



Atellica® Solution

Operator's Guide

Atellica[®] Solution

Operator's Guide

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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.



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1 Intended Use

This chapter provides information for the intended use of the system and modules.

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.

Atellica CH with Direct Load 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 with Direct Load 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.

2 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.

Analyzer and System Configuration

Certain features and procedures in the operator's guide are dependent on the analyzer and system configuration and may not be available.

Conventions

The operator's guide 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.
Note	Note statements alert the operator to important information that requires attention.

Convention	Description
Bold	Bold type indicates commands on the user interface, keys, or the exact text that an operator needs to type.
<i>Italic</i>	Italic type refers to the title of a document or a section title in the operator's guide.

Terminology

The following table describes the terminology in the operator's guide 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.

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 browser, such as Internet Explorer, on a standalone computer or tablet, enter **www.siemens.com/eIFU**  [siemens.com/eIFU](http://www.siemens.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.com/elifu**.
2. In the top-right corner, select **Login/Register > Login**.
NOTE: If this is the first time entering the site, register (Page 25 *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 browser, such as Internet Explorer, on a standalone computer or tablet, enter **www.siemens.com/elifu**.
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: To locate documentation, see (Page 509 *Downloading Software Release Notes*) or (Page 27 *Accessing the Operator's Guide and CH Analyzer Open Channel Operator's Guide Supplement*).

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 25 *Registering for Online Services*).

1. From a browser, such as Internet Explorer, on a standalone computer or tablet, enter **www.siemens.com/elfu**.
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 browser, such as Internet Explorer, on a standalone computer or tablet, enter **www.siemens.com/elfu**.
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 27 *Accessing the Operator's Guide and CH Analyzer Open Channel Operator's Guide Supplement*) (Page 24 *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 browser, such as Internet Explorer, on a standalone computer or tablet, enter www.siemens.com/elifu.
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 Operator's Guide and CH Analyzer Open Channel Operator's Guide Supplement

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.com/elifu.
2. In the top-right corner, select **Login/Register > Login**.

NOTE: If this is the first time entering the site, register (Page 25 *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. In Products, select **Atellica Solution > Atellica Platform**.
5. In Document types, select **Instrument and Software Information > Manuals/Guides**.
6. Select appropriate guide.
7. Select **Download** to print or save the guide.

Security Whitepaper

See the Atellica Solution Product Security Whitepaper, SMN 11313481, 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.

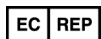
3 Symbols

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.

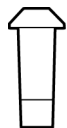
For symbols on the assay packaging, refer to the assay IFU.

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
Compliance		
	Consult instructions for use	5.4.3 ^a

Symbol	Symbol title	Source
 Rev. 01	Consult instructions for use	5.4.3 ^a
 siemens.com/document-library	Consult electronic instructions for use (eIFU)	5.4.3 ^a
 siemens.com/eifu	Consult electronic instructions for use	5.4.3 ^a
	<i>In vitro</i> 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
 UK.TR.067.	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
Package Markings		
	Keep away from sunlight	5.3.2 ^a
	Fragile, handle with care	5.3.1 ^a
	Keep dry	5.3.4 ^a

Symbol	Symbol title	Source
	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
	First in First Out: Use oldest inventory first	Proprietary
	Do not re-use	5.4.2 ^a

Symbol	Symbol title	Source
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 Analyzer dilution segments	Proprietary
	CH Analyzer reaction segments	Proprietary
	IM Analyzer cuvettes: Quantity indicators display adjacent to the symbol	Proprietary

Symbol	Symbol title	Source
	IM Analyzer 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
	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

Symbol	Symbol title	Source
	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
	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

Symbol	Symbol title	Source
	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 152231:2020-04. 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.

4 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.

About Reagent and Sample LED Barcode Scanners

Characteristic	Specification
Wavelength	650 nm
Pulse duration	Continuous wave (cw)

No direct exposure to hazard exists for persons in the immediate area.

NOTE: 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.

Reagent and Sample LED Barcode Scanner 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.

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.

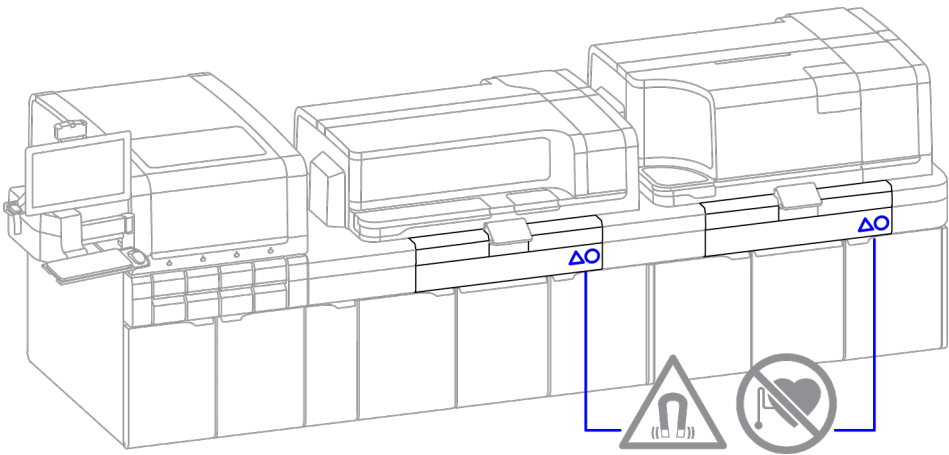
The system cleaning procedures require the cleaning materials listed in each procedure. Siemens Healthineers has approved these cleaning materials for use on the system. Operators should only use the cleaning materials specified in the system cleaning procedures.

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.

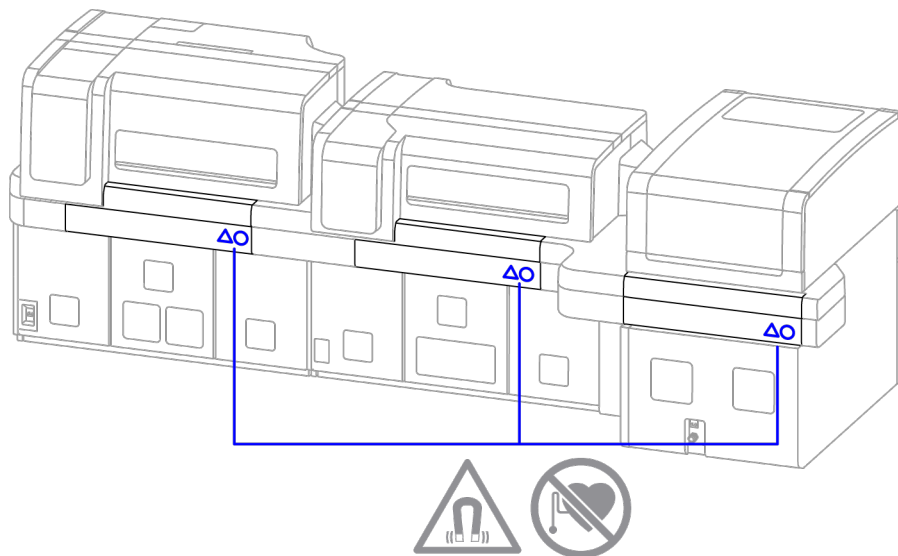
The following figures show the locations of these safety hazard symbols.

Symbols on the system exterior (front view)



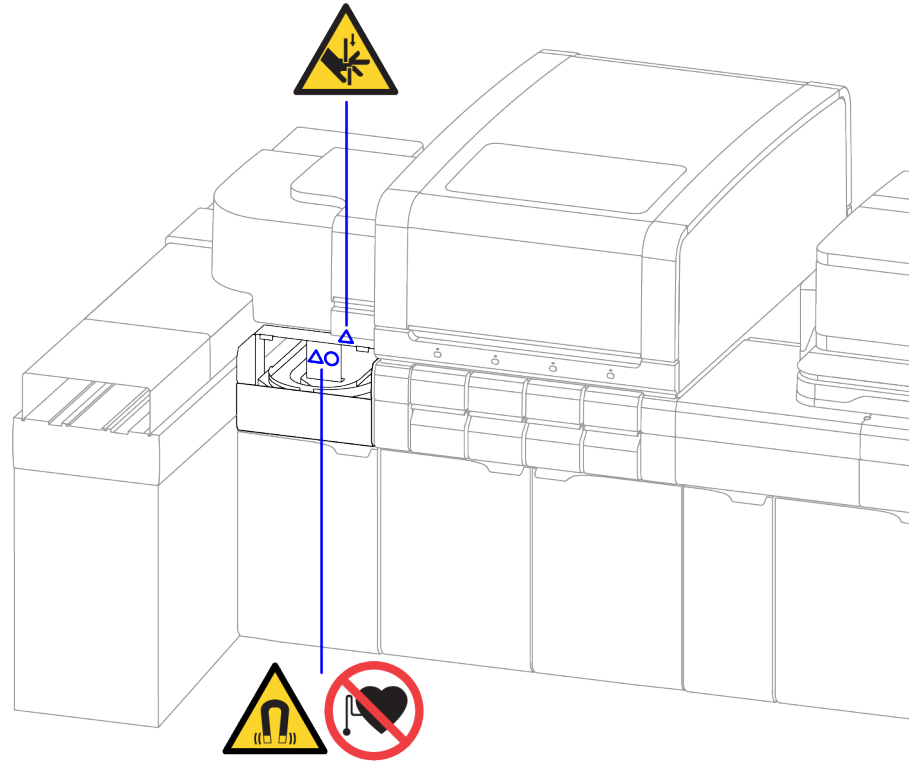
Safety symbol	Hazard description
	Strong magnetic field / No pacemakers (Page 88 <i>Strong Magnetic Field / No Pacemakers Warning</i>)

Symbols on the system exterior (back view)

**Safety symbol****Hazard description**

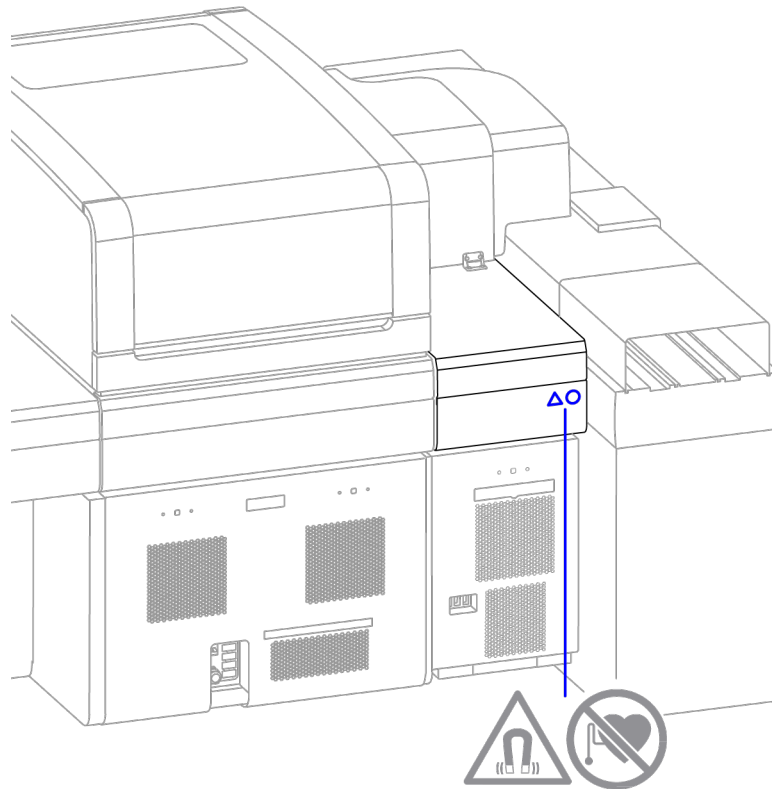
Strong magnetic field / No pacemakers (Page 88 *Strong Magnetic Field / No Pacemakers Warning*)

Symbols on the SHC (front view)



Safety symbol	Hazard description
	Pinch Hazard (Page 87 <i>Pinch Hazard</i>)
	Strong magnetic field / No pacemakers (Page 88 <i>Strong Magnetic Field / No Pacemakers Warning</i>)

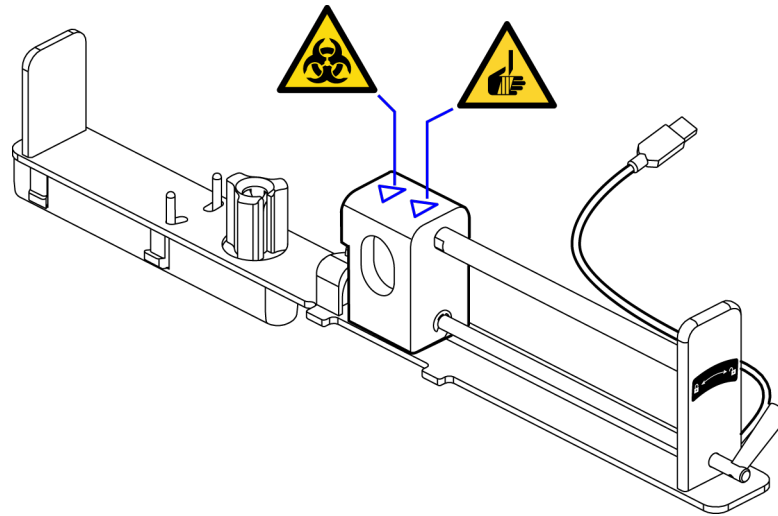
Symbols on the SHC (back view)



Safety symbol	Hazard description
	Strong magnetic field / No pacemakers (Page 88 <i>Strong Magnetic Field / No Pacemakers Warning</i>)



Symbols on the ESL carrier



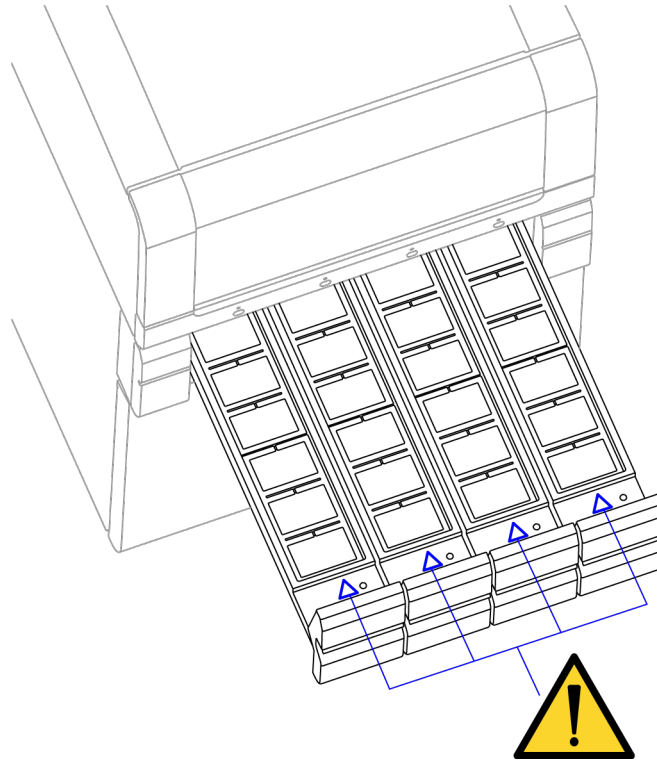
Safety symbol	Hazard description
	Biohazard (Page 86 <i>Biohazard</i>)
	Puncture Hazard (Page 87 <i>Puncture Hazard</i>)

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

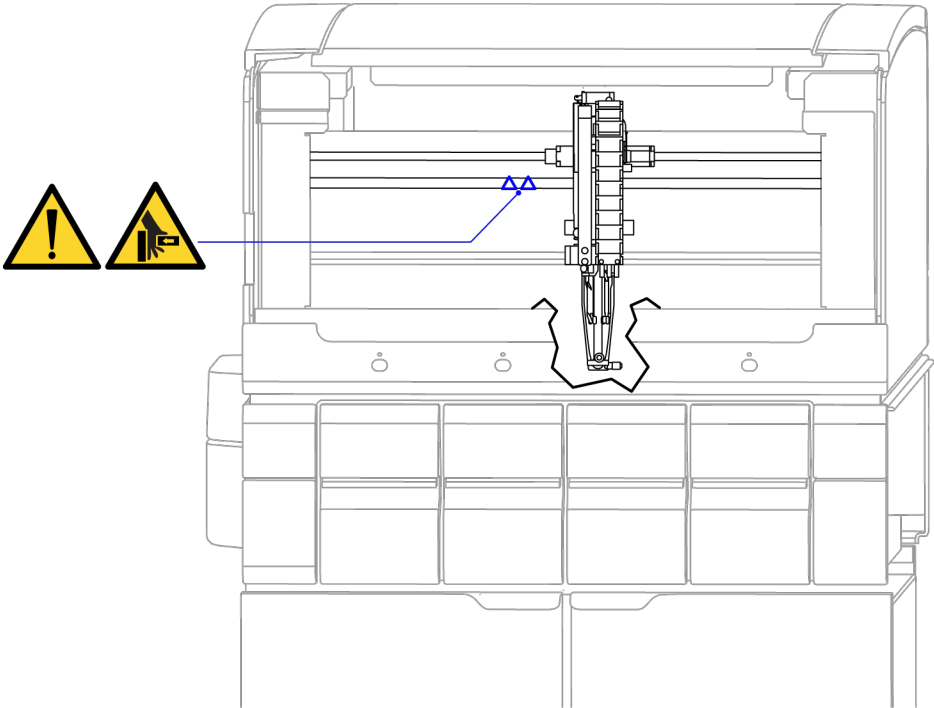


Safety symbol

Hazard description

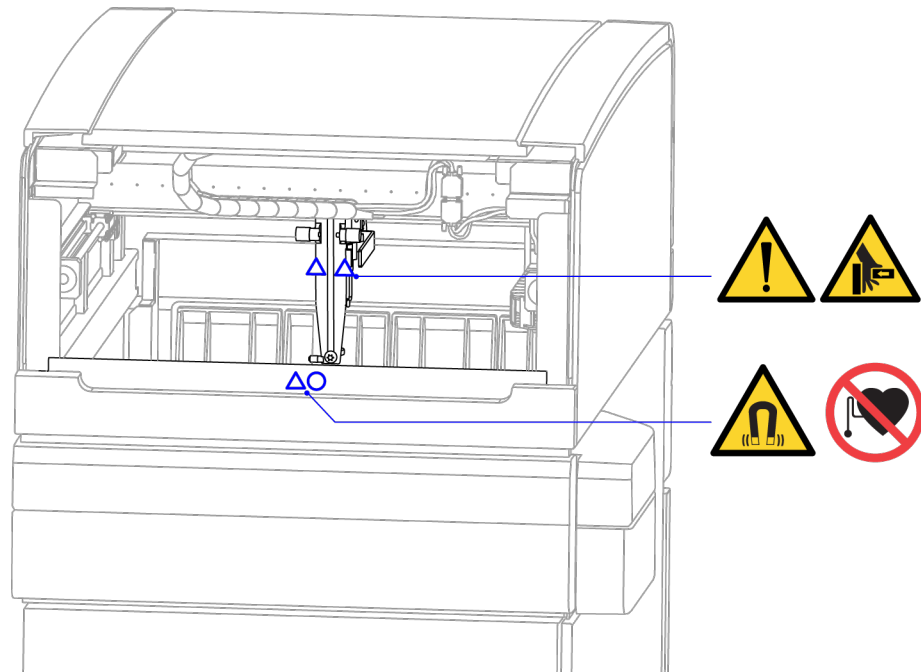
SH Robot Impact Hazard
(Page 87 *SH Robot Impact Hazard*)

Symbols on the robot



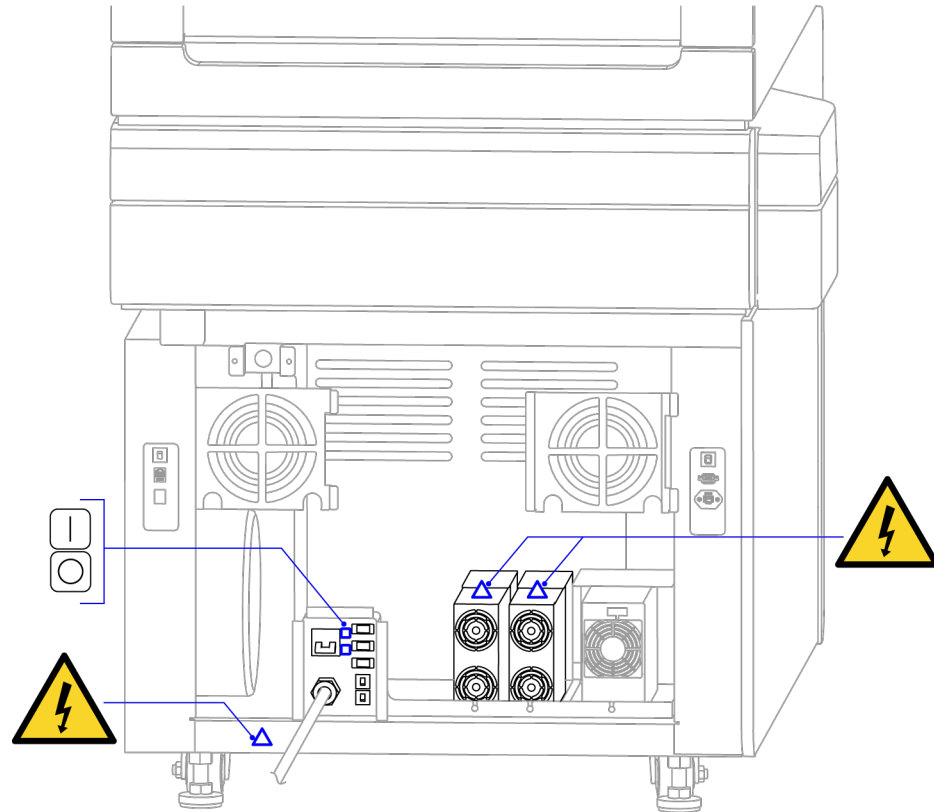
Safety symbol	Hazard description
	SH Robot Impact Hazard (Page 87 <i>SH Robot Impact Hazard</i>)

Symbols on the SH (back top view)



Safety symbol	Hazard description
 	SH Robot Impact Hazard (Page 87 <i>SH Robot Impact Hazard</i>)
 	Strong Magnetic Field / No Pacemakers (Page 88 <i>Strong Magnetic Field / No Pacemakers Warning</i>)

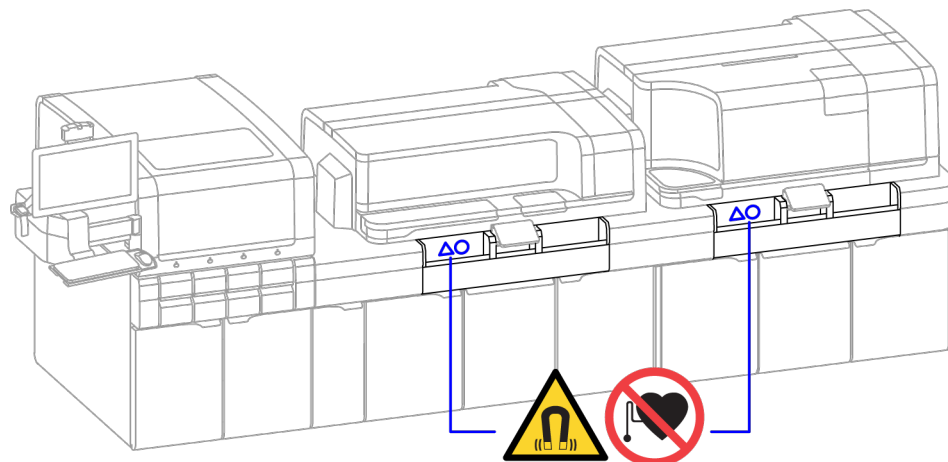
Symbols on the SH (back bottom view)



Safety symbol	Hazard description
	Electric Shock Hazard (Page 86 <i>Electric Shock Hazard</i>)

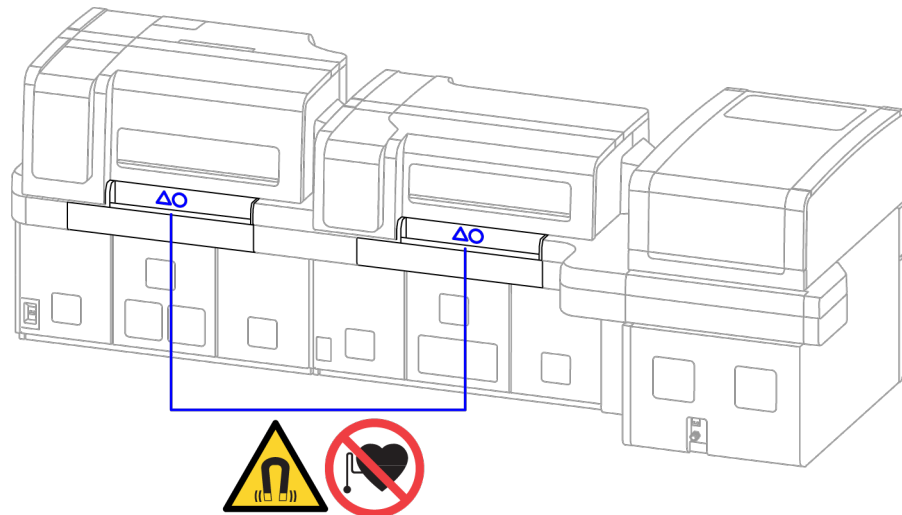


Symbols on the Atellica Magline Transport (front view)



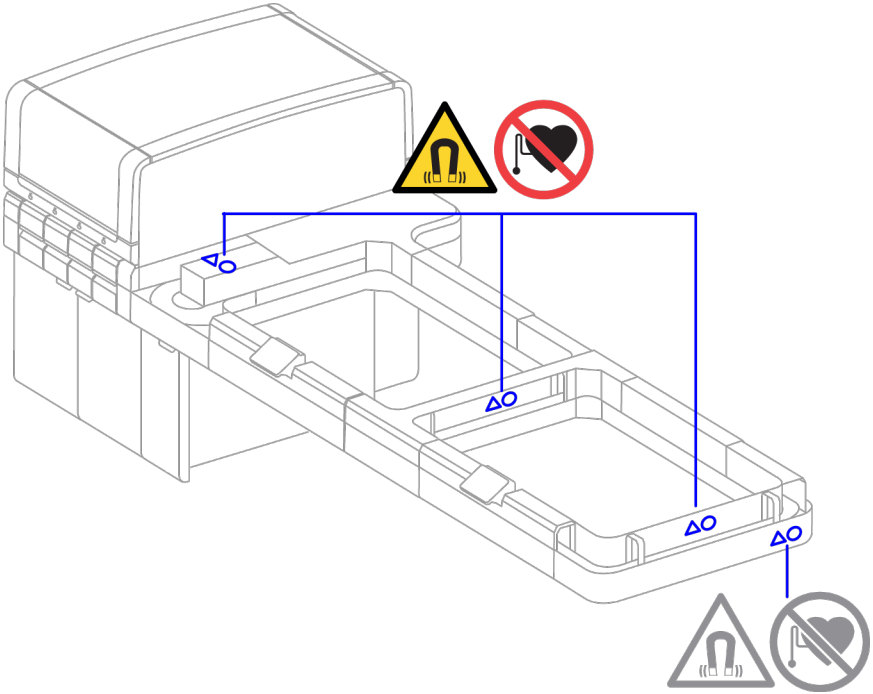
Safety symbol	Hazard description
	Strong Magnetic Field / No Pacemakers (Page 88 <i>Strong Magnetic Field / No Pacemakers Warning</i>)

Symbols on the Atellica Magline Transport (back view)



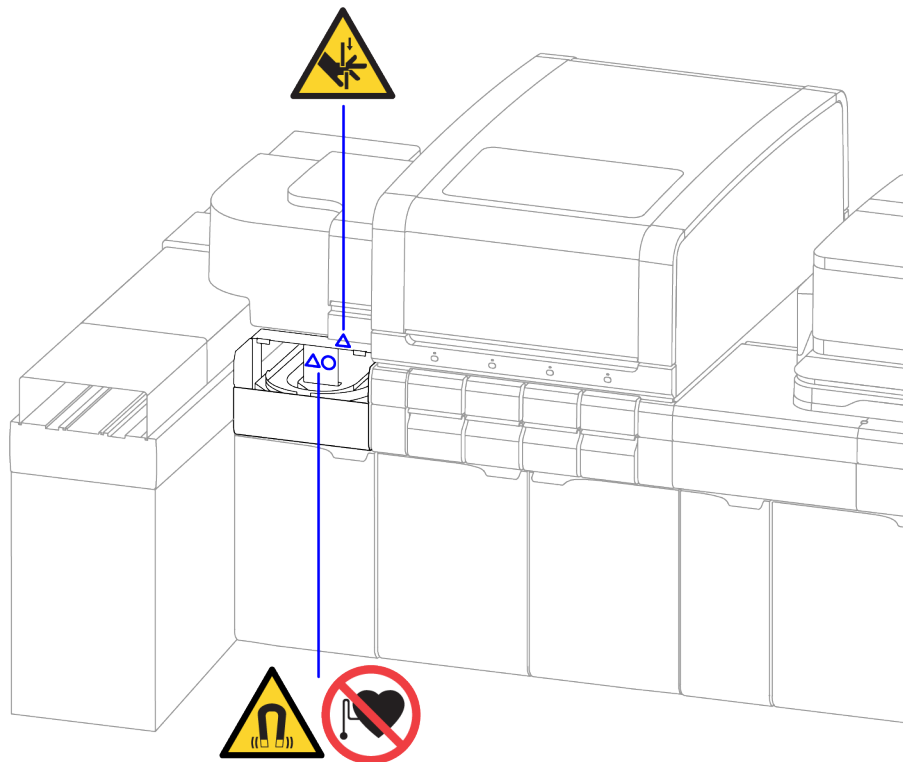
Safety symbol	Hazard description
	Strong Magnetic Field / No Pacemakers (Page 88 <i>Strong Magnetic Field / No Pacemakers Warning</i>)

Symbols on the Atellica Magline Transport (side view)



Safety symbol	Hazard description
	Strong Magnetic Field / No Pacemakers (Page 88 <i>Strong Magnetic Field / No Pacemakers Warning</i>)

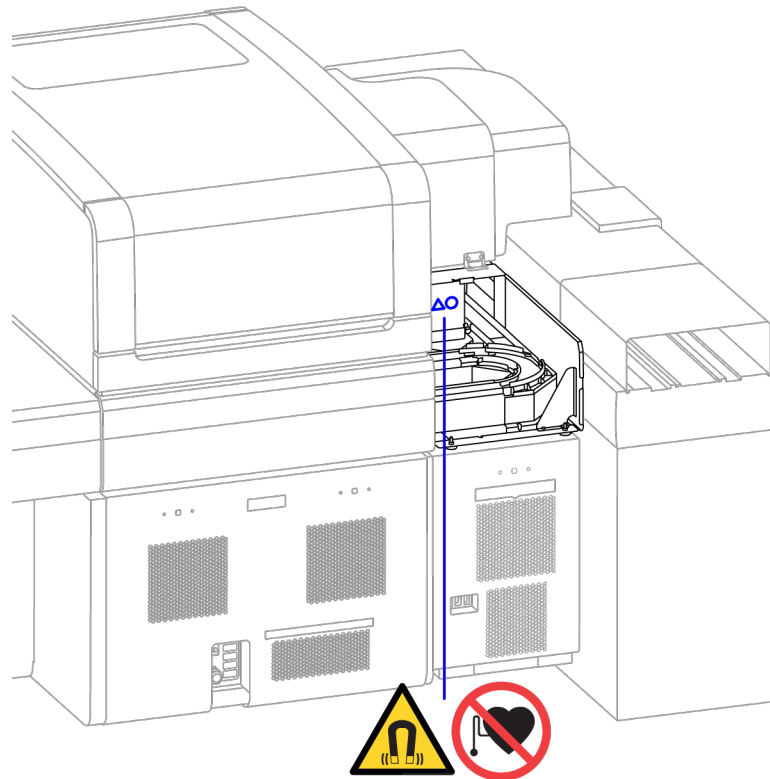
Symbols on the SHC (front view)



Safety symbol	Hazard description
	Pinch Hazard (Page 87 <i>Pinch Hazard</i>)
	Strong Magnetic Field / No Pacemakers (Page 88 <i>Strong Magnetic Field / No Pacemakers Warning</i>)



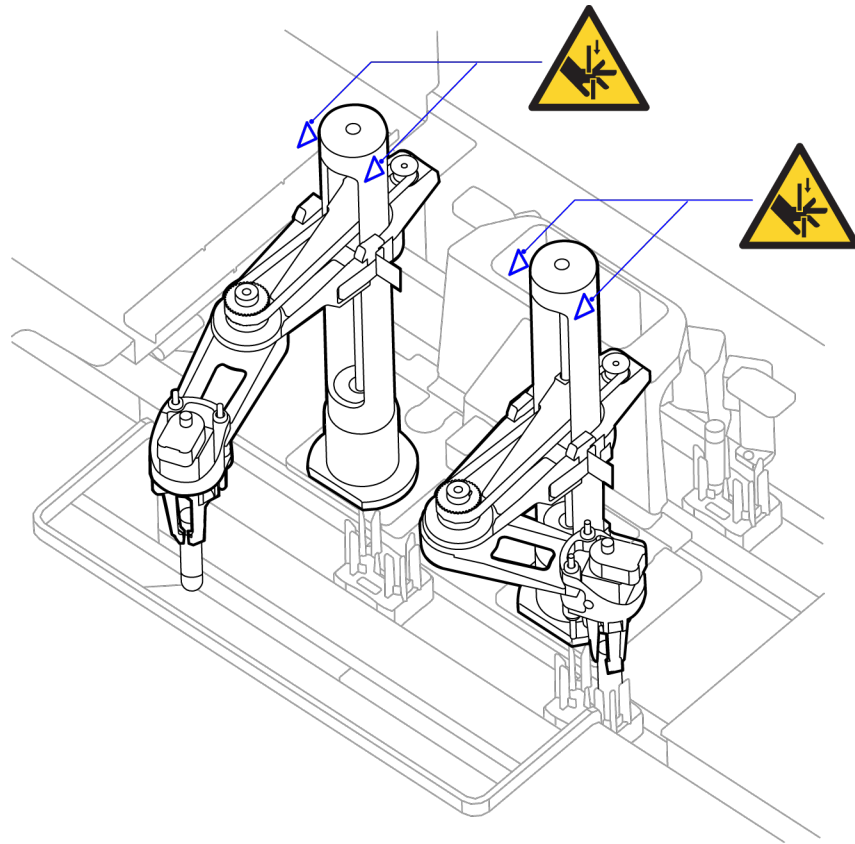
Symbols on the SHC (back view)



Safety symbol	Hazard description
	Strong Magnetic Field / No Pacemakers (Page 88 <i>Strong Magnetic Field / No Pacemakers Warning</i>)

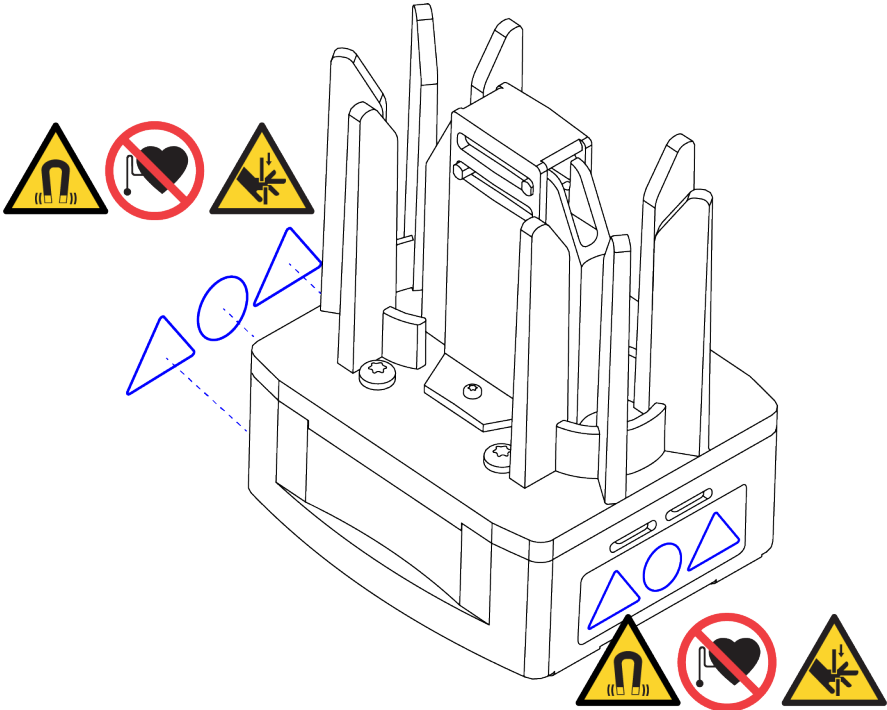


Symbols on the SHC robots

**Safety symbol****Hazard description**

Pinch Hazard (Page 87 *Pinch Hazard*)

Symbols on the carrier



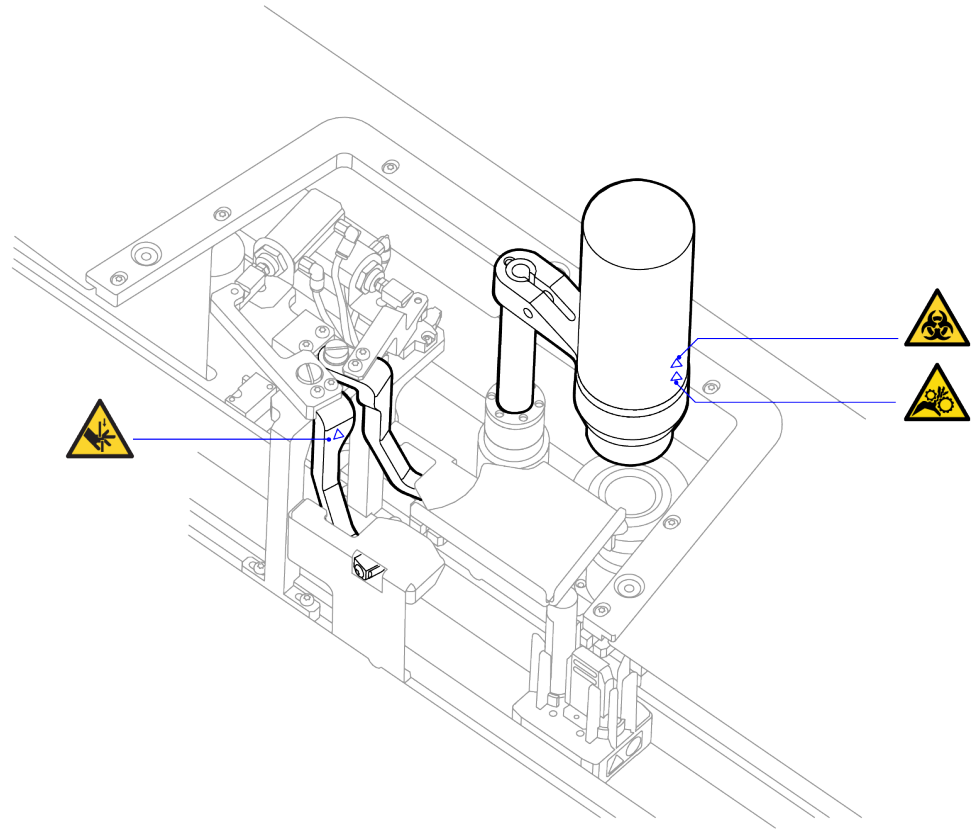
Safety symbol	Hazard description
	Strong Magnetic Field / No Pacemakers / Carrier Pinch Hazard • (Page 88 <i>Strong Magnetic Field / No Pacemakers Warning</i>) • (Page 86 <i>Carrier Pinch Hazard</i>)

Location of Safety Hazard Symbols on the Decapper Interior

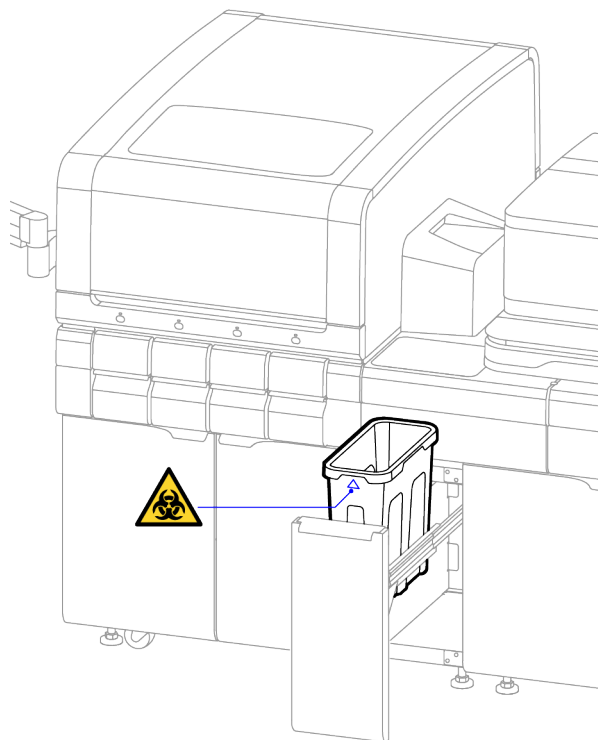
Symbols on the interior of the Decapper indicate possible safety hazards the operator may encounter while operating and maintaining the module.

The following figures show the locations of these safety hazard symbols. For descriptions of the symbols, see (Page 29 *Symbols*).

Decapper open cover



Decapper chute waste drawer open



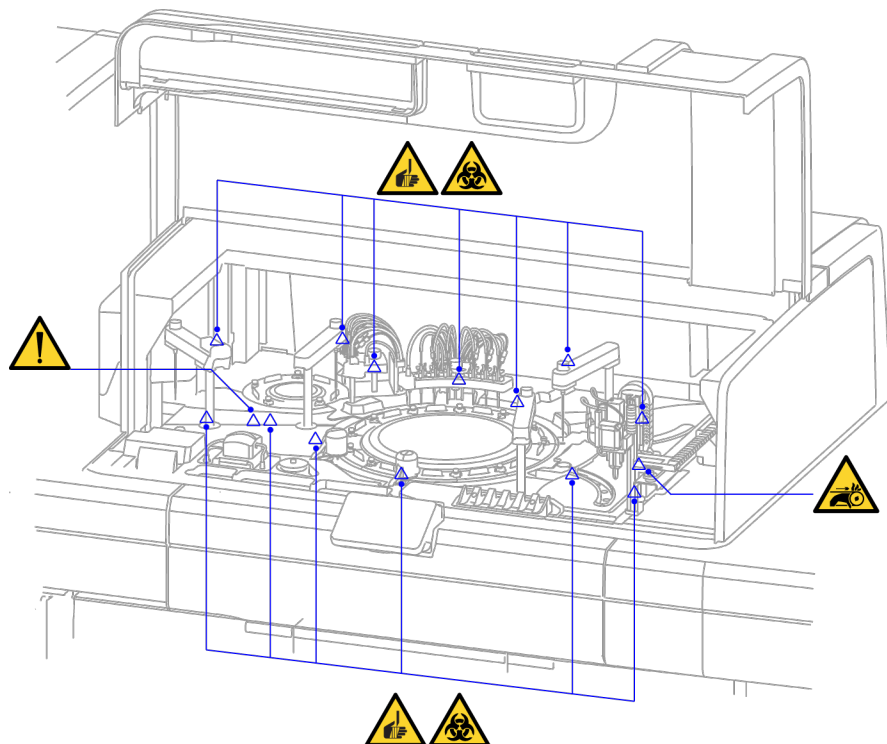
Safety Symbol	Hazard Description
	Biohazard (Page 86 <i>Biohazard</i>)
	Pinch hazard (Page 87 <i>Pinch Hazard</i>)
	Entanglement hazard: Moving parts can cause entrapment and serious injury.

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.

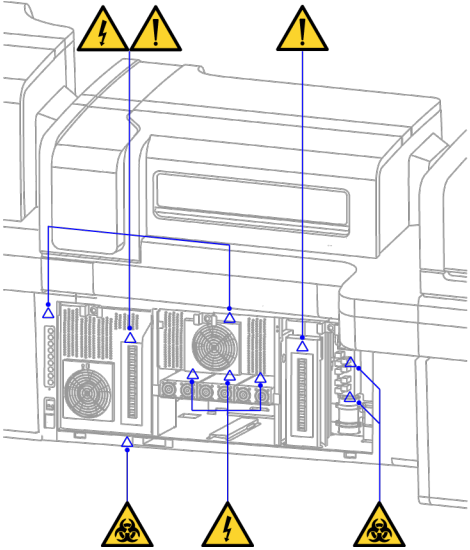
The following figures show the locations of these safety hazard symbols. For descriptions of the symbols, see System Symbols (Page 29 *Symbols*).

CH Analyzer open front cover



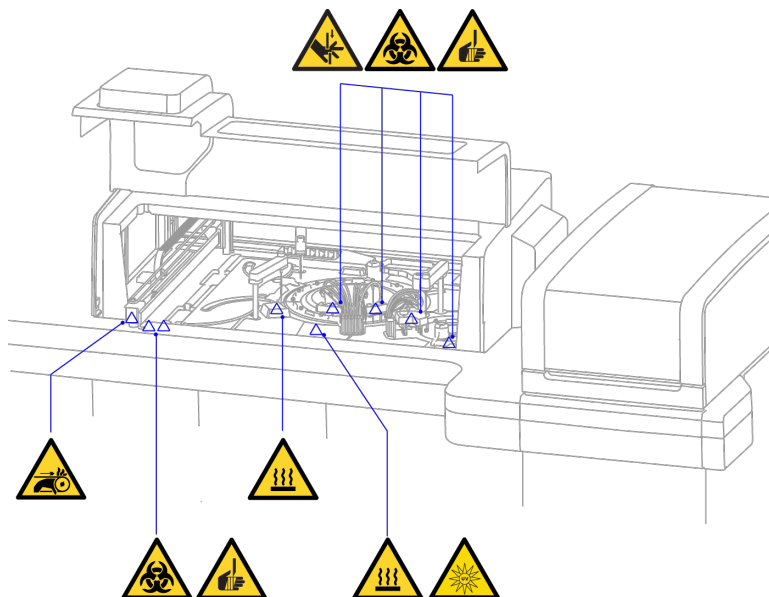
Safety Symbol	Hazard Description
	Biohazard (Page 86 <i>Biohazard</i>)
	Puncture Hazard (Page 87 <i>Puncture Hazard</i>)
	Caution: Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.
	Entanglement hazard: Moving parts can cause entrapment and serious injury.

CH Analyzer back panels off



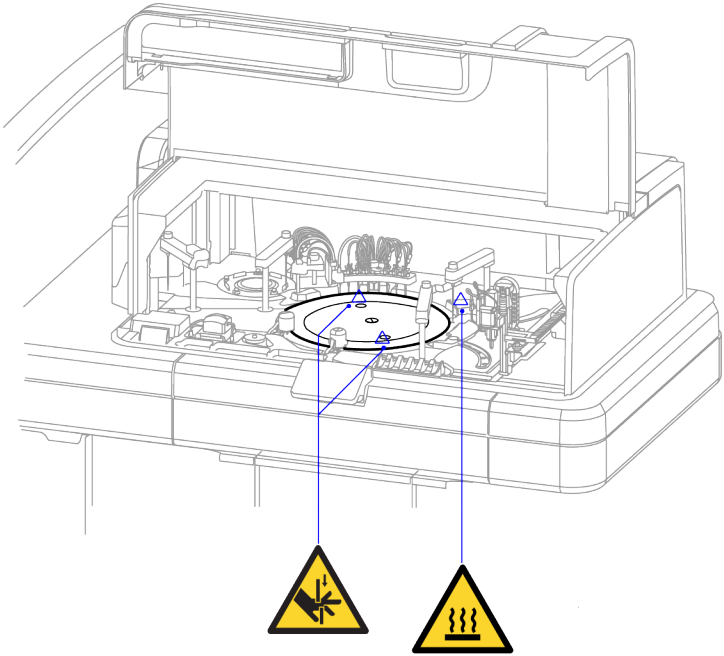
Safety Symbol	Hazard Description
	Biohazard (Page 86 <i>Biohazard</i>)
	Caution: Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.
	Electric shock (Page 86 <i>Electric Shock Hazard</i>)

CH Analyzer open back cover



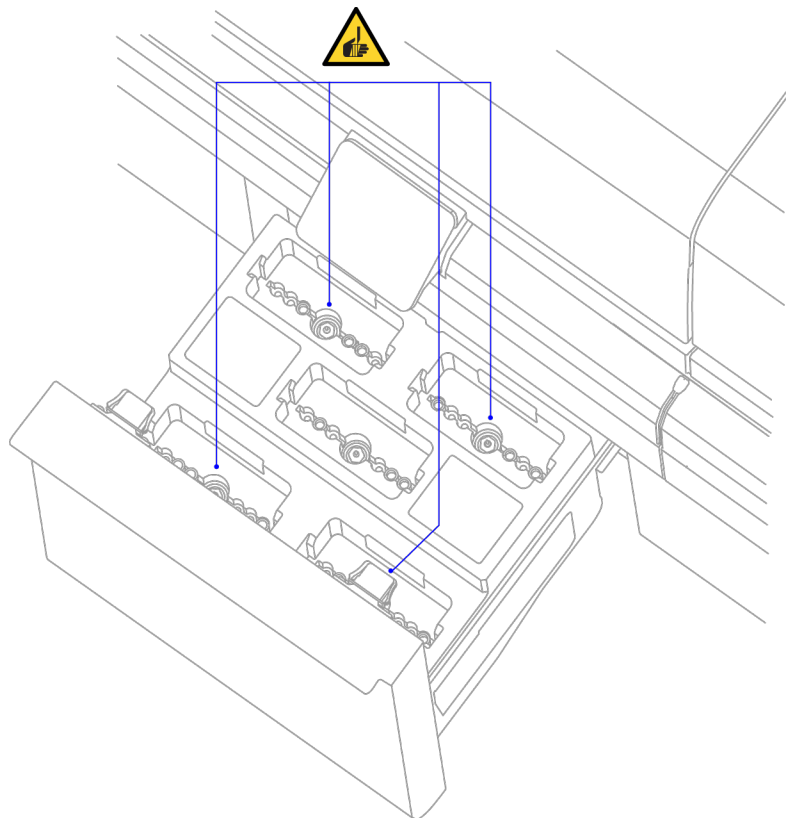
Safety Symbol	Hazard Description
	Biohazard (Page 86 <i>Biohazard</i>)
	Puncture Hazard (Page 87 <i>Puncture Hazard</i>)
	Caution: Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.
	Entanglement hazard: Moving parts can cause entrapment and serious injury.
	Pinch hazard (Page 87 <i>Pinch Hazard</i>)
	Hot surface hazard (Page 86 <i>Hot Surface Warning</i>)
	Ultraviolet (UV) light hazard (Page 88 <i>UV Lamp Warning</i>)

Under the CH Analyzer reaction ring cover



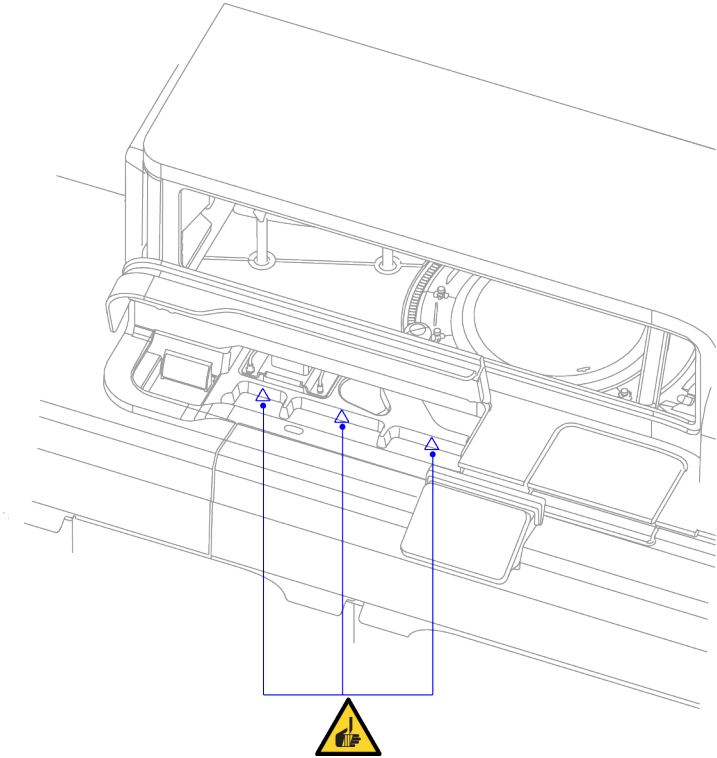
Safety Symbol	Hazard Description
	Pinch hazard (Page 87 <i>Pinch Hazard</i>)
	Hot surface hazard (Page 86 <i>Hot Surface Warning</i>)

CH Analyzer system fluids drawer

**Safety Symbol****Hazard Description**

Puncture Hazard (Page 87 *Puncture Hazard*)

IMT fluids



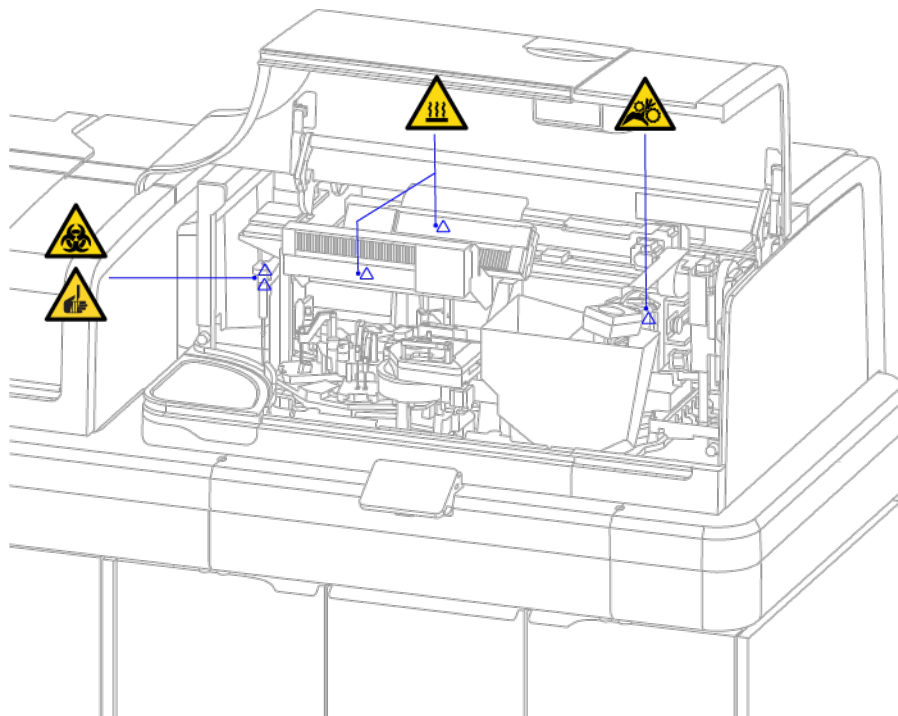
Safety Symbol	Hazard Description
	Puncture Hazard (Page 87 <i>Puncture Hazard</i>)

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 29 *Symbols*).

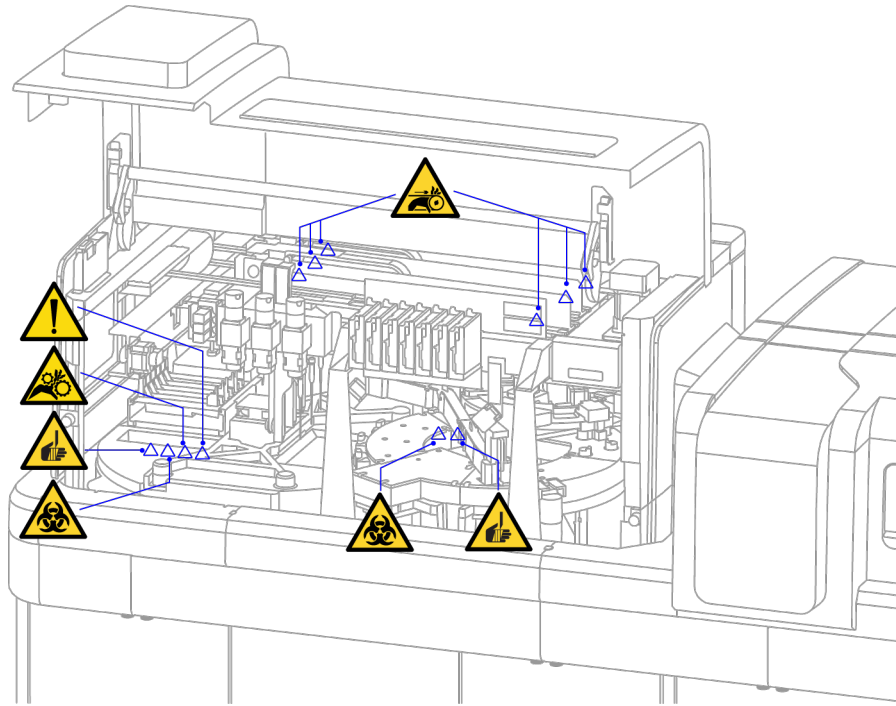
IM front cover open



Safety symbol	Hazard description
	Puncture Hazard (Page 87 <i>Puncture Hazard</i>) Sharp element.
	Biohazard (Page 86 <i>Biohazard</i>)
	Emits high temperature hazard Hot surface hazard.
	Entanglement hazard Moving parts can cause entrapment and serious injury.



IM back cover open



Safety symbol

Hazard description

Biohazard (Page 86 *Biohazard*)Puncture Hazard (Page 87 *Puncture Hazard*)

Sharp element.



Entanglement hazard

Moving parts can cause entrapment and serious injury.



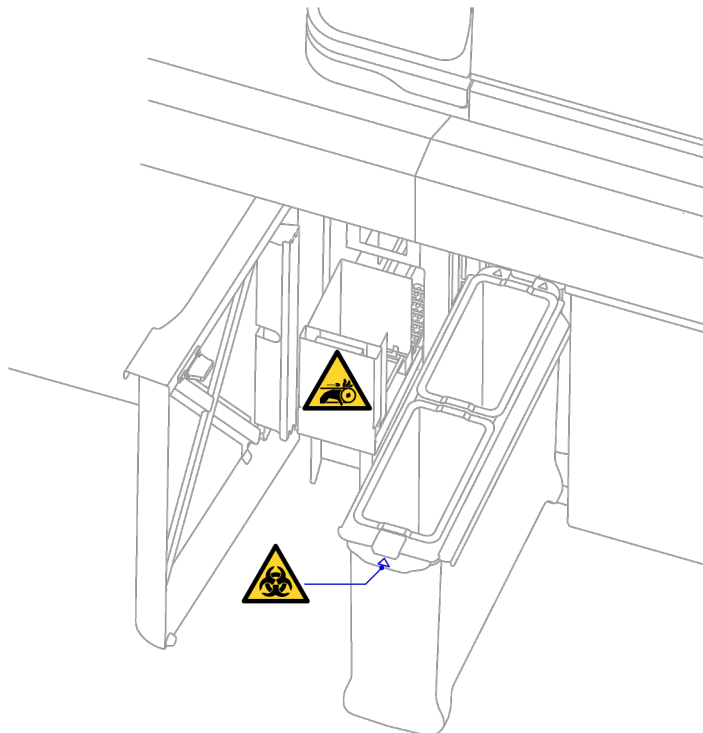
Caution

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.



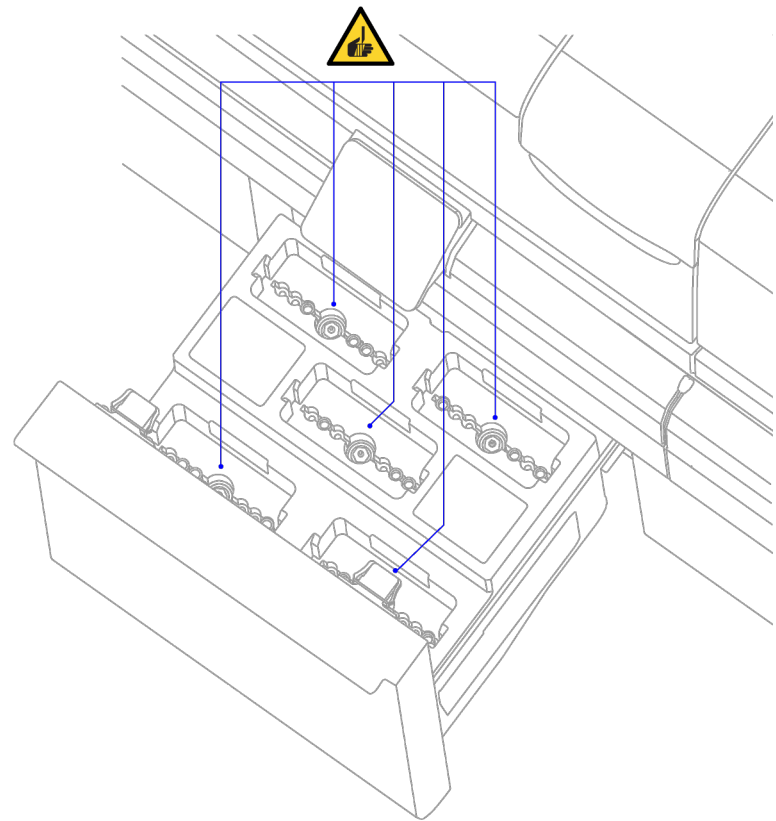
Moving belt hazard

IM solid waste

**Safety symbol****Hazard description**Biohazard (Page 86 *Biohazard*)

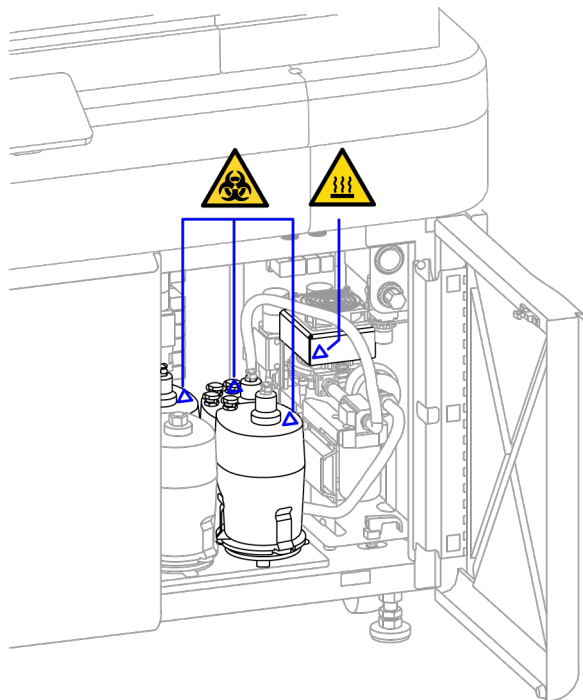
Entanglement hazard
Moving parts can cause entrapment
and serious injury.

IM system fluids drawer

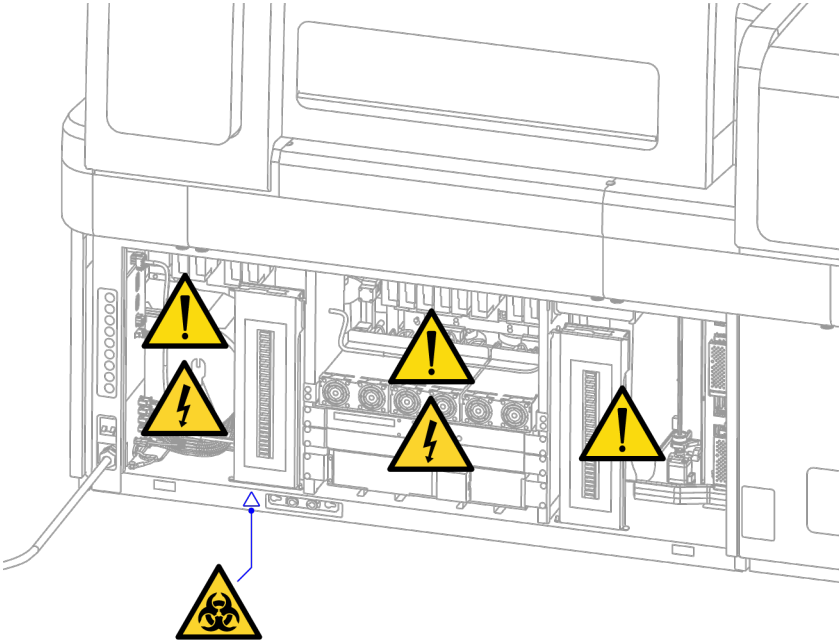


Safety symbol	Hazard description
	Puncture Hazard (Page 87 <i>Puncture Hazard</i>) Sharp element.

IM water and liquid waste

**Safety symbol****Hazard description**Biohazard (Page 86 *Biohazard*)Emits high temperature hazard
Hot surface hazard.

IM back panels off



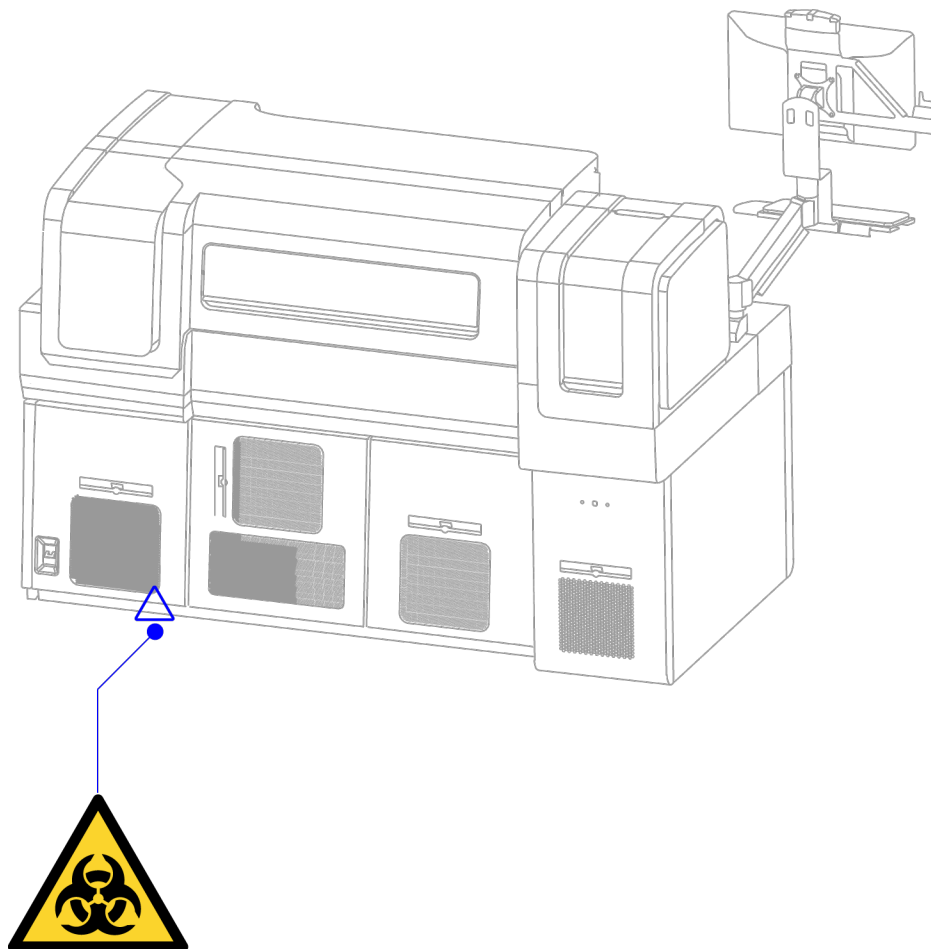
Safety symbol	Hazard description
	Biohazard (Page 86 <i>Biohazard</i>)
	Electric Shock Hazard (Page 86 <i>Electric Shock Hazard</i>) Dangerous voltage.
	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.

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 29 *Symbols*).

CH DL exterior back view



Safety Symbol	Hazard Description
	Biohazard (Page 86 <i>Biohazard</i>)

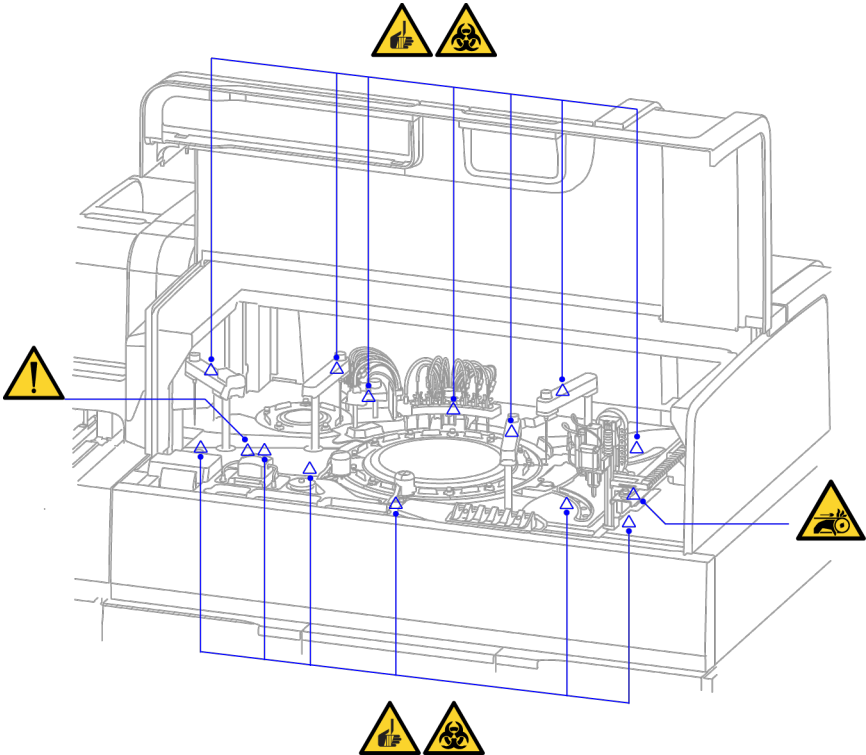


Location of Safety Hazard Symbols on the CH DL Interior

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.

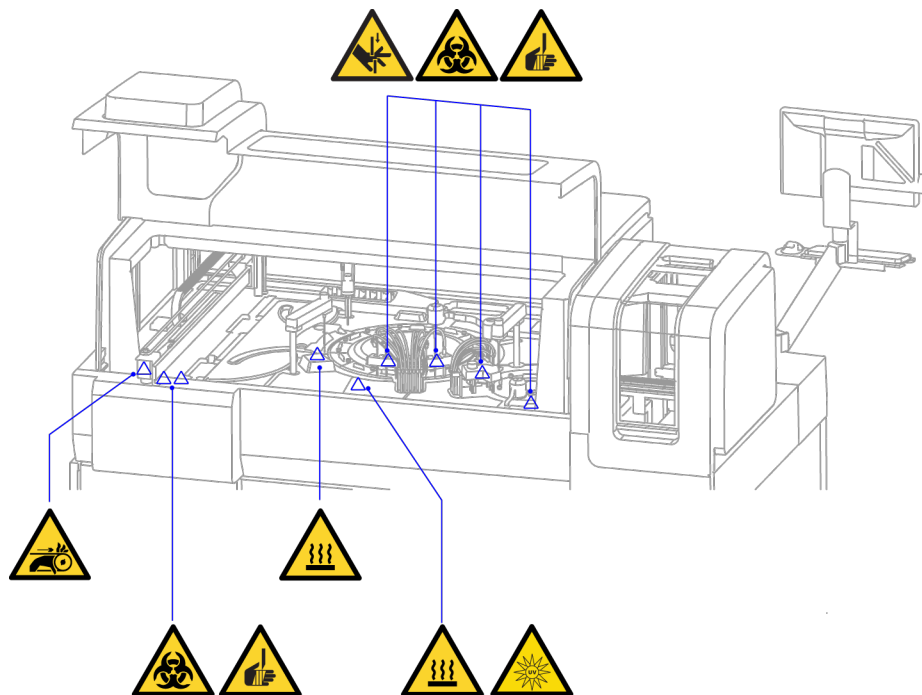
For more information on safety hazard symbols, see System Symbols (Page 29 *Symbols*).

CH DL front (cover open)



Safety Symbol	Hazard Description
	Biohazard (Page 86 <i>Biohazard</i>)
	Puncture Hazard (Page 87 <i>Puncture Hazard</i>)
	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.
	Entanglement hazard: Moving parts can cause entrapment and serious injury.

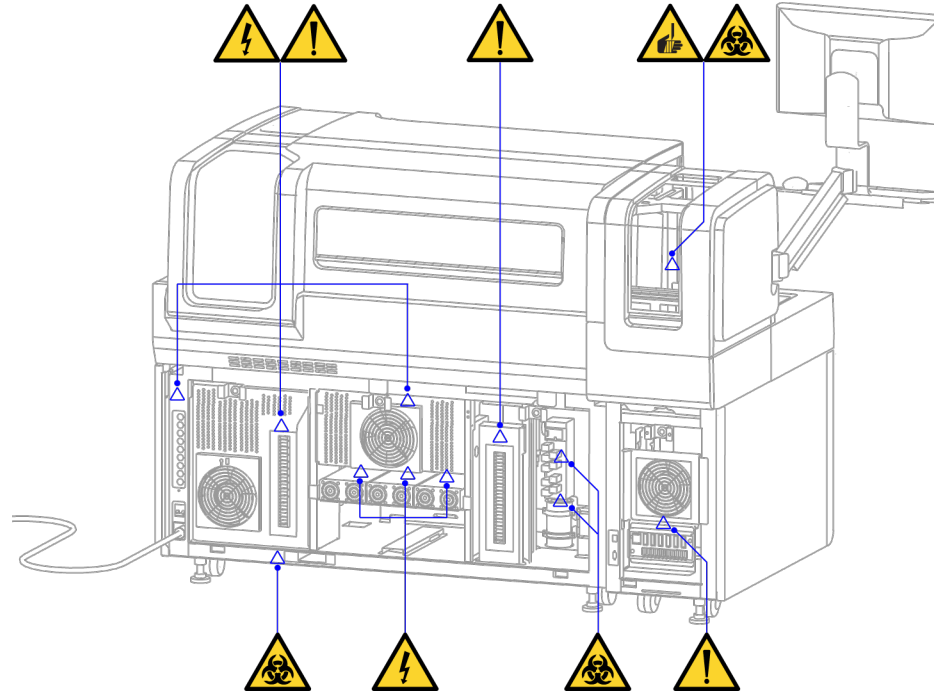
CH DL back (cover open)



Safety Symbol	Hazard Description
	Biohazard (Page 86 <i>Biohazard</i>)
	Puncture Hazard (Page 87 <i>Puncture Hazard</i>)
	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.
	Entanglement hazard: Moving parts can cause entrapment and serious injury.
	Pinch hazard (Page 87 <i>Pinch Hazard</i>)
	Hot surface hazard (Page 86 <i>Hot Surface Warning</i>)

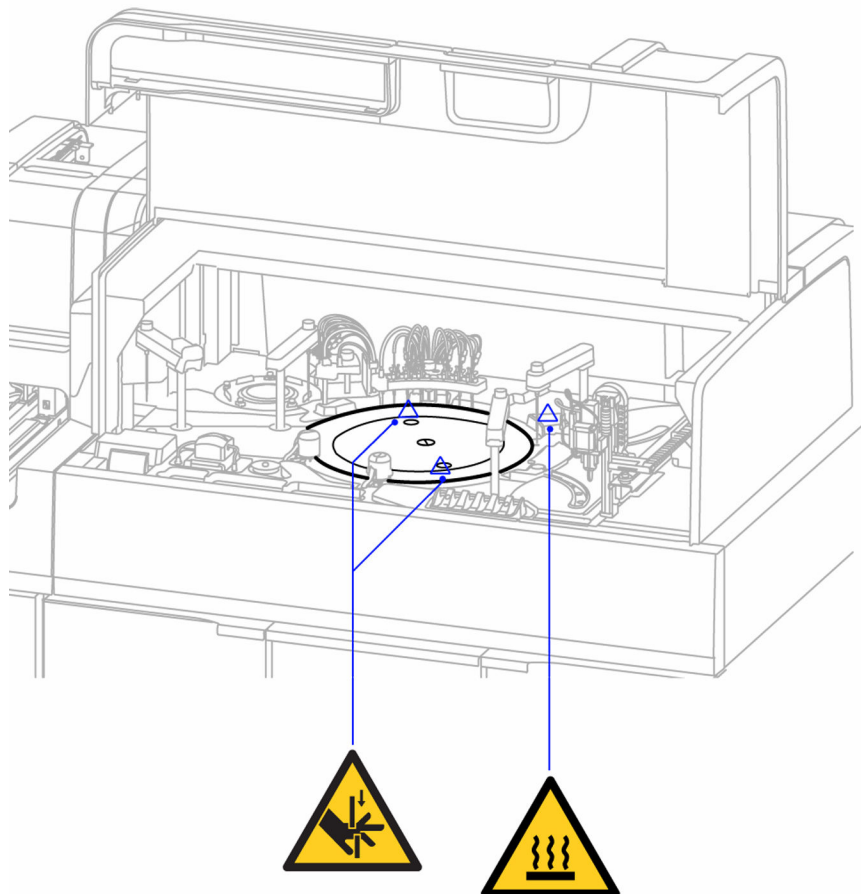
Safety Symbol	Hazard Description
	Ultraviolet (UV) light hazard (Page 88 <i>UV Lamp Warning</i>)

CH DL behind the back panels



Safety Symbol	Hazard Description
	Biohazard (Page 86 <i>Biohazard</i>)
	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.
	Electric shock (Page 86 <i>Electric Shock Hazard</i>)

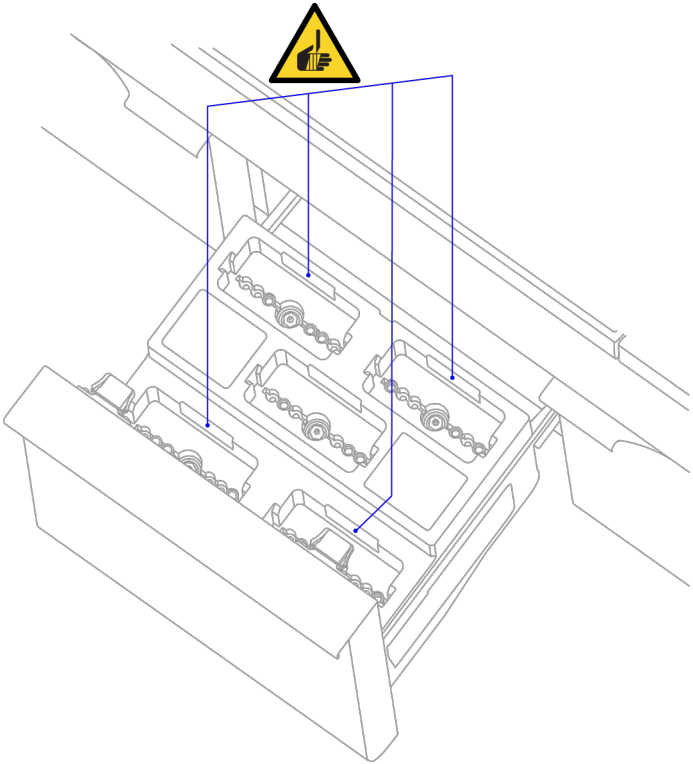
Under the CH DL reaction ring cover



Safety Symbol	Hazard Description
	Pinch hazard (Page 87 <i>Pinch Hazard</i>)
	Hot surface hazard (Page 86 <i>Hot Surface Warning</i>)

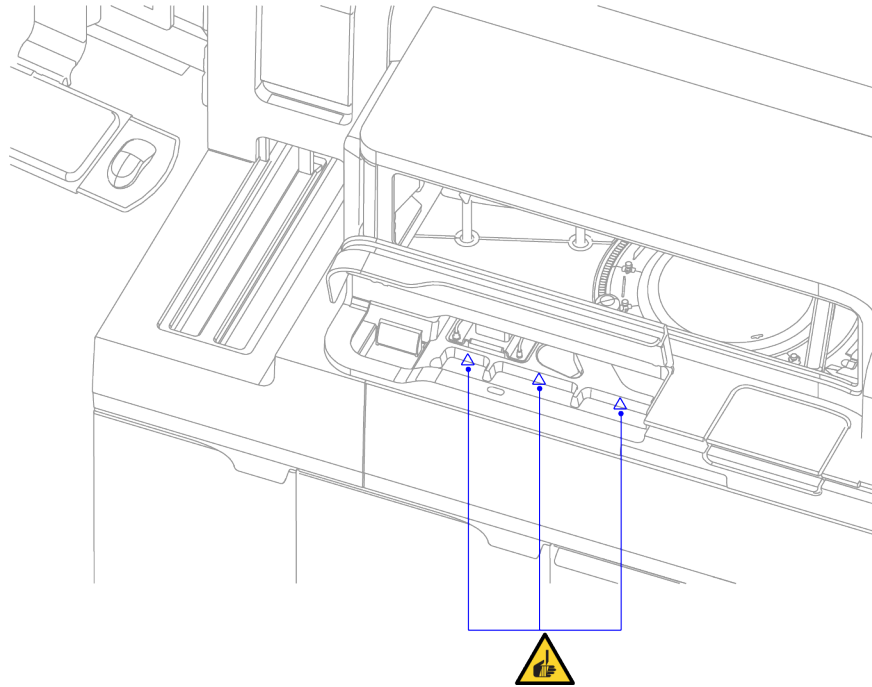


CH DL system fluids drawer

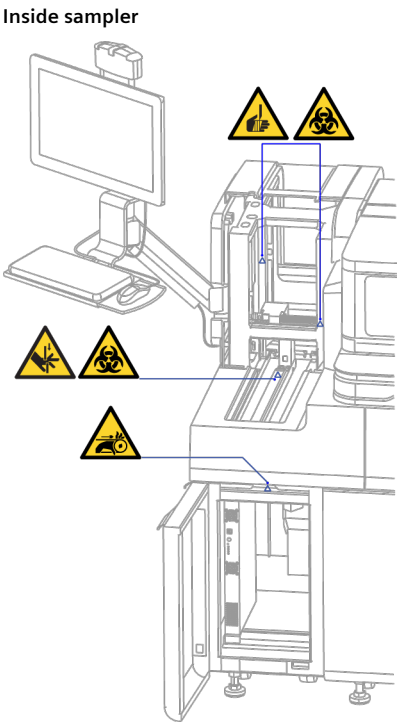


Safety Symbol	Hazard Description
	Puncture Hazard (Page 87 <i>Puncture Hazard</i>)

IMT fluids

**Safety Symbol****Hazard Description**

Puncture Hazard (Page 87 *Puncture Hazard*)



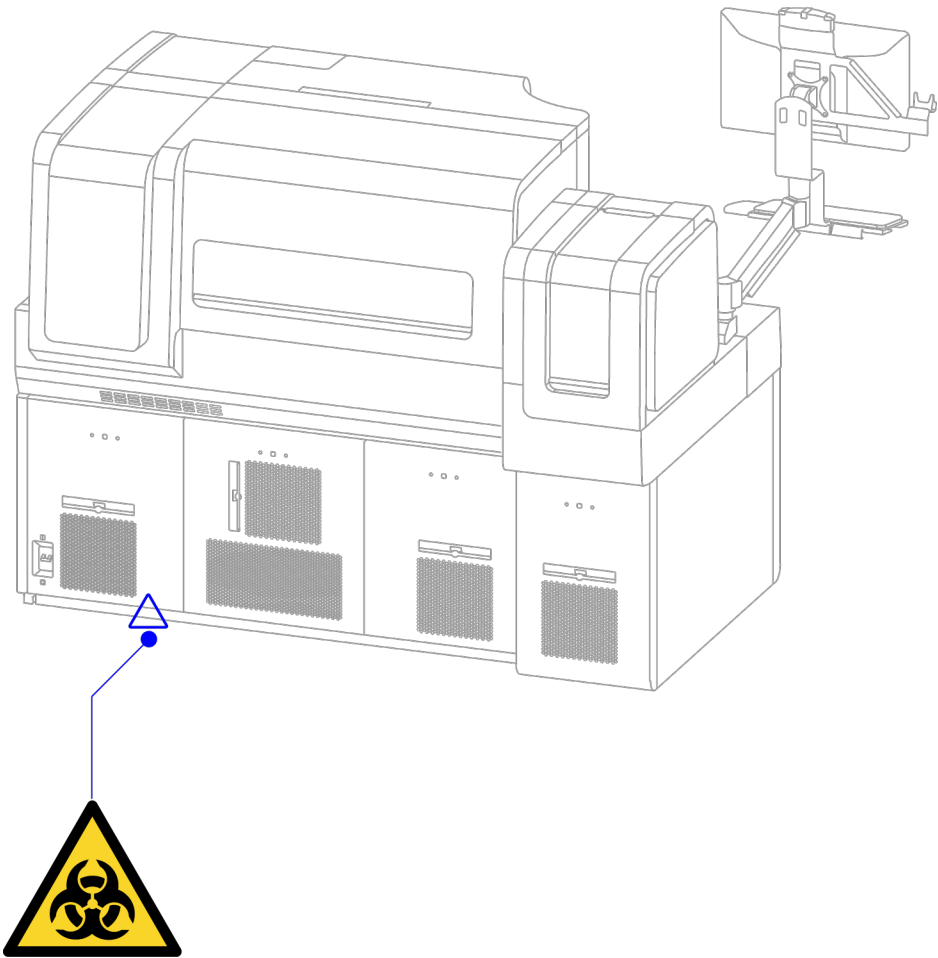
Safety Symbol	Hazard Description
	Biohazard (Page 86 <i>Biohazard</i>)
	Puncture Hazard (Page 87 <i>Puncture Hazard</i>)
	Entanglement hazard: Moving parts can cause entrapment and serious injury.
	Pinch hazard (Page 87 <i>Pinch Hazard</i>)

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 29 *Symbols*).

IM DL exterior back view



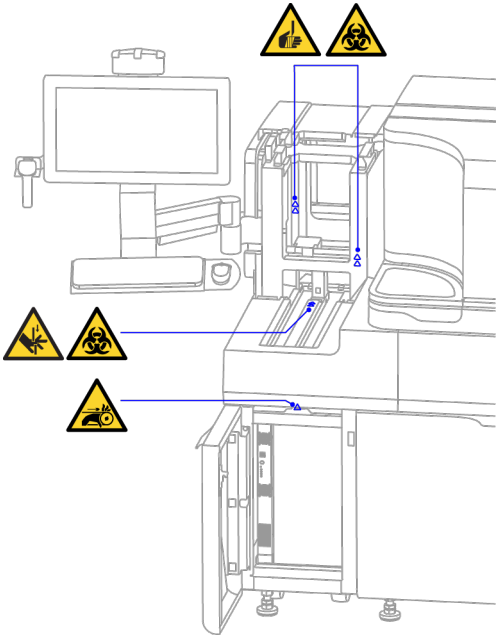
Safety Symbol	Hazard Description
	Biohazard (Page 86 <i>Biohazard</i>)

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.

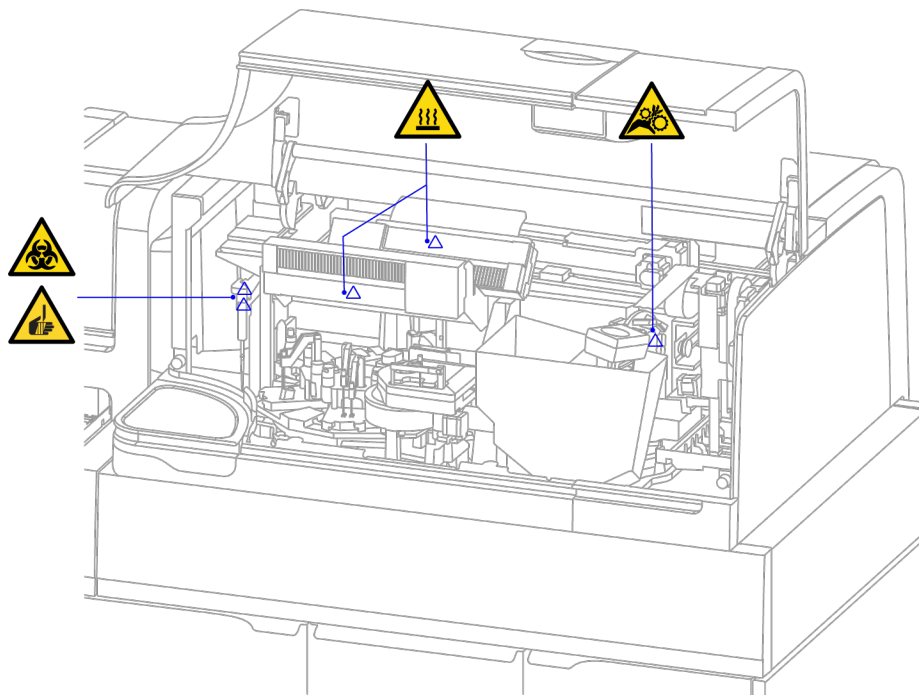
For more information, refer to System Symbols (Page 29 *Symbols*).

IM DL entry and exit queues and computer door



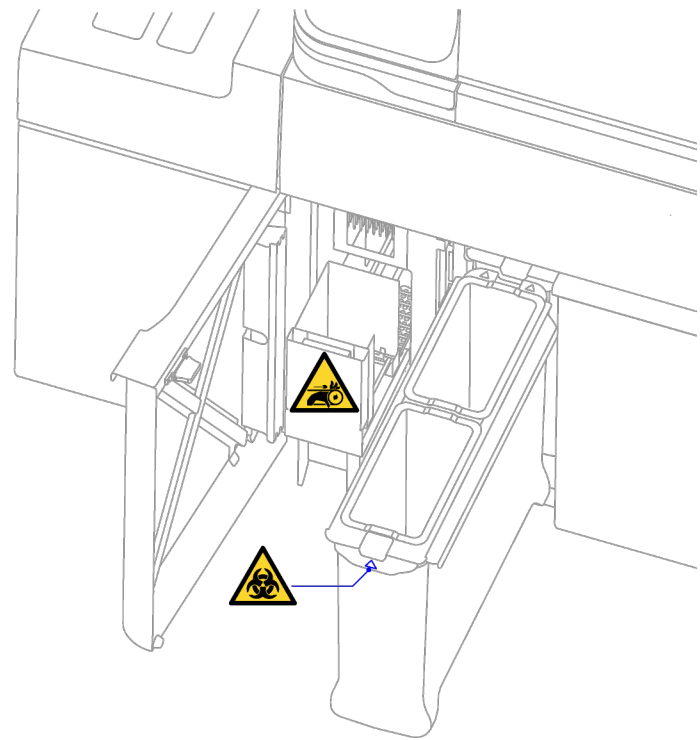
Safety symbol	Hazard description
	Moving belt hazard
	Pinch Hazard (Page 87 <i>Pinch Hazard</i>)
	Biohazard (Page 86 <i>Biohazard</i>)
	Puncture Hazard (Page 87 <i>Puncture Hazard</i>) Sharp element.

IM DL front cover open



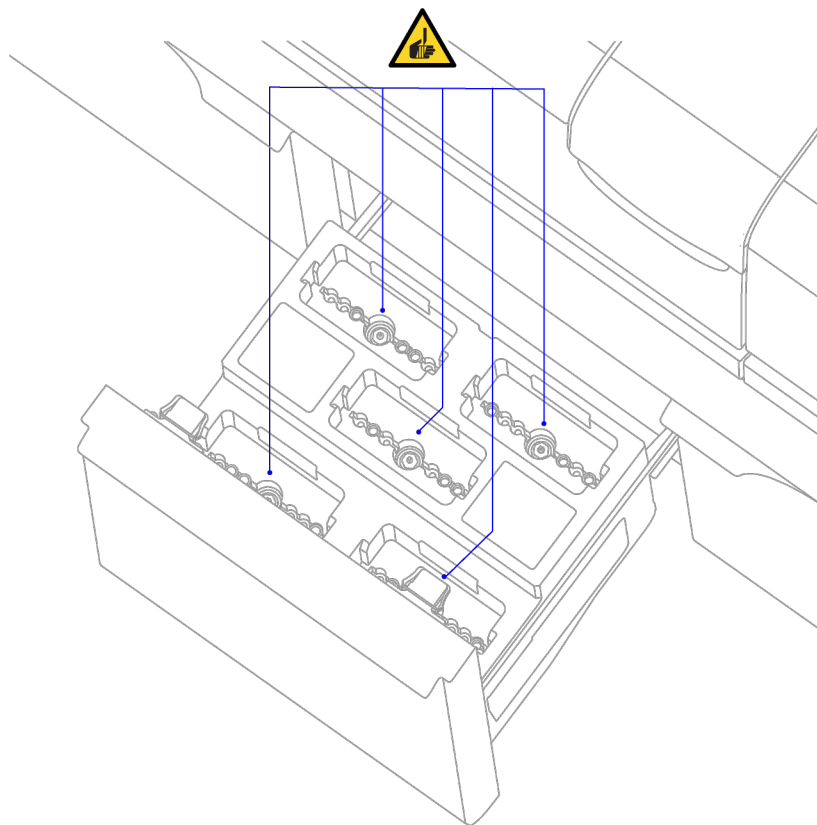
Safety symbol	Hazard description
	Puncture Hazard (Page 87 <i>Puncture Hazard</i>) Sharp element.
	Biohazard (Page 86 <i>Biohazard</i>)
	Entanglement hazard Moving parts can cause entrapment and serious injury.
	Emits high temperature hazard Hot surface hazard.

IM DL solid waste



Safety symbol	Hazard description
	Biohazard (Page 86 <i>Biohazard</i>)
	Entanglement hazard Moving parts can cause entrapment and serious injury.

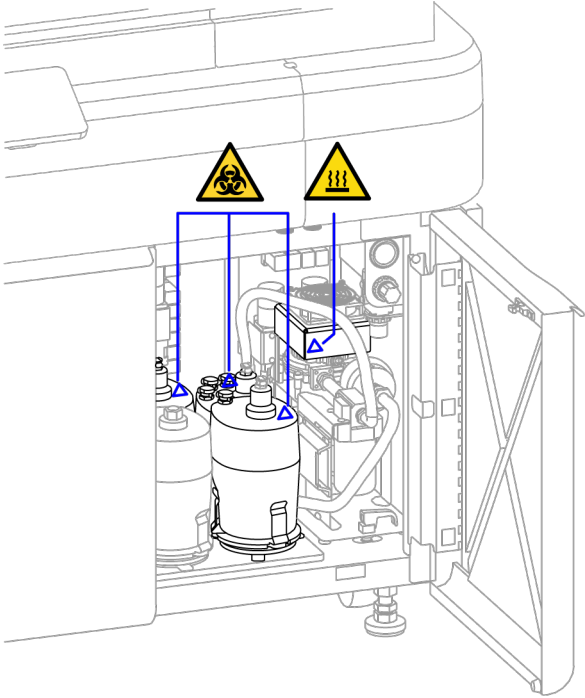
IM DL liquid waste

**Safety symbol****Hazard description**

Puncture Hazard (Page 87 *Puncture Hazard*)

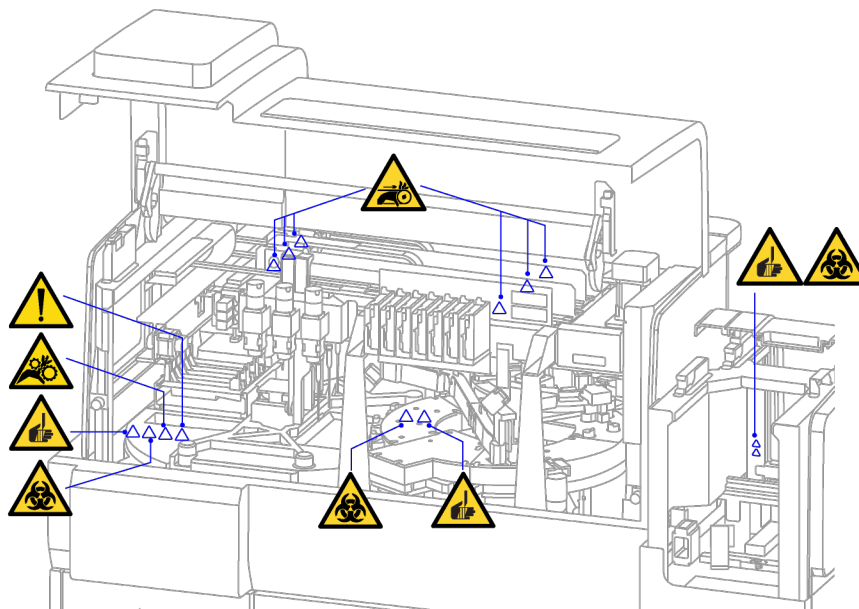
Sharp element.

IM water and liquid waste



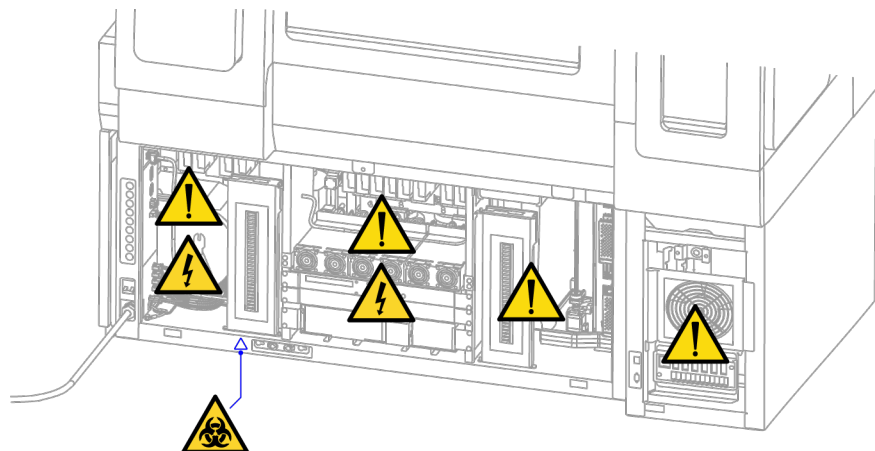
Safety symbol	Hazard description
	Biohazard (Page 86 <i>Biohazard</i>)
	Emits high temperature hazard Hot surface hazard.

IM DL back cover open



Safety symbol	Hazard description
	Biohazard (Page 86 <i>Biohazard</i>)
	Puncture Hazard (Page 87 <i>Puncture Hazard</i>) Sharp element.
	Entanglement hazard Moving parts can cause entrapment and serious injury.
	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.
	Moving belt hazard

IM DL back panels off



Safety symbol	Hazard description
	Biohazard (Page 86 <i>Biohazard</i>)
	Electric Shock Hazard (Page 86 <i>Electric Shock Hazard</i>) Dangerous voltage.
	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.

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 41 *Location of Safety Hazard Symbols on the System Exterior*)
- (Page 45 *Location of Safety Hazard Symbols on the SH, SHC, and Atellica Magline Transport Interior*)
- (Page 57 *Location of Safety Hazard Symbols on the CH Analyzer Interior*)
- (Page 63 *Location of Safety Hazard Symbols on the IM Analyzer Interior*)

- (Page 69 *Location of Safety Hazard Symbols on the CH DL Exterior*)
- (Page 70 *Location of Safety Hazard Symbols on the CH DL Interior*)
- (Page 77 *Location of Safety Hazard Symbols on the IM DL Exterior*)
- (Page 78 *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 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**

Be careful when opening or working around the open SHC front cover. 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.

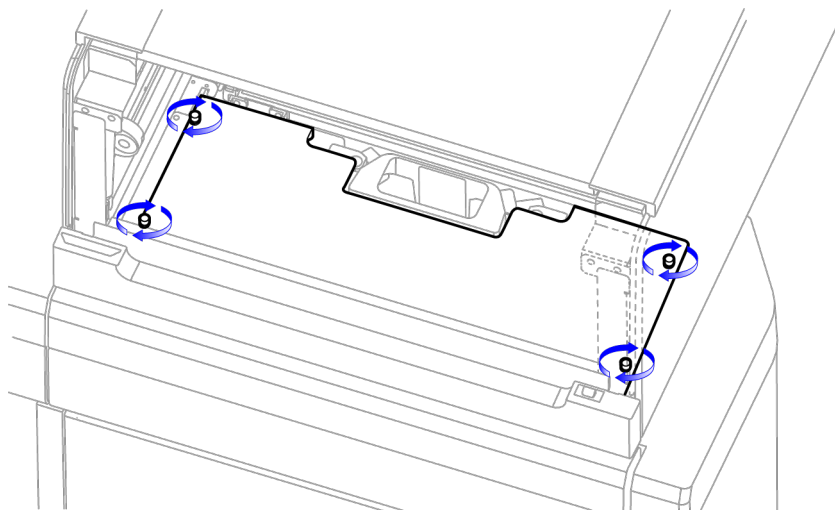
1. If the SH internal Atellica Magline Transport cover is not in position, manually move the SH robot to a position where it does not block access to the cover location.



CAUTION

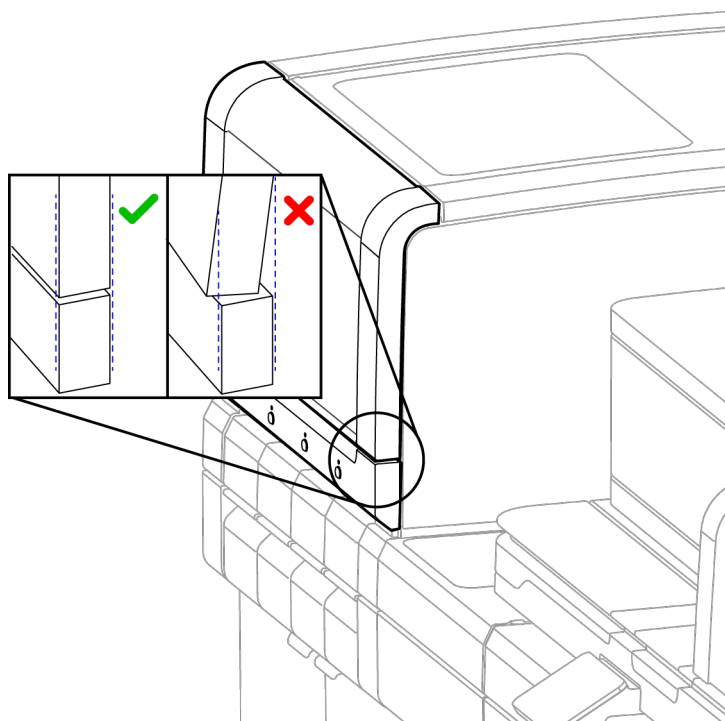
Do not touch the TCS when removing or installing the SH internal Atellica Magline Transport cover. Touching the TCS may misalign the cameras and the SH would be unable to scan sample containers. If the TCS cameras are misaligned, contact the local technical support provider to realign the cameras. Use 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 Command bar, select **System > Status**.
5. Select the SH.
6. Select **Front Cover** or **Back Cover**, as appropriate.
7. Wait for  to change to .
8. To restart the SH, select .

Unlocking SH Covers

1. On the Command bar, select **System > Status**.
2. Select the SH.

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

 - Pausing the SH enables the system to complete all tests currently in process.
 - Stopping the SH stops the SH immediately.
3. To unlock the cover by pausing the SH, select .
4. To unlock the cover by stopping the SH:
 - a. Select .
 - b. Select **Yes**.
5. Select **Front Cover** or **Back Cover**.
6. Wait for  to change to .
7. 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 .



CAUTION

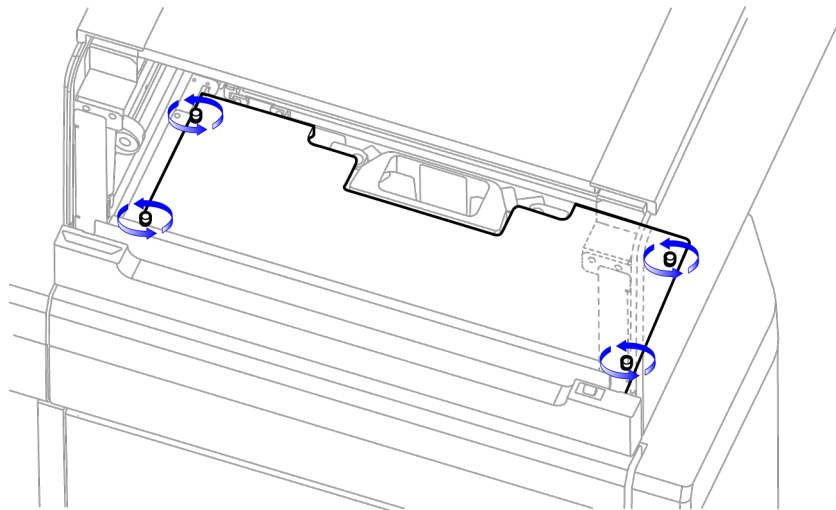
Do not hold the SH robot grippers or push the robot down when moving the robot manually. Holding the grippers to move the robot may damage the crash sensor. Moving the robot down may cause the robot grippers to impact another object, possibly resulting in damage to the robot gripper or sample container 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. On the Command bar, select **System > Status**.
2. Select the Sample Handler Connect.

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.

3. To unlock the cover by pausing the SHC, select .

4. To unlock the cover by stopping the SHC:
 - a. Select .
 - b. Select **Yes**.
5. Select **Front Cover**.
6. Wait for  to change to .
7. 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 471 *Installing Atellica Magline Transport Covers*).
2. Close the SHC cover.
3. On the Command bar, select **System > Status**.
4. Select the SHC.
5. Select **Front Cover**.
6. Wait for  to change to .
7. To restart the SHC, select .

Location of CH Analyzer 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. On the Command bar, select **System > Status**.
2. Select an analyzer.
3. Ensure the analyzer is in the paused or stopped state (Page 125 *Changing the Module Status*).

NOTE: The operator must pause or stop the analyzer before unlocking the cover.

4. To unlock the cover, select **Front Cover** or **Back Cover**.
5. Wait for the lock glyph to indicate the appropriate state.

NOTE: The lock glyph 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.

6. 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.

7. 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 96 *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 505 *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

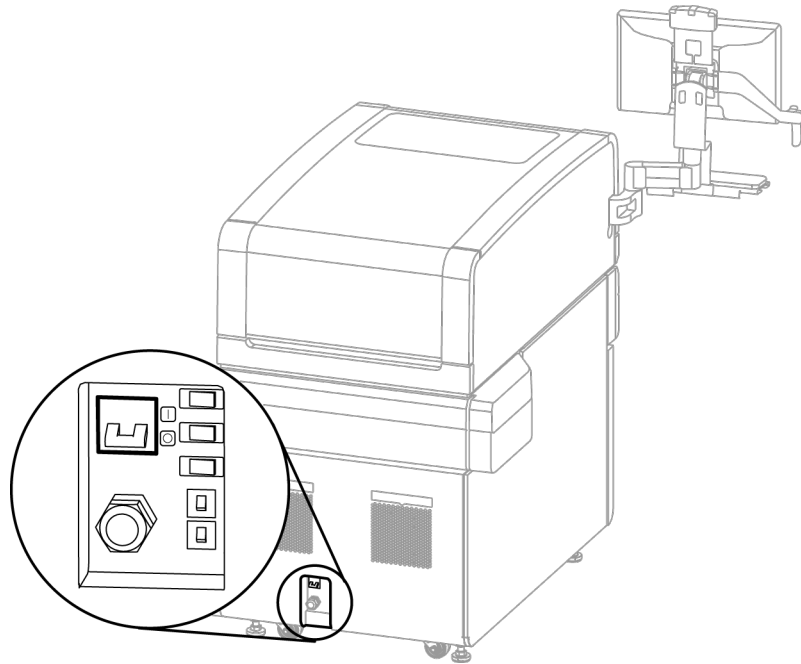
1. In the Command bar, select **System > Status**.
2. Select .
3. Select .
4. Select **Front Cover** or **Back Cover**.

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 Front Cover or Back Cover area becomes yellow to indicate that samples cannot be processed.

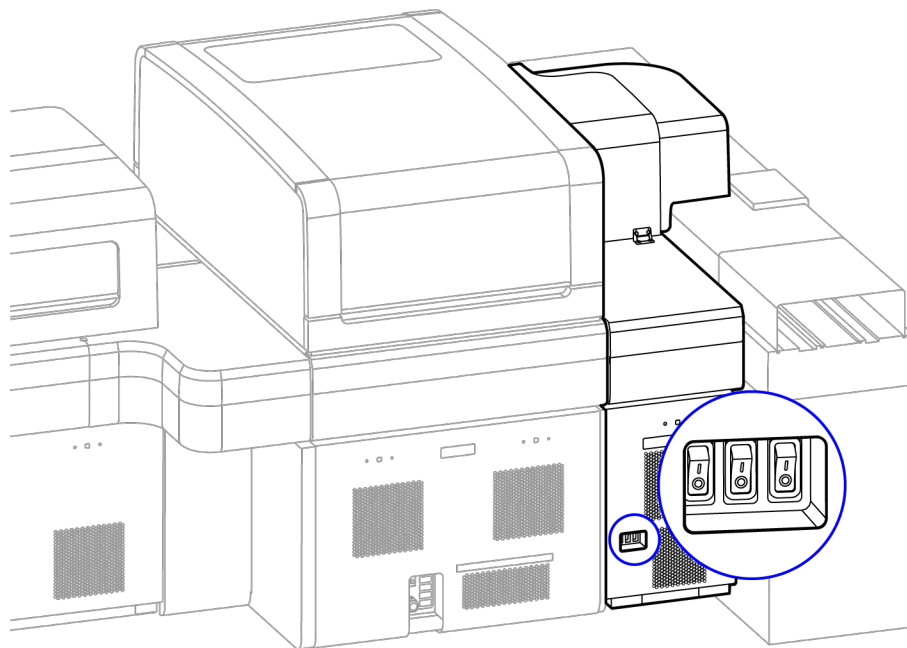
Location of the System Main Power Switches

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

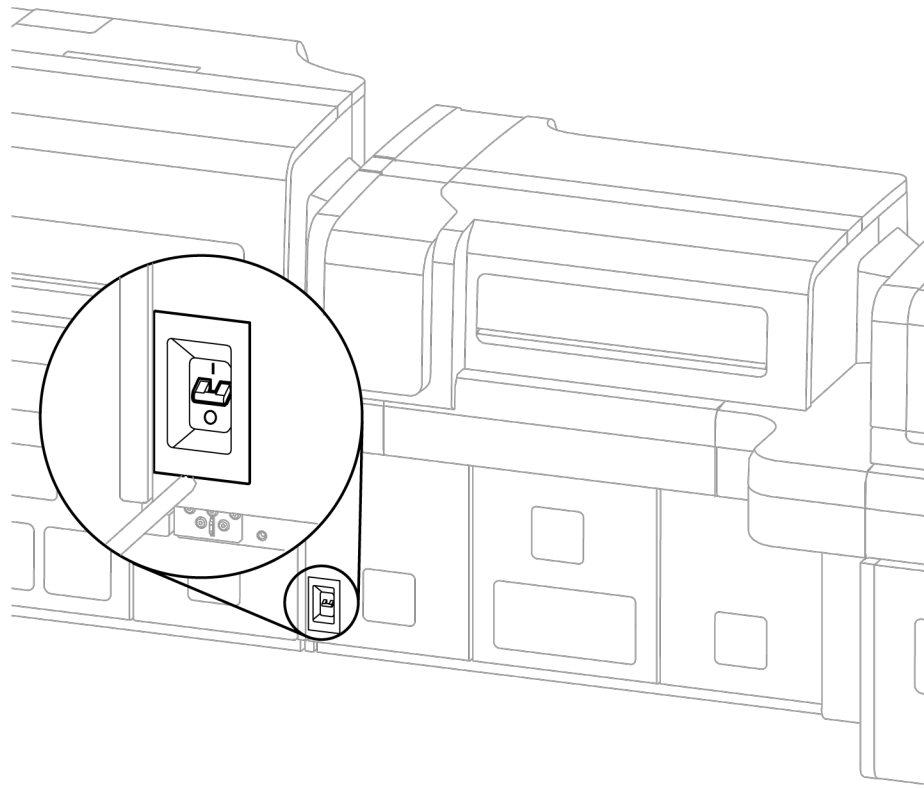
SH main power switch



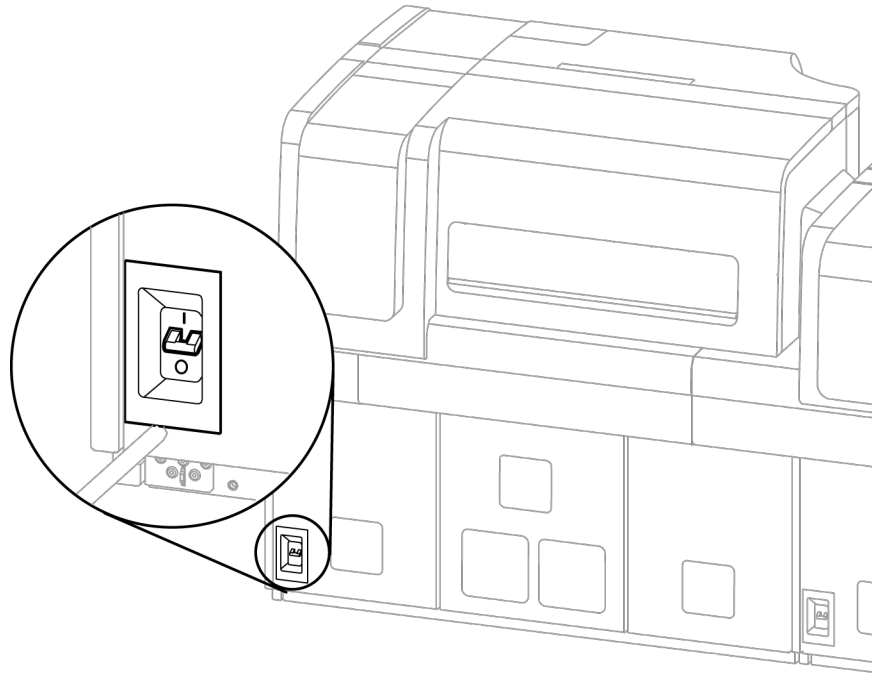
SHC main power switches



CH Analyzer main power switch

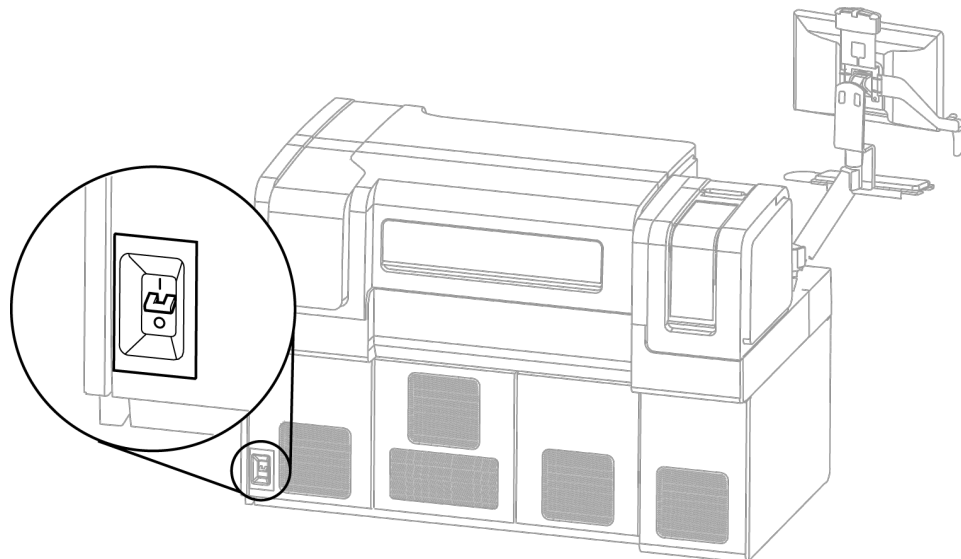


IM Analyzer main power switch



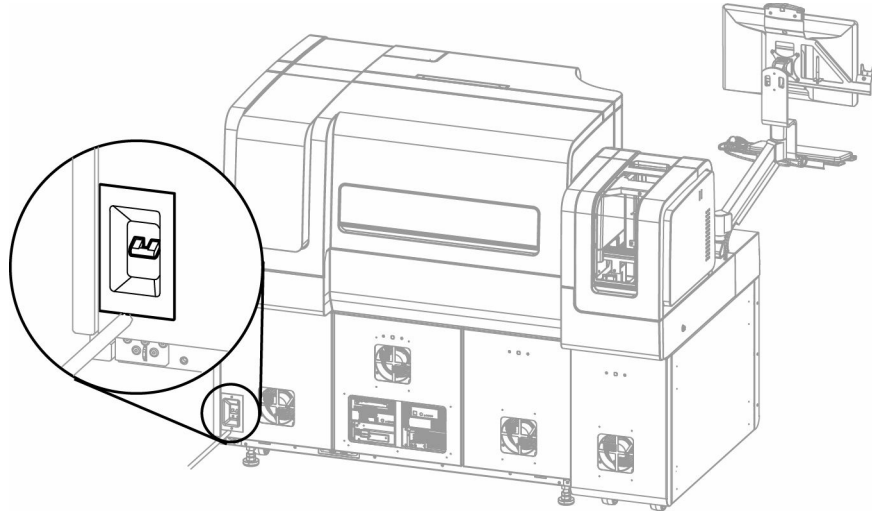
Location of Main Power Switch on the CH DL

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.



5 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.
Flexible configuration	Up to 3 customizable configurations.

Feature	Notes
High capacity	Waste bin has capacity of up to 2000 sample caps and supports a bagged biohazard removal.

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.
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 Analyzer Technology

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

About CH Photometric Measurements

The CH 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	Reagent probe 1 aspirates the first reagent from reagent compartment 1 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	Reagent probe 2 aspirates the second reagent from reagent compartment 2 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.
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 CH 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 $\times 10^{-3}$). The analyzer collects the absorbance measurements every 9 seconds between the reagent probe 1 reagent dispense up to 5 minutes after the reagent probe 2 dispense. 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 CH Analyzer calculates photometric assays as follows:

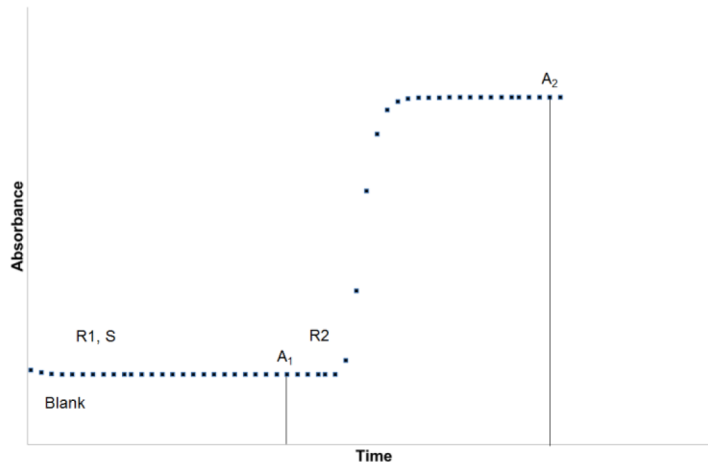
- Endpoint (Page 105 *About CH Endpoint Assay Calculation*)
- Rate (Page 107 *About CH Rate Assay Calculation*)
- 2-point (Page 106 *About CH 2-point Assay Calculation*)

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

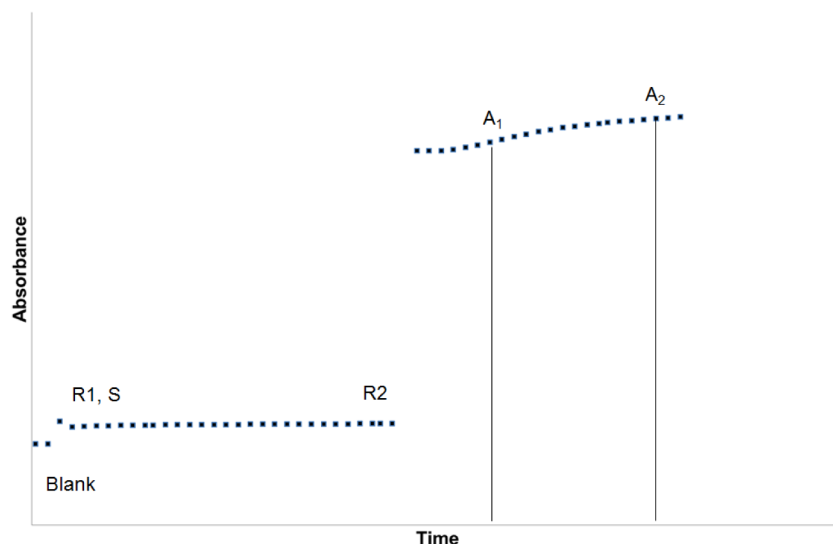
The endpoint assay measures absorbance after the reaction or color formation completes. For most endpoint assays, the analyzer collects 3 absorbance measurements and uses the median measurement in the calculated signal. This format can use a sample blank correction by measuring absorbance prior to the reagent probe 2 dispense. 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: reagent probe 1 addition
- S: sample addition
- R2: reagent probe 2 addition
- 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 reagent probe 2 dispense. 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.

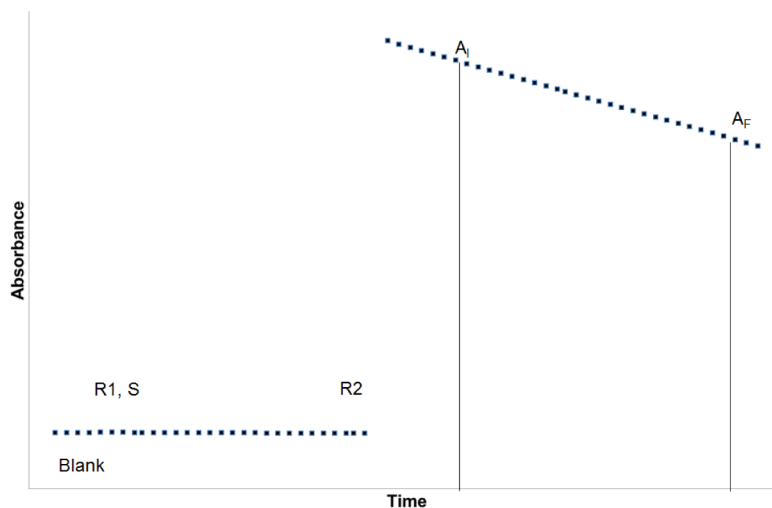


- Blank: cuvette water blank
- R1: reagent probe 1 addition
- S: sample addition
- R2: reagent probe 2 addition
- A1: first absorbance time point
- A2: second absorbance time point

About CH Rate Assay Calculation

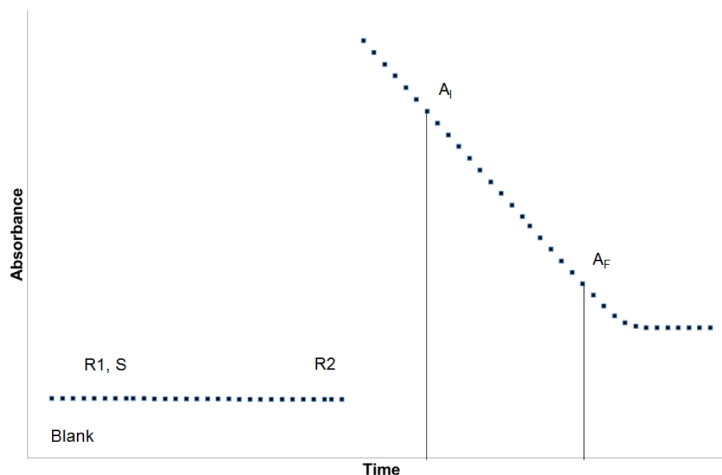
The rate assay measures absorbance as the reaction proceeds. The linear, zero-order reaction kinetics calculate the rate of absorbance versus time using a least-squares linear regression fit. The rate assay format can use a sample blank correction by measuring the change in absorbance versus time prior to the reagent probe 2 dispense. 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: reagent probe 1 addition
- S: sample addition
- R2: reagent probe 2 addition
- A_i : initial absorbance time point
- A_f : 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 Analyzer 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 IM 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

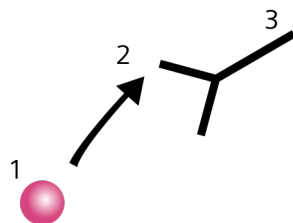
Immunoassay Technology References

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.
6. Kricka LJ. *Chemiluminescence immunoassay. The immunoassay handbook*. 1st ed. New York, NY: Stockton Press; 1994:341–343.

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

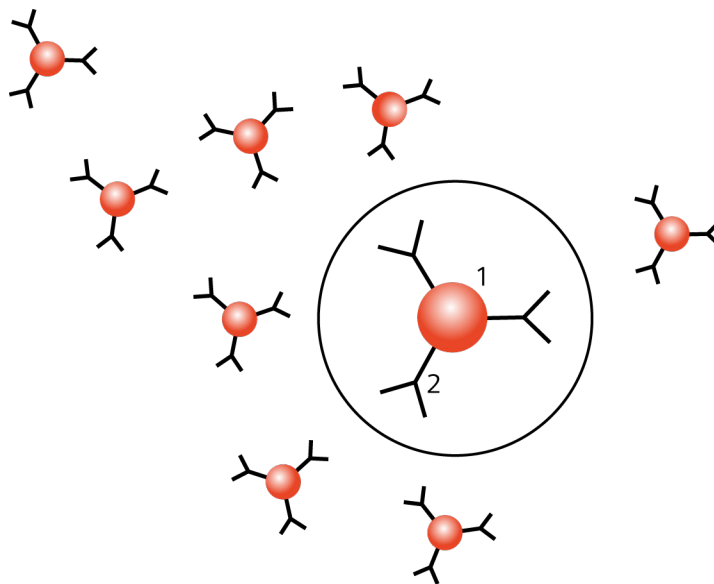
To measure antigen, IM assays use antibodies that are covalently bound to AE without altering the ability of the antibody to bind to an antigen.

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.

Free PMPs



-
- 1 PMP
 - 2 Antibody

Immunoassay Technology References

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

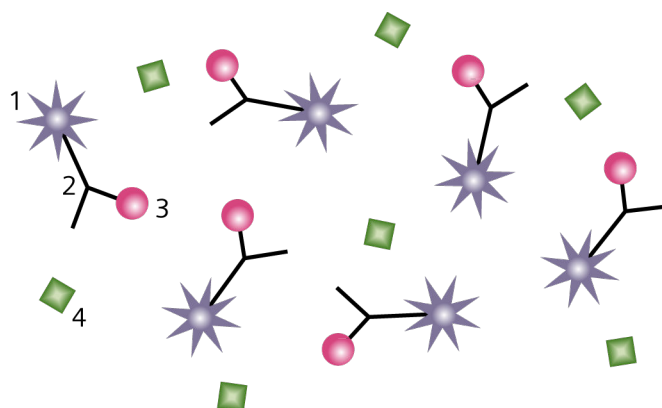
About IM Assays Sandwich Assay Complex Format

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

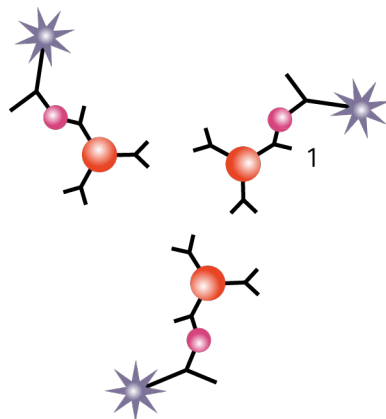


-
- 1 Acridinium ester (AE)
 - 2 Antibody
 - 3 Analyte-specific antigen in the sample
 - 4 Other antigens

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.

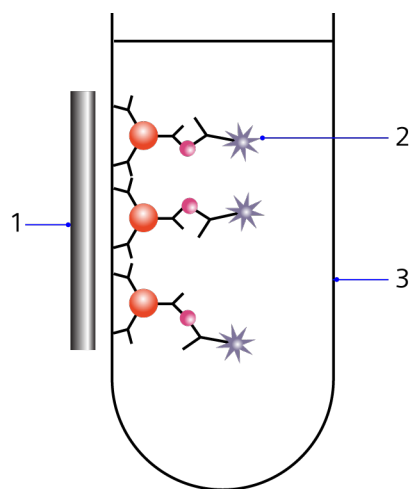
Sandwich complex assay format with Solid Phase



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

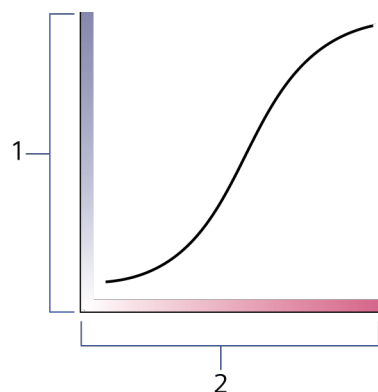


-
- 1 Magnets
 - 2 PMP-Antibody-Antigen-Antibody-AE complex
 - 3 Cuvette

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

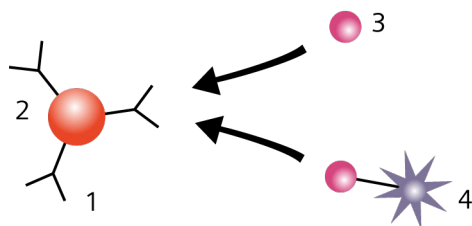
The IM Analyzer adds the following to the sample:

- 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.

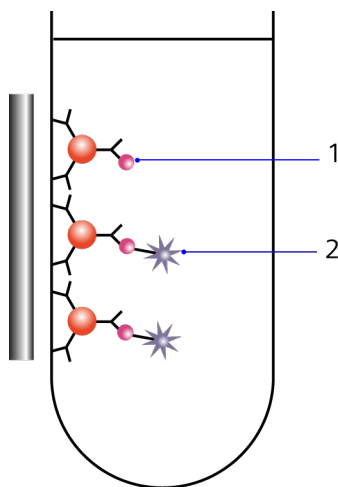
AE-labeled antigen



-
- 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

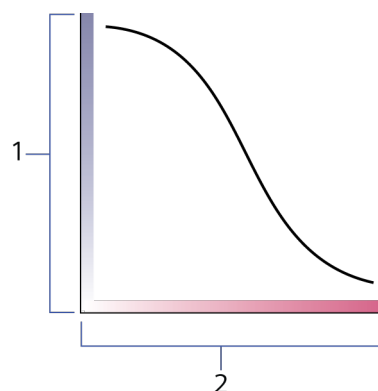
The IM Analyzer adds IM Acid and IM Base to initiate the chemiluminescent reaction and measures the emission of light in RLUs. The system quantitates the light the oxidation of AE produces and calculates the concentration of the analyte.

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

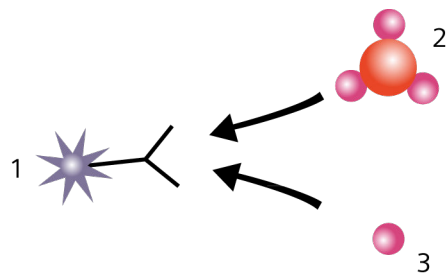
The IM Analyzer adds the following to the sample:

- 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.

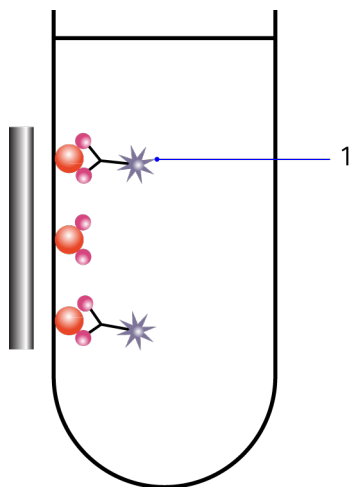
AE-labeled antibody



-
- 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

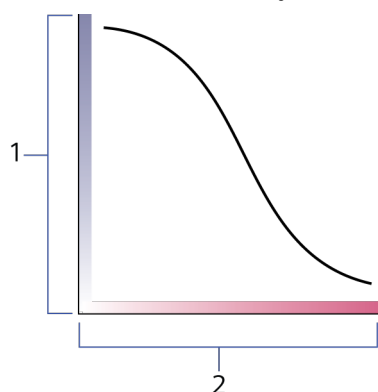
The system adds IM Acid and IM Base to initiate the chemiluminescent reaction and measures the emission of light in RLUs. The system quantitates the light the oxidation of AE produces and calculates the concentration of analyte.

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 IM Analyzer adds the following to the sample:

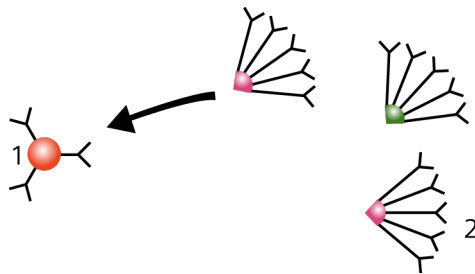
- Lite Reagent, containing AE-labeled antigen
- Solid Phase, containing anti-human IgG antibody or IgM antibody-labeled PMPs

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

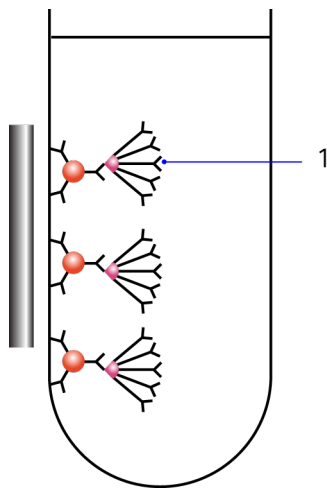


-
- 1 Anti-human IgM Antibody bound to PMP
 - 2 Human IgM Antibody in sample

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-IgM Antibody-IgM from the sample complex.

Antibody-capture Assay Format in the Cuvette

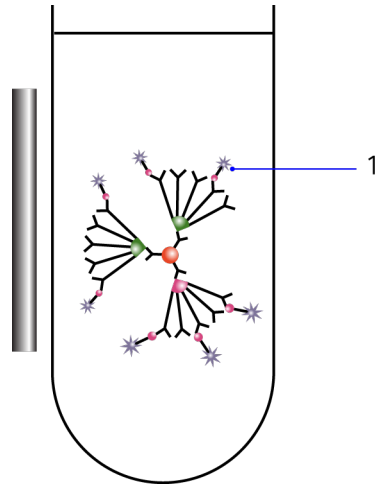


-
- 1 PMP-Anti-IgM Antibody-IgM complex

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.

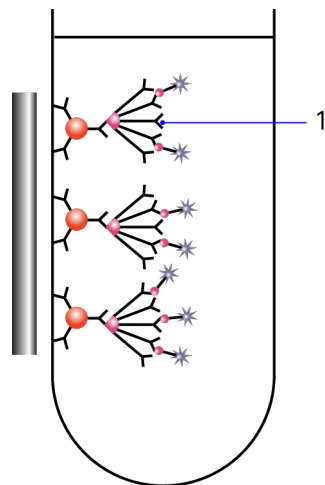
Antibody-capture assay format in the cuvette



1 AE-labeled antigen

The 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 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



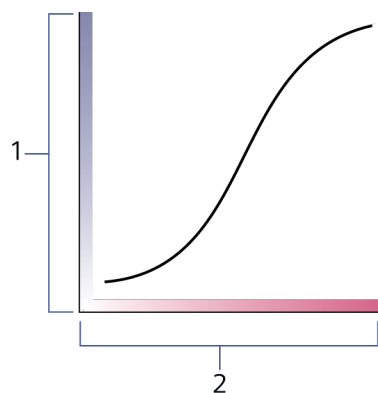
1 PMP-Anti-IgM Antibody-IgM-AE-labeled antigen complex

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.

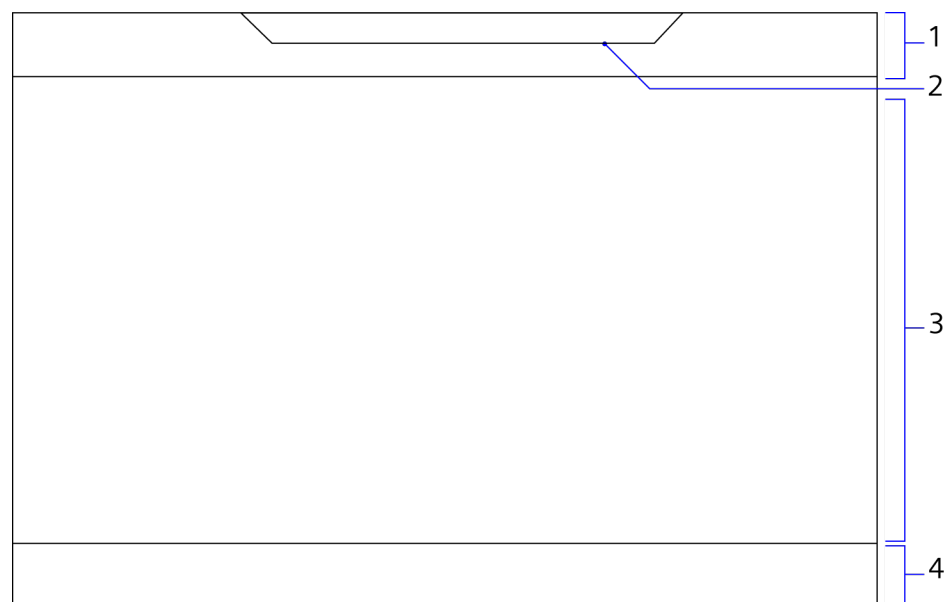
The analyzer utilizes the following result calculation formulas:

- 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

6 Software

Software Overview

The system uses 4 areas of the screen to access system functions and information.



- 1 Command bar
- 2 Alert module
- 3 Workspace
- 4 Status bar

The Command bar allows the operator to perform and manage laboratory activities.

The Alert module displays a summary of active system and module alerts.

The Workspace area contains task buttons and displays sample and system information.

The Status bar reports current system information and has selectable icons for quick access to system functions.

About the Command Bar

The Command bar provides access to system functions and information for performing and managing laboratory activities.

Each tab and subtab on the Command bar that has an associated alert displays red or yellow until the alert is resolved. The operator can determine which area is causing the alert by opening the appropriate tab and finding the colored line below a subtab. The operator can suppress specific alerts from displaying on the Alert Module, Command bar, System Overview, and Module Details. The associated Command bar tab does not display red or yellow for suppressed alerts.

Command Bar Icon	Notes
 System	Displays system and module status, access to logs, and diagnostic features.
 Samples	Tracks and manages patient, calibration, and control samples.
 Inventory	Displays and manages reagents and system supplies.
 Calibration	Creates and edits calibrator definitions and orders, accepts and rejects pending calibrations, and displays calibration details and status for reagent lots.
 QC	Creates QC orders, defines rules for monitoring QC tests, displays QC results, and accesses QC and QC profile definitions.
 Patient Orders	Creates, displays, and edits patient and batch orders.
 Worklist	Displays and accepts test results and performs additional result-related tasks.
 Maintenance	Schedules and creates maintenance procedures, monitors automated procedures, and displays a maintenance log of activities and alerts.

Command Bar Icon	Notes
 Setup	Displays test definition information and configures basic system operations.

About the System Status Display

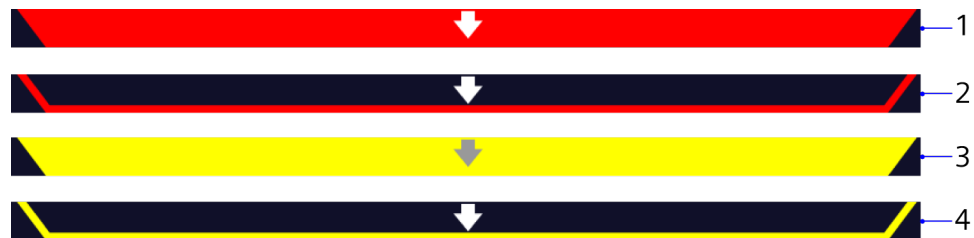
The System Status display provides an overall view of the system, each module, and the following information:

- An interactive glyph of each module in the system, the module name, and its status:
 -  indicates the System display.
 -  indicates the CH Analyzer display.
 -  indicates the IM Analyzer display.
 -  indicates the SH display.
 -  indicates the SHC display.
 -  indicates the Atellica Magline Transport display.
 -  indicates the Decapper display.
- All system alerts.
- Include the Module in System Alerts check box. When checked, the system displays module alerts on the System Overview and Module Details. The operator can uncheck the check box to display only module alerts on the specific Module Details.

About the Alert Module

The Alert Module displays all active module and system alerts. The operator accesses the Alert Module using the colored tab above the Command bar. The operator can filter alerts by selecting a Module or Category from the Alert Module.

The color of the Alert Module tab designates the status of system alerts:



1	One or more unacknowledged error system alerts.
2	Acknowledged errors. Error conditions still exist.
3	One or more unacknowledged warning system alerts.
4	Acknowledged warnings. Warning conditions still exist.

Each tab and subtab on the Command bar that has an associated alert displays red or yellow until the alert is resolved. The operator can determine which area is causing the alert by opening the appropriate tab and finding the colored line below a subtab.

The operator can suppress specific alerts that display on the Alert Module, System Overview, or Module Details screens.

NOTE: The system response to suppressed alert conditions remains the same and operators must continue to resolve the alert condition. 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 System Alerts

1. Above the Command bar, select the Alert Module colored tab.
2. To filter the alert list, select a Module or Category.
3. To view system alerts from the System Overview, on the Command bar, select **System > Status**.
4. Select .
5. To include module alerts on the System Overview, select the Include the Module in System Alerts check box.

NOTE: Suppressed alerts do not display on the System Overview or Module Details.

Responding to System Alerts

1. On the Command bar, select **System > Status**.

2. Ensure that the System Status displays (Page 125 *Changing the Module on the Status Display*).
3. To acknowledge all alerts, select **Acknowledge System Alerts**.
4. To access troubleshooting information for a specific alert:
 - a. Select the alert.
 - b. Select .

Viewing Module Status

1. On the Command bar, select **System > Status**.
2. Select a module.

About Communications

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

Changing the Module on the Status Display

1. On the Command bar, select **System > Status**.
2. Select the appropriate module glyph.

Changing the Module Status

1. On the Command bar, select **System > Status**.
2. Select the appropriate module.
3. Change the module state by selecting:
 -  to shut down the module
 -  to stop processing
 -  to pause sample processing
 -  to resume sample processing

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
- Capabilities and status of the following components:
 - Carriers
 - Atellica Magline Transport
- 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

- Capabilities and status of the following components:
 - Robot
 - TCS
 - Cal-QC Storage
 - Cal-QC Storage Temperature
 - Front Cover
 - Back Cover
 - Drawers
- 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
- Capabilities and status of the following components:
 - Robot 1
 - Robot 2
 - TCS
 - LAS
 - 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 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
- Capabilities and status of the following components:
 - Cap Waste Bin
 - Cover
 - Assembly
- Alerts specific to the Decapper with the category and time for each

About the CH Analyzer Status

The CH Status displays:

- Name and type of analyzer
- Activity or transition state
- Date and time of the last analyzer status update
- Timespan until the state transition completes
- Communication status
- If not connected to the PCC, the date and time of the last connection to the PCC
- Analyzer control buttons
- Status of critical System Capabilities and associated alerts
- Controls that allow the operator to lock and unlock the following covers:
 - Front Cover
 - Back Cover
- General analyzer Alerts with the Category and Time for each
- Patient Sample Processing check box indicating whether the module is processing patient samples.

About the IM Analyzer Status

The IM Status displays:

- Name and type of analyzer
- Activity or transition state
- Date and time of the last analyzer status update
- Timespan until the state transition completes
- Communication status
- If not connected to the PCC, the date and time of the last connection to the PCC
- Analyzer control buttons
- Status of critical System Capabilities and associated alerts
- Controls that allow the operator to lock and unlock the following covers:
 - Front Cover
 - Back Cover
- General analyzer Alert with the Category and Time for each
- Patient Sample Processing check box indicating whether the module is processing patient samples.

About Log Files

The operator can access the following log files:

- Operator Event Log
- System Message Log
- LIS Logs
- LAS Logs
- Audit Trail Log

About the Operator Event Log

The Operator Event Log displays all system events as the events occur. By default, the log lists the most recent events in reverse chronological order.

The following features are available on the Operator Event Log:

- Filter... for locating specific events.
- Unacknowledged and Corrective Action categories to provide a breakdown of these events by module.

- Export... to save the log file in a spreadsheet.
- Acknowledge All to address any events that do not have corrective action.
- Comments to add information to a specific event.
- Event Help to provide details about the event (Page 461 *About Event Help*).
- Completed to close the event when a corrective action is complete.
- System Details to view the Configuration Change Log.

Operator Event Log	Notes
Severity	The severity of the event.  designates errors.  designates warning events. Events that are for information only do not show a severity indicator.
Module	The module name or serial number on which the event occurs.
Code	A unique number the system assigns to the event.
Event	A description of the event.
Date	The date and time when the event occurred.

Reviewing the Operator Event Log

1. Select **Troubleshooting > Operator Event Log**.
2. Filter events by time, module, type, or all.
3. Select an event.

NOTE: Detailed information for the selected event displays at the bottom of the workspace.
4. Review the event, possible causes, corrective actions with procedures, and perform as appropriate.
5. Resolve or acknowledge events, as appropriate.

Reviewing Operator Events

1. On the Command bar, select **System > Logs > Operator Event Log**.
2. Select an event.
NOTE: Detailed information for the selected event displays at the bottom of the workspace.
3. Select **Event Help**.
4. Review the event, possible causes, corrective actions, and corrective action procedures, and perform corrective action procedures as appropriate.
5. Resolve or acknowledge events, as appropriate.

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 Logs

The LIS Logs tab 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 Logs. The operator must turn Capture ON to collect information for LIS Logs.

Viewing LIS Logs Messages

- ◆ On the Command bar, select **System > Logs > LIS Logs**.

About the Audit Trail Log

This feature requires the appropriate security level.

The Audit Trail Log displays all operator actions that affect patient health information and modify assay test definitions or system configurations as well as other auditable system activities. The entries in the log are in ascending or descending order by Date. Each entry includes the following information:

Column header	Notes
Category	The functional area associated with the entry. NOTE: The Audit Trail Filter provides a listing of all functional areas.

Column header	Notes
Operator ID	The operator who performed the auditable action. NOTE: When the system performs the action, such as confirming the contents of the Cal-QC Storage Area, the Operator ID is the System.
Group	The group the operator belongs to (Page 575 <i>About Groups on the Accounts Tab</i>). If the Operator ID is the system, the Group is blank.
Date	The Date and time of the auditable action.
Message	Additional details about the entry.

The operator can use the Filter... to view a subset of the entries. The  and  glyphs indicate whether the log is displaying all entries or a filtered subset:

Status	Notes
	The Audit Trail Filter is clear. All audit trail entries are visible on the log.
	The Audit Trail Filter is active. The log only displays entries that meet the currently specified criteria and display to the right of the glyph.

The operator can also use the Find feature to locate entries with specific text.

The Audit Trail Log has a capacity of 60,000 entries. When it 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.

Viewing the Audit Trail Log

This task requires the appropriate security level.

1. On the Command bar, select **System > Logs > Audit Trail Log**.
2. To view only entries that meet specific criteria, filter the log.
3. To search for specific text, use the Find feature.
4. To sort the entries in the reverse chronological order, select the Date column header.

5. To view entries longer than 10 lines, select **More...** in the Message field.

About Exporting Log Files

This feature requires the appropriate security level.

The system encrypts all patient health information when exporting log files. The operator creates a password to protect the files during export and uses this same password to view the files after exporting the files.

About Operator Diagnostics

Operator Diagnostics allows the operator to manually manipulate the analyzer 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 analyzer 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	Notes
Subsystems	Filters the diagnostic procedures according to CH or IM analyzers.
Diagnostic Name	Displays the subsystem task.
Description	Describes the subsystem task.
Perform	Starts the selected diagnostic task.
Status	Re-displays an IM Analyzer diagnostic task progress window that is closed.
Enter Diagnostics	Enters the analyzer 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	Engages all IM Analyzer mechanical components.
Turn Mechanics Off	Disengages all IM Analyzer mechanical components.

Enter Diagnostics State in CH Operator Diagnostics

1. Perform 1 of the following, as appropriate:
 - On the system Command bar, select **System > Operator Diagnostics**
 - On the application Dashboard, select **Troubleshooting > Diagnostics**
2. Select the appropriate CH Analyzer.
3. Select **Enter Diagnostics > Yes**.
4. Wait for analyzer to enter diagnostic state.

Enter Diagnostics in IM Operator Diagnostics

1. Perform 1 of the following, as appropriate:
 - On the system Command bar, select **System > Operator Diagnostics**
 - On the application Dashboard, select **Troubleshooting > Diagnostics**
2. Select the appropriate IM Analyzer.
3. Select **Enter Diagnostics**.
4. Wait for analyzer to enter diagnostic state.

Entering Diagnostics State in SH Operator Diagnostics

1. On the Command bar, select **System > Operator Diagnostics**.
2. Select the appropriate SH.
3. Select **Enter Diagnostics**.
4. Select **Yes**.
5. Wait for the SH to enter the diagnostics state.

Entering Diagnostics State in Atellica Magline Transport Operator Diagnostics

1. On the Command bar, select **System > Operator Diagnostics**.
2. Select **VMM**.
3. Select **Enter Diagnostics**.
4. Select **Yes**.
5. Wait for the Atellica Magline Transport to enter the diagnostics state.

Entering Diagnostics State in SHC Operator Diagnostics

1. On the Command bar, select **System > Operator Diagnostics**.
2. Select the appropriate SHC.
3. Select **Enter Diagnostics**.
4. Select **Yes**.
5. Wait for the SHC to enter the diagnostics state.

About the Software Information and System Information Tabs

The operator can view the System About tab to access software and hardware information when troubleshooting the system during a service call.

The Software Information tab displays the software and other tools the system uses and the corresponding versions. For more information, see Atellica® Solution Software Copyright Information.

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

About the Status Bar

The Status bar on the bottom of the screen contains current system information and icons for quick access to functions.

Information on the Status bar includes:

- The ID of the active operator
- The current date and time

Status Bar Icon	Notes
 Online Help	Displays online help.
 PEPconnect	Connects to the Personal Education Portal.
 Print	Prints the workstation screen.

Status Bar Icon	Notes
 Quick Find	Searches for a specific patient or QC result.
 Keyboard	Displays an on-screen keyboard for text input.
 Deactivated keyboard pop-up	Indicates the on-screen keyboard is deactivated.
 File Manager	Accesses folders containing archives, back-ups, and exports, and manages data transfer to USB.
 Sign Out	Locks or signs the operator out of the system.
 Atellica Process Manager (APM)	Indicates the system is communicating and sending updates to the APM.
 Operator control of the APM	Indicates the operator at the APM is remotely connected and controlling the system.
 Connected Technical Support	Indicates that there is a remote session active with remote support. In addition, the system transfers data to remote service for condition-based maintenance alerts.
 Disabled Technical Support	Indicates that Remote Service is disabled.

Status Bar Icon	Notes
 Enabled Technical Support	Indicates that Remote Service is enabled, connected, and pushing data for remote diagnostics monitoring. The operator can initiate a remote session or submit a ticket for assistance.
 No Ticket Technical Support	Indicates that the system can communicate with Remote Services but the operator must call technical support to log a ticket.
 Technical Support Warning	Indicates the system cannot communicate with Remote Services. The operator should check network connections, LCM server status, and LCM server proxy to the internet to troubleshoot.
 Minimized Technical Support	Indicates the system is creating a Service Support Request and the Remote Services window is minimized. The operator can select the icon to reopen the window.
 Laboratory Information System (LIS)	Displays or changes the current status of the LIS connection and performs diagnostics.
 Disconnected LIS	Indicates the LIS is disconnected.
 Connected LIS	Indicates the LIS is connected.
 Dashboard	Displays a summary of samples, tests, and their status.
 Volume	Adjusts the volume of the system alerts.

Status Bar Icon	Notes
 Volume Muted	Indicates muted system volume.
 Watch List	Displays a list of STAT and other samples the operator specifies as the Watch List.

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 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 Status bar.

The Help icon  on the Status bar is accessible from every tab and is context sensitive. Selecting  accesses links to help topics specific for that area and the table of contents (TOC) for the entire online help package.

An additional Help icon  on the bottom left of some windows opens help topics specific to that window.

Accessing Online Help

1. On the Status bar, select .
2. To view related help topics, select the appropriate topic from the Table of Contents on the right side of the window.

About PEPconnect

PEPconnect allows the operator to access the Personal Education Portal, the education and performance support experience that includes product-specific content for initial training and ongoing operations. Connection to this feature occurs during product install. The operator can select  on the Status bar to access PEPconnect.

Printing Reports

1. On the Status bar, select .
2. If appropriate, set Print Options.
3. Select **OK**.

About the Status Bar Quick Find

The  on the Status bar allows the operator to search for patient or QC results 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. The Active database contains current orders not yet in Historical. The Historical database contains past records that cannot be changed.

About LIS Communication Status

LIS Communication allows the operator to connect or disconnect from the LIS, perform diagnostics on the LIS Communication status, and respond to LIS connectivity messages.

About the Dashboard

The Dashboard displays the number of ordered samples in each state and the total number of tests in each state. The Dashboard also displays alerts if Critical Results, STAT, or ASAP samples are present.

The current numbers of orders and tests in their respective states update in real time. The number of each type of sample (patient, control, or calibrator) and the status of each ordered test also update in real time. The system removes deleted samples or tests from the count.

If more than 1 alert occurs in the indicated sample state or test state, the dashboard shows only the highest priority counter.

The operator can filter the records displayed by Time, Sample Type, and Analyzer.

Viewing STAT Sample Status on the Watch List

- ◆ On the Status bar, select .

Cybersecurity Glyphs

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

Glyph	Notes
	Indicates that the filter is clear.
	Indicates that the operator has applied a filter.
	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 a sortable column.
	Searches in the ascending direction.
	Searches in the descending direction.
	Provides a calendar to use in selecting a date.
	Indicates a warning.
	Indicates that online help is available for the window.
	Signs in or signs out an 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 518 *Contacting Local Technical Support*). 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 131 *About the Audit Trail Log*).

About Operator Sessions

An operator session is the total time that an 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 141 *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 476 *Signing out of the System*) (Page 143 *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 131 *About the Audit Trail Log*).

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 that the system can be idle can range from 1–1440 (or 24 hours). When the number of minutes elapse, the system displays the Lock window.

The Lock window indicates that all data is hidden and the system is secure from unauthorized access.

NOTE: Laboratories can also disable the Automatic Screen Lock.

The Lock window 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 143 <i>Unlocking the Screen</i>).
Change Operator	Enables a different operator to sign in to the system. The current operator session ends and a new session begins (Page 143 <i>Changing the Operator of Locked Screens</i>). NOTE: The system discards any unsaved data before the new session begins (Page 141 <i>About Operator Sessions</i>).

NOTE: Operators can also manually lock the system (Page 143 *Locking the Screen*).

About Manually Locking the Screen

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

The Lock window 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 143 <i>Unlocking the Screen</i>).

Option	Notes
Change Operator	Enables a different operator to sign in to the system. The current operator session ends and a new session begins (Page 143 <i>Changing the Operator of Locked Screens</i>). NOTE: The system discards any unsaved data before the new session begins (Page 141 <i>About Operator Sessions</i>).

Locking the Screen

1. On the Status bar, select .
2. Select **Lock**.

Unlocking the Screen

1. Select **Unlock**.

NOTE: The current operator can unlock the screen by selecting **Unlock** and entering their credentials. A new operator can unlock the screen by selecting **Change Operator** and entering the appropriate credentials.
2. Enter the Password.
3. Select **Unlock**.

Changing the Operator of Locked Screens

1. At the Lock window, 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 144 *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 4–20 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. Operators must be a member of the G1 Group to enter the PHI key (Page 575 *About Groups on the Accounts Tab*).

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.

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 will also be unavailable.



CAUTION

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

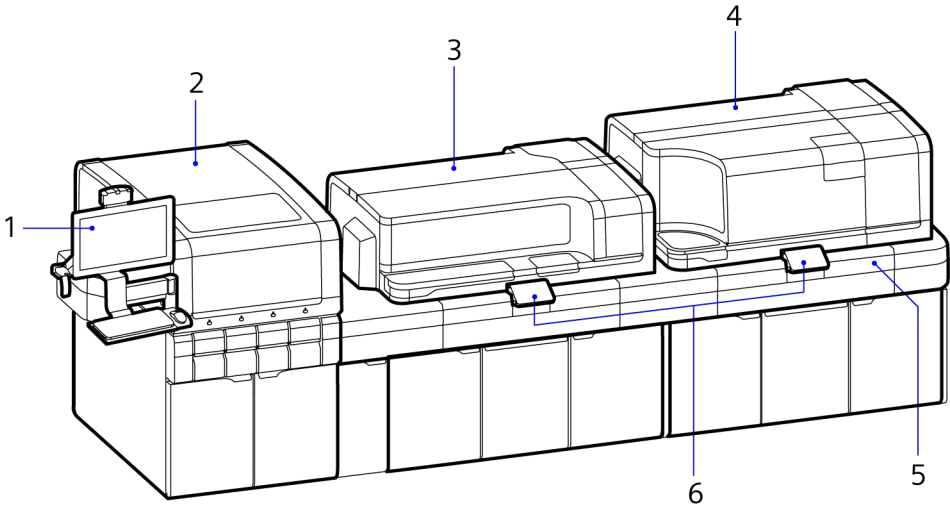
The system enables operators in the G1 Group to change the PHI key (Page 575 *About Groups on the Accounts Tab*).

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

7 Hardware

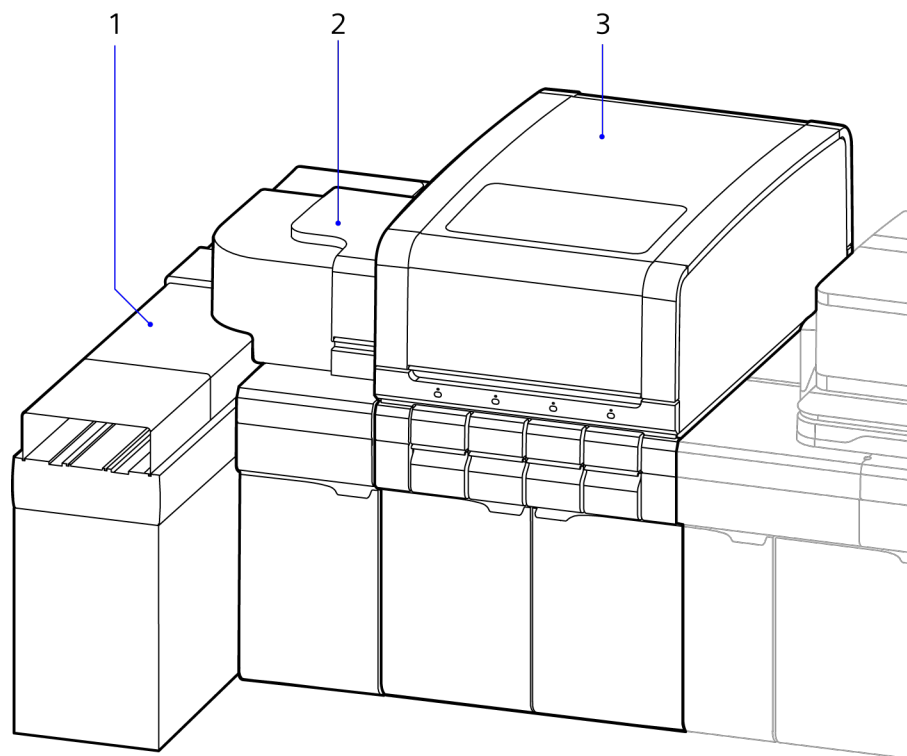
About the Atellica Solution with Sample Handler

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



- 1LAS
- 2SHC
- 3SH

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 stand-alone 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	Operators uses 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.
Smart Remote Services (SRS)	Service that allows operator to obtain remote troubleshooting help.

Feature	Notes
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 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

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 into each tablet and system display simultaneously, with different or the same credentials.

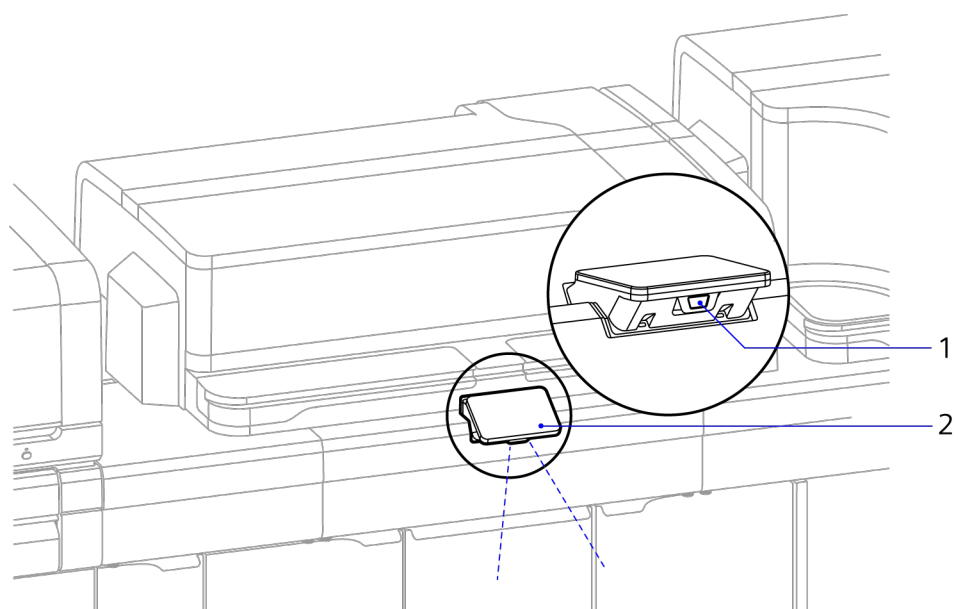
NOTE: The maximum distance the operator can be from the system depends on the effective range of the system Wi-Fi signal.

About 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 473 *About Emergency Sample Load Mode*).



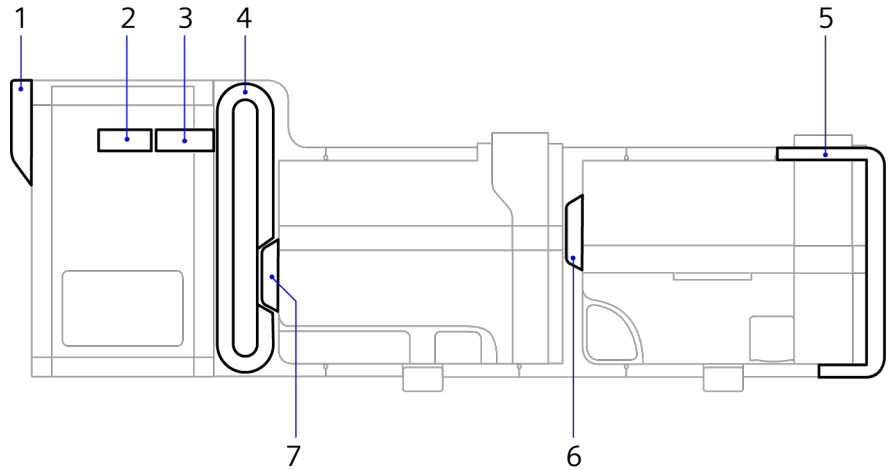
-
1	Barcode reader
2	Module display
-

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 154 *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 Carriers

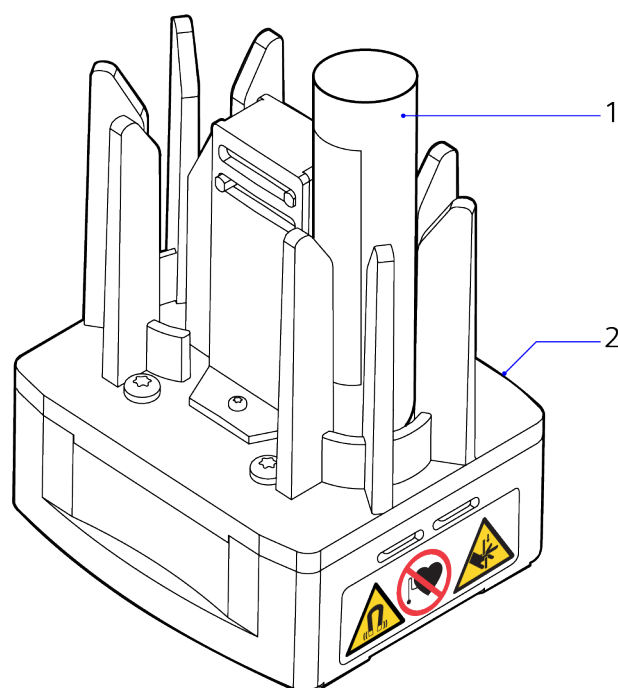
The system uses carriers to transport patient samples, calibrators, and QC materials between the SH and the analyzers on the Atellica Magline Transport.

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:



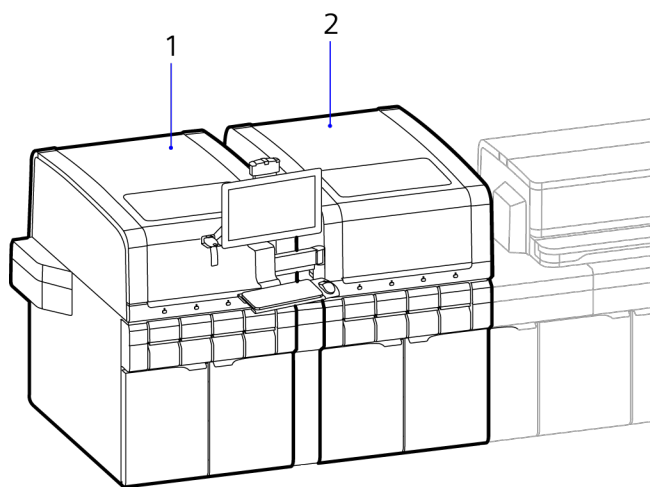
-
1	Sample container
2	Carrier
-

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 SHs with each SH capable of processing up to 500 samples per hour.

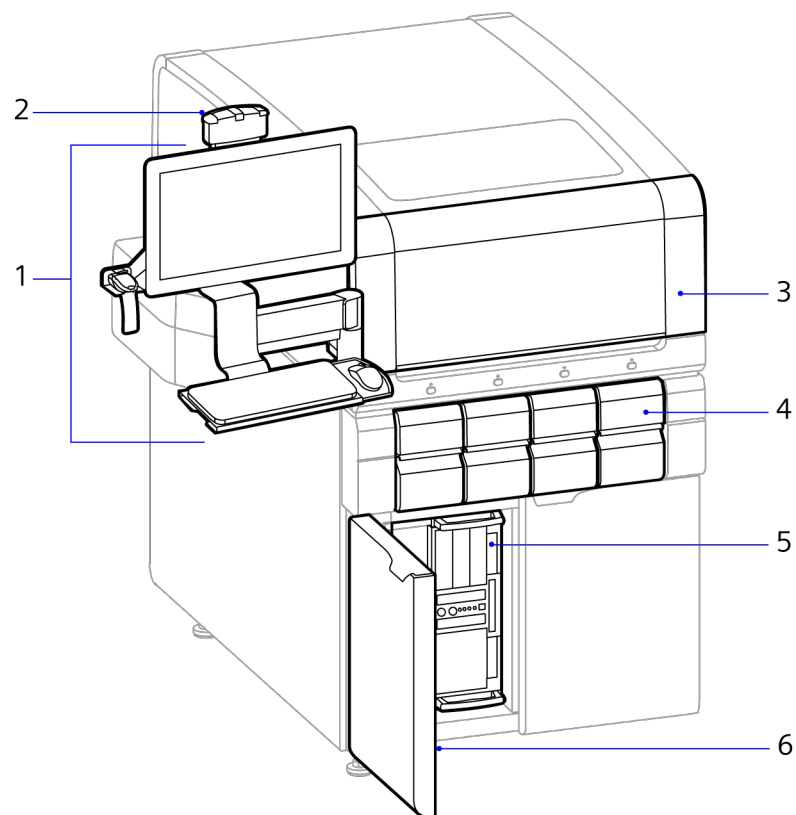
When a system is equipped with 1 SH, that SH is referred to as SH Prime and includes the Process Center Computer (PCC) and system display. When equipped with more than 1 SH, the SH with the PCC and system display is the SH Prime and any other SH is an SH Additional.



-
1	SH Additional
2	SH Prime
-

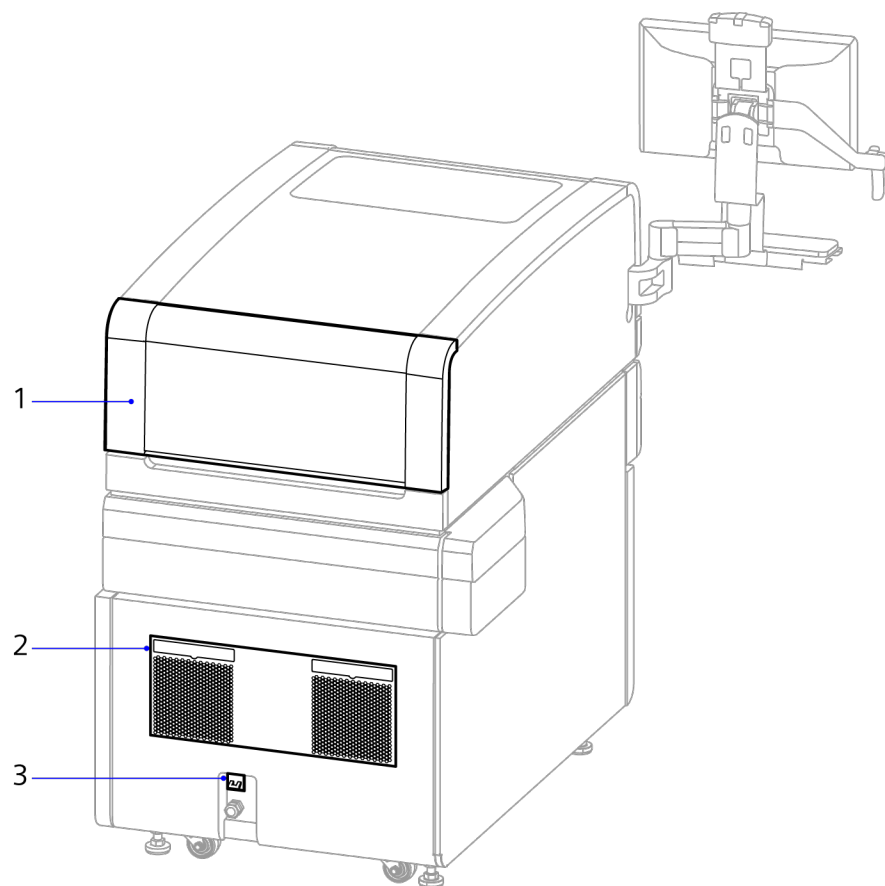
The SH front and back covers lock during normal operation. To open the front or back cover, the operator requests to unlock the cover from the system display or operator tablet. After the operator unlocks and opens the cover, the system removes power from the SH robot so it cannot move. After the operator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

SH (front view)



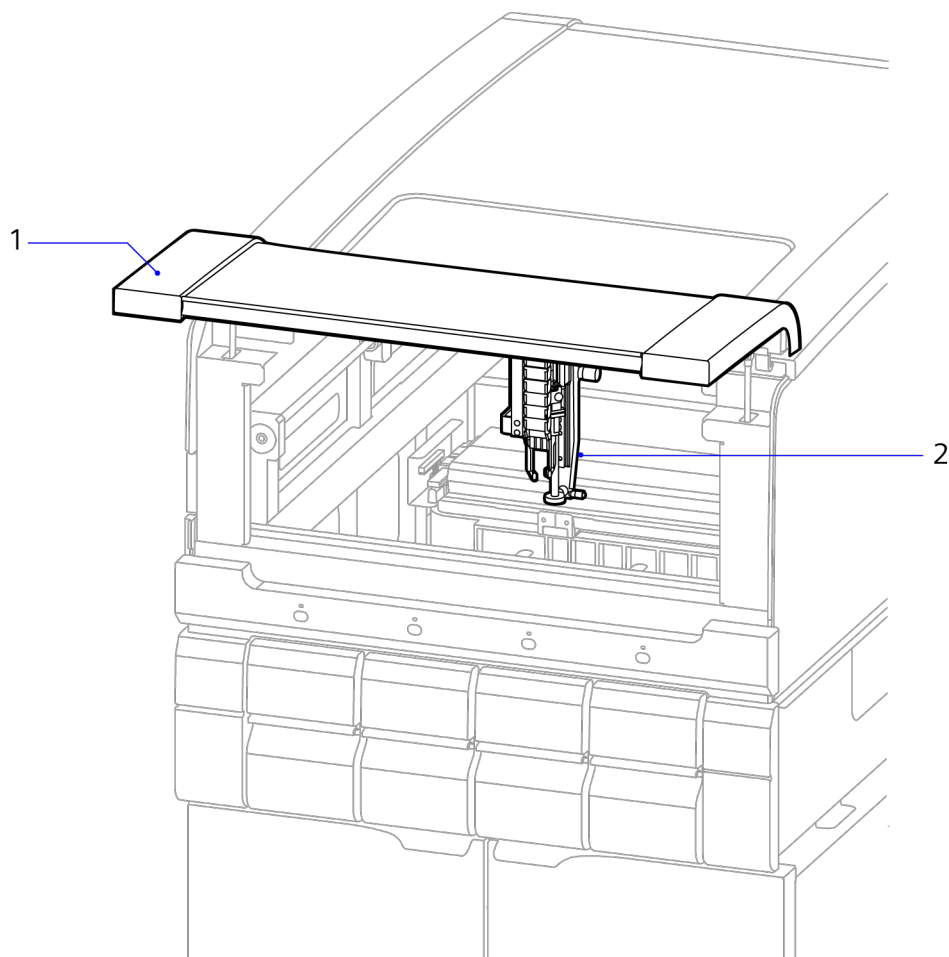
1	System display	4	Sample drawers
2	Visible status light	5	PCC
3	Front cover	6	PCC door

SH (back view)



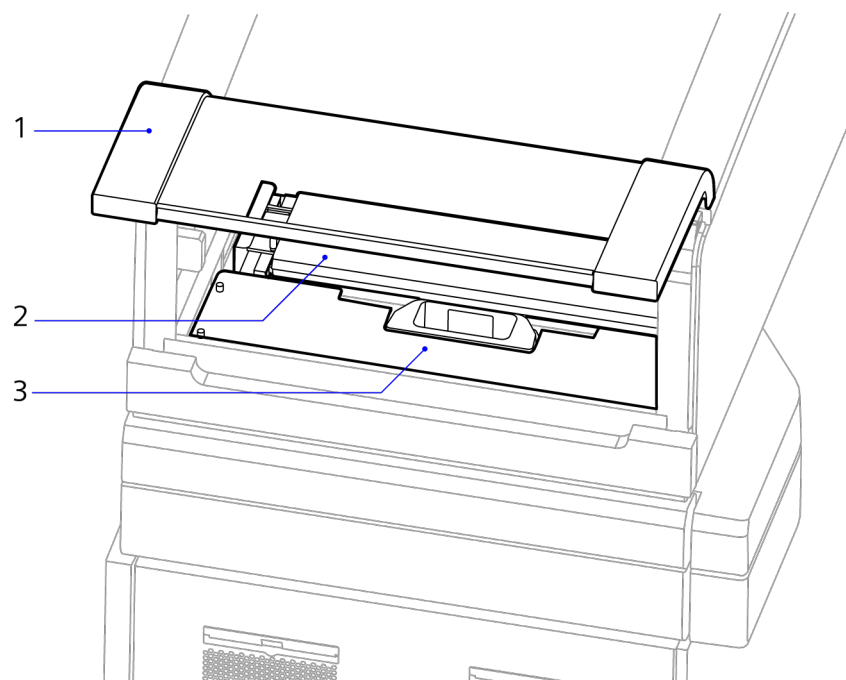
-
1	Back cover
2	Air vents
3	Main power switch
-

SH (inside front view)



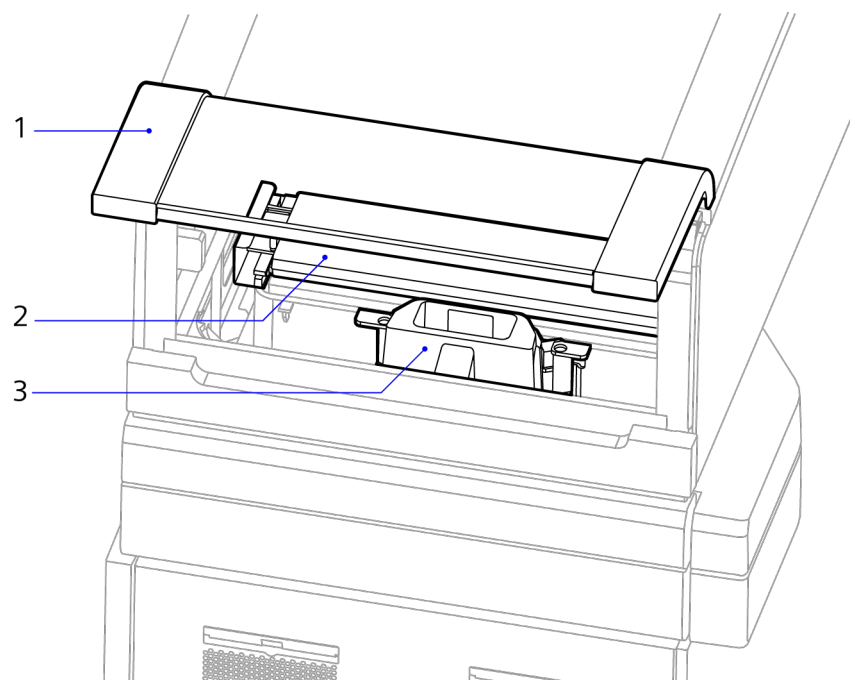
-
1	Front cover
2	Robot
-

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)

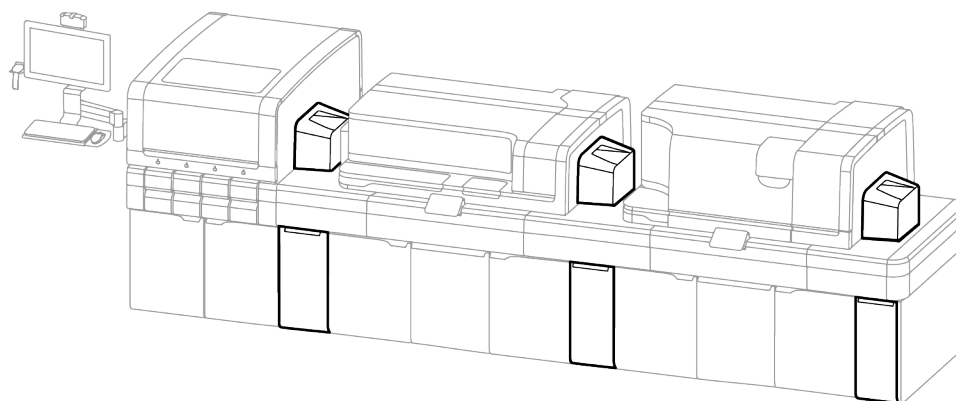


-
1	Back cover
2	Cal-QC storage area
3	Tube Characterization Station (TCS)
-

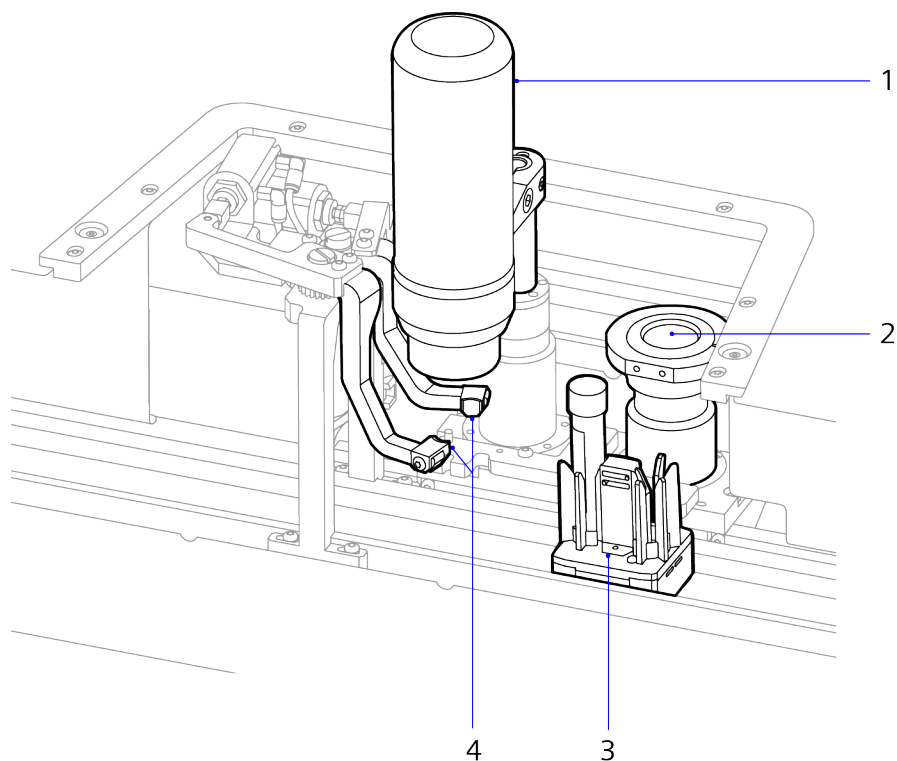
About the Decapper Module

The Decapper module removes and discards caps from all approved sample containers (Page 618 *About Supported Sample Containers*).

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

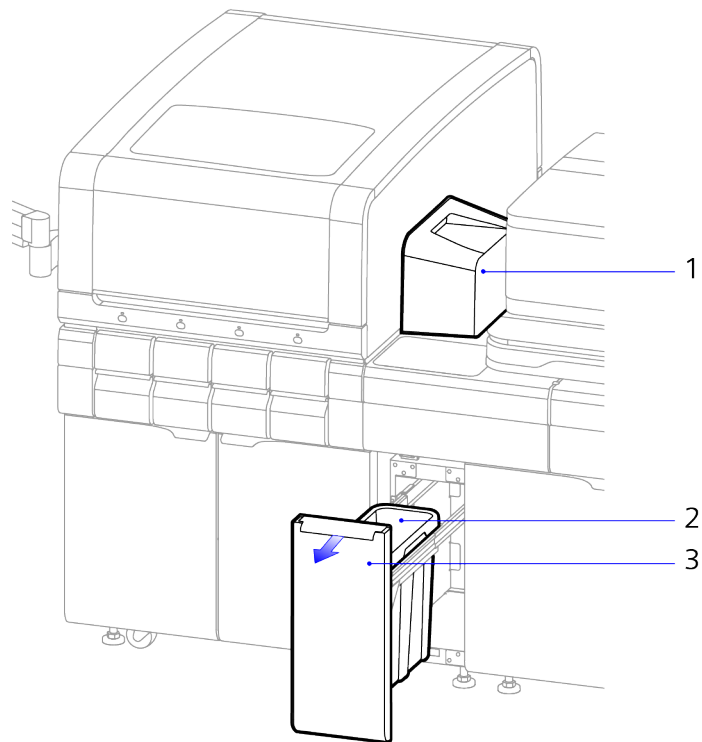


The sample carrier approaches the Decapper and stops. Sample tubes that do not require decapping are diverted and bypass the Decapper. If the sample tube requires decapping, the diverter opens and the carrier moves to the Decapper module.

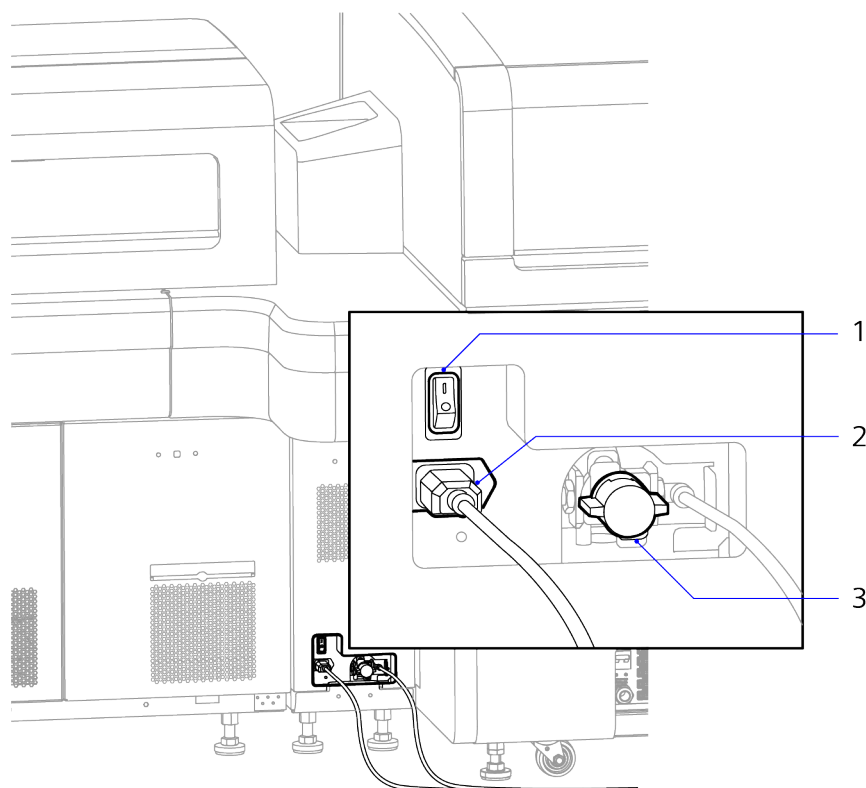


-
1	Cap remover
2	Cap waste chute
3	Sample tube in carrier
4	Tube gripper
-

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 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.



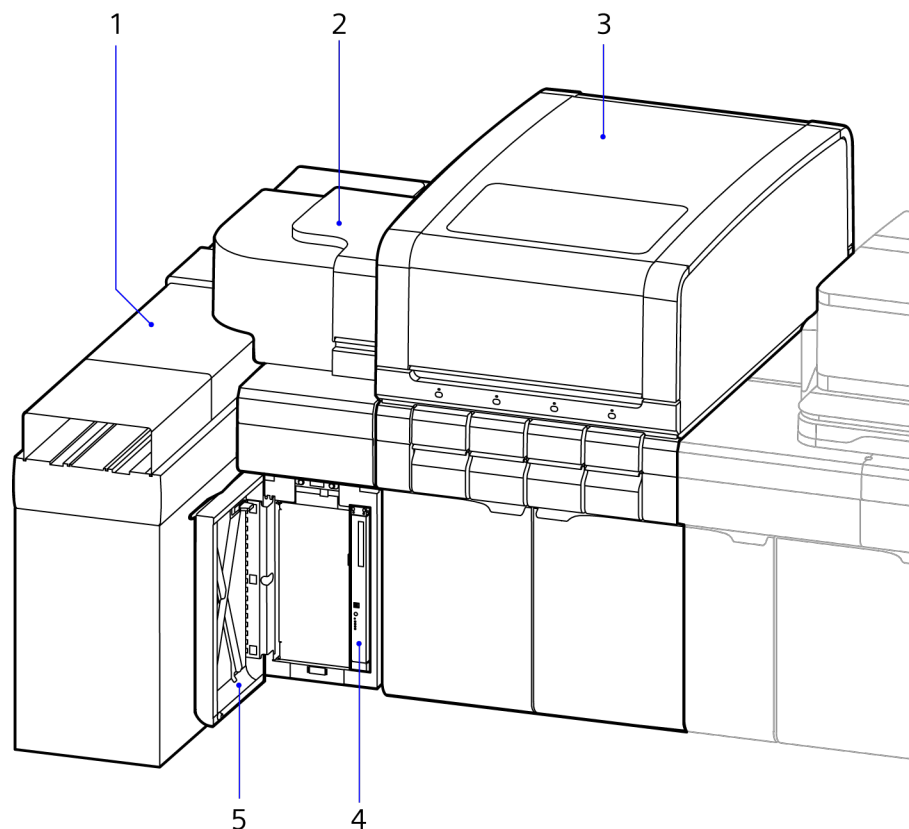
CAUTION

Be careful when opening or working around the open SHC front cover. 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.

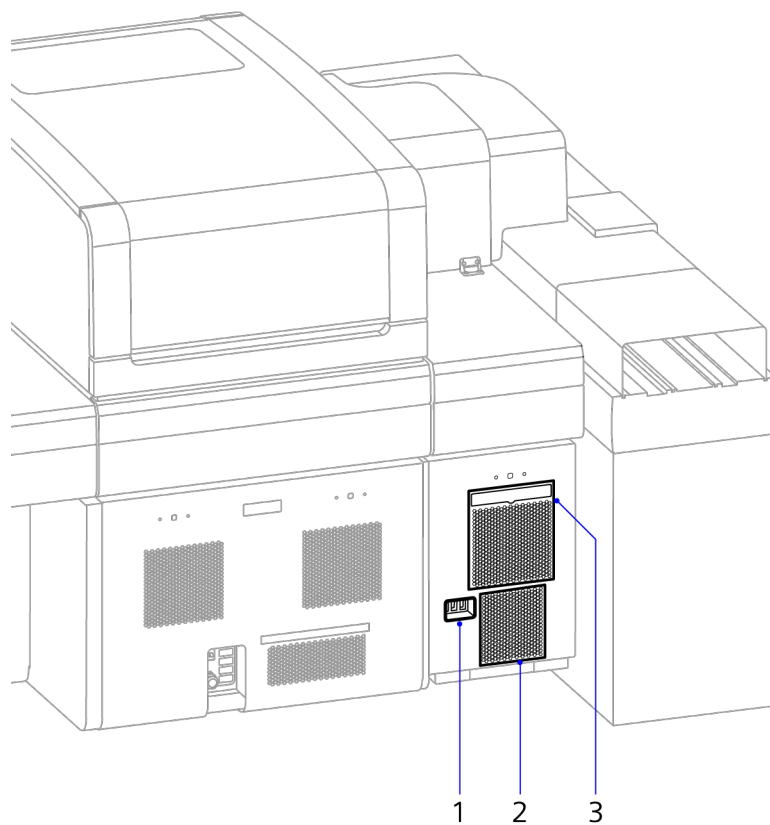
SHC (front view)



- 1 LAS track
- 2 SHC
- 3 SH (primary user interface not shown)

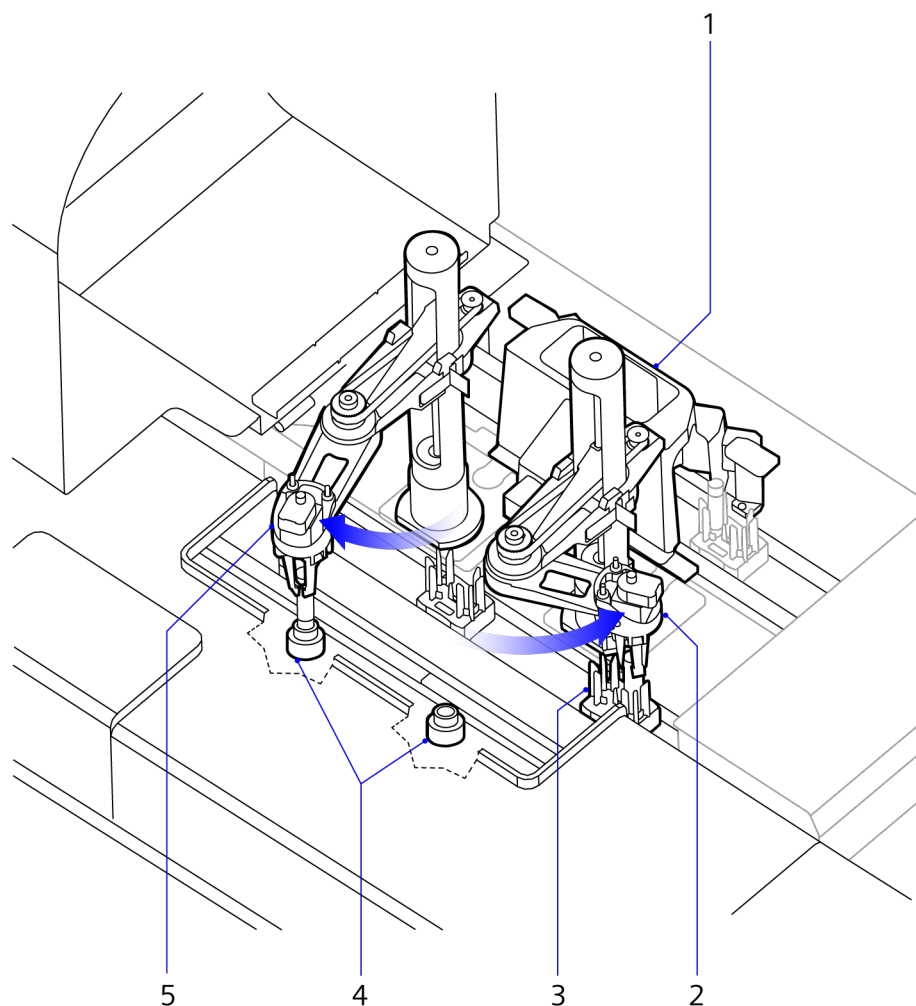
- 4 SHC computer
 - 5 SHC computer access door
-

SHC (back view)



-
- 1 Main power switches
 - 2 Air vent
 - 3 Fan filter
-

SHC (inside view)

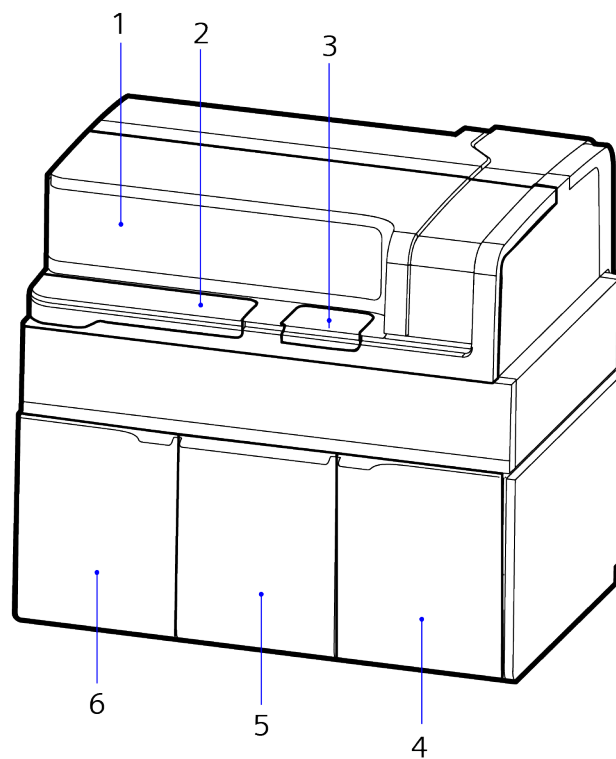


-
1	SHC TCS
2	Robot 1 (input robot)
3	Atellica Magline Transport carrier
4	LAS puck
5	Robot 2 (output robot)
-

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.

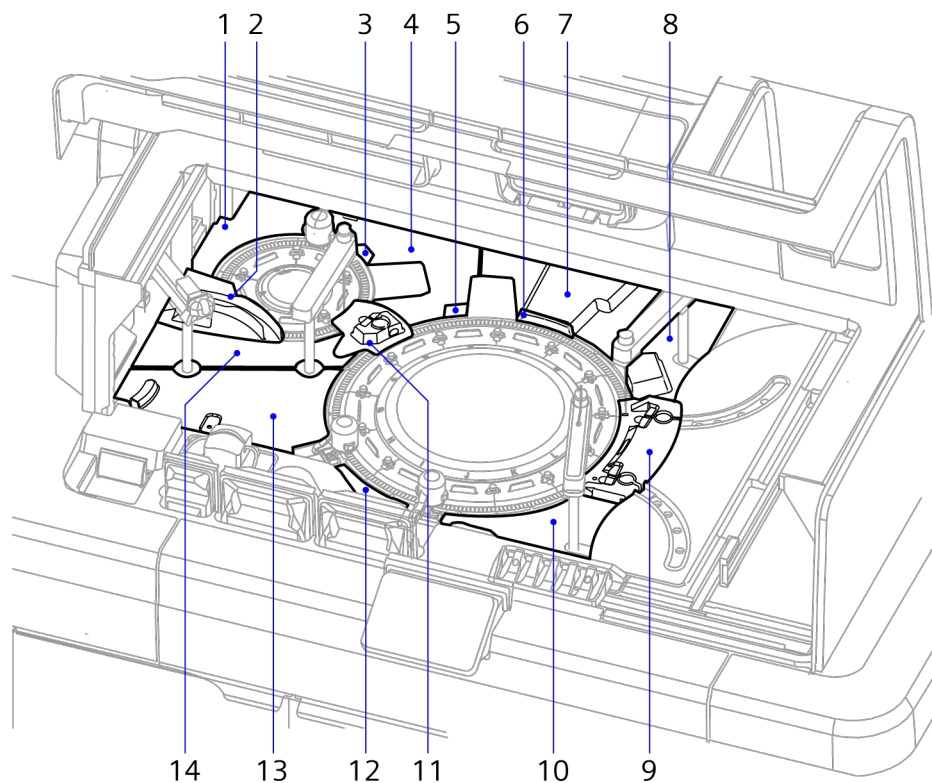
CH front with covers closed



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.

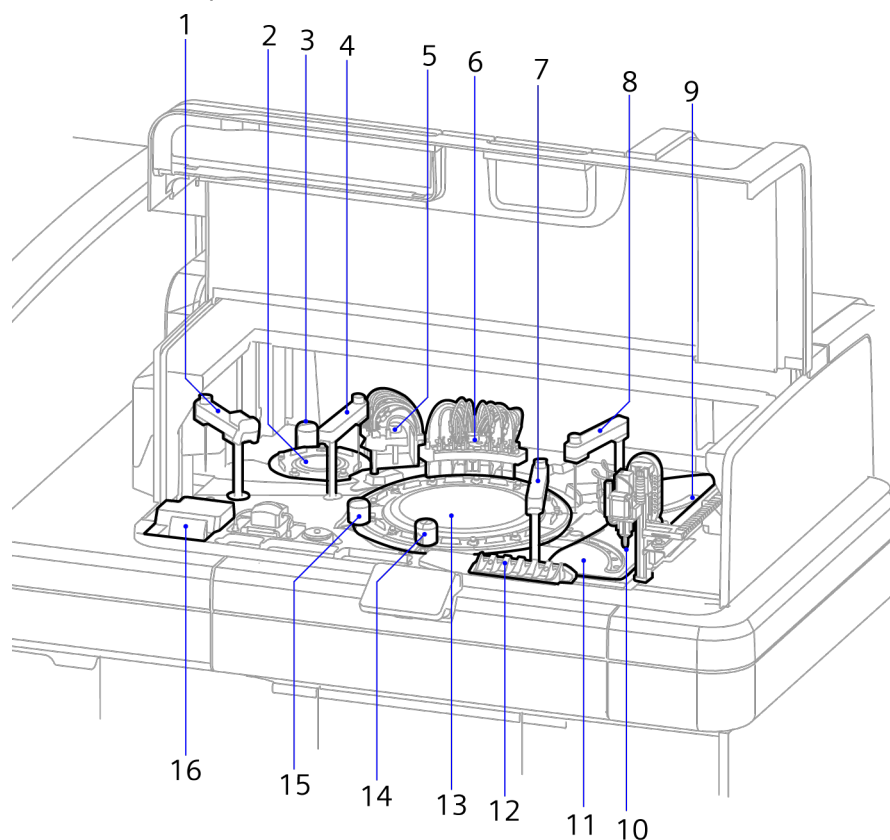
CH plates from front with cover open



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

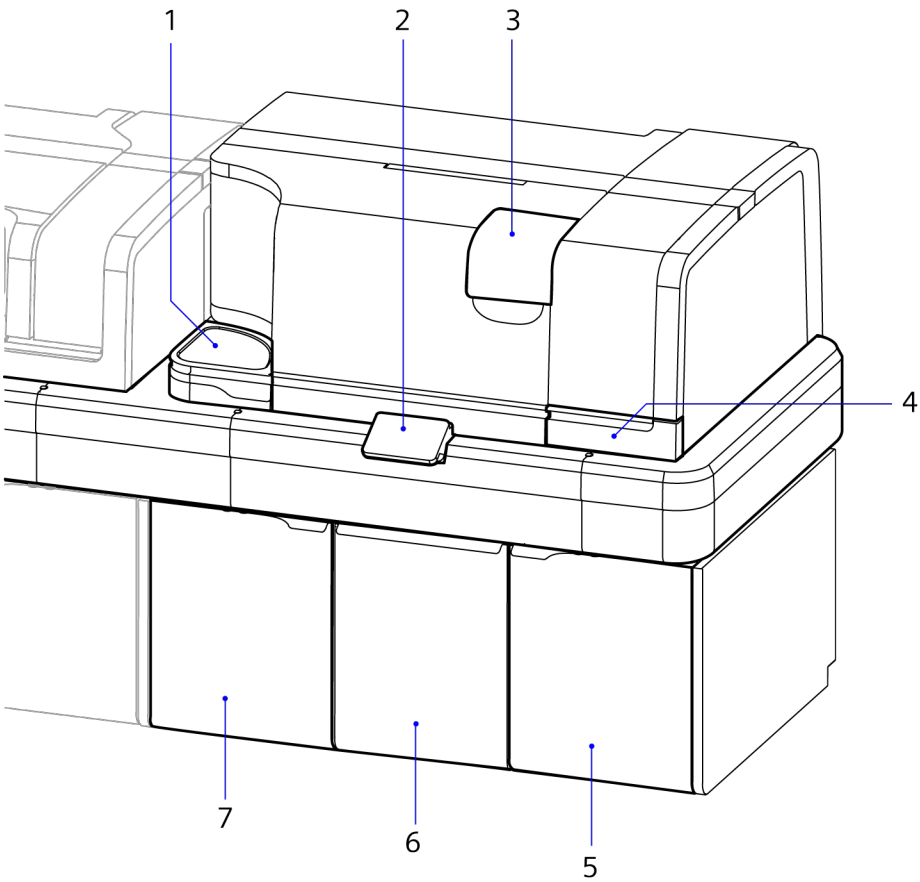


1	Dilution arm	9	Reagent compartment 1
2	Dilution ring	10	Reagent loader
3	Dilution mixer	11	Reagent compartment 2
4	Sample arm	12	Reagent manual load station
5	Dilution washer	13	Reaction ring
6	Reaction washer	14	Sample mixer
7	Reagent arm 2	15	Reagent mixer
8	Reagent arm 1	16	IMT system

About the IM Analyzer

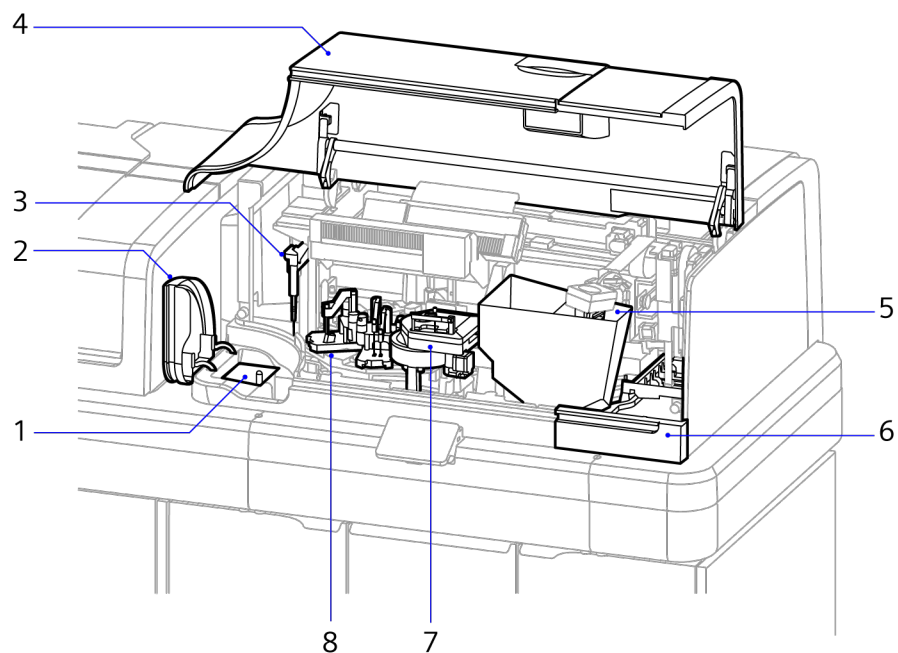
The automated IM Analyzer contains all the necessary hardware, electronics, and software to process samples and generate results, including sample and reagent dispensing, mixing, and incubating.

IM front view with covers closed



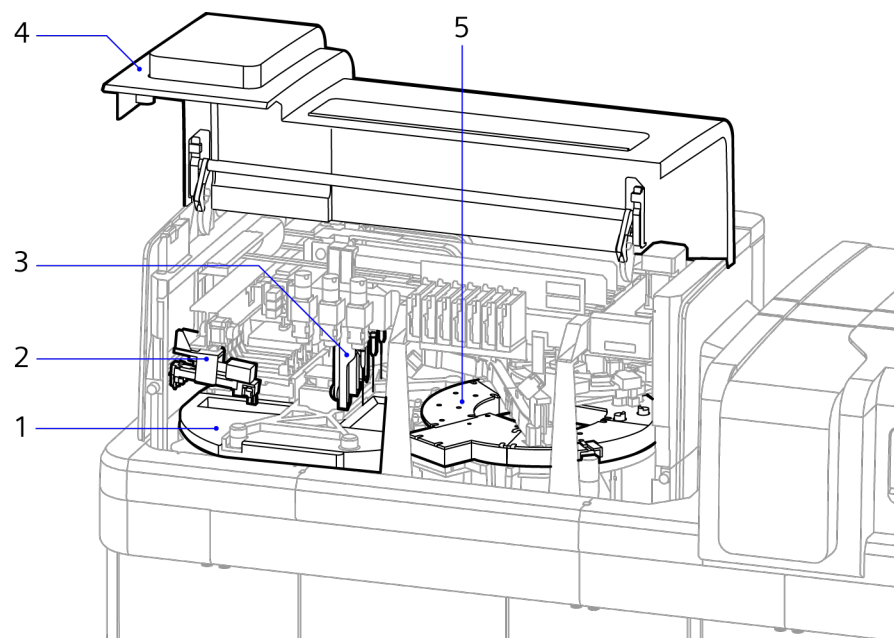
1	Sample tip loading lid	5	Water and liquid waste door
2	Module display	6	System fluids drawer
3	Cuvette bin lid	7	Solid waste door
4	Reagent drawer		

IM front view with cover open



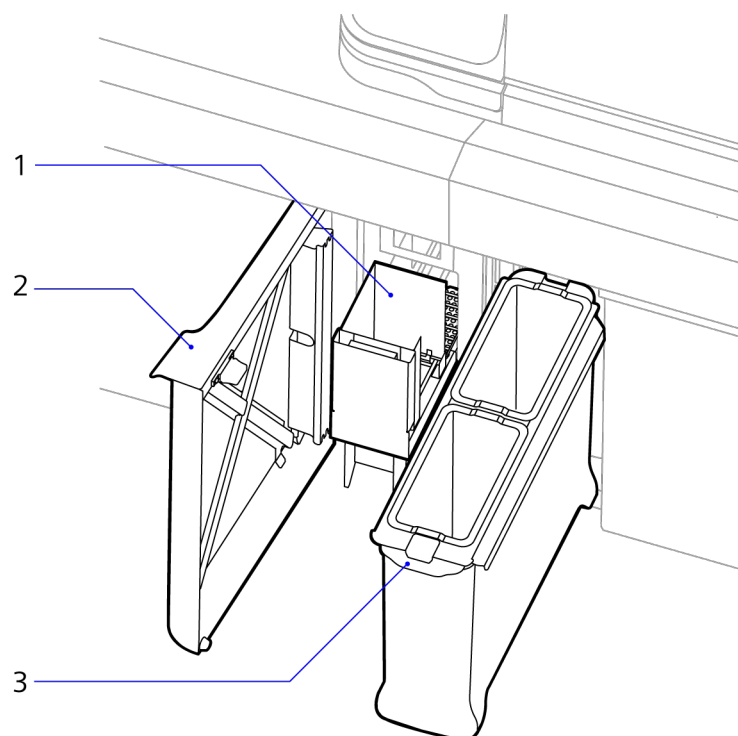
1	Sample tip loader	5	Cuvette bin
2	Sample tip loading lid	6	Reagent drawer
3	Sample probe	7	Luminometer
4	Front system cover	8	Wash ring

IM back view with cover open



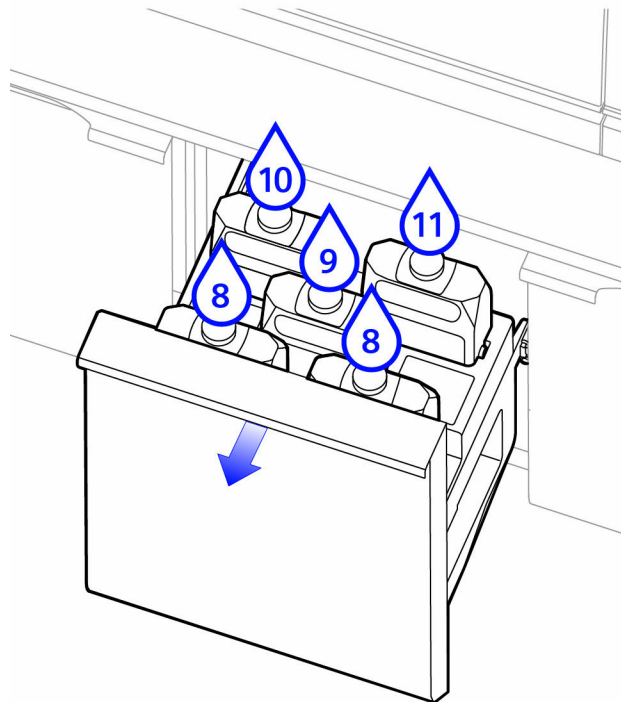
-
1	Reagent compartment
2	Reagent loader
3	Reagent probes
4	Back system cover
5	Incubation ring
-

IM Solid Waste



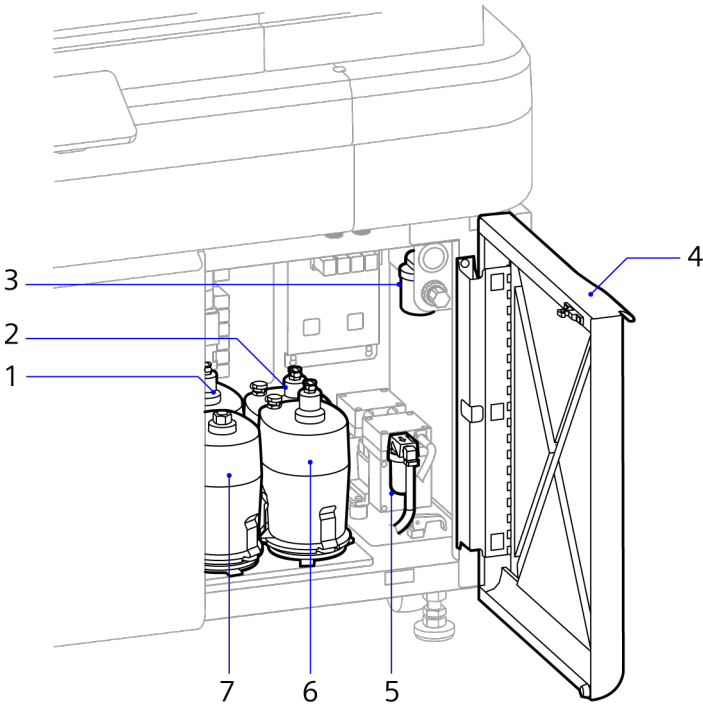
-
1	Sample tip tray waste drawer
2	Solid waste door
3	Solid waste bin drawer (cuvette and sample tip waste)
-

IM system fluids drawer



Symbol	System Fluid
	IM Wash
	IM Cleaner
	IM Acid
	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 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.

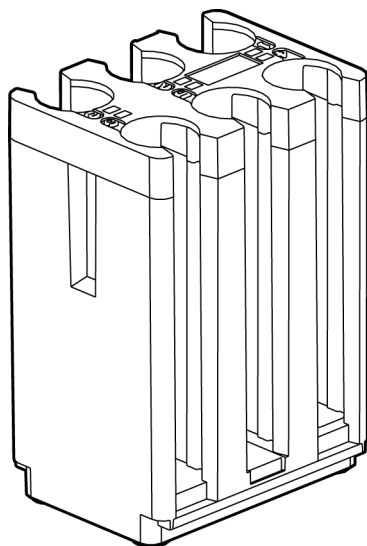
Feature	Notes
Sample rack lanes: entry and exit queue	Consists of an entry queue with a maximum capacity of 10 sample racks, for a total of 60 sample tubes. The exit queue is next to the entry queue and also holds a maximum of 10 racks. A magnetic conveyor system controls the movement of the racks on 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 DL Entry and Exit Queues

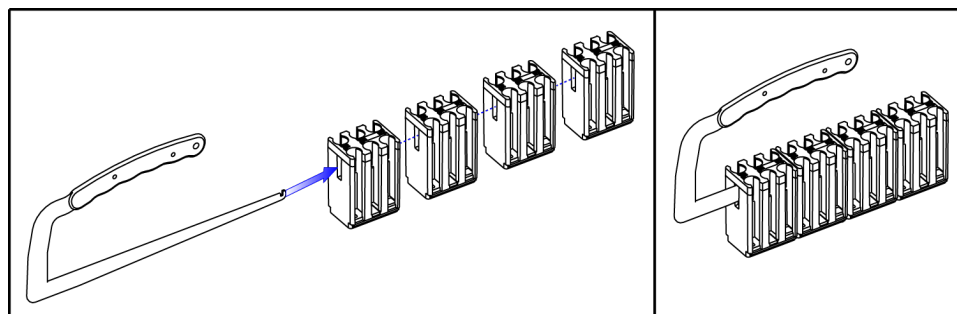
The entry and exit queues provide a means of loading and unloading, identifying, and presenting samples to the system for aspiration.

About DL Sample Racks and Adapters

The system introduces patient samples to the DL 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 DL sample 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 area to the DL.



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:

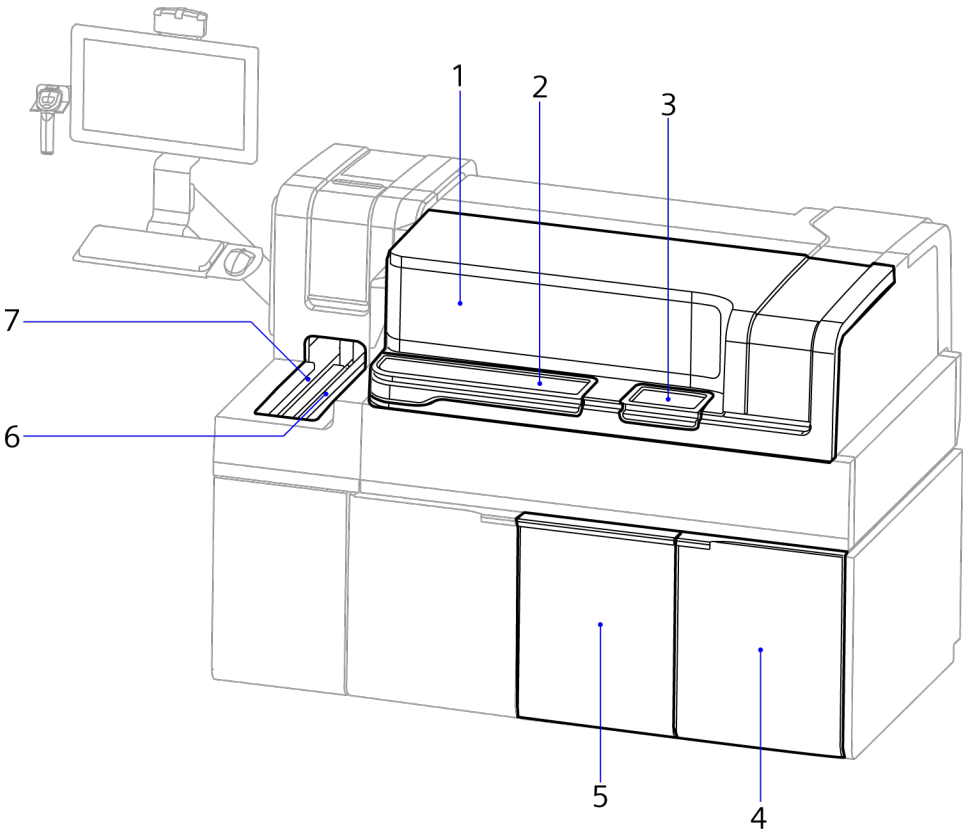
- Tube diameter and length must fit the sample rack insert.
- Sample container must have a valid barcode.
- No stoppers allowed.

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 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.

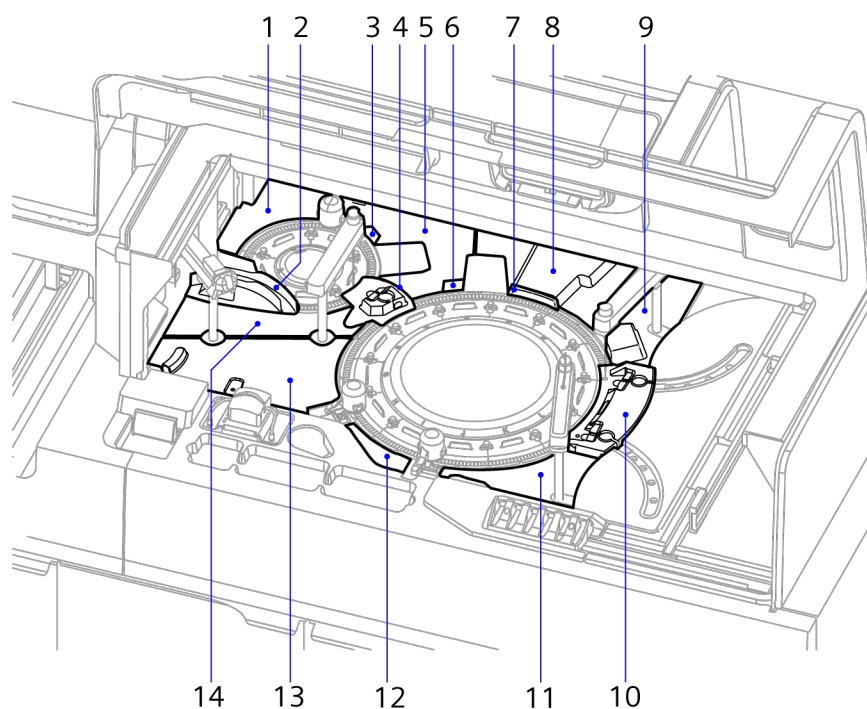
CH DL with covers closed



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.

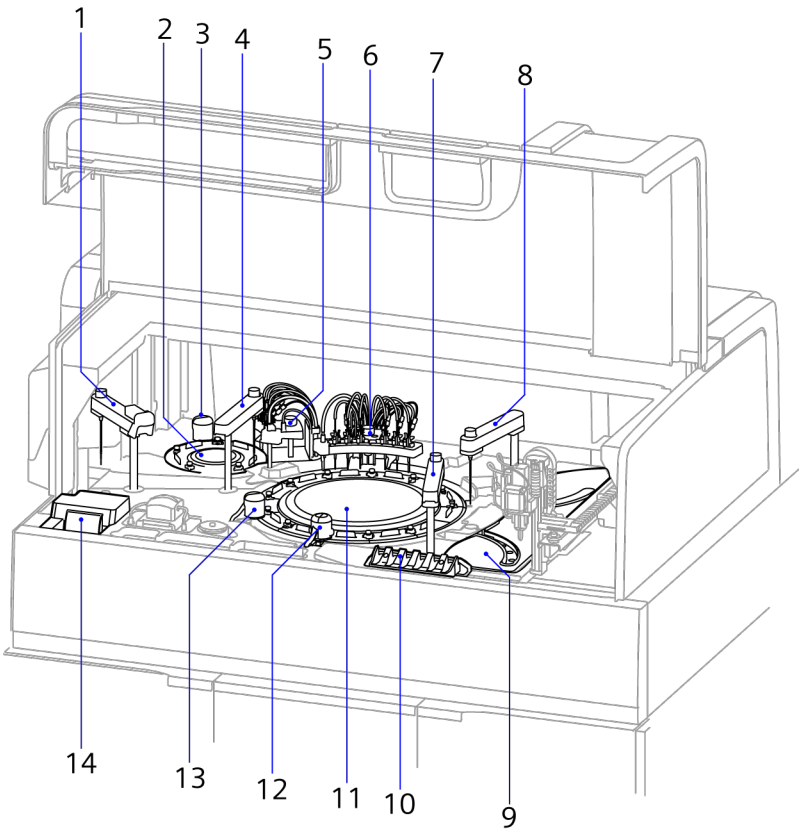
CH interior plates and probe shields



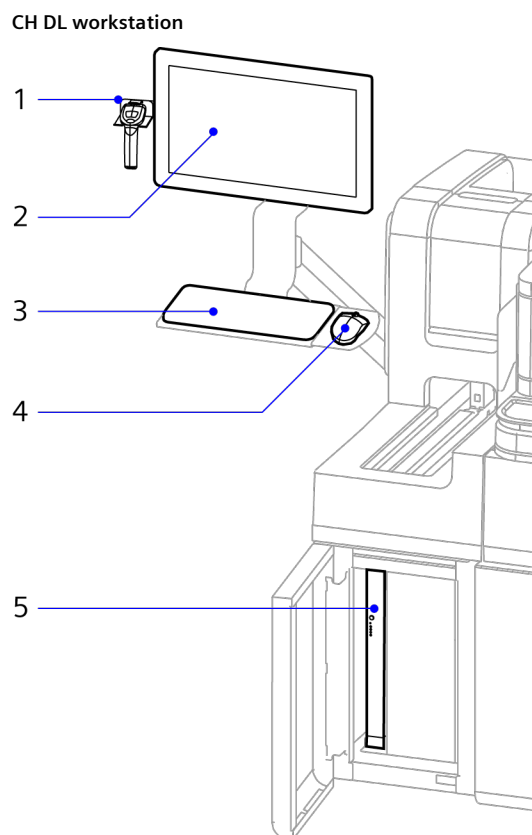
1	D1	7	R3
2	Shield dilution wash probe	8	R4
3	D2	9	R2
4	Shield reaction wash probe LS	10	R1
5	Shield reaction wash probe RS	11	D3
6	Bulb access		

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

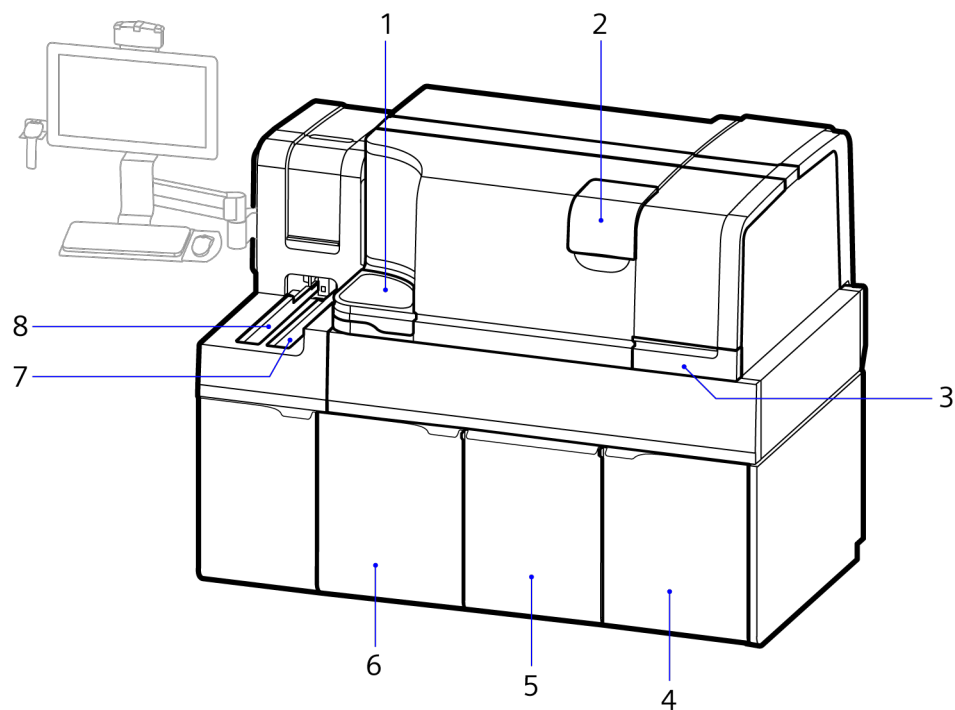


-
1	Barcode reader
2	Monitor
3	Keyboard
4	Pointing device
5	Computer
-

About the IM DL

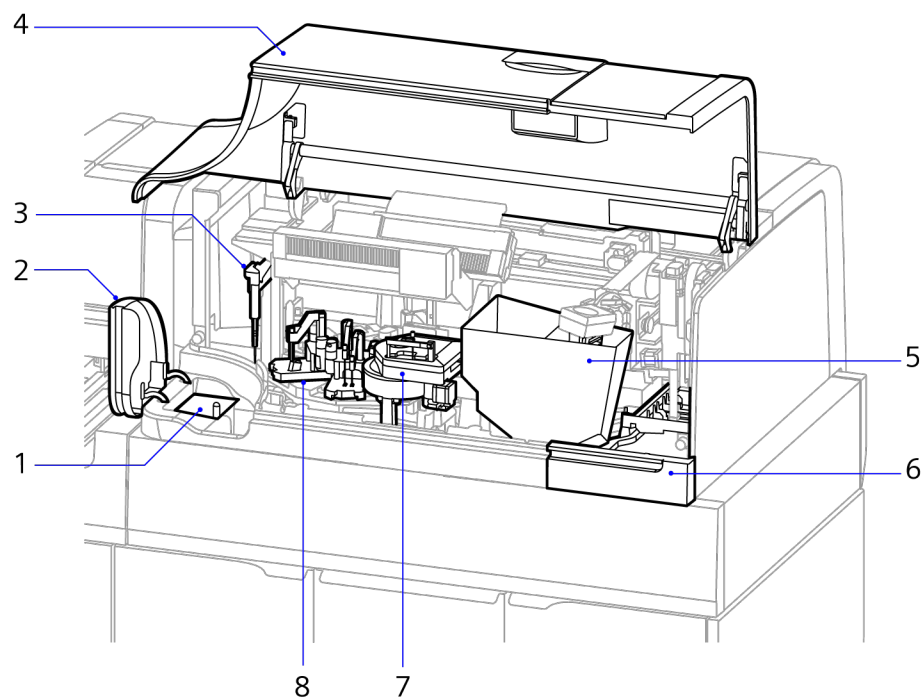
The automated IM DL contains all the necessary hardware, electronics, and software to process samples and generate results, including sample and reagent dispensing, mixing, and incubating.

Full system with covers closed



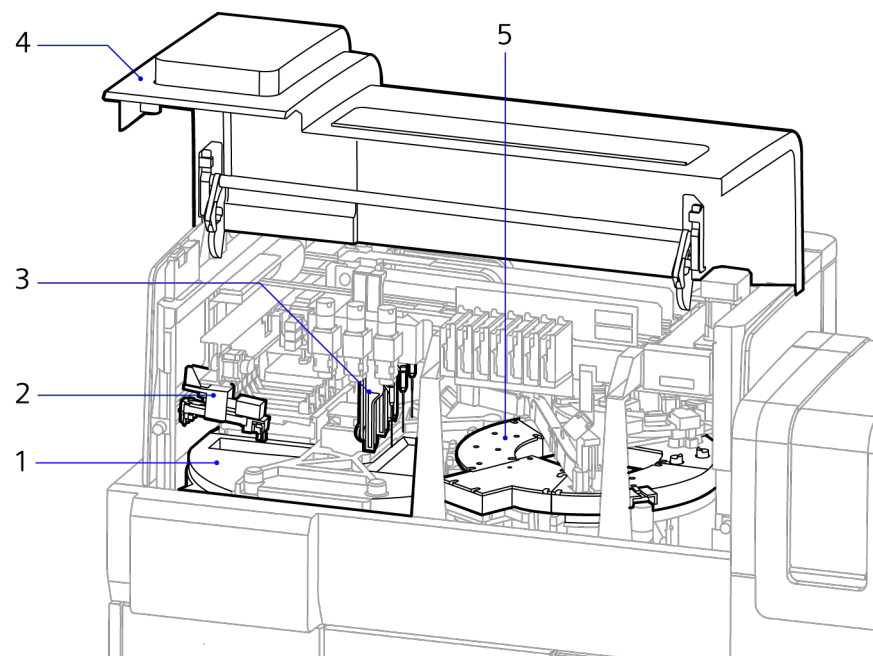
1	Sample tip loading lid	5	System fluids drawer
2	Cuvette bin lid	6	Solid waste door
3	Reagent drawer	7	Exit queue
4	Water and liquid waste door	8	Entry queue

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
-

8 Routine Operations

This chapter provides information on performing routine tasks on the system. For more detailed information about these tasks, refer to the respective chapters in this guide.

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 biohazardous materials can cause bodily harm.

The following workflow list is an example of daily operations:

- Sign in (Page 476 *Signing in to the System*).
- Respond to system alerts (Page 124 *Viewing System Alerts*).
- Ensure required maintenance is complete (Page 415 *Responding to Maintenance Alerts*).
- Check CH fluids status and supplies status (Page 217 *Checking CH System and IMT Fluids*).
- Check IMT fluids status (Page 217 *Checking CH System and IMT Fluids*).
- Check IM fluids and supplies status (Page 236 *Checking IM Waste and Supplies Status*).
- Check IM waste status (Page 236 *Checking IM Waste and Supplies Status*).
- Check reagent status in Reagent Needs (Page 213 *Reviewing Reagent Needs*).
- Check assay reagent calibration status in Calibration Overview or Calibration Needs (Page 252 *Reviewing Calibration Needs*).
- Review assay reagent QC status in QC Needs (Page 255 *Reviewing QC Needs*).
- Order routine and STAT samples (Page 258 *Ordering Patient Tests*).
- Load samples and.
- Review results (Page 265 *About Worklist Overview*).

- Remove samples.
- Sign out (Page 476 *Signing out of the System*).

9 Inventory

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

About Inventory Reagent Overview

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

- Onboard Stability
- Calibration Status and Calibration Interval
- QC Status

Reagent Overview	Notes
Analyzer	Reagent resides on this analyzer.
Reagent	Short name for the assay, cleaning solution, or ancillary material associated with the reagent pack. When a Reagent row is selected, each row in the table starts with a check box adjacent to selectable rows. The check box selects all assays in the table header row.
Inventory	Tests remaining for the primary reagent packs. Volume remaining in mL for CH cleaning solutions, IM probe washes, and IM ancillary materials.
Onboard Stability	Count down timer in days and hours for the remaining pack onboard stability (OBS). OBS starts when: • The operator initially loads the 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 pack. • IM ancillary reagent and diluent are based on the IM test definition configuration. • The CH Analyzer pierces a pack or well.

Reagent Overview	Notes
Sequence	For CH packs, 5-digit pack identification portion of the barcode. For IM packs, 6-digit pack identification portion of the barcode.
Calibration Status	A glyph displays when a calibration is required for the pack or reagent lot. Not all assays require reagent calibration. • No glyph: No calibration required. • Green glyph: Valid calibration exists. • Yellow glyph: – Only a partial calibration exists for that reagent. – One or more of the following expires soon for that reagent: Lot or pack calibration, pack OBS, or reagent lot • Red glyph: 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
Calibration Interval	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 Calibration Interval.
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.

Reagent Overview	Notes
QC Status	A glyph displays only when the QC results for at least 1 assay using this reagent pack generate on the system. • No glyph: QC Statistics is not enabled or QC has not processed. • Green glyph: QC processes, did not violate any rules, and is in range. • Yellow glyph: Warning condition. • Red glyph: Error or expired lot or OBS.
Lot	Lot of the reagent, ancillary, wash, or humidity 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 not fresh enough 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 reagents by short name. Allows the operator to view the total inventory by assay. Recommended to use when performing inventory manually.
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.
Lot ID	Lot of the reagent or wash packs.
Pack Location	Analyzer reagent compartment where the reagent pack resides.

CH Reagent Details	Notes
Position	Position of the reagent pack in the reagent compartment.
Status	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. • Unloading: The pack is unloading from the reagent compartment. Wait for the unload to complete. • 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. • Loading: The pack is loading into the reagent compartment. Wait for process to complete. • Processing: The pack is processing tests. If the system requests an unload, the analyzer waits for scheduled tests to complete processing. • Expired: The pack reagent lot or OBS is expired and unusable. Unload and discard the pack. • Empty: No reagent in the pack. 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.
Sequence Number	5-digit pack identification portion of the barcode.
Paired Pack	5-digit pack identification portion of the CH paired reagent barcode located in Reagent Details.
Count Remaining	Remaining tests in reagent pack.
Onboard Stability	Count down timer in days and hours for the remaining OBS. OBS starts when the operator initially loads the CH reagent pack onto an analyzer. The reagent lot expiration and analyzer vent time affect the OBS.

CH Reagent Details	Notes
Lot Expiration	Date and time the reagent lot expires.
Calibration Expiration	The calibration expiration time in date and time format.
Well 1	Status and Test Count 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	Status and Test Count for Well 2 of reagent pack.
Calibrate Lot	Button enabled after a specific CH Analyzer is selected and a reagent pack or CH 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.
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	Button requires the appropriate security level. If the QC fails in Well 1, the operator disables that well and continues processing QC with Well 2.
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.
Count	Remaining tests in reagent pack.

IM Reagent Details	Notes
OBS	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.
Calibration Expiration	The calibration expiration time in date and time format.

IM Reagent Details	Notes
Pack Status	The following conditions have an impact on the pack's availability for use: • Temperature Error: The pack is exposed to an out of range temperature for a significant period of time. Unload and discard the pack. • Volume Check Error: The pack has insufficient fluid volume and can no longer be used. Unload and discard the 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. • 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. • Unknown: The pack is unusable because it references an unknown reagent product code or reagent lot. If appropriate, scan the corresponding Master Curve / Test definition card. • Contaminated: Another reagent compromised the pack contents rendering it unusable. Unload and discard the pack. • 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. • Mixing in Progress: The pack is unusable because it is insufficiently mixed. Wait until mixing is complete.

IM Reagent Details	Notes
	• Use for Inventory: The operator loads a reagent and multiple assays share it. The system flags the pack as Use for Inventory because the operator scans a secondary assay but not the primary assay. An accurate inventory reading is not available. • Unload Immediately: The pack is queued for immediate unload and does not need to wait for any test processing to complete. Wait for pack to unload. • Unload: The pack is queued for unload after all associated tests scheduled complete. Wait for processing to complete and pack to unload.
Calibrate Lot	Button enabled after a specific IM Analyzer is selected and a reagent pack is eligible for a lot calibration. Creates a calibration order for the selected pack. Edit this order if it is not in process.
Calibrate Pack	Button enabled after a specific IM Analyzer is selected and a reagent pack is eligible for a pack calibration.
Refresh	Reagent Details updates with current count and status.
Edit	The operator edits Count and OBS.

Reviewing Reagent Inventory

1. On the Command bar, select **Inventory > Reagent Overview**.
2. Select a reagent.
3. Review Reagent Details.

About Inventory Glyphs

A glyph alerts the operator to a required action or more information. The assay short name and position number displays on the assay glyphs. "Undefined" displays for CH Analyzer operator-defined assays.

Inventory glyph	Glyph description
	Unusable supply or reagent pack error. This includes: • 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
	Expiring or low reagent pack or supply. The glyph displays 24 hours prior to the expiration date. The operator-defined reagent warning thresholds (low reagent level) are defined by remaining test count in Alert Settings in System Configuration.
	Supply status is OK.
	Reagent pack transfer in process.
	System fluid is empty.
	Current system fluid level.
	System fluid is full.
	Packs are empty or expired. Pack removal required.
	Barcode error or bad read.
	Batch code.

Inventory glyph	Glyph description
	Use-by date. Use by the designated date.
CH glyph	Glyph description
	Amount of Pretreatment reagent remaining.
	Amount of IMT tests remaining.
	Empty position.
	Low or expiring soon.
	Depleted or expired pack.
	Unassigned operator-defined pack or bad barcode or read error.
	Ready for use.
IM glyph	Glyph description
	Empty position.
	Primary reagent ready for use.
	Primary reagent low or expiring soon.
	Primary reagent depleted or expired.
	Ancillary reagent ready for use.

IM glyph	Glyph description
	Ancillary reagent low or expiring soon.
	Ancillary reagent depleted or expired.
	Ancillary or primary reagent bad barcode or barcode read error.
	Primary reagent pack in the drawer for > 30 minutes and requires re-mixing.
	Reagent drawer locked.
	Reagent drawer unlocked.
Cal-QC status glyph	Glyph 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.
	The assay lot or pack calibration is expiring soon.
	The QC results for the assay are within target range.
	The QC results for the assay have generated a QC error.
	The QC results for the assay have generated a QC warning.

About Reagent Loader

Reagent Loader displays the status of the following:

- Loader
- Loader door lock (IM only)
- Activity (IM only)
- Reagent Inventory in the loader

For more information, see topic on the CH Reagent Loader (Page 200 *About CH Reagent Loader*).

For more information, see topic on the IM Reagent Loader (Page 205 *About IM Reagent Loader*).

About CH Reagent Management

The CH Analyzer 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 CH Analyzer 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 glyph 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 glyph	Position status
	Empty position
	Reagent low or expiring soon
	Empty or expired pack.
	Unassigned operator-defined pack or bad barcode or read error.
	Ready to load

The following displays in Loader Status:

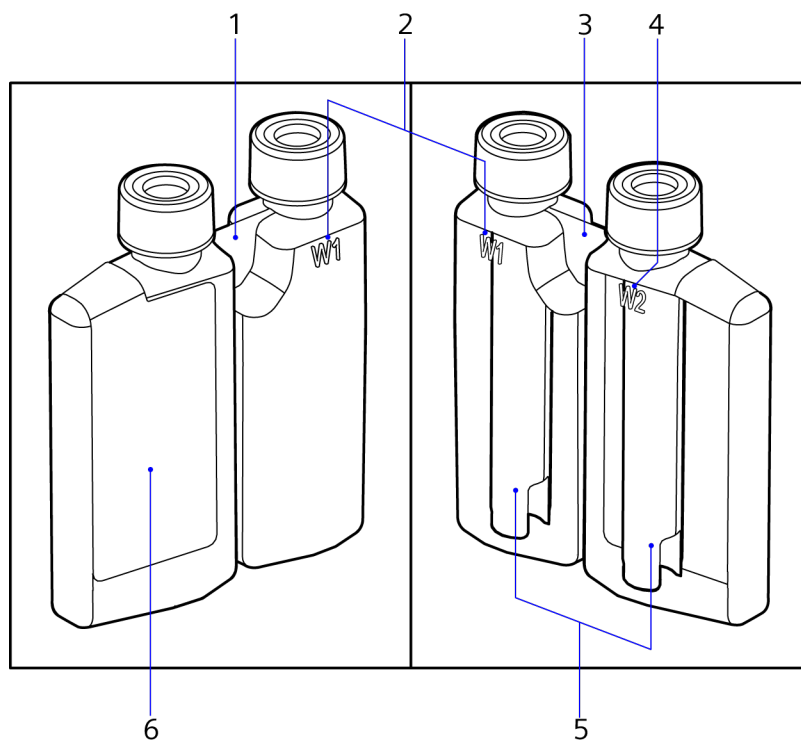
- Status of the reagent loader arm (Idle, Transfer inprocess, Scanning inprocess, or a loader error description)
- Status of reagent loader lid (Reagent loader lid is closed or Reagent loader lid is open)

In Reagent Inventory, a glyph indicates the level of total packs and empty positions in each reagent compartment. P1 Reagents are on reagent compartment 1. P2 Reagents are on reagent compartment 2.

If the operator selects Clear All before emptying loader, the operator must ensure all positions are empty in the reagent loader.

About CH Reagent Packs

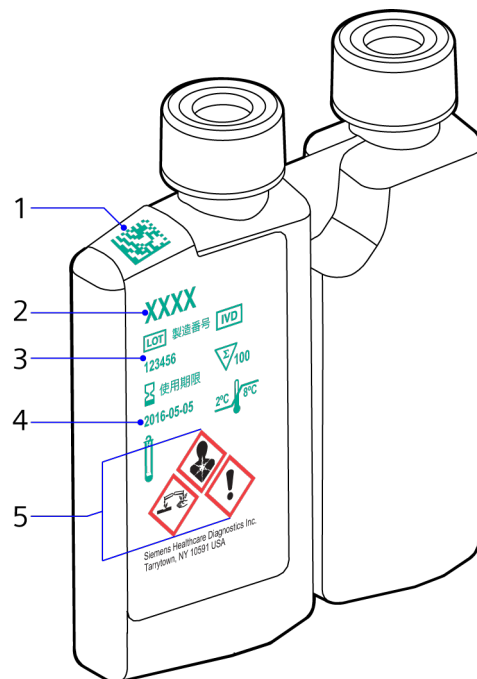
Reagent packs are double-well packs. A well contains up to 25 mL of reagent. In most cases, the double well allows for longer onboard stability because the second well in the pack is not opened until the analyzer needs reagent. For some assays, both wells are opened at the same time. Some of these packs contain a chimney to minimize absorption of CO₂ 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 CH Analyzer. 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 CH Analyzer loads assays containing packs with a single color cap as single packs.

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

Loading CH Reagents



BIOHAZARD

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

1. Open the reagent tray lid.
2. Insert up to 6 reagent packs.

3. Close the reagent tray lid.

NOTE: When the reagent tray lid closes, the gripper scans the packs and automatically loads valid packs. Opening the reagent tray lid during the loading process completes the processing before the reagent tray moves back to the loading area.

4. Review Reagent Loader and resolve any issues.

About CH Auto Reagent Pack Unload

The Auto Reagent Pack Unload setting in Module Configuration enables the system to automatically unload CH reagent packs that are no longer usable for processing tests. Reagent packs are no longer usable under the following conditions:

Condition	Notes
Depletion	The reagent pack is empty.
Pack OBS (onboard stability) expiration	The OBS of the reagent pack is expired.
Reagent lot expiration	The reagent lot is expired.
Duplicate pack	One or more reagent packs on the tray have the same pack ID.
Contamination	The reagent pack is contaminated. NOTE: Contamination may occur if the reagent loader drops a pack and it spills within the reagent compartment.
Permanent temperature error	The pack is in a compartment with a temperature error condition for greater than 3 hours.
Excessive volume check errors	Level-sense checks determine that a reagent pack is unexpectedly empty. The CH Analyzer considers 3 consecutive volume check errors on the same reagent pack as excessive.

The Auto Reagent Pack Unload setting is on by default. The Audit Trail Log records any change to this setting.

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.

About IM Reagent Loader

The status of the IM reagent pack displays in Reagent Loader. The color and glyph 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 is updated.

IM reagent glyph	Position status
	Empty position
	Primary reagent ready for use
	Primary reagent low or expiring soon
	Primary reagent depleted or expired
	Ancillary reagent ready for use
	Ancillary reagent low or expiring soon
	Ancillary reagent depleted or expired
	Ancillary or primary reagent bad barcode or barcode read error

The following statuses display for the Reagent Drawer:

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

The following displays in Loader Status:

- Idle
- Transfer in process
- Loader error description

In Reagent Inventory, a glyph indicates the level of total Primary Reagents and Ancillary Reagents packs and empty positions in the reagent compartment.

If the operator selects Clear All, the operator must ensure all positions are empty in the reagent loader since all status information is removed.

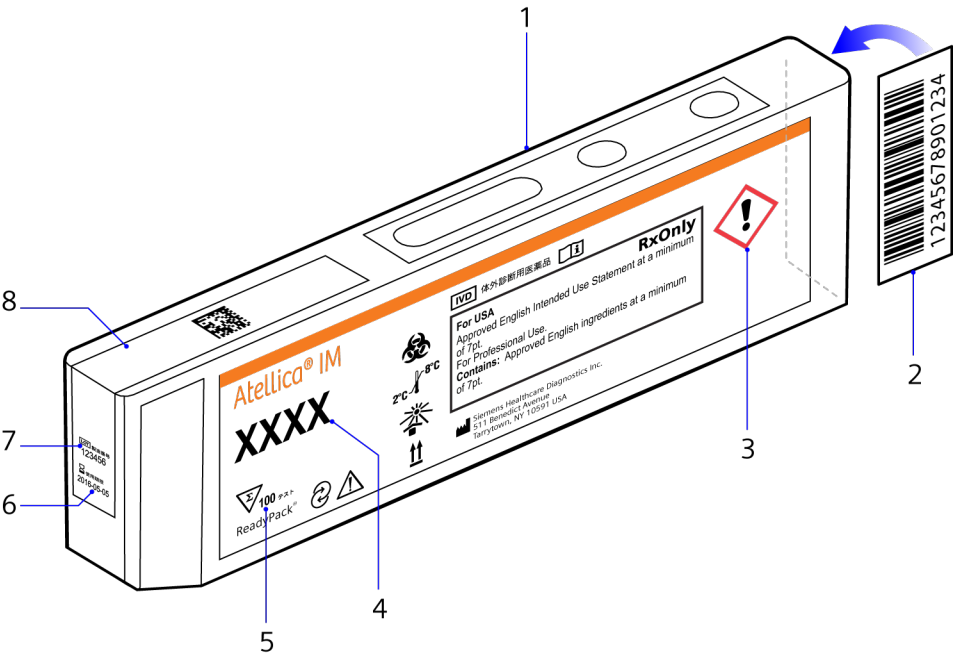
**CAUTION**

Do not select Issue Resolved 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.

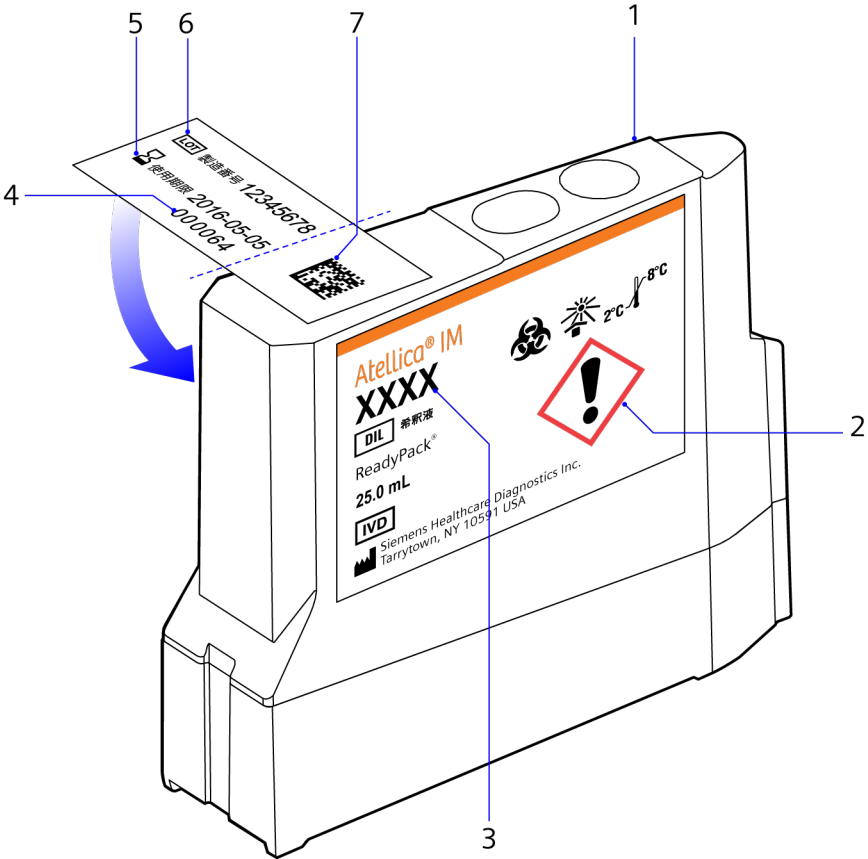
About IM Reagent Packs

The IM Analyzer uses primary and ancillary reagent packs.



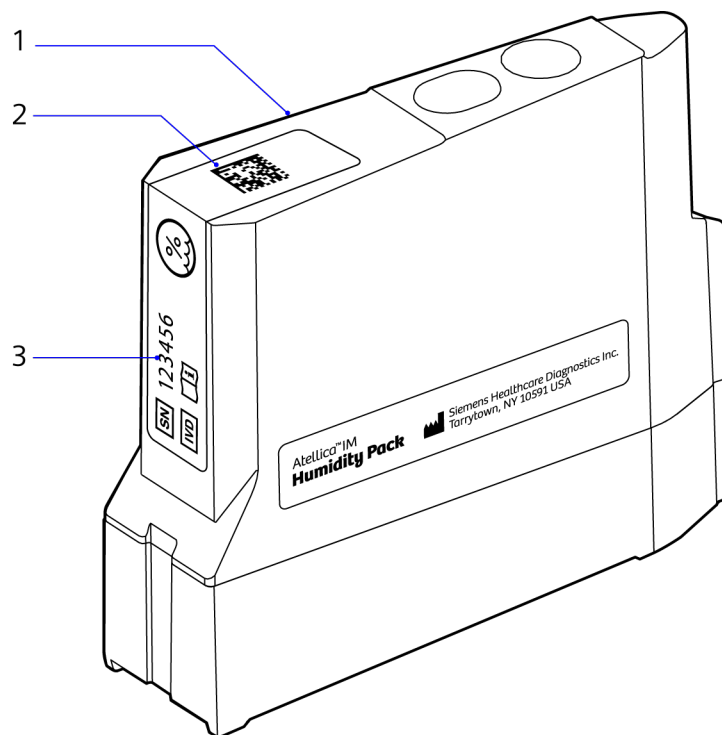
1	IM primary reagent pack	5	Number of tests
2	Barcode number	6	Expiration date
3	Safety hazards		
4	Assay short name		

- 7 Lot
- 8 2D barcode



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

For information about handling IM reagent packs, see on-line help (Page 211 *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 Inprocess state.
2. Manually mix primary reagent packs (Page 209 *Manually Mixing IM Reagents*).
3. Open the reagent drawer.
4. Insert up to 5 primary or ancillary reagent packs.
5. Close the reagent drawer.

Manually Mixing IM Reagents

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 clumps are broken up and no longer visible on the bottom of the pack.
 - No large aggregates are visible floating inside the pack.
- 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 analyzer (Page 208 *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 Reagent Packs

NOTE: Use this procedure to allow Inprocess tests associated with the selected reagent packs to complete before removal. To immediately stop processing and cancel tests associated with the selected IM reagent packs, use the Unload Immediately procedure (Page 210 *Unloading IM Reagent Packs Immediately*).



BIOHAZARD

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

1. On the Command bar, select **Inventory > Reagent Overview**.
2. Select the analyzer icon.
3. Select appropriate reagent packs.
4. Select **Unload**.
5. Check the status of the appropriate reagent packs from step 2 in Reagent Loader before opening the reagent tray lid.
6. Open the reagent tray lid or 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 pack with self-sealing laboratory film.
9. Store useable reagent packs according to the assay IFU.

Unloading IM Reagent Packs Immediately



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling 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 (Page 209 *Unloading Reagent Packs*).

1. On the Command bar, select **Inventory > Reagent Overview**.
2. Select the analyzer icon.
3. Select 1–5 reagent packs.
4. Select **Unload Immediately**.

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

5. Select **Reagent Loader**.
6. Select the analyzer icon.
7. Ensure the IM reagent drawer status is .
8. Open the reagent drawer.
9. Remove the reagent packs from the reagent tray.
10. If the reagent pack is pierced and intended for reuse, cover the pierced film area of the reagent pack with self-sealing laboratory film.
11. If intended for reuse, store reagent packs at 2–8 °C.

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.
3. Before loading primary reagent packs onto the system, manually mix the packs to resuspend the particles homogeneously (Page 209 *Manually Mixing IM Reagents*).
4. Return the reagent packs to the system when the reagent compartment temperature is 2–8 °C.
5. Verify reagent performance based on acceptable QC results (Page 381 *Performing Quality Control*) 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.

About Reagent Needs

Reagent Needs posts a need for a reagent based on the expected tests for that day compared to the current inventory. The operator configures the thresholds and reagent inventory monitoring in **Setup > Settings > System Configuration > Reagent Requirements Settings**.

The reasons for a posted need include the following:

- Predictive: Suggested need based on the cutoff defined by the operator or system historic assay utilization.
- Below Threshold: The reagent inventory level has reached the red alert threshold the operator defined in Reagent Requirements Settings. This includes CH reagent probe cleaners and WBA with predefined and unchangeable limits.
- Pending Orders: The reagent inventory level has reached the red alert status because existing orders exist in the Worklist and no reagent is onboard for the assay.

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
Name	The name of the assay reagent is red when test counts onboard fall below the operator-defined Manual threshold in Reagent Requirements Settings.
Average Tests	The operator configures manually or collected automatically by the system. When collected automatically, the system calculates the average assay usage from the last 5 weeks for the current 24 hour period. This is configured in Reagent Requirements Settings.
Tests to Perform	The difference between the Average Tests and the number of test performed.
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	A comma separates list of active analyzers if more than 1 analyzer requires the same reagent pack.

Reagent Needs	Notes
Reasons	• Predictive: Suggested need based on the cutoff defined by the operator or system historic assay utilization. • Below Threshold: The reagent inventory level has reached the red alert threshold the operator defined in Reagent Requirements Settings. This includes CH reagent probe cleaners and WBA with predefined and unchangeable limits. • Pending Orders: The reagent inventory level has reached the red alert status because existing orders exist in the Worklist and no reagent is onboard for the assay.

Reviewing Reagent Needs

1. On the Command bar, select **Inventory > Reagent Needs**.
2. Determine the reagent need and replace, as appropriate.

About Inventory Supplies Overview

Inventory Supplies Overview provides information about the status of the onboard supplies.

The CH Analyzer includes system fluids, Pretreatment pack, and IMT fluids.

The IM Analyzer includes system fluids, supplies, and waste.

System and IMT fluids are yellow when the level is below the remaining levels percentage and red when the usable remaining volume is 0 or when the onboard stability expires within the expiration period. Consumables are red when their count is less than the sample warning level. These alert levels are configured in **Setup > Settings > System Configuration > Alert Settings**.

Supplies Overview	Notes
System Fluids	System fluids list by analyzer.
Volume	The remaining volume on the analyzer displayed as an inventory glyph.

Supplies Overview	Notes
Status	Status of the remaining volume of supply. CH Status: • OK • On reserve: Container empty, reservoir full • Almost empty: Low supply • Empty: Reservoir and container empty • Expires Soon: < 2 days remaining until Lot or OBS expires for the container • Full: Container empty, reservoir full IM Status: • OK • On reserve: Container empty, reservoir full • Almost empty: Low supply • Reserve empty: Reservoir and container empty
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.
Lot Expiration	Date and time the supply lot expires.
Lot	Lot of the supply.
Sequence Number	The 5-digit supply identification portion of the barcode.
IMT	IMT fluids on CH Analyzer.
Supplies	IM Analyzer consumables includes Tips, Cuvettes, and Water, if appropriate.
Waste	IM Analyzer waste levels includes Cuvette and Tip Waste, Tip Tray Waste, and Liquid Waste, if appropriate.
Replace System Fluids	Operator selects to start system fluids replacement.
Replace Pretreatment	Operator selects to start Pretreatment pack replacement on CH Analyzer.

Supplies Overview	Notes
Cuvette Status	Operator selects to view the CH cuvette status after performing the quality check during CH Daily Maintenance and CH Weekly Maintenance.
Cuvette State Information	Operator selects to view the CH cuvette status definitions: • Clean: Wash is complete. The cuvette is ready for use. • Need Replacement: Cannot use the cuvette. Cuvette QC, washing and cleaning failed too often. Replace the cuvette. • 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.
Replace IMT Supplies	Operator selects to start IMT fluids replacement on CH Analyzer.
Open Tip Tray Waste Drawer	Operator selects to open the tip tray waste drawer on IM Analyzer.

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 CH Analyzer stores the following 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

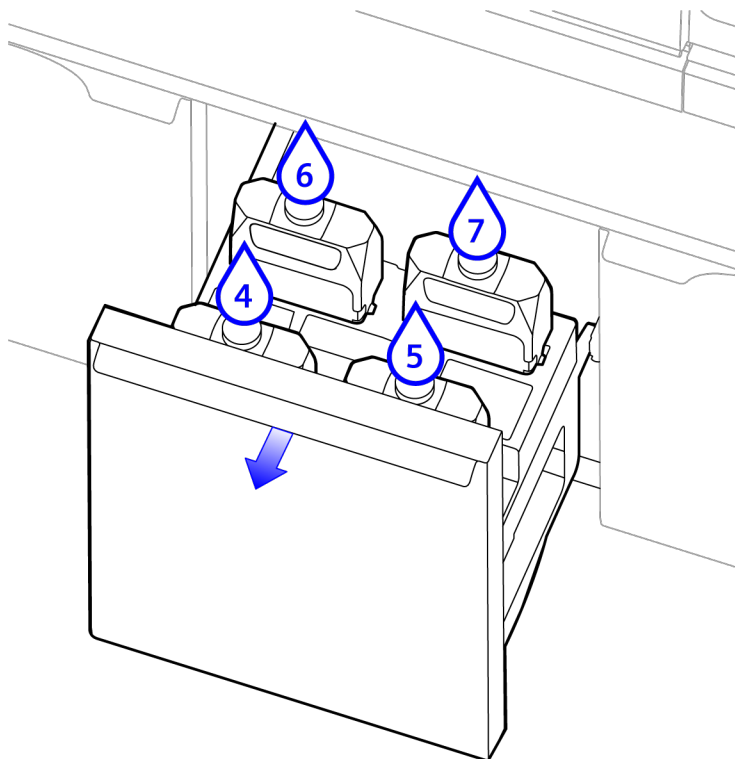
Do not replenish a system fluids container. Replenishing a container can cause contamination. Remove the container from the system fluids drawer and install a new container. Dispose of the old container according to laboratory protocol.



CAUTION

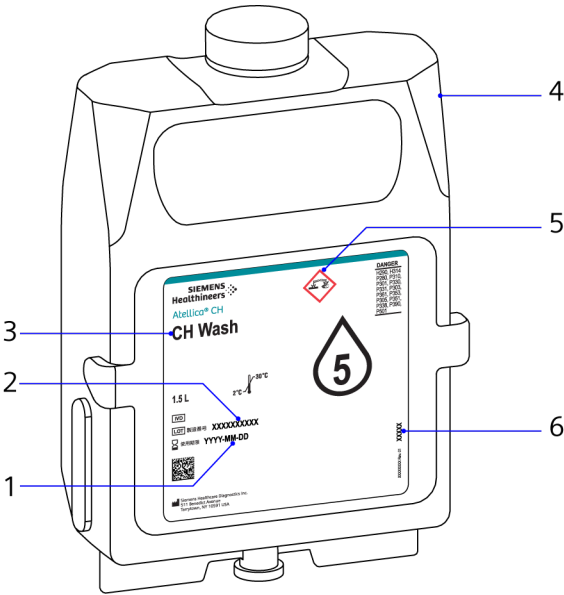
Do not load the same system fluids container multiple times. Removing and reloading a system fluids container can cause the punctured membrane to leak. Load only new and unused containers on the analyzer.

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



Symbol	System fluid
	CH Diluent
	CH Wash

Symbol	System fluid
	CH Conditioner
	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 CH System and IMT Fluids

- 1. On the Command bar, select **Inventory > Supplies Overview**.
- 2. Select .
- 3. Identify system fluid alerts.
- 4. If appropriate, replace the system fluids, Pretreatment pack, or IMT fluids (Page 218 *Replacing CH System Fluids*) (Page 227 *Replacing the Pretreatment Pack*) (Page 224 *Replacing IMT Fluids*).

Replacing CH 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.

NOTE: A window opens if the IMT Advanced Clean is required. The analyzer pauses the IMT when the operator selects Replace IMT Supplies to replace system fluids from this window.

Selecting Replace IMT Supplies while IMT calibration is in process may require a system restart. Wait until the IMT completes calibrating before selecting Replace IMT Supplies.

1. Tighten the system fluid container cap.
2. Discard the container per laboratory protocol.
3. Hold the system fluids container 150 mm (6 inches) at a 45° angle under the barcode reader.
4. Ensure the analyzer displays the correct Lot, Sequence, and Expiration under the appropriate fluid.
5. 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

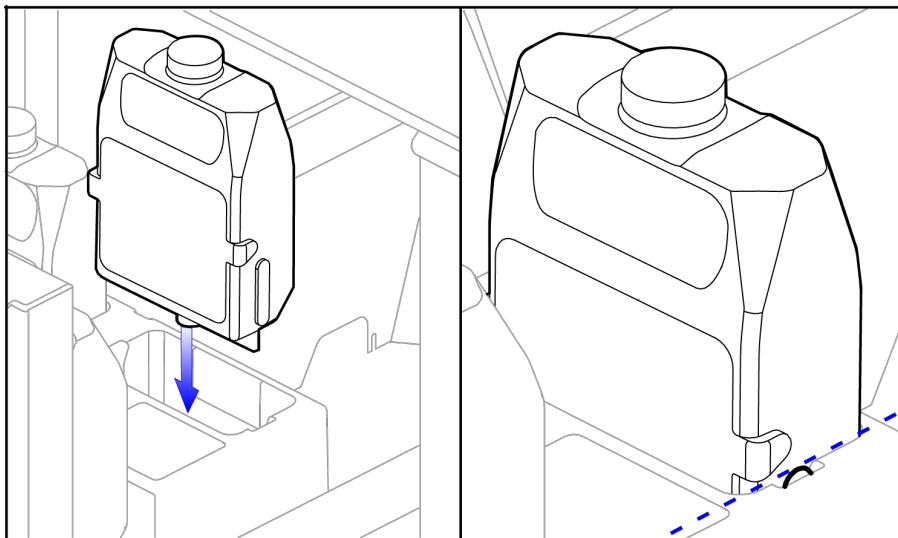
Do not load the same system fluids container multiple times. Removing and reloading a system fluids container can cause the punctured membrane to leak. Load only new and unused containers on the analyzer.



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.

6. 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.

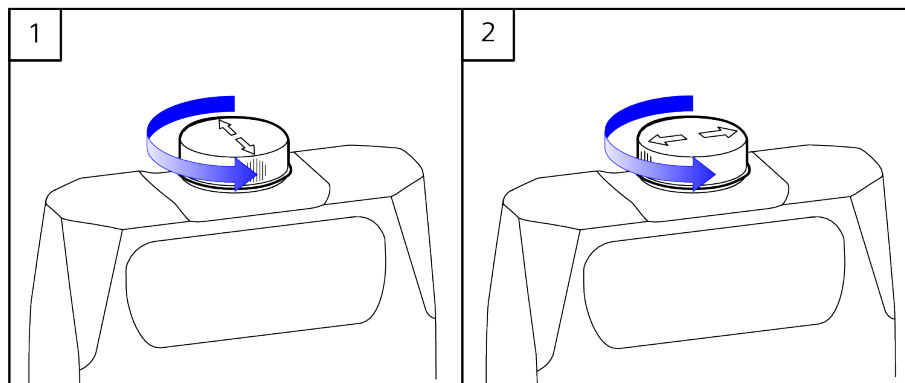
7. Ensure the container is securely seated with the tabs on both sides of the container even with the drawer surface.

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.

8. 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.
9. To replace each additional system fluid, repeat steps 3–8.
10. Close the fluids drawer.

NOTE: To locate replacement catalog number, see (Page 604 *CH Supplies*)

About CH Cuvette Status in Supplies Overview

The Cuvette Status in Inventory Supplies Overview 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 **Cuvette State Information** to review the definitions for each of the following cuvette states:

Cuvette State Information	Notes
Clean	Wash is complete. The cuvette is ready for use.
Need Replacement	Cannot use the cuvette. Cuvette QC, washing and cleaning failed too often. Replace the cuvette.
Disabled	Cannot use the cuvette. The cuvette was disabled by service in Diagnostics.

Cuvette State Information	Notes
Waiting for acceptable QC	Cannot use until the cuvette is washed and checked again. The cuvette failed the last Cuvette QC check.

Reviewing CH Cuvette Status in Supplies Overview

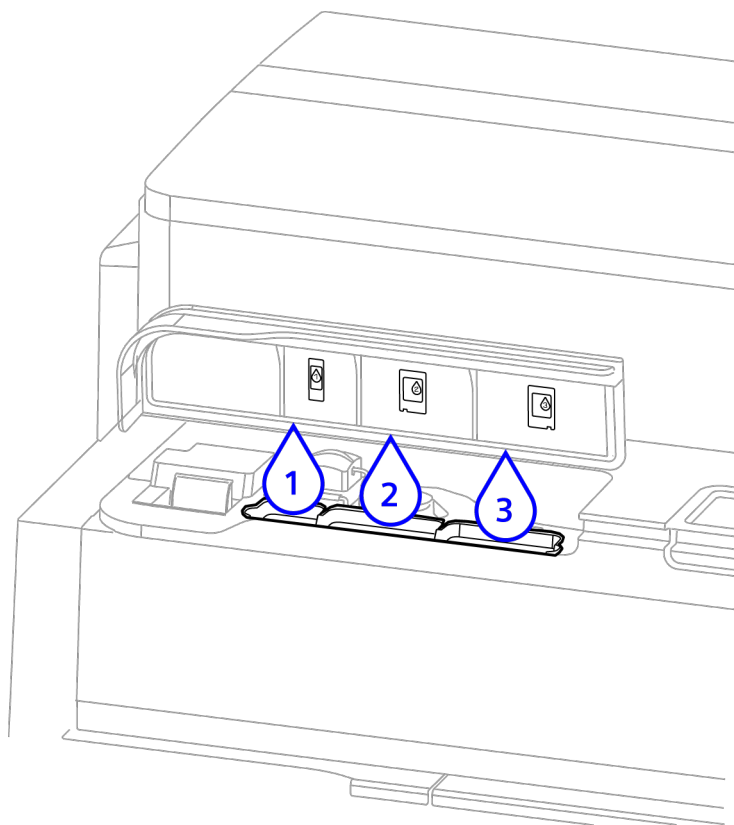
1. On the Command bar, select **Inventory > Supplies Overview**.
2. Select the appropriate CH Analyzer.
3. To review the current CH cuvette quality status, select **Cuvette Status**.
4. To review the definitions of each status, select **Cuvette State Information**.
5. To navigate back to Cuvette Status, select **Close**.
6. To navigate back to Supplies Overview, select **Close**.

About IMT Fluids

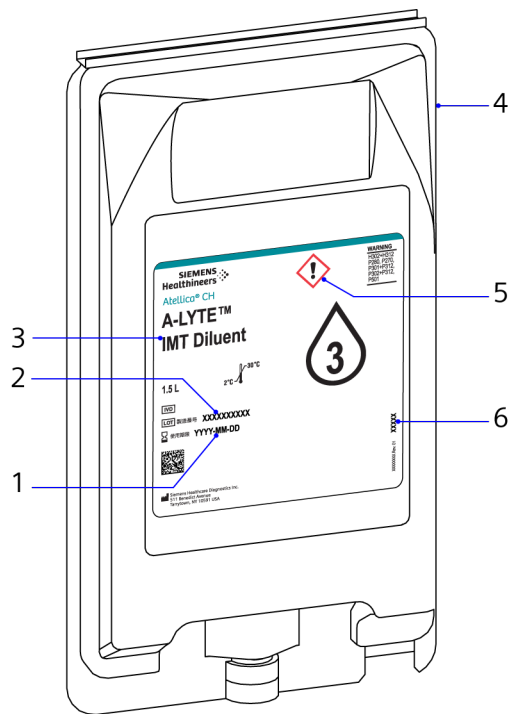
The IMT fluids are located in the front of the CH Analyzer on the top left. The location of each IMT fluid is inside the IMT fluids lid.

NOTE: A window opens if the IMT Advanced Clean is required. The analyzer pauses the IMT when the operator selects Replace IMT Supplies to replace system fluids from this window.

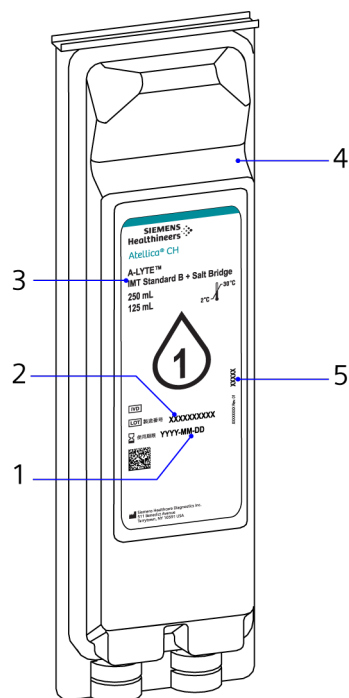
Selecting Replace IMT Supplies while IMT calibration is in process may require a system restart. Wait until the IMT completes calibrating before selecting Replace IMT Supplies.



Symbol	IMT fluid
	IMT Standard B + Salt Bridge
	IMT Standard A
	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

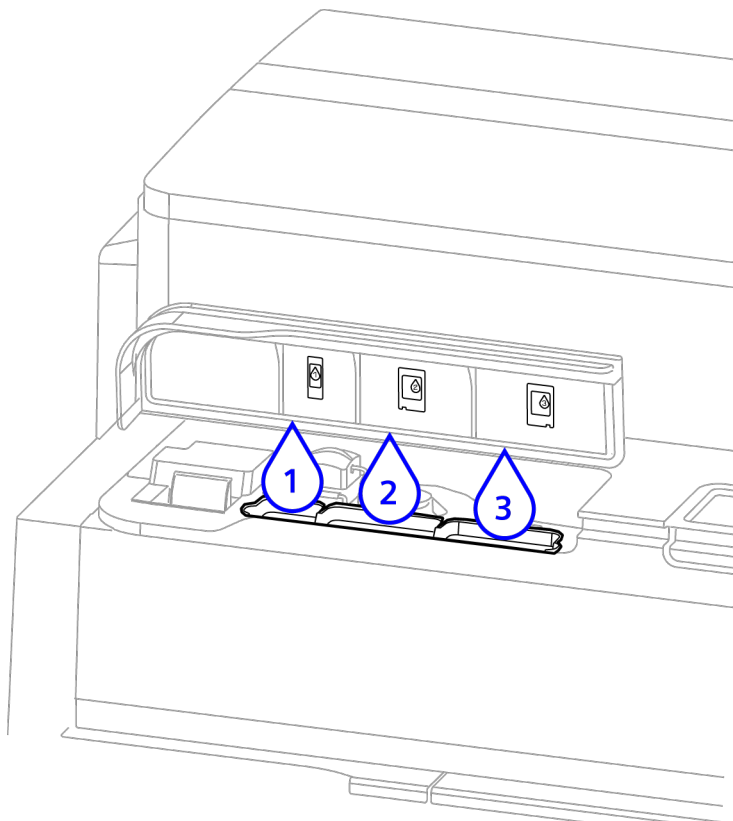


WARNING

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 125 *Changing the Module Status*).

2. Open the IMT fluids lid.



-
1	A-LYTE IMT Standard B + Salt Bridge
2	A-LYTE IMT Standard A
3	A-LYTE IMT Diluent
-

3. To replace IMT fluids from the primary display:
 - On the Command bar, select **Inventory > Supplies Overview > Replace IMT Supplies**.
 - 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 Advanced Clean before replacing the A-LYTE multisensor, select Perform IMT Advanced Clean.
 - b. To replace IMT supplies directly without performing the IMT Advanced Clean, select Replace IMT Supplies.
 - Select **Replace IMT Supplies** then **Pause IMT** and wait for this process to complete.
 - Continue to step 5.

4. To replace IMT fluids from the module display:
 - a. Select **IMT Supplies**.

NOTE: If an IMT Advanced Clean is required at the next multisensor replacement, a window displays with 2 options:

 - To begin the Advanced Clean before replacing the A-LYTE multisensor, select Perform IMT Advanced Clean.
 - To replace IMT supplies directly without performing the IMT Advanced Clean, select Replace IMT Supplies.
 - b. Select **Pause IMT** and wait for this process to complete.
5. Locate and remove the appropriate IMT fluid container.

**CAUTION**

Remove the bottle from the IMT fluids area and install a new container. Dispose of the old container according to proper laboratory protocol.

6. Discard the IMT fluid container per laboratory protocol.
7. 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.
8. Hold the IMT fluid container 150 mm (6 inches) at a 45° angle under the barcode reader.
9. Ensure the analyzer displays the Lot, Sequence, 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.

10. Holding the new IMT fluid container vertically with the septum facing down, insert the new container into position.

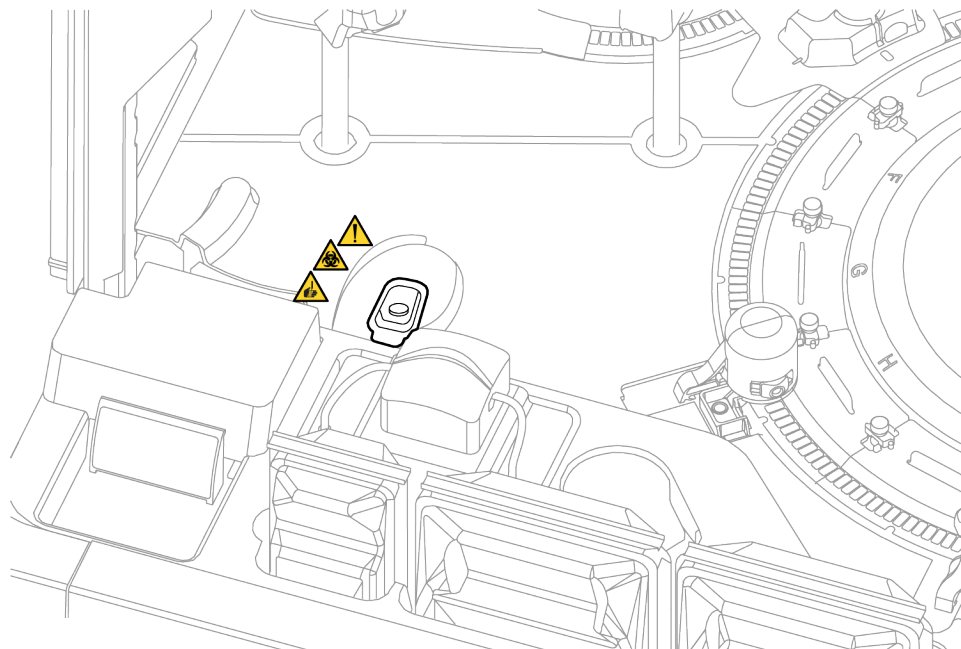
NOTE: The IMT fluid containers only fit in the designated position when the cannulas punctures the septum.
11. To replace each additional IMT fluid, repeat steps 5–9.
12. Close the IMT fluids lid.
13. Perform 1 of the following, as appropriate:
 - From the primary display, select **Save**.
 - From the module display, select **OK**.

NOTE: To locate replacement catalog number, see (Page 604 *CH Supplies*)

About the 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



BIOHAZARD

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

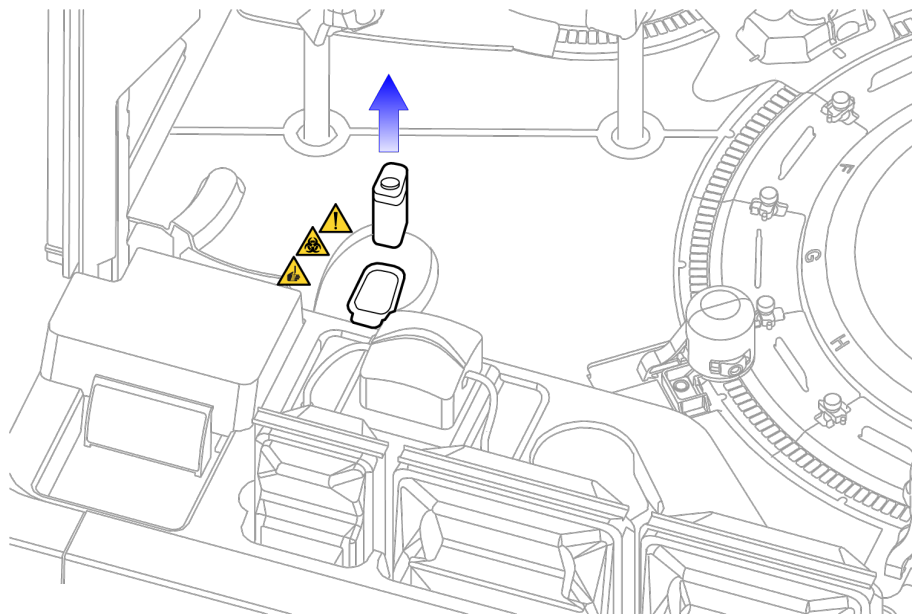


WARNING

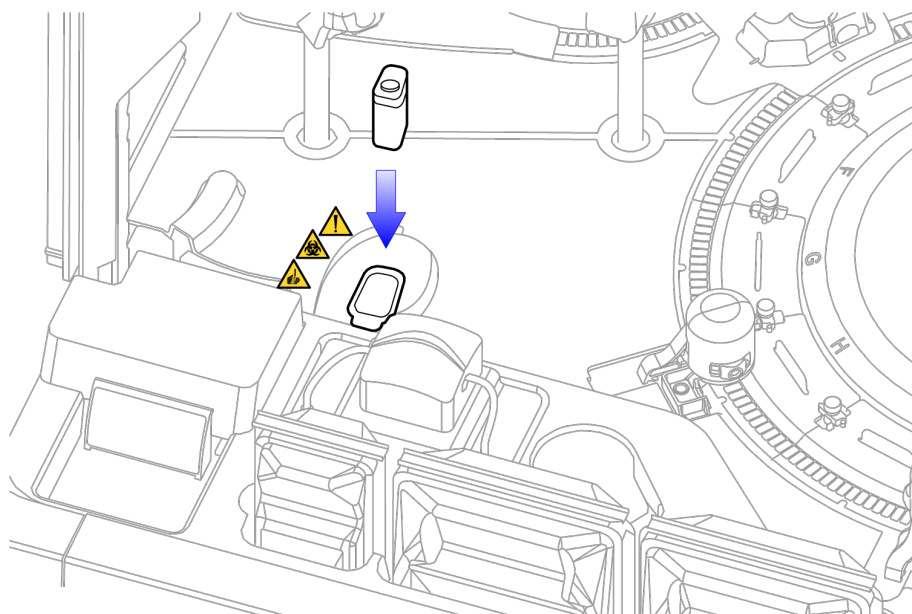
Do not turn on the system mechanics while near subassemblies that can move. When the analyzer is powered on, moving subassemblies can cause injury.

1. Unlock and open the CH Analyzer front cover (Page 95 *Locking or Unlocking Analyzer Covers*).

2. Locate the Pretreatment pack.



3. Grasp the pack and pull up and out.
4. Discard the pack per laboratory protocol.
5. On the Command bar, select **Inventory > Supplies Overview > Replace Pretreatment**.
6. Read message and select **OK**.
7. Scan the new pack.



8. Insert the new pack.
9. Remove the pack cap and discard.
10. Select **OK**.
11. Close the cover.
12. On the Command bar, select **System > Status**.
13. Select **Resume**.

NOTE: To locate replacement catalog number, see (Page 604 *CH Supplies*)

About CH Lamp Coolant

The CH lamp coolant (LC) is located in a refillable reservoir to the right of the IMT fluid containers. The CH Analyzer uses the LC to cool the photometer system.

Refilling CH Lamp Coolant

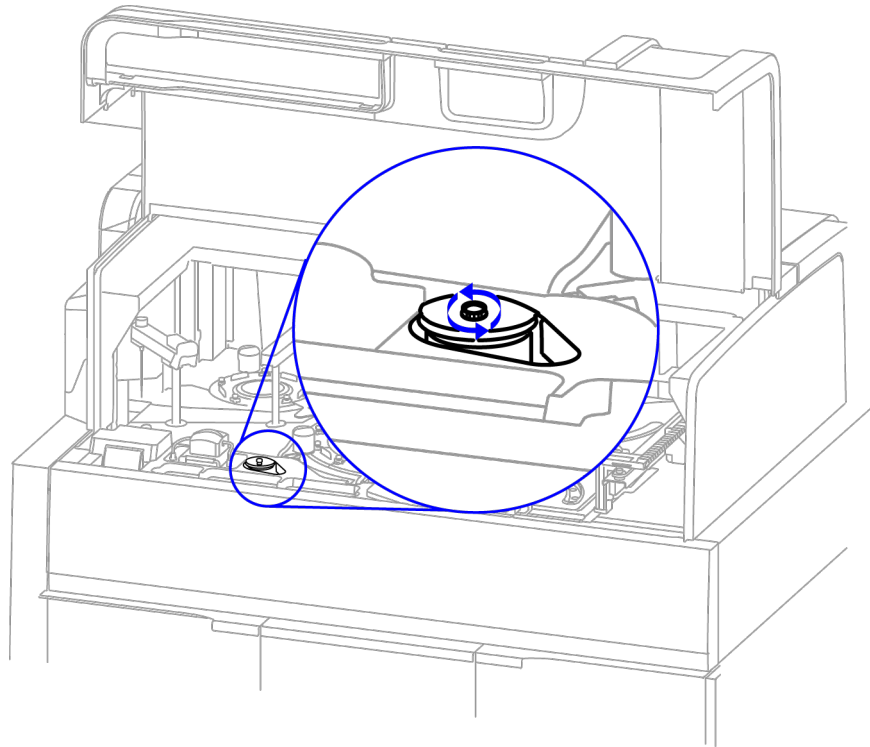


BIOHAZARD

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

1. Unlock and open the CH Analyzer front cover (Page 95 *Locking or Unlocking Analyzer Covers*).

2. 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.

3. Unscrew the small screw cap at the top of the reservoir and set aside.
4. Using the spout on the lamp coolant bottle, replenish the lamp coolant until the fluid level is approximately 1–2 cm from the LC reservoir cover (Page 229 *Refilling CH Lamp Coolant*).
5. Replace the small screw cap.
6. Close the front cover.
7. On the Command bar, select **System > Status**.
8. Select ►.
9. Mark the lamp coolant maintenance activity complete (Page 420 *Performing Manual Maintenance Activities*).

NOTE: To locate replacement catalog number, see (Page 604 *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.

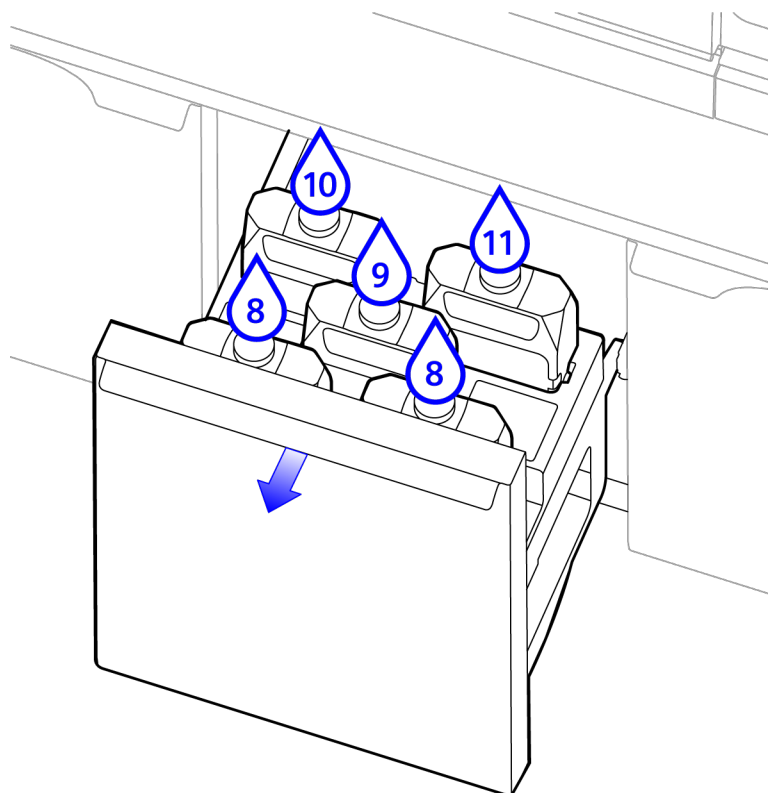


CAUTION

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.

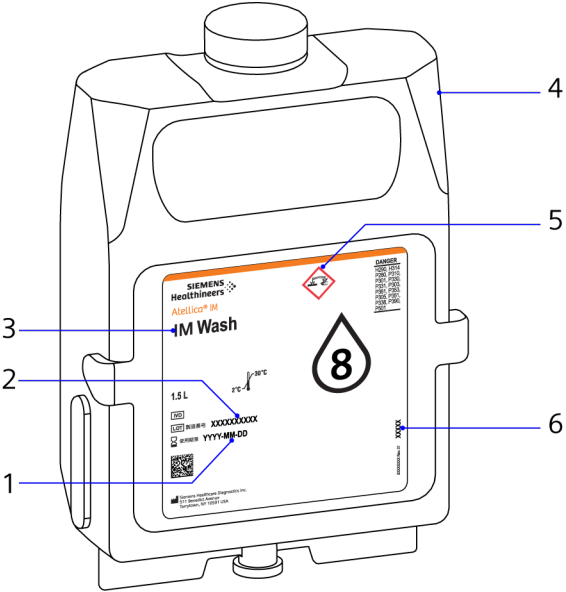
IM System Fluids fluids drawer



Symbol	System fluid
	IM Wash



Symbol	System fluid
	IM Cleaner
	IM Acid
	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.

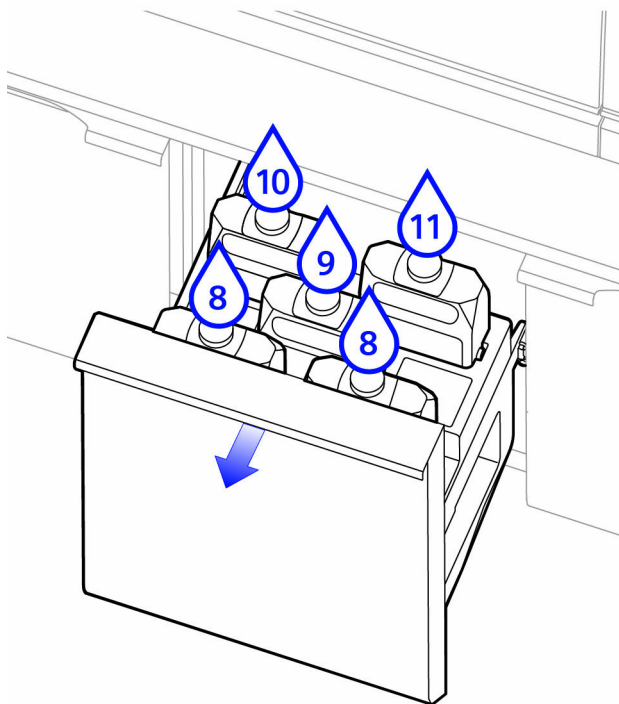
**CAUTION**

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. On the Command bar, select **Inventory > Supplies Overview**.
2. Select the appropriate analyzer.
3. Determine the system fluids that require replacement.
4. Select **Replace System Fluids**.
5. Open the system fluids drawer.



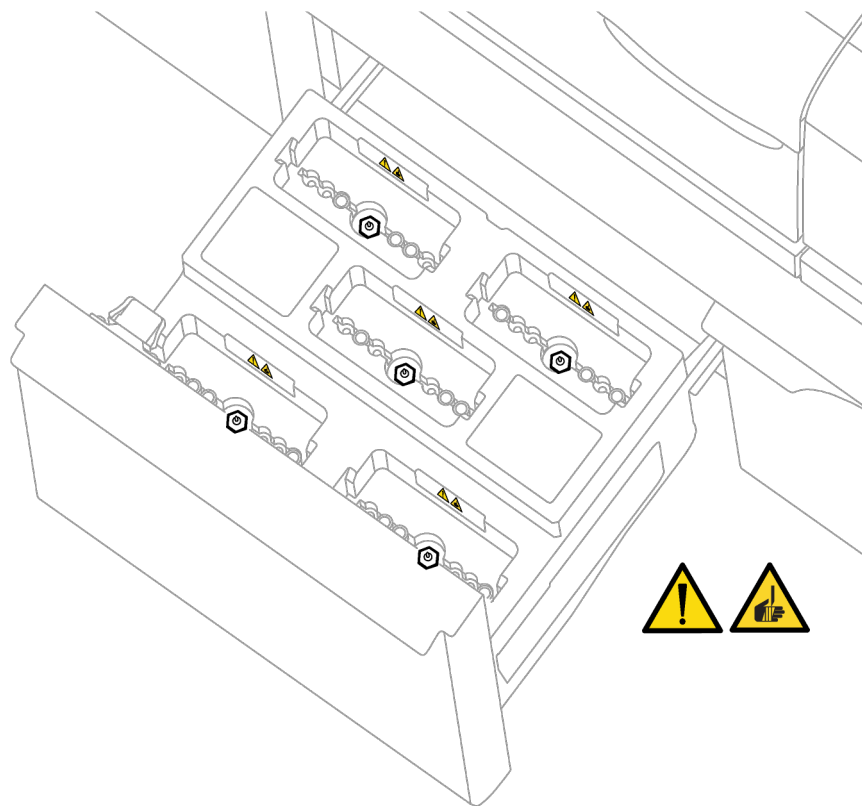
Symbol	System Fluid
	IM Wash

Symbol	System Fluid
	IM Cleaner
	IM Acid
	IM Base

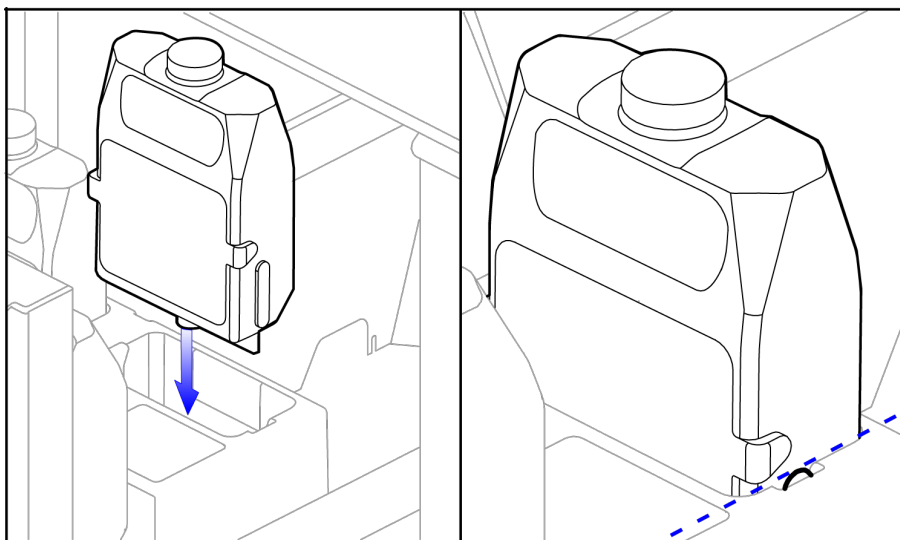
6. Tighten the cap of the system fluid container to be removed.
7. Remove the appropriate system fluid container.
8. Discard the system fluid container according to laboratory protocol.
9. Scan the new fluid container.
10. Ensure the analyzer displays the correct Lot, Sequence, and Expiration under the appropriate fluid.
11. 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.



12. 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.

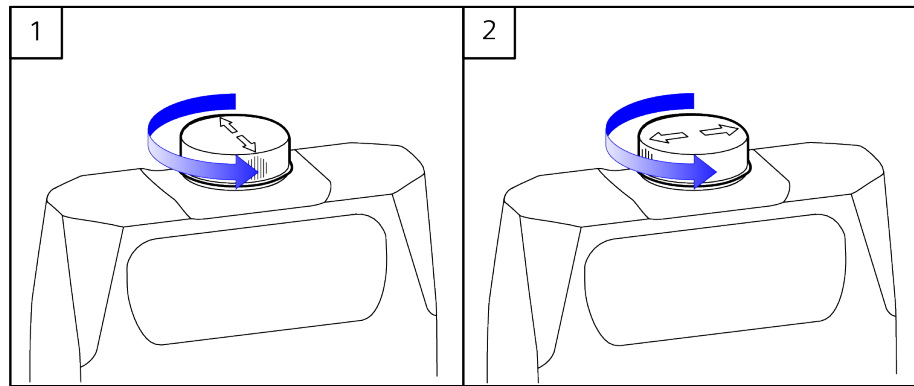
13. Ensure the container is securely seated with the tabs on both sides of the container even with the drawer surface.

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.

14. 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.
15. To replace each additional system fluid, repeat steps 3–14.
 16. Close the fluids drawer.

NOTE: To locate replacement catalog number, see (Page 607 *IM Supplies*)

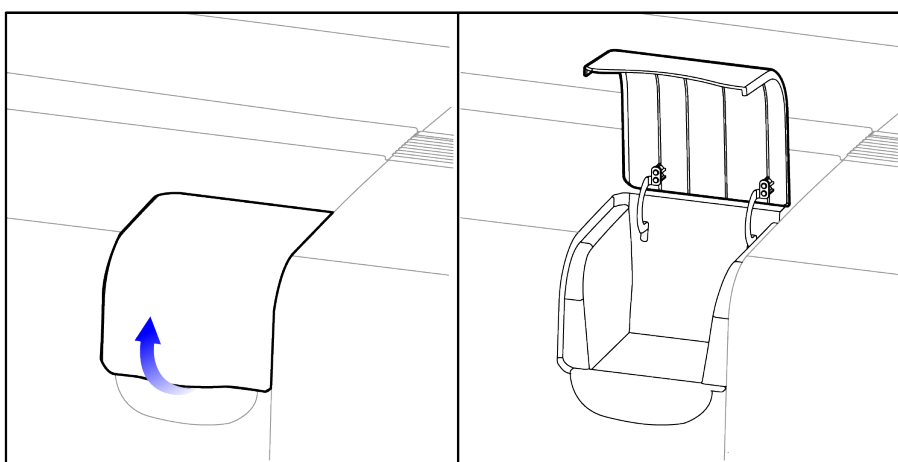
Checking IM Waste and Supplies Status

1. On the Command bar, select **Inventory > Supplies Overview**.
2. Select the appropriate analyzer.

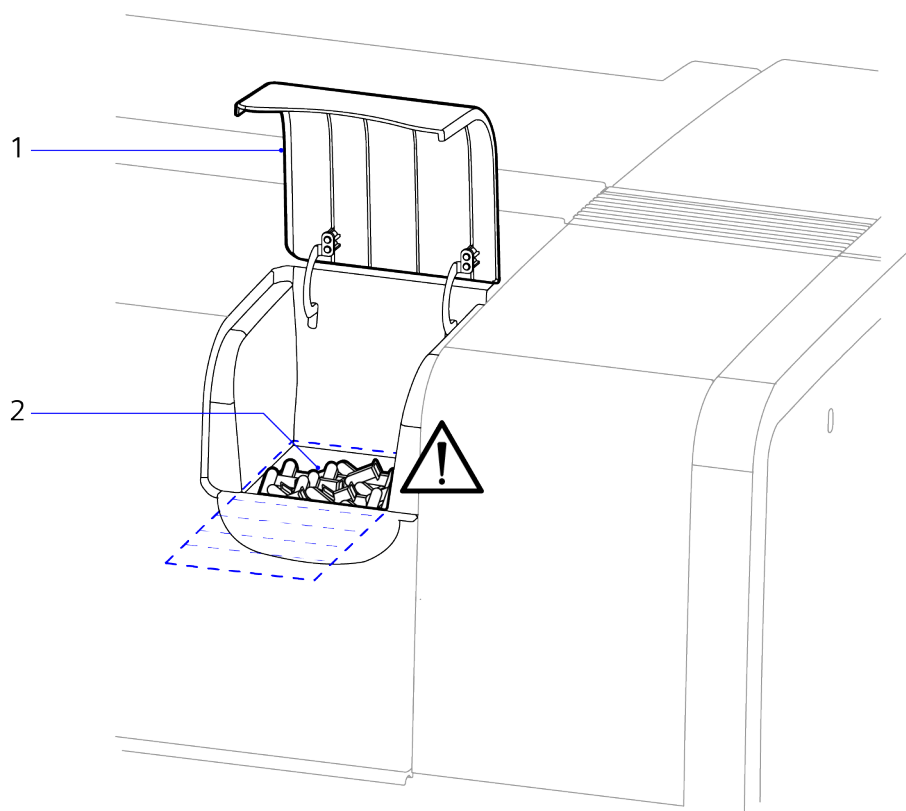
3. Check the status of the following:
 - System Fluids
 - Supplies
 - Waste
4. If appropriate, replace system fluids or supplies or empty the waste.

Replacing IM Cuvettes

1. Open the cuvette bin 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.

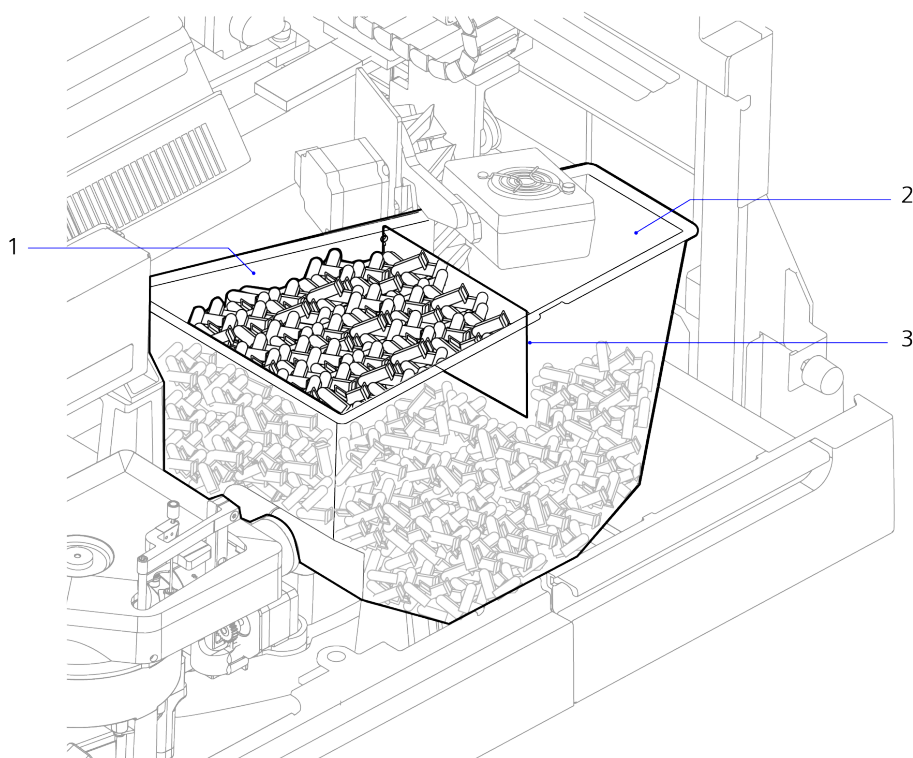


- 1 Cuvette bin lid
- 2 Cuvette bin

**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
-

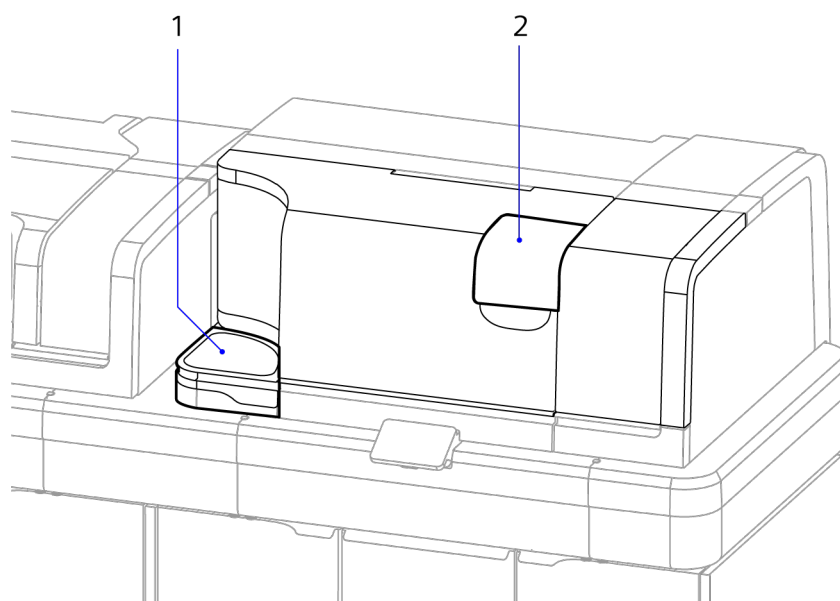
4. Close the cuvette bin lid and ensure the lid completely closes.

Replacing IM Sample Tips



CAUTION

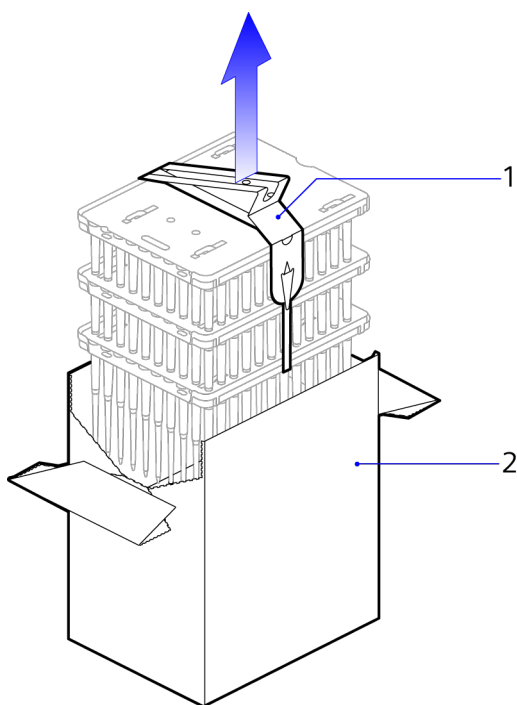
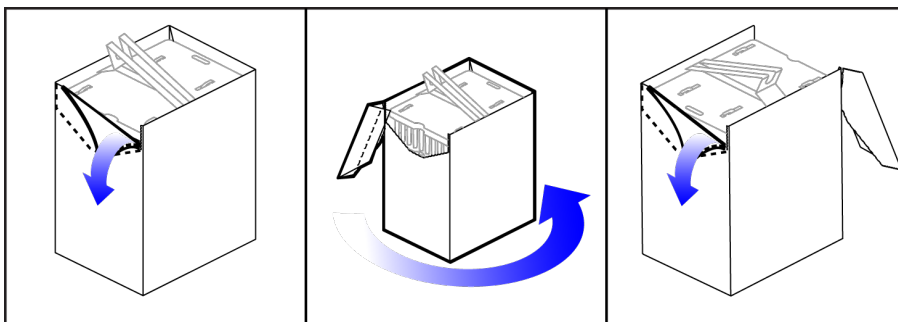
Do not handle sample tips without wearing new, uncontaminated gloves. Handling sample tips without wearing new gloves can cause cross contamination.



-
1	Sample tip loading lid
2	Cuvette bin lid
-

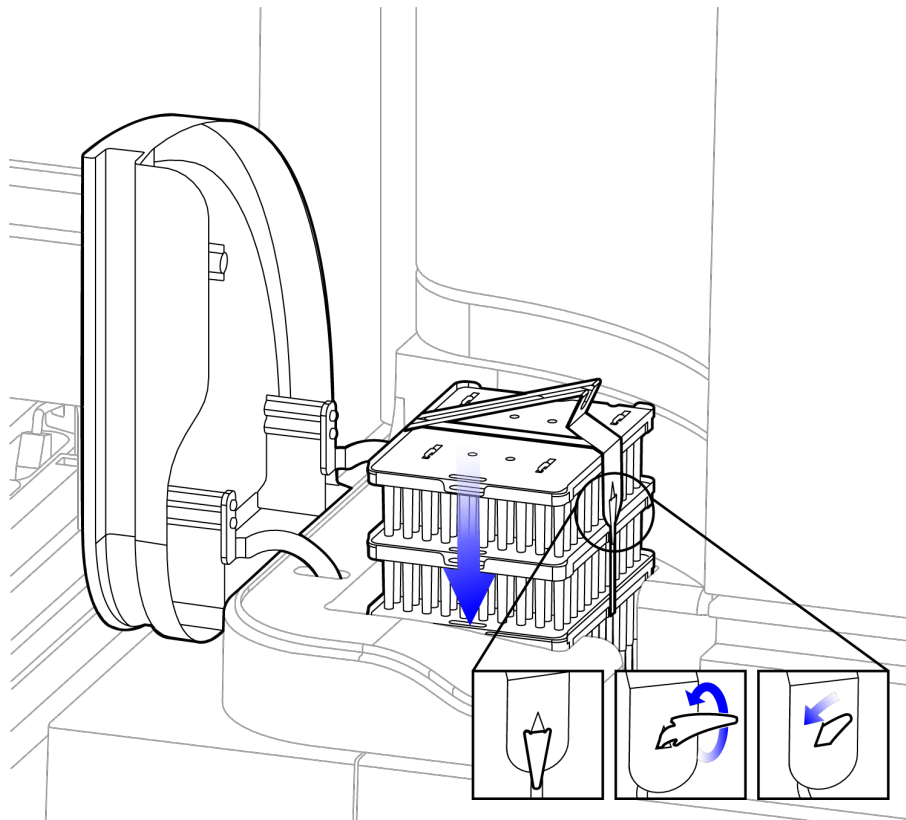
1. Open the sample tip loading lid.

2. Remove the protective cover from the sample tip tray bundle.



-
- 1 Tip tray bundle strap
2 Protective cover
-

3. 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.



4. Twist then pull the tab down and out to release the strap from the trays.
5. Pull the strap out to remove it from the bundle.
NOTE: Leave the top on the upper tip tray.
6. After the analyzer lowers the bundle into the tip tray storage area, close the sample tip loading lid.

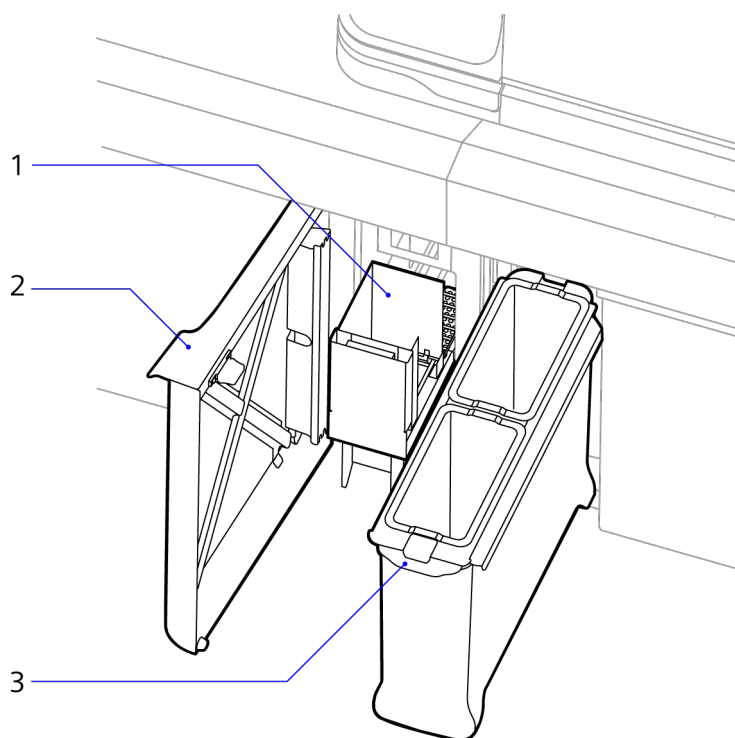
Emptying the IM Sample Tip Tray Waste



BIOHAZARD

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

1. On the Command bar, select **Inventory > Supplies Overview**.
2. Select the appropriate analyzer.
3. Select **Open Tip Tray Waste Drawer > Yes**.



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

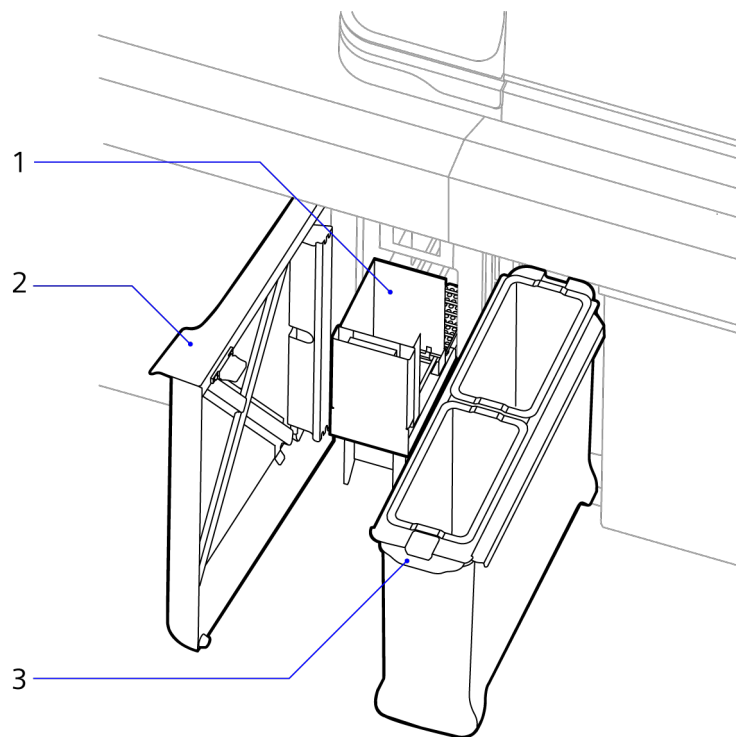
4. Open the solid waste door.
5. Pull out the sample tip tray waste drawer.
6. Remove the empty sample tip trays.
7. Close the sample tip tray waste drawer.
8. Select **Yes**.

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 biohazardous materials can cause bodily harm.



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

1. Open the solid waste door.
2. 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.
3. Empty the contents of the solid waste bins into a laboratory-approved container for biohazardous waste.
4. Return the bins to the solid waste drawer.
5. Push the drawer in.
6. Close the door.
7. To confirm the cuvette and sample tip waste is empty, select **Yes**.

Checking Decapper Waste

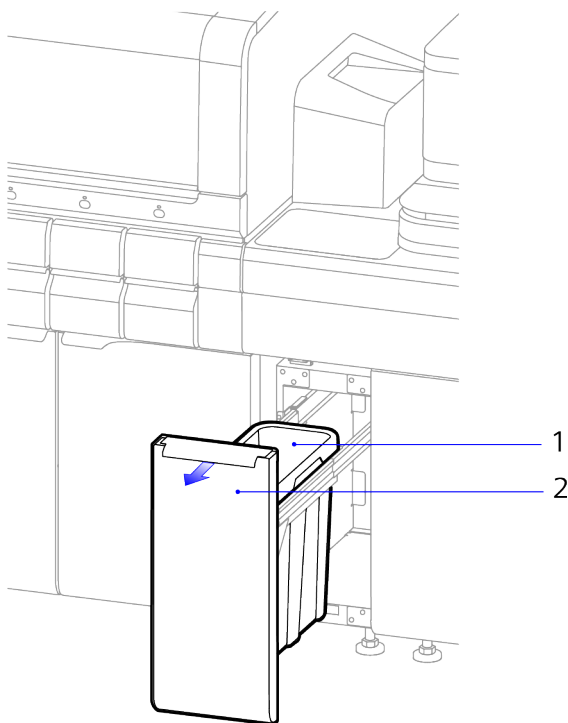
**BIOHAZARD**

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 lift the biohazard bag without being able to lift 15 pounds (6.8 kg). Lifting the biohazard bag without proper care risks personal injury.

1. On the Command bar, select **Inventory > Supplies Overview**.
2. Select .
3. Identify Decapper waste alerts.
4. If appropriate, 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

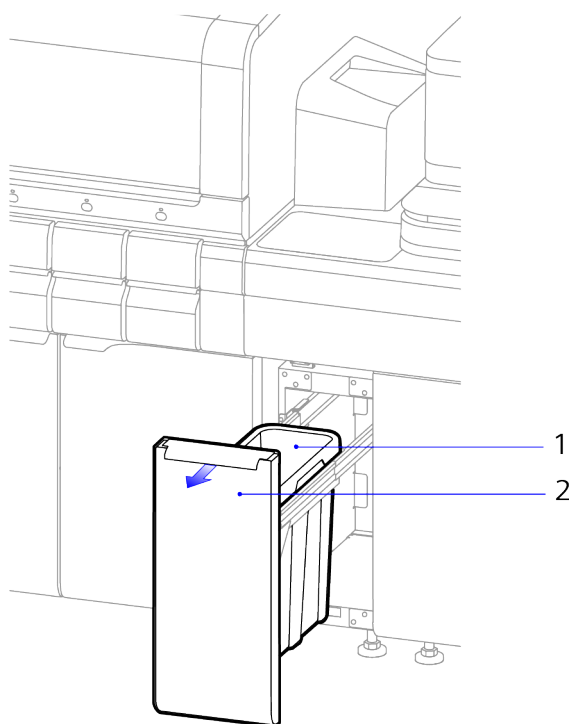
Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling biohazardous materials can cause bodily harm.



WARNING

Do not lift the biohazard bag without being able to lift 15 pounds (6.8 kg). 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 the Cal-QC Storage Inventory Tab

The Cal-QC Storage Inventory tab provides details about the individual calibrator and QC tubes in the Cal-QC storage area of all SHs or on the Atellica Magline Transport.

The Cal-QC Storage Inventory has 4 areas:

- Capacity
- Filter
- Cal-QC Sample Details
- Assay Details

About the Capacity Area

The Capacity area provides information on the total number of available and unusable Cal-QC storage positions.

Field	Notes
Available	The total number of Cal-QC storage positions available (positions with tube covers) for additional Cal or QC materials from all SHs.  displays if the number of available positions is greater than 0 but less than 5.  displays if the number of available positions is 0.

Field	Notes
Unusable	The total number of Cal-QC storage positions from all SHs 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 greater than 0.  displays if the number of unusable positions is greater than 10 % of the total capacity. NOTE: When the number of unusable positions equals 0, the Unusable field does not display and no alert icon displays.

About the Cal-QC Sample Details Area

The Cal-QC Sample Details area provides information for each Cal or QC tube available.

Functions are also available to display assay details for Cals or QCs or to unload selected tubes from the Cal-QC storage area.

Field	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.

Field	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.

Assay Details Area

The Assay Details area provides a list of the assays that use the selected Cal-QC material and expiration information for the assay.

Field	Notes
Assay	The assays that use 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 Calibration Needs

The system creates a forecast for the appropriate calibrator materials. The system determines the Calibration 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 CO adjustments.

Calibration Needs resets at end of operator-defined day. A need is red if the calibration expires within the period of time configured in **Setup > Settings > System Configuration > Alert Settings > Calibration Needs Configuration**.

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.

Calibration Needs	Notes
Selector column	Operator selects global check box for all or appropriate calibrators to create calibration orders when Create Cal Order is selected.
Calibrator Name	Name of the calibrator material from Calibrator Definitions Material Name.
Calibrator Lot	Calibrator material lot.
Onboard Status	States if the calibrator material is onboard and available (not expired or depleted).
Comment	Operator enters calibrator material comments.
Assay	Assays impacted by the calibrator need. The material must be loaded because the calibration on assays is required.
Calibration Expiration	Expiration date and time of the current calibration interval that requires calibration.
Reagent Lot and Pack	The appropriate reagent pack lot or Any if the order does not specify a reagent pack lot.

Calibration Needs	Notes
Analyzer	The analyzer associated with the calibration. A comma separates list of active analyzers if more than 1 analyzer requires the same calibrator.
Storable	Whether the calibrator material is stored onboard.
Create Cal Order	The system displays a calibration order on the appropriate rows. The operator confirms calibration order before saving.
Group by Calibrator Material	The system displays calibrator by Calibrator Material.
All	The system displays calibrator material onboard and not onboard the analyzer.

Reviewing Calibration Needs

1. On the Command bar, select **Inventory > Calibration Needs**.
2. To group calibrator material by Calibrator Name, select **Group by Calibrator Material**.
3. To sort calibrator material that is onboard, select **All**.
4. To sort the calibrator information, select any Calibrator Name row.
NOTE: Select the same column header a second time to reverse the sort order.

About QC Needs

QC Needs is created for a QC material based on:

- Tests set by the QC scheduler performed before the end of the operator-defined day.
- Any pending QC orders in Worklist.
- The required control material is expired, low, or not onboard.

QC Needs resets at end of the operator-defined day. A need is red when 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
Name	The name of the control material from QC Definitions Control Name.
Control ID	A unique identifier for the control from QC Definitions Control ID.
Control Lot	The lot of the control material.
Level	The concentration level of the control material.
Onboard Status	Whether the control material is onboard and available (not expired or depleted).
Scheduled	Whether the control is automatically scheduled.
Usable Volume Needed (µL)	The volume of the control required for the day.
Assay	The assays associated with the control.
Storable	Whether the control material is stored onboard.
Group by QC Material	The system displays control by Name.
All	The system displays control material onboard and not onboard the analyzer.
QC Order	The operator manually creates 1 or more QC orders on demand for multiple reagent packs or analyzers for a QC product where all selected assays perform.

Create QC Orders displays when the operator selects **QC Order** to manually create 1 or more QC orders on demand for multiple reagent packs or analyzers for a QC product where all selected assays perform.

Create QC Orders	Notes
Select Assays	The operator selects analyzers and assays for QC orders in this section.
Perform QC On	The operator selects the appropriate analyzer or analyzer group from the drop-down menu: • All Analyzers • All CH Analyzers • All IM Analyzers • List of all the analyzer names on the system All active assays display for the selected analyzers.
Search	The operator enters the assay name to search for the appropriate assay and selects 1 or more assays from the table.
Select Packs	The operator selects which reagent packs are included (current or all) in the QC order.
Select Current Pack for All Assays	The analyzer performs the QC order on the pack in use for the assay during the execution of the order.
Current Pack	The pack the analyzer uses to perform QC for the assay during the execution of the order. To place an order for all assays and their current pack, the operator selects Select Current Pack for All Assays .
Select All Packs for All Assays	When a single analyzer is selected in Perform QC On, the operator selects to include all reagent packs onboard for that analyzer.
Add All Assays	The operator selects to add all assays in assay table to QC orders.

Create QC Orders	Notes
Remove All Assays	The operator selects to clear all assays in assay table.
Create Order	The analyzer creates the configured QC orders.
Cancel	The analyzer clears Create QC Orders without creating any orders.

Reviewing QC Needs

1. On the Command bar, select **Inventory > 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.

Creating QC Orders from QC Needs

The operator uses Create QC Orders in QC Needs to manually create 1 or more QC orders on demand for multiple reagent packs or analyzers for a QC product where selected assays perform.

1. Ensure that 1 of the following is configured in the Material for Automatic QC Order section of **Setup > Settings > General Setup > QC**:
 - To order a single QC level for each enabled specimen, select **1 Level**.
NOTE: When 1 Level is selected, the analyzer selects the QC material to expire first for the assay regardless of its level in the QC Definitions.
 To select specific QC levels for an order, create the order in QC Orders.
 - To order all levels of a QC material for each enabled specimen, select **All Levels**.
2. On the Command bar, select **Inventory > QC Needs**.
3. Select **Create QC Orders**.
4. In Perform QC On, select the appropriate analyzer or the analyzer group from the drop-down menu.
NOTE: All active assays display for the selected analyzers.
5. To search for an assay, enter the assay name in Search.
6. Select 1 or more assays from table.

7. To select the in use reagent packs for the selected analyzers in step 3, select the option **Select Current Pack for All Assays**.

NOTE: The analyzer performs the QC order on the pack in use for the assay during the execution of the order.

8. To select all reagent packs onboard when 1 analyzer is selected in step 3, select the option **Select All Packs for All Assays**.

NOTE: The selected analyzer punctures all the reagent packs for the selected assays to perform QC.

9. Select **Create Order**.

NOTE: The analyzer creates QC orders using the onboard QC materials for each fluid type of the defined QC material for the selected assays or the oldest active offboard QC product if nothing onboard.

10 Patient Orders

The chapter provides information about patient orders.

About Create Patient Orders

Create Patient Orders allows the operator to manually enter sample information, print barcodes for a single patient order, or configure Run ID settings for a worklist.

Patient orders require a sample ID, a 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.

Sample Information	Notes
Sample ID	The identification code for the sample. This field accepts upper and lower case characters as well as some special characters. It does not accept the following special characters: !, @, #, ^, & or ?. This field is case-insensitive and can accept up to 20 characters.
Rack ID	The identification number of the rack. The second field designates which section of the rack holds the sample tube.
Specimen	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	The operator can select For Study for lot to lot comparison studies, duplicate measurements, or performing evaluations with patient samples. For Study results transmit to the LIS only if the operator manually transmits them.

Sample Information	Notes
Priority	The order in which the system processes the samples. Routine is the default. The system processes STAT samples first.
Test Selections	Notes
Module Type	The analyzer type performing the tests. This field is optional and functions only to filter the test selection options.
Select Tests	A drop-down menu displaying the tests available for that specimen type and analyzer, if selected.
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. The  next to the test deletes the test from the order.
Dilution	The dilution factors available to the assay as defined in the test definition and performed by the analyzer.
Replicates	The number of times to perform the test. The IM Analyzer uses replicates to determine the mean test result.
System Test Options	The option to change the reagent lot and analyzer associated with this test.

Ordering Patient Tests

1. On the Command bar, select **Patient Orders > Create Patient Orders**.
2. Scan the sample tube barcode or manually enter a Sample ID.

NOTE: Barcode scans automatically activate the entry fields. To advance to any field for additional information, select the field or select **Tab** on the keyboard.

3. Select a Specimen.

NOTE: To add more information about the sample, including collection and receipt date and sample comments, in the Sample Information area, select **Additional Sample Information**.

4. Select a STAT, ASAP or Routine Priority.

NOTE: Routine is the default priority.

5. Enter the Patient Demographics.

NOTE: To add more details about the patient, including Patient Status, in the Patient Demographics area, select **Additional Patient Information**.

6. Select the Select Tests drop-down menu.

NOTE: The operator can only select tests that support the specified Specimen.

7. Select 1 or more Tests.

8. To add the same test to an order, select  next to that test in the Orders area.

NOTE: When adding a test more than once to the same order, the operator can run the same test on different modules, reagent lots or packs. This option provides additional result choices. The operator can change these settings in System Test Options.

9. Select **Save**.

About Create Batch Order by Rack ID

Create Batch Order by Rack ID allows the operator to order the same tests for samples in specific racks.

Sample Information	Notes
Batch Name	A unique name for the batch.
Specimen	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.

Sample Information	Notes
Comment 1, Comment 2, Comment 3	Comments the operator enters or selects from the drop-down menu.
Rack ID	The rack or racks holding the samples in the batch. Add or Edit Rack IDs allows the operator to add, edit, or delete the Rack ID.
Test Selections	Notes
Module Type	The analyzer type performing the batch tests. This is an optional field for filtering the test selections.
Select Tests	A drop-down menu displaying the tests available for that specimen type and analyzer.
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. The  next to the test deletes the test from the order.
Dilution	The dilution factors available to the assay as defined in the test definition and performed by the analyzer.
Replicates	The number of times to perform the test. The IM analyzer uses replicates to determine the mean test result.
System Test Options	The option to change the reagent lot and analyzer associated with this test.

Creating Batch Orders by Rack ID

1. On the Command bar, select **Patient Orders > Create Batch Order by Rack ID**.
2. Enter a Batch Name.
3. Select a Specimen type from the drop-down menu.
4. Select up to 3 comments from the drop-down menus or enter a unique comment.
5. 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.
6. Select the Select Tests field to add tests from the selection menu.
7. Select 1 or more tests.
8. To add the same test to an order, select **+** next to that test in the Orders area.
NOTE: When adding tests more than once to the same order, the operator can perform the same test on different modules, reagent lots or packs. This option provides additional result choices. The operator can change these settings under System Test Options.
9. Select **Save**.
NOTE: To process batch orders, the operator must **Activate Batch**.

About Create Batch Orders by SID

Create Batch Orders by SID allows the operator to create orders using the same assays for a range of sample IDs.

When creating batch orders by SID, the following guidelines apply:

- The starting and last IDs cannot match any sample IDs the system defines 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	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	The operator can select For Study for lot to lot comparison studies, duplicate measurements, or performing evaluations with patient samples. For Study results transmit to the LIS only 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.
Test Selections	Notes
Module Type	The analyzer type performing the batch tests. This is an optional field for filtering the test selections.
Select Tests	A drop-down menu displaying the tests available for that specimen type and analyzer.
Orders	Notes
Tests	The selected test or tests. The operator can select  next to each test to add multiple instances of the same test to the order. The  next to the test deletes the test from the order.

Orders	Notes
Dilution	The dilution factors available to the assay as defined in the test definition and performed by the analyzer.
Replicates	The number of times to perform the test. The IM analyzer uses replicates to determine the mean test result.
System Test Options	The option to change the reagent lot and analyzer associated with the test and sample.

11 Worklist

The chapter provides information about test results.

About Worklist Overview

Worklist Overview displays information about the Sample, patient demographics, results, and the associated tests.

In Worklist Overview, 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 2 additional operator-configured columns.

The following information is available for worklist:

Feature	Notes
Priority	Displays the following order priority: • Blank for Routine • * for ASAP • ! for STAT
One of Order Time, Scanned Time, or Result Time. This column displays when the Filter pane is collapsed.	An operator-configured column that displays Order Time, Scanned Time, or Result Time in the header. The operator selects the column header and 1 of the following radio buttons: • Order Date: The time the system received the order. • Scanned Date and Time: The time the system scanned the sample. • Result Date and Time: The time the test resulted.

Feature	Notes
SID or Run ID	An operator-configured column that displays SID or Run ID. The operator selects the column header and 1 of the following: • SID as the sample identifier. • Run ID as an identifier the operator applies to orders. The operator configures Run ID when creating an order. Selecting an SID or Run ID opens Sample Details. Sample Details provides additional information about the Sample and associated tests.
Test	The test display name as configured in the test definition. Selecting a Test name opens Test Details. Test Details provides additional information about the Test and the associated Sample.
Result or RLU/ABS	An operator-configured column that displays Concentration/Index or RLU/ABS. The operator selects the column header and 1 of the following: • Concentration/Index Displays the result value for concentration or index. The column header changes to Result. • RLU/ABS Displays the relative light units (RLU) that the luminometer measures. The column header changes to RLU/ABS.

Feature	Notes
Interpretation	The test result is Positive, Negative, Equivocal (unclear) or, depending on the assay, Reactive, or Nonreactive (Page 558 <i>About Interpretation Ranges</i>).
Flags	Flag glyphs or text associated with the test. The operator can select the Flag to display additional information.
The last column This column displays when the Filter pane is collapsed.	Operator-configured columns. The operator selects the column header and 1 of the following radio buttons: • Analyzer • Aspirated Date Time • Calibration Lot • Control Lot • Patient / Control / Calibrator Name • Patient ID, Control / Calibrator Lot • Rack ID • Reagent Lot • Run ID • Specimen Type • Sample Type • Patient Location • RLU/ABS • None
The following functions are available for samples:	
Function	Notes
Edit/View...	Opens the Sample Details.
Add Test to Order	Opens Order Details. Only available for 1 Sample selection at a time.

Function	Notes
Start Watching	Adds the Order to the Watch List.
Stop Watching	Removes the Order from the Watch List.
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.
Delete Order	Deletes the Order for the selected Sample including all associated tests.
Unsuspend	Resumes Orders in the Suspend test state due to Rack ID Alarm or Rack ID Conflict errors.

The following functions are available for eligible Tests:

Function	Notes
Repeat	Repeats the test and provides access to Repeat Options... The system can only repeat patient sample test. Tests must have active results and must not be in the Historical Database.
Accept	Accepts the Result. Tests must have active results and be in the Hold test state.
Comment	Provides the option to enter new or select up to 3 predefined result comments. Predefined comments must be configured in Directories.

Function	Notes
Transmit	Transmits results to the LIS manually. Tests must be in the Complete, Transmit Failed, or Transmitted test states.
Cancel	Changes the test state to the previous test state. Tests must be in the Repeat, Error, or Inprocess without an ETA (not aspirated) test states.
Delete Test	Removes ordered Tests from the sample. Tests must be in the New test state. Only available for tests from 1 Sample at a time.

The following functions are available for Worklist Overview:

Function	Notes
Filter	Provides the option to Select
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.

About Starting to Watch Samples

Start Watching adds a sample to the Watch List. The Watch List follows any set of individual samples or tests as a group. The operator can select the Watch List in the filter section to display it in Worklist Overview.

Adding Samples to the Watch List

1. On the Command bar, select **Worklist > Worklist Overview**.
2. To narrow the displayed samples, filter the list.
3. To sort the Worklist Overview list, select an option from the Sort By drop-down menu or select a column header.
NOTE: Select the same column header a second time to reverse the sort order.
4. Select the check box of the appropriate SIDs.
5. Select **Start Watching**.
6. Select **OK**.

Removing Samples From the Watch List

1. On the Command bar, select **Worklist > Worklist Overview**.
2. To narrow the displayed samples, filter the list.
3. To sort the Worklist Overview list, select an option from the Sort By drop-down menu or select a column header.
NOTE: Select the same column header a second time to reverse the sort order.
4. Select the check box of the appropriate SIDs.
5. Select **Stop Watching**.
6. Select **OK**.

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.
Abnormal Assay	CH	Alphanumeric	Yes	Results monitoring detected an abnormal assay.

Flag	Analyzer	Result Type	To LIS	Notes
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.
Cal Expired	CH/IM	Calibration	Yes	The active calibration expired.
Cal Extended	IM	Alphanumeric	Yes	The operator extended the active calibration.

Flag	Analyzer	Result Type	To LIS	Notes
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.

Flag	Analyzer	Result Type	To LIS	Notes
Check Stability	IM	None	Yes	The result aspiration exceeded the Analyte Stability or First Aspiration Time Out in the test definition.
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.

Flag	Analyzer	Result Type	To LIS	Notes
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.
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.

Flag	Analyzer	Result Type	To LIS	Notes
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.
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.

Flag	Analyzer	Result Type	To LIS	Notes
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/IM	None	Yes	The reaction ring bath (CH) or reaction ring compartment (IM) 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.

Flag	Analyzer	Result Type	To LIS	Notes
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.
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.

Flag	Analyzer	Result Type	To LIS	Notes
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.
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.

Flag	Analyzer	Result Type	To LIS	Notes
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 Open Channel. 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.

Flag	Analyzer	Result Type	To LIS	Notes
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.
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.

Flag	Analyzer	Result Type	To LIS	Notes
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.
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 Time-out	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.

Flag	Analyzer	Result Type	To LIS	Notes
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.
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.

Flag	Analyzer	Result Type	To LIS	Notes
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.
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.

Flag	Analyzer	Result Type	To LIS	Notes
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.
Signal shape error	IM	Error	No	The system did not obtain a result because a signal shape error occurred.

Flag	Analyzer	Result Type	To LIS	Notes
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
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 LYLES	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.
Unknown Error	CH	None	Yes	The system detected an error in the methpar.

Flag	Analyzer	Result Type	To LIS	Notes
Waiting for HIL	CH/IM	Alphanu- meric	Yes	The result is pending the results of the serum indices: hemolysis, icterus, or lipemia.
Waiting for H	CH/IM	Alphanu- meric	No	The result is pending the results of the hemolysis serum index.
Waiting for I	CH/IM	Alphanu- meric	No	The result is pending the results of the icterus serum index.
Waiting for L	CH/IM	Alphanu- meric	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.

Flag	Analyzer	Result Type	To LIS	Notes
Within Check	CH/IM	Alphanumeric	Yes	The result is within the check range in the test definition.
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.

Monitoring

12 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 294 *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.

HIL Absorbance Measurements

The system can perform HIL processing in 1 of 2 ways. The CH Analyzer can pipette a known quantity of sample into an empty cuvette with system water to process HIL tests or use an HIL provider assay:

HIL Processing type	Description
HIL with system water	Report results in 66 seconds.
HIL with provider assay	Report results when the provider assay completes.

For HIL with a provider assay, the CH Analyzer uses a cuvette with 1 of the following reagents, in order of priority:

1. ALT
2. ALTPLc
3. AST
4. ASTPLc
5. LDLP

The system uses a provider assay if 1 is available on the work order with the HIL test. If more than 1 provider assay is on the work order, it uses the provider assay with the highest priority. The analyzer prepares the cuvette as it does for routine patient testing.

The analyzer takes absorbance measurements 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 295 *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 for Hemolysis (H), Icterus (I), and Lipemia (L):

Index Level	H	I	L
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 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.
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.

Rack status	Notes
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.

Rule	Notes
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.
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.
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 the Sample Handler Tab

The Sample Handler tab provides an overview of the status of the SH, sample drawers, and all racks and sample containers in the sample drawers.

The system displays a colored glyph for each sample container position in every rack in the sample drawers and descriptive text beside each glyph.

NOTE: The shape and color of the glyph describes the status of the sample container position:

- A round glyph identifies a patient sample container.
- A square glyph identifies a calibrator or QC container.

Sample container position glyph	Glyph description
	The status of the position is unknown.
	The position is empty.
	An unidentified container. The DVS scanned the position and a container is present but the TCS has not yet scanned the barcode.
	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.

Sample container position glyph	Glyph description
	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.
 	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 identified a container and is waiting to sort the container.
	The sample status is "Waiting" or "Started."
	The sample status is "Aspirated."
	The sample status is "Complete."

Sample container position glyph	Glyph description
	A sample error occurred. Errors include: • Insufficient sample • Clot error • Integrity error • Whole blood timeout The operator must remove the sample container from the system and address the error. The operator may return the container to the system after resolving the error.
	The sample container has no orders. The operator must check for orders. If no orders exist, the operator may enter an order manually or remove the container from the system.
	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.
	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.

Sample container position glyph	Glyph description
	The operator configured the calibration or QC container to store in the Cal-QC storage area, but the storage area is full. 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 the Cal-QC storage area. The operator did not configure the calibration or QC container to store in the Cal-QC storage area and the sample status is "Waiting" or "Started", but aspiration is not complete.
	The sample status is "Aspirated" and the operator did not configure the container to store in the Cal-QC storage area.
	The system identified the container as a calibrator or QC usable container. If the operator did not configure the calibration or QC container to store in the Cal-QC storage area, the sample is complete. All orders for the calibrator or QC material have results.
 	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.

Sample container position glyph	Glyph description
	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.
	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 may enter an order manually or remove the container from the system.

The Sample Handler tab has 2 subtabs:

- Racks
- Sample Details

About the Racks Subtab

The Racks subtab displays glyphs to show the status of the sample drawers, rack positions, and each sample container position in every rack in the sample drawers.

The system displays 1 of the following glyphs below each drawer position in the Racks subtab:

Drawer glyph	Glyph 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 is initializing the drawer DVS. The system waits until initialization is complete before accessing samples in the drawer.
	The system detected a drawer hardware error.
	The system detected a drawer DVS error.
No glyph 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 glyphs below each rack zone in the Racks subtab:

Rack zone glyph	Glyph 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.

Rack zone glyph	Glyph description
	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.
No glyph displays	Combined The system uses a rack in the zone for sample processing input and output. The system takes samples from a rack in the zone, processes them, then returns them to the same rack or another rack. NOTE: The system does not always return samples to the same rack or the original sample position.

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 area to the left of the Racks subtab.

The system displays a colored glyph for each sample container position in every rack in the sample drawers. The shape and color of the glyph describes the status of the sample container position (Page 303 *About the Sample Handler Tab*).

About the Sample Details Subtab

The Sample Details subtab provides access to the sample details for all samples present in the sample drawers.

The Sample Details subtab displays the following sample information:

Sample detail	Notes
Priority	The sample priority, such as Routine or STAT.

Sample detail	Notes
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.
Location	The position of the sample in the rack with the rack barcode displayed.
Sample Attributes	The sample container special attributes. The attributes include: Tube Top Cup, Capillary, Capped, False Bottom, or None (no special attributes).
Reason Not Stored	The reason the system did not store a calibrator or QC material in the Cal-QC storage area, such as Refrigeration Not Required.
Error List	The errors associated with the sample. If no errors are associated, the system displays None.

About the Sample List

Sample List provides access to the current sample status details for all samples on the system.

Filters 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
Lot/Patient ID	The lot number or patient ID associated with the sample.

Sample detail	Notes
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.
Cap Status	The sample container cap status. The statuses include: Unknown, No Cap, Capped, Decap Pending, Decapped, and Decap Error.
Sample Type	The sample type. The types include: Patient, QC, and Cal.
Sample Container Type	The type of sample container.
Location	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.
Scanned Time	The time the system reads the sample barcode at the TCS.
Sample Attributes	The sample container special attributes. The attributes include: Tube Top Cup, Capillary, Capped, False Bottom, or None (no special attributes).
Reason Not Stored	The reason the system did not store a calibrator or QC material in the Cal-QC storage area.
Problems Associated	The causes associated with all sample errors. If no errors are associated, the system displays None.

Sample Volume Requirements

System sample volume requirements depend on assay requirements, specific unusable volumes by analyzer and container type.

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 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_3: 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

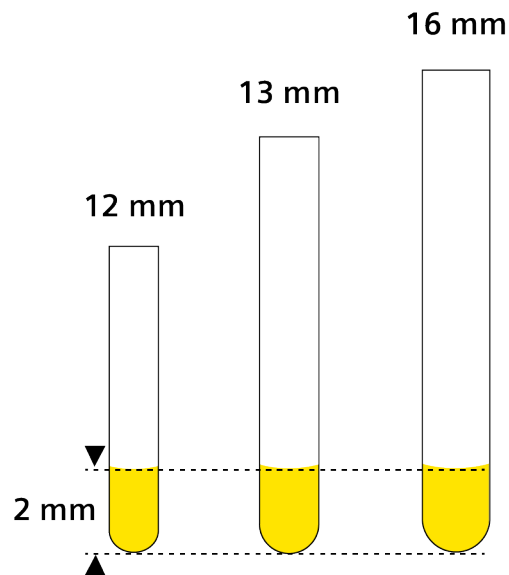
The assay IFU includes:

- Sample volume: The analyzer delivers pre-diluted sample to the reaction cuvette.
- Primary sample dilution by sample type located in the Assay Procedure section.

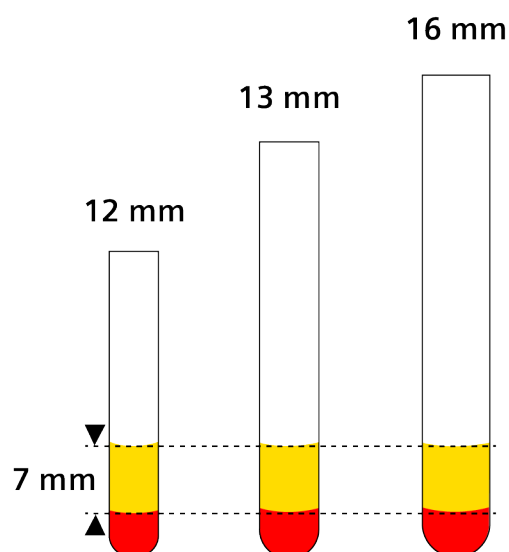
About CH Minimum Sample Height

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 618 *About Supported Sample Containers*).

The operator uses the following table to calculate CH sample volume requirements:

Sample container type	Sample container unuseable 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 μ L	35 μ L	25 μ L
Atellica Solution Tube-Top Sample Cups (TTSC) 2 mL green	25 μ L	50 μ L	25 μ L
False-Bottom - Sarstedt Pour-off Tube 12X75	50 μ L	75 μ L	25 μ L

Sample container type	Sample container unusable volume	Minimum sample volume for sample height	Usable volume with minimum sample height volume
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.

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 313 *About Determining the Minimum CH Assay Sample Volume*) for primary sample volume requirements and the CH Sample Container Volume Requirements (Page 315 *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 TSC container:

1. Primary sample volume for 16 chemistries ($2 \times 50 \mu\text{L}$) + 3 IMT ($25 \mu\text{L}$) + unusable volume for 1 ml TTSC ($10 \mu\text{L}$)
 $(2 \times 50) \mu\text{L} + 25 \mu\text{L} + 10 \mu\text{L} = 135 \mu\text{L}$
2. Volume required for minimum height for 1 mL TTSC = $35 \mu\text{L}$ total volume required
 Use the greater value ($135 \mu\text{L}$) for the minimum required volume $135 \mu\text{L} > 35 \mu\text{L}$
 MRV = $135 \mu\text{L}$

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 ($50 \mu\text{L}$) + 3 IMT ($25 \mu\text{L}$) + unusable volume 16 mm tube ($200 \mu\text{L}$)
 $50 \mu\text{L} + 25 \mu\text{L} + 200 \mu\text{L} = 275 \mu\text{L}$
2. Volume required for minimum height for 16 mm tube with separator gel (7 mm above the gel) = $1600 \mu\text{L}$ total volume required.
 Use the greater value ($1600 \mu\text{L}$) for the minimum required volume
 $1600 \mu\text{L} > 275 \mu\text{L}$ MRV = $1600 \mu\text{L}$ (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 .

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 318 *IM Sample Volume Requirements*).

- For a single replicate of 1 test:

$$\text{Sample Volume} + \text{Tip Prime Volume} + \text{Unusable Volume} = \text{MRV}$$

- For multiple replicates of 1 test:

$$(\text{Sample Volume} + \text{Tip Prime Volume}) \times \text{Number of Replicates} + \text{Unusable Volume} = \text{MRV}$$

- For multiple tests scheduled for a sample:

$$\text{Sum of (Sample Volume} + \text{Tip Prime Volume) for all replicates for all tests} + \text{Unusable Volume} = \text{MRV}$$

IM Sample Volume Requirements

The IM Analyzer can use multiple sample containers (Page 618 *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

13 Calibration

This chapter provides information about calibrating assays.

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 saline 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.

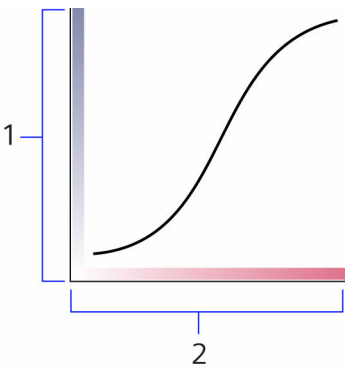
About IM Assay Master Curves

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.

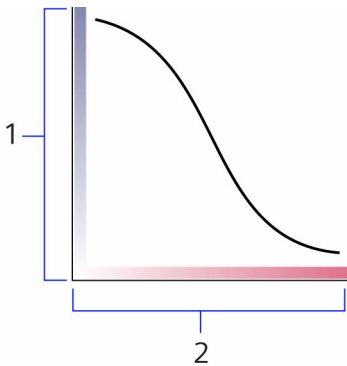
Master curve for a sandwich test



- 1 RLU
- 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



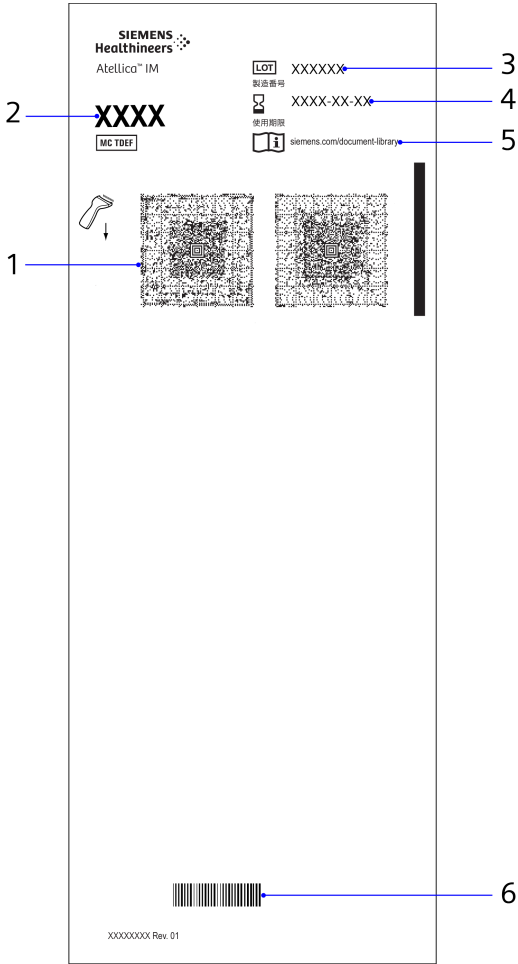
1	RLUs
2	Analyte concentration

About 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	6	Linear barcode for manufacturer use only
3	Lot		
4	Expiration date		

About Quantitative and Qualitative IM Assay Reagent Calibrations

The system calculates and reports quantitative assay results to indicate the concentration of the analyte and qualitative assay results to indicate the presence or absence of the analyte.

The IM Analyzer performs a 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:

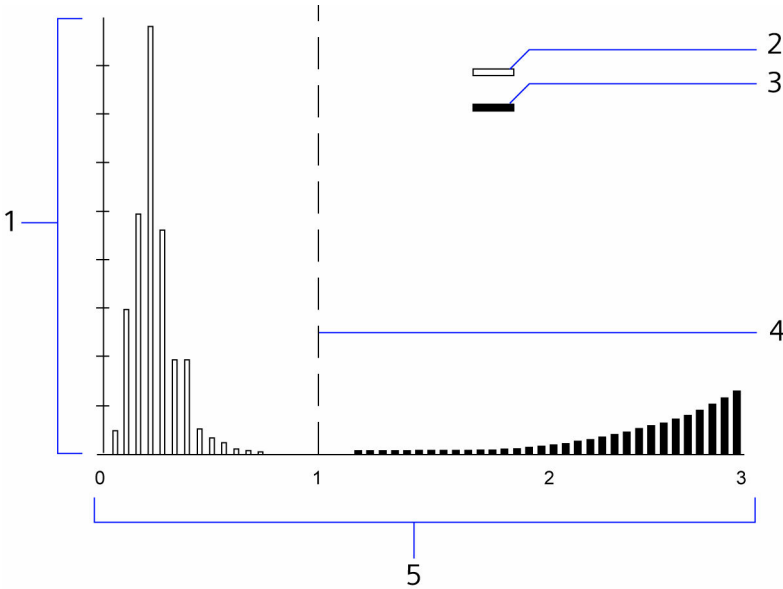
$$\text{adjusted RLUs} = \text{observed RLUs} \times \text{defined slope} + \text{defined intercept}$$

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 IM Analyzer 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 Assay Reagent Calibration Frequency

Perform assay reagent calibration according to the following:

- Expired assay reagent calibration
- New assay reagent lot
- 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 335 *About CH Lot and Pack Assay Reagent Calibrations*) (Page 338 *About IM Lot and Pack Assay Reagent Calibrations*)
- Reagent pack

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 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 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 a CH DL, load the calibrator samples on a rack and place the rack on 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: Some CH calibrator material is not eligible for onboard 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.

Load calibrator samples directly into the SH drawer for processing.
8. 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 biohazardous materials can cause bodily harm.

**CAUTION**

Do not reuse IM 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 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 a IM DL, load the calibrator samples on a rack and place the rack on 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.

Prepare and bring the IM calibrator samples to ambient temperature. Load the calibrator samples directly into the SH drawer for processing.

8. Review the calibration results.

About Calibration Overview

Calibration Overview provides information for assay reagent calibrations on the system. Calibration Overview provides the following functions:

- Manage extending calibrations
- View calibration result details
- Access Cal-QC Inventory
- Print calibrator or QC material reports
- Print calibrator or QC material barcodes

Red and yellow highlights alert the operator to critical and impending warning calibration or QC events.

Alert highlight	Notes
Red	• Calibration or QC material status is Expired or Invalid. • The master curve for an IM assay is missing.
Yellow	• Calibration status of Expires Soon. • Calibration acceptance data requires operator intervention to accept or reject the calibration. • Calibrator or QC material is not onboard the system. • QC requires operator intervention.

The Filters area provides the following filter options:

- Analyzer
- Assays
- Expiration
- Order Status

 icons sort the column contents in ascending or descending alphanumeric order.

Column header	Notes
Assay	Assays with TDefs and usable reagents on the system display.

Column header	Notes
Analyzer	The identified analyzer containing the assay reagent.
Order Status	Glyphs display calibration order status (Page 331 <i>Assay Reagent Calibration Order Status Glyphs</i>).
Cal Type	The type of calibration: • Lot • Pack • Blank, no calibration exists
Calibration Interval	Days and hours before the calibration expires.
Reagent Lot	Assay reagents and lots on the system.
Pack Barcode	Reagent pack barcodes display for Pack cal types. Well numbers display for CH pack calibrations.
Calibrator Lot	The lot ID of the calibrator displays.
QC Material	Control lot displays.

About the Calibration Overview Filter

The Calibration Overview Filters area provides the following options:

- Analyzer
- Assays
- Expiration
- Order Status

The operator can use the Analyzer drop-down menu to select the appropriate analyzer. The Assays drop-down menu displays an alphabetical list of available assays.

Expiration	Notes
Expired	Filters according to expired calibrations.
Expires Within	Filters according to the time period before the calibration expires. Select the time in hours from the drop-down menu.
Order Status	Notes
Ordered	Filters according to existing calibration orders.
Processing	Filters according to calibration orders in process.
Intervention Needed	Filters according to calibration orders the system cannot process due to correctable issues.
Error	Filters according to calibration orders that the system cannot process.

Assay Reagent Calibration Order Status Glyphs

The system displays calibration order status glyphs in the Order Status column.

Calibration Order Status Glyph	Notes
	Ordered
	Valid
	Processing
	Intervention Needed
	Error

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 to report results with an expired calibration, the operator may choose to extend the lot calibration. The system uses the extended calibration to calculate results and flags the results as Cal Extended. Extending a calibration is available for lot calibrations but not available for pack calibrations.

NOTE: The system cannot report results for samples processed after a calibration expires and before the operator extends the calibration.

The feature provides the laboratory the option for extending lot calibration intervals for all CH assays and only specific IM assays. The IM test definition contains the setting options for extending IM assay calibrations.

The system sets the extended calibration interval for an assay reagent lot to 180 days.

NOTE: Recalibrate the assay reagent lot as soon as possible following a calibration extension.

About Create Calibration Orders

The system performs automatic and manual calibrations. The Create Calibration Orders tab provides the following functions for placing manual calibration orders:

- Select assays and calibrator products.
- Edit calibration orders.
- Place 1 or more orders.

If multiple calibrator definitions exist for the selected assay, the calibrators display in the Calibrator Material area. If only 1 calibrator definition exists for the selected assay, the calibrator displays directly in the Orders area.

The operator can view information and create calibration orders in the Calibrator Material area.

Calibrator Material area	Notes
	System creates a calibrator order
Cal Name	Name of the calibrator material
Cal ID	A unique identifier, containing 0–2 alphanumeric characters, for the calibrator associated with an analyzer
Cal Lot	Calibrator lot number
Cal Lot Exp	Expiration date of the calibrator lot
Assays	Calibrator definition includes specific assays

New orders display in the Orders area. The operator can view, edit, remove, or duplicate the order to calibrate multiple packs or lots.

Orders field	Notes
	System removes the order.
Cal Name	Name of the calibrator material.
Reagent Lot	Primary reagent pack lot.
Tests Remaining	Total number of usable tests remaining on the analyzer for multiple packs of the same assay reagent lot.
Analyzer Identifier	The analyzer associated with the calibration.
Assay	Selected assay for calibration.
Cal Lot	Calibrator lot number.
Pack ID	ID number of the reagent pack.

Orders field	Notes
Edit Cal Order 	Edit the order to assign the following: • Assay reagent lot • Calibration type • Pack ID • Ancillary 1, Ancillary 2, or Diluent pack IDs for IM assay reagents • Replicates • Perform QC with Calibration • A rack ID for an analyzer with a DL

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.

If the assay reagent pack is onboard the system beyond 24 hours, the system may override the lot calibration designation and save the results as a pack calibration (Page 335 *About CH Lot and Pack Assay Reagent Calibrations*) (Page 338 *About IM Lot and Pack Assay Reagent Calibrations*). To ensure the system performs a lot calibration, in Edit Cal Order, select the unpierced well of the pack or load a new pack.

Assay Reagent Calibration Types

Calibration type	Notes
Autoselect Cal Type	The system automatically creates a lot or pack calibration order for a reagent according to the status of the pack.
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.

Calibration type	Notes
Automatic Measuring Interval Verification	If selected in Edit Cal Order, the CH Analyzer performs automated serial dilutions using calibrator material.
Manual Measuring Interval Verification	If selected in Edit Cal Order, the system performs manual measuring interval verifications using prepared linear material that the operator defines as measuring interval verification material.

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.

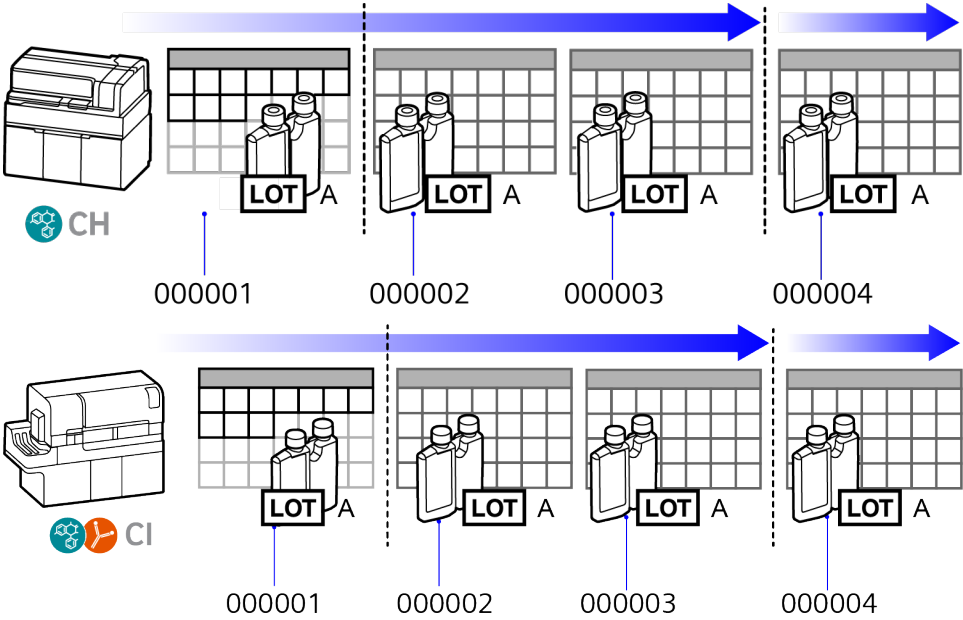
To establish a lot calibration, calibrate a new assay reagent pack within 24 hours after loading the first pack of the lot on the system. When the system opens subsequent reagent packs or wells of the same lot, the system uses the lot calibration to calculate test results until the lot calibration interval 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 337 *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 CH Assay Pack Calibrations

The CH Analyzer supports 2 types of pack calibrations:

- Full
- CO Adjust

The system uses multiple calibrator levels for a full pack calibration but only a low level calibrator for CO Adjust pack calibrations.

The system determines if a pack or well is eligible for CO Adjust pack calibration.

Assays require CH Diluent for the low level calibrator for CO Adjust pack calibrations. The operator orders a Pack Calibration for a CO 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 on the system longer than 24 hours, the system overrides the CO Adjust pack calibration setting in the CH Test Definition and performs a Full pack calibration. Ensure the appropriate calibrator level samples are available (Page 335 *About CH Lot and Pack Assay Reagent Calibrations*).

NOTE: If a Lot Calibration does not already exist, the system overrides a CO Adjust calibration order and performs a Full pack calibration.

About IM 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 only.

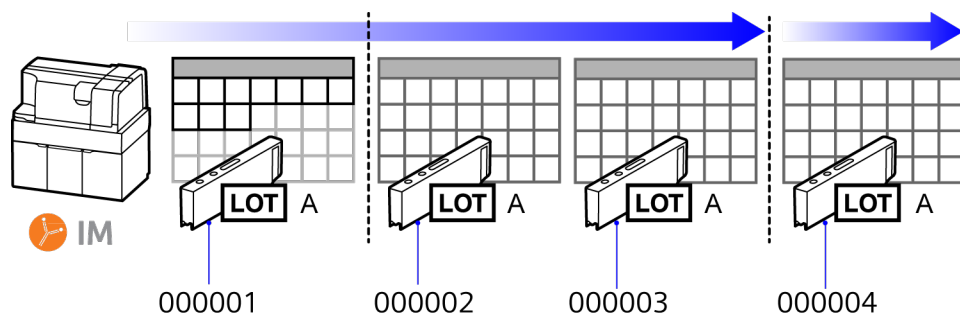
To establish a lot calibration, calibrate a new assay reagent pack shortly after loading the first pack of the lot on the system. When the system opens subsequent reagent packs of the same lot, the system uses the lot calibration to calculate test results until the lot calibration interval expires. A 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. A reagent pack calibration interval has a shorter duration than a reagent lot calibration interval.

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
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 calibration interval expires. 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.
Lot A, Pack 000002	Day 15: Pack 000002 does not require calibration because the lot calibration for Lot A is still valid.
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 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 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.
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 Calibrating Assay Reagents Directly in Reagent Overview

The system supports calibrating the following directly in Reagent Overview (Page 189 *About Inventory Reagent Overview*):

- CH reagent packs and wells
- IM reagent packs

2 selectable options display in Reagent Details:

- Calibrate Lot
- Calibrate Pack

Calibrate Lot is enabled when an IM reagent pack or CH pack or well is eligible for a lot calibration. Calibrate Pack is enabled when an IM reagent pack or CH pack or well is eligible for a pack calibration (Page 189 *About Inventory Reagent Overview*).

The system performs lot calibrations or pack calibrations depending on eligibility requirements (Page 335 *About CH Lot and Pack Assay Reagent Calibrations*) (Page 337 *About CH Assay Pack Calibrations*) (Page 338 *About IM Lot and Pack Assay Reagent Calibrations*).

When calibrating reagent packs or wells directly from Reagent Overview, the system requires 1 active calibrator definition. If more than 1 calibrator definition exists on the system for a reagent, the system defaults to using the oldest calibrator material and definition to calibrate the reagent. To ensure the system uses a specific calibrator material and definition, in Calibrator Definitions, the operator selects Active for the preferred calibrator definition and deselects Active for the remaining calibrator definitions as appropriate. If the Cal-QC storage area contains multiple calibrator sample sets for 1 calibrator definition and material, the system uses the oldest calibrator sample set.

When the operator selects Calibrate Lot or Calibrate Pack for reagents that the system uses to process more than 1 test, the system displays a menu listing the assays. For example, if the operator selects HBsII the displayed menu includes HBsII and CONF. The operator selects HBsII or CONF as appropriate.

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 Automatic Assay Reagent Calibration Orders

The system automatically creates a calibration order when the following conditions apply:

- At least 1 automatic calibration trigger selection exists in the assay test definition.
- 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, Extended, Due to Expire, or Not Calibrated**.
- For IM assays with control bracketing, 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:

- Calibrator lot is not expired.
- Calibrators belong to the same lot.

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.

About CH Assay Measuring Interval Verifications

Laboratories use measuring interval verifications to verify CH assay measuring intervals.

If selected in Edit Calibration Order, the system performs automated measuring interval verifications. The system uses an existing calibrator definition and dilutes the high level calibrator to create varying concentrations of the assay's analyte that span the entire measuring range of the system. The system checks the measured values against the assay-specific TDef calibration acceptance criteria.

The system also performs manual measuring interval verifications. Measuring interval verification material is commercially available or the operator can use an existing multilevel calibrator. To prepare the system for a manual measuring interval verification, the operator performs the following activities:

- Creates a measuring interval verification material definition using level concentration values for a commercially available material or a multilevel calibrator.
- Prepares the samples.
- Creates a calibration measuring interval verification order.
- Loads the measuring interval verification samples on the system.

The system checks the measured values against the assay-specific TDef calibration acceptance criteria.

Measuring interval verifications result with **Awaiting Acceptance**. Evaluate the criteria and accept or reject the measuring interval verification results.

NOTE: IMT measuring interval verifications are not available.

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 biohazardous materials can cause bodily harm.



CAUTION

Do not reuse calibrator tubes after removing 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, 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.

About IM Assay Measuring Interval Verifications

Laboratories use measuring interval verifications to verify the linear reportable range for IM assays.

If selected in Edit Calibration Order, the system performs manual measuring interval verifications using a measuring interval verification calibrator definition.

Measuring interval verification material is commercially available or the operator can manually dilute calibrator material. To prepare the system for a manual measuring interval verification, the operator performs the following activities:

- Creates a measuring interval verification material definition using level concentration values for a commercially available material or a manually diluted calibrator.
- Prepares the samples.
- Creates a calibration measuring interval verification order.
- Loads the measuring interval verification samples on the system.

IM measuring interval verification results display in Calibration Results Details. Evaluate the measuring interval verification results.

NOTE: In Calibration Results, the IM measuring interval calibration status appears as Invalid because the system does not use the measuring interval verification to calibrate the assay reagent.

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 biohazardous materials can cause bodily harm.



CAUTION

Do not reuse IM 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 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, 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.

Ordering Automated Measuring Interval Verifications on the CH Analyzer

1. On the Command bar, select **Calibration > Create Calibration Orders**.
2. In Select Assays, select the analyzer.
3. Select an assay.
4. In the Calibrator Material area, select a **Cal Name**, **Cal ID**, or **Cal Lot**.
5. Select **+**.
6. In the Orders area, select **Edit Cal Order**.

7. In Edit Calibration Order, select or enter information about the measuring interval verification:
 - Select an assay reagent lot from the Assay and Lot drop-down menu.
 - Select **Automatic Measuring Interval Verification**, the only available option when using an existing calibrator definition.
 - Select a reagent pack from the Pack ID drop-down menu.
 - Select a specific reagent pack well.
 - To increase the number of replicates, enter a number greater than the minimum number of replicates the system requires to calibrate the assay reagent in Number of Replicates.
8. To save the measuring interval verification order, select **Save**.

Ordering Measuring Interval Verifications Using an Analyzer with DL

1. On the Command bar, select **Calibration > Create Calibration Orders**.
2. In Select Assays, select the analyzer.
3. Select an assay.
4. Select a measuring interval verification material.
5. Select **+**.
6. In the Orders area, select **Edit Cal Order**.
7. In Edit Calibration Order, select or enter information about the measuring interval verification:
 - Select an assay reagent lot from the Assay and Lot drop-down menu.
 - If using an existing calibrator definition on a CH Analyzer, the system enables Automatic Measuring Interval Verification.
 - If using a defined measuring interval verification material, the system defaults to Manual Measuring Interval Verification.
 - Select a reagent pack and well from the Pack ID drop-down menu.
 - To increase the number of replicates, enter a number greater than the minimum number of replicates the system requires to calibrate the assay reagent in Number of Replicates.
8. In the Calibrator Rack Position area, select 1 of the following options:
 - Use barcoded tubes
 - By Position

If selecting By Position, enter the Calibration Rack barcode number and the First Cal Position information.

9. To save the manual measuring interval verification order, select **Save**.

About Calibration Results

Calibration Results provides calibration results data from a minimum of 20 different reagent lots and 20 reagent packs for each assay.

In addition to viewing information about the calibration results, the operator can also use Calibration Results to perform the following functions:

- Evaluate calibration results
- Accept or reject calibration results
- Invalidate a calibration
- Access calibration result details
- Export calibration results
- Edit calibration orders
- Delete calibration orders

Red and yellow highlights indicate critical and impending warning calibration events. Red highlighted calibration results indicate the calibration is expired, rejected, or the calibration acceptance criteria exceeds limitations and the calibration is invalid. A yellow bar beneath the Calibration Results tab indicates the calibration acceptance criteria requires operator intervention to accept or reject an assay reagent calibration.

The system displays a check mark glyph beside a calibration result under the following conditions:

- The current valid assay calibration and lot in use to calculate test results
- A Valid assay calibration for the same assay but different lot
- A Processing recalibration for a particular assay and lot

To limit the number of calibrations that display, filter by the following:

- Analyzer
- Assay
- Reagent Lot
- Reagent Pack
- A date range
- Attributes

Calibration Results displays calibration result information for the selected Filters.

Column header	Notes
Assay	Assays display in alphabetical order.
Analyzer	Analyzer that performs the calibration.
Cal Lot	Calibrator lot ID.
Result Date	Date and time the calibration completes.
Cal Status	Current status of the calibration.
Cal Exp	Date and time the calibration expires.
Type	Type of calibration (Page 334 <i>Assay Reagent Calibration Types</i>)
Reagent Lot	Reagent lot number.
Pack/Well	CH reagent pack and well ID. IM reagent pack ID.
Flags	Messages about the status of a calibrator sample or result. (Page 351 <i>Calibration Results Flags</i>)

A calibration can have 1 of the 4 following result outcomes:

Calibration Result	Notes
Valid	Calibration acceptance criteria are within the assay test definition specifications. The operator accepted an Awaiting Acceptance calibration.

Calibration Result	Notes
Rejected	- Calibration results do not meet the acceptance criteria. - The operator did not accept an Awaiting Acceptance calibration before a second calibration for the same assay and lot completed with a Valid result. - The operator did not accept an Awaiting Acceptance calibration within the Awaiting Acceptance timeout period. - The operator rejected an Awaiting Acceptance calibration.
Awaiting Acceptance	Calibration results do not meet the acceptance criteria for 1 or more expected calibration values and the following conditions apply: - Automatic Acceptance is disabled in the CH assay test definition - Accept Cal is enabled in the IM assay test definition
Invalid	The system could not compute a CH calibration result. Number of resulting IM calibration replicates did not meet minimum requirements or the laboratory invalidated a calibration.

About Assay Reagent Calibration Order Status in Calibration Results

Assay reagent calibration orders have 1 of the following calibration statuses (Cal Status):

Cal Status	Notes
Calibration in Use	System uses the current valid calibration to calculate patient and QC results.

Cal Status	Notes
Ordered	Cal Status remains Ordered as the system identifies the calibrator samples and confirms the intended analyzer is ready to process the calibration.
Preparing	System checks for reagent and calibrator sample availability.
Reserved	System schedules when to process the calibration.
Processing	System processes the calibrator tests.
Valid	Calibration acceptance criteria are within specifications.
Invalid	Calibration acceptance criteria are outside specifications.
Canceled	Operator canceled and deleted a calibration order.
Extended	Operator extended a calibration expiration beyond the calibration interval date to continue processing samples.
Awaiting Acceptance	Calibration acceptance criteria are outside specifications for 1 or more expected calibration values. The operator must analyze the calibration data and accept or reject the calibration.
Rejected	Operator rejected the calibration after analysis of the out of range acceptance criteria.
Expired	Calibration for a reagent lot or pack exceeds the calibration interval.

Calibration Results Flags

The system displays calibration result flags when the status of a calibrator result requires additional attention. The system may display 1 or more of the following calibration result flags.

Flag	Type	Notes
Abnormal Reaction	CH	A foam error occurred.
Absorbance Error	CH	The photometer is outside the measuring range.
Absorbance Limit (D)*	CH	Lamp energy was low during cell blank measurement check.
Analyzer Rejected	CH/IM	The analyzer rejected the order.
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 or insufficient sample error.
Cal Invalid	IM	The operator did not perform the calibration or the calibration failed.
Cal Range H (j)*	CH	The result exceeded the calibration high range.
Cal Range L (k)*	CH	The result exceeded the calibration low range.
Calibrator OBS Expired	CH	A calibrator sample exceeds the Cal-QC storage stability limit.
Canceled	CH/IM	The system canceled the test.

Flag	Type	Notes
Check Atellica Magline State	CH/IM	The system cannot process tests because the Atellica Magline Transport is not in the correct state or covers are open.
Check SH State	CH/IM	The system cannot process tests because the Sample Handler is not in the correct state or the covers are open.
Clog	IM	The system detected a probe clog.
Contaminated	CH/IM	The reagent probe was contaminated.
Crash (G)*	CH	The system detected a probe crash.
Cuvette Loader Error	IM	The system was unable to complete the test because the cuvette jammed or did not load.
Cuvette Temperature Out of Range	IM	The cuvette ring temperature was out of range.
Final Optical Density	CH	The final optical density (OD) is 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 detected insufficient IM Acid to perform the test.
IM Base Error	IM	The system detected insufficient IM Base to perform the test.
Incomplete Set	IM	A required calibrator level is not on the system.

Flag	Type	Notes
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 is outside the predefined range.
Initial Optical Density	CH	The Initial Optical Density (OD) is 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 is not sufficient for the ordered test.
Insufficient Sample	CH/IM	The sample volume is not sufficient for the ordered test.
Internal Error	IM	The scheduler lost control of this test. The system is unable to continue with this test for safety reasons.
Invalid Test	CH	The test definition for this assay does not exist or the IMT subsystem is not on.

Flag	Type	Notes
Investigational	CH/IM	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.
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.
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.

Flag	Type	Notes
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 cannot process tests because 1 or more system capabilities are not available.
Missing Consumable	IM	System fluids are not available on the analyzer. Replace system fluids 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, rerun the test.
Mix Error (M)*	CH	The system detected a mixer motion error.
Module Unavailable	CH/IM	The system cannot perform the test because a subsystem is offline.

Flag	Type	Notes
No Ancillary	IM	The test requires an ancillary reagent.
No Diluent	IM	The system scheduled an automatic dilution and did not load a diluent for this test.
No Lot Match	CH/IM	The test requires a specific primary reagent and ancillary reagent lot combination.
No Primary	CH/IM	Primary reagent is disabled, unusable, or not loaded for this test.
No Prior Lot Cal	CH/IM	The system cannot perform a pack calibration because a prior lot calibration does not exist.
Patient Processing Disabled	CH/IM	The system cannot Perform QC with Calibration because Patient Sample Processing is disabled.
PMT Temperature	IM	PMT temperature was out of range.
Priming	CH	The system cannot 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 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.

Flag	Type	Notes
Rack ID Timeout	CH/IM	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	The system is unable to dispense reagents due to 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 is 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 cannot process tests because reagent mixing is in process.
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.

Flag	Type	Notes
Reagent Ring Temperature is Out of Range.	IM	The system detected a reagent ring temperature that was out of range.
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.
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 is unable to load a sample tip.
Sample Unloaded	CH/IM	The sample is no longer on the system.
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.

Flag	Type	Notes
Substrate Error	CH	The substrate depleted.
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 is outside the range that the operator configured.
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 are not onboard.
Waiting for QC Samples	CH/IM	The assay configuration includes Perform QC with Calibration but the QC samples are not onboard.
Wash Ring Error	IM	The analyzer cannot perform the test because the wash ring subsystem is Offline. Check your capabilities.

Flag	Type	Notes
Waste Full	IM	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	The analyzer cannot perform the test because water pressure is 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 Attributes of Calibration Results

The Attributes on the Calibration Results Filters area provides calibration status filter options.

Attributes	Notes
Pending	In 1 of the following statuses: • Preparing • Scheduling • Processing • Awaiting Acceptance
Expired	Beyond the calibration interval.
Invalid	Calibration acceptance criteria are outside the assay test definition specifications.
Rejected	Operator-rejected calibrations.
Extended	Extended calibration results (Page 332 <i>About Extending Calibrations</i>).

Attributes	Notes
Valid	Calibration acceptance criteria are within the assay test definition specifications or the operator accepted the results manually after evaluating the data.
Canceled	Operator or system-canceled calibration orders.
Ordered	Calibration order exists and the system checks for reagent and calibrator availability.
Measuring Interval Verification	Linearity study results.
Calibration	Lot or pack calibration.
Active	Calibration in use to calculate patient and control results.

About Calibration Result Definitions

Calibration Result	Notes
Valid	Calibration acceptance criteria are within the assay test definition specifications.
Invalid	Calibration acceptance criteria are outside the assay test definition specifications.
Awaiting Acceptance	Calibration acceptance criteria are outside the assay test definition specifications for 1 or more expected calibration values.

About Accepting Calibrations

The system compares calibration results to the assay acceptance criteria and determines 1 of the 4 following result outcomes:

- Valid
- Rejected

- Awaiting Acceptance
- Invalid

Automatic and manual acceptance of assay calibrations depends on system configuration settings (Page 362 *About Accepting CH Assay Calibrations*), (Page 362 *About Accepting IM Assay Calibrations*).

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 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. 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.
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.

Calibrator level accuracy evaluation data	Notes
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.
The CH assay calibration feature includes 2 non-editable acceptance criteria.	
System acceptance criteria	Notes
No flags or comments	The system checks for process or measurement errors.
No auto-excluded replicates	The system automatically excludes the results of replicates containing process or measurement errors.

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 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 366 <i>About IM Calibration Signal Slope</i>).
Signal Ratio	Comparison of low and high calibrator RLUs (Page 366 <i>About IM Calibration Signal Ratio</i>).
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 367 <i>About IM Calibration Allowed Level Deviation</i>).
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. 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 acceptable value is 50% neutralization.

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:

$$\text{Slope} = (\text{High Cal Expected RLU} - \text{Low Cal Expected RLU}) / (\text{High Cal Measured RLU} - \text{Low Cal Measured RLU})$$

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:

$$\text{Ratio} = (\text{High Cal Mean RLU} - \text{Low Cal Mean RLU}) / \text{Low Cal Mean RLU}$$

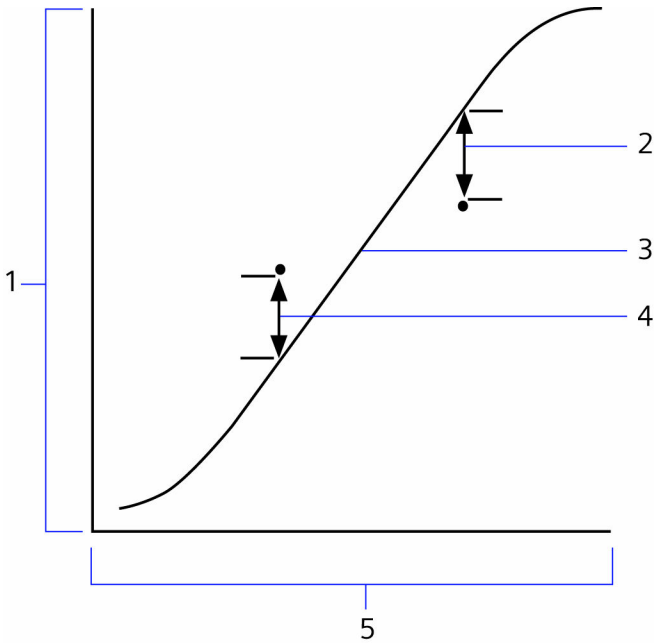
For competitive assays, the ratio value is the difference between the mean RLU value of the low calibrator and the mean RLU value of the high calibrator divided by the mean RLU value of the high calibrator:

$$\text{Ratio} = (\text{Low Cal Mean RLU} - \text{High Cal Mean RLU}) / \text{High Cal Mean RLU}.$$

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 IM Analyzer 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 IM Analyzer 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 Calibration Results Details

Calibration Results Details window provides the following areas of interest:

- Calibration order information (Page 369 *About Calibration Results Details Information*)
- Data (Page 371 *About Calibration Results Details*)
- QC Performed with Calibration
- Acceptance Criteria (Page 363 *About CH Assay Reagent Calibration Data Evaluation Values*), (Page 364 *About IM Assay Reagent Calibration Data Evaluation Values*)
- Comments
- Graph

In addition to viewing information about the calibration results, the operator can also use Calibration Results Details to perform the following functions:

- Print
- Accept
- Reject
- Invalidate

About Calibration Results Details Information

The Calibration Results Details window 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 334 <i>Assay Reagent Calibration Types</i>).
Assay	Calibrated assay reagent name.
Units	Assay result units.
Calculation Type	A specific standard curve logarithm 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.
Pack/Well	Calibrated IM assay primary reagent pack identification. Calibrated CH assay reagent pack and well identification.

Information	Notes
Ancillary 1	Calibrated assay that requires 1 ancillary reagent pack.
Ancillary 1 Lot/Pack	Ancillary reagent 1 lot and pack identification.
Ancillary 2	Calibrated assay that requires a second ancillary reagent pack.
Ancillary 2 Lot/Pack	Ancillary reagent 2 lot and pack identification.
Calibrator Name	Calibrator material name.
Calibrator Lot	Calibrator material lot.
Cal Status	Calibration status.
Acceptance Criteria	CH Analyzer calibration acceptance criteria (Page 363 <i>About CH Assay Reagent Calibration Data Evaluation Values</i>). IM Analyzer calibration acceptance criteria (Page 364 <i>About IM Assay Reagent Calibration Data Evaluation Values</i>).
Acceptance Mode	Acceptance mode includes: • Manual • Automatic

Information	Notes
Trigger Mode	Manually created calibration orders display Operator Initiated. Automatic calibration orders display Automatic. Automatic calibration triggers are assay-specific according to the 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
Cal Expiration	Date and time the calibration expires.

About Calibration Results Details

The Calibration Results Details window displays information about the calculated Analyte concentration and the measured Signal values for multiple calibrator replicates.

The Data area provides the following interactive functions and data:

Data	Notes
Replicate	Recovered replicate results and calculations
Include	Options for excluding or including replicate results
Calibrator levels	Up to 6 CH calibrator levels IM low and high calibrator levels
Mean	Average of the replicate results
Median	Middle value between the highest and lowest replicate result values

Data	Notes
SD	Standard deviation or the amount of variation for the recovered result values
Target %CV	Acceptable precision according to the IM assay master curve
Observed %CV	Precision of the recovered results
The QC Performed with Calibration area displays quality control result parameters.	
QC	The ID of the QC material
QC Limits	QC results must be within QC limits as defined in the quality control product value sheet.
New Observed	The system calculates a new QC observed range from new QC data.
Old Observed	The system calculates the QC observed range from previous QC data.
The Acceptance Criteria area displays calibration result parameters.	
Acceptance Criteria	Notes for the specified criteria
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 observed calibrator values

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 calibration to fail. If specific criteria are met, excluding an outlier may correct an Invalid or Awaiting Acceptance calibration result. The IM Analyzer can autoexclude 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 IM Analyzer autoexcludes outlier 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 Assay QC Results in Calibration Results Details

When the system performs QC with a calibration, a summary of the results display in the QC Performed with Calibration area of the Calibration Results Details window.

The system automatically performs QC with a calibration when the operator enables the Perform QC with Calibration option in the assay test definition Calibration tab or if the operator selects the option when editing a calibration order.

Use 1 of the following options if a QC check fails:

- 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.

About Calibrator Definitions

Calibrator Definitions provides the following functions for creating calibrator definitions:

- Add new calibrator material definitions (Page 375 *About Installing Calibrator Definitions*)
- Edit calibrator material definitions
- Delete calibrator material definitions
- Print calibrator material definition barcodes

The Filters area provides the following filter options:

- Assays
- Status

 icons sort the column contents in ascending or descending alphanumeric order.

Column header	Notes
Material Name	Name of the calibrator material definition.
Lot ID	Lot for the calibrator.

Column header	Notes
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.

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

Manually Adding CH Calibrator Definitions

1. On the Command bar, select **Calibration > Calibrator Definitions**.
2. Select **Add New**.
3. In Add Calibrator Definition, select the Calibrator Material option circle.
NOTE: If manually adding a CH calibrator definition for a measuring interval verification, select the Measuring Interval Verification Material option circle in Add Calibrator Definition.
4. From the Assay Type drop-down menu, select .
5. In Material Name, enter a name for the calibrator definition.
6. 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.

7. In Lot ID, enter the calibrator lot.
8. In Expiration Date, select the calibrator material expiration date from the drop-down calendar.
9. In Revision, enter the revision number from the calibrator lot-specific value sheet.
10. To enable the calibrator material for calibration, select **Active**.
11. 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. 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.

12. Select 1 or more assays associated with the calibrator material.
13. Enter the concentration values for each level from the calibrator lot-specific value sheet.
14. Select **Save**.

NOTE: Some assays require calibrator material levels with a different Material ID, Lot ID, or Expiration Date.

Manually Adding CH Measuring Interval Verification Material Definitions

1. On the Command bar, select **Calibration > Calibrator Definitions**.
2. Select **Add New**.
3. In Add Calibrator Definition, select the Measuring Interval Verification Material option circle.
4. From the Assay Type drop-down menu, select .
5. In Material Name, enter a name for the measuring interval verification definition.
6. In Material ID, enter the ID from the measuring interval verification value sheet.
7. In Lot ID, enter the measuring interval verification material lot.
8. In Expiration Date, select the measuring interval verification material expiration date from the drop-down calendar.
9. In Revision, enter the revision number from the measuring interval verification value sheet.

10. From Specimen Type for Measuring Interval Verification, select the specimen type.
11. In Number of Levels for Measuring Interval Verification, select a number.
12. Select an assay associated with the measuring interval verification material.
13. Enter the concentration values for each level.
14. Select **Save**.

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

Manually Adding IM Measuring Interval Verification Material Definitions

1. On the Command bar, select **Calibration > Calibrator Definitions**.
2. Select **Add New**.
3. In Add Calibrator Definition, select the Measuring Interval Verification Material option circle.
4. From the Assay Type drop-down menu, select the appropriate IM Analyzer.
5. In Material Name, enter a name for the measuring interval verification material definition.
6. In Material ID, enter the ID from the measuring interval verification material value sheet.
7. In Lot ID, enter the measuring interval verification material lot.
8. In Expiration Date, select the measuring interval verification material expiration date from the drop-down calendar.
9. In Revision, enter the revision number from the measuring interval verification material value sheet.

10. From Specimen Type for Measuring Interval Verification, select the specimen type.
11. In Number of Levels for Measuring Interval Verification, enter a number from 2–9. The system defaults to 9.
12. Select an assay associated with the measuring interval verification material.
13. Enter the concentration values for each level from the measuring interval verification material value sheet or the appropriate value of the manually diluted calibrator material.
14. Select **Save**.

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.

Barcode Information	Length	Content
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 IMT Calibrations on the CH Analyzer

NOTE: A window opens if the IMT Advanced Clean is required. The analyzer pauses the IMT when the operator selects Replace IMT Supplies to replace system fluids from this window.

Selecting Replace IMT Supplies while IMT calibration is in process may require a system restart. Wait until the IMT completes calibrating before selecting Replace IMT Supplies.

The CH Analyzer uses a 2-point calibration to automatically calibrate the IMT subsystem in the following situations:

- System startup
- After a reset from a paused or stopped state
- 4-hour intervals
- After 250 IMT tests complete since the last calibration
- A-LYTE® multisensor temperature changes outside of specifications
- IMT successful error recovery
- IMT cleaning procedure
- A-LYTE multisensor, Standard A, or Standard B replacement

The operator can perform a manual IMT calibration.

During IMT calibrations, the system does not process IMT tests.

About IMT Calibration Status Glyphs

Glyphs alert the operator to information or a required action.

IMT calibration status glyph	Description
	Apply
	Error

Viewing IMT Calibrations

1. On the Command bar, select **Calibration > IMT Calibration**.
2. View results.

14 Quality Control

This chapter 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



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 use barcode labels from 1 lot of QC material for another lot of QC material. Quality control 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. Ensure the following items exist on the system for the assays that the control tests:
 - Assay master curve, for IM only
 - Test definition
 - Assay calibration
 - Assay reagent
2. Enter the control definitions for all required levels (Page 402 *Manually Adding QC Definitions*).
3. Create a control order.

4. If appropriate, place the control barcodes on tubes and add the appropriate control level material.

NOTE: Optimum control reproducibility requires consistent QC sample processing. For a given QC material, consistently process cold QC samples directly from the Cal-QC storage area or the sample handler drawer at ambient temperature.

5. Place the controls in a sample rack and place it in the sample drawer.

NOTE: To process the controls immediately, place the controls in a STAT rack.

6. Review the control results.

Monitoring QC Results

1. Create QC Orders.
2. Schedule QC (Page 406 *About the QC Scheduler*).
3. Review in-process QC orders.
4. Analyze QC Results.
5. View QC Statistics data and charts.
6. Create QC Reports.
7. Maintain the QC database.

About Create QC Orders

The operator can manually create QC orders to process materials that verify the performance of the system and assays.

To associate controls with QC orders, the operator must define the controls in QC Definitions. The operator can also add QC Panels to QC orders. The operator specifies how to use the QC results in QC Statistics.

Auto QC Configurations

The system provides independent options for scheduling QC to run automatically in different circumstances.

Laboratory Practice	Settings
Schedule QC to perform automatically, according to time, assay count or control name.	Configure a QC Schedule in QC > QC Scheduler .

Laboratory Practice	Settings
Configure QC to perform automatically with calibration.	Configure Perform QC with Calibration in General Setup. Enable Perform QC with Calibration in the QC Definition (Page 402 <i>Manually Adding QC Definitions</i>).
Configure QC to perform automatically with a pack change.	Enable Perform QC on Pack Change in General Setup. Enable Perform QC on Pack Change in the QC Definition (Page 402 <i>Manually Adding QC Definitions</i>).

About IM Control Bracketing

The following features and procedures are specific for the IM Analyzer.

The 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 QC Statistics

QC Statistics provides real-time and long-term evaluation of system and assay performance through the following features:

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 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.

About QC Statistics Review

QC Statistics Review displays current QC results.

The left panel displays a list of control files, ordered by Control or Test. The right panel displays control file results. The operator can choose to filter the results according to Reviewed, Unreviewed, or All data. The operator can also choose to 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.

Typical QC Statistics Configurations

QC Statistics provides options for performing statistical analysis on control data, specifying QC ranges, 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.

Laboratory Practice	QC Statistics Settings
Use all QC Statistics features	Enable QC Statistics and Patient QC Flagging
	Enable Patient QC Flagging
	Enable Autodisable Patient Tests
Use QC statistical analysis and flags. Do not automatically disable patient tests based on QC.	Enable QC Statistics and QC Rules
	Enable Patient QC Flagging
	Disable Autodisable Patient Tests
Use QC statistical analysis but disable flagging. Do not automatically disable patient tests based on QC.	Enable QC Statistics and QC Rules
	Disable Patient QC Flagging
	Disable Autodisable Patient Tests
Turn off QC Statistics features.	Disable QC Statistics and QC Rules

Laboratory Practice	QC Statistics Settings
	Disable Patient QC Flagging
	Disable Autodisable Patient Tests

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 Tab	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 the Chart tab. 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 Chart, QC, and Patient tabs populate with newly retrieved QC and patient QC data points. The operator can specify the retrieved data using Filter settings.
Customize	Customizes the Analysis tab view. The operator can select Display Fields, specifying the type of data currently showing in the Analysis tab.
Statistics	Displays the Statistics Summary view. If no control or patient QC data display on the Analysis tab, the Statistics feature is not available.

QC Statistics Analysis Feature	Notes
Events	Displays the Events view. If no control or patient QC data display on the Analysis tab, the Events feature is not available.
Reports	Displays the Reports window. 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.
Comment	Adds comments to a result.
QC Details	Displays error details for data points that are part of the rule violation.

About the Levey-Jennings Chart

The Levey-Jennings Chart plots control values against dates of analyses. The operator can view the chart for each open 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 Rule

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 are required in Germany, but laboratories elsewhere may adopt them voluntarily. The RiliBÄK can be effective as an additional quality control tool for monitoring methods.

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 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 Report Name drop-down menu 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 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 that 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. -OR- Indicates that 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 that 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. -OR- Indicates that 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 that the range between 2 sequential control values from 1 control exceeds 4 standard deviations. -OR- Indicates that the range between 2 consecutive control values from 2 controls exceeds 4 standard deviations.
3–1s	Indicates that 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. -OR- Indicates that 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 that 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. -OR- Indicates that 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.

Multipoint Error	Notes
10x	Indicates that 10 sequential control values from 1 control are either all above or all below the mean. -OR- Indicates that 10 consecutive control values from 2 or more controls are either all above or all below the mean.
12x	Indicates that 12 sequential control values from 1 control are either all above or all below the mean. -OR- Indicates that 12 consecutive control values from 2 or more controls are all above or all below the mean.
nx	Indicates that n sequential control values from 1 control are all above or all below the mean. -OR- Indicates that 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 from 2 to 29.
nT	Indicates 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 and 27. -OR- Indicates 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 and 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

The Patient Median and Patient Mean features provide additional tools within QC Statistics to help monitor the performance of the system and troubleshoot systematic errors. The operator can collect patient result data on 1 or more analyzers in the configuration and use that data to perform QC for selected tests. In QC Statistics Setup, the operator can choose to monitor the Mean or Median of defined bin sizes of patient results, according to laboratory protocol.

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.

Patient QC Data Configuration	Notes
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.
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.

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.

Patient Data	Notes
System	The friendly name or ID of the System, assigned by the laboratory.
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.

Patient Data	Notes
Last Result Date	The date and time of the most recent patient result in the bin.
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. On the Command bar, select **QC > QC Statistics > Setup > Patient**.
2. Select the appropriate Test on the appropriate Module Name.
NOTE: Each Test enabled for each Module Name has a separate entry.
3. To define the number of data points for QC analysis, specify a Bin Size.
4. To define the upper and lower limits for Patient Median and Mean analysis, specify an Upper Trim Limit and Lower Trim Limit.
5. To define reference lines to display with patient sample QC data, specify Upper Line, Lower Line, and Ref Line.
6. To turn on data collection for the Test on the specific analyzer, select the Active check box.
7. Select **Save**.

About Patient QC Flagging

Patient QC Flagging initiates when a QC error rule violation occurs for a test

that has Patient QC Flagging turned on.  displays for patient test results indicating that a QC violation error occurred at least for one level. 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, the Patient QC Flagging tab displays the current flag status and allows manual flag reset for a test.

Patient QC Flagging	Notes
Test	The name of the test.
Specimen Type	The type of control sample: Serum, Plasma, Urine, CSF, Oral Fluids, Whole Blood, Buffer-based Solutions, or Other.
Module Serial Number	The serial number of the module performing the QC.
Module Name	Unique module names the lab assigns.
Clear Option	The option by which the operator chooses to clear the flag. The status can be Manual, Automatic, or None, as indicated by a blank column.
Failed QC Details	Information about rule violations.

About Patient QC Flagging Settings

The operator can enable or edit Patient QC Flagging through Edit/View.....

Patient QC Flagging	Notes
Automatic	Patient QC Flagging flags failed QC results and resets automatically once previously failed QC levels produce results that pass QC.

Patient QC Flagging	Notes
Manual	Patient QC Flagging flags failed QC results. The operator must reset manually Patient QC Flagging #H-10-4148_qc_Clearing_Patient_QC_Flag-t# .
None	Patient QC Flagging is disabled. This is the default setting for each test.

About QC Definitions

The operator can import QC Definitions from an XML file provided by the control supplier or from an Atellica Solution configuration, or manually add QC Definitions in Add QC Definition.... When manually adding new QC Definitions, the operator must define the control details, and then the associated tests.

The operator can export QC Definitions from an Atellica Solution configuration and import them to another Atellica Solution configuration, or the same system, 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 should edit the settings if appropriate.

About Add New QC Definitions

Control Details	Notes
Control Name	The name of the control material.
Control ID	A unique identifier for the control.
Control Level	The concentration level of the control material.
Control Lot	The lot number of the control material.
Control Lot Expiration	The date the control expires.

Control Details	Notes
Specimen	The Specimen type associated with the tests that the control supports. Note: The operator must select Serum/Plasma specimen type for controls associated with tests for Serum, Plasma, or both. This specimen type applies to QC samples only.
Control Type	Whether the control is part of the reagent: • Routine controls are independent from the reagent kits and do not require a checksum. • Kit controls require a checksum and may be lot-locked or control bracketed.
Usage	The Usage drop-down menu specifies the purpose of the controls for system and assay performance: • Primary: Primary controls produce QC results that determine Patient QC Flagging in QC Statistics. • Alternate: The operator performs Alternate control lots for additional QC flagging and statistical data. • Parallel: The operator can perform new control lots in parallel with primary control lots for QC Statistics. Parallel control results generate observed ranges, but do not generate violations or flags for test evaluations. • Not In Use: The control lot is expired or unavailable.

Control Details	Notes
Onboard	The system can store some controls onboard. This option applies to SH configurations only.
Perform QC with Calibration	When selected, the system uses this control material to order QC with an assay calibration. Note: To Perform QC with Calibration, the operator must also set the appropriate setting in General Setup.
Perform QC on Pack Change	When selected, the system uses this control material to order QC with a pack change. Note: To Perform QC on Pack Change, the operator must also set the appropriate setting in General Setup.
Tests	Notes
Test Name	Tests associated with the control.
Units	Units of concentration, obtained from the control packaging.
SD Type	The standard deviation the system uses to derive the range. Note: The operator can select Other for no range.
Low	Low range value for QC flagging (enter if the +/- Range is not available).
High	High range value for QC flagging (enter if the +/- Range is not available).
Mean	Mean value of the range for QC flagging.
+/- Range	Defines the upper and lower values of the range around the mean.

Tests	Notes
Open Stability Days	Number of days the control remains stable.
Open Stability Hours	Number of hours the control remains stable.

Manually Adding QC Definitions

1. On the Command bar, select **QC > QC Definitions**.
2. Select **Add QC Definition....**
3. Enter the following information:
 - Control Name
 - Control ID
 - Level
 - Control Lot
 - Control Lot Expiration
 - Usage
 - Specimen
 - Control Type (Select **Kit** if adding a new QC definition for a control-bracketed assay)

NOTE: Select Specimen type **Serum/Plasma** for controls that support tests for Serum or Plasma.
4. If the system stores the controls onboard, select the Store Onboard check box.

NOTE: When performing QC with onboard controls, the system retrieves the control sample automatically as part of the QC order.
5. If appropriate, select the Perform QC with Calibration check box.
6. If appropriate, select the Perform QC on Pack Change check box.
7. Select the appropriate Tests.
8. Enter the SD for each assay.
9. Define ranges by 1 of the following methods for each assay:
 - Specify Low and High.
 - Specify Mean and +/- Range.

10. Enter 1 of the following for each assay:

- Open Stability Days.
- Open Stability Hours.

11. Select **Save**.

About Importing QC Definitions from XML Files

The control material supplier provides the QC Definition information. If the QC Definition is available in an XML file, the operator can import the QC Definition directly to the system. To obtain the xml file from the supplier, the operator must follow the supplier instructions.

In addition, the system can import an XML file that was 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 tries 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 the laboratory protocol for use of the supplied ranges. 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. 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	:&

Barcode Information	Length	Content
Operator-defined Control ID	1–11 characters	Enter the Operator-defined Control ID from the control definition.
Operator-defined tube tracking number	6 digits	Enter a unique 6 digit number from 000000–999999.

The Control ID must match the Control ID in the control definition.

The following is an example of a routine QC sample barcode where the Operator-defined Control 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 Control ID	1–11 characters	Enter the Operator-defined Control ID from the control definition.
Operator-defined tube tracking number	6 digits	Enter a unique 6 digit number from 000000–999999.

The Control ID must match the Control 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

Control level	Name	Control lot	Control ID	Sample barcode
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 Edit QC Definition

In Edit QC Definition, 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 choose to 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.

About QC Panels

QC Panels	Notes
Panel Name	A unique name for the panel. Panel Name is a required entry.
Panel Status	The status of the controls in the panel: Not In Use, In Use.
Next Expiration Date	The earliest expiration date of all selected control materials in the panel.
Date Last Modified	The latest date of any changes to the QC Panels.

QC Panels	Action
Filter...	Categorize QC Panels by Status.
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.

QC Panels	Action
QC Orders...	Open Create QC Orders. Add defined QC Panels to new or existing QC orders.
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 control material.
- The operator cannot change a Panel Name after saving QC Panels.
- If the status of 1 or more control materials in a QC panel is In Use, the panel status displays In Use.
- When using QC Panels in QC orders, the following restrictions apply:
 - The operator can only create orders for control lots with a Primary, Parallel, or Alternate Usage.
 - The operator can only select enabled tests in QC Panels.
- When QC Panels contain tests associated with control lots, any QC definitions for that control lot are restricted as follows:
 - The operator cannot delete a test from a QC definition if a QC panel uses that test with the same control lot as the QC definition.
 - The operator cannot delete a QC definition with a control lot that any QC panel uses.
 - The operator cannot delete a QC panel any scheduled QC event uses.

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

About the QC Scheduler By Test Count

The QC Scheduler By Test Count orders QC for 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, or edit QC By Test Count schedules, set warnings when a specific percentage of the test count is complete, and reset the test counter.

NOTE: QC Scheduler warnings are not available for DL systems.

Test Count Schedule	Notes
Test	The scheduled test.
Test Count	The current test count in the scheduled set.
Definitions & Panels	The QC definitions and panels associated with the counter test. The operator can use this option to schedule QC for all tests in the same panel as the counter test.
Operator Reset	The date and time the operator restores the test counter.
Last Order	The date and time of the last automatically created QC order for the test. The operator can use this option to manually reset the Test Count.

Test Count Schedule Feature	Notes
Edit/View...	Views and modifies the specific Test Count settings for a scheduled test.
Restore Counter	Resets the selected test counter.
Delete	Deletes the entire Test Count event.
Set Warning...	Posts an alert to the Operator Event Log and the Alert Module if the onboard control is unavailable at a specific percentage of the scheduled test count.

Test Count Schedule Feature	Notes
Add Schedule...	Creates new Test Count schedule for automatic QC orders.

About the QC Scheduler By Control

The QC Scheduler By Control prompts the system to create an order for the scheduled control. This feature is useful for controls used for tests that perform intermittently. When the system recognizes the matching barcode for the scheduled control, the system orders and processes the QC test associated with the control. This feature applies only to manually loaded controls.

The operator can add, delete, or edit QC By Control schedules.

By Control Schedule	Notes
Control Name	The scheduled control.
Control Lot	The control lot in the scheduled test set.
Control ID	The ID assigned to the scheduled control.
Control Lot Exp	The expiration date of scheduled control.
Usage	The usage assigned to the scheduled control, obtained from the QC definition.
Definitions & Panels	The QC definitions and panels associated with the selected control and scheduled to process.
Last Order Submitted	The date and time of the last QC order for the control.

By Control Schedule Feature	Notes
Edit/View...	Views and modifies the details for a scheduled control.
Delete	Deletes the selected control from the schedule.

By Control Schedule Feature	Notes
Add Schedule...	Adds controls to the schedule.

15 Maintenance

This chapter provides information about system maintenance. The system monitors maintenance activities and provides notification when a scheduled activity is due.

About the Maintenance Schedule

The Maintenance Schedule displays the maintenance activities and their status. The current day is highlighted with 3 days before and 3 days after that date. These activities include automated and manual procedures.

The operator filters all maintenance activities by module, frequency, time, performed by, and search text. The drop-down menu filters at top of filter panel displays all activities scheduled for next 24 hours by default. The check box filters apply to activities scheduled within the 7-day view.

The system sorts upcoming maintenance activities based on scheduled date and time. The schedule displays the oldest activities not executed 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 tab. When an automated maintenance activity completes successfully, the analyzer updates the schedule to display the next due date or resets the current count.

Manual activities require the operator to perform or complete the activity. The operator documents completion of manual maintenance activities from this tab.

If an automated scheduled maintenance activity fails, the activity displays a red alert and the due date does not update. The analyzer creates a log entry recording the failed status.

The operator cannot delete system-defined maintenance activities.

For Maintenance Schedule glyph definitions, see (Page 413 *About Maintenance Glyphs*).

Maintenance Sched- ule	Notes
Activity check box	The option to select the check boxes does not display until the operator selects an activity row. The operator can select multiple activity rows or select the global check box at the top of the column to select all activities.
Module	The module that the activity is assigned to.

Maintenance Schedule	Notes
Activity	The name of the activity with a glyph indicating whether it is automated or the operator or local technical support provider performs it.
Scheduled	The date, time, and frequency of the activity. The analyzer automatically displays: • The next scheduled frequency (date and time) • Frequency glyph
Weekly status section	The weekly status displays future, completed, and those activities Overdue (⚠) and Failed (❗).
Activity Details	Opens Activity Details: • Actions: If appropriate, the operator selects Perform..., Mark as Completed, or Not Perform.... • Comment 1, Comment 2, and Comment 3: The operator enters up to 3 comments to explain any details including why the operator did not perform the activity or why the activity fails.
Perform...	Processes an automated activity.
Mark as Completed	Documents that the selected manual activity is complete.
Not Perform...	Documents that the selected manual or automated activity is not complete.
Procedure Details	Accesses the online help procedure for the selected manual or automated activity.
Edit/View...	Edits the name, Module, External Reporting, and frequency, if appropriate.
Delete	Deletes maintenance activities that are not system-defined.
Add Activity...	Adds a new activity.
Set Warning...	Configures a time the warning message displays prior to the start of any automated activity.

Viewing the Maintenance Schedule

1. On the Command bar, select **Maintenance > Schedule**.

NOTE: The analyzer displays overdue and failed activities in the following order since they are Not Performed or not completed:

- The oldest Not Performed or not completed maintenance activity is listed first based on the scheduled date and time.
- The next oldest Not Performed or not completed maintenance activity is listed next based on scheduled date and time.
- This progression continues until all Not Performed or not completed maintenance activities display.
- The remaining scheduled activities are listed based on current scheduled date and time.

2. To sort the activity list, select options in Filter.

About Maintenance Glyphs

A glyph alerts the operator to a required action or more information.

Maintenance glyph	Glyph description
	Failed activity requires completion.
	Overdue activity requires completion.
	Inprocess activity or waiting for the analyzer to be in Ready state to complete the maintenance task.
	Performed by operator activity.
	Performed by customer service engineer activity.
	Performed by system activity.
	Completed activity.
	Completed activity approved.

Maintenance glyph	Glyph description
	Automatic module activity.
	Comment attached to activity.
	Not performed activity.
	Not performed activity approved.
	Daily frequency.
	Weekly frequency.
	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.
	Not Scheduled
	Postponed activity.
Maintenance tab status	Tab description
	No issues with maintenance activities
	New overdue activities present only
	New failed activities present only
	Acknowledged failed activities present

Maintenance tab status	Tab description



	Acknowledged overdue activities present

About Maintenance Activity Statuses

Maintenance activity statuses provide information on an activity. The system has 3 activity statuses.

Maintenance status glyph	Glyph description



	Failed activity requires completion



	Overdue activity requires completion



	Inprocess activity or waiting for the analyzer to be in Ready state to complete the maintenance task.

The activity status is located in the status column in Maintenance Schedule. When a maintenance activity fails or is overdue, Maintenance displays 1 of the following colors on the Command bar:

Maintenance tab status	Tab description



	No issues with maintenance activities



	New overdue activities present only



	New failed activities present only



	Acknowledged failed activities present



	Acknowledged overdue activities present

When a maintenance activity completes successfully or resets, the analyzer updates the schedule to display the next due date or the analyzer resets the current count.

Responding to Maintenance Alerts

1. On the Command bar, select **Maintenance > Schedule**.

2. Select any maintenance activities with red or yellow alerts.
NOTE: Overdue maintenance activities display yellow alerts and failed maintenance activities display red alerts.
3. Filter log and select appropriate activity.
4. To remove the alert from the Command bar:
 - Resolve issues by performing the necessary maintenance.
 - To reset overdue activity to next frequency, select **Reset**.
5. To view historical information about an activity that has an alert, select **Log**.

About Maintenance Activities Frequency

This section describes the 3 frequencies of maintenance activities: Day and Time, Count Based, or As Needed.

Maintenance activity Frequency	Notes
Day and Time	Activity the analyzer schedules to recur daily, weekly, or monthly. Due Date updates to the next date and time in the frequency every time the activity completes successfully.
Count Based	Activity the analyzer schedules for the following increments. The analyzer sends notification 14 days prior to the due date. • 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.

Maintenance activity Frequency	Notes
As Needed	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 2 types of maintenance activities:

Manual	Operator initiates
Automated	Module or operator initiates

Performing Automated Maintenance Activities

The analyzer initiates automated maintenance activities according to an operator-defined maintenance schedule. The operator can initiate automated maintenance activities between scheduled times.

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. Use the reset option 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.

1. On the Command bar, select **Maintenance > Schedule**.
2. In Module, select the appropriate activity module from the drop-down menu.
3. Select an automated maintenance activity.

NOTE: The analyzer designates automated maintenance activities with ● in the Performed By column of the Maintenance Schedule.

4. Select **Perform... > Yes**.

About Scheduling Automated Maintenance Activities in Parallel

Operators schedule automated Maintenance activities in parallel to optimize total maintenance time. The following are recommendations when scheduling activities in parallel:

- The operator must ensure all consumables have a Status of OK in **Inventory > Supplies Overview** prior to the start of the first activity. The required inventory must be onboard.
- The operator schedules 1 activity at a time per module and schedules 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 schedules the next activity 1 minute after the previous activity starts.
- The operator schedules the system database activities during off-peak hours in the following order:
 - a. System Display Optimization
 - b. Database Backup
 - c. Move to Historical
 - d. Database Archiving (Copy and Delete)
 - e. Database: Optimizing
- The Database: Optimizing activity cannot complete successfully if other activities are performing concurrently.
- The operator must wait 4–5 minutes for the analyzers to transition to **Maintenance > Ready** except for these activities:
 - System Display Optimization
 - Database Backup
 - Move to Historical

The following table lists a daily automated activities schedule with an example start time:

Daily automated activity	Start time (hours:minutes)	Duration (minutes)
System Display Optimization	12:57	20–30 seconds
Database Backup	01:00	up to 30
SH Autocheck	01:05	<5
SHC Autocheck (if appropriate)	01:05	<5

Daily automated activity	Start time (hours:minutes)	Duration (minutes)
Atellica Magline Transport Autocheck	01:05	10
IM Daily Maintenance	01:05	≤20
IMT Daily Cleaning	01:05	<5
CH Daily Maintenance	01:10	12–40
Move to Historical	01:35	5
IM Autocheck	01:40	≤10
Database Archiving (Copy and Delete)	01:40	up to 30
Database: Optimizing*	01:55	5–10

* In the daily automated activities schedule, the operator schedules the start time for Database: Optimizing prior to all activities completing. All other activities must complete before Database: Optimizing completes.

The following table lists a weekly automated activities schedule with an example start time:

Weekly automated activity	Start time (hours:minutes)	Duration (minutes)
System Display Optimization	12:57	20–30 seconds
Database Backup	01:00	up to 30
SH Autocheck	01:05	<5
SHC Autocheck (if appropriate)	01:05	<5
Atellica Magline Transport Autocheck	01:05	10
IM Weekly Maintenance	01:05	≤30
IMT Daily Cleaning	01:05	<5
CH Weekly Maintenance	01:10	65
Move to Historical	01:35	5
Database Archiving (Copy and Delete)	01:40	up to 30

Weekly automated activity	Start time (hours:minutes)	Duration (minutes)
IM Autocheck	01:40	≤10
Database: Optimizing*	01:55	5–10

* In the weekly automated activities schedule, the operator schedules the start time for Database: Optimizing prior to all activities completing. All other activities must complete before Database: Optimizing completes.

Performing Manual Maintenance Activities



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 perform maintenance inside the analyzer unless the analyzer is stopped or in the diagnostic state. Analyzer subassemblies can move and cause bodily harm.

1. On the Command bar, select **Maintenance > Schedule**.
2. In Module, select the appropriate activity module from the drop-down menu.
3. Select a manual Activity.

NOTE: The analyzer designates manual maintenance activities with  in the Performed By column of the Maintenance Schedule. A manual activity requires the operator to perform or complete the activity.

4. Complete activity.
5. Select **Mark as Completed**.

Accessing Maintenance Procedures

1. On the Command bar, select **Maintenance > Schedule**.
2. Select a maintenance Activity.
3. Select **Procedure Details**.

Marking Completed Manual Maintenance Tasks

1. On the Command bar, select **Maintenance > Schedule**.

2. In Module, select the appropriate module from the drop-down menu.
3. Select the completed activity from the list.
4. Select **Mark as Completed > Yes**.

NOTE: The analyzer logs the activity as completed in **Maintenance > Log**.

About Adding Maintenance Activities

The operator can configure up to 60 additional maintenance activities not listed as a predefined activity in Maintenance Schedule. This task requires the appropriate security level.

Add Activity...	Notes
Name	The activity title has a limit of 40 alphanumeric characters. The name is not case sensitive.
Module	Drop-down menu operator selects to assign the activity to a module.
Description	The activity description has a limit of 300 alphanumeric characters. The description is not case sensitive.
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	The selected time or frequency that is in the activity definition. Operator selects from a drop-down menu or configures day and time.
	When frequency selected, the operator selects the days and up to 3 times. Select  to close window.
Clear	When selected, it clears selections.
Save	Saves new activity.
Close	Closes Add Activity...

About Maintenance Set Warning

The operator can configure automatic warnings prior to start time for maintenance activities in Maintenance Schedule Set Warning.

Maintenance Set Warning	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.
Minutes	Displays the warning for the number of minutes prior to the start of the automated maintenance activity.
Save	Saves warning configuration.
Close	Closes the Set Warning window.

About System Maintenance Activities

System maintenance activities display under Module All in Maintenance Schedule. The system has Daily and As Needed system-defined automated maintenance activities.

Daily system-defined automated activities	Notes
Database: Optimizing	The system automatically completes defragmentation of the workstation databases daily.
Database Backup	The system automatically completes a database backup.
Database: Archiving and Deleting	The system automatically archives and deletes databases.
System Display Optimization	The system automatically performs after the Database: Optimizing activity and during sign out. No data is lost during sign out and it does not affect any current processing or system operation.

As Needed system-defined automated activities	Notes
Move to Historical	The system automatically moves samples from the Completed or Transmitted status to Historical to allow reuse of SIDs. The operator schedules the frequency for this automated activity (Daily is the default).
Cleaning the Exterior Covers	The operator manually cleans the exterior covers of the analyzers.
Cleaning the Keyboard and Mouse	The operator manually cleans the keyboard and mouse to remove dust and residue.
Inspecting archive racks and springs	The operator inspects the archive rack springs and cleans racks, if appropriate.

About Database: Optimizing Activity

Database: Optimizing is an automated maintenance activity the system performs daily by default. The operator can edit this in Maintenance Schedule Database: Optimizing. All analyzers and SH or DL must be in the Ready or Standby state before scheduling optimization.

During database optimization, the analyzer marks defragmentation of databases.

If the LIS is online, it disconnects during database optimization and reconnects when the activity completes.

Database: Optimizing completes in 5–10 minutes.

The operator schedules the system database activities during off-peak hours in the following order:

1. Database Backup
2. Move to Historical
3. Database Archiving (Copy and Delete)
4. Database: Optimizing

About Database Backup Activity

Database Backup is an automated maintenance activity the system performs daily. The operator can modify the options for the backup through Database Backup in Maintenance Schedule.

A full database backup includes:

- Test results: patient and QC
- Patient flagging
- QC: definitions, statistics, and flagging
- Calibration: definitions, data, and master curves (IM Analyzer only)
- Lab metrics: assay utilization (tracks data)
- Configuration: security, operator and reports setup, directories, LIS, and QC
- Maintenance: definitions, schedule, and log
- Test definition: configuration and ranges
- PCM databases
- Module databases
- Events: operator event message, system message, audit trail, LIS, and LAS logs

The Database Backup completes in up to 30 minutes.

A partial database backup does not combine the databases. The database backup file saves, but the backup operation fails with an event message.

About Database Archiving (Copy and Delete)

Database Archiving (Copy and Delete) completes in up to 30 minutes. The system completes this process while other analyzer maintenance activities perform.

The operator schedules the system database activities during off-peak hours in the following order:

1. Database Backup
2. Move to Historical
3. Database Archiving (Copy and Delete)
4. Database: Optimizing

The following options are available when the operator archives or deletes a database.

Database Archiving (Copy and Delete)	Notes
File	The file type and location for saved databases.
Save in	The location where the system stores archived databases.
Browse	The search function to select the location where the system saves the archived databases.
File Type	Archived databases save in either text or XML.
Archive Item	The data type to archive or delete.
Archive Choice	The database action to Archive and Delete, Delete (No Archive), or Do Not Delete or Archive.
Time Interval	The system archives and deletes data based on the time interval. For example, if the operator enters a value of 30 days, the system archives and deletes any data older than 30 days.
Cancel	The cancel function clears current selections.
Continue	Starts the Archive Choice action.

About SH, SHC, and Atellica Magline Transport Maintenance

The system displays maintenance activities on the Maintenance Schedule. 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.
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 replaces the SH robot gripper O-rings.

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 Schedule 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.

The Maintenance Schedule 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 Schedule 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 Schedule records and stores this activity.

Performing Decapper Autocheck Manually

1. On the Command bar, select **Maintenance > Schedule**.
2. In Module, select Decapper from the drop-down menu.
3. Select **Decapper Autocheck > Perform....**
4. Wait approximately 5 minutes for autocheck to complete.

NOTE: The system logs Decapper Autocheck activity as completed in **Maintenance > Log**.

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.
Refreshing the Water Bath Additive	The analyzer automatically adds water bath additive (WBA) to the reaction ring bath.

As Needed system-defined activities	Notes
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 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.
Replacing the Reaction Wash Probe 3	The operator manually replaces the reaction wash probe 3.

As Needed system-defined activities	Notes
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 Reagent Probe 1	The operator manually replaces the reagent probe 1.
Replacing the Reagent Probe 2	The operator manually replaces the reagent probe 2.
Replacing the Sample Probe	The operator manually replaces the sample probe.
Replacing the IMT Peristaltic Pump Tubing	The operator manually replaces the IMT peristaltic pump tubing yearly.
Replacing the Source Lamp	The operator manually replaces the source lamp based on lamp intensity.
Annually system-defined activities	Notes
CH Maintenance	The local technical support provider performs preventative maintenance once a year or every 1,200,000 cycles.

About IMT Daily Cleaning Activity

IMT Daily Cleaning is an automated daily procedure that cleans the IMT in 4 minutes. The system restricts IMT Daily Cleaning from performing more than once every 6 hours.

The duration of the daily maintenance activities count down. All other activities duration count up.

Maintenance Schedule records and stores this activity.

About CH Daily Maintenance Activity

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 Schedule records and stores this activity. To perform this activity, see Performing CH Daily Maintenance [#H-06-1086_maint_Performing_CH_Daily_Maintenance-t#](#).

About Inspecting the Washer Probes Activity

The CH Inspecting the Washer Probes activity alerts the operator or support to inspect the washer probes daily. Maintenance Schedule records and stores this activity.

The duration of the daily maintenance activities count down. All other activities duration count up.

To inspect washer probes, see (Page 434 *Inspecting CH Wash Probes*).

Inspecting CH Wash Probes



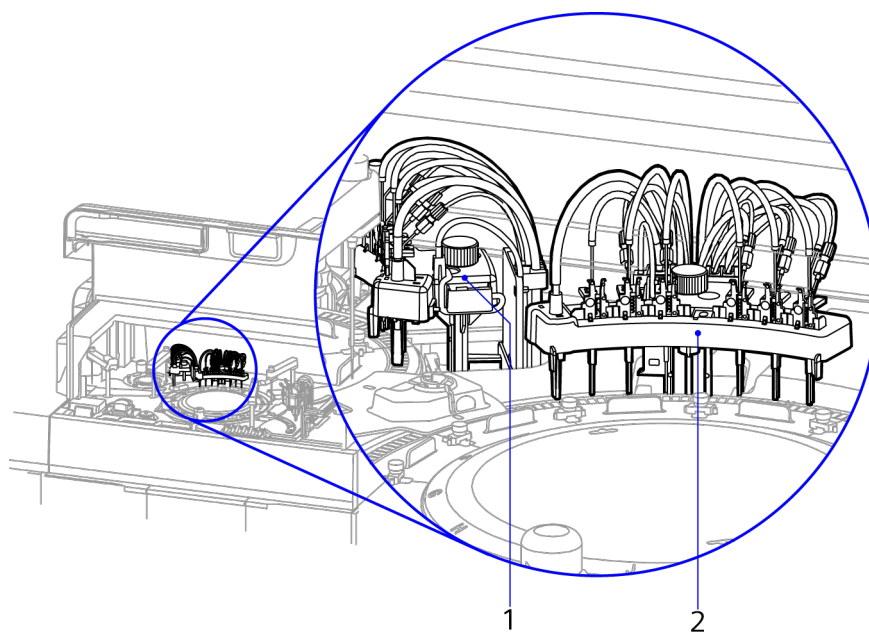
BIOHAZARD

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 134 *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 95 *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 420 *Marking Completed Manual Maintenance Tasks*):

NOTE: The analyzer logs the activity as completed in **Maintenance > Log**.

About CH Weekly Maintenance Activity

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 Schedule records and stores this activity.

About Checking the Lamp Coolant Activity

The analyzer alerts for the operator to check the analyzer lamp coolant level weekly. Maintenance Schedule records and stores this activity.

To check the lamp coolant level, see (Page 435 *Checking the Lamp Coolant*).

Checking the Lamp Coolant



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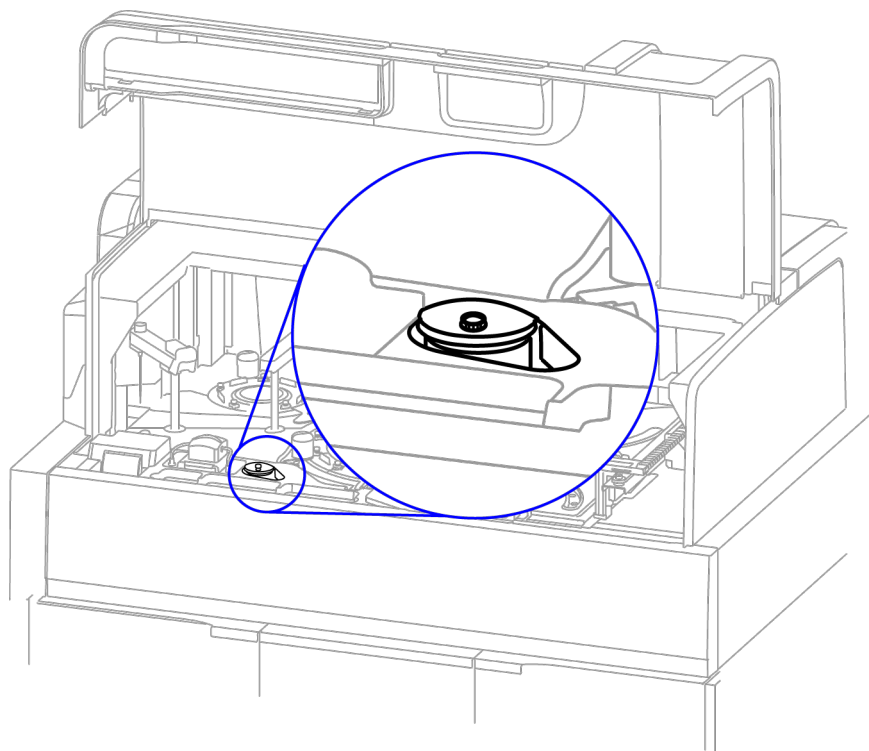


WARNING

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 134 *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 (LC) directly behind the IMT fluids.



7. If the LC fluid level is not visible, replenish the lamp coolant (Page 229 *Refilling CH Lamp Coolant*).
8. Close the cover.
9. Select **Continue > Close**.
10. Select **Exit Diagnostics > Yes**.
11. Mark **Checking the Lamp Coolant** as completed (Page 420 *Marking Completed Manual Maintenance Tasks*).
NOTE: The analyzer logs the Checking the Lamp Coolant activity as completed in **Maintenance > Log**.

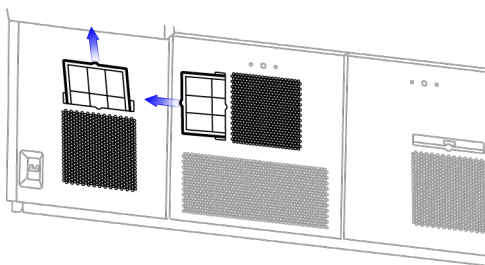
Cleaning the CH Fan Filter

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, and as needed 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.

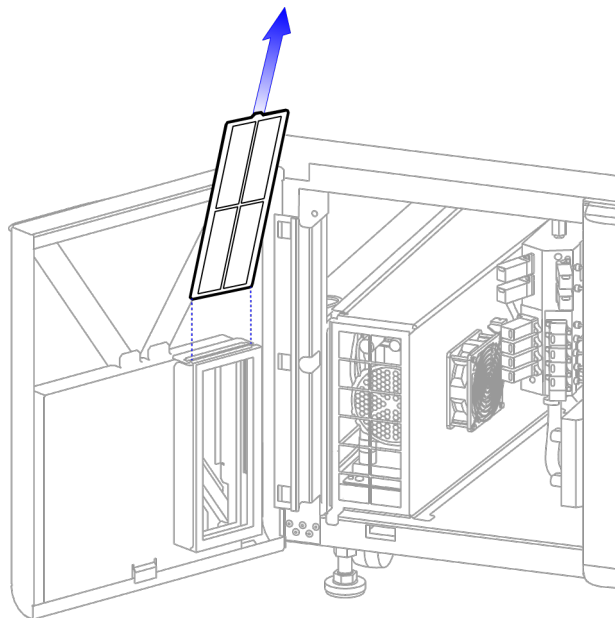
1. To remove and clean the back panel fan filters:



- 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 420 *Marking Completed Manual Maintenance Tasks*).
5. If original filter discarded, order a replacement filter.

NOTE: The analyzer logs the activity as completed in **Maintenance > Log**.

NOTE: To locate replacement catalog number, see (Page 604 *CH Supplies*).

Inspecting and Cleaning the Probe Wash Stations



BIOHAZARD

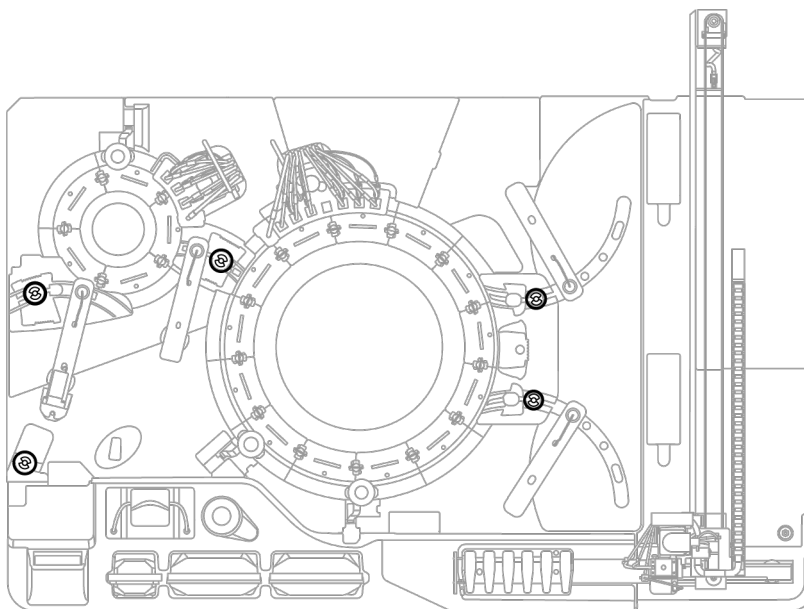
Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling biohazardous materials can cause bodily harm.

NOTE: The operator can edit the frequency for weekly, monthly, and as needed activities. Daily activities frequency cannot be modified.

1. Enter diagnostics (Page 134 *Enter Diagnostics State in CH Operator Diagnostics*).
2. Select **Subsystems > Inspect and Clean.**
3. Select **Inspecting and Cleaning the Probe Wash Stations.**
4. Select **Perform > Yes.**
5. Wait for analyzer to prepare for maintenance.

NOTE: The covers automatically unlock. If the covers lock, select **Unlock Covers.**

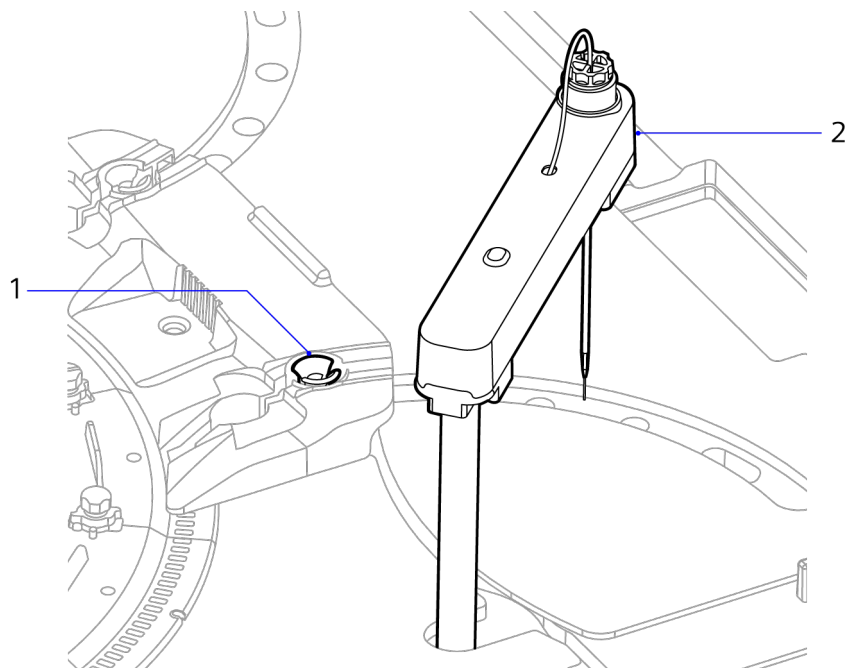
6. Open the CH front and back covers.



NOTE: The dilution and R2 probe wash ports are accessible from the front of the analyzer. The sample and R1 probe wash ports are accessible from the back of the analyzer. The analyzer raises the selected probe while it lowers the other probes into the drains.

7. Cover the cuvettes with a paper towel to protect the cuvettes from debris.

8. Locate the appropriate probe and inspect the wash port.



1	Wash port
2	Raised probe

9. If appropriate, wipe off any debris on the port with an alcohol pad or lint-free tissue dampened with alcohol.
 10. Repeat steps 6–9 for each of the remaining ports.
 11. Remove and discard the paper towel from the cuvettes.
 12. Close the cover.
 13. Select **Continue**.
 14. Select **Exit Diagnostics > Yes**.
 15. Mark Inspecting and Cleaning the Probe Wash Stations as completed (Page 420 *Marking Completed Manual Maintenance Tasks*).
- NOTE:** The analyzer logs the activity as completed in **Maintenance > Log**.

About IM Maintenance Activities

All maintenance activities display in Maintenance Schedule. The IM Analyzer contains system-defined automated and manual maintenance activities. In Maintenance Schedule, 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.

As Needed system-defined activities	Notes
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 IM Daily Maintenance

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 20 minutes.

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 Schedule 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 Schedule records and stores this activity.

About IM Weekly Maintenance Activity

The IM Analyzer has an 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 IM Weekly Maintenance completes in ≤ 30 minutes. Maintenance Schedule records and stores this activity.

Cleaning the Exterior of the Reagent Probes



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 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**

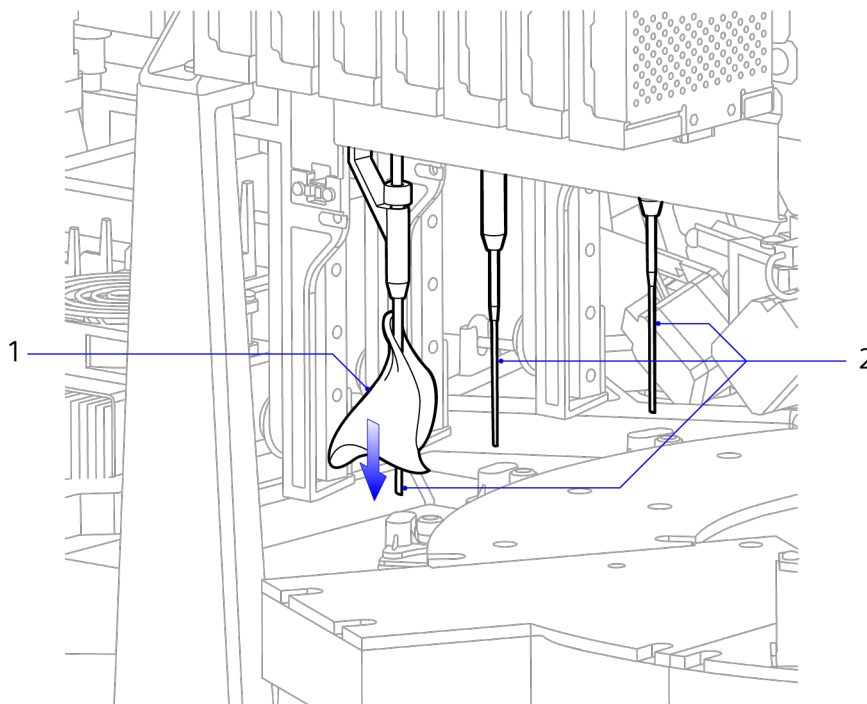
Do not bend the probe. Bending the probe can cause system errors.

Clean the exterior of the IM reagent probes weekly.

1. Unlock and open the IM Analyzer back cover (Page 95 *Locking or Unlocking Analyzer Covers*).

NOTE: Do not remove the reagent probes.

2. Using lint-free tissues or gauze dampened with IM Cleaner, clean the visible portion of the probe using 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. On the Command bar, select **System > Status**.
8. Select .
9. Select  to bring the analyzer back to Ready state.
10. Mark Cleaning the Exterior of the Reagent Probes as completed (Page 420 *Marking Completed Manual Maintenance Tasks*).

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 Activity

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 pauses 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 Schedule records and stores this activity.

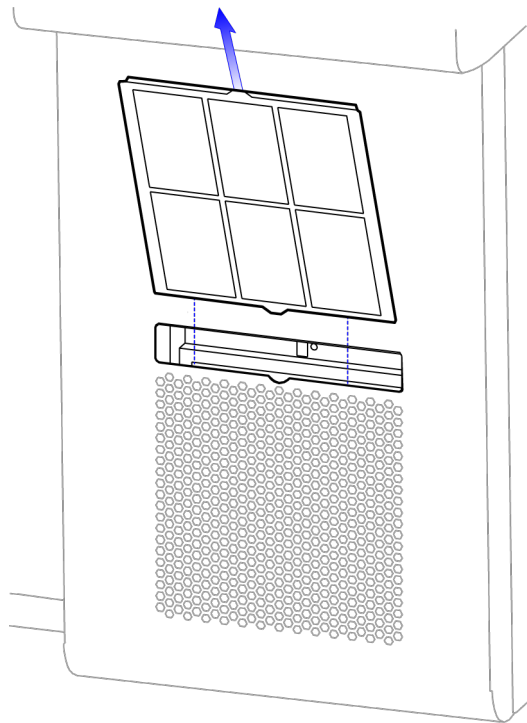
About Cleaning the DL Fan Filter Activity

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. Maintenance Schedule records and stores this activity.

To clean the fan filter, see (Page 446 *Cleaning the DL Fan Filter*).

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. If original filter discarded, order a replacement filter (Page 608 *DL Supplies*).

Cleaning System



BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling 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 447 *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
 - Minimal impurities
2. Combine 10 mL of undiluted bleach with 90 mL of deionized water to prepare 100 mL of a 10% bleach solution.

About Maintenance Report

The operator views 3 months of maintenance activities, 1 month at a time, in Maintenance Report. The default view is the current month. 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 up to 3 comments to an activity 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.

- Marks  (weekly) ,  (monthly), or  (as needed) activities complete or not performed. If the activity is completed or marked as complete on a day other than the scheduled day, the  is on the scheduled date. The Started Date or Count and End Date display the date when the maintenance was performed.

- Approves the displayed month with the appropriate security level.

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 Report	Notes
Module	Module name with serial number
Frequency	Frequency glyph with description
Activity	Activity performance glyph and title
Daily column	Month listed by day
Current status glyph	Glyph status of activity in day column
	Comments attached to activity

About Maintenance Log

The Maintenance Log displays a record of the most recently performed maintenance activities to a maximum of 10,000 entries. When the log reaches maximum capacity, the analyzer stores the maintenance log and deletes oldest entries.

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.
Part Number*	A Part Number glyph displays when an operator has added a part number.
Comment *	When an activity has a comment, a Comment glyph displays in the left side of the column. The right side of the column displays an icon representing the current status of the activity.
Sign-Off *	When an activity requires a sign off, the Sign-Off glyph displays. When an authorized operator signs off the activity, the Sign-Off glyph changes to a check mark.
Status*	Failed, Successful, or Reset.
Operator	The name of the operator performing the following activity: • For a manual activity, the operator who selected Mark as Completed. • For an automated activity initiated by an operator, the Log displays the operator's sign in ID. • For an automated activity initiated by the analyzer, "System" displays.
Start Date/Count	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.

Maintenance Log	Notes
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.
Scheduled Date/ Count	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.

NOTE: * Indicates columns containing symbols to indicate the setting. To see the text definition, tap on the symbol.

Viewing the Maintenance Log

1. On the Command bar, select **Maintenance > Log**.
2. If appropriate, filter the log.

About Maintenance Log Part Number

Store hardware part numbers for traceability in Maintenance Log Part Number.

About Exporting Maintenance Logs

The operator exports maintenance logs in Maintenance Log Export....

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.
Export	The function to execute the export.
Cancel	The function to cancel the request.

Exporting Maintenance Logs

1. On the Command bar, select **Maintenance > Log**.
2. Select the Log data to export:
 - a. To export the entire Maintenance Log, remove all filters.
 - b. To export specific Log data, select **Filter...** and select the filter criteria.
3. Select **Export....**
4. Select a File Type.
5. Select a storage location.

NOTE: If the storage location is different than the analyzer default, enter the location or select **Browse** for a location.
6. Select **Export**.

About Maintenance IMT

The following tasks are available within Maintenance IMT:

- Prime IMT
- IMT Routine Clean
- IMT Advanced Clean
- IMT Dilution Check

The status of IMT calibrations, A-LYTE multisensor, and the last performed IMT maintenance displays in **Maintenance > IMT > IMT Clean and Prime**.

IMT dilution check date is available in **Maintenance > IMT > IMT Dilution Check**.

About IMT Clean and Prime

IMT Clean and Prime displays the status of IMT maintenance and calibration, messages, and the ability to start IMT maintenance. The following are available within **Maintenance > IMT > IMT Clean and Prime**:

- IMT Details
- IMT Messages
- Operation Status
- Prime IMT

- IMT Routine Clean
- IMT Advanced Clean

IMT Details	Notes
IMT Calibration	IMT calibration status including in progress and complete.
A-LYTE Multisensor	Date and time the multisensor was last replaced and how many tests are currently performed on the new multisensor.
Routine Clean	IMT cleaning performed at required intervals or as a troubleshooting step. Date and time Routine Clean was last performed.
Advanced Clean	Longer IMT cleaning performed at required intervals or as a troubleshooting step. The multisensor must be replaced following this clean. Date and time Advanced Clean was last performed.

About IMT Dilution Check

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



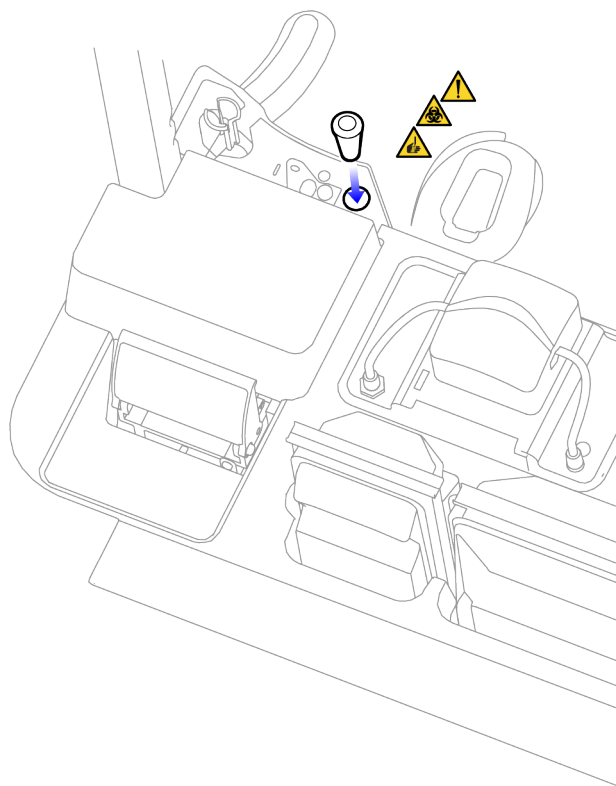
BIOHAZARD

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

1. Unlock and open CH front cover (Page 95 *Locking or Unlocking Analyzer Covers*).
2. 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.

3. Place the tube-top sample cup in the dilution check position behind the IMT multisensor.



4. Close the cover and select ► to resume the analyzer.
5. Select **Maintenance > IMT > IMT Dilution Check**.
6. Select **Perform IMT Dilution Check > OK**.
7. Wait for dilution check to complete.
8. When an IMT Dilution Check completes, review the IMT Dilution Check Status and Recommendation areas.
9. Select **Apply Correction**, if appropriate.

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.
10. Unlock and open CH front cover (Page 95 *Locking or Unlocking Analyzer Covers*).

11. Remove and dispose of the dilution check sample cup according to laboratory protocol.
12. To resume the analyzer, select .
13. Review the report for the acceptance criteria. For more information, see *About IMT Dilution Check* (Page 452 *About IMT Dilution Check*).
14. If the results are outside the acceptance criteria, check *Resolving Failed IMT Dilution* in online help to troubleshoot.

About Maintenance Database Backup

The system automatically performs a Database Backup daily. The system completes this process, while processing samples, as other analyzer maintenance activities perform.

The Database Backup completes in 30–40 minutes.

The operator can view and restore previous database backups from Maintenance Utility.

The operator schedules the system database activities during off-peak hours in the following order:

1. Database Backup
2. Move to Historical
3. Database Archiving (Copy and Delete)
4. Database: Optimizing

Restoring from Database Backups

A system restore restores the database to the last saved backup. This backup is a snapshot of the system at the date and time it saves. Anything that occurred on the system after that backup cannot be restored. For example, reagent pack inventories are lower than on system volumes which results in expected Reagent Volume Check (RVC) errors.

If a database backup does not include data for 1 or more modules, those module selections are disabled because nothing requires restoration.

1. On the Command bar, select **Maintenance > Data Restore**.
2. In Select Database Backup, select the required database.

NOTE: Database backups locations can include a drive on the network.

3. Select the following criteria of the database restore:
 - a. To overwrite all the data in the file, select **All** in Perform Data Restore.
 - b. To restore data from specific modules, select **Selected** then select the module.
 - c. To restore all data except specific files, select the data groups to exclude in Exclude from Restore
4. Select **Restore... > Yes**.

NOTE: If the restore fails, consider excluding any data that has failed.
5. Check and correct status for all system inventory, QC, and calibration.

About Move to Historical Activity

The system automatically moves samples from the Completed or Transmitted status to Historical during Move to Historical. The operator schedules the frequency for this automated activity with Daily as the default. The operator cannot restore any samples the system moved to Historical back to the active sample database. Samples moved to historical allow the reuse of SIDs. The operator modifies the options to move samples from Move to Historical in Maintenance Schedule.

The system automatically performs a Move to Historical daily. The system completes this process while other analyzer maintenance activities perform.

The Move to Historical completes in ≤ 5 minutes.

The operator schedules the system database activities during off-peak hours in the following order:

1. Database Backup
2. Move to Historical
3. Database Archiving (Copy and Delete)
4. Database: Optimizing

Move to Historical Settings	Notes
Patient and QC Order Status	The options are Completed, Transmitted, or All. Default is All.
Age (1–30 Days)	The age begins at the sample date and time then is measured in days. Default for Patient and QC Order Status is 5 days.

About Software and Online Help Updates

The 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.

The Maintenance tab provides access to the Install Manager. The Install Manager displays all available software and online help update packages in a panel on the left side of the screen. The most recent update packages are at the bottom of the list.

Installing Software Updates and Online Help Using Smart Remote Services

NOTE: The system displays a yellow alert: "A new software update is available and is ready to install."

Read the software release notes prior to installing software updates.

1. If the optional Operator Tablet is available, ensure it is connected to power and has a strong connection to the system.
2. Ensure all modules are in the stopped state (Page 125 *Changing the Module Status*).
3. On the Command bar, select **Maintenance > Software Updates**.
4. To display the Install Manager, select **Install**.
5. In the Install Manager, select the appropriate update:
 - a. Select **System Software Min**.
 - b. If Install is not available, select the System Software package without "Min" in the name.
 - c. For Online Help, select the most recent version.
6. For Online Help, expand the drop-down menu in the Include column and select any additional languages.
7. To start the installation, select **Install**.
8. At the confirmation, select **OK**.

NOTE: A green check mark next to the software update filename indicates the install is complete.

9. When the install is complete, select **Restart** to restart the system.

Performing Reset Databases

1. Ensure all modules are in the stopped state (Page 125 *Changing the Module Status*).
2. On the Command bar, select **Maintenance > Software Updates**.
3. Select **Install**.

4. In the Install Manager, select **Modules**.
5. Select the checkbox under Include for each module.
6. Select **Restore**.
7. Select **OK**.

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.

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 configuration settings	Section for exporting current system configuration settings
System Serial Number	Serial number of the current system
System Name	Name of the current system
Export Configuration	Button that exports the current system configuration settings
Browse and Import Configuration Settings	Section for importing system 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

Copy Configuration	Notes
Date and Time	Date and time the operator copied the configuration settings
System Name	Serial number of the system from which the operator copies the configuration settings
Select Configuration Settings	Section for selecting which configuration settings to import
Import	Button that imports selected configuration settings

Exporting Configuration Settings

1. On the Command bar, select **Maintenance > Copy Configuration**.
2. Select **Export Configuration**.
NOTE: The system exports all configuration settings.
3. Browse to location for the exported system configuration file.
NOTE: The location in step 3 cannot be on the same disk as the system files.
4. Create a password for the exported file.
5. Select **Save**.

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. On the Command bar, select **Maintenance > Copy Configuration**.
2. Select **Browse....**
3. Navigate to the folder where the operator saves the exported configuration settings.
4. Select the file to Import.
5. Select **Open**.

6. Enter the password for the exported configuration settings file.
7. Select **Yes**.
8. Select the configuration settings to Import.
9. Select **Import**.

16 Troubleshooting

This chapter provides information about identifying and correcting system problems.

About Event Help

Event Help provides more information about an Operator Event. The operator can select an event and access the Event Help to find Possible Causes for the event and Corrective Action options. The operator can also access troubleshooting information from Event Help.

Event Help	Notes
Event	Displays a description of the event.
Possible Causes	Displays possible reasons for the event.
Corrective Action	Displays options for the operator to correct the event. The operator can select a link to access related procedures, if available.
Contents	Displays the contents of the online help. The operator can browse the help contents or do an online search for a topic.

Viewing Event Help

1. On the Command bar, select **System > Logs > Operator Event Log**.
2. Select an event.
3. Select **Event Help**.

Completing Corrective Action Events

1. On the Command bar, select **System > Logs > Operator Event Log**.
2. Select the appropriate Event.
3. Select **Completed**.

Acknowledging Operator Events

1. On the Command bar, select **System > Logs > Operator Event Log**.
2. Select **Acknowledge All**.

NOTE: The operator can only acknowledge events without corrective actions. Selecting Acknowledge All sets the Unacknowledged count to 0. The Corrective Action count remains the same.

3. Select **Yes**.

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 494 *Unlocking SH Covers Manually*).

3. Wait 30 seconds before initiating recovery procedures (Page 463 *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

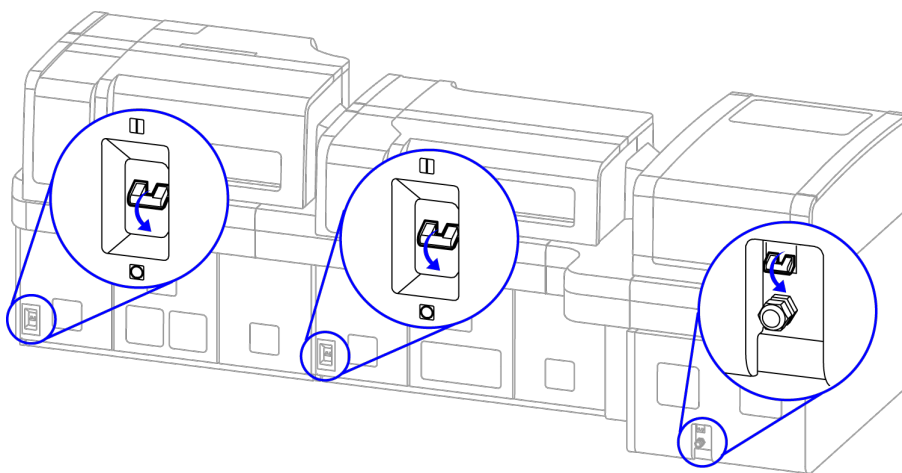
Do not operate modules without a protective grounding connection that prevents electrical shock. Electrical shock can cause equipment damage and bodily harm. Use caution when working around these locations or contact a local technical support provider for more information about using a protective grounding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



ELECTRICAL HAZARD

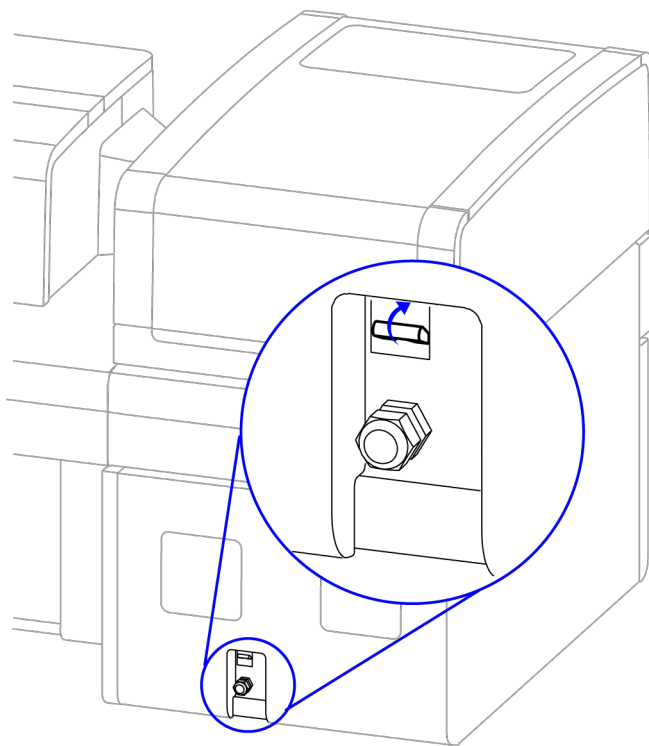
Do not plug in power cord with module power switch in on position. If the operator inserts the plug with power switch on, electrical shock may occur and cause bodily harm and equipment damage.

1. Ensure each module power switch is in the off position.



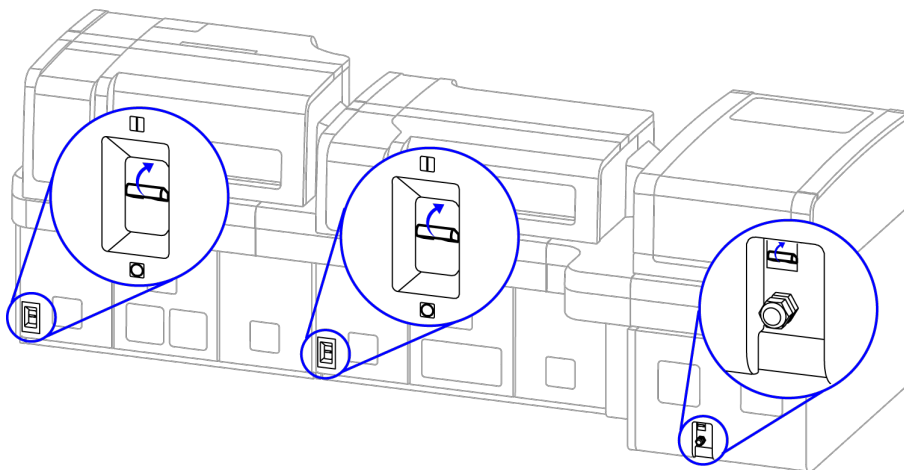
2. Ensure Atellica Magline Transport is clear (Page 465 *Clearing the Atellica Magline Transport Prior to Startup*).
3. Reconnect the module power cords to their power sources.

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, if appropriate, start the SHC (Page 499 *Starting the SHC*).
8. Completely open and close the SH 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 to the system (Page 476 *Signing in to the System*).
12. Confirm the contents of each SH Cal-QC storage area.
13. Ensure all modules are in Ready or Standby state (Page 125 *Changing the Module Status*).
14. In Module State, ensure all module 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, manually mix, and reload all onboard reagents (Page 209 *Manually Mixing IM Reagents*).
 - For > 2 hours, discard any assay reagents remaining in the reagent compartment and calibrators or QC remaining in the Cal-QC storage area.

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 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.

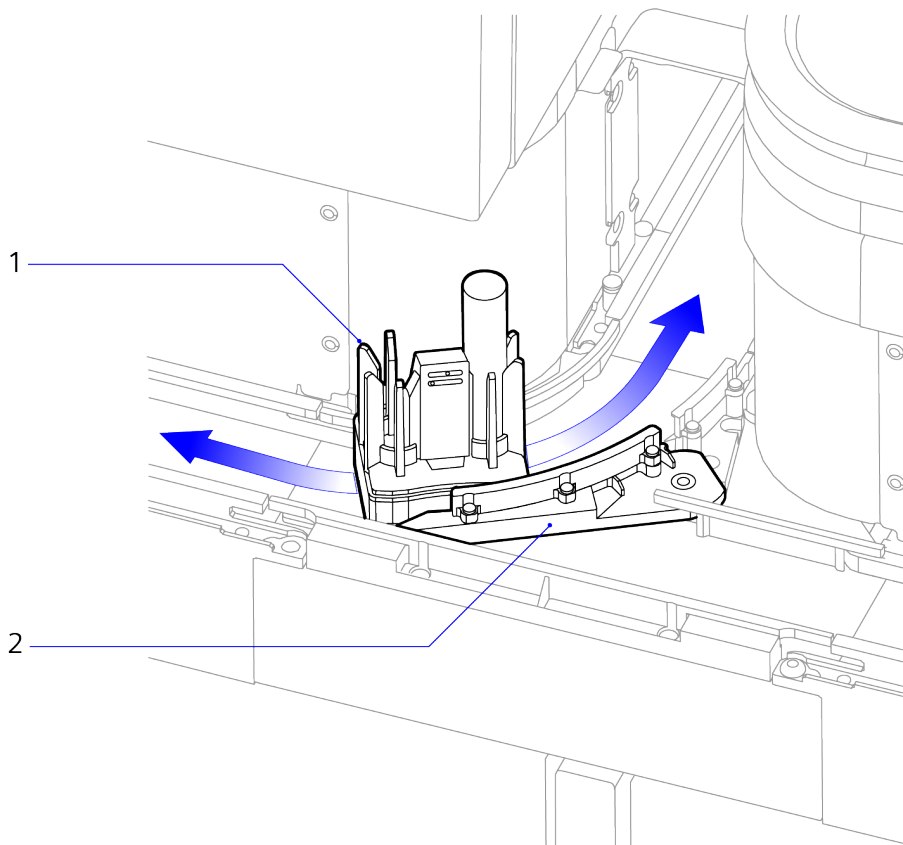
**CAUTION**

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 469 *Removing Atellica Magline Transport Covers*).
 - b. Push the carriers away from the diverters.
 - c. Replace the cover (Page 471 *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 494 *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**

Be careful when opening or working around the open SHC front cover. 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 504 *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 504 *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.

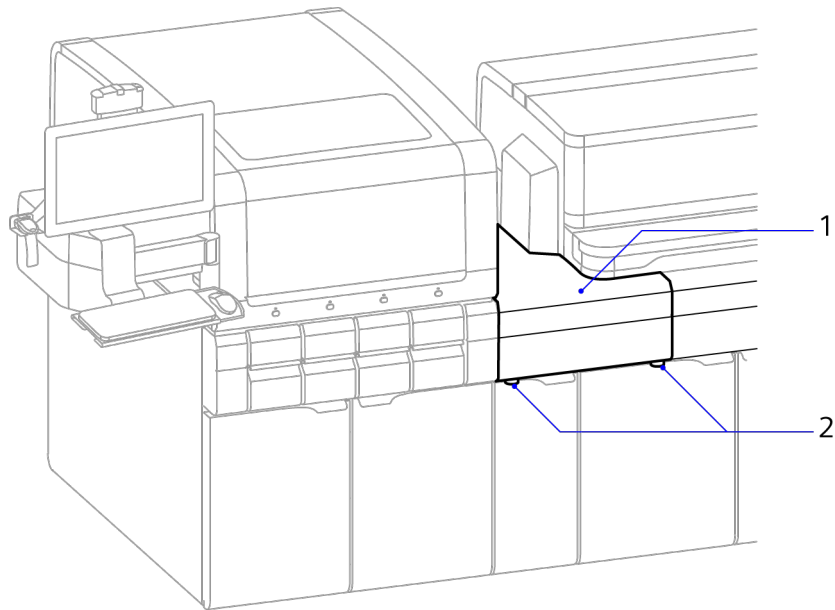


CAUTION

Be careful when opening or working around the open SHC front cover. The SHC front cover is heavy and can result in injury if a body part is caught between the cover and the SHC frame.

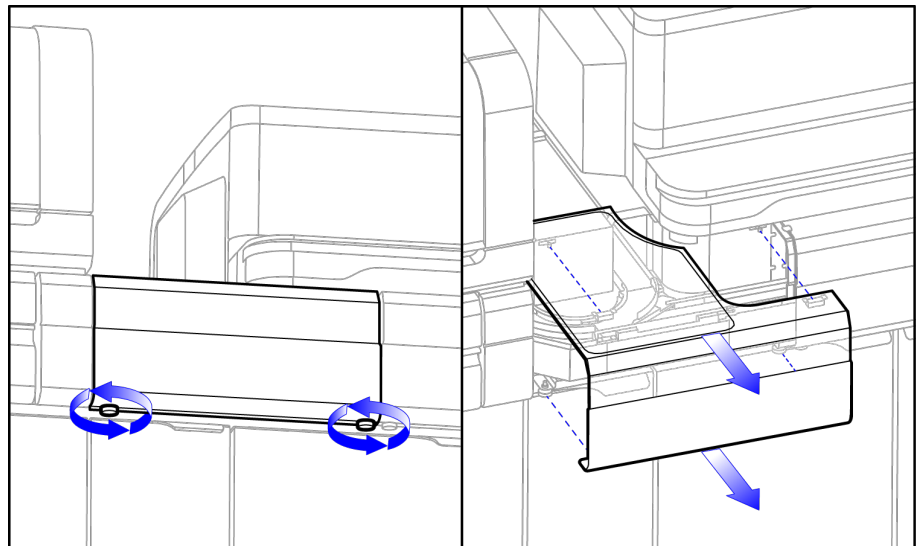
1. Stop the Atellica Magline Transport (Page 125 *Changing the Module Status*).
2. If removing the SHC front Atellica Magline Transport cover, open the SHC cover (Page 93 *Unlocking the SHC Cover*).

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

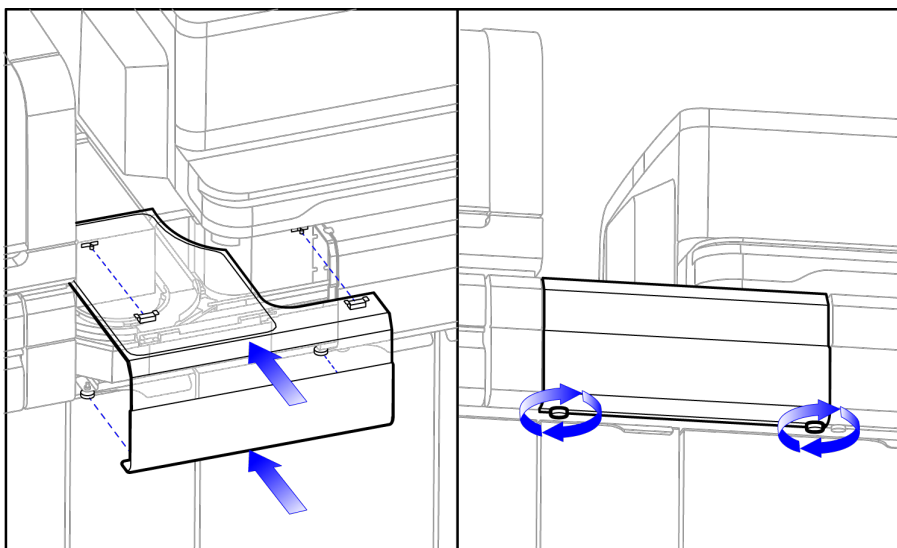
Do not remove the carriers from the Atellica Magline Transport. The carriers have strong magnets in the base and handling them in close proximity to metal objects can result in a body part being pinched between the carrier and the metal object. Only authorized service personnel should handle carriers.



CAUTION

Be careful when opening or working around the open SHC front cover. 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 94 *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 472 *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.



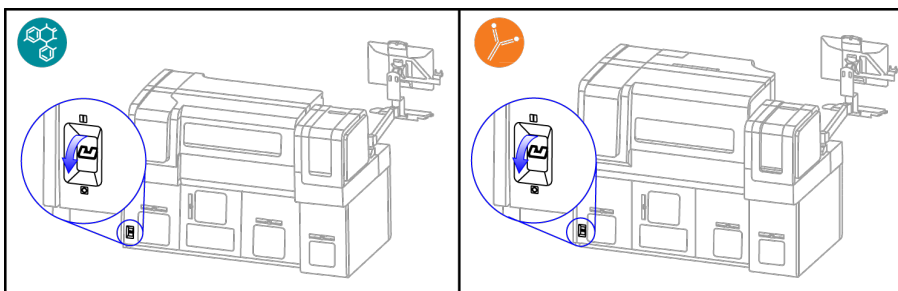
ELECTRICAL HAZARD

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.

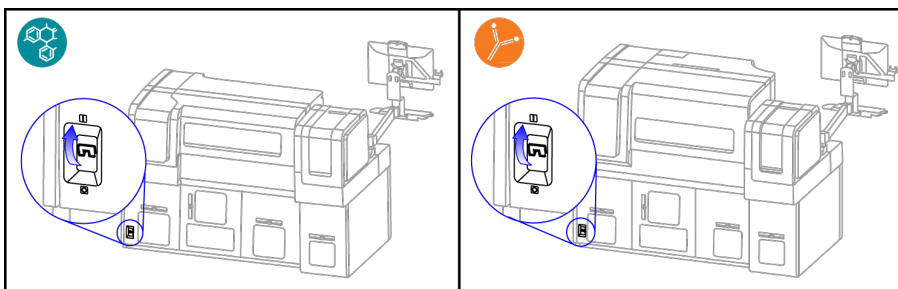
**ELECTRICAL HAZARD**

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 501 *Starting the Analyzer with DL*).
6. If the analyzer power is off:
 - For > 30 minutes on IM Analyzer, unload, manually mix, and reload all onboard reagents (Page 209 *Manually Mixing IM Reagents*).
 - For > 2 hours, discard any reagents left in the reagent compartment.

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 SHs 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.

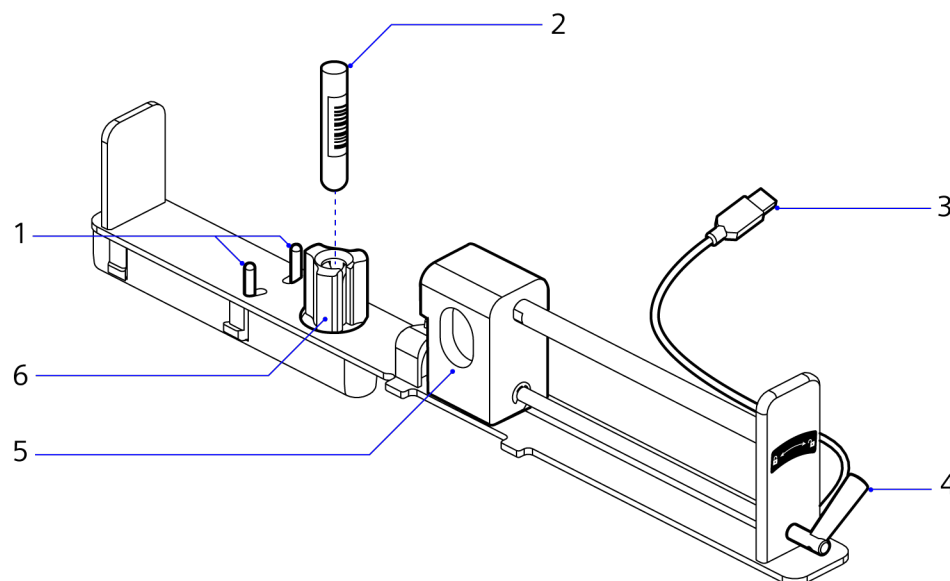
The operator can process the following sample types using the ESL carrier:

- 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 125 *Changing the Module Status*).
2. Select **Enter Emergency Sample Load**.
3. Select **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. On the Command bar, select **System > Status**.
2. Select the Atellica Magline Transport icon.
3. Select **Exit Emergency Sample Load**.
4. Select **Yes**.
5. Restart the system software (Page 508 *Restarting the PCC*).

Signing in to the System

1. In the Status bar, select .
2. At the Sign In window, enter the Operator ID and Password.
3. Select **Sign In**.

Signing out of the System

1. On the Status bar, select .
2. Select **Sign Out**.
3. Select **Yes**.

Stopping Analyzer Processing Immediately

1. On the Command bar, select **System > Status**.
2. Select an analyzer.
3. Select .
4. Select **Yes**.

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.

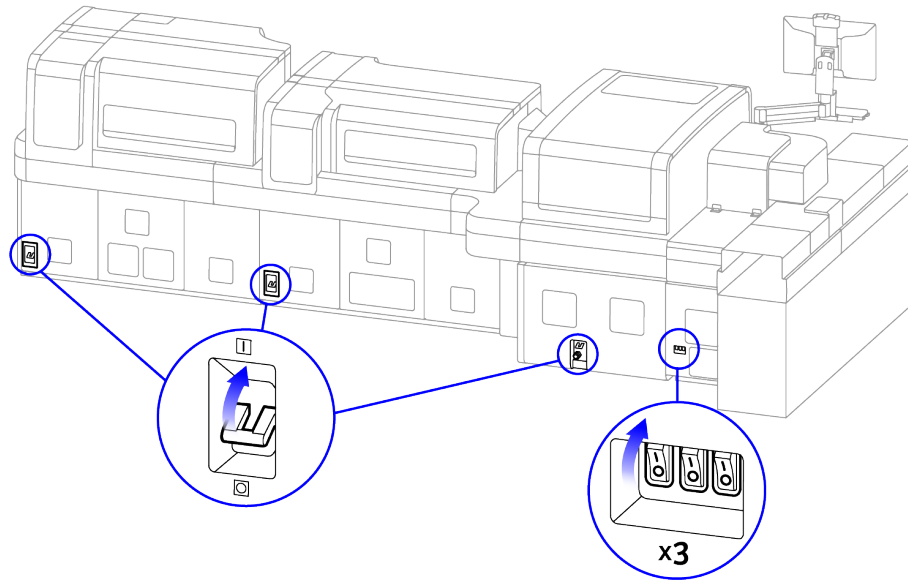


BIOHAZARD

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

1. Ensure Atellica Magline Transport is clear (Page 465 *Clearing the Atellica Magline Transport Prior to Startup*).

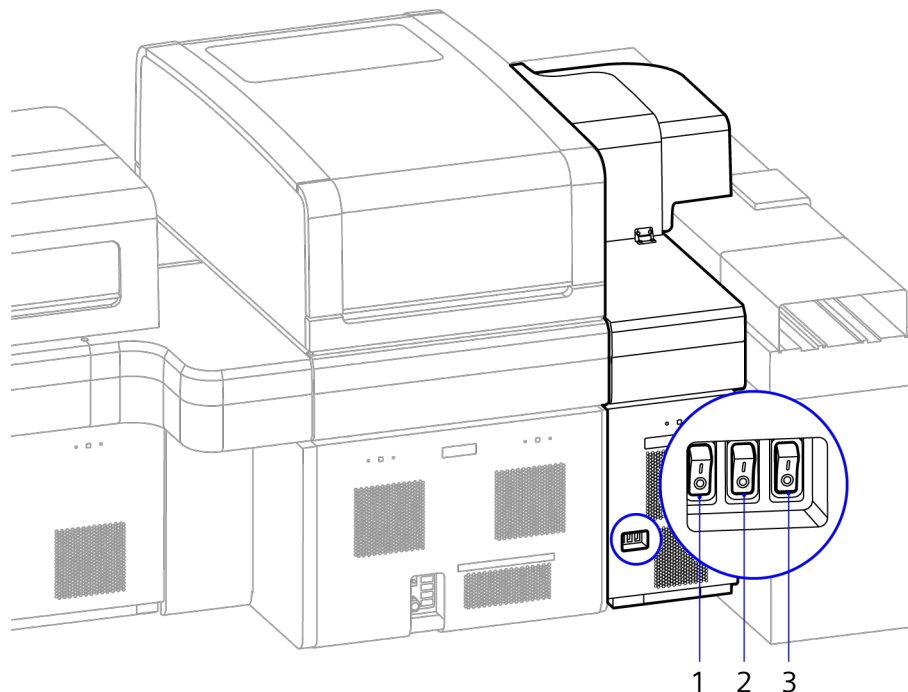
2. If appropriate, power on the SH Prime and wait 30–60 seconds.



NOTE: The analyzers and SH have 1 power switch each. The SHC has 3 power switches.

3. If appropriate, power on each SH Additional.

4. 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 10 seconds.
 - b. Power on the middle +48VDC power switch and wait 10 seconds.
 - c. Power on the computer power switch to the right.
5. 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.
 6. Wait for the system display login screen to display.
 7. Ensure the barcode label printer power is on.
 8. Sign in to the system (Page 476 *Signing in to the System*).
 9. Initialize the SH drawers then completely open and close.
 10. Confirm the contents of each SH Cal-QC storage area.
 11. Ensure all modules are in Ready or Standby state (Page 125 *Changing the Module Status*).

NOTE: If a module doesn't display within 5 minutes, proceed to next step.

12. If any module status 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 211 *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 209 *Manually Mixing IM Reagents*).
 - For > 2 hours on CH Analyzer or IM Analyzer, discard any assay reagents remaining in the reagent compartment and calibrators or QC materials remaining in the Cal-QC storage area.

Shutting Down and Powering Off the System

NOTE: 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 508 *Restarting the PCC*).

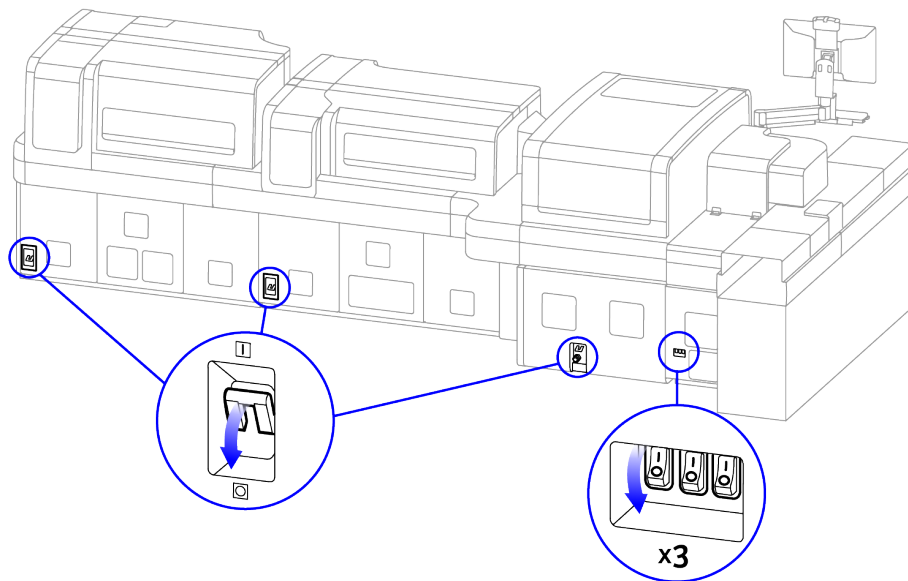
Use the following shut down procedure on a system configuration. Skip any steps for modules not present in the laboratory system configuration.

1. To shut down the system:
 - a. On the Status bar, select .
 - b. Select **Sign Out > Yes**.
 - c. Select **Shutdown > Yes**.

NOTE: The system deletes pending calibration orders when the analyzer shuts down. Patient and QC orders remain.

2. Wait for all modules to shut down.

3. When the primary user interface no longer displays, 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.

4. Wait 30 seconds before restarting the system (Page 476 *Starting the System*).

NOTE: The 30 second wait:

- Ensures the router connection to the intranet stops for this time period to terminate communication.
- Allows capacitors to drain residual power to avoid data corruption.

5. If any module power is off:
 - For > 30 minutes on IM Analyzer, unload and store reagents. Then manually mix primary reagents and reload all onboard reagents (Page 209 *Manually Mixing IM Reagents*).
 - For > 2 hours on CH Analyzer or IM Analyzer, discard any assay reagents remaining in the reagent compartment and calibrators or QC materials remaining in the Cal-QC storage area.

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.

Recovering from a System Power Disruption



CAUTION

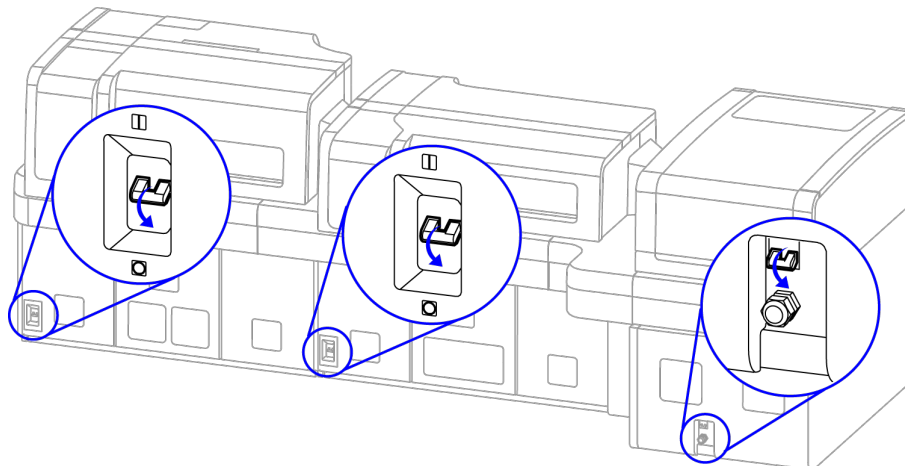
Do not leave a module's main power switch on during a power disruption. This can cause significant damage to the system when the operator restores power. When a power disruption occurs, turn off the main power switch for each module.



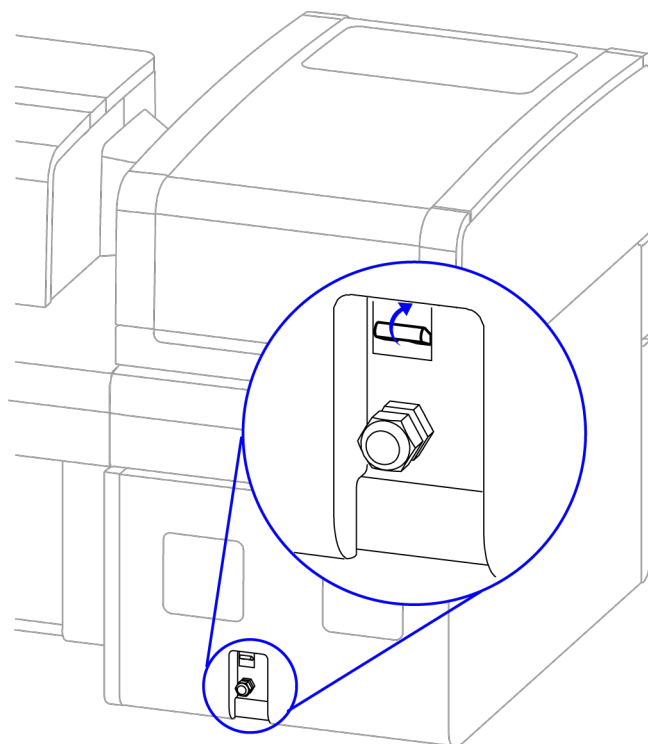
BIOHAZARD

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

1. Turn off all module power switches.



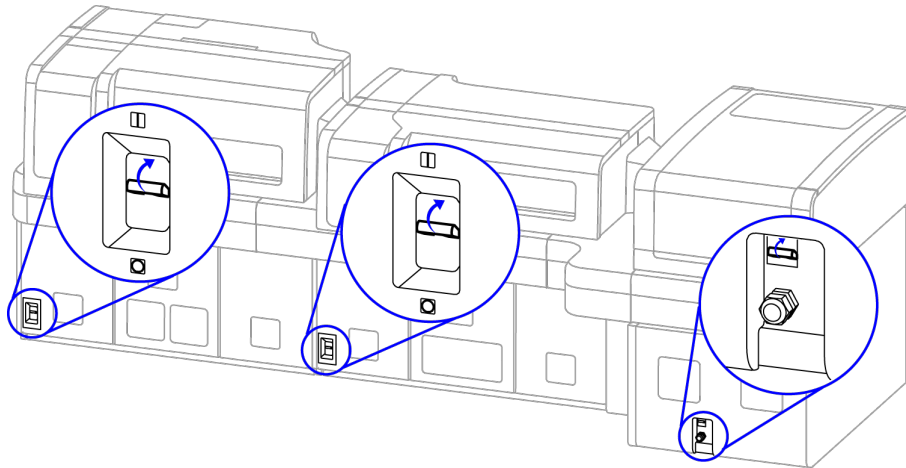
2. Ensure Atellica Magline Transport is clear (Page 465 *Clearing the Atellica Magline Transport Prior to Startup*).
3. If appropriate, power on the SH Prime and wait 30 seconds before proceeding.



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 499 *Starting the SHC*).
 7. Completely open and close the SH drawers.
 8. Wait for the system display login screen to display.
 9. Wait for each of the analyzer's module display to come up before proceeding.
- NOTE:** If a module display does not come on within 5 minutes, proceed to next step.
10. Sign in to the system (Page 476 *Signing in to the System*).
 11. Confirm the contents of the Cal-QC storage area.
 12. Ensure all modules are in Ready or Standby state (Page 125 *Changing the Module Status*).
 13. In Module State, ensure all modules display appropriate statuses.
 14. If any module status does not display or any problems occur, contact the local technical support provider.
 15. If any module power is off:
 - For > 30 minutes on IM Analyzer, unload, manually mix, and reload all onboard reagents (Page 209 *Manually Mixing IM Reagents*).
 - For > 2 hours, discard any assay reagents remaining in the reagent compartment and calibrators or QC materials remaining in the Cal-QC storage area.

Recovering from a Slow User Interface

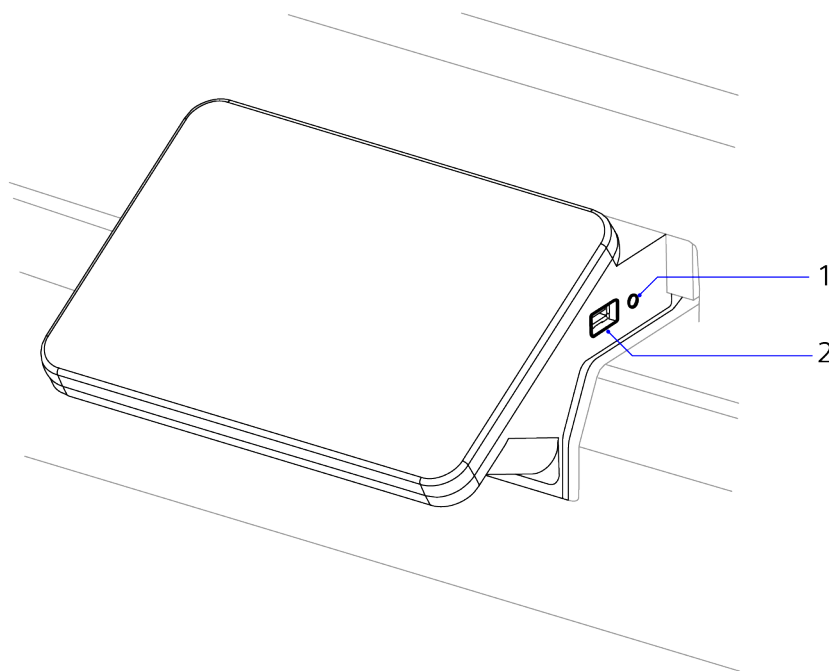
A slow user interface (UI) occurs when a window requires more than 5–10 seconds to load. For example, 200,000 patient results or 500,000 events take up to 10 seconds for the window to fully display. This does not apply when data is loading (when features take up to 30 seconds to load) or progress window (indicates time in a progress bar). To recover from a slow user interface:

1. Sign out (Page 476 *Signing out of the System*) and back into the system (Page 476 *Signing in to the System*).
2. If slow UI persists, restart the PCC (Page 508 *Restarting the PCC*).
3. If a slow UI 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.

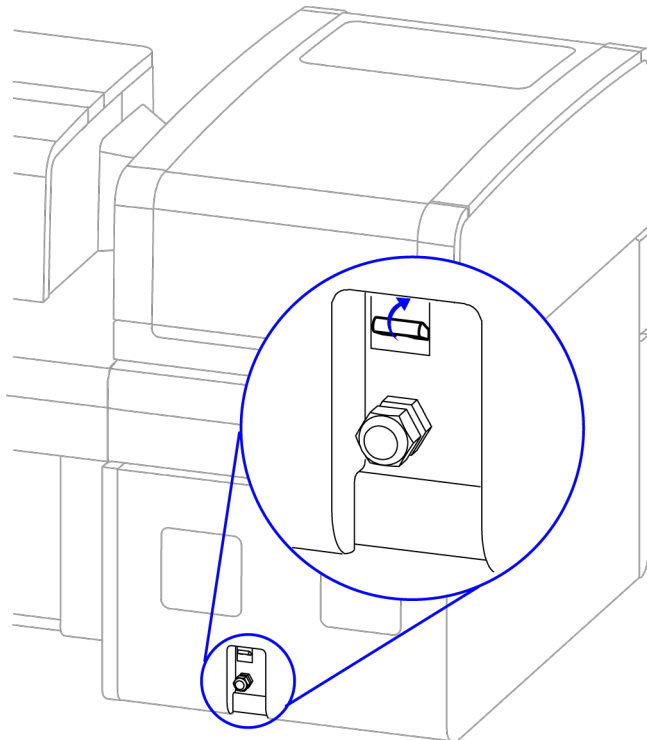
Starting the SH



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 465 *Clearing the Atellica Magline Transport Prior to Startup*).
2. If appropriate, power on the SH Prime and wait 30–60 seconds before proceeding.



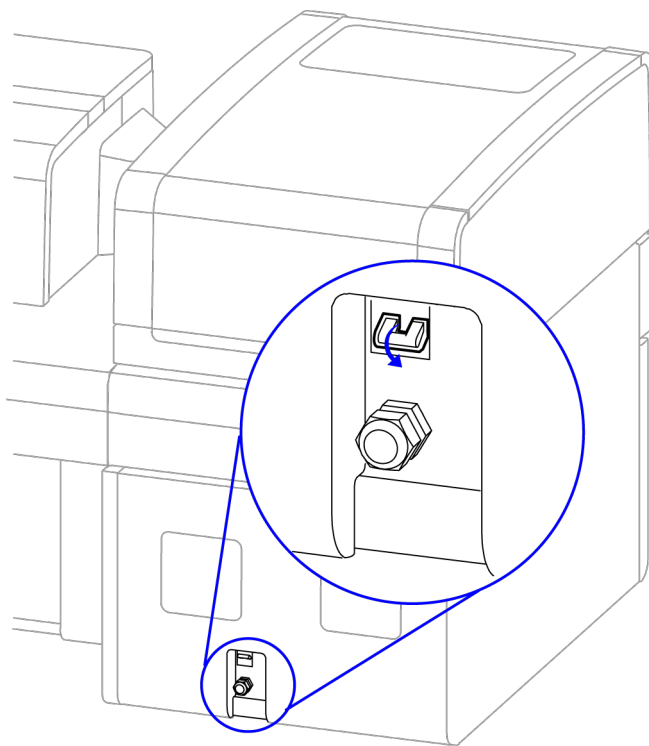
NOTE: The SH Prime is the SH closest to the analyzers. The SH Prime powers the PCC.

3. After power restores to the SH Prime, if appropriate, start the SHC (Page 499 *Starting the SHC*).
4. If appropriate, power on each additional SH power switch.
5. Initialize the SH drawers and completely open and close.
6. Sign in (Page 476 *Signing in to the System*).
7. Confirm the contents of each SH Cal-QC storage areas.
8. 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. On the Command bar, select **System > Status**.
2. If appropriate, power off the SHC (Page 501 *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. On the Command bar, select **System > Status**.
 - b. Select an additional SH module.
 - c. Select .
 - If no tests processing, select **Yes**.
 - If tests processing, select the appropriate shutdown option.
4. Repeat steps b–c with each additional SH module.
5. Select the SH Prime module and repeat step c.
6. To shut down the PCC:
 - On the Status bar, select .
 - Select **Sign Out > Yes**.
 - Select **Shutdown > Yes**.

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.

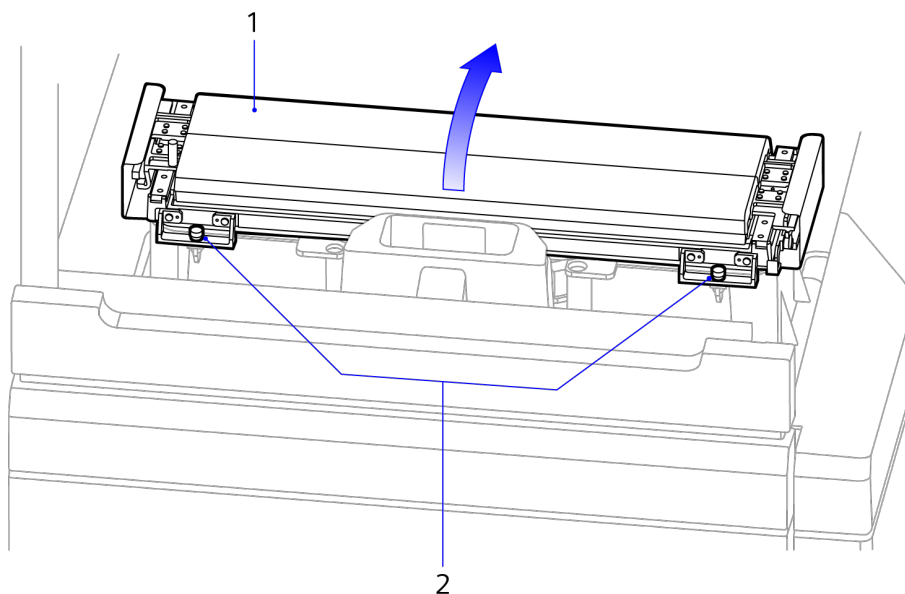
NOTE: Do not reload Cal-QC tubes manually. Only load Cal-QC tubes through the SH drawers.

1. If the system still has power:
 - a. Stop the SH (Page 125 *Changing the Module Status*).
 - b. Unlock the SH back cover (Page 91 *Unlocking SH Covers*).
2. Open the SH back cover.

**CAUTION**

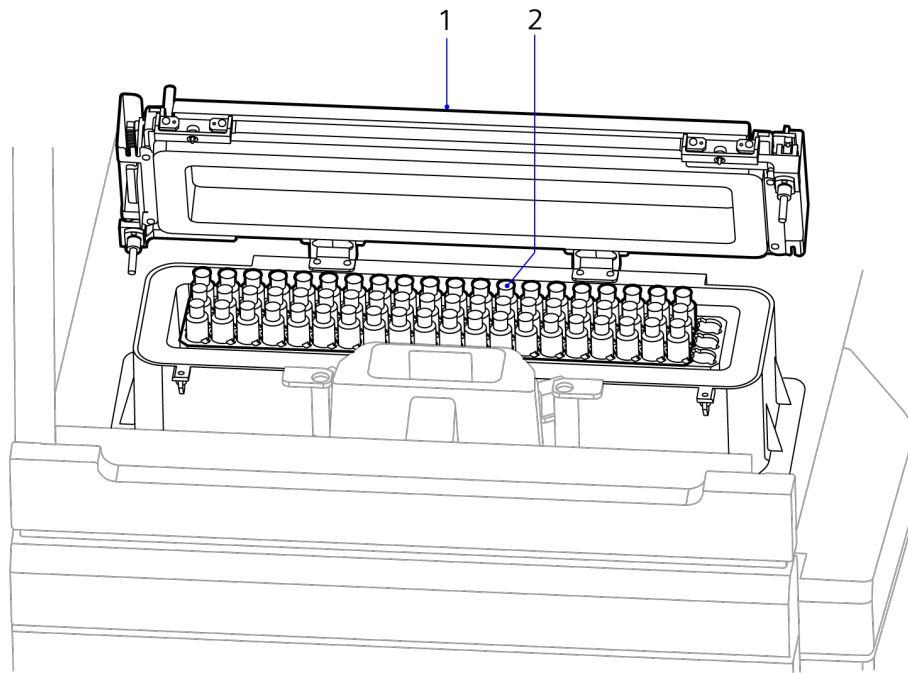
Do not hold the SH robot grippers or push the robot down when moving the robot manually. Holding the grippers to move the robot may damage the crash sensor. Moving the robot down may cause the robot grippers to impact another object, possibly resulting in damage to the robot gripper or sample container 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.



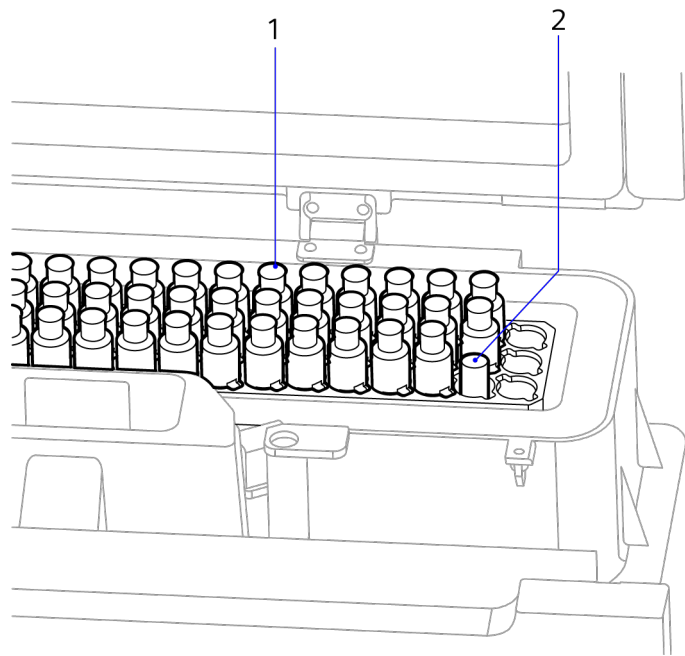
-
1	Cal-QC storage area cover
2	Thumbscrews
-

6. Rotate the Cal-QC storage area cover open.



-
1	Cal-QC storage area cover
2	Cal-QC tube covers
-

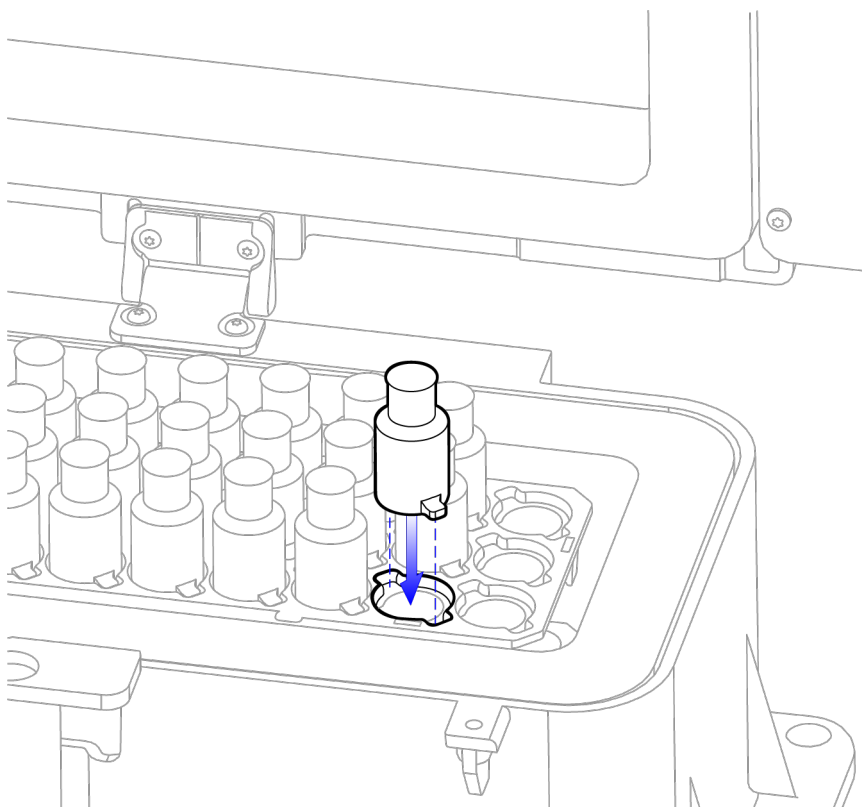
7. Remove all Cal-QC tubes from the storage area.



-
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

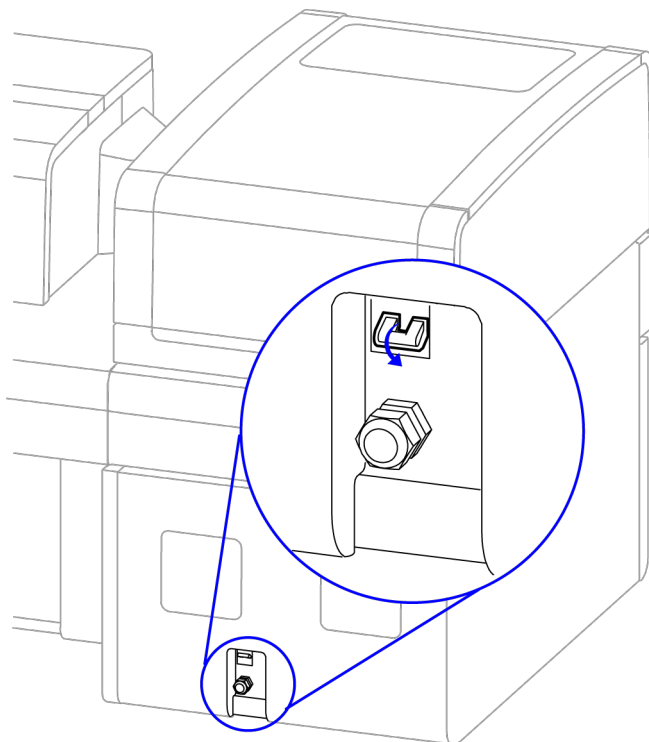
Do not leave a module's main power switch on during a power disruption. This can cause significant damage to the system when the operator restores power. When a power disruption occurs, turn off the main power switch for each module.



BIOHAZARD

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

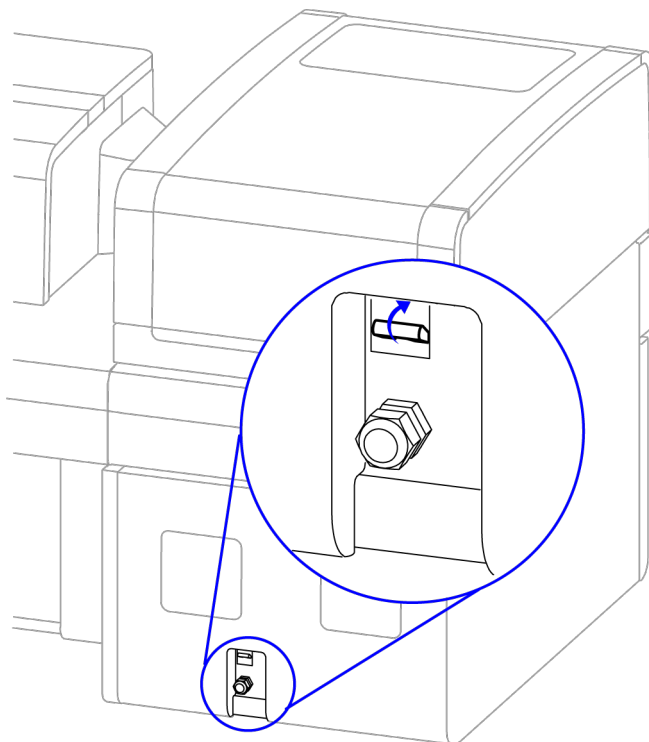
1. Ensure the SH Prime and additional SH module power switches are off.



NOTE: The SH Prime is the SH closest to the analyzers.

2. Ensure Atellica Magline Transport is clear (Page 465 *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 499 *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.
8. Start the SH (Page 485 *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

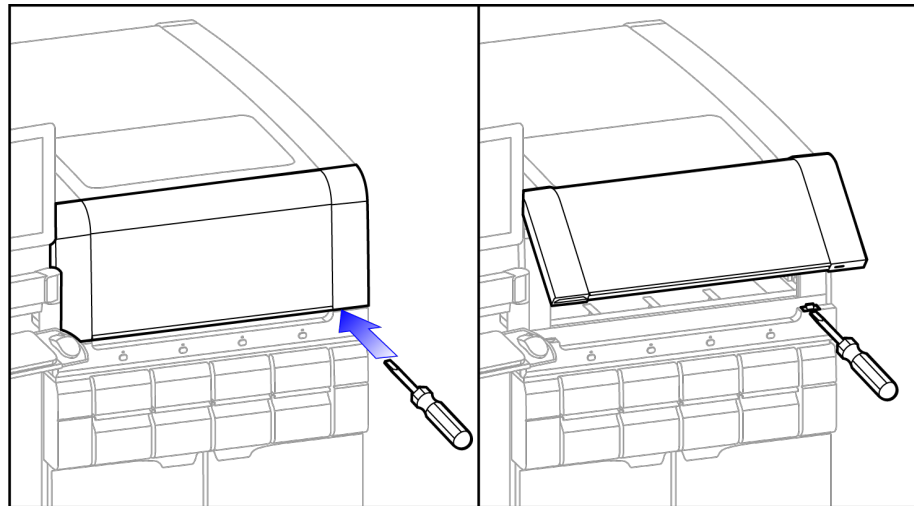


BIOHAZARD

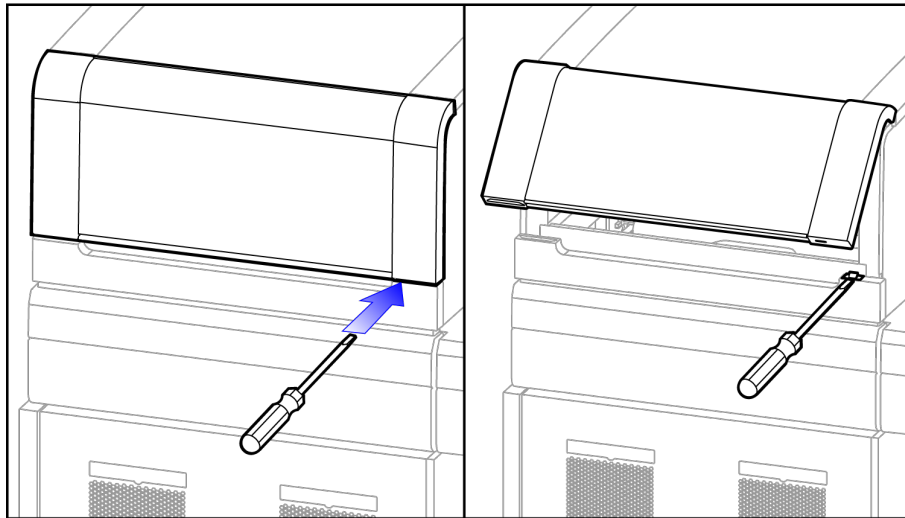
Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling biohazardous materials can cause bodily harm.

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.

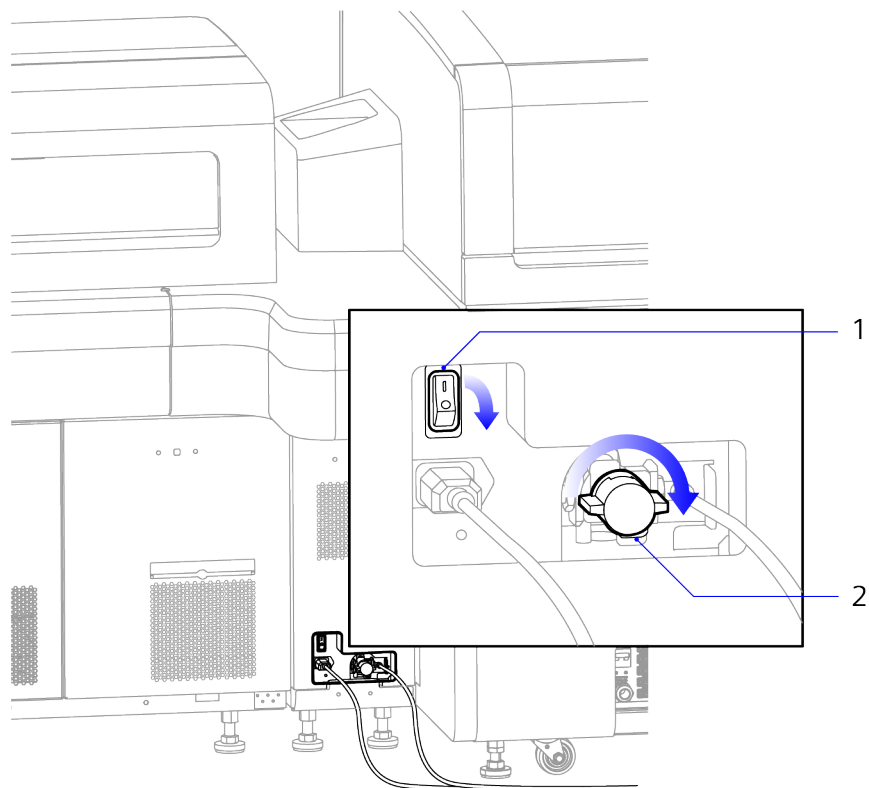


2. To unlock the SH back cover manually:
 - a. Insert the tip of a flat-blade screwdriver into the seam below the lower-right corner of the SH back cover.
 - b. Press in against the cover lock.
 - c. Open the SH back cover.



Powering Off the Decapper

1. On the Command bar, select **System > Status**.
2. Select .
3. Select  and wait for Decapper to pause (Page 125 *Changing the Module Status*).
4. To shut down the Decapper, select .

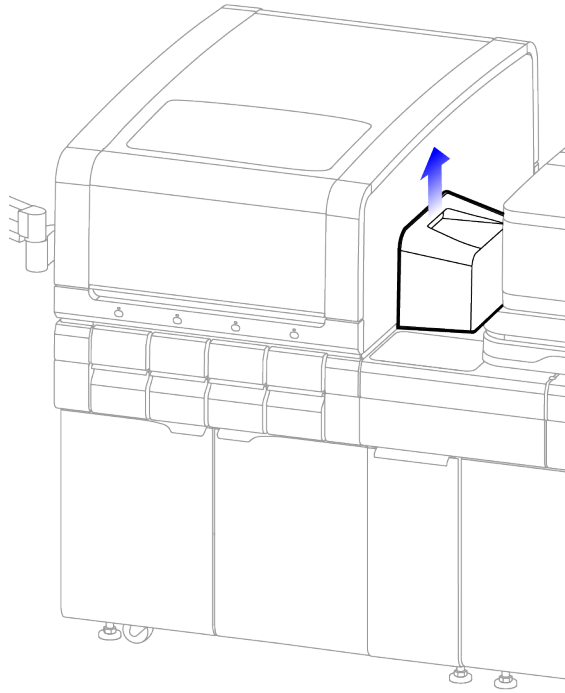


-
1	Power switch
2	Pressure valve
-

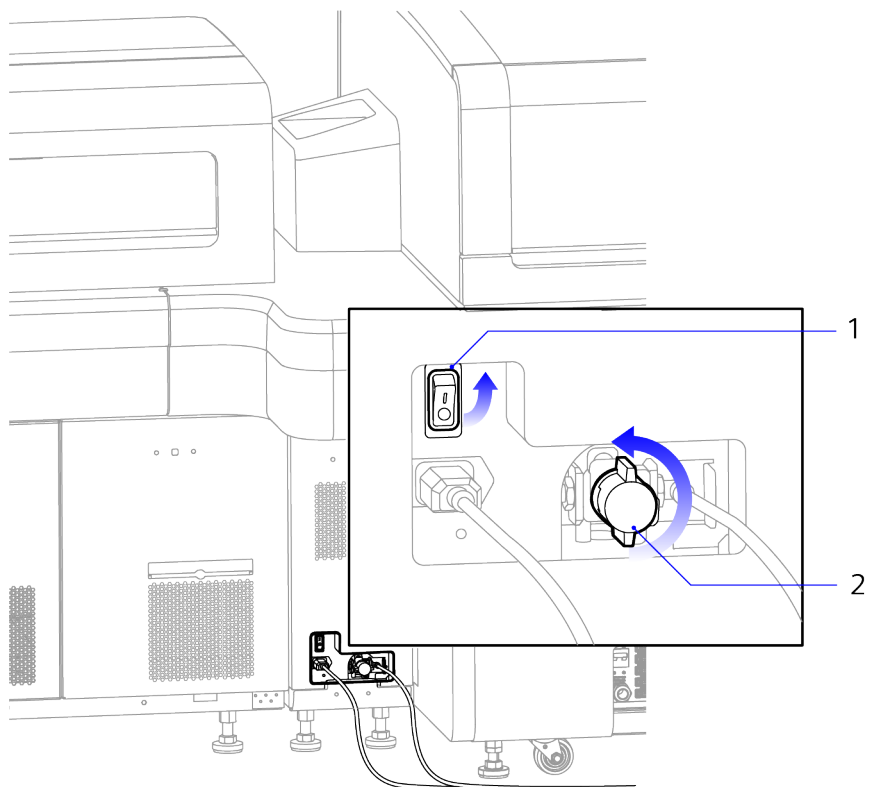
5. To shut off the pressure valve on the back of the Decapper, turn the valve clockwise.
6. Power off the Decapper.
7. Wait 30 seconds before powering on the Decapper (Page 496 *Powering On the Decapper*).

Powering On the Decapper

1. Lift the Decapper cover and ensure there are no tubes in the tube gripper.

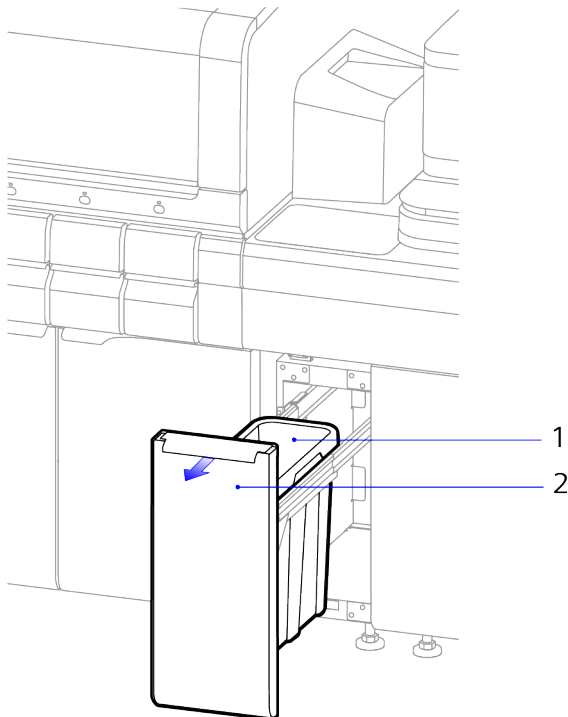


2. Reinsert the cover.



-
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, select ► and wait ≤ 10 minutes for the Decapper to reconnect.

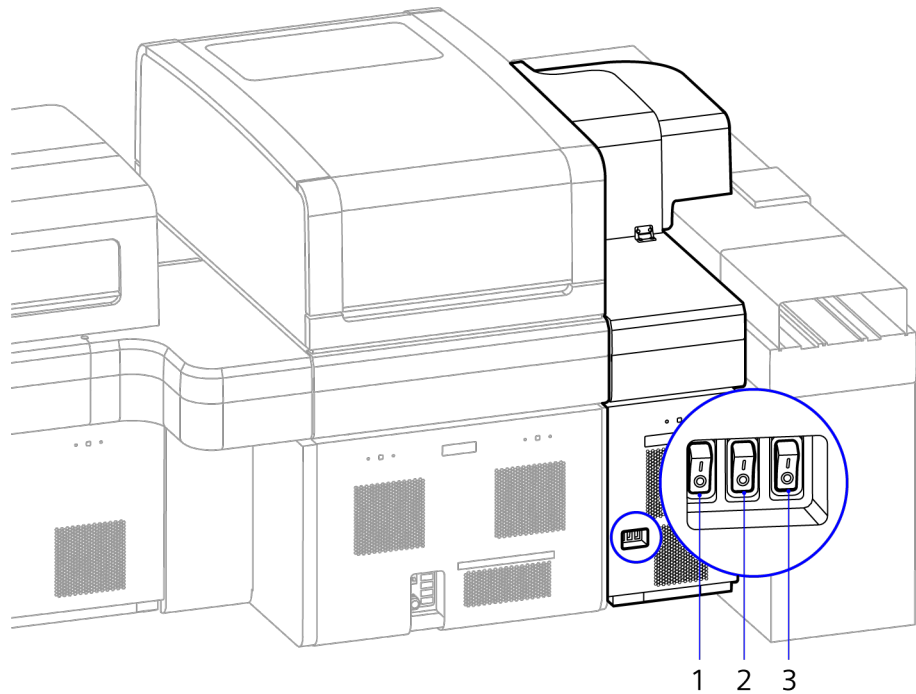
Starting the SHC



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 all SHC power switches are in the off position.

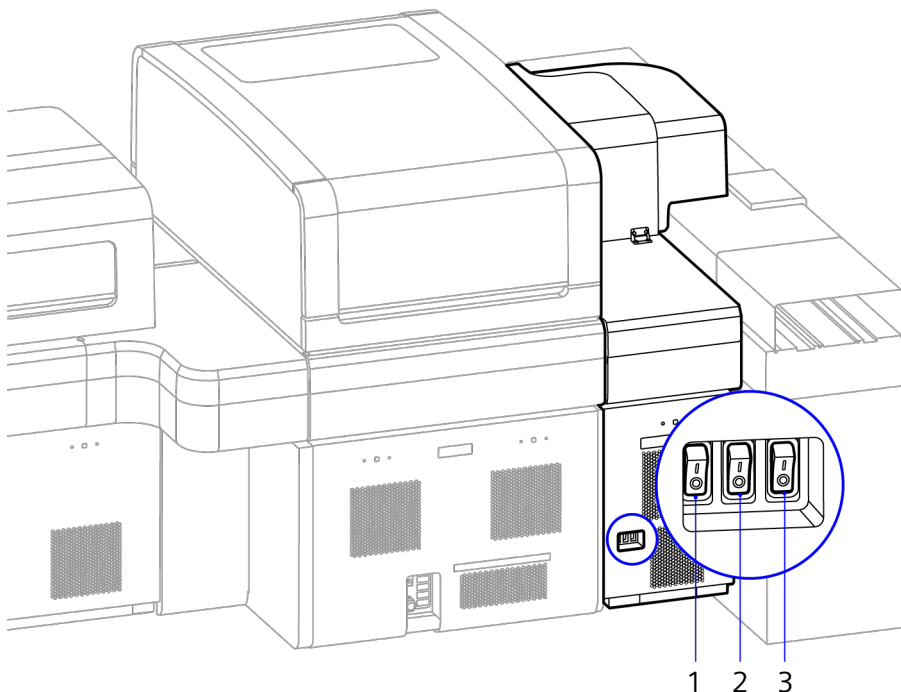


-
1	+24VDC power switch
2	+48VDC power switch
3	Computer power switch
-

2. Start the SH and wait 30–60 seconds (Page 485 *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 486 *Shutting Down and Powering Off the SH Modules*).
 - b. Power on the SH (Page 485 *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.

Starting the Analyzer with DL

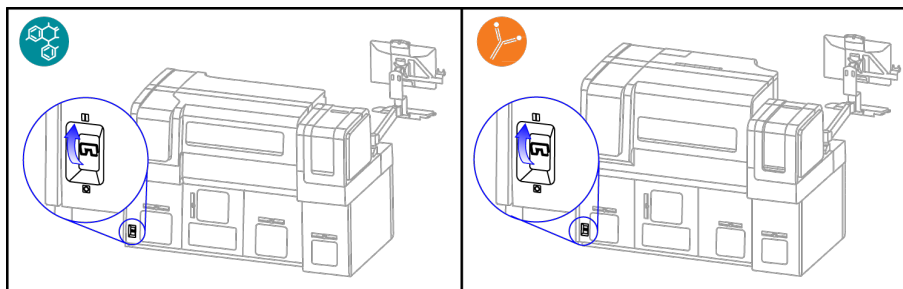


BIOHAZARD

Do not handle biohazardous materials without wearing personal protective equipment and observing universal precautions. Improperly handling 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 476 *Signing in to the System*).
4. If the analyzer does not start or any problems occur, contact the local technical support provider.

Shutting Down and Powering Off the Analyzer with DL

If the analyzer is powered off for over 2 hours, remove and refrigerate the reagents from the reagent compartment.

1. On the Command bar, select **System > Status**.
2. Select the analyzer icon.
3. To power down the analyzer, select .
 - If no tests processing, select **Yes**.
 - If tests processing, select the appropriate shutdown option.

NOTE: The system deletes pending calibration orders when the analyzer shuts down.
4. To power down the DL:
 - a. Select .
 - b. Select .
5. To shut down the analyzer with DL:
 - On the Status bar, select .
 - Select **Sign Out > Yes**.
 - Select **Shutdown > Yes**.
6. Wait for the monitor to turn black then 30 seconds before restarting the analyzer (Page 501 *Starting the Analyzer with DL*).

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 an Analyzer with DL 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.



ELECTRICAL HAZARD

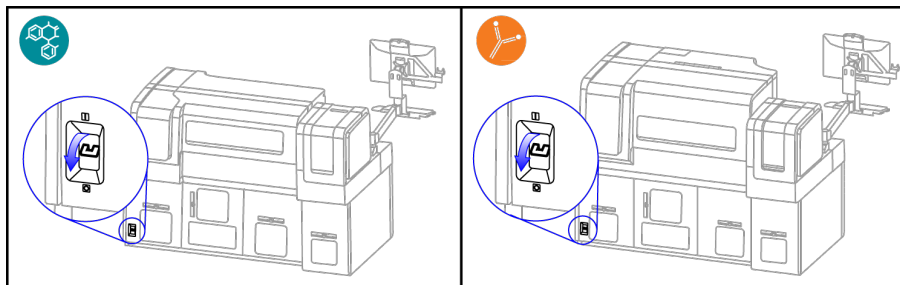
Do not operate modules without a protective grounding connection that prevents electrical shock. Electrical shock can cause equipment damage and bodily harm. Use caution when working around these locations or contact a local technical support provider for more information about using a protective grounding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



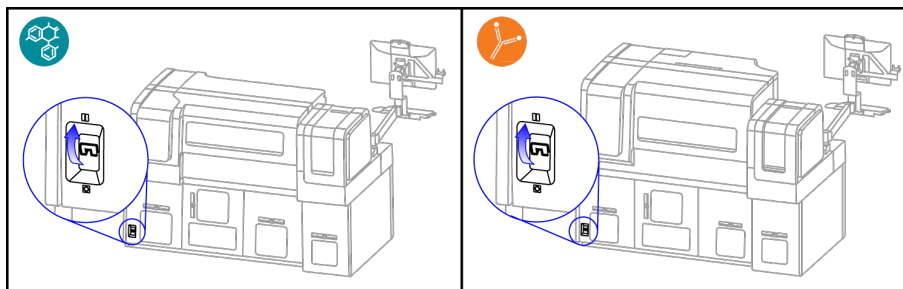
ELECTRICAL HAZARD

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. Turn off power switch.



- When power restores, turn on the power switch.



- Start the analyzer (Page 501 *Starting the Analyzer with DL*).
- If the analyzer power is off:
 - For > 30 minutes on IM Analyzer, unload, manually mix, and reload all onboard reagents (Page 209 *Manually Mixing IM Reagents*).
 - For > 2 hours, discard any reagents left in the reagent compartment.

Unlocking Analyzer Covers Manually

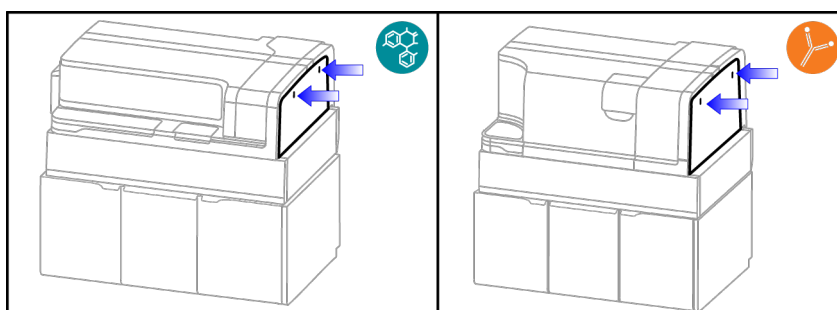


BIOHAZARD

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

Only perform this task during a power disruption.

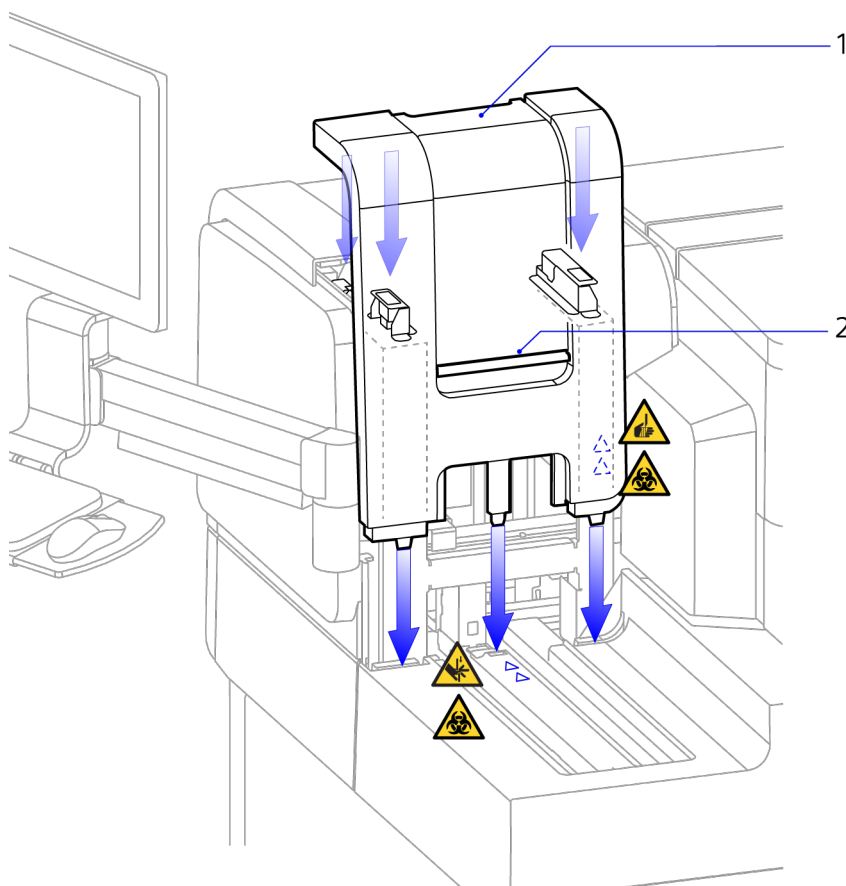
- Locate the appropriate lock access opening of the right side of the analyzer.



- Insert the tip of a flat-blade screwdriver into the appropriate opening.
- Press down to unlock the cover.
- Open the appropriate cover front cover.

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
-

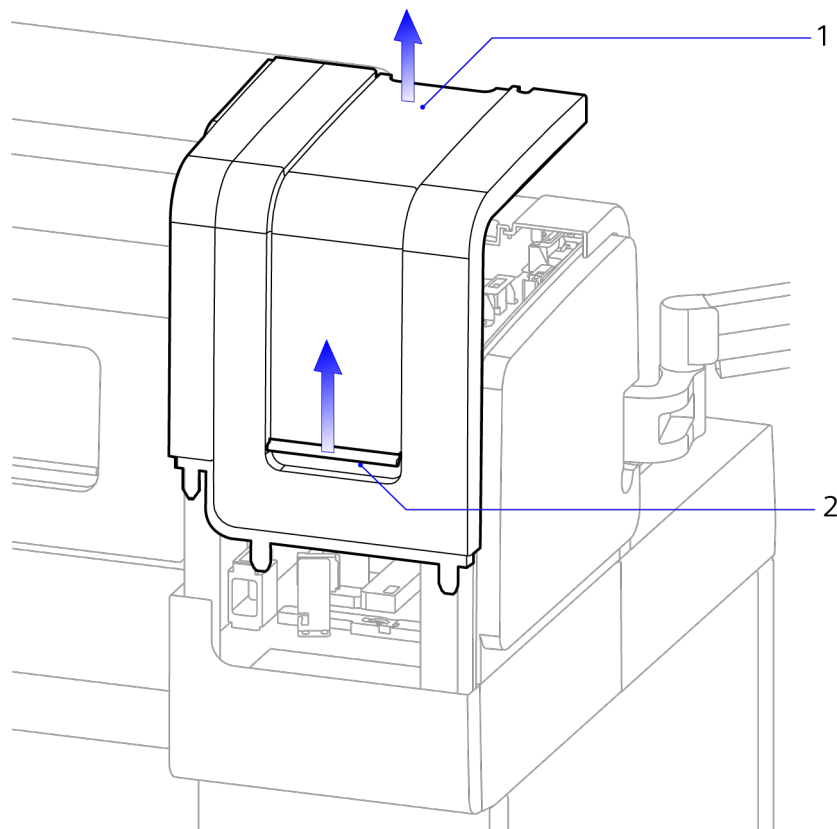
2. Slide the cover downward until it is recessed into the receptacles.
3. Press down on the top of the cover to ensure posts snap into the receptacles.

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 Front Cover glyph is no longer yellow.

Removing the DL Back Cover

1. Pause and unlock the DL back cover (Page 96 *Locking and Unlocking DL Covers*).

2. Place a hand under the DL back cover handle.



-
1	Top of back cover
2	Back cover handle
-

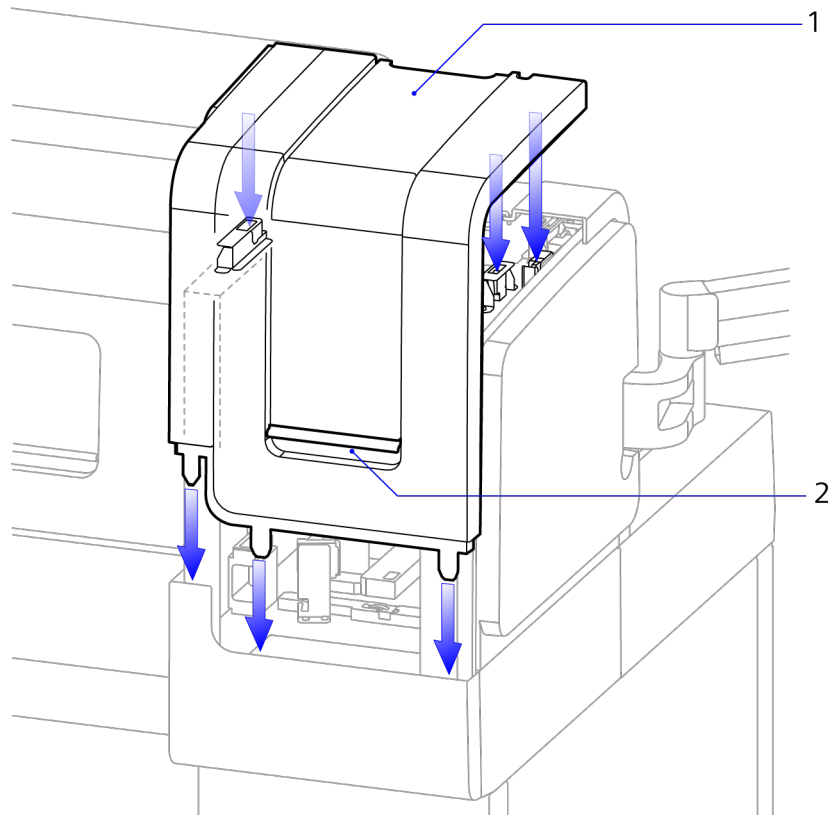
3. Place the other hand on the top of the cover for guidance.
4. Push the cover up and away from system.

NOTE: When the cover is no longer securely seated, the Back Cover glyph 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 Back Cover glyph is no longer yellow.

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.

Restarting the PCC

1. Ensure none of the following tasks are inprocess to prevent data loss:
 - Tests are processing: choose 1 of the following:
 - Select **Worklist > Worklist Overview** and select **All** filters
 - Select **System > Status** and check analyzer states for processing.
 - Database optimization processing.
 - LIS transmitting results: select **Worklist > Worklist Overview** and ensure  is attached to all test results.
 - Maintenance activities including database backup, archiving and deletion, and move to historical: select in **Maintenance > Schedule** and search for the appropriate activity.
 - Exporting: located in several areas.
 - Printing to a printer or file.
 - System states such as Processing and Diagnostics: select **System > Status**.
 - IM Analyzer: Any control-bracketed test results pending release with a closing bracket (Waiting For Bracket: select **Worklist > Worklist Overview**).
2. On the Status bar, select .
3. Select **Sign Out > Yes > Restart**.
4. Read the caution message: To prevent loss of data, ensure sample processing and maintenance activities are complete before attempting a Restart.

5. Select 1 of the following:
 - Restart the PCC Workstation and the SH or DL only
 - Restart the PCC Workstation and All Modules
6. Ensure the system is not processing tests, then select **Restart**.

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 476 *Signing in to the System*).

About Software Documentation and Installation

With each Atellica Solution software version release, the customer receives:

- Software application and installation instructions
- Software Release Notes
- Online help package
- Operator's Guide pdf file

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.com/elifu**.
2. In the top-right corner, select **Login/Register > Login**.

NOTE: If this is the first time entering the site, register (Page 25 *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. In Products, select **Atellica Solution > Atellica Platform**.
5. In Document types, select **Instrument and Software Information > Release Notes**.
6. Select appropriate software version.
7. Select **Download** to print or save the release notes (RN).

- 8. To understand any known issues, software enhancements, or bug fixes, read the RN.

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 and desktop-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 :

Remote assistance workflow	Notes
Create a Service Support Request	The operator generates a support ticket (Page 513 <i>Submitting a Phone Call Back Service Request</i>). The local technical support provider calls by phone or text chat the operator within a pre-configured minimum time directly on the display. The operator also has the option for the provider to call at a later time beyond the pre-configured minimum time in half-hour increments up to 6 hours later.
Start a Remote Session	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 516 <i>Starting a Remote Session with No Service Support Ticket Creation</i>).

Remote assistance workflow	Notes
See All Service Support Requests Created on the System	The operator searches through existing tickets to view the status on reported issues (Page 517 <i>Viewing Service Support Tickets Opened through Remote Assistance</i>). 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.
Service Support Request	Notes
 Enabled Technical Support	Indicates that Remote Service is enabled, connected, and pushing data for remote diagnostics monitoring. The operator can initiate a remote session or submit a ticket for assistance.
 Connected Technical Support	Indicates that there is a remote session active with remote support. In addition, the system transfers data to remote service for condition-based maintenance alerts.
 Minimized Technical Support	Indicates the system is creating a Service Support Request and the Remote Services window is minimized. The operator can select the icon to reopen the window.
 No Ticket Technical Support	Indicates that the system can communicate with Remote Services but the operator must call technical support to log a ticket.
 Technical Support Warning	Indicates the system cannot communicate with Remote Services. The operator should check network connections, LCM server status, and LCM server proxy to the internet to troubleshoot.
Next	Moves to the next step.
Refresh List	Updates the ticket list for the selected module or system.

Service Support Request	Notes
Back	Returns to the previous step.
Phone	Initiates a call back.
Remote Session with Chat	Initiates a remote control with chat session.
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.
File 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.
Launch Camera	Takes photos or records a video to attach to a service support ticket. Available only on the operator tablet.
Screen Capture	Adds screen captures to the service support ticket to capture the screen displayed behind the Service Support Request window.
Add File	Adds files to the service support ticket.
End Remote Session	Ends a remote service session immediately. To initiate a remote session, a new passcode is required (Page 516 <i>Starting a Remote Session with No Service Support Ticket Creation</i>).
	Minimizes the support request window. To reopen the window, select  .
Cancel	Cancels the workflow process.
TeamViewer	Notes
	Initiates video from the operator to the support provider.

TeamViewer	Notes
	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.
	Opens more details for each feature.
	Terminates remote service session. To initiate a remote session, a new passcode is required (Page 516 <i>Starting a Remote Session with No Service Support Ticket Creation</i>).

Submitting a Phone Call Back Service Request

1. On the Status bar, select .
2. Select **Create a Service Support Request > Next**.
3. Select the appropriate module or system.
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.
4. Select **Next**.
5. To view, filter, or refresh open service support tickets for this module or system, see (Page 517 *Viewing Service Support Tickets Opened through Remote Assistance*).
6. Select **Next**.

7. Choose 1 Service Type:
 - 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 Type: 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.
8. Select **Next**.
9. Select **Phone**.

NOTE: Mandatory fields start with a purple stripe.
10. Select **ASAP** or if a specific time is required for support to call back, select that time from the Time drop-down menu.

NOTE: If the operator selects ASAP, a message displays to indicate call back time per their service level agreement and is configured at system installation.
11. Enter operator's First Name, Last Name, and Phone Number.
12. Select **Next**.
13. Enter a Short Description and Problem Description.
14. If the service support ticket is initiated from an operator tablet, select **Launch Camera** to attach photos or a video.
15. To attach an appropriate file to the ticket, select **Add File**, search and select file, and 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.
16. Select **Next**.
17. Wait for confirmation that the request was completed.
18. To minimize Service Support Request window, select .
19. Wait for the local technical support provider to call within the contract time or preference.
20. To disconnect from the remote session at any time, select **End Remote Session > Yes > OK**.
21. To close Service Support Request window, select .

Submitting a Chat Session Service Request

1. On the Status bar, select .
2. Select **Create a Service Support Request > Next**.
3. Select the appropriate module or system.
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.
4. Select **Next**.
5. To view, filter, or refresh open service support tickets for this module or system, see (Page 517 *Viewing Service Support Tickets Opened through Remote Assistance*).
6. Select **Next**.
7. Choose 1 Service Type:
 - 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 Type: 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.
8. To use desktop sharing and chat, select **Remote Session with Chat**.
NOTE: Mandatory fields start with a purple stripe.
9. Select **ASAP** or if a specific time is required for support to call back, select that time from the Time drop-down menu.
NOTE: If the operator selects ASAP, a message displays to indicate call back time per their service level agreement and is configured at system installation.
10. Enter operator's First Name, Last Name, and Phone Number.
11. Select **Next**.
12. Enter a Short Description and Problem Description.
13. If the service support ticket is initiated from an operator tablet, select **Launch Camera** to attach photos or a video.
14. To include a screen capture, select **Screen Capture**.
15. To attach a file to the ticket, select **Add File**, search and select file, and 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.

16. Select **Next**.
 17. Wait for Ticket ID with the pre-configured minimum wait time and local technical support provider's name to display.
 18. Wait for the local technical support provider to begin a chat 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,  displays.
19. In TeamViewer, select .
 20. Enter text in chat section and select **Send**.
 21. To minimize Service Support Request window, select .
 22. To disconnect from the remote session at any time, select **End Remote Session > Yes > OK**.
 23. To close Service Support Request window, select .

Starting 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.

1. On the Status bar, select .
2. Select **Start a Remote Session > Next**.
3. 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.
4. Give the 4-digit Passcode to the provider on the phone.
5. 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,  and the TeamViewer window displays.

6. To minimize Service Support Request window, select .
7. To disconnect from the remote session at any time, select **End Remote Session > Yes > OK**.
8. To close Service Support Request window, select .

Viewing Service Support Tickets Opened through Remote Assistance

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 Status bar, select .
2. Select **See All Service Support Requests Created on the System > Next**.
3. Select the appropriate module or system.
NOTE: The operator can select only 1 module or system with each request.
4. Select **Next**.
NOTE: Only open service support tickets the operator opens via the on-system Service Support Request feature display here for this module or system. A message displays if no open service support tickets exist. Existing service support tickets are read-only and display:
 - For reference only.
 - By module or system name and ticket number.
 - Most current ticket first.
5. To filter the list, select **Filter**:
 - To filter by Status, select **Open**.
 - To filter by Reported by, select an operator from the drop-down menu.
 - To filter by Service Type, select 1 from the drop-down menu.
 - To filter by Module, select a module.
 - To filter by date range, select **Creation Date Range**, select the From and To dates from each , and select **OK**.
6. To refresh the list to show any new tickets, select **Refresh**.

7. To close, select  .

Contacting Local Technical Support

1. To connect to a live service support request, select  (Page 510 *About Remote Assistance*).
2. To contact support via the phone, locate the local technical support contact information on the system.

17 Setup: Test Definition

Use **Setup > Test Definition** to customize sample options, test parameters, and system options for the laboratory.

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 Test Definition

The Test Definition tab 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.
Ratios, Panels, and Off-System	Enables the viewing, defining, and editing of the following: • Ratio tests • Dilution panels • Test panels • Off-system tests
Test Display Order	Enables the customization of the order in which the tests display on the system.

Feature	Notes
Open Channel	Enables the configuration of operator-defined assays for the CH Analyzer.
Sort Test Definition	Enables laboratories to add and delete sort codes. The system uses these codes to sort samples in SH rack rows according to processing requirements.

About Assay List

Laboratories use Assay List to enable or disable assays on the system or place assays in Troubleshooting mode. Assay List also enables laboratories that have more than 1 CH Analyzer or more than 1 IM Analyzer to designate the assays and Specimen Types that will process on each analyzer within the system.

Assay List is divided into an IM and a CH tab. Each tab consists of the Filters and Enable Assays and Specimen Type Usage panel. The Filters panel limits the number of assays that display in the Enable Assays and Specimen Type Usage panel, and the Enable Assays and Specimen Type Usage provides options for configuring assay processing on the system and each analyzer in the system.

The Enable Assays and Specimen Type Usage displays all assays with test definitions on the system that meet the filtering criteria. The following criteria are available:

Criteria	Notes
System Enabled Only	All assays that are only Enabled on the System. NOTE: For systems that contain more than 1 IM Analyzer or more than 1 CH Analyzer, laboratories can enable an assay on the system, but disable it on all but 1 analyzer.
Assay	A single assay. NOTE: The operators access the assay with a drop-down menu. Each assay is listed with a parenthetical element that contains the reagent code.
Enabled	All assays that are Enabled on 1 or more analyzers.

Criteria	Notes
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 Filters panel, then 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.

The Enable Assays and Specimen Type Usage panel 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 Specimen Type table for changing the status of each type of specimen that the assay supports. The Specimen Type table lists each type of specimen that the assay supports and its current status on each analyzer in the system. Each analyzer has a separate Specimen Type drop-down menu. The operator opens the appropriate drop-down menu to change the status.

Column	Notes
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 mode, then the  glyph 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.

* If the system contains more than 1 IM Analyzer or more than 1 CH Analyzer, then the Enable Assays and Specimen Type Usage panel includes a separate column for each 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 Glyphs

The following glyphs alert the operator to a required action or more information:

Glyph	Notes
	Closes or removes the window
	Indicates a filter is available to limit the number of assays that display
	Clears an applied filter
	Indicates that online help is available for the window.
	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
	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

Glyph	Notes
	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 on the following tabs:

- Definition
- Calculation (Page 527 *About the Calculation Parameters in CH Test Definition*)
- Calibration

During configuration of the assay test definitions, laboratories can take the following actions:

Action	Notes
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.
Save	Updates parameters to the laboratory-specified values.
Cancel	Reverts any unsaved changes to the parameters to their last saved values.

CH Test Definition also provides access to the following features:

Feature	Notes
Ranges...	Enables configuration of the available range checks for the selected assay (Page 534 <i>About Range Types</i>).

Feature	Notes
Reflex Groups...	Enables the automatic ordering of different tests or panels in response to patient results (Page 562 <i>About Reflex Groups Setup</i>).
Repeat Conditions...	Enables the automatic repeat ordering of patient tests in response to system flags.

CH Test Definition Glyphs

The following glyphs alert operators to a required action or more information:

Glyph	Notes
	Indicates a column is sorted in alphabetical order, from A–Z.
	Indicates a column is sorted in reverse alphabetical order, from Z–A.
	Closes or removes the selection or feature.
	Indicates that the CH Test Definition filter is clear.
	Indicates a sortable column.
	Indicates more information is available.
	Indicates an error condition.
	Indicates a warning condition.
	Indicates that online help is available for the window.
	Indicates that a feature is not using or applying the setting.

Glyph	Notes
	Indicates that the setting is enabled for a feature.
	Indicates that the field cannot be blank.
	Indicates that a setting is unavailable to the operator or for the feature.
	Indicates that a setting is always enabled.
	Indicates that an option is not selected.
	Indicates that an option is selected.

About Assay Identification in CH Test Definition

The Assay Identification area in the Definition tab 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.
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 are present on the system.

NOTE: The Display Name and the Print Name are mandatory fields.

About the Advanced Definition Settings in CH Test Definition

The Advanced area on the Definition tab of CH Test Definition enables configuration of the following features:

Field	Notes
Troubleshooting	Provides options for diagnosing issues with CH assay performance.
Measuring Intervals	Enables or disables the automatic repeat of patient tests for results that fall outside the assay measuring interval for the assay.

About the Calculation Parameters in CH Test Definition

The Calculation tab in CH Test Definition provides information about the parameters that the system uses to calculate and report test results for the selected assay.

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. • Fixed Digits After Decimal or Significant Figures: The Fixed Digits After Decimal is the number of decimal places in the test results, and the Significant Figures is the number of digits in the result that signify accuracy. NOTE: The system uses Significant Figures to report results for CL, K, and NA assays and Fixed Digits After Decimal for all other CH assays.

Area	Notes
HIL Alert Indices	Enables the automatic flagging of patient results for tests that meet or exceed the configured Threshold level for HIL interference. NOTE: Laboratories must also select the According to TDef option for the global HIL Ordering setting in General Setup to fully enable HIL alert processing. 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 determine the relationship between the results on 2 different systems.

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 295 *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 the Reagent Tab in IM Test Definition

The Reagent tab 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 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 calibration code fields include the following information:

Field	Notes
Cal Code	The unique 3-digit label the associated Calibration Material definition uses to identify this test.
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.

Field	Notes
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

The Lots... button on IM Test Definition 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	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 120 <i>About IM Assay Result Calculation Formulas</i>) • 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. • 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. • Expiration: The date on which the reagent lot expires. • 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.

Field	Notes
Result Range	The reportable measuring interval when using an Index Calculation and a Concentration Calculation.

About Ranges in CH Test Definition and IM Test Definition

This feature requires the appropriate security level.

The Ranges button in CH Test Definition and IM Test Definition provides access to the available range configuration tabs for each assay (Page 534 *About Range Types*). 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 Reflex Groups Setup.

By default, Ranges opens to the Reference Range for every assay (Page 539 *About Reference Ranges*). In addition, each assay can have 1 or more of the following types of Ranges:

- Delta Check (Page 543 *About Delta Check Ranges*)
- Check (Page 545 *About Check Ranges*)
- Concentration (Page 548 *About Concentration Ranges*)
- Index (Page 550 *About Index Ranges*)
- Dilution Point (Page 553 *About Dilution Point Ranges*)
- Linearity (Page 556 *About Linearity Ranges*)
- Interpretation (Page 558 *About Interpretation Ranges*)

The types of Ranges that are available depend on the assay. The following range types are only available for IM assays:

- Index (Page 550 *About Index Ranges*)
- Dilution Point (Page 553 *About Dilution Point Ranges*)
- Linearity (Page 556 *About Linearity Ranges*)

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.

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 spaces but cannot start or end with one. 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 536 <i>About Configuration Options in Ranges</i>). NOTE: The system disables fields that are not available for the range.
Demographics Information	The available demographic options for the range.

Operators 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.

Action	Notes
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.
Print...	Generates a printed report that contains all saved Ranges for the assay.
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.
Clear	Reverts any unsaved changes in the settings to the last saved values. NOTE: The system warns the operator of any unsaved changes before clearing the settings.
Close	Cancels any unsaved changes and closes the window. NOTE: The system warns the operator of any unsaved changes before clearing the settings.

About Range Types

This feature requires the appropriate security level.

The system supports 1 or more of the following types of Ranges for each assay:

Range	Notes
Reference	Enables configuration of alerts and system actions for patient results that fall in laboratory-defined intervals for a population (Page 539 <i>About Reference Ranges</i>).
Delta Check	Enables configuration of alerts and system actions that depend on the amount of change in patient test results over time (Page 543 <i>About Delta Check Ranges</i>).
Check	Provides the laboratory with greater flexibility to configure result checking and provide alerts and additional system actions on 1 or more intervals of result values (Page 545 <i>About Check Ranges</i>).
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 548 <i>About Concentration Ranges</i>).
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 550 <i>About Index Ranges</i>). NOTE: Index Ranges are only available for IM assays that report results as Index values.

Range	Notes
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 553 <i>About Dilution Point Ranges</i>). 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 556 <i>About Linearity Ranges</i>). NOTE: Linearity Ranges are only available for IM assays.
Interpretation	Enables configuration of an alert and reflex testing for a specified result Interpretation (Page 558 <i>About Interpretation Ranges</i>). Also enables laboratories to define interpretations for result ranges and configure a result review and reflex testing.

About Configuration Options in Ranges

This feature requires the appropriate security level.

The Details area 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.
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 563 <i>About the Repeat Option in Ranges</i>).
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.

Field	Notes
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.
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 540 *About Configuration Options in Reference Range Details*)
- Delta Check (Page 544 *About Configuration Options in Delta Check Ranges*)
- Check (Page 546 *About the Configuration Options in Check Ranges*)
- Concentration (Page 549 *About the Configuration Options in Concentration Ranges*)
- Index (Page 551 *About Configuration Options in Index Ranges*)

- Dilution Point (Page 554 *About the Configuration Options in Dilution Point Ranges*)
- Linearity (Page 557 *About the Configuration Options in Linearity Ranges*)
- Interpretation (Page 559 *About Configuration Options in Operator-Defined Interpretation Ranges*) (Page 560 *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 General Setup, 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 536 *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 542 <i>About the Result Flags for Reference Ranges</i>). NOTE: The system does not flag results in the Normal interval.

Option	Notes
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.
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.

Option	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 in 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 General Setup 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 in the General Setup area, 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 536 *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.

Option	Exceeded	Within
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 can only perform 1 replicate of CH tests.	Not available.
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 547 *About the Result Flags for Check Ranges*). Depending on the assay and laboratory practice, the laboratory can configure 1, 2, or all intervals (Page 546 *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:

- A name
- A 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 547 <i>About the Result Flags for Check Ranges</i>). • 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.

Field	Notes
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.
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 550 *About Index Ranges*). The system automatically displays the correct range type for the assay.

NOTE: Some IM assays report results with both 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. These Limits form the measuring interval for the assay and are based on thorough testing by the manufacturer 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 547 *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 549 *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 536 *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.

Field	Notes
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 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 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 548 *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 549 *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 536 *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 • In 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.

Field	Notes
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 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 In 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 536 *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.

NOTE: Dilution Point Ranges are not currently available for CH assays.

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 548 *About Concentration Ranges*) or Index Range (Page 550 *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 Within 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 Below Range and Above Range intervals in Linearity Ranges have the following configuration options* (Page 536 *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.

Field	Notes
Reflex	Configurable in intervals with defined Limits. 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 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 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 560 *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 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.

Field	Notes
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 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 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.

Field	Notes
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 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 a Sort Test which improves efficiency by allowing 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 Groups Setup specifies. 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 Reflex Groups Setup

This feature requires the appropriate security level.

Reflex Groups Setup defines up to 3 reflex tests for assays based on a set of operator-defined conditions. Reflex tests display in Worklist.

NOTE: Contact local technical support provider to change the default settings.

Reflex Groups 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 open channel tests are not available options.
Check Reaction Logic	Operator-defined conditions or rules using a cut-off value. Available when the operator chooses a test name. Includes Below or equal to or Above or equal to. Default is Below or equal to.

Reflex Groups Setup	Notes
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 open channel 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 Groups Setup is located within Setup Test Definition.

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
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.

Dilution	Notes
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 continue to perform Repeat tests until reaching 1 of the following conditions: • The result is within range. • No additional Dilution factors remain for the assay. • The maximum number of Auto Dilution steps in General Setup. NOTE: If the laboratory does not specify a maximum number of Auto Dilution steps in General Setup, 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 Test Display Order

The operator customizes the order that tests display in Test Display Order located in Setup Test Definition. This test order displays in:

- All Create Patient Orders sections
- QC order entry
- Worklist Overview
- 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
Find	Locates a test.
Number of Selections	Displays the number of tests currently selected in the list in a read-only field.
Move Selected Tests to Position	Re-orders the position of 1 or more selected tests. Valid values are 1–9999. Specifying a value greater than the number of tests in the list moves the selected test to the end of the list.
Position	Displays the position of the test.
Test	Defines the tests in the system. By default, tests display alphabetically.
Move Selection	Moves selected tests to a new test display order.
Clear Selection	Clears the test selection boxes.
Refresh	Refreshes the test display order to include the removal of tests disabled on the system and adds recently imported tests to the list.
Save	Saves changes made to test display order.
Clear	Reverts to the last saved Test Display Order in the database.

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 Groups 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.

When processing is complete, the system routes the sample to the SH output rack location the operator configured in Test Sort Groups.

18 Setup: Settings

Use **Setup > Settings** to customize system configuration options for the laboratory.

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 General Setup

This feature requires the appropriate security level.

Laboratories use General Setup to configure system settings according to laboratory preferences and protocol. The system globally applies these settings.

The system groups the settings on the following tabs:

Tab	Notes
Regional	Enables configuration of the display language and the format for the date and time.

Tab	Notes
Connectivity	Enables configuration of the following features: • Virtual keyboard • Mouse & Printer Configuration • USB Option • Operator Tablets • Informatics Connection • Prefix for export and copy configuration files • Network Share Access
Patient	Enables configuration of the following features: • Patients Results Review Mode • Patient QC Flagging • Test Order • STAT Sample Settings • HIL Ordering • Multiple Reference Intervals or Delta Check • Delta Check Previous Result • Order Alert Settings
QC	Enables configuration of the following features: • QC Results Review Mode Settings • RiliBÄK Feature • Send Results to QC Statistics
Accounts	Enables the creation of a password for the Alternate System Display.

Tab	Notes
Maintenance	Enables configuration of an off-peak time period for performing automated Maintenance activities.
Security Settings	Enables the display of Banner Text (Page 572 <i>About Banner Text in General Setup</i>).

The configuration screens in General Setup indicate the current setting for each feature.

NOTE: The manufacturer provides the system with a default setting for every feature in General Setup.

When customizing the settings for the laboratory, the operator can Save or Clear the change. These functions have the following effects:

- Save updates the setting to the new values.
- Clear returns the setting to the last saved values.

After configuring the General Setup, laboratories can copy the settings as part of the Export configuration settings file and export it for use on another system.

System Configuration

SH Configuration or DL Configuration

About IM Standard Configuration

The IM Standard Configuration tab in Settings enables laboratories to configure features for the IM Analyzer.

Feature	Notes
Test Scheduling	Sets the order that the analyzer processes tests on a given patient sample.
Sample Scheduling	Sets the order that the analyzer processes samples.
Fluid Percentage Volume Threshold	Sets the level of fluid in an IM system fluid container at which the system provides a warning level alert to the operator.

Feature	Notes
Reagent Pack EOL Warning Threshold	Sets the end-of-life (EOL) conditions for IM reagent packs. The system posts an alert when a reagent pack meets 1 or more of these laboratory-specified conditions.
Control Bracket: Reagent Reserve	Sets the number of control sets that the analyzer reserves for processing end-of-bracket controls of inprocess control-bracketed tests.
Repeat Sample Aspiration	Sets the conditions that automatically trigger repeat sample aspirations.
Other Options	Enables and disables the automatic unloading of IM reagent packs.

About Banner Text in General Setup

The Banner Text area on the Security Settings tab in General Setup allows laboratories to display or hide customized information that is visible on the splash screen while the software launches. Although only local technical support providers can create and edit the Banner Text, laboratories can display or hide it.

19 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 the Accounts Tab in Setup

This feature requires the appropriate security level.

Laboratories use the Accounts tab in Setup to manage the operator accounts and control access to system features. The Accounts tab includes the following subtabs:

Subtab	Notes
Groups	Provides a hierarchical structure of operator Groups. Each group can have a different level of access to system features (Page 575 <i>About Groups on the Accounts Tab</i>).
Accounts	Enables the creation of operator accounts and the assignment of operator accounts to a group (Page 576 <i>About Accounts on the Accounts Tab</i>).

Subtab	Notes
Settings	Manages the access level of each group to securable features.

Accounts Glyphs

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

Glyph	Notes
	Sorts a column in the descending direction.
	Sorts a column in the ascending direction.
	Closes or removes the selection or feature.
	Indicates that the operator has changed a setting, and it requires saving or clearing.
	Indicates a sortable column.
	Indicates more information is available.
	Indicates that online help is available for the window.
	Accesses folders containing archives, back-ups, and exports, and manages data transfer to USB.
	Signs in or signs out an operator.
	Indicates that the setting is enabled for a feature.
	Indicates that a feature is not using or applying the setting.
	Indicates that an entry is required.
	Indicates that a setting is unavailable to the operator or for the feature.

Glyph	Notes
	Indicates that a setting is always enabled.
	Indicates that an option is selected.
	Indicates that an option is not selected.

About Groups on the Accounts Tab

This feature requires the appropriate security level.

Laboratories use Groups to view the hierarchical structure of the system groups and to customize the names for their own use.

NOTE: The Groups feature enables the laboratory to manage the access level of operators. Each group can have a different level of access to system features.

The following operator Groups are available on the system:

Group ID	Default Group Name
G1	Lab Manager
G2	Customer Service Engineer
G3	Chief Technician
G4	Day Time Operator
G5	Night Time Operator

Every operator in a group has the same security privileges and access rights to the system.

The G1 Group has the greatest access to the system. Operators in this group determine the privileges and access rights of the other Groups. Operators in this group also assign each operator to the appropriate Group according to the access that the operator requires and laboratory protocol.

NOTE: 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. The G1 Group cannot assign operators to the G2 Group.

Operators in the G1 Group also have the following administrative rights:

- Setting the required password length and the number of failed sign in attempts before locking the account
- Setting the number of days that passwords remain valid on the system
- Clearing passwords
- Creating accounts
- Deleting accounts

Laboratories cannot create or delete a Group, but they can rename the Groups as appropriate.

About Accounts on the Accounts Tab

This feature requires the appropriate security level.

Laboratories use Accounts for the following activities:

- Create new operator Accounts
- Edit and view existing Accounts
- Delete Accounts
- Disable Accounts
- Clear account passwords
- Change account passwords
- Change the security questions of an account

NOTE: Every operator of the system requires an account with a unique Operator ID.

The Accounts summary table lists all accounts on the system along with the following information:

Column	Notes
Operator ID	The name the operator uses to sign in to the system. NOTE: Accounts displays a list of every account on the system. The Operator ID column is sortable in ascending or descending order.
Full Name	The Full Name of the person associated with the Operator ID.

Column	Notes
Group	The Group (G1 and G3–G5) that the operator belongs to. The operator has all the privileges assigned to the Group (Page 575 <i>About Groups on the Accounts Tab</i>).
Status	The current Status, Enabled or Disabled, of the account. Operators of Disabled Accounts cannot sign in to the system.

The system supports the following number of Accounts for each Group:

Group	Number of Accounts
G1: Lab Manager	25
G3: Chief Technician	100
G4: Day Time Operator	100
G5: Night Time Operator	100

NOTE: The laboratory should create more than 1 member of the G1 Group to ensure that a member of this group is always available for password resets and other G1 security functions.

20 About the Atellica Asa Application

The Atellica Asa™ Application is a tablet-based 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 supplies
- Troubleshooting using Atellica Solution Remote Assistance, Diagnostics, and Online Help

The application operates on a tablet that connects to the system using a Wi-Fi or wired Ethernet connection. 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.

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).

Signing in to the Atellica Asa Application

1. Connect the tablet to a Wi-Fi network.
2. On the tablet desktop or start menu, select the Atellica Asa Application icon.
3. To connect to an Atellica Solution without its IP address, enable **Automatic Discovery** and select the appropriate Atellica Solution from the System list.

NOTE: To use the Automatic Discovery feature, the tablet and the PCC must be on the same network.

NOTE: If the system does not display the appropriate Atellica Solution, select  then select the **System** list.

4. To connect to an Atellica Solution using its IP address, disable **Automatic Discovery** and enter the IP address and Port number for the appropriate Atellica Solution.
5. Enter the Operator ID and Password.

NOTE: The Operator ID and Password are authenticated based on the configured accounts on the connected Atellica Solution system.
6. 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.

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 interface to select a feature to display.

The tile-based interface 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 performing
- 3 No issues

Dashboard	Notes
System Status Map	Displays the status of each module for the connected system, accesses the active alerts that stop a module, and inprocess maintenance activities.
Troubleshooting	Accesses: • Online Help • Diagnostics • Service Support Request
STAT Samples	Displays summary information about STAT samples on the system. The top half of the tile displays: • One of two colors – Green: no STAT samples require intervention or all samples that require intervention are ignored – Red: at least 1 STAT sample requires intervention • The count of STAT samples that require intervention The bottom half of the tile displays the number of: • STAT samples in progress • STAT samples that require intervention

Dashboard	Notes
Routine Samples	Displays summary information about routine samples on the system. The top half of the tile displays green and the count of all samples that require intervention. The bottom half of the tile displays the number of: • Calibration samples that require intervention • QC Needs samples that require intervention • Routine patient samples that require intervention
Maintenance	Displays summary information about the maintenance activities for the operator-defined day. The top half of the tile displays: • One of two colors – Green: No automated maintenance activities are performing – Yellow: At least 1 automated maintenance activity is performing • The count of maintenance activities that are due, including failed and overdue. The bottom half of the tile displays: • The next scheduled automatic activity • The next manual activity the operator performs

Dashboard	Notes
Supply Needs	Displays summary information about the supply needs for the operator-defined day. The top half of the tile displays: • One of two colors – Green: No supply is below threshold – Red: Any supply is below threshold • The count of required supplies
Reagent Needs	Displays summary information about the reagent needs for the operator-defined day. The top half of the tile displays: • One of two colors – Green: No reagents are below threshold – Red: At least 1 reagent is below threshold or a pending order exists for an assay that has no reagent onboard • The count of required reagents

Dashboard	Notes
Calibrator Needs	Displays summary information about the calibrator requirements for the operator-defined day. The top half of the tile displays: • One of two colors – Green: No analyzer has an immediate need for a calibrator material – Red: Any analyzer that falls within the configured calibration needs. • The count of required calibrator materials
QC Needs	Displays summary information about the QC needs for the operator-defined day. The top half of the tile displays: • One of two colors – Green: No analyzer has an immediate need for a QC material – Red: Any analyzer requires QC material for an ordered quality control that is not onboard, expired, or QNS • The count of required QC materials

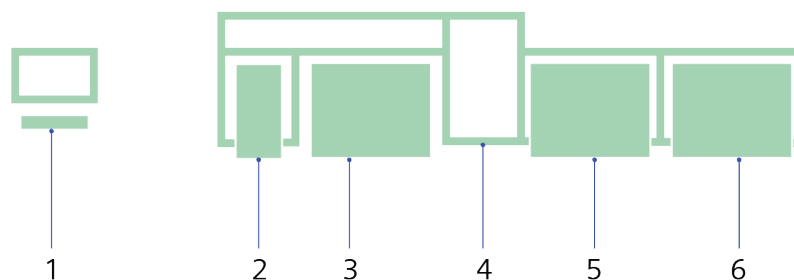
About the Title Bar

The Title bar displays at the top of every Atellica Asa Applications screen and contains system information, system status icons, and operator controls. Some items do not display on the Dashboard.

Title 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: A module is able to process samples. • Red: A module is not able to process samples. • Yellow: A module is in maintenance. NOTE: Does not display on the Dashboard.
	Launches Teamviewer, which allows the service provider to access the tablet remotely.
	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, About, and  (switch applications)

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	4	Atellica Magline Transport
2	Sample Handler Connect	5	CH Analyzer
3	Sample Handler	6	IM Analyzer

The System Status Map displays the status of each module and automatically refreshes when changes occur on the system:

- Green: Module is processing without any issues.
- Yellow: Module in maintenance or diagnostics mode. Selecting a module displays the maintenance activities in process.
- 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.

The System Status Map displays in linear form even when the system is configured as L- or U-shaped.

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 application, event help, troubleshooting, and maintenance. Animations are available for some hardware maintenance tasks. The operator accesses the online help from the menu (≡) on the Title bar.

The menu on the Title bar is accessible from every screen and is context sensitive. Selecting ≡ > **Help** accesses links to help topics specific for that area and the table of contents (TOC) for the entire online help package.

About Information Available on the Atellica Asa Application

The operator can access the About information from the menu () on the Title bar. Software and hardware information for the Atellica Asa Application and the connected system is available when troubleshooting during a service call.

The Software Information tab displays the software and other tools the connected system uses and the corresponding versions. For more information, see 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.

About STAT Samples on the Atellica Asa Application

STAT Samples details the current status for all STAT samples on the system:

- Intervention Needed
- Inprocess

Intervention Needed	Notes
Sample ID	The code that identifies a sample.
Description	The error description if 1 test displays or all assays have the same error. If more than 1 error occurs, Multiple Errors display and the operator can expand the row to view the error for each test.
Assay	The tests that require intervention.
Time On System	The number of minutes since the system read the sample barcode at the TCS.
Location	The last known location of the sample, including the position of the sample in the rack with the rack location and barcode displaying or on the Atellica Magline Transport.

Intervention Needed	Notes
Ignore	The system ignores any errors for the appropriate sample. Selecting Ignore for all rows changes the tile color to green.
Inprocess	Notes
Sample ID	The code that identifies a sample.
Assays	The tests that the operator orders for the sample. When multiple tests display, the operator can expand the row to display the status and time to complete for all tests.
Time to Complete	The amount of time until a test completes.
Time On System	The number of minutes since the system read the sample barcode at the TCS.
Location	The last known location of the sample including the position of the sample in the rack with the rack location and barcode displaying or on the Atellica Magline Transport.

Switching From the Atellica Asa Application to the Operator Tablet Application

NOTE: The Operator Tablet application must be online in order to switch to it. The Atellica Asa Application remains online after switching to the Operator Tablet application and no data is lost.

1. Select .
2. Select .

About Routine Samples on the Atellica Asa Application

Routine Samples details the current status for the following types of samples on the system that require intervention:

- Calibration
- QC
- Patient

Patient	Notes
Sample ID	The code that identifies a sample.
Description	The error description if 1 test displays or all assays have the same error. If more than 1 error occurs, Multiple Errors display, and the operator can expand the row to view the error for each test.
Assays	The tests that require intervention.
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, including the position of the sample in the rack with the rack location and barcode displaying or on the Atellica Magline Transport.
Calibration and QC	Notes
Material Name	The calibrator or QC material product name.
Description	The error description if 1 test displays or all assays have the same error. If more than 1 error occurs, Multiple Errors display, and the operator can expand the row to view the error for each test.
Assays	The tests that require intervention.
Location	The last known location of the sample, including the Cal-QC storage area or on the Atellica Magline Transport.

About Maintenance on the Atellica Asa Application

Maintenance displays the scheduled maintenance activities and their status for Atellica analyzers and modules for the configured time period. These activities include automated and manual procedures.

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 analyzer 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 a red alert and the due date does not update. The analyzer creates a log entry recording the failed status.

The operator cannot delete any maintenance activities from this screen.

For Maintenance glyph definitions, see.

Maintenance schedule	Notes
Module	The drop down list to filter the Maintenance schedule.
Activity	The name of the maintenance activity with a glyph that indicates if it is automated or the operator or local technical support provider performs it.
Scheduled	The date, time, and frequency of the maintenance activity.
Status	The status displays future, Overdue () and Failed () activities.
Perform	An automated maintenance activity performs or the operator performs and documents a manual activity.

Maintenance schedule	Notes
Procedure Details	The Atellica Solution online help procedure for the selected manual or automated 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. The CH Analyzer includes system fluids, Pretreatment pack, and IMT fluids. The IM Analyzer includes system fluids, supplies, and waste.

Supply Needs	Notes
Name	The name of the supply material.
Lot	The lot of the supply material.

Supply Needs	Notes
Status	Status of the remaining volume of supply. CH Status: • OK • On reserve: Container empty • Empty: Reservoir and container empty IM Status: • OK • On reserve: Container empty • Empty: Reservoir and container empty
	To add an item to the cart, the operator selects  in the appropriate row.
All Supplies	Notes
System Fluids	System fluids list by analyzer.
Volume	The remaining volume, in percent, on the analyzer.
Status	Status of the remaining volume of supply. CH Status: • OK • On reserve: Container empty • Empty: Reservoir and container empty IM Status: • OK • On reserve: Container empty • Empty: Reservoir and container empty
Onboard Stability	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.
Lot Expiration	Date and time the supply lot expires.

All Supplies	Notes
Lot	The lot of the supply material.
Sequence Number	The 5-digit supply identification portion of the barcode.
For CH Analyzer  :	
IMT Supplies	IMT fluids on CH Analyzer.
For IM Analyzer  :	
Supplies	IM Analyzer consumables includes Tips, Cuvettes, and Water, if appropriate.
Status	Status of the remaining volume of supply. • OK • On reserve: Container empty, reservoir full • Reserve empty: Reservoir and container empty
Waste	IM Analyzer waste levels includes Cuvette and Tip Waste, WasteTip Tray Waste, and Liquid Waste, if appropriate.
Status	Status of the remaining volume of waste. • OK • Full: Waste container full; displays red.

About Reagent Needs for the Atellica Asa Application

Reagent Needs posts a need for a reagent based on the expected tests for that day compared to the current inventory.

- **Predictive:** Suggested need based on the operator-defined cutoff or system historic assay utilization.
- **Below Threshold:** The reagent inventory level reaches the red alert threshold the operator defines in Reagent Requirements Settings. This includes CH reagent probe cleaners and WBA with predefined and unchangeable limits.
- **Pending Orders:** The reagent inventory level reaches the red alert status because existing orders exist in the Worklist and no reagent is onboard for the assay.

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
Name	The name of the assay reagent is red when test counts onboard fall below the operator-defined Manual threshold in Reagent Requirements Settings.
Average Tests	The operator configures manually or collected automatically by the system. When collected automatically, the system calculates the average assay usage from the last 5 weeks for the current 24-hour period. This is configured in Reagent Requirements Settings.
Tests to Perform	The difference between the Average Tests and the number of performed tests.
Packs to Load	The number of reagent packs required until the day ends as defined by the operator. System calculates as Tests to Perform ÷ tests per pack from the appropriate IFU.
Analyzers	The analyzer where the operator loads the required reagent packs. A comma separates list of active analyzers.

Reagent Needs	Notes
Reasons	• Predictive: Suggested need based on the operator-defined cutoff or system historic assay utilization. • Below Threshold: The reagent inventory level reaches the red alert threshold the operator defines in Reagent Requirements Settings. This includes CH reagent probe cleaners and WBA with predefined and unchangeable limits. • Pending Orders: The reagent inventory level reaches the red alert status because existing orders exist in the Worklist and no reagent is onboard for the assay.
	To add an item to the cart, the operator selects  in the appropriate row.

Reviewing Reagent Inventory on the Atellica Asa Application

NOTE: The operator can not perform any action on the Reagent Overview screen.

1. On the Title bar, select .
2. Select **Reagent Needs**.
3. Select **Reagent Overview**.
4. Select an analyzer.
5. Review reagent details.
6. To view reagents grouped by lot, select **Group by Reagent**.

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 QNS.

No need displays for CO adjustments.

Calibrator Needs resets at end of an operator-defined day. A need is red if the operator/system orders a calibration or it expires during an operator-defined day and no calibrator is onboard, is expired, or is QNS.

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 Name	Name of the calibrator material from Calibrator Definitions Material Name.
Calibrator Lot	The appropriate calibrator lot.
Onboard Status	States if the calibrator material is onboard and available (not expired or depleted).
Comment	Displays levels of required calibrator for assay calibration and any message that the reagent on board is not eligible for a lot calibration.
Assay	Assays impacted by the calibrator need. The material must be loaded because the calibration on assays is required.
Expiration	Expiration date and time of the current calibration interval that requires calibration.
Reagent Lot And Pack	The appropriate reagent pack lot or Any if the order does not specify a reagent pack lot.
Analyzer	The analyzer associated with the calibration. A comma separates list of active analyzers if more than 1 analyzer requires the same calibrator.
	To add an item to the cart, the operator selects  in the appropriate row.

About QC Needs for the Atellica Asa Application

QC Needs is created for a QC material based on:

- The QC scheduler to perform before the end of the operator-defined day.
- Any pending QC orders in Worklist.

QC Needs resets at end of operator-defined day. A need is red when an order has been placed and there is:

- No QC onboard.
- QC is onboard but the control material is low 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
Name	The name of the control material from QC Definitions Control Name.
Control ID	A unique identifier for the control from QC Definitions Control ID.
Lot	The lot of the control material.
Level	The concentration level of the control material.
Onboard Status	Whether the control material is onboard and available (not expired or depleted).
Scheduled	Whether the control is automatically scheduled.
Volume Needed (mL)	The volume of the control required for the day.
Assay	The assays associated with the control.
	To add an item to the cart, the operator selects  in the appropriate row.

About the Cart List on the Atellica Asa Application

The Cart List tab displays the materials needed for the system displayed in the Title bar. Operators add materials from 1 of the 4 needs screens. 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.

The Cart List tab contains:

- Reagents
- Calibration
- Quality Control
- Supplies

Reagents	Notes
Reagent Name	The name of the required reagent.
Module	The name of the module for the required reagent.
Lot	The lot of the reagent.
Calibration	Notes
Calibrator Name	The name of the calibrator material
Calibrator Lot	The appropriate calibrator material lot
Quality Control	Notes
QC	The name of the QC material
Lot	The appropriate QC material lot
Level	The appropriate QC material level
Supplies	Notes
Module	The name of the module for the required supply
Supply Name	The name of the supply

Supplies	Notes
Lot	The lot of the supply

Adding Materials to the Cart List on the Atellica Asa Application

1. On the Title bar, select .
2. Select a needs tile.
3. To add an item to the cart, select  in that row.
4. To add all items to the cart:
 - a. Select **Add All to Cart**.
 - b. Select **Yes**.
5. Repeat steps 1–4 to add other appropriate material to the Cart List.
6. To redo the list:
 - a. Select **Clear Cart**.
 - b. Select **Yes**.
 - c. Repeat steps 1–4.

About Troubleshooting on 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 CH and IM maintenance and troubleshooting functions.
Service Support Request	Accesses the Service Support Request system. The operator can submit a new service support request or view previously submitted tickets.

Troubleshooting	Notes
PEPconnect	Connects to the Personal Education Portal.
	Opens TeamViewer that allows remote access of the application interface during technical support calls.

About Service Support Request on 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
Open a Service Support Ticket	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.
Previous Tickets	The operator views existing tickets for the status on reported issues. Existing tickets are read-only. Only tickets the operator opens via the Service Support Request feature display here. The support tickets the local technical support provider opens do not display.

Open a Service Support Ticket	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.
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.
	Takes photos or records a video to attach to a service support ticket.
Add File	Adds files to the service support ticket.

Open a Service Support Ticket	Notes
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.
	Opens more details for each feature.
	Terminates remote service session. To initiate a remote session, a new passcode is required.

21 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 Capil- lary (Blue)	11069064	N/A	1000 holders/ba g
Holder Tube Capil- lary False-Bottom (Green)	11069063	N/A	1000 holders/ba g
COVER CAL AND QC TUBES	11085756	Visual inspection reveals damaged or missing cov- ers.	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 POLY- PROPYLENE LABELS	11481335	N/A	8 rolls/case
SH customer parts	REF		
O RING 0.14ID X 0.1W EPDM	11085685		
TRAY ASSY 15 POSITION	11069024		
TRAY ASSY 55 POSITION	11069025		
ASSY TRAY 15 POSITION STAT	11085987		

SH customer parts	REF
ASSY TRAY 55 POSITION SPECIAL TUBE1	11273251
ASSY TRAY 15 POSITION SPECIAL TUBE1	11273252
ASSY TRAY 15 POSITION SPECIAL STAT1	11273253

Decapper Supplies

The following table lists Decapper consumable part with the catalog number to assist in the ordering process:

Decapper con- sumables	REF	Trigger	Quantity
Waste Chute Liner	11069416	Failed manual inspection	10 pack

SHC Supplies

The following table lists SHC customer parts with the catalog number to assist in the ordering process:

SHC customer parts	REF
FILTER AIR REAR PANEL	11083036
PAD GRIPPER FINGER	11085807

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	Supplies Over- view alert	2 x 1.5 L
CH Conditioner	11099302	Supplies Over- view alert	2 x 1.5 L

CH consumables	REF	Trigger	Quantity
CH Diluent	11099300	Supplies Over-view alert	2 x 1.5 L
CH Wash	11099301	Supplies Over-view alert	2 x 1.5 L
CH Check Reagent (CHK)	11099311	Reagent Over-view alert	8 x 47 mL
IMT Diluent	11099305	Supplies Over-view alert	2 x 1.5 L
IMT Dilution Check	11099325	Initiating IMT Dilution Check	6 x 2 mL
IMT Standard A	11099304	Supplies Over-view alert	2 x 1.5 L
IMT Standard B + Salt Bridge	11099306	Supplies Over-view alert	1 x 250 mL & 1 x 125 mL
CH Lamp Coolant	11099307	Supplies Over-view alert	1 x 250 mL
High-Volume Pre-treatment	10721048	Supplies Over-view alert	2 x 1 liter
High-Volume 180-mL Pretreatment Bottles and Caps Kit	11597087	As needed	5 bottles, 5 caps
High-Volume Pre-treatment Bottle Label Kit	11597090	As needed	1 roll of 50
CH Reagent Probe Cleaner 1 (RPC1)	11099312	Reagent Over-view alert	8 x 44.6 mL
CH Reagent Probe Cleaner 2 (RPC2)	11099313	Reagent Over-view alert	8 x 44.6 mL
CH Reagent Probe Cleaner 4 (RPC4)	11099309	Reagent Over-view alert	4 x 47 mL
CH Water Bath Additive (WBA)	11099308	System alert	4 x 36 mL

CH consumables	REF	Trigger	Quantity
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	
FILTER AIR REAR PANEL		11083036	
FILTER AIR INTAKE		11075725	
TUBING PERISTALTIC PUMP		11075682	
Atellica IMT Na K CL (A-LYTE Multisensor)		11099315	
MIXER IMPELLER ASSY		11075703	
PROBE TRIPLE ASSY CUVETTE WASH		11075642	
PROBE SINGLE ASSY CUVETTE WASH		11075641	
PROBE METERING ASSY HS - REAGENT		11075751	
PROBE METERING ASSY HS - DIL - SAMPLE		11075752	
LAMP ASSY HALOGEN BULB		11075676	
SPRING COMP CUVT 7.6X17X.56		11075667	
NOZZLE PROBE VACUUM		11075610	
PROBE VACUUM ASSY CUVETTE WASH		11075643	
High-Volume Pretreatment Keyed Lid		11597266	

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	Supplies Overview alert	3000/box
IM Acid and IM Base	11098500	Supplies Overview alert	2 x 1.5 L
IM Cleaner	11098502	Supplies Overview alert	2 x 1.5 L
IM Wash	11098501	Supplies Overview alert	1 x 3.0 L
Solid waste bin liner	11070709	Visual inspection	1
Tips, sample probe	10309547	Supplies Overview alert	6480/box
Humidity Packs, 5	11313505	System alert, replace every 240 days	5/box
SWAB POLYUR-ETHANE FOAM	11349138	Reagent probe rinse station requires cleaning	25/box
IM customer parts	REF		
FILTER AIR REAR PANEL	11083036		
PROBE ASSY REAGENT	11071144		
PROBE ASSY ASPIRATE	11070782		
PROBE WASTE ASPIRATE	11070785		
CHUTE WASTE CUVETTE ASSEMBLY	11070572		
Gasket, Water Trap	11071032		

DL Supplies

The DL module comes with a customer parts kit at installation. This kit includes replaceable parts.

DL customer part	REF
SAMPLE RACK ASSY GRAY	10714017
SAMPLE RACK ASSY BLUE	10714021
SAMPLE RACK ASSY YELLOW	10714019
SAMPLE RACK ASSY GREEN	10714022
SAMPLE RACK ASSY ORANGE	10714018
SAMPLE RACK ASSY RED	10714020
RACK CALIBRATION ASSY CAMERA PROBE	11080560
TRAY SAMPLE RACK	10707472
CARRIER RACK ASSY BULK LOADING	10708458
ADAPTER TUBE ASSY QC/CAL 12MMX75L	10946757
ADAPTER 13MM LONG TUBE SAMPLE RACK	10702457
ADAPTER 13MM SHORT TUBE SAMPLE RACK	10702458
FILTER REAR PANELS	11083036

22 Specifications

This chapter provides the system design specifications.

Product Catalog Numbers

Module	REF
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
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
- syngo® Lab 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
- The Atellica Solution 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	

Electromagnetic Capability Reference

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, 2012.

Atellica Solution Dimensions

The area around the system must be free of obstacles and properly vented after installation.

	Scl	SccI	SSccII	Scl 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 in)	5702 mm (224.5 in)	8026 mm (316 in)	4650 mm (183.1 in)
Weight	1520 kg (3351 lb)	1990 kg (4387 lb)	3040 kg (6702 lb)	1634 kg (3602 lb)

SH and SHC Dimensions

SH dimensions

Depth	1451 mm (57 inches)
Height	1465 mm (57.7 inches)
Width	985 mm (38.8 inches)
SH only	
Width	1306 mm (51.5 inches)
SH with Atellica Magline Transport loop (1 required per system)	
Weight	476 kg (1050 lbs)

SHC dimensions

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).

Depth	1109 mm (44 inches)
Height	1223 mm (48 inches)
Width	250 mm (10 inches)
Weight	79 kg (175 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.

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
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.

Voltage rating	200–240 V 1~
Current rating	8 A
Frequency rating	50/60 Hz

Decapper Environmental Specifications

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
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

Voltage rating	200–240 Vac
Current rating	1.2 A
Frequency rating	50/60Hz

CH Environmental Specifications

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	200, 208, 220, 230, 240 VAC 1~
Current rating	9A, 9A, 8.5A, 8A, 8A
Frequency rating	50/60 Hz

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 636 <i>About Special Reagent Water</i>)
Water consumption	Maximum of 33 L/hour
Liquid waste output	Minimum of 40 L/hour per analyzer

IM Environmental Specifications

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	4507 BTU/hour
Noise	Compliant with NC-55 Noise Control specification, Average sound pressure of 65 dBA (1 m away from analyzer)
Overvoltage classification	Category II
Pollution classification	Degree 2
Maximum water pressure	207 kPa (30 PSI)

IM Electrical Requirements

Voltage rating	200/208/220/230/240 V 1~
Current rating	12 A
Frequency rating	50/60 Hz

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 (5 psi and 30 psi) at a temperature of 10–30 °C (Page 636 <i>About Special Reagent Water</i>)
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: 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.

Primary Tubes

The system supports the following primary tubes:

NOTE: Container type measurements are in mm.

13x75 Vacutainer Hemogard - BD 367983

Material	Plastic
Cap type	Safety
Volume	3.5 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes Requires a teal 13x75 rack insert.
ESL	Yes
Decapper	Yes

13x75 Vacutainer - BD 367981

Material	Plastic
Cap type	Stopper
Volume	3.5 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes Requires a teal 13x75 rack insert.
ESL	Yes
Decapper	No

13x75 Vacuette - Greiner 454067

Material	Plastic
Cap type	Safety
Volume	4 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes Requires a teal 13x75 rack insert.
ESL	Yes
Decapper	Yes

13x100 Vacutainer Hemogard - BD 367977

Material	Plastic
Cap type	Safety
Volume	6 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes Requires a brown 13x100 rack insert.
ESL	Yes
Decapper	Yes

13x100 Vacutainer - BD 368660

Material	Plastic
Cap type	Stopper
Volume	6 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes Requires a brown 13x100 rack insert.
ESL	Yes
Decapper	No

13x100 Vacuette - Greiner 456073

Material	Plastic
Cap type	Safety
Volume	5 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes Requires a brown 13x100 rack insert.
ESL	Yes
Decapper	Yes

16x100 Vacutainer Hemogard - BD 362799

Material	Plastic
Cap type	Safety
Volume	8.5 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes
ESL	Yes
Decapper	Yes

16x100 Vacutainer glass - BD 366430

Material	Glass
Cap type	Stopper
Volume	10 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes
ESL	Yes
Decapper	No

16x100 Vacutainer - BD 367820

Material	Plastic
Cap type	Stopper
Volume	10 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes
ESL	Yes
Decapper	No

16x100 Vacuette - Greiner 455010

Material	Plastic
Cap type	Safety
Volume	9 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes
ESL	Yes
Decapper	Yes

16x92 S-Monovette - Sarstedt 02.1388.100

Material	Plastic
Cap type	Thread
Volume	9 mL
Bottom shape	Syringe
SH	Yes
SHC	Yes
DL	No
ESL	Yes
Decapper	No

13x90 S-Monovette - Sarstedt 04.1935.001

Material	Plastic
Cap type	Thread
Volume	4.9 mL
Bottom shape	Syringe
SH	Yes
SHC	Yes
DL	Yes Requires a brown 13x100 rack insert.
ESL	Yes
Decapper	Yes

15x75 S-Monovette - Sarstedt 03.1397.100

Material	Plastic
Cap type	Thread
Volume	5.5 mL
Bottom shape	Syringe
SH	Yes
SHC	Yes
DL	No
ESL	Yes
Decapper	Yes

15x92 S-Monovette - Sarstedt 01.1602.001

Material	Plastic
Cap type	Thread
Volume	7.5 mL
Bottom shape	Syringe
SH	Yes
SHC	Yes
DL	Yes
ESL	Yes
Decapper	Yes

Cal-QC Tubes

The system supports the following Cal-QC tubes:

NOTE: To maintain the stability of Atellica calibrator or QC materials, use a glass sample container for onboard storage.

NOTE: Container type measurements are in mm.

12x75 glass Cal-QC tube for onboard storage

Material	Glass
Cap type	None
Volume	5 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes Requires a grey 12x75 rack insert.
ESL	Yes
Decapper	No

Bio-Rad control tube

Material	Plastic
Cap type	Thread
Volume	4 mL
Bottom shape	Round
SH	Yes
SHC	No
DL	Yes Requires a grey 12x75 rack insert.
ESL	Yes
Decapper	Yes

Pour-Off Tubes

The system supports the following pour-off tubes:

NOTE: Container type measurements are in mm.

12x75 Plastic: VWR 82050-128, Greiner 115101

Material	Plastic
Cap type	None
Volume	5 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes Requires a grey 12x75 rack insert.
ESL	Yes
Decapper	No

12x75 Glass: VWR 60826-836, Corning 99445-12

Material	Glass
Cap type	None
Volume	6 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes Requires a grey 12x75 rack insert.
ESL	Yes
Decapper	No

13x100 Plastic: VWR 82050-202, Greiner 125101

Material	Plastic
Cap type	None
Volume	9 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes Requires a brown 13x100 rack insert.
ESL	Yes
Decapper	No

13x100 Glass: VWR 60826-847, Corning 99445-13

Material	Glass
Cap type	None
Volume	9 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes Requires a brown 13x100 rack insert.
ESL	Yes
Decapper	No

14x100 Plastic: VWR 82050-228, Greiner 136101

Material	Plastic
Cap type	None
Volume	5 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	No
ESL	Yes
Decapper	No

16x75 Plastic: VWR 89206-934, Globe 119040A

Material	Plastic
Cap type	None
Volume	8 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	No
ESL	Yes
Decapper	No

16x100 Plastic: VWR 82050-234, Greiner 160101

Material	Plastic
Cap type	None
Volume	10 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes
ESL	Yes
Decapper	No

16x100 Glass: VWR 60826-869, Corning 99445-16

Material	Glass
Cap type	None
Volume	10 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	Yes
ESL	Yes
Decapper	No

15.3x92 Transfer Tube - Sarstedt 60.610.100

Material	Plastic
Cap type	Thread
Volume	10 mL
Bottom shape	Round
SH	Yes
SHC	Yes
DL	No
ESL	Yes
Decapper	No

Tube-Top Sample Cups

The system supports the following tube-top sample cups:

NOTE: Only use 1 mL tube-top sample cups with 13 mm sample containers.

Atellica Solution Tube-Top Sample Cups (1 mL) REF 11069061

Material	Plastic
Cap type	None
Volume	1 mL
Bottom shape	Conical
SH	Yes
SHC	No
DL	Yes
ESL	Yes
Decapper	No

NOTE: Only use 2 mL tube-top sample cups with 16 mm sample containers.

Atellica Solution Tube-Top Sample Cups (2 mL) REF 11069062	
Material	Plastic
Cap type	None
Volume	2 mL
Bottom shape	Conical
SH	Yes
SHC	No
DL	Yes
ESL	Yes
Decapper	No

Capillary Collection Containers

The system supports the following capillary collection containers:

NOTE: The system must include at least 1 IM Analyzer to support the use of capillary collection containers.

NOTE: The operator must place capillary collection containers in an appropriate holder before loading them in an SH rack.

- For false-bottom capillary collection containers, use the green Holder Tube Capillary False Bottom (11069063).
- For plain conical-bottom capillary collection containers, use the blue Holder Tube Capillary (11069064).

Becton Dickinson Microtainer 365967

Material	Plastic
Cap type	Stopper
Volume	1 mL
Bottom shape	Conical
Required holder	False-bottom capillary tube holder (green)
SH	Yes
SHC	No
DL	No
ESL	No
Decapper	No

Terumo Capiject T-MG

Material	Plastic
Cap type	Stopper
Volume	1 mL
Bottom shape	Conical
Required holder	Capillary tube holder (blue)
SH	Yes
SHC	No
DL	No
ESL	No
Decapper	No

Greiner MiniCollect 450472

Material	Plastic
Cap type	Stopper
Volume	1 mL
Bottom shape	Conical
Required holder	Capillary tube holder (blue)
SH	Yes
SHC	No
DL	No
ESL	No
Decapper	No

NOTE: The Greiner MiniCollect Complete must load in a special false-bottom tube rack due to the construction of the sample container.

Greiner MiniCollect Complete 450550

Material	Plastic
Cap type	Stopper
Volume	0.8 mL
Bottom shape	Conical (false-bottom)
Required holder	None
	NOTE: The capillary collection container comes preassembled with a 13x75 carrier tube and does not require a capillary tube holder.
SH	Yes
SHC	No
DL	No
ESL	No
Decapper	No

Sarstedt Microvette 20.1344

Material	Plastic
Cap type	Stopper
Volume	1 mL
Bottom shape	Conical
Required holder	False-bottom capillary tube holder (green)
SH	Yes
SHC	No
DL	No
ESL	No
Decapper	No

Ram Scientific Safe-T-Fill 07 7121

Material	Plastic
Cap type	Stopper
Volume	1 mL
Bottom shape	Conical
Required holder	Capillary tube holder (blue)
SH	Yes
SHC	No
DL	No
ESL	No
Decapper	No

False-Bottom Tubes

The system supports the following false-bottom tubes:

15.3x92 False-Bottom - Sarstedt 62.612	
Material	Plastic
Cap type	Screw
Volume	4 mL
Bottom shape	Flat
SH	Yes
SHC	No
DL	Yes
ESL	No
Decapper	No

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

23 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 640 *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 642 *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 642 *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.

Information for Technical Assistance

When calling for technical assistance, have the following information available:

- System name (Page 642 *Locating the System Name and Serial Number*)
- System serial number (Page 642 *Locating the System Name and Serial Number*)
- System version (Page 642 *About System Software Version Information*)

Locating the System Name and Serial Number

1. On the Command bar, select **Setup > Settings > General Setup > Connectivity**.
2. In the System Configuration area, locate the system name and serial number.

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:

- Upper left corner
- **System > About**

NOTE: In **System > About**, locate Siemens Healthcare Diagnostics Atellica®.

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

24 Revision Information

The revision information lists topics that have changed since the previously published version of this document.

Updated topics

Topic	Link
Legal Information	(Page 4 <i>Legal Information</i>)
Customer Documentation	(Page 23 <i>Customer Documentation</i>)
Terminology	(Page 24 <i>Terminology</i>)
Accessing Product Information in the Document Library	(Page 24 <i>Accessing Product Information in the Document Library</i>)
Symbols	(Page 29 <i>Symbols</i>)
Safety	(Page 37 <i>Safety</i>)
Biohazard Safety	(Page 37 <i>Biohazard Safety</i>)
About Reagent and Sample LED Barcode Scanners	(Page 39 <i>About Reagent and Sample LED Barcode Scanners</i>)
LED Classification	(Page 39 <i>LED Classification</i>)
About Cleaning Materials	(Page 40 <i>About Cleaning Materials</i>)
Reviewing the Operator Event Log	(Page 130 <i>Reviewing the Operator Event Log</i>)
Entering Diagnostics State in SH Operator Diagnostics	(Page 134 <i>Entering Diagnostics State in SH Operator Diagnostics</i>)
Unlocking the Screen	(Page 143 <i>Unlocking the Screen</i>)
About the Atellica Solution with Sample Handler	(Page 147 <i>About the Atellica Solution with Sample Handler</i>)
About the Atellica Magline Transport	(Page 152 <i>About the Atellica Magline Transport</i>)
About the Atellica SH	(Page 155 <i>About the Atellica SH</i>)
About the CH Analyzer	(Page 167 <i>About the CH Analyzer</i>)
About the IM Analyzer	(Page 170 <i>About the IM Analyzer</i>)
About CH DL	(Page 179 <i>About CH DL</i>)

Topic	Link
About the IM DL	(Page 182 <i>About the IM DL</i>)
Loading IM Reagent Packs	(Page 208 <i>Loading IM Reagent Packs</i>)
About Inventory Supplies Overview	(Page 213 <i>About Inventory Supplies Overview</i>)
Replacing CH System Fluids	(Page 218 <i>Replacing CH System Fluids</i>)
Replacing the Pretreatment Pack	(Page 227 <i>Replacing the Pretreatment Pack</i>)
Refilling CH Lamp Coolant	(Page 229 <i>Refilling CH Lamp Coolant</i>)
Replacing IM System Fluids	(Page 232 <i>Replacing IM System Fluids</i>)
Replacing IM Cuvettes	(Page 237 <i>Replacing IM Cuvettes</i>)
About Assay Reagent Calibration Frequency	(Page 326 <i>About Assay Reagent Calibration Frequency</i>)
About CH Lot and Pack Assay Reagent Calibrations	(Page 335 <i>About CH Lot and Pack Assay Reagent Calibrations</i>)
About CH Assay Pack Calibrations	(Page 337 <i>About CH Assay Pack Calibrations</i>)
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25 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 a result exceeds Concentration Range. The IM Analyzer 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 the CH Analyzer uses in cuvette wash cycles.
CH Cuvette Detergent	Solution the CH Analyzer uses 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.
Command bar	The tool bar at the top of the system interface that provides access to system functions and information for performing and managing laboratory activities.
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 bracket reagent reserve	A setting that ensures the system has adequate reagent to complete the end-of-bracket controls of an inprocess control-bracketed test.
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.
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)	CH component that moves the dilution probe.

Dilution mixer (CH)	Mechanical component that mixes the contents of dilution cuvettes on the dilution ring on the CH Analyzer.
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 area.
Dilution ring (CH)	Mechanical component that dilutes and stores sample dilutions for use in photometric assays on the CH Analyzer.
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.
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 on the Direct Load 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.
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.
Laboratory Information System	Laboratory computer system that can interface with the Atellica Solution. 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 of the IM Analyzer 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. The CH Analyzer 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 CH 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 Analyzer measures the light absorbance of samples. These absorbances convert to qualitative, quantitative, and semi-quantitative test results that the analyzer reports.

Photomultiplier tube	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.
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 CH Analyzer suspends cuvettes in an incubation fluid maintained at a constant $37^{\circ}\text{C} \pm 0.3^{\circ}\text{C}$. 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 IM 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.
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 IM 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: IM component 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. The Direct Load has a 6-position rack.
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.
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.
Status bar	The tool bar at the bottom of the Primary Display or Operator Tablet screen that contains current system information and icons for quick access to critical system functions.
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 Handler or Direct Load module. The monitor is a Microsoft Windows device.
TCS	See tube characterization station.
Test panel	Group of different assays that the operator defines for ease of ordering.
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. Abbreviation: TCS. See Pick-and-Place Station.
Tube top sample cup	Sample cup placed at the top of a specimen tube that holds a small amount of specimen for testing. Abbreviation: 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.

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