Policy Statement	The Saint Agnes Core Laboratory ensures quality sample testing through proper instrument operation.
Purpose	This procedure outlines the appropriate operational usage of the ADVIA Centaur XP.
Scope	This procedure applies to all utilization of the Centaur XP. This includes the testing of calibrators, control materials and patient samples.
Responsibility	It is the responsibility of all Medical Technologists in the Core Laboratory to ensure that the ADVIA Centaur XP is utilized according to this operation document.

Workspace Overview

The workspace provides access to all system functions and information that an operator requires to operate the system. The workspace allows you to open several windows at once to review different information. Although you can work on only one document at a time (active window), the others are still open on the screen.

The workspace has two views:

- System view, offering access to system functions
- Applications view, offering access to a set of applications including the ADVIA QC analyzer, the BayerCare Connect service, and the online documentation browser.

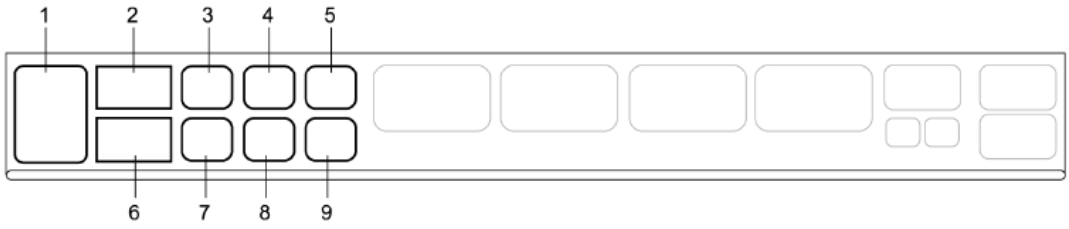
To change from one view to the other view press the QC symbol key (F6) on the system keyboard or the QC status button on the screen.

Workspace Toolbar

The Workspace Toolbar is comprised of a series of buttons that provide access to system status, tasks and functions including signing in or out of the system.

Status Buttons

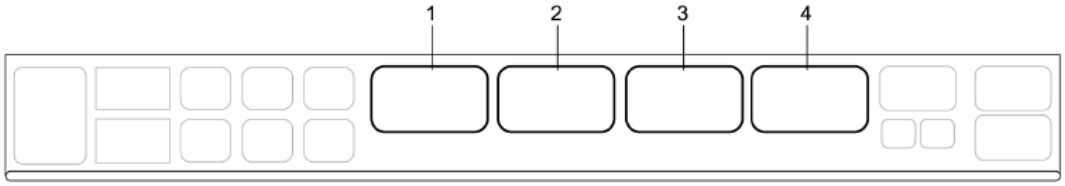
The status buttons open windows that provide information on the condition of the entire system, specific system areas, supplies, and reagents. The status buttons are only available in the system view.



1	System Status	**6**	Current system state field
2	Date and Time field.	**7**	Reagent Status button
3	Supplies Status	**8**	Maintenance Status
4	Sample Status.	**9**	Event Log Status
5	Exception button		

Task Buttons

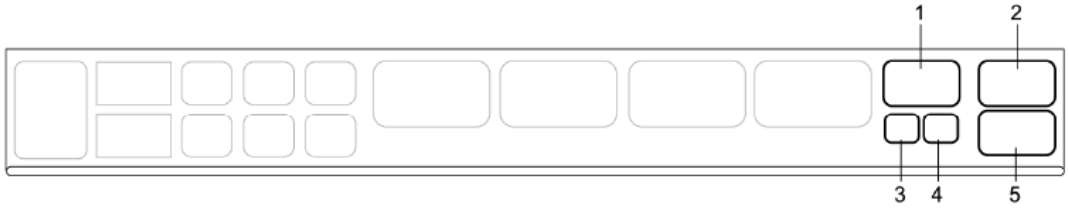
The task buttons provide access to windows associated with specific tasks. When selected, each button displays a list of the windows that are available.



1 Worklist button.
2 Quality Control button
3 Calibration button
4 Setup button.

Function Buttons

The function buttons provide additional capabilities related to the workspace, such as signing in, closing all windows, and requesting printed reports.



1 Close All
2 Sign In
3 BayerCare Connect - available in the Applications View
4 Instructions for Use - available in the Applications View
5 Print

Workspace Status Indicators

The status buttons change color from neutral to yellow or red to indicate that a system area requires attention:

- Yellow indicates that a warning condition exists, such as a low supply.
- Red indicates that a critical condition exists, such as an empty supply.

A critical condition can cause the system to stop aspirating or processing samples. The status buttons blink to indicate that a new condition has occurred since the last time you reviewed that status window. The visible status light on the top of the analyzer

Calibration

The ADVIA Centaur XP system uses a Master Curve and a 2-point, operator-initiated calibration to calibrate assays. Calibration frequency is based on assay definition and troubleshooting necessity. The appropriate sample matrix based on the characteristics for the clinical specimen and specific method is determined by the analyzer manufacturer. Calibration verification criteria are built into the analyzer software. In the

event that a calibration fails it should be repeated. If a calibration fails but is within the expected manufacturer's ranges, it can be accepted in the software under the Calibration Summary details. If the calibration fails and is outside of the expected manufacturer's ranges two times the technical hotline should be contacted for further instructions.

Defining a Master Curve

Each ADVIA Centaur XP assay kit includes a Master Curve Card that lists the analyte concentration and the RLUs for each Master Curve point. The Master Curve card is entered into the system with each new lot of reagent. The barcode scanner should be used to define the Master Curve.

Ensure that the system is in the Ready state.

1. At the workspace, select **Calibration.** (Task button 3)
2. Select **Master Curve Definition.**
3. At the Calibration-Master Curve Definition window, select **Scan Data.**
4. Scan the barcodes on the Master Curve Card from top to bottom.
5. Select **Save.**

Adding a New Calibrator Definition

Each Calibrator Kit includes a Calibrator Assigned Value Card that provides the calibrator values for each analyte in the low and high calibrators. The Calibration Assigned Value Care is entered into the system with each new lot of reagent. Use the barcode scanner to enter the calibrator values.

Ensure that the system is in the Ready state.

1. At the workspace, select **Calibration.** (Task button 3)
2. Select **Calibrator Definition**
3. At the Calibration-Calibrator Definition window, select **Scan Data.**
4. Scan the barcodes on the Calibrator Assigned Value Card.
5. Ensure that the calibrator values are correct.
6. Select **Save.** (Information can not be added or deleted from the definition after you select save.)

Scheduling Calibrators

For all tests, the reagent lot must be loaded before you schedule the calibrator.

1. At the workspace, select **Worklist.** (Task button 1)
2. Select **Schedule**
3. At the Worklist-Schedule window, select **Calibrator.**
4. Select how you want the system to identify the calibrator:
    a. Select **Schedule by SID** (if you have the calibrator barcode)
    b. Select **Schedule by Rack** (if the barcode is not available)
5. Select the test for the calibrator
6. Select the calibrator

   a. When scheduling by SID, select the appropriate SID. The system fills in the Rack ID after the rack is placed on the system.
   b. When scheduling by rack, you can select specific racks for the calibrators.
7. If you schedule by rack, enter the rack ID and position.
8. Select **Save**
9. Repeat steps 4 through 9 to schedule additional tests for a calibrator.
10. Load low and high calibrators in a rack.
11. Load the rack in the sample entry queue.

All information regarding the calibration data is lot specific. Materials should not be used from multiple lots.

Quality Control

Quality Control samples are performed every shift that a patient sample is resulted. Prior to running any patient samples, all quality control samples must be performed and reviewed. The analyzer print-out must be reviewed for all results and to ensure that all quality controls samples were assayed. The analyzer will alarm yellow or red for each QC sample that is out of range. Quality Control must be repeated. Once the results are within range, a comment must be entered into the quality control application and the result must be manually reviewed. All Quality Control results are reviewed monthly by the laboratory director designee, at a minimum. The review consists of reviewing the graphs from the ADVIA QC Application, for trends and shifts.

All information regarding the quality control data is lot specific. Materials should not be used from multiple lots.

Adding a New Control Definition

1. At the workspace, select **Quality Control.** (Task button 2)
2. Select **Control Definition.**
3. At the Quality Control-Control Definition window, select **Add.**
4. Enter the name of the control as it appears on the package insert.
5. In the Type field, select **Routine.**
6. Enter the information for the new lot of control, such as type, SID, lot, and expiration date. The lot number will be preceded by the letter K. The format for the date is DD MMM YY.
7. Select a test:
   a. Select the **Test** button.
   b. Select the specific test.
   c. To close the Test-Selection window, select **Continue.**
8. Enter the expected high and low range values.
9. Select **Save Test.**
10. Repeat steps 3 through 9 for all tests for the control.
11. Select **Save.**

Scheduling QC Samples

1. At the workspace, select **Worklist.** (Task button 1)
2. Select **Schedule.**
3. At the Worklist-Schedule window, select **Control.**
4. Select **Schedule by SID.**
5. Select the desired test.
6. Select the control.
7. Select **Save.**
8. Repeat steps 4 through 8 to schedule the test for additional controls.
9. Load the sample aliquot tubes of QC material in a rack.
10. Load the rack in the sample entry queue.

Normal Patient Sample Testing

Patient samples are loaded into the provided racks. Any size vacutainer or aliquot tube can be placed in rack. The sample barcode should be visible through the window on the rack. Racks can be entered on the analyzer through the Sample Entry Queue or the Stat Entry Queue. The start button must be pressed to initiate the process.

Manually Scheduling Patient Samples

In the event that the LIS is not working, sample will need to be manually programmed. The following steps should be used to program the samples.

1. At the workspace, select **Worklist.** (Task button 1)
2. Select **Schedule.**
3. At the Worklist-Schedule window, select **Patient.**
4. Select how you want the system to identify the sample:
    - **Schedule by SID**
    - **Schedule by Rack**
5. Enter the SID or the Rack ID and then press **Enter.**
6. Select **Save.**

   In all other cases, barcoded samples can be placed on a sample rack and loaded in the sample entry queue.

Evaluating Patient Results

Prior to verifying results in Meditech, all patient results should be reviewed. The analyzer print-out should be reviewed for all results, interpretations and flags. Each flag should be reviewed. For any test that required testing in duplicate, a check should be conducted to ensure that each required test was completed. **No results should be verified prior to review of the print-out.**

Maintenance

The ADVIA Centaur XP monitors maintenance activities and notifies you when a scheduled activity is due. In addition, the system notifies you through a color change at

the Maintenance status button and the Status-Maintenance window when routine and extended certification procedures are due. The background of the maintenance activities changes color to indicate status:

- Yellow indicates that a maintenance activity is due or overdue
- Red indicates that an automated maintenance procedure did not finish.

Performing Daily Cleaning

The ADVIA Centaur XP has been preset to automatically go into Daily Cleaning mode at 00:00 (midnight). Prior to this time the following items should be stocked appropriately;

- Cuvettes
- Cleaning Solution

In the event that the system does not automatically complete the cleaning, complete the following steps to start the process manually:

1. At the workspace, select **Maintenance Status.** (Status button 8)
2. Select **Perform Daily Cleaning.**
3. Select **Perform.**
4. At the prompt, select **Yes.**

Performing Weekly Maintenance

To access the weekly maintenance procedures on the system, use the following procedure:

1. At the workspace, select the maintenance status icon. (Status button 8)
2. At the Status-Maintenance window, select an activity.
3. Select **Procedure.**
4. To print the procedure, select **File**, and the select **Print.**

OR

See CORE 6910 Jb Centaur Weekly Maintenance

Performing Monthly Maintenance

To access the monthly maintenance procedures on the system, use the following procedure:

1. At the workspace, select the maintenance status icon. (Status button 8)
2. At the Status-Maintenance window, select an activity.
3. Select **Procedure.**
4. To print the procedure, select **File**, and the select **Print.**

OR

See CORE 6910 Jc Centaur Monthly Maintenance

Performing As-needed Cleaning Procedures

The ADVIA Centaur XP has defined maintenance that occurs at various schedules.

5. At the workspace, select the maintenance status icon. (Status button 8)
6. At the Status-Maintenance window, select an activity.

7. Select **Procedure.**
8. To print the procedure, select **File**, and the select **Print.**

For all maintenance procedures, refer to the ADVIA Centaur XP Operator's Guide, *Performing Maintenance.*

Troubleshooting

Using the Event Log

Use the System-Event Log window to identify errors and access online information about possible causes and corrective action procedures.
Any warning or critical condition that is captured in the event log causes a change in the background color of the Event Log Status button:

- Yellow indicates that a warning condition exists.
- Red indicates that a critical condition exists that may cause the system to stop aspirating or processing samples.

Accessing Help for Event Codes (Finding a Procedure)

1. At the workspace, select **Event Log.** (Status button 9)
2. Identify the event condition.
   To search for a specific event code in the event log, select **Event Code** in Search for and then enter the event code.
3. Locate the possible causes and corrective action procedure for the error.
   a. At the System-Event Log window, select **Procedure.** (Right side of window)
   b. At the online information window, select **Find.** (Fourth button on menu at top of window)
   c. At the Search window, type the event code exactly as it displays in the event log, including spaces. (*e.g.* 600 02 13)
   d. Select **Enter.**
   e. Click on the event code of interest.
4. Select the corrective action item. The system will display the procedure for performing the corrective action.
5. If you perform a procedure that is a maintenance activity, log the activity at the Status-Maintenance window.

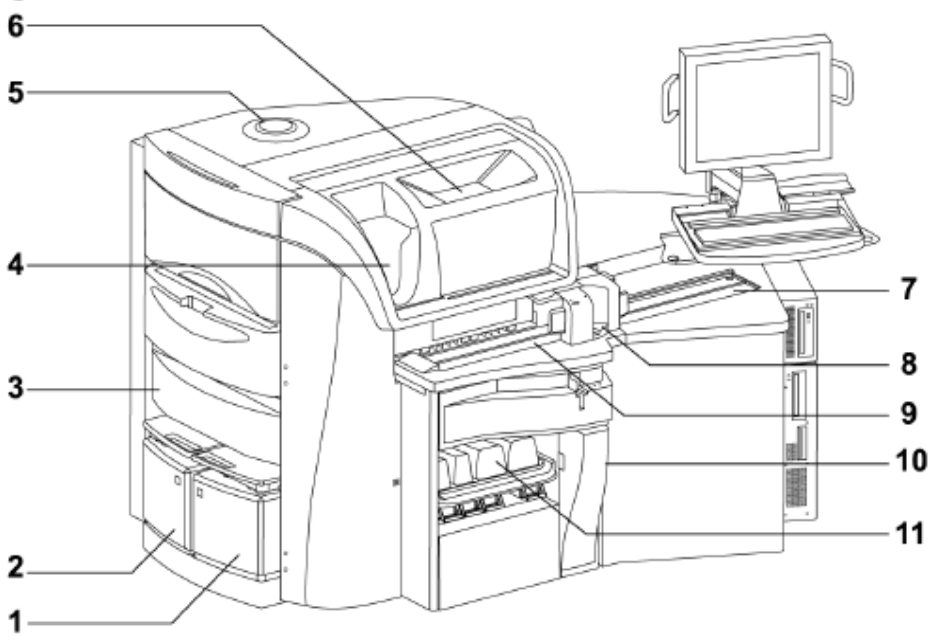
Using Diagnostic Tools

Diagnostic Tools allow you to prime the system, test the operation of the system components, and move system components when you perform corrective action procedures.

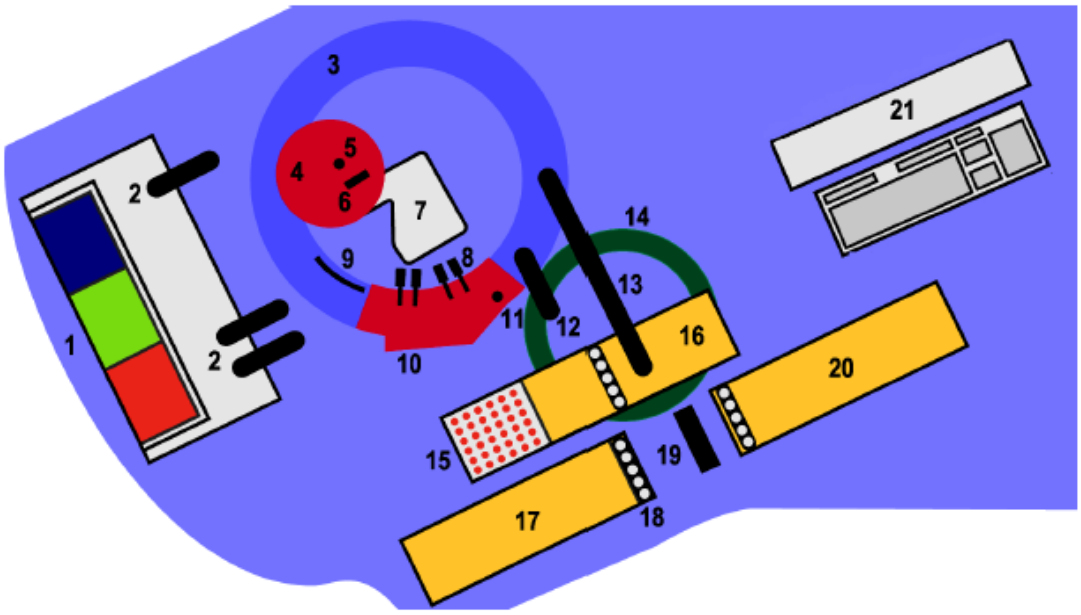
The System-Diagnostics Tools window puts the system in Diagnostics Mode. Any errors that occur while they system is in Diagnostics Mode will appear in the event log. Wait until the system is not processing samples to use diagnostic tools.

Note: The system stops mixing the reagents while in Diagnostic Mode. If reagent mixing is turned off for longer than 2 hours, mix all primary reagent packs following the reagent pack procedures before resuming operation.

Analyzer Diagrams



1	Water Bottle	7	Sample Exit Queue
2	Waste Bottle	8	Stat Entry
3	Primary Reagent Compartment	9	Sample Entry Queue
4	Sample Tip Loader	10	Cleaning Solution
5	Visible status light	11	System Fluids
6	Cuvette Loader		



1	Primary Reagent Compartment	**12**	Ancillary Probe
2	Primary Reagent Probes	**13**	Sample Probe
3	Incubation Ring	**14**	Ancillary Reagent Queue
4	Luminometer	**15**	Sample Tip Tray
5	Base Probe	**16**	Inprocess Queue
6	Waste Probe	**17**	Sample Entry Queue
7	Cuvette Loading Bin	**18**	Sample Rack
8	Aspirate Probes	**19**	Stat Entry
9	Magnets	**20**	Sample Exit Queue
10	Wash Block	**21**	User Interface Workstation
11	Acid Probe		

Related Documents

CORE 6910 Ja Centaur Testing and Notification Information
CORE 6910 Jb Centaur Weekly Maintenance
CORE 6910 Jc Centaur Monthly Maintenance
CORE 6910 Jd Weekly Centaur Task Schedule

References

ADVIA Centaur XP Operator's Guide
ADVIA Centaur XP Quick Reference Guide