UniCel DxI In-Lab Training Manual

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UniCel DxI In-Lab Training Manual
Course Overview

What is it?
This course is designed to be facilitated in your laboratory.

This course will allow you to watch your trainer demonstrate basic operational tasks associated with operating your UniCel DxI system, then take some time to practice those tasks for yourself.

Who is it for?
This course is designed for anyone who is assigned to operate a Beckman Coulter UniCel DxI instrument and has met the pre-requisites.

Restrictions for Use
This workbook is not intended to replace the information in your instrument Instructions for Use Manual (IFU) or On Line Help. The information in the IFU or On Line Help supersedes information in any other manual.

Content is for information and illustration purposes only. Each person assumes full responsibility and all risks arising from the use of the information. The information is presented “AS IS” and may include technical inaccuracies or typographical errors. Beckman Coulter reserves the right to make additions, deletions, or modifications to the information at any time without prior notice.

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How does it work?

This course is modular in format, and designed so that you can complete modules as they fit into your laboratories schedule.

Your instructor will demonstrate a procedure and then give you some time to complete a practice exercise. The practice exercises are found in the training book behind the “Practice” tab. There is a “Reference Key” tab so that you can verify that you were able to complete each practice exercise correctly. When you feel comfortable completing one module, let your trainer know.

There are tabs of information that you can use as a reference when learning and/or training. Each tab has specific information related to the topic. The reference information topics include: Instrument Overview, Resources, Supplies, Calibration, Quality Control, Samples, Shutdown/Restart, Maintenance, Filters and Assay Summary Tables. There is additional information that may be useful to you in the Appendix.

Prerequisites

The person(s) completing this course should have basic laboratory knowledge; including background in basic laboratory instrumentation, quality control theory, and calibration theory.
How long does it take?

Each module takes approximately 1 hour to complete. This includes the time for the demonstration by your instructor and the time for you to complete your practice exercise. You should be able to complete all modules over a 1-2 day period.

Course Objectives

The course is designed to prepare the operator to be able to perform the following basic operational tasks:

- navigate the system software
- identify basic instrument components
- utilize the resources available
- replenish and manage supplies
- setup new calibrator lot numbers
- program and process a calibration
- setup new QC files
- program and process QC
- review QC data
- program and process patient samples
- monitor in progress samples
- recall patient results
- perform basic maintenance
- utilize screen filters

Course Map

An outline of the Course Map can be found on the next page.
# UniCel DxI In-Lab Training Manual
## Instrument Overview

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## Software Overview

### Navigation

The UniCel DxI system provides three navigation methods that you can use in any combination to select an item on a screen or in a window:

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Touch</td>
<td>Touch a part of the screen using the tip of your finger or fingernail.</td>
</tr>
<tr>
<td>Mouse</td>
<td>Use the mouse to point the cursor and click the left mouse button to select an item.</td>
</tr>
<tr>
<td>Keyboard</td>
<td>Press a keyboard equivalent such as a function key or the tab key to select an item. A list of keyboard equivalents can be found in the Operator’s Guide or the Help system.</td>
</tr>
</tbody>
</table>
System Modes

The current system mode is displayed in the upper left corner of each screen. The Instrument status can be monitored from any Menu. The system operates in one of four system modes:

<table>
<thead>
<tr>
<th>Mode</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ready</td>
<td>The system is ready to begin processing samples. Sample Processing Unit (SPU) operations such as aliquotting of samples can take place in the READY mode.</td>
</tr>
<tr>
<td>Running</td>
<td>The system is performing a function, such as processing samples or running a maintenance routine.</td>
</tr>
<tr>
<td>Paused</td>
<td>No new tests are scheduled, but currently scheduled tests continue processing.</td>
</tr>
<tr>
<td>Not Ready</td>
<td>The system is not ready to process samples. The system requires initialization, or it is checking the status of subsystems, initializing motors, or homing movable parts.</td>
</tr>
</tbody>
</table>
Software Overview
Common Screen Elements-Continued

System Status Buttons
System Status buttons are available from all screens to alert the operator of any caution or warning status. The buttons change color to notify the operator when the system requires attention. Neutral color indicates a normal condition, yellow indicates a caution condition and red indicates a warning condition. A button may be selected to view its related screen. These include:

- Select to display the Exceptions view of the Sample Manager screen. Yellow button color indicates that one or more sample containers has an error associated with it.
- Select to display the Work Pending screen for information about test requests that the system cannot schedule. Yellow button color indicates a test cannot be processed because a sample is required.
- Select to display the Supplies Required screen for information about needed supplies or calibrations. Yellow button color indicates supplies or calibration is required to complete a test. Red button color indicates the system cannot start tests and the instrument condition needs to be resolved.
- Select to display the Bulk Supplies screen for information on the available quantities of substrate, wash buffer, and RVs; or about the available space in the liquid waste and solid waste. Yellow button color indicates a supply is low or nearing expiration. Red button color indicates a supply is empty/full or expired.
- Select to display the Quality Control screen to setup quality control or review quality control results. Red button color indicates that a quality control result is not within the acceptable range of expected values.
- Select to display the Event Log screen for information about events generated by the system. Yellow button indicates the system has generated a caution event that requires operator attention soon. Red button color indicates that the system generated a warning event, indicating a serious fault or serious condition exists.
Software Overview
Common Screen Elements-Continued

Command Buttons

System Command Buttons are available from all screens to allow the operator to stop, pause, or resume processing.

<table>
<thead>
<tr>
<th>Button</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stop</td>
<td>Select to stop the instrument. The system stops processing and cancels any tests in progress. The system requires initialization before tests can be run again. Stop should only be selected when there is a mechanical or safety issue.</td>
</tr>
<tr>
<td>Pause</td>
<td>Select to pause the instrument. The system stops aliquoting after it finishes the current aliquot. No new tests are scheduled. Processing continues on samples already in progress. Pause should only be selected when there is a mechanical or safety issue.</td>
</tr>
<tr>
<td>Resume</td>
<td>Select to resume processing when the system is in the Paused mode.</td>
</tr>
</tbody>
</table>

Help

The DxI contains an on-board Help system which provides complete operating instructions.

Help

Select to access the Help System. The Help System contains step-by-step operating instructions, background, theory, system setup and advanced maintenance information, flowcharts, screen shots and more to help the operator maintain the system.
Software Overview
Main Menu Function Buttons

<table>
<thead>
<tr>
<th>Function Buttons</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Manager F1</td>
<td>Select to display the Sample Manager screen. The Sample Manager screen is used to request new tests for QC, Patients, Calibrations, and Maintenance, view sample status information, edit test requests, and display details for samples.</td>
</tr>
<tr>
<td>Test Results F2</td>
<td>Select to display the Test Results screen. The Test Results screen is used to view or print test results, troubleshoot test results with flags, delete test results, send/copy results, rerun a test, manage results manually.</td>
</tr>
<tr>
<td>Supplies F3</td>
<td>Select to display the Supplies screen(s). There are two supplies screens: Bulk Supplies and Reagent Supplies. The Bulk Supplies screen is used to view the status of the bulk supplies and waste containers, and change the in-use bottle of substrate, wash buffer, or liquid waste. The Reagent Supplies screen is used to view reagent packs, unload reagent packs, and print the reagent supplies report. The Reagent Inventory screen can be accessed from either supply screen and is used to view reagent and calibration status.</td>
</tr>
<tr>
<td>Quality Control F4</td>
<td>Select to display the Quality Control screen. The Quality Control screen is used to set up quality control files, view the chart and data for quality control results, compare quality controls, and print the QC Review Report.</td>
</tr>
<tr>
<td>Calibration F5</td>
<td>Select to display the Calibration screen. The Calibration screen is used to add or delete calibrator lots, view, print or delete calibration data; and print a calibration report.</td>
</tr>
<tr>
<td>Maintenance Review F6</td>
<td>Select to display the Maintenance Review screen. The Maintenance Review screen is used to check the temperatures of thermal zones, display the System Check screen; and run, enable or disable the Utility assay.</td>
</tr>
<tr>
<td>Diagnostics F7</td>
<td>Select to access the Diagnostics menu. Diagnostics is used to initialize the system, prime fluidics, view or print system parameters; run diagnostics or maintenance procedures, and perform validation procedures after troubleshooting.</td>
</tr>
<tr>
<td>Configure F8</td>
<td>Select to access the Configure menu. The Configure menu is used to display the screen and windows used to set up the system, display configuration information about the system, and display the screens and windows used for administrative tasks such as backing up data and shutting down the system.</td>
</tr>
</tbody>
</table>
Software Overview

Additional Tools

There are additional tools available throughout the software to allow the operator to view additional information on a screen or to navigate the software efficiently.

Scroll Bar: select to extend viewing area of a window
Back Tab: select to navigate to the previous window displayed
Menu Tab: select to display the Main Menu function buttons from any screen
Instrument Overview

1. Left Main Upper Cover
2. Right Main Upper Cover
3. Vessel Hopper
4. Status Indicator Lights
5. Sample Presentation Unit (SPU)
6. Reagent Load/Unload Area
7. Liquid Waste Drawer
8. Solid Waste Drawer
9. Wash Buffer Drawer
10. Main Power Switch (Behind door)
Status Indicator Lights

Four status indicator lights can be seen from a distance. They inform the operator of the operational status of the instrument.

Red, blinking: Not Ready. Indicates either the system has stopped, or that initialization is in progress. System console displays the Not Ready system mode.

Amber, steady: Supplies required. One or more system supply areas are low, or waste containers are almost full. The system will continue to process samples and schedule new tests.

Amber, blinking: Supplies required. One or more system supply are out, or an area requires attention. The system will not schedule new tests, but will complete tests in progress. System mode may vary.

Green: Running. System is processing tests or performing a maintenance routine. The system console displays the Running mode.

Blue: Ready. No processing operations are in progress, but the system is ready to begin processing. The system console displays the Ready mode. SPU operations such as aliquoting of samples can take place while in the Ready mode.
Indicators

System Status Panel (DxI 800 only): Icons indicate if a supply is low or approaches the expiration date and if the waste container(s) are almost full. Console panel icon lights if one or more system status buttons turns yellow or red.

SPU Cover Sensor: Light indicates when the SPU is in use. When the SPU is in use, press either the Routine or the STAT load buttons to request a load and unlock the SPU cover.

Reagent Tray In-Use Light: Light indicates when the reagent load door is locked. Wait for the light to go out and the reagent load door to unlock before loading reagents.
Instrument Components Under the Main Covers

Opening the covers without navigating to Device Diagnostics may damage the instrument. Always navigate to Device Diagnostics before opening the Main Covers.

Software Path: Main Menu → Diagnostics F7 → Device Diagnostics F4

Some of the primary components that you may interact with during maintenance and/or troubleshooting include the following:

- Sample Pipettor
- Sample Storage
- Sample Pick and Place
- Bulk Feeder
- Supply Carriage
- Incubator Pick and Place
- Reagent Carriages (4-Dxl 800 and 2-Dxl 600)
- Reagent Pipettors (4-Dxl 800 and 2-Dxl 600)
- Wash Pick and Place
- Analytical Module:
  * Incubator (center wheel)
  * Wash Carousel (outer wheel)
  * Luminometer
Practice: Instrument Overview

You have had a chance to observe your instructor overview the use of the instrument software and point out the exterior hardware features of the instrument.

Now you can take some time to practice utilizing the software and identifying hardware components for yourself. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
1. Use the information contained in the ‘Instrument Overview’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following:

- Navigate to the Sample Manager Screen using the touch screen feature.

- Navigate to the Maintenance Review screen using the mouse to select the Menu Tab, then Maintenance Review.

- Navigate to the Main Menu using the F9 key on the keyboard.

  Reminder: The F9 key on the Keyboard is the quickest way to navigate to the Main Menu.

- Navigate to the Test Results Screen using the keyboard by selecting the F2 key.

  Note the scroll bar on the right side of the screen allows you to view results outside of the view of the screen. Scroll down within the Test Results screen using either the touch screen, mouse, or keyboard.

2. Use the information contained in the “Instrument Overview” tab or the Instructions for Use Manual (IFU) to answer the following questions:

- What is the color of the System Mode Icon when the system is Paused?

  __________________________________________

- When the system is performing a function, what is the System Mode?

  __________________________________________

- What is the System Mode when the system is homing moving parts?

  __________________________________________
3. Use the information contained in the “Instrument Overview” tab or the Instructions for Use Manual (IFU) to answer the following questions:

- Which System Status button would alert you if you did not have a valid calibration on file for a run?

- What System Status button would alert you if the system generated a reflex test and the sample needed to be loaded back on the system?

- What System Status button would alert you if the system had an unreadable barcode?

4. What are the three System Command buttons?

- ________________________________

- ________________________________

- ________________________________

- ________________________________
5. Use the information contained in the “Instrument Overview” tab or the Instructions for Use Manual (IFU) to perform the following:

6. Locate each of the covers of your instrument

7. Locate each of the supply drawers on your instrument.

8. Locate the System Status Panel, the SPU Cover Sensor, and the Reagent Tray In-Use light on your instrument.

9. What does a blinking Amber Status Indicator light signify?

__________________________________________

10. When the SPU Cover Sensor is lit, what action should you take to load a rack?

__________________________________________
11. Navigate to Device Diagnostics in the instrument software, then open the upper left and right main covers.

**Software Path:** Main Menu → Diagnostics F7 → Device Diagnostics F4

12. While the upper covers are open, locate the listed components. Ask your trainer if you have trouble locating a component.

- Sample Pipettor
- Sample Storage
- Sample Pick and Place
- Bulk Feeder
- Supply Carriage
- Incubator Pick and Place
- Reagent Carriages (4-DxI 800 and 2-DxI 600)
- Reagent Pipettors (4-DxI 800 and 2-DxI 600)
- Wash Pick and Place
- Analytical Module:
  * Incubator (center wheel)
  * Wash Carousel (outer wheel)
  * Luminometer
13. Close the upper left and right Main covers and Initialize the System.

   Software Path: Main Menu→Diagnostics F7→Initialize System F1

14. Verify the System Mode returned to Ready after initialization.

15. Congratulations! You have completed the Instrument Overview practice. Consult with your instructor if you have any questions or need clarification.
UniCel DxI In-Lab Training Manual
Operational Overview

Objectives
During this discussion you will discover:

- Sample Handling
- Test processing checks
- Sample processing priority
- Sample processing overview
- Principle of chemiluminescence
- Enzyme Immunoassay (EIA) process

Knowledge of instrument function is a resource an operator will use during normal and abnormal operations.

Reference
DxI Help System
Tips on Sample Preparation:

- Verify adequate sample volume for sample containers using the Sample Volume Guidelines template.
- **Remove the caps from all tubes**
- Use only DxI validated sample containers
  - A list of validated containers can be found in the appendix of this workbook
- Place the sample container in the rack designated for its use (only one container type per rack)
- Ensure the sample containers are seated correctly in the rack
- Ensure that the bar code label is properly placed on the tube and is aligned so that it is visible through the slot in the rack
- Ensure there are no bubbles or remove bubbles from samples
- Ensure the rack is positioned properly on the SPU rails and the rack barcode is to the right.

When a sample is loaded, the DxI checks to make sure that

- ____________________________________________________________________
- ____________________________________________________________________
- ____________________________________________________________________
- ____________________________________________________________________

Testing Priority

1. ____________________________________________________________________
2. ____________________________________________________________________
3. ____________________________________________________________________
4. ____________________________________________________________________
5. ____________________________________________________________________
Sample Processing

1. A vessel is moved from the Bulk Feeder to the Supply Carriage, which transports it to the Sample Pick and Place (PnP).

2. The Sample PnP moves the empty Sample Vessel (SV) to Sample Storage, which rotates, aligning the SV with the Sample Pipettor.

3. Sample racks are transported to the Sample Pipettor by the Sample Presentation Unit (SPU).

4. The Sample Pipettor aspirates an aliquot of the sample and delivers it to the empty SV.

5. The sample rack is no longer required and is moved to the offload area.

6. The Supply Carriage receives another empty vessel from the Bulk Feeder, which is delivered by the Sample PnP to one of the Reagent Carriages for use as a Reaction Vessel (RV).
DxI Sample Processing

7. The SV with the sample aliquot is delivered to the Reagent Carriage containing the RV by the Sample PnP.

8. The Reagent Carriage and a reagent pack are moved into alignment with the Reagent Pipettor.

9. The Reagent Pipettor transfers sample* from the SV to the empty RV.

10. The required reagent components* are added to the RV with the sample and mixed by the Reagent Pipettor.

11. The RV is transported to the Incubator PnP, which transports it to the incubator in the Analytical Module for incubation.

12. The SV may be sent back to Sample Storage if required by the system.

13. When incubation is complete, the RV is transferred to the wash carousel in the Analytical Module by the Wash PnP.

14. The RV is washed three times. After the final wash, substrate is added.

15. After substrate addition, the RV is incubated again and light is generated by chemiluminescence**.

16. RLU values are read from the RV by the Luminometer.

17. The used RV is transported to waste.

18. If the SV is no longer needed by the system, it is also transported to waste.

*The order of sample and reagent addition to the RV is assay dependent.
**Additional information on the theory of chemiluminescence may be found in the Appendix section of this workbook.
Chemiluminescence is defined as:

____________________________________________________

____________________________________________________

Note: Examples of the immunoassay reaction process are available in the Appendix section of this workbook.
# UniCel DxI In-Lab Training Manual

## Resources

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</tr>
<tr>
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<td>11</td>
</tr>
</tbody>
</table>
Note: Database Maintenance button in Software version 4.4 allows operators to perform functions under the direction of technical support.
Help Contents

The contents of the Help system can be accessed by selecting the Help button then using the button windows toolbar to select Help Topics.

**UniCel DxI Immunoassay System**: This topic describes the UniCel DxI system; including links to the documentation; how to use the Help system; a system overview; a technology overview; information regarding notes, cautions, and warnings; and how to contact Technical support.

**Using the Help System**: This topic describes the Help system, how to access information in the Help system, how to use quick navigational links, and how to exit the Help system.

**Publication Notes**: This topic provides information about how documentation will be updated on your UniCel DxI system.

**UniCel DxI Documentation**: This topic describes the documentation provided with your UniCel System.

**Glossary**: Provides an alphabetical glossary defining terms used in conjunction with your UniCel DxI system.

**Operator’s Procedures Book**: Provides the step-by-step information needed for everyday operation of the UniCel DxI system. Contains the same information as the Operator’s Guide.

**Reference Information Book**: Provides background, theory, system setup, and advanced maintenance information for your system. Contains the same information as the Reference Manual.

**Flowcharts**: This topic provides alphabetical access to all flowcharts within the Help system.

**Forms/Logs/Worksheets**: This topic provides alphabetical access to examples of all Forms/Logs/Worksheets within the Help system.

**Reports**: This topic provides alphabetical access to examples of all reports generated by the UniCel DxI system.

**Screens/Menus/Windows**: This topic provides alphabetical access to examples of all Screens/Menus/Windows within the instrument software.
Helpful Hints: Help System

- The HELP system can be accessed utilizing the Help Button. The Help Button is available from any software screen on the DxI.

- You can also access HELP by selecting the F12 button on the keyboard.

- The information displayed in HELP will be specific to the screen you requested help from. When selecting HELP from the Main Menu, links are provided to all DxI help topics.

- Selecting green text navigates you to that help topic.

- Help topics can be selected from the windows buttons toolbar to display a list of the entire contents of the HELP system.

- The HELP system is designed to be used as Reference only. The user must return to the DxI User Interface to actually perform tasks.

- Do not use the minimize control button when in Help. There is no way in the DxI user interface to maximize a window again once it has been minimized.

- The Print Screen key on the keyboard does not function in HELP.

- The majority of users find it most convenient to use the mouse when in Help, regardless of their navigational preference in the DxI screens.

- When a window is open a Help F12 button is available. The information displayed when the Help F12 button is selected is specific to that window.
Instructions For Use

The Instructions for Use (IFU) manual is a printed document, designed for use after you have become familiar with the UniCel DxI system. It contains short instructions for everyday use and routine maintenance. It also contains general information about the UniCel DxI system, such as theory of operation, system specifications, safety labeling, and troubleshooting.
Other Resources

Technical Support (Hotline) may be contacted by phoning 1-800-854-3633

Your application specialist is ________________________________, and

(Name)

can be reached at ________________________________.

(Phone #)

Your Field Service Engineer is ________________________________, and

(Name)

can be reached at ________________________________.

(Phone #)
Practice: Resources

You have had a chance to observe your instructor demonstrate the use of the different resources available to you.

Now you can take some time to practice utilizing the references for yourself. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
Main Menu

Workflow

1. Use the software tree contained in the ‘Resources’ tab of this workbook or in the Instructions for Use Manual (IFU) to answer the following questions:

- What are the three types of requests you can program, using the following pathway:
  
  Menu→Sample Manager F1→New Request F3

- What is the software pathway you would use to Add a Quality Control file?

- What is the software pathway you would use to check the function of the Panel Lights?

- What is the software pathway you would use to Shut Down the System?

- What software pathway would you use to Delete a reagent Pack from the system memory?
Help System

2. Review the information contained in the ‘Resources tab’ of this workbook: Help Contents and Helpful Hints: Help System. Use the Help system to perform the following:

- Verify that the Main Menu is displayed on the console monitor.

  Hint: You may access the Main Menu at any time by selecting the [F9] key on the keyboard

- Touch the HELP button or click the left mouse button with the cursor positioned on the HELP button.

- Select the topic Using the Help System.

- Select the topic Help System Link Buttons.

  ▪ Use the information in this help topic to supply the name for each button shown below:

<table>
<thead>
<tr>
<th>BUTTON</th>
<th>NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Button 1" /></td>
<td><img src="name1.png" alt="Name 1" /></td>
</tr>
<tr>
<td><img src="image2.png" alt="Button 2" /></td>
<td><img src="name2.png" alt="Name 2" /></td>
</tr>
<tr>
<td><img src="image3.png" alt="Button 3" /></td>
<td><img src="name3.png" alt="Name 3" /></td>
</tr>
<tr>
<td><img src="image4.png" alt="Button 4" /></td>
<td><img src="name4.png" alt="Name 4" /></td>
</tr>
</tbody>
</table>

  ▪ Which of the above buttons would you select if you wanted to see an illustration of a topic such as a report or drawing?

  ![Button 5](image5.png)
Help System

- From any menu, select the Help button.

- Select “Help Topics” from the Window bar of the Help System.

- Select the “Contents” tab.

- Select the “Operator’s Procedures” book from the Help topics window.

- Note that the “Operator’s Procedures” book contains additional “books” that can be used to access the references for the most commonly needed operational tasks.

  The Operator’s Procedures book can be very useful when looking for basic operational HELP.

- Select the “Supplies” book and note that there are references on how to monitor the supplies and change each supply.

- Print the reference on how to change an empty bulk wash buffer container.

- Navigate to the Maintenance Review Screen.

  Hint: You can use the software tree in the “Resource tab” of this manual if you need assistance.

- Select the Help button.
  Note that the information displayed is specific to the Maintenance Review screen.

- Select the green link to navigate to the Maintenance Overview topic.

- Select the green link to the Daily Maintenance topic.

- Using the information contained in this topic, answer the following question:

  Which Clean Routine will you run daily in your laboratory?

  ____________________________________
Instructions for Use

3. Use the Instructions for Use manual to answer the following questions:

- What does each of these safety symbols represent?

  ![Safety Symbols]

- What do the following test result flags indicate?

  - **CLT:**  ______________
  - **EXS:**  ______________
  - **OVR:**  ______________
  - **QCF:**  ______________
  - **SYS:**  ______________

- What is the part number for Wash Buffer?

  ❧  ______________
4. Fill in the names and phone numbers of your applications specialist and field service engineer in the “Other Resources” section of the “Resources Tab” of this workbook.

5. Congratulations! You have completed the Resources practice. Consult with your instructor if you have any questions or need clarification.
# UniCel DxI In-Lab Training Manual

## Supplies

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- Reagent Load ........................................................................................ 17
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<table>
<thead>
<tr>
<th>Dxl Supply</th>
<th>Capacity</th>
<th>Yellow Caution</th>
<th>Red Warning</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wash Buffer</td>
<td>2 x 10 L</td>
<td>1 Container Empty</td>
<td>Both Containers Empty</td>
<td>Red Warning: Completes testing in progress, but no new tests scheduled</td>
</tr>
<tr>
<td>Liquid Waste</td>
<td>Dxl 800: 2 x 9.5 L Dxl 600: 2 x 5.0 L</td>
<td>1 Container Full</td>
<td>Both Containers Full</td>
<td>Red Warning: Completes testing in progress, but no new tests scheduled Not used on systems plumbed directly to a drain</td>
</tr>
<tr>
<td>Reaction Vessels</td>
<td>1700-1800</td>
<td>&lt;1000</td>
<td>&lt;100</td>
<td>Red Warning: When the vessel hopper is empty, it completes testing in progress, but no new tests scheduled</td>
</tr>
<tr>
<td>Solid Waste</td>
<td>Dxl 800: 20 pounds (9.1 kg) Dxl 600: 10 pounds (4.6 kg)</td>
<td>10% capacity or less</td>
<td>Container is Full</td>
<td>Red Warning: When the container is full, it completes testing in progress, but no new tests scheduled</td>
</tr>
<tr>
<td>Substrate</td>
<td>2 x 130 mL (1200 tests)</td>
<td></td>
<td></td>
<td>A lot expires in 3 days An open bottle expires in 3 days One on-board bottle is empty Only one bottle on-board and it has &lt;60 tests left One bottle is not present or not recognized by the system All lots are expired One or both open bottles are expired All on-board bottles are empty No bottles present, or bottles are not recognized by the system Red Warning: When both on-board bottles are empty or expired, the system completes any in progress tests, but no new tests scheduled</td>
</tr>
<tr>
<td>Reagent Packs</td>
<td>50 positions</td>
<td></td>
<td></td>
<td>&lt;10 tests left 3 days or less to lot expiration 3 days or less to calibration expiration Expired pack lot Expired open stability Expired or not calibrated &lt;Supplies Required&gt; button turns yellow to alert operator when reagent is empty, expired or not calibrated</td>
</tr>
</tbody>
</table>
Supply Loading

Use the Help System to identify detailed instructions for supply loading. Use the following software path to access the detailed instructions. Follow all cautions and warning when loading/unloading supplies.

Reference: from the Bulk Supplies screen
Select Help
Select the specific supply you need to replenish

The flowcharts on the following pages are abbreviated instructions. They should only be used after you have read and understand the detailed operating instructions found in the Help system.
Open the substrate load door and release the load tray

Remove the empty or expired bottle and discard

Remove a new bottle from the substrate equilibration area

Remove the cap from the new bottle and place the bottle in the load tray with the bar code facing out

Push in the load tray until it locks in place and the system closes the door

Scan the bar-code label

Place an unequilibrated bottle in the substrate equilibration area

Check the Substrate panel icons (DxI 800) or Bulk Supplies screen for bottle status
Check the **Wash Buffer** panel icons (DxI 800) or the Bulk Supplies screen for container status

Pull out the wash buffer supply drawer

Remove the perforated panels from a new container and gently mix the container

Extend the neck of the new container and remove the cap and inner seal

Press the disconnect button on the empty container to release the tubing

Remove the cap/draw tube assembly from the empty container and insert it into the new container

Remove the empty container from the drawer and replace it with the new container

Connect the tubing to the new container and close the drawer

--

**Wash Buffer**

Wash Buffer
Reaction Vessels

Check the RVs panel icon (Dxi 800) or the Bulk Supplies screen for the number of RVs required

Open the vessel hopper door

Open a bag of RVs and pour the contents into the vessel hopper

Close the vessel hopper door
Liquid Waste

Check the **Liquid Waste** panel icons (DxI 800) or the Bulk Supplies screen for container status

Pull Out the liquid waste drawer

Press the disconnect button on the full container to release the tubing

Remove the full container and replace it with an empty container

Connect the tubing to the empty container and close the drawer

Decontaminate the contents of the full container and dispose of the liquid waste

Rinse the container thoroughly and store it for future use
Solid Waste

Check the **Solid Waste** panel icon (Dxi 800) or the Bulk Supplies screen for container status

Pull down on the solid waste door handle

Slide the full container out of the storage area and seal the waste bag

Remove the full waste bag and insert a new bag into the container

Slide the empty container and bag into the storage area

Press the green reset button and close the door
Unload Reagent

Any screen

Bulk Supplies

Reagent Supplies
Dxl 800: Select up to 4 reagent packs
Dxl 600: Select up to 2 reagent packs

Reagent Inventory
Select one reagent pack

Unload Reagent Pack

F2

Wait for the screen to display unload complete message and the reagent tray in-use light to turn off

Open the reagent load door and remove the packs

Close the reagent load door
Reagent Load

Check the status of the reagent tray in-use light

Is the light off?

No → Wait until the green light turns off

Yes → Invert unpunctured packs several times and open the reagent load door

DxI 800: Place up to 4 packs in the tray positions
DxI 600: Place up to 2 packs in the tray positions

Close the reagent load door

Confirm the reagent display on the Reagent Supplies screen
Practice: Supply Loading and Management

You have had a chance to observe your instructor demonstrate the correct procedure to replenish each supply.

Now you can take some time to practice those tasks for yourself. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
- Reaction vessels
- Wash Buffer
- Spare Liquid Waste bottle
- Biohazard waste bag
- Spare Substrate Bottle
- Reagent Packs
Supply Replenishment

1. Use the flowcharts contained in the ‘Supplies’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following:

   - Change a substrate bottle
     Note: For practice purposes you may practice changing a substrate bottle that is not empty. Make sure that you change the container that is not in-use.
   - Change a bulk wash buffer container
     Note: For practice purposes you may practice changing a bulk wash buffer container that is not empty. Make sure that you change the container that is not in-use.
   - Add RVs
   - Change a bulk liquid waste container, if not plumbed to a drain
     Note: For practice purposes you may practice changing a bulk liquid waste container that is not full. Make sure that you change the container that is not in-use.
   - Empty the solid waste container
     Note: For practice purposes you may practice changing the bag in the solid waste container that is not full.

Reagent Unload/Load

2. Use the flowcharts contained in the ‘Supplies tab’ of this workbook or in the Instructions for Use Manual (IFU) to view the Reagent Inventory and perform the following:

   - Unload the reagent pack with the fewest tests remaining.
   - Load the reagent pack just unloaded

Reagent Inventory

Reagent and calibration status can be monitored using the Reagent Inventory Report.

3. Access the reagent inventory screen for your instrument and determine if any reagents need to be replenished. Add any reagents needed for today’s work using the flowchart on the previous page or in the Instructions for Use Manual.

4. How often will you review the reagent inventory screen in your laboratory?
Supply Management

The answers to the following questions can be found in the Supplies Tab of the Instructions for Use Manual (IFU). Knowing the answers to these questions will aid you to effectively manage the supplies on your system. Answer the questions below:

5. What are the two ways the system alerts you that a supply is required?
   - 
   - 

6. Is the software required to load any supply?
   __________________________________________________________

7. What are the System Modes during which the following supplies can be loaded on the system:
   
   Substrate: ________________________________

   Wash Buffer: ________________________________

   Reaction Vessels: ____________________________

   Liquid Waste: ________________________________

   Solid Waste: ________________________________

   Reagent: ________________________________
Supply Management (Continued)

8. What are the three indicators that notify the operator when reagent needs to be loaded for a requested run?
   - __________________________________________
   - __________________________________________
   - __________________________________________

Finish Line

9. Compare your answers to the questions to the Reference Key tab. If there are any discrepancies or questions, talk it over with your instructor.
UniCel DxI In-Lab Training Manual

Calibration

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Calibration

Use the Help System to identify detailed instructions for calibration. Use the following software path to access the detailed instructions. Follow all cautions and warning when performing calibrations.

Reference: from the Calibration screen
Help
  ➔ Setting Up Calibrators
  ➔ Adding a Calibrator Lot

Reference: from the Sample Manager screen
Help
  ➔ Patient Test Requests
    ➔ Running a Calibration
    ➔ Entering Calibration Requests

The flowcharts on the following pages are abbreviated instructions. They should only be used after you have read and understand the detailed operating instructions found in the Help system.
Assay Calibration Overview

Set Up Calibrators*

Run a Calibration
- Prepare samples
- Request the calibration*
- Load racks

Did the calibration pass?

Yes
Use the calibration to process QC and samples

No
Review Calibration data and troubleshoot

Repeat calibration before it expires

*Flowchart is available for this procedure
Setting Up Calibrators

1. Calibration
2. Calibrator Setup F5
3. Calibrator Setup
4. Add Calibrator F1
   - Scan the calibrator barcode information
   - When typing barcode information press [Enter] after each barcode
5. Is the calibrator information correct?
   - No
   - Yes
6. OK F1
Calibration Test Requests

1. Sample Manager
   - New Request F3
     - Calibration F2
       - Request Calibration
         - Select the calibrator lot number
           - OK F1
             - Test Requests
               - Enter the rack ID and press [Enter] (Repeat as needed)
                 - Place the samples in the racks and exit the Test Requests screen
                   - Load the racks
Reviewing Calibrations

1. Select the On-Board Radio Button to limit the reagents to those that are on-board the system.
2. Select the Assay button for the reagent lot # you want to review

The Active Curve for the reagent lot will be displayed. Review the curve for acceptability.

If a printed copy of the selected curve is desired:

Options
Select Curve F2
1. Active F1
2. Previous Active F2
3. Last Run F3

Print F7
## Calibration Failure Codes

<table>
<thead>
<tr>
<th>Failure Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bad Fit</td>
<td>The curve does not meet the acceptance criteria defined in the APF. Possible causes are poor precision or a curve that was too flat or too steep.</td>
</tr>
<tr>
<td>CV Std 0</td>
<td>The %CV of the S0 (zero) calibrator replicates does not meet the limits defined by the APF</td>
</tr>
<tr>
<td>Insuff Data</td>
<td>The system did not have enough data to perform the necessary calibration calculations. This failure occurs when two or more replicates are not calculated, due to a short sample or an instrument error.</td>
</tr>
<tr>
<td>Limits</td>
<td>The RLUs of either a replicate or the mean of the replicates are outside the ranges defined in the APF.</td>
</tr>
<tr>
<td>Max Iter</td>
<td>The system was unable to create a curve before performing the maximum number of calculation iterations. The system attempts to calculate the curve 100 times before generating this error.</td>
</tr>
<tr>
<td>No Fit</td>
<td>The system was unable to fit a curve to the data points. Possible causes include math rule violations, such as division by zero or calculating the log of a negative number.</td>
</tr>
<tr>
<td>Resp Delta</td>
<td>The total response of the curve, which is the difference between the highest RLU reading and the lowest RLU reading, is too small.</td>
</tr>
<tr>
<td>Temp Out</td>
<td>The upper cabinet temperature changed more than 6°C while the system processed the curve replicates.</td>
</tr>
</tbody>
</table>
### Assay Calibration Troubleshooting Table

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Possible Causes</th>
<th>Corrective Action</th>
</tr>
</thead>
</table>
| Although precision is good, the calibration fails for any reason other than Insuff Data | Multi-level calibrators aliquoted out of order, resulting in:                   | 1. Place the calibrators in the rack in the order displayed on the Test Requests screen.  
2. Repeat the calibration                                                           |
|                                                                          | • A calibration curve that does not ascend or descend smoothly.                   |                                                                                  |
|                                                                          | • A calibration cutoff that is opposite of the expected result                  |                                                                                  |
|                                                                          | Expired calibrator lot (CLX flag)                                               | 1. Check the expiration date on the calibrator vials or the Calibrator Setup screen.  
2. If the calibrator is expired, set up a new, unexpired calibrator.  
3. Repeat the calibration using the same reagent lot, if available.             |
|                                                                          | Calibrator set beyond its stability date                                        | 1. Compare the date of thaw or the date of expiration recorded on the calibrator vials to the product stability information provided in the reagent instructions for use.  
2. If the calibrator vial is beyond its stability date, discard the calibrator  
3. Repeat the calibration using the same reagent lot, if available.             |
|                                                                          | Calibrator unstable or contaminated due to improper handling                    | Repeat the calibration. If possible, repeat with a new set of the same calibrator lot. |
|                                                                          | Reagent pack unstable or contaminated due to improper handling                  | 1. Unload the reagent pack and load a new reagent pack.  
2. Repeat the calibration.                                                      |
|                                                                          | Incorrect calibration information entered during calibrator setup              | 1. Confirm the calibrator information on the Calibrator Setup screen.  
• In the information is incorrect, edit the information.  
• If you cannot edit the incorrect information, delete and set up the calibrator again.  
2. Repeat the calibration.                                                      |
## Assay Calibration Troubleshooting Table-Continued

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Possible Causes</th>
<th>Corrective Action</th>
</tr>
</thead>
</table>
| **Although precision is good, the calibration fails for any reason other than Insuff Data (Continued)** | A rack of patient samples was processed as a rack of calibrators because the racks had the same rack ID (when processing LIS requests with host query) | 1. Unload the racks and look for duplicate rack IDs.  
2. If a patient sample rack has the same rack ID as the calibration request, process the patient samples again, making sure that:  
   - Adequate sample is in the container for processing.  
   - The rack has unique rack ID.  
3. Request the calibration again, making sure that each rack has adequate sample for processing and that calibrators are loaded in the correct racks with unique rack IDs. |
| **Contaminated substrate supply**                                         |                                                                                | 1. Call Technical Support.                                                                                                                                                           |
| **Although precision is good, the quantitative curve is flat or the qualitative assay has no response; calibration fails for any reason other than Insuff Data** | Wrong calibrator placed in rack.                                                | 1. Place the correct calibrator in the rack.  
2. Repeat the calibration                                                                                                           |
<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Possible Causes</th>
<th>Corrective Action</th>
</tr>
</thead>
</table>
| Poor precision, and calibration fails for any reason other than Insuff Data | Routine maintenance not performed | 1. Perform routine maintenance.  
2. Repeat the calibration. |
| | Problems with the pipettor, substrate, or RV wash system | 1. If the results of all System Check routines are within the expected ranges, these systems are not the cause of the calibration failure.  
2. If the results of any of the System Check routines are not within the expected range, contact Technical Support for assistance in troubleshooting. |
| | Reagent gone because it leaked out of the pack during off-board storage or a partial pack from another Access Immunoassay System was loaded on the UniCel DxI system | 1. Unload the reagent pack and load a new reagent pack.  
2. Repeat the calibration. |
| RLU's are too low at one end of the calibration curve, and calibration fails for any reason other than Insuff Data | Some reagent loss or evaporation during off-board storage (first few test replicates between 6,000-9,000 RLU, remaining replicates acceptable) | Repeat the calibration with the open reagent pack.  
Note: During processing, the instrument attempted to aliquot the lost or evaporated reagent from the reagent pack and aspirated air for the first few test replicates, resulting in low RLU's. Once the pipettor reached the actual level of reagent in the pack, the RLU's returned to acceptable levels. |
<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Possible Causes</th>
<th>Corrective Action</th>
</tr>
</thead>
</table>
| Calibration fails for the reason     | Quantity of calibrator not sufficient for testing (QNS result flag and event) | 1. Calculate the correct volume of calibrator needed for the number of replicates and type of sample container used.  
2. Pipette the amount of calibrator calculated in step 1 into the appropriate sample container.  
3. Be sure the rack and rack ID are correct.  
4. Repeat the calibration.  
5. If the calibration fails again for the same reason, contact Technical Support for assistance. |
| Insuff Data                          |                                                                               |                                                                                                                                                   |
| Two or more replicates not calculated due to instrument error |                                                                               | 1. Review the Event Log messages for device errors prior to the calibration failure.  
2. Review the Test Results screen for flags.  
3. Troubleshoot the device errors. If necessary, contact Technical Support for assistance.  
4. After resolving the device errors, repeat the calibration. |
| Calibrator sample missing from the required position |                                                                               | 1. Place the sample containers in the rack in the order displayed on the Test Requests screen.  
2. Repeat the calibration. |
|                                     |                                                                               |                                                                                                                                                   |
**Practice: Calibration**

You have had a chance to observe your instructor demonstrate the calibration process for the system.

Now you can take some time to practice calibrating your instrument. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

---

**What Will I Need?**

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
- Sample racks
- Reagent of your choice
- Calibrator set to match reagent on board the system
Calibrator Setup

Use the flowcharts contained in the ‘Calibration’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following:

1. Select an assay that you wish to calibrate for this practice.
   
   Note: Your trainer may identify the assay to calibrate.

2. Verify that you have adequate reagent on-board the system to calibrate. If necessary add additional reagent.

   Hint: You can use the Reagent Inventory screen to determine the reagent status.

3. Add a new calibrator lot number to the currently existing calibrator information in your instrument memory.

   If you do not have a new lot number, delete the current lot, then add it back into the system database. This will allow you to practice adding a new lot! You can use the Software Tree in the Resource tab to help you determine the software path to delete a calibrator.

Calibrate

4. Use the flowcharts contained in the ‘Calibration’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform a calibration for the assay selected in step 1:

   - Prepare samples
   - Request the calibration
   - Load calibrator racks

Review Calibration

5. Review the calibration report for acceptability.

The Finish Line

6. Congratulations! You have completed the Calibration practice. Consult with your instructor if you have any questions or need clarification.
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Helpful Hints

- Handle Quality Control samples as recommended in the QC product insert.

- The Access Immunoassay System reagent insert specifies how often QC should be run for that assay.

- In addition to the recommendation in the reagent insert, QC should also be processed after any scheduled or un-scheduled maintenance and after successfully installing new software.

- You can run tests on QC samples and patient samples in the same rack, even if different tests are requested for each sample.

- When the system flags a QC result because of a violation of an applied QC rule, the QC button turns red. The button will remain red until selected by the operator.

- Each new lot # of Quality Control must be defined before it can be processed.

- Follow your lab’s policy for Quality Control processing and evaluation before reporting patient samples.
Quality Control

Use the Help System to identify detailed instructions for quality control. Use the following software path to access the detailed instructions. Follow all cautions and warning when performing quality control.

Reference: from the Quality Control screen
Help
  ➔ Setting Up Quality Controls
  ➔ Adding or Editing a Quality Control

Reference: from the Sample Manager screen
Help
  ➔ Patient Test Requests
  ➔ Running Quality Control Tests
  ➔ Entering QC Test Requests

Reference: from the Quality Control screen
Help
  ➔ Quality Control Overview
  ➔ QC Status Indicators and Flags

The flowcharts on the following pages are abbreviated instructions. They should only be used after you have read and understand the detailed operating instructions found in the Help system.
Quality Control Flowchart

Set Up Quality Controls by Lot Number

Periodically run QC tests
- Prepare samples
- Request the Quality Control
- Load racks

Did tests produce results?

No
- Troubleshoot failed QC and correct problem as indicated

Yes
- Review QC chart and data or compare charts

Are all results in range?

No
- Troubleshoot out of range QC, correct problem, or adjust QC ranges, as indicated

Yes
- Process patient samples
Setting Up Quality Controls

Quality Control

QC Setup
F5

Add Control
F1

Enter the name, lot number, expiration date, and sample type for the control

Select an assay from the drop-down Test Name list

Enter mean, SD, and Westgard QC rules.

OK
F1
Quality Control Test Requests

1. Sample Manager
2. New Request F3
3. Patient/QC Requests F1
4. Test Requests
   Enter the rack ID and press [Enter]
5. Request QC F5
6. Request QC
   Select quality controls
7. OK F1
8. Test Requests
   Select tests for each quality control
   Optional: Select Change Reag. Lot to select a specific lot of reagent
9. Place the samples in the rack and load the rack
Reviewing Quality Control

Select the button for the QC to be viewed

Review Chart and Data F2

Review the Data for acceptability

Acceptable?

Yes

Select and review additional data for acceptability

No

Troubleshoot out of range QC, correct problem and reprocess QC
Practice: Quality Control

You have had a chance to observe your instructor demonstrate how to setup, program and process, and review quality control.

Now you can take some time to practice setting up QC, processing QC and reviewing the QC you processed. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
- Sample racks
- Practice QC Samples
1. Use the flowcharts contained in the ‘Quality Control’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following:

- Select a minimum of two assays that you wish to QC for this practice.
- Verify that you have adequate calibrated reagent on-board the system to process quality control.
  
  Hint: You can use the Reagent Inventory screen to determine the reagent status.
- Add a new quality control file to the currently existing quality control information using the information in the table below.

<table>
<thead>
<tr>
<th>QC Information</th>
<th>Quality Control Setup</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC Identifiers</td>
<td>Name: Practice QC 1</td>
</tr>
<tr>
<td>Name: Practice QC 2</td>
<td></td>
</tr>
<tr>
<td>Lot #: XXXXX</td>
<td>Lot #: ZZZZZ</td>
</tr>
<tr>
<td>Expiration Date: 12-31-2015</td>
<td>Expiration Date: 12-31-2015</td>
</tr>
<tr>
<td>Sample Type: Serum</td>
<td>Sample Type: Serum</td>
</tr>
<tr>
<td>QC range info</td>
<td>Select test(s) that are on board and calibrated and enter the mean and SD from the package insert for the Quality control materials selected. You may enter the same means and SDs for both Practice QC 1 and Practice QC 2.</td>
</tr>
</tbody>
</table>
**QC Processing**

2. Use the flowcharts contained in the ‘Quality Control’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following:

- Follow the steps in the Step/Action table below:

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Create a QC test request for the Practice QC1 and Practice QC2 samples, requesting tests for which you defined mean(s) and SD(s) for in Step 1 of the Practice Exercise.</td>
</tr>
<tr>
<td>2</td>
<td>Pour the appropriate QC material into a 2 mL cup programmed for Practice QC1</td>
</tr>
<tr>
<td>3</td>
<td>Pour water into a 2 mL cup programmed for Practice QC2.</td>
</tr>
<tr>
<td>4</td>
<td>Complete the steps listed in the flowchart in the “Quality Control” tab of this workbook to process the QC you just requested.</td>
</tr>
</tbody>
</table>

**Review QC**

3. Use the flowcharts contained in the ‘Quality Control’ tab of this workbook to view the results for each test processed on your Practice QC 1 and Practice QC 2.

   Note: Practice QC 2 should be flagged because you placed water in the cup that had QC ranges defined. Use this opportunity to familiarize yourself with the QC flagging utilized by the system.

   Reminder: QC buttons turn red when the QC violates defined QC rules. Selecting the button will clear the red flag.

4. Process additional material for QC if you would like additional practice.
Delete QC

5. Use the HELP system to delete the Practice QC 1 and the Practice QC 2 files form the system database.

Reference:
Navigate to the QC Screen, then Select HELP.
← Setting Up Quality Controls
  ← Deleting a Quality Control

OR
Select HELP from any screen.
Help Topics
← Operators Procedures
  ← Quality Control
    ← Setting Up Quality Controls
      ← Deleting a Quality Control

The Finish Line

6. Congratulations! You have completed the Quality Control practice. Consult with your instructor if you have any questions or need clarification.
Unicel DxI In-Lab Training Manual
Sample Processing and Management

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Sample Processing

Use the Help System to identify detailed instructions for sample processing. Use the following software path(s) to access detailed instructions. Follow all cautions and warnings when processing samples.

Reference: from the Sample Manager screen
Help
↳ Sample Manager Overview
↳ Loading and Unloading Racks
↳ Loading a Rack for Routine Processing
↳ Loading a STAT Rack

Reference: from the Sample Manager screen
Help
↳ Patient Test Requests
↳ Manual Test Requests

Reference: from the Test Results screen
Help
↳ Rerunning a Test

Reference: from the Test Results screen
Help
↳ Printing Test Result Reports

Reference: from the Sample Manager screen
Help
↳ Sample Manager Overview
↳ Loading and Unloading Racks
↳ Unloading a Rack

Reference: from the Sample Manager screen
Help
↳ Sample Manager Screen Views

Reference: DxI Instructions for Use
/Racks & Sample Containers tab
↳ Calculating Minimum Sample Volume
↳ Sample Volume by Assay
↳ Sample Containers
Reference: from any screen

Help

Help Topics

Index – type “flags” – select “see result flags” – Display

The flowcharts on the following pages are abbreviated instructions. They should only be used after you have read and understood the detailed operating instructions found in the Help system.
Loading Racks

1. Place the sample containers for the requested tests in the appropriate rack for the container type.
2. Check the status of the sample processing unit (SPU) cover sensor.
3. Is the sensor off?
   - Yes: Open the SPU cover.
   - No: Select the ROUTINE button and wait until the system unlocks the cover.
4. Place the rack(s) in the SPU onload area.
5. Close the SPU cover.
**Processing LIS Test Requests**

1. Verify that there is adequate sample volume in the sample container.

2. Place the bar coded sample containers in racks.

3. Check the status of the SPU cover sensor:
   - Sensor off: SPU unlocked. Proceed.
   - Sensor on: Press the Routine button and wait for the sensor to go off (SPU unlocked).

4. Load the rack(s) onto the onload area of the SPU, loading any racks that contain STAT samples first.

5. Close the SPU cover.

6. The system reads the barcode, queries the LIS, and begins sample processing.
**Manual Test Requests**

1. **Sample Manager**
   - **New Request** F3

2. **Patient/QC Requests** F1
   - **Test Request**
     - Enter the rack ID, sample ID, sample information, and test requests for each sample
     - **Verify the sample and test information for the rack**

3. **Options**
   - 1. Select STAT
   - 2. Select alternate sample type
   - 3. Enter an off-line dilution factor
   - 4. Enter a comment

4. **Does the rack contain a STAT sample?**
   - **No**
     - **Are all tests requested?**
       - **No**
         - **New Request** F3
       - **Yes**
         - **Yes**
           - **Place the requested samples in a rack**
           - **Load the rack***
             - **See the Loading a Rack flowchart**

*See the Loading a Rack flowchart*
Editing Test Requests

Sample Manager Screen
From the Requested view, select the rack that contains the test request that you intend to edit

Edit Request
F2

Test Request Screen
Select the sample position that you intend to edit

Edit the sample information and the test list

Done editing the rack?

No

Yes

Test Request Screen
Exit the Test Request screen to save changes
Monitoring Sample Progress

Sample Manager

Select the “In Progress” button

Use the scroll bar to find a specific sample

OR

Find F6

Find Sample ID

Enter the Sample ID of the sample you are searching for

Find F1

The system highlights the Sample ID

Close F8

View the status and completion time of the sample
Recall Test Results

Test Results Screen

Configure screen to select a range of data so that the sample is within the search field

Filter
F6

Select the appropriate filter from the list displayed in the Filter window

OK
F1

Find
F2

Enter either Sample ID, Patient ID, Rack ID, or Test Name in the fields provided

Find Next
F1

The sample is highlighted by the system in the Test Results window

Options
1. Rerun-F3
2. Send to LIS-F5
3. Print-F7
Rerun a Test

Test Results Screen
Configure screen to select a range of data so that the sample is within the search field

Filter
F6

Select the appropriate filter from the list displayed in the Filter window

OK
F1

Find
F2

Enter either Sample ID, Patient ID, Rack ID, or Test Name in the fields provided

Find Next
F1

The sample is highlighted by the system in the Test Results window

Rerun Test
F3

If the sample displays on the Work Pending screen, load the bar coded sample on the SPU. If the sample does not display on the Work Pending screen, it will run automatically.
Calculating Sufficient Sample Volume

The sample volume in a container must be sufficient to process the tests you requested:

Use this equation to calculate the required sample volume for each container in a rack:

\[
A \quad \text{Sample assay volume} + \quad B \quad \text{System dead volume} + \quad C \quad \text{Reserve volume} + \quad D \quad \text{Sample pipettor overdraw} + \quad E \quad \text{Sample container dead volume}
\]

= Total sample volume required

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>The sample assay volume is the sum of the sample volumes for each requested test. To find the sample volume for each test, see the corresponding directional inserts.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>The system dead volume is the amount of sample that cannot be drawn from an RV inside of the instrument. The system dead volume is 60 ul for each RV.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>(If set up) The reserve volume is the amount of sample the system stores for additional testing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>The sample pipettor overdraw is 20uL or 5% of the volume of sample in the RV (A+B+C), whichever is greater</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>The sample container dead volume is the amount of sample that cannot be aliquoted from the sample container</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: if the sum of the sample and reserve volumes (A+C) is greater than 500 uL, the system aliquots the reserve volume into 1-2 additional RVs. For each additional RV, include the system dead volume and sample pipettor overdraw calculation.
Standard and Flexible Reserve Volume

Software version 4.1 and above provides the option to use both Standard and Flexible Reserve Volume with the stand alone DxI.

Users may enable/disable the option to draw reserve volume

Standard:

- A standard volume is specified for standard reserve racks
- Used for reruns and add ons

Flexible:

- A calculated volume for flexible reserved racks
- Flexible reserve volume will only be drawn from containers placed in flexible reserve volume racks and have a test ordered which has a reflex condition applied to it.
- Flexible reserve volume for each sample is calculated considering:
  - number of tests and replicates ordered on the sample
  - reflex conditions assigned to requested tests
  - the maximum reserve volume
  - the suppress option
Sample Containers

Warning
Racks are configured to accept only one type of sample container. Sample containers must match the ID configured for the racks you use. Placing an incorrect container in a rack may damage the system and compromise the integrity of your test results. You can find the rack ID ranges set up for each type of container from the System Setup screen.

<table>
<thead>
<tr>
<th>Sample Container Information</th>
<th>Container Type Label</th>
<th>Sample Container Information</th>
<th>Container Type Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.5 x 66 mm 3.5 mL S.60.549 Sarstedt tube</td>
<td><img src="3.5mL" alt="Image" /></td>
<td>12 or 13 x 75 mm glass tube</td>
<td><img src="12/13x75" alt="Image" /></td>
</tr>
<tr>
<td>• Dead Volume: 200 uL</td>
<td></td>
<td>Dead volume: 500 uL</td>
<td></td>
</tr>
<tr>
<td>12 or 13 x 75 mm plastic tube</td>
<td><img src="Plastic" alt="Image" /></td>
<td>13 x 100 mm tube</td>
<td><img src="13x100" alt="Image" /></td>
</tr>
<tr>
<td>• Dead volume: 200 uL</td>
<td></td>
<td>• Dead volume: 500 uL</td>
<td></td>
</tr>
<tr>
<td>15.3 x 92 mm 5 mL S.61.611 Sarstedt tube</td>
<td><img src="5mL" alt="Image" /></td>
<td>16 x 75 mm tube</td>
<td><img src="16x75" alt="Image" /></td>
</tr>
<tr>
<td>• Dead volume: 200 uL</td>
<td></td>
<td>• Dead volume: 800 uL</td>
<td></td>
</tr>
<tr>
<td>16 x 85 mm tube</td>
<td><img src="16x85" alt="Image" /></td>
<td>16 x 100 mm tube</td>
<td><img src="16x100" alt="Image" /></td>
</tr>
<tr>
<td>• Dead volume: 200 uL</td>
<td></td>
<td>• Dead volume: 800 uL</td>
<td></td>
</tr>
<tr>
<td>1 mL insert cup in a 13 x 75 tube</td>
<td>![Image](1mL in 13x75)</td>
<td>1 mL insert cup in a 13 x 100 tube</td>
<td>![Image](1mL in 13x100)</td>
</tr>
<tr>
<td>• Dead volume: 350 uL</td>
<td></td>
<td>• Dead volume: 400 uL</td>
<td></td>
</tr>
</tbody>
</table>
## Sample Containers (Continued)

<table>
<thead>
<tr>
<th>Sample Container Information</th>
<th>Container Type Label</th>
<th>Sample Container Information</th>
<th>Container Type Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>75 x 15 mm 5.5 mL Sarstedt S-Monovette tube</td>
<td>5.5 mL Sarstedt</td>
<td>92 x 15 mm 7.5 mL Sarstedt S-Monovette tube</td>
<td>7.5 mL Sarstedt</td>
</tr>
<tr>
<td>• Dead volume: 1100 ul</td>
<td></td>
<td>• Dead volume: 1200 uL</td>
<td></td>
</tr>
<tr>
<td>2 mL cup</td>
<td>2 mL</td>
<td>0.5 mL cup</td>
<td>0.5 mL</td>
</tr>
<tr>
<td>• Dead volume: 150 uL</td>
<td></td>
<td>• Dead volume: 80 uL</td>
<td></td>
</tr>
<tr>
<td>3 mL cup in a 16 x 100 mm rack</td>
<td>3 mL</td>
<td>Autoaliquot tube</td>
<td>Autoaliquot</td>
</tr>
<tr>
<td>• Dead volume: 150 uL</td>
<td></td>
<td>• Dead volume: 150 uL</td>
<td></td>
</tr>
<tr>
<td>Pediatric insert cup in a rack adapter</td>
<td>PED</td>
<td>2 mL insert cup in a 16 x 100 mm tube</td>
<td>2 mL in 16x100</td>
</tr>
<tr>
<td>• Dead volume: 150 uL</td>
<td></td>
<td>Dead volume: 200 uL</td>
<td></td>
</tr>
</tbody>
</table>
Practice: Sample Processing and Management

You have had a chance to observe your instructor demonstrate the sample handling capabilities of the system.

Now you can take some time to practice processing samples and managing sample handling. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
- Sample racks
- Practice QC Samples
Sample Processing
LIS Requests

Use the flowcharts contained in the ‘Samples’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following:

1. Follow the steps in the Step/Action table below:

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Create a test request at your LIS for six (6) practice sample(s). Have your LIS print a barcode for each request.</td>
</tr>
<tr>
<td>2</td>
<td>Apply the barcode to a primary sample tube and add fluid for the practice sample. Note: Pooled serum or control material may be used for practice.</td>
</tr>
<tr>
<td>3</td>
<td>Load the samples into the appropriately designated racks for the sample container(s) available for each practice sample.</td>
</tr>
<tr>
<td>4</td>
<td>Load the racks onto the Sample Processing Unit (SPU).</td>
</tr>
</tbody>
</table>

IF your LIS system prohibits you from following the instructions in the Step/Action table above, use the alternate method below:

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Obtain patient samples that are requested in your LIS and require processing.</td>
</tr>
<tr>
<td>2</td>
<td>Load the samples into the appropriately designated racks for the sample container(s) available for each sample.</td>
</tr>
<tr>
<td>3</td>
<td>Load the racks onto the Sample Processing Unit (SPU).</td>
</tr>
</tbody>
</table>

Sample Processing Manual Requests

2. Use the flowcharts contained in the ‘Samples’ tab of this workbook or in the Instructions for Use Manual (IFU) to program six (6) additional practice sample(s).

- Create unique identifiers such as Sample ID and Patient ID for each practice sample.
- Request tests that have reagent loaded and calibrated on your system.
- Request a minimum of 2 samples that are routine priority and a minimum of 2 samples that are STAT priority.
- Add the comment “Hemolyzed” to one of your manual requests.

Reminder: Reagent and calibration status can be viewed by assessing the Reagent Inventory. See the “Supply” tab of this workbook.
### Sample Progress

3. Use the flowcharts contained in the ‘Samples’ tab of this workbook to determine what time each assay will be complete for each practice sample.

   **Suggestion!** Use the Find feature to find one of the samples that are in progress.

### Rerun a test

4. Use the flowcharts contained in the ‘Samples’ tab of this workbook to rerun the result for the first practice sample that completed.

### Recall Results

5. Use the flowcharts contained in the ‘Samples’ tab of this workbook to recall and reprint the result for the first practice sample you processed in step 1 above.

### The Finish Line

6. Congratulations! You have completed the Sample Processing practice. Consult with your instructor if you have any questions or need clarification.
# UniCel DxI In-Lab Training Manual
## Shutdown/Rstart

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<tr>
<td>Restart the Instrument</td>
<td>13</td>
</tr>
<tr>
<td>Practice: Shut Down/Rstart</td>
<td>15</td>
</tr>
</tbody>
</table>
Helpful Hints: Shut Down and Restart

- When shutting down the instrument and/or PC you must follow the proper procedure or you may damage the instrument or corrupt the system database.

- Shut down the system only when directed by a technical support representative or the system documentation.

- The PC and the instrument may be shut down independently of each other.

- If you shut down and restart the PC, the instrument continues processing samples. The test data is automatically sent when the PC re-establishes communication with the instrument.

- When shutting down both the instrument and the PC, the instrument should be shut down first.

- When shutting down the instrument, you need the system password. Contact your lab supervisor to obtain your system’s password.

- Shutting down the instrument turns off the refrigeration in the reagent storage area. If the instrument will be shut down for an extended time period, the reagents should be unloaded and stored refrigerated until the system is returned to operating condition.

- If the PC was shut down for more than 30 minutes and the instrument was processing tests, it may take a few minutes for the instrument to send results to the PC. Do not use the system until the PC receives all of the test results.
When the software has shut down, a message will display instructing you to turn off the instrument power.

Open the lower right door and turn the instrument power switch to the off (O) position.

Wait at least 20 seconds, then turn the instrument power switch on.
Shut Down the PC with the User Interface Software

The Shut Down window displays. **DO NOT** select the **Shut down the instrument software** box.

Optional: To shut off the power to the PC, press and hold the power switch for at least 10 seconds. Wait at least 20 seconds before restarting the PC.
Shut Down the PC with the Computer Keyboard

Simultaneously press the [Ctrl], [Alt] and [Delete] keys on the computer keyboard.

Did the computer respond?

Yes

From the Windows Security window select Shut Down.

No

Wait for the instrument to stop processing samples

Turn the PC power off by pressing and holding the power switch for at least 10 seconds.

Use this procedure if you do not have access to the User Interface software.
Restart the PC and User Interface Software

Press and hold the power switch on the PC for at least two seconds to turn the power on and restart the UI

Wait for DxI Main Menu to display.
Restart the Instrument

- Restart the PC
- Verify the main upper cover is closed.
- Open the lower right door, and press the top part of the power switch to turn the power on (position).
- Verify the system is in the Ready mode and no message is displayed in the system mode area.
- Wait for the system to restore the internal temperatures before processing samples.

**CAUTION**
Do not select any buttons or press any keys while the instrument restarts and initializes.
Practice: Shut Down/Restart

You have had a chance to observe your instructor demonstrate the proper shut down and restart of the DxI system.

Now you can take some time to practice shutting down and restarting the system for yourself. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
1. Use the information contained in the Shutdown/Restart tab of this workbook or in the Instructions for Use Manual (IFU) to answer the following questions:

   - If you are shutting down the instrument and the PC, which should be shut down first?
     ____________________________________________________________

   - When should you shut down the PC?
     ____________________________________________________________

2. Shut down your training instrument using the User Interface.

3. Shut down your training instrument PC using the User Interface.

4. Restart the PC.

5. Restart the instrument.

6. Verify that the system mode of your training instrument is READY

7. Congratulations! You have completed the Shut Down/Restart practice. Consult with your instructor if you have any questions or need clarification.
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Maintenance Information

- Some maintenance procedures are based on Test Count. Refer to the Maintenance log for Maintenance tasks that need to be performed after a specific number of test counts.

- Maintenance recommendations may change. Always refer to the most recent documentation for current maintenance requirements.

- The Utility routine primes the reagent pipettors, aspirate probes, and dispense probes every four hours if the system is not processing samples. It is important to always keep the Utility routine enabled. If the routine is disabled, you must enable the routine and prime fluidics before running a clean routine as part of your daily maintenance.

- The flowcharts are not meant to replace the instructions in the Help or IFU. See the Help system for detailed instructions. Only use the flowcharts after you have read and understand the information in the Help system.

- IMPORTANT: After performing maintenance you must verify system performance by running a clean routine and processing QC. Evaluate out-of-range QC results before analyzing patient samples.
Daily Maintenance

**Clean Routine Options**
- **Daily Clean System**
- **Special Clean**: Select if you have run the Vitamin B12 assay in the last 24 hrs.

**Positions**
1. Add 3 mL Contrad 70
2. Add 3 mL 1:5 dilution of Citranox
3. (Special Clean only) - Add 4 mL 70% Ethanol (Methanol ok)

**Time to Completion**
- **Daily Clean System**: Approximately 10 minutes
- **Special Clean**: Approximately 13 minutes

**Request Maintenance**
- With the Utility routine enabled, select a Clean Routine
- Enter the rack ID and press [Enter]

**Mainteance Request**
- Prepare and load a rack
- The system begins the clean routine
- Record completed maintenance on the maintenance log

**Event Log**
- Select the most recent event listed on the screen

**Details**
- F4

**Sample Manager**
- New Request F3
- Maintenance F3

**Back up the system**

**Record the test count on the Maintenance Log**

**Shake down the solid waste container**
5,000 Test Interval Maintenance

- **Device Diagnostics**
  - F4
  - Open the right main upper cover
  - Replace duck bill valve (See separate flowchart)
  - Close the right main upper cover

- **Device Diagnostics**
  - Exit using the Back or Menu tab

- **Main**
  - Diagnostics F7
  - Initialize System F1

- **Perform Daily Maintenance**
  - Verify System Performance with QC
  - Record completed maintenance on the maintenance log
Replacing the Duck Bill Valve

**Diagnostics**

- **Device Diagnostics F4**

  - **Device Diagnostics**

  - Open the right main upper cover

  - Gently lift the dispense probe plate and slide a sample rack beneath the plate

  - Loosen the A1 aspirate probe fitting and remove the probe

  - Turn the wash collar clockwise and pull the collar down through the key slot

  - **Push the wash collar up through the key slot and turn counterclockwise to secure**

  - **Return the A1 aspirate probe to its proper position**

  - **Tighten the probe fitting and verify the aspirate probe deflection**

  - **Continue with 10,000 test interval maintenance if needed**

**WARNING**

You will come in contact with potentially infectious materials during this procedure. Handle and dispose of biohazard materials according to proper laboratory procedures. Proper hand, eye, and facial protection is required.

- **Turn the retaining nut counterclockwise and remove the wash collar**

  - **Lift the duck bill valve out of the retaining nut and discard the valve in the biohazard waste**

  - **Insert a new valve into the retaining nut**

  - **Attach the retaining nut to the wash collar by turning it clockwise**

  - **Inspect the duck bill valve**

  - **Is the valve closed?**

    - **No**

    - **Yes**
10,000 Test Interval Maintenance

**Diagnostics**

**Device Diagnostics**

F4

Open the right main upper cover

Install clean aspirate probes

If 5,000 test maintenance is due, replace the duck bill valve.

Remove and inspect the dispense probes

**Main**

**Diagnostics**

F7

**Initialize System**

F1

Inspect the liquid waste and wash buffer drawers

Clean the air filter

Perform daily maintenance

Perform QC

Record completed maintenance on the maintenance log

Open the left main upper cover

Inspect the pump connections at the wash buffer reservoir and upper aspirate peristaltic pump

Inspect the reagent pipettors and clean the wash towers

Inspect for fallen RVs

Close the main upper covers

Exit using the **Back** or **Menu** tab

**Device Diagnostics**
Cleaning the Aspirate Probes

1. Brush out the inside of the aspirate probe with Contrad 70
2. Place the aspirate probe fitting in deionized water
3. Attach the syringe fitting assembly to the aspirate probe tip
4. Draw deionized water through the tubing fitting and into the syringe
5. Disconnect the syringe from the fitting assembly and discard the water in the sink
6. Reattach the syringe to the fitting assembly and draw and discard water two more times
7. Remove aspirate probe fitting from deionized water
8. Reattach the syringe to the fitting assembly and draw air through the tubing fitting and into the syringe
9. Disconnect the syringe and fitting assembly from the probe tip
10. Position the probe upright on absorbent paper for 10 minutes
11. Wipe down the aspirate probe exterior with an alcohol wipe
12. Store the clean aspirate probes in your CARE kit
# DxI Maintenance Log

## Daily Maintenance

| Maintenance Item | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|------------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Date             | D | D | D | D | D | D | D | D | D | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  | D  |

### Special Weekly Maintenance

- [ ] Install Clean Aspirate Probes
- [ ] Verify System Performance (Run Clean Routine and QC)
- [ ] Tech Initials

### 5,000 Test Interval Maintenance

- [ ] Replace the Duck Bill Valve
- [ ] Verify System Performance (Run Clean Routine and QC)
- [ ] Tech Initials

### 10,000 Test Interval Maintenance

- [ ] Install Clean Aspirate Probes
- [ ] Remove and Inspect Dispense Probes
- [ ] Inspect the Pump Connections at the Wash Buffer Reservoir
- [ ] Inspect the Upper Aspirate Peristaltic Pump Connections
- [ ] Inspect the Reagent Pipetters and Clean the Wash Towers
- [ ] Inspect for Fallen RVs
- [ ] Inspect the Liquid Waste Drawer
- [ ] Inspect the Wash Buffer Supply Drawer
- [ ] Clean the Air Filter
- [ ] Verify System Performance (Run Clean Routine and QC)
- [ ] Tech Initials

Complete the maintenance procedures in the order listed in each table. When a maintenance procedure is complete, draw a check (✓) or circle the code in the corresponding box. When all procedures are complete for a scheduled maintenance, add your initials. Add the date and test count as appropriate.

If you schedule the 10,000 and 5,000 test interval maintenance procedures consecutively, perform the 10,000 test interval procedures first. Perform the daily maintenance procedures after you complete the 10,000 and 5,000 test interval procedures.

When you combine daily maintenance with special weekly or test interval maintenance, you only need to run a clean routine once in your final maintenance step.

This page may be reproduced for laboratory use.
You have had a chance to observe your instructor demonstrate the correct procedures to maintain the DxI system. Routine maintenance keeps the system working properly.

Now you can take some time to practice those tasks for yourself. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
- Contrad 70 Cleaning solution
- 1/5 dilution of Citranox
- 70% Methanol
- Safety goggles
- Gloves
- Sample containers that hold at least 4 mL of solution
- Sample rack with the appropriate rack ID for the container used
- Maintenance Log (photocopy from IFU)
Utility Routine

The Utility Routine is an automated maintenance procedure that runs automatically every 4 hours if the system is not processing samples.

1. Enable the Utility Assay on your instrument.

Software navigational path:
Main Menu-F9 or Menu tab→Maintenance Review-F5→Enable Utility Routine-F6

Note: The Utility button name switches between Enable Utility Routine and Disable Utility Routine each time it is selected. When the Utility button displays “Enable Utility” that means the utility assay is currently disabled and needs to be enabled. When the Utility button displays “Disable Utility” that mean the utility assay is currently enabled and can be disabled by selecting the button.

5,000 & 10,000 Test Interval Maintenance

The 10,000 test interval maintenance procedures include a step to perform the 5,000 test interval maintenance. Perform daily maintenance procedures after you complete 10,000 and 5,000 test interval procedures.

1. Perform 10,000 and 5,000 test interval maintenance. Use the references in the Help to ensure all procedures are completed. For efficiency, perform the procedures in the order listed below.

Reference: from the Maintenance Review screen
Help
¬ Maintenance Overview
¬ Test Interval Maintenance: 10,000 Tests
¬ Use the green link for each procedure

• Install clean aspirate probes
• Replace the duck bill valve
• Remove and inspect dispense probes
• Inspect:
  ▪ Pump connections at the wash buffer reservoir
  ▪ Upper aspirate peristaltic pump connections
  ▪ Reagent pipettors and clean the wash towers
  ▪ For fallen RVs
  ▪ Liquid waste drawer
  ▪ Wash buffer supply drawer

2. Close the covers and initialize the system.

3. While the system is initializing:
• Clean the air filter
• Clean the aspirate probes
4. Use the flowcharts contained in the ‘Maintenance’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following Daily Maintenance:

- **Back up the system (verify back up successful)**

  Note: Based on your lab’s system configuration, the back up is done on a tape or USB flash drive. Eject and rotate back up tapes. USB flash drives do not need to be rotated.

- **Record the test count**

- **Shake down the solid waste container**

- **Run a clean routine**

  Note: If your laboratory has processed Vitamin B12 in the last 24 hours you should run the Special Clean Routine. If your laboratory has not processed Vitamin B12 in the last 24 hours you should run the Daily Clean Routine.

5. Verify system performance by processing QC.


7. This completes your practice. Consult with your instructor if you have any questions.
# Filters

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Helpful Hints

- Filters are tools that you can use to change the view displayed on a screen.

- Filters can narrow the view displayed so that you only view information you are interested in.

- Filters can expand the view displayed so that you can find a specific entry when reviewing information on a particular screen.

- Filters may have a sort order function. Sort order allows you to have the data displayed in the order specified.

- Some filters can be customized, allowing you to create and save specialized filters for future use.

- Filters are available for the following screens:
  - Work Pending
  - Test Results
  - Reagent Inventory
  - Calibration
  - Quality Control
  - QC Chart and Data
  - Tests
  - Test Panels
  - Event Log

- Remember that filters are your friend. They can make it easier to find specific information.
Filter Use

- The **Work Pending** filter allows you to select the kinds of samples you want to display on the Work Pending screen. You can select or clear any of the following options:
  - Reflex tests: Select to include samples with an associated reflex test
  - Manual reruns: Select to include samples with tests to be rerun
  - Automatic rerun: Select to include samples with tests that were automatically requested for rerun by the system and there was insufficient reserve volume to process the request
  - Obstruction: Select to include samples from which the system did not make an aliquot due to a clot or some other obstruction
  - LIS Requests: Select to include samples with an LIS test request (dynamic downloads)
  - Sample Expiration: Select to include samples that have expired
  - Insufficient Sample Volume: Select to include samples that do not have enough volume (QNS)
  - Other: Select to include samples with test requests from an undefined origin

- You can choose a Sort Order to display sample requests by request time or sample ID. The ascending box sorts the tests in ascending order when checked. Clear the Ascending box to sort the requests in descending order.

- The **Test Results** filters allow you to select the sample results that you want to display in the Test Results screen. You can select any of the following system-defined filters:
  - All flagged results (last 30 days)
  - All patient samples (last 30 days)
  - All patient samples loaded between…
  - All samples (last 30 days)
  - All samples loaded between…
  - Failed auto-verify and not sent to LIS
  - LIS transmission failed
  - On-board patient samples
  - On-board samples
  - On-board STAT samples

- In addition, you can create custom filters to meet your lab’s specific needs.

- The Test Results filters will allow you to choose a 1st Sort Order and a 2nd Sort Order to customize the view.
• The **Reagent Inventory** filter allows you to select the reagent packs you want to display in the Reagent Inventory screen. You can select any of the following categories or reagent packs:
  - All packs
  - On-Board packs
  - Off-Board packs
• The Reagent Inventory filter will allow you to choose a Sort Order to customize the view.

• The **Quality Control** filter allows you to choose the quality controls displayed on the Quality Control screen. You can select any of the following options:
  - All controls
  - All flagged controls
  - Expired controls
  - Non-expired controls
• The Quality Control filter will allow you to choose a 1st Sort Order and a 2nd Sort Order to customize the view.
• In addition to customizing the view on the Quality Control screen, once you have selected a QC Chart and Data for review, you can further filter the amount of data displayed on the QC Chart and Data screen. You can limit the data according to the following categories:
  - Date Range: you can display data for the last week, the last month, or specify a starting and ending date.
  - Reagent Lot: you can display data from a specific reagent lot or all reagent lot numbers.
  - Reagent Pipettor: you can display data from any combination of the four reagent pipettors.

• The **Calibration** filter allows you to choose the calibrations displayed on the Calibration screen. You can select any of the following options:
  - All calibrations: displays the active calibrations for each assay, or the most recent failed calibration of a calibration that has not yet passed.
  - On-Board reagent lots: limits the calibrations displayed to those with reagent on board the instrument.
• The Calibration filter will allow you to choose a Sort Order to customize the view.
• The **Tests** filter allows you to choose the tests displayed on the Configure Tests screen. You can select any of the following options:
  - All tests
  - Enabled tests
  - Disabled tests

• The Tests filter will allow you to choose a Sort Order to customize the view.

• The **Test Panels** filter allows you to choose the test panels displayed on the Configure Test Panels screen. You can select any of the following options:
  - All panels
  - Enabled panels
  - Disabled panels

• The Test Panels filter will allow you to choose a Sort Order to customize the view.

• The **Event Log** filter allows you to choose the events displayed in the Event log. You can select any of the following options.
  - Date Range: you can display event log messages for all dates, the last 24 hours, the last 7 days, or a specified date range.
  - Type: you can display event log messages based on the following categories:
    * Information
    * Caution
    * Warning
    * Diagnostics (used by Technical Support)

• The system uses the selected Event Log filter until you apply a new one.
Work Pending Filter

- Reflex Tests
- Manual Rerun
- Automatic Rerun
- Obstruction
- LIS Requests
- Sample Expiration
- Insufficient Sample Volume
- Other

Options

- Request Time
- Sample ID

View screen for desired entries
Test Results Filter

**Options**
- All flagged Results (Last 30 days)
- All patient samples (last 30 days)
- All patient samples loaded between…
- All samples (last 30 days)
- All samples loaded between…
- Failed auto-verify and not sent to LIS
- LIS transmission failed
- On-board patient samples
- On-board samples
- On-board STAT samples

**Select Filter Options**
- All flagged Results (Last 30 days)
- All patient samples (last 30 days)
- All patient samples loaded between…
- All samples (last 30 days)
- All samples loaded between…
- Failed auto-verify and not sent to LIS
- LIS transmission failed
- On-board patient samples
- On-board samples
- On-board STAT samples

**Select Sort Order**
1st Sort Order
- Sample ID
- Patient ID
- Test Name
- Rack ID
- Comp. Time

2nd Sort Order
- No second sort
- Sample ID
- Patient ID
- Test Name
- Rack ID
- Comp. Time

View screen for desired entries
Reagent Inventory Filter

Supplies

Bulk Supplies
F1

Reagent Inventory
F8

Filter
F1

Select Filter Options

Options
- All Packs
- On-Board Packs
- Off-Board Packs

Select type of pack

Options
- All packs
- Reagent Packs
- Diluent packs

Select Sort Order

Options
- Pack Name
- Tests Left
- Days Open
- Pack Expiration
- Slot

View screen for desired entries
Quality Control Filter

Select Filter Options

Options
- All Control
- All Flagged Controls
- Expired Controls
- Non-Expired Controls

Select Instruments

Options
1\textsuperscript{st} Sort Order
- Test Name
- Control Name
- Control Lot
- Flagged Controls
- Instrument
2\textsuperscript{nd} Sort Order
- No second sort
- Test Name
- Control Name
- Control Lot
- Flagged Controls
- Instrument

Select Sort Order

OK

View screen for desired entries
QC Chart and Data Filter

Quality Control
Select specific QC button to review the QC for that analyte

Review Chart and Data
F2

Filter
F1

Select Date Range
Options
- Last Week
- Last Month
- Specify

Select Reagent Lot(s)

Select Specific Pipettors

OK
F1

View screen for selected entries

Options
- #1
- #2
- #3
- #4
Calibration Filter

- Calibration
- Filter F1
- Select Options
- Options: All Calibrations, On-board Reagent Lots
- OK F1
- Select Specific Reagent
- Review Data F2
- View screen for Active Curve of select Reagent
Tests Filter

Configure

Tests F2

Filter F1

Select Filter Options

Options
- All Tests
- Enabled Tests
- Disabled Tests

Select Sort Order

Options
- Test Name
- Test ID

OK F1

View screen for selected entries
Test Panels Filter

Configure

Test Panels F3

Filter F1

Select Filter Options

Select Sort Order

OK F1

View screen for selected entries

Options
- All Panels
- Enabled Panels
- Disabled Panels

Options
- Panel Name
- Test ID
Event Log Filter

Event Log

Filter F1

Select Date Range Options

Options
- View All Dates
- Last 24 Hours
- Last 7 Days
- Specify

Select Type

Options
- Information
- Caution
- Warning
- Diagnostics

OK F1

View screen for selected entries
Practice: Filters

You have had a chance to observe your instructor demonstrate how to effectively use the Filters feature of the instrument. Filters allow you to customize the view of certain screens and allow viewing specific information.

Now you can take some time to practice those tasks for yourself. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
Test Results

When monitoring work in progress you may want to have a place to view the status of all samples that are on-board the instrument with predicted completion times for each test. You can view this information using a test results filter.

1. Navigate to the Test Results screen and filter the view to show all On-board samples sorted 1st by Sample ID, then by Test Name.

A physician just called and would like the results of a sample on a patient processed yesterday.

2. Change the Test Results filter so that you can view results from yesterday.

You are responsible for releasing results, and want to spend your time concentrating on the abnormal results.

3. Change the Test Results filter so that only flagged results are displayed, sorted 1st by Sample ID, then by Completion Time.

Reagent Inventory

You are responsible for preparing your instrument for the days run. The Reagent Inventory filter will allow you to view the reagent inventory screen in a manner that is most useful to you.

4. Navigate to the Reagent Inventory screen and change the filter so that only On-Board packs are displayed with the packs with the fewest tests remaining displayed at the top of the Reagent Inventory report.

Now you have a quick way to see what reagents need to be replenished.

5. Change the Reagent Inventory filter so that only On-Board packs are displayed, but now list them in order of pack expiration.

This will let you know if you have any packs that will be expiring today.

6. Explore other Sort Options on the Reagent Inventory filter screen to determine which Sort Orders will be useful for you.
**Quality Control**  
You have just completed your QC and need to review it before processing samples.

7. Navigate to the Quality Control screen and set the filter so that All Controls are available and are sorted so that flagged controls appear first and are then sorted by Test Name.

8. Now view all of the flagged controls QC Chart and Data. Filter the QC Chart and Data so that you can view the last months of data listed on the current lot # of reagent using all pipettors.

---

**Calibration**  
You are troubleshooting a failed calibration and want to compare the results of the current calibration with a previous calibration.

9. Navigate to the Calibration screen and set the filter so that only calibrations for On-Board reagents are displayed. Select the reagent lot you wish to view.

---

**Event Log**  
You are viewing the Event Log and wish to see if a particular warning event has been happening with any specific pattern.

10. Navigate to the Event Log and set the filter so that only warning events are displayed for All Dates.

    Note that the Event Log can now be reviewed more effectively to check for repeat events.

Your QC looks a little suspicious- you need to determine if the Daily Maintenance Clean Routine was completed before the QC was processed.

11. Change the Event Log filter so that only Information events are displayed for the last 24 hours. View the log to determine if the Clean Routine was completed.

---

**Finish Line**  
12. This completes your practice. Consult with your instructor if you have any questions.
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Practice: Instrument Overview

You have had a chance to observe your instructor overview the use of the instrument software and point out the exterior hardware features of the instrument.

Now you can take some time to practice utilizing the software and identifying hardware components for yourself. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
1. Use the information contained in the ‘Instrument Overview’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following:

- Navigate to the Sample Manager Screen using the touch screen feature.

- Navigate to the Maintenance Review screen using the mouse to select the Menu Tab, then Maintenance Review.

- Navigate to the Main Menu using the F9 key on the keyboard.

  Reminder: The F9 key on the Keyboard is the only way to navigate to the Main Menu.

- Navigate to the Test Results Screen using the keyboard by selecting the F2 key.

  Note the scroll bar on the right side of the screen allows you to view results outside of the view of the screen. Scroll down within the Test Results screen using either the touch screen, mouse, or keyboard.

2. Use the information contained in the “Instrument Overview” tab or the Instructions for Use Manual (IFU) to answer the following questions:

- What is the color of the System Mode Icon when the system is Paused?

  Yellow

- When the system is performing a function, what is the System Mode?

  Running

- What is the System Mode when the system is homing moving parts?

  Not Ready
Software Overview (Continued)

3. Use the information contained in the “Instrument Overview” tab or the Instructions for Use Manual (IFU) to answer the following questions:

- Which System Status button would alert you if you did not have a valid calibration on file for a run?

**Supplies Required**

- What System Status button would alert you if the system generated a reflex test and the sample needed to be loaded back on the system?

**Work Pending**

- What System Status button would alert you if the system had an unreadable barcode?

**Rack Exceptions**

4. What are the three System Command buttons?

- Stop
- Pause
- Resume
5. Use the information contained in the “Instrument Overview” tab or the Instructions for Use Manual (IFU) to perform the following:

6. Locate each of the covers of your instrument

7. Locate each of the supply drawers on your instrument.

8. Locate the System Status Panel, the SPU Cover Sensor, and the Reagent Tray In-Use light on your instrument.

9. What does a blinking Amber Status Indicator light signify?

   Supplies required, one or more system supplies are out or an area requires attention.

10. When the SPU Cover Sensor is lit, what action should you take to load a rack?

    Press either the Routine or STAT load button to request a load and unlock the SPU cover.
11. Navigate to Device Diagnostics in the instrument software, then open the upper left and right main covers.

**Software Path:** Main Menu → Diagnostics F7 → Device Diagnostics F4

12. While the upper covers are open, locate the listed components. Ask your trainer if you have trouble locating a component.

- Sample Pipettor
- Sample Storage
- Sample Pick and Place
- Bulk Feeder
- Supply Carriage
- Incubator Pick and Place
- Reagent Carriages (4-DxI 800 and 2-DxI 600)
- Reagent Pipettors (4-DxI 800 and 2-DxI 600)
- Wash Pick and Place
- Analytical Module:
  * Incubator (center wheel)
  * Wash Carousel (outer wheel)
  * Luminometer
13. Close the upper left and right Main covers and Initialize the System.

   Software Path: Main Menu → Diagnostics F7 → Initialize System F1

14. Verify the System Mode returned to Ready after initialization.

The Finish Line

15. Congratulations! You have completed the Instrument Overview practice. Consult with your instructor if you have any questions or need clarification.
Classroom Discussion: Operational Overview

Objectives

During this discussion you will discover:

- Sample preparation
- Test processing checks
- Sample processing priority
- Sample processing overview
- Principle of chemiluminescence
- Enzyme Immunoassay (EIA) process

Knowledge of instrument function is a resource an operator will use during normal and abnormal operations.

Reference

DxI Help System
Sample Preparation

Tips on Sample Preparation:

- Verify adequate sample volume for sample containers using the Sample Volume Guidelines template found in the DxI Instructions for Use
- Remove the caps from all tubes
- Use only DxI validated sample containers
- Place the sample container in the rack designated for its use (only one container type per rack)
- Ensure the sample containers are seated correctly in the rack
- Ensure that the bar code label is properly placed on the tube and is aligned so that it is visible through the slot in the rack
- Ensure there are no bubbles or remove bubbles from samples

Test Processing Checks

When a sample is loaded, the DxI checks to make sure that

- Supplies and reagents are loaded
- Verifies calibration
- Determines priority

Testing Priority

1. STAT tests
2. Calibration tests
3. QC tests
4. Patient tests
5. Maintenance
**DxI Sample Processing**

1. A vessel is moved from the Bulk Feeder to the Supply Carriage, which transports it to the Sample Pick and Place (PnP).

2. The Sample PnP moves the empty Sample Vessel (SV) to Sample Storage, which rotates, aligning the SV with the Sample Pipettor.

3. Sample racks are transported to the Sample Pipettor by the Sample Presentation Unit (SPU).

4. The Sample Pipettor aspirates an aliquot of the sample and delivers it to the empty SV.

5. The sample rack is no longer required and is moved to the offload area.

6. The Supply Carriage receives another empty vessel from the Bulk Feeder, which is delivered by the Sample PnP to one of the Reagent Carriages for use as a Reaction Vessel (RV).
Dxl Sample Processing

7. The SV with the sample aliquot is delivered to the Reagent Carriage containing the RV by the Sample PnP.

8. The Reagent Carriage and a reagent pack are moved into alignment with the Reagent Pipettor.

9. The Reagent Pipettor transfers sample* from the SV to the empty RV.

10. The required reagent components* are added to the RV with the sample and mixed by the Reagent Pipettor.

11. The RV is transported to the Incubator PnP, which transports it to the incubator in the Analytical Module for incubation.

12. The SV may be sent back to Sample Storage if required by the system.

13. When incubation is complete, the RV is transferred to the wash carousel in the Analytical Module by the Wash PnP.

14. The RV is washed three times. After the final wash, substrate is added.

15. After substrate addition, the RV is incubated again and light is generated by chemiluminescence**.

16. RLU values are read from the RV by the Luminometer.

17. The used RV is transported to waste.

18. If the SV is no longer needed by the system, it is also transported to waste.

*The order of sample and reagent addition to the RV is assay dependent.

**Additional information on the theory of chemiluminescence may be found in the Appendix section of this workbook.
Chemiluminescence is defined as:

*A chemical reaction in which one of the final end products is light.*
Practice: Resources

You have had a chance to observe your instructor demonstrate the use of the different resources available to you.

Now you can take some time to practice utilizing the references for yourself. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
Main Menu Workflow

1. Use the software tree contained in the ‘Resources’ tab of this workbook or in the Instructions for Use Manual (IFU) to answer the following questions:

- What are the three types of requests you can program, using the following pathway:

  Menu → Sample Manager F1 → New Request F3

  Patient/QC Requests

  Calibration

  Maintenance

- What is the software pathway you would use to Add a Quality Control file?

  Quality Control F4 → QC Setup F5 → Add Control F1

- What is the software pathway you would use to check the function of the Panel Lights?

  Diagnostics F7 → Device Diagnostics F4 → Digital Diagnostics F3 → Panel Lights F1

- What is the software pathway you would use to Shut Down the System?

  Configure F8 → PC Admin F7 → System Admin F8 → Shut down instrument F1 & Shutdown PC F2

- What software pathway would you use to Delete a reagent Pack from the system memory?

  Supplies F3 → Reagent Supplies F2 → Reagent Inventory F8 → Delete Pack F5
Help System

2. Review the information contained in the ‘Resources tab’ of this workbook: Help Contents and Helpful Hints: Help System. Use the Help system to perform the following:

- Verify that the Main Menu is displayed on the console monitor.

  Hint: You may access the Main Menu at any time by selecting the [F9] key on the keyboard

  ◆ Touch the HELP button or click the left mouse button with the cursor positioned on the HELP button.

  ◆ Select the topic Using the Help System.

  ◆ Select the topic Help System Link Buttons.

  ▪ Use the information in this help topic to supply the name for each button shown below:

<table>
<thead>
<tr>
<th>BUTTON</th>
<th>NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>See Also</td>
</tr>
<tr>
<td></td>
<td>Flowchart</td>
</tr>
<tr>
<td></td>
<td>View Screen or View Window</td>
</tr>
<tr>
<td></td>
<td>Show Me</td>
</tr>
</tbody>
</table>

  ▪ Which of the above buttons would you select if you wanted to see an illustration of a topic such as a report or drawing?

  **Show Me**
Help System

- From any menu, select the Help button.

  Specify “Help Topics” from the Window bar of the Help System.

  Select the “Contents” tab.

  Select the “Operator’s Procedures” book from the Help topics window.

  Note that the “Operator’s Procedures” book contains additional “books” that can be used to access the references for the most commonly needed operational tasks.

  **The Operator’s Procedures book can be very useful when looking for basic operational HELP.**

  Select the “Supplies” book and note that there are references on how to monitor the supplies and change each supply.

  Print the reference on how to change an empty bulk wash buffer container.

- Navigate to the Maintenance Review Screen.

  Hint: You can use the software tree in the “Resource tab” of this manual if you need assistance.

  Select the Help button.

  Note that the information displayed is specific to the Maintenance Review screen.

  Select the green link to navigate to the Maintenance Overview topic.

  Select the green link to the Daily Maintenance topic.

  Using the information contained in this topic, answer the following question:

  **Which Clean Routine will you run daily in your laboratory?**

  **Daily clean**

  or

  **Special Clean if running Vitamin B12 in your lab**
3. Use the Instructions for Use manual to answer the following questions:

- What does each of these safety symbols represent?

  - Electrical safety
  - Moving parts
  - Biohazard
  - Laser
  - Electrostatic discharge
  - Sharp objects
  - Attention safety

- What do the following test result flags indicate?

  - **CLT**: Obstruction was detected in the sample tube before aliquoting or in the RV during processing
  - **EXS**: Substrate expired
  - **OVR**: Calculated concentration is above the highest or most concentrated calibrator (quantitative or semi-quantitative assay)
  - **QCF**: QC violates on or more QC rules
  - **SYS**: Device error occurred during processing

- What is the part number for Wash Buffer?

  - 8547197
4. Fill in the names and phone numbers of your applications specialist and field service engineer in the “Other Resources” section of the “Resources Tab” of this workbook.

**Names of your applications specialists and field engineer.**

________________________________________________________________________

5. Congratulations! You have completed the Resources practice. Consult with your instructor if you have any questions or need clarification.

________________________________________________________________________
Practice: Supply Loading and Management

You have had a chance to observe your instructor demonstrate the correct procedure to replenish each supply.

Now you can take some time to practice those tasks for yourself. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
- Reaction vessels
- Wash Buffer
- Spare Liquid Waste bottle
- Biohazard waste bag
- Spare Substrate Bottle
- Reagent Packs
Supply Replenishment

1. Use the flowcharts contained in the ‘Supplies’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following:

   - Change a substrate bottle  
     Note: For practice purposes you may practice changing a substrate bottle that is not empty. Make sure that you change the container that is **not** in-use.
   - Change a bulk wash buffer container  
     Note: For practice purposes you may practice changing a bulk wash buffer container that is not empty. Make sure that you change the container that is **not** in-use.
   - Add RVs
   - Change a bulk liquid waste container, if not plumbed to a drain  
     Note: For practice purposes you may practice changing a bulk liquid waste container that is not full. Make sure that you change the container that is **not** in-use.
   - Empty the solid waste container  
     Note: For practice purposes you may practice changing the bag in the solid waste container that is not full.

---

Reagent Unload/Load

2. Use the flowcharts contained in the ‘Supplies tab’ of this workbook or in the Instructions for Use Manual (IFU) to view the Reagent Inventory and perform the following:

   - Unload the reagent pack with the fewest tests remaining.
   - Load the reagent pack just unloaded

---

Reagent Inventory

Reagent **and** calibration status can be monitored using the Reagent Inventory Report.

3. Access the reagent inventory screen for your instrument and determine if any reagents need to be replenished. Add any reagents needed for today’s work using the flowchart on the previous page or in the Instructions for Use Manual.

4. How often will you review the reagent inventory screen in your laboratory?

   **Answers will vary**
Supply Management

The answers to the following questions can be found in the Supplies Tab of the Instructions for Use Manual (IFU). Knowing the answers to these questions will aid you to effectively manage the supplies on your system. Answer the questions below:

16. What are the two ways the system alerts you that a supply is required?
   - System status icon
   - Status indicator lights
   - Supply status pad (800 only)

17. Is the software required to load any supply?
   No

18. What are the System Modes during which the following supplies can be loaded on the system:
   Substrate: Any
   Wash Buffer: Any
   Reaction Vessels: Any
   Liquid Waste: Any
   Solid Waste: Any
   Reagent: Ready, Running
19. What are the three indicators that notify the operator when reagent needs to be loaded for a requested run?

- Status Indicator Lights
- Bulk Supply Status Button
- Dxl 800 only: System Status Panel

20. Compare your answers to the questions to the Reference Key tab. If there are any discrepancies or questions, talk it over with your instructor.
Practice: Calibration

You have had a chance to observe your instructor demonstrate the calibration process for the system.

Now you can take some time to practice calibrating your instrument. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
- Sample racks
- Reagent of your choice
- Calibrator set to match reagent on board the system
Calibrator Setup

Use the flowcharts contained in the ‘Calibration’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following:

1. Select an assay that you wish to calibrate for this practice.

   Note: Your trainer may identify the assay to calibrate.

2. Verify that you have adequate reagent on-board the system to calibrate. If necessary add additional reagent.

   Hint: You can use the Reagent Inventory screen to determine the reagent status.

3. Add a new calibrator lot number to the currently existing calibrator information in your instrument memory.

   If you do not have a new lot number, delete the current lot, then add it back into the system database. This will allow you to practice adding a new lot! You can use the Software Tree in the Resource tab to help you determine the software path to delete a calibrator.

Calibrate

4. Use the flowcharts contained in the ‘Calibration’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform a calibration for the assay selected in step 1:

   - Prepare samples
   - Request the calibration
   - Load calibrator racks

Review Calibration

5. Review the calibration report for acceptability.

The Finish Line

6. Congratulations! You have completed the Calibration practice. Consult with your instructor if you have any questions or need clarification.
Practice: Quality Control

You have had a chance to observe your instructor demonstrate how to setup, program and process, and review quality control.

Now you can take some time to practice setting up QC, processing QC and reviewing the QC you processed. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
- Sample racks
- Practice QC Samples
1. Use the flowcharts contained in the ‘Quality Control’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following:

- Select a minimum of two assays that you wish to QC for this practice.

- Verify that you have adequate calibrated reagent on-board the system to process quality control.

  Hint: You can use the Reagent Inventory screen to determine the reagent status.

- Add a new quality control file to the currently existing quality control information using the information in the table below.

<table>
<thead>
<tr>
<th>QC Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>QC Identifiers</td>
<td></td>
</tr>
<tr>
<td>Name: Practice QC 1</td>
<td>Name: Practice QC 2</td>
</tr>
<tr>
<td>Lot #: XXXXX</td>
<td>Lot #: ZZZZZ</td>
</tr>
<tr>
<td>Expiration Date: 12-31-2008</td>
<td>Expiration Date: 12-31-2008</td>
</tr>
<tr>
<td>Sample Type: Serum</td>
<td>Sample Type: Serum</td>
</tr>
<tr>
<td>QC range info</td>
<td></td>
</tr>
<tr>
<td>Select test(s) that are on board and calibrated and enter the mean and SD from the package insert for the Quality control materials selected. You may enter the same means and SDs for both Practice QC 1 and Practice QC 2.</td>
<td></td>
</tr>
</tbody>
</table>
QC Processing

2. Use the flowcharts contained in the ‘Quality Control’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following:

- Follow the steps in the Step/Action table below:

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Create a QC test request for the Practice QC1 and Practice QC 2 samples, requesting tests for which you defined mean(s) and SD(s) for in Step 1 of the Practice Exercise.</td>
</tr>
<tr>
<td>2</td>
<td>Pour the appropriate QC material into a 2 mL cup programmed for Practice QC1</td>
</tr>
<tr>
<td>3</td>
<td>Pour water into a 2 mL cup programmed for Practice QC2.</td>
</tr>
<tr>
<td>4</td>
<td>Complete the steps listed in the flowchart in the “Quality Control” tab of this workbook to process the QC you just requested.</td>
</tr>
</tbody>
</table>

Review QC

3. Use the flowcharts contained in the ‘Quality Control’ tab of this workbook to view the results for each test processed on your Practice QC 1 and Practice QC 2.

Note: Practice QC 2 should be flagged because you placed water in the cup that had QC ranges defined. Use this opportunity to familiarize yourself with the QC flagging utilized by the system.

Reminder: QC buttons turn red when the QC violates defined QC rules. Selecting the button will clear the red flag.

4. Process additional material for QC if you would like additional practice.
5. Use the HELP system to delete the Practice QC 1 and the Practice QC 2 files form the system database.

**Reference:**
Navigate to the QC Screen, then Select HELP.
* Setting Up Quality Controls
  * Deleting a Quality Control

OR
Select HELP from any screen.
**Help Topics**
* Operators Procedures
  * Quality Control
    * Setting Up Quality Controls
      * Deleting a Quality Control

---

6. Congratulations! You have completed the Quality Control practice. Consult with your instructor if you have any questions or need clarification.
Practice: Sample Processing and Management

You have had a chance to observe your instructor demonstrate the sample handling capabilities of the system.

Now you can take some time to practice processing samples and managing sample handling. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
- Sample racks
- Practice QC Samples
Sample Processing LIS Requests

Use the flowcharts contained in the ‘Samples’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following:

1. Follow the steps in the Step/Action table below:

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Create a test request at your LIS for six (6) practice sample(s). Have your LIS print a barcode for each request.</td>
</tr>
<tr>
<td>2</td>
<td>Apply the barcode to a primary sample tube and add fluid for the practice sample. Note: Pooled serum or control material may be used for practice.</td>
</tr>
<tr>
<td>3</td>
<td>Load the samples into the appropriately designated racks for the sample container(s) available for each practice sample.</td>
</tr>
<tr>
<td>4</td>
<td>Load the racks onto the Sample Processing Unit (SPU).</td>
</tr>
</tbody>
</table>

IF your LIS system prohibits you from following the instructions in the Step/Action table above, use the alternate method below:

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Obtain patient samples that are requested in your LIS and require processing.</td>
</tr>
<tr>
<td>2</td>
<td>Load the samples into the appropriately designated racks for the sample container(s) available for each sample.</td>
</tr>
<tr>
<td>3</td>
<td>Load the racks onto the Sample Processing Unit (SPU).</td>
</tr>
</tbody>
</table>

2. Use the flowcharts contained in the ‘Samples’ tab of this workbook or in the Instructions for Use Manual (IFU) to program six (6) additional practice sample(s).

- Create unique identifiers such as Sample ID and Patient ID for each practice sample.
- Request tests that have reagent loaded and calibrated on your system.
- Request a minimum of 2 samples that are routine priority and a minimum of 2 samples that are STAT priority.
- Add the comment “Hemolyzed” to one of your manual requests.

Reminder: Reagent and calibration status can be viewed by assessing the Reagent Inventory. See the ‘Supply’ tab of this workbook.
Sample Progress

3. Use the flowcharts contained in the ‘Samples’ tab of this workbook to determine what time each assay will be complete for each practice sample.

   Suggestion! Use the find feature to find one of the samples that are in progress.

Rerun a test

4. Use the flowcharts contained in the ‘Samples’ tab of this workbook to rerun the result for the first practice sample that completed.

Recall Results

5. Use the flowcharts contained in the ‘Samples’ tab of this workbook to reprint the result for the first practice sample you processed in step 1 above.

The Finish Line

6. Congratulations! You have completed the Sample Processing practice. Consult with your instructor if you have any questions or need clarification.
Practice: Shut Down/Restart

You have had a chance to observe your instructor demonstrate the proper shut down and restart of the DxI system.

Now you can take some time to practice shutting down and restarting the system for yourself. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
1. Use the information contained in the Shutdown/Restart tab of this workbook or in the Instructions for Use Manual (IFU) to answer the following questions:

- If you are shutting down the instrument and the PC, which should be shut down first?

**Instrument**

- When should you shut down the PC?

**When directed by technical support**

2. Shut down your training instrument using the User Interface.

3. Shut down your training instrument PC using the User Interface.

4. Restart the PC.

5. Restart the instrument.

6. Verify that the system mode of your training instrument is READY.

---

7. Congratulations! You have completed the Shut Down/Restart practice. Consult with your instructor if you have any questions or need clarification.
Practice: Maintenance

You have had a chance to observe your instructor demonstrate the correct procedures to maintain the DxI system. Routine maintenance keeps the system working properly.

Now you can take some time to practice those tasks for yourself. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
- Contrad 70 Cleaning solution
- 1/5 dilution of Citranox
- 70% Methanol
- Safety goggles
- Gloves
- Sample containers that hold at least 4 mL of solution
- Sample rack with the appropriate rack ID for the container used
- Maintenance Log (photocopy from IFU)
Utility Routine

The Utility Routine is an automated maintenance procedure that runs automatically every 4 hours if the system is not processing samples.

1. Enable the Utility Assay on your instrument.

   Software navigational path: 
   Main Menu-F9 or Menu tab → Maintenance Review-F5 → Enable Utility Routine-F6

   Note: The Utility button name switches between Enable Utility Routine and Disable Utility Routine each time it is selected. When the Utility button displays “Enable Utility” that means the utility assay is currently disabled and needs to be enabled. When the Utility button displays “Disable Utility” that mean the utility assay is currently enabled and can be disabled by selecting the button.

5,000 & 10,000 Test Interval Maintenance

The 10,000 test interval maintenance procedures include a step to perform the 5,000 test interval maintenance. Perform daily maintenance procedures after you complete 10,000 and 5,000 test interval procedures.

1. Perform 10,000 and 5,000 test interval maintenance. Use the references in the Help to ensure all procedures are completed. For efficiency, perform the procedures in the order listed below.

   Reference: from the Maintenance Review screen
   Help
   • Maintenance Overview
   • Test Interval Maintenance: 10,000 Tests
   • Use the green link for each procedure

   • Install clean aspirate probes
   • Replace the duck bill valve
   • Remove and inspect dispense probes
   • Inspect:
     ▪ Pump connections at the wash buffer reservoir
     ▪ Upper aspirate peristaltic pump connections
     ▪ Reagent pipettors and clean the wash towers
     ▪ For fallen RVs
     ▪ Liquid waste drawer
     ▪ Wash buffer supply drawer

2. Close the covers and initialize the system.

3. While the system is initializing:
   • Clean the air filter
   • Clean the aspirate probes
Daily Maintenance
4. Use the flowcharts contained in the ‘Maintenance’ tab of this workbook or in the Instructions for Use Manual (IFU) to perform the following Daily Maintenance:

- **Back up the system (verify back up successful)**

  Note: Based on your lab's system configuration, the back up is done on a tape or USB flash drive. Eject and rotate back up tapes. USB flash drives do not need to be rotated.

- **Record the test count**

- **Shake down the solid waste container**

- **Run a clean routine**

  Note: If your laboratory has processed Vitamin B12 in the last 24 hours you should run the Special Clean Routine. If your laboratory has not processed Vitamin B12 in the last 24 hours you should run the Daily Clean Routine.

5. Verify system performance by processing QC.


Finish Line
7. This completes your practice. Consult with your instructor if you have any questions.
Practice: Filters

You have had a chance to observe your instructor demonstrate how to effectively use the Filters feature of the instrument. Filters allow you to customize the view of certain screens and allow viewing specific information.

Now you can take some time to practice those tasks for yourself. Practicing each task will give you some hands-on experience and build your skill level. Should you have any questions or need assistance during your practice, your instructor is here to help!

What Will I Need?

You will need the materials listed below to complete this practice:

- UniCel DxI Instructions for Use Manual
- UniCel DxI Instrument
**Test Results**

When monitoring work in progress you may want to have a place to view the status of all samples that are on-board the instrument with predicted completion times for each test. You can view this information using a test results filter.

1. Navigate to the Test Results screen and filter the view to show all On-board samples sorted 1st by Sample ID, then by Test Name.

A physician just called and would like the results of a sample on a patient processed yesterday.

2. Change the Test Results filter so that you can view results from yesterday.

You are responsible for releasing results, and want to spend your time concentrating on the abnormal results.

3. Change the Test Results filter so that only flagged results are displayed, sorted 1st by Sample ID, then by Completion Time.

---

**Reagent Inventory**

You are responsible for preparing your instrument for the days run. The Reagent Inventory filter will allow you to view the reagent inventory screen in a manner that is most useful to you.

4. Navigate to the Reagent Inventory screen and change the filter so that only On-Board packs are displayed with the packs with the fewest tests remaining displayed at the top of the Reagent Inventory report.

Now you have a quick way to see what reagents need to be replenished.

5. Change the Reagent Inventory filter so that only On-Board packs are displayed, but now list them in order of pack expiration.

This will let you know if you have any packs that will be expiring today.

6. Explore other Sort Options on the Reagent Inventory filter screen to determine which Sort Orders will be useful for you.
Quality Control

You have just completed your QC and need to review it before processing samples.

7. Navigate to the Quality Control screen and set the filter so that All Controls are available and are sorted so that flagged controls appear first and are then sorted by Test Name.

8. Now view all of the flagged controls QC Chart and Data. Filter the QC Chart and Data so that you can view the last months of data listed on the current lot # of reagent using all pipettors.

Calibration

You are troubleshooting a failed calibration and want to compare the results of the current calibration with a previous calibration.

9. Navigate to the Calibration screen and set the filter so that only calibrations for On-Board reagents are displayed. Select the reagent lot you wish to view.

Event Log

You are viewing the Event Log and wish to see if a particular warning event has been happening with any specific pattern.

10. Navigate to the Event Log and set the filter so that only warning events are displayed for All Dates.

   Note that the Event Log can now be reviewed more effectively to check for repeat events.

   Your QC looks a little suspicious- you need to determine if the Daily Maintenance Clean Routine was completed before the QC was processed.

   11. Change the Event Log filter so that only Information events are displayed for the last 24 hours. View the log to determine if the Clean Routine was completed.

Finish Line

12. This completes your practice. Consult with your instructor if you have any questions.
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Pre-Analytical Factors for Patient Samples

Preparing sample for testing is one of the most routine, yet most critical, processes to ensure accurate results in the clinical laboratory. Improperly handled sample can give misleading results and compromise the function of diagnostic instruments.

Although the key steps for blood collection and handling discussed in the following section provide general guidelines:

- Refer to the applicable blood collection tube manufacturer’s IFU for blood sample collection, mixing, and centrifugation requirements
- Refer to the applicable Beckman Coulter reagent IFU for appropriate sample type(s) and handling requirements for each assay
- Each laboratory should establish its own policies and procedures for blood collection and handling

1. **Draw Collection Tubes in Correct Order**

The Clinical and Laboratory Standards Institute (CLSI) provides recommendations for the collection of different blood collection tube types. To minimize cross contamination that could adversely impact analytical results, the recommended draw order can be summarized as follows:

<table>
<thead>
<tr>
<th>Draw Order</th>
<th>Tube Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Tubes for sterile sample (e.g., blood culture)</td>
</tr>
<tr>
<td>2</td>
<td>Tubes for coagulation studies (i.e., citrate)</td>
</tr>
<tr>
<td>3</td>
<td>Serum tubes (with or without clot activator additive) (with or without separator gel)</td>
</tr>
<tr>
<td>4</td>
<td>Heparin tubes (with or without separator gel)</td>
</tr>
<tr>
<td>5</td>
<td>EDTA tube</td>
</tr>
<tr>
<td>6</td>
<td>Glycolytic Inhibitor tubes</td>
</tr>
</tbody>
</table>
2. **Draw Correct Sample Volumes**
   It is very important, especially when collecting blood into a tube with an additive, that the tube is filled to the specified draw volume. An incorrect blood draw volume will result in an incorrect ratio of blood to additive. This incorrect ratio can adversely impact analytical results.

3. **Mix Collection Tubes**
   Adequate mixing by complete inversion is critical for all collection tubes containing an additive. Refer to the BD and Greiner websites for how many inversions are required for each tube type.

4. **Allow Time to Clot**
   Refer to the BD and Greiner websites for the required clotting time for each type of serum collection tube.

5. **Centrifuge Correctly**
   - Refer to the BD and Greiner websites for centrifugation requirements for each tube type
   - Horizontal rotors are preferable to fixed angle rotors. A fixed angle rotor can cause gel or cellular debris to remain in the sample layer
   - Do not re-spin primary tubes; cells can rupture and leak, contaminating the sample. Transfer the sample layer to another container first

6. **Aspirate to transfer Samples (Do Not “Pour Off”)**
   To avoid potentially contaminating a plasma sample with cellular debris and/or platelets or a serum sample with cellular debris, transfer sample from the primary container to a secondary container by aspirating and dispensing rather than by inverting the tube and pouring off the sample.
The Role of Preanalytical Factors in Immunoassays

Introduction

Measurement of biochemical markers is an important aid to clinicians in the early detection, diagnosis, monitoring, and prognosis of disease. Specimen quality plays a key role in assuring accuracy of those measurements in clinical laboratory testing.

To gain efficiencies in workflow and decrease turn-around time (TAT), many laboratories have adopted new strategies and practices, including transitioning from:

- glass to plastic specimen collection tubes
- serum to anticoagulated plasma samples
- manual processing to lab automation, and
- sample collection by laboratory staff to non-laboratory personnel.

As laboratories automate more processes, less time is dedicated to sample inspection steps, which could monitor specimen quality. Preanalytical factors can be magnified by sensitive immunoassays and present an increasing challenge to quality clinical care.

Preanalytical Variables that Could Affect Results

As much as 84% of laboratory error can be attributed to the preanalytical phase of clinical laboratory testing, which is comprised of patient condition, as well as specimen collection, transport, processing, and placement on the analyzer.\(^1,2,3,4,5\)

Patient samples with circulating protein interferants such as human anti-mouse antibodies (HAMA) and rheumatoid factor (RF) may affect the results in certain assays and is an example of a potential source of error outside of the control of the laboratory.\(^6,7\) Knowledge of such factors is important when determining the appropriate interpretations of results.

The large majority of preanalytical errors are due to compromised sample quality as affected by specimen collection, storage, transport, and processing.\(^1,2,3,4,5\) Common factors contributing to error include: incorrect labeling of tubes, insufficient blood draw volume, insufficient mixing, cellular contamination in plasma specimens, and inadequate clotting of serum specimens.

To maintain sample quality, each stage in sample preparation is important and it is critical that personnel performing blood collection adhere to all recommendations specified by blood collection tube manufacturers. Deviations from the manufacturers’ recommendations must be validated in individual laboratories.
Factors Affecting Plasma Samples

While serum may provide the cleanest sample from an interference perspective, there are, at times, issues with being able to process the sample in a timely manner. Because urgent, critical decisions are based on STAT results, heparinized plasma samples have become the preferred sample type and are widely used. Laboratory Practice Guidelines, published by the National Academy of Clinical Biochemistry (NACB), recommend plasma for STAT analysis of cardiac markers. Plasma provides the best opportunity for achieving desired TAT, however, there are variables that must be controlled to obtain the best possible sample for analysis.

Because a plasma sample contains anticoagulants, the cellular components (i.e., white blood cells, red blood cells, and platelets) are not trapped in a clot during the normal coagulation process of a serum sample. Following centrifugation, plasma samples can still contain trace amounts of cellular material, as well as latent fibrin. Gel separator tubes reduce the incidence of resuspension; however, small material, especially platelets, will remain above the plasma gel interface barrier. These factors can cause non-specific binding of the antibodies, leading to erroneous results.

Heparin as an Anticoagulant

Heparin, a negatively charged molecule used to inhibit clotting, can bind to some analytes, antibodies, and cellular material, and interfere with the antigen-antibody interaction in the test method.

If a tube has insufficient blood volume, there is an excess of heparin. Maintaining an optimum, sample-to-additive ratio is important for effective heparin activity. A key step in the sample handling process is ensuring that the blood draw sample volume is at least 90% of the stated volume on the collection tube. Clinical and Laboratory Standards Institute (CLSI) has published guidelines for blood specimen handling. Heparin is also a commonly used pharmaceutical agent to inhibit clotting in critical care patients. Inadequate clearing of an intravenous line prior to blood collection can also create an excess in the sample.

Possible Mechanisms that Could Interfere with Heparin Anticoagulant Activity

There are mechanisms that could interfere with heparin anticoagulant action resulting in fibrin formation in a plasma sample. These include:

1. The ability of heparin to bind to cell membranes/proteins, such as platelets. Heparin has a tendency to bind to plasma proteins and cell membranes, thus making its pharmacological action unpredictable. The presence of cellular proteins and membranes could result in binding of heparin, therefore, competing and interfering with anticoagulation.

2. Some patients upon re-exposure to heparin will exhibit heparin-induced thrombocytopenia (HiT). This condition can cause heparin-induced or facilitated
platelet aggregation resulting in low platelet counts. The activated platelets release platelet factor 4 (PF4) that allows clotting by neutralizing heparin.

Effect of Fibrin in Plasma and Serum Samples

Imunoassays are susceptible to interference by fibrin. Small amounts of fibrin (and other protein debris membranes or cell stroma) may affect sensitive immunoassays. The presence of gross amounts of fibrin in the specimen (serum or plasma) may cause blockage of instrument sample aspiration probes, leading to erroneous assay results.

Plasma Samples

Inadequate tube mixing may result in uneven distribution of the heparin additive throughout the specimen. This could lead to localized areas within the specimen where the anti-thrombin effect of the additive is insufficient to prevent the formation of fibrin. Thus, thorough mixing by gentle inversion (at least 8 times) immediately after blood is drawn in the tube is essential. A liquid anticoagulant was used in many glass tubes, facilitating easy mixing. Today the walls of the tube are coated with a powdered anticoagulant, which is not as easily mixed in the sample unless the required mixing occurs immediately after collection.

Since the heparin additive in specimens typically degrades over time, residual thrombin in the specimen can convert soluble fibrinogen to insoluble fibrin. Flocculent matter can frequently be observed in stored samples. Care should be taken to recentrifuge such samples prior to analysis.

Serum Samples

Inadequate clotting time, improper mixing, and failure to place the tube in an upright position can lead to incomplete clot formation. Following centrifugation, the resulting sample may appear satisfactory with a defined layer of cells at the base of the tube and a clear layer of serum above. Despite this appearance, the clotting process may not have been completed prior to transportation, centrifugation, and placement of the specimen on the analyzer. Further coagulation in the serum may subsequently occur, leading to the production of “latent” fibrin, which can interfere with the quality of a result.

For plastic tubes, thorough mixing by gentle inversion (at least 5 times) is essential to ensure even distribution of the clot activator throughout the specimen and to allow completion of the clotting process. Note that some cardiac patients will have therapeutic levels of anticoagulant in their blood that will increase clotting time in the tube and thus increase the potential for the formation of “latent” fibrin in the preanalytical phase.
Conclusions

Considering all of the above factors, serum appears to be the superior sample for immunoassays. Many laboratories use heparinized plasma for faster test turn around times, and to avoid prolonged clotting times in patients with high circulating levels of heparin. Regardless of which sample type is used, following the blood collection tube manufacturer's specimen collection and handling recommendations will help to reduce preanalytical laboratory error. In order to minimize laboratory error due to specimen quality, the key preanalytical actions are:

1. Adequately fill the collection tube to the full volume.
2. Ensure proper mixing immediately after collection.
3. Allow adequate clotting time (minimum 15 minutes, 30 minutes optimum) for serum specimens.
4. Proper centrifugation.
5. Avoid resuspension of separated samples, including tubes with a gel barrier.

References

<table>
<thead>
<tr>
<th>Task</th>
<th>Resource</th>
<th>How Measured?</th>
<th>Achieved?</th>
<th>N/A</th>
<th>Date</th>
<th>Trainee Initial</th>
<th>Trainer Initial</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUPPLIES</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Checking and replenishing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>- Reagent Packs</td>
<td>From the Reagent Supplies Screen:</td>
<td>Direct Observation</td>
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<td></td>
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</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>OR</td>
<td>Other _________</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Instructions for Use:</td>
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<td>N</td>
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<tr>
<td></td>
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<td></td>
<td>N</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>• Vessels</td>
<td>From the Bulk Supplies Screen:</td>
<td>Direct Observation</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
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### Competency Checklist

#### UniCel™ DxI 600 Access® Immunoassay System

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# Competency Checklist

## UniCel™ DxI 800 Access® Immunoassay System

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## UniCel™ Dxl 800 Access® Immunoassay System

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