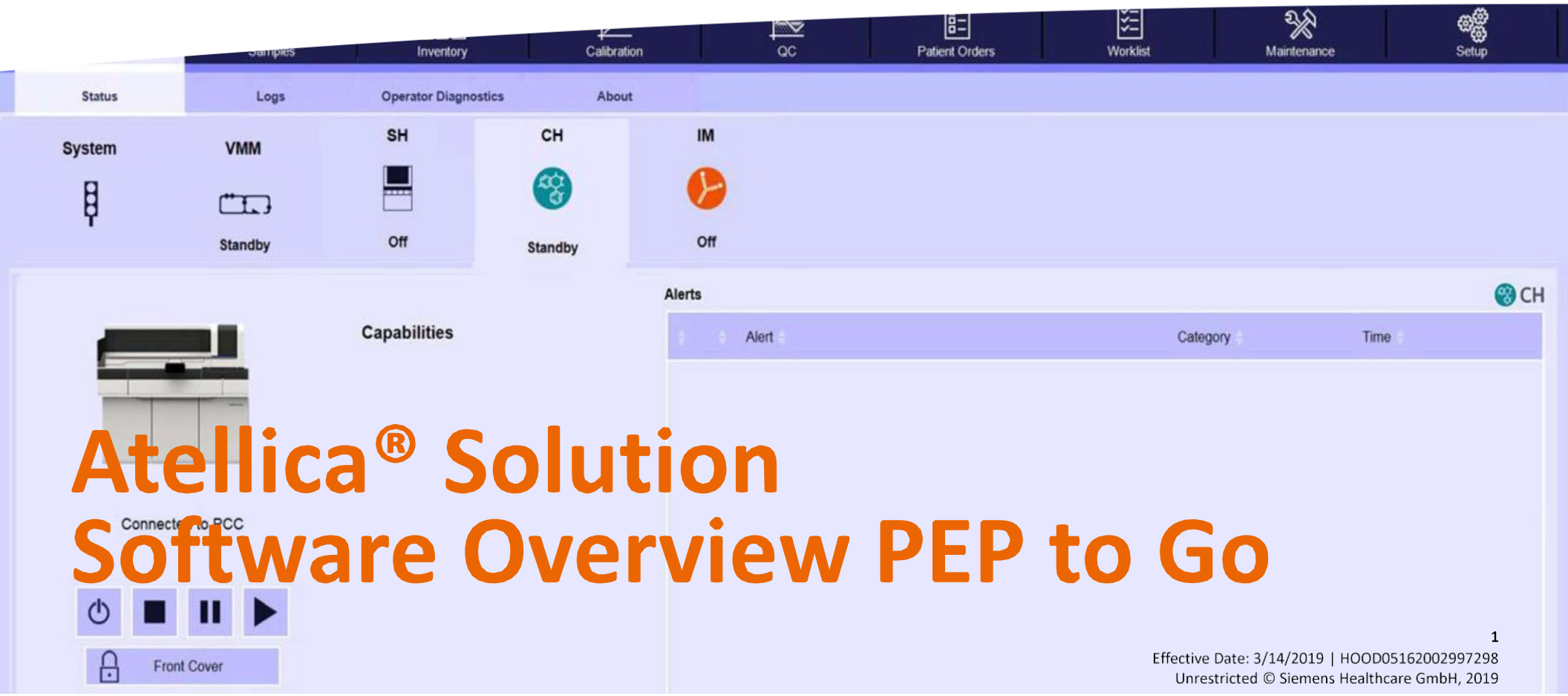
SIEMENS Healthineers



Atellica® Solution Software Overview PEP to Go

Effective Date: 3/14/2019 | HOOD05162002997298

Atellica® Solution Software Overview

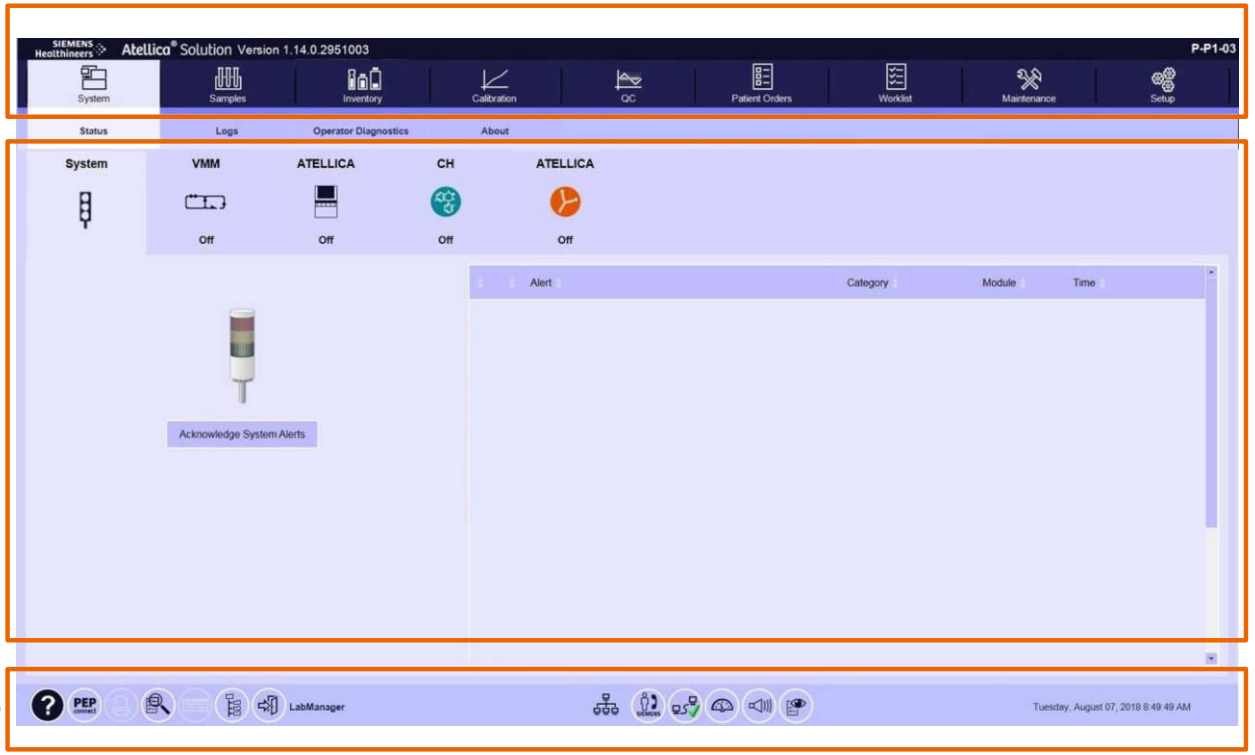
Navigate the Software

The system uses three areas of the screen to access system functions and information:

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

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

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



Effective Date: 3/14/2019 | HOOD05162002997298

Atellica® Solution Software Overview

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The Command Bar

1. System - Displays system and module status, access to logs, and diagnostic features
2. Samples - Tracks and manages patient, calibration, and control samples
3. Inventory - Displays and manages reagents and system supplies
4. Calibration - Creates and edits calibrator definitions and orders, accepts and rejects pending calibrations, displays calibration details and status
5. QC - Creates QC orders, defines rules for monitoring QC tests, displays QC results, and accesses QC and QC profile definitions
6. Patient Orders - Creates, displays, and edits patient and batch orders
7. Worklist - Displays and accepts test results and performs additional result-related tasks
8. Maintenance - Schedules and creates maintenance procedures, monitors automated procedures, and displays a maintenance log of activities and alerts
9. Setup - Displays test definition information and configures basic system operations

Effective Date: 3/14/2019 | HOOD05162002997298

Atellica® Solution
Software Overview

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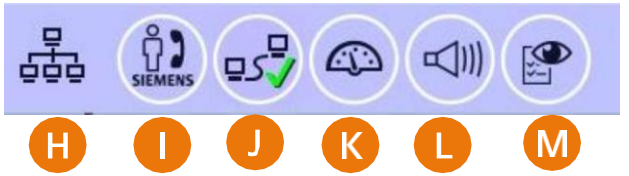
The Status Bar



A. Online Help - Displays online help
B. PEPconnect - Connects to PEPconnect (Personalized Education Plan)
C. Print - Prints the workstation screen
D. Quick Find - Searches for a specific result in the Worklist Overview screen
E. Keyboard - Displays an on-screen keyboard for text input
F. File Manager - Accesses folders containing archives, back-ups, and exports, and manages data transfer to USB
G. Sign Out - Locks or signs the operator out of the system
H. Atellica Process Manager (APM) - Indicates the system is communicating and sending updates to the APM
I. Remote Assistance - Can be used to initiate a remote session with Siemens Technical Support or submit a ticket for assistance
J. Laboratory Information System (LIS) - Displays or changes the current status of the LIS connection and performs diagnostics
K. Dashboard - Displays a summary of samples, tests, and their status
L. Volume - Adjusts the volume of the system alerts
M. Watch List - Displays a list of STAT and other samples the operator specifies as the Watch List

Effective Date: 3/14/2019 | HOOD05162002997298

Atellica® Solution Software Overview

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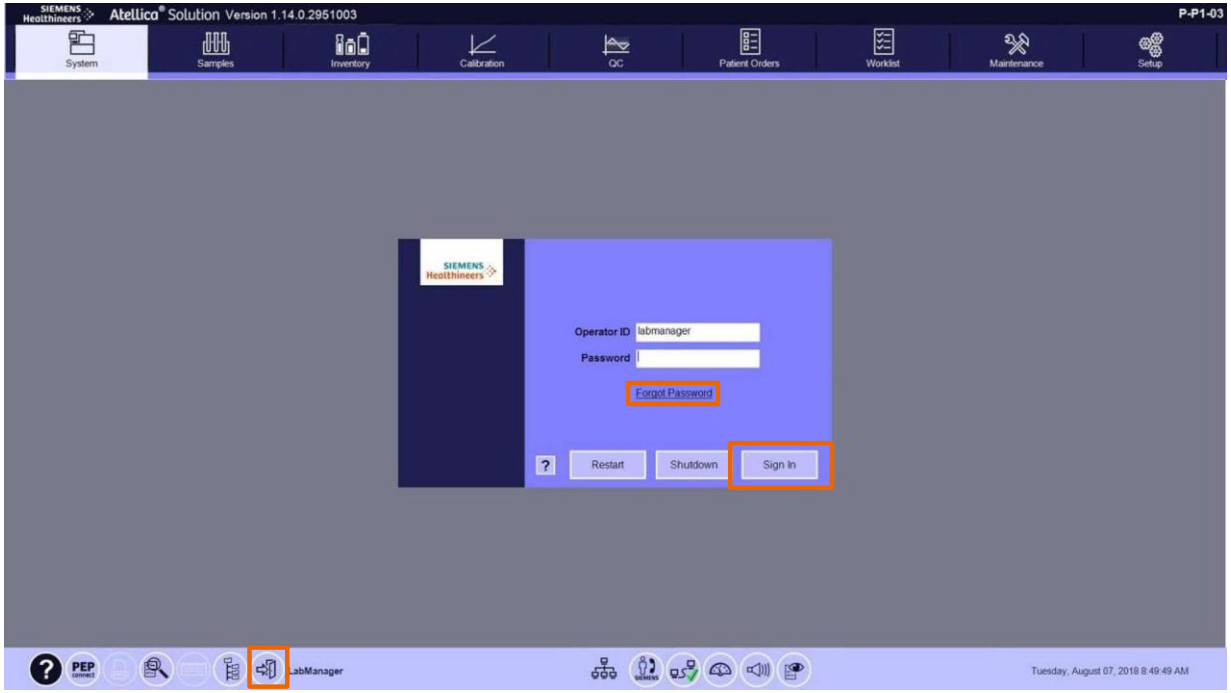
Signing out of the System

1. On the Status bar, select the sign out icon 
2. Select **Sign Out**
3. Select **Yes**

Signing into the System

1. At the Sign In window, enter the Operator ID and password
2. Select **Sign In**



NOTE: If the operator forgets their password, select the **Forgot Password** link. Then, answer 1 of the 2 security questions to reset the password. The security questions are configured in **Setup > Accounts > Accounts.**

NOTE: If an incorrect password is entered too many times, the account will be locked. After approximately 10 minutes the account will automatically unlock so the operator can use the account to try again to sign into the system.

Effective Date: 3/14/2019 | HOOD05162002997298

Atellica® Solution Software Overview

SIEMENS Healthineers

System Alerts

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

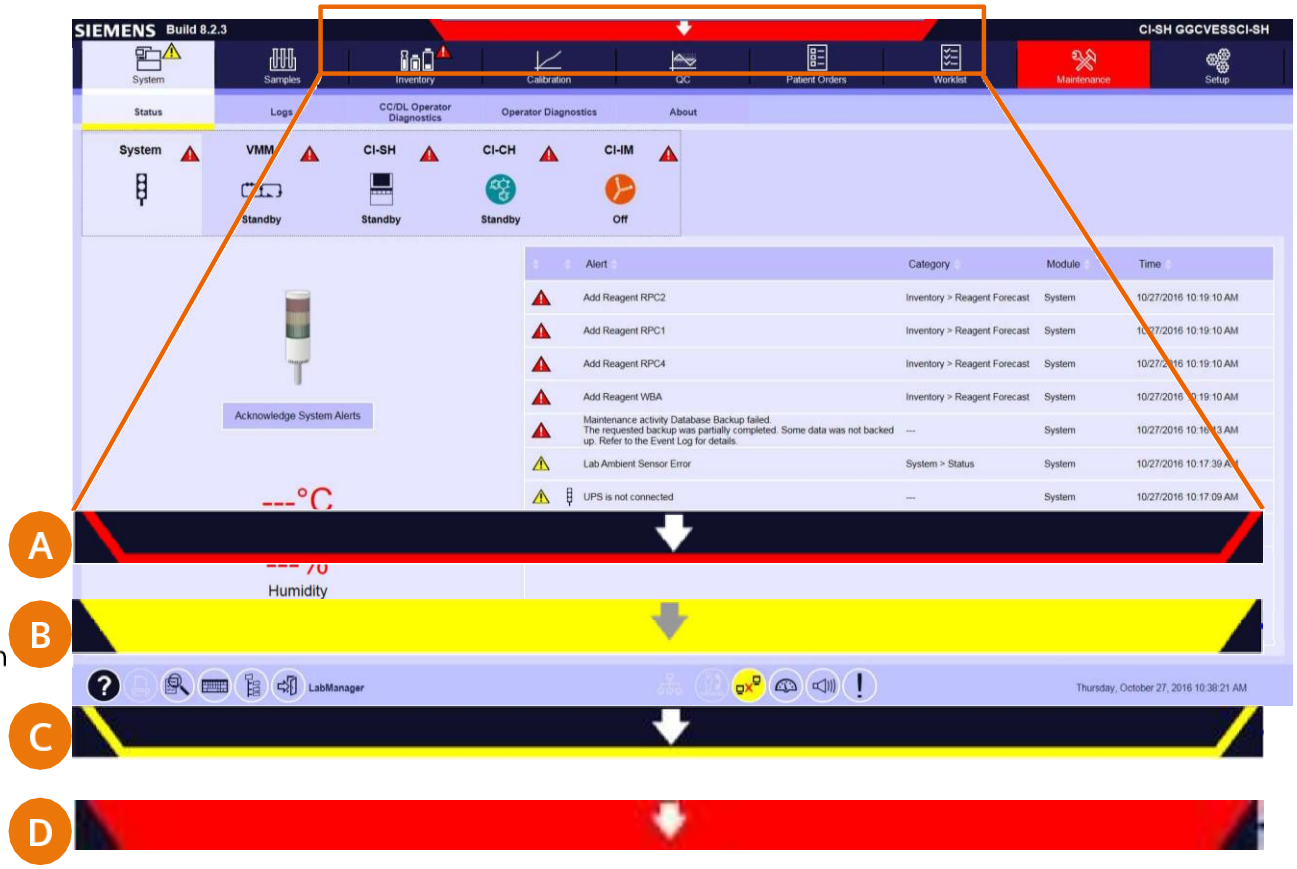
The system alerts are designated as follows:

A. Black tab with a red outline - errors have been acknowledged but error conditions still exist

B. Solid yellow tab - there are one or more unacknowledged warnings

C. Black tab with a yellow outline - warnings have been acknowledged but warning conditions still exist

D. Solid red tab - there are one or more unacknowledged errors



Effective Date: 3/14/2019 | HOOD05162002997298

Atellica® Solution Software Overview

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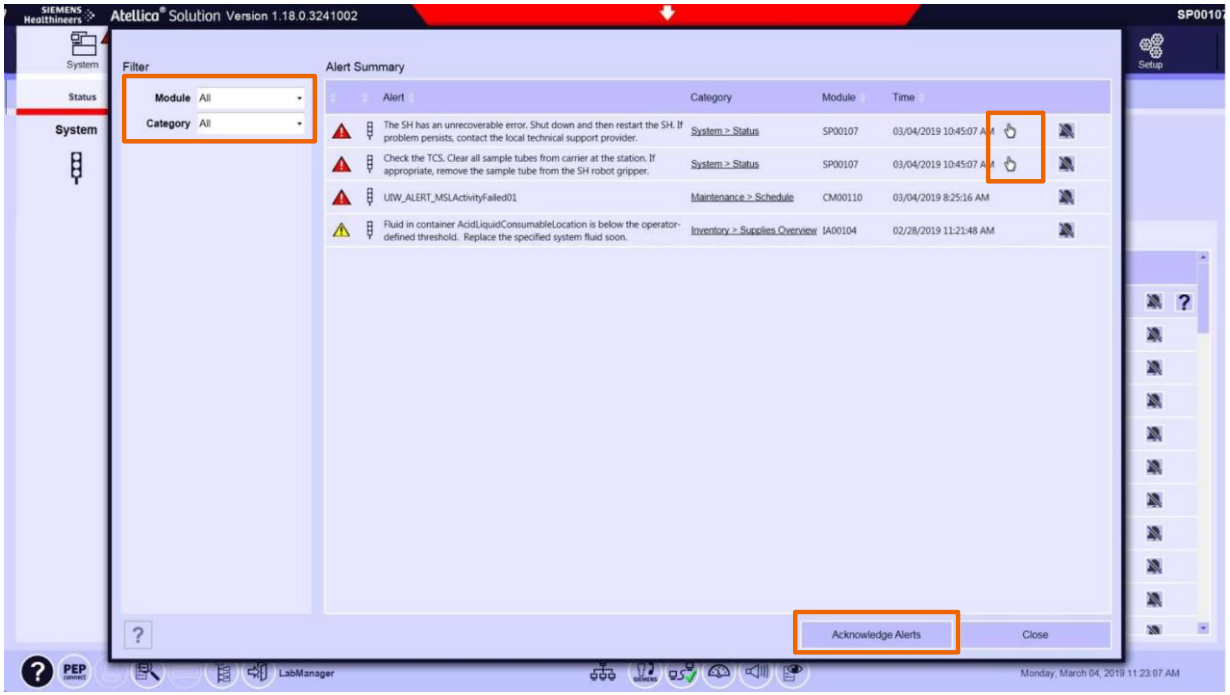
Viewing and Acknowledging System Alerts

The operator can view the Alert Module to display all active module and system alerts.

To view and acknowledge system alerts:

1. Above the Command bar, select the colored tab
2. To filter the alert list, select a **Module** or **Category**
3. To acknowledge individual alerts, select the **hand symbol** to the right of the alert
4. To acknowledge all alerts, select the **Acknowledge Alerts** button



NOTE: Selecting **Acknowledge Alerts** does not resolve the system alerts. Action must be taken on the system.

NOTE: Acknowledging alerts on the Operator Tablet and/or primary workstation will be reflected on both the tablet and primary workstation.

Effective Date: 3/14/2019 | HOOD05162002997298

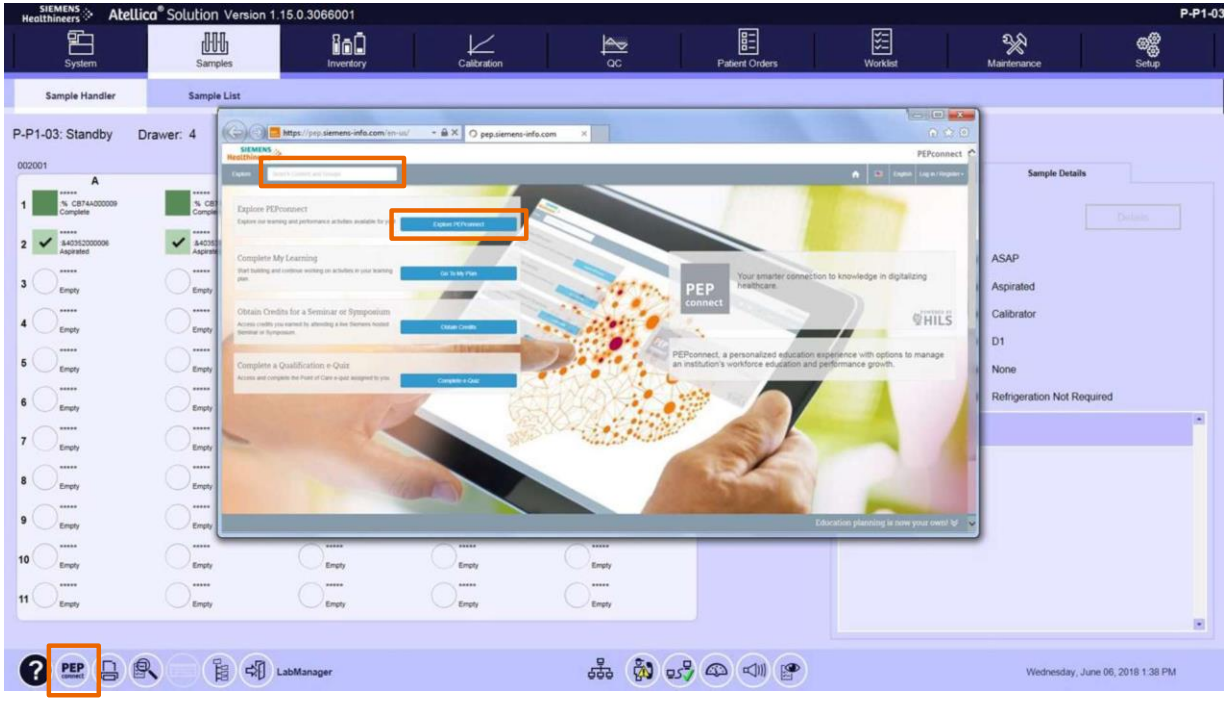
Atellica® Solution Software Overview

Using PEPconnect

The e-learning experience PEPconnect enables the operator to access product-specific content for initial training and ongoing operations.

Accessing PEPconnect in the Atellica Solution software:

1. On the Status bar, select the PEPconnect icon
2. PEPconnect will open in a separate window
3. To access the Atellica Solution content in PEPconnect, either:
   - Enter search words in the **Search Content and Groups** field at the top of the screen
     OR
   - Navigate to **Explore PEPconnect** > **Laboratory Diagnostics** > **Integrated Systems** > **Atellica Solution**



NOTE: The connection to PEPconnect needs to be setup by your field service engineer during product install.

Effective Date: 3/14/2019 | HOOD05162002997298

Atellica® Solution Software Overview

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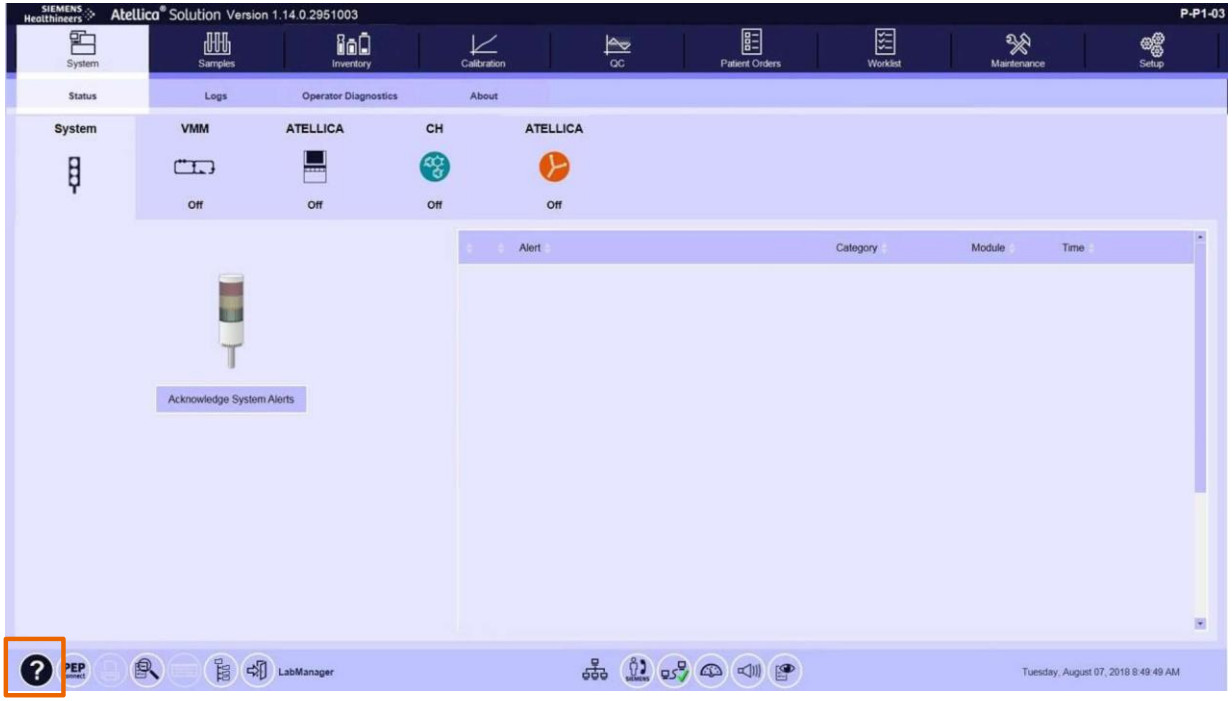
Accessing Online Help

The Online Help icon on the Status bar is accessible from every screen.

- Provides links to help topics specific to the screen currently displayed, and provides access to the table of contents where the entire Online Help package can be accessed



Effective Date: 3/14/2019 | HOOD05162002997298

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The Operator's Manual shall be used as your main reference, in particular for relevant safety information like warnings and cautions.

Note: Some functions shown in this material are optional and might not be part of your system.

Certain products, product related claims or functionalities (hereinafter collectively “Functionality”) may not (yet) be commercially available in your country. Due to regulatory requirements, the future availability of said Functionalities in any specific country is not guaranteed. Please contact your local Siemens Healthineers sales representative for the most current information.

All names and data of patients, parameters and configuration dependent designations are fictional and examples only.

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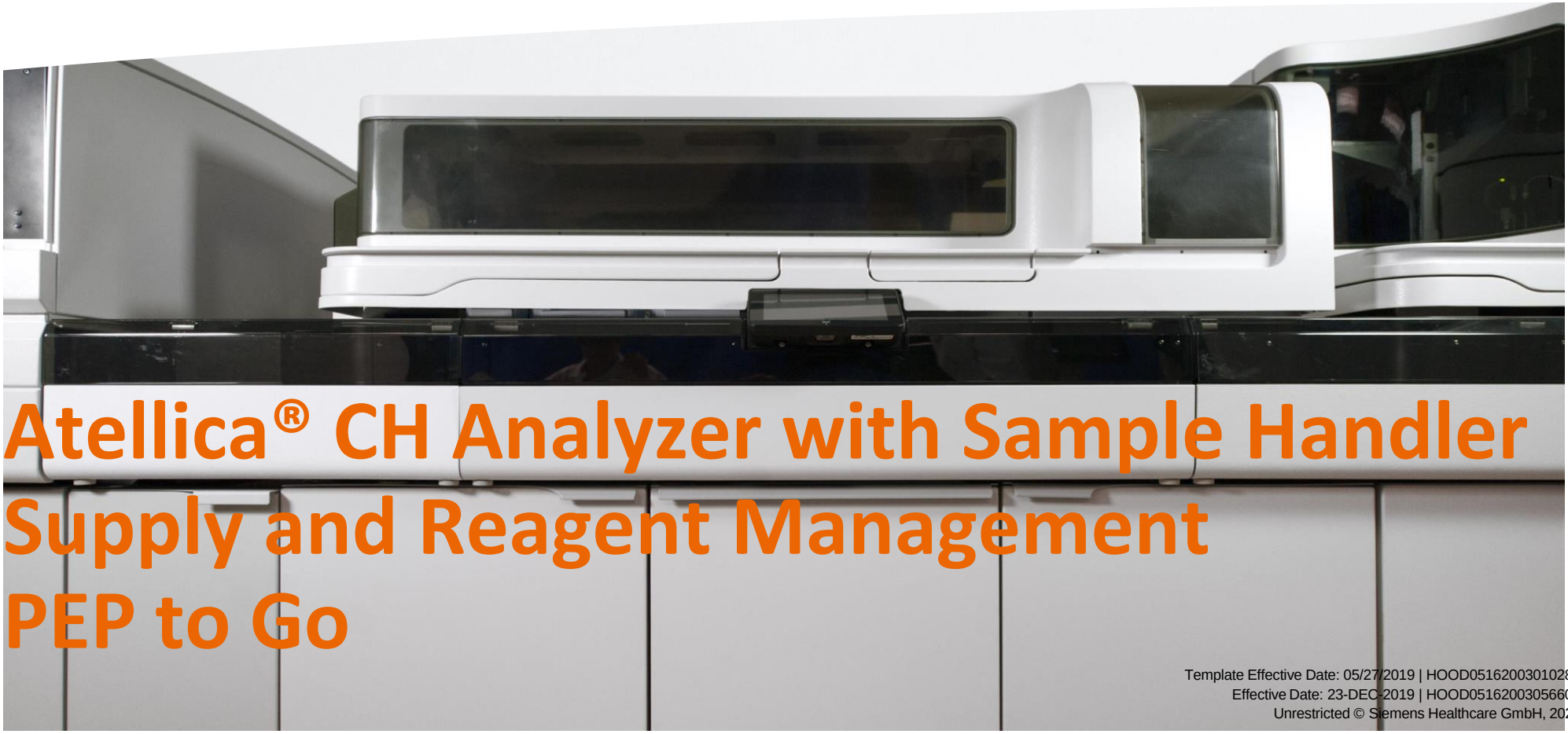


Atellica® CH Analyzer with Sample Handler Supply and Reagent Management PEP to Go

Template Effective Date: 05/27/2019 | HOOD05162003010284
Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® CH Analyzer with Sample Handler
Reagent Management

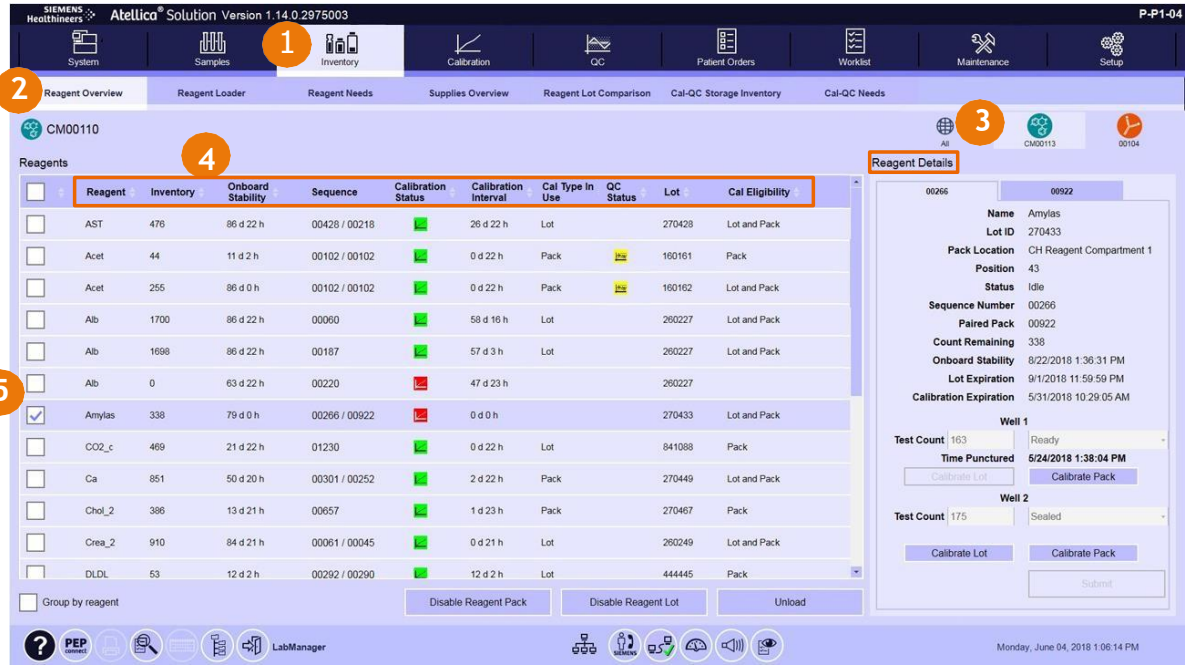
SIEMENS Healthineers

Reviewing Reagent Inventory

The Reagent Overview screen allows the operator to review the status of onboard reagents.

To review reagent inventory:

1. On the Command bar, select **Inventory**
2. Select the **Reagent Overview** tab
3. Select the CH analyzer graphic to view the CH reagents
4. To sort, select a column heading
   - ➢ Inventory: to bring reagents that are empty or running low to the top of the screen
   - ➢ Calibration Status: to bring reagents that have an invalid calibration or have not been calibrated to the top of the screen
   - ➢ Calibration Interval: to bring the reagents that have a calibration that will expire soon to the top of the screen
5. To view details about a reagent pack, select the checkbox for the reagent
   - ➢ Reagent Details for that pack will display on the right side of the screen



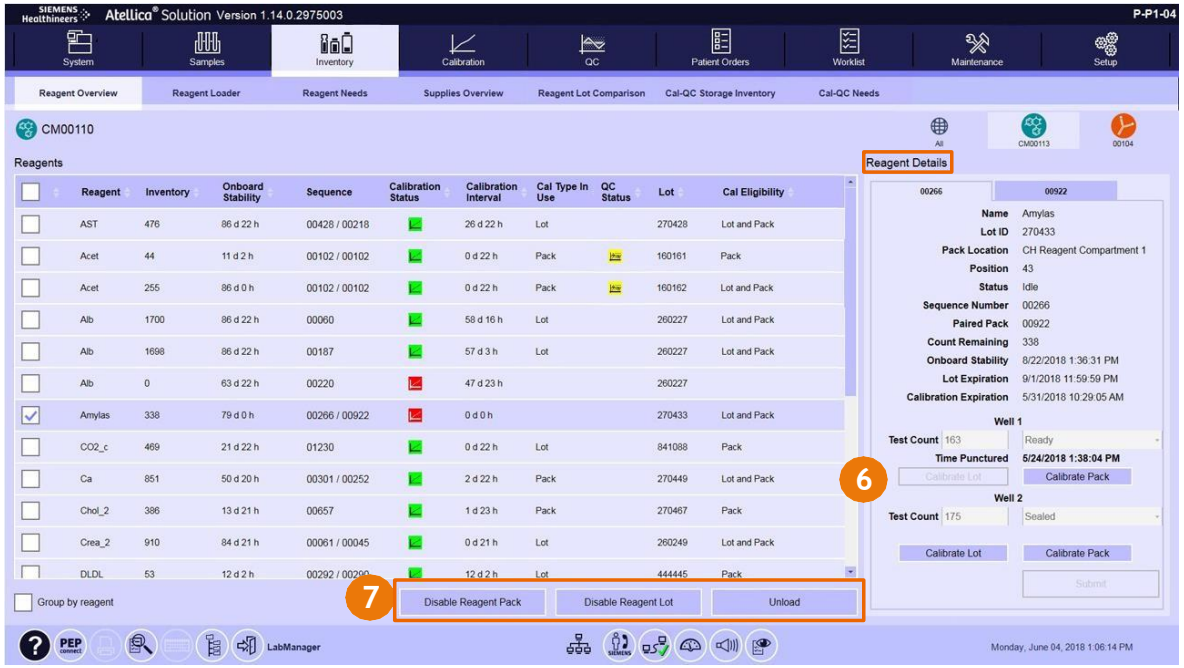
*This procedure is continued on the next slide.

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® CH Analyzer with Sample Handler
Reagent Management

Reviewing Reagent Inventory (continued)

6. At the bottom of the Reagent Details area of the screen, there are buttons that can be used to order a calibration on that reagent pack
7. There are options at the bottom of the screen to disable a selected reagent pack, to disable an entire reagent lot, or to manually unload a reagent pack



NOTE: Disabling a reagent pack with a paired reagent pack on another CH analyzer server disables both reagent packs.

NOTE: For more information on ordering calibrations, refer to the "Manually Ordering Calibration Tests" training topic in PEPconnect.

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® CH Analyzer with Sample Handler
Reagent Management

Loading CH Reagent Packs

1. Open the reagent tray lid
2. Insert up to six reagent packs
3. Close the reagent tray lid
   - ➢ When the reagent tray lid closes, the gripper scans the packs and automatically loads valid packs
4. Review the Reagent Loader screen and resolve any loading issues that may occur

NOTE: Some reagent packs must be manually prepared and mixed before loading them on the CH analyzer. Refer to the assay IFU for preparation instructions. All material needed for manual preparation of the reagent are found in the reagent package.

NOTE: Opening the reagent tray drawer during the loading process halts the loader and moves the reagent tray back to the loading area.

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® CH Analyzer with Sample Handler
Reagent Management

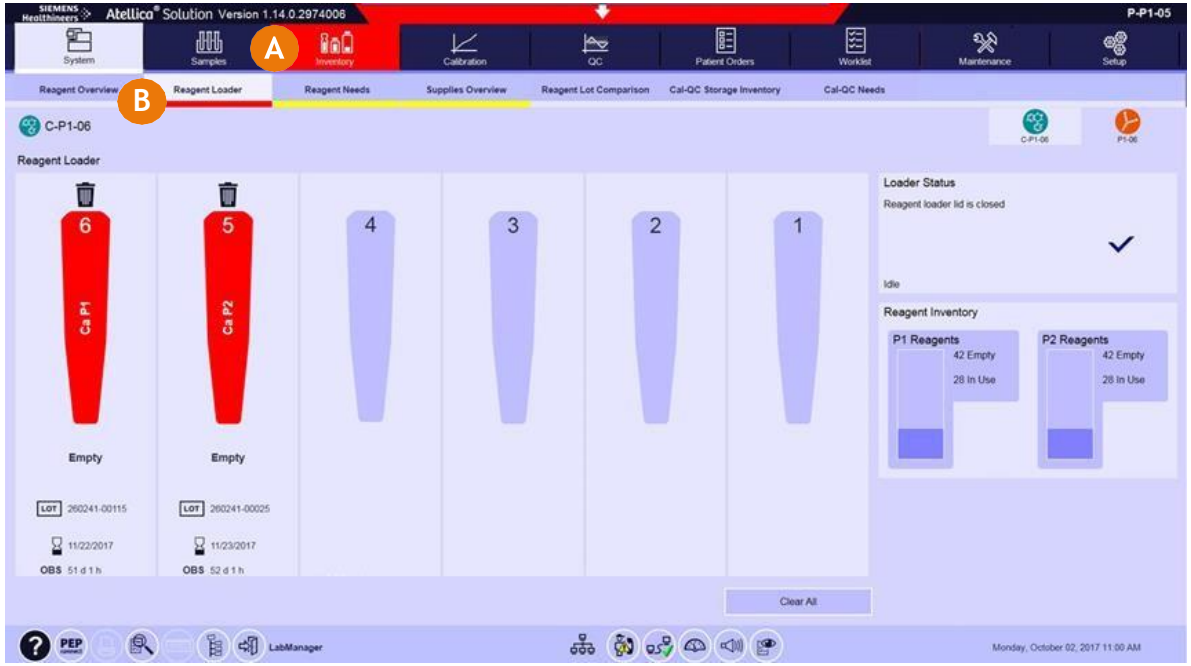
SIEMENS Healthineers

Unloading Reagent Packs - Automatically

The system is configured to automatically send reagent packs to the reagent tray when the packs are empty or expired.

The system will alert the operator that there are reagents waiting in the reagent tray to be removed by displaying an alert on the Inventory button in the Command Bar.

1. To view the reagents that are waiting to be removed:
   A. On the Command bar, select **Inventory**
   B. Select the **Reagent Loader** tab
2. Open the reagent tray lid
3. Remove reagent packs from the reagent tray
4. Close the reagent tray lid
   ➢ Once the lid is closed, the analyzer scans the tray and displays as all empty



Effective Date: 23-DEC-2019 | HOOD05162003056603

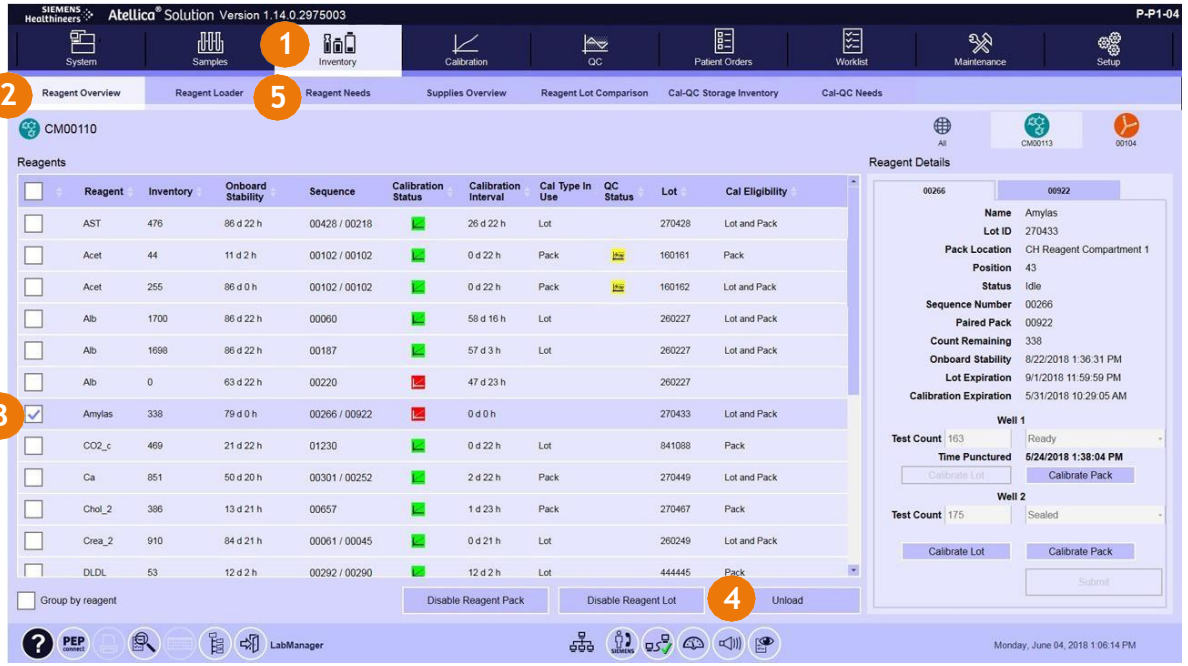
Atellica® CH Analyzer with Sample Handler
Reagent Management

SIEMENS Healthineers

Unloading Reagent Packs - Manually

Reagent packs can be removed manually by the operator. Use this procedure to allow in-process tests, associated with the selected reagent packs, to complete before removal:

1. On the Command bar, select **Inventory**
2. Select the **Reagent Overview** tab
3. Select appropriate reagent packs
4. Select **Unload**
5. Check the status of the selected reagent packs in the Reagent Loader screen before opening the reagent tray lid
6. Open the reagent tray lid
7. Remove reagent packs from the reagent tray
8. Close the reagent tray lid
   - ➢ Once the lid is closed, the analyzer scans the tray and displays as all empty



Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® CH Analyzer with Sample Handler
Supply Management

SIEMENS Healthineers

Checking CH System and IMT Fluids

The system will alert the operator that system fluids and IMT fluids need to be replenished by displaying an alert on the Inventory button in the Command Bar.

To check the status of waste and supplies:

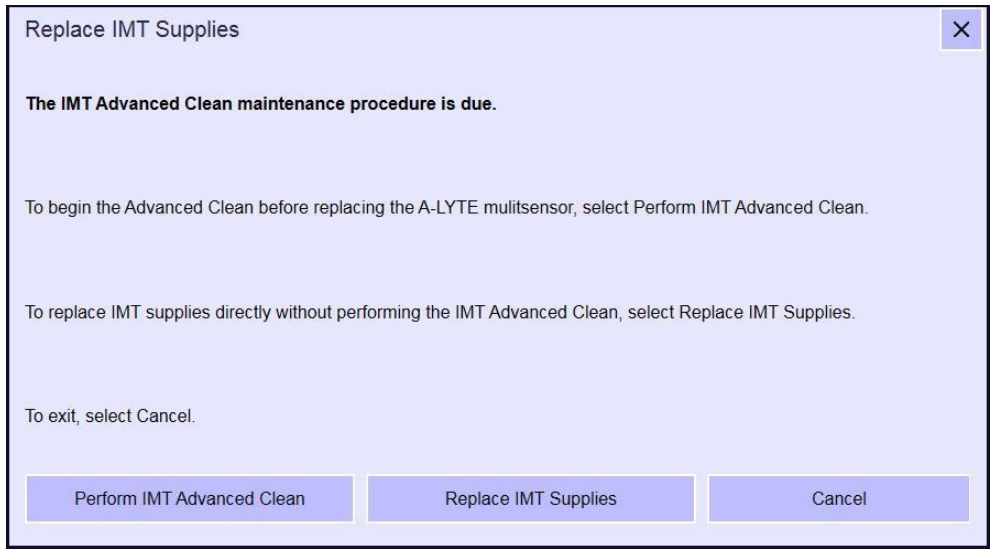
1. On the Command bar, select **Inventory**
2. Select the **Supplies Overview** tab
3. Select the CH analyzer
4. Identify system fluid alerts
5. If appropriate, replace the system fluids, pretreatment pack, or IMT fluids

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® CH Analyzer with Sample Handler Supply Management

Replacing IMT Fluids

1. Ensure the analyzer is in Ready, Processing, or Standby state by navigating to **System** > **Status** and checking the status of the appropriate module
2. Open the IMT fluids lid
3. Select **IMT Supplies** on the module display
4. If an IMT Advanced Clean is required at the next multisensor replacement, a window displays with options to either perform IMT Advanced Clean or replace IMT supplies (see image on the right)
   - If you are only replacing the IMT fluids and are not replacing the A-LYTE multisensor, select **Replace IMT Supplies** and wait for the analyzer to pause
5. Locate and remove the appropriate IMT fluid container
6. Discard the IMT fluid container per laboratory protocol



NOTE: Do not refill an IMT fluid container. Refilling a container can cause contamination. Remove the bottle from the IMT fluids area and install a new container.

*This procedure is continued on the next slide.

Effective Date: 23-DEC-2019 | HOOD05162003056603

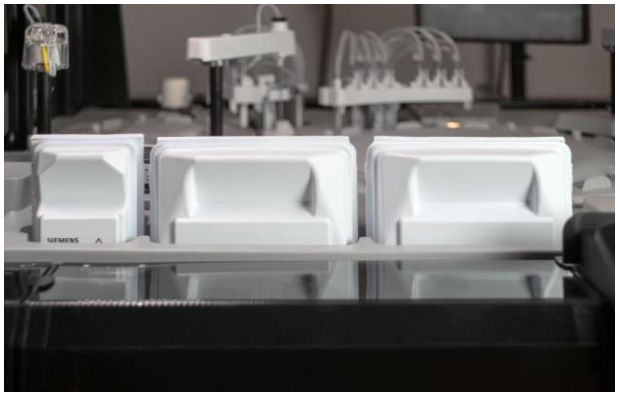
Atellica® CH Analyzer with Sample Handler Supply Management

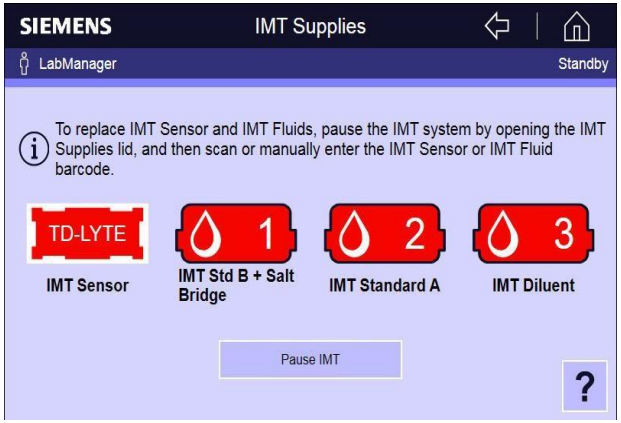
Replacing IMT Fluids (continued)

7. Using the module display, scan the new IMT fluid container
8. Ensure the module displays the correct Lot, Sequence, and Expiration under the appropriate fluid
9. Holding the new IMT fluid container vertically with the septum facing down, insert the new container into position
10. To replace each additional IMT fluid, repeat steps 5-9
11. Close the IMT fluids lid
12. Select **OK**

NOTE: Do not touch the cannulas in the keyed areas at the bottom of the system fluids drawer. The cannulas can puncture skin.

NOTE: The system and IMT fluid containers only fit in the designated position when the cannulas puncture the septum.



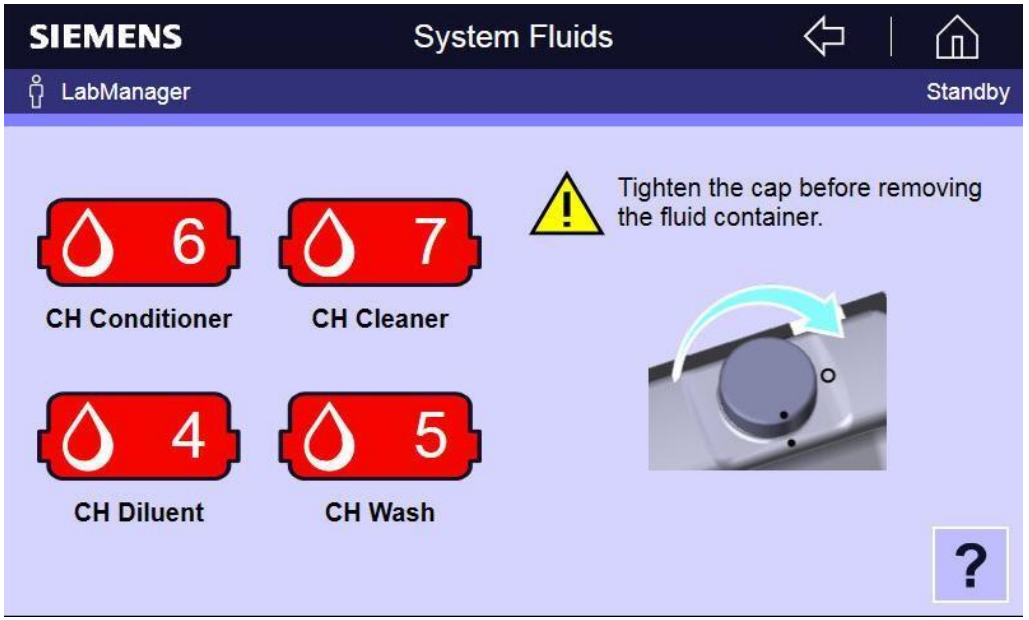


Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® CH Analyzer with Sample Handler Supply Management

Replacing CH System Fluids

1. Open the system fluids drawer
   - ➢ The System Fluids screen will display on the module display
2. Locate and tighten the cap of the system fluid container to be removed
3. Remove the appropriate system fluid container
4. Discard the system fluid container according to laboratory protocol
5. Using the module display, scan the new fluid container using the barcode on the front label. To scan the new fluid container:
   A. Hold the container 150 mm (6 inches) at a 45 ° angle under the module display barcode reader
   B. Ensure the module display shows the correct Lot and Lot Expiration. If the Lot and Lot Expiration are incorrect, enter the Lot and Lot Expiration listed on the container manually into the system software
6. Select **OK**



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

*This procedure is continued on the next slide.

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® CH Analyzer with Sample Handler Supply Management

Replacing CH System Fluids (continued)

7. Holding the new system container vertically with the septum facing down, firmly insert the container straight down into the drawer with the label away from the analyzer

NOTE: The fluid containers are keyed to fit only in the designated drawer position.

NOTE: The container only delivers fluid when the operator fully seats it into the designated location. Refer to the fluid chart within the drawer for correct container placement. To securely seat the container, do not insert container at an angle.

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

*This procedure is continued on the next slide.

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® CH Analyzer with Sample Handler
Supply Management

Replacing CH System Fluids (continued)

9. To prevent a vacuum from forming inside the container that could cause the analyzer to stop processing, vent the container. To vent the container, squeeze and twist the cap counterclockwise to pass the first designated stop, then no longer squeeze but twist the cap until it reaches the next designated stop
10. Close the system fluid drawer

Effective Date: 23-DEC-2019 | HOOD05162003056603

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Atellica® IM Analyzer with Sample Handler Supply and Reagent Management PEP to Go

Template Effective Date: 05/27/2019 | HOOD05162003010284
Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® IM Analyzer with Sample Handler
Reagent Management

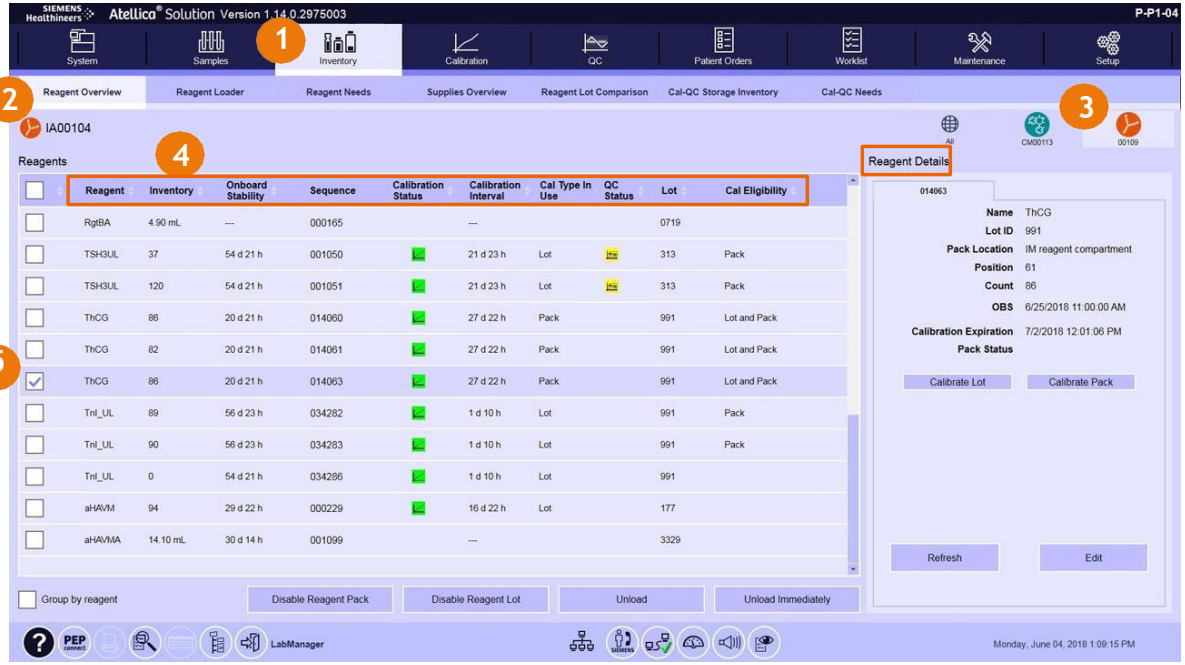
SIEMENS Healthineers

Reviewing Reagent Inventory

The Reagent Overview screen allows the operator to review the status of onboard reagents.

To view reagent inventory:

1. On the Command bar, select **Inventory**
2. Select the **Reagent Overview** tab
3. Select the IM analyzer icon to view the IM reagents
4. To sort, select a column heading:
   - ➢ Inventory: to bring reagents that are empty or running low to the top of the screen
   - ➢ Calibration Status: to bring reagents that have an invalid calibration or have not been calibrated to the top of the screen
   - ➢ Calibration Interval: to bring the reagents that have a calibration that will expire soon to the top of the screen
5. To view details about a reagent pack, select the checkbox for the reagent
   - ➢ Reagent Details for that pack will display on the right side of the screen

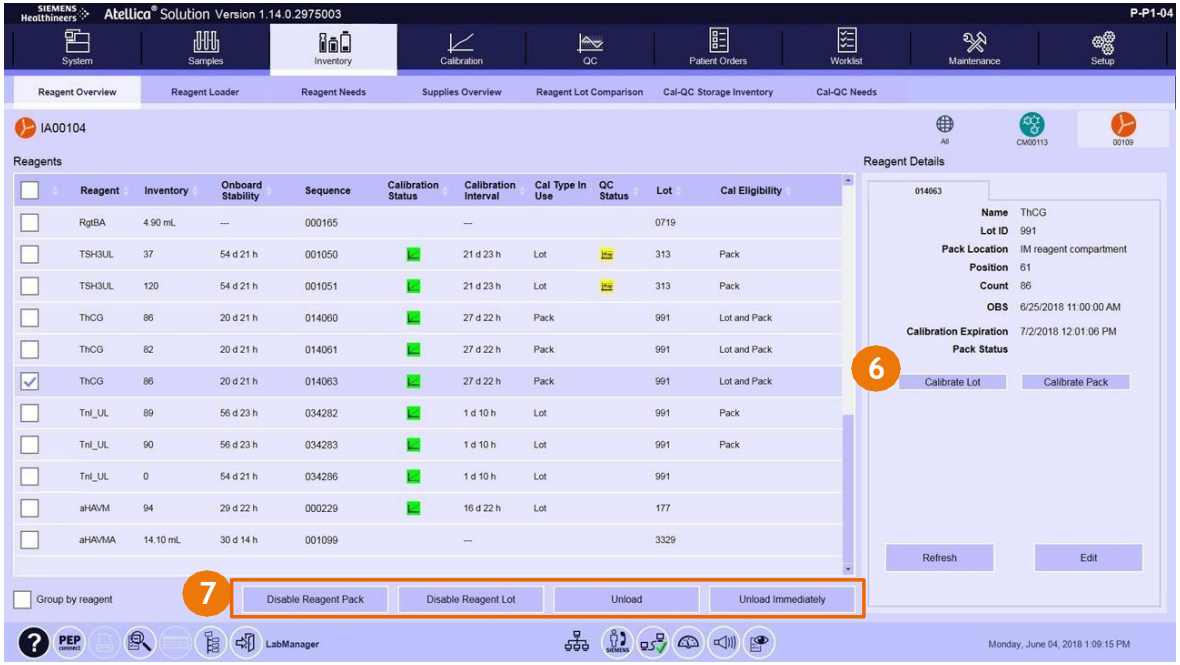


*This procedure is continued on the next slide.

Atellica® IM Analyzer with Sample Handler
Reagent Management

Reviewing Reagent Inventory (continued)

6. At the bottom of the Reagent Details area of the screen, there are buttons that can be used to order a calibration on that reagent pack
7. There are options at the bottom of the screen to disable a selected reagent pack, to disable an entire reagent lot, or to manually unload a reagent pack



NOTE: For more information on ordering calibrations, refer to the "Manually Ordering Calibration Tests" training topic in PEPconnect.

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® IM Analyzer with Sample Handler
Reagent Management

SIEMENS Healthineers

Handling IM Reagent Packs

NOTE: During off-system storage, solid phase particles settle as a pellet at the bottom of the primary reagent pack.

1. If shutting down the analyzer reagent compartment refrigeration for longer than 2 hours, remove and store the reagent packs
   A. Cover the pierced film area of the reagent pack with self-sealing laboratory film
   B. Store any off-system reagent packs at 2-8 °C
   C. Before loading primary reagent packs onto the system, manually mix the packs to re-suspend the particles homogeneously
   D. Return the reagent packs to the system when the reagent compartment temperature is 2-8 °C
   E. Verify reagent performance based on acceptable QC results or laboratory criteria
2. If the analyzer has not mixed reagent packs for 30 minutes or longer, remove all primary reagent packs and manually mix before resuming normal operations

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® IM Analyzer with Sample Handler
Reagent Management

SIEMENS Healthineers

Manually Mixing IM Primary Reagents

Primary reagents must be manually mixed before being loaded on the system:

1. If the reagent pack is pierced, gently press on the self-sealing laboratory film that covers the pierced film area, while mixing, to prevent leakage
2. With the film side up, loosely hold the reagent pack at each end
3. Raise one end of the pack 90° to its vertical position
4. Return the pack to a horizontal position
5. Raise the other end of the pack 90° again to its vertical position

NOTE: If foam appears inside the pack, use a slower mixing speed.

6. Return the pack to a horizontal position
7. Repeat steps 2–5 a minimum of 20 times or until:
   - ➢ Any clumps are broken up and no longer visible on the bottom of the pack
   - ➢ No large aggregates are visible floating inside the pack
8. Mix 5–10 times more to ensure complete mixing
9. If the reagent pack is pierced, remove the self-sealing laboratory film
10. Load the reagent pack onto the analyzer

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® IM Analyzer with Sample Handler
Reagent Management

Loading IM Reagent Packs – Primary and Ancillary

1. Ensure the system is in the Ready or Inprocess state
2. Manually mix primary reagent packs and open the reagent drawer

3. Insert any combination of up to 5 primary or ancillary reagent packs. Ensure the top barcode is on the right side of the drawer and the pack is well-seated in the slot
4. Close the reagent drawer

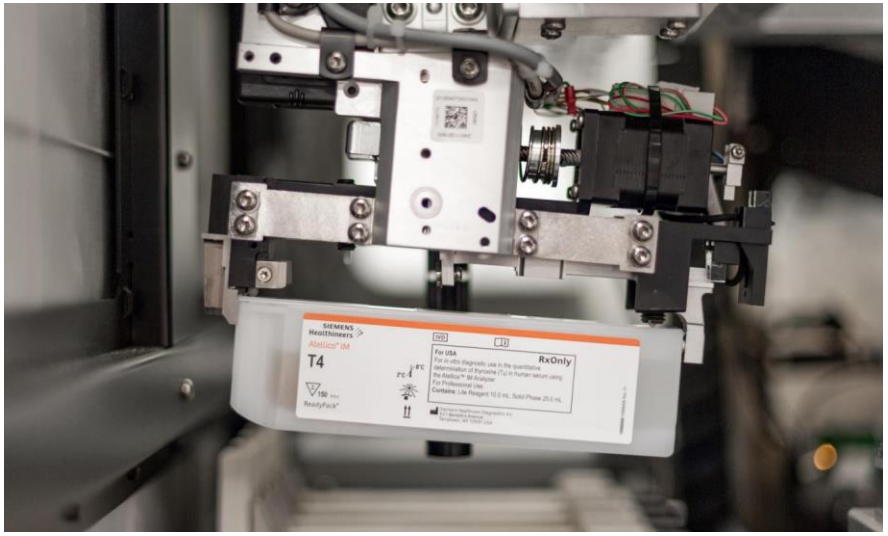
*This procedure is continued on the next slide.

Effective Date: 23-DEC-2019 | HOOD05162003056603

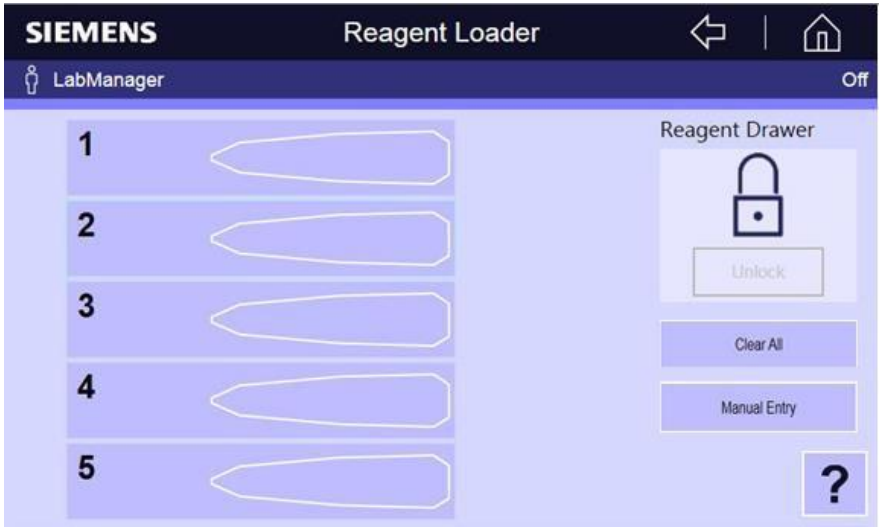
Atellica® IM Analyzer with Sample Handler Reagent Management

Loading IM Reagent Packs – Primary and Ancillary (continued)

5. When the reagent tray drawer closes, the gripper scans the packs and automatically loads valid packs



6. Review the Reagent Loader screen and resolve any loading issues that may occur



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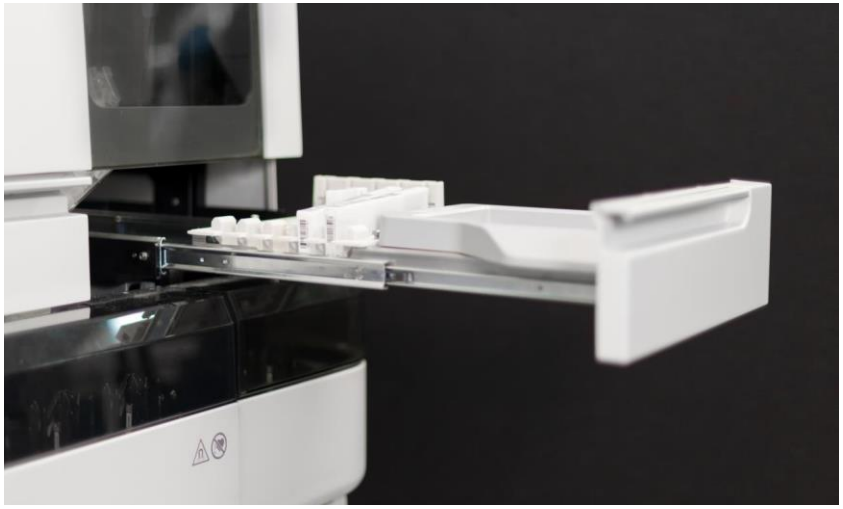
Atellica® IM Analyzer with Sample Handler
Reagent Management

Loading IM Humidity Packs

Humidity packs maintain reagent compartment humidity between 70–100%. The operator loads 7 empty humidity packs initially. The system automatically fills the packs with water during the daily maintenance procedure. The system monitors humidity in the reagent compartment and, if the humidity falls below 70%, may require up to 3 additional humidity packs for a total of 10.

<u>To load humidity packs:</u>

1. Open the reagent drawer
2. Insert 5 empty humidity packs
3. Close the reagent drawer
4. To load 2 more packs, repeat steps 1-3 after the system finishes loading the first 5 humidity packs



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Atellica® IM Analyzer with Sample Handler
Reagent Management

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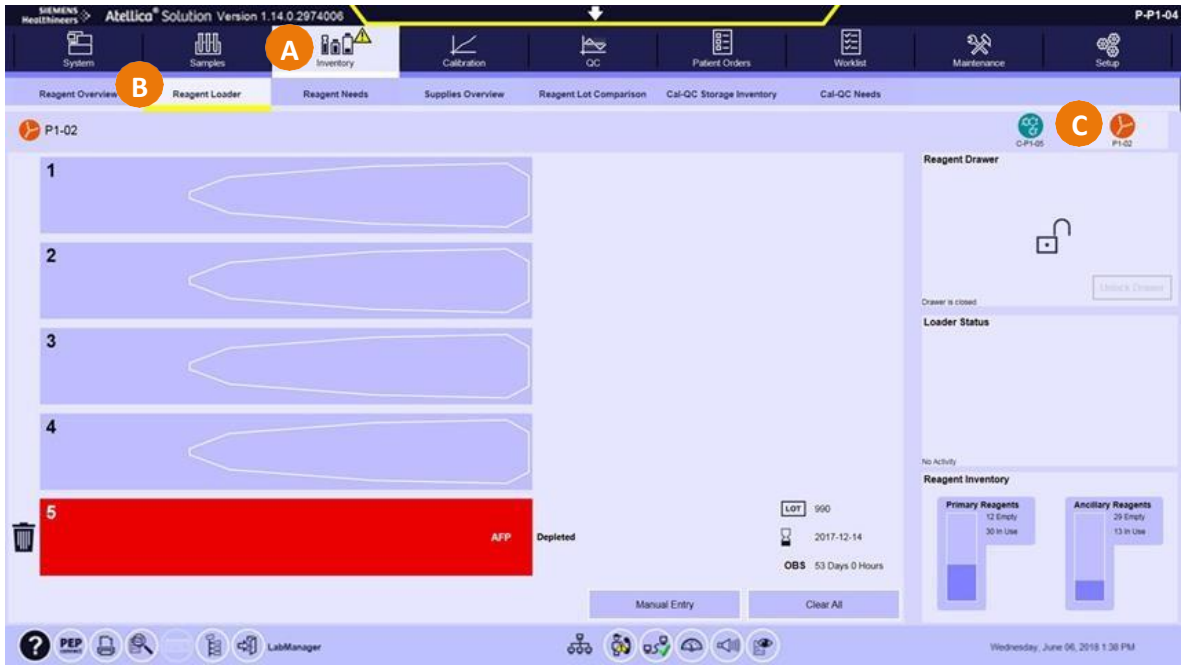
Unloading IM Reagent Packs - Automatically

The system is configured to automatically send reagent packs to the reagent drawer when the packs are empty or expired.

The system will alert the operator that there are reagents waiting in the reagent drawer to be removed by displaying an alert on the Inventory button in the Command Bar.

1. To view the reagents that are waiting to be removed:
   A. On the Command bar, select **Inventory**
   B. Select the **Reagent Loader** tab
   C. Select the IM analyzer icon
2. Open the reagent drawer
3. Remove reagent packs from the reagent drawer
4. Close the reagent drawer
   ➢ Once the drawer is closed, the analyzer scans the drawer and displays as all empty



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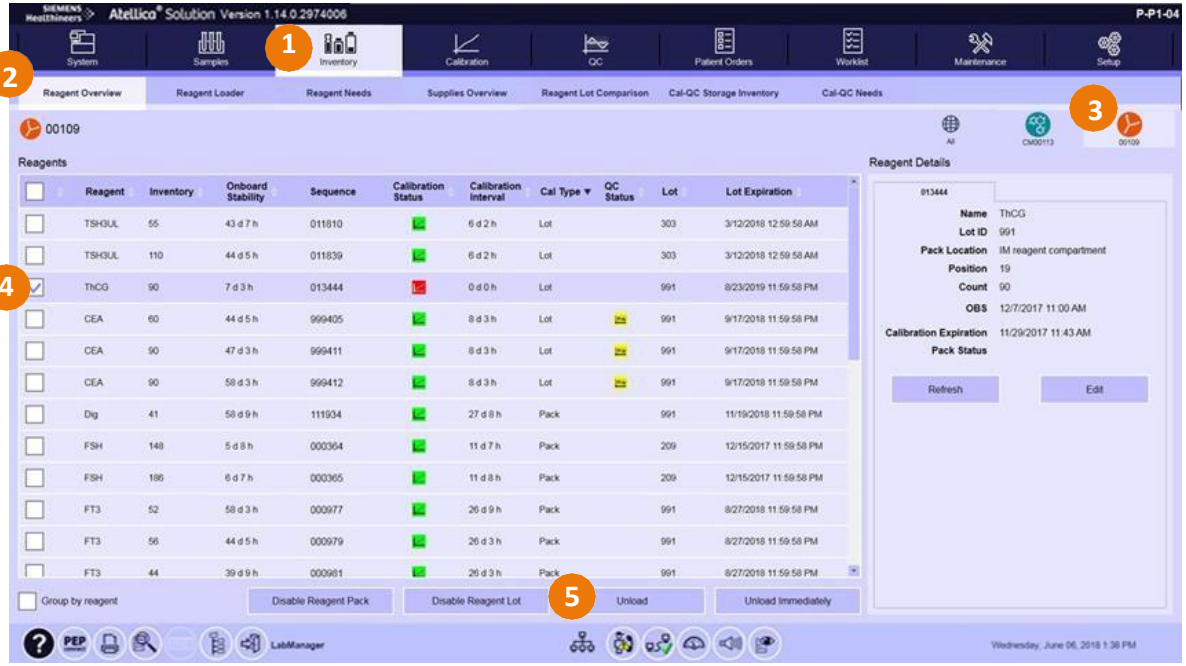
Atellica® IM Analyzer with Sample Handler
Reagent Management

SIEMENS Healthineers

Unloading IM Reagent Packs - Manually

Reagent packs can be removed manually by the operator. Use this procedure to allow in-process tests, associated with the selected reagent packs, to complete before removal:

1. On the Command bar, select **Inventory**
2. Select **Reagent Overview**
3. Select the IM analyzer icon
4. Select the appropriate reagent packs
5. Select **Unload**
6. Check the status of the appropriate reagent packs from the Reagent Loader screen
7. Open the reagent tray drawer
8. Remove the reagent packs from the reagent drawer
9. If the reagent pack is pierced and intended for reuse, cover the pierced film area of the reagent pack with self-sealing laboratory film
10. Store usable reagent packs according to the assay IFU



NOTE: Use **Unload Immediately** to stop processing and cancel tests associated with the selected reagent packs.

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Atellica® IM Analyzer with Sample Handler
Supply Management

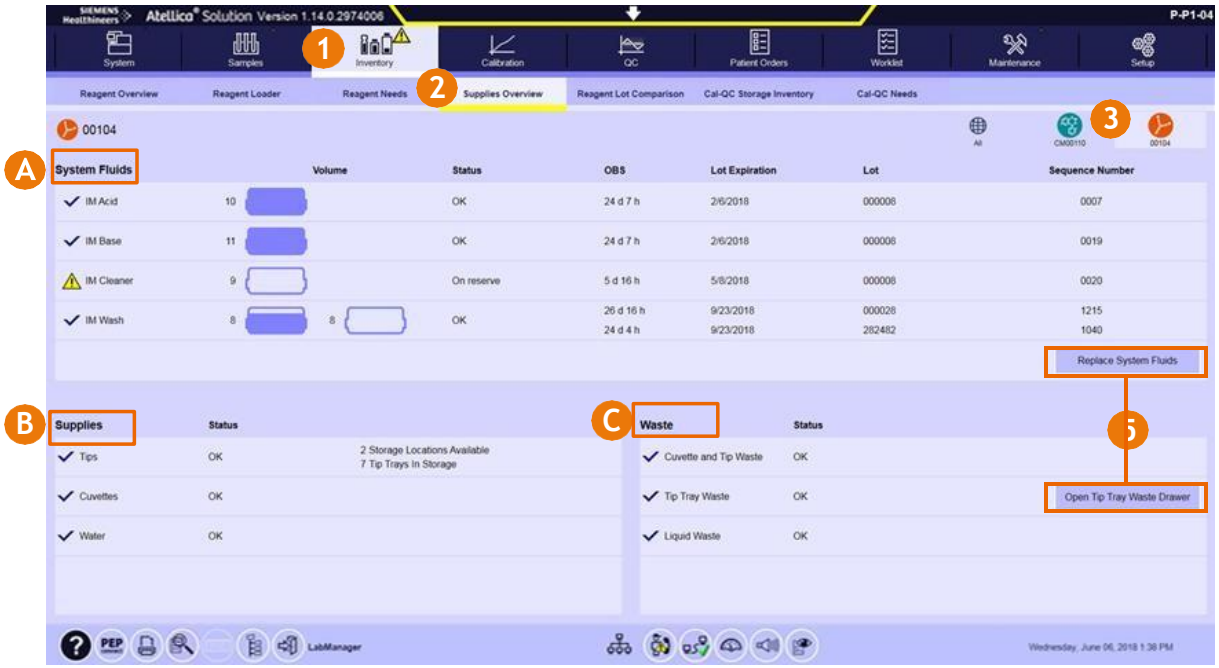
SIEMENS Healthineers

Checking IM Waste and Supplies Status

The system will alert the operator that supplies need to be replenished or waste is getting full by displaying an alert on the Inventory button in the Command Bar.

To check the status of waste and supplies:

1. On the Command bar, select **Inventory**
2. Select **Supplies Overview**
3. Select the IM analyzer icon
4. Check the status of the following:
   A. System Fluids
   B. Supplies
   C. Waste
5. If appropriate, replace system fluids or supplies or empty the waste



Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® IM Analyzer with Sample Handler
Supply Management

Replacing IM Cuvettes

1. Open the cuvette bin lid
2. Pour cuvettes into the cuvette bin
3. Close the cuvette bin lid

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Atellica® IM Analyzer with Sample Handler
Supply Management

SIEMENS Healthineers

Replacing IM Sample Tips

NOTE: Wear new, uncontaminated gloves when handling sample tips to prevent cross contamination.

1. Open the sample tip loading lid
2. Remove the protective cover from the sample tip tray bundle
3. Install the sample tip trays ensuring that the tab is facing the opening on the right and the rounded notches in the trays are facing the back of the system

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

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® IM Analyzer with Sample Handler
Supply Management

Replacing IM System Fluids Using the Module Display

1. Open the system fluids drawer
   - ➢ The System Fluids screen will display on the module display
2. Locate and tighten the cap of the system fluid container to be removed
3. Remove the appropriate system fluid container
4. Discard the system fluid container according to laboratory protocol
5. Using the module display, scan the new fluid container using the barcode on the front label. To scan the new fluid container:
   A. Hold the container 150 mm (6 inches) at a 45° angle under the module display barcode reader
   B. Ensure the module display shows the correct Lot and Lot Expiration under the appropriate fluid
6. Select **OK**

*This procedure is continued on the next slide.

NOTE: If replacing the IM Wash the operator will have to select the container location after scanning the fluid container.

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

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® IM Analyzer with Sample Handler
Supply Management

Replacing IM System Fluids (continued)

7. Holding the new system container vertically with the septum facing down, firmly insert the container straight down into the drawer with the label away from the analyzer

NOTE: The fluid containers are keyed to fit only in the designated drawer position.

NOTE: The container only delivers fluid when the operator fully seats it into the designated location. Refer to the fluid chart within the drawer for correct container placement. To securely seat the container, do not insert container at an angle.

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

*This procedure is continued on the next slide.

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® IM Analyzer with Sample Handler
Supply Management

Replacing IM System Fluids (continued)

9. To prevent a vacuum from forming inside the container that could cause the analyzer to stop processing, vent the container. To vent the container, squeeze and twist the cap counterclockwise to pass the first designated stop, then no longer squeeze but twist the cap until it reaches the next designated stop
10. Close the system fluid drawer

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® IM Analyzer with Sample Handler Supply Management

Emptying the IM Sample Tip Tray Waste

1. On the module display, select **Open Tip Tray Waste Drawer** > **Yes**
2. Open the solid waste door

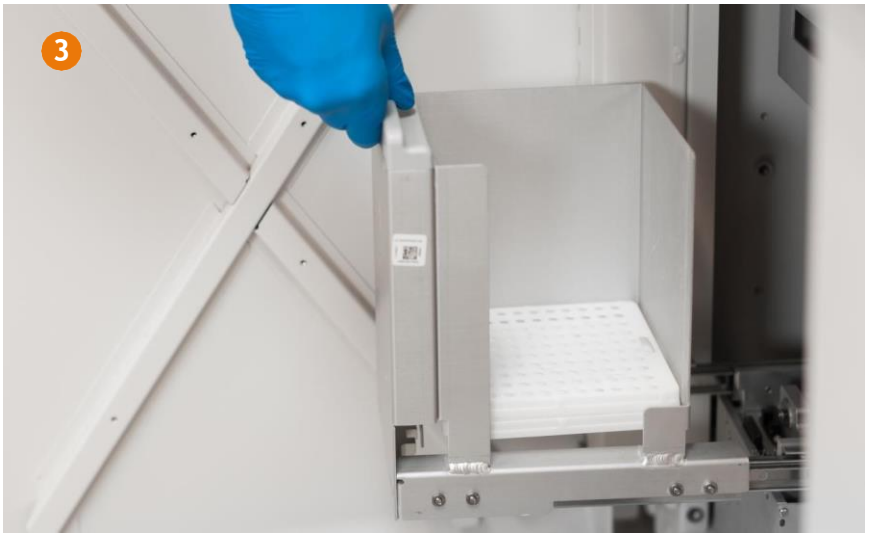
*This procedure is continued on the next slide.

Effective Date: 23-DEC-2019 | HOOD05162003056603

Atellica® IM Analyzer with Sample Handler
Supply Management

Emptying the IM Sample Tip Tray Waste (continued)

3. Pull open the sample tip tray waste drawer
4. Remove the empty sample tip trays



5. Close the sample tip tray waste drawer
6. Select **Yes** to the message "Did you empty the Sample Tip Tray waste area?“

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Atellica® IM Analyzer with Sample Handler
Supply Management

Emptying the IM Solid Waste – Cuvettes and Sample Tips

1. Open the solid waste door
2. Pull out the solid waste drawer and remove the solid waste bins
3. Empty the contents of the solid waste bins into a laboratory-approved container for biohazardous waste

4. Return the bins to the solid waste drawer
5. Push the drawer in and close the door
6. To confirm the cuvette and sample tip waste is empty, select **Yes** to "Did you empty the Sample Tip Tray waste area?"

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All names and data of patients, parameters and configuration dependent designations are fictional and examples only.

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Atellica® Sample Handler Sample Processing PEP to Go

Effective Date: 6/30/2019 | HOOD05162003008554

Atellica® Sample Handler
Sample Processing

SIEMENS Healthineers

Load Samples on the SH

1. Place sample containers in the appropriate type of rack. STAT samples in a STAT rack for immediate processing. Routine samples in a routine rack. False bottom tubes in a special false bottom tube rack. Ensure all sample containers are fully seated to the bottom of the rack.

Rack sizes:

- 55 position
- 15 position

Rack Types:

- Standard rack
- STAT rack – pink label
- Special False-Bottom Tube rack – blue label

NOTE: Do not fill sample containers past the maximum recommended level of 1 container diameter below the top of the container. Overfilling may cause splashing while the container moves in the SH or on the Atellica Magline® Transport.

For example: the maximum fluid height for a 16 mm diameter container is 16 mm from the top of the container.

*This procedure is continued on the next slide

NOTE: Do not position pacemakers or other implanted medical devices closer than 7.5 cm (3 inches) from the base of a carrier on the Atellica Magline® Transport. Magnets in the carrier base generate magnetic fields that can interfere with cardiac medical implants.

NOTE: Refer to the Atellica Solution Online Help for a complete list of the supported sample containers.

Effective Date: 6/30/2019 | HOOD05162003008554

Atellica® Sample Handler
Sample Processing

SIEMENS Healthineers

Load Samples on the SH (continued)

2. Locate the appropriate sample drawer that will be used to load the samples. Load the rack in the appropriate sample drawer position. Load 1 or more empty routine racks in an appropriate output area or sort area in a sample drawer. The LED indicator above the drawer indicates if the drawer is locked:
   - If the LED is off, the drawer is unlocked
   - If the LED is on, the robotic arm is currently accessing tubes from the drawer and the drawer is locked. To access the drawer, either:
     - Wait until the LED indicator turns back to off

       OR
     - Press the button above the drawer. The LED above the drawer will 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

*This procedure is continued on the next slide

Effective Date: 6/30/2019 | HOOD05162003008554

Atellica® Sample Handler
Sample Processing

SIEMENS Healthineers

Load Samples on the SH (continued)

3. 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 racks when the drawer is closed.
4. If there are any old racks in the sample drawer, remove the racks by lifting the racks from the sample drawer.

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

Effective Date: 6/30/2019 | HOOD05162003008554

Atellica® Sample Handler
Sample Processing

SIEMENS Healthineers

Load Samples on the SH (continued)

5. Load the rack in the appropriate sample drawer position. Load 1 or more empty routine racks in an appropriate output area.
   - Each drawer has a front slot and a back slot for loading racks. Each slot can accommodate either three 15 position racks or one 55 position rack
   - When loading the rack into the drawer, observe the arrow on the rack. The arrow should be pointed in, towards the SH
   - Seat the rack so it clicks securely into the guides in the desired location within the drawer. Ensure the rack is fully seated in the drawer. If a rack is not fully seated in the drawer, the drawer may not close. Do not force the drawer closed
6. Close the drawer
   - The system will scan the racks as they are loaded into the system, and then the robotic arm will start processing the sample containers

NOTE: Do not open or close the sample drawer too quickly. Opening or closing the sample drawer too quickly or forcefully can damage the drawer self-closing mechanism or cause splashing of the samples.

Effective Date: 6/30/2019 | HOOD05162003008554

Atellica® Sample Handler
Sample Processing

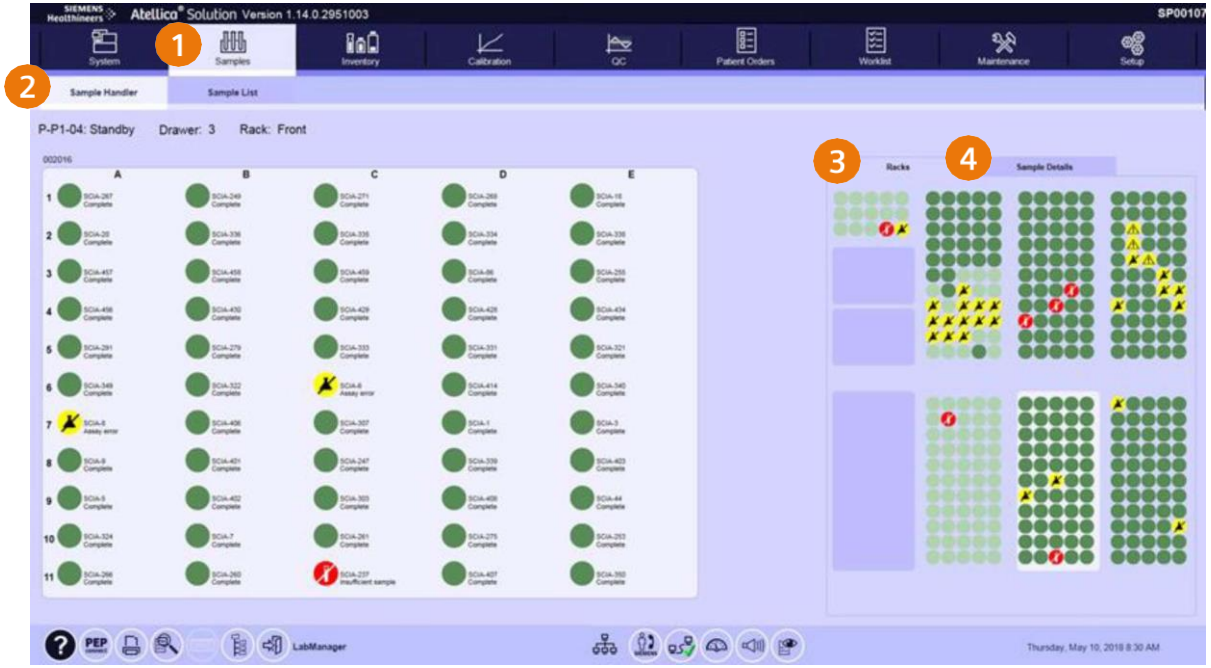
SIEMENS Healthineers

Monitor Sample Tube Status - Sample Handler tab

The Sample Handler tab displays the status of samples that are currently in the Sample Handler drawers.

To view sample status via the Sample Handler tab:

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
4. To view information for a sample, select the sample on the left side of the screen
   - ➢ The Sample Details tab (on the right side of the screen) will display status information for that sample



NOTE: Refer to the Operator's Guide for a list of the meaning of the sample container position glyph colors and symbols.

*This procedure is continued on the next slide

Effective Date: 6/30/2019 | HOOD05162003008554

Atellica® Sample Handler
Sample Processing

SIEMENS Healthineers

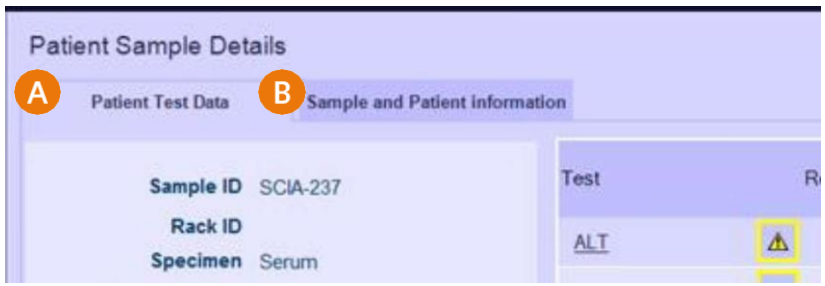
Monitor Sample Tube Status - Sample Handler tab (continued)

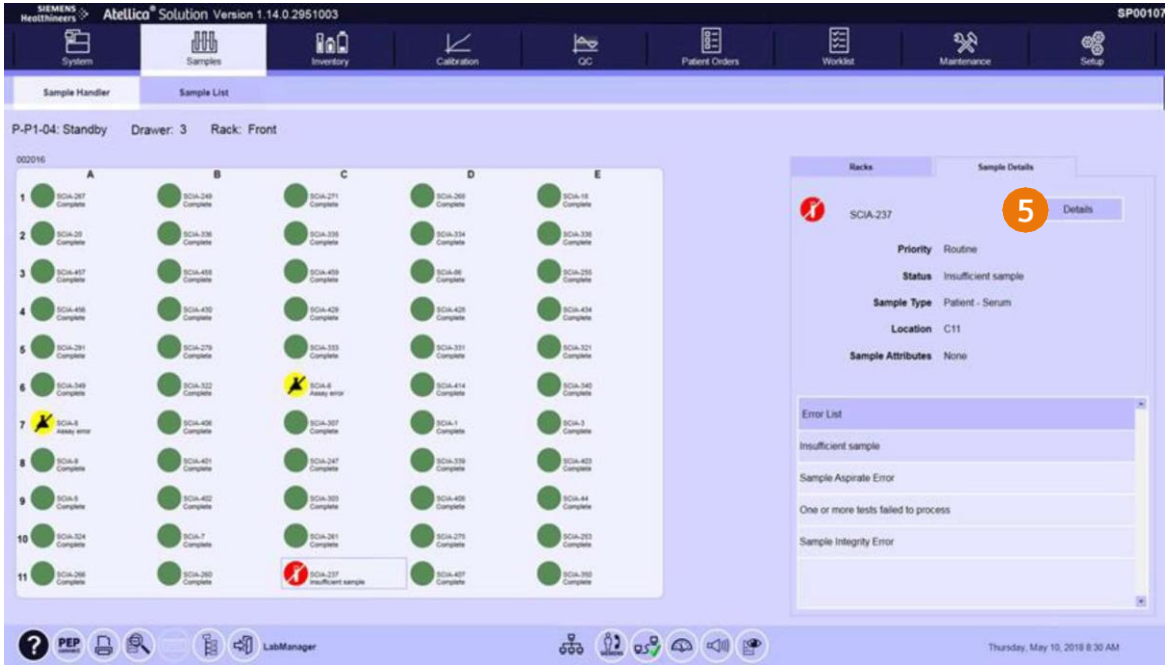
5. To view the status of the tests ordered on the sample, select the **Details** button in the Sample Details tab

   ➢ The Patient Sample Details screen displays. There are 2 tabs:

   A. Patient Test Data – displays the status of the tests ordered on the sample*

   B. Sample and Patient Information – displays detailed sample information on the sample (sample ID, specimen type, priority, etc)





*Additional information on the Patient Test Data tab is on the next slide

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Atellica® Sample Handler
Sample Processing

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Monitor Sample Tube Status – Sample List tab

The Sample List tab displays the current sample status for all samples on the system.

- Includes samples in the SH drawers, samples in the Cal-QC storage area, and samples on the Atellica Magline® Transport

To access the Sample List tab:

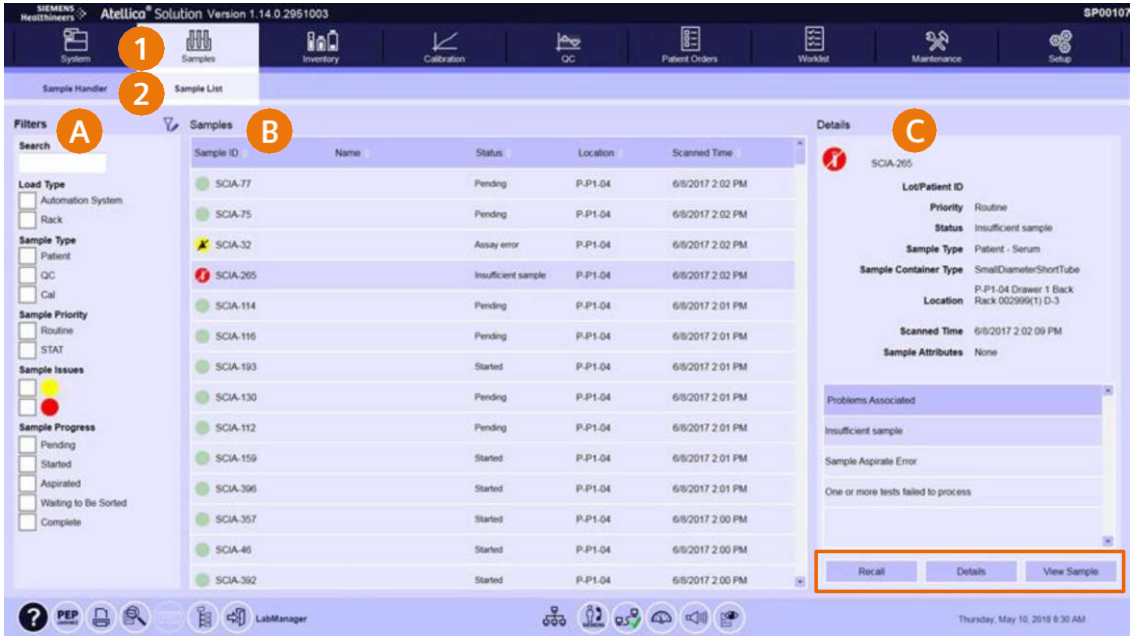
1. At the Command Bar, select **Samples**
2. Select the **Sample List** tab

The Sample List has 3 areas:

A. Filters – used to filter the sample list by load type, sample type, sample priority, sample issues, or sample progress

B. Samples – displays information for each sample. To sort the list, select a column header

C. Details – displays further details for a sample selected from the Samples area of the screen



*See the next slide for information on the function buttons at the bottom of the Details area of the screen

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Atellica® Sample Handler
Sample Processing

SIEMENS Healthineers

Monitor Sample Tube Status – Sample List tab (continued)

There are task buttons at the bottom of the Details area of the screen:

A. Recall – to return a sample that is on the Atellica Magline® Transport to a SH drawer

- At least one empty routing rack with empty positions must be available in an appropriate output area or sort area in a sample drawer
- The operator can recall a sample while it is on the Atellica Magline Transport or after the system unloads it to a sample drawer. The system unloads or relocates, as appropriate, the recalled sample to a position in the right-most, front-most output rack
- After selecting the **Recall** button, wait for the system to display a message indicating the location (SH, drawer, rack, and rack position) of the recalled sample

B. Details – to view the status of tests ordered on the sample (Patient Sample Details screen)

C. View Sample – to display the Sample Handler / Sample Details screen for that sample

NOTE: To recall calibrator or QC materials, use the Unload button on the Cal-QC Storage Inventory screen.

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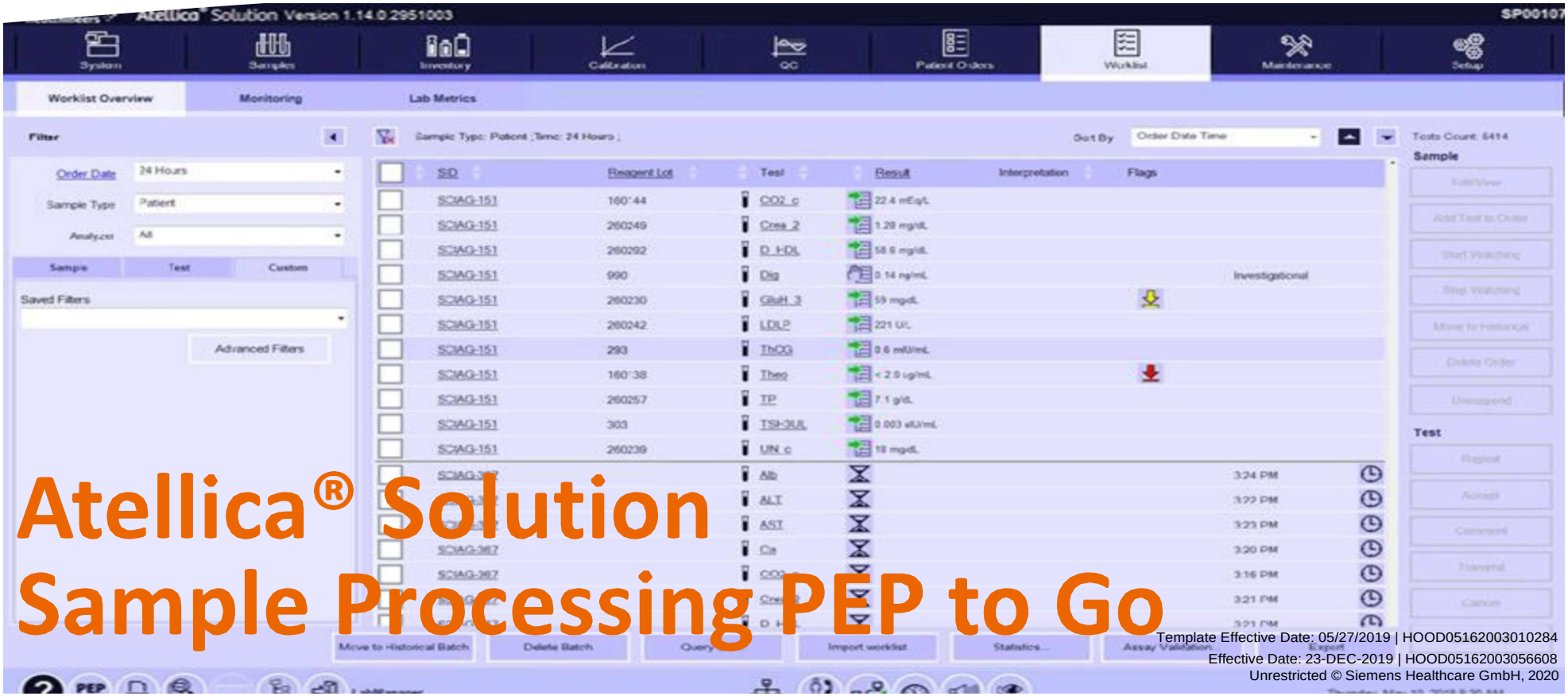

Atellica® Solution Sample Processing PEP to Go

Template Effective Date: 05/27/2019 | HOOD05162003010284
Effective Date: 23-DEC-2019 | HOOD05162003056608

Atellica® Solution
Sample Processing

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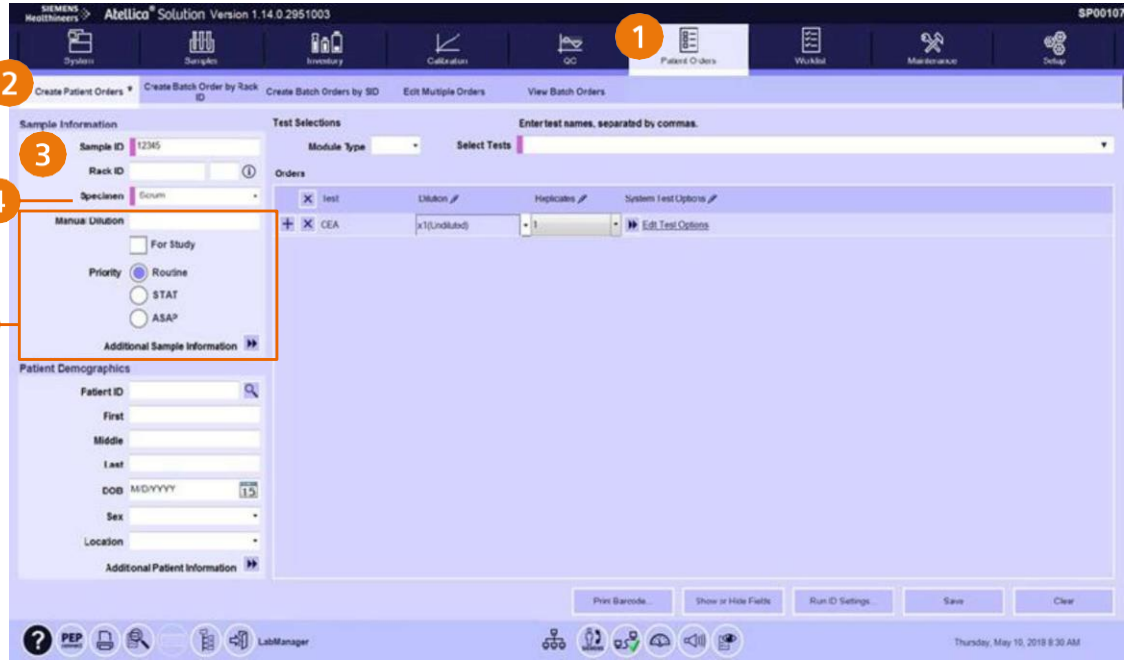
Creating Patient Orders Manually

1. At the Command Bar, select **Patient Orders**
2. Select the **Create Patient Orders** tab
3. Scan the sample tube barcode or manually enter a Sample ID
   - ➢ Barcode scans automatically activate the entry fields. To advance to any field, select the field or select Tab on the keyboard
4. Select the specimen type from the Specimen dropdown list
5. If applicable, enter the following information:
   - Manual Dilution factor
   - For Study checkbox – used for lot to lot comparison studies, duplicate measurements, or performing evaluations. The result will transmit to the LIS only if the operator manually selects to transmit
   - Priority - STAT samples have the highest priority, followed by ASAP samples, and then routine samples. The priority is included in information sent to the LIS
   - Additional Sample Information (collection/receipt date, comments)



NOTE: The required fields to create a test order are Sample ID, Specimen type, and Test.

NOTE: There is an option to enter a Rack ID. This would be used in a Direct Load configuration if non-barcoded tubes were being run.

* This procedure is continued on the next slide.

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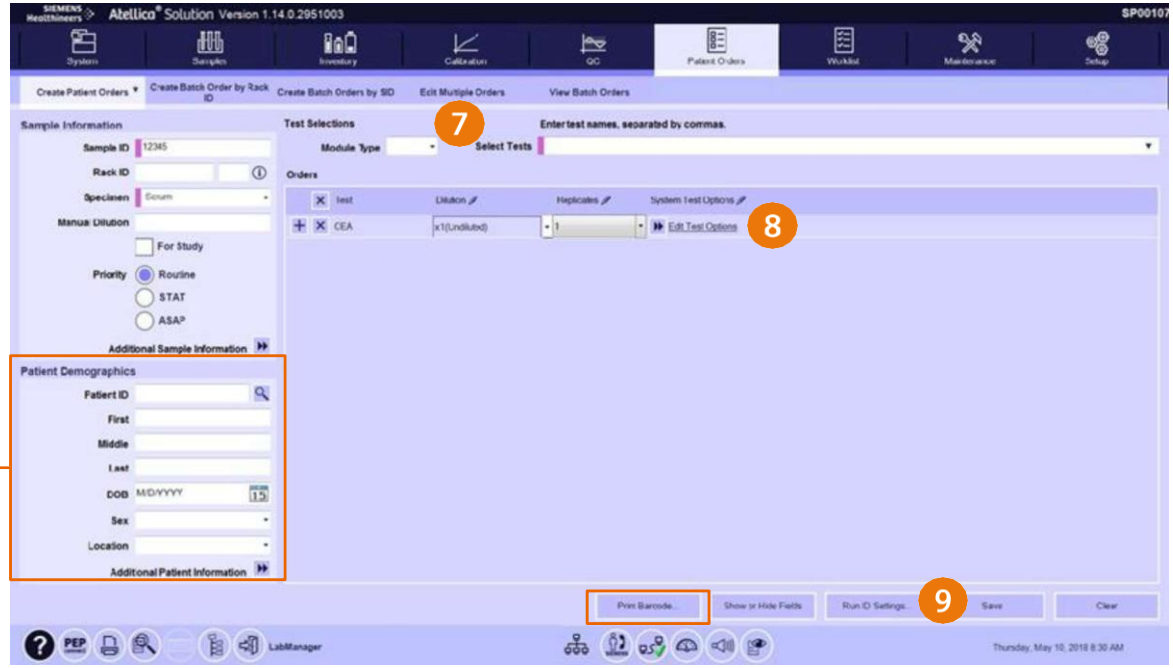
Atellica® Solution
Sample Processing

Creating Patient Orders Manually (continued)

6. If applicable, enter patient demographics
7. Select the tests to be ordered
   A. The tests displayed can be filtered by Module Type if the Atellica Solution has more than one type of analyzer connected
   B. In the Select Tests field, either type the test code or select the test code from the dropdown list. If you type, the tests in the list will be filtered as you type
8. Make any edits to the tests ordered, replicates, or analyzer the tests will be run on*
9. Select **Save**

NOTE: To print a barcode for one patient at a time, enter the Sample ID and then select **Print Barcode**.



* See the next slide for more information on the Orders section of the screen

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Creating Patient Orders Manually (continued)

In the Orders section of the Creating Patient Orders screen, the following edits can be made to the orders:

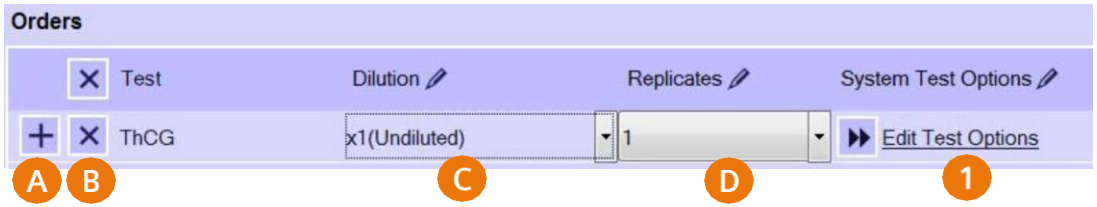
A. Select the **+** icons to create multiple orders of the test

- When adding a test more than once to the same order, the operator can run the same test on different modules, reagent lots or packs. This option provides additional result choices. See step E below for information on editing the test options

B. Select the **X** icons to delete tests

C. Select the Dilution dropdown field to change the system performed dilution factor

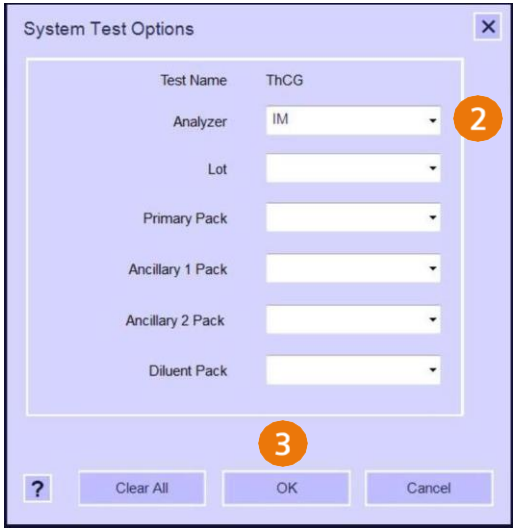
D. Select the replicates dropdown field to change the number of replicates for that order



E. The specific analyzer, reagent lot, or specific reagent pack that the order will be run on can be defined:

1. Select **Edit Test Options**
2. Select the analyzer (this would apply if the Atellica Solution has multiple modules of the same type of analyzer connected; more than one CH analyzer for example), reagent lot, and/or reagent pack
3. Select **OK**

NOTE: If you don't specify an analyzer or materials, the system will use an algorithm to determine which analyzer and materials to run the order on.



* See the next slide for more information on Multiple and Replicate test orders

Effective Date: 23-DEC-2019 | HOOD05162003056608

Atellica® Solution
Sample Processing

SIEMENS Healthineers

Worklist Overview

This 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

<u>Areas of the screen:</u>

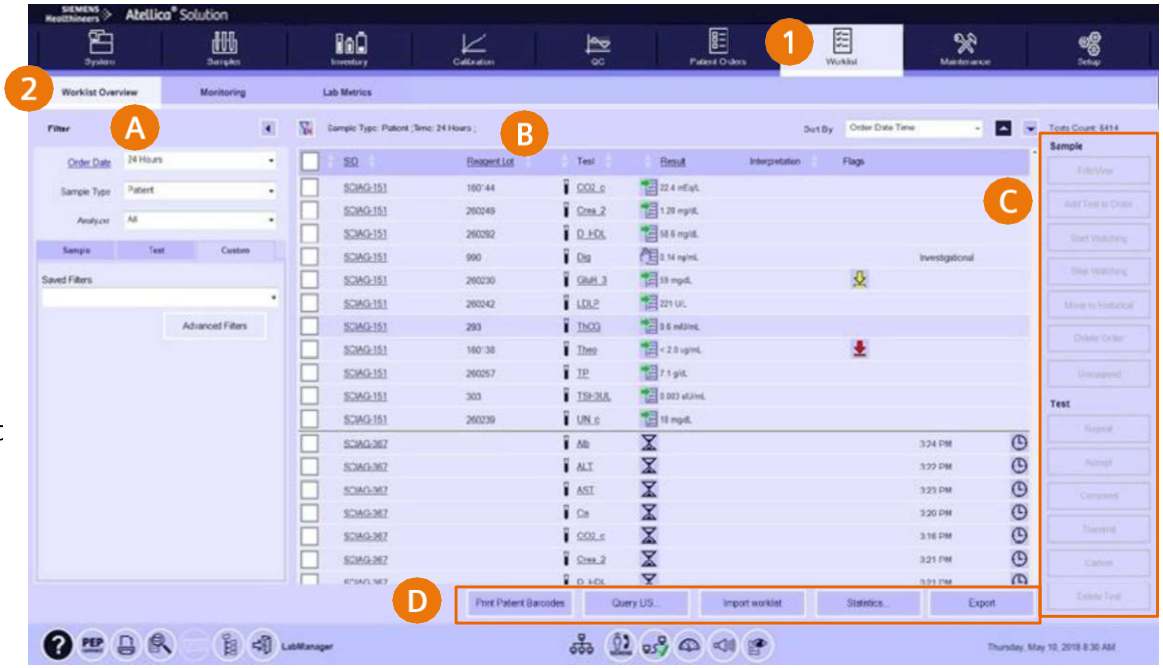
A. Filters – can be displayed or hidden by selecting the arrow at the top of the screen

B. 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

C. Sample and Test functions – used to perform various functions on selected orders

D. General functions – used to print patient barcodes, query the LIS, import a worklist, generate a statistics report, and export test results



Effective Date: 23-DEC-2019 | HOOD05162003056608

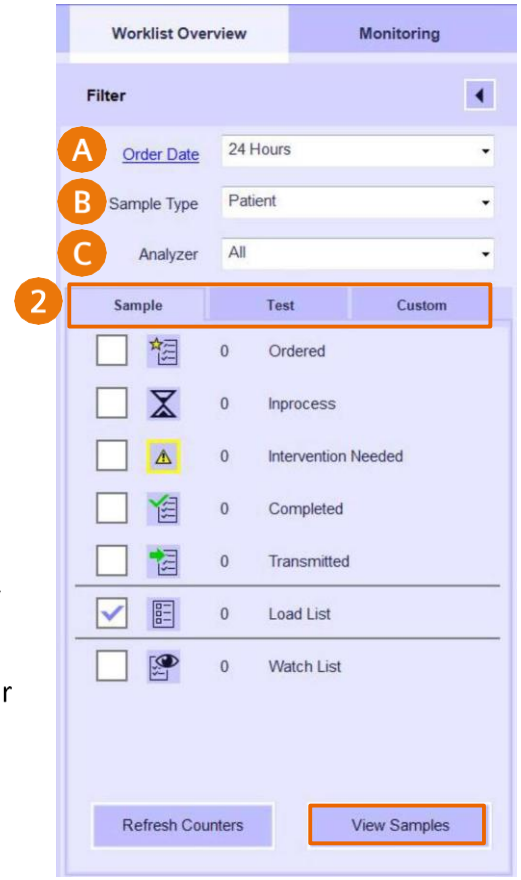
Atellica® Solution
Sample Processing

SIEMENS Healthineers

Worklist Overview – Filters

The Filter area of the screen is used to filter the orders that are displayed:

1. Select an option from each of the dropdown filters:
   A. Time – select the underlined time filter title to select which time criteria to use: Order Date, Scanned Date and Time, or Result Date and Time
      - ➢ For each of the time filter criteria, the dropdown options include various timeframes from 15 minutes to 24 hours
   B. Sample Type – All, Patient, Control, Calibrator
   C. Analyzer – the analyzers connected to the Atellica Solution
2. Select the Sample, Test, or Custom tab
   - ➢ The Sample and Test tabs display a count of the number of samples or tests that are currently in various states:
     - The symbols shown for each state correspond to the symbols displayed for each test order in the Orders area of the screen
       - The Sample tab includes options for filtering a Load List (samples that should be loaded immediately for pending orders) and the Watch List
     - There are checkboxes to select which sample or test states will be displayed
     - At the bottom of the screen, select the **View Samples** or **View Tests** button to display the selected sample or test states in the Orders area of the screen



*This procedure is continued on the next slide

Effective Date: 23-DEC-2019 | HOOD05162003056608

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All names and data of patients, parameters and configuration dependent designations are fictional and examples only.

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SIEMENS Healthineers

Atellica® CH Analyzer Calibration PEP to Go

Effective Date: 11/12/2018 | HOOD05162002965558

Atellica® CH Analyzer Calibration

SIEMENS Healthineers

IMT Calibrations

- The CH Analyzer uses a 2-point calibration to automatically calibrate the IMT subsystem in the following situations:
  - System startup
  - After a reset from a paused or stopped state
  - 4-hour intervals
  - After 250 tests have been completed since the last calibration
  - A-LYTE® multisensor temperature changes outside of specifications
  - IMT successful error recovery
  - IMT cleaning procedure
  - A-LYTE multisensor, Standard A, or Standard B replacement
- The operator can 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

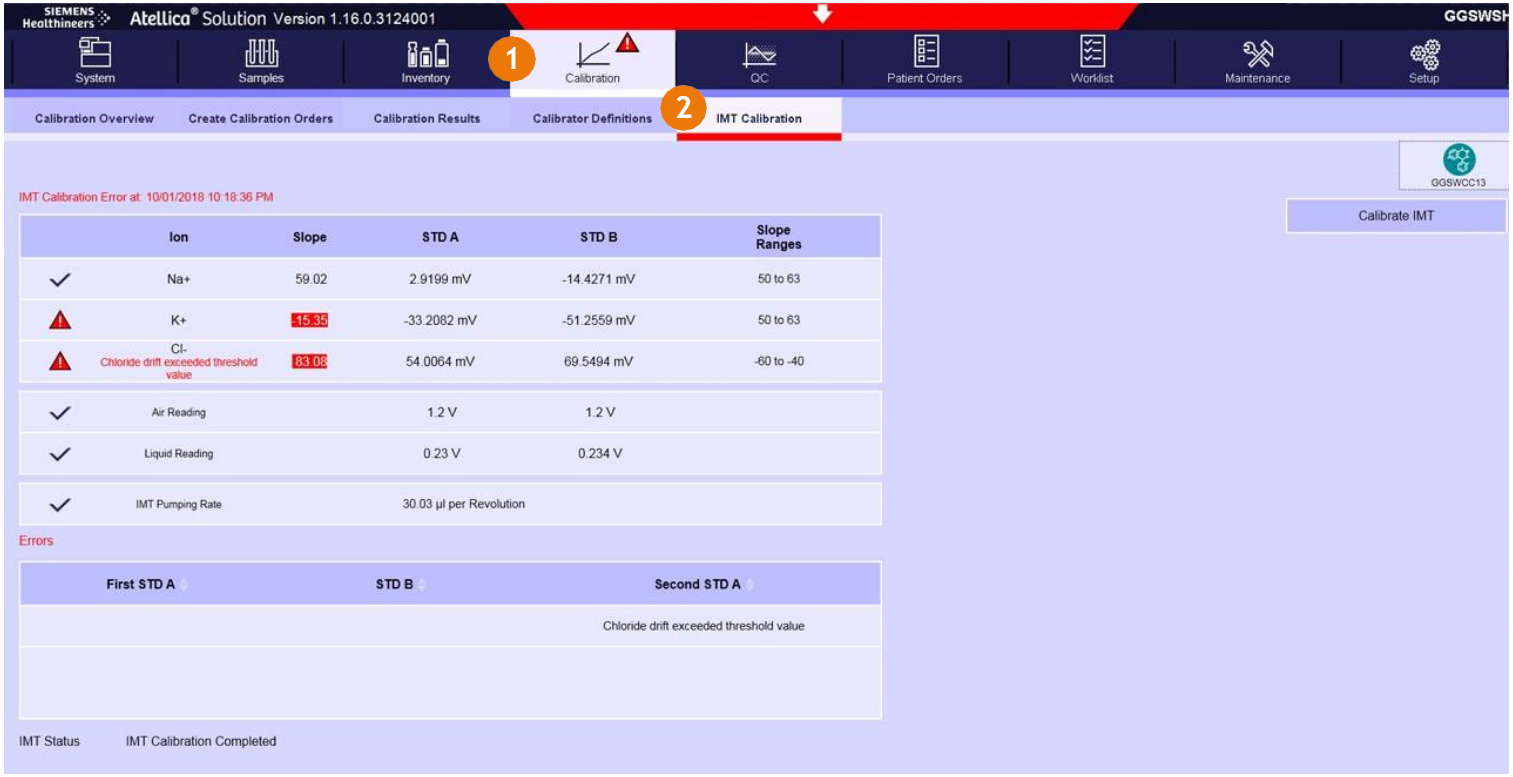
Effective Date: 11/12/2018 | HOOD05162002965558

Atellica® CH Analyzer Calibration

SIEMENS Healthineers

Viewing IMT Calibrations

1. On the Command Bar, select **Calibration**
2. Select the **IMT Calibration** tab
3. View results



Effective Date: 11/12/2018 | HOOD05162002965558

Atellica® CH Analyzer Calibration

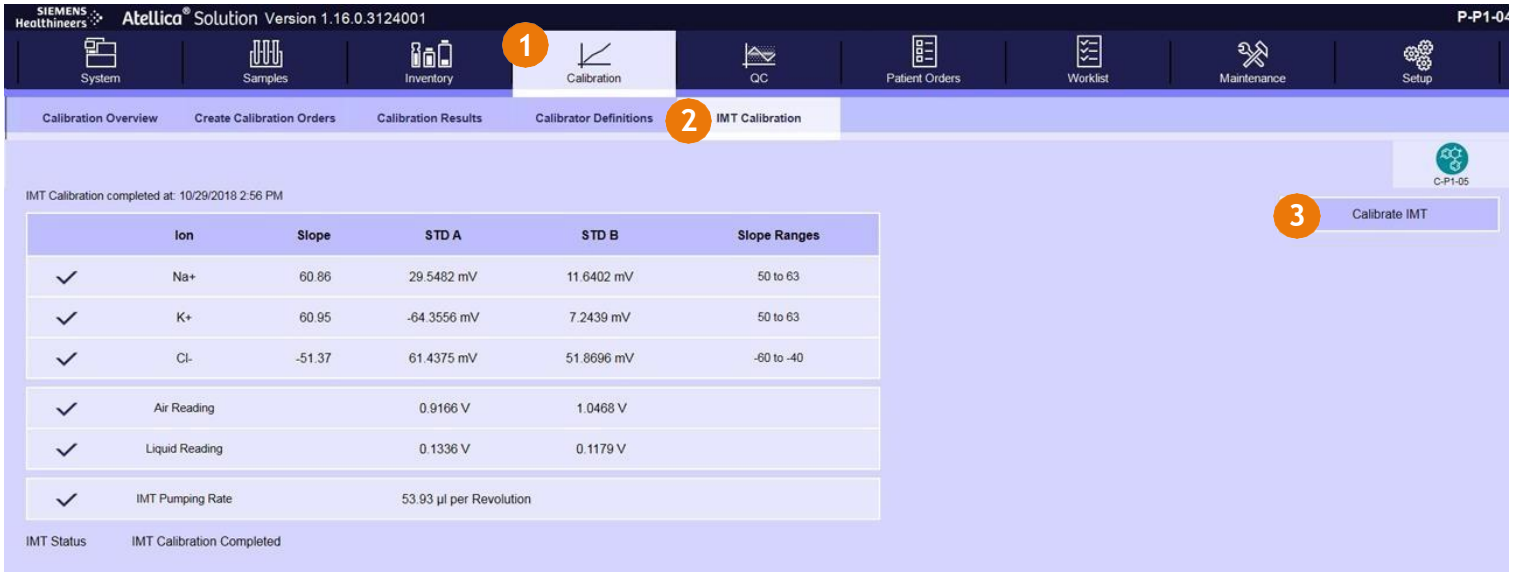
SIEMENS Healthineers

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**



Effective Date: 11/12/2018 | HOOD05162002965558

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SIEMENS Healthineers

Atellica® Solution Calibration PEP to Go

Template Effective Date: 05/27/2019 | HOOD05162003010284
Effective Date: 8/23/2019 | HOOD05162003031090

Atellica® Solution Calibration

SIEMENS Healthineers

Calibration Frequency

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
  - The reagent lot calibration will be valid for any pack with the same lot that is loaded on the system until the lot calibration interval expires
- Pack calibration interval
  - Shorter duration than a reagent lot calibration interval
  - The reagent pack calibration interval is valid for an individual pack or well, and not used for subsequent packs placed on the system

The assay-specific lot and pack calibration interval information is contained in the assay test definition.

The system tracks lot and pack calibrations 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 pack is loaded on the system. If a new pack is not calibrated within 24 hours after it is loaded, the calibration will be a pack calibration.

Effective Date: 8/23/2019 | HOOD05162003031090

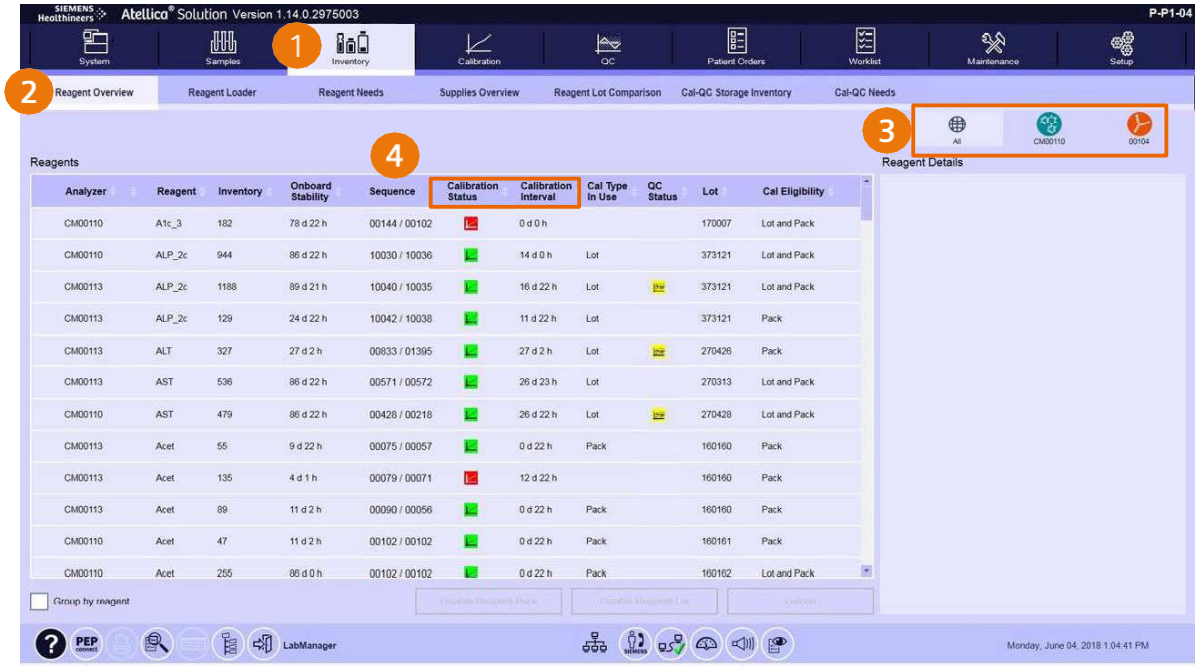
Atellica® Solution
Calibration

SIEMENS Healthineers

Review Calibration Status: Reagent Overview Screen

To view information for onboard reagents on the Reagent Overview screen:

1. On the Command bar, select **Inventory**
2. Select the **Reagent Overview** tab
3. If desired, select to view reagent information for all connected analyzers or a selected analyzer
4. To sort, select a column heading
   - ➢ Calibration Status: to bring reagents that have an invalid calibration or have not been calibrated to the top of the screen
   - ➢ Calibration Interval: to bring the reagents that have a calibration that will expire soon to the top of the screen



* Refer to the Creating Calibration Orders section of this document for information on using the Reagent Overview screen to create calibration orders

Effective Date: 8/23/2019 | HOOD05162003031090

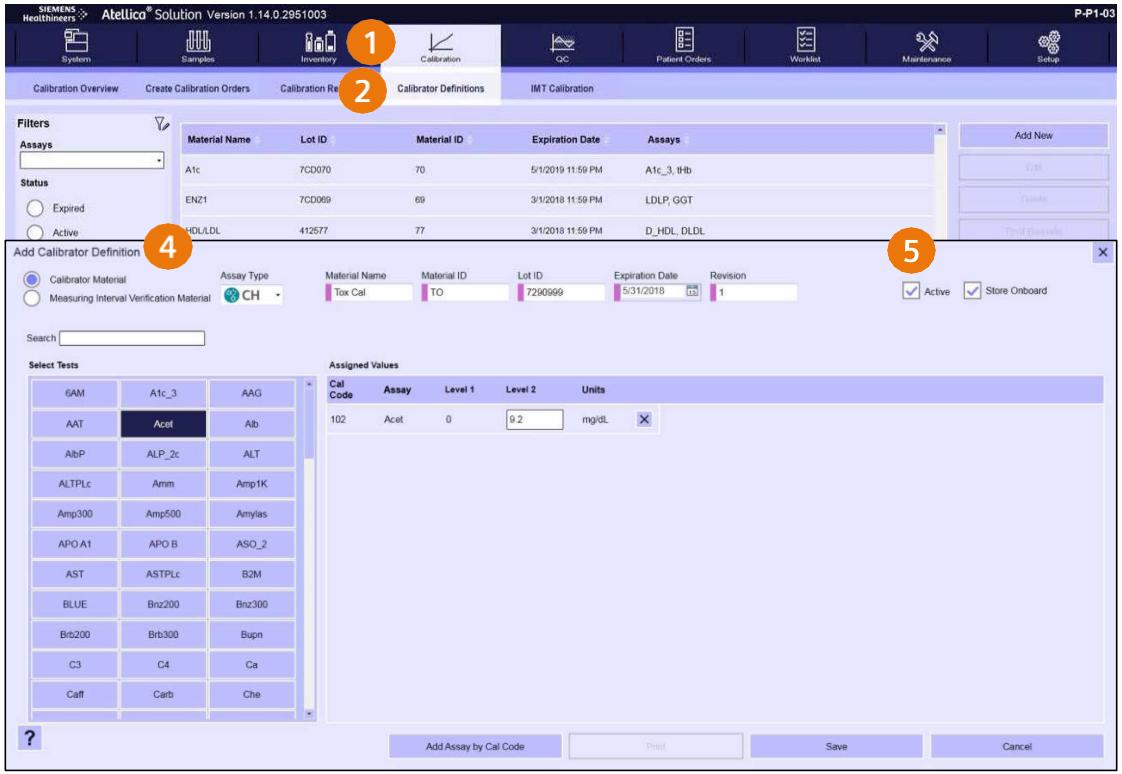
Atellica® Solution Calibration

SIEMENS Healthineers

Installing New Calibrator Definitions

Calibrator definitions must be installed when a new lot of calibrator will be used. To install a new calibrator definition:

1. On the Command Bar, select **Calibration**
2. Select the **Calibrator Definitions** tab
3. Scan the barcode(s) from the calibrator lot-specific value sheet using the barcode reader (the value sheet can be found in the box with the calibrator material)
   - IM assays: all the linear barcodes on the value sheet must be scanned
   - CH assays: the 2D barcode on the value sheet is scanned
4. Confirm the scanned information on the Add Calibrator Definition window
5. To enable the calibrator material for calibration, select the **Active** checkbox
   - More than 1 calibrator definition may exist on the system for an assay. To ensure the system uses the calibrator definition as the primary calibrator when calibrating a reagent directly from **Inventory** > **Reagent Overview**, deselect the **Active** checkbox for additional calibrator definitions associated with the assay



* This procedure is continued on the next slide

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Atellica® Solution
Calibration

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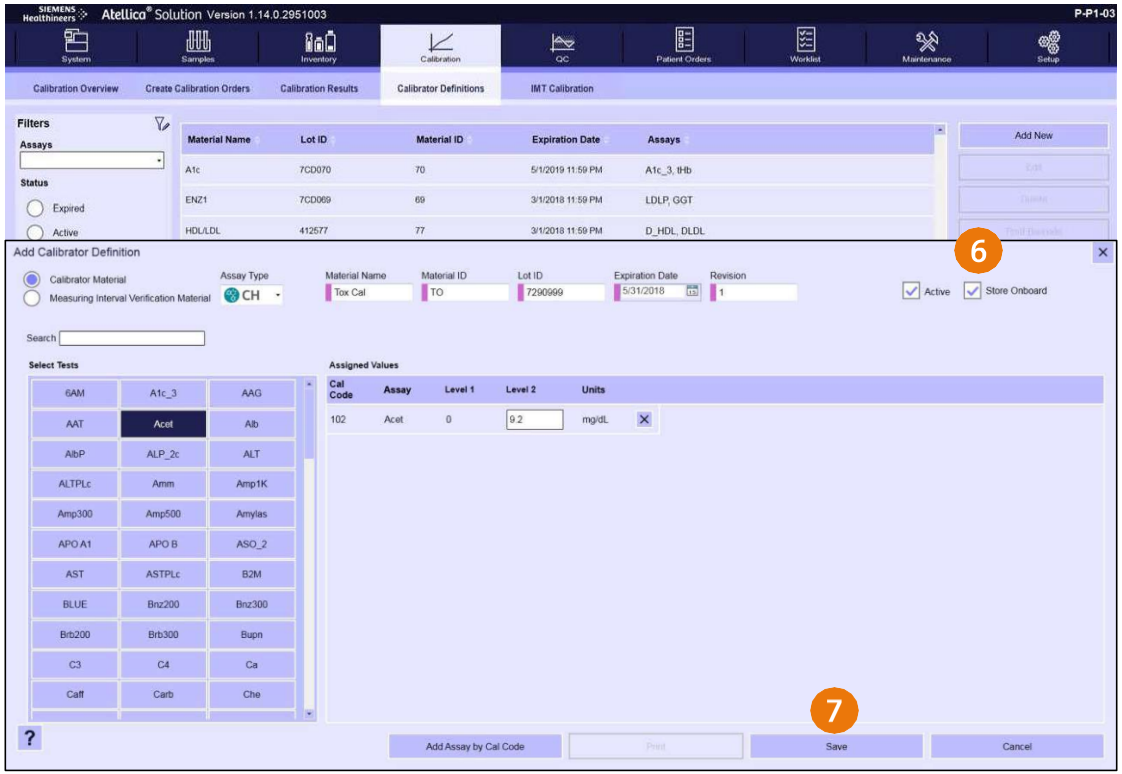
Installing New Calibrator Definitions (continued)

6. If storing the calibrator in the Cal-QC storage area, select the **Store Onboard** checkbox (only applies to Sample Handler configurations)
   - ➢ Certain assay calibrators are not compatible with onboard storage in the Cal-QC area. The operator cannot select the **Store Onboard** checkbox and save a calibrator definition that includes an assay that is incompatible with onboard storage
7. Select **Save**



NOTE: If the barcode reader is not available, the calibrator definition can be manually added by selecting the **Add New** button on the Calibrator Definitions screen.

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Atellica® Solution
Calibration

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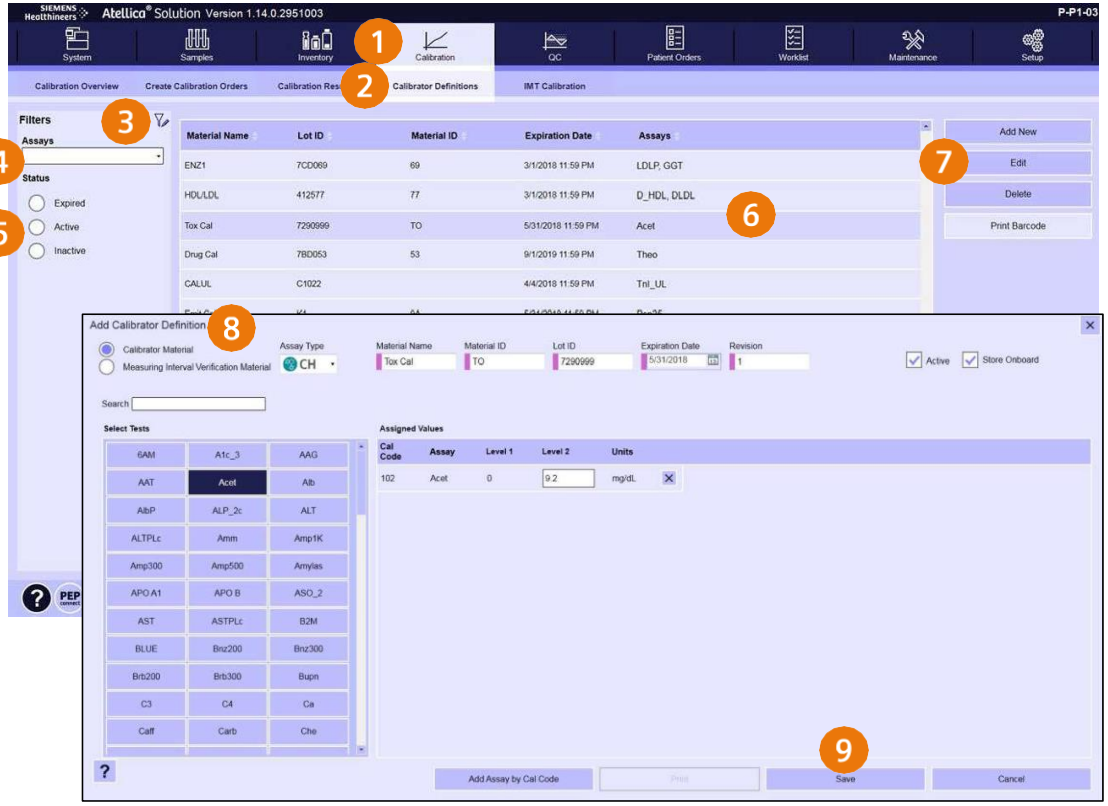
Editing Calibrator Definitions

To edit a calibrator definition:

1. On the Command Bar, select **Calibration**
2. Select the **Calibrator Definitions** tab
3. To remove existing filters, select  from the Filters area
4. To view a calibrator definition for an assay, select from the Assays dropdown menu in the Filters area
5. To view calibrations with a specific status, select a Status filter
6. Select a calibrator definition
7. Select **Edit**
8. The following edit options are available:
   - Add an assay
   - Delete an assay
   - Modify the level values from the calibrator value sheet
   - Correct the expiration date
   - Activate or deactivate the calibrator
   - Enable Store Onboard
9. Select **Save**



Effective Date: 8/23/2019 | HOOD05162003031090

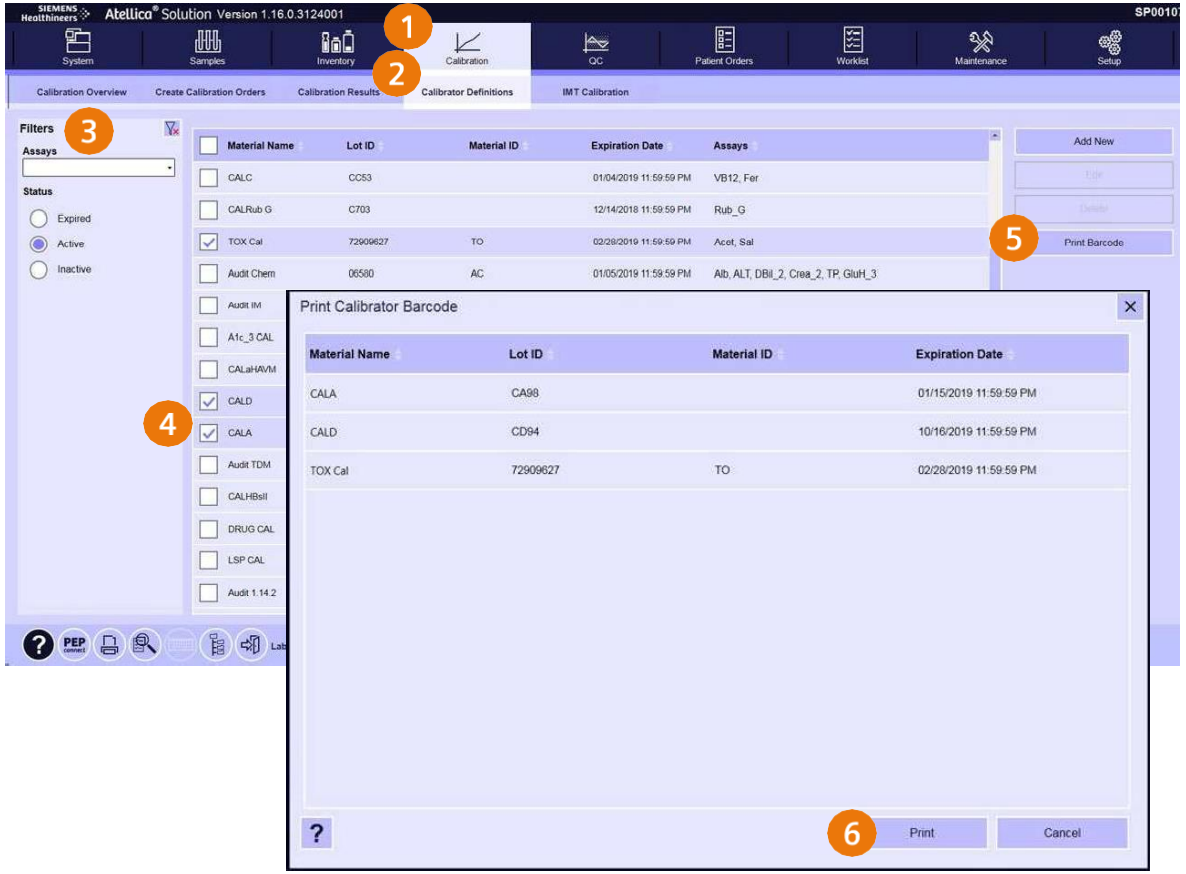
Atellica® Solution Calibration

Print Calibrator Barcodes – Calibrator Definitions screen

Calibrator barcodes must be printed using the Atellica Solution software to ensure that each barcode has the correct sequence number.

To print calibrator barcodes from the Calibrator Definitions screen:

1. On the Command Bar, select **Calibration**
2. Select the **Calibrator Definitions** tab
3. To limit the number of Calibrator Definitions that display, use the filters in the Filters area of the screen
4. Select the material name for 1 or more calibrator definitions
5. Select the **Print Barcode** button
   - ➢ The system displays all selected calibration definition barcode labels in the Print Calibrator Barcode screen
6. Select **Print**
   - ➢ Barcodes print on the system barcode label printer



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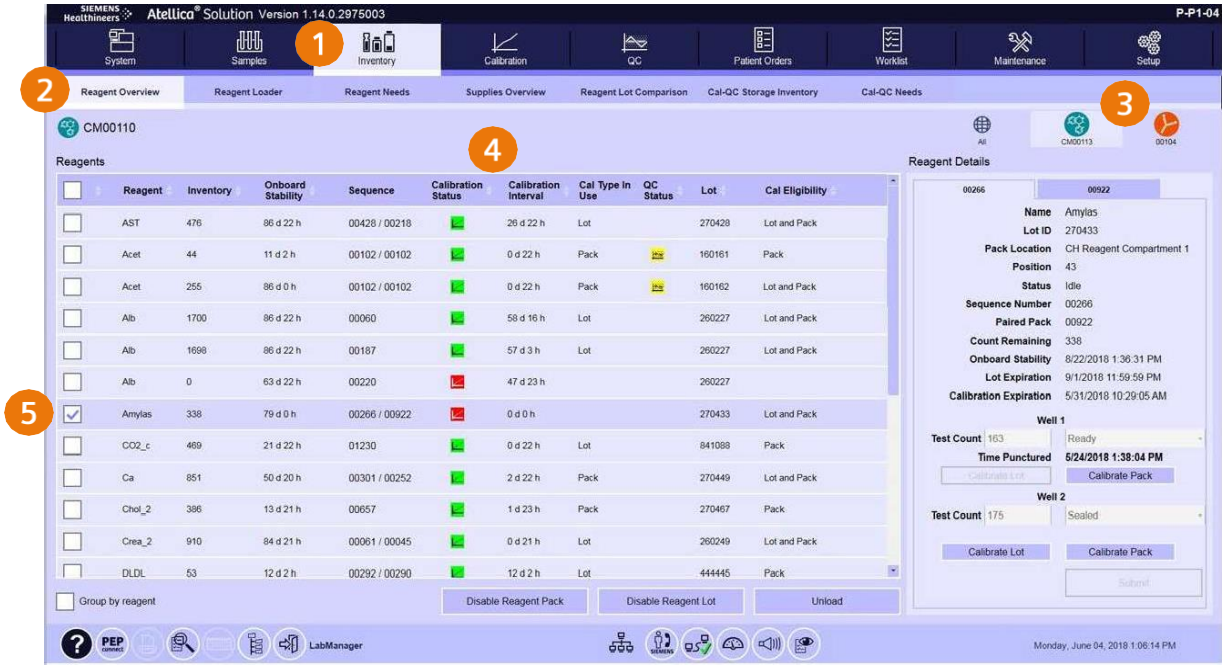
Atellica® Solution
Calibration

SIEMENS Healthineers

Creating Calibration Orders Manually – Reagent Overview Screen

1. On the Command Bar, select **Inventory**
2. Select the **Reagent Overview** tab
3. Select the analyzer
4. To sort, select a column heading
   - ➢ Calibration Status: to bring reagents that have an invalid calibration or have not been calibrated to the top of the screen
   - ➢ Calibration Interval: to bring reagents with a calibration that will expire soon to the top of the screen
5. Select the desired reagent pack



* This procedure is continued on the next slide

<u>Calibration Status Glyphs:</u>

Green – Valid calibration exists

Yellow – The pack supports more than one assay and not all assays are calibrated

Red – Invalid calibration or the pack does not have a calibration

Effective Date: 8/23/2019 | HOOD05162003031090

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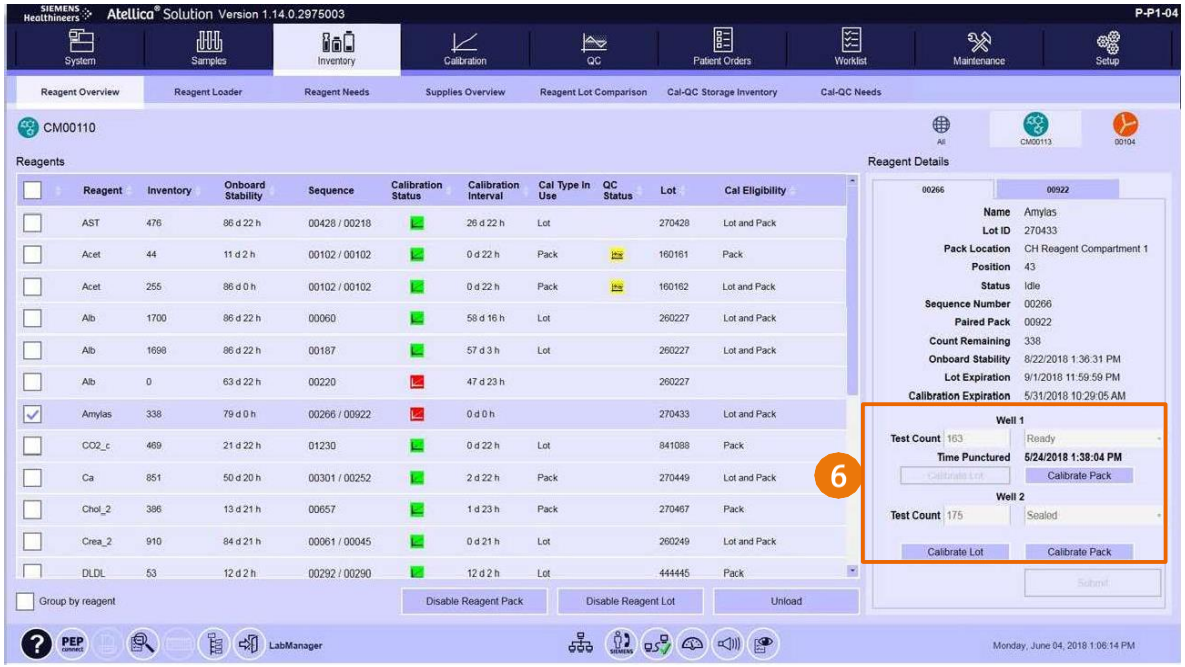
Creating Calibration Orders Manually – Reagent Overview Screen (continued)

6. In the Reagent Details area of the screen, select the appropriate button to order either a pack calibration or a lot calibration
   - ➢ If there are multiple wells in the pack, there will be separate options to calibrate each well
   - ➢ The options available will depend on what type of calibration the pack is eligible for (pack/lot)
7. If the reagent includes multiple assays, the system will display a menu listing the analytes. Select the appropriate assay name in the displayed list
   - ➢ For example, if the operator selects HBsII the displayed menu includes HBsII and CONF. The operator selects HBsII or CONF as appropriate
8. Select **Yes** in the confirmation window



NOTE: When calibrating reagent packs or wells directly from **Reagent Overview**, the system requires 1 active calibrator definition. If more than 1 calibrator definition exists on the system for a reagent, the system defaults to using the oldest calibrator material and definition to calibrate the reagent.

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Atellica® Solution
Calibration

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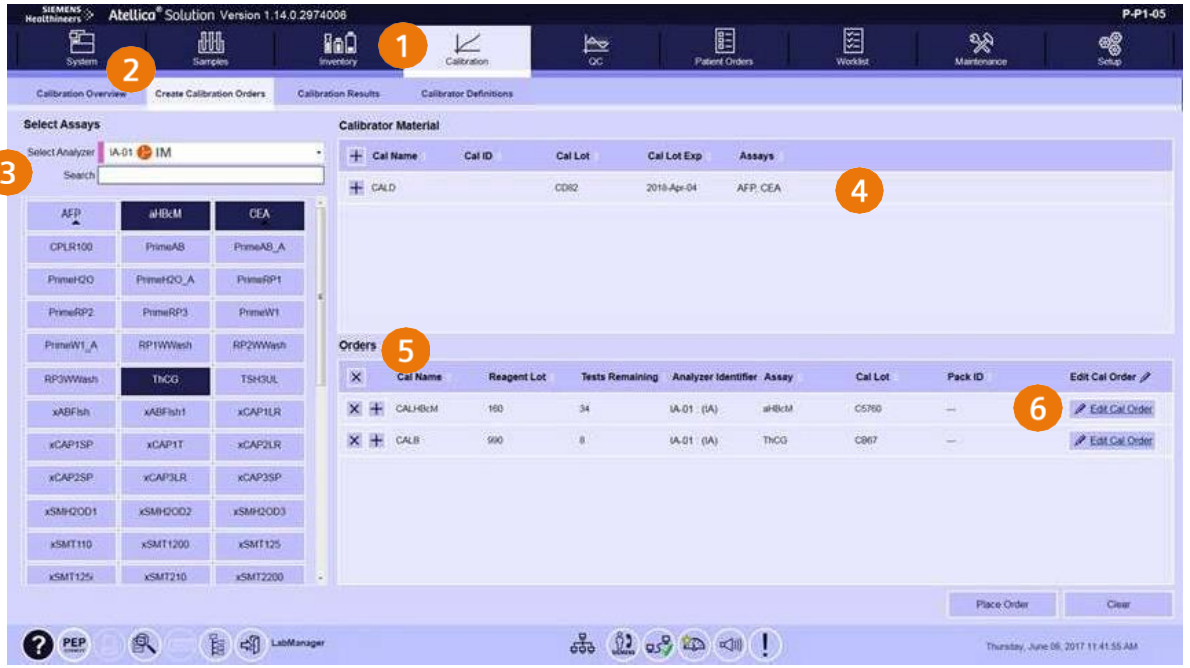
Creating Calibration Orders Manually – Create Calibration Orders Screen

1. On the Command Bar, select **Calibration**
2. Select the **Create Calibration Orders** tab
3. Select the tests to be ordered
4. If the selected test has multiple calibrator materials defined for it, the calibrator materials will appear in the Calibrator Materials area of the screen
   - ➢ Select one or more materials to include in the order
   - ➢ Once selected, the calibrator test orders will appear in the Orders area of the screen
5. If the selected test only has one calibrator material defined for it, the calibrator test order will appear in the Orders area of the screen as soon as the test is selected
6. To edit the calibration order, select **Edit Cal Order** in the Orders area



NOTE: If the **Edit Cal Orders** button is not selected, the system will automatically determine whether the calibration is a lot or pack calibration according to the status of the pack.

* This procedure is continued on the next slide

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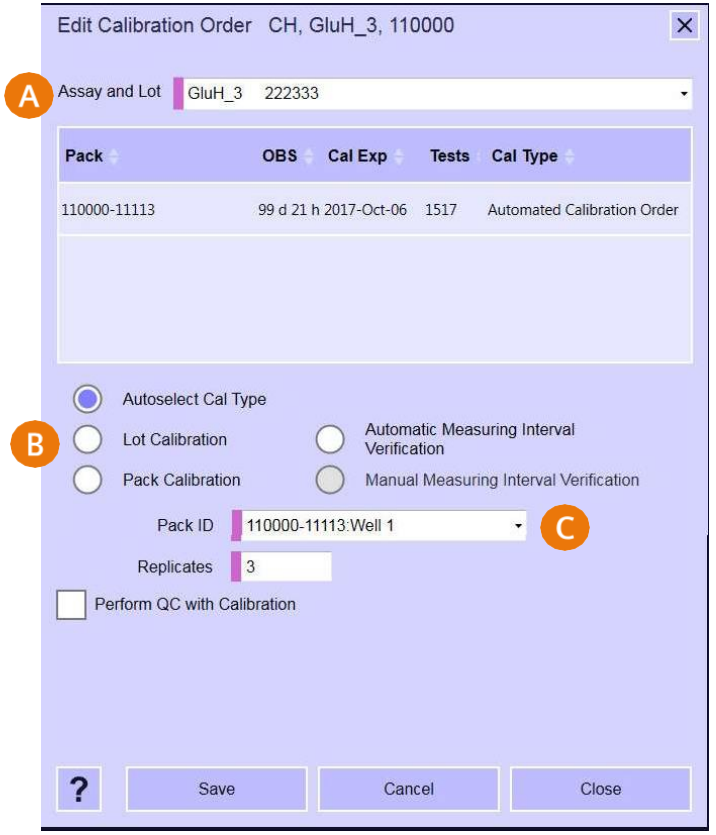
Creating Calibration Orders Manually – Create Calibration Orders Screen (continued)

7. In Edit Calibration Order, select or enter specific information about the calibration:
   A. Select an assay reagent lot from the Assay and Lot dropdown menu
   B. Select a type of calibration:
      - **Autoselect Cal Type** – the system automatically creates a lot or pack calibration according to the status of the pack
      - **Lot Calibration** – valid for an entire lot until the lot calibration interval expires
      - **Pack Calibration** – valid for an individual pack only until the pack calibration interval expires
      - **Automatic Measuring Interval Verification** – the system dilutes onboard, high level calibrator material to create the linear samples
      - **Manual Measuring Interval Verification** – the system dilutes high level calibrator material that the operator defines as manual linearity material and loads on the system
   C. Select a reagent pack from the Pack ID dropdown menu. For CH calibration orders, select a specific reagent pack well



* This procedure is continued on the next slide

NOTE: To replace a valid lot or pack calibration with recalibration results, the operator must edit the new calibration order and select the appropriate type of calibration. If a valid calibration already exists and the operator does not select the calibration type, the calibration will not be ordered.

Effective Date: 8/23/2019 | HOOD05162003031090

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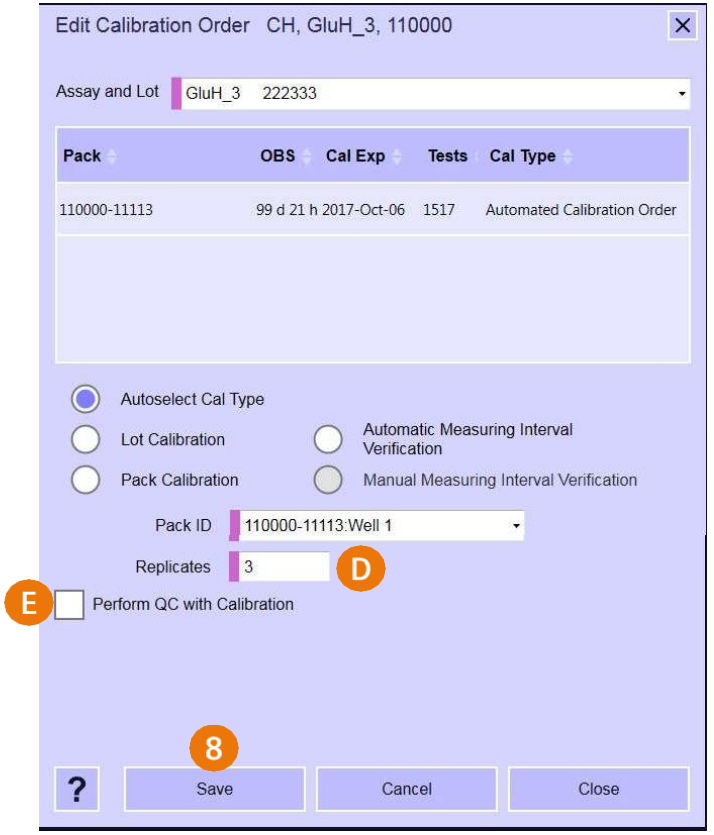
Creating Calibration Orders Manually – Create Calibration Orders screen (continued)

D. In Replicates, enter a number equal to or greater than the minimum number of replicates required to calibrate the assay reagent

E. Select the **Perform QC with Calibration** checkbox to have the system automatically order QC when the calibration order completes

- If this option is selected, ensure the appropriate QC material is onboard the system
- Changing the Perform QC with Calibration setting in Edit Calibration Order applies to the current calibration order only and does not change the Perform QC with Calibration setting in the assay test definition

8. Select **Save**
9. On the Create Calibration Orders screen, select **Place Order**



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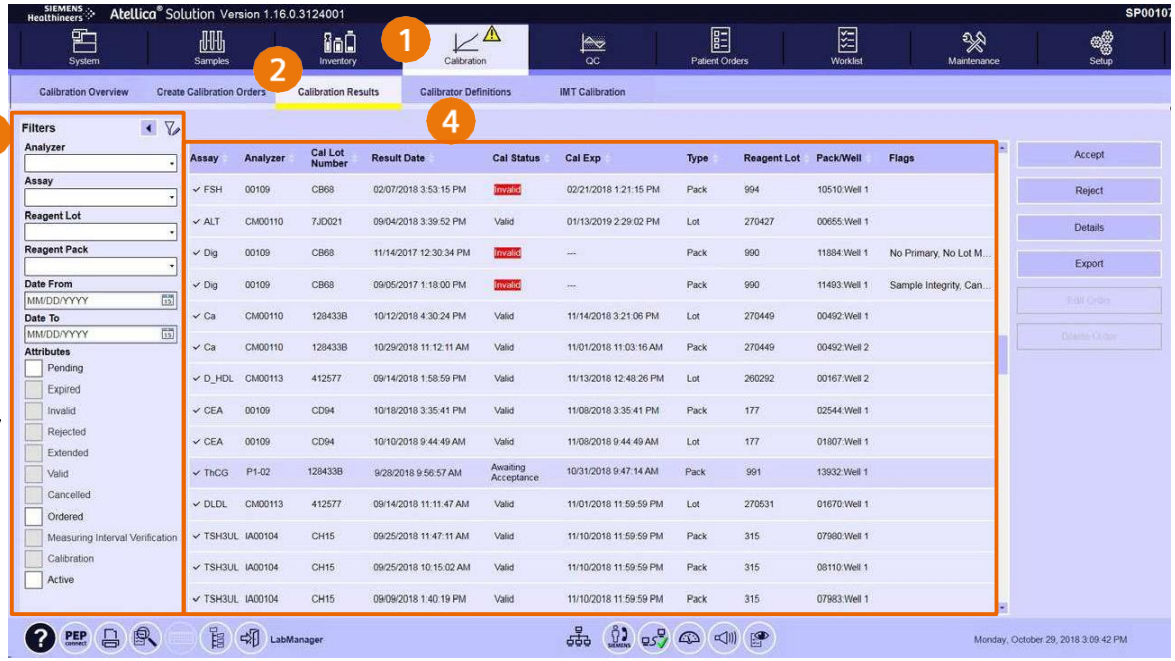
Atellica® Solution
Calibration

SIEMENS Healthineers

Review Calibration Results: Calibration Results Screen

To utilize the Calibration Results screen:

1. On the Command Bar, select **Calibration**
2. Select the **Calibration Results** tab
3. Use the Filters area to filter by Analyzer, Assays, Reagent Lot/Pack, Date, and Attributes (Valid, Invalid, Expired, etc)
   - ➢ If no analyzer is selected in the Analyzer filter, the only attributes that will display are Pending, Ordered, and Active. To be able to select to view the other attributes, you must first select an analyzer
4. The calibration results area displays information including calibration lot number, calibration status, calibration expiration, and reagent lot
   - ➢ Red in the Cal Status column indicates the calibration is expired, rejected, or the calibration acceptance criteria exceeds limitations and the calibration is invalid
   - ➢ A check mark in the Assay column indicates that the system is using the active calibration to calculate patient results



* This procedure is continued on the next slide

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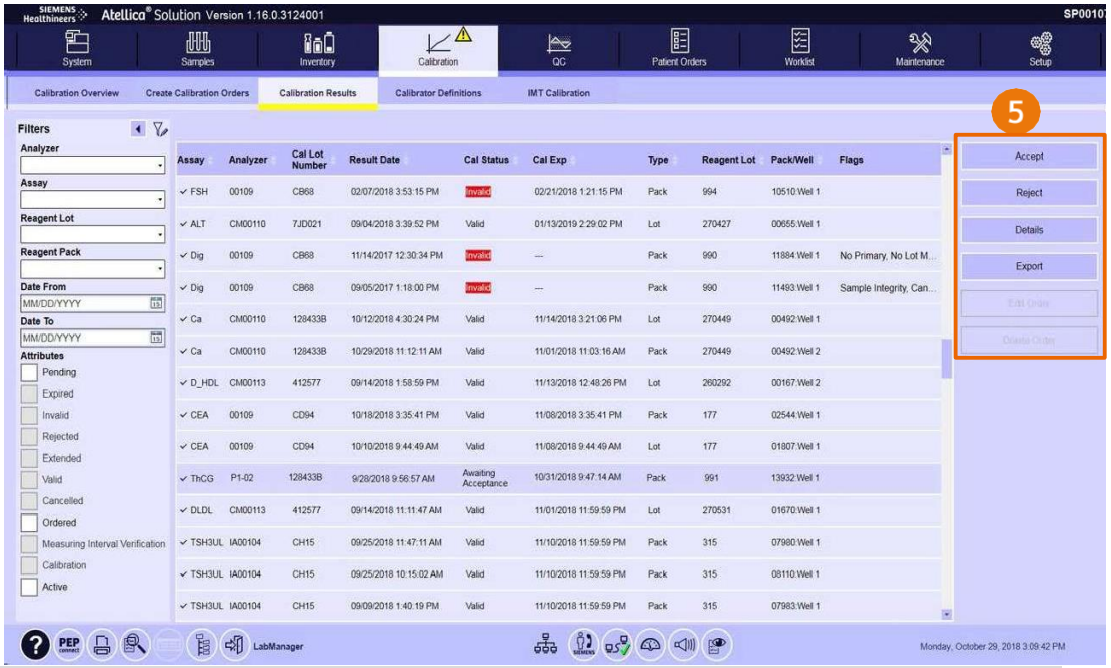
Atellica® Solution
Calibration

SIEMENS Healthineers

Review Calibration Results: Calibration Results Screen

To utilize the Calibration Results screen (continued):

5. The following tasks can be performed on a selected calibration:
   - A. Select **Accept** or **Reject** for calibrations with a Cal Status of "Awaiting Acceptance"
     - ➢ "Awaiting Acceptance" indicates the results do not meet the acceptance criteria for 1 or more expected calibration values and the following conditions apply:
       - o Automatic Acceptance is disabled in the CH assay test definition
       - o Accept Cal is enabled in the IM assay test definition
     - ➢ The operator must select to accept or reject the calibration
   - B. Select **Details** to view Calibration Result Details displaying additional information to aid in troubleshooting*
   - C. Select **Export** to create a file with calibration results
   - D. Select **Edit Order** or **Delete Order** to edit or delete calibration orders



NOTE: If there is an "Awaiting Acceptance" calibration result, there will be a yellow bar beneath the Calibration Results tab at the top of the screen.

* See more information on Calibration Results Details on the next slide

Atellica® Solution
Calibration

SIEMENS Healthineers

Calibration Results Screen-Details

The Calibration Results Details can be accessed from either the Worklist Overview or the Calibration Results screen.

A. Information – summary of the calibration order information

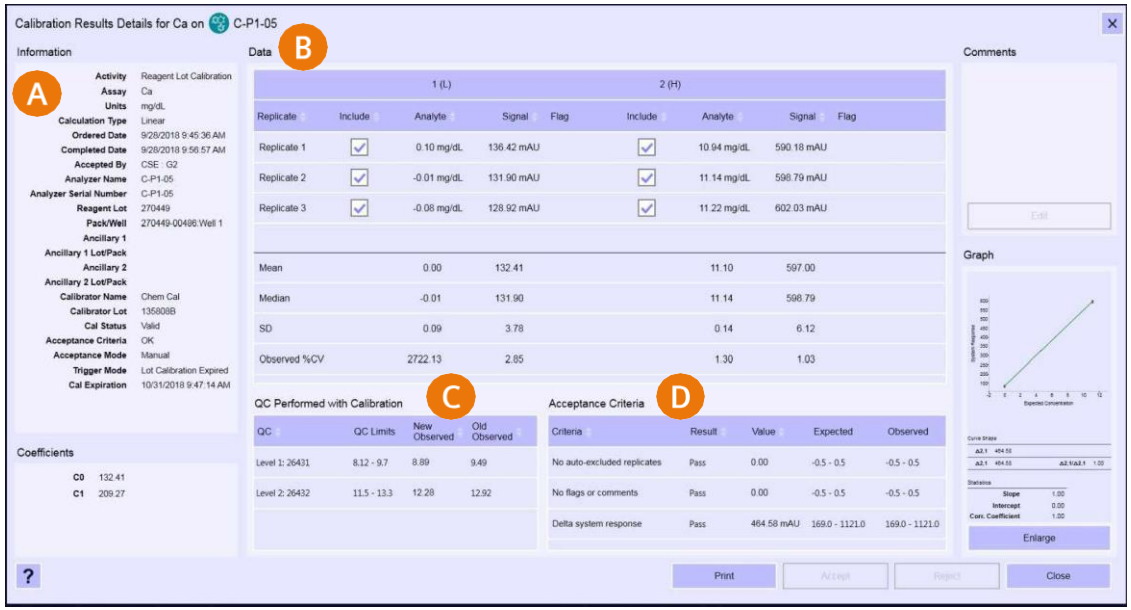
B. Data – calibration data for each replicate

- If applicable, the **Include** checkboxes can be used to exclude or include replicate results

C. QC Performed with Calibration – provides a summary of QC results, when the system automatically performed QC with calibration (enabled in the Test Definition or selected as part of the calibration order)

D. Acceptance Criteria – displays the criteria used by the system to evaluate the calibration, and indicates whether each criteria failed or passed for the selected calibration

- The system automatically accepts calibration results if the acceptance criteria passes



* See the next slide for more information on this screen

NOTE: In order to exclude a replicate, the minimum number of replicates the system requires for a valid calibration must remain after the exclusion of the replicate. After excluding an outlier replicate result, the system recalculates the calibration data and rechecks the calibration criteria. The Atellica® IM Analyzer can be configured to automatically exclude outlier calibration replicates.

Effective Date: 8/23/2019 | HOOD05162003031090

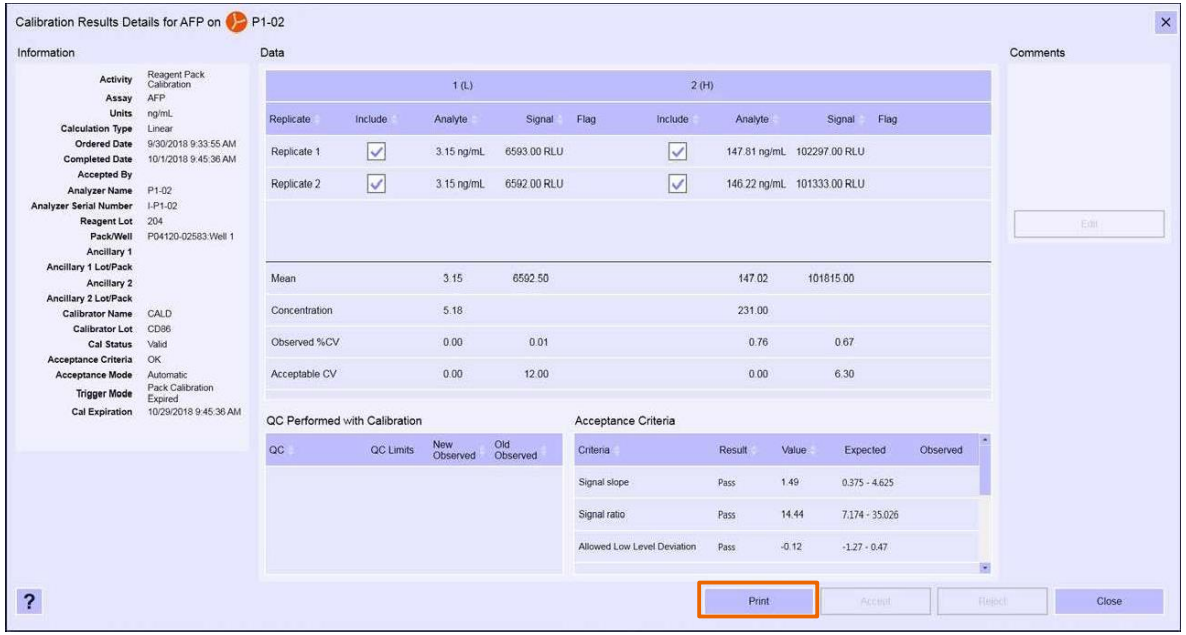
Atellica® Solution
Calibration

SIEMENS Healthineers

Printing Calibration Result Details

To print calibration result details:

1. Navigate to **Calibration** > **Calibration Results**
2. Select a calibration
3. Select **Details**
4. Select **Print**
5. To view the data, select **Preview…**
6. To print, select **OK**
7. To print to a file:
   A. Select **Print to file**
   B. Browse to select file name and location
   C. Select **OK**



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SIEMENS Healthineers

Atellica® Solution
Quality Control PEP to Go

Template Effective Date: 27-MAY-2019 | HOOD05162003010284
Effective Date: 06-SEP-2019 | HOOD05162003030847

Atellica® Solution
Process QC Samples

Options for Creating QC Orders

- Create QC orders manually using the **Create QC Orders** screen
  - Option to create orders using a panel
- Configure the system to automatically create QC orders:
  - By Day and Time
  - By Test Count
  - By Control

Effective Date: 06-SEP-2019 | HOOD05162003030847

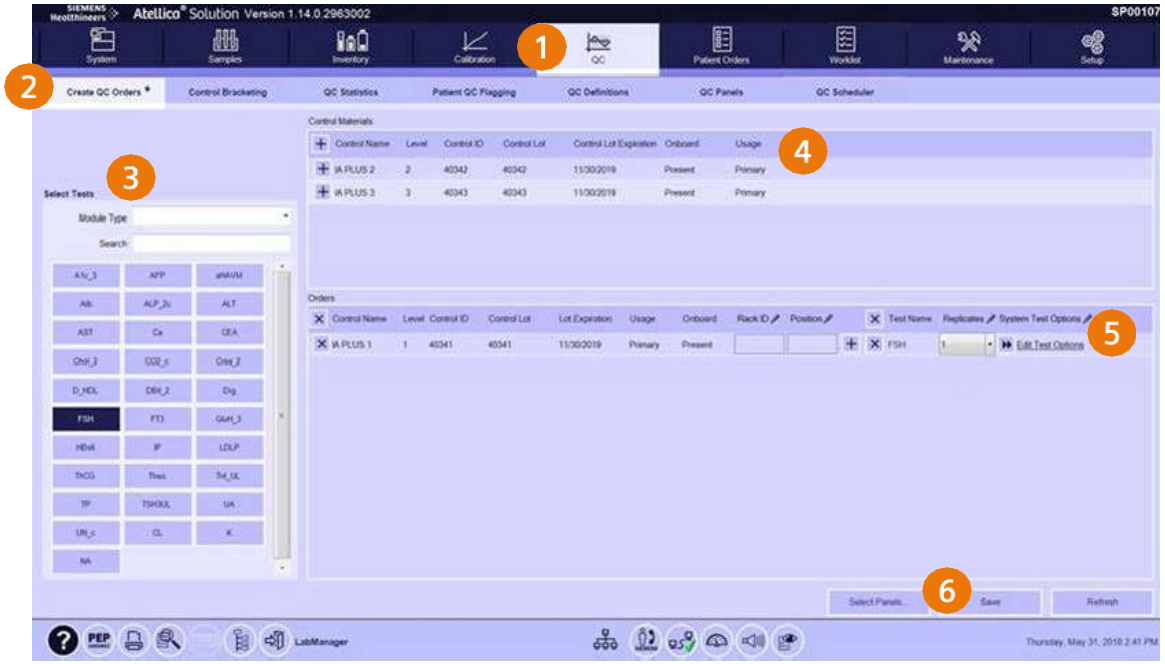
Atellica® Solution
Process QC Samples

SIEMENS Healthineers

Creating QC Orders Manually

1. At the Command Bar, select **QC**
2. Select the **Create QC Orders** tab
3. Select the tests to be ordered
   - The tests displayed can be filtered by Module Type if the Atellica Solution has more than one type of analyzer connected
   - The Search field can be used to locate a test name
4. If the selected test has multiple control materials defined, the control materials will appear in the Control Materials area of the screen. Select one or more materials to include in the QC order. Once selected, the control test orders will appear in the Orders area of the screen

   If the selected test only has one control material defined, the control test order will appear in the Orders area of the screen as soon as the test is selected
5. Make any edits to the tests ordered, replicates, or analyzer the tests will be run on*
6. Select **Save**



NOTE: To associate controls with QC orders, the controls must be defined in QC Definitions.

* See the next slide for more information on the Orders section of the screen

Effective Date: 06-SEP-2019 | HOOD05162003030847

Atellica® Solution
Process QC Samples

SIEMENS Healthineers

Creating QC Orders Manually (continued)

In the Orders section of the Creating QC Orders screen, the following edits can be made to the orders:

A. Select the **+** icons to create duplicate orders of the test

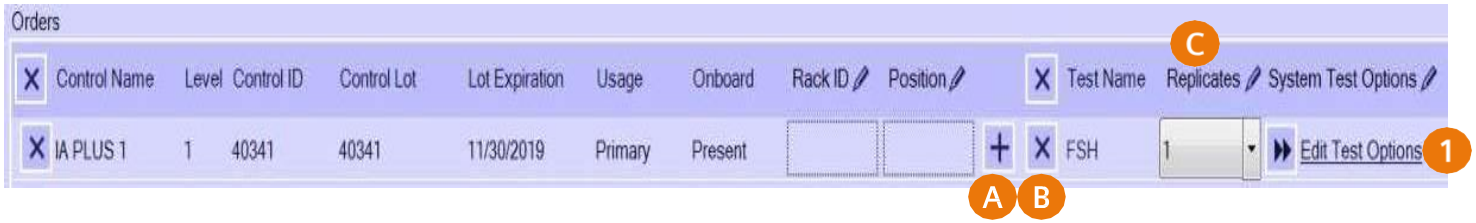
B. Select the **X** icons to delete tests or controls

C. Select the replicates dropdown arrow to change the number of replicates for that order

NOTE: There is a difference in how the result is reported for tests ordered as duplicates (using the + icon) versus tests ordered as replicates (using the Replicates dropdown):

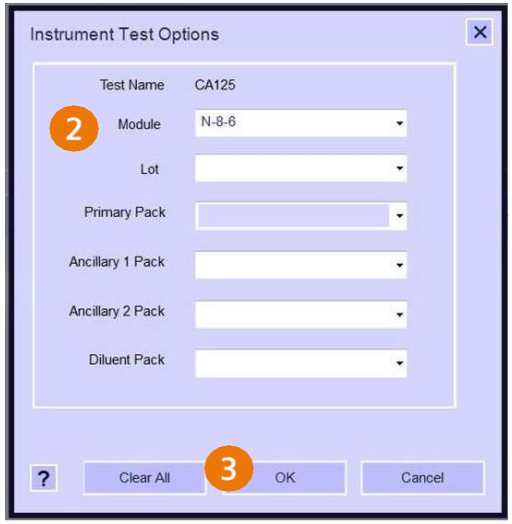
Duplicates: The individual results for each order will be reported

Replicates: Only the mean result will be reported



D. If the Atellica Solution has multiple modules of the same type of analyzer connected (more than one chemistry analyzer for example), the specific analyzer that the order will be run on can be defined:

1. Select **Edit Test Options**
2. Select the analyzer using the Module dropdown list. If desired, the reagent lot or specific reagent pack can also be specified
3. Select **OK**



NOTE: If you do not specify an analyzer, an order will be created on all the analyzers that have that test.

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Atellica® Solution
Process QC Samples

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Ordering QC Panels

A QC Panel is a collection of tests or QC materials, allowing you to add a defined group of tests or QC materials to a QC order without selecting the tests or QC materials individually.

To order a QC Panel:

1. At the Command Bar, select **QC**
2. Select the **Create QC Orders** tab
3. Select the **Select Panels** button
4. Select the panel(s) to be ordered
5. The control materials and tests associated with the selected panel(s) will display in the Orders area of the screen
6. Select the **Select** button
7. Make any edits to the tests ordered, replicates, or analyzer the tests will be run on
8. Select the **Save** button to create the orders

Effective Date: 06-SEP-2019 | HOOD05162003030847

Atellica® Solution
Process QC Samples

SIEMENS Healthineers

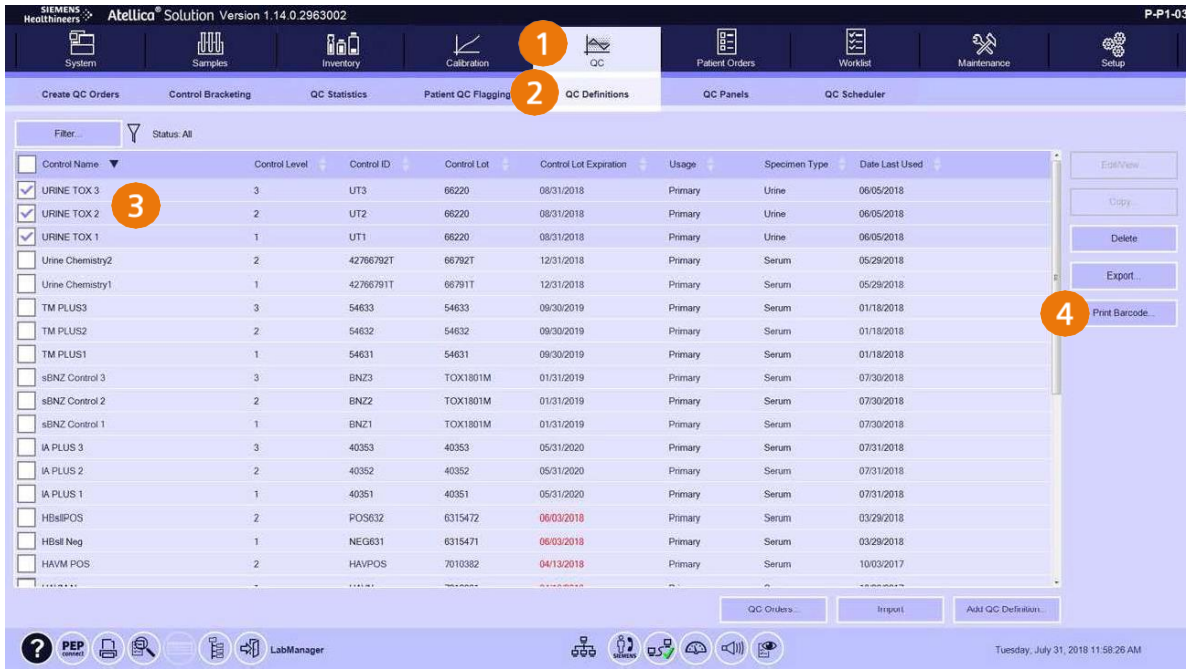
QC Barcodes

QC barcodes must be printed using the Atellica Solution software to ensure that each barcode has the correct sequence number.

To print QC barcodes:

1. At the Command Bar, select **QC**
2. Select the **QC Definitions** tab
3. Select the checkbox(es) for the Control Name(s) to print
4. Select the **Print Barcode** button

The barcodes will print to a local barcode printer, or to a networked barcode printer shared with the system.



NOTE: Some QC manufacturers will provide pre-labeled QC tubes.

NOTE: For the Sample Handler configuration, all tubes must be barcoded.

For the Direct Load configuration, tubes may be run either barcoded or non barcoded.

Atellica® Solution
Process QC Samples

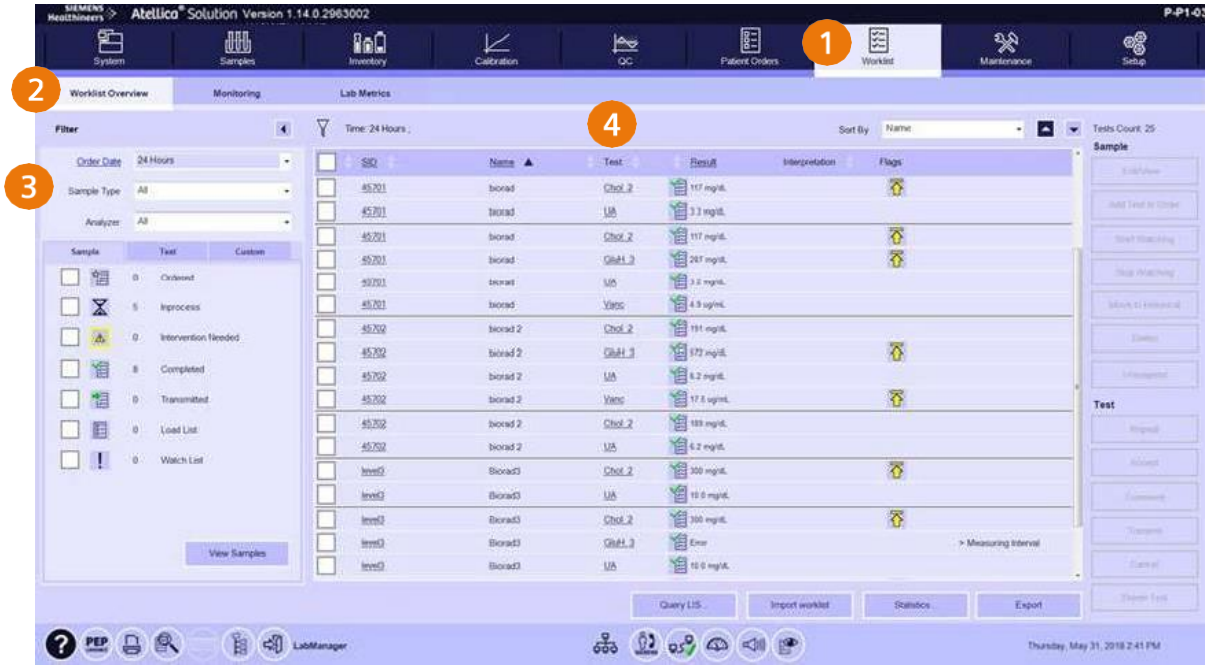
SIEMENS Healthineers

Viewing Test Orders and Results

The **Worklist Overview** screen can be used to view the status of test orders and results for calibration, QC, and patient orders.

To view test orders and results:

1. At the Command Bar, select **Worklist**
2. Select the **Worklist Overview** tab
3. The Filter area of the screen is used to filter the orders displayed. Under Sample Type, QC can be selected
4. The Orders area of the screen displays the result time for inprocess test orders, and the result value and units for resulted test orders



* See the next slide for more information on the Worklist Overview screen

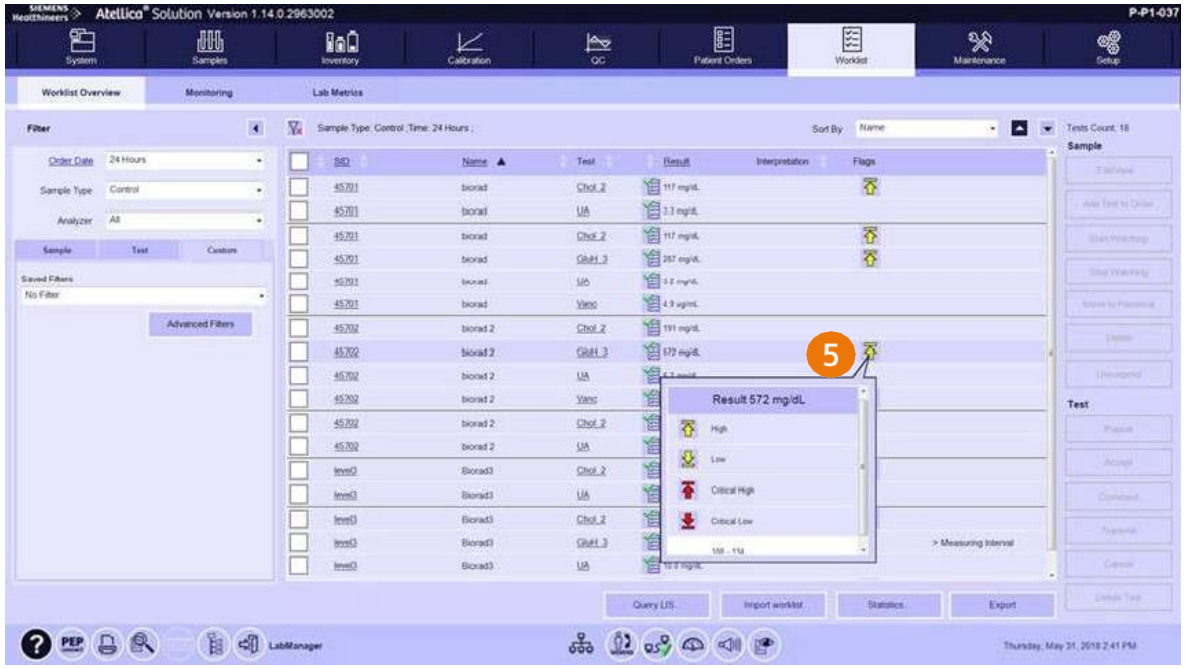
Effective Date: 06-SEP-2019 | HOOD05162003030847

Atellica® Solution
Process QC Samples

SIEMENS Healthineers

Viewing Test Orders and Results (continued)

5. Selecting one of the Flags symbols will display a list of what the symbols mean. Scroll down to the bottom of the list to view the low and high limits that are defined in the QC Definition screen for that control



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Atellica® Solution
Monitor QC Results

SIEMENS Healthineers

Viewing QC Data – Review screen

The QC Statistics screen provides real-time and long-term evaluation of system and assay performance.

The Review screen displays current QC results.

To access the QC Review screen:

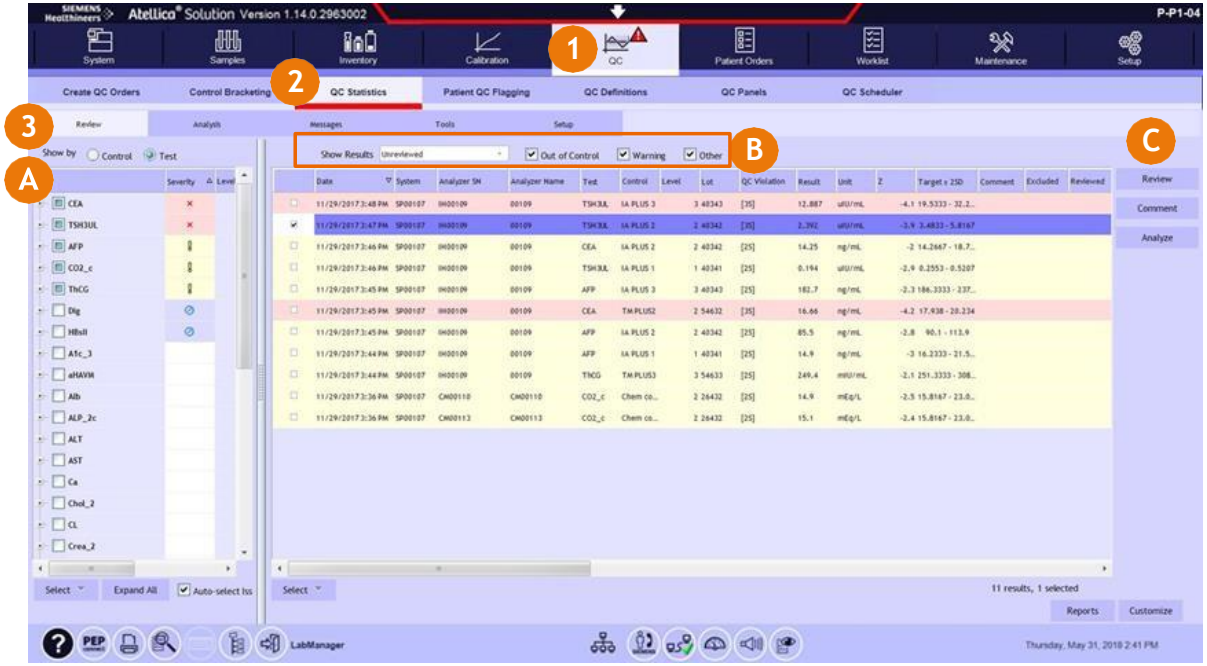
1. At the Command Bar, select **QC**
2. Select the **QC Statistics** tab
3. Select the **Review** tab

<u>Areas of the screen:</u>

A. Control file selection – contains options for selecting the control files to be viewed

B. Filters – used to filter the types of files displayed

C. Functions – used to mark files as reviewed, add comments, and analyze files to create QC graphs and statistics



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Atellica® Solution
Monitor QC Results

SIEMENS Healthineers

Viewing QC Graphs – Analysis screen

Select the Analysis screen Chart tab to display a graph of the data:

1. Select the **Display** dropdown list to select whether to view Levey-Jennings charts or Z-score charts
   - The Levey-Jennings chart marks the mean and first, second, and third standard deviation (SD) limits on the Y-axis
   - When the Z-score chart is selected, the graphs from multiple control files can be overlayed
2. Select the **Filter** button to apply a date or time range to the data
   - Another option to change the time range is to use the scale beneath the chart
3. Select the **Statistics** button to view statistics for the data displayed
4. Select the **Exclude** button to remove a data point from the statistical calculations. The excluded point will be displayed in the chart and will not be connected to the other data points
   - The **Include** button can be used to reinstate excluded points for statistical calculations
5. To add a comment to a data point, select a data point and then select the **Comment** button

NOTE: When a control file has more than 1 target, the system displays the original and the changed target value, resulting in an offset view.

Effective Date: 06-APR-2020 | HOOD05162003077519

Atellica® Solution
Define QC

SIEMENS Healthineers

Creating New QC Definitions

To manually create a QC definition:

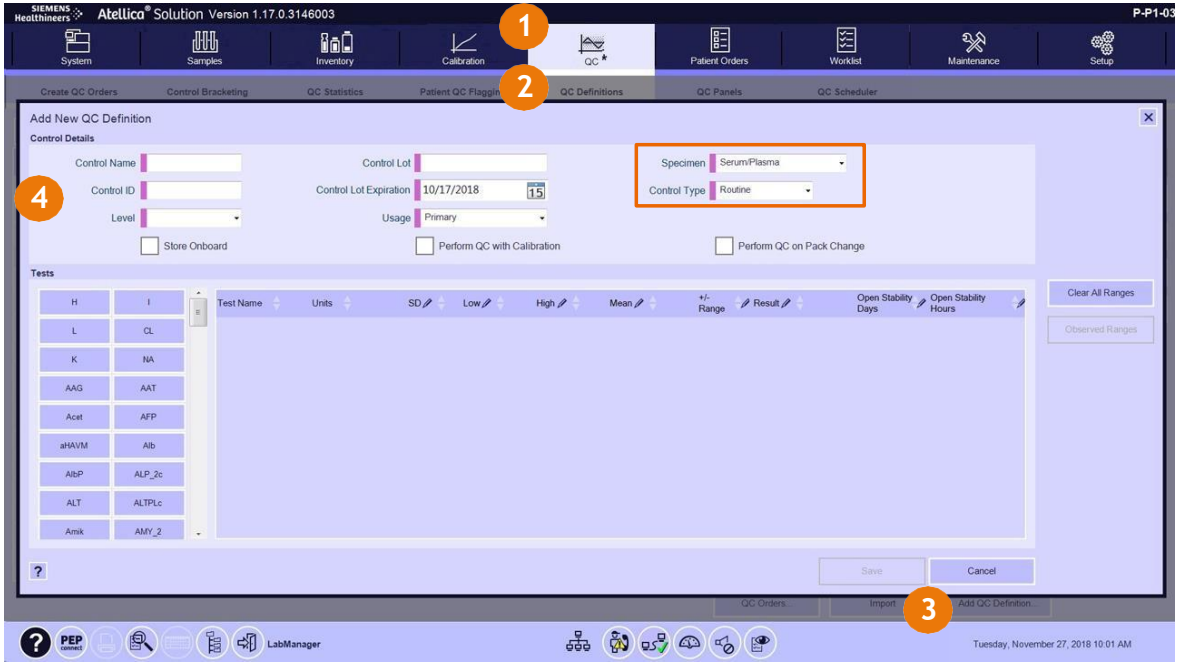
1. At the Command Bar, select **QC**
2. Select the **QC Definitions** tab
3. Select the **Add QC Definition** button
4. Enter the following information: Control Name, Control Lot, Specimen, Control ID, Control Lot Expiration, Control Type, Level, Usage

   Specimen - Select the Specimen type associated with the tests that the control supports

   - The operator must select Serum/Plasma specimen type for controls associated with tests for Serum, Plasma, or both. This specimen type applies to QC samples only

   Control Type - The following options are available:

   - **Routine controls** – independent from the reagent kits and do not require a checksum
   - **Kit controls** – require a checksum and may be lot-locked or control bracketed



*This procedure is continued on the next slide

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Atellica® Solution
Define QC

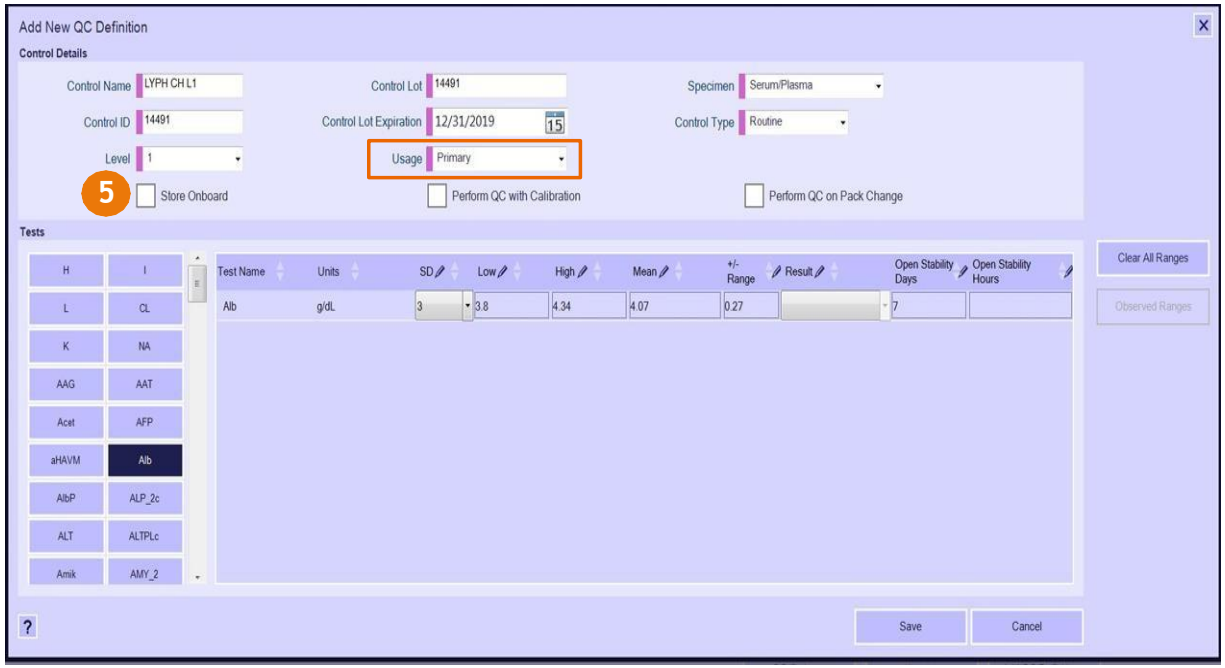
SIEMENS Healthineers

Creating New QC Definitions (continued)

Usage - The following options are available:

- **Primary** – Primary controls that produce QC results that determine patient QC flagging in QC statistics
- **Parallel** – The operator can perform new control lots in parallel with primary control lots for QC statistics. Parallel control results generate observed ranges, but do not generate violations or flags for test evaluations
- **Alternate** – The operator performs alternate control lots for additional QC flagging and statistical data
- **Not in Use** – The control lot is expired

5. If the QC material will be stored onboard, select the **Store Onboard** checkbox. (Only available in Sample Handler configurations)
   - When running QC with onboard controls, the system retrieves the control sample automatically as part of the QC order



*This procedure is continued on the next slide

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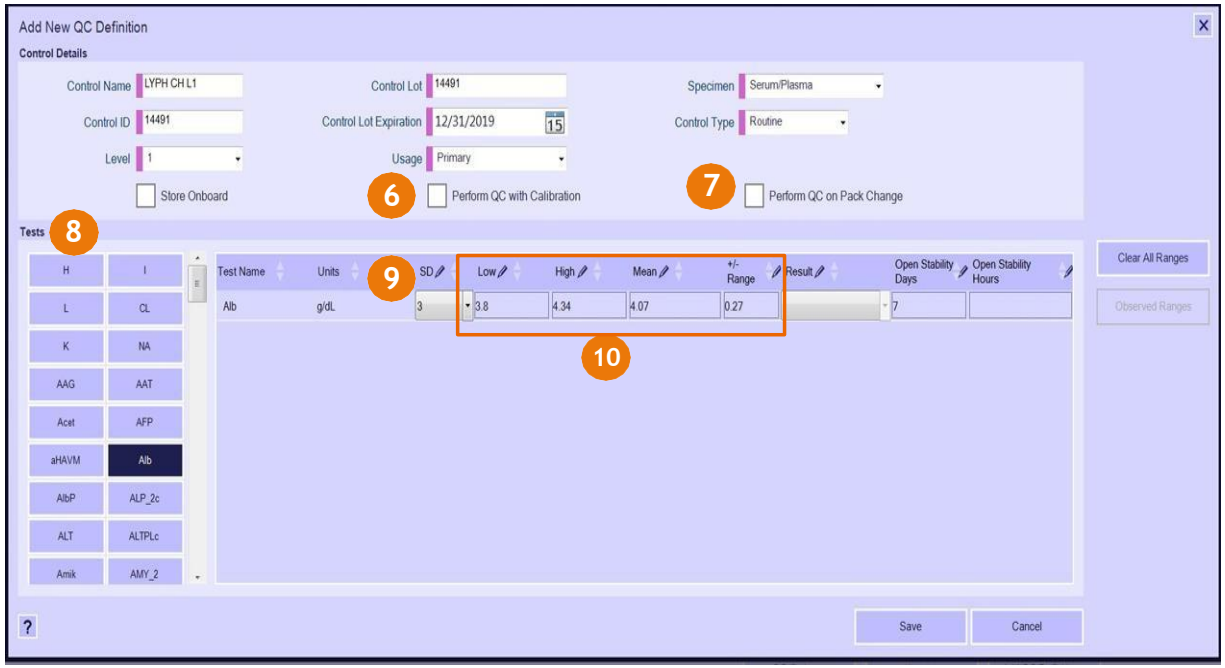
Atellica® Solution
Define QC

SIEMENS Healthineers

Creating New QC Definitions (continued)

6. To enable the QC lot to be configured to run automatically with calibrations, select the **Perform with Calibration** checkbox
   - ➢ To complete the setup of performing QC with calibration, navigate to **Setup > Test Definition** and select the **Perform QC with Calibration** checkbox for the desired test definition
7. To enable the QC to be run automatically with a reagent pack change, select the **Perform QC on Pack Change** checkbox
   - ➢ To complete the setup of performing QC with pack change, navigate to **Setup > Settings > General Setup** and select the appropriate QC on Pack Change setting under QC Mode Settings
8. Select a test
9. Enter the SD (Standard Deviation)*
10. Enter the target values by entering either the Low and High limits OR the mean and +/- Range *



***NOTE:** There is an option to enter "N/A" for SD and to not enter target values, which would allow the controls to run without entering ranges. There is also an option to enter "QUAL" for SD.

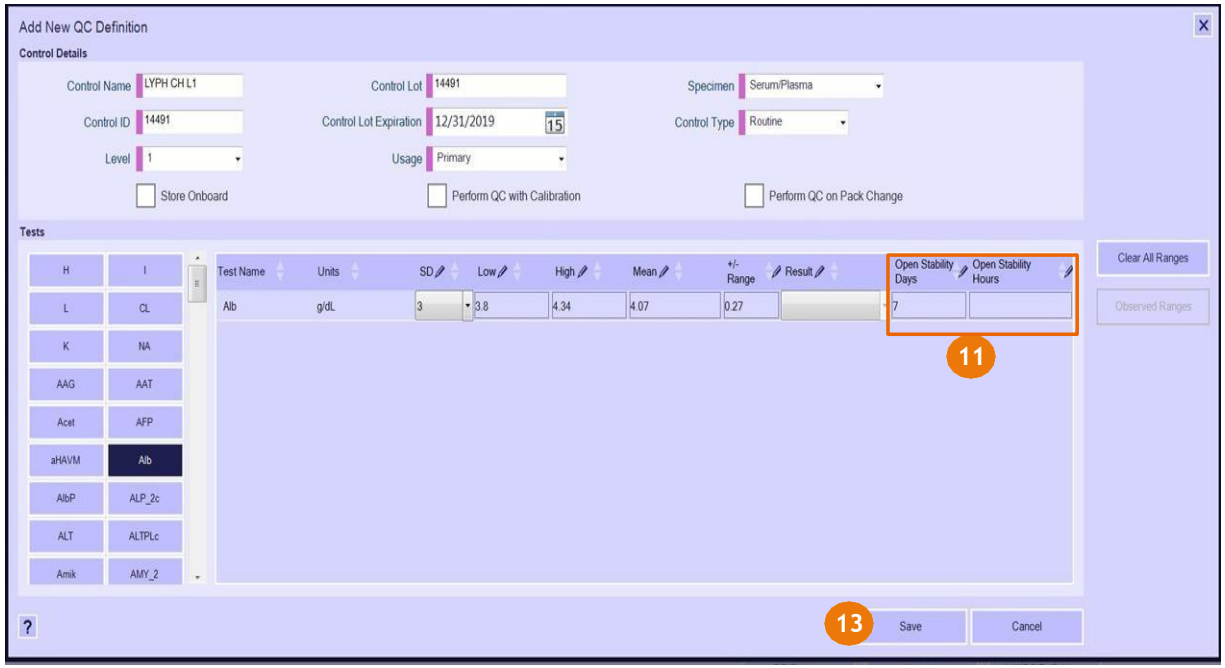
*This procedure is continued on the next slide

Effective Date: 06-APR-2020 | HOOD05162003077519

Atellica® Solution
Define QC

Creating New QC Definitions (continued)

11. Enter the Open Stability Days and the Open Stability Hours *
12. Add additional tests as needed
13. Select the **Save** button



***NOTE:** The Open Stability fields are only applicable to Sample Handler configurations.

Effective Date: 06-APR-2020 | HOOD05162003077519

Atellica® Solution
Define QC

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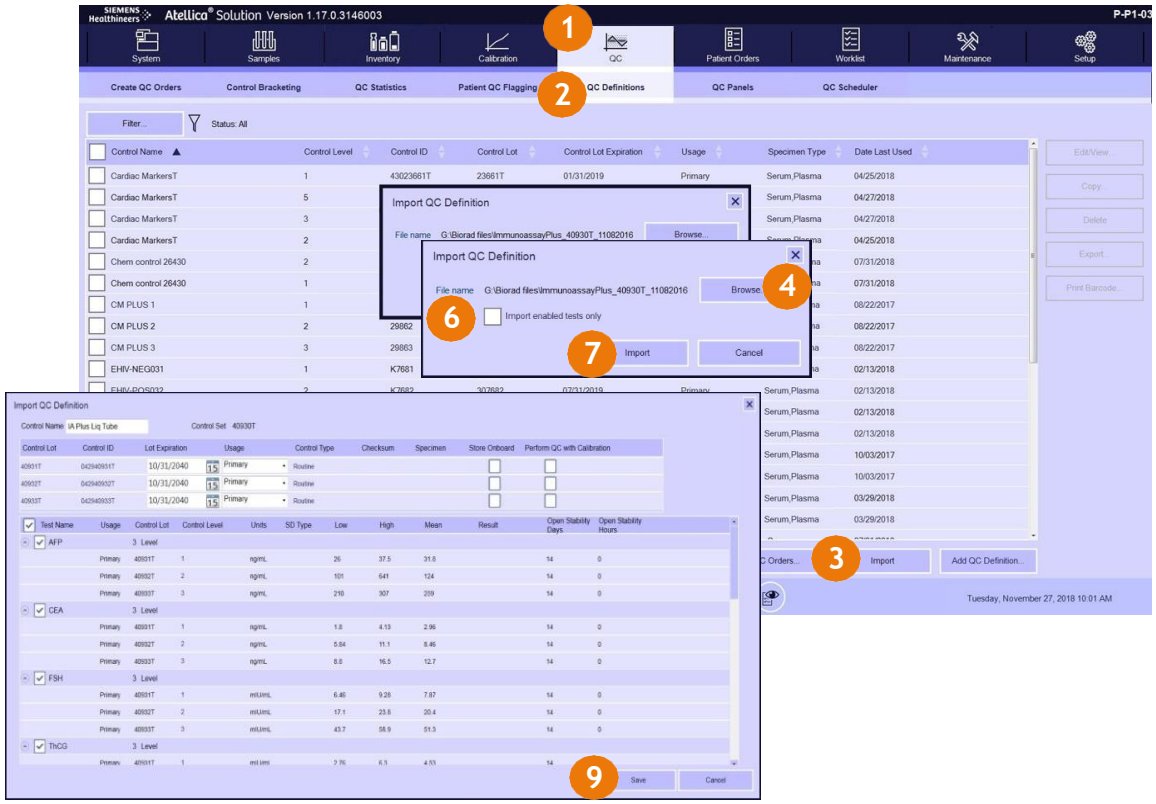
Importing QC Definitions

To import the QC definition xml file into the Atellica Solution software:

1. At the Command Bar, select **QC**
2. Select the **QC Definitions** tab
3. Select **Import**
4. Select **Browse** and navigate to the QC definition xml file
5. Select **OK**
6. To import only the tests enabled on the system, select the **Import enabled tests only** checkbox
7. Select **Import**
   - ➢ The Import QC Definition screen will display, with the definition data filled in
8. Select the appropriate tests to import
9. Select **Save**



***NOTE:** When importing QC Definitions for Serum or Plasma controls, the system defines the Specimen type as Serum/Plasma and imports all tests defined in the Test Definition as Serum or Plasma or both.

Effective Date: 06-APR-2020 | HOOD05162003077519

Atellica® Solution
Process QC Samples

SIEMENS Healthineers

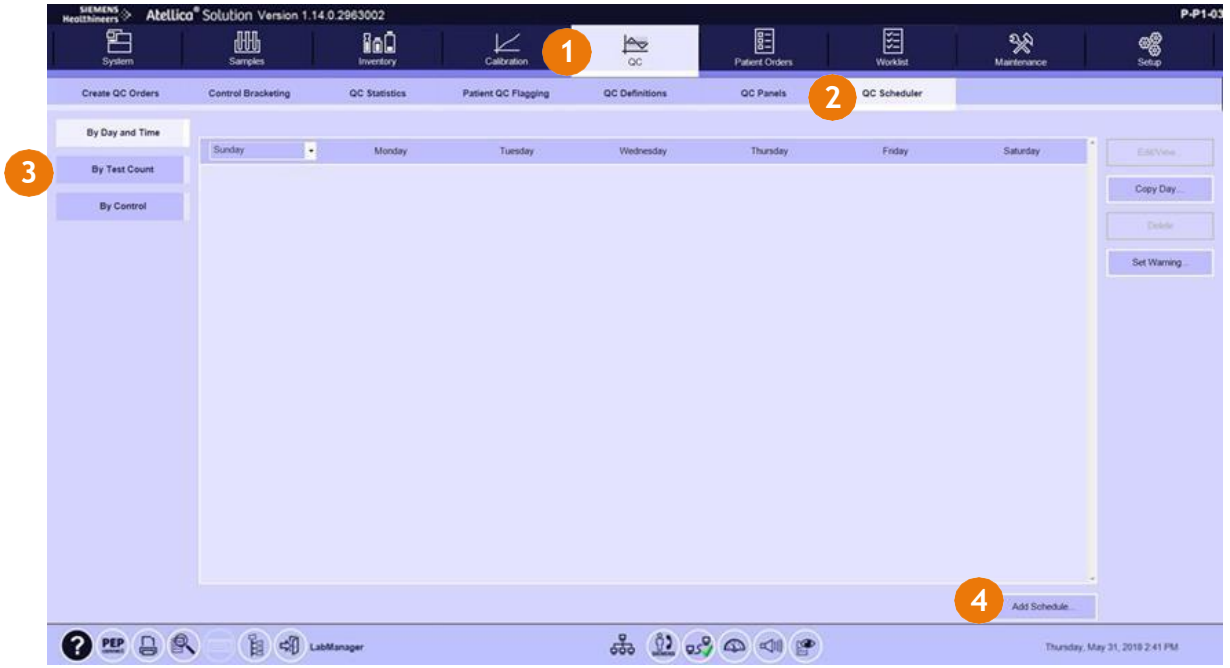
Configuring Automatic QC Scheduling

QC samples can be scheduled according to day and time, test count, or control.

To configure QC to be automatically scheduled:

1. At the Command Bar, select **QC**
2. Select the **QC Scheduler** tab
3. Select the appropriate scheduling type:
   - By Day and Time
   - By Test Count
   - By Control
4. Select the **Add Schedule** button

The Add Schedules screen for that scheduling type will display.



NOTE: To edit an existing QC schedule, on the QC Scheduler screen, select the QC schedule to edit and then select the **Edit/View** button. Make the necessary edits and select the **Save** button.

*This procedure is continued on the following slides with the specific procedures for configuring each scheduling type.

Effective Date: 06-APR-2020 | HOOD05162003077519

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Atellica® Sample Handler Daily Maintenance PEP to Go

Effective Date: 3/12/2018 | HOOD05162002822815

Atellica® Sample Handler
Daily Maintenance

Daily Maintenance

- Perform Sample Handler (SH) Autocheck
- Perform Atellica Magline® Transport Autocheck

Effective Date: 3/12/2018 | HOOD05162002822815

Atellica® Sample Handler
Daily Maintenance

SIEMENS Healthineers

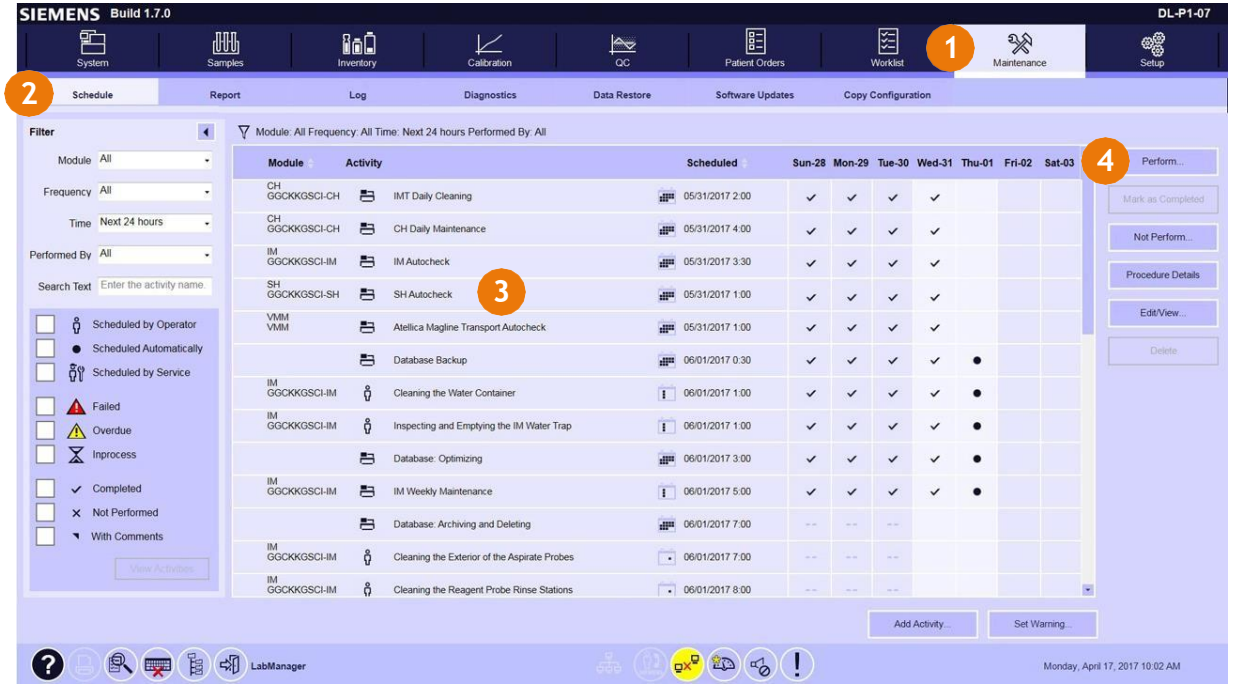
Performing Automated SH Autocheck Activity

The SH Autocheck is an automated maintenance activity that tests the health of various SH components.

The system alerts the operator 15 minutes before the scheduled activity begins. After the system initiates the SH Autocheck, the SH pauses sample processing until the autocheck completes in approximately 5 minutes.

The task will run automatically daily, but can be run manually if needed:

1. On the Command bar, select **Maintenance**
2. Select the **Schedule** tab
3. Select **SH Autocheck**
4. Select **Perform**
5. Wait for autocheck to complete



Effective Date: 3/12/2018 | HOOD05162002822815

Atellica® Sample Handler
Daily Maintenance

SIEMENS Healthineers

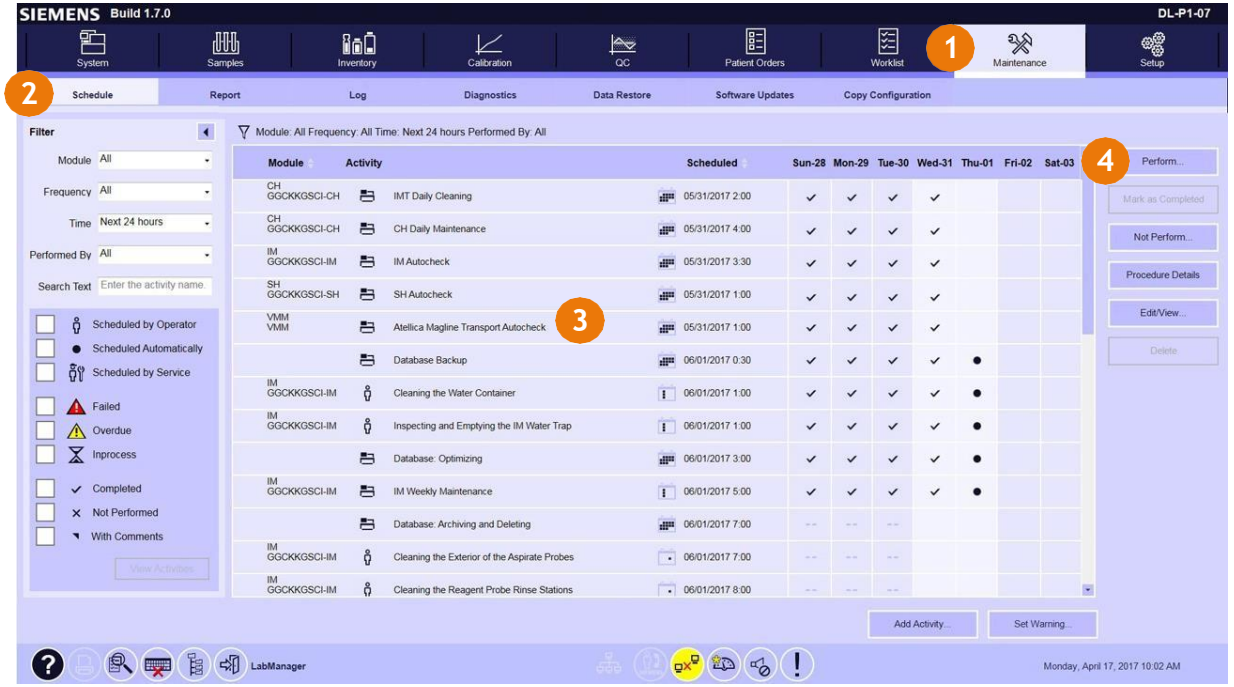
Performing Automated Atellica Magline® Transport Autocheck Activity

The Atellica Magline Transport Autocheck is an automated maintenance activity that tests the health of various Atellica Magline Transport components.

The system alerts the operator 15 minutes before the scheduled activity begins. After the system initiates the Atellica Magline Transport Autocheck, the Atellica Magline Transport pauses transporting samples until the autocheck completes in approximately 10 minutes.

The task will run automatically daily, but can be run manually if needed:

1. On the Command bar, select **Maintenance**
2. Select the **Schedule** tab
3. Select **Atellica Magline Transport Autocheck**
4. Select **Perform**
5. Wait for autocheck to complete



Effective Date: 3/12/2018 | HOOD05162002822815

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SIEMENS Healthineers

Atellica® CH Analyzer Daily Maintenance PEP to Go

Template Effective Date: 05/27/2019 | HOOD05162003010284
Effective Date: 8-MAR-2020 | HOOD05162003073784

Atellica® CH Analyzer
Daily Maintenance

Daily Maintenance

- Perform CH Daily Maintenance
- Perform IMT Daily Clean
- Inspect CH Washer Probes

Effective Date: 8-MAR-2020 | HOOD05162003073784

Atellica® CH Analyzer
Daily Maintenance

SIEMENS Healthineers

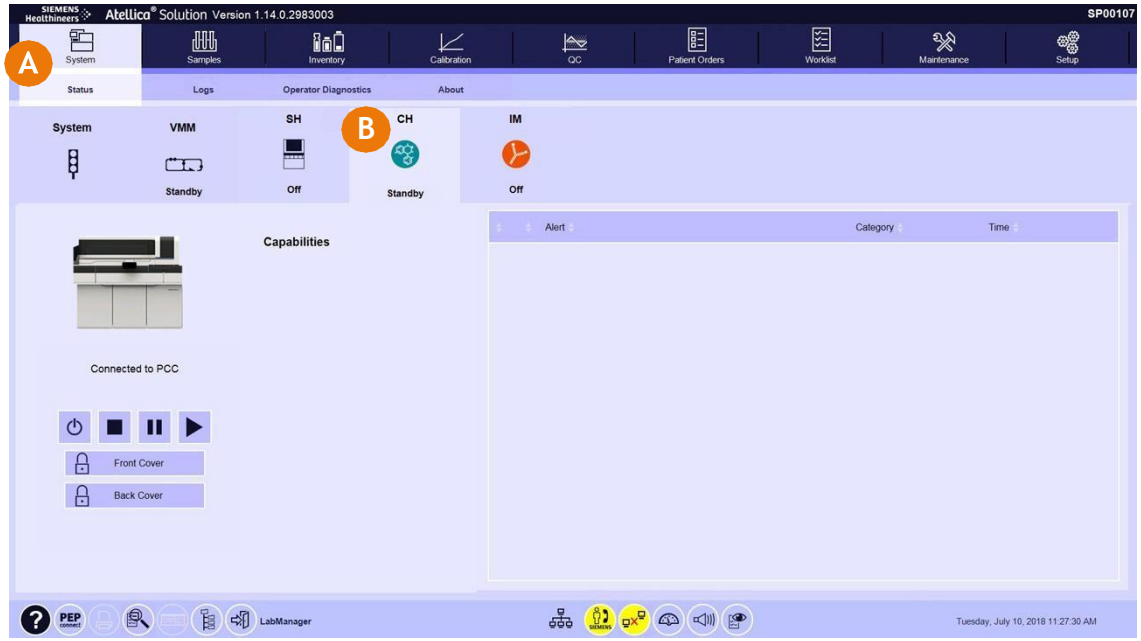
Performing CH Daily Maintenance

The automated CH Daily Maintenance task will run automatically daily but can be run manually if needed.

<u>To manually run CH Daily Maintenance:</u>

1. Ensure the analyzer is in Ready, Processing or Standby state:
   A. On the Command bar, select **System** > **Status**
   B. Review the status of the CH analyzer
2. Ensure the Water Bath Additive (WBA) and RPC4 are onboard by viewing **Inventory > Reagent Overview**

*This procedure is continued on the next slide.



Note: The WBA is loaded and unloaded onto the system the same as all other reagents. The WBA will automatically be kicked off of the system when the Onboard Stability and/or expiration date passes.

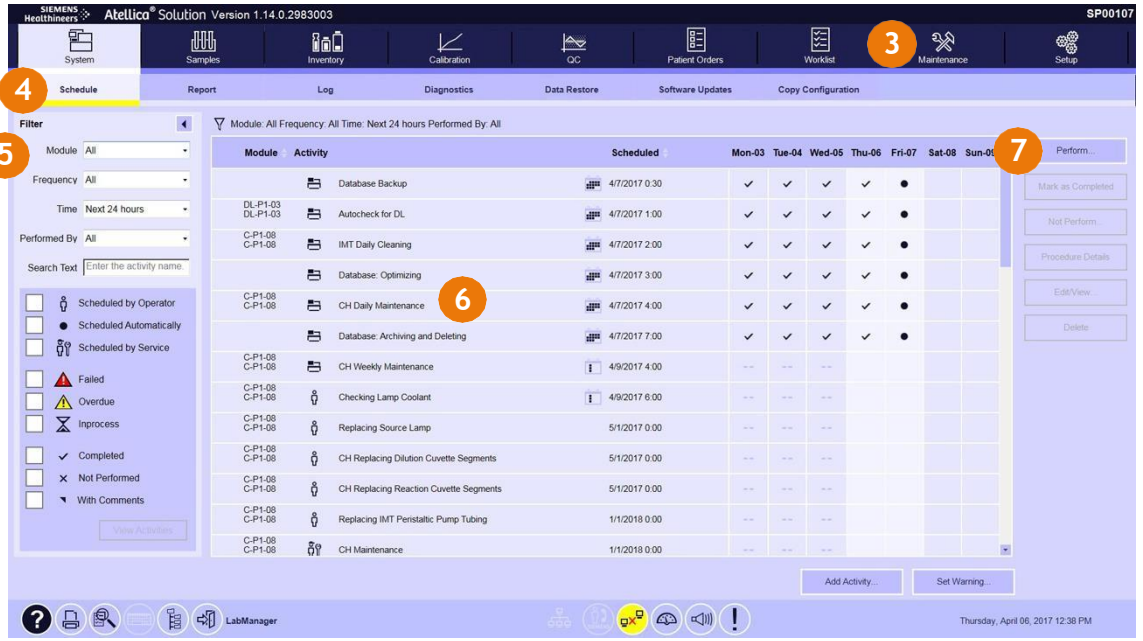
Effective Date: 8-MAR-2020 | HOOD05162003073784

Atellica® CH Analyzer
Daily Maintenance

SIEMENS Healthineers

Performing CH Daily Maintenance (continued)

3. At the Command bar, select **Maintenance**
4. Select the **Schedule** tab
5. In Module, select the CH analyzer from the dropdown menu
6. Select **CH Daily Maintenance**
7. Select **Perform**
8. Select **Yes**
9. Wait 12-40 minutes for maintenance to complete



Note: The analyzer checks for In-process samples prior to the start of this daily maintenance. The analyzer waits for these samples to process and then starts the activity.

Effective Date: 8-MAR-2020 | HOOD05162003073784

Atellica® CH Analyzer
Daily Maintenance

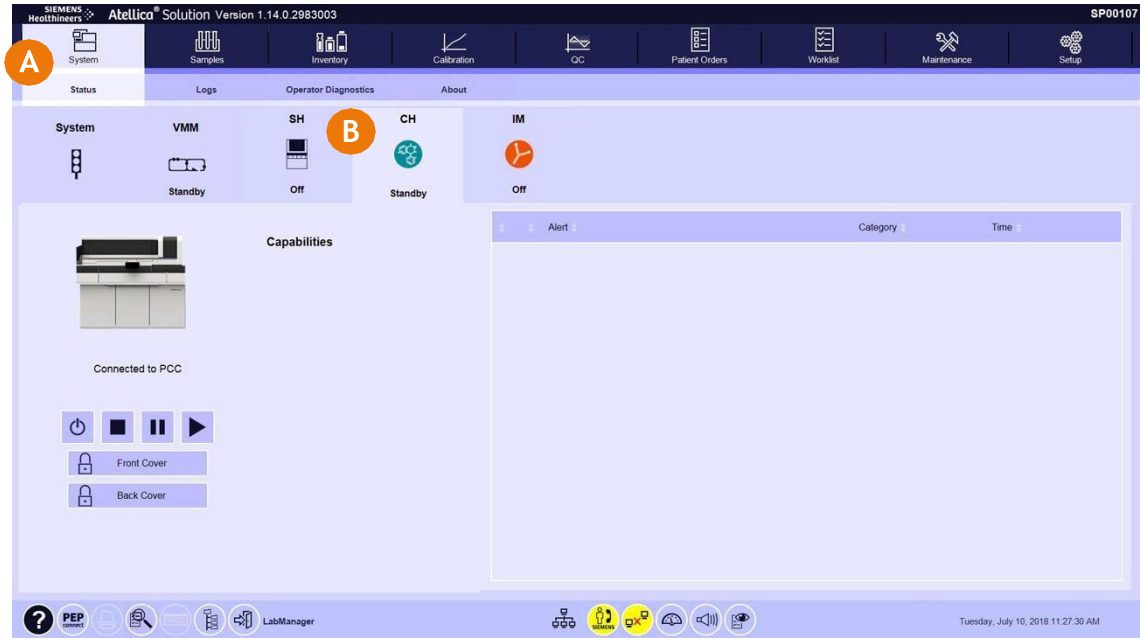
SIEMENS Healthineers

Performing IMT Daily Clean

The automated CH IMT Clean task will run automatically daily but can be run manually if needed.

<u>To manually run CH IMT Daily Clean:</u>

1. Ensure the analyzer is in Ready, Processing or Standby state:
   A. On the Command bar, select **System** > **Status**
   B. Review the status of the CH analyzer



*This procedure is continued on the next slide.

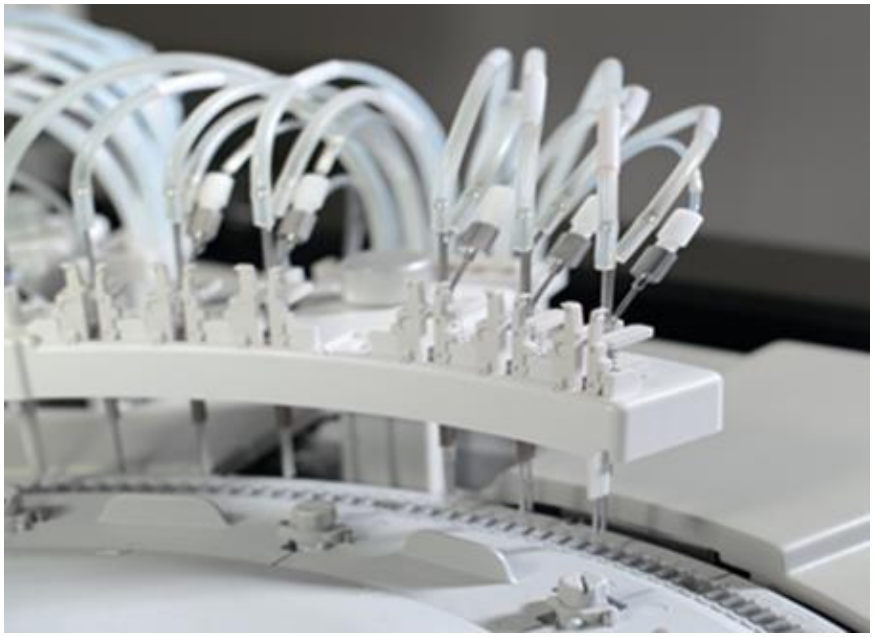
Effective Date: 8-MAR-2020 | HOOD05162003073784

Atellica® CH Analyzer
Daily Maintenance

SIEMENS Healthineers

Inspecting CH Washer Probes

1. Enter the system into Diagnostic State:
   A. Navigate to the CH Status screen: **System** > **Operator Diagnostics** > CH icon
   B. Select **Enter Diagnostics** > **Yes**
2. Under Subsystems, select **Inspect and Clean**
3. Select **Inspecting the Washer Probes**
4. Select **Perform** > **Yes**
5. Wait for the analyzer to prepare for maintenance. Lift open the CH back cover
6. Check the outside of each washer probe for residue buildup
7. Cover the cuvettes with a paper towel
8. Wipe the washer probes with a lint-free tissue dampened with special reagent water if residue is present
9. Remove the paper towel from the cuvettes. Close the CH back cover
10. Select **Continue** > **Close**
11. Select **Exit Diagnostics** > **Yes**
12. Mark **Inspecting the Washer Probes** as completed in the **Maintenance** > **Schedule** screen



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Atellica® CH Analyzer Weekly Maintenance PEP to Go

Template Effective Date: 05/27/2019 | HOOD05162003010284
Effective Date: 8-MAR-2020 | HOOD05162003073784

Atellica® CH Analyzer
Weekly Maintenance

Weekly Maintenance

- Perform CH Weekly Maintenance
- Check CH Lamp Coolant

Effective Date: 8-MAR-2020 | HOOD05162003073784

Atellica® CH Analyzer
Weekly Maintenance

SIEMENS Healthineers

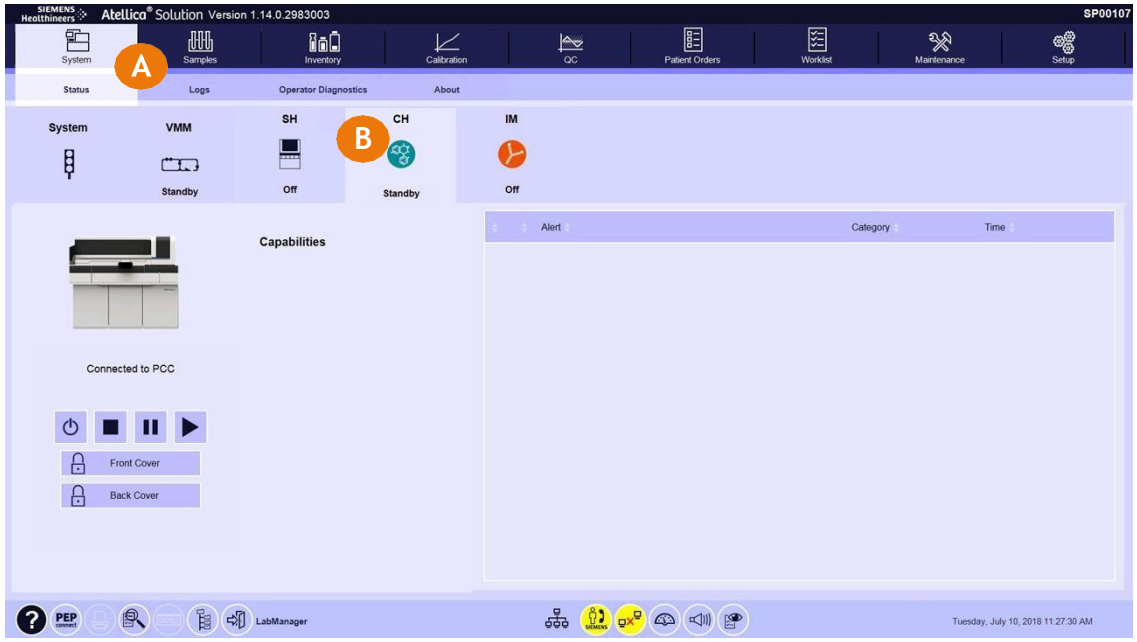
Performing CH Weekly Maintenance

The automated CH Weekly Maintenance task will run automatically weekly but can be run manually if needed.

<u>To manually run CH Weekly Maintenance:</u>

1. Ensure the analyzer is in Ready, Processing or Standby state:
   A. On the Command bar, select **System** > **Status**
   B. Review the status of the CH analyzer
2. Ensure the Water Bath Additive (WBA) is onboard by viewing **Inventory > Reagent Overview**

*This procedure is continued on the next slide.



Note: The CH Daily Maintenance is not required on the same scheduled day the analyzer performs the CH Weekly Maintenance.

Note: The WBA is loaded and unloaded onto the system the same as all other reagents. The WBA will automatically be kicked off of the system when the Onboard Stability and/or expiration date passes.

Effective Date: 8-MAR-2020 | HOOD05162003073784

Atellica® CH Analyzer
Weekly Maintenance

SIEMENS Healthineers

Checking CH Lamp Coolant

1. Enter the system into Diagnostic State:
   A. Navigate to the CH Status screen: **System** > **Operator Diagnostics** > CH icon
   B. Select **Enter Diagnostics** > **Yes**
2. Wait for the analyzer to enter diagnostic state
3. Under Subsystems, select **Lamp**
4. Select **Checking Lamp Coolant > Perform** > **Yes**
5. Wait for the analyzer to prepare for maintenance. Lift open the CH front cover
6. Locate the CH lamp coolant directly behind the IMT fluids
7. If the lamp coolant fluid level is not visible, replenish the fluid:
   A. Unscrew the small screw cap at the top of the reservoir and set aside
   B. Using the spout on the lamp coolant bottle, replenish the lamp coolant until the fluid level is approximately 1–2 cm from the lamp coolant reservoir cover
   C. Replace the small screw cap

*This procedure is continued on the next slide.

Effective Date: 8-MAR-2020 | HOOD05162003073784

Atellica® CH Analyzer
Weekly Maintenance

Checking CH Lamp Coolant (continued)

8. Close the CH front cover
9. Select **Continue** > **Close**
10. Select **Exit Diagnostics** > **Yes**
11. Mark **Checking Lamp Coolant** as completed in the **Maintenance** > **Schedule** screen

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Atellica® CH Analyzer Monthly Maintenance PEP to Go

Template Effective Date: 05/27/2019 | HOOD05162003010284
Effective Date: 8-MAR-2020 | HOOD05162003073784

Atellica® CH Analyzer Maintenance

Monthly Maintenance

- Clean CH Fan Filters
- Clean and Inspect the CH Probes and Mixer Impellers
- Clean and Inspect the CH Probe Wash Stations

Effective Date: 8-MAR-2020 | HOOD05162003073784

Atellica® CH Analyzer
Monthly Maintenance

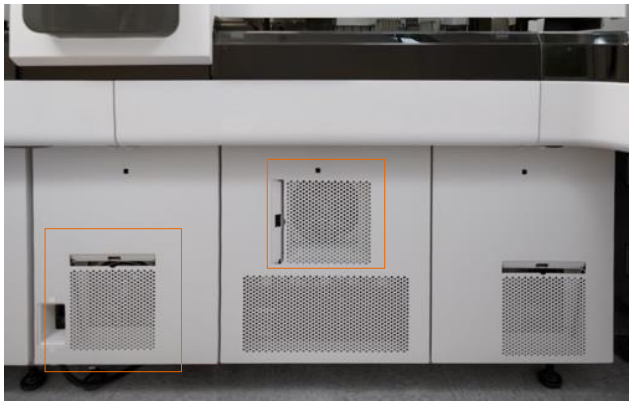
SIEMENS Healthineers

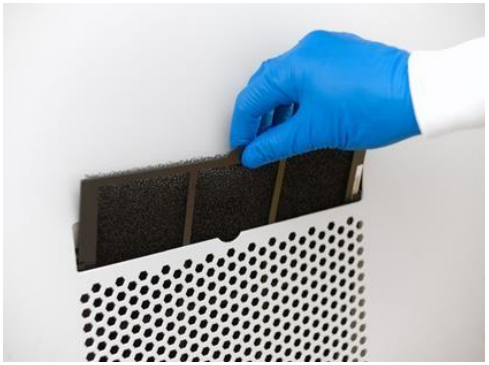
Clean the CH Fan Filters

The CH Analyzer has 1 filter located inside the left front door and 2 filters on the back left and center panels. Clean and inspect the fan filters monthly to ensure they are free from dust, dirt or debris.

1. Grasp the top or side of each fan filter and pull it up and out of the slot
2. Inspect and discard damaged filters
3. Rinse the filter with tap water
4. Tap the filter to remove excess water and let it air dry
5. Reinstall a spare fan filter with the plastic grid facing away from the panel or door
6. Mark **Cleaning the CH Fan Filter** as completed in the **Maintenance > Schedule** screen
7. If original filter discarded, order a replacement filter

Note: The customer parts kit includes spare fan filters. Use a spare filter while the cleaned filter dries. When dry, place the cleaned filter in the customer parts kit for future use.





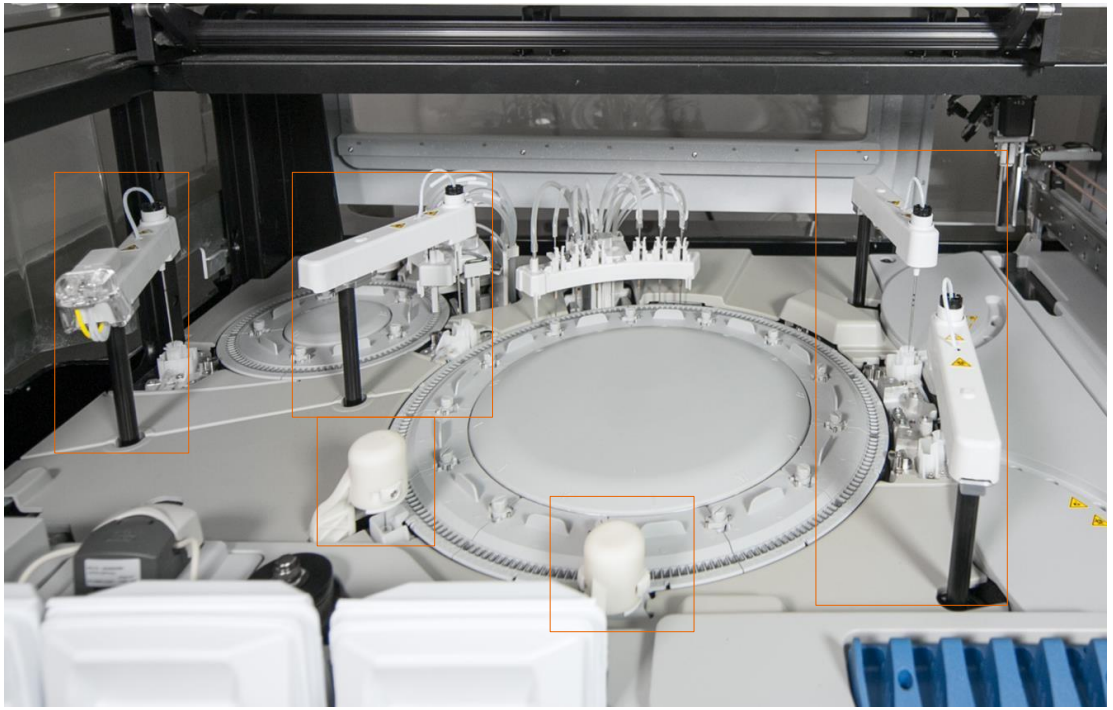
Effective Date: 8-MAR-2020 | HOOD05162003073784

Atellica® CH Analyzer
Monthly Maintenance

SIEMENS Healthineers

Cleaning and Inspecting CH Probes and Mixer Impellers

1. Enter the system into Diagnostic State:
   A. Navigate to the CH Status screen: **System** > **Operator Diagnostics** > CH icon
   B. Select **Enter Diagnostics** > **Yes**
2. Wait for analyzer to enter diagnostic state
3. Under Subsystems, select **Inspect and Clean**
4. Select **Cleaning and Inspecting the CH Probes and Mixer Impellers**
5. Select **Perform** > **Yes**
6. Wait for analyzer to prepare for maintenance. Lift open the CH front and back covers
7. To protect the cuvettes from debris, cover with paper towel
8. Inspect the exterior of each impeller/probe
9. Wipe off any debris on each impeller or probe with an alcohol pad or lint-free tissue dampened with alcohol



Note: Do not touch the probe tip when working with the probes. The probe tip is sharp and can cause bodily harm.

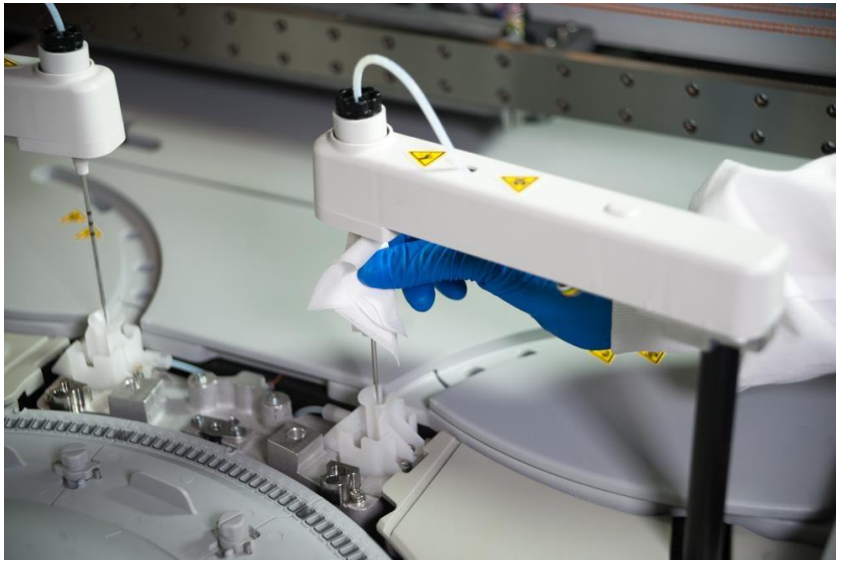
*Procedure is continued on the next slide.

Effective Date: 8-MAR-2020 | HOOD05162003073784

Atellica® CH Analyzer
Monthly Maintenance

Cleaning and Inspecting CH Probes and Mixer Impellers (continued)

10. Remove and discard the paper towel from the cuvettes
11. Close the CH cover
12. Select **Continue** > **Close**
13. Select **Exit Diagnostics** > **Yes**
14. Mark **Cleaning and Inspecting CH Probes and Mixer Impellers** as complete in the **Maintenance > Schedule** screen



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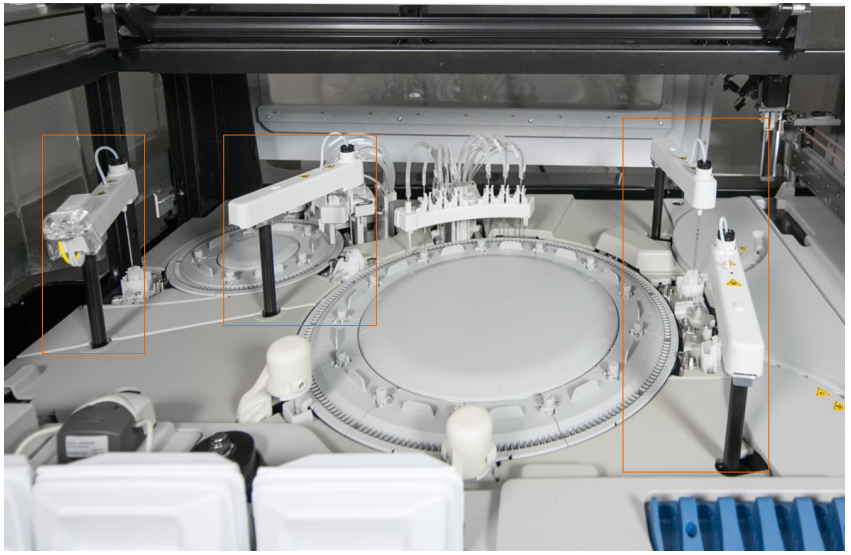
Atellica® CH Analyzer
Monthly Maintenance

SIEMENS Healthineers

Cleaning and Inspecting the CH Probe Wash Stations

1. Enter the system into Diagnostic State:
   A. Navigate to the CH Status screen: **System** > **Operator Diagnostics** > CH icon
   B. Select **Enter Diagnostics** > **Yes**
2. Wait for analyzer to enter diagnostic state
3. Under Subsystems, select **Inspect and Clean**
4. Select **Cleaning and Inspecting the CH Probe Wash Stations > Perform** > **Yes**
5. Wait for analyzer to prepare for maintenance. Open the CH front and back covers
6. To protect the cuvettes from debris, cover with paper towel
7. Inspect each probe wash station
8. If appropriate, wipe off any debris on the wash station with an alcohol pad or lint-free tissue dampened with alcohol
9. Remove the paper towel from the cuvettes and discard
10. Close the CH covers
11. Select **Continue** > **Close**
12. Select **Exit Diagnostics** > **Yes**
13. Mark **Cleaning and Inspecting the Probe Wash Stations** as completed in the **Maintenance > Schedule** screen



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Atellica® IM Analyzer Daily Maintenance PEP to Go

Effective Date: 10/29/2018 | HOOD05162002956766

Atellica® IM Analyzer
Daily Maintenance

Daily Maintenance

- Perform Automated IM Daily Maintenance
- Perform IM Autocheck

Effective Date: 10/29/2018 | HOOD05162002956766

Atellica® IM Analyzer
Daily Maintenance

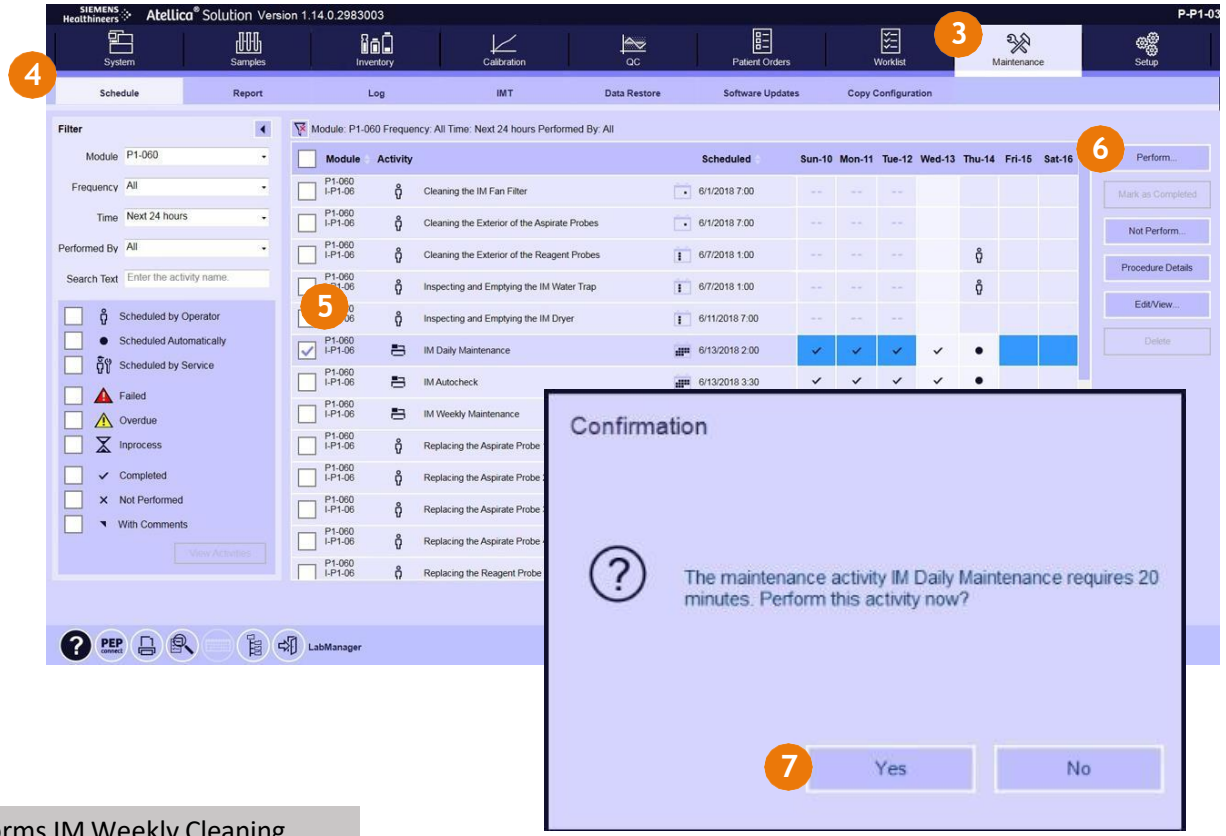
SIEMENS Healthineers

Performing Automated IM Daily Maintenance

IM Daily Maintenance contains automated maintenance activities. The system performs a series of cleaning and rinsing operations to decontaminate the analyzer at configured times or on demand. The operator can configure the time this is performed.

To perform the Daily Maintenance activity manually:

1. Ensure the analyzer is in ready or standby state
2. Ensure cuvettes and IM Cleaner are loaded on the system
3. On the Command bar, select **Maintenance**
4. Select the **Schedule** tab
5. Select **IM Daily Maintenance**
6. Select **Perform**
7. Select **Yes**
8. Wait for maintenance to complete



Note: IM Daily Maintenance is not required when the system performs IM Weekly Cleaning.

Note: If the cleaning procedure stops before it completes, the system logs an error and does not allow processing samples until it completes the cleaning procedure or completes a rinse procedure.

Effective Date: 10/29/2018 | HOOD05162002956766

Atellica® IM Analyzer
Daily Maintenance

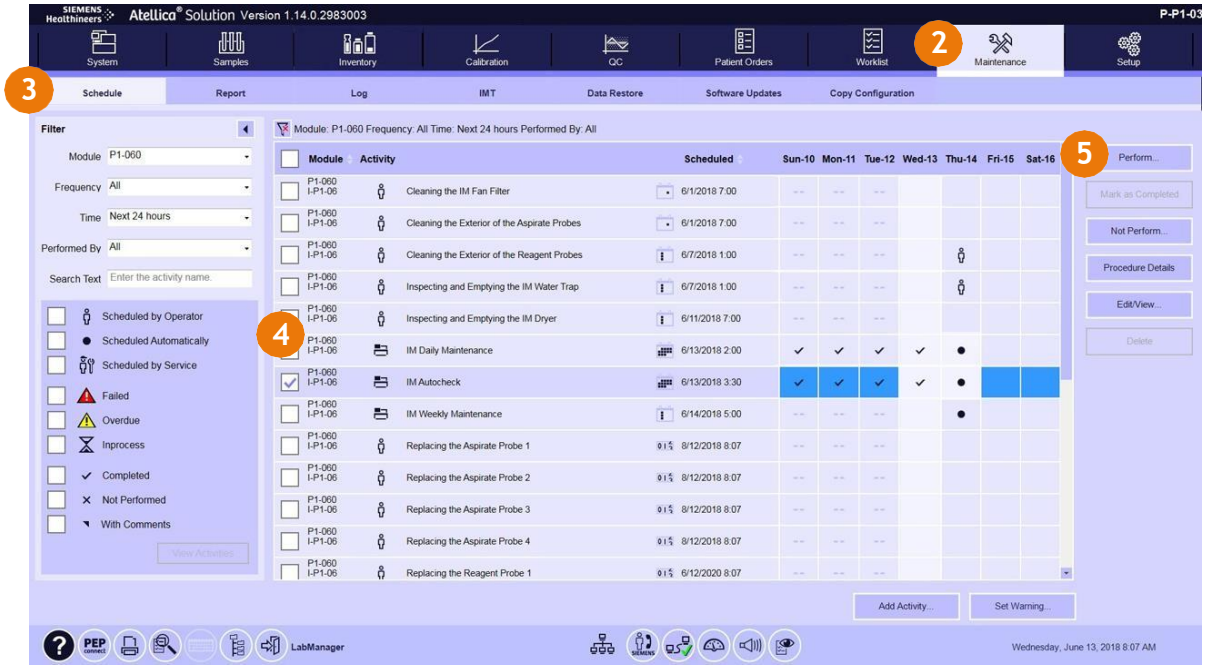
SIEMENS Healthineers

Performing Automated IM Autocheck Activity

IM Autocheck performs a self diagnostics maintenance when the operator selects it. The IM Analyzer pauses sample processing until the autocheck completes in approximately 10 minutes. The system automatically performs the autocheck daily at a specified time or it can be manually performed on demand. The system alerts the operator 15 minutes before the scheduled activity begins.

To perform the IM Autocheck activity manually:

1. Ensure the analyzer is in ready or standby state
2. On the Command bar, select **Maintenance**
3. Select the **Schedule** tab
4. Select **IM Autocheck**
5. Select **Perform**
6. Wait for autocheck to complete



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Atellica® IM Analyzer Weekly Maintenance PEP to Go

Effective Date: 10/29/2018 | HOOD05162002956766

Atellica® IM Analyzer Maintenance

SIEMENS Healthineers

Weekly Maintenance

- Perform Automated IM Weekly Maintenance
- Clean the Exterior of the Reagent Probes
- Inspect and Empty the IM Water Trap
- Inspect and Empty the IM Dryer

Effective Date: 10/29/2018 | HOOD05162002956766

Atellica® IM Analyzer
Weekly Maintenance

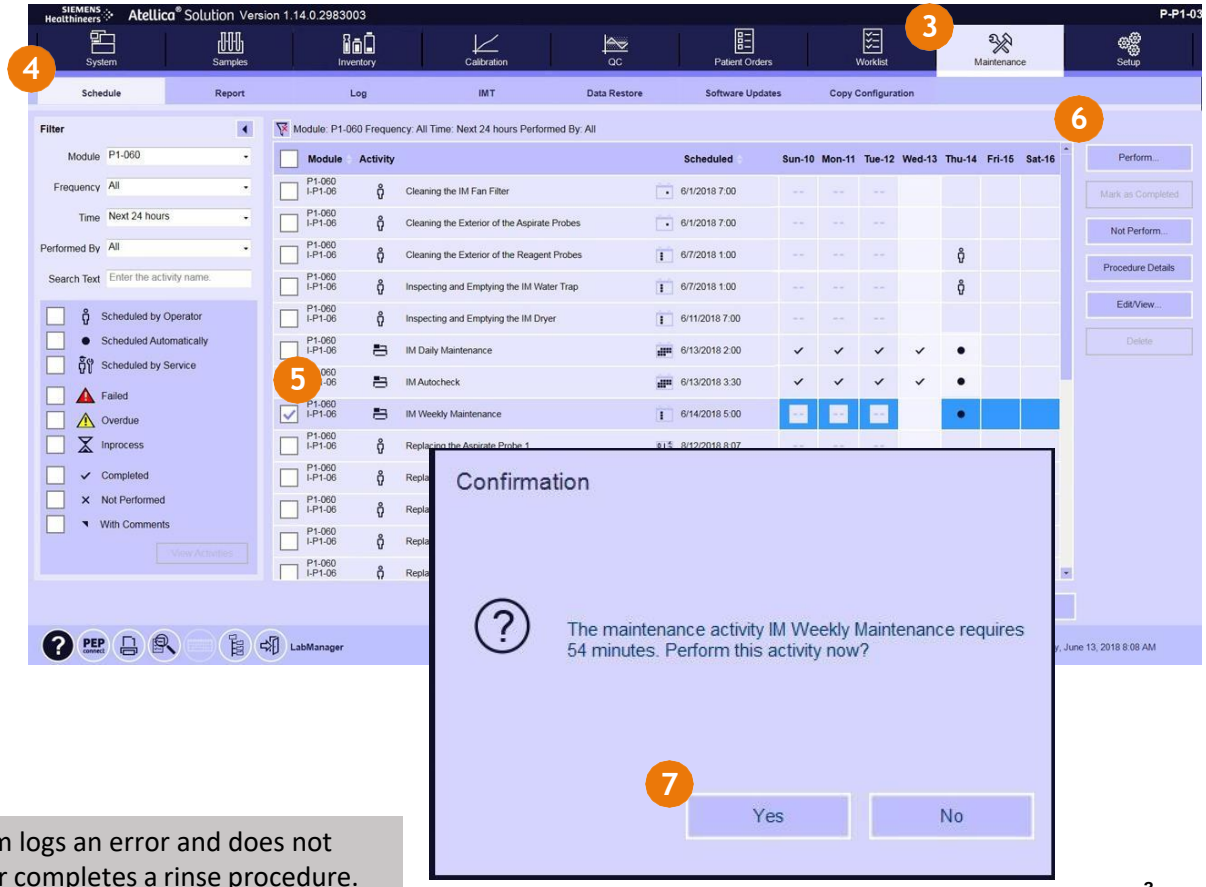
SIEMENS Healthineers

Performing Automated IM Weekly Maintenance

The IM Analyzer has an automated weekly maintenance that includes reagent, wash block, and wash lines cleaning. The analyzer performs a series of cleaning and rinsing operations to decontaminate the analyzer at configured times or on demand.

To perform the Weekly Maintenance activity manually:

1. Ensure the analyzer is in ready or standby state
2. Ensure cuvettes and IM Cleaner are loaded on the system
3. On the Command bar, select **Maintenance**
4. Select the **Schedule** tab
5. Select **IM Weekly Maintenance**
6. Select **Perform**
7. Select **Yes**
8. Wait for maintenance to complete



Note: If the cleaning procedure stops before it completes, the system logs an error and does not allow processing samples until it completes the cleaning procedure or completes a rinse procedure.

Effective Date: 10/29/2018 | HOOD05162002956766

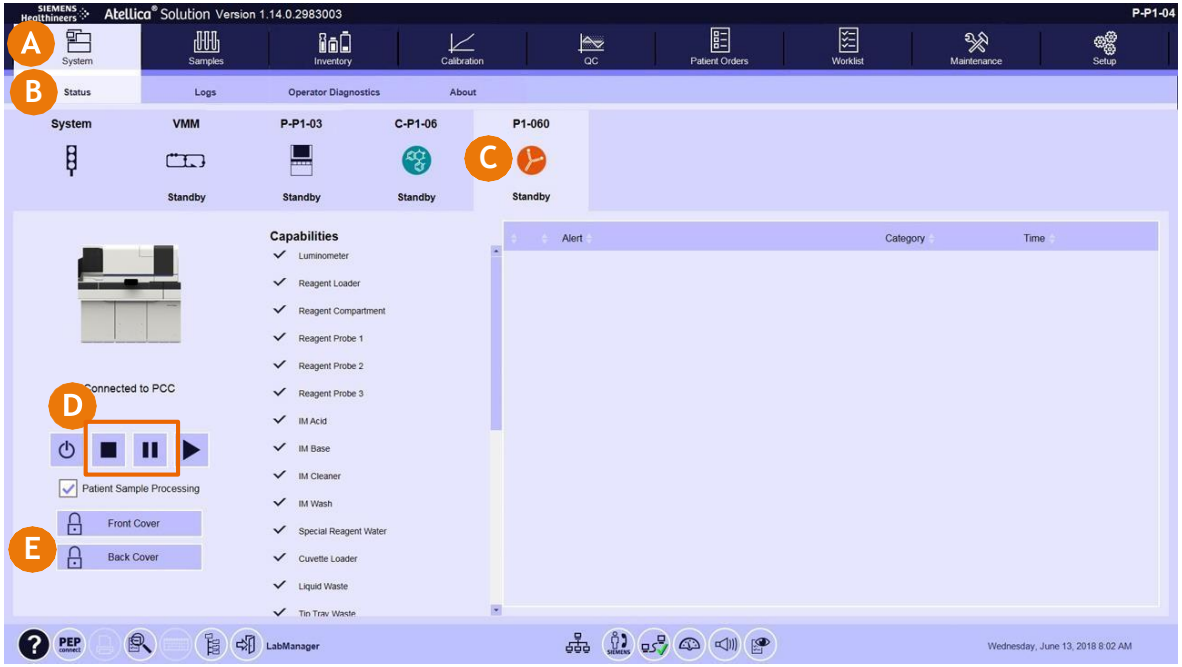
Atellica® IM Analyzer
Weekly Maintenance

SIEMENS Healthineers

Cleaning the Exterior of the Reagent Probes

1. Unlock the IM Analyzer back cover:
   A. On the Command bar, select **System**
   B. Select the **Status** tab
   C. Select the IM analyzer
   D. Select to pause or stop the analyzer
   E. Select **Back Cover** to unlock the back cover
2. Lift open the IM back cover

Note: Do not remove the reagent probes.



* This procedure is continued on the next slide.

Effective Date: 10/29/2018 | HOOD05162002956766

Atellica® IM Analyzer
Weekly Maintenance

SIEMENS Healthineers

Cleaning the Exterior of the Reagent Probes (continued)

3. Clean the visible portion of the probe using a gentle downward motion with lint-free tissues or gauze moistened with IM Cleaner
4. Rinse the probe using a gentle downward motion with lint-free tissues or gauze saturated with special reagent water

Note: Refer to Operator's Guide for special reagent water criteria.

5. Repeat the rinsing step 3–5 times with clean lint-free tissues or gauze
6. Repeat with the remaining probes
7. Close the IM analyzer back cover
8. On the command bar, select **System** > **Status**, then select the IM analyzer
9. Select ▶ to bring the analyzer back to Ready state
10. Mark the Cleaning the Exterior of Reagent Probes activity as completed by selecting > **Maintenance** > **Schedule** > select the **Cleaning the Exterior of Reagent Probes** activity > select **Mark as Completed** button

Note: Do not remove the reagent probes. Do not touch the probe tip when working with the probes. The probe tip is sharp and can cause bodily harm.

Effective Date: 10/29/2018 | HOOD05162002956766

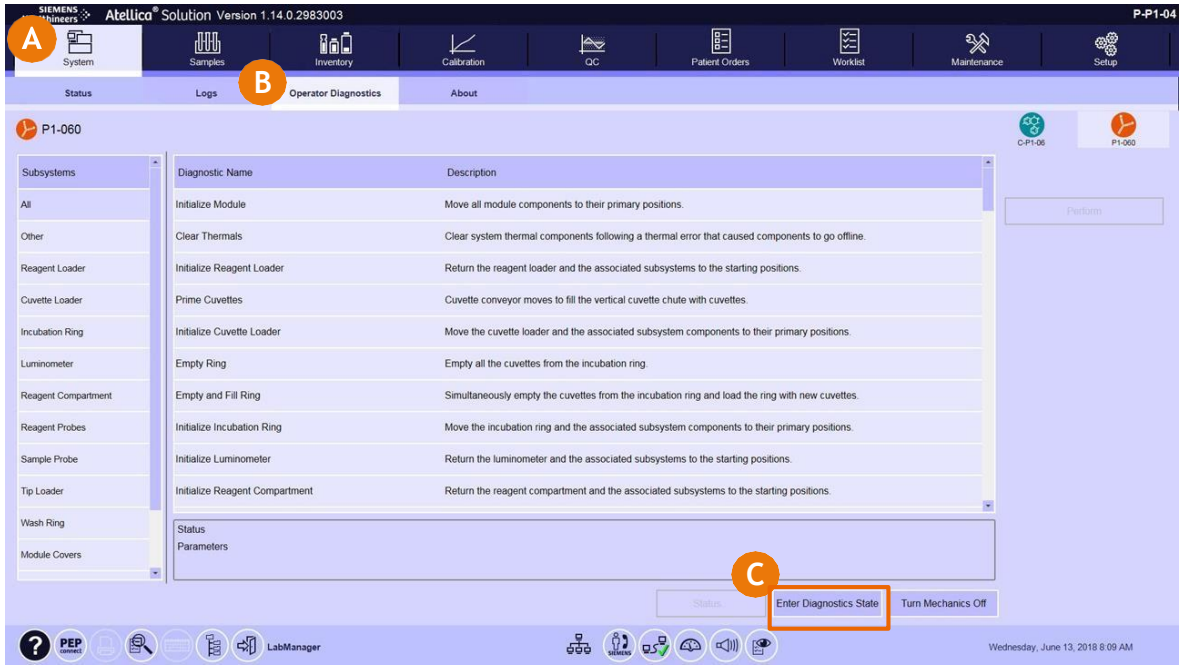
Atellica® IM Analyzer
Weekly Maintenance

SIEMENS Healthineers

Inspecting and Emptying the IM Water Trap

Inspect the IM water trap weekly for condensation. If the water trap fills with condensation, the system can have vacuum problems. If no condensation is visible, the operator can mark the task as completed.

1. Put the IM Analyzer in the Diagnostic State:
   A. On the Command bar, select **System**
   B. Select the **Operator Diagnostics** tab
   C. Select **Enter Diagnostics State**



Note: Do not remove the water trap container when the system is in the Processing or Maintenance state. Removing the container in these states can cause a low vacuum error and cause the system to stop sampling and cancel the tests in process.

* This procedure is continued on the next slide.

Effective Date: 10/29/2018 | HOOD05162002956766

Atellica® IM Analyzer
Weekly Maintenance

SIEMENS Healthineers

Inspecting and Emptying the IM Water Trap (continued)

2. Open the fluidics compartment door

Note: Do not remove the water trap container when the system is in the Processing or Maintenance state. Removing the container in these states can cause a low vacuum error and cause the system to stop sampling and cancel the tests in process.

Note: Do not drop the glass water trap container. If dropped, the container may break.

* This procedure is continued on the next slide.

Effective Date: 10/29/2018 | HOOD05162002956766

Atellica® IM Analyzer
Weekly Maintenance

SIEMENS Healthineers

Inspecting and Emptying the IM Water Trap (continued)

3. Remove the water trap from the bracket
4. Unscrew the water trap

Note: The liquid in the water trap is waste condensation.

5. Dispose of the liquid from the water trap per laboratory protocol. If no condensation is visible, the operator can mark the task as completed
6. Ensure the float ball moves freely in the water trap
7. Ensure the rubber gasket is not damaged or missing from the water trap lid. If the gasket is cracked, damaged, or missing, replace with gasket
8. Clean the rubber gasket and lid with a lint-free tissue moistened with water
9. Replace the water trap lid. Turn the lid one-eighth of a turn past initial resistance to ensure the water trap lid seals properly
11. Place the water trap back in the bracket
12. Close the fluidics compartment door
13. Select **System** > **Operator Diagnostics** > **Exit Diagnostic State**
14. Mark the Inspecting and Emptying the IM Water Trap activity as completed by selecting > **Maintenance** > **Schedule** > select the **Emptying the IM Water Trap** activity > select **Mark as Completed** button

Effective Date: 10/29/2018 | HOOD05162002956766

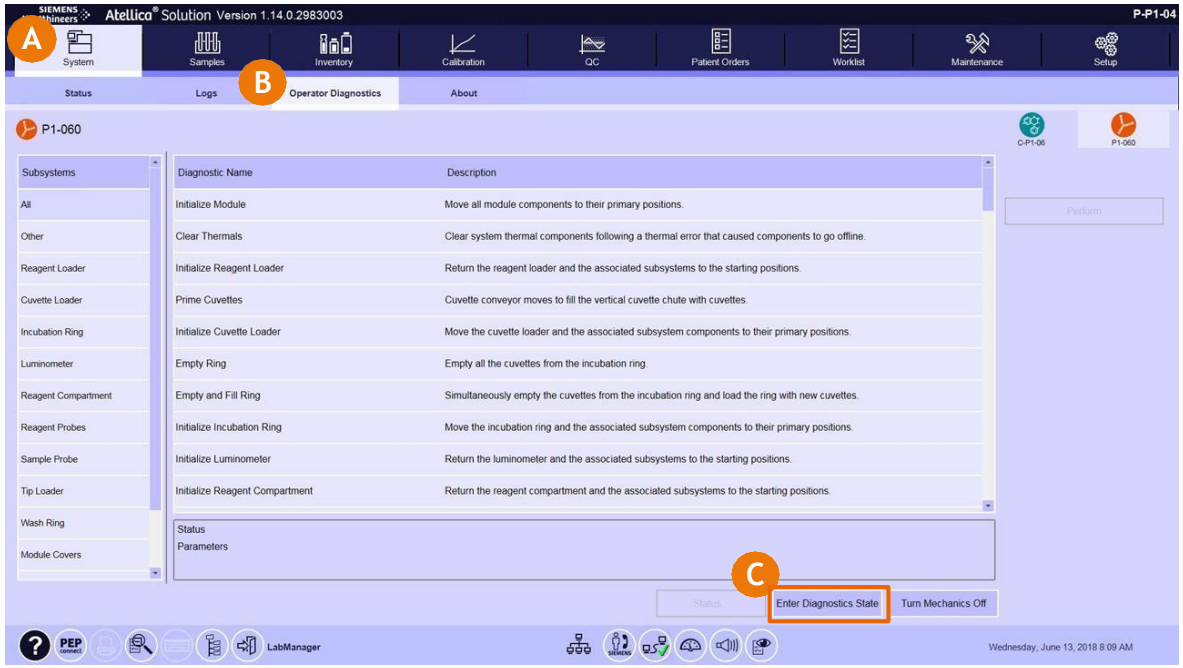
Atellica® IM Analyzer
Weekly Maintenance

SIEMENS Healthineers

Inspecting and Emptying the IM Dryer

Inspect the IM dryer weekly for condensation. Do not allow condensation in the IM dryer. If the dryer fills with condensation, the analyzer can have vacuum problems. Empty the IM dryer to remove the condensation. If no condensation is visible, the operator can mark the task as completed.

1. Put the IM Analyzer in the Diagnostic State to power off the blower:
   A. On the Command bar, select **System**
   B. Select the **Operator Diagnostics** tab
   C. Select **Enter Diagnostics State**



Note: Do not remove the dryer container when the system is in the Processing or Maintenance state. Removing the container in these states can cause a low vacuum error and cause the system to stop sampling and cancel the tests in process.

Note: Do not drop the glass water trap container. If dropped, the container may break.

* This procedure is continued on the next slide.

Effective Date: 10/29/2018 | HOOD05162002956766

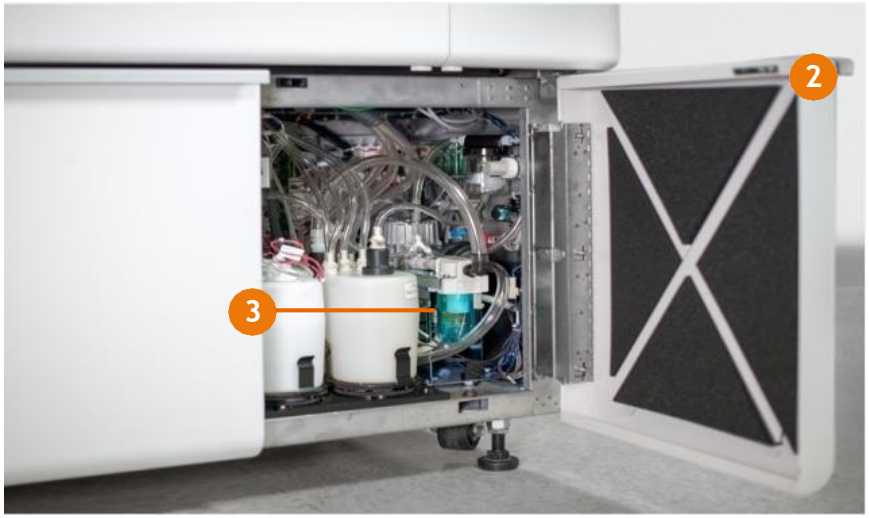
Atellica® IM Analyzer
Weekly Maintenance

Inspecting and Emptying the IM Dryer (continued)

2. Open the fluidics compartment door
3. Locate the dryer below the water trap

Note: If there is liquid present inside the dryer continue with the following steps to remove the liquid. If there is no liquid present, mark the maintenance activity as completed from the Maintenance Schedule screen.

* This procedure is continued on the next slide.



Effective Date: 10/29/2018 | HOOD05162002956766

Atellica® IM Analyzer
Weekly Maintenance

Inspecting and Emptying the IM Dryer (continued)

4. Remove the dryer from the system:
   A. Pull down and hold the lever on the side of the dryer
   B. While holding down the lever, turn the dryer jar to bring the lever to the front
   C. Pull the dryer jar down and away from the top

Note: The liquid in the dryer is waste condensation.

5. Remove the insert and dispose of any liquid from the dryer per laboratory protocol

* This procedure is continued on the next slide.

Effective Date: 10/29/2018 | HOOD05162002956766

Atellica® IM Analyzer
Weekly Maintenance

Inspecting and Emptying the IM Dryer (continued)

6. If the gasket is cracked, damaged, or missing, replace with gasket
7. Replace the insert
8. Insert the dryer jar into the dryer top. Turn the dryer jar until it clicks in place
9. Close the fluidics compartment door
10. Select **System** > **Operator Diagnostics** > **Exit Diagnostic State**
11. Mark the Inspecting and Emptying the IM Dryer activity as completed by selecting: **Maintenance** > **Schedule** > **Inspecting and Emptying the IM Dryer Maintenance** > **Mark as Completed**

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SIEMENS Healthineers

Atellica® IM Analyzer Monthly Maintenance PEP to Go

Effective Date: 10/29/2018 | HOOD05162002956766

Atellica® IM Analyzer
Monthly Maintenance

Monthly Maintenance

- Clean the Exterior of the Aspirate Probes
- Clean the IM Fan Filters

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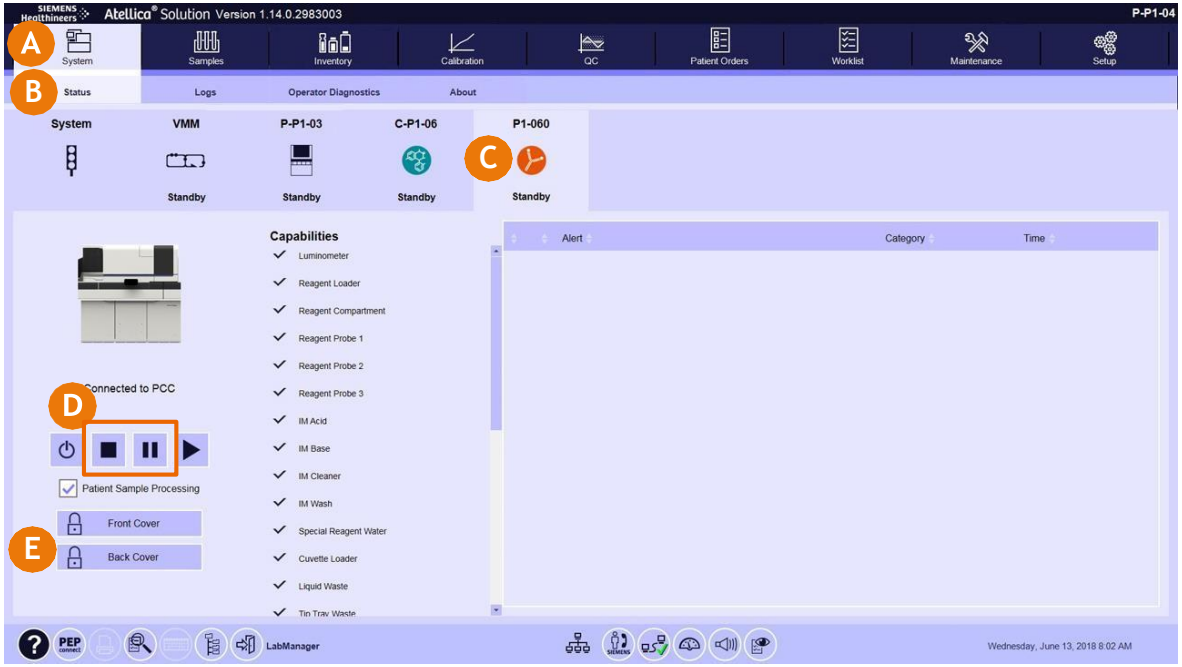
Cleaning the Exterior of the Aspirate Probes

1. Unlock the IM analyzer front cover:
   A. On the Command bar, select **System**
   B. Select the **Status** tab
   C. Select the IM analyzer
   D. Select to pause or stop the analyzer
   E. Select **Front Cover** to unlock the front cover
2. Lift open the IM front cover



* This procedure is continued on the next slide.

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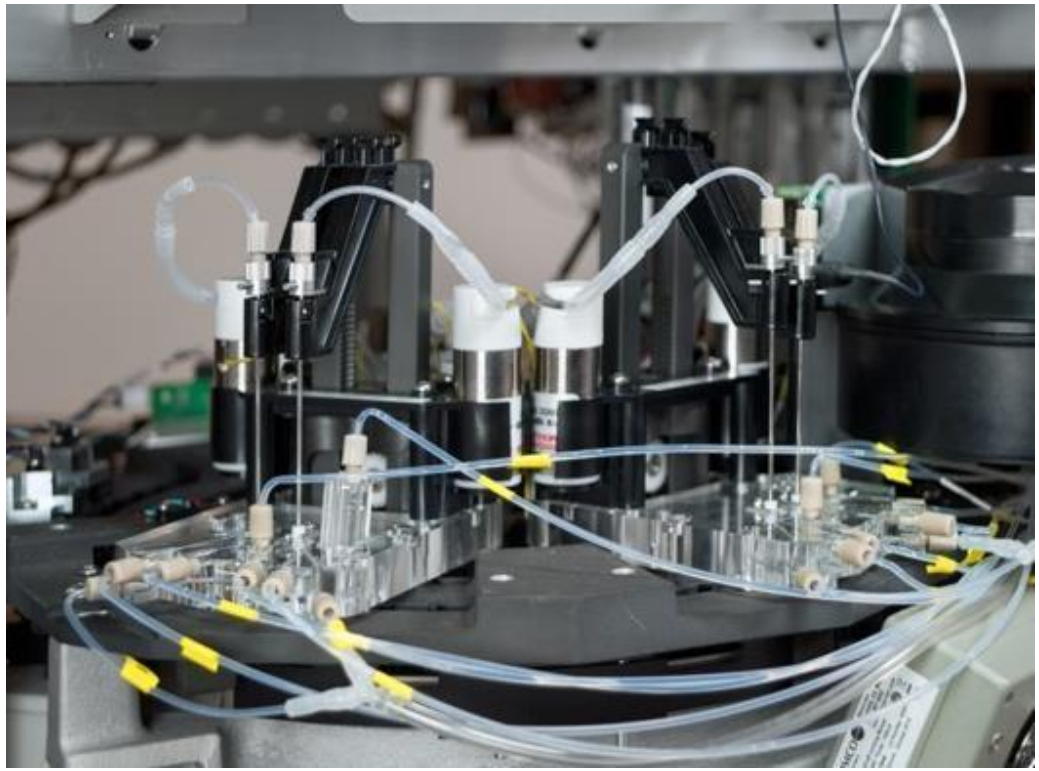
Cleaning the Exterior of the Aspirate Probes (continued)

3. Carefully lift the aspirate probe arms to the highest position

Note: Do not remove the aspirate probes. Do not touch the probe tip when working with the probes. Do not bend the probe.

4. Clean the visible portion of each probe using a gentle downward motion with lint-free tissues moistened with IM Cleaner
5. Wipe each probe with lint-free tissue saturated with special reagent water, using a gentle downward motion
6. Repeat step five 3-5 times with clean lint-free tissues
7. Close the IM front cover
8. On the command bar, select **System** > **Status**, then select the IM analyzer
9. To restart the analyzer, select ▶
10. Mark the Cleaning the Exterior of the Aspirate Probes activity as completed by selecting: **Maintenance** > **Schedule** > **Cleaning the Exterior of the Aspirate Probes** > **Mark as Completed**



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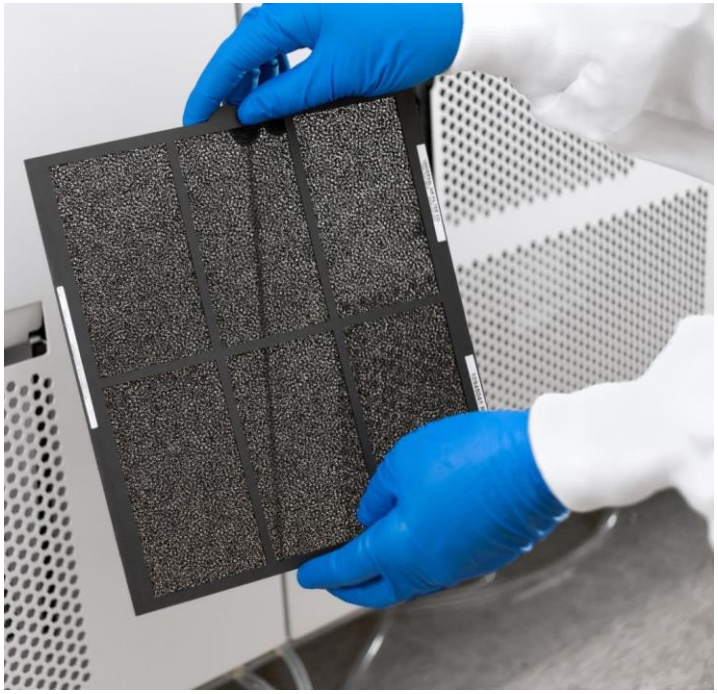
Cleaning the IM Fan Filter

The IM analyzer has 1 filter located on the back center panel.

1. Grasp the left side of the fan filter and pull it out of the slot
2. Inspect and discard damaged filters
3. Rinse the filter with tap water
4. Tap the filter to remove excess water and let it air dry

Note: The customer parts kit includes spare fan filters. Use a spare filter while the cleaned filter dries. Once dry, place the cleaned filter in the customer parts kit for future use.

5. Reinstall a spare fan filter with the plastic grid facing away from the panel
6. If the original filter was damaged or discarded, order a replacement filter
7. Mark the Cleaning the IM Fan Filter activity as completed by selecting: **Maintenance** > **Schedule** > **Cleaning the IM Fan Filter**> **Mark as Completed**



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Please note that the learning material is for training purposes only!

For the proper use of the software or hardware, please always use the Operator Manual or Instructions for Use (hereinafter collectively “Operator Manual”) issued by Siemens Healthineers. This material is to be used as training material only and shall by no means substitute the Operator Manual. Any material used in this training will not be updated on a regular basis and does not necessarily reflect the latest version of the software and hardware available at the time of the training.

The Operator's Manual shall be used as your main reference, in particular for relevant safety information like warnings and cautions.

Note: Some functions shown in this material are optional and might not be part of your system.

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All names and data of patients, parameters and configuration dependent designations are fictional and examples only.

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