Frequently Asked Questions (FAQs)

System Calibration FAQs

This purpose of this document is to address common questions customers may have regarding system calibration on the Atellica Solution. If you have any questions which are not included in this document please refer to the Operator's Manual and/or contact your local Siemens Healthineers Customer Service. This document has 4 main sections:

I.   Basic Facts for Atellica Calibrations

A. Atellica IM 1300/1600 Analyzer employs 2-point calibrations; 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 A or Low and Cal B or High) calibrates the specific system and specific lot to the master curve.

B. Atellica CH 930 Analyzer has several different calibration schemes; linear using 2- 3 calibrators and non-linear, using up to 6 calibrators. *Note: CH reagents are divided into 2 wells and each well operates independently for the lot and pack calibration criteria.*

C. Calibration Types

1. Lot Calibrations
a. *Lot calibrations are only performed with a reagent which has been onboard the system <24 hours.*
b. *Lot calibrations are used for all packs in the same reagent lot until the Calibration Lot Interval has been reached. Recalibration of the lot is then required.*

2. Pack Calibrations
a. *Pack calibrations are used to maintain individual packs which have been onboard the system for an extended period of time. This period of time is called the pack calibration interval.*
b. *The pack calibration is only valid for one specific reagent pack and is assay-specific. If multiple packs of the same lot are onboard, it is possible to have multiple calibrations in use. For example, pack with lot calibration, and a pack with a pack calibration.*
c. *If the lot calibration expires, and the pack has been on the system >24 hours a lot calibration will be prevented from being performed.   A pack calibration will allow continued use of that pack.*

D. Atellica CH Specific Pack Calibrations

1. For select CH assays, the Pack calibration is done using the CH Diluent (saline) and is similar to a reagent blank, requiring **no calibrator** to be loaded. The assays are:

   Acetaminophen   *Triglycerides*
   Cholesterol 2   *Uric Acid*
   Glucose Oxidase   *Urea Nitrogen*
   Inorganic Phosphorus

2. This pack calibration is also known as the C0 Adjust.

3. The only time calibrators are used for a pack calibration for these assays is IF there is no lot calibration for the assay. Then the pack calibration will be a full calibration requiring calibrators.

4. For Amylase and PAmylase, CH Diluent (saline) is used for all calibrations and is a C0 adjust. No calibrator required.

II.   Tips/Guidelines for Successful Calibrations

- Allow any calibration material not stored in the Atellica Sample Handler Cal/QC tube storage area to come to room temperature before loading onto the system.

- Ensure the calibrator material is the correct active lot for the appropriate assay.

- Ensure the barcode for the calibrator material is printed from the system performing the calibration.

- If the calibrator material is stored in the Sample Handler Cal/QC tube storage area, ensure it has not expired for the assays requiring calibration.

- Ensure all the correct materials are loaded including the appropriate QC if using the Perform QC with Calibration feature.

- For the calibration type desired (lot or pack), verify the assay reagent pack is eligible in the Inventory Reagent Overview.

Calibration Troubleshooting Questions:

A. Why didn't my Calibration Order start to process after placing the order?

1. The calibrator material vial barcode was printed from another Atellica Sample Handler.

2. Analyzer is in wrong state when calibration order was placed. *Wait for Ready/Standby mode after analyzer maintenance or diagnostics.*

3. Not enough material was loaded.

   a. *QC or Cal material is missing, expired or the volume is insufficient.*

   b. *"Perform QC with Cal" is enabled for the assay and all of the QC materials are not onboard.*

4. A previous calibration order has a problem and is blocking the new order. *Resolve the problem with the previous order and the calibration will proceed.*

5. Calibrator lot loaded is not marked as "Active". *Go to calibration definition screen to verify active calibrator lot is checked as active*

6. Assay for calibration order not enabled or the reagent is not onboard system.

7. Insufficient tests remaining in reagent pack. *Lot calibration must have enough reagents to complete all necessary calibration aspiration replicates. Pack calibration must have enough to complete all replicates + 1 test.*

8. Unable to order lot calibration because the pack is ineligible for lot calibration. *Go to Reagent Overview to determine calibration type eligibility*

9. Aspiration errors block calibration orders. *Check samples for sufficient volume, or troubleshoot analyzer issue, and create calibration order again.*

10. CH "C0 Adjust" calibration order does not process if no prior lot calibration performed for the appropriate lot. *Perform lot (if eligible), or full pack calibration*

11. The IM Analyzer rejects a calibration order for a control-bracketed assay when a control bracket is open with retained results or the analyzer is processing control-bracketed tests. *Open bracketed assay must be closed before proceeding.*

12. Other open calibration orders exist for the test, reagent lot, or calibrator lot. *Wait until the open calibration order completes, and then place a new order.*

13. Material required (Cal or QC) is onboard but has errors associated with it (expired, insufficient volume, recalled, cap / cup detect mismatch etc.). *Correct material issue.*

14. Calibrator / QC samples stuck on the track due to lack of empty slots in sample rack on the Atellica Sample Handler and this blocks further orders involving the same Calibrator / QC samples. *Remove samples in racks to create empty slots.*

B. **Why didn't the system correctly process an Automatic Calibration (these are in addition to the items in A)?**

1. No automatic calibration trigger selection was configured in the assay test definition. *Go to system Setup, TDef and activate auto calibration triggers.*

2. Restarting the main computer (PCC) causes loss of the trigger command to perform an automatic calibration. *Recreate the Order.*

3. Automatic calibration does not process due to expired status of calibration reagent lot. *New lot must be defined and loaded.*

4. Automatic calibration does not process for IM assays with control bracketing. *See A, 11.*

5. Another calibration order exists in ordered state for same assay and same pack on the same analyzer. An operator event is created that states the calibration order was not created because another order exists. *Resolved by one of the following: Delete the existing order or wait for existing order to complete before creating new manual order.*

6. CH only: When lot cal is about to expire and onboard packs are not eligible for lot calibration, introducing a new pack doesn't generate lot calibration order right away. *Existing packs first need to reach 15% available test counts or less for a lot calibration trigger to be generated.*

III.   Flags Associated with Calibration Orders and Action Required

A. Address the issue and re-create the order

Flag created with Order	Scenarios when flag is shown	User action (Calibration must be reordered)
Module Unavailable	1. For QC / Patients, the Analyzer rejected work and re-planning attempts exhausted. 2. When analyzer is not available for planning the work.	1. Analyzer has rejected work. Check event log for reason and address the issue. Place order again after addressing issues. 2. Check analyzer state and ensure analyzer is in standby / ready / processing state. Order will automatically be processed.
Check Sample Handler State	Tests could not be run because Sample Handler (SH) is not available to load required Calibration / QC material to Atellica Magline® Transport.	Check SH state. Ensure SH covers are closed and SH is in standby / ready / processing state. If system is not automatically processing blocked tests, then delete the order and re-create the order.
Analyzer Rejected	Analyzer rejected work for Cals.	Analyzer has rejected work. Check event log for reason as and address the issue. Place order again.
System Error	1. Samples are waiting in DWQ for an extended time. 2. PCC is being shut down preventing Cal order from processing.	Check analyzer, Atellica Magline Transport and SH states. Check operator event log for errors. Address any identified issues and re-create the order.
Atellica Magline Error	Error when attempting to deliver tubes to INPUT queue.	Check operator log for Atellica Magline Transport errors. Address any identified issues and re-create the order.
Sample Error	Cal / QC order could not be processed since one or more required calibrator or QC material has errors associated.	Check sample error from sample details screen. Address any identified issues and re-create the order.
Manually Cancelled	Cal/QC is recalled from SH storage compartment but not yet removed off the system.	Remove recalled sample off the system and introduce new material through SH. Re-create the order.
Sample Unloaded	Sample has been removed from the system.	Load all the missing calibrator and QC material needed for this order. Re-create the order.

B. Address the issue and order will automatically process*

Order will not automatically process if Calibration is in the Invalid state. In this case it will need to be re-created.

Flag created with Order	Scenarios when flag is shown	User action (Calibration will automatically process)
Cal None	Patient / QC tests could not be run because specific assay and lot is not calibrated on the specific analyzer.	Calibrate the specific assay and analyzer. Once calibration is valid, system will automatically process the blocked QC / patient order(s).
QC Error	Tests could not be run because specific assay is out of QC on the specific analyzer.	QC the specific assay on the specific analyzer. Once calibration is valid, system will automatically process the blocked QC / patient order(s).
Patient Processing Disabled	Tests could not be run because patient processing has been disabled on specific analyzer.	Enable patient processing on the specific analyzer. Once calibration is valid, system will automatically process the blocked QC / patient order(s).
No Primary	Tests could not be run because the specific assay is not having sufficient primary reagent to complete the test(s).	Add primary reagent packs and calibrate if needed. System will automatically process the blocked tests once there are sufficient tests onboard.
Consumables required	Tests could not be run because one or more consumables needed to run the tests are not onboard or are not sufficient.	Ensure all needed consumables are onboard. System will automatically process the blocked tests once all needed consumables are onboard.
Missing Module Capability	Test processing is blocked because the specific analyzer is missing one or more required capability to process the test(s).	Check analyzer state screen and alerts / event logs and ensure missing capabilities are restored. System will automatically process the blocked tests once all needed capabilities are restored.
Reagent Prep in Progress	Test processing is blocked because specific reagent is still being mixed.	No action needed from operator. System will automatically process the blocked tests once reagent preparation is complete.
Missing Lot Locked Reagent	Tests could not be run because the specific lot locked reagent is not onboard or is not having sufficient test counts.	Ensure needed lot locked reagent is onboard and has sufficient test counts. System will automatically process the blocked tests.
No Ancillary	Tests could not be run because needed ancillary reagents are missing or there is not enough to process the tests.	Ensure ancillary is onboard and is sufficient. System will automatically process the blocked tests.
No Diluent	Tests could not be run because needed diluent is missing or there is not enough to process the tests.	Ensure diluent is onboard and is sufficient System will automatically process the blocked tests.
Check Atellica Magline State	Tests could not be run because Atellica Magline Transport is not available to transport samples to specific analyzer.	Check Atellica Magline Transport state. Ensure all Atellica Magline Transport covers are closed and it is in standby / ready / processing state. System will automatically process blocked tests.

Abbreviations

Abbreviation	Meaning
Cal or Cals	Calibrator or Calibration materials
CH Analyzer	Atellica CH Analyzer (clinical chemistry)
DWQ	Designated Waiting Queue
IM Analyzer	Atellica IM Analyzer (immunoassay)
PCC	Process Center Computer (main computer)
QC	Quality Control
SH	Atellica Sample Handler