



Atellica® CH Analyzer Operator-Defined Assays

Operator's Guide Supplement

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Atellica® CH Analyzer Operator-Defined Assays Operator's Guide Supplement

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Using this CH Analyzer Operator-defined Assays Operator's Guide Supplement

The Atellica® CH Analyzer Operator-defined Assays Operator's Guide Supplement helps the operator configure Operator-defined assays on the CH Analyzer. Operator-defined assays expand capabilities of Siemens Healthineers assays and can configure third-party reagents. This guide includes the configuration workflow, tasks, and About topics to describe each software configuration feature.

NOTE: This supplement is compatible with the Operator-defined features in Atellica Solution software version 1.26 and replaces Operator-defined procedures in previous software versions.

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-healthineers.com/eIFU  [siemens.com/eIFU](http://www.siemens-healthineers.com/eIFU).

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

Accessing the Operator's Guide and CH Analyzer Operator-defined 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-healthineers.com/elfu**.
2. In the top-right corner, select **Login/Register > Login**.
NOTE: If this is the first time entering the site, register (*Registering for Services*).
If Laboratory Diagnostics Document Library was selected during registration, this area displays after logging in. If not, select that service.
3. To filter documents by language, ensure the appropriate language is selected.
4. In Products, select **Atellica Solution > Atellica Platform**.
5. In Document types, select **Instrument and Software Information > Manuals/Guides**.
6. Select the appropriate guide.
7. Select **Download** to print or save the guide.

Accessing Product Information in the Document Library

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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.

Atellica CH Analyzer Operator-defined Assay Configuration Procedures

This section provides procedures to configure, modify, delete, copy, and print Operator-defined assay information on the Atellica CH Analyzer. Each procedure has an About topic that describes all of the columns, fields, windows, and buttons.

Adding CH Operator-defined Assays Workflow

This task requires the appropriate security level (*Privileges in Account Settings*).

To configure and analyze an Atellica CH Operator-defined assay, the operator performs the following tasks in sequence:

The following displays at the top of each configuration in the workflow:

"Siemens Healthineers does not support operator modifications. Unsupported modifications may affect system performance and test results." The Available Channels displays to the right of this message.

Operator-defined configuration workflow	Task topic
Create the assay name, units of measure, sample pre-dilution and type, and assay range.	(Page 9 <i>Configuring Operator-defined Assays</i>)
Configure reagents and sample delivery volumes, reagent use, number of tests per pack well, and stability.	(Page 10 <i>Configuring Sample/Reagent for Operator-defined Assays</i>)
Configure the processing parameters for calculating the final result.	(Page 11 <i>Configuring Operator-defined Assays Calculation</i>)
Configure High-dose Hook Effect (optional).	(Page 13 <i>Configuring Operator-defined Assays High-dose Hook Effect Calculation</i>)
Configure calibration pre-dilutions and calibration-fit algorithms.	(Page 15 <i>Configuring Operator-defined Assays Calibration</i>)
Configure carryover mitigation (optional).	(Page 17 <i>Configuring Mitigation for Operator-defined Assays</i>)
Configure ranges (optional).	(Page 18 <i>Configuring Operator-defined Assay Ranges</i>)
Configure Repeat (optional).	(Page 18 <i>Configuring Operator-defined Assay Repeat Conditions</i>)
Manually fill a new, empty reagent pack.	(Page 60 <i>Filling Empty CH Reagent Packs</i>)
Load reagent pack.	(Page 62 <i>Loading Operator-filled Atellica CH Empty Reagent Packs</i>)
Calibrate the assay.	(Page 63 <i>Calibrating CH Assay Reagent Workflow</i>)
Perform QC.	(Page 64 <i>Performing Quality Control</i>)
Load and analyze patient samples.	For a system configuration: (Page 65 <i>Loading Samples into SH Racks</i>) For an analyzer DL configuration: (Page 66 <i>Loading Sample Racks on the DL</i>)

Configuring Operator-defined Assays

This task requires the appropriate security level (*Privileges in Account Settings*).

1. Navigate to **Operator-defined**.
2. Select **Create New**.
3. Enter required **Assay Name**.
4. Select **OK**.
5. Read warning statement then select **Yes**.

NOTE: The warning includes laboratory responsibility to validate any modifications:

Siemens Healthineers does not support operator-defined modifications. Unsupported modifications may affect performance of the system and test results. The laboratory is responsible for validating any modifications they make to the instructions, systems, reagents, or software provided by Siemens Healthineers. Accept responsibility?

6. Configure Definition (Page 9 *Configuring Definition for Operator-defined Assays*).
7. Configure Sample/Reagent (Page 10 *Configuring Sample/Reagent for Operator-defined Assays*).
8. Configure Calculation (Page 11 *Configuring Operator-defined Assays Calculation*).
9. If appropriate, configure High-dose Hook Effect (Page 13 *Configuring Operator-defined Assays High-dose Hook Effect Calculation*).
10. Configure Calibration (Page 15 *Configuring Operator-defined Assays Calibration*).
11. If appropriate, configure Mitigation (Page 17 *Configuring Mitigation for Operator-defined Assays*).
12. Configure Ranges (Page 18 *Configuring Operator-defined Assay Ranges*).
13. Configure Repeat (Page 18 *Configuring Operator-defined Assay Repeat Conditions*).
14. Select **Save > OK**.

Configuring Definition for Operator-defined Assays

This task requires the appropriate security level (*Privileges in Account Settings*).

This procedure is the first configuration step when creating an Operator-defined assay (Page 9 *Configuring Operator-defined Assays*).

The operator must configure 4 of the 8 areas before selecting **Save**. Configuring Mitigation, High-dose Hook Effect, Ranges, and Repeat are optional.

1. Confirm the Assay Name.

NOTE: This name defaults as the Display Name, Print Name, and LIS Code. The operator can modify each, if appropriate, but cannot remove the X.
2. From the drop-down menu, select the appropriate **Units**.
3. If appropriate, modify the Display Name, Print Name, or LIS Code.
4. If appropriate, enter LOINC.
5. If appropriate, select **Investigation Only**.

6. Select the appropriate sample type and Predilution:
 - a. Select the appropriate sample type tab.
 - b. Select the sample type check box.
 - c. Enter the Low and High Measuring Intervals.
 - d. In Predilution, enter the Sample Volume and Dilution Factor.
NOTE: The Total Volume calculates automatically.
 - e. In Above Assay Repeat Configuration, enter the Sample Volume and Dilution Factor.
 - f. In Sample Below Assay Repeat Configuration, enter the Sample Volume and Dilution Factor.
 - g. If appropriate, repeat steps a–f for each required sample type.
7. Configure Sample/Reagent (Page 10 *Configuring Sample/Reagent for Operator-defined Assays*).

Configuring Sample/Reagent for Operator-defined Assays

This task requires the appropriate security level (*Privileges in Account Settings*).

This procedure is the second configuration step when creating an Operator-defined assay (Page 9 *Configuring Operator-defined Assays*).

The operator must configure 4 of the 8 areas before selecting **Save**. Configuring Mitigation, High-dose Hook Effect, Ranges, and Repeat are optional.

1. To configure the R1 probe delivery to the reaction cuvette:
 - a. In the required R1 Reagent row, enter a Component 1 Volume (Well 1).
 - b. If appropriate, enter a Component 2 Volume (Well 2) (optional).
 - c. If appropriate, enter a Diluent Volume.
NOTE: The Total Volume calculates automatically.
 - d. If appropriate, select a Mix from the drop-down menu.
2. To configure the amount of sample the analyzer adds to the reaction cuvette, enter a Component 1 Volume (Well 1) in Sample row.
3. To configure the R2 probe delivery the analyzer adds to the reaction cuvette:
 - a. In R2 Reagent row, enter a Component 1 Volume (Well 1).
 - b. If appropriate, enter a Component 2 Volume (Well 2).
 - c. If appropriate, enter a Diluent Volume.
NOTE: The Total Volume calculates automatically.
 - d. If appropriate, select a Mix speed from the drop-down menu.
4. To share an onboard reagent pack with another defined assay, select the appropriate reagent in **Select Reagent**.
NOTE: Only configure onboard reagent if an existing reagent is shared with the Operator-defined assay. Do not select if the Operator-defined assay requires an empty reagent packed filled.

The Test Count, Life (hours), and Onboard Life (hours) populate.

5. Confirm the Test Count, Life (hours), and Onboard Life (hours).
NOTE: The analyzer calculates the pack well Volume when the Test Count is entered.
6. If Well 2 is to contain the same reagent as Well 1 (all required packs), select Use Well 2.
NOTE: Use Well 2 is disabled if Component 2 Volume (Well 2) is configured for R1 Reagent or R2 Reagent.
7. Configure Calculation (Page 11 *Configuring Operator-defined Assays Calculation*).

Configuring Operator-defined Assays Calculation

This task requires the appropriate security level (*Privileges in Account Settings*).

This procedure is the third configuration step when creating an Operator-defined assay (Page 9 *Configuring Operator-defined Assays*).

The operator must configure 4 of the 8 areas before selecting **Save**. Configuring Mitigation, High-dose Hook Effect, Ranges, and Repeat are optional.

1. Configure 1 of the following:
 - To configure an End Point (EPA) calculation, see (Page 11 *Configuring Operator-defined Assays End Point (EPA) Calculation*).
 - To configure a 2-Point Rate (2PA) calculation, see (Page 12 *Configuring Operator-defined Assays 2-Point Rate (2PA) Calculation*).
 - To configure a Linear Reaction Rate (RRA) calculation, see (Page 12 *Configuring Operator-defined Assays Linear Reaction Rate (RRA) Calculation*).
2. To configure High-dose Hook Effect, see (Page 13 *Configuring Operator-defined Assays High-dose Hook Effect Calculation*).
3. Configure Calibration (Page 15 *Configuring Operator-defined Assays Calibration*).

Configuring Operator-defined Assays End Point (EPA) Calculation

This task requires the appropriate security level (*Privileges in Account Settings*).

1. Navigate to **Calculation**.
2. From the Analysis Methods drop-down menu, select **End Point (EPA)**.
NOTE: Most applications are End Point (EPA) or Linear Reaction Rate (RRA). Check the assay kit specific IFU.
3. From the drop-down menu, select a Primary Wavelength.
4. If appropriate, select a Blank Wavelength from the drop-down menu.
5. From the drop-down menu, select a Main Start Time and Main End Time.
NOTE: For an assay with an R1 probe delivery only, the Main End Time should be ≥ 36 seconds. For an assay with an R1 and R2 probe delivery, the Main Start Time should be ≤ 259 seconds.
6. If appropriate, enter an Absorbance Offset.
7. If appropriate, select Start-Point Estimation then select a Blank Start Time and Blank End Time from the drop-down menus.
8. To configure High-dose Hook Effect, see (Page 13 *Configuring Operator-defined Assays High-dose Hook Effect Calculation*).

9. Configure Calibration (Page 15 *Configuring Operator-defined Assays Calibration*).

Configuring Operator-defined Assays 2-Point Rate (2PA) Calculation

This task requires the appropriate security level (*Privileges in Account Settings*).

1. Navigate to **Calculation**.
2. From the Analysis Methods drop-down menu, select **2-Point Rate (2PA)**.
NOTE: Most applications are End Point (EPA) or Linear Reaction Rate (RRA). Check the assay kit specific IFU.
3. From the drop-down menu, select a Primary Wavelength.
4. If appropriate, select a Blank Wavelength from the drop-down menu.
5. From the drop-down menu, select a Main Start Time.
NOTE: See the assay kit specific IFU for the start read times.
 The Main Start Time must be ≥ 21 seconds. An invalid calculation error displays if the operator enters < 21 seconds.
6. From the drop-down menu, select a Main End Time.
NOTE: See the assay kit specific IFU for the end read times.
7. If appropriate, enter an Absorbance Offset.
8. To configure High-dose Hook Effect, see (Page 13 *Configuring Operator-defined Assays High-dose Hook Effect Calculation*).
9. Configure Calibration (Page 15 *Configuring Operator-defined Assays Calibration*).

Configuring Operator-defined Assays Linear Reaction Rate (RRA) Calculation

This task requires the appropriate security level (*Privileges in Account Settings*).

1. Navigate to **Calculation**.
2. From the Analysis Methods drop-down menu, select **Linear Reaction Rate (RRA)**.
NOTE: Most applications are End Point (EPA) or Linear Reaction Rate (RRA). Check the assay kit specific IFU.
3. From the drop-down menu, select a Primary Wavelength.
4. If appropriate, select a Blank Wavelength from the drop-down menu.
5. From the drop-down menu, select a Main Start Time.
NOTE: See the assay kit specific IFU for the start read times. The Main Start Time for a Linear Reaction Rate (RRA) assay must be ≥ 21 seconds. An invalid calculation error displays if the operator enters < 21 seconds.
6. From the drop-down menu, select a Main End Time.
NOTE: See the assay kit specific IFU for the end read times. In most cases, the previous steps are all that is required to configure a Linear Reaction Rate (RRA) calculation. Evaluate assay linearity to determine if alternate end times are appropriate. The following steps are optional.
7. If appropriate, enter an Absorbance Offset.
8. If appropriate, select **Decreasing Reaction Absorbance**.

9. From each drop-down menu, select the Short End Time, and Medium End Time.
10. Enter a Linearity Factor.
NOTE: Most assays use a Linearity Factor of 50.
11. If appropriate, select **Reaction Limits** to enable quality check of the reaction then:
 - a. Select **Increasing** or **Decreasing** from Reaction Type drop-down menu.
 - b. From each drop-down menu, select the Initial Read Time and Final Read Time.
 - c. If appropriate, select a Substrate Depletion (FOD) Limit and Low Signal Cutoff from drop-down menus.
12. If appropriate, configure Blank Rate Corrections:
 - a. Select a Blank Start Time from the drop-down menu.
 - b. Select a Blank End Time from the drop-down menu.**NOTE:** The analyzer uses a linear regression to estimate the background reaction absorbance change in a non-reactive portion of the third-party assay for the Blank Rate Correction. Any interim reaction volume changes scale the resulting Blank Rate and is subtracted from the Reaction Rate determined from the reactive portion of the assay.
13. To configure High-dose Hook Effect, see (Page 13 *Configuring Operator-defined Assays High-dose Hook Effect Calculation*).
14. Configure Calibration (Page 15 *Configuring Operator-defined Assays Calibration*).

Configuring Operator-defined Assays High-dose Hook Effect Calculation

This task requires the appropriate security level (*Privileges in Account Settings*).

High-dose Hook Effect is an optional configuration of an Operator-defined assay (Page 9 *Configuring Operator-defined Assays*).

1. Navigate to **High-dose Hook Effect**.
2. Select **Enable Hook-effect Check**.
3. In Hook-effect Formula, select **Prozone Formula** or **Rate Method** from the drop-down menus.
4. If appropriate, select **Primary Wavelength Only**.
5. From the drop-down menu, select the Hook-effect Limit Type.
6. To configure the Hook-effect Limit :
 - a. Enter the Hook-effect Limit.
 - b. If appropriate, enter the Evaluation Threshold.
7. To generate a hook limit during calibration, select **Automatic Limit Determination** and enter supporting details.
8. From the drop-down menu:
 - a. Select the times for Main Window Start Time and Main Window End Time.
 - b. If appropriate, select the times for Initial Window Start Time and Initial Window End Time.
9. To generate a hook limit during calibration, select **Automatic Limit Determination** then:
 - a. If appropriate, enter a Calibration Level.
 - b. If appropriate, enter a Scaling Factor.

10. Configure Calibration (Page 15 *Configuring Operator-defined Assays Calibration*).**Configuring CH Operator-defined HIL Donor Assay Workflow**

This task requires the appropriate security level (*Privileges in Account Settings*).

To define a CH Operator-defined HIL donor assay, 2 options are available:

- Uses donor-specific assay reagents.
- Uses special reagent water. This assay produces no test result and is for HIL tests only.

NOTE: If the laboratory enables the Always Order option in **HIL Configuration**, the system automatically performs HIL processing on all serum and plasma samples (Page 69 *Configuring HIL Ordering*).

If the laboratory enables the According to TDef option in **HIL Configuration**, the system automatically performs HIL processing on serum and plasma samples that contain assays that are configured for HIL interference flagging. If a serum or plasma sample does not contain a test that is configured for at least 1 of H, I, or L interferences, then the system does not perform HIL on that sample (Page 69 *Configuring HIL Ordering*).

Operator-defined HIL configuration workflow	Topic reference
HIL donor assay configuration	Configure an Operator-defined HIL donor assay that uses donor-specific assay reagents (Page 14 <i>Configuring Operator-defined HIL Calculations</i>).
	Configure an Operator-defined HIL donor assay that uses special reagent water (Page 15 <i>Configuring Operator-defined Donor HIL Assay on the CH Analyzer</i>).
Enable HIL donor assays	(Page 70 <i>Enabling HIL Donor Assays</i>).
Configure HIL donor assay priority	(Page 70 <i>Configuring Donor Assay Priority at HIL Donor Configuration</i>)

Configuring Operator-defined HIL Calculations

This task requires the appropriate security level (*Privileges in Account Settings*).

NOTE: If the laboratory enables the Always Order or According to TDef option in HIL Configuration, the system automatically performs HIL processing on all serum and plasma samples (Page 69 *Configuring HIL Ordering*).

1. Navigate to **Operator-defined**.
2. In the Assay drop-down menu, select the appropriate assay.
3. Select **Calculation**.

4. To configure this assay as an HIL donor in HIL Calculations:
 - a. Select **Use as HIL Donor**.

NOTE: Default values populate.
 - b. Modify any appropriate scalar limit for each HIL setting.
 - c. In Alternate HIL Factors, modify any appropriate factor values.
5. Select **Save > OK**.
6. To configure another Operator-defined assay as an HIL donor, repeat steps 2–5.
7. Ensure the HIL donor assay is enabled in HIL Donor Configuration (Page 70 *Enabling HIL Donor Assays*).

Configuring Operator-defined Donor HIL Assay on the CH Analyzer

This task requires the appropriate security level (*Privileges in Account Settings*).

NOTE: If the laboratory enables the Always Order option in **HIL Configuration**, the system automatically performs HIL processing on all serum and plasma samples (Page 69 *Configuring HIL Ordering*).

1. Navigate to **Operator-defined**.
2. Select **Create HIL**.
3. To configure Definition and Sample Settings:
 - a. Enter the Assay Name.

NOTE: This name defaults as the Display Name, Print Name, and LIS Code. The operator can modify each, if appropriate, but cannot remove the "X".
 - b. Enter appropriate Sample Volume and Water Volume.
 - c. Select the appropriate sample type.
 - d. In Sample Predilution, enter the appropriate Sample Volume and Dilution Factor.
4. To modify default Calculation settings:
 - a. Select the Calculation tab and, if appropriate, modify the default Main Start Time and Main End Time.
 - b. Select **Use as HIL Donor** and, if appropriate, modify the scalars and factors.
5. To modify default Mitigation settings:
 - a. In Target, select **Reagent** or **Cuvette**.
 - b. Select 1 of the Mitigation Reagent.
6. Select **Save > OK**.
7. Ensure the HIL donor assay is enabled in HIL Donor Configuration (Page 70 *Enabling HIL Donor Assays*).

Configuring Operator-defined Assays Calibration

This task requires the appropriate security level (*Privileges in Account Settings*).

This procedure is the fourth configuration step when creating an Operator-defined assay (Page 9 *Configuring Operator-defined Assays*).

The operator must configure 4 of the 8 areas before selecting **Save**. Configuring Mitigation, High-dose Hook Effect, Ranges, and Repeat are optional.

1. In Calibration, select **General**:
 - a. From the drop-down menu, select the appropriate **Specimen Type**.
 - b. From the drop-down menu, select the appropriate a Standard Curve.

NOTE: Logit is the default calibration Standard Curve for nonlinear assays. For assays that have at least 6 calibrator levels, Logit3 improves curve fitting if the Logit feature produces an unacceptable curve fit.

Multi-Linear is the calibration for assays that require a multi-linear spline or line graph calibration.
 - c. Enter a Threshold cutoff if:
 - Semi Quant is selected.
 - Qualitative is selected as the Standard Curve.
2. For Logit calibrations, select a value for C4.

NOTE: Typical values for C4 are 1.0, 0.5, 0.01, or 0.
3. If appropriate, select **C0 Adjust**.

NOTE: Pack calibrations requiring a blank and not a full pack calibration use C0 Adjust.
4. Enter the Lot Calibration Interval (Days) Interval.
5. If appropriate, select **Semi Quant** and enter threshold value.
6. In Calibrator Onboard Stability (Hours), enter Refrigerated or Unrefrigerated onboard stability in hours.

NOTE: See the assay kit specific IFU refrigeration requirement and onboard stability.
7. To configure Calibrator Levels and Predilution:
 - a. Select **Calibrator Levels and Predilution**.
 - b. To choose the total number of calibrator levels, select the Level up and down arrows.
 - c. If appropriate, enter a Weight and Replicates for each Level.
 - d. To configure the predilutions for each Level, enter a Dilution Factor, Sample, and Sample Volume.

NOTE: The predilution for all configured sample types must be the same when using a Logit3 calibration.

The Total Volume calculates automatically.
8. Enter the Pack Calibration Interval (Days) Interval.
9. To configure a saline calibrator as Level 1, select the **CH Diluent Only** checkbox.
10. If required, configure Mitigation (Page 17 *Configuring Mitigation for Operator-defined Assays*).

Weighting Operator-defined Calibrations

1. Calibrate the assay prior to configuring Weight.
2. Process calibrator n=10 from 3 cups for each level of calibrator.

NOTE: This produces 30 replicates for each calibrator level.

3. For each calibrator level, calculate the SD of the 30 replicates.
4. Calculate the variance (VAR) and 1/VAR for each level.
NOTE: The VAR calculation is SD^2 .
5. Divide each 1/VAR value by the smallest value to normalize the 1/VAR values.
6. To view the example table, see (Page 52 *About Operator-defined Weighted Calibrations*).
NOTE: The smallest 1/VAR value is for calibrator level 5 = 0.000816 and it normalizes the 1/VAR for levels 1–4.
7. Round the normalized values to obtain the weight for each level of calibrator.

Changing Operator-defined Assay Calibration Curve

This task requires the appropriate security level (*Privileges in Account Settings*).

1. Delete calibration orders for the assay with Ordered status (Page 68 *Deleting Assay Reagent Calibration Orders in Calibration Results*).
2. Navigate to **Operator-defined**.
3. In Assay, enter in the appropriate Assay.
4. Select **Edit**.
5. Select **Calibration**.
6. From the drop-down menu, select the appropriate Standard Curve.
7. Select **Save > OK**.
8. Modify the calibration definition (link to modifying Cal Def).
9. Recalibrate the assay (Page 69 *Creating Assay Reagent Lot Calibration Orders*).

Configuring Mitigation for Operator-defined Assays

Mitigation is an optional configuration of an Operator-defined assay (Page 9 *Configuring Operator-defined Assays*).

1. Delete calibration orders for the assay with Ordered status (Page 68 *Deleting Assay Reagent Calibration Orders in Calibration Results*).
2. Select **Mitigation > Add**.
3. From the Donor Assay drop-down menu, select an existing assay.
4. In Target, select Reagent or Cuvette.
5. In Mitigation Reagent, select 1 of the following:
 - **Rinse:** With special reagent water
 - **Clean 1:** Uses the basic CH Reagent Probe Cleaner 1 (RPC1)
 - **Clean 2:** Uses the acidic CH Reagent Probe Cleaner 2 (RPC2)
6. To configure another rinse or clean, select **Add**.
7. Repeat Step 2–5 for each additional rinse or clean required.
8. Modify the calibration definition (*Editing Calibration Definitions*).
9. Recalibrate the assay (Page 69 *Creating Assay Reagent Lot Calibration Orders*).

10. To remove a carryover mitigation, select **Remove** at the end of the appropriate row.
11. To save mitigation, select **Save > OK**.

Configuring Operator-defined Assay Ranges

This task requires the appropriate security level (*Privileges in Account Settings*).

Ranges is an optional configuration of an Operator-defined assay (Page 9 *Configuring Operator-defined Assays*).

1. Navigate to **Operator-defined** and **Assay**.
2. Search and select the appropriate assay then Edit.
3. Select **Ranges**.
4. To add a range:
 - a. Select **Add Range**.
 - b. Select the Reference tab.
 - c. Enter **Range Name**.
 - d. In Details, enter the appropriate **Limits**.
 - e. If appropriate, select the **Repeat** check boxes.
 - f. Select **Save**.
 - g. If appropriate, configure the other tabs then select **Save**.
5. To edit an existing range:
 - a. Select **Edit Range**.

NOTE: Edit Range is not available unless the assay has at least 1 defined range.

- b. Edit the appropriate fields.
- c. If editing a manufacturer-defined range, ensure that an underscore is not in the Range Name.
- d. Select **Save**.

NOTE: The system only allows the saving of an edited range if all of its parameters meet the range criteria.

Configuring Operator-defined Assay Repeat Conditions

This task requires the appropriate security level (*Privileges in Account Settings*).

Repeat is an optional configuration of an Operator-defined assay (Page 9 *Configuring Operator-defined Assays*).

1. Navigate to **Operator-defined** and **Assay**.
2. Search and select the appropriate assay.
3. Select **Edit > OK**
4. Ensure that a check is in the Repeat check box for every system flag that requires a Repeat test.
5. Select the appropriate Dilution for each flag.

NOTE: The system performs 1 replicate for every Operator-defined assay. The laboratory cannot change this number.

6. Select **Save > OK**.

Configuring Negative Operator-defined Test Results

This task requires the appropriate security level (*Privileges in Account Settings*).

1. Navigate to **Operator-defined**.
2. In Assay, select an existing operator-defined assay.
3. Select **Result Setting**:
 - If a negative test result reports as an error, select **Report a negative result as Error**.
NOTE: The result displays as "error."
 - If the assay reports a negative test result, select **Report the negative value**.
NOTE: Negative results report with the Less than Zero flag. For the CH Analyzer to report negative Operator-defined test results, the lower range of the Measuring Intervals must be a negative number.
4. Select **Save**.

Copying Existing Operator-defined Assays

This task requires the appropriate security level (*Privileges in Account Settings*).

The operator copies an existing assay on the system to use as a starting point template or when an exact copy of a test definition for a currently defined assay is required. Each assay copy must have a unique Assay Name.

1. Navigate to **Operator-defined**.
2. Select **Create from Existing Assay**.
3. From the existing Assay menu, select the appropriate assay to copy then select **Next**.
4. Select **Copy Test > Yes**.
NOTE: Assay Name populates beginning with an X and ends with -Copy. The -Copy can be removed, if required.
5. Modify any configuration values within each tab.
NOTE: The following configurations do not copy:
 - Reagent carryover Mitigation (Page 17 *Configuring Mitigation for Operator-defined Assays*)
 - Ranges (Page 18 *Configuring Operator-defined Assay Ranges*)
 - Repeat conditions (Page 18 *Configuring Operator-defined Assay Repeat Conditions*)If appropriate, configure appropriate areas.
6. Select **Save > OK**.

Printing Operator-defined Assay Test Definition

1. Navigate to **Operator-defined**.
2. From Assay, select the appropriate assay.
3. Select **Edit**.
4. On the Tool bar, select .
5. If appropriate, set Print Options (Page 67 *Setting Print Options*).
6. Select **OK**.

Modifying Existing Operator-defined Assays

This task requires the appropriate security level (*Privileges in Account Settings*).

1. Navigate to **Operator-defined**.
2. From Assay, select the appropriate assay.
3. Select **Edit** and modify the appropriate configuration.
4. Select **Save > OK**.

Deleting Existing Operator-defined Assays

This task requires the appropriate security level (*Privileges in Account Settings*).

Deleting an Operator-defined assay deletes data including calibration data and reagent history. If another test shares a reagent, that reagent history is not deleted. If the Operator-defined assay is successfully deleted, this action is captured in the Audit Trail Log.

The operator cannot delete assays if that assay is included in any of the following:

- Test is part of an active or historical order
- Reagent onboard that only uses that assay
- Historical patient results
- QC definition
- Calibrations
- Ratios or Profiles
- Panels

1. Prior to deletion, complete the following:
 - a. Archive the appropriate assay results (Page 68 *Performing Move to Historical*).
 - b. Delete the historical patient and QC results for the appropriate assay.
 - c. Reject or accept the appropriate assay calibration results waiting for acceptance (*Accepting Calibration Results*) (*Rejecting Calibration Results*).
 - d. Remove the appropriate assay QC definitions (Page 69 *Editing QC Definitions*).
 - e. Remove the appropriate assay from ratios and panels (*Editing Ratios and Panels*).
 - f. Remove all appropriate packs from the analyzer (Page 66 *Unloading Reagent Packs*).

2. Navigate to **Operator-defined**.
3. From Assay, search or select the appropriate assay.
4. To delete all calibration data associated with the assay and the assay, select **Delete Assay > Yes**.

NOTE: If any patient or QC results for this assay are not deleted from historical, a message displays to delete these results before the assay deletion completes.

Discarding New Operator-defined Assays Before Saving

1. Navigate to **Operator-defined**.
2. Configure a new Operator-defined assay (Page 9 *Configuring Operator-defined Assays*).
3. To discard the new assay before saving, select **Cancel > No**.

Atellica CH Analyzer Operator-defined Features

This section provides information about the Operator-defined assay UI features. Each tab has a corresponding About topic that describes all the features within that tab or section of the UI.

About CH Operator-defined Assays

Each CH Analyzer has a default of 25 Operator-defined CH assays. The laboratory can purchase additional Operator-defined assays through Siemens Healthineers.

The number of available channels indicates the remaining number of assays and is located at the end of the following message at the top of the window: "The laboratory is responsible for validating any modifications made to the instructions, systems, reagents, or software provided by Siemens Healthineers. Available Channels {0}."

For more information on locating the CH Analyzer Operator-defined Assays Operator's Guide Supplement, see (Page 7 *Accessing the Operator's Guide and CH Analyzer Operator-defined Operator's Guide Supplement*).

Each Operator-defined test result is flagged with Operator-defined Assay.

The system groups the configurable parameters of the Operator-defined Test Definition for each assay into the following categories:

- Definition (Page 22 *About Definition for Operator-defined Assays on the CH Analyzer*)
- Sample/Reagent (Page 24 *About Sample/Reagent for Operator-defined Assays on the CH Analyzer*)
- Calculation (Page 30 *About Configuring Operator-defined Assays Calculation on the CH Analyzer*)
- Calibration (Page 47 *About Configuring Operator-defined Assays Calibration on the CH Analyzer*)
- Mitigation (Page 53 *About Reagent Carryover Mitigation for Operator-defined Assays on the CH Analyzer*)
- Ranges (Page 18 *Configuring Operator-defined Assay Ranges*)
- Repeat (Page 18 *Configuring Operator-defined Assay Repeat Conditions*)

About Definition for Operator-defined Assays on the CH Analyzer

The operator begins the configuration of a new Operator-defined assay and sample type configuration within Definition. The operator can modify, delete, copy, and print an existing Operator-defined assay in Definition.

Definition	Notes
Assay Identification	Section that includes Assay Name, Units, LIS Code, LOINC, and Investigation Only.
Assay Name	Short name beginning with an X for Operator-defined assays.
ID	The number the system assigns to an Operator-defined assay.
Units	Drop-down menu to select an assay unit of measure. The analyzer does not support free text as a unit of measure.
Test Version	The system automatically assigns the version of the test definition that updates with each saved revision. The operator can edit this field.
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 optional unique identifier from the Logical Observation Identifiers Names and Codes (LOINC) database.
Investigation Only	The assay contains a check mark when the assay result reports with the Investigational Use Only flag.
Create New	Function to create a new operator-defined assay.
Create from Existing Assay	Function to copy an existing assay on system to use as a starting point template or when an exact copy of a test definition for a currently defined assay is required. NOTE: Mitigation configuration does not copy.
Result Settings	Function to configure reporting of negative result values.
Save	Function to save a new or modified operator-defined assay.
Cancel	Function to discard changes in all Operator-defined configuration windows for an operator-defined assay.

Specimen Type Tabs	Notes
Serum, Plasma, Urine, CSF and RBC Hemolysate	Each sample type for the assay is configured on individual tabs. When the sample type is configured, the tab title is underlined. NOTE: The operator must pretreat all whole blood Operator-defined assays samples prior to placing them on a system, analyzer with DL, or LAS.
Measuring Intervals	The reportable Measuring Intervals that includes the check box for that specimen type. The operator selects the check box to enable Measuring Intervals and Sample configurations.
Low and High	The Low and High limits for the Measuring Intervals.
Sample	The predilution and sample for automatic retesting of assay. Sample volume for dilution must be between 4–100 µL.
Predilution	Free text field. A Predilution factor of 1 specifies an undiluted sample transferred to the Dilution Cuvette Ring. The analyzer does not add CH Diluent to the sample in the dilution cuvette. Wherever possible, the operator should configure the sample predilution using the standard 50 µL with 5X dilution factor. Matching the standard dilution conserves overall sample demand and analyzer throughput. The sample diluent volume affects the final ratios in the application. When using an undiluted sample as the predilution, the appropriate sample volume must be 39 µL greater than the desired sample transfer to the reaction cuvette. The maximum predilution in 250 µL using a 50 µL sample volume is 5X. The operator must decrease the sample volume when configuring a dilution of > 5X. The analyzer creates dilutions > 5X by decreasing the sample volume. The software allows sample and dilution factor combinations that scales to ≤ 250 µL, the maximum allowable volume for the dilution cuvette and wash station.
Sample Volume	The volume the system aspirates from the primary tube and delivers to the Dilution Ring Cuvette.
Dilution Factor	The dilution factor the system uses to determine the final volume of a predilution or Autodilution.
Total Volume	The automated product of the Sample Volume and Dilution Factor.

Specimen Type Tabs	Notes
Below Measuring Interval Configuration	The operator configures the Sample Volume, Dilution Factor, and Total Volume. For assays requiring a below measuring interval dilution when a test result is below the measuring interval: • The system routes the primary sample tube back to the analyzer. • For CH DL analyzers, the operator must place the primary tube in a rack and place the rack in the entry queue. NOTE: The operator cannot configure an increased sample volume for the initial predilution when the below measuring interval repeat is required.
Above Measuring Interval Configuration	The operator configures the Sample Volume, Dilution Factor, and Total Volume. Depending on sample availability, the analyzer dilutes the sample for results that are Above Measuring Interval Configuration. For assays requiring an above measuring interval dilution when a test result is above the measuring interval: • The system routes the primary sample tube back to the analyzer. • For CH DL analyzers, the operator must place the primary tube in a rack and place the rack in the entry queue. NOTE: The operator cannot configure a decreased sample volume when the above measuring interval repeat is required.

About Sample/Reagent for Operator-defined Assays on the CH Analyzer

The operator has the capability to configure sample and reagent dispense volumes to the reaction cuvette, mix strength, and the appropriate reagent in Sample/Reagent. The operator configures up to 4 reagents and 1 sample delivery volumes for Operator-defined assays in Sample/Reagent of Operator-defined. The CH Analyzer requires at least 1 reagent and sample delivery within the following limitations:

Aspiration and delivery volume limitations	Minimum (µL)	Maximum (µL)
Reaction cuvette fill volume	80	200
Reagent delivery	0 or 10	100
Chased reagent delivery	10	No limitation on maximum volume

Aspiration and delivery volume limitations	Minimum (µL)	Maximum (µL)
Reaction sample delivery	2	25

Primary sample delivery is the initial volume of sample the dilution probe transfers to the dilution cuvette (Page 28 *About Operator-defined Primary Sample Delivery and Optimization*).

The software and volumes defined in Sample/Reagent automatically determine if the reagent will be delivered with or without the addition of special reagent water to the dilution or reaction cuvette.

When filling reagent packs, the unusable volume in each well is 1.5 mL. Many third party reagents contain a large volume of 1 reagent and a significantly smaller volume of another. In order to optimize the number of tests per reagent pack, there is no benefit to splitting smaller volume reagents into 2 wells as this causes an additional loss of 1.5 mL of reagent.

Sample/Reagent	Notes
R1 Reagent	The Reagent Probe 1 reagent delivery from the P1 pack to the cuvette for testing. Maximum reagent dispense volume is 100 µL. For assays with > 2 reagents, a Component 2 Volume (Well 2) may exist for the R1 Reagent Probe. The R1 Reagent Probe aspirates from Well 2 first, followed by aspiration from Well 1, then dispenses both reagents into the reaction cuvette at the same time. In rare circumstances, a 2 reagent assay may require both reagents in P1 (1 reagent in each well). The analyzer uses this format if a long incubation time is required for reagents 1 and 2.
Sample	The sample probe delivery from the dilution cuvette to the reaction cuvette. Maximum sample delivery volume is 25 µL.
R2 Reagent	The Reagent Probe 2 delivery from the P2 pack to the cuvette for testing. Maximum reagent dispense volume is 100 µL. For assays with > 2 reagents, a Component 2 Volume (Well 2) may exist for the R1 Reagent Probe. The R1 Reagent Probe aspirates from Well 2 first, followed by aspiration from Well 1, then dispenses both reagents into the reaction cuvette at the same time. When the assay requires different reagents from 1 pack, the analyzer adds both components to the cuvette at the same time, aspirating R1 Reagent first followed by R2 Reagent delivering it to the same cuvette.
Time	The delivery time for the addition of reagents or sample to the reaction cuvette. These are fixed and cannot be changed.
Component 1 Volume (Well 1)	The first reagent volume delivered to the reaction cuvette.

Sample/Reagent	Notes
Component 2 Volume (Well 2)	The second reagent volume delivered to the reaction cuvette.
Diluent Volume	The amount of special reagent water the analyzer adds to the reaction cuvette with the dispense of reagent. Only required in instances where the reagents require a dilution.
Total Volume	The automated sum of each sample and reagent definitions. Volumes must be whole numbers. The minimum reaction cuvette volume must be $\geq 80 \mu\text{L}$.
Mix	Rotational speed defines the mix levels. The reaction cuvette mixers have 6 available speeds: • None: No mixer • Slow: 3000 RPM • Gentle: 6000 RPM • Moderate: 9000 RPM • Strong: 10500 RPM • Extra Strong: 12000 RPM For R1 Reagent mix, consider selecting Gentle as a starting point for volumes $< 125 \mu\text{L}$. For R2 Reagent mix, consider selecting Strong as a starting point for volumes $> 125 \mu\text{L}$. For R2 Reagent mix, consider selecting Extra Strong for volumes $> 150 \mu\text{L}$. The mix associated with R1 Reagent occurs when the analyzer combines R1 Reagent (the first reagent delivery) and Sample in the cuvette. NOTE: Erroneous results and imprecision may result from the following: • Strong and Extra Strong mixing may cause foaming in the reaction cuvette when applied to reaction volumes $< 125 \mu\text{L}$. • Insufficient mixing may occur for assays using None, Slow, or Gentle when applied to reaction volumes $> 150 \mu\text{L}$.
Total Volume	The analyzer calculates the total volume delivered to the cuvette using the volumes entered. The maximum volume in the cuvette is $200 \mu\text{L}$. If the configured volumes exceed this limit or the calculated reaction cuvette volume is $< 80 \mu\text{L}$, the system returns an error.

Sample/Reagent	Notes
Select Reagent	If an enabled Siemens Healthineers assay and Operator-defined assay share the same reagent pack, the operator configures this section. NOTE: When using the same reagent pack for 2 or more Test Definitions, the calibration is not shared. In this case, The operator must configure separate calibrations and QC.
Test Count*	The operator specifies the appropriate number of tests per reagent pack well. The allowable number of tests in a pack are dependent upon the required reaction volumes for the test to process, reagent manufacturer's packaging, allowable volume in a reagent pack, and reagent pack unusable volume. The test count must be the same in all wells of all packs when configuring the assay. When the same reagent is in both wells of a pack, the test count applies to each well. A test count of 250 equates to 500 tests per pack when Use Well 2 is selected.
Volume*	The system automatically calculates reagent pack volume based on reagent delivery and entered tests. The maximum volume in a well is 23.5 mL.
Onboard Life (hours)*	Onboard storage period for unopened pack wells. Default is 2160hours (90 days). See the assay kit specific IFU for appropriate stability durations for the prepared reagents.
Use Well 2*	The operator specifies if Well 2 of the reagent pack should be configured identically to Well 1: • If Well 2 contains the same reagent as Well 1 for all required packs, select Use Well 2. • If wells 1 and 2 of the same pack do not contain the same reagent, Use Well 2 is disabled.
Pack 1 Volume	The analyzer automatically displays the required fill volume including unusable volume in each well of reagent pack 1.
Pack 2 Volume	The analyzer automatically displays the required fill volume including unusable volume in each well of reagent pack 2.
Create New	Function to create a new operator-defined assay.
Create from Existing Assay	Function to copy an existing assay on system to use as a starting point template or when an exact copy of a test definition for a currently defined assay is required. NOTE: Mitigation configuration does not copy.
Result Settings	Function to configure negative result values.

Sample/Reagent	Notes
Cancel	Function to discard changes in all Operator-defined configuration windows for an operator-defined assay.
Save	Function to save a new or modified operator-defined assay.

NOTE: * indicates that these fields are disabled when:

- Configuring an Operator-defined assay to share a commercial Atellica reagent pack
- Configuring an Operator-defined assay to share a reagent pack with another Operator-defined assay

About Operator-defined Primary Sample Delivery and Optimization

Primary sample delivery is the initial volume of sample the dilution probe transfers to the dilution cuvette.

Optimization tip 1: Maximize the utilization of the assay kit

A total reaction volume of 80 µL maximizes utilization of the kit.

Optimization tip 2: Optimizing the number of tests per reagent pack

The dead volume in each reagent pack well is 1.5 mL. Many reagents contain a large volume of 1 reagent in well 1 and a significantly smaller volume in well 2. The operator cannot split smaller volume reagents into 2 wells as this results in an unnecessary doubling of the dead volume.

Optimization tip 3: Filling empty reagent packs

To avoid reagent level detection errors, the operator must fill reagent packs using a calibrated pipet to deliver the amount displayed under Total Volume within ± 0.5 mL. The operator must not fill packs by pouring over the contents of the reagent into the empty pack. The analyzer adjusts and accommodates some error in reagent pack preparation. Reagent level sensing tolerance for this initial filling inaccuracy is approximately -3 – +4 mL from the volume in Sample/Reagent. Inaccurately filling packs causes the analyzer to reject the packs during processing, wasting sample and reagents, and leads to other analyzer level errors.

Optimization tip 4: Conserve sample demand and analyzer throughput

Wherever possible, the operator should use the standard 50 µL with 5X sample predilution instead of an undiluted sample. Matching the standard dilution conserves overall sample demand and analyzer throughput. The sample diluent volume affects the final ratios in the application.

The number of reagents and volumes for the assay determines the amount of required sample.

Single reagent assay example

The operator can assume a total reaction volume of 80 µL as the standard and a 1:5 sample predilution.

Single reagent assay example

Assay kit specific requirements:

- Sample volume = 6 µL
- R1 Reagent volume = 120 µL
- Total Volume = 126 µL

Calculating reagent ratios- divide the individual component by the total volume calculates the ratios:

- Sample volume = $6/126 = 0.05$ or 5%
- R1 Reagent volume = $120/126 = 0.95$ or 95%

If a ratio of sample to total volume is 0.05 in the assay kit specific IFU, the amount of prediluted sample from the dilution cuvette is:

- Total Volume X Sample Ratio = Volume of sample in reaction cuvette.
- $(80) \times (0.05) = 3.8 \mu\text{L}$
- Total Volume X (R1 Ratio) = R1 Volume (R1 Reagent)
- $(80) \times (0.95) = 76.2 \mu\text{L}$

Two reagent assay example

The minimum reagent volume dispensed is 10 µL. The operator can assume a total reaction volume of 80 µL.

Assay kit specific requirements:

- Sample volume = 6 µL
- R1 Reagent volume = 120 µL
- R2 Reagent volume = 20 µL
- Total Volume = 146 µL

Calculating reagent ratios- divide the individual component by the total volume calculates the ratios:

- Sample volume = $6/146 = 0.41$ or 4.1%
 - R1 Reagent volume = $120/146 = 0.822$ or 82.2%
 - R2 Reagent volume = $20/146 = 0.137$ or 13.7%
-

Two reagent assay example

If a ratio of sample to total volume is 0.41 in the assay kit specific IFU, the amount of prediluted sample from the dilution cuvette is:

- Total Volume X Sample Ratio = Volume of sample in reaction cuvette.
 - $(80) \times (0.041) = 3.3 \mu\text{L}$
 - Total Volume X (R1 Ratio) = R1 Volume (R1 Reagent)
 - $(80) \times (0.822) = 65.8 \mu\text{L}$
 - Total Volume X (R2 Ratio) = R2 Volume (R2 Reagent)
 - $(80) \times (0.137) = 11 \mu\text{L}$
-

About Operator-defined Reagent Pack Holders

Third party reagent racks can hold empty Siemens Healthineers reagent packs during the fill process. The recommended peg style test tube racks for 20–25 mm size tubes include:

- VWR™: SCIENCEWARE® Full-View Test Tube Supports, Bel-Art
- Fisher Scientific: Endicott-Seymour Polypropylene Holders and Dryers (C,P)

About Configuring Operator-defined Assays Calculation and HIL on the CH Analyzer

The operator defines the processing parameters for calculating the final result and reporting error conditions for operator-defined assays in Operator-defined Calculation.

- Calculation: Processing parameters for calculating the final result and reporting error conditions for operator-defined assays (Page 30 *About Configuring Operator-defined Assays Calculation on the CH Analyzer*).
- HIL Donor Settings: Define HIL donor assay parameters (Page 40 *About Configuring Operator-defined HIL Calculations on the CH Analyzer*).

About Configuring Operator-defined Assays Calculation on the CH Analyzer

The operator configures the processing parameters for calculating the final result and reporting error conditions for operator-defined assays in Operator-defined Calculation.

Calculation	Notes
Analysis Methods	Drop-down menu to select: • End Point (EPA) • 2-Point Rate (2PA) • Linear Reaction Rate (RRA) (Page 36 <i>About Operator-defined Assay Calculation Analysis Methods</i>)

Calculation	Notes
Primary Wavelength	Drop-down menu to select a primary wavelength for measurement of reaction-product absorbance.
Blank Wavelength	Optional setting. Drop-down menu to select a secondary wavelength to correct for non-specific absorbance from cuvette, sample, and reagents. Blank Wavelength examples include: • If kit blank is 700 nm or a turbidimetric assay, 694 nm is the Blank Wavelength. • For standard NAD-coupled reaction assays, 410 nm is the Blank Wavelength.
Main Start Time	Drop-down menu to select available time of the first absorbance read in seconds. Expected values: 0–579 seconds. NOTE: The Main Start Time for a Linear Reaction Rate (RRA) and 2-Point Rate (2PA) assay must be ≥ 21 seconds. An invalid calculation error displays if the operator enters < 21 seconds.
Main End Time	Drop-down menu to select available time of the last absorbance read in seconds. Expected values: 21–579 seconds (End Point (EPA)= 570 seconds).
Absorbance Offset	Optional setting. A fixed value added to the final reaction signal, commonly used for Logit3 assays. The Logit3 calculations do not accept negative values. Available range: -3000–3000. NOTE: For example, the immunoglobulin assays (IgA, IgG, and IgM) add 20 mAU to the final calculated signal to avoid generation of negative raw values.
Decreasing Reaction Absorbance	Optional setting for assays that use a spline calibration curve. The smooth spline interpolation algorithm cannot accept the negative numbers produced when a reaction's absorbance decreases during the measuring period. Enabling this reverses the calculation to provide positive values.

Calculation	Notes
Short End Time	Optional setting. Drop-down menu to select an optional alternate reaction-rate end time. Allows expansion of a linear rate assay's range by calculating the rate over a shorter time period. Displays for Linear Reaction Rate (RRA) only. Value between Main Start Time and Main End Time.
Medium End Time	Optional setting. Drop-down menu to select an optional alternate reaction rate end time. Allows expansion of a linear rate assay's range by calculating the rate over a shorter time period. Displays for Linear Reaction Rate (RRA) only. Value between Short End Time and Main End Time.
Linearity Factor	Optional setting. The check for substrate depletion addressed by a Short End Time or Medium End Time. The Linearity Factor is the % difference between the reaction rates at the Main Start Time and either alternate reaction rate end time (Short End Time or Medium End Time) or the Main End Time in a 20 second window. The factor permits the optimal reaction window to be selected and used. Range is 0–100. The most common value is 50. To improve assay linearity, use 50 and reduce by 2X as needed. Displays when Linear Reaction Rate (RRA) selected. NOTE: If the Linearity Factor is set too low, there is a risk of generating nuisance > Measuring Interval flags.
Reaction Limits	Optional setting. Selected for absorbance checks on the reaction integrity. Displays for Linear Reaction Rate (RRA) only.

Calculation	Notes
Reaction Type	Optional setting. Function to set the correct relationship between the reaction checks and the expected assay behavior for Linear Reaction Rate (RRA) only. Drop-down menu for operator to select 1: - Increasing reaction: When the reaction absorbance increases with time as the product is created. Reaction slope or signal output is a positive number. - Using up all the reactants creates a maximum amount of product. The depletion check is for absorbance greater than the Substrate Depletion (FOD) Limit. - Using very little reactant, the product absorbance remains below the Low Signal Cutoff. - Decreasing reaction: When the reaction absorbance decreases with time as the reactant is consumed. Reaction slope or signal output is a negative number. - Using up all reactants results in a minimum amount of reactant. The depletion check is for absorbance lower than the Substrate Depletion (FOD) Limit. - Using up very little reactant, product absorbance remains above the Low Signal Cutoff.
Initial Read Time	Optional setting. The read time drop-down menu where the first absorbance reading supports the Substrate Depletion (FOD) Limit and the Low Signal Cutoff calculations. Displays when Linear Reaction Rate (RRA) selected. Allowed values: 0–579 seconds. The Initial Read Time provides a baseline of the reaction cuvette contents before the active reaction takes place: - After adding the initial reagent and sample. - Before the final reagent addition (> 273 seconds) or in the first moment before the complete reaction starts.

Calculation	Notes
Final Read Time	Optional setting. Drop-down menu required to define the Substrate Depletion (FOD) Limit calculation. Displays when Linear Reaction Rate (RRA) selected. Allowed values: 21–579 seconds. Provides a final absorbance reading for the Substrate Depletion (FOD) Limit calculation. Most effective when the Final Read Time value is equal to or just prior to the shortest main-reaction read time (Medium End Time or Short End Time).
Substrate Depletion (FOD) Limit	Optional setting. The absorbance change in the reaction to confirm that sufficient excess reagent is available to support an accurate analyte result. If the analyte is in excess, the check triggers a corresponding outside Measuring Interval error that initiates an autodilution and repeat testing. Displays when Linear Reaction Rate (RRA) selected. Expected values: -3000–3000. Substrate Depletion (FOD) Limit is assay dependent. The operator must determine if an Substrate Depletion (FOD) Limit is required then define the correct limit for the assay.
Low Signal Cutoff	Optional setting. The optional blank corrected absorbance value per minute between the Initial Read Time and the Main End Time. The Low Signal Cutoff only applies to Linear Reaction Rate (RRA) reactions where it is part of the decision for the various rates. It enhances the Linearity Factor by automatically using the longest rate to evaluate low analyte samples. There is no flag triggered by the Low Signal Cutoff in a simple single rate assay. Expected values: -3000–3000.

Calculation	Notes
Start-Point Estimation	Optional setting used for End Point (EPA) format only. Most 2-reagent endpoint assay calculations benefit from a read window just before the R2 addition to correct for absorbance from the patient's sample. Without this correction, that absorbance may influence later readings of the reaction End Point. If a 2-reagent design cannot provide at least 80µl of reaction cuvette volume with the initial reagent (R1) and sample deliveries, reading before the final reagent (R2) addition is not possible. Start-Point Estimation can extrapolate backward to estimate that initial reagent (R1) and sample absorbance. Start-Point Estimation is achieved by configuring a Blank Start Time and Blank End Time for the initial linear portion of the active reaction. The analyzer uses all photometric readings in that period in a linear regression to obtain an accurate absorbance value for the time point prior to final reagent (R2) addition defined by the operator's input for the Main Start Time. This Start-Point Estimation value replaces the reading of absorbance at the Main Start Time (the pre-reaction read) in the determination of the End Point (EPA) result.
Blank Rate Correction	Optional setting. Value that displays for Linear Reaction Rate (RRA) only. A correction for non-specific reaction rates (prior to the desired reaction start time) subtracted from the final rate. Linear regression from the Blank Start Time to the Blank End Time is used to provide a rate. The correction assumes a concentration-dependent process and scales the rate by subsequent volume changes.
Blank Start Time	Optional setting. Drop-down menu to select the time of the first read used for the blank start estimate or rate correction.
Blank End Time	Optional setting. Drop-down menu to select the time of the last read used for the blank start estimate or rate correction.
Create New	Function to create a new operator-defined assay.

Calculation	Notes
Create from Existing Assay	Function to copy an existing assay on system to use as a starting point template or when an exact copy of a test definition for a currently defined assay is required. NOTE: Mitigation configuration does not copy.
Result Settings	Function to configure negative result values.
Save	Function to save a new or modified operator-defined assay.
Cancel	Function to discard changes in all Operator-defined configuration windows for an operator-defined assay.

About Operator-defined Assay Calculation Analysis Methods

Three types of assay absorbance methods exist on the CH Analyzer:

- Linear Reaction Rate (RRA) and 2-Point Rate (2PA) (kinetic reactions)
- End Point (EPA) (endpoint reactions)

The assay kit IFU typically states how long the analyzer processes the assay. See the IFU or reference another platform application sheet to determine the duration of the assay for the final read configuration.

Linear Reaction Rate (RRA) Kinetic Reactions

The Linear Reaction Rate (RRA) assay format evaluates absorbance as the reaction proceeds. The linear, zero-order reaction kinetics calculates the rate of absorbance change versus time and is not dependent on the reactant concentration.

Once these fields are configured, the analyzer automatically determines which rate to use for the sample:

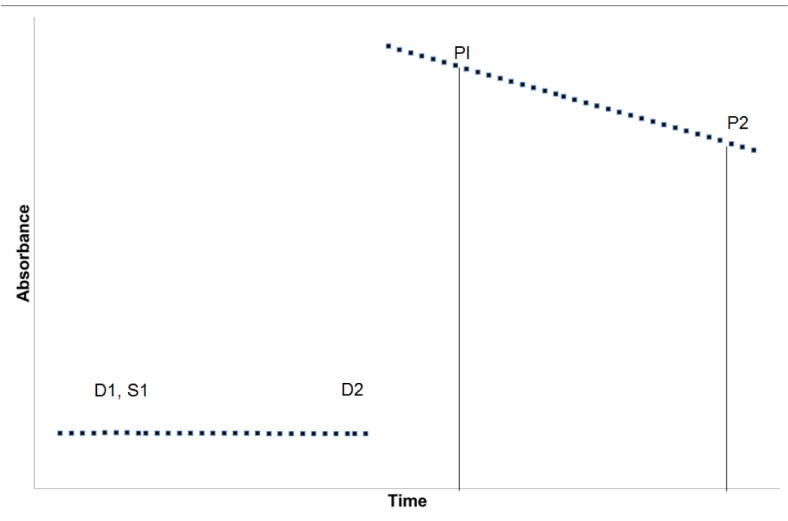
- Long Rate is for low and medium concentration samples and the operator must use the full Main End Time as the end of the reaction.
- Medium Rate is for high concentration samples and the reaction time is shorter than the long rate.
- Short Rate is for extremely high samples and have the shortest reaction time.

When configured for a Blank Rate Correction, a volume correction factor is applied to the calculation to account for the differential reaction volume before and after the reagent probe 2 addition. Most serum enzyme assays belong to this category. The reaction kinetics progress linearly (signal versus time). When RRA format is configured, the analyzer records reaction signals with particular wavelengths at each read cycle over the period defined by the Main Start Time to Main End Time then calculates a slope. A calibration curve fit transforms the calculated reaction rate to an analyte concentration.

Each time the cuvette passes the photometer between the Main Start Time and Main End Time, the analyzer records the absorbance in the reaction cuvette to calculate the reaction rate. Additional reads may occur depending on setup of optional features.

The Short End Time and Medium End Time are optional and configured for enzyme assays, such as ALT and AST. The Main End Time represents the Long End Time. These end times evaluate the best read window to calculate the result. Three cycle time based read windows are defined as long, medium, and short. The appropriate read window to determine where the rate is linear based on the change in slope from the start of the window to the end. The Linearity Factor defines the threshold for this change as a percentage. If the change in slope exceeds this percentage, the read fails and the analyzer evaluates the next read window. If all read windows fail this check, the analyzer flags the result as > Measuring Interval and may dilute and reprocess the sample. The long, medium, and short rates represent the percent change in slope for each window and are located in the SRS calculation data.

Linear Reaction Rate (RRA) reaction format



Linear Reaction Rate (RRA) reaction format	Notes
D1 (R1 Reagent)	The Reagent Probe 1 reagent delivery from the P1 pack to the cuvette for testing. Maximum reagent probe dispense volume is 100 µL.
S1 (Sample)	The sample probe delivery from the dilution cuvette to the reaction cuvette. Maximum sample probe dispense volume is 25 µL.
D2 (R2 Reagent)	The Reagent Probe 2 delivery from the P2 pack to the cuvette for testing. Maximum reagent probe dispense volume is 100 µL. For assays with > 2 reagents, a second volume addition may exist for the R1 Reagent Probe. The R1 Reagent Probe aspirates from Well 1 first, followed by aspiration from Well 2, then dispenses both reagents into the reaction cuvette at the same time.

Linear Reaction Rate (RRA) reaction format	Notes
P1 (Main Start Time)	Initial absorbance time point. NOTE: The Main Start Time for a Linear Reaction Rate (RRA) assay must be ≥ 21 seconds. An invalid calculation error displays if the operator enters < 21 seconds.
P2 (Main End Time)	Final absorbance time point.

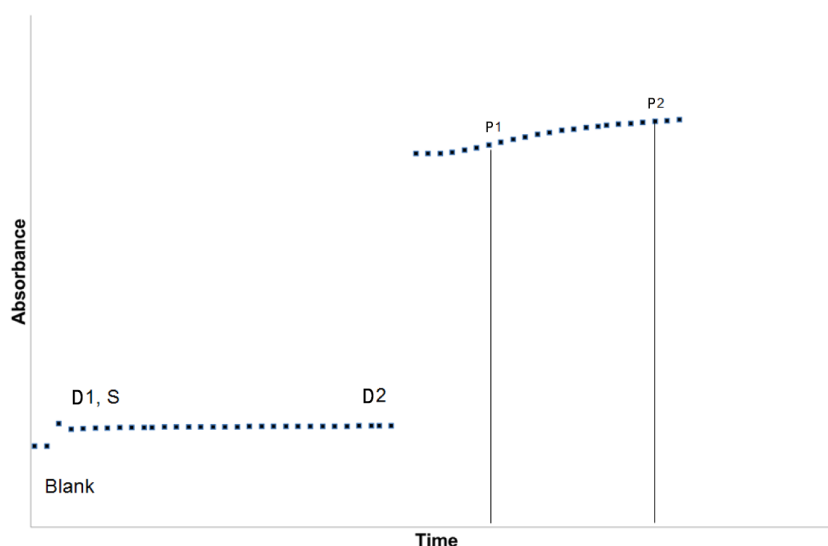
2-Point Rate (2PA) Kinetic Reactions

The 2-Point Rate (2PA) assay format evaluates absorbance as the reaction proceeds. The rate of absorbance change versus time and is dependent on the reactant concentration. The reaction kinetics are a non-linear pattern.

With a 2-Point Rate (2PA) configuration, the analyzer records reaction signals with particular wavelengths between 2 defined points in time (Main Start Time to Main End Time). The delta signal calculates the final signal. The calculated signal converts to an analyte concentration by mapping to a calibration curve.

The analyzer captures 2 additional reaction-absorbance readings immediately after and immediately before the Main Start Time and Main End Time respectively to calculate the result.

2-Point Rate (2PA) reaction format



2-Point Rate (2PA) reaction format	Notes
D1 (R1 Reagent)	The Reagent Probe 1 reagent delivery from the P1 pack to the cuvette for testing. Maximum reagent probe dispense volume is 100 μL .
S (Sample)	The sample probe delivery from the dilution cuvette to the reaction cuvette. Maximum sample probe dispense volume is 25 μL .

2-Point Rate (2PA) reaction format	Notes
D2 (R2 Reagent)	The Reagent Probe 2 delivery from the P2 pack to the cuvette for testing. Maximum reagent probe dispense volume is 100 µL. For assays with > 2 reagents, a second volume addition may exist for the R1 Reagent Probe. The R1 Reagent Probe aspirates from Well 1 first, followed by aspiration from Well 2, then dispenses both reagents into the reaction cuvette at the same time.
P1 (Main Start Time)	Initial absorbance time point. NOTE: The Main Start Time for a 2-Point Rate (2PA) assay must be ≥ 21 seconds. An invalid calculation error displays if the operator enters < 21 seconds.
P2 (Main End Time)	Final absorbance time point.

End Point (EPA) Reaction

Endpoint assays with a D2 reagent delivery:

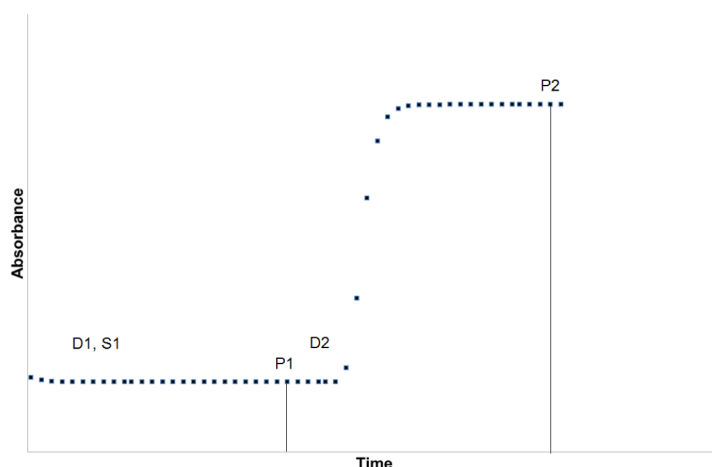
- P1 should be set to 259 seconds.
- R2 delivery occurs at cycle 91 or 273 seconds. The 259 second input defines a 16 second read window prior to the reagent delivery at 273 seconds.

The End Point (EPA) assay format measures absorbance after the reaction or color formation completes. This format uses a sample or initial reagent blank correction (12 seconds) by measuring absorbance prior to the active reaction process. A volume correction factor applies to the sample blank absorbance to account for the differential reaction volume before and after the reagent addition. The blank measurement adjusts the endpoint absorbance measurements. The calculated signal converts to an analyte concentration by mapping to a calibration curve. The analyzer reads reaction absorbance before and after the Main Start Time and Main End Time to calculate the result. Additional reads may occur depending on setup of optional features.

Endpoint assays with a single reagent delivery (End Point (EPA):

- P1 should be set to 0 or 12 for washed-cuvette or reagent filled cuvette blanking respectively.
- The reaction starts after sample addition at 13 seconds after D1.

Absorbance reaction with R2 reagent-initiated endpoint assay



R2-Initiated End Point Assay	Notes
D1 (R1 Reagent)	The Reagent Probe 1 reagent delivery from the P1 pack to the cuvette for testing. Maximum reagent probe dispense volume is 100 µL.
S1 (Sample)	The sample probe delivery from the dilution cuvette to the reaction cuvette. Maximum sample probe dispense volume is 25 µL.
P1 (Main Start Time)	Initial absorbance time point.
D2 (R2 Reagent)	The Reagent Probe 2 delivery from the P2 pack to the cuvette for testing. Maximum reagent probe dispense volume is 100 µL. For assays with > 2 reagents, a second volume addition may exist for the R1 Reagent Probe. The R1 Reagent Probe aspirates from Well 1 first, followed by aspiration from Well 2, then dispenses both reagents into the reaction cuvette at the same time.
P2 (Main End Time)	Final absorbance time point.

About Configuring Operator-defined HIL Calculations on the CH Analyzer

To define a CH Analyzer HIL donor assay, 2 options are available:

- Uses special reagent water that does not require QC or calibration. This assay produces no test result and is for HIL tests only. To define this HIL donor, see (Page 15 *Configuring Operator-defined Donor HIL Assay on the CH Analyzer*).
- Uses donor-specific assay reagents.

The operator defines the HIL donor assay parameters for operator-defined assays in Operator-defined Calculation.

NOTE: If the laboratory enables the Always Order or According to TDef option in HIL Configuration, the system automatically performs HIL processing on all serum and plasma samples (Page 69 *Configuring HIL Ordering*).

The analyzer uses the following wavelengths for the interferents:

Interferent	Absorbance measurement and wavelength
Hemolysis (H)	Blanked, bichromatic measurement at 571 nm and 596 nm. The system corrects for absorption from Lipemia.
Icterus (I)	Blanked, bichromatic measurement at 478 nm and 505 nm. The system corrects for absorption from Lipemia and Hemolysis.
Lipemia (L)	Blanked, bichromatic measurement at 658 nm and 694 nm.

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 71 *Approximate Concentration Ranges for HIL Alert Indices*):

$$H = \text{factor B0} + \text{factor B} * (\text{Hemolysis absorbance} - \text{factor D} * \text{Lipemia absorbance})$$

$$I = \text{factor C0} + \text{factor C} * (\text{Icterus absorbance} - \text{factor E} * (\text{Hemolysis absorbance} - \text{factor D} * \text{Lipemia absorbance}) - \text{factor F} * \text{Lipemia absorbance})$$

$$L = \text{factor A0} + \text{factor A} * \text{Lipemia absorbance}$$

The system determines the HIL concentrations after linear corrections:

$$H \text{ concentration} = H \text{ Intercept} + (H \text{ Slope} * H \text{ index value})$$

$$I \text{ concentration} = I \text{ Intercept} + (I \text{ Slope} * I \text{ index value})$$

$$L \text{ concentration} = L \text{ Intercept} + (L \text{ Slope} * L \text{ index value})$$

The default factors were developed empirically by assaying known concentrations of hemolysate, bilirubin and Intralipid.

Operator-defined HIL Calculations	Notes
Use as HIL Donor (Use as HIL Donor)	Check box to enable the assay as a HIL donor assay.
HIL Scalers	HIL linear correction values.
H Slope	Linear slope correction to the Hemolysis result.
H Intercept	Intercept correction to the Hemolysis result.
I Slope	Linear slope correction to the Icterus result.
I Intercept	Intercept correction to the Icterus result.
L Slope	Linear slope correction to the Lipemia result.
L Intercept	Intercept correction to the Lipemia result.

Operator-defined HIL Calculations	Notes
Alternate HIL Factors	Nine factor values exist for each serum indices measurement: • Factors A, A0, B, B0, C, and C0 are direct calibration factors for the Lipemia, Hemolysis, and Icterus indices, respectively. • Factor D corrects the Lipemia contribution for the Hemolysis indices measurement. • Factor E corrects Hemolysis contribution to the Icterus measurement. • Factor F corrects the Lipemia contribution to the Icterus measurement.
Factor A	Calibration slope fixed factor for the Lipemia indices that relates absorbance to the interferent concentration. The factor is sample dilution dependent.
Factor A0	Calibration intercept for the Lipemia indices that relates absorbance to the interferent concentration. The factor is sample dilution dependent.
Factor B	Calibration slope fixed factor for the Hemolysis indices that relates absorbance to the interferent concentration. The factor is sample dilution dependent.
Factor B0	Calibration intercept for the Hemolysis indices that relates absorbance to the interferent concentration. The factor is sample dilution dependent.
Factor C	Calibration slope fixed factor for the Icterus indices that relates absorbance to the interferent concentration. The factor is sample dilution dependent.
Factor C0	Calibration intercept for the Icterus indices that relates absorbance to the interferent concentration. The factor is sample dilution dependent.
Factor D	Factor that corrects the Lipemia contribution for the Hemolysis indices. It is the ratio of Lipemia absorbance at the Hemolysis wavelength divided by the absorbance of Lipemia at the Lipemia wavelength.

Operator-defined HIL Calculations	Notes
Factor E	Factor that corrects the Hemolysis contribution for the Icterus indices. It is the ratio of Hemolysis absorbance at the Icterus wavelength divided by the absorbance of Hemolysis at the Hemolysis wavelength.
Factor F	Factor that corrects the Lipemia contribution for the Icterus indices. It is the ratio of Lipemia absorbance at the Icterus wavelength divided by the absorbance of Lipemia at the Lipemia wavelength.
Create HIL	Function to define the Operator-defined HIL donor assay using special reagent water.
Discard Changes	Function to discard changes in all Operator-defined configuration windows for an operator-defined assay.
Save Changes	Function to save a new or modified operator-defined HIL donor assay.

About Configuring Operator-defined Assays High-dose Hook Effect on the CH Analyzer

The High-dose Hook Effect is an evaluation for antigen excess that triggers a > Measuring Interval result flag and an auto-dilution if configured for that assay in the Operator-defined High-dose Hook Effect. This feature is not required unless specified in the assay kit specific IFU. All fields are optional.

High-dose Hook Effect	Notes
Enable Hook-effect Check	A check box that enables the High-dose Hook Effect feature.
Hook-effect Formula	Drop-down menu that includes: • Prozone Formula: An absolute absorbance or difference in absorbance within a single reaction. • Rate Method: An evaluation of reaction rates where the operator can enter 1 or 2 regions of the reaction to monitor.
Primary Wavelength Only	Uses the single monochromatic main-wavelength in all Hook Effect calculations.

High-dose Hook Effect	Notes
Hook-effect Limit Type	The operator specifies how the Hook-effect Limit relates to the output from the assay's Hook Effect Check. The drop-down menu includes a limit type: • Upper: An error generates when the Hook-effect Formula result is greater than the Hook-effect Limit. This limit type is for reactions where increasing absorbance is proportional to increasing analyte concentration. • Lower: An error generates when the Hook-effect Formula result is less than the Hook-effect Limit. This limit type is for reactions where decreasing absorbance is proportional to increasing analyte concentration.
Hook-effect Limit	Mandatory if the operator disables Automatic Limit Determination and checks Enable Hook-effect Check. Deactivated when operator enables Automatic Limit Determination. If the formula value exceeds or falls below the Hook-effect Limit, the > Measuring Interval flag triggers. Expected values: -6000–6000 mAU. The operator enters a limit value to trigger the antigen excess flag when the substrate is depleted. If the Hook-effect Limit Type is configured as: • Upper: A Hook Effect Check result greater than this limit triggers the > Measuring Interval flag. • Lower: A Hook Effect Check result below this limit triggers the > Measuring Interval flag.

High-dose Hook Effect	Notes
Evaluation Threshold	Available only when the Hook-effect Formula is Rate Method. Identifies a threshold on the Initial Rate to define when Hook Effect checking is permitted. Suppresses false flags of normal low-analyte samples. This threshold is a check on the initial rate of signal change during the time specified by Initial Window Start Time and Initial Window End Time. The Evaluation Threshold identifies the initial reaction rate that activates the Hook Effect checking.
Evaluation Limit	Optional setting or is this required for 2-Point Rate (2PA). A reaction absorbance or rate limit for the subsequent high-dose hook effect calculations and integrity checks to occur. Specifies the test's final reaction signal value that restricts when the analyzer applies the check. The Hook-effect Limit Type setting controls the relationship between the Evaluation Limit and test's final reaction signal.
Main Window Start Time	The first read time of the main reaction read window for High-dose Hook Effect checking. Acceptable values include: 21, 30, 39, 48, 57, 66, 75, 84, 100, 109, 118, 127, 136, 145, 153, 162, 171, 180, 189, 198, 207, 216, 225, 234, 243, 252, 259, 268, 277, 286, 295, 304, 312, 321, 330, 339, 348, 357, 366, 375, 384, 393, 402, 411, 420, 427, 436, 445, 454, 463, 472, 480, 489, 498, 507, 516, 525, 534, 543, 552, 561, or 570.
Main Window End Time	The last read time of the main reaction read window for High-dose Hook Effect checking. Acceptable values include: No entry, 12, 21, 30, 39, 48, 57, 66, 75, 84, 100, 109, 118, 127, 136, 145, 153, 162, 171, 180, 189, 198, 207, 216, 225, 234, 243, 252, 259, 268, 277, 286, 295, 304, 312, 321, 330, 339, 348, 357, 366, 375, 384, 393, 402, 411, 420, 427, 436, 445, 454, 463, 472, 480, 489, 498, 507, 516, 525, 534, 543, 552, 561, or 570.

High-dose Hook Effect	Notes
Initial Window Start Time	The first read time of the subsidiary or initial read window for High-dose Hook Effect checking. Acceptable values include: No entry, 0, 12, 21, 30, 39, 48, 57, 66, 75, 84, 100, 109, 118, 127, 136, 145, 153, 162, 171, 180, 189, 198, 207, 216, 225, 234, 243, 252, 259, 268, 277, 286, 295, 304, 312, 321, 330, 339, 348, 357, 366, 375, 384, 393, 402, 411, 420, 427, 436, 445, 454, 463, 472, 480, 489, 498, 507, 516, 525, 534, 543, 552, 561, or 570.
Initial Window End Time	The final read time of the subsidiary or initial read window for High-dose Hook Effect checking. Acceptable values include: No entry, 12, 21, 30, 39, 48, 57, 66, 75, 84, 100, 109, 118, 127, 136, 145, 153, 162, 171, 180, 189, 198, 207, 216, 225, 234, 243, 252, 259, 268, 277, 286, 295, 304, 312, 321, 330, 339, 348, 357, 366, 375, 384, 393, 402, 411, 420, 427, 436, 445, 454, 463, 472, 480, 489, 498, 507, 516, 525, 534, 543, 552, 561, or 570.
Automatic Limit Determination	A unique value for each lot and pack calibration. This enables the High-dose Hook Effect to empirically derive a Hook-effect Limit during the calibration process.
Calibration Level	Mandatory selection when Automatic Limit Determination is enabled. The input value defines the single-level source the analyzer uses to set the Hook-effect Limit. The operator enters the number of the calibration level from Operator-defined assay Calibration.
Scaling Factor	A multiplier to adjust the automatically-derived, empirical value from the Automatic Limit Determination process. The default is 1.0 to use the full value (100%) of the Hook-effect Limit without adjustment. NOTE: A Scaling Factor of 0.8 would reduce the applied Hook-effect Limit by a factor of 0.8X or = 80% of the empirically derived number.

About Configuring Operator-defined Assays Calibration on the CH Analyzer

The operator configures Operator-defined assay Calibration in Operator-defined. From Calibration, the operator configures automatic:

- Pack and lot calibration
- Calibration order
- Perform QC with Calibration

Dilution configuration uses separate calibrators. If 5 levels exist, 5 cups are required. Shared cups are not permitted.

When the CH Analyzer saves the assays, the minimum aspiration of the calibrator calculates and displays. The minimum dilution factor is 1 and the maximum is 100.

Calibration	Notes
General	Specimen Type, Standard Curve, Threshold, C1, C4, C0 Adjust, and Semi Quant
Specimen Type	Drop-down menu includes the specimen types configured in Definition Sample area: • Serum • Plasma • Urine • CSF • RBC Hemolysate
Standard Curve	Drop-down menu to select: • Linear • Logit: Requires a minimum of 4 levels configured with a maximum of 6 levels • Logit3: Requires 5 levels configured with a maximum of 6 levels • Qualitative • Fixed Slope: Requires 1 level configured • Multi-Linear: Requires 3 levels configured with a maximum of 6 levels • Spline: Requires 2 levels configured with a maximum of 6 levels (Page 50 About Operator-defined Calibration Standard Curve).

Calibration	Notes
Threshold	Field that displays when Qualitative is selected with Standard Curve or Semi Quant. Semi-quantitative and qualitative assays have a cut-off point that remains constant for each lot of assay reagent. The operator enters the analyte concentration associated with the cut-off. See the assay IFU for the assay cut-off value.
C1	Field that displays when Fixed Slope is selected as the Standard Curve. It is the slope of the calibration curve. See the assay IFU for the assay C1 value.
C4	Field that displays when Logit is selected as the Standard Curve. It is the parameter in the equation describing the Logit curve. Typical values for C4 are 1.0, 0.5, 0.01, or 0.
C0 Adjust	A special type of pack calibration that uses low calibrator or CH Diluent to adjust the cal coefficient for intercept (C0). The operator loads the zero level calibrator or the system automatically prepares and processes a CH Diluent sample. If not checked, the analyzer performs a full calibration during a pack calibration.
Semi Quant	Assays that give the read-out in an approximate fashion rather than an exact number for the quantity of the analyte.
Calibration Interval (Days)	Lot Calibration Interval (Days) and Pack Calibration Interval (Days)
Lot Calibration Interval (Days)	The number of days the Lot Calibration Interval (Days) remains usable.
Pack Calibration Interval (Days)	The number of days before a pack calibration or C0 Adjust is required to correct for reactivity changes in an opened pack well.
Calibrator Onboard Stability (Hours)	The operator specifies the number of hours that an opened calibrator remains stable on the analyzer for Refrigerated and Unrefrigerated conditions.
Refrigerated	If refrigerated, the calibrator onboard stability in hours.
Unrefrigerated	If not refrigerated, the calibrator onboard stability in hours.
Calibrator Levels and Predilution	The number of calibrator levels for the assay. The analyzer requires a minimum of 2 and up to 6 configured levels. The Total Volume is calculated from the defined calibrator volume and the pre-dilution factor entered. Level 1 saline calibrator configured when CH Diluent Only is selected.

Calibration	Notes
Levels	The number of calibrator levels for the assay. The analyzer requires a minimum of 2 and up to 6 configured levels.
Level	Calibration listed by level number. Level limits are 1–6 where 1 is for fixed factor only. Level 1 saline calibrator is configured when CH Diluent Only is selected. Toggle to the required Level using the arrows glyphs.
Weight	The specified weight for each calibration level in the calibration curve. This ensures that each data point has an appropriate level of influence on the final parameter estimates. Weighting lower calibrator levels can improve the curve fit at the low end. Non-negative values required. Unweighted calibration includes all the level weights = 1.0.
Replicates	The operator configures a minimum of 3 and maximum of 5 Replicates. Default is 3.
Dilution Factor	The predilution factor, in combination with the Sample Volume, configures the total volume of diluted calibrator (Page 28 <i>About Operator-defined Primary Sample Delivery and Optimization</i>).
Sample	The calibrator sample in the preparation of a calibrator Level. Allows preparation of independent calibrator levels from a single loaded calibrator sample.
Sample Volume	Volume of calibrator required to create the predilution (Page 28 <i>About Operator-defined Primary Sample Delivery and Optimization</i>).
Total Volume	The volume calculated from the defined calibrator volume and the pre-dilution factor entered.
CH Diluent Only	Level 1 system fluids CH Diluent replaces the need to submit a Level 1 calibrator when selected.
Create New	Function to create a new operator-defined assay.
Create from Existing Assay	Function to copy an existing assay on system to use as a starting point template or when an exact copy of a test definition for a currently defined assay is required. NOTE: Mitigation configuration does not copy.
Cancel	Function to discard changes in all Operator-defined configuration windows for an operator-defined assay.
Save	Function to save a new or modified operator-defined assay.

About Operator-defined Calibration Standard Curve

The Calibration Standard Curve options for Operator-defined assays are as follows:

- Linear
- Logit
- Qualitative
- Logit3
- Fixed Slope
- Multi-Linear
- Spline: not in emulator; removed in SW?

Standard Curve	Formula	Notes
Linear	$Y = C_0 + C_1X$	C_0 and C_1 are updated with each calibration. Initial coefficients are not required. X= analyte concentration.
Logit	$y = C_0 + \frac{C_1}{1 + \left(C_4 + \frac{X}{C_3} \right)^{C_2}}$	Logit calibrations requires a minimum of 4 levels configured with a maximum of 6 levels. C_0–C_3 are updated with each calibration. C_4 is a fixed assay parameter. Typical values for C_4 are 0, 1.0, 0.5, or 0.01. X= analyte concentration.
Qualitative		Single calibrator where the units are qualitative. The curve is a linear fit with a threshold value in qualitative units.
Logit3	$y = C_0 + \frac{C_1}{1 + \exp[-(C_2 + C_3 \ln x + C_4x)]}$	Logit3 calibrations require a minimum of 5 calibrator levels configured with a maximum of 6 levels and cannot be a negative value. C_0–C_4 are updated with each calibration. X= analyte concentration. exp= exponential.

Standard Curve	Formula	Notes
Fixed Slope	$Y = C_0 + FV \times X$	FV (fixed value) is the expected change in absorbance from the reaction of single analyte unit in the reaction cuvette. This value serves as the slope (C1) in a linear equation where reaction of a single calibrator containing no analyte provides a reagent blank (C₀) intercept. FV (fixed value) = C1 or slope of the calibration curve is a unit of absorbance/unit of analyte. An example is mAU per mg/dL. X= analyte concentration. Requires 1 level configured.
Multi-Linear	Equation 1: $C_0 + C_1X$ Equation 2: $C_2 + C_3X$ Equation (N-1) : $C_{N-1} + C_NX$	An N-1 series of linear equations where N = the number of calibrator levels. • If X is between calibrator level 1 and 2, the analyzer uses equation 1. • If X is between calibrator level 2 and 3, the analyzer uses equation 2. • NOTE: The potential number of equations increases from 2 up to 5 based on the number of calibrator levels. If X is between calibrator level N-1 and calibrator level N, the analyzer uses equation N-1. Multi-Linear requires a minimum of 3 calibrator levels configured with a maximum of 6 levels.

Standard Curve	Formula	Notes
Spline	$Y =$ $(S_1(X) = a_1 X^3 + b_1 X^2 + c_1 X + d_1 \text{ if } X_1 \leq X \leq X_2$ $S_2(X) = a_2 X^3 + b_2 X^2 + c_2 X + d_2 \text{ if } X_2 \leq X \leq X_3$ $S_{(n-1)}(X) = a_{(n-1)} X^3 + b_{(n-1)} X^2 + c_{(n-1)} X + d_{(n-1)} \text{ if } X_{(n-1)} \leq X \leq X_n$	The knotted cubic spline is a set of curves (segments) that connect points (knots). The knot points are the assigned values for each calibrator level. Segments are the component pieces of the overall spline curve. Each segment is mathematically defined as a cubic polynomial. Cubic knotted spline: An n-1 series of cubic equations where n = the number of calibrator levels. Requires a minimum of 3 calibrator levels configured with a maximum of 6 levels and reaction signal response cannot be a negative value. Collectively, these polynomial segments are denoted S(X), the spline X = analyte concentration.

About Operator-defined Weighted Calibrations

Ordinary linear least square regression requires all data points to have equivalent imprecision. Imprecision frequency increases with analyte concentration for many Operator-defined assays, especially Immunoassays.

In these cases, weighting forces the regression algorithm to increase emphasis on those data points with lower imprecision, putting less emphasis on data points resulting in greater error.

Weighted regression avoids data points with the greatest uncertainty from influencing the overall curve fit.

The operator can only apply weighted calibrations to assays with 3 or more calibrator levels.

NOTE: Most assays do not require weighting.

An example to determine a weighted calibration:

Cal Level	[Analyte]	SD	VAR (SD ²)	1/VAR	Normalized	Weights
1	0	0.5	0.25	4	4900	5000
2	10	0.7	0.49	2.040816	2500	2500
3	50	3.5	12.25	0.081633	100	100
4	200	14	196	0.005102	6.25	6
5	500	35	1225	0.000816	1	1

To weight a calibration, see (Page 16 *Weighting Operator-defined Calibrations*).

About Reagent Carryover Mitigation for Operator-defined Assays on the CH Analyzer

NOTE: For reagent carryover to and from third party products, where Siemens Healthineers is not the manufacturer, consult the assay kit specific IFU for the appropriate contamination avoidance parameters.

The CH Analyzer automatically rinses before the Operator-defined assay processes then rinses and cleans after it processes. The operator configures the following in Operator-defined Mitigation:

- Conditions for avoiding CH reagent probe and reaction cuvette contamination.
- Type of rinse or wash to prevent reagent carryover contamination from the previous sample.

Mitigation	Notes
Donor Assay	A drop-down menu containing all assays on the analyzer that contain an interfering substance that require mitigation, such as extra rinse or clean before other assay are performed.
Target	The component the analyzer rinses or cleans. The operator selects either Reagent (includes reagent probes and reaction mixers cleaning) or Cuvette from drop-down menu.
Mitigation Reagent	The type of rinse or clean delivered to the Target: • Rinse: With special reagent water. • Clean 1: Cleans with the basic CH Reagent Probe Cleaner 1 (RPC1). • Clean 2: Cleans with the acidic CH Reagent Probe Cleaner 2 (RPC2).
Action	Function to Remove the rinse or cleaning mitigation from an assay.
Add	Function to add carryover mitigation to an existing assay.
Create New	Function to create a new operator-defined assay.
Create from Existing Assay	Function to copy an existing assay on system to use as a starting point template or when an exact copy of a test definition for a currently defined assay is required. NOTE: Mitigation configuration does not copy.
Result Settings	Function to configure or modify the negative test results for an operator-defined assay.
Save	Function to save a new or modified operator-defined assay.
Cancel	Function to discard changes in all Operator-defined configuration windows for an operator-defined assay.

About ADVIA System Read Time Conversion for Operator-defined Assays

The operator must use the appropriate read time conversion when configuring ADVIA® system assays in Atellica Solution Operator-defined.

Action	ADVIA 2400/XPT system (seconds)	CH Analyzer read time (seconds)	ADVIA 1800 system (seconds)	CH Analyzer read time (seconds)
Reagent 1 addition	2	0	0	0
Sample addition	8	12	3	12
Mix 1	20	15	6	15
Reagent 2	282	273	294	273
Mix 2	284	279	300	279

The relative timing of sample and reagent additions is essential when transferring an assay application from an ADVIA system to a CH Analyzer. The operator uses the following table of common conversion values for End Point (EPA) analysis.

ADVIA 1800 system EPA inputs	ADVIA 2400/XPT system EPA inputs	ADVIA system rationale	CH Analyzer EPA equivalent
No subsidiary detection start point (Sub DET.Pp) or endpoint (b DET.Pp)	No Sub DET.Pp or b DET.Pp	Only a Main Detection Endpoint.	Main Start Time= 0 second (uses Washed Cuvette Blank)
Measurement point (DET.Pp) = 45, Sub DET.Pr = 47	DET.Pp = 17, Sub DET.Pr = 19	The last reads before R2 Delivery at approximately 280 seconds.	Main Start Time= 259 seconds (prior to the R2 delivery)
Main detection start point (DET.Pm) = 96; Main detection end point (DET.Pn) = 98	DET.Pm = 37; DET.Pn = 39	The longest time, the last read before Cuvette Wash at approximately 580 seconds.	Main End Time= 570 seconds (last EPA value before Cuvette Washer Probe1)
DET.Pm = A; DET.Pn = B	DET.Pm = A; DET.Pn = B	A read window between the times of cycles A and B.	Main End Time= XXX seconds (creates a read widow centered on the stated end)

The ADVIA 2400/XPT system Operator-defined configuration defines events by reaction cycle which is not common between the systems. The following table translates the ADVIA system cycles to the reaction time (in seconds) convention used by the CH Analyzer which provides a system-independent value of CH Analyzer reaction time (in seconds).

NOTE: The CH Analyzer reaction times relate to the time elapsed after the initial delivery event (D1, 0 seconds) that introduces reagents to the reaction cuvette. The CH Analyzer has a fixed delivery timing of sample (14 seconds) and the D2 delivery (273 seconds).

ADVIA 2400/XPT system event and read cycle reference	ADVIA 2400/XPT system event and read cycle timing (seconds)	CH Analyzer event and read timing (seconds)
Reagent 1	0	0

ADVIA 2400/XPT system event and read cycle reference	ADVIA 2400/XPT system event and read cycle timing (seconds)	CH Analyzer event and read timing (seconds)
Sample	6	14
1,2	14	21
Mix 1	19	17
3	28	21
4	42	39
5	56	48
Reagent 2	58	–
Mix 2	60	–
6	70	66
7	84	84
8	111	109
9	101	100
10	125	118
11	139	136
12	153	153
13	166	162
14	180	180
15	194	189
16	208	207
17	222	216
18	236	234
19	250	243
20	264	259
21	278	268
Reagent 3	280	273
Mix 3	282	275
22	292	286
23	306	304
24	333	330

ADVIA 2400/XPT system event and read cycle reference	ADVIA 2400/XPT system event and read cycle timing (seconds)	CH Analyzer event and read timing (seconds)
25	347	339
26	361	357
27	375	375
28	388	384
29	402	402
30	416	411
31	430	427
32	444	436
33	458	454
34	472	472
35	486	480
36	500	498
37	514	507
38	528	525
39	542	534
40	555	552
41	569	561

The ADVIA 1800 system Operator-defined configuration defines events by reaction cycle which is not common between the systems. The following table translates the ADVIA system cycles to the reaction time (in seconds) convention used by the CH Analyzer which provides a system-independent value of CH Analyzer reaction time (in seconds).

NOTE: The CH Analyzer reaction times relate to the time elapsed after the initial delivery event (D1, 0 seconds) that introduces reagents to the reaction cuvette. The CH Analyzer has a fixed delivery timing of sample (14 seconds) and the D2 delivery (273 seconds).

ADVIA 1800 system event and read cycle reference	ADVIA 1800 system event and read cycle timing (seconds)	CH Analyzer system event and read timing (seconds)
Reagent 1	0	0
Sample	3	14
Mix 1	6	17
1	13	21
2	19	21
3	25	21

ADVIA 1800 system event and read cycle reference	ADVIA 1800 system event and read cycle timing (seconds)	CH Analyzer system event and read timing (seconds)
4	31	30
5	37	30
6	43	39
7	49	48
8	55	48
9	61	57
10	67	66
11	73	66
12	79	75
13	85	84
14	91	84
15	97	84
16	103	100
17	108	100
18	114	109
19	120	118
20	126	118
21	132	127
22	138	136
23	144	136
24	150	145
25	156	153
26	162	162
27	168	162
28	178	171
29	184	180
30	190	189
31	196	189
32	202	198

ADVIA 1800 system event and read cycle reference	ADVIA 1800 system event and read cycle timing (seconds)	CH Analyzer system event and read timing (seconds)
33	208	207
34	214	207
35	220	216
36	226	225
37	232	225
38	238	234
39	244	243
40	250	243
41	256	252
42	262	259
43	268	268
44	274	268
45	280	268
46	286	286 (268)*
47	292	286 (268)*
Reagent 2	294	273
48	298	295
Mix 2	300	275
49	304	304
50	310	304
51	316	312
52	322	321
53	327	321
54	333	330
55	339	339
56	345	339
57	351	348
58	357	357
59	363	357

ADVIA 1800 system event and read cycle reference	ADVIA 1800 system event and read cycle timing (seconds)	CH Analyzer system event and read timing (seconds)
60	369	366
61	375	375
62	381	375
63	387	384
64	393	393
65	403	402
66	409	402
67	415	411
68	421	411
69	427	427
70	433	427
71	439	436
72	445	445
73	451	445
74	457	454
75	463	463
76	469	463
77	475	472
78	481	480
79	487	480
80	493	489
81	499	498
82	505	498
83	511	507
84	517	516
85	523	516
86	529	525
87	535	534
88	541	534

ADVIA 1800 system event and read cycle reference	ADVIA 1800 system event and read cycle timing (seconds)	CH Analyzer system event and read timing (seconds)
89	546	543
90	552	552
91	558	552
92	564	561
93	570	570
94	576	570
95	582	579

* The operator uses the 268 value when there is a read before the addition of Reagent 2. If there is no addition of Reagent 2, then the operator uses 286.

About Operator-defined Negative Results

The operator configures Operator-defined negative results on existing assays by selecting **Result Setting** in Operator-defined (Page 19 *Configuring Negative Operator-defined Test Results*).

Operator-defined Negative Result Reporting Options	Notes
Report a negative result as Error	Configured when a test result is negative and reports as "error."
Report the negative value	Reported as a negative number if within the Measuring Intervals. Any negative results reports with the Less than Zero flag. NOTE: For the CH Analyzer to report negative Operator-defined test results, the lower range of the Measuring Intervals must be a negative number.

Atellica CH Analyzer Operator-defined Related Procedures

This section provides procedures included in the Operator-defined workflow topic that are common to the system.

Filling Empty CH Reagent Packs

For Atellica Alliance Application supported assay reagents or Operator-defined defined assays that do not share reagent packs with commercial assays, transfer the reagent into an empty Atellica CH reagent pack then load on the CH Analyzer prior to testing.

NOTE: For reagent preparation, storage information, and full product details, refer to the assay IFU or application sheet.

Use only liquid reagents as no onboard preparation is available.



WARNING

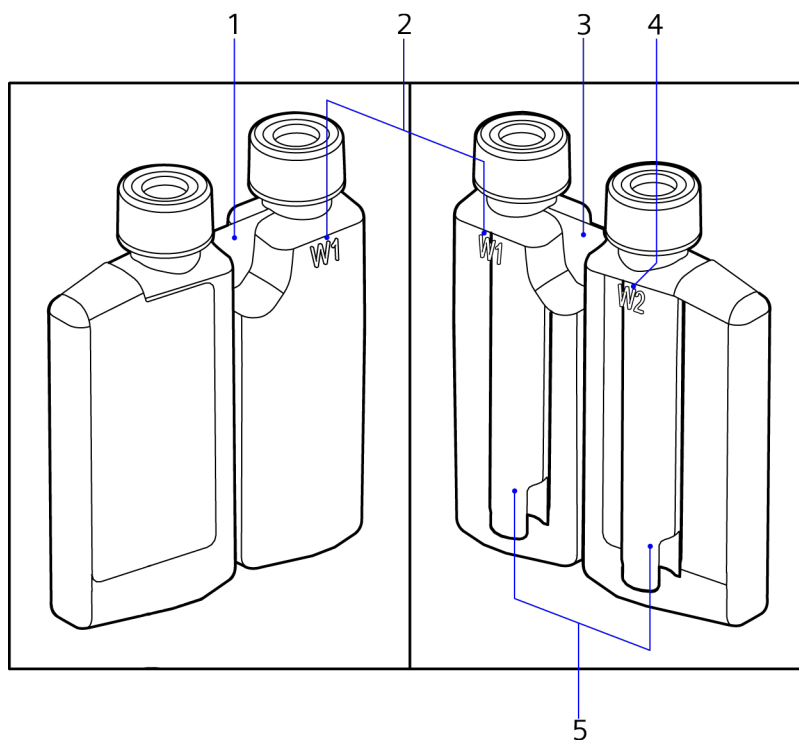
Do not handle chemicals without wearing protective equipment, including gloves, laboratory coat, and safety glasses or a protective face shield. Handling chemicals without proper personal protective equipment can cause injury.



BIOHAZARD

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

1. Locate new Atellica CH empty packs, P1 and P2, if appropriate.



- | | |
|---|----------------------------------|
| 1 | CH reagent pack, without chimney |
| 2 | Well 1 |
| 3 | CH reagent pack with chimney |
| 4 | Well 2 |
| 5 | Chimney inside reagent pack |

2. Fill the Atellica CH empty pack wells with the appropriate volume of reagent.

NOTE: Use a volumetric pipet when filling Atellica CH empty packs. Over or underfilled packs may generate system errors.

To avoid system errors, packs must be filled within ± 0.5 mL of the stated fill volume:

- For Atellica Alliance Application assay, in assay application sheet.
- For Operator-defined assay, in Sample/Reagent of Setup Operator-defined.

3. To fill P1 packs:
 - a. Remove Well 1 cap and transfer the prepared reagent into the pack.
 - b. Replace and hand-tighten the cap.
 - c. If appropriate, remove Well 2 cap and transfer the prepared reagent into the pack.
 - d. Replace and hand-tighten the cap.
4. If appropriate, fill P2 packs by repeating step a–d.
5. Load the operator-defined reagent packs (Page 62 *Loading Operator-filled Atellica CH Empty Reagent Packs*).

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

Loading Operator-filled Atellica CH Empty Reagent Packs

Atellica Alliance Application supported assay reagents are packaged as a Siemens Healthineers Syva or BN assay kit or a third party kit that Siemens Healthineers distributes. CH Test Definition includes these assays. The operator must transfer the reagent into an Atellica CH empty pack, and then load on the analyzer prior to testing.

For Operator-defined defined assays that do not share reagent packs with commercial assays, transfer the reagent into an Atellica CH empty pack then load on the CH Analyzer prior to testing.

For reagent preparation, storage information, and full product details, refer to the assay IFU. Hand-tighten the pack before loading onboard the analyzer.

NOTE: Use a volumetric pipet when filling Atellica CH empty packs. Over or underfilled packs may generate system errors.

To avoid system errors, packs must be filled within ± 0.5 mL of the stated fill volume:

- For Atellica Alliance Application assay, in assay application sheet.
- For Operator-defined assay, in Sample/Reagent of Operator-defined.



BIOHAZARD

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

1. Fill the appropriate Atellica CH empty packs (Page 60 *Filling Empty CH Reagent Packs*).
2. Load the filled reagent packs on the CH Analyzer:
 - a. Open the reagent tray lid.
 - b. Insert up to 6 reagent packs.
 - c. Close the reagent tray lid.

NOTE: When the reagent tray lid closes, the gripper scans the packs and identifies the operator-defined reagent pack as Undefined.



CAUTION

Do not open the reagent tray lid after loading the reagent packs. Opening the lid erases all configured operator-defined information.

3. Select **Assign**.
4. From the Select Assay drop-down menu, select the appropriate assay.

5. To choose an existing lot:
 - a. From the drop-down menu, select the Lot.
 - b. Verify the Lot Expiration.
 - c. Select **OK**.
6. To enter a new lot:
 - a. Select **New Lot**.
 - b. Enter the Lot and Lot Expiration.
 - c. Select **OK**.
7. Review Reagent Loader and resolve any issues.

Calibrating CH Assay Reagent Workflow



BIOHAZARD

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CAUTION

Do not reuse calibrator tubes after removing them from the Cal-QC storage area and storing them offline. Reusing removed calibrator tubes results in a false onboard stability that may cause unwarranted calibration troubleshooting if a calibration fails.

1. Ensure the following items are on the system:
 - Assay 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.

Manually Adding CH Calibrator Definitions

1. Navigate to **Calibrator Definitions**.
2. Select **Add New**.
3. From the Assay Type drop-down menu, select **Chemistry**.
4. In Material Name, enter a name for the calibrator definition.
5. In Material ID, enter the ID from the calibrator lot-specific value sheet.

NOTE: The Material ID is an optional field that contains 1 or 2 alphanumeric characters. The calibrator lot-specific value sheet specifies the Material ID.

6. In Lot ID, enter the calibrator lot.
7. In Expiration Date, select the calibrator material expiration date from the drop-down calendar.
8. In Revision, enter the revision number from the calibrator lot-specific value sheet.
9. If storing the calibrator in the Cal-QC storage area, select **Store Onboard**.

NOTE: Some CH calibrator material is not eligible for onboard storage in the Cal-QC area. The operator cannot select Store Onboard and save a calibrator definition that includes an assay that is not eligible for onboard storage.

Load calibrator samples directly into the SH drawer for processing.

10. To enable the calibrator material for calibration, select **Active**.
11. Select 1 or more assays associated with the calibrator material.
12. Enter the concentration values for each level from the calibrator lot-specific value sheet.
13. Select **Save**.

NOTE: Some assays require calibrator material levels with a different Material ID, Lot ID, or Expiration Date (*Manually Adding CH Calibrator Definitions with Different Material ID, Lot ID, or Expiration Date*).

Performing Quality Control



BIOHAZARD

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



CAUTION

Do not use barcode labels from 1 lot of QC material for another lot of QC material. 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 QC material tests:
 - Assay master curve, for IM only
 - Test definition
 - Assay calibration
 - Assay reagent
2. Enter the QC definitions for all required levels (*Manually Adding QC Definitions*).
3. Create a QC order (*Creating QC Orders*).
4. If appropriate, place the QC material barcodes on tubes (*Printing QC Material Barcodes*) then add the appropriate QC material levels.

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

5. Place the QC material samples in a sample rack and place the rack in the sample drawer.

NOTE: To process the QC material samples immediately, place the tubes in a STAT rack.
6. Review the QC results.

Loading Samples into SH Racks

**BIOHAZARD**

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

**CAUTION**

Do not fill sample containers past the maximum recommended level of 1 container diameter below the top of the container (for example, the maximum fluid height for a 16 mm diameter container is 16 mm from the top of the container). Overfilling sample containers may cause splashing while the container moves in the SH or on the Atellica Magline® Transport. Fill sample containers to no more than the maximum recommended level.

NOTE: If the system does not include a Decapper, remove caps from sample containers before loading the containers in racks.

1. Place 1 or more sample containers in the appropriate type of rack.
 - For immediate processing, place STAT samples in a STAT rack.
 - Place routine samples in a routine rack.
 - Place false-bottom tubes in a special False-Bottom Tube rack.



CAUTION

Do not load false-bottom sample containers in any rack other than a specifically designated special rack for false-bottom sample container use. Placing the sample containers in a rack other than the special rack may result in damage to the system if the probe impacts the sample container bottom.

2. Ensure all sample containers are fully seated to the bottom of the rack.



CAUTION

Do not open or close the sample drawer without using caution. Opening or closing the sample drawer too quickly or forcefully can damage the drawer self-closing mechanism or cause splashing of the samples. Open or close the sample drawer slowly. Contact the local technical support provider if the self-closing mechanism is damaged.

3. Load the appropriate racks in a sample drawer (*Loading Racks into SH Drawers*):
 - a. Load the rack with patient samples in the appropriate sample drawer position.
 - b. Load 1 or more empty routine racks in an appropriate output area or sort area in a sample drawer.

Loading Sample Racks on the DL



BIOHAZARD

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



CAUTION

Do not fill sample containers past the maximum recommended level. Overfilling sample containers may cause splashing while the container moves in the entry and exit queues. Fill pour-off tubes no more than 1 container diameter below the top of the container or sample containers to the manufacturer-recommended max fill level.

1. Place sample tubes in the appropriate sample rack and positions.
2. Load the sample rack in the entry queue.

NOTE: Place STAT samples in racks in the front of the entry queue.

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 (*Mixing IM Reagent Packs*).



BIOHAZARD

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

1. Navigate to **Reagent Overview**.

2. If appropriate, filter by Reagent Type and Pack Status.
3. In Select a Module:, select the appropriate analyzer from the drop-down menu.
4. Select appropriate reagent packs.
5. Select **Unload**.
6. Check the status of the appropriate reagent packs from step 4 in Reagent Loading before opening the reagent tray lid or drawer.
7. Open the reagent tray lid or drawer.
8. Remove the reagent packs from the reagent tray.
9. If the reagent pack is pierced and intended for reuse, cover the pierced film area of the pack with self-sealing laboratory film.
10. Store useable reagent packs according to the assay IFU.

Setting Print Options

1. In the appropriate area, select .
2. In Print Type, select 1 of the following:
 - Report
 - Screen Capture
3. Select options in the Print Options:
 - Select Send to Printer or Save to File (not encrypted).
 - Verify the printer Name.
 - If appropriate, select a Paper Size.
 - To change the print properties such as color and duplex printing, select **Properties**.
4. Select a number of Copies.
5. In Page Range, select to print All pages or a specific range of pages.
6. To view the report before it prints, select **Print Preview**.
7. To print the report, select **Print > OK**.

Viewing CH Reaction Curves

NOTE: Only available for CH tests.

1. To view all reaction points on the reaction curve to troubleshoot an assay, enable Kinetic Mode in the Test Definition of the appropriate assay (*Enabling or Disabling Kinetic Mode in CH Test Definition*).

NOTE: The Kinetic Mode puts additional stress on the database. The laboratory should disable this setting after Troubleshooting the appropriate assays. The system flags all results for an assay in Kinetic Mode as Investigational.

2. Navigate to **Worklist**.
3. In View By, select **Tests**.
4. To narrow the displayed samples, filter the list (*Filtering Worklist Overview*).

5. To sort the list, select an option from the Sort By filter or select a column header.
NOTE: Select the same column header a second time to reverse the sort order.
6. Select the appropriate test name.
7. Select **Curves**.
8. To graph wavelength values, select wavelengths check boxes.
9. To exit the window, select **Close**.

Performing Move to Historical

1. Select **Maintenance > All Activities**.
2. From the Filters Module drop-down menu, select **System**.
3. Select **Move to Historical > Perform > Yes**.
4. Wait 5–10 minutes for Move to Historical to complete.

NOTE: Maintenance Log records and stores this activity.

Deleting Assays from Calibrator Definitions



CAUTION

Do not delete any IM Assays in the calibrator lot-specific value sheet. This can cause a checksum error.

1. Before adding assays to an existing Calibrator Definition, remove the calibrator samples associated with the Calibrator Definition from the Cal-QC Storage Area.
2. Navigate to **Calibrator Definitions**.
3. To remove existing filters, select  from the Filter area.
4. To view a calibrator definition for an assay, select a definition from the Assays drop-down menu.
5. To view calibrations with a specific status, select a definition from the Status list.
6. Select a calibrator definition.
7. Select **Edit**.
8. To delete an assay from the calibrator definition, select the  adjacent to the assay.
9. Select **Save**.
10. Restore the calibrator samples associated with the Calibrator Definition to the Cal-QC Storage Area (*Loading Calibrator and QC Materials*).

Deleting Assay Reagent Calibration Orders in Calibration Results

1. Navigate to **Calibration Results**.
2. To limit the number of calibrations that display, use the Calibration Results Filter (*Filtering Calibration Results*).
3. Select the calibration order to delete.

NOTE: To delete the Calibration Order, the status must be Ordered.

4. Select **Delete Order**.
5. To delete and cancel the order, select **Yes**.

NOTE: The system cannot delete completed orders.

Creating Assay Reagent Lot Calibration Orders

1. Navigate to **Calibration Orders**.
2. Select by **Assay** or **Material**
3. Select an analyzer.
4. Select an assay or material.
5. Select a reagent.
6. In Type to Run, select **Lot**.
7. Select a material.
8. Select **Next**.
9. Select **Place Order**.
10. To schedule the calibration order, select **Place Order**.
11. Select **OK**.

Editing QC Definitions

This task requires the appropriate security level.

NOTE: Before editing an existing QC definition, remove the QC Material samples associated with the QC definition from the Cal-QC Storage Area.

1. Navigate to **QC Definitions**.
2. Select the appropriate check box for Material Name for the QC definition to edit.

NOTE: The operator cannot edit a QC definition if an open or scheduled QC order exists for the QC Material or if the QC definition is included in a QC panel.
3. Select **Edit/View**.
4. Make all appropriate edits.
5. Select **Save**.
6. Return the QC Material samples associated with the QC definition to the Cal-QC Storage Area.

Configuring HIL Ordering

This task requires the appropriate security level (*Access Levels in General Setup*).

1. Navigate to **HIL Configuration**.

2. In HIL Ordering area, select 1 of the following mode settings:
 - To require the operator to manually order HIL tests, select **Manual HIL**.
 - To automatically order HIL tests on all patient orders, select **Always Order**.
 - To automatically order HIL tests using the settings in the assay Test Definition, select **According to TDef**.
3. Select **Save**.

Enabling HIL Donor Assays

This task requires the appropriate security level (*Privileges in Account Settings*).

1. Ensure the system is in 1 of the following states (*Changing System State*):
 - Stopped
 - Off
 - Maintenance
 - Diagnostics
2. Ensure the intended donor assay is enabled on the system (*Enable Disable Test Defs*).
3. Navigate to **HIL Configuration**.
4. To enable all donor assays in the list, in HIL Donor Configuration toggle **HIL using Donor** to on and select the **Select as Donor** check box.
5. To enable a subset of donor assays, select the check box for 1 or more assays from the assay list.
6. Select **Save**.
7. Ensure the donor test are ordered using the default x1 dilution (*Patient Test Orders*).

NOTE: The operator can enable and set donor assay priority at the same time (Page 70 *Configuring Donor Assay Priority at HIL Donor Configuration*).

Configuring Donor Assay Priority at HIL Donor Configuration

This task requires the appropriate security level (*Privileges in Account Settings*).

1. Ensure the system is in 1 of the following states (*Changing System State*):
 - Stopped
 - Off
 - Maintenance
 - Diagnostics
2. Navigate to **HIL Configuration > HIL Donor Configuration**.
3. Turn the HIL using Donor toggle on.
4. Select the row of any donor assay.
5. Select  or  until assays are in priority order.
6. Select **Save**.

NOTE: The operator can enable and set donor assay priority at the same time (Page 70 *Enabling HIL Donor Assays*).

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.

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>)
Using this CH Analyzer Operator-defined Assays Operator's Guide Supplement	(Page 6 <i>Using this CH Analyzer Operator-defined Assays Operator's Guide Supplement</i>)
About Document Library	(Page 6 <i>About Document Library</i>)
Accessing the Operator's Guide and CH Analyzer Operator-defined Operator's Guide Supplement	(Page 7 <i>Accessing the Operator's Guide and CH Analyzer Operator-defined Operator's Guide Supplement</i>)
Accessing Product Information in the Document Library	(Page 7 <i>Accessing Product Information in the Document Library</i>)
Atellica CH Analyzer Operator-defined Assay Configuration Procedures	(Page 7 <i>Atellica CH Analyzer Operator-defined Assay Configuration Procedures</i>)

Topic	Link
Adding CH Operator-defined Assays Work-flow	(Page 8 <i>Adding CH Operator-defined Assays Workflow</i>)
Configuring Operator-defined Assays	(Page 9 <i>Configuring Operator-defined Assays</i>)
Configuring Definition for Operator-defined Assays	(Page 9 <i>Configuring Definition for Operator-defined Assays</i>)
Configuring Sample/Reagent for Operator-defined Assays	(Page 10 <i>Configuring Sample/Reagent for Operator-defined Assays</i>)
Configuring Operator-defined Assays Calculation	(Page 11 <i>Configuring Operator-defined Assays Calculation</i>)
Configuring Operator-defined Assays End Point (EPA) Calculation	(Page 11 <i>Configuring Operator-defined Assays End Point (EPA) Calculation</i>)
Configuring Operator-defined Assays 2-Point Rate (2PA) Calculation	(Page 12 <i>Configuring Operator-defined Assays 2-Point Rate (2PA) Calculation</i>)
Configuring Operator-defined Assays Linear Reaction Rate (RRA) Calculation	(Page 12 <i>Configuring Operator-defined Assays Linear Reaction Rate (RRA) Calculation</i>)
Configuring Operator-defined Assays High-dose Hook Effect Calculation	(Page 13 <i>Configuring Operator-defined Assays High-dose Hook Effect Calculation</i>)
Configuring Operator-defined Assays Calibration	(Page 15 <i>Configuring Operator-defined Assays Calibration</i>)
Changing Operator-defined Assay Calibration Curve	(Page 17 <i>Changing Operator-defined Assay Calibration Curve</i>)
Configuring Mitigation for Operator-defined Assays	(Page 17 <i>Configuring Mitigation for Operator-defined Assays</i>)
Configuring Negative Operator-defined Test Results	(Page 19 <i>Configuring Negative Operator-defined Test Results</i>)
Copying Existing Operator-defined Assays	(Page 19 <i>Copying Existing Operator-defined Assays</i>)
Printing Operator-defined Assay Test Definition	(Page 20 <i>Printing Operator-defined Assay Test Definition</i>)
Modifying Existing Operator-defined Assays	(Page 20 <i>Modifying Existing Operator-defined Assays</i>)
Deleting Existing Operator-defined Assays	(Page 20 <i>Deleting Existing Operator-defined Assays</i>)
Discarding New Operator-defined Assays Before Saving	(Page 21 <i>Discarding New Operator-defined Assays Before Saving</i>)

Topic	Link
Atellica CH Analyzer Operator-defined Features	(Page 21 <i>Atellica CH Analyzer Operator-defined Features</i>)
About CH Operator-defined Assays	(Page 21 <i>About CH Operator-defined Assays</i>)
About Operator-defined Primary Sample Delivery and Optimization	(Page 28 <i>About Operator-defined Primary Sample Delivery and Optimization</i>)
About Operator-defined Reagent Pack Holders	(Page 30 <i>About Operator-defined Reagent Pack Holders</i>)
About Configuring Operator-defined Assays Calculation and HIL on the CH Analyzer	(Page 30 <i>About Configuring Operator-defined Assays Calculation and HIL on the CH Analyzer</i>)
About Configuring Operator-defined Assays Calculation on the CH Analyzer	(Page 30 <i>About Configuring Operator-defined Assays Calculation on the CH Analyzer</i>)
About Configuring Operator-defined Assays High-dose Hook Effect on the CH Analyzer	(Page 43 <i>About Configuring Operator-defined Assays High-dose Hook Effect on the CH Analyzer</i>)
About Configuring Operator-defined Assays Calibration on the CH Analyzer	(Page 47 <i>About Configuring Operator-defined Assays Calibration on the CH Analyzer</i>)
About Operator-defined Calibration Standard Curve	(Page 50 <i>About Operator-defined Calibration Standard Curve</i>)
About Operator-defined Weighted Calibrations	(Page 52 <i>About Operator-defined Weighted Calibrations</i>)
About Reagent Carryover Mitigation for Operator-defined Assays on the CH Analyzer	(Page 53 <i>About Reagent Carryover Mitigation for Operator-defined Assays on the CH Analyzer</i>)
About ADVIA System Read Time Conversion for Operator-defined Assays	(Page 54 <i>About ADVIA System Read Time Conversion for Operator-defined Assays</i>)
About Operator-defined Negative Results	(Page 60 <i>About Operator-defined Negative Results</i>)
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