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UniCel DxI

Access Immunoassay System

Instructions for Use
For *In Vitro* Diagnostic Use

EC REP

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Publication Notes

This manual, D02458-AE, release date 2025-05, supports:

- UniCel DxI published system software version 5, including full versions 5.1, 5.2, 5.3.0, 5.3.1, 5.5.0, 5.6.0, and 5.7.0.
- UniCel DxI published system software version 7, including full versions 7.0.0, 7.1.0, 7.2.0, 7.2.1, and 7.3.0.

Changes to this Revision:

Chapter	Page	Change Description
Publication Notes	Publication Notes	Added software version 7.3.0.
5 Sample Manager	5-1, 5-2, 5-3	Added a Caution about loading STAT racks if the system is connected to an LAS.
A Temperature-Sensitive Assays	A-1	Updated the list of assays.
B Ordering Information	Assay-Specific Reagents	Updated the list of assays.
	UniCel DxI System Documentation	Deleted manuals that are no longer available as paper copies.

Revision History:

D02458-AB, July 2024	UniCel DxI software versions 5.1, 5.2, 5.3.0, 5.3.1, 5.5.0, 5.6.0, 5.7.0, 7.0.0, 7.1.0 and 7.2.0.
D02453-AA, July 2023	UniCel DxI software versions 5.1, 5.2, 5.3.0, 5.3.1, 5.5.0, 5.6.0, 5.7.0, 7.0.0, and 7.1.0.
C96782-AA, December 2022	UniCel DxI software versions 5.1, 5.2, 5.3.0, 5.3.1, 5.5.0, 5.6.0, 5.7.0, and 7.0.0.
C94099-AA. October 2022	UniCel DxI software versions 5.1, 5.2, 5.3.0, 5.3.1, 5.5.0, 5.6.0, and 5.7.0

This manual is intended for use with:

- The UniCel DxI 800 Access Immunoassay System
- The UniCel DxI 600 Access Immunoassay System

This guide also can be used as supplemental material for the UniCel DxC 880i, 860i, 680i, and 660i Synchron Access Clinical System Integrated Workstations. Not all instructions in this manual are applicable to the UniCel DxC Synchron Access Integrated Workstation running in integrated mode. Refer to the UniCel DxC Synchron Access Integrated Workstation *Instructions for Use* manual.

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1 System Overview

Intended Use

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.

FOR PROFESSIONAL USE ONLY

Scope of Manual

The UniCel DxI *Instructions for Use* manual is designed for use after you have become familiar with the UniCel DxI system. This manual 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.

Reference Materials

Additional UniCel DxI system documentation is listed in Appendix B. For more information, contact your Beckman Coulter representative.

Technical Support

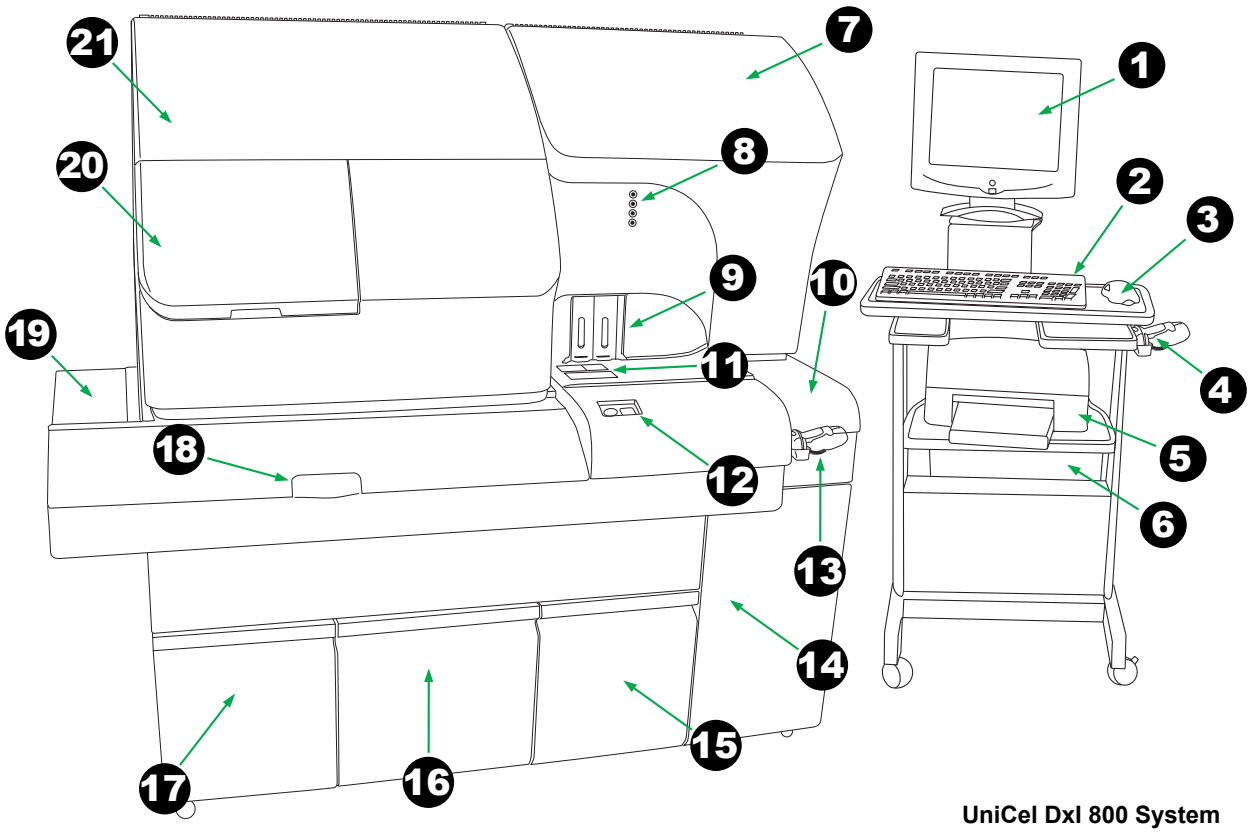
For technical assistance with the UniCel DxI Access Immunoassay System:

- In the U.S.A. or Canada, contact Beckman Coulter Technical Support by phone at 1-800-854-3633, or online at www.beckmancoulter.com/. Beckman Coulter Technical Support is available 24 hours a day to customers in the continental United States, Alaska, Hawaii, and Canada. Before using online support the first time, you will need to register online.
- Outside the U.S.A. and Canada, contact your technical support representative.

Be prepared to provide your system ID.

System Description

The UniCel DxI system consists of two major subsystems: the instrument, which performs all sample processing functions, and the system console, which provides the human interface. There are several points of operator interaction:



UniCel DxI 800 System

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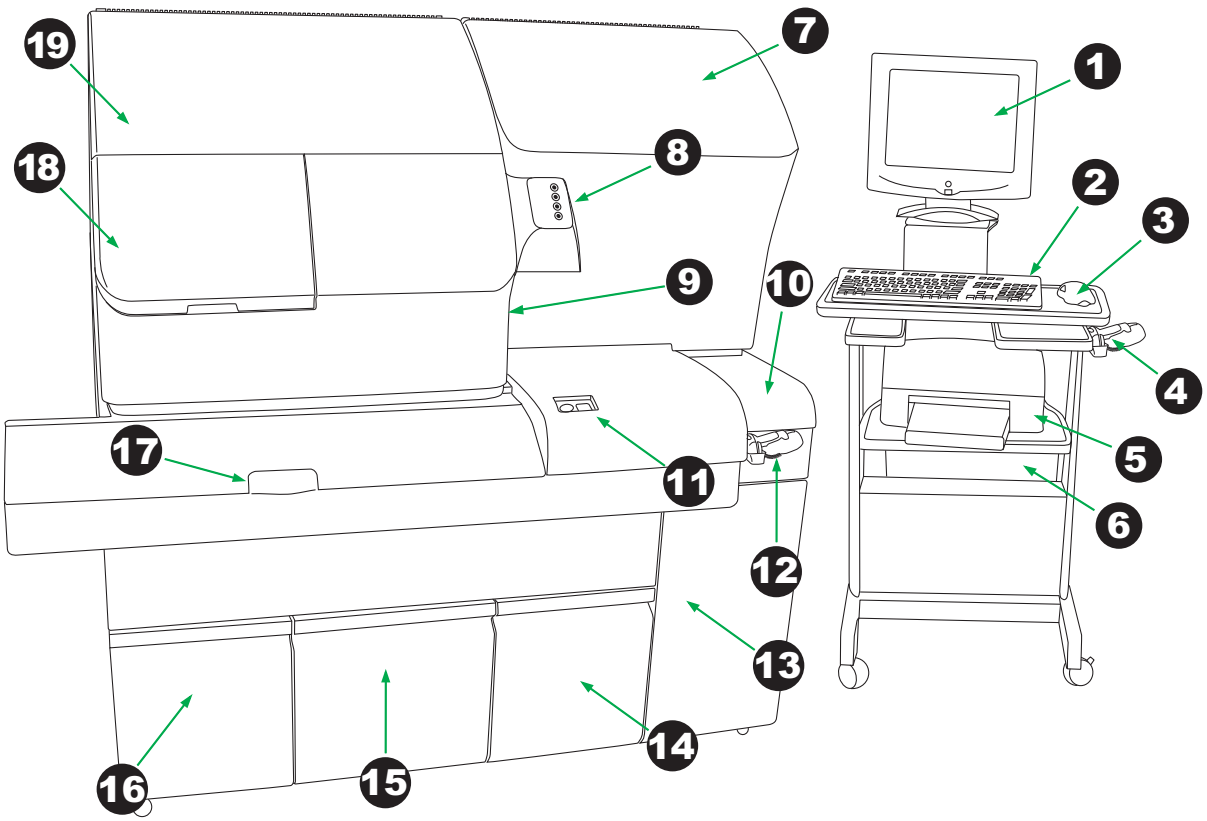
1	Touchscreen monitor	**2**	Keyboard	**3**	Mouse
4	PC bar code reader	**5**	Printer	**6**	External Computer
7	Right main upper cover	**8**	Status indicator lights	**9**	Substrate load area
10	Reagent load/unload area	**11**	System status panel (if equipped)	**12**	STAT/Routine buttons
13	Substrate bar code reader	**14**	Main power switch (behind door)	**15**	Wash buffer supply drawer
16	Solid waste door	**17**	Liquid waste drawer (optional)	**18**	Sample presentation unit (SPU)
19	Side offload area	**20**	Vessel hopper door	**21**	Left main upper cover



UniCel DxI 600 System

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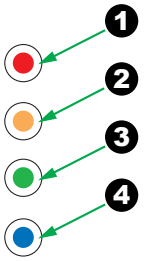
1	Touchscreen monitor	**2**	Keyboard	**3**	Mouse
4	PC bar code reader	**5**	Printer	**6**	External Computer
7	Right main upper cover	**8**	Status indicator lights	**9**	Substrate load area (hidden in picture)
10	Reagent load/unload area	**11**	STAT/Routine buttons	**12**	Substrate bar code reader
13	Main power switch (behind door)	**14**	Wash buffer supply drawer	**15**	Solid waste door
16	Liquid waste drawer (optional)	**17**	Sample presentation unit (SPU)	**18**	Vessel hopper door
19	Left main upper cover				

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.



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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 operations such as aliquoting of samples can take place while in the **Ready** mode.

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.

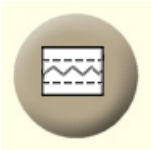
System Mode	Description
Ready	The system is ready to begin processing samples. SPU operations such as aliquoting of samples can take place while in the **Ready** mode.
Running	The system is performing a function, such as processing samples or running a maintenance routine.
Paused	No new tests are scheduled, 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.

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
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.
Work Pending 	Select to display the Work Pending screen for information about test requests that the system cannot schedule.	**Yellow** A test request cannot be processed because a sample is required.
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. Certain conditions provide a **Help** button in the Status column that link directly to the corresponding Help procedure topic for rectifying the condition. **NOTE** The icon color reflects the condition currently displayed on the screen with the highest concern level. If there is at least one instrument condition that meets a red icon state, that condition takes precedence and the **Supplies Required** icon displays red.

System Status Button	Description	Button Colors
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 container and in the bulk liquid waste container.	**Yellow** A supply is low or near expiration, or a waste container is nearly full. The needle on the gauge is displayed near the left end of the scale. **Red** A supply is empty or expired, or a waste container is full. The needle on the gauge is displayed all the way to the left.
Quality Control 	Select to display the Quality Control screen to set up quality controls or to review quality control results.	**Red** A quality control result is not within the acceptable range of expected values.
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.

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.

System Command Buttons

You use the three system command buttons to stop, pause, or resume processing.

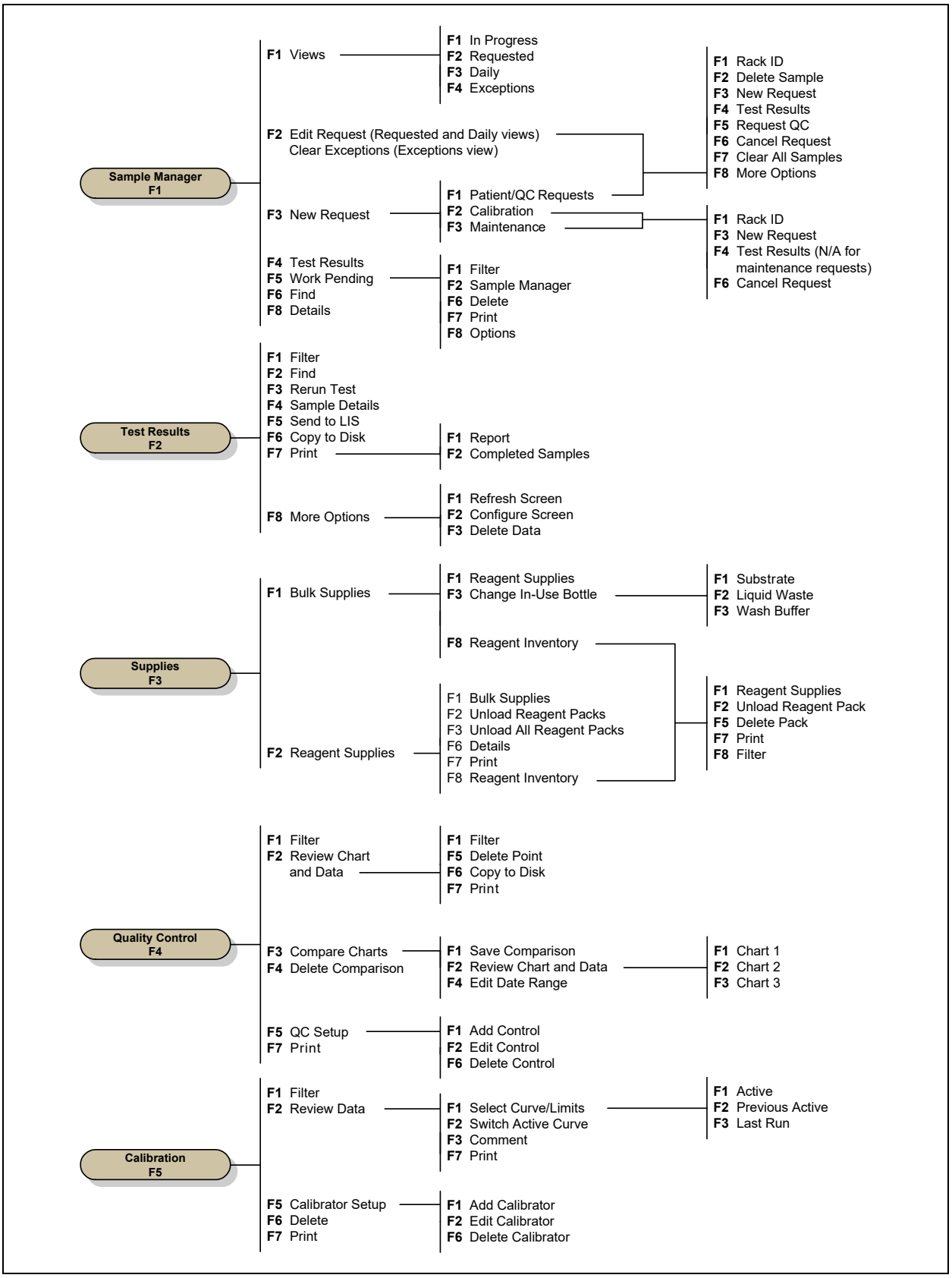
Button Screen Display	Description
Stop 	Select to stop the instrument. The system stops processing and cancels any tests in progress. The system requires initialization before tests can be run again.
Pause 	Select to pause the instrument. The system stops aliquoting **after it finishes the current aliquot**. No new tests are scheduled. Processing continues on samples already in progress.
Resume 	Select to resume processing when the system is in the **Paused** mode.

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.

The following flowchart outlines the workflow for each of the Main Menu function buttons.

Main Menu Workflow



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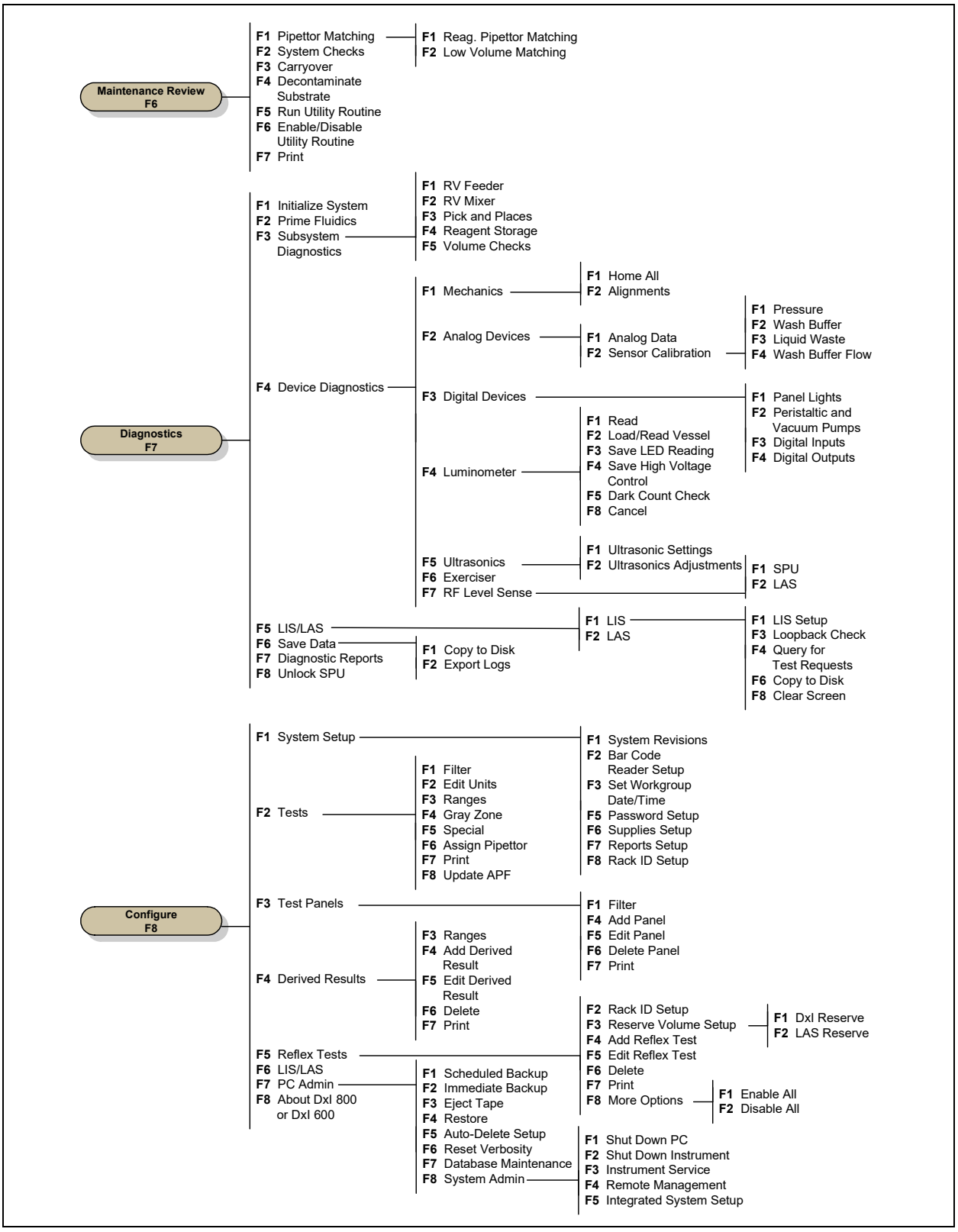
Main Menu Workflow, continued



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Precautions and Hazards

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.

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.

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. These symbols are defined in the Access Immunoassay Systems *Symbol Glossary*, available at techdocs.BeckmanCoulter.com.

Laser Symbol

	The laser symbol indicates areas of the instrument where laser light is used. **Do not stare into the laser beam.**

Laser Warning Labels

The UniCel DxI system uses lasers that read and process bar code information. Under certain conditions laser light can cause eye injuries. As a safety measure, the locations of lasers on the UniCel DxI system are marked with warning labels. The lasers are located and shielded beneath housings that protect operators from accidental exposure to the laser beam.

The UniCel DxI laser products conform with the provisions outlined in Code of Federal Regulations Title 21 (subchapter J, section 1040.10), and with IEC 60825-1.

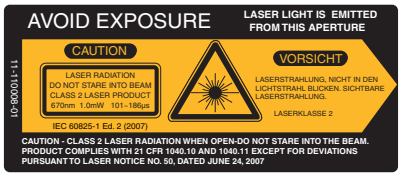
CAUTION

Do not remove the laser warning labels or the protective housings that shield the lasers. The lasers are accessible if the protective housings are removed. Only a trained Beckman Coulter technical support representative should service the lasers. Do not stare directly into a laser beam if the instrument cover is opened or removed.

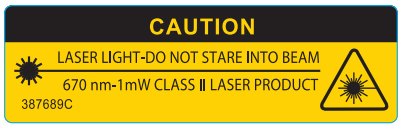
NOTE

The laser warning labels on your UniCel DxI instrument may not match exactly with the example labels shown here.

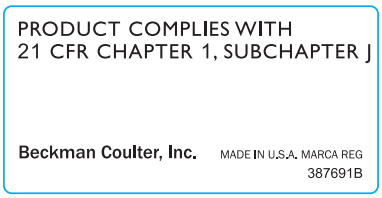
This label is attached to the sample presentation unit (SPU) bar code reader and the reagent storage bar code reader.



One or more of these labels are attached to the housing that shields the reagent storage bar code reader.



One or more of these labels are attached to the back of the UniCel DxI instrument.



Safety Statements

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

WARNINGS

- **The UniCel DxI instrument has moving parts and uses high voltage in the ultrasonic transducers. Both 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 (8/16/76)*.**
- **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.**

CAUTION

Replace substrate bottles only with the main upper covers closed to avoid spillage into the instrument.

Regulatory Symbols and Statements

The UniCel DxI Access Immunoassay System meets the requirements of a variety of domestic and international regulatory agencies, standards, and directives. This compliance is indicated by symbols and marks on the instrument,. These symbols are defined in the Access Immunoassay Systems *Symbol Glossary*, available at techdocs.BeckmanCoulter.com.

Notice to User

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU or In vitro Diagnostic Medical Devices): if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

Radio Frequency Emissions Statement

This IVD equipment complies with the emission and immunity requirements described in IEC 61326-2-6.

The UniCel DxI system has been tested and shown to be compliant with the requirements of CISPR 11 and part 15 of FCC rules for a Class A digital device. These requirements are intended to provide reasonable protection from interference when the instrument is operated in a commercial environment.

CAUTIONS

- **This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it could cause radio interference, in which case you may need to take measures to mitigate the interference.**
- **Prior to operation of this device, the electromagnetic environment should be evaluated. Do not use this device in close proximity to sources of strong electromagnetic radiation (for example, unshielded intentional RF sources) as these could interfere with proper operation.**
- **If you suspect interference between the UniCel DxI system and other equipment, you must take whatever action is required to correct the interference. Beckman Coulter suggests the following actions:**
  - **Move the equipment so there is a greater distance between the equipment and the UniCel DxI system.**
  - **Re-orient the equipment with respect to the UniCel DxIsystem.**
  - **Be sure that the equipment is operating from a different power service connector than that of the UniCel DxI system.**

LED Safety Statement

The handheld bar code reader has been tested in accordance with EN60825-1 LED safety, and has been certified to be under the limits of a Class 1 LED device.

Other Symbols

In addition to safety and regulatory symbols, other symbols are placed on the instrument to identify functional elements such as network jacks and the air filter. These symbols are defined in the Access Immunoassay Systems *Symbol Glossary*, available at techdocs.BeckmanCoulter.com.

System Specifications and Characteristics

Space Requirements

The dimensions of the instrument and the peripheral devices are listed in the following table. Be sure that the area designated for these components is large enough to accommodate the system.

	UniCel DxI 800 System	UniCel DxI 600 System
Instrument: Covers and Drawers Closed	Width = 67.5 inches (171 cm) Height = 67 inches (170 cm) Depth = 37.5 inches (97 cm)	Width = 61.5 inches (156 cm) Height = 67 inches (170 cm) Depth = 37.5 inches (97 cm)
Instrument: Covers and Drawers Opened	Width = 67.5 inches (171 cm) Height = 75.2 inches (191 cm) Depth = 67.7 inches (172 cm)	Width = 61.5 inches (156 cm) Height = 75.2 inches (191 cm) Depth = 67.7 inches (172 cm)
Instrument Clearance Required for Ventilation	Rear = 11.8 inches (30 cm) Top = 8.5 inches (22 cm)	Rear = 11.8 inches (30 cm) Top = 8.5 inches (22 cm)
Instrument Clearance Required for Opening Covers and Drawers	Front = 15.5 inches (39 cm) Rear = 14.5 inches (37 cm) Top = 8.5 inches (22 cm)	Front = 15.5 inches (39 cm) Rear = 14.5 inches (37 cm) Top = 8.5 inches (22 cm)
Service Clearance Required for Opening SPU	Front = 38.5 inches (98 cm)	Front = 36.5 inches (93 cm)
System Console (Cart with External Computer and Peripherals)	Width = 29.8 inches (76 cm) Height = 67.5 inches (171 cm) Depth = 37.8 inches (96 cm)	Width = 29.8 inches (76 cm) Height = 67.5 inches (171 cm) Depth = 37.8 inches (96 cm)

Instrument and Peripheral Device Weights

The weight of the instrument and the peripheral devices are listed in the following table. Be sure that the surface where these components will reside can support the system.

UniCel DxI 800 Instrument (before supplies and samples are added)	1390 pounds (630 kg)

UniCel DxI 600 Instrument (before supplies and samples are added)	1065 pounds (483.1 kg)
External Computer	See documentation provided by the manufacturer
Monitor	See documentation provided by the manufacturer
Printer	See documentation provided by the manufacturer

Operating Environment Requirements

The UniCel DxI system is **for indoor use only** and requires the following environmental conditions to operate properly:

Humidity, RH (Non-condensing)	Operational: 20-85% Exposure: 10-85%
Maximum Altitude	Operational: 7,500 feet (2,300 m) Exposure: 40,000 feet (12,200 m)
Temperature	Operational*,†: 64°F to 86°F (18°C to 30°C) Exposure: -22°F to 122°F (-30°C to 50°C)
Maximum Ambient Temperature Change Rate During Operation	3.6°F per 30 minutes (2°C)
Ambient Light	Results not affected by ambient light levels between 0-200 foot-candles
Pollution Degrees	2

* Some assays require additional temperature restrictions. See Appendix A of this manual for information on these restrictions.

† The operating environment temperature is influenced by factors such as room temperature, air circulation, heat sources near the system, and direct sunlight.

Electrical Requirements

The UniCel DxI system uses two separate power supplies: one for the instrument, and one for the external computer. Each power supply must meet specific requirements.

Electrical Line: Instrument

The electrical line supplies power to the UniCel DxI instrument. To avoid damaging the instrument, the electrical line at the outlet should meet the following requirements:

Line Power Supply	200-240 VAC at 1,100 VA, at 50/60 hertz (Hz), single phase power
Line Dedication	Dedicated (UniCel DxI instrument is the only equipment connected to the electrical line)

Line Outlet	Located within 5 feet (1.5 m) of the UniCel DxI system. Must be compatible with the L6-20P twist lock plug on the instrument.
Line Protection Device	**AC outlet:** must be protected by a circuit breaker rated at 20 amps (250 VAC line) **Instrument line fuse:** T 10A, 240V
Line Voltage Fluctuations	Not to exceed ±10 VAC per cycle
Minimum Tested Operating Voltage	180 VAC
Maximum Tested Operating Voltage	264 VAC
Maximum Voltage Between Neutral Conductor and Safety Ground Conductor	Not to exceed 2 VAC root mean square (RMS)
Maximum Resistance Between the Safety Ground Conductor and an Accessible Building Safety Ground	Not to exceed 0.1 ohm
Transient Overvoltages	According to UL3101 Installation Category II

Electrical Line: External Computer

Line Power Supply	110-120 VAC at 6 amps, 50/60 Hz, or 220-240 VAC at 3 amps, 50/60 Hz

Electrical Power Consumption and Heat Production

The UniCel DxI components consume current and power, and produce heat at the following levels:

Component	Power Consumption	Heat Production
Instrument	< 1,100 watts	3,775 British Thermal Units (BTU)/hour
External Computer	See documentation provided by the manufacturer	See documentation provided by the manufacturer
LCD Monitor	See documentation provided by the manufacturer	See documentation provided by the manufacturer
Laser Printer	See documentation provided by the manufacturer	See documentation provided by the manufacturer

Surge Suppressors

Beckman Coulter recommends that you do not use a surge suppressor with the UniCel DxI instrument. The instrument has built-in protection similar to that provided by a surge suppressor.

PC Backup Power Supply (UPS Unit)

The UniCel DxI system is shipped with a backup power supply (UPS) for the PC only. This UPS unit is designed to provide continuous AC power to the PC when the main AC line power is lost.

NOTE

Consult the documentation provided by the UPS unit manufacturer for proper and safe operation, including ventilation clearance requirements, of UPS units.

Instrument Backup Power Supply (UPS Unit)

If you intend to use an uninterruptable power supply (UPS unit) as a backup power supply, Beckman Coulter recommends a UPS unit with local ground isolation and a low-battery indicator. UPS units are designed to provide continuous AC power to equipment when the main AC line power is lost. These units use a standby battery with an AC inverter circuit to provide the required electrical output. Some units also provide various combinations of the protection features found in surge suppressors and line conditioning transformers.

NOTES

- Contact Beckman Coulter Technical Support for a recommended backup power supply.
- Consult the documentation provided by the UPS unit manufacturer for proper and safe operation, including ventilation clearance requirements, of UPS units.

Your UPS unit should meet the following requirements:

Minimum Output Capacity	2,400 VA
Output Voltage	240 VAC, 120 VAC
Output Frequency	50 or 60 Hz, single phase
Output Wave Form	True sine wave (< 5% distortion)
Standby Runtime	Minimum 15 minutes at 1,500 watts output
Approvals	UL 1778, CSA C22.2 107.1 (UL 544, optional), CE Mark (Europe only)

LIS Interface

The UniCel DxI system can be directed by a laboratory information system (LIS) through the LIS interface. When connected to an LIS, the UniCel DxI instrument receives test requests from, and sends test results to, the LIS. The LIS interface consists of two major components:

- The physical, or hardware, interface, which is a port located on the external computer
- The logical, or software, interface, which includes the frame-layer protocols and message formats for sending and receiving messages

For information about setting up the LIS interface on the UniCel DxI system, see Help topic LIS Setup or the *LIS Vendor Information* document.

Integrated Workstations

The UniCel DxI system can be integrated with the UniCel DxC (chemistry) system and the UniCel CTA (closed tube aliquoter) to form the UniCel DxC Integrated Workstation. There are four versions of the integrated workstation, depending on which versions of the DxI and DxC systems are used.

For information about integrated workstations, refer to the UniCel DxC Synchron Access Integrated Workstation *Instructions for Use* manual.

LAS Interface

The UniCel DxI system can be connected to a laboratory automation system (LAS), When connected to an LAS, the UniCel DxI instrument receives samples from a track in addition to samples that are loaded on the sample presentation unit. The track can route samples to multiple instruments in the laboratory.

The LAS interface on the UniCel DxI system consists of a sample pipettor mechanism that extends horizontally beyond the back of the instrument to aspirate the required volume of sample directly from the sample tube on the connector unit.

For information about connecting the UniCel DxI system to an LAS, contact your Beckman Coulter representative.

Installation

The UniCel DxI Access Immunoassay System must be installed by a qualified Beckman Coulter technical support representative. Do not remove the instrument from the shipping crate until a technical support representative is present.

Warranty

The UniCel DxI Access Immunoassay System is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents.

The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals will be made at the discretion of Beckman Coulter, and at the customer’s expense.

2 Shut Down and Restart

As you operate the UniCel DxI system, you occasionally need to shut down the PC, the instrument, or both. The shut down and restart procedures explain how to properly shut down and restart the system.

CAUTION

If you do not follow these procedures, you may damage the instrument or corrupt the system database.

Shut down and restart the PC if you are directed to do so by a technical support representative or by the system documentation.

NOTE

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

Restarting an instrument after shut down resets the software, and returns all instrument devices to their home positions.

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**

NOTES

- Depending on the version of your PC, you may need the system password to restart the PC. If you do not know the password, contact the lab supervisor.
- In emergencies you can shut down the PC when the instrument is in the **Running** or **Paused** mode.

1. From the Configure menu, select **PC Admin F7** to display the PC Admin screen.
2. 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.

3. Select **Yes F1**.
4. 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

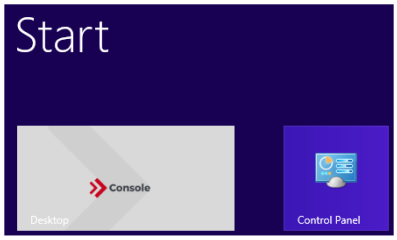
If you do not have access to the UI software, use this procedure to shut down the PC with the computer keyboard.

NOTES

- Depending on the version of your PC, you may need the system password to restart the PC. If you do not know the password, contact the lab supervisor.
- Only use the computer keyboard to shut down the UI if you have no other alternative.
- If the keyboard does not respond during the performance of this procedure, 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.

System Mode: Not Applicable

1. Identify the software operating system on your UniCel DxI system PC.
   a. If you know the software operating system on your UniCel DxI system PC, proceed to the appropriate instructions below.
   b. To determine the software operating system on your UniCel DxI system PC, press the Windows® key [⊞®] on the computer keyboard, or press **[Ctrl]** + **[Esc]**.
   c. For PCs operating with Windows® Embedded 8, the Windows® 8 Start screen is displayed. The image below is visible in the upper left portion of the screen. Go to step 2.

Windows® 8 Start Screen	 2379A.bmp

d. If the Windows® 8 Start screen is not displayed, your system is operating with Windows® XP Embedded or Windows® 10 Enterprise LTSC. Go to step 3.

2. If your PC uses the Windows® Embedded 8 operating system, use this procedure to shut down the PC using the keyboard.

a. If necessary, press the Windows® key [⊞®] on the keyboard to display the Start screen.

b. Move the mouse cursor to the lower-right corner of the Start screen. A narrow vertical panel of icons is displayed along the right side of the screen.

c. Select the **Settings** icon. The Settings panel is displayed.

2380A.bmp

d. Select the **Power** icon.

1054B.eps

e. Select **Shut down** or **Restart**, depending upon whether you want to immediately restart the PC software.

f. If a screen displays with a button named **Shut down anyway** or **Restart anyway** near the bottom of the screen, select the button.

g. If you selected to shut down the PC, wait 20 seconds, then perform the restarting procedure.

3. If your PC uses the Windows® XP Embedded or Windows® 10 Enterprise LTSC operating system, use this procedure to shut down the PC using the keyboard.

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

b. Select **Shutdown**. If **Shutdown** is not present, select the **Power** icon in the lower right corner of the screen.

1054B.eps

c. Select **Shut down** or **Restart**, depending upon whether you want to immediately restart the PC software. If necessary, select **OK**.

d. If a screen displays with a button named **Shut down anyway** or **Restart anyway** near the bottom of the screen, select the button.

e. If you selected to shut down the PC, wait 20 seconds, then perform the restarting procedure.

Restarting the PC and UI Software

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

System Mode: Not Applicable

1. 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.

❑ Depending on the version of your PC, you may need the system password to restart the PC. If you do not know the password, contact the lab supervisor.

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

3. 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.

4. Continue normal operation.

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.

NOTES

- 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

1. From the Configure menu, select **PC Admin F7** to display the PC Admin screen.
2. From the PC Admin screen, select **System Admin F8** and then select **Shut Down Instrument F2** to display the Shut Down Instrument Software window.
3. Enter the system password, 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 shut down operation. If this occurs, contact Technical Support before attempting to shut down the instrument with the power switch.

4. 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.
5. The instrument power switch is behind the lower right door as you face the instrument. Open the door and locate the power switch.
6. 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.
7. Wait at least 20 seconds to restart the instrument.

Shutting Down the System for an Extended Period

If you plan to have the instrument moved, or if power to the system will be turned off for an extended period of time (more than five days), shut down the entire UniCel DxI system. Before moving or shutting down the system, contact Technical Support to confirm your strategy.

WARNINGS

- **You will come in contact with potentially infectious materials during these procedures. Handle and dispose of biohazard materials according to proper laboratory procedures. Proper hand, eye, and facial protection is required.**
- **If you plan to have the instrument moved, make sure that the new location is properly plumbed. 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 (8/16/76)*.**

NOTE

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

System Mode: Ready | Not Ready

1. Run the Special Clean routine.
2. Remove all racks and sample containers from the onboard and offboard areas of the sample presentation unit (SPU).
3. Unload and refrigerate all of the reagent packs.
4. Change the bulk liquid waste containers if your system uses them.
5. Change the solid waste container.
6. Remove the on-board substrate bottles and replace with empty substrate bottles. Discard the in-use substrate bottle in the biohazard waste. Refrigerate the second bottle if it has not been used.
7. Remove and refrigerate the bottles equilibrating in the substrate equilibration area.
8. Shut down the PC and the instrument. This includes shutting off the power switch for the instrument and the PC.

Restarting the Instrument

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

To re-establish communication between the instrument and console PC, it is necessary to restart the console PC *after* restarting the instrument. Consequently, this procedure contains steps to verify that the console PC is off before restarting the instrument, and to restart the console PC after restarting the instrument.

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.

1. Verify that the console PC is shut down. For more information, see the Shutting Down the PC procedure.
2. Verify that the main upper covers are closed.
3. Locate the instrument power switch behind the lower right door as you face the instrument.
4. Press the top part of the switch to turn the power on (| position) and then wait 90 seconds.
5. Press and hold the console PC power switch for two seconds to turn power on and start the UI software.
6. 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.
7. 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.
8. 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.
9. Continue normal operation.

Restarting the System After an Extended Shut Down

Use this procedure to restart the UniCel DxI system following an extended shut down.

WARNINGS

- **Wash buffer contains a preservative which may cause sensitization by skin contact. After contact with skin, wash immediately with soap and water. Wear suitable gloves.**
- **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.**

System Mode: Not Applicable

1. Restart the PC and the UI software.
2. Restart the instrument.

NOTE

Wait for the system to restore the internal temperatures. Because the system was shut down for an extended period of time, it will take up to one hour for the system to restore the internal temperatures. Do not load samples on the instrument until all temperature zones are in range.

3. Verify that the wash buffer supply is adequate. If necessary, change the bulk wash buffer containers.
4. Empty the solid waste container if it is full. If your system uses bulk liquid waste containers, empty them if they are full. Check the RV supply. If necessary, add more RVs.
5. Load new substrate bottles.

NOTE

Before you load substrate onto the instrument, the bottles must equilibrate at room temperature for the time specified in the reagent instructions for use.

6. From the Diagnostics menu, *s*elect **Prime Fluidics F2** to display the Prime Fluidics window.
7. Select **All F3**. All of the components are selected for priming.
8. Enter the following number of priming cycles in the **Cycles Requested** field for each component:
   - **Substrate In Use** - Enter **6** cycles.
   - **Sample Pipettor** - Enter **5** cycles.
   - **Aspirate 1 & Dispense Probes**- Enter **3** cycles.
   - **Reagent Pipettors #1 to #4** - Enter **4** cycles in each box.
9. Select **Start Priming F2**. When the priming is complete, a message is displayed.
10. Select **OK F1** to exit the message window.
11. Select **Done F1** to exit the Prime Fluidics window.

12. Depending upon how long the system has been shut down, perform the following procedures.

	> 2 Weeks	1-2 Weeks	< 1 Week
10,000 Test Interval Maintenance	X		
Special Clean Routine	X	X	X
All System Check Routines	X	X	
Run QC	X	X	X

3 Supplies

System Status Panel

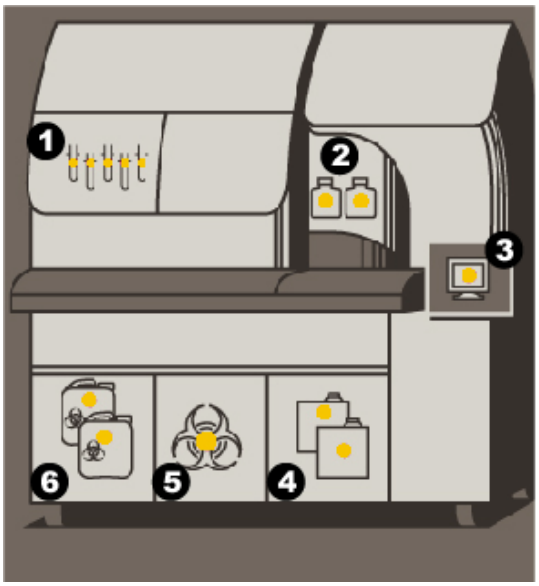
(UniCel DxI 800 System Only; not all systems are equipped)

Some UniCel DxI 800 instruments have a system status panel located directly below the status indicator lights. The panel has six icons that correspond to specific supply areas. A panel icon is lit if a supply is low, approaches its expiration date, or a waste container is almost full. The icon blinks if a supply runs out, expires, or if a waste container is full.

The **Console** panel icon is lit if one or more of the following system status buttons turns yellow or red:

- **Rack Exceptions**
- **Work Pending**
- **Supplies Required**
- **Quality Control**
- **Event Log**

The **Console** panel icon blinks if the **Event Log** button turns red.



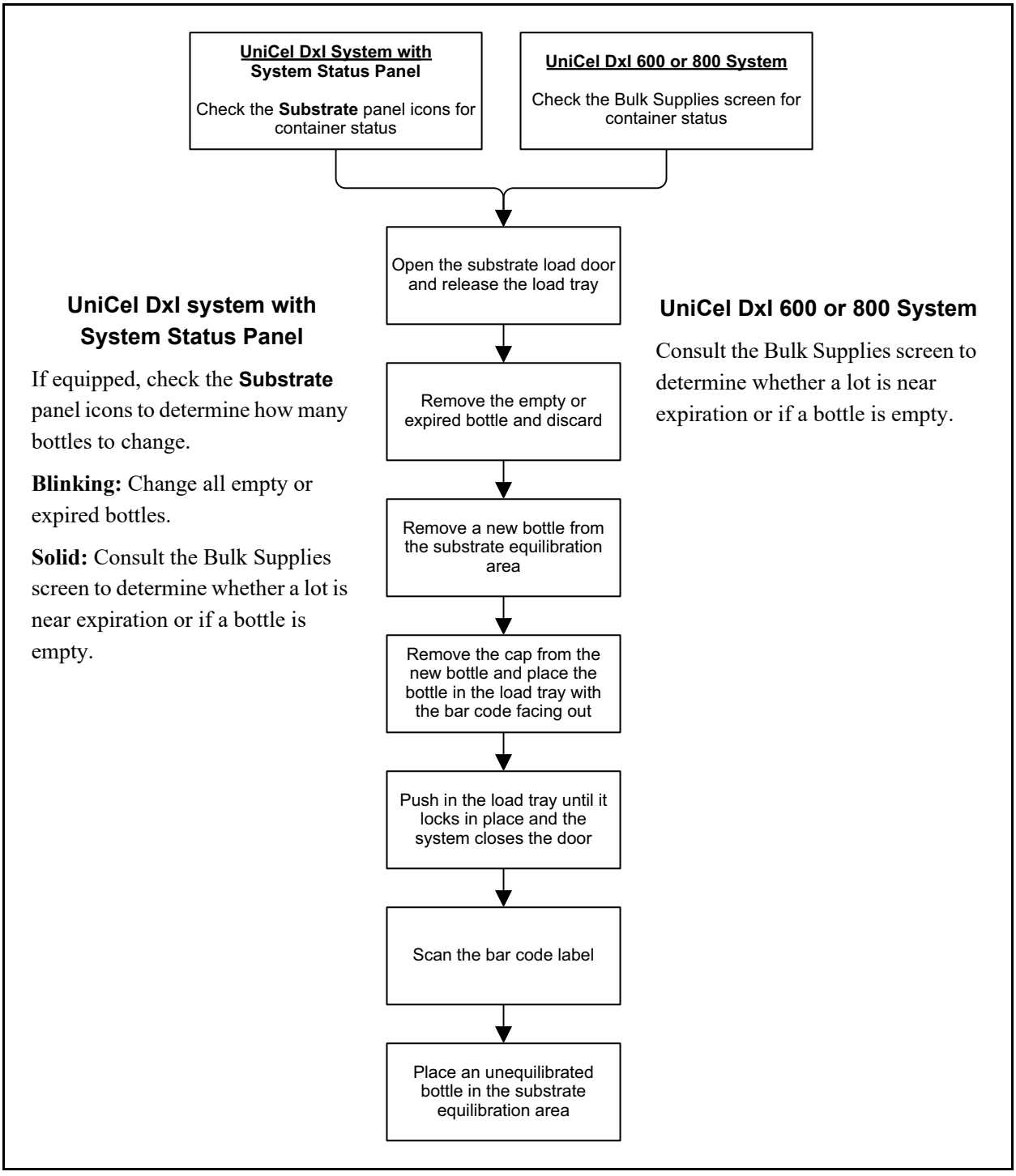
2033A.bmp

1	**RVs** icon
2	**Substrate** icons
3	**Console** icon
4	**Wash Buffer** icons
5	**Solid Waste** icon
6	**Liquid Waste** icons

Changing an Empty or Expired Substrate Bottle

Check the substrate status to determine how many bottles to change. When all of the on-board substrate bottles are empty or expired, the system completes any in progress tests, but does not schedule any new tests until you change at least one bottle.

System Mode: Any Mode

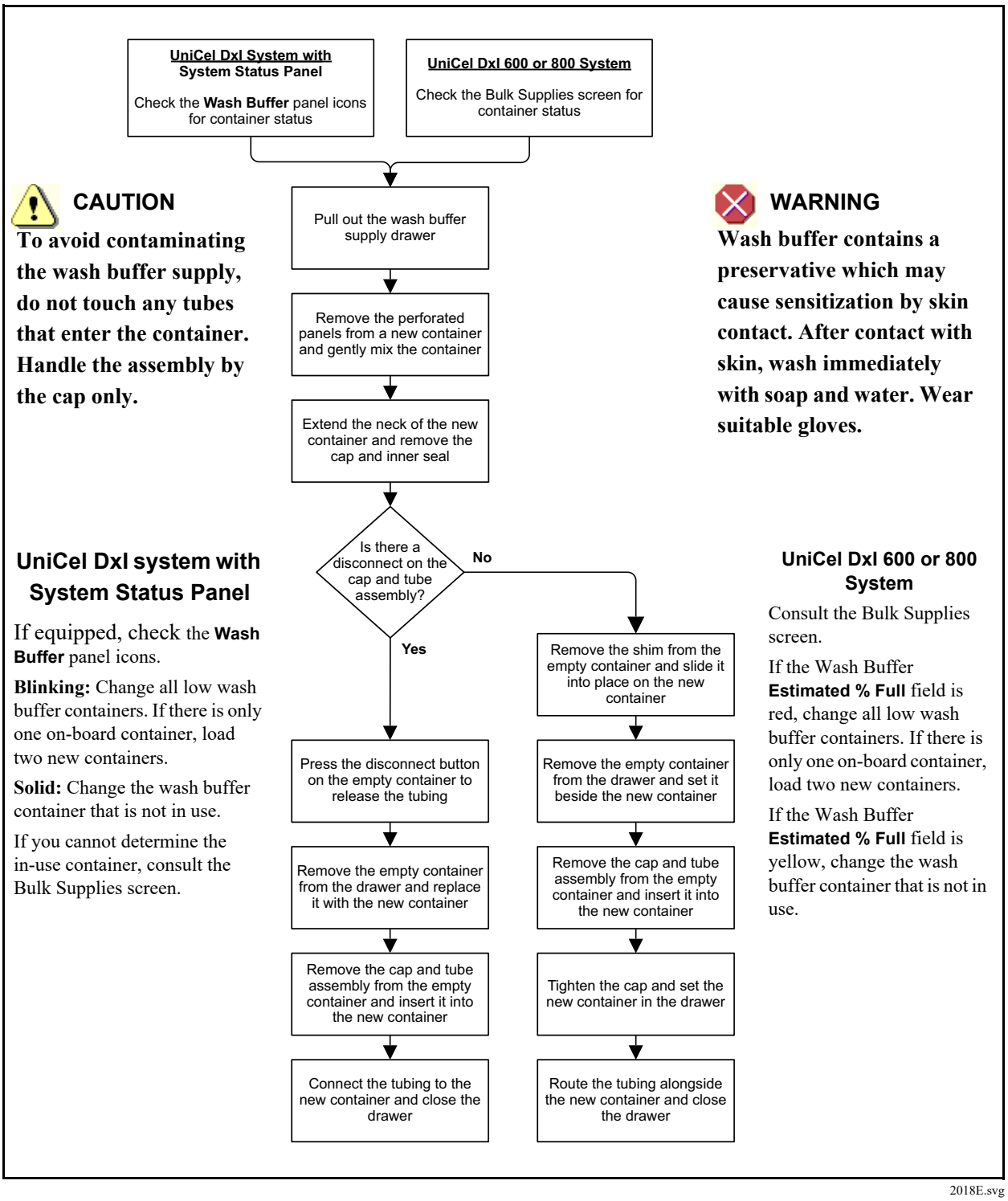


2017D.svg

Changing an Empty Bulk Wash Buffer Container

Check the wash buffer status to determine how many containers to change. When all of the on-board containers are empty, the system completes any in progress tests, but does not schedule any new tests until you change at least one container.

System Mode: Any Mode



2018E.svg

Adding RVs

Check the RV status to determine how many bags of RVs to add to the vessel hopper. When the vessel hopper is empty, the system completes any in progress tests, but does not schedule any new tests until you add more RVs.

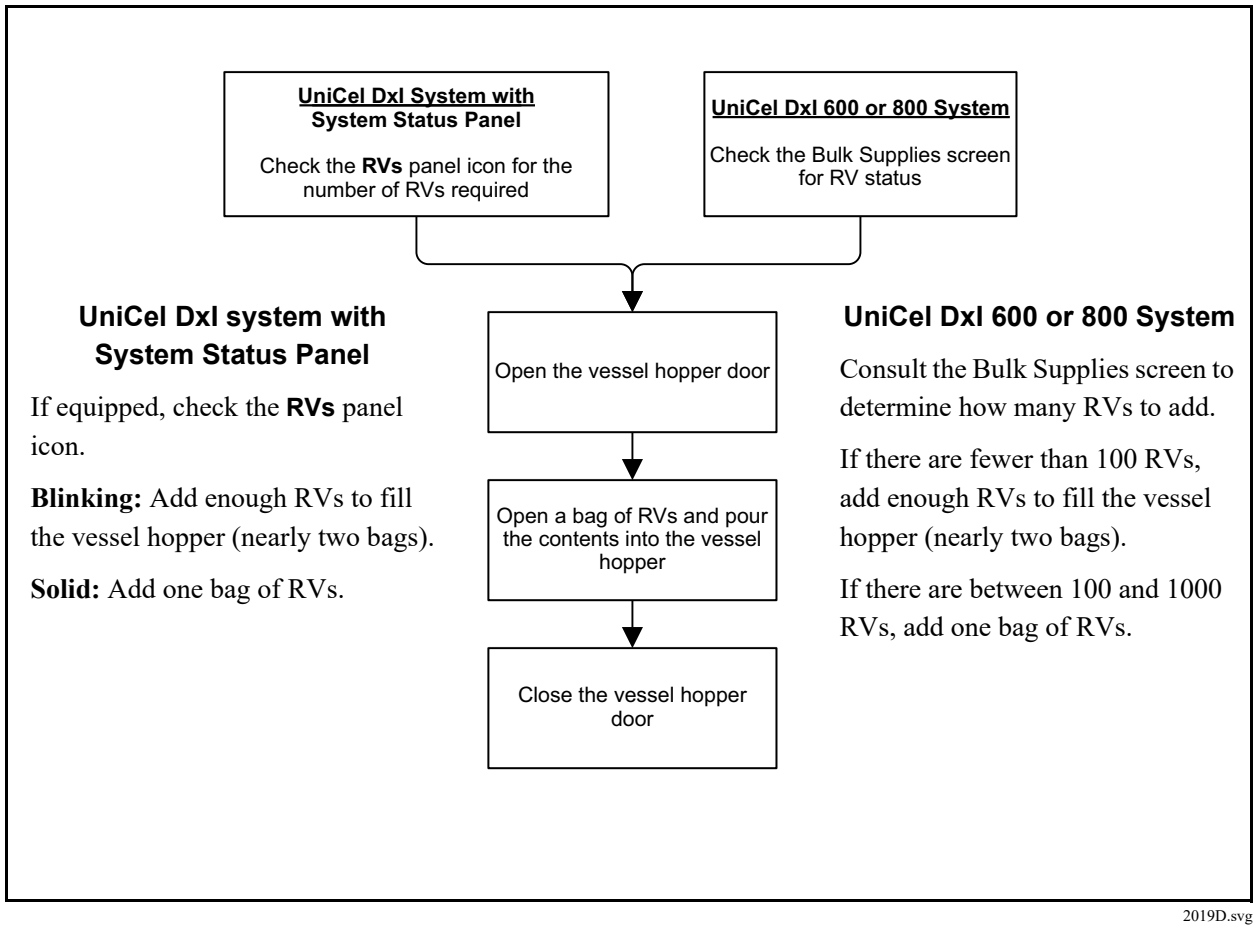
WARNING

To avoid contaminating the RV supply, only add full, previously unopened bags to the hopper whenever it is possible. If you add a previously opened bag of RVs to the hopper, be sure the bag was closed to protect the RVs from dust and other contaminants.

CAUTION

Only add UniCel DxI system RVs to the hopper. If you add other RVs or containers, the instrument will malfunction.

System Mode: Any Mode



2019D.svg

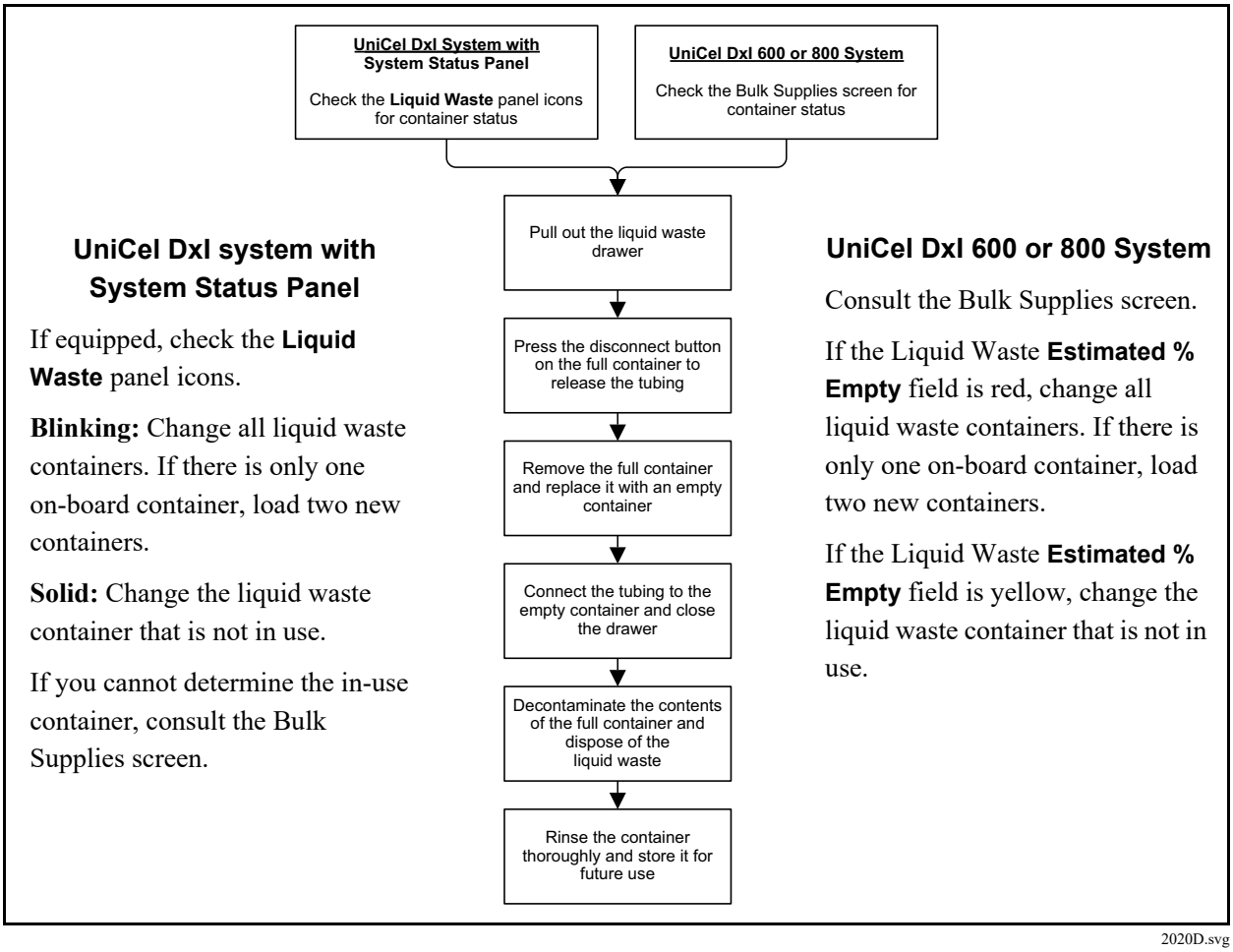
Changing a Full Bulk Liquid Waste Container

Use this procedure only if your system uses bulk liquid waste containers. Check the liquid waste status to determine which container is in use and how many containers to change. When all on-board containers are full, the system completes any in progress tests, but does not schedule any new tests until you change at least one container.

WARNINGS

- **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.**
- **Thoroughly flush any decontaminant from the bulk liquid waste container before you store the container. If you reuse a container without flushing it, any remaining decontaminant may react with chemicals dispensed into the waste container. The resulting chemical reactions may create gases harmful to you or the instrument.**
- **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 (8/16/76)*.**

System Mode: Any Mode



2020D.svg

Changing a Full Solid Waste Container

Check the solid waste status. When the container is full, the system completes any tests in progress, but does not schedule any new tests until you change the solid waste container bag.

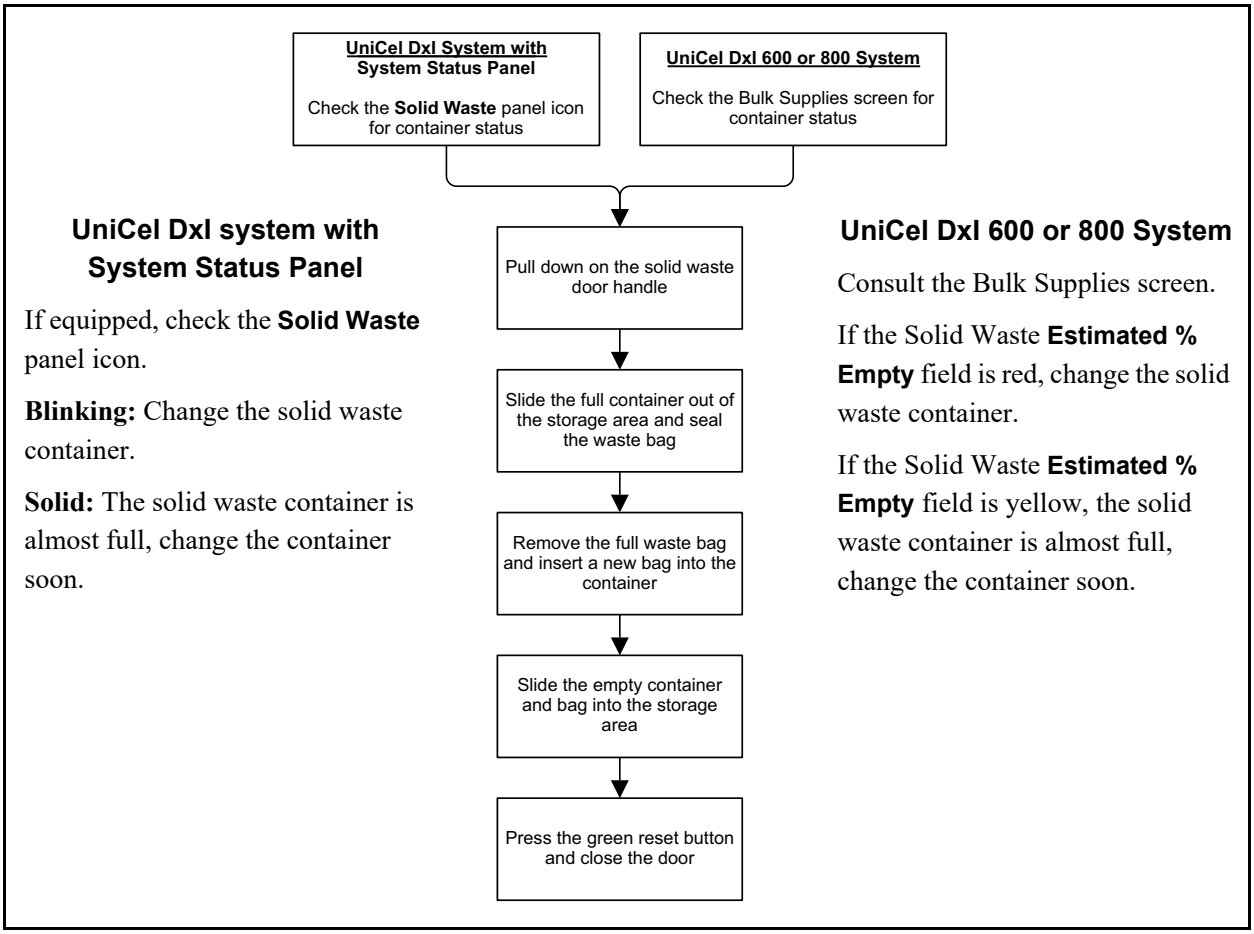
WARNING

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.

CAUTIONS

- **If you change a full solid waste container while the system is in the Running or Paused mode, be sure to complete the procedure within five minutes. Solid waste may accumulate and obstruct the waste chute if it takes longer than five minutes to change the container.**
- **Do not overfill the solid waste container. Excess solid waste may obstruct the waste chute.**
- **Do not open the solid waste door while the system is initializing, running a Daily Clean System routine, or running a Special Clean routine. Opening the solid waste door will cancel the routine and the system will enter the Not Ready mode.**

System Mode: Any Mode



UniCel DxI system with System Status Panel

If equipped, check the **Solid Waste** panel icon.

Blinking: Change the solid waste container.

Solid: The solid waste container is almost full, change the container soon.

UniCel DxI 600 or 800 System

Consult the Bulk Supplies screen.

If the Solid Waste **Estimated % Empty** field is red, change the solid waste container.

If the Solid Waste **Estimated % Empty** field is yellow, the solid waste container is almost full, change the container soon.

2021D.svg

Loading a Reagent Pack

When a reagent is not present, an on-board pack does not contain enough reagent to process the requested tests, or if the lot or open pack stability has expired, the system assigns the **Supply Wait** status to those tests and turns the **Supplies Required** button yellow. On a UniCel DxI 800 system equipped with the system status panel, the **Console** panel icon also is lit.

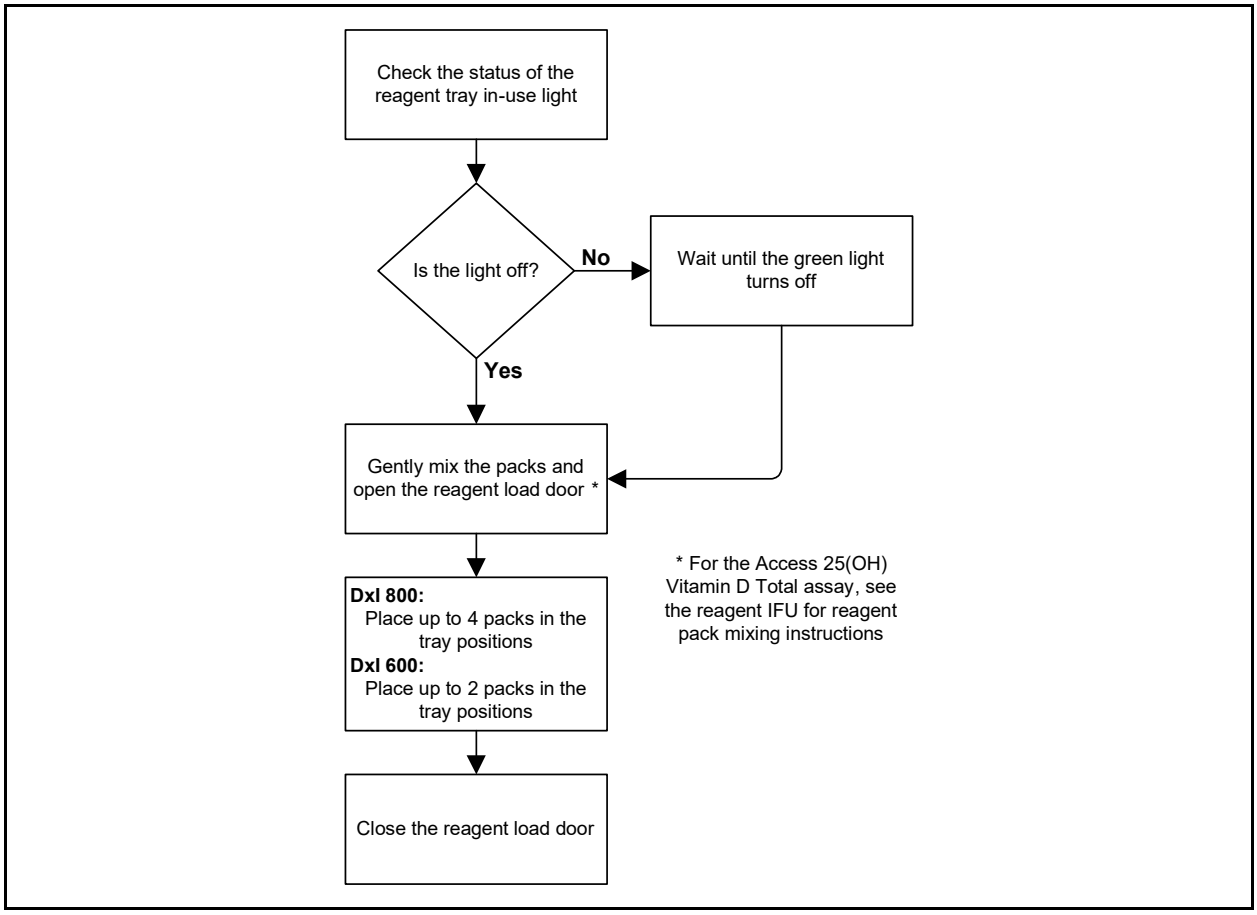
WARNINGS

- **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.**
- **Do not load partial packs from another system onto your instrument.**
- **If you load a used pack, make sure the number of tests displayed for the pack is less than 50. Erroneous but believable results may be obtained if a used pack is incorrectly identified as a new pack containing 50 tests. If a used pack is identified as a new pack, unload it and use this procedure to load a fresh pack.**

CAUTION

To prevent damaging the reagent packs, be sure they are properly seated in the tray positions.

System Mode: Any Mode



2022D.wmf

Unloading a Reagent Pack

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

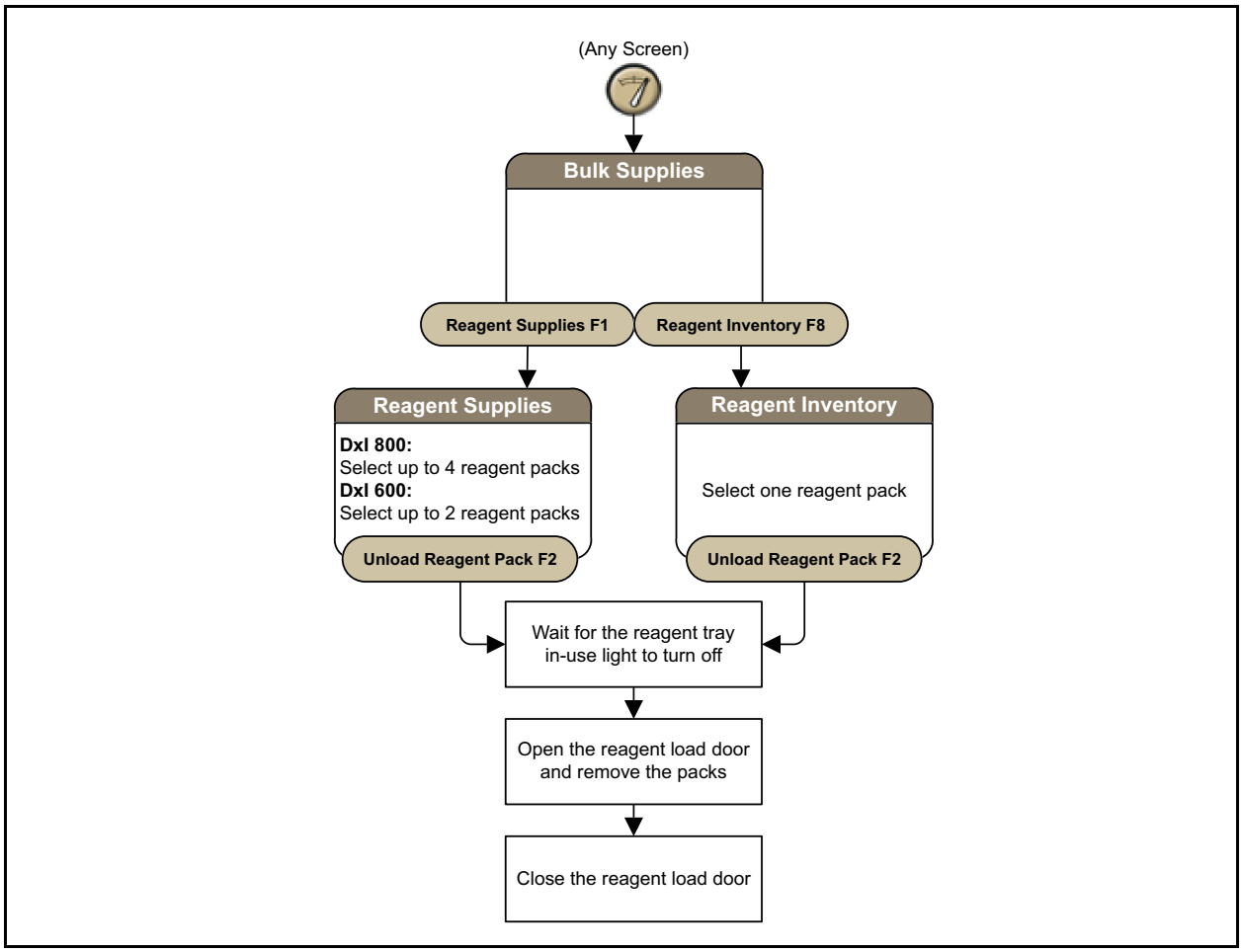
WARNING

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.

NOTES

- You can unload up to four reagent packs at a time on the Reagent Supplies screen for the UniCel DxI 800 instrument (up to two packs on the UniCel DxI 600 instrument). You can only unload packs one at a time on the Reagent Inventory screen.
- If a reagent pack is in use, you cannot unload it from the system (identified by the in-use [padlock] icon on the Supplies screen).

System Mode: Any Mode



2023C.svg

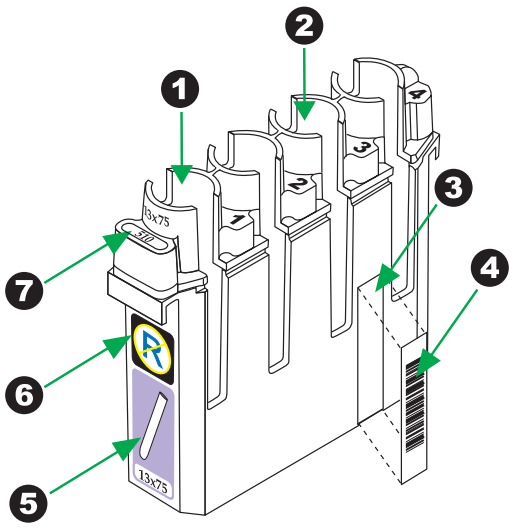
4 Racks and Sample Containers

You load sample containers 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 800 instrument holds approximately 30 sample racks. The onload area of the UniCel DxI 600 instrument holds approximately 15 racks.

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 four different labels: Rack bar code label, Container type label, Rack ID label, and the Reserve Volume label.



2149B.eps

1	Sample container position 1
2	Sample container position 3
3	Rack indentation
4	Rack bar code label
5	Container type label
6	Reserve Volume label **Flexible Reserve**  **Standard Reserve**  **No Reserve** 
7	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. The Reserve Volume label indicates what type of reserve volume is designated for the rack.

NOTE

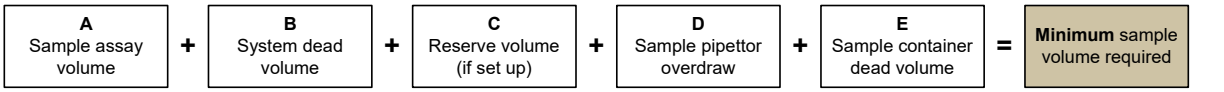
You can find the rack ID ranges set up for each type of sample container from the System Setup screen.

The instrument recognizes the type of sample containers held in the sample rack when it scans the rack bar code label.

Calculating Minimum Sample Volume

The sample volume in a container must be sufficient to process the requested tests, and can be increased to accommodate reflex tests or patient and QC reruns.

Use this equation whenever you need to calculate the minimum sample volume for a container in a rack:



2223B.wmf

A	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 reagent instructions for use.
B	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 µL for each RV.
C	(If set up) The reserve volume is the amount of sample the system stores for additional testing.
D	The sample pipettor overdraw is 20 µL or 5% of the volume of sample in the RV (A + B + C), whichever is greater.
E	The sample container dead volume is the amount of sample that cannot be aliquoted from the sample container.

NOTE

If the sum of the sample and reserve volumes (A + C) is greater than 500 µL, the system aliquots the reserve volume into 1-2 additional reaction vessels (RVs). For each additional RV, include the system dead volume and sample pipettor overdraw calculation.

Example

Sample volume aliquot in one RV - The PSA assay has a sample volume of 25 µL, and the fPSA assay has a sample volume of 25 µL. The system is set up to draw 200 µL of reserve volume. Here is how to calculate the minimum sample volume required for these two assays if you are using a 2 mL cup.

A	Total sample volume for the requested tests (25 µL + 25 µL)	50 µL
B	System dead volume for one RV	60 µL
C	Reserve volume (Standard or Flexible)	200 µL
D	Overdraw of 20 µL or 5% of the volume in the RV, whichever is larger **One RV:** 5% of (50 µL + 60 µL + 200 µL) = 16 µL, so use an overdraw of 20 µL	20 µL
E	Dead volume for a 2 mL cup	150 µL
	Minimum sample volume required for one RV	480 µL

Example

Sample volume aliquot in two RVs - The PSA assay has a sample volume of 25 µL, and the fPSA assay has a sample volume of 25 µL. The system is set up to remove 500 µL of reserve volume. Here is how to calculate the minimum sample volume required for these two assays if you are using a 2 mL cup.

A	Total sample volume for the requested tests (25 µL + 25 µL)	50 µL
B	System dead volume for two RVs (60 µL + 60 µL)	120 µL
C	Reserve volume (Standard or Flexible)	500 µL
D	Overdraw of 20 µL or 5% of the volume for each RV, whichever is larger **First RV:** 5% of (50 µL + 60 µL) = 6 µL, so use an overdraw of 20 µL **Second RV:** 5% of (60 µL + 500 µL) = 28 µL	48 µL
E	Dead volume for a 2 mL cup	150 µL
	Minimum sample volume required for two RVs	868 µL

Sample Containers

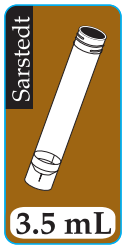
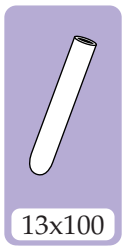
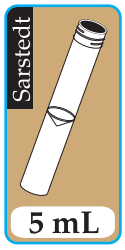
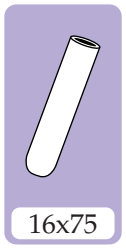
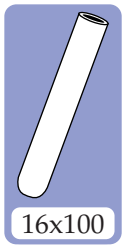
The following table lists the sample containers that are accepted on the UniCel DxI instrument, along with their dead volume requirements.

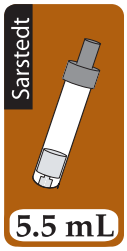
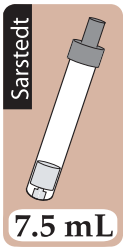
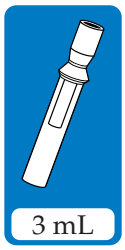
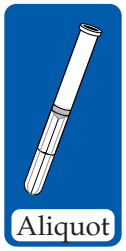
WARNING

Racks are configured to accept only one type of sample container. The sample containers used must match the ID configured for the rack. 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.

CAUTION

Remove caps from all sample containers before loading on the UniCel DxI system.

Sample Container Information	Container Type Label	Sample Container Information	Container Type Label
11.5x66 mm 3.5 mL S.60.549 Sarstedt tube • Dead volume: 200 µL • Sample rack: 13x75 mm		12 or 13x75 mm glass tube • Dead volume: 500 µL • Sample rack: 13x75 mm	
12 or 13x75 mm plastic tube • Dead volume: 200 µL • Sample rack: 13x75 mm		13x100 mm tube • Dead volume: 500 µL • Sample rack: 13x100 mm	
15.3x92 mm 5 mL S.62.611 Sarstedt tube • Dead volume: 300 µL • Sample rack: 16x100 mm		16x75 mm tube • Dead volume: 800 µL • Sample rack: 16x75 mm	
16x85 mm tube • Dead volume: 200 µL (This information only applies to the 16x85 mm SBCL 10 mL screw-cap tube) • Sample rack: 16x100 mm		16x100 mm tube • Dead volume: 800 µL • Sample rack: 16x100 mm	

Sample Container Information	Container Type Label	Sample Container Information	Container Type Label
75x15 mm 5.5 mL Sarstedt S-Monovette tube • Dead volume: 1100 µL • Sample rack: 16x75 mm		92x15 mm 7.5 mL Sarstedt S-Monovette tube • Dead volume: 1200 µL • Sample rack: 16x100 mm	
Beckman Coulter 1 mL insert cup in a 13x75 tube • Dead volume: 350 µL • Sample rack: 13x75 mm		Beckman Coulter 1 mL insert cup in a 13x100 mm tube • Dead volume: 400 µL • Sample rack: 13x100 mm	
Beckman Coulter 0.5 mL cup • Dead volume: 80 µL • Sample rack: 13x75 mm or 13x100 mm		Beckman Coulter 2 mL cup • Dead volume: 150 µL • Sample rack: 13x75 mm or 13x100 mm	
Beckman Coulter 2 mL insert cup in a 16x100 mm tube • Dead volume: 200 µL • Sample rack: 16x100 mm		Beckman Coulter 3 mL cup in a 16x100 mm rack • Dead volume: 150 µL • Sample rack: 16x100 mm	
Beckman Coulter autoaliquot tube (use only Beckman Coulter P/N 2910034) • Dead volume: 150 µL • Sample rack: 13x100 mm		Beckman Coulter pediatric insert cup in a Beckman Coulter pediatric tube adapter • Dead volume: 150 µL • Sample rack: 13x100 mm	

5 Sample Manager

Sample processing begins when the UniCel DxI system queries the laboratory information system (LIS) for sample test requests, downloads test requests from the LIS, or when a test request is entered on the Test Requests screen.

Downloading LIS Test Requests

Use this procedure to process test requests downloaded from the LIS. When you load bar coded sample containers for the samples listed on the Work Pending screen, the system matches the downloaded test requests to the samples and runs the tests.

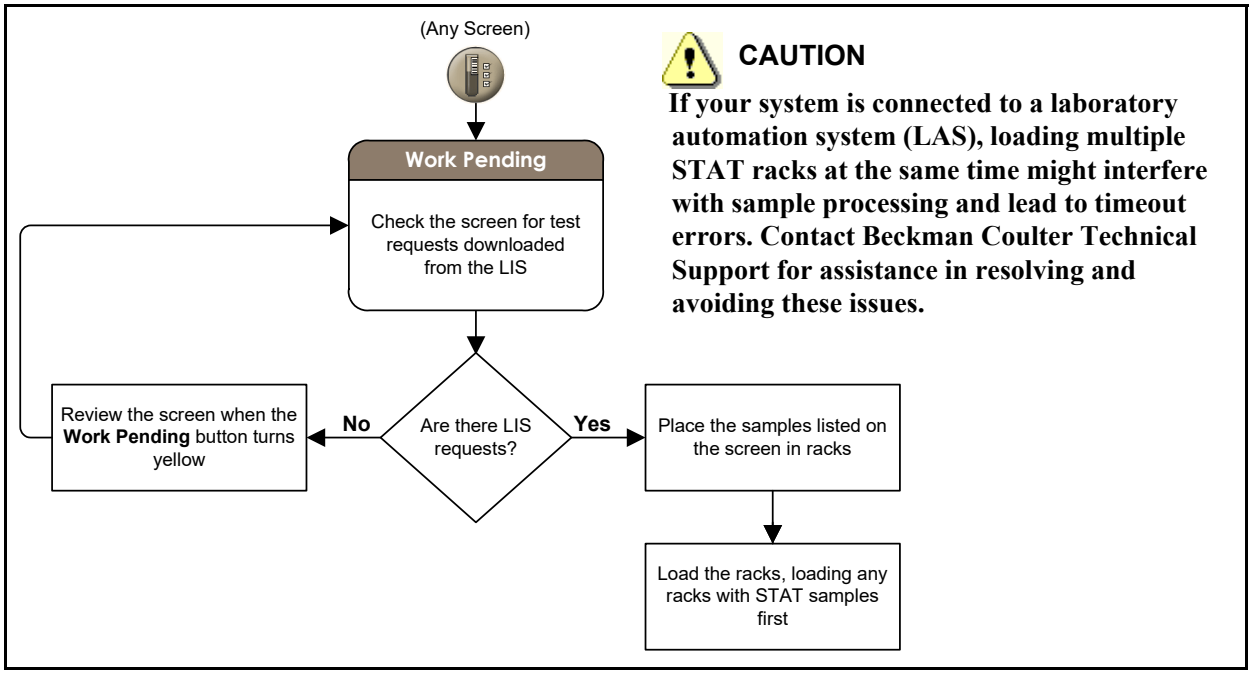
WARNING

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.

NOTES

- When downloading test requests, be sure that LIS host query is not enabled.
- When setting up new tests to run on the instrument, enable the tests before downloading test requests from the LIS. The system rejects an LIS test request if the associated test is not enabled.

System Mode: Ready Running Paused



2095C.wmf

Querying the LIS for Test Requests

Use this procedure to query the laboratory information system (LIS) for test requests.

System Mode: Ready Running Paused

NOTES

- Be sure that LIS host query is enabled.
- When setting up new tests to run on the instrument, enable the tests before querying the LIS for test requests. The system rejects an LIS test request if the associated test is not enabled.

1. Place the bar coded sample containers in racks.

NOTE

If the reserve volume feature is enabled, be sure to place containers with sufficient volume in racks that are set up to draw reserve volume.

2. Load the racks. Load any racks that contain STAT samples first.

CAUTION

If your system is connected to a laboratory automation system (LAS), loading multiple STAT racks at the same time might interfere with sample processing and lead to timeout errors. Contact Beckman Coulter Technical Support for assistance in resolving and avoiding these issues.

3. The system scans the bar code labels for each sample container in the rack, queries the LIS for the associated test requests, and then waits for the LIS to send the requests.

NOTES

- You set the length of time the system waits for a request in the LIS Setup window.
- If the system does not receive a test request within the specified time period, the system does not remove an aliquot for processing and moves to the next container in the rack. The container with no assigned test requests is not placed in the work pending list. The container must be reloaded after the system aliquots the remaining samples in the rack.

4. When the system receives the test requests from the LIS, it updates the Sample Manager screen and scans the bar code label on the next sample container in the rack.

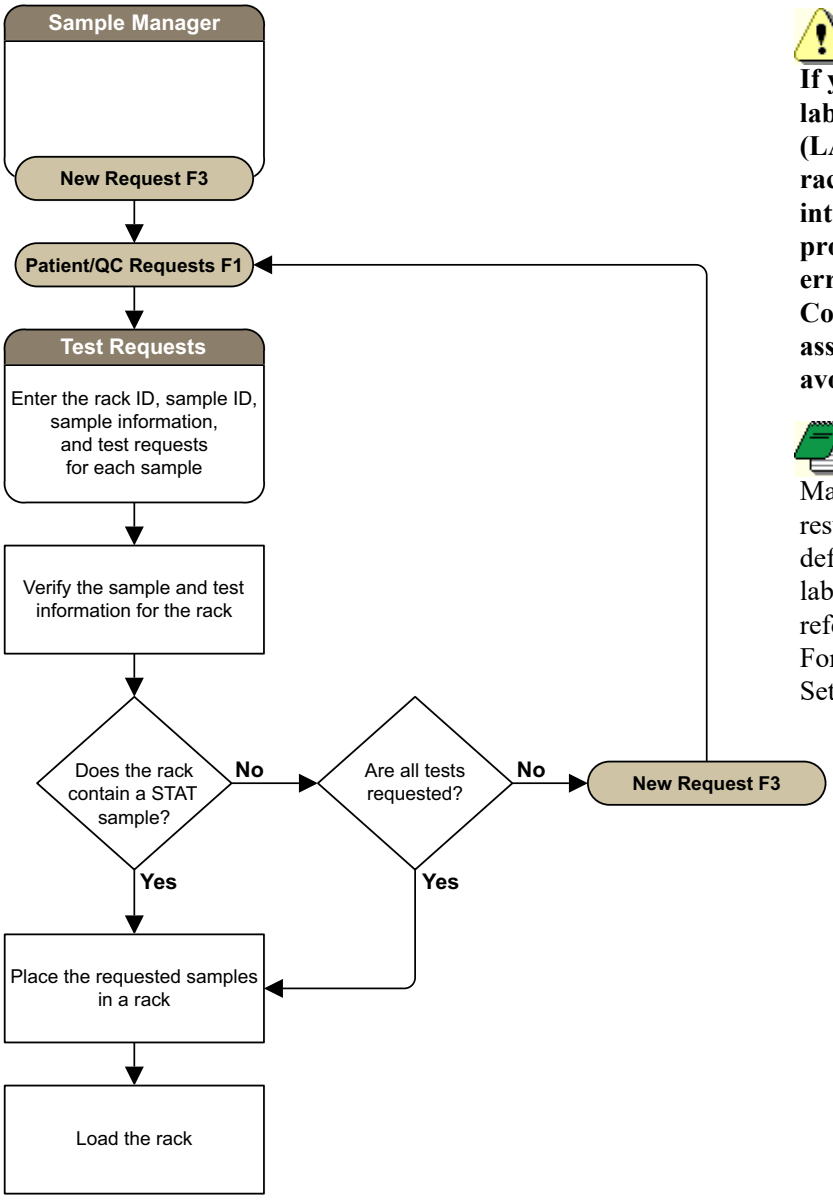
Manual Test Requests

Use this procedure to manually enter patient test requests that do not originate from the LIS.

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.

System Mode: Any Mode



CAUTION

If your system is connected to a laboratory automation system (LAS), loading multiple STAT racks at the same time might interfere with sample processing and lead to timeout errors. Contact Beckman Coulter Technical Support for assistance in resolving and avoiding these issues.

NOTE

Manually requested patient test results are evaluated against default ranges, even if your laboratory has established reference, critical, or LIS ranges. For more information, see Ranges Setup in the Help system.

2096C.svg

Calibration Test Requests

Use this procedure to request a calibration, which can consist of up to seven calibrator samples.

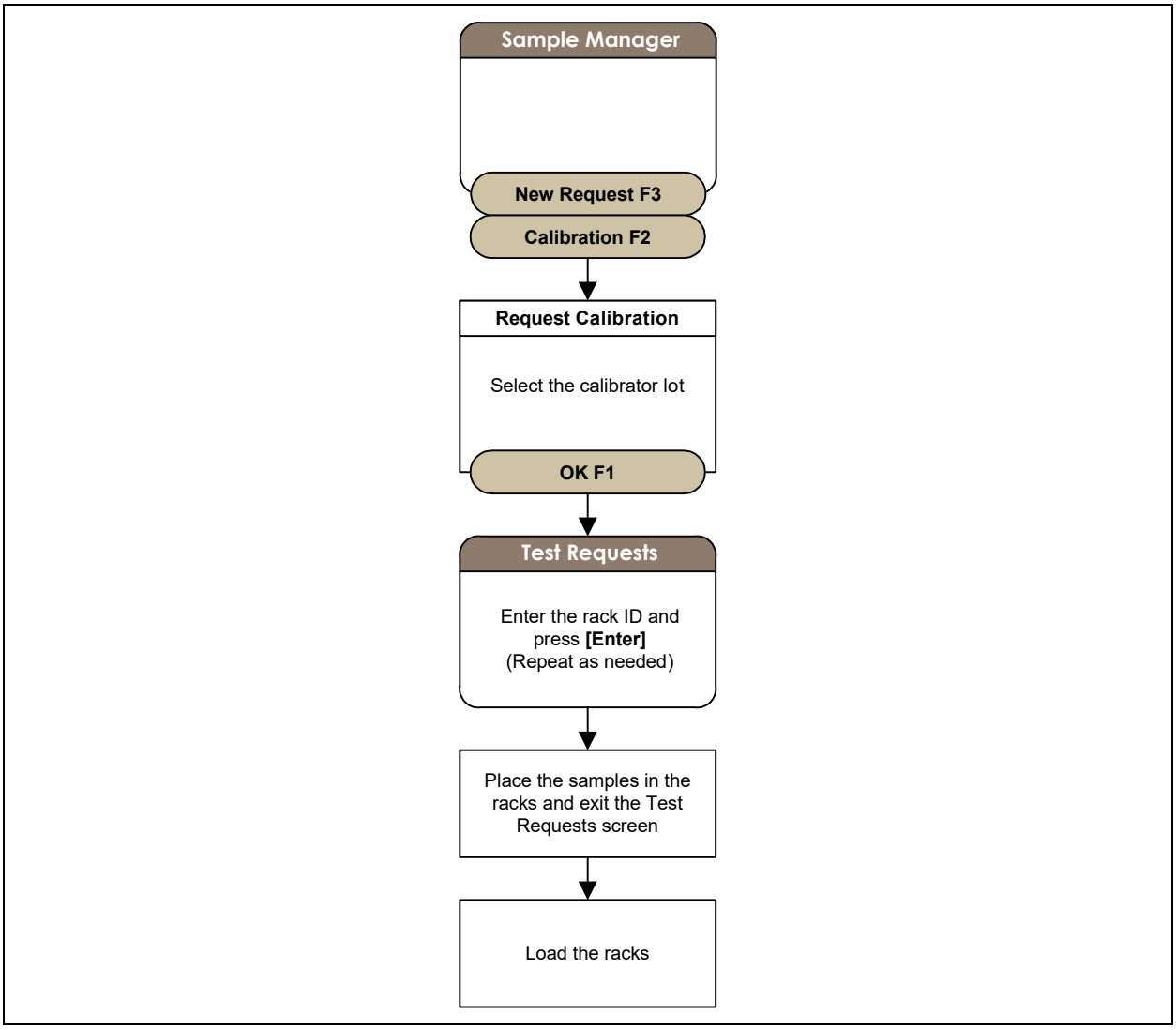
WARNING

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.

NOTE

Before you can enter a calibration request, the calibrator must be set up, the test must be enabled, and sufficient reagent must be in inventory.

System Mode: Any Mode



2101B.wmf

Quality Control Test Requests

Use this procedure to enter a test request for a quality control sample or a multi-level set of samples.

You should run quality control samples as recommended in the reagent instructions for use and after any scheduled or unscheduled maintenance to verify assay calibration. After installing new software, run quality controls for all assays you use to report patient results, then recalibrate any assays with out-of-range quality control results. You may choose to run quality controls more frequently based on good laboratory practices or laboratory accreditation requirements and applicable laws.

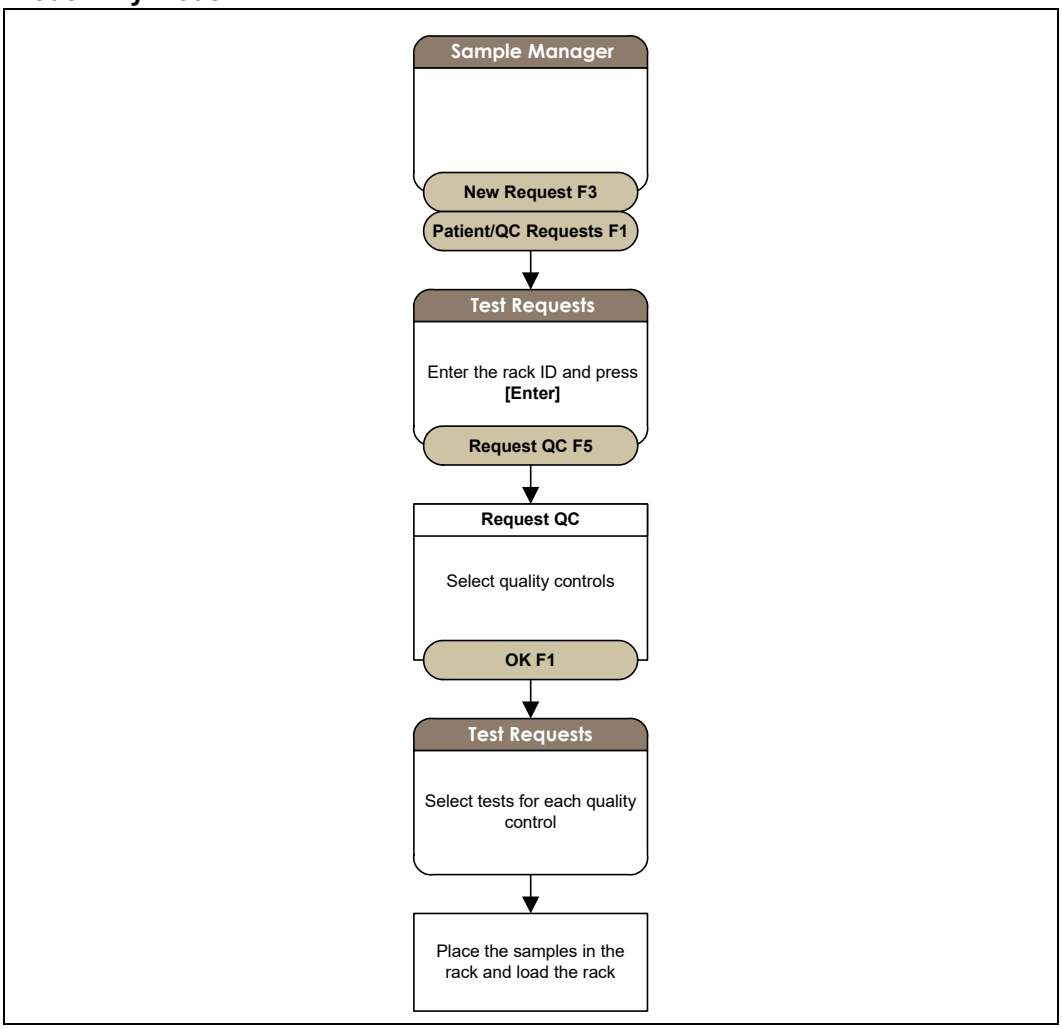
WARNING

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.

NOTE

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

System Mode: Any Mode



2057B.wmf

6 Maintenance

Maintenance Overview

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

- Daily maintenance
- Special weekly maintenance
- Maintenance after a 5,000 test interval
- Maintenance after a 10,000 test interval
- The Utility routine

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.

Special weekly maintenance is only for laboratories that run tests for HIV antibody levels. Special weekly maintenance consists of a procedure for installing clean aspirate probes.

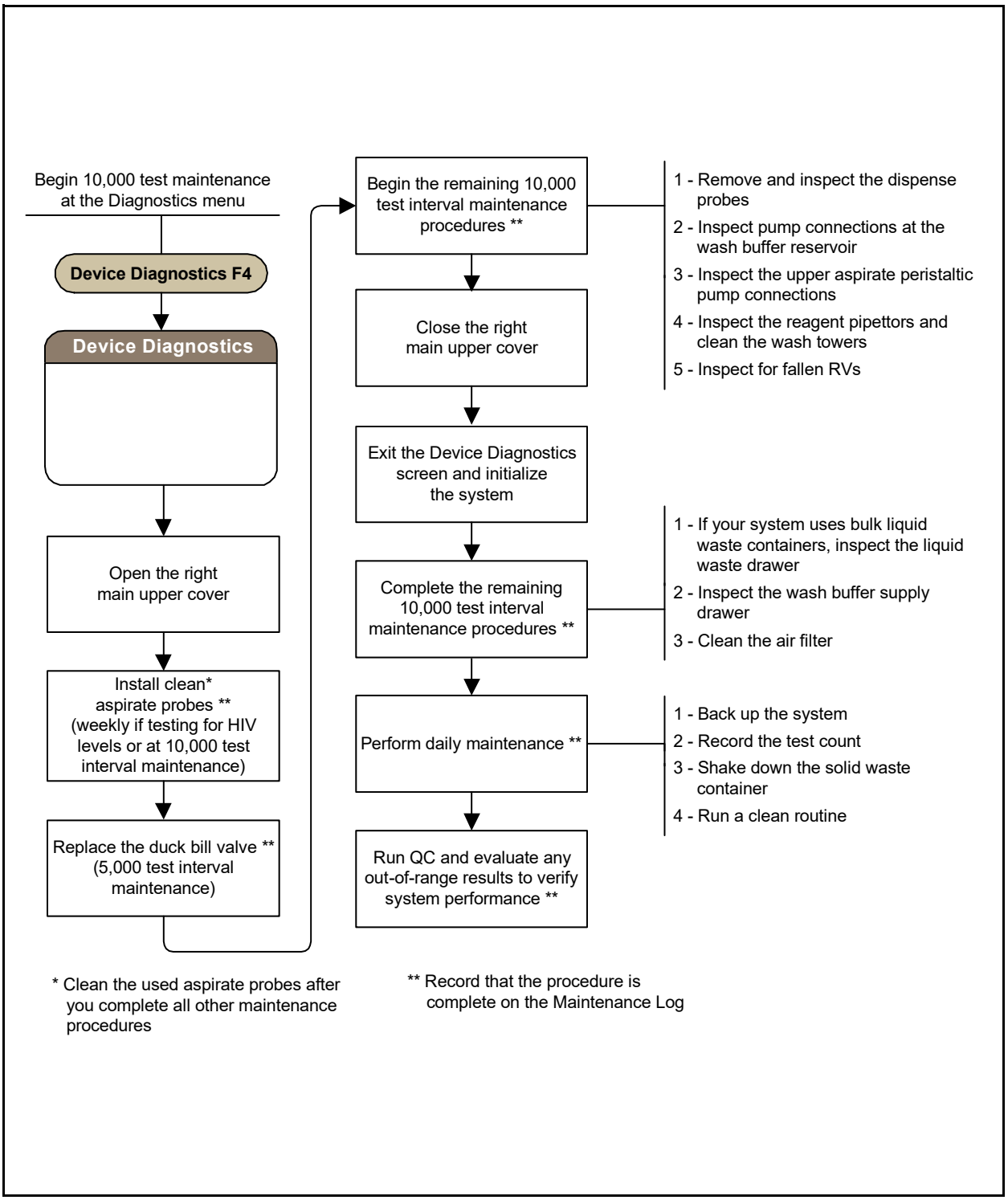
Maintenance after a 5,000 test interval consists of a procedure for replacing the duck bill valve.

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 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.

Maintenance Overview Flowchart



2270G.wmf

Daily Maintenance

Beckman Coulter recommends that you perform daily maintenance once every 24 hours. Perform daily maintenance prior to beginning your daily workload. If your laboratory runs the instrument continuously, perform maintenance at the end of the longest period of inactivity. Even if the system is not used routinely, perform daily maintenance each day.

Perform daily maintenance to prepare the instrument to process samples for the day.

- Back up the system
- Record the test count
- Shake down the solid waste container
- Run a clean routine

Perform one of two clean routines each day to clean the sample, reagent, and aspirate probes. Run the Special Clean routine daily if your laboratory has run the Vitamin B_{12} assay during the last 24-hour time period. Otherwise, run the Daily Clean System routine.

NOTE

You can load patient sample racks while a clean routine is in process. Samples are aspirated after the clean routine rack is aspirated, and are held in the sample wheel until the clean routine is complete.

If the special weekly maintenance procedure is scheduled, perform the daily maintenance procedures after you complete the weekly procedure. If the 10,000 or 5,000 test interval maintenance procedures are scheduled, perform the daily maintenance procedures after you complete the test interval procedures.

Performing Daily Maintenance

Required Materials

- A backup tape (if your DxI system uses a tape drive for backup)
- Sample containers that hold at least 4 mL of solution
- Sample rack with the appropriate rack ID for the container used
- UniCel DxI wash buffer
- Contrad 70 cleaning solution
- 1:5 dilution of Citranox cleaning solution - mix 1 part Citranox and 4 parts deionized water
- 70% ethanol solution—mix 7 parts of 95% ethanol and 3 parts wash buffer (alternatively, you can substitute methanol for the 95% ethanol) (Special Clean routine only)
- Maintenance Log

WARNINGS

- **You will come in contact with potentially infectious materials during these procedures. Handle and dispose of biohazard materials according to proper laboratory procedures. Proper hand, eye, and facial protection is required.**
- **Citranox cleaning solution is acidic and may cause eye or skin irritation. Handle according to proper laboratory procedures. See the manufacturer's label for details.**
- **Contrad 70 cleaning solution is alkaline and may cause severe eye irritation or mild skin irritation. Handle according to proper laboratory procedures. See the manufacturer's label for details.**
- **Ethanol and methanol are extremely flammable. Do not use near heat or flame. Do not ingest. Avoid contact with eyes, skin, and clothing. Use with adequate ventilation.**

CAUTION

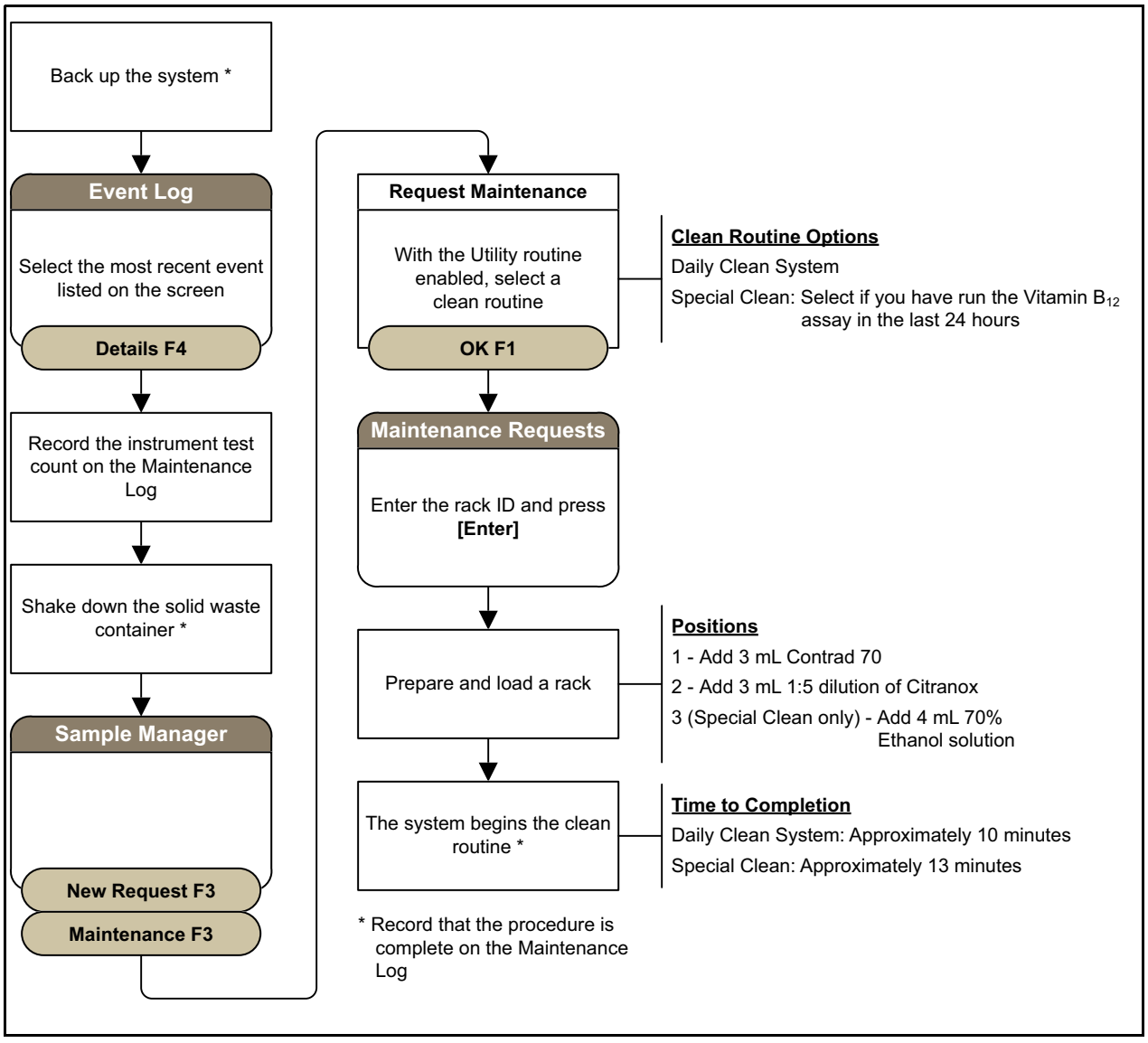
Racks are configured to accept only one type of sample container. The sample containers used must match the ID configured for the rack. Placing an incorrect sample container in a rack may damage the system. You can find the rack ID ranges set up for each type of sample container from the System Setup screen.

Daily Maintenance Flowchart

WARNINGS

- **You will come in contact with potentially infectious materials during these procedures. Handle and dispose of biohazard materials according to proper laboratory procedures. Proper hand, eye, and facial protection is required.**
- **Ethanol and methanol are extremely flammable. Do not fill sample tubes on the instrument or in a rack positioned in the sample presentation unit. Remove sample tubes from the instrument immediately after completing the Special Clean routine.**

System mode: Ready



2105F.svg

Special Weekly Maintenance

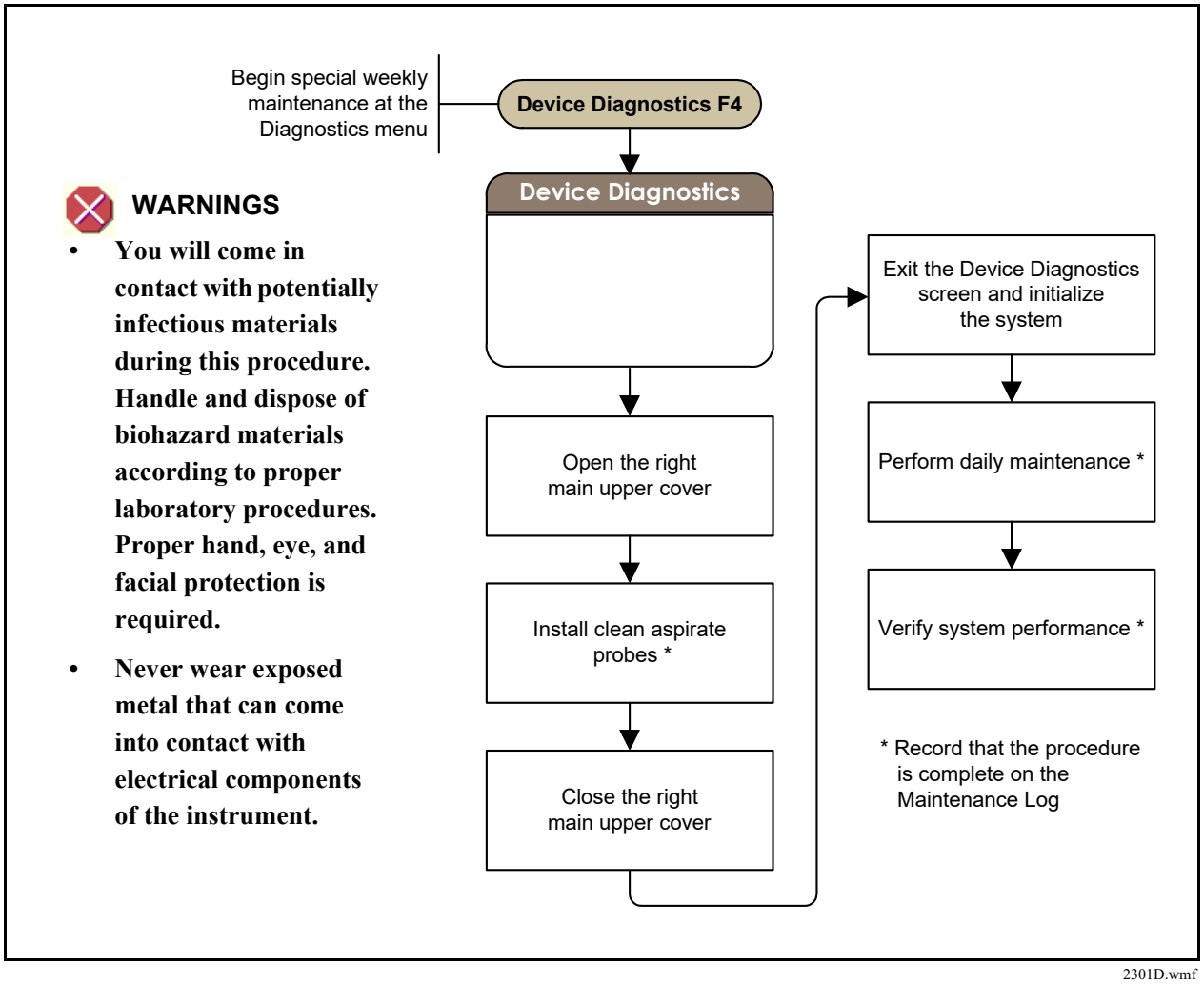
If your laboratory runs tests for HIV antibody levels, Beckman Coulter recommends that you perform special weekly maintenance. Special weekly maintenance consists of a procedure for installing clean aspirate probes.

Laboratories that install clean aspirate probes during special weekly maintenance are not required to install clean probes during 10,000 test interval maintenance.

After you complete the special weekly maintenance procedure, perform daily maintenance and verify system performance.

Special Weekly Maintenance Flowchart

System Mode: Ready | Not Ready



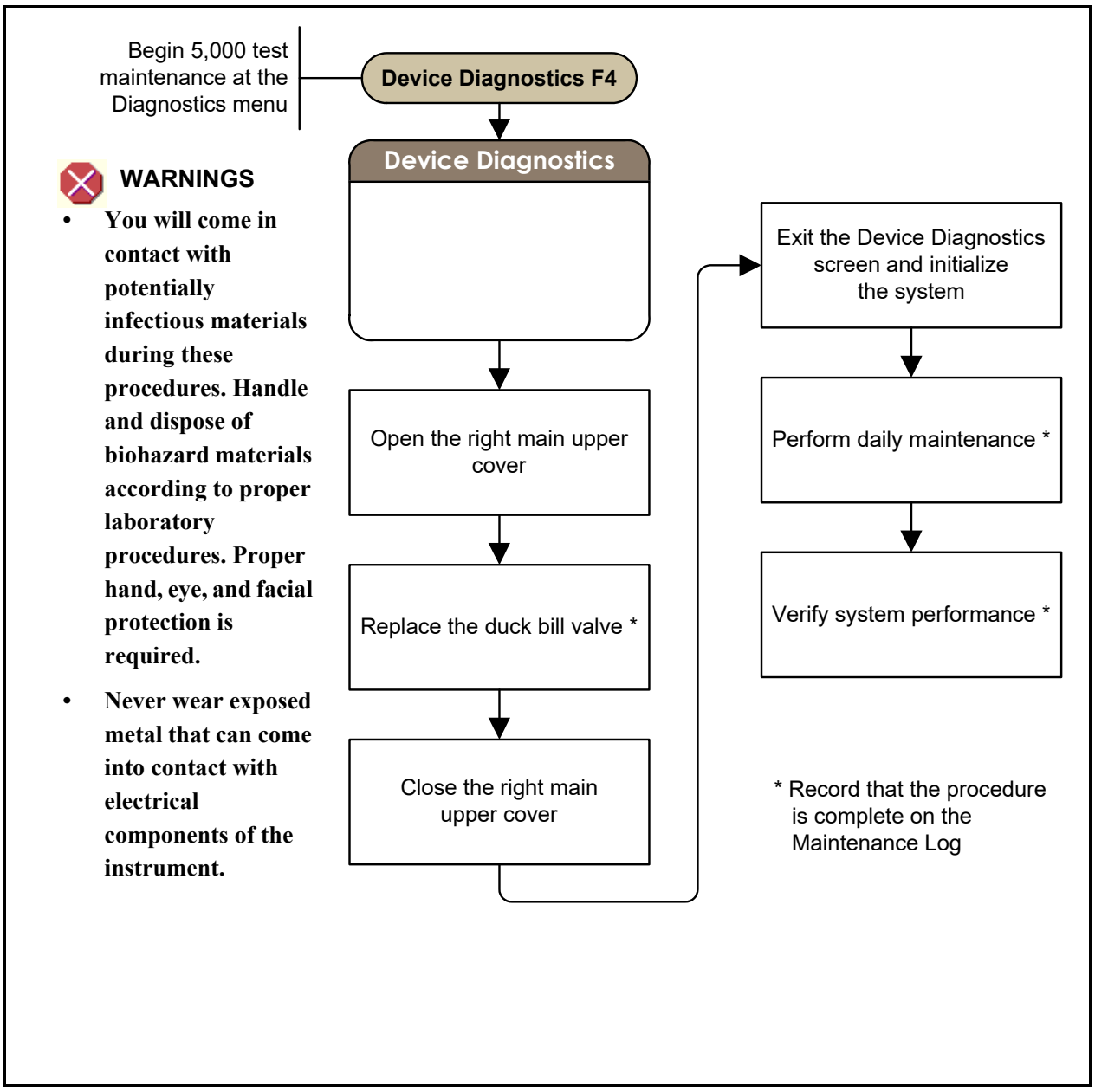
2301D.wmf

Test Interval Maintenance: 5,000 Tests

Beckman Coulter recommends that you replace the duck bill valve after each 5,000 test interval. The duck bill valve prevents wash buffer from entering the RVs in the wash carousel during the aspirate probe wash.

If the 10,000 and 5,000 test interval maintenance procedures are scheduled for the same day, begin with the 10,000 test interval maintenance procedures. The 10,000 test interval procedures include a step to perform 5,000 test interval maintenance. Perform the daily maintenance procedures after you complete the 10,000 and 5,000 test interval procedures.

Test Interval Maintenance: 5,000 Tests Flowchart



2300D.wmf

Replacing the Duck Bill Valve

Use this procedure to replace the duck bill valve. Replace the duck bill valve 5,000 tests after the valve was last replaced, or as instructed by the system documentation, or by a technical support representative.

WARNINGS

- **Never wear exposed metal that can come into contact with electrical components of the instrument.**
- **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.**

CAUTIONS

- **Opening the covers abruptly shuts off power to the upper cabinet, and may cause damage if the system is not in the proper mode and the user interface is not displaying the correct screen. Follow this procedure carefully.**
- **Before you begin this procedure, verify that you have a replacement valve in your CARE kit. If there is no replacement valve, do not perform this procedure. Order a new set of valves and replace the duck bill valve at your earliest opportunity.**

Required Materials

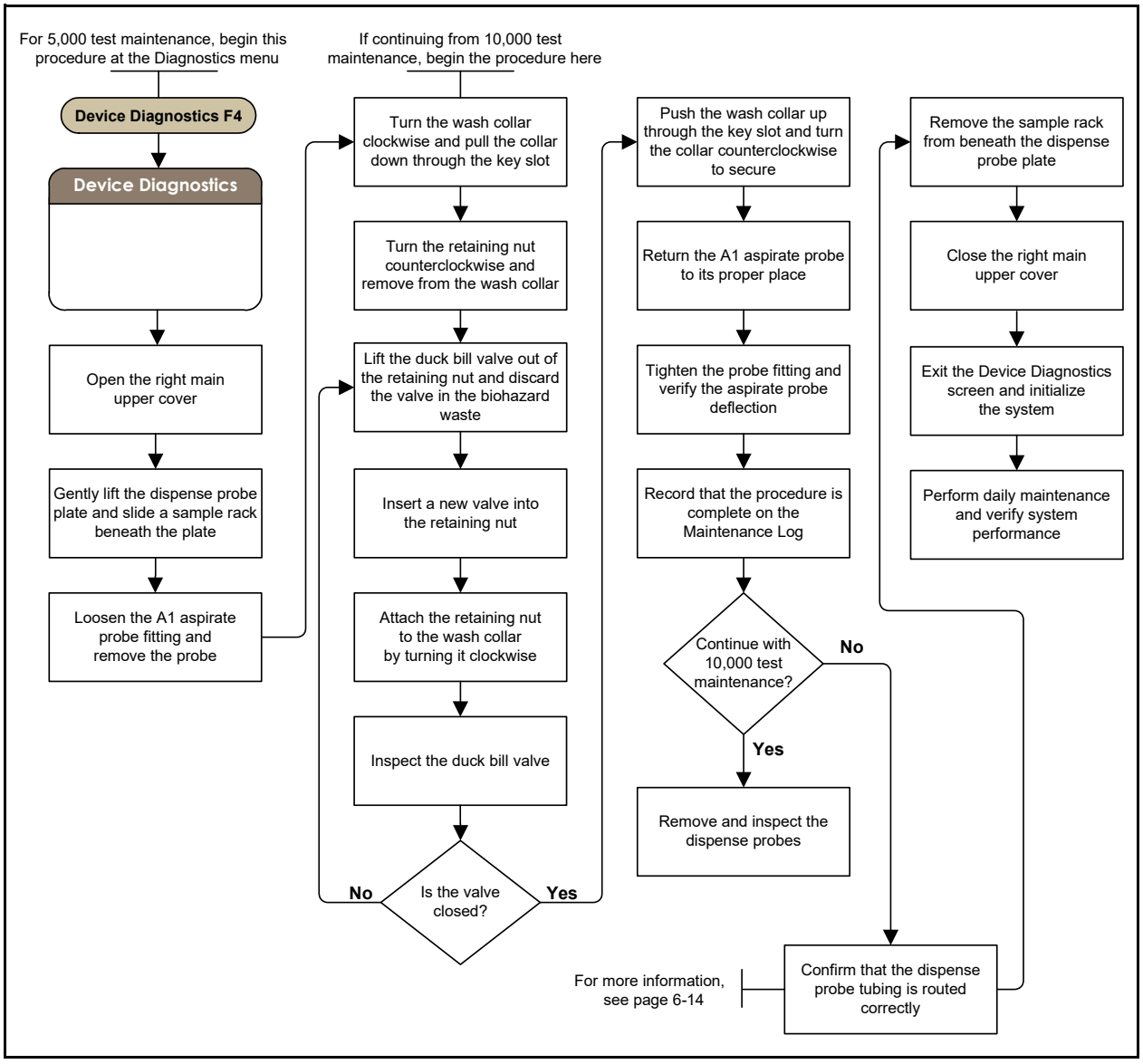
- An empty sample rack
- Several clean lint-free tissues
- New duck bill valve

Replacing the Duck Bill Valve Flowchart

System Mode: Ready | Not Ready

WARNINGS

- **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.**
- **Never wear exposed metal that can come into contact with electrical components of the instrument.**



2240K.wmf

Test Interval Maintenance: 10,000 Tests

Beckman Coulter recommends that you perform the following maintenance procedures after each 10,000 test interval:

- Install clean aspirate probes
- Remove and inspect the dispense probes
- Inspect the pump connections at the wash buffer reservoir
- Inspect the upper aspirate peristaltic pump connections
- Inspect the reagent pipettors and clean the wash towers
- Inspect for fallen RVs
- If your system uses bulk liquid waste containers, inspect the liquid waste drawer
- Inspect the wash buffer supply drawer
- Clean the air filter

NOTE

If your laboratory runs tests for HIV antibody levels, you will install clean aspirate probes each week as part of special weekly maintenance instead of installing clean probes during 10,000 test interval maintenance.

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

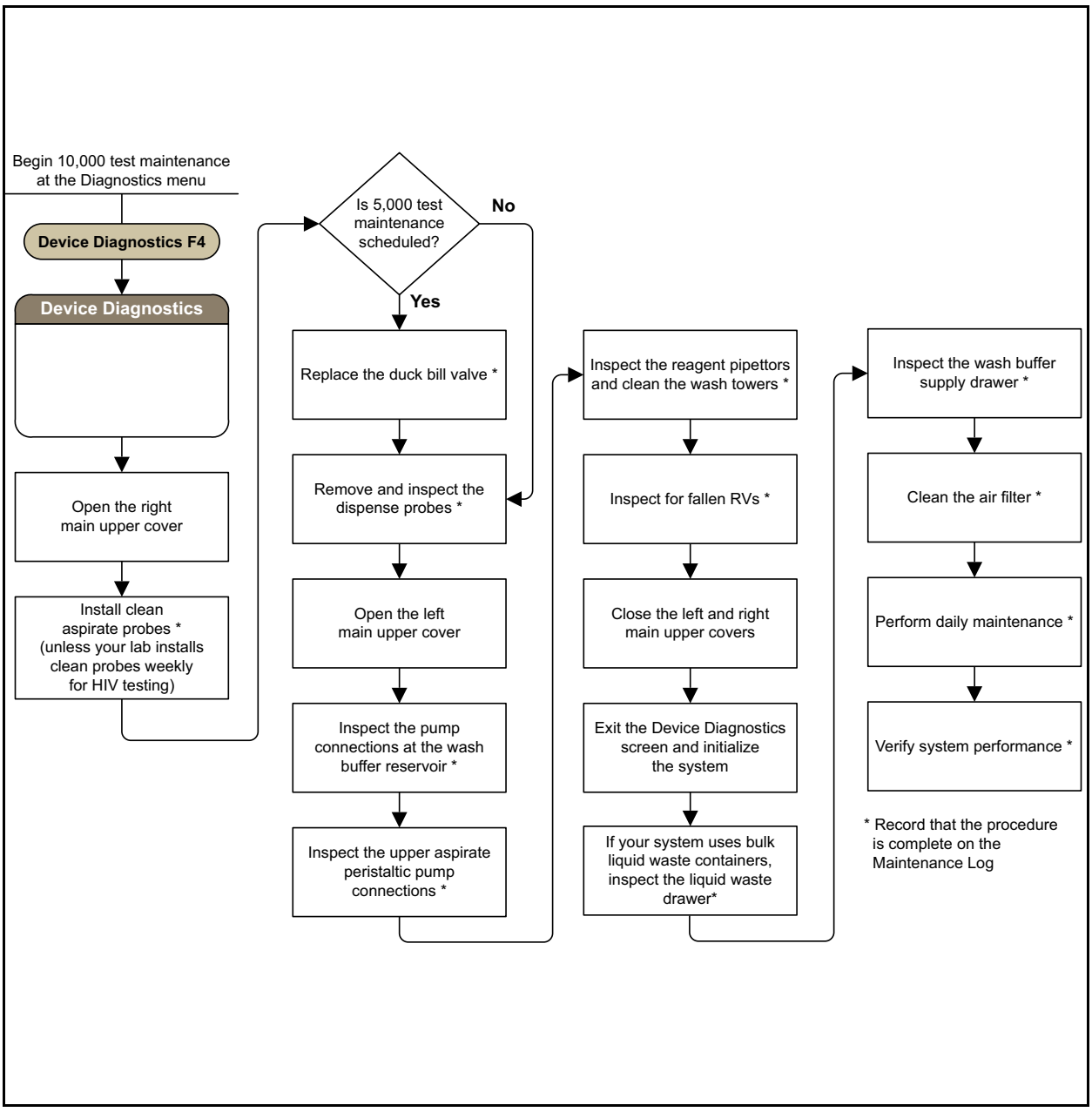
Required Materials

- Several clean, lint-free tissues
- Three clean aspirate probes
- Proper hand, eye, and facial protection
- Small beakers (2)
- Contrad 70 cleaning solution
- Disposable aspirate probe brush
- Deionized water
- Syringe and syringe fitting assembly
- Alcohol wipe
- Hand-held vacuum device

Test Interval Maintenance: 10,000 Tests Flowchart

WARNINGS

- **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.**
- **Never wear exposed metal that can come into contact with electrical components of the instrument.**



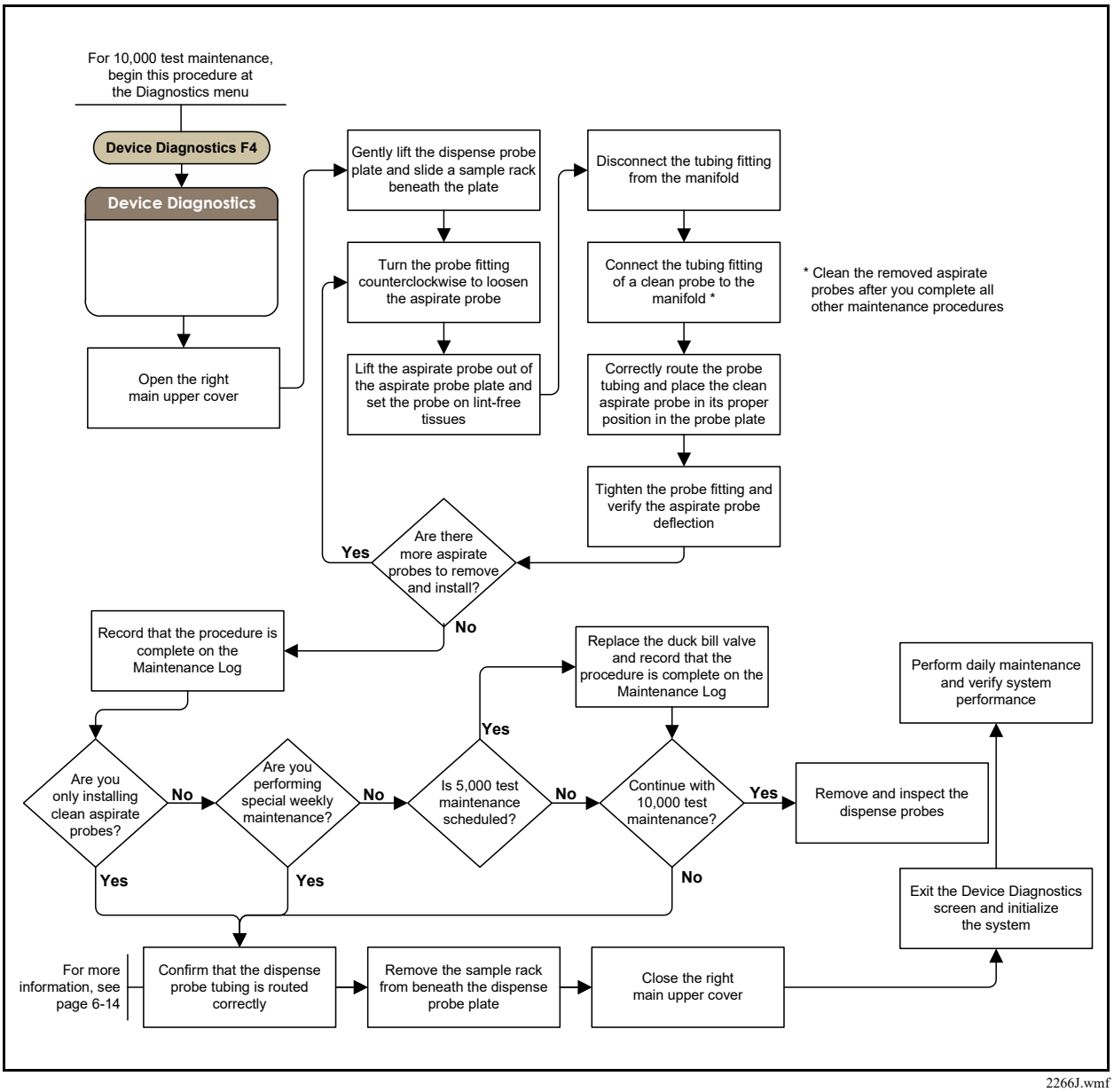
2260G.svg

Installing Clean Aspirate Probes

System Mode: Ready Not Ready

WARNINGS

- **Never wear exposed metal that can come into contact with electrical components of the instrument.**
- **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.**

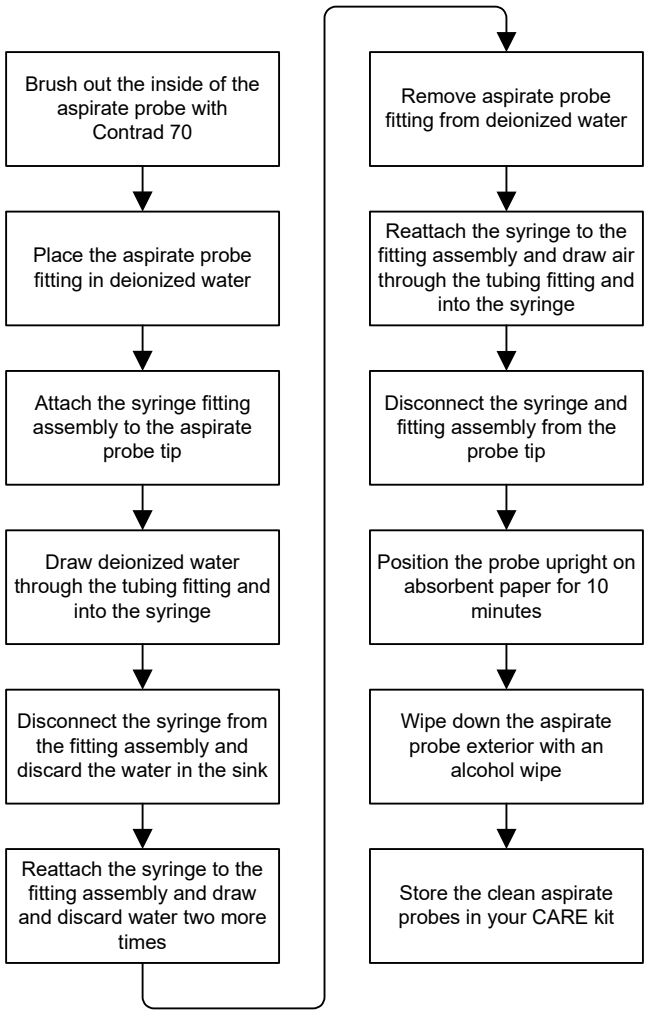


2266J.wmf

Cleaning an Aspirate Probe

WARNINGS

- **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.**
- **The disposable aspirate probe brush is considered a biohazard after it has been used to clean from 1 to 3 aspirate probes. Discard the brush with your biohazard waste. Do not save a used brush for future use.**
- **When cleaning a probe, inserting and removing the aspirate probe brush can disperse biohazard materials that are lodged inside the probe. Work carefully to prevent scattering small droplets of these materials into the air.**



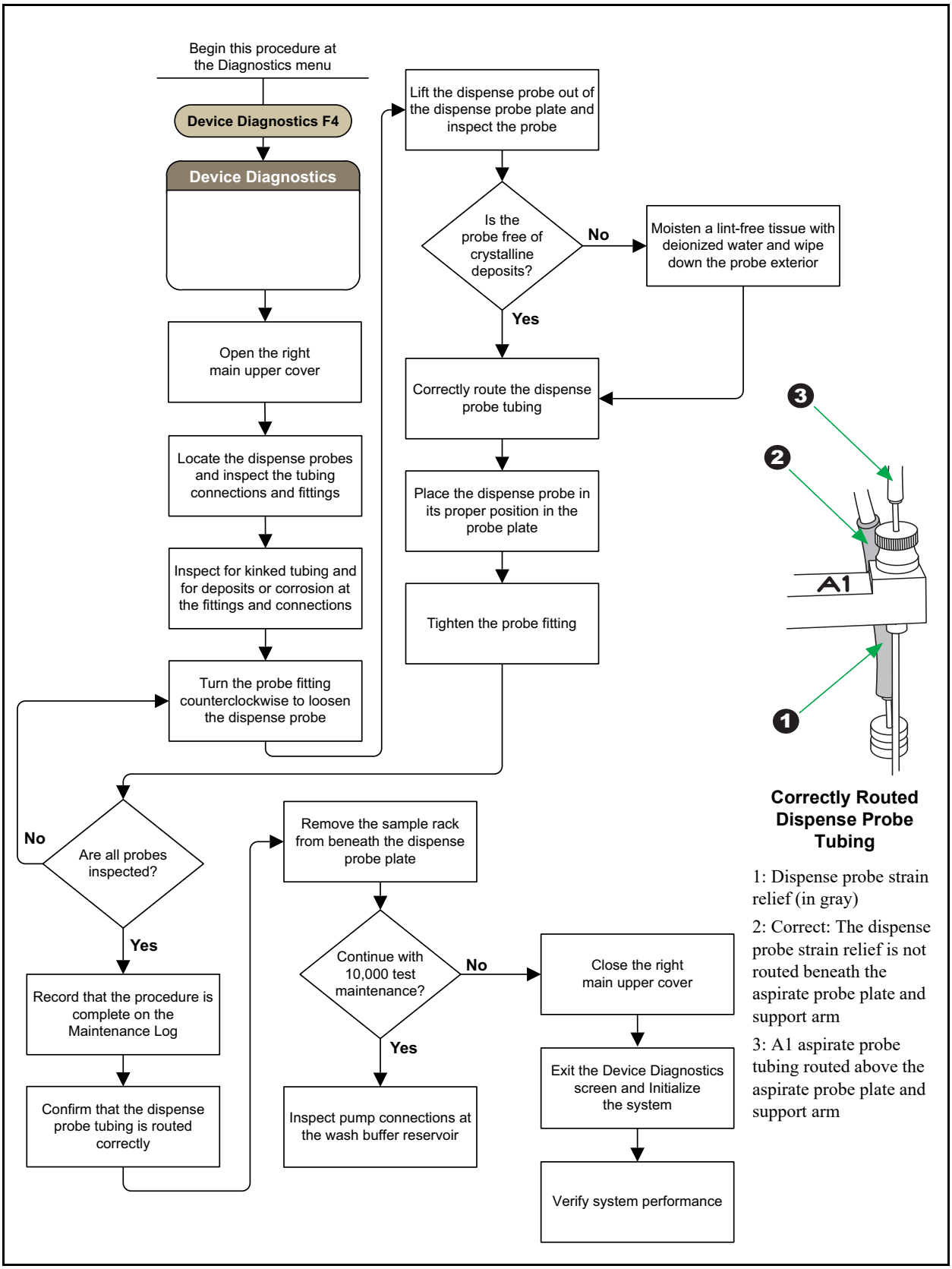
2267C.wmf

Removing and Inspecting the Dispense Probes

System Mode: Ready | Not Ready

WARNINGS

- **Never wear exposed metal that can come into contact with electrical components of the instrument.**
- **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.**



Correctly Routed Dispense Probe Tubing

1: Dispense probe strain relief (in gray)

2: Correct: The dispense probe strain relief is not routed beneath the aspirate probe plate and support arm

3: A1 aspirate probe tubing routed above the aspirate probe plate and support arm

2268J.svg

Maintenance Log

UniCel Dxl system **Serial # _____ System ID _____ Month _____Year _____**

DAILY MAINTENANCE	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
Back Up the System																															
Record the Test Count *(Rotate the form to record the test count number)*																															
Shake the Solid Waste Container																															
Run the Daily Clean Routine (D) or the Special Clean Routine (S)	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S	D S
Tech Initials																															

SPECIAL WEEKLY MAINTENANCE (if running tests for HIV antibody levels)	On Date	On Date	On Date	On Date	On Date
Install Clean Aspirate Probes					
Verify System Performance (Run Clean Routine and QC)					
Tech Initials					

5,000 TEST INTERVAL MAINTENANCE	On Date	On Date	On Date	On Date	On Date	On Date
Replace the Duck Bill Valve						
Verify System Performance (Run Clean Routine and QC)						
Tech Initials						

10,000 TEST INTERVAL MAINTENANCE	On Date	On Date	On Date
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 Pipettors and Clean the Wash Towers			
Inspect for Fallen RVs			
If your system uses bulk liquid waste containers, 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.

7 Troubleshooting

Event Log

The Event Log is a list of events the UniCel DxI system generates as it monitors the status of various system parameters. You can use these events to keep informed of system operations and to assist with troubleshooting.

Troubleshooting Events

You can view technical information about an event in the Details window. The event details can be useful for troubleshooting. Caution and Warning events may include suggestions for fixing the problem.

Before you contact Technical Support for assistance, either print the event details or write down all of the information displayed in the Details window.

QC Troubleshooting

QC results can fail for a variety of reasons including past-due maintenance, cold substrate, QC material stability, reagent stability, calibrator stability, and instrument hardware or software problems.

Use the following procedure to troubleshoot QC problems.

NOTE

For assays that have more than one reagent pipettor assigned, any troubleshooting step that produces acceptable QC results should be repeated on all pipettors that previously produced failed QC results.

1. Identify event log errors. Contact Technical Support if you need help troubleshooting event log errors.
2. Troubleshoot test result flags.
3. Verify that the sample container has sufficient volume, and has been loaded in the correct rack and the correct sample container position. If not, correct the problem and repeat the test.
4. Verify that routine maintenance has been performed. If it has not, perform the required maintenance tasks and then repeat the QC test.
5. Verify that the substrate was equilibrated to room temperature before being loaded. If it was not equilibrated, repeat the QC test after the substrate has equilibrated. For the recommended temperature and equilibration time, see the substrate reagent instructions for use.

6. To eliminate random errors as a cause of the QC failure, pipette a fresh sample from the vial in use and rerun the test. Use the Rerunning a QC Test procedure to ensure that the test is repeated with the same reagent pipettor and reagent pack.

NOTE

Statistically, even with an appropriate mean and 2SD range, 1 of 20 QC results will be out of range, and 1 of 333 QC results will be out of the 3SD range.

7. Check for problems with QC materials:

Quality control material stability	1. Prepare new quality control according to the procedure provided by the manufacturer. 2. Load the freshly prepared quality control and repeat the test.
Wrong quality control loaded onto the sample rack	1. Load the correct quality control. 2. Repeat the test.
Wrong quality control lot number selected for the test	Repeat the test using the correct lot number.
Wrong mean and/or standard deviation information entered when setting up the quality controls	1. Review the QC information using **Edit Control F2** from the QC Setup screen. 2. If necessary, edit the information. 3. Repeat the test.

WARNING

System Check Solution and wash buffer contain a preservative which may cause sensitization by skin contact. After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves.

8. Run the System Check routines. If results are out of range, contact Technical Support.

9. Identify any reagent pipettor that is producing failed QC results for all assays that run on that pipettor.

   a. If QC failures are coming from one pipettor, clear the assignment of that pipettor in the test setup for each failing assay.

   b. If the pipettor that became unassigned in step a was the only pipettor assigned to a test, assign a different pipettor to that test.

   c. Repeat the QC test by entering a new QC test request.

NOTE

Because the reagent pipettor that was used for the failed QC test is no longer assigned to that test, you cannot rerun the test by using the Rerunning a QC Test procedure.

   d. If QC results from other pipettors are satisfactory, disable the failing pipettor on the Supplies Setup screen until repairs can be made.

10. Recalibrate the assay to compensate for subtle changes in the instrument or reagent.

11. If none of the preceding steps resolve the problem, contact Technical Support.

Rerunning a QC Test

If a quality control test produces questionable results, use this procedure to rerun the test. The system uses the same reagent pipettor and reagent pack to eliminate random errors as a cause of the questionable result.

System Mode: Any Mode

1. Go to the Test Results screen, then locate and select the result you want to rerun.

   NOTE

   Only select a single result. If you select a group of results and then select **Rerun Test F3**, only the result indicated with the Arrow button is rerun.

2. Select **Rerun Test F3.** A message informs you that the test has been reordered, and the test is added to the work pending list.

   NOTE

   After the test has been added to the work pending list, the test will be applied automatically to the next request for that QC.

3. Go to the Sample Manager screen and select **New Request F3**, then select **Patient/QC Requests F1** to display the Test Requests screen.

4. Enter the rack ID in the **Enter ID** field and press **[Enter]**.

5. Select **Request QC F5**.

   The Request QC window is displayed.

6. Select the quality control to rerun. The test is automatically removed from the work pending list, and is added to the test list for the quality control.

7. Complete the test request by exiting the Test Requests screen.

8. Place the QC sample in the rack entered in step 4, and load the rack on the instrument.

   NOTE

   If the reagent pipettor or the reagent pack are unavailable, the sample status will be changed to **Supply Wait** and the test will not rerun until both the reagent pipettor and the reagent pack are available. When the supply condition has been cleared, the test will rerun automatically.

Test Result Flags and Troubleshooting

The following tables provide troubleshooting information associated with test result flags that are fatal (no calculated result) or non-fatal (calculated result, but a condition exists for that result). Use the information to identify and correct assay related problems. This information is also provided online when you select **Troubleshoot F2** from the Sample Details window.

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.

NOTE

Before performing corrective actions, make sure that you are familiar with the troubleshooting process.

Fatal Flags

Fatal Flag	Description	Corrective Action
AEX	The aliquoted sample cannot be used for one or more of the following reasons: • An error occurred when the aliquot was dispensed into the vessel. • The aliquot has been on board the instrument for up to three hours and has expired. • The last test taken from the aliquot was completed one hour ago.	1. Review the Event Log for error events with a similar date and time to this event. If events are found, troubleshoot according to available information or contact Technical Support. 2. Make sure that required supplies are on board before running the test again. 3. Check the test status in the Result column of the Test Result screen and take one of the following actions: • For calibrator and maintenance samples with the test status **Cancelled:** Request the test again and load a fresh quantity of sample. • For patient and QC samples with the test status **Requested:** Load a fresh quantity of sample. The test is run automatically.
CCR	A result could not be calculated because: • One of the tests included in a derived result formula did not produce a result. • A confirmatory test result could not be calculated. Usually this occurs because the samples for the qualitative and confirmatory tests were not aspirated at the same time. • Another error prevented the system from calculating a result.	1. Take one of the following actions: • For results other than derived results, skip to step 2. • For derived results, review each test result used in the derived result formula. If a result failed, troubleshoot according to the flag for that result. 2. Review the Event Log for error events with a similar date and time to this event. If events are found, troubleshoot according to available information or contact Technical Support. 3. Repeat the test. • For a derived result, repeat all tests included in the derived result formula. • For a confirmatory result, repeat the confirmatory and qualitative tests.

Fatal Flag	Description	Corrective Action
CLT	An obstruction was detected in the sample tube before aliquoting or in the RV during processing.	Check the test status in the Result column of the Test Result screen. • For patient and QC samples with the test status **Requested:** 1. Take the necessary steps to remove or disperse the obstruction, or obtain a fresh quantity of sample. 2. Load the sample. The test is run automatically. 3. If the problem persists, contact Technical Support. • For samples with the test status **Cancelled**: 1. Take the necessary steps to remove or disperse the obstruction, or obtain a fresh quantity of sample. 2. Determine if the Automatic Rerun feature is enabled and take one of the following actions. • If the Automatic Rerun feature is not enabled, proceed to step 3. • If the Automatic Rerun feature is enabled, the test has been reordered automatically. Proceed to step 4. 3. Request the test again. 4. Load the sample. **Note:** Do not load the sample for automatic rerun requests unless the test has been added to work pending. If sufficient reserve volume is onboard the instrument, and all other supplies are acceptable, the test runs automatically. 5. If the problem persists, contact Technical Support.
IND	• For **sandwich assays,** which use positive slope calibration curves, the result is at the **low** end of the concentration curve and cannot be distinguished from a system failure because the RLU reading is too **low**. • For **competitive assays**, which use negative slope calibration curves, the result is at either: • The **high** end of the concentration curve and cannot be distinguished from a system failure because the RLU reading is too **low**, or • The **low** end of the concentration curve and cannot be distinguished from a system failure because the RLU reading is too **high**.	1. For IND flagged results which meet the following criteria, dilute and rerun the sample: • The result is on a **competitive** assay, **and** • Sample dilution is allowed for the assay, **and** • The sample RLU is **low**. See the reagent instructions for use to determine the assay type and whether sample dilution is allowed. 2. Rule out a system problem by reviewing the Event Log for error events with a date and time shortly before this event. Troubleshoot accordingly. 3. If you have ruled out a system problem and the IND flag event is the only issue, recalibrating the affected assay may resolve the problem. • Recalibrate the assay using a new reagent pack and a new set of calibrators. • Run QC. • Repeat the test on the affected sample. If IND flags persist, contact Technical Support.
NCR	No calibration data existed for the reagent lot when the patient or QC result was processed.	1. Calibrate the assay. 2. Repeat the test.

Fatal Flag	Description	Corrective Action
QNS	The sample volume is insufficient in the sample container or in the RV during processing. If the flag is applied because of insufficient volume in the RV, and Automatic Rerun is enabled, the test will be reordered. Otherwise, additional tests will not be scheduled for this sample. Tests already scheduled will be completed.	Check the test status in the Result column on the Test Result screen. • For patient and QC samples with the test status **Requested**: 1. Identify event log errors. Contact Technical Support if you need help troubleshooting event log errors. 2. Pipette sufficient sample volume into the sample container and make sure the rack is appropriate for the sample container. 3. Load the sample. The test is run automatically. 4. If the problem persists, contact Technical Support. • For samples with the test status **Cancelled**: 1. Identify event log errors. Contact Technical Support if you need help troubleshooting event log errors. 2. Determine if the Automatic Rerun feature is enabled and take one of the following actions. - If the Automatic Rerun feature is not enabled, proceed to step 3. - If the Automatic Rerun feature is enabled, the test has been reordered automatically. Take one of the following actions. - If sufficient reserve volume is not onboard the instrument, the test is added to work pending. Proceed to step 4. - If sufficient reserve is onboard the instrument, and all other supplies are acceptable, the test runs automatically. Proceed to step 6. 3. Request the test again. 4. Pipette sufficient sample volume into the sample container and make sure the rack is appropriate for the sample container. 5. Load the sample. **Note:** Do not load the sample for automatic rerun requests unless the test has been added to work pending. If sufficient reserve volume is onboard the instrument, and all other supplies are acceptable, the test runs automatically. 6. If the problem persists, contact Technical Support.
QSB	A substrate dispense failure occurred during processing.	1. Prime the substrate for four cycles. 2. Determine if the Automatic Rerun feature is enabled and take one of the following actions. • If the Automatic Rerun feature is not enabled, proceed to step 3. • If the Automatic Rerun feature is enabled, the test has been reordered automatically. Proceed to step 4. 3. Request the test again. 4. Load the sample. **Note:** Do not load the sample for automatic rerun requests unless the test has been added to work pending. If sufficient reserve volume is onboard the instrument, and all other supplies are acceptable, the test runs automatically. 5. If the problem persists, contact Technical Support.

Fatal Flag	Description	Corrective Action
QSD	Insufficient sample volume or reagent volume was dispensed into an RV.	1. Review the Event Log. Contact Technical Support if you need help troubleshooting event log errors. 2. Determine if the Automatic Rerun feature is enabled and take one of the following actions. • If the Automatic Rerun feature is not enabled, proceed to step 3. • If the Automatic Rerun feature is enabled, the test has been reordered automatically. Proceed to step 4. 3. Request the test again. 4. Load the sample. **Note:** Do not load the sample for automatic rerun requests unless the test has been added to work pending. If sufficient reserve volume is onboard the instrument, and all other supplies are acceptable, the test runs automatically. 5. If the problem persists, contact Technical Support.
QSS	Insufficient sample volume was withdrawn from the sample container or from an RV.	Follow the Corrective Action instructions for the QSD flag.
RLU	The relative light units (RLUs) are outside the acceptable luminometer measuring range.	Follow the Corrective Action instructions for the QSD flag.
SYS	A device error occurred during processing.	Follow the Corrective Action instructions for the QSD flag.
TRI	The temperature of the analytical module was outside the acceptable limits when the test was being incubated.	1. Check the wash carousel temperature on the Maintenance Review screen. If the temperature is outside the acceptable limits, periodically monitor the wash carousel temperature on this screen until it is within the acceptable limits. • If the instrument was restarted or instrument covers were recently opened, you may need to wait up to 10 minutes for the temperature to normalize. • If the system was powered down for an extended period of time, you may need to wait up to one hour for the temperature to normalize. 2. When the wash carousel temperature is within the acceptable limits, determine if the Automatic Rerun feature is enabled and take one of the following actions. • If the Automatic Rerun feature is not enabled, proceed to step 3. • If the Automatic Rerun feature is enabled, the test has been reordered automatically. Proceed to step 4. 3. Request the test again. 4. Load the sample. **Note:** Do not load the sample for automatic rerun requests unless the test has been added to work pending. If sufficient reserve volume is onboard the instrument, and all other supplies are acceptable, the test runs automatically. 5. If the temperature does not normalize, or if the problem persists, contact Technical Support.

Fatal Flag	Description	Corrective Action
TRS	The temperature of the substrate was outside the acceptable limits when the substrate was dispensed.	1. Check the substrate temperature on the Maintenance Review screen. If the temperature is outside the acceptable limits, periodically monitor the substrate temperature on this screen until it is within the acceptable limits. • If the instrument was restarted or instrument covers were recently opened, you may need to wait up to 10 minutes for the temperature to normalize. • If the system was powered down for an extended period of time, you may need to wait up to one hour for the temperature to normalize. 2. When the substrate temperature is within the acceptable limits, determine if the Automatic Rerun feature is enabled and take one of the following actions. • If the Automatic Rerun feature is not enabled, proceed to step 3. • If the Automatic Rerun feature is enabled, the test has been reordered automatically. Proceed to step 4. 3. Request the test again. 4. Load the sample. **Note:** Do not load the sample for automatic rerun requests unless the test has been added to work pending. If sufficient reserve volume is onboard the instrument, and all other supplies are acceptable, the test runs automatically. 5. If the temperature does not normalize, or if the problem persists, contact Technical Support.
TRW	The temperature of the analytical module was outside the acceptable limits when the reaction vessel was in the wash carousel.	Follow the corrective actions provided for the TRI flag.

Non-Fatal Flags

Non-Fatal Flag	Description	Corrective Action
CEX	The calibration curve or cut-off value is expired.	1. Recalibrate the assay. 2. Repeat the test.
CLX	The calibrator lot is expired. **Note:** For patient and QC tests, the calibrator lot may have expired after a successful calibration.	• For patient and QC tests: Review the Calibration Data screen to determine whether replicates of the active calibration are associated with the CLX flag. Then take one of the following actions: • If the calibration is not associated with the flag, the patient or QC test result is a valid result. No corrective action is necessary. • If the calibration is associated with the flag, and you did not intend to run the QC or patient test using this calibration, calibrate the assay again with a calibrator lot that has not expired. Request the QC or patient test again. • If the calibration is associated with the flag, and you intended to run the QC or patient test using this calibration, no corrective action is necessary. • For calibrations: If you did not intend to calibrate with an expired lot, run another calibration with a calibrator lot that has not expired. Otherwise, no corrective action is necessary.

Non-Fatal Flag	Description	Corrective Action
CRH	The patient test result is above the upper limit of the critical range.	This is a valid test result. No corrective action is necessary.
CRL	The patient test result is below the lower limit of the critical range.	This is a valid test result. No corrective action is necessary.
DEX	The open pack stability time has expired for the diluent pack. The system measures open pack stability separately by well. **Note:** For an LIS attached to a DxI instrument, the PEX flag is sent to the LIS in place of the DEX flag.	1. Make sure sufficient unexpired diluent is available. 2. Repeat the test.
EXS	The substrate is expired.	1. Review the expiration date on the Bulk Supplies screen. 2. If necessary, change the substrate bottle. 3. Repeat the test.
GRY	For qualitative assays, the patient or QC result is within the specified gray zone, also known as the equivocal zone.	This is a valid test result. No corrective action is necessary. In some cases, the GRY flag may be applied to a result with an S/CO value which appears to be at the upper or lower limit of the gray zone, so would not be expected to be in the gray zone. You may also observe multiple results with the same S/CO, some of which have the GRY flag and some of which do not. This is because the GRY flag is applied before the final rounding of the S/CO to two decimal places. If your laboratory prefers to avoid these situations, contact Technical Support for instructions on setting the gray zone limits.
LEX	The reagent or diluent pack lot is expired.	1. Unload all of the packs from the expired reagent lot and load a pack from a new lot. 2. Repeat the test.
LOW	The patient or QC result is lower than the minimum reportable result value defined in the APF.	No corrective action is necessary.
LRH	The patient result is above the upper limit of the LIS range. **Notes:** • If the **Auto-Send to LIS** option is set to **Verify**, the system does not automatically send results with this flag to the LIS. • This flag is for quantitative assays, semi-quantitative assays, and derived results only.	1. Review the result. 2. Take one of the following actions: • Send the result to the LIS manually. • Delete the result and repeat the test.
LRL	The patient result is below the lower limit of the LIS range. **Notes:** • If the **Auto-Send to LIS** option is set to **Verify**, the system does not automatically send results with this flag to the LIS. • This flag is for quantitative assays, semi-quantitative assays, and derived results only.	1. Review the result. 2. Take one of the following actions: • Send the result to the LIS manually. • Delete the result and repeat the test.
ORH	The patient result is above the upper limit of the reference range.	No corrective action is necessary.
ORL	The patient result is below the lower limit of the reference range.	No corrective action is necessary.

Non-Fatal Flag	Description	Corrective Action
OVR	The calculated concentration is above the highest or most concentrated calibrator. This flag is only used for quantitative and semi-quantitative assays.	1. Review the Event Log for error events with a similar date and time to this event. • If events occurred, troubleshoot. 2. Take one of the following actions: • If events occurred, and you performed troubleshooting procedures, run controls and then repeat the test. - If the controls are in range, and the test result is reported as greater than the value of the highest calibrator (>X), you may be able to dilute the sample. To identify whether the assay allows dilutions, see the reagent instructions for use. - If the controls are not in range, follow the QC troubleshooting instructions. • If no events occurred, take one of the following actions: - If the test result is reported as >X, you may be able to dilute the sample. To identify whether the assay allows dilutions, see the reagent instructions for use. - If dilutions are allowed, dilute and repeat the test. - If dilutions are not allowed, no further action is necessary. 3. If you have questions about the result, or if the problem persists, contact Technical Support.
PEX	The open pack stability time has elapsed for the reagent pack. The system starts measuring open pack stability when it first punctures the pack. **Note:** For an LIS attached to a DxI instrument, the PEX flag is sent to the LIS in place of the DEX flag.	1. Unload the expired reagent pack and load a new one. • If the lot number of the new reagent pack is different than the expired pack, recalibrate the assay. 2. Repeat the test.
QCF	The quality control result violates one or more QC rules.	1. Display the QC Chart and Data screen to review which criteria is not met. 2. Follow the QC troubleshooting instructions.
QEX	The quality control lot is expired.	1. Add a new, unexpired quality control lot. Make sure that expected means and SDs are established according to laboratory guidelines. 2. Repeat the test.
RFX	The patient sample result is from a reflex test.	No corrective action is necessary for this flag alone.
TRA	The temperature of the sample wheel was outside the acceptable limits when the sample aliquot was in the sample wheel.	1. Check the sample wheel temperature on the Maintenance Review screen. If the temperature is outside the acceptable limits, periodically monitor the sample wheel temperature on this screen until it is within the acceptable limits. • If the system was restarted or instrument covers were opened recently, you may need to wait up to 10 minutes for the temperature to normalize. • If the system was powered down for an extended period of time, you may need to wait up to one hour for the temperature to normalize. 2. When the sample wheel temperature is within the acceptable limits, repeat the test. 3. If the temperature does not normalize, or if the problem persists, contact Technical Support.

Non-Fatal Flag	Description	Corrective Action
TRR	The temperature of the reagent storage chamber was outside the acceptable limits when reagents were pipetted.	1. Check the reagent storage chamber temperature on the Maintenance Review screen. If the temperature is outside the acceptable limits, periodically monitor the reagent storage chamber temperature on this screen until it is within the acceptable limits. • If the system was restarted or the instrument storage chamber cover was recently opened, you may need to wait up to 10 minutes for the temperature to normalize. • If the system was powered down for an extended period of time, you may need to wait up to one hour for the temperature to normalize. 2. When the reagent storage chamber temperature is within the acceptable limits, repeat the test. 3. If the temperature does not normalize, or if the problem persists, contact Technical Support.

8 Theory of Operation

Sample Processing

The UniCel DxI Access Immunoassay System is an automated analyzer that performs a wide variety of immunoassays on body fluid samples. The system starts sample processing when it receives a test request either from the laboratory information system (LIS), or from the system console.

Once a test request is entered, you place the sample in a rack and load it in the sample presentation unit (SPU) onload area. The instrument automatically moves the rack to the aliquot station, scans the bar codes on the rack and sample tube, aliquots enough sample to complete all requested tests and replicates into one or more reaction vessels (RVs), and stores the RVs in the refrigerated sample storage area. The rack is then moved to the SPU offload area, where you can unload and reclaim any unused quantity of sample for further testing.

Reserve Volume

The system can be set up to draw an additional volume of sample that can be used for system generated reflex tests, LIS downloaded reflex tests, reruns, or late LIS requests. The additional volume is called a reserve volume. When the system is set up to draw reserve volumes, a reserve volume may be drawn from patient and QC samples in racks that are designated for reserve volume.

Individual sample racks can be designated by rack ID for no reserve volume, or for one of two types of reserve volume: flexible or standard.

- For samples in flexible reserve volume racks, the system calculates the reserve volume for each sample based on the tests requested for that sample and the reflex conditions set up for the requested tests. A flexible reserve volume is drawn only when at least one reflex condition is defined and enabled for at least one of the tests requested for the sample.
- For samples in standard reserve volume racks, the system always draws a fixed volume, regardless of other considerations.

NOTE

If the instrument is connected to a laboratory automation system (LAS), you can also set up the system to draw flexible or standard reserve volumes from all sample containers presented to the instrument by the LAS. This function is independent of rack designations, and has no effect on the way samples in racks are handled by the SPU.

You enable the reserve volume feature and set up the standard quantity of sample to draw in the Reserve Volume Setup window.

The system calculates the dead volume and overdraw and draws enough sample to make the entire reserve volume available for tests. If the volume required for requested tests plus the reserve volume will not fit in one RV, all of the reserve volume is dispensed into one or more additional RVs.

The system draws reserve volumes only from sample containers in racks that are designated for reserve volumes. You designate racks for reserve volumes and select the type of reserve volume to be used for each rack in the Add/Edit Racks window. Racks should be labeled according to their designation, with either a Flexible Reserve or a Standard Reserve label, or, if no reserve volume is to be drawn, with a No Reserve label.

Unused reserve volume is discarded when the sample expires, or when sample storage capacity is reached and more room is needed to process samples, whichever comes first.

Onboard Dilutions*

Assays with the onboard dilution feature provide two tests in the assay protocol file (APF): the parent test, which analyzes a neat (undiluted) sample, and the onboard dilution test, which uses the same protocols as the parent test, but performs a dilution step before processing. The dilution factor used for onboard dilution tests is fixed in the APF.

NOTE

The parent test can be diluted manually, in which case the dilution factor for the sample must be entered in the Test Requests screen.

See the reagent instructions for use to determine if onboard dilutions are supported for a particular assay.

You can use the reflex test feature, with reserve volume, to automatically request onboard dilution tests of samples that have analyte concentrations that exceed the calibration limits of the assay.

If you expect the analyte concentration in a sample to be high, you can request onboard dilution tests directly from the console or with a LIS.

Onboard dilution tests use the same processes and calibration curves as the corresponding parent tests. Onboard dilution tests have test names beginning with **d** and they require separate setup, including ranges, units of measure, default sample type, and decimal places.

NOTE

Another type of onboard dilution is the special dilution. Special dilution tests work similarly to onboard dilution tests, but only a small number of assays support this feature. Special dilution tests have names beginning with Dil-, and must be set up on the system by a technical support representative.

Supply and Calibration Verification

Before the system runs a test, it verifies that it has sufficient quantities of the required supplies. If supplies are needed or waste containers need to be emptied, the system prompts you to take appropriate action.

The system also verifies that the substrate, reagent pack, and assay calibration for the requested test are not expired. If a calibration or a time-sensitive supply is expired, the system prompts you to replace the supply or recalibrate the assay.

* The availability of the UniCel DxI onboard dilution feature in your country depends on the status of submissions to local regulatory agencies. Please contact you Beckman Coulter representative if you have questions about the availability in your geography.

NOTES

- You can run tests with expired supplies or calibrations by overriding the conditions, but the system applies appropriate flags to the test results.
- Quality control tests run with expired supplies or calibrations will produce results, but the results will not be added to the QC database.

The system notifies you when it cannot run a test because of certain critical instrument conditions. The Supplies Required screen identifies the affected instrument subsystem and the procedure that is required to correct the condition. Select the **Help** button in the notification to view related information and instructions.

Sample Processing Order

The UniCel DxI system determines the optimal processing order using the criteria listed below. The system processes the samples with the highest priority first.

Processing Order	Criteria
1	STAT samples
2	Calibrator sample sets
3	QC samples
4	Patient samples
5	Maintenance sets

The priority is assigned when the sample is aliquoted. Sets of calibrator and maintenance samples are prioritized after all of the samples in the set are aliquoted.

If two or more samples have the same priority, the system gives priority to the first sample aliquoted. If a higher-priority test cannot start because a system resource (such as a reagent pack) is not available, a lower-priority test may be processed first.

Reagent Addition

When the system is ready to process a sample, the RV is moved by a robotic module to one of the reagent carriages, where a dedicated reagent pipettor transfers the required volume of sample into another RV. If required by the assay protocol file (APF), a dilution is made at this time.

The reagent pipettor transfers specified quantities of reagents into the RV. The robotic module moves the RV to the incubator, where it remains for a period of time specified in the APF. During the incubation period, paramagnetic particles from the reagents bind with analyte from the sample.

In two-step assays, the RV returns to one of the reagent carriages for additional reagents, followed by another incubation period.

Sample Washing and Reading

When the sample incubation is complete, the RV is moved to the wash carousel to begin final processing. As the wash carousel rotates, the RV moves through three wash stations.

In each wash station, a dispense probe adds wash buffer to the RV. Magnets then draw the paramagnetic particles out of suspension, and pull them to the side of the RV. Finally, an aspirate probe removes the wash buffer, along with the unbound analyte.

After completing three wash cycles, the RV is moved to the substrate probe, which dispenses chemiluminescent substrate into the RV.

As the RV continues to move around the wash carousel, the substrate reacts with the enzyme-tagged analyte, producing light.

The final position on the wash carousel is the luminometer, which reads the light output from the chemiluminescent reaction. The electrical output of the luminometer is measured and expressed in relative light units (RLU). RLUs are used, in conjunction with assay calibration data, to calculate the test result.

After the luminometer reading, the RV is moved to a waste chute and discarded.

Device Calibration

Luminometer Calibration

The luminometer is calibrated in the factory against a luminous standard. Thereafter, the UniCel DxI system 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.

Ultrasonics Calibration

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

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.

Pressure Sensor Calibration

Pressure sensors in the sample pipettor 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.

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 of 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 for priming the substrate line.

Assay Characteristics

See the reagent instructions for use for each assay for information about assay characteristics including:

- Reagent composition, storage, and handling precautions
- Analytical performance
- Sample handling
- Calibrator characteristics and calibration interval
- Calibrator and control traceability

Assay Calibration Theory

The UniCel DxI system performs the following types of assay calibrations:

Quantitative	In general, calibrator test results provide a multi-point calibration curve. The system uses the calibration curve to convert a measured response in RLUs to an analyte concentration and then expresses the result in numerical units.
Semi-Quantitative	Calibrator test results provide a multi-point calibration curve. The system uses the calibration curve to convert a measured response in RLUs to an analyte concentration and then expresses the result in numerical units. These assays may report their quantitative result as a qualitative interpretation, such as positive, negative, or equivocal.
Qualitative	Calibrator test results provide a cutoff value based on a formula defined 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. In the case of a reactive test result, a confirmatory test may be indicated, and automatically requested as a reflex test. The confirmatory assay produces a result of confirmed or not confirmed.

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.

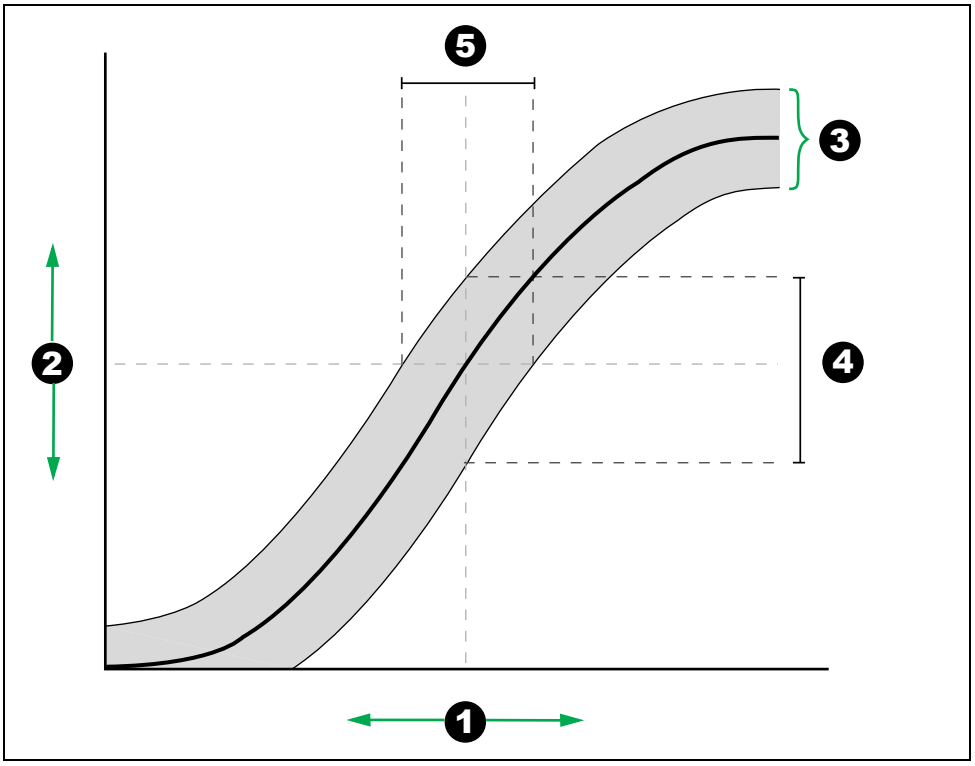
3. Comparing predicted precision and the limits defined in the APF for that assay.

NOTE

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

Calculating Predicted Precision

After an acceptable calibration curve is obtained, the system calculates an error band around the curve. This calculation is based on the 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.



2239A.eps

1	X axis - analyte concentration
2	Y axis - RLUs
3	Error band (shaded area - the width of the error band is exaggerated for illustration purposes)
4	Response precision
5	Concentration precision

Comparing Predicted Precision to Defined Limits

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.

A Temperature-Sensitive Assays

The Access assays listed in the table below are affected by changes in the room temperature of the UniCel DxI system. The result for a given sample test may shift if the room temperature changes significantly from the temperature at which the assay was calibrated. Depending on the assay, an increase or decrease in room temperature causes test results to increase or decrease. The magnitude and direction of the result shift for each assay is shown in the table.

If the change in room temperature exceeds the restricted calibration temperature range, the assay must be recalibrated at the new temperature before samples are tested. Recalibrating these assays at the new room temperature limits the magnitude of the shift on sample results.

For each of the affected assays, Beckman Coulter has established a restricted calibration temperature range in which the assay should be calibrated and run. Within this range, the change in assay results due to temperature is expected to be within the allowable performance characteristics of the assay.

Part #*	Product*	Restricted calibration temperature range	Allowable % Change i n result	If the temperature increases, the assay result…
33000	Access Vitamin B_{12}	±4 °C (±7.2 °F)	±14%	Increases
33210	Access AFP (100 Test Kit)	±4 °C (±7.2 °F)	±10%	Increases
33211	Access AFP (300 Test Kit)	±4 °C (±7.2 °F)	±10%	Increases
33410	Access Ultrasensitive Insulin	±4 °C (±7.2 °F)	±9%	Increases
33540	Access Estradiol	±4 °C (±7.2 °F)	±19%	Decreases
33560	Access Testosterone	±4 °C (±7.2 °F)	±9%	Decreases
33580	Access Ultrasensitive hGH	±4 °C (±7.2 °F)	±10%	Increases
33600	Access Cortisol	±4 °C (±7.2 °F)	±12%	Decreases
33880	Access Free T4	±4 °C (±7.2 °F)	±12%	Increases
34210	Access HAV IgM	±4 °C (±7.2 °F)	±10%	Increases
34240	Access HBc Ab	±4 °C (±7.2 °F)	±10%	Increases
34250	Access HBc IgM	±4 °C (±7.2 °F)	±15%	Increases
34430	Access Rubella IgG	±4 °C (±7.2 °F)	±15%	Increases
98200	Access BNP	±4 °C (±7.2 °F)	±9%	Decreases
386371	Access CK-MB	±4 °C (±7.2 °F)	±10%	Increases
A12985	Access TPO Antibody	±4 °C (±7.2 °F)	±14%	Increases

Part #*	Product*	Restricted calibration temperature range	Allowable % Change i n result	If the temperature increases, the assay result…
A13422	Access Free T3	±4 °C (±7.2 °F)	±16%	Increases
A16972	Access Intact PTH - Intraoperative Mode (Test IDs 215 & 11215 only)	±4 °C (±7.2 °F)	±14%	Increases
A31588	Access Toxo IgG	±5 °C (±9.0 °F)	±20%	Increases
A36097	Access Inhibin A	±4 °C (±7.2 °F)	±10%	Decreases
A40702	Access CMV IgG	±5 °C (±9.0 °F)	±15%	Increases
A48617	Access SHBG	±5 °C (±9.0 °F)	±18%	Increases
A49752 B03704	Access Hybritech p2PSA	±6°C (±10.8 °F)	±16.9%	Decreases

* The availability of these assays in your country depends on the status of submissions to local regulatory agencies. Contact your Beckman Coulter representative if you have questions about the availability of particular assays.

The UniCel DxI system does not monitor the room temperature or alert the operator if room temperature changes from the original calibration temperature for assays identified in the table. You should ensure that your laboratory has established a procedure to monitor and review temperature during system operation. Quality control may not detect temperature related change in assay results and cannot be used as a substitute for temperature monitoring.

If your laboratory is unable to maintain the required temperature ranges, do not report results out of the laboratory. Please contact Beckman Coulter for additional suggestions regarding temperature monitoring and control.

B Ordering Information

Assay-Specific Reagents

The availability of these assays in your country depends on the status of submissions to local regulatory agencies. In addition, an assay may not be available for use on all systems. Contact your Beckman Coulter representative if you have questions about the availability of particular assays.

To obtain assay-specific reagents:

- In the U.S.A. or Canada, contact Beckman Coulter Customer Service at 1-800-526-3821.
- Outside the U.S.A. and Canada, contact your local Beckman Coulter representative.

Access Assay Name	Analyte	Part #	Description	Volume*	# Tests or # Calibrations (@ 500 µL/ Calibration)
Adrenal/ Pituitary					
Cortisol	Cortisol	33600	Reagent	2 x 50 tests	100
		33605	Calibrator	6 x 4.0 mL	8
		33606	Diluent (S0)	1 x 4.0 mL	
Anemia					
Active-B12† / Active-B12-Diluted	Holotranscobalamin (holoTC); Active B12	C01772	Reagent	2 x 50 tests	100
		C01773	Calibrator	6 x 2.0 mL	4
		C01774	QC	2 levels, 3.0 mL each	
EPO/ EPO-Diluted	Erythropoietin	A16364	Reagent	2 x 50 tests	100
		A16365	Calibrator	6 total; S0 @ 10 mL S1–S5 @ 2.5 mL	5
		A79783	Diluent Pack	2 x 90 tests	180
Ferritin / Diluted Ferritin / Ferritin-Diluted	Ferritin	33020	Reagent	2 x 50 tests	100
		33025	Calibrator	6 x 4.0 mL	8
		A79784	Diluent Pack	2 x 102 tests	204
Folate / Red Blood Cell (RBC) Folate / Folate-Diluted	Folic acid; Folate	A98032	Reagent	2 x 50 tests	100
		A98033	Calibrator	6 x 4.0 mL	8
		A99250	Diluent (S0)	1 x 4.0 mL	
		A14206	Lysing Agent	2 x 100 mL	
		A79784	Diluent Pack	2 x 174 tests	348
Intrinsic Factor Ab	Intrinsic factor blocking antibody	387992	Reagent	2 x 50 tests	100
		387993	Calibrator	1 level; 2 x 4.0 mL	16
		387999	QC	2 levels; 3 x 4.0 mL each	
sTfR / sTfR-Diluted	Soluble transferrin receptor	A32493	Reagent	2 x 50 tests	100
		A32494	Calibrator	6 total; S0 @ 4 mL S1–S5 @ 2.5 mL	5
		B11056	QC1	1 level; 2 x 2.5 mL each	
		B11057	QC2 & QC3	2 levels; 2 x 2.5 mL each	
		A79784	Diluent Pack	2 x 70 tests	140

Access Assay Name	Analyte	Part #	Description	Volume*	# Tests or # Calibrations (@ 500 µL/ Calibration)
Vitamin B_{12} / Vitamin B_{12}-Diluted	Vitamin B12; Cobalamin	33000	Reagent	2 x 50 tests	100
		33005	Calibrator	6 x 4.0 mL	8
		33006	Diluent (S0)	1 x 4.0 mL	
		A79783	Diluent Pack	2 x 102 tests	204
Vitamin B_{12} II Calibrators		D06116	Calibrator	6 x 4.0 mL	8
Blood Virus					
HAV Ab†	Hepatitis A virus antibody	34200	Reagent	2 x 50 tests	100
		34205	Calibrator	5 x 2.0 mL	4
		34209	QC	2 levels; 3 x 3.5 mL each	
HAV IgM†	Hepatitis A virus IgM antibody	34210	Reagent	2 x 50 tests	100
		34215	Calibrator	2 x 1.0 mL	2
		34219	QC	2 levels; 3 x 2.5 mL each	
HBc Ab†	Hepatitis B virus core antibody	34240	Reagent	2 x 50 tests	100
		34245	Calibrator	2 x 1.0 mL	2
		34249	QC	2 levels; 3 x 2.0 mL each	
HBc IgM†	Hepatitis B virus core IgM antibody	34250	Reagent	2 x 50 tests	100
		34255	Calibrator	2 x 1.0 mL	2
		34259	QC	2 levels; 3 x 2.5 mL each	
HBs Ab†	Hepatitis B virus surface antibody	A24296	Reagent	2 x 50 tests	100
		A24297	Calibrator	6 x 2.5 mL	5
		A24298	QC	2 levels; 3 x 3.5 mL each	
HBs Ag†	Hepatitis B virus surface antigen	A24291	Reagent	2 x 50 tests	100
		A24292	Calibrator	2 x 2.7 mL	5
		A24294	QC	2 levels; 3 x 4.0 mL each	
HBs Ag Confirmatory†	Hepatitis B virus surface antigen confirmatory	A24295	Confirmatory	2 x 50 tests (2 x 25 patient samples)	100 (50 patient samples)
HCV Ab PLUS†,**	Anti-hepatitis C virus antibodies	34330	Reagent	2 x 50 tests	100
		34335	Calibrator	2 x 1.0 mL	2
		34339	QC (Pos/Neg)	2 levels; 3 x 2.5 mL each	
HCV Ab V3†,**	Anti-hepatitis C virus antibodies	B33458	Reagent	2 x 50 tests	100
		B33459	Calibrator	2 levels; 1 x 1.0 mL each	4
		B33460	QC	2 levels; 2 x 3.5 mL each	
HIV Combo†,**	HIV p24 antigen and antibodies to HIV-1/O/2	A59428	Reagent	2 x 50 tests	100
		A59429	Calibrator (Pos/Neg)	2 x 1.7 mL	3
		A59430	QC1, QC2, and QC3	3 levels; 2 x 4.4 mL each	
		B22822	QC4 and QC5	2 levels; 2 x 4.4 mL each	
Bone Metabolism					
Intact PTH / Intact PTH-Diluted	Parathyroid hormone, intact (routine and intraoperative)	A16972	Reagent	2 x 50 tests	100
		A16953	Calibrator	6 x 1.0 mL	2
		A79783	Diluent Pack	2 x 60 tests	120

Access Assay Name	Analyte	Part #	Description	Volume*	# Tests or # Calibrations (@ 500 µL/ Calibration)
Ostase / Ostase-Diluted	Bone specific alkaline phosphatase	37300	Reagent	2 x 50 tests	100
		B83876	Calibrator	6 x 2.5 mL	5
		B83877	QC	2 levels; 4.0 mL each	
		A79783	Diluent Pack	2 x 123 tests	246
Ultrasensitive hGH / Ultrasensitive hGH-Diluted	Growth hormone	33580	Reagent	2 x 50 tests	100
		33585	Calibrator	6 x 2.0 mL	4
		A79783	Diluent Pack	2 x 174 tests	348
25(OH) Vitamin D Total†	25(OH) vitamin D	A98856	Reagent	2 x 50 tests	100
		A98857	Calibrator	6 x 1.4 mL	2
Cardiovascular					
BNP / BNP-Diluted	B-type natriuretic peptide (BNP)	98200	Reagent	2 x 50 tests	100
		98202	Calibrator	6 x 1.5 mL	3
		98201	QC	3 levels; 2 x 2.5 mL each	
CK-MB / CK-MB-Diluted	Creatine kinase, isoenzyme MB	386371	Reagent	2 x 50 tests	100
		386372	Calibrator	6 x 2.0 mL	4
		A79783	Diluent Pack	2 x 174 tests	348
Digoxin / Digoxin-Diluted	Digoxin	33710	Reagent	2 x 50 tests	100
		33715	Calibrator	6 x 4.0 mL	8
		33716	Diluent (S0)	1 x 4.0 mL	
		A79783	Diluent Pack	2 x 174 tests	348
hsTnI / hsTnI-Diluted	High sensitivity troponin I	B52699	Reagent	2 x 50 tests	100
		B52700	Calibrator (Outside US only)	7 total; S0-S2 @ 1.5 mL S3-S6 @ 1.0 mL	2
		C26909	Calibrator (US only)	7 total; S0-S2 @ 1.5 mL S3-S6 @ 1.0 mL	2
		A79783	Diluent Pack	2 x 60 tests	120
Myoglobin / Myoglobin-Diluted	Myoglobin	973243	Reagent	2 x 50 tests	100
		973244	Calibrator	6 x 1.0 mL	2
		A79783	Diluent pack	2 x 60 tests	120
Diabetes					
C-Peptide / C-Peptide Onboard Pre-Dilution	C-peptide; Connecting peptide	C33451	Reagent	2 x 50 tests	100
		C31860	Calibrator	6 x 2.0 mL	4
		A79783	Diluent pack	2 x 60 tests	120
Ultrasensitive Insulin / Ultrasensitive Insulin-Diluted	Insulin	33410	Reagent	2 x 50 tests	100
		33415	Calibrator	6 x 2.0 mL	4
		A79783	Diluent Pack	2 x 60 tests	120
Infectious Disease					
CMV IgG†	Cytomegalovirus antibody, IgG	A40702	Reagent	2 x 50 tests	100
		A40703	Calibrator	6 x 1.0 mL	2
		A40704	QC	2 levels; 3 x 2.5 mL each	
CMV IgM†	Cytomegalovirus antibody, IgM	A40705	Reagent	2 x 50 tests	100
		A40706	Calibrator	2 x 1.0 mL	2
		A40707	QC	2 levels; 3 x 2.5 mL each	

Access Assay Name	Analyte	Part #	Description	Volume*	# Tests or # Calibrations (@ 500 µL/ Calibration)
Rubella IgG	Rubella antibody, IgG	34430	Reagent	2 x 50 tests	100
		34435	Calibrator	6 x 1.0 mL	2
		34439	QC (Pos/Neg)	2 levels; 3 x 2.5 mL each	
Rubella IgM†	Rubella antibody, IgM	A32937	Reagent	2 x 50 tests	100
		34445	Calibrator	4 x 1.0 mL	2
		34449	QC (Pos/Neg)	2 levels; 3 x 2.5 mL each	
Toxo IgG	*Toxoplasma gondii* antibody, IgG	A31588	Reagent	2 x 50 tests	100
		A31589	Calibrator	6 x 1.0 mL	2
		A31590	QC (Pos/Neg)	2 levels; 3 x 2.5 mL each	
Toxo IgM II	*Toxoplasma gondii* antibody, IgM	34470	Reagent	2 x 50 tests	100
		34475	Calibrator	2 x 1.5 mL	3
		34479	QC (Pos/Neg)	2 levels; 3 x 3.5 mL each	
Inflammation					
IL-6†† / IL-6-Diluted	Interleukin-6	A16369	Reagent	2 x 50 tests	100
		A16370	Calibrator	6 total; S0 @ 4.0 mL S1–S5 @ 2.5 mL	5
		A16371	QC	3 levels; 2 x 2.5 mL each	
		A79783	Diluent Pack	2 x 123 tests	246
Reproductive					
AFP / Diluted AFP / AFP-Diluted	Alpha-fetoprotein	33211	300 test kit (Cals included)	6 x 50 tests Cals: 7 x 2.5 mL	300 5
		33210	100 test kit (outside US only)	2 x 50 tests	100
		33215	Calibrators (for 100 test kit)	7 x 2.5 mL	5
		33216	Diluent	1 x 14.0 mL	
		A79784	Diluent Pack	2 x 132 tests	264
AMH	Anti-Müllerian hormone (AMH)	B13127	Reagent	2 x 50 tests	100
		B13128	Calibrator	6 x 2.0 mL	4
		B13129	QC	3 levels; 2 x 2 mL each	
AMH Advanced†	Anti-Müllerian hormone (AMH)	C62997	Reagent	2 x 50 tests	100
		B13128	Calibrator	6 x 2.0 mL	4
		B13129	QC	3 levels; 2 x 2 mL each	
DHEA-S / DHEA-S-Diluted	Dehydroepiandro-sterone sulfate	A10826	Reagent	2 x 50 tests	100
		A10827	Calibrator	6 x 2.0 mL	4
		A79784	Diluent Pack	2 x 60 tests	120
hFSH / hFSH-Diluted	Follicle stimulating hormone	33520	Reagent	2 x 50 tests	100
		33525	Calibrator	6 x 4.0 mL	8
		A79783	Diluent Pack	2 x 174 tests	348
hLH / hLH-Diluted	Luteinizing hormone	33510	Reagent	2 x 50 tests	100
		33515	Calibrator	6 x 4.0 mL	8
		A79783	Diluent Pack	2 x 174 tests	348

Access Assay Name	Analyte	Part #	Description	Volume*	# Tests or # Calibrations (@ 500 µL/ Calibration)
Inhibin A / Inhibin A-Diluted	Inhibin A	A36097	Reagent	2 x 50 tests	100
		A36098	Calibrator	7 x 2.5 mL	5
		A36100	QC	3 levels; 2 x 2.5 mL each	
		A79783	Diluent Pack	2 x 123 tests	246
PAPP-A† / PAPP-A-Diluted	Pregnancy-associated plasma protein A	A48571	Reagent	2 x 50 tests	100
		A48572	Calibrator	6 x 1.0 mL	2
		A48573	QC	3 levels; 2 x 2.5 mL each	
		A79784	Diluent Pack	2 x 174 tests	348
Progesterone	Progesterone	33550	Reagent	2 x 50 tests	100
		33555	Calibrator	6 total; S0 @ 4.0 mL S1–S5 @ 2.5 mL	5
		33556	Diluent (S0)	1 x 4.0 mL	
Prolactin / Prolactin-Diluted	Prolactin	33530	Reagent	2 x 50 tests	100
		33535	Calibrator	6 total; S0 @ 4.0 mL S1–S5 @ 2.5 mL	5
		A79783	Diluent Pack	2 x 60 tests	120
Sensitive Estradiol / Sensitive Estradiol-Diluted	Estradiol	B84493	Reagent	2 x 50 tests	100
		B84494	Calibrator	6 total; S0 @ 4.0 mL S1-S5 @ 2.0 mL	4
		A79783	Diluent Pack	2 x 174 tests	348
SHBG/ SHBG-Diluted	Sex hormone binding globulin	A48617	Reagent	2 x 50 tests	100
		A48618	Calibrator	6 x 1.0 mL	2
		A48619	QC	2 levels; 3 x 2.0 mL each	
		A79784	Diluent Pack	2 x 60 tests	120
Testosterone	Testosterone, total	33560	Reagent	2 x 50 tests	100
		33565	Calibrator	6 x 2.5 mL	5
Total βhCG (5th IS) / Diluted Total βhCG (5th IS) / Total βhCG (5th IS)-Diluted	βhCG; Beta-hCG	A85264	Reagent	2 x 50 tests	100
		B11754	Calibrator	6 x 4.0 mL	8
		A79784	Diluent Pack	2 x 135 tests	270
Unconjugated Estriol	Unconjugated estriol	C22255	Reagent	2 x 50 tests	100
		C22256	Calibrator	7 total; S0 @ 4.0 mL S1-S6 @ 2.5 mL	5
		33570	Reagent	2 x 50 tests	100
		33575	Calibrator	7 total; S0 @ 4.0 mL S1-S6 @ 2.5 mL	5
Sepsis					
PCT / PCT-Diluted	Procalcitonin (Outside US only)	C22593†	Reagent	2 x 50 tests	100
		C22594†	Calibrator	7 x 2.0 mL	4
	Procalcitonin (US only)	C53987	Reagent	2 x 50 tests	100
		C53986	Calibrator	7 x 2.0 mL	4

Access Assay Name	Analyte	Part #	Description	Volume*	# Tests or # Calibrations (@ 500 µL/ Calibration)
Thyroid					
Free T3	Triiodothyronine, free	A13422	Reagent	2 x 50 tests	100
		A13430	Calibrator	6 x 2.5 mL	5
Free T4	Thyroxine, free	C76421	Reagent	2 x 50 tests	100
		33880	Reagent	2 x 50 tests	100
		33885	Calibrator	6 x 2.5 mL	5
Thyroglobulin	Thyroglobulin	C71762	Reagent	2 x 50 tests	100
		33860	Reagent	2 x 50 tests	100
		33865	Calibrator	6 x 2.0 mL	4
		33866	Diluent	1 x 14.0 mL	
Thyroglobulin Antibody II	Thyroglobulin antibody	C86552	Reagent	2 x 50 tests	100
		A32898	Reagent	2 x 50 tests	100
		A36920	Calibrator	6 total; S0 @ 4.0 mL S1–S5 @ 2.5 mL	5
Total T3	Triiodothyronine	33830	Reagent	2 x 50 tests	100
		33835	Calibrator	6 x 4.0 mL	8
Total T4	Thyroxine	33800	Reagent	2 x 50 tests	100
		33805	Calibrator	6 x 4.0 mL	8
Thyroid Uptake	Thyroxine-binding capacity	33810	Reagent	2 x 50 tests	100
		33815	Calibrator	1 level; 6 x 1.0 mL	12
TPO Antibody/ TPO Antibody-Diluted	Thyroperoxidase Antibody	A12985	Reagent	2 x 50 tests	100
		A18227	Calibrator	6 x 2.0 mL	4
		A79783	Diluent Pack	2 x 60 tests	120
TSH (3rd IS) / Diluted TSH (3rd IS)	Thyroid-stimulating hormone; Thyrotropin	B63284	Reagent	2 x 100 tests	200
		B63285	Calibrator	6 x 2.5 mL	5
Tumor Markers					
AFP / Diluted AFP/ AFP-Diluted	Alpha-fetoprotein	33211	300 test kit (Cals included)	6 x 50 tests Cals: 7 x 2.5 mL	300 5
		33210	100 test kit (outside US only)	2 x 50 tests	100
		33215	Calibrators (for 100 test kit)	7 x 2.5 mL	5
		33216	Diluent	1 x 14.0 mL	
		A79784	Diluent Pack	2 x 132 tests	264
BR Monitor / BR Monitor-Diluted	Cancer antigen 15-3	387620	Reagent	2 x 50 tests	100
		387647	Calibrator	6 x 1.5 mL	3
		A79783	Diluent Pack	2 x 60 tests	120
CEA	Carcinoembryonic antigen	33200	Reagent	2 x 50 tests	100
		33205	Calibrator	6 x 2.5 mL	5
		33206	Diluent	1 x 4.0 mL	
		33209	QC	2 levels; 3 x 2.5 mL each	
GI Monitor / GI Monitor-Diluted	Cancer antigen 19-9	387687	Reagent	2 x 50 tests	100
		387688	Calibrator	6 x 2.5 mL	5
		A79783	Diluent Pack	2 x 60 tests	120

Access Assay Name	Analyte	Part #	Description	Volume*	# Tests or # Calibrations (@ 500 µL/ Calibration)
Hybritech PSA / Hybritech PSA-Diluted	Prostate-specific antigen	37200	Reagent	2 x 50 tests	100
		37205	Calibrator	6 x 2.5 mL	5
		37206	Diluent	1 x 14.0 mL	
		37209	QC	3 levels; 1 x 5.0 mL each	
		A79784	Diluent Pack	2 x 60 tests	120
Hybritech free PSA	Free prostate-specific antigen	37210	Reagent	2 x 50 tests	100
		37215	Calibrator	6 total; S0 @ 5.0 mL S1 - S5 @ 2.5 mL	5
		37219	QC	2 levels; 1 x 5.0 mL each	
Hybritech p2PSA	[-2]proPSA	A49752†	Reagent	2 x 50 tests	100
		A49753†	Calibrator	7 x 2.1 mL	4
		B03704	Reagent	2 x 50 tests	100
		B03705	Calibrator	7 x 2.1 mL	4
		A56934	QC	3 levels; 1 x 5.0 mL each	
OV Monitor / OV Monitor-Diluted	Cancer antigen 125	386357	Reagent	2 x 50 tests	100
		386358	Calibrator	6 x 2.5 mL	5
		A79783	Diluent Pack	2 x 63 tests	126
Research Use Only					
IL-6 (RUO) / IL-6 (RUO)-Diluted	Interleukin-6	A30945	Reagent	2 x 50 tests	100
		A30944	Calibrator	6 total; S0 @ 4.0 mL S1–S5 @ 2.5 mL	5
		A30946	QC	3 levels; 2 x 2.5 mL each	
		A79783	Diluent Pack	2 x 123 tests	246
PAPP-A (RUO) /PAPP-A (RUO)-Diluted	Pregnancy-associated plasma protein A	A49209	Reagent	2 x 50 tests	100
		A49210	Calibrator	6 x 1.0 mL	2
		A49211	QC	3 levels; 2 x 2.5 mL each	
		A79784	Diluent Pack	2 x 174 tests	348

* All onboard dilution assays use diluent pack A79783 or A79784. The volume of diluent used for each test is assay dependent. Consequently, the number of tests available per diluent pack differs by assay.

† Not available in the US.

** Distributed by Beckman Coulter for Bio-Rad for use on Beckman Coulter immunoassay systems.

†† In the U.S.A., this assay is for use under the Emergency Use Authorization (EUA) only. The Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling, are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas or at https://www.beckmancoulter.com. Authorized laboratories using this assay must adhere to the Conditions of Authorization indicated in the Letter of Authorization.

System Supplies

System supplies are organized alphabetically in two tables. The first table contains supplies ordered through Customer Service. The second table contains supplies ordered through Customer Technical Support.

To obtain the following supplies:

- In the U.S.A. or Canada, contact Beckman Coulter Customer Service at 1-800-526-3821.
- Outside the U.S.A. and Canada, contact your local Beckman Coulter representative.

Description	Part #	Quantity
Citranox acid cleaner and detergent	81912	1 gallon
Contrad 70 cleaning solution	81911	1 liter
Data Storage Device:		
USB Flash Drive	A81923	1
Diluent Packs (For onboard dilution tests)		
Sample Diluent A	A79783	Box of 2 packs
Wash Buffer II	A79784	Box of 2 packs
Duck Bill Check Valve (White)*	A32775	10
Lubricant, Type 2 Lithium, 1 mL*	6981C†	1
Printer supplies are no longer available from Beckman Coulter, Inc. Obtain printer supplies from your local office supplier or the printer manufacturer.		
Probes/pipettors and related supplies:		
Aspirate Probe Clean Kit	386191	1
Disposable Aspirate Probe Brush	386190	10
Probes identified with a colored sleeve containing a probe number		
Aspirate Probe, A1W	C69778	1
Aspirate Probe, A2	C69779	1
Aspirate Probe, A3	C69780	1
Dispense Probe, D1	C69781	1
Dispense Probe, D2	C69782	1
Dispense Probe, D3	C69783	1
Pump Tube, Aspirate Peristaltic, 1.30 mm*	77372	1
Reaction vessels (RVs), UniCel DxI	386167	Box of 10,000
Sample Diluent A, vial	81908	1 x 4.0 mL
Sample Containers:		
0.5 mL Sample cups, Beckman Coulter	651412	1000
2.0 mL Sample cups, Beckman Coulter	81902/652730	1000
1.0 mL/13 mm insert cups, Beckman Coulter	81915	1000
1.0 mL/13 mm insert cup caps	81920	1000
2.0 mL/16 mm insert cups, Beckman Coulter	81917	1000
3.0 mL sample containers, Beckman Coulter	81914	500
3.0 mL sample container caps	81922A†	1000
Autoaliquot tubes (13x100 mm false bottom), Beckman Coulter	2910034	4000
Pediatric insert cups, 1.0 mL, Beckman Coulter	81916	1000
Pediatric tube adapters for 13 mm rack, Beckman Coulter	472987	100
Sample Probe	A92071	1

Description	Part #	Quantity
Sample Racks and Accessories:		
Sample Racks:		
13 x 75, Blue	471918	Pack of 10
13 x 75, Gray	A25337	Pack of 10
13 x 100, Blue	471919	Pack of 10
16 x 75, Blue	471920	Pack of 10
16 x 100, Blue	471921	Pack of 10
13 x 100, Brown	471922	Pack of 10
13 x 100, Gray	473491	Pack of 10
16 x 100, Gray	473492	Pack of 10
Sample Rack Holders	B06330	1 box of 4
Sample Rack ID Label kit	386180	50 labels per container type
Sample Rack Barcode Labels		
Labels 1-500	471891	1
Labels 501-999	471892	1
Solid Waste Bags, UniCel DxI	C62616	1 box of 100
Substrate	81906	4 @ 130 mL
Swab applicators, fiber-free polyester	104838	100
System Check Solution	81910	6 @ 4.0 mL
Wash Buffer II, UniCel DxI	A16793	1 @ 10 L

* Item is also a component of the UniCel DxI CARE Kit (Catalog # A34821)

† An item with a catalog number ending in a letter may be revised from time to time. If you have difficulty ordering this item, ask your Beckman Coulter representative to check for a more recent revision.

To obtain the following supplies:

- In the U.S.A. or Canada, contact Beckman Coulter Technical Support by phone at 1-800-854-3633.
- Outside the U.S.A. and Canada, contact your local Technical Support representative.

Description	Part #	Quantity
CARE Kit, UniCel DxI	A34821	1
Keyboard template (English)	A46608	1
Liquid Waste Bottle, UniCel DxI 800	129071	1
Liquid Waste Bottle, UniCel DxI 600	A45817	1
Pipettor, Reagent, 3-inch probe*	6071	1
Tool Kit, Access Customer *	7014C†	1

* Item is also a component of the UniCel DxI CARE Kit (Catalog # A34821)

† An item with a catalog number ending in a letter may be revised from time to time. If you have difficulty ordering this item, ask your Beckman Coulter representative to check for a more recent revision.

UniCel DxI System Documentation

Manuals, instructions for use, and other supporting documents for your UniCel DxI system are available on the Beckman Coulter website. Examples of available documents include:

- UniCel DxI *Instructions for Use*
- UniCel DxI *Operator's Guide & Reference Manual*
- Access 2/UniCel DxI *LIS Vendor Information* document
- Access Assay Instructions for Use
- Safety Data Sheets for Access assays and consumables
- Certificates of Analysis

To view or download electronic copies of UniCel DxI system documentation, visit the Beckman Coulter website at techdocs.beckmancoulter.com. To receive email alerts when new or updated UniCel DxI system documents are released on the website, register for the "My Technical Documents" notification tool.

In addition, some printed documents, listed below, are available for order from Beckman Coulter. To obtain these documents:

- In the U.S.A. or Canada, contact Technical Support by phone at 1-800-854-3633.
- Outside the U.S.A. and Canada, contact your technical support representative.

UniCel DxI System Documentation	Part #	Quantity
System Maintenance and Service Log binder	986182	1