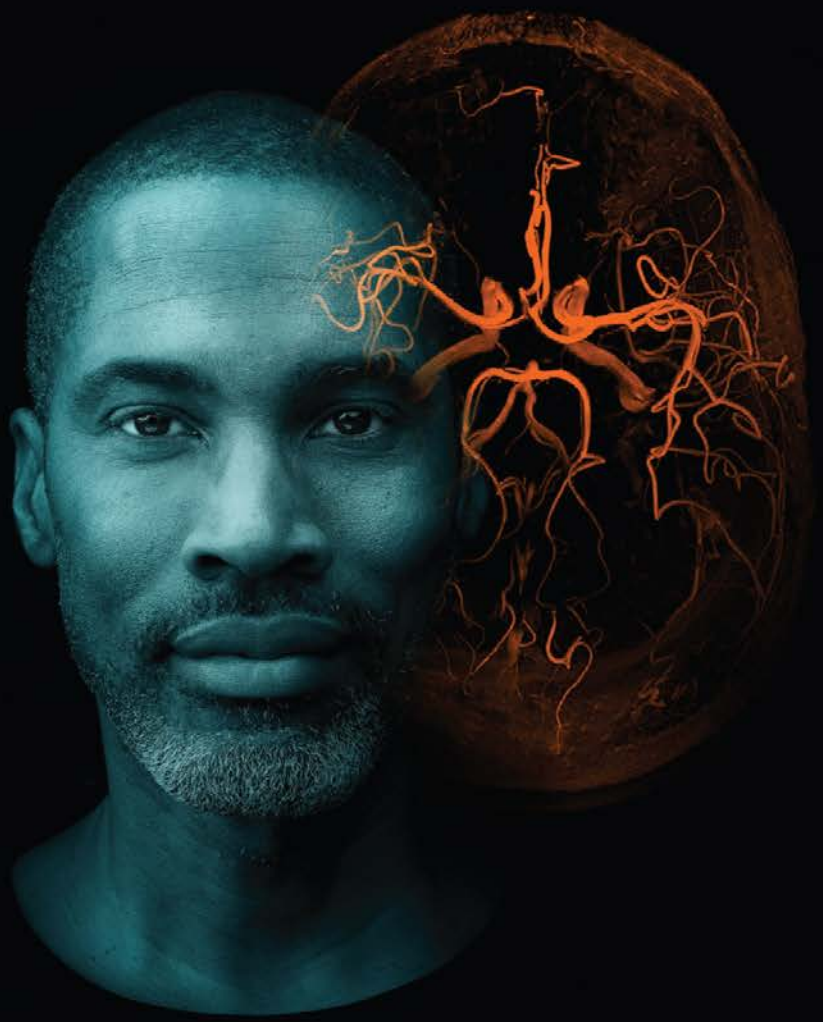
ADVIA Centaur® XPT System

Virtual Training Workbook



SIEMENS Healthineers

Siemens Healthineers

ADVIA Centaur® XPT System

Virtual Training

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1 Welcome

Welcome to training

Siemens Healthineers would like to welcome you to the ADVIA Centaur® XPT System Virtual Training course.

This course is designed to teach you the skills needed to operate and maintain the ADVIA Centaur XPT Immunoassay System.

Our staff welcomes the opportunity to present this virtual training program to you.

Training Material

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

ADVIA Centaur® XPT System Virtual Training

Objectives

To prepare the customer to operate, maintain the ADVIA Centaur XPT Immunoassay System.

Course Objectives

After participating in the virtual lectures and hands-on exercises, you will be able to:

- Identify the system components and their functions.
- Navigate the software.
- Manage supplies and reagents.
- Setup, process and manage quality controls.
- Process and manage patient samples.
- Setup, process and manage calibrations.
- Perform maintenance.
- Utilize the Event Log to troubleshoot system errors.
- Utilize the instrument Operator's Guide and online help.
- List the steps to do a system restart

ADVIA Centaur® XPT System Virtual Training

Training Agenda

Day 1

- System Components
- User Interface
- Event Log
- Supplies, System Fluids and Reagents
- Hands-on Practice Exercise (Loading supplies and reagents)
- Calibration
- Hands-on Practice Exercise

LUNCH

- Quality Control
- Processing Patient Samples Part 1
- Hands-on Practice Exercise
- Maintenance

Day 2

- Morning Review
- Sample Processing Part 2
- Hands-on Practice Exercise
- Event Log/ Basic Troubleshooting
- Hands-on Practice Exercise/LUNCH
- Perform IM Daily and/or Weekly-Monthly Maintenance

ADVIA Centaur® XPT System Virtual Training

Course Validation Checklist

The student places a checkmark beside the competency when it is completed. When all competencies are checked, the instructor and operator sign and date below as record of completion.

Topics	Competencies	Completed
System Components	Identify the system components, compartments and their functions	
User Interface	Log onto the software	
	Locate key Status and Command bar buttons	
	Access Online Help	
Supplies and Reagents	Monitor supplies and reagents statuses	
	Load/unload supplies and reagents	
	Empty wastes	
Quality Control (QC)	Add and Edit a control definition	
	Order and process QC and QC profiles	
	Configure automatic QC ordering	
	Access ADVIA QC program	
Processing and Managing Samples	Process and monitor patient samples	
	Print results	
Calibration	Check calibration status	
	Locate and scan MC Def and Calibrator Definition cards	
	Order a calibration	
	Review and print calibration data	
Maintenance	Locate, review and update the maintenance tasks	
	Access maintenance procedures through Online Help	
	Perform daily, weekly, monthly and as-needed maintenance procedures	
Event Log	Utilize the Operator Event Log and the Online help to identify troubleshooting procedures	
Document Library	Access Siemens Document Library	

System Restart	List the steps to perform a system reboot	

Observer: _____

Participant: _____

Date: _____

What was most helpful to you during this program?

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

2 System Components

System Components

Resources

- *ADVIA Centaur CP Operators Guide*
- Online Help
- PEP Connect

Objectives

Upon completion of this exercise you will be able to:

- Identify System Components and their functions.

System Components

Exercise Activity and Questions

1. Identify the following compartments in the image below.

A. ___ System Fluids
B. ___ Cuvette Loader
C. ___ Water Bottle
D. ___ Sample Tip Loader
E. ___ Ancillary Reagent Entry
F. ___ Primary Reagent Compartment
G. ___ Cleaning Solution / Tip Waste
H. ___ Tip Tray Waste / Cuvette Waste

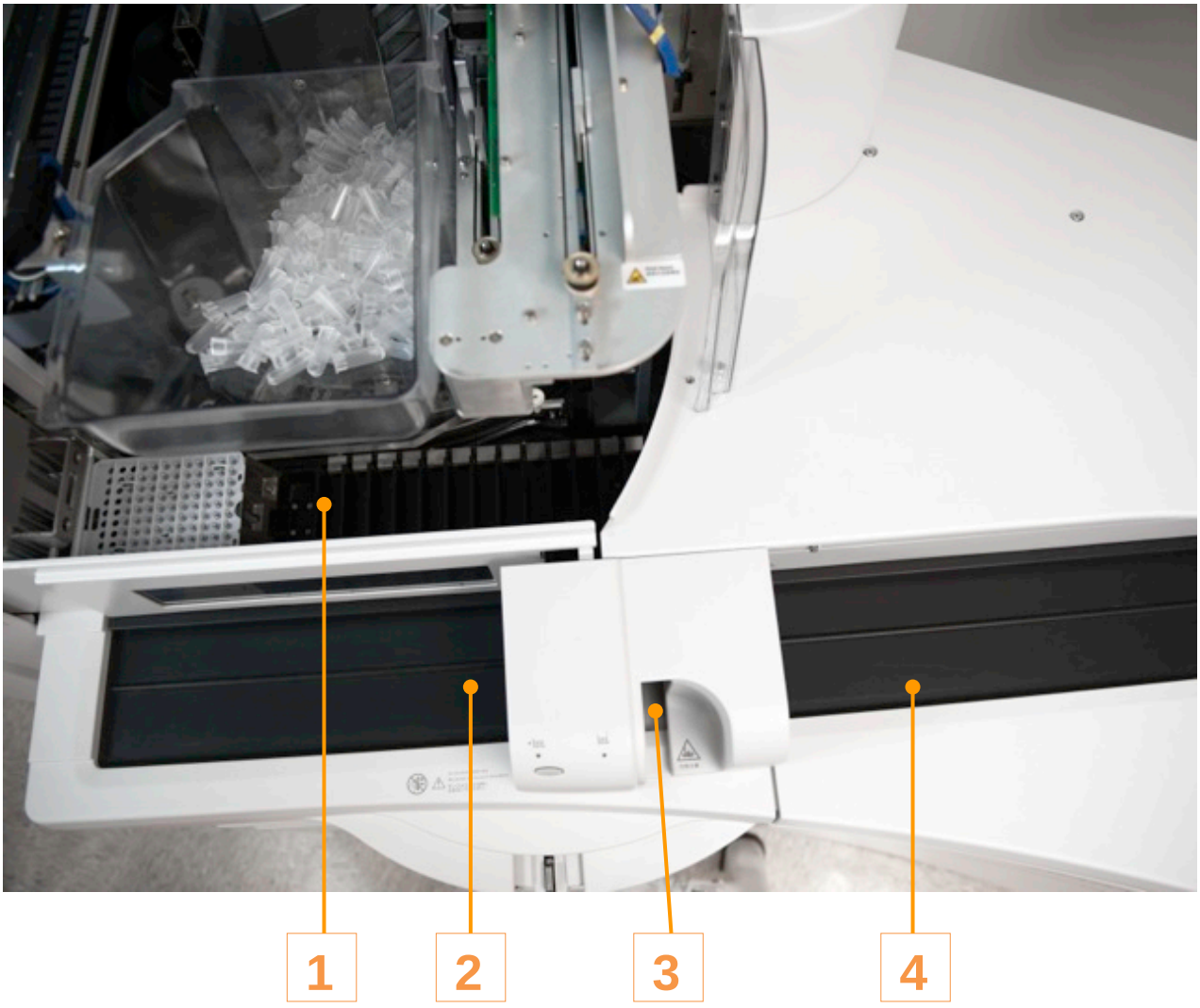
2. Identify following system components in the image below.

A. ___ STAT Entry

B. ___ Sample Entry Queue

C. ___ Sample Exit Queue

D. ___ In Process Queue



3. Identify the following system interior components in the next two images below.

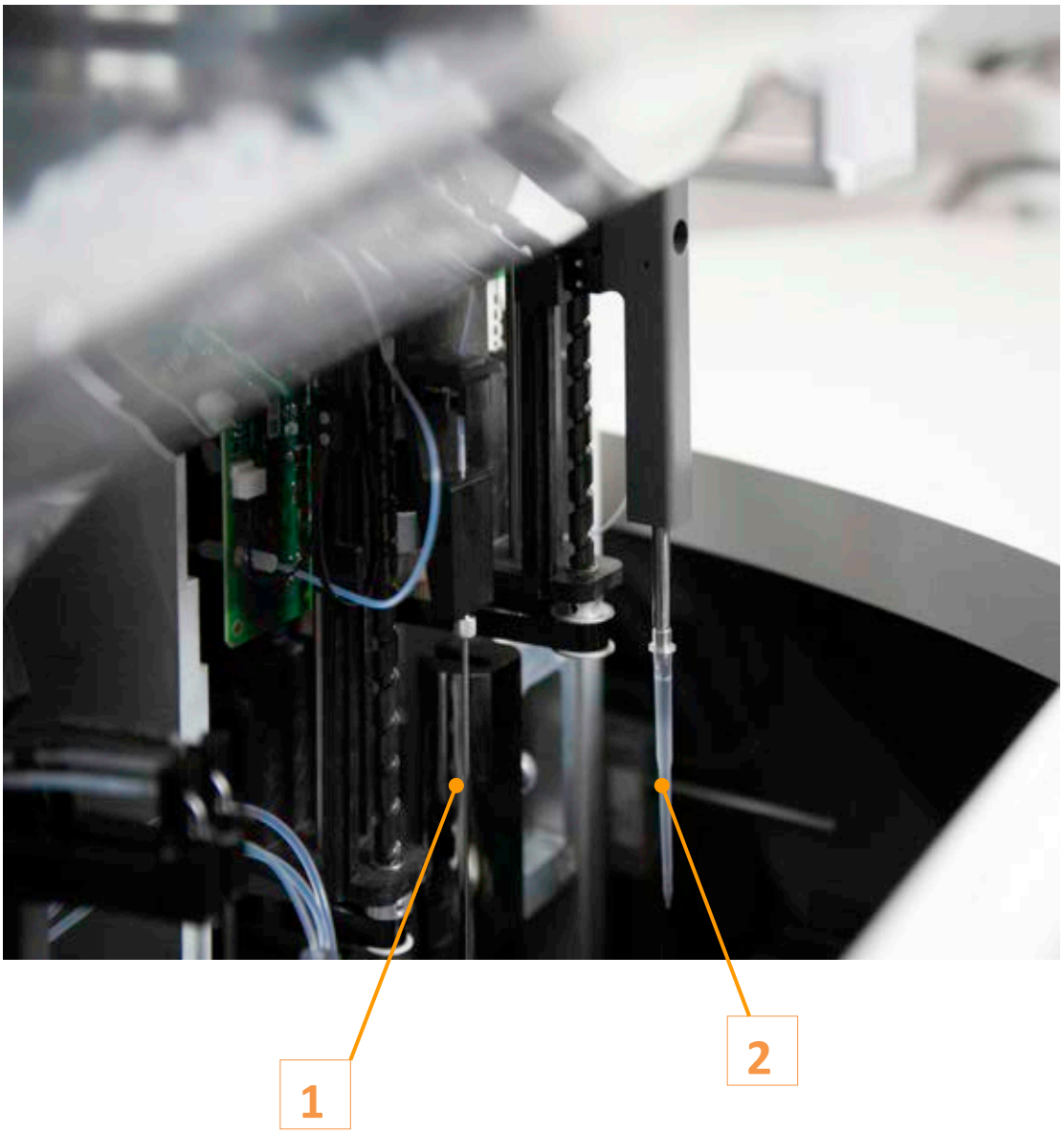
A. ___ Ancillary Probe

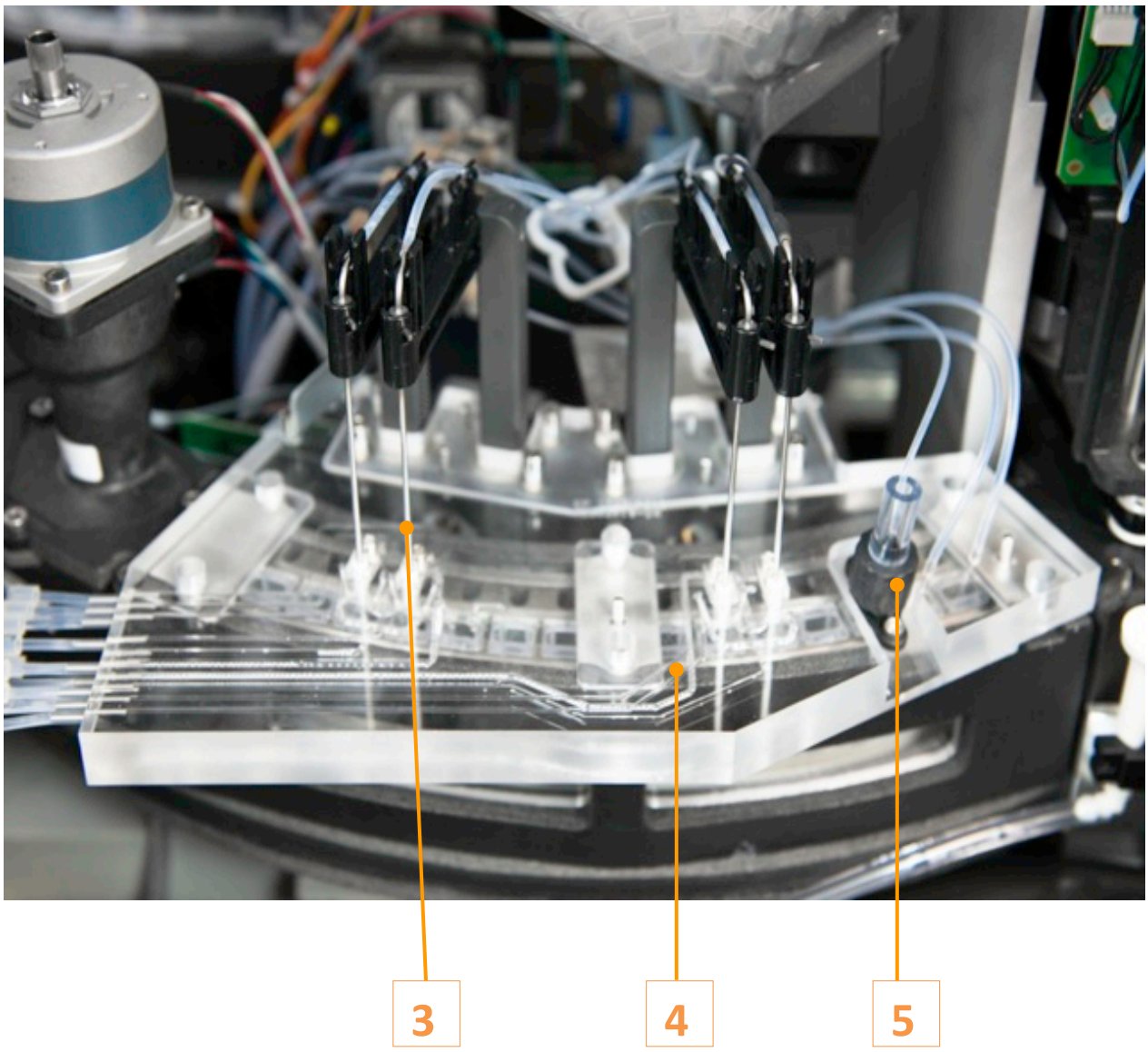
B. ___ Wash Block

C. ___ Sample Probe

D. ___ Aspirate Probes

E. ___ Acid Probe




3
4
5

4. Identify the following system interior components in the next two images below.

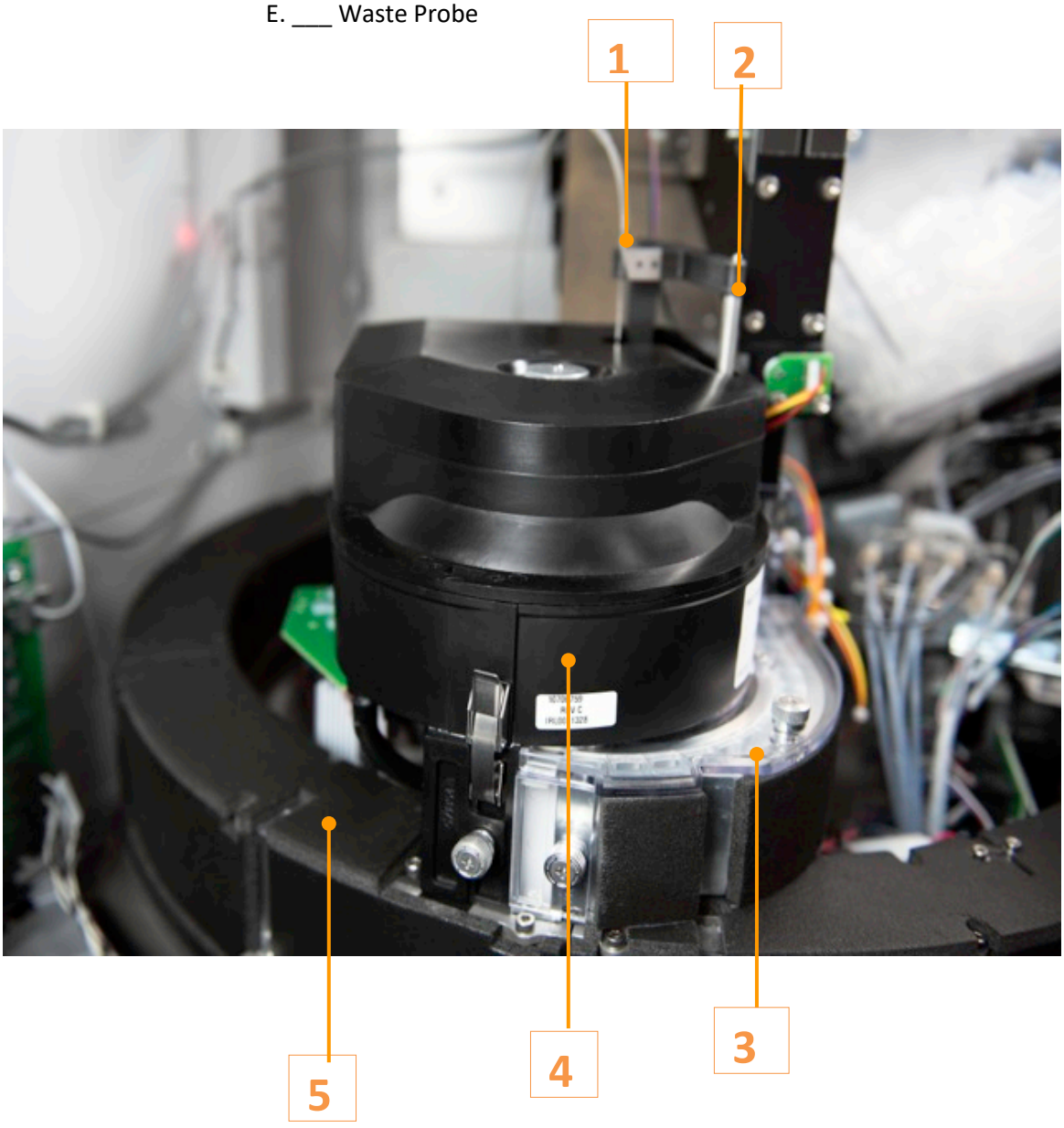
A. ___ Luminometer

B. ___ Incubation Ring

C. ___ Preheater

D. ___ Ejector Rod

E. ___ Waste Probe



5. Identify the following system components in the image below.

A. _____

B. _____

C. _____

3 User Interface

User Interface

Resources

- Software Overview section in *ADVIA Centaur XPT Immunoassay System Operator's Guide*
- ADVIA Centaur XPT System PEP To Go
- Online Help
- PEP Connect

Objectives

After completing this section, you will be able to:

- Log onto the ADVIA Centaur XPT System Software.
- Navigate the main software windows.
- Navigate the online help function.

Login

Log in to the ADVIA Centaur XPT System with the provided username and password.

Main Software Windows

Navigate the User Interface to answer the following questions.

1. Where is the Software Version located?

2. Where is the system serial number located?

3. Which button is selected to check the reagents status?

4. Which button is selected to check the sample tips status?

5. List the steps to access the Daily Cleaning Procedure.

6. Which button can be selected to order a sample?

7. Where would you gather information about ambient temperature and humidity?

8. Where is the test efficiency monitored? How is it calculated?

9. Which button of the command bar is flashing red when a critical condition happens on the system?

Online Help

1. Access the Online Help.
2. Look for the Operator Manual.

4 Supplies and Reagents

Supplies and Reagents

Resources

- Consumable Management section in *ADVIA Centaur XPT Immunoassay System Operator's Guide*
- ADVIA Centaur XPT System PEP To Go
- Online Help
- PEP Connect

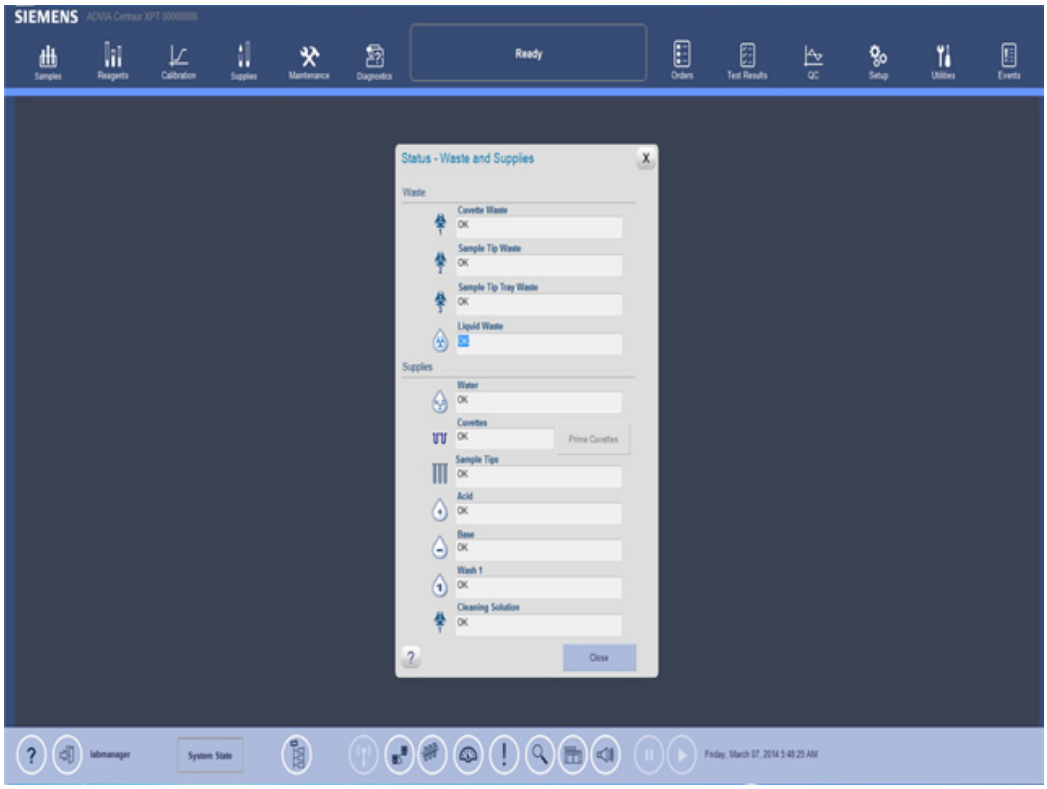
Objectives

After completing this section, you will be able to:

- Determine the status of supplies.
- Load supplies and empty waste.
- Determine the status of reagents.
- Load primary and ancillary reagents.

Determine the Status of Supplies

1. Select the **Supplies** button on the Command Bar.



Questions

1. What does it mean if one of the waste or supplies is red?

2. What does it mean if one of the waste or supplies is yellow?

Load Supplies and Empty Waste

a) Examine the connections on the liquid waste bottle. Practice disconnecting and reconnecting the tubing. Empty the bottle if needed.

b) Withdraw and empty the cuvette and tip waste bins.

c) Remove any empty tip trays or tip tray lids from the tip tray waste area.

d) Examine the connection on the water bottle. Practice disconnecting and reconnecting the tubing. Fill the water bottle with deionized water if needed.

e) Examine the quantity of cuvettes in the cuvette loading bin. If needed, load a new bag.

f) Remove the protective cover of a sample tip tray bundle. Open the supplies access cover and examine the position of the tip trays in the loader. Load the new sample tip tray bundle if there is adequate space.

g) If the Acid, Base or Wash 1 bottles need to be replaced, obtain new bottles and replace them. If none need to be replaced, practice removing and replacing the existing bottle.

Questions

1. Which supplies can be loaded while the system is processing samples?

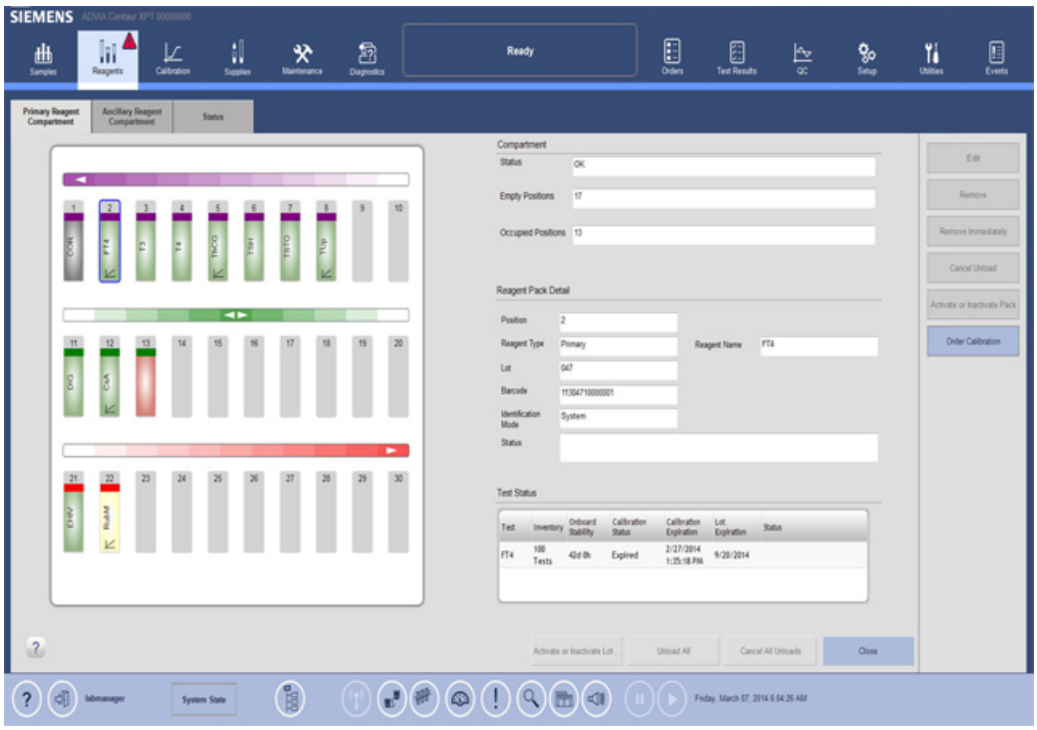
2. If the system runs out of cuvettes, what button would you select to restart the cuvette loader?

3. What is the on-board stability of the Acid, Base and Wash 1?

Determine the Status of Reagents

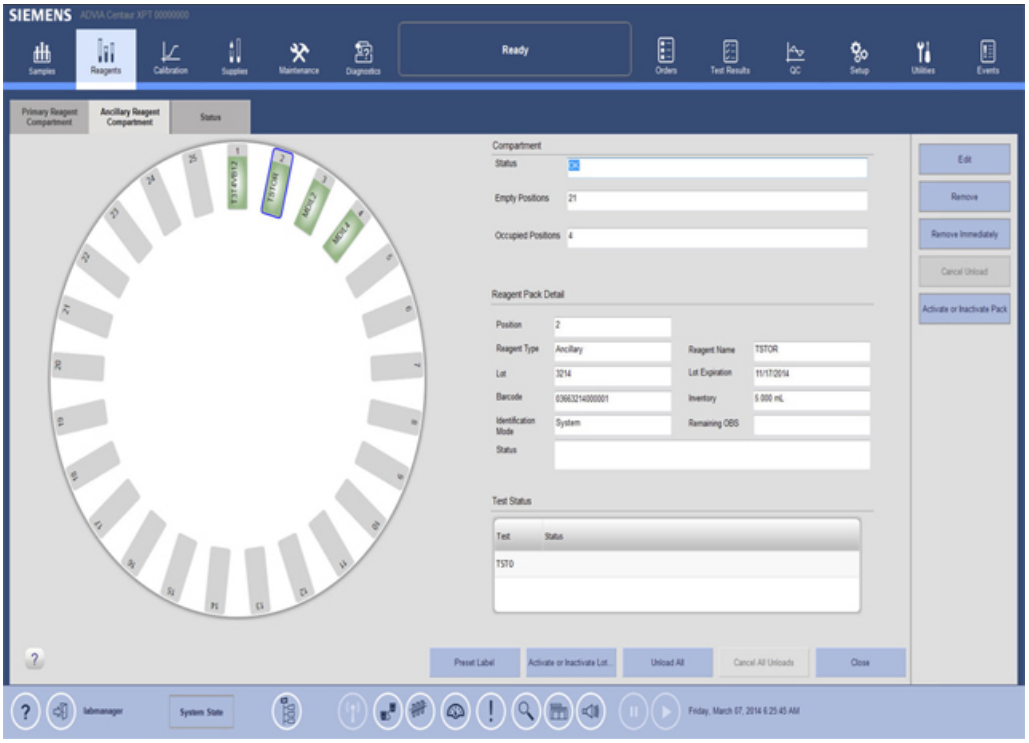
1. Select the **Reagents** button on the Command Bar.

2. Select the **Primary Reagent Compartment** tab. Select one of the packs. Observe the information that displays for the selected pack.

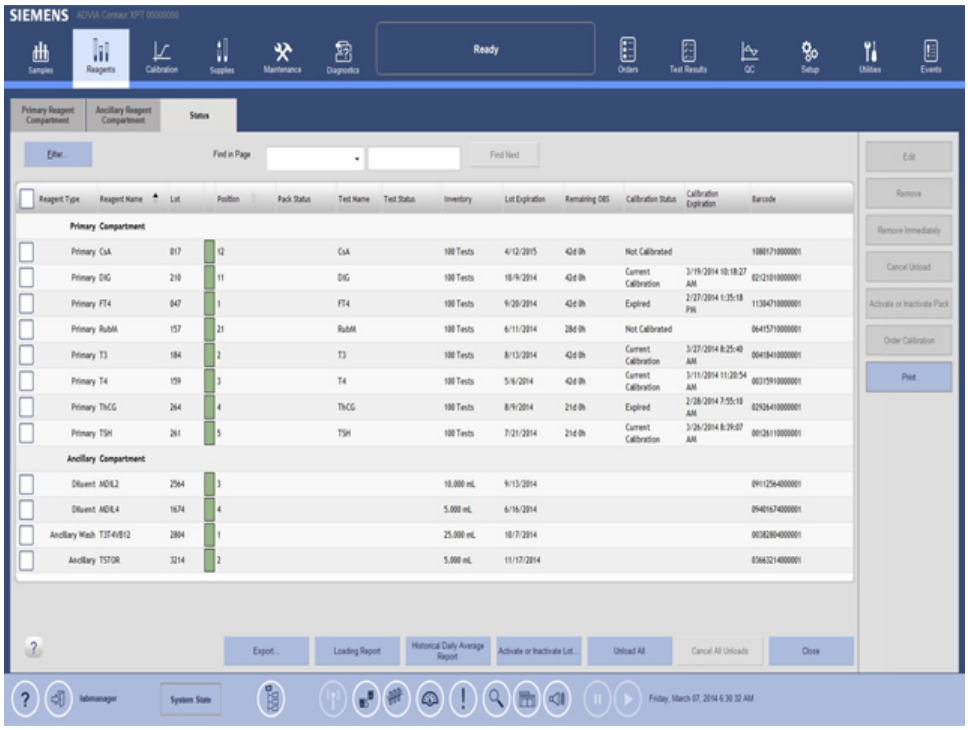


1.

2. Select the **Ancillary Reagent Compartment** tab. Select one of the packs. Observe the information that displays for the selected pack.



3. Select the **Status** tab.



a. Sort the screen by Reagent Name.

b. List the steps to print the information on the Status screen.

Load Primary and Ancillary Reagents

Primary Reagent Handling

- Mix end-to-end at least 20 times.
- CEA and H2n require a special mixing technique. Shake the pack vigorously back and forth for 15 seconds and then tap the pack on the bench 5 times.
- Onboard stability starts as soon as the reagent pack is scanned.

Ancillary Reagent Handling

- Gently invert pack before loading.
- VB12 and Folate releasing agent require manual preparation.
- Onboard stability starts when the pack is pierced.

1. Use the software to remove a pack from the primary reagent compartment. Replace the pack in another position.
2. Access the Ancillary Reagent Compartment screen.
3. Use the software to remove an ancillary pack from the system.
4. Remove and then replace the ancillary pack onto the loader.

Questions

5. Do primary reagent packs need to be placed in a specific area of the compartment? Explain

6. VB12 and Folate ancillary reagents require manual preparation. Where can the instructions be found?

5 Quality Control

Quality Control

Resources

- Quality Control section in *ADVIA Centaur XPT Immunoassay System Operator's Guide*
- ADVIA Centaur XPT System PEP To Go
- Online Help
- PEP Connect

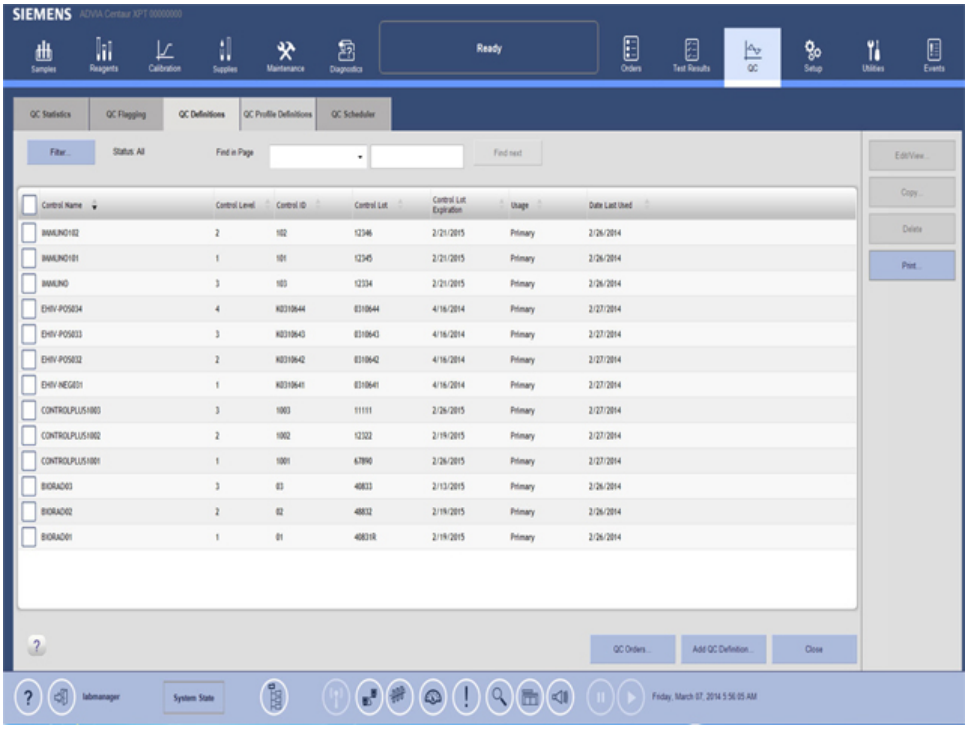
Objectives

After completing this section, you will be able to:

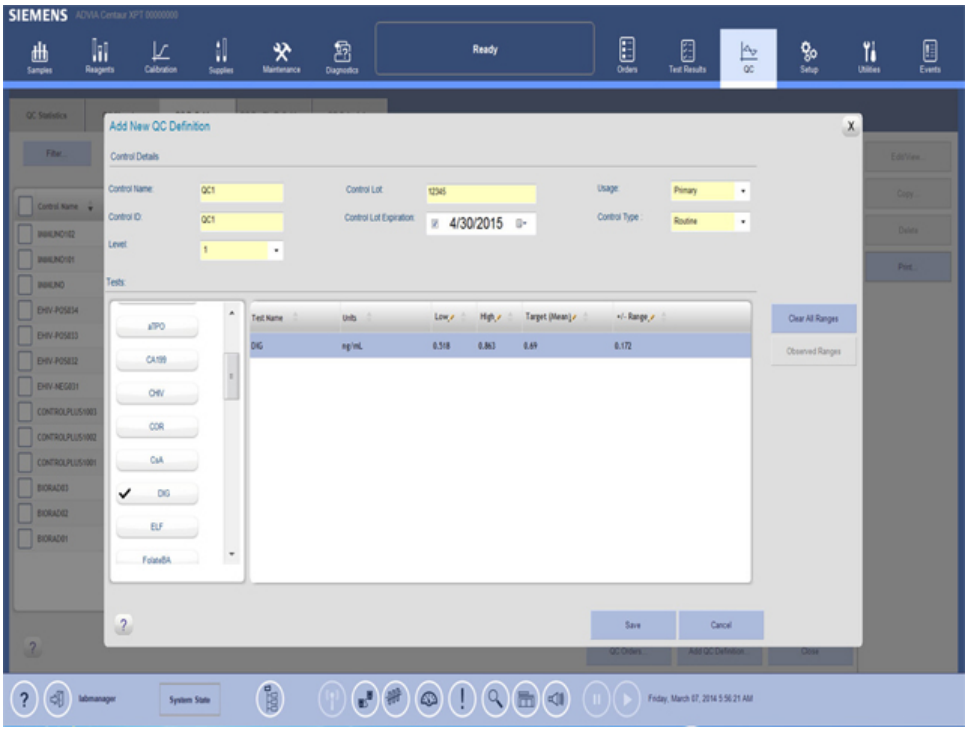
- Add and Edit a quality control definition.
- Process QC samples and profiles.
- View QC data.
- Access QC statistics.

Create and Edit a Control Definition

1. Select the **QC** button on the Command Bar. Select the **QC Definitions** tab.



2. Select **Add QC Definition**. Define and save at least one level of control using the attached Expected Value sheet.



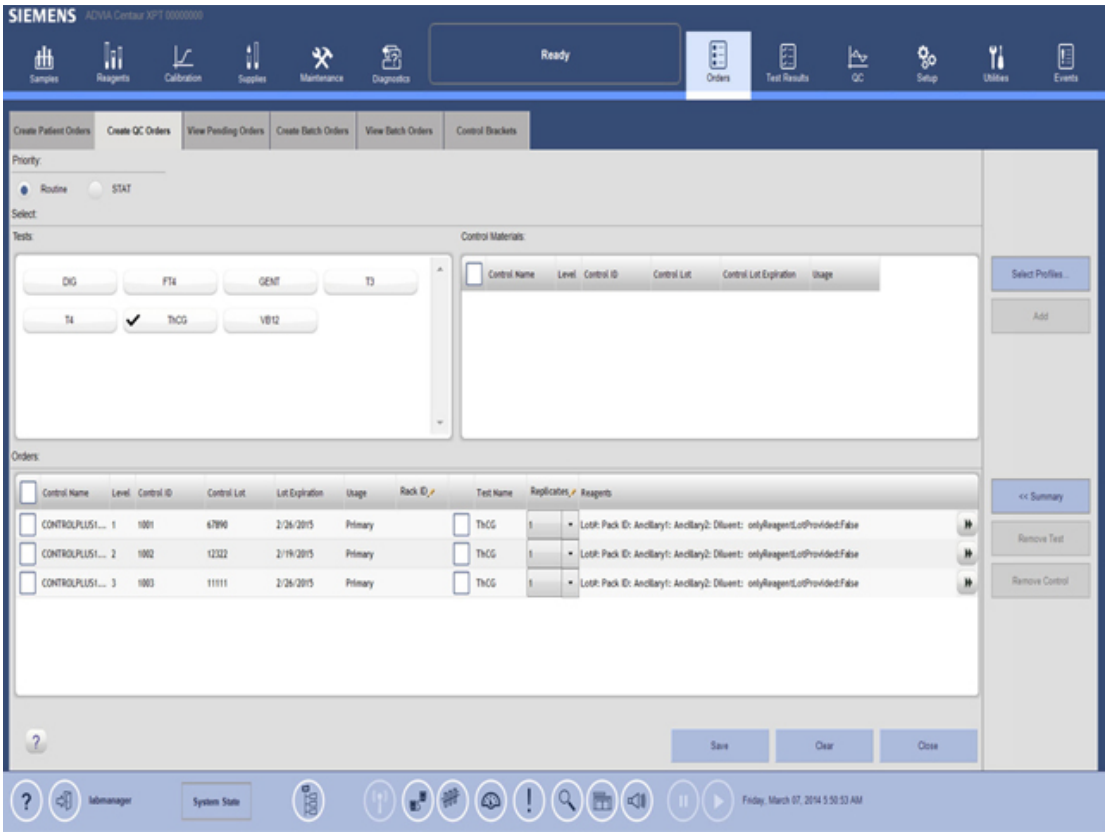
3. On the QC Definitions screen, select the level of control you defined in the previous step. Change the low and high values for one of the assays.

Questions

1. Can QC definitions be edited while the system is In Process?

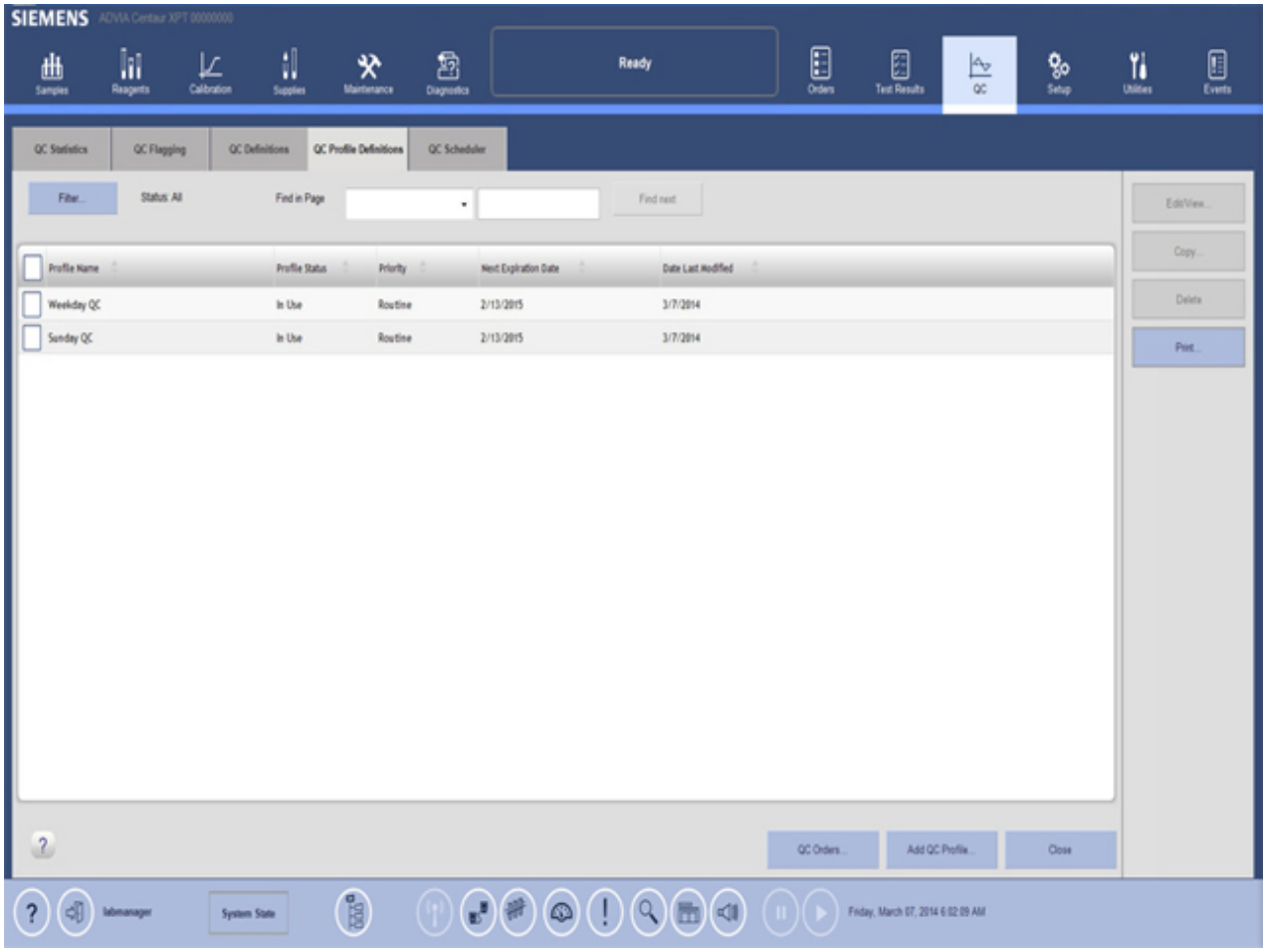
2. What button do you select in order to update the low and high values for a control?

Process QC Samples



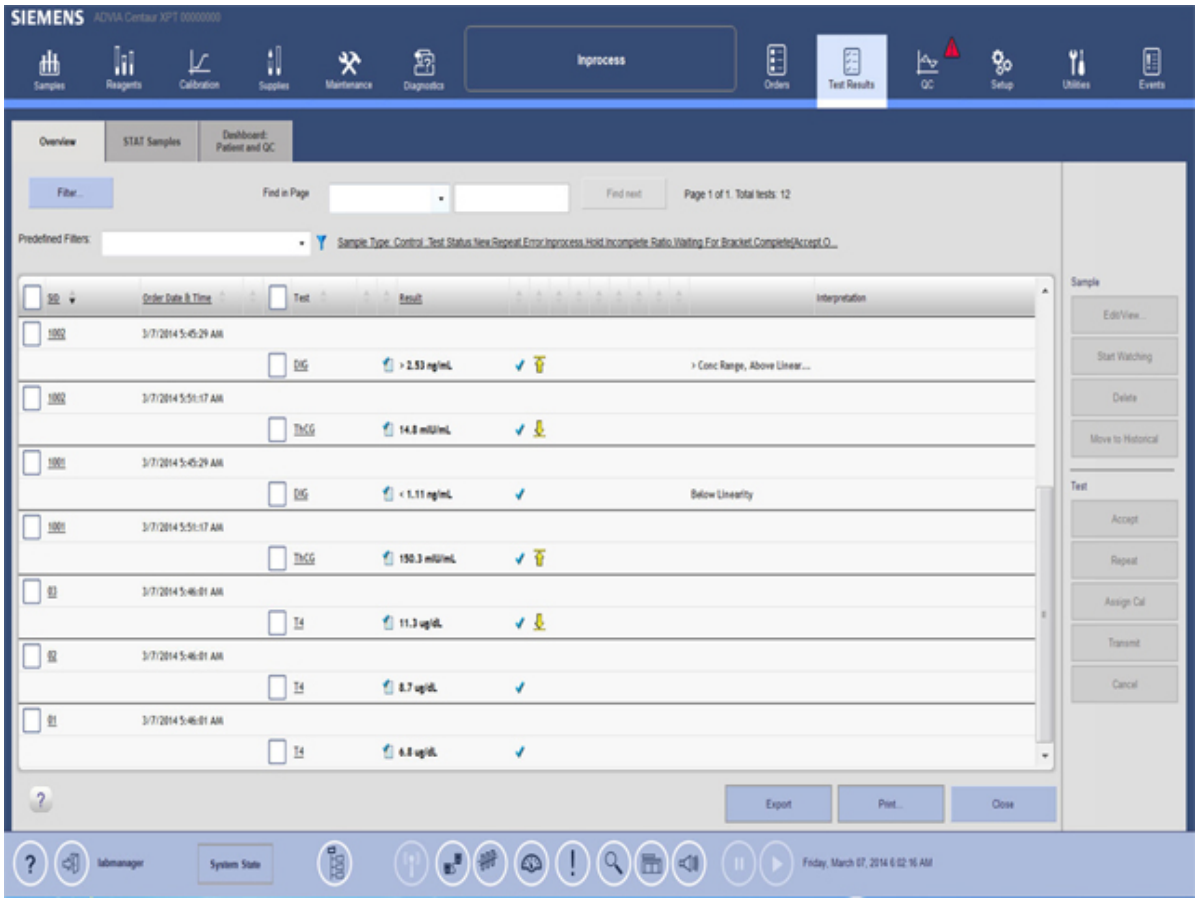
1. Order QC for the assays you would like to run. **Note:** Make sure reagent is available for the assays.
2. Select **Orders** at the Command Bar. Select the **Create QC Orders** tab.
3. Select a priority. In the Tests area, select one or more tests.
4. In the Control Materials area, select each control material to include in this order. Select the **Add** button.
5. In the Orders area, select or enter the order and test information if needed by selecting the **Details** button.
6. Select the **Save** button.
7. Load the rack with the QC onto the Sample Entry Queue. Start the run.

Create and Order QC Profiles



1. Access the QC Profile Definition screen and define a QC test profile.
2. Order QC using the profile you just defined.

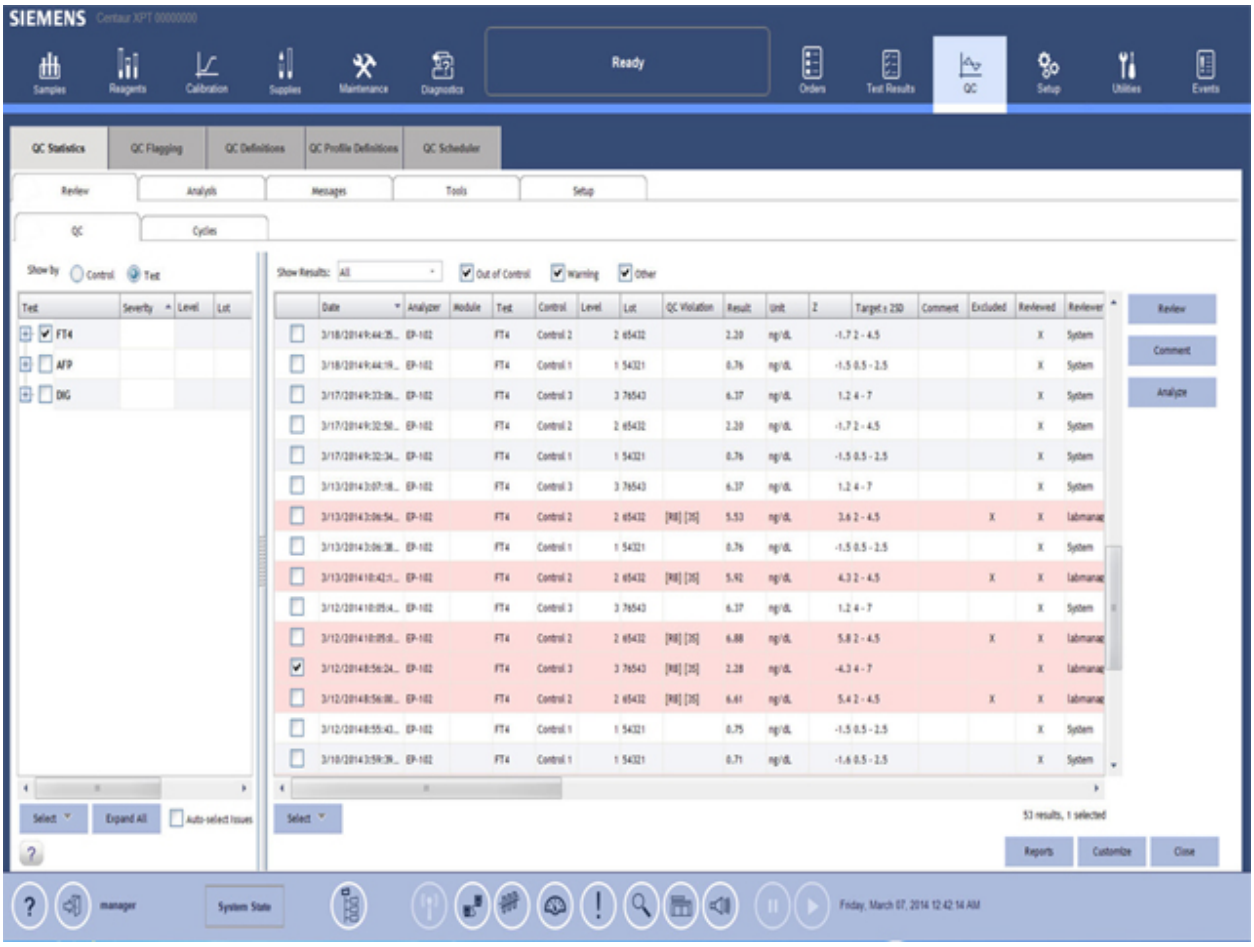
View QC Data



1. When the QC tests are complete, select the **Test Results** button on the Command Bar. Select the **Overview** tab. View the QC results.

Access QC Statistics

1. Select the **QC** button on the Command Bar. Select the **QC Statistics** tab. Select the **Review**



2. Add a comment to a control point.
3. Select a control file and then select the **Analyze** button.
4. Change the date range for the displayed control data by selecting the **Filter** button.
5. Remove a data point from the statistical calculations by selecting a point and then selecting **Exclude**. Reinstate the point by selecting **Include**.

Print QC Data

Print QC data using the **Reports** button on the **QC Statistics > Review screen**.

6 Processing and Managing Samples

Processing and Managing Samples

Resources

- Sample Management section in *ADVIA Centaur XPT Immunoassay System Operator's Guide*
- ADVIA Centaur XPT System PEP To Go
- Online Help
- PEP Connect

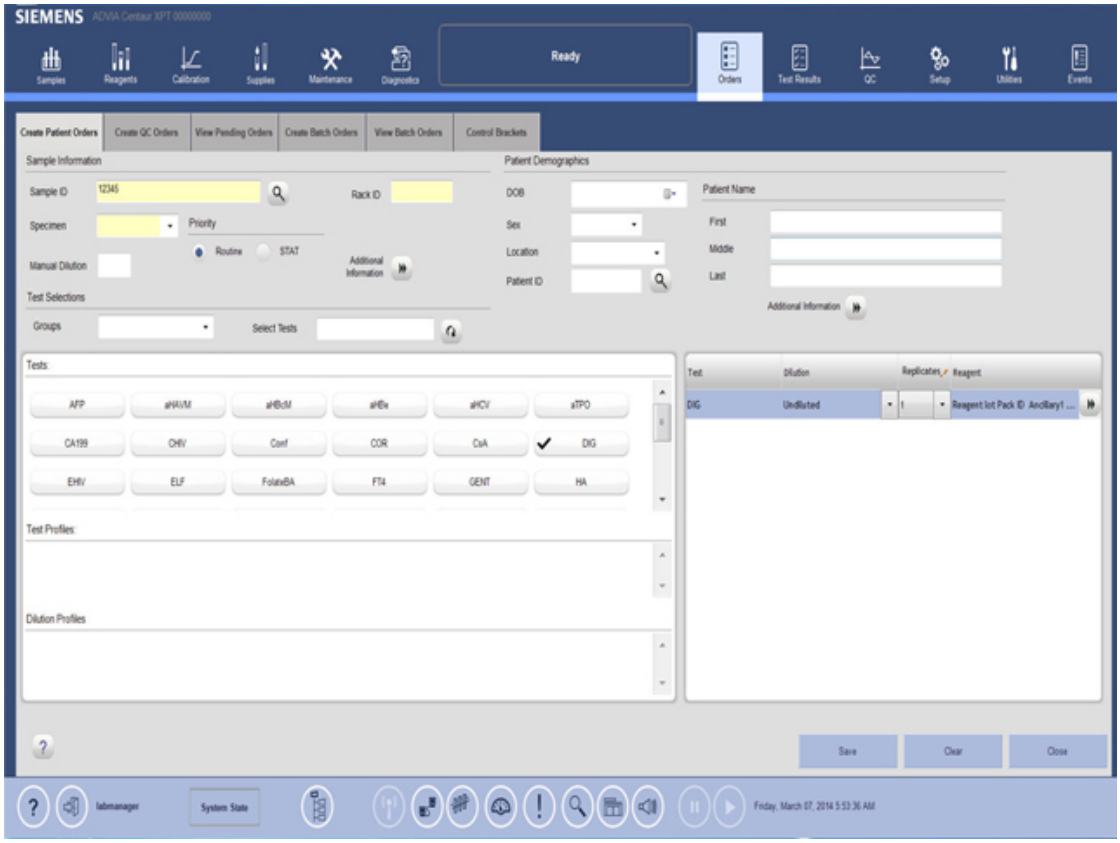
Objectives

After completing this section, you will be able to:

- Process patient samples.
- Monitor sample status and results.
- Print and export results.

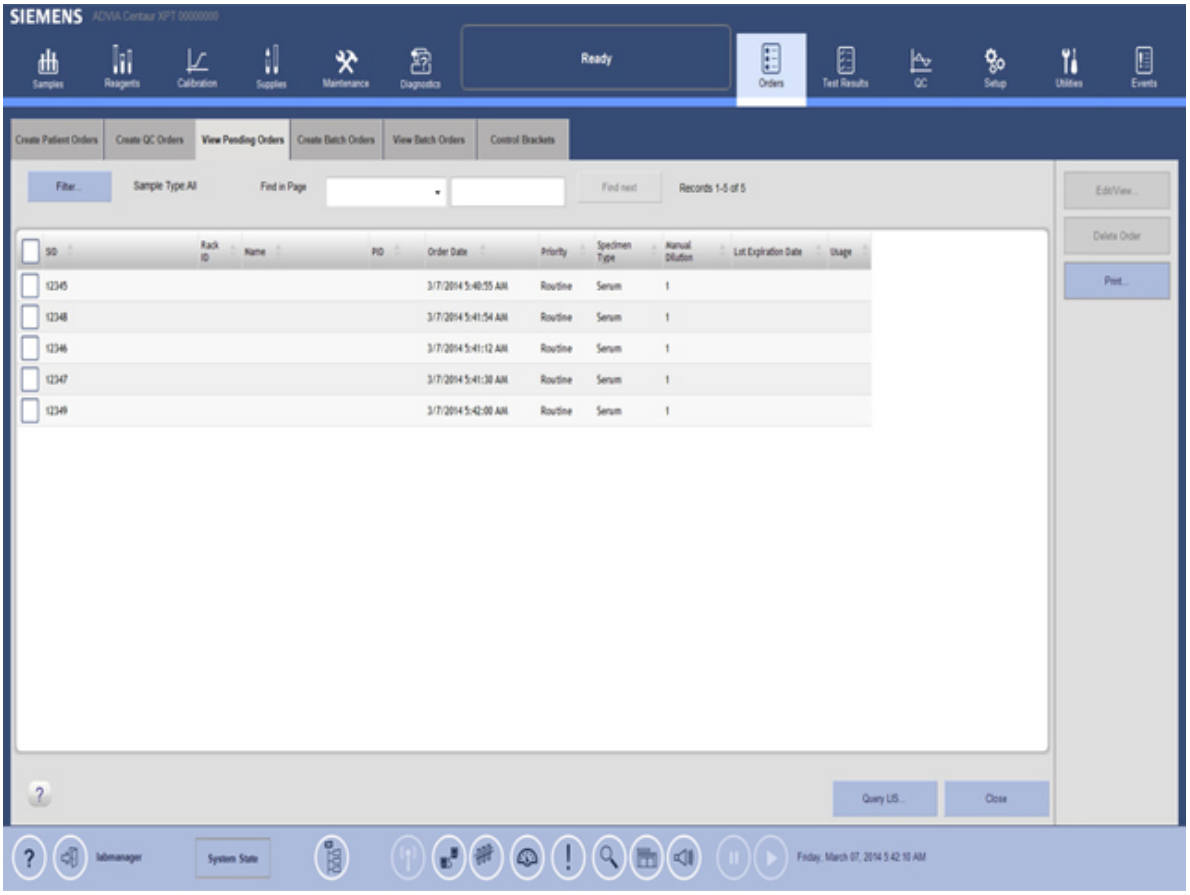
Process patient samples

1. Select the **Orders** button on the Command Bar. The first tab is Create Patient Orders.



2. Order tests for the following samples:
   a. A barcoded patient sample
   b. A barcoded patient sample with manual dilution
   c. A barcoded patient sample with a system-performed dilution
   d. A STAT patient sample
   e. A batch of patient samples
   f. An non-barcoded rack of patient samples

3. View the test orders on the View Pending Orders tab.



4. Load the samples onto the system and press the Start button.

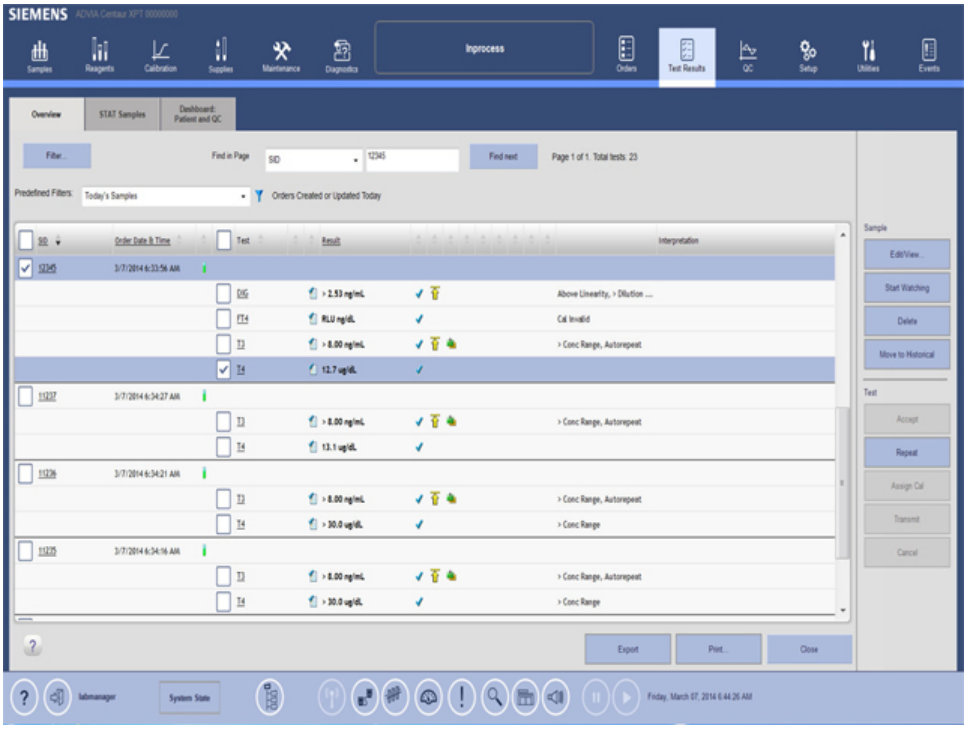
Questions

1. How are replicates ordered?

2. List two ways that a sample can be designated as a STAT?

Monitor Sample Status and Results

1. Select the **Test Results** button on the Command Bar. Select the **Overview** tab.



2. Review the time to completion for the in-process orders.
3. Select a test and then select the Start Watching button. Access the **Watch List** screen.
4. Select the Dashboard icon on the Status Bar at the bottom of the screen.

Select the In Process and Intervention needed counters.

5. Filter the **Test Results Overview** screen to view only results.

Questions

1. How can you determine if the sample is inside the system?

2. How can a repeat test be ordered?

3. Which button would you select in order to transmit a result to the LIS?

7 Calibration

Calibration

Resources

- Calibration section in *ADVIA Centaur XPT Immunoassay System Operator's Guide*
- ADVIA Centaur XPT System PEP To Go
- Online Help
- PEP Connect

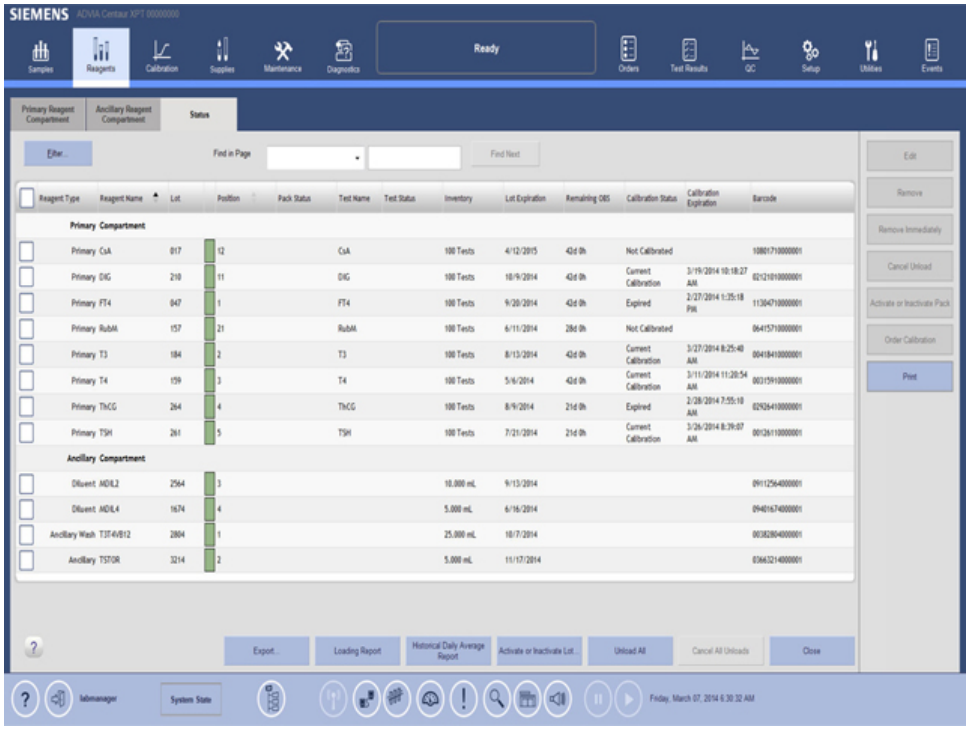
Objectives

After completing this section, you will be able to:

- Check calibration status.
- Locate and scan a Master Curve Definition (MC DEF) card.
- Locate and scan a Calibrator Definition card.
- Order and run a calibration.
- Review and print calibration data.

Check Calibration Status

Access the Reagents screens and check to see if any current reagent lots need to be calibrated.



Questions

1. How can you tell from the Reagents screens that a reagent lot needs to be calibrated?

2. Which other screen could you view to check calibration status?

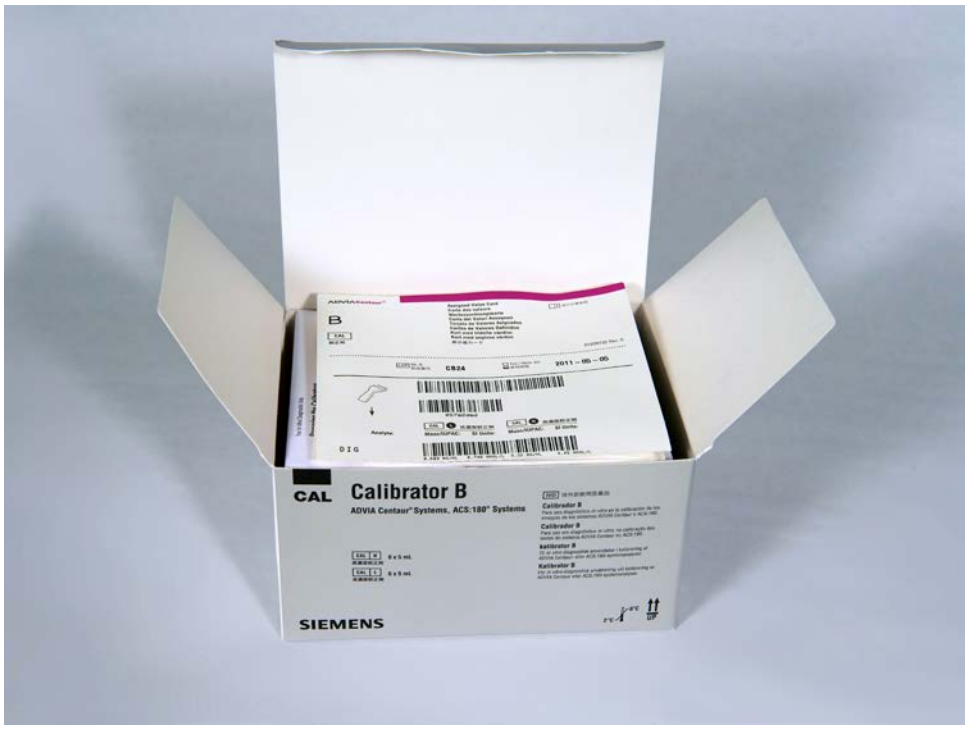
Scan the Master Curve and Test Definition (MC DEF) Card

The MC DEF Card:

- Is located in the Primary Reagent box.
- Can only be scanned while the system is in Ready.
- Can be scanned from any screen.

1. Locate the MC DEF card for the reagent lot you will be calibrating.
2. Scan the MC DEF card into the software using the barcode scanner.
3. Save the scanned information.

Scan the Calibrator Definition Card



The Calibrator Definition Card:

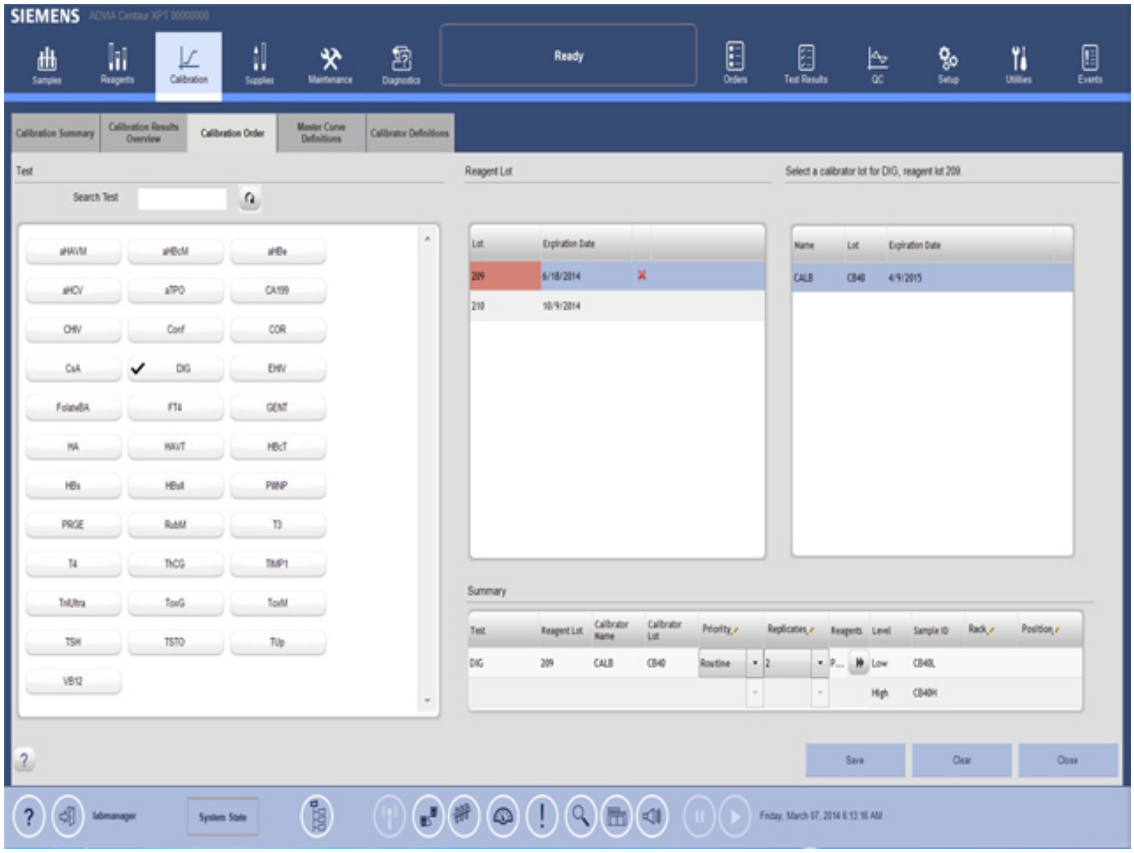
- Is typically located in the calibrator box/bag.
- Can be scanned while the system is In Process.
- Must be scanned from the Add Calibrator Definition screen.

1. Locate the Calibrator Definition card.
2. Access the Calibrator Definitions screen, and then select **Add Calibrator**.
3. Scan the Calibrator Definition card into the software and select **Save**.

Question

1. How can you determine what calibrator is used to calibrate an assay?

Order and Run a Calibration



1. Order the calibration.
   a. Select **Calibration** at the Command Bar.
   b. Select the **Calibration Order** tab.
   c. Select a test.
   d. Select a reagent lot for the test, and then a calibrator lot.
   e. Select **Save**.
   f. Repeat the same steps to order additional tests for the calibrator.

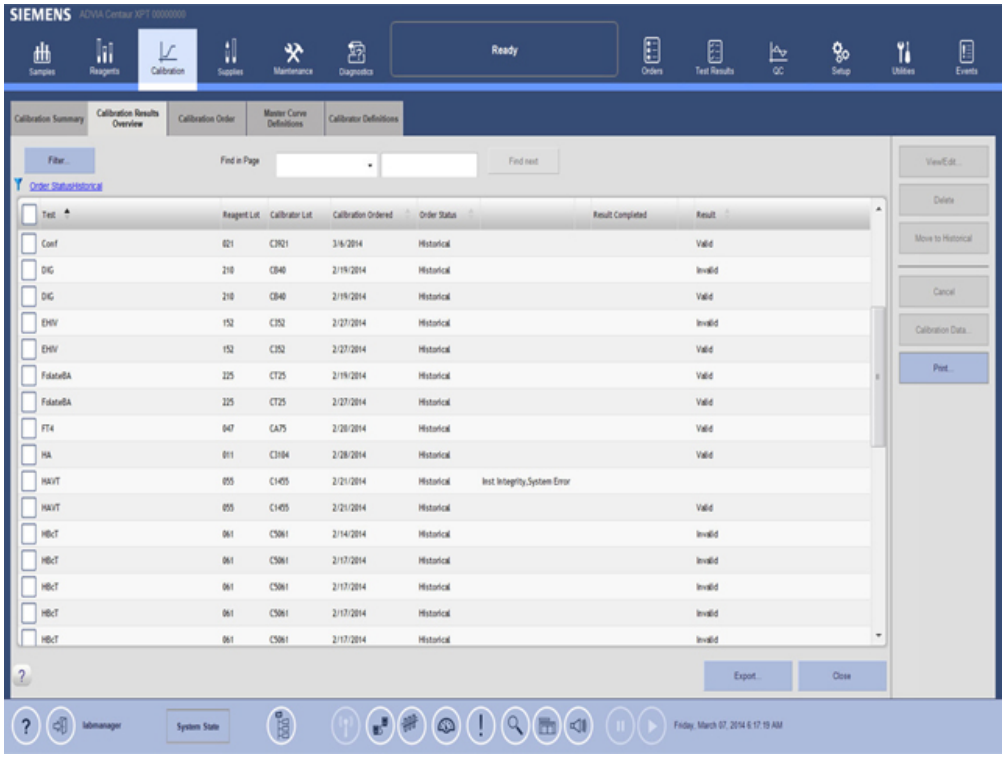
2. Load the rack with the calibrators onto the Sample Entry Queue and start the run.

Question

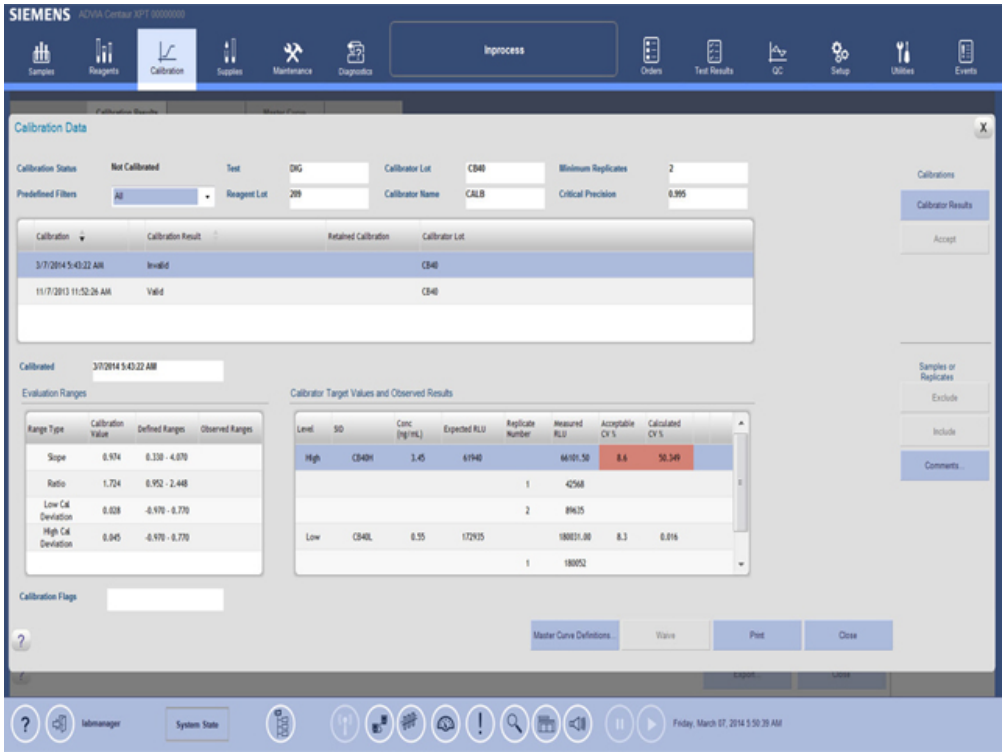
1. What is another option for ordering calibration?

Review Calibration Data

1. When the calibration is complete, access the Calibration Results Overview screen. Review the calibration results.



2. Access the Calibration Data screen for one of the calibrations. Review the Calibration Evaluation Criteria for the selected calibration.



Calibration Evaluation Ranges (CERs)

The metrics are based on the high and low calibrator RLUs compared to those defined when the Master Curve was entered.

The 5 CERs must be met to validate the integrity of a calibration.

- Precision – checked first by the system. If critical precision is not met, the system deems the calibration to be invalid.
- Slope
- Ratio of high calibrator RLU to low calibrator RLU
- Deviation of the high calibrator
- Deviation of the low calibrator

A calibration is valid if:

- All CERs fall within a defined range.
- All CERs fall with an observed range if an observed range exists.

An observed range is created after 4 valid calibrations using the same lot of reagent and calibrator combination.

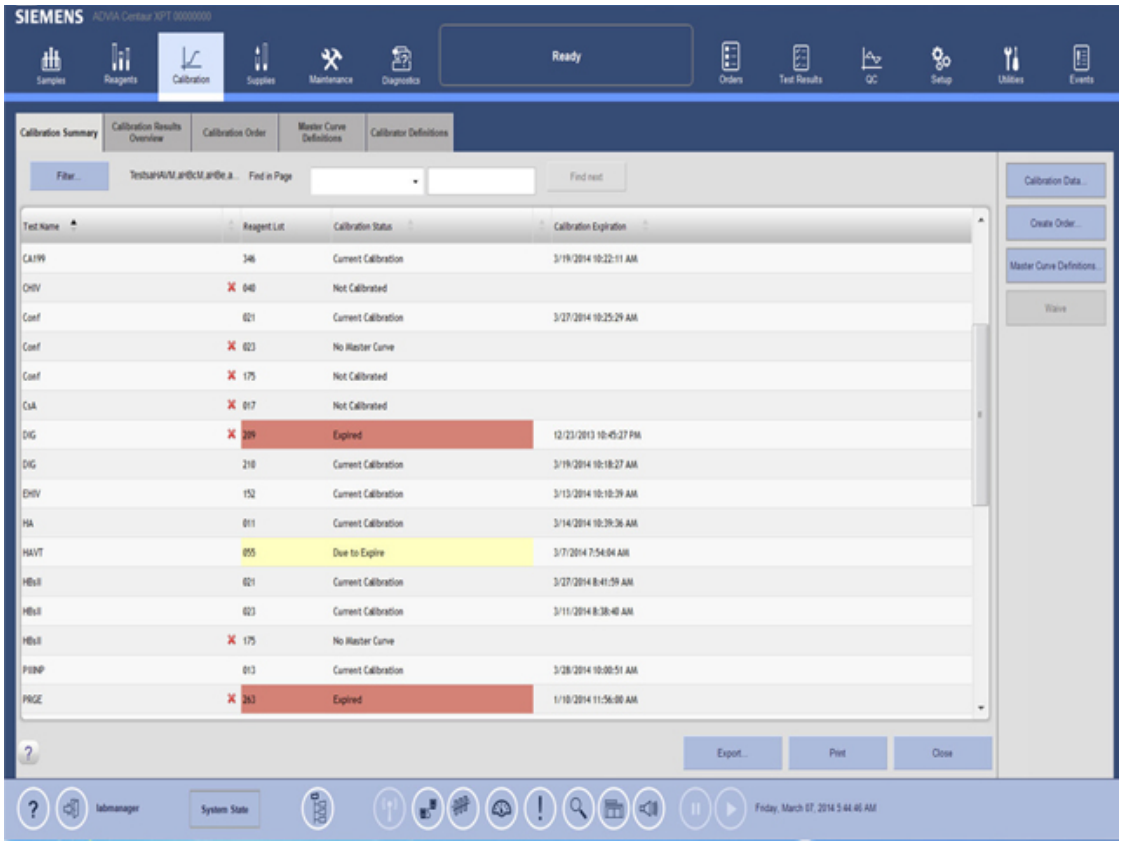
Questions

1. What should the status be if the calibration has passed?

2. What would you do if the calibration was Invalid?

3. What would need to be done if the status was Pending Accept?

Print Calibration Data



1. Access the Calibration Summary screen and select Print. Select Preview.
2. Access the Calibration Results Overview screen. Select a test and then select Print and Preview.

8 Maintenance

Maintenance

Resources

- Maintenance section in *ADVIA Centaur XPT Immunoassay System Operator's Guide*
- ADVIA Centaur XPT System PEP To Go
- Online Help
- PEP Connect

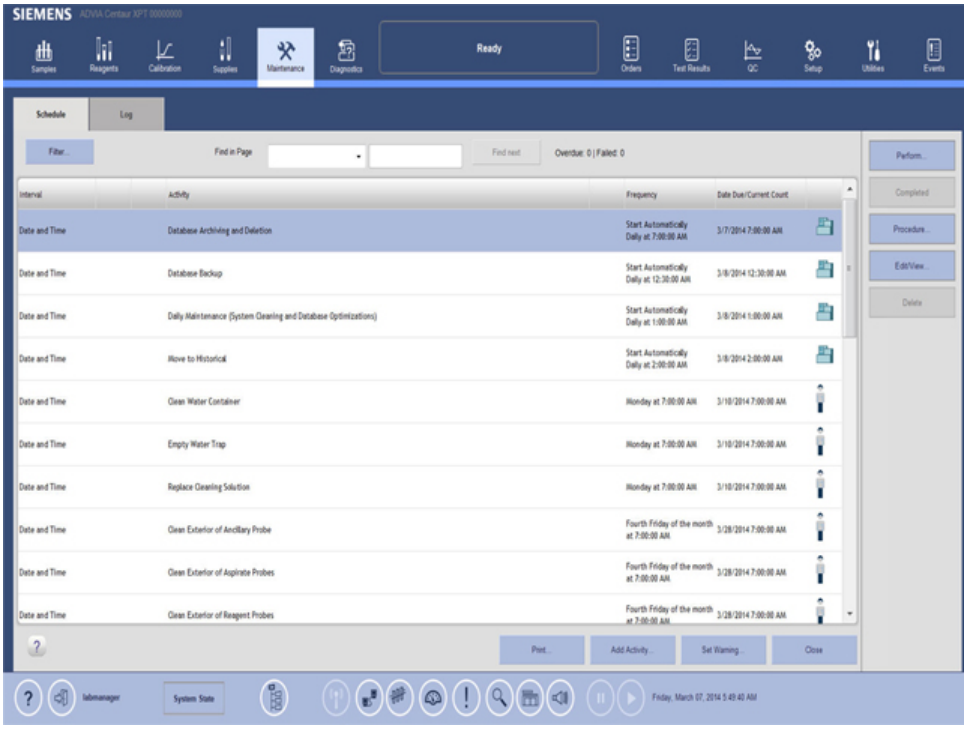
Objectives

Upon completion of this exercise you will be able to:

- Navigate the maintenance windows.
- Perform daily maintenance.
- Perform weekly maintenance.
- Perform monthly maintenance.
- Perform the as-needed maintenance.

Navigate the Maintenance Screens

1. Select the **Maintenance** button on the Command Bar. The first tab is Schedule.



Questions

1. What happens when the question mark in the lower left corner of the Maintenance Schedule screen is selected instead of the **Procedures** button?

2. How can you determine which tasks are due to be done now?

3. What is the difference between the Schedule and Log tabs?

Perform Daily Maintenance

1. Make sure the system is in the Ready state
2. Make sure the necessary supplies are loaded on the system to run the daily cleaning procedure.
3. From the Maintenance Schedule screen, select the **Daily Maintenance** activity and then select **Perform**.

Question

1. What supplies are used by the system during the daily cleaning procedure?

Perform Weekly Maintenance

1. Clean the water bottle.
2. Locate the water trap.
3. Restart the system. Select System State from the Status Bar, and then select Turn System Off. When the system has powered down, turn off the main power switch, wait 30 seconds, and then turn the main power switch back on. Sign in.

Questions

1. How can you record that the water bottle was cleaned in the Maintenance Schedule screen?

2. What should be done to the water trap during weekly maintenance?

Perform Monthly Maintenance

1. Clean the primary reagent, ancillary reagent, and aspirate probes.
2. Clean the air filter.

Questions

1. What items should be cleaned during the monthly required maintenance?

Perform As Needed Maintenance

1. Clean the reagent probe shutter.
2. Clean the cuvette waste area.
3. Clean the sample tip waste area.

Questions

1. What should the status of the system be before the reagent probe shutter is cleaned?

2. What items should be used to clean the cuvette waste chute?

9 Event Log

Event Log

Resources

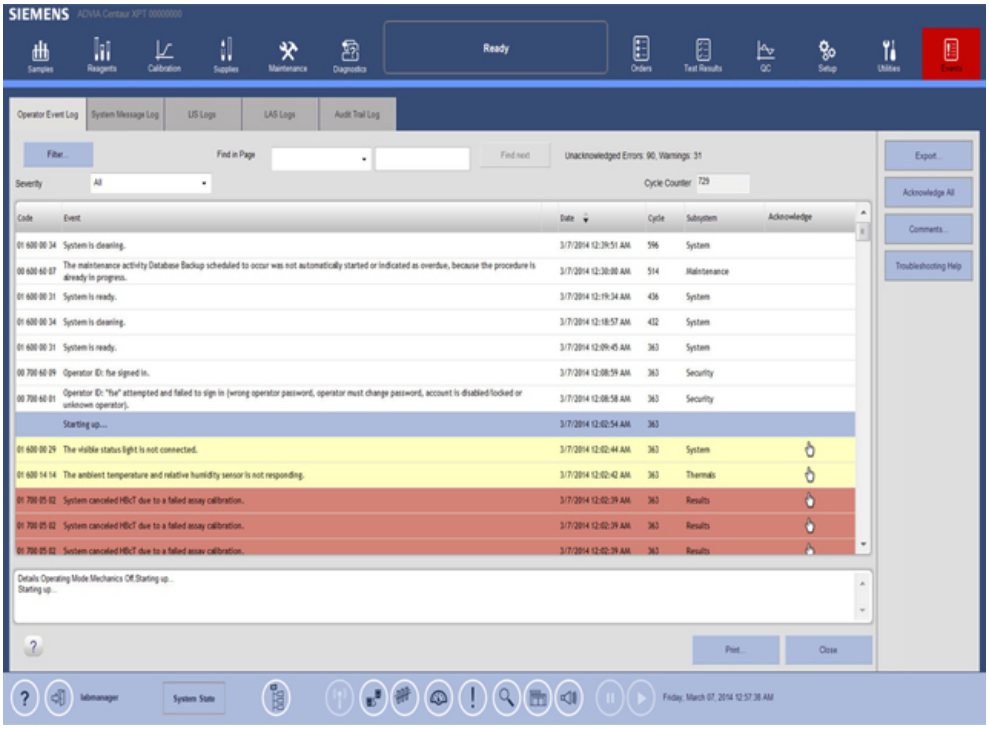
- ADVIA Centaur XPT Immunoassay System Operator's Guide
- ADVIA Centaur XPT System PEP to Go
- Online Help
- PEP Connect

Objectives

After completing this section, you will be able to utilize the Operator Event log and the Online Help to identify troubleshooting procedures.

Access the Operator Event Log

Select the **Events** button on the Command Bar. The first tab is Operator Event Log.



Filter the screen to view only warnings.

Use the Troubleshooting Help to view the possible causes and corrective actions for one of the warnings.

Questions

1. What is the difference between events highlighted in yellow and events highlighted in red?

2. What does it mean if an event has a hand symbol in the Acknowledge column?