SIEMENS

ADVIA Centaur® XPT System
PEP to Go

Answers for life.

Table of Contents

Hardware Overview

A. **Sample Tip Loader**

B. **Cuvette Loader**

C. **Sample Entry Queue**

D. **STAT Entry**

E. **Sample Exit Queue**

F. **Ancillary Reagent Entry**

   25 positions in Ancillary Compartment

G. **Cleaning Solution and Sample Tip Waste**

H. **System Fluids**

   Acid, Base, and Wash 1

I. **Tip Tray Waste and Cuvette Waste**

J. **Waste/Water Drawer**

K. **Primary Reagent Compartment**

   30 positions

Software Overview
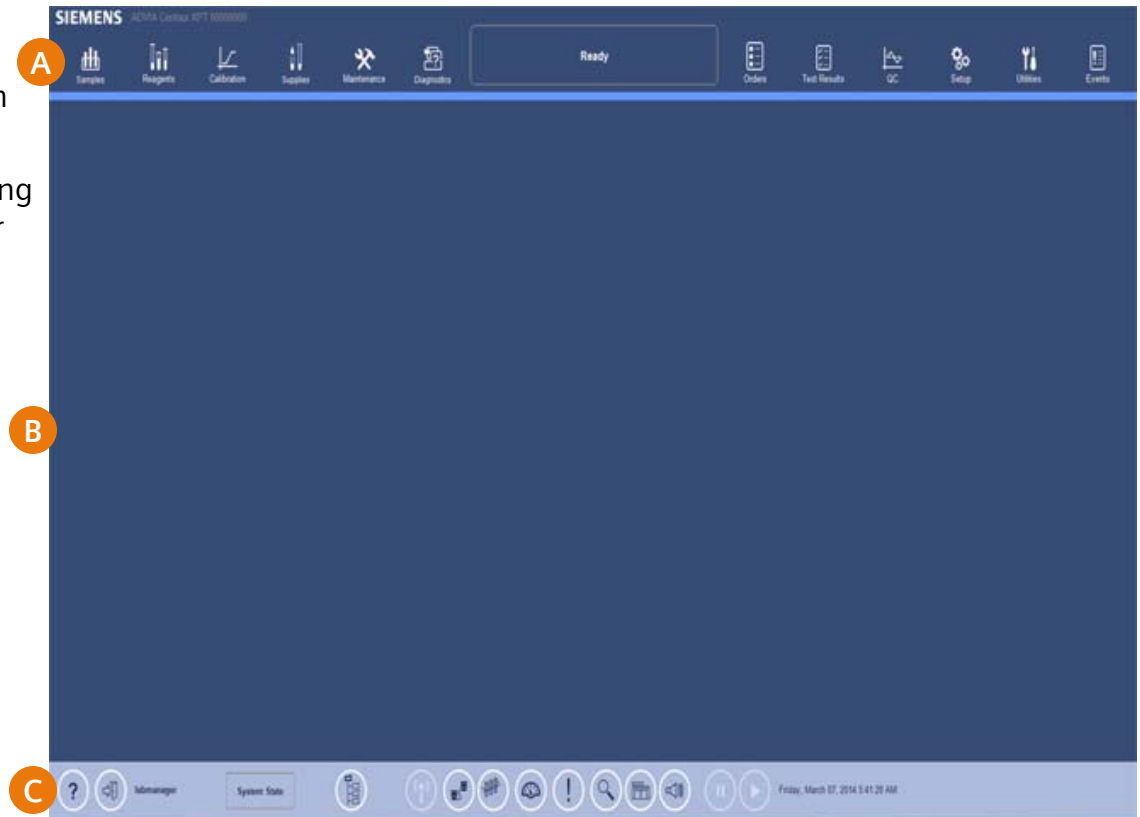
A. Command Bar
Provides access to all system functions and information required to operate the system

B. Workspace
Displays a set of tabs or a window containing tasks or information when a Command Bar button is selected

C. Status bar
Provides access to windows that display information about the entire system

Software Overview

Status Bar

A. Online Help

B. Sign-In with Operator Name and Password

C. Change the System State

D. File Explorer

E. Remote Connection

F. Change the status of the LIS connection

G. LAS connection – view status and reset

H. Dashboard – quick count of all samples and tests currently managed by the system

I. STAT Samples screen

J. Find Patient/QC results

K. System Status Display

L. Turn on/off alarm sounds
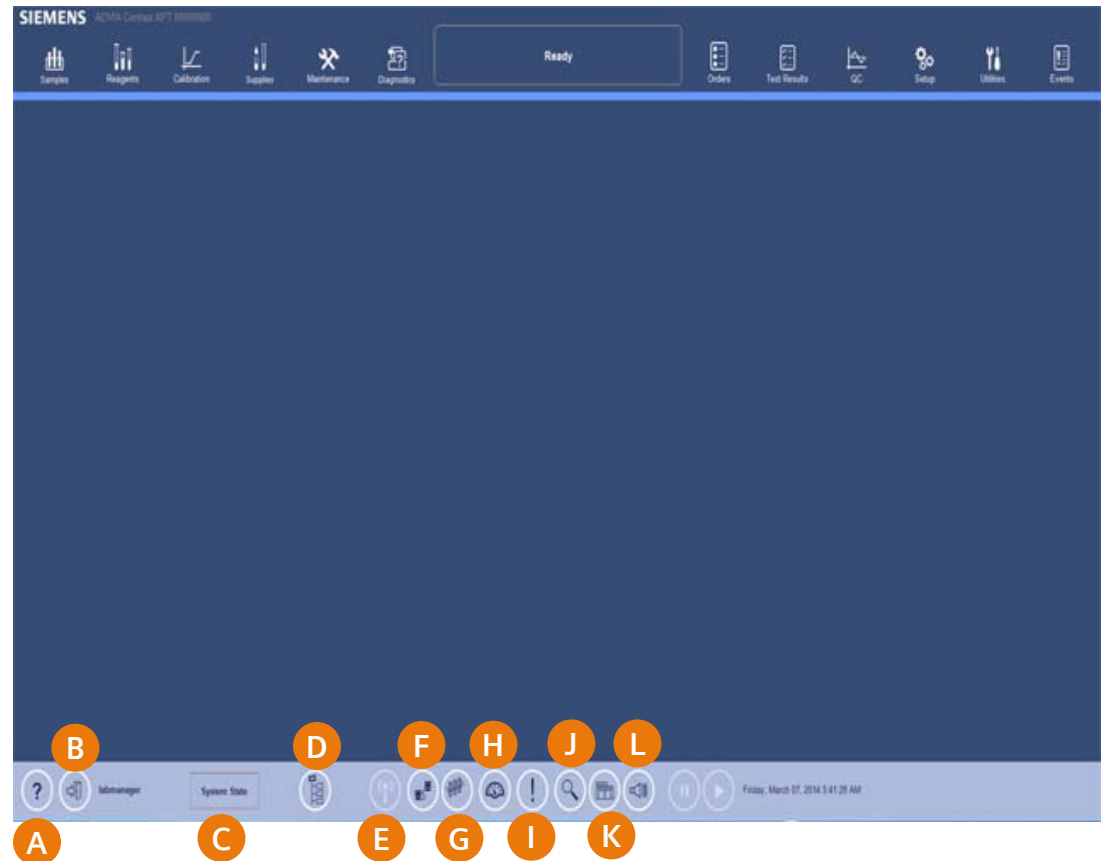
Loading Supplies and Reagents

Loading Supplies and Emptying Waste

Cuvettes
- May be loaded at any time
- The cuvette loading bin holds up to 1000 cuvettes (approximately 5 bags)

Sample Tips
- May be loaded at any time
- Each tip tray holds 120 tips. Up to 840 tips can be loaded onto the system

Deionized Water Bottle
- May be removed from the system at any time
- The capacity of the water bottle is 10L
- Option for direct plumbing

Acid, Base, and Wash 1 Bottles
- May be replaced at any time
- Should be replaced when any of the following conditions exist:
  They have been on the system for a month
  The reagent has expired
  The reagent has insufficient volume

Waste
- The cuvette waste, tip waste, tip tray waste, and liquid waste may be emptied at any time
- After emptying waste, respond appropriately to the popup on the Workspace
- Option for liquid waste direct plumbing

Note:
Replace acid and base bottle at the same time to manage lot numbers and to obtain optimum reagent performance. It is important to place the acid and base bottles in the correct positions on the system.

Loading Primary Reagents

1. Mix by hand to resuspend the paramagnetic particles of the Solid Phase reagent

   - Raise one end of the pack to a 90° angle and return to a horizontal position

   - Raise the other end of the pack to a 90° angle and return to a horizontal position

   - Repeat at least 20 times or until the paramagnetic particles are no longer visible on the bottom of the pack

2. Load the pack

   - Open the primary reagent compartment and identify a position for the pack

   - Pull the reagent holder toward you and load the pack

   - Push the reagent holder back

   - Close the primary reagent compartment door

Note:
For optimal throughput, install packs of similar types next to one another. Similar types of reagents are identified by the color on the end of the label.
Certain methods require special primary reagent handling. Refer to Instructions for Use for more details.

Removing Primary Reagents

1. At the Command Bar, select **Reagents**

2. The first tab is **Primary Reagent Compartment**

3. Select the reagent pack

4. Select **Remove**

5. After the system verifies the pack is no longer in use, the Safe to Unload indicator displays next to the pack
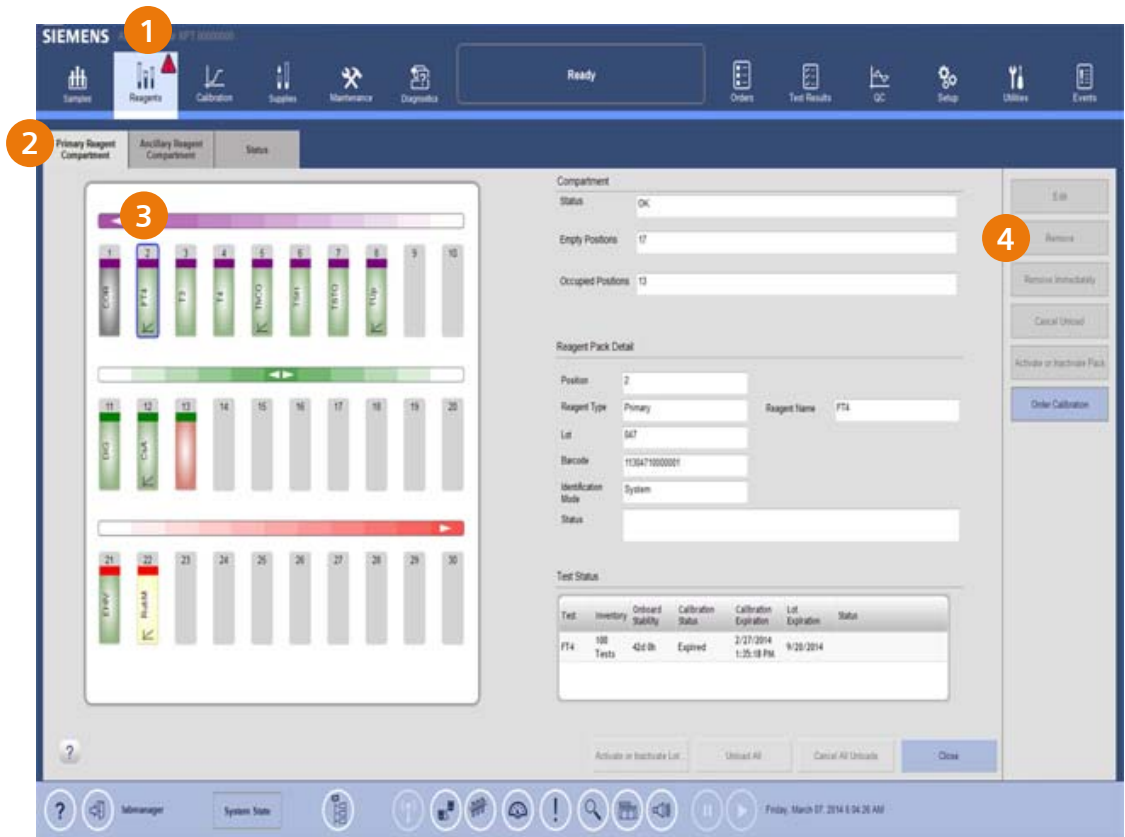
Note:
Do not remove a primary pack when the system is in process if the LED on the primary reagent door is green.

Loading Ancillary Reagents

1. Gently invert ancillary reagent packs several times while minimizing foaming

2. Place the reagent pack in the ancillary reagent entry with the barcoded side facing outward

3. An LED under the ancillary reagent entry turns green to indicate that the pack is loading

4. The system moves the pack into the ancillary reagent compartment

Removing Ancillary Reagents

1. At the Command Bar, select **Reagents**

2. Select the **Ancillary Reagent Compartment** tab

3. Select the ancillary pack

4. Select **Remove**

5. The system ejects the pack into the ancillary reagent entry

6. An LED next to the ancillary reagent entry turns orange to indicate that the pack is exiting the system
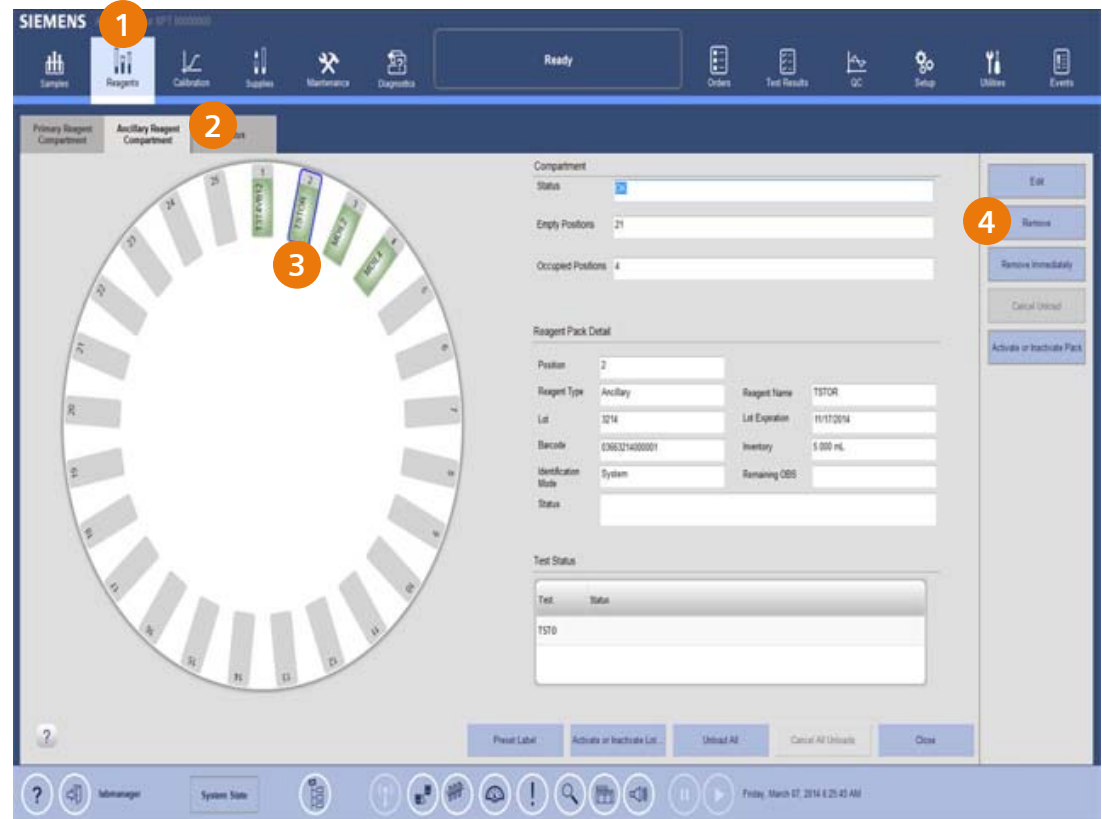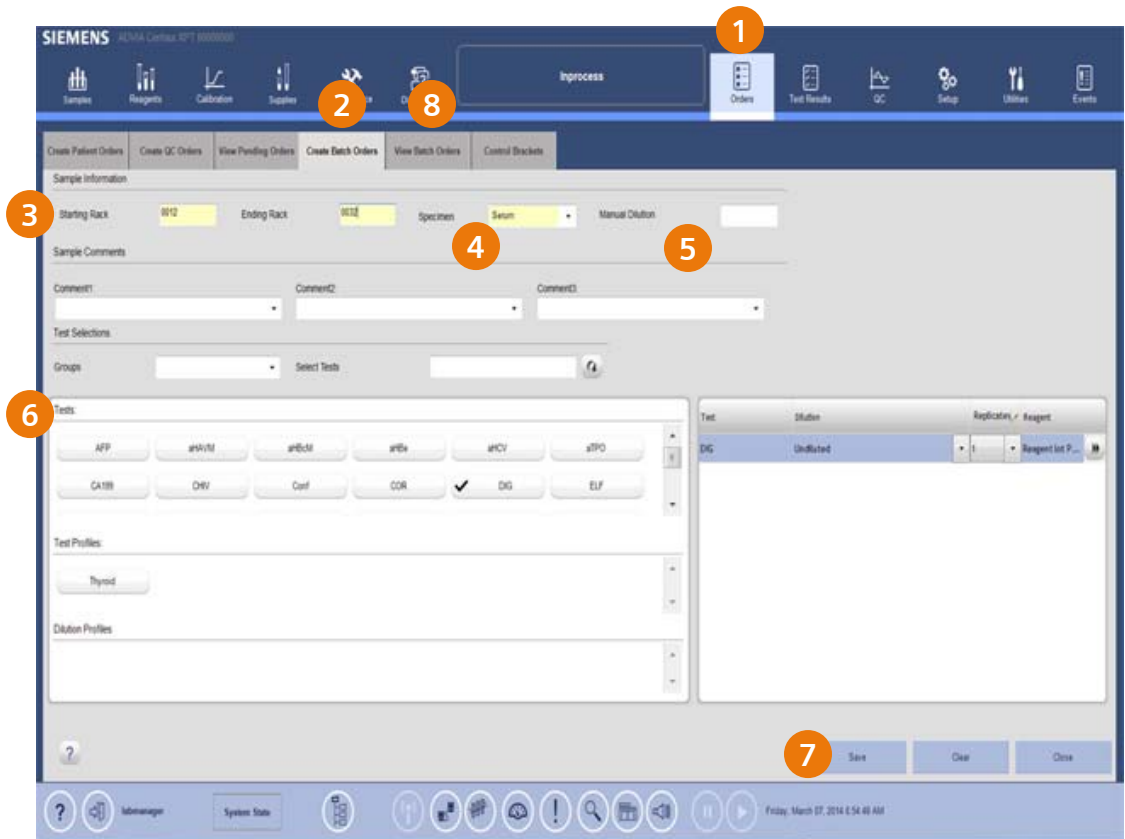
Sample Processing

Manually Ordering Patients By SID

1. At the command bar, select **Orders**

2. The first tab is **Create Patient Orders**

3. Enter the Sample Identification Number (SID) and then select the Enter key on the keyboard to activate the test menu

4. In the Sample Information area, select a Specimen Type and other sample information, as needed

5. In the Tests area, select one or more tests. Test profiles and dilution profiles can also be selected

6. Select the **Save** button
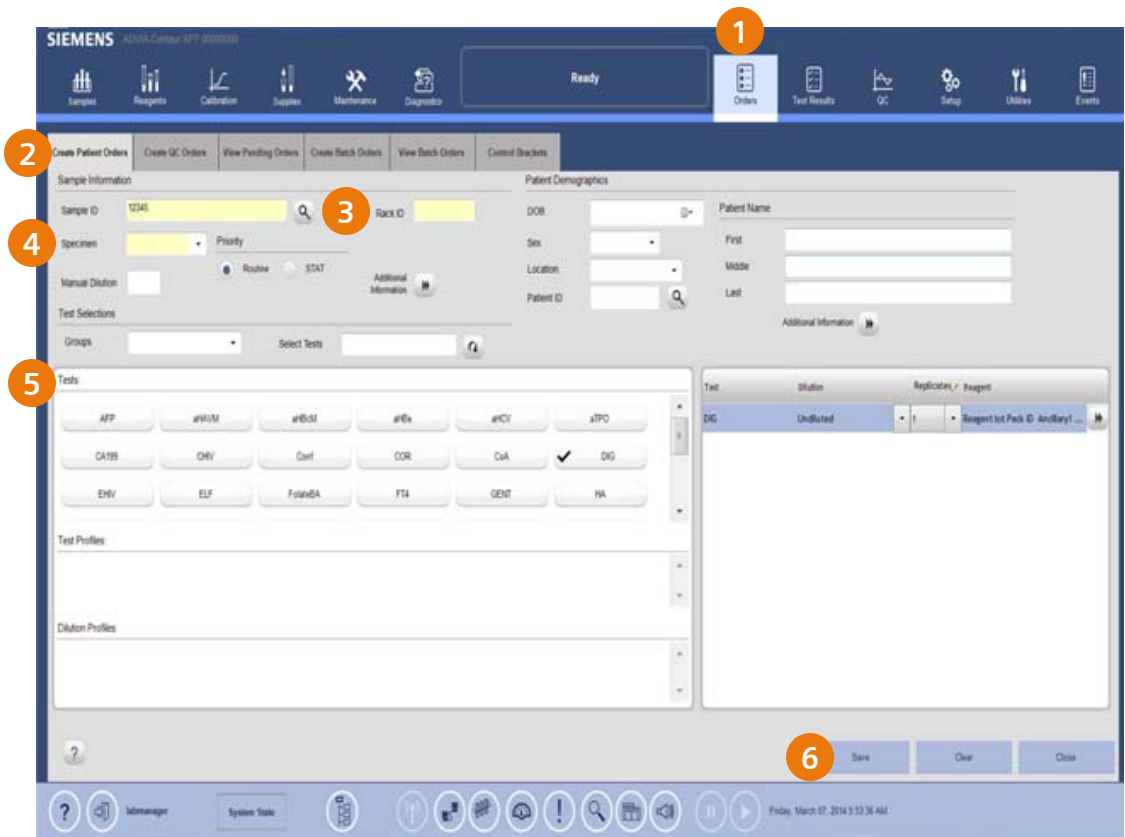
Entering SID for Non-Barcoded Samples

For samples onboard the system with test orders:

1. At the command bar, select **Samples**

2. The first tab is **InProcess Queue**

3. Select the rack that contains the unidentified sample tube

4. On the Rack and Tube diagram, select the unidentified sample tube

5. Select **Enter Barcode**

6. Select the type of sample

7. Enter the barcode for the sample in the Sample ID text box

8. Select the **OK** button
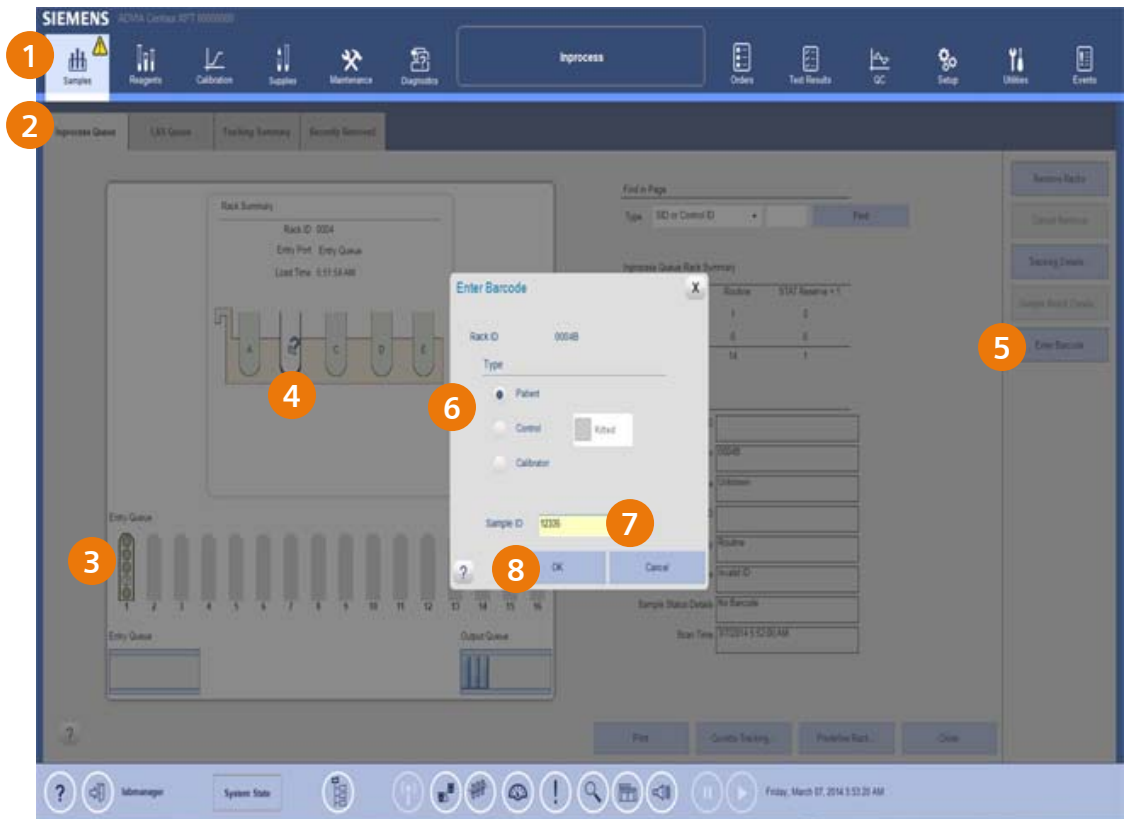
Processing STATs

There are three options for processing STAT patient samples:

1. LIS – STAT orders received from the LIS are given priority over routine samples

2. STAT Entry – load racks in the STAT entry that require processing before racks in the sample entry queue

3. Create Patient Orders Screen – select the STAT priority when ordering the sample
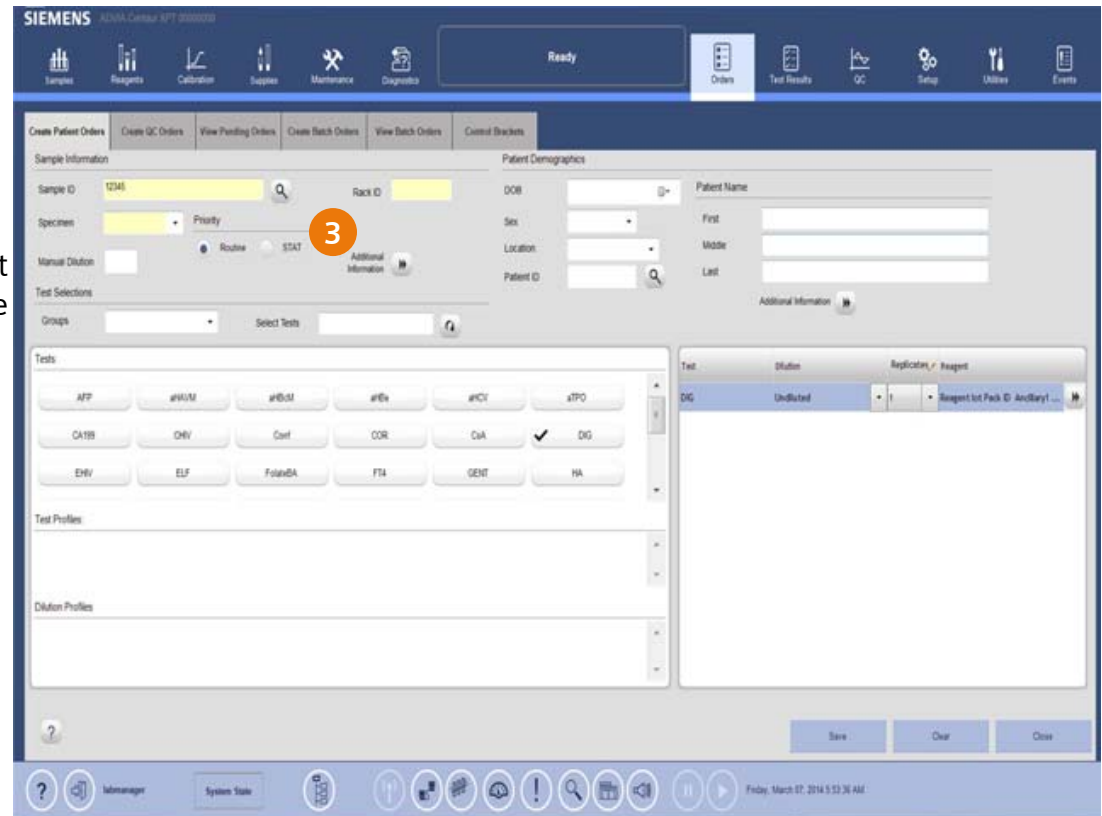
Ordering Dilutions and Replicates

1. At the command bar, select **Orders**

2. The first tab is **Create Patient Orders**

3. Enter the SID and then select the Enter key on the keyboard

4. In the Sample Information area, select a Specimen Type and other sample information, as needed

5. For a Manual Dilution (prepared on the bench): In the Manual Dilution field, enter the manual dilution factor

6. In the Tests area, select the test

7. For a System Performed Dilution (performed by the system using an onboard diluent): Under the Dilution heading, select the appropriate dilution factor

8. If needed, select the number of replicates and reagent pack information. If there are multiple reagent lots onboard, the reagent lot can be selected

9. Select the **Save** button
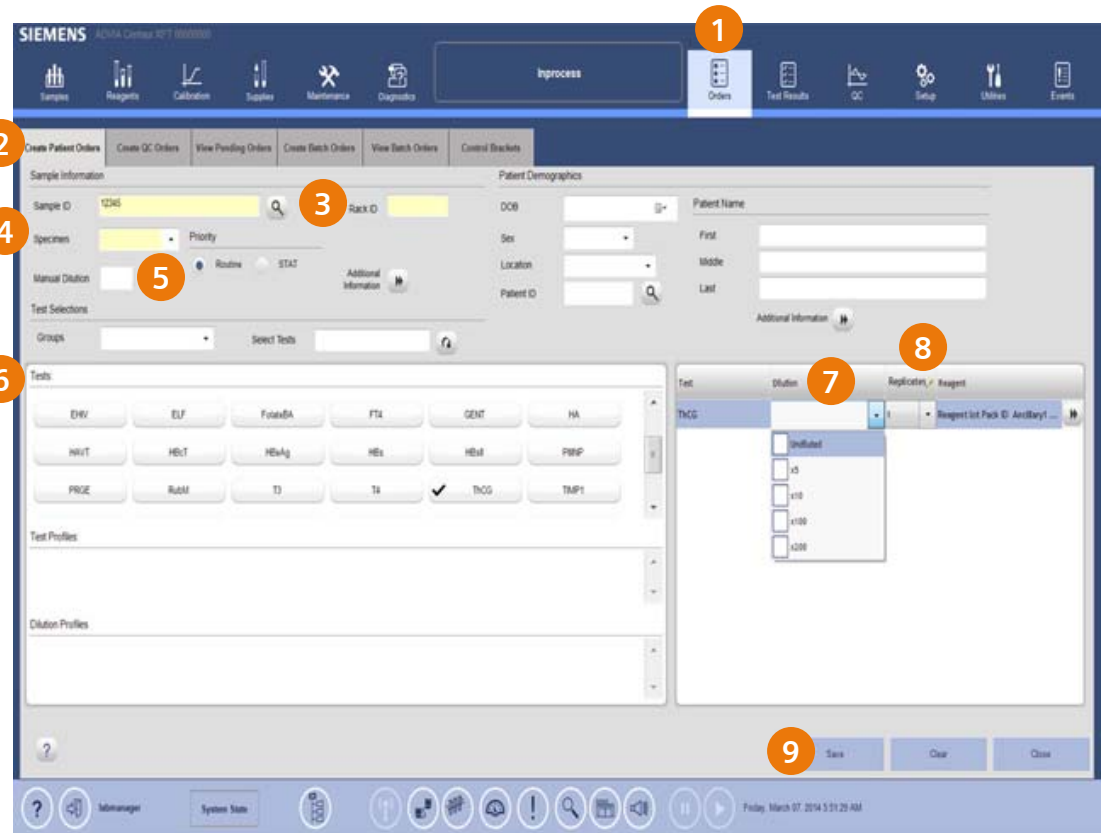
Ordering Batches

1. At the command bar, select **Orders**

2. Select the **Create Batch Orders** tab

3. Enter a starting rack number and an ending rack number

4. Select a specimen type

5. Enter a manual dilution factor and comments if applicable

6. Select the tests to run. The system performs the selected tests on all samples loaded in the starting rack, ending rack and all racks in between

7. Select the **Save** button

8. To view the status of the batch order, select the **View Batch Orders** tab

Monitoring Samples and Results

View Pending Orders screen

- To access, select **Orders** from the Command Bar, and then select the **View Pending Orders** tab

- Used to view QC and patient test orders that have not yet started processing

- Options are available to:

  1. Edit orders

  2. Delete orders

  3. Query LIS
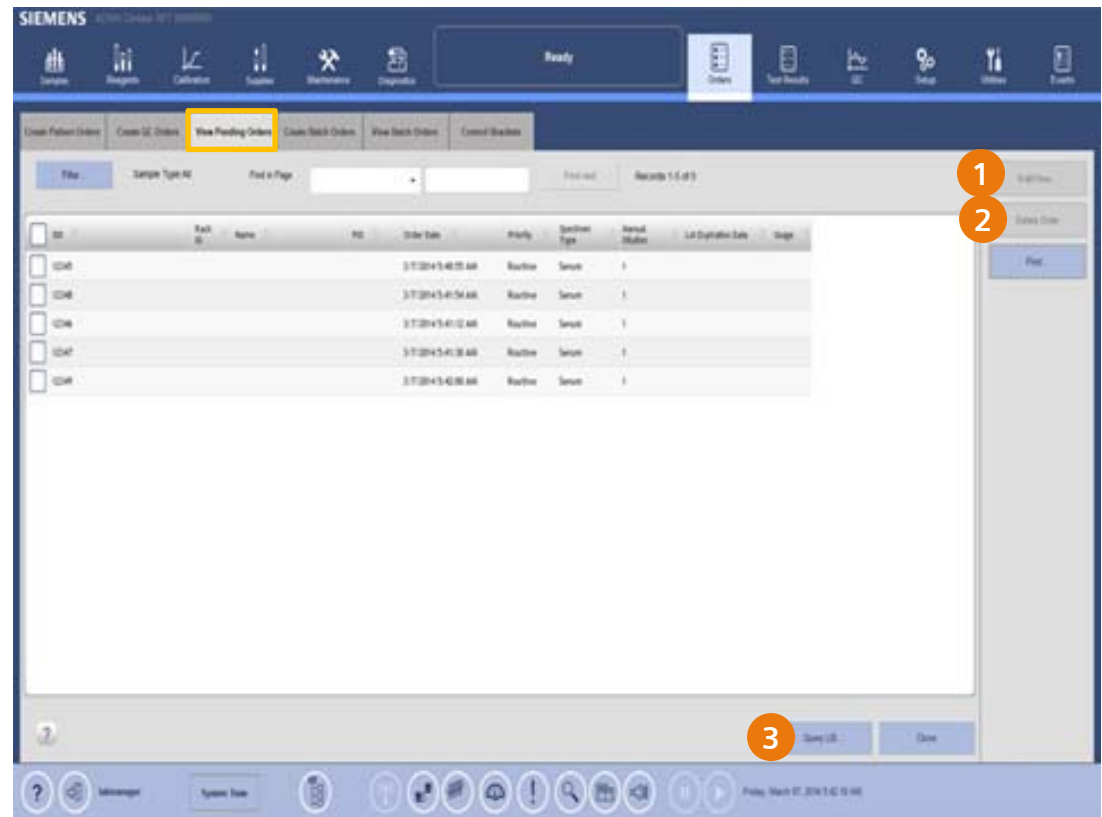
Test Results Overview screen

- To access, select **Test Results** from the Command Bar, and then select the **Overview** tab

- Used to view test orders and results

- Options are available to:

  1. Post an order to the Watch List screen – used to selectively monitor certain test orders

  2. Repeat a test

  3. Transmit results to the LIS

  4. Export data

  5. Print reports

Dashboard screen

- To access, select the Dashboard icon from the Status Bar at the bottom of the screen

- Used to post a quick view of samples and tests by their current state

- The system updates the counters for the samples and the tests in real time until the sample or test is deleted or moved to Historical

- Selecting one or more counter on either tab launches the Test Results Dashboard tab. The counters selected will be highlighted

Calibration

Reviewing Calibration Status

1. At the Command Bar, select **Reagents**

2. Select the **Status** tab

3. Review the calibration status and expiration date for the onboard reagents

Note:
Calibration status can also be viewed on the Calibration Summary screen. Select **Calibration** from the Command Bar, and then select the **Calibration Summary** tab.

Scanning Master Curve Test Definition (MC DEF) Cards

1. Locate the MC DEF card in the primary reagent box. Select the ADVIA Centaur® side of the card

2. Scan the first 2D barcode on the MC DEF card by placing the card on the barcode reader platform to the right of the touchscreen. Pass the card under the scanner until the blue light points at the center of the 2D barcode. The scanner beeps once and the green light on the scanner flashes once after successfully reading the first 2D barcode

3. Scan the second 2D barcode. The scanner beeps twice and the green light on the scanner flashes twice after successfully reading the second 2D barcode

4. Scan the third and fourth 2D barcodes if included on the MCDEF card. The scanner beeps 3 times and 4 times after successfully reading the third and fourth 2D barcodes

5. Select **Save** in the confirmation window to save the master curve and test definition and close the window

Note:
The MC DEF cards must be scanned with every new lot of reagent. The MC DEF cards can only be scanned when the system is in the Ready state.

Scanning Calibrator Definition Cards

1. Locate the Calibrator Definition card in the calibrator kit. It is labeled ADVIA Centaur® Assigned Value Card and has a purple bar at the top

2. At the Command Bar, select **Calibration**

3. Select the **Calibrator Definitions** tab

4. Select the **Add Calibrator Definition** button

5. Scan all of the barcodes on the Calibrator Definition card from top to bottom

6. Select the **Save** button

Note:

The Calibrator Definition cards must be scanned with every new lot of calibrator.

The Calibrator Definition cards can be scanned while the system is In Process.
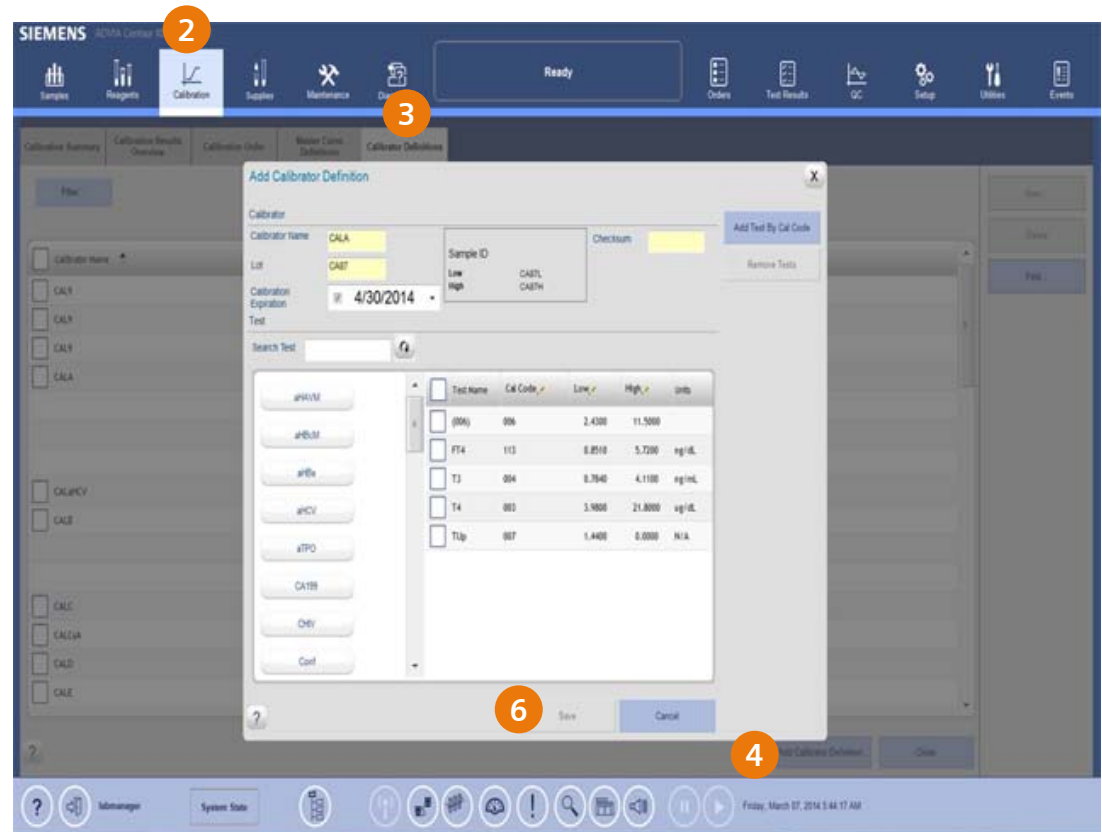
Manually Ordering Calibrations

1. At the Command Bar, select **Calibration**
2. Select the **Calibration Order** tab
3. Select a test to calibrate
4. Select a reagent lot
5. Select a calibrator lot
6. Select the **Save** button

Reviewing Calibration Data

1. At the Command Bar, select **Calibration**

2. Select the **Calibration Results Overview** tab

3. Review the Result column for each calibration test

   - A Valid calibration indicates that the Calibration Evaluation Criteria have passed

   - An Invalid calibration indicates that one of the criteria did not pass and further investigation will be required

4. To view more information on an Invalid calibration, select the test and then select the **Calibration Data** button

Accepting a Calibration

- Required when the calibration status is "Pending Accept" status on the Calibration Results Overview screen

- "Pending Accept" calibrations are outside of observed ranges but within defined ranges

  - Observed ranges: After 4 calibrations of the same reagent lot and calibrator lot combination, the system calculates observed ranges

  - Defined ranges: The values for Slope, Ratio, Low Cal Deviation and High Cal Deviation entered from the MC DEF card

- To accept, select the **Accept** button on the Calibration Data screen

- After accepting, the calibration status changes to "Valid Operator Accepted"

Quality Control

Adding a QC Definition

1. At the Command Bar, select **QC**

2. Select the **QC Definitions** tab

3. Select the **Add QC Definition** button. The Add New QC Definition screen displays

4. Enter the appropriate information in the Control Details area

5. Select a test

6. Enter the expected values – mean and 2SD or low and high range

7. Add additional tests as needed

8. Select the **Save** button

Editing a QC Definition

To edit an existing QC definition, on the QC Definition screen, select the QC definition to edit and then select the **Edit/View** button. Make the necessary edits and select the **Save** button.

Manually Ordering QC

1. At the Command Bar, select **Orders**

2. Select the **QC Orders** tab

3. Select a priority

4. In the Tests area, select one or more tests

5. To order a QC profile, select the **Select Profiles** button and then select the desired profile

6. In the Control Materials area, select each control material to include in this order

7. Select the **Add** button

8. In the Orders area, select or enter the order and test information as needed by selecting the Details/Summary button

9. Select the **Save** button

Printing QC Data

1. At the Command Bar, select **QC**

2. Select the **QC Statistics** tab

3. Select either the **Review** or **Analysis** tab

4. Select **Reports**

Exporting QC Data

1. At the Command Bar, select **QC**

2. Select the **QC Statistics** tab

3. Select the **Tools** tab

4. Select the **Export** tab

5. Select the data to export, the time filter, and the file type

6. Select **Export**

Daily Maintenance

Daily Cleaning Procedure

1. Check/replenish cleaning solution (7 day onboard stability)

   - Add 1 container of ADVIA Centaur® Cleaning Solution Concentrate to the cleaning solution bottle

   - Fill the cleaning solution bottle to the neck with DI water

   - Place the bottle onto the system

2. Check/replenish cuvettes

3. Check/replenish the water bottle

4. Check/empty the liquid waste bottle

5. Check/empty the cuvette waste bin

6. Start the Daily Cleaning Procedure:

   A. Select **Maintenance** on the Command Bar

   B. Select **Daily Maintenance** on the Schedule tab

   C. Select **Perform**
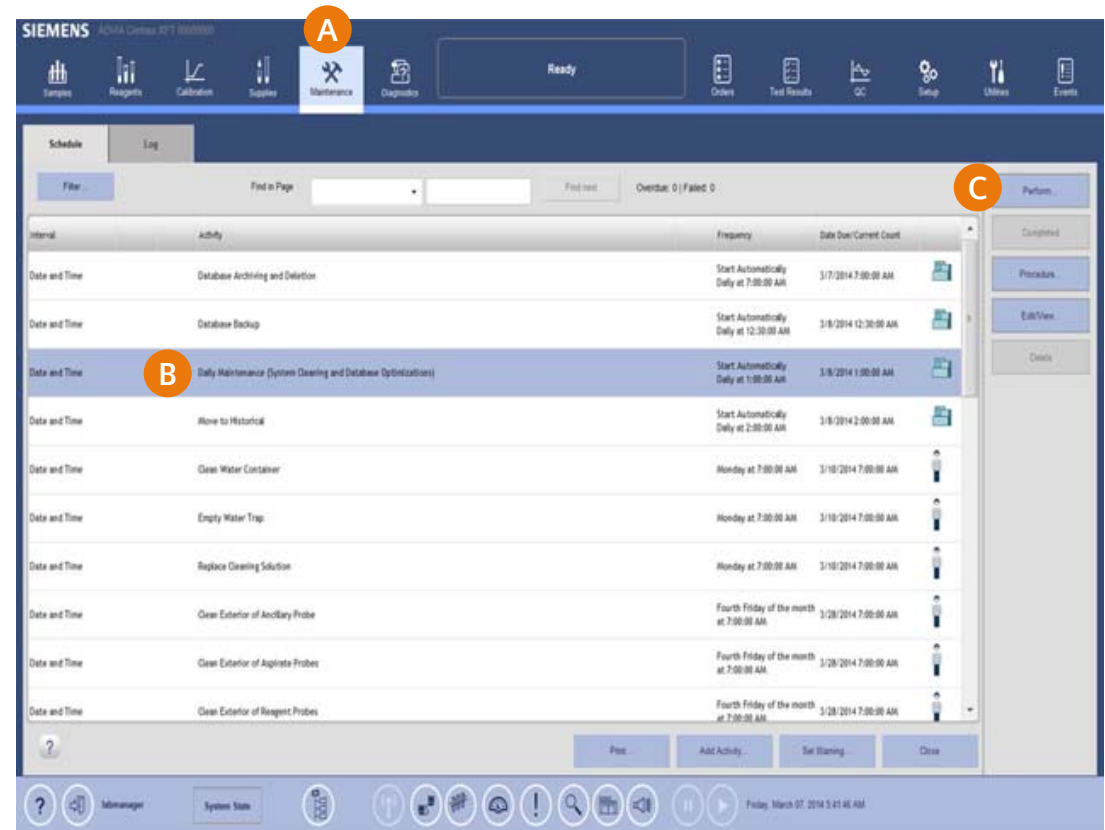
Weekly Maintenance

Cleaning the Water Bottle

1. Remove the cap and empty any water from the water bottle

2. Pour approximately 1L of cleaning solution into the water bottle

3. Place the cap on the bottle and close tightly

4. Swirl the solution around the inside of the bottle a few times

5. Press some gauze over the holes in the top of the bottle

6. Invert the bottle, swirl the solution a few times and then return the bottle to the upright position

7. Soak the bottle in the upright position for 5 minutes

8. Repeat steps 5 and 6

9. Swirl the solution again and then empty the bottle

10. Rinse the inside of the bottle including the tubing at least 5 times with fresh reagent water

11. Invert the bottle to dry

Note:
This procedure is not required if the system is direct plumbed for water.

Emptying the Water Trap

1. Ensure that the system is in one of the following states:

   - Ready
   - Warming Up
   - Diagnostic
   - Mechanics Off
   - Check Status

2. Pull out the waste and water drawer to access the water trap

3. Unscrew and remove the water trap. The liquid in the water trap is waste condensation

4. Remove any liquid from the water trap

5. Ensure that the float ball moves freely in the water trap. Ensure that the inner seal of the lid is not missing or damaged

6. Tightly install the water trap

7. Close the waste and water drawer

Monthly Maintenance

Cleaning the Primary Reagent Probes

1. Turn the system mechanics off, and then use the key to unlock the top cover. Lift open the cover and the reagent probes cover

2. To clean the primary reagent probes, push the reagent probe assemblies toward the incubation ring by pushing the motors

3. Wipe each probe with lint-free tissue with cleaning solution, followed by thoroughly rinsing each probe with lint-free tissue with reagent water

4. Reinstall the reagent probes cover, close the top cover, and turn the system mechanics back on

Cleaning the Ancillary Probe and Aspirate Probes

1. Turn the system mechanics off, and then use the key to unlock the top cover. Lift open the top cover

2. To clean the ancillary reagent probe, move the inprocess queue to the right and then pull the probe toward you by holding the top of the probe assembly

3. Clean the probe using a gentle downward motion with lint-free tissue with cleaning solution, followed by thoroughly rinsing the probe with lint-free tissue with reagent water

4. Clean the exterior of the aspirate probes with a lint-free tissue dampened with cleaning solution, followed by rinsing the exterior of the probes with DI water and a lint-free tissue

5. Close the top cover and turn the system mechanics back on

Cleaning the Air Filter

1. Remove the air filter by lifting the cover up and then pulling the cover out of the bracket

2. Remove the old filter and then install the spare, dry air filter

3. Put the cover back onto the system by pushing in and down at the same time

4. Rinse the old air filter with water and then allow it to thoroughly dry

As Needed Maintenance

Cleaning the Reagent Probe Shutter

1. Turn the system mechanics off, and then use the key to unlock the top cover. Lift open the cover and the reagent probes cover

2. Remove the primary reagent packs and refrigerate them

3. Push the reagent probe assemblies toward the incubation ring by pushing the motors

4. Remove the reagent probe shutter by lifting the shutter drive arm up and off the shutter drive and sliding the shutter to the left. Lift the shutter out of the system

5. Wipe the shutter with lint-free tissue with cleaning solution, then rinse with water and thoroughly dry

6. Wipe the surface under the shutter with lint-free tissue with cleaning solution, then rinse with water and thoroughly dry

7. Install the shutter by sliding it to the right until the screw slots are under the screws. Place the shutter arm down on the shutter drive

8. Replace the reagent probes cover, close the top cover, and turn the system mechanics on
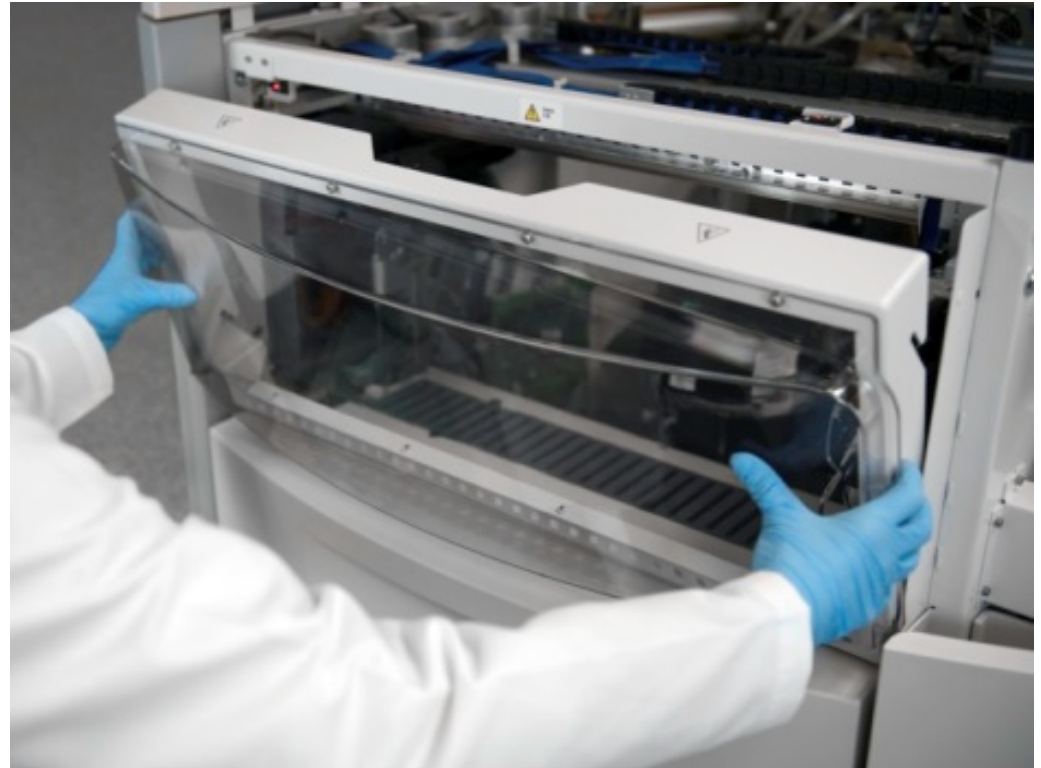
Cleaning the Probe Rinse Stations

1. Turn the system mechanics off, and then use the key to unlock the top cover. Lift open the cover and the reagent probes cover

2. Push the reagent, ancillary, and sample probe assemblies toward the incubation ring by pushing the motors

3. Use a transfer pipette to add ~1mL of cleaning solution to each rinse station, then swirl with small maintenance brush. Remove the cleaning solution with a transfer pipette

4. Clean the rinse station with lint-free tissue with cleaning solution, and then rinse the rinse station with lint-free tissue with reagent water

5. Reinstall the reagent probes cover, close the top cover, and turn the system mechanics back on
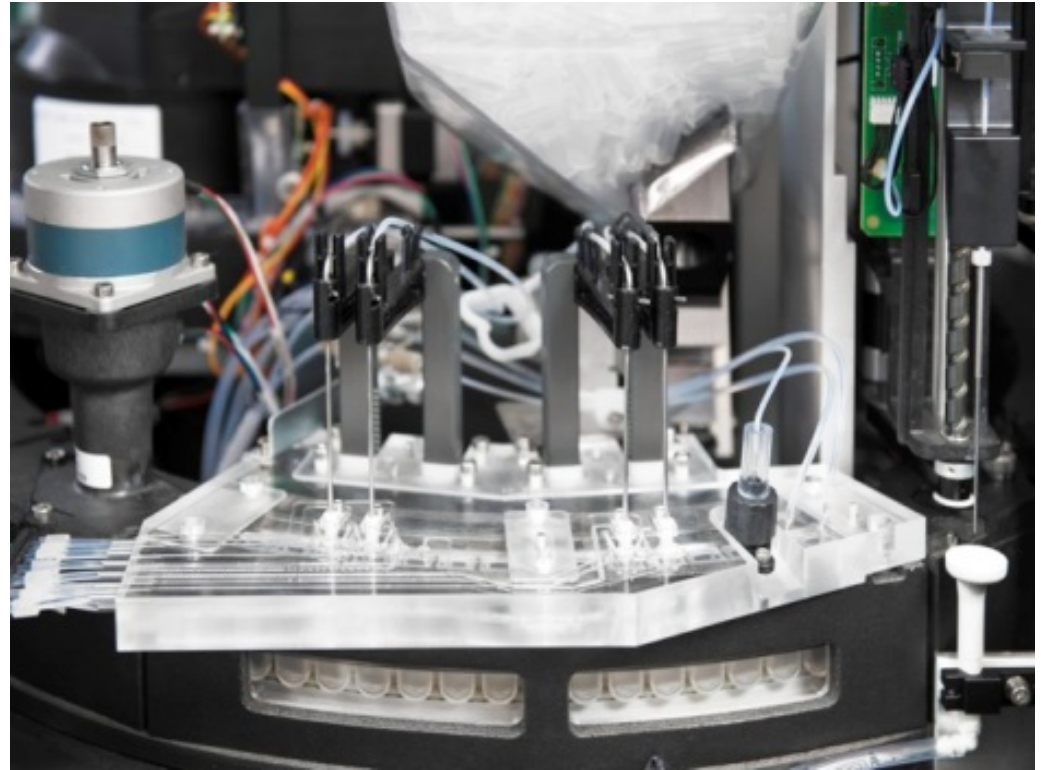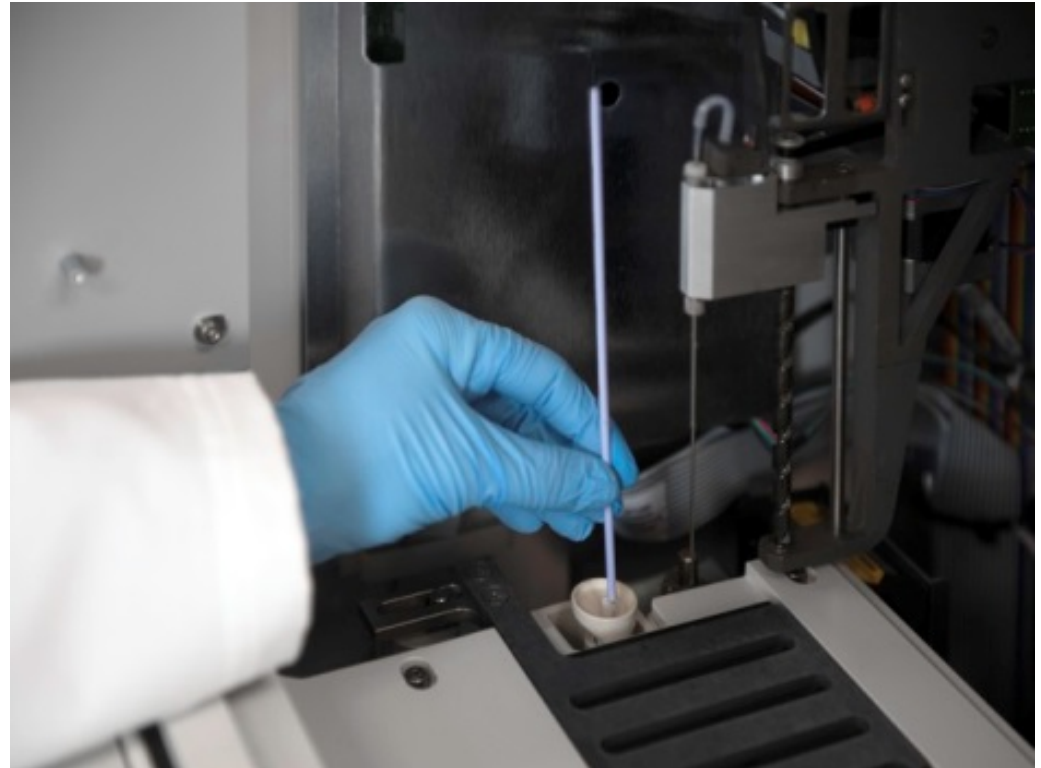
Cleaning the Primary Reagent Compartment

1. Turn the system mechanics off, and then use the key to unlock the top cover. Lift open the cover and the reagent probes cover

2. Remove the primary reagent packs from the system and refrigerate them

3. Wipe excess water from the primary reagent compartment, and then wipe the surfaces of the compartment with lint-free tissue with water

4. If reagent has spilled onto the reagent pack holders, wipe them with lint-free tissue with water

5. Dry the primary reagent compartment

6. Reinstall the reagent probes cover, close the top cover, and turn the system mechanics back on

Cleaning the Cuvette Waste Chute

1. Open the cuvette waste area door, and remove empty sample tip trays and covers from the tip tray bin

2. Lift the tip tray bin up and then out of the system.

3. Remove the cuvette waste chute by releasing it from the magnetic fitting. Slightly rotate the cuvette waste chute, then pull it out and down

4. Clean the cuvette waste chute with the large maintenance brush and cleaning solution, and then rinse the chute with DI water

5. Dry the inside of the chute with paper towels

6. Install the cuvette waste chute by place the locator pins at the bottom of the chute in the reservoir. Lift the top of the chute until it attaches to the magnetic fitting

7. Install the sample tip tray bin. Install the cuvette waste bin and close the door

Cleaning the Sample Tip Waste Tube

1. Turn the system mechanics off, and then use the key to unlock the top cover. Lift open the cover, and push the sample and ancillary probes back toward the incubation ring

2. Loosen the knurled knob on the sample tip remover, and lift the sample tip remover and sample tip waste tube out of the system

3. Unscrew the sample tip waste tube from the sample tip remover

4. Soak the sample tip remover and sample tip waste tube in cleaning solution for 5 minutes

5. Clean the inside of the sample tip waste tube with cleaning solution and the large maintenance brush

6. Rinse the sample tip remover and sample tip waste tube with water, and then dry thoroughly

7. Connect the sample tip remover to the sample tip waste tube

8. With the slot on the sample tip remover facing away from you, place the bottom of the sample tip waste tube into the opening below the sample probe. Align the 2 holes on the right side with the locator pins on the mounting block. Turn the knurled knob until the sample tip remover is secure

9. Close the top cover, and turn the system mechanics back on

Cleaning the Sample Tip Waste Chute

1. Turn the system mechanics off, and then open the sample tip waste area door and remove the sample tip waste bin

2. Pull out the drawer and lift the lid to the cleaning solution. Ensure the lid remains in the upright position. Wipe the cleaning solution tubing with fresh lint-free tissue to remove excess cleaning solution. Remove the cleaning solution bottle

3. Remove the sample tip waste chute

4. Soak the sample tip waste chute in cleaning solution for 5 minutes

5. While the sample tip waste chute is soaking, wipe the sample tip waste reservoir with lint-free tissue with cleaning solution, and then wipe the reservoir with lint-free tissue with water. Dry the sample tip waste reservoir with lint-free tissue

6. When the sample tip waste chute has finished soaking, clean the chute with the large maintenance brush, and then rinse with water and thoroughly dry the chute

7. Install the sample tip waste chute onto the system with the bottom of the chute in the reservoir

8. Install the cleaning solution bottle and the sample tip waste bin. Close the sample tip waste area door, and turn the system mechanics back on

Cleaning the Covers, Keyboard, and Mouse

1. Carefully clean the following components with lint-free tissue with cleaning solution:

   - Sample entry queue
   - Exterior covers
   - Sample exit queue
   - Ancillary entry
   - Stat entry
   - Keyboard
   - Mouse
   - System fluids tray
   - Tray under the system fluids reservoirs

2. Rinse the components with lint-free tissue with water

3. Dry the components thoroughly

Cleaning the Sample Barcode Scanner

1. Turn the system mechanics off

2. Access the scanner by reaching your hand over and behind the housing

3. Carefully wipe the scanner with an alcohol prep pad

4. Turn the system mechanics back on

Troubleshooting

Clearing Cuvette Obstructions

1. Access the Operator Event Log by selecting **Events** at the Command Bar. Any of these events may lead to checking the orientation and vertical chutes for cuvette jams:

    • Cuvette pusher is offline

    • Cuvette bin is empty (provided the cuvette bin isn't actually empty)

2. Turn the system mechanics off, and then use the key to unlock the top cover. Lift open the cover

3. Observe the cuvette loading bin. Verify that it is not empty

4. Remove any obstructions from the orientation chute

5. Check the vertical chute:

    •   Unscrew the vertical chute captive screw and remove the window

    •   Remove any obstructions

    •   Reinstall the vertical chute window

6. Turn the system mechanics on
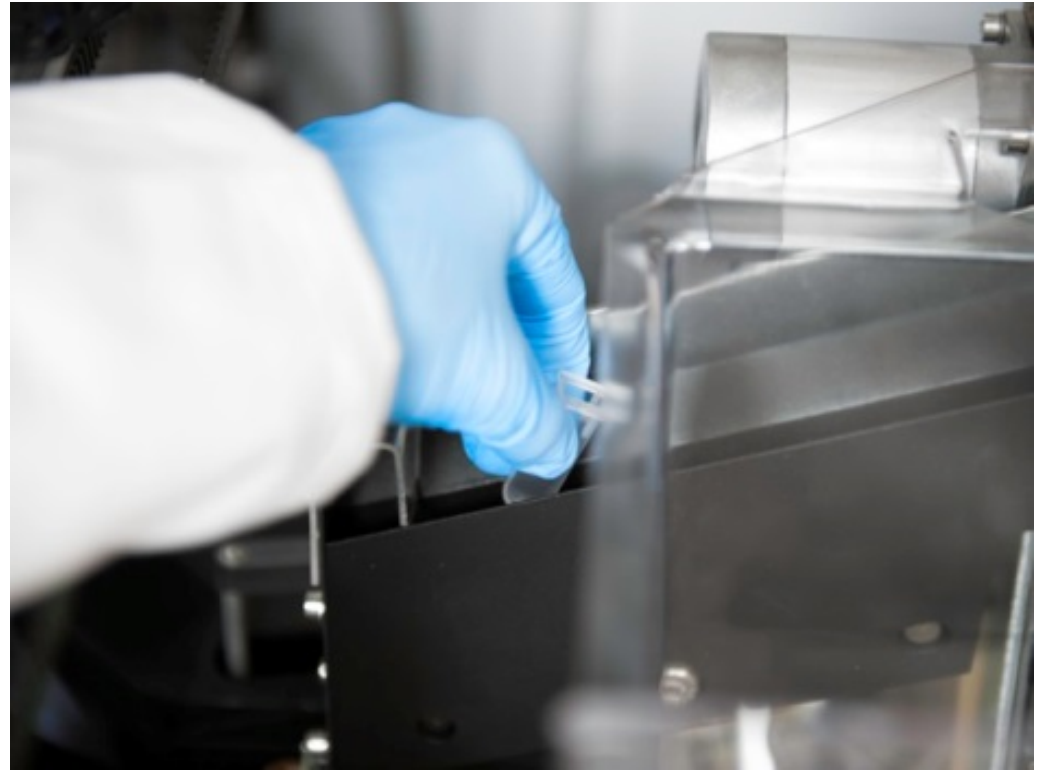
Clearing Preheater Jams

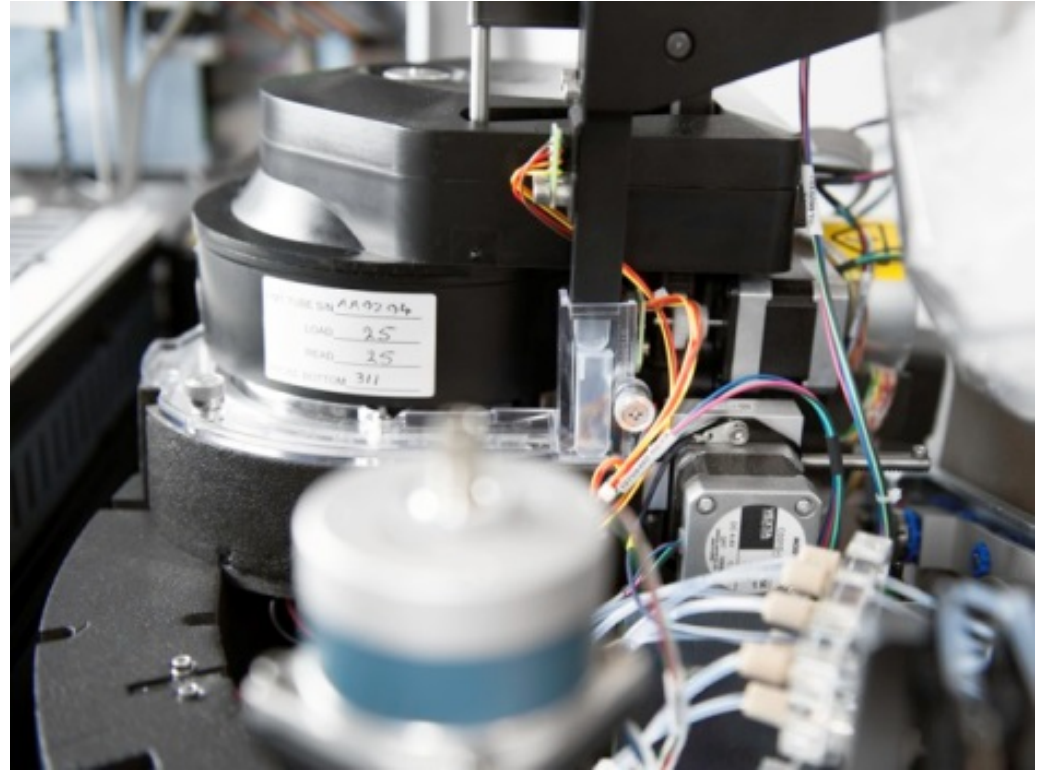1. Access the Operator Event Log by selecting **Events** at the Command Bar. Any of these events may lead to checking the preheater for cuvette jams:

    -   Cuvette pusher is offline

    -   Ring Loader is offline

2. Turn the system mechanics off, and then use the key to unlock the top cover. Lift open the cover and the reagent probes cover

3. Loosen the thumbscrew on the preheater cover and remove the preheater cover

4. Remove any jammed cuvettes. Ensure that there are 14 cuvettes in the preheater and that the cuvettes do not overlap

5. Replace the preheater cover and tighten the thumbscrew

6. Replace the reagent probes cover, close the top cover, and turn the system mechanics on

Resolving Reagent Probe Errors

1. Access the Operator Event Log by selecting **Events** at the Command Bar. Any of these events may lead to troubleshooting reagent errors:

   - Reagent Probe Volume Check Failure

   - Reagent Probe Vertical Move Error

2. Check the reagent pack for proper placement and volume. The reagent pack that is affected will be displayed in the event message

3. If necessary, continue by removing the pack and checking the probe puncture point. If the point is near the edge of the pack opening, you may need to replace the reagent probe

4. If the reagent pack placement and puncture point are not the issue, perform a dispense test in Diagnostic Tools. If the stream of water is not straight and steady, you may need to replace the reagent probe

Replacing Reagent Probes

1. Turn the system mechanics off, and then use the key to unlock the top cover. Lift open the cover and the reagent probes cover

2. Lift off the reagent probe tubing

3. Use pliers to loosen the reagent probe sleeve

4. Turn the sleeve clockwise, then pull the probe and the sleeve down into the rinse station. Remove the probe and sleeve from the system

5. Place a new reagent probe in the sleeve

6. Lift the probe up into the heater coil and turn it counter clockwise. Tighten the sleeve one quarter turn with pliers

7. Connect the tubing to the top of the probe

8. Replace the reagent probes cover, close the top cover, and turn the system mechanics on

Replacing Aspirate Probes

1. Turn the system mechanics off, and then use the key to unlock the top cover. Lift open the cover

2. Move the inprocess queue to the right

3. Locate the probe that will be replaced and lower the adjacent probe to improve access

4. Disconnect the tubing on the probe being replaced. If the grounded aspirate probe is being replaced, carefully remove the grounding wire from the probe

5. Push the probe pin down and turn counter clockwise to release the spring-loaded probe

6. Remove and discard the aspirate probe

7. Push the new probe down into the probe guide and turn the pin clockwise to secure the spring-loaded probe

8. Connect the probe tubing. If the grounded aspirate probe is being replace, connect the grounding wire

9. Raise the adjacent probe back up

10. Close the top cover, and turn the system mechanics on
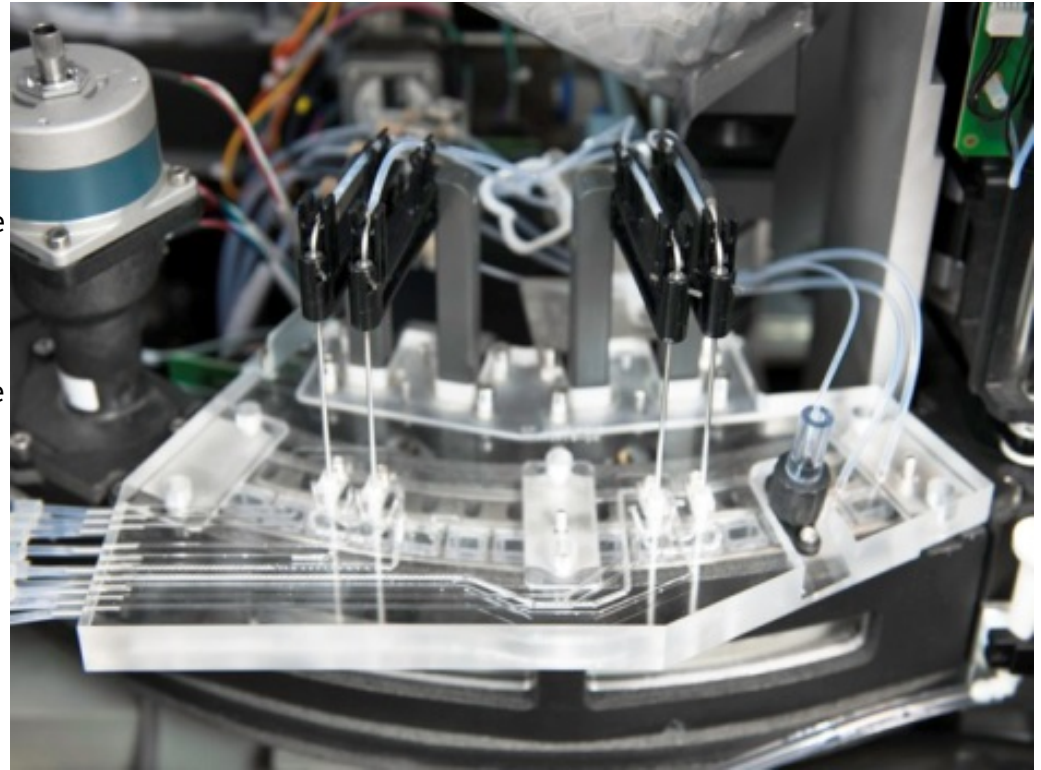
System Restart

Restarting the System

1. At the Status Bar on the bottom of the screen, select System State

2. Select Turn System Off

3. Wait while the system powers down

4. Turn the main power switch off, wait 30 seconds, and then turn the main power switch back on

5. When the software has restarted, sign into the system

6. Turn the mechanics on

7. Wait until the system state is ready, and then return to normal operation

Note: This document is for supplemental use only, and not meant to be used in place of primary technical materials.