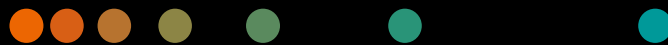


Atellica[®] Solution

Advanced Operator

Training Workbook



Siemens Healthineers

Atellica Solution

Advanced Operator Training Workbook



©2023 Siemens Healthineers. All rights reserved.

Table of Contents

- 1: Welcome
- 2: Functional Overview
- 3: IMT Assay Troubleshooting
- 4: CH Assay Troubleshooting
- 5: IM Assay Troubleshooting
- 6: Event Log and Operator Diagnostics
- 7: SH Hardware Troubleshooting
- 8: CH Hardware Troubleshooting
- 9: IM Hardware Troubleshooting
- 10: Software Troubleshooting
- 11: Restart vs. Reboot
- 12: Appendix

1 Welcome

Welcome to Training

Siemens Healthineers would like to welcome you to training on the Atellica Solution. This course is designed to teach you the skills needed to troubleshoot and maintain the Atellica Solution. Our staff welcomes the opportunity to present this training program to you.

Training Material

This training workbook includes an agenda, learning objectives, troubleshooting procedures, and practical exercises.

Atellica Solution Advanced Operator Training

Course Objectives

Upon completion of the class, you will be able to:

- Describe the functional overview of CH/IMT/IM modules
- Describe different CH calibration types
- Describe IM assay principles
- Process calibrations and QC for CH and IM modules
- Distinguish between manually and automatically ordering calibration and QC
- Identify corrective actions to resolve calibration and QC issues
- Interpret Event Log and Utilize Operator Diagnostics
- Utilize Online Help to identify troubleshooting procedures
- Perform as needed maintenance tasks for SH, IMT, CH, and IM modules
- Resolve common hardware issues for SH, VMM, IMT, CH, and IM modules
- Resolve common software issues
- Differentiate steps and scenarios to Restart/Reboot the analyzer

Atellica Solution Advanced Operator Training

Agenda

Day 1

- Introductions
- Functional Overview
- Configurations
- Resources
- Assay Troubleshooting

Day 2

- Morning Review
- Software/Hardware Troubleshooting
- As Needed Maintenance

Day 3

- Morning Review
- Troubleshooting Exercises
- Restart vs. Reboot

Atellica Solution Advanced Operator Training

Training Center Safety Information

While you are at the Training Center, please follow these safety practices:

- Always wear your name badge.
- In the event of a fire alarm, stop work immediately and leave the building through the nearest exit. Instructors will discuss the evacuation route.
- Note the location of the fire extinguisher.
- Use the eyewash located near the sink if you should happen to get anything in your eye(s). Report any injury to the instructor.
- Carefully read the warnings, cautions, and notes in the guides and manuals.
- Eating and drinking are not allowed in the instrument area of the classroom.
- You must wear laboratory coats and gloves which are provided. Do not wear these garments outside the classroom.
- Use safety glasses when operating the instrument or preparing samples.
- Dispose of waste materials appropriately:
 - Biohazard Waste: Wastebaskets with red plastic liners
 - Paper Waste: Wastebaskets with clear plastic liners
- Wash your hands before leaving the classroom and after removing your gloves.

Atellica Solution Advanced Operator Training

Course Validation Checklist

The participant places a checkmark beside the competency when it is completed. When all competencies are checked, participant signs and dates below as record of completion.

Topics	Competencies	Completed
Functional Overview	Describe the functional overview of SH module	
	Describe the functional overview of CH module	
	Describe the functional overview of IM module	
Assay Troubleshooting	Review Lot and Pack calibration for CH and IM modules	
	Identify IM Assay Principles	
	Process, review, and troubleshoot calibration and QC orders	
	Analyze calibration and QC troubleshooting scenarios	
Event Log	Utilize the Event Log and Operator Diagnostics to troubleshoot	
	Identify troubleshooting procedures by utilizing Online Help	
Hardware Troubleshooting	Perform As Needed maintenance for SH, CH, IMT and IM modules	
	Troubleshoot common SH, VMM, IMT, CH, and IM hardware issues	
Software Troubleshooting	Troubleshoot common software issues	
Restart and Reboot	Review the steps to perform PCC restart	
	Review the steps to perform a module shutdown	
	Review the steps to perform a full system shutdown	
	Use PEP Rebooting Job aid to discuss restart and rebooting scenarios	

Atellica Solution Advanced Operator Training

Instructor: _____

Participant: _____

Date: _____

What was most helpful to you during this program?

How can we improve this program to make it more meaningful to you?

2 Functional Overview

2 Functional Overview

Resources

- Online Help
- PEPconnect

Objective

Upon completion of this exercise you will be able to:

- Describe the functional overview of SH, CH, IMT, and IM modules

CH Functional Overview

1. Diluted sample is transferred into a dilution cuvette on the dilution ring, and then mixed.
2. The first reagent is transferred into a reaction cuvette on the reaction ring.
3. An aliquot of diluted sample is transferred into the reaction cuvette containing the first reagent. The remaining diluted sample in the dilution cuvette can be used for additional tests on an order.
4. The first reagent and diluted sample are mixed.
5. The second reagent (if necessary) is transferred into the reaction cuvette containing the first reagent and the diluted sample.
6. The diluted sample and both reagents are mixed.
7. The reaction takes place for the amount of time designated in the assay.
8. The absorbance data is read by the photometer.



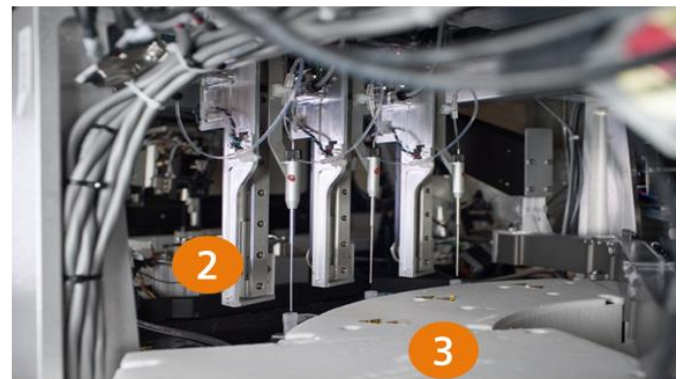
IMT Functional Overview

1. Standard A solution is pulled through the IMT cartridge.
2. The potential difference is measured between each of the 3 analytes in the Standard A solution and the reference.
3. Air and fluidic segments of Standard A are pulled into the IMT cartridge to both clean and prepare the sensor chip for sample measurement.
4. IMT diluent is pulled through the IMT cartridge.
5. The dilution probe transfers sample from a sample tube and then water into the IMT port.
6. The mixed sample is pulled through the IMT cartridge.
7. The system measures the potential difference between each of the 3 analytes in the sample and the reference.
8. The system uses an algorithm to convert the potential differences into ion concentrations and reports this value.



IM Functional Overview

1. Sample is transferred into the cuvette.
2. Primary and ancillary reagent are transferred into the cuvette.
3. The cuvette incubates in the incubation ring.
4. The paramagnetic particles (PMPs) in the cuvette are washed in the wash ring.
5. Acid and base are dispensed into the cuvette (*not shown in images below).
6. The photomultiplier tube (PMT) takes the chemiluminescent measurement.
7. Liquid waste is removed from the cuvette.
8. The cuvette falls into the solid waste bin.



Functional Overview Notes

3 IMT Assay Troubleshooting

3 IMT Assay Troubleshooting

Resources

- Online Help
- PEPconnect

Objectives

Upon completion of this exercise, you will be able to:

- Describe IMT calibration
- Identify and troubleshoot failed IMT Calibrations
- Discuss IMT troubleshooting scenarios

IMT Calibration

- The system performs 2-point calibration using Standard A and Standard B.
 1. The system pumps Standard A through the sensor cartridge and takes voltage readings from the Na⁺, K⁺, and Cl⁻ sensors.
 2. Standard B is pumped through the sensors, and a second set of readings is taken.
 3. The difference in readings between Standards A and B at each electrode is used to calculate the calibration slope.
- To determine whether calibration was successful, the system compares these slope values to the acceptable slope ranges.
- Standard A is performed as confirmation of the 1-point calibration prior to each sample measurement.
- Standard A is used as a rinse solution for the IMT port.
- If the two-point auto calibration fails, the system will retry calibration 2 more times.

SIEMENS Healthineers Atellica® Solution Version 1.20.0.3399001

System Samples Inventory Calibration QC Patient

Calibration Overview Create Calibration Orders Calibration Results Calibrator Definitions **IMT Calibration**

IMT Calibration completed at: 10/04/2019 7:45:26 AM

	Ion	Slope	STD A	STD B	Slope Ranges
✓	Na+	52.66	65.1671 mV	49.6902 mV	50 to 63
✓	K+	60.88	-34.8632 mV	36.7416 mV	50 to 63
✓	Cl-	-41.32	62.1716 mV	54.4409 mV	-60 to -40
✓	Air Reading		0.9553 V	1.0397 V	
✓	Liquid Reading		0.1102 V	0.1002 V	
✓	IMT Pumping Rate		61.33 µl per Revolution		

IMT Status IMT Calibration Completed

IMT Calibration

For IMT assays, the analyzer measures sodium (Na⁺), potassium (K⁺), and chloride (Cl⁻) ions in a sample through using potentiometry methodology.

The CH Analyzer uses a 2-point calibration to automatically calibrate the IMT at:

- System startup
- System reset from a paused or stopped state
- 4-hour intervals
- 250 tests have been completed since the last calibration
- A-LYTE sensor temperature changes outside of specifications
- IMT successful error recovery
- IMT cleaning procedure
- A-LYTE multisensor, Standard A, or Standard B replacement
 - The operator can also manually calibrate the IMT subsystem if needed during troubleshooting.
 - The materials used for IMT calibration are the IMT fluids (Standard A and Standard B).
 - During IMT calibrations, the system does not process IMT tests.

Manually Calibrating IMT

The system will automatically calibrate the IMT.

If there is a need to manually calibrate:

1. On the Command Bar, select Calibration.
2. Select the IMT Calibration tab.
3. Select Calibrate IMT.

IMT Calibration Error at: 9/7/2017 8:52:54 AM

	Ion	Slope	STD A	STD B	Slope Ranges
✓	Na+	59.02	2.9199 mV	-14.4271 mV	The IMT is not configured on the analyzer.
⚠	K+	-15.35	-33.2082 mV	-51.2559 mV	The IMT is not configured on the analyzer.
⚠	Cl-	83.08	54.0064 mV	69.5494 mV	The IMT is not configured on the analyzer.
✓	Air Reading		1.2 V	1.2 V	
✓	Liquid Reading		0.23 V	0.234 V	
✓	IMT Pumping Rate		30.03 µl per Revolution		

IMT Status IMT Calibration Finished

IMT Calibration Troubleshooting

If auto-calibration fails during three consecutive attempts, the module will go offline, and an error will be generated. Perform the following:

1. Try another calibration series
2. Prime IMT fluids
3. Perform IMT maintenance
4. Replace system fluids and the IMT sensor

Note: Refer to Online Help for more information on IMT troubleshooting.

	Events/Errors	Corrective Actions
IMT Calibration failure	Check Operator Event log for Supplies related warnings or errors. Check Inventory – Supplies Overview for Low and empty system fluids	Verify IMT system fluids are not empty and properly seated
	Check Inventory – Supplies Overview for Multisensor OBS	Ensure OBS of system fluids and Multisensor
	N/A	Prime All IMT System Fluids
	Check Operator Event log for peristaltic pump errors.	Check peristaltic pump tubing
	N/A	Recalibrate IMT
	Check Operator Event log for related warnings or errors. Utilize Event Help to troubleshoot accordingly	Determine which IMT calibration parameters have failed (i.e. Pump Rate, Slope, or Air Reading? – Refer to OLH for corrective actions on each parameter failure.
	IF IMT Advanced Clean is due, an alert will come up when “Replace IMT Fluids” is selected.	Perform IMT Advanced Clean
	N/A	If issue persists, contact technical support

When Advanced Clean is not performed prior to sensor replacement, it may cause the following complications:

- Shortened sensor use life
- Calibration errors leading to premature sensor change
- Potassium Drift errors leading to premature sensor change
- Imprecision
- QC accuracy shifts, especially for high or low levels

IMT Troubleshooting Scenarios

Scenario #1

A newly trained operator was replacing IMT system fluids on a working IMT system. The operator realized the calibration failed all parameters after replacing system fluids. What do you think went wrong?

Cause:

Resolution:

Scenario #2

IMT fails to calibrate. Upon investigation, you observe that everything passed except your Chloride. What are the next steps you can take to troubleshoot this issue?

Cause:

Resolution:

Scenario #3:

Your IMT fails to calibrate. You have primed the IMT System Fluid 3x and ordered a manual calibration and the calibration still fails. Earlier that day, a co-worker changed the A-Lyte Diluent in the system. What are the next steps you can take to troubleshoot this issue?

Cause:

Resolution:

IMT Assay Troubleshooting Notes

4 CH Assay Troubleshooting

4 CH Assay Troubleshooting

Resources

- Online Help
- PEPconnect

Objectives

Upon completion of this exercise you will be able to:

- Describe CH calibration types
- Identify and troubleshoot CH calibration and QC orders
- Discuss CH troubleshooting scenarios

CH Calibration Overview

- The CH Analyzer uses photometric technology to measure the light absorbance of samples.
- The analyzer allots approximately 10 minutes of incubation time from the start of sample addition.
- The photometer reads the absorbance data approximately once every 9 seconds and reports results in MAU (milli absorbance units).
- Calibration reports identify the method, the reagent lot, the reagent well and the module.

CH Calibration Types

1. Linear
 - 2-point calibration (low and high)
 - Example: Mg
2. Non-Linear
 - Up to 6 calibrators
 - Specific protein and drug markers
 - Example: A1c
3. Fixed Factor
 - Adjustment of C_0 for certain assays:
 1. Acetaminophen
 2. Cholesterol_2
 3. Glucose oxidase
 4. Inorganic phosphorus
 5. Triglycerides
 6. Uric acid
 7. Urea nitrogen
 8. ETOH

CH Calibration Orders

1. Manual or Automatic ordering
2. Troubleshooting calibrations:
 - a. Placing orders
 - i. Reagent overview vs Calibration Orders
 - ii. Duplicate orders: calibration results
 - b. Calibrator definitions: Active file and editing calibration definitions
 - c. Place order before printing barcodes
 - d. Replicates: CH Sample Container Volume Requirements
 - e. Run QC with calibration
3. Automatic Acceptance: Using QC results to determine quality of the calibration result
 - a. Hardware vs Software

CH Calibration Acceptance Criteria

The expected values are defined in the TDef for all or for some of the acceptance criteria listed:

- Slope
- Intercept
- Correlation coefficient range
- Bias Percentage
- Recovery Level
- % CV
- Percentage Deviation
- Percentage Deviation Excluding Low Level
- SD
- Delta System Response

The assay test definition defines the Minimum # of Replicates the system requires to obtain a valid calibration.

Outliers can cause a calibration to fail. If specific criteria are met, excluding an outlier may correct an Awaiting Acceptance CH calibration result.

- The operator can manually exclude CH calibration replicate results.
- After excluding an outlier, the system recalculates the calibration data and rechecks the calibration criteria.
- In order to exclude an outlier, the minimum number of replicates the system requires for a valid calibration must remain after exclusion.

The calibration will fail if:

- Process, result or instrument (measurement, foam, etc.) errors are confirmed.
- Any of the acceptance criteria fails.
- The number of resulting replicates has not met the minimum requirements.

The operator cannot manually accept the calibration.

The calibration will be in "awaiting acceptance" if:

- The calibration results do not meet the acceptance criteria for one or more of the expected calibration values.
- One of the three replicates do not satisfy the acceptance criteria.
- If calibration passes but QC is not within its observed range.

The operator can accept or reject the calibration manually.

NOTE: The system will only use the "Awaiting Acceptance" calibration status if Automatic Acceptance is disabled in the CH assay test definition.

Troubleshooting Calibration Orders

Possible Cause	Corrective Actions
Manual and Automatic Calibration Orders not processing	Confirm Calibration order in Calibration – Calibration Results Screen
	Cancel any duplicate, incorrect and/or pending orders
	If calibrations show as ordered, but are not running, check for any outstanding requirements: missing paired reagents, wrong lot of calibrator material, missing QC material
	Move all results to Historical
	Re-order as correct calibration type (Lot vs Pack)
	If calibration still does not run, reboot PCC

Troubleshooting QC Orders and Results

Possible Cause	Corrective Actions
QC Orders not processing	Check for system errors/supply needs <ul style="list-style-type: none"> Confirm enough QC and Calibrator material onboard, Reagent is onboard, correct barcode sequence number
	Delete pending Cal/QC order and reorder <ul style="list-style-type: none"> If not stored onboard-reprint labels It is not recommended to print a new barcode if material is stored onboard due to OBS
	Move all results to Historical
	If issue persists, contact Siemens Support.
QC Results Drifting or Failing	Check QC material <ul style="list-style-type: none"> OBS
	Review Calibration result

CH Calibration and QC Troubleshooting Scenarios

Scenario #1

An operator receives a new lot of Chem Calibrators from Siemens Healthineers.

- The operator scans the Calibrator Definition and saves it successfully.
- Operator barcodes the calibrator material to store onboard.
- Operator notices Glucose (GluH_3) reagent needs to be calibrated. He creates the calibration order and walks away from the analyzer.
- Upon returning to view the calibration results, operator notices that the order was never processed and the Chem Cal was in the output lane of SH.

Using the Calibration FAQ, why didn't the Calibration order process? What could have gone wrong?

Cause:

Resolution:

Scenario #2

An operator was performing an as needed maintenance task on the Chemistry analyzer. Upon completion, QC was automatically scheduled to run within 10 minutes. Operator returns to the analyzer to view the CH QC results and notices a flag in the worklist "Module Unavailable."

What is the issue impacting the analyzer?

Cause:

Resolution:

What do you have to do to get the CH QC to run?

Resolution:

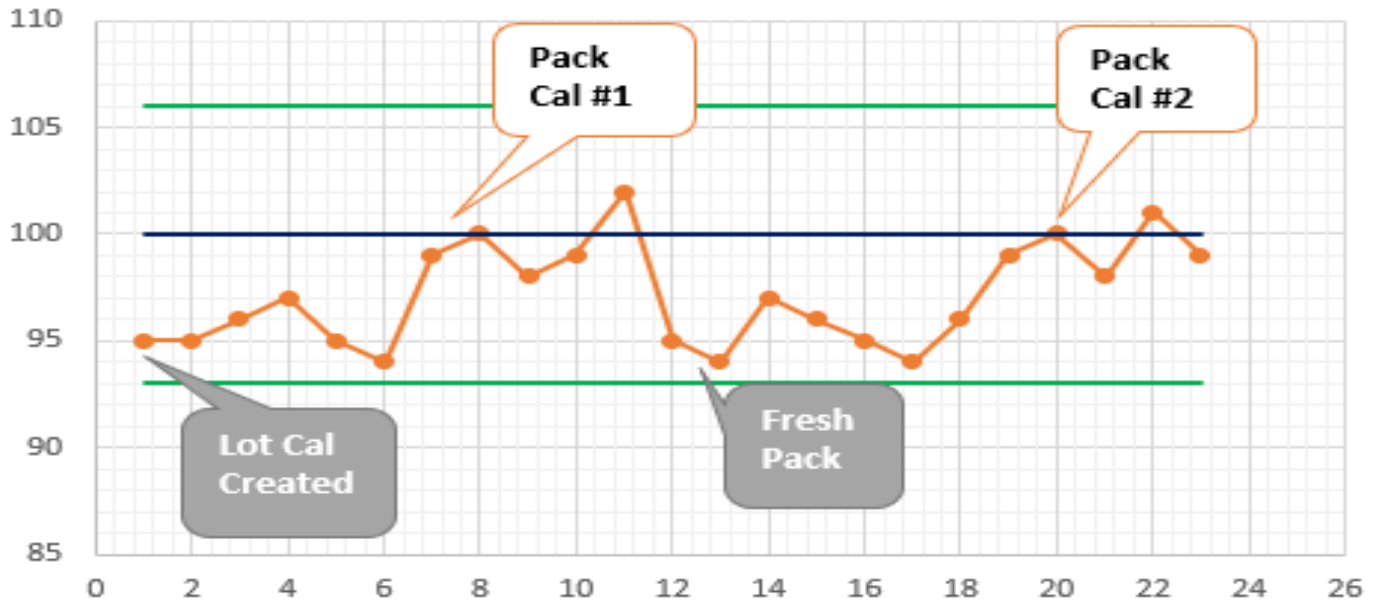
Scenario #3

The lab supervisor notices some imprecision in the QC data for an assay. To troubleshoot the imprecision, they look at when calibrations have been performed.

Lot Calibration Interval = 50 days

Pack Calibration Interval = 7 days

Onboard Stability Interval = 26 days



1. On day 1, a lot calibration was created. Following this, the QC data was within range, but not on the mean.
2. On day 7, a pack/well calibration is performed on the same pack.
 - a. Following this pack/well calibration, how does the QC data look?
3. On day 12, a new pack is loaded.
 - a. What type of calibration will be used for the new pack?
 - b. How does the QC data look following day 12?
4. On day 20, pack calibration is performed.
 - a. Following this pack/well calibration, how does the QC data look?
 - b. What could be causing the imprecision?

Scenario #4 – Troubleshooting Calibration and QC post Source Lamp replacement

Refer to Online Help for procedures for Replacing the CH Source Lamp

1. What must be done after replacing the source lamp on the Atellica CH analyzer?
2. What must be done if QC is out of range post lamp change?
3. Which type of calibration would you most likely perform on this current well?
4. What happens when a new well is pierced?
5. What issues could arise for assays that reverted to previous lot calibration?
6. What needs to be done if the current reagent pack reverted to a previous lot calibration?

CH Assay Troubleshooting Notes

5 IM Assay Troubleshooting

5 IM Assay Troubleshooting

Resources

- Online Help
- PEPconnect

Objectives

Upon completion of this exercise you will be able to:

- Describe IM calibration
- Identify assay principles for IM module
- Review IM calibration acceptance criteria
- Identify and troubleshoot calibration and QC orders
- Discuss IM troubleshooting scenarios

IM Calibration Overview

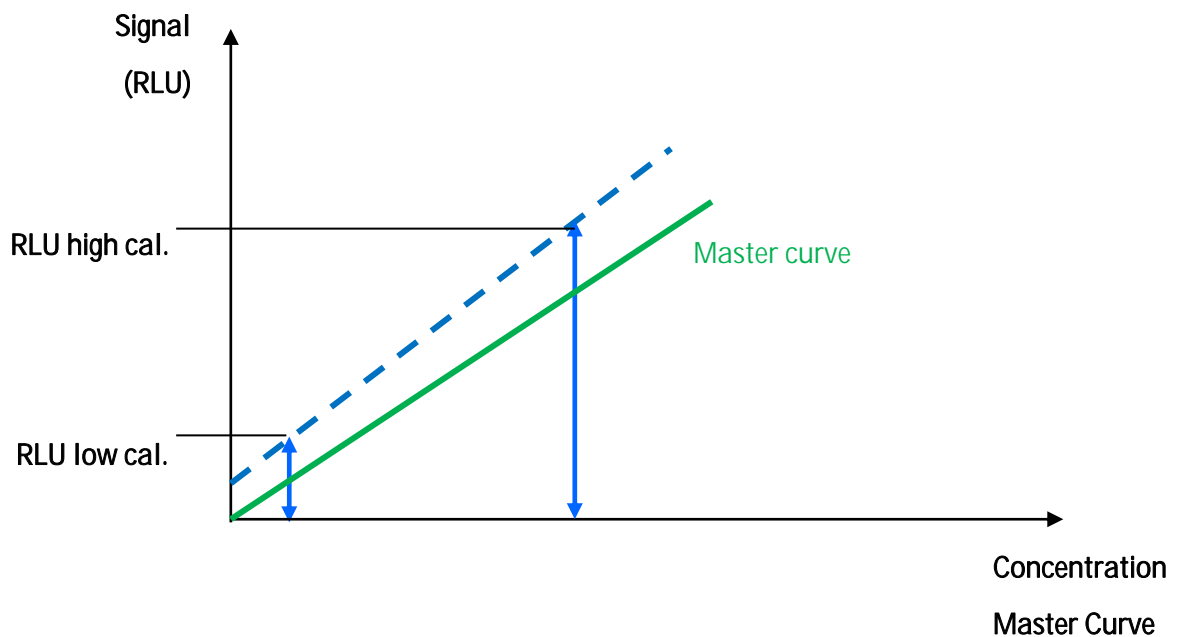
Atellica IM 1300/1600 Analyzers employ a 2-point calibration. Every lot of reagent has a test definition (TDef) scanned into the analyzer before the new reagent lot is loaded onto the analyzer. The TDef contains the master curve for that lot created at the manufacturing site. The 2-pt lot calibration (Cal 1 or Low and Cal2 or High) calibrates the specific system and specific lot to the master curve.

Master Curve Development:

- Established as part of the production process for each assay lot.
- The system uses the master curve and a two-point calibration to calibrate the assays and calculate QC and patient results.
- Determines the relationship between the defined analyte levels and the measured RLUs.
- Eliminates the need to measure a full standard curve each time a new assay is run on the system.
- Encoded in a 2D barcode on the lot-specific Master Curve and Test Definition (MC TDEF) sheet.

When an Assay is Calibrated:

- Calibrators with known values are analysed to generate RLUs.
- The calibrator concentrations and RLUs are then used to generate a curve (line) that is fitted to the original Master Curve - the Master Curve is adjust to the instrument specific RLUs.



IM Calibration Acceptance Criteria

The Master Curve and Test Definition (MC TDEF) 2D barcode includes the defined ranges (referred to as *expected ranges* on the analyzer software) for the acceptance criteria for calibrations.

The IM Analyzer uses these values to evaluate calibration results.

1. Minimum Replicates – minimum # of calibrator samples the system aspirates for each calibrator level.
2. Low & High Level Coefficient of Variation (%CV) – precision for low & high calibrator replicates.

The remaining defined ranges for the acceptance criteria are:

- Signal Slope
- Signal Ratio
- Allowed Low Level Deviation
- Allowed High Level Deviation

IM Calibration Acceptance Criteria

Signal Slope is a comparison of high and low calibrator RLUs to the Master Curve.

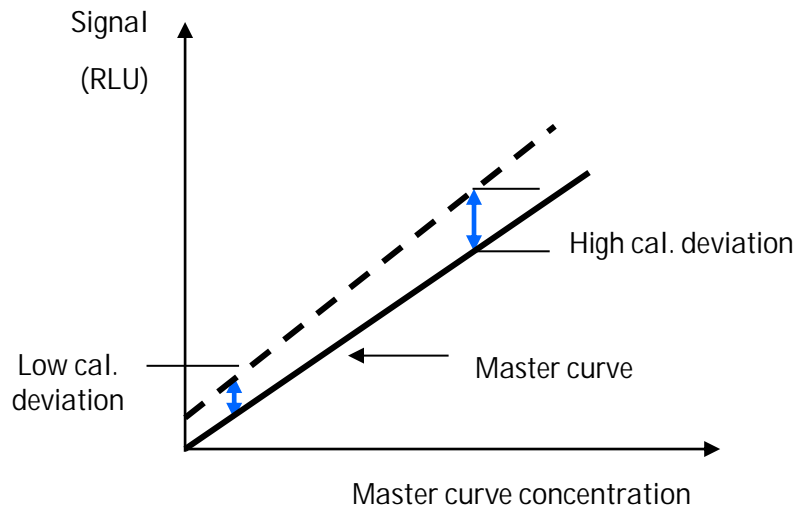
$$\text{Slope} = \frac{\text{RLU Expected High Cal} - \text{RLU Expected Low Cal}}{\text{RLU Measured High Cal} - \text{RLU Measured Low Cal}}$$

Signal Ratio is a comparison of high and low calibrator RLUs.

$$\text{Sandwich Ratio} = \frac{\text{RLU Mean High Cal} - \text{RLU Mean Low Cal}}{\text{RLU Mean Low Cal}}$$

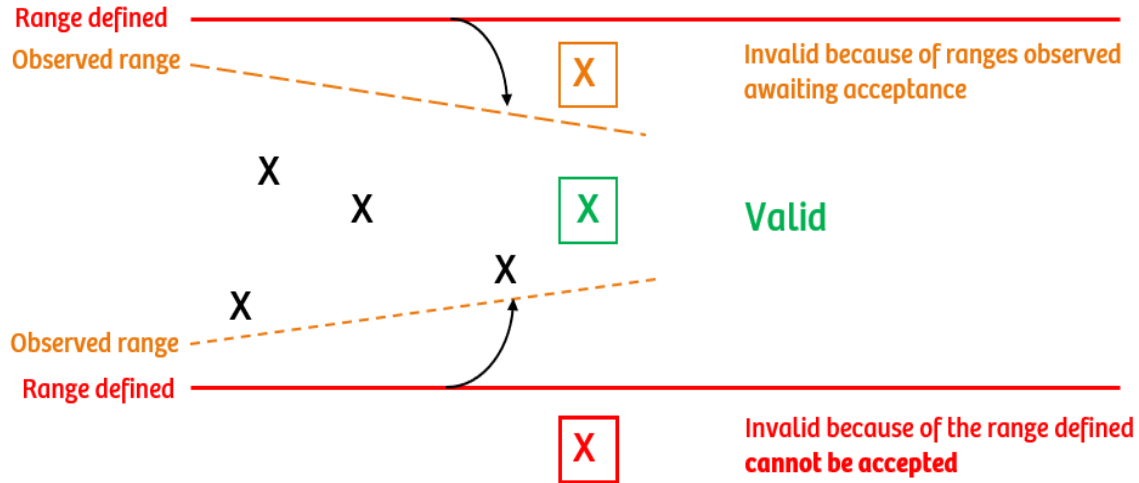
$$\text{Competitive Ratio} = \frac{\text{RLU Mean Low Cal} - \text{RLU Mean High Cal}}{\text{RLU Mean High Cal}}$$

The Level Deviation measures how well the high and the low calibrator RLU's fit the master curve. The values are a relative measure of the deviation of the average RLU's of the low calibrator and the high calibrator from the master curve.



IM Calibration Acceptance Criteria – Observed Ranges

- The defined range for each acceptance criteria is included in the MC TDEF barcode for each assay.
- An observed range is established after 4 calibrations with the same combination of reagent lot and calibrator lot.
- The observed ranges are then updated after each successive valid calibration.
- Observed ranges are specific for the system and are narrower than the defined ranges.



The calibration will fail:

- If process or instrument (measurement, foam, etc.) errors are confirmed.
- If any of the defined range acceptance criteria fail.
- The number of resulting replicates has not met the minimum requirements.

The operator cannot manually accept the calibration.

The calibration will be in “awaiting acceptance”:

- If the result is outside of the observed range but inside the defined range acceptance criteria.

The operator can accept or reject the calibration manually.

NOTE: The system will only use the “Awaiting Acceptance” calibration status if Manual Acceptance is enabled in the IM assay test definition or Automatic Acceptance is enabled and result is outside the observed range but inside expected range.

IM Assay Principles

Atellica IM Core Technology and Assay Reaction Formats

Chemiluminescent Technology

- Paramagnetic Particles (PMP)
- Acridinium Ester (AE)

3 Different Assay Reaction Formats

- Sandwich (Direct)
- Competitive (Indirect)
- Antibody-Capture (Direct)

Direct → the concentration of an analyte increases as the RLU's increase

Indirect → the concentration of analyte decreases as RLU's increase

What is chemiluminescence?

- Chemical reaction that emits energy in the form of light
- The light the reaction produces, measured in relative light units (RLU's) indicates the amount of analyte in a sample

Invalid Calibration Results Troubleshooting

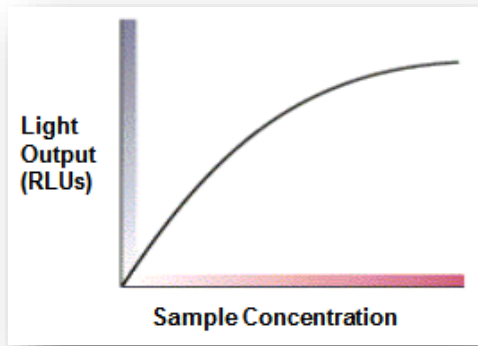
Possible Causes	Corrective Actions
Reconstitution issues: <ul style="list-style-type: none"> • Incorrect volume • Impure special reagent water • Incomplete calibrator (Missing level) 	<ol style="list-style-type: none"> 1. Use the correct volume for reconstitution. Refer to the reagent assay or calibrator IFU for reconstitution instructions. 2. Ensure calibration of the pipette. 3. Verify the integrity of the special reagent water 4. Reconstitute fresh lyophilized, thaw a new set of frozen, or open fresh liquid calibrators. 5. Recalibrate the assay.
Calibrator material loaded and processed on system before coming to room temperature.	Wait for the calibrator material to come to room temperature before loading if instructed by the IFU.
The operator did not store the offboard calibrators correctly.	<ol style="list-style-type: none"> 1. Verify the calibrator IFU for the storage requirements of lyophilized, reconstituted, frozen, and liquid calibrators. 2. Store reconstituted, thawed, or open calibrators according to their respective IFU. 3. Mix calibrators according to the calibrator IFU. 4. Recalibrate the assay.
The operator uses mislabeled calibrator: <ul style="list-style-type: none"> • Wrong assay • Wrong level 	<ol style="list-style-type: none"> 1. Refer to the assay IFU for the correct calibrator to use with an assay. 2. Store offboard calibrators in their original packaging. Store SH calibrator in the properly labeled sample tube. 3. If the calibrator is in a mislabeled tube: <ol style="list-style-type: none"> a. Discard the mislabeled tube and pour a fresh aliquot of calibrator into a new, correctly labeled tube. b. Prepare fresh calibrators according to the calibrator IFU. 4. Recalibrate the assay.

The operator stores the reagent pack at room temperature or in direct light for a prolonged period.	<ol style="list-style-type: none"> 1. Store reagent packs according to the assay IFU. 2. Discard any reagent that exceeds the opened stability. 3. Obtain a fresh reagent pack. 4. Recalibrate the assay.
Reagent evaporation or spill because of loss or torn pack seal.	<ol style="list-style-type: none"> 1. Discard the old reagent pack and replace with a fresh reagent pack. 2. Recalibrate the assay.
Analyzer displays Autocheck failures or system events.	<ol style="list-style-type: none"> 1. Repeat Autocheck. 2. Troubleshoot Autocheck failures. 3. Troubleshoot system events or issues that improper alignment post part replacement may have caused.
Storage of sample tips on their side or a tray exchange failure damages the sample tips.	<ol style="list-style-type: none"> 1. Store sample tips in an upright position. 2. Do not place the tip tray on the counter. 3. Do not use trays containing damaged tips. 4. Recalibrate the assay.
Reagents are clumped, expired, or the operator stores them on their side or at freezing temperatures.	<ol style="list-style-type: none"> 1. Store reagent packs according to the assay IFU. 2. Inspect reagent packs for valid expiration date and clumping. 3. Discard the old reagent pack and replace with a fresh reagent. 4. Recalibrate the assay.

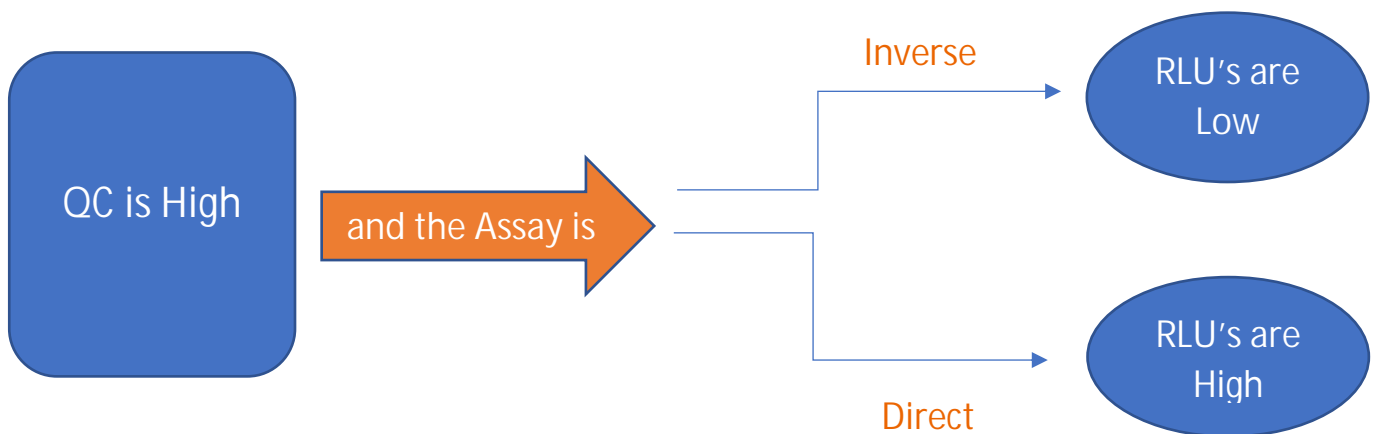
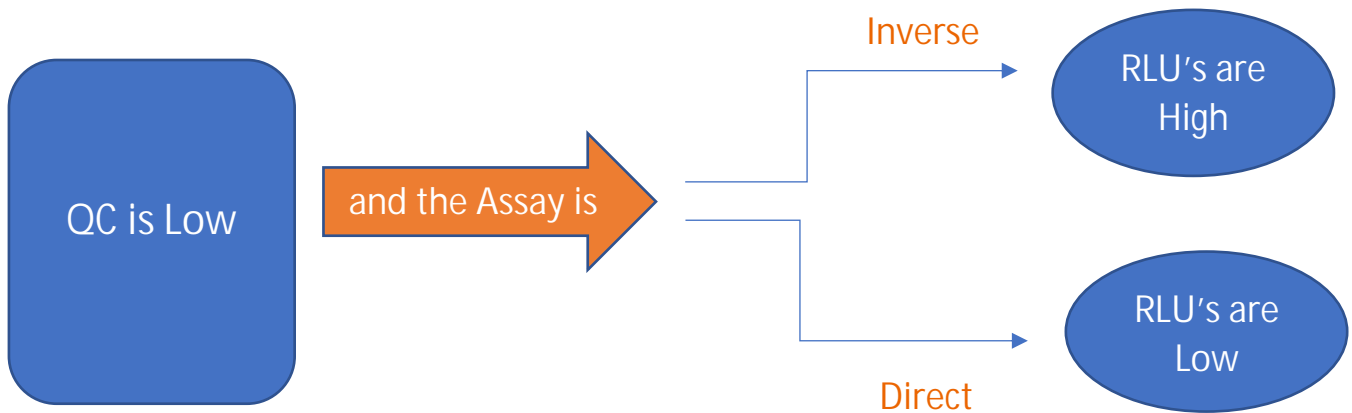
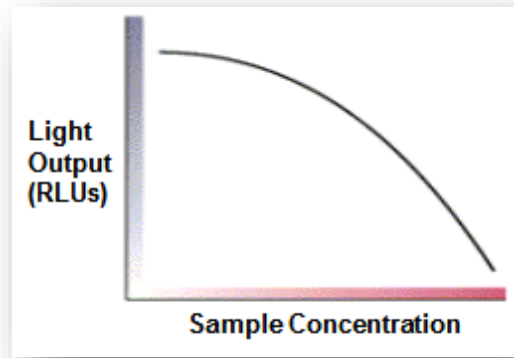
QC Results Troubleshooting

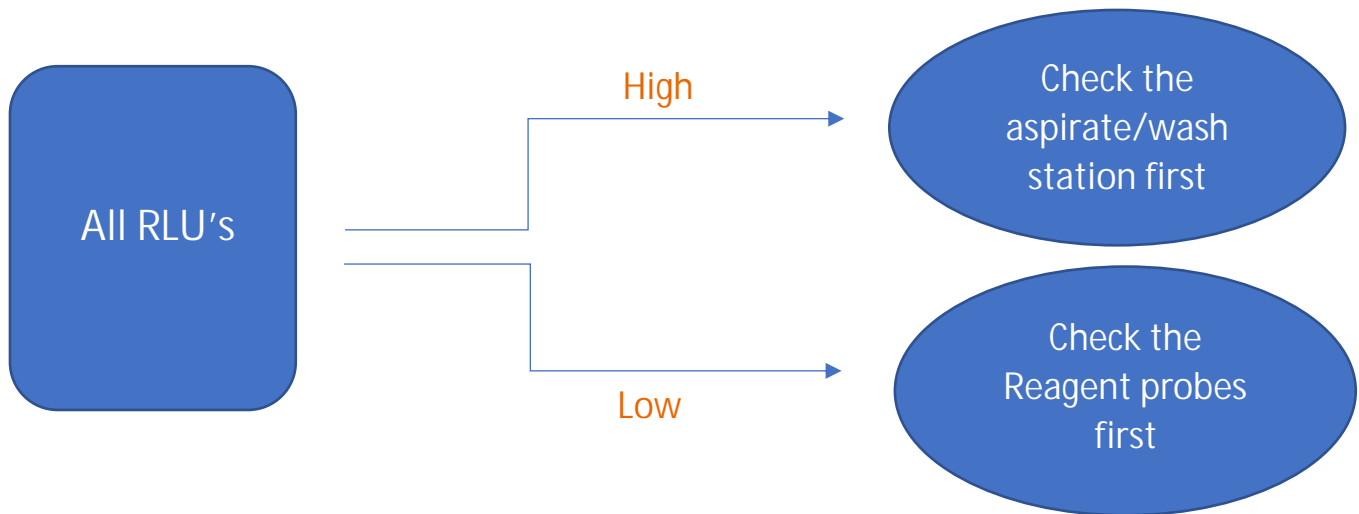
Possible Cause	Corrective Actions
<p style="text-align: center;">QC shifts</p>	<p>Repeat with fresh QC material, prepare according to instructions for use.</p> <ul style="list-style-type: none"> • Be sure to unload the old materials. • Ensure all fresh ancillary and probe wash consumables are loaded. • Confirm correct QC material and lot numbers used.
	<p>Compare to Peer Range data</p> <ul style="list-style-type: none"> • Ranges may be too tight in comparison to peer, or matrix effects may be causing a shift in recovery. • Review QC data (RLUs) compared to previous.
	<p>If any recent calibrations were performed, check results for poor recoveries or manual acceptance</p> <ul style="list-style-type: none"> • Perform a new calibration with all fresh materials, fresh reagent, fresh calibrator, and fresh QC.
	<p>Review previous QC data and analyze trends (probes, potential carryover).</p> <ul style="list-style-type: none"> • Confirm no hardware issues (check event log). • Confirm maintenance is complete and up to date.
	<p>Perform an Autocheck on the IM and address any hardware issues.</p>
	<p>If issue persists, replace reagent pack, recalibrate, and rerun QC.</p>
	<p>If issue persists, Contact Technical Support.</p>

Direct Assay



Indirect Assay





Check the sample probe next if:

- All RLUs are high and only running inverse assays
- All RLUs are low and only running direct assays

IM Calibration and QC Troubleshooting Scenarios

Scenario #1

An operator ordered a Folate calibration and noticed the slope ratio failed the acceptance criteria. The operator recalibrated two more times and observed invalid calibration results. Review the RLU data below to investigate the failure.

	Attempt #1	Attempt #2	Attempt #3
Cal Low	35,123	37,112	41,200
Cal High	38,456	42,987	37,678

Why did the calibration acceptance criteria fail for Folate?

Scenario #2

- CEA, AFP, T4, & T3 are calibrated at the same time.
- The calibrators were all made fresh that day.

Test	QC Results	Flag
CEA	Level 1 – 2.20 ng/mL	QC Low
	Level 2 – 5.06 ng/mL	
	Level 3 – 22.8 ng/mL	
T4	Level 1 – 5.31 ug/mL	QC in range
	Level 2 – 10.60 ug/mL	
	Level 3 – 12.70 ug/mL	
T3	Level 1 – 2.5 pg/mL	QC in range
	Level 2 – 6.23 pg/mL	
	Level 3 – 9.84 pg/mL	
AFP	Level 1 – 0.852 IU/mL	QC Low
	Level 2 – 8.923 IU/mL	
	Level 3 – 50.212 IU/mL	

Using the IM Assay chart, determine the possible cause for these results.

Scenario #3

A new lot of QC ranges were manually entered on both of their Atellica Solutions by a new operator.

An Operator ran all three level of FT4 QC. Levels 1 and 2 were within range, Level 3 was flagged high.

The Operator ran all three levels on another Atellica system and observed all three results were within range.

Operator reviewed calibration data and observed no problems.

Determine the possible cause for these results.

Scenario #4

A newly trained medical technologist was running a Thyroid and Oncology QC panel.

He noticed in the reagent needs window that additional CEA and TSH reagent pack were needed to satisfy the order.

He mixes and loads both packs together.

Upon reviewing QC for both panels, he notices CEA is off the target mean.

Determine the possible cause for these results.

Scenario #5

An operator is running QC on TniH, Ferritin, and BNP. She obtains the following results:

Level	Test	QC Results	Limits	Flag
Level 1	TniH	0.5	0.8 – 1.2	QC OUT
	Fer	41	48 - 62	QC OUT
	BNP	114	80 - 149	
Level 2	TniH	3.5	4.1 – 6.2	QC OUT
	Fer	115	124 - 158	QC OUT
	BNP	409	304 - 513	
Level 3	TniH	20	23 - 35	QC OUT
	Fer	249	260 - 364	QC OUT
	BNP	817	615 - 1018	

Using the IM Assay chart, determine the possible cause for these results.

Scenario #6

An operator is running ThCG, PRGE, COR, aTPO, FT4, and Tup on their Atellica IM.

At the end of the day, they are having discrepant patients results and decide to run QC on all the assays on board.

Test	QC Results	Flags
ThCG	Level 1 – 2.20 ng/mL	QC High
	Level 2 – 5.06 ng/mL	
	Level 3 – 22.8 ng/mL	
PRGE	Level 1 – 5.31 ug/mL	QC Low
	Level 2 – 10.60 ug/mL	
	Level 3 – 12.70 ug/mL	
COR	Level 1 – 2.5 pg/mL	QC Low
	Level 2 – 6.23 pg/mL	
	Level 3 – 9.84 pg/mL	
aTPO	Level 1 – 0.852 IU/mL	QC in range
	Level 2 – 8.923 IU/mL	
	Level 3 – 50.212 IU/mL	
FT4	Level 1 – 2.58 ng/dL	QC in range
	Level 2 – 6.74 ng/dL	
	Level 3 – 11.20 ng/dL	
Tup	Level 1 – 1.63 ng/mL	QC in range
	Level 2 – 3.21 ng/mL	
	Level 3 – 9.93 ng/mL	

Using the IM Assay chart, determine the possible cause for these results.

IM Assay Troubleshooting Notes

6 Operator Event Log and Diagnostics

6 Operator Event Log and Diagnostics

Resources

- Online Help
- PEPconnect

Objectives

Upon completion of this exercise you will be able to:

- Interpret the Operator Event log
- Perform corrective actions based on event logs
- Utilize SH, VMM, CH, and IM Operator Diagnostics for verification of system performance

Operator Event Log

At the Command Bar, select System > Logs > Operator Event Log.


Operator Event Log

- Displays system events as the events occur.
- Can be filtered based on time, module, error/warning.
- An event can be selected, the detailed information will display at the bottom of the workspace.
- Event Help enables you to review the event, possible causes, corrective actions, and corrective action procedures.
- Comments can be added to an event.

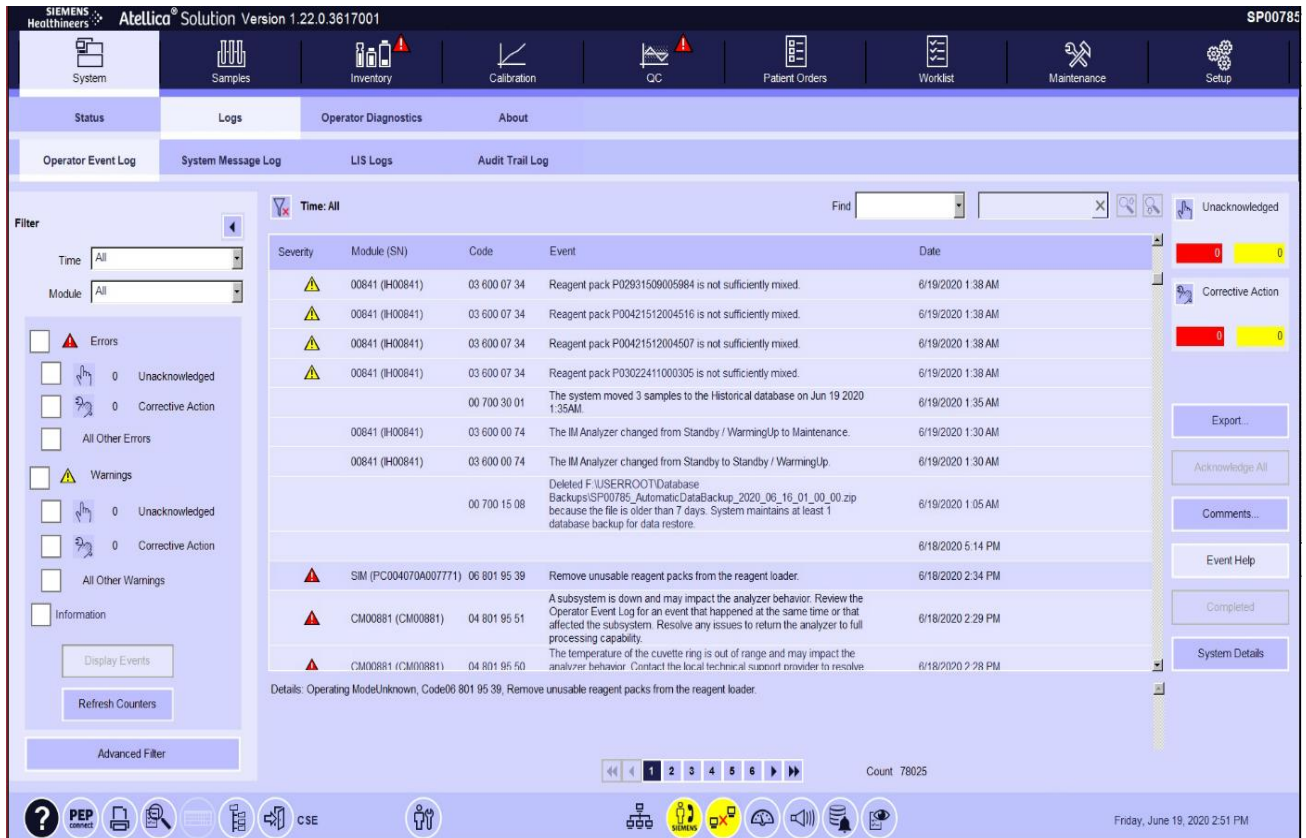
Corrective Actions

Events marked with the corrective action symbol  must be resolved by the operator. After resolving, the event can be marked completed.

Unacknowledged Events

Events marked with the unacknowledged symbol  can be acknowledged by the operator. To acknowledge an event:

- Select the event.
- Either select the unacknowledged symbol for an event or select Acknowledge All to acknowledge all events.



SIEMENS Healthineers Atellica® Solution Version 1.22.0.3617001 SP00785

System Samples Inventory Calibration QC Patient Orders Worklist Maintenance Setup

Status Logs Operator Diagnostics About

Operator Event Log System Message Log LIS Logs Audit Trail Log

Filter

Time: All

Module: All

Errors

0 Unacknowledged

0 Corrective Action

All Other Errors

Warnings

0 Unacknowledged

0 Corrective Action

All Other Warnings

Information

Display Events

Refresh Counters

Advanced Filter

Severity	Module (SN)	Code	Event	Date
Warning	00841 (H00841)	03 600 07 34	Reagent pack P02931509005984 is not sufficiently mixed.	6/19/2020 1:38 AM
Warning	00841 (H00841)	03 600 07 34	Reagent pack P00421512004516 is not sufficiently mixed.	6/19/2020 1:38 AM
Warning	00841 (H00841)	03 600 07 34	Reagent pack P00421512004507 is not sufficiently mixed.	6/19/2020 1:38 AM
Warning	00841 (H00841)	03 600 07 34	Reagent pack P03022411000305 is not sufficiently mixed.	6/19/2020 1:38 AM
Information		00 700 30 01	The system moved 3 samples to the Historical database on Jun 19 2020 1:35AM	6/19/2020 1:35 AM
Information	00841 (H00841)	03 600 00 74	The IM Analyzer changed from Standby / WarningUp to Maintenance.	6/19/2020 1:30 AM
Information	00841 (H00841)	03 600 00 74	The IM Analyzer changed from Standby to Standby / WarningUp.	6/19/2020 1:30 AM
Information		00 700 15 08	Deleted F:\USERROOT\Database Backups\SP00785_AutomaticDataBackup_2020_06_16_01_00_00.zip because the file is older than 7 days. System maintains at least 1 database backup for data restore.	6/19/2020 1:05 AM
Error	SIM (PC004070A007771)	06 801 95 39	Remove unusable reagent packs from the reagent loader.	6/18/2020 2:34 PM
Error	CM00881 (CM00881)	04 801 95 51	A subsystem is down and may impact the analyzer behavior. Review the Operator Event Log for an event that happened at the same time or that affected the subsystem. Resolve any issues to return the analyzer to full processing capability.	6/18/2020 2:29 PM
Error	CM00881 (CM00881)	04 801 95 50	The temperature of the cuvette ring is out of range and may impact the analyzer behavior. Contact the local technical support provider to resolve.	6/18/2020 2:28 PM

Details: Operating ModeUnknown, Code06 801 95 39, Remove unusable reagent packs from the reagent loader.

Count 78025

Friday, June 19, 2020 2:51 PM

The screenshot displays the Atellica Solution software interface. At the top, the title bar reads "SIEMENS Healthineers Atellica® Solution Version 1.22.0.3617001" and "SP00785". The main menu includes System, Samples, Inventory, Calibration, QC, Patient Orders, Worklist, Maintenance, and Setup. Below this, there are tabs for Status, Logs, and Operator. The "Operator Event Log" tab is active, showing a list of events with columns for Time, Severity, and Module. A filter panel on the left allows filtering by Time (All) and Module (All), with checkboxes for Errors, Warnings, and Information. A detailed help window is open for event "06 801 95 39", which is described as "Remove unusable reagent packs from the reagent loader." The help window includes sections for "Possible Causes" (Unusable reagent packs) and "Corrective Action" (Remove the unusable reagent pack from the CH or IM reagent loader). The bottom status bar shows "Count: 78025" and the date "Friday, June 19, 2020 2:52 PM".

Operator Diagnostics

At the Command Bar, select System and Operator Diagnostics.

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

Operator Diagnostics

- Operator Diagnostics allows the operator to manually manipulate the analyzer during maintenance or troubleshooting.
- Certain diagnostic procedures require the operator to manually move hardware, initialize, prime, and open and close covers.
- The operator can safely enter the analyzer into a diagnostic state, halting the mechanics to perform these procedures.
- The operator exits the diagnostic state after the maintenance or troubleshooting is complete.

The screenshot displays the Siemens Atellica Solution software interface. The top navigation bar includes icons for System, Samples, Inventory, Calibration, QC, Patient Orders, Worklist, Maintenance, and Setup. The 'Operator Diagnostics' menu item is highlighted with an orange box labeled '2'. Below the navigation bar, the 'VMM' (Virtual Maintenance Module) section is visible, with a 'Perform' button highlighted by an orange box labeled '3'. The main content area shows a table with diagnostic procedures:

Diagnostic Name	Description
Resetting the Atellica Magline Transport	Resets the Atellica Magline Transport

At the bottom of the interface, there are buttons for 'Enter Diagnostics' and 'Exit Diagnostics', with the 'Enter Diagnostics' button highlighted by an orange box labeled '4'. The bottom status bar shows the date and time: Monday, June 7, 2021 1:42 PM.

Operator Event Log and Diagnostics Notes

7 SH Hardware Troubleshooting

7 SH Hardware Troubleshooting

Resources

- Online Help
- PEPconnect

Objectives

Upon completion of this exercise you will be able to:

- Perform As Needed maintenance for SH module
- Utilize Online Help to identify troubleshooting procedures
- Identify and resolve hardware issues for the SH and VMM module

SH As Needed Maintenance

Task	Frequency	Errors/Comments
Replacing SH Gripper O-Rings	As needed/ upon failure	
Cleaning the Sample Handler Drawer and the Racks	As needed	

SH Hardware Troubleshooting

1. Cal-QC Storage

Issue: Cal-QC Storage Inventory Issues

Description: Unusable Position, Tube Missing, or Robot is breaking tubes. Cal-QC inventory issues are usually related to operators manually removing individual tubes and/or not resetting to default positions.

Troubleshooting Steps

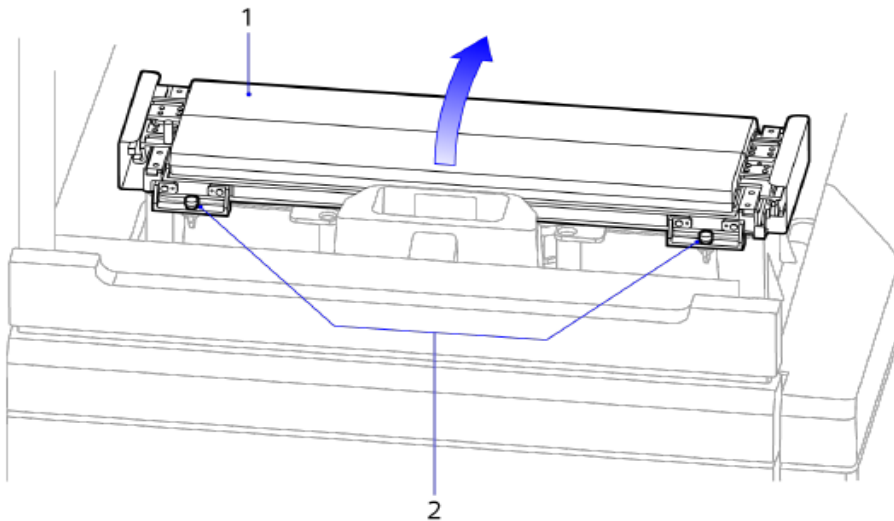
1. Reset Cal-QC storage if tubes were manually removed (follow Online help, see procedure below)
2. For safety issues if there are broken tubes, the CSE needs to be dispatched.

➤ Unloading Cal-QC Tubes Manually

Perform this task only when the system is unable to unload tubes from the Cal-QC storage area using the robot, such as during a power failure or robot failure.

NOTE: Do not reload Cal-QC tubes manually. Only load Cal-QC tubes through the SH drawers.

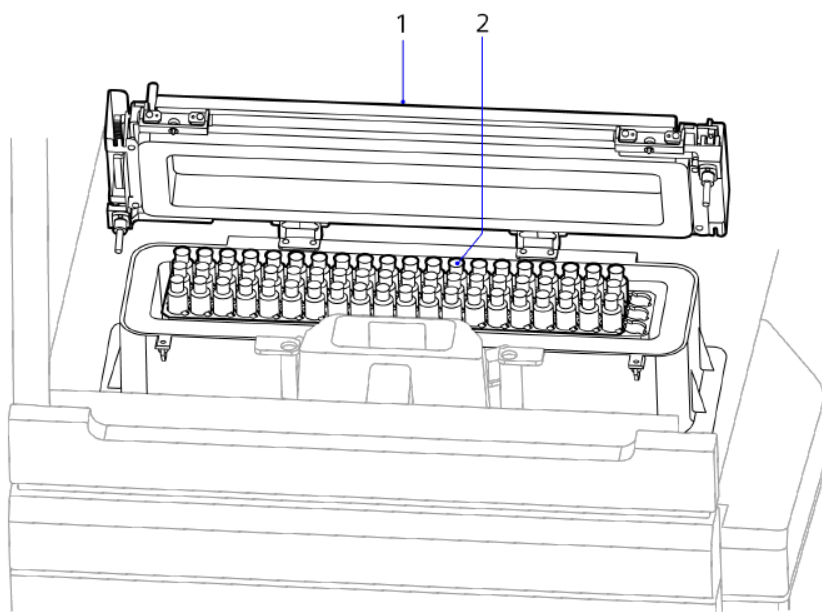
1. If the system still has power:
 - a. Stop the SH
 - b. Unlock the SH back cover
2. Open the SH back cover.
3. Manually pull the SH robot (towards the operator) to the right-side, back corner of the SH.
4. Ensure the SH robot and cabling do not block the Cal-QC storage area.
5. Loosen the 2 thumbscrews on the back of the Cal-QC storage area.



- 1 Cal-QC storage area cover
- 2 Thumbscrews

6. Rotate the Cal-QC storage area cover open.





- 1 Cal-QC storage area cover
- 2 Cal-QC tube covers

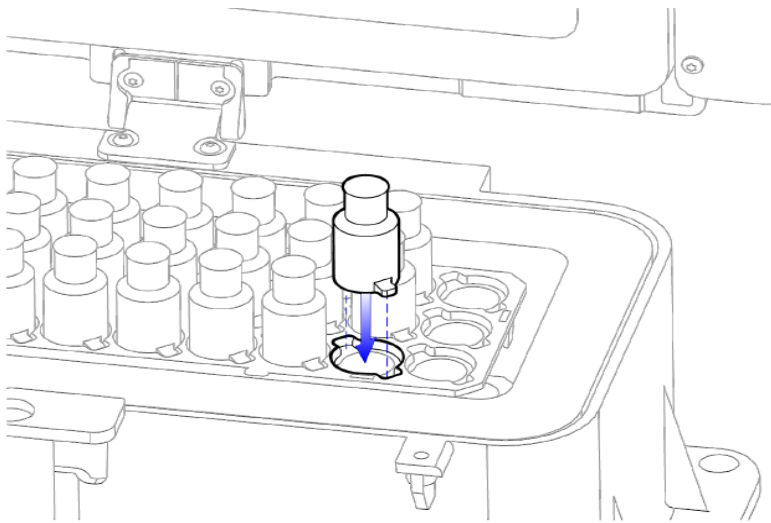


7. Remove all Cal-QC tubes from the storage area.
 - a) Remove the Cal-QC tube cover.
 - b) Place the Cal-QC tube cover aside.
 - c) Remove the Cal-QC tube.
 - d) Place the Cal-QC tube in a rack.
 - e) Repeat steps a–d to remove all Cal-QC tubes.

8. If appropriate, clean the Cal-QC storage area.

- a) Wipe the Cal-QC storage area with lint-free tissues or gauze saturated with a 10% bleach solution.
- b) Wipe the Cal-QC storage area with lint-free tissues or gauze saturated with reagent water.
- c) Dry the Cal-QC storage area thoroughly with clean lint-free tissues or gauze.

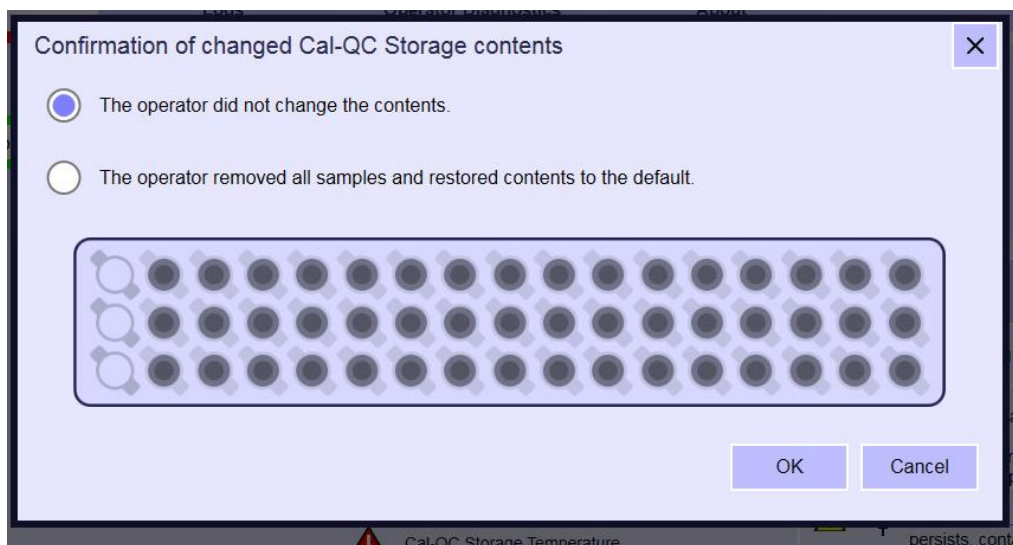
9. Install all Cal-QC tube covers from left to right, leaving the 3 right-most positions empty (default configuration).



NOTE: Align the tabs on the tube cover so the cover properly seats in the Cal-QC storage area.

10. Close the Cal-QC storage area cover.

11. Tighten the 2 Cal-QC storage area cover thumbscrews.



2. Drawer Vision System

Issue: Drawer Vision System errors

Description: DVS unable to see tubes and racks, seeing tubes that are not there, or receiving communication errors.

Troubleshooting Steps

1. Reopen and close drawer (fully and gently).
2. Visually check for flashing lights.
 - a. If no lights are present – contact technical support.
3. Reboot SH.
4. If issue persists, contact technical support.

3. Robotic Gripper

Issue: Tube stuck in the gripper or the gripper is unable to pick up a tube. Gripper may also be open too wide

Description: Robotic Arm offline, Gripper errors in event log, SH stopped.

Troubleshooting Steps

1. Manually close the Gripper fingers (but not completely) if they are open too far (due to manually removing the tube and opening the gripper too far). (use online help to guide with this procedure).
2. Run Autocheck to test functionality.
3. If issue persists, contact technical support.

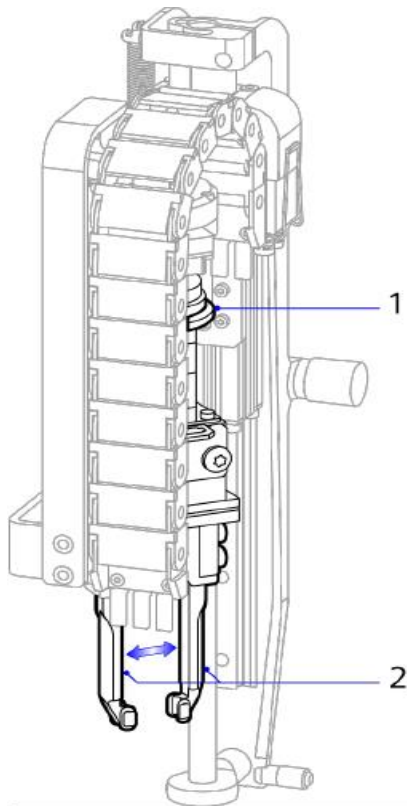
➤ Removing Tubes from SH Robot Grippers Manually

Perform this task only if the system displays an alert to manually remove a tube in the robot gripper. The SH is in the Stopped state.

1. Open the SH front cover.
2. Manually move the SH robot to the front of the SH, if appropriate.

NOTE: If the robot is out of reach from the front of the SH, open the SH back cover to move the robot into position.

3. While holding the sample tube and robot gripper with 1 hand, turn the gripper manual release on the robot counterclockwise to release the tube.



-
- | | |
|---|----------------------------------|
| 1 | Manual release for robot gripper |
| 2 | Robot gripper |
-

4. Place the tube in a rack.
5. Lock the SH front cover.
6. Lock the SH back cover, if appropriate.
7. Start the SH.

4. Magline Transport

Issue: Sample Carriers stuck on VMM track.

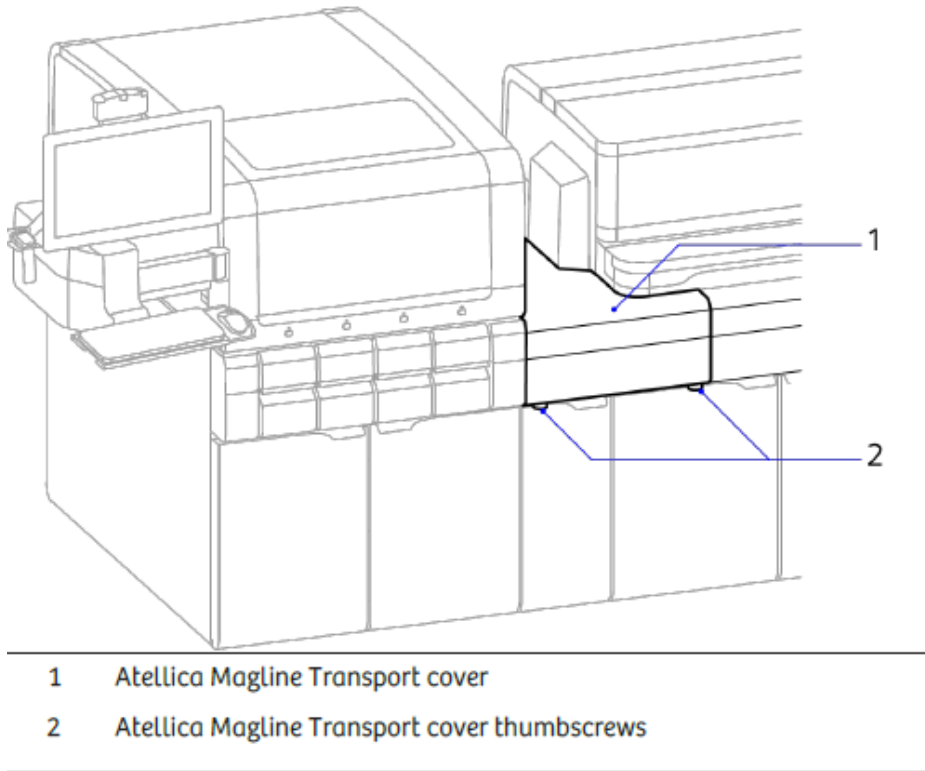
Description: Sample carriers are stuck at a diverter gate or they are not moving due to debris or obstruction on the track.

Troubleshooting Steps

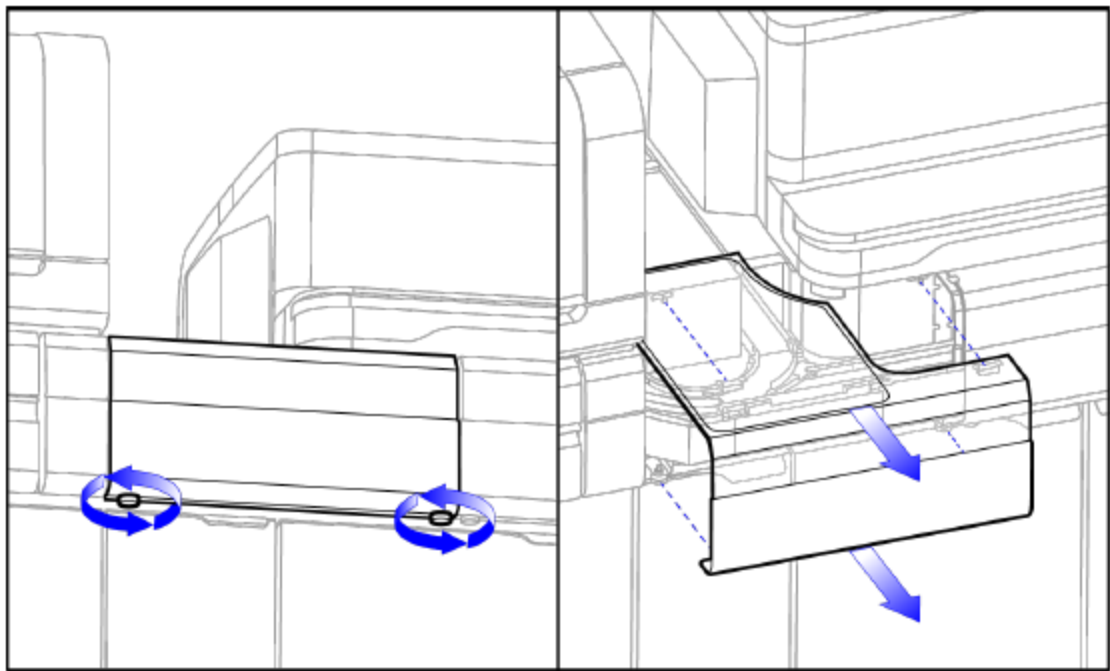
1. Remove Magline covers and clear the obstructions (Use online help for procedures).
2. If issue persists, contact technical support.

➤ Removing Atellica Magline Transport Covers

1. Stop the Atellica Magline Transport.
2. If removing the SHC front Atellica Magline Transport cover, open the SHC cover.
3. Locate the 2 thumbscrews under the Atellica Magline Transport cover.



4. Loosen the 2 Atellica Magline Transport cover thumbscrews enough to allow the cover to slide off, but do not completely remove the thumbscrews.



5. Pull the Atellica Magline Transport cover away from the Atellica Magline Transport.
6. Set the cover aside.
7. If appropriate, repeat this task to remove additional Atellica Magline Transport covers.

5. Tube Characterization Station

Issue: Barcode Reader errors

Description: TCS does not read sample barcodes or errors are generated upon loading/reading.

Troubleshooting Steps

1. Error with lower case "a" - TCS will auto recover after 2 minutes (firmware version X running QC sample with test name begins "a" – only way this happens).
2. Check barcode label integrity.
3. Print a new barcode, if needed.
4. Open covers and clean camera lenses and reflector (Only if prompted by CSE or Technical Support).

SH Hardware Troubleshooting Notes

8 CH Hardware Troubleshooting

8 CH Hardware Troubleshooting

Resources

- Online Help
- PEPconnect

Objectives

Upon completion of this exercise you will be able to:

- Identify and resolve common IMT issues
- Perform As Needed maintenance for CH module
- Utilize Online Help to identify troubleshooting procedures
- Identify and resolve common hardware CH issues

IMT Troubleshooting

1. IMT Sensor Troubleshooting

Comments / Issues	Explanation / Solution
Serum/Plasma conditioning is not needed	IMT Fluids contain 0.01% Bovine serum albumin and the Sodium and Chloride membranes have a new design that does not require Serum/Plasma conditioning.
Running DilChek and accepting a new factor will adjust the recovery of Na, K, and Cl by the same amount that the factor changes. A change from 1.000 to 1.015 will increase Na, K, and Cl results by ~1.5%.	<ul style="list-style-type: none"> • QC ranges should be established using a single Dilcheck factor if the factor changes. • QC ranges should be reassessed after performing Dilcheck.
Instances of elevated Chloride QC results on new sensors has been observed, within hours it returns to normal.	<ul style="list-style-type: none"> • If this is observed the sensor may have failed to hydrate properly. • Recovery can be improved by running a routine clean and priming IMT Fluids 5X.

2. Failing Chloride Slope

Issue: Poor gel separation

Troubleshooting Steps

1. Tube manufacturer's IFU instructions must be followed in order to maintain proper pre-analytical sample quality.
2. Cellular components in the plasma portion of the sample also have an affinity for the CL sensor causing reduced sensitivity with subsequent CL slope failure.
3. Factors other than the generation of platelet poor plasma impact sample quality. Modification of the centrifuge speed and time can impact sample and gel separation causing the formation of gel droplets in the plasma portion, oil droplets on the top of the samples, and cellular components remaining in the plasma portion of the sample with non-gel tubes. The gel captures protein rich cellular components that have an affinity for the CL sensor causing reduced sensitivity of the sensor as the gel/protein accumulates with subsequent CL slope failure.

3. Low Sodium Results / Low Anion Gaps

Probable Cause	Solution
Advanced Clean not performed	Perform IMT Advanced Clean.
Water on dilution probe	Ensure all fittings on the dilution arm are tight. Clean the dilution probe with a lint free tissue.
Dried salt buildup and leaks	Inspect and clean and residual dried salt buildup from spills and/or leaks especially around fluid grounds.
Dilution check factor not current	Perform dilution check.

4. IMT Calibration Failure

Issue: IMT Calibration Failures

Description: The current common causes for IMT Calibration Failures are Chloride (CL) Slope and Potassium (K) Drift errors.

Troubleshooting Steps

1. CL^- Slope
 - Replace IMT Multisensor (run Advanced Clean first, if required).
2. K^+ Drift
 - Prime all IMT fluids 3-5 times, then recalibrate.
3. All other failures
 - Replace all IMT fluids and prime, the recalibrate.
 - If issue persists, perform Advanced Clean and replace sensor and contact Tech support.

CH As Needed Maintenance

Module	Task	Frequency	Errors/Comments
IMT	Replacing Peri-Pump Tubing	Every 50,000 cycles of Once a year/Upon failure	
CH	Replacing Triple washer probes	Upon failure	
CH	Replacing Reagent, Sample and Dilution Probes	Upon failure	
CH	Replacing Mixer Impellers	Upon failure	
CH	Photometer Lamp	4 months/ wavelength errors	

CH Hardware Troubleshooting

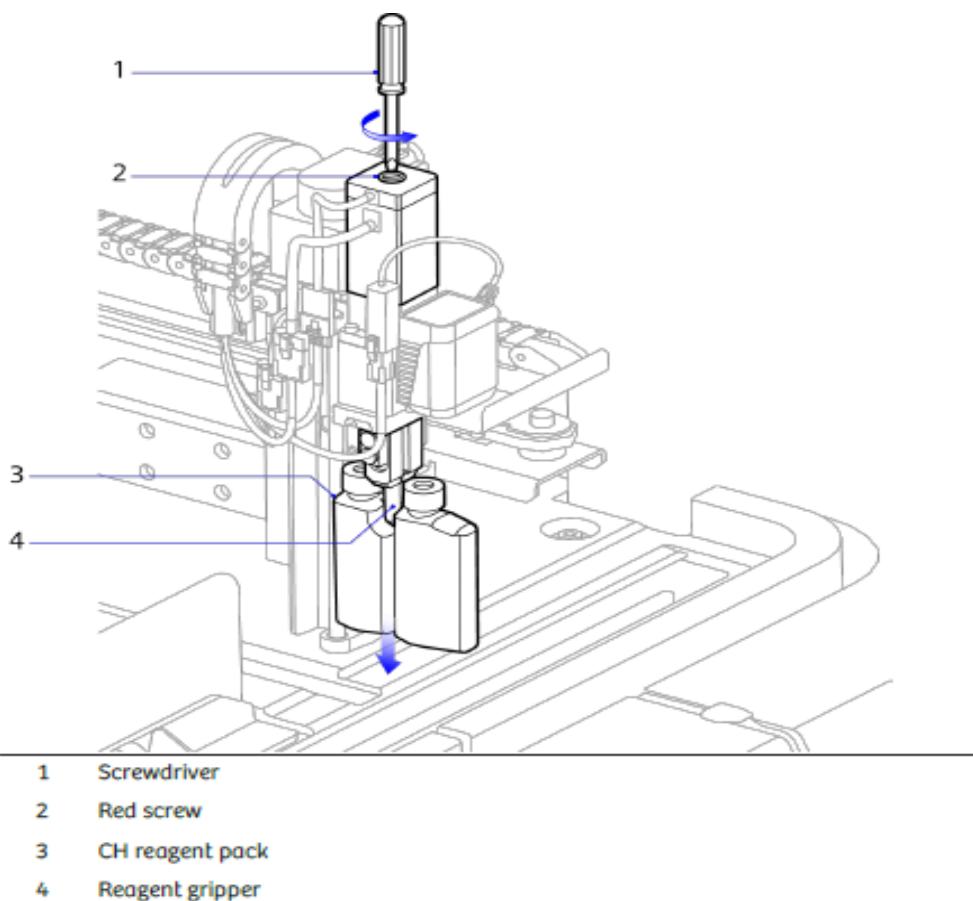
1. CH Reagent Loader

Issue: Reagent Loader capability offline

Description: Reagent Loader can experience motion errors, causing a motor mismatch and flagging an abnormal load or unload of a reagent.

Troubleshooting Steps

1. Ensure that reagents are fully seated before loading and check that the barcode is visible.
2. In the event of a jam, stop the CH, open the front cover and remove the jammed reagent.
3. Press Resume and load reagent to confirm functionality.
4. If issue persists, contact technical support.



To release the CH pack from the gripper:

- a. Grasp the bottom of the pack with 1 hand.
- b. Using other hand and a small flat edged screwdriver, turn the red screw on top of the gripper counterclockwise.
- c. Remove the pack.

2. CH Transfer Arms

Issue: Transfer Arm Pressure Sensor / Aspiration Errors

Description: Transfer Arms are any arm with a probe that transfers fluid from one place to another (Dilution, Sample, Reagent). Dilution Probe fails to sense an air-fluid transition, causing Sample Integrity and Level Sense errors. Sample and Reagent Probes can cause system errors due to failed well punctures and sample transfer issues.

Troubleshooting Steps

1. Stop the CH analyzer and use Operator Diagnostics to perform the 'replace probe' procedure.
2. Initially, only inspect the probe. Look for precipitate or static build-up on probe and clean with a lint-free tissue and DI water.
3. Check for damage to probe (bent, internal clots, etc.) and replace as necessary.
4. Perform an Autocheck.
5. If probe was replaced, run QC.
6. If issue persists, contact technical support.

3. CH Module Display Lock-Up

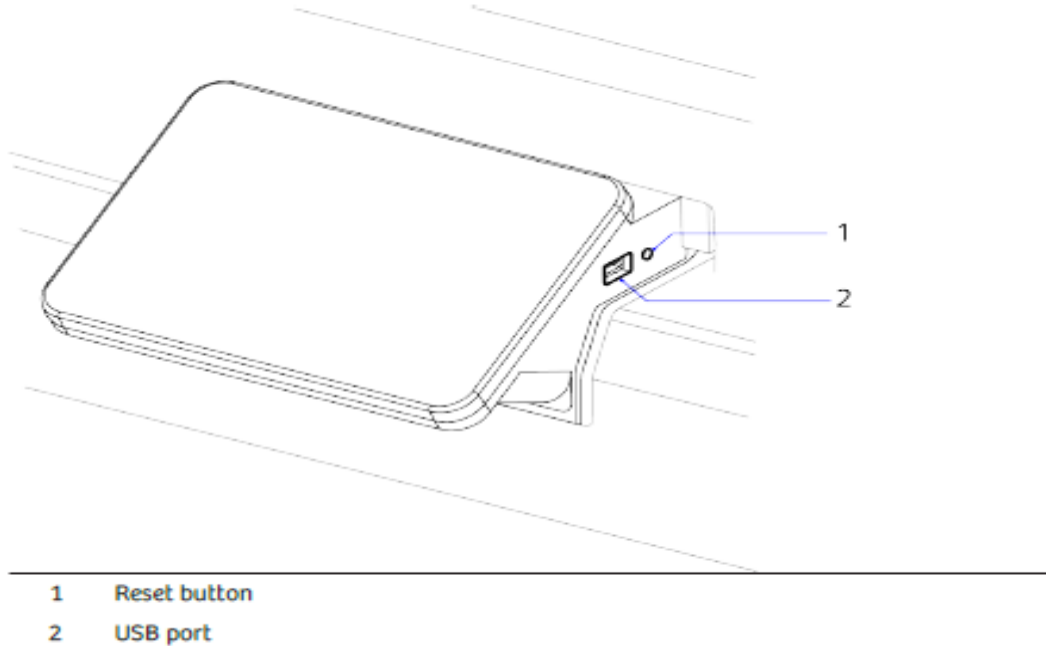
Issue: Module Display is locked-up

Description: Operator is unable to change screens on the module display.

Troubleshooting Steps:

1. Reset module display by pressing the reset button on the right side of the module display
2. If issue persists, power down and restart module.

Locate the reset button on the right side of the module display.



4. Reaction Ring Bath Level Low/High

Issue: Reaction Ring Bath Level Low/High

Description: Reaction Ring Bath is not at the appropriate level. Correct Bath level is needed to maintain cuvette temperature, consistent Photometer readings, and to keep from overflowing.

Troubleshooting Steps

1. In Operator Diagnostics perform quick Empty and Fill (with WBA).
2. If issue persists, reseal Sensor Clip to reposition sensors (Perform only if instructed by CSE or Technical Support).

CH Hardware Troubleshooting Notes

9 IM Hardware Troubleshooting

9 IM Hardware Troubleshooting

Resources

- Online Help
- PEPconnect

Objectives

Upon completion of this exercise you will be able to:

- Perform As Needed maintenance for IM module
- Utilize Online Help to identify troubleshooting procedures
- Identify and resolve common hardware issues for IM module

IM As Needed Maintenance

Task	Frequency	Errors/Comments
Replace Reagent Probes	Upon failure/ Volume check errors	
Replace Aspirate Probes	Upon failure/ Wash station errors	
IM Waste Probe Replacement	Upon failure	
Cleaning Sample Tip Drip Tray	Weekly/As Needed	

IM Hardware Troubleshooting

1. Cuvette Jams

Issue: Cuvette Loader jams

Description: Cuvettes get jammed somewhere along the cuvette path. The potential for jams are at each transition: cuvette loader, pusher/channel, ring loader, wash ring elevators (2 up, 1 down) and luminometer elevator.

Troubleshooting Steps

1. Verify presence of cuvettes in Hopper - manually move cuvettes within bin so that the Cuvette Presence Sensor is covered.
2. Verify that the Cuvette Belt can move freely.
 - a. If unable to move, remove all cuvettes and look for cause of jammed belt.
3. If the channel is not receiving cuvettes but the bin is full:
 - a) Open rear cover and verify cuvettes are not stuck/hung up at Vertical Drop Chute.
 - b) If possible, remove covers to cuvette channel and pusher area (below Drop Chute) and clear any obstructed cuvettes.
 - c) Check cuvettes for malformations and escalate if warranted.
4. Clear cuvette at Incubation Ring Loader.
5. From Operator Diagnostics, select Initialize Cuvette Loader, afterwards select Prime cuvettes
Note: This will only prime cuvettes until Cuvette Present Sensor at Vertical Drop Chute is covered.
6. If further testing is needed, perform the Empty and Fill sequence located in operator diagnostics under incubation ring.

Cuvette Loader Jams Event Codes with Operator Diagnostics Troubleshooting

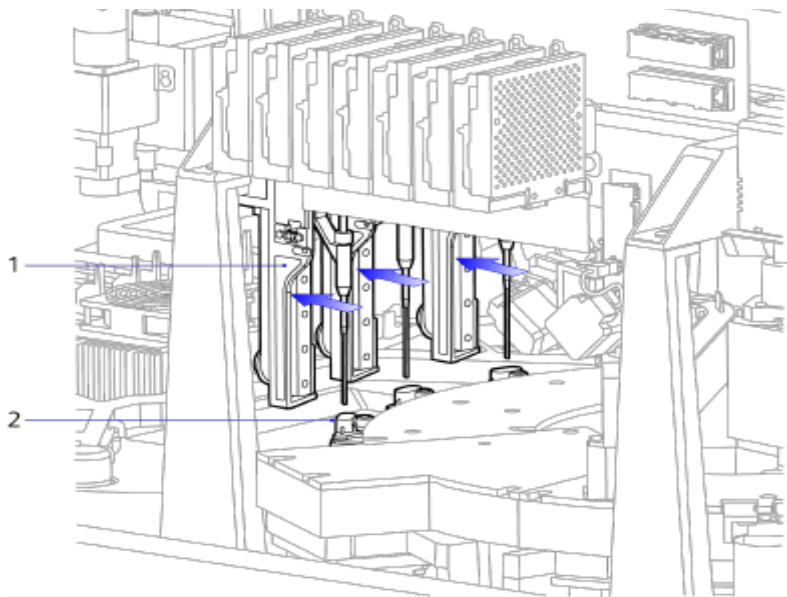
Event Code	Description	Corrective Action
03 310 00 01	The IM wash ring has a motion error	<ol style="list-style-type: none"> 1. Perform the Recover from the Wash Ring Motion Error activity in Operator Diagnostics. 2. Check for obstructions in the wash ring or in the up elevators.
03 310 00 02	A cuvette was not lifted into the luminometer.	<ol style="list-style-type: none"> 1. Perform the Recover from the Luminometer Elevator Lift Error activity in Operator Diagnostics. 2. Check for obstructions in the luminometer elevator.
03 310 00 03	The luminometer elevator did not complete the upward motion.	<ol style="list-style-type: none"> 1. Perform the Recover from the Luminometer Elevator Lift Error activity in Operator Diagnostics. 2. Check for obstructions in the luminometer elevator.
03 310 00 04	The wash ring follower did not complete its downward motion.	<ol style="list-style-type: none"> 1. Perform the Recover from the Downward Transfer of Cuvette Error activity in Operator Diagnostics. 2. Check for obstructions in the down elevator.
03 600 01 01	Cuvette Pusher driver is offline because of a motion error.	Check for obstructions in the pusher / channel area.
03 600 01 02	Cuvette Bin driver is offline because of a motion error.	Check for obstructions to the loader belt.
03 600 01 03	Cuvette Ring Loader driver is offline because of a motion error.	Check for obstructions in the ring loader area
03 600 01 04	Channel assembly is not receiving cuvettes.	<p>Check cuvette bin.</p> <p>Check for obstructions in the orientation chute and drop tube.</p>
03 600 01 05	The ring loader did not complete its downward motion while loading cuvettes.	Check for obstructions in the ring loader area.

➤ Clearing IM Cuvette Jams

NOTE: Perform this task only when prompted by an error message.

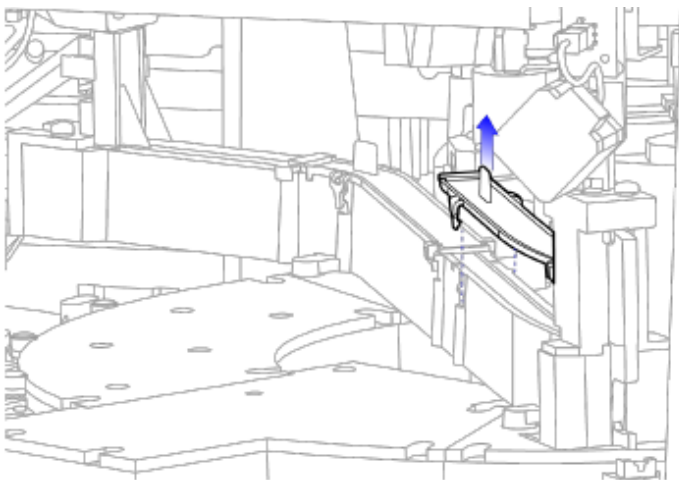
The channel assembly is not receiving the cuvettes, even though the cuvette bin has enough cuvettes. The elevator entry might be clogged due to the cuvette jam, and manual removal of damaged or deformed cuvettes is required

1. Ensure analyzer is in Stopped state.
2. Unlock and open the IM front cover.
3. Move the reagent probes to the left side and out of the way while avoiding pushing on the probe tips.



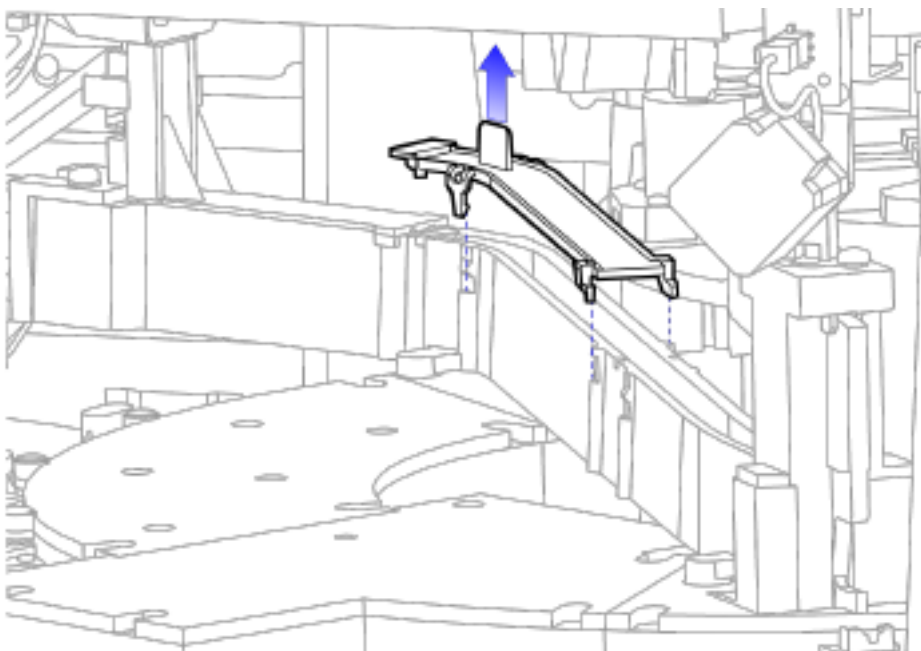
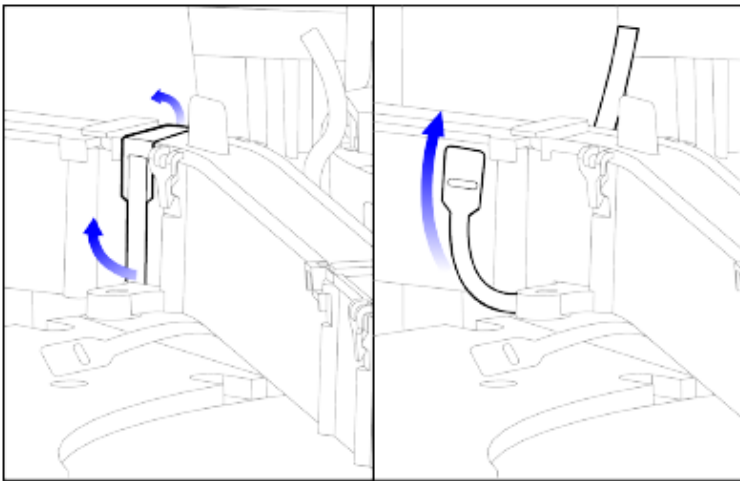
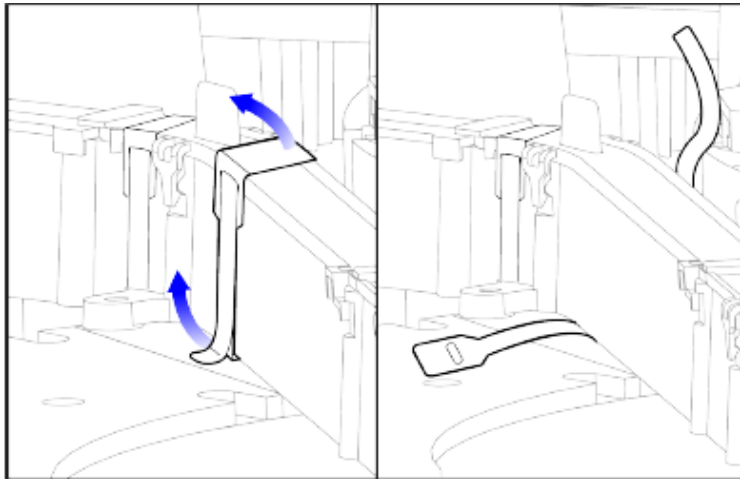
- 1 Reagent probe assembly
- 2 Probe rinse station

4. If appropriate, remove the cuvette channel cover nearest the incubation ring loader.



NOTE: Verify the positions of the velcro straps before removing.

5. If appropriate, remove the cover from the middle cuvette channel section:
 - a) Unfasten the right velcro strap and open. The strap stays in place.
 - b) Unfasten the left velcro strap and remove. Ensure it does not fall into the analyzer. Set aside in a safe location.



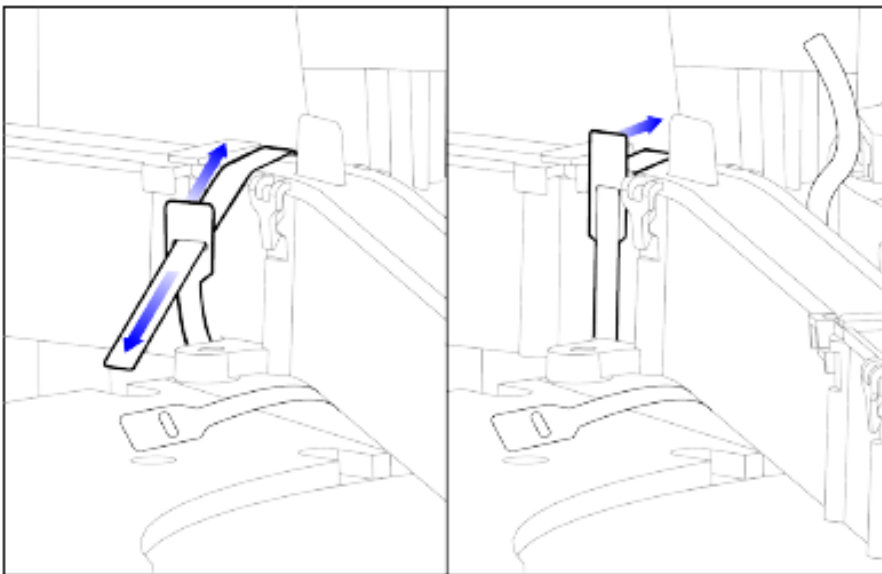
6. If appropriate, remove the cover from the section nearest the cuvette pusher:
 - a) Place a paper towel under the cuvette channel area near the pusher to catch any cuvettes.
 - b) Open the retaining clip.
 - c) Slide the cover back and lift upward.



7. Inspect the cuvette loader orientation chute, drop chute, and cuvette channel for jams.
8. If appropriate, remove any remaining cuvettes.

NOTE: Ensure the cuvette channel cover tabs align and insert into the track notches.

9. Reinstall the pusher area channel cover.
10. Replace the remaining channel covers, starting with the middle section:
 - a. Replace the middle channel cover.
 - b. Replace the left velcro strap by inserting under the middle channel and around the top cover, then fastening.
 - c. Fasten the right velcro strap on the middle channel cover.
 - d. Replace the right channel cover.


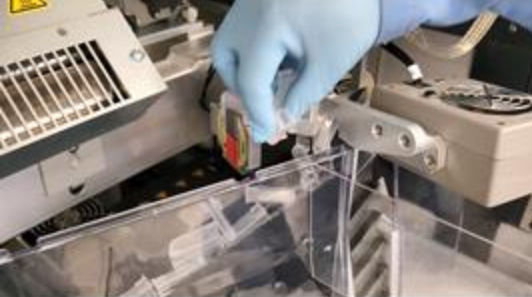

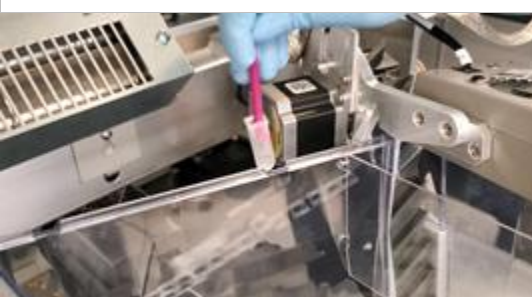


11. Close the cover and select resume to bring the analyzer back to the Ready state.

➤ Clearing the IM Cuvette Loading Area

1. Unlock and open the IM Analyzer front cover
2. Inspect the IM cuvette loading area for jams:
 - a. Inspect the cuvette bin and clear any jams. Remove cuvettes, if appropriate.
 - b. Inspect the conveyor to clear jams. Remove cuvettes, if appropriate.
 - c. Inspect the orientation chute and clear any jams. Remove cuvettes, if appropriate.
3. Close the cover and select resume to bring the analyzer back to the Ready state.

Following images demonstrate the corrective action in detail:

<p>a. Locate the cuvette jam in the channel assembly</p>	
<p>b. Remove the excess cuvettes from the assembly</p>	
<p>c. Using either an inverted sample tip or an appropriate tool, remove the remaining cuvettes from assembly channel one-by-one</p>	
<p>d. Repeat the step detailed in step (c) until all the cuvettes have been removed from the cuvette channel assembly using an inverted sample tip</p>	

e. Discard damaged or bent cuvettes per laboratory protocol



f. Clear the channel assembly entry point and any cuvettes on the up elevator



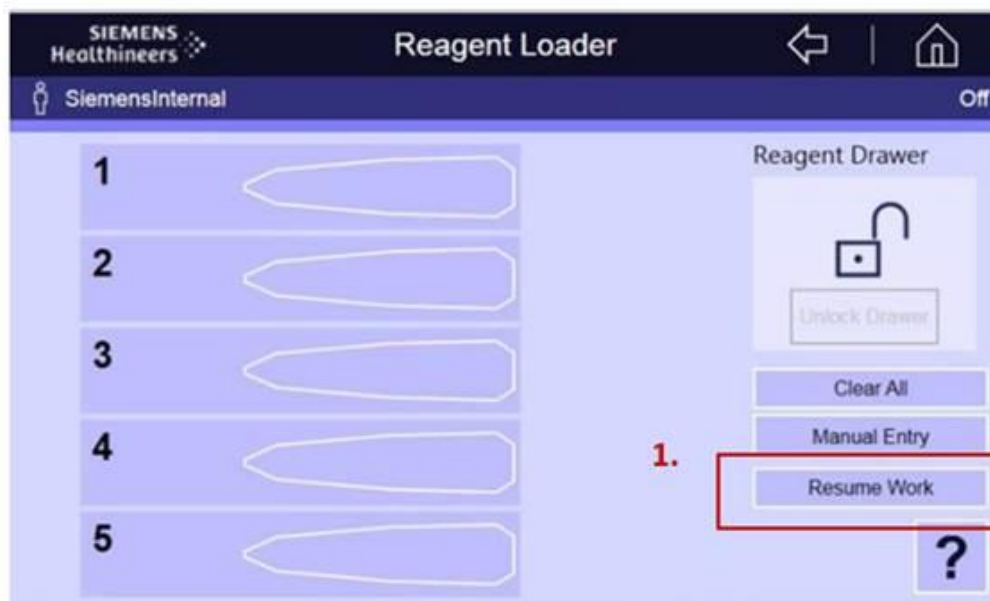
2. Reagent Loader

Issue: Reagent Loader offline or jams

Description: The Reagent Loader can go offline for several reasons. Some include Motion Errors, Reagent Pack jams, in the reagent compartment or at the reagent loader drawer.

Troubleshooting Steps

1. Put IM analyzer in Stopped state and open the rear cover. Remove any jammed reagent packs or obstructions.
2. If Reagent Loader Arm is in the Reagent Compartment:
 - a) Turn Mechanics Off.
 - b) Raise up Loader Arm.
 - c) Confirm no obstructions in Reagent Compartment and close compartment door (shutter).
 - d) Turn Mechanics On.
3. Check the Reagent Loader Drawer. Open the front cover and remove any obstructions if present.
4. Check the Reagent Loader screen for the "Resume Work" button located on the module display or under Inventory – Reagent Loader screen and select.



5. From Operator Diagnostics, initialize the Reagent Loader and the Reagent Compartment. Check that no errors occurred on the Reagent loader or Reagent compartment while initializing and both are back online.
6. Press Resume and wait for system to start up to confirm that everything is operational.

Regent Loader Offline / Jams Related Event Codes

Error Codes	Explanation
03 600 07 09	Reagent Loader Gripper driver is offline because of a motion error.
03 600 07 10	Reagent Loader Horizontal driver is offline because of a motion error.
03 600 07 11	Reagent Loader Vertical driver is offline because of a motion error.
03 600 07 12	Reagent Compartment driver is offline because of a motion error.

3. Reagent Probe

Issue: Reagent Probe Volume Check errors

Description: Volume Check errors are produced when a Reagent Probe pressure sensor does not detect air or liquid as expected based on pressure readings when trying to aspirate or dispense reagent.

Troubleshooting Steps

1. Enter Diagnostics, open back cover, and inspect Reagent Probe.
2. From Operator Diagnostics, perform Dispense Tests:
 - a) Check that the fluid stream is straight and not sputtering.
 - b) Check the probe tip for bubbles or dripping after dispense.
 - c) Check for bubbles in the reagent pumps.
 - d) Check for loose Click-n-Seal connections at each end of probe tubing.
 - e) Check for loose connections at the reagent probe pumps Click-N-Seal connections and fluid heaters lure lock connections.
 - f) Clean the probe, confirm it is straight, and check for pinched tubing.
3. If probe is bent, tubing is pinched, or bad fluid stream persists, replace probe.
4. Exit diagnostics and unload affected reagent pack(s) and determine if puncture is centered in the well. If puncture not centered, probe is bent or needs re-alignment.
5. If issue persists, contact Technical Support.

Reagent Probe Volume Check Errors and Event Codes

Error Codes	Explanation
Reagent Probe 1	
03 600 06 16	Volume Check Error on reagent probe 1 at pack {0} for the test {1}
03 600 06 01	Level check error at reagent probe 1. Pressure transducer failure at pack {0}, well position {1}.
03 600 06 02	Level check error at reagent probe 1. Insufficient reagent aspiration from pack {0}, well position {1}.
03 600 06 03	Level check error at reagent probe 1. Dispense duration is too short for pack {0}, well position {1}.
03 600 06 04	Level check error at reagent probe 1. Dispense pressure is too low for pack {0}, well position {1}.
03 600 06 05	Level check error at reagent probe 1. Reagent probe 1 is offline for pack {0}, well position {1}.

4. Sample Probe

Issue: Sample Probe Integrity Errors

Description: The Sample probe is unable to aspirate fluid from the sample tube due to clot detection, insufficient sample, or level sense related issues.

Troubleshooting Steps

1. Confirm whether current sample or any previous samples had clots or bubbles.
2. Open back cover and wipe tip of sample probe plunger with gauze.
3. Ensure that the sample tip tray is locked on the stage. If not, load a new tip tray in Operator Diagnostics.
4. Inspect sample trays for warping and sample tips for deflection and escalate as needed. Provide lot number and box information.
5. Inspect the sample probe plunger for damage.

Sample Probe Integrity Event Codes:

Error Codes	Explanation
03 600 03 08	The IM Analyzer cannot aspirate sample (SID {0}) because the maximum pressure is too high. Check the sample integrity.
03 600 03 09	The IM Analyzer cannot aspirate sample (SID {0}) because the final pressure is too high. Check the sample integrity.
03 600 03 10	The IM Analyzer cannot aspirate sample (SID {0}) because the final pressure is too low. Check the sample integrity.
03 600 03 11	The IM Analyzer cannot aspirate sample (SID {0}) because the maximum pressure is too low. Check the sample integrity.
03 600 03 13	The IM Analyzer cannot aspirate sample (SID {0}) because the final dispense pressure is too low. Check the sample integrity.
03 600 03 14	The IM Analyzer cannot aspirate sample (SID {0}). The sample contains bubbles or foam. Check the sample integrity or volume.
03 600 03 15	The IM Analyzer cannot aspirate the sample (SID {0}). Check the sample or sample aspiration subsystem.
03 600 03 01	The IM Analyzer cannot sense the liquid level of sample (SID {0}). Ensure that the sample tube contains sufficient sample volume.
03 600 03 05	The IM Analyzer cannot aspirate sample (SID {0}) because the analyzer did not retrieve a tip from the tray.
03 600 03 06	The IM Analyzer cannot aspirate sample (SID {0}) because of a collision when the analyzer was retrieving a tip from the tray.

5. Sample Tip Tray Loader

Issue: Sample Tip Tray Loader jams

Description: Tip Tray is jammed somewhere within the Tip Loader mechanism - usually at the staging area or while ejecting to the waste.

Troubleshooting Steps

1. Find the obstruction:
 - a) Open the Sample Tip Loader area lower door. Empty the tip tray waste through software if possible (or else open manually) and remove trays and covers, and check for obstructions. If found, go to step 2.
 - b) Open tip tray input queue door remove all trays and check for obstructions at or below the input queue. If found, go to step 2.
 - c) Select Open Front Cover through software, then put the analyzer into Stopped state and Open the front cover. Check if a tip tray is on the stage. If tray is not locked, manually remove the tray, and go to step 3.
 - d) If possible, remove 3 screws to remove the lower front cover. Check inside tip loader for obstructions.
2. Clear the obstruction by manually removing the jammed Tip Tray. If unable to remove, Turn Mechanics off to be able to manually move the Sample Tip Loader mechanisms to help clear the jam.
3. Press Resume. A new tray will load to the stage during start-up.
 - If new tray does not load automatically, unload and load a new tip tray in Operator Diagnostics.
 - Tip Tray exchange takes the empty tray to waste (or the tray with tips to the input queue). It then takes a tray from storage and loads it onto the stage.

Sample Tip Tray Loader Jams Event Codes:

Event Code	Explanation
03 800 06 01	Tip Tray Transfer Horizontal driver is offline because of a motion error.
03 800 06 02	Tip Tray Transfer Vertical driver is offline because of a motion error.
03 800 06 03	Tip Pickup Stage driver is offline because of a motion error.

6. Secondary Vacuum

Issue: Secondary Vacuum out of range

Description: Secondary waste vacuum (for the aspirate probes) is out of range/will stop the system/waste bottles may or may not have liquid waste.

Troubleshooting Steps

1. Check that the secondary vacuum reservoir black cap is tight, there are no cracks in the cap, and reseal the connectors.
2. Run IM Autocheck.
3. Turn Mechanics off and back on.
4. If issue persists, contact technical support.

Secondary Vacuum Out of Range Event Code:

Event Code	Explanation
03 400 13 28	Secondary vacuum pressure is out of range.

7. Waste Reservoir

Issue: Waste Reservoir full

Description: Waste Reservoir does not empty automatically, and system will post an alert. This could be due to clogged tubing, vacuum errors, etc.

Troubleshooting Steps

1. Manually lift each of the three waste reservoirs off the load scales and reseal them.
 - a. Confirm no additional cables, tubing, or anything else are resting on top of the waste reservoirs, and that reservoirs are sitting flat on scales
2. Perform the Maintenance to clean the waste transfer pumps.
3. From Operator Diagnostics, perform the Empty Waste Reservoirs sequence under Fluidics.
 - a. If Empty Waste Reservoirs sequence fails, turn Mechanics Off and back on, then repeat the sequence.
4. If issue persists, CSE may be needed for scale re-calibration and/or additional troubleshooting to check for clogged tubing between bottles and waste transfer pumps due to accumulated PMP preventing waste from being sent to drain.

Waste Reservoir Event Codes:

Error Codes	Explanation
03 600 15 75	Liquid waste error {0}. Processing stopped.
03 400 13 06	Sampling stopped because the liquid waste reservoirs are almost full. If using an external waste container, ensure it is installed correctly and empty if full.
03 400 13 07	Processing stopped because the liquid waste reservoirs are full. If using an external waste container, ensure it is installed correctly and empty if full.

IM Hardware Troubleshooting Notes

10 Software Troubleshooting

10 Software Troubleshooting

Resources

- Online Help
- PEPconnect

Objective

Upon completion of this exercise you will be able to:

- Identify and resolve common software issues

Software Troubleshooting

1. Calibration

Issue: Calibration not running or running too frequently

Troubleshooting Steps

1. Review Event Logs to determine if calibration is not processing due to a system issue.
2. Review Reagent/Ancillary, Calibrator, QC and System Fluid needs and review lot-locked pairs if required.
3. Confirm correct calibration (Lot vs. Pack) was ordered on correct reagent lot.
4. Cancel pending calibration orders for reagent lots no longer in use or onboard the system.
5. Order calibration for correct calibration type and reagent lot.
6. If calibration still does not run, move all results to Historical and reorder.
7. If calibration still does not run, restart the PCC and reorder.
 - a. Sign out.
 - b. At the logon screen, do not sign in but instead select Restart followed by Restart the PCC Workstation only.
 - c. When the logon screen appears, sign in.

2. LIS Connectivity

Issue: Connection to LIS lost

Troubleshooting Steps

1. Restart LIS Connection on the Atellica Solution.
2. Turn on LIS log capture.
3. Confirm Atellica Solution is scanning the barcodes to get the Sample ID.
4. Try ordering sample from Atellica Solution and see if the result crosses over.
5. If issue persists, troubleshoot Middleware and physical connections.
6. Restart the PCC.

3. Maintenance

Issue: Stuck in maintenance or maintenance not starting

Troubleshooting Steps

1. Verify the Maintenance schedule is correct (i.e., no conflicts).
2. Follow the optimized maintenance schedule for assistance (refer to the 1.20 software release notes in Document Library).
3. Confirm that there are no conflicts with QC Schedule.
4. Check for system errors/supply needs.
5. Make sure module is in Standby/Ready and not stopped.
6. Reboot associated module.
7. Reboot PCC.

4. Module Connectivity

Issue: Module Offline or "Not Connected to PCC"

Troubleshooting Steps

1. Press Resume and wait a couple minutes to allow system to restart.
2. Log out of UIW and back in to allow screen to update.
3. Open the cover and leave open for at least 15 seconds and then close.
 - a. This may force the computers to start communicating again.
4. If issue persists, reboot PCC.
 - a. Sign out.
 - b. At the logon screen, do not sign in but instead select Restart followed by Restart the PCC Workstation only.
 - c. When the logon screen appears, sign in.
5. If still unresolved, power down and restart entire line.
6. If issue persists, contact technical support.

5. Quality Control (QC)

Issue: QC not running

Troubleshooting Steps

1. Review Event Logs or SRS Process Error data to determine if QC is not processing due to a system issue.
2. Review Reagent/Ancillary, Calibrator, QC and System Fluid Needs and review lot-locked pairs if required.
3. Check QC Definition and Schedule for accuracy.
4. Delete pending Cal/QC order and reorder.
5. For QC not stored onboard, reprint QC barcodes. It is not recommended to print a new barcode if material is stored onboard due to OBS.
6. For QC stored in CCS, remove from CCS and place in input drawer of Sample Handler.
7. If QC still does not run, move all results to Historical and reorder.
8. If QC still does not run, restart the PCC and reorder.
 - a) Sign out.
 - b) At the logon screen, do not sign in but instead select Restart followed by Restart the PCC Workstation only.
 - c) When the logon screen appears, sign in.

6. Sample Processing

Issue: Samples not processing

Troubleshooting Steps

1. Verify that sample processing is enabled under Module Status.
2. Check for system errors (VMM, Sample integrity, LIS).
3. "No Orders": verify the sample was not on board previously. For samples that have previously been on the system, reorder the sample manually.
4. Review Reagent/Ancillary, Calibrator, QC and System Fluid Needs and review lot-locked pairs if required.
5. Verify operator is loading samples into an input drawer.

6. Log out and log back into the PCC.
7. Stop the SH, open and close the lids, then start the SH.
8. Restart the PCC.
 - a) Sign out.
 - b) At the logon screen, do not sign in but instead select Restart followed by Restart the PCC Workstation only.
 - c) When the logon screen appears, sign in.

7. Setup

Issue: Incorrect Cal, QC, and Test Definition configuration. Set-up/editing definitions (i.e. removing assays from QC Definitions).

Troubleshooting Steps

1. Verify that sample processing is enabled under Module Status.
2. Check for system errors (VMM, Sample integrity, LIS).
3. "No Orders": verify the sample was not on board previously. For samples that have previously been on the system, reorder the sample manually.
4. Review Reagent/Ancillary, Calibrator, QC and System Fluid Needs and review lot-locked pairs if required.
5. Verify operator is loading samples into an input drawer.
6. Log out and log back into the PCC.
7. Stop the SH, open and close the lids, then start the SH.
8. Restart the PCC.
 - a) Sign out.
 - b) At the logon screen, do not sign in but instead select Restart followed by Restart the PCC Workstation only.
 - c) When the logon screen appears, sign in.

Software Troubleshooting Notes

11 Restart vs. Reboot

11 Restart vs Reboot

Resources

- Online Help
- PEPconnect

Objectives

Upon completion of this exercise you will be able to:

- Perform PCC restart
- Perform a module shutdown
- Perform a full system shutdown
- Utilize Rebooting Job Aid to discuss restart vs rebooting scenarios

Restart and Reboot Procedures

1. Restarting PCC

1. Ensure none of the following tasks are in process to prevent data loss:
 - Tests are processing: choose 1 of the following:
 - i. Select Worklist > Worklist Overview and select All filters
 - ii. Select System > Status and check analyzer states for processing.
 - Database optimization processing.
 - LIS transmitting results: select Worklist > Worklist Overview and ensure results are complete.
 - Maintenance activities including database backup, archiving and deletion, and move to historical: select in Maintenance > Schedule and search for the appropriate activity.
 - Exporting: located in several areas.
 - Printing to a printer or file.
 - System states such as Processing and Diagnostics: select System > Status.
 - IM Analyzer: Any control-bracketed test results pending release with a closing bracket (Waiting for Bracket: select Worklist > Worklist Overview).
2. On the Status bar, select Sign out icon.
3. Select Sign Out > Yes > Restart.
4. Read the caution message: To prevent loss of data, ensure sample processing and maintenance activities are complete before attempting a Restart.
5. Select 1 of the following:
 - Restart the PCC Workstation and the SH or DL only.
 - Restart the PCC Workstation and All Modules.
6. Ensure the system is not processing tests, then select Restart.

NOTE: If the PCC fails to restart, the keyboard is not responding, or the UI is locked after a 2-minute wait:

 - a. Select CTRL+ALT+DEL then select the power button from lower right corner of screen.
 - b. Select Restart > Yes.
7. The system closes out the session, refreshes the UI, and returns the operator to the login screen.

2. Shutting down and powering off an analyzer within the system

Use this procedure to shut down and power off an analyzer and not the entire system.

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

2. Select the appropriate analyzer icon.

NOTE: If an analyzer is powered off for over 2 hours, remove and refrigerate the reagents from the reagent compartment.

3. To power down the analyzer, select Power button.

a. If no tests processing, select Yes.

b. If tests are processing, select the appropriate shutdown option.

4. Wait for the analyzer status to display "Not connected to PCC."

5. Power off the analyzer.

6. Wait for the system display screen to turn black for the analyzer.

7. Turn off the power switch for the respective analyzer.

8. After the monitor to turns black, wait 30 seconds before restarting the analyzer.

3. Full System Shutdown

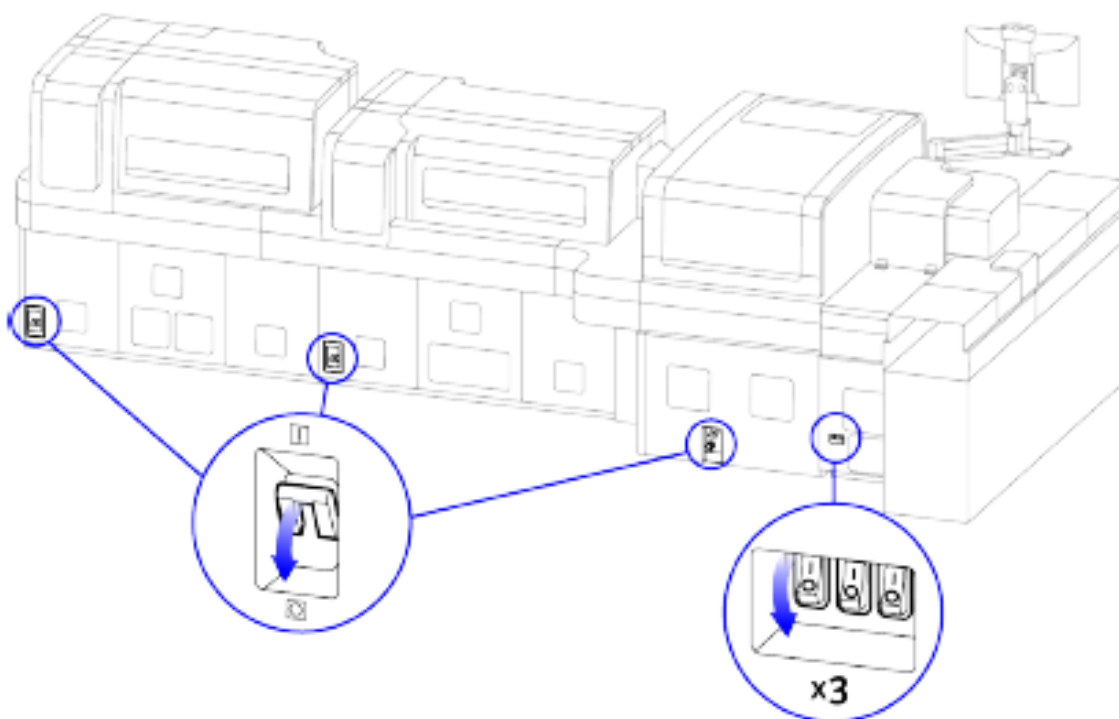
NOTE: Complete this procedure only when the system requires a complete shut down for troubleshooting or maintenance. If the system requires a restart, the operator should restart the PCC.

Use the following shut down procedure on a system configuration. Skip any steps for modules not present in the laboratory system configuration.

1. To shut down the system:
 - a. On the Status bar, select Sign Out icon.
 - b. Select Sign Out > Yes.
 - c. Select Shutdown > Yes.

NOTE: The system deletes pending calibration orders when the analyzer shuts down. Patient and QC orders remain.

2. Wait for all modules to shut down.
3. When the primary user interface no longer displays, power off all modules.
 - Power off the module farthest from the PCC.
 - Power off the next module. Continue powering off all modules in sequence including the SH.



NOTE: The analyzers and SH have 1 power switch each. The SHC has 3 power switches.

4. Wait 30 seconds before restarting the system.

NOTE: The 30 second wait:

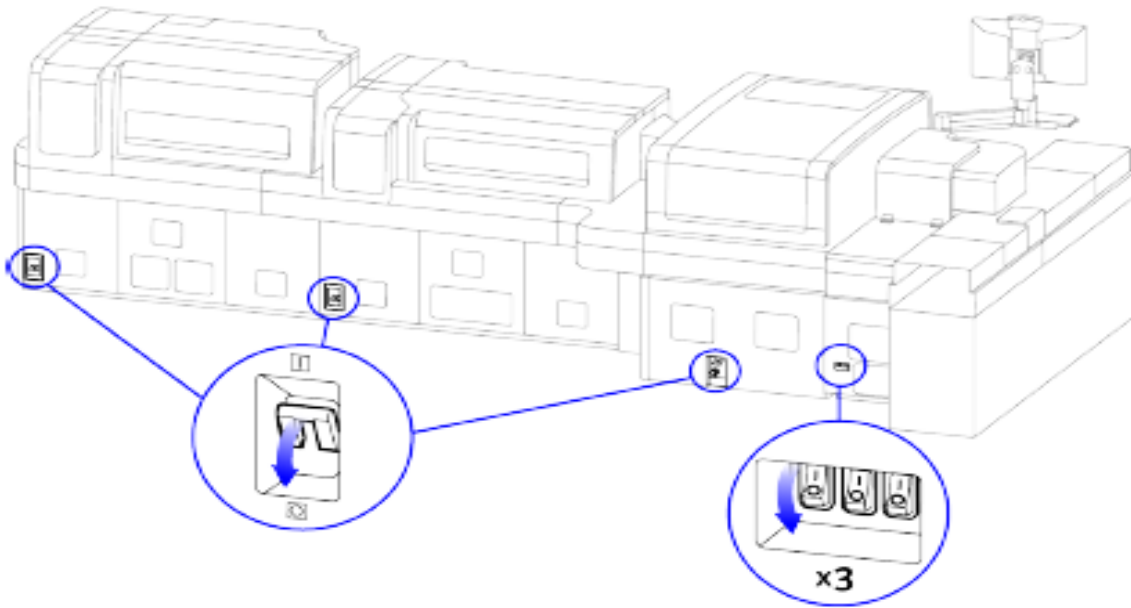
- Ensures the router connection to the intranet stops for this time period to terminate communication.
- Allows capacitors to drain residual power to avoid data corruption.

5. If any module power is off:

- For > 30 minutes on IM Analyzer, unload, and store reagents. Then manually mix primary reagents and reload all onboard reagents.
- For > 2 hours on CH Analyzer or IM Analyzer, discard any assay reagents remaining in the reagent compartment and calibrators or QC materials remaining in the Cal-QC storage area.

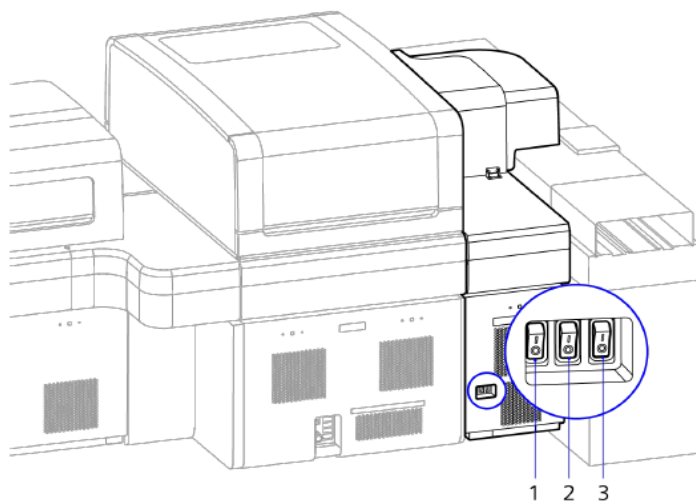
4. Starting the system

1. Ensure Atellica Magline Transport is clear.
2. If appropriate, power on the SH Prime and wait 30-60 seconds.



NOTE: The analyzers and SH have 1 power switch each. The SHC has 3 power switches.

3. If appropriate, power on each SH Additional.
4. If appropriate, start the SHC.
5. If appropriate, power on each analyzer in sequence.



- | | |
|---|-----------------------|
| 1 | +24VDC power switch |
| 2 | +48VDC power switch |
| 3 | Computer power switch |

- a) Power on the left +24VDC power switch and wait 10 seconds.
 - b) Power on the middle +48VDC power switch and wait 10 seconds.
 - c) Power on the computer power switch to the right.
6. If appropriate, power on each analyzer in sequence and wait 30 seconds before powering on the next analyzer.

NOTE: Start with the analyzer adjacent to the SH and proceed 1 by 1 to the other analyzers in the order they are connected.

7. Wait for the system display login screen to display.
8. If appropriate, Ensure the barcode label printer power is on.
9. Sign into the system.
10. Initialize the SH drawers Completely open and close the SH drawers.
11. Confirm the contents of each SH Cal-QC storage area.
12. Ensure all modules are in Ready or Standby state.

NOTE: If a module doesn't display within 5 minutes, proceed to next step.

13. In Module State, ensure all modules display appropriate statuses.
14. If any module status does not display or any problems occur, contact the local technical support provider.

Restart vs. Reboot Notes

12 Appendix

FUNCTIONAL OVERVIEW

SH System Components (Outside)

__A__ Visual status light

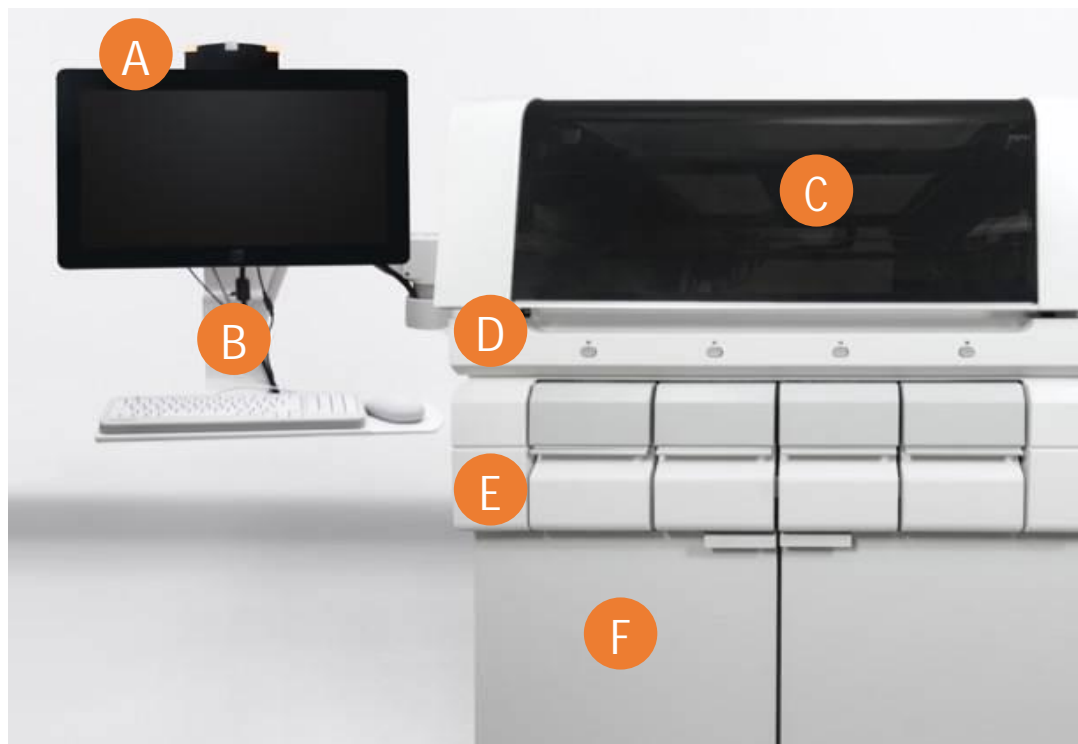
__B__ Monitor, keyboard, and mouse

__C__ System front cover

__D__ Lock/unlock drawer buttons

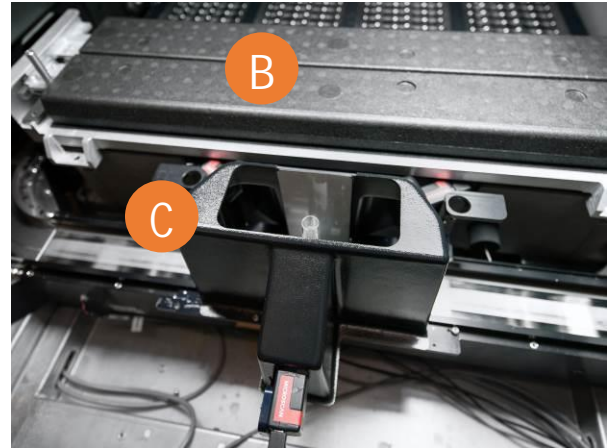
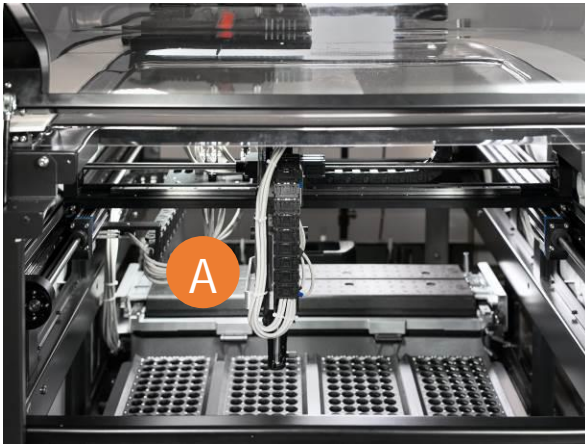
__E__ Sample drawers

__F__ Process Center Computer (PCC)



SH System Components (Inside Front and Back)

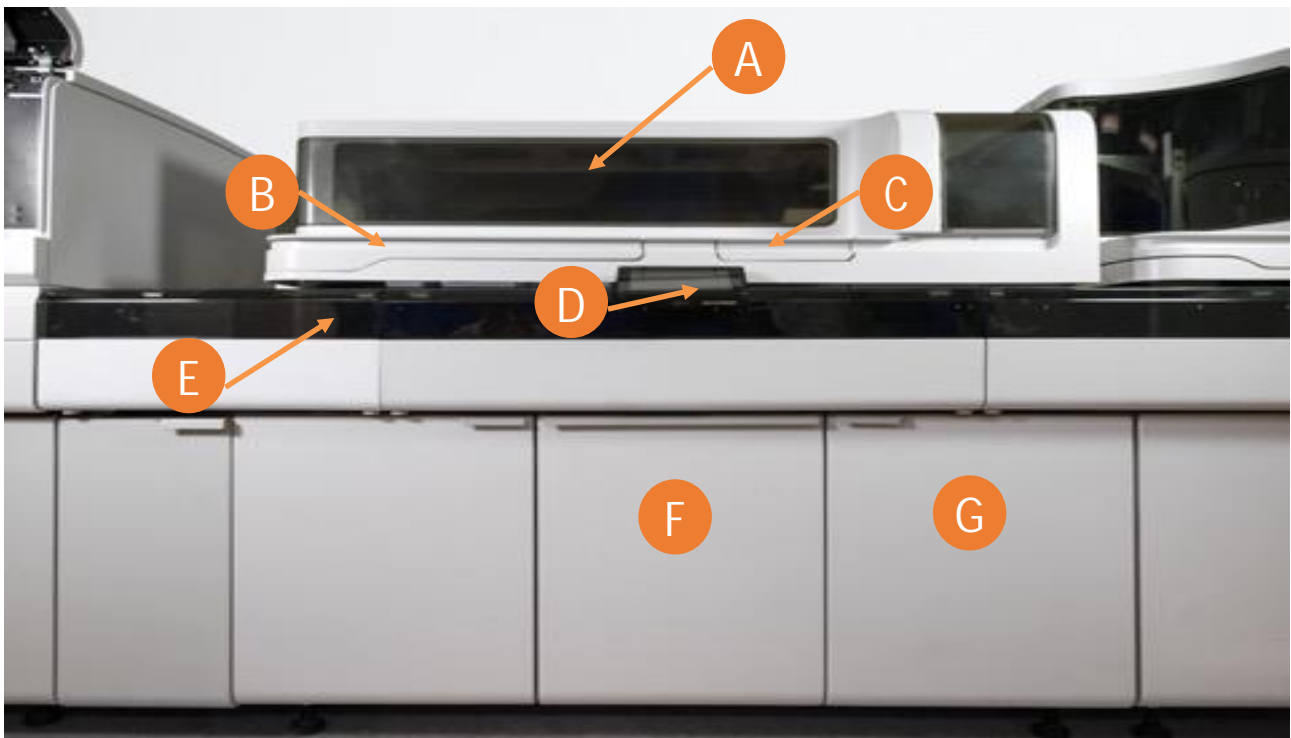
- __A__ Robotic arm
- __B__ Cal-QC Storage area
- __C__ Tube Characterization System (TCS)
- __D__ Carrier
- __E__ Atellica Magline™ Transport



CH System Components (Outside)

1. Identify the following CH system components in the image below

- __A__ System front cover
- __B__ IMT (integrated multisensor technology) fluids lid
- __C__ Reagent tray lid
- __D__ Module Display
- __E__ Atellica Magline™ Transport
- __F__ System fluid drawer
- __G__ Water and liquid waste



CH System Components (Inside Front and Back)

__A__ IMT

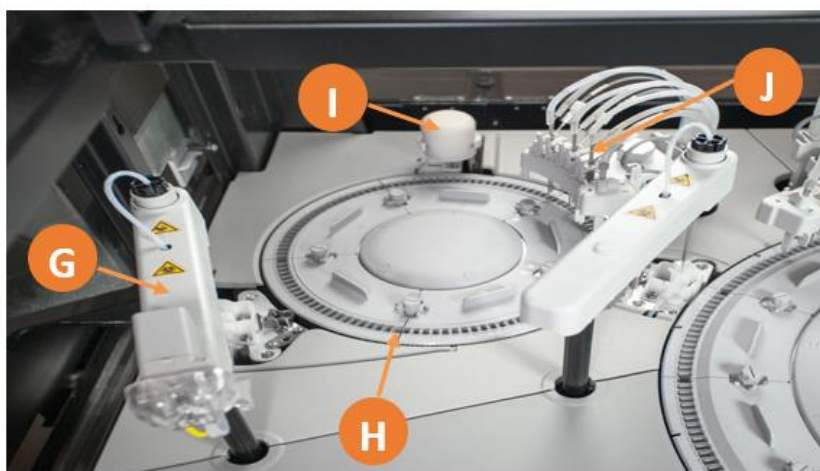
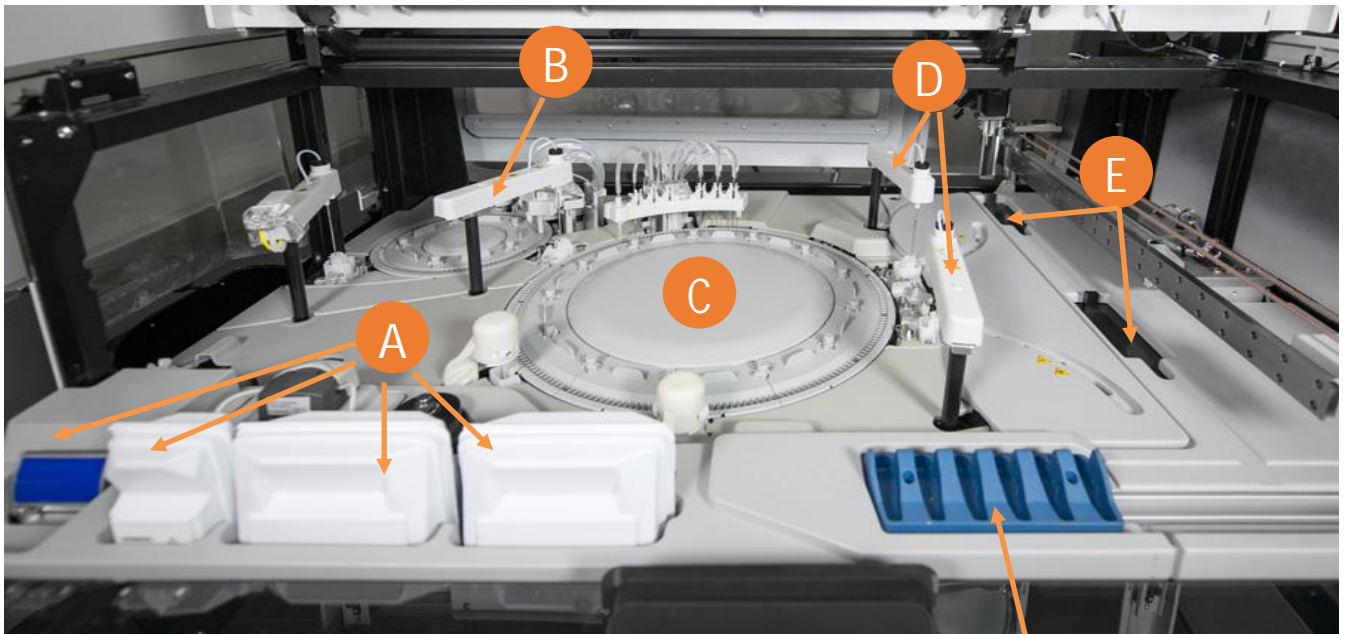
__B__ Sample Probe

__C__ Reaction ring

__D__ Reagent probes 1 and 2

__E__ Reagent compartment

__F__ Reagent tray



__G__ Dilution Probe

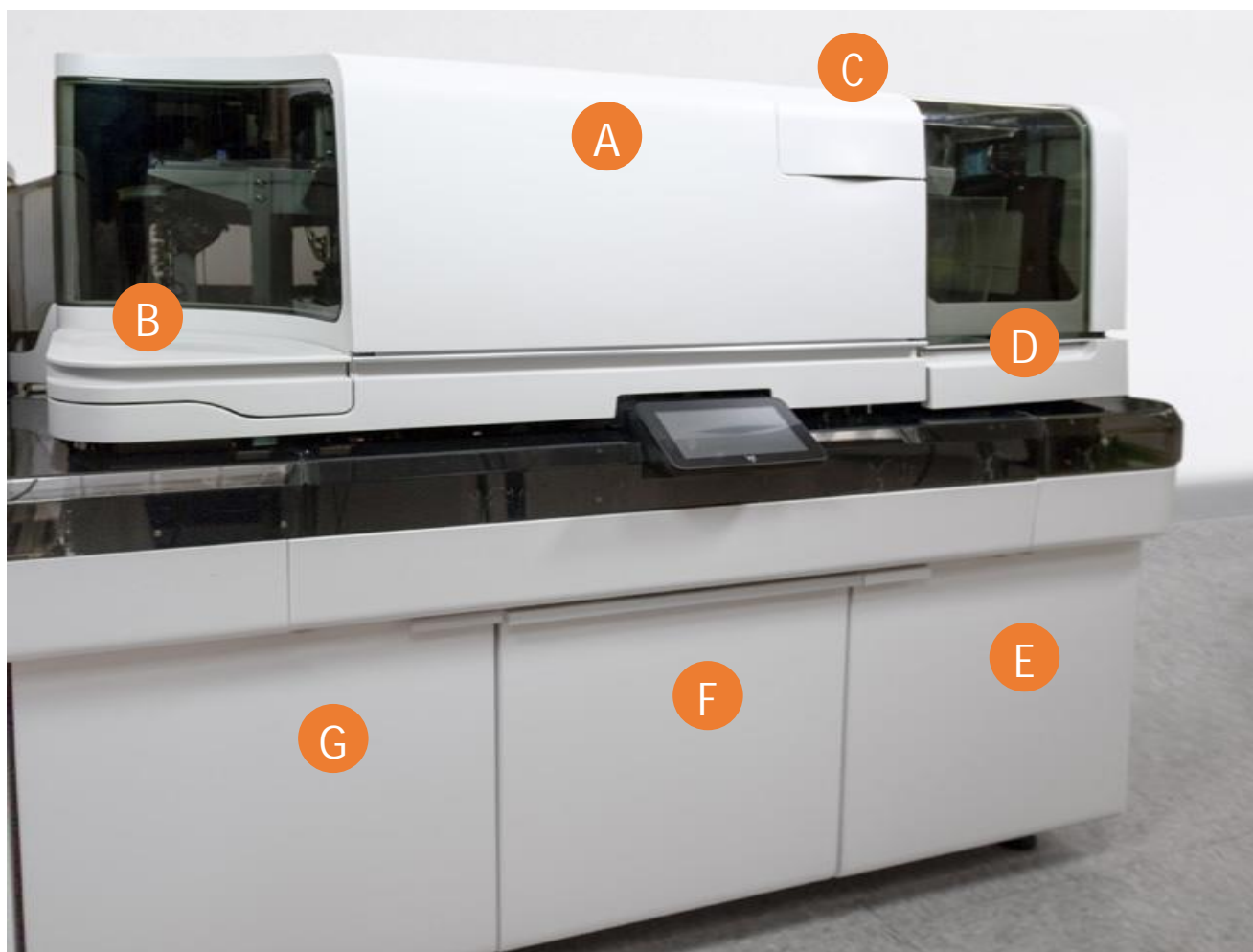
__H__ Dilution Ring

__I__ Dilution Mixer

__J__ Dilution Washer

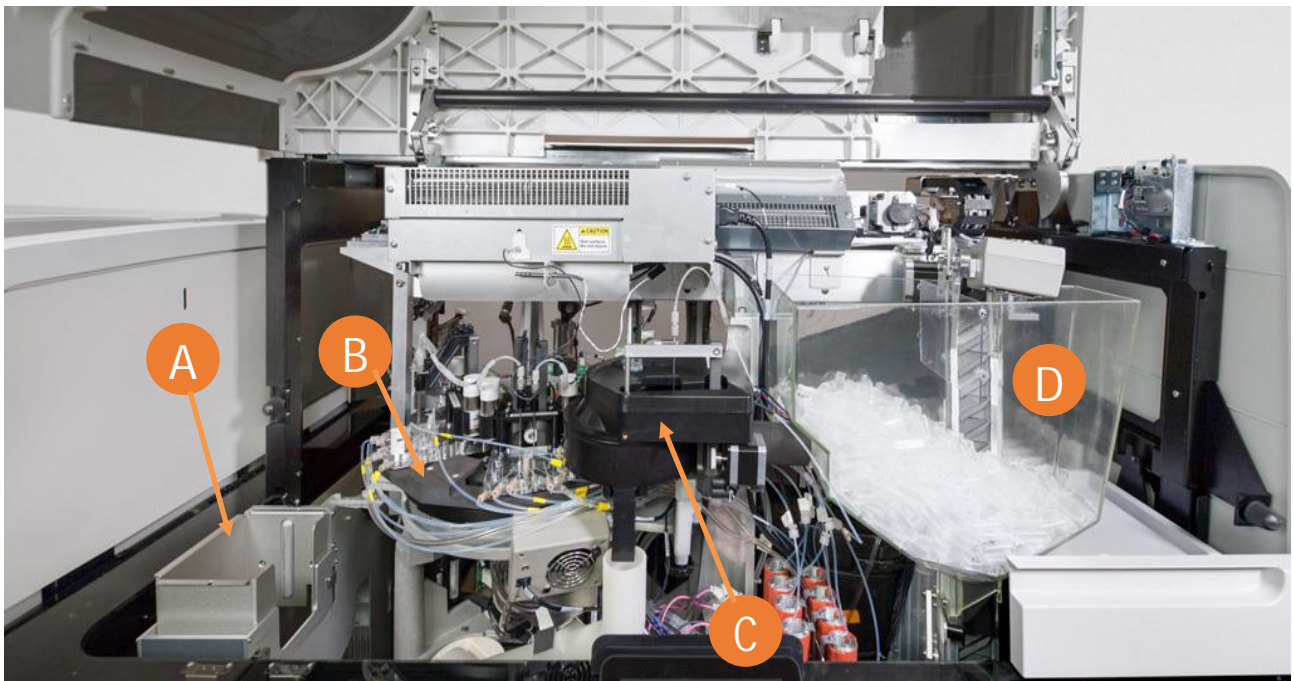
IM System Components (Outside)

- __A__ System front cover
- __B__ Sample tip loading lid
- __C__ Cuvette bin lid
- __D__ Reagent drawer
- __E__ Water and liquid waste drawer
- __F__ System fluid drawer
- __G__ Solid waste drawer



IM System Components (Inside Front)

- __A__ Sample tip loader
- __B__ Wash ring
- __C__ Luminometer
- __D__ Cuvette bin



IM System Components (Inside Back)

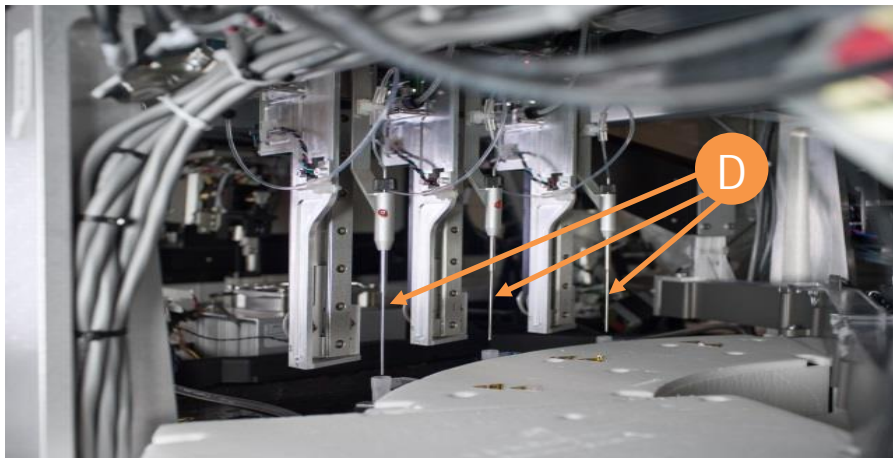
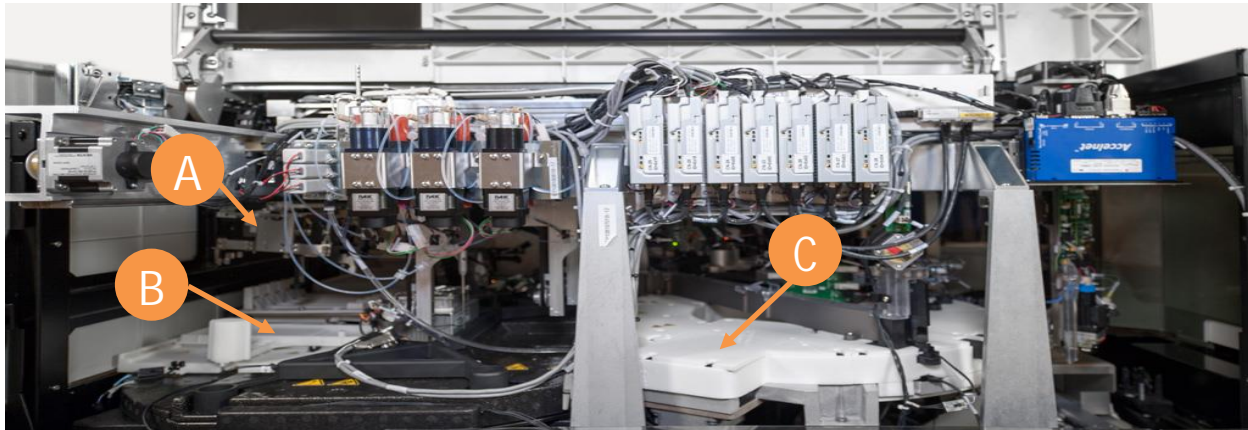
__A__ Reagent Loader

__B__ Reagent Compartment

__C__ Incubation ring

__D__ Reagent probes

__E__ Sample probe



Assay Troubleshooting:

Lot and Pack Calibration Overview

The system utilizes both reagent lot and reagent pack calibration intervals to determine when a reagent needs to be calibrated.

Lot Calibration Interval

- Starts when a reagent pack with a new lot is calibrated within 24 hours after it is loaded on the system for IM reagents, or 24 hours after the well is pierced for CH reagents.
- The lot calibration will be valid for any pack with the same lot that is loaded on the system until the lot calibration interval expires.
- A reagent pack that uses a lot calibration to calculate results for the duration of the Pack calibration interval or Lot calibration, whichever comes first.

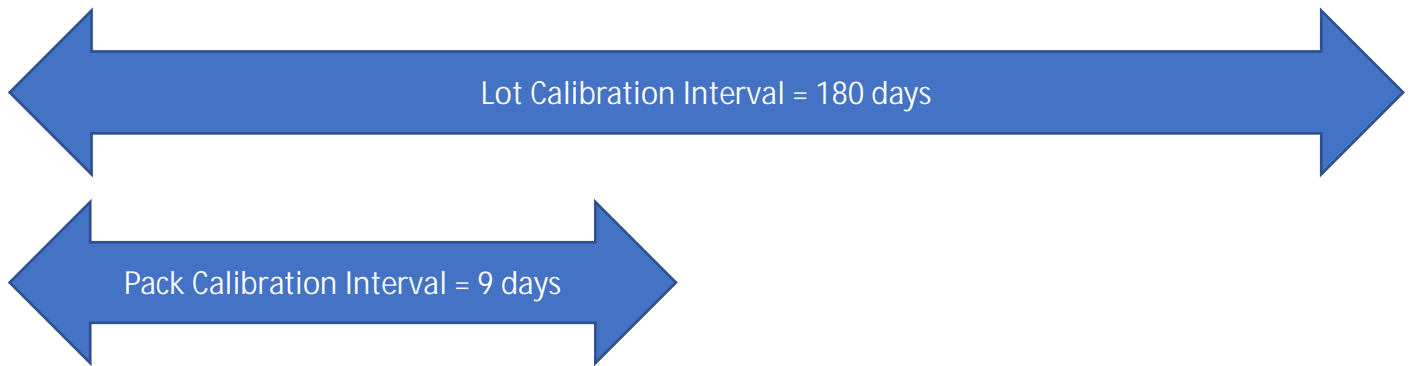
Pack Calibration Interval

- On the CH analyzer, a pack calibration is actually a well calibration. There are 2 wells in most CH packs, which are treated as separate reagents by the system.
- The pack/well calibration interval is valid for an individual pack for IM or well for CH, and not used for subsequent packs/wells placed on the system.
- Useful for labs that perform a low volume of tests because they can avoid disposing of reagent packs due to QC shifts seen when calibrating aged packs.

The system tracks lot and pack calibration and displays reminders when calibration or recalibration of an assay reagent pack is due.

NOTE: In order for a calibration to qualify as a lot calibration, the calibration must be done within 24 hours after a new IM pack is loaded on the system or 24 hours after a CH well is pierced. If a new pack/well is not calibrated within 24 hours, the calibration will be a pack calibration.

Lot and Pack Calibration



If you load a new pack with a new lot and use it to calibrate, shortly after it is loaded (within 24 hours), this will be the lot calibration.

High Volume Assays:

At any point during the 180 days after creation of the lot calibration, if you remove the original pack and load a new pack with the same lot, or pierce the second well of the pack, you do not need to calibrate the new pack/well because the lot calibration does not expire until day 180. If you keep replacing packs within 9 days, you only need to recalibrate every 180 days.

Low Volume Assays:

9 days after the start of using the lot calibration, if the pack/well is still being used, it needs to be recalibrated because the pack/well calibration interval has now expired. The calibration is a pack/well calibration, because a lot calibration must be done within the 24-hour lot calibration limit for a newly loaded pack/pierced well. If the pack remains onboard, it will have to be recalibrated every 9 days until it reaches the reagent's onboard stability.

CH Calibration Types

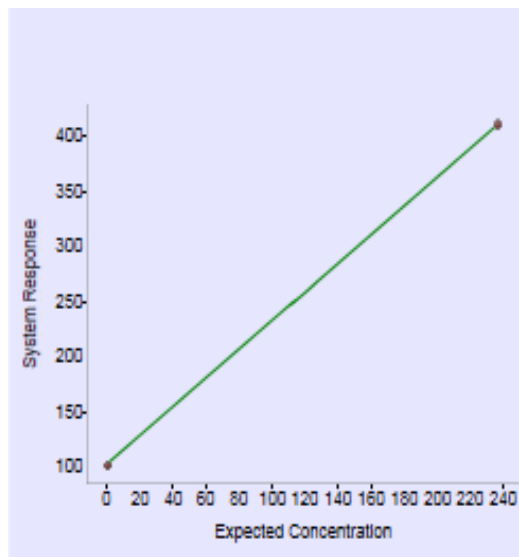
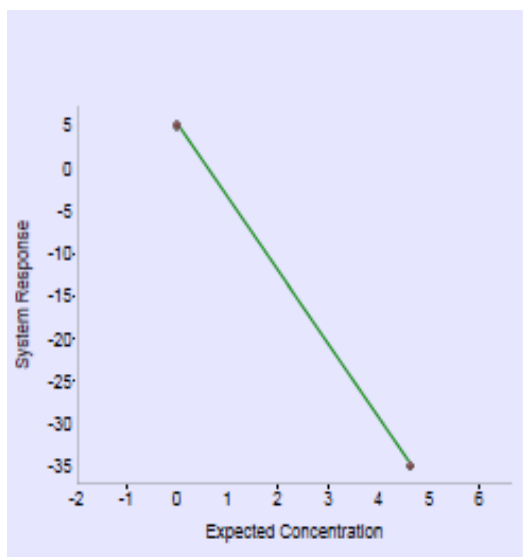
1. Linear Calibration

Analyte concentration (x) is directly proportional to absorbance (MAU).

In addition, the system determines a correlation factor (r), which states how many points lie directly on the straight line.

Factor	Variable	Limit	Limits with linear calibration:
Slope C_1	m	1.00 (0.97 to 1.03)	
Intercept C_0	b	0.0 (near 0)	
Correlation Factor	r	0.990 to 1.000	

calibration:



Examples of Linear Calibration Glucose (GluH-3)

Calibration Results Details for GluH_3 on CM00144 X

Information	Data	Comments																																																																																																																							
Activity Reagent Lot Calibration Assay GluH_3 Units mg/dL Calculation Type Linear Ordered Date 9/13/2019 12:30:51 PM Completed Date 9/13/2019 12:43:35 PM Accepted By Automatically accepted Analyzer Name CM00144 Analyzer Serial Number CM00144 Reagent Lot 290875 Pack/Well 04735:Well 1 Ancillary 1 Ancillary 1 Lot/Pack Ancillary 2 Ancillary 2 Lot/Pack Calibrator Name CHEM CAL Calibrator Lot 128433B Cal Status Valid Acceptance Criteria OK Acceptance Mode Automatic Trigger Mode Operator Initiated Cal Expiration 3/13/2020 11:33:22 AM	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th colspan="3">1 (L)</th> <th colspan="3">2 (H)</th> </tr> <tr> <th>Replicate</th> <th>Include</th> <th>Analyte</th> <th>Signal</th> <th>Flag</th> <th>Include</th> <th>Analyte</th> <th>Signal</th> <th>Flag</th> </tr> </thead> <tbody> <tr> <td>Replicate 1</td> <td><input checked="" type="checkbox"/></td> <td>-0.13 mg/dL</td> <td>24.31 mAU</td> <td></td> <td><input checked="" type="checkbox"/></td> <td>235.53 mg/dL</td> <td>385.10 mAU</td> <td></td> </tr> <tr> <td>Replicate 2</td> <td><input checked="" type="checkbox"/></td> <td>0.03 mg/dL</td> <td>24.56 mAU</td> <td></td> <td><input checked="" type="checkbox"/></td> <td>233.83 mg/dL</td> <td>382.50 mAU</td> <td></td> </tr> <tr> <td>Replicate 3</td> <td><input checked="" type="checkbox"/></td> <td>0.10 mg/dL</td> <td>24.66 mAU</td> <td></td> <td><input checked="" type="checkbox"/></td> <td>234.86 mg/dL</td> <td>384.08 mAU</td> <td></td> </tr> <tr> <td>Mean</td> <td></td> <td>0.00</td> <td>24.51</td> <td></td> <td></td> <td>234.74</td> <td>383.89</td> <td></td> </tr> <tr> <td>Median</td> <td></td> <td>0.03</td> <td>24.56</td> <td></td> <td></td> <td>234.86</td> <td>384.08</td> <td></td> </tr> <tr> <td>SD</td> <td></td> <td>0.12</td> <td>0.18</td> <td></td> <td></td> <td>0.86</td> <td>1.31</td> <td></td> </tr> <tr> <td>Observed %CV</td> <td></td> <td></td> <td>0.74</td> <td></td> <td></td> <td>0.36</td> <td>0.34</td> <td></td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>QC</th> <th>QC Limits</th> <th>New Observed</th> <th>Old Observed</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Criteria</th> <th>Result</th> <th>Value</th> <th>Expected</th> <th>Observed</th> </tr> </thead> <tbody> <tr> <td>No auto-excluded replicates</td> <td>Pass</td> <td>0.00</td> <td>-0.5 - 0.5</td> <td>-0.5 - 0.5</td> </tr> <tr> <td>No flags or comments</td> <td>Pass</td> <td>0.00</td> <td>-0.5 - 0.5</td> <td>-0.5 - 0.5</td> </tr> <tr> <td>Delta system response</td> <td>Pass</td> <td>359.38 mAU</td> <td>178.0 - 753.0</td> <td>178.0 - 753.0</td> </tr> </tbody> </table>		1 (L)			2 (H)			Replicate	Include	Analyte	Signal	Flag	Include	Analyte	Signal	Flag	Replicate 1	<input checked="" type="checkbox"/>	-0.13 mg/dL	24.31 mAU		<input checked="" type="checkbox"/>	235.53 mg/dL	385.10 mAU		Replicate 2	<input checked="" type="checkbox"/>	0.03 mg/dL	24.56 mAU		<input checked="" type="checkbox"/>	233.83 mg/dL	382.50 mAU		Replicate 3	<input checked="" type="checkbox"/>	0.10 mg/dL	24.66 mAU		<input checked="" type="checkbox"/>	234.86 mg/dL	384.08 mAU		Mean		0.00	24.51			234.74	383.89		Median		0.03	24.56			234.86	384.08		SD		0.12	0.18			0.86	1.31		Observed %CV			0.74			0.36	0.34		QC	QC Limits	New Observed	Old Observed					Criteria	Result	Value	Expected	Observed	No auto-excluded replicates	Pass	0.00	-0.5 - 0.5	-0.5 - 0.5	No flags or comments	Pass	0.00	-0.5 - 0.5	-0.5 - 0.5	Delta system response	Pass	359.38 mAU	178.0 - 753.0	178.0 - 753.0	<div style="text-align: center; border: 1px solid gray; padding: 5px; width: fit-content; margin: 0 auto;">Edit</div> <div style="border: 1px solid gray; padding: 5px;"> <p>Graph</p> <p>Line Shape</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>$\Delta 2.1$</td> <td>359.38</td> </tr> <tr> <td>$\Delta 2.1$</td> <td>359.38</td> </tr> <tr> <td>$\Delta 2.1 \Delta 2.1$</td> <td>1.00</td> </tr> </table> <p>Statistics</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>Slope</td> <td>0.97</td> </tr> <tr> <td>Intercept</td> <td>0.00</td> </tr> <tr> <td>Corr. Coefficient</td> <td>1.00</td> </tr> </table> <p style="text-align: right;">Enlarge</p> </div>	$\Delta 2.1$	359.38	$\Delta 2.1$	359.38	$\Delta 2.1 \Delta 2.1$	1.00	Slope	0.97	Intercept	0.00	Corr. Coefficient	1.00
	1 (L)			2 (H)																																																																																																																					
Replicate	Include	Analyte	Signal	Flag	Include	Analyte	Signal	Flag																																																																																																																	
Replicate 1	<input checked="" type="checkbox"/>	-0.13 mg/dL	24.31 mAU		<input checked="" type="checkbox"/>	235.53 mg/dL	385.10 mAU																																																																																																																		
Replicate 2	<input checked="" type="checkbox"/>	0.03 mg/dL	24.56 mAU		<input checked="" type="checkbox"/>	233.83 mg/dL	382.50 mAU																																																																																																																		
Replicate 3	<input checked="" type="checkbox"/>	0.10 mg/dL	24.66 mAU		<input checked="" type="checkbox"/>	234.86 mg/dL	384.08 mAU																																																																																																																		
Mean		0.00	24.51			234.74	383.89																																																																																																																		
Median		0.03	24.56			234.86	384.08																																																																																																																		
SD		0.12	0.18			0.86	1.31																																																																																																																		
Observed %CV			0.74			0.36	0.34																																																																																																																		
QC	QC Limits	New Observed	Old Observed																																																																																																																						
Criteria	Result	Value	Expected	Observed																																																																																																																					
No auto-excluded replicates	Pass	0.00	-0.5 - 0.5	-0.5 - 0.5																																																																																																																					
No flags or comments	Pass	0.00	-0.5 - 0.5	-0.5 - 0.5																																																																																																																					
Delta system response	Pass	359.38 mAU	178.0 - 753.0	178.0 - 753.0																																																																																																																					
$\Delta 2.1$	359.38																																																																																																																								
$\Delta 2.1$	359.38																																																																																																																								
$\Delta 2.1 \Delta 2.1$	1.00																																																																																																																								
Slope	0.97																																																																																																																								
Intercept	0.00																																																																																																																								
Corr. Coefficient	1.00																																																																																																																								

Coefficients

C0	24.51
C1	7.65

Print Accept Reject Close

2. Non-Linear Calibration

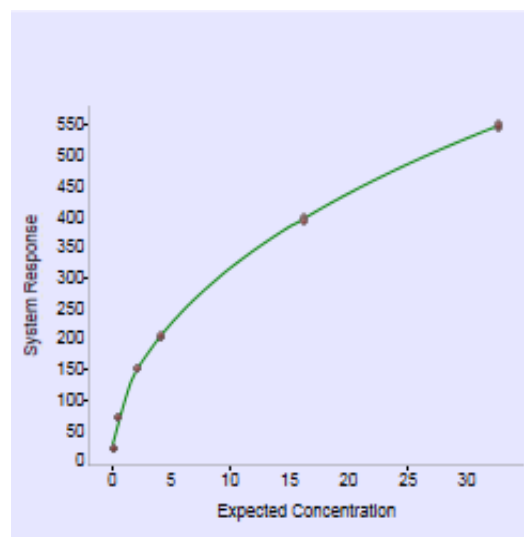
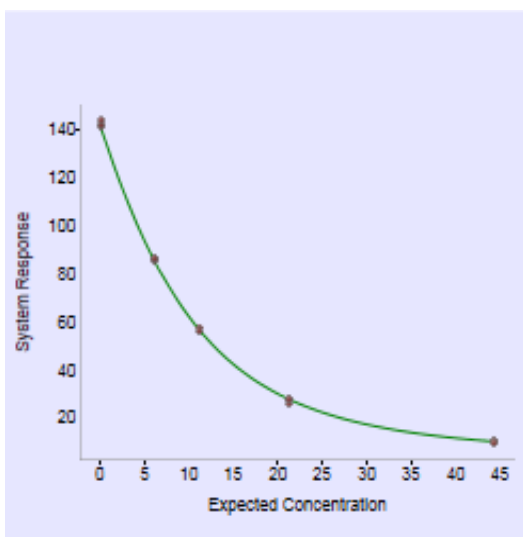
Non-linear calibration is carried out in two steps:

1. Linearization of the curve with the aid of a LOGIT (logarithmic unit) arithmetical function. For the linearization of the curve, needs additional calibration terms (C terms) besides C_0 and C_1 . These are C_2 , C_3 and C_4 (Up to 6 calibrators) and linearization the curve. A straight line is produced.
2. This straight line is now moved sideways in parallel and tipped by means of C_0 and C_1 , so that the Slope is now 1 and the intercept 0.

Ex.: Therapeutic Drug Markers and Specific Proteins.

Limits with non-linear calibration:

Factor	Variable	Limit
Slope	m	1.00 (0.95 to 1.05)
Intercept	b	0 (near 0)
Correlation Factor	r	0.990 to 1.000



Examples of Non-Linear Calibrations

Phny (PETINIA) – (1/2)

Calibration Results Details for Phny on CM00144
✕

Information

Activity Reagent Lot Calibration
Assay Phny
Units ug/mL
Calculation Type Logit
Ordered Date 9/13/2019 12:30:54 PM
Completed Date 9/13/2019 12:43:50 PM
Accepted By Automatically accepted
Analyzer Name CM00144
Analyzer Serial Number CM00144
Reagent Lot 190119
Pack/Well 01374:Well 1
Ancillary 1
Ancillary 1 Lot/Pack
Ancillary 2
Ancillary 2 Lot/Pack
Calibrator Name DRUG CAL
Calibrator Lot 8HD050
Cal Status Valid
Acceptance Criteria OK
Acceptance Mode Automatic
Trigger Mode Operator Initiated
Cal Expiration 10/11/2019 12:32:21 PM

Data

	1 (L)			2 (H)			3		
Replicate	Include	Analyte	Signal	Flag	Include	Analyte	Signal	Flag	Include
Replicate 1	<input checked="" type="checkbox"/>	0.15 ug/mL	60.00	mAU	<input checked="" type="checkbox"/>	4.53 ug/mL	51.38	mAU	<input checked="" type="checkbox"/>
Replicate 2	<input checked="" type="checkbox"/>	0.10 ug/mL	60.09	mAU	<input checked="" type="checkbox"/>	4.68 ug/mL	51.08	mAU	<input checked="" type="checkbox"/>
Replicate 3	<input checked="" type="checkbox"/>	0.03 ug/mL	60.22	mAU	<input checked="" type="checkbox"/>	4.81 ug/mL	50.83	mAU	<input checked="" type="checkbox"/>
Mean		0.09	60.10			4.67	51.10		
Median		0.10	60.09			4.68	51.08		
SD		0.06	0.11			0.14	0.28		
Observed %CV		64.58	0.18			3.00	0.54		

QC Performed with Calibration

QC	QC Limits	New Observed	Old Observed

Acceptance Criteria

Criteria	Result	Value	Expected	Observed
Correlation coefficient range	Pass	1.00	0.95 - 1.0	0.95 - 1.0
Percent deviation	Pass	3.76 %	0.0 - 10.0	0.0 - 10.0
No auto-excluded replicates	Pass	0.00	-0.5 - 0.5	-0.5 - 0.5

Comments

Edit

Graph

Curve Shape
 $\Delta S.1$ -46.94
 $\Delta S.4$ -13.03 $\Delta S.4/\Delta S.1$ 0.30

Statistics
Slope 1.01
Intercept -0.04
Corr. Coefficient 1.00

Enlarge

?

Print

Accept

Reject

Close

Phny (PETINIA) – (2/2)

Calibration Results Details for Phny on CM00144 X

Information	Data	Comments																																																																
Activity Reagent Lot Calibration Assay Phny Units ug/mL Calculation Type Logit Ordered Date 9/13/2019 12:30:54 PM Completed Date 9/13/2019 12:43:50 PM Accepted By Automatically accepted Analyzer Name CM00144 Analyzer Serial Number CM00144 Reagent Lot 190119 Pack/Well 01374:Well 1 Ancillary 1 Ancillary 1 Lot/Pack Ancillary 2 Ancillary 2 Lot/Pack Calibrator Name DRUG CAL Calibrator Lot 8HD050 Cal Status Valid Acceptance Criteria OK Acceptance Mode Automatic Trigger Mode Operator Initiated Cal Expiration 10/11/2019 12:32:21 PM	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">3</th> <th style="text-align: center;">4</th> <th style="text-align: center;">5</th> </tr> <tr> <th>Replicate</th> <th>Include</th> <th>Analyte</th> <th>Signal Flag</th> </tr> </thead> <tbody> <tr> <td>Replicate 1</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>20.23 ug/mL</td> <td>26.46 mAU</td> </tr> <tr> <td>Replicate 2</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>19.59 ug/mL</td> <td>27.17 mAU</td> </tr> <tr> <td>Replicate 3</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>19.17 ug/mL</td> <td>27.65 mAU</td> </tr> <tr> <td>Mean</td> <td>19.66</td> <td>27.09</td> <td>40.30</td> </tr> <tr> <td>Median</td> <td>19.59</td> <td>27.17</td> <td>40.31</td> </tr> <tr> <td>SD</td> <td>0.53</td> <td>0.60</td> <td>1.47</td> </tr> <tr> <td>Observed %CV</td> <td>2.71</td> <td>2.21</td> <td>3.64</td> </tr> </tbody> </table> <p>QC Performed with Calibration</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>QC</th> <th>QC Limits</th> <th>New Observed</th> <th>Old Observed</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>Acceptance Criteria</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Criteria</th> <th>Result</th> <th>Value</th> <th>Expected</th> <th>Observed</th> </tr> </thead> <tbody> <tr> <td>No auto-excluded replicates</td> <td>Pass</td> <td>0.00</td> <td>-0.5 - 0.5</td> <td>-0.5 - 0.5</td> </tr> <tr> <td>No flags or comments</td> <td>Pass</td> <td>0.00</td> <td>-0.5 - 0.5</td> <td>-0.5 - 0.5</td> </tr> <tr> <td>Delta system response</td> <td>Pass</td> <td>46.94 mAU</td> <td>20.0 - 102.0</td> <td>20.0 - 102.0</td> </tr> </tbody> </table>		3	4	5	Replicate	Include	Analyte	Signal Flag	Replicate 1	<input checked="" type="checkbox"/>	20.23 ug/mL	26.46 mAU	Replicate 2	<input checked="" type="checkbox"/>	19.59 ug/mL	27.17 mAU	Replicate 3	<input checked="" type="checkbox"/>	19.17 ug/mL	27.65 mAU	Mean	19.66	27.09	40.30	Median	19.59	27.17	40.31	SD	0.53	0.60	1.47	Observed %CV	2.71	2.21	3.64	QC	QC Limits	New Observed	Old Observed					Criteria	Result	Value	Expected	Observed	No auto-excluded replicates	Pass	0.00	-0.5 - 0.5	-0.5 - 0.5	No flags or comments	Pass	0.00	-0.5 - 0.5	-0.5 - 0.5	Delta system response	Pass	46.94 mAU	20.0 - 102.0	20.0 - 102.0	<p>Graph</p> <p>Statistics</p> <p>Curve Shape Δ5.1 -48.94 Δ5.4 -13.93 Δ5.4/Δ5.1 0.30</p> <p>Statistics Slope 1.01 Intercept -0.04 Corr. Coefficient 1.00</p> <p style="text-align: right;">Enlarge</p>
	3	4	5																																																															
Replicate	Include	Analyte	Signal Flag																																																															
Replicate 1	<input checked="" type="checkbox"/>	20.23 ug/mL	26.46 mAU																																																															
Replicate 2	<input checked="" type="checkbox"/>	19.59 ug/mL	27.17 mAU																																																															
Replicate 3	<input checked="" type="checkbox"/>	19.17 ug/mL	27.65 mAU																																																															
Mean	19.66	27.09	40.30																																																															
Median	19.59	27.17	40.31																																																															
SD	0.53	0.60	1.47																																																															
Observed %CV	2.71	2.21	3.64																																																															
QC	QC Limits	New Observed	Old Observed																																																															
Criteria	Result	Value	Expected	Observed																																																														
No auto-excluded replicates	Pass	0.00	-0.5 - 0.5	-0.5 - 0.5																																																														
No flags or comments	Pass	0.00	-0.5 - 0.5	-0.5 - 0.5																																																														
Delta system response	Pass	46.94 mAU	20.0 - 102.0	20.0 - 102.0																																																														

?	Print	Accept	Reject	Close
---	-------	--------	--------	-------

3. Fixed Factor Calibration

Fixed Factor Calibration (Enzyme Verification or C_0) = linear reaction

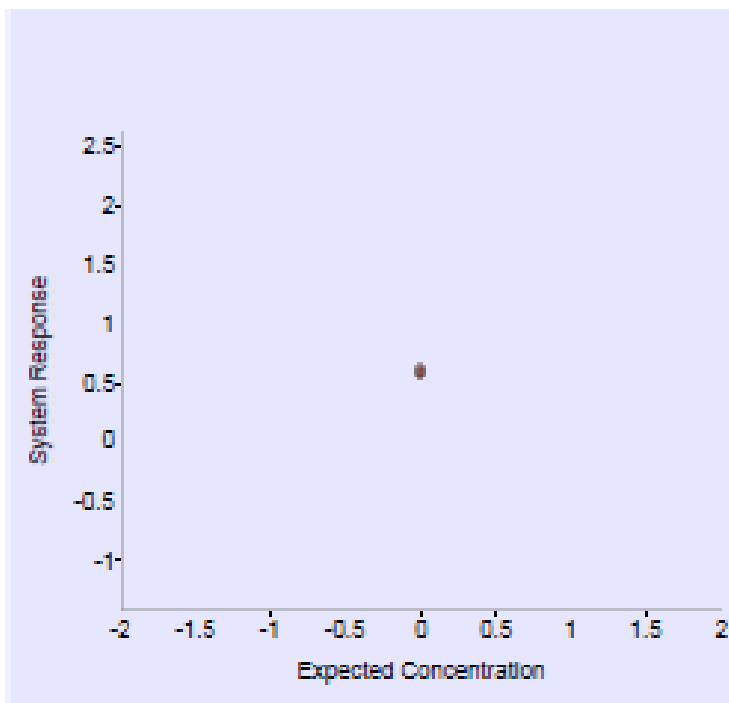
C_0 Adjustment:

- Determined by the TDef and the operator cannot select it.
- Takes reagent variations into account.
- Could be performed every day or as a pack calibration.
- Performed with CH Diluent (saline) or with water.

For assays that use C_0 Adjust pack calibrations:

- When the system alerts that a pack calibration is needed because the previous *pack calibration* has expired, and the operator orders a pack calibration, the system will perform a *C_0 Adjust* pack calibration. For Siemens assays, the operator does not need to load calibrator samples in this case because the system automatically uses CH Diluent.
- When the system alerts that a pack calibration is needed because the previous *lot calibration* has expired, and the operator orders a pack calibration, the system will perform a *full* pack calibration. The operator must load the appropriate calibrator level samples.

Ex: Amylase or Pancreatic Amylase (Use only CH diluent for Lot and Pack calibration)



Example of Fixed Factor Calibration

Amylase

Calibration Results Details for Amylase on CM00144 X

Information

Activity: Reagent Pack Calibration
 Assay: Amylase
 Units: U/L
 Calculation Type: Linear
 Ordered Date: 10/3/2019 12:17:24 PM
 Completed Date: 10/3/2019 12:28:08 PM
 Accepted By: Automatically accepted
 Analyzer Name: CM00144
 Analyzer Serial Number: CM00144
 Reagent Lot: 280807
 Pack/Well: 00721:Well 1
 Ancillary 1
 Ancillary 1 Lot/Pack
 Ancillary 2
 Ancillary 2 Lot/Pack
 Calibrator Name: No Calibrator Cal Def
 Calibrator Lot: 00
 Cal Status: Valid
 Acceptance Criteria: OK
 Acceptance Mode: Automatic
 Trigger Mode: Pack Calibration Expired
 Cal Expiration: 10/4/2019 12:17:25 PM

Data

1 (L)

Replicate	Include	Analyte	Signal	Flag
Replicate 1	<input checked="" type="checkbox"/>	-0.09 U/L	0.32 mAU	
Replicate 2	<input checked="" type="checkbox"/>	0.15 U/L	0.36 mAU	
Replicate 3	<input checked="" type="checkbox"/>	-0.06 U/L	0.32 mAU	
Mean		0.00	0.33	
Median		-0.06	0.32	
SD		0.13	0.02	
Observed %CV			6.93	

QC Performed with Calibration

QC	QC Limits	New Observed	Old Observed

Comments

Edit

Coefficients

C0 0.33
C1 0.88

Acceptance Criteria

Criteria	Result	Value	Expected	Observed
Allowed C0 adjust signal limits	Pass	0.33	0.0 - 6.0	0.0 - 6.0

Graph

Curve Slope
 $\Delta 1.1$ 0.00
 0.00 0.00

Statistics
 Slope: NaN
 Intercept: NaN
 Corr. Coefficient: NaN

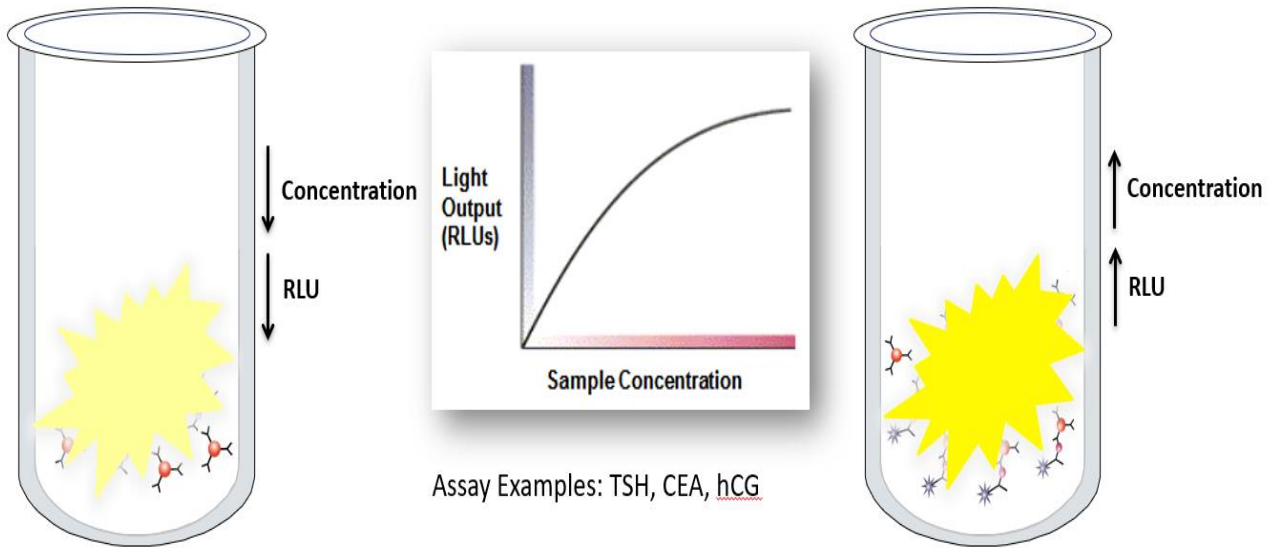
Enlarge

? Print Accept Reject Close

IM Calibration Types

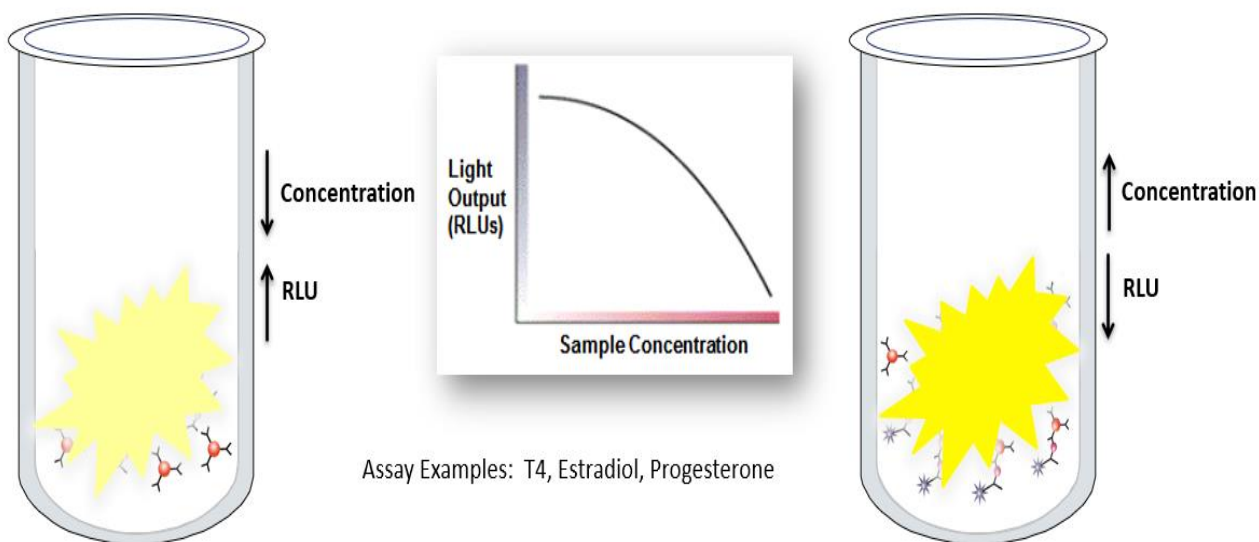
Sandwich Format (Direct Assay)

In a sandwich assay format, the analyte-specific antigen concentration in the sample and the light emission in Relative Light Unit (RLU), have a direct relationship. If more analyte-specific antigen molecules are present in the sample, more AE is present, and the light emission is greater.



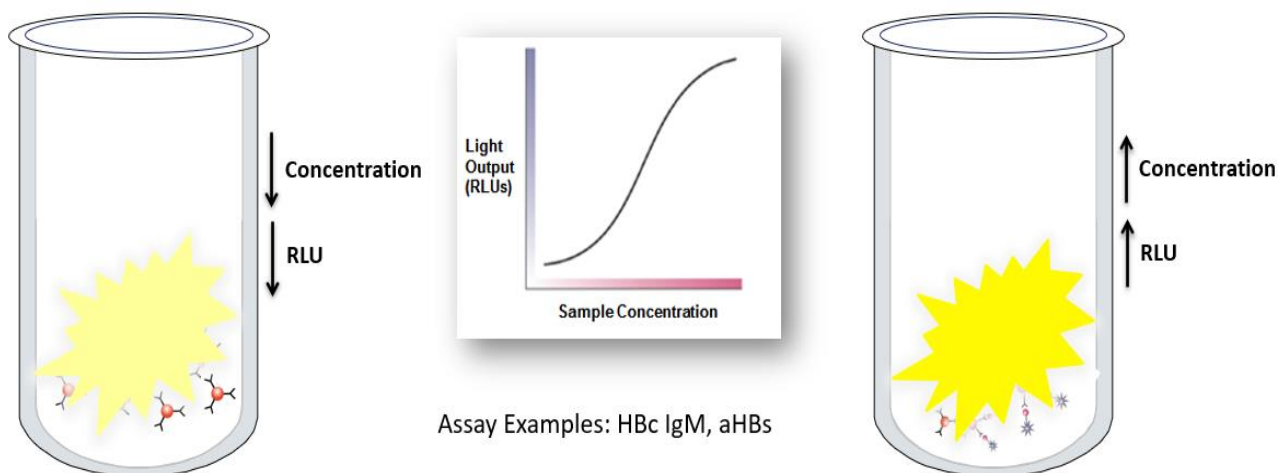
Competitive Format (Indirect Assay)

In a competitive assay format, the analyte-specific antigen concentration in the sample and the light emission in Relative Light Unit (RLU) have an indirect relationship. If more antigen is present in the sample, then less antigen bound AE complex is present to measure, therefore, less light is emitted.



Antibody-Capture Format (Direct Assay)

In an antibody capture assay format, the analyte being measured in the sample and the light emission in Relative Light Unit (RLU) have a direct relationship. If more antibody is present in the sample, then more antigen bound A-E complex is present to measure, therefore, more light is emitted.



IM Acceptance Criteria

The assay test definition defines the Minimum # of Replicates the system requires to obtain a valid calibration.

Outliers can cause a calibration to fail. If specific criteria are met, excluding an outlier may correct an Invalid IM calibration result.

- The IM Analyzer can be configured to auto-exclude qualified outliers, OR they can be manually excluded.
- After excluding an outlier, the system recalculates the calibration data and rechecks the calibration criteria.
- In order to exclude an outlier, the minimum number of replicates the system requires for a valid calibration must remain after exclusion.

Low Cal

Replicate 1	20998 RLU
Replicate 2	21324 RLU
<u>Replicate 3</u>	<u>20301 RLU</u>
Mean	20874.33 RLU
CV	2.5
Accept. CV	7.0

High Cal

Replicate 1	82689 RLU
Replicate 2	78450 RLU
<u>Replicate 3</u>	<u>78190 RLU</u>
Mean	79776.34 RLU
CV	3.2
Accept. CV	6.6