



Access 2

IMMUNOASSAY SYSTEM

Instructions for Use for *In Vitro* Diagnostic Use

EC REP

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Publication Notes

This manual, D22446-AA, release date 2025-02, supports:

- Access 2 published system software version 3, including full versions 3.4.2, 3.4.3, 3.5.0, 3.6.0, and 3.7.0.
- Access 2 published system software version 4, including full versions 4.0.0 and 4.1.0.
- Access 2i published system software version 6, including full versions 6.2.2, 6.2.3, and 6.3.0.

Changes to this Revision:

Chapter	Page	Change Description
Publication Notes	Publication Notes	Added software version 4.1.0.
1 System Overview	1-1	Added statement that Beckman Coulter support is available 24 hours.
B Ordering Information	Assay-Specific Reagents	Updated the list of assays.
	System Supplies	Updated the list of supplies.
	Access 2 System Documentation	Deleted manuals that are no longer available as paper copies.

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C94059-AA, October 2022	Access 2: software versions 3.4.2, 3.4.3, 3.5.0, 3.6.0, 3.7.0, and 4.0.0 Access 2i: software versions 6.2.2, 6.2.3, and 6.3.0
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C30219, December 2018	Access 2: software versions 3.4.2, 3.4.3, 3.5.0, and 3.6.0 Access 2i: software versions 6.2.2, 6.2.3, and 6.3.0

This manual is intended for use with the Access 2 Immunoassay System. This manual also can be used as supplemental material for the UniCel DxC 600i system, which consists of an Access 2 system integrated with a UniCel DxC 600 system.

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1 System Overview

Intended Use

The Access 2 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 *Access 2 Instructions for Use* is intended for use after you have become familiar with the Access 2 system. The *Instructions for Use* contains short instructions for everyday use and routine maintenance. It also contains general information about the Access 2 instrument, such as theory of operation, system specifications, safety labeling, and troubleshooting.

NOTE

Regardless of the frequency with which you perform a procedure, regularly review the complete procedures, including their cautions for protecting the instrument from damage, and their warnings for ensuring your personal safety.

Reference Materials

Additional Access 2 system documentation is listed in Appendix B. For more information, contact your Beckman Coulter representative.

Technical Support

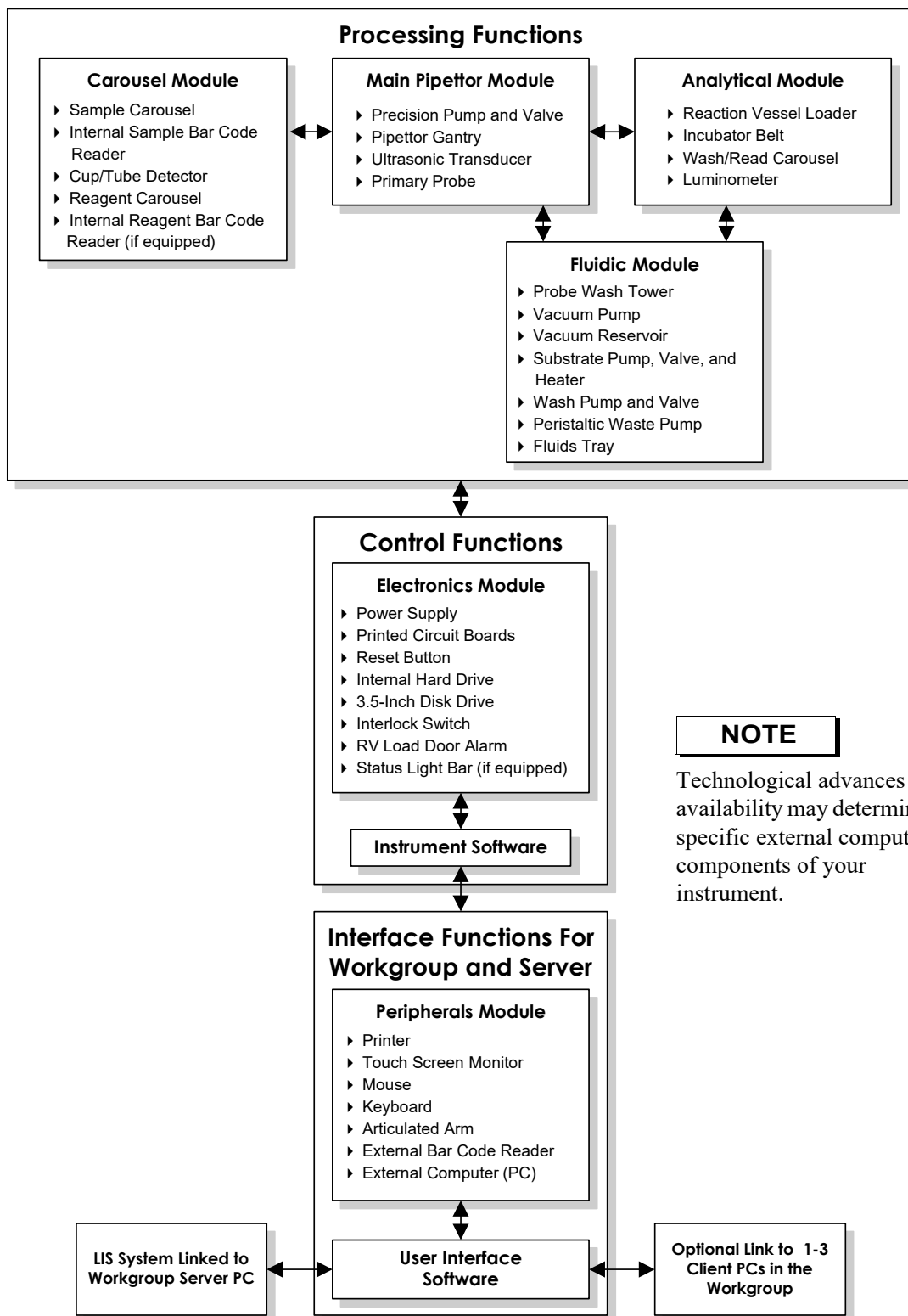
For technical assistance with the Access 2 Immunoassay System:

- 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.

NOTE

Be prepared to provide your system ID.

System Description


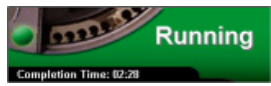




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System Modes





The Access 2 system has four system modes that indicate the operating state of the system. 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 requested function is displayed as a text line above the three system command buttons. Additional system messages are displayed at various times at this location.


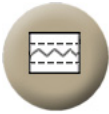



Some instruments are equipped with a status light bar that changes color to indicate the operational status of the instrument. The color of the light bar matches the color of the system mode area of the user interface.


Mode	Screen	Status Light Bar Color	Description
Ready		Blue	The system is ready to begin processing samples.
Running		Green	The system is performing a function, such as processing samples, running a maintenance routine, or performing a diagnostic procedure.
Paused		Yellow	The system continues current test processing, but no new tests are scheduled.
Not Ready		Red	The system is not ready to process samples. The system is checking the status of subsystems, initializing motors, priming fluid lines, homing movable parts, warming necessary modules, or requires initialization.

System Status Buttons

Most buttons are color-coded to alert you when a supply level requires your attention, a sample processing issue exists, or the instrument has recorded a system event. Under normal operating conditions the color of the button is neutral. The color of some buttons can change to yellow to indicate a caution condition or red to indicate a warning condition. The Help button color is always neutral.




Button	Description	Button Colors
	<p>Wash Buffer</p> <p>Select to view the status of the wash buffer bottle. You can change the wash buffer bottle at any time during sample processing.</p>	<p>Red</p> <p>The wash buffer reservoir is almost empty, and no new tests can be scheduled. You must change the wash buffer bottle to continue processing tests.</p>
	<p>Liquid Waste</p> <p>Select to view the status of the liquid waste bottle. You can change the liquid waste bottle at any time during sample processing.</p>	<p>Red</p> <p>The liquid waste bottle is full, and no new tests can be scheduled. You must change the liquid waste bottle to continue processing tests.</p>
	<p>Substrate</p> <p>Select to display the Supplies screen to check the level of onboard substrate, or change the substrate bottle. You can only change the substrate bottle while the system is in the Ready mode.</p>	<p>Yellow</p> <p>The system can process 60 or fewer test requests with the remaining substrate. Change the bottle at your next opportunity.</p> <p>Red</p> <p>The substrate bottle is empty, and no new tests can be scheduled. You must change the substrate bottle to continue processing tests.</p>
	<p>Reaction Vessels (RVs)</p> <p>Select to display the Supplies screen to check the RV supply, or load an RV cartridge. You can load RVs at any time during sample processing.</p>	<p>Yellow</p> <p>The system can process 60 or fewer test requests with the remaining RVs. Load an RV cartridge now, or at your next opportunity.</p> <p>Red</p> <p>The system can process 28 or fewer test requests with the remaining RVs, and no new tests can be scheduled. You must load an RV cartridge to continue processing tests.</p>

Button	Description	Button Colors
	<p>RV Waste Bag</p> <p>Select to display the Supplies screen to check the RV waste bag capacity, or change the RV waste bag.</p>	<p>Yellow</p> <p>The system can process 60 or fewer test requests with the remaining capacity in the waste bag. Change the RV waste bag at your next opportunity.</p> <p>Red</p> <p>The RV waste bag is full, and no new tests can be scheduled. You must change the waste bag to continue processing tests.</p>
	<p>Quality Control</p> <p>Select to display the Quality Control screen to set up quality control samples, or review quality control results.</p>	<p>Red</p> <p>A QC result is not within the acceptable range of expected values. You should review this result as soon as possible.</p>
	<p>Event Log</p> <p>Select to display the Event Log screen for information about events generated by the Access 2 system. From the Event Log screen you can also display troubleshooting information about caution or warning events.</p>	<p>Yellow</p> <p>The system has generated a caution event that requires your attention.</p> <p>Red</p> <p>The system has generated a warning event, indicating a serious fault or error condition has occurred.</p>
	<p>Work Pending</p> <p>Select to display the Work Pending screen for information about samples for which the system cannot schedule tests. The Work Pending screen allows you to navigate to the Sample Manager screen to load samples or delete sample requests.</p>	<p>Yellow</p> <p>A sample required condition has occurred. You should load the required sample, or delete it from the work list.</p>
	<p>Supplies Required</p> <p>Select to display the Supplies Required screen for information about supply and calibration conditions. You can correct most conditions from the Supplies Required screen.</p>	<p>Yellow</p> <p>The system requires supplies or calibration(s) to complete the requested tests.</p>

Button	Description	Button Colors
	<p>Help</p> <p>Select to display specific information about the screen you are on, or to navigate to a picture with descriptions of the screen, to a list of related topics, or to any topic within the Help system.</p>	<p>The Help button color is always neutral.</p>

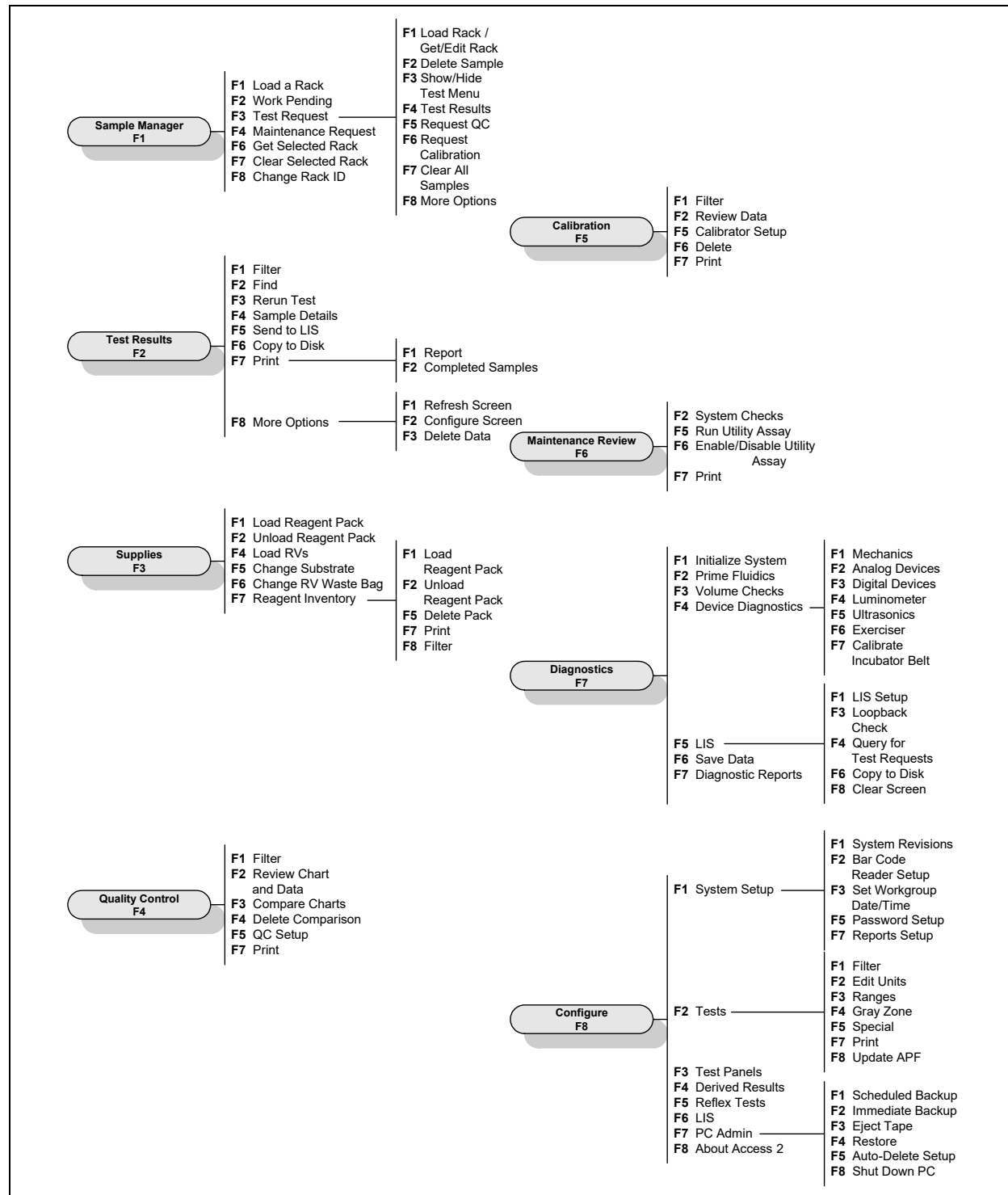
System Command Buttons

You use the three system command buttons to run, pause, and stop the Access 2 instrument.

Button	Description
	<p>Run</p> <p>Select to process samples or run a maintenance routine.</p>
	<p>Pause</p> <p>Select to pause the instrument. The system stops pipetting after it finishes pipetting the current sample. Processing continues on samples already in progress.</p>
	<p>Stop</p> <p>Select to stop the instrument. The system stops processing and cancels any tests in progress.</p>

Main Menu Workflow

The Main Menu is the first screen you see when the system is installed or initialized. To get to this menu from any screen, press **Main Menu F9**. You can navigate everywhere through the Access 2 system using the eight function buttons across the bottom of the Main Menu.



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Precautions and Hazards

Safety Features

The Access 2 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 Switch

WARNING

Do not defeat the safety interlock switch on the cover.

The Access 2 system is equipped with an interlock switch to protect you from injury. If you open the front panel of the instrument, the interlock switch stops the movement of the main pipettor. Other mechanical devices will continue to operate with the front panel open. If you open the front panel while the system is processing samples, the system may cancel tests.

Safety Statements

The following statements describe general safety concerns.

WARNINGS

- **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)*.**
- **The Access 2 instrument has moving parts and uses high voltage in the ultrasonic transducer. Both present an injury hazard. You should not operate the Access 2 instrument with the covers open.**


CAUTION

Always plug the Access 2 system into a grounded three-conductor outlet. DO NOT bypass the grounding prong on the plug.

Safety Symbols

Certain areas of the Access 2 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

	<p>The laser symbol indicates areas of the instrument where laser light is used. Do not stare into the laser beam.</p>
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Regulatory Symbols and Statements

The Access 2 instrument 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, and by related statements in the system documentation. 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 Access 2 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 Access 2 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 Access 2 system.**
 - **Re-orient the equipment with respect to the Access 2 system.**
 - **Be sure that the equipment is operating from a different power service connector than that of the Access 2 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.

The handheld bar reader that also operates in a hands-free mode is exempt from an LED safety class, according to IEC 62471.

System Specifications and Characteristics

Space Requirements

The dimensions of the instrument and the peripheral devices as of the date of this document are listed in the following table. The Access 2 system operates from a bench top. Be sure that the surface and surrounding area designated for these components is large enough to accommodate the system. For information about the external computer, monitor, and printer, see the documentation provided by the manufacturer.

Instrument	Width = 99 cm (39 in) Height = 47 cm (18.5 in) (Instrument Serial Numbers < 570000) Height = 49.54 cm (19.5 in) (Instrument Serial Numbers ≥ 570000) Depth = 61 cm (24 in)
Instrument clearance required <ul style="list-style-type: none"> • Left clearance is for the fluids tray • Right clearance is for the monitor and keyboard on the articulated arm • Top clearance is measured from the bench top 	Rear = 5 cm (2 in) Left = 30 cm (12 in) Right = 76 cm (30 in) Top = 76 cm (30 in)

Instrument and Peripheral Device Weights

The weight of the instrument is listed in the following table. Be sure that the surface where the instrument, external computer, monitor, and printer will reside can support the system.

Instrument (before supplies and samples added)	91 kg (200 lb)
External computer	See the documentation provided by the manufacturer
Monitor	
Printer	

Operating Environment Requirements

The Access 2 system is **for indoor use only** and requires the following environmental conditions to operate properly:

Humidity	Operational: 20% to 80% Exposure: 10% to 80%
Maximum altitude	Operational: 2 km (6,500 ft) Exposure: 12.2 km (40,000 ft)

Temperature	Operational ^{*,†} : 18 °C to 28 °C (64 °F to 82 °F) Exposure: -30 °C to 50 °C (-22 °F to 122 °F)
Maximum ambient temperature change rate	2°C per 30 min (3.6°F)
Ambient light	Results not affected by ambient light levels 0–2,152 lx (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 electrical line and any surge suppressors, backup power supplies (UPS units), and line conditioning transformers you use with the instrument must meet specific requirements.

Electrical Line

The electrical line supplies power to the Access 2 instrument. To avoid damaging the instrument, the electrical line should meet the following requirements:

Line power supply	115–120 volts alternating current (V AC) at 15 A, or 220–240 V AC at 6 A, at either 50 or 60 Hz, single phase power
Line dedication	Dedicated (Access 2 instrument is the only equipment connected to the electrical line)
Line outlet	Located within 1.5 m (5 ft) of the Access 2 system NOTE The Access 2 system may be connected to a line conditioner. In this case, locate the line conditioner within 5 ft (1.5 m) of the outlet.
Line protection device	Circuit breaker rated: <ul style="list-style-type: none"> • 15 A (115–120 V AC line) • 6 A (220–240 V AC line)
Line voltage fluctuations	Not to exceed ±10 V AC per cycle
Line voltage sags	Not to fall below: <ul style="list-style-type: none"> • 90 V AC at 15 A • 180 V AC at 6 A

Line voltage surges	Not to exceed: <ul style="list-style-type: none"> • 135 V AC at 15 A • 250 V AC at 6 A
Line voltage supplied to printer	See documentation provided by the manufacturer
Maximum voltage between neutral conductor and safety ground conductor	Not to exceed 2 V AC root mean squared (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 Current Consumption, Power Consumption, and Heat Production

The Access 2 instrument consumes current and power, and produce heat at the following levels. For information about the external computer, monitor, and printer, see the documentation provided by their manufacturers.

Electrical Current Consumption	Power Consumption	Heat Production
<1.5 kV·A	800 W	2 880 kJ/h (2,730 Btu/h)

Surge Suppressors

Beckman Coulter recommends that you do not use a surge suppressor with the Access 2 instrument. The instrument has built-in protection similar to that provided by a surge suppressor.

Beckman Coulter does recommend that you use a surge suppressor with the external computer, monitor, and printer. You should connect the surge suppressor to an outlet, not a line conditioner.

Instrument Line Conditioning Transformers

If you suspect you have alternating current (AC) power line problems, Beckman Coulter recommends that you connect the Access 2 instrument to a line conditioning transformer with local ground and high frequency isolation. If you use a line conditioning transformer, it should meet the following requirements:

Minimum output capacity	1.3 kV·A
Output voltage	120 or 240 V AC
Output frequency	50 or 60 Hz, single phase
Output wave form	True sine wave (<5% distortion)
Output safety ground	Isolated local ground
Approvals	UL 1012, CSA C22.2 107.1 (UL 544, optional)

Instrument Backup Power Supplies (UPS Units)

If you want to use an uninterruptible power supply (UPS) unit as a backup power supply, Beckman Coulter recommends a UPS unit with local ground isolation. UPS units are designed to provide continuous AC power to equipment when the main AC power line 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. If your system is in a workgroup, the external computer acting as the server for your workgroup should be connected to a UPS unit. Your UPS unit should meet the following requirements:

Minimum output capacity	1.3 kV·A
Output voltage	120 or 240 V AC
Output frequency	50 or 60 Hz, single phase
Output wave form	True sine wave (<5% distortion)
Standby runtime	Minimum 15 min at 1 kW output (low battery indicator and/or shutdown recommended)
Approvals	UL 1778, CSA C22.2 107.1 (UL 544, optional)

LIS Interface

The Access 2 system can be directed by a laboratory information system (LIS) through the LIS interface. When connected to an LIS, the Access 2 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 Access 2 system, see Help topic LIS Setup or the *LIS Vendor Information* document.

Installation

The Access 2 instrument 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 Access 2 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

You can reboot the PC, the instrument, or both. Rebooting either one does not affect the other. You may use a reboot procedure in the following situations:

- The user interface (UI) is not responding correctly (PC reboot).
- You are directed to do so by a technical support representative or if you are following instructions in *Help* system or in an Access 2 manual (PC and/or instrument reboot).

During the instrument rebooting process, the instrument system software is reset and a routine brings all devices to their home, or known, states. This routine is called initialization, and it prepares the system for further processing.

NOTES

- If you are rebooting both the PC and the instrument, you can reboot them in any order. For simplicity, the procedures instruct you to reboot the PC first, then the instrument.
- If you are rebooting an Access 2 PC that is a workgroup server, first you must shut down the other PCs (clients) in the workgroup. Next, restart the server PC. Finally, restart the client PCs.
- If you reboot only the PC, the instrument continues sample processing if it is in the **Running** mode. When the PC reestablishes communication with the instrument, the test data is automatically sent to the PC.

The instrument does not require periodic shutdowns. However, you should shut down the instrument before moving it or whenever the power will be turned off for an extended period of time (more than 5 days). Before shutting down the instrument, contact Technical Support to confirm your decision.

Rebooting the PC

To reboot the PC, you shut it down and then restart it. You do not need to reboot the instrument unless you are directed to do so. Use this procedure to reboot the PC.

Shutting Down the PC Under Normal Conditions

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.
 - If you are shutting down a workgroup server PC, you must shut down each of the client PCs in the workgroup first.
1. Go to the PC Admin screen. To get to this screen from the Main Menu, select **Configure F8** to display the Configure menu, then select **PC Admin F7**.
 2. Select **Shut Down PC F8**. A confirmation message is displayed.
 3. Select **Yes F1** to shut down the PC.

If you are preparing to shut down the server, repeat step 1 through step 3 for each of the client PCs first. Then repeat step 1 through step 3 for the server.
 4. Press and hold the PC power switch for at least 15 seconds to turn off the power to the PC.
 5. Wait about 20 seconds, then perform the restarting procedure.

Shutting Down the PC When the UI is not Accessible

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.
 - If the server UI is the only UI that is not accessible, shut down each of the client PCs. Then use this procedure to shut down the server.
 - If a client UI is not accessible, use this procedure to shut down that client PC.
 - If the keyboard does not respond during the performance of this procedure, press the PC power switch on the front of the PC to turn the power off. The power switch is identified by the power switch symbol.
1. Identify the software operating system on your Access 2 system PC.
 - a. If you know the software operating system on your Access 2 system PC, proceed to the appropriate instructions below.
 - b. To determine the software operating system on your Access 2 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.



- 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 a PC that Is Shut Down

NOTE

If you are restarting multiple Access 2 PCs in a workgroup, restart the workgroup server first, then restart the client PCs.

1. Press the PC power switch on the front of the PC to turn the power on. The power switch is identified by the power switch symbol.



PC Power Switch Symbol

1054B.eps

- 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 Main Menu screen appears before you continue normal operation.

If rebooting fails, contact Technical Support.

NOTE

If communication between the PC and the instrument is interrupted for an extended time (more than 30 minutes) while the instrument is processing tests, it may take a few minutes for test results to be sent to the PC after communication is reestablished. Do not use the system until the PC receives all the test results.

Go directly to the Test Results screen and filter the results by completion time. Watch the **Result** and **Comp. Time** columns. When it appears that the test results that were obtained while communication was interrupted have been transferred to the PC, you can continue normal operation.

If you have any questions, contact Technical Support.

Rebooting the Instrument

Use this procedure to reboot the Access 2 instrument. There are two different ways to reboot the instrument:

- You can reboot using the reset button. This is also called a warm boot.
- You can reboot using the power switch. This is also called a cold boot.

NOTES

- Do not select any buttons or press any keys until rebooting is complete. After you initiate a reboot, there is a pause of approximately 2 minutes as the software resets. Then the system enters the **Not Ready** mode and system initialization begins.
- 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 changes to the **Ready** mode.
- The system continues to initialize the remaining devices and displays a flashing message in the system mode area. When the message disappears, system initialization is complete.
- If the system does not successfully initialize, contact Technical Support.

Rebooting Using the Reset Button

WARNING

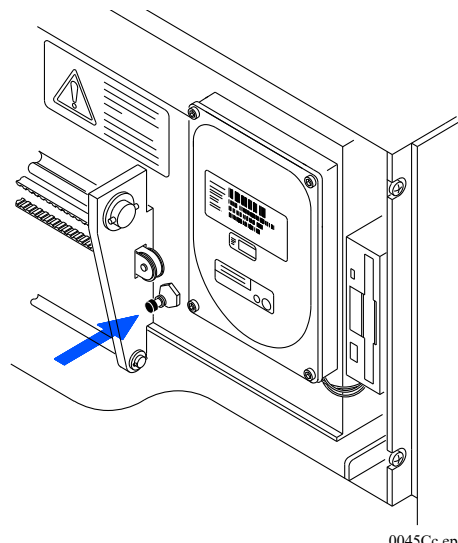
You will come in contact with potentially infectious materials during this procedure. Handle and dispose of biohazard materials according to proper laboratory procedures. Proper hand, eye, and facial protection is required.

1. Open the front panel of the instrument.
2. Locate the reset button, just to the right of the pipettor gantry.
3. Push and hold in the reset button for one second, then release.
4. Close the front panel of the instrument immediately.

NOTE

If the front panel remains open too long, the system cannot home the mechanical devices. If this occurs, press the reset button a second time, then close the front panel immediately.

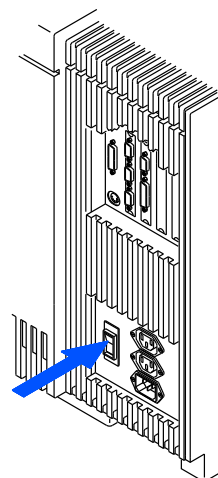
5. Wait until the system is in the **Ready** mode and no message appears in the blue system mode area before you continue normal operation.



Reset Button

Rebooting Using the Power Switch

1. Be sure the front panel of the instrument is closed.
2. Locate the power switch on the lower, right side near the back of the instrument. Press the lower part of the switch to turn the power off (O position).
3. Wait about 20 seconds, then press the top part of the switch to turn the power on (I position).
4. Wait until the system is in the **Ready** mode and no message appears in the blue system mode area before you continue normal operation.



0042Dc.eps

Instrument Power Switch

Shutting Down the Instrument

Use this procedure only if you plan to move the instrument or if the system power will be turned off for an extended period of time (more than 5 days). Before you shut down the instrument, contact Technical Support to confirm your decision.

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.
- If you are moving the instrument, 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)*.

Use this procedure to shut down the Access 2 system.

1. Run the Special Clean routine. For more information about performing the Special Clean routine, see the *Help* system.
2. Empty the liquid waste bottle.
3. If necessary, shut down the PC.
4. Locate the power switch on the lower, right side near the back of the instrument. Press the lower part of the switch to turn the power off (O position).

Restarting the Instrument

Use this procedure to restart the instrument from a shutdown state.

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.**
- **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.**

NOTE

You must equilibrate the substrate used in this procedure to room temperature for the time specified in the reagent instructions for use before you load it onto the instrument. For detailed information, see the substrate reagent instructions for use.

Turning the Power On

1. If the PC was shut down, restart it.
2. Locate the power switch on the lower right side near the back of the instrument. Press the upper part of the switch to turn the power on (| position).
3. Wait until the system is in the **Ready** mode and no message appears in the blue system mode area before you continue the procedure.

If initialization fails, review the Event Log and troubleshoot according to any error event with a similar date and time to the attempted initialization.

- (Optional, except following an extended shutdown) Prime the system fluidics.
 - (Optional, except following an extended shutdown) Perform the probe volume checks.
 - (Optional) Replenish supplies.
 - (Optional, except following an extended shutdown) Run the Special Clean routine.
 - (Optional, except following an extended shutdown) Run the System Check routine.
-

3 Supplies

Changing the Wash Buffer Bottle

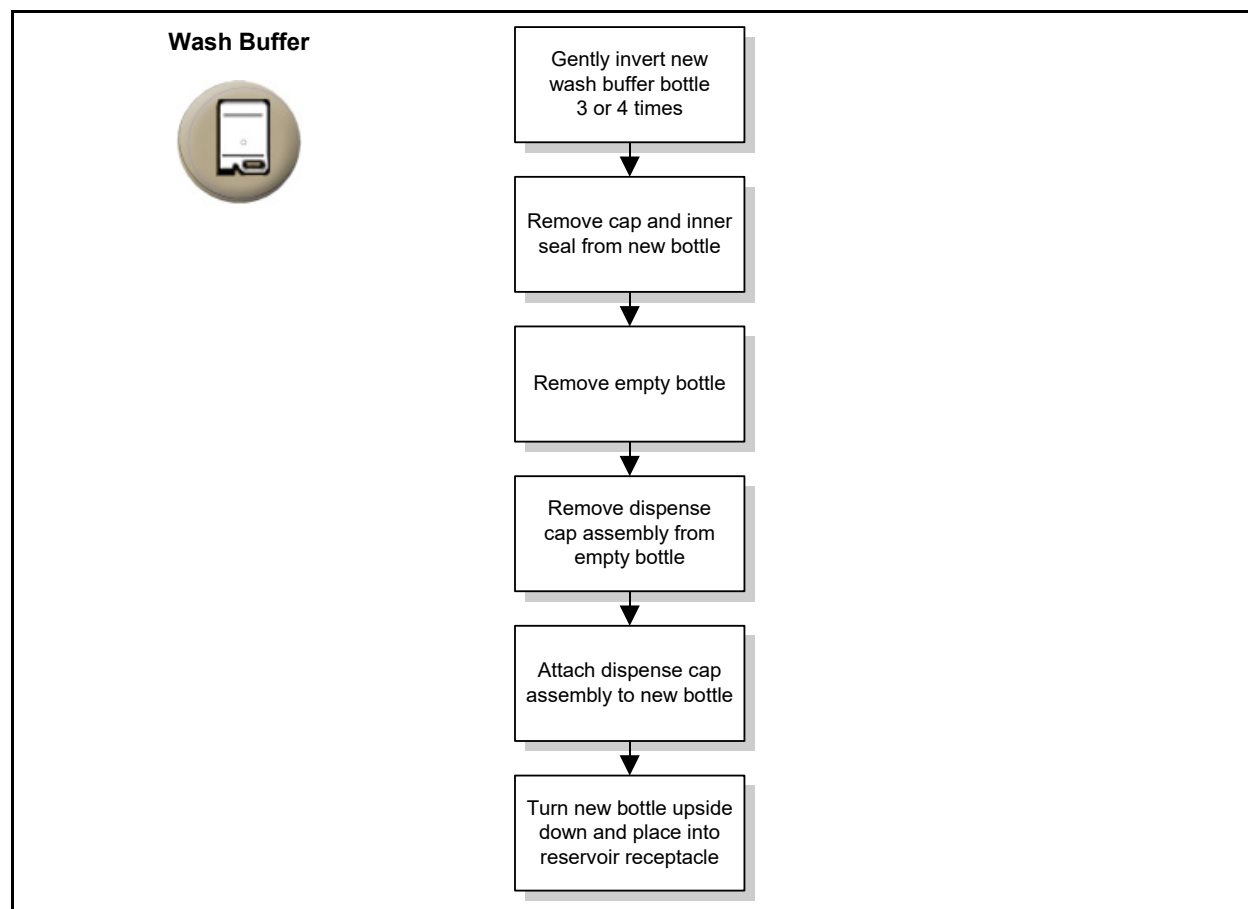
You can change the wash buffer bottle at any time. Because of the internal reservoir, the system continues processing samples even when you remove the wash buffer bottle. If you wait until the **Wash Buffer** button is red, the system schedules no new tests because the internal reservoir is almost empty.

WARNING

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.

CAUTION

To avoid contaminating the wash buffer, do not touch any part of the dispense cap assembly that enters the reservoir. Handle the dispense cap assembly only by the screw cap, not the nozzle.



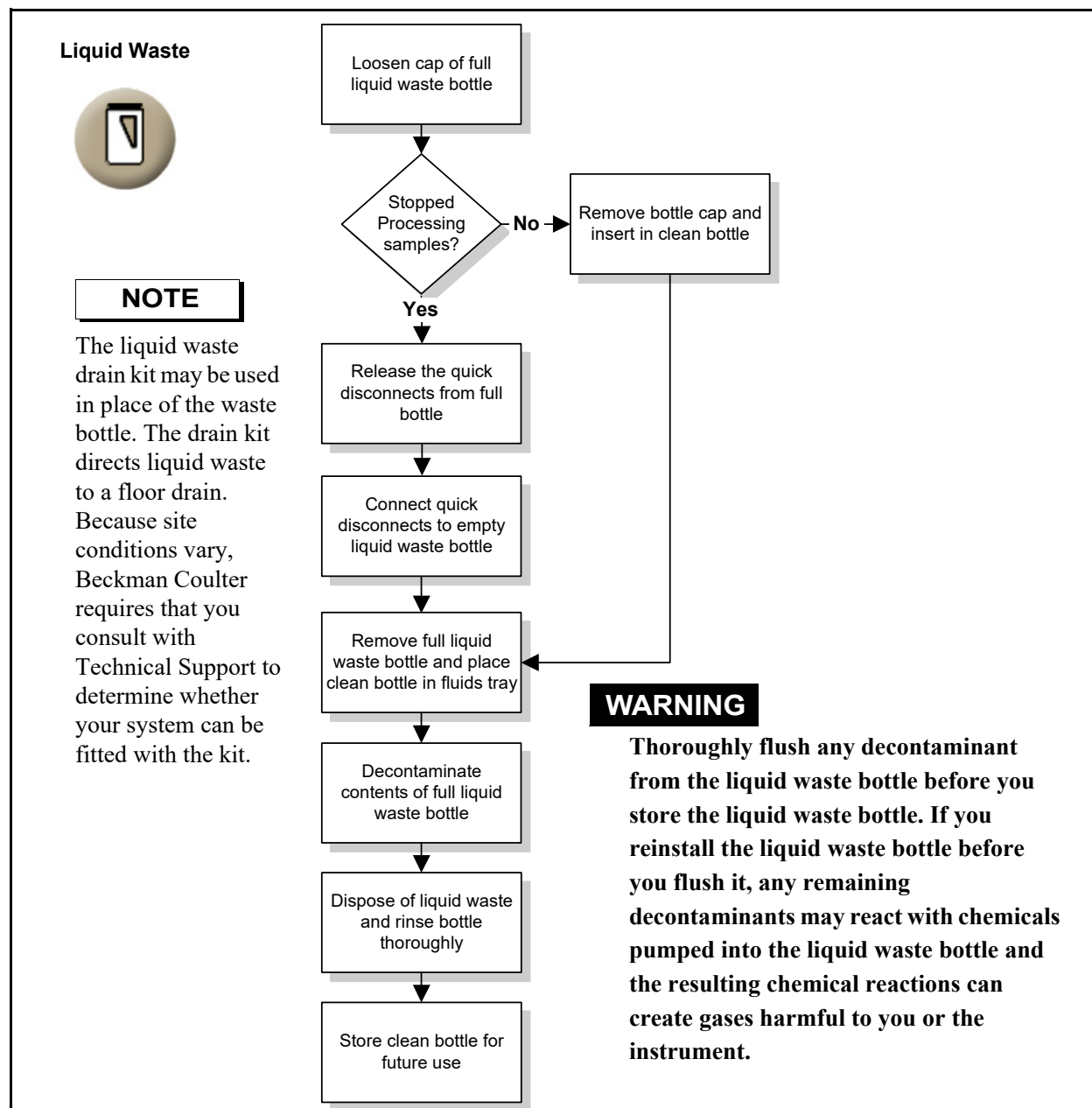
0588B.wmf

Changing the Liquid Waste Bottle

The **Liquid Waste** button turns red when the waste bottle is full. The system will not schedule any new tests until you change the liquid waste bottle. You can change the liquid waste bottle at any time, even during sample processing, but preferably before the bottle is full. The **Liquid Waste** button does not turn yellow.

WARNING

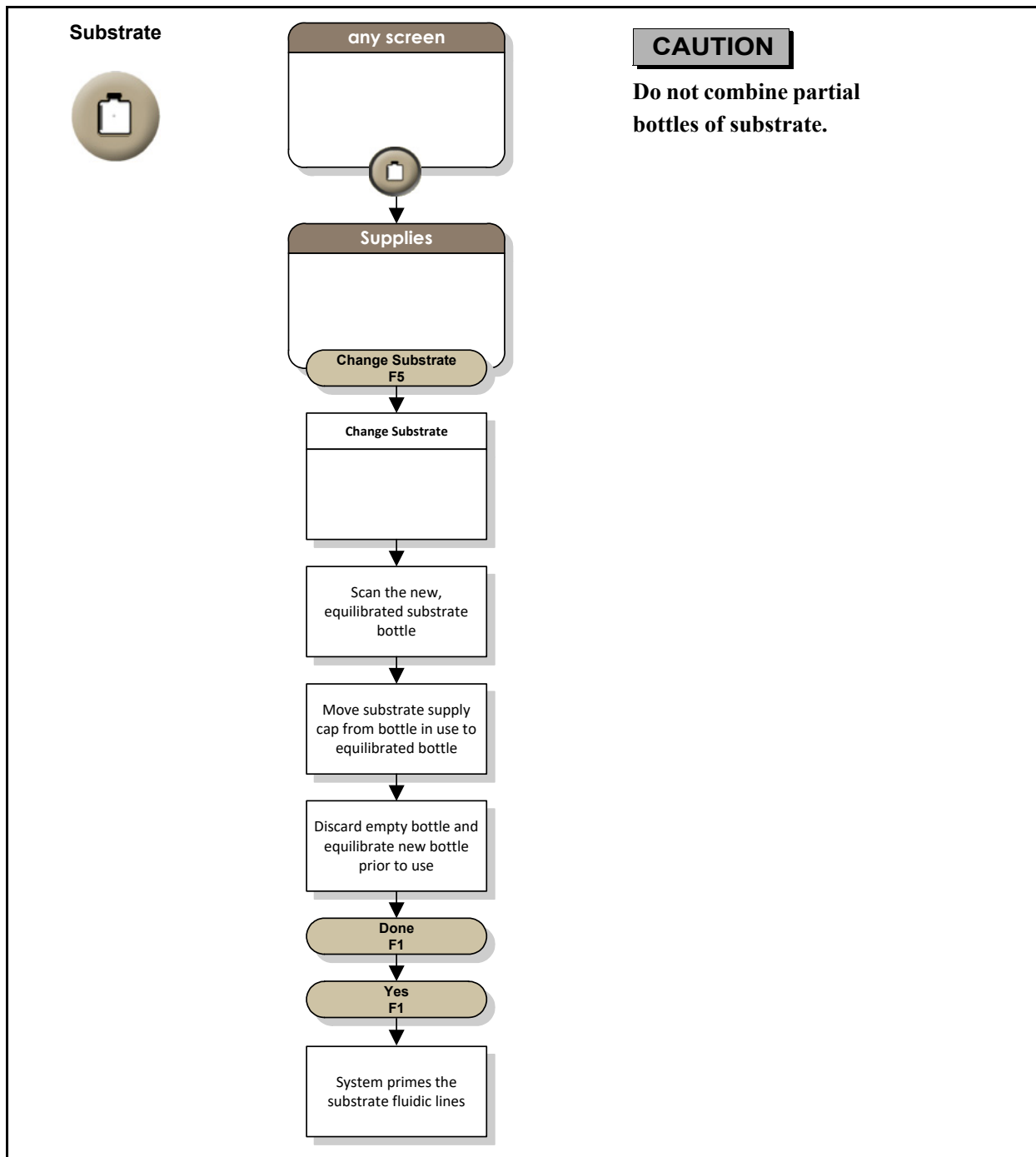
You will come in contact with potentially infectious materials during this procedure. Handle and dispose of biohazardous materials according to proper laboratory procedures. Proper hand, eye, and facial protection is required.



0589C.wmf

Changing the Substrate Bottle

When the system can process 60 or fewer tests with the current supply of substrate, the **Substrate** button turns yellow. When the substrate bottle is empty, the button turns red, and the system cannot start processing samples until you connect a new bottle of substrate. You can only change the substrate bottle while the system is in the **Ready** mode.



0505B.wmf

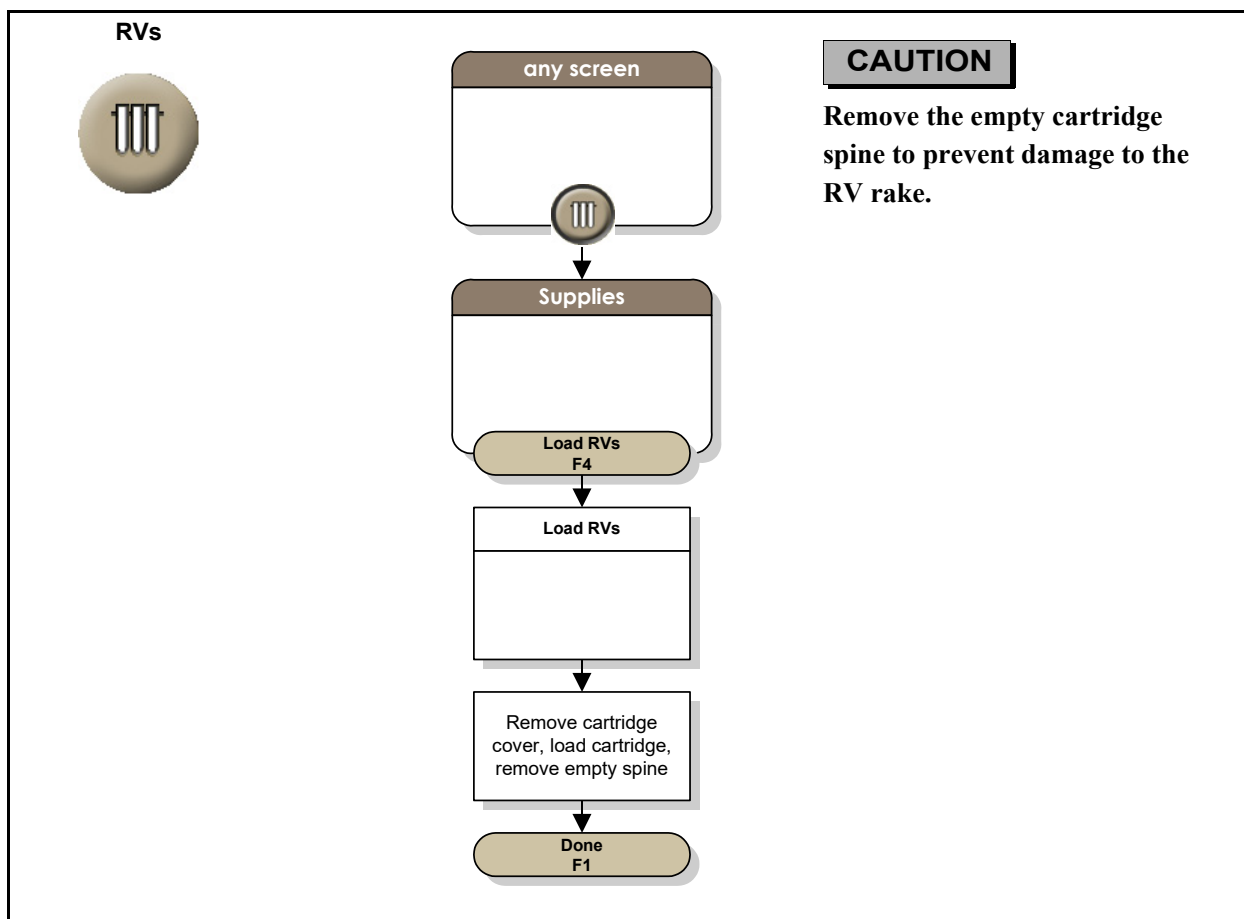
Loading Reaction Vessels

During an Access 2 test, the chemical reaction occurs in a container called a reaction vessel (RV). Each test uses one or two RVs.

- When there are 60 or fewer RVs available, the **RVs** button turns yellow.
- When there are 28 or fewer RVs available, the **RVs** button turns red.
- When no RVs are available, the system cannot process another sample until you load a new RV cartridge onto the instrument.

NOTES

- You can load only full cartridges of RVs. If you try to load RVs when the instrument has room for only a partial cartridge, the system displays a message.
- If the system is processing samples and has one row or fewer RVs left when you try to load more, the system displays a message. You must wait until the instrument stops before you load the new cartridge.
- RVs can fall between the rake and the wall of the incubator if you do not load RVs properly by selecting **Load RVs F4** from the Supplies screen or Supplies Required screen.
- To be sure that all 98 RVs are firmly seated in the cartridge spine, press down on the spine before you load the cartridge.



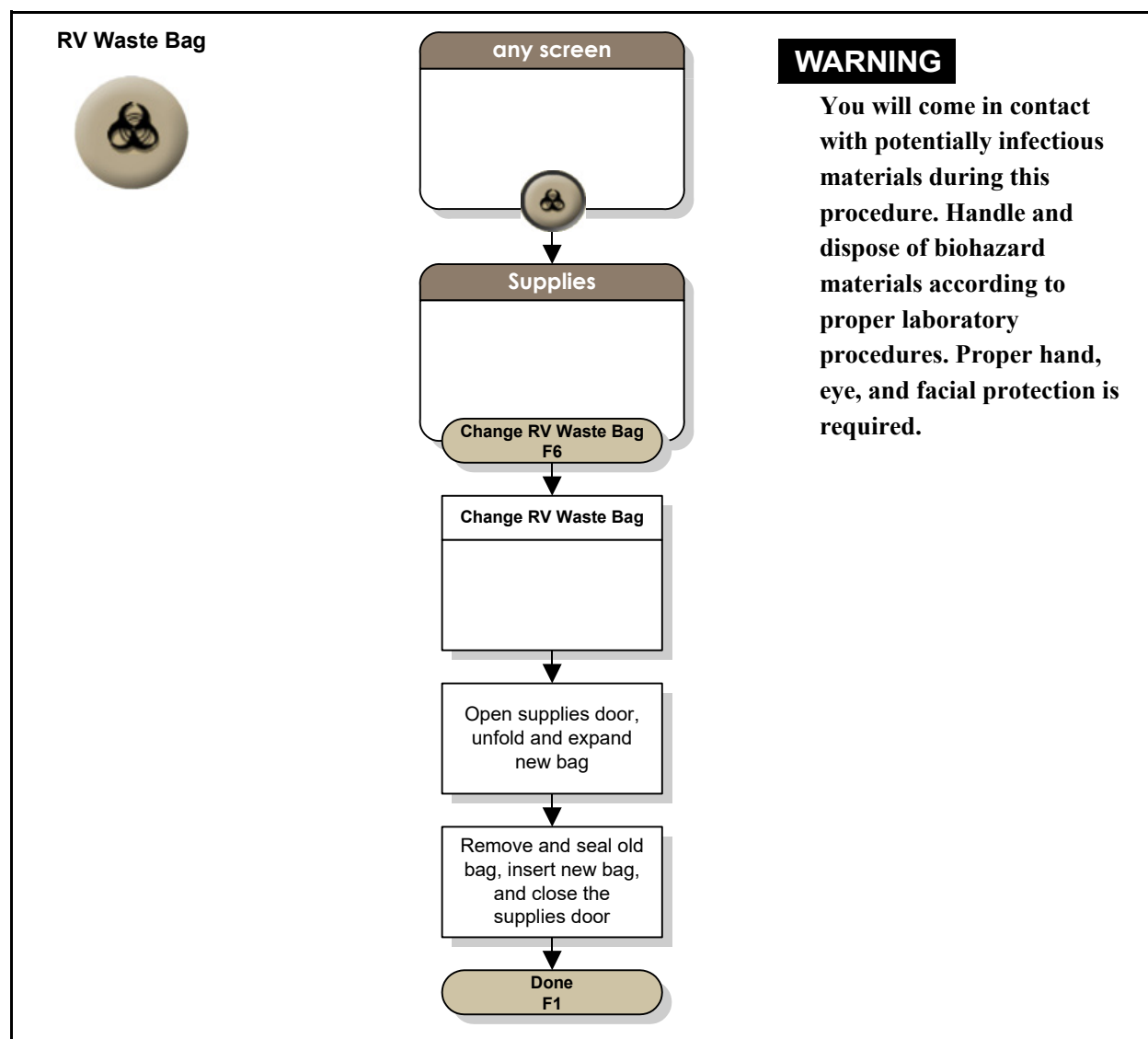
0504A.wmf

Changing the Reaction Vessel Waste Bag

When the waste bag has room for 60 or fewer RVs, the **RV Waste Bag** button turns yellow. When the RV waste bag is full, the button turns red and the system will not start processing samples. You must change the RV waste bag.

CAUTIONS

- If the system is in the **Running** mode when you change the RV waste bag, the system may try to eject an RV when the plastic collar on the waste bag is blocking the ejection chute. This will cause a jam.
- To prevent damaging the system, **DO NOT** push an RV that is sticking out from the ejection chute all the way back into the chute.



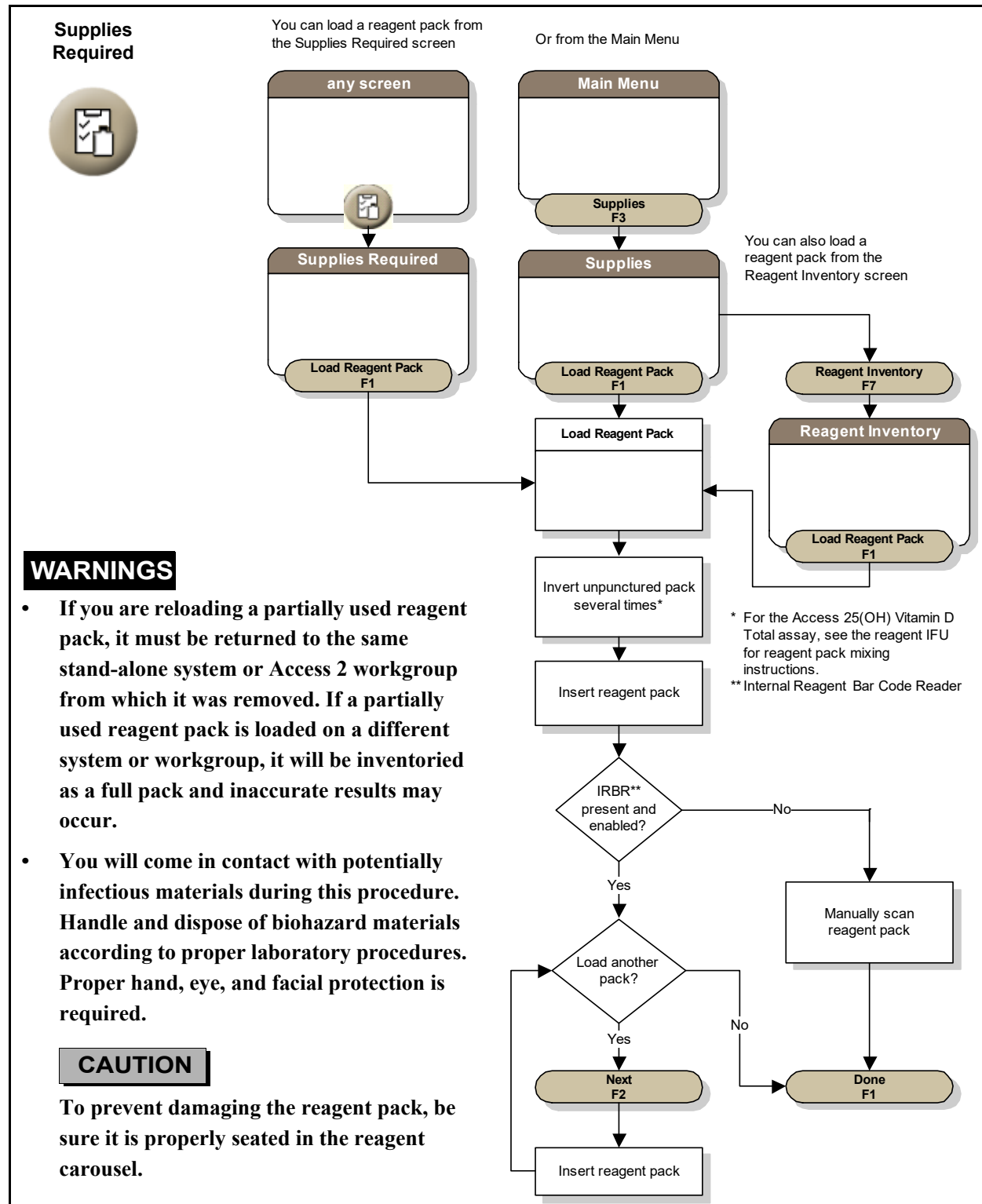
WARNING

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.

0507A.wmf

Loading a Reagent Pack

When an onboard reagent pack does not contain enough reagent to process requested tests, the system assigns those tests the **Supply Wait** status and the **Supplies Required** button turns yellow.



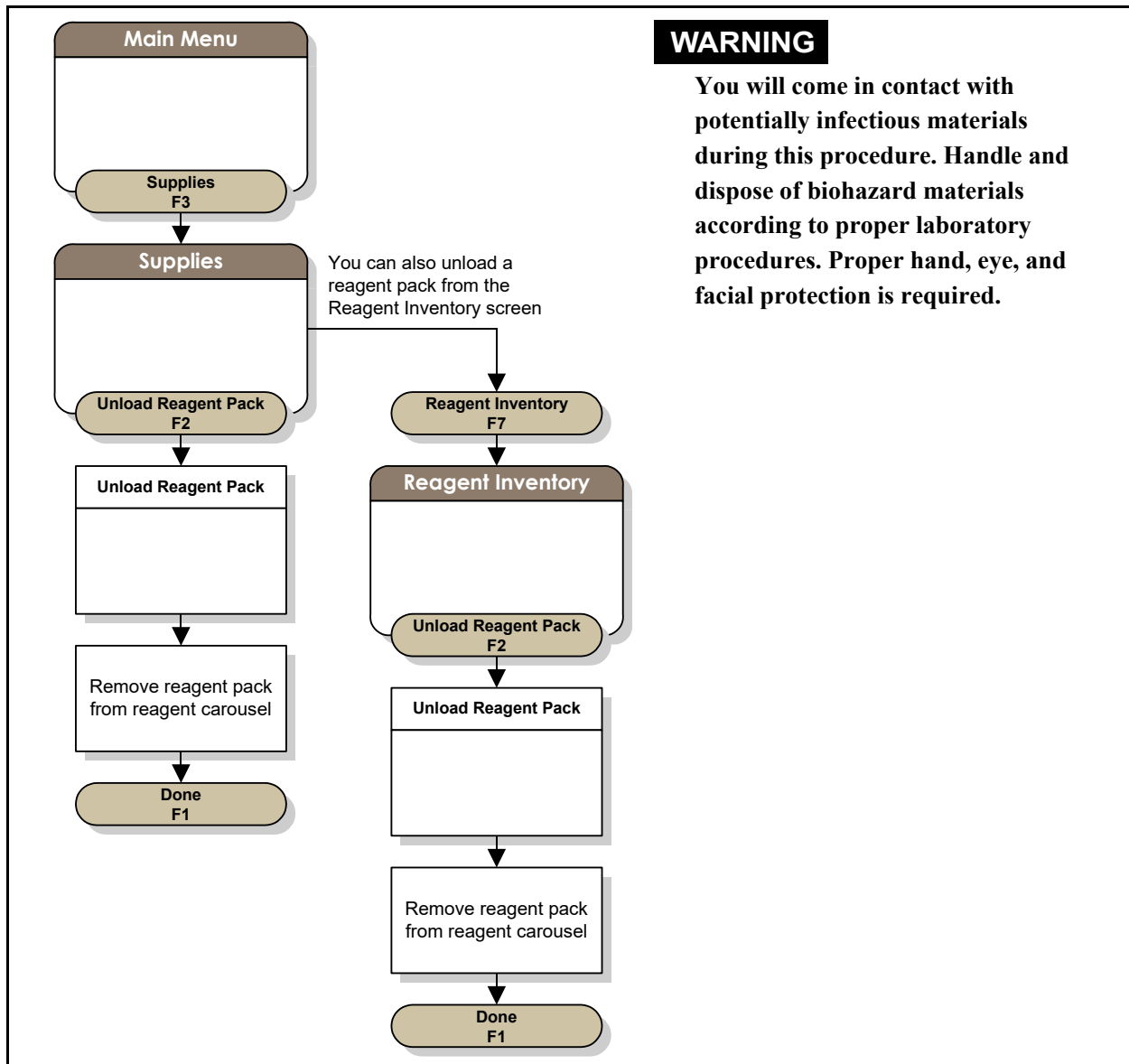
0502Ea.wmf

Unloading a Reagent Pack

Use this procedure to unload a reagent pack from the instrument.

NOTES

- If the system is using a reagent pack to process tests, you cannot unload it (identified by the in-use [padlock] icon on the Supplies screen).
- When you unload a partially full reagent pack, the system keeps track of the number of tests left in the pack until you reload it or manually delete it from inventory.
- Immediately unload any reagent packs that are empty or are rejected as a result of reagent pack monitoring.



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.

0503A.wmf

Retrieving Misplaced Reagent Packs

For the Access 2 system to accurately track the proper locations of reagent packs on the reagent carousel, the packs must be loaded and unloaded using the appropriate system windows. If you load a pack and do not use the Load Reagent Pack window, or if you use the Unload Reagent Pack window, but do not remove the pack, you will have a misplaced pack on your system.

Use this procedure to retrieve a misplaced reagent pack.

NOTE

If your system is equipped with an internal reagent bar code reader, you can use the Remap feature to automatically identify misplaced packs and add them to the reagent inventory.

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.

1. Be sure the system is in the **Ready** mode or **Not Ready** mode, and then unload all reagent packs from the reagent carousel.
2. Go to the Mechanics screen. To get to this screen from the Main Menu, select **Diagnostics F7** to display the **Diagnostics** menu, then
Select **Device Diagnostics F4** to display the Device Diagnostics screen, then
Select **Mechanics F1**.
3. Select **Disable Motors F8**.
4. Slide the carousel door to the left to open it, and then open the reagent carousel door.
5. Gently turn the reagent carousel one rotation. If you find any reagent packs remaining on the carousel, remove them as they come into position at the reagent carousel door.
6. After verifying that all packs are removed, close the reagent carousel door and then slide the carousel door to the right to close it.
7. Select **Enable Motors F8**.
8. Home the reagent carousel.
9. When homing is complete, initialize the system.
10. When system initialization is complete, reload all of the packs you removed from the reagent carousel.

Remapping Packs

On systems equipped with an internal reagent bar code reader (instruments with serial numbers ≥ 570000), you can perform a Remap operation to scan for bar codes in all slots of the reagent carousel to identify loaded packs.

Packs that were originally manually loaded due to an unreadable bar code may not be identified by this remap and will be assumed to still be loaded.

1. Confirm that the system is in the **Ready** mode.
2. Go to the Supplies screen. To get to this screen from the Main Menu, select **Supplies F3**.
3. Select **Remap F3**.

The system scans all of the onboard reagent packs and updates the inventory.

NOTE

If the **Remap F3** button is unavailable, check the bar code reader configuration to ensure that the internal reagent bar code reader is enabled. For more information, refer to the *Access 2 Reference Manual*.

4 Racks and Sample Containers

Racks

To accommodate sample containers of different sizes, the instrument uses three types of racks:

- 13 mm (for 12 mm and 13 mm sample tubes)
- 16 mm elevated (for 16x75 mm sample tubes)
- 16 mm (for 16x100 mm sample tubes)

Racks are identified by a bar code label. When the instrument scans the rack bar code label, it identifies the type of sample containers in the rack and determines the appropriate pipetting depth for aspirating sample.

CAUTION

Only load sample containers on a rack with the appropriate ID.

Calculating Sufficient Sample Volume

To be sure the sample volume is sufficient for the tests to be run, calculate the total volume of sample needed for the sample container by using this equation:

$$\begin{array}{|c|} \hline \text{Sample volume} \\ \text{required per} \\ \text{replicate} \\ \hline \end{array} \times \begin{array}{|c|} \hline \text{Number of} \\ \text{replicates} \\ \hline \end{array} + \begin{array}{|c|} \hline \text{Dead volume} \\ \hline \end{array} = \begin{array}{|c|} \hline \text{Total sample} \\ \text{volume required} \\ \hline \end{array}$$

0616A.wmf

NOTES

- To find the sample volume required per replicate, see the reagent instructions for use.
- Dead volume is the amount of sample in the bottom of a sample container that is required to be sure that enough sample is available for the instrument to complete an assay.

WARNING

If you use tubes with separator gel, be sure that the tube contains sufficient sample volume. Insufficient sample volume may cause the instrument to attempt to aspirate the separator gel, which can damage the instrument and compromise the integrity of the test results.

Sample Containers

Place all samples to be tested on the Access 2 system in racks before loading them onto the instrument. The rack ID on each rack identifies what type of sample containers you may use in that rack. Each rack holds up to ten sample containers. Place all sample containers except insert cups directly in the rack. Place insert cups into another sample container appropriate for the rack you are using.

WARNINGS

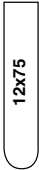
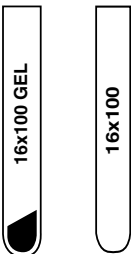
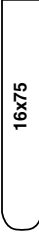

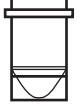
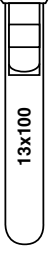


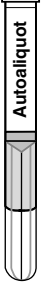

- You will come in contact with potentially infectious materials during this procedure. Handle and dispose of biohazard materials according to proper laboratory procedures. Proper hand, eye, and facial protection is required.
- Air bubbles in samples can affect level sensing by the Access 2 system and compromise the integrity of the test results. Avoid creating bubbles when transferring samples to a secondary container. Always inspect samples before loading on the analyzer, and remove or break any bubbles.
- Use only recommended sample containers and place them in a rack with a rack ID defined for that type of sample container. Using containers other than those specified for use with a particular rack ID may damage the system and compromise the integrity of test results.


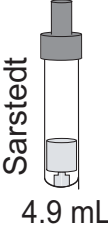
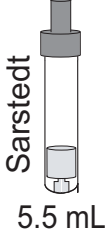


The following table lists all of the sample containers you can currently use on the Access 2 instrument, the corresponding rack ID range and the dead volume for each container.

WARNINGS

- You must have a sufficient volume of sample to process the tests you requested. To be sure you have enough sample, calculate the total volume needed for the sample container using the Calculating Sufficient Sample Volume procedure in this section. If you do not follow the provided procedure, sample processing problems may occur without warning.
- Remove caps from all sample containers before loading on the Access 2 system.

Sample Container Information	Bar Code Label Icon	Sample Container Information	Bar Code Label Icon
13x75 mm Tube with or without separator gel <ul style="list-style-type: none"> • Border: Lime green • Rack IDs: 1300–1399 • Dead Volume: 500 μL • Sample rack: 13 mm NOTE: 13x75 mm tubes may also be used with Rack IDs 1–99 or 800–899, at a Dead Volume of 3.4 mL.		13x100 mm Tube with or without separator gel <ul style="list-style-type: none"> • Border: Forest green • Rack IDs: 1400–1499 • Dead Volume: 3.0 mL • Sample rack: 13 mm NOTE: 13x100 mm tubes may also be used with Rack IDs 1–99 or 100–199, at a Dead Volume of 4.9 mL.	

Sample Container Information	Bar Code Label Icon	Sample Container Information	Bar Code Label Icon
<p>12x75 mm Tube with or without separator gel</p> <ul style="list-style-type: none"> • Border: Lime green • Rack IDs: 1300–1399 • Dead Volume: 500 µL • Sample rack: 13 mm <p>NOTE: 12x75 mm tubes may also be used with Rack IDs 1–99, at a Dead Volume of 3.4 mL.</p>		<p>16x100 mm Tube with or without separator gel</p> <ul style="list-style-type: none"> • Border: Midnight blue • Rack IDs: 1500–1599 • Dead Volume: 4.5 mL • Sample rack: 16 mm <p>NOTE: 16x100 mm tubes may also be used with Rack IDs 900–999, at a Dead Volume of 7.6 mL.</p>	
<p>16x75 mm Elevated Tube</p> <ul style="list-style-type: none"> • Border: Purple • Rack IDs: 1000–1099 • Dead Volume: 700 µL • Sample rack: 16x75 mm ELEV 		<p>Beckman Coulter Access 3.0 mL Sample Container</p> <ul style="list-style-type: none"> • Border: Red • Rack IDs: 500–599 • Dead Volume: 150 µL • Sample rack: 13 mm or 16 mm 	
<p>Beckman Coulter Access 2.0 mL/13 mm Sample Cup</p> <ul style="list-style-type: none"> • Border: Dark green • Rack IDs: 1–99 or 400–499 (only 400–499 have the icon) • Dead Volume: 150 µL • Sample rack: 13 mm 	 <p>2.0 mL</p>	<p>Beckman Coulter Access 1.0 mL/13 mm Insert Cup in 13x100 mm Tube</p> <ul style="list-style-type: none"> • Border: Blue • Rack IDs: 600–699 • Dead Volume: 400 µL • Sample rack: 13 mm 	
<p>Beckman Coulter Access 1.0 mL/13 mm Insert Cup in 13x75 mm Tube</p> <ul style="list-style-type: none"> • Border: Light green • Rack IDs: 700–799 • Dead Volume: 300 µL • Sample rack: 13 mm 		<p>Beckman Coulter 0.5 mL Sample Cup</p> <ul style="list-style-type: none"> • Border: Light pink • Rack IDs: 2500–2599 • Dead Volume: 80 µL • Sample rack: 13 mm 	 <p>0.5 mL</p>
<p>Beckman Coulter Auto Aliquot Tube (use only Beckman Coulter P/N 2910034)</p> <ul style="list-style-type: none"> • Border: Purple • Rack IDs: 1600–1699 • Dead Volume: 400 µL • Sample rack: 13 mm 		<p>Beckman Coulter Access 2.0 mL/16 mm Insert Cup in 16x100 mm Tube</p> <ul style="list-style-type: none"> • Border: Orange • Rack IDs: 200–299 • Dead Volume: 400 µL • Sample rack: 16 mm 	

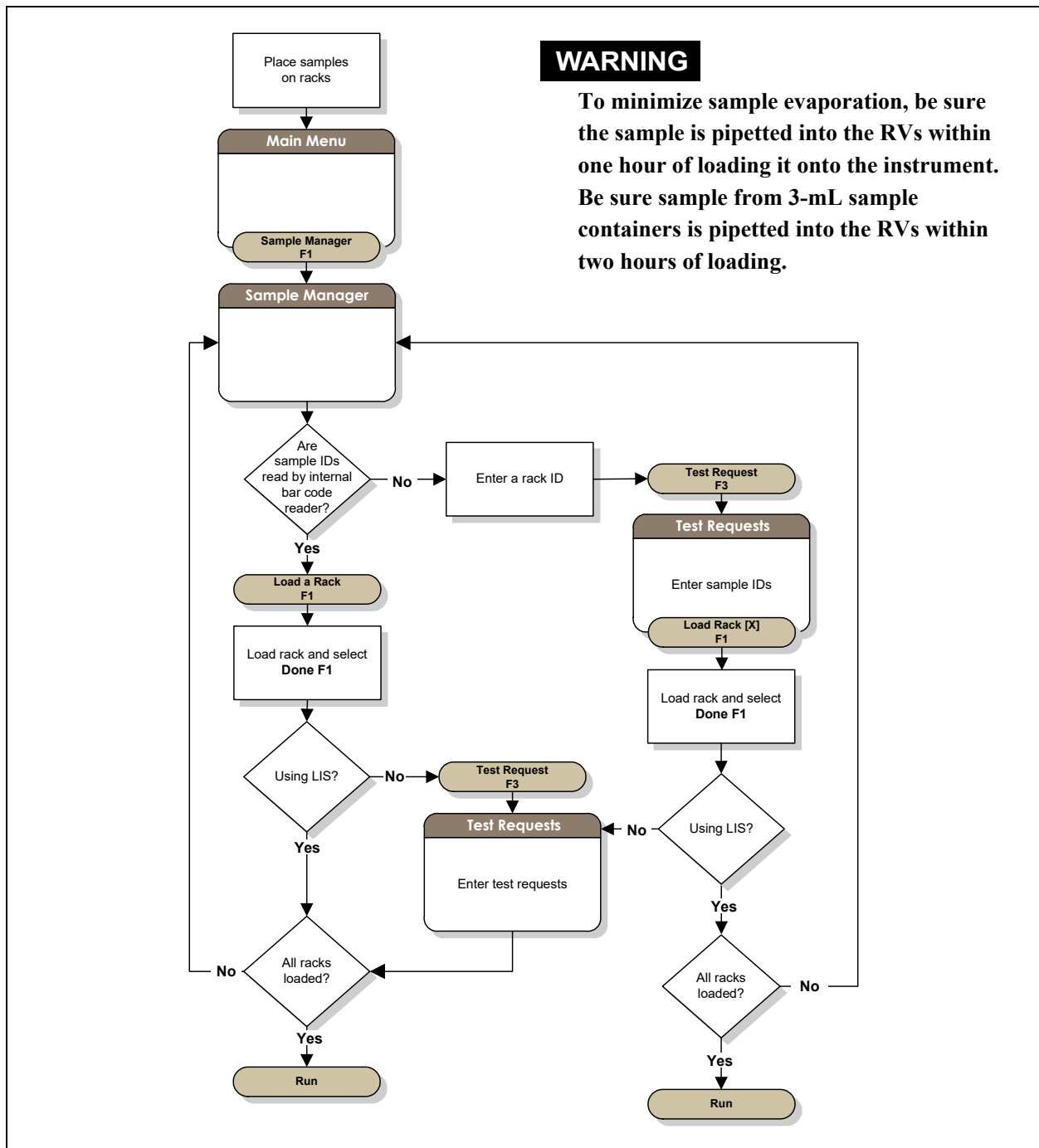
Sample Container Information	Bar Code Label Icon	Sample Container Information	Bar Code Label Icon
<p>Beckman Coulter Pediatric Insert Cup in a Beckman Coulter Pediatric Tube Adapter</p> <ul style="list-style-type: none"> • Border: Pink • Rack IDs: 1800–1899 • Dead Volume: 100 μL • Sample rack: 13 mm 		<p>Sarstedt S-Monovette Tube 90x13 mm 4.9 mL</p> <ul style="list-style-type: none"> • Border: Dark brown • Rack IDs: 2100–2199 • Dead Volume: 3 mL • Sample rack: 13 mm 	
<p>Sarstedt S-Monovette Tube 75x15 mm 5.5 mL</p> <ul style="list-style-type: none"> • Border: Red-brown • Rack IDs: 2200–2299 • Dead Volume: 3.6 mL • Sample rack: 16x75 mm ELEV 		<p>Sarstedt S-Monovette Tube 92x15 mm 7.5 mL</p> <ul style="list-style-type: none"> • Border: Light brown • Rack IDs: 2300–2399 • Dead Volume: 5 mL • Sample rack: 16x100 mm 	
<p>Sarstedt S-Monovette Tube 92x16 mm 9 mL</p> <ul style="list-style-type: none"> • Border: Gray-brown • Rack IDs: 2400–2499 • Dead Volume: 6 mL • Sample rack: 16x100 mm 			

5 Sample Manager

Sample management is the process of placing patient, maintenance, quality control, or calibration samples in racks, entering test requests, and loading the racks onto the Access 2 instrument for processing.

WARNING

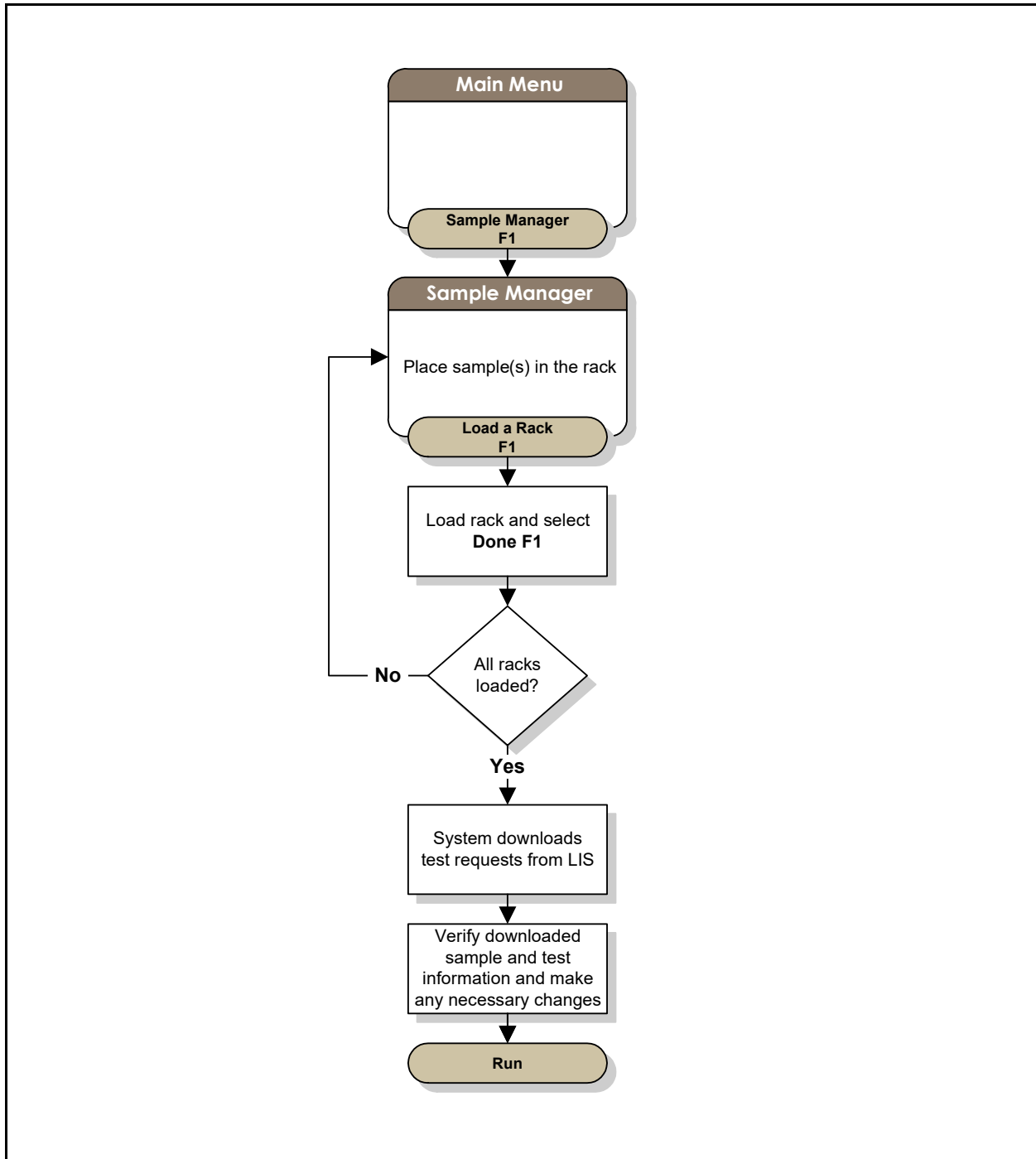
To minimize sample evaporation, be sure the sample is pipetted into the RVs within one hour of loading it onto the instrument. Be sure sample from 3-mL sample containers is pipetted into the RVs within two hours of loading.



0619D.wmf

Processing LIS Patient Test Requests

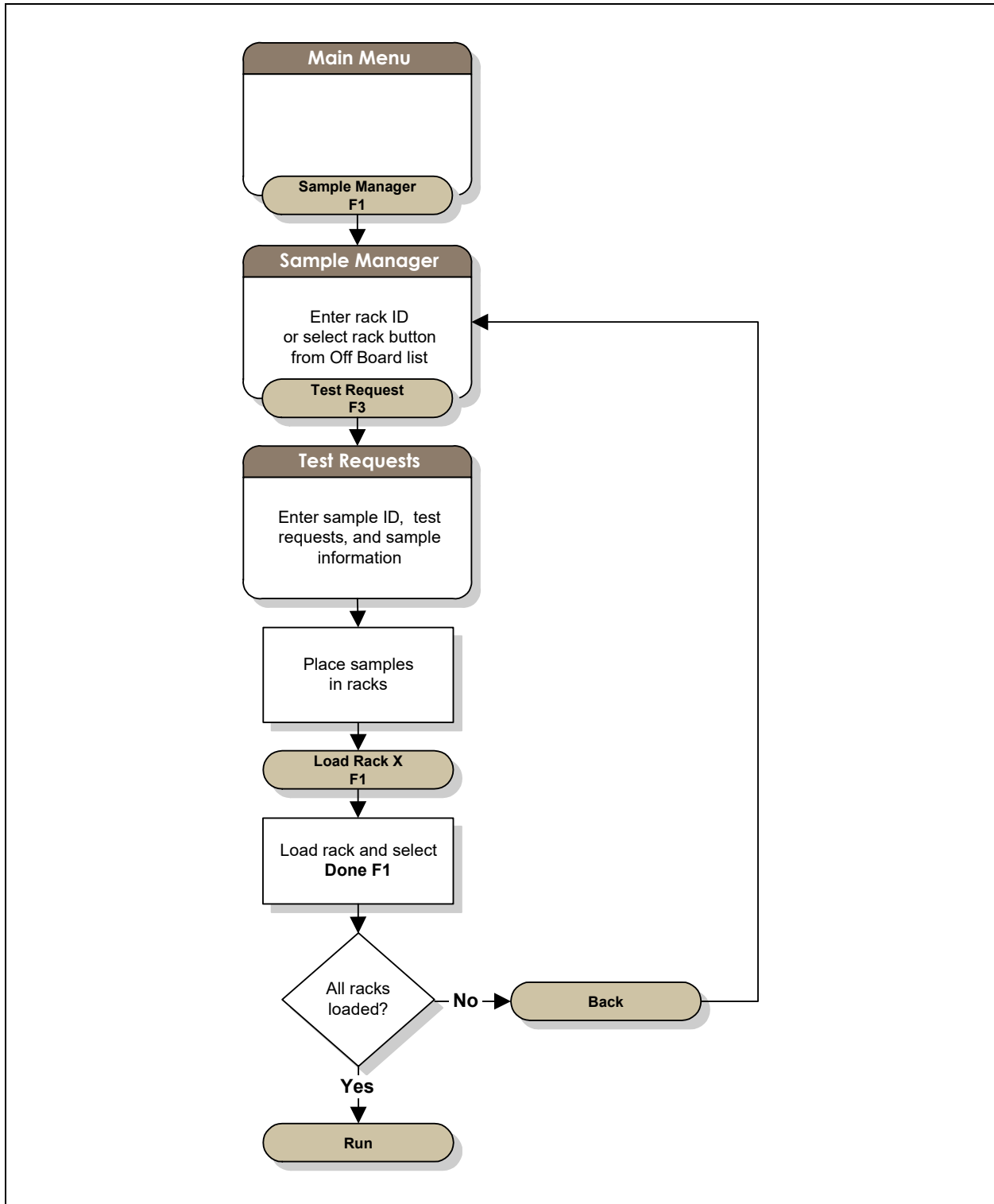
If you are using bar-coded sample containers and are downloading test requests from an LIS, use this procedure to load racks and run the tests for LIS patient test requests. You can load up to six racks at one time.



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Entering Patient Test Requests Manually

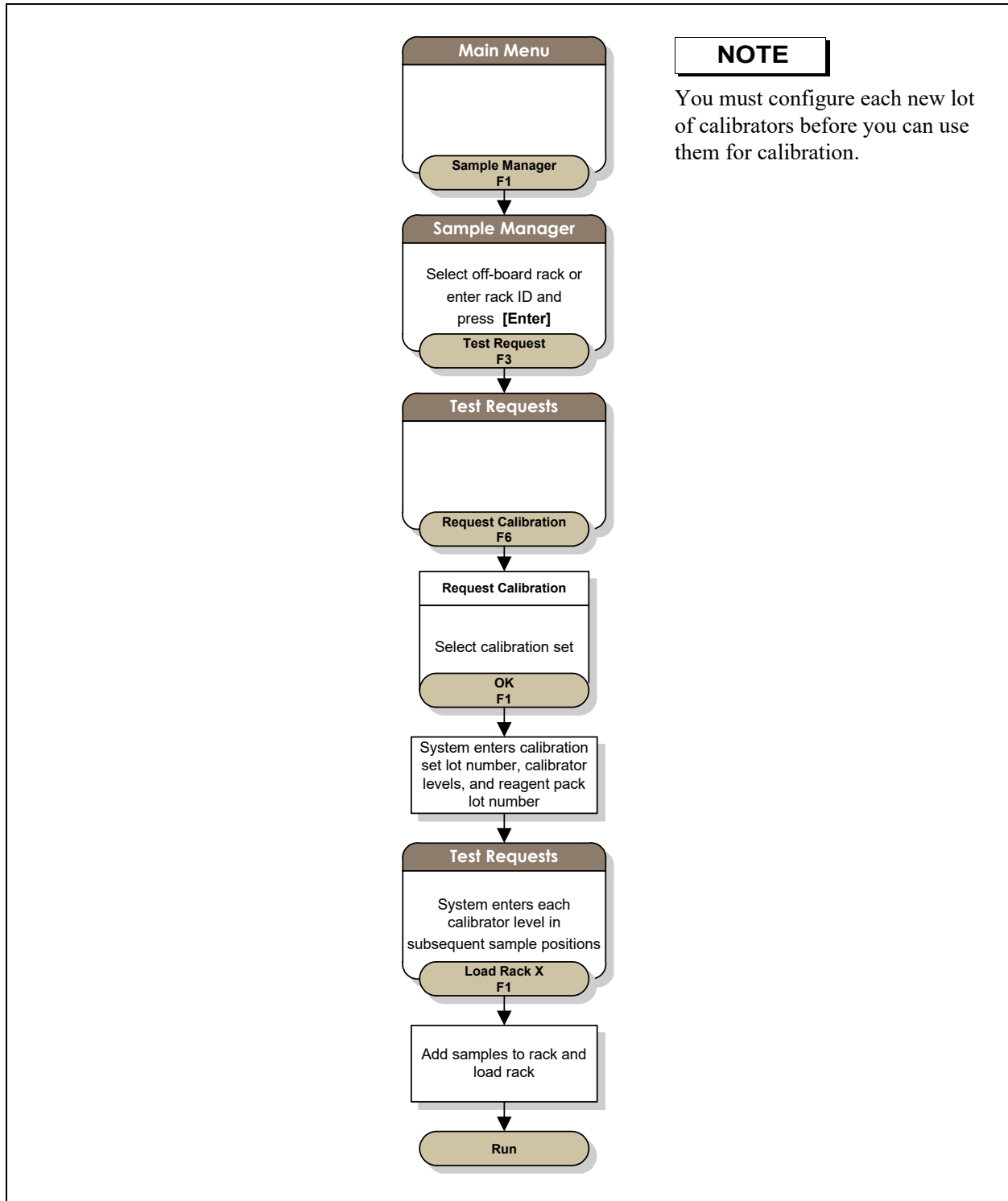
If you have disabled sample bar code scanning, or need to enter test requests and sample information manually, use this procedure to manually enter test requests.



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Entering Calibration Test Requests

You run a calibration by setting up a set of calibrators specific for an assay or group of assays. Each calibration is associated with a specific reagent pack lot number.



NOTE

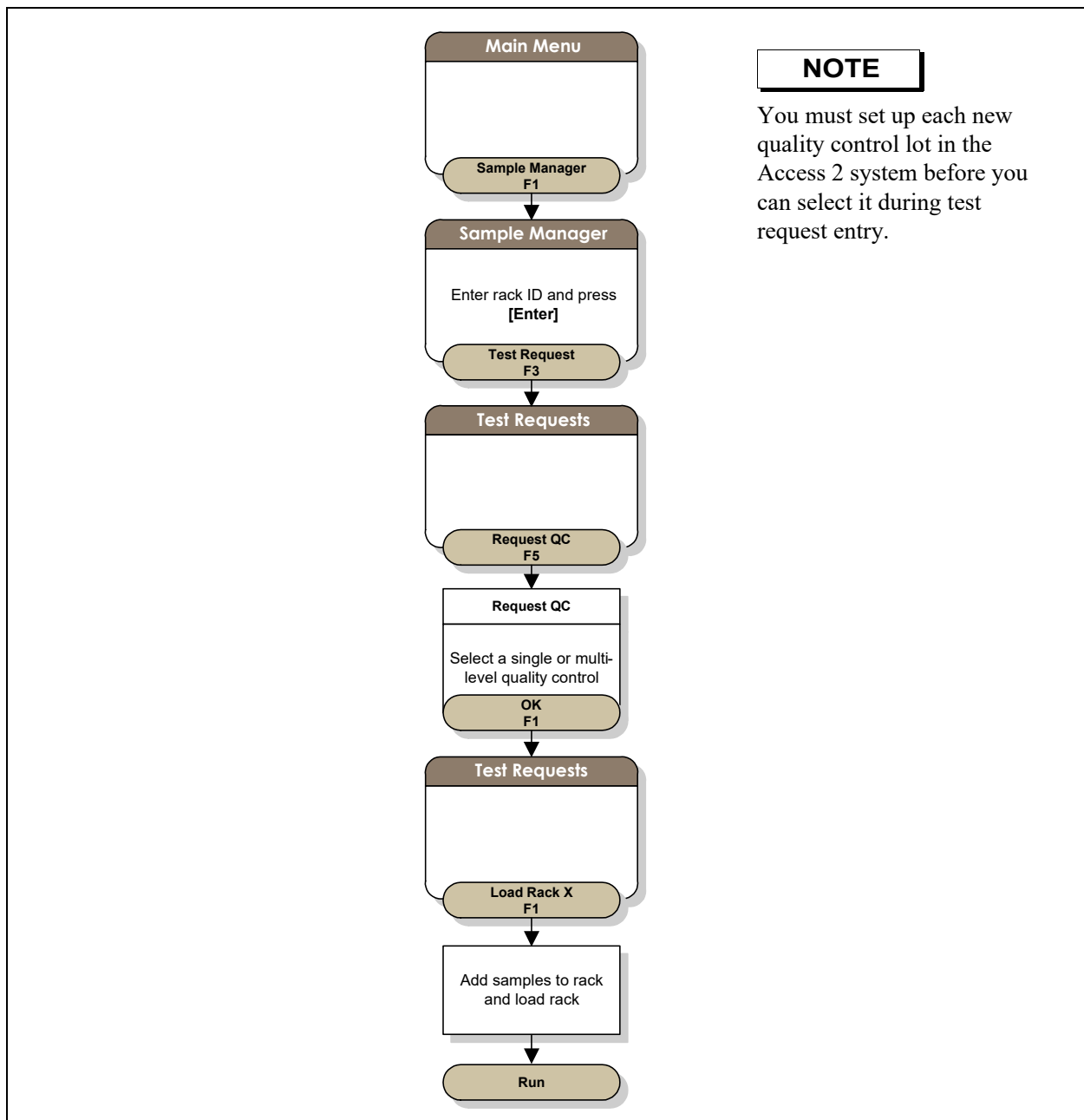
You must configure each new lot of calibrators before you can use them for calibration.

0510C.wmf

Entering Quality Control Test Requests

You run quality control by entering a quality control test request for a quality control sample or set of samples. When you enter a quality control test request, you select a specific quality control lot number from the Request QC window.

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 QC results. You may choose to run QC more frequently based on good laboratory practices or laboratory accreditation requirements and applicable laws.



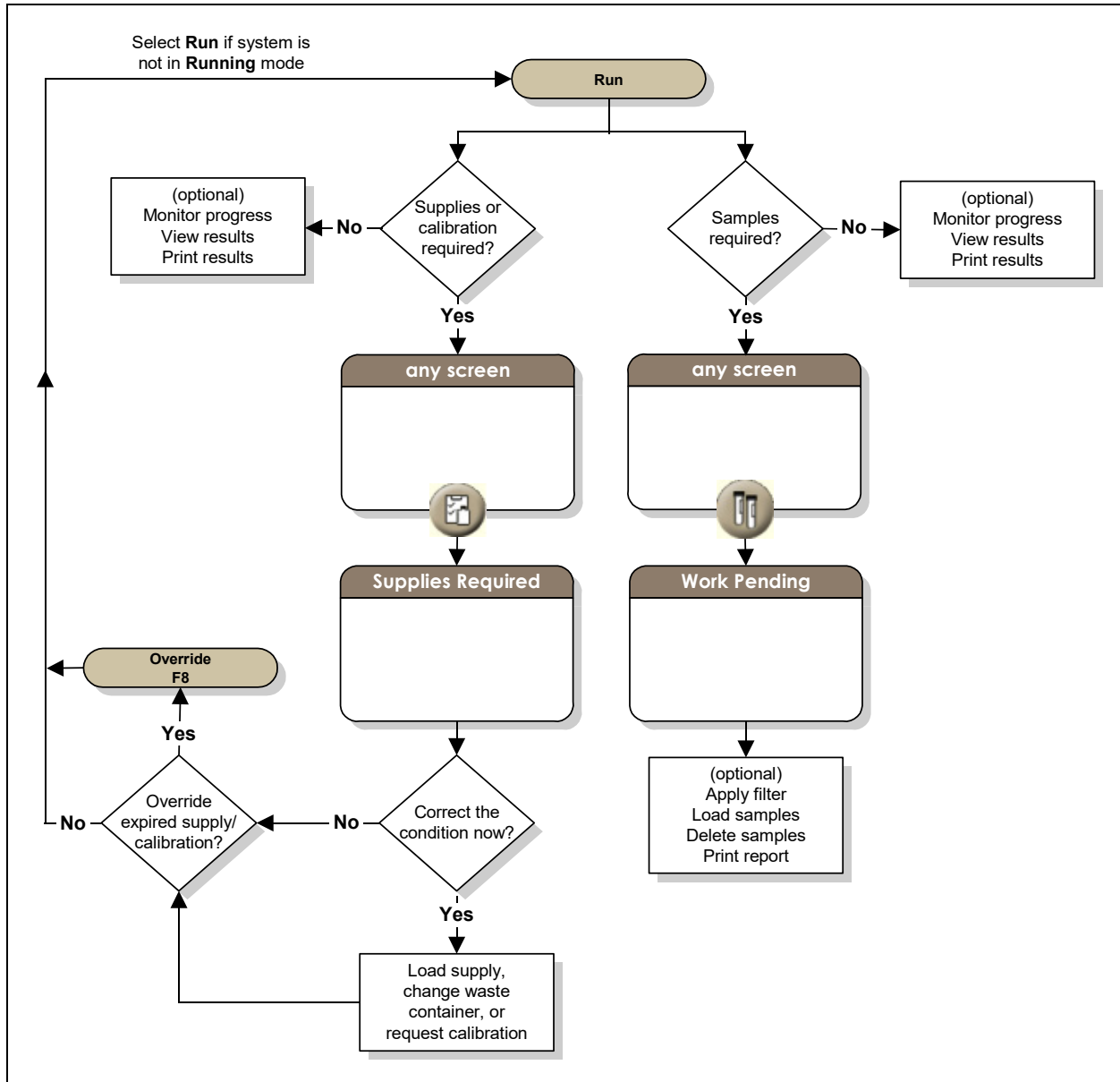
NOTE

You must set up each new quality control lot in the Access 2 system before you can select it during test request entry.

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Processing Samples

Sample processing begins after you verify supplies, load samples, and enter or verify test request information. Select **Run**.



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6 Maintenance

Maintenance Overview

For optimal performance, the Access 2 system requires routine maintenance, including Daily Maintenance and Weekly Maintenance.

A technical support representative will schedule periodic preventive maintenance procedures on your Access 2 instrument in accordance with the terms of your service agreement, if applicable. For more information about preventive maintenance, contact technical support.

Daily Maintenance

In order to keep the Access 2 system running properly, perform daily maintenance once every 24 hours.

NOTES

- If you use the Access 2 system to process the Vitamin B₁₂ assay, you should also run the Special Clean routine at the end of every day or whenever you will not use the instrument to process samples for 8 hours or more. For more information about performing the Special Clean routine, see the *Help* system.
- Even if you do not use the system every day to run assays, it is still important to perform daily maintenance on schedule to ensure that the system is ready when needed.

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. See the manufacturer's label for details.**
- **Contrad 70 cleaning solution is alkaline and may cause severe eye irritation or mild skin irritation. See the manufacturer's label for details.**
- **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.**

Required Materials

- Fiber-free polyester swabs (or equivalent fiber-free applicators)
- Maintenance Log (see the Maintenance Log in this section)
- 13-mm rack for 2-mL sample cups; the rack must have a rack ID between 1 and 57 or 400 and 456
- Wash buffer (or deionized water)
- Citranox cleaning solution
- Contrad 70 cleaning solution
- 2.0-mL sample cups (three cups)

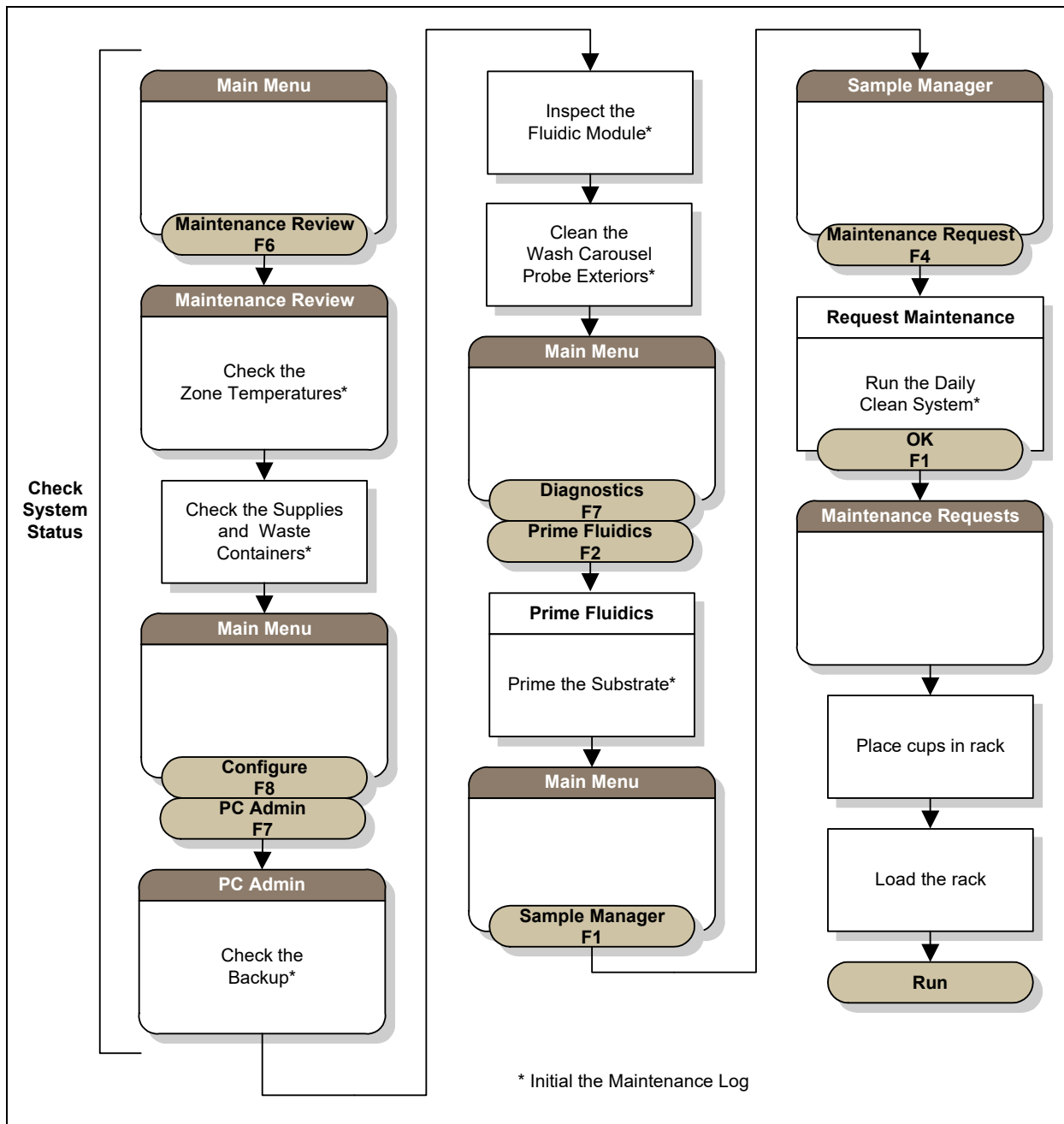
NOTE

Use only the 2.0-mL sample cups when performing the maintenance routines. Using any other sample containers may result in level sensing errors and cancellation of the maintenance routine.

CAUTIONS

- **Be sure not to bend or damage the fragile probe tips.**
- **To avoid contamination, use a new applicator on each type of probe.**
- **Do not wipe the tip of the probe. Fibers on or inside the probes can clog the probes or valves in the fluidic module.**

Daily Maintenance Steps



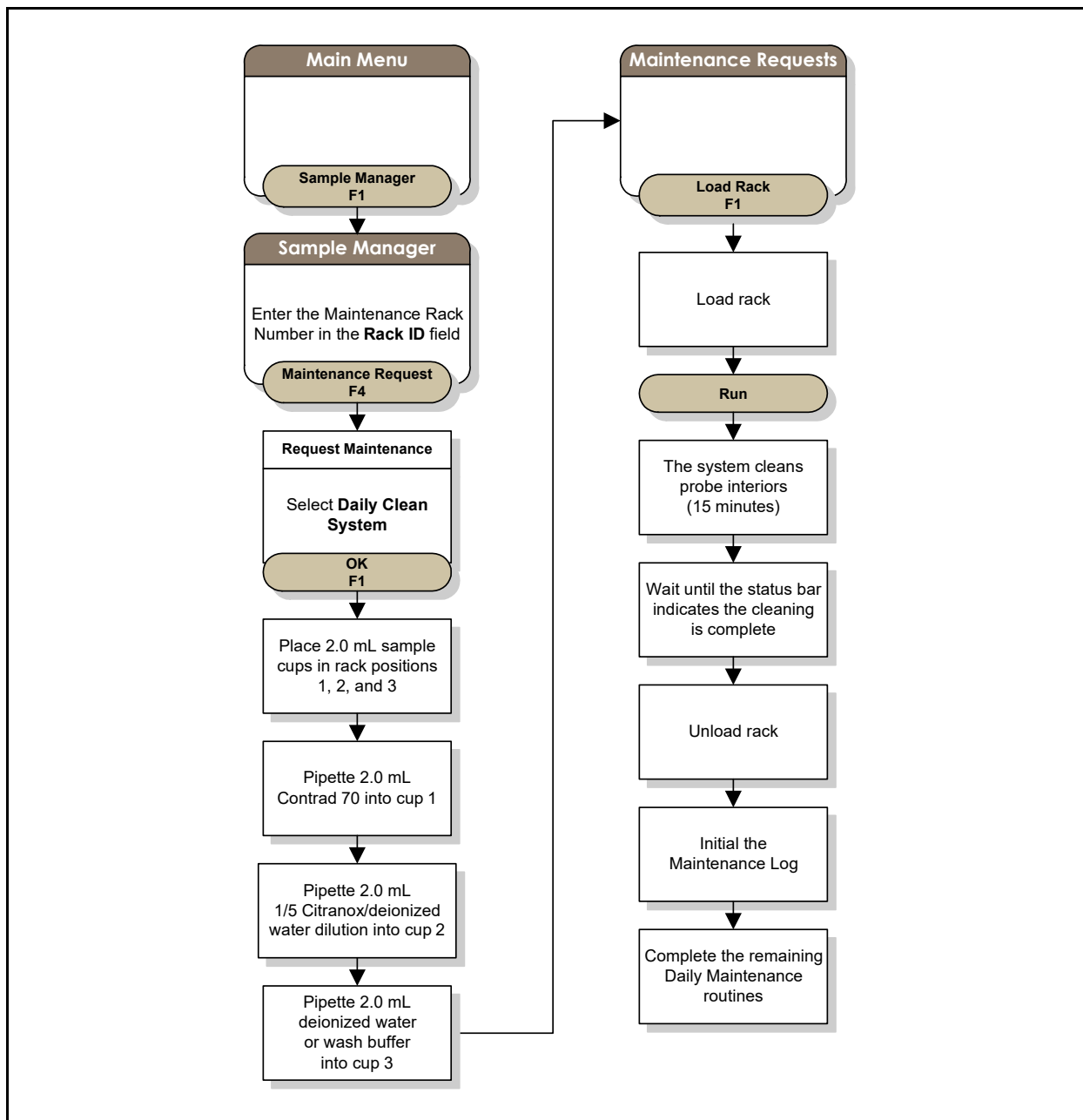
1. Check the System Status
2. Inspect the Fluidic Module
3. Clean the Wash Carousel Probe Exteriors
4. Prime the Substrate
5. Run the Daily Clean System Routine

0787D.wmf

Daily Clean System Routine

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.
- Unless there is an emergency, let the maintenance routine run to completion. Canceling the routine may damage the instrument and compromise the integrity of subsequent test results.
- If you cancel the routine, do not initialize the system. Contact Technical Support for assistance.



0596B.wmf

Weekly Maintenance

In order to keep the Access 2 system running properly, perform weekly maintenance once every seven days.

NOTE

If the system is not used to run assays every day, it is still important to perform weekly maintenance on schedule to ensure that the system is ready when needed.

WARNINGS

- **Methanol is extremely flammable. Do not use near heat or flame. Do not ingest. Avoid contact with eyes, skin, and clothing. Use with adequate ventilation.**
- **Contrad 70 cleaning solution is alkaline and may cause severe eye irritation or mild skin irritation. See the manufacturer's label for details.**
- **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.**

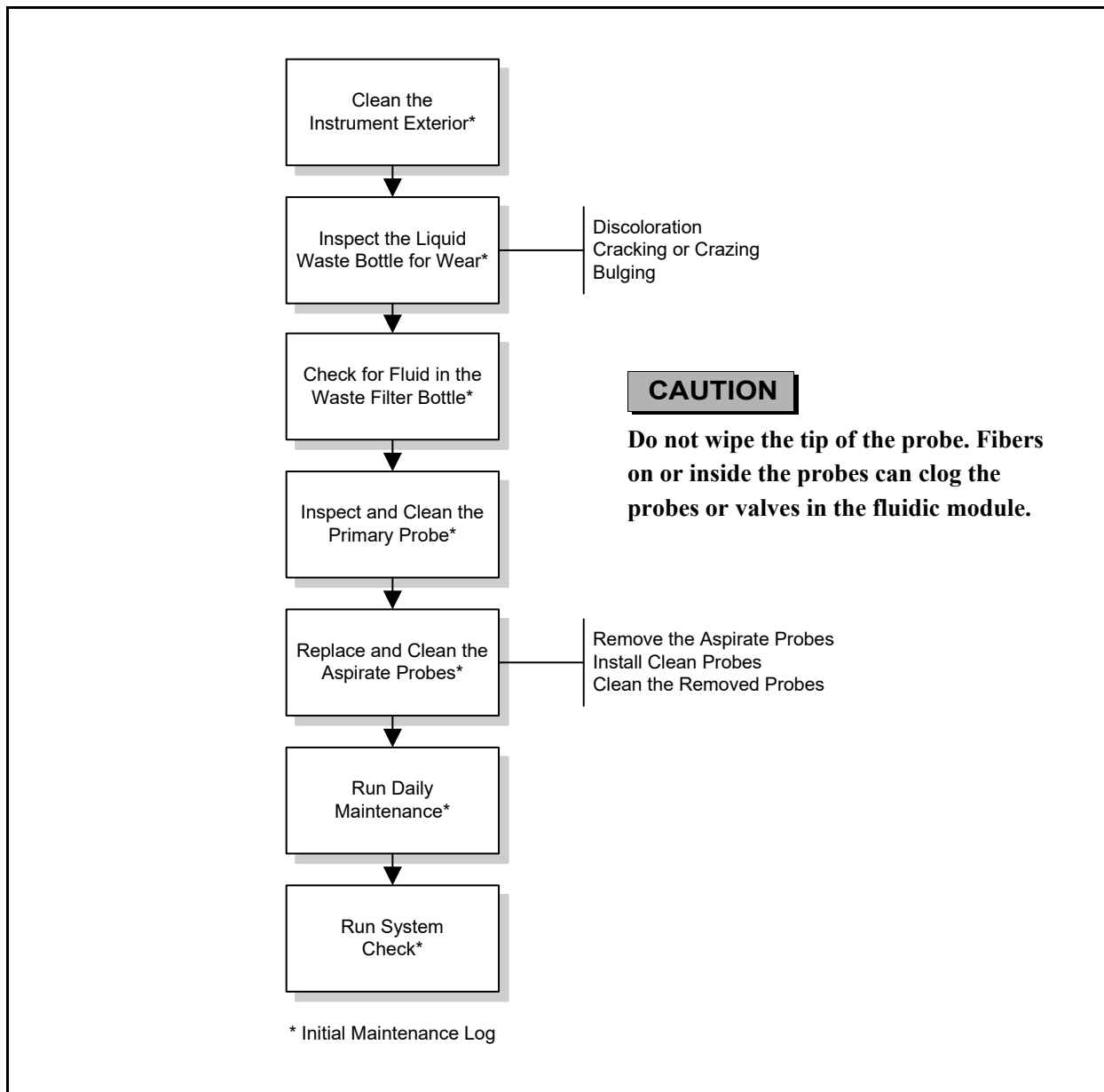
Required Materials

- Lint-free cloth
- Deionized or distilled water
- Maintenance Log (see the Maintenance Log in this section)
- Spare liquid waste bottle (as needed)
- Spare waste filter bottle (as needed)
- Alcohol or alcohol swabs or wipes (methanol can be substituted for cleaning the exterior of the aspirate probes)
- Proper hand, eye, and facial protection for handling biohazardous materials
- Clean aspirate probes (three)
- Contrad 70 cleaning solution
- Beakers (two)
- Aspirate Probe Cleaning Kit (3.0-mL syringe, disposable aspirate probe brush, aspirate probe syringe fitting assembly consisting of a fitting and tubing)
- Disposable aspirate probe brushes (as needed)
- Absorbent paper
- Wash buffer

Weekly Maintenance Steps

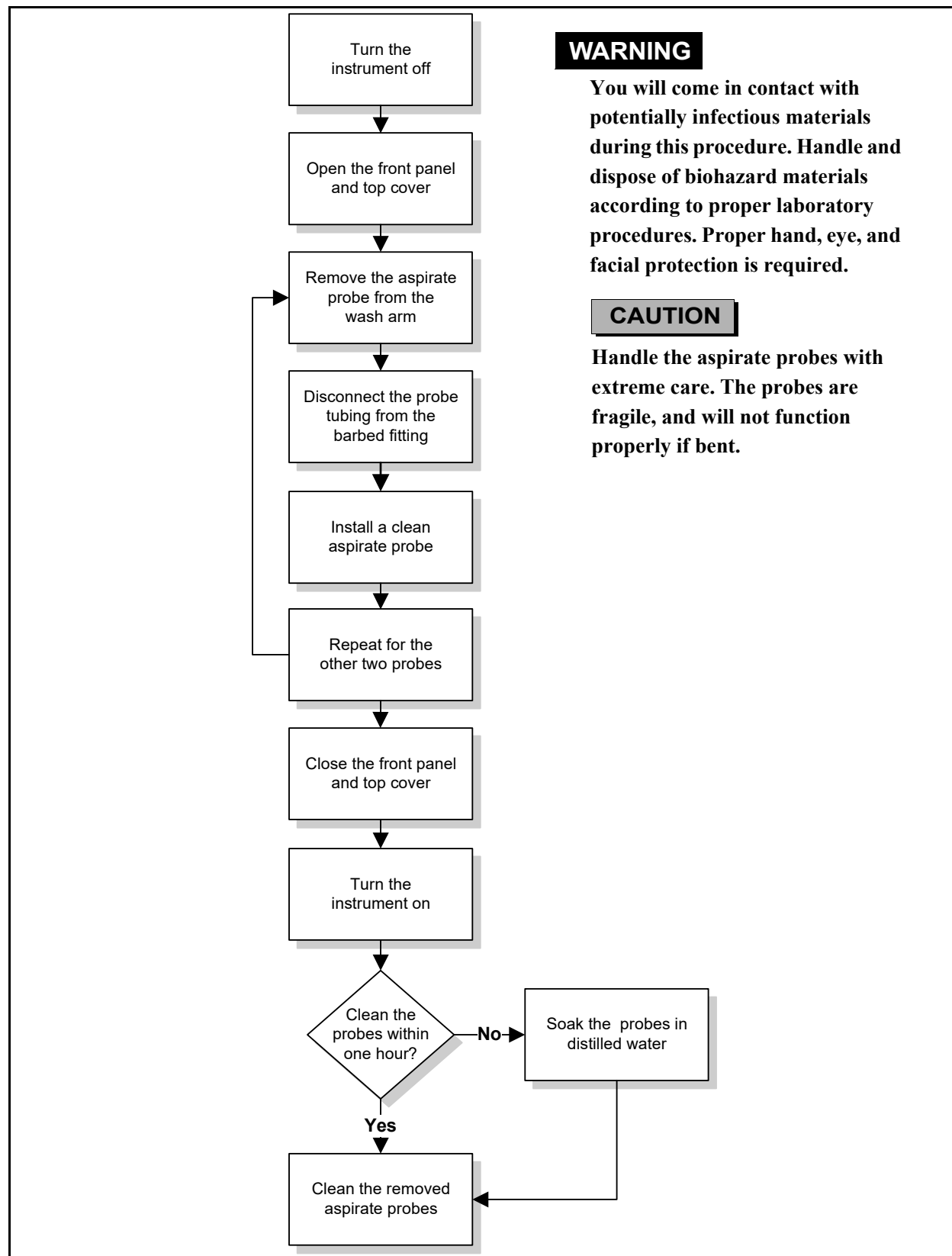
WARNING

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.



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Replacing the Aspirate Probes



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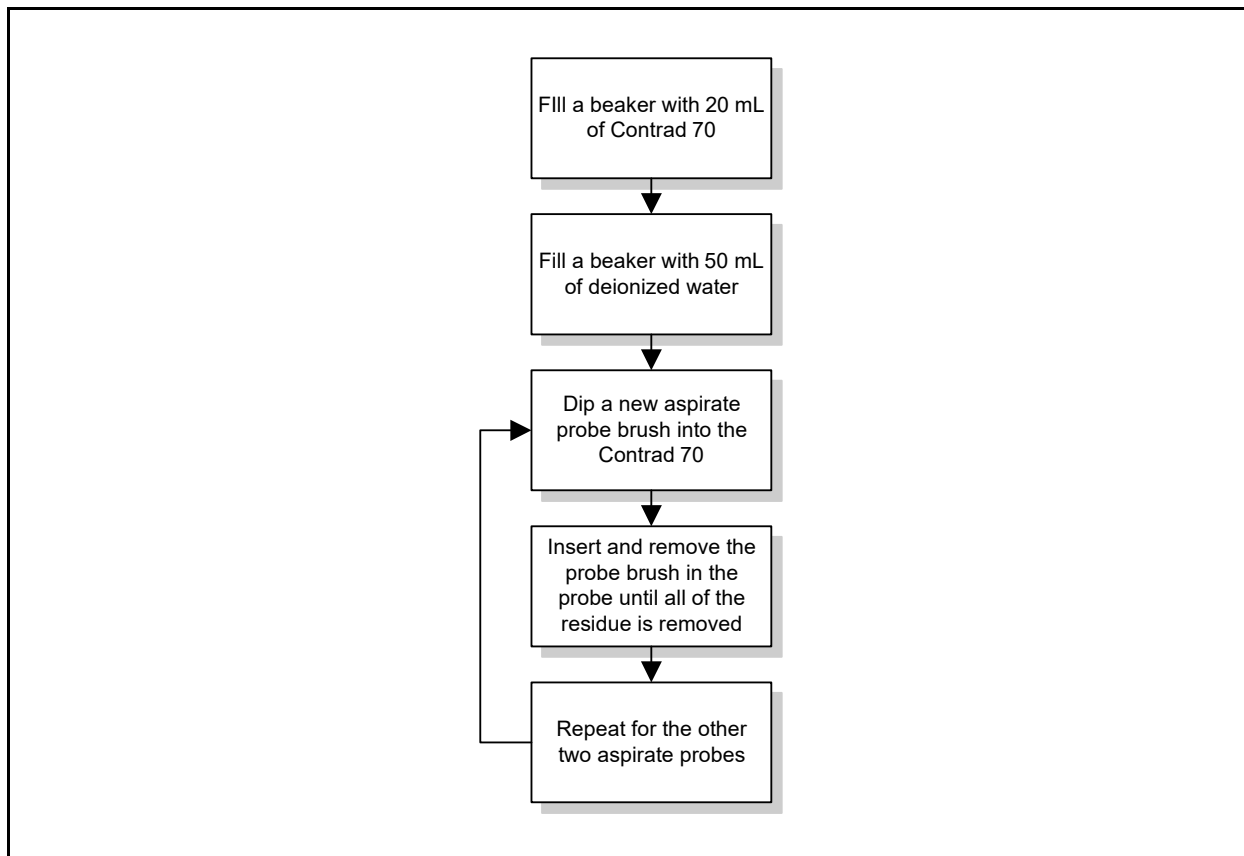
Precleaning the Aspirate Probes

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.
- Contrad 70 cleaning solution is alkaline and may cause severe eye irritation or mild skin irritation. See the manufacturer's label for details.
- Once a disposable aspirate probe brush has been used to clean 1 to 3 aspirate probes, it is considered a biohazard. Handle and dispose of the brush according to appropriate laboratory safety procedures. Do not save a used brush for future use.
- Take the necessary precautions when removing and reinserting the probe brush to avoid scattering droplets of biohazardous material into the air.

CAUTIONS

- Handle the aspirate probes with extreme care. The probes are fragile, and will not function properly if bent.
- The disposable aspirate probe brush handle bends easily.



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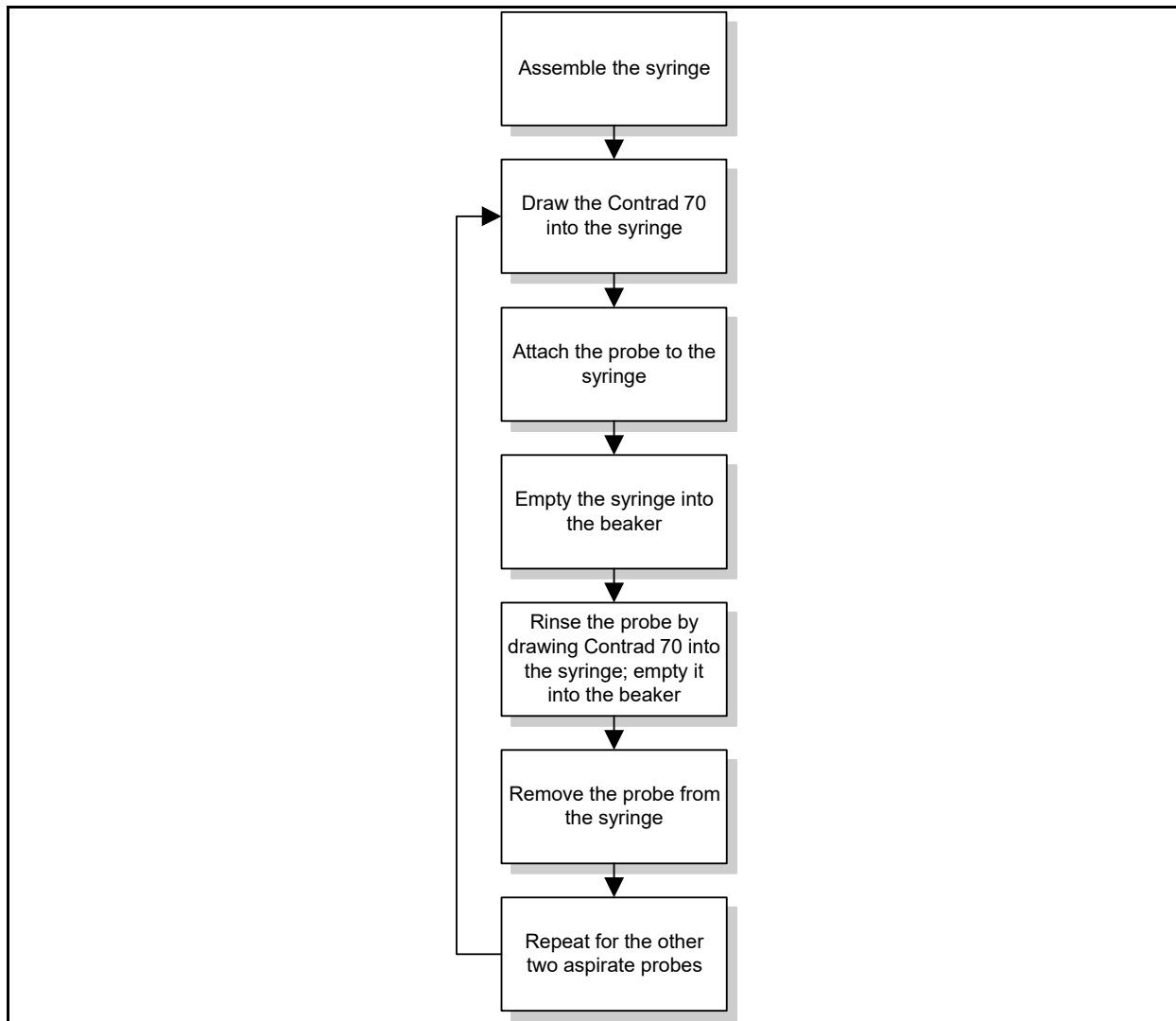
Cleaning the Aspirate Probes with Contrad 70 Cleaning Solution

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.
- Contrad 70 cleaning solution is alkaline and may cause severe eye irritation or mild skin irritation. See the manufacturer's label for details.

CAUTIONS

- Do not wipe the tip of the probe. Fibers on or inside the probes can clog the probes or valves in the fluidic module.
- Handle the aspirate probes with extreme care. The probes are fragile, and will not function properly if bent.

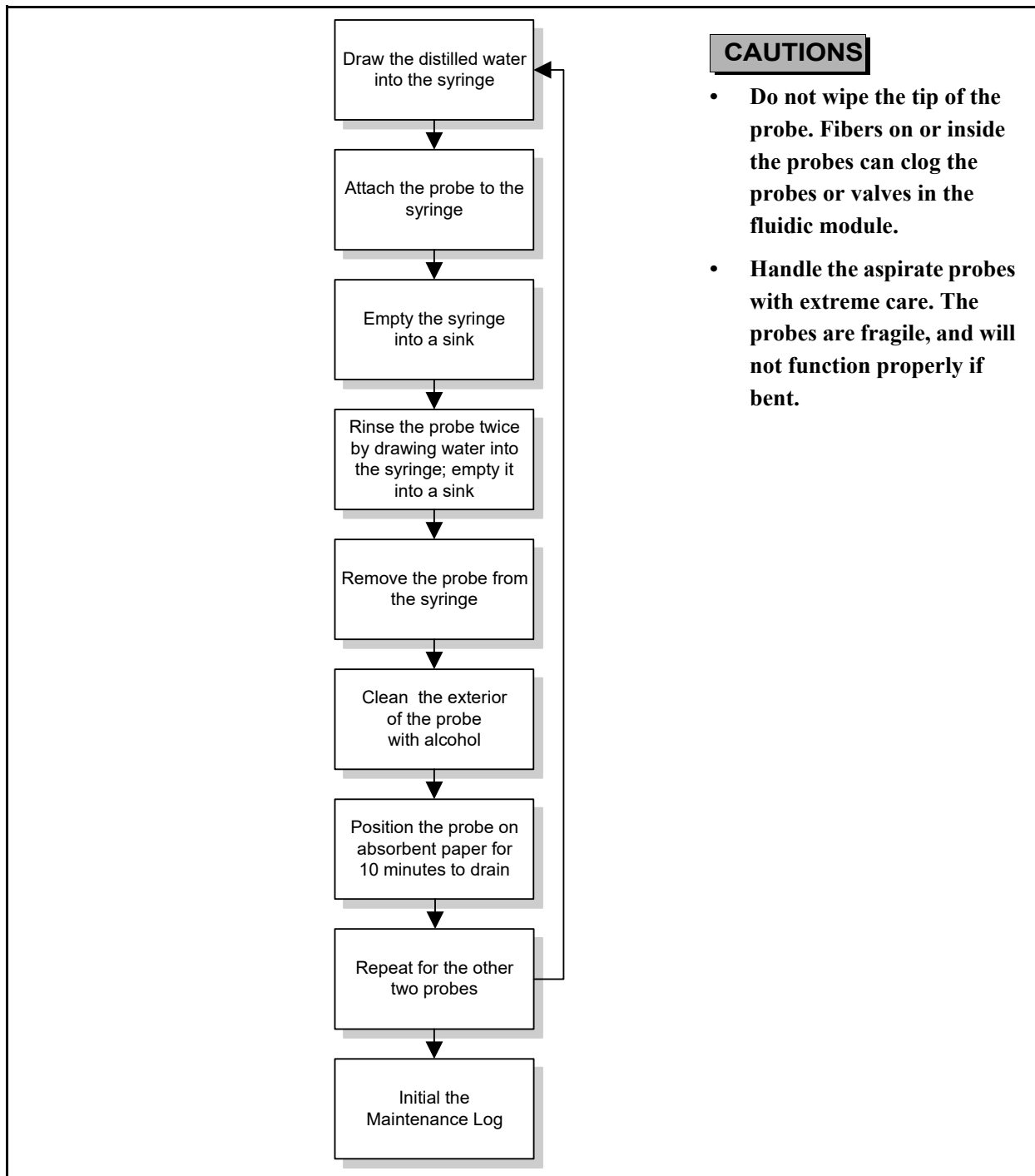


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Cleaning the Aspirate Probes with Distilled Water

WARNING

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.



CAUTIONS

- Do not wipe the tip of the probe. Fibers on or inside the probes can clog the probes or valves in the fluidic module.
- Handle the aspirate probes with extreme care. The probes are fragile, and will not function properly if bent.

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System Check

You perform the System Check routine as part of weekly maintenance to verify system performance. During weekly maintenance, the three System Checks (washed, unwashed, and substrate) are run together. You can also run the System Check routine more often, or perform individual checks.

WARNINGS

- **Unless there is an emergency, let the System Check routine run to completion. Cancelling the routine may damage the instrument and compromise the integrity of subsequent test results.**
- **If you cancel the routine, do not initialize the system. Contact Technical Support for assistance.**
- **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.**

Required Materials

- 13-mm rack for 2-mL sample cups; the rack must have a rack ID between 1 and 57 or 400 and 456
- 2.0-mL sample cups (four cups)

NOTE

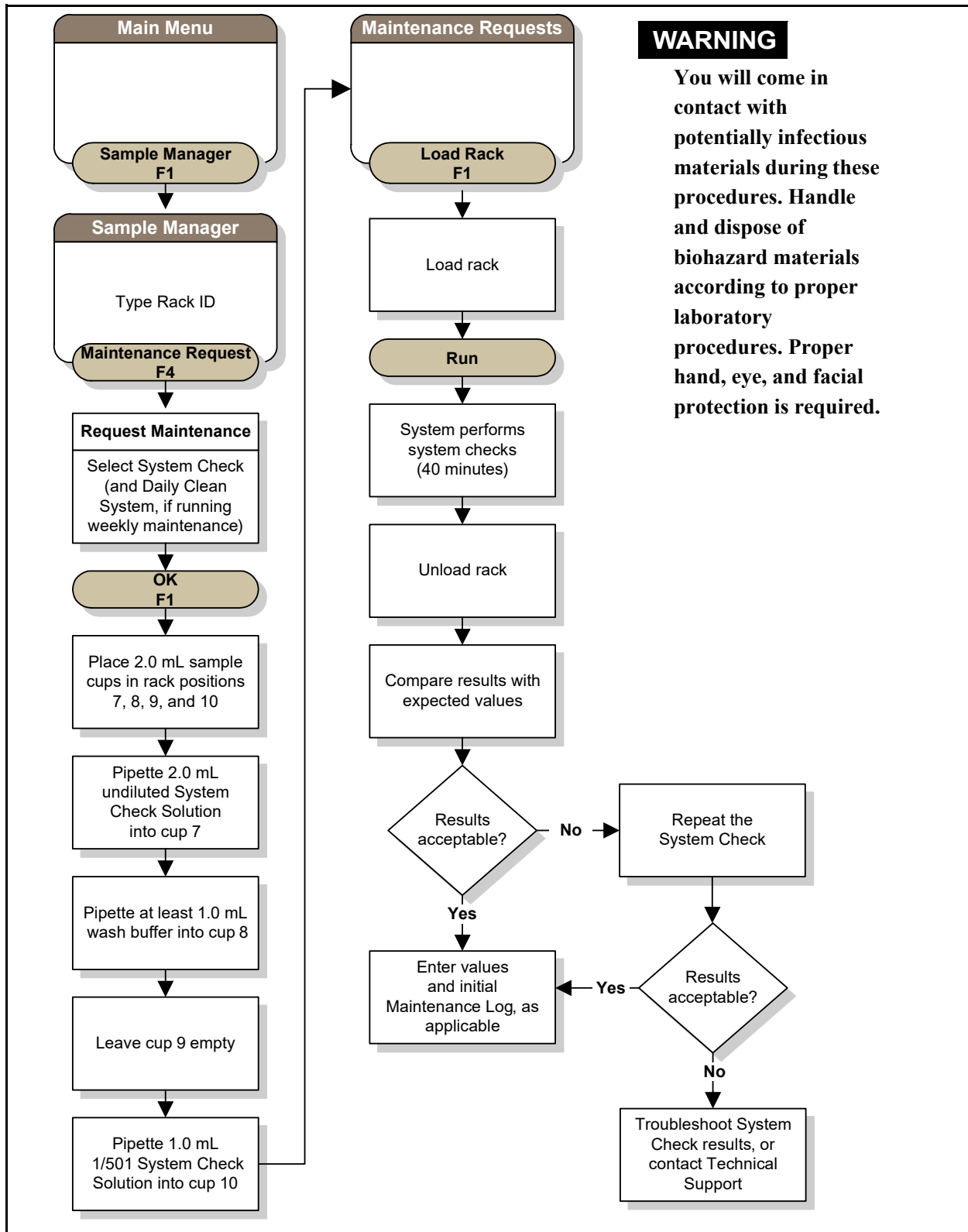
Use only the 2.0-mL sample cups when performing the maintenance routines. Using any other sample containers may result in level sensing errors and cancellation of the maintenance routine.

- Undiluted System Check Solution
- Wash buffer
- 1/501 dilution of System Check Solution (mix 20 μ L of System Check Solution with 10.0 mL of Wash Buffer)
- Maintenance Log

System Check Expected Results

Compare the obtained results with the expected results. Expected results are listed in the Maintenance Log, included in this section.

Running the System Check Routine



WARNING

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.

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7 Troubleshooting

Event Log

The Event Log is a list of events the Access 2 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.

NOTE

If you have a workgroup with more than one instrument, you can view only the events that are specific for the instrument attached to the PC displaying the Event Log.

Troubleshooting Events

If a system error or potential problem generates an event in the Event Log, you can view troubleshooting information for the event. This troubleshooting information includes:

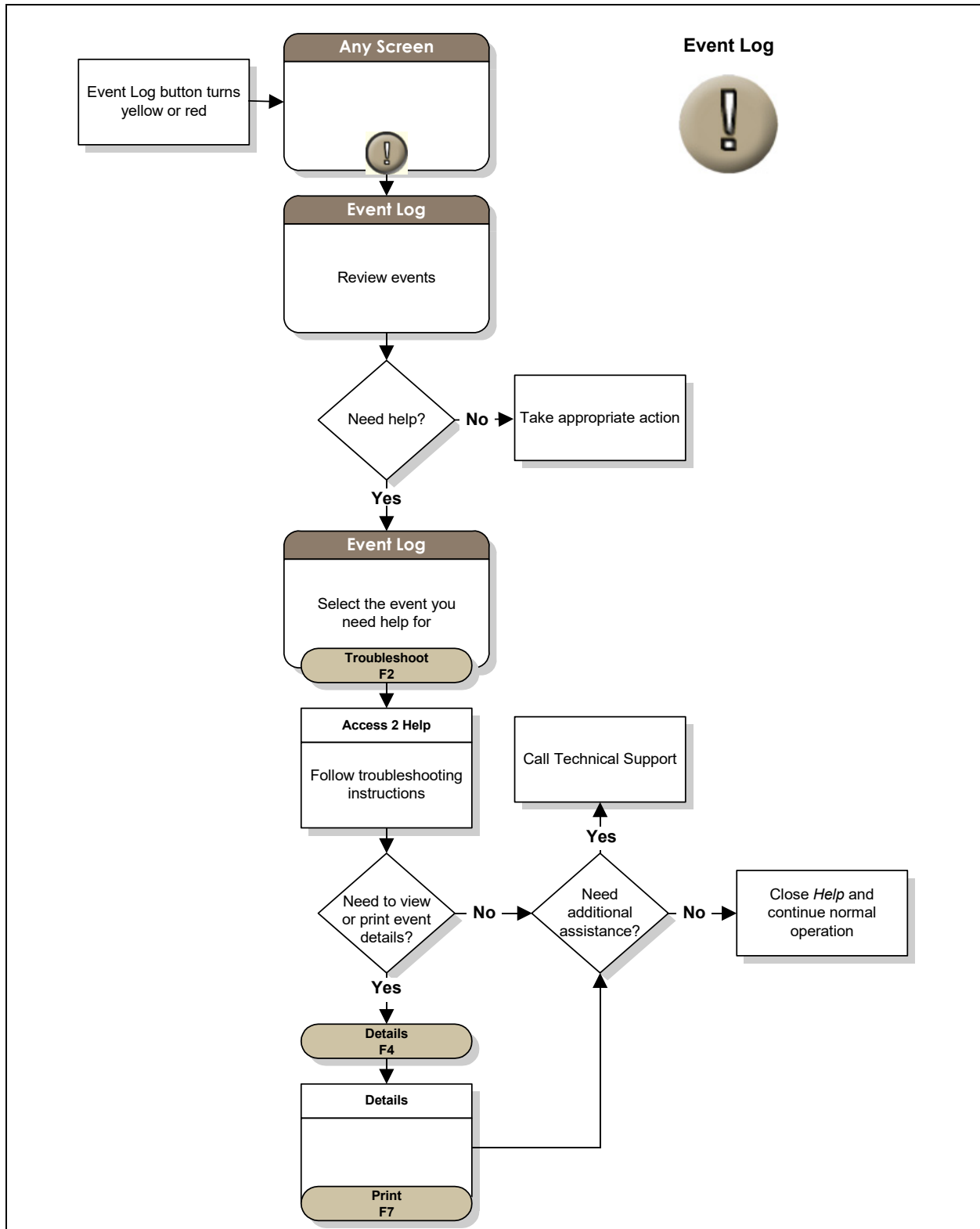
- Possible causes for the event.
- Brief outline of troubleshooting instructions.
- Links to detailed procedures. Always review the detailed procedures if you are not completely familiar with them.

You can view technical information about an event in the Details window. The event details, particularly the event code, can be useful for troubleshooting. If you contact Technical Support for assistance, the representative may request the details for one or more events.

NOTE

Event troubleshooting information is available online within the Access 2 Help system.

Troubleshooting Events



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System Check Troubleshooting

The System Check routine is typically run as part of weekly maintenance to verify that the Access 2 system is operating properly. It may also be run to troubleshoot another problem with the system or to verify proper operation after unscheduled maintenance is performed.

NOTE

The corrective actions in the troubleshooting tables contain abbreviated procedures. Regardless of the frequency with which you perform a procedure, regularly review the complete procedures, including their cautions for protecting the instrument from damage, and their warnings for ensuring your personal safety. Links to the procedures are available for the tables in the Help system.

Substrate Check Problems

If the System Check results are not within the expected ranges, troubleshoot the substrate check first. You should start here because problems with the substrate system can directly affect the unwashed and washed checks, and because the substrate check uses the fewest system components. When the substrate check results are within the expected ranges, the substrate and substrate system can be ruled out as the cause of the problem you are troubleshooting.

Substrate Check Troubleshooting

Symptoms	Possible Causes	Corrective Action
High %CV throughout the run	Insufficient supply of substrate	<ol style="list-style-type: none"> 1. Check the level of substrate in the bottle. 2. If necessary, change the substrate bottle from the Supplies screen. 3. Repeat the System Check routine.
	Air in the substrate lines	<ol style="list-style-type: none"> 1. Open the front panel. 2. Visually inspect the tubing at the substrate pump and heater for air bubbles. 3. If air bubbles are present: <ul style="list-style-type: none"> • Check the substrate pump and heater fittings, and the fitting on top of the substrate bottle. Finger-tighten any loose connections. Be careful not to overtighten any of the fitting connections. • Close the front panel and prime the substrate system for 4 cycles. 4. Open the front panel and inspect the tubing again. <ul style="list-style-type: none"> • If the bubbles are gone, close the front panel and repeat the System Check routine. • If you still see bubbles, contact Technical Support for further instructions.

Substrate Check Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
High %CV throughout the run (continued)	Leak in the substrate system tubing	<ol style="list-style-type: none"> 1. With the front panel open, open the top cover. 2. Visually inspect the tubing leading to and away from the substrate pump/valve/heater assembly for leaks and/or crystalline deposits. 3. Deposits may indicate the tubing is damaged and should be replaced. <ul style="list-style-type: none"> • If you find deposits, contact Technical Support for further instructions. • If you find no deposits, continue troubleshooting other possible causes.
	Kinked substrate system tubing	<ol style="list-style-type: none"> 1. With the front panel and top cover open, visually inspect the tubing leading to and away from the substrate pump/valve/heater assembly for kinks. <ul style="list-style-type: none"> • If no kinks are found, continue troubleshooting other possible causes. 2. Straighten any kinks. Close the top cover and front panel. <ul style="list-style-type: none"> • If the kinked tubing is part of the substrate probe, remove and replace the substrate probe. 3. Close the top cover and front panel. 4. If you straightened kinks, but did not need to replace the substrate probe: <ul style="list-style-type: none"> • Prime the substrate system for 4 cycles. • Repeat the System Check routine.
	Bent substrate probe tip	<ol style="list-style-type: none"> 1. With the front panel open, inspect the substrate probe tip. <ul style="list-style-type: none"> • If the substrate probe tip is not bent, continue troubleshooting other possible causes. 2. If the substrate probe tip is bent, remove and replace the substrate probe.
	Substrate pump or valve failure	Contact Technical Support.
	Luminometer problem	Contact Technical Support.
High %CV from high values in the last one or two replicates	System Check solution diluted incorrectly	<ol style="list-style-type: none"> 1. Prepare a new 1/501 dilution using a new vial of System Check solution. 2. Repeat the System Check routine.
	Sample containers out of order in the maintenance rack	<ol style="list-style-type: none"> 1. Place the sample containers in the correct order. 2. Repeat the System Check routine.
High RLU mean	Wash/read carousel or substrate temperatures too high (results may be flagged TRS or TRW)	<ol style="list-style-type: none"> 1. Check the wash carousel and substrate temperatures on the Maintenance Review screen. 2. If the temperatures for either device is displayed in red (out of range), contact Technical Support.
	System Check solution diluted incorrectly	<ol style="list-style-type: none"> 1. Prepare a new 1/501 dilution using a new vial of System Check solution. 2. Repeat the System Check routine.
	Sample containers out of order in the maintenance rack	<ol style="list-style-type: none"> 1. Place the sample containers in the correct order. 2. Repeat the System Check routine.

Substrate Check Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
High RLU mean (continued)	Substrate pump delivering too much substrate	Run the Visual Substrate Volume Check procedure. <ul style="list-style-type: none"> If the results do not fail, continue troubleshooting other possible causes. If the results fail, contact Technical Support.
	Contaminated substrate supply	<ol style="list-style-type: none"> Contact Technical Support to verify the need to decontaminate the substrate system. If Technical Support agrees, decontaminate the substrate system and then verify system performance.
	Luminometer problem	Contact Technical Support.
Low RLU mean	Expired substrate	<ol style="list-style-type: none"> Review the expiration date on the Supplies screen. If necessary, change the substrate bottle from the Supplies screen. Repeat the System Check routine.
	Improperly stored substrate (bottle stored at room temperature for too long)	<ol style="list-style-type: none"> Check the date the bottle was placed at room temperature. If necessary, change the substrate bottle from the Supplies screen. Repeat the System Check routine.
	Insufficient supply of substrate	<ol style="list-style-type: none"> Check the level of substrate in the bottle. If necessary, change the substrate bottle from the Supplies screen. Repeat the System Check routine.
	Wash/read carousel or substrate temperatures too low (results may be flagged TRS or TRW)	<ol style="list-style-type: none"> Check the wash carousel and substrate temperatures on the Maintenance Review screen. If the temperatures for either device are displayed in red (out of range), contact Technical Support.
	Incomplete priming of the substrate after substrate system decontamination	<ol style="list-style-type: none"> Prime the substrate system for 20 cycles again. Repeat the System Check routine.
	Substrate bottle contaminated with Citranox cleaning solution during substrate system decontamination	<ol style="list-style-type: none"> Change the substrate bottle from the Supplies screen. Do not prime the substrate system when prompted as you change the bottle. Prime the substrate system from the Prime Fluidics window for 20 cycles. Repeat the System Check routine.
	Substrate dispense volume too low	Run the Visual Substrate Volume Check procedure. <ul style="list-style-type: none"> If the results do not fail, continue troubleshooting other possible causes. If the results fail, contact Technical Support.
	Luminometer problem	Contact Technical Support.

Substrate Check Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
No RLU values	Substrate bottle contaminated with Citranox cleaning solution during substrate system decontamination	<ol style="list-style-type: none"> 1. Change the substrate bottle from the Supplies screen. Do not prime the substrate system when prompted as you change the bottle. 2. Prime the substrate system from the Prime Fluidics window for 20 cycles. 3. Repeat the System Check routine.
	Luminometer problem	Contact Technical Support.
RLUs trending up or down over time	Substrate delivery inconsistent	Troubleshoot according to the High %CV symptoms for substrate check.
	Substrate bottle contaminated with Citranox cleaning solution during substrate system decontamination	<ol style="list-style-type: none"> 1. Change the substrate bottle from the Supplies screen. Do not prime the substrate system when prompted as you change the bottle. 2. Prime the substrate system from the Prime Fluidics window for 20 cycles. 3. Repeat the System Check routine.
High substrate ratio	Dirty or plugged aspirate probes	<ol style="list-style-type: none"> 1. Clean the aspirate probes. 2. Repeat the System Check routine.
	Fluid dripping from aspirate probes	<ol style="list-style-type: none"> 1. Open the front panel. 2. Visually inspect the tubing and the area under the tubing, from the peristaltic waste pump to the aspirate probes for leaks and/or crystalline deposits. 3. Deposits may indicate that the tubing is damaged and should be replaced. <ul style="list-style-type: none"> • If you find deposits, contact Technical Support for further assistance. • If you find no leaks/deposits, continue troubleshooting other possible causes.
	Plugged waste air filter	<ol style="list-style-type: none"> 1. Check the tubing from the liquid waste bottle for constrictions. <ul style="list-style-type: none"> • If the tubing is constricted, clear it and repeat the System Check routine. 2. If the results fail, remove the tubing from the waste filter at the quick disconnect and place the end of the tubing in one of the adjacent holes. This may temporarily resolve the error until you can install a new waste filter assembly. 3. Repeat the System Check routine. <ul style="list-style-type: none"> • If the results are acceptable, contact Technical Support for assistance in ordering and replacing the waste filter assembly. • If the results fail, contact Technical Support.

Unwashed Check Problems

Begin troubleshooting the unwashed check once you have determined that the substrate check results are within the expected ranges. The unwashed check troubleshooting table provides information about the pipetting system, and does not provide detail on problems related to the substrate or washing systems.

Unwashed Check Troubleshooting

Symptoms	Possible Causes	Corrective Action
High %CV	Air in the main pipettor fluid lines	<ol style="list-style-type: none"> 1. Open the front panel. 2. Visually inspect the main pipettor line for air bubbles. Be sure to check the tubing leading out of the precision pump and entering the main pipettor. 3. If bubbles are present, prime the pipettor. 4. Inspect the tubing again. <ul style="list-style-type: none"> • If the bubbles are gone, run the System Check routine. • If you still see bubbles, contact Technical Support for further instructions.
	Wash buffer supply lines kinked	<ol style="list-style-type: none"> 1. Open the front panel. 2. Visually inspect the tubing from the wash buffer supply to the main pipettor for kinks. <ul style="list-style-type: none"> • If no kinks are found, continue troubleshooting other possible causes. 3. Straighten any kinks and close the front panel. 4. Prime the pipettor. 5. Repeat the System Check routine.
	No wash buffer	<ol style="list-style-type: none"> 1. Check the wash buffer supply in the fluids tray. <ul style="list-style-type: none"> • If the wash buffer reservoir is empty, but the Wash Buffer status button is not red, contact Technical Support. 2. If necessary, change the wash buffer bottle. 3. Repeat the System Check routine.
	Precision pump, valve, fittings, or tubing damaged and leaking	<ol style="list-style-type: none"> 1. Open the front panel and the top cover. 2. Visually inspect the tubing leading from the precision pump valve, to the pressure monitor if applicable, to the main pipettor for leaks and/or crystalline deposits. 3. Examine the precision pump and valve for leaks and/or crystalline deposits. 4. Deposits may indicate that the pipetting system is damaged and should be replaced. <ul style="list-style-type: none"> • If you see deposits, contact Technical Support for further assistance. • If you do not see deposits, continue troubleshooting other possible causes.
	Worn or damaged precision pump seals	Contact Technical Support.

Unwashed Check Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
High %CV (continued)	Problems with the substrate system: <ul style="list-style-type: none"> • Insufficient supply of substrate • Air in the substrate lines • Leak in the substrate system tubing • Kinked substrate system tubing • Bent substrate probe • Substrate pump or valve failure 	<ol style="list-style-type: none"> 1. If the substrate check %CV result is within the expected range, the substrate system is not the cause of the high %CV for the unwashed check. Continue troubleshooting other possible causes. 2. If the substrate check result is not within the expected range, troubleshoot the substrate check result.
	Primary probe partially plugged	<ol style="list-style-type: none"> 1. Look at the Pressure Monitor screen to determine if a pressure sensor is present, and that obstruction detection is enabled. <ul style="list-style-type: none"> • If the pressure sensor is not present, or if it is present but obstruction detection is disabled, continue with step 2. • If obstruction detection is enabled, review the Event Log, and troubleshoot according to the events related to main pipettor obstructions or abnormal pressures. 2. Run the Special Clean routine. 3. Run the System Check routine. 4. If the results fail, contact Technical Support to verify the need to replace the primary probe. 5. When needed, remove and replace the primary probe.
	Splashing in the RVs	Contact Technical Support.
	Luminometer problem	Contact Technical Support.
High RLU mean	System Check solution diluted incorrectly	<ol style="list-style-type: none"> 1. Prepare a new 1/501 dilution using a new vial of System Check solution. 2. Repeat the System Check routine.
	Sample containers out of order in the maintenance rack	<ol style="list-style-type: none"> 1. Place the sample containers in the correct order. 2. Repeat the System Check routine.
	Problems with the substrate system: <ul style="list-style-type: none"> • Wash/read carousel or substrate temperatures too high • Contaminated substrate supply • Substrate pump delivering too much substrate 	<ol style="list-style-type: none"> 1. If the substrate check mean RLU result is within the expected range, the substrate system is not the cause of the high mean RLU result for the unwashed check. Continue troubleshooting other possible causes. 2. If the substrate check result is not within the expected range, troubleshoot the substrate check result.
	Luminometer problem	Contact Technical Support.

Unwashed Check Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
Low RLU mean	System Check solution diluted incorrectly	<ol style="list-style-type: none"> 1. Prepare a new 1/501 dilution using a new vial of System Check solution. 2. Repeat the System Check routine.
	Sample containers out of order in the maintenance rack	<ol style="list-style-type: none"> 1. Place the sample containers in the correct order. 2. Repeat the System Check routine.
	System Check expired or stored incorrectly	<ol style="list-style-type: none"> 1. Prepare a new 1/501 dilution using a new vial of unexpired System Check solution. 2. Repeat the System Check routine.
	Problems with the substrate system: <ul style="list-style-type: none"> • Expired substrate • Insufficient supply of substrate • Wash/read carousel or substrate temperatures too low • Incomplete priming after substrate system decontamination • Substrate supply contaminated with Citranox cleaning solution during substrate system decontamination • Substrate dispense volume too low 	<ol style="list-style-type: none"> 1. If the substrate check RLU mean result is within the expected range, the substrate system is not the cause of the low RLU mean result for the unwashed check. Continue troubleshooting other possible causes. 2. If the substrate check result is not within the expected range, troubleshoot the substrate check result.
	Luminometer problem	Contact Technical Support.
Low RLU outliers	Ultrasonic transducer problem	Contact Technical Support.

Washed Check Problems

Begin troubleshooting the washed check once you have determined that the substrate check and unwashed check results are within the expected ranges. The washed check troubleshooting table provides information about the RV wash system, and does not provide detail on problems related to the substrate or the pipetting systems.

Washed Check Troubleshooting

Symptoms	Possible Causes	Corrective Action
High %CV	Dirty or plugged aspirate probes	<ol style="list-style-type: none"> 1. Clean the aspirate probes. 2. Repeat the System Check routine.
	Damaged aspirate probes	<ol style="list-style-type: none"> 1. Open the front panel. 2. Visually inspect the aspirate probes on the wash arm. 3. Replace any probes that are damaged. 4. With the front panel closed, repeat the System Check routine. 5. If the problem persists, contact Technical Support.

Washed Check Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
High % CV (continued)	Plugged waste air filter	<ol style="list-style-type: none"> Check the tubing from the liquid waste bottle for constrictions. <ul style="list-style-type: none"> If the tubing is constricted, clear it and repeat the System Check routine. If the results fail, remove the tubing from the waste filter at the quick disconnect and place the end of the tubing in one of the adjacent holes. This may temporarily resolve the error until you can install a new waste filter assembly. Repeat the System Check routine. <ul style="list-style-type: none"> If the results are acceptable, order a new waste filter assembly and replace the current one. If the results fail, contact Technical Support.
	Damaged peristaltic waste pump tubing	<ol style="list-style-type: none"> Open the front panel and top cover. Visually inspect the tubing and area under the tubing, from the peristaltic waste pump to the aspirate probes for leaks and/or crystalline deposits. Deposits may indicate that the tubing is damaged and should be replaced. <ul style="list-style-type: none"> If you see deposits, contact Technical Support for further assistance. If you do not see deposits, continue troubleshooting other possible causes.
	One or more aspirate probes stuck in the “up” position	<ol style="list-style-type: none"> With the front panel open, verify that the aspirate probes can move up and down. <ul style="list-style-type: none"> Grasp each probe gently just below the wash arm. The probe should move up and down slightly. Replace any probe that does not move freely. With the front panel closed, repeat the System Check routine. If the problem persists, contact Technical Support.
	Air in the wash pump system tubing	<ol style="list-style-type: none"> With the front panel open, visually inspect the tubing from the wash buffer supply to the dispense probes for air bubbles. If you see bubbles, close the front panel and prime the dispense probes for 4 cycles. Open the front panel and inspect the tubing again. <ul style="list-style-type: none"> If the bubbles are gone, close the front panel and repeat the System Check routine. If you still see bubbles, contact Technical Support for further instructions.
	Kinked wash pump system tubing	<ol style="list-style-type: none"> With the front panel open, visually inspect the tubing from the wash buffer supply to the dispense probes for kinks. <ul style="list-style-type: none"> If no kinks are found, continue troubleshooting other possible causes. Straighten any kinks. Close the front panel and prime the dispense probes for 4 cycles. Repeat the System check routine.

Washed Check Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
High % CV (continued)	Problems with the substrate system: <ul style="list-style-type: none"> • Insufficient supply of substrate • Air in substrate lines • Leak in the substrate system tubing • Kinked substrate system tubing • Bent substrate probe • Substrate pump or valve failure 	<ol style="list-style-type: none"> 1. If the substrate check %CV result is within the expected range, the substrate system is not the cause of the high %CV for the washed check. Continue troubleshooting other symptoms. 2. If the substrate check result is not within the expected range, troubleshoot the substrate check result.
	Problems with the pipetting system: <ul style="list-style-type: none"> • No wash buffer • Worn or damaged precision pump seals • Partially plugged primary probe • Precision pump, valve, fittings, or tubing damaged and leaking 	<ol style="list-style-type: none"> 1. If the unwashed check %CV result is within the expected range, the pipetting system is not the cause of the high %CV for the washed check. Continue troubleshooting other possible causes. 2. If the unwashed check result is not within the expected range, troubleshoot the unwashed check result.
	Incorrect aspirate probe height	Contact Technical Support.
	Defective peristaltic waste pump	Contact Technical Support.
	RV mixing problem	Contact Technical Support.
	Splashing in the RVs	Contact Technical Support.
High RLU mean	Dirty or plugged aspirate probes	<ol style="list-style-type: none"> 1. Clean the aspirate probes. 2. Repeat the System Check routine.
	Damaged aspirate probes	<ol style="list-style-type: none"> 1. Open the front panel. 2. Visually inspect the aspirate probes on the wash arm. 3. Replace any probes that are damaged. 4. With the front panel closed, repeat the System Check routine. 5. If the problem persists, contact Technical Support.
	One or more aspirate probes stuck in the “up” position	<ol style="list-style-type: none"> 1. With the front panel open, verify that the aspirate probes can move up and down. <ul style="list-style-type: none"> • Grasp each probe gently just below the wash arm. • The probe should move up and down slightly. 2. Replace any probe that does not move freely. 3. With the front panel closed, repeat the System Check routine. 4. If the problem persists, contact Technical Support.

Washed Check Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
High RLU mean (continued)	Problems with the substrate system: <ul style="list-style-type: none"> Wash/read carousel or substrate temperatures too high Contaminated substrate supply Substrate pump delivering too much substrate 	<ol style="list-style-type: none"> If the substrate check RLU mean result is within the expected range, the substrate system is not the cause of the high RLU mean. Continue troubleshooting other possible causes. If the substrate check result is not within the expected range, troubleshoot the substrate check result.
	Incorrect aspirate probe height	Contact Technical Support.
	Luminometer problem	Contact Technical Support.
Low RLU mean	Diluted System Check solution used instead of undiluted	<ol style="list-style-type: none"> Be sure that sample container 1 contains undiluted System Check solution. Repeat the System Check routine.
	Containers 1 and 4 switched in the maintenance rack	<ol style="list-style-type: none"> Be sure that sample container 1 contains undiluted System Check solution and sample container 4 contains 1/501 diluted System Check. Repeat the System Check routine.
	Problems with the pipetting system	<ol style="list-style-type: none"> If the unwashed check %CV result is within the expected range, the main pipettor is not the cause of the low RLU mean result for the washed check. Continue troubleshooting other possible causes. If the unwashed check result is not within the expected range, troubleshoot the unwashed check result.
	Problems with the substrate system: <ul style="list-style-type: none"> Air in the substrate lines Leak in the substrate system tubing Kinked substrate system tubing Bent substrate probe Substrate pump or valve failure Expired substrate Insufficient supply of substrate Wash/read carousel or substrate temperatures too low Incomplete priming after substrate system decontamination Substrate supply contaminated with Citranox cleaning solution during substrate system decontamination Substrate dispense volume too low 	<ol style="list-style-type: none"> If the substrate check %CV and RLU mean results are within expected ranges, the substrate system is not the cause of the low RLU mean result for the washed check. Continue troubleshooting other possible causes. If the substrate check results are not within the expected ranges, troubleshoot the substrate check result.
	Luminometer problem	Contact Technical Support.

Wash Efficiency Problems

The wash efficiency is a calculation based upon the results from the substrate, washed, and unwashed checks of the System Check routine. The wash efficiency value provides information about the washing system.

Wash Efficiency Troubleshooting

Symptoms	Possible Causes	Corrective Action
Wash Efficiency PPM fails to meet criteria	Problems with the RV wash system (washed check mean RLUs or %CVs too high)	Troubleshoot the washed check result.
	Problems with the pipetting system (unwashed check mean RLUs too low)	Troubleshoot the unwashed check result.
	Problems with the substrate system (contaminated substrate bottle)	Troubleshoot the substrate check result.

Instrument Troubleshooting

Instrument troubleshooting information can help you identify and correct instrument problems that are not resolved during System Check troubleshooting. Most instrument troubleshooting is available through the Event Log. The information in this section addresses problems you notice during operation or inspection that do not generate a caution or warning event.

NOTE

The corrective actions in the troubleshooting tables contain abbreviated procedures. Regardless of the frequency with which you perform a procedure, regularly review the complete procedures, including their cautions for protecting the instrument from damage, and their warnings for ensuring your personal safety. Links to these procedures are available for these tables in the *Help* system.

General Instrument Problems

General Instrument Troubleshooting

Symptoms	Possible Causes	Corrective Action
System mode is Not Ready	System rebooting or initializing	Wait for the instrument to finish rebooting or initializing. When this occurs, the system mode will change to the Ready mode and any text message in the system mode area will disappear.
	Many circumstances other than rebooting or initializing can place the instrument in the Not Ready mode, some examples are: <ul style="list-style-type: none"> • Front panel of the instrument is open • Pipettor gantry was just cleaned • System detected a device motion error • Stop was selected during a maintenance routine 	<p>Warning: If the system is in the Not Ready mode because Stop was selected during a maintenance routine, do not initialize the system. Contact Technical Support for assistance.</p> <p>The system must be initialized to return to the Ready mode.</p> <ul style="list-style-type: none"> • If you are experienced at initializing the system, and are following instructions in the <i>Help</i> system or in an Access 2 manual, initialize the system. • If you are not experienced at initializing the system or you are not following instructions in <i>Help</i> system or in an Access 2 manual, contact Technical Support.

General Instrument Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
The Event Log button is yellow or red	System event occurred	Review the event log message and its troubleshooting information. Take the recommended corrective action.
System performance is slow	Database contains too many test and QC results	<ol style="list-style-type: none"> 1. Set up the system to automatically delete test and QC results from the database. 2. If the Auto-Delete function is already set up, consider reducing the number of days that must elapse before the test results are deleted.

Instrument Start-Up Problems

Use the following table to troubleshoot the instrument if you are having problems rebooting or initializing the Access 2 system and no events report in the Event Log. If an event is generated, follow the Event Log troubleshooting procedures.

Instrument Start-Up Troubleshooting

Symptoms	Possible Causes	Corrective Action
System fails during reboot	No power to instrument	Refer to the power supply troubleshooting table.
	CD in CD-ROM or DVD drive, or data disk in 3.5-inch disk drive	Remove the CD from the CD-ROM or DVD drive, or remove the disk from 3.5-inch disk drive and reboot the instrument.
	Instrument hardware (power supply, internal hard drive, CPU, printed circuit board) or software failure	Reboot the instrument.
System fails during initialization	Interlock switch detects front panel of instrument is open	Close the front panel of the instrument and initialize the system.

Power Supply Problems

Use the following table to troubleshoot when the instrument or the peripheral devices do not have power. The peripheral devices that require a power supply include the external computer (PC), touch screen monitor, and printer.

Power Supply Troubleshooting

Symptoms	Possible Causes	Corrective Action
No power to the instrument or peripherals	Faulty power outlet or power strip	<ol style="list-style-type: none"> 1. Plug the instrument and the peripherals into a different power outlet or strip. 2. If the problem persists, troubleshoot the power system for the instrument and each peripheral device individually. 3. When the source of the problem has been identified, contact Technical Support if necessary.

Power Supply Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
No power to the instrument	Instrument power switch not on	Turn on the power switch located on the right side of the instrument.
	Power cord connector loose at either end	Be sure that the power cord connections to the outlet and instrument are plugged in tightly.
	Faulty power supply or circuit breaker	Contact Technical Support.
No power to peripheral(s)	Peripheral device power switch not on	1. Turn on the peripheral device power switch. 2. If you cannot locate the power switch, see the documentation provided by the manufacturer.
	Peripheral device power cord connector loose at either end	Be sure that the power cord connections to the outlet and peripheral device are plugged in tightly.
	Defective peripheral device	Contact Technical Support.

Keyboard Problems

Use the following table to troubleshoot situations when the computer keyboard is not responding to your key strokes.

Keyboard Troubleshooting

Symptoms	Possible Causes	Corrective Action
No response from the keyboard	Loose connector	Be sure that the cable connections (located on the back side of the external computer) between the keyboard, the external bar code reader, and the computer are plugged in tightly.
	Invalid key selected	Look at the status line above the function buttons near the bottom of the screen to verify that the key selected is an acceptable keyboard response.
	System software not responding	Reboot the PC.
	Hardware problem	Contact Technical Support.

Printer Problems

Use the following table to troubleshoot problems with the printer.

Printer Troubleshooting

Symptoms	Possible Causes	Corrective Action
Print job was not printed, or is incomplete	Communication interrupted between system and printer	<ol style="list-style-type: none"> 1. Check the printer paper tray. <ul style="list-style-type: none"> • If empty, load paper into the printer paper tray. 2. Try to print the missing or incomplete report once. <ul style="list-style-type: none"> • If print service is restored, continue normal operation. 3. If print service is not restored, reboot the PC. 4. If print service is not restored, locate missing report and print from the appropriate screen. For example, print a missing Calibration report from the Calibration screen. 5. If the report does not print, be sure the cable connections between the printer and the computer are plugged in tightly. 6. Reload paper into the printer paper tray. 7. Try to print the report again. 8. If report still does not print, contact Technical Support.

Bar Code Reading Problems

Use the following table to troubleshoot when the bar code reader does not scan bar code information.

Bar Code Reader Troubleshooting

Symptoms	Possible Causes	Corrective Action
Sample rack bar code label was not read by the internal bar code reader	Bar code label attached incorrectly to the rack	Attach the bar code label correctly.
	Incorrect system bar code label on rack	If the sample rack is labeled with an Access (not an Access 2) system label, the rack cannot be used. Either replace the bar code label with an Access 2 rack label or move the samples to an Access 2 labeled rack.
	Bar code reader not operating properly	Contact Technical Support.
Sample bar code label was not read by the internal bar code reader	Sample bar code reading not enabled	Set up the bar code reader to read sample IDs.
	Sample container placed incorrectly in the rack	Turn the sample container until its bar code label faces the same direction as the rack bar code label, and is visible through the slot in the sample rack.
	Bar code label applied incorrectly on the sample container	Apply the bar code label correctly on the sample container.
	Bar code reader not set up to read the sample bar code symbology	Setup the bar code reader parameters to match the symbology you are using.

Bar Code Reader Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
Sample bar code label was not read by the internal bar code reader (continued)	Bar code symbology or parameters not supported	<ol style="list-style-type: none"> 1. Verify that the bar code symbology and parameters used on the sample label are supported. 2. If the symbology or parameters are not supported, contact Technical Support.
	Number of bar code characters on label does not agree with the number of characters specified in the Bar Code Reader Setup window (for Interleaved 2 of 5 only)	<ol style="list-style-type: none"> 1. Check the number of characters entered for the Interleaved 2 of 5 symbology in the Bar Code Reader Setup window. 2. If necessary, change the number of characters to match the number of characters on the label. 3. If the number of characters match, contact Technical Support.
No response from the external bar code reader	Incorrect scanning technique	<ol style="list-style-type: none"> 1. Verify the following: <ul style="list-style-type: none"> • The correct screen or window is displayed for the item you are scanning. • The correct field is selected. 2. Scan the label a second time.
	Loose connector	Be sure that the cable connections (located on the back side of the external computer) between the keyboard, the external bar code reader, and the computer are plugged in tightly.
	System software not responding	Reboot the PC.
	External bar code reader not configured properly	Contact Technical Support.
	Hardware problem	Contact Technical Support.

Air in the System

Air bubbles in the fluid lines can lead to poor precision. If you notice air in the lines, use the following table to troubleshoot the problem.

Troubleshooting Air in the System

Symptoms	Possible Causes	Corrective Action
Air in the fluid lines	Insufficient priming	<ol style="list-style-type: none"> 1. Prime all fluidic components. 2. Run the System Check routine. 3. If the problem persists, contact Technical Support.
	System prime lost due to a leak in the fluidic system	<ol style="list-style-type: none"> 1. Be sure the connections between the fittings (located on the left side of the instrument) and the fluids tray fit together tightly. Visually inspect the tubing and fittings for leaks and deposits. 2. Visually inspect the fluidic module tubing and fittings for leaks and deposits. 3. Inspect the precision pump valve and valve fittings for leaks and deposits. 4. Leaks and deposits may indicate that the fluidics system is damaged. <ul style="list-style-type: none"> • If you find leaks and deposits, contact Technical Support for further assistance. • If you find no leaks or deposits, continue troubleshooting other possible causes.
	Kinked tubing in the fluids tray	<ol style="list-style-type: none"> 1. Visually inspect all tubing leading away from the fluids tray components for kinks. Pay close attention to the tubing leading away from the substrate bottle. <ul style="list-style-type: none"> • If no kinks are found, continue troubleshooting other possible causes. 2. Straighten any kinks. 3. Prime all fluidic components. 4. Run the System Check routine.
	Plugged waste air filter	<ol style="list-style-type: none"> 1. Check the tubing from the liquid waste bottle for constrictions. <ul style="list-style-type: none"> • If the tubing is constricted, clear it and repeat the System Check routine. 2. If the results fail, remove the tubing from the waste filter at the quick disconnect and place the end of the tubing in one of the adjacent holes. This may temporarily resolve the error until you can install a new waste filter assembly. 3. Repeat the System Check routine. <ul style="list-style-type: none"> • If the results are acceptable, order a new waste filter assembly and replace the current one. • If the results fail, contact Technical Support.

Main Pipettor Problems

Problems with the main pipettor can lead to poor precision. If you notice any leaking or deposits, use the following table to troubleshoot the problem.

Main Pipettor Troubleshooting

Symptoms	Possible Causes	Corrective Action
Main pipettor leaking	Primary probe partially plugged	<ol style="list-style-type: none"> Look at the Pressure Monitor screen to determine if a pressure sensor is present, and that obstruction detection is enabled. <ul style="list-style-type: none"> If the pressure sensor is not present, or if it is present but obstruction detection is disabled, continue with step 2. If obstruction detection is enabled, review the Event Log, and troubleshoot according to the events related to main pipettor obstructions or abnormal pressures. Run the Special Clean routine. Run the System Check routine. If the results fail, contact Technical Support to verify the need to replace the primary probe. When needed, remove and replace the primary probe.
	Loose fitting between the main pipettor and precision pump valve	<ol style="list-style-type: none"> Open the front panel and top cover. Visually inspect the fittings between the primary probe and precision pump valve for leaks and deposits. Inspect all fluid fittings to the manifold for leaks and deposits. Leaks or deposits may indicate that the tubing or fittings are damaged. <ul style="list-style-type: none"> If you find leaks or deposits, contact Technical Support for further assistance. If you find no leaks or deposits, continue troubleshooting other possible causes.
Main pipettor dispensing fluid with excess pressure	Primary probe partially plugged, causing the main pipettor to dispense fluid with too much pressure	<ol style="list-style-type: none"> Look at the Pressure Monitor screen to determine if a pressure sensor is present, and that obstruction detection is enabled. <ul style="list-style-type: none"> If the pressure sensor is not present, or if it is present but obstruction detection is disabled, continue with step 2. If obstruction detection is enabled, review the Event Log, and troubleshoot according to the events related to main pipettor obstructions or abnormal pressures. Check RV locations 1 and 2 of the RV Shuttle for crystalline deposits. <ul style="list-style-type: none"> If you find no deposits, continue troubleshooting other possible causes. Run the Special Clean routine. Run the System Check routine. If the results fail, contact Technical Support to verify the need to replace the primary probe. When needed, remove and replace the primary probe.

Communication Problems

Use the following table to troubleshoot communication problems between the external computer (PC) and the instrument, or other systems in your workgroup.

Communications Troubleshooting

Symptoms	Possible Causes	Corrective Action
Communication between PC and instrument interrupted for more than 30 minutes during a run, PC locks up after communication is reestablished	Function that requires communication between the PC and the instrument, such as getting a rack or loading supplies, was attempted while the PC was updating the Test Results screen	Contact Technical Support.
Workgroup communication error occurs during rebooting process	Loose connection between PC and other systems in the workgroup	<ol style="list-style-type: none"> Be sure that the Access 2 instrument power switch is on. <ul style="list-style-type: none"> If the power switch is off, restart the instrument. If the power switch is on, but there is no power to the instrument, refer to the power supply troubleshooting table. Check both ends of the cable connecting the PC to the other systems in your workgroup: <ul style="list-style-type: none"> If the cable connection is loose at either end, connect it securely. If the cable is not loose, contact Technical Support. Reboot the PC.

Assay Troubleshooting

Assay troubleshooting information provides troubleshooting tables to help you identify and correct assay-related problems. Before using assay troubleshooting information to troubleshoot assay issues, run the System Check routine and troubleshoot unexpected results. Running the System Check routine will help you to identify and correct, or rule out, some system issues as the cause of your problem.

NOTE

The corrective actions in the troubleshooting tables contain abbreviated procedures. Regardless of the frequency with which you perform a procedure, regularly review the complete procedures, including their cautions for protecting the instrument from damage, and their warnings for ensuring your personal safety. Links to these procedures are available for these tables in the *Help* system.

Assay Calibration Problems

When a calibration fails, the system displays a failure code in the **Reason** field on the Calibration Data screen. Use the following table to help you troubleshoot the calibration problem.

Assay Calibration Troubleshooting

Symptoms	Possible Causes	Corrective Action
Although precision is good, the calibration fails for any reason other than Insuff Data	Multi-level calibrators pipetted out of order: <ul style="list-style-type: none"> • Calibration curve does not ascend or descend smoothly • Calibration cutoff is opposite of the expected result 	<ol style="list-style-type: none"> 1. Be sure that the calibrators are placed in the rack in the proper order. 2. Repeat the calibration.
	Expired calibrator	<ol style="list-style-type: none"> 1. Check the expiration date on the calibrator vial(s) or the Calibrator Setup screen. 2. If the calibrator is expired, add a new, unexpired calibrator on the Calibrator Setup screen. 3. Repeat the calibration.
	Calibrator unstable or contaminated due to improper handling	Repeat the calibration. If possible, repeat with a new set of the same calibrator lot.
	Reagent pack unstable or contaminated due to improper handling	<ol style="list-style-type: none"> 1. Unload the reagent pack and load a new reagent pack. <ul style="list-style-type: none"> • If the lot number of the new reagent pack is different than the removed pack, recalibrate the assay. 2. For calibration problems, repeat the calibration.
	Contaminated substrate supply	<ol style="list-style-type: none"> 1. Contact Technical Support to verify the need to decontaminate the substrate system. 2. If Technical Support agrees, decontaminate the substrate system and then verify system performance.
	Incorrect calibration information entered during calibrator setup	<ol style="list-style-type: none"> 1. Verify the calibration information on the Calibrator Setup screen. 2. If necessary, edit the information on the Calibrator Setup screen. 3. Repeat the calibration.
Although precision is good, the quantitative curve is flat or the qualitative result is No Value; calibration fails for any reason other than Insuff Data	Wrong calibrator placed in rack	<ol style="list-style-type: none"> 1. Be sure that the correct calibrator is loaded on the rack. 2. Repeat the calibration.
	Wrong reagent pack loaded, or placed in an incorrect position on the reagent carousel	<ol style="list-style-type: none"> 1. Verify that the reagent pack was loaded by checking the Supplies screen. If it is missing, load a reagent pack. 2. If the reagent pack is listed on the screen, verify its location by unloading it from the carousel. <ul style="list-style-type: none"> • If the reagent pack is onboard, but is not presented during this process, contact Technical Support for assistance. • If Technical Support confirms a misplaced reagent pack, retrieve the pack. 3. Reload the reagent pack after you have verified its location. 4. Repeat the calibration.

Assay Calibration Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
Poor precision, and calibration fails for any reason other than Insuff Data	Daily or weekly maintenance not performed	<ol style="list-style-type: none"> 1. Perform daily or weekly maintenance. 2. Repeat the calibration.
	Problems with the pipetting system: <ul style="list-style-type: none"> • Air in the main pipettor fluid lines • Wash buffer supply lines kinked • Precision pump, valve, fittings, or tubing damaged and leaking 	<ol style="list-style-type: none"> 1. If the System Check routine results are within the expected ranges, the pipetting system is not the cause of the calibration failure. Continue troubleshooting other possible causes. 2. If the unwashed check result is not within the expected range, troubleshoot the unwashed check result.
	Problems with the substrate system: <ul style="list-style-type: none"> • Insufficient supply of substrate • Air in the substrate lines • Kinked substrate system tubing • Leak in the substrate system tubing 	<ol style="list-style-type: none"> 1. If the System Check routine results are within the expected ranges, the substrate system is not the cause of the calibration failure. Continue troubleshooting other possible causes. 2. If the substrate check result is not within the expected range, troubleshoot the substrate check result.
	Reagent gone because it leaked out of the pack during off-board storage	<ol style="list-style-type: none"> 1. Load a new reagent pack. 2. Repeat the calibration.
RLUs are too low at one end of the calibration curve, and calibration fails for any reason other than Insuff Data	Reagent pack switch occurred, and the second reagent pack is missing or loaded incorrectly (RLUs drop off suddenly at the end of the calibration curve)	<ol style="list-style-type: none"> 1. Verify that the second reagent pack was loaded by checking the Supplies screen. If the pack is missing, load a new reagent pack. 2. If the second reagent pack is listed on the screen, verify its location by unloading it from the carousel. <ul style="list-style-type: none"> • If the reagent pack is onboard, but is not presented during this process, contact Technical Support for assistance. • If Technical Support confirms a misplaced reagent pack, retrieve the pack. 3. Reload the second pack after you have verified its location. 4. Repeat the calibration.
Calibration fails for the reason Insuff Data	Quantity of calibrator not sufficient for testing (QNS result flag and event)	<ol style="list-style-type: none"> 1. Calculate the correct volume of calibrator needed for the number of replicates and type of sample container used. 2. Pipette the amount of calibrator calculated in step 1 into the appropriate sample container. 3. Be sure the rack and rack ID are correct. 4. Repeat the calibration. 5. If the calibration fails again, contact Technical Support for assistance.

Assay Calibration Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
Calibration fails for the reason Insuff Data (continued)	Two or more replicates not calculated due to instrument error	<ol style="list-style-type: none"> 1. Review the Event Log messages for device errors prior to the calibration failure. 2. Review the Test Results screen for any error messages. 3. Troubleshoot the device errors. If necessary, contact Technical Support for assistance. 4. After resolving the device errors, repeat the calibration.
	Sample container missing or placed in incorrect position in the rack	<ol style="list-style-type: none"> 1. Be sure that the sample containers are in the proper order in the rack. 2. Repeat the calibration.

Quality Control Problems

When a QC result violates an applied QC rule, the **Quality Control** button turns red. The button remains red until you review the QC Data screen. Use the following table to help you troubleshoot problems with your QC results.

Quality Control Troubleshooting

Symptoms	Possible Causes	Corrective Action
Controls violate applied QC rule	Daily or weekly maintenance not performed	<ol style="list-style-type: none"> 1. Perform daily or weekly maintenance. 2. Repeat the test(s).
	Wrong QC control loaded onto the sample rack	<ol style="list-style-type: none"> 1. Load the correct QC control. 2. Repeat the test(s).
	Wrong QC control lot number selected for the test	Repeat the test(s) using the correct lot number.
	Wrong mean and/or standard deviation information entered when setting up the QC controls	<ol style="list-style-type: none"> 1. Review the QC information using Edit Control F2 from the QC Setup screen. 2. If necessary, edit the information. 3. Repeat the test(s).
	QC control sample type does not match QC setup	<ol style="list-style-type: none"> 1. Verify that the sample type used matches what is listed on the Test Request screen. 2. Verify that the sample type used matches the sample type set up for the QC control. 3. If the QC control sample type entered during setup is incorrect, you must delete the control and set up the control again using the correct sample type.
	Expired QC control	Load new, unexpired QC control, and repeat the test(s).
	QC controls unstable or contaminated due to incorrect handling	<ol style="list-style-type: none"> 1. Prepare new QC controls according to the procedure provided by the manufacturer. 2. Load the freshly prepared QC controls and repeat the test(s).
	QC controls reconstituted incorrectly	<ol style="list-style-type: none"> 1. Reconstitute new QC controls according to the procedure provided by the manufacturer. 2. Load the freshly reconstituted QC controls and repeat the test(s).

Quality Control Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
Controls violate applied QC rule (continued)	Quantity of QC control not sufficient for testing (QNS result flag and event)	<ol style="list-style-type: none"> 1. Calculate the correct volume of QC control needed for the number of replicates and type of sample container used. 2. Pipette the amount of QC control calculated in step 1 into the appropriate sample container. 3. Be sure the rack and rack ID are correct. 4. Repeat the test(s). 5. If the test(s) fail again, contact Technical Support for assistance.
	QC controls evaporating from being on the instrument too long	<ol style="list-style-type: none"> 1. Load a fresh aliquot of each QC control. 2. Repeat the test(s). Be sure the controls are pipetted into the RVs within 1 hour of loading onto the instrument. Be sure controls from 3-mL sample containers are pipetted into the RVs within two hours of loading.
	Reagent pack unstable or contaminated due to improper handling	<ol style="list-style-type: none"> 1. Unload the reagent pack and load a new reagent pack. <ul style="list-style-type: none"> • If the lot number of the new reagent pack is different than the removed pack, recalibrate the assay. 2. Repeat the test(s).
	Wrong reagent pack loaded, or placed in an incorrect position on the reagent carousel	<ol style="list-style-type: none"> 1. Verify that the reagent pack was loaded by checking the Supplies screen. If it is missing, load a reagent pack. 2. If the reagent pack is listed on the screen, verify its location by unloading it from the carousel. <ul style="list-style-type: none"> • If the reagent pack is onboard, but is not presented during this process, contact Technical Support for assistance. • If Technical Support confirms a misplaced reagent pack, retrieve the pack. 3. Reload the reagent pack after you have verified its location. 4. Repeat the test(s).
	Expired reagent pack	<ol style="list-style-type: none"> 1. Check the reagent pack expiration date on the Reagent Inventory screen. 2. Unload the expired reagent pack and load a new one. <ul style="list-style-type: none"> • If the lot number of the new reagent pack is different than the expired pack, recalibrate the assay. 3. Repeat the test(s).
	Wrong sample container and/or rack	Load the samples using appropriate sample containers and racks. Be sure that the sample containers are in a rack with the correct rack ID.
	Sample container missing or placed in incorrect position in the rack	<ol style="list-style-type: none"> 1. Be sure that the sample containers are in the proper order in the rack. 2. Repeat the test(s).
	Expired assay calibration	<ol style="list-style-type: none"> 1. Check the Reagent Pack button on the Supplies screen. If the lot number is red, the calibration has expired. 2. View the test results. Any test results calculated with an expired calibration will be flagged. 3. Recalibrate the assay. 4. Repeat the test(s).

Quality Control Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
Controls violate applied QC rule (continued)	QC controls not run after preventive maintenance or repair	<ol style="list-style-type: none"> 1. Run QC. 2. Evaluate any out-of-range QC results according to your established laboratory procedures. 3. Troubleshoot any test result flags, and recalibrate the assay if necessary. 4. Repeat the test.
	Substrate not equilibrated to room temperature when loaded on the system	<p>The substrate must be at room temperature for the specified period of time before it is loaded.</p> <p>For more information about the substrate, refer to the reagent instructions for use.</p>
Increasing values across the run	QC controls evaporating from being on the instrument too long	<ol style="list-style-type: none"> 1. Load a fresh aliquot of each QC control. 2. Repeat the test(s). Be sure the controls are pipetted into the RVs within 1 hour of loading onto the instrument. Be sure controls from 3-mL sample containers are pipetted into the RVs within two hours of loading.

Patient Sample Problems

Use the following table to troubleshoot problems with your patient sample test results. If a special circumstance exists for a test result, the Access 2 system will code the result with a flag. The flags are either fatal (no calculated result), or non-fatal (the result was calculated, but a condition exists for that result). You can use these flags to assist you in the troubleshooting process.

Patient Sample Troubleshooting

Symptoms	Possible Causes	Corrective Action
Unexpected sample results	Incorrect patient sample type	Refer to the reagent instructions for use for the appropriate sample types for each assay.
	Patient sample handled incorrectly	Be sure that sample is stored and handled according to proper laboratory procedures. Refer to individual assay reagent instructions for use for proper sample handling instructions.
	Microclots present in the serum sample	<ol style="list-style-type: none"> 1. Spin the sample again or use a serum filter to separate the serum from any microclots. 2. Repeat the test(s).
	Quantity of patient sample not sufficient for testing (QNS result flag and event)	<ol style="list-style-type: none"> 1. Calculate the correct volume of patient sample needed for the number of replicates and type of sample container used. 2. Pipette the amount of QC control calculated in step 1 into the appropriate sample container. 3. Be sure the rack and rack ID are correct. 4. Repeat the test(s). 5. If the test(s) fail again, contact Technical Support for assistance.

Patient Sample Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
Unexpected sample results (continued)	Patient samples evaporating from being on the instrument too long	<ol style="list-style-type: none"> 1. Load a fresh aliquot of each patient sample. 2. Repeat the test(s). Be sure the sample is pipetted into the RVs within 1 hour of loading it onto the instrument. Be sure sample from 3 mL sample containers is pipetted into the RVs within two hours of loading.
	Wrong reagent pack loaded, or placed in an incorrect position on the reagent carousel	<ol style="list-style-type: none"> 1. Verify that the reagent pack was loaded by checking the Supplies screen. If it is missing, load a reagent pack. 2. If the reagent pack is listed on the screen, verify its location by unloading it from the carousel. <ul style="list-style-type: none"> • If the reagent pack is onboard, but is not presented during this process, contact Technical Support for assistance. • If Technical Support confirms a misplaced reagent pack, retrieve the pack. 3. Reload the reagent pack after you have verified its location. 4. Repeat the test(s).
	Expired reagent pack	<ol style="list-style-type: none"> 1. Check the reagent pack expiration date on the Reagent Inventory screen. 2. Unload the expired reagent pack and load a new one. <ul style="list-style-type: none"> • If the lot number of the new reagent pack is different than the expired pack, recalibrate the assay. 3. Repeat the test(s).
	Reagent pack unstable or contaminated due to improper handling	<ol style="list-style-type: none"> 1. Unload the reagent pack and load a new reagent pack. <ul style="list-style-type: none"> • If the lot number of the new reagent pack is different than the removed pack, recalibrate the assay. 2. Repeat the test(s).
	Expired assay calibration	<ol style="list-style-type: none"> 1. Check the Reagent Pack button on the Supplies screen. If the lot number is red, the calibration has expired. 2. View the test results. Any test results calculated with an expired calibration will be flagged. 3. Recalibrate the assay. 4. Repeat the test(s).
	QC controls not run after preventive maintenance or repair	<ol style="list-style-type: none"> 1. Run QC. 2. Evaluate any out-of-range QC results according to your established laboratory procedures. 3. Troubleshoot any test result flags, and recalibrate the assay if necessary. 4. Repeat the test.
	Partial bottles of substrate combined	<ol style="list-style-type: none"> 1. Change the substrate bottle and prime the substrate. 2. Repeat the test(s).
	Daily or weekly maintenance not performed	<ol style="list-style-type: none"> 1. Perform daily or weekly maintenance. 2. Repeat the test(s).
	Wrong sample container and/or rack	Load the samples using appropriate sample containers and racks. Be sure that the sample containers are in a rack with the correct rack ID.

Patient Sample Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
Unexpected sample results (continued)	Sample container missing or placed in incorrect position in the rack	<ol style="list-style-type: none"> 1. Be sure that the sample containers are in the proper order in the rack. 2. Repeat the test(s).
Sample values are too high	Patient samples evaporating from being on the instrument too long	<ol style="list-style-type: none"> 1. Load a fresh aliquot of each patient sample. 2. Repeat the test(s). Be sure the sample is pipetted into the RVs within 1 hour of loading it onto the instrument. Be sure sample from 3-mL sample containers is pipetted into the RVs within two hours of loading.
Low sample value flag	Incorrect dilution factor	<ol style="list-style-type: none"> 1. If the sample result was generated with an automated dilution (for example, the Diluted βhCG assay), repeat the sample in the standard assay format (Total βhCG assay). 2. If the results are still too high, contact Technical Support.
	Patient sample handled incorrectly	Be sure that sample is stored and handled according to proper laboratory procedures. Refer to individual assay reagent instructions for use for proper sample handling instructions.
Increased assay variability/poor precision	Wrong reagent pack loaded, or placed in an incorrect position on the reagent carousel	<ol style="list-style-type: none"> 1. Verify that the reagent pack was loaded by checking the Supplies screen. If it is missing, load a reagent pack. 2. If the reagent pack is listed on the screen, verify its location by unloading it from the carousel. <ul style="list-style-type: none"> • If the reagent pack is onboard, but is not presented during this process, contact Technical Support for assistance. • If Technical Support confirms a misplaced reagent pack, retrieve the pack. 3. Reload the reagent pack after you have verified its location. 4. Repeat the test(s).
Unexpected shift in assay results	Expired reagent pack	<ol style="list-style-type: none"> 1. Check the reagent pack expiration date on the Reagent Inventory screen. 2. Unload the expired reagent pack and load a new one. <ul style="list-style-type: none"> • If the lot number of the new reagent pack is different than the expired pack, recalibrate the assay. 3. Repeat the test(s).
	Expired assay calibration	<ol style="list-style-type: none"> 1. Check the Reagent Pack button on the Supplies screen. If the lot number is red, the calibration has expired. 2. View the test results. Any test results calculated with an expired calibration will be flagged. 3. Recalibrate the assay. 4. Repeat the test(s).
	QC controls not run after preventive maintenance or repair	<ol style="list-style-type: none"> 1. Run QC. 2. Evaluate any out-of-range QC results according to your established laboratory procedures. 3. Troubleshoot any test result flags, and recalibrate the assay if necessary. 4. Repeat the test.

Patient Sample Troubleshooting (continued)

Symptoms	Possible Causes	Corrective Action
Unexpected shift in assay results (continued)	Wash buffer contaminated	<ol style="list-style-type: none"> Contact Technical Support to verify the need to rinse the wash buffer reservoir. If Technical Support confirms, rinse the wash buffer reservoir. If the System Check results are acceptable: <ul style="list-style-type: none"> Recalibrate the assay. Run controls and repeat the test(s). If the System Check results are not acceptable, contact Technical Support.
Increasing values across the run	Patient samples evaporating from being on the instrument too long	<ol style="list-style-type: none"> Load a fresh aliquot of each patient sample. Repeat the test(s). Be sure the sample is pipetted into the RVs within 1 hour of loading it onto the instrument. Be sure sample from 3-mL sample containers is pipetted into the RVs within two hours of loading.

Test Result Flags

Use the following tables to troubleshoot fatal (no calculated result) or non-fatal (the result was calculated, but a condition exists for that result) test result flags.

NOTE

The system may print the same test result flag twice on a sample report. Ignore the duplicate flag.

Fatal Flags

Fatal Flag	Description	Corrective Action
CCR	<p>A result could not be calculated because:</p> <ul style="list-style-type: none"> 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. 	<ol style="list-style-type: none"> Take one of the following actions: <ul style="list-style-type: none"> 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. Review the Event Log and troubleshoot according to the error events with a similar date and time to this event. Repeat the test. <ul style="list-style-type: none"> For a derived result, repeat all tests included in the derived result formula. For a confirmatory result, repeat the confirmatory and qualitative tests. If the problem persists, contact Technical Support.
CLT	An obstruction was detected.	<ol style="list-style-type: none"> Review the Event Log and troubleshoot according to the error events with a similar date and time to this event. Repeat the test. If the problem persists, contact Technical Support.

Fatal Flags (continued)

Fatal Flag	Description	Corrective Action
IND	<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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. 	<ol style="list-style-type: none"> 1. For IND flagged results which meet the following criteria, dilute and rerun the sample: <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> • 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 result was processed.	<ol style="list-style-type: none"> 1. Calibrate the assay. 2. Repeat the test(s).
QNS	The sample volume is insufficient. Additional tests will not be scheduled for this sample. Tests already scheduled will be completed.	<ol style="list-style-type: none"> 1. Follow the troubleshooting instructions for the QNS event in the Event Log. 2. Repeat the test(s). 3. If the problem persists, contact Technical Support.
QSD	Insufficient reagent volume was dispensed into an RV.	<ol style="list-style-type: none"> 1. Review the Event Log and troubleshoot according to the error events with a similar date and time to this event. 2. Run canceled tests again. 3. If the problem persists, contact Technical Support.
RLU	The relative light units (RLUs) are outside the acceptable luminometer measuring range.	<ol style="list-style-type: none"> 1. Review the Event Log and troubleshoot according to the error events with a similar date and time to this event. 2. Repeat the test(s). 3. If the problem persists, contact Technical Support.
SYS	A device error occurred during processing.	<ol style="list-style-type: none"> 1. Review the Event Log and troubleshoot according to the error events with a similar date and time to this event. 2. Repeat the test(s). 3. If the problem persists, contact Technical Support.

Fatal Flags (continued)

Fatal Flag	Description	Corrective Action
TRI	The temperature of the incubator was outside the acceptable limits. All tests being incubated when the temperature was outside limits are flagged.	<ol style="list-style-type: none"> 1. Check the incubator temperature on the Maintenance Review screen. If the temperature is outside the acceptable limits, periodically monitor the incubator temperature on this screen until it is within the acceptable limits. <ul style="list-style-type: none"> • If the system was rebooted or instrument covers were recently opened, you may need to wait up to 30 minutes for the temperature to normalize. • If the system was recently restarted, you may need to wait up to 1 hour for the temperature to normalize. 2. When the incubator temperature is within the acceptable limits, repeat the test(s). 3. If the temperature does not normalize, or if the problem persists, contact Technical Support.
TRS	The temperature of the substrate was outside the acceptable limits when it was dispensed.	<ol style="list-style-type: none"> 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. <ul style="list-style-type: none"> • If the system was rebooted or instrument covers were recently opened, you may need to wait up to 30 minutes for the temperature to normalize. • If the system was recently restarted, you may need to wait up to 1 hour for the temperature to normalize. 2. When the substrate temperature is within the acceptable limits, repeat the test(s). 3. If the temperature does not normalize, or if the problem persists, contact Technical Support.
TRW	The temperature of the wash/read carousel was outside the acceptable limits. All tests with RVs in the wash/read carousel when the temperature was outside limits are flagged.	<ol style="list-style-type: none"> 1. Check the wash/read carousel temperature on the Maintenance Review screen. If the temperature is outside the acceptable limits, periodically monitor the wash/read carousel temperature on this screen until it is within the acceptable limits. <ul style="list-style-type: none"> • If the system was rebooted or instrument covers were recently opened, you may need to wait up to 30 minutes for the temperature to normalize. • If the system was recently restarted, you may need to wait up to 1 hour for the temperature to normalize. 2. When the wash/read carousel temperature is within the acceptable limits, repeat the test(s). 3. If the temperature does not normalize, or if the problem persists, contact Technical Support.

Non-Fatal Flags

Non-Fatal Flag	Description	Corrective Action
CEX	The calibration curve or cut-off value is expired.	<ol style="list-style-type: none"> 1. Recalibrate the assay. 2. Repeat the test(s).
CRH	The result is above the upper limit of the critical range. Not applicable for QC or Calibrations.	This is a valid test result. No corrective action is necessary.

Non-Fatal Flags (continued)

Non-Fatal Flag	Description	Corrective Action
CRL	The result is below the lower limit of the critical range. Not applicable for QC or Calibrations.	This is a valid test result. No corrective action is necessary.
EXS	The substrate is expired.	<ol style="list-style-type: none"> 1. Change the substrate bottle from the Supplies screen. 2. Repeat the test(s).
GRY	For qualitative assays, the result is within the specified gray zone, also known as the equivocal zone..	<p>This is a valid test result. No corrective action is necessary.</p> <p>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</p>
LEX	The reagent pack lot is expired.	<ol style="list-style-type: none"> 1. Unload the expired reagent pack and load a new one. <ul style="list-style-type: none"> • If the lot number of the new reagent pack is different than the expired pack, recalibrate the assay. 2. Repeat the test(s).
LOW	The result is lower than the minimum reportable result value defined in the APF.	No corrective action is necessary.
LRH	<p>The result is above the upper limit of the LIS range. The system does not send results with this flag to the LIS.</p> <p>Notes:</p> <ul style="list-style-type: none"> • This flag is displayed only when the Auto-Send to LIS option is set to Verify. • This flag is for quantitative assays, semi-quantitative assays, and derived results only. 	<ol style="list-style-type: none"> 1. Review the result. 2. Take one of the following actions: <ul style="list-style-type: none"> • Send the result to the LIS manually. • Delete the result and repeat the test(s).
LRL	<p>The result is below the lower limit of the LIS range. The system does not send results with this flag to the LIS.</p> <p>Notes:</p> <ul style="list-style-type: none"> • This flag is displayed only when the Auto-Send to LIS option is set to Verify. • This flag is for quantitative assays, semi-quantitative assays, and derived results only. 	<ol style="list-style-type: none"> 1. Review the result. 2. Take one of the following actions: <ul style="list-style-type: none"> • Send the result to the LIS manually. • Delete the result and repeat the test(s).
ORH	The result is above the upper limit of the reference range. Not applicable for QC or calibrations.	No corrective action is necessary.

Non-Fatal Flags (continued)

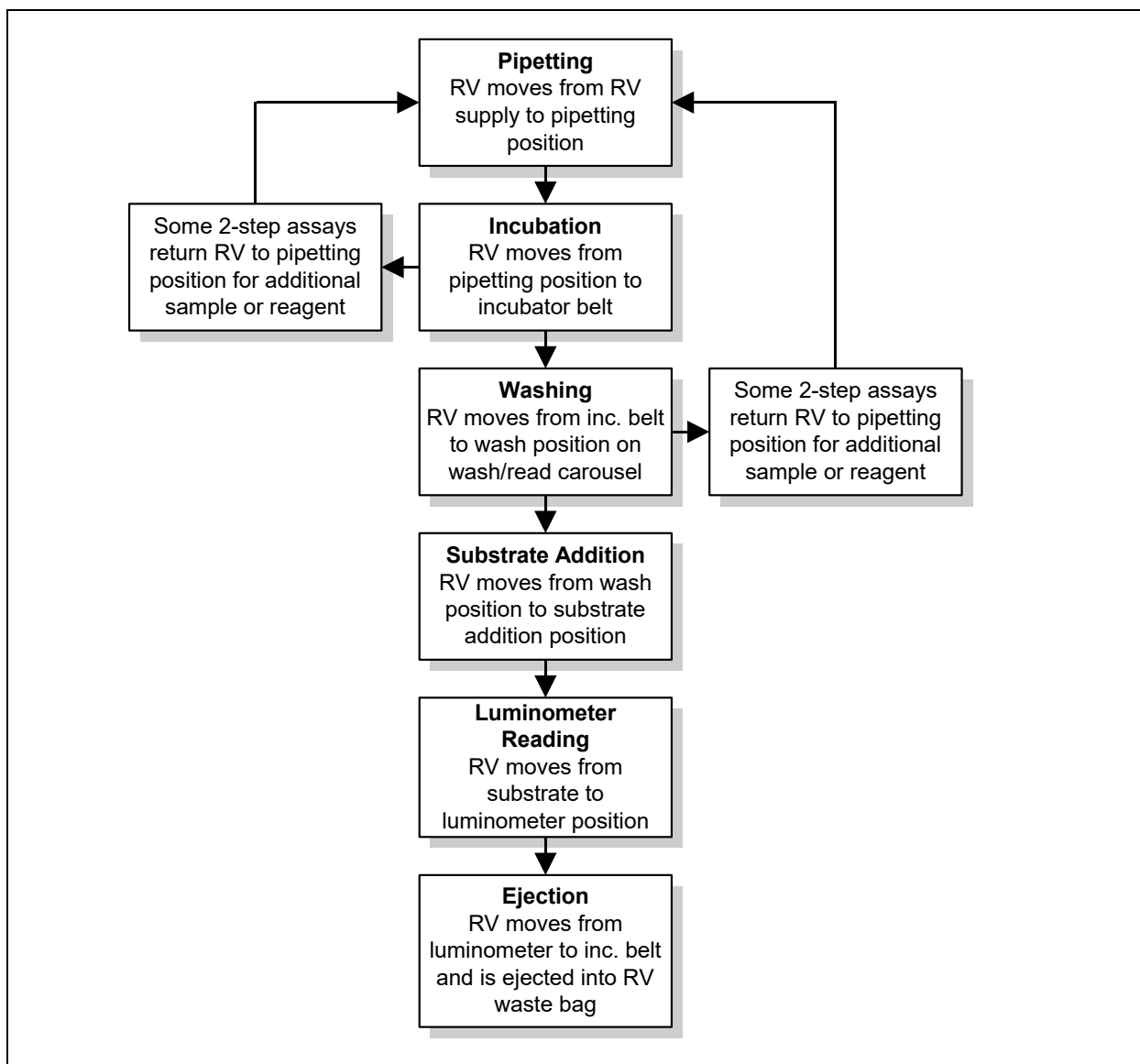
Non-Fatal Flag	Description	Corrective Action
ORL	The result is below the lower limit of the reference range. Not applicable for QC or calibrations.	No corrective action is necessary.
OVR	The calculated concentration is above the highest or most concentrated calibrator. This flag is only used for quantitative and semi-quantitative assays.	<ol style="list-style-type: none"> Review the Event Log for error events with a similar date and time to this event. <ul style="list-style-type: none"> If events occurred, troubleshoot. Take one of the following actions: <ul style="list-style-type: none"> If events occurred, and you performed troubleshooting procedures, run controls and then repeat the test. <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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. 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 measures this from the time it first punctures the pack.	<ol style="list-style-type: none"> Unload the expired reagent pack and load a new one. <ul style="list-style-type: none"> If the lot number of the new reagent pack is different than the expired pack, recalibrate the assay. Repeat the test(s).
QCF	A QC control violates one or more QC rules.	<ol style="list-style-type: none"> Display the QC Chart and Data screen to review which criteria is not met. Follow the QC troubleshooting instructions in Assay Troubleshooting on page 7-23.
QEX	The QC control lot is expired.	<ol style="list-style-type: none"> Add a new, unexpired QC control. Repeat the test(s).
RFX	The result is from a reflex test.	This is a valid test result. No corrective action is necessary.

8 Theory of Operation

The Access 2 Immunoassay System is an automated analyzer that performs a wide variety of immunoassays on body fluid samples. Samples are processed on the Access 2 system by assigning them a position on a sample rack, entering test requests for those samples, and then loading the sample racks onto the instrument for processing.

Reaction Vessel Transport

The instrument moves the RV through the following stages:



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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

Assay calibrations are used to establish values that the system uses to report test results for patient and quality control samples on an instrument.

To report a test result, the system requires a current calibration for each requested test. The number of calibrators required, the math model, and all other calibration parameters are defined in the assay protocol file (APF) for each assay, and by the information you enter into the system when you set up a new calibrator set.

The Access 2 system performs the following types of assay calibrations:

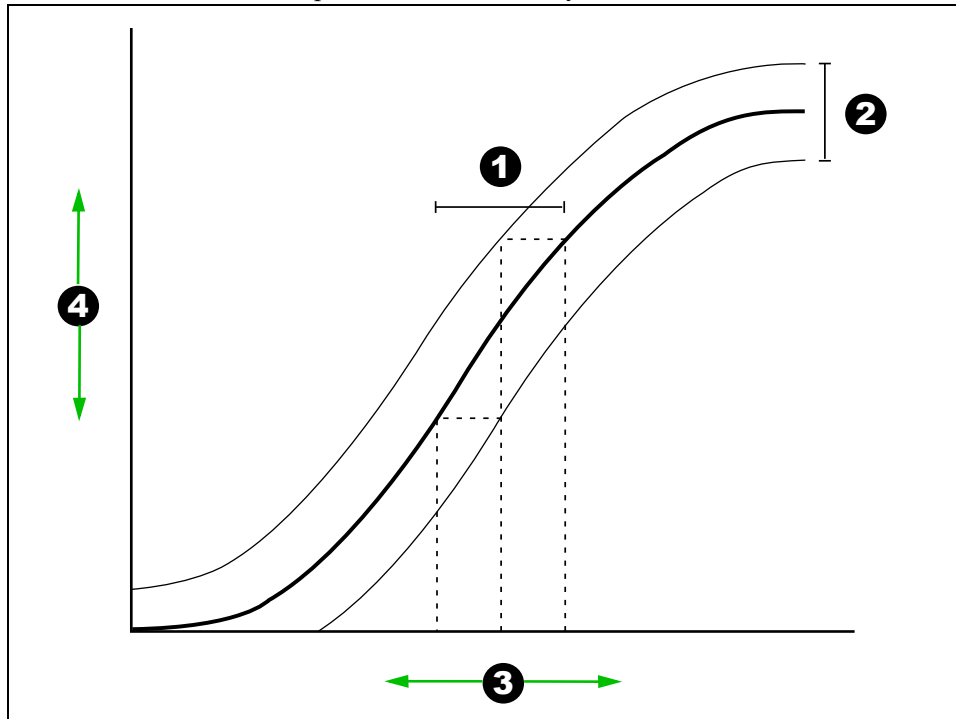
Quantitative	Calibrator test results provide a multi-point calibration curve. The system uses the calibration curve to convert a measured response in RLUs to an analyte concentration and then expresses the result in numerical units.
Semi-Quantitative	Calibrator test results provide a multi-point calibration 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 reactive, non-reactive, or equivocal.
Qualitative	Calibrator test results provide a cutoff value based on a predefined formula. The system compares a test result to the cutoff value and then classifies the result as reactive or non-reactive for the analyte.

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 predefined analyte concentrations.

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.



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1	Precision
2	Error Band (the Width of the Error Band is Exaggerated for Illustration Purposes)
3	X Axis: Analyte Concentration
4	Y Axis: RLUs

Calculating Test Results

To determine the analyte concentration in a sample, the system must have a current (accepted) calibration curve. When the patient or quality control sample is tested, the system measures the RLUs and then uses the calibration curve to convert the result to an analyte concentration.

Obstruction Detection Theory

An Access 2 instrument equipped with a pressure monitor can detect an obstruction in the primary probe while aspirating sample by monitoring the pressure required to draw a sample.

If the pressure required to draw a sample exceeds an accepted threshold, the test is cancelled and flagged with the CLT (obstruction) fatal flag, and an event is logged. If two consecutive failures occur on the same sample, any remaining tests for that sample are cancelled. If five consecutive failures occur, the system stops scheduling tests and goes to the **Not Ready** mode when the tests in progress are completed. The operator must then initialize the system and inspect, clean, or replace the probe as necessary.

Pressure Monitor Reference Curve Determination

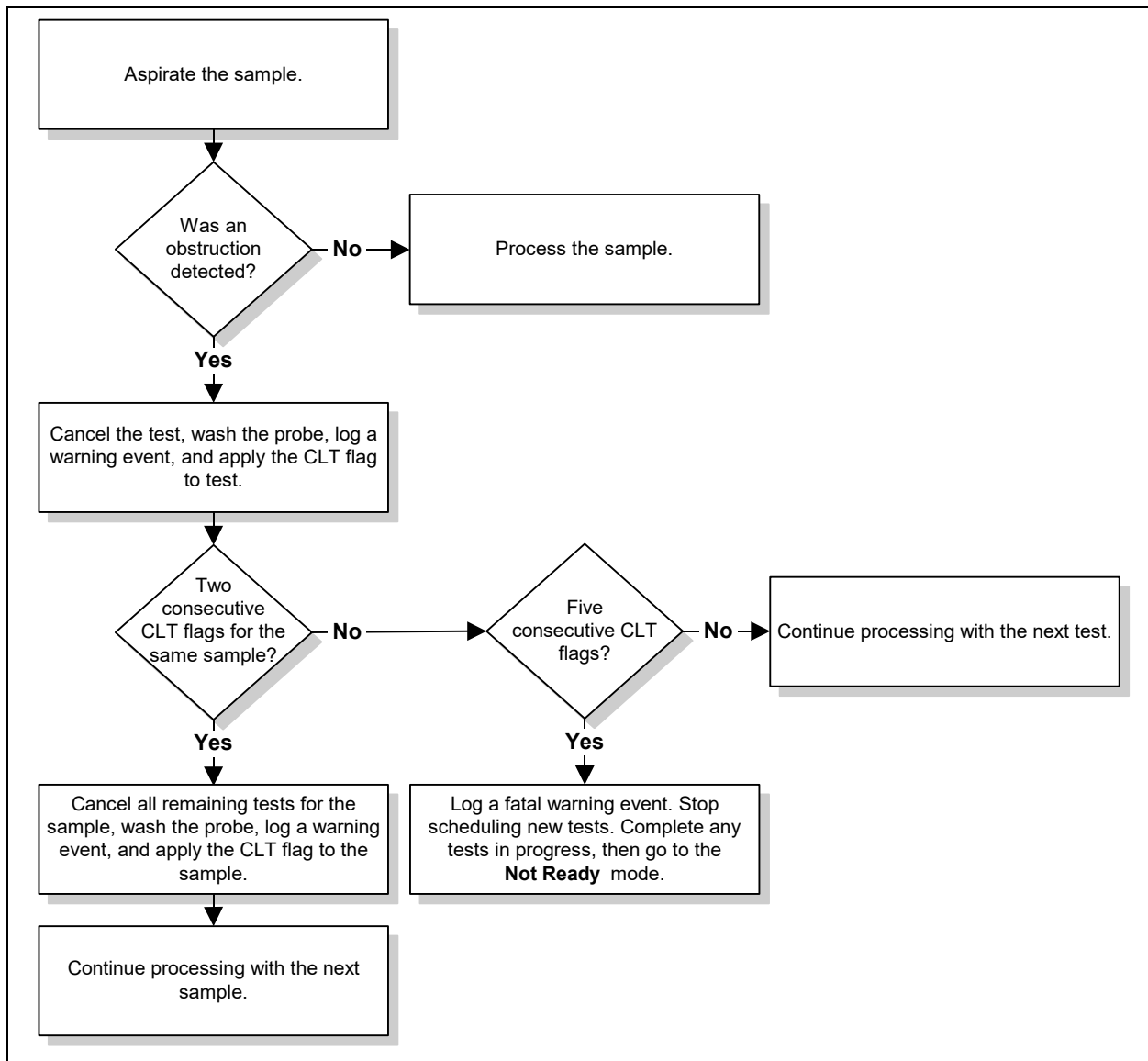
The system determines a reference curve for the pressure monitor by measuring the pressure profiles for two different sample volumes. The reference curve is used to identify the expected pressure profile for any given sample volume.

A reference curve is determined when the obstruction detection hardware is installed. Determine a new curve after the main pipettor is cleared of an obstruction; after the main pipettor, pressure sensor, or associated tubing is replaced; when following troubleshooting instructions; or as instructed by a technical support representative.

NOTE

The reference curve has no impact on reagent pack monitoring, which is also a function of the pressure monitor.

Obstruction Detection Flowchart



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A Temperature-Sensitive Assays

The Access assays listed in the table below are affected by changes in the room temperature of the Access 2 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 in result	If the temperature increases, the assay result...
33600	Access Cortisol	±4 °C (±7.2 °F)	±12%	Increases
98200	Access BNP	±4 °C (±7.2 °F)	±9%	Decreases
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 Access 2 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*	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	Erythropoietin	A16364	Reagent	2 x 50 tests	100
		A16365	Calibrator	6 total; S0 @ 10 mL S1-S5 @ 2.5 mL	5
Ferritin / Diluted Ferritin	Ferritin	33020	Reagent	2 x 50 tests	100
		33025	Calibrator	6 x 4.0 mL	8
Folate / Red Blood Cell (RBC) Folate	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	
Intrinsic Factor Ab	Intrinsic factor blocking antibody	387992	Reagent	2 x 50 tests	100
		387993	Calibrator	2 x 4.0 mL	16
		387999	QC	2 levels; 3 x 4.0 mL each	
sTfR	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 and QC3	2 levels; 2 x 2.5 mL each	

Access Assay Name	Analyte	Part #	Description	Volume	# Tests or # Calibrations (@ 500 µL/ Calibration)
Vitamin B₁₂	Vitamin B ₁₂ ; Cobalamin	33000	Reagent	2 x 50 tests	100
		33005	Calibrator	6 x 4.0 mL	8
		33006	Diluent (S0)	1 x 4.0 mL	
		D06116	Calibrator	6 x 4.0 mL	8
Vitamin B₁₂ II Calibrators					
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 Reagent	2 x 50 tests	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	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	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	Parathyroid hormone, intact (routine and intraoperative)	A16972	Reagent	2 x 50 tests	100
		A16953	Calibrator	6 x 1.0 mL	2
Ostase	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	

Access Assay Name	Analyte	Part #	Description	Volume	# Tests or # Calibrations (@ 500 µL/ Calibration)
Ultrasensitive hGH	Growth hormone	33580	Reagent	2 x 50 tests	100
		33585	Calibrator	6 x 2.0 mL	4
25(OH) Vitamin D Total	25(OH) vitamin D	B24838	Reagent	2 x 50 tests	100
		B24839	Calibrator	6 x 1.4 mL	2
Cardiovascular					
BNP	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	Creatine kinase, isoenzyme MB	386371	Reagent	2 x 50 tests	100
		386372	Calibrator	6 x 2.0 mL	4
Digoxin	Digoxin	33710	Reagent	2 x 50 tests	100
		33715	Calibrator	6 x 4.0 mL	8
		33716	Diluent	1 x 4.0 mL	
hsTnl	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
Myoglobin	Myoglobin	973243	Reagent	2 x 50 tests	100
		973244	Calibrator	6 x 1.0 mL	2
Diabetes					
C-Peptide	C-peptide; Connecting peptide	C33451	Reagent	2 x 50 tests	100
		C31860	Calibrator	6 x 2.0 mL	4
Ultrasensitive Insulin	Insulin	33410	Reagent	2 x 50 tests	100
		33415	Calibrator	6 x 2.0 mL	4
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 levels; 1.0 mL each	2
		A40707	QC	2 levels; 3 x 2.5 mL each	
Rubella IgG	Rubella antibody, IgG	34430	Reagent	2 x 50 tests	100
		34435	Calibrator	6 x 1.0 mL	2
		34439	QC	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	2 levels; 3 x 2.5 mL each	
Syphilis	<i>Treponema pallidum</i> antibody	C80411	Reagent	2 x 100 tests	200
		C80412	Calibrator	2 x 2.0 mL	4
		C80413	QC (Pos/Neg)	2 levels; 3 x 4.0 mL each	
Toxo IgG	<i>Toxoplasma gondii</i> antibody, IgG	A31588	Reagent	2 x 50 tests	100
		A31589	Calibrator	6 x 1.0 mL	2
		A31590	QC	2 levels; 3 x 2.5 mL each	

Access Assay Name	Analyte	Part #	Description	Volume	# Tests or # Calibrations (@ 500 µL/ Calibration)
Toxo IgM II	<i>Toxoplasma gondii</i> antibody, IgM	34470	Reagent	2 x 50 tests	100
		34475	Calibrator	2 x 1.5 mL	3
		34479	QC	2 levels; 3 x 3.5 mL each	
Inflammation					
IL-6**	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	
Reproductive					
AFP / Diluted AFP	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*	Calibrator (for 100 test kit)	7 x 2.5 mL	5
		33216	Diluent	1 x 14.0 mL	
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	Dehydroepiandrosterone sulfate	A10826	Reagent	2 x 50 tests	100
		A10827	Calibrator	6 x 2.0 mL	4
hFSH	Follicle stimulating hormone	33520	Reagent	2 x 50 tests	100
		33525	Calibrator	6 x 4.0 mL	8
hLH	Luteinizing hormone	33510	Reagent	2 x 50 tests	100
		33515	Calibrator	6 x 4.0 mL	8
Inhibin A	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	
PAPP-A*	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	
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	
Progesterone II	Progesterone	C78020	Reagent	2 x 50 tests	100
		C78021	Calibrator	6 x 2.5 mL	5
		C81798	Diluent (S0)	1 x 4.0 mL	
Prolactin	Prolactin	33530	Reagent	2 x 50 tests	100
		33535	Calibrator	6 total; S0 @ 4.0 mL S1-S5 @ 2.5 mL	5

Access Assay Name	Analyte	Part #	Description	Volume	# Tests or # Calibrations (@ 500 µL/ Calibration)
Sensitive Estradiol	Estradiol	B84493	Reagent	2 x 50 tests	100
		B84494	Calibrator	6 total; S0 @ 4.0 mL S1-S5 @ 2.0 mL	4
		B97145	Diluent (S0)	1 x 4.0 mL	
SHBG	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 mL each	
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)	βhCG; Beta-hCG	A85264	Reagent	2 x 50 tests	100
		B11754	Calibrator	6 x 4.0 mL	8
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
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

Access Assay Name	Analyte	Part #	Description	Volume	# Tests or # Calibrations (@ 500 µL/ Calibration)
TPO Antibody	Thyroperoxidase Antibody	A12985	Reagent	2 x 50 tests	100
		A18227	Calibrator	6 x 2.0 mL	4
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	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 *	Calibrator (for 100 test kit)	7 x 2.5 mL	5
		33216	Diluent	1 x 14.0 mL	
BR Monitor	Cancer antigen 15-3	387620	Reagent	2 x 50 tests	100
		387647	Calibrator	6 x 1.5 mL	3
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	Cancer antigen 19-9	387687	Reagent	2 x 50 tests	100
		387688	Calibrator	6 x 2.5 mL	5
Hybritech PSA	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; 5.0 mL each	
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; 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; 5.0 mL each	
OV Monitor	Cancer antigen 125	386357	Reagent	2 x 50 tests	100
		386358	Calibrator	6 x 2.5 mL	5
Research Use Only (RUO)					
APOE ε4 (RUO)	ApoE	D16691	Reagent	2 x 50 tests	100
		D16692	QC	3 levels; 2.5 mL each	
GFAP (RUO)	GFAP	D11672	Reagent	2 x 50 tests	100
		D11673	Calibrator	6 x 2.5 mL	5
		D11674	QC	3 levels; 2 x 2.5 mL each	

Access Assay Name	Analyte	Part #	Description	Volume	# Tests or # Calibrations (@ 500 µL/ Calibration)
IL-6 (RUO)	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	
NFL (RUO)	NFL	D15673	Reagent	2 x 50 tests	100
		D15674	Calibrator	6 x 2.5 mL	5
		D15675	QC	3 levels; 2 x 2.5 mL each	
PAPP-A (RUO)	Pregnancy-associated plasma protein A	A49209	Reagent	2 x 50 tests	100
		A49210	Calibrator	6 x 1 mL	2
		A49211	QC	3 levels; 2 x 2.5 mL each	

* Not available in the U.S.

† 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 Technical Support. To obtain the following supplies:

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

System Supply Description	Part #	Quantity
Aspirate probe supplies:		
Aspirate probe, stainless steel universal	8409B*	1
Aspirate probe cleaning kit	80769	(Syringe, fitting assembly, and 10 brushes)
Aspirate probe brushes, disposable	973001	10
Citranox acid cleaner and detergent	81912	1 gallon
Contrad 70 cleaning solution	81911	1 liter
Data storage devices†:		
Travan 8 GB tape†	973087	1
Travan 20 GB tape†	386175	1 box of 3 tapes
USB Flash Drive†	A81923	1
Printer supplies are no longer available from Beckman Coulter, Inc. Obtain printer supplies from your local office supplier or the printer manufacturer.		
Reaction vessel cartridges	81901	16 @ 98 vessels each
Sample Diluent A	81908	1 x 4 mL
Sample containers		
0.5 mL sample cups, Beckman Coulter	651412	1000

System Supply Description	Part #	Quantity
1.0 mL/13 mm insert cups, Beckman Coulter	81915	1000
1.0 mL/13 mm insert cup caps	81920	1000
2.0 mL/13 mm sample cups, Beckman Coulter	81902 or 652730	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 racks:		
13 mm	81606	6
16 mm x 100 mm	81608	6
16 mm x 75 mm Elevated	81609	6
Sample rack bar code label kit	973099	57 bar code label
Substrate	81906	4 @ 130 mL each
Swab applicators, fiber-free polyester	104838	100
System Check Solution	81910	6 @ 4 mL each
Wash buffer II, Access	A16792	4 @ 1950 mL each
Waste bags, reaction vessel	81904	20

* An item with a part 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.

† Be sure to order the appropriate data storage device for your Access 2 system. Storage devices are not interchangeable. Contact Technical Support if you cannot determine which storage device to order for your system.

To obtain the following supplies:

- 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.

System Supply Description	Part #	Quantity
CARE Kit	973077	1
Keyboard templates:		
English	973041	1
French	973254	1
German	973256	1
Italian	973257	1
Spanish	973255	1
Nozzle/O-ring (for probe wash tower)	81051	1
Probes/pipettors and supplies:		
Dispense probe	C69776	1
Pipettor tip, 3-inch (Primary probe)	6071	1
Pipettor torque tool	7343A*	1
Substrate probe	7143C*	1
Tubing:		
Aspirate probe	79102	1 foot length
Peristaltic pump aspirate	77372	1
Peristaltic pump vacuum	77512	1

System Supply Description	Part #	Quantity
Vessel holders:		
Chamfered (hole in top), no magnet	973005	65
Home position, chamfered, with magnet	973006	1
Wash buffer valve assembly (dispense cap assembly)	A49183	1
Waste bottle with lid and fittings	6769C*	1
Waste drain kit	7154A*	1
Waste filter/bottle assembly	80171	1

* An item with a part 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.

Access 2 System Documentation

Manuals, instructions for use, and other supporting documents for your Access 2 system are available on the Beckman Coulter website. Examples of available documents include:

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

To view or download electronic copies of Access 2 system documentation, visit the Beckman Coulter website at techdocs.beckmancoulter.com. To receive email alerts when new or updated Access 2 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.

Access 2 System Documentation	Part #	Quantity
Maintenance and Service Log; Paper, with binder	973266	1