064	:&K1064000004

NOTE: Printing the barcode requires a 300 DPI printer and 6.66 MIL.

About Editing QC Definitions

In Edit QC Definitions, the operator can view or edit the properties of existing QC Definitions. The operator can also Clear All Ranges already defined for a control lot and use Observed Ranges from previously acquired lab data. If an open QC order exists for the control material, the operator cannot edit the QC definition.

Downloading QC Definitions from Document Library

1. Sign in to Document Library.
2. In the Search field, enter the QC material lot number or name.
3. Select the check box next to the appropriate QC definitions.
4. Select **Download**.
5. Select **Open**.

   NOTE: Ensure the search results contain ZIP files.
6. From the File menu, select **Extract all**.
7. Save to a network folder that the system can access or to an external USB drive that was scanned with anti-virus software.
8. Import the QC definition on the system.

   CAUTION

   Do not make any changes to the text or values in the XML file. Changes may cause the files to become unstable.
9. If appropriate, edit the QC information on the system display.

About QC Panels

QC Panels	Notes
Panel Name	A unique name for the panel. Panel Name is a required entry.
Module	The analyzer or analyzers the system uses to perform the test.
Test Name	The names of the assays associated with the controls included in the panel.
Status	The status of the controls in the panel: Not In Use or In Use.
Next Expiration Date	The earliest expiration date of all levels defined within the control materials included in the panel.
Date Last Modified	The latest date of any changes to the selected QC panel.

QC Panels	Action
Filter	Categorize QC Panels by Module, Status, or Assay.
Edit/View	Edit or view existing QC Panels.
Copy	Copy existing QC panel information to rename and edit for new QC Panels.
Delete	Delete QC Panels.
Add QC Panel	Define new QC Panels.

About Adding New QC Panels

The following guidelines apply when adding, editing, copying, or deleting QC Panels:

- QC Panels must have at least 1 test and 1 QC material.
- The operator can create a QC panel for more than 1 analyzer, if available, by adding the panel to each analyzer separately.
- The operator cannot change a Panel Name after saving QC Panels.

- If the status of 1 or more QC material in a QC panel is In Use, the panel status displays In Use.
- When using QC panel in QC orders, the following restrictions apply:
  - The operator can only create orders for QC material lots with a Primary, Parallel, or Alternate Usage.
  - The operator can only select enabled tests in QC Panels.
- The following restrictions occur when QC Panels contain tests associated with QC material lots.

  The operator cannot delete:
  - A test from a QC definition that includes a test using the same QC material lot as the QC Definition
  - A QC definition with a QC material lot that any QC panel uses
  - A QC panel that any scheduled QC event uses

About QC Orders

The operator can manually create QC Orders to process materials that verify the performance of the system and assays.

To associate QC Material with QC Orders, the operator must define the QC material in QC Definitions.

NOTE: QC Orders always process with a priority of ASAP. The operator cannot select a priority when creating QC Orders.

The operator specifies how to use the QC results in QC Statistics.

The operator can create QC Orders by:

- Assay
- Material
- QC Panel

QC Orders	Notes
Select By	Specifies the QC order according to: • Assay • Material • QC Panel **NOTE:** Select By Assay is the default option.

QC Orders	Notes
Analyzer	Selects the analyzer or analyzers associated with the assays for the QC order, if available. Analyzer is required to create QC Orders for multi-analyzer configurations only.
Material Status	Specifies whether the QC material is Primary, Alternate, Parallel or Not In Use. **NOTE:** Material Status applies only when ordering QC by Assay or by Material.
Material Level Selection	Specifies whether the material levels displayed are configured: • By Operator allows the operator to select all material levels for the QC order. • 1 Level by System allows the system to select 1 material level for the QC order. **NOTE:** The operator cannot select the material level with 1 Level by System. **NOTE:** Material Level Selection applies only when ordering QC by Assay.
Select Assays for QC	The operator enters or selects the assays associated with the QC order.
Select QC Material	Filters available QC materials corresponding to the selected assays with QC Needed, if appropriate. **NOTE:** Select QC Material applies only when ordering QC by Material.

QC Orders	Notes
Filter QC Panels	Filters available QC panels to add to a QC order. **NOTE:** Filter QC Panels applies only when ordering QC by QC Panel.
Status	Filters QC panels by All or In Use.
Search	Filters QC panels by assays included in the panel.
Next	Displays QC Orders review window. The operator can Place Order from the QC Orders review window.
Clear	Clears data from the QC Orders window. Restores Select By panel to default options.

Select By Assay	Notes
Select Reagents grid	Details about the onboard reagents for the selected analyzers.
Analyzer ID	The selected analyzer or analyzers.
Assay	The selected assay names.
Reagent Pack ID	The reagent pack ID with the following: • Selected by System: Indicates the system selects a reagent pack at the time of the test. This is the default value. • Selected by Operator: Indicates the operator selects the reagent pack.
Inventory	The total count of all the reagent packs for each assay along with the remaining test counts for each reagent pack.

Select By Assay	Notes
QC Needed	The reagent pack status: • Needed: At least 1 reagent pack has a QC trigger or a QC Statistics violation detected for the assay. • No: No QC needed. • NA: Packs are available but not pierced.
Select QC Material grid	Details about available onboard and offboard QC materials and lots for the selected assays.
Material Name	The available QC materials for the selected assay.
Level	The selected levels to perform, according to the QC definition. **NOTE:**: Selected by System displays when the operator selects 1 Level by System for the Material Level Selection
Onboard	Whether the selected material is on the system.
Lot	The lot number of the selected QC material.
Material ID	The ID number of the selected QC material.
Lot Expiration	The expiration date or dates for each for QC material level.
Usage	Whether the material is a Primary QC material, an Alternate, Parallel, or Not In Use.
Specimen Type	The type of specimen associated with the QC material.
Assay	The assay or assays defined for the QC material.

Select By Material	Notes
Select QC Material grid	Details about the selected QC materials.
Material Name	The available QC materials for the selected assay.
Level	The selected levels to perform, according to the QC Master List. **NOTE:** Selected by System displays when the operator selects 1 Level by System for the Material Level Selection
Onboard	Whether the selected QC material is on the system.
Lot	The lot number of the selected QC material.
Material ID	The ID number of the selected QC material.
Lot Expiration	The expiration date or dates for each for QC material level.
Usage	Whether the material is a Primary QC material, an Alternate, Parallel, or Not In Use.
Specimen Type	The type of specimen associated with the QC material.
Assay	The assay or assays defined for the QC material.

Select by QC Panel	Notes
Select QC Panels grid	Selects QC Panels for the QC order.
Panel Name	The available QC Panels for the analyzer or analyzers.
Analyzer	The analyzer associated with the QC Panel.
Test Name	The assays associated with the QC Panel.

Select by QC Panel	Notes
Status	Whether the QC material is In Use.
Next Expiration Date	The earliest expiration date associated with the QC materials included in the panel.
Date Last Modified	The last time the QC Panel was changed.

About IM Control Bracketing

The IM control bracketing feature enables laboratories to comply with procedural recommendations for closely regulated tests. A control bracket consists of a set of designated controls preceding and following a group of patient samples for a specific test.

The set of controls preceding the group of patient tests opens a new control bracket. The system retains patient sample results until the set of controls following the group of tests closes the control bracket. The close bracket set of controls also opens a new control bracket. The system does not report sample results until the close-bracket controls complete with acceptable results. If the close-bracket controls do not complete with acceptable results within a designated time interval, the system discards the retained patient results.

NOTE: Use the same control lot to open and close the control bracket.

The following is an example of a complete control bracket:

1. Open bracket EHIV control levels 1–4
2. EHIV patient orders
3. Close bracket EHIV control levels 1–4

The test definition indicates if an assay requires control brackets. In the Definition tab, the Control-bracketed Test option box is active and checked. The test definition for a control-bracketed assay includes a timeout setting for the maximum allowable time between the opening of a bracket and the aspiration of the first control in the close bracket set. If the timeout expires, the control bracket does not close and the system discards the retained patient results. The system displays a reminder to close the bracket before the timeout expires. Edit the Reminder (Hours) setting in the assay test definition.

About IM Control Bracketing Overview

IM Control Bracketing overview summarizes reagent, control, and control bracket data for control bracketed tests. It consists of the following areas:

- Module selector: When available
- Reagent displays Lot and Reagent Reserve
- Control displays Lot and Lot Expiration
- Control Bracket displays Inprocess Tests, Waiting for Bracket, Timeout, QC Schedule, and Status
- QC Levels displays Level and QC Material ID

The laboratory views and manages control brackets in **QC > Control Bracketing**.

Control Bracketing	Notes
Module Selection	When available, the operator selects the appropriate analyzer for the control-bracketed test or tests.
Test	The control-bracketed test. **NOTE:** Blank if the row above displays information for the same test.
Reagent Lot	Non-expired Reagent Lot for the control bracketed test.
Reagent Reserve	Warning indicator of the Reagent Reserve threshold status for this test and reagent lot combination. ⚠ indicates that the system has reached the threshold and not enough reagent is present to continue performing the test with this reagent lot.
Control Lot	QC Material Parent Lot number for the appropriate QC Material set for the selected test and reagent lot.
Control Lot Expiration	The expiration date of each QC material level.

Control Bracketing	Notes
Control Lot Expiration Warning (no column label)	Displays ⚠ if the QC Material lot is close to the expiration date.
Control Bracket Inprocess Tests	The number of in-progress patient control-bracketed tests in the control bracket.
Waiting for Bracket	The number of completed patient control-bracketed tests with the QC Material Lot that have a status of Waiting for Bracket.
Timeout	The date and time that the selected Control Bracket expires.
QC Schedule	Whether a QC Schedule by Sample, Time or Count is currently defined for this test, reagent lot, and QC Material Lot combination.
Status	The status of each test in the selected Control Bracket. Status flags include the following: • [⚠]: Bracket has failed. •][⌛]: Bracket is pending open or closed. • [▮: Bracket is open with concealed results. • [: Bracket is open with no concealed results.
Create Bracket	Orders a QC Material set and opens the bracket for the selected test.
Cancel Bracket	Cancels the active control bracket for the selected test.

Reagent Lot	Notes
Calibration Expiration	The expiration date and time of the calibration for the selected test and reagent lot.
Lot Expiration	The expiration date and time of the selected reagent lot.
Total Packs Onboard	The number of primary reagent packs that are currently onboard for the selected reagent lot. **NOTE:** This count does not consider depletion, OBS, lot inactivation, or pack inactivation.
Total Available Tests	The combined number of selected tests that are currently available to perform with the corresponding reagent. **NOTE:** This includes tests within the Reagent Reserve threshold.
Primary Pack ID	The IDs for the primary reagent packs that are currently onboard for the selected reagent lot.
Onboard Stability Expiration	The expiration day and time of the onboard stability for the selected reagent pack.
Available Tests	The number of tests in the currently selected pack that are available to perform the selected control-bracketed test.
Position	The reagent tray slot where the system loads the selected pack.

QC Levels Details	Notes
Level	The level of the selected control sample
QC Material ID	The ID of the QC material sample for this level

About Patient QC Flagging

Patient QC Flagging initiates when a QC error rule violation occurs for a test that has Patient QC Flagging enabled. To configure Patient QC Flagging for specific tests, the check box for Suspend Patient QC Flagging must be unchecked in QC Settings (Page 503 *Configuring QC Settings*).

The column for Patient QC in Patient QC Flagging displays flags for patient test results indicating that a QC violation error has occurred for at least 1 level by analyzer and specimen type. The flag applies to patient test results until the operator resets the QC event or the system resets the event automatically. For each test that has Patient QC Flagging enabled, Patient QC Flagging displays the current flag status and allows a manual flag reset for a test.

Patient QC flags display with the test result in Worklist and enable the operator to hold the results for manual review before transmitting to LIS.

Patient QC Flagging Display	Notes
Test	The name of the test.
Specimen Type	The type of control sample.
Analyzer SN	The serial number of the module performing the QC.
Analyzer Name	The laboratory assigns a unique module-friendly name. For multi-analyzer systems, each analyzer displays in a separate row.
Clear Option	Whether the operator selected to clear flags manually or automatically for each test, specimen and anayzer combination. The status can be Manual, Automatic, or None, as indicated by a blank column.

Patient QC Flagging Display	Notes
Patient QC	The status of the Patient QC for that test on the analyzer specified. The flags display as follows: • ⊘ indicates that Patient QC Flagging is disabled for that test. • indicates that QC has failed for that test. • indicates that the control bracket has failed and the system has discarded results for that test.
Failed QC Details	Information about which level or levels failed QC Statistics. **NOTE:** The operator should follow laboratory protocol to resolve patient results that fail QC Statistics.

Patient QC Flagging Actions	Notes
Clear Patient QC Flagging	The operator selects to clear all flags for the selected test on the selected analyzer. **NOTE:** When Patient QC Flagging is set to Manual, the operator must use Clear Patient QC Flagging to clear flags.
QC Statistics	The operator selects to view results for the selected test or tests.
Edit/View	The operator selects to access the Patient QC Flagging settings for the selected test for editing or viewing.

About Patient QC Flagging Settings

In QC Setup, Patient QC Flagging can be enabled or disabled globally for all tests on the system (Page 503 *Configuring QC Settings*). The operator can enable or edit Patient QC Flagging settings for specific tests from Patient QC Flagging using Edit/View.

Patient QC Flagging displays each test, specimen, and analyzer combination in separate rows.

NOTE: To configure Patient QC Flagging, the check box for Suspend Patient QC Flagging must be unchecked in QC Settings (Page 503 *Configuring QC Settings*).

Patient QC Flagging	Notes
Automatic	Patient QC Flagging flags failed QC results. These flags automatically reset once previously failed QC levels produce results that pass QC.
Manual	Patient QC Flagging flags failed QC results. The operator must manually reset Patient QC Flagging.
None	Patient QC Flagging is disabled. This is the default setting for each test.

About the QC Scheduler

The QC Scheduler allows the operator to schedule QC testing to perform automatically:

- By Day and Time
- By Test Count
- By Control

The QC Scheduler overview contains the following features:

QC Scheduler	Notes
QC Scheduler tabs	Selects QC Scheduler: • By Day and Time • By Test Count • By Control
⚙	Configures QC Scheduler warnings
Add Schedule	Adds QC testing to the schedule

About the QC Scheduler By Day and Time

The QC Scheduler By Day and Time orders QC for a specific day and time each week and performs the tests automatically if the QC materials are onboard the system. The operator can create and schedule analyzer-specific QC Panels for systems with multiple analyzers.

NOTE: When a scheduled QC panel is updated in Edit QC Panel, the QC panel information in the QC Scheduler updates also.

The By Day and Time schedule displays the scheduled QC materials and panels for each day and the scheduled time of the QC test.

The operator can add, delete, or edit QC By Day and Time schedules and postpone, disable, or copy day schedules to perform the same QC tests at the same time on different days.

By Day and Time	Notes
Edit/View	Views and modifies the specific day and time settings for a scheduled control.
Delete	Deletes the selected event from the schedule.
Postpone	Postpones the next occurrence of that scheduled event.
Disable	Suspends the selected schedule until the operator enables it.
Enable	Resumes a suspended schedule.
Copy Day	Copies a selected schedule from 1 day to another for easy modifications.
Show Maintenance Schedule	Displays when each module is scheduled for maintenance activities along with the QC schedules. **NOTE:** Maintenance schedule displays only when enabled globally.
Show Calibration Schedule	Displays a global schedule time for calibrations along with QC schedules.

About the QC Scheduler By Test Count

The QC Scheduler By Test Count orders QC after a specific test count and performs the scheduled QC orders automatically if the controls are onboard the system. The By Test Count schedule displays details for each scheduled test, the number of completed tests in the schedule, and the date and time of the last test count reset.

The operator can add, delete, disable, or edit QC By Test Count schedules and reset the test counter.

Test Count Schedule	Notes
Test	The scheduled test.
Module	The analyzer associated with the test count schedule. **NOTE:** When All is selected, the system performs QC when the total tests on the associated assay across the system meets the count.
Test Count	The current test count in the scheduled set.
Material	The QC definitions associated with the counter test. The operator can use this option to schedule QC for the selected test.
Operator Reset	The date and time the operator resets the test counter to 0 to restart counting.
Last Order	The date and time of the last automatically created QC order for the test.
State	The state of the schedule when the operator enables or disables the schedule by Test Count.

Test Count Schedule Feature	Notes
Edit/View	Views and modifies the specific Test Count settings for a scheduled test
Reset Counter	Resets the selected test counter

Test Count Schedule Feature	Notes
Delete	Deletes the entire Test Count event
Enable or Disable	Suspends or restarts the schedule
Add Schedule	Creates new Test Count schedule for automatic QC orders

About the QC Scheduler by QC Material

The QC Scheduler By Control prompts the system to create an order for the scheduled QC material. This feature is useful for QC materials the system uses for intermittently performed tests. When the system recognizes the matching barcode for the scheduled QC material, the system orders and processes the QC test associated with the QC material. This feature applies only to manually loaded QC materials.

The operator can add, delete, or edit By Control schedules.

By Control Schedule	Notes
QC Material	The scheduled QC material
QC Lot	The QC material lot in the scheduled assay set
QC Material ID	The ID assigned to the scheduled QC material
QC Lot Expiration	The expiration date of scheduled QC material
Usage	The usage assigned to the scheduled QC material, obtained from the QC definition
Tests	The assay or assays associated with the scheduled QC material
Material	The QC definitions and panels associated with the selected QC material and scheduled to process

By Control Schedule	Notes
State	The state of the schedule when the operator enables or disables the schedule
Last Order Submitted	The date and time of the last QC order for the material

By Control Schedule Feature	Notes
Delete	Deletes the selected QC material from the schedule
Add Schedule	Adds QC materials to the schedule
Enable or Disable	Suspends or restarts the schedule

About QC Setup

This task requires the appropriate security level.

QC Setup includes 2 workflows for configuring QC:

- QC Settings provides global settings for performing QC and patient test actions based on QC results and QC Statistics. The system software provides default settings for QC Setup (Page 501 *About QC Settings*). Restore Defaults returns all global QC settings to the default values.
- QC Master List displays all QC definition settings for all QC material levels for each assay and specimen combination configured on the system (Page 509 *About the QC Master List*).

About QC Settings

The settings in QC Settings are global settings. The system posts an entry to the Audit Trail Log each time an operator changes a setting.

QC Settings	Notes
Send Results to QC Statistics	Enables a Global setting to automatically send 1 of the following QC Results to QC Statistics for evaluation: • QC results only (Default) • QC and Patient results • No results
QC Mode Settings	Applies QC Mode Settings globally to the system or each assay type. Provides the selections for the following features: • QC Statistics Violation: Patient Test Action: Defines the type of patient test action the system performs when various QC violations have occurred. • QC on Pack Change: Enables the system to perform QC after reagent pack changes. • QC Required: Enables the system to automatically schedule QC after a Timeframe. • IMT QC Required after Changing the IMT Sensor: Enables the system to perform QC after IMT sensor changes.
Patient QC Flagging	Enables or disables Patient QC Flagging for all tests on the system (Page 496 *About Patient QC Flagging Settings*). **NOTE:** The default value for this feature is unchecked. When Suspend Patient QC Flagging is checked, the system does not modify the configuration for Patient QC Flagging for individual assays.

QC Settings	Notes
RiliBÄK Feature	Enables or disables the evaluation of control results according to the German RiliBÄK guidelines (Page 516 *About the RiliBÄK Feature*). **NOTE:** The laboratory must delete all QC definitions when enabling this feature.
QC Results Review Mode Settings	Defines how the system holds or releases control results to the LIS.
QC Schedule	Defines QC Scheduler warnings for whether onboard controls are available. The operator can define QC Warnings for QC Scheduled by Day and Time and QC Scheduled by Test Count. QC Scheduler warnings display in the Operator Event Log.

Configuring QC Settings

This task requires the appropriate security level.

1. Navigate to **QC Settings**.
2. In Send Results to QC Statistics, perform 1 of the following:
   - To send QC results to QC Statistics, select the check box for QC.
   - To send patient and QC results to QC Statistics, select the check boxes for QC and Patient.
   - To send no results to QC Statistics, deselect the check box for QC.

   NOTE: The check box for QC is selected by default.
3. In QC Mode Settings, configure global settings By System or By Assay Type, as appropriate. (Page 508 *Configuring QC Mode Settings in QC Settings*).
4. To disable Patient QC Flagging for all tests on the system, select the check box for Suspend Patient QC Flagging.

   NOTE: Patient QC Flagging is enabled by default.

5. In RiliBÄK Feature, perform 1 of the following:
   - If enabling the RiliBÄK Feature, select **On** then delete all QC definitions.
   - If disabling the RiliBÄK Feature, select **Off** then enable single-point and multipoint QC rules in QC Statistics.
6. In QC Results Review Mode Settings, select the appropriate mode from the drop-down menu.
7. To Hold Results by Analyzer, ensure a check is in the Hold Results check box of the appropriate Analyzer.

   NOTE: The area for Hold Results by Analyzer does not display if the laboratory selects **Review All**.
8. In QC Schedule, to specify warnings for scheduled automatic QC, ensure a check is in the check box for Warn prior to QC Schedule if onboard control is unavailable.
9. In When to Warn, perform 1 or both of the following:
   - Configure QC warnings for QC Scheduled by Day and Time
   - Configure QC warnings for QC Scheduled by Test Count
10. Select **Save**.

About QC Mode Settings

QC Mode Settings provides configuration options for patient testing when the control result has a violation in QC Statistics. QC Mode Settings also provides configuration options to trigger QC tests after reagent pack changes, a specified timeframe, or IMT maintenance. Laboratories can select 1 of the following modes to apply the settings globally to the system or each assay type:

- By System: The QC Mode Settings apply to all assays.
- By Assay Type: The QC Mode Settings is specified for each assay type.

QC Mode Settings	Notes
QC Statistics Violation: Patient Test Action Settings	Configures the following conditions for disabling patient tests when a QC Statistics violation occurs: • Never Disable: Patient tests are not disabled for a QC Statistics violation. • Disable for Errors: Patient tests are only disabled when a QC Statistics violation occurs for a test that has a severity level of error. • Disable for Warning or Error: Patient tests are disabled if a QC Statistics violation occurs for a test that has a severity level of error or warning. • Use TDef Settings: Patient tests are disabled when a QC Statistics violation occurs as specified in the Test Definition. **NOTE:** This setting only applies to IM assays when QC Mode Settings By Assay Type is selected.
QC on Pack Change	Enables the system to perform QC automatically after the reagent pack or well changes. This setting lists the following options: • Disable: A reagent pack change does not trigger the system to automatically perform QC. This is the default setting. • Enable: A reagent pack change triggers the system to automatically perform QC. The system disables the pack for patient samples until QC results are available.

QC Mode Settings	Notes
QC Required	Enables the system to automatically schedule QC after a Timeframe. The following options are described in the QC Required: Conditions for options table: • Disable • Enable When enabled for an assay, QC Required performs the following: • Disables the assay on an analyzer without QC results within the required timeframe until QC results are available. • Locates any QC result for that assay, including assays that support multiple specimen types. • Automatically orders the configured QC levels when a patient order for an assay is blocked because QC results are beyond the required timeframe.
IMT QC Required after Changing the IMT Sensor	Enables the system to automatically perform QC after an IMT sensor change. This setting displays the following options: • Enable: IMT sensor change triggers the system to automatically perform QC. This is the default setting. • Disable: IMT sensor change does not trigger the system to automatically perform QC. **NOTE:** This setting only applies to CH assays and is available in QC Mode Settings when By System or By Assay Type is selected.

Each of the following options for QC Required results in specific conditions for the QC levels:

QC Required: Conditions for options	Information
Adding a new assay to an existing QC definition.	• If the feature is already enabled, the system automatically enables all QC levels applicable to the new assay. • If the feature is disabled, no levels are selected. • If the feature is subsequently enabled, the system automatically enables all QC levels applicable to the new assay.
Adding a new level to an existing QC definition.	• If the feature is already enabled, the system automatically enables the new QC level for all applicable assays. • If the feature is disabled, no levels are selected. • If the feature is subsequently enabled, the system automatically enables the new QC level for all applicable assays.
During upgrade, existing settings are migrated. QC Required is disabled by default.	If a feature is enabled after upgrade: • QC on Pack Change and QC with Cal: The last setting that was defined when it was last enabled, persists for QC Levels and assays. The feature is enabled for new QC levels and assays. • QC Required: If the feature is enabled the first time, the system automatically enables all QC levels for all applicable assays. For subsequent times the last setting persists for QC Levels and assays. The feature is enabled for new QC levels and assays.

QC Required: Conditions for options	Information
During new install. QC on Pack Change, QC with Cal, and QC Required are disabled by default.	For QC on Pack Change, QC with Cal, and QC Required: • If the feature is enabled for the first time after upgrade, the system automatically enables all QC levels for all applicable assays. • After the first time enabling a feature, the last setting persists for QC Levels and assays. The feature is enabled for new QC levels and assays.

Configuring QC Mode Settings in QC Settings

This task requires the appropriate security level.

1. Navigate to **QC Settings**.
2. In QC Mode Settings, select **By System** or **By Assay Type**.
3. To configure QC Mode Settings By System:
    a. Select the appropriate QC Statistics Violation: Patient Test Action setting from the drop-down menu.
    b. Select the appropriate QC on Pack Change setting from the drop-down menu.
    c. Select the appropriate QC Required setting from the drop-down menu and enter a Timeframe in hours.
    d. Select the appropriate IMT QC Required after Changing the IMT Sensor setting from the drop-down menu.
4. To configure QC Mode Settings By Assay Type:
    a. Select the appropriate QC Statistics Violation: Patient Test Action for each assay type as appropriate from the drop-down menu.
    b. Select the appropriate QC on Pack Change for each assay type as appropriate from the drop-down menu from the drop-down menu.
    c. Select the appropriate QC Required setting from the drop-down menu and enter a Timeframe in hours.
    d. For IMT assays, select the appropriate IMT QC Required after Changing the IMT Sensor setting from the drop-down menu.

About the QC Master List

This feature requires the appropriate security level.

The QC Master List displays the QC materials required to perform QC for each combination of assay and specimen type. The system generates the default QC Master List from the primary QC Definitions. The operator can edit the QC Master List, if appropriate.

NOTE: The QC Master List displays Multiple in the columns for Material, Lot, and Lot Expiration for assays with more than 1 primary QC definition.

QC Master List	Notes
Tests	The assay for performing QC. Each row is expandable for lot details.
Specimen Type	The specimen type for the assay.
Material Name	The QC material the system uses for processing QC.
Lot	The QC material lot the system uses for processing QC for the assay.
Expiration Date	The expiration date of the control material lot the system uses for processing QC for the assay.
Levels Scheduled to Run	For each level configured in the QC definition, the following displays for each test: • Pack Change: Whether QC is configured to perform on a pack change for that QC Material Level. Configure QC on Pack Change in QC Settings. • QC with Cal: Whether QC is configured to perform with calibration for that QC Material Level. Configure Perform QC with Calibration in Calibration Setup. • QC Required: Displays the setting from QC Settings

QC Master List	Notes
	The operator can expand the rows to view or edit the appropriate check boxes for each level to enable QC automatically. Selecting the check box for Levels selects all levels.

About QC Statistics

QC Statistics provides real-time and long-term evaluation of system and assay performance through the tile for QC Statistics on the Dashboard (Page 143 *About the Dashboard*):

QC Statistics	Notes
Review	Displays current QC results. The left panel categorizes a list of control files by Control or Test. The right panel displays specific control file results.
Analysis	Provides graphical and tabular views of the data shown in Review. The operator can analyze QC and patient data and evaluate errors.
Messages	Displays violation notifications through QC messages and the audit log.
Tools	Contains Maintenance for control and patient median files, including data Export and Database/Backup.
Setup	Provides access to QC settings including QC Rules, patient QC, Customize, Comments, and QC Configuration.

Typical QC Statistics Configurations

QC Statistics provides options for performing statistical analysis on control data, alerting the operator of QC violations, flagging QC data, and automatically disabling patient tests with alerts. The operator can set up QC Statistics features to analyze data according to laboratory standard practices. The QC Master List allows the operator to select which levels to perform QC for specific assays (Page 509 *About the QC Master List*). The operator should refer to the QC Master List before setting up QC Statistics

Laboratory Practice	QC Statistics Settings
Using all QC Statistics features	Enable QC Statistics and Patient QC Flagging (Page 503 *Configuring QC Settings*)
	Enable Autodisable Patient Tests (Page 508 *Configuring QC Mode Settings in QC Settings*)
Using QC statistical analysis and flags. Not automatically disabling patient tests based on QC.	Enable QC Statistics and Patient QC Flagging (Page 503 *Configuring QC Settings*)
	Enable QC Rules
	Disable Autodisable Patient Tests (Page 508 *Configuring QC Mode Settings in QC Settings*)
Using QC statistical analysis but disabling flagging. Not automatically disabling patient tests based on QC.	Enable QC Statistics and disable Patient QC Flagging (Page 503 *Configuring QC Settings*)
	Enable QC Rules
	Disable Autodisable Patient Tests (Page 508 *Configuring QC Mode Settings in QC Settings*)
Turning off QC Statistics features.	Disable QC Statistics and Patient QC Flagging (Page 503 *Configuring QC Settings*)
	Disable QC Rules
	Disable Autodisable Patient Tests (Page 508 *Configuring QC Mode Settings in QC Settings*)

About QC Statistics Review

QC Statistics Review displays QC results.

The left-hand area displays a list of control files, ordered by Control or Test. When reviewing by Test, the operator can select to view specific tests or a group of tests defined in QC Panels.

The right-hand area displays control file results. The operator can filter the results according to Reviewed, Unreviewed, or All data. The operator can Auto-select Issues to automatically select control files that contain issues or Customize the column display order.

About QC Results Review Mode Settings

QC Results Review Mode Settings allows the operator to select how the system manages the review of the following active results:

Settings	Description
Review None	No result is held for review.
Review All	All results are held for review.
Review By Exception	Active results with any flags are held for review.

About QC Statistics Reports

The operator can generate reports from Review or Analysis to display the control and Patient median files. With an active time filter, only the filtered QC and Patient median points display for reporting. The operator can send reports to a printer or a file.

The drop-down menu for Report Name provides the following types of reports:

- Monthly report
- Summary report
- Exception report
- Custom report 1
- Custom report 2
- Patient Median Report

The operator can include the following data in QC statistical reports:

Report Contents	Notes
Data Points	
None	The report does not include data points.
All	The report includes selected control files and all data points the system filters using the time filter.
Only violations	The report includes all data points from selected and time-filtered control files that violate active QC rules.
Sort By	
Test	The report lists control files alphanumerically by Test Name and Test Unit.
Control	The report lists control files alphanumerically by Control Name, Control Level, and Control Lot number. For each group, the sort order is Control Name and Control Level.
Options	
Charts	The report includes a Levey-Jennings chart with data points based upon the time filter.
Events	The report includes events associated with the selected data point.
Timeframe Summary	The report includes time-filtered statistics associated with the data point.
Cumulative Summary	The report includes statistics associated with the data point, regardless of time-filtering. The statistics consider all data points in the control file.
Comments	The report includes all comments for a selected data point.

About QC Statistics Audit Log

The QC Statistics Audit Log displays a list of QC Statistics events, the Time they occurred, and the logon ID of the User at the time of the event. The operator can search by date to find a specific event.

About Maximum Limits for QC Database Storage

QC Statistics software monitors the current data usage of control results, patient median or mean data, and total control files. The system alerts the operator when the database is close to maximum storage. If the capacity reaches 90%, the system stops accepting new orders until the operator addresses the condition. The operator can schedule a reminder to maintain the QC database regularly and delete old records.

Data Type	Notes
Total number of Control Sample Results	Maximum 65000
Total number of Control Files	Maximum 3000
Total number of Patient Median Points or Patient Mean Points	Maximum 315072
Total number of Patient Median Files or Patient Mean Files	Maximum 3000
Total number of Unprocessed control sample results	Maximum 65000
Total number of Messages	Maximum 500

About QC Statistics Analysis

QC Statistics Analysis calculates and displays statistical data based on the selected controls in the Review tab. Analysis allows assessment of data for errors and displays the data according to 3 tabs:

QC Statistics Analysis	Notes
Chart	QC data displays in a Levey-Jennings chart or in a Z-score chart.
QC	Detailed view of files that currently display in Chart. Each row of the table represents a QC data point.
Patient	Detailed view of individual data points in the patient median or mean data file. The operator can display the closest event in time to a selected data point.

The operator can view and process QC information using the following features:

QC Statistics Analysis Feature	Notes
Refresh	Refreshes the data from the database. The tabs for Chart, QC, and Patient populate with newly retrieved QC and patient QC data points. The operator can specify the retrieved data using Filter settings.
Customize	Customizes the Analysis view. The operator selects **Display Fields**, specifying the type of data currently displaying in Analysis.
Statistics	Displays the Statistics Summary view. If no control or patient QC data display in Analysis, the Statistics feature is not available.
Events	Displays the Events view. If no control or patient QC data display in Analysis, the Events feature is not available.
Reports	Displays the window for Reports. The operator can select files in Review or Analysis to display in Reports and customize the Report view.
Exclude	Excludes data points from the statistical calculation.
Include	Specifies previously excluded data points to include in the statistical calculation.

QC Statistics Analysis Feature	Notes
Comment	Adds comments to a result.
QC Details	Displays error details for data points that are part of the rule violation.

NOTE: QC Statistics does not factor in non-numeric QC results for QC analysis.

About the Levey-Jennings Chart

The Levey-Jennings Chart plots control values against dates of analyses. The operator can view the chart for each control file in the database. The chart plots dates of analyses on the X-axis, and control values on the Y-axis. The chart also marks the mean and first, second, and third standard deviation (SD) limits on the Y-axis. The chart is scalable to display a portion of the date range.

NOTE: When a control file has more than 1 target, the system displays the original and the changed target value, resulting in an offset view.

Z-score Chart

The Z-score Chart displays values using the standard deviation. The structure is similar to the Levey-Jennings Chart except that the Z-score Chart shows relative values for the selected controls using a standard deviation (SD).

The Z-score Chart displays data on 2 axes: X-axis and Y-axis.

The Y-axis represents the distance from the mean for all the displayed controls: +3SD, +2SD, +1SD, Mean, -1SD, -2SD, and -3SD. The X-axis displays the time frame. The chart is scalable to display a portion of the date range.

About the RiliBÄK Feature

This feature requires the appropriate security level.

The RiliBÄK are a set of German guidelines administered by the German Federal Medical Association that specify requirements for any laboratory performing quantitative clinical assessments. The RiliBÄK rule compares the target mean of an individual test with a range of valid values and reports any result falling outside the prescribed range as an error. The operator can activate or deactivate the link between a test and the RiliBÄK table of valid values and confirm which specimens, analytes, and units are associated with each specific test.

The RiliBÄK Feature in QC Settings enables the system to evaluate all QC results according to the German RiliBÄK guidelines.

This feature is a global setting that applies to all QC Definitions and QC Statistics.

NOTE: Germany requires the use of the RiliBÄK rule, but laboratories elsewhere may adopt the rule voluntarily.

NOTE: Laboratories must delete all existing control definitions when modifying the RiliBÄK Feature in QC Settings.

About the QC Statistics Analysis Split Panel View

The Analysis split panel view displays QC or Patient chart and table information in a single window.

The chart and chart functions display on the top panel and the data display on the bottom panel.

The QC and Patient data appear on separate tabs in the split panel view.

About QC Auto Review

The operator can automatically send all in-control QC data points to QC Statistics Review without operator intervention.

About QC Rules Configuration

The operator can enable or disable QC Rules to alert the operator when a violation occurs. The operator can assign QC Rules to flag as errors or as warnings.

QC Rules has 3 different tabs for configuring: Test Based, Group Based, and Rule Based.

QC Rules	Notes
Test Based	The operator can define QC Rules for individual tests.
Group Based	The operator can define a group of tests and enable or disable rules for the entire group.
Rule Based	The operator can enable or disable 1 or more rules for all tests.

About Test Based QC Rules

The Test Based QC Rules feature allows the operator to define QC statistical analysis rules for all QC performed for a specific test. Using this feature, the operator can disable all rules for a specific test and restore defaults. Test Based QC Rules are useful for Patient QC Flagging or performing patient samples based upon QC settings.

About Single Point Rules

Single Point Rules flag results when 1 data point exceeds the upper or lower range defined for the control.

NOTE: The selections Use 2SDa and Use 3SDa are not applicable to Atellica Solution QC Statistics.

Range error	Notes
1–3s	1 result is > 3s or < -3s
1–2.5s	1 result is > 2.5s or < -2.5s
1–2s	1 result is > 2s or < -2s
xs (Custom single-point rule)	1 result is > xs or < -xs The operator can define x = any value from 0.10 - 9.90

About Multipoint Rules

Multipoint Rules flag results when more than 1 data point exceed the range defined for the control.

Multipoint Error	Notes
2–2s	Indicates 1 of the following: • 2 sequential control values from 1 control are outside of 2 standard deviations from the mean and are both above or both below the mean. • 2 consecutive control values from 2 controls are outside of 2 standard deviations from the mean and are both above or both below the mean.

Multipoint Error	Notes
2 of 3–2s	Indicates 1 of the following: • 2 out of 3 sequential control values from 1 control are outside of 2 standard deviations from the mean and are both above or both below the mean. • 2 out of 3 consecutive control values from 2 controls are outside of 2 standard deviations from the mean and are both above or both below the mean.
R–4s	Indicates 1 of the following: • The range between 2 sequential control values from 1 control exceeds 4 standard deviations. • The range between 2 consecutive control values from 2 controls exceeds 4 standard deviations.
3–1s	Indicates 1 of the following: • 3 sequential control values from 1 control are outside of 1 standard deviation from the mean and are all above or all below the mean. • 3 consecutive control values from 2 or more controls are outside of 1 standard deviation from the mean and are all above or all below the mean.
4–1s	Indicates 1 of the following: • 4 sequential control values from 1 control are outside of 1 standard deviation from the mean and are all above or all below the mean. • 4 consecutive control values from 2 or more controls are outside of 1 standard deviation from the mean and are all above or all below the mean.
10x	Indicates 1 of the following: • 10 sequential control values from 1 control are either all above or all below the mean. • 10 consecutive control values from 2 or more controls are either all above or all below the mean.

Multipoint Error	Notes
12x	Indicates 1 of the following: • 12 sequential control values from 1 control are either all above or all below the mean. • 12 consecutive control values from 2 or more controls are all above or all below the mean.
nx	Indicates 1 of the following: • The n sequential control values from 1 control are all above or all below the mean. • The n consecutive control values from 2 or more controls are all above or all below the mean. The operator can customize the number of control values. Valid control values for n are 2–29.
nT	Indicates 1 of the following: • A trend of n sequential control values from 1 control with standard deviation indexes that are either increasing or decreasing. The value of n ranges between 3–27. • A trend of n consecutive control values from 2 or more controls with standard deviation indexes that are either increasing or decreasing. The value of n ranges between 3–27.

About Group Based QC Rules

The Group Based QC Rules feature allows the operator to define a group of tests and enable or disable rules for the entire group.

About Default Groups

Default groups include all tests with current data. When the operator creates a new group, the system removes those tests from the default group. When the operator deletes a group, the tests in that group return to the default group. The default group allows the operator to enable or disable rules globally.

About Rule Based QC Rules

The Rule Based QC Rules feature allows the operator to enable or disable 1 or more rules for all tests.

About Printing QC Rules Reports

The Rule Based feature creates and prints reports listing each group or test that contains modified QC Rules. The reports include:

- Severity level for each rule: Off, Warning, or Error.
- If the rule is enabled or disabled.
- If the system uses an adjusted value (3s or 2s).
- Condition of each rule: Evaluate Regardless or Evaluate After.
- List of all the tests in the group.
- Value of the customized rule.

About Configuring Patient Data for QC Statistics

In **QC Statistics > Setup > Patient**, the operator defines bin sizes of patient results to monitor the Mean or Median, according to laboratory protocol. Laboratories can use the Median and Mean results to detect deviations over time to help monitor the performance of the system and troubleshoot systematic errors.

Patient QC Data Configuration	Notes
Bin Size	The number of patient results the system uses for QC analysis. The system also uses the Bin Size to calculate the Patient Mean.
Upper Trim Limit and Lower Trim Limit	The upper and lower limits of the range of patient data points the system uses to calculate the patient Median or Mean. Results outside of these limits are excluded from calculations to prevent outliers from skewing the data.

Patient QC Data Configuration	Notes
Upper Line, Ref Line, and Lower Line	Reference lines the system uses when displaying and flagging patient sample control data.
Active	The operator can turn patient sample control data collection on or off for a specific test and analyzer, when available.

About Patient Median and Mean Data in QC Statistics Analysis

When viewing patient data in a chart, the operator can select individual patient median and mean data points for investigation. The operator can also view the closest event in time to a selected data point.

Patient Data	Notes
Date	The date and time when the system analyzes the data. The system local settings determines the format of this field.
Median	The middle patient result in the ordered bin or the average of the 2 results when the bin has 2 middle values.
Mean	The average of all qualifying data points in the bin. The system omits outliers from the calculation, according to the defined upper and lower trim limits.
SD	The standard deviation used in the QC Analysis calculation as defined in the QC Rules.
Partial	An indication of whether the bin is a full bin or partial bin.
System	The friendly name or ID of the System, assigned by the laboratory.

Patient Data	Notes
Analyzer Name	The friendly name or ID of the Analyzer, assigned by the laboratory.
Analyzer SN	The serial number of the Analyzer.
Test	The assay name associated with the data point.
Unit	The display unit of the assay. Up to 15 characters.
Excluded	The statistical or summary calculations exclude the data point.
Reviewed	The operator has reviewed the bin.
Reviewer	The ID of the operator who reviewed the bin. This field can be an Operator ID or System.
Review Date	The date and time that the operator reviews the bin.
Comment	Any comments including a date and time associated with the bin.
97.5%	The concentration of patient results within a bin that are equal to or below the 97.5 percentile.
75%	The concentration of patient results within a bin that are equal to or below the 75th percentile.
25%	The concentration of patient results within a bin that are equal to or below the 25th percentile.
2.5%	The concentration of patient results within a bin that are equal to or below the 2.5 percentile.
First Result Date	The date and time of the oldest patient result in the bin.
Last Result Date	The date and time of the most recent patient result in the bin.

Patient Data	Notes
Inactive	The state of the patient QC data file: active or inactive. In an inactive state, QC Statistics does not collect any patient sample results from the System. The System does not calculate or display statistics.
Primary Reagent Lot	The primary reagent lot number. Up to 20 characters.
Ancillary Reagent Lot	The ancillary reagent lot number (IM only). Up to 20 characters.
Primary Reagent Pack	The primary reagent pack number. Up to 14 characters.
Ancillary Reagent Pack	The ancillary reagent pack number (IM only). Up to 14 characters.

Configuring Patient QC Data Collection

1. Navigate to **QC Statistics**.
2. Select **Setup > Patient**.
3. Select the appropriate Test on the appropriate Module Name.

   NOTE: Each Test enabled for each Module Name has a separate entry.
4. To define the number of data points for QC analysis, specify a Bin Size.
5. To define the upper and lower limits for Patient Median and Mean analysis, specify an Upper Trim Limit and Lower Trim Limit.
6. To define reference lines to display with patient sample QC data, specify Upper Line, Lower Line, and Ref Line.
7. To turn on data collection for the Test on the specific analyzer, select the check box for Active.
8. Select **Save**.

16 Lab Evaluation

About Reagent Comparison Study

Reagent Comparison allows the operator to compare the results of a group of samples across reagent lots or analyzers. Different reagent packs within the same lot cannot be identified for this study. The laboratory can calculate and evaluate the % deviation between matched sample results. The operator evaluates the result of the Reagent Comparison study according to their laboratory's standard operating procedures.

Reagent Comparison is located in **Lab Evaluations > Reagent Comparison**.

Between-reagent lot variation can affect results for QC materials, patient samples, or both. Ensure the samples selected for the Reagent Comparison properly characterize the comparison study. Use the following considerations:

1. Material: Patient samples, QC material, or proficiency samples.
2. Number of samples: The amount of samples to ensure a single sample does not have an undue influence on the overall conclusion of the study.
3. Concentration: Select samples that span the measuring interval of the assay or at least 2 key medical decision points depending on the use of the assay.
4. Integrity and handling: The storage, centrifugation, mixing, and temperature of the samples should be the same for both runs of the study.

The operator completes a Reagent Comparison study:

- Before using a new reagent lot with patient samples.
- To evaluate % difference based on laboratory's standard operating procedure.
- To determine the % difference in results between reagent, packs or lots.
- To determine the % difference in results across analyzers within a system.

A study may include multiple analyzers and displays data in the following formats:

- Plot
- Bias Plot
- Data

Reagent lots are not included in a Reagent Comparison study when patent samples processing is stopped to perform calibrations and QC.

Reagent Comparison	Notes
Create Evaluation	A 3-part configuration for a Reagent Comparison study: • Parameters • Samples • Summary
Parameters	The first Reagent Comparison configuration that identifies the Evaluation Name, Candidate Reagent , and Current Reagent.
Evaluation Name	The operator enters the name of the Reagent Comparison study.
Evaluation ID	Defaults in with an assigned ID number. The Evaluation ID displays as Run ID in Worklist. The operator views all samples grouped together for the study in Worklist.
Search	Identifies the Search and Specimen Type in the study. • Search: Operator selects the assay from a drop-down menu. • Specimen Type: The system automatically enters configured Specimen Type for that Search.
Candidate Reagent	Identifies the new lot of reagent, pack number, and the analyzer it is stored. • Candidate Analyzer: Operator selects the analyzer from a drop-down menu. • Candidate Reagent Lot: Operator selects the lot from a drop-down menu. • Candidate Reagent Pack ID: Operator selects the pack ID from a drop-down menu.

Reagent Comparison	Notes
Current Reagent	Identifies the existing reagent on the analyzer with its lot and pack ID. • Current Analyzer: Operator selects the analyzer from a drop-down menu. • Current Reagent Lot: Operator selects the lot from a drop-down menu. • Current Reagent Pack ID: Operator selects the pack ID from a drop-down menu.
Samples	The second Reagent Comparison configuration that identifies the Samples. The operator selects 1 of the following: • New SIDs • Use Existing SIDs
New SIDs	The operator selects New SIDs and enters the following: • First SID: The operator enters the first new sample ID in the study. • Number of Samples: The operator uses the arrows to add more that 3 samples, if appropriate. • SID Range: populates when the operator selects the appropriate Number of Samples.
Use Existing SIDs	The operator selects Use Existing SIDs and enters or scans the Sample ID.
Summary	The final review of the Reagent Comparison study defined.
Place Order	The operator selects after final review completed to place the Reagent Comparisonstudy order.
Print Barcodes	The operator selects to print Reagent Comparison study sample barcodes. Study samples with barcodes are loaded on appropriate analyzer.

Reagent Comparison	Notes
Back	The operator selects to go back to previous configuration area.
Next	The operator enters all the required data then selects **Next** to configure the next new study section.
Save	The operator selects to save the Reagent Comparison configuration before the study order is placed.
Cancel	The operator selects to cancel the Reagent Comparison study configurations.

To create a Reagent Comparison study, see.

About Reviewing Reagent Comparison Study Details

The operator confirms the new reagent lot is equivalent to the old reagent lot according to their laboratory's acceptance criteria. A study may include multiple analyzers and displays data in the following formats:

- Plot
- Bias Plot
- Data

When a Reagent Comparison study has completed, the operator reviews then rejects or approves that study in Details.

Reagent Comparison Summary	Notes
Reagent Comparison Summary	Identifies the study selected for the summary.
Evaluation Name	The name of the reagent comparison study.
Evaluation ID	The assigned study ID number.
Assay	Identifies the Assay in the study.
Specimen Type	Identifies the Specimen Type in the study.
Candidate Analyzer	Identification of analyzer where study performed.

Reagent Comparison Summary	Notes
Candidate Reagent Lot	New lot of reagent used in study.
Candidate Reagent Pack ID	New pack ID of reagent used in study.
Current Analyzer	Identification of analyzer where current reagent is in use.
Current Reagent Lot	Lot of reagent used on Current Analyzer.
Current Reagent Pack ID	Reagent pack ID used on Current Analyzer.
Samples	Identifies the sample collection as New SIDs or Use Existing SIDs.
First SID	First sample ID.
Number of Samples	The number of samples included in the study.
SID Range	Identification of study sample ID range.
Samples	Same as SID.
Lot	Candidate Reagent Lot
Lot 2	Current Reagent Lot
Difference (%)	Bias between the results for processing (individual samples or the sum over all the samples) on Candidate Reagent Lot and Current Reagent Lot. The Difference (%) is next to each sample. Difference (%)= (Result of Candidate Reagent Lot – Result of Current Reagent Lot) / Result of Candidate Reagent Lot.

Reagent Comparison Summary	Notes
Statistical Tool	Operator selects 1 of the following statistical tool to view the data: • Least Square • Passing-Bablock • Weighted Least Square • Deming • Weighted Deming
Slope (95% CI)	Linear comparison of the Candidate Reagent Lot values versus the Current Reagent Lot values.
Intercept (95% CI)	The Y-intercept of the plot of the Candidate Reagent Lot values versus the Current Reagent Lot values.
Correlation Coefficient	The degree of correlation between the Candidate Reagent Lot values versus the Current Reagent Lot values.
Total Number of Tests	The number of tests in the study.
$\bar{x}$ Lot 1	Mean of Candidate Reagent Lot results.
$\bar{x}$ Lot 2	Mean of Current Reagent Lot results.
Range of Results	Lowest to highest result range.
Average Difference (%)	Absolute value of the % bias of each sample (with Candidate Reagent Lot representing the expected), then takes the average of all the data points. Average Difference (%)= sum of all Difference (%) ÷ total number of individual % Deviation values.
Refresh	The operator selects to refresh the Details data.

Reagent Comparison Summary	Notes
Reject	The operator reviews the statistical graph and results for the study then rejects the study.
Approve	The operator reviews the statistical graph and results for the study then approves the study. If approved, the study status is Accepted.
Close	The operator selects to close Details.

About Filtering Lab Evaluations

The Lab Evaluations filter allows the operator to narrow down the study list so only those studies that match the filter criteria display. The filter automatically revises the results as choices are made.

Lab Evaluations Filter	Notes
Analyzer	Operator selects from a drop-down menu that includes analyzers with a defined study assigned.
Assay	Operator selects from a drop-down menu that includes assays within the defined studies.
Evaluation Type	Operator selects from a drop-down menu that includes the following types of studies defined: • QC Parallel • Reagent Comparison • Automatic Measuring Interval Verification • Manual Measuring Interval Verification • Simple Precision • Within Lab Precision

Lab Evaluations Filter	Notes
Status	Operator selects from a drop-down menu that includes All or the 1 of the following: • Not Ordered: A study that is not ordered by the operator. • In Progress: A study that has not completed. • Awaiting Acceptance: A completed study waiting for review. • Accepted: A study that has been reviewed and approved by an operator. • Rejected: A study that has been reviewed and rejected by an operator. • Archive: A study that has been archived and no longer in use.
By Start Date Range	Operator selects to narrow down the studies listed by a date range From and To. The operator selects  to open the calendar.

About QC Parallel Lab Evaluations

This evaluation allows the laboratory to analyze a new lot of QC material for each assay in parallel with the lot of QC material in use.

Step	Notes
Matching orders	Each time the system performs the Current Lot, the system schedules the number of defined matching orders for the Candidate Lot. This applies to Stop the evaluation at a set number of points and Stop the evaluation on a specific date. For example, if the matching orders is 2, the system generates 2 candidate lot results each time the system generates a current lot result.
Set number of points	The system performs the defined number of results for the Candidate Lot. The count includes the results for matching orders. For example, if the set number of points is 30 and the matching orders is 2, the system generates 30 candidate lot results after generating 15 current lot results. If the set number of points is 30 and the matching orders is 3, the system generates 30 candidate lot results after generating 10 current lot results.
Specific date	The system performs the matching number of Candidate Lot each time the Current Lot result is generated until the end date.

Step	Notes
QC Material	• Evaluation Name • Evaluation ID automatically populates • Current Lot to use for the evaluation • Candidate Lot to evaluate • Stop the evaluation at a set number of points: Sets the number of parallel candidate lot orders (matching orders) to perform each time the current lot completes. • Stop the evaluation on a specific date: Sets an end date during which the system collects candidate lot results.
Assays	• Assay Selection: The operator selects the assays to associate with the candidate lot. • QC Parallel Summary: A list of the evaluation settings.

The operator performs the following steps:

1. Selects the current and candidate lots
2. Selects the number of points or the specific end date of the evaluation
3. Selects the assays for the evaluation
4. Reviews the summary of the evaluation
5. Optionally prints the barcodes
6. Places the order

After placing an order, the operator can view the status of all lab evaluations and perform the following functions:

- View details
- Review progress
- Review results
- Approve an evaluation

- Print the barcodes
- Export an evaluation
- Repeat an evaluation, which copies the parameters, generates a new evaluation ID, and allows the operator to enter a new evaluation name and modify the settings
- Delete an evaluation

The table includes the following information:

- Evaluation Type
- Evaluation Name
- Evaluation ID
- Start date and time of when the operator selects Place Order for the evaluation
- End date and time when the system completes the last dilution of the evaluation. For evaluations scheduled for a specific date, the end date matches the target date and the time when the operator defined the evaluation.
- Analyzer the system uses to perform the evaluation
- Assay the system uses for the evaluation
- Status of the evaluation:
  - Accepted: The operator approved the evaluation.
  - In Progress: The operator placed the order, and the order is inprocess or requires intervention.
  - Rejected: The operator rejected the evaluation during or after completing the evaluation.
  - Awaiting Acceptance: The evaluation is complete and waiting for the operator to approve or reject it.
  - Not Ordered: The operator created the evaluation but has not placed the order. If the operator selects the evaluation, the evaluation opens to the last completed step.

Preparing for CH Assay Reagent Measuring Interval Verifications



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

CAUTION

Do not reuse calibrator tubes after removing them from the Cal-QC storage area and storing them offline. Reusing removed calibrator tubes results in a false onboard stability that may cause unwarranted calibration troubleshooting if a calibration fails.

1. Ensure the following items are on the system:
   - Assay reagent calibrations
   - Assay test definitions
   - Measuring interval verification material definitions if performing a manual procedure
   - Calibrator definition if performing an automatic procedure
   - Assay reagents
2. Confirm the system is in 1 of the following states:
   - Ready
   - Standby
   - Processing
3. Prepare the measuring interval verification material samples.
4. Create a measuring interval verification order.
5. Print the measuring interval verification material sample barcodes.
6. Place the barcode labels on the appropriate measuring interval verification material sample tubes.
7. Load the measuring interval verification material samples on the system.
   - For a CH-DL analyzer, load the measuring interval verification material samples on a rack and place the rack on the entry queue.
   - For an Atellica Solution, load the measuring interval verification material samples in a rack and place the rack in an SH sample drawer.
8. Review the measuring interval verification results.

Preparing for IM Assay Reagent Measuring Interval Verifications

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

CAUTION

Do not reuse calibrator material remaining in the sample tubes or refill calibrator sample tubes after use. If an operator reuses the calibrator material, errors occur. Always dispense fresh calibrators.

CAUTION

Do not reuse calibrator tubes after removing them from the Cal-QC storage area and storing them offline. Reusing removed calibrator tubes results in a false onboard stability that may cause unwarranted calibration troubleshooting if a calibration fails.

1. Ensure the following items exist on the system:
   - Assay reagent calibrations
   - Assay master curves and test definitions
   - Measuring interval verification material definitions
   - Assay reagents
2. Confirm the system is in 1 of the following states:
   - Ready
   - Standby
   - Processing
3. Prepare the measuring interval verification material samples.
4. Create a measuring interval verification order.
5. Print the measuring interval verification material sample barcodes.
6. Place the barcode labels on the appropriate measuring interval verification material sample tubes.
7. Load the measuring interval verification samples on the system:
   - For an Atellica Solution, load the measuring interval verification material samples in a rack and place the rack in an SH sample drawer.
   - For a IM DL analyzer, load the measuring interval verification material samples on a rack and place the rack on the entry queue.

   NOTE: If using more than 6 measuring interval verification material levels on an IM DL, load the samples in 2 racks.
8. Review the measuring interval verification results.

About Automatic Measuring Interval Verifications

Laboratories use measuring interval verifications to verify assay measuring intervals.

Automatic Measuring Interval Verification uses serial dilutions and shows the relationship of the dilutions (linearity). Manual Measuring Interval Verification verifies the recovery of known concentrations across the interval (calibration verification).

Measuring interval verification material is commercially available or the operator can use an existing multilevel calibrator. To create a new automatic measuring interval verification, the operator views, selects, or enters the following information:

Step	Notes
Parameters	• Evaluation Name • Evaluation ID automatically populates • Analyzer to use for the evaluation • Assay to evaluate* • Reagent Lot of the assay
Samples	• Defined Calibrator or Other Sample • Calibrator • Material Name • Material ID • Lot ID • Expiration Date of the lot • Number of Replicates

* Measuring Interval and units auto-populate, based on the assay.

After placing an order, the operator can view the status of all lab evaluations and perform the following functions:

- View details
- Review progress
- Review results
- Approve an evaluation
- Print the barcodes
- Export an evaluation

- Repeat an evaluation, which copies the parameters, generates a new evaluation ID, allows the operator to enter a new evaluation name and modify the settings
- Delete an evaluation

The table includes the following information:

- Evaluation Type
- Evaluation Name
- Evaluation ID
- Start date and time of when the operator selected Place Order for the evaluation
- End date and time when the system completes the last dilution of the evaluation. For evaluations scheduled for a specific date, the end date matches the target date and the time of the time when the evaluation was defined.
- Analyzer the system uses to perform the evaluation
- Assay the system uses for the evaluation
- Status of the evaluation:
  - Accepted: The operator approved the evaluation.
  - In Progress: The operator placed the order, and the order is inprocess or requires intervention.
  - Rejected: The operator rejected the evaluation during or after completing the evaluation.
  - Awaiting Acceptance: The evaluation is complete and waiting for the operator to approve or reject it.
  - Not Ordered: The operator created the evaluation but has not placed the order. If the operator selects the evaluation, the evaluation opens to the last completed step.

The operator can also view the evaluation progress and results from Worklist, where the Evaluation ID displays as the Run ID. The evaluations in Worklist display with an Evaluation flag.

About Manual Measuring Interval Verifications

Laboratories use measuring interval verifications to verify assay measuring intervals.

Automatic Measuring Interval Verification uses serial dilutions and shows the relationship of the dilutions (linearity). Manual Measuring Interval Verification verifies the recovery of known concentrations across the interval (calibration verification).

Measuring interval verification material is commercially available or the operator can use an existing multilevel calibrator. To create a new manual measuring interval verification, the operator selects or enters the following information:

Step	Notes
Parameters	• Evaluation Name • Evaluation ID automatically populates • Analyzer to use for the evaluation • Assay to evaluate • Reagent Lot of the assay
Samples	• Material Lot • Expiration Date of the Material Lot • SID Prefix • Each Level with a maximum of 9 • Each SID automatically populates • Each Target • Each Low (optional) • Each High (optional) • Number of Replicates

After placing an order, the operator can view the status of all lab evaluations and perform the following functions:

- View details
- Review progress
- Review results
- Approve an evaluation
- Print the barcodes
- Export an evaluation
- Repeat an evaluation, which copies the parameters, generates a new evaluation ID, and allows the operator to enter a new evaluation name
- Delete an evaluation

The table includes the following information:

- Evaluation Type
- Evaluation Name
- Evaluation ID
- Start date and time of when the operator selected Place Order for the evaluation
- End date and time when the system completes the last dilution of the evaluation. For evaluations scheduled for a specific date, the end date matches the target date and the time of the time when the evaluation was defined.
- Analyzer the system uses to perform the evaluation
- Assay the system uses for the evaluation
- Status of the evaluation:
  - Accepted: The operator approved the evaluation.
  - In Progress: The operator placed the order, and the order is inprocess or requires intervention.
  - Rejected: The operator rejected the evaluation during or after completing the evaluation.
  - Awaiting Acceptance: The evaluation is complete and waiting for the operator to approve or reject it.
  - Not Ordered: The operator created the evaluation but has not placed the order.

The operator can also view the evaluation progress and results from Worklist, where the Evaluation ID displays as the Run ID. The evaluations in Worklist display with an Evaluation flag.

About Precision Studies

This study tests within-run precision or repeatability of the system. Laboratories can perform precision studies to evaluate Assay and Analyzer performance. The Assay must be ready to use, and the reagent must be onboard and calibrated.

Step	Notes
Parameters	• Evaluation Name • Evaluation ID automatically populates • Analyzer to use for the evaluation • Assay to evaluate • Number of Replicates to order for the evaluation
Samples	SID 1–3 Sample IDs for evaluation
Reagent Pack	Pack ID

17 Maintenance

Maintenance

This chapter provides information about system maintenance. The system monitors maintenance activities and provides notification when a scheduled activity is due.

About Maintenance

CAUTION

Do not fail to perform predefined maintenance activities. Failure to comply with required maintenance may affect system performance. Maintenance activities are defined to ensure optimal operation of the system.

The large count on the Maintenance tile is the number of activities that are Due and Failed. This number is the total number of current day maintenance activities in those states for the system as displayed in Maintenance.

The Maintenance tile dynamically displays all modules that have maintenance in progress or Due within the configured warning threshold along with a count of the following:

- The number of Maintenance activities Due or not completed for the current calendar day.
- The number of Maintenance activities with a Failed status for the current calendar day.
- The modules that are starting maintenance.
- The modules where maintenance is in progress.

The Maintenance tile header displays 1 of the following colors on the dashboard:

Maintenance tile title color	Notes
Green	No Failed, Inprocess, or Due maintenance activities exist to automatically start within the configured maintenance activity reminder time.
Yellow	One or more Inprocess or Due activities exist within the configured maintenance activity reminder time.
Red	Immediate operator intervention required as 1 or more maintenance activities have failed for the day. The title remains red until these activities successfully complete or the operator reschedules them to a new day.

In Maintenance, the operator:

- Schedules activities.
- Reviews or modifies activities.
- Initiates manual activities.
- Reviews and approves activities with the appropriate security level.
- Create operator-defined activities.

NOTE: The operator cannot delete system-defined maintenance activities.

Maintenance displays the maintenance activities and their status for the selected day, week, or month selected in View By. The current day is highlighted by default. These activities include automated and manual procedures. The system sorts upcoming maintenance activities based on status. Status displays in the following order:

- Inprocess activity or waiting for the module to be in Ready state to complete the maintenance task.
- Failed activity that requires completion.
- Due
- Due with time
- Not Performed activity.

- Not Performed with Comment ( ).
- Completed activity ( ).

The operator filters all maintenance activities by frequency, module, activity type, and activity status.

Automated activities do not require operator assistance. The operator may start automated maintenance activities. When an automated maintenance activity completes successfully, the system updates the Maintenance to display the date and time completed.

NOTE: The system pauses sample processing when performing automated activities on an analyzer. If the system includes multiple analyzers, sample processing can continue on other analyzers that are not involved in these activities. In SH configurations, sample processing is also paused when automated maintenance activities are inprocess on the Sample Handler and Atellica Magline Transport.

Manual activities require the operator to perform or complete the activity. The operator documents completion of manual maintenance activities in Maintenance Activity Details.

If an automated scheduled maintenance activity fails, the activity displays a red alert and the due date does not update. The system creates a log entry recording the failed status.

The operator uses < or > in Filter to display activities in the previous 3 months, current month, or future 3 months.

The online help provides a list of Maintenance icon definitions (Page 548 *About Maintenance Icons*).

Maintenance	Notes
Module	The module that the activity is assigned to.
Activity	The name of the activity with an icon indicating whether it is automated or the operator or local technical support provider performs it.

Maintenance	Notes
Frequency	When the filter is collapsed, the system displays: • The next scheduled frequency: Day or Daily with time • Frequency icon When the filter is expanded, the system displays: • The next scheduled frequency: Daily, Weekly, or Monthly. • Frequency icon
Counts	The number of counts left on count based maintenance activities. When the filter is collapsed, Counts displays.
Status	The activity status displays as follows: • Inprocess (): The activity currently performing or waiting for the module to be in Ready state to complete the maintenance task. • Failed (): The activity failed to complete when it last performed. This only applies to automated activities. If the system marks an As Needed activity as Failed, that activity is automatically removed at the end of that day. • Due (): The activity is due and the operator should perform it prior to the end of the duration period.

Maintenance	Notes
	• Not Performed (✕): The operator edits the activity for the duration period as Not Performed or the activity did not perform prior to the end of the duration time. • Not Performed with Comment (✕💬): The operator adds comments to a Not Performed activity or changes the Due status to Not Performed with Comment. • Completed (✓): The operator marks the activity complete or the automated activity completes successfully.
Maintenance Activity Details	The operator selects the appropriate activity to: • Review status of that activity. • View online help task topic linked to that activity
All Activities	The operator selects to display all maintenance activities, including As Needed.

Reviewing Maintenance

1. To sort the activity list, select options in Filter.

NOTE:

The system displays the Maintenance statuses in the following order:

- Inprocess ()
- Failed ()
- Due ()
- Due with time ()
- Not Performed ()
- Not performed with Comment ()

2. Review and ensure required maintenance is complete.
3. Troubleshoot and resolve any failed activity ().

About Maintenance Icons

An icon alerts the operator to a required action or more information.

Maintenance icon	Icon description
	Maintenance required. Located on the Maintenance tile.
	The operator performs this activity.
	The operator performs the By Count activity.
	The operator performs the Weekly activity.
	The operator performs the Monthly activity.
	The customer service engineer performs this activity.
	The customer service engineer performs the By Count activity.

Maintenance icon	Icon description
	The customer service engineer performs the Weekly activity.
	The customer service engineer performs the Monthly activity.
	The system performs this activity.
	The system performs the By Count activity.
	The system performs the Weekly activity.
	The system performs the Monthly activity.
	Failed activity requires completion.
	Inprocess activity or module in preparation state waiting for the analyzer to be in Maintenance state to complete the maintenance task.
	Completed activity.
	Due activity.
	Not performed activity.
	Not performed activity with comment.
	Daily frequency.
	Weekly frequency.

Maintenance icon	Icon description
	Monthly frequency.
	By Count frequency. The count of an analyzer sample, test replicate, system cycle, connected time, or working time. When the count reaches the limit, the activity alerts to complete.
	As Needed frequency.

About Maintenance Activity Status

Maintenance activity statuses provide information on an activity. The system has the following activity statuses:

Activity Status icon	Glyph description
	Inprocess activity or waiting for the module to be in Ready state to complete the maintenance task.
	Failed activity requires completion.
	Due activity.
	Not Performed activity.
	Not Performed with comment activity.
	Completed activity.

The activity status is located in the Status column in Maintenance.

When a maintenance activity completes successfully or resets, the system updates Maintenance to display the next due date or the module resets the current count.

Responding to Maintenance Alerts in System Status Area

1. In the area for System Status, select a module.
2. Review and resolve all Maintenance alerts.
3. To view alerts by module, select the red or yellow module in System status area.

   NOTE: Failed maintenance activities display ⚠ alerts.

4. To resolve ⚠ alerts:
   a. If consumable low, replenish supply.
   b. If maintenance failed, troubleshoot and repeat the maintenance activity.
5. To resolve maintenance activities due today:
   a. Navigate to **Maintenance**.
   b. Wait for Inprocess activities to complete.
   c. Perform the required maintenance to resolve any issues.
   d. To postpone an activity within the frequency duration, select the appropriate activity then select **Postpone > OK**.
6. To view historical information about an activity that has an alert, navigate to **Maintenance Log** then select the appropriate activity.

About Maintenance Activities Frequency

This section describes the 3 frequencies of maintenance activities: Date and time, By Count, or As Needed.

Frequency icon	Notes
	Daily frequency. Activity the system schedules to recur daily. Frequency updates with time after the day range is reached.
	Weekly frequency. Activity the system schedules to recur weekly. Frequency updates to the next date and time in the frequency every time the activity completes successfully.

Frequency icon	Notes
	Monthly frequency. Activity the system schedules to recur monthly. Frequency updates to the next date and time in the frequency every time the activity completes successfully.
	By Count frequency. The count of an analyzer sample, test replicate, system cycle, connected time, or working time. When the count reaches the limit, the activity alerts to complete. Activity the analyzer schedules for the following increments: • Sample counter increments when the analyzer scans an onboard control, or off-board control, patient, or calibrator sample. • Test Replicate counter increments when a patient, control, or calibrator replicates results. • Cycle counters increment when component cycle completes, such as a probe count. • Working Time counter increments when the system is on.
	As Needed frequency. Activity with no set schedule, such as a replaceable part that the analyzer documents when the operator performs the maintenance.

About Maintenance Activities Types

Maintenance activities are predefined or operator defined. The operator can edit predefined activities but cannot delete them. The system has 3 types of maintenance activities:

Maintenance icon	Notes
	The operator performs this activity manually.
	The customer service engineer performs this activity manually.
	The system automatically performs this activity.

Each icon includes the frequency in the icon:

Operator icon frequency indicator	Frequency
	Weekly (purple)
	Monthly (teal)
	By Count (gray)

Performing Automated Maintenance Activities

The analyzer initiates automated maintenance activities according to an automated system-determined schedule or operator-defined maintenance schedule. The operator can initiate automated maintenance activities to perform earlier than the scheduled date and time:

- Daily: The operator selects the activity to perform earlier than the schedule time in that same day.
- Weekly or Monthly: The operator locates the activity in All Activities then selects the activity to perform.

NOTE: Performing a maintenance activity before the due date automatically reschedules that activity to the next frequency.

Performing periodic maintenance activities based on cycle, date and time, or count before the due date automatically reschedules that activity to the next frequency.

1. Navigate to **Maintenance > All Activities**.
2. To filter by Module, select the appropriate module from the drop-down menu.
3. Select an automated maintenance activity.

   NOTE: The analyzer designates automated maintenance activities with  in the Activity column.
4. Select **Perform > Yes**.
5. Wait for activity to complete.

About Scheduling Automated Maintenance Activities in Parallel

The operator can manually schedule automated Maintenance activities in parallel to optimize total maintenance time. When scheduled, the system automatically performs the maintenance activities with no further operator intervention.

The following are recommendations when scheduling activities in parallel:

- In Supply Needs, ensure all consumables have a status of OK prior to the start of the first activity. The required inventory must be onboard.
- The operator should only schedule 1 activity at a time per module and schedule the next activity 1 minute after the previous activity ends.
- Parallel activities are permitted between different modules. For example, the daily or weekly maintenance on CH and IM perform at the same time. The operator should schedule the next activity 1 minute after the previous activity starts.

The operator must wait 4–5 minutes for the analyzers to transition to Maintenance.

The following table lists a daily automated activities schedule with an example start time:

Daily automated activity	Start time (hours:minutes)	Duration (minutes)
SH Autocheck	01:00	<5
SHC Autocheck (if appropriate)	01:05	<5
Atellica Magline Transport Autocheck	01:05	10
IM Daily Maintenance (Standard and Additional Short Washes)*	01:05	23–66

Daily automated activity	Start time (hours:minutes)	Duration (minutes)
IMT Daily Cleaning	01:05	<5
CH Daily Maintenance	01:10	12–40
IM Autocheck	01:35	≤10

* If the laboratory has configured Additional Long Washes or Enhanced Maintenance, contact the local technical support provider to determine the parallel activity schedule.

The following table lists a weekly automated activities schedule with an example start time:

Weekly automated activity	Start time (hours:minutes)	Duration (minutes)
SH Autocheck	01:00	<5
SHC Autocheck (if appropriate)	01:05	<5
Atellica Magline Transport Autocheck	01:05	10
IM Weekly Maintenance (Standard and Additional Short Washes)*	01:05	32–75
IMT Daily Cleaning	01:05	<5
CH Weekly Maintenance	01:10	65
IM Autocheck	01:40	≤10

* If the laboratory has configured Additional Long Washes or Enhanced Maintenance, contact the local technical support provider to determine the parallel activity schedule.

Performing Manual Maintenance Activities



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

WARNING

Do not perform maintenance inside the analyzer unless the analyzer is stopped or in the diagnostic state. Analyzer subassemblies can move and cause bodily harm.

1. Navigate to **Maintenance > All Activities**.
2. To filter by Module, select the appropriate module from the drop-down menu.
3. Select a manual Activity.

   NOTE: The analyzer designates manual maintenance activities with in the Activity column. A manual activity requires the operator to perform or complete the activity.
4. Select **Perform > Yes**.
5. Select the appropriate response for the next scheduled time for that activity.
6. Complete activity.
7. Select **Mark as Completed > Yes**.

Accessing Maintenance Procedure Details

1. Navigate to **Maintenance > All Activities**.
2. To filter by Module, select the appropriate activity module from the drop-down menu.
3. Select a maintenance Activity.
4. Select **Procedure Details**.

Marking Completed Manual Maintenance Activities

For all manual maintenance, the operator must mark the appropriate activity as completed.

The operator cannot mark a Not Performed activity as complete. The operator adds comments describing why they did not perform that maintenance.

The operator marks a Failed or Due activity as Not Performed then adds a comment. The operator cannot edit saved comments but can add new comments.

1. Navigate to **Maintenance**.
2. Filter by Module and search for the completed manual activity.
3. In Maintenance Activity Details, select **Mark as Completed > Yes**.

About Adding Maintenance Activities

This feature requires the appropriate security level.

The operator can configure up to 60 additional maintenance activities not listed as a predefined activity in Maintenance Configuration.

Add Activity	Notes
Information	The activities name, description, and module are configured in this section.
Activity Name	The activity title has a limit of 40 alphanumeric characters. The name is not case sensitive.
Description	The activity description has a limit of 300 alphanumeric characters. The description is not case sensitive.
Module	Drop-down menu operator selects to assign the activity to a module.
External Reporting	If Mandatory selected, the activity is included in the monthly external report. System-defined activities are included by default. The laboratory generates the external report for presentation to inspection agencies.
Frequency Settings	The duration, frequency, and when performed configured in this section.
Duration	The completion time in minutes.
Frequency	The selected time or frequency that is in the activity definition. Operator selects from a drop-down menu.
Perform Every	How often the activity performs.

Add Activity	Notes
Time Settings	The day of the week and time configured in this section.
Day of Week	Drop-down menu operator assigns the day each week when the activity performs.
Time	The time the activity starts.
Save	Saves new activity.
Cancel	Cancels adding new activity and closes window.

About Maintenance Reminders

The operator can configure automatic warnings prior to start time for maintenance activities in **Maintenance Configuration > Schedule**.

Schedule Set Reminder	Notes
Confirm Prior to an Automatically Started Activity	Warns the operator that an automated maintenance activity status changes to Inprocess or Pending Inprocess until it completes.
Time (minutes)	Displays the warning for the number of minutes prior to the start of the automated maintenance activity.
Save	Saves the maintenance activity reminder configuration.
Cancel	Cancels the maintenance activity reminder configuration and closes the Set Reminder window.

About System Maintenance Activities

The system has Daily and As-Needed maintenance activities. The system performs the following maintenance activities on a daily basis:

Daily activities*	Notes
Database: Archiving and Deleting	The system automatically archives and deletes data from the system (Page 563 *About Archiving and Deleting System Data*).
Database Backup	The system automatically backs up system data (Page 560 *About the Database Backup Activity*).
Database: Optimizing	The system automatically performs a defragmentation of the system databases (Page 559 *About the Data Optimization Activity*).
Move to Historical	The system automatically moves completed and transmitted patient sample results from the Active database to the Historical database.

*The system performs the database activities in the background while performing other automated maintenance activities. Although the operator cannot schedule these activities, the laboratory can perform these activities manually on an as-needed basis.

The operator performs the following maintenance activities on an as-needed basis:

As-Needed activities	Notes
Cleaning the Exterior Covers	Cleans the exterior covers of the analyzers.
Cleaning the Keyboard and Mouse	Removes dust and residue from the keyboard and mouse.
Inspecting archive racks and springs	Ensures that the archive racks are free from dirt and debris and the springs can hold tubes securely.
System Display Optimization	Restarts the user interface.

About the Data Optimization Activity

The Database Optimization activity automatically performs a defragmentation of the system databases to ensure that the system is storing the data in the most efficient way.

The system automatically performs this activity on a daily basis in the background while the system is performing other maintenance activities. The laboratory can also perform this activity manually on an as-needed basis. The activity takes 5–10 minutes to complete.

If the LIS is online, it disconnects during Database: Optimizing and reconnects when the activity completes.

In Maintenance Configuration, the operator can edit the following defragmentation settings:

Setting	Notes
Time Out	The amount of time, in minutes, that the system takes to perform the activity. By default, the value is 12 minutes. When this time is reached, the defragmentation process ends. All defragmentation that can occur in this time frame is complete.
Defrag Level	The level of defragmentation at which the data optimization activity occurs. By default, the level is set at 30.

The field for External Reporting enables the system to log the activity in the Maintenance Log.

After editing the settings, the operator can save or cancel the changes. Reset to Defaults returns all settings to their default values.

About the Database Backup Activity

This feature requires the appropriate security level.

The database backup activity creates a copy of system data in case the data becomes corrupted or damaged. Database backups allow the laboratory to recover data before it becomes unusable.

A full database backup includes all data that the system needs to restore the functionality of the system. A partial database backup does not contain all the required data. The partial backup saves, but the backup activity fails with an event message.

NOTE: The system encrypts all PHI data.

The system automatically performs this activity on a daily basis in the background while the system is performing other maintenance activities. The laboratory can also perform this activity manually on an as-needed basis. The system takes ≤ 5 minutes to complete this activity when the system is not processing samples and ≤ 12 minutes to complete if the system is processing samples.

In Maintenance Configuration, the operator can edit the following settings as appropriate:

Setting	Notes
Location	Enables the operator to specify the location where the system stores archived databases. By default, the Location is F:\USERROOT\Database Backups\. **NOTE:** To store files off-system within the system security protocols and certificates, set the path to **F: > USERROOT > FTP > Export**. The files securely transfer to the laboratory FTP server. These files then route to the location the IT administrator has defined.
Prefix	Enables the operator to specify the prefix that the system appends to the file name. The prefix is an optional field and by default is blank. It can be a maximum of 10 characters. The prefix cannot contain the following characters: \ / : * ? " < > and |.

Setting	Notes
Print Confirmation	Enables the operator to specify whether the system automatically prints a report detailing the activity. The following options are available: • True: The system prints a report. • False: The system does not print a report. **NOTE:** By default, the option is set to False. The report contains the following information: • Header and footer, as configured in Print Reports • Backup file name • Information as to whether the system automatically or the operator manually performed the backup • Number of volumes in the backup • Location of the backup • Date and time the system started the backup • System name, if available • System serial number, if available • Software version

Setting	Notes
FileName	Specifies the file name of the backup file. The file name has the following format: PREFIX_SYSTEMSERIAL_TYPE_YYYY_MM_DD_HH_MM_SS, where • PREFIX: Operator-defined prefix **NOTE:** When the prefix is blank, the system prints nothing in this part of the file name. • SYSTEMSERIAL: Serial number of the system **NOTE:** When the serial number is unknown or unavailable, the system prints "UnknownSerial" in the filename. • TYPE: AutomaticDataBackup or ManualDataBackup. • YYYY_MM_DD: Year, month, and day that the system started the backup. • HH_MM_SS: Hours, minutes, and seconds that the system started the backup (24-hour clock).
AUTO Delete > 7	Enables the system to delete the oldest backup when the total number of backups in the operator-defined Location reaches 7. The following options are available: • True: The system deletes the oldest backup when the total number reaches 7. • False: The system does not delete the oldest backup when the total number reaches 7. **NOTE:** By default, the option is set to True.

The field for External Reporting enables the system to automatically log the activity in the Maintenance Log.

After editing the settings, the operator can save or cancel the changes. Reset to Defaults returns all settings to their default values.

About Archiving and Deleting System Data

This feature requires the appropriate security level.

The database archiving and deleting activity provides for the off-system, long-term storage of system data. Data includes Historical patient and control results, patient mean or median QC files, QC Statistics Data, the Audit Trail Log, the Maintenance Log and Reports, Lot Log, and Calibration Results (by Lot). The laboratory has access to the archived data but cannot restore the data to the system.

The system automatically performs this activity on a daily basis in the background while performing other maintenance activities. The laboratory can also perform this activity manually on an as-needed basis. The activity can take up to 30 minutes to complete.

In Maintenance Configuration, the system specifies a default archiving option for each type of data from the following options:

- Archive and Delete: The system archives and then deletes the data.
- Delete (No Archive): The system deletes the data without archiving it first.
- Do Not Delete or Archive: The system performs no action on the data.
- Archive without Deleting: The system archives the data but does not delete it.

The system also specifies a possible age range (in days) and a default age for each type of data that is marked for the archiving activity. The system performs the appropriate archiving options on all data older than the specified age. The operator can also change these values as appropriate in Maintenance Configuration.

The following table specifies the default option for the archiving activity and the age range and default age for each type of data:

Data	Default archiving option	Age of the data*
Historical Patient Samples	Archive and Delete	1–180 days, with a default value of 12 days
Historical Control Samples	Archive and Delete	1–180 days, with a default value of 30 days
Audit Trail Log	Archive and Delete	1–90 days, with a default value of 45 days
Patient Median or Mean QC Data	Archive and Delete	1–365 days, with a default value of 90 days
QC Statistics Data	Delete (No Archive)	1–365 days, with a default value of 90 days

Data	Default archiving option	Age of the data*
Maintenance Log	Archive without deleting	3 months**
Maintenance Reports	Archive without deleting	3 months**
Lot Log	Archive and Delete	2 years**
Calibration Results (By Lot)	Archive and Delete	30 days–2 years, with a default value of 2 years

* For example, if the age of the data ranges from 1–180 days and the default age is 12, the system performs the selected archiving option on data older than 12 days.

**The operator cannot change these values.

The operator can also configure the following settings:

Setting	Notes
Location	Specifies the location where the system stores archived databases. By default, the location is F:\USERROOT\Database Archives and Deletions\. **NOTE:** To store files off-system within the system security protocols and certificates, set the path to **F: > USERROOT > FTP > Export**. The files securely transfer to the laboratory FTP server. These files then route to the location the IT administrator has defined.
File Type	Specifies whether the system saves the archived databases as a text (TAB) or XML file.
Prefix	Specifies the prefix that the system appends to the file name. The prefix is an optional field and by default is blank. It can be a maximum of 10 characters. The prefix cannot contain the following characters: \ / : * ? " < > and |.

The External Reporting field enables the system to log the activity in the Maintenance Log.

After editing the settings, the operator can save or cancel the changes. Reset to Defaults returns all settings to their default values.

About SH, SHC, and Atellica Magline Transport Maintenance

The system displays maintenance activities in Maintenance. Each Module selection contains a list of system-defined automated and manual maintenance activities appropriate for that module.

Daily system-defined automated activities	Notes
SH Autocheck	The system automatically performs autocheck on the SH.
Atellica Magline Transport Autocheck	The system automatically performs autocheck on the Atellica Magline Transport.
SHC Autocheck	The system automatically performs autocheck on the SHC.

Monthly system-defined activities	Notes
Inspecting or Replacing the SH Robot Gripper O-Rings	The operator manually inspects the SH robot gripper O-rings.
Cleaning the SHC Fan Filter	The operator manually cleans the SHC filter.

As needed system-defined activities	Notes
Cleaning the Sample Handler Drawer and the Racks	The operator manually cleans the SH sample drawers and racks.
Inspecting or Replacing the SH Robot Gripper O-Rings	The operator manually replaces the SH robot gripper O-rings.
Inspecting archive racks and springs	The operator manually inspects the archive rack springs and cleans racks, if appropriate.
Inspecting the SHC Robot Gripper Tips	The operator manually inspects the SHC robot gripper tips.
Replacing the SHC Gripper Tips	The operator manually replaces the SHC gripper tips.

The system also automatically deletes the following items from the SH and SHC computer hard drives daily:

- SH hard drive
  - Database data older than 730 days
  - Log files, DVS images, and TCS images older than 15 days
- SHC hard drive
  - Database data older than 730 days
  - Log files and TCS images older than 15 days

About SH Autocheck

The SH Autocheck is an automated maintenance activity that tests the health of various SH components. The system automatically performs the autocheck daily at a specified time.

The system alerts the operator 15 minutes before the scheduled activity begins. After the system initiates the SH Autocheck, the SH pauses sample processing until the autocheck completes in <5 minutes.

The SH Autocheck maintenance activity performs the following:

- Test memory usage
- Home all motors
- Test robot gripper open and close
- Test robot crush sensor
- Test robot X-motor electrical current
- Test robot Y-motor electrical current
- Test robot Z-motor electrical current
- Test robot gripper motor electrical current
- Cal-QC storage area open and close
- Cal-QC storage area temperature
- Cal-QC storage area thermoelectric device current and duty cycle
- Cal-QC storage area thermoelectric device speed

The duration of the daily maintenance activities count down. All other activities duration count up.

Maintenance Log records and stores this activity.

About Atellica Magline Transport Autocheck

The Atellica Magline Transport Autocheck is an automated maintenance activity that tests the health of various Atellica Magline Transport components. The system automatically performs the autocheck daily at a specified time.

The system alerts the operator 15 minutes before the scheduled activity begins. After the system initiates the Atellica Magline Transport Autocheck, the Atellica Magline Transport pauses transporting samples until the autocheck completes in approximately 10 minutes.

The Atellica Magline Transport Autocheck maintenance activity performs the following:

- Test coil board coil coupling
- Test coil board coil impedance
- Check memory and processor usage
- Check carrier mileage
- Check driver board status
- Check motor status

The duration of the daily maintenance activities count down. All other activities duration count up.

Maintenance Log records and stores this activity.

About SHC Autocheck

The SHC Autocheck is an automated maintenance activity that tests the health of various SHC components. The system automatically performs the autocheck daily at a specified time.

The system alerts the operator 15 minutes before the scheduled activity begins. After the system initiates the SHC Autocheck, the SHC pauses sample transfer until the autocheck completes in approximately 5 minutes.

The SHC Autocheck maintenance activity performs the following checks on each robot:

- Check amplifier temperature
- Check operation of the Home sensor
- Check operation of the limit switch
- Check backlash

The duration of the daily maintenance activities count down. All other activities duration count up.

Maintenance Log records and stores this activity.

About Decapper Maintenance Activities

All maintenance activities display on Maintenance Schedule. The Decapper contains system-defined automated and manual maintenance activities.

Daily system-defined activities	Notes
Decapper Autocheck	The system automatically performs a self diagnostics maintenance.

Monthly system-defined activities	Notes
Cleaning the Decapper (Monthly)	The operator manually cleans the tube gripper pads, drip tray, and inside of the cap waste bin.

As Needed system-defined activities	Notes
Decapper Preventive Maintenance	The local technical support provider performs preventative maintenance on the Decapper a minimum of once a year.

About Decapper Autocheck

Decapper Autocheck is an automated maintenance activity that tests the health of various Decapper components. The system automatically performs the autocheck daily at a specified time.

The Decapper pauses processing until the autocheck completes in approximately 5 minutes. The system alerts the operator 15 minutes before the scheduled activity begins.

The Decapper Autocheck maintenance activity performs the following checks:

- Sensor functionality checks (tube gripper open sensor, CCW sensor, and CW sensor)
- Cap remover target position checks (decapping vertical up and down positions)
- Movement timing checks (rotation to waste and decapping position, ascend to decapping vertical up position, descend to decapping vertical down position, and tube gripper open and close)

The duration of the daily maintenance activities count down. All other activities duration count up.

Maintenance Log records and stores this activity.

Performing Decapper Autocheck

1. Navigate to **Maintenance > All Activities**.
2. In Module, select Decapper from the drop-down menu.
3. Select **Decapper Autocheck > Perform > OK**.
4. Wait approximately 5 minutes for autocheck to complete.

   NOTE: Maintenance Log records and stores this activity.

About Sealer Maintenance Activities

All maintenance activities display on the Maintenance Schedule. The Sealer contains system-defined automated and manual maintenance activities.

Daily system-defined activities	Notes
Sealer Autocheck	The system automatically performs a self diagnostics maintenance.

As Needed or Count-based System-defined activities	Notes
Cleaning the Sealer Plunger and Primary Crimper	The operator manually cleans the plunger and primary crimper every 20,000 cycles.
Cleaning the Sealer Foil Guide	The operator manually cleans the foil guide every 20,000 cycles.
Cleaning the Sealer Surfaces	The operator manually cleans the external surfaces as needed
Sealer Preventive Maintenance	The local technical support provider performs preventative maintenance every 140,000 cycles or once a year.

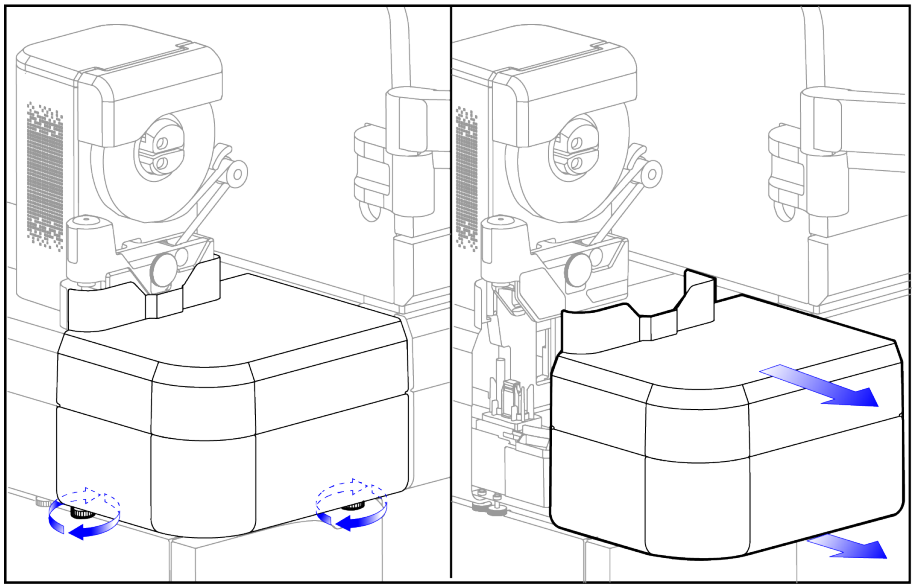
Cleaning the Sealer Plunger and Primary Crimper



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

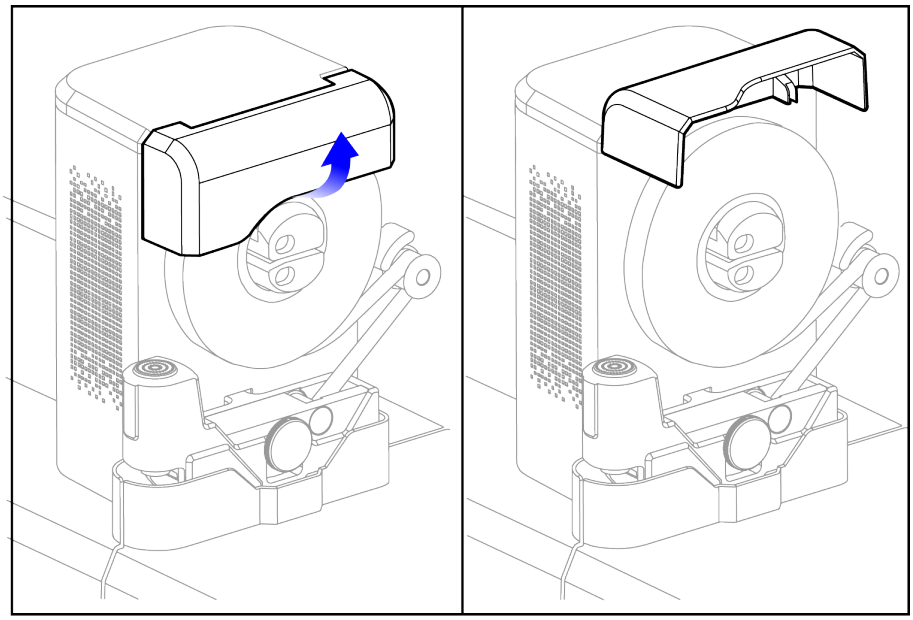
1. Stop the Sealer (Page 137 *Changing the Module Status*).
2. Open the Atellica Magline Transport cover.



WARNING

Do not handle foil without wearing personal protective equipment. Improperly handling the foil can cause bodily harm. The foil has sharp edges and may cause injury.

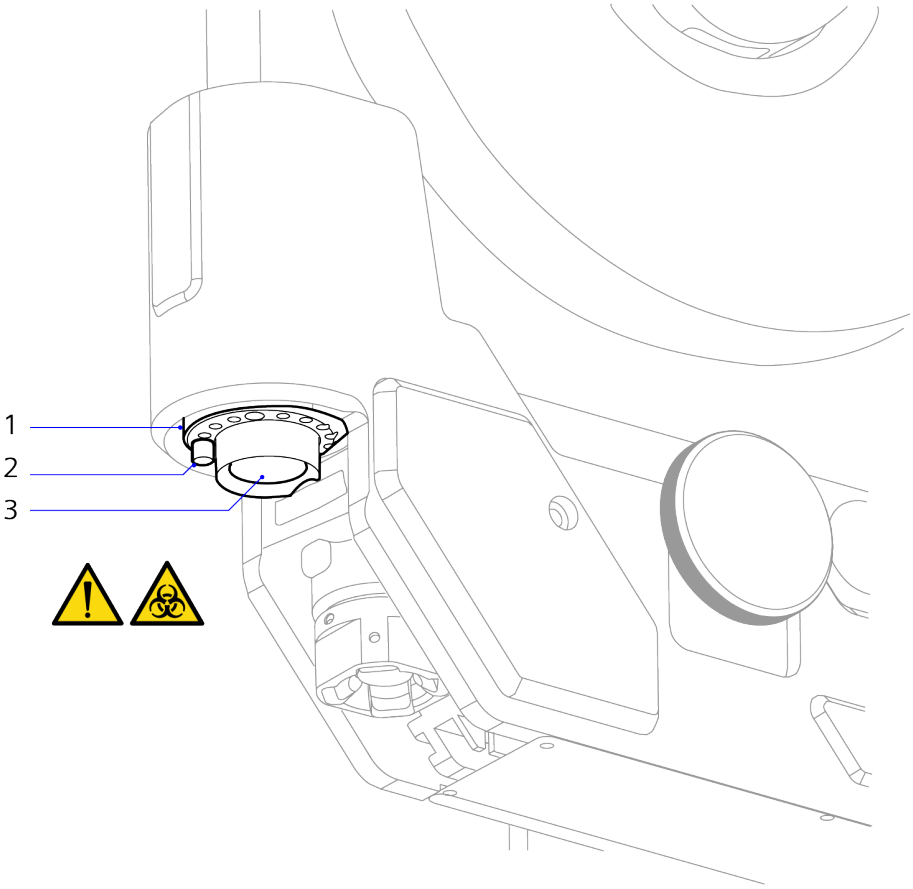
3. Open the Sealer foil roll cover.



CAUTION

Do not use Ethyl Acetate Cleaning Wipes, solvents, or any other harsh chemicals near or on the foil feed sensor. This can damage the sensor and cause incorrect functionality.

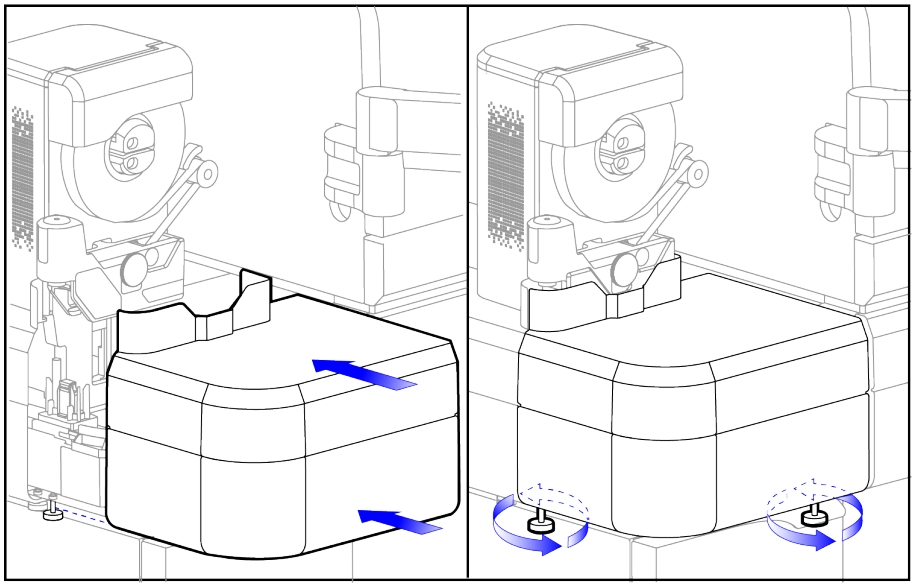
4. Gently wipe the Sealer plunger with a lint-free tissue saturated with 10% bleach solution.



1	Primary crimper
2	Foil feed sensor
3	Plunger

5. Repeat step 4 until no residue exists on the plunger.
6. Remove any debris from the crimper.
7. Close the Sealer foil roll cover.

8. Close the Atellica Magline Transport cover.



9. Resume the Sealer (Page 137 *Changing the Module Status*).
10. Mark **Cleaning the Sealer Plunger and Primary Crimper** as completed (Page 556 *Marking Completed Manual Maintenance Activities*).

    NOTE: Maintenance Log records and stores this activity.

Cleaning the Sealer Foil Guide

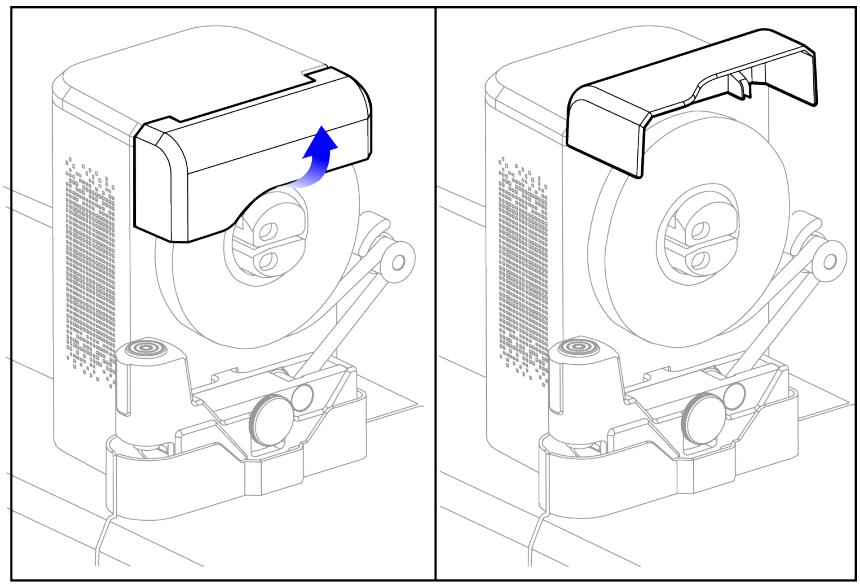
BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

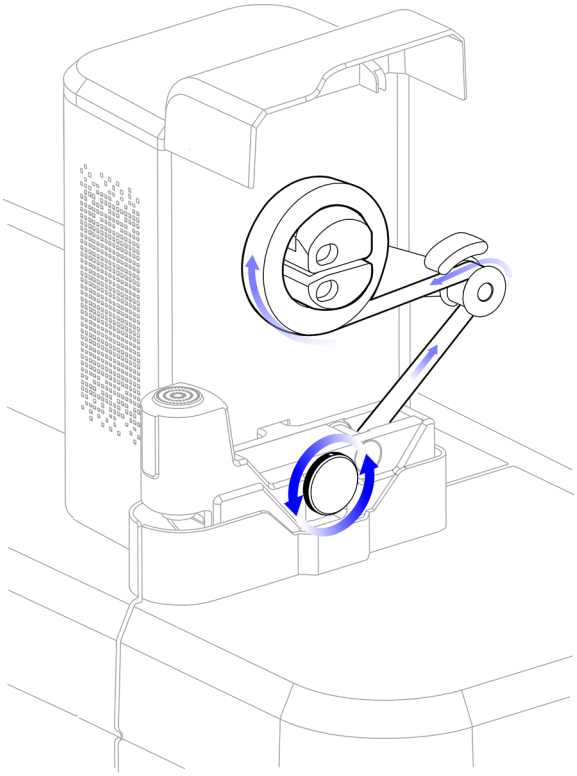
1. Stop the Sealer (Page 137 *Changing the Module Status*).

> **WARNING**
>
> Do not handle foil without wearing personal protective equipment. Improperly handling the foil can cause bodily harm. The foil has sharp edges and may cause injury.

2. To remove the foil from the foil track:
   a. Open the Sealer foil roll cover.



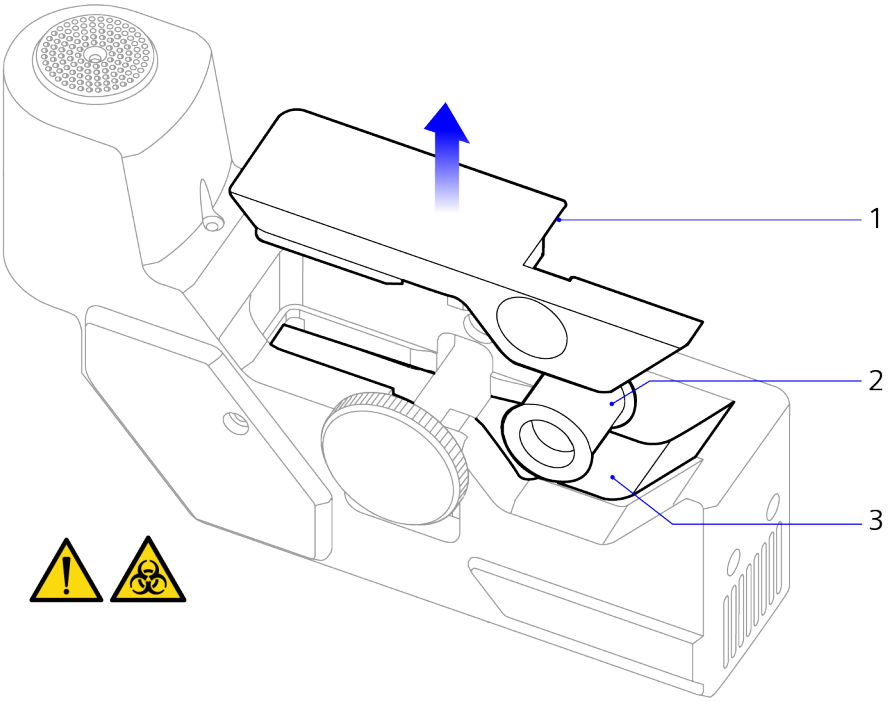
   b. Rotate the foil feed wheel counter-clockwise to remove the existing foil from the carriage.



c. Ensure foil is not in the foil track.

3. Remove the foil feed cover.

4. Clean the foil track and feed roller with a lint-free tissue saturated with 10% bleach solution to remove all residue.

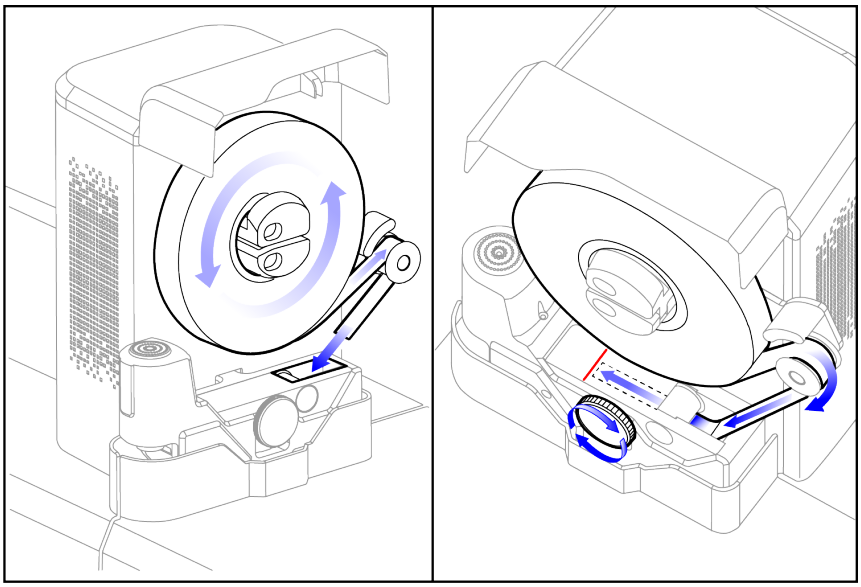


1	Foil feed cover
2	Foil feed roller
3	Foil track

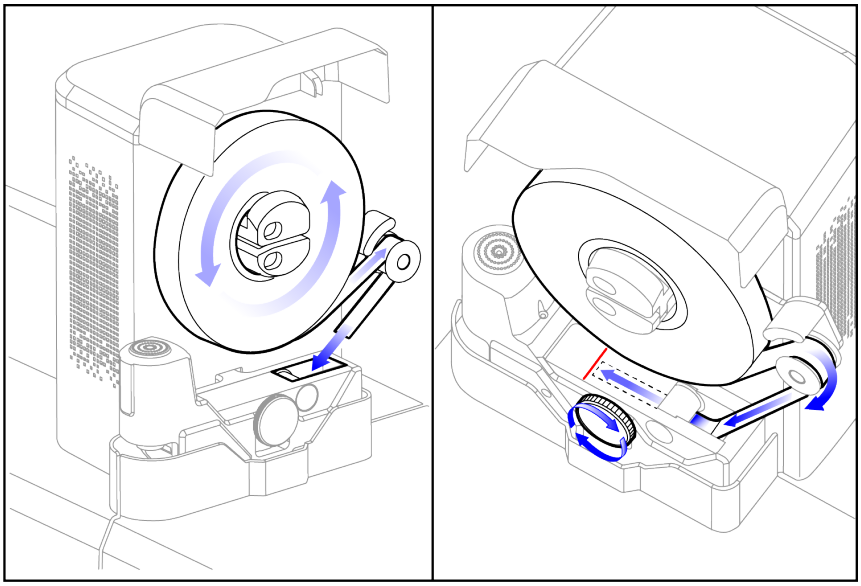
CAUTION

Do not use a damaged replacement Foil Roll. This can cause system errors on the Sealer. Ensure the replacement Foil Roll is round.

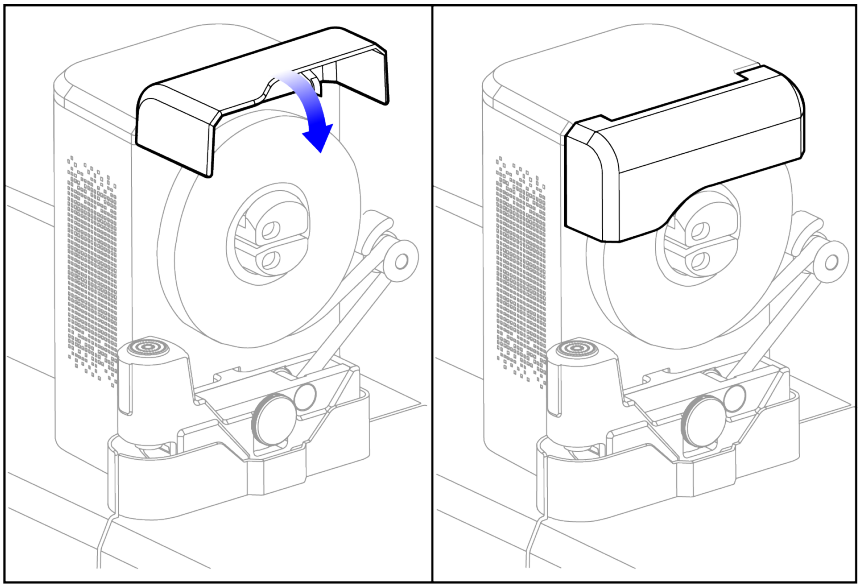
5. To reinstall the foil:
   a. Unroll 10 cm (3.94 inches) of foil.
   b. Cut the end of the foil perpendicular to the length and ensure no creases or wrinkles are present.
   c. Feed foil over the tension wheel and under the foil guide roller.



   d. Turn the foil feed wheel clockwise until it reaches the indicator line in the foil feed cover.



e. Close the foil roll cover.



CAUTION

Do not operate the Sealer without first ensuring the Foil Feed cover is correctly fitted. This could lead to foil feeding issues and cause system errors on the Sealer.

6. Replace the foil feed cover.

7. Resume the Sealer (Page 137 *Changing the Module Status*).
8. Mark **Cleaning the Sealer Foil Guide** as completed (Page 556 *Marking Completed Manual Maintenance Activities*).

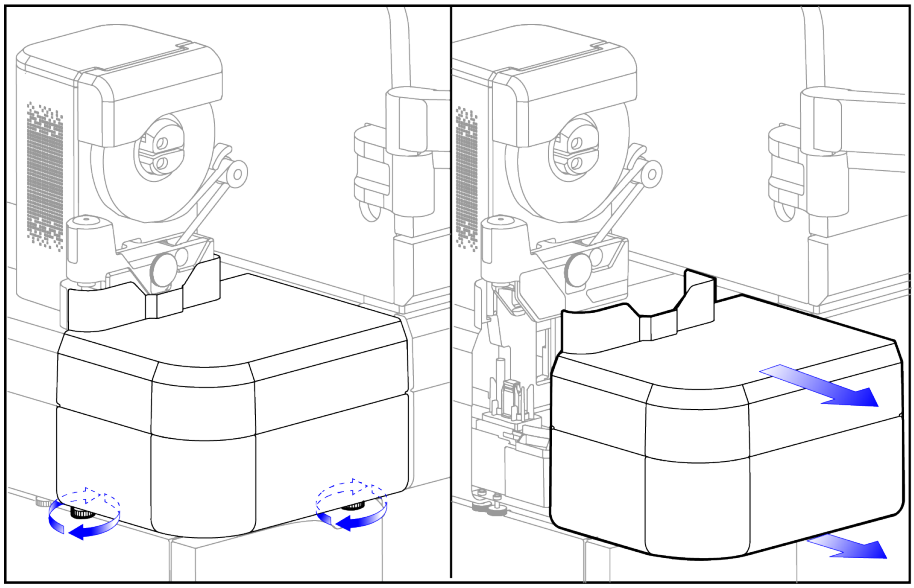
   NOTE: Maintenance Log records and stores this activity.

Cleaning the Sealer Surfaces

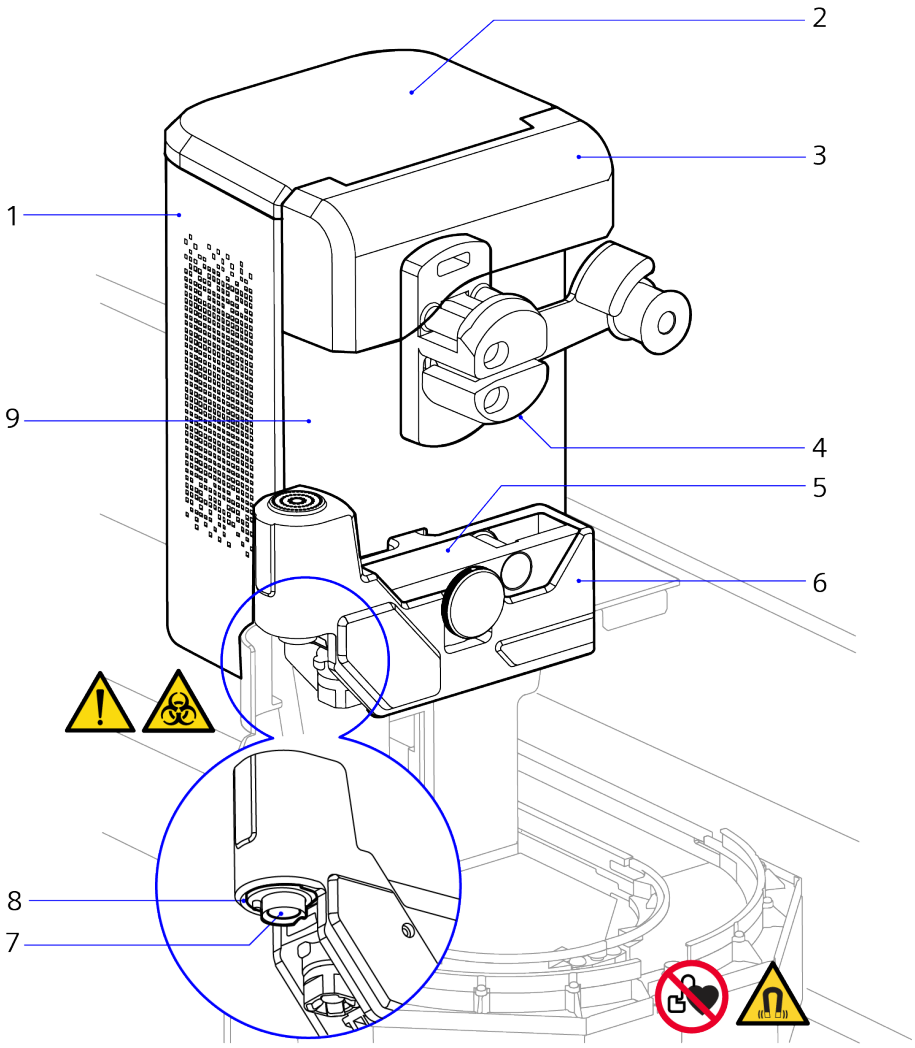
BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

1. Stop the Sealer (Page 137 *Changing the Module Status*).
2. Open the Atellica Magline Transport cover.

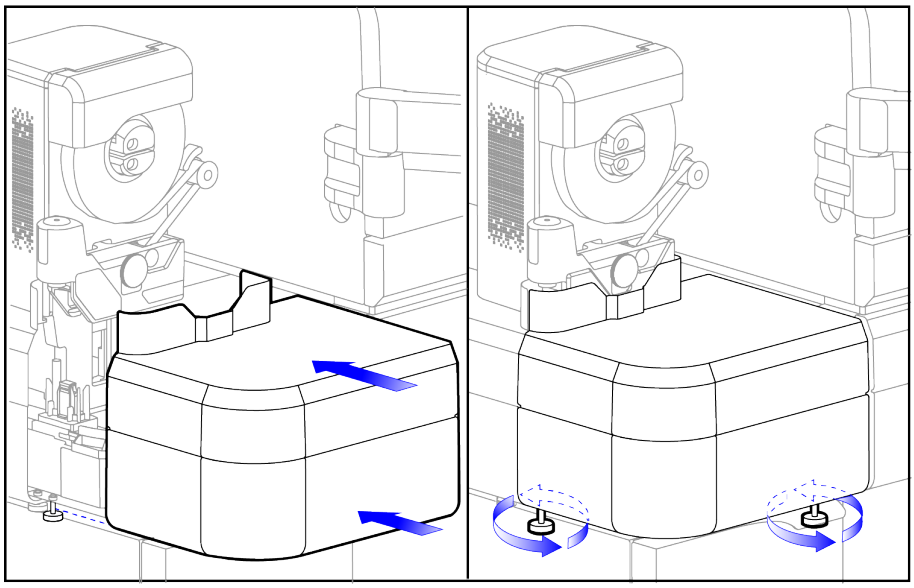


3. To clean the foil roll and foil feed cover:
   a. Wipe each cover with a lint-free tissue saturated with special reagent water.
   b. Dry the covers with a new lint-free tissue.



1	Side cover	6	Foil feed carriage
2	Top cover	7	Plunger
3	Foil roll cover	8	Primary crimper
4	Spindle	9	Front cover
5	Foil feed cover		

4. If appropriate, clean the Sealer top cover, spindle, foil feed carriage, front, and side covers:
   a. Wipe each with a lint-free tissue saturated with 10% bleach solution.
   b. Dry each cover with a new lint-free tissue.
5. Close the Atellica Magline Transport cover.



6. Resume the Sealer (Page 137 *Changing the Module Status*).
7. Mark **Cleaning the Sealer Surfaces** as completed (Page 556 *Marking Completed Manual Maintenance Activities*).

   NOTE: Maintenance Log records and stores this activity.

Replacing the Sealer Foil Roll

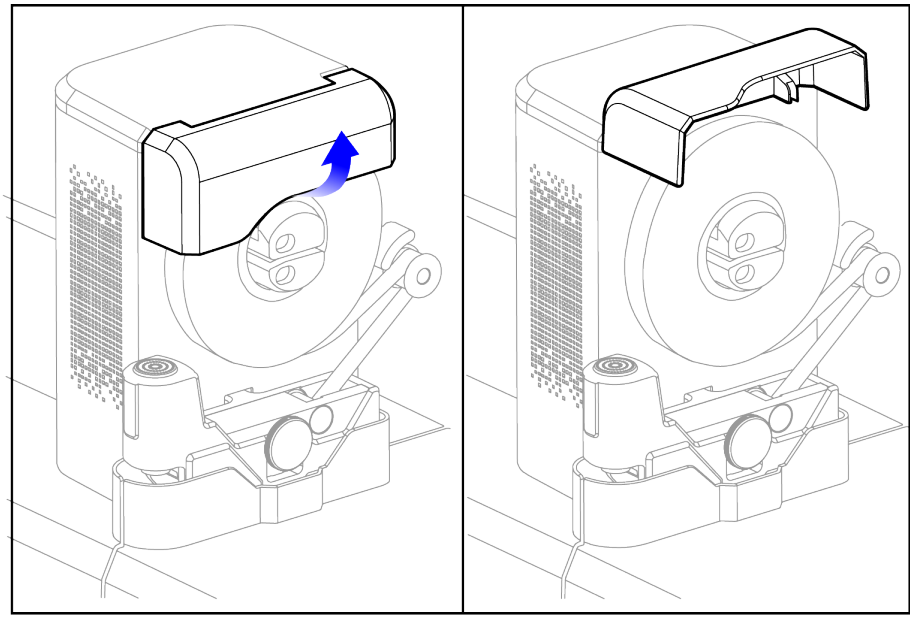
BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

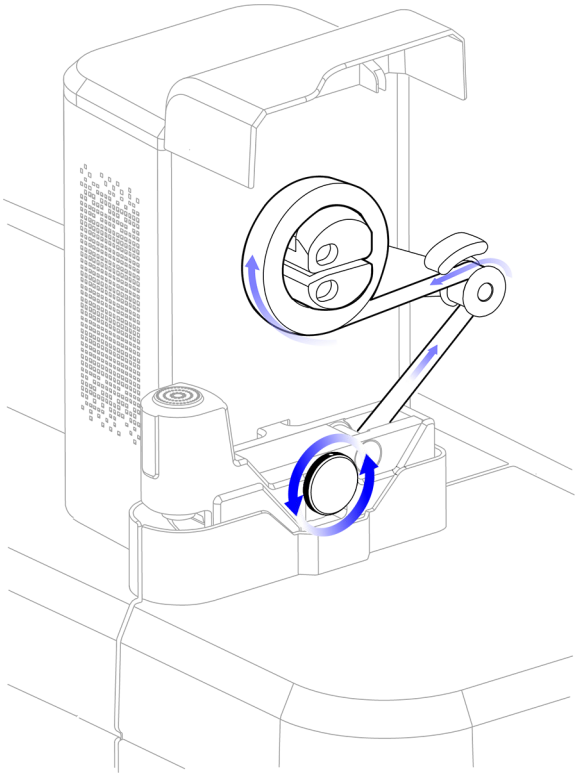
1. Stop the Sealer (Page 137 *Changing the Module Status*).

> **WARNING**
>
> Do not handle foil without wearing personal protective equipment. Improperly handling the foil can cause bodily harm. The foil has sharp edges and may cause injury.

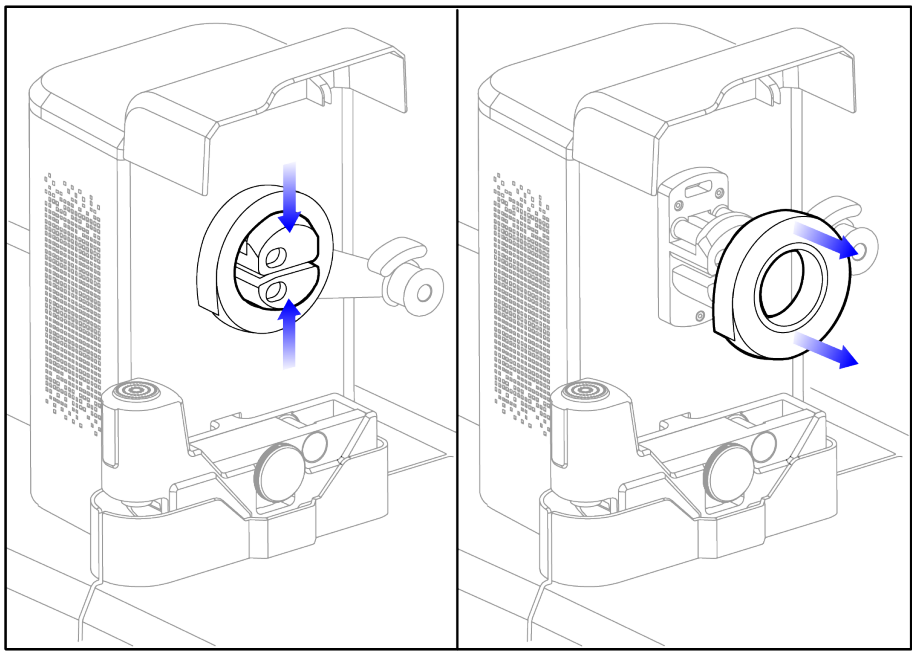
2. Open the Sealer foil roll cover.



3. Rotate the foil feed wheel counter-clockwise to remove the remaining foil from the carriage.



4. Remove the empty roll from the spindle:
   a. Squeeze the upper and lower sections of the spindle together.
   b. Pull the roll off the spindle.

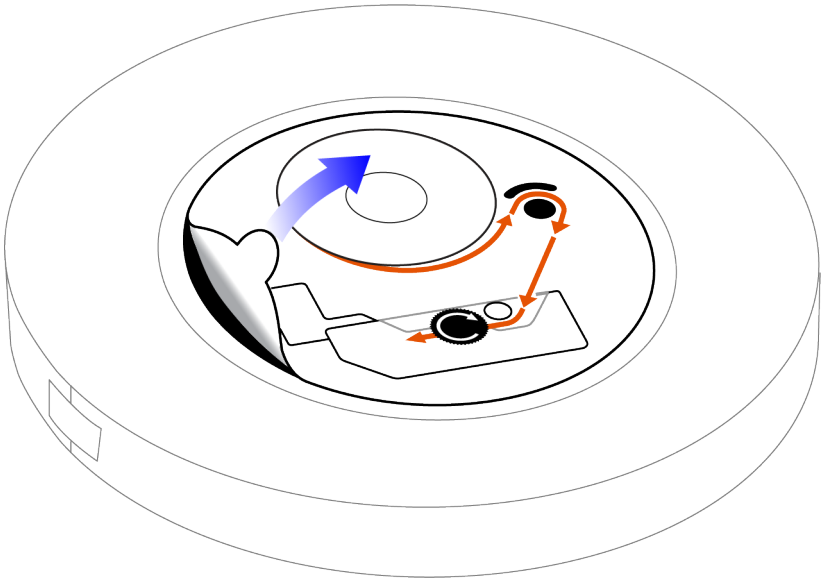


5. Dispose of the empty foil roll in accordance with laboratory protocols.

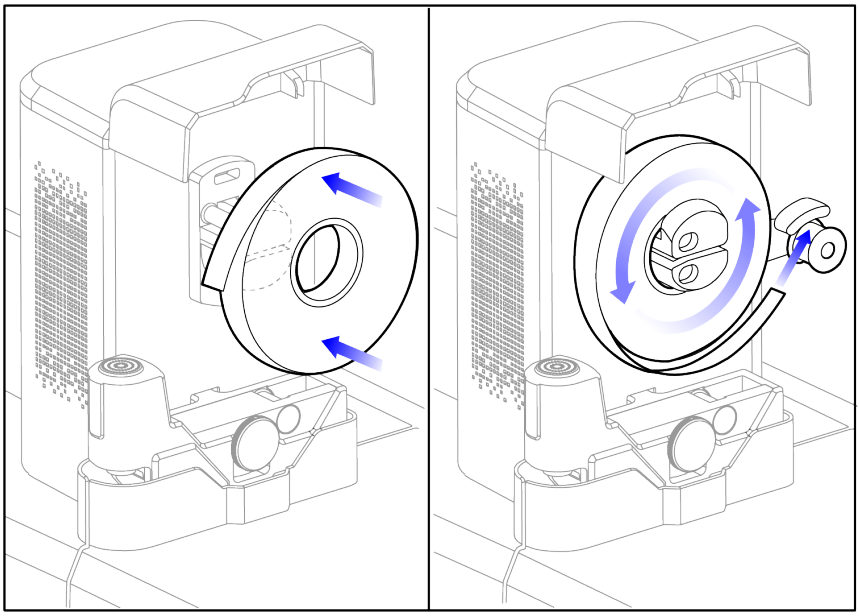
> **CAUTION**
>
> Do not use a damaged replacement Foil Roll. This can cause system errors on the Sealer. Ensure the replacement Foil Roll is round.

6. Locate and remove the tape fastening the end of the new foil to the roll.
7. Using scissors, cut off a full rotation of foil and discard it.

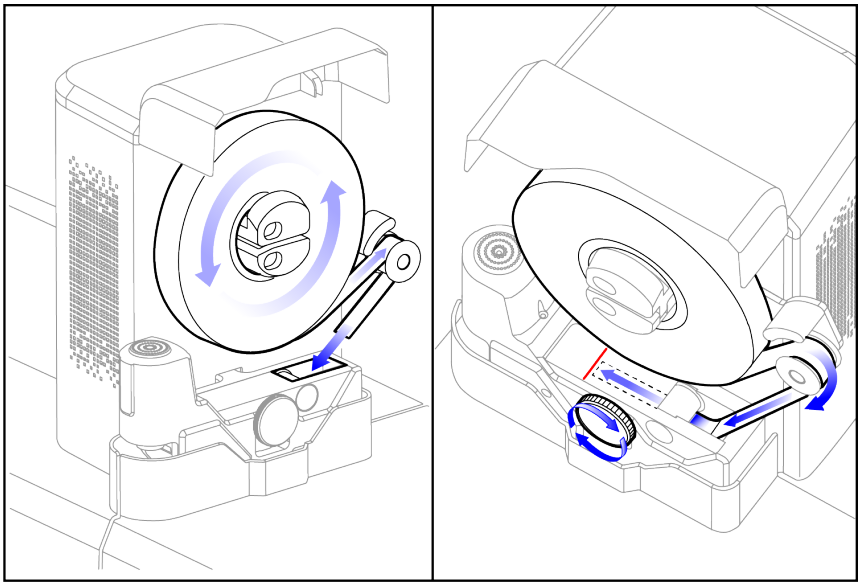
8. Remove the instruction sticker from the center of the roll.



9. Insert the new foil roll:
    a. Place the roll onto the spindle with the roll unravelling counter clockwise.

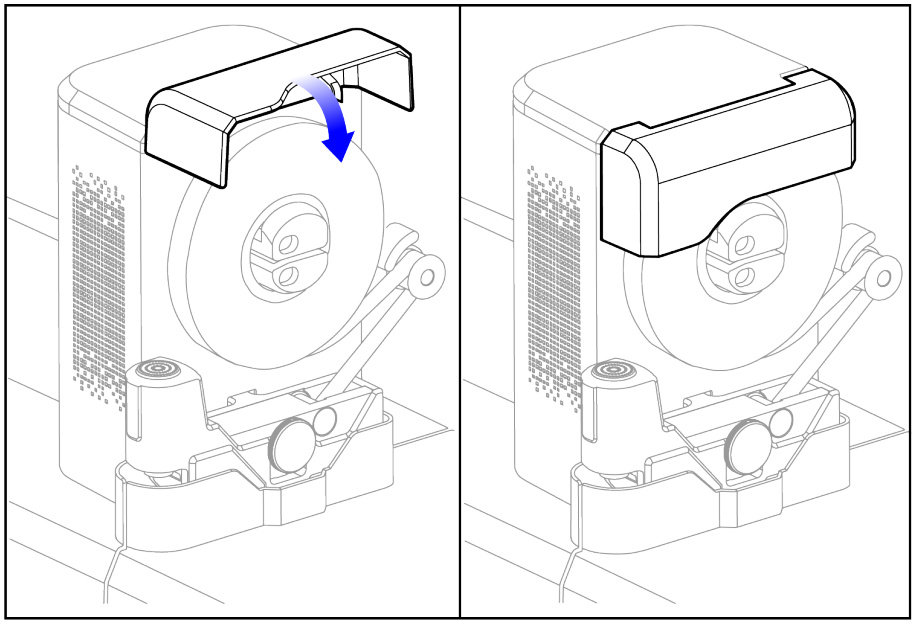


    b. Push the roll until it snaps into position.
    c. Unroll 10 cm (4 inches) of foil.
    d. Carefully lift up the roll to prevent the foil from unraveling.
    e. Cut the end of the foil perpendicular to the length and ensure no creases or wrinkles are present.
    f. Ensure no adhesive from the removed roll exists and remove, if appropriate.
    g. Feed foil over the tension wheel and under the foil guide roller.



h. Turn the foil feed wheel clockwise until it reaches the indicator line in the foil feed cover.

10. Close the foil roll cover.



11. Resume the Sealer (Page 137 *Changing the Module Status*).

About Sealer Autocheck

Sealer Autocheck is an automated maintenance activity that tests the health of various Sealer components. The system automatically performs the autocheck daily at a specified time.

The Sealer pauses processing until the autocheck completes in approximately 10 minutes. The system alerts the operator 15 minutes before the scheduled activity begins.

The Sealer Autocheck maintenance activity checks the ability of the system to perform the tube seal by checking health of different Sealer component.

The duration of the daily maintenance activities count down. All other activities duration count up.

Maintenance Log records and stores this activity.

Performing Sealer Autocheck

1. Navigate to **Maintenance > All Activities**.
2. In Module, select **Sealer** from the drop-down menu.
3. Select **Sealer Autocheck > Perform > OK**.
4. Wait approximately 10 minutes for autocheck to complete.

   NOTE: Maintenance Log records and stores this activity.

About CH Maintenance Activities

All maintenance activities display on Maintenance Schedule. The CH Analyzer contains system-defined automated and manual maintenance activities.

Daily system-defined activities	Notes
IMT Daily Cleaning	The analyzer automatically performs IMT system cleaning daily.
CH Daily Maintenance	The analyzer automatically performs cuvette, probe, mixer, and drain cleaning, autocheck, and reaction ring bath refresh daily.
Inspecting the Washer Probes	The operator manually inspects the washer probes.

Weekly system-defined activities	Notes
CH Weekly Maintenance	The analyzer automatically performs cuvette, probe, and mixer cleaning, autocheck, and reaction ring bath drain and refill weekly.
Checking the Lamp Coolant	The operator manually inspects the lamp coolant level.

Monthly system-defined activities	Notes
Cleaning the CH Fan Filter	The operator manually cleans the fan filters.
Inspecting and Cleaning the Probe Wash Stations	The operator manually inspects and cleans the wash probe stations.
Inspecting and Cleaning the CH Probes and Mixer Impellers	The operator manually inspects and cleans the exterior of the CH probes and mixer impellers.

As Needed system-defined activities	Notes
Cleaning the CH Cuvettes	The analyzer automatically cleans dilution and reaction cuvettes as well as the washer probe 1 aspirate line.
Cleaning the Reagent Loader	The operator manually cleans the reagent loader.
Cleaning the System Fluids Drawer	The operator manually cleans the system fluids drawer.
Cleaning the Washer Probes	The operator manually cleans the washer probes.
Draining and Filling the Reaction Ring Bath	The analyzer automatically drains and refills reaction ring bath to flush debris. During this process, the software monitors the fill and drain time to assess the health of analyzer.
IMT Advanced Cleaning	The analyzer cleans the IMT system to prevent protein buildup before replacing the A-LYTE multisensor.

As Needed system-defined activities	Notes
IMT Enzyme Cleaning with IMT Cleaner	The analyzer cleans the IMT system without requiring the replacement of the A-LYTE multisensor.
IMT Routine Cleaning	The analyzer cleans the IMT system to remove salt crystals.
Refreshing the Water Bath Additive	The analyzer automatically adds water bath additive (WBA) to the reaction ring bath.
Replacing Reagent Mixer Impeller	The operator manually replaces the reagent mixer impeller.
Replacing Sample Mixer Impeller	The operator manually replaces the sample mixer impeller.
Replacing the Dilution Mixer Impeller	The operator manually replaces the dilution mixer impeller.
Replacing the Dilution Probe	The operator manually replaces the dilution probe.
Replacing the Dilution Wash Dryer Nozzle	The operator manually replaces the dilution washer dryer nozzle.
Replacing the Dilution Wash Probe 1	The operator manually replaces the dilution wash probe 1.
Replacing the Dilution Wash Probe 2	The operator manually replaces the dilution wash probe 2.
Replacing the Dilution Wash Probe 3	The operator manually replaces the dilution wash probe 3.
Replacing the Dilution Wash Dryer Probe	The operator manually replaces the dilution wash probe dryer.
Replacing the Reaction Wash Dryer Nozzle	The operator manually replaces the reaction washer dryer nozzle.
Replacing the Reaction Wash Probe 1	The operator manually replaces the reaction wash probe 1.
Replacing the Reaction Wash Probe 2	The operator manually replaces the reaction wash probe 2.

As Needed system-defined activities	Notes
Replacing the Reaction Wash Probe 3	The operator manually replaces the reaction wash probe 3.
Replacing the Reaction Wash Probe 4	The operator manually replaces the reaction wash probe 4.
Replacing the Reaction Wash Probe 5	The operator manually replaces the reaction wash probe 5.
Replacing the Reaction Wash Probe 6	The operator manually replaces the reaction wash probe 6.
Replacing the Reaction Wash Dryer Probe	The operator manually replaces the reaction wash probe dryer.
Replacing the Sample Probe	The operator manually replaces the sample probe.
Replacing the Dilution Ring Cuvette Segments	The operator manually replaces the dilution ring cuvettes every 4 months.
Replacing the CH Reaction Ring Cuvette Segments	The operator manually replaces the reaction ring cuvettes every 4 months.
Replacing the IMT Peristaltic Pump Tubing	The operator manually replaces the IMT peristaltic pump tubing every 50,000 cycles.
Replacing the Source Lamp	The operator manually replaces the source lamp based on lamp intensity.

Annual system-defined activities	Notes
CH Maintenance	The local technical support provider performs preventative maintenance once a year or every 1,200,000 cycles.
Replacing the Reagent Probe 1	The operator manually replaces the reagent probe 1.
Replacing the Reagent Probe 2	The operator manually replaces the reagent probe 2.

About CH Daily Maintenance Activity on the CH Analyzer

The CH Analyzer has an automated daily maintenance that includes cuvette, probe, mixer, and washer cleaning; an autocheck; and a reaction ring bath refresh. The analyzer performs a series of cleaning and rinsing operations to decontaminate the analyzer at configured times or on demand. This cleaning requires the water bath additive (WBA) and RPC4 reagent packs. The analyzer checks for Inprocess samples prior to the start of this daily maintenance. The analyzer waits for these samples to process and then starts the activity. The CH Analyzer pauses sample processing until the activity completes in 12–40 minutes.

The CH Autocheck completes in 11 minutes and must complete before any other maintenance activity processes.

If required, the Cleaning the CH Cuvettes has a daily cleaning time of 30 minutes. If < 4500 processed tests and <4 days since the last cuvette cleaning, the CH Daily Maintenance skips the Cleaning the CH Cuvettes which results in a daily cleaning time of 12 minutes. This activity reduces system fluids usage and prolongs component life. See About Cleaning the CH Cuvettes activity.

The Refreshing the Water Bath Additive activity completes in 2 minutes and is performed in parallel with the Cleaning the CH Cuvettes activity. If the Refreshing the Water Bath Additive activity completed by the operator within the past 24 hours, this task is skipped at the next scheduled CH Daily Maintenance.

The CH Daily Maintenance is not required on the same scheduled day the analyzer performs the CH Weekly Maintenance. If any part of this maintenance fails, the analyzer automatically repeats that maintenance.

The duration of the daily maintenance activities count down. All other activities duration count up.

Maintenance Log records and stores this activity.

To perform this activity, see Performing CH Daily Maintenance.

About Inspecting the Washer Probes Activity on the CH Analyzer

The CH Inspecting the Washer Probes activity alerts the operator or support to inspect the washer probes daily (Page 604 *Inspecting CH Wash Probes*).

The duration of the daily maintenance activities count down. All other activities duration count up.

Maintenance Log records and stores this activity.

About CH Weekly Maintenance Activity on the CH Analyzer

The CH Analyzer has an automated weekly maintenance that includes cuvette, probe, and mixer cleaning, an autocheck, and a reaction ring bath drain and refill. The analyzer performs a series of cleaning and rinsing operations to decontaminate the analyzer at configured times or on demand. This cleaning requires the water bath additive (WBA) and RPC4 reagent packs.

The analyzer checks for Inprocess samples prior to the start of this weekly maintenance. The analyzer waits for these samples to process and then starts the activity. The CH Analyzer pauses sample processing until the activity completes in 65 minutes.

The CH Daily Maintenance is not required on the same scheduled day the analyzer performs the CH Weekly Maintenance.

Maintenance Log records and stores this activity.

About Checking the Lamp Coolant Activity on the CH Analyzer

The analyzer alerts for the operator to check the analyzer lamp coolant level weekly (Page 593 *Checking the Lamp Coolant on the CH Analyzer*).

Maintenance Log records and stores this activity.

Checking the Lamp Coolant on the CH Analyzer



BIOHAZARD

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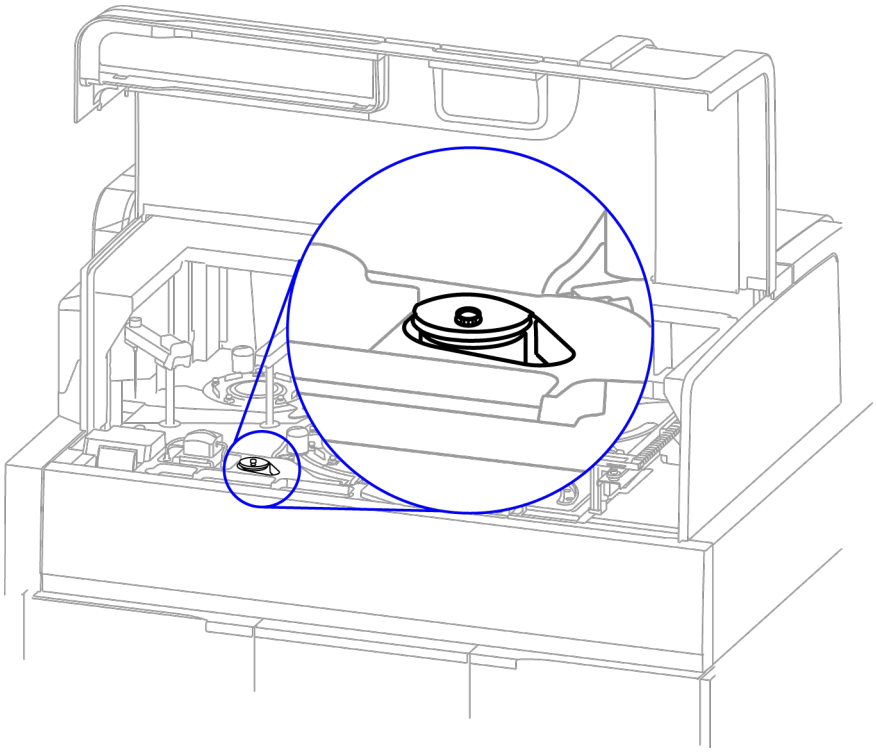
WARNING

Do not perform maintenance inside the analyzer unless the analyzer is stopped or in the diagnostic state. Analyzer subassemblies can move and cause bodily harm.

1. Enter diagnostic state (Page 704 *Enter Diagnostics State in CH Operator Diagnostics*).
2. Select **Subsystems > Lamp**.

3. Select **Checking the Lamp Coolant > Perform > Yes**.
4. Wait for the analyzer to prepare for maintenance.

   NOTE: The covers automatically unlock. If the covers lock, select **Unlock Covers**.
5. Open the CH front cover.
6. Locate the lamp coolant directly behind the IMT fluids.



7. If the lamp coolant fluid level is not visible, replenish the lamp coolant (Page 285 *Refilling Lamp Coolant on the CH Analyzer*).
8. Close the cover.
9. Select **Continue > Close**.
10. Select **Exit Diagnostics > Yes**.
11. Mark **Checking the Lamp Coolant** as completed (Page 556 *Marking Completed Manual Maintenance Activities*).

    NOTE: The analyzer logs the Checking the Lamp Coolant activity as completed in Maintenance Log.
12. If appropriate, order a replacement catalog number (Page 888 *CH Supplies*).

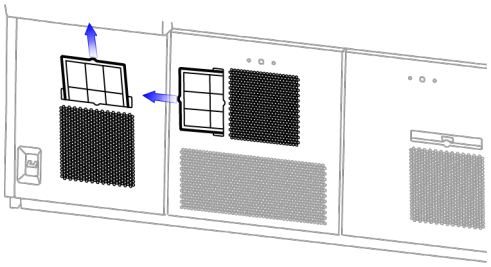
Cleaning the CH Fan Filter on the CH Analyzer

The CH Analyzer has 1 filter located inside the left front door and 2 filters on the back right and center panels.

NOTE: The operator can edit the frequency for weekly, monthly, as needed, and count activities. Daily activities frequency cannot be modified.

NOTE: The customer parts kit includes spare fan filters. Use a spare filter while the cleaned filter dries. Once dry, place the cleaned filter in the customer parts kit for future use.

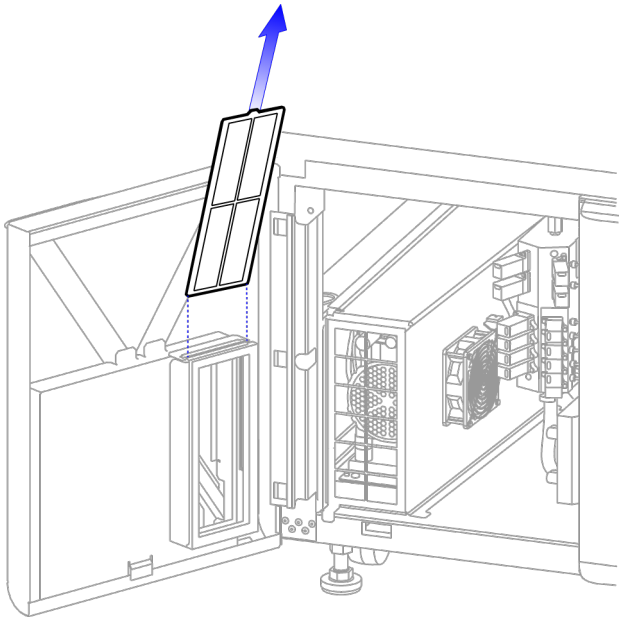
1. To remove and clean the back panel fan filters:



   a. Locate the 2 fan filters on the back panels.
   b. Grasp the top or side of each fan filter and pull it out of the slot.
   c. Inspect and discard damaged filters.
   d. Rinse the filter with tap water.
   e. Tap the filter to remove excess water and let it air dry.
   f. Repeat steps b–e for the remaining filter.

NOTE: The customer parts kit includes spare fan filters. Use a spare filter while the cleaned filter dries. Once dry, place the cleaned filter in the customer parts kit for future use.

2. To remove and clean the fan filter in the front left door:



   a. Locate the fan filter on the analyzer front left door.
   b. Grasp the top of the fan filter and pull up and out of the slot.
   c. Inspect and discard damaged filters.
   d. Rinse the filter with tap water.
   e. Tap the filter to remove excess water and let it air dry.
3. Reinstall a spare fan filter with the plastic grid facing away from the panel or door.
4. Mark Cleaning the CH Fan Filter as completed (Page 556 *Marking Completed Manual Maintenance Activities*).

   NOTE: Maintenance Log records and stores this activity.
5. If original filter discarded, order a replacement filter (Page 888 *CH Supplies*).

About IMT Routine Cleaning Activity on the CH Analyzer

IMT Routine Cleaning is a manual procedure that cleans the IMT in 4 minutes on an as-needed basis.

NOTE: The system automatically performs IMT Routine Cleaning as part of IMT Daily Cleaning. The operator can also perform it manually as needed.

Maintenance Log records and stores this activity.

About IM Maintenance Activities

All maintenance activities display in Maintenance Log. The IM Analyzer contains system-defined automated and manual maintenance activities. In Maintenance Log the operator can access online help for a selected manual maintenance activity.

Daily system-defined activities	Notes
IM Daily Maintenance	The system automatically cleans reagent probes and wash block water lines daily.
IM Autocheck	The system automatically performs autocheck.

Weekly system-defined activities	Notes
IM Weekly Maintenance	The system automatically cleans reagent probes and wash block water and wash lines weekly.
Cleaning the Exterior of the Reagent Probes	The operator manually cleans the exterior of the reagent probe.
Inspecting and Emptying the IM Water Trap	The operator manually inspects the IM water trap and removes condensation.
Inspecting and Emptying the IM Dryer	The operator manually inspects the IM dryer and removes condensation.

Monthly system-defined activities	Notes
Cleaning the Exterior of the Aspirate Probes	The operator manually cleans the exterior of the aspirate probes monthly to remove residue.
Cleaning the IM Fan Filter	The operator manually inspects and cleans the IM fan filter.

As Needed system-defined activities	Notes
Cleaning the Cuvette Waste Area	The operator manually removes liners and cleans the waste bins.
Cleaning the Reagent Drawer	The operator manually cleans the reagent drawer to remove residue.
Cleaning the Reagent Probe Rinse Stations	The operator manually cleans the reagent probe rinse stations to remove residue.
Cleaning the Sample Tip Waste Area	The operator manually removes liners and cleans the waste bins.
Cleaning the System Fluids Drawer	The operator manually cleans the system fluids drawer to remove residue.
Cleaning the Waste Probe and the Cuvette Ejector Rod	The operator removes the waste probe from the luminometer and performs a manual cleaning.
Cleaning the IM Primary Waste Reservoir	The system cleans and rinses the IM primary waste reservoir.
Replacing the Reagent Probe 1	The operator manually replaces reagent probe 1.
Replacing the Reagent Probe 2	The operator manually replaces reagent probe 2.
Replacing the Reagent Probe 3	The operator manually replaces reagent probe 3.
Replacing the Aspirate Probe 1	The operator manually replaces aspirate probe 1.
Replacing the Aspirate Probe 2	The operator manually replaces aspirate probe 2.
Replacing the Aspirate Probe 3	The operator manually replaces aspirate probe 3.
Replacing the Aspirate Probe 4	The operator manually replaces aspirate probe 4.

Annually system-defined activities	Notes
IM Maintenance	The local technical support provider performs preventative maintenance once a year or every 200,000 cycles.

About Daily Maintenance on the IM Analyzer

IM Daily Maintenance contains automated maintenance activities. The analyzer performs a series of cleaning and rinsing operations to decontaminate the analyzer at configured times or on demand. The operator configures the schedule.

The analyzer checks for Inprocess samples prior to the start of this daily maintenance. The analyzer waits for these samples to process and then starts the activity. The IM Analyzer pauses sample processing until the activity completes in 23–66 minutes. The duration of this activity is based on the configuration of the wash cycle.

Service wash cycle configuration	Duration in minutes
Standard	23
Additional Short Washes	33
Additional Long Washes	37
Enhanced Maintenance	66

The IM Daily Maintenance is not required on the same scheduled day the analyzer performs the IM Weekly Maintenance. If any part of this maintenance fails, the analyzer automatically repeats that maintenance.

The duration of the daily maintenance activities count down. All other activities duration count up.

Maintenance Log records and stores this activity.

About IM Autocheck

IM Autocheck performs a self diagnostics maintenance when the operator selects it. The IM Analyzer pauses sample processing until the autocheck completes in ≤10 minutes. The system automatically performs the autocheck daily at a specified time. The system alerts the operator 15 minutes before the scheduled activity begins.

The duration of the daily maintenance activities count down. All other activities duration count up.

Maintenance Log records and stores this activity.

About Weekly Maintenance on the IM Analyzer

The IM Analyzer has automated weekly maintenance that includes reagent, wash block, and wash lines cleaning. The analyzer performs a series of cleaning and rinsing operations to decontaminate the analyzer at configured times or on demand.

The analyzer checks for Inprocess samples prior to the start of this daily maintenance. The analyzer waits for these samples to process and then starts the activity. The IM Analyzer pauses sample processing until the activity completes in 32–75 minutes. The duration of this activity is based on the configuration of the wash cycle.

Service wash cycle configuration	Duration in minutes
Standard	32
Additional Short Washes	42
Additional Long Washes	46
Enhanced Maintenance	75

Maintenance Log records and stores this activity.

Cleaning the Exterior of the Reagent Probes on the IM Analyzer



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.



WARNING

Do not touch the probe tip when working with the probes. The probe tip is sharp and can cause bodily harm.



WARNING

Do not handle cleaner solution without wearing protective equipment, including gloves, laboratory coat, and safety glasses or a protective face shield. Cleaner solution can cause eye and skin irritation.

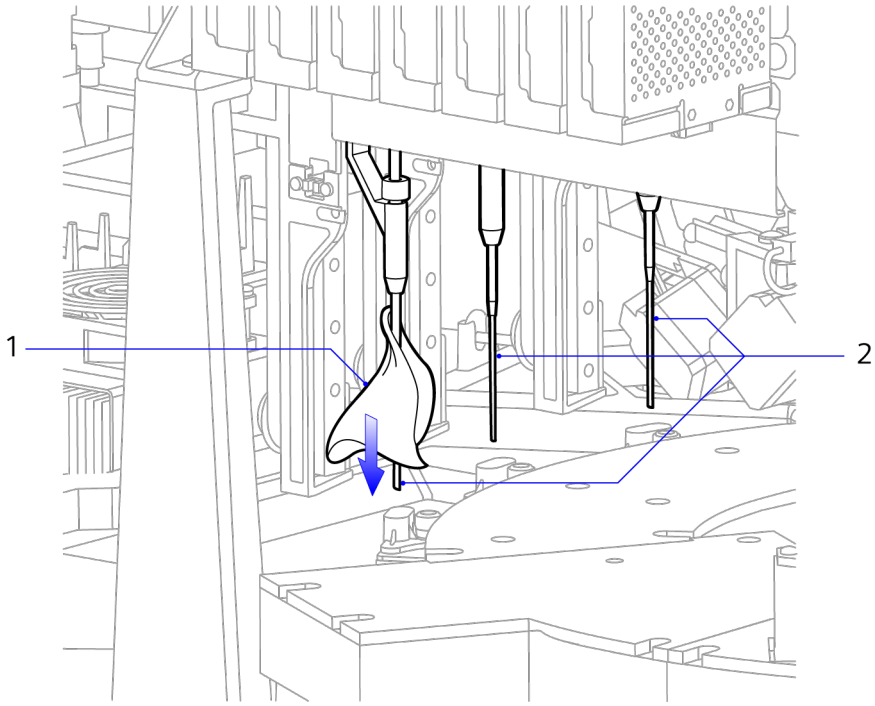


CAUTION

Do not bend the probe. Bending the probe can cause short aspirations and carryover leading to erroneous results.

Clean the exterior of the IM reagent probes weekly.

1. Unlock and open the IM Analyzer back cover (Page 98 *Locking or Unlocking Analyzer Covers*).
2. Without removing the probe, clean the visible portion of the probe using lint-free tissues or gauze dampened with IM Cleaner, in a gentle downward motion.



1	Tissue or gauze
2	Reagent probe

3. Using a lint-free tissue dampened with special reagent water, wipe each probe using a gentle downward motion.
4. Repeat step three 3–5 times with clean lint-free tissues or gauze.
5. Repeat with the remaining probes.
6. Close the cover.
7. To resume the analyzer, select the appropriate IM Analyzer in the System Status area and then select ▶.
8. Mark Cleaning the Exterior of the Reagent Probes as completed (Page 556 *Marking Completed Manual Maintenance Activities*).

   NOTE: Maintenance Log records and stores this activity.

About IM Monthly Maintenance

IM Monthly Maintenance is a manual maintenance activity.

About DL Maintenance Activities

All maintenance activities display in Schedule. The Direct Load (DL) module contains a system-defined automated maintenance activity.

Daily system-defined activities	Notes
DL Autocheck	Measures the DL motor backlash and performs a connectivity test.

Monthly system-defined activities	Notes
Cleaning the DL Fan Filter	The operator manually cleans the fan filters.

About DL Autocheck

The daily automated DL Autocheck maintenance activity ensures all components of the DL are connected and reports the health of the DL drive systems to service personnel. The analyzer alerts the operator 15 minutes before the scheduled activity begins. Once the analyzer initiates the DL autocheck, the DL processes all loaded racks. The DL stops and no additional racks process until autocheck completes.

The DL Autocheck:

- Measures the DL motor backlash for the positioner drives and amount of play in the shuttle.
- Completes a connectivity test to verify that all the motors, sensors, and solenoids report to the module.
- Checks database integrity.
- Completes in 2.6 minutes.

The duration of the daily maintenance activities count down. All other activities duration count up.

Maintenance Log records and stores this activity.

About Cleaning the DL Fan Filter Activity

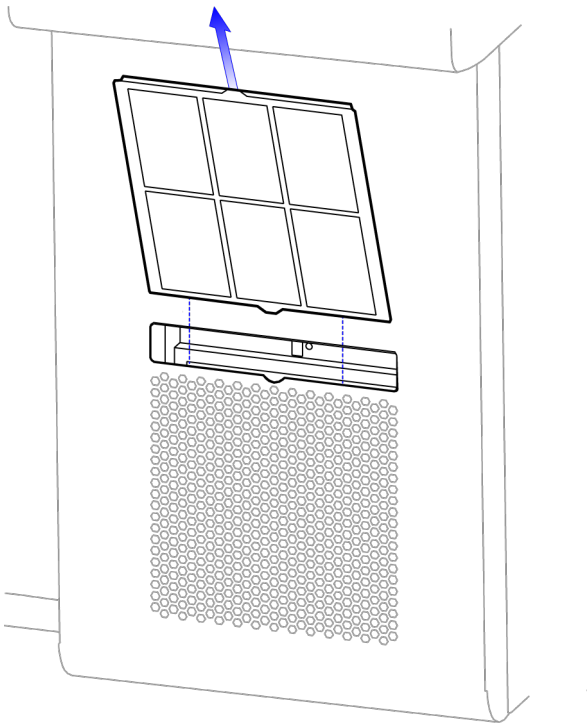
Cleaning the DL Fan Filter alerts the operator or support to clean and inspect the fan filter monthly to ensure it is free from dust, dirt, or debris.

To clean the fan filter, see (Page 603 *Cleaning the DL Fan Filter*).

Maintenance Log records and stores this activity.

Cleaning the DL Fan Filter

1. Locate the fan filter on the back DL panel.



2. Grasp the top of the fan filter and pull it up and out of the slot.
3. Inspect and discard damaged filters.
4. Rinse the filter with tap water.
5. Tap the filter to remove excess water and let it air dry.

   NOTE: The customer parts kit includes spare fan filters. Use a spare filter while the cleaned filter dries. When dry, place the cleaned filter in the customer parts kit for future use.
6. Reinstall a spare fan filter with the plastic grid facing away from the module.
7. Mark **Cleaning the DL Fan Filter** as completed (Page 556 *Marking Completed Manual Maintenance Activities*).

   NOTE: Maintenance Log records and stores this activity.
8. If original filter discarded, order a replacement filter (Page 893 *DL Supplies*).

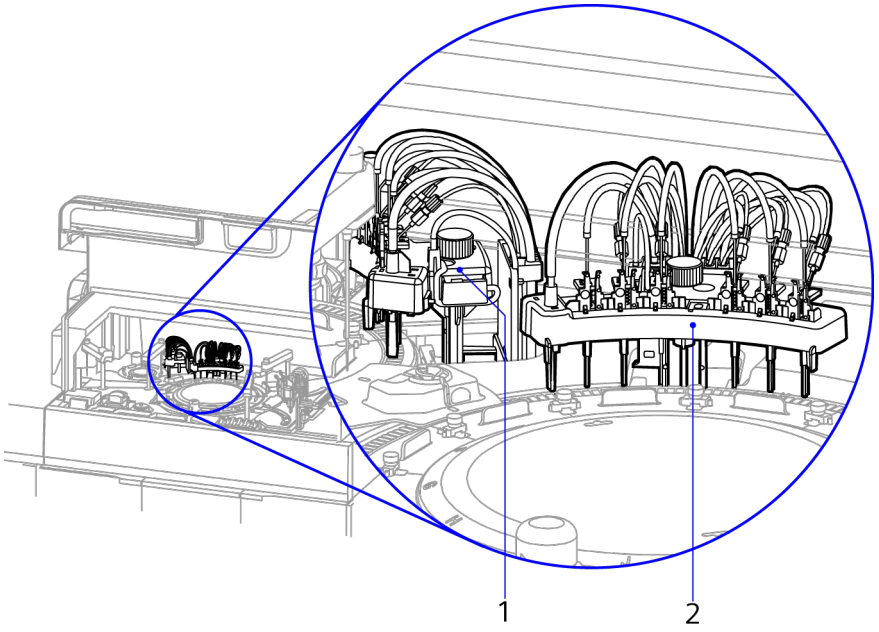
Inspecting CH Wash Probes

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling biohazardous materials can cause bodily harm.

1. Enter diagnostic state (Page 704 *Enter Diagnostics State in CH Operator Diagnostics*).
2. Select **Subsystems > Inspect and Clean**.
3. Select **Inspecting the Washer Probes**.
4. Select **Perform > Yes**
5. Wait for the analyzer to prepare for maintenance.

   NOTE: The covers automatically unlock. If the covers lock, select **Unlock Covers**.
6. Open the CH back cover (Page 98 *Locking or Unlocking Analyzer Covers*).
7. Check the outside of each wash probe for residue buildup.



1	Dilution wash probe assembly (D-CW)
2	Reaction wash probe assembly (R-CW)

8. If residue buildup is present on the wash probe, clean the probe.
9. Close the back cover.

10. Select **Continue > Close**.
11. Select **Exit Diagnostics > Yes**.
12. Mark Inspecting the Washer Probes as completed (Page 556 *Marking Completed Manual Maintenance Activities*):

    NOTE: Maintenance Log records and stores this activity.
13. If appropriate, order a replacement catalog number (Page 888 *CH Supplies*).

Cleaning the System



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

The system and surrounding areas should be kept clean based on guidelines set forth by the US Department of Labor (OSHA) 29 CFR 1910.1030, Occupational Exposure to Blood Borne Pathogens: Final Rule.

Clean up spills immediately.

Routinely clean the outside surfaces of the entire system using a lint-free cloth dampened with 10% bleach solution (Page 605 *Preparing 10% Bleach Cleaning Solution*).

Preparing 10% Bleach Cleaning Solution



WARNING

Do not handle cleaner solution without wearing protective equipment, including gloves, laboratory coat, and safety glasses or a protective face shield. Cleaner solution can cause eye and skin irritation.

A 10% bleach solution used for cleaning should be made by diluting bleach with water. All bleach solutions should be freshly prepared prior to use.

1. Ensure bleach meets the following criteria:
   - 5–12% sodium hypochlorite
   - No additives, detergents, surfactants, or fragrances
2. Combine 10 mL of undiluted bleach with 90 mL of deionized water to prepare 100 mL of a 10% bleach solution.

About Maintenance Review and Approve

This task requires the appropriate security level.

Lab Manager (G1 security account level) is required in Maintenance Review and Approve. A mandatory comment is required for any activities with the status of Not Performed.

Review and Approve includes 3 completed months and the partial current month of maintenance activities, 1 month at a time. These activities include completed, performed successfully, or not performed statuses. The default view is the current month. The current month cannot be approved until month has ended.

From this report, the operator:

- Evaluates to ensure all required maintenance for the month is completed.
- Maintenance performed today displays on the report the following day.
- Adds comments to only Not Performed activities such as why it was not completed.
- Generates an internal or external report. The laboratory prints or exports an external report for presentation to inspection agencies.
- If the activity is completed or marked as complete on a day other than the scheduled day, the  is on the scheduled date. The Status displays the date and time when the maintenance was performed.
- Approves the displayed month with the appropriate security level. The current month and a month with 1 or more Not Performed activities cannot be approved.

The report is grouped by module and frequency. Activities common to the system display before specific module activities. Each module's maintenance activities display within their frequency type before the next module's maintenance activities display.

Maintenance Review and Approve	Notes
Module	Module name. Activities separated by Module and Frequency.
Activity	Activity separated by Frequency and icon.
Approval Status	Status includes: • Activities awaiting approval • The date, time, and operator displays when approved

Maintenance Review and Approve	Notes
Approve	The appropriate operator security level approves maintenance displaying.
Activities Not Completed ({0})	The system displays activities not completed from today followed by each day in past. The operator selects an activity and Maintenance Activity Details opens. The operator adds comments for reason activity was not completed.

About Printing Maintenance Activities Reports

The following Maintenance reports are available:

- Maintenance Overview: Upcoming maintenance activities for the selected period.
- All Activities: All the activities for all the modules when they last completed regardless of the schedule frequency.
- Review and Approve: Historical completion in a month view with any exceptions. The operator selects calendar only, calendar with exceptions, or calendar with exceptions and completions. The calendar with exceptions and completions is the default. The optimal report is the calendar with exceptions that includes Completed and Not Performed with Comment.
- Maintenance Log: A report that includes Completed or Failed activities for that time period.
- Maintenance Configuration Schedule: Hourly view to evaluate the overlapping and uptime planning for each module with Daily, Weekly, and Monthly overlap.
- Maintenance Configuration Maintenance Activities: Displays the summary of the scheduled configuration for every maintenance activity.

To print a Maintenance report, navigate to the appropriate area.

About Maintenance Log

The Maintenance Log displays a record of the most recently performed maintenance activities to a maximum of 100,000 entries or the life of the system with up to 14 modules under intended and scheduled maintenance. When the log reaches maximum capacity, the analyzer stores the maintenance log and deletes oldest entries.

The operator adds comments to only Not Performed activities.

Maintenance Log	Notes
Activity	The name of the maintenance activity and up to 3 lines of activity information.
Module	If a maintenance activity is specific to a module, the name of the module displays. If the activity applies to the entire system, "System" displays.
Status icon*	The corresponding Status icon displays to the left of the Status.
Status*	• Completed activity (✔). • Failed activity that requires completion (⚠). • Not Performed activity (✖). • Not Performed with Comment (✖💬). Activities with Failed and Not Performed with Comment statuses include an expandable row to include the details of the failure or comment.
Operator	The name of the operator performing the following activity: • For a manual activity, the operator who selects Mark as Completed. • For an automated activity that an operator initiates, the log displays the operator's sign in ID. • For an automated activity initiated by the analyzer, "System" displays.
Start Date	For automated activities, the log displays the date the activity started and, when applicable, the current analyzer cycle count. For manual activities based on cycle, time, or count, the column displays blank when the operator selects **Mark as Completed**.
End Date	For automated activities, the column displays the date the activity ended. For manual activities, the column displays the date and time the operator selects **Mark as Completed**.

Maintenance Log	Notes
Scheduled Date	This column displays the scheduled date and time or cycle count the module performs the activity.
Cycle	The current cycle count when the operator selects **Mark as Completed**.
REF*	A Part Number icon displays when an operator has added a part number.

* Indicates columns containing symbols to indicate the setting. To see the text definition, select the symbol.

Reviewing the Maintenance Log

1. Navigate to **Maintenance Log**.
2. If appropriate, filter the log.

About Maintenance Part Number

Store hardware part numbers for traceability in **Maintenance Log**.

About Exporting Maintenance Log

The operator exports maintenance logs in Maintenance Log.

Maintenance Log Export	Notes
File Name	The selected maintenance activity file name.
File Type	The selected file type the log exports: Text (tab delimited) (*.txt) or XML Data (*.xml).
Location	The selected maintenance log saves to this location.
Browse	The function to look for the location. **NOTE:** To store files off-system within the system security protocols and certificates, set the path to **F: > USERROOT > FTP > Export**. The files securely transfer to the laboratory FTP server. These files then route to the desired location according to the IT administrator.
Export	The function to execute the export.
Cancel	The function to cancel the request.

Maintenance Log records and stores this activity.

Exporting Maintenance Log Data

1. Navigate to **Maintenance Log**.
2. Select the appropriate filter settings to identify the log data to export.
3. Select the log data to export:
   a. To export the entire Maintenance Log, remove all filters.
   b. To export specific Log data, select the filter criteria.
4. Select **Export**.
5. Select a File Type.
6. Select a storage location.

   NOTE: If the storage location is different than the analyzer default, enter the location or select **Browse** for a location.

   NOTE: To store files off-system within the system security protocols and certificates, set the path to **F: > USERROOT > FTP > Export**. The files securely transfer to the laboratory FTP server. These files then route to the appropriate location according to the IT administrator.
7. Select **Export**.
8. When export completes, select **OK**.

About IMT Dilution Check Activity

The IMT Dilution Check is performed to calibrate and verify the system dilution ratio delivered by the dilution arm on the IMT system. The operator performs the IMT Dilution Check:

- When troubleshooting a consistent shift in QC recovery.
- After parts replaced on IMT system or dilution probe.
- During annual CH Maintenance that the local technical support provider performs.

On a new installation, the correction factor must be applied to establish a baseline correction factor.

IMT Dilution Check is located within Maintenance IMT.

IMT Dilution Check parameters	Accepted criteria
SD for Na	<1.40
SD for K	<0.040
Na/K relative % bias	<3.00%

IMT Dilution Check parameters	Accepted criteria
% Bias	<1.00%
Correctable range or correction factor range	±5% (0.95–1.05)

When an IMT Dilution Check completes, the operator reviews the IMT Dilution Check Status and Recommendation then applies the correction factor, if appropriate.

An unacceptable IMT Dilution Check generates a failed status or a recommendation to apply the new correction factor. A dilution check fails if 1 of the following is true:

- The bias is >1.00%.
- The standard deviation (SD) for Na is >1.40, and for K is >0.040.
- The Na/K relative bias is >3.00%.
- The IMT Dilution Check did not completely process.

Na/K relative % bias is the difference between Na and K means, in comparison to the container values (Na 1.00% high and K 1.00% low yields a 2.00% relative bias). The relative % bias displays in IMT Dilution Check. The Na/K relative bias is flagged in the bias field as a failure even if the % bias is less than 1.00%.

% Bias is the average bias between the Na and K mean compared to the Na and K assigned value.

The correctable range is the limit that correction factor can be adjusted (0.95–1.05).

Performing IMT Dilution Check on the CH Analyzer

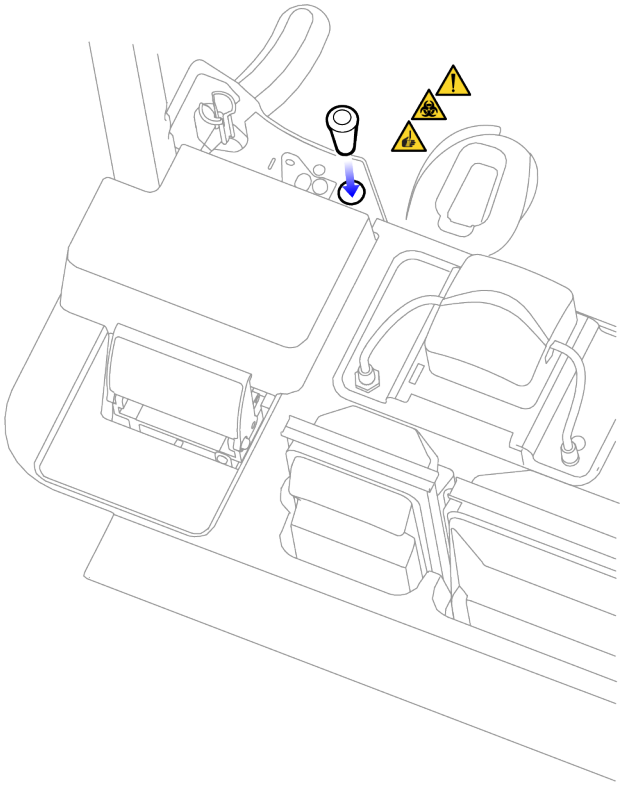
BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

1. Navigate to **Troubleshooting > Operator Diagnostics**.
2. Open CH front cover.
3. Fill a 1 mL tube-top sample cup with 500–750 µL IMT dilution check.

   NOTE: The IMT dilution check must be performed within 15 minutes of opening the ampule.

4. Place the tube-top sample cup in the dilution check position behind the IMT multisensor.



5. Close the cover.
6. Select **Subsystems > IMT > IMT Dilution Check**.
7. Select **Perform > Yes**.
8. Wait for dilution check to complete.
9. When an IMT Dilution Check completes, review the IMT Dilution Check Status and Recommendation.

10. To perform another IMT Dilution Check if it fails:
    a. Unlock and open CH front cover (Page 98 *Locking or Unlocking Analyzer Covers*).
    b. Remove and dispose of the dilution check sample cup according to laboratory protocol.
    c. Fill a new 1 mL tube-top sample cup with 500–750 µL IMT dilution check.
    d. Place the tube-top sample cup in the dilution check position behind the IMT multisensor.
    e. Close the cover.
    f. Select **Ignore and Perform**.

    NOTE:

    An unacceptable IMT Dilution Check generates a failed status. A dilution check fails if 1 of the following is true:

    – The% Bias is >1.00%.
    – The standard deviation (SD) for Na is >1.40, and for K is >0.040.
    – The Na/K Relative % Bias is >3.00%.
    – The IMT Dilution Check did not completely process.

    Apply Correction is disabled when an SD error occurs, an Na/K Relative % Bias error occurs, or if the % Bias is >5.00%.
11. To apply the correction, select **Apply Correction**.
12. Unlock and open CH front cover (Page 98 *Locking or Unlocking Analyzer Covers*).
13. Remove and dispose of the dilution check sample cup according to laboratory protocol.
14. To resume the analyzer, select the appropriate analyzer from the System Status area and select ▶.
15. Review the report for the acceptance criteria. For more information, see About IMT Dilution Check (Page 610 *About IMT Dilution Check Activity*).
16. If the results are outside the acceptance criteria, check Resolving Failed IMT Dilution in online help to troubleshoot.

Restoring Databases

1. Ensure all modules are Stopped (Page 137 *Changing the Module Status*).
2. Navigate to **Utilities > Data Restore**.

3. In Perform Data Restore, select **All Modules** or 1 or more Selected Modules.
4. If appropriate, select data to be excluded in Exclude from Restore.
5. In Select Database Backup, select **Browse** to choose a different Path, if appropriate.
6. In Date and Time, select the database to restore
7. Select **Restore > Yes**.
8. Wait for the system to complete the restore.
9. Select **OK**.

About Software and Online Help Updates

Software Updates in System Configuration provides access to the online help and system software updates. All available software and online help update packages display in a panel, with the most recent update packages at the top of the list.

NOTE: Atellica® Solution can download software and online help updates through Smart Remote Services (SRS). The system displays an alert when a new software update is available through SRS.

Install Manager Icons

Icons alert the operator to information or a required action. Hovering over an icon displays additional information.

Icons	Notes
	A new software package is available.
	The software package installation is in progress on the system or module.
	The software package installation succeeded on 1 or more modules but failed in other modules.
	The software package installation was successful.
	The pre-installation steps failed.

Icons	Notes
	The software package installation failed on the system or a module.
	The system or module is connected.
	System connection is in progress, busy or unknown.
	A module is disconnected.
	Software installation packages copied successfully.
	The software package installation progress status with expected time to complete.

About Copy Configuration

The operator can copy system configuration settings, such as maintenance schedules, from 1 system and apply them to another system of the same type and configuration using the same software version.

Copy Configuration is in Utilities.

When performing Export Configuration, the system exports all configuration settings.

Importing configuration settings copied from another system overwrites those configuration settings on the current system.

After applying the copied configuration, the operator must sign in again.

NOTE:

Perform a Data Reset before importing the following configuration settings:

- Test Definitions, Assay List, Ranges, Repeat Conditions, Reflex Group Setup, and Test Display Order
- Ratios, Panels, and Off-System
- QC Definitions, QC Profiles and QC Schedules

Copy Configuration	Notes
Export or Import	Section for which configuration settings to export or import.
Export configuration settings	Section for exporting current system configuration settings.
Export Configuration	• System Serial Number: Serial number of the current system. • System Name: Name of the current system.
Export Configuration button	Button that exports the current system configuration settings: • Filename: Zipped filename. • Location: Where the zipped files is exported. • Password: Protects exported file with a password.
Import Configuration Settings	Lists All or individual files.
Import Configuration	Section for importing system configuration settings and button that imports selected configuration settings: • Browse: Button that browses for configuration settings to import. • System Serial Number: Name of the system from which the operator copies the configuration settings. • System Name: Name of the current system.
Import Configuration button	Button that imports selected system configuration settings.
Reset	The system clears Import Configuration Settings.

Exporting Configuration Settings

1. Navigate to **Utilities > Copy Configuration**.
2. Select **Export configuration settings**.

   NOTE: The system exports all configuration settings.
3. Select **Export Configuration**.
4. Browse and select location of the exported system configuration file.

   NOTE: The location cannot be on the same disk as the system files.

   NOTE: To store files off-system within the system security protocols and certificates, set the path to **F: > USERROOT > FTP > Export**. The files securely transfer to the laboratory FTP server. These files then route to the appropriate location according to the IT administrator.
5. Create a password for the exported file.

   NOTE: Password must contain 6–20 characters that includes letters, numbers, and special characters ($, #, and %) with no spaces.
6. Select **Save**.
7. When a copy of configuration settings saves, select **OK**.

Importing Configuration Settings

NOTE:

Perform a Data Reset before importing the following configuration settings:

- Test Definitions, Assay List, Ranges, Repeat Conditions, Reflex Group Setup, and Test Display Order
- Ratios, Panels, and Off-System
- QC Definitions, QC Profiles and QC Schedules

1. Navigate to **Utilities > Copy Configuration**.
2. Select **Import Configuration Settings**.
3. Select **All** or the appropriate files to import.
4. In Import Configuration, select **Browse**.
5. Navigate to the folder where the operator saves the exported configuration settings.
6. Enter the password for the exported configuration settings file.
7. Select **OK**.
8. Select **Import Configuration**.

18 Troubleshooting

Troubleshooting

This chapter provides information about identifying and correcting system problems.

About Troubleshooting the Events

This feature requires the appropriate security level.

The operator uses the ? in each event entry on the Operator Event Log to launch the Online Help and access the procedures to resolve the event.

NOTE: The Online Help contains troubleshooting help for every event that occurs on the system.

The procedures for resolving the event are in the form of a table that includes possible causes of the event and any actions that the operator must perform to resolve the cause. The Online Help lists each event and its troubleshooting table according to the 9-digit numerical code associated with the event.

Each troubleshooting table contains the following information:

Troubleshooting table	Notes
Possible Causes	One or more possible reasons for the event.
Corrective Action	A short statement of the actions that the operator must perform to resolve the given possible cause for the event. For complex actions, the corrective action includes a link that describes each step in detail that the operator must perform.

Each possible cause may require multiple corrective actions. The operator must perform the corrective actions in the order listed.

NOTE: If more than 1 possible cause is present, the table typically lists the easiest cause to correct first. The operator can perform the troubleshooting of the causes in any order. In some cases, the operator may need to perform the corrective actions for every cause before successfully resolving the event.

Accessing Troubleshooting Help for Operator Events

This task requires the appropriate security level.

1. Navigate to **Operator Event Log**.
2. If appropriate, select  in the text box for any applied Filter.

   NOTE: This action clears the Filter.
3. To view a subset of the events, use the Filter.
4. If appropriate, select  to collapse the Filter.

   NOTE: Some attributes are only visible if the Filter is collapsed.
5. Select the appropriate event:
   - Enter the appropriate alphanumeric characters in the text box to Search Filtered Data.
   - Select the appropriate page navigation tool to move through the Operator Event Log.
6. View the Additional Details about the event.
7. To add a Comment:
   a. Select  .
   b. Enter the appropriate text in the text boxes.

      NOTE: The system allows up to 3 comments on each event.
   c. Select **OK**.
8. To edit a Comment:
   a. Select  .
   b. Select **Edit**.
   c. Type over the text in the appropriate Comment.
   d. Select **OK**.
9. To view the troubleshooting help for the event, select  .
10. If appropriate, perform the corrective actions to resolve the event.

Completing Corrective Action Events

1. Navigate to **Troubleshooting > Operator Event Log**.
2. Select the appropriate Event.
3. To add a comment to the event:
   a. Select .
   b. Enter the appropriate comment.
   c. Select **Save**.

   NOTE: The updates to once a comment is entered.

Adding and Editing Comments to Operator Events

This task requires the appropriate security level.

1. Navigate to **Operator Event Log**.
2. If appropriate, select in the text box for the Filter to clear the Filter.
3. To view a subset of the events, use the Filter.
4. If appropriate, select to collapse the Filter.

   NOTE: Some attributes are only visible if the Filter is collapsed.
5. To select an event, use the following features:
   – Use the text box to Search Filtered Data.
   – Use the page navigation tools to move through the Operator Event Log.
6. To add a Comment:
   a. Select .
   b. Enter the appropriate text in the text boxes.

      NOTE: The system allows up to 3 comments on each event.
7. To edit an existing Comment:
   a. Select .
   b. Select **Edit**.
   c. Type over the text in the appropriate Comment.
8. Select **OK**.

About Emergency Shutdown

When the operator cannot perform a controlled shutdown and the system must power off to ensure the safety of personnel and equipment, the operator must perform an emergency shutdown.

NOTE: The operator must wait 30 seconds before restarting the system.

Shutting Down the System in an Emergency

ELECTRICAL HAZARD

Do not operate modules without a protective grounding connection that prevents electrical shock. Electrical shock can cause equipment damage and bodily harm. Use caution when working around these locations or contact a local technical support provider for more information about using a protective grounding connection and avoiding electrical shock hazards.

ELECTRICAL HAZARD

In the case of fire or electrical arcing, disconnect each module's power cord.

1. Disconnect each module's power cord.

   NOTE: If the emergency initiates from only 1 module, disconnect that module's power cord.

   This stops all motion immediately. The modules each have a UPS to provide battery backup to the Process Center Computer (PCC) and analyzer Module Managers (MM) to allow for a software shutdown when a power disruption occurs. If the operator pulls the SH Prime power cord for safety reasons, all module computers start shutting down, including the PCC computer. After 5 minutes elapse from shut down, all module computers and the PCC operating systems shut down.

2. To remove samples or calibrator and QC materials from the SH , manually unlock the SH cover (Page 678 *Unlocking SH Covers Manually*).

3. Wait 30 seconds before initiating recovery procedures (Page 622 *Recovering from a System Emergency Shut Down*).

Recovering from a System Emergency Shut Down

CAUTION

Do not leave a module's main power switch on during a power disruption. This can cause significant damage to the system when the operator restores power. When a power disruption occurs, turn off the main power switch for each module.

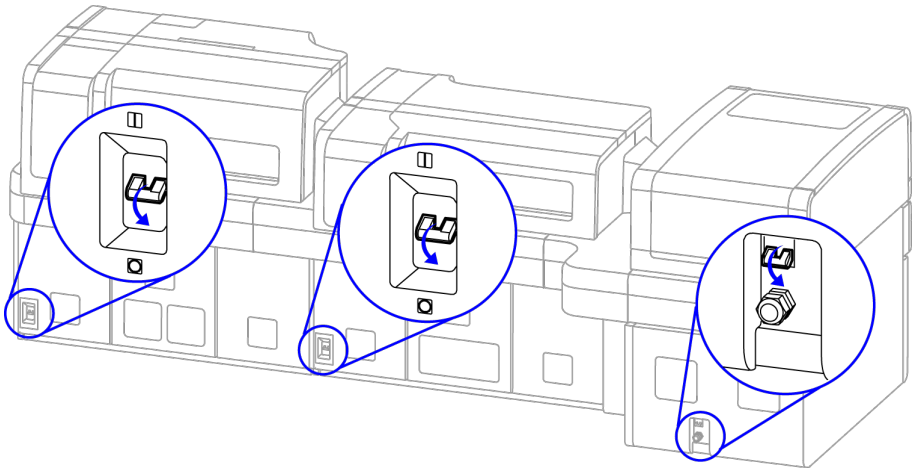
ELECTRICAL HAZARD

Do not operate modules without a protective grounding connection that prevents electrical shock. Electrical shock can cause equipment damage and bodily harm. Use caution when working around these locations or contact a local technical support provider for more information about using a protective grounding connection and avoiding electrical shock hazards.

ELECTRICAL HAZARD

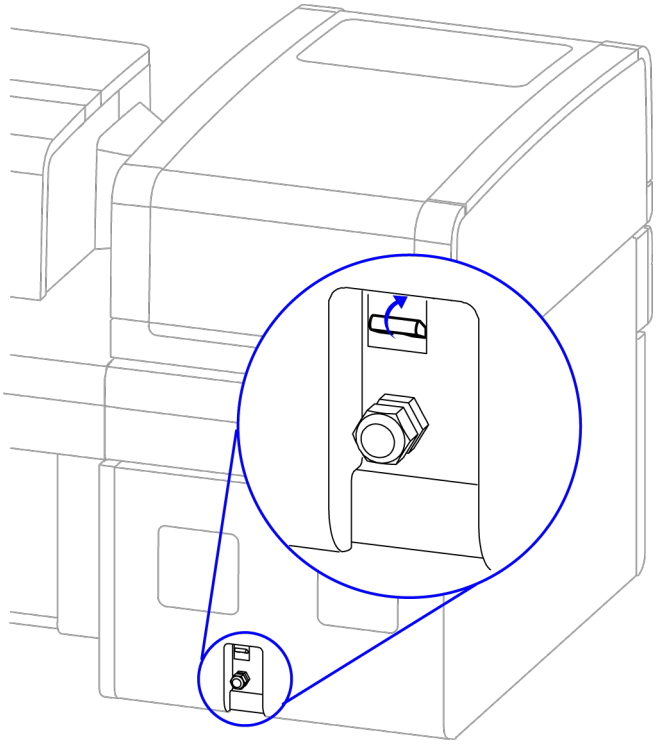
Do not plug in power cord with module power switch in on position. If the operator inserts the plug with power switch on, electrical shock may occur and cause bodily harm and equipment damage.

1. Ensure each module power switch is in the off position.



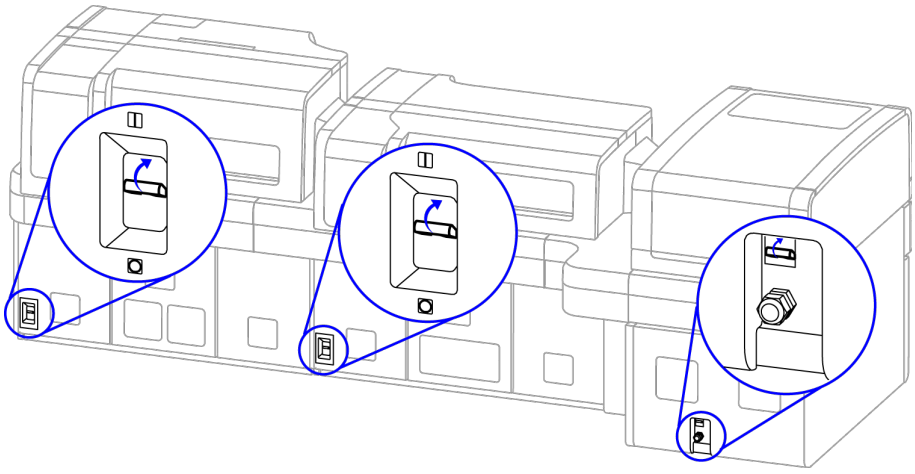
2. Ensure Atellica Magline Transport is clear (Page 625 *Clearing the Atellica Magline Transport Prior to Startup*).
3. Reconnect the module power cords to their power sources.

4. If appropriate, power on the SH Prime and wait 30 seconds before proceeding.



NOTE: The SH Prime is the SH closest to the analyzers. The SH Prime powers the PCC.

5. If appropriate, power on each SH Additional and wait 30 seconds before proceeding.
6. If appropriate, power on each module.



NOTE: Start with the module adjacent to the SH and proceed 1 by 1 to the other modules in the order they are connected.

7. After power restores to the SH Prime, if appropriate, start the SHC (Page 680 *Starting the SHC*).
8. Initialize the SH drawers and completely open and close (Page 387 *Opening Sample Drawers*).
9. Wait for the system display login screen to display.
10. Wait for each of the analyzer's module display to come up before proceeding.

    NOTE: If a module doesn't display within 5 minutes, proceed to next step.
11. Sign in (Page 643 *Signing in to the System*).
12. Confirm the contents of each SH Cal-QC storage areas.
13. Ensure all modules are in Ready or Standby state (Page 137 *Changing the Module Status*).
14. In System Status area, ensure all modules display appropriate statuses.
15. If any module status does not display or any problems occur, contact the local technical support provider.
16. If any module power is off:
    - For > 30 minutes on IM Analyzer, unload and store reagents (Page 250 *Handling IM Reagent Packs*). The analyzer must be in Ready or Standby state to unload reagents. Then manually mix primary reagents and reload all onboard reagents (Page 249 *Manually Mixing IM Reagents*).
    - For > 2 hours on CH Analyzer or IM Analyzer, discard any assay reagents remaining in the reagent compartment.
    - For calibrators or QC materials remaining in the Cal-QC storage area, refer to the calibrator and QC material IFU for stability information. If QC is out of range after the system was shut down, discard the stored QC and replace with fresh QC material.

Clearing the Atellica Magline Transport Prior to Startup

The operator must ensure the Atellica Magline Transport is clear of obstructions prior to startup. The system cannot properly initialize the Atellica Magline Transport if an obstruction blocks the diverters or the carriers are not free to move.



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.



WARNING

Do not position pacemakers or other implanted medical devices closer than 7.5 cm (3 inches) from the base of a carrier on the Atellica Magline Transport. Magnets in the carrier base generate magnetic fields that can interfere with cardiac medical implants.



CAUTION

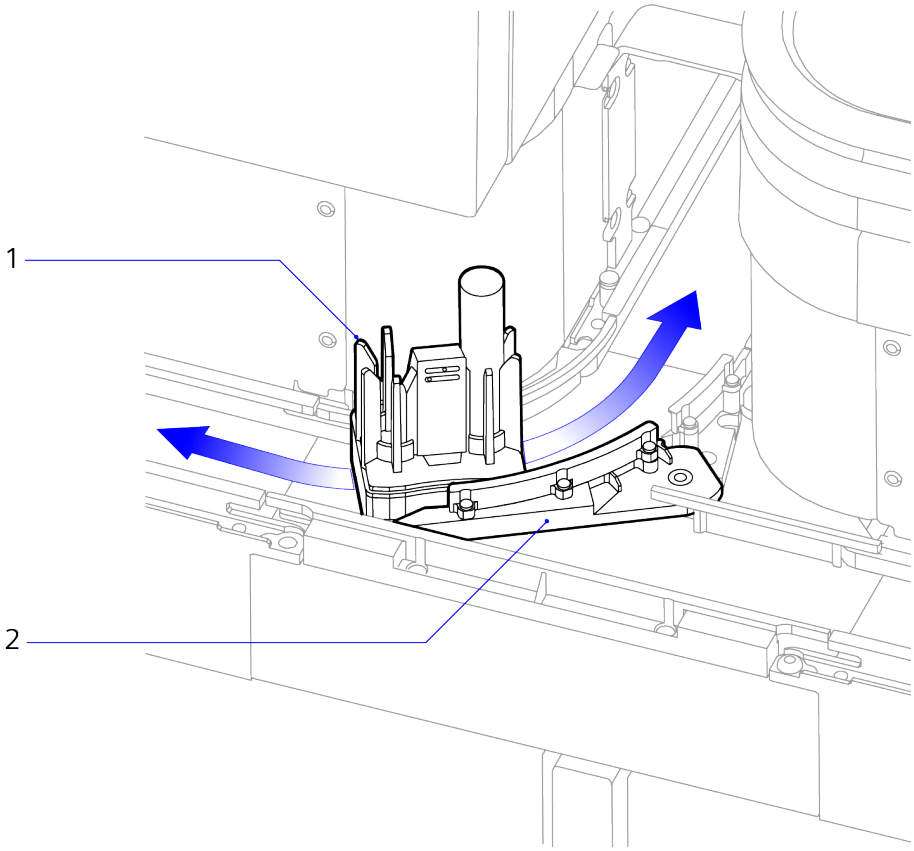
Do not remove the carriers from the Atellica Magline Transport. The carriers have strong magnets in the base and handling them in close proximity to metal objects can result in a body part being pinched between the carrier and the metal object. Only authorized service personnel should handle carriers.



CAUTION

Do not manually place sample containers in an Atellica Magline Transport carrier. Manually placing sample containers in a carrier could violate chain of custody and may result in a broken sample container.

1. Ensure no carriers are in the Atellica Magline Transport diverters:
   a. If a carrier is in the diverter, remove the appropriate Atellica Magline Transport cover (Page 631 *Installing Atellica Magline Transport Covers*).
   b. Push the carriers away from the diverters.
   c. Replace the cover (Page 631 *Installing Atellica Magline Transport Covers*).



1 Carrier
2 Diverter

> **CAUTION**
>
> Do not hold the SH robot grippers or push the robot down when moving the robot manually. Holding the grippers to move the robot may damage the crash sensor. Moving the robot down may cause the robot grippers to impact another object, possibly resulting in damage to the robot gripper or sample container breakage. Only move the robot by holding the robot body, and keep the robot grippers clear of all obstacles.

2. Ensure the SH robot gripper is clear of the Atellica Magline Transport:

a. If the SH robot gripper is blocking the Atellica Magline Transport, open the SH back cover.

   NOTE: If the SH cover remains locked, manually open (Page 678 *Unlocking SH Covers Manually*).

b. Manually raise and move the SH robot so the gripper is not over the Atellica Magline Transport.

c. Close the SH back cover.



CAUTION

Do not work or open the SHC front cover without caution. The SHC front cover is heavy and can result in injury if a body part is caught between the cover and the SHC frame.

3. Ensure the SHC robot grippers are clear of the Atellica Magline Transport:

   a. If the SHC robot grippers are blocking the Atellica Magline Transport, open the SHC cover.

      NOTE: If the SHC cover remains locked, contact the local technical support provider.

   b. Manually raise and move both SHC robots so the grippers are not over the Atellica Magline Transport.

   c. Close the SHC cover.

WARNING

Do not touch the probe tip when working with the probes. The probe tip is sharp and can cause bodily harm.

4. If the IM Analyzer sample probe is blocking the Atellica Magline Transport:
   a. Unlock and open the analyzer front cover (Page 660 *Unlocking Analyzer Covers Manually*).
   b. Manually raise and move the sample probe so it is inside the analyzer.
   c. Close the cover.

WARNING

Do not touch the probe tip when working with the probes. The probe tip is sharp and can cause bodily harm.

5. If the CH Analyzer dilution probe is blocking the Atellica Magline Transport:
   a. Unlock and open the analyzer front cover (Page 660 *Unlocking Analyzer Covers Manually*).
   b. Manually raise and move the dilution probe to its home port.
   c. Lower the probe into the port.
   d. Close the cover.

Removing Atellica Magline Transport Covers

WARNING

Do not position pacemakers or other implanted medical devices closer than 7.5 cm (3 inches) from the base of a carrier on the Atellica Magline Transport. Magnets in the carrier base generate magnetic fields that can interfere with cardiac medical implants.

CAUTION

Do not remove the carriers from the Atellica Magline Transport. The carriers have strong magnets in the base and handling them in close proximity to metal objects can result in a body part being pinched between the carrier and the metal object. Only authorized service personnel should handle carriers.

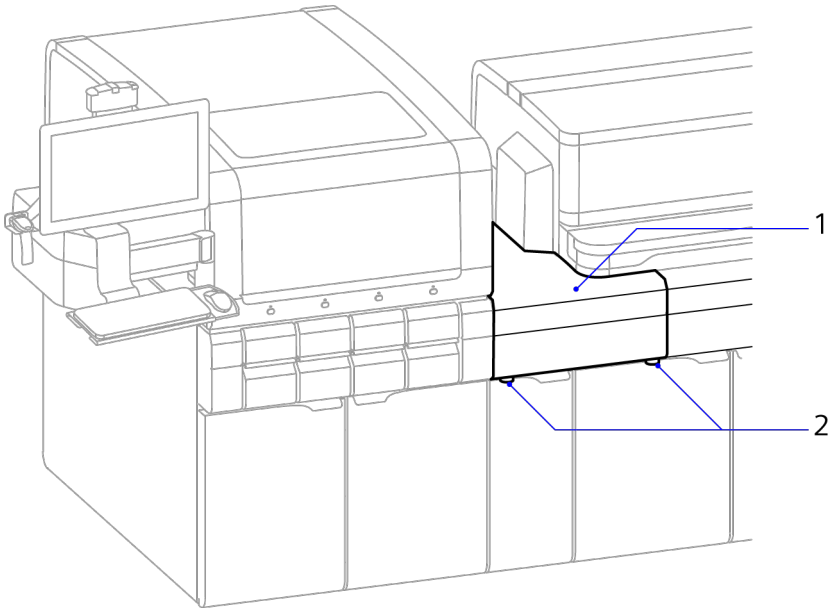
CAUTION

Do not manually place sample containers in an Atellica Magline Transport carrier. Manually placing sample containers in a carrier could violate chain of custody and may result in a broken sample container.

CAUTION

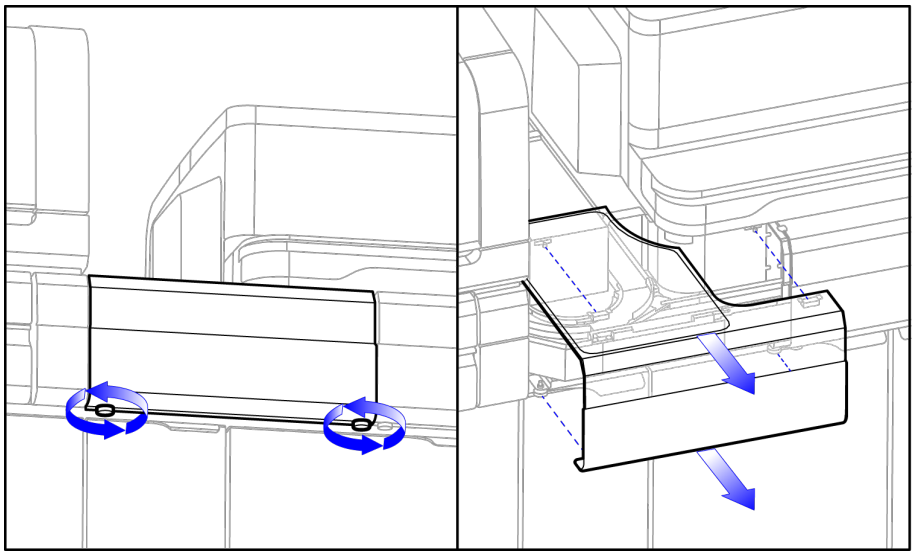
Do not work or open the SHC front cover without caution. The SHC front cover is heavy and can result in injury if a body part is caught between the cover and the SHC frame.

1. Stop the Atellica Magline Transport (Page 137 *Changing the Module Status*).
2. If removing the SHC front Atellica Magline Transport cover, open the SHC cover (Page 96 *Unlocking the SHC Cover*).
3. Locate the 2 thumbscrews under the Atellica Magline Transport cover.



1	Atellica Magline Transport cover
2	Atellica Magline Transport cover thumbscrews

4. Loosen the 2 Atellica Magline Transport cover thumbscrews enough to allow the cover to slide off, but do not completely remove the thumbscrews.



5. Pull the Atellica Magline Transport cover away from the Atellica Magline Transport.
6. Set the cover aside.
7. If appropriate, repeat this task to remove additional Atellica Magline Transport covers.

Installing Atellica Magline Transport Covers

WARNING

Do not position pacemakers or other implanted medical devices closer than 7.5 cm (3 inches) from the base of a carrier on the Atellica Magline Transport. Magnets in the carrier base generate magnetic fields that can interfere with cardiac medical implants.

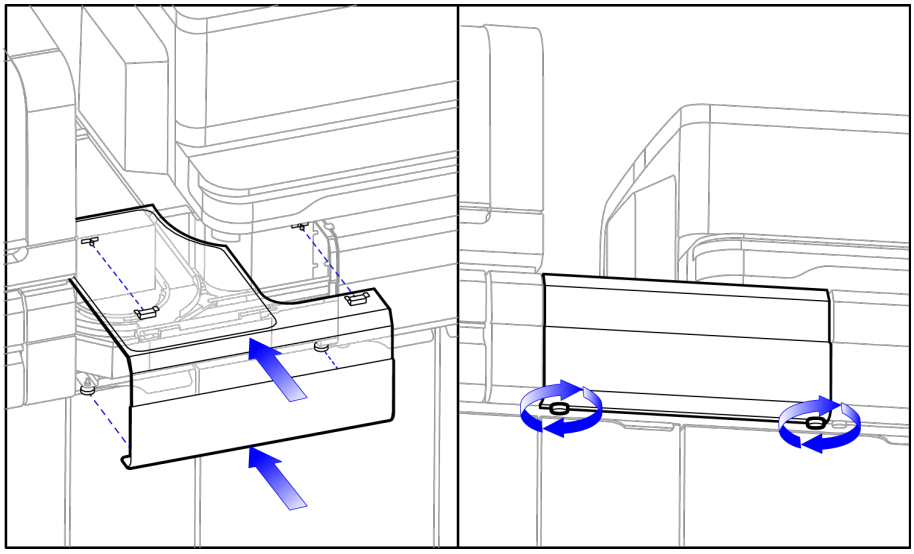
CAUTION

Do not remove the carriers from the Atellica Magline Transport. The carriers have strong magnets in the base and handling them in close proximity to metal objects can result in a body part being pinched between the carrier and the metal object. Only authorized service personnel should handle carriers.

CAUTION

Do not work or open the SHC front cover without caution. The SHC front cover is heavy and can result in injury if a body part is caught between the cover and the SHC frame.

1. Loosen the 2 thumbscrews under the Atellica Magline Transport cover position, but do not completely remove the thumbscrews.
2. Position the Atellica Magline Transport cover so the edges of the cover fit into the slots on either side of the opening.
3. Slide the Atellica Magline Transport cover in until the spring clips lock the cover into place.



4. Tighten the 2 thumbscrews under the Atellica Magline Transport cover.
5. If appropriate, repeat this task to install additional Atellica Magline Transport covers.
6. If appropriate, close the SHC cover (Page 97 *Locking the SHC Cover*).

Shutting Down the Analyzer with DL in an Emergency

ELECTRICAL HAZARD

Do not operate modules without a protective grounding connection that prevents electrical shock. Electrical shock can cause equipment damage and bodily harm. Use caution when working around these locations or contact a local technical support provider for more information about using a protective grounding connection and avoiding electrical shock hazards.

ELECTRICAL HAZARD

In the case of fire or electrical arcing, disconnect each module's power cord.

1. Disconnect the analyzer power cord.

   NOTE: This stops all motion immediately. The UPS powers the PCC to prevent data loss. The module computers start shutting down, including the PCC. After 5 minutes elapse from shut down, the module computer and the PCC operating systems shut down.

2. Wait 30 seconds before restarting the analyzer (Page 633 *Recovering from an Analyzer with DL Emergency Shutdown*) .

Recovering from an Analyzer with DL Emergency Shutdown

CAUTION

Do not leave a module's main power switch on during a power disruption. This can cause significant damage to the system when the operator restores power. When a power disruption occurs, turn off the main power switch for each module.

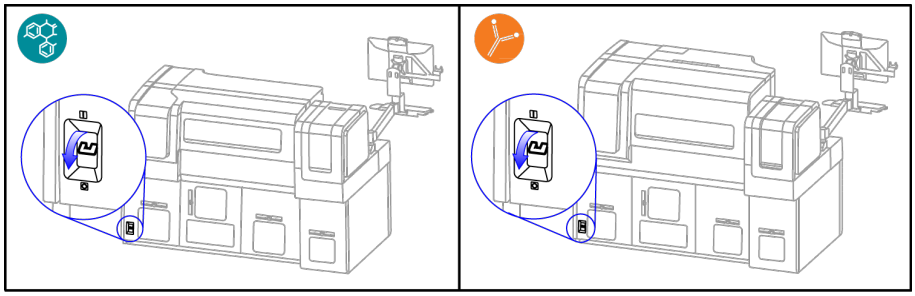
ELECTRICAL HAZARD

Do not operate modules without a protective grounding connection that prevents electrical shock. Electrical shock can cause equipment damage and bodily harm. Use caution when working around these locations or contact a local technical support provider for more information about using a protective grounding connection and avoiding electrical shock hazards.

ELECTRICAL HAZARD

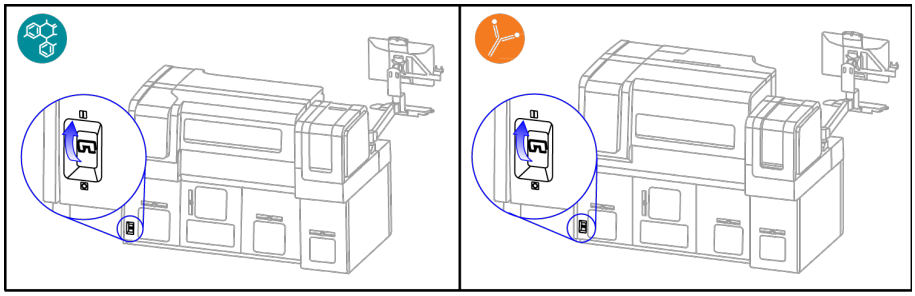
Do not plug in power cord with module power switch in on position. If the operator inserts the plug with power switch on, electrical shock may occur and cause bodily harm and equipment damage.

1. If appropriate, remove any obstructions from the following areas:
   - Entry queue
   - Exit queue
2. Ensure the power switch is off.



3. Reconnect the analyzer power cord to its power source.

4. Turn on the power switch.



5. Start the analyzer (Page 655 *Starting the Analyzer with DL*).
6. If the analyzer power is off:
   - For > 30 minutes on IM Analyzer, unload and store reagents (Page 250 *Handling IM Reagent Packs*). The analyzer must be in Ready or Standby state to unload reagents. Then manually mix primary reagents and reload all onboard reagents (Page 249 *Manually Mixing IM Reagents*).
   - For > 2 hours on CH Analyzer or IM Analyzer, discard any assay reagents remaining in the reagent compartment.

Troubleshooting System Issues

The following table identifies possible causes that prevent the system from processing:

Scenario	Corrective Action
QC or calibrator samples not processing.	This scenario can occur for a number of reasons including the following 1. Move previous orders to historical then delete these from historical. 2. Reorder test and reload the sample with new barcode for QC or calibrator samples (Page 320 *Ordering Patient Tests Workflow*). 3. Power down and restart the module. 4. If problem persists, contact the local technical support provider for assistance.

Scenario	Corrective Action
Unacceptable QC results.	. .
Troubleshooting calibration orders.	.
Unacceptable calibration results.	.
Unacceptable patient results.	.
Unacceptable single assay results.	.
Unacceptable multiple assay results.	.
Unscheduled laboratory power loss.	System recovery after power disruption (Page 644 *Recovering from a System Power Disruption*).
Emergency shutdown of system.	Shut down system quickly (Page 622 *Shutting Down the System in an Emergency*).
Recover from an emergency shut down.	(Page 622 *Recovering from a System Emergency Shut Down*).
Module display is locked up.	(Page 657 *Recovering from a Module Display Lockup*).
Stop a module from processing.	(Page 651 *Stopping Analyzer from Processing Patient Samples Immediately*).
Slow user interface.	(Page 656 *Recovering from a Slow User Interface*).
Software is locked up.	(Page 657 *Recovering from a Software Lockup*).
LAS is down. Unload samples.	.

The following table identifies possible causes that prevent the SH from processing:

SH Possible Causes	Corrective Action
The SH is offline. Enter ESL mode (optional).	(Page 662 *Entering ESL Mode on the System*)
The SH is online. Exit ESL mode (optional).	(Page 662 *Exiting ESL Mode*)
An alert displays to inspect and clear the SH TCS.	
The SH robot dropped a Cal-QC tube or tube cover.	
The SH robot dropped a sample container.	
The system displays an alert to manually remove a tube in the robot gripper.	

The following table identifies possible causes that prevent the Atellica Magline Transport from processing:

Atellica Magline Transport Possible Causes	Corrective Action
Carrier jams on the Atellica Magline Transport.	(Page 625 *Clearing the Atellica Magline Transport Prior to Startup*)
The operator must manually remove sample containers from the Atellica Magline Transport.	
A spill occurred.	

The following table identifies possible causes that prevent an analyzer from processing:

Analyzer Possible Causes	Corrective Action
Hardware error.	1. Shut down the appropriate module. 2. Resume module (Page 137 *Changing the Module Status*). 3. If problem persists, contact the local technical support provider for assistance.
CH Analyzer	
Reagent pack is stuck in the gripper.	.
IMT failing to pause.	1. Shut down the appropriate module. 2. If problem persists, contact the local technical support provider for assistance.
An unacceptable IMT Dilution Check generates a Failed Status.	.
IMT calibration failed.	.
IM Analyzer	
Reagent pack is stuck in the gripper.	.
Unacceptable sandwich assay calibration result.	.
Unacceptable competitive assay calibration result.	.
IM reagent loader offline.	1. Remove any obstructions in the IM reagent loader and compartment. 2. If appropriate, select **Issue Resolved** and resume the IM Analyzer. 3. If problem persists, contact the local technical support provider for assistance.
IM cuvettes are jammed.	.

Analyzer Possible Causes	Corrective Action
IM cuvette loading area is jammed.	.
IM tip tray replacement.	.
Issue with the waste subsystem.	1. Shut down and restart the IM Analyzer (Page 650 *Shutting Down and Powering Off the Analyzer with DL*). 2. If problem persists, contact the local technical support provider for assistance.
The inprocess queue is full.	1. Shut down and restart the IM Analyzer (Page 650 *Shutting Down and Powering Off the Analyzer with DL*). 2. If problem persists, contact the local technical support provider for assistance.
Prepare the IM Analyzer for extended downtime.	.
Restart the IM Analyzer after extended downtime.	.

The following table identifies possible causes that prevent the SHC from processing:

SHC Possible Causes	Corrective Action
Cleaning sample spills.	
Clearing carrier jams.	
Sample tubes stuck in SHC robot grippers.	
Clearing the SHC Pick and Place Stations (PPS).	
Inspecting the SHC robot gripper tips.	

The following table identifies possible causes that prevent the Decapper from processing:

Decapper Possible Causes	Corrective Action
Decapper obstructions.	
Sample tube stuck in the Decapper tube gripper.	
Decapper gripper obstructions.	
Cap stuck in the Decapper cap remover.	
Obstructions in Decapper cap remover.	

The following table identifies possible causes that result in restarting the system or a module:

System Possible Causes	Corrective Action
System cannot clear the order cache.	1. Restart the PCC (Page 659 *Restarting the PCC*). 2. If problem persists, contact the local technical support provider for assistance.
An issue with the internal router, cables, or port.	1. Wait for the system to automatically reconnect, and restart the PCC (Page 659 *Restarting the PCC*). 2. If the system does not automatically reconnect, shut down the system (Page 647 *Shutting Down and Powering Off the System*).

System Possible Causes	Corrective Action
An internal software issue.	1. Shut down and restart the appropriate module or analyzer. – Shut down CH or IM Analyzer (Page 650 *Shutting Down and Powering Off the Analyzer with DL*). – Shut down the SH (Page 670 *Shutting Down and Powering Off the SH Modules*). – Shut down the SHC (Page 681 *Powering Off the SHC*). – Shut down the Decapper (Page 682 *Powering Off the Decapper*). 2. If problem persists, contact the local technical support provider for assistance.
Barcode reader failed, out of alignment, or communication error.	1. If an issue exists with the handheld barcode reader, disconnect then reconnect the reader. If the problem persists, contact the local technical support provider for assistance. 2. For all other barcode readers, shut down the system (Page 647 *Shutting Down and Powering Off the System*). 3. Restart the system (Page 651 *Starting the System*). 4. If problem persists, contact the local technical support provider for assistance.

System Possible Causes	Corrective Action
Module hardware error.	1. Shut down the appropriate module. 2. Resume module (Page 137 *Changing the Module Status*). 3. If problem persists, contact the local technical support provider for assistance.
The specified module component did not complete the homing process because of another error.	1. Review the Operator Event Log for an event that happened at the same time or that affected the component (Page 709 *Viewing the Operator Event Log*). 2. Resolve any issues identified in the Operator Event Log. 3. If the issue is resolved, resume the appropriate analyzer or module (Page 137 *Changing the Module Status*). 4. If this error persists, contact the local technical support provider.

The following table identifies appropriate start up topics:

Starting System or Module	Procedure
Restart the system.	Perform system restart (Page 651 *Starting the System*).
Restart the PCC.	(Page 659 *Restarting the PCC*).

Starting System or Module	Procedure
Restart the appropriate module.	Perform the appropriate module startup: • Restart the CH or IM Analyzer. • Restart the SH (Page 668 *Starting the SH*). • Restart the SHC (Page 680 *Starting the SHC*). • Restart the Decapper (Page 683 *Powering On the Decapper*).
Starting the SH.	(Page 668 *Starting the SH*).
Starting the SHC.	(Page 680 *Starting the SHC*).
Starting the Decapper.	Restart the Decapper (Page 683 *Powering On the Decapper*).
Starting an analyzer with DL.	(Page 655 *Starting the Analyzer with DL*).

The following table identifies appropriate shut down topics:

Shutting Down System or Module	Procedure
Shut down and power off the system.	(Page 647 *Shutting Down and Powering Off the System*).
Shut down the SH.	(Page 670 *Shutting Down and Powering Off the SH Modules*).
Shut down and restart the Atellica Magline Transport.	(Page 662 *Shutting Down and Restarting the Atellica Magline Transport*).
Shut down and powering off the analyzer with DL.	(Page 650 *Shutting Down and Powering Off the Analyzer with DL*).
Shut down and power off analyzers within the system.	.

Shutting Down System or Module	Procedure
Shut down the appropriate module within the system only.	Perform the appropriate module shut down: • Shut down CH or IM Analyzer (Page 650 *Shutting Down and Powering Off the Analyzer with DL*). • Shut down the SH (Page 670 *Shutting Down and Powering Off the SH Modules*). • Shut down the SHC (Page 681 *Powering Off the SHC*). • Shut down the Decapper (Page 682 *Powering Off the Decapper*).

Signing in to the System

1. At the window for Sign In, enter the Operator ID and Password.
2. Select **Sign In**.

Signing out of the System

1. Select  .
2. Select  .
3. Select  again.

   NOTE: If the operator selects  , the system display is locked. Locking does not sign out the current operator.
4. In Sign Out, select **Yes**.

About System Power Disruption

The modules each have a UPS to provide battery backup to the Process Center Computer (PCC) and analyzer computers to allow for a software shutdown when a power disruption occurs. The SHC draws power from the SH. When a power disruption occurs or the operator turns off the IM or CH power switch, the reagent refrigeration turns off as well.

When a SH power disruption occurs or the operator turns off the SH main power switch:

- The SH and SHC covers lock and require manual steps to unlock and retrieve samples. Should this occur, contact the local technical support provider.
- The Cal-QC refrigeration turns off. If the power is off for more than 1/2 an hour, the operator should manually unload the Cal-QC storage area.
- The PCC, SH computer, and SHC computer initiate a complete shutdown.
- If power is lost to SH only, the other analyzers continue to process started tests.
- The analyzers store and transfer sample test data to the PCC when power is restored to the SH.
- All SH and SHC robot movement stops.
- The LAS interface module stops.

NOTE: With loss of power, the SH drawers unlock, making the tubes in the drawers accessible.

About the Analyzer with DL Power Disruption

Each analyzer has a UPS to provide battery backup to the Module Manager (MM) computer to allow an orderly software shutdown when a power disruption occurs. When a power disruption occurs or the operator turns off the IM or CH power switch, the reagent refrigeration turns off as well.

Recovering from a System Power Disruption



CAUTION

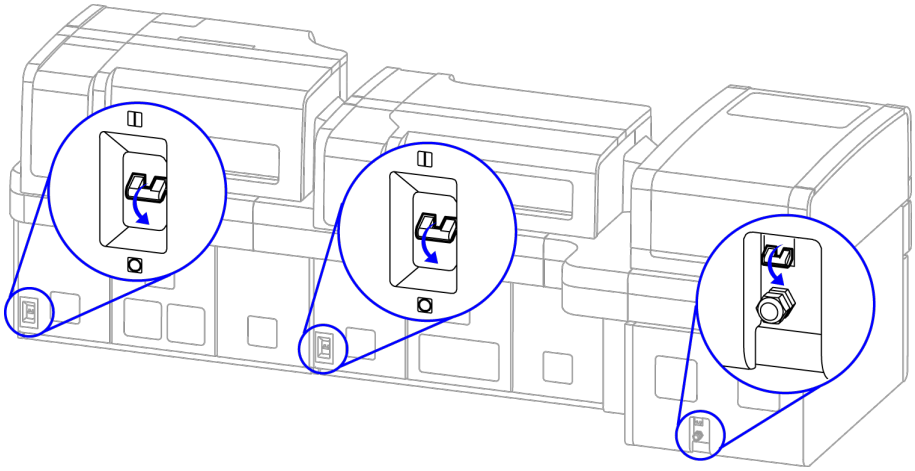
Do not leave a module's main power switch on during a power disruption. This can cause significant damage to the system when the operator restores power. When a power disruption occurs, turn off the main power switch for each module.



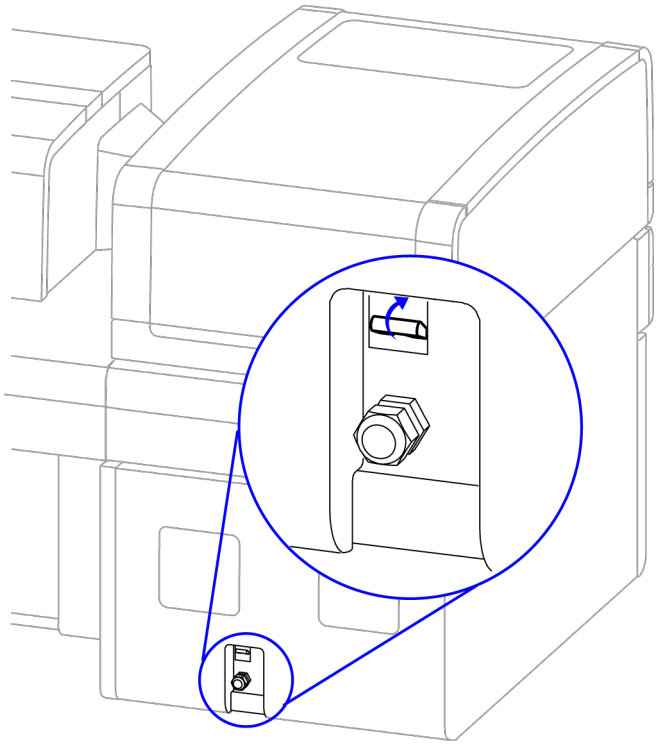
BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

1. Turn off all module power switches.



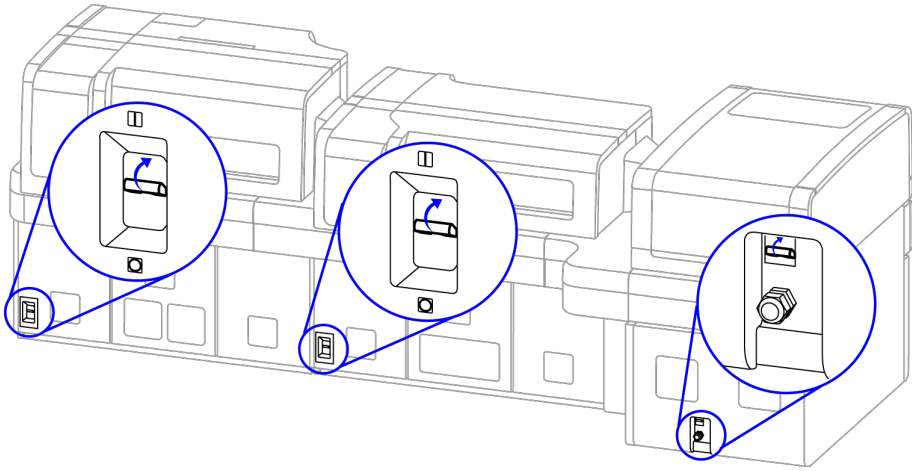
2. Ensure Atellica Magline Transport is clear (Page 625 *Clearing the Atellica Magline Transport Prior to Startup*).
3. If appropriate, power on the SH Prime and wait 30 seconds before proceeding.



NOTE: The SH Prime is the SH closest to the analyzers. The SH Prime powers the PCC.

4. If appropriate, power on each SH Additional and wait 30 seconds before proceeding.

5. If appropriate, power on each module.



NOTE: Start with the module adjacent to the SH Prime and proceed 1 by 1 to the other modules in the order they are connected.

6. After power restores to the SH Prime, if appropriate, start the SHC (Page 680 *Starting the SHC*).
7. Completely open and close the SH drawers (Page 387 *Opening Sample Drawers*).
8. Wait for the system display login screen to display.
9. Sign in to the system (Page 643 *Signing in to the System*).
10. Confirm the contents of the Cal-QC storage area.
11. Ensure all modules are in Ready or Standby state (Page 137 *Changing the Module Status*).
12. If any module status or module display does not display or any problems occur, contact the local technical support provider.
13. If any module power is off:
    - For > 30 minutes on IM Analyzer, unload and store reagents (Page 250 *Handling IM Reagent Packs*). The analyzer must be in Ready or Standby state to unload reagents. Then manually mix primary reagents and reload all onboard reagents (Page 249 *Manually Mixing IM Reagents*).
    - For > 2 hours on CH Analyzer or IM Analyzer, discard any assay reagents remaining in the reagent compartment.
    - For calibrators or QC materials remaining in the Cal-QC storage area, refer to the calibrator and QC material IFU for stability information. If QC is out of range after the system was shut down, discard the stored QC and replace with fresh QC material.

Shutting Down and Powering Off the System

NOTE: Use the following shut down procedure on a system configuration. Skip any steps for modules not present in the laboratory system configuration.

Complete this procedure only when the system requires a complete shut down for troubleshooting or maintenance. If the system requires a restart, the operator should restart the PCC (Page 659 *Restarting the PCC*).



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

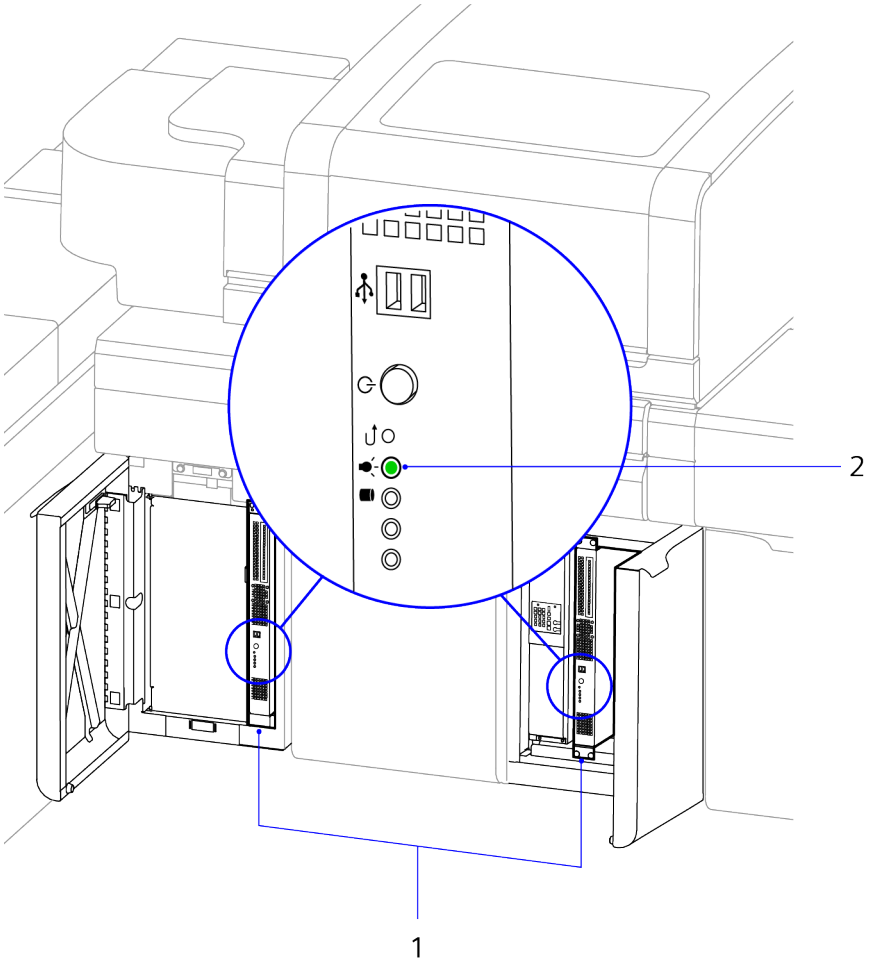
1. Before the operator powers off any analyzer and if the system is scheduled to be offline:
   - For > 30 minutes on IM Analyzer, unload and store reagents. Then manually mix primary reagents and reload all onboard reagents (Page 249 *Manually Mixing IM Reagents*).
   - For > 2 hours on CH Analyzer or IM Analyzer, discard any assay reagents remaining in the reagent compartments.
   - For calibrators or QC materials remaining in the Cal-QC storage area, refer to the calibrator and QC material IFU for stability information. If QC is out of range after the system was shut down, discard the stored QC and replace with fresh QC material.
2. Ensure the modules are in Standby, Stopped, or Off state (Page 137 *Changing the Module Status*).
3. To shut down the system:
   a. Select .
   b. Select .
   c. Confirm by selecting then select **Yes**.
   d. Select **Shutdown > Yes.**

   NOTE: The system deletes pending calibration orders when the analyzer shuts down. Patient and QC orders remain.

CAUTION

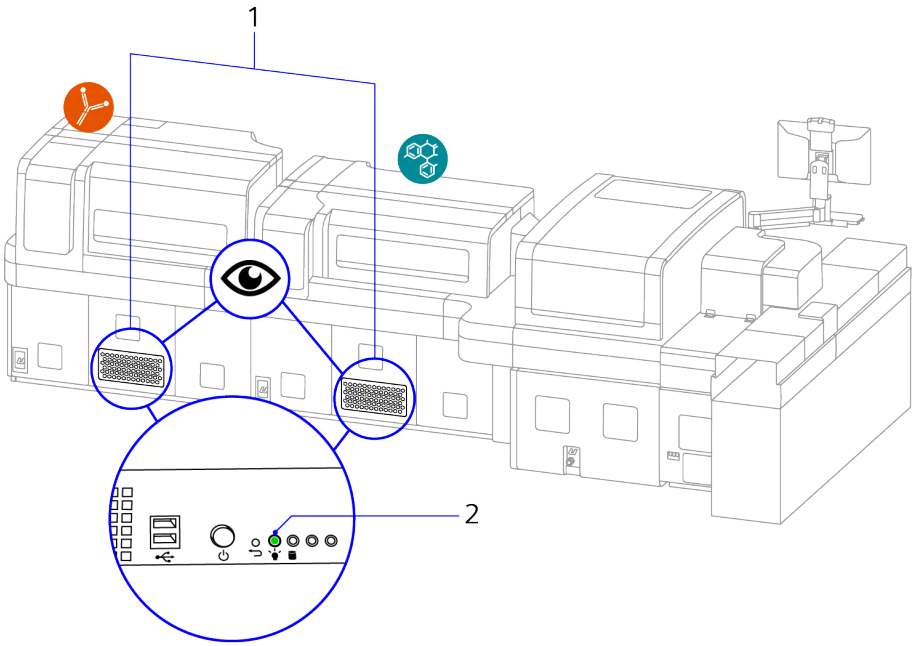
Do not power off a module when its computer light is green. Powering off a module before the green light is off can cause data loss. Ensure all module computer lights are not green before powering off the system.

4. Locate the SH and SHC computers and ensure the lights are not green.



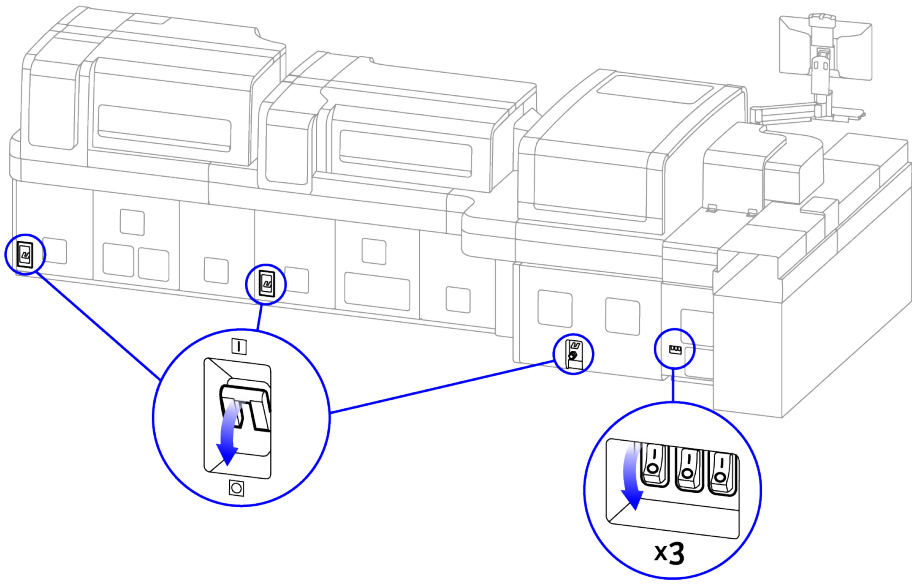
1	SHC and SH computer
2	Location of green light

5. Locate the CH and IM computers through the air vent and ensure the lights are not green.



1	Analyzer computer air vents
2	Location of green light

6. Power off all modules.
   a. Power off the module farthest from the PCC.
   b. Power off the next module.
   c. Continue powering off all modules in sequence including the SH.



NOTE: The analyzers and SH have 1 power switch each. The SHC has 3 power switches.

7. Wait 5 minutes before restarting the system (Page 651 *Starting the System*).

   NOTE:

   The 5 minute wait:

   – Ensures the router connection to the intranet stops for this time period to terminate communication.

   – Ensures a proper shutdown and avoids data corruption.

Shutting Down and Powering Off the Analyzer with DL

1. Before the operator powers off any analyzer and if the system is scheduled to be offline:

   – For > 30 minutes on IM Analyzer, unload and store reagents. Then manually mix primary reagents and reload all onboard reagents (Page 249 *Manually Mixing IM Reagents*).

   – For > 2 hours on CH Analyzer or IM Analyzer, discard any assay reagents remaining in the reagent compartments.

2. In System Status area, select the appropriate analyzer.

3. To power down the analyzer software and hardware, select ⏻ then **Yes**.

   NOTE: The system deletes pending calibration orders when the system shuts down.

4. To power down the DL software and hardware, select ⏻ then **Yes**.
5. To shut down the analyzer with DL:

   a. On the Access bar, select 👤.

   b. Select 🔑.

   c. Confirm by selecting 🔑 and **Yes**.

   d. Select Shutdown and **Yes** to confirm.
6. Wait for the monitor to turn black then 30 seconds before restarting the analyzer (Page 655 *Starting the Analyzer with DL*).

Stopping Analyzer from Processing Patient Samples Immediately

1. In System Status area, select the appropriate analyzer.
2. Select **Patient Sample Processing**.
3. To confirm, select **Yes**.

Stopping Analyzer Processing Immediately

1. In the area for System Status, select the appropriate analyzer.
2. Select ■.
3. Select **Stop Immediately**.
4. Wait for subsystem status to display Stopped.

Starting the System

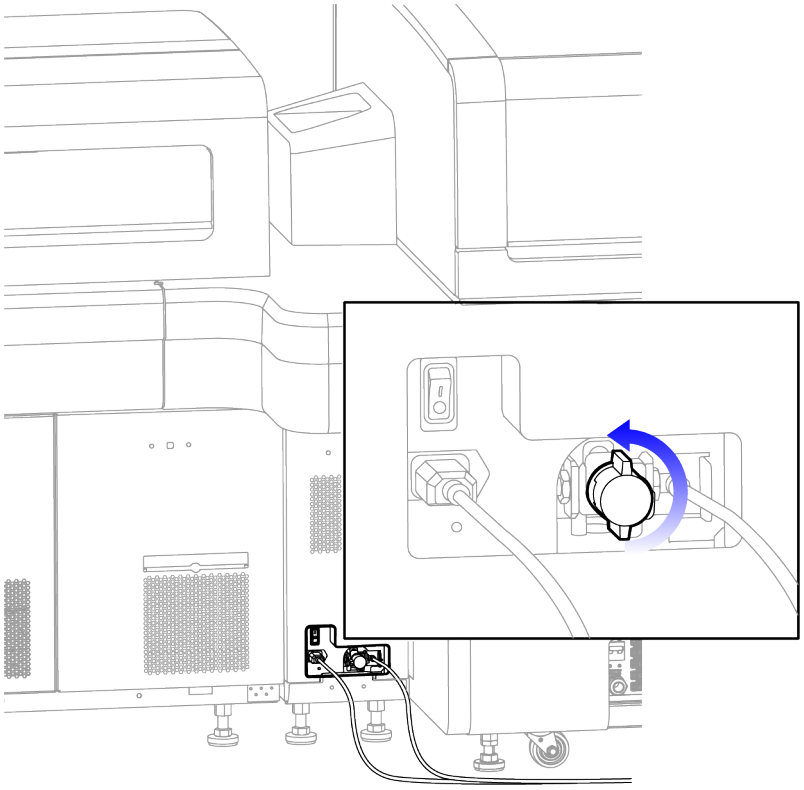
NOTE: The following startup procedure is only for a system configuration that is shut down and powered off. The operator can skip any steps for modules not present in the laboratory system configuration.



BIOHAZARD

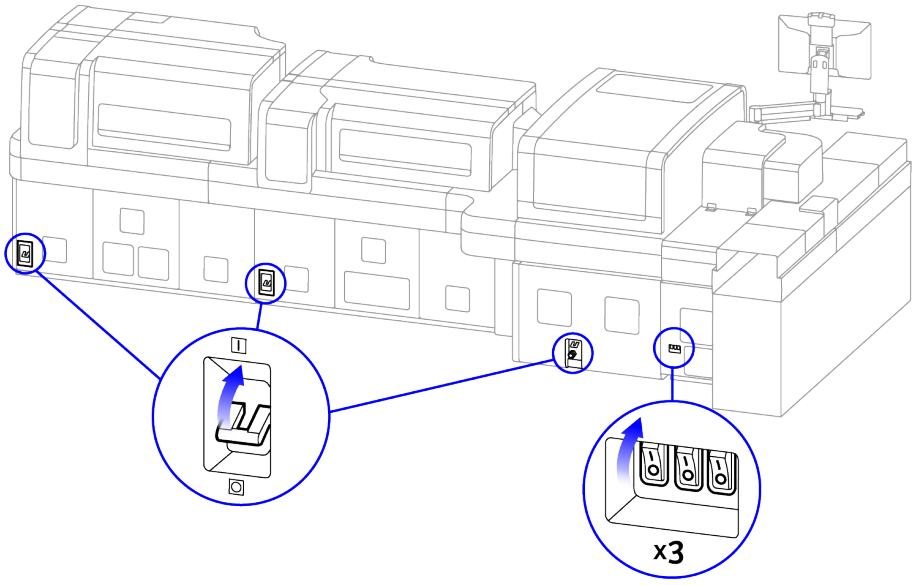
Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

1. To turn on the Decapper pressure valve, turn it counterclockwise.



2. Ensure Atellica Magline Transport is clear (Page 625 *Clearing the Atellica Magline Transport Prior to Startup*).

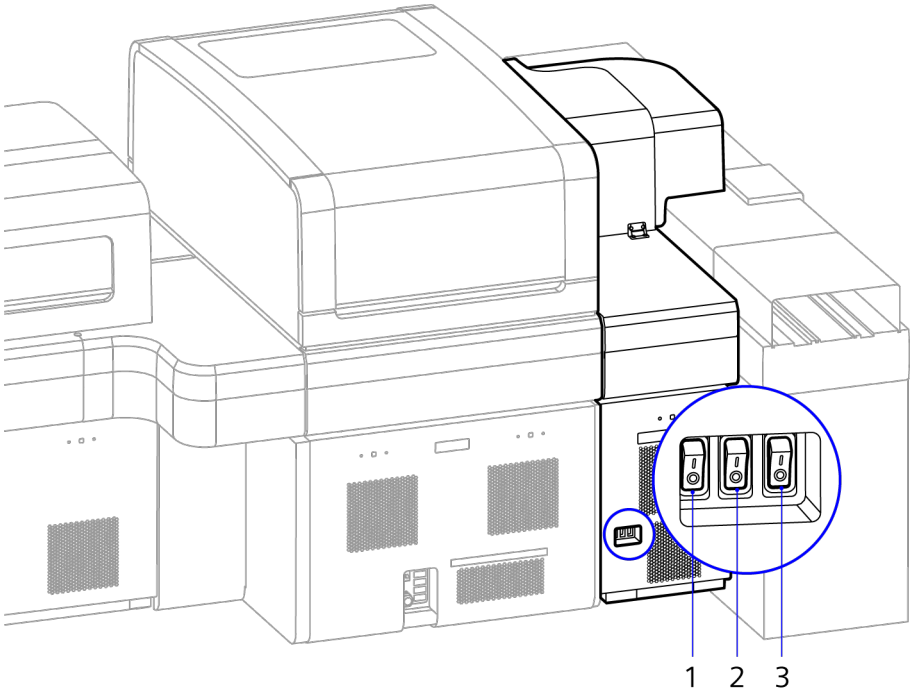
3. If appropriate, power on the Atellica Sample Handler Prime and wait 5–10 minutes until the PCC starts.



NOTE: The analyzers and SH have 1 power switch each. The SHC has 3 power switches.

4. If appropriate, power on each Atellica Sample Handler Additional.

5. If appropriate, start the SHC:



1	+24VDC power switch
2	+48VDC power switch
3	Computer power switch

   a. Power on the left +24VDC power switch and wait 30 seconds.
   b. Power on the middle +48VDC power switch and wait 30 seconds.
   c. Power on the computer power switch to the right.
6. If appropriate, power on each analyzer in sequence and wait 30 seconds before powering on the next analyzer.

   NOTE: Start with the analyzer adjacent to the SH and proceed 1 by 1 to the other analyzers in the order they are connected.
7. If appropriate, power on the Decapper (Page 683 *Powering On the Decapper*).
8. Wait for the system display login screen to display.
9. Wait for each analyzer's module display screen to display.
10. Ensure the barcode label printer power is on.
11. Sign in to the system (Page 643 *Signing in to the System*).
12. To initialize the SH drawers, completely open and close the drawers (Page 387 *Opening Sample Drawers*).
13. Confirm the contents of each SH Cal-QC storage area.

14. Ensure all modules are in Ready or Standby state (Page 137 *Changing the Module Status*).

    NOTE: After the operator selects ▶, a window displays identifying a module that did not connect to the Atellica Magline Transport and the option to proceed without it.

15. If the popup window displays, clear all Atellica Magline Transport obstructions and select **OK** to proceed without the listed modules.
16. Troubleshoot the modules in popup window and, if unresolved, contact the local technical support provider.
17. If any module power is off:
    - For > 30 minutes on IM Analyzer, unload and store reagents (Page 250 *Handling IM Reagent Packs*). The analyzer must be in Ready or Standby state to unload reagents. Then manually mix primary reagents and reload all onboard reagents (Page 249 *Manually Mixing IM Reagents*).
    - For > 2 hours on CH Analyzer or IM Analyzer, discard any assay reagents remaining in the reagent compartment.
    - For calibrators or QC materials remaining in the Cal-QC storage area, refer to the calibrator and QC material IFU for stability information. If QC is out of range after the system was shut down, discard the stored QC and replace with fresh QC material.

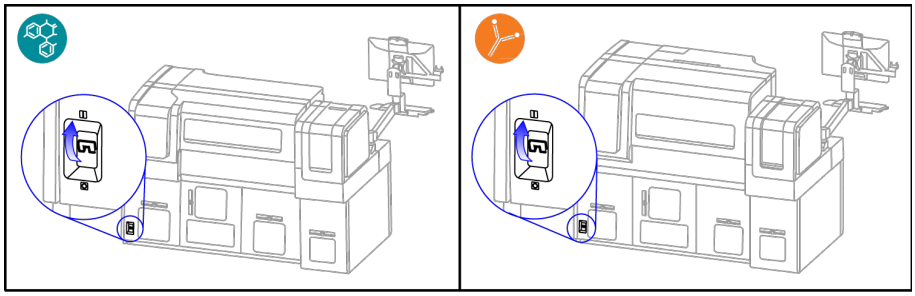
Starting the Analyzer with DL



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

1. If appropriate, remove any obstructions from the following areas:
   - Entry queue
   - Exit queue
2. Ensure the power switch is on.



3. Sign into the analyzer (Page 643 *Signing in to the System*).
4. If the analyzer does not start or any problems occur, contact the local technical support provider.
5. If the analyzer power is off:
   - For > 30 minutes on IM Analyzer, unload and store reagents (Page 250 *Handling IM Reagent Packs*). The analyzer must be in Ready or Standby state to unload reagents. Then manually mix primary reagents and reload all onboard reagents (Page 249 *Manually Mixing IM Reagents*).
   - For > 2 hours on CH Analyzer or IM Analyzer, discard any assay reagents remaining in the reagent compartments.

Recovering from a Slow User Interface

A slow user interface (UI) occurs when a window requires more than 5–10 seconds to load. For example, 200,000 patient results or 500,000 events take up to 10 seconds for the window to fully display. This does not apply when data is loading (when features take up to 30 seconds to load) or progress window (indicates time in a progress bar). To recover from a slow user interface:

1. Sign out (Page 643 *Signing out of the System*)and back into the system (Page 643 *Signing in to the System*).
2. If slow UI persists, restart the PCC (Page 659 *Restarting the PCC*).
3. If a slow UI persists, contact the local technical support provider.

Recovering from a Software Lockup

1. When the system displays a blue screen, wait for the display to restore.

   NOTE: In most occurrences, the system requires 1–3 minutes to repair itself. Wait for the system to automatically complete the repairs for the full 10 minutes to avoid canceling or interrupting all patient testing. If the system does not restart after 10 minutes, the PCC automatically restarts. The system logs an event after a successful restart.

   –  : indicates system repair or maintenance in progress

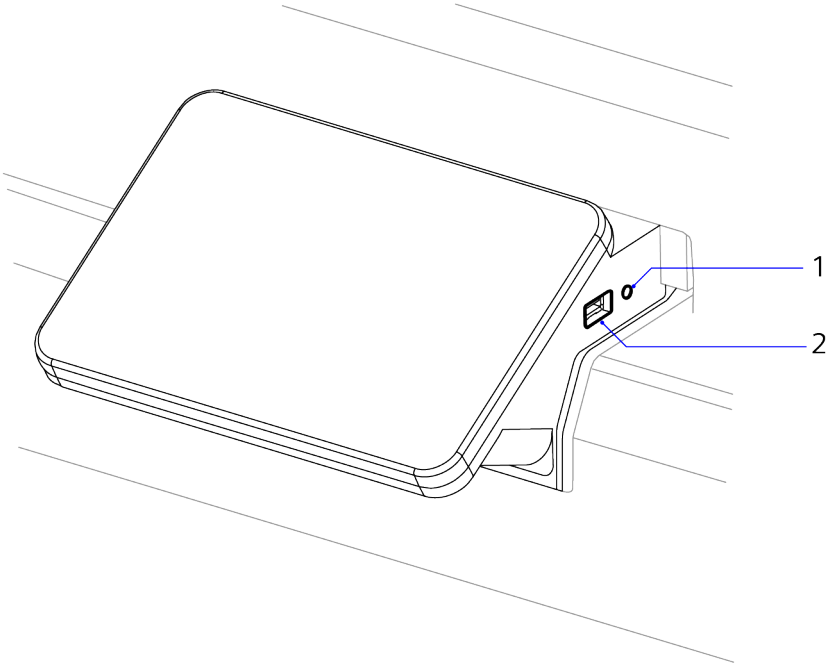
   –  : indicates a maximum wait time of 10 minutes

2. If a software lockup persists, contact the local technical support provider.

Recovering from a Module Display Lockup

The module display may encounter intermittent problems that prevent the operator from changing screens. To recover from a module display lockup:

1. Locate the reset button on the right side of the module display.



1	Reset button
2	USB port

2. Using a thin object, such as a paper clip, press and hold the module display reset button for 10 seconds.

   NOTE: During the module display reset, the screen goes black. Within approximately 10 seconds the screen should display the appropriate screen.

3. Wait for approximately 1 minute after the screen returns to allow the module display drivers to fully load, then test to determine if the module display screen is no longer locked up.
4. If the module display screen is still locked up, reset the module display a second time.
5. If the issue persists after 2 reset attempts, restart the analyzer.

Restarting the PCC

1. Ensure none of the following tasks are Inprocess to prevent data loss:
   - If tests are processing, choose 1 of the following:
     - Navigate to **Worklist** then select **All** in filters.
     - On the Status bar, select appropriate analyzer and check analyzer states for processing.
   - Database optimization processing.
   - LIS transmitting results: Navigate to **Worklist** and ensure is attached to all test results.
   - Maintenance activities including database backup, archiving and deletion, and move to historical: Navigate to **Maintenance > All Activities** then search for the appropriate activity.
   - Exporting: located in several areas.
   - Printing to a printer or file.
   - System states such as Processing and Diagnostics: in System Status area, select each module.
   - IM Analyzer: Any control-bracketed test results pending release with a closing bracket (Waiting For Bracket: navigate to **Worklist**.
2. In the System Status area, select .
3. Select .
4. Confirm by selecting again then **Yes**.
5. Ensure the system is not processing tests, then select **Restart**.
6. Select **Restart** then select 1 of the following:
   - Restart the PCC Workstation only.
   - Restart the PCC Workstation and all Modules.

   NOTE:

   If the PCC fails to restart, the keyboard is not responding, or the UI is locked after a 2 minute wait:

   a. Select **CTRL+ALT+DEL** then select from lower right corner of screen.

   b. Select **Restart > Yes**.

   The system closes out the session, refreshes the UI, and returns the operator to the login prompt (Page 643 *Signing in to the System*).

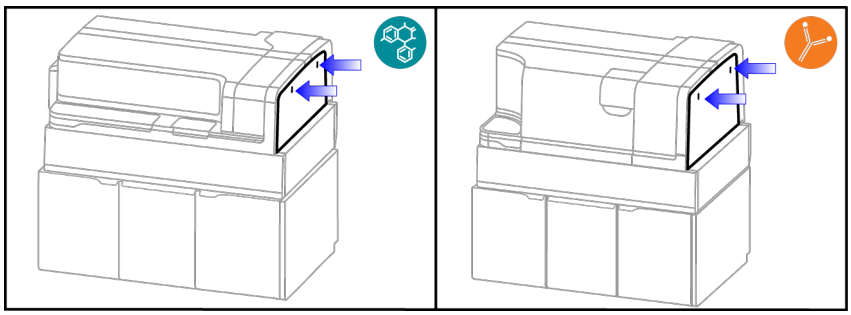
Unlocking Analyzer Covers Manually

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

Only perform this task during a power disruption.

1. Locate the appropriate lock access opening of the right side of the analyzer.



2. Insert the tip of a flat-blade screwdriver into the appropriate opening.
3. Press down to unlock the cover.
4. Open the appropriate cover front cover.

About Emergency Sample Load Mode

Emergency Sample Load (ESL) mode is an optional feature that allows the operator to continue processing samples directly on an analyzer if 1 or more of the following error conditions occur:

- A full failure of all SH modules and SHC, if equipped
- A full failure of all Tube Characterization Stations (TCS)
- A partial or full failure of the Atellica Magline Transport

The operator enables ESL mode at the primary user interface and uses the ESL carrier to manually load and process a sample on the appropriate analyzer. The analyzer module display provides the operator with step-by-step instructions for installing and using the ESL carrier.

For a sample with orders for IM and CH tests, the operator processes the sample on 1 analyzer first. After sample aspiration is complete, the operator moves the ESL carrier to the other analyzer to complete the sample aspiration on the sample.

NOTE: When sample aspiration is complete on the first analyzer, the system marks the tests for the remaining analyzer with a System Error on the Worklist and displays the error on the module display. After the operator moves the ESL carrier to the other analyzer and sample aspiration is complete, the system removes the System Error from the Worklist and displays the Sample Aspiration Successful screen on the module display.

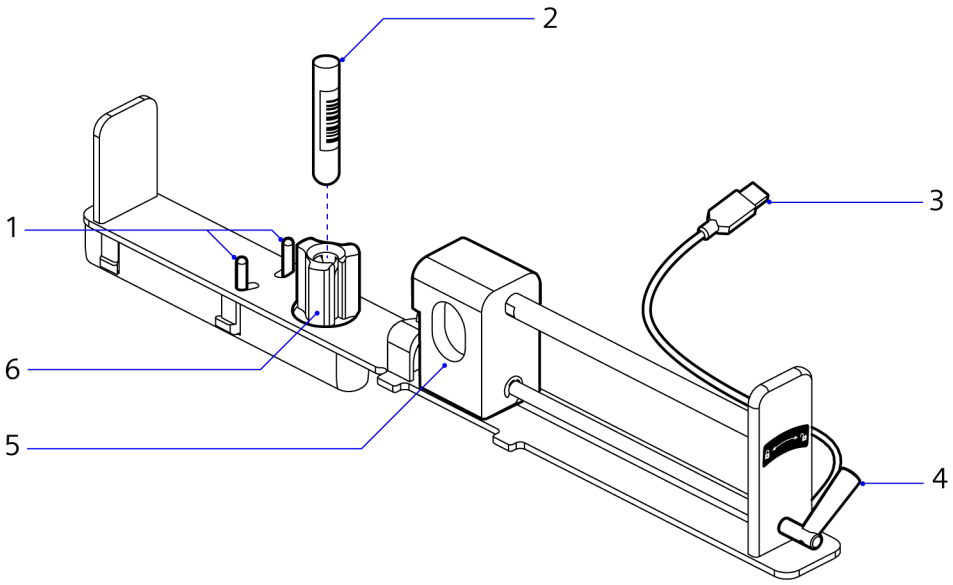
The operator can process the following sample types using the ESL carrier:

- Patient samples
- QC samples

NOTE: The operator cannot use the ESL carrier to perform calibrations or control bracketing.

The ESL carrier requires a plain sample tube or a tube-top sample cup. The system does not support capillary collection containers or false bottom tubes in ESL mode.

The ESL carrier includes a sample container holder, a barcode reader, latches that secure the ESL carrier into the analyzer input queue, and a locking mechanism that secures the ESL carrier into the pipetting position.



1	Carrier latch pins	4	Locking handle
2	Sample container	5	Barcode reader
3	Barcode reader USB cable	6	Sample holder

Entering ESL Mode on the System

1. Stop the Atellica Magline Transport (Page 137 *Changing the Module Status*).
2. Select **Enter ESL Mode > Yes**.

   NOTE: After the system enters ESL mode, the operator controls the system from the appropriate analyzer module display. The system provides all instructions for how to use ESL mode on the module display.

Exiting ESL Mode

1. In System Status area, select Atellica Magline Transport module.
2. Select **Exit ESL Mode > Yes**.
3. Restart the system software (Page 659 *Restarting the PCC*).

Troubleshooting the Atellica Magline Transport

The operator should perform Atellica Magline Transport troubleshooting steps before contacting the local technical support provider.

Shutting Down and Restarting the Atellica Magline Transport

1. In System Status area, select the Atellica Magline Transport.
2. Select ⏻ to shut down the Atellica Magline Transport.
3. Ensure that all carriers are clear of the diverters (Page 625 *Clearing the Atellica Magline Transport Prior to Startup*).
4. Select ▶ to restart.

Emptying the Sample Tip Loader

CAUTION

Do not load sample trip trays above the gray collar. Loading sample trip trays above the gray collar raises the trays up and causes jams on the collar.

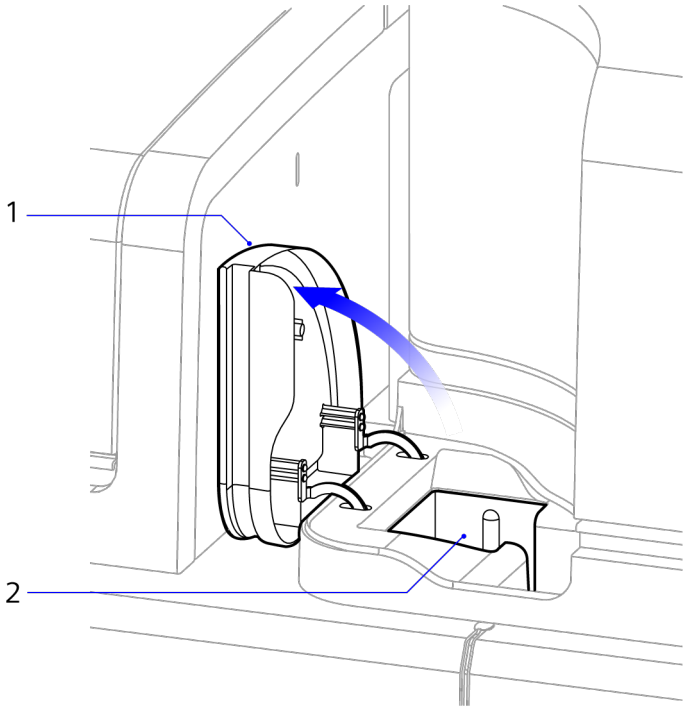
CAUTION

Do not place the tip tray bundle on a surface. Contamination or damage could occur. Hold the tip bundle with both hands to unlock the tip tray bundle strap.

CAUTION

Do not place the sample tip trays on their side. Placing the trays on their sides can damage the tips. If removing tips from the tip tray loading area, keep the lid on while placing the tip trays upside down on a flat surface.

1. Check for any sample tip tray obstructions in the sample tip loading area.



1	Sample tip cover
2	Sample tip loading area

NOTE: Obstructions may include loose tips, empty sample tip trays, tip tray straps, or tray covers in the tip loader.

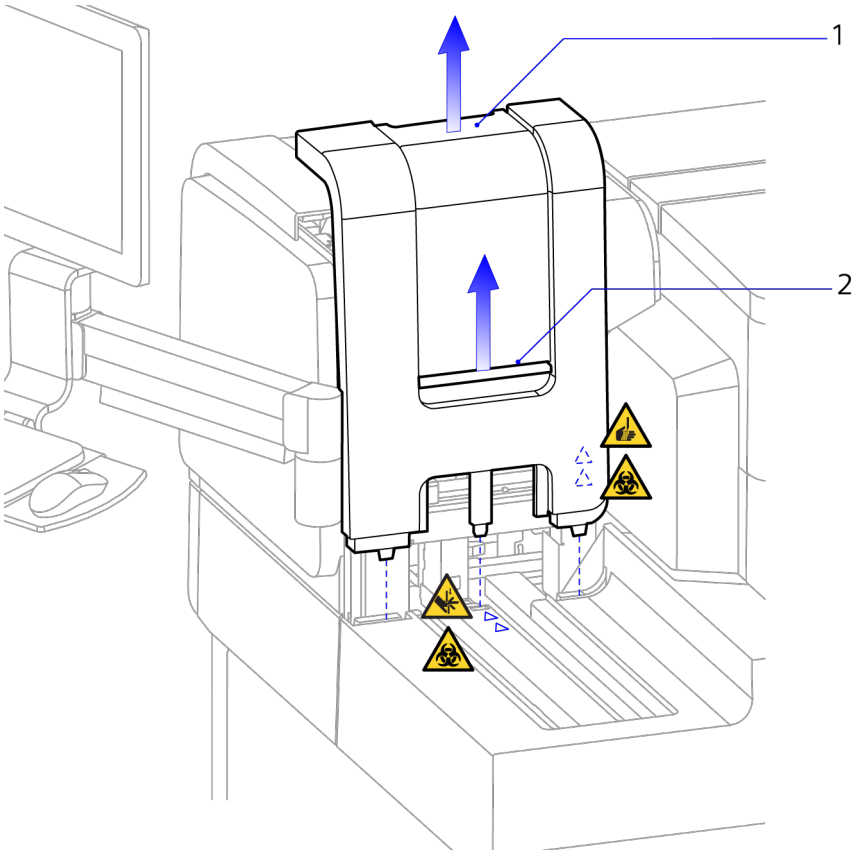
2. If appropriate, manually remove obstructions.
3. Enter diagnostic state (Page 704 *Entering the Diagnostic State*).
4. Select **Subsystems > Tip Loader**.
5. Select **Emptying the Sample Tip Loader**.
6. Select **Perform > Yes > OK**.
7. Remove and inspect sample tip trays on a flat surface as the trays arrive at the loading area.
8. Reload any undamaged sample tip trays.
9. Select **Exit Diagnostics**.

Removing the DL Front Cover

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

1. Stop and unlock the DL front cover (Page 99 *Locking and Unlocking DL Covers*).
2. Push the workstation away from the DL cover.
3. Place a hand under the DL front cover handle.



1	Top of front cover
2	Front cover handle

4. Place the other hand on the top of the cover for guidance.

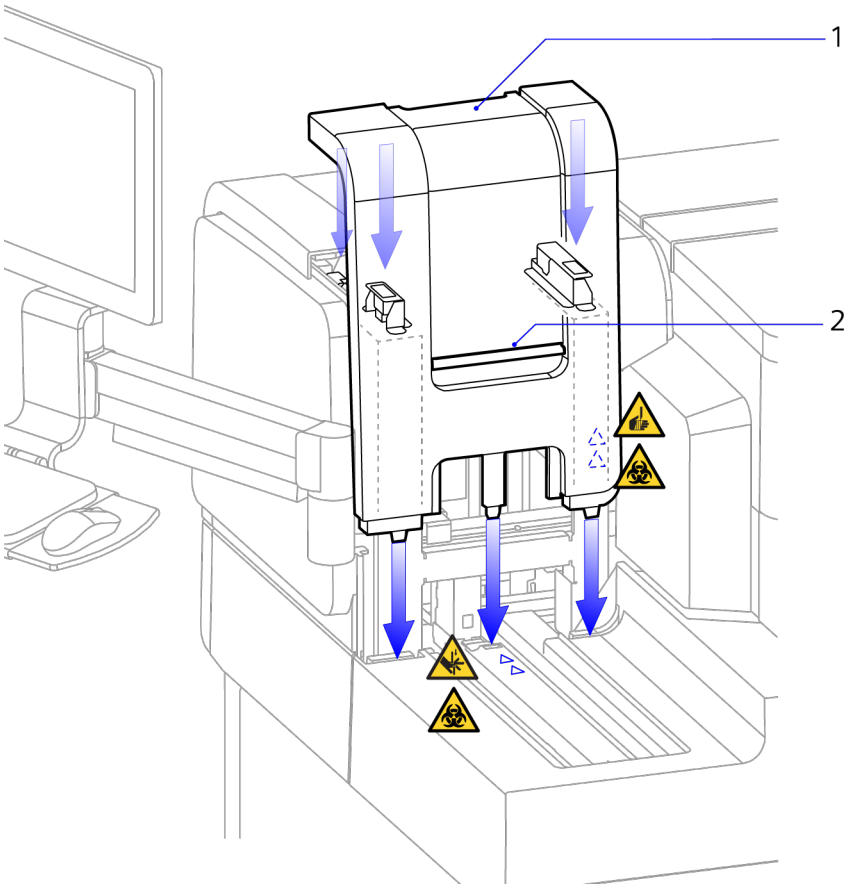
5. Push the cover up and away from system.

   NOTE: When the cover is no longer securely seated, the DL icon becomes yellow to indicate the analyzer cannot process samples.

6. Set the cover aside.

Reinstalling the DL Front Cover

1. Grasp the DL front cover with 2 hands and place them firmly against the front of the DL assembly.



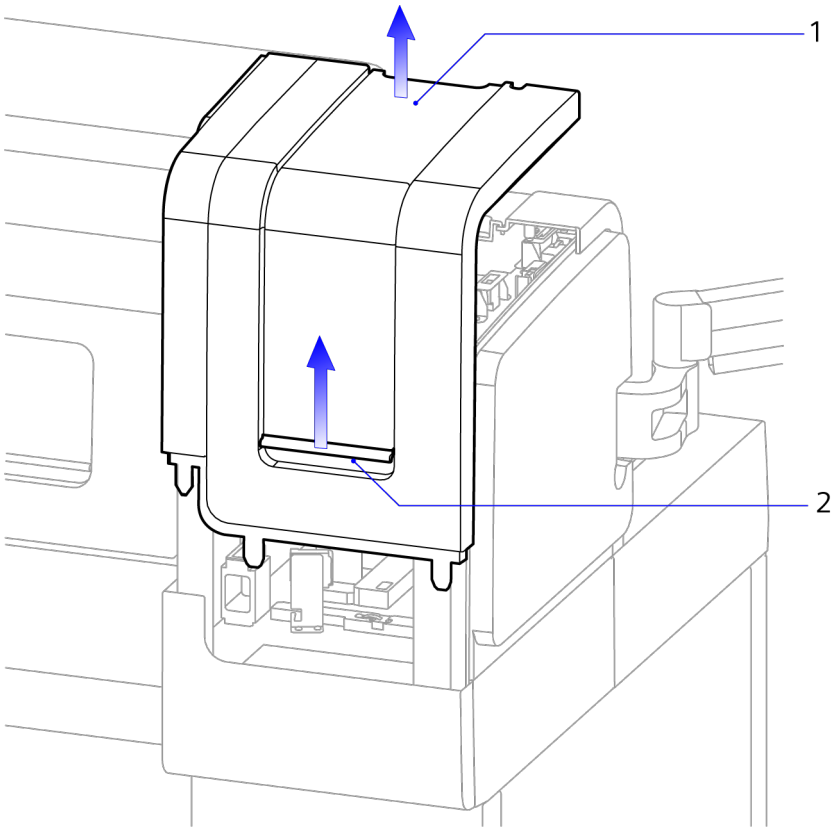
1	Top of front cover
2	Front cover handle

2. Slide the cover downward until it is recessed into the receptacles.
3. Press down on the top of the cover to ensure posts snap into the receptacles.

   NOTE: Gaps should not exist between the DL and the cover. The bottom of the cover must nest into the work surface. The cover is securely seated when the DL door icon is no longer yellow.

Removing the DL Back Cover

1. Stop and unlock the DL back cover (Page 99 *Locking and Unlocking DL Covers*).
2. Place a hand under the DL back cover handle.



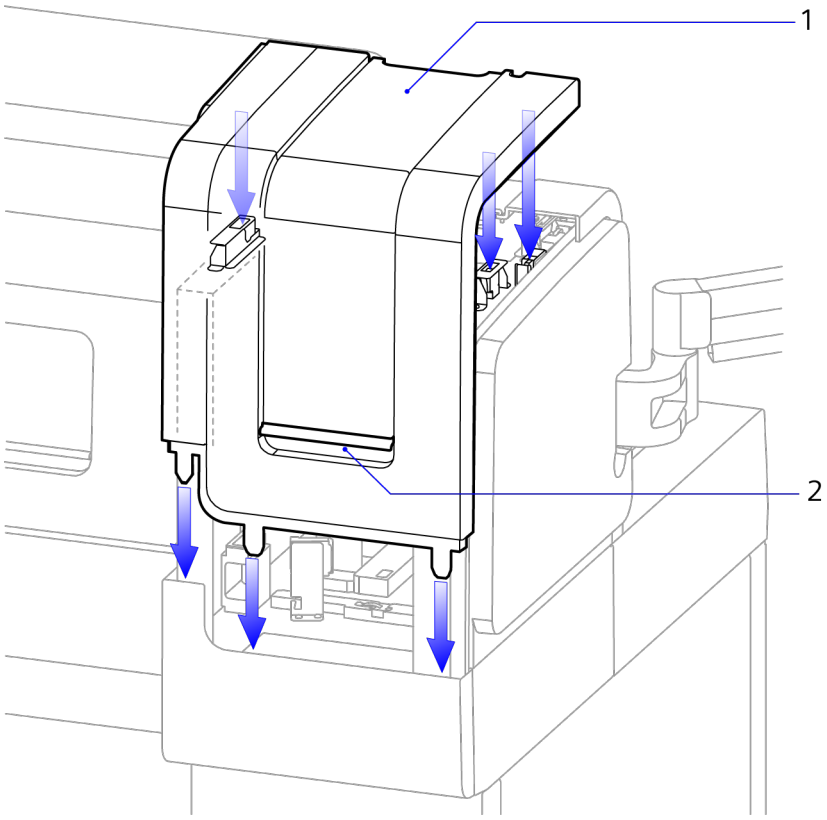
1	Top of back cover
2	Back cover handle

3. Place the other hand on the top of the cover for guidance.
4. Push the cover up and away from system.

   NOTE: When the cover is no longer securely seated, the DL door icon becomes yellow to indicate that the analyzer cannot process samples.
5. Set the cover aside.

Reinstalling the DL Back Cover

1. Grasp the DL back cover with 2 hands and place it firmly against the back of the DL assembly.



1	Top of back cover
2	Back cover handle

2. Slide the cover downward until it is recessed into the receptacles.
3. Press down on the top of the cover to ensure posts snap into receptacles.

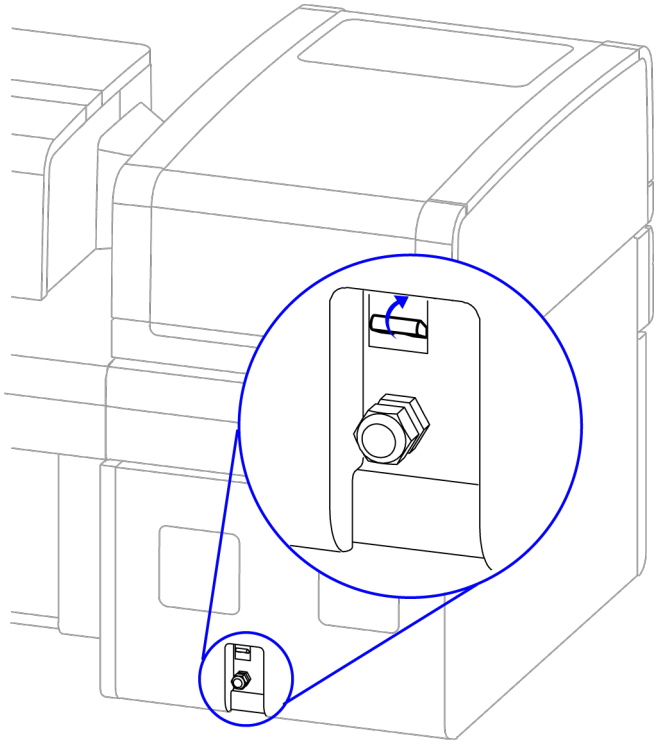
   NOTE: Gaps should not exist between the DL and the cover. The bottom of the cover must nest into the work surface. The cover is securely seated when the DL icon is no longer yellow.

Starting the SH

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling biohazardous materials can cause bodily harm.

1. Ensure Atellica Magline Transport is clear (Page 625 *Clearing the Atellica Magline Transport Prior to Startup*).
2. If appropriate, power on the SH Prime and wait 30–60 seconds before proceeding.



NOTE: The SH Prime is the SH closest to the analyzers. The SH Prime powers the PCC.

3. After power restores to the SH Prime, if appropriate, start the SHC (Page 680 *Starting the SHC*).
4. If appropriate, power on each additional SH power switch.
5. Initialize the SH drawers and completely open and close (Page 387 *Opening Sample Drawers*).
6. Sign in (Page 643 *Signing in to the System*).
7. If the SH was offline and refrigeration for the Cal/QC storage area was off, refer to the calibrator and QC material IFU for stability information and remove the contents of the Cal-QC storage areas, if appropriate (Page 671 *Unloading Cal-QC Tubes Manually*).
8. If QC is out of range after the system was shut down, discard the stored QC and replace with fresh QC material.
9. Confirm the contents of each SH Cal-QC storage areas.
10. If any SH does not start or any problems occur, contact the local technical support provider.

Shutting Down and Powering Off the SH Modules

1. If the SH modules are scheduled to be offline for an extended time, refer to the calibrator and QC material IFU for stability information and unload, if appropriate.

   NOTE: If QC is out of range when stored after the system was shut down, discard the stored QC and replace with fresh QC material.

2. If appropriate, power off the SHC (Page 681 *Powering Off the SHC*).

   NOTE: The SH Prime is the SH closest to the analyzers. Power off the additional SH module furthest from the SH Prime. Continue with each additional SH module. The SH Prime is powered down last.

3. Power off each additional SH module before shutting down the SH Prime:

   a. In System Status area, select the additional SH module.

   b. Select ⏻.

   c. If no tests are processing, select **Yes**.

4. Repeat step 2 with each additional SH module.

5. Power off SH Prime:

   a. In System Status area, select the SH Prime module.

   b. Select ⏻.

   c. If no tests are processing, select **Yes**.

6. To shut down the system:

   a. Select 👤.

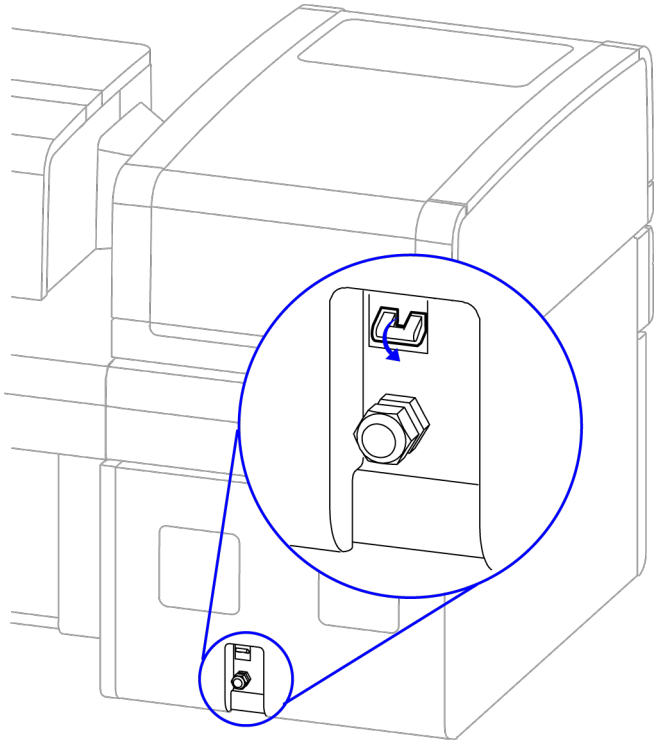
   b. Select 🔑.

   c. Confirm by selecting 🔑 then select **Yes**.

   d. Select **Shutdown > Yes.**

   NOTE: The system deletes pending calibration orders when the analyzer shuts down. Patient and QC orders remain.

7. When the primary user interface no longer displays, use the power switch to power off all SH.



8. Wait 30 seconds before restarting any SH module.

Unloading Cal-QC Tubes Manually

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling biohazardous materials can cause bodily harm.

CAUTION

Do not remove or switch sample containers through an open SH cover. The vision system does not identify samples the operator removes or switches through an open cover and may not process them. Only remove sample containers through the SH drawers.

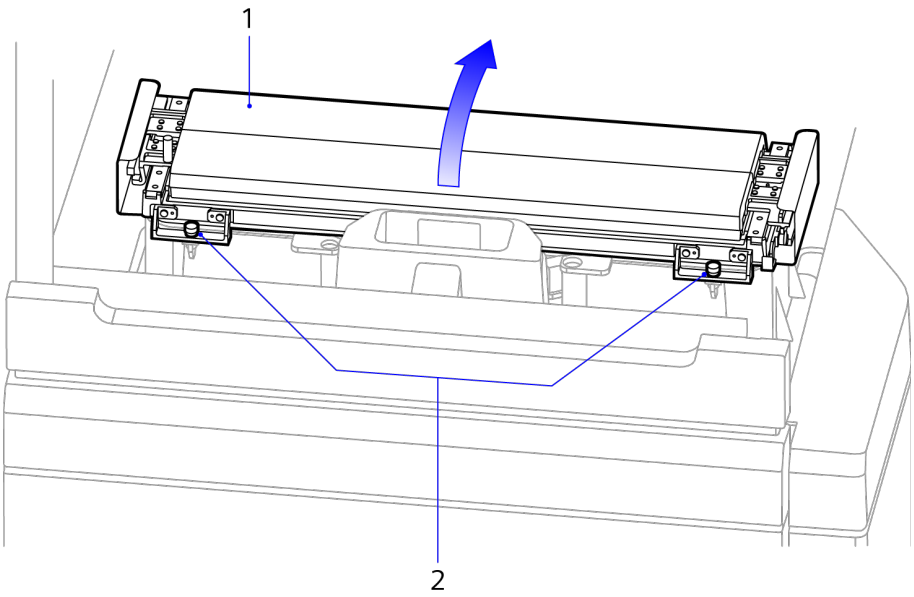
Perform this task only when the system is unable to unload tubes from the Cal-QC storage area using the robot, such as during a power failure or robot failure.

NOTE: Do not reload Cal-QC tubes manually. Only load Cal-QC tubes through the SH drawers.

1. If the system still has power:
   a. Stop the SH (Page 137 *Changing the Module Status*).
   b. Unlock the SH back cover (Page 93 *Unlocking SH Covers*).
2. Open the SH back cover.

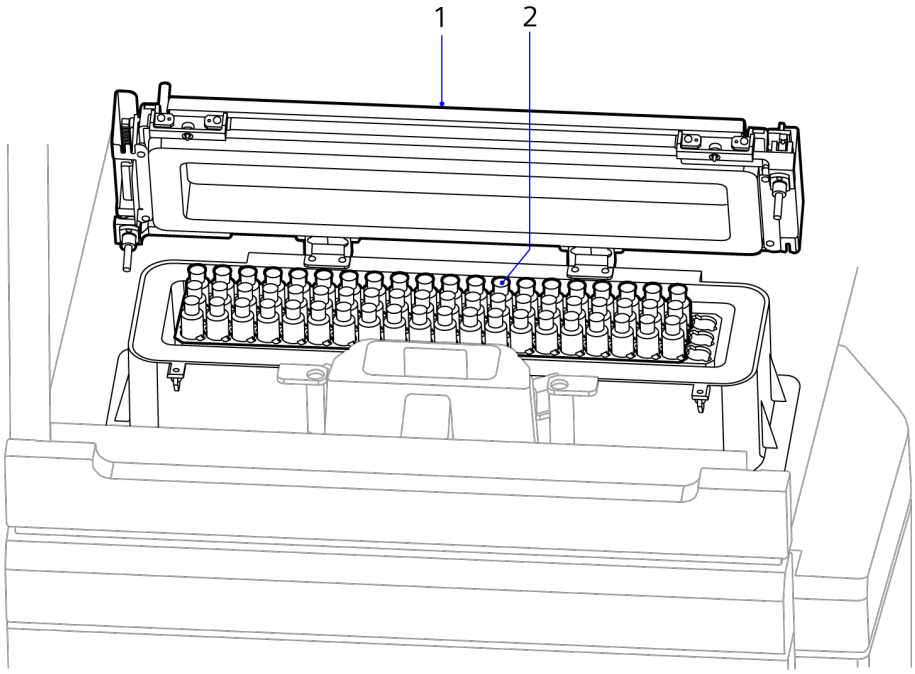
> **CAUTION**
>
> Do not hold the SH robot grippers or push the robot down when moving the robot manually. Holding the grippers to move the robot may damage the crash sensor. Moving the robot down may cause the robot grippers to impact another object, possibly resulting in damage to the robot gripper or sample container breakage. Only move the robot by holding the robot body, and keep the robot grippers clear of all obstacles.

3. Manually pull the SH robot (towards the operator) to the right-side, back corner of the SH.
4. Ensure the SH robot and cabling do not block the Cal-QC storage area cover.
5. Loosen the 2 thumbscrews on the back of the Cal-QC storage area cover.



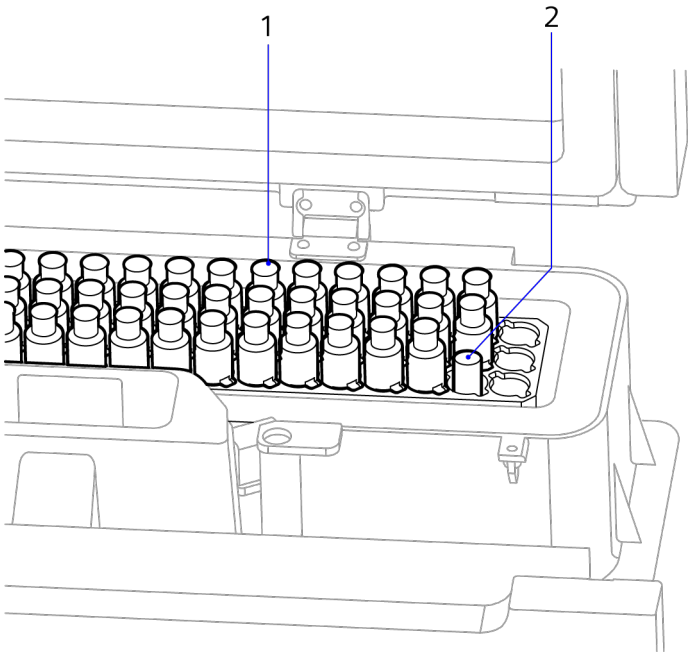
1	Cal-QC storage area cover
2	Thumbscrews

6. Rotate the Cal-QC storage area cover open.



1	Cal-QC storage area cover
2	Cal-QC tube covers

7. Remove all Cal-QC tubes from the storage area.

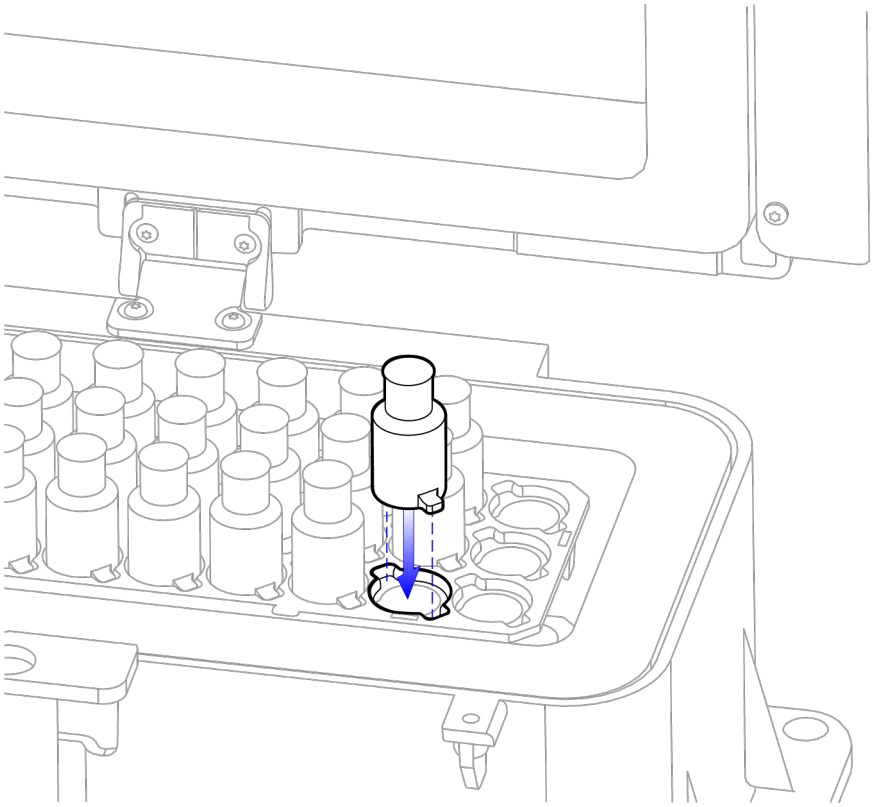


1	Cal-QC tube cover
2	Cal-QC tube

   a. Remove the Cal-QC tube cover.
   b. Place the Cal-QC tube cover aside.
   c. Remove the Cal-QC tube.
   d. Place the Cal-QC tube in a rack.
   e. Repeat steps a–d to remove all Cal-QC tubes.

8. If appropriate, clean the Cal-QC storage area.
   a. Wipe the Cal-QC storage area with lint-free tissues or gauze saturated with a 10% bleach solution.
   b. Wipe the Cal-QC storage area with lint-free tissues or gauze saturated with reagent water.
   c. Dry the Cal-QC storage area thoroughly with clean lint-free tissues or gauze.

9. Install all Cal-QC tube covers from left to right, leaving the 3 right-most positions empty (default configuration).



NOTE: Align the tabs on the tube cover so the cover properly seats in the Cal-QC storage area.

10. Close the Cal-QC storage area cover.
11. Tighten the 2 Cal-QC storage area cover thumbscrews.

SH Recovering from a Power Disruption

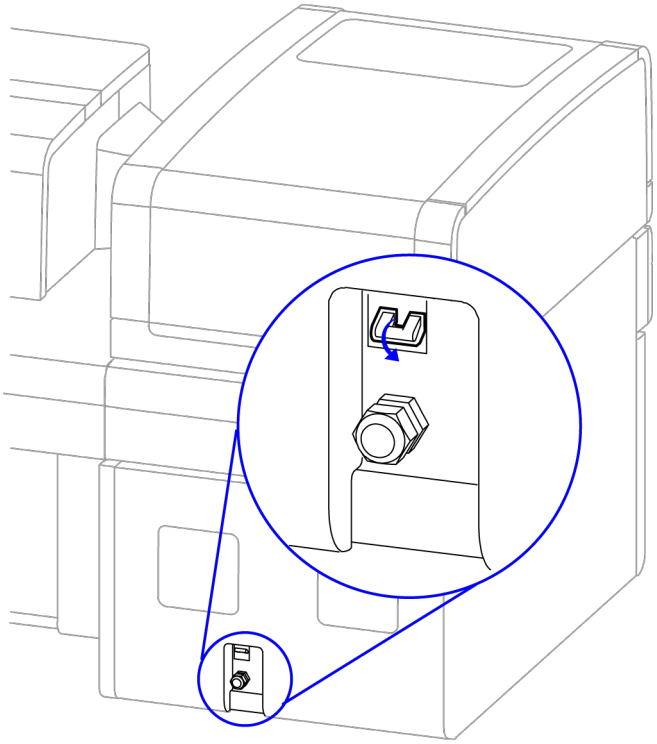
CAUTION

Do not leave a module's main power switch on during a power disruption. This can cause significant damage to the system when the operator restores power. When a power disruption occurs, turn off the main power switch for each module.

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling biohazardous materials can cause bodily harm.

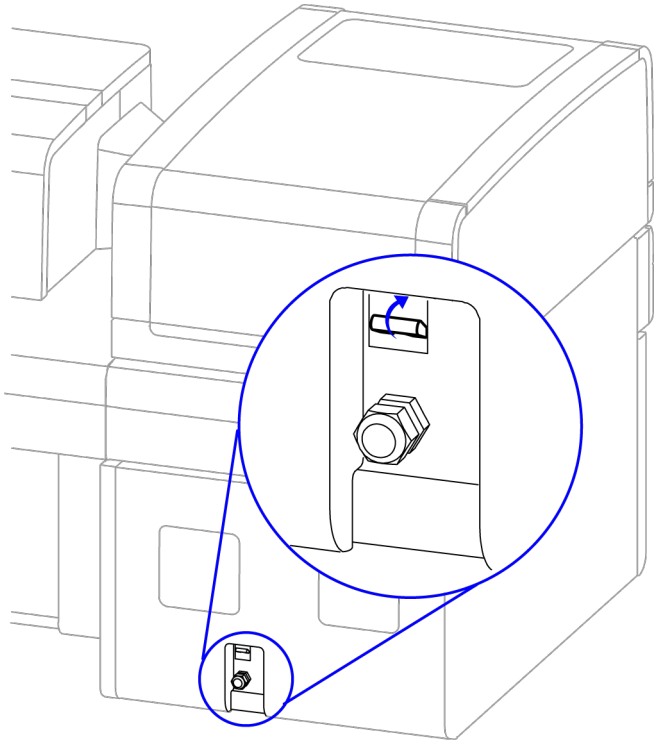
1. Ensure the SH Prime and additional SH module power switches are off.



NOTE: The SH Prime is the SH closest to the analyzers.

2. Ensure Atellica Magline Transport is clear (Page 625 *Clearing the Atellica Magline Transport Prior to Startup*).

3. Power on the SH Prime and wait 30 seconds before proceeding.



NOTE: The SH Prime powers the PCC.

4. If appropriate, power on additional SH and wait 30 seconds before proceeding.
5. After power restores to the SH Prime, if appropriate, start the SHC (Page 680 *Starting the SHC*).
6. If appropriate, power on each additional SH power switch and wait 30 seconds before proceeding.
7. Completely open and close the SH drawers (Page 387 *Opening Sample Drawers*).
8. Start the SH (Page 668 *Starting the SH*).
9. Confirm the contents of each SH Cal-QC storage areas.
10. If any SH does not start or any problems occur, contact the local technical support provider.

About Unlocking SH Covers Manually

When an SH power disruption occurs, the SH front and back covers may lock. The operator can manually unlock the SH covers to retrieve any samples or calibrator and QC materials from the SH.

NOTE: During a power disruption, the SH drawers unlock and make the sample containers in the drawers accessible.

Unlocking SH Covers Manually

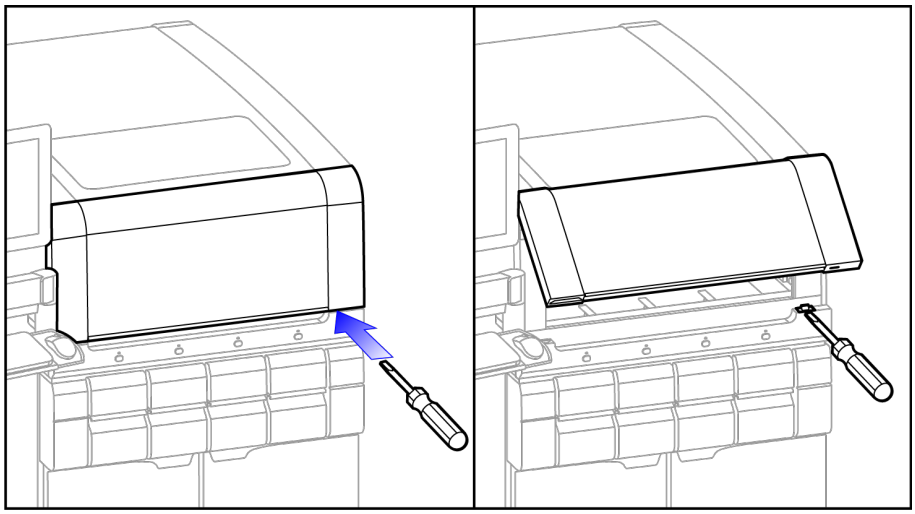


BIOHAZARD

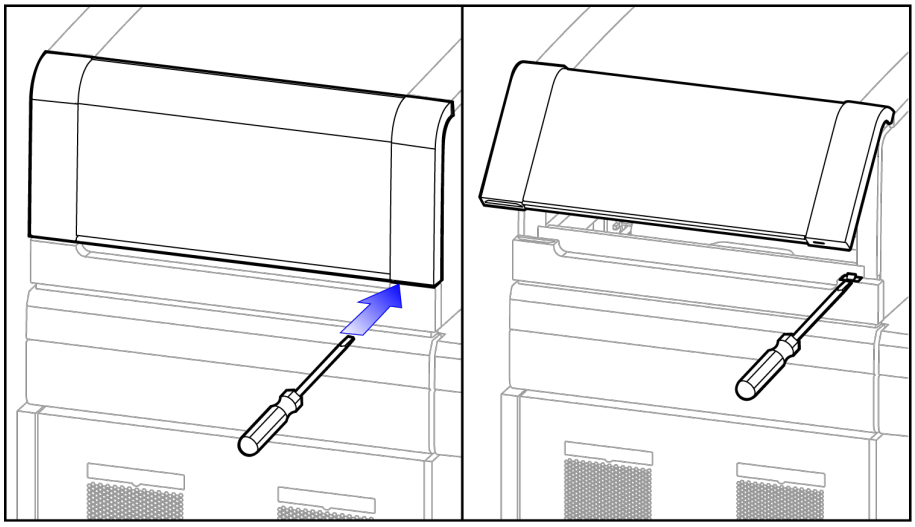
Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

Only perform this task during a power disruption, when the system may be unable to unlock the covers and the operator must manually remove samples or calibrator and QC materials from the SH.

1. To unlock the SH front cover manually:
   a. Insert the tip of a flat-blade screwdriver into the seam below the lower-right corner of the SH front cover.
   b. Press in against the cover lock.
   c. Open the SH front cover.



2. To unlock the SH back cover manually:
   a. Insert the tip of a flat-blade screwdriver into the seam below the lower-right corner of the SH back cover.
   b. Press in against the cover lock.
   c. Open the SH back cover.

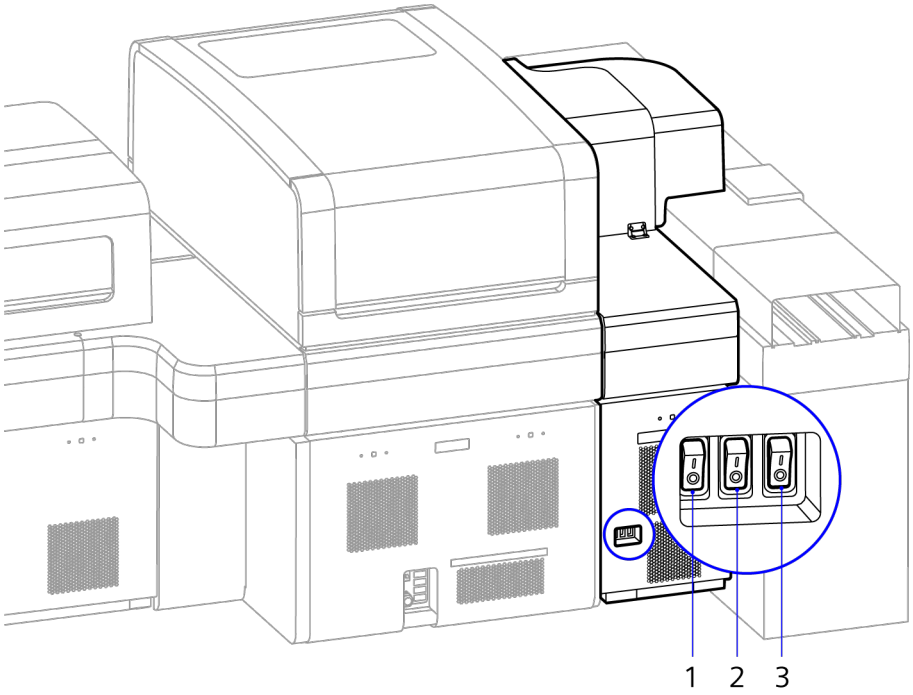


Starting the SHC

BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling of biohazardous materials can cause bodily harm.

1. Ensure all SHC power switches are in the off position.



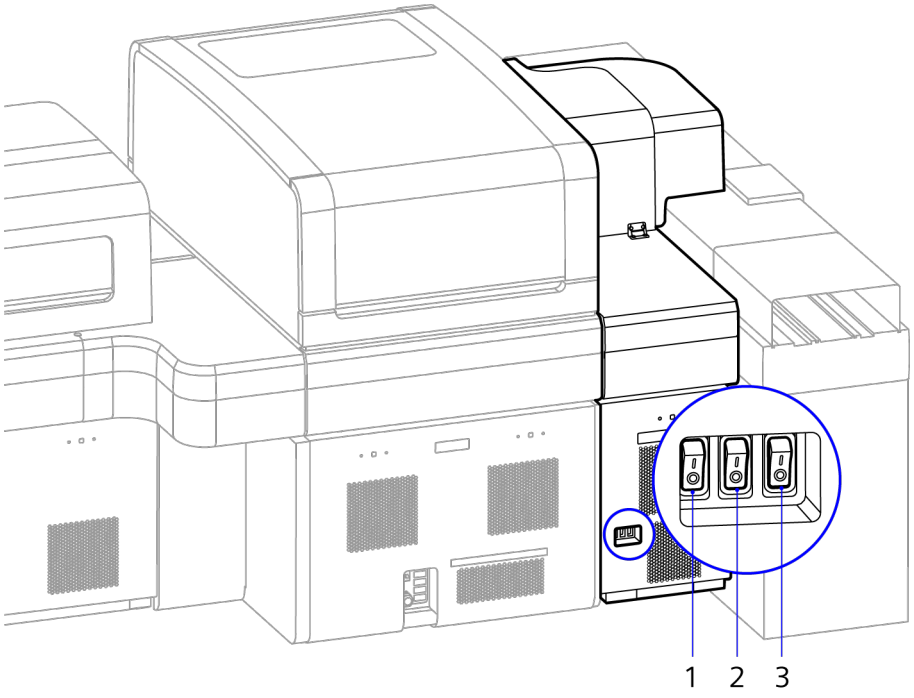
1	+24VDC power switch
2	+48VDC power switch
3	Computer power switch

2. Start the SH and wait 30–60 seconds (Page 668 *Starting the SH*).

3. Start the SHC:
   a. Power on the left +24VDC power switch and wait 10 seconds.
   b. Power on the middle +48VDC power switch and wait 10 seconds.
   c. Power on the computer power switch to the right.
4. If the SHC does not power on correctly:
   a. Power off the SH (Page 670 *Shutting Down and Powering Off the SH Modules*).
   b. Power on the SH (Page 668 *Starting the SH*).
   c. Repeat steps 1 and 3 to power on the SHC.

Powering Off the SHC

1. Turn off the SHC computer power switch.

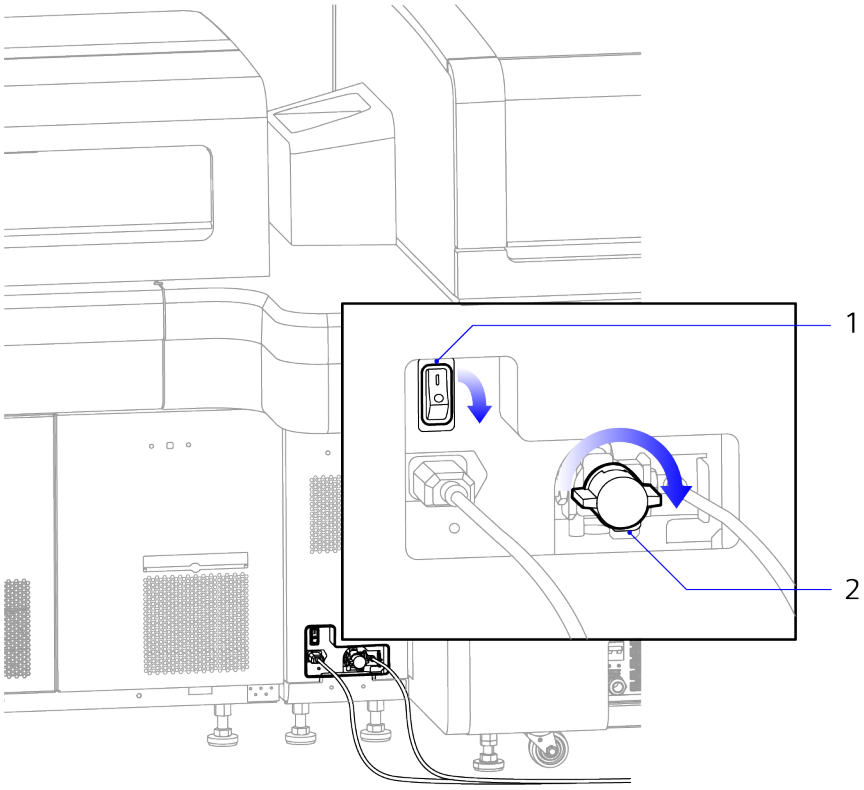


1	+24VDC power switch
2	+48VDC power switch
3	Computer power switch

2. Turn off the SHC +48VDC power switch.
3. Turn off the SHC +24VDC power switch.

Powering Off the Decapper

1. In the System Status area, select the Decapper module.
2. Select ■ then **Yes**.
3. Wait for Decapper to stop.
4. To shut down the Decapper, select ⏻.

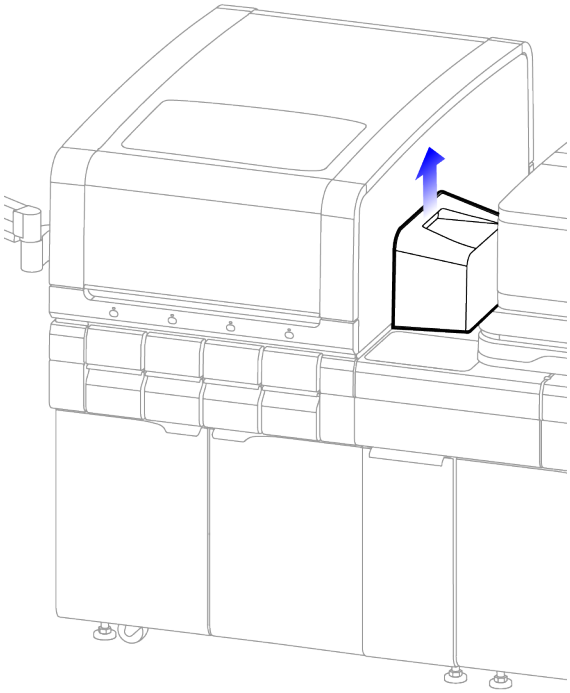


1 Power switch
2 Pressure valve

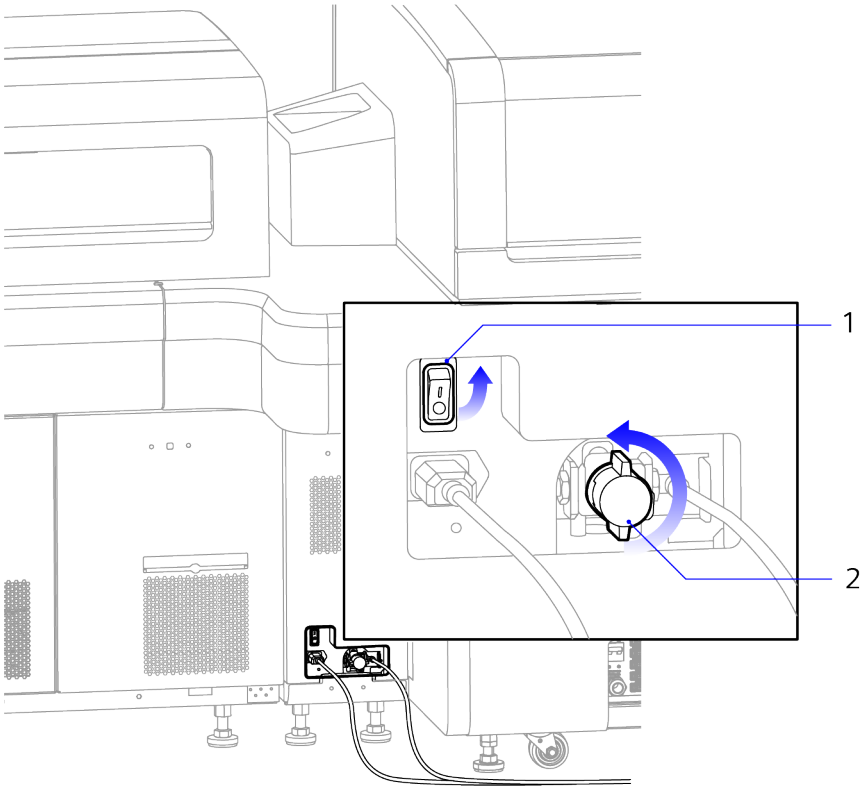
5. To shut off the pressure valve on the back of the Decapper, turn the valve clockwise.
6. Power off the Decapper.
7. Wait 30 seconds before powering on the Decapper (Page 683 *Powering On the Decapper*).

Powering On the Decapper

1. Lift the Decapper cover and ensure there are no tubes in the tube gripper.

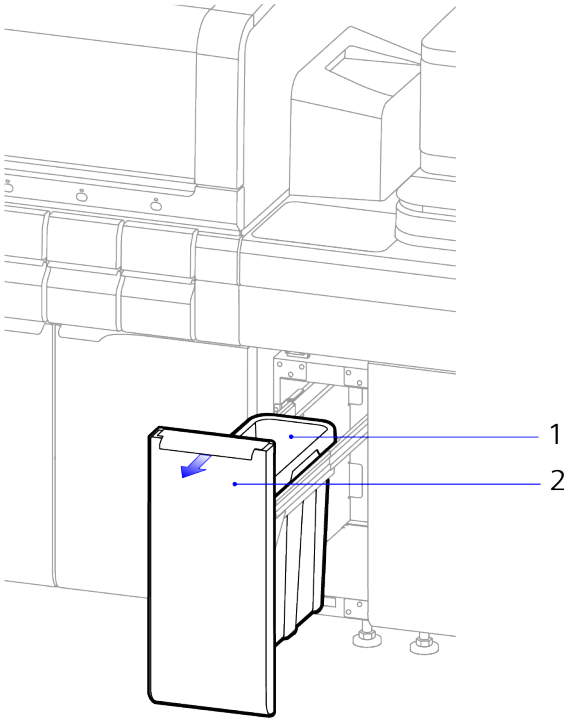


2. Reinsert the cover.



1	Power switch
2	Pressure valve

3. Ensure the cap waste bin is present.



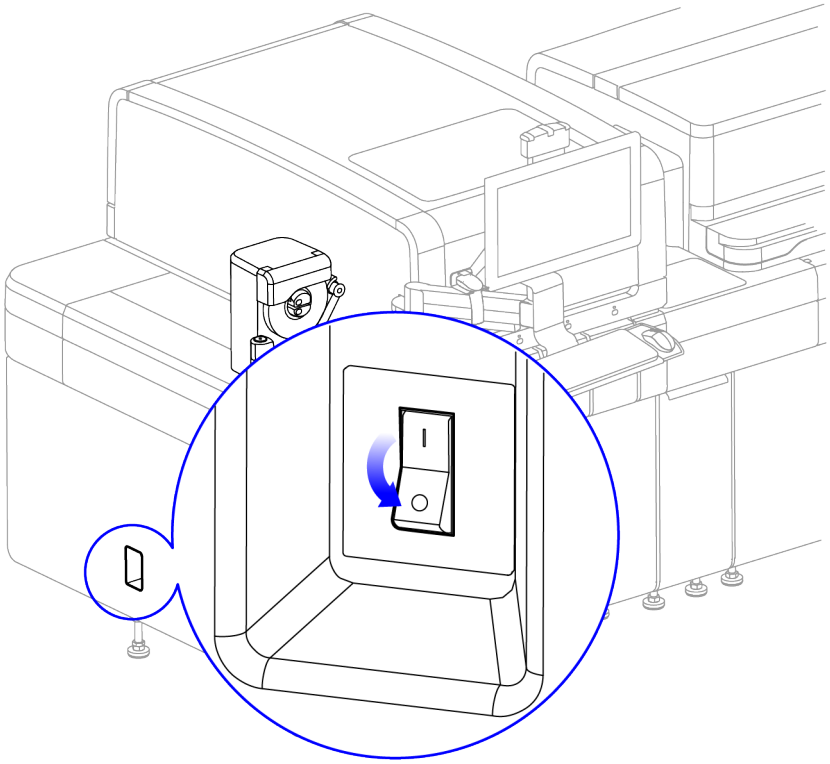
1	Cap waste bin
2	Cap waste drawer

4. Ensure cap waste drawer is closed.
5. To restore the pressure, turn the valve counter clockwise.
6. Power on the Decapper.
7. To resume the Decapper on the primary display:
   a. In the System Status area, select ▶.
   b. Wait ≤ 10 minutes for the Decapper to reconnect.

Powering Off the Sealer

1. In System Status, select the Sealer module.
2. Select ■ then **Yes**.
3. Wait for Sealer to stop.
4. To shut down the Sealer, select ⏻.
5. Wait 3 minutes for shut down to complete.

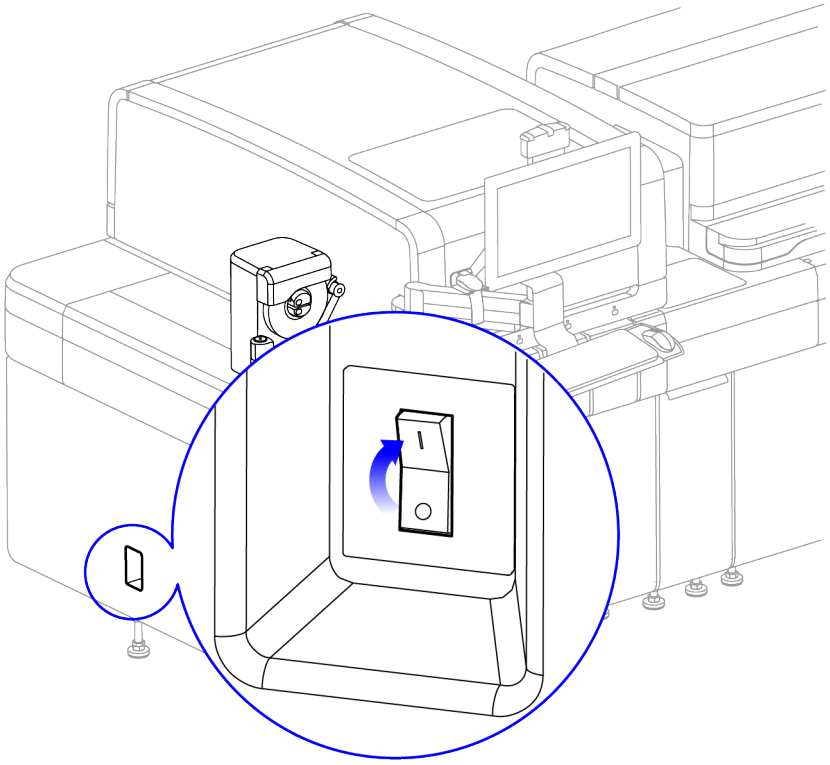
6. Power off the Sealer.



7. Wait 30 seconds before powering on the Sealer.

Powering On the Sealer

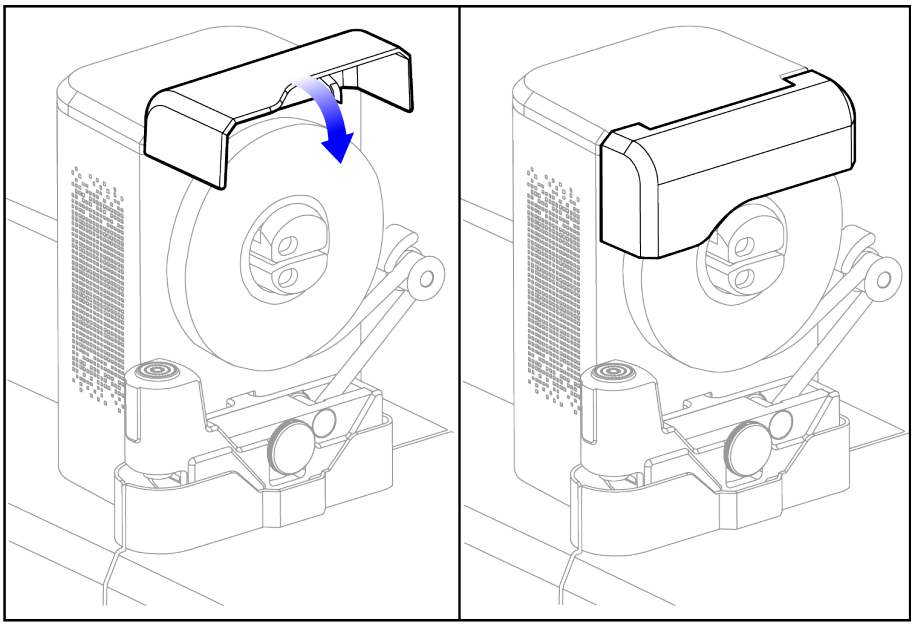
1. Remove the Sealer cover and ensure no tubes are in the sealer position.
2. Reinsert the cover.



3. Power on the Sealer.
4. To resume the Sealer on the primary display:
   a. In the System Status, select ▶.
   b. Wait ≤ 10 minutes for the Sealer to reconnect.

Closing the Sealer Foil Roll Cover

1. Close the foil roll cover.



2. If appropriate, resume the Sealer (Page 137 *Changing the Module Status*).

About Sealer Preventive Maintenance

The local technical support provider performs preventive maintenance on the Sealer every 140,000 cycles or once a year. Sealer Preventive Maintenance displays in Maintenance to inform the laboratory of the upcoming maintenance. The operator then schedules a date for service with the local technical support provider.

Maintenance Log records and stores this activity.

The local service provider performs the following:

- Cleans the foil cutter
- Cleans the primary and secondary crimper
- Cleans the foil track
- Cleans the foil feed sensor
- Cleans the foil rollers
- Visually inspects the Sealer

- General cleaning of surfaces
- Generates log files and uploads through SRS to Siemens Healthineers

Maintenance Log records and stores this activity.

About Remote Assistance

If appropriate, the local technical support provider connects directly to the system to initiate remote control, query system diagnostics, or retrieve database information. From the system, the operator uses to contact the local technical support provider to ask a question, request information, or troubleshoot issues quickly through an encrypted connection to ensure patient data privacy.

The operator initiates the request using 1 of the following:

- System display: Includes with chat, desktop-sharing, and file-sharing features.
- Operator tablet: Includes with video sharing, chat, camera, and audio features to send photos and audio with each service support request.

The operator can select from the following 3 workflows after selecting :

Service Support Request workflow	Notes
Create a Service Support Request	The operator generates a support ticket (Page 691 *Submitting Phone Call Back Service Requests*) (Page 692 *Submitting Chat Session Service Requests*). The local technical support provider calls by phone or text chat within a pre-configured minimum time directly on the display. The operator also has the option for the provider to call at a Preferred Time.
View Previous Tickets	The operator searches through existing tickets to view the status on reported issues (Page 694 *Viewing Service Support Tickets Opened through Service Support Requests*). Existing tickets are read only. Only tickets the operator opens via the on-system Service Support Request feature display here. The support tickets the local technical support provider opens do not display.
Start a remote session with no service support ticket creation	The operator initiates a support request by phone. The local technical support provider asks the operator to open a remote session while remaining on the phone (Page 694 *Starting Remote Sessions with No Service Support Ticket Creation*).

When the remote session is active, the TeamViewer window displays.

TeamViewer icons	Notes
	Initiates video from the operator to the support provider.
	Initiates chat session between operator and support provider.
	Initiates the Whiteboard for operator to highlight or draw on screens.
	Displays support provider is connected with IP address.
	Minimizes TeamViewer display.

TeamViewer icons	Notes
	Opens more details for each feature.
	Terminates remote service session. To initiate a remote session, a new passcode is required (Page 694 *Starting Remote Sessions with No Service Support Ticket Creation*).

Submitting Phone Call Back Service Requests

1. On the Tool bar, select .
2. To view open service support tickets for this module or system, select **Previous Tickets** (Page 694 *Viewing Service Support Tickets Opened through Service Support Requests*).
3. Select **Create a Service Support Request**.
4. Select the appropriate Module from the drop-down menu.

   NOTE: The operator can select only 1 module or system with each request. If the issue involves the UI, the entire system, or is not module specific, select the system.
5. Select 1 Severity:
   - Urgent Service Request - System is not able to process: An issue exists that has the highest priority, such as the system is offline or troubleshooting does not resolve the issue.
   - Service Request - System is partially operable: An issue exists with only 1 module and the system is online and functioning without that module.
   - Information Request: The system does not lose functionality but the operator requires a callback for guidance on operating the system, clarification of operator instructions, or an answer to a question.
6. In Callback Preference, select **Phone**.
7. In Preferred Time, enter the time or select and use arrows to set the time.

> **CAUTION**
>
> Do not use the operator's full name and personal phone number when submitting a request. Using personally identifiable information (PII) can violate Protected Health Information (PHI) rules. Use only the operator's first name and the laboratory phone number.

8. Enter the operator's first Name and the laboratory Phone Number.
9. Enter a Short Description and Problem Description.

> **CAUTION**
>
> Do not send screen captures or other files that include personally identifiable information (PII). Attaching files that include PII violate Protected Health Information (PHI) rules.

10. Select **Take Photo** to attach photos.
11. To attach an appropriate file to the ticket:
    a. Select **Add File**.
    b. Search and select the appropriate file.
    c. Select **Open**.

    NOTE: The operator can attach up to 10 files for a total uncompressed size of 1 GB to 1 service support ticket. The operator must attach all files prior to saving the ticket and cannot add attachments to a submitted ticket.
12. Select **Submit**.
13. Wait for confirmation that the request is completed.
14. To minimize Service Support Request window, select —.
15. Wait for the local technical support provider to call within the contract time or preference.
16. To disconnect from the remote session at any time, select ✕ then the remote session ends and the window closes.

Submitting Chat Session Service Requests

1. On the Tool bar, select .
2. To view open service support tickets for this module or system, select **Previous Tickets** (Page 694 *Viewing Service Support Tickets Opened through Service Support Requests*).
3. Select **Create a Service Support Request**.

4. Select the appropriate Module from the drop-down menu.

   NOTE: The operator can select only 1 module or system with each request. If the issue involves the UI, the entire system, or is not module specific, select the system.

5. Select 1 Severity:

   – Urgent Service Request - System is not able to process: An issue exists that has the highest priority, such as the system is offline or troubleshooting does not resolve the issue.

   – Service Request - System is partially operable: An issue exists with only 1 module and the system is online and functioning without that module.

   – Information Request: The system does not lose functionality but the operator requires a callback for guidance on operating the system, clarification of operator instructions, or an answer to a question.

6. In Callback Preference, select **Remote session with Chat**.

7. In Preferred Time, enter the time or select and use arrows to set the time.

   CAUTION

   Do not use the operator's full name and personal phone number when submitting a request. Using personally identifiable information (PII) can violate Protected Health Information (PHI) rules. Use only the operator's first name and the laboratory phone number.

8. Enter the operator's first Name and the laboratory Phone Number.

9. Enter a Short Description and Problem Description.

   CAUTION

   Do not send screen captures or other files that include personally identifiable information (PII). Attaching files that include PII violate Protected Health Information (PHI) rules.

10. To attach an appropriate file to the ticket:

    a. Select **Add File**.

    b. Search and select the appropriate file.

    c. Select **Open**.

    NOTE: The operator can attach up to 10 files for a total uncompressed size of 1 GB to 1 service support ticket. The operator must attach all files prior to saving the ticket and cannot add attachments to a submitted ticket.

11. Select **Submit**.

12. Wait for confirmation that the request is completed.

13. To minimize Service Support Request window, select —.
14. Wait for the local technical support provider to call within the contract time or preference.
15. To disconnect from the remote session at any time, select ✕ then the remote session ends and the window closes.

Starting Remote Sessions with No Service Support Ticket Creation

The operator initiates a support request by phone. The local technical support provider asks the operator to open a remote session while remaining on the phone.

1. On the Tool bar, select .
2. Wait for the Passcode to display.

   NOTE: If a Passcode does not generate, an error message displays. Inform the provider on the phone that no Passcode generated.
3. Give the 4-digit Passcode to the provider on the phone.
4. Wait for the local technical support provider to begin the remote session:
   a. Read warning message and select **Unlock**.
   b. Sign in.
   c. To confirm service provider remote session access, select **Allow**.

   NOTE: When the remote session is active, TeamViewer displays.

Viewing Service Support Tickets Opened through Service Support Requests

Only tickets the operator opens via the on-system Service Support Request feature display here. The support tickets the local technical support provider opens or the customers add through a call to their local technical support provider phone do not display.

1. On the Tool bar, select .
2. Select **Previous Tickets**.
3. Review previous tickets.
4. To close, select ✕.

Contacting the Local Technical Support Provider

1. To start a service support request, select on the Tool bar (Page 689 *About Remote Assistance*).
2. To contact support via phone, locate the local technical support contact information on the system.

Information for Technical Assistance

When calling for technical assistance, have the following information available:

- System name and serial number (Page 695 *Locating the Module Friendly Name and Serial Number*).
- System version (Page 695 *About System Software Version Information*)

Locating the Module Friendly Name and Serial Number

1. Navigate to **Modules**.
2. Locate the Friendly Name.
3. For each Friendly Name, locate the Module Serial Number.

   NOTE: The serial number of the SH Prime or the DL is the serial number of the system.

About System Software Version Information

Locate the system software version before contacting the local technical support provider. The system software version is located in the following areas:

- Lower right corner.
- Navigate to **General > About**.

NOTE:

In Software Information, locate:

- Siemens Healthcare Diagnostics Atellica®
- Siemens Healthcare Diagnostics Atellica® Release Version

Troubleshooting LIS

The following tables address troubleshooting for common LIS issues, as well as issues specific to the ASTM and HL7 protocols:

There are delays in automatic Worklist requests. Wide gaps exist between cuvettes in the track because 1 or more minutes separates each sample ID query from the system.

Possible Causes	Corrective Actions
Termination record does not close the query.	Use a value of "F" in the Termination Code field of the termination record to close the sequence of messages the LIS sends to the system in response to each query: L|1|F
LIS slow response to the query.	Contact the LIS Administrator to check the parameters at the LIS.

Invalid Test Order: The system receives a valid order for a test. The accepted Worklist entry does not display in Test Results.

Possible Causes	Corrective Actions
Test is not enabled. The test is not enabled at the Assay List screen.	1. Open the event log for additional details. 2. At the Assay List screen, enable the test. The operator should not request disabled or undefined tests.

Rejected Test Request for Control Sample: The system rejects a request for a test on a control sample.

Possible Causes	Corrective Actions
The SID field of the order record and the Control Name and Control Lot Number fields of the manufacturer's order record do not match the corresponding fields on the system.	The system transmits a comment record explaining this condition to the LIS. Compare the responses from the system to the messages from the LIS.

Rejected Test Order for Patient Sample: The system rejects an order for a test on a patient sample.

Possible Causes	Corrective Actions
The order record does not contain the SID or Rack ID. The SID or Rack ID is required.	Enter the SID or Rack ID for the patient sample in the order record.
For a control-bracketed test, the order record does not contain the SID. Control-bracketed tests require an SID in the order record.	Enter the SID for the patient sample in the order record.
The patient SID entered is the same as the SID defined for a control or a calibrator.	Check the SID for the patient sample. Edit the SID in Worklist so that it is not the same as the SID for the control or the calibrator.
The SID is in use by a QC sample or calibrator.	Specify a different SID.
The Rack ID is in use by an active sample.	Specify a different Rack ID and position.
The system specifies the Rack ID but does not specify a rack position.	Specify a Rack ID and position.
The LIS has sent a duplicate test. The requested test is already Inprocess.	No action necessary as the test is already performing on the analyzer.

Test Results Transmitted with Wrong Test Name: The system sends the incorrect test name for the selected test results for a particular test.

Possible Causes	Corrective Actions
The operator uses the LIS Code defined for the test in place of the test name in the Universal Test ID field of the result record.	Enter the correct LIS code.

Result Reporting is Malfunctioning: The result reporting is malfunctioning.

Possible Causes	Corrective Actions
The results are not reportable. The system only flags final results for control and patient samples with Sample IDs (SIDs) that do not have a Signal Error or a No Calculation.	Correct the conditions causing the flags and use SIDs in Worklist.
The Automatically Send All Patient Results Except Results on Hold option for result reporting is not enabled.	In LIS Configuration, select **Automatically Send All Patient Results Except Results on Hold**.
The system is holding test results for operator review and release.	Release the results.
QC result settings is not selected.	Enable QC result settings.
The option to Send All Results Per Sample is selected and a test is not complete.	Wait until all tests are complete.

Cannot Start LIS Communication: The system and the LIS are not communicating.

Possible Causes	Corrective Actions
The wrong protocol is selected.	Select proper protocol in LIS Configuration.
The network cable between the system and the LIS is not connected correctly.	If the communication channel is TCP/ IP, check the network cable. Ensure that the network cable is connected correctly.
The system and the LIS communication parameters do not match.	Ensure that the settings in LIS Configuration match the LIS Configuration.

Possible Causes	Corrective Actions
The cable between the system and LIS is damaged.	Replace the cable.
The LIS port is malfunctioning.	Call for technical assistance.
The connecting port on the LIS is not enabled.	Enable the connecting port on the LIS.
The LIS connection is not enabled.	Enable the LIS and switch the LIS online.
The active database, historical database, or QC statistics databases are full to capacity.	Delete samples from the database.
The incorrect protocol is selected.	Select the appropriate protocol.
Incorrect port configuration.	Configure the port to match the LIS.
The incorrect IP address is specified.	Specify the LIS IP address.
No network connection exists.	Establish the network connection by navigating to **LIS Configuration > Physical Layer**.
Incorrect physical layer setting (ASTM only).	Select the proper physical layer.

Existing QC Order in System: A new patient order matches the existing QC order.

Possible Causes	Corrective Actions
The system receives a Patient order from the LIS with an SID that matches the control ID of an existing QC order, and it issues a message in the Event Log and notifies the host LIS.	Create a new patient order with a different SID.

Control Definition Not Found: The control material definition cannot be found for a Control order.

Possible Causes	Corrective Actions
The system receives a Control order from the LIS, but when the control material definition cannot be found, and the system issues a message in the Event Log and notifies the host LIS.	Verify the LIS if the control ID is correct. If incorrect, check the system for a control material definition. If a control material definition does not exist, create it.

Canceled Worklist Requests (ASTM only): An operator requests a Worklist but the system cancels the query before it is complete.

Possible Causes	Corrective Actions
Query Timeout: If the response from the LIS requires more than 5 minutes to complete and the query timeout is set to 5 minutes, the query timer expires and the system sends a query cancellation to the LIS.	The query timeout is too short or the LIS does not indicate that it sends order records in response to a query. A value of O\Q in the Report Type field of an order record indicates that the record is requesting tests in response to a query. The system resets the query timer every time it encounters a value of Q in the Report Type field of an order record. The system ignores all received result records. Each time the query timer expires, the system sends a message to the LIS that cancels the query. Replace **O** with **O\Q** in the Report Type of order record and in Result Status of the result record.

Message Received Caused Fatal Parse Error (ASTM only): The system receives a message that causes a fatal parse error. The logged event is for an unexpected sequence number.

Possible Causes	Corrective Actions
The system sends an incorrect sequence number with the application layer record.	Contact the LIS Administrator to verify the LIS format.

Invalid ASTM Record Type Received (ASTM only): Only some of the information in a patient record displays in the Worklist, and the Event Log displays that the system has received an invalid ASTM record type.

Possible Causes	Corrective Actions
Inactive tests: Not all of the tests in the patient order record are active.	Verify the status of the tests in the patient order record at the Test – Summary window. Activate the test, if appropriate.
Transmission Interference: the system receives invalid records due to transmission interference.	The cable between the system and LIS is damaged. Check the continuity of the wires. Replace the cable, if appropriate.
Carriage Return: A carriage return (<CR>) is embedded in the demographic data in the fields of the patient record. This truncates the application layer record and the system interprets the remainder as another record.	1. Remove the <CR> from the demographic data fields of the patient record. 2. Use ASTM escape sequences for any required carriage returns.

Unexpected Data Received in Response to a Query (ASTM only): The LIS receives unexpected data from the system in response to a query.

Possible Causes	Corrective Actions
The query record is invalid.	Review the protocol for query records and revise the record.

Delay Between Messages Sent by system (ASTM only): An extended period of time elapses between messages the systems sends.

Possible Causes	Corrective Actions
The LIS does not terminate its query responses with an F, Q, or I code in the Termination Code field of the termination record.	Terminate queries with the appropriate termination code.
The connecting port on the LIS is not enabled.	Enable the connecting port on the LIS.

Possible Causes	Corrective Actions
The LIS is not terminating its last session at the data link layer.	Always use a terminate session message to relinquish line control when a session is complete.
The cable between the system and LIS is not correctly connected.	Properly connect the cable.
The cable between the system and LIS is damaged.	Check the continuity of the wires with a breakout box. Replace the cable, if appropriate.
The system and LIS communication parameters do not match.	Check for multiple character errors. Ensure that the settings at the LIS Configuration window match the LIS configuration.

Parsing Error (HL7 only): The system records a parsing error.

Possible Causes	Corrective Actions
The message is not structured according to HL7 protocol.	Review the protocol and adjust the message structure.

About Online Help

CAUTION

Do not operate the system without the most recent version of online help installed. Using the system without online help could lead to system or operator errors. Ensure the most recent version online help is installed prior to operating the system.

The online help includes procedures for setting up and operating the system, event help, troubleshooting, and maintenance. Animations are available for some hardware maintenance tasks. The operator can access the online help using the ? on the Tool bar.

On the Tool bar, ? is accessible from every feature and is context sensitive. Selecting ? accesses links to help topics specific for that area.

For certain windows, selecting the additional ? in the bottom left opens the help topics specific to that window.

Accessing Online Help

1. To view complete Online Help:
   a. Navigate to **Online Help**.
   b. To view related Online Help topics, search for or select the appropriate topic from the Table of Contents on the left side of the window.
2. To review Online Help specific to the current window:
   a. Select ? on the bottom-left corner of the window.
   b. Review the specific Online Help that displays or select the appropriate topic from the Table of Contents on the left side.

About Operator Diagnostics

Operator Diagnostics allows the operator to manually manipulate the module during maintenance or troubleshooting. Certain diagnostic procedures require the operator to manually move hardware, initialize, prime, and open and close covers. The operator can safely enter the module into a diagnostic state, halting the mechanics to perform these procedures. The operator exits the diagnostic state after the maintenance or troubleshooting is complete.

Operator Diagnostics is an option in Troubleshooting.

Operator Diagnostics	Notes
Subsystems	Filters the diagnostic procedures according to the module.
Diagnostic Name	Displays the subsystem task.
Description	Describes the subsystem task.
Perform	Starts the selected diagnostic task.
Cancel	Cancels the selected diagnostic task.
Status	Displays when IM Analyzer is selected. Re-displays an IM Analyzer diagnostic task progress window that is closed.
Enter Diagnostics	Enters the module into the diagnostic state so the operator can safely perform manual maintenance.

Operator Diagnostics	Notes
Exit Diagnostics	Exits the diagnostic state after completing maintenance or troubleshooting.
Turn Mechanics On	Displays when IM Analyzer is selected. Engages all IM Analyzer mechanical components.
Turn Mechanics Off	Displays when IM Analyzer is selected. Disengages all IM Analyzer mechanical components.

Enter Diagnostics State in CH Operator Diagnostics

1. Navigate to **Troubleshooting > Operator Diagnostics**.
2. In Select a Module, select the appropriate CH Analyzer.
3. Select **Enter Diagnostics > Yes**.
4. Wait for the analyzer to enter diagnostic state.

Entering the Diagnostic State

1. Navigate to **Operator Diagnostics**.
2. Select the appropriate module.
3. Select **Enter Diagnostics > Yes**.
4. Wait for the module to enter the diagnostic state.

Entering Diagnostics State in SH Operator Diagnostics

1. Navigate to **Troubleshooting > Operator Diagnostics**.
2. In Select a Module, select the appropriate SH.
3. Select **Enter Diagnostics > Yes**.
4. Wait for the SH to enter diagnostic state.

Resetting the SH Front and Back Covers in Operator Diagnostics

Updates the system's status of the SH frame covers with the physical status of the covers.

1. Close and lock the front and back SH covers (Page 92 *Locking SH Covers*).
2. Enter diagnostics (Page 704 *Entering Diagnostics State in SH Operator Diagnostics*).
3. In Select a Module:, select the appropriate SH.
4. Select **Subsystems > Covers**.
5. Select **Resetting the Front and Back Cover**.
6. Select **Perform > Yes**.
7. Ensure the front and back covers are physically closed and locked.

   NOTE: This diagnostic activity does not check if the covers are physically closed and locked.
8. Select **Continue** and wait for the activity to complete.
9. Select **Exit Diagnostics > Yes**.
10. To resume the module if in stopped state, select ▶ (Page 137 *Changing the Module Status*).

Entering Diagnostics State in Atellica Magline Transport Operator Diagnostics

1. Navigate to **Troubleshooting > Operator Diagnostics**.
2. In Select a Module, select the Atellica Magline Transport.
3. Select **Enter Diagnostics > Yes**.
4. Wait for the Atellica Magline Transport to enter the diagnostics state.

Entering Diagnostics State in SHC Operator Diagnostics

1. Navigate to **Troubleshooting > Operator Diagnostics**.
2. In Select a Module, select the appropriate SHC.
3. Select **Enter Diagnostics > Yes**.
4. Wait for the SHC to enter diagnostic state.

About Log Files

The following log files are available in Troubleshooting:

Log file	Notes
LIS Logs	Displays information about the communication between the system and the LIS (Page 710 *About the LIS Log*)
Operator Event Log	Displays information about events that may affect system processing (Page 706 *About the Operator Event Log*)
System Message Log	Stores information about all system events (Page 710 *About the System Message Log*)

The following log files are available in Utilities:

Log file	Notes
Audit Trail Log	Stores all information related to auditable actions (Page 710 *About the Audit Trail Log*)
Lot Log	Stores all the lot information for consumables and supplies (Page 311 *About Lot Log*)

The following log file is available in Maintenance:

Log file	Notes
Maintenance Log	Displays a record of the most recently performed maintenance activities (Page 609 *About Exporting Maintenance Log*)

About the Operator Event Log

This feature requires the appropriate security level.

The laboratory uses the Operator Event Log in Troubleshooting to view events that may affect system processing and access troubleshooting help to resolve the events. By default, the log lists the events in reverse chronological order, with the most recent events at the top.

The Operator Event Log has a collapsible Filter and the main log area. The Filter enables the operator to reduce the number of events that display by specifying operator-defined criteria.

The top of the main Operator Event Log displays the currently applied Filter and Search tools that enable the operator to input a text string into a text box. The system highlights all entries that match the text string and the operator can use  or  to move up or down through the entries that match the text string. The operator can also use the check box to Only Show Found Results and display only the entries that match the text string.

The bottom of the log area provides page navigation icons. The operator can select the page number to navigate directly to a different page or and to move sequentially backward or forward through the pages. The number of available pages depends on the filters that the operator has set.

NOTE: If the Operator Event Log has only 1 page of data, then no page numbers display.

Each event entry on the Operator Event Log includes the following attributes:

Attribute	Notes
Severity	Provides an icon that indicates the severity of the event: •  represents an error condition An error condition is the most severe event and requires nearly immediate operator action or attention. Failure to address the error condition in a timely fashion could be hazardous to patient health. • represents a warning condition A warning condition has a medium severity. The operator should resolve the warning condition in the near future to maintain system operation. **NOTE:** Informational events do not have a severity indicator. These events have the lowest severity and typically provide information about the system operation.
Module	Indicates the part of the system on which the event occurred. **NOTE:** The attribute includes the unique portion of the serial number for the appropriate Module.

Attribute	Notes
Code	Provides the unique number 9-digit number that the system assigns to the event. The first 2 numbers indicate the Module on which the event occurred: • 00 is for Data Manager events • 03 is for IM Analyzer events • 04 is for CH Analyzer events • 05 is for Sample Handler events • 06 is for System Manager events • 07 is for Atellica Magline Transport events • 08 is for Software Planner events • 09 is for Direct Load events • 10 is for Sample Handler Connect events • 13 is for Decapper events **NOTE:** The Code is useful for filtering the events.
Event	Provides a short description of the event.
Date	Indicates the date and time the event occurs.
	Enables the operator to add a comment. **Note:** The icon changes to  if the event already has a comment.
	Launches the online help. The help opens to the page with the troubleshooting for the selected entry.
Cycle	Indicates the number of aspirations the system has completed.
Subsystem	Indicates the area of the Module or analyzer that caused the event.
Operating Mode	Indicates the status of the system when the event occurred.

NOTE: After selecting an event, a pane opens below the main log that provides Additional Details about the event.

The Operator Event Log also includes the following functionality:

Functionality	Notes
Export	Saves the Operator Event Log as a .TXT or .XML file to a specified location
System Details	Indicates the configuration at the time that the system issued the message
 *	Enables the operator to print a copy of the log or save the log as a .PDF file

* indicates that the Print functionality is on the Tool bar.

By default, all Groups have Full Control to the Operator Event Log and its features. Only operators in the G1 Group can modify the access level for other Groups (G2, G3, G4, and G5).

NOTE: The available access level is Full Control or No Access. Read Only access is not available for this feature.

The system records an audit trail record when an operator restores a backup of the Operator Event Log.

Viewing the Operator Event Log

This task requires the appropriate security level.

1. Navigate to **Operator Event Log**.
2. To clear an applied Filter, select  in the text box of the Filter.
3. To view a subset of the events, use the Filter.
4. To collapse the Filter, select  .

   NOTE: Some attributes in the Operator Event Log only display if the Filter is collapsed.
5. To further limit the events that display:
   - Enter the appropriate alphanumerical characters in the text box for Search Filtered Data.
   - Select the page navigation tools to move through the Operator Event Log.

About the System Message Log

The System Message Log collects information on all system events. The operator can filter and export the System Message Log to technical support for troubleshooting system errors.

About the LIS Log

The LIS Log window displays information about the status of communication between the system and the LIS, and the LIS Configuration settings. The operator can turn on and configure Capture settings from the LIS Log window. The operator must turn Capture ON to collect information for the LIS Log.

Viewing LIS Log Messages

1. Navigate to **LIS Log**.
2. If appropriate, select a log file from the Log Files drop-down list.

About the Audit Trail Log

This feature requires the appropriate security level.

The laboratory uses the Audit Trail Log in Utilities to view auditable actions that affect the following:

- Patient health information
- Assay test definitions
- System configurations
- Other auditable system activities

The entries in the log are in ascending or descending order by Date. Each entry includes the following attributes:

Attribute	Notes
Category	Identifies the functional area where the action occurred. **NOTE**: The Audit Trail Filter provides a listing of all functional areas.
Operator ID	Identifies the operator who performed the action. **NOTE:** When the system performs the action, the Operator ID is the System.

Attribute	Notes
Group	Identifies the level of access that the operator has to the system (Page 840 *About Groups*). **NOTE:** If the Operator ID is the system name, the Group is blank.
Date	Identifies the Date and Time that the action occurred.
Message	Provides a short description of the action.

The Audit Trail Log has a collapsible Filter that enables the operator to reduce the number of entries that display on the log according to operator-defined criteria. The operator selects > or < to expand or collapse the Filter as appropriate.

The top of the Audit Trail Log shows any currently applied filters. The operator can select the  or  icon to remove the filters and display all entries. The Audit Trail Log also includes Search tools that enable the operator to search for entries that match an operator-provided text string.

NOTE: Operators use the or icons to highlight each entry that matches the text string. Operators can also use the check box to Only Show Found Results and display only the entries that match the text string.

The Audit Trail Log has the following functionality:

Functionality	Notes
Archive	Stores the log in a secure location on the system
Print	Enables a written record of the log
Export	Moves the log to an off-system location

The Audit Trail Log has a capacity of 60,000 entries. When the log is near capacity, the system posts a message to the Operator Event Log. The operator can reduce the current entry count by archiving the log.

NOTE: If the Audit Trail Log is at capacity and the operator has not yet archived it, the system begins to delete entries to create room for new entries. The system then posts a message every day to the Operator Event Log requesting the operator archive the Audit Trail Log until the log is archived.

The Audit Trail Log is a securable entity, requiring the operator to have the appropriate access level.

Access level	Notes
Full Control	Has access to all features
Read Only	Has access to all features, except the Export functionality
No Access	No access to the log

By default, all Groups have Full Control to the Audit Trail Log and its features.

Viewing the Audit Trail Log

This task requires the appropriate security level.

1. Navigate to **Audit Trail Log**.
2. To view only entries that meet specific criteria, filter the log.
3. To find entries that match specific text, use the tool to Search Filtered Data.
4. To sort the entries in the reverse chronological order, select the Date column header.

19 Test Definitions

About Test Definition

Test Definition provides access to the following features:

Feature	Notes
Assay List	Enables or disables the assays on the system or analyzer.
CH Test Definition	Enables the viewing and editing of CH assay parameters.
IM Test Definition	Enables the viewing and editing of IM assay parameters.
Off-System	Enables the viewing, defining, and editing of Off-System tests.
Operator-defined	Enables the configuration of operator-defined CH assays.
Panels	Enables the viewing, defining, and editing of dilution and test panels.
Ratios	Enables the viewing, defining, and editing of ratio tests.
Advanced Reflex Groups	Configures the reflex tests for assays based on a set of operator-defined conditions.
Test Display Order	Customizes the order that tests display on the system.

About Advanced Reflex Groups

This feature requires the appropriate security level.

Advanced Reflex Groups defines up to 3 reflex tests for assays based on a set of operator-defined conditions. All conditions must be valid before the system performs the reflex tests. Reflex tests display in Worklist. The operator can set up a reflex test from one assay to another in Ranges in test definitions.

NOTE: Contact the local technical support provider to change the default settings.

Reflex Group Setup	Notes
Group	Reflex groups contain up to 3 conditions to perform up to 3 reflex tests. Maximum number of reflex groups is 30.
Test Name	Drop-down menu of available assays and ratio tests the operator adds to the group for reaction logic. Dilution profiles, test profiles, and operator-defined tests are not available options.
Check Reaction Logic	Operator-defined conditions or rules using a cut-off value. Available when the operator selects a test name. Includes Below or equal to or Above or equal to. Default is Below or equal to.
Conc. Cut-off Value	Value the analyzer uses in reaction logic rule. Values greater than 999999.999 produce an error showing the valid range. The default value is 0. The analyzer only presents numbers (0–9) and the international decimal character.
Units	The units of measure the analyzer automatically populates for the selected test name.
Reflex Tests	The analyzer orders up to 3 assays after meeting all rules. These include assays, ratio tests, test profiles, sort tests, and operator-defined assays. Does not include serum indices.
Dilution	The dilution drop-down menu enables if a reflex test has 1 or more dilution factors or corrections in Test Definition. The default is undiluted.
Replicates	Number of replicates the analyzer performs for the selected reflex test.

When a reflex group exists, options display to Print, Clear, Save, or Close. Clear includes options to remove a single group, a specific range of groups, or all groups.

Reflex Group Setup is located within Setup Test Definition.

About Reflex Tests

Reflex tests are the subsequent tests that the analyzer automatically orders when up to 3 test results fall outside a specified range. The operator can select different assays for reflex processing based on results that fall within the check reaction logic. A reflex test can also be Sort Tests that improve efficiency of the system to sort samples meeting specific criteria to be sorted into the SH drawer, such as all reactive HCV.

Reflex testing improves the timeliness of results by automatically performing subsequent tests based on the rules of the Reflex Group Setup specifies. All conditions must be valid before the system performs the reflex tests. Common examples of reflex testing include:

- Total PSA within a range of 4–10 adds a Free PSA and then the analyzer reports a FPSA/TPSA ratio
- TSH <0.3 mIU/L or >4.2 mIU/L adds a Free T4
- Triglycerides >400 mg/dL adds a direct LDL

About Assay List

Laboratories use Assay List to enable or disable assays on the system or set assays to Troubleshooting. Assay List also allows laboratories that have more than 1 analyzer to designate the assays and Specimen Types to process on each analyzer within the system.

Assay List is divided into CH Assays and IM Assays. Each tab consists of a collapsible Filter and the main Assay List window. The Filter limits the number of assays that display for CH Assays and IM Assays.

The main Assay List window displays all assays with test definitions on the system that meet the following filtering criteria.

Criteria	Notes
System Enabled Only	All assays that are enabled on the system. **NOTE:** For systems that contain more than 1 analyzer, laboratories can enable an assay on the system but disable it on all but 1 analyzer.
Assay	A single assay.

Criteria	Notes
Enabled	All assays that are enabled on 1 or more analyzers.
Troubleshooting	All assays that the operator is troubleshooting.
Disabled	All assays that are disabled on 1 or more analyzers.
Specimen Types	All assays that use the specified Specimen Type.

If the operator selects no criteria in the Filter, the panel displays all assays that have a test definition on the system.

NOTE: Assay List does not include IM component tests, such as RgtA and RgtB.

Assay List contains at least 3 columns:

Column	Notes
Assay	The short name of all assays that meet the filtering criteria. The operator selects the downward arrow next to the assay short name to expand the view and display a table for Specimen Type for changing the status of each type of specimen that the assay supports. The Specimen Type lists each type of specimen that the assay supports and its current status on each analyzer in the system.

Column	Notes
	Each analyzer has a separate drop-down menu for Specimen Type. The operator opens the appropriate drop-down menu to change the status.
System	A checked or unchecked box for each assay that meets the filtering criteria. A checked box indicates that the assay is enabled on the system, and an unchecked box indicates the assay is disabled. The operator selects the check box to enable or disable the assay on the system, as appropriate. Disabling the assay with the system check box also disables the assay on each analyzer and Specimen Type.
Name of an analyzer in the system	A checked or unchecked box for each assay that meets the filtering criteria. A checked box indicates the assay is enabled on the analyzer. If the assay is enabled, the check box is labeled with the appropriate Specimen Types. **NOTE**: If at least 1 Specimen Type is in Troubleshooting, the ◯ icon precedes the Specimen Types. The operator expands the assay to determine the status of each Specimen Type. An unchecked box indicates the assay is disabled for every Specimen Type. The operator selects the check box to enable or disable the assay on the analyzer, as appropriate. Selecting the check box to disable the assay also disables the assay for each Specimen Type on that analyzer.

NOTE: Laboratories enable and disable reagent lots and reagent packs in Inventory.

All operators can view the settings in Assay List. However, only operators in the G1 or G3 group can edit this feature. The system posts an entry to the Audit Trail Log when an operator saves changes in Assay List.

Assay List Icons

The following icons alert the operator to a required action or more information:

Icon	Notes
	Closes or removes the window
	Indicates a filter is available to limit the number of assays that display
	Clears an applied filter
	Enables searching on the basis of a text string
	Indicates that online help is available for the window.
	Indicates a collapsible panel
	Indicates that the setting for an assay feature is not Enabled
	Indicates that the setting is Enabled for a feature
	Indicates that an assay is Disabled on 1 or more analyzers
	Indicates that an assay is Enabled on 1 or more analyzers
	Indicates that an assay is in the Troubleshooting mode on 1 or more analyzers

Icon	Notes
	Expands the list of available Specimen Types and their usage for an assay
	Collapses the list of available Specimen Types and their usage for an assay
	Moves 1 or more assays to the next lower priority band
	Moves 1 or more assays to the lowest priority band
	Moves 1 or more assays to the next higher priority band
	Moves 1 or more assays to the highest priority band

About CH Test Definition

CH Test Definition provides laboratories with access to each assay Test Definition for informational and configuration purposes. The system groups the assay parameters as follows:

- Definition (Page 721 *About the Definition Parameters in CH Test Definition*)
- Calculation (Page 722 *About the Calculation Parameters in CH Test Definition*)
- Calibration
- Mitigation (Page 726 *About Mitigation in CH Test Definition*)
- Ranges
- Repeat

During configuration of the assay test definitions, laboratories can perform the following:

Feature	Notes
Restore Defaults	Restores saved changes to the parameters to the manufacturer's default settings. **NOTE:** This feature only restores the default values of the currently selected assay. This feature is not available for mitigations.
Save	Updates parameters to the laboratory-specified values.
Cancel	Reverts any unsaved changes to the parameters to their last saved values.

CH Test Definition Icons

The following icons alert the operator to a required action or more information:

Icon	Notes
	De-selects a drop-down list
	Selects a drop-down list
	Clears the Test Definition filter
	Indicates a search bar is available for the window
	Indicates an editable field
	More information is available.
	Indicates an error condition.

Icon	Notes
	Indicates a warning condition.
	Indicates that online help is available for the window.
	Indicates that a feature is not using or applying the setting.
	Indicates that the setting is enabled for a feature.

About the Definition Parameters in CH Test Definition

The Definition panel in CH Test Definition groups assay parameters in the following 3 areas:

Area	Notes
Assay Identification	Identifying information and configuration options for each assay (Page 721 *About Assay Identification in CH Test Definition*)
General	Configuration options for the Result Review Mode and the Reuse Result for Ratio features
Advanced	Configuration options for features specific to CH assays

About Assay Identification in CH Test Definition

The Assay Identification area in Definition of CH Test Definition provides identifying information about the assay. This information identifies the assay on printed reports, on the system interface, and in the software.

The following information is available in this area:

Field	Notes
Test Name/ID	The unique name of the test
Test Type	The type of processing analysis for the test
Test Version	The version of the test definition
Display Name	The name of the test that displays on the system

Field	Notes
Print Name	The name of the test that the system prints on reports
LIS Code	The code that the LIS uses to identify the test in communications with the system
LOINC	The unique identifier from the Logical Observation Identifiers Names and Codes (LOINC) database

Laboratories can edit the following information:

- Display Name
- Print Name
- LIS Code
- LOINC

Laboratories can only edit these parameters if no open orders that include the test exist on the system.

NOTE: The Display Name and the Print Name are mandatory fields.

About the Calculation Parameters in CH Test Definition

Calculation provides information about the parameters that the system uses to calculate and report test results for the selected assay.

The system uses the system calibration assigned value in the unit the test definition defines to calculate the results. Calibration-assigned values must correspond to the selected unit in the calculation parameters. The default values in the measuring interval, Ranges, and Ratios correspond to the default unit in the Instructions for Use. If the alternate unit from the IFU is selected in the unit field, the measuring interval, Ranges, and Ratios update with the corresponding values.

NOTE: If the operator previously modified the measuring interval, it does not automatically update when the alternate units are selected.

If selecting a unit of measure other than the default or alternate unit, the operator must convert the measuring interval, Ranges, and Ratios values to correspond to the selected unit.

The parameters are grouped in the following 3 areas:

Area	Notes
General	Enables configuration of the following parameters: • Units: The Units of measure that the system uses to report test results. • Significant Figures or Fixed Digits After Decimal: This label changes depending on assay. – Significant Figures: Specifies the number of digits in the test results for IMT assays (CL, K, and NA) that signify accuracy. – Fixed Digits After Decimal: Specifies the number of decimal places in the test results for all other CH assays.
HIL Alert Indices	Enables the automatic flagging of patient results for tests that meet or exceed the configured Threshold level for HIL interference. By default, the system sets the Threshold level at the assay manufacturer-recommended level. Laboratories can change this default level.
Advanced	Enables entry of the Assay Comparison Correlation Factors for slope or intercept. These factors enable the laboratory to adjust results between analyzers.

About HIL Absorbance Measurements

The system processes HIL in 2 ways:

HIL processing type	Notes
HIL without donor	Uses special reagent water that does not require QC or calibration. This assay produces HIL tests only. Reports result in 66 seconds.
HIL using donor	Uses donor-specific assay reagent or special reagent water. Reports result when the donor assay completes.

For HIL using a donor assay, the system measures the HIL values during the performance of the donor assay. The operator can determine use of donor assays and their priority in HIL Donor Configuration.

NOTE: Any operator-defined assay configured as a donor assay populates the donor list in its saved order. Each operator-defined test result is flagged with operator-defined assay.

Donor Assay Criteria

The system uses a donor assay if 1 is available on the order with the HIL test. If more than 1 donor assay is on the order, the system uses the donor assay with the highest priority. The analyzer prepares the cuvette as it does for routine patient testing.

To use the donor assay, the following is required:

- HIL using Donor is set to Enable (toggled on)
- The specific donor assay is enabled
- The operator orders the HIL donor test using the default dilution (Page 320 *Ordering Patient Tests Workflow*)

NOTE: If a donor assay meeting the defined criteria cannot complete processing or no donor assay is enabled, the system tests HIL without using a donor assay.

The system measures absorbance on the cuvette at 2 different wavelengths for each interferent and then converts these measurements into index values. The index values provide a semi-quantitative representation of the level of Hemolysis (H), Icterus (I), and Lipemia (L) in the sample (Page 724 *Approximate Concentration Ranges for HIL Alert Indices*).

The analyzer uses the following wavelengths for the interferents:

Interferent	Absorbance measurement and wavelength
H	Blanked, bichromatic measurement at 571 nm and 596 nm. The system corrects for absorption from Lipemia.
I	Blanked, bichromatic measurement at 478 nm and 505 nm. The system corrects for absorption from Lipemia and Hemolysis.
L	Blanked, bichromatic measurement at 658 nm and 694 nm.

Approximate Concentration Ranges for HIL Alert Indices

The HIL Alert Indices correlate to the following approximate concentration ranges (in mg/dL) for Hemolysis (H), Icterus (I), and Lipemia (L):

Index Level	H (mg/dL)	I (mg/dL)	L (mg/dL)
0	≤ 10.0	≤ 1.9	≤ 124.0
1	10.1–130.0	2.0–10.0	124.1–250.0
2	130.1–250.0	10.1–20.0	250.1–500.0
3	250.1–500.0	20.1–30.0	500.1–700.0
4	500.1–750.0	30.1–40.0	700.1–1000.0
5	750.1–1000.0	40.1–60.0	1000.1–3000.0
6	≥ 1000.1	≥ 60.1	≥ 3000.1

NOTE: Laboratories cannot use the results of this feature to report hemoglobin, bilirubin, or triglyceride concentrations or change test results because of HIL interference. When reporting results for a Hemolyzed, Icteric, or Lipemic sample, laboratories should follow their appropriate reporting procedures.

About the HIL Index Interval Configuration

This feature requires the appropriate security level.

The Calculation tab of the H (Hemolysis), I (Icterus), and L (Lipemia) test definitions in CH Test Definition enables laboratories to customize each Index Level at laboratory-defined absorbance values.

NOTE: The absorbance values indicate the approximate concentrations of H, I, or L in a patient sample (Page 724 *Approximate Concentration Ranges for HIL Alert Indices*).

Seven index levels (0–6) are available for customization. Laboratories can modify the upper limit of each interval, with the exception of Index Level 6. The system automatically adjusts the lower limit of the next Index Level to ensure the intervals are continuous. Laboratories cannot decrease the value of the limit for Index Level 0 below the minimum value for the interferent, but they can increase the value. In addition, laboratories cannot increase the value of the upper limit of Index Level 5 beyond the maximum value for the interferent, but they can decrease the value. The following table indicates the minimum and maximum values for each interferent:

Interferent	Minimum value	Maximum value
H	10.0	1000.0
I	1.9	60.0
L	124.0	3000.0

NOTE: The system cannot have any existing orders for tests that are enabled for HIL alert processing when customizing the index levels. Operators must wait for all inprocess tests to complete and delete or move all existing orders to the historical database.

If the laboratory does not configure the intervals, the system uses the assay manufacturer-defined absorbance values for each level.

The system only enables operators in the G1 Group to customize the index levels of HIL alert flagging. All changes to the HIL index intervals are included as an entry into the Audit Trail Log.

About Mitigation in CH Test Definition

Mitigations specify the following:

- Conditions for avoiding CH reagent probe and reaction cuvette contamination
- Type of rinse or wash to prevent reagent carryover contamination from the previous sample

NOTE: Siemens Healthineers does not support operator modifications. Unsupported modifications may affect system performance and test results.

Mitigation is divided into the following sections:

- System-Defined Mitigations configured for the selected pre-provided CH assay test definition, for reference
- Operator-Defined Mitigations that the lab adds to the selected CH assay

The operator cannot delete or modify system-defined mitigations. However, they can add additional mitigations to the assay test definition and modify the Mitigation Reagent for existing operator-defined mitigations in CH assays.

> **CAUTION**
>
> Do not configure more than 1 mitigation reagent per donor assay. The system only performs 1 mitigation and would not complete additional rinses or cleans.

Mitigation Donor Assay and Target pairs must be unique.

- When a mitigation exists for an individual assay, the operator cannot add another mitigation for that same assay that uses the same Target.
- When a mitigation exists for an individual assay, the operator cannot add another mitigation for All Assays that uses the same Target.
- When a mitigation exists for All Assays, operators cannot add another mitigation for an individual assay that uses the same Target.

To add a mitigation that uses the same Target as another operator-defined mitigation, first remove the existing mitigation and then add the new one. The operator cannot add mitigations that conflict with system-defined mitigations. However, the operator can add a mitigation that uses a different Target (such as Cuvette instead of Reagent) than a system-defined mitigation.

Mitigation	Notes
Donor Assay	The assay on the analyzer that contains an interfering substance that requires mitigation, such as an extra rinse or clean, before performing the selected assay. When adding an operator-defined mitigation, select 1 of the following: • **All Assays**: Process the mitigation step prior to performing the selected assay for any preceding assay on the analyzer. • Assay name: Process the mitigation for only the individual assay that contains an interfering substance.
Target	The component the analyzer rinses or cleans. When adding an operator-defined mitigation, select 1 of the following: • **Reagent** (includes reagent probes and reaction mixers cleaning) • **Cuvette** Mitigation Donor Assay and Target pairs must be unique.

Mitigation	Notes
Mitigation Reagent	The type of rinse or clean delivered to the Target. Select 1 of the following: • **Rinse**: With special reagent water. • **Clean 1**: Cleans with the basic CH Reagent Probe Cleaner 1 (RPC1). • **Clean 2**: Cleans with the acidic CH Reagent Probe Cleaner 2 (RPC2). After an operator-defined mitigation has been saved, the operator can change only the Mitigation Reagent for that mitigation. To change either the Donor Assay or Target, remove the mitigation and add a new one.

When configuring mitigations, the operator can perform these actions:

Action	Notes
Add Mitigation	Adds a new mitigation to the Operator-Defined Mitigations list.
Remove All	Removes all operator-defined mitigations from the selected assay.
Remove	Removes only the selected mitigation from the assay.

During a software upgrade, the system checks the existing operator-defined mitigations against the mitigations in updated test definitions included in the upgrade. Any operator-defined mitigations that conflict with new system-defined mitigations are removed and identified in the Audit Trail Log. All other operator-defined mitigations are retained.

About Ranges in CH Test Definition

This feature requires the appropriate security level.

Ranges in CH Test Definition provides access to the available range configuration tabs for each assay. Laboratories configure Ranges to flag abnormal samples and to enable the system to automatically perform Repeat and Reflex tests and sample dilutions according to the range criteria.

NOTE: Laboratories can also configure Repeat tests for system flags in Repeat Conditions. They can also configure Reflex tests in Reflex Group Setup.

By default, Ranges opens to the Reference Range for every assay (Page 755 *About Reference Ranges*). In addition, each assay can have 1 or more of the following types of Ranges:

Range	Notes
Reference	Enables configuration of alerts and system actions for patient results that fall in laboratory-defined intervals for a population (Page 755 *About Reference Ranges*).
Delta Check	Enables configuration of alerts and system actions that depend on the amount of change in patient test results over time (Page 759 *About Delta Check Ranges*).
Check	Provides the laboratory with greater flexibility to configure result checking, alerts, and additional system actions on 1 or more intervals of result values (Page 762 *About Check Ranges*).
Concentration	Provides alerts and enables configuration of system actions for patient test results that are outside the manufacturer-specified measuring interval for the assay (Page 765 *About Concentration Ranges*).
Interpretation	Enables configuration of an alert and reflex testing for a specified result Interpretation (Page 767 *About Interpretation Ranges*). Also enables laboratories to define interpretations for result ranges and configure a result review and reflex testing.

The types of Ranges that are available depend on the assay.

The system does not support Ranges for the following:

- Dilution panels
- Test panels
- Sort tests

The system supports Ranges for the individual tests in dilution panels, test panels, and sort tests.

NOTE: The system also supports limited range checking for off-system tests. Laboratories configure the measuring interval when defining the off-system test (Page 771 *About Off-System Tests*).

The header of each range tab indicates the short name of the Assay and the Units from the assay Test Definition, if appropriate.

NOTE: Assays that report only Index results do not have defined Units.

The following information is available on each tab in Ranges:

Field or information	Notes
Range Name	The name of the range. Names can be 1–25 alphanumeric characters. They can include but cannot start or end with a space. **NOTE:** For range types that can have multiple defined Ranges, laboratories should name each range in order of priority for range matching.
Defined Ranges	The list of configured Ranges for the range type. **NOTE:** Some range types can have up to 10 configured Ranges, including manufacturer-defined Ranges.
Details	The configuration options for the range (Page 753 *About Configuration Options in Ranges*). **NOTE:** The system disables fields that are not available for the range.
Demographics Information	The available demographic options for the range.

The operator can perform 1 or more of the following actions:

Action	Notes
Add Range	Provides a blank template of the range type to enable configuration of another range.
Edit Range	Enables the laboratory to change the values of the parameters in an existing range.
Copy Range	Enables the laboratory to define a new range by copying an existing range and modifying the settings.
Delete Range	Removes the selected range from the list of saved ranges.
Reset Ranges	Resets the parameters in all Ranges for an assay to their predefined values.
Save	Updates the parameters in the range to reflect operator changes. All changes must meet the criteria for the parameter and range before the system saves the range.
Cancel	Cancels any unsaved changes. **NOTE:** The system warns the operator of any unsaved changes before clearing the settings.

About IM Test Definition

IM Test Definition provides laboratories with access to each assay Test Definition for informational and configuration purposes. The system groups the assay parameters on the following tabs:

- Definition
- Calculation
- Calibration
- Reagent

During configuration of the assay test definitions, the operator can perform the following actions:

Action	Notes
Scan Barcodes	Scans new test definitions
Save	Updates parameters to the laboratory-specified values
Cancel	Reverts any unsaved changes to the parameters to their last saved values

IM Test Definition also provides access to the following features:

Feature	Notes
Lots	Provides detailed information about the IM reagent lots that are available for the selected assay.
Ranges...	Enables configuration of the available range checks for the selected assay.
Advanced Reflex Groups	Enables the automatic ordering of different tests or panels in response to patient results.
Repeat	Enables the automatic ordering of repeat patient tests in response to system flags.
Restore Defaults	Restores saved changes to parameters to the manufacturer's default settings. **NOTE:** This feature only restores the default values of the currently selected assay.

About the Calculation Parameters in IM Test Definition

Calculation in IM Test Definition provides information about the parameters that the system uses to calculate and report results for the selected assay.

The system uses the system calibration and master curve data in default units to calculate the results. The default unit corresponds to a conversion factor of 1. If the IFU defines an alternate unit, selecting the alternate unit in Units displays a corresponding conversion factor. If a unit other than the default or alternate unit is selected, the operator must enter the corresponding conversion factor.

When making modifications to calculation parameters, the operator must verify that the conversion factor between the selected unit and the master curve data unit is correct and Ranges and Ratios properly correspond to the conversion factor.

The parameters are grouped in the following 3 areas:

Area	Notes
General	Enables configuration of the following parameters: • Units: The Units of measure that the system uses to report test results. • Conversion Factor: The multiplier that the system uses to convert the Master Curve Units into the selected reporting Units. • Concentration Decimal: The number of decimal places the system uses to report results in terms of concentration values. • Index Decimal: The number of decimal places the system uses to report results in terms of index values. **NOTE:** The Concentration Decimal and Index Decimal applies to the displaying, printing, and transmitting of results.
HIL Alert Indices	Enables the automatic flagging of patient results for tests that meet or exceed the configured Threshold level for HIL interference. By default, the system sets the Threshold level at the assay manufacturer-recommended level. Laboratories can change this default level.
Advanced	Provides information about the parameters that the system uses to calculate results and enables entry of the parameters that the laboratory uses to determine the relationship between the results on 2 different systems.

About Ranges in IM Test Definition

This feature requires the appropriate security level.

Ranges in IM Test Definition provides access to the available range configuration tabs for each assay. Laboratories configure Ranges to flag abnormal samples and to enable the system to automatically perform Repeat and Reflex tests and sample dilutions according to the range criteria.

NOTE: Laboratories can also configure Repeat tests for system flags in Repeat Conditions and for sample errors in IM Standard Configuration. They can also configure Reflex tests in Advanced Reflex Groups.

By default, Ranges opens to the Reference Range for every assay (Page 755 *About Reference Ranges*). In addition, each assay can have 1 or more of the following types of Ranges:

Range	Notes
Reference	Enables configuration of alerts and system actions for patient results that fall in laboratory-defined intervals for a population (Page 755 *About Reference Ranges*).
Delta Check	Enables configuration of alerts and system actions that depend on the amount of change in patient test results over time (Page 759 *About Delta Check Ranges*).
Check	Provides the laboratory with greater flexibility to configure result checking, alerts, and additional system actions on 1 or more intervals of result values (Page 762 *About Check Ranges*).
Concentration	Provides alerts and enables configuration of system actions for patient test results that are outside the manufacturer-specified measuring interval for the assay (Page 765 *About Concentration Ranges*).

Range	Notes
Index	Provides alerts and enables configuration of system actions for patient test results that are outside the manufacturer-specified measuring interval for the assay (Page 737 *About Index Ranges*). **NOTE:** Index Ranges are only available for IM assays that report results as Index values.
Dilution Point	Enables the automatic repeat of tests with less or more system dilutions for results that are less than the Overdilution Point or greater than the Dilution Point of an assay (Page 740 *About Dilution Point Ranges*). **NOTE:** Dilution Point Ranges are only available for IM assays that have dilution factors. The manufacturer specifies the Overdilution Point in the Test Definition of some IM assays.
Linearity	Enables configuration of alerts and system actions for a narrower reportable result range than the manufacturer-specified measuring interval in the Concentration Range (Page 743 *About Linearity Ranges*). **NOTE:** Linearity Ranges are only available for IM assays.
Interpretation	Enables configuration of an alert and reflex testing for a specified result Interpretation (Page 767 *About Interpretation Ranges*). Also enables laboratories to define interpretations for result ranges and configure a result review and reflex testing.

The types of Ranges that are available depend on the assay.

The system does not support Ranges for the following:

- Dilution panels
- Test panels
- Sort tests

It supports Ranges for the individual tests in dilution panels, test panels, and sort tests.

NOTE: The system also supports limited range checking for off-system tests. Laboratories configure the measuring interval when defining the off-system test (Page 771 *About Off-System Tests*).

The header of each range tab indicates the short name of the Assay and the Units from the assay Test Definition, if appropriate.

NOTE: Assays that report only Index results do not have defined Units.

The following information is available on each tab in Ranges:

Field or information	Notes
Range Name	The name of the range. Names can be 1–25 alphanumeric characters. They can include but cannot start or end with a space. **NOTE:** For range types that can have multiple defined Ranges, laboratories should name each range in order of priority for range matching.
Defined Ranges	The list of configured Ranges for the range type. **NOTE:** Some range types can have up to 10 configured Ranges, including manufacturer-defined Ranges.
Details	The configuration options for the range (Page 753 *About Configuration Options in Ranges*). **NOTE:** The system disables fields that are not available for the range.
Demographics Information	The available demographic options for the range.

The operator can perform 1 or more of the following actions:

Action	Notes
Add Range	Provides a blank template of the range type to enable configuration of another range.
Edit Range	Changes the values of the parameters in an existing range.
Copy Range	Defines a new range by copying an existing range and modifying the settings.
Delete Range	Removes the selected range from the list of saved ranges.
Reset Ranges	Resets the parameters in all Ranges for an assay to their predefined values.
Save	Updates the parameters in the range to reflect operator changes. All changes must meet the criteria for the parameter and the range before the system saves the range.
Cancel	Cancels any unsaved changes. **NOTE:** The system warns the operator of any unsaved changes before clearing the settings.

About Index Ranges

This feature requires the appropriate security level.

Index Ranges enable laboratories to configure 1 or more of the following actions for samples that have results outside the manufacturer-specified measuring interval for the assay:

- Perform automatic Repeat tests
- Perform automatic Reflex tests
- Add a Comment to the result

Index Ranges are available for those IM assays that report results as Index values.

NOTE: Index Ranges are not available for CH assays.

Assays that report results as Concentration values use the Concentration Range (Page 765 *About Concentration Ranges*). The system displays the type of result on the Calculation tab of the assay Test Definition and automatically displays the correct range type for the assay.

NOTE: Some IM assays report results with Index and Concentration values. The system displays both range types for these assays.

The system does not automatically create an Index Range for an assay. The laboratory must define the range and configure the appropriate range options (Page 766 *About the Configuration Options in Concentration Ranges*). During configuration, the system uses the lower and upper bound of the measuring interval to create an In Range interval on the result continuum. The system will automatically flag any result that is less than the lower limit and greater than the upper limit:

Range interval	Result flag
Below Range	< Measuring Interval
Above Range	> Measuring Interval

NOTE: The system automatically reports results that are Below Range as being less than the manufacturer-specified lower limit of the measuring interval and results that are Above Range as being greater than the upper limit of the measuring interval.

Laboratories can only define 1 Index Range for each IM assay. The system requires a minimum of a laboratory-defined name to Save an Index Range.

NOTE: The system does not require the laboratory to define an Index Range.

The system posts an entry to the Audit Trail Log whenever an operator defines, edits, or deletes an Index Range.

About Configuration Options in Index Ranges

This feature requires the appropriate security level.

The Below Range and Above Range intervals in Index Ranges have the following configuration options* (Page 753 *About Configuration Options in Ranges*):

Field	Notes
Limits	Not configurable. The system uses the manufacturer-specified measuring interval to define 3 intervals along the result continuum: • Below Range • Within Range • Above Range Results that are less than the lower limit of the measuring interval are in the Below Range interval of the range. Results that are greater than the upper limit of the measuring interval are in the Above Range interval.
Flag result	Not configurable. **NOTE:** If the laboratory defines the range, the system automatically reports results that are Below Range with a result flag and sets the result value as being less than the manufacturer-specified lower limit of the measuring interval and results that are Above Range with a result flag and sets the result value as being greater than the upper limit of the measuring interval.
Repeat	Configurable.
Number of Repeats	Not available.
Dilution	Configurable if the laboratory defines the interval with a Repeat test. The system provides the available Dilution options for the test in a drop-down menu. Assays that support more than 1 Dilution factor also support the auto step feature. **NOTE:** If an assay has no Dilution factors, the system performs the Repeat test using the Original Dilution (the same Dilution as that of the initial test result).
Replicates	Configurable if the laboratory defines the interval with a Repeat test. A blank value indicates that the system performs the same number Replicates as that for the initial test result.
Reflex	Configurable. **NOTE:** Cannot Reflex to off-system tests.

Field	Notes
Dilution	Configurable if the laboratory defines the interval with a Reflex test and if the Reflex test supports Dilution. The system provides the available Dilution options for the test in a drop-down menu. **NOTE:** Undiluted indicates that the Reflex test only supports a neat sample.
Replicates	Configurable if reflexing to an IM test. If the laboratory does not specify the number of Replicates, the system uses the number in the assay Test Definition. **NOTE:** The system can only perform 1 replicate of CH assays.
Comment	Configurable.

* No configuration options are available for results that are Within Range.

About Dilution Point Ranges

This feature requires the appropriate security level.

Dilution Point Ranges are available for IM assays that have 1 or more dilution factors. The range tab does not display if the system only performs the assay test with Undiluted samples.

NOTE: Dilution Point Ranges are not currently available for CH assays.

The system uses an upper and lower limit to specify the interval on the result continuum that does not require additional dilutions. These results are Within Range. The upper limit represents the Dilution Point for the assay and signifies the point at which the system must repeat a test with dilution. The lower limit represents the Overdilution Point and signifies the point at which the sample is too diluted to provide an accurate result.

NOTE: Laboratories can specify 1 limit or both.

Laboratories can configure Dilution Point Ranges to automatically perform Repeat tests with more or less dilution for results that are greater than the Dilution Point or less than the Overdilution Point, as appropriate.

The system automatically flags any result that is less than the Overdilution Point and greater than the Dilution Point of an assay. The following flags alert the operator to these results:

Result value	Result flag
Less than the Overdilution Point	Overdiluted
Greater than the Dilution Point	> Dilution Point

Laboratories can only define 1 Dilution Point Range for each IM assay. The system requires a minimum of the following to Save a Dilution Point Range:

- A name for the range
- An Overdilution Point or a Dilution Point

The assay manufacturer specifies the Overdilution Point in the assay Test Definition of some IM assays. For these assays, the system uses this value to populate the lower limit and create a Dilution Point Range for the assay. The laboratory cannot change this limit or delete the range.

NOTE: The Overdilution Point only applies to diluted (non-neat) assays.

If the assay manufacturer changes the Overdilution Point in a new version of the assay Test Definition, the system replaces the Lower Limit in the range with the new Overdilution Point. All existing Repeat and Reflex actions remain the same. If the new Overdilution Point is greater than or equal to the upper limit (the Dilution Point), the system deletes the existing Dilution Point Range and replaces it with a new Dilution Point Range that only has a lower limit (the Overdilution Point). The system does not delete the Dilution Point Range if the assay manufacturer no longer specifies the Overdilution Point in the assay Test Definition.

The system posts an entry to the Audit Trail Log whenever an operator defines, edits, or deletes a Dilution Point Range.

About the Configuration Options in Dilution Point Ranges

This feature requires the appropriate security level.

Dilution Point Ranges have the following configuration options (Page 753 *About Configuration Options in Ranges*):

Detail	Notes
Limits	Configurable. The laboratory enters the Limits for the range in the Within Range text boxes. The system uses the value in the left text box as the Overdilution Point and the value in the right text box as the Dilution Point. The Overdilution Point must be less than the Dilution Point. Laboratories can define both Limits, but the system requires only 1 to save the range. **Note:** The lower limit is not configurable if the assay manufacturer specifies the Overdilution Point in the assay Test Definition.
Flag result	• Not available for results that are Within Range. • Not configurable for results that are less than the Overdilution Point or greater than the Dilution Point. The system automatically reports results in these intervals with a result flag if the laboratory defines the intervals.
Repeat	• Not available for the Within Range interval. • Configurable for the Overdilution Point and Dilution Point intervals if the laboratory defines the interval.
Number of Repeats	Not available.
Dilution	• Not available for the Within Range interval. • Configurable for the Overdilution Point and Dilution Point intervals if the laboratory defines a Repeat test for the interval. **NOTE:** For assays that have more than 1 dilution factor, the system defaults to AUTO --or AUTO +, as appropriate.
Replicates	• Not available for the Within Range interval. • Configurable for the Overdilution Point and Dilution Point intervals if the laboratory defines the interval with a Repeat test. A blank value indicates that the system performs the same number Replicates as that for the initial test result.

Detail	Notes
Reflex	Not available.
Dilution	Not available.
Replicates	Not available.
Comment	• Not available for the Within Range interval. • Configurable for the Overdilution Point and Dilution Point intervals if the laboratory defines the interval.

NOTE: The system disables fields that are not configurable for the range.

About Linearity Ranges

This feature requires the appropriate security level.

Linearity Ranges enable the laboratory to create a range check that is within the manufacturer-specified Concentration Range (Page 765 *About Concentration Ranges*) or Index Range (Page 737 *About Index Ranges*).

NOTE: Linearity Ranges are not currently available for CH assays.

Laboratories specify an upper and lower limit to create the interval on the result continuum that is Within Range. The system automatically flags any result that is less than the lower limit or greater than the upper limit and reports the result as less than or greater than that limit. The following flags alert the operator to results that are outside the Withing Range interval:

Result value	Result flag
Less than the lower limit of the Within Range interval	Below Linearity
Greater than the upper limit of the Within Range interval	Above Linearity

Laboratories can also configure Linearity Ranges to automatically perform Repeat and Reflex tests for results that fall outside the Within Range interval.

The system only allows 1 Linearity Range for each IM assay. The system requires a minimum of the following to Save a Linearity Range:

- A name for the range
- An upper or lower limit to the range

  NOTE: The Limits must be within the measuring intervals as specified in the assay IFU.

NOTE: For valid results, the Limits must be within the manufacturer-specified measuring intervals as specified in the assay IFU.

The system posts an entry to the Audit Trail Log whenever an operator defines, edits, or deletes a Linearity Range.

About the Configuration Options in Linearity Ranges

This feature requires the appropriate security level.

The intervals for Below Range and Above Range in Linearity have the following configuration options* (Page 753 *About Configuration Options in Ranges*):

Field	Notes
Limits	Configurable. The laboratory enters the Limits for the range in the Within Range text boxes. Any result that is less than the value in the left text box is Below Range, and any result greater than the value in the right text box is Above Range. **Note:** Laboratories can define both Limits, but the system only requires 1 to save the range. The lower limit cannot equal the upper limit.
Flag result	Not configurable. The system automatically reports results in these intervals with a result flag and sets the result value as being less than the lower limit or greater than the upper limit to the range.
Repeat	Configurable in intervals with defined Limits.
Number of Repeats	Not available.
Dilution	Configurable if the laboratory defines the interval with a Repeat test. The system provides the available Dilution options for the test in a drop-down menu. Assays that support more than 1 Dilution factor also support the auto step feature. **NOTE:** If an assay has no Dilution factors, the system performs the Repeat test using the Original Dilution (the same Dilution as that of the initial test result).
Replicates	Configurable if the laboratory defines a Repeat test for the interval. A blank value indicates that the system performs the same number Replicates as that for the initial test result.
Reflex	Configurable in intervals with defined Limits. **NOTE:** Cannot reflex to off-system tests.

Field	Notes
Dilution	Configurable if the laboratory defines the interval with a Reflex test and if the Reflex test supports Dilution. The system provides the available Dilution options for the test in a drop-down menu. **NOTE:** Undiluted indicates that the Reflex test only supports a neat sample.
Replicates	Configurable if the laboratory defines an IM Reflex test for the interval. If reflexing to an IM test and the laboratory does not specify the number of Replicates, the system uses the number in the assay Test Definition. **NOTE:** The system can only perform 1 replicate of CH assays.
Comment	Configurable.

* No configuration options are available for the Within Range interval.

Demographics Information is not available for Linearity Ranges.

About the Calibration Parameters in IM Test Definition

Calibration in IM Test Definition groups assay parameters that affect IM assay calibrations into the following areas:

Field Name	Notes
Calibration Settings	Configures Calibration Settings in Calibration Setup.
Autoexclude Cal Replicates	Enables the system to automatically exclude calibration replicates that fail an acceptance criteria (Page 747 *About Autoexcluding IM Assay Reagent Calibration Replicates*). **NOTE:** The system can only exclude a replicate if the number of replicates exceeds the minimum number required for the assay.
QC Statistics Violation: Patient Tests	Enables the selection of the quality control error conditions for performing patient tests.

Field Name	Notes
Replicates	Specifies the following information: • The number of calibration Replicates the analyzer performs when calibrating a new reagent lot • The number of calibrator Replicates for the current reagent lot • The Minimum number of Replicates the assay requires for calibration
Lot Calibration Interval	Specifies the length of the calibration interval in Days and Hours. The assay reagent lot requires another calibration after this duration. **NOTE:** Laboratories can only shorten this duration.
Pack Calibration	Specifies the following information: • The age of the pack when the system can no longer use it for a lot calibration. • The age of the pack when it requires a pack calibration. The system displays the manufacturer-recommended age of the pack in number of Days and Hours. **NOTE:** Laboratories can only shorten this duration.

Field Name	Notes
Calibrator Onboard Stability (Hours)	Specifies the number of Hours that an opened calibrator remains stable on the system for Refrigerated and Unrefrigerated conditions.
Calculation Parameters	Specifies the Calibration Method that the assay manufacturer uses to generate the master curve. Also indicates whether the assay requires a calibration before use.

About Excluding and Including Calibration Replicate Results

The assay test definition defines the minimum number of replicates the system requires to obtain a valid calibration. Outliers can cause a calibrations to fail. If specific criteria are met, excluding an outlier may correct an Invalid or Awaiting Acceptance calibration result. The system can autoexclude IM qualified outliers. The operator can manually exclude CH or IM calibration replicate results. After excluding an outlier replicate result, the system recalculates the calibration data and rechecks the calibration criteria.

The system autoexcludes IMoutlier calibration replicate results under the following conditions:

- The IM assay test definition setting for Autoexclude Cal Replicates is enabled.
- The calibration replicate result is an outlier.
- The minimum number of replicates the system requires for a valid calibration remain after the exclusion of the replicate.

The operator may manually exclude outlier calibration replicate results under the following conditions:

- The IM assay test definition setting for Autoexclude Cal Replicates is not enabled.
- The minimum number of replicates the system requires for a valid calibration remain after the exclusion of the replicate.

About Autoexcluding IM Assay Reagent Calibration Replicates

The Autoexclude Cal Replicates feature requires the appropriate setting in the IM assay test definition.

The system evaluates the calibration results for all replicates and excludes replicate results based on test definition parameters and performs the following actions:

- Analyzes the %CV of the replicates for each calibrator level
- Searches for an outlier or a replicate causing the unacceptable %CV
- Checks the critical precision of outliers
- Confirms the number of replicates is greater than the minimum required replicates
- Excludes the replicate if the deviation does not exceed the critical precision limit
- Does not exclude the replicate if the deviation exceeds the critical precision limit and reports an invalid calibration
- Re-evaluates the calibration criteria

The system only excludes the appropriate replicates to obtain a valid calibration if the minimum number of replicates remains greater than or equal to the test definition requirement.

About Reagents in IM Test Definition

Reagents in IM Test Definition provides information about the reagents for each IM assay. Laboratories use this information to ensure that the system has the correct reagents to perform the required tests. The Cal Code field provides the unique 3-digit label the associated Calibration Material definition uses to identify this test.

The Primary Reagent area contains the following information:

Field	Notes
Name	The short name of the assay test
Code	The product code of the selected reagent

The IM Analyzer-specific area contains the following information:

Field	Notes
Minimum Energy	The smallest amount of current energy that the system requires to use the solid phase from the reagent pack. Below this value, the system cannot aspirate the solid phase reagent.
Settling Rate	The rate in which the current energy decreases when the system is not mixing the reagent pack. The units are in energy per second.
Energy Cap	The maximum level for the current energy.
Energy Buffer	The level at which the system must mix the reagent pack to prevent the current energy of the pack from falling below the Minimum Energy level.

The fields for the Ancillary/Diluent Reagents:

Field Name	Description
Type	The Type of the selected reagent
Name	The Name of the selected reagent
Code	The product code of the selected reagent
Onboard Stability Trigger	When the onboard stability begins
Volume	The amount required for each aspiration in µL

About Lot-specific Master Curve Definition for IM Tests

Lots provides access to Master Curve data for the appropriate test. The following information is provided for each lot. This window divides the information into the following areas:

Field	Notes
Lot	The numeric identifier for a specific manufactured batch of an IM reagent.
Compatibility Code	A numeric identifier that links this reagent lot to compatible test definition versions. **NOTE:** When the assay manufacturer updates the version of the test definition, the Compatibility Code can stay the same or increase. If the manufacturer updates the Compatibility Code, the system cannot use older reagent lots with this and future Test Definition versions.
Checksum verification	A string of 8 hex digits that ensures the system has a complete and accurate set of Master Curve data.

Field	Notes
Test	Field that provides the following information about the selected Test: • Test Name: The unique short name of the assay. • Curve Type: The type of formula the system uses to calculate IM assay results (Page 125 *About IM Assay Result Calculation Formulas*) • Units: The unit of measure the system applies to the calculated results. **NOTE:** The operator can apply a conversion factor to report results in different Units.
Primary Reagent	Field that provides the following information about the selected lot of the Primary Reagent: • Product Code: The numeric identifier of the primary reagent. • Compatibility Code: A numeric identifier that links this reagent lot to compatible Test Definition versions. **NOTE:** When the assay manufacturer updates the version of the Test Definition, the Compatibility Code can stay the same or increase. If the manufacturer updates the Compatibility Code, the system cannot use older reagent lots with this and future Test Definition versions.

Field	Notes
	• Expiration: The date on which the reagent lot expires. • Lot: The numeric identifier for a specific manufactured batch of an IM reagent. • Onboard Stability: The amount of time in Days and Hours that the lot remains stable on the system.
Curve Points	The data pairs that the system uses to calculate a concentration value from a relative light unit (RLU) value.
Calibration Validation	A set of values and ranges that determines if a calibration is acceptable.
Lot Details	Optional lot-locking relationships to system samples and test reagents, and Onboard Stability time frames for the test reagents.
Result Range	The reportable measuring interval when using an Index Calculation and a Concentration Calculation.

About the Repeat Option in Ranges

This feature requires the appropriate security level.

When the laboratory configures an interval in a range with the Repeat option, the system automatically orders a Repeat test if the patient test result is in that interval.

NOTE: The Interpretation Range does not support a Repeat option.

The system performs Repeat tests in 1 of the following ways:

- At the same Dilution as the initial test result
- According to the Dilution factors specified in the assay Test Definition

The following Ranges require Repeat tests to have the same Dilution as the initial test result:

Range	Interval
Check	• Below Check • Within Check • Above Check

Range	Interval
Reference	• Low • Critical Low • High • Critical High
Delta Check	• Exceeded Delta Check

The following Ranges support Dilution of the initial test result:

Range	Interval
Concentration or Index	• Below Range • Above Range
Linearity	• Below Range • Above Range
Dilution Point	• Overdilution Point • Dilution Point

The system supports the following types of dilutions:

Dilution	Notes
Single	Repeats the patient test at only 1 of the available dilutions.
Multiple	Repeats the patient test at 1 or more of the available dilutions, as defined in the assay Test Definition. The system automatically decreases (AUTO --) or increases (AUTO +) the Dilution factor from that of the initial result to the next available Dilution factor. The system continues to perform Repeat tests until meeting 1 of the following conditions: • The result is within range. • No additional Dilution factors remain for the assay.

Dilution	Notes
	• The maximum number of Auto Dilution steps. **NOTE:** If the laboratory does not specify a maximum number of Auto Dilution steps, the system only performs 1 Dilution. AUTO -- is available if the result is below the Concentration, Index, or Linearity limit or Overdiluted, and AUTO + is available if the result is above the Concentration, Index, or Linearity limit or the Dilution Point.

The system provides all available Dilution options in a drop-down menu.

About Configuration Options in Ranges

This feature requires the appropriate security level.

Details for each range have 1 or more of the following configuration options:

Field	Notes
Limits	Enables the laboratory to define 1 or more intervals along the result continuum for the test. The laboratory can configure different actions for each interval. The system places each result in the appropriate interval and performs the defined actions for that interval. **NOTE:** The manufacturer defines the Limits of certain Ranges.
Flag result or Result Review	Enables the laboratory to configure the system to add a flag to the patient result or to hold the result for operator review. The option that is available depends on the range. **NOTE:** The Result Review option is only available for Interpretation Ranges. The system requires the flagging of some results if the laboratory defines the range.

Field	Notes
Repeat	Enables the laboratory to configure the system to automatically order Repeat tests for the appropriate results. The availability of Repeat testing depends on the type of range (Page 751 *About the Repeat Option in Ranges*).
Number of Repeats	Specifies the number of reportable results that the analyzer generates and can send to the LIS. The system sets this number to 2 if the range and the assay requires this option. **NOTE:** This feature is limited to IM assays that enable the final result rule.
Dilution	Enables the laboratory to configure the Dilution for Repeat tests. **NOTE:** The ability of the laboratory to configure this feature depends on the assay and the range.
Replicates	Enables the laboratory to configure the number of times the system aspirates the patient sample for Repeat tests. This field is available if the laboratory enables Repeat testing. **NOTE:** The system only performs 1 replicate of CH assays.
Reflex	Enables the laboratory to configure the system to automatically order a Reflex test for the appropriate results. Available Reflex tests are all enabled tests that support the specimen type including test panels, dilution panels, ratio tests, off-system tests, and sort tests.
Dilution	Enables the laboratory to configure the appropriate Dilution for the Reflex test. This field is available if the laboratory enables Reflex testing when defining the range. **NOTE:** Available options depend on the selected Reflex test. The system does not support Dilution when reflexing to test panels, dilution panels, ratio tests, or off-system tests.

Field	Notes
Replicates	Enables the laboratory to configure the number of Replicates for IM Reflex tests. This field is available if laboratories configure an IM Reflex test when defining the range. **NOTE:** The system only performs 1 replicate of CH assays.
Comment	Enables the laboratory to configure the system to automatically add a Comment to the appropriate results.

The system disables fields that are unavailable or not configurable for the range type. In addition, the system configures some fields according to assay requirements. The laboratory cannot change these settings.

The configuration options that are available depend on the type of range and assay:

- Reference (Page 756 *About Configuration Options in Reference Range Details*)
- Delta Check (Page 760 *About Configuration Options in Delta Check Ranges*)
- Check (Page 763 *About the Configuration Options in Check Ranges*)
- Concentration (Page 766 *About the Configuration Options in Concentration Ranges*)
- Index (Page 738 *About Configuration Options in Index Ranges*)
- Dilution Point (Page 741 *About the Configuration Options in Dilution Point Ranges*)
- Linearity (Page 744 *About the Configuration Options in Linearity Ranges*)
- Interpretation (Page 770 *About Configuration Options in Operator-Defined Interpretation Ranges*) (Page 768 *About Configuration Options for Predefined Interpretation Ranges*)

About Reference Ranges

This feature requires the appropriate security level.

Reference Ranges establish the following 5 intervals to better qualify patient results:

- Critical Low
- Low

- Normal
- High
- Critical High

The system uses manufacturer-suggested Limits to create a default Reference Range for each CH assay. Laboratories use Edit Range to modify these Limits.

Default Reference Ranges are not available for IM assays. Laboratories must define their own Limits to create a Reference Range.

NOTE: Laboratories should not define the Limits in Reference Ranges so that they are greater than those of the Concentration or Index Ranges. If this occurs, the system posts a warning message before saving the range.

Laboratories must define the Low Limit before the Critical Low Limit and the High Limit before the Critical High. The system then uses the Low and the High Limit to define the Normal interval.

The system does not require the configuration of each interval for a valid Reference Range. The minimum requirements for saving a Reference Range are the following:

- Specification of a Low or a High Limit
- A Range Name

Laboratories can define up to 10 Reference Ranges for each assay by modifying the Demographics Information.

NOTE: The system does not allow the demographics of multiple Reference Ranges to overlap.

If the laboratory defines multiple Reference Ranges, the system evaluates the demographics in each range to determine which range matches the patient. Depending on the patient matching selection in Patient Results Management, the system performs the Repeat or Reflex actions for any range that matches the currently reported result.

The system posts an entry to the Audit Trail Log whenever an operator adds, edits, or deletes a Reference Range.

About Configuration Options in Reference Range Details

This feature requires the appropriate security level.

The intervals in Reference Ranges have the following configuration options (Page 753 *About Configuration Options in Ranges*):

Option	Notes
Limits	Configurable for the following intervals: • Critical Low • Low • High • Critical High The Low and the High limit become the Limits for the Normal interval. All results up to and including the Low and the High values are in the Normal interval. **NOTE:** The operator must enter the Low Limit before the Critical Low Limit and the High before the Critical High.
Flag result	Not configurable. The system automatically reports results in defined intervals with a result flag (Page 759 *About the Result Flags for Reference Ranges*). **NOTE:** The system does not flag results in the Normal interval.
Repeat	Configurable for the following intervals: • Critical Low • Low • High • Critical High **NOTE:** The interval must have defined Limits to enable configuration of this field.
Number of Repeats	Not available.

Option		Notes
	Dilution	Not configurable. **NOTE:** The system uses the Dilution of the Original result for all Repeat tests.
	Replicates	For IM assays, configurable for intervals that the laboratory configures with a Repeat test. If the laboratory leaves this field blank, the system uses the number of Replicates in the assay Test Definition. **NOTE:** The system only performs 1 replicate of CH assays.
Reflex		Configurable in all defined intervals. **NOTE:** Cannot Reflex to off-system tests.
	Dilution	Configurable if the laboratory defines the interval with a Reflex test.
	Replicates	Configurable if the laboratory defines the interval with an IM Reflex test. **NOTE:** If reflexing to an IM test and the laboratory does not specify the number of Replicates, the system uses the number in the assay Test Definition. The system only performs 1 replicate of CH assays.

Option	Notes
Comment	Configurable for the following intervals: • Critical Low • Low • High • Critical High **NOTE:** The interval must have defined Limits to enable configuration of this field.

NOTE: The system requires configuration of at least the Low or the High Limit to save the range.

Laboratories can also configure all demographic fields.

About the Result Flags for Reference Ranges

The following flags alert the operator to results in the following Reference range intervals:

Result value	Result flag
In the Critical Low interval	Critical Low
In the Low interval	Low
In the High interval	High
In the Critical High interval	Critical High

NOTE: For IM assays, laboratories must configure the Reference range before the system flags results. In addition, the system only reports flags for defined intervals within the range.

About Delta Check Ranges

This feature requires the appropriate security level.

Delta Check Ranges compare the change in patient test results over time to see if the change is greater than or less than a specified delta. The laboratory configures the delta as an Absolute value or a specified percentage of the first result.

NOTE: The global Delta Check Previous Result setting in Patient Results Management specifies whether the system retrieves the previous result from the LIS or from the active and historical database on the System.

This delta change creates the following 2 intervals in Delta Check Ranges:

Interval	Notes
Exceeded	Configures the Repeat and Reflex actions for results that exceed the specified delta value.
Within	Configures the delta value as a Percentage or Absolute value of the previous test result.

The system automatically posts an Exceeded Delta Check flag if the change in the result exceeds the laboratory-specified value. Laboratories can also configure the system to flag Within Delta results because results that do not change over time may indicate a condition that is not improving.

The Time Limit configures the length of time (in Days and Hours) that previous results remain valid for use in a Delta Check comparison.

The Days can range from 1–999 and the Hours from 1–23. The result remains valid for delta checking if the time duration between the last result and the current result equals the specified time duration.

NOTE: The Time Limit is an optional field. If the laboratory does not specify a time limit, the system uses the last result regardless of the date of the result.

Laboratories can create up to 10 Delta Check ranges for each assay by modifying the Demographics Information. The demographic values cannot overlap the demographics of a previously saved Delta Check range.

If overlapping out-of-range values and multiple flags occur, the system posts a Delta Check Range Conflict flag with the result. If the laboratory configures the patient matching option, the system performs the Repeat or Reflex actions for all matching Ranges.

The system posts an entry to the Audit Trail Log whenever an operator adds, edits, or deletes a Delta Check Range.

About Configuration Options in Delta Check Ranges

This feature requires the appropriate security level.

The intervals in Delta Check Ranges have the following configuration options (Page 753 *About Configuration Options in Ranges*):

Option	Exceeded	Within
Limits	Any value greater than the specified delta.	Configurable.
Flag result	Not configurable. A result flag always posts with the result.	Configurable.
Repeat	Configurable.	Not available.
Number of Repeats	Not available.	Not available.
Dilution	Not configurable. All Repeat tests use the Dilution of the Original result.	Not available.
Replicates	Configurable.	Not available.
Reflex	Configurable.	Not available.
Dilution	Configurable if the laboratory defines the interval with a Reflex test and if the Reflex test supports dilution. The system provides all available options in a drop-down menu.	Not available.
Replicates	Configurable if the laboratory defines the interval with an IM Reflex test. The system provides all available options in a drop-down menu. A blank indicates that the system performs the same number as in the assay Test Definition.	Not available.

Option	Exceeded	Within
	NOTE: The system can only perform 1 replicate of CH tests.	
Comment	Configurable.	Not available.

NOTE: The system disables fields that are unavailable or are not configurable for an assay or for an interval within the range.

Laboratories can also configure all demographic fields and the length of time that previous results remain valid in Time Limit.

About Check Ranges

This feature requires the appropriate security level.

Check Ranges provide the laboratory with the ability to configure a range that focuses on a specific portion of the result continuum. Laboratories can specify an upper and lower limit for the result checking and any additional Repeat and Reflex testing that the assay requires.

The upper and lower Limits create the following 3 intervals in Check Ranges:

- Below
- Within Check
- Above

NOTE: For valid results, the Limits must be within the measuring intervals as specified in the assay IFU.

The system automatically flags any result that falls in the Within Check interval (Page 764 *About the Result Flags for Check Ranges*). Depending on the assay and laboratory practice, the laboratory can configure 1, 2, or all intervals (Page 763 *About the Configuration Options in Check Ranges*).

IM assays can only have 1 Check Range per assay. CH assays can have 1 Check Range for each specimen type that the assay supports.

Some IM assays, such as those that test for infectious diseases, require a Check range. For these assays, the system uses the manufacturer-specified Limits to create the required Check Ranges. Laboratories can edit the Limits and other configuration options, as appropriate.

NOTE: For valid results, the Limits must not fall outside the measuring intervals as specified in the assay IFU.

The system requires a minimum of the following to Save a Check Range:

- Name
- Lower or upper limit for the Within Check interval

The system posts an entry to the Audit Trail Log whenever an operator adds, edits, or deletes a Check Range.

About the Configuration Options in Check Ranges

This feature requires the appropriate security level.

Check Ranges have the following configuration options:

Field	Notes
Limits	Configurable for the Within Check interval. The laboratory enters a lower limit and an upper limit to create an interval on the result continuum that is within range. The system uses the lower limit to create a Below Check interval and the upper limit to create an Above Check interval. **NOTE:** Laboratories can define both Limits, but the system only requires 1 to save the range.
Flag result	• Not configurable for the Within Check interval. The system automatically reports results in this interval with a result flag (Page 764 *About the Result Flags for Check Ranges*). • Configurable for the Below and Above intervals. Laboratories must define the limit of the Within Check interval to enable flagging of results in the Below and Above intervals.
Repeat	Configurable for all defined intervals.
Number of Repeats	Not configurable. **NOTE:** For IM assays that can use the final result rule (FRR), the system populates this field with 2 if the laboratory enables the FRR.
Dilution	Not configurable. **NOTE:** All Repeat tests use the same Dilution as that of the Original result.

Field	Notes
Replicates	Configurable if the laboratory defines the interval with an IM Repeat test for the interval. The system provides all available options in a drop-down menu. A blank indicates that the system uses the number of Replicates as that of the initial test result. **NOTE:** The system performs 1 replicate of all CH tests.
Reflex	Configurable for all defined intervals.
Dilution	Configurable if the laboratory defines the interval with a Reflex test and if the Reflex test supports dilution. The system provides all available options in a drop-down menu.
Replicates	Configurable if the laboratory defines the interval with an IM Reflex test. The system provides all available options in a drop-down menu. A blank indicates that the system performs the same number as in the assay Test Definition. **NOTE:** The system performs 1 replicate of all CH tests.
Comment	Configurable for all defined intervals.

NOTE: The system disables fields that are unavailable for a particular assay or range.

CH assays also enable configuration of the range according to Specimen type. This demographic is not available for IM assays.

About the Result Flags for Check Ranges

The system reports results with the following result flags:

Result value	Result flag
Less than the lower limit of the Within Check interval	Below Check
Within Check	Within Check
Greater than the upper limit of the Within Check interval	Above Check

NOTE: Laboratories must enable result flagging in the Below and Above interval before the system flags results in those intervals. The system always flags the Within Check interval if the laboratory defines the range for the assay.

About Concentration Ranges

This feature requires the appropriate security level.

Concentration Ranges enable the system to automatically repeat test results that are outside the manufacturer-specified measuring interval for the assay. This range is available if the assay reports results in terms of Concentration. Assays that report results in terms of Index values use the Index Range (Page 737 *About Index Ranges*). The system automatically displays the correct range type for the assay.

NOTE: Some IM assays report results with Concentration and Index values. The system displays both range types for these assays.

The assay manufacturer specifies the lower and upper Limits for the Within Range interval if a different dilution is available. These Limits form the measuring interval for the assay and are based on manufacturer testing and conform to the assay claims in the IFU. Laboratories that require tighter restrictions on the measuring interval can configure the Linearity Range for this purpose.

Specification of the Within Range Limits also creates the following 2 intervals:

- Below Range
- Above Range

The system automatically flags any result that falls in the Below Range and Above Range Intervals (Page 764 *About the Result Flags for Check Ranges*). The following flags post in these intervals:

Range interval	Result flag
Below Range	< Measuring Interval
Above Range	> Measuring Interval

The system also enables laboratories to configure Repeat and Reflex actions for results in these intervals (Page 766 *About the Configuration Options in Concentration Ranges*).

Laboratories can only define 1 Concentration Range for each IM assay. CH assays can have 1 Concentration Range for each Specimen type that the assay supports.

The system requires a minimum of a laboratory-defined name to Save a Concentration Range.

The system posts an entry to the Audit Trail Log whenever an operator defines, adds, edits, or deletes a Concentration Range.

About the Configuration Options in Concentration Ranges

This feature requires the appropriate security level.

The Below Range and Above Range intervals in Concentration Ranges have the following configuration options* (Page 753 *About Configuration Options in Ranges*):

Field	Notes
Limits	Not configurable. The system uses the manufacturer-specified measuring interval to define 3 intervals along the result continuum: • Below Range • Within Range • Above Range Results that are less than the lower limit of the measuring interval are in the Below Range interval of the range. Results that are greater than the upper limit of the measuring interval are in the Above Range interval.
Flag result	Not configurable. **NOTE:** If the laboratory defines the range, the system automatically reports results that are Below Range with a result flag and sets the result value as less than the manufacturer-specified lower limit of the measuring interval and results that are Above Range with a result flag and sets the result value as greater than the upper limit of the measuring interval.
Repeat	Configurable.
Number of Repeats	Not available.
Dilution	Configurable if the laboratory defines the interval with a Repeat test. The system provides the available Dilution options for the test in a drop-down menu. Assays that support more than 1 Dilution factor also support the auto step feature.

Field	Notes
Replicates	Configurable if the laboratory defines the interval with an IM Repeat test. A blank value indicates that the system performs the same number Replicates as that for the initial test result. **NOTE:** The system only performs 1 replicate of CH assays.
Reflex	Configurable. **NOTE:** Cannot reflex to off-system tests.
Dilution	Configurable if the laboratory defines the interval with a Reflex test and if the Reflex test supports Dilution. The system provides the available Dilution options for the test in a drop-down menu. **NOTE:** Undiluted indicates that the Reflex test only supports a neat sample.
Replicates	Configurable if the laboratory defines the interval with an IM Reflex test. **NOTE:** The system can only perform 1 replicate of CH assays.
Comment	Configurable.

* No configuration options are available for the Within Range interval.

CH assays can also specify the type of Specimen for the range. This field is not available for IM assays.

About Interpretation Ranges

This feature requires the appropriate security level.

Interpretation Ranges enable the laboratory to provide a qualitative judgment of any numerical test result. The laboratory specifies the interval on the result continuum and provides the appropriate judgment in the form of a Range Name. The system then attaches this Range Name to results in this interval.

NOTE: The system allows open-ended range limits.

The laboratory can also configure Interpretation Ranges to perform 1 or more of the following:

- Hold results for operator review
- Perform Reflex testing
- Add a Comment to the result

Some assays require an interpretation of the results in addition to the result value. The assay can use 1 of the following Interpretation schemes when reporting results:

- Negative, Equivocal, or Positive
- Confirmed, Equivocal, or Unconfirmed
- Reactive, Equivocal, or Nonreactive

NOTE: The assay manufacturer designates the appropriate Interpretation scheme for assays that require a qualitative result. Laboratories cannot change this designated Interpretation.

The system creates an Interpretation Range for assays that require a qualitative result. It uses the manufacturer-specified assay cutoff to establish the appropriate intervals along the result continuum for the designated Interpretation scheme. By default, this predefined range does not require an operator review of the results. The laboratory can edit predefined Interpretation Ranges to hold results for operator review and to configure additional range actions (Page 768 *About Configuration Options for Predefined Interpretation Ranges*).

NOTE: The laboratory cannot delete predefined Interpretation Ranges or change the result values (Limits) that result in a specific Interpretation.

Laboratories can define up to 10 Interpretation Ranges in addition to any predefined Interpretation Ranges for each assay. The Limits of operator-defined Interpretation Ranges can overlap those of any predefined Interpretation Ranges. When overlap occurs, the system posts all of the matching operator-defined interpretations with the numerical result.

The system posts an entry to the Audit Trail Log whenever an operator defines, edits, or deletes an Interpretation Range.

About Configuration Options for Predefined Interpretation Ranges

This feature requires the appropriate security level.

Predefined Interpretation Ranges have the following configuration options:

Field	Notes
Limits	Not configurable. The system uses the cut-off value in the assay IFU to create Limits for each Interpretation within the required Interpretation Scheme for the assay.
Result Review	Configurable.
Repeat	Not available.
Number of Repeats	Not available.
Dilution	Not available.
Replicates	Not available.
Reflex	Configurable. **NOTE:** Cannot Reflex to off-system tests.
Dilution	Configurable if the laboratory defines the interval with a Reflex test and if the Reflex test supports Dilution. The system provides the available Dilution options for the test in a drop-down menu. **NOTE:** Undiluted indicates that the Reflex test only supports a neat sample.
Replicates	Configurable if the laboratory defines the interval with an IM Reflex test. **NOTE:** If reflexing to an IM test and the laboratory does not specify the number of Replicates, the system uses the number in the assay Test Definition. The system only performs 1 replicate of CH assays.
Comment	Configurable.

The Equivocal interval is only configurable if the assay manufacturer defines Limits for this interval.

In addition, the Specimen demographics field for CH assays is configurable if the assay supports more than 1 Specimen type. The Specimen type is not available for IM assays.

About Configuration Options in Operator-Defined Interpretation Ranges

This feature requires the appropriate security level.

Operator-defined Interpretation Ranges have the following configuration options:

Field	Notes
Limits	Configurable. Laboratories can define an upper and lower value for the range, but the system only requires 1 to save the range.
Result Review	Configurable.
Repeat	Not available.
Number of Repeats	Not available.
Dilution	Not available.
Replicates	Not available.
Reflex	Configurable. **NOTE:** Cannot Reflex to off-system tests.
Dilution	Configurable if the laboratory defines the interval with a Reflex test and if the Reflex test supports Dilution. The system provides the available Dilution options for the test in a drop-down menu. **NOTE:** Undiluted indicates that the Reflex test only supports a neat sample.

Field	Notes
Replicates	Configurable if the laboratory defines the interval with an IM Reflex test. **NOTE:** If reflexing to an IM test and the laboratory does not specify the number of Replicates, the system uses the number in the assay Test Definition. The system only performs 1 replicate of CH assays.
Comment	Configurable.

The Specimen demographics field is configurable for CH assays that support more than 1 Specimen type. The Specimen type is not available for IM assays.

About Off-System Tests

This feature requires the appropriate security level.

Off-System in Test Definition enables the laboratory to add tests that the system does not perform. When the laboratory adds the test to the system, the operator can add the test to a patient order or include the test in repeat and reflex actions. The laboratory obtains the result from an external source, and the operator adds this result to the patient sample order. The maximum number of off-system tests is 500.

The following are examples of possible uses for off-system tests:

- To calculate an RBC folate, the operator must enter the Hematocrit from a Hematology system.
- To obtain a complete Triple Screen panel, the operator must enter a result for Unconjugated Estriol.
- To include a manually performed test such as ionized calcium with PTH.
- To include a test code that corresponds to a factor for a specialty calculation.

  NOTE: An example of a specialty calculation is the Estimated Glomerular Filtration Rate (GFR) for children. The operator enters the height in: GFR (mL/min/1.73 m^2) = (0.41 × Height in cm) / Creatinine in mg/dL
- To enter volumes for 24-hour urine determinations.

About Adding Off-System Tests

This feature requires the appropriate security level.

Off-System Test enables the laboratory to add the appropriate information for off-system tests. After adding the information, operators can include the off-system test in a patient order and add the result to the patient report.

Off-System Test includes information fields for Test Identification and Calculation. The following fields are part of Test Identification:

Test Identification	Notes
Test Name	Unique name the operator assigns to orders and results that transmit to the LIS: • Starts with alphanumeric chars or % • Includes 1–10 alphanumeric chars, %), or _
Test Version	Version of Test Name when more than 1 Test Name is enabled. Default is 1.0.
Display Name	Unique name the operator assigns to distinguish a version of the test. Default is Test Name.
Print Name	Unique test name that prints on reports. Default is Test Name.
LIS Code	Code the operator assigns to Test Name and transmits to the LIS. Default is Test Name: • Starts with alphanumeric chars or % • Includes 1–10 alphanumeric chars, %), or _

The following fields are part of Calculation:

Calculation	Notes
Low Limit	The lowest possible value of the reference interval for the assay (0–100). The system flags results below this value.
High Limit	The highest possible value of the reference interval for the assay (0–100). Indicates results above this value flag. **Note:** The High Limit must be greater than the Low Limit.
Decimal	The number of decimal places the analyzer uses to display, report, and print results for this test. Choice of 0, 1, 2, or 3. Default is 2.
Units	The units of measure for reporting test results. Choices include Units in Test Definition Calculation. Default is mg/dL.

Enable/Disable	Notes
Enable	Includes this test in all order processing and test selections (default).
Disable	Excludes the operator, LIS, or system from ordering or selecting it.

About Panels

Panels enable the laboratory to group multiple tests together when creating a patient order. Operators can select this panel (or group of tests) and order all the tests simultaneously. Laboratories can define the following types of Panels:

Panel	Notes
Dilution Panel	Automatically orders multiple dilutions for an assay test. A dilution panel includes 1 assay and at least 1 selected dilution. Only system dilutions are available to enter in a Dilution Panel. A dilution panel cannot be configured to include manual dilutions.
Test Panel	Automatically orders multiple assays the operator orders as a group

About Dilution Panel Definition

Dilution Panel Definition schedules multiple dilutions for assays. A dilution panel includes 1 assay and at least 1 selected dilution. Only system dilutions are available to enter in a Dilution Panel. A dilution panel cannot be configured to include manual dilutions.

When adding a dilution panel, the following applies to the panel and its test and dilution:

- In patient orders, panels of the same specimen type display.
- The system automatically orders all the dilutions the operator selects in the Dilution Panel Definition.
- When the operator selects a dilution panel, the analyzer displays the Panel Name with the test name in the selected tests table. The operator can configure dilution panel test options.
- The operator can clear a selected dilution panel but not an individual dilution in that panel.

Dilution Panel Definition	Notes
Panel Name	Operator-defined unique panel name. Must be 1–10 alphanumeric characters, %, or _ and must start with a % or letter.
Print Name	Name for this dilution panel in print on a report. Populates when the Panel Name is entered but is editable.

Dilution Panel Definition	Notes
Selected Test	Read-only field for the Display Name of the test.
LIS Code	Code for the dilution panel for use by the LIS. Populates when the Panel Name is entered but is editable.
Enable or Disable	Enable (default) includes this test in all order processing and test selections. Disable excludes the dilution panel from the operator, LIS, or analyzer ordering or selecting it.
Search	The system searches for the test Display Name for the selected test from Tests list.
Specimen	The specimen type for the tests in the dilution panel. The drop-down menu contains the same fixed list of specimen types as in patient orders. The default is Serum. Selecting a specimen type filters specimen-incompatible tests from the Tests list. Multiple specimen types are not permitted.

Dilution Panel Definition	Notes
Tests	Scrollable list of all orderable tests defined on the analyzer. The tests include: • All enabled configured assays • Tests with at least 1 dilution defined including Undiluted • Tests with Standard or ID Standard Test Types The test order in this list is fixed and identical to an existing order. The operator can select only 1 test in a dilution panel.
Dilutions	List of all the available dilutions for the selected test. A check box accompanies each individually selected dilution. The Dilutions header check box selects or de-selects all the list entries at once. Assays with no dilution defined exist on the system.

When a dilution panel exists, options display to Save, Clear, or Close. Clear returns the screen to the default fields.

About Adding Test Panels

Test Panel Definition	Notes
Panel Name	Operator-defined unique panel name. Must be 1–10 alphanumeric characters, %, or _ and must start with a % or letter.
LIS Code	Code for the test panel transmitted to the LIS. The Panel Name and the LIS Code are identical only by default. Populates when the Panel Name is entered but is editable.

Test Panel Definition	Notes
Group	The test list displays by groups. Groups include: All, Routine Assays, Ratio, ID Assays, and Other.
Enable or Disable	Enable (default) includes this test in all order processing and test selections. Disable excludes the dilution panel from the operator, LIS, or analyzer ordering or selecting it.
Test Selections	The assays included in the panel display as the operator selects them from Search or select from the list of tests.
Search	Search of the Display Name for the appropriate test from list.
List of tests	Scrollable list of all orderable and enabled tests defined on the system. The order of this list is fixed and identical to a Workorder.

When a test profile exists, options display to Save, Clear, or Cancel. Clear returns the screen to the default fields.

About Ratios

The operator can define, edit, and delete operator-defined ratios using Add New. After saving a ratio, the operator can modify or create a new ratio based on the save ratio in Add Predefined. The lab manager configures security access to Ratios.

The sort order of the summary table is in ascending order based on the creation date and time. By default, no row is selected.

Ratios	Notes
Check box located before Panel Name	Selects of 1 or more ratios for deletion or print. This check box must be selected to edit or view a ratio.
Panel Name	Displays the operator-defined title for the ratio.

Ratios	Notes
LIS Code	Displays the code for use by the LIS. The Panel Name and the LIS Code are identical only by default. As the operator enters the ratio name, the system populates the LIS Code that the operator can edit.
Status	Displays Enabled or Disabled.
Details	Displays the details of the ratio equations.

Filter refines the rows of the summary table by test name.

About Ratio Test Definition

Ratio Test Definition configures new and edits existing ratio tests. A ratio test is a mathematical expression, containing 1 or more assays and a given set of arithmetic and mathematical formulas, that calculates the result.

Ratio Test Definition	Notes
Ratio Test Name	Operator-defined unique ratio name. Must be 1–10 alphanumeric characters, %, or _ and must start with a % or letter.
LIS Code	Code for the ratio for use by the LIS. Populates when the operator enters the Ratio Test Name but is editable.
Units	Units the analyzer appends to the result. The operator must confirm the units selected are appropriate to the test definitions in use as this impacts every result. The drop-down menu contains the same fixed list of units as in the Definition tab in Setup Test Definition. Default is mg/dL. The analyzer allows manual entries of units.
Result Review Mode	Drop-down menu that specifies whether the analyzer automatically reviews and accepts the ratio test results. Choices include: Review None (Default), Review All, and Review By Exception.

Ratio Test Definition	Notes
Enable/Disable	Enable (default) includes this test in all order processing and test selections. Disable excludes the ratio from the operator, LIS, or analyzer ordering or selecting it.
Print Name	Name of the ratio in a printed report. Autofills with identical Ratio Test Name.
Decimal	Number of decimal places the analyzer uses to display, report, and print results for this test. Choice of 0, 1, 2 or 3 decimal places to display. By default, 2 decimal places display.
Formula	A mathematical formula, containing 1 or more tests and a given set of arithmetic and mathematical operators, that calculates the results for a ratio test. The operator enters the formula (select Operators, Numbers, and Tests), selects common predefined ratios, or pastes in an existing formula. By default, the Formula text box is blank.
Operators	Options of arithmetic and mathematical operations to include in the formula. The system calculates the formula from left to right and applies the following order of operations: 1. Negative operator, such as (–3.14) 2. Paired grouping operators “(...)” 3. Natural logarithm (ln), square root (R), and exponential operators (^) 4. Multiplication (*) and division (/) operators 5. Addition (+) and subtraction (-) operators
Numbers	Choice of digits and up to 1 decimal place for numeric entry into the formula.
Tests	Scrollable list of all orderable tests the operator defines. Tests include all enabled configured assays per specimen type chosen. The order of this list is fixed and identical to placing an order. The operator can select multiple tests in the ratio.

Ratio Test Definition	Notes
Specimen	The specimen type for the ratio test. The drop-down menu contains the same fixed list of specimen types as in the Definition tab in Setup Test Definition. The default is Serum. Selecting a specimen type filters specimen-incompatible tests from the Tests list. Multiple specimen types are not permitted.
Search	The system searches for the Display Name of the selected test from the list.
Predefined Ratios	A list of predefined laboratory ratio calculations or customized calculation.

The operator configures a formula in Ratio Test Definition. The following rules apply when entering a ratio test formula:

- Format for entered values:
  - Numeric values must be from 0–9999999.0000, with up to 4 decimal places of precision.
  - Total formula string cannot exceed 512 characters in length.
  - Negative values must be in parenthesis and use – before the number, such as (–3.14).
- The system:
  - Populates opening and closing parentheses and the function when R or In values are entered by the operator.
  - Performs operations from left to right in the following order: Negative operator, paired operations in parentheses, log and square root operators, multiply and divide operators, add and subtract operators.
- Available formula functions:
  - Verify Formula: Verifies the syntax of the current formula string and informs operator of the result.
  - Clear: Functions as the BACKSPACE key.
- Test selection criteria:
  - Enabled
  - Supports the selected specimen type
  - Cannot be a Component test
  - Cannot be an ID Manual FRR or ID Auto FRR test
  - Cannot be a ratio test, a dilution profile, or a test profile

When the operator enters a ratio test, options display to Save, Clear, or Cancel. Clear returns the screen to the default fields.

About Test Display Order

The operator can customize the order that assays display. This test order displays in:

- Any assay list for creating patient orders
- QC order entry
- Any assay list in Worklist
- Printed Lab Results Reports

The system displays the operator-defined tests for ratios, dilution, and test panels after the system-defined tests.

Test Display Order	Notes
Search	Allows the operator to search for an assay.
Selected Assays	Displays the number of assays currently selected in the list in a read-only field.
Move Selected Tests to Position	Re-orders the position of 1 or more selected assays. Valid values are 1–9999. Specifying a value greater than the number of assays in the list moves the selected assay to the end of the list.
Position	Displays the position of the assay.
Test	Displays the name of the assay. By default, assays display alphabetically.
Move Selection	Moves selected assays to a new test display order.
Clear Selection	Clears the assay selection boxes.
Restore Defaults	Restores the list to the default order.
Save	Saves changes made to test display order.
Cancel	Cancels all the changes since the last time the operator saved the order.

About CH Operator-defined Assays

Each analyzer has a default of 25 Operator-defined CH assay channels. The laboratory can purchase additional Operator-defined assay channels through Siemens Healthineers.

The number of available channels indicates the remaining number of assays and is located at the end of the following message at the top of the window: "The operator is responsible for validating any modifications made to the instructions, systems, reagents, or software provided by Siemens Healthineers."

Each Operator-defined test result is flagged with Operator-defined Assay.

The system groups the configurable parameters of the Operator-defined Test Definition for each assay into the following categories:

- Definition
- Sample/Reagent
- Calculation
- Calibration
- Mitigation
- Ranges
- Repeat

Customer Responsibility

For products not purchased from Siemens Healthineers, the customer assumes all responsibility for selecting the proper reagents, entering the proper test parameters, using proper test protocols, determining the correctness of test results, and resolving any associated errors or omissions. In addition, the customer assumes all responsibility for any adverse impact on the system from the use of such products.

Warranty

Siemens Healthineers expressly disclaims all warranties with respect to this operator-defined product, where express or implied, including all warranties or merchantability or fitness for a particular purpose. For reagents not purchased from Siemens Healthineers, the warranty for Atellica Solution analyzers does not extend to the performance of operator-defined reagents (including operator-defined test results or standard Atellica test results that are affected by operator-defined testing), their effect on system operation and types and frequency of maintenance, or their effect on operator safety.

About Configuring CH Operator-defined Assays Calculation and HIL

The operator defines the processing parameters for calculating the final result and reporting error conditions for operator-defined assays in Operator-defined Calculation:

- Calculation: Processing parameters for calculating the final result and reporting error conditions for operator-defined assays.
- HIL Donor Settings: Define HIL donor assay parameters.

About Configuring CH Operator-defined Assays High-dose Hook Effect

The High-dose Hook Effect is an evaluation for antigen excess that triggers a > Measuring Interval result flag and an auto-dilution if configured for that assay in the Operator-defined High-dose Hook Effect. This feature is not required unless specified in the assay kit specific IFU. All fields are optional.

High-dose Hook Effect	Notes
Enable Hook-effect Check	A check box that enables the High-dose Hook Effect feature.
Hook-effect Formula	Drop-down menu that includes: • Prozone Formula: An absolute absorbance or difference in absorbance within a single reaction. • Rate Method: An evaluation of reaction rates where the operator can enter 1 or 2 regions of the reaction to monitor.
Primary Wavelength Only	Uses the single monochromatic main-wavelength in all Hook Effect calculations.

High-dose Hook Effect	Notes
Hook-effect Limit Type	The operator specifies how the Hook-effect Limit relates to the output from the assay's Hook Effect Check. The drop-down menu includes a limit type: • Upper: An error generates when the Hook-effect Formula result is greater than the Hook-effect Limit. This limit type is for reactions where increasing absorbance is proportional to increasing analyte concentration. • Lower: An error generates when the Hook-effect Formula result is less than the Hook-effect Limit. This limit type is for reactions where decreasing absorbance is proportional to increasing analyte concentration.

High-dose Hook Effect	Notes
Hook-effect Limit	Mandatory if the operator disables Automatic Limit Determination and checks Enable Hook-effect Check. Deactivated when operator enables Automatic Limit Determination. If the formula value exceeds or falls below the Hook-effect Limit, the > Measuring Interval flag triggers. Expected values: -6000–6000 mAU. The operator enters a limit value to trigger the antigen excess flag when the substrate is depleted. If the Hook-effect Limit Type is configured as: • Upper: A Hook Effect Check result greater than this limit triggers the > Measuring Interval flag. • Lower: A Hook Effect Check result below this limit triggers the > Measuring Interval flag.
Evaluation Threshold	Available only when the Hook-effect Formula is Rate Method. Identifies a threshold on the Initial Rate to define when Hook Effect checking is permitted. Suppresses false flags of normal low-analyte samples. This threshold is a check on the initial rate of signal change during the time specified by Initial Window Start Time and Initial Window End Time. The Evaluation Threshold identifies the initial reaction rate that activates the Hook Effect checking.

High-dose Hook Effect	Notes
Evaluation Limit	Optional setting or is this required for 2-Point Rate (2PA). A reaction absorbance or rate limit for the subsequent high-dose hook effect calculations and integrity checks to occur. Specifies the test's final reaction signal value that restricts when the analyzer applies the check. The Hook-effect Limit Type setting controls the relationship between the Evaluation Limit and test's final reaction signal.
Main Window Start Time	The first read time of the main reaction read window for High-dose Hook Effect checking. Acceptable values include: 21, 30, 39, 48, 57, 66, 75, 84, 100, 109, 118, 127, 136, 145, 153, 162, 171, 180, 189, 198, 207, 216, 225, 234, 243, 252, 259, 268, 277, 286, 295, 304, 312, 321, 330, 339, 348, 357, 366, 375, 384, 393, 402, 411, 420, 427, 436, 445, 454, 463, 472, 480, 489, 498, 507, 516, 525, 534, 543, 552, 561, or 570.
Main Window End Time	The last read time of the main reaction read window for High-dose Hook Effect checking. Acceptable values include: No entry, 12, 21, 30, 39, 48, 57, 66, 75, 84, 100, 109, 118, 127, 136, 145, 153, 162, 171, 180, 189, 198, 207, 216, 225, 234, 243, 252, 259, 268, 277, 286, 295, 304, 312, 321, 330, 339, 348, 357, 366, 375, 384, 393, 402, 411, 420, 427, 436, 445, 454, 463, 472, 480, 489, 498, 507, 516, 525, 534, 543, 552, 561, or 570.

High-dose Hook Effect	Notes
Initial Window Start Time	The first read time of the subsidiary or initial read window for High-dose Hook Effect checking. Acceptable values include: No entry, 0, 12, 21, 30, 39, 48, 57, 66, 75, 84, 100, 109, 118, 127, 136, 145, 153, 162, 171, 180, 189, 198, 207, 216, 225, 234, 243, 252, 259, 268, 277, 286, 295, 304, 312, 321, 330, 339, 348, 357, 366, 375, 384, 393, 402, 411, 420, 427, 436, 445, 454, 463, 472, 480, 489, 498, 507, 516, 525, 534, 543, 552, 561, or 570.
Initial Window End Time	The final read time of the subsidiary or initial read window for High-dose Hook Effect checking. Acceptable values include: No entry, 12, 21, 30, 39, 48, 57, 66, 75, 84, 100, 109, 118, 127, 136, 145, 153, 162, 171, 180, 189, 198, 207, 216, 225, 234, 243, 252, 259, 268, 277, 286, 295, 304, 312, 321, 330, 339, 348, 357, 366, 375, 384, 393, 402, 411, 420, 427, 436, 445, 454, 463, 472, 480, 489, 498, 507, 516, 525, 534, 543, 552, 561, or 570.
Automatic Limit Determination	A unique value for each lot and pack calibration. This enables the High-dose Hook Effect to empirically derive a Hook-effect Limit during the calibration process.

High-dose Hook Effect	Notes
Calibration Level	Mandatory selection when Automatic Limit Determination is enabled. The input value defines the single-level source the analyzer uses to set the Hook-effect Limit. The operator enters the number of the calibration level from Operator-defined assay Calibration.
Scaling Factor	A multiplier to adjust the automatically-derived, empirical value from the Automatic Limit Determination process. The default is 1.0 to use the full value (100%) of the Hook-effect Limit without adjustment. **NOTE:** A Scaling Factor of 0.8 would reduce the applied Hook-effect Limit by a factor of 0.8X or = 80% of the empirically derived number.

About Operator-defined Assays Calculation Analysis Methods

Three types of CH assay absorbance methods exists:

- Linear Reaction Rate (RRA) and 2-Point Rate (2PA) (kinetic reactions)
- End Point (EPA) (endpoint reactions)

The assay kit IFU typically states how long the analyzer processes the assay. See the IFU or reference another platform application sheet to determine the duration of the assay for the final read configuration.

Linear Reaction Rate (RRA) Kinetic Reactions

The Linear Reaction Rate (RRA) assay format evaluates absorbance as the reaction proceeds. The linear, zero-order reaction kinetics calculates the rate of absorbance change versus time and is not dependent on the reactant concentration.

When these fields are configured, the analyzer automatically determines which rate to use for the sample:

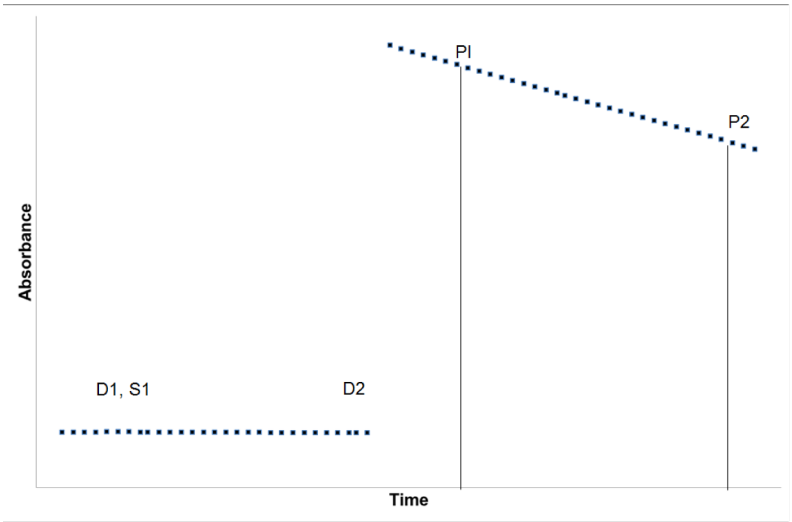
- Long Rate is for low and medium concentration samples and the operator must use the full Main End Time as the end of the reaction.
- Medium Rate is for high concentration samples and the reaction time is shorter than the long rate.
- Short Rate is for extremely high samples and have the shortest reaction time.

When configured for a Blank Rate Correction, a volume correction factor is applied to the calculation to account for the differential reaction volume before and after the second reagent probe addition. Most serum enzyme assays belong to this category. The reaction kinetics progress linearly (signal versus time). When RRA format is configured, the analyzer records reaction signals with particular wavelengths at each read cycle over the period defined by the Main Start Time to Main End Time then calculates a slope. A calibration curve fit transforms the calculated reaction rate to an analyte concentration.

Each time the cuvette passes the photometer between the Main Start Time and Main End Time, the analyzer records the absorbance in the reaction cuvette to calculate the reaction rate. Additional reads may occur depending on setup of optional features.

The Short End Time and Medium End Time are optional and configured for enzyme assays, such as ALT and AST. The Main End Time represents the Long End Time. These end times evaluate the best read window to calculate the result. Three cycle time based read windows are defined as long, medium, and short. The appropriate read window to determine where the rate is linear based on the change in slope from the start of the window to the end. The Linearity Factor defines the threshold for this change as a percentage. If the change in slope exceeds this percentage, the read fails and the analyzer evaluates the next read window. If all read windows fail this check, the analyzer flags the result as > Measuring Interval and may dilute and reprocess the sample. The long, medium, and short rates represent the percent change in slope for each window and are located in the SRS calculation data.

Linear Reaction Rate (RRA) reaction format



Linear Reaction Rate (RRA) reaction format	Notes
D1 (R1 Reagent)	The reagent probe reagent delivery from the P1 pack to the cuvette for testing. Maximum reagent probe dispense volume is 100 µL.
S1 (Sample)	The sample probe delivery from the dilution cuvette to the reaction cuvette. Maximum sample probe dispense volume is 25 µL.
D2 (R2 Reagent)	The reagent probe delivery from the P2 pack to the cuvette for testing. Maximum reagent probe dispense volume is 100 µL. For assays with > 2 reagents, a second volume addition may exist. The reagent probe aspirates from Well 1 first, followed by aspiration from Well 2, then dispenses both reagents into the reaction cuvette at the same time.

Linear Reaction Rate (RRA) reaction format	Notes
P1 (Main Start Time)	Initial absorbance time point. **NOTE:** The Main Start Time for a Linear Reaction Rate (RRA) assay must be ≥ 21 seconds. An invalid calculation error displays if the operator enters < 21 seconds.
P2 (Main End Time)	Final absorbance time point.

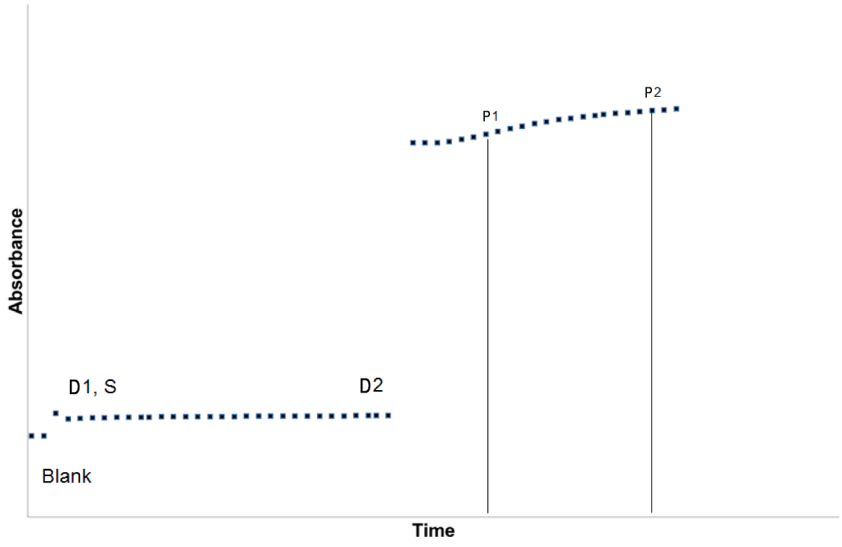
2-Point Rate (2PA) Kinetic Reactions

The 2-Point Rate (2PA) assay format evaluates absorbance as the reaction proceeds. The rate of absorbance change versus time and is dependent on the reactant concentration. The reaction kinetics are a non-linear pattern.

With a 2-Point Rate (2PA) configuration, the analyzer records reaction signals with particular wavelengths between 2 defined points in time (Main Start Time to Main End Time). The delta signal calculates the final signal. The calculated signal converts to an analyte concentration by mapping to a calibration curve.

The analyzer captures 2 additional reaction-absorbance readings immediately after and immediately before the Main Start Time and Main End Time respectively to calculate the result.

2-Point Rate (2PA) reaction format



2-Point Rate (2PA) reaction format	Notes
D1 (R1 Reagent)	The reagent probe reagent delivery from the P1 pack to the cuvette for testing. Maximum reagent probe dispense volume is 100 µL.
S (Sample)	The sample probe delivery from the dilution cuvette to the reaction cuvette. Maximum sample probe dispense volume is 25 µL.
D2 (R2 Reagent)	The reagent probe delivery from the P2 pack to the cuvette for testing. Maximum reagent probe dispense volume is 100 µL. For assays with > 2 reagents, a second volume addition may exist. The reagent probe aspirates from Well 1 first, followed by aspiration from Well 2, then dispenses both reagents into the reaction cuvette at the same time.
P1 (Main Start Time)	Initial absorbance time point. **NOTE:** The Main Start Time for a 2-Point Rate (2PA) assay must be ≥ 21 seconds. An invalid calculation error displays if the operator enters < 21 seconds.
P2 (Main End Time)	Final absorbance time point.

End Point (EPA) Reaction

Endpoint assays with a D2 reagent delivery:

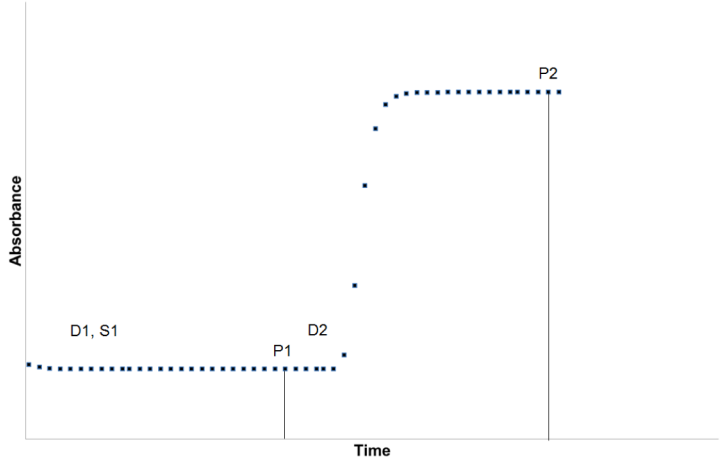
- P1 should be set to 259 seconds.
- R2 delivery occurs at cycle 91 or 273 seconds. The 259 second input defines a 16 second read window prior to the reagent delivery at 273 seconds.

The End Point (EPA) assay format measures absorbance after the reaction or color formation completes. This format uses a sample or initial reagent blank correction (12 seconds) by measuring absorbance prior to the active reaction process. A volume correction factor applies to the sample blank absorbance to account for the differential reaction volume before and after the reagent addition. The blank measurement adjusts the endpoint absorbance measurements. The calculated signal converts to an analyte concentration by mapping to a calibration curve. The analyzer reads reaction absorbance before and after the Main Start Time and Main End Time to calculate the result. Additional reads may occur depending on setup of optional features.

Endpoint assays with a single reagent delivery (End Point (EPA):

- P1 should be set to 0 or 12 for washed-cuvette or reagent filled cuvette blanking respectively.
- The reaction starts after sample addition at 13 seconds after D1.

Absorbance reaction with R2 reagent-initiated endpoint assay



R2-Initiated End Point Assay	Notes
D1 (R1 Reagent)	The reagent probe reagent delivery from the P1 pack to the cuvette for testing. Maximum reagent probe dispense volume is 100 µL.
S1 (Sample)	The sample probe delivery from the dilution cuvette to the reaction cuvette. Maximum sample probe dispense volume is 25 µL.
P1 (Main Start Time)	Initial absorbance time point.

R2-Initiated End Point Assay	Notes
D2 (R2 Reagent)	The reagent probe delivery from the P2 pack to the cuvette for testing. Maximum reagent probe dispense volume is 100 µL. For assays with > 2 reagents, a second volume addition may exist. The reagent probe aspirates from Well 1 first, followed by aspiration from Well 2, then dispenses both reagents into the reaction cuvette at the same time.
P2 (Main End Time)	Final absorbance time point.

About HIL Interference

Hemolysis, icterus, and lipemia (HIL) in patient specimens can interfere with spectrophotometric measurement of analytes and cause innacurate results. Laboratories should identify specimens with HIL to reduce or eliminate some of these preanalytical interferents.

Hemoglobin, bilirubin, and lipids have photometric, fluorescence, chemiluminescence, and turbidimetric properties that can cause chemical or optical interference. Hemoglobin interferes by its absorption, fluorescence, and chemiluminescence properties, bilirubin by its absorption and fluorescence properties, and lipids by their light-scattering (turbidimetric) properties:

- Hemolysis: The release of the intracellular contents of erythrocytes into a blood sample. It is characterized by red color in a serum or plasma sample after separation of blood cells because of the presence of extracellular hemoglobin.

  Hemolysis can originate *in vivo* (for example, because of malaria or an adverse transfusion reaction) or *in vitro* (for example, during pre-analytical sampling, transport, and storage).

- Icterus: An elevated level of conjugated and unconjugated bilirubin in serum or plasma that can result from diseases or conditions in which bilirubin is produced faster than the liver can metabolize it.

  Impairment of bilirubin conjugation can cause elevation of circulating unconjugated bilirubin. Bile duct obstruction or hepatocellular damage result in increased levels of conjugated and unconjugated circulating bilirubin.

- Lipemia: Turbidity (cloudiness) in serum and plasma samples that can result from an elevated triglyceride concentration in a serum or plasma sample.

  Lipemia can result from food intake, an infusion of lipids, or a disturbance of a patient's lipoprotein metabolism.

Previously, visual inspection of specimens detected HIL interference. Automating the specimen inspection process improves HIL detection by introducing standardization and uniformity.

20 System Configuration

About Analyzer Configuration

Analyzer Configuration enables laboratories to configure settings that apply to all analyzers, CH Analyzers, and IM Analyzers in the system.

Settings	Notes
All Analyzer Settings	Provides configuration options for the order the system processes samples on each analyzer in the system.
CH Analyzer Settings	Enables the laboratory to modify the IMT settings on each CH Analyzer to improve performance.
IM Analyzer Settings	Provides configuration options for the following features: • Test Scheduling • Repeat Sample Aspiration • Control Bracket: Reagent Reserve **NOTE:** These settings apply to all IM Analyzers connected to the system.

SH Configuration or DL Configuration

About Error Sort Groups

Error Sort Groups allow the operator to specify how the system sorts samples based on errors during processing.

When the operator enables sample sorting and defines at least 1 SH rack as Output Sort, the system uses the error sort groups to determine how to sort samples after an error occurs:

- When the system generates an error status that is part of a sort group, the system returns the sample to the appropriate Output Sort rack.
- When the system generates an error status that is not part of any sort group, the system returns the sample to an appropriate Output Normal rack with no sorting.

NOTE: Error sorting takes precedence over test sorting.

Error Sort Groups	Notes
Error Sort Groups	The list of available error sort groups.
Select Error statuses to add to the Selected Sort Group.	The errors the operator can select to include in the sort group.
	The operator selects to add a new error sort group.
	The operator selects to edit the name of the error sort group.
	The operator selects to save a new error sort group or the changes made to an existing sort group.
	The operator selects to remove the error sort group.

About Test Sort Groups

Test Sort Groups allow the operator to specify how the system sorts samples based on ordered tests, including Atellica tests and operator-defined codes.

When the operator enables sample sorting, selects at least 1 SH rack as Output Sort, and assigns a test sort group to the Output Sort rack, the system uses the test sort groups to determine how to sort samples:

- If the operator configures the system to never remove a cap from a capped sample in the sort group, the system sorts the sample without decapping and aspirating any enabled Atellica tests.
- If the operator configures the system to remove caps from samples in the sort group, when a sample meets the sort criteria for a test, the system returns the sample to the appropriate Output Sort rack after aspiration of all enabled Atellica tests is complete, subject to the Wait for Results Workflow configuration (Page 809 *About Wait for Results Workflow*).

- If the operator configures the system to decap capped samples If needed for analysis in the sort group, the system:
  - Decaps capped samples with on-system work and processes them prior to sorting.
  - Processes uncapped samples with on-system work prior to sorting.
  - Sends capped sample with no on-system work directly to the sort group.
  - Sends uncapped samples with no on-system work directly to the sort group.

NOTE: Error sorting takes precedence over test sorting. If samples meet sorting and archive criteria, sample sorting takes precedence over archiving.

Test Sort Groups	Notes
Test Sort Groups	The list of available test sort groups.
Test Type	The type of test the operator can include in a sort group. The selection determines the tests the system displays in Select Tests: • All • CH • IM • Operator-defined
Select Assay	The tests the operator can select to include in the sort group. The operator can also type in test names, separated by commas.
Tests in Group	The list of tests included in the sort group.

Test Sort Groups	Notes
Decap Tubes	This setting specifies when the system will decap tubes: • Never: The system does not decap tubes prior to sorting. For example, the operator would select this option to sort samples for a hematology system that requires caps on tubes but they do not want the system to process any tests before sorting the sample for the other system. • If needed for analysis: The system only decaps tubes if tests exist for the sample. • Always: The system always decaps tubes in the sort group even if no tests exist for the sample. **NOTE:** If the Decapper is not available, the system sorts a sample with no tests with the tube capped. The system does not wait for the Decapper to become available.
Seal Sample Tubes	When enabled, the system seals samples that are eligible for unloading to all displayed sort groups before sorting.
	The operator selects to add a new test sort group.
	The operator selects to edit the name of the test sort group.

Test Sort Groups	Notes
	The operator selects to save a new test sort group or the changes made to an existing test sort group.
	The operator selects to remove the test sort group.

About Sort Test Definition

Operators use Sort Test Definition to add or delete sort test codes.

The system uses sort test codes as a marker to identify the appropriate samples to route to a particular SH output rack location.

When operators add the sort test codes in Sort Test Definition, they can select the codes from the list of available tests when configuring Test Sort Groups, creating patient orders, or configuring reflex tests.

When configured in Test Sort Groups, the system automatically associates sort test codes with saved orders or orders from the LIS.

When configured in Reflex Group Setup or Ranges..., the system can automatically associate sort test codes with orders as determined by test results.

NOTE: Orders can have multiple test sort codes. The system applies test sort codes according to Sort Priorities (Page 801 *About Sort Priorities*).

When processing is complete, the system routes the sample to the SH output rack location the operator configured in Test Sort Groups (Page 797 *SH Configuration or DL Configuration*).

About Sort Priorities

Sort Priorities specify the sample sort priority order when processing is complete.

When the operator enables sample sorting and selects Separate Entry and Exit Queues, the system assigns the Empty sort group type to all rack rows by default. The system does not sort samples to rack rows set to Empty. The operator can use Empty rows as a separator between other sort groups in the rack, if appropriate.

The following table describes the additional sort group types and their sort priority:

NOTE: The operator cannot change the sort priority of the sort group types.

Sort priority	Sort group type	Notes
1	Controls and Calibrators	The system sorts controls and calibrators to this rack row.
2	Error Sort Groups	The system sorts samples to this rack row based on available error sort groups. The operator selects the sort priority of the error sort groups. The system displays this sort group type only if the operator defines error sort groups.
3	Partially Processed	The system sorts partially processed patient samples to this rack row.
4	Other Sort Groups	The system sorts samples to this rack row based on available test sort groups. The operator selects the sort priority of the test sort groups. The system displays this sort group type only if the operator defines test sort groups.

About Rack Processing Configuration

Rack Processing allows the operator to:

- Identify the type of false-bottom sample containers present in a rack
- Assign custom labels to Atellica Solution racks (Page 803 *About Rack Label Assignment*).

CAUTION

Do not load false-bottom sample containers in any rack other than a specifically designated special rack for false-bottom sample container use. Placing the sample containers in a rack other than the special rack may result in damage to the system if the probe impacts the sample container bottom.

The following custom container assignment options are supported:

Container type	Notes
Sarstedt 62.612	The rack contains Sarstedt 62.612 false-bottom sample containers. When selected, all sample containers in a rack must be of the same type. Default bottom offset: 41 mm.
Greiner Mini Collect Complete (Greiner 450550)	The rack contains Greiner Mini Collect Complete false-bottom capillary collection sample containers. When selected, all sample containers in a rack must be of the same type. Default bottom offset: 51 mm.
Custom False Bottom	The rack contains false-bottom sample containers that require a custom bottom offset.

CAUTION

The system supports only the Sarstedt 62.612 (bottom offset: 41 mm) and Greiner Mini Collect Complete (bottom offset: 51 mm) container types. Configuring bottom offsets of less than the defaults may result in damage to the system if the probe impacts the sample container bottom on the Atellica CH Analyzer.

About Rack Label Assignment

Rack Label Assignment allows the operator to assign custom labels to Atellica Solution racks that the system uses as an alternative to the rack ID. The custom labels contain a number of at least 4 digits and can include a human-friendly prefix. The operator scans rack barcodes to assign them to labels. The system then sends the custom labels to the LIS with sample results.

The following functions are available for Rack Label Assignment:

- Create custom label groups
- Assign and unassign racks to or from custom labels
- Add labels to an existing group
- Delete label groups or individual labels from a group
- Export label settings to a file and import them to other systems
- Print label settings

The following table describes the window for Rack Label Assignment:

Rack Label Assignment	Notes
Enable Rack Label Assignment	Enables or disables the Rack Label Assignment option.
Label Range	Displays the list of all label groups.
Rack Labels	Displays the number of rack labels in the group. The number of unassigned racks displays in parentheses.
View or Edit	Displays the window for Assign Rack Labels for assigning racks to labels.
Print	Prints all label groups and the rack ID assigned to each label.
Import	Imports rack label groups and assignments from the selected file. Importing overwrites all rack labels on the system.
Export	Creates a CSV file containing all rack label groups and assignments.

The following table describes the window for Assign Rack Labels:

Assign Rack Labels	Notes
Rack Label	Displays the list of label groups and individual labels assigned to each group
Rack ID	Displays the rack barcode assigned to a specific label

Assign Rack Labels	Notes
Add New Labels	Displays the Edit Rack Label Group window for adding labels to an existing group
Unassign	Removes the rack ID from the selected label
Delete	Deletes the selected group or the selected labels from a group
Add New Group	Displays the window for Add Rack Label Group for adding a new label group to the system

The following table describes the windows for Add Rack Label Group and Edit Rack Label Group:

Add/Edit Rack Label Group	Notes
Current Labels	The parameters for the selected label group.
Prefix	Optional prefix for the rack labels. Maximum of 6 characters. Special characters are allowed. The operator can only create 1 label group without a prefix but cannot change the prefix for an existing label group. No 2 groups can have the same prefix.
Starting Number	The first number in the new label range. Maximum of 4 digits.
Number of Labels	The number of labels to add to the group. The system generates the labels sequentially beginning with the Starting Number.
Rack Labels	The system generates labels Samples of the labels based on the input parameters.

Add/Edit Rack Label Group	Notes
First Label	The starting number of a group.
Last Label	The ending number of a group. If the operator adds labels to the group and saves, the Last Label updates.

About Archive Rack Management

Archive Rack Management allows the operator to enable or disable archive rack management. In addition to enabling this setting, the operator must configure at least 1 Archive zone on any SH on the system (Page 813 *About Sample Processing Configuration Profiles*).

The system archives the following sample types:

- Routine patient samples without errors that the operator loads from the SH
- STAT patient samples, if configured

The system cannot archive the following container and sample types:

- Samples that originate from the LAS
- Samples with no Atellica tests
- Sample containers loaded from False-bottom racks
- Sample containers with tube-top sample cups
- Calibrator or QC materials
- Samples with errors
- Samples that meet other sort criteria
- STAT patient samples (unless the operator configures the system to archive STAT samples)

Rack Archive Settings	Notes
Archive Rack Management	When enabled, the SH drawer areas are configurable as Archive zones and Holding Areas.

About Sample Workflow

Sample Workflow enables configuration of the following features:

Sample Workflow options	Notes
Wait for Results Workflow	Settings that control when the system moves samples from a Holding Area to an output or archive rack. (Page 809 *About Wait for Results Workflow*)
Capillary Tube Setting	The system disables the sample volume check for capillary tubes when no IM analyzer is present on the system.
Decapper Settings	Enables the system to decap sample containers with a No Work status. **NOTE:** This setting does not apply to samples that have sort test codes but no orders for Atellica Solution tests.
Sealer Settings	Seal Archiving Samples: Enables the system to seal sample containers when configured for archiving.
Seal Strength	Selects the strength of the seal for all sample containers eligible for sealing. The following seal strength options are available: • High: High seal strength is recommended for polypropylene or mixed material type tubes for ground transport or freezer storage. **NOTE:** PET material type tubes sealed using the High seal strength could experience tube top deformation. • Medium: Medium seal strength is recommended for polypropylene or mixed material type tubes.

Sample Workflow options	Notes
	• Low: Low seal strength is recommended for PET material type tubes to avoid tube deformation. **NOTE:** Low seal strength is not recommended for polypropylene or mixed material type tubes.
Sample Tube Sorting	Temporarily suspends and reenables sample sorting. Sort group assignments are retained. **NOTE:** The system continues to place tubes in rack rows that are not configured for sorting even if the zone is configured as Output Sort.
Archive Settings	Enables the system to archive STAT samples in addition to routine samples.

Sample Workflow options	Notes
Sample Priority	Configures and displays Sample Priority for systems connected to Automation that are configured with an SHC and 1 SH. **NOTE:** The SH must be in the Stopped state to make changes and only the Lab Manager account can modify these settings. The following 2 settings are available: • Load Cal/QC samples with STAT priority: The system loads all Cal/QC samples from the SH with STAT priority on to the Atellica Magline® Transport. The system loads Cal/QC samples from the SH drawers or the Cal/QC storage area. • Process patient STAT orders with Routine priority: The system processes all automation samples with Routine priority. This setting is automatically checked if Load Cal/QC samples with STAT priority is checked **NOTE:** This setting affects the turnaround time of STAT samples.

About Wait for Results Workflow

This feature requires the appropriate security level.

The Wait for Results Workflow determines when the system will move samples to an output or archive rack after aspirating all tests.

Options	Notes
Time after results before moving a sample	The amount of time that must elapse after the system receives results for the tests requiring wait for results. The system then moves the sample to an available Output Normal, Output Sort, or Archive rack, depending on system configuration. The sample status changes to Ready to Remove. **NOTE:** If the operator selects 0 Minutes, the system waits to receive test results but does not wait an additional amount of time before moving the sample to an available output rack.
Wait for results before moving samples to the output area	A setting that determines how the system handles non-archiving samples after aspirating tests. If set to Off (default), the system moves samples to an output rack after aspirating all tests and does not wait for test results. The sample status changes to Aspirated. If set to Customize by Assay and a sample does not include any tests the operator selects to wait for results, the system moves the sample to an available Output Normal or Output Sort rack, depending on system configuration, after aspirating all tests. The sample status changes to Ready to Remove.

Options	Notes
	If set to Customize by Assay and a sample includes 1 or more tests the operator selects to wait for results, the system temporarily holds the sample in 1 of the following available locations while waiting for test results: • Available Holding Area • Input Only or Combined area if a Holding Area is not available The sample status changes to Waiting for Results while the system waits for the required test results and the operator-defined time delay to elapse.
Wait for results before moving samples to the archive area **NOTE:** This option is available when Rack Archive Management is enabled.	A setting that determines how the system handles archiving samples after aspirating tests. If set to By Assay and a sample does not include any tests the operator selects to wait for results, the system moves the sample to an available archive rack after aspirating all tests. The sample status changes to Ready to Remove. If set to By Assay and a sample includes 1 or more tests the operator selects to wait for results, the system temporarily holds the sample in an available Holding Area while waiting for test results. If set to By Assay and no tests are included under Waiting for Results, the system moves the sample to an available archive rack after aspirating all tests.

Options	Notes
	If set to All Results, the system temporarily holds the sample in an available Holding Area while waiting for all test results. The sample status changes to Waiting for Results while the system waits for the required test results and the operator-defined time delay to elapse.
Wait for results before moving samples to the LAS **NOTE:** This option is available when the system is connected to Automation.	A setting that determines how the system handles LAS samples after aspirating tests. If set to Off (default), the system returns samples to the LAS after aspirating all tests and does not wait for test results. The sample status changes to Aspirated. If set to Customize by Assay and a sample does not include any tests the operator selects to wait for results, the system returns the sample to the LAS after aspirating all tests. The sample status changes to Ready to Remove If set to Customize by Assay and a sample includes 1 or more tests the operator selects to wait for results, the system temporarily holds the sample in 1 of the following available locations while waiting for test results: • Available Holding Area • Input Only or Combined area if a Holding Area is not available The sample status changes to Waiting for Results while the system waits for the required test results and the operator-defined time delay to elapse.

Options	Notes
Not Waiting for Results	The system does not hold samples for results for tests in this list.
Waiting for Results	The system holds samples for results for tests in this list.

About Sample Processing Configuration Profiles

Sample processing configuration profiles define which function the racks in an SH drawer perform during sample processing.

NOTE: Holding Area and Archive zone options are available only when Archiving is enabled.

The operator can create the following configuration profiles, each with different entry and exit queues. There is a Default profile that can be modified but cannot be deleted. Only 1 profile is active at any time:

Sample processing entry and exit queues	Notes
Combined Entry and Exit Queues	The operator defines the front and back SH drawer areas as Combined, Output Sort, or Archive zones. **NOTE:** The operator must configure at least 1 rack to Combined.
Separate Entry and Exit Queues	The operator defines the front and back SH drawer areas as Input Only, Output Normal, Holding Area, Archive, or Output Sort zones. **NOTE:** The operator configures at least 1 rack to Output Normal and 1 rack to Input Only.

A drawer status area indicates the type of sample processing configuration zone the operator assigns to each drawer area (front or back).

Sample processing configuration zones	Notes
Input Only	The system uses a rack in the zone for sample processing input only. The system then takes samples from an input rack for processing. **NOTE:** The system also uses a rack in an Input Only zone as alternative storage if a Holding Area rack is not available. △ displays in the drawer status area.
Output Normal	The system uses a rack in the zone for sample processing output only. The system then returns samples that do not meet output sort or archive criteria to the first available position in an output normal rack. ▽ displays in the drawer status area.
Output Sort	The system uses a rack in the zone for sample processing output if the operator defines test sort groups (Page 798 *About Test Sort Groups*) or error sort groups (Page 797 *About Error Sort Groups*). The operator can select **By Zone** to assign a sort group to an entire rack or **By Rows** to assign sort groups to specific rows in the rack. The system then returns samples that meet sort criteria to the appropriate Output Sort rack. Each rack displays the list of assigned sort groups. **NOTE:** If a sample meets sort criteria but has pending work, the system returns the sample to 1 of the following areas, in priority order: • Holding Area • Partially Processed • Input Only or Combined If the operator temporarily suspends sample sorting, the system returns samples to the first available position in any rack designated as an Output Normal or Combined rack.

Sample processing configuration zones	Notes
	If samples meet any sort criteria and the appropriate Output Sort rack is not available, the system returns the sample to an available Holding Area rack. When the appropriate Output Sort rack is available, the system moves the sample to the Output Sort rack. ▼ displays in the drawer status area.
Combined	The system uses a rack in the zone for sample processing input and output. The system then takes samples from the rack, processes them, and returns them to the same rack or another rack. The system does not always return samples to the same rack or original position. displays in the drawer status area.
Holding Area	The system uses a rack in a Holding Area for the following samples: • Completed samples if an Output Sort area is not available • Samples that are waiting for results (with or without archiving configured) • Samples with pending tests **NOTE:** If a Holding Area is not configured or available, the system places completed samples and samples waiting for results in an Input Only rack and places samples with pending tests in a Partially Processed rack. For samples eligible for archiving, the system moves the samples from the Holding Area to an available rack in an Archive zone based on the Wait for Results Workflow settings (Page 809 *About Wait for Results Workflow*).

Sample processing configuration zones	Notes
	For samples with incomplete work requests, the system moves the samples to the Holding Area. After the issue causing the hold resolves, the system retrieves the sample to complete testing then moves the sample to an appropriate Output Normal or to an Output Sort rack based on sort criteria. **NOTE:** It is recommended to set at least 1 zone as a Holding Area.  displays in the drawer status area.
Archive	The system uses a routine rack in an Archive zone or a dedicated archive rack anywhere in the system for sample archiving. **NOTE:** The system does not retrieve a sample from a rack in an archive zone if it receives new work for the sample. The system sends the rack identifier and position of each archived sample to the LIS. **NOTE**: If a sample is configured to wait for results for a certain period prior to archiving, the ARCHV sort code is required on LIS orders. A sample that is eligible to move directly to the archive area after aspirations complete (no waiting period applies) does not require the ARCHV sort code (Page 809 *About Wait for Results Workflow*).  displays in the drawer status area.

When the operator selects an Output Sort drawer zone, the rack details area displays the current sort group assignments for each rack row. The operator uses this area to make sort group assignments.

About Configuring Tube Type to a Rack Color for Standalone Analyzers

Standalone analyzers can circumvent the vision system for tube type identification and read the sample barcodes. This allows an operator to configure a specific tube type per rack color. Six rack colors are available (Page 218 *About Sample Racks and Adapters for Standalone Analyzers*) to support false bottom tubes that the vision system cannot detect and provide quick support for other tubes that the analyzer does not support.

The operator enters a measurement of the difference between the bottom of the tube to the bottom of the sample rack tube position. The sample racks for standalone analyzers support 16 x 100 mm tubes. The bottom offset for these tubes is 0. A 13 mm long tube adapter (Page 893 *DL Supplies*) supports the 13 X 100 tubes that accommodates their diameter, but their bottom offset is also 0.

CAUTION

Do not load false-bottom sample containers in any rack other than a specifically designated special rack for false-bottom sample container use. Placing the sample containers in a rack other than the special rack may result in damage to the system if the probe impacts the sample container bottom.

Rack Container Assignment	Notes
Rack Color	The racks identified by color.
Container Type	The operator selects 1 of the following: • Autodetected: Analyzer automatically detects the tube. • Sarstedt False Bottom. • Sentinel Tube. • Custom: Operator configures tube.
Bottom Offset (mm)	The measurement of the difference between the bottom of the tube to the bottom of the sample rack tube position.
	The operator selects this icon to enter or edit the Container Type and Bottom Offset (mm) for each color rack.

Rack Container Assignment	Notes
Save	The operator saves rack assignment configuration.
Cancel	The operator closes window without saving

The system supports the following container assignment options:

Primary tube	Bottom Offset (mm)
16x100	0
13x75	25
13x100	0
12x75	25

Sarstedt	Bottom Offset (mm)
15x92	21
13x65	45
13x90	20

Sentinel	Bottom Offset (mm)
13x98	68

Tube Top Sample Cup (TTSC- 1 and 2 mL)	Bottom Offset (mm)
16x100	74
13x75	74
13x100	74
15x92	63
13x65	63
13x90	63

About Alert Settings in System Configuration

This feature requires the appropriate security level.

Alert Settings in System Configuration has the following tabs:

Tab	Notes
General	Configures audible and visible notifications about error conditions.
Configure Alerts	Suppresses selected Alerts on the system (Page 819 *About Suppressing Alerts*).

About Suppressing Alerts

This feature requires the appropriate security level.

Configure Alerts in Alert Settings enables the laboratory to Suppress and Unsuppress the visibility of selected Alerts. Once an alert is supressed, the system no longer alerts the operator. Alert suppression is useful for laboratories that address these event conditions through workflow practices instead of system notifications.

NOTE: Alerts that are not visible in Configure Alerts are not available for suppression.

The system performs the following upon suppressing an alert:

- Removes the alert from displaying on the visible status light, in Alerts, in the dashboard, and in the area for system status.
- Removes any audible alarms from sounding.
- Continues to require the appropriate corrective action for the alert, but does not generate an alert.

  For example, if the laboratory suppresses an alert that causes the system to stop processing samples and the alert condition occurs, then the system does not allow new tests to start until the operator resolves the condition.
- Includes an entry in the Audit Trail Log regarding the suppression (Page 712 *Viewing the Audit Trail Log*)

The following information is available in Configure Alerts:

Information	Notes
☐	The check box that enables selection of the alert for suppression. **NOTE:** By default, the system does not suppress any alert.
Severity	The icon that indicates the severity of the alert: • ⚠ indicates a Warning condition. • ⚠ indicates an Error condition. **NOTE:** Error conditions affect system processing.
Alert Code	The unique numerical identifier of the alert. An operator can use this code to search the Operator Event Log or the Online Help for additional information.
Suppress Status	The current state of the alert: • Yes indicates the alert is suppressed. • No indicates the alert is unsuppressed. The default Suppress Status setting is No for every alert. **NOTE:** The operator uses the arrow to sort Suppress Status and reviews the alert suppression configurations.
Alert Text	A short description of the event condition.

NOTE: The operator can view suppressed Alerts on an operator tablet and module consoles, if available. However, the operator cannot suppress the alerts from these devices.

Operators must belong to the G1 Group to Suppress or Unsuppress alerts. The suppression or unsuppression of Alerts occurs immediately upon selecting Suppress or Unsuppress. The system displays a message to confirm the action.

NOTE: The Troubleshooting of all Alerts, including suppressed Alerts, are available in the online help.

Show Suppressed displays any suppressed alerts that occurred on the system and includes the date and time of the occurrence. The default setting is enabled.

About Connectivity in System Configuration

This feature requires the appropriate security level.

The Connectivity feature provides the settings and configuration options for connecting the system to a network. Connectivity consists of the following tabs:

Tab	Notes
General	Provides the configuration options for the following features: • Informatics Connection • Network Share Access • Alternate System Display Settings • Operator Tablets (Page 169 *About the Operator Tablet*)
Router Settings	Enables configuration of the router

NOTE: The Connectivity settings are global settings that apply to every operator who uses the system.

About the Tab for General in Connectivity

This feature requires the appropriate security level.

The tab for General in the tab for Connectivity includes the following settings:

Setting	Notes
Informatics Connection	Includes the settings for connecting the system to the Smart Remote Services (SRS) gateway. The gateway connection then enables the Atellica® Process Manager () and Remote Assistance () feature on the Tool bar. **NOTE**: Connection to the gateway is only available to laboratories that have a service contract.
Network Share Access	Enables data transfer to and from off-system locations.
Alternate System Display Settings	Creates a password so an operator can use the Windows Remote Desktop Protocol to sign in to the system on an alternate system display.
Operator Tablets	Provides a listing of all Operator Tablets that are registered with SRS (Page 169 *About the Operator Tablet*). **NOTE**: The local technical support provider must add operator tablets, but the laboratory can disable the tablets from usage in this area.

NOTE: These are global settings that apply to every operator using the system.

About Hardware Configurations in System Configuration

This feature requires the appropriate security level.

The Hardware Configurations tab in System Configuration includes the following areas:

Area	Notes
System Configuration	Provides the System Name and Serial Number and enables the virtual keyboard.
Touchscreen, Mouse, and Printer Configuration	Enables access to the local computer control panel for configuration of the touchscreen, mouse, and printer.
USB Options	Enables or disables USB ports on the system.
Export and Copy Configuration Files	Sets the prefix of Export and Copy Configuration Files.
Barcode Printer	Selects and tests the Barcode Printer.
Barcode Symbology Configurations	Configures the symbology that the system uses to read sample barcodes.

NOTE: These are global settings that apply to every operator who uses the system.

About Barcode Symbology Configurations

The Barcode Symbology Configurations area in Hardware Configurations enables the laboratory to select the types of barcodes that the system can use to read barcodes on sample tubes.

NOTE: The Barcode Symbology Configurations affect the handheld scanner, analyzer module display scanners, SH and SHC TCS, and the DL vision system. Contact the local technical support provider to change the barcode symbology configuration of the ESL carrier scanners.

The following table describes the system-supported symbologies:

Barcode Symbology Configurations	Notes
Code 128 (Permanently enabled)	An alphanumeric or numeric barcode that allows all uppercase and lowercase letters, numbers, and the following symbols: - . $ / + % =* : \. The system supports Code 128 sub-variants A, B, and C. **NOTE:** This symbology provides the most robust encoding, minimizing the chance of barcode errors.
Code 39	An alphanumeric or numeric barcode that allows uppercase letters, numbers, the space character, and the following symbols: - . $ / + %=. **NOTE:** The system supports this symbology with or without a check digit.
USS Codabar	A barcode that represents the numbers 0–9, the uppercase letters A–D, and the following symbols: - . $ / +=.
Interleaved 2 of 5	A numeric barcode that encodes pairs of numbers into a self-checking, high-density format. This symbology interleaves every 2 digits with each other to create a single symbol. **NOTE:** The system supports this symbology with or without a check digit. If using Interleaved 2 of 5 with an encoded check digit, the TCS may not properly scan the barcode without enabling the TCS camera checksum feature. Contact the local technical support provider to enable the TCS camera checksum feature.

NOTE: Barcodes that include a check digit provide a secondary check on the accuracy of the barcode scan. The system supports barcodes without a check digit for laboratories that receive samples from locations that do not include a check digit in the barcode.

About Calibrating the Touchscreen

This feature requires the appropriate security level.

The primary user interface includes a touchscreen that requires calibration to function correctly. This calibration allows the operator to properly select fields, buttons, and enter data.

During initial installation, the local service provider calibrates the touchscreen. The operator may need to calibrate the touchscreen in the following situations:

- The laboratory replaces the existing monitor.
- The cursor on the screen is not tracking correctly.

Calibrating the Touchscreen

This task requires the appropriate security level.

1. Navigate to **Hardware Configurations**.
2. In Touchscreen, Mouse, and Printer Configuration, select **Open the Local Computer Control Panel**.
3. In the Control Panel, select **Elo Touchscreen**.
4. In the Elo Touchscreen dialog box, select **Calibrate Touch Screens...**.
5. Select **Align**.
6. Tap the target that displays in the upper-left corner of the screen.
7. Tap the target again after it moves to the lower-right corner of the screen.
8. Tap the target again after it moves to the upper-right corner of the screen.

   The "Touch the screen. Does the Cursor follow your finger?" dialog box displays.
9. Touch and move around the screen.
10. Verify the cursor follows around the screen.

11. Perform 1 of the following:
    - If all calibration steps complete successfully, tap the green check mark.

      NOTE: The "Touch the screen. Does the Cursor follow your finger?" dialog box closes after approximately 1 minute.
    - If the calibration steps do not complete successfully, tap the curved arrow and repeat the calibration procedure.
12. Close the Elo Touchscreen dialog box.
13. Close the Control Panel.

About Lab Settings in System Configuration

This feature requires the appropriate security level.

Lab Settings provides information and configuration options for the workstation interface, online help, and Keyboard Layout. Laboratories can also configure the appropriate format for the date and time on patient reports.

Lab Settings includes the following areas:

Area	Notes
Display Language & Regional Settings	Sets the language of the workstation interface, keyboard, and online help.
Date, Time & Numbers	Sets the long and short format for the date and time.
Test Definition Region	Indicates the regional version of the assay test definitions in use on the system. **NOTE:** This setting is for informational purposes only. The local technical support provider sets the required version for the laboratory.

NOTE: The Lab Settings are global settings that apply to every operator who uses the system. The system requires a restart for all changes to these settings to take effect.

About LAS Configuration

LAS Configuration enables the laboratory to connect the LAS to the system. When connected, the system can index the samples that are loaded onto the system from the LAS.

The laboratory configures the following Operator Settings:

Field	Notes
Reagent Level Step Size	A change in the reagent level that triggers a message to the LAS. For example, if the current reagent level is 100 and the step size is 20, the system sends an inventory update when the level reaches 80, 60, 40, and so on.

The following fields are available if the laboratory selects a Serial Connection Type:

Field	Notes
Baud Rate	The rate at which the system transfers the communication channel information to the serial port connection.
COM Port	The serial communication interface through which the information transfers in or out, 1 bit at a time.
Data Bits	The number of bits allocated for data with a serial port connection.
Flow Control	The signals in the interface to pause and resume the transmission of data with a serial port connection.
Parity	The bit the system uses for error detection with a serial port connection.
Stop Bits	The end of a frame with a serial port connection.

An Ethernet connection contains the following fields:

Field	Notes
Local IP	The system IP address that communicates with the LAS.
Local Port	The ethernet port on the system that communicates with the LAS.

Field	Notes
Remote IP	The LAS IP address.
Remote Port	The LAS ethernet port.

NOTE: The local technical support provider configures the Service Settings area of LAS Configuration:

Field	Notes
Connection Reset Wait Period	The wait period prior to restoring the LAS connection. The range is 10–600 seconds. The default value is 15 seconds.
Inactivity Timeout for Sending Keep Alive Message	The idle time before sending a Keep Alive message to the LAS. The system uses the Keep Alive message to check the connection status. The range is 5–300 seconds. The default value is 15 seconds.
System Health Response Message Delay	The minimum delay time between 2 Instrument Health Response messages. The range is 2–60 seconds. The default value is 20 seconds.
Max Message Retries on Ack Timeout	The maximum number of times the system resends a message on Acknowledgment Timeout (the maximum time the SHC waits for an ACK message from the LAS). The range is 1–9 attempts. The default value is 5 attempts.
Max message retries on Nack	The maximum number of times the system resends a message after receiving a Negative Acknowledgment (the system sends the LAS a message and the LAS sends a NACK instead of an ACK to the SHC).The range is 1–9 attempts. The default value is 5 attempts.
Message Resend Wait Period on Ack Timeout	The system waits this minimum amount of time before resending a message on Acknowledgment Timeout. The range is 1–9 seconds. The default value is 1 second.
Test Inventory Response Message Delay	The minimum delay time between 2 Test Inventory Response messages (a response message containing assay details for a test inventory request). The range is 2–60 seconds. The default value is 20 seconds.

The Service Settings also includes the following fields:

Field	Notes
Enable Partial System Processing Capability	—
Enable Greiner MiniCollect Complete Tube	—

About LIS Configuration

This feature requires the appropriate security level.

LIS Configuration	Notes
Enable LIS Connection	Specifies whether the system is configured to connect to the LIS or middleware computer. When enabled, a message displays stating that the data sent to the LIS is not encrypted. The default is disabled.
Start LIS Client Automatically	Starts the communication between the LIS and the system on system startup. If disabled, the operator restarts the LIS when restarting the system.

LIS Configuration	Notes
System Transmits Manufacturer Order Record (ASTM)	Defines if the system transmits and receives the Manufacturer's Order Record for QC samples using the American Society for Testing and Materials (ASTM) protocol. Selected by default. • Enabled: the rules specified for Manufacturer's Order Record apply. If the system does not receive the Manufacturer's Order Record, then the message is rejected. • Disabled: system does not transmit or receive the Manufacturer's Order Record to or from the LIS. The system uses the sample ID and action code from the incoming test order record to identify the sample. If a Manufacturer's Order Record is received, it is ignored.
Protocol	Defines the protocol the system uses to communicate with the LIS computer. The default is ASTM.

LIS Configuration	Notes
ASTM	Uses an 8-bit, single-byte characters, 3-layered communications protocol, if selected. Sending non-8 bit ASCII values in the ASTM records to the LIS causes invalid data in those fields. Each layer performs a related subset of required functions to communicate with another system. The operator configures communication protocol standards for each layer. • Application Layer: provides the information services of the system. • Data Link Layer: ensures the system correctly receives and transmits outgoing application messages. This layer transfers information across the physical medium and sends blocks of data with additional synchronization and error control information to ensure a reliable transfer. • Physical Layer: directs the transmission of the bit stream across the physical medium.
HL7 (Health Level-7)	Uses HL7 protocol with Integrating the Healthcare Enterprise (IHE)-Laboratory Analytical Workflow (LAW) profile codes. Uses 2 communication channels so the system requires 2 network connections.
System Name	Requires the system name of up to 10 characters, with the default set to UIW_LIS.
LIS ID	Requires the LIS name of up to 10 characters, with the default set to LIS_ID.
Application Layer	Transfers the ASTM application layer messages between the LIS and the system.

LIS Configuration	Notes
Data Link Layer	Provides an error-free exchange of data between the system and the LIS computer.
Physical Layer	Mechanically and electrically connects the TCP/IP data transmission between the system and the LIS computer.
Cancel	Clears all current changes.
Restore Defaults	Clears all changes and restores system defaults.
Save	Saves all settings without restarting the system.

The system groups the configurable settings of the LIS into the following categories:

- Common area
- Application Layer
- Data Link Layer
- Physical Layer

About Modules in System Configuration

Modules in System Configuration enables the laboratory to label each module and analyzer connected to the system with an easily identifiable name.

Field	Notes
Analyzer Type	Lists each module that is connected to the system
Module Serial Number	Provides the serial number of each module connected to the system
Friendly Name	Enables the laboratory to give each module an easily recognizable name

About Patient Results Management in System Configuration

This feature requires the appropriate security level.

The laboratory uses Patient Results Management in System Configuration to manage the patient test results. Patient Results Management enables configuration of the following features:

Feature	Notes
Mode	Specifies whether the system automatically holds results for review
Test Order	Specifies the type of actions that the system can automatically perform on patient test orders
Delta Check Previous Result	Specifies the source of previous results for delta checks
Multiple Reference Intervals or Delta Check	Specifies how the system performs repeat and reflex actions when patient results match multiple reference intervals or delta check ranges

These global settings apply to every operator who uses the system. The laboratory can change these settings at any time.

About Result Reports

This feature requires the appropriate security level.

Reports Setup consists of the following 2 tabs:

Tab	Notes
Settings	Enables the laboratory to customize Worklist reports (Page 833 *About Result Reports*)
Automatic Reports	Enables the laboratory to automatically print 1 Results Report and 1 Calibration Report (Page 833 *About Result Reports*)

Settings in Reports Setup enables customization of result reports for laboratory use. Laboratories can select the information for inclusion and can also rearrange the order in which the information displays on the report. Settings consists of the following areas:

Area	Notes
Report Type	Specifies the report that needs customization
Mask Patient ID and Name for all tests	Enables the laboratory to hide identifying patient data as appropriate
Footer Information	Enables standardization of the laboratory details
Paper Size	Enables selection of the appropriate paper size for the printer
Configuration	Provides the available fields on each report

The following reports are available for customization:

Report Type	Notes
General	Enables customization of the footer information and selection of the paper size for all reports. Report configuration is unavailable.
Lab Results Report	Provides a report of test results that are grouped according to sample ID, patient ID, or a date range. The report contains the final test results for 1 or more sample (patient only, control only, or patient and control) and is suitable for internal laboratory use.
Assay Report	Provides a chronological list of calibrators, QC, and patient results in a date range for 1 or more assays.
Patient Summary Report	Provides a report of all test results for a single patient over a specified time period. This report is suitable for physician use.
Runtime Reports	Provides a report that lists all results in chronological order of test completion.

NOTE: The pre-defined (default) settings enables laboratories to print worklist reports without needing to create a template.

When an operator modifies any setting, the following options are available:

Option	Notes
Restore Defaults	Returns the settings to the predefined settings
Save	Implements the customization changes
Cancel	Returns the settings to the last saved

About Calibrator or Control Sample Fields for Result Reports

The system enables the laboratory to select the appropriate information to display on result reports.

The following Calibrator or Control Sample Fields are available for Control, depending on the selected report type:

- Calibrator Lot or QC Lot
- Calibrator Name or QC Material Name
- Control Usage

The following Calibrator or Control Sample Fields are available for Sample, depending on the selected report type and the analyzer configuration:

- Calibrator ID or QC Material ID
- Container Type (CH)
- Last Aspirated Date Time
- Priority
- Rack and Position or Onboard Location
- Sample Type
- Scanned Location

The following Calibrator or Control Sample Fields are available for Results, depending on the selected report typeand the analyzer configuration:

- Ancillary 1 Lot and Pack ID (IM)
- Ancillary 2 Lot and Pack ID (IM)
- Aspirated Date Time
- Cal Status

- Calibration Date and Time
- Comments
- CV
- CV (IM)
- Diluent Lot and Pack ID (IM)
- Flags
- IMT Calibration Data (CH)
- Operator (Accepted or Omitted by)
- Primary Reagent (IM)/Reagent 1 (CH) Lot and Pack ID
- R2
- Reagent 2 Lot and Pack ID (CH)
- Reagent Lot
- Reaction Data and Statistics (CH)
- Replicates (IM)
- Result
- Result Accepted/Omitted Date/Time
- Result Date/Time
- Result Disposition
- RLU or MAU
- Run ID
- Scanned Date and Time
- Target Range
- Test Name
- Test State
- Wavelengths (CH)

About Directories

Directories provide a selectable database of information, such as comments and physician names.

The operator can sort directory lists in ascending or descending order by column and can filter them to display only records that meet the filter criteria. The total number of records in the directory displays on the right side of the screen. For a filtered view, this number is the total number of records in the view.

In addition, the operator can create, copy, edit, view, and delete directory records.

Note the following:

- Each directory type allows up to 255 entries.
- A colored bar at the bottom of the field indicates required information.
- Directory entries are not case-sensitive.

The following table lists the available directories:

Directory	Notes
Physician	Profile information of the referring physician
Location	Origination of the sample
Patient Status	Information about the patient status as it relates to the sample
Species	Type of sample
Sample Comment	Comments about samples
Patient Comment	Comments about patients
Result Comment	Comments about test results

21 Accounts and Security

Setup: Accounts

Use **Setup > Accounts** to customize the following:

- Groups
- Accounts
- Settings
- Operator Sign In Information

Changing system settings requires the appropriate security level.

> **CAUTION**
>
> Do not customize options without selecting the appropriate value for the laboratory and continually evaluating the integrity of that value. Improper customization can cause reporting of unexpected results.

The laboratory is responsible for ensuring that all system settings are correct whether the laboratory personnel set the values, a Siemens technical support provider set the values specified by the laboratory, or a Siemens technical support provider set the values to the original default values.

For more detailed information about the Setup features, refer to the system online help.

About Accounts and Security

This feature requires the appropriate security level.

Laboratories use Accounts and Security in System Configuration to manage and control access to the system and its features. Accounts and Security includes the following tabs:

Tab	Notes
Groups	Organizes the operators of the system according to their designated level of access
Accounts	Controls the access of each operator to the system

Tab	Notes
Account Settings	Manages the access to securable features or those features that require a higher level of security, sets the global password and screen locking policies, and enables updates to the PHI key
Operator Sign In Information	Provides information about the current operator session
Security Settings	Enables the display of customized information during system start

Accounts and Security Icons

The following icons alert the operator to a required action or more information:

Icon	Notes
	Sorts a column in the ascending direction.
	Sorts a column in the descending direction.
	Indicates a drop-down menu
	Indicates that the operator can decrease the value
	Indicates that the operator can increase the value

About Groups

This feature requires the appropriate security level.

Laboratories use Groups in Accounts and Security to organize operators of the system according to their designated level of access. The system places the Groups in the following hierarchical structure:

Group ID	Group Name
G1	Laboratory Managers
G2	Customer Service Engineer
G3	Chief Technicians
G4	Day Time Operators
G5	Night Time Operators

NOTE: Laboratories cannot create or delete a Group, but they can rename the Groups as appropriate.

Each Group can have a different level of access to system features, with the G1 Group having the greatest access and the G5 Group having the least. However, every operator in a Group has the same security privileges and access rights to the system.

Operators in the G1 Group can perform the following administrative tasks:

- Determine the privileges and access rights of the G3, G4, and G5 Groups to system features that require controlled access
- Assign operators to the appropriate Group during account creation.
- Modify the Group that operators belong to, as appropriate

  Operators in the G1 Group can disable or enable the account of an operator in the G2 Group but cannot assign operators to this Group.

NOTE: A laboratory should create more than 1 account in the G1 Group to ensure that an operator of this group is always available for password resets and other security functions. If a laboratory does not have an operator in this Group who can sign in to the system, the laboratory must contact the local technical support provider to reset the account and add a new operator to the Group.

The G2 Group is for technical support providers who require access to the software application and its underlying operating system to ensure proper functioning of the system.

By default, the system provides a similar level of access to operators in the G3, G4, and G5 Groups. The laboratory can keep this level the same or modify the access level to restrict operators in those Groups to certain features, in accordance to their role.

About Accounts

This feature requires the appropriate security level.

Laboratories use Accounts in Accounts and Security to manage the operators who can access the system. All operators who have an account and are authorized to access the system display on this window.

The following information is provided for each operator account:

Column*	Notes
Operator ID	The unique name that the owner of the account uses to sign in to the system. **NOTE**: Every operator of the system has their own account with a unique Operator ID.
Full Name	The name of the account owner. **NOTE:** The Full Name is optional.
Group	The level of access that the account owner has to securable system features. The operator has all the privileges assigned to the Group (Page 840 *About Groups*). NOTE: Securable features are system features that require additional access privileges.
Status	The current state of the account. **NOTE:** Operators of Disabled Accounts cannot sign in to the system, even with the appropriate Operator ID and password.

* Each column is sortable in ascending or descending order.

The system supports the following number of Accounts for each Group:

Group	Number of Accounts
G1	25 **NOTE**: A laboratory should create more than 1 account in the G1 Group to ensure that an operator of this group is always available for password resets and other security functions. If a laboratory does not have an operator in this Group who can sign in to the system, the laboratory must contact the local technical support provider to reset the account and add a new operator to the Group.
G2	1 **NOTE**: The system provides the local technical support provider with a randomly generated password for signing in to the system when the laboratory needs assistance. The Operator ID and password are authenticated at the workstation.
G3	100
G4	100
G5	100

Accounts also provides access to the following activities:

- Creating new operator Accounts
- Editing and viewing existing Accounts
- Deleting Accounts
- Disabling Accounts
- Clearing account passwords
- Changing account passwords
- Changing the security questions of an account

About Account Settings

This feature requires the appropriate security level.

Account Settings in Accounts and Security includes the following areas:

Area	Notes
Privileges	Enables laboratories to assign the appropriate access level to operator accounts for the securable features.
Global Policies	Enables laboratories to set the global password and screen locking policies and enables updates to the PHI key.

About Access Levels to Securable Features

This feature requires the appropriate security level.

Laboratories use Privileges to assign each Group with the appropriate access level for securable features.

NOTE: Securable features are features that require additional Privileges to modify or view.

Each Group has 1 of the following levels of access to each securable feature:

Access level	Notes
Full Control	Operators can modify and view the feature.
Read Only	Operators can view the feature, but make no modifications.
No Access	Operators have no access to the feature. The feature is not visible on the user interface.

NOTE: The access level applies to all accounts in the selected Group. An operator cannot change the access level to a securable feature of an account in their Group or an account in a higher level Group.

The securable features are grouped into the following categories:

- Lab Metrics
- Events
- File Management
- Maintenance
- QC
- Results

- Security
- Setup

Each Category includes 1 or more securable features. All is the default Category and enables the laboratory to set the access level for every securable feature instead of by a single Category.

About Global Policies

This feature requires the appropriate security level.

Laboratories use Global Policies to configure the following settings:

Area	Note
Expiration Policy	Sets the frequency of expiration for the Operator Password.
Other Policy	Provides configuration options for the Password Length and the Number of failed sign-in attempts before an account is locked out: **NOTE**: The system locks an operator account for approximately 10 minutes if the operator enters the wrong password too many times. After 10 minutes, the account unlocks and the operator can attempt to sign in again or reset the password by using password help.
Automatic Screen Lock	Sets the number of inactive minutes before the system automatically locks.

Global Policies also includes the Change PHI Key, which enables the laboratory to modify the PHI key.

CAUTION

Do not unnecessarily change the PHI key. Changing the PHI key makes the LIS log, patient names, and patient IDs for previous orders unavailable. Delta checks on previous results are also unavailable.

NOTE: The settings in Global Policies apply to every operator.

About Setting the Global Password Expiration Policy

This feature requires the appropriate security level.

Laboratories can configure operator passwords to expire 30 or 60 days after creation of the password.

NOTE: Laboratories can also configure the operator passwords to never expire.

This setting is a global setting and applies to every operator password.

NOTE: If a password expires before the owner of the account changes it, the system disables the account. Another operator with the appropriate security level must clear the expired password, assign a temporary password, and then re-enable the account. The account owner must change the temporary password after signing in.

About the Automatic Screen Lock

This feature requires the appropriate security level.

Laboratories use the Automatic Screen Lock to set a maximum number of minutes that the system can be idle before automatically locking the screen. The number of minutes can range from 1–1440 (or 24 hours). When the number of minutes elapse, the system displays the window for Lock.

Lock indicates that all data is hidden and the system is secure from unauthorized access.

NOTE: Laboratories can also disable the Automatic Screen Lock.

Lock has the following options:

Option	Notes
Unlock	Enables the operator who locked the current session to sign back in and continue the current operator session (Page 135 *Unlocking the Screen*).
Change Operator	Enables a different operator to sign in to the system. The current operator session ends and a new session begins (Page 162 *Changing the Operator of Locked Screens*). **NOTE:** The system discards any unsaved data before the new session begins (Page 161 *About Operator Sessions*).

Operators can also manually lock the system (Page 134 *Locking the Screen*).

About Security Settings

Laboratories use Security Settings in Accounts and Security to display or hide customized information. This Banner Text is visible on the splash screen while the software launches.

22 Atellica Asa Application

About the Atellica Asa Application

The Atellica Asa™ Application is a web application for the Atellica® Solution that organizes operator tasks by laboratory workflow, including:

- Remote monitoring of all patient samples and system status
- Monitoring of all system supplies, consumables, and reagents with the ability to create a supplies list for use when gathering suppliesScan Barcodes
- Troubleshooting using Remote Assistance, Diagnostics, and Online Help

The application operates on a customer-provided tablet that connects to an Atellica® Solution or customer network using a Wi-Fi or wired Ethernet connection. Microsoft, Android, and Apple tablets are supported. The system supports the connection of multiple tablets. An operator can sign into each tablet and system display simultaneously, with different or the same credentials.

When connected through the customer network, Diagnostics and Remote Assistance (using TeamViewer) is not available.

The operator cannot update any records from the application.

The application interface displays in the same language as the primary user interface.

NOTE: The application does not display Protected Health Information (PHI) or Patient Identification Information (PII).

NOTE: Due to the space limitations of the tablet screen, some labels use shorter text and display differently than the same label on the primary UI.

NOTE: Information for Atellica Solution also pertains to Atellica CI Analyzer.

Installing Atellica Asa Application Shortcut on Tablet Desktop for Atellica Networks

NOTE: Use for operator tablets.

1. In the browser address field, enter the security certificate URL.
2. Install the certificate using operating system specific procedures.
3. In the browser address field, enter the Atellica Asa Application URL and select **Enter**.
4. Install a shortcut for the Atellica Asa Application URL on the tablet desktop using browser-specific procedures.

Installing Atellica Asa Application Shell Shortcut on Tablet Desktop for Site Networks

NOTE: Use for customer-provided tablets.

1. In the browser address field, enter the security certificate URL.
2. Install the certificate using operating system specific procedures.
3. In the browser address field, enter the Atellica Asa Application Shell URL and select **Enter**.
4. Install a shortcut for the Atellica Asa Application Shell URL on the tablet desktop using browser-specific procedures.

Signing in to the Atellica Asa Application

1. Connect the tablet to a Wi-Fi network or wired Ethernet connection.
2. On the tablet desktop, select  .
3. If connecting over the customer network, select the appropriate Atellica Solution from the drop-down for System and select **Connect**.

   NOTE: If the appropriate Atellica Solution does not display in the System list, select  then select the **System** list.
4. Enter the Operator Name and Password.

   NOTE: The Operator Name and Password are authenticated based on the configured accounts on the connected system.
5. Select **Sign in**.

   NOTE: After the system verifies the operator sign-in credentials, the operator is not required to sign in again unless a communication error occurs or the operator signs out manually. The application does not have automatic signout.

About the Access Bar

The Access bar displays at the top of every Atellica Asa Applicationscreen and contains system information, system status icons, and operator controls. Some items do not display on the Dashboard.

Access bar	Notes
	Displays the Dashboard.
Screen title	Displays the name of the current screen.
System Status Map	Displays the current status of all modules on the system: • Green: The module is able to process samples. • Gray: The module is paused or stopped. • Red: The module is not able to process samples. • Yellow: The module is in maintenance.
	Launches Teamviewer, which allows the service provider to access the tablet remotely.
	Remote session is active. The screen also displays a red border. Selecting this icon ends remote session.
	Displays the Cart List. The number of items currently in the cart displays and updates dynamically.
Connection status	Displays  only when a Wi-Fi issue occurs.
System name	Displays the system that is connected to the Atellica Asa Application.
	Displays the menu containing Sign Out, Help, and About.

About Online Help for the Atellica Asa Application

CAUTION

Do not operate the system without the most recent version of online help installed. Using the system without online help could lead to system or operator errors. Ensure the most recent version online help is installed prior to operating the system.

The Online Help includes procedures for operating the system, event help, troubleshooting, and maintenance. Animations are available for some hardware maintenance tasks.

Selecting > **Help** accesses links to help topics specific for the displayed screen.

Online Help is accessible in Troubleshooting.

Accessing Online Help on the Atellica Asa Application

1. On the Access bar, select .
2. Select **Troubleshooting**.
3. To view related help topics, search for or select the appropriate topic from the Table of Contents on the right side of the window.

About Information Available on the Atellica Asa Application

The operator can access the About information from the menu ( ) on the Access bar. Software and hardware information for the Atellica Asa Application and the connected system is available when troubleshooting during a service call. The following entries describe the relevant versions: ASA and Siemens Healthcare Diagnostics Atellica.

The Software Information tab displays the software and other tools the connected system uses and the corresponding versions. For more information, see (Page 132 *Atellica® Solution Software Copyright Information*)

The System Information tab displays the hardware information about the modules included in the connected system.

The Legal information tab displays copyright and other legal notices.

Signing out of the Atellica Asa Application

1. Select **> Sign Out**.
2. Select **Yes**.

About the Atellica Asa Application Dashboard

The Atellica Asa Application Dashboard provides a touchscreen, tile-based interface that allows the operator to perform the following tasks without being physically present at the system display:

- Viewing system status
- Viewing sample status
- Viewing consumable status
- Creating a supply list for daily needs
- Viewing maintenance activity status
- Performing system troubleshooting
- Submitting service support request tickets or conducting live service support sessions

The top portion of each tile displays a status color:



1	Critical alerts exist
2	Automated maintenance activity is inprocess or due to start.
3	No issues that need immediate attention exist but issues that need to be resolved later in the day may exist.

Dashboard	Notes
System Status Map	Displays the status of each module for the connected system. Selecting a module displays the active alerts.
Troubleshooting	Accesses: • Online Help • Diagnostics • Service Support Request
STAT Samples	Summary information about STAT samples on the system. The title displays 1 of 2 colors: • Green: no STAT samples require intervention or all samples that require intervention are ignored • Red: at least 1 STAT sample requires intervention The tile body displays: • The combined count of the number of STAT samples that require intervention and the number of STAT samples inprocess. • The count of STAT samples inprocess. • The count of STAT samples that require intervention.

Dashboard	Notes
Sample Interventions	Summary information about all samples on the system that require intervention. The title displays 1 of 2 colors: • Red: At least 1 patient, Cal, or QC sample requires intervention. • Green: No samples require intervention. The tile body displays the combined count of the number of patient, Cal, and QC samples that require intervention. • The combined count of the number of patient, Cal, and QC samples that require intervention. • The individual counts for each sample type.

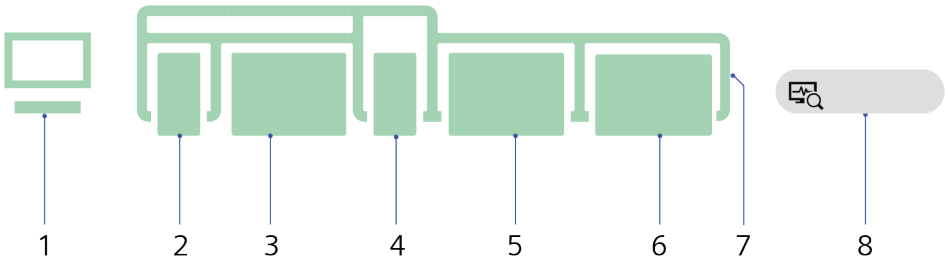
Dashboard	Notes
Maintenance	Summary information about the maintenance activities for the operator-defined day. The tile title displays 1 of 3 colors: • Red: Immediate operator intervention required. One or more maintenance activities failed for the day. The title remains red until these activities successfully complete or the operator reschedules them to a new day. • Yellow: One or more Inprocess or Due activities exist within the configured maintenance activity reminder time. • Green: No Failed, Inprocess, or Due maintenance activities exist to automatically start within the configured maintenance activity reminder time. The tile body displays: • Number of current calendar day's Maintenance activities not completed and Due. • Number of current calendar day's Maintenance activities completed with a failed status. • Modules that are starting maintenance. • Modules where maintenance is in progress.

Dashboard	Notes
Supply Needs	Summary information about the supply needs. The tile title displays 1 of 2 colors: • Red: If 1 or more supply or waste alert conditions exist: – The consumable usable remaining volume is 0. – The onboard stability expires within the operator-defined threshold. – The count is less than the sample warning level. – Waste status is above the operator-defined threshold. • Green: No supply or waste alert conditions exist. The tile body displays the count of required supplies.
Reagent Needs	Summary information about the reagent needs for the operator-defined day. The tile title displays 1 of 2 colors: • Red: One or more of the reagent alert conditions exist. • Green: No reagent alert conditions exist. The tile body displays the total number of reagent needs required to complete testing for the day.

Dashboard	Notes
Calibrator Needs	Summary information about the calibrator requirements for the operator-defined day. The title displays 1 of 2 colors: • Green: No analyzer has an immediate need for a calibrator material • Red: Any analyzer that falls within the configured calibration needs. The tile body displays the count of required calibrator materials.
QC Needs	Summary information about the QC Needs for the operator-defined day. The title displays 1 of 2 colors: • Green: No alert conditions exist. • Red: An order is placed and there is: – No QC onboard. – QC is onboard but the control material is unusable due to insufficient sample volume or stability expired errors. The tile body displays: • The total number of alert conditions. • The tile size can be small or medium and the same information displays on both.

About the System Status Map

The System Status Map is a graphical representation of the system connected to the Atellica Asa Application. The name of each module displays below it.



1	PCC	5	CH Analyzer
2	Sample Handler Connect	6	IM Analyzer
3	Sample Handler	7	Atellica Magline Transport
4	Decapper		

The System Status Map displays the status of each module and automatically refreshes when changes occur on the system:

Status Indicator	Notes
Green	Module is processing without any issues.
Yellow	Module in maintenance or diagnostics mode. Selecting a module displays the maintenance activities inprocess.
Red	Module has stopped because of a failure. The count of alerts displays. The entire Atellica Magline® Transport displays in red when errors or alerts occur anywhere on the track. When selecting anywhere on the track, the exact sections with errors highlight in red and errors display.
Red with or	Module is in diagnostic state.
Gray	Module is in stopped state with no errors.
Gray with	Module is in startup.
Gray with	Module is in off state.

The System Status Map displays in linear form even when the system is configured as L- or U-shaped.

About STAT Samples on the Atellica Asa Application

STAT Samples details the current status for all STAT samples on the system:

- Intervention Needed
- Inprocess

STAT Samples	Notes
Time of Error	The exact time when the first error for the sample occurred.
Sample ID	The code that identifies a sample. Selecting Sample ID displays Patient Sample Details. The Sample and Patient information tab does not display for the Atellica Asa Application.
Tests	The tests related to the Sample ID.
Description	The error description displays if 1 test or all tests have the same error. If more than 1 error occurs, Multiple errors displays and the operator can expand the row to view the error for each test.
Impacted Tests	The tests that require intervention.
Time to Completion	The number of minutes until results complete for a sample or an individual test.
Time On System	The amount of time since the system read the sample barcode at the TCS.
Location	The last known location of the sample: • The position of the sample in the rack with the rack location and barcode displaying, or • On the Atellica Magline Transport

The following functions are available for eligible Tests:

Function	Notes
Ignore	The system ignores any errors for the appropriate sample. Selecting Ignore for all rows changes the tile color to green.
Undo	Reverses the actions of Ignore.
Accept	The system accepts the result. Tests must have active results and be in the Hold or Transmit Failed test state.
Repeat	The system repeats the test. Tests must have active results and be in the Hold or Transmit Failed test state. The operator cannot perform test options, such as changing dilution, when repeating tests.

About Sample Interventions on the Atellica Asa Application

Sample Interventions details the current status for the following types of samples on the system that require intervention:

- Calibration
- QC
- Patient (non-STAT)

Sample Interventions	Notes
Time of Error	The exact time when the first error for the sample occurred.
Sample ID	The code that identifies a patient sample. Selecting Sample ID displays Patient Sample Details. The Sample and Patient information tab does not display for the Atellica Asa Application.

Sample Interventions	Notes
Description	The error description displays if 1 test or all tests have the same error. If more than 1 error occurs, Multiple errors displays and the operator can expand the row to view the error for each test.
Impacted Tests	The tests that require intervention.
Time On System	The amount of time since the system read the sample barcode at the TCS.
Analyzer	Friendly name of affected analyzer.
Assay	Impacted assay.
Material Name	Calibrator or QC material name.
Material Lot	Lot ID from Calibrator Definitions
Location	The last known location of the sample is 1 of the following: • The rack position of the sample: – SH Configurations: SH Name/ Drawer Number/(Back/Front)/ Rack ID/Rack Position or on the Atellica Magline Transport – Standalone Configurations: Rack ID and Position

The following functions are available for eligible Tests:

Function	Notes
Accept	The system accepts the result. Tests must have active results and be in the Hold or Transmit Failed test state.
Repeat	The system repeats the test. The system can only repeat a patient sample test. Tests must have active results and be in the Hold or Transmit Failed test state. The operator cannot perform test options, such as changing dilution, when repeating tests.

About Maintenance for the Atellica Asa Application

Maintenance displays the scheduled maintenance activities and their status for the connected systems for the configured time period. These activities include automated and manual procedures.

The large count on the tile is the number of activities that are Due and Failed. This number is the total number of current day maintenance activities in those states for the system that displays in Maintenance.

The Maintenance tile dynamically displays all modules that have maintenance in progress or Due within the configured warning threshold along with a count of the following:

- Number of current calendar day's Maintenance activities not completed and Due.
- Number of current calendar day's Maintenance activities completed with a failed status.
- The modules that are starting maintenance.
- The modules where maintenance is in progress.

The Maintenance tile header displays 1 of the following colors on the dashboard:

Maintenance tile title color	Notes
Green	No Failed, Inprocess, or Due maintenance activities exist to automatically start within the configured maintenance activity reminder time.
Yellow	One or more Inprocess or Due activities exist within the configured maintenance activity reminder time.
Red	Immediate operator intervention required as 1 or more maintenance activities have failed for the day. The title remains red until these activities successfully complete or the operator reschedules them to a new day.

The operator filters maintenance activities by all modules or a specific module on the system.

The system sorts upcoming maintenance activities based on the scheduled date and time. The schedule displays the oldest activities the operator did not perform first followed by the next scheduled activities. For count-based activities, the system estimates the date and when the activity is due. For as-needed activities, the system lists them after time-date and count-based activities.

Automated activities do not require operator assistance. The operator may start automated maintenance activities from this screen. When an automated maintenance activity completes successfully, the system updates the schedule and removes the activity.

Manual activities require the operator to perform or complete the activity. The operator documents completion of manual maintenance activities from this screen.

If an automated scheduled maintenance activity fails, the activity displays

⚠ and the due date does not update. The system creates a log entry recording the failed status.

The operator cannot delete any maintenance activities from Maintenance.

More information about Maintenance icons is available.

Maintenance	Notes
Module	The module that is assigned to the activity.
Activity	The name of the activity with an icon indicating whether it is automated or the operator or local technical support provider performs it.

Maintenance	Notes
Frequency	The next scheduled frequency: Daily, Weekly, or Monthly
Status	The activity Status displays as 1 of the following: • Inprocess (): The activity currently performing or waiting for the module to be in Ready state to complete the maintenance task. • Failed (): The activity failed to complete when it last performed. This only applies to automated activities. If the operator marks an As Needed activity as Failed, the system removes that activity automatically at the end of that day. • Due (): The activity is due within time displayed. The operator should perform it prior to the end of the duration period. • Overdue (): The operator marks the activity complete or the automated activity completes successfully. Values update every 30 seconds.
Procedure Details	The online help procedure for the selected manual or automated activity.
Perform	An automated maintenance activity performs or the operator performs and documents a manual activity.

About Automated Maintenance Activities for the Atellica Asa Application

The analyzer initiates automated maintenance activities according to an operator-defined maintenance schedule. The operator can initiate automated maintenance activities between scheduled times. The operator creates the maintenance schedule on the Atellica Solution.

NOTE: Performing a maintenance activity before the due date does not automatically reschedule that activity to the next frequency unless it completes after the scheduled time. The operator can use the reset option on the Atellica Solution to reschedule an activity.

Performing periodic maintenance activities based on cycle, time, or count before the due date automatically reschedules that activity to the next frequency.

About Supply Needs for the Atellica Asa Application

Supply Needs provides information about the status of the onboard supplies:

- CH supplies: System fluids, IMT supplies, reagent supplies (RPC1, RPC2, RPC4, and WBA), and other supplies (Pretreatment and cuvette status).
- IM supplies: System fluids, supplies (tips, cuvettes, and water supply), and waste (solid and liquid).

The Supply Needs tile displays the total number of alerts in View Alerts Only.

Supply Needs tile title color	Notes
Green	No supply or waste alert conditions exists.
Red	If 1 or more supply or waste alert conditions exist: • The consumable usable remaining volume is 0. • The onboard stability expires within the expiration period. • The count is less than the sample warning level. • Waste status is not OK.

These alert levels are configured in Supplies Alert Threshold Configuration.

Supply Needs	Notes
Module	The Supply Needs is separated by analyzers.
Alert Time	The time the alert was generated.
Supply	The supply name.

Supply Needs	Notes
Position	For system fluids only. The system fluids bottle number or location in system fluid drawer.
Status	Status of the remaining volume: • Counts remaining by supply • Empty: Supply empty • OK • Almost empty: Container empty, reservoir full • Expiring in {0} hours: Hours remaining until Lot or OBS expires for the container • Full: Container full IM Status only: • Tips: Identifies which tray is in use, count remaining, or Empty • Cuvettes: Operator selects **Prime Cuvettes** after filling
	Operator selects to add each supply to the Cart List.
Add All to Cart	Operator selects to add all supply needs to the Cart List.
Remove	The operator selects to remove the item from the Cart List.

To view the status of all supplies for all modules, select **View All Supplies**.

View All Supplies	Notes
View All Supplies	Operator selects to see all system fluids, IMT fluids, A-LYTE Multisensor, and Other Supplies on all analyzers.
Select an Analyzer	Operator selects the analyzer icon to filter view.
System Fluids	System fluids list by system.
IMT Supplies	CH IMT fluids and A-LYTE Multisensor.
	The remaining number of counts per system fluids and IMT fluids.
Volume	The remaining volume on the analyzer displayed in %.
Onboard Stability (OBS)	Count down timer in days and hours for the remaining supply onboard stability. OBS starts when the operator initially loads the supply onto an analyzer. OBS expiration date and time = date and time the consumable is loaded + OBS interval for consumable. OBS remaining = OBS expiration date and time – current date and time.
Lot Expiration	Date and time the system fluids or IMT fluids lot expires. This date and time expires at the end of the supply expiration date. An event is generated when the consumable expires.
Lot	Lot of the supply.
	Operator selects to add the supply to the Cart List.

View All Supplies	Notes
Other Supplies	CH consumables include: • Cuvettes • View Cuvette Status • RPC4, RPC2, and RPC1 • WBA IM consumables include: • Tips • Cuvettes • Water • IM Wash
Status	Status of the remaining volume: • View Cuvette Status: Displays the CH Cuvette State Information for the reaction and dilution cuvettes onboard. • Counts remaining (drop with number icon) • Empty: Supply empty • Reserve empty: • OK • Almost empty: Container empty, reservoir full • Expires Soon: < 2 days remaining until Lot or OBS expires for the container • Full: Container full IM Status only: • Tips: Identifies which tray is in use, count remaining, or Empty. • Cuvettes: Operator selects **Prime Cuvettes** after filling.

View All Supplies	Notes
Cuvette State Information (CH only)	Operator selects to view the CH cuvette status definitions: • Clean (blue): Wash is complete. The cuvette is ready for use. • Need Replacement (Red): Cannot use the cuvette. Cuvette QC, washing, and cleaning failed too often. Replace all the cuvettes in the ring. • Disabled (white): Cannot use the cuvette. The cuvette was disabled by service in Diagnostics. • Waiting for acceptable QC (yellow): Only applicable to Reaction cuvettes. Cannot use until the cuvette is washed and checked again. The cuvette failed the last Cuvette QC check. If greater than 35 cuvettes require replacement, an alert is generated in Operator Event Log.
Pretreatment (CH only)	Only displays if the A1C assay is enabled. Status includes: • Inventory Remaining (Pretreatment): The remaining Pretreatment in test counts. • Inventory Remaining (A1C): The remaining A1C reagent test counts. • Onboard Stability (OBS): Count down timer in days and hours for the remaining supply onboard stability. OBS starts when the operator initially loads the supply onto the analyzer.

View All Supplies	Notes
	• Lot Expiration: The date and time the system fluids or IMT fluids lot expires. • Lot: Lot of pretreatment.
Waste (IM only)	The IM waste includes: • Cuvette and Tip Waste • Tip Tray Waste: to replace, the operator selects **Open Tip Tray Waste Drawer**. • Liquid Waste
View Needs Only	Operator selects to review only supplies with an alert.

About Reagent Needs for the Atellica Asa Application

In Reagent Needs, the operator views current inventory that falls below the configured reagent threshold. Only enabled reagents display. The operator configures this threshold in Reagent Thresholds. Reagent Needs updates every 3 minutes.

The number on the Reagent Needs tile is the total number of reagent needs. This number equals the total rows in Reagent Needs.

Reagent Needs tile title color	Notes
Green	No reagent alert conditions exist.
Red	One or more of the reagent alert conditions exist.

Reagent Needs posts a need for a reagent based on the expected tests for that day compared to the current inventory:

- No Available Reagent: Reagent is unavailable (Empty, error, expired OBS or lot).
- Below Threshold ({0}): The reagent inventory level has reached the red alert threshold the operator defined in Reagent Thresholds.

A need is red when the current inventory drops below a threshold defined by the operator or when there are pending orders with no reagent available.

If an alert occurs or packs are loaded, the data updates to reflect the change. The remaining columns refresh every 1–5 minutes.

Reagent Needs	Notes
Reagent Overview	The operator selects to displays Reagent Overview.
Name	Short name for the assay, cleaning solution, or ancillary material associated with the reagent pack. The operator selects the arrow to sort the column contents in ascending or descending alphanumeric order.
Average Tests	The average number of tests per assay.
Inventory	The current inventory for the specified analyzer remaining for that reagent: • Primary reagents: Tests remaining. • Ancillary reagents: Amount remaining in mL.
Packs to Load	The number of reagent packs required until the operator-defined day ends. System calculates as Tests Remaining ÷ tests per pack from the appropriate IFU.
Analyzers	The analyzer where pack is located.
Reason	• No Available Reagent: Reagent is unavailable (Empty, error, expired OBS or lot). • Below Threshold ({0}): The reagent inventory level has reached the red alert threshold the operator defined in Reagent Thresholds.
	The operator selects to add an individual reagent to the cart.
Add All to Cart	Operator selects to add all reagents listed to the cart.
Remove	The operator selects to remove the item from the Cart List.

About Calibrator Needs for the Atellica Asa Application

The system creates a forecast for the appropriate calibrator materials. The system determines the Calibrator Needs information based on the following:

- Pack calibration intervals expiring before an operator-defined day ends.
- Lot calibration intervals expiring before an operator-defined day ends.
- If operator/system orders calibration during an operator-defined day and no calibrator is onboard, is expired, or is Insufficient Volume.

No need displays for C0 adjustments.

Calibrator Needs resets at end of an operator-defined day.

Calibrator Needs tile title color	Notes
Green	No calibrator material required.
Red	The calibrator material expires within the configured Calibration Due Warning (hours).

If an alert occurs or calibrator materials are loaded, the data updates to reflect the change. The remaining columns refresh every 1–5 minutes.

The operator can filter the forecast information for materials based on alerts (immediate need) or for forecasted needs for the current or the operator-defined day.

Calibrator Needs	Notes
Calibrator Material	Name of the calibrator material.
Levels	The level of the calibrator material.
Calibrator Lot	The appropriate calibrator lot.
Assay	Assays impacted by the calibrator need. The material must be loaded because the calibration on assays is required.
Store Onboard	Whether the control material is onboard and available (not expired or depleted).

Calibrator Needs	Notes
Reason	Calibrations statuses are: • Scheduled: The analyzer orders the calibration at that time then updates to Ordered. Scheduled calibrations highlight as an immediate need when the scheduled time is within the configured Calibration Due Warning (hours) in Calibration Setup. • Ordered: Immediate need and highlighted red.
	The operator selects to add an individual calibrator material to the cart.
Add All to Cart	The operator selects to add all the calibrator material to the cart.
Remove	The operator selects to remove the item from the Cart List.

About QC Needs for the Atellica Asa Application

The operator reviews the required QC materials to load to perform current or scheduled QC orders in QC Needs. If appropriate, the operator adds the required materials to the Cart List then prints the required barcode labels.

QC Needs is created for a QC material based on:

- Tests the QC scheduler sets to perform before midnight of the defined day.
- Any pending QC orders in Worklist.
- The required control material is expired, low, or not onboard.

QC Needs resets at end of operator-defined day.

The number displayed on the QC Needs tile is the number of alert conditions.

QC Needs tile title color	Notes
Green	No alert conditions exist.
Red	An order is placed but either: • No QC is onboard. • The QC is onboard but the control material is insufficient (low volume or expired).

If an alert occurs or QC materials are loaded, the data updates to reflect the change. The remaining columns refresh every 1–5 minutes.

QC Needs	Notes
Cal-QC Inventory	The operator selects to display a view only Cal-QC Inventory with details about Cal-QC storage. **NOTE:** This options is only available when connected to systems configured with an SH.
Name	The name of the control material from QC Definitions QC Material.
Level	The concentration level of the control material.
QC Lot	The lot of the control material.
QC Material ID	A unique identifier for the control from QC Definitions QC Material ID.
Store Onboard	Whether the control material is onboard and available (not expired or depleted).
Scheduled	The next scheduled QC test.
Volume Needed (mL)	The total volume (in mL) the system needs of the material.
Reason	Whether the control is Scheduled or Ordered.
Assay	Assays impacted by the QC need. The material must be loaded because the QC test on assays is required.

QC Needs	Notes
	The operator selects to add the item to the Cart List.
Add All to Cart	Operator selects to add all reagents listed to the cart.
Remove	The operator selects to remove the item from the Cart List.

About the Cal-QC Storage Inventory

The Cal-QC Storage Inventory provides details about the individual calibrator and QC tubes in Cal-QC storage for all SHs or on the Atellica Magline Transport.

The Cal-QC Storage Inventory has 3 areas:

- Filter
- No Filter
- Assay Details

The Cal-QC Sample Details provide information for each calibrator or QC tube available.

Functions are also available to display assay details for calibrators or QCs or to unload selected tubes from Cal-QC storage.

Cal-QC Storage Inventory	Notes
Type	The material type: Cal or QC.
Material	The Cal or QC material product name.
Lot	The lot of the material.
Sequence	A unique number (from the barcode sequence) that identifies the specific container of a Cal-QC material.

Cal-QC Storage Inventory	Notes
Status	The material status: • OK: Material is acceptable to use. No status indicator displays. • Insufficient volume: The total volume of Cal-QC material is less than the low volume threshold. The text displays with a yellow background. • Partially Expired: The material is usable for some assays but has exceeded the onboard stability for use with at least 1 assay. The text displays with a yellow background. • Expired: The onboard expiration date for the material expires. The text displays with a red background.
Vol (µL)	The total usable volume for the material in the tube. For approximated volume values, the number contains a prefix of "~".
Location	The location of the tube: SH name or In Use (on the Atellica Magline Transport).
Expiration	The manufacturer's expiration date for the lot of materials.

The Cal-QC Storage Inventory Assay Details provides a list of the assays that use the selected Cal-QC material and expiration information for the assay.

Assay Details	Notes
Assay	The assays that uses the selected Cal-QC material.
Expiration	The onboard stability date of each assay defined by the Cal-QC material or Expired with a red background for expired assays.

About the Cart List for the Atellica Asa Application

The Cart List provides the operator with the following:

- Consumables, system fluids, supplies, reagent, and other materials required for the system that day.
- The option to create a list to retrieve the items from storage.
- Custom supply option to add an item to the cart that is not listed in the needs tiles.

Items in the list include the following:

- Reagents: Added through Reagent Needs
- Calibrators: Added through Calibrator Needs
- Quality Control: Added through QC Needs
- Supplies: Added through Supply Needs
- Other: Only displays when the operator adds items manually from Cart List

The workflow for using the Cart List is as follows:

1. The operator adds materials from 1 of the 4 needs screens.
2. When all needs are added, the operator selects from the Access bar and reviews the complete set of required needs.
3. If appropriate, the operator selects **Add Item** to add a customized item not in the system to the list and enters a description and quantity.
4. The operator takes the list to obtain the needs from the supply locations and manually checks off the list.
5. When all the required needs are gathered collected, the operator selects **Clear Cart**.
6. The operator then replaces all required needs.

Reagents	Notes
Name	The name of the required reagent
Analyzers	The name of the analyzer for the required reagent
Packs to Load	The total number of packs added to the cart for the specified reagent lot
Complete	

Calibrators	Notes
Calibrator Name	The name of the calibrator material
Calibrator Lot	The appropriate calibrator material lot
Complete	

Quality Control	Notes
QC Name	The name of the QC material
QC Material ID	A unique identifier for the control from QC Definitions QC Material ID.
Complete	

Supplies	Notes
Module	The name of the module for the required supply
Name	The name of the supply
Lot	The lot of the supply
Complete	

To remove all items from the Cart List, the operator selects **Remove**.

To add a custom item to the Cart List, the operator selects **Add Item**.

To clear all the items from the Cart List, the operator selects **Clear Cart**.

The Completed tab displays the materials that the operator obtains from the supply location and checks off the list. The system removes items automatically from the needs screens and the Completed tab when the operator loads materials onto the system. If Wi-Fi connectivity is lost, the application retains the information and the Cart List is still usable while collecting material even though the list cannot update with new information.

About Troubleshooting for the Atellica Asa Application

Troubleshooting provides access to tools that maintain and diagnose problems with the system.

Troubleshooting	Notes
Online Help	Opens the online help system with access to search, favorites, and table of contents.
Diagnostics	Provides access to all operator diagnostics functions. **NOTE:** Diagnostics is available when accessing the Atellica Asa Application on operator tablets connected to the Atellica Solution network.
Service Support Request	Accesses the Service Support Request system. The operator can submit a new service support request or view previously submitted tickets.

About Diagnostics for the Atellica Asa Application

NOTE: Diagnostics is available when accessing the Atellica Asa Application on operator tablets connected to the Atellica Solution network.

Diagnostics allows the operator to manually manipulate the module during maintenance or troubleshooting. Certain diagnostic procedures require the operator to manually move hardware, initialize, prime, and open and close covers. The operator can safely enter the module into a diagnostic state, halting the mechanics to perform these procedures. The operator exits the diagnostic state after the maintenance or troubleshooting is complete.

Diagnostics is an option in Troubleshooting.

Diagnostics	Notes
Subsystems	Filters the diagnostic procedures according to the module.
Diagnostic Name	Displays the subsystem task.
Activity Description	Describes the subsystem task.
Perform	Starts the selected diagnostic task.
Cancel	Cancels the selected diagnostic task.

Diagnostics	Notes
Status	Displays when IM Analyzer is selected. Re-displays an IM Analyzer diagnostic task progress window that is closed.
Enter Diagnostics	Enters the module into the diagnostic state so operator can safely perform manual maintenance.
Exit Diagnostics	Exits the diagnostic state after completing maintenance or troubleshooting.
Turn Mechanics On	Displays when IM Analyzer is selected. Engages all IM Analyzer mechanical components.
Turn Mechanics Off	Displays when IM Analyzer is selected. Disengages all IM Analyzer mechanical components.

About Service Support Request for the Atellica Asa Application

If appropriate, the local technical support provider connects directly to the application to initiate remote control and query system diagnostics. From the application, the operator uses the Service Support Request to contact the local technical support provider to ask a question, request information, or troubleshoot issues quickly through an encrypted connection to ensure patient data privacy. The operator initiates the request using video sharing, chat, camera, and audio features to send photos and audio with each service support request.

The operator can select from the following 3 workflows:

Remote assistance workflow	Notes
Create a Service Support Request	The operator generates a support ticket. The local technical support provider calls the operator by phone or text chat. The operator has the option for the provider to call as soon as possible or at a later time in 30 minute increments. or.
Remote session with no ticket creation	The operator initiates a support request by phone. The local technical support provider asks the operator to open a remote session while remaining on the phone.
Review Previous Tickets	The operator views existing tickets for the status on reported issues. Existing tickets are read-only. Only tickets the operator opens via Service Support Request display here. The support tickets the local technical support provider opens do not display.

Create a Service Support Request	Notes
Analyzer list	Provides a list of the available modules on the system.
Service Request	Submits a ticket for 1 of the following: • Urgent Service Request - System is not able to process: An issue exists that has the highest priority, such as the system is offline or troubleshooting does not resolve the issue. • Service Request - System is partially operable: Performance loses some functionality or degradation that requires service. • Information Request: The system does not lose functionality but the operator requires a callback for guidance on operating the system, clarification of operator instructions, or an answer to a question.
Contact Preference	Requests contact from the local technical support provider by phone or by chat.

Create a Service Support Request	Notes
Preferred Time	Requests call back as soon as possible or at a specific time.
Name	Displays the name of the operator.
Phone Number	Displays the phone number operator.
Short Description	Indicates a unique title to distinguish from other open service support tickets. Limit of 40 characters.
Problem Description	Indicates a detailed description describing information or support service required. Limit of 2000 characters.
Files List	Lists all the photo, video, or data files attached to ticket. The operator can attach up to 10 files with a total uncompressed of 1GB to a service support ticket. Select a file in the list to view it.
	Takes photos or records a video to attach to a service support ticket.
Add File	Adds files to the service support ticket. **NOTE:** Screen captures save to the Pictures > Screenshots folder.
Submit	Generates a support request ticket.

TeamViewer	Notes
	Initiates video from the operator to the support provider.
	Initiates chat session between operator and support provider.
	Initiates the Whiteboard for operator to highlight or draw on screens.
	Displays support provider is connected with IP address.
	Minimizes TeamViewer display.

TeamViewer	Notes
	Opens more details for each feature.
	Terminates remote service session. To initiate a remote session, a new passcode is required.

23 Supplies

Supplies and Customer Parts

This chapter provides a list of supplies.

SH Supplies

The following table lists SH consumable and customer parts with the catalog number to assist in the ordering process:

SH consumables	REF	Trigger	Quantity
Atellica Solution Tube-Top Sample Cup 2 mL	11069062	N/A	1000 cups/bag
Atellica Solution Tube-Top Sample Cup 1 mL	11069061	N/A	1000 cups/bag
Holder Tube Capillary (Blue)	11069064	N/A	1000 holders/bag
Holder Tube Capillary False-Bottom (Green)	11069063	N/A	1000 holders/bag
COVER CAL AND QC TUBES	11085756	Visual inspection reveals damaged or missing covers.	1 cover
Ribbon Printer 2.32"X295ft qty 24	11480802	Visual inspection reveals poor print quality.	24 ribbons
Barcode Label 2" X 1" THERM/TRANS POLYPROPYLENE LABELS	11481335	N/A	1 roll

SH customer parts	REF	Quantity	Recommended stock quantity per module	Replacement frequency
Robot gripper O-ring (O RING 0.14ID X 0.1W EPDM)	11085860	4	1	When needed. Replace all 4 O-rings at the same time even if only one appears to need replacement.
15-position routine rack (TRAY ASSY 15 POSITION)	11069024	1	N/A	Every 30,000 samples for best tube handling
55-position routine rack (TRAY ASSY 55 POSITION)	11069025	1	N/A	Every 100,000 samples for best tube handling
55-position routine rack (TRAY ASSY 55 POSITION)	11616054	10	N/A	Every 100,000 samples for best tube handling
15-position STAT rack (ASSY TRAY 15 POSITION STAT)	11473286	1	N/A	Every 30,000 samples for best tube handling
55-position false-bottom tube rack (ASSY TRAY 55 POSITION SPECIAL TUBE1)	11473289	1	N/A	Every 100,000 samples for best tube handling
55-position false-bottom tube rack (ASSY TRAY 55 POSITION SPECIAL TUBE1)	11616177	10	N/A	Every 100,000 samples for best tube handling
15-position false-bottom tube rack (ASSY TRAY 15 POSITION SPECIAL TUBE1)	11473287	1	N/A	Every 30,000 samples for best tube handling

SH customer parts	REF	Quantity	Recommended stock quantity per module	Replacement frequency
15-position STAT rack for false-bottom tubes (ASSY TRAY 15 POSITION SPECIAL STAT1)	11473288	1	N/A	Every 30,000 samples for best tube handling
55-position archive rack (ASSY TRAY 55 POSITION ARCHIVAL)	11069071	8	N/A	Every 20,000 samples for best tube handling
Cover for 55-position racks - fits both archive and routine racks (TRAY COVER KIT)	11090284	8	N/A	When damaged

SHC Supplies

The following table lists SHC customer parts with the catalog number to assist in the ordering process:

SHC customer parts	REF	Recommended stock quantity per module	Replacement frequency
Back panel fan filters (FILTER AIR REAR PANEL)	11083036	1	When damaged
Robot gripper tip (PAD GRIPPER FINGER)	11095807	6	When missing, damaged, worn, or after 60,000 containers. Replace all 6 pads at the same time even if only one appears to need replacement.

CH Supplies

The following table lists CH Analyzer consumable and customer parts with the catalog number to assist in the ordering process:

CH consumables	REF	Trigger	Quantity
CH Cleaner	11099303	Supply Needs alert	2 x 1.5 L
CH Conditioner	11099302	Supply Needs alert	2 x 1.5 L
CH Diluent	11099300	Supply Needs alert	2 x 1.5 L
CH Wash	11099301	Supplies Overview alert	2 x 1.5 L
CH Check Reagent (CHK)	11099311	Supply Needs alert	8 x 47 mL
IMT Diluent	11099305	Supply Needs alert	2 x 1.5 L
IMT Dilution Check	11099325	Initiating IMT Dilution Check	6 x 2 mL
IMT Standard A	11099304	Supply Needs alert	2 x 1.5 L
IMT Standard B + Salt Bridge	11099306	Supply Needs alert	1 x 250 mL & 1 x 125 mL
A-LYTE IMT Cleaner	11556782	Initiating IMT Enzyme Cleaning with IMT Cleaner	6 X 2.5 mL
CH Lamp Coolant	11099307	Supply Needs alert	1 x 250 mL
High-Volume Pretreatment	10721048	Supply Needs alert	2 x 1 liter
High-Volume 180-mL Pretreatment Bottles and Caps Kit	11597087	As needed	5 bottles, 5 caps

CH consumables	REF	Trigger	Quantity
High-Volume Pretreatment Bottle Label Kit	11597090	As needed	1 roll of 50
CH Reagent Probe Cleaner 1 (RPC1)	11099312	Supply Needs alert	8 x 44.6 mL
CH Reagent Probe Cleaner 2 (RPC2)	11099313	Supply Needs alert	8 x 44.6 mL
CH Reagent Probe Cleaner 4 (RPC4)	11099309	Supply Needs alert	4 x 47 mL
CH Water Bath Additive (WBA)	11099308	System alert	4 x 36 mL
Dilution cuvette segments	11099327	Every 4 months / 3x a year	5 segments/box
Reaction cuvette segments	11099326	Every 4 months / 3x a year	5 segments/box
Empty CH reagent packs	11097534	As needed	4 P1 packs and 4 P2 packs
Empty CH reagent packs, P1	11538114	As needed	8 P1 packs
Empty CH reagent packs, P2	11538115	As needed	8 P2 packs

CH customer parts	REF	Recommended stock quantity per module	Replacement frequency
Back panel fan filters (FILTER AIR REAR PANEL)	11083036	2	When damaged
Fan Filter in front left door (FILTER AIR INTAKE)	11075725	2	When damaged or missing

CH customer parts	REF	Recommended stock quantity per module	Replacement frequency
IMT peristaltic pump tubing (TUBING PERISTALTIC PUMP)	11075682	1	Every 50,000 cycles
Atellica IMT Na K CL (A-LYTE Multisensor)	11099315	2	Every 5000 samples or 14 days
Mixer impeller (MIXER IMPELLER ASSY)	11075703	1	When appropriate
Triple wash probes 1–5 (PROBE TRIPLE ASSY CUVETTE WASH)	11075642	1	When appropriate
Reaction washer probe 6 (PROBE SINGLE ASSY CUVETTE WASH)	11075641	1	When appropriate
Reagent probe (PROBE METERING ASSY HS - REAGENT)	11075751	3	When appropriate
Dilution and sample probe (PROBE METERING ASSY HS - DIL - SAMPLE)	11075752	2	When appropriate
Source lamp (LAMP ASSY HALOGEN BULB)	11075676	2	Based on lamp intensity and use rate
Washer probe dryer spring (SPRING COMP CUVT 7.6X17X.56)	11075667	3	When missing or damaged
Dilution or Reaction Wash Dryer Nozzle (NOZZLE PROBE VACUUM)	11075610	1	When appropriate

CH customer parts	REF	Recommended stock quantity per module	Replacement frequency
Reaction washer 1–6 (PROBE VACUUM ASSY CUVETTE WASH)	11075643	1	When appropriate
High-Volume Pretreatment Keyed Lid	11597266	N/A	N/A

IM Supplies

The following is a list of IM Analyzer consumables and customer parts with the catalog numbers to assist in the ordering process.

IM consumables	REF	Trigger	Quantity
Cuvettes	10309546 	Supply Needs alert	3000/box
IM Acid	11417929	Supply Needs alert	2 x 1.5 L
IM Base	11417930	Supply Needs alert	2 x 1.5 L
IM Cleaner	11098502	Supply Needs alert	2 x 1.5 L
IM Wash	11098501	Supply Needs alert	1 x 3.0 L
IM Ancillary Probe Wash 1 (AWP1)	10995458	Supply Needs alert	2 X 25 mL
IM Ancillary Probe Wash 3 (APW3)	10998580	Supply Needs alert	2 X 25 mL
IM Probe Wash 3 (PW3)	10995666	Reagent Needs alert	50 mL
Solid waste bin liner	11070709	Visual inspection	1
Tips, sample probe	10309547 	Supply Needs alert	6480/box

IM consumables	REF	Trigger	Quantity
Humidity Packs, 5	11313505	System alert, replace every 240 days	5/box
SWAB POLYURETHANE FOAM	11349138	Reagent probe rinse station requires cleaning	25/box

IM customer parts	REF	Recommended stock quantity per module	Replacement frequency
Back panel fan filters (FILTER AIR REAR PANEL)	11083036	1	When damaged
Reagent probe (PROBE ASSY REAGENT)	11071144	3	When damaged or not performing properly
Aspirate probe (PROBE ASSY ASPIRATE)	11070782	3	When damaged or not performing properly
Waste probe (PROBE WASTE ASPIRATE)	11070785	2	When damaged or not performing properly

IM customer parts	REF	Recommended stock quantity per module	Replacement frequency
Cuvette waste chute (CHUTE WASTE CUVETTE ASSEMBLY)	11070572	1	As needed
Water trap gasket (Gasket, Water Trap)	11071032	2	When cracked, damaged, or missing

Decapper Supplies

The following table lists Decapper consumable part with the catalog number to assist in the ordering process:

Decapper consumables	REF	Trigger	Quantity
Waste Chute Liner	11069416	Failed manual inspection	10 pack

Sealer Supplies

The following table lists a Sealer consumable part with the catalog number to assist in the ordering process:

Sealer consumables	REF	Trigger	Quantity
Foil Roll	11069411	Supply Needs alert	1 roll/case

DL Supplies

The DL module comes with a customer parts kit at installation. This kit includes replaceable parts.

DL customer part	REF	Recommended stock quantity per module	Replacement frequency
SAMPLE RACK ASSY GRAY	10714017	N/A	When damaged
SAMPLE RACK ASSY BLUE	10714021	N/A	When damaged
SAMPLE RACK ASSY YELLOW	10714019	N/A	When damaged
SAMPLE RACK ASSY GREEN	10714022	N/A	When damaged
SAMPLE RACK ASSY ORANGE	10714018	N/A	When damaged
SAMPLE RACK ASSY RED	10714020	N/A	When damaged
TRAY SAMPLE RACK	10707472	N/A	When damaged
CARRIER RACK ASSY BULK LOADING	10708458	N/A	When damaged
ADAPTER TUBE ASSY QC/CAL 12MMX75L	10946757	N/A	When damaged
ADAPTER 13MM LONG TUBE SAMPLE RACK	10702457	N/A	When damaged
ADAPTER 13MM SHORT TUBE SAMPLE RACK	10702458	N/A	When damaged
FILTER REAR PANELS	11083036	1	When damaged

24 Specifications

Specifications

This chapter provides the system design specifications.

System Key Features

The system has features for enhancing laboratory operations.

Feature	Notes
Pause-free reloading	Load samples and calibration and QC materials while the system processes samples.
System display	The graphical user interface employs a primary user interface touchscreen making it possible to perform daily tasks directly on the screen without using the keyboard.
Cybersecurity	Security features protect system integrity and confidential patient information.

Product Catalog Numbers

Module	REF
Atellica® Decapper	Model 11069400
Atellica® Sealer Head	Model 11069408
Atellica® Sealer Base	Model 11069409
Atellica® CH 930 Analyzer	Model 11067000
Atellica® IM 1600 Analyzer	Model 11066000
Atellica® IM 1300 Analyzer	Model 11066001
Atellica® Sample Handler Prime	Model 11069001
Atellica® Sample Handler Additional	Model 11069004

Module	REF
Atellica® Direct Load	Model 11068008
Atellica® Sample Handler Connect	Model 11069018

System Interoperability

Customers can connect Atellica Solution to the following products:

- Atellica Data Management System
- Atellica Process Manager
- Atellica Connectivity Manager
- Smart Remote Services (SRS)
- Aptio® Automation
- Atellica Asa™ Application
- FlexLab STD (DMS)
- FlexLab HT (DMS)

NOTE: Contact the local technical support provider for supported configurations and versions.

Electromagnetic Compatibility

Specification	Notes
Electromagnetic Emission Compliance	CISPR 11 Class A[1)]

- The system complies with the emission and immunity requirements in IEC 61326-2-6.[1]
- The laboratory should evaluate the electromagnetic environment prior to operation of the device.[1]
- Sources of strong electromagnetic radiation in close proximity to the device may interfere with proper operation.[1]
- This equipment is designed and tested to CISPR 11 Class A. It may cause radio interference in a domestic environment. In this case, the laboratory may need to take measures to mitigate the interference.[1]

1) International Standard. Electrical equipment for measurement, control, and laboratory use – EMC requirement – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment; Applies in conjunction with IEC 61326-1. International Electrotechnical Commission, 3 rue de Varembé, PO Box 131, CH-1211, Geneva 20, Switzerland, 2020

- This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
- This equipment is designed for use in a professional healthcare facility environment. It is likely to perform incorrectly if used in a home healthcare environment. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

Atellica Solution Dimensions

The area around the system must be free of obstacles and properly vented after installation.

	ScI	SccI	SSccII	ScI with SHC
Depth	1520 mm (59.8 inches) : includes the Atellica Magline Transport and module display 1451 mm (57.1 inches) : includes the Atellica Magline Transport, no module display			
Height	1500 mm (59.1 inches)			
Width	4250 mm (167.3 inches)	5702 mm (224.5 inches)	8026 mm (316 inches)	4650 mm (183.1 inches)
Weight	1520 kg (3351 lb)	1990 kg (4387 lb)	3040 kg (6702 lb)	1634 kg (3602 lb)

SH and SHC Dimensions

SH dimensions

Dimensions	Measurement
Depth	1451 mm (57 inches)
Height	1465 mm (57.7 inches)
Width SH only	985 mm (38.8 inches)

Dimensions	Measurement
Width	1306 mm (51.5 inches)
SH with Atellica Magline Transport loop (1 required per system)	
Weight	476 kg (1050 lbs)

SHC dimensions

Dimensions	Measurement
Depth	1430 mm (56.3 inches)
Height	1307 mm (51.5 inches)
Width	400 mm (16 inches)
Weight	114 kg (250 lbs)

Decapper Dimensions

The Decapper is an optional feature. Allow enough space to access all sides of the Decapper. The area around the Decapper must be free of obstacles and properly vented after installation.

The space requirement for the Decapper between any 2 analyzers or at the end of the system configuration is 25.4 cm (10 inches).

Dimensions	Measurement
Depth	1109 mm (44 inches)
Height	1223 mm (48 inches)
Width	250 mm (10 inches)
Weight	79 kg (175 lbs)

Sealer Dimensions

The Sealer is an optional feature. Allow enough space to access all sides of the Sealer. The area around the Sealer must be free of obstacles and properly vented after installation.

Dimensions	Measurement
Depth	1432 mm (56 inches)
Height	1307 mm (51 inches)
Width	392 mm (15 inches)
Weight	134 kg (296 lbs)

CH Analyzer Dimensions

Allow enough space to access all sides of the analyzer. The area around the analyzer must be free of obstacles and properly vented after installation.

Dimensions	Measurement
Depth	1156 mm (45.5 inches)
Height	1364 mm (53.7 inches)
Width	1491 mm (58.7 inches)
Weight	470 kg (1036 lb)

These dimensions include the analyzer with covers and panels but do not include the following:

- Workstation
- Atellica Magline Transport
- Module Display
- Sample Handler
- Direct Load

IM Analyzer Dimensions

Dimensions	Measurement
Depth	1155.5 mm (45.5 inches)
Height	1500 mm (59.1 inches)
Width	1491 mm (58.7 inches)
Weight	574 kg (1265 lbs)

The dimensions include the analyzer with covers and panels but do not include the following:

- Workstation
- Atellica Magline Transport
- Module Display
- Sample Handler
- Direct Load

DL Dimensions

The area around the analyzer must be free of obstacles and properly vented after installation. Width and height does not include the primary user interface.

Dimensions	Measurement
Depth	1100 mm (43.3 inches)
Height	1360 mm (53.5 inches)
Width	425 mm (16.7 inches)
Weight	141.7 kg (312 lb)

SH and SHC Environmental Specifications

The environmental specifications are the same for SHs with and without an SHC.

Specification	Description
Laboratory ambient operating temperature	SH and SHC: 18–30 °C (64–86 °F) up to 2000 meters (6562 feet) SH: 18–27 °C (64–80.6 °F) above 2000 meters (6562 feet)
Laboratory ambient relative humidity	20–80%, noncondensing
Storage temperature	0–50 °C (32–122 °F) (before and after shipping)
Indoor use only	Yes

Specification	Description
Altitude	SHC: Up to 2000 meters (6562 feet) SH: Up to 4000 meters (13123 feet)
Thermal output	2180 BTU/hour
Noise	Compliant with NC-46 Noise Control Specification. Average sound pressure of 53 dBA, 1 m away from the SH.
Overvoltage classification	Category II
Pollution classification	Degree 2

SH and SHC Electrical Requirements

When a system is equipped with an SHC, the SHC receives power from the connected SH. Systems equipped with an SHC have no additional electrical requirements.

Requirement	Description
Voltage rating (Vac, 1~)	200–240
Current rating (A)	8
Frequency rating (Hz)	50/60

Decapper Environmental Specifications

Specification	Description
Laboratory ambient operating temperature	18–30 °C (64–86 °F)
Laboratory ambient relative humidity	20–80%, noncondensing
Storage temperature	-11–50 °C (12.2–122 °F) (before and after shipping)
Storage relative humidity	10–90%, noncondensing

Specification	Description
Altitude	Up to 2000 meters (6561 feet)
Indoor use only	Yes
Thermal output	≤983 BTU/hour
Noise	Compliant with NC-43 Noise Control specification. Average sound pressure of 65 dBA, 1 m away from Decapper.
Overvoltage classification	Category II
Pollution classification	Degree 2
Laboratory air supply or operator-supplied air compressor requirements	Compressor supplies between 0.6–0.7 MPa (87–101 PSI) to Decapper; supplies air flow of 1.76 NLPM (0.062 CFM) per minute to Decapper; uses a compressed Air Purity Class 1 output rating per ISO 8573-1:2010.

Decapper Electrical Requirements

Requirement	Description
Voltage rating	200–240 Vac
Current rating	1.2 A
Frequency rating	50/60Hz

Sealer Electrical Requirements

Requirement	Description
Voltage rating	200–240 Vac
Current rating	1 A
Frequency rating	50/60 Hz

Sealer Environmental Specifications

Specification	Description
Laboratory ambient operating temperature	18–30 °C (64–86 °F)
Laboratory ambient relative humidity	20–80%, noncondensing
Storage temperature	-11–50 °C (12.2–122 °F) (before and after shipping)
Storage relative humidity	10–80%, noncondensing
Altitude	Up to 4000 meters (6561 feet)
Indoor use only	Yes
Thermal output	< 900 BTU/hour
Noise	Compliant with ANSI S12.51-2012/ISO 3741: 2010 specification, average sound pressure of < 55 dBA when 1 m away from Sealer
Overvoltage classification	Category II
Pollution classification	Degree 2

Sealer Foil Environmental Specifications

Specification	Description
Storage temperature	-20–40 °C (-4–104 °F) (before and after shipping)
Storage relative humidity	10–80%, noncondensing.

CH Environmental Specifications

Specification	Description
Laboratory ambient operating temperature	18–30 °C (64–86 °F) up to 2000 meters (6562 feet) 18–27 °C (64–80.6 °F) above 2000 meters (6562 feet)
Laboratory ambient relative humidity	20–80%, noncondensing
Storage temperature	1–50 °C (33.8–122 °F) (before and after shipping)
Storage relative humidity	5–80%, noncondensing
Altitude	Up to 4000 meters (13123 feet)
Indoor use only	Yes
Thermal output	≤ 5210 BTU/hour
Noise	Compliant with NC-43 Noise Control specification. Average sound pressure of 50 dBA, 1 m away from analyzer.
Overvoltage classification	Category II
Pollution classification	Degree 2
Maximum water pressure	207 kPa (30 PSI)

CH Analyzer Electrical Requirements

Requirement	Description				
Voltage rating (Vac, 1~)	200	208	220	230	240
Current rating (A)	9	9	8.5	8	8
Frequency rating (Hz)	50/60				

CH Analyzer General Product Specifications

Specification	Description
Test throughput	1800 assays/hour: 1200 photometric assays/hour, 600 IMT assays/hour, depending upon laboratory assay mix
Walkaway time	Up to 5 hours
Assays onboard	Up to 70 assays
Water requirements	Special reagent water (SRW) connected directly to a pressurized water source (5 psi and 10 psi) (Page 908 *About Special Reagent Water*)
Water consumption	Maximum of 33 L/hour
Liquid waste output	Minimum of 40 L/hour per analyzer

IM Environmental Specifications

Specification	Description
Laboratory ambient operating temperature	18–30 °C (64–86 °F)
Laboratory ambient relative humidity	20–80%, noncondensing
Storage temperature	1–50 °C (33.8–122 °F) (before and after shipping)
Storage relative humidity	5–80 %, noncondensing
Altitude	up to 2000 meters (6561 feet)
Indoor use only	Yes
Thermal output	1320.55 W (4507 BTU/hour)
Noise	Compliant with NC-55 Noise Control specification, Average sound pressure of 65 dBA (1 m away from analyzer)

Specification	Description
Overvoltage classification	Category II
Pollution classification	Degree 2
Maximum water pressure	207 kPa (30 PSI)

IM Electrical Requirements

Requirement	Description
Voltage rating (Vac, 1~)	200/208/220/230/240
Current rating (A)	12
Frequency rating (Hz)	50/60

IM Analyzer General Product Specifications

Specification	Description
Test throughput	Atellica IM 1600 Analyzer maximum throughput of up to 440 tests/hour Atellica IM 1300 Analyzer Maximum throughput of up to 220 tests/hour
Walkaway time	Atellica IM 1600 Analyzer: Up to 5 hours Atellica IM 1300 Analyzer: Up to 7.5 hours
Assays onboard	Up to 42 assays and humidity controls
Water requirements	Special Reagent Water (SRW) connected directly to a pressurized water source 34.5 kPa and 207 kPa (5 psi and 30 psi) at a temperature of 10–30 °C (Page 908 *About Special Reagent Water*)

Specification	Description
Water consumption	Atellica IM 1600 Analyzer: Average of 6 L/hour Atellica IM 1300 Analyzer: Average of 3.5 L/hour
Liquid waste output	Minimum of 15 L/hour per analyzer

IM Waste and Supplies Capacity

Description	Capacity
Cuvettes	1500 cuvettes
Cuvette Waste	1500 cuvettes
Tips	1800 sample tips
Tip Waste	1500 sample tips
Tip Tray Waste	15 trays
Liquid Waste	3.6 L or direct plumbed
Water	10.0 L or direct plumbed
IM Acid	1500 mL
IM Base	1500 mL
IM Wash	6000 mL
IM Cleaner	1500 mL

About Supported Sample Containers

CAUTION

Do not use unapproved sample containers. The use of unapproved sample containers may result in damage to the system. Use only approved sample containers.

The system supports the following types of sample containers:

- Primary tubes
- Cal-QC tubes

- Pour-off tubes
- Tube-top sample cups
- Capillary collection containers
- False-bottom tubes

NOTE: See the online help for details about supported sample containers.

NOTE: If the system does not include a Decapper, capped sample containers are not supported. The operator must remove caps from sample containers before loading the containers in racks. The system does not support Decappers in configurations connected to Aptio.

NOTE: Cal-QC tubes, tube-top sample cups, capillary containers, and false-bottom tubes cannot be sealed.

About Special Reagent Water

The analyzer requires the use of special reagent water (SRW) typically through direct plumbing. SRW acceptable water quality criteria:

- Total Organic Carbon (TOC) < 500 ppb
- Microbial content < 50 CFU/mL
- Resistivity > 10 MΩ-cm
- Particles and colloids > 0.2 µm (units/mL) include 0.22 µm filtration

25 Warranty

Warranty and Support

About Limited System Warranty and Service Delivery Policy

Siemens Healthineers and its authorized distributors may provide customers who acquire new Siemens Healthineers systems with a limited warranty either in a specific agreement or standard language on their invoices. This limited warranty is designed to protect customers from the cost associated with repairing systems that exhibit malfunctions due to defects in materials and/or workmanship during the warranty period.

Siemens Healthineers, at its election, provides warranty service either by providing repair service of the system on site, or by exchanging the defective system or component, subject to the limitations and exclusions set forth in Replacement of Parts and Warranty and Service Exclusions (Page 912 *About Warranty and Service Exclusions*). Repairs, replacements, or exchanges of systems or components provided during the warranty or any additional service period, do not extend the warranty or service period beyond the initially agreed upon period.

When the customer calls for service, the representative or authorized distributor informs the customer of the type of service available for the customer's system, and instructs the customer how to obtain that service.

About the Warranty Period

The limited warranty period generally commences upon installation of the original system at the customer's location and extends for a period of 1 year thereafter, unless otherwise specifically agreed upon between Siemens Healthineers (or its authorized distributors) and the customer in a writing signed by duly authorized representatives of both parties (sales representatives are generally not authorized representatives of Siemens Healthineers for these purposes).

About Additional Service Periods

The customers, with some exceptions, may purchase additional service coverage beyond any initial warranty period as part of the original system acquisition for second or subsequent years beyond the original installation date. The customer's original Purchase Invoice or appropriate Agreement Addendum must indicate the term in months for additional service coverage.

About Service During Normal Hours

Operators may obtain service for systems during normal business hours by contacting the nearest Siemens Healthineers location or authorized distributor (Page 914 *Addresses*).

About Service Outside Normal Business Hours

Operators, with some exceptions, can request service outside normal business hours, including evenings, weekend days, or nationally observed holidays by contacting the nearest Siemens Healthineers location or authorized distributor (Page 914 *Addresses*). Service performed outside normal hours is subject to a surcharge unless the customer has purchased a service product option that provides service at the time requested.

About the Extent of Service Calls

Warranty or service calls generally include onsite repair or exchange of systems or components, travel to the location of the system, and onsite labor during normal business hours. The customer initiates the warranty or service call by following the instructions on how to obtain service for the customer's system. The service call is complete when repairs or replacements correct the defects in material or workmanship and the system conforms to the applicable specifications. When service is complete, the customer receives a copy of the documentation detailing all work the Siemens Healthineers representative or authorized distributor performed.

About Replacement of Parts

In performing service under a warranty or service contract, Siemens Healthineers or its authorized distributors provide appropriate parts to repair the system or arrange for the exchange of the system or affected parts at no charge, with the exception of customer replaceable parts. Customer replaceable parts include, but are not limited to, the following items: lamps, electrodes or sensors (which are covered by a separate warranty), reagents, calibrators, controls, paper, and pens. Consult the appropriate system operator's guides for a complete list of customer replaceable parts for any specific model of system.

About Design Changes and System Retrofits

Siemens Healthineers reserves the right to change the design or construction of specific models of systems at any time without incurring any obligation to make such changes available to individual customers or systems. If Siemens Healthineers notifies customers of a change that improves the performance or reliability of their system, and requests to retrofit that system, the customer must agree to allow Siemens Healthineers or an authorized distributor, at the expense of Siemens Healthineers, to retrofit components or make design changes that do not adversely affect the system's performance characteristics.

About Designating a Key Operator

Each customer designates a key operator who is available to authorized representatives of Siemens Healthineers to describe system malfunctions by telephone and to perform simple adjustments and corrections as requested. If a key operator is not designated or is unavailable when the customer requests service, the delivery of service may be delayed.

Smart Remote Services (SRS)

Where remote monitoring service for systems is offered by Siemens Healthineers, and where permitted by law, the customer's provision of remote access to the system through the customer's network to Siemens Healthineers or its authorized representative is a condition of the obligation to provide service under a warranty or service contract. Remote access will be established through a high-speed internet-based connection to Siemens Healthineers Data Center. In the event that the customer fails to provide or maintain the remote access connection, service may be delayed, Siemens Healthineers may decline to provide service or may charge for service on a time-and-materials basis including travel time to and from the customer site, notwithstanding any warranty or service contract coverage that might otherwise be in effect.

Siemens Healthineers remote monitoring services are not a substitute for and do not diminish in any way the customer's duty to exercise appropriate diligence and care in operating and maintaining the system. The customer is responsible to perform all routine and periodic maintenance checks and procedures on the system to the same extent as though the software was not installed and Siemens Healthineers was not providing the remote monitoring services.

Where remote monitoring service for systems is offered by Siemens Healthineers, and where permitted by law, Siemens Healthineers uses certain software to provide remote monitoring service for systems. In connection with using the software and providing the remote monitoring service, Siemens Healthineers will gain access to information from the system. Such information generally consists of data measuring the performance of processes by the system but may include data with respect to patients that is protected from disclosure by applicable law. Siemens Healthineers may use all information obtained from the system for any lawful purpose, including product development and the provision of technical support to customer and other customers, provided that Siemens Healthineers will not disclose any information as originating from a specific customer and shall not use or disclose any patient information in violation of applicable laws or regulations.

OSHA Requirements (US only)

When service is required at a customer location, the customer must provide the Siemens Healthineers representative with adequate facilities that comply with the regulations of the Secretary of Labor under the Occupational Safety and Health Act (OSHA) of 1970, as amended.

About Reporting a Serious Incident

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

About Warranty and Service Exclusions

The following exclusions are in addition to any exclusions provided for in any written warranty or service agreement.

IF ANY OF THE FOLLOWING EVENTS OCCUR, THE WARRANTY OR SERVICE PROVISIONS DO NOT APPLY:

- Someone other than an authorized representative of Siemens Healthineers made modifications or repairs to the system
- The customer operates the system using accessories and supplies other than Siemens Healthineers brand accessories, consumable supplies and/or reagents that do not have the same grade, quality, and composition as defined in the system operator's manuals.
- Siemens Healthineers notifies customers of a change that improves the performance or reliability of their system and customer does not agree to retrofit or make design changes to the system.

- The customer did not purchase the system from Siemens Healthineers or an authorized distributor.
- The system has not been installed within 90 days of shipment to the customer's facility unless otherwise specified.
- The customer does not perform appropriate customer maintenance procedures, as outlined in the system operator's manuals.
- The system has been misused or used for a purpose for which it was not intended.
- The system is damaged in transit to the customer or damaged by the customer while moving or relocating it without supervision by an authorized representative.
- Damage was caused by floods, earthquakes, tornados, hurricanes, or other natural or man-made disasters.
- Damage was caused by Acts of War, vandalism, sabotage, arson, or civil commotion.
- Damage was caused by electrical surges or voltages exceeding the tolerances outlined in the system operator's manuals.
- Damage was caused by water from any source external to the system.
- The customer purchases an alternative agreement whose terms of warranty or service supersede these provisions.

Siemens Healthineers or its authorized distributors can invoice customers, at current standard labor and parts rates, for systems repaired to correct damage or malfunctions due to any of the reasons listed above.

OTHER THAN AS STATED ABOVE, THERE ARE NO OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE SYSTEM, ITS SALE TO THE CUSTOMER, ITS LEASE TO THE CUSTOMER, OR THE SALE OF THE SYSTEM TO THE CUSTOMER AT THE EXPIRATION OR TERMINATION OF THE LEASE AGREEMENT.

SIEMENS HEALTHINEERS SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE. SIEMENS HEALTHINEERS' LIABILITY FOR BREACH OF ANY WARRANTY OR SERVICE AGREEMENT SHALL BE LIMITED ONLY TO THE REPAIR OR REPLACEMENT OF DEFECTIVE EQUIPMENT AND SHALL NOT INCLUDE ANY DAMAGES OF ANY KIND, WHETHER DIRECT, INDIRECT, INCIDENTAL, CONTINGENT, OR CONSEQUENTIAL. SIEMENS HEALTHINEERS SHALL NOT BE LIABLE FOR DELAY FROM ANY CAUSE IN PROVIDING REPAIR OR EXCHANGE SERVICE.

ANY LIMITATIONS OR OTHER PROVISIONS NOT CONSISTENT WITH APPLICABLE LAW IN PARTICULAR JURISDICTIONS OR A SPECIFIC WRITTEN AGREEMENT DO NOT APPLY TO CUSTOMERS IN THOSE JURISDICTIONS OR SUBJECT TO THOSE AGREEMENTS.

Addresses

For technical assistance, customer service, or additional information, contact the local technical support provider.

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591 USA
siemens-healthineers.com

26 Glossary

Glossary

2-Point calibration (IM)	An assay calibration that uses 2 known concentrations to normalize the Master Curve for current operating conditions.
Ab	See antibody.
Acid probe (IM)	Mechanical component that dispenses IM Acid into a cuvette to resuspend the magnetic particles and prepare the acridinium ester for light emission.
Acridinium ester (IM)	Chemical tag responsible for the flash when the system adds IM Base to the acidified magnetic particle, analyte, or acridinium ester mixture in the cuvette. Abbreviation: AE.
Activate	Function used to enable a test or a pack for full use on the system.
AE	See acridinium ester.
Ag	See antigen.
Analyte	Substance of unknown concentration in a sample.
Ancillary pack (IM)	Container for the additional reagents an assay requires.
Ancillary reagent (IM)	Additional required reagents for an IM assay.
Antibody	Protein (immunoglobulin molecule) that the body produces in response to the presence of an antigen. The body uses antibodies to resist disease. Abbreviation: Ab.
Antibody-capture assay (IM)	Assays that detect specific IgG antibody or IgM antibody in patient samples. The IM assay reagent contains an additional antibody that attaches to the antibody in the sample. Antibody-capture formats require 2 cycles of incubation and wash. The first incubation and wash removes interfering substances, sample, and reagent not bound to PMP. The second incubation and wash prepares the antibody and AE-labeled antigen complex.
Antigen	Substance that stimulates the production of and combines specifically with corresponding antibodies. Abbreviation: Ag. See immunogen.
Aspirate probe (IM)	Mechanical component that draws fluid (water or wash reagent) from the cuvette. The system has 4 aspirate probes: aspirate probe 1, aspirate probe 2, aspirate probe 3, and aspirate probe 4.
Assay	Generic term that refers to the chemical analysis for a specific analyte in a sample. Each assay has a unique test protocol.

Atellica Magline Transport	A magnetic sample transport system that moves samples between analyzers and Sample Handlers.
Automatic dilutions	Dilutions the system performs when an immunoassay result exceeds Concentration Range. Immunoassay analyzers can also perform automatic dilutions with linearity and dilution point ranges.
Automatic transmit	Option that automatically sends test results from the system to a remote device, such as the LIS, or automatically receives worklist requests from a remote device.
Background (IM)	Electronic signal of the photomultiplier tube in the absence of light.
Back up	Process of copying the data files on the system hard disk to external storage media.
Barcode	A linear sequence of vertical lines and spaces (1D) or a sequence of black and white areas in a 2-dimensional pattern (2D) that an optical scanner reads.
Barcode label	A label containing encoded information that is on sample containers, carriers, racks, reagents, and bulk fluids. See barcode.
Barcode scanner	Optical device that scans and decodes the label barcode on a sample container, carrier, rack, reagent, and bulk fluid.
Base probe (IM)	Mechanical component that dispenses IM Base into a cuvette.
Batch	Type of order entry that specifies 1 or more of the same tests on multiple samples.
Baud rate	Speed of data transmission in bits per seconds (bps) between the system and a remote device.
Bidirectional interface	Interface configuration allowing the transfer of information to and from another device.
Calibration	CH: Process that establishes the relationship between the system response (absorbance values) and reported results (concentration). The relationship is unique for each assay. The system determines the relationship by measuring the absorbance of a material with known concentrations (or levels) of the analytes for the assay. IM: Process that establishes the relationship between the system response in RLUs and reported concentration results. The relationship is unique for each assay. The system determines the relationship by measuring the RLU of a material with known concentrations or levels of the analytes for the assay.

Calibration curve (IM)	Data that normalizes the system against stored Master Curve data for the tested analyte. The calibration data compensates for current processing conditions and system variability. The system calculates the required sample dose from the normalized curve.
Calibration data (IM)	Details of the calibration including Cal IDs, concentrations, RLUs, CVs, and flags for the low and high calibrators.
Calibration interval	The time period in days or hours between required assay reagent lot or pack calibration.
Calibrator-assigned values card	Card that contains the lot and expiration date and the calibrator values for each assay the calibrator contains.
Calibrator material	Solution that contains a known concentration or reactivity of 1 or more assays and provides a reference for converting measured signals into concentrations. The system analyzes calibrators with reagents to obtain calibration data points. See calibration data.
Cal-QC tube storage area	Refrigerated area on the Sample Handler that stores calibrator and QC materials for automated calibrations or control testing.
Carrier	Holder that moves tubes around the Atellica Magline Transport.
Character parity	Transmission setting that tracks for transmission errors between the system and a remote device. This setting must be the same at the system and remote device to maintain compatibility between the systems.
CH Cuvette Conditioner	Solution clinical chemistry analyzers use in cuvette wash cycles.
CH Cuvette Detergent	Solution clinical chemistry analyzers use in cuvette wash cycles.
CH Diluent	Saline-based solution that dilutes a sample.
Check digit	Digit at the end of a 1D barcode that verifies the system correctly scans the barcode.
Check range	A range that enables laboratories to create their own intervals along the result continuum as an additional check on results. See ranges.
Chemiluminescence (IM)	A chemical reaction that emits light. In combination with immunoassay technology, the light the reaction produces indicates the amount of analyte in a sample.
Chemiluminescent reaction (IM)	A type of chemical transformation that emits light upon the oxidation of an organic chemical compound.
Coefficient of variation	The statistical variation among a set of numbers as a percentage. Abbreviation: CV.

Communication port	Ports on the system that can connect the system to an external, remote device, such as an LIS or a data management system.
Competitive assay (IM)	Antibody-antigen reaction in which the antigen (Ag) of unknown concentration in a sample and a labeled antigen in an assay reagent compete for a limited amount of antibody (Ab) in an assay reagent. The reaction produces a measurable signal that is inversely proportional to the concentration in the sample.
Conc	See concentration.
Concentration	Amount of analyte in a sample. Abbreviation: Conc.
Concentration range	A range that specifies the intervals on the result continuum according to the manufacturer-specified measuring interval for the assay. The assay must report results in terms of concentration values. See range.
Confidence interval	A statistical value that describes how likely the statistical results are to be accurate.
Configuration	Settings of software and hardware.
Continuous operation	Mode enabling the system to process samples without interruption from activities such as adding or removing samples, emptying waste containers, or replenishing supplies.
Control	The quality control material and process that determines if the system is reporting valid results.
Control-bracketed test	An assay that requires the operator to begin and end a group of patient samples with a set of controls. The system does not report samples until the results of the start-of-bracket controls are acceptable and does not report patient results until the closing bracket controls complete successfully.
Control material	See QC material.
Control reminder	A system alert that notifies the operator to process end-of-bracket controls and prevent the system from discarding retained patient test results. The control reminder applies only to control-bracketed tests.
Control value range	Range of acceptable results for the QC material.
Control warning	A system alert in QC Statistics to warn the operator of a control condition.
Corrective action	The steps the operator must take to resolve a system event.
Cut-off point	The point at which the interpretation of a patient result changes.
Cuvette	Plastic, disposable container that holds the reaction mixture on the system.

CV	See coefficient of variation.
Cycle count	The count of cumulative items, including samples, tests, and units of time, that represent a 1 cycle.
Data bits	Number of bits that transmit between a system and a remote device.
Decapper	An Atellica system module that removes and discards caps from all approved sample containers prior to sample testing.
Decapper	An Atellica system module that removes and discards caps from all approved sample containers prior to sample testing.
Default value	Preset value that Siemens Healthineers defines.
Delta check range	A range that evaluates the change in patient test results over time. See range.
Demographics	Information about a patient or sample such as name, date of birth, sex, location, and physician.
Dilution arm (CH)	Component that moves the dilution probe.
Dilution mixer (CH)	CH mechanical component that mixes the contents of dilution cuvettes on the dilution ring.
Dilution point range (IM)	A range that enables laboratories to perform repeat and reflex actions on results that are greater than the Dilution Point or less than the Overdilution Point. See ranges.
Dilution probe (CH)	CH component that aspirates from the sample container and dispenses into the dilution tray or Integrated Multisensor Technology (IMT) area.
Dilution ring (CH)	Mechanical component that dilutes and stores sample dilutions for use in photometric assays.
Dilution washer (CH)	Mechanical component that washes dilution cuvettes after the analyzer completes the sample analysis. The washing process enables the analyzer to reuse the cuvettes without risk of contaminating the next sample.
Direct Load	An optional sample handling subsystem that routes samples to a single analyzer. Direct Load systems do not use the Atellica Magline Transport. Abbreviation: DL.
Disable	Command or condition that does not allow a specific event to proceed.
DL	See Direct Load.
Drawer vision system	A subassembly of the Sample Handler. A camera system located above each Sample Handler drawer that images each rack and rack position in the drawer as the operator closes the drawer. Abbreviation: DVS.
DVS	See drawer vision system.

Emergency Sample Load	When the system cannot automatically deliver samples to analyzers, the operator uses this device to manually place a sample at an analyzer's aspiration station. Abbreviation: ESL.
Enable	Command or condition that permits a specific event to proceed.
Entry queue	Area on the standalone sample handling subsystem where the system moves sample racks into the inprocess queue.
Equiv	See equivocal.
Equivocal	A result that does not allow for a definitive interpretation of a qualitative assay. Certain qualitative assays have equivocal ranges that provide an interval on either side of the cut-off point. Also called indeterminate. Abbreviation: Equiv.
ESL	See Emergency Sample Load.
Ethernet	A network connection that allows a computer to connect to other computers on the same network.
Event	System occurrence, such as an error, that the system records in the Event Log.
Exit queue	Area where the system moves sample racks after leaving the inprocess queue.
Expiration date	The date beyond which the manufacturer does not guarantee correct performance of the reagent or material.
Extend calibration	Function that allows an operator to extend the expiration of a valid calibration.
Firmware	Software that the system downloads to the machine controller boards.
Flag	Remark or message about the status of a sample or result. The flag is next to the result on the screen and on printed reports.
Flash	Short burst of light that the chemiluminescent reaction produces when acridinium ester oxidizes. Acridinium ester oxidizes when the pH rapidly changes from acidic to basic with the addition of IM Base.
ID	Identification that the system uses in sample identification (SID) and patient identification (PID).
Immunoassay	Chemical test that uses an antibody-antigen reaction to determine the presence of a specific analyte or to quantify a specific analyte. The test measures an antibody or an antigen. Abbreviation: IM.
IMT	See Integrated Multisensor Technology.

Incubation ring (IM)	Area where cuvettes incubate at 37°C to prepare the sample and reagent for the chemiluminescent reaction. The incubation ring also positions the cuvettes for sample and reagent dispenses.
Index range (IM)	A range that specifies the interval on the result continuum according to the manufacturer-specified measuring interval for the assay. The assay must report results in terms of index values. See range.
Inprocess	Status of a test when the sample is in the inprocess queue and the system detects it or the sample is in progress.
Inprocess queue	Area of the Atellica Magline Transport where samples wait for processing by the aspiration station. The inprocess queue can be bidirectional to enable random access or uni-directional to enable sequential access to any sample in the inprocess queue. Abbreviation: IPQ.
Integrated Multisensor Technology (CH)	Subsystem that uses potentiometry to determine the concentration of sodium (Na), potassium (K), and chloride (Cl) ions in patient samples. The dilution probe presents samples to a flow-through sensor cartridge, which encloses a reference electrode and 3 ion-selective electrodes. Abbreviation: IMT.
Intercept	A point where the graph of a function or relation intersects the y-axis of the coordinate system.
Interpretation range	Laboratory-specified result values that require the operator to review before the system reports them.
IPQ	See inprocess queue.
Label	Substance coupled to an antigen or antibody that provides the measurement signal for an immunoassay.
Laboratory Automation System	Automated track system that connects multiple analyzers for high workload capacity and efficient workflow. The Atellica Solution connects to a Laboratory Automation System through the Sample Handler Connect. Abbreviation: LAS.
Laboratory Information System	Laboratory computer system that can interface with the Atellica system. Abbreviation: LIS.
LAS	See Laboratory Automation System.
LED	See light-emitting diode.
Light-emitting diode	Electronic device containing semiconductor materials that emits light when current flows through it. Abbreviation: LED.
Linearity range (IM)	A range that enables laboratories to specify tighter intervals on the result continuum than the manufacturer-specified measuring interval for the assay. See range.

Link	Method of directly accessing information or data. Selection of a link transfers information to a related window. Required data must be present for the information to transfer. In the online help system, a link is a quick way to access more information about a topic.
Liquid-level sensing	Component that detects the liquid surface level for samples, controls, and calibrators. Abbreviation: LLS.
Liquid waste (IM)	The analyzer pumps liquid waste into 3 waste reservoirs for automatic disposal in the laboratory's waste lines.
Liquid waste container	Container that is the main receptacle for liquid waste for a non-directly plumbed system.
LIS	See Laboratory Information System.
LIS code	Alphanumeric code that identifies an assay result to the LIS.
Lite Reagent	Assay reagent containing antibody or antigen labeled with acridinium ester in buffer.
LLS	See liquid-level sensing.
Lot and pack calibration intervals	A lot calibration interval is the time period in days or hours between required assay reagent lot calibrations. A pack calibration interval is the time period in days or hours when the system requires a pack IM or well CH calibration.
Luminometer (IM)	Subassembly and component where the chemiluminescent reaction occurs.
Lyophilized material	A liquid material that is freeze-dried to a powder for long term stability.
Manual dilution	A dilution of the sample the operator makes before placing the sample on the system.
Master curve (IM)	The reference curve that converts a measured signal into sample concentration. Calibration data normalizes the system against stored Master Curve data for the tested analyte.
Minimum required volume	Smallest reagent or sample volume the system can detect. Abbreviation: MRV. • CH: Sample volume plus the unusable sample volume. Requires a minimum of 7 mm of sample above a gel layer and at least 2 mm of sample in a sample container without a gel layer. • IM: For a single replicate of 1 test: Sample Volume + Tip Prime Volume + Unusable Volume = MRV.

Module Display	A touchscreen, attached to the analyzer and equipped with a barcode reader, that allows the operator to perform analyzer-specific functions such as maintenance, reagent loading, scanning of system fluids barcodes, and viewing the analyzer status.
Monoclonal antibody	A single fusion event between a myeloma cell and a B lymphocyte produces a monoclonal antibody. Monoclonal antibodies have identical structure, affinity, and specificity for a given antigen.
MRV	See minimum required volume.
Multiple tests	Number of times that the system performs a scheduled test for a sample. Tests process simultaneously on the same analyzer with the same specified dilution, but report separate results.
Normal range	A reference interval for the healthy population. See ranges.
Operator Event Log	List of system occurrences (events), including errors, from the most recent to the oldest. This information includes the date and time of each occurrence.
Operator Tablet	Tablet computer the operator can use to control the system and assist with system maintenance and troubleshooting. It is connected to the system wirelessly or by cable.
Pack ID	Identification code that is unique to a reagent pack.
Panel	A group of tests or a set of dilutions for a test defined as a panel for ease of ordering.
Para-magnetic particles	Magnetic particles in the Solid Phase reagent. Abbreviation: PMP.
Patient identification code	Unique code on a sample that identifies the patient. Abbreviation: PID.
PCC	See process center computer.
Pending samples	Status of samples with orders that did not yet start processing.
Pending tests	Status of tests for a pending or inprocess sample before the system aspirates the sample for those tests.
Photometer (CH)	The light source on the analyzer. The light source is a replaceable quartz halogen lamp with a 340-nm UV LED. An active circulating system, consisting of a circulating pump with a fill reservoir and a radiator with a fan, cools the light source. The 2 beams combine to a single beam of light that goes directly through a 1.5 mm.
Photometric measurements (CH)	The analyzer measures the light absorbance of samples. These absorbances convert to qualitative, quantitative, and semi-quantitative test results that the analyzer reports.

Photomultiplier tube (IM)	Device that measures the chemiluminescent reaction. Abbreviation: PMT.
PID	See patient identification code.
PMP	See para-magnetic particles.
PMT	See photomultiplier tube.
Polyclonal antibody	Antibodies that different B cell lineages secrete within the body.
Pretreatment	Process that prepares a sample for testing.
Primary pack (IM)	A container that holds the primary reagents (Lite Reagent and Solid Phase). The primary pack may contain additional reagent.
Probe crash detection	Process that allows analyzer probes to detect an obstruction during its downward motion. When the probe encounters an obstacle, the probe immediately stops to prevent damage.
Probe pressure sensing	Process that allows the analyzer to monitor and record probe pressures during all aspirations. Pressure sensing monitors for probe clogs, short aspirations, and other abnormal aspirations.
Process center computer	A subassembly of the Sample Handler Prime that performs the main software tasks of the system. Abbreviation: PCC.
Prompt	Questions, instructions, or commands that help complete the current task.
QC	See quality control.
QC material	Product containing specific analytes within a predetermined concentration range that verifies system and assay performance.
Quality control	Process of verifying the performance of the system and assay using products containing specific analytes within a predetermined concentration range. Abbreviation: QC.
Query timeout	Maximum number of seconds for a remote device to respond to a query from the system.
Rack ID	The unique code that identifies each sample rack.
RAID	See redundant array of independent disks.
Random access	Mode of operation in which the system processes samples for multiple assays in the most efficient order.
Range	A designated interval on the result continuum that enables the system to perform laboratory-configured repeat and reflex actions according to the initial result value.
Ratio definition	Formula the system uses to calculate the results of a ratio test.
Ratio test	Test that calculates results from the results of other tests.

Raw data	• CH: The absorbances the spectrophotometer detects from the main and, if applicable, the sub wavelengths. • IM: Total photon count that the system receives for a flash. The system does not correct raw data.
Reaction-CW (CH)	R-CW washes and dries the 221-position reaction cuvette ring (13 segments with 17 cuvettes each).
Reaction ring (CH)	Contains and incubates the sample reaction volumes and presents them to each processing step. The major functions of the reaction ring include controlling sample temperature, positioning cuvettes, controlling cuvette motion during photometric measurement, and triggering photometric measurements.
Reaction ring bath (CH)	The analyzer suspends cuvettes in an incubation fluid maintained at a constant 37°C ± 0.3°C. This bath maintains the reaction volume at the target temperature and provides a consistent thermal profile.
Reaction washer (CH)	Component that washes the CH reaction cuvettes after sample analysis to enable the reuse of cuvettes.
Reagent compartment	Area on the analyzer that stores reagent packs in 1 or more refrigerated reagent compartments.
Reagent mixer (CH)	Mixers located on the outside of the reaction ring. The reagent mixer mixes the reaction solution after delivery of reagent from reagent probe 2. The mixer speed controls the intensity of the mixing.
Reagent packs	• CH: Reagent packs are double-well packs. A well contains up to 25 mL of reagent. • IM: The analyzer uses primary and ancillary reagent packs.
Reagent probes (CH)	Reagent probes 1 and 2 aspirate and dispense the required reagent into the reaction cuvettes for analysis.
Redundant array of independent disks	A method for storing the same data in different places on multiple hard disks to protect data in the case of a drive failure.
REF	See reference number.
Reference number	A unique number associated with each Siemens Heathineers product. The laboratory uses this number when ordering the product. Abbreviation: REF.
Reference range	Patient results that fall in laboratory-defined intervals for a population. See ranges.
Relative light unit	Counts the system generates when the photomultiplier tube detects light during the chemiluminescent reaction. A relative light unit is calibrated against a tritium source and is unique to its measurement. Abbreviation: RLU.

Repeat tests	Tests that process in sequence with the same specified dilution. The operator orders repeat tests separately. The system can repeat a test if the result falls within the repeat interval setting.
Replicate	Number of times that the system performs a scheduled test for a sample. The analyzer calculates the mean result and CV of the replicate results.
Replicate tests (IM)	Tests that process simultaneously with the same specified dilution that the system reports as a mean result. The test definition specifies the minimum number of replicates that the assay requires. The operator can increase this number, as appropriate.
Reservoir	A container holding water, waste fluid, or system fluids to allow for continuous operation while the operator replenishes reagents.
Results	Numeric value for a test.
RLU	See relative light unit.
Robot	A subassembly of the Sample Handler. A 3-axis robot that transports sample containers between racks in the sample drawers, Cal-QC tube storage area, and the carriers on the Atellica Magline Transport.
Sample	Specimen the system uses for testing such as a patient sample, control, or calibrator material.
Sample container	Disposable container that holds patient, control, or calibrator samples. The system supports primary sample containers, pour-off tubes, capillary collection containers, false-bottom tubes, and tube top sample cups.
Sample Handler	An Atellica Solution sample management module with 4 drawers for loading samples, a Cal/QC tube storage area, and a robot that moves samples between the loading drawers, the storage area, and the Atellica Magline Transport. Abbreviation: SH.
Sample Handler Additional	When a system is equipped with more than 1 Sample Handler, the Sample Handler with the PCC and primary user interface is the Sample Handler Prime and any other Sample Handler is a Sample Handler Additional.
Sample Handler Connect	A sample transfer unit that connects an Atellica Solution to a Lab Automation System. The Sample Handler Connect uses 2 robots to transfer routine and STAT samples to and from the Lab Automation System. Abbreviation: SHC.
Sample Handler Prime	The Sample Handler that includes the PCC and primary user interface. For systems with 1 Sample Handler, that module is the Sample Handler Prime.

Sample identification code	Unique code that identifies each sample. Abbreviation: SID.
Sample mixer (CH)	Component located on the outside of the reaction ring. The sample mixer mixes the reaction solution after delivery of reagent from reagent probe 1 and sample from the sample probe. The mixer speed controls the intensity of the mixing.
Sample probe	• CH: Probe that aspirates a sample from a dilution cuvette and then dispenses it into a reaction cuvette. • IM: Probe that aspirates from the sample container and dispenses into cuvettes, using a new sample tip for each aspiration.
Sample rack	Component that presents sample containers to the system. The rack contains space for 15 or 55 sample containers. Specialized sample racks also exist for STAT samples, false-bottom tubes, and STAT false-bottom tubes.
Sample rack (standalone system)	Sample racks that hold 6 barcoded samples and each position has a number to communicate the location of the sample. The capacity of the exit queue is 10 sample racks.
Sandwich assay (IM)	Antibody-antigen reaction in which the antigen of unknown concentration in a sample is bound directly to antibody-labeled acridinium ester. The measurable signal the reaction produces is directly proportional to the concentration of antigen in the sample.
Sealer	An Atellica system module that seals sample containers after analysis is completed before the operator removes the samples and places them in an archive storage device.
Search	Function that locates an item in a list.
SH	See Sample Handler.
SHC	See Sample Handler Connect.
SID	See sample identification code.
SI units	International units of measure.
Slope	The change in 'y' over the change in 'x,' or the gradient of a line. A regression equation determines the slope.
Solid Phase (IM)	An assay reagent consisting of paramagnetic particles covalently bound to antigen or antibody suspended in a buffer.
Solid waste (IM)	Used cuvettes and sample tips fall down separate chutes into solid waste bins. Reservoirs collect cuvettes and sample tips in the temporary absence of the solid waste bins.
Sort	Function that changes the order of items in a list.
Source lamp (CH)	A replaceable quartz halogen lamp with a 340-nm UV LED.

Specified range	A range containing 1 or more specified demographic fields. See range.
Stability	Degree of a sample or reagent's resistance to chemical change or degradation.
Startup	Events that occur when initializing the system.
Stop bits	Number of data bits that maintain synchronization between the system and a remote device during data transmission.
Subsystem	A hardware functional area of the system, such as incubation ring, luminometer, and reagent probes. Machine controller boards drive subsystems.
Subsystem failure	Message classification category meaning a subsystem failure that may be operator recoverable. The message has a red background.
Subsystem warning	Message classification category meaning a subsystem will go offline if the operator does not interact. The message has a yellow background.
Symbology	Set of rules for encoding information in a barcode.
System clock	Twenty-four hour clock that the system uses to monitor various system functions, such as calibration intervals, and track the time of events.
System Display	Monitor attached to a sample loading module.
TCS	See tube characterization station.
Test panel	Group of different assays that the operator defines for ease of ordering.
Tool bar	The tool bar at the bottom of the display screen that contains current system information and icons for quick access to critical system functions.
Troubleshooting	Function to determine the cause of a system or assay performance problem.
TTSC	See tube top sample cup.
Tube characterization station	A subassembly of the Sample Handler that provides an integrated system of 3 cameras that reads the barcodes on the sample containers, determines other sample container characteristics, and acts as the SH Pick-and-Place Station. Vision systems also exist in the Direct Load. Abbrevation: TCS.
Tube top sample cup	Sample cup placed at the top of a specimen tube that holds a small amount of specimen for testing. Abbrevation: TTSC.
Universal serial bus	A serial bus standard for connecting devices, usually to a computer. Abbreviation: USB.
Unusable volume	The volume of a sample in a sample container that is unusable.

Update	Function to overwrite information with new information.
Usable volume	The amount of sample that exceeds the unusable volume and is available for aspiration by the sample probe.
USB	See universal serial bus.
Valid	Acceptable calibration results.
Water container	Container on the system that holds the main supply of the reagent water for a non-directly plumbed system.
Window	Screen display area that an operator can independently move or manipulate. Windows can overlap each other.
Worklist	List of scheduled patient samples, controls, and calibrators, including identification and requested tests for each entry.

27 Revision Information

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