CHEM.DXI.1.0 Operating Procedure for UniCel DXI 600 Access Immunoassay System

PRINCIPLE

The UniCel DxI Access Immunoassay System is an in -vitro diagnostic device used for the quantitative, semi-quantitative or qualitative determination of various analyte concentrations found in human body fluids.

> **Note:** see Theory of Operation in the UniCel DxI Instructions for Use manual section 8 pages 8-1 through 8-6 for more specific information. Also see individual analyte procedure.

OWNERS

Manager, Regional Chemistry

RELATED DOCUMENTS

CHEM.QC. REGCHEM.2.0	Quality Control Testing Intervals
CHEM. QC.REGCHEM.2.2	QC Prep and Stability
CHEM.DXI.1.1	Test Codes, AMR, Critical and Normal Ranges
CHEM.DXI.1.2	Charts for Diluents
CHEM.DXI.1.0	Alpha Fetoprotein (AFP)
CHEM.DXI.2.0	DHEA
CHEM.DXI.3.0	PTH, Intact (iPTH)
CHEM.DXI.4.0	CA125 Antigen (OV)
CHEM.DXI.5.0	Thyroglobulin (TG)
CHEM. DXI.6.0	Thyroglobulin Antibody (ATG)
CHEM.DXI.7.0	Thyroperoxidase Antibody (ATA)
CHEM.DXI.8.0	Sex Hormone Binding Globulin (SHBG)

SPECIMEN

See procedure for specific analyte

REAGENTS

See procedure for specific analyte

EQUIPMENT

UniCel DxI Access Immunoassay System 600

CALIBRATION

A. Luminometer calibration

The luminometer is calibrated in the factory against a luminous standard. Thereafter, the Unicel DxI adjusts the Luminometer automatically at system-defined intervals. The system uses an on-board

reference standard to maintain luminometer reading consistency. The system calculates a drift correction factor based on the reference standard reading and applies this factor to RLU output.

B. Ultrasonics Calibration
The ultrasonic transducers on the reagent pipettors are calibrated in the factory

C. Bulk Supply Sensor Calibration
The bulk supply sensors for wash buffer and liquid waste are calibrated by measuring the sensor output voltage with empty and full containers

D. Pressure Sensor Calibration
Pressure sensors in the sample pipette and in the reagent pipettors are used for obstruction detection. The instrument calibrates the pressure sensors by drawing volumes of wash buffer and measuring the pressure required for each draw.

E. Substrate Drawback Calibration
After substrate is dispensed to an RV, a quantity of substrate remains in the tubing between the substrate probe and the pump. This quantity is drawn back into the pump to keep it at the correct operating temperature until the next dispense cycle.
Because the potential variations in the length and diameter of substrate tubing, the volume of the tubing must be measured by the system whenever maintenance is performed on the substrate probe or tubing. The measurement is performed in conjunction with the procedure of priming the substrate line

F. Assay Calibration Theory
The UniCel DxI system performs the following types of assay calibrations:

1. **Quantitative:** In general, calibrator test results provide a multi-point calibration curve. The system uses the calibration curve to convert a measured response in RLU's to an analyte concentration and then expresses the result in numerical units.

2. **Semi-Quantitative:** Calibrator test results provide a multi-point calibration curve. The system uses the calibration curve to convert a measured response in RLU's to an analyte concentration and then expresses the result in numerical units.
These assays may report their quantitative result as a quantitative interpretation, such as positive, negative, or equivocal.

3. **Qualitative:** Calibrator test results provide a cutoff value based on a formula in the APF. The system compares a test RLU value to the cutoff value and then classifies the result as reactive or non-reactive for the analyte.

G. Acceptance Criteria
For quantitative and semi-quantitative assays, the system uses the precision profile method to determine if the calibration meets acceptance criteria. The precision profile method consists of three steps:

1. Fitting calibration data using the math model defined in the APF for that assay.
2. Calculating predicted precision at various analyte concentrations.
3. Comparing predicted precision and the limits defined in the APF for that assay.

Note: Some assays have further acceptance criteria, as defined in the APF.

H. Calculating Predicted Precision

After an acceptable calibration curve is obtained, the system calculates an error band around the curve. This calculation is based on distance of the calibration data points from the curve. The system uses the calibration data and the shape of the math model to predict the precision at the analyte concentrations stated in the APF.

Comparing Predicted Precision: The system compares the calculated predicted precision to the limits defined in the APF. If the result for any analyte concentration is outside the acceptable limits defined by the error band, the calibration fails.

Note: see individual procedure for detailed information

QUALITY CONTROL

See Quality Control Testing Interval CHEM.QC.REGCHEM.2.0

See Sunquest Quality Control and QC codes CHEM.REGCHEM2.1

See QC Prep and stability CHEM.QC.REGCHEM.2.2

PROCEDURE

A. System Description

The Unicel DxI System consists of two major subsystems: the instrument, which performs all sample processing functions, and system console, which provides human interface.

B. Status Indicator Lights

The four status indicator lights are arranged vertically on the front panel of the instrument. The **Red**, **Green**, and **Blue** indicator lights designate a specific instrument operating mode. The **Amber** indicator light informs you when a supply level requires your attention.

1. **Red:** Not ready, indicates either that the system has stopped, or that initialization is in progress.
2. **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 supplies are out, or an area requires attention. The system will not schedule new tests, but will complete tests in progress.
3. **Green:** Running. System is processing tests or performing a maintenance routine.
4. **Blue:** Ready. No processing operations are in progress, but the system is ready to begin processing. SPU operation such as aliquoting of samples can take place while in the **Ready** mode.

C. System Modes

The UniCel DxI system operates in one of four system modes. The current mode is displayed in the upper left corner of each screen. When the system is in the **Running** mode, the estimated completion time for the scheduled tests is displayed as a text line above the three system command buttons.

Ready: The system is ready to begin processing samples. SPU operations such as aliquoting of samples can take place while in the Ready mode.

Running: The system is performing a function, such as processing samples or running a maintenance routine.

Paused: No new tests are scheduled, but currently scheduled tests continue processing.

Not Ready: 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.

D. System Status Buttons

There are six system status buttons. Under normal operating conditions the button colors are neutral. Select a button to view its related screen.

The buttons change color to inform you when a supply level requires your attention, a sample processing issue exists, or the Event Log is reporting a caution or a warning. A button stays red or yellow until you select it to review the alert condition.

System Status Button	Description	Button Colors
1. Rack Exceptions	Select to display the Exceptions view of the Sample Manager screen	**Yellow** One or more sample containers has an error associated with it
2. Work Pending	Select to display the Work Pending screen for information about test requests that the system cannot schedule.	**Yellow** A test cannot be processed because a sample is required.
3. Supplies Required	Select to display the Supplies Required screen for information about needed supplies or calibrations.	**Yellow** The system requires supplies or calibration to complete the requested tests **Red** The system cannot start tests until the underlying instrument condition has been resolved.
4. Bulk Supplies	Select to display the Bulk Supplies screen for information on the available quantities of substrate, wash buffer and RVs, and the available space in the solid waste	**Yellow** A supply is low or near expiration, or a waste container is nearly full. **Red** A supply is empty or expired, or a

	container and in the bulk liquid waste container	waste container is full. The needle on the gauge is displayed all the way to the left
5. Quality Control	Select to display the Quality Control screen to setup quality controls, or review quality control results	**Red** A quality control result is not within the acceptable range of expected values
6. Event Log	Select to display the Event Log screen for information about events generated by the system. From this screen you can display troubleshooting information about caution or warning events	**Yellow** The system has generated a caution event indicating a condition that requires your attention soon. **Red** The system has generated a warning event, indicating that a serious fault or error condition exists.

E. Help Button

Select the **Help** button to display a topic with information about the screen you are on, a View Screen link to a picture with descriptions of the screen, and a list of related topics. From the screen topic, you can navigate to anywhere in the *Help* system. The Help button also provides links to procedures for critical instrument conditions displayed on the Supplies Required screen

F. System Command Buttons

Button Screen Display	**Description**
1. Stop	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
	Description.
2. Pause	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.
3. Resume	Select to resume processing when the system is in the **Paused** mode

G. Main Menu Workflow

Select one of the Main Menu function buttons to display an associated screen or menu. Across the bottom of a new screen is another row of function buttons. Select one of these buttons to perform an action or to display a menu with additional function buttons.

H. Precautions and Hazards

1. Safety Features

The UniCel DxI Access Immunoassay System is designed to meet U.S. and international safety standards. Safety labels are affixed to the instrument to alert you to safety considerations. Interlock switches stop the movement of the pipettors and robotic modules to protect you from injury if you open the instrument covers while the system is running.

2. Interlock Switches

The UniCel DxI system is equipped with interlock switches to protect you from injury. If you open the covers of the instrument, the interlock switches stop all moving parts. If you open the covers while the system is processing samples, the system cancels all tests in progress.

3. Safety Symbols

Certain areas of the UniCel DxI instrument present a risk of personal injury or damage to the instrument if proper safety procedures are not followed. These areas are marked with one or more safety symbols to identify the hazard. The following topics show the symbols and describe the hazards.

Symbol	Description
a. Attention Safety Symbol	A symbol with an exclamation point calls attention to important information to read, or is accompanied by another symbol indicating a particular safety hazard. The information is located either on the label with the symbol, or in the UniCel DxI customer documentation. In a document or in the Help system, the text following the symbol provides additional information regarding safety conditions. Also see the Safety Statements topic.
b. Electrical Safety Symbol	The general electrical safety symbol indicates an electrical shock hazard. The luminometer contains a high voltage power supply that presents a shock hazard. The power supply box does not contain operator-serviceable parts.
c. Biohazard Symbols	The biohazard symbols indicate areas of the instrument and associated fluid handling equipment that can contain potentially infectious human serum or blood products. Follow proper laboratory procedures in handling and disposing of materials from these areas.

4. **Safety Statements**

The following statements describe general safety concerns and provide information about attention symbols with no accompanying text.

a. WARNINGS

- The UniCel DxI instrument has moving parts which present an injury hazard. Do not operate the UniCel DxI instrument with the covers or doors open.

- Reagents, calibrators, and controls used with the system may contain small quantities of sodium azide preservative. Sodium azide preservative may form explosive compounds in metal drain lines. Refer to National Institute

for Occupational Safety and Health Bulletin: Explosive Azide Hazards (8/18/76).

- Always plug the UniCel DxI system into a grounded three-conductor outlet. DO NOT bypass the grounding prong on the plug.

- Do not defeat the safety interlock switches on the covers.

b. CAUTION

Replace substrate bottles only with the top cover closed to avoid spillage into the instrument.

J. Racks and Sample Containers

Sample containers are loaded onto the UniCel DxI instrument in sample racks. Each rack holds up to four sample containers in the available rack positions. The onload area of the sample presentation unit (SPU) of the UniCel DxI 600 instrument holds approximately 15 racks.

1. **Racks**

   There are four sample rack sizes: 13 x 75 mm, 13 x 100 mm, 16 x 75 mm, and 16 x 100 mm. Sample racks are identified by 3 different labels: Rack bar code label, Container type label, and Rack ID label.

   The rack bar code label includes the bar code and rack ID number. The container type label includes an illustration of the only sample container type you can use with the rack.

   The Rack ID label distinguishes one sample rack from another, and also identifies the accepted sample container type for the rack.

   Note: You can find the rack ID ranges set up for each type of sample container from the System Setup screen. The instrument recognizes the type of sample containers held in the sample rack when it scans the rack bar code label.

K. Supplies

- **Changing an Empty or Expired Substrate Bottle**
- **Changing an Empty Bulk Wash Buffer Container**
- **Adding RVs**
- **Changing a Full Solid Waste Container**
- **Loading a Reagent Pack**
- **Unloading a Reagent Pack**

  the UniCel DxI system automatically unloads empty reagents packs and places them in the solid waste container. Use this procedure to manually unload a reagent pack from the instrument.

L. Shut Down and Restart

1. Shutting Down the PC

There are two methods for shutting down the PC:

- Using the user interface (UI) software
- Using the computer keyboard

Use the UI software for standard shut downs. Use the keyboard only when the UI is not available. If you use the computer keyboard to shut down the PC, you may require additional assistance from Technical Support to clean up your database.

Note: If you are shutting down the PC and the instrument at the same time, shut down the instrument first.

Shutting Down the PC with the UI Software

Use this procedure to shut down the PC with the UI software.

System Mode: Ready- Not Ready

Note: In emergencies you can shut down the PC when the instrument is in the **Running** or **Paused** mode.

a. From the Configure menu, select **PC Admin F7** to display the PC Admin screen

b. From the PC Admin screen, select **System Admin F8** and then select **Shut Down PC F1** to display the UniCel DxI Shut Down window.

WARNING

Do not select the Shut down the instrument software box.

c. Select **Yes F1**.

d. Select **OK F1** to shut down the PC software.

(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.

Shutting Down the PC Using the Computer Keyboard

If you do not have access to the UI software, use this procedure to shut down the PC with the computer keyboard.

Note: Only use the computer keyboard to shut down the UI if you have no other alternative.

System Mode: Not Applicable

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

Note: If the keyboard does not respond, shut down the PC by turning off the power. Press and hold the power switch for at least 10 seconds. Then wait at least 20 seconds before restarting the PC.

b. Select **Shut Down**.

c. Select one of the shutdown options, depending upon whether you want to immediately restart the PC software.

d.Select **OK**.

2. Restarting the PC and UI Software

Use this procedure to restart the PC and the UI software.

System Mode: Not Applicable

a. Restart the PC or the UI software.

- If the power to the PC is not off, select **Restart** in the Shutdown Computer window to restart the UI software.
- If the power to the PC is off, locate the power switch and press and hold the switch for 2 seconds to turn the power on and start the UI software.

b. Wait until the UniCel DxI Main Menu is displayed. If this procedure fails to restart the PC or the UI software, contact Technical Support.

c. 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 test results to the PC. Do not use the system until the PC receives all of the test results.

Note: To be sure that all test results are sent, display the Test Results screen and filter the results by completion time. Watch the **Result** and **Comp. Time** columns for the system to stop sending results. If you have any questions, contact Technical Support.

d. Continue normal operation.

3.Shutting Down the Instrument

In some circumstances, it may be necessary to shut down the instrument and not the PC. Shut down the instrument only if instructed to do so by a technical support representative or by the system documentation.

Note:
- You need the system password to use this feature. If you do not know the password, contact your lab supervisor.
- If you are shutting down the PC and the instrument at the same time, shut down the instrument first.
- Shutting down the instrument turns off the refrigeration in the reagent storage area.

System Mode: Ready- Not Ready

a. From the Configure menu, select **PC Admin F7** to display the PC Admin screen.

b. From the PC Admin screen, select **System Admin F8** and then select **Shut Down Instrument F2** to display the Shut Down Instrument Software window.

c. Enter the system password, and then select **OK F1**.

Note: If there is no connection between the UI software and your UniCel DxI instrument, a message is displayed informing you that the connection was lost. The system cancels the shutdown operation. If this occurs, contact Technical Support before attempting to shut down the instrument with the power switch.

d. When the software has shut down, a message is displayed instructing you to turn off the instrument power switch. Select **OK F1** to exit the message window.

e. The instrument power switch is behind the lower right door as you face the instrument. Open the door and locate the power switch.

f. Press the lower part of the switch to turn the power off (O position).

The system mode area of the system software screen turns red, but no system mode is displayed.

g. Wait at least 20 seconds to restart the instrument.

Note: Shutting down the instrument turns off the refrigeration in the reagent storage chamber and other areas.

5. Restarting the Instrument

Use this procedure to restart the UniCel DxI instrument if the power to the instrument is off.

CAUTION

Do not select any buttons on the PC touchscreen or press any keys while the instrument restarts and initializes. After you start this procedure, the system pauses for approximately two minutes as it resets the software. Then the system enters the Not Ready mode and begins the system initialization process.

System Mode: Not Applicable

Note: If the PC is on, the system mode area of the system software screen is red, but no system mode is displayed.

a. If the PC or the UI software is not running, restart either component.
b. Verify that the main upper covers are closed.
c. Locate the instrument power switch behind the lower right door as you face the instrument.
d. Press the top part of the switch to turn the power on (| position). The system restarts and initializes. Observe the following sequence of events:
• During system initialization, the system homes mechanical devices and displays a flashing message in the system mode area. When most system devices complete initialization, the system enters the **Ready** mode.
• While in the **Ready** mode, the system continues to initialize any remaining devices and displays a flashing message in the system mode area. When this message disappears, system initialization is complete.
e. Verify that the system is in the **Ready** mode and no message is displayed in the system mode area. If the instrument does not initialize successfully, contact Technical Support.
f. Wait for the system to restore the internal temperatures. If the instrument was shut down for a short period of time, it will take 15-20 minutes for the system to restore the internal temperatures. Do not load samples on the instrument until all temperature zones are in range.
g. Continue normal operation.

M. Maintenance

Routine maintenance for the UniCel DxI system includes the following maintenance procedures

- Daily maintenance

Daily maintenance consists of procedures for preparing the system to process samples each day. When the 10,000 and 5,000 test interval procedures are scheduled on the same day, always end by performing daily maintenance.

- Maintenance after a 5,000 test interval

Maintenance after a 5,000 test interval consists of a procedure for replacing the duck bill valve.

- Maintenance after a 10,000 test interval

Maintenance after a 10,000 test interval consists of cleaning and closely inspecting internal components and tubing connections. The 10,000 test interval procedures include a step to perform 5,000 test interval maintenance before the 10,000 interval procedures are complete.

- The Utility routine

The Utility routine primes the reagent pipettors, aspirate probes, and dispense probes. The system automatically runs the routine every four hours if the system is not processing samples. You can also run the Utility routine manually. The Utility routine should always be enabled. If the Utility routine is disabled, you should enable the routine and prime fluidics before running a clean routine as part of your daily maintenance procedures.

A technical support representative will schedule periodic preventive maintenance procedures on your UniCel DxI instrument in accordance with the terms of your service agreement, if applicable.

See Unicel DxI Instructions for Use manual for details on performing maintenance Section 6 pages 6/1-6/14 and the information update (Jan 2014) that is included in Maintenance section.

REFERENCES

UniCel DxI Access Immunoassay System Online Instructions for Use. June 2015