TRAINING UPDATE

Lab Location:	SGMC	**Date Distributed:**	5/26/2021
Department:	Core Lab	**Due Date:**	6/26/2021

DESCRIPTION OF PROCEDURES

Name of procedure:

SOP #	Title
SGMC.C3068	Atellica Solution Operating, QC, Calibration and Maintenance
AG.F589.1	Atellica Solution Limits Chart
AG.F590.1	Atellica Solution Maintenance Log

Description of change(s):

These are the new SOPs and forms for the Atellica Solution analyzers. Core technical staff must review and be familiar with -

- General steps to utilize the instruments
- Handling of reagents, calibrator & QC and how to run them
- Required maintenance including how to perform and document

These SOPs were implemented on May 19, 2021

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

Title	**Atellica Solution Operating, QC, Calibration and Maintenance**	
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Owner	Robert SanLuis	Date: 5/14/2021

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

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1. PURPOSE

This procedure outlines the operational daily start up procedure for the Siemens Atellica Solution instruments and describes other maintenance that must be performed as scheduled.

2. SCOPE

This procedure applies to all Core Laboratory personnel working with the Siemens Atellica Solution instruments.

3. RESPONSIBILITY

Core Laboratory Personnel are responsible for performing and complying with this procedure.

4. DEFINITIONS

Pour-off: portion of a sample removed from the primary specimen into a Tube Top Sample Cup (TTSC) which is placed on top of the primary specimen and remains with it until the pour-off is disposed.

5. PROCEDURE

A. General Information

- If a manual dilution is required, never pour sample back into the primary tube.
- When preparing a dilution, only handle one patient sample at a time
- A pour-off into a TTSC does not require additional labeling if there is sample left in the primary tube and the following conditions are met:
  a. Handle one patient at a time
  b. Pour off patient sample from the primary tube into a TTSC and immediately place the TTSC on top of the primary tube.
  c. If there is not specimen left in the primary tube, label the TTSC with an LIS small label (foot) or an EZ link label. When testing is complete parafilm the top to secure the TTSC to the primary tube and save.
  d. If there is specimen left in the primary tube, discard the TTSC when testing is complete.
- To make dilutions, handle one patient at a time. Label s tube with patient name and accession number, and then proceed with the dilution. Never dilute into TTSC.
- All saved specimens must be labeled with patient identification.

B. Operating Atellica Solution

Atellica solution has five major components:

a. Command Bar
b. Magline Transport
c. Sample Handler
d. CH Module
e. IM Module

Detailed descriptions of these are included in addenda A.

Loading samples:

- Place the sample in the appropriate type of rack (STAT or Routine racks) in the sample drawer. The LED indicator above the drawer indicates if the drawer is locked:
  1. If the LED is off, the drawer is unlocked
  2. If the LED is on, the robotic arm is currently accessing tubes from the drawer.
     - Wait until the LED indicator turns back to off
     - Press the button above the drawer. The LED above the drawer still start blinking, indicating that as soon as it is able to, the system will unlock the drawer. When the LED light stops blinking and remains off, the drawer will be unlocked and can be opened.

- Open the unlocked sample drawer by grasping the drawer handle and pulling open the drawer. Ensure the sample drawer is pulled fully open. If the drawer is not fully open, the system may not properly scan the rack when the drawer is closed.
- Push the drawer shut until you feel a stop; the drawers were designed to have a "soft close"; handle carefully to not force the drawer shut.
- The SH robot automatically transfers the container to the Atellica Magline Transport. After the Tube Characterization Station identifies the sample, and starts processing the appropriate testing.

Monitoring Sample Tube Status:

- The Sample Handler tab displays the status of samples that are currently in the Sample Handler drawers.
    1. At the Command Bar, select **Samples**
    2. Select the **Sample Handler** tab
    3. Under the Racks tab on the right side of the screen, select a rack position
        - On the left side of the screen, the Sample ID and sample status will display for each sample in that rack
        - The shape and color of the glyph describes the status of the sample:
            - A round glyph identifies a patient sample container
            - A square glyph identifies a calibrator or QC container
- To view the status of the tests ordered on the sample, select the **Details** button in the **Sample Details** tab
    1. Patient Test Data – displays the status of the test ordered on the sample
    2. Sample and Patient Information – displays detailed sample information on the sample (Sample ID, sample type, priority, etc.)

Worklist Overview:

The screen can be used to view the status of all samples processed by the system (including ordered, in-process, and completed tests).

- To access the Worklist Overview screen:
    1. At the Command Bar, select **Worklist**
    2. Select the **Worklist Overview** tab
- Areas of the screen:
    1. Filters – can be displayed or hidden by selecting the arrow at the top of the screen
    2. Orders – displays the status and result(s) for each order
        - If the test is in process, the result time will display
        - When a test order results, the result and any applicable result flags will display
    3. Sample and Test functions – the functions under the Sample heading can be performed on selected samples, and the functions under the Test heading can be performed on selected tests
    4. General functions – used to print patient barcodes, query the LIS, import a worklist, generate a statistics report and export test results

C. Daily System Operation Workflow:

1. Sign in the system
2. Respond to system alerts
3. Ensure required maintenance is complete
4. Check CH fluid status and supply status
5. Check IMT fluid status
6. Check IM fluids and supplies status
7. Check IM waste status
8. Check reagent status in Reagent Needs
9. Check assay reagent calibration status in Calibration Overview
10. Review assay reagent QC status in QC needs

D. Inventory:

Reagent Inventory:

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

The reasons for a posted need include the following:

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

A need is red when the current inventory drops below a threshold defined by the operator or when there are pending orders with no reagent available.

NOTE: All necessary primary AND ancillary reagents, Diluent (if applicable), QC and calibrators should be loaded prior to ordering a calibration. Rule of thumb: if you open a box of reagent and see two types of packs (one with white cap, one with blue cap) – then BOTH reagent packs must be loaded simultaneously.
See Addendum B for a list of reagents that require special handling / preparation.

Calibrator Inventory:

From the Command bar:

1. Select **Inventory** > **Calibration Needs**.
2. To group calibrator material by Calibrator Name, select **Group by Calibrator Material**.
3. To sort calibrator material that is onboard, select **All**.
4. To sort the calibrator information, select any Calibrator Name row.
5. To create an order for a selected calibration, select **Create Cal Order** > **Order**

QC Inventory:

From the Command bar:

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

E. Calibration

Calibrate the new lot of reagent as soon as it is loaded on the instrument. If the reagent sits un-calibrated for a short period of time (24 hours) then it will not be eligible for a "Lot Calibration" and another new reagent will need to be loaded onboard.

Calibration Needs

1. The Calibration Needs provides a list of the calibrations that must be performed. A calibration need is created if one of the following applies:
   - A pack or lot calibration will be needed before the current day ends
   - There is a pending calibration in the Worklist
2. A need will also be created if a lot calibration is required and no fresh packs are available. In this case, the Comment will display "No valid pack onboard".
3. A need is red when the calibration is due to expire within the threshold set on the Alert Setting screen and there is no calibrator material available.

Pack vs. Lot Calibrations

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

LOT calibration interval:

1. 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
2. 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
3. A reagent pack that uses a lot calibration to calculate results for the duration of the Pack calibration interval or Lot expiration, whichever comes first

PACK Calibration Interval:

1. On the CH analyzer, a pack calibration is actually a well calibration. There are 2 wells in most CH packs, which are treated at separate reagents by the system.
2. The pack/well calibration interval is valid for an individual pack for IM or well for CH, and not used for subsequent packs/well placed on the system
3. This is 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.

Note: The system tracks lot and pack calibration and displays reminders when calibration or re-calibration of an assay reagent pack is due.

CH Module:

1. Ensure Assay test definitions, Calibrator definitions, Assay reagents are on the system.
2. Confirm the system is in either Ready, Standby, or Processing mode.
3. Prepare the calibrator samples according to the calibrator IFU.
4. Create a calibration order.

   Note: When programming Drugs of Abuse Calibrations, the appropriate cutoff must be selected.

   BARB: 200
   BENZ: 200
   COC: 300
   THC: 50
   OPI: 300
   AMP: 1000
   METH: 300

5. Print the calibrator sample barcodes.
6. Place the barcode labels on the appropriate calibrator sample tubes.
   Note: For Drugs of Abuse, there is a specific order of labeling the calibrators which needs to be followed. Pay special attention to the prompts on the screen and label accordingly.
7. Load the calibrator samples on the system.

IM Module:

1. From the home page of the **IM Module Screen** (small screen attached on the IM Module) make sure the analyzer status is in **Standby**.
2. On the IM Module Screen select **Reagent Loader**. Make sure the **Reagent Drawer** status is **unlocked**. Open the reagent drawer, load the reagent and then close it. Once the reagent is scanned, the IM Module Screen will populate message "**Missing TDef for lot**" next to the reagent. The Reagent Drawer status remains unlocked.
3. Both Reagent Master Curve and Calibrator Package Insert need to be scanned using the **Atellica Solution's main monitor**. To differentiate between the two:
   a. Reagent Master Curve has **MC TDEF** printed right below the assay name.
   b. Calibrator Package Insert has **CAL** printed right above the assay name.
4. To scan the Reagent Master Curve, go to **Set up** – **Test Definition** – **IM Test Definition**. Scan the barcode.
5. To scan the Calibrator Package Insert, go to **Calibration** – **Calibrator Definition**. Scan the barcode.
6. Re-open the **Reagent Drawer** and close it. This time its status should change to **locked**, meaning the reagent is going to be loaded onboard ready for calibration.

F. Quality Control:

Quality Control has been programmed to run at appropriate intervals (see QC schedule). To manually trigger a QC order, select **QC** > **Create QC Order** from the Command bar. (eg: repeating QC after a QC failure / outlier)

G. Maintenance:

The Atellica solution system monitors maintenance tasks and notifies the operator when a scheduled task is due. The system notifies the operator on maintenance status command bar with an overdue icon next to the maintenance task for each system components.

The system provides a maintenance schedule for the operator to record as completed upon the completion of a scheduled maintenance task. The system then uses this information to automatically update the maintenance schedule with the next time the task is due.

The maintenance is documented on the Atellica solution maintenance log.

To view the maintenance schedule from the Command bar select **Maintenance** > **Schedule**.
Daily and weekly automated activities are done by the instrument automatically.
To perform manual maintenance activities:

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

1. Daily maintenance

1.1. SH and Atellica Magline Transport Daily Maintenance

a. SH auto check - the system automatically performs autocheck on the SH.
b. Atellica Magline Transport Autocheck - The system automatically performs autocheck on the Atellica Magline Transport.

1.2. CH Daily Maintenance

a. IMT Daily Cleaning – The analyzer automatically performs IMT system cleaning daily.
b. CH Daily Maintenance – The analyzer automatically performs cuvette, probe, mixer, and drain cleaning autocheck and reaction ring bath refresh daily.
c. Inspecting the washer Probes – the operator inspects the washer probes.

1.3. IM Daily Maintenance

The system automatically cleans reagent probes, wash block water lines daily and perform daily autocheck.

2. Weekly Maintenance

2.1. CH weekly maintenance

a. The analyzer automatically performs cuvette, probe and mixer cleaning, autocheck, and reaction ring bath drain and refill weekly.
b. The operator manually inspects the lamp coolant level and refill.

2.2. **IM weekly Maintenance**

a. The system automatically cleans reagent probes and wash block water and wash lines weekly.
b. Clean the exterior of the reagent probes – the operator manually cleans the exterior of the reagent probe.
c. Inspect and empty the IM water trap – the operator manually inspects the IM water trap. If there is Condensation, call technical support for further assistance.
d. Inspect and empty the IM dryer - the operator manually inspects the IM dryer. If there is Condensation, call technical support for further assistance. Clean the IM sample tip drip tray - the operator must inspect the sample tip drip tray weekly and clean as needed. If cleaning is required, you must be in "Diagnostics" to remove the tip dip tray and soak in diluted bleach off-board. Utilize the "Help" screen for further instructions.

3. Monthly cleaning

3.1. **CH monthly cleaning**

a. Cleaning the CH fan filter – the operator manually cleans the fan filters
b. Inspect and clean the probes wash stations – the operator manually does this
c. Inspect and clean the CH probes and mixer impellers – the operator manually does this

3.2. **IM monthly maintenance**

a. Clean the exterior of the aspirate probes - the operator manually cleans these monthly to remove residue.
b. Clean the IM fan filter – the operator manually inspects and cleans IM fan filter.

3.3. **Water culture process –**

a. Collect the appropriate volume and then close the valve on the external water system.
b. Order water culture in the LIS:
    1) Log in to Sunquest through **Order Entry**
    2) For **Look up Mode: Name:** type **MILLIPORE**
    3) Three options appear: MILL-1 for SGMC, MILL-3 for WOMC, MILL-7 for GEC
    4) Highlight the preferred location, then press ***Enter***
    5) Enter **Collection Date, Collection Time** and **Received date.**
    6) For **Ordering PHYS**: type **40658**
    7) At order code type **XH2O**
    8) At **SDES** prompt type **WATER-; Instrument Name**
        Example: WATER-;Atellica 1
    9) Retrieve the LIS labels and label the water specimen.
    10) Submit sample to Processing for FES and transport for culture.

11) **Sample must be refrigerated within 2 hours of collection** (stable for 24 hours).

c. Document collection on the Atellica Maintenance Log
d. Culture result will be processed as follows. Group Lead / Tech in Charge will:
    1) Access and print results from LIS one week after sending.
    2) Record results as CFU/mL on the Atellica Maintenance Log
    3) Acceptable values are ≤ 10 CFU/mL
    4) If the result is unacceptable, obtain another water sample and repeat the culture. If the repeat value is also unacceptable, call the Siemens Hot Line and request decontamination. Document all corrective actions on the log.

4. As needed maintenance –

a. Replace Dilution Cuvettes
b. Replace Reaction Cuvettes

H. Troubleshooting

1. Monitoring the operator event log

At the command bar, select **system > logs > operator event log.**

- Displays system event 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 the operator to review the event, possible causes, corrective actions and corrective action procedure.

Corrective actions

- Events marked with a corrective actions symbol must be resolved by the operator.
- After resolving, the event can be marked completed.
- Events marked with the unacknowledged symbol for an event can be acknowledged by the operator. To acknowledge an event, select the event and either select the unacknowledged symbol for an event, or select the ACKNOWLEDGE ALL to acknowledge all events.

2. Software lockup

- When the system displays a blue screen, wait for the display to restore. In most cases the system requires 1-3 minutes to repair itself.
- Wait for the system to automatically complete the repairs for the full 10 minutes to avoid cancelling od interrupting all patient testing.
- If the system does not restart after 10 minutes, the PCC automatically reboots. The system logs an event after a successful reboot.
- If a software lockup persists, contact the local technical support provider.

3. Emergency Sample Loader

   Emergency sample loader (ESL) mode is an optional feature that allows the operator to continue processing samples directly on an analyzer if one or more of the following error conditions occur.

   - A full failure to all SHS and SHC, if equipped
   - A full failure of all Tube Characterization Stations (TSC)
   - A partial or full failure of the Attellica Magline Transport.

   The operator enables ESL mode at the primary user interface and uses the ESL carrier to manually load and process sample on the appropriate analyzer. The analyzer module display provides the operator with step by step instructions for installing and using the ESL carrier.

4. Siemens Remote Assistance

   This feature can be utilized in the Status bar.
   - Allows the operator to contact the local technical support provider to ask a question, request information, or troubleshoot issues
   - The local technical support provider will call the operator by phone or text chat within a pre-configured minimum time or at a requested time

I. Manual Dilutions:

The instrument will perform on-board dilutions for some assays when the AMR exceeds the upper range.
If the on-board dilution does not calculate a value within the AMR, then

- Report as > **OR**
- Perform manual off-board dilution.
  Look at chart of AMR / CRR and dilutions to determine what to dilute the sample with and how far to dilute it.

Programming manual dilutions:

1. Go to **Patient Order** tab:
2. Click on **Create Patient Orders** tab:
3. Enter the nine-digit accession number:
4. Press **Enter.** A list of tests will display.
5. Select the test that needs a manual dilution.
6. You will see the test appear and it will be defaulted to x1 or undiluted.
7. Some assays will have an option for onboard dilutions. (If you wish the instrument to do an on-board dilution, select the appropriate box.) If you wish to do an off-board dilution, ensure the **X1 / undiluted** is checked **off** and enter the manual dilution factor in the appropriate field on the left-hand side of the screen.
8. Press **Enter**
9. Print barcode. The barcode has the dilution factor embedded in it and the instrument will do the calculation automatically. No multiplication is required on the user end.
10. Label tube with barcode and load.

6. RELATED DOCUMENTS

Atellica Solution Limits Chart (AG.F589)
Atellica Solution Maintenance Log (AG.F590)
Atellica Basic Operation Guide

7. REFERENCES

1. Atellica Solution Operator's Guide, Siemens Healthcare Diagnostics, Rev. 06/2020.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By

9. ADDENDA AND APPENDICES

A. Atellica Solution Components
B. Reagents that Require Special Handling / Preparation
C. LIS and DI (Data Innovation) Actions

Addendum A

Atellica Solution Components

Command Bar:
The Command bar provides access to system functions and information for performing and managing laboratory activities. Each tab and subtab on the Command bar that has an associated alert displays red or yellow until the alert is resolved. The operator can determine which area is causing the alert by opening the appropriate tab and finding the colored line below a subtab.

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

The system uses carriers to transport patient samples, calibrators, and QC materials between the Sample Handler and the analyzers on the Magline Transport. Each carrier has 2 positions to hold sample containers. The system uses only 1 position to transport 1 sample at a time. The system leaves the other position empty so the SH robot can place the next sample container in the carrier before removing the completed sample container. This allows the system to maximize throughput by minimizing the number of robot moves in order to load and unload samples.

Sample Handler:
The Sample Handler is the primary way the operator interfaces with the system. It allows the operator to load and unload routine patient samples, STAT samples, and calibrator and QC (Cal-QC) materials. The Sample Handler front and back covers lock during normal operation. To open the front or back cover, the operator requests to unlock the cover from the system display or operator tablet. After the operator unlocks and opens the cover, the system removes power from the SH robot so it cannot move. After the operator closes and locks the cover, the system resumes normal operation.

Each Sample Handler has 4 sample drawers. Each drawer can store up to 110 sample containers. The operator can load up two 55-position racks in any appropriate location within a single drawer. Sample drawers are locked when the robot is accessing the sample racks in that drawer and any time the Drawer Vision System (DVS) is downloading images. The drawers are unlocked at all other times. An LED and button located above each drawer indicates the drawer locked/unlocked status and allows the operator to request the system to unlock a currently locked drawer.

The operator uses sample racks to load sample containers into and unload sample containers from the Sample Handler. These racks are “Routine 55-position rack” or “STAT 15-position rack”.

The Drawer Vision System (DVS) is a series of 8 cameras with built-in illumination. Two cameras are located above each sample drawer. The cameras image each rack and rack position in the drawer as the operator closes the drawer. After capturing images, the Sample Handler analyzes them to determine the rack characteristics, including whether the rack is a routine rack or STAT rack, and sample container characteristics.

The Sample Handler robot is a 3-axis robot that transports sample containers (patient samples and calibrator or QC materials) between racks in the sample drawers, Cal-QC tube storage area, and the carriers on the Magline Transport inside the Sample Handler. After the operator loads the racks and closes the sample drawer, the robot receives the information decoded from the DVS images and begins selecting sample containers from the rack according to STAT or routine status and loading order.
The Cal-QC storage area, located between the sample loading area and the TCS, provides a space that maintains the temperature at 2-8°C. This refrigerated space allows for prolonged storage for up to 60 sample containers containing calibrator or QC material for up to 7 days.

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

CH Module:
The dilution mechanism services the photometric and IMT systems. The dilution probe transfers a sample from the sample container to the IMT system or to the dilution ring. The dilution ring has 5 dilution ring segments, each with 23 dilution cuvettes, for a total of 115 cuvettes. The cuvettes contain dilution volumes of up to 250 µL. The analyzer washes the dilution cuvettes so the cuvettes can remain on the analyzer for approximately 400 sample deliveries before replacement. The CH dilution washer washes dilution cuvettes after the analyzer completes the sample analysis. The washing process enables the analyzer to reuse the cuvettes without risk of contaminating the next sample. The reagent compartments maintain the fluid in each pack at 4°–12°C. Each reagent compartment has an inner ring, which holds 24 packs, and an outer ring, which holds 46 packs, for a total of 70 packs. The refrigerated reagent compartments 1 and 2 contain reagents as well as the cleaners that the CH Analyzer uses for daily washing and preventing contamination. Reagent probes 1 and 2 aspirate and dispense the required reagent into the reaction cuvettes for analysis. The CH sample probe aspirates a sample from the dilution ring and dispenses it into a reaction cuvette for analysis. The sampling pump assists in the aspirating and dispensing functions. The operator loads and unloads reagents without stopping or pausing the CH Analyzer. The reagent loader scans reagent barcodes and moves reagent packs from the reagent tray to the reagent compartments or from the reagent compartments to the reagent tray. The CH reaction washer washes the reaction cuvettes after sample analysis to enable the reuse of cuvettes. The CH reaction ring contains and incubates the sample reaction volumes and presents them to each processing step. The CH sample and reagent mixers use an impeller to mix the contents of reaction cuvettes in their respective mixer positions. The CH Analyzer suspends cuvettes in an incubation fluid maintained at a constant 37°C ± 0.3°C. This bath maintains the reaction volume at the target temperature and provides a consistent thermal

profile. On the CH Analyzer photometer, the light source is directly opposite the detection assembly on the reaction ring. The reaction cuvettes pass between the light source and the detection side with the analyzer making measurements on each cuvette. The CH Analyzer has 2 separate cuvette wash stations: Reaction-CW (RCW) and Dilution-CW (D-CW). R-CW washes and dries the 221-position reaction cuvette ring (13 segments with 17 cuvettes each). The D-CW washes and dries the 115-position dilution cuvette ring (5 segments with 23 cuvettes each). The IMT system on the CH Analyzer uses potentiometry to determine the concentration of sodium (Na), potassium (K), and chloride (Cl) ions in patient samples. The dilution probe presents samples to a flow-through sensor cartridge. This cartridge encloses a reference electrode and 3 ionselective electrodes: Na+, K+, and Cl-. The analyzer amplifies the potential of the Na, K, and Cl electrodes and measures the potential against the reference electrode and then converts it to ion concentrations.

IM Module:
The sample tip loader accepts triple, double, or single sample tip tray configurations. Notches in the trays ensure correct orientation. The system stores up to 1800 sample tips. The cuvette bin holds up to 1500 cuvettes. An elevator transfers cuvettes from the bin up into the orientation chute. The cuvette pusher moves cuvettes along the channel towards the incubation ring. The preheater warms the cuvettes to 37°C. A direct plumbed IM Analyzer uses special reagent water from the laboratory water system for rinsing reagent probes and for washing the reaction mixture particles in the wash ring. The analyzer pumps liquid waste into 3 waste reservoirs for automatic disposal in the waste lines. Used cuvettes and sample tips fall down separate chutes into solid waste bins. Reservoirs collect cuvettes and sample tips in the temporary absence of the solid waste bins. The reagent compartment stores primary and ancillary reagent packs in a single refrigerated tray at 4–8°C. The rotary tray motion maintains solid phase particle suspension. The reagent loader scans and transfers packs from the reagent drawer to the access shuttle and places the packs into the reagent compartment. The rotary tray moves packs to the reagent probe aspiration positions. The incubation ring is a circular, insulated compartment comprised of 2 independently movable rings that advance cuvettes to the sample and reagent dispense positions. The IM wash ring is a circular track that washes and prepares reaction cuvettes for the final chemiluminescent measurement. Magnets located along the wash ring pull antigen- or antibody-bonded magnetic particles to the side of the cuvette. Aspirate probes draw fluid out of the cuvette leaving the magnetic particles behind. Dispense ports wash and re-suspend the magnetic particles.

Addendum B

Reagents that Require Special Handling / Preparation

- BUP
- Amikacin
- Lactate
- HA1C
- Vitamin B12
- Folate

Refer to the specific SOP for detailed information.

Manually Mixing IM Primary Reagents:
Primary reagents must be manually mixed before being loaded on the system:

- If the reagent pack is pierced, gently press on the self-sealing laboratory film that covers the pierced film area, while mixing, to prevent leakage
- With the film side up, loosely hold the reagent pack at each end
- Raise one end of the pack 90 degrees to its vertical position
- Return the pack to the horizontal position
- Raise the other end of the pack 90 degrees again to its vertical position
  NOTE: If foam appears inside the pack, use a slower mixing speed.
- Return the pack to a horizontal position
- Repeat steps 20 times, or until any clumps are broken up and no longer visible on the bottom of the pack / no large aggregates are visible floating inside of the pack
- Mix 5-10 times more to ensure complete mixing
- If the reagent pack is pierced, remove the self-sealing laboratory film
- Load the reagent pack onto the analyzer

Addendum C

LIS and DI (Data Innovations) Actions

Transmitting partially resulted Patient and QC results

The Atellica instruments are set to transmit result by specimen. This means that only completed specimens will transmit.
If the specimen has one test that is still pending, even if the rest of the tests are done, the instrument will wait for that pending test to be completed for it to transmit all the results.

To manually transmit the result:

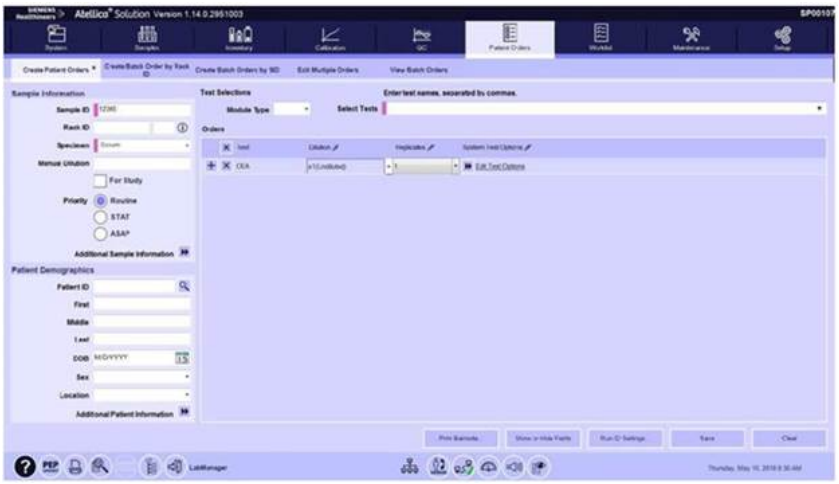
- Go to the worklist and find the accession number
- Select all the individual tests that you want to transmit
- Press Transmit

Troubleshooting tips:

Your scheduled QC did not transmit?
If the QC has not transmitted and it has been a while since the scheduled QC run, go to the instrument and view the QC results. Most likely, the instrument run the QC, but there was a pending test from that panel. When this happens, select the individual test and press transmit

Programming Manual Test Using the Atellica

- Select Patient Order->Create Patient Order from the Command Bar
- Enter the sample information. Manually enter the specimen ID exactly as you see on the label. *Example*: if the SQ label shows M1234, enter M1234 in the specimen ID field
- Select the tests to be ordered
- Select the fluid type, and the test
- Select Save
- Print the barcode
- Attach the barcode to the specimen. It is very important that the newly printed barcode is the only barcode that is showing on the tube. If there is another barcode that is showing, then that extra barcode must be blocked
- Load the specimen on the analyzer
- The result will be held by DI. Manually result in SQ



How to Stop/Start the LIS Communication on Atellica

- Select the  (LIS icon) from the status bar of the Atellica application to stop/start the LIS connection. The LIS Communication window will appear

- Select **Disconnect from LIS**. This will make the LIS connection icon to turn red
- Go to Status Display on DI and select the Atellica connection that is having the LIS problem

Instrument Name	Connection Name on DI
Atellica 1	Atellica-SA1
Atellica 2	Atellica-SA2

- Select the **Stop Selected Connection**. This will stop the connection on DI for the selected instrument
- Wait for the connection to be in OFF status. At this point, the LIS connections on both the instrument and on DI should be turned off. Once the DI connection is in OFF status, it needs to be turned back on
- Select **Start Selected Connection** on DI. The DI connection will remain in "Connecting" status until the instrument LIS connection has been turned on
- Select **Connect to LIS** on the Atellica. Once the instrument is fully connected, the LIS icon on the status bar should have a green check mark. 

How to Enable/Disable Automatic Printing of Results

- On the Command Bar, select Setup -> Settings->Report Setup
- Select **Automatic Reports**
  - To Enable automatic reports, select **Enable Automatic Reports**.
    - Select a report configuration: **Lab Results Report by Sample**
    - Select **Save**
  - To Disable automatic reports, **Select Disable Automatic Report** and save

Tests with Special Fluid Mapping

- The BNPT and IPTH are done on the Centaur. The download fluid for those tests in Sunquest Production is OT. To prevent issues with the Centaur at WOMC, OT has been mapped to PL
- The FOLA and PSA are done at SGMC. The Atellica can only do FOLA and PSA on fluid type of SE. On the day of the go-live, those tests will be removed from the SR (Specimen Routing) for the Vista and be added to the SR for the Atellica. After the go-live, the Vista will no longer receive the orders for FOLA and PSA
- The fluid type for VTB12 has been changed to SE to accommodate for the FOLB12 panel (Folate and VitB12)
- The PCAL is done on the Vidas. The Vidas is not a query instrument. On the day of the go-live, the download fluid type of PL must be added to DIDD in SunQuest Production and add PCT to the SR for the Atellica

PL = Plasma
OT = Other
SE = Serum

	Download Fluid Type	
TESTCODE	**Sunquest Production**	**Atellica Instrument**
FOLA	PL	SE
PSA	PL	SE
BNPT	OT	PL
IPTH	OT	PL
PCAL	n/a	PL
VTB12	PL	SE

Adventist HealthCare

ATELLICA SOLUTION LIMITS CHART

Shady Grove Medical Center

ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT for OFF BOARD DILUTION
ACTM	µg/mL	3	2.0 - 600.0	Not Available	2.0 – 600.00	N/A, Do NOT Dilute
ALB	g/dL	2	0.0 - 12.0	Not Available	0.0 - 12.0	N/A, Do NOT Dilute
ALC	mg/dL	3	3 - 900	Not Available	3 - 900	N/A, Do NOT Dilute
ALPI	U/L	10	10 – 10,000	Not Available	10 – 10,000	N/A, Do NOT Dilute
ALTI	U/L	3	7 – 3,300	Not Available	7 – 3,300	N/A, Do NOT Dilute
Amikacin	µg/mL	2	2.5 – 50.0	Not Available	2.5 – 100.0	N/A, Do NOT Dilute
AMM	µmol/L	2	10 - 1,500	Not Available	10 – 1,500	N/A, Do NOT Dilute
AMY_2	U/L	3	20 – 4,500	Not Available	20 - 4,500	N/A, Do NOT Dilute
AST	U/L	6	8 - 6,000	Not Available	8 - 6,000	N/A, Do NOT Dilute
BUN	mg/dL	2	5 - 300	Not Available	1 - 300	N/A, Do NOT Dilute
CA	mg/dL	2	1.0 – 32.0	Not Available	1.0 - 32.0	N/A, Do NOT Dilute
CHOL	mg/dL	2	25 – 1,236	Not Available	25 – 1,236	N/A, Do NOT Dilute
CK_L	U/L	50	50 - 65,000	Not Available	50 - 65,000	N/A, Do NOT Dilute
CL	mmol/L	Not Available	50 - 200	Not Available	50 - 200	N/A, Do NOT Dilute
CRBM	µg/mL	2	0.4 - 40.0	Not Available	0.4 - 40.0	N/A, Do NOT Dilute
CREAT	mg/dL	2	0.15 - 60.00	Not Available	0.15 - 60.00	N/A, Do NOT Dilute
CRP	mg/dL	3	0.4 – 91.2	Not Available	0.4 – 91.2	N/A, Do NOT Dilute
DBIL	mg/dL	1.5	0.1 - 22.5	Not Available	0.1 – 22.5	N/A, Do NOT Dilute
DGN	ng/mL	2	0.14 - 10.00	Not Available	0.14 - 10.00	N/A, Do NOT Dilute
CO2	mmol/L	2	10 - 80	Not Available	1 - 80	N/A, Do NOT Dilute
FER	ng/mL	10	0.9 – 16,500	Not Available	0.9 – 16,500	N/A, Do NOT Dilute
Folate	ng/mL	2	0.56 – 48.0	Not Available	0.56 – 48.0	N/A, Do NOT Dilute
FT4	ng/dL	Not Available	0.10 - 12.00	Not Available	0.10 - 12.00	N/A, Do NOT Dilute
GENT	µg/mL	2	0.5 - 24.0	Not Available	0.5 - 24.0	N/A, Do NOT Dilute
GGT	U/L	3	7 - 3,600	Not Available	7 – 3,600	N/A, Do NOT Dilute
GLUC	mg/dL	3	4 - 2,100	Not Available	4 - 2,100	N/A, Do NOT Dilute
A1C	%	Not Available	Not applicable	Not Available	3.8 – 14.0	N/A, Do NOT Dilute
HCG	mIU/mL	1,000	1 – 1,000,000	Not Available	1 - 1,000,000	N/A, Do NOT Dilute
HDLC	mg/dL	2	20 - 258	Not Available	20 - 258	N/A, Do NOT Dilute
IRON	µg/dL	2	2 – 2000	Not Available	2 – 2,000	N/A, Do NOT Dilute
K	mmol/L	Not Available	1.0 - 10.0	Not Available	1.0 - 10.0	N/A, Do NOT Dilute
LA	mmol/L	10	0.07 - 122.1	Not Available	0.07 – 122.1	N/A, Do NOT Dilute
LDI	U/L	6	14 - 4,500	Not Available	14 – 4,500	N/A, Do NOT Dilute
LITH	mmol/L	2	0.10 - 6.00	Not Available	0.10 - 6.00	N/A, Do NOT Dilute
LIPL	U/L	50	8 - 35,000	Not Available	8 - 35,000	N/A, Do NOT Dilute
MG	mg/dL	2	0.5 - 10.0	Not Available	0.5 - 10.0	N/A, Do NOT Dilute
MMB	ng/mL	10	0.18 - 3,000	Not Available	0.18 - 3,000	N/A, Do NOT Dilute

Adventist HealthCare

ATELLICA SOLUTION LIMITS CHART

Shady Grove Medical Center

ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT for OFF BOARD DILUTION
MYO	ng/mL	100	3 - 100,000	Not Available	3 - 100,000	N/A, Do NOT Dilute
NA	mmol/L	Not Available	50 - 200	Not Available	50 - 200	N/A, Do NOT Dilute
PHNO	µg/mL	2	3 - 160.0	Not Available	3 - 160.0	N/A, Do NOT Dilute
PHOS	mg/dL	2	0.3 - 40.0	Not Available	0.3 - 40.0	N/A, Do NOT Dilute
Pre-albumin	mg/dL	2	5 – 140	Not Available	5 – 140	N/A, Do NOT Dilute
PSA Total	ng/mL	50	0.04 – 5,000	Not Available	0.04 – 5,000	N/A, Do NOT Dilute
PTN	µg/mL	2	2 - 80	Not Available	2 - 80	N/A, Do NOT Dilute
SAL	mg/dL	4	3 - 400.0	Not Available	3 - 400.0	N/A, Do NOT Dilute
TBIL	mg/dL	2	0.15 – 70.0	Not Available	0.15 - 70.0	N/A, Do NOT Dilute
TRIG	mg/dL	2	10 – 1,100	Not Available	10 – 1,100	N/A, Do NOT Dilute
THEO	µg/mL	2	2.0 - 80.0	Not Available	2.0 - 80.0	N/A, Do NOT Dilute
TIBC	µg/dL	Not Available	40 – 670	Not Available	40 – 670	N/A, Do NOT Dilute
TNIH	pgmL	5	2.5 – 125,000	Not Available	2.5 – 125,000	N/A, Do NOT Dilute
TOBR	µg/mL	2	0.3 - 24.0	Not Available	0.3 - 24.0	N/A, Do NOT Dilute
TP	g/dL	2	2.0 - 24.0	Not Available	2.0 - 24.0	N/A, Do NOT Dilute
TSH	µIU/mL	5	0.008 - 750.00	Not Available	0.008 - 750.00	N/A, Do NOT Dilute
UCFP (CSF)	mg/dL	10	6 – 2,500	Not Available	6 - 2500	N/A, Do NOT Dilute
URCA	mg/dL	5	0.5 - 100.0	Not Available	0.5 - 100.0	N/A, Do NOT Dilute
VALP	µg/mL	2	3.0 - 300.0	Not Available	3.0 - 300.0	N/A, Do NOT Dilute
VANC	µg/mL	2	3.0 - 100.0	Not Available	3.0 - 100.0	N/A, Do NOT Dilute
VB12	pg/mL	2	45 – 4,000	Not Available	45 – 4,000	N/A, Do NOT Dilute

ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT for OFF BOARD DILUTION
Urine CREA	mg/dL	3	3.00 - 735.00	Not Available	3.00 - 735.00	N/A, Do NOT Dilute
Urine K	mmol/L	Not Available	2.0 - 300.0	Not Available	2.0 - 300.0	N/A, Do NOT Dilute
Urine SOD	mmol/L	Not Available	10 - 300	Not Available	10 - 300	N/A, Do NOT Dilute
UCFP (urine only)	mg/dL	10	6 – 2,500.0	Not Available	6 – 2,500.0	Reagent Grade Water

Adventist HealthCare

Atellica Solution Maintenance Log

Shady Grove Medical Center

Month: _____ Year: _____ Instrument Serial Number: _____

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily																															
Sample handler and magline transport auto check (√)																															
CH IMT daily cleaning (√)																															
CH inspect washer probes (√)																															
CH daily maintenance [1] (√)																															
IM daily maintenance[1] and autocheck (√)																															
Tech Code																															

[1] cuvette, probe, mixer, and drain cleaning autocheck and reaction ring bath refresh daily.
[2] Auto reagent probe cleaning and daily wash block water lines.

Weekly

Chemistry Module weekly maintenance (√)					
Check lamp coolant (√)					
CH weekly maintenance[1]					
IM weekly maintenance[2]					
Inspect and empty IM water trap and dryer					
Clean the IM sample tip drip tray					
Clean IM exterior reagent probe					
Tech Code / Date					

Monthly

	Tech Code / Date
Clean CH & IM fan filter	
Inspect and clean probe wash stations	
Inspect and clean CH probe and mixer impellers	
Collect water for bacterial content	
As needed	
Replacing dilution ring cuvette segment	
Replacing CH reaction ring cuvette segments	

Bacterial Content

Acceptable value: ≤ 10 CFU/mL Document corrective action if unacceptable	**Result**

Comments:

_____

_____

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review: