GeneXpert® Xpress II and IV

User's Guide

IVD In Vitro Diagnostic Medical Device

Cepheid®
A better way.

GeneXpert® Xpress System

User's Guide

Xpress Software Version 5.1

IVD

301-6994, Rev. C December 2018

Cepheid®

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Part 15 Compliance

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

California Proposition 65 Warning

This instrument may contain chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

Preface

About This Guide

The *GeneXpert Xpress System User's Guide* describes the user operation and maintenance of the GeneXpert Xpress system. Information is provided about safely using the system with the GeneXpert Xpress software and performing maintenance. Information about the antivirus software and its operation is also included.

Safety Information

Chapter 2 provides important safety information that you should use when operating the GeneXpert instrument. Read and understand the safety information thoroughly before you begin operating the instrument. Make sure you follow the precautionary statements presented in this guide:

Warning

A warning indicates a possibility of adverse reactions, injury or death to the user or other persons if the precautions or instructions are not observed.

Caution

A caution indicates that damage to the system, loss of data or invalid results could occur if the user fails to comply with the advice given.

Important

An important note highlights information that is critical for the completion of a task or the optimal performance of the system.

Note

A note identifies information that is useful for completion of a task or identifies information that applies only in specific cases.

The warnings and cautions always use the same keyword but the icon may change to more clearly indicate the type of hazard.

Related Documents

For other information outside the scope of this document, see the following publications:

- GeneXpert Xpress System Getting Started Guide (P/N 301-7046 for a system with the GeneXpert Xpress II and P/N 301-7047 for a system with the GeneXpert Xpress IV)
- Assay Quick Reference Instructions
- Assay Package Insert

Table of Symbols

The following symbols are used in this manual and on the instrument labels:

Symbol	Meaning
	in vitro diagnostic medical device
	CE marking – European Conformity
	Separate collection for electrical and electronic equipment waste per Directive 2002/96/EC in the European Union
	Manufacturer
	Caution
	Biological risks
	This type of symbol indicates a possibility of loss of data or data corruption if proper procedures are not followed. Read any additional information following the symbol to avoid the data loss.

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Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Lot number
- Serial number of the instrument
- Error messages (if any)
- Software version and, if applicable, Computer Service Tag number

Region	Telephone	Email
US	+1 888.838.3222	TechSupport@cepheid.com
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1 Introduction

Note The GeneXpert Xpress System is designed for touchscreen operation. A keyboard, mouse and stylus may be used, but are not required or supplied.

Note GeneXpert Dx software version 5.1 supports Microsoft Windows 7, and Windows10 operating systems. All screens shown in this guide are from GeneXpert Xpress software version 5.1 and were correct at the time of publication. If a different version of software is installed on the system, screens may vary from those shown. If the software version does change, a technical update will be sent.

Note For assistance, see the Technical Assistance section in the Preface of this document.

1.1 Intended Use

The GeneXpert Xpress System platform automates and integrates sample preparation, nucleic acid extraction and amplification, and detection of the target sequence in samples using real-time PCR and reverse transcriptase PCR (RT-PCR) with Cepheid *in vitro* diagnostic use assays. The GeneXpert Xpress System can be used in the laboratory or point-of-care settings.

Refer to assay-specific package insert for details on specific tests.

1.2 Software Installation

The GeneXpert Xpress System comes with the software pre-installed. If it is necessary to reinstall software or install a software update, contact Cepheid Technical Support. See the Technical Assistance section in the Preface for contact information.

1.3 System Components

Cepheid tested and qualified the GeneXpert Xpress system components to provide optimal performance. See Figure 1-1, GeneXpert Xpress System Components.

Caution

Altering computer settings, pre-installed software, or replacing system components without guidance from Cepheid can result in the loss of data, impact system performance, damage the instrument, and void your warranty.

Do not install non-approved software.

DO NOT turn off the GeneXpert or the computer when a test is in progress because it will terminate the test.

Caution

It is highly recommended that a surge protector (not provided) be connected to a properly grounded circuit. Make sure the system is connected properly to the surge protector.

Using a non-grounded circuit can cause damage to the system.

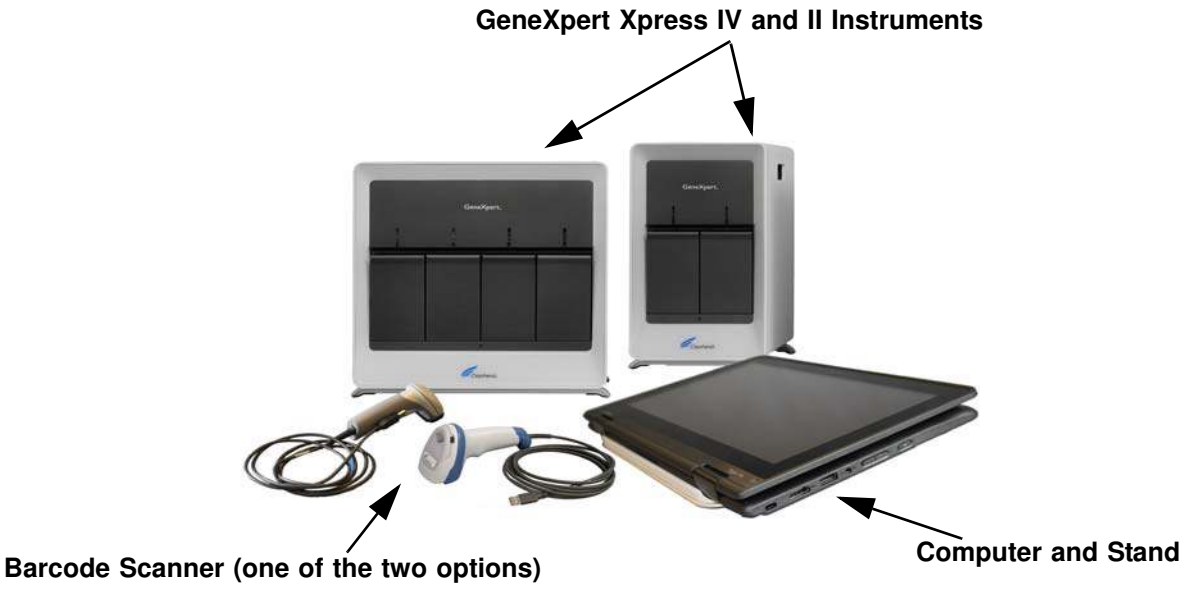


Figure 1-1. GeneXpert Xpress System Components

For systems using the GeneXpress II system, please refer to Section 3, Operation - GeneXpert Xpress II or for the GeneXpress IV system, please refer to Section 4, Operation - GeneXpert Xpress IV.

1.4 LIS Uploads

Note

Only LIS uploads are supported on this system.

Note

An Ethernet® adapter is provided for uploading LIS files. The adapter is packaged separately in an accessories box.

Please contact your local IT/LIS administrator first for assistance in configuring your system for LIS uploads or connecting the Ethernet adapter. Refer to the GeneXpert Xpress System Getting Started Guide (P/N 301-7046 for the system with the GeneXpert II and P/N 301-7047 for the system with the GeneXpert IV) for further information about connecting the Ethernet adapter.

If further assistance is required, contact Cepheid Technical Support. See the Technical Assistance section in the Preface for contact information.

Note

Cepheid recommends to always confirm that LIS uploaded results match GeneXpert results after any changes to the GeneXpert or host system, including, but not limited to, changes to the following:
- GeneXpert Xpress software version
- GeneXpert assay definition files and version
- GeneXpert host communication settings
- Host middleware software or configuration changes
- LIS software or configuration changes

1.5 Antivirus Software

Caution

The GeneXpert Xpress system computer running Windows 7 is provided with pre-installed Norton Security™ AntiVirus software. Do not install or use other virus protection products. Doing so can prevent data collection. See Appendix C for additional antivirus information.

The GeneXpert Xpress system computer running Windows10 is provided with pre-installed Windows Defender AntiVirus software. Do not install or use other virus protection products. Doing so can prevent data collection.

1.6 Network Connection

Caution

Do not change the Internet Protocol (IP) settings for the Ethernet connection to the GeneXpert Xpress instrument. Changing the IP settings can cause instrument communication failure.

Do not unplug the Ethernet cable from the computer after starting the GeneXpert Xpress software.

1.7 Windows® User Accounts

The GeneXpert Xpress system computer is configured for a Cepheid user account. You must log on as the Cepheid user to operate the system. When logging on for the first time, use the following:

- User name: **Cepheid-Admin**
- Password: **cphd**

Caution

Do not change the Cepheid user profile. Changing the profile can cause loss of data during a test.

1.8 Software Buttons, Icons and Symbols

The following table is a short description of the most common buttons icons and symbols encountered in the GeneXpert Xpress software.

Table 1-1. Software Buttons, Icons and Symbols

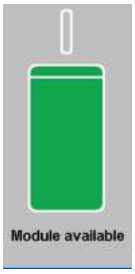
Symbol	Definition
	Home - Go to the Home screen.
	Exit - Exit the GeneXpert Xpress Software.
	Indicates a module that is available to run a test.
	Indicates a module with test in progress.
	Indicates a module with test complete.
	Cancel Test- Cancels the current test.

Table 1-1. Software Buttons, Icons and Symbols (Continued)

Symbol	Definition
	Print Result- Print the result of the assay or test.
	QC- Navigate to the Quality Control page, (only present if QC Lockout has been enabled).
	Sign Out- signs the current user out of the software, (only present if User Login has been enabled).

1.9 Creating Patient/Sample IDs

The character limit for a sample ID is 25 characters. Invalid characters which may not be used in a sample ID are **\ / : * ? < >** “ |.

2 Safety

2.1 Safety Labels on the Instrument

Table 2-1 lists the electrical labels that you will find on the GeneXpert Xpress instrument.

Table 2-1. Electrical Labels on the Instrument

Label	Description
|	Indicates the on position of the main power switch.
○	Indicates the off position of the main power switch.
~	Indicates the designated connector either receives or delivers alternating current or voltage.

2.2 Electrical Safety

Warning

ELECTRICAL HAZARD: Do not attempt to open or remove the instrument covers. Doing so can expose you to electrical hazards and result in significant injury or death. If any liquid were to be spilled into the instrument, unplug the instrument and contact Cepheid Technical Support for instructions.

The GeneXpert Xpress instrument enclosure is designed to protect you from electrical shock hazards. Under normal operating conditions, you are protected from electrical shock hazards.

2.3 Biological Hazard Safety

Biological Risks

Treat all biological specimens, including used cartridges, as capable of transmitting infectious agents. Because it is often impossible to know what might be infectious, all biological specimens should be treated with standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention and the Clinical Laboratory Standards Institute.

2.4 Chemical Safety

- Follow standard laboratory safety procedures for working with chemicals.

Warning

Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional disposal procedures. If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

- Safety Data Sheets (SDS) for all reagents used with this system are available upon request from Cepheid Technical Support, and are available on Cepheid's websites (www.cepheid.com and www.cepheidinternational.com).
- Refer to the Cepheid website for additional environmental health and safety information on Cepheid products.

2.5 Environmental Data

- Recyclability of GeneXpert Xpress System: the WEEE mark is affixed to Cepheid electronic products.
- It is recommended to retain packaging materials. The materials may be useful for repackaging any items for re-shipment to Cepheid.
- Additional information on the above, including EU and country directives concerning packaging, energy consumption, RoHS, REACH, Prop. 65, etc. can be obtained by contacting Cepheid Technical Support: techsupport@cepheid.com.

3 Operation - GeneXpert Xpress II

This chapter describes how to run tests using the GeneXpert Xpress II instrument in the normal system configuration as shipped from Cepheid. In this configuration:

- No passwords are required to run tests
- No special user accounts have been created
- Quality Control (QC) lockout has not been enabled
- The computer has been set up in tablet mode as described in Appendix A and is on the computer stand
- All cables have been have been connected as described in the GeneXpert Xpress II Getting Started Guide (P/N 301-7046)

If passwords and user accounts are required or QC lockout is required, an administrator must perform the setup instructions shown in Chapter 5, Administrative Tasks before the GeneXpert Xpress II is used to run tests.

For information on signing in (if user accounts are required), see Section 3.6, User Sign In and Sign Out (Optional). For more information on Quality Control or QC Lockout features, see Section 3.7, Quality Control Lockout (Optional).

To aid in using the GeneXpert Xpress II, see the following reference documents:

- GeneXpert Xpress II Getting Started Guide (P/N 301-7046), shipped with the system.
- Assay Quick Reference Instructions, shipped with the assay lot.

3.1 Starting the GeneXpert Xpress II and GeneXpert Xpress Software

This section describes how to power up and log onto the system.

1. Turn on the GeneXpert Xpress II instrument. The power switch is located on the back of the instrument. Press the switch to the **ON** (|) position. See Figure 3-1. After power has been turned on, the blue light on the front of the instrument will be **ON**.
2. Turn on the computer by sliding or pressing the power switch on the side of the computer. See Figure 3-2.

Note On start-up, the Windows screen may be in the wrong orientation for tablet mode. Please wait until the screen re-adjusts itself.

Note If the printer will be required, power it on following the instructions in the user manual that was provided with the printer.

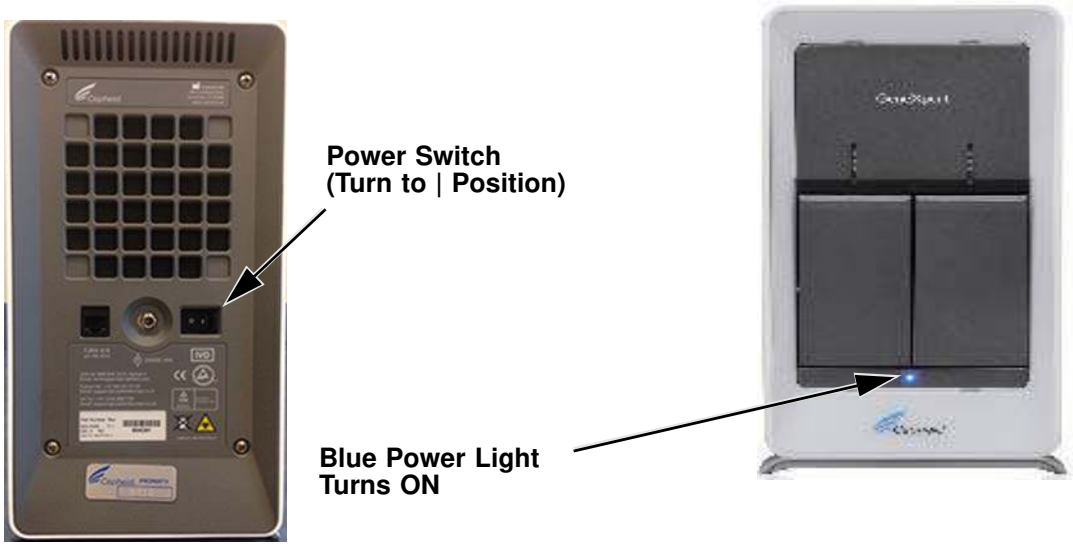


Figure 3-1. Turn on Instrument

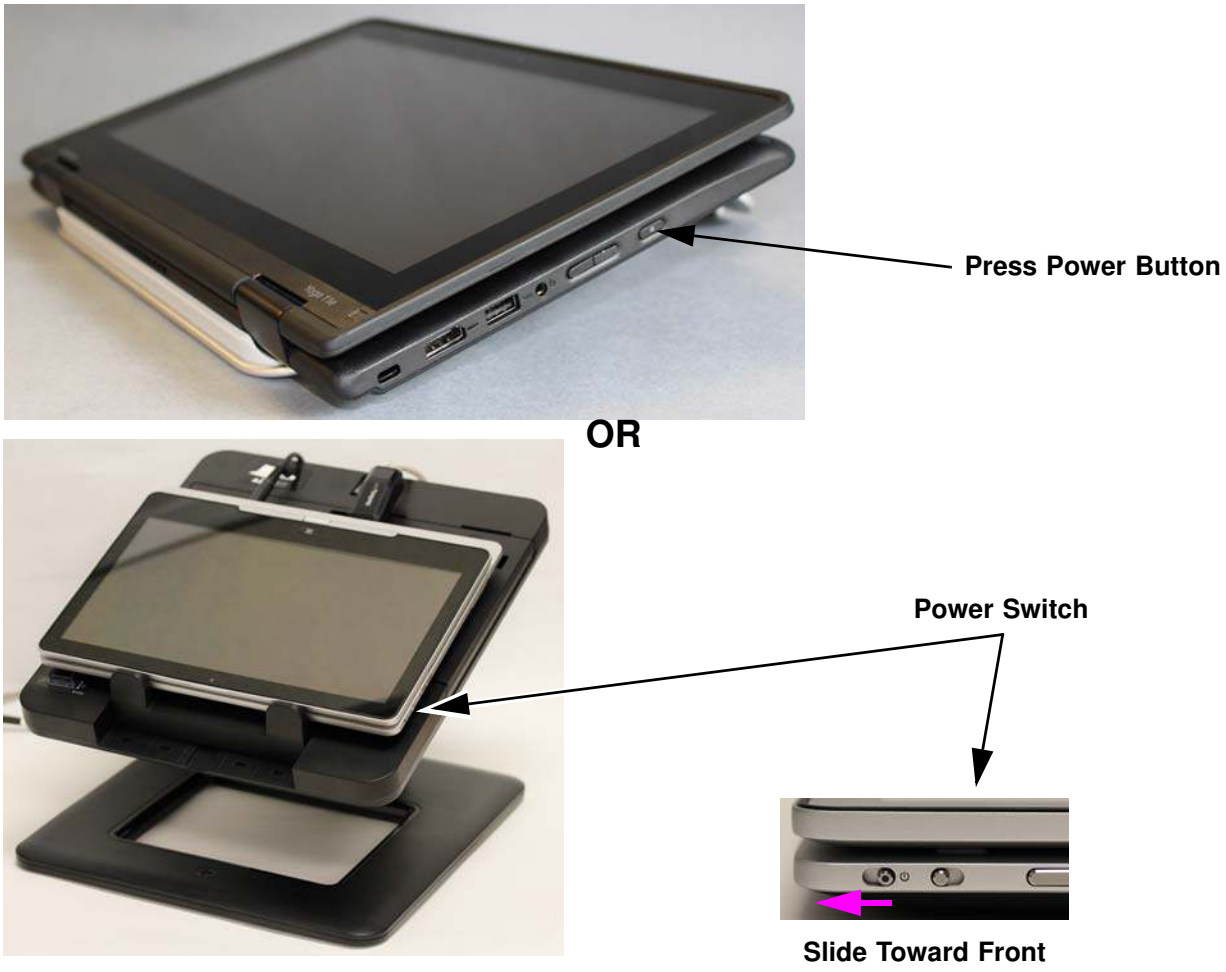


Figure 3-2. Turn on Computer

3. Wait for the system to boot.
   - On Windows 7, the Windows Account screen appears. See Figure 3-3.
   - On Windows 10, the Windows Lock screen appears. See Figure 3-4. Touch anywhere on the screen and swipe up to display the Windows Account and Password screen. See Figure 3-6.
4. On the Windows Account screen, select the Cepheid user account (see Figure 3-3 and Figure 3-6).
   - On Windows 7, the Windows Password screen appears. See Figure 3-5.
   - On Windows 10, the Cepheid user account password field appears. See Figure 3-6.

Figure 3-3. Windows 7 Account Screen

Figure 3-4. Windows 10 Lock Screen

The initial login password is provided below. You will be required to change the password upon first login. Do not change the user name or profile settings. When logging on, use the following:

- Account name: **Cepheid-Admin**
- Password: **cphd**

5. On the Windows Password screen (see Figure 3-5 and Figure 3-6), enter the password and touch the arrow next to the password field. The default password is **cphd** and must be changed upon initial login (as instructed by the software). After the password has been changed by the system administrator, enter the assigned password for future logins.

Figure 3-5. Windows 7 Password Screen

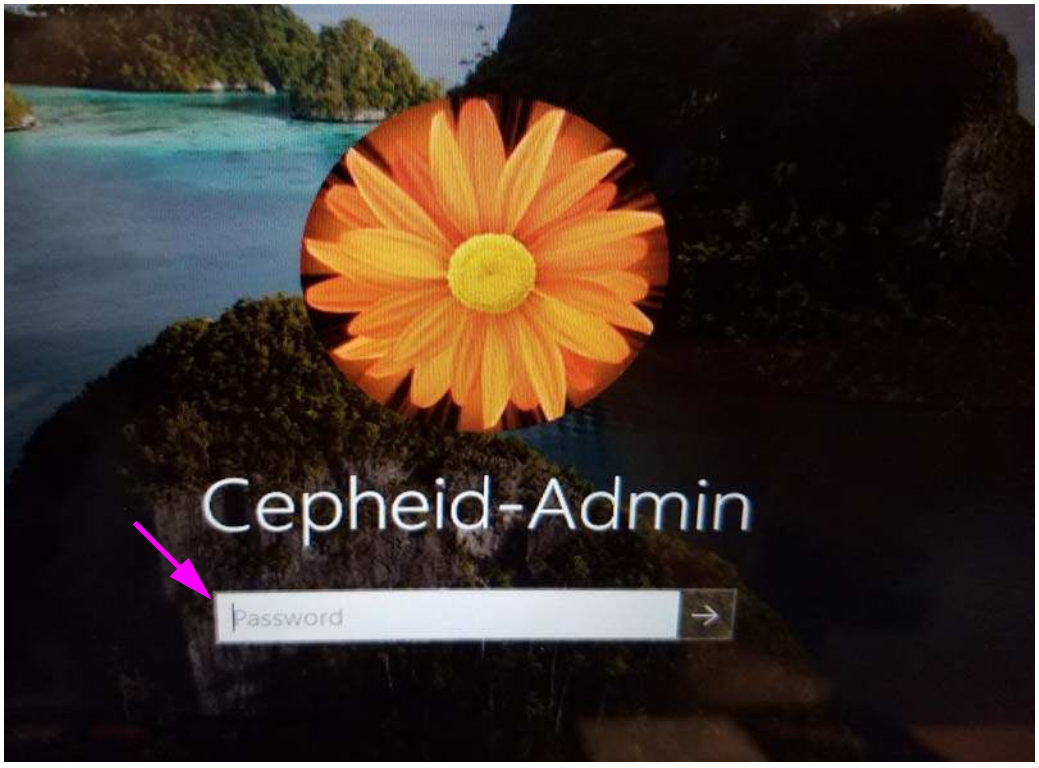


Figure 3-6. Windows 10 Account and Password Screen

6. The Windows Welcome screen will be displayed for a short time followed by the Windows desktop. After the Windows desktop is displayed, the GeneXpert Xpress software will load.

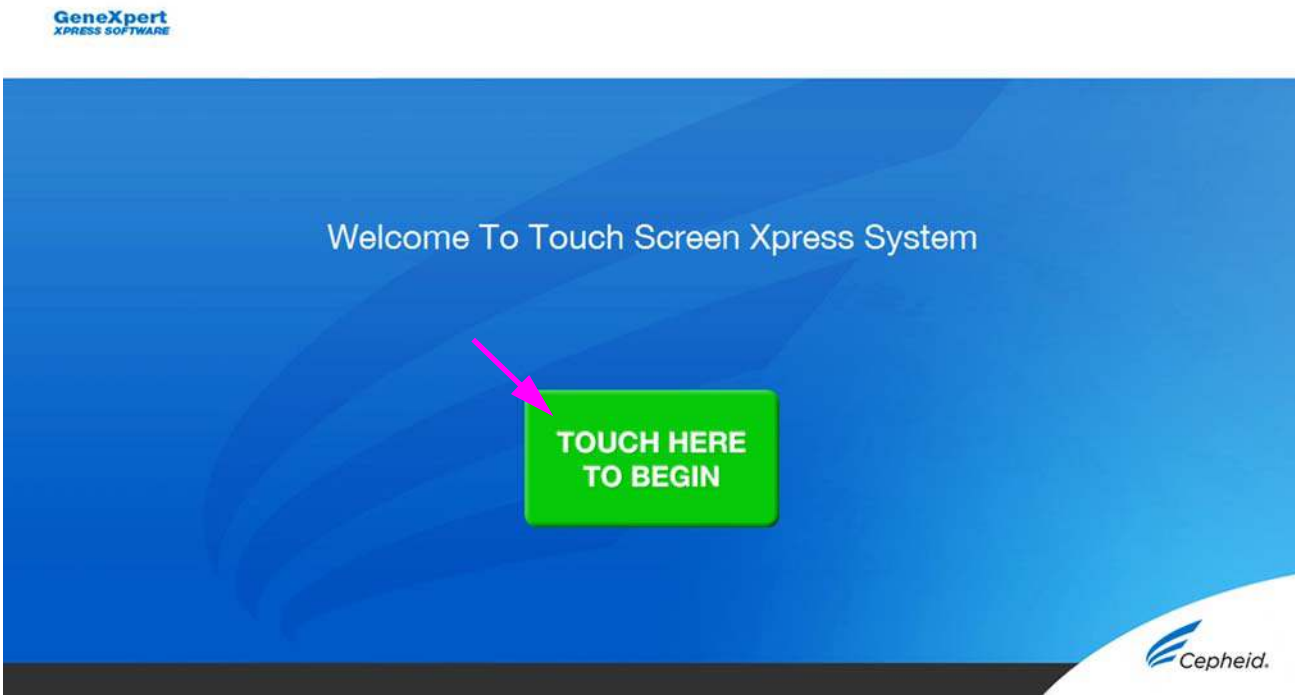


Figure 3-7. GeneXpert Xpress Welcome Screen

7. The GeneXpert Xpress splash screen will be displayed for a short time and then the GeneXpert Xpress Welcome screen will be displayed (see Figure 3-7). Touch the **TOUCH HERE TO BEGIN** button. The GeneXpert Xpress Home screen will be displayed. See Figure 3-8.

Note

If user accounts have been set up, refer to Section 3.6, User Sign In and Sign Out (Optional) for information on signing in and out.

Note

The Home screen shown in Figure 3-8 may initially show only the **VIEW PREVIOUS TESTS** button until the instrument initializes. The **RUN NEW TEST** button should be displayed within 3 minutes.

The instrument is now initialized and is ready to run tests. See Section 3.2, Starting a Test.

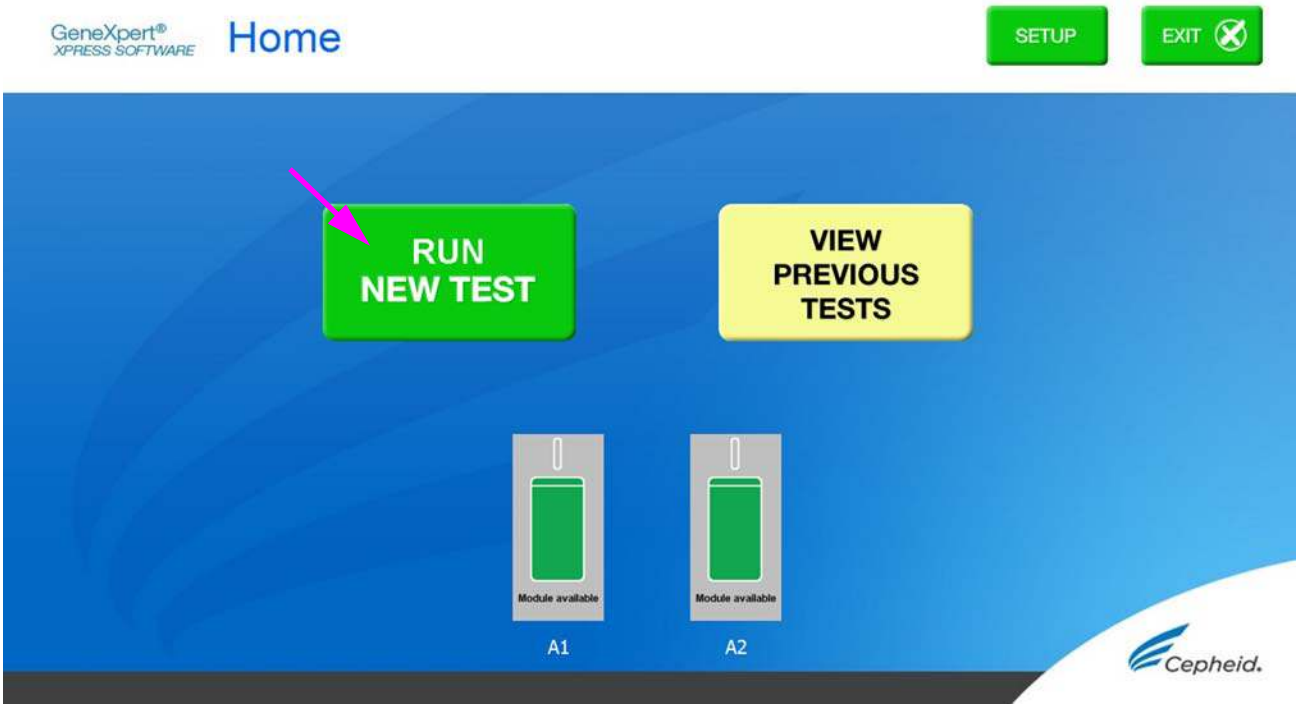


Figure 3-8. GeneXpert Xpress II Home Screen

3.2 Starting a Test

Note Read the package insert provided with the cartridges for more information. Instructions showing how to prepare the sample and the cartridge are shown on-screen in videos as well as in the following procedure.

Important **After adding the sample to the cartridge, start the test within the timeframe indicated in the assay package insert.**

Note This section uses the Xpert Xpress Flu/RSV assay as an example. Other assays may have minor differences.

This section describes how to run a test using the GeneXpert Xpress instrument.

1. Touch the **RUN NEW TEST** button on the Home screen (see Figure 3-8). The Enter Patient/Sample ID screen is displayed. See Figure 3-9.

Note The Patient/Sample ID is a unique identifier that links the sample being processed to the patient that provided the sample.

2. Check the patient sample for a Patient/Sample ID barcode.
   A. If there is a Patient/Sample ID barcode, touch the **YES** button on the Enter Patient/Sample ID screen. The Step 1 of 7 Scan Patient/Sample ID screen will be displayed. See Figure 3-10.

B. As shown on the screen, use the barcode scanner to scan the Patient/Sample ID. The Step 2 of 7 Confirm Patient/Sample ID screen will be displayed. See Figure 3-12.

C. Verify that the Patient/Sample ID on the Step 2 of 7 Confirm Patient/Sample ID screen matches the Patient/Sample ID on the sample (see Figure 3-12). If it matches, touch the **YES** button. If it does not match, then touch the **NO** button. The Step 1 of 7 Scan Patient/Sample ID screen will be displayed. See Figure 3-10. You can either scan the barcode again or touch the **NO** button and enter the barcode manually.

or

A. If there is no Patient/Sample ID barcode, touch the **NO** button on the Enter Patient/Sample ID screen (see Figure 3-9). The Step 1 of 7 Enter Patient/Sample ID screen will be displayed. See Figure 3-11.

B. As shown on the screen, use the touchscreen keypad to manually enter the Patient/Sample ID and touch the **OK** button. The Step 2 of 7 Confirm Patient/Sample ID screen will be displayed. See Figure 3-12.

C. Verify that the Patient/Sample ID on the Step 2 of 7 Confirm Patient/Sample ID screen matches the Patient/Sample ID on the sample. If it matches, touch the **YES** button. If it does not match, then touch the **NO** button and re-enter the Patient/Sample ID.

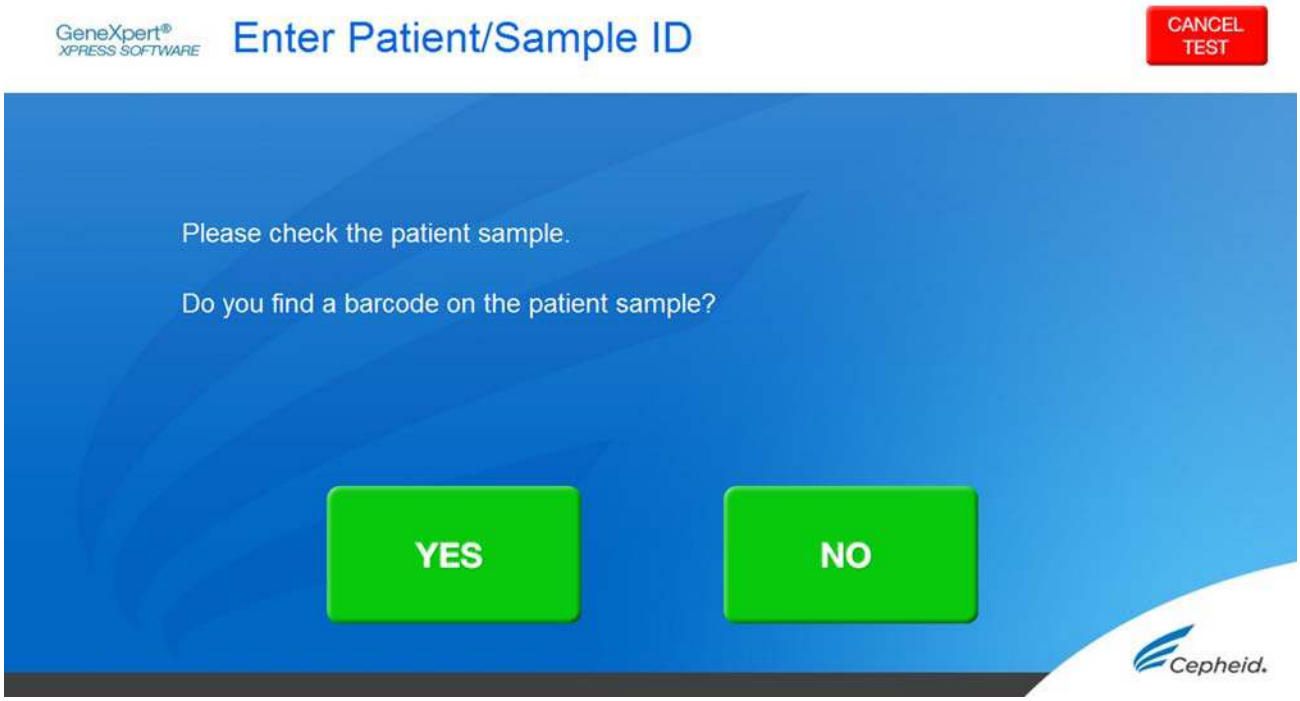


Figure 3-9. Enter Patient/Sample ID Screen

Figure 3-10. Step 1 of 7 - Scan Patient/Sample ID Screen

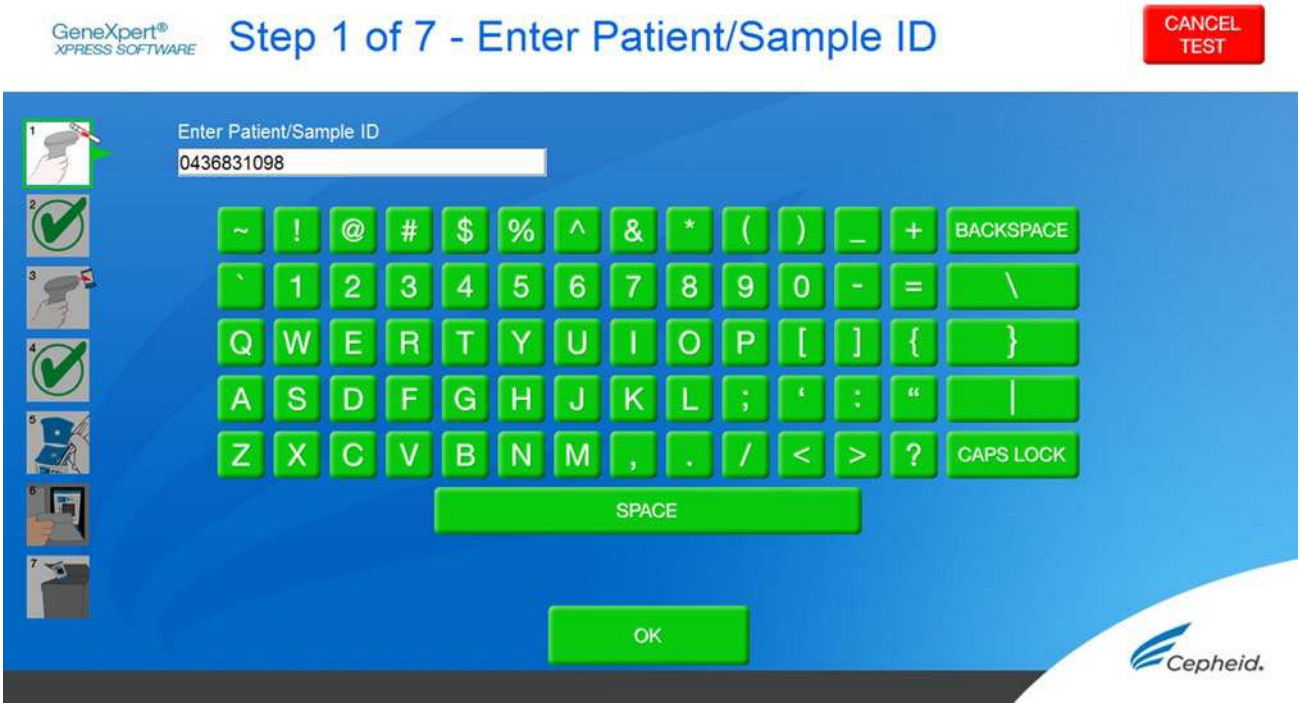


Figure 3-11. Step 1 of 7 - Enter Patient/Sample ID Screen

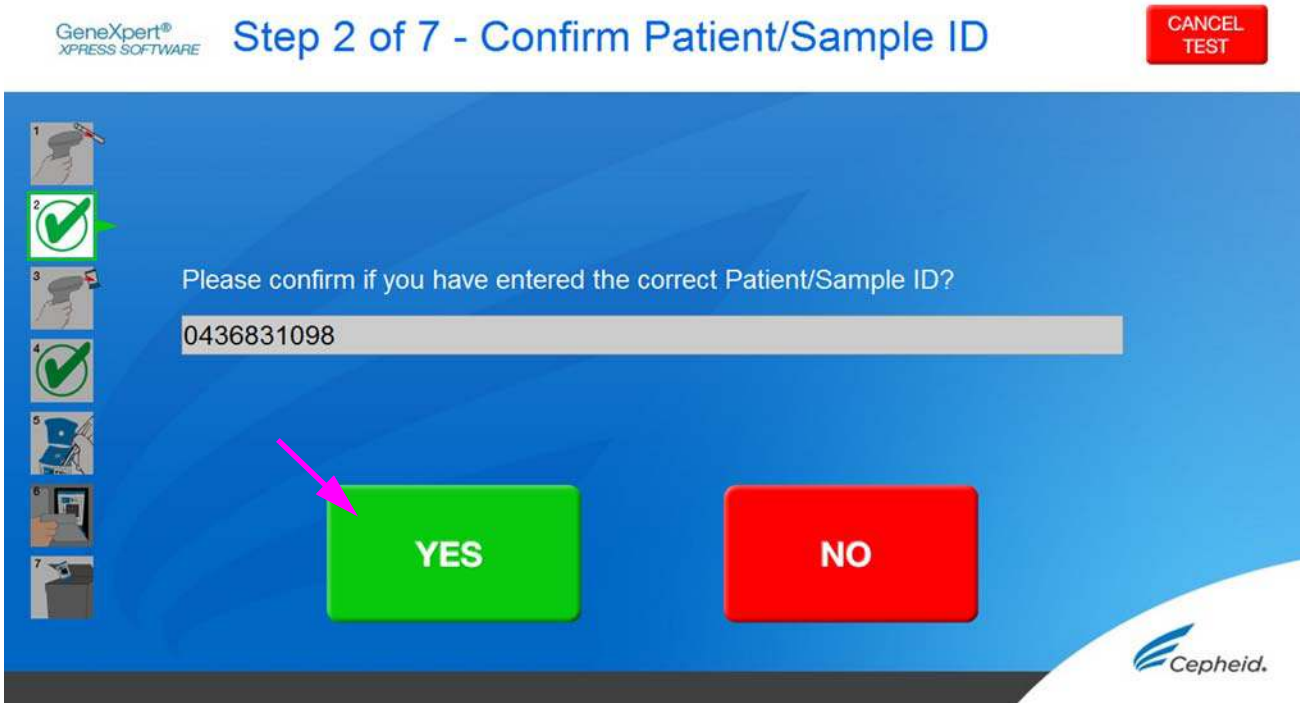


Figure 3-12. Step 2 of 7 Confirm Patient/Sample ID Screen

3. After confirming that the Patient/Sample ID is correct, the Step 3 of 7 Scan Cartridge Barcode screen will be displayed (see Figure 3-13). Select the cartridge with the sample and use the barcode scanner to scan the cartridge label. When you hear the beep, the cartridge barcode has been scanned and the Step 4 of 7 Confirm Test screen will be displayed. Select the assay required and then confirm the selected test is correct by touching the **YES** button. See Figure 3-14.

Note

For assays with multiple options, select the correct assay then touch the **YES** button. The **YES** button will remain gray until an assay has been selected.

4. Verify that the correct cartridge has been scanned and that the test type shown on the Step 4 of 7 Confirm Test screen (see Figure 3-14) matches the name of the test on the cartridge. If it matches, touch the **YES** button. The Step 5 of 7 Cartridge Preparation screen will be displayed. See Figure 3-15.

   If it does not match, then touch the **NO** button and scan the correct cartridge barcode.

5. The Step 5 of 7 Cartridge Preparation screen will play a short video showing how to prepare the cartridge for testing (see Figure 3-16). Once complete, the video will restart from the beginning automatically. Prepare the cartridge according to the directions shown in the video and in the assay package insert.

6. After the cartridge has been prepared, touch the **SKIP VIDEO AND CONTINUE** button on the Step 5 of 7 Cartridge Preparation screen (see Figure 3-16). The Step 6 of 7 Load Cartridge screen is displayed. See Figure 3-17.

Figure 3-13. Step 3 of 7 Scan Cartridge Barcode Screen

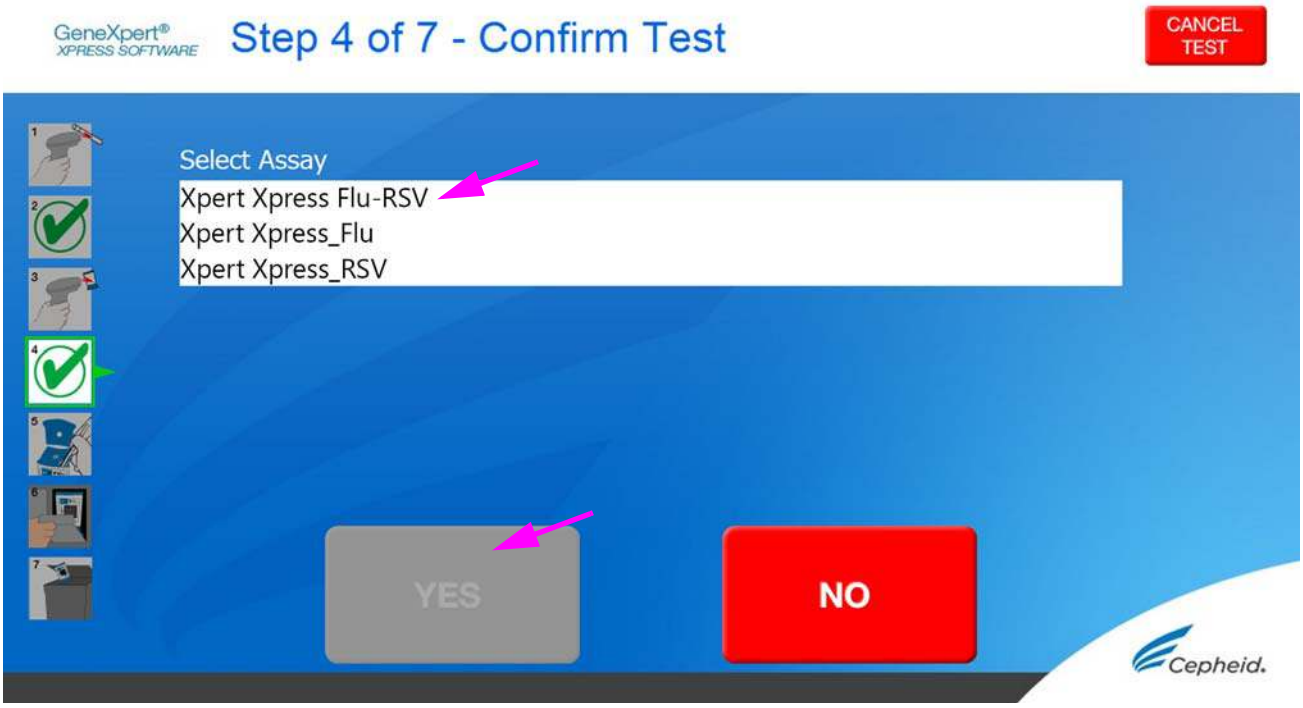


Figure 3-14. Step 4 of 7 Confirm Test Screen

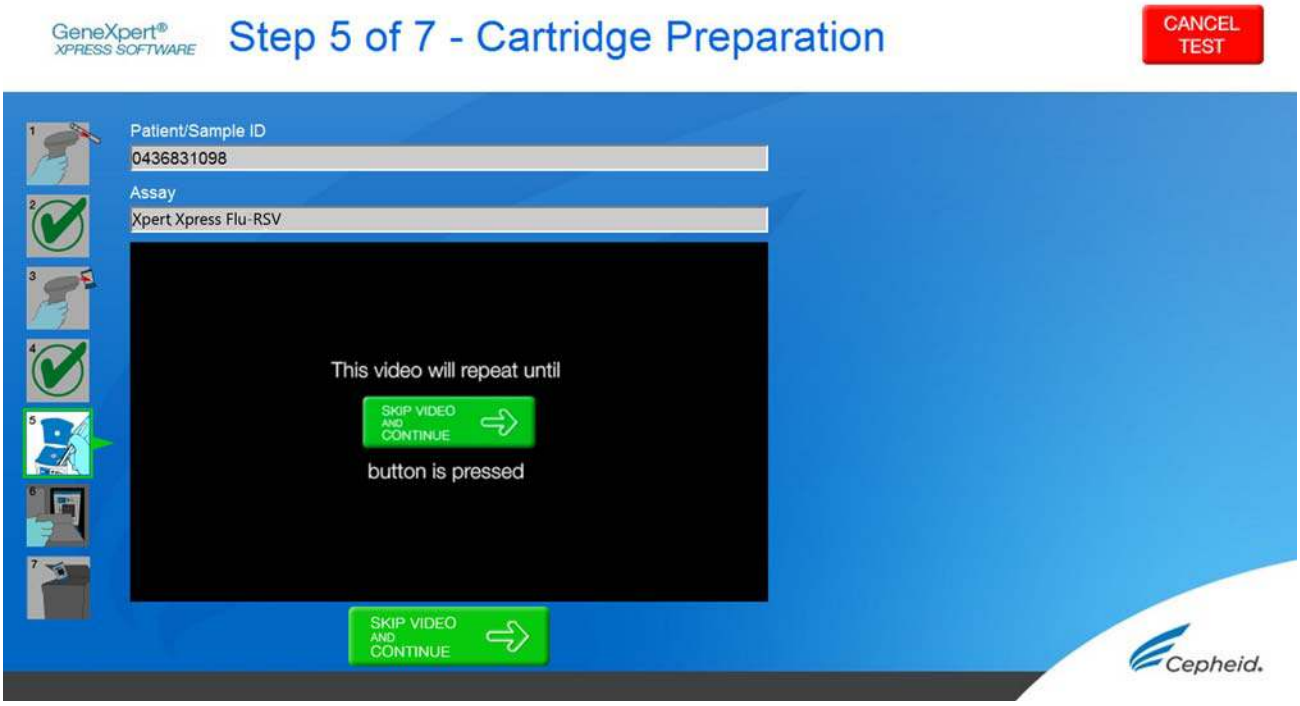


Figure 3-15. Step 5 of 7 Cartridge Preparation Screen Before Video Plays

Figure 3-16. Step 5 of 7 Cartridge Preparation Screen While Video Plays

Figure 3-17. Step 6 of 7 Load Cartridge Screen (1 of 2)

7. On the Step 6 of 7 Load Cartridge screen (see Figure 3-17), insert the cartridge into the system module with the blinking green light. Ensure that the door of the system is completely closed. The door will latch and the blinking green light will turn solid green. As soon as the cartridge is loaded, the next Step 6 of 7 Load Cartridge screen will be displayed. See Figure 3-18.

   The Step 6 of 7 Load Cartridge screen will show a progress bar at the bottom of the screen as the cartridge is loaded (see Figure 3-18). As soon as the load process is completed, the Step 6 of 7 Test in Progress screen will be displayed. See Figure 3-19.

8. The Step 6 of 7 Test in Progress screen will show a progress bar at the bottom of the screen indicating the progress of the test and the time remaining until a result is available (see Figure 3-19). As soon as the test is completed, the Step 7 of 7 Remove Cartridge screen will be displayed. See Figure 3-20.

Note

At this point, an additional test can be started. To start an additional test, see Section 3.3, Starting Another Test While a Test is Running.

Figure 3-18. Step 6 of 7 Load Cartridge Screen (2 of 2)

Figure 3-19. Step 6 of 7 Test in Progress Screen

Figure 3-20. Step 7 of 7 Remove Cartridge Screen

9. The Step 7 of 7 Remove Cartridge screen shows instructions for removing the cartridge (see Figure 3-20). Open the instrument door, remove the used cartridge and properly dispose of the cartridge according to your institution's hazardous waste disposal policies. After removing the cartridge, close the module door and touch the **CONTINUE** button.

Note

Verify that the printer is powered on, has paper and is communicating with the Xpress computer before printing the results.

10. The Test Result screen will provide the results for the test that has just completed (see Figure 3-21). After viewing and recording the results, touch the **HOME** to return to the Home screen, **VIEW PREVIOUS TESTS** to view another result or touch the **PRINT RESULT** button to print the results. See Section 3.5, Print Results.

This completes the procedure for running a test using the GeneXpert Xpress II instrument.

If any error messages occur while running the test, see Section 3.9, Error Handling.

Figure 3-21. Test Result Screen

3.3 Starting Another Test While a Test is Running

An additional test may be started after the first test is in progress.

1. When a test is in progress, see Step 8 of Section 3.2, Starting a Test and Figure 3-19. Touch the **HOME** button.
2. The Home screen will display the module in use as slightly gray and with the notation that a test is in progress. See Figure 3-22.
3. Touch **RUN NEW TEST** and start the new test. See Section 3.2, Starting a Test.
4. After the second test is in progress, touch the **HOME** button. The status of both tests is displayed.
5. When one test is complete, the icon text will change to **Test complete** and will show a check mark on the icon. See Figure 3-23. Touch the icon to show the Remove Cartridge screen. See Figure 3-20. Follow the instructions on the screen to remove the cartridge.

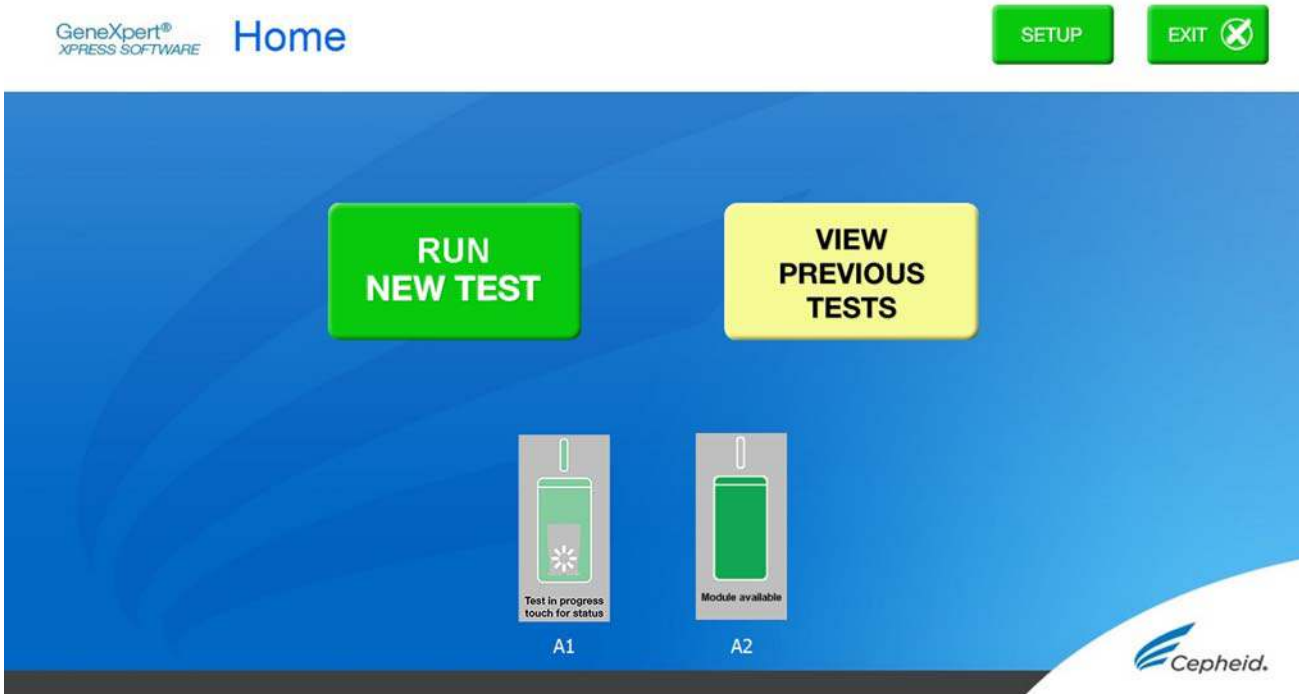


Figure 3-22. GeneXpert Xpress II Home Screen with One Test in Progress

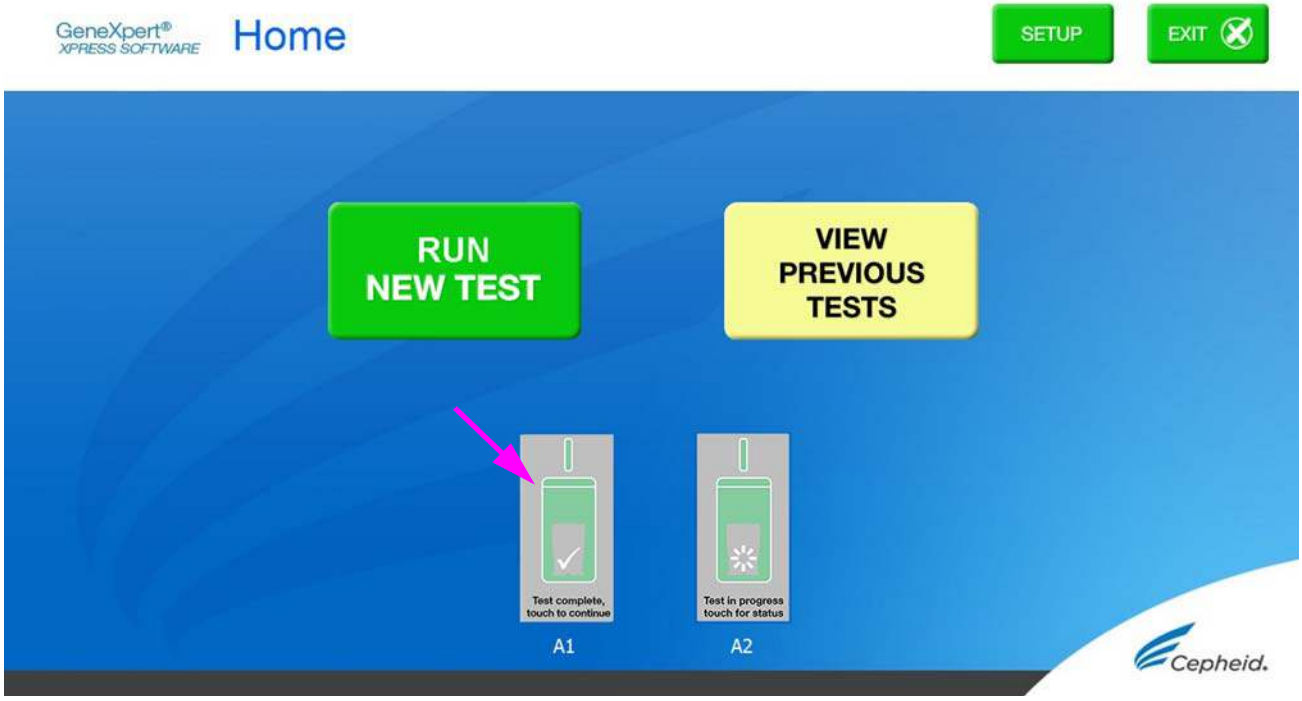


Figure 3-23. GeneXpert Xpress II Home Screen with One Test Completed

This completes the procedure for starting another test while a test is running.

3.4 Viewing Previous Test Results

This section describes how to view the results of previously run tests using the GeneXpert Xpress II system.

1. Touch the **VIEW PREVIOUS TESTS** button on the Home screen (see Figure 3-24). The Select Test screen is displayed. See Figure 3-25.
2. On the Select Test screen, select the test to view. Tests are arranged in order by the date and time that the test was run. Touch the arrow keys to navigate to the desired test.

   The single arrow keys move the selection up or down by one test result. The double arrow keys move the selection up or down by one page at a time.
3. After selecting the desired test, touch the **Select** button to view the test results. The Test Result screen for the selected test will be displayed. See Figure 3-26.

   To interpret the results for a specific assay, see the package insert provided in the assay kit.

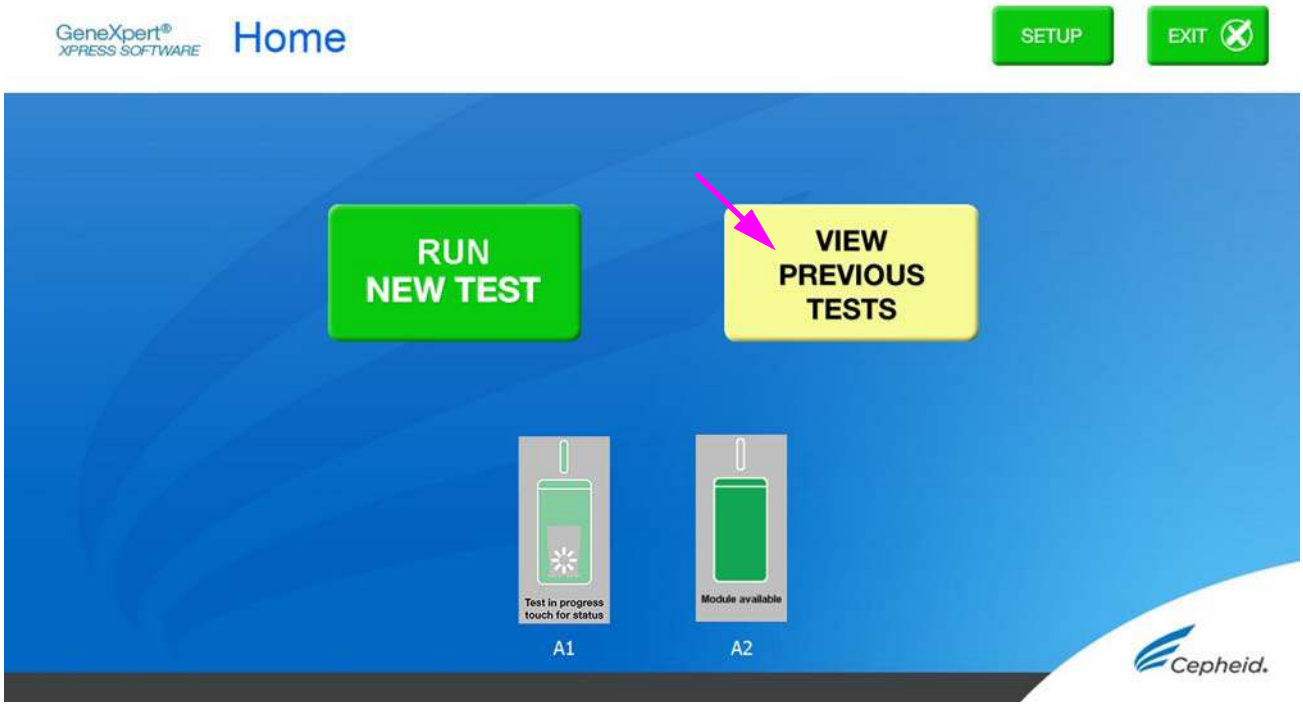


Figure 3-24. GeneXpert Xpress Home Screen

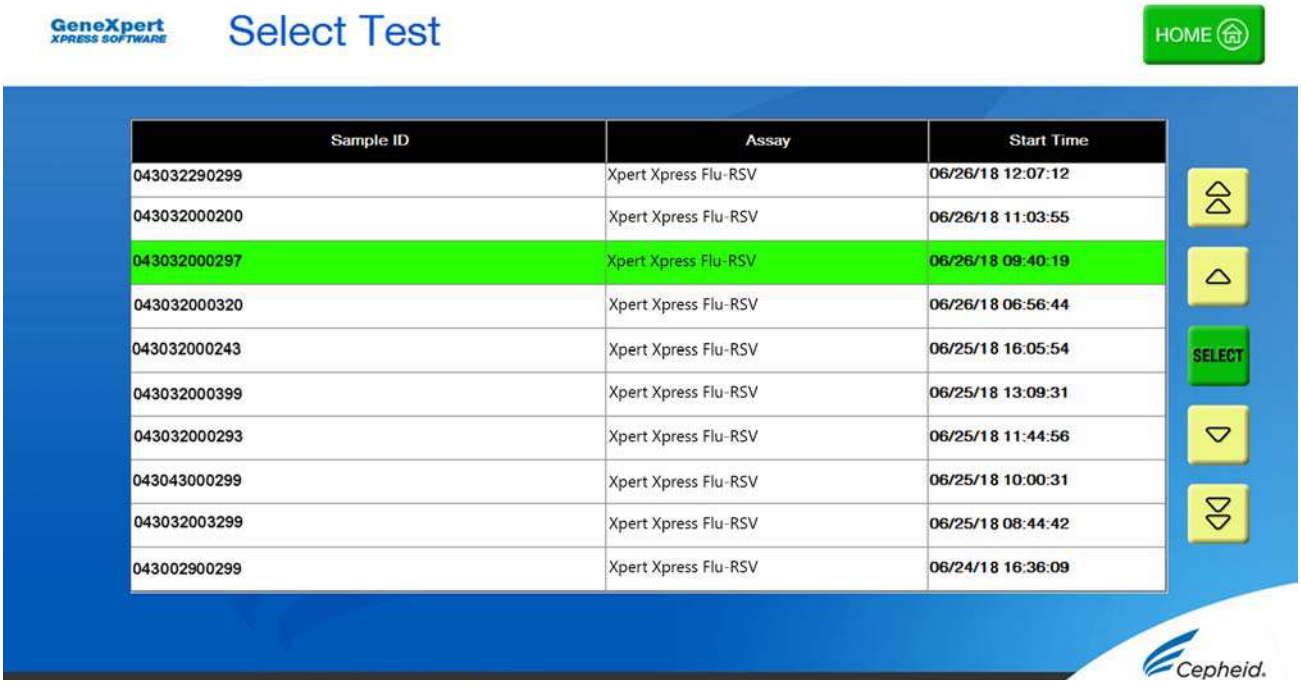


Figure 3-25. Select Test Screen

Figure 3-26. Test Result Screen

Note Verify the printer is powered on, has paper and is communicating with the Xpress computer before printing the results.

4. After viewing the results, touch the **HOME** button to return to the Home screen and run additional tests, touch the **VIEW PREVIOUS TESTS** button to return to the Select Test screen and view additional tests or print the results by touching the **PRINT RESULT** button. See Section 3.5, Print Results.

This completes the procedure for viewing previous test results.

3.5 Print Results

If the option to print the results was selected, a screen indicating the report was sent to the printer will display. See Figure 3-27. Touch the **OK** button to return to the **HOME** screen.

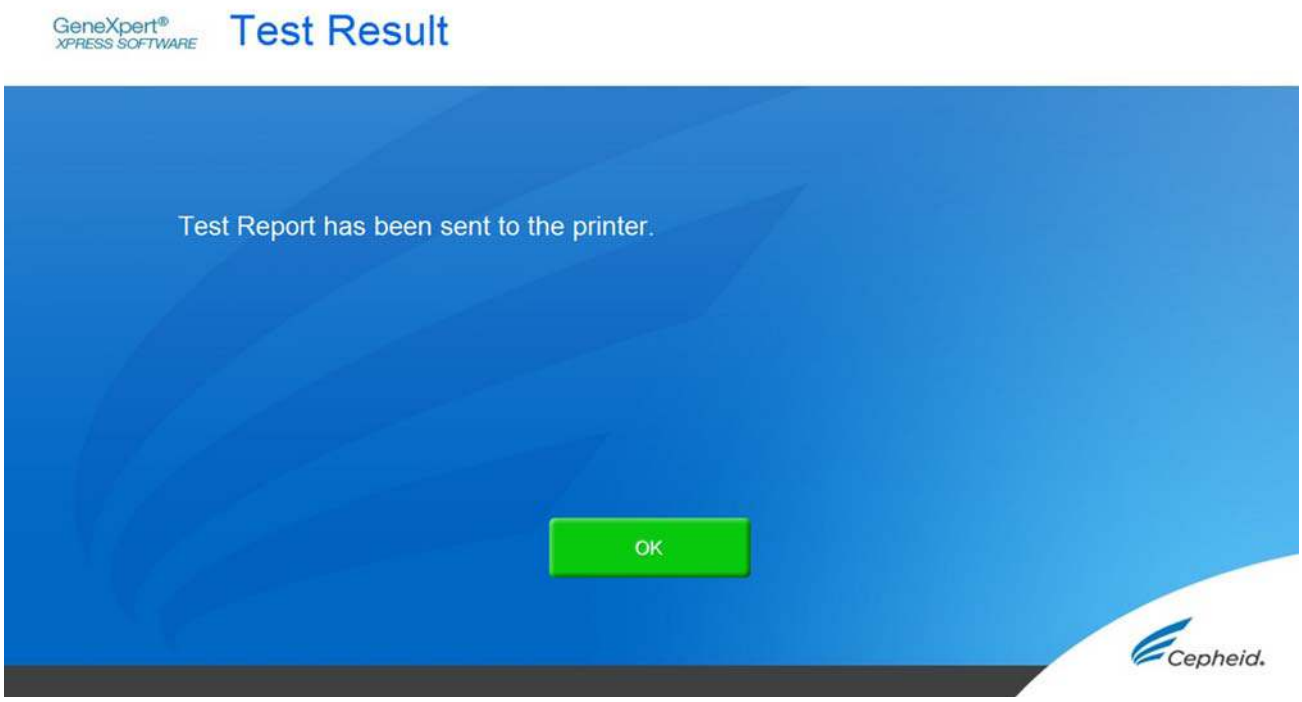


Figure 3-27. Report Sent to Printer Confirmation

If there is a problem communicating with the printer, see Section 6.18.2, Troubleshooting Wireless Printer Connection or Section 5.9, Connecting to the Printer with a Direct USB Connection for further assistance.

This completes the procedure for printing results.

3.6 User Sign In and Sign Out (Optional)

When multiple users will be using the same system, user sign in and sign out may be required. Please see your system administrator for individual sign in information. To sign in:

1. Follow Section 3.1, Starting the GeneXpert Xpress II and GeneXpert Xpress Software. Instead of the Home screen being displayed in Step 7, the Sign-In User Name screen will be displayed. See Figure 3-28.

Figure 3-28. Sign In-User Name Screen

2. Enter your user name and touch **OK**. The Password entry box will appear.
3. Enter your user password and touch **OK**. See Figure 3-29.

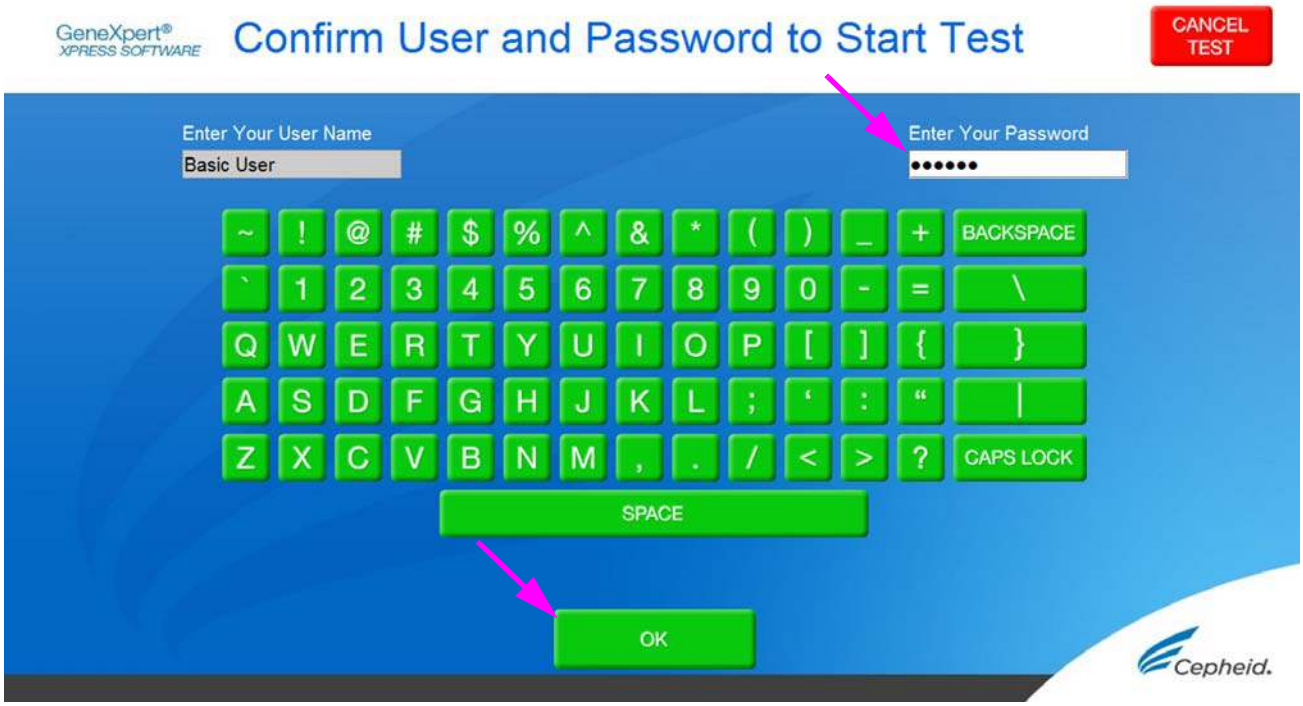


Figure 3-29. Confirm User and Password to Start Test Screen

The Home screen will appear with a **SIGN OUT** button added at the top of the screen. See Figure 3-30.

Note

The screen captures in both this section and the Quality Control Lockout section were taken with both features enabled on the system so the **QC** button and **Sign Out** button will be visible in the images for these sections.

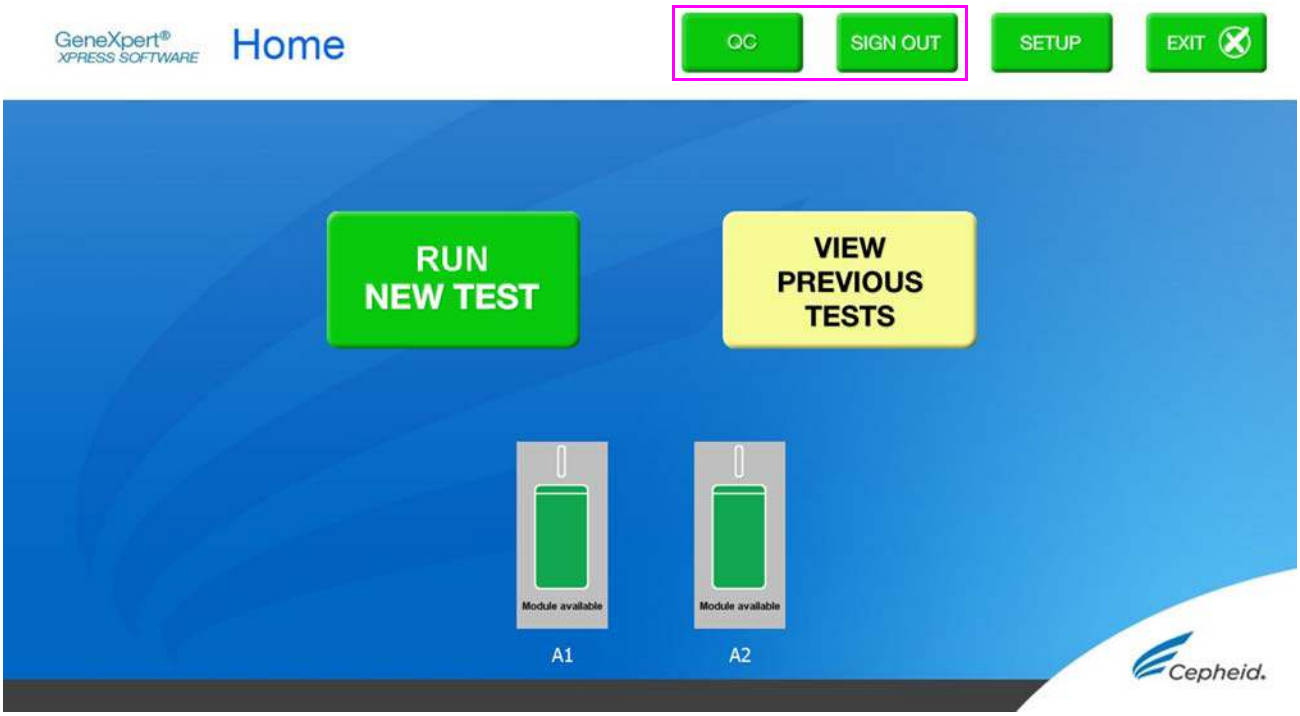


Figure 3-30. Home Screen with Sign Out and QC Buttons

4. When you are finished with the session, touch the **SIGN OUT** button to sign out of the system. You will be signed out and the screen will return to the Sign In-User Name screen as shown in Figure 3-28. You should sign out if you are going to be away from the system for an extended period of time. Signing out prevents the software from recording other users' activities under your account.

Note If you sign off while a test is in progress, the system will finish the test and save the results.

Note A new user can start a separate test if a test is in progress. The first user must sign off, the new user sign on and start an additional test following the steps in Section 3.3, Starting Another Test While a Test is Running

This completes the procedure for signing in and out of the GeneXpert Xpress software.

3.7 Quality Control Lockout (Optional)

3.7.1 QC Lockout Overview

Quality Control samples can be run at any time; the lockout feature does not need to be enabled. The steps are the same as running any test, however, if the Quality Control (QC) Lockout feature is enabled, a **QC** button will appear at the top of the Home screen. See Figure 3-30.

Click the **QC** button to begin a quality control test or to view the Quality Control Summary page. See Figure 3-31.

The Select Quality Control Type screen provides the choice of running either a positive or negative sample, looking at the summary page or returning to the Home screen. To run a positive or negative sample, touch the button of the sample type to run the test. See Section 3.7.3, Running a Quality Control Test Using the QC Lockout Feature.

To view the summary page, touch **SUMMARY**.

Figure 3-31. Select Quality Control Type Screen

The summary page will display important information about the QC status for assays. See Figure 3-32.

Note

It is a good practice to check the Quality Control Summary page each time you sign on to the system to see if any assays will require a QC lot run during the work session.

Figure 3-32. Quality Control Summary Screen

3.7.2 Quality Control Lockout

If the QC lockout feature has been enabled and is required for new assay lots, the Quality Control Required screen will display when a new lot is used. See Figure 3-33. If the Quality Control Required screen is displayed, touch the **OK** button to close the screen and then run QC for the selected assay and lot id.

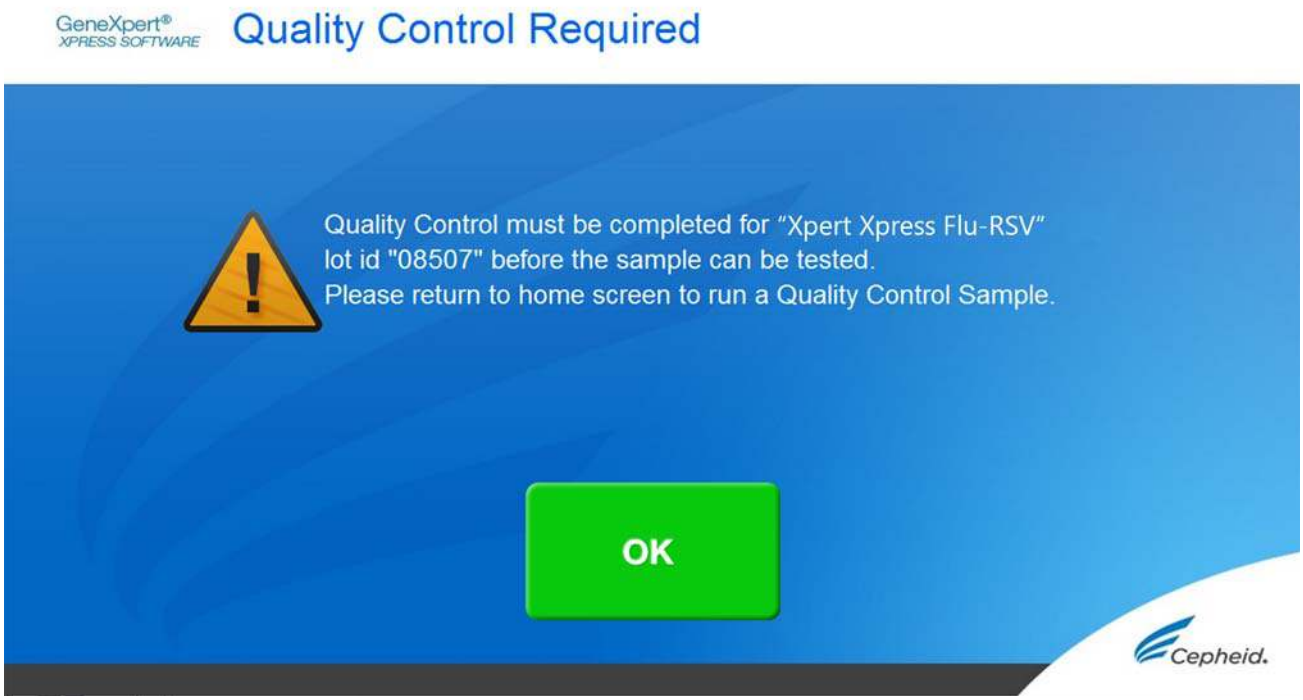


Figure 3-33. Quality Control Required Screen

If the QC lockout feature is set so that QC must be run at regular intervals, reminders will appear indicating how long is left before the system will lock out that particular assay. QC intervals are set by the system administrator. If the set time limit runs out and QC lots were not run, the system will not process any patient tests for the assay requiring QC until QC is completed. See Figure 3-34. Touch the **OK** button to close the reminder.

Note

You may continue running tests until the time limit runs out, however allowing the time to run out may cause unexpected delays for urgent tests.

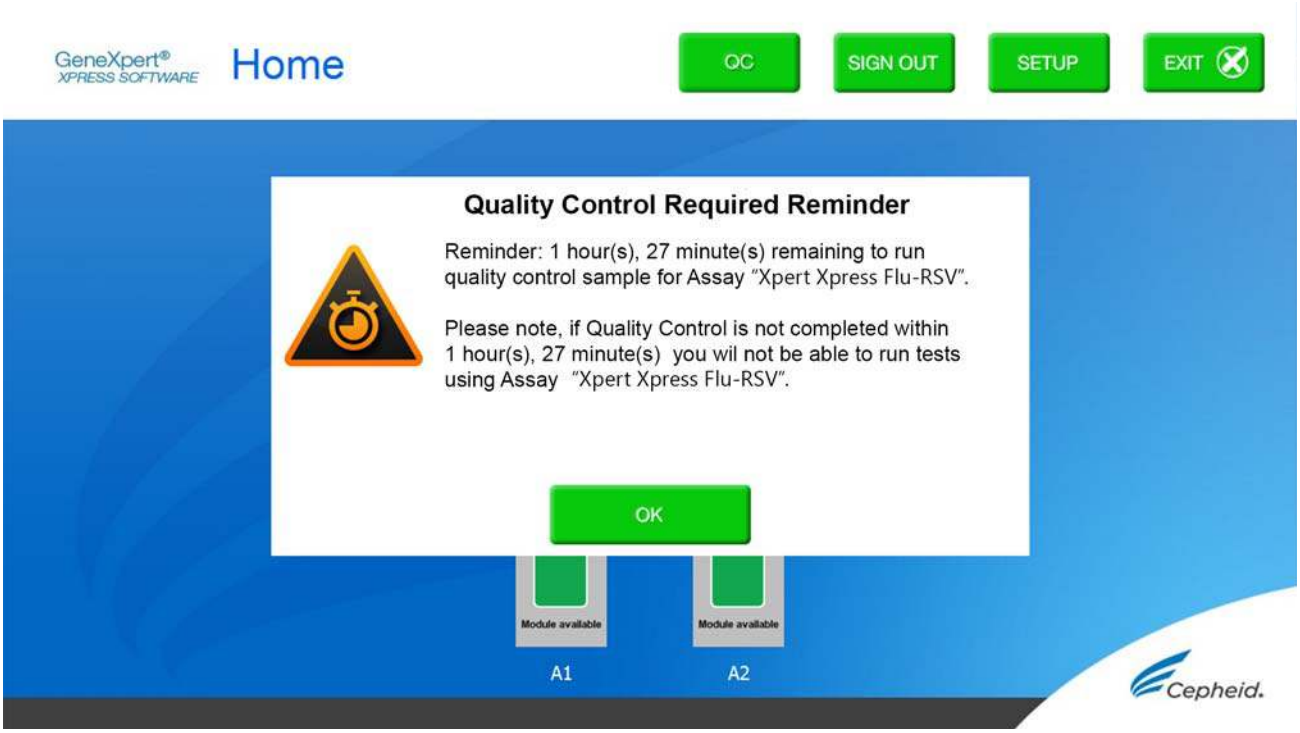


Figure 3-34. Quality Control Reminder Screen

QC may also be required if the Database has been restored. See Figure 3-35. If the Database Restore Detected reminder is displayed, touch the **OK** button to close the reminder. Run QC for all active assays and lots.

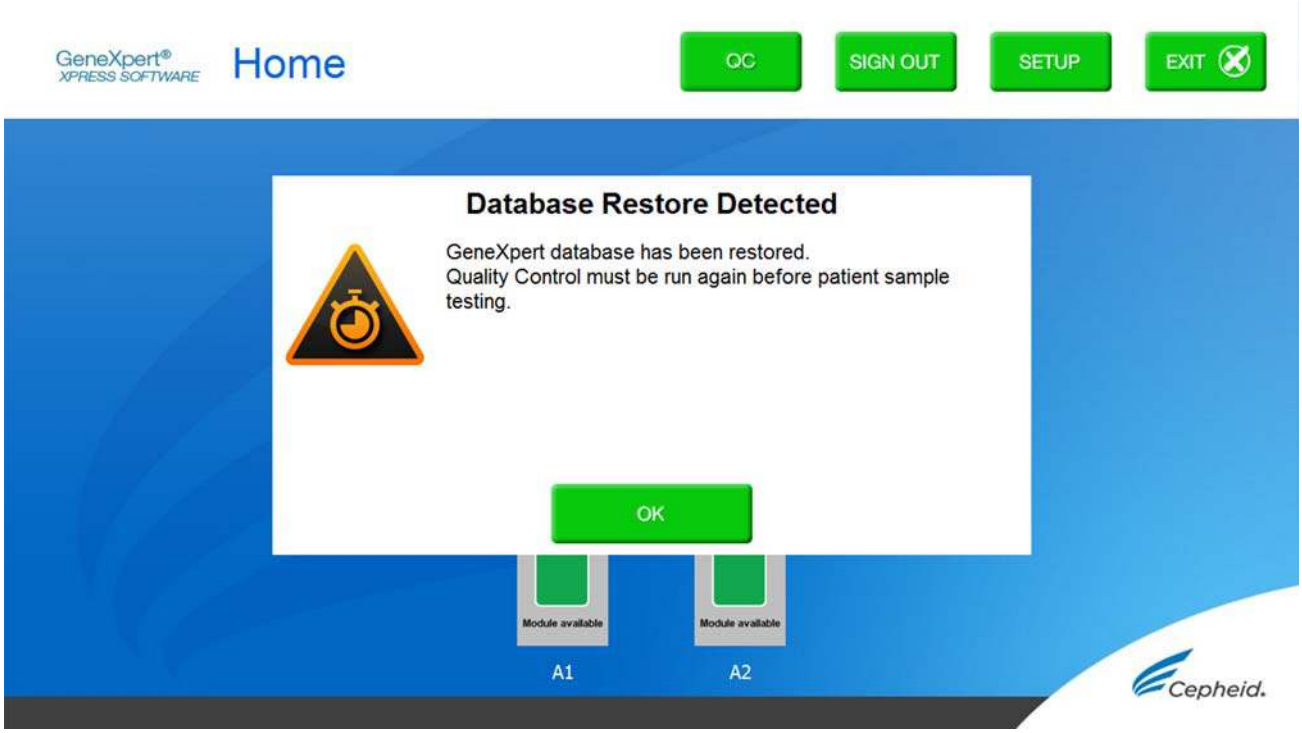


Figure 3-35. Database Restore Detected Screen

3.7.3 Running a Quality Control Test Using the QC Lockout Feature

This procedure assumes the computer and GeneXpert instrument are powered on and that the GeneXpert Xpress software is open and at the Home screen. The screen shots displayed in this section show buttons indicating that both the Sign In feature and QC Lockout feature have been enabled.

1. Touch the **QC** button on the Home screen (see Figure 3-36). The Select Quality Control Type screen is displayed. See Figure 3-37.
2. Select either **POSITIVE** or **NEGATIVE** for the control type that will tested.

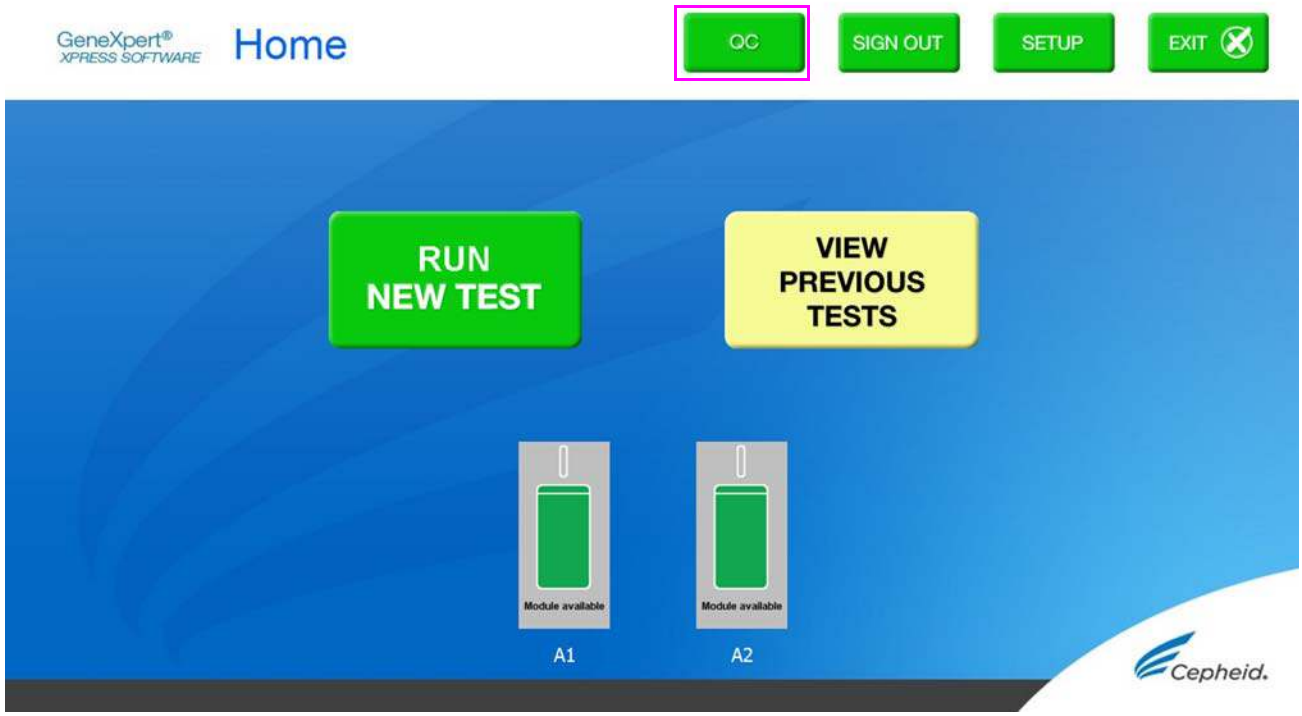


Figure 3-36. Home Screen with Sign Out and QC Buttons

Figure 3-37. Select Quality Control Type Screen

3. The Enter Patient/Sample ID screen will be displayed. See Figure 3-38.

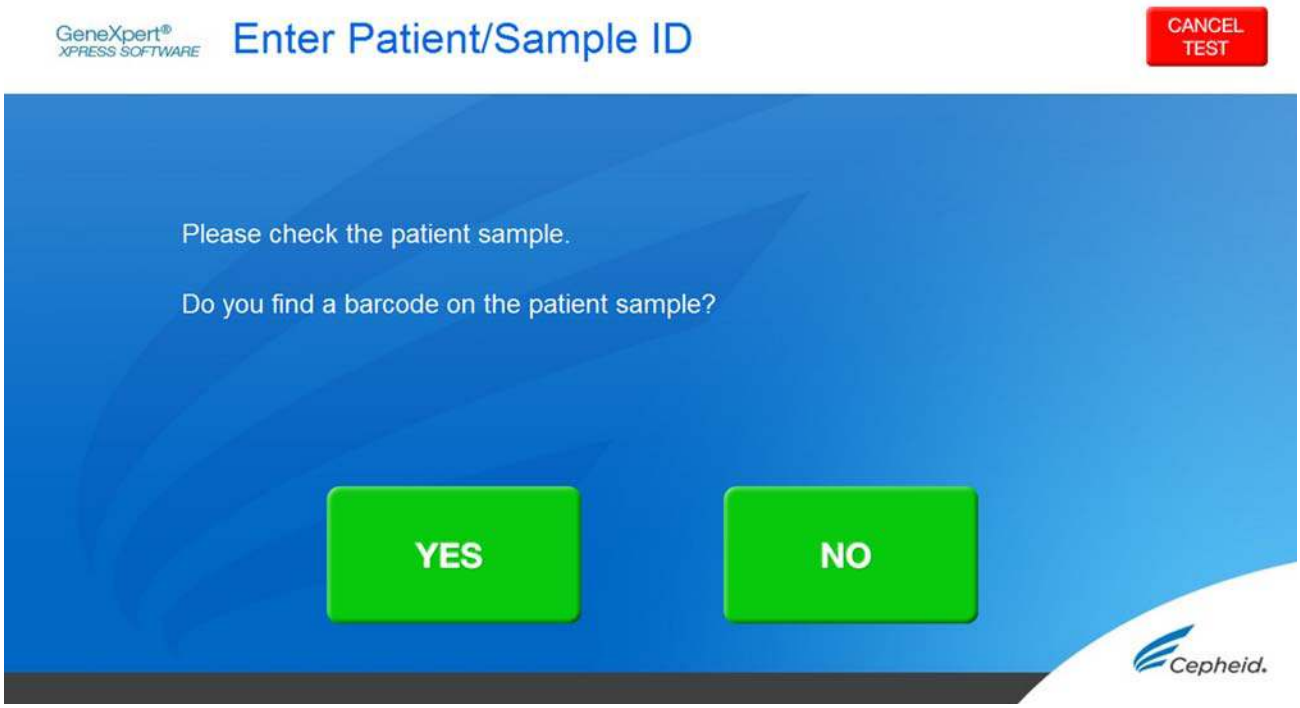


Figure 3-38. Enter Patient/Sample ID

4. If there is a sample ID barcode, touch **YES** and scan it, proceeding with Step 5. If there is no barcode:

   A. Touch the **NO** button on the Enter Patient/Sample ID screen. The Step 1 of 7 Enter Patient/Sample ID screen will be displayed. See Figure 3-39.

   B. Use the touchscreen keypad to manually enter the negative control ID for the Negative External Control or the positive control ID for the Positive External Control and touch the **OK** button. The Step 2 of 7 Confirm Patient/Sample ID screen will be displayed. See Figure 3-40.

5. Verify that the control ID on the Step 2 of 7 Confirm Patient/Sample ID screen matches the External Control ID on the sample. If it matches, touch the **YES** button. If it does not match, then touch the **NO** button and re-enter the External Control ID.

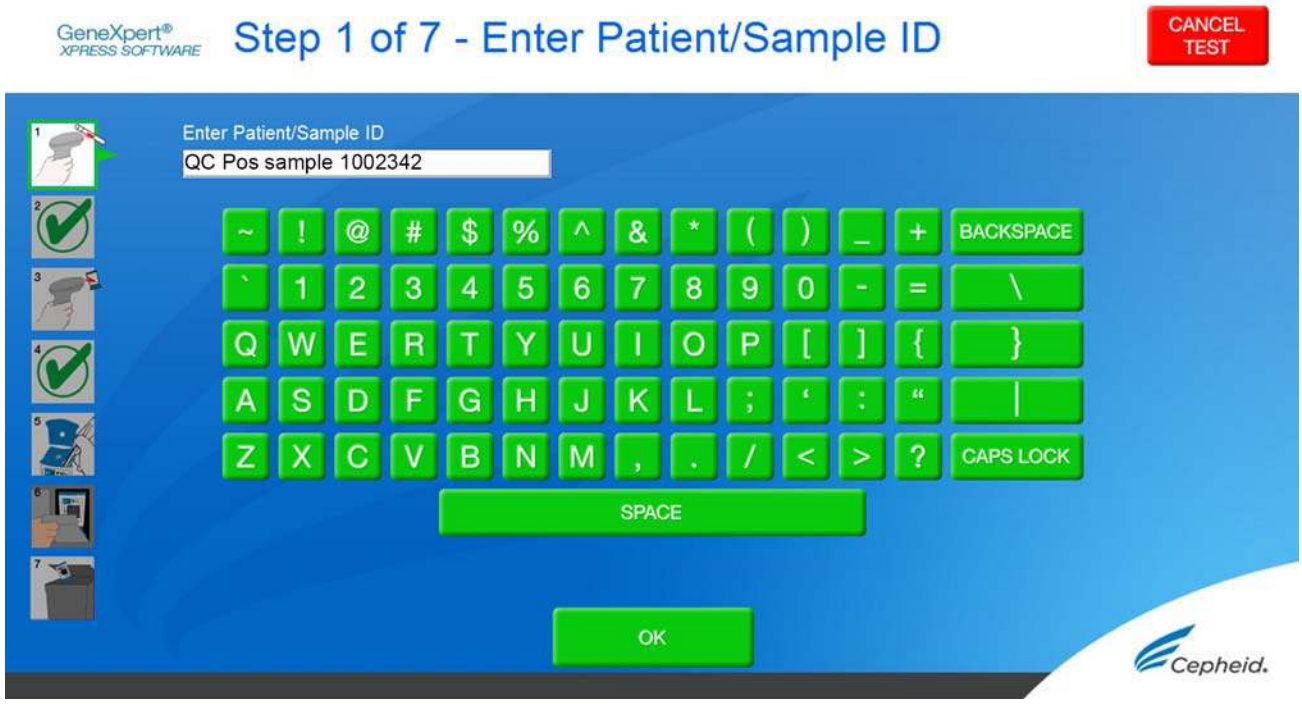


Figure 3-39. Step 1 of 7 - Enter Patient/Sample ID Screen

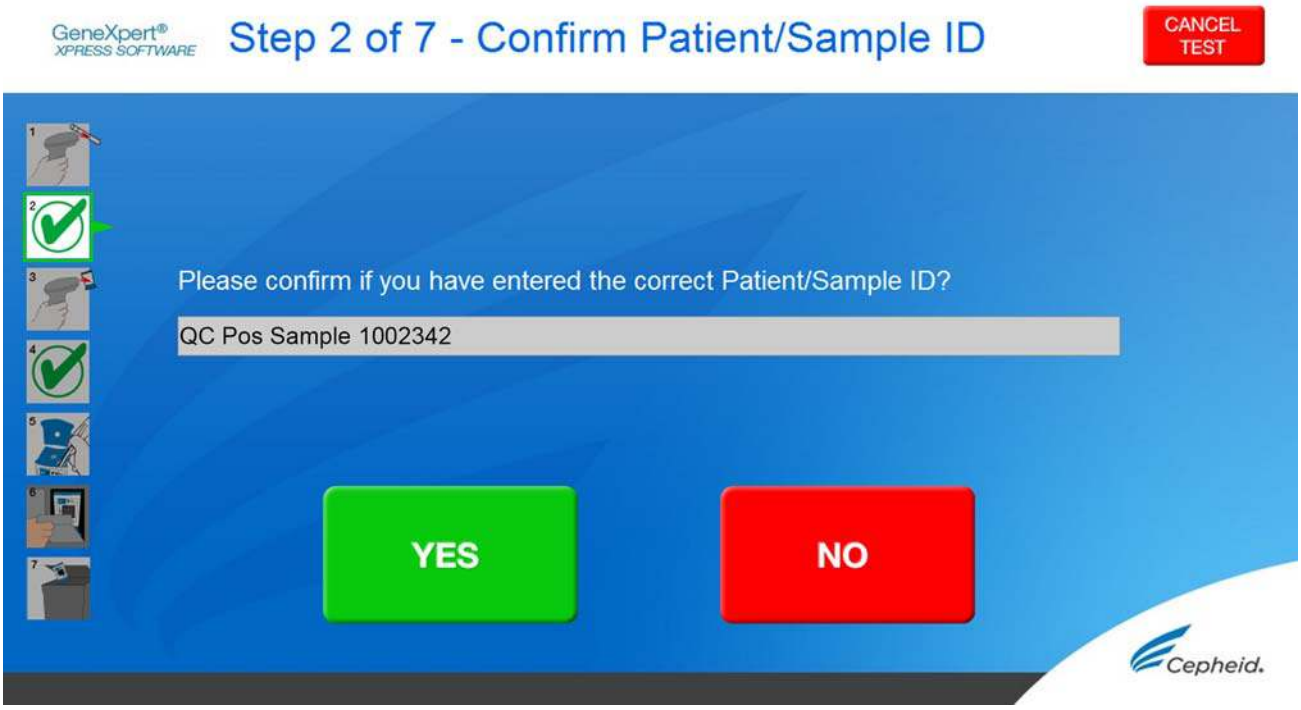


Figure 3-40. Step 2 of 7 Confirm Patient/Sample ID Screen

6. After confirming that the Patient/Sample ID is correct, the Step 3 of 7 Scan Cartridge Barcode screen will be displayed (see Figure 3-41). Use the barcode scanner to scan the cartridge label. When you hear the beep, the cartridge barcode has been scanned and the Confirm Quality Control Test screen will be displayed. See Figure 3-42.

Figure 3-41. Step 5 of 7 Cartridge Preparation Screen

7. Touch the **CONTINUE** button if the control information is correct. Touch the **Cancel Test** button if the control information is incorrect.

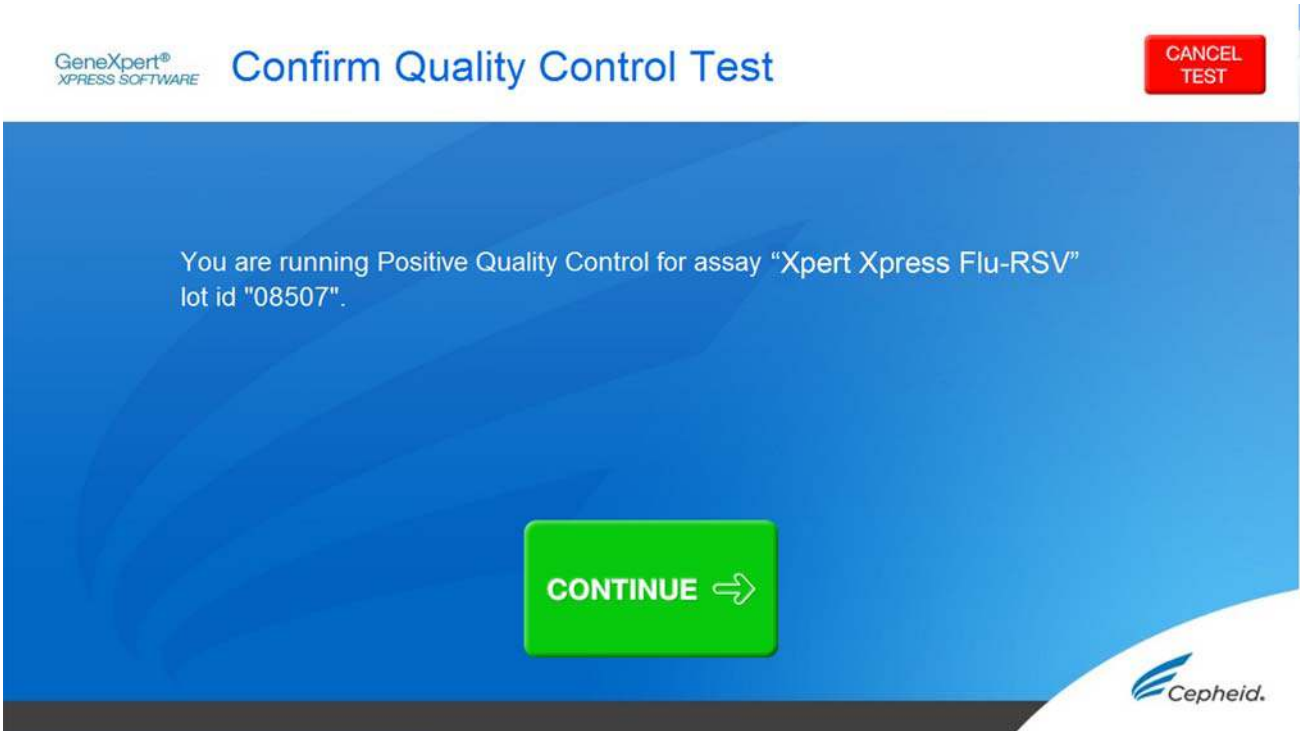


Figure 3-42. Confirm Quality Control Test Screen

8. The Step 5 of 7 Cartridge Preparation screen will play a short video showing how to prepare the cartridge for testing. Once complete, the video will restart from the beginning automatically. Prepare the cartridge according to the directions shown in the video and in the assay package insert.

9. After the cartridge has been prepared, touch the **SKIP VIDEO AND CONTINUE** button on the Step 5 of 7 Cartridge Preparation screen. The Step 6 of 7 Load Cartridge screen is displayed.

10. On the Step 6 of 7 Load Cartridge screen, insert the cartridge into the system module with the blinking green light. See Figure 3-17. Ensure that the door of the system is completely closed. The door will latch and the blinking green light will turn solid green.

11. The Step 7 of 7 Remove Cartridge screen shows instructions for removing the cartridge (see Figure 3-20). Open the instrument door, remove the used cartridge and properly dispose of the cartridge according to your institution's hazardous waste disposal policies. After removing the cartridge, close the module door. Touch the **CONTINUE** button to view the result of the test. The QC Test Result screen will be displayed with the results of the control test.

12. The Test Result screen will provide the results for the test that has just completed (see Figure 3-43). After viewing and recording the results, touch the **HOME** to return to the Home screen.

13. Test the second control tube. Repeat Step 1 through Step 12 with the second control tube. In this example the first test was with the positive control, therefore the second test would be with the negative control.

Figure 3-43. QC Test Result

This completes the procedure for running a quality control test with the QC lockout enabled using the GeneXpert Xpress II instrument.

If any error messages occur while running the test, see Section 3.9, Error Handling.

3.8 Exiting the Software and Turning Off the System

This section describes how to exit the GeneXpert Xpress software and power down the system.

Important **Do not shut down the software and turn off the system if a test is running. Wait until the test finishes running.**

1. To exit the software, you must be in the Home screen.
   - If you are in one of the test screens (but not actually running a test), touch the **CANCEL TEST** button in the upper right corner of the screen. See Figure 3-9 for the location of the **CANCEL TEST** button. A Cancel New Test screen will be displayed. Touch **YES** to go to the Home screen.

- If you are in one of the View Test Result screens, touch the **HOME** button in the upper right corner of the screen to go to the Home screen. See Figure 3-25 and Figure 3-26 for the location of the **HOME** button.

2. From the Home screen, touch the **EXIT** button (see Figure 3-44). The Exit screen will be displayed. See Figure 3-45.

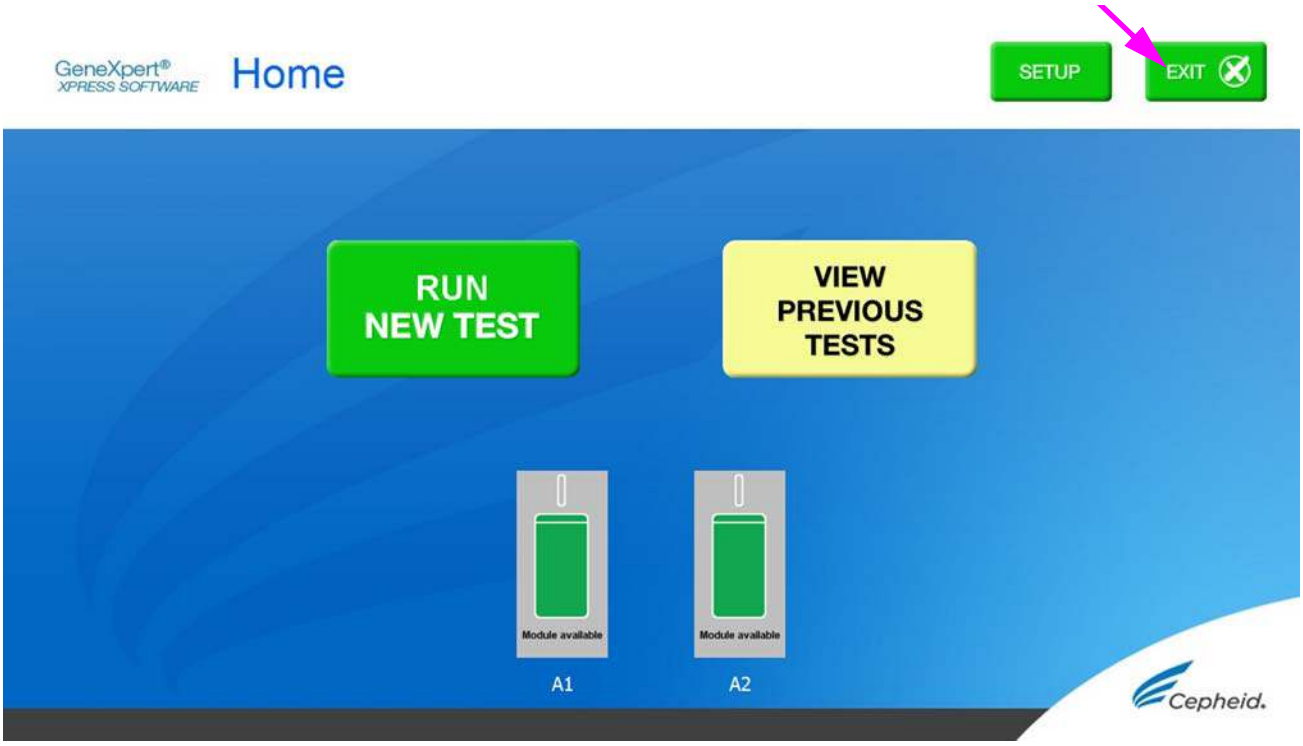


Figure 3-44. GeneXpert Xpress II Home Screen

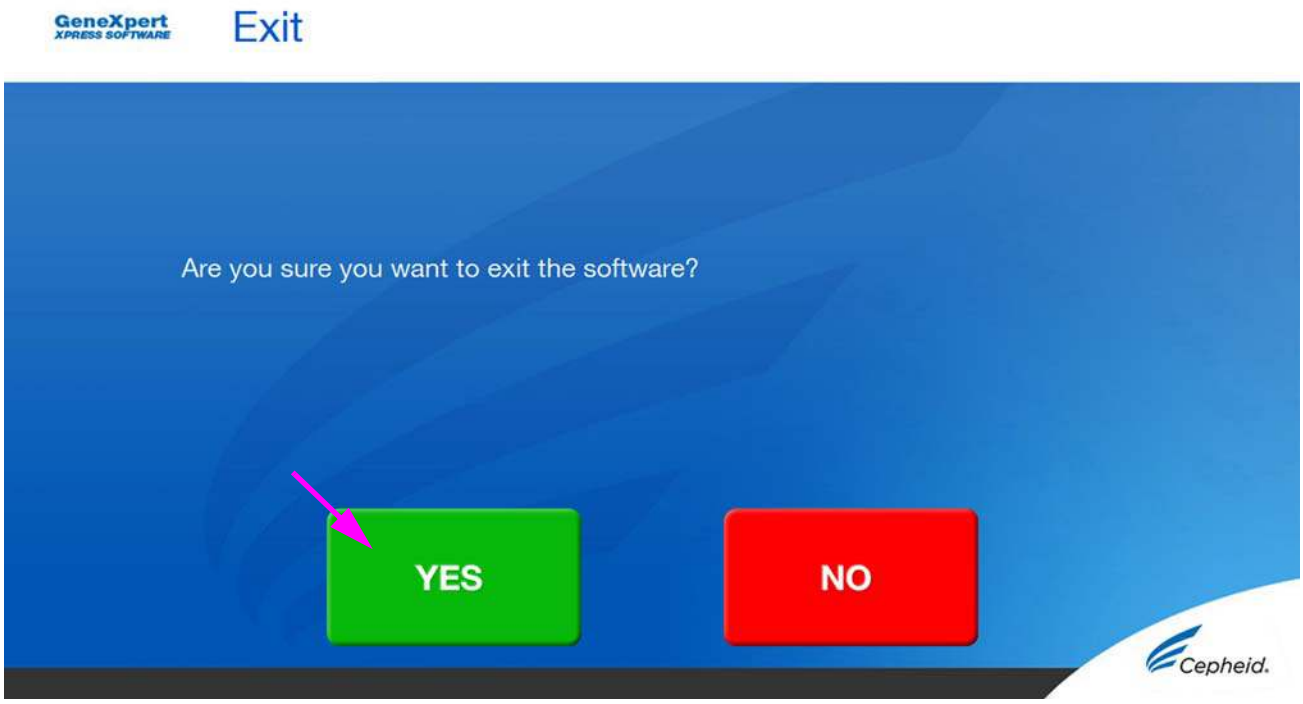


Figure 3-45. GeneXpert Xpress II Exit Screen

3. On the Exit screen (see Figure 3-45), select **YES** to exit the software to the Windows desktop. See Figure 3-47. The Window desktop will be displayed.

   If you do not want to exit the software, select **NO** (see Figure 3-45).

4. Shut down the computer.

   - For Windows 7, touch the **Start** icon and then touch the **Shut down** button. See Figure 3-47. Windows will shut down and the computer will turn off.
   - For Windows 10, touch the **Power** icon and then select the **Shut down** option. See Figure 3-47. Windows will shut down and the computer will turn off.

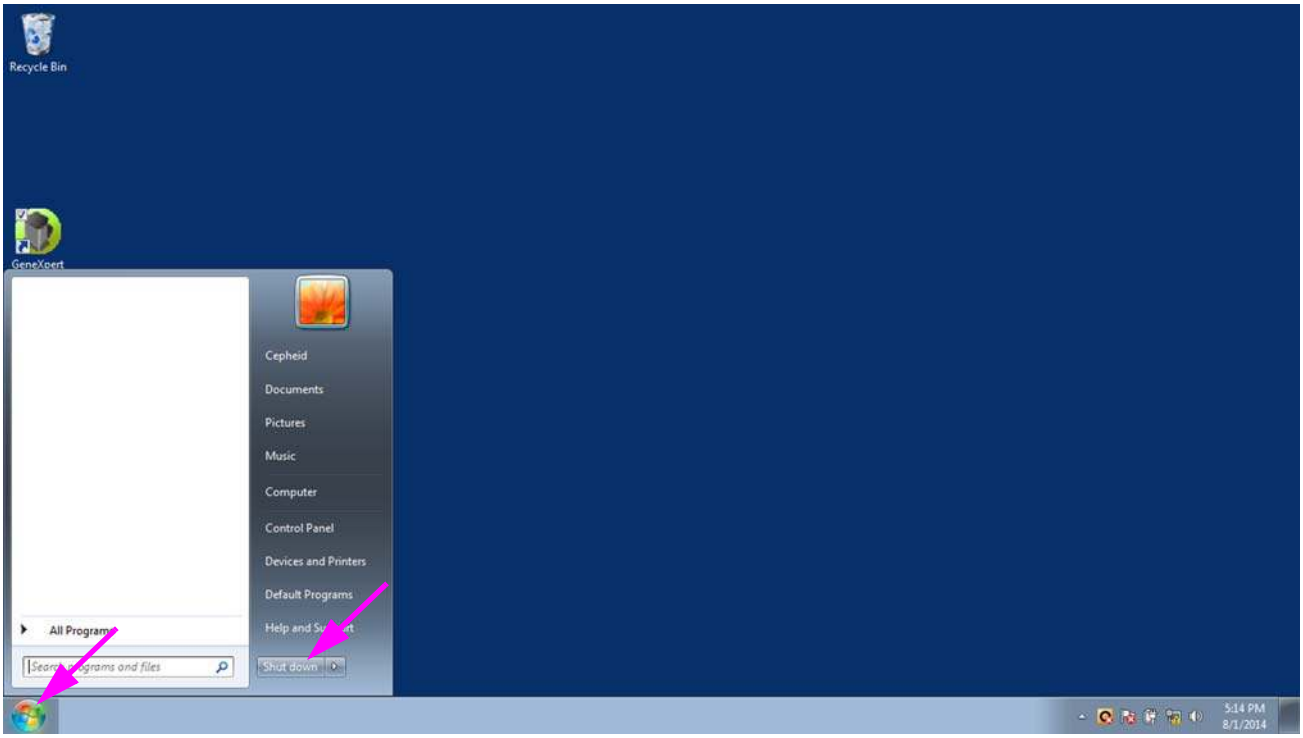


Figure 3-46. Windows 7 Desktop - System Shutdown

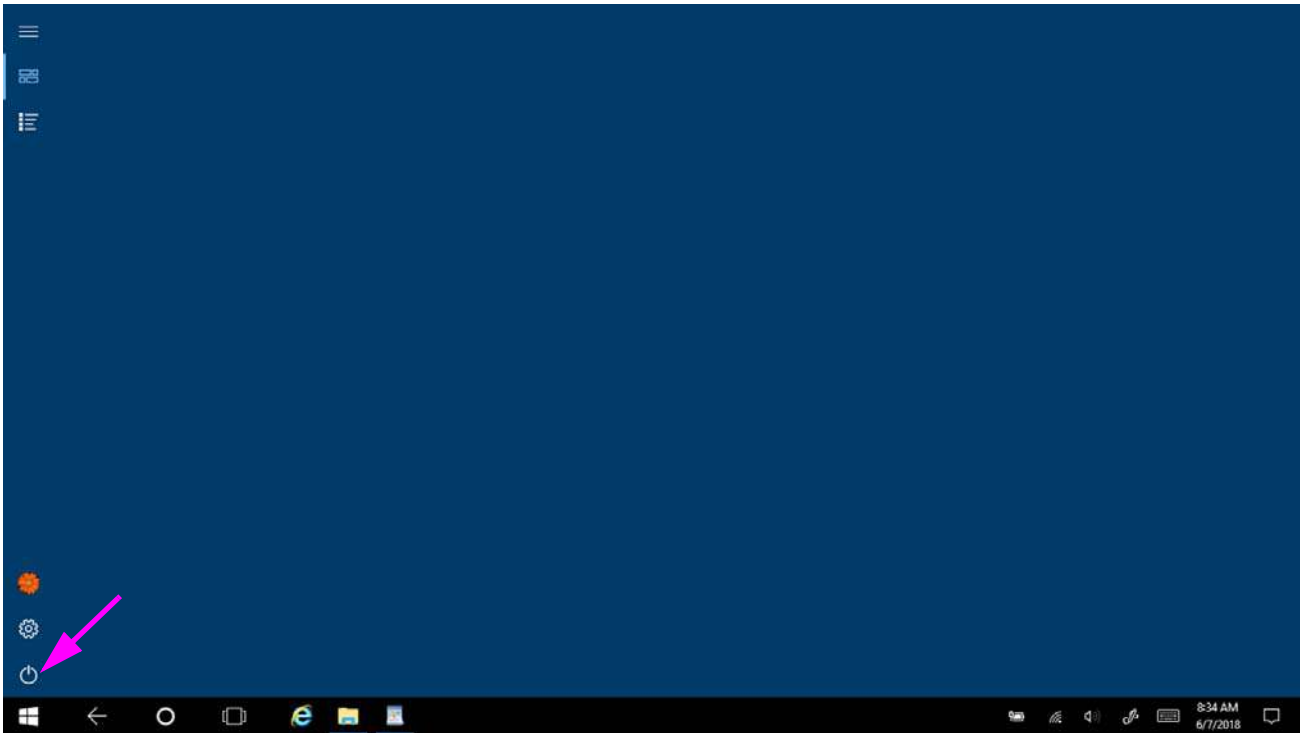


Figure 3-47. Windows 10 Desktop - System Shutdown

5. Turn off the GeneXpert Xpress II instrument. The power switch is located on the back of the instrument. Press the switch to the **OFF** (**O**) position. See Figure 3-48.

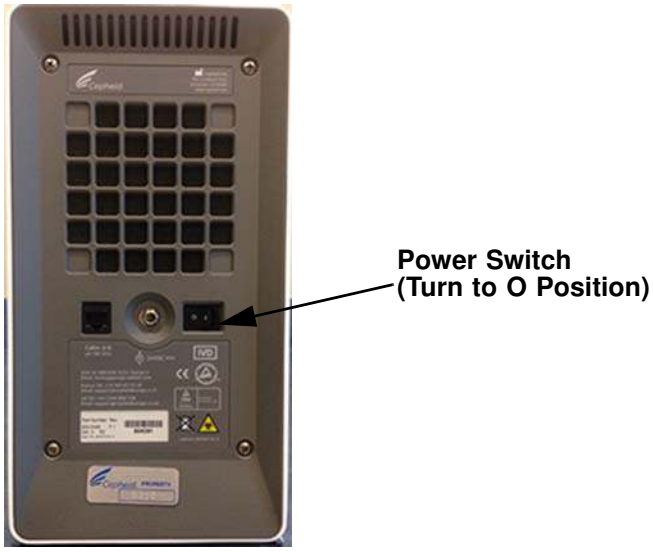


Figure 3-48. Turn OFF the Instrument

The GeneXpert Xpress II system is now shut down. To run tests later, see Section 3.1, Starting the GeneXpert Xpress II and GeneXpert Xpress Software.

3.9 Error Handling

This section describes how to handle any errors that may occur when using the GeneXpert Xpress II system. Some of the errors that may occur are shown below.

Cartridge Already Used Error Screen

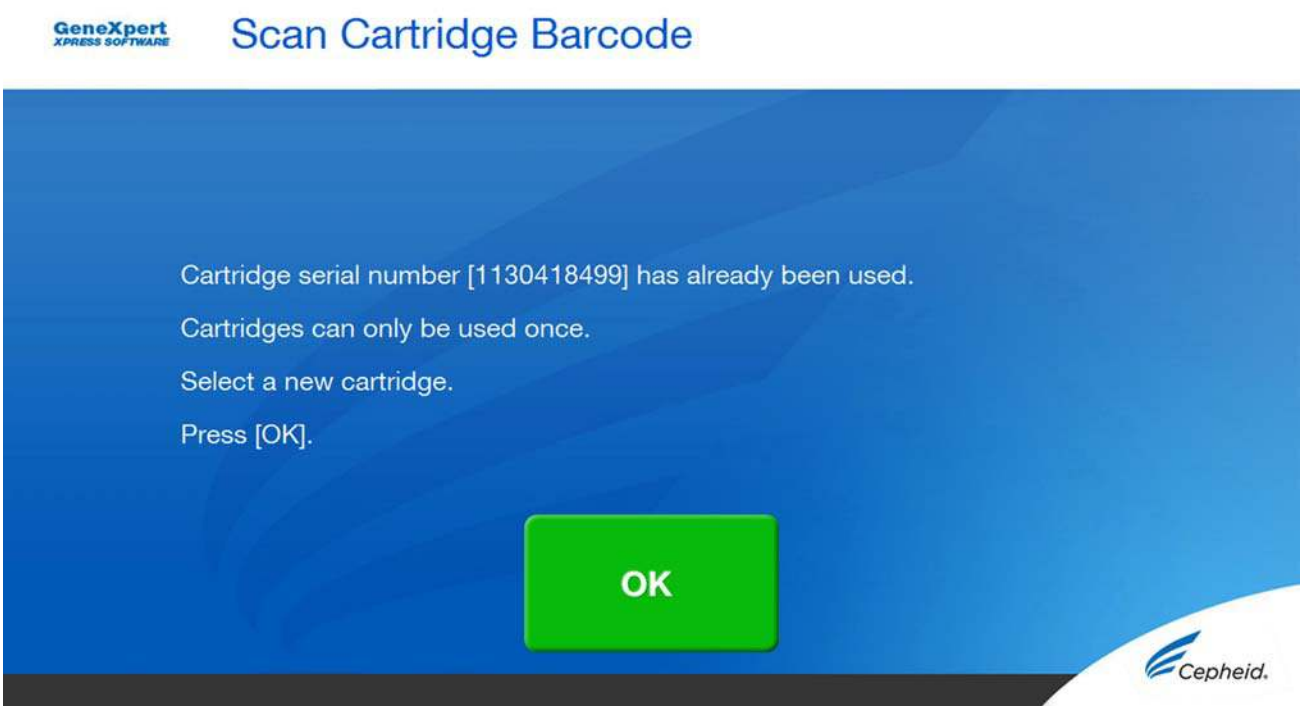


Figure 3-49. Cartridge Already Used Error Screen

If the Cartridge Already Used error screen is displayed, a cartridge with the same serial number has already been run on the system. Click **OK** to repeat the test using a new cartridge and leftover specimen from the initial test. Follow the instructions on the screen.

Communication Error Screen

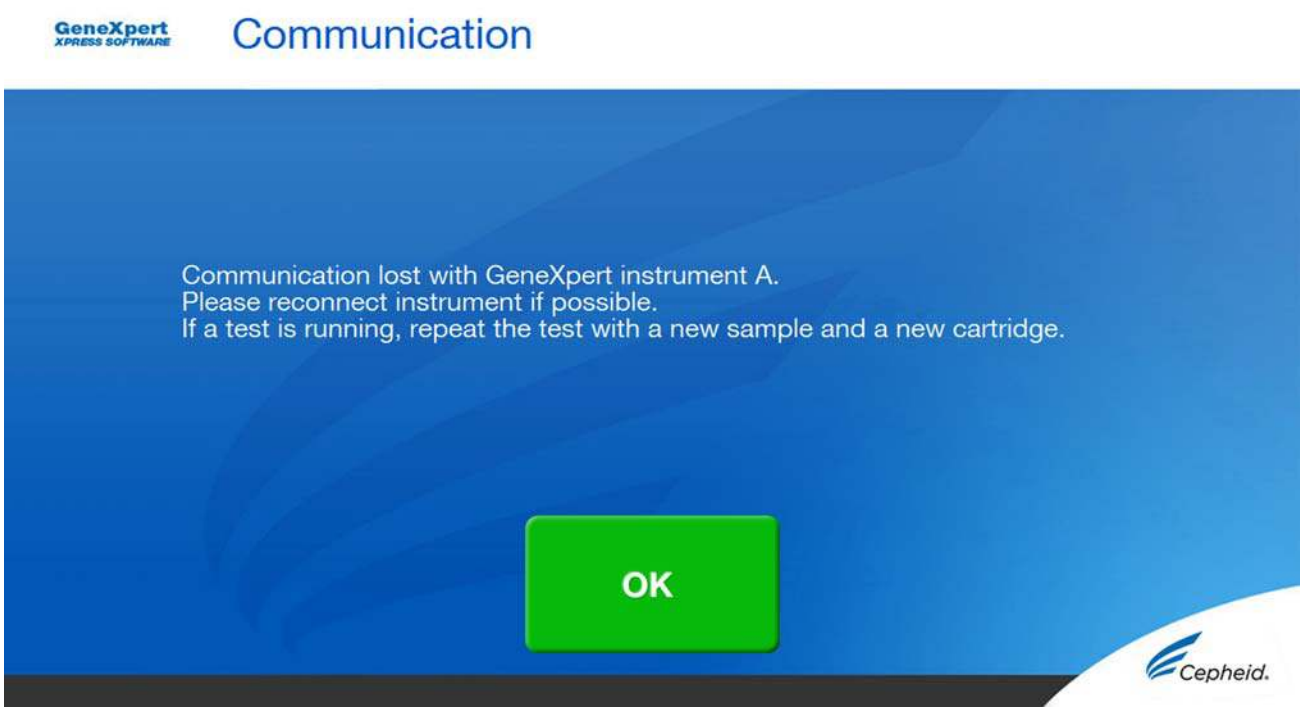


Figure 3-50. Communication Error Screen

If the Communication error screen is displayed, communication has been lost between the computer and the instrument. Ensure that the instrument is plugged into the power outlet, the power switch is on and the blue light on the front of the instrument is on. Check that the communication cable between the instrument and the computer is plugged in at both ends. Call Cepheid Technical Support if the problem continues.

If the problem has been resolved and this occurred while the system was running a test, click **OK** to repeat the test using a new cartridge and leftover specimen from the initial test. Follow the instructions on the screen.

Clear Instrument Error Screen

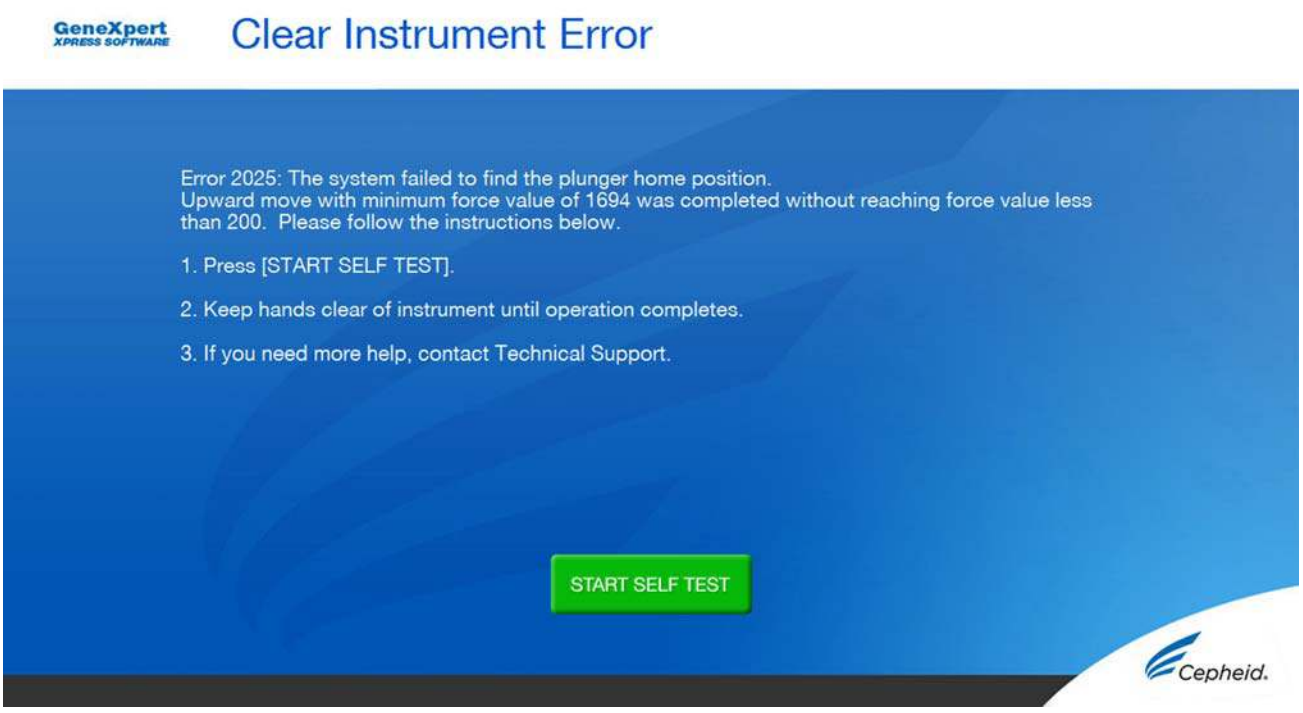


Figure 3-51. Clear Instrument Error Screen

If the Clear Instrument Error screen is displayed, a mechanical error has occurred on the instrument. Touch the **START SELF TEST** button. The instrument will reset the mechanics and the Home screen will be displayed. Call Cepheid Technical Support if the problem continues.

Repeat the test using a new cartridge and leftover specimen from the initial test. Follow the instructions on the screen.

3.10 Setup

This section describes the use of the Setup functions of the GeneXpert Xpress software. The Setup screen allows you to display and read the software license information.

1. To access the Setup screen, you must be in the Home screen.
2. From the Home screen, touch the **SETUP** button (see Figure 3-52). The Setup screen will be displayed. See Figure 3-53.

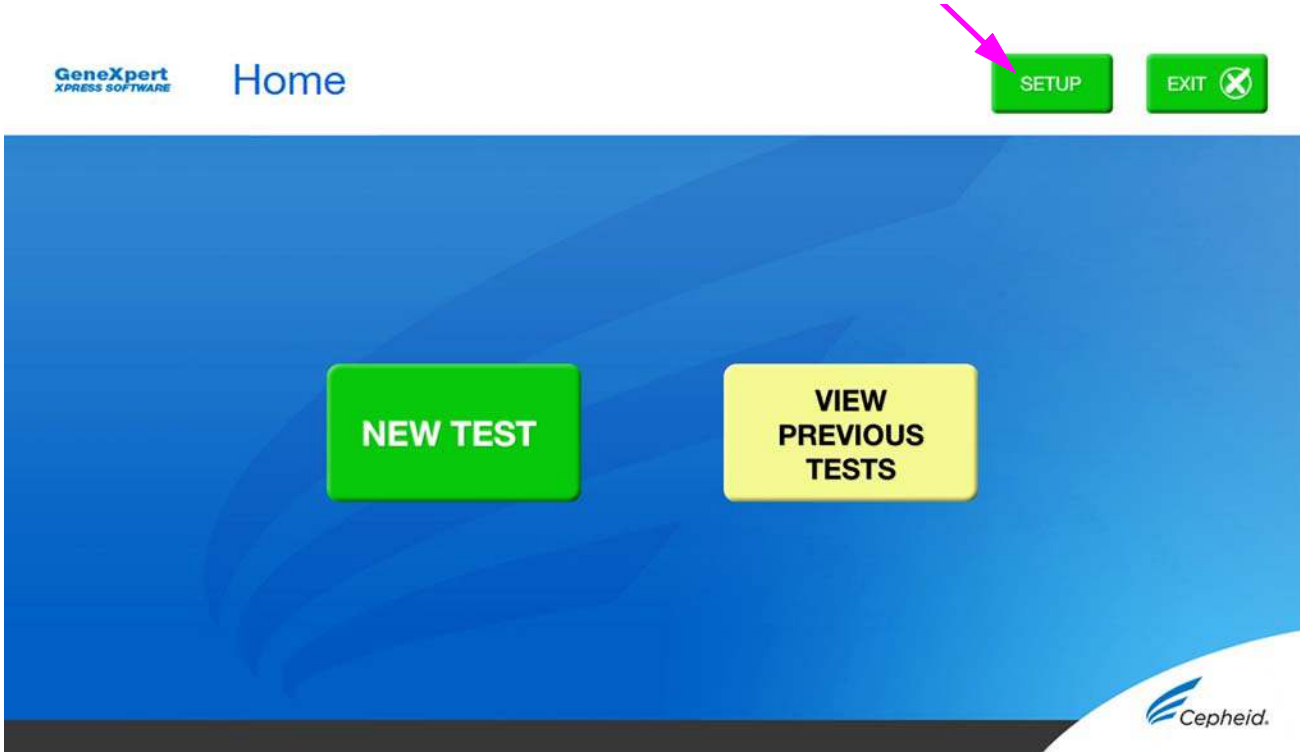


Figure 3-52. GeneXpert Xpress II Home Screen

Figure 3-53. GeneXpert Xpress II Setup Screen

3. On the Setup screen (see Figure 3-53), touch **ABOUT** to view the software license agreement. The License Information screen is displayed. See Figure 3-54.

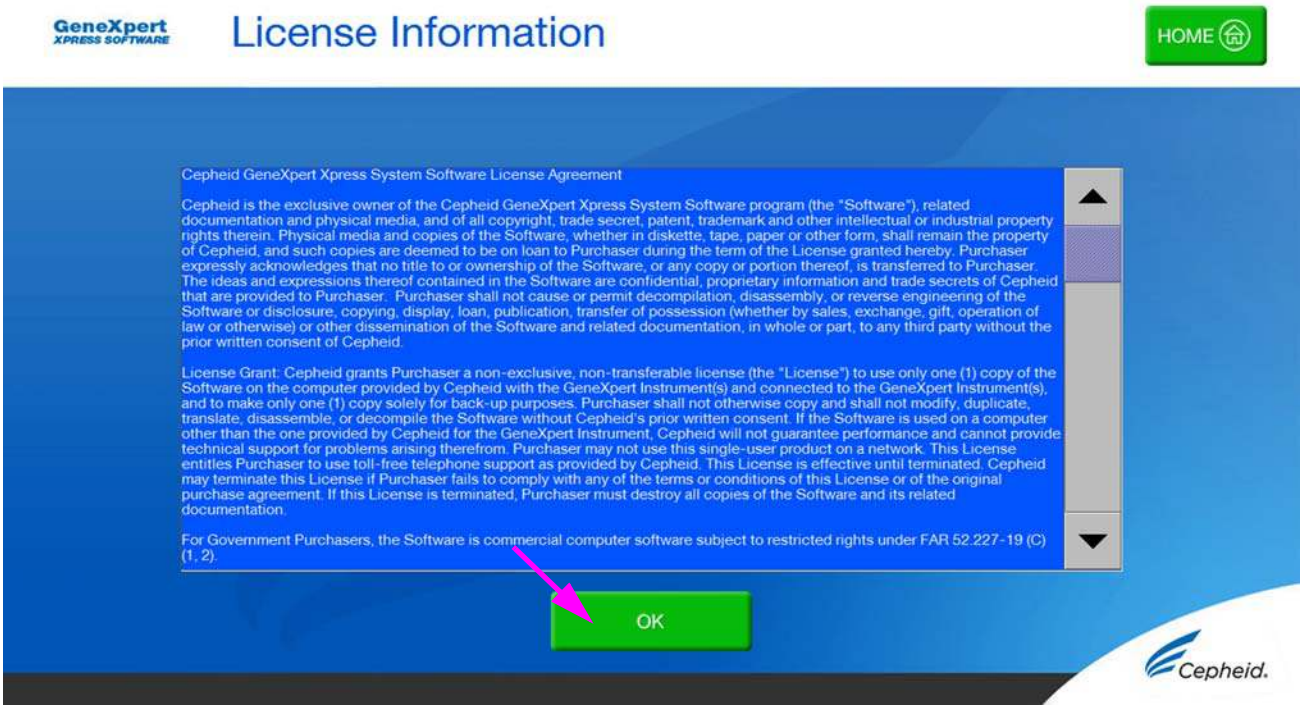


Figure 3-54. GeneXpert Xpress II License Information Screen

4. On the License Information screen (see Figure 3-54), you can read the software license agreement for GeneXpert Xpress II. Use the scroll bar on the right to scroll down to read the entire agreement.

5. To return to the Setup screen, touch the **OK** button or to return to the Home page, touch the **HOME** button.

4 Operation - GeneXpert Xpress IV

This chapter describes how to run tests using the GeneXpert Xpress IV instrument in the normal system configuration as shipped from Cepheid. In this configuration:

- No passwords are required to run tests.
- No special user accounts have been created.
- Quality Control (QC) lockout has not been enabled
- The computer has been set up in tablet mode as described in Appendix A and is on the computer stand.
- All cables have been have been connected as described in the GeneXpert Xpress IV System Getting Started Guide (P/N 301-7047).

If passwords and user accounts are required, or QC lockout is required, an administrator must perform the setup instructions shown in Chapter 5, Administrative Tasks before the GeneXpert Xpress IV instrument is used to run tests.

For information on signing in (if user accounts are required), see Section 4.6, User Sign In and Sign Out (Optional). For more information on Quality Control or QC Lockout features, see Section 4.7, Quality Control Lockout (Optional).

To aid in using the GeneXpert Xpress IV instrument, see the following reference documents:

- GeneXpert Xpress IV Getting Started Guide (P/N 301-7047), shipped with the system.
- Assay Quick Reference Instructions, shipped with the assay lot.

4.1 Starting the GeneXpert Xpress IV and GeneXpert Xpress Software

This section describes how to power up and log onto the system.

1. Turn on the GeneXpert Xpress IV instrument. The power switch is located on the back of the instrument. Press the switch to the **ON** (|) position. See Figure 4-1. After power has been turned on, the blue light on the front of the instrument will be **ON**.
2. Turn on the computer by sliding or pressing the power switch on the side of the computer. See Figure 4-2.

Note On start-up, the Windows screen may be in the wrong orientation for tablet mode. Please wait until the screen re-adjusts itself.

Note If the printer will be required, power it on following the instructions in the user manual that was provided with the printer.

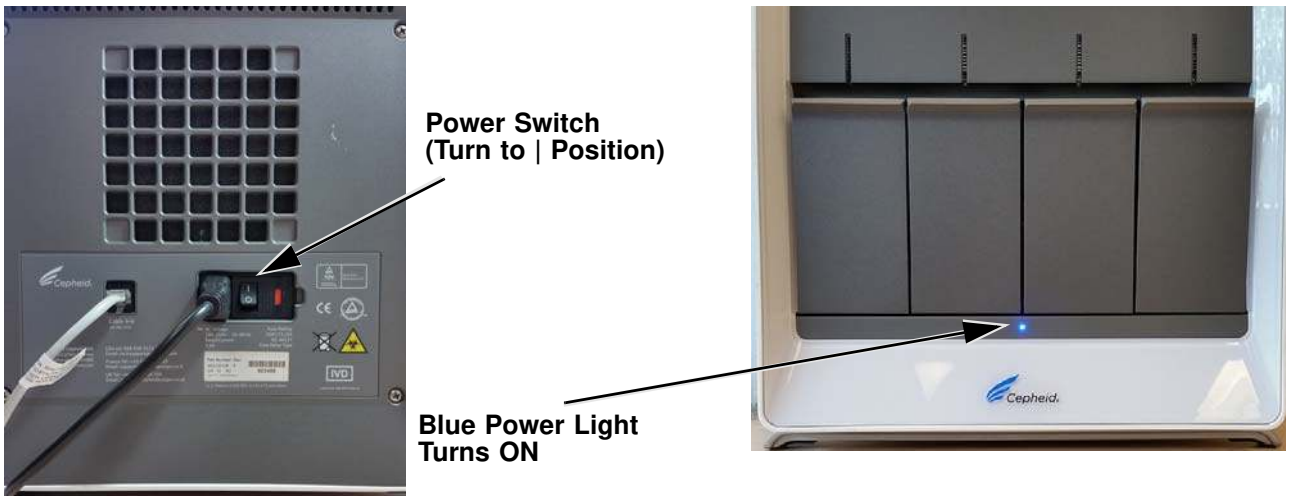


Figure 4-1. Turn on Instrument

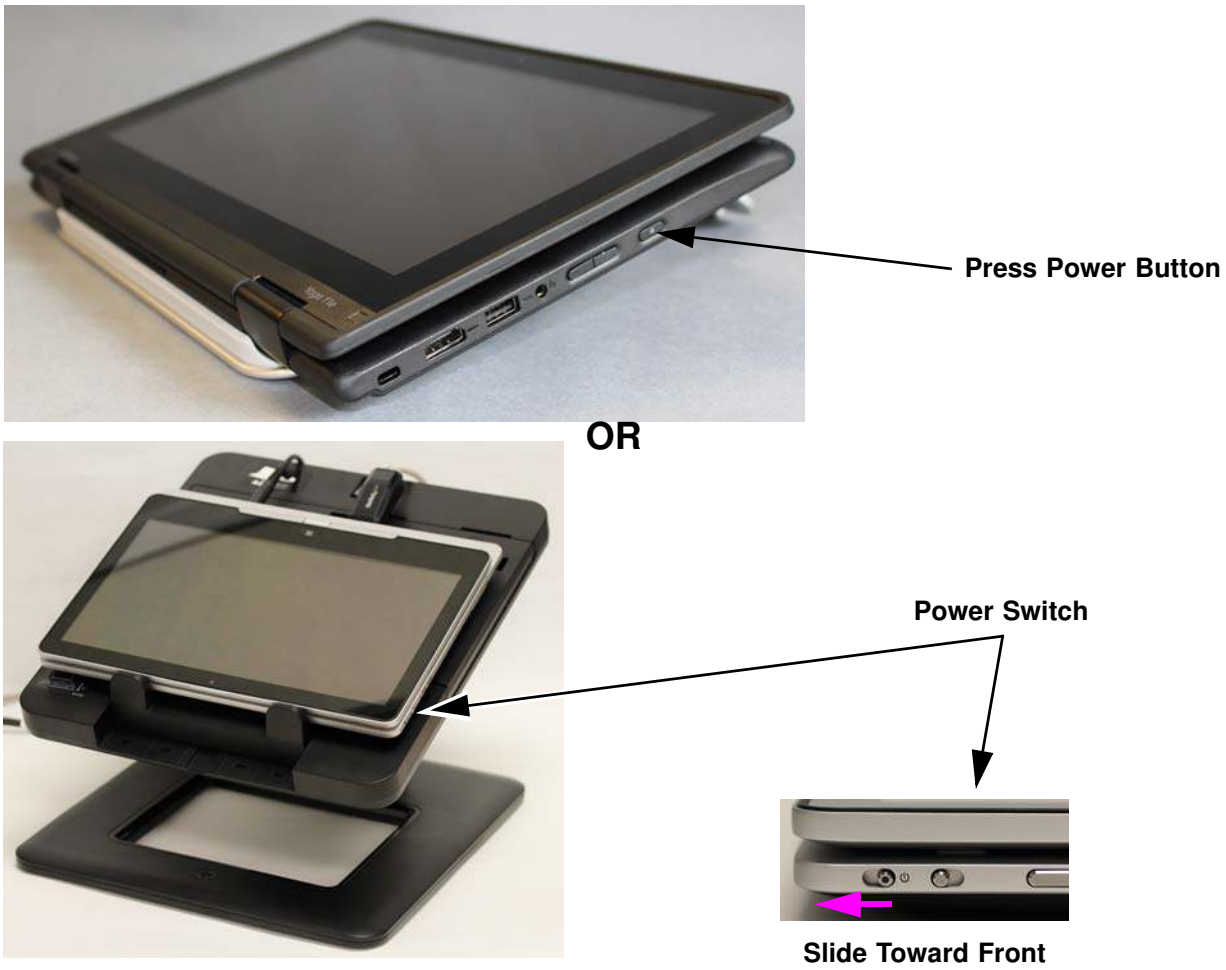


Figure 4-2. Turn on Computer

3. Wait for the system to boot.
   - On Windows 7, the Windows Account screen appears. See Figure 4-3.
   - On Windows 10, the Windows Lock screen appears. See Figure 4-4. Touch anywhere on the screen and swipe up to display the Windows Account and Password screen. See Figure 4-6.
4. On the Windows Account screen, select the Cepheid user account (see Figure 4-3 and Figure 4-6).
   - On Windows 7, the Windows Password screen appears. See Figure 4-5.
   - On Windows 10, the Cepheid user account password field appears. See Figure 4-6.

Figure 4-3. Windows 7 Account Screen

Figure 4-4. Windows 10 Lock Screen

The initial login password is provided below. You will be required to change the password upon first login. Do not change the user name or profile settings. When logging on, use the following:

- Account name: **Cepheid-Admin**
- Password: **cphd**

5. On the Windows Password screen (see Figure 4-5 and Figure 4-6), enter the password and touch the arrow next to the password field. The default password is **cphd** and must be changed upon initial login (as instructed by the software). After the password has been changed by the system administrator, enter the assigned password for future logins.

Figure 4-5. Windows 7 Password Screen

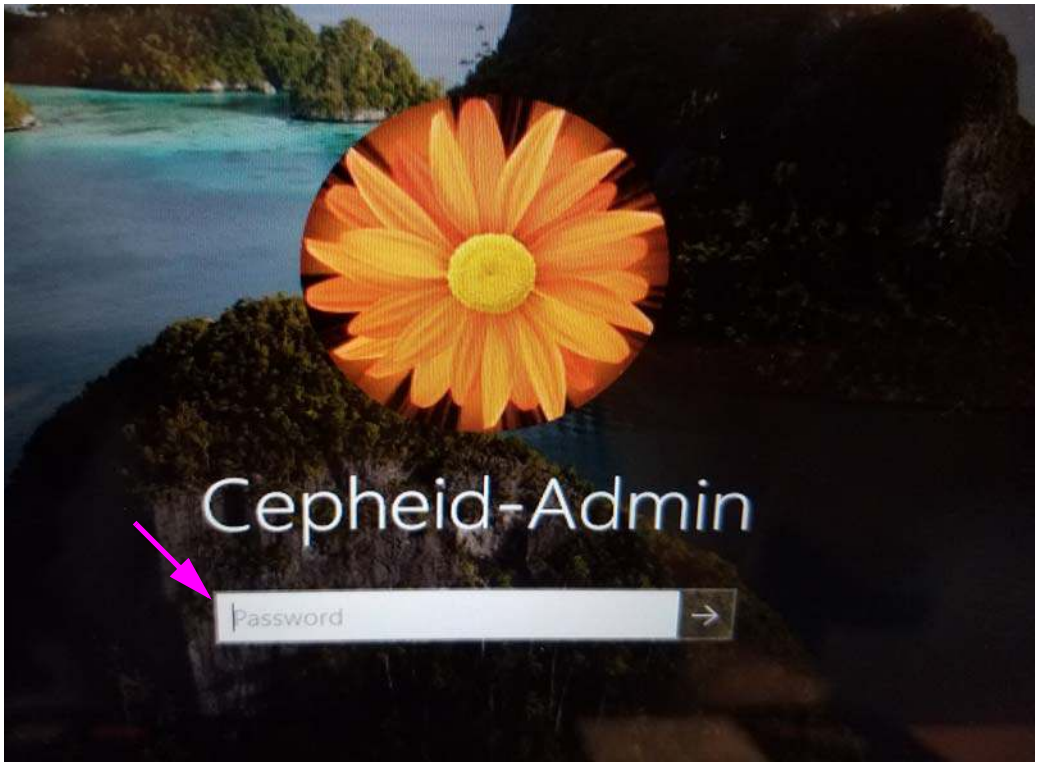


Figure 4-6. Windows 10 Account and Password Screen

6. The Windows Welcome screen will be displayed for a short time followed by the Windows desktop. After the Windows desktop is displayed, the GeneXpert Xpress software will load.

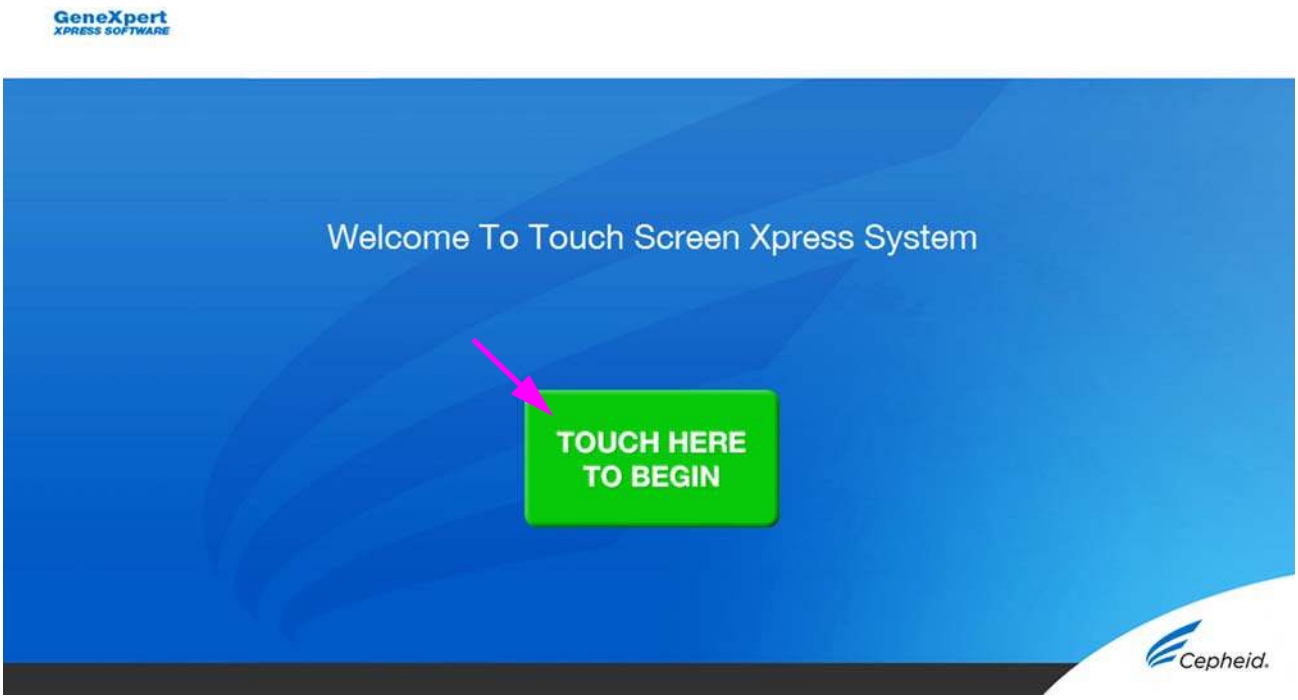


Figure 4-7. GeneXpert Xpress Welcome Screen

7. The GeneXpert Xpress splash screen will be displayed for a short time and then the GeneXpert Xpress Welcome screen will be displayed (see Figure 4-7). Touch the **TOUCH HERE TO BEGIN** button. The GeneXpert Xpress IV Home screen will be displayed. See Figure 4-8.

Note If user accounts have been set up, refer to Section 4.6 for information on signing in and logging out.

Note The Home screen shown in Figure 4-8 may initially show only the **VIEW PREVIOUS TESTS** button until the instrument initializes. The **RUN NEW TEST** button should be displayed within 3 minutes.

The instrument is now initialized and is ready to run tests. See Section 4.2, Starting a Test.

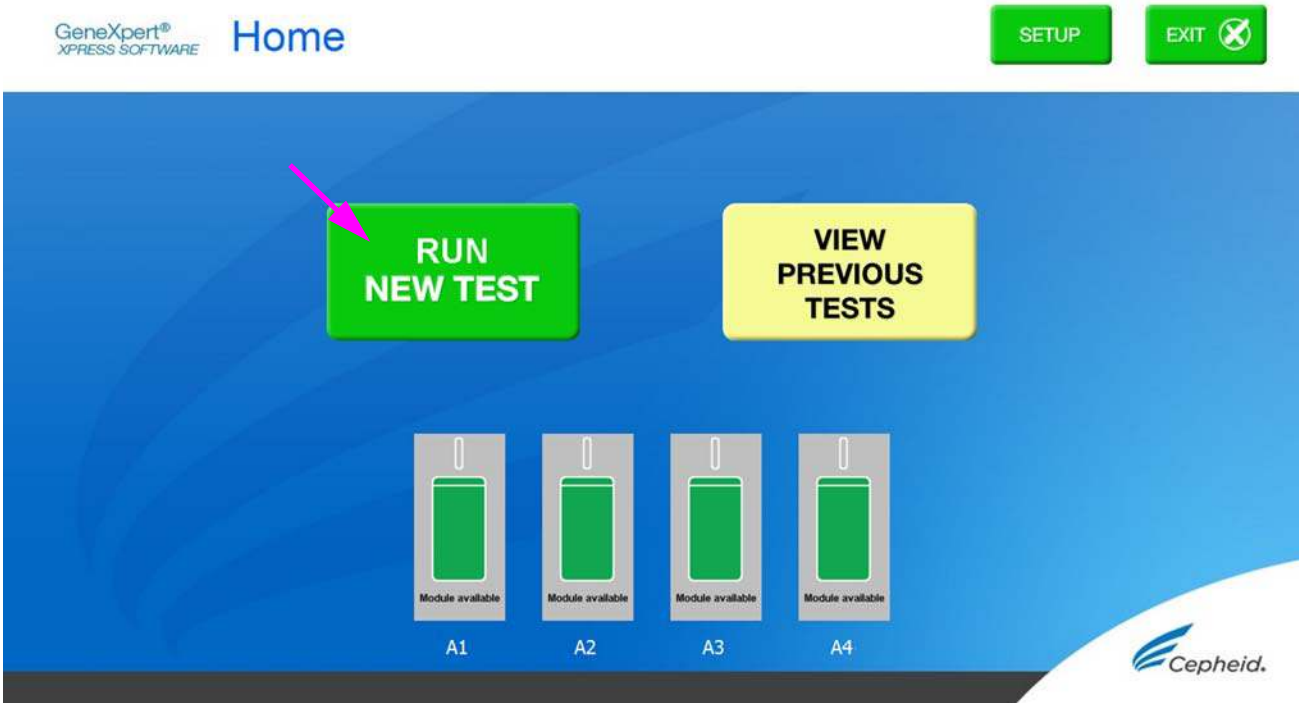


Figure 4-8. GeneXpert Xpress IV Home Screen

4.2 Starting a Test

Note Read the package insert provided with the cartridges for more information. Instructions showing how to prepare the sample and the cartridge are shown on-screen in videos as well as in the following procedure.

Important **After adding the sample to the cartridge, start the test within the time frame indicated in the assay package insert.**

Note This section uses the Xpert Xpress Flu/RSV assay as an example. Other assays may have minor differences.

This section describes how to run a test using the GeneXpert Xpress IV instrument.

1. Touch the **RUN NEW TEST** button on the Home screen (see Figure 4-8). The Enter Patient/Sample ID screen is displayed. See Figure 4-9.

Note The Patient/Sample ID is a unique identifier that links the sample being processed to the patient that provided the sample.

2. Check the patient sample for a Patient/Sample ID barcode.
   A. If there is a Patient/Sample ID barcode, touch the **YES** button on the Enter Patient/Sample ID screen. The Step 1 of 7 Scan Patient/Sample ID screen will be displayed. See Figure 4-10.

B. As shown on the screen, use the barcode scanner to scan the Patient/Sample ID. The Step 2 of 7 Confirm Patient/Sample ID screen will be displayed. See Figure 4-12.

C. Verify that the Patient/Sample ID on the Step 2 of 7 Confirm Patient/Sample ID screen matches the Patient/Sample ID on the sample (see Figure 4-12). If it matches, touch the **YES** button. If it does not match, then touch the **NO** button. The Step 1 of 7 Scan Patient/Sample ID screen will be displayed. See Figure 4-10. You can either scan the barcode again or touch the **NO** button and enter the barcode manually.

or

A. If there is no Patient/Sample ID barcode, touch the **NO** button on the Enter Patient/Sample ID screen (see Figure 4-9). The Step 1 of 7 Enter Patient/Sample ID screen will be displayed. See Figure 4-11.

B. As shown on the screen, use the touchscreen keypad to manually enter the Patient/Sample ID and touch the **OK** button. The Step 2 of 7 Confirm Patient/Sample ID screen will be displayed. See Figure 4-12.

C. Verify that the Patient/Sample ID on the Step 2 of 7 Confirm Patient/Sample ID screen matches the Patient/Sample ID on the sample. If it matches, touch the **YES** button. If it does not match, then touch the **NO** button and re-enter the Patient/Sample ID.

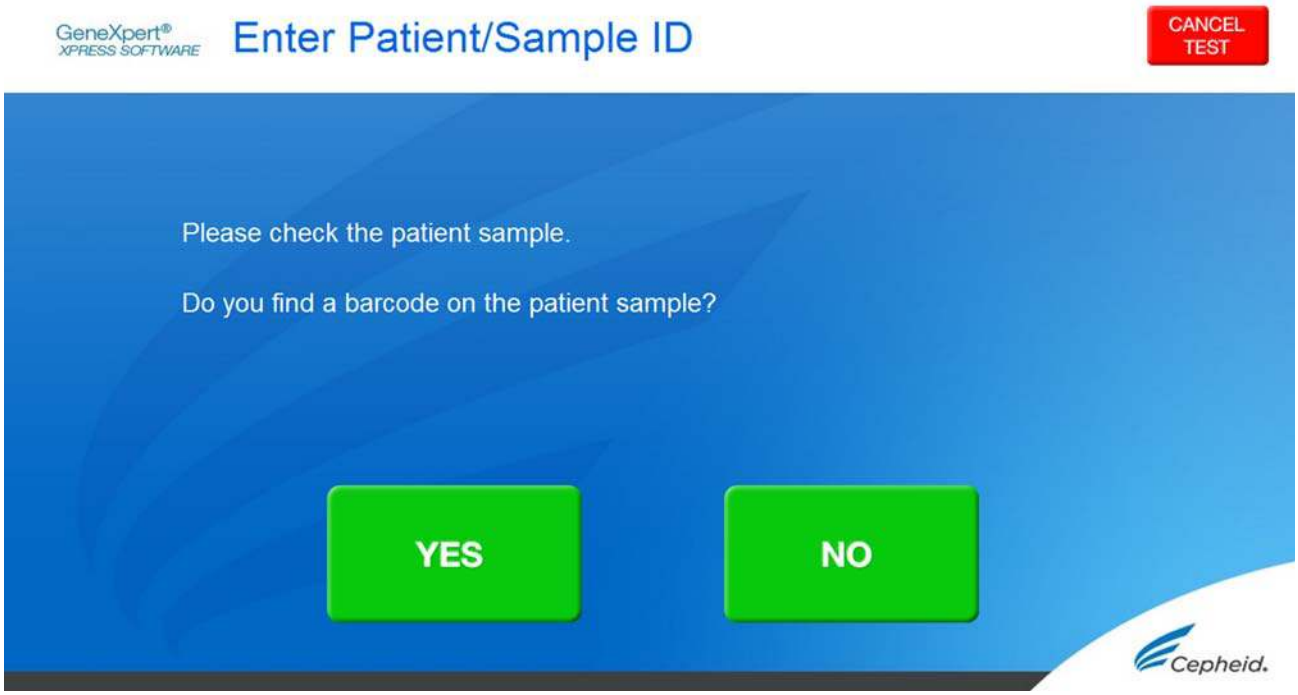


Figure 4-9. Enter Patient/Sample ID Screen

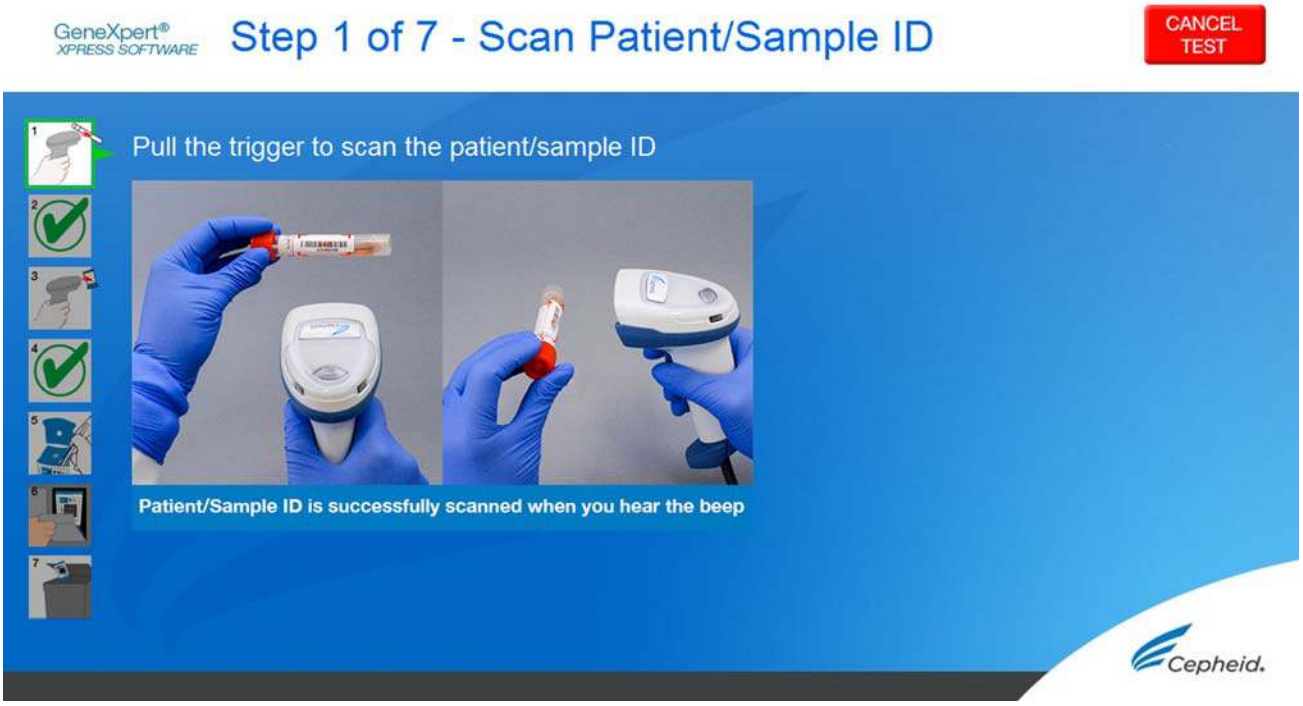


Figure 4-10. Step 1 of 7 - Scan Patient/Sample ID Screen

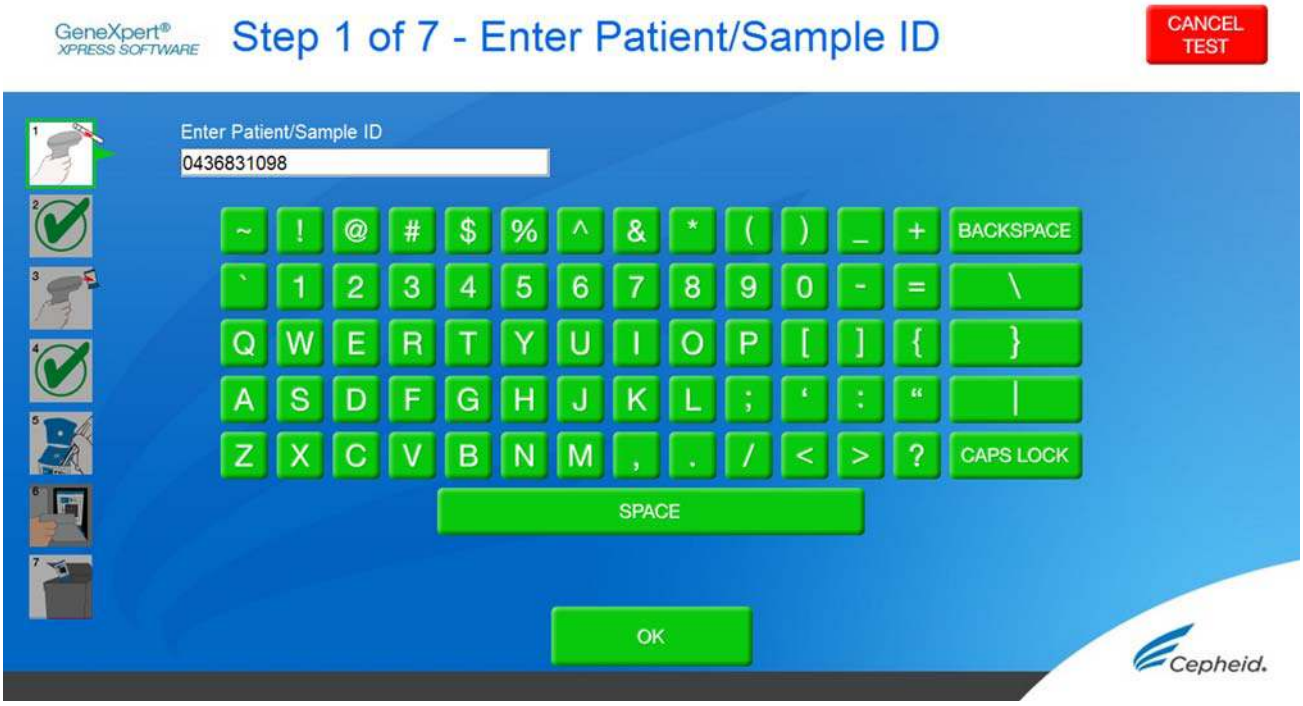


Figure 4-11. Step 1 of 7 - Enter Patient/Sample ID Screen

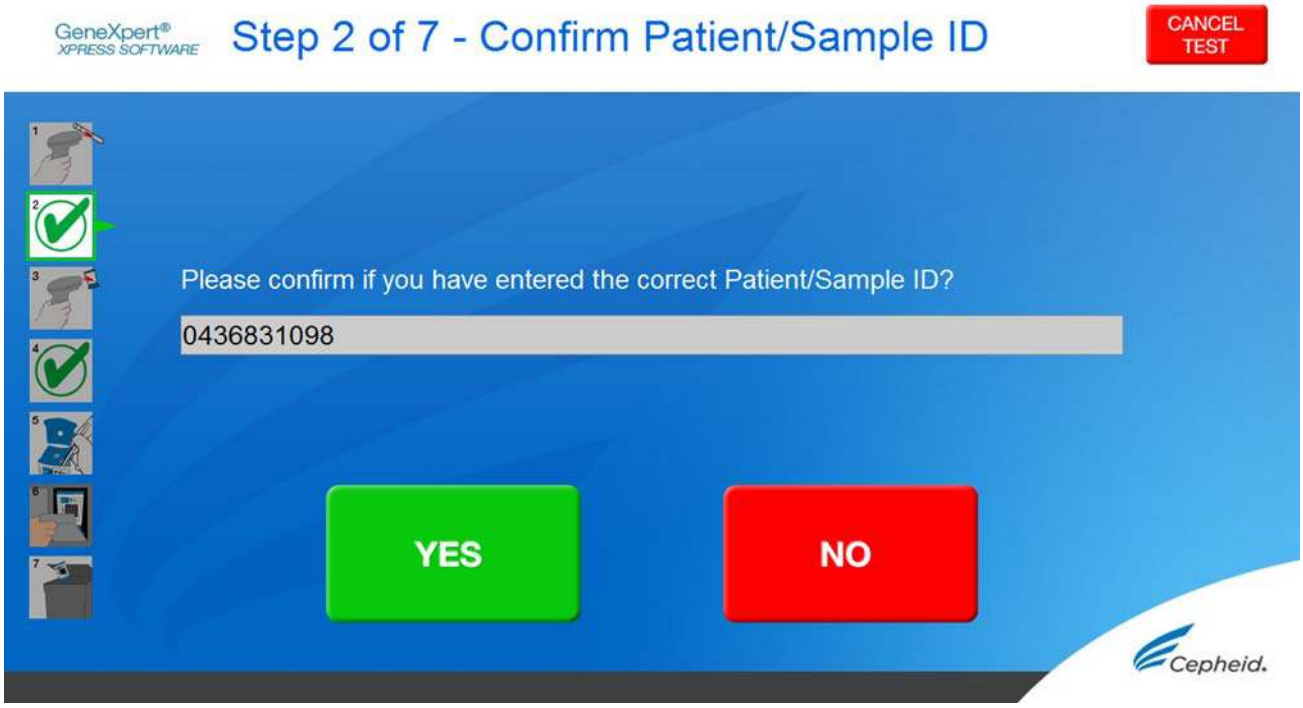


Figure 4-12. Step 2 of 7 Confirm Patient/Sample ID Screen

3. After confirming that the Patient/Sample ID is correct, the Step 3 of 7 Scan Cartridge Barcode screen will be displayed (see Figure 4-13). Select the cartridge with the sample and use the barcode scanner to scan the cartridge label. When you hear the beep, the cartridge barcode has been scanned and the Step 4 of 7 Confirm Test screen will be displayed. Select the assay required and then confirm the selected test is correct by touching the **YES** button. See Figure 4-14.

Note

For assays with multiple options select the correct assay, then touch the **YES** button. The **YES** button will remain gray until an assay has been selected.

4. Verify that the correct cartridge has been scanned and that the test type shown on the Step 4 of 7 Confirm Test screen (see Figure 4-14) matches the name of the test on the cartridge. If it matches, touch the **YES** button. The Step 5 of 7 Cartridge Preparation screen will be displayed. See Figure 4-15.

   If it does not match, then touch the **NO** button and scan the correct cartridge barcode.

5. The Step 5 of 7 Cartridge Preparation screen will play a short video showing how to prepare the cartridge for testing (see Figure 4-16). Once complete, the video will restart from the beginning automatically. Prepare the cartridge according to the directions shown in the video and in the assay package insert.

6. After the cartridge has been prepared, touch the **SKIP VIDEO AND CONTINUE** button on the Step 5 of 7 Cartridge Preparation screen (see Figure 4-16). The Step 6 of 7 Load Cartridge screen is displayed. See Figure 4-17.

Figure 4-13. Step 3 of 7 Scan Cartridge Barcode Screen

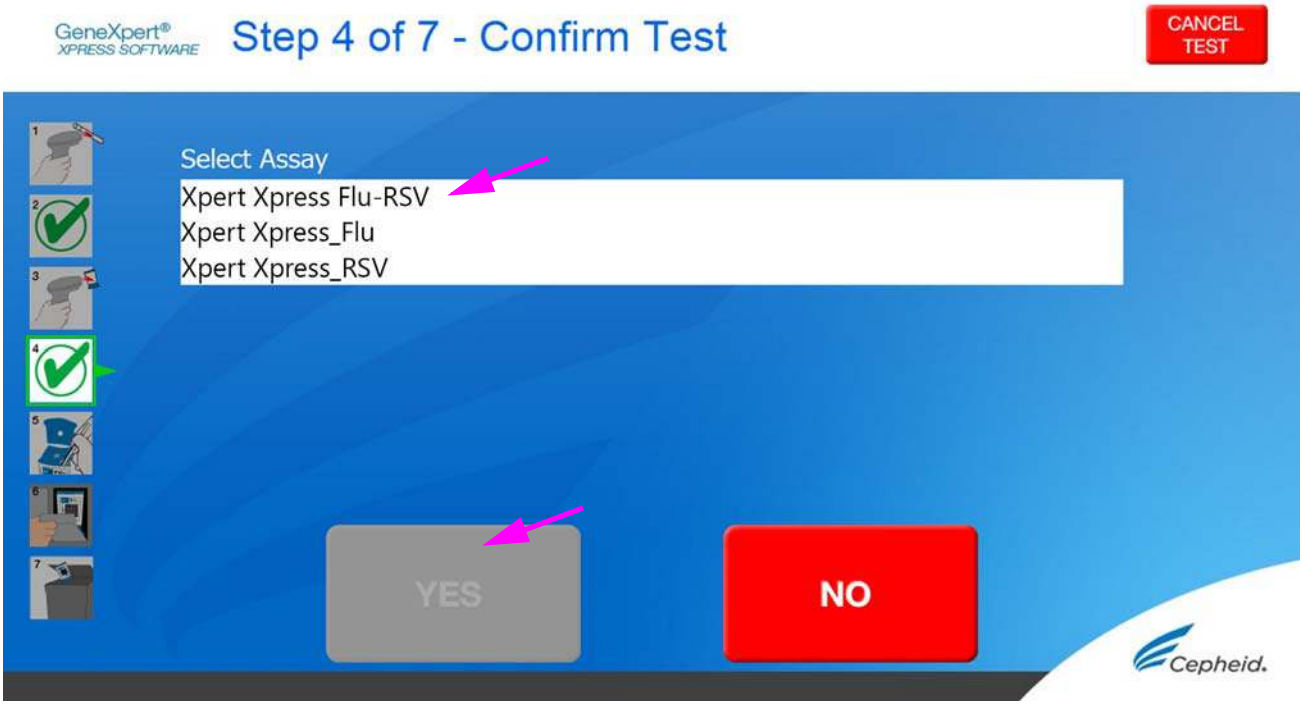


Figure 4-14. Step 4 of 7 Confirm Test Screen

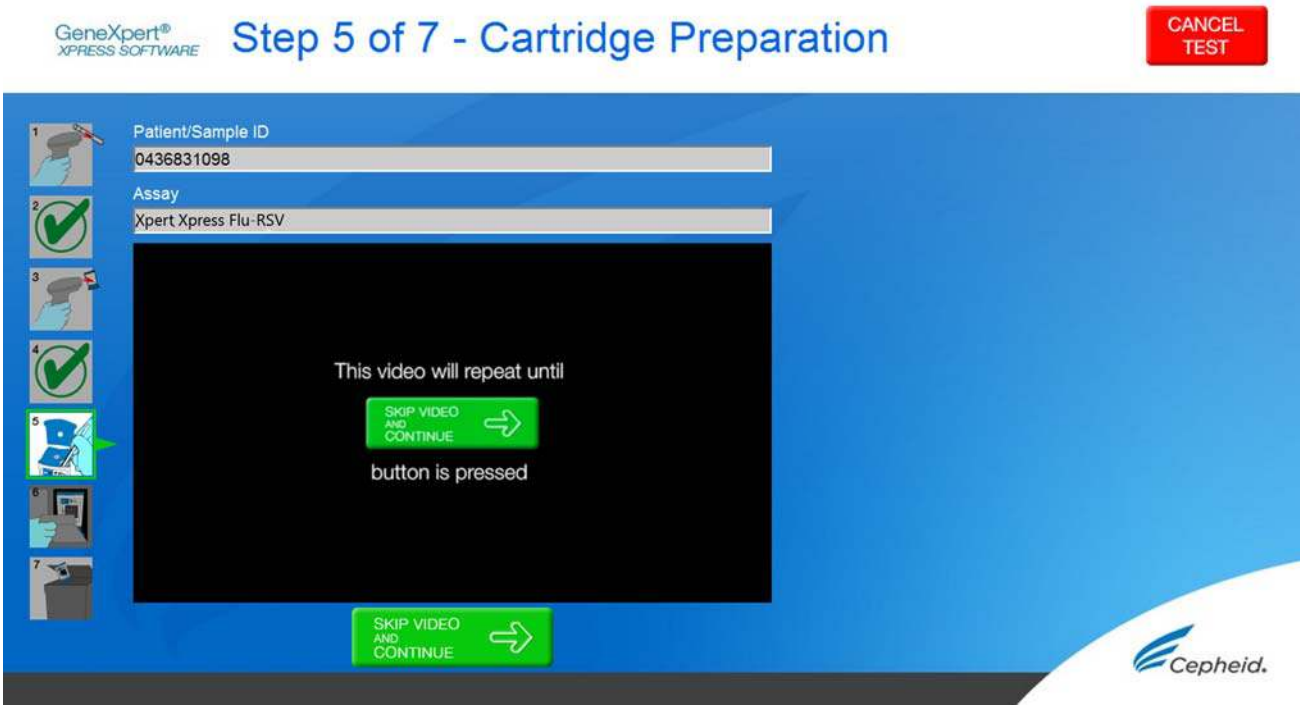


Figure 4-15. Step 5 of 7 Cartridge Preparation Screen Before Video Plays

Figure 4-16. Step 5 of 7 Cartridge Preparation Screen While Video Plays

Figure 4-17. Step 6 of 7 Load Cartridge Screen (1 of 2)

7. On the Step 6 of 7 Load Cartridge screen (see Figure 4-17), insert the cartridge into the system module with the blinking green light. Ensure that the door of the system is completely closed. The door will latch and the blinking green light will turn solid green. As soon as the cartridge is loaded, the next Step 6 of 7 Load Cartridge screen will be displayed. See Figure 4-18.

   The Step 6 of 7 Load Cartridge screen will show a progress bar at the bottom of the screen as the cartridge is loaded (see Figure 4-18). As soon as the load process is completed, the Step 6 of 7 Test in Progress screen will be displayed. See Figure 4-19.

8. The Step 6 of 7 Test in Progress screen will show a progress bar at the bottom of the screen indicating the progress of the test and the time remaining until a result is available (see Figure 4-19). As soon as the test is completed, the Step 7 of 7 Remove Cartridge screen will be displayed. See Figure 4-20.

Note

At this point, an additional test can be started. To start an additional test, see Section 4.3, Starting Another Test While a Test is Running.

Figure 4-18. Step 6 of 7 Load Cartridge Screen (2 of 2)

Figure 4-19. Step 6 of 7 Test in Progress Screen

Figure 4-20. Step 7 of 7 Remove Cartridge Screen

9. The Step 7 of 7 Remove Cartridge screen shows instructions for removing the cartridge (see Figure 4-20). Open the instrument door, remove the used cartridge and properly dispose of the cartridge according to your institution's hazardous waste disposal policies. After removing the cartridge, close the module door and touch the **CONTINUE** button.

Note

Verify the printer is powered on, has paper and is communicating with the Xpress computer before printing the results.

10. The Test Result screen will provide the results for the test that has just completed (see Figure 4-21). After viewing and recording the results, touch the **HOME** to return to the Home screen, **VIEW PREVIOUS TESTS** to view another result. or touch the **PRINT RESULT** button to print the results. See Section 4.5, Print Results.

This completes the procedure for running a test using the GeneXpert Xpress IV instrument.

If any error messages occur while running the test, see Section 4.9, Error Handling.

Figure 4-21. Test Result Screen

4.3 Starting Another Test While a Test is Running

Additional tests may be started after the first test is in progress.

1. When a test is in progress, see Step 8 of Section 4.2, Starting a Test and Figure 4-19. Touch the **HOME** button.
2. The Home screen will display the module in use as slightly gray and with the notation that a test is in progress. See Figure 4-22.
3. Touch **RUN NEW TEST** and start the new test. See Section 4.2, Starting a Test.
4. After the second test is in progress, touch the **HOME** button. The status of both tests is displayed.
5. When a test is complete, the icon text will change to **Test complete** and will show a check mark on the icon. See Figure 4-23. Touch the icon to show the Remove Cartridge screen. See Figure 4-20. Follow the instructions on the screen to remove the cartridge.

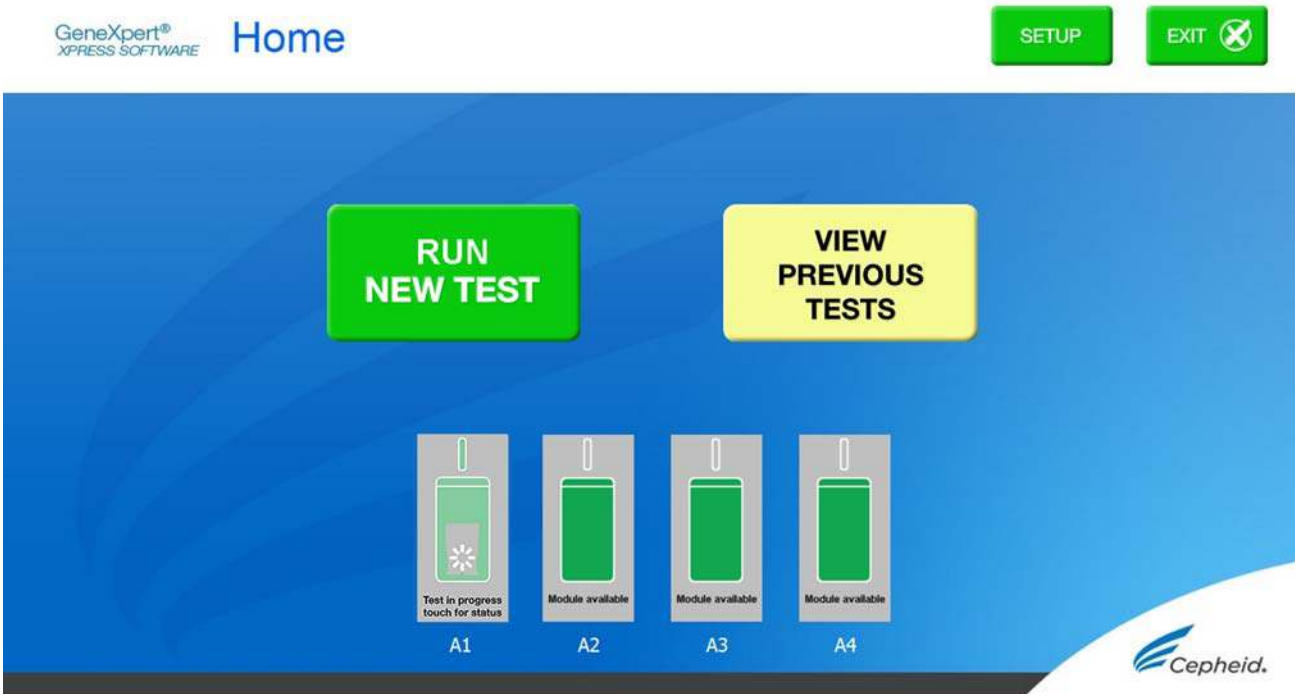


Figure 4-22. GeneXpert Xpress IV Home Screen with One Test in Progress

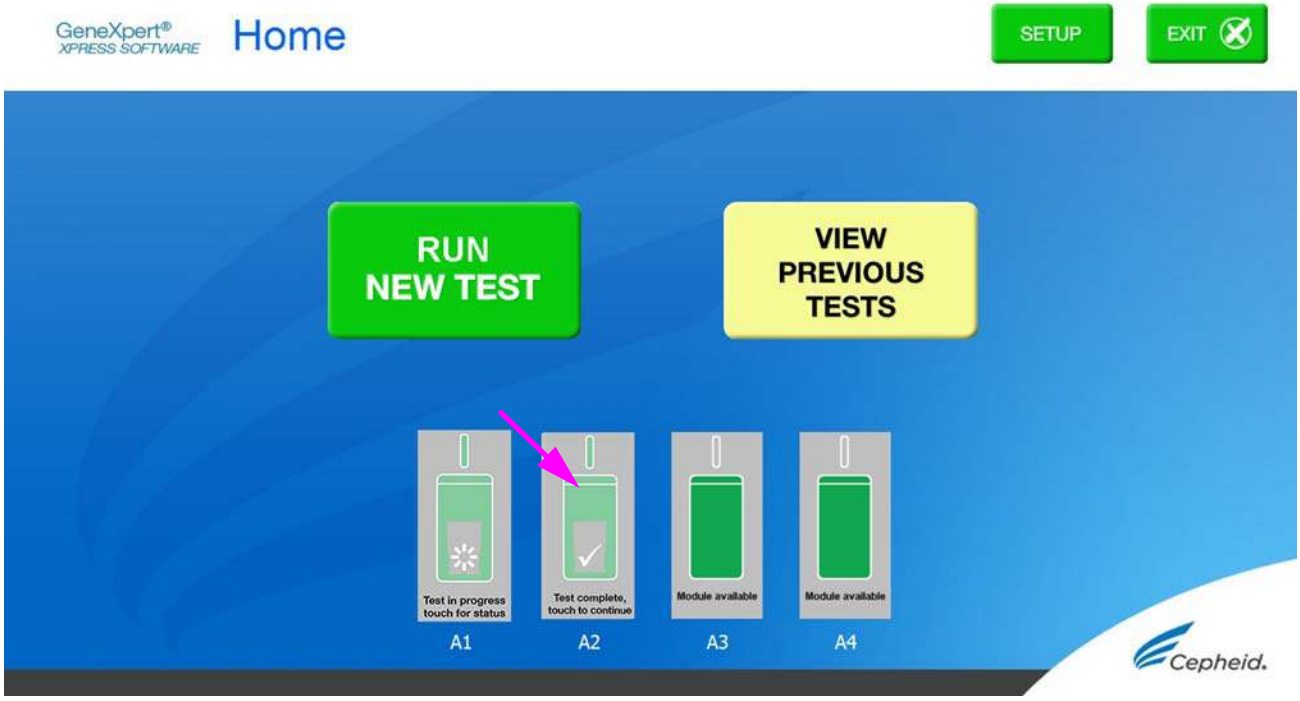


Figure 4-23. GeneXpert Xpress IV Home Screen with One Test Completed

This completes the procedure for starting another test while a test is running.

4.4 Viewing Previous Test Results

This section describes how to view the results of previously run tests using the GeneXpert Xpress IV instrument.

1. Touch the **VIEW PREVIOUS TESTS** button on the Home screen (see Figure 4-24). The Select Test screen is displayed. See Figure 4-25.
2. On the Select Test screen, select the test to view. Tests are arranged in order by the date and time that the test was run. Touch the arrow keys to navigate to the desired test.

   The single arrow keys move the selection up or down by one test result. The double arrow keys move the selection up or down by one page at a time.
3. After selecting the desired test, touch the **Select** button to view the test results. The Test Result screen for the selected test will be displayed. See Figure 4-26.

   To interpret the results for a specific assay, see the package insert provided in the assay kit.

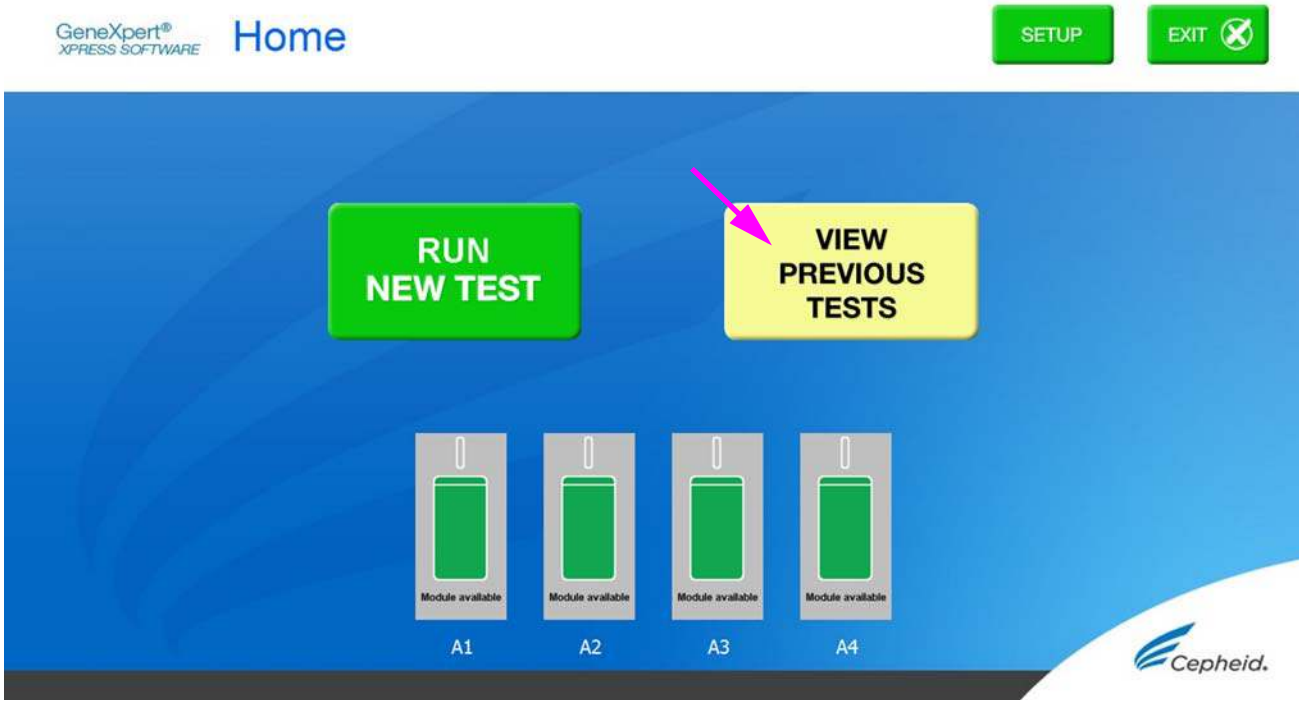


Figure 4-24. GeneXpert Xpress IV Home Screen

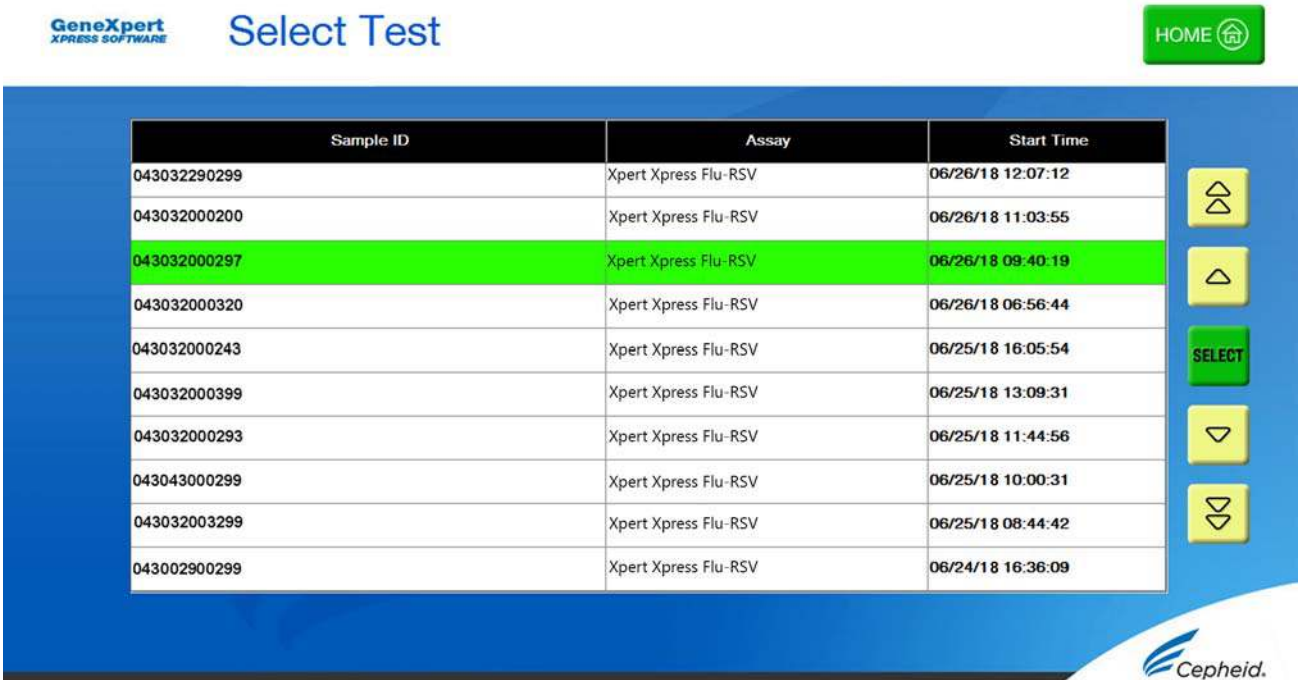


Figure 4-25. Select Test Screen

Figure 4-26. Test Result Screen

Note Verify the printer is powered on, has paper and is communicating with the Xpress computer before printing the results.

4. After viewing the results, touch the **HOME** button to return to the Home screen and run additional tests, touch the **VIEW PREVIOUS TESTS** button to return to the Select Test screen and view additional tests, or print the results by touching the **PRINT RESULT** button, See Section 4.5, Print Results.

This completes the procedure for viewing previous test results.

4.5 Print Results

If the option to print the results was selected, a screen indicating the report was sent to the printer will display. See Figure 4-27. Touch the OK button to close to return to the **HOME** screen.

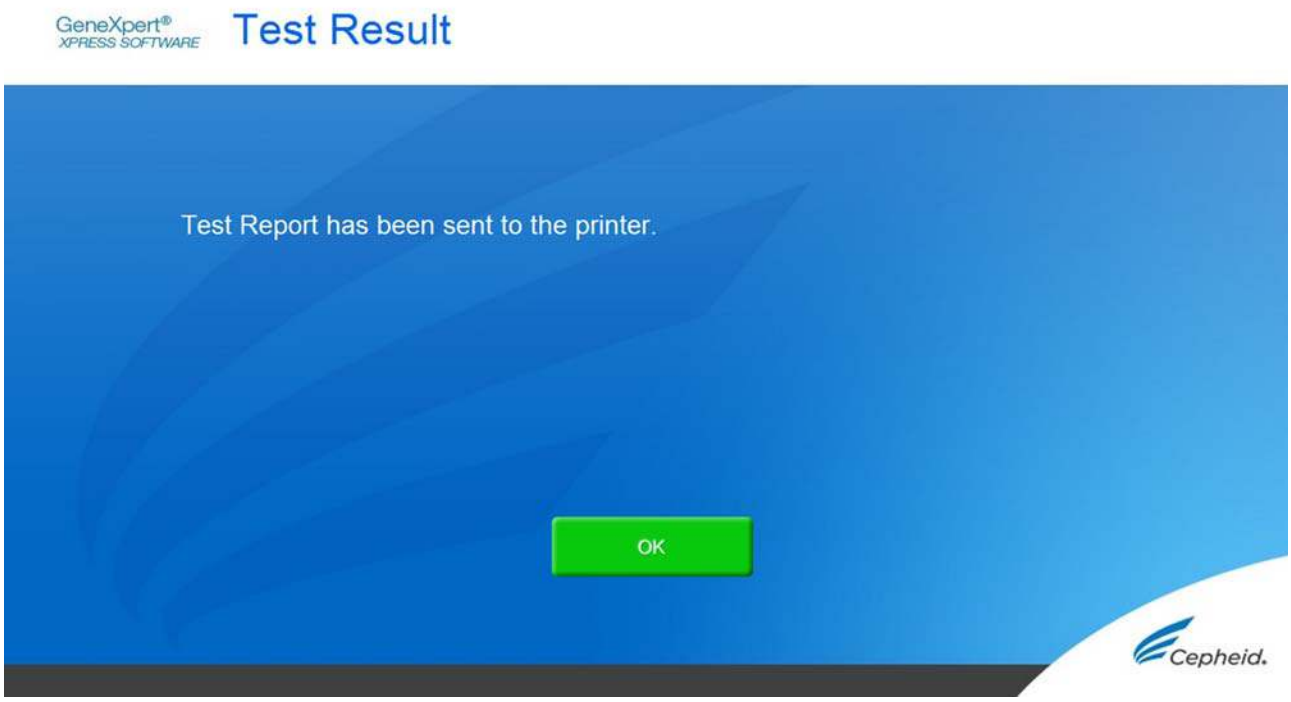


Figure 4-27. Report Sent to Printer Confirmation

If there is a problem communicating with the printer, see Section 6.18.2, Troubleshooting Wireless Printer Connection or Section 5.9, Connecting to the Printer with a Direct USB Connection for further assistance.

This completes the procedure for printing results.

4.6 User Sign In and Sign Out (Optional)

When multiple users will be using the same system, user sign in and sign out may be required. Please see your system administrator for individual sign in information. To sign in:

1. Follow Section 4.1, Starting the GeneXpert Xpress IV and GeneXpert Xpress Software. Instead of the Home screen being displayed in Step 7, the Sign-In User Name screen will be displayed. See Figure 4-28.

Figure 4-28. Sign In-User Name Screen

2. Enter your user name and touch **OK**. The Password entry box will appear.
3. Enter your user password and touch **OK**. See Figure 4-29.

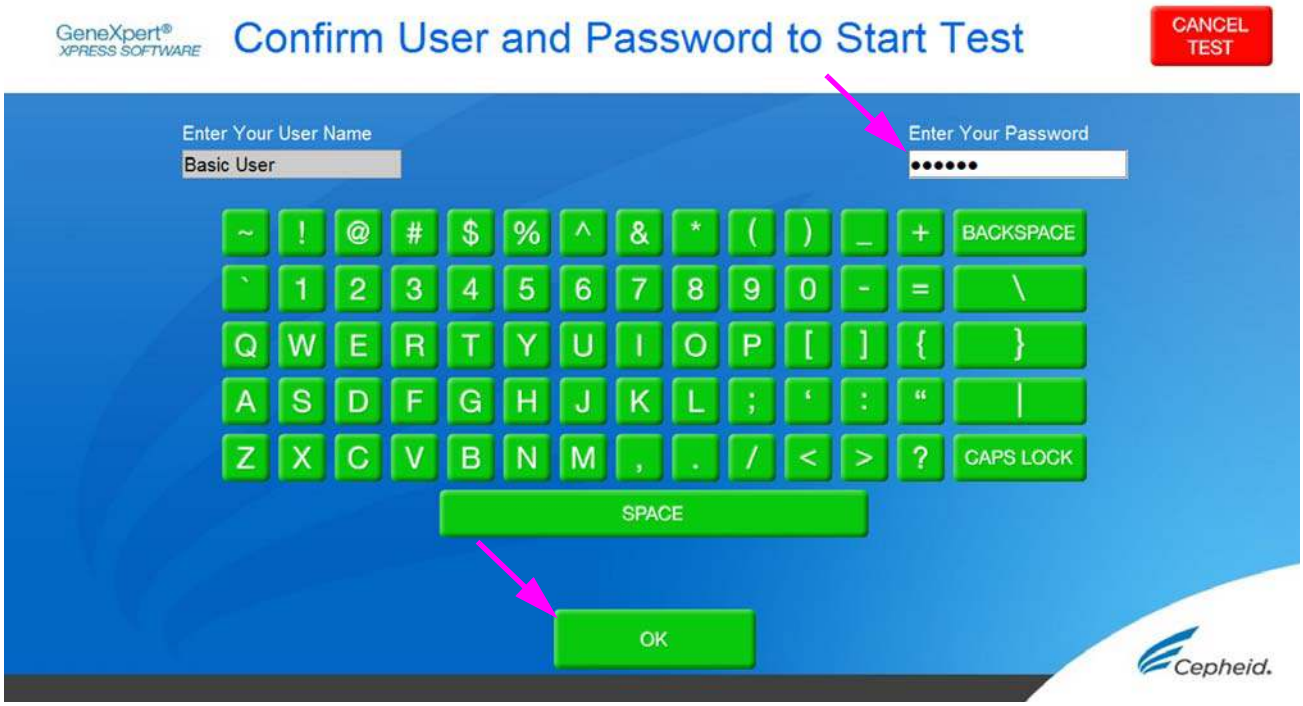


Figure 4-29. Confirm User and Password to Start Test Screen

The Home screen will appear with a **SIGN OUT** button added at the top of the screen. See Figure 4-30.

Note

The screen captures in both this section and the Quality Control Lockout section were taken with both features enabled on the system so the **QC** button and **Sign Out** button will be visible in the images for these sections.

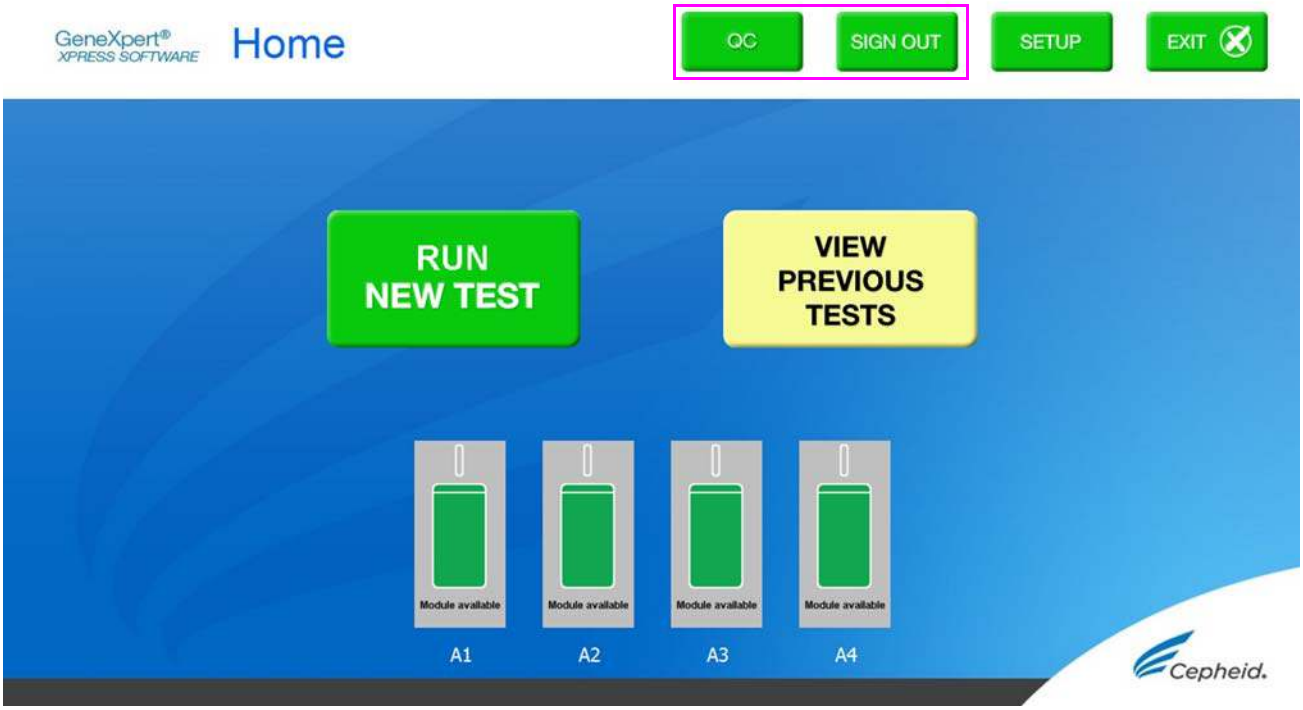


Figure 4-30. Home Screen with Sign Out and QC Buttons

4. When you are finished with the session, touch the **SIGN OUT** button to sign out of the system. You will be signed out and the screen will return to the Sign In-User Name screen as shown in Figure 4-28. You should sign out if you are going to be away from the system for an extended period of time. Signing out prevents the software from recording other users' activities under your account.

Note If you sign off while a test is in progress, the system will finish the test and save the results.

Note A new user can start a separate test if a test is in progress. The first user must sign off, the new user sign on and start an additional test following the steps in Section 4.3, Starting Another Test While a Test is Running

This completes the procedure for signing in and out of the GeneXpert Xpress software.

4.7 Quality Control Lockout (Optional)

4.7.1 QC Lockout Overview

Quality Control samples can be run at any time; the lockout feature does not need to be enabled. The steps are the same as running any test, however, if the Quality Control (QC) Lockout feature is enabled, a **QC** button will appear at the top of the Home screen. See Figure 4-30.

Click the **QC** button to begin a quality control test or to view the Quality Control Summary page. See Figure 4-31.

The Select Quality Control Type screen provides the choice of running either a positive or negative sample, looking at the summary page or returning to the Home screen. To run a positive or negative sample, touch the button of the sample type to run the test. See Section 4.7.3, Running a Quality Control Test Using the QC Lockout Feature. To view the summary page, touch **SUMMARY**.

Figure 4-31. Select Quality Control Type Screen

The summary page will display important information about the QC status for assays. See Figure 4-32.

Note

It is a good practice to check the Quality Control Summary page each time you sign on to the system to see if any assays will require a QC lot run during the work session.

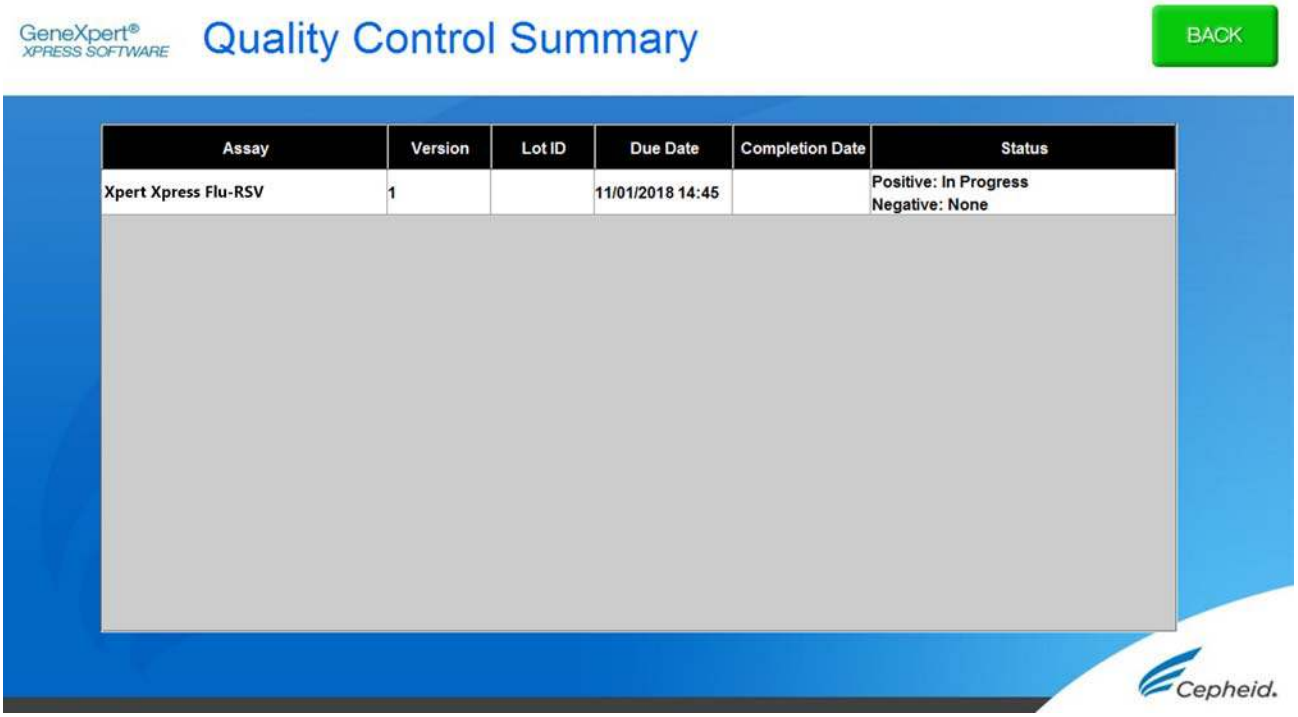


Figure 4-32. Quality Control Summary Screen

4.7.2 Quality Control Lockout

If the QC lockout feature has been enabled and is required for new assay lots, the Quality Control Required screen will display when a new lot is used. See Figure 4-33. If the Quality Control Required screen is displayed, touch the **OK** button to close the screen and then run QC for the selected assay and lot id.

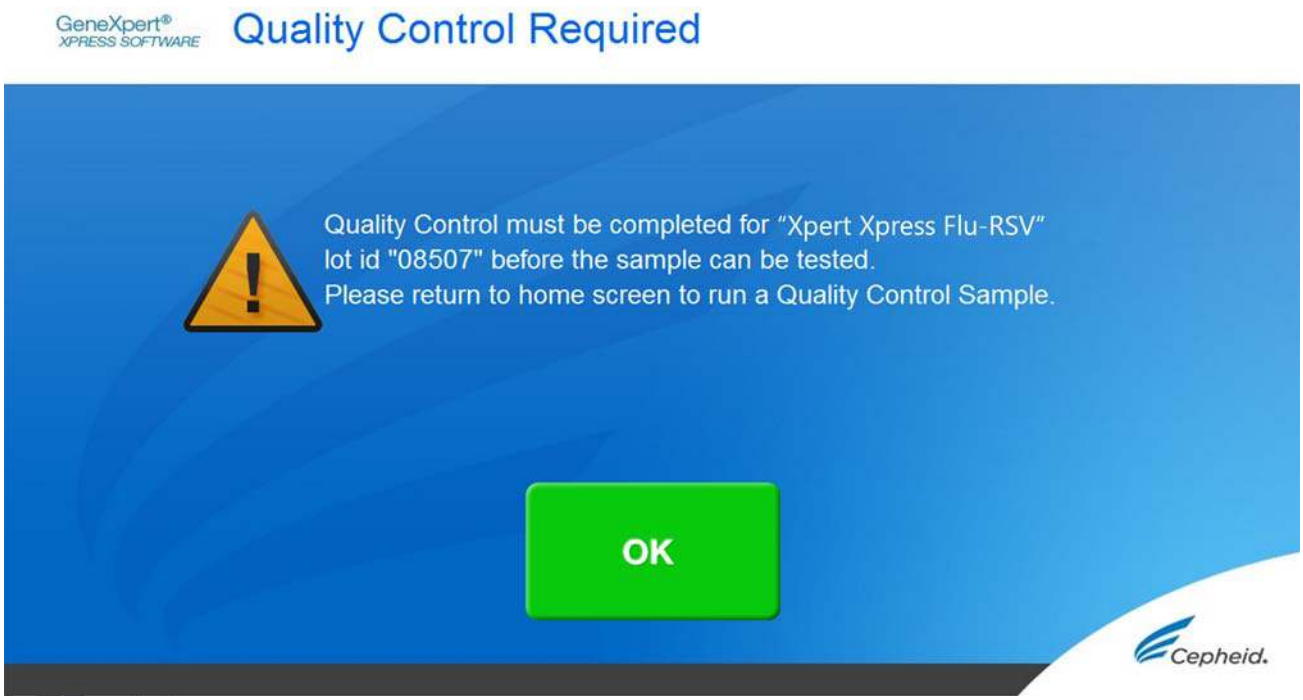


Figure 4-33. Quality Control Required Screen

If the QC lockout feature is set so that QC must be run at regular intervals, reminders will appear indicating how long is left before the system will lock out that particular assay. QC intervals are set by the system administrator. If the set time limit runs out and QC lots were not run, the system will not process any patient tests for the assay requiring QC until QC is completed. See Figure 4-34. Touch the **OK** button to close the reminder.

Note

You may continue running tests until the time limit runs out, however allowing the time to run out may cause unexpected delays for urgent tests.

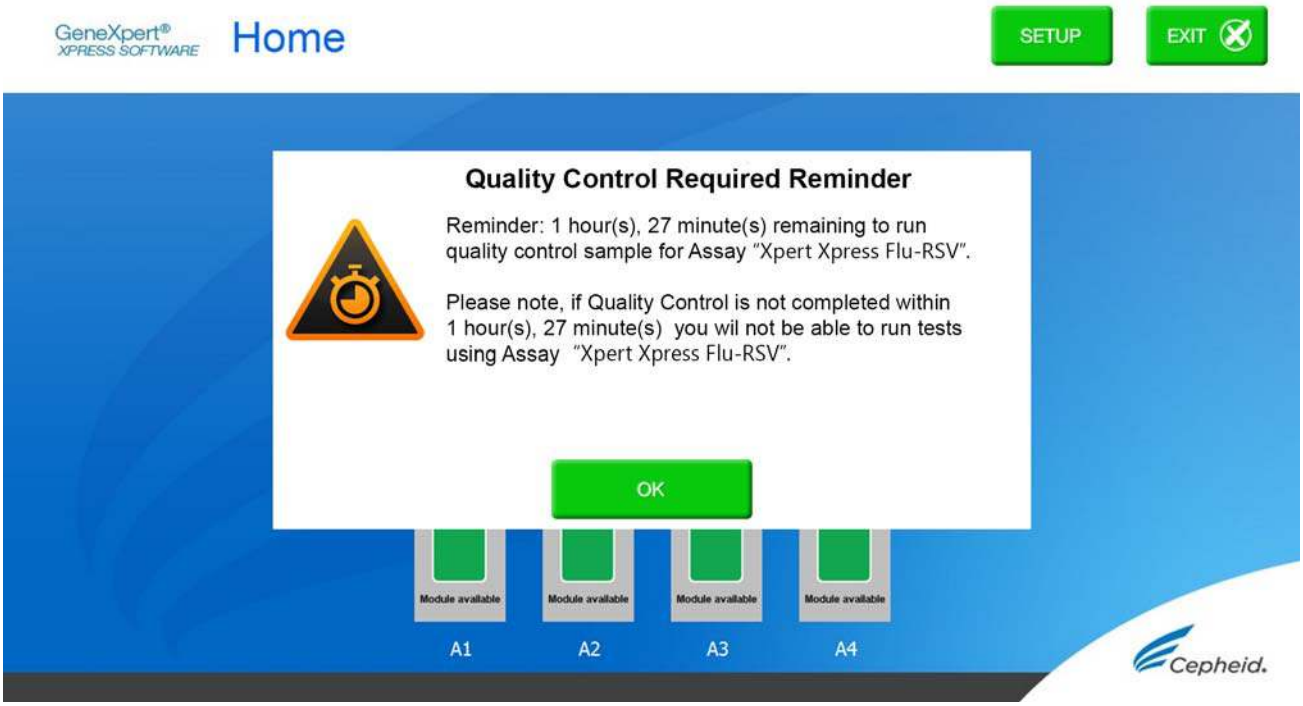


Figure 4-34. Quality Control Reminder Screen

QC will also be required if the Database has been restored. See Figure 4-35. If the Database Restore Detected reminder is displayed, touch the **OK** button to close the reminder. Run QC for all active assays and lots.

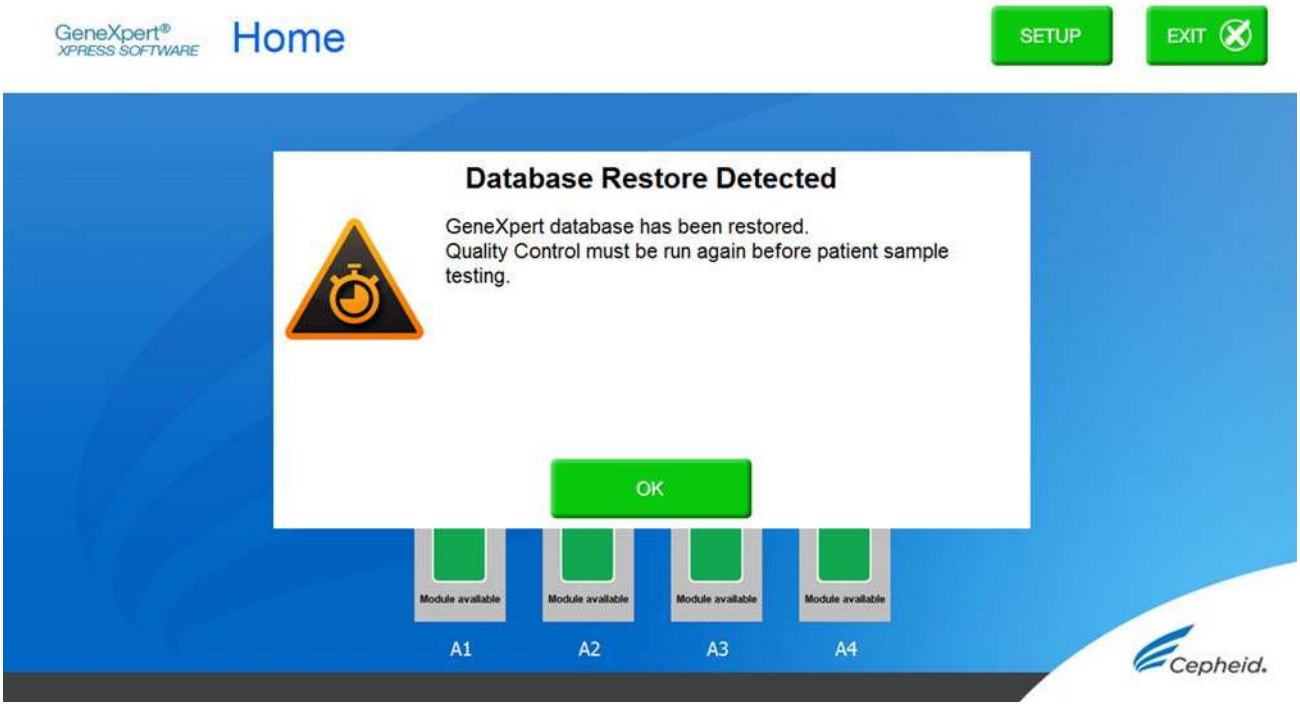


Figure 4-35. Database Restore Detected Screen

4.7.3 Running a Quality Control Test Using the QC Lockout Feature

This procedure assumes the computer and GeneXpert instrument are powered on and that the GeneXpert Xpress software is open and at the Home screen. The screen shots displayed in this section show buttons indicating that both the Sign In feature and QC Lockout feature have been enabled.

1. Touch the **QC** button on the Home screen (see Figure 4-36). The Select Quality Control Type screen is displayed. See Figure 4-37.
2. Select either **POSITIVE** or **NEGATIVE** for the control type that will tested.

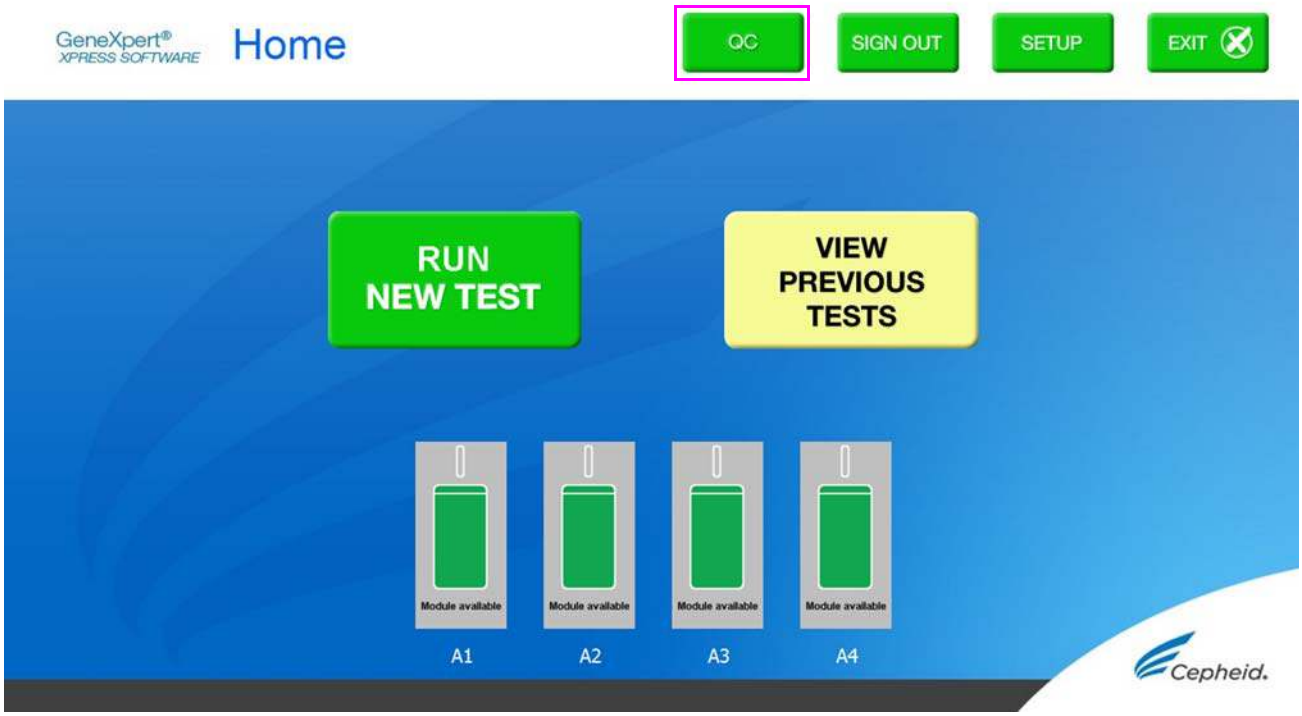


Figure 4-36. Home Screen with Sign Out and QC Buttons

Figure 4-37. Select Quality Control Type Screen

3. The Enter Patient/Sample ID screen will be displayed. See Figure 4-38.

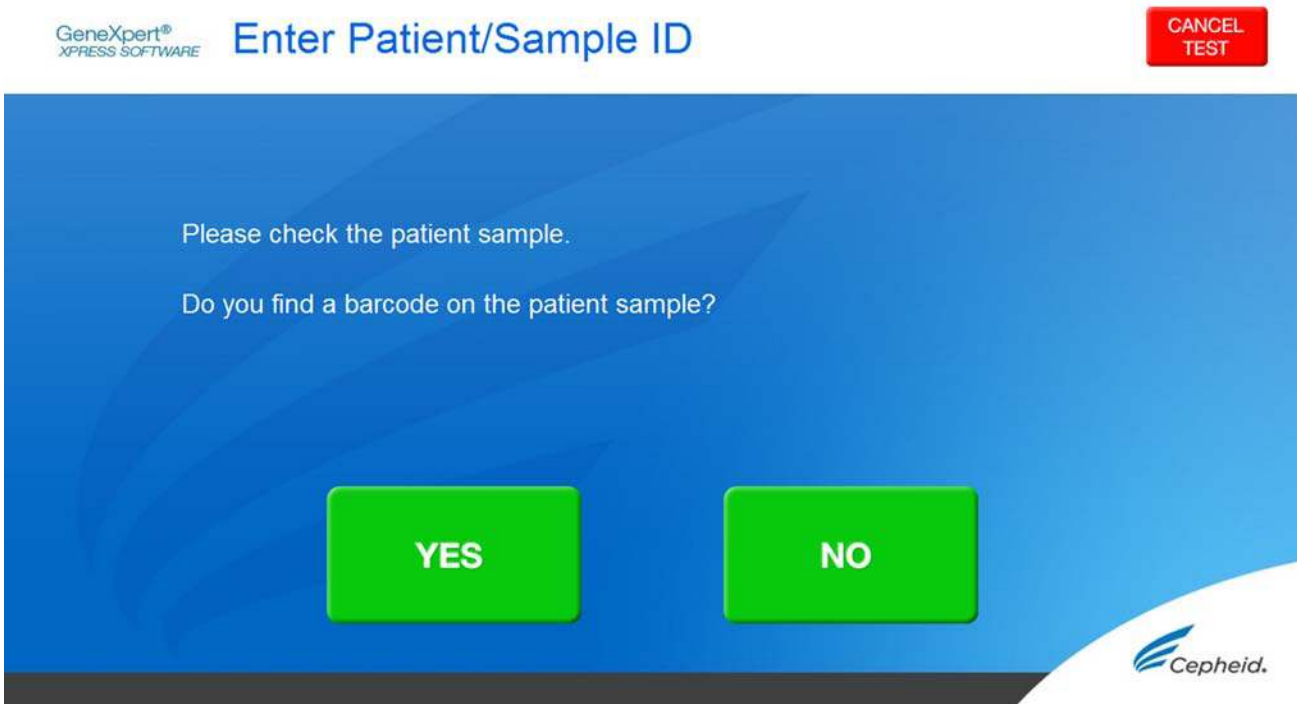


Figure 4-38. Enter Patient/Sample ID

4. If there is a sample ID barcode, touch **YES** and scan it, proceeding with Step 5. If there is no barcode:

   A. Touch the **NO** button on the Enter Patient/Sample ID screen. The Step 1 of 7 Enter Patient/Sample ID screen will be displayed. See Figure 4-39.

   B. Use the touchscreen keypad to manually enter the negative control ID for the Negative External Control or the positive control ID for the Positive External Control and touch the **OK** button. The Step 2 of 7 Confirm Patient/Sample ID screen will be displayed. See Figure 4-40.

5. Verify that the control ID on the Step 2 of 7 Confirm Patient/Sample ID screen matches the External Control ID on the sample. If it matches, touch the **YES** button. If it does not match, then touch the **NO** button and re-enter the External Control ID.

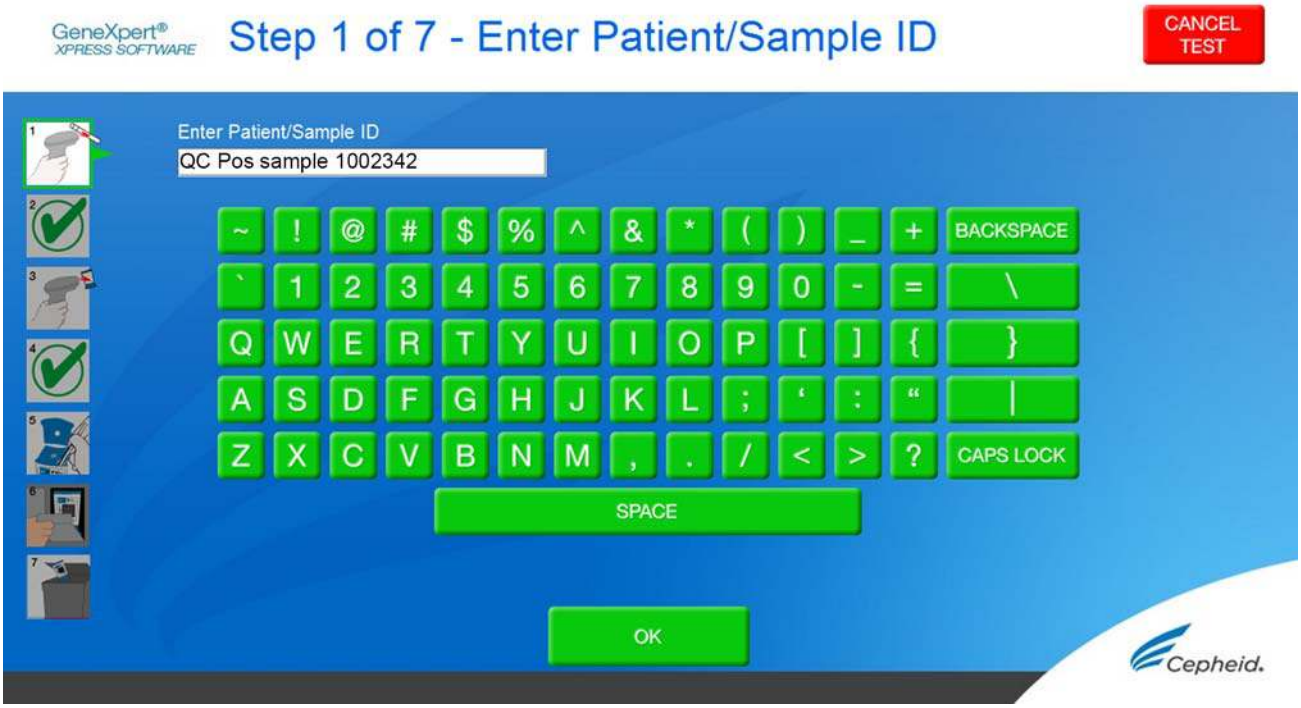


Figure 4-39. Step 1 of 7 - Enter Patient/Sample ID Screen

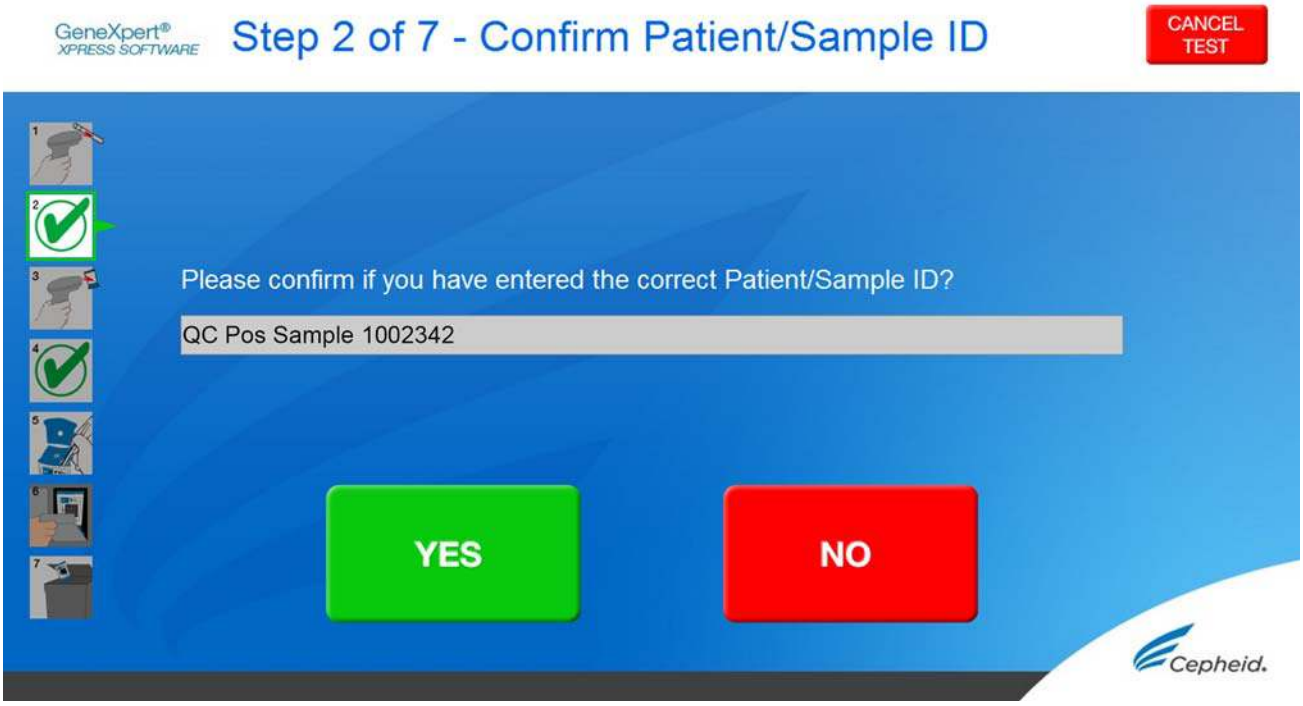


Figure 4-40. Step 2 of 7 Confirm Patient/Sample ID Screen

6. After confirming that the Patient/Sample ID is correct, the Step 3 of 7 Scan Cartridge Barcode screen will be displayed (see Figure 4-41). Use the barcode scanner to scan the cartridge label. When you hear the beep, the cartridge barcode has been scanned and the Confirm Quality Control Test screen will be displayed. See Figure 4-42.

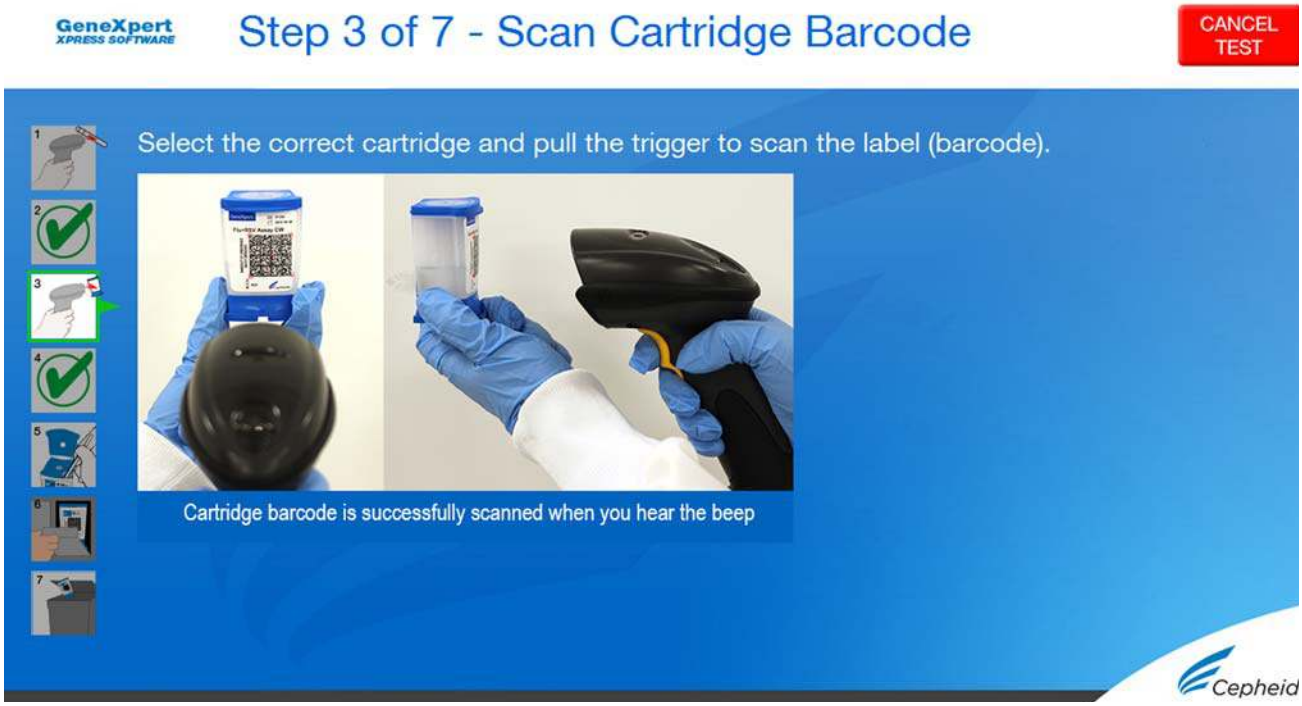


Figure 4-41. Step 5 of 7 Cartridge Preparation Screen

7. Touch the **CONTINUE** button if the control information is correct. Touch the **Cancel Test** button if the control information is incorrect.

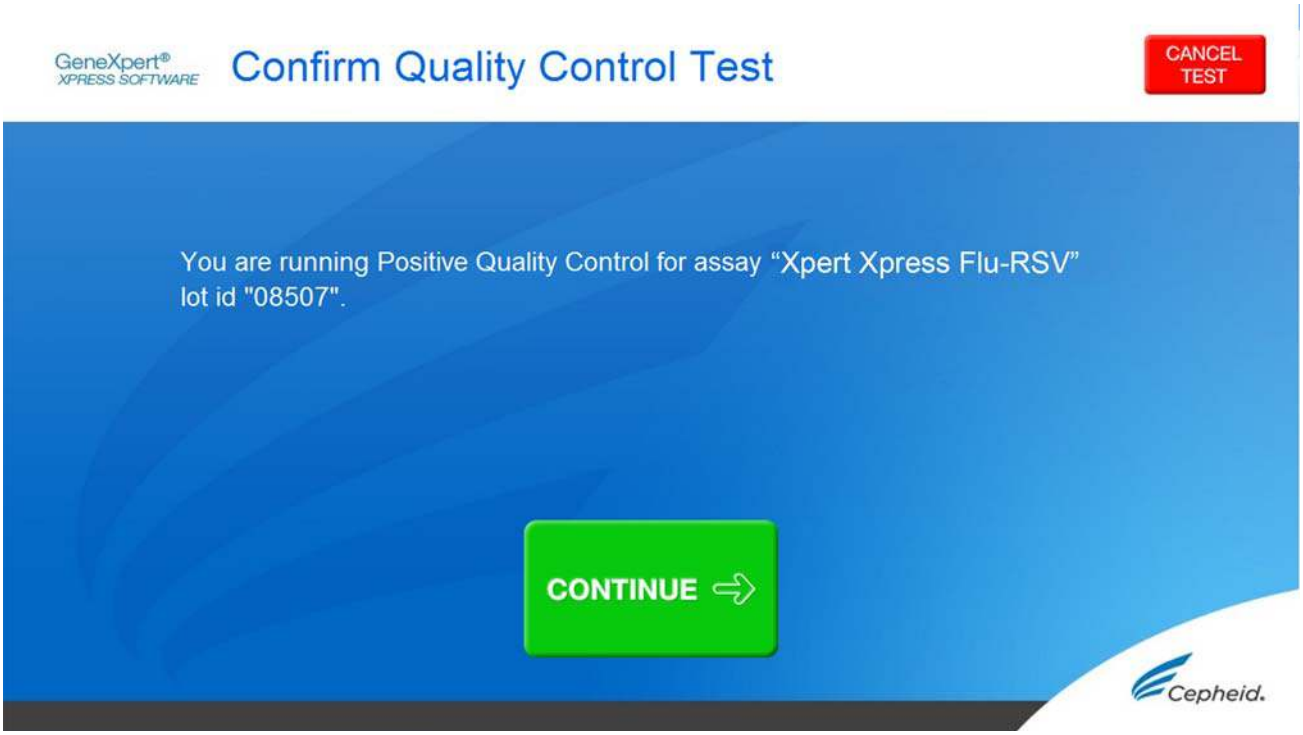


Figure 4-42. Confirm Quality Control Test Screen

8. The Step 5 of 7 Cartridge Preparation screen will play a short video showing how to prepare the cartridge for testing. Once complete, the video will restart from the beginning automatically. Prepare the cartridge according to the directions shown in the video and in the assay package insert.

9. After the cartridge has been prepared, touch the **SKIP VIDEO AND CONTINUE** button on the Step 5 of 7 Cartridge Preparation screen. The Step 6 of 7 Load Cartridge screen is displayed.

10. On the Step 6 of 7 Load Cartridge screen, insert the cartridge into the system module with the blinking green light. See Figure 4-17. Ensure that the door of the system is completely closed. The door will latch and the blinking green light will turn solid green.

11. The Step 7 of 7 Remove Cartridge screen shows instructions for removing the cartridge (see Figure 4-20). Open the instrument door, remove the used cartridge and properly dispose of the cartridge according to your institution's hazardous waste disposal policies. After removing the cartridge, close the module door. Touch the **CONTINUE** button to view the result of the test. The QC Test Result screen will be displayed with the results of the control test.

12. The Test Result screen will provide the results for the test that has just completed (see Figure 4-43). After viewing and recording the results, touch the **HOME** to return to the Home screen.

13. Test the second control tube. Repeat Step 1 through Step 12 with the second control tube. In this example the first test was with the positive control, therefore the second test would be with the negative control.

Figure 4-43. QC Test Result

This completes the procedure for running a quality control test with the QC lockout enabled using the GeneXpert Xpress II instrument.

If any error messages occur while running the test, see Section 4.9, Error Handling.

4.8 Exiting the Software and Turning Off the System

This section describes how to exit the GeneXpert Xpress IV software and power down the system.

Important **Do not shut down the software and turn off the system if a test is running. Wait until the test finishes running.**

1. To exit the software, you must be in the Home screen.
   - If you are in one of the test screens (but not actually running a test), touch the **CANCEL TEST** button in the upper right corner of the screen. See Figure 4-9 for the location of the **CANCEL TEST** button. A Cancel New Test screen will be displayed. Touch **YES** to go to the Home screen.

- If you are in one of the View Test Result screens, touch the **HOME** button in the upper right corner of the screen to go to the Home screen. See Figure 4-25 and Figure 4-26 for the location of the **HOME** button.

2. From the Home screen, touch the **EXIT** button (see Figure 4-44). The Exit screen will be displayed. See Figure 4-45.

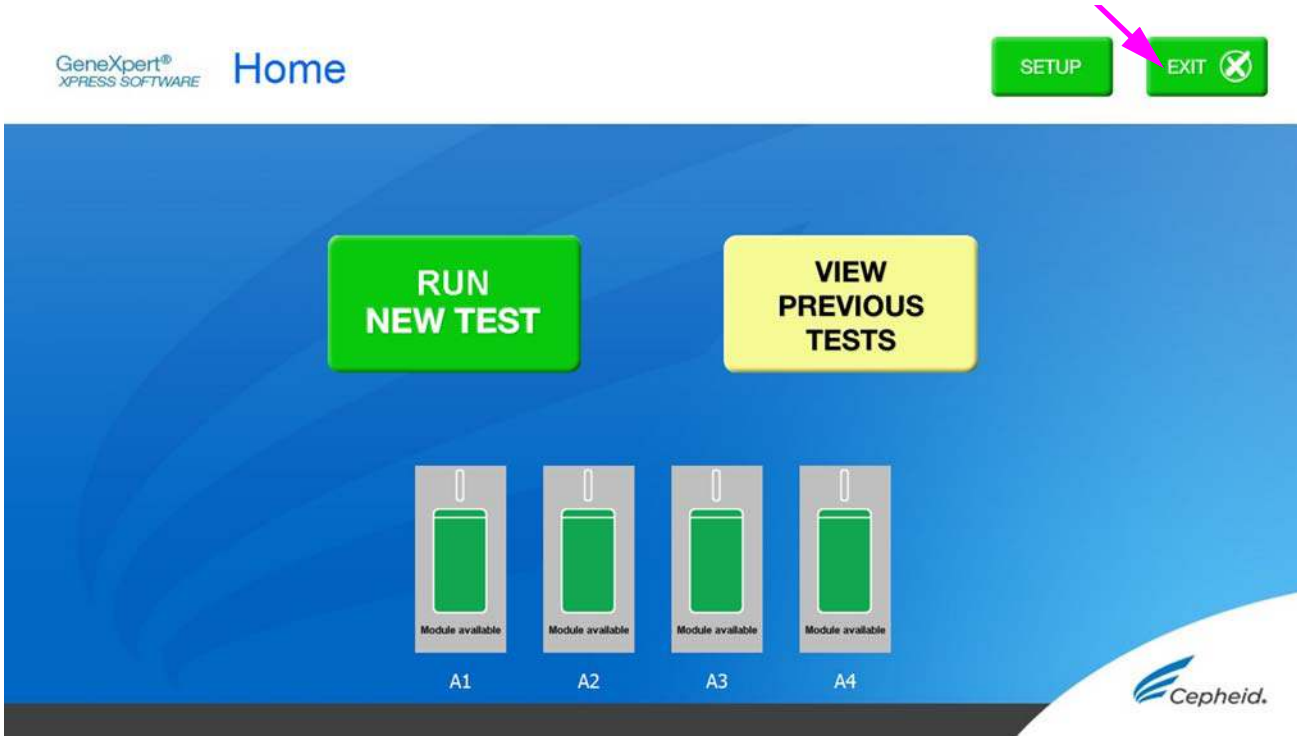


Figure 4-44. GeneXpert Xpress IV Home Screen

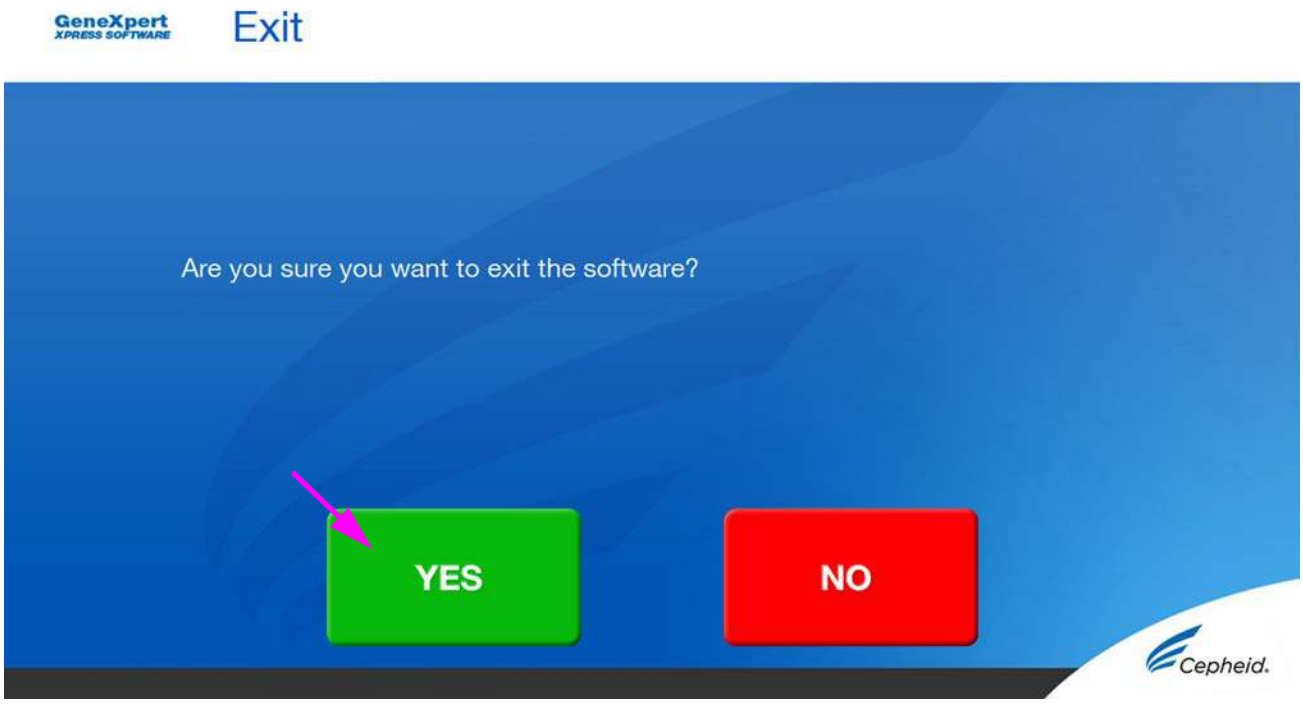


Figure 4-45. GeneXpert Xpress IV Exit Screen

3. On the Exit screen (see Figure 4-45), select **YES** to exit the software to the Windows desktop. See Figure 4-47. The Window desktop will be displayed.

   If you do not want to exit the software, select **NO** (see Figure 4-45).

4. Shut down the computer.

   - For Windows 7, touch the **Start** icon and then touch the **Shut down** button. See Figure 4-47. Windows will shut down and the computer will turn off.
   - For Windows 10, touch the **Power** icon and then select the **Shut down** option. See Figure 4-47. Windows will shut down and the computer will turn off.

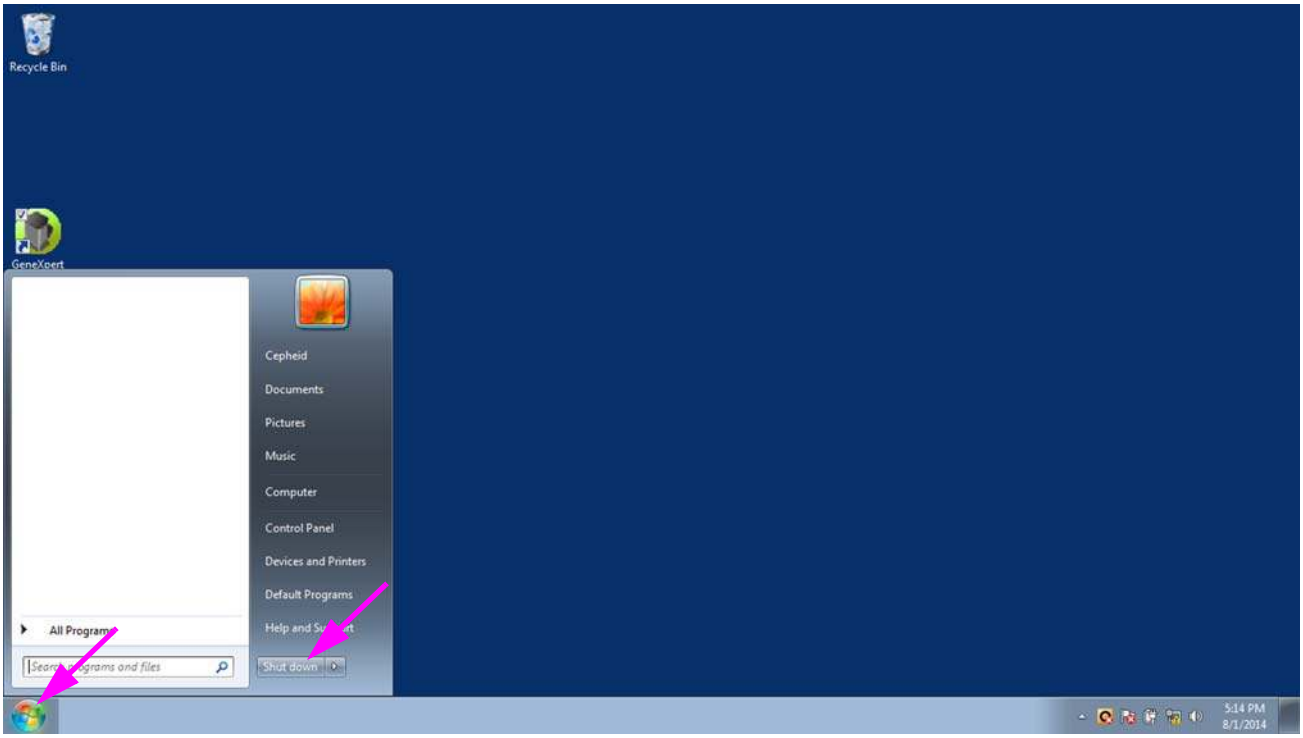


Figure 4-46. Windows 7 Desktop - System Shutdown

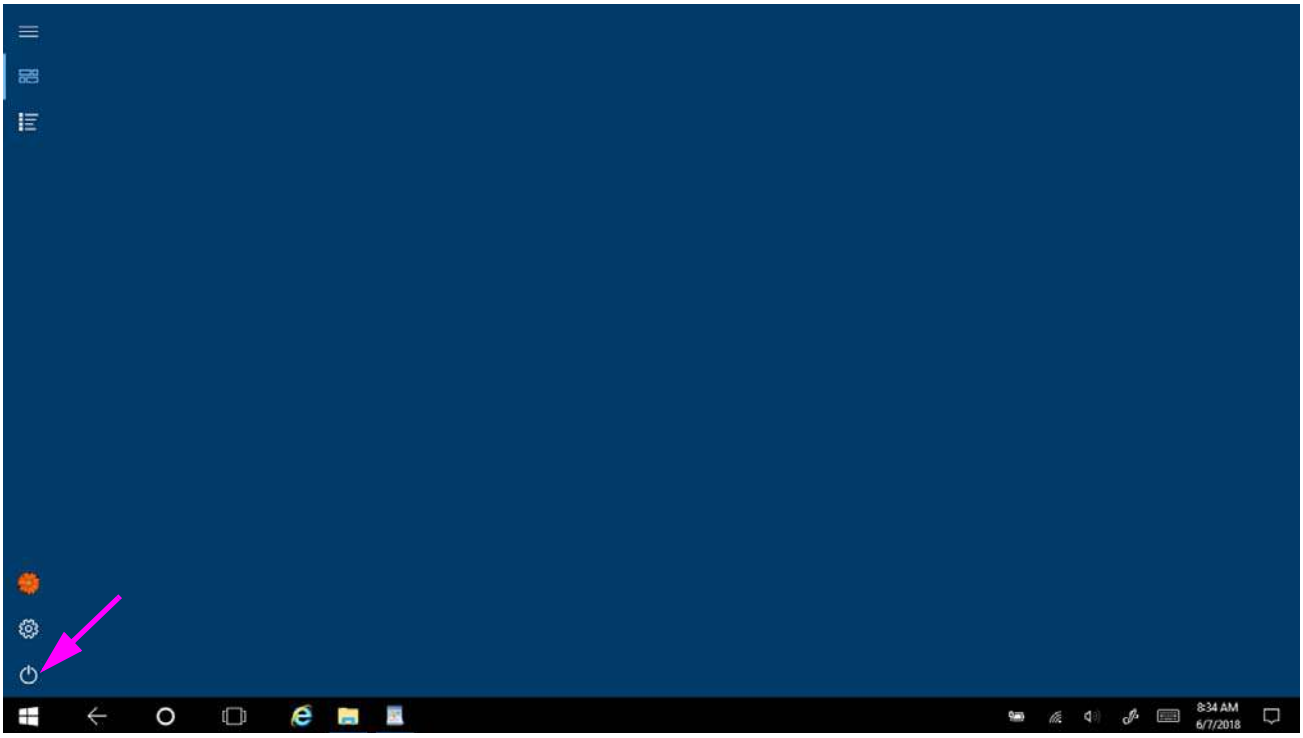


Figure 4-47. Windows 10 Desktop - System Shutdown

5. Turn off the GeneXpert Xpress instrument. The power switch is located on the back of the instrument. Press the switch to the **OFF** (**O**) position. See Figure 4-48.

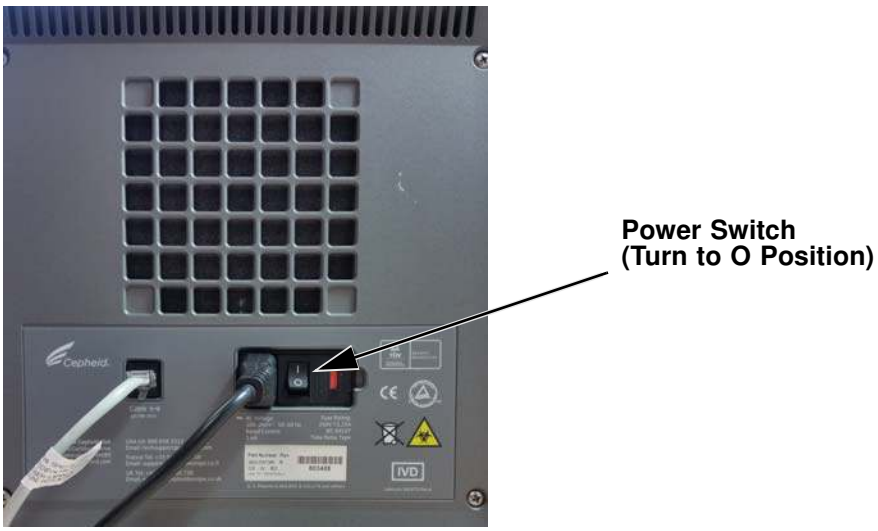


Figure 4-48. Turn OFF the Instrument

The GeneXpert Xpress system is now shut down. To run tests later, see Section 4.1, Starting the GeneXpert Xpress IV and GeneXpert Xpress Software.

4.9 Error Handling

This section describes how to handle any errors that may occur when using the GeneXpert Xpress system. Some of the errors that may occur are shown below.

Cartridge Already Used Error Screen

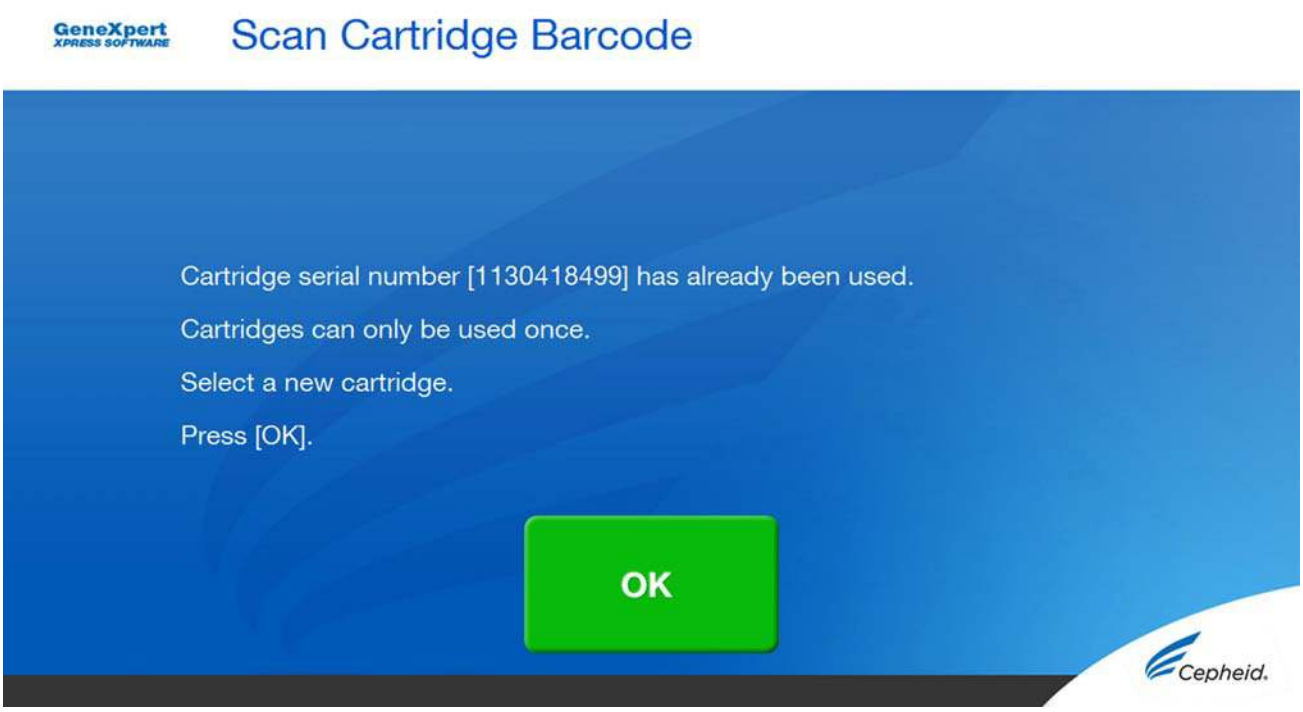


Figure 4-49. Cartridge Already Used Error Screen

If the Cartridge Already Used error screen is displayed, a cartridge with the same serial number has already been run on the system. Click **OK** to repeat the test using a new cartridge and leftover specimen from the initial test. Follow the instructions on the screen.

Communication Error Screen

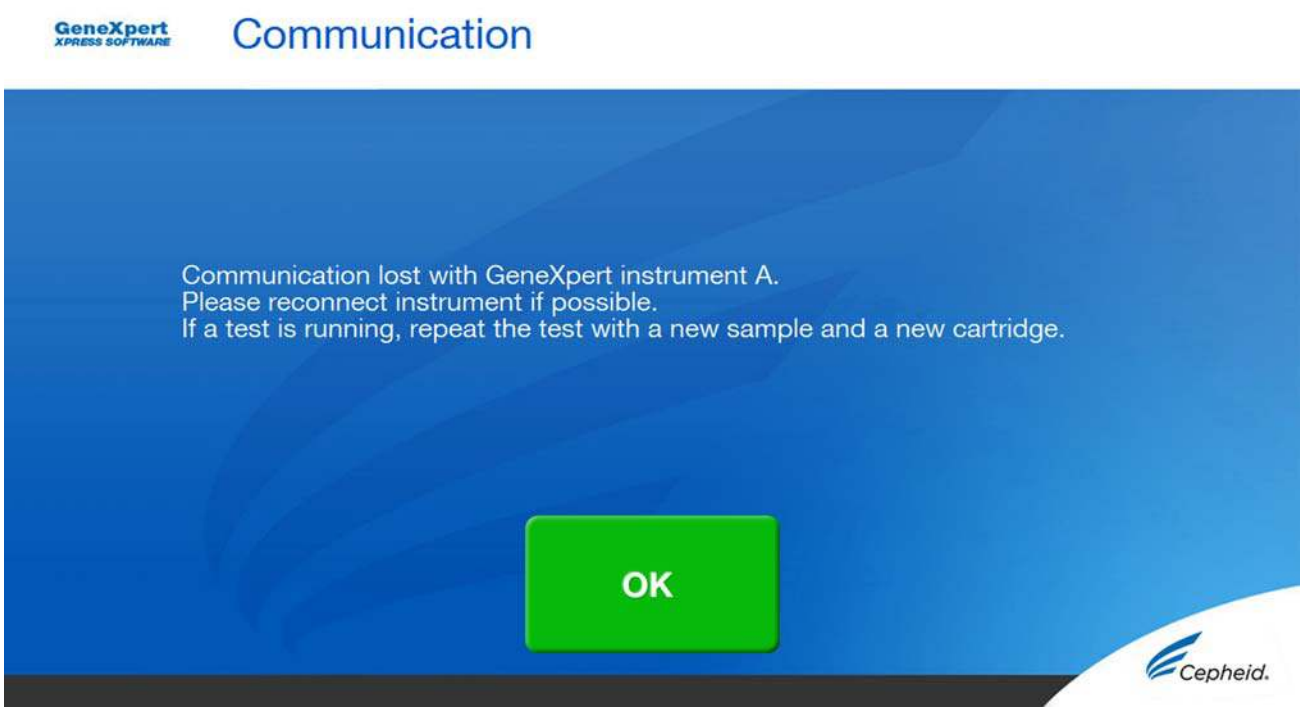


Figure 4-50. Communication Error Screen

If the Communication error screen is displayed, communication has been lost between the computer and the instrument. Ensure that the instrument is plugged into the power outlet, the power switch is on and the blue light on the front of the instrument is on. Check that the communication cable between the instrument and the computer is plugged in at both ends. Call Cepheid Technical Support if the problem continues.

If the problem has been resolved and this occurred while the system was running a test, click **OK** to repeat the test using a new cartridge and leftover specimen from the initial test. Follow the instructions on the screen.

Clear Instrument Error Screen

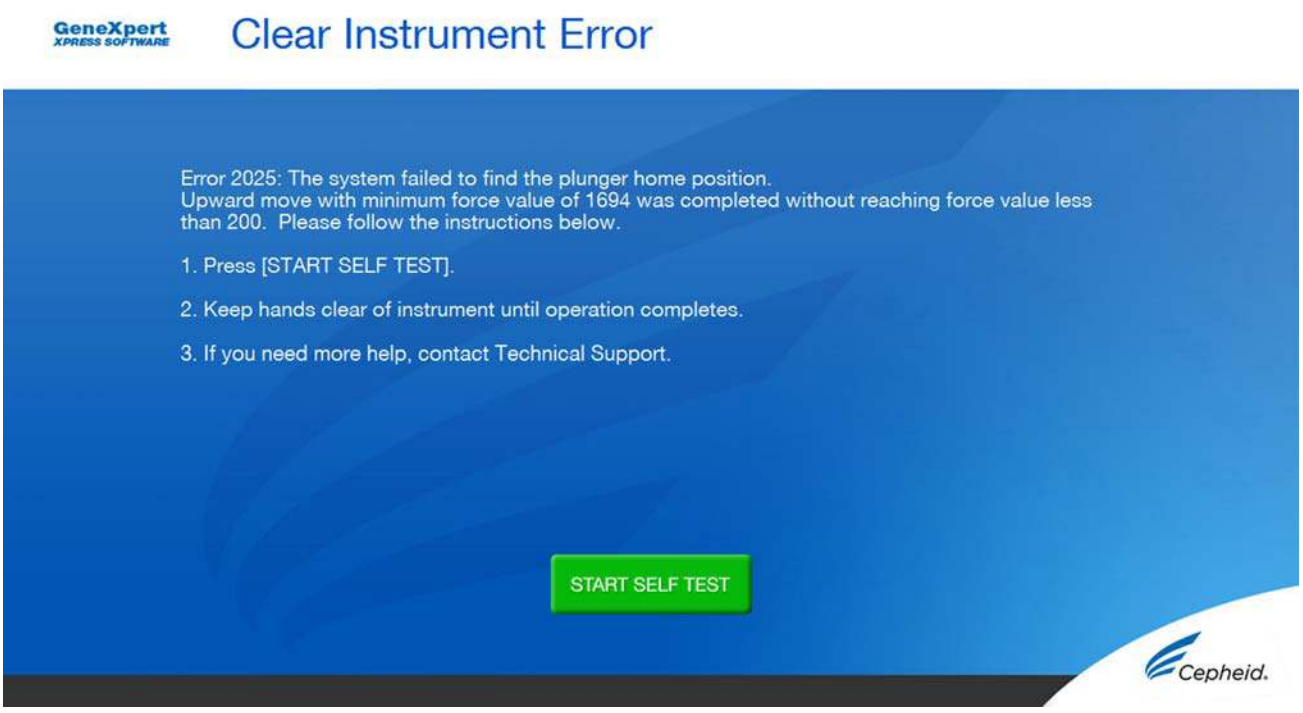


Figure 4-51. Clear Instrument Error Screen

If the Clear Instrument Error screen is displayed, a mechanical error has occurred on the instrument. Touch the **START SELF TEST** button. The instrument will reset the mechanics and the Home screen will be displayed. Call Cepheid Technical Support if the problem continues.

Repeat the test using a new cartridge and leftover specimen from the initial test. Follow the instructions on the screen.

4.10 Setup

This section describes the use of the Setup functions of the GeneXpert Xpress software. The Setup screen allows you to display and read the software license information.

1. To access the Setup screen, you must be in the GeneXpert Xpress IV Home screen.
2. From the Home screen, touch the **SETUP** button (see Figure 4-52). The Setup screen will be displayed. See Figure 4-53.

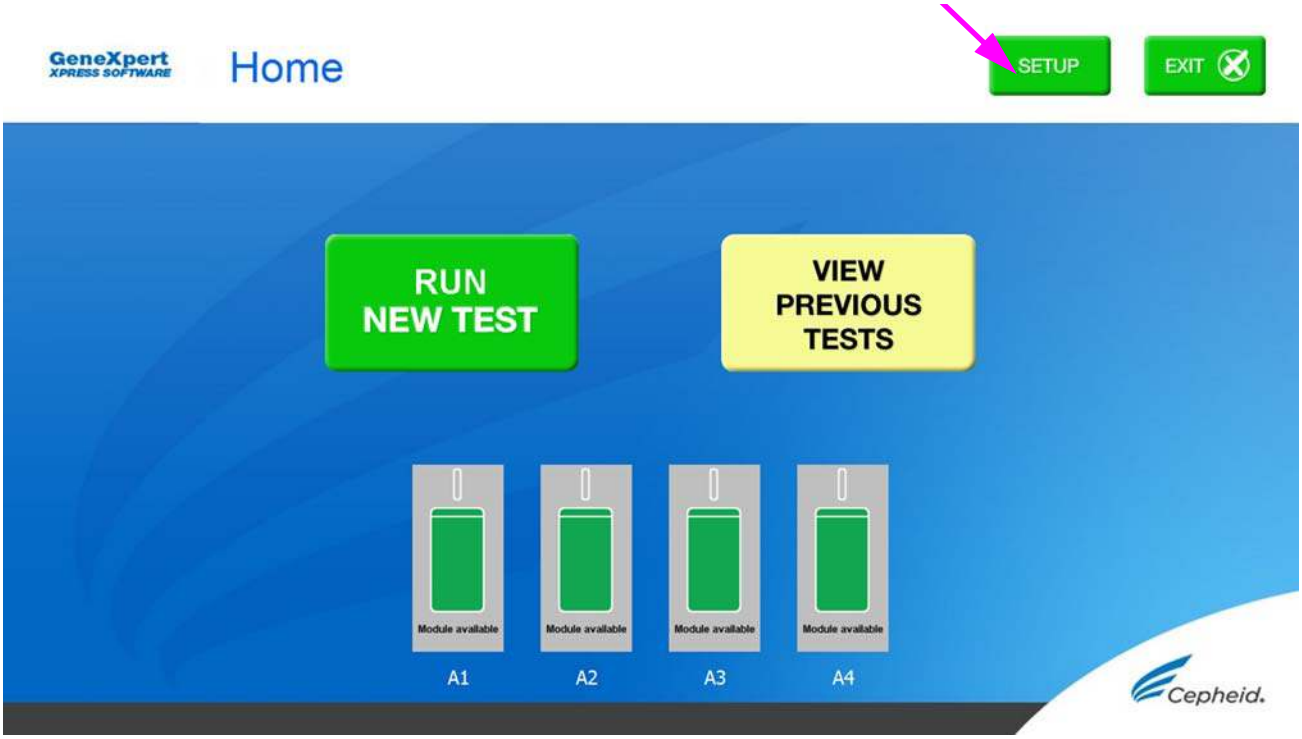


Figure 4-52. GeneXpert Xpress Home Screen

Figure 4-53. GeneXpert Xpress Setup Screen

3. On the Setup screen (see Figure 4-53), touch **ABOUT** to view the software license agreement. The License Information screen is displayed. See Figure 4-54.

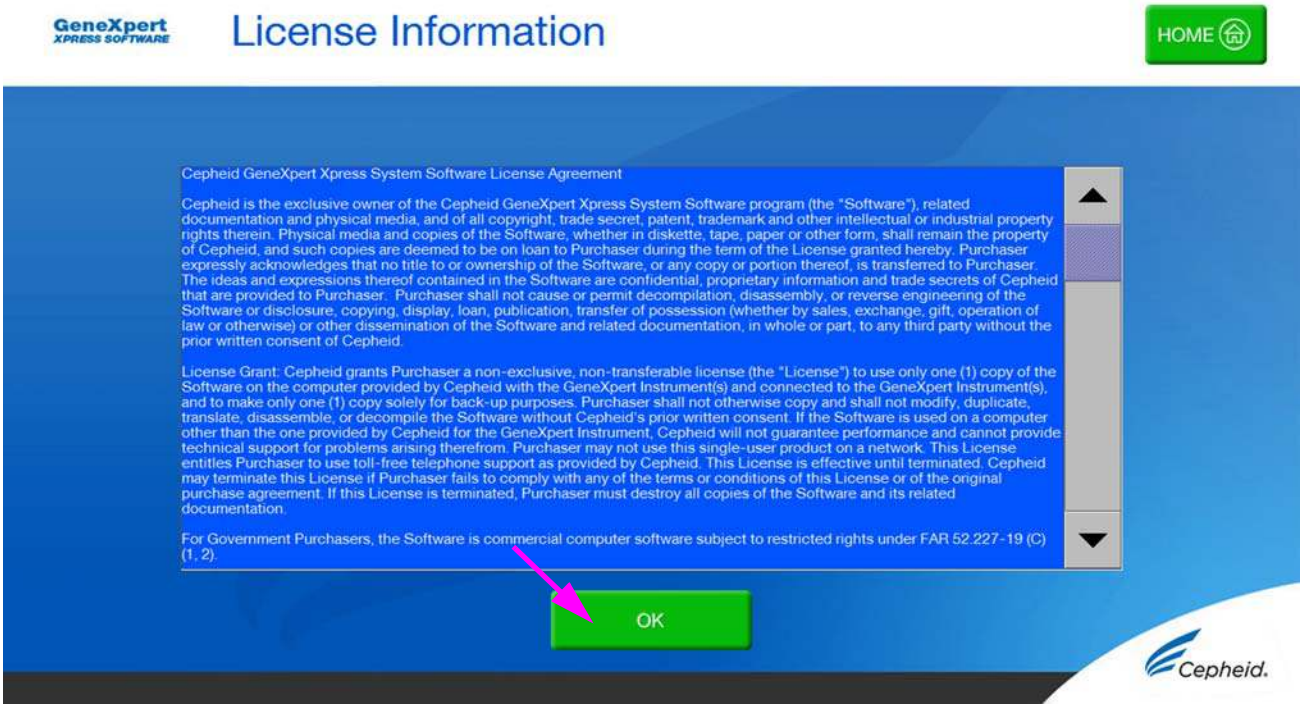


Figure 4-54. GeneXpert Xpress IV License Information Screen

4. On the License Information screen (see Figure 4-54), you can read the software license agreement for GeneXpert Xpress IV. Use the scroll bar on the right to scroll down to read the entire agreement.

5. To return to the Setup screen, touch the **OK** button or to return to the Home page, touch the **HOME** button.

5 Administrative Tasks

This chapter explains how to use the run administrative tasks for the GeneXpert Xpress using the GeneXpert Dx software. The topics are as follows:

- Section 5.1, Creating User Accounts and Passwords
- Section 5.2, Starting the GeneXpert Dx Software
- Section 5.3, Enabling Logins and Passwords
- Section 5.4, Assigning Instrument Letters
- Section 5.5, Managing Assay Definitions
- Section 5.6, Archiving the Tests
- Section 5.7, Performing Database Management Tasks
- Section 5.8, Purging Tests from the Database
- Section 5.9, Connecting to the Printer with a Direct USB Connection
- Section 5.10, Returning to the GeneXpert Xpress Software

Note The actions described in this chapter are intended for the administrative user and may not be required by all organizations.

Note Use the GeneXpert Dx software to perform the activities described in this chapter. If assistance is required, contact Cepheid Technical Support. See the Technical Assistance section in the Preface for contact information.

5.1 Creating User Accounts and Passwords

Note The GeneXpert Xpress software is configured to run with no user accounts and no passwords required. Use this section to set up user accounts and passwords only if your organization requires it.

This section provides instructions to change Windows passwords, and manage GeneXpert Xpress user accounts and passwords. Included is information on adding new users, editing profiles and removing users. Adding user accounts is optional for operation of the GeneXpert Xpress software.

By default, GeneXpert Xpress passwords are not enabled so the user will not be prompted to log in during software start-up or when performing a test. However, if passwords are enabled, the user will be asked to log in during software start-up and to log in each time a new test is performed.

5.1.1 Logging Onto the System

This section describes how to log onto the system.

1. Turn on the computer by sliding or pressing the power switch on the side of the computer.
2. Wait for the system to boot.
   - On Windows 7, the Windows Account screen appears. See Figure 5-1.
   - On Windows 10, the Windows Lock screen appears. See Figure 5-2. Touch anywhere on the screen and swipe up to display the Windows Account and Password screen. See Figure 5-4.
3. On the Windows Account screen, select the Cepheid user account (see Figure 5-1 and Figure 5-4).
   - On Windows 7, the Windows Password screen appears. See Figure 5-3.
   - On Windows 10, the Cepheid user account password field appears. See Figure 5-4.

Figure 5-1. Windows 7 Account Screen

Figure 5-2. Windows 10 Lock Screen

The initial login password is provided below. You will be required to change the password upon first login. Do not change the user name or profile settings. When logging on, use the following:

- Account name: **Cepheid-Admin**
- Password: **cphd**

4. On the Windows Password screen (see Figure 5-3 and Figure 5-4), enter the password and touch the arrow next to the password field. The default password is **cphd** and must be changed upon initial login (as instructed by the software). After the password has been changed by the system administrator, enter the assigned password for future logins.

Figure 5-3. Windows 7 Password Screen

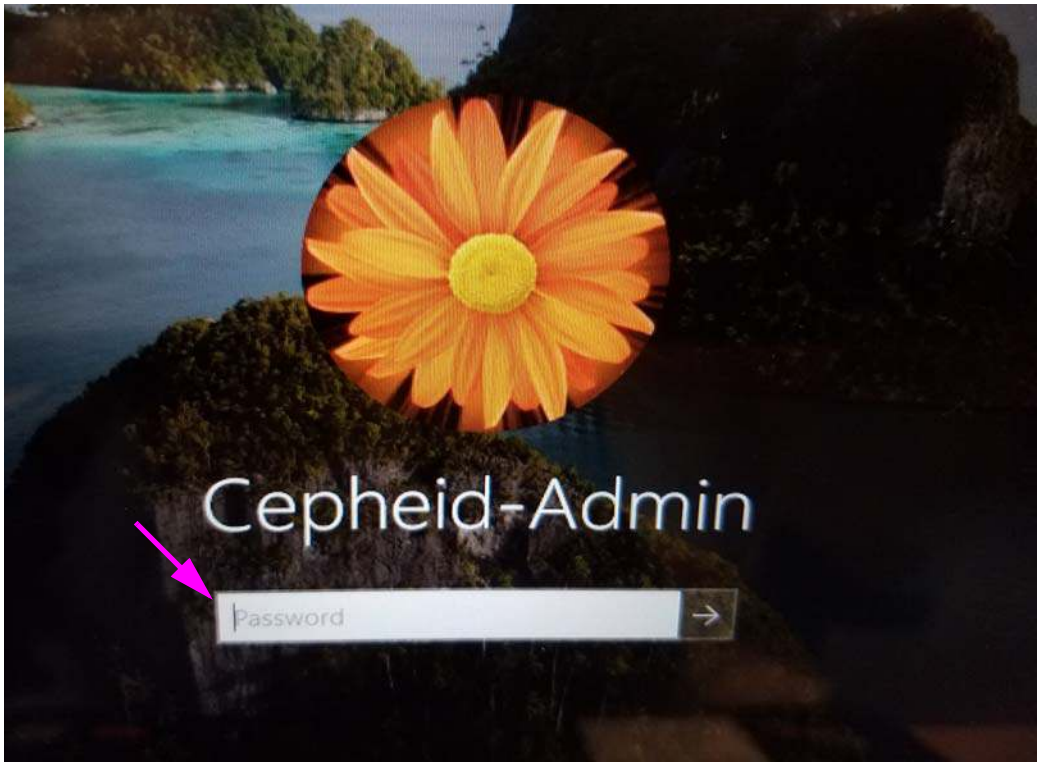


Figure 5-4. Windows 10 Account and Password Screen

5.1.2 Changing the Windows Password

To change your Windows password, log out of the Xpress software but do not shut off the system. Section 3.8, Exiting the Software and Turning Off the System or Section 4.8, Exiting the Software and Turning Off the System. Then perform one of the following steps. For Windows 7, see Section 5.1.2.1, Changing the Windows 7 Password. For Windows 10, see Section 5.1.2.2, Changing the Windows 10 Password.

5.1.2.1 Changing the Windows 7 Password

Note

In tablet mode, touch the icon in the bottom left corner of the screen to display the keyboard (see Figure 5-5).

1. From the opening screen desktop, touch **CTRL**+**ALT**+**DEL**.
2. When the menu displays, touch **Change a password...** from the items listed (see Figure 5-5).

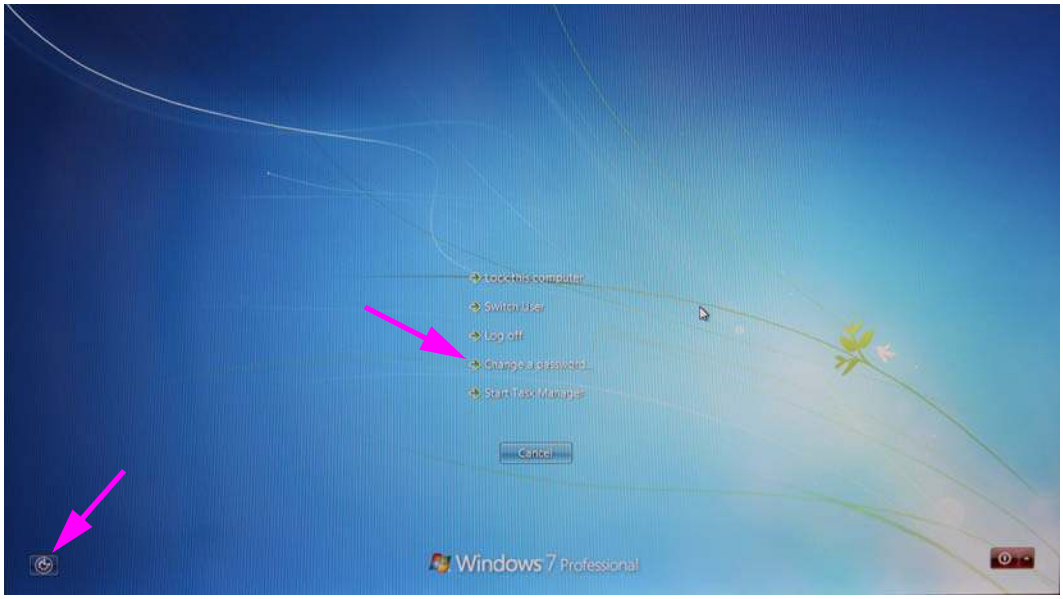


Figure 5-5. Windows Task Menu

3. The dialog box for changing the password is displayed. See Figure 5-6. In the first space provided, enter **cphd**, or if previously changed, your **old password**.

Figure 5-6. Windows Password Dialog Box

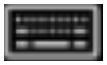
4. Enter your **new password** in the next box.
5. Enter your **new password** once more in the next box to confirm your entry.
6. Touch the blue arrow button.

Note

Remember to record and store your new password information in a safe location.

5.1.2.2 Changing the Windows 10 Password

Note

In tablet mode, touch the keyboard icon  in the bottom right corner of the screen to display the keyboard.

1. From the desktop, touch **CTRL+ALT+DEL**.
2. When the menu displays, touch **Change a password** from the items listed (see Figure 5-7).

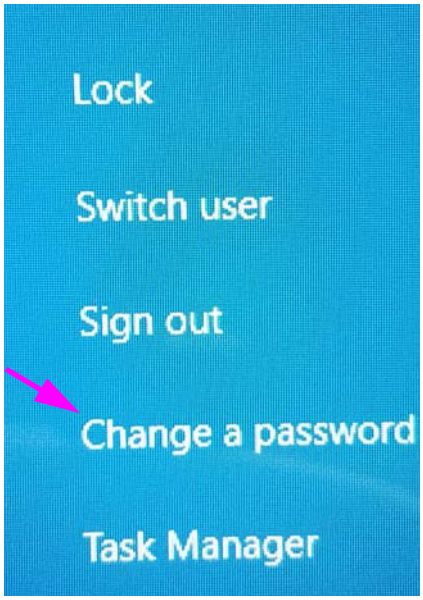


Figure 5-7. Windows Task Menu

3. The dialog box for changing the password is displayed. See Figure 5-8. In the first space provided, enter **cphd**, or if previously changed, your **old password**.

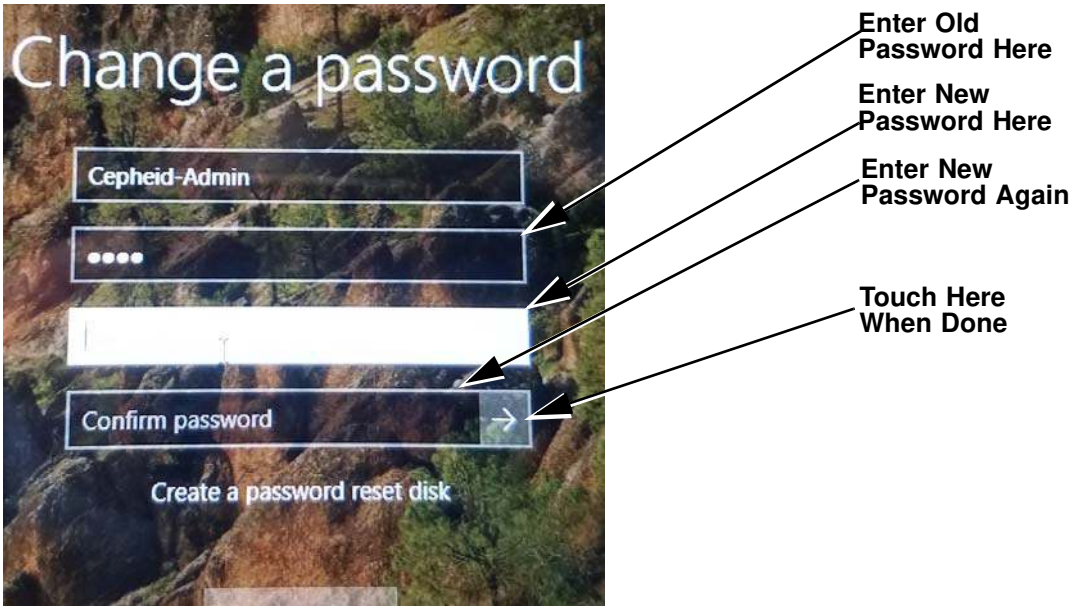


Figure 5-8. Windows Password Dialog Box

4. Enter your **new password** in the next box.
5. Enter your **new password** once more in the next box to confirm your entry.
6. Touch the blue arrow button.

Note Remember to record and store your new password information in a safe location.

5.2 Starting the GeneXpert Dx Software

Use the GeneXpert Dx software to enable logins, define users and set passwords.

Note

It is recommended to use the computer in laptop mode when working with GeneXpert Dx screens, rather than using the touch screen function. This requires a software modification and a physical configuration change for the computer. See Appendix A.This procedure assumes you are working in laptop mode.

Exit the GeneXpert Xpress software.

1. When the system initially starts up, it will be running GeneXpert Xpress. Exit the GeneXpert Xpress software by touching **TOUCH HERE TO BEGIN** button (see Figure 3-7 or Figure 4-7) and then the **EXIT** icon on the Home screen (see Figure 3-8 or Figure 4-8).
2. A prompt will be displayed asking if you are sure you want to exit the software. select the **YES** button.The Windows desktop will be displayed.

For Windows 7 systems, see Section 5.2.1, Starting the GeneXpert DX Software for Windows 7 Systems. For Windows 10 systems, see Section 5.2.2, Starting the GeneXpert DX Software for Windows 10 Systems.

5.2.1 Starting the GeneXpert DX Software for Windows 7 Systems

1. Start the GeneXpert Dx Software by performing the following steps:

   A. On the Windows desktop, select the **Start** icon .
   B. Select **All Programs**.
   C. Select the **Cepheid** folder.
   D. Select **GeneXpert Dx**.
   E. Go to Section 5.2.3, GeneXpert DX Software Initialization

5.2.2 Starting the GeneXpert DX Software for Windows 10 Systems

1. Start the GeneXpert Dx Software by performing the following steps:

   A. On the Windows desktop, select the **Start** icon. Select the **Cepheid** folder.
   B. Select **GeneXpert Dx**.
   C. Go to Section 5.2.2, Starting the GeneXpert DX Software for Windows 10 Systems

5.2.3 GeneXpert DX Software Initialization

The GeneXpert Dx software starts. The GeneXpert Dx splash screen displays followed by the GeneXpert Dx System screen. See Figure 5-10.

Note

The screens shown in this manual are from GeneXpert Dx software running on Windows 7. Screens for GeneXpert Dx software running on Windows 10 will be similar.

Note

During a normal GeneXpert Dx software startup, no login is required. However, if the Login dialog box (see Figure 5-9) displays, log in with your defined credentials or contact Cepheid Technical Support to set up your new login and password to access the GeneXpert Dx software. Be aware that this screen only displays if new user accounts have already been created or if passwords have been enabled by the administrator. See Technical Assistance section in the Preface of this document for contact information.

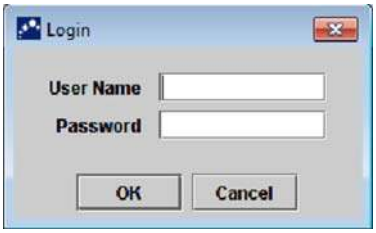


Figure 5-9. Login Dialog Box

The Database Management dialog box displays on top of the GeneXpert Dx System screen. See Figure 5-10.

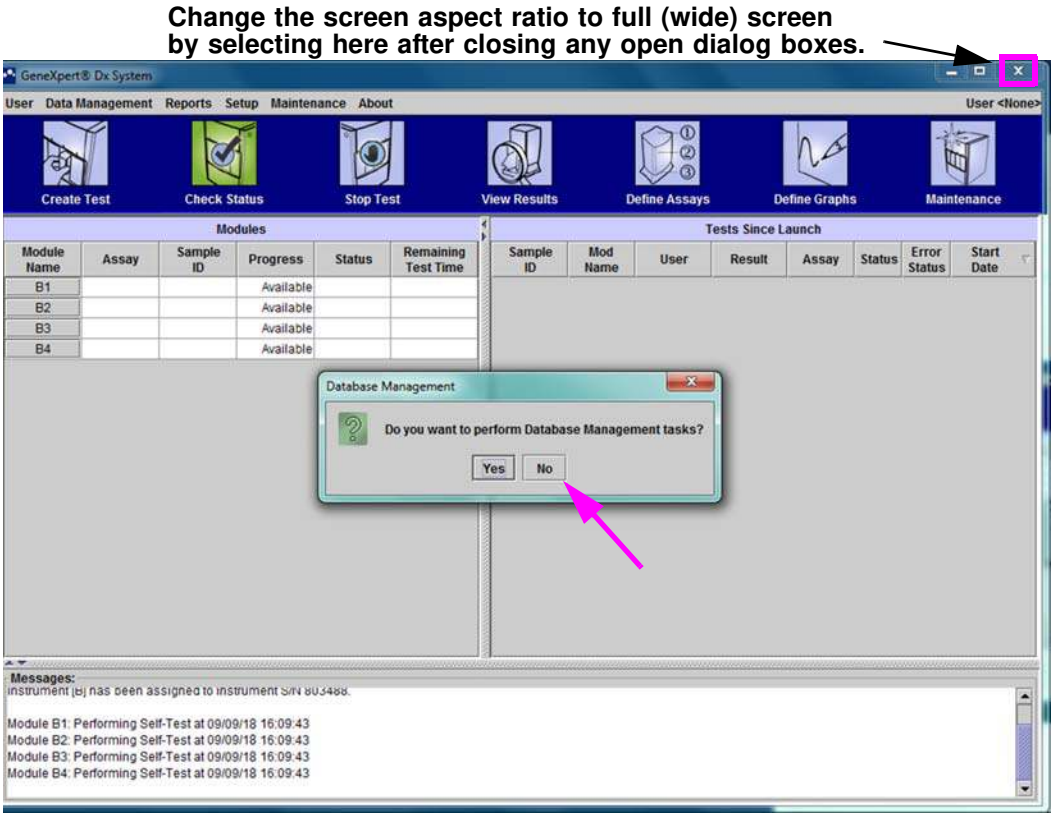


Figure 5-10. GeneXpert Dx System Window Database Management Dialog Box

2. Select **No** in the Database Management dialog box. See Figure 5-10.
3. If an archive is overdue, the Test Archive Reminder dialog box displays (see Figure 5-11). Select **No**.

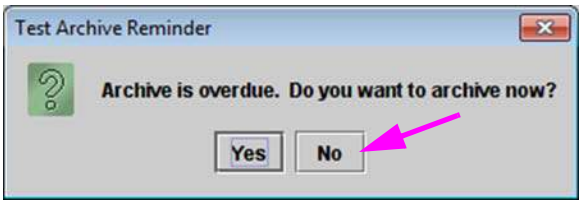


Figure 5-11. Test Archive Reminder Dialog Box

The GeneXpert System screen is displayed.

5.3 Enabling Logins and Passwords

This section describes how to add new users to the system, remove users from the system and enable logins for GeneXpert Xpress.

5.3.1 Adding New Users

Important

The first user to be added must be the administrator. The administrator profile allows for the addition and removal of other users and to configure the system. If an administrator is not assigned, then anyone using the GeneXpert Xpress system has full access to the software.

To add users:

1. In the GeneXpert Dx System window (see Figure 5-12), select the **Setup** menu, and then select **User Administration**. The User Administration dialog box displays. See Figure 5-13.

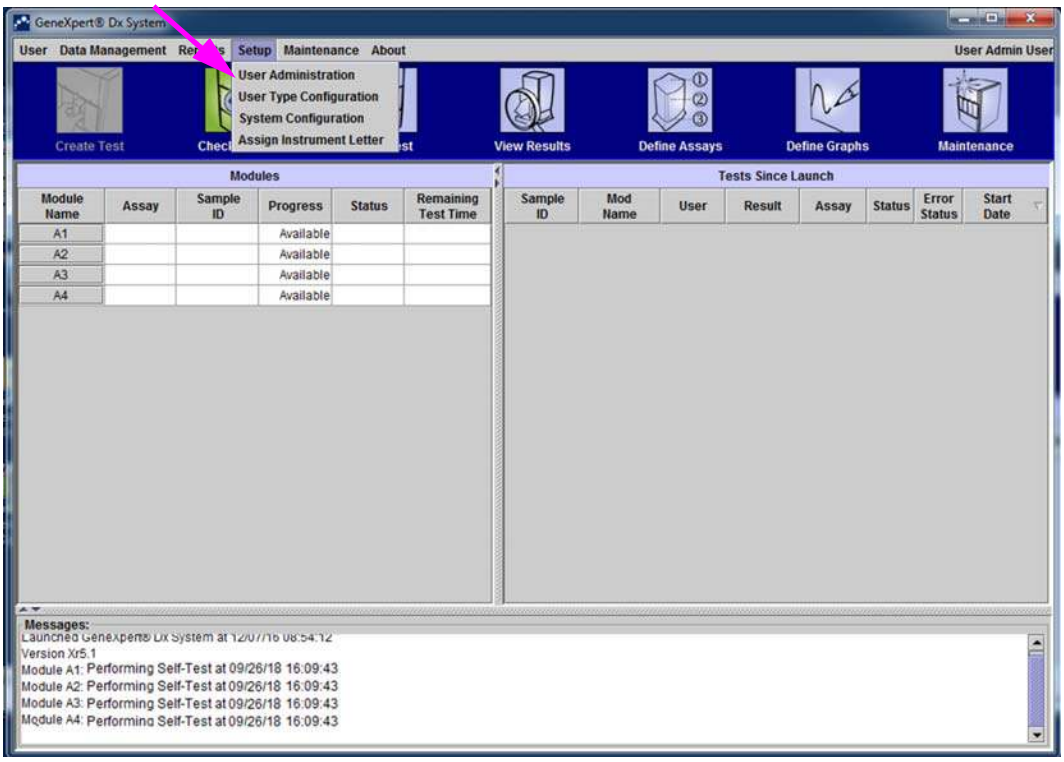


Figure 5-12. GeneXpert Dx System Window with Setup Selected

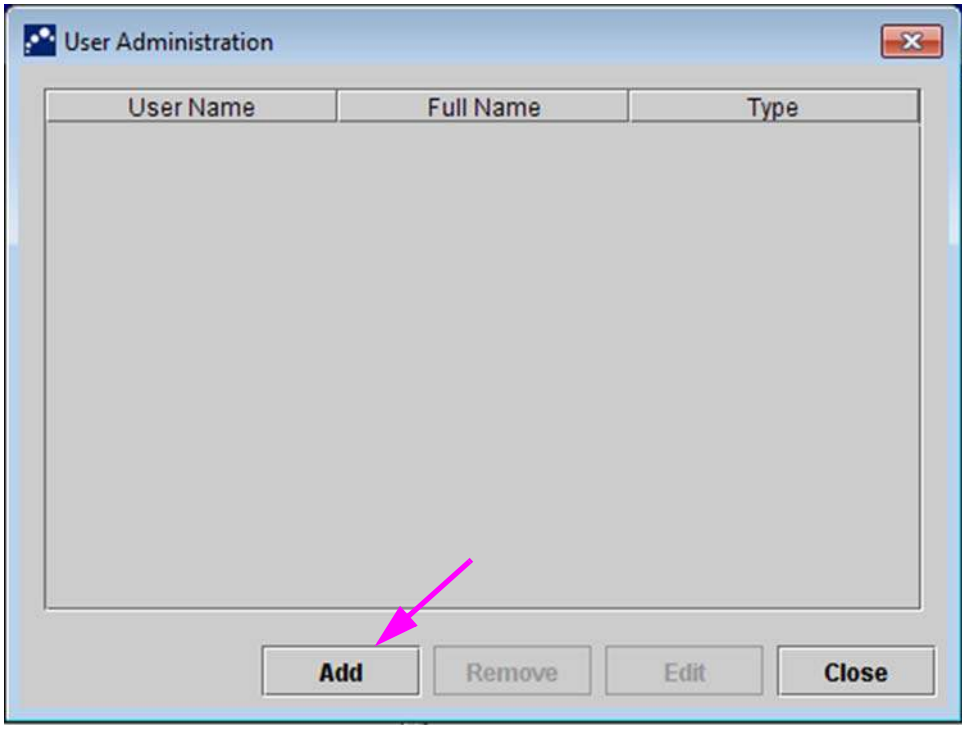


Figure 5-13. User Administration Dialog Box

2. In the User Administration dialog box, select **Add** (see Figure 5-13). The Add User dialog box displays. See Figure 5-14.

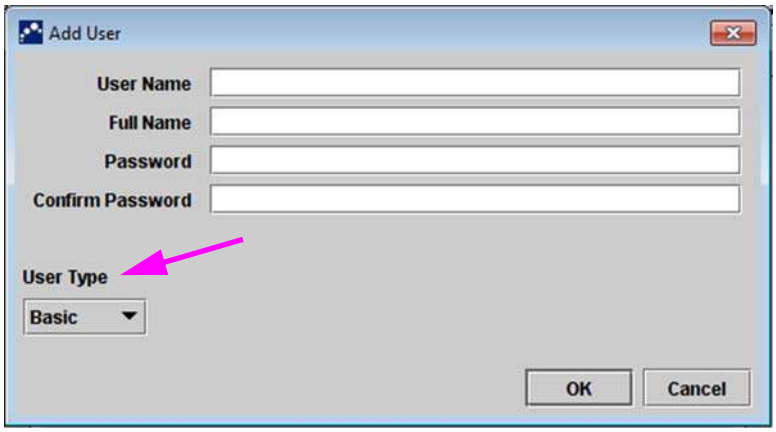


Figure 5-14. Add User Dialog Box

3. In the **User Type** drop-down list, select either **Admin** or **Xpress** for each user (see Figure 5-15). The first user should be an **Admin** user. All other users for the Xpress system will be Xpress users.

Important

The first user to be added must be the administrator. The administrator profile allows for the addition and removal of other users and to configure the system. If an administrator is not assigned, you cannot exit the User Administration dialog box.

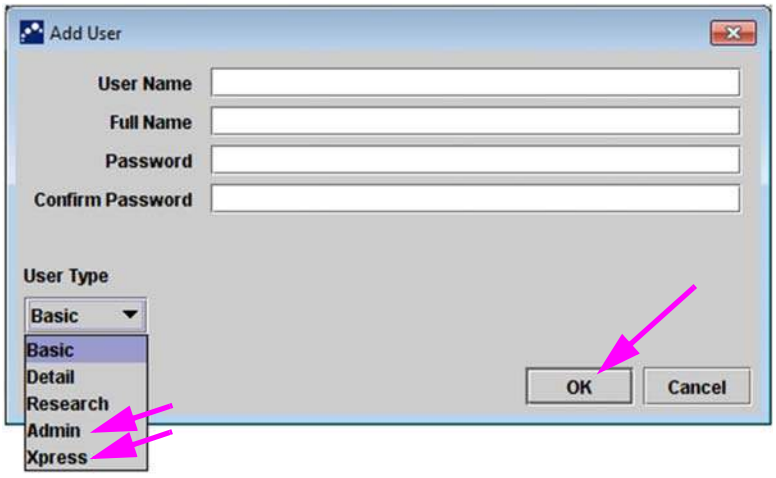


Figure 5-15. Selecting User Type

4. In the **User Name** box, type a unique user name containing 6 to 10 characters that can include spaces. For example, the first user to be added is the administrator, so enter **admin1** (or an equivalent user name).
5. (Optional) In the **Full Name** box, type the full or actual name of the user. For this example, the full name of the administrator will be **Administration User**. The full name can contain a maximum of 32 characters. Do not use special characters, such as the quotation marks (" "). If a name is not provided, the software will automatically insert the user name in this box. This name appears in the test reports.
6. In the **Password** and **Confirm Password** boxes, type the password for the user. The password must contain 6 to 10 characters. See Figure 5-16.

Note Remember to record and store your new password information in a safe location.

7. Repeat Step 2 through Step 6 to add additional users, as needed.

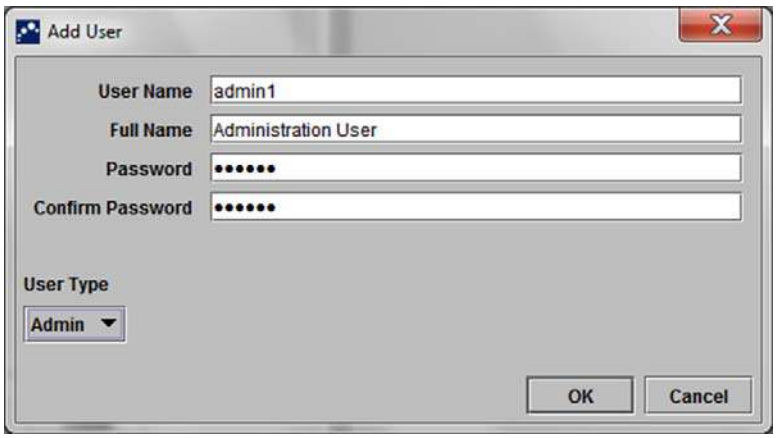


Figure 5-16. Add User Dialog Box

8. When all users have been added, select the **Close** button to close the User Administration dialog box.

This completes the addition of users. If there are no additional changes, exit the GeneXpert Dx software and return to the Xpress software. See Section 5.10.

5.3.2 Edit User Profiles

To change a user name or password, or to make other changes to a user profile:

1. In the User Administration dialog box (see Figure 5-13), in the **User Name** column, select the name of the user you want to edit.
2. Select the **Edit** button (see Figure 5-13). The Edit User dialog box displays. See Figure 5-17.
3. Revise the information as needed, and then select **OK** to save the changes and close the Edit User dialog box.

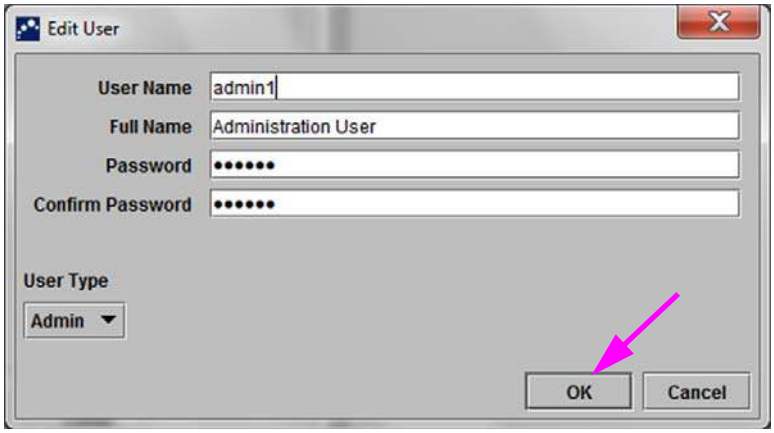


Figure 5-17. Edit User Dialog Box

4. Repeat Step 1 through Step 3 to edit additional user profiles, as needed.
5. When all user profiles have been edited, select the **Close** button to close the User Administration dialog box.

This completes the editing of users. If there are no additional changes, exit the GeneXpert Dx software and return to the Xpress software. See Section 5.10.

5.3.3 Removing Users

To remove a user, in the User Administration dialog box (see Figure 5-13), select the user to be removed, and then select the **Remove** button. Select the **Close** button to save the change and close the User Administration dialog box.

Note When a user is removed from the system, the tests created by that user will remain in the database.

This completes the removing of users. If there are no additional changes, exit the GeneXpert Dx software and return to the Xpress software. See Section 5.10.

5.3.4 Enabling Login for GeneXpert Xpress Users

The default setting for the system is to not require a login for GeneXpert Xpress users. If login is required, first create the administration user and Xpress users as described in Section 5.3.1, Adding New Users. Then perform the following procedure:

1. In the GeneXpert Dx System window (see Figure 5-12), select **Setup** on the menu bar, then select **System Configuration.** The System Configuration dialog box and the **General** tab will be displayed. See Figure 5-18.
2. Select the **Xpress Settings** tab. The **Xpress Settings** tab will be displayed. See Figure 5-19.

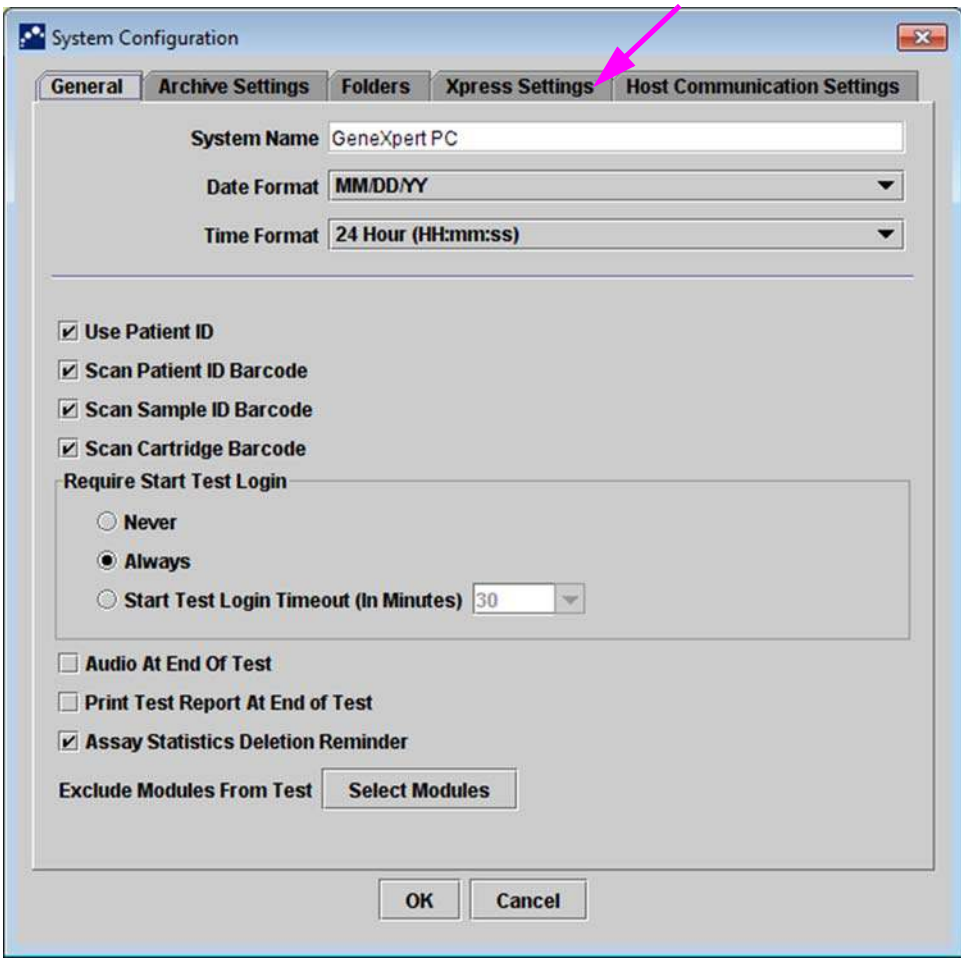


Figure 5-18. System Configuration Dialog Box (General Tab)

3. To require users to log in for each test, check the **Require User Login in Xpress Software** check box on the **Xpress Settings** tab. See Figure 5-19.

   If Xpress User Login is enabled and you do not want to require users to log in when running a test, uncheck the **Require User Login in Xpress Software** check box on the **Xpress Settings** tab. This is the default setting.

Note

If the computer is used in the tablet format, keep the **Use Graphical Keyboard** setting checked. Otherwise, the physical keyboard will be required.

4. When you are finished setting Xpress User login, select the **OK** button. See Figure 5-19. The System Configuration dialog box will close.

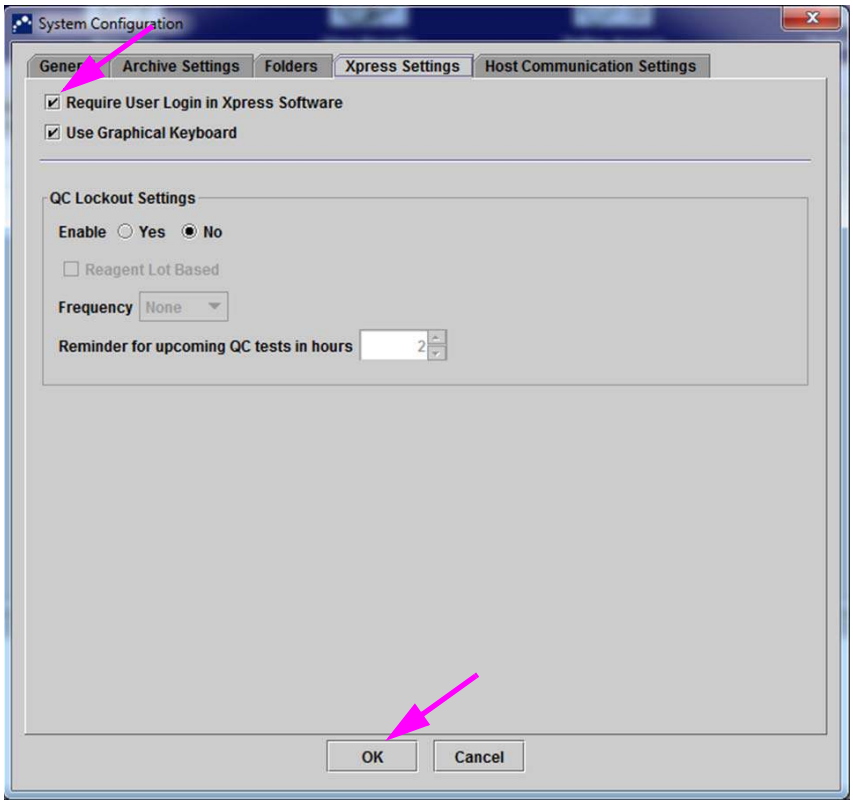


Figure 5-19. Xpress Settings Tab, showing Require User Login Enabled

This completes the procedure for enabling login for GeneXpert Xpress users. If there are no additional changes, exit the GeneXpert Dx software and return to the Xpress software. See Section 5.10.

5.3.5 QC Lockout Settings

Quality Control (QC) samples can run on the Xpress system at any time; however, the system can be set so that QC is required when a new reagent lot is used and/or on a time based interval.

The default setting for the system is to not enable QC Lockout for GeneXpert Xpress users. If QC lockout is required, perform the following procedure:

1. In the GeneXpert Dx System window (see Figure 5-12), select **Setup** on the menu bar, then select **System Configuration.** The System Configuration dialog box and the **General** tab will be displayed. See Figure 5-18.
2. Select the **Xpress Settings** tab. The **Xpress Settings** tab will be displayed. See Figure 5-20.
3. Select the desired options:
    1) To enable QC Lockout, select the **Yes** radio button; to disable it, select **No**.

2) If QC is required with each new reagent lot, check the box next to **Reagent Lot Based.**

3) To require QC based on a time interval, select the desired frequency in the Frequency drop-down box. The available time intervals are **None**, **Daily**, **Weekly**, and **Monthly**. This feature will work if the Reagent Lot Based option is checked or not.

4) Set the numbers of hours the reminder will pop up before QC Lockout will prevent processing patient samples. The time range for the reminder can be set in half hour increments using the up and down arrows on the screen, or typed in.

5) Select **OK.**

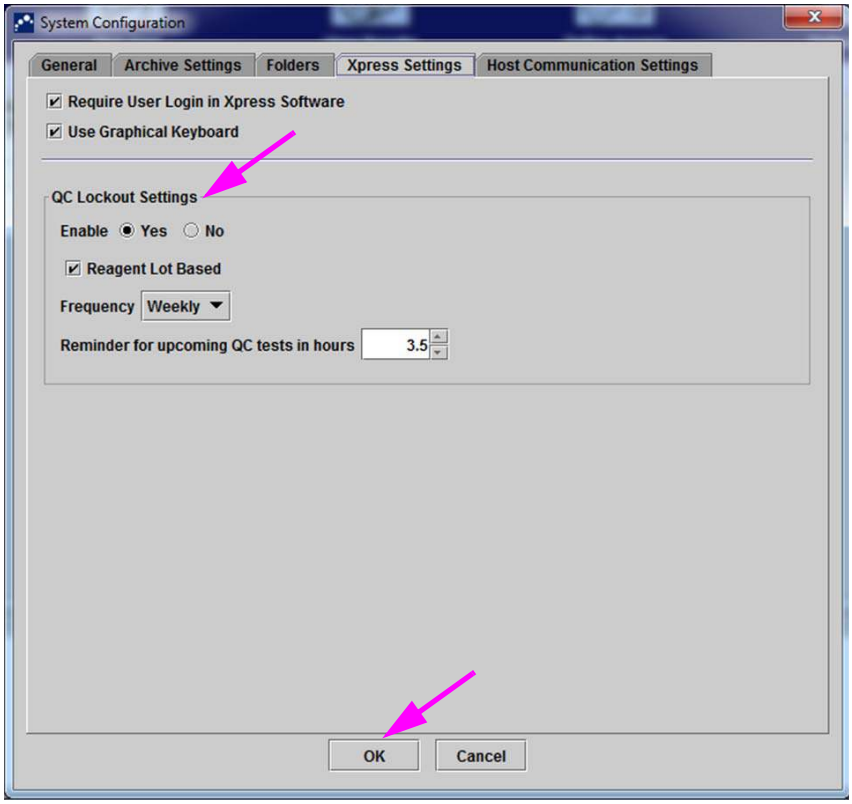


Figure 5-20. Xpress Settings Tab QC Lockout Settings

This completes the procedure for enabling QC for GeneXpert Xpress users. If there are no additional changes, exit the GeneXpert Dx software and return to the Xpress software. See Section 5.10.

5.3.6 Host Communication Settings

To configure the GeneXpert Xpress software for a Laboratory Information System (LIS) interface connection, contact Cepheid Technical Support. See the Technical Assistance section in the Preface for contact information.

5.4 Assigning Instrument Letters

By default, the system is set up to assign a letter (A) to identify the instrument connected to the computer. The following instructions detail how to change the assigned letter to one of your choosing. In addition to assigning an instrument letter, the system also assigns a number (1, 2, 3 or 4) to each module that is installed, from left to right. For example, A1 is the first or left-most module of the instrument. The instrument and module identification displays in the **Module Name** column in all the software windows. See Figure 5-21.

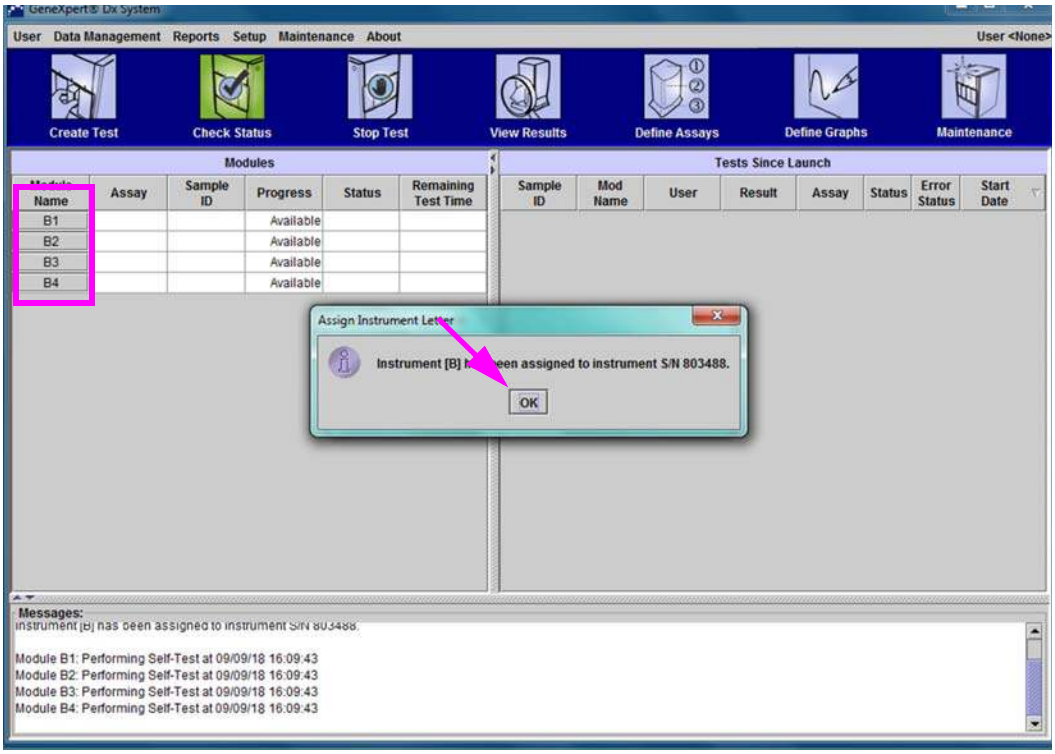


Figure 5-21. GeneXpert Dx System Window with Assign Instrument Letter Dialog Box Overlay

1. In the Assign Instrument Dialog box, select **OK** to acknowledge the assignment of the instrument letter(s), which closes the dialog box. The Database Management dialog box displays (see Figure 5-22).

Note

You will have an opportunity to change the instrument letter assignment later in this section, if needed.

Note

The examples in this section shows how to change instrument letter “B” to “A” on a four module system. The procedure is the same for a 2 module system.

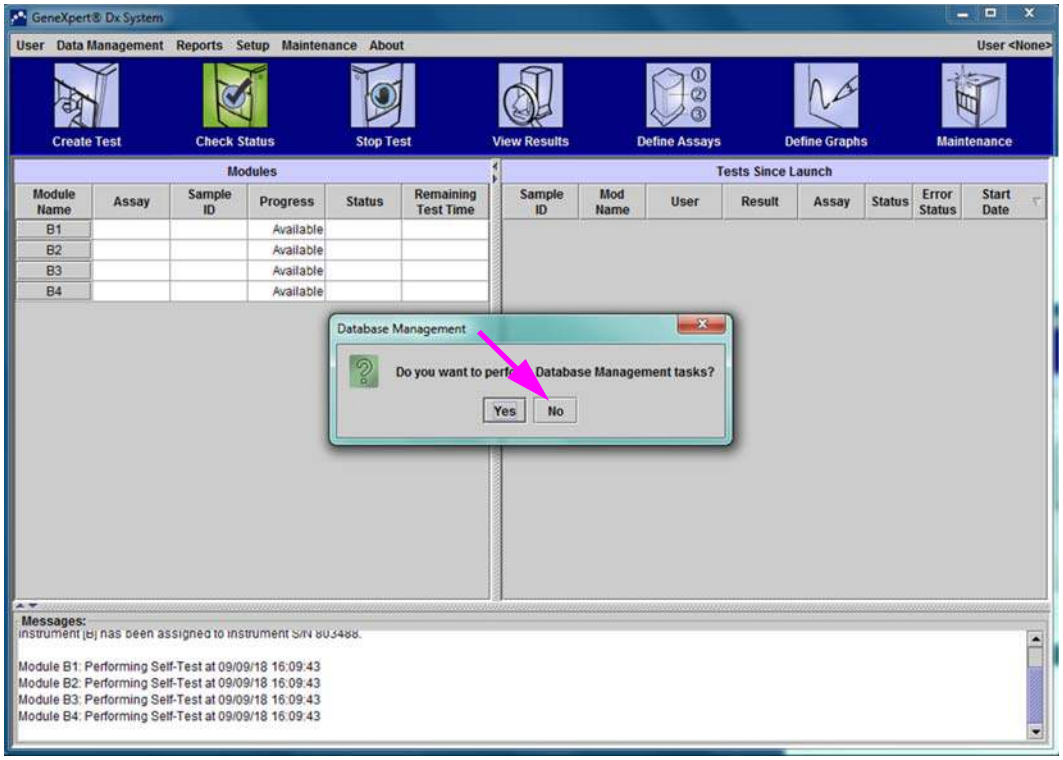


Figure 5-22. GeneXpert Dx System Window - Database Management Dialog Box Overlay

2. In the Database management dialog box, select **NO** to proceed. The GeneXpert Dx System screen displays (see Figure 5-23).

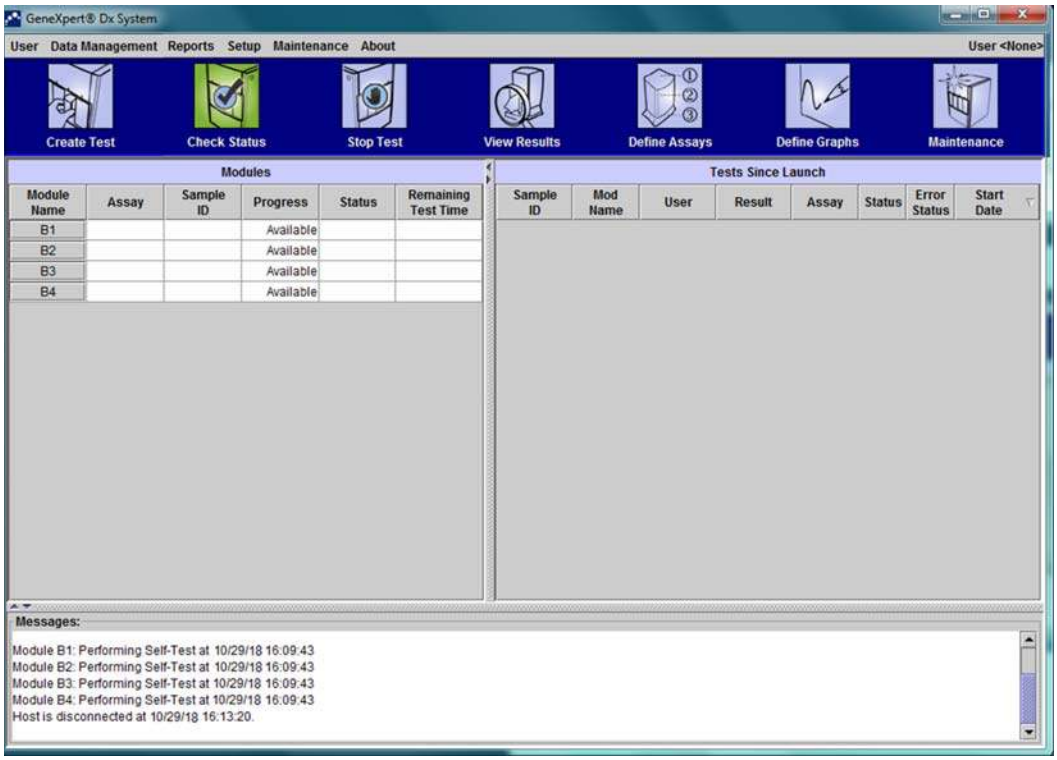


Figure 5-23. GeneXpert Dx System Window

3. In the GeneXpert Dx System window, select **Setup** in the menu bar, and then select **Assign Instrument Letter**. The Assign Instrument Letter dialog box displays. See Figure 5-24. At the same time, the green LED indicators of four modules will flash.

4. To change the assignment letter, select to select the instrument to change and then select **Change Letter** in the Assign Instrument Letter dialog box (see Figure 5-24).

   The Change Letter dialog box displays, as shown in Figure 5-25. Select the letter to be assigned to the module(s) by using the up and down arrows of the Change Letter dialog box.

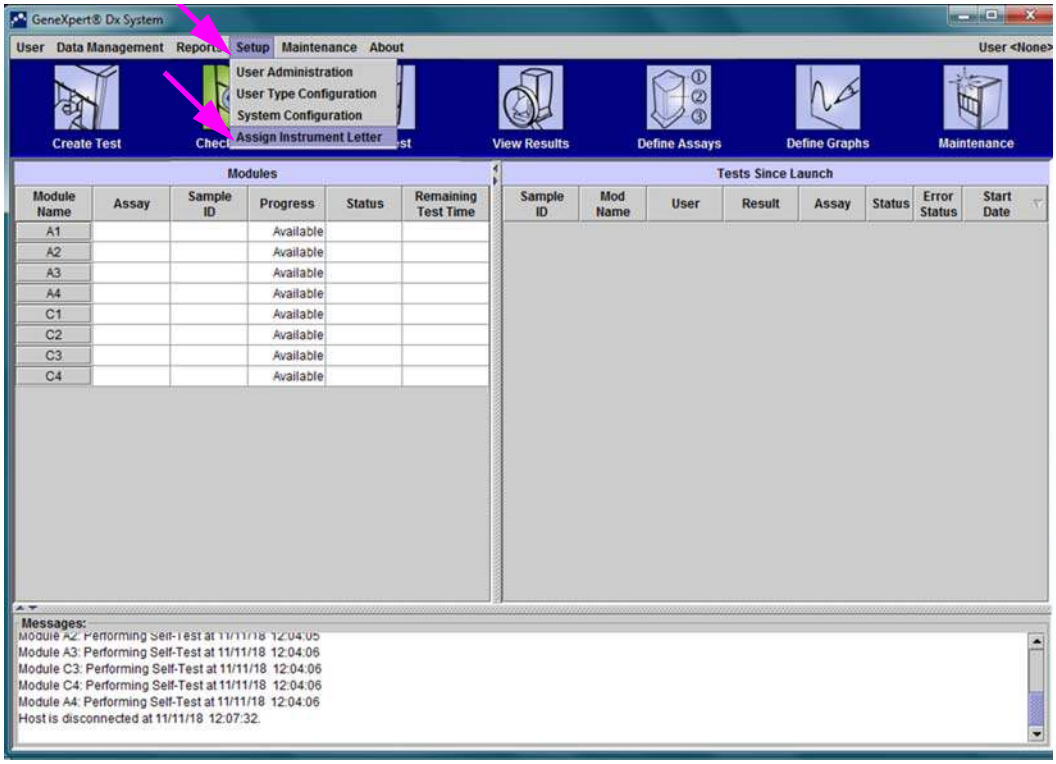


Figure 5-24. GeneXpert Dx System Window, showing the Setup Drop-Down Menu

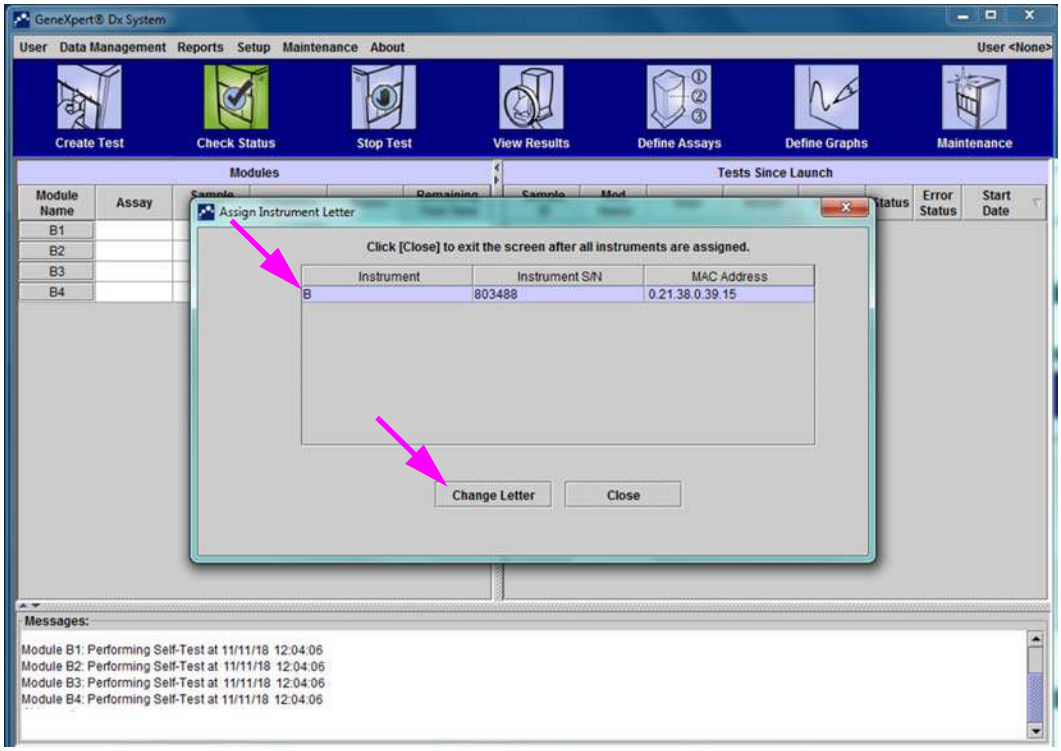


Figure 5-25. GeneXpert Dx System Window with Assign Instrument Letter Dialog Box Overlay

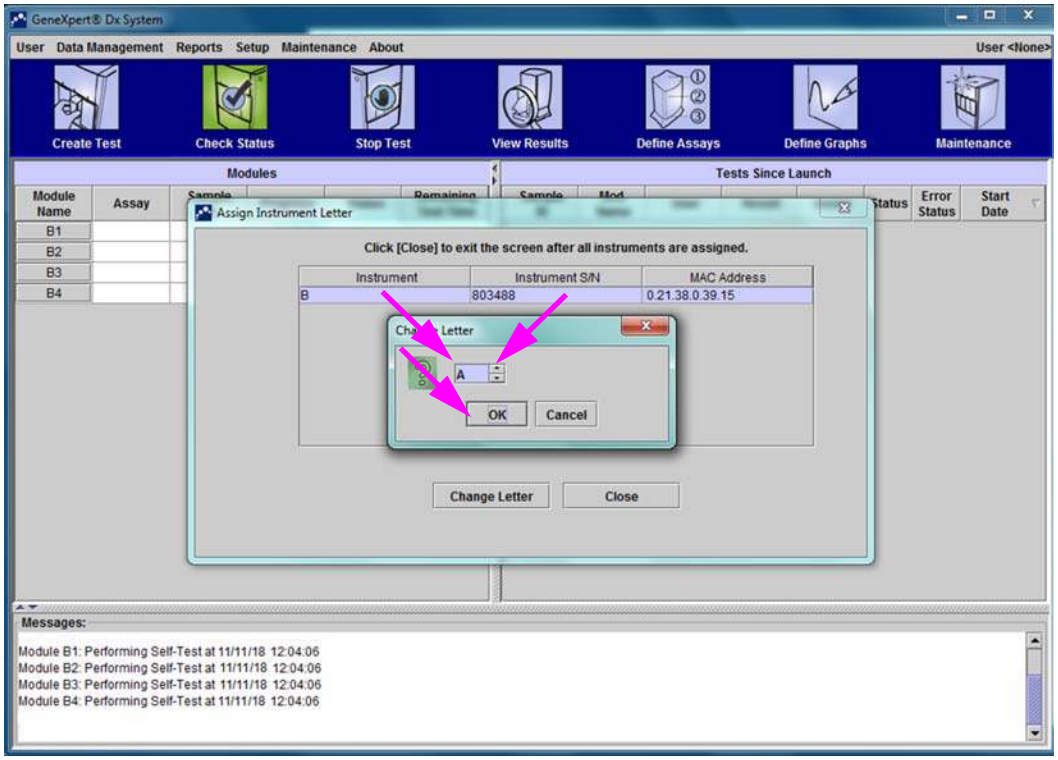


Figure 5-26. GeneXpert Dx System Window with Change Letter Dialog Box Overlay

5. After changing the assignment letter, select **OK**. See Figure 5-26.
6. Select **Close** to close the Assign Instrument Letter dialog box (see Figure 5-26).
7. Select **Close** and another dialog box will display, indicating that updated instrument letters will be effective after the software is restarted (see Figure 5-27)
8. Acknowledge the overlay message about restarting the software (see Figure 5-27) by selecting **OK**.
9. On the **User** Drop-Down menu on the GeneXpert Dx system window, select **Exit** to shut down the software (see Figure 5-28).

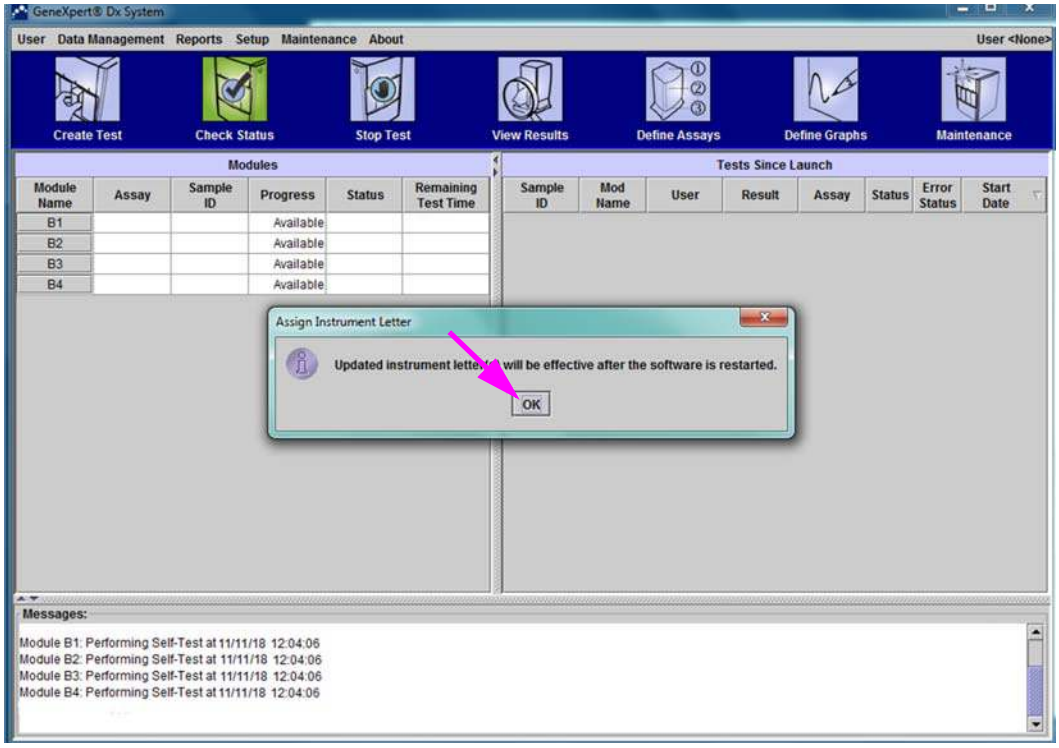


Figure 5-27. GeneXpert Dx System Window with Assign Instrument Letter Dialog Box Overlay

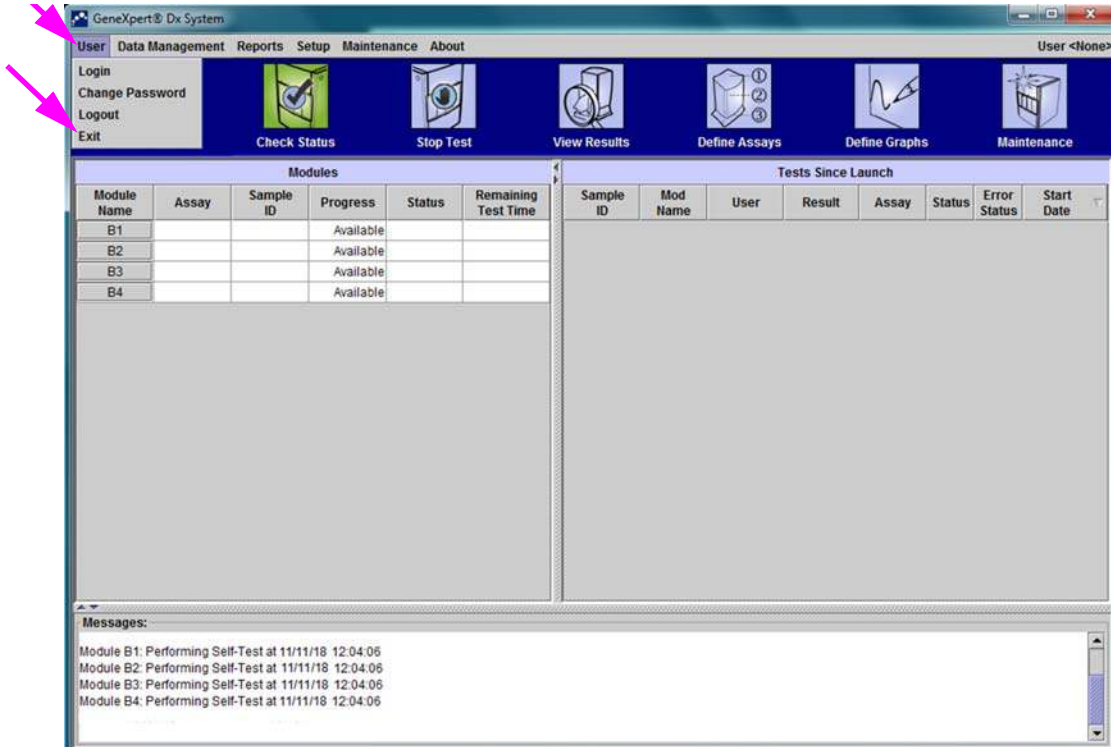


Figure 5-28. GeneXpert Dx System Window showing User Drop-Down Menu and Exit Selection

10. The Database Management dialog box will display on top of the GeneXpert Dx System window (see Figure 5-22). Select **No** in the Database Management dialog box to continue with the software shut down.
11. Restart the system by double-selecting the GeneXpert Dx icon on the desktop.
12. When the software restarts, the GeneXpert Dx system window will be displayed showing the updated instrument letter assignment(s). The Database Management dialog box will be displayed on top of the GeneXpert Dx System window (see Figure 5-22). Select **No** in the Database Management dialog box to continue.

Note Since this is the initial startup of the software, there are no database management tasks to perform.

The GeneXpert Dx system window will be displayed, showing the updated letter assignments (see Figure 5-29).

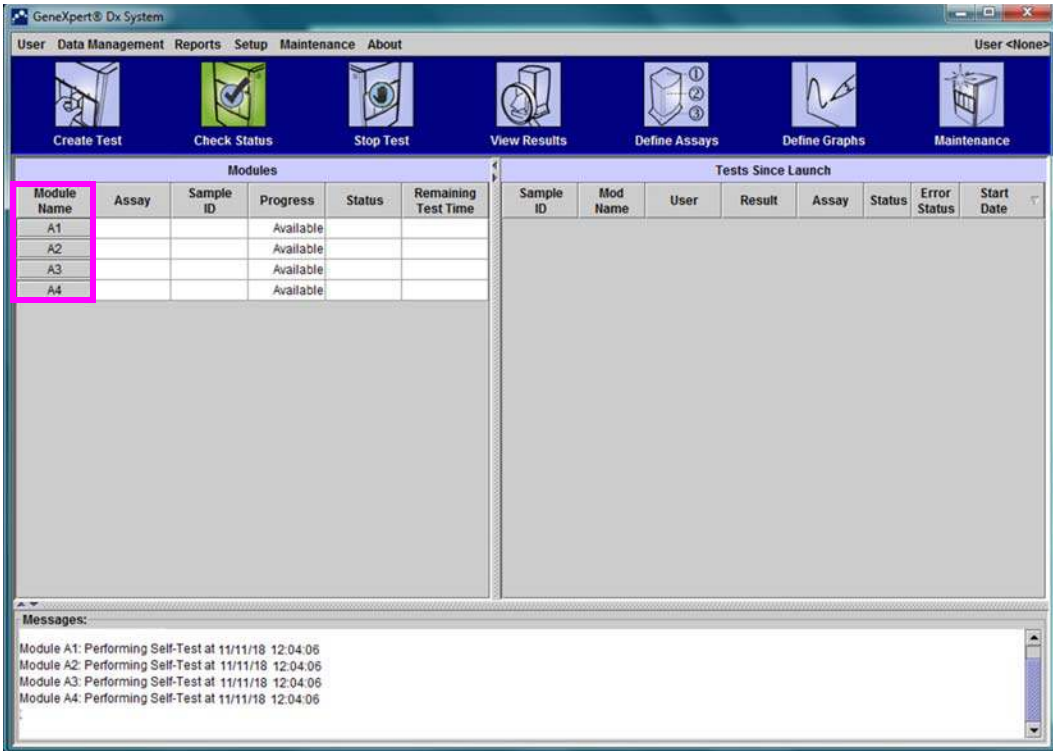


Figure 5-29. GeneXpert Dx System Window at System Restart

This completes the procedure for assigning instrument letters. If there are no additional changes, exit the GeneXpert Dx software and return to the Xpress software.
See Section 5.10.

5.5 Managing Assay Definitions

Note This section describes tasks that users with the appropriate permissions can perform.

An assay definition contains a series of programmed steps that the GeneXpert Xpress uses to perform sample preparation, amplification and detection procedures. *In vitro* diagnostic assay definition (.gxa) files are located on the CDROM located in the assay kit and imported into the software (see Section 5.5.2, Importing Assay Definitions). Assay definitions that are no longer in use can also be deleted (see Section 5.5.3, Deleting Assay Definitions).

5.5.1 The DVD Drive

The usual way to import assay definitions from the CDROM is by using the DVD drive supplied with the system.

Depending on the computer supplied with your system, the DVD drive is connected in one of two ways.

1. Locate the DVD drive. The DVD drive is shipped in the accessories box and is labeled as an item to save.
2. Plug the DVD drive in as shown. You will need to disconnect the scanner.

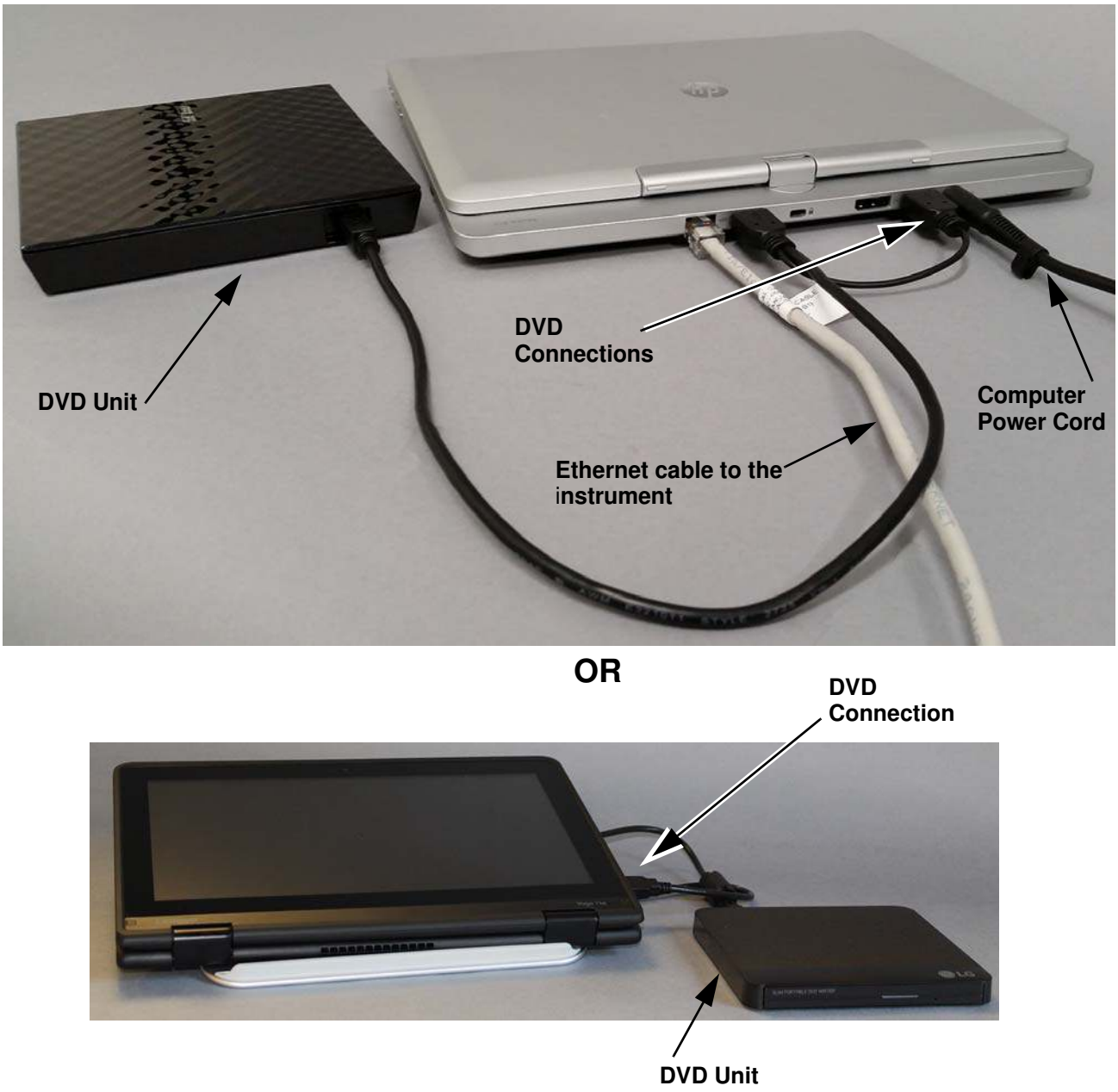


Figure 5-30. DVD

3. Press the **Eject** button on the front of the DVD drive to open the door.
4. The CDROM is located in the assay kit. Insert the assay definitions CD into the DVD drive and close the DVD drive door. The green light on the front of the DVD drive will flash while the drive reads the CD.

Import the assay definitions following the procedure in Section 5.5.2.

5.5.2 Importing Assay Definitions

Note

Although *in vitro* diagnostic assay definitions can be imported, the GeneXpert Dx software does not allow the assay definitions to be modified.

To import new assay definitions open the GeneXpert Dx software as described in Section 5.2, Starting the GeneXpert Dx Software:

1. In the GeneXpert Dx System window, select **Define Assays** on the menu bar. The Define Assays window displays. Figure 5-33 shows the Define Assay window for the GeneXpert Xpress administrator. (see Figure 5-31).

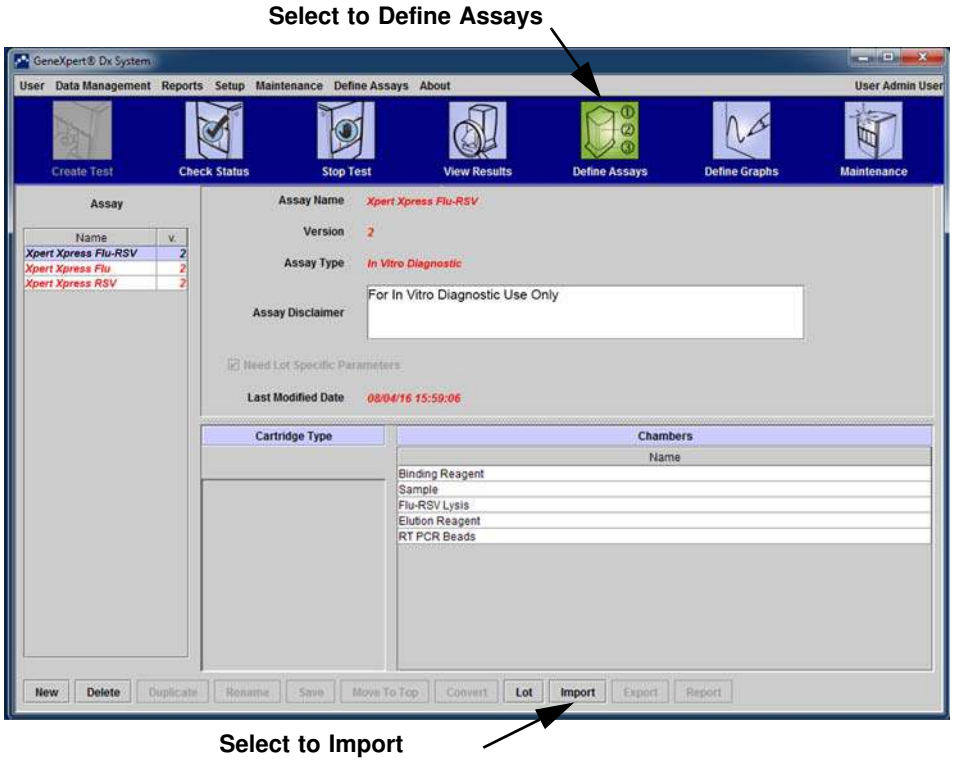


Figure 5-31. System - Define Assays Window (Detail User View)

2. Select **Import**. The Import Assay dialog box displays. See Figure 5-32.

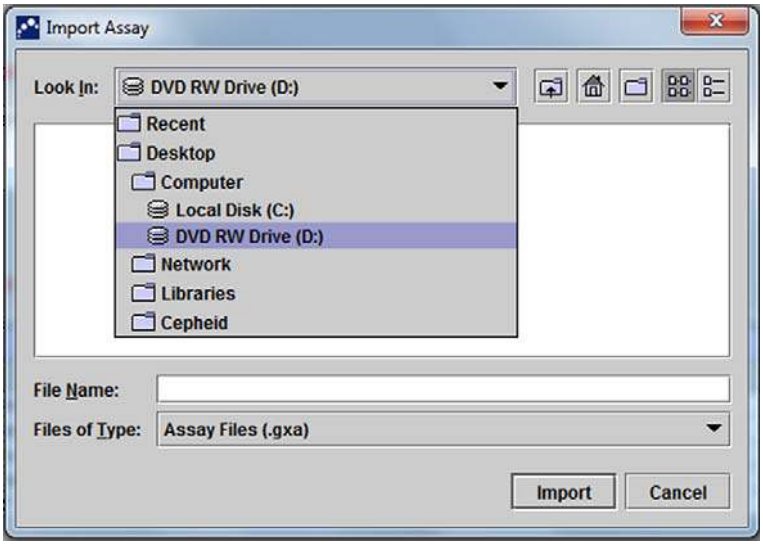


Figure 5-32. Import Assay Dialog Box

3. Navigate to the DVD folder. Locate and select the assay definition (.gxa) file, and then select **Import**. The new assay name and version number appear in the Assay list (on the left side of the window) and details about the assay appear to the right of the list. See Figure 5-31.
4. Check the assay name and version number to make sure the correct assay definition has been imported.
5. If you need to import additional assay definition files from the same CD, repeat Step 2 through Step 4.

Note

For combination assays that have multiple .gxa files, import only the assay definition files for assays that will be performed in your lab.

6. Remove the CD from the DVD drive and store the CD in a safe location in the event it is needed in the future.
7. Disconnect the DVD drive from the computer and store it and the cables to it in the event they are needed in the future.

5.5.3 Deleting Assay Definitions

Caution

Deleting assay definitions from the system is a permanent operation. Ensure that the assay definitions are no longer needed. If they are needed, they will need to be imported again from the assay definitions CDROM.

1. To delete an assay definition file, in the Define Assays window (see Figure 5-33), select the assay name in the Assay list (on the left side of the window), and then select **Delete.** A confirmation message displays.
2. Select **Yes** to delete the assay definition. The assay definition file will be deleted and is removed from the list of assays.

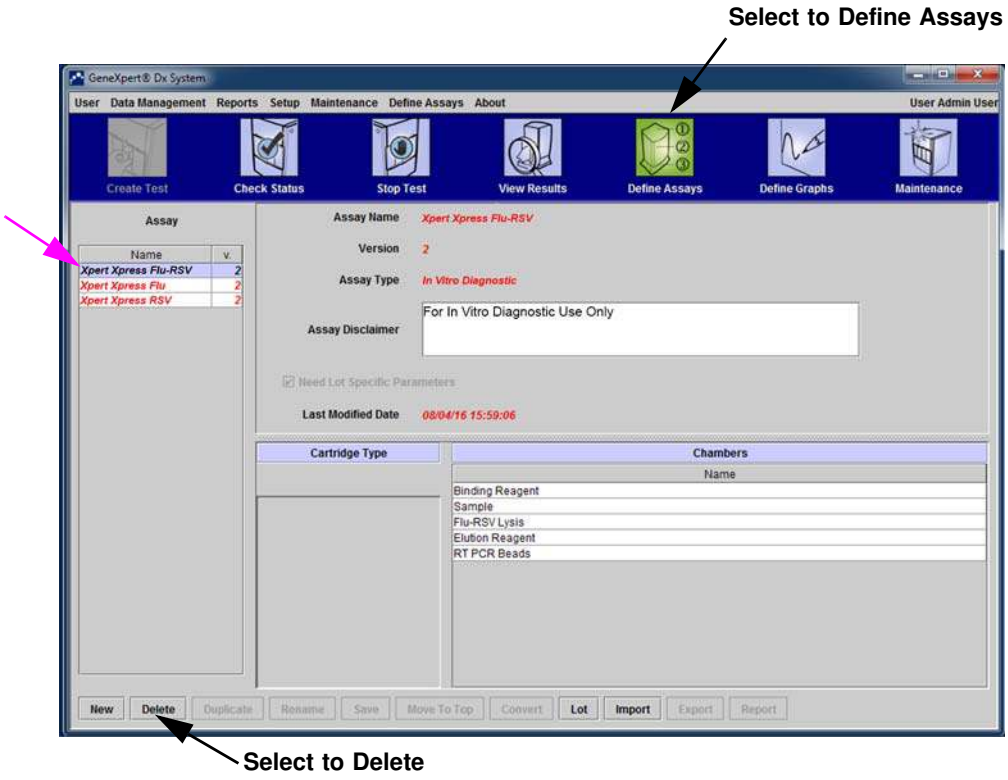


Figure 5-33. GeneXpert Dx System - Define Assays Window

This completes the procedures for assay definitions files. If there are no additional changes, exit the GeneXpert Dx software and return to the Xpress software. See Section 5.10.

5.6 Archiving the Tests

Archiving tests allows you to move your data and, if desired, free up space in the database. You can archive multiple tests at a time. In addition to serving as a safe-keeping mechanism, you can provide the archive files to Cepheid for analysis when troubleshooting. The archive process creates a copy of the test and saves the data in a .gxx file.

Important

Some e-mail filters may block files with .gxx extensions. Adjust your email filter, if possible, or change the extensions, if required.

To archive the test data:

1. In the GeneXpert Dx System window, select on the **Data Management** menu. SeeFigure 5-34.

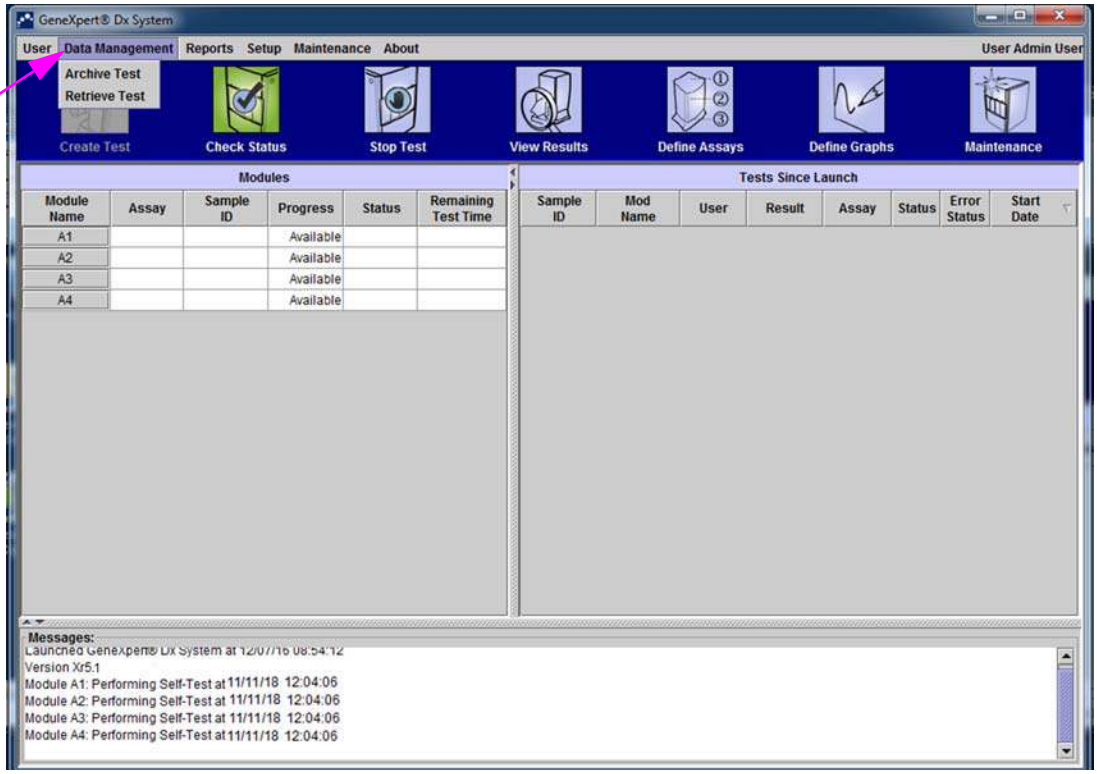


Figure 5-34. GeneXpert Dx System Window showing the Data Management Menu

2. Select **Archive Test.** The Select Test(s) To Be Archived dialog box displays. See Figure 5-35.

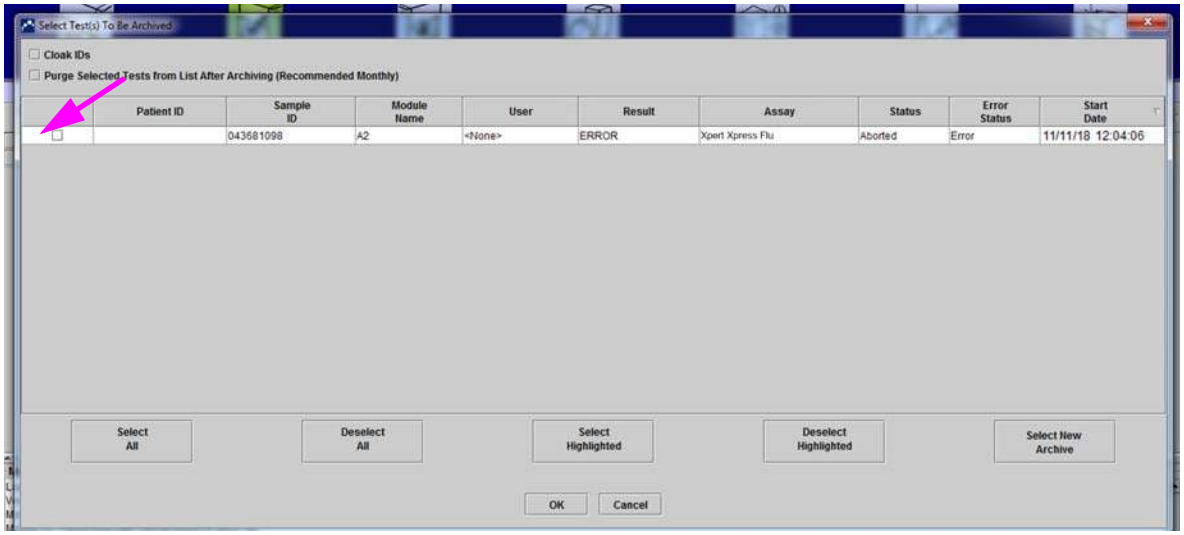


Figure 5-35. Select Test(s) To Be Archived Dialog Box

3. Select the test(s) you want to archive. Select the check box that is adjacent to each test you want to archive. See Figure 5-35. You can select the individual tests one-by-one, or select a large number of tests by selecting one of the following buttons at the bottom of the Select Tests To Be Archived screen:

- **Select All** – Selects all of the tests in the table.
- **Select Highlighted** – Selects the tests you highlighted.
- **Select New Archive** – Selects only the tests that have not been archived before.

Note

You can also hold the **Shift** or **Ctrl** keys to highlight continuous and discontinuous multiple tests on the Select Tests To Be Archived screen.

After selecting tests on the Select Tests To Be Archived screen, select one of the following buttons to deselect some or all tests:

- **Deselect All** – Deselects all of the test selections in the window.
- **Deselect Highlighted** – Deselects the tests you highlighted.

In addition to selecting the tests to archive, there are two check boxes located near the top of the Select Tests To Be Archived screen that may need to be selected:

- **Cloak IDs** – Select this check box if you want to send Cepheid Technical Support some data in question, but want to hide patient-sensitive information. See Masking Patient and Sample IDs During Test Archive (below) for more information.
- **Purge Selected Tests from List After Archiving (Recommended monthly)**– Select this check box to free up space on the computer. After the selected tests have been successfully archived, they are removed from the database.

4. Select **OK.** A message displays and asks you to confirm the archive request.
5. Select **Proceed**. The Save dialog box displays.

   Select **Cancel** to not perform the Archive Test operation.
6. Locate and select the folder in which you want to store the archive (.gxx) file, type a name for the archive file, and then select **Save.**

Caution

The default archive location is the export folder which is located on the computer hard drive. To guard against loss of data, the files in the export folder should be periodically copied to a different computer or external hard drive or different storage medium.

7. After the files have been archived, the Archive Test(s) dialog box is displayed indicating that the tests have been successfully archived. Select **OK**.
8. If you selected the **Purge Selected Tests from List After Archiving (Recommended Monthly)** option, a Purge Test(s) dialog box displays indicating that the selected test(s) will be deleted from the database. Select **Yes** to confirm or select **No** to not delete the selected test(s) from the database.

Caution

It is important to understand that when tests have been archived, they have not been permanently deleted from the computer. They have been removed from the main system database and saved to an archive file when the Purge Selected Tests from List After Archiving (Recommended Monthly) option has been selected. Tests may be retrieved from the archive file if needed for later use. See Section 5.6.1, Retrieving Data from an Archive File.

Masking Patient and Sample IDs During Test Archive

Masking sample and Patient IDs allow customers to send Cepheid Technical Support some data in question, but hides patient-sensitive information.

When the **Cloak IDs** check box, located in the top left area of the Select Test(s) To Be Archived dialog box, (see Figure 5-35) is checked, all information about the sample ID and patient ID is masked.

Caution

Once you mask sample and or patient ID information for an archived test, if you retrieve the test information, the sample and patient ID information will still be masked. You should maintain an on-site copy of the archived test information without the masked information.

5.6.1 Retrieving Data from an Archive File

Caution

If a test you are retrieving already exists in the current database, the software will overwrite it and existing data will be lost.

You can retrieve test data from an archived file. To do this:

1. In the GeneXpert Dx System window, on the **Data Management** menu, select **Retrieve Test.** The Open dialog box displays.
2. Locate and select the archive (.gxx) file, and then select **Open** to retrieve the selected test(s) from the archive file.

   If there are tests in the archive that already exist in the database, the Retrieve Test(s) dialog box will be displayed indicating the number of duplicate tests. Select **OK**.
3. The Select Test(s) To Be Retrieved From dialog box displays (see Figure 5-36). The tests that already exist in the current database display in red text.

   Select **Cancel** in the Open dialog box to not retrieve any archived tests.

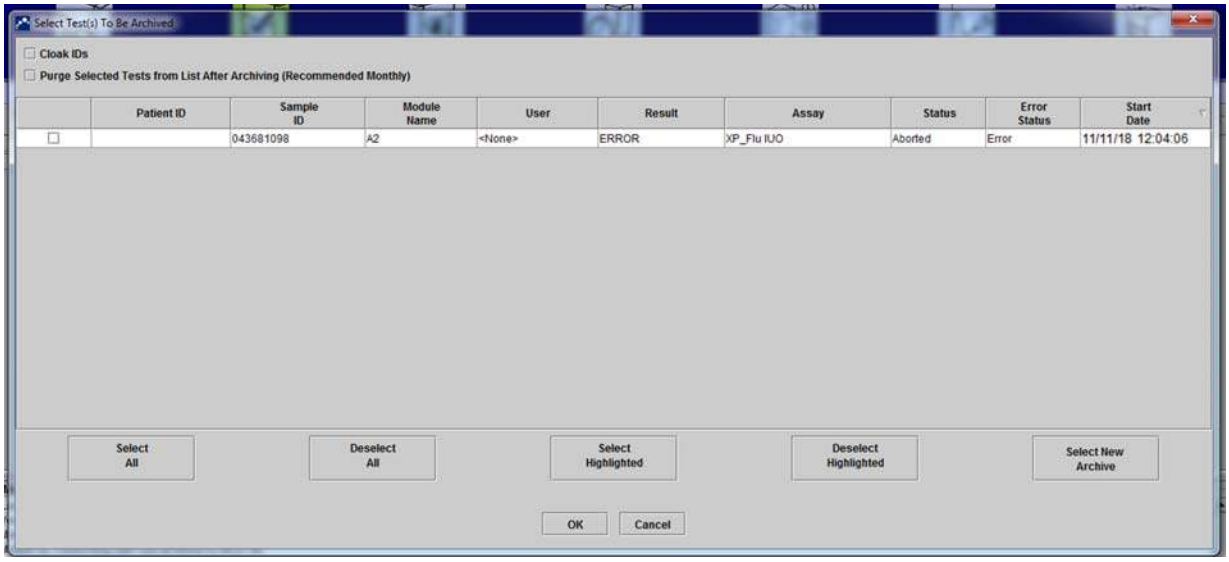


Figure 5-36. Select Test(s) to Be Retrieved Dialog Box

4. Select the tests you want to retrieve. You can select the individual tests one-by-one, or select multiple tests by selecting one of the following:
   - **Select All**—Selects all of the tests in the table.
   - **Select Highlighted**—Selects the tests you highlighted.
   - **Select With No Duplicate**—Selects only the tests that do not exist in the current database.
   - After selecting tests in the Select Tests to Retrieved From dialog box, select one of the following buttons to deselect some or all tests:
     - **Select Deselect All** to clear all of the selections in the dialog box.
     - Select **Deselect Highlighted** to clear the tests you highlighted.
5. Select **OK** to retrieve the selected test(s). The Retrieve Test(s) dialog box displays and asks you to confirm the retrieval.

   Select **Cancel** to not retrieve the selected test(s) from the database.
6. In the Retrieve Test(s) dialog box, select **Proceed.** The selected test)s) are retrieved and a message displays and confirms that the tests are retrieved.
7. In the Retrieve Test(s) confirmation dialog box, select **OK**.

This completes the procedure for managing and archiving files. If there are no additional changes, exit the GeneXpert Dx software and return to the Xpress software.
See Section 5.10.

5.7 Performing Database Management Tasks

The database management tasks can only be performed during system startup and shutdown.

- Back up the database (see Section 5.7.1, Backing up the Database).
- Restore the database (see Section 5.7.2, Restoring the Database).
- Compact the database (see Section 5.7.3, Compacting the Database).
- Check the integrity of the database (see Section 5.7.4, Checking the Integrity of the Database).

The GeneXpert Xpress administrator specifies whether you have permission for the data management tasks. See the GeneXpert Xpress administrator to adjust the permissions to meet your requirements. The user is prompted on startup to perform database management. The prompt appears only if the user has privileges to perform these tasks. If the user does not have any of these privileges, the prompt will not be displayed. See Figure 5-37.

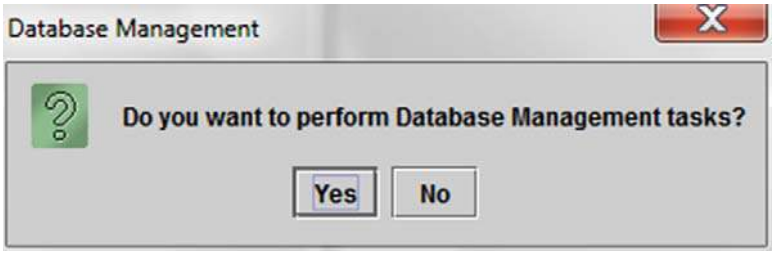


Figure 5-37. Database Management Dialog Box

8. **If you do not want to perform database management tasks**, select **No** in the Database Management dialog box (see Figure 5-37).and skip to Section 5.8, Purging Tests from the Database.

   If you want to perform database management tasks, select **Yes** in the Database Management dialog box (see Figure 5-37). The Database Management window displays. See Figure 5-38.

5.7.1 Backing up the Database

You should back up the entire database periodically and store the backup on a different computer or on a different storage medium. If the computer fails, you can restore the entire database using the backup copy.

To back up the database:

1. Select **Database Backup** on the Database Management window (see Figure 5-38).
2. Select **Proceed**.

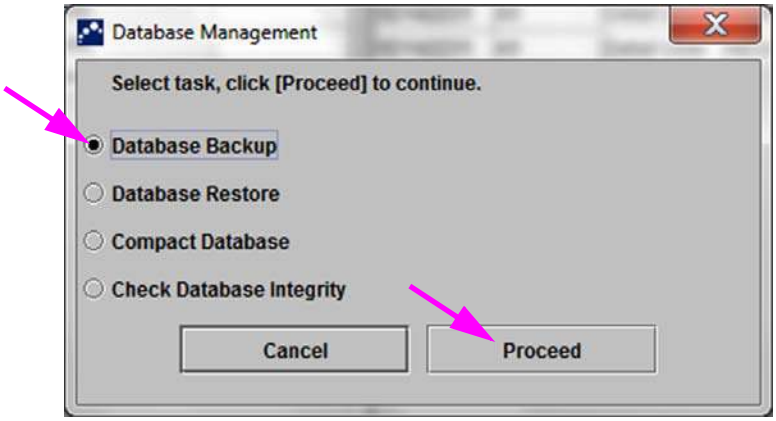


Figure 5-38. Database Management Window

3. Locate and select the folder in which you want to store the backup file, type a name for the backup file (or use the default file name), and then select **Save.** The backup process creates a .zip file in the location you specified (see Figure 5-39).

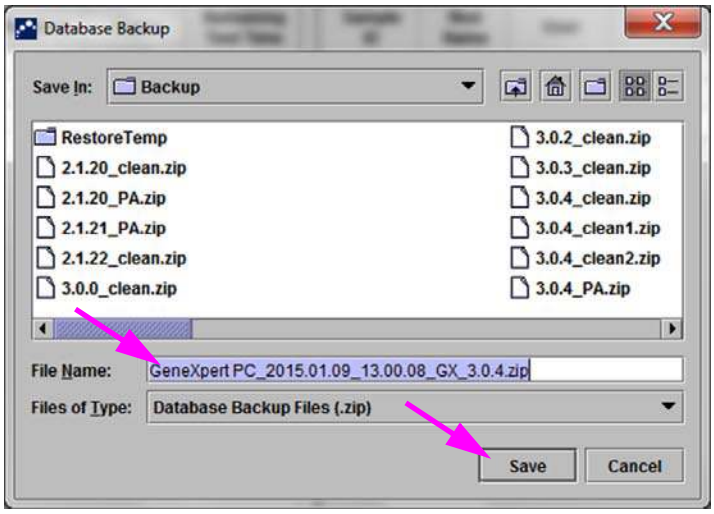


Figure 5-39. Backup File Naming

4. The backup process varies, depending on the amount of data in the database and the speed of the computer (older computers may take longer).

Note

It has been found that 1000 tests takes less than 30 seconds, and 3000 tests takes less than a minute.

For large database backups, a progress bar will be displayed. When the backup process is finished, a process completion message displays (see Figure 5-40).

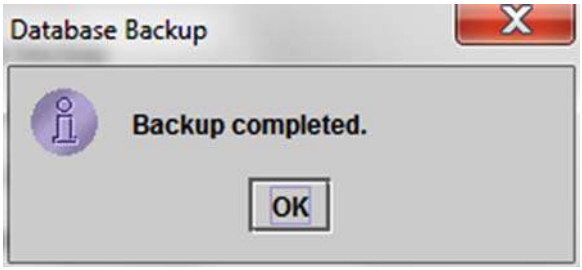


Figure 5-40. Backup Completed Screen

Caution

The default database backup location is the export folder which is located on the computer hard drive. To guard against loss of data, the files in the export folder should be periodically copied to a different computer or different storage medium.

5.7.2 Restoring the Database

Caution

The database restore process overwrites the data in the current database. Do not restore a database unless the current database is corrupted or needs to be replaced.

You can restore the entire database using the backup database file. Because the restore process overwrites the data in the current database, first archive any test data to be retained (see Section 5.6, Archiving the Tests), restore the database, and then retrieve the data from the archive file (see Section 5.6.1, Retrieving Data from an Archive File).

To restore the database:

1. Select **Database Restore** on the Database Management window. See Figure 5-41.

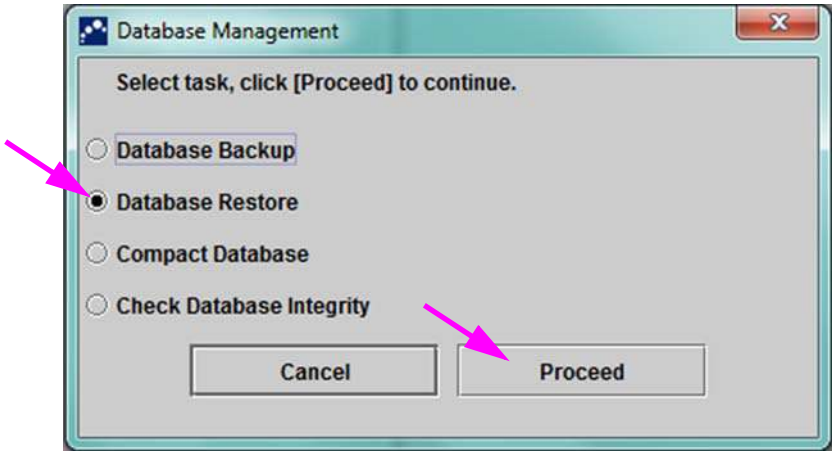


Figure 5-41. Database Management Window

2. Select **Proceed**. A dialog box displays asking if you want to back up the current database (recommended) before restoring. See Figure 5-42.

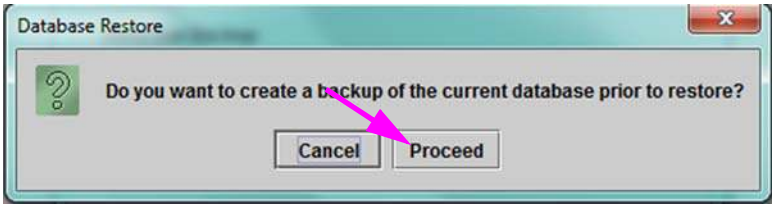


Figure 5-42. Database Restore Dialog Box

3. Select **Proceed** in the Database Restore confirmation dialog box to continue with the database backup (see Figure 5-42). The Database Backup dialog will be displayed. See Figure 5-43.

   Select **Cancel** to not back up the database and proceed directly to the Select File To Restore the Database screen (see Figure 5-45).

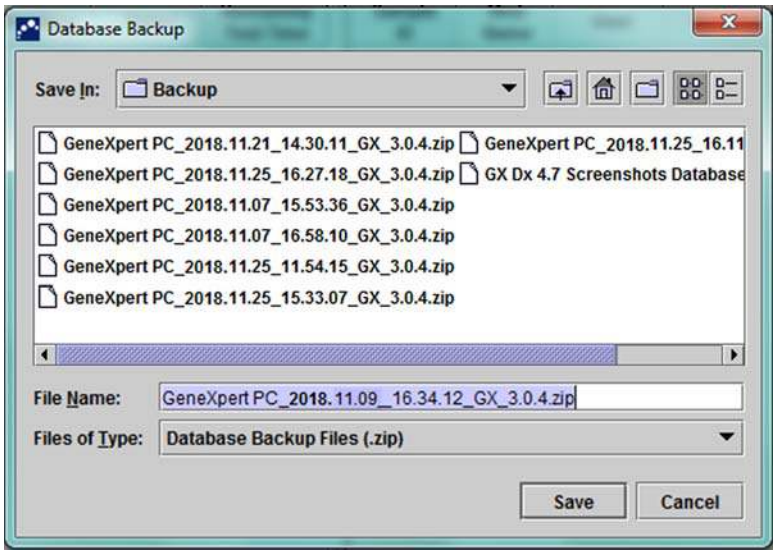


Figure 5-43. Database Backup Dialog Box

4. Locate and select the folder in which you want to store the backup file, type a name for the backup file (or use the default filename) and select **Save**. See Figure 5-43

5. The database will be backed up to the selected location. The Backup process time varies, depending on the amount of data in the database and the speed of the computer (older computers may take longer).

Note

It has been found that 1000 tests takes less than 30 seconds, and 3000 tests takes less than a minute.

For large database backups, a progress bar will be displayed. The Backup completed screen displays when the database backup is complete. See Figure 5-44.

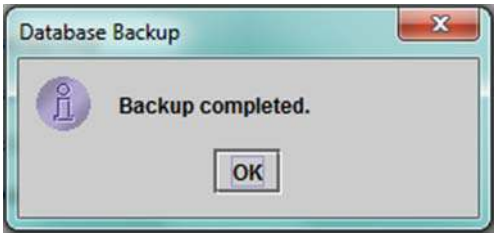


Figure 5-44. Backup Completed Screen

6. Select **OK.** The Select File to Restore the Database screen displays. See Figure 5-45.

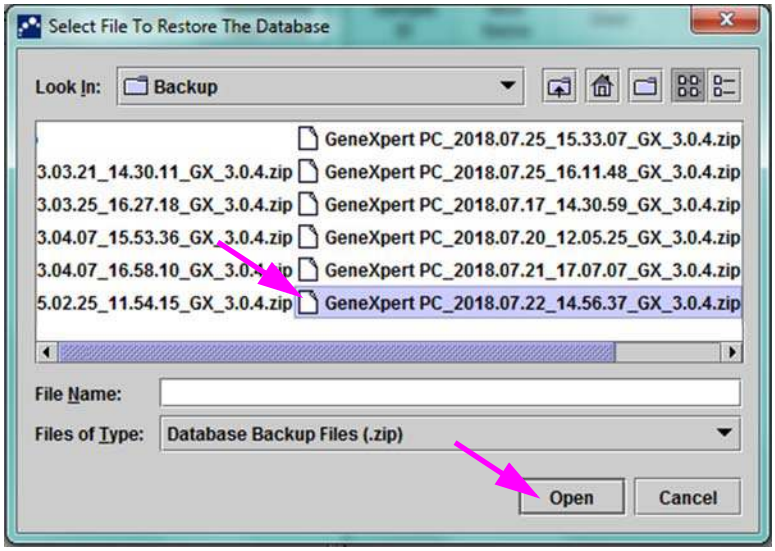


Figure 5-45. Select File to Restore the Database Screen, with Filename

7. Select the file to restore, and then select the **Open** button.
8. The Database Restore confirmation dialog box displays. See Figure 5-46.

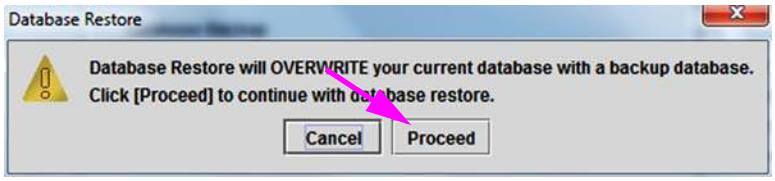


Figure 5-46. Database Restore Confirmation Dialog Box

9. Either select **Proceed** in the Database Restore confirmation dialog box to continue, or select **Cancel** to discontinue and return to the Database Management screen (see Figure 5-41).
10. If you selected **Proceed**, the restore process will begin. The restore process time varies, depending on the amount of data in the database and the speed of the computer (older computers may take longer).

Note

It has been found that 1000 tests takes less than 30 seconds, and 3000 tests takes less than a minute.

For large database restores, a progress bar will be displayed. When the restoration process is finished, a process completion message displays (see Figure 5-47).

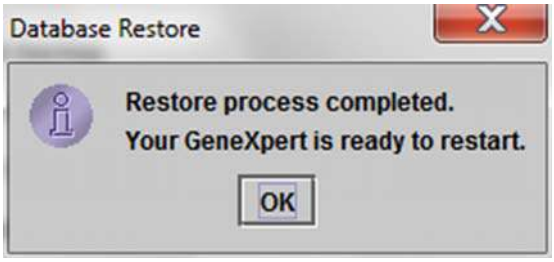


Figure 5-47. Database Restore Completed Confirmation Screen

11. Select **OK** to close the GeneXpert Dx software application.
12. If desired, restart the GeneXpert Dx software. For details on starting the software, see Section 5.2, Starting the GeneXpert Dx Software.

5.7.3 Compacting the Database

Compact the database periodically to ensure efficient use of the space in the database and to save hard disk space.

To compact the database:

1. Select **Compact Database** on the Database Management window. See Figure 5-41.
2. Select **Proceed** on the Database Management window. The Compact Database confirmation dialog box displays. See Figure 5-48.

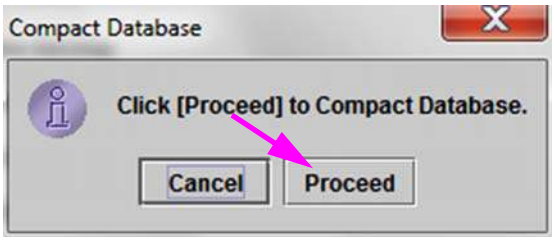


Figure 5-48. Compact Database Confirmation Dialog Box

3. Select **Proceed** to compact the database. When the database compacting has completed, the Compact Database complete dialog box will display. See Figure 5-49.

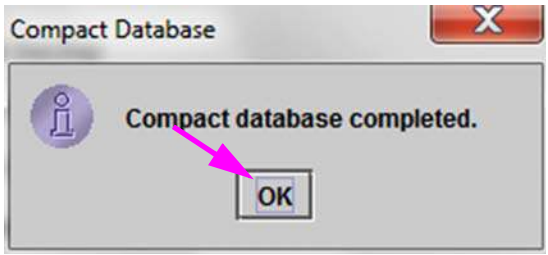


Figure 5-49. Compact Database Completed Dialog Box

4. Select **OK**.

Note

In addition to compacting the database, you can also save space by purging tests from the database after archiving. For details on deleting archived tests, see Section 5.6, Archiving the Tests.

5. Select **Cancel** to close the Database Management window.

5.7.4 Checking the Integrity of the Database

The software automatically checks the integrity of the database at start-up. To manually check the integrity of the database, perform the following steps:

1. Select on **Check Database Integrity** on the Database Management window. See Figure 5-41.
2. Select **Proceed**. The Check Database Integrity confirmation dialog box displays (see Figure 5-50), asking to confirm the check request.

Figure 5-50. Check Database Integrity Confirmation Dialog Box

3. Select **Proceed** to start the integrity check. If the software finds integrity errors, a message alert will display. Select **Proceed** to repair the database.
4. When the check database integrity is successfully completed, the Check Database Integrity complete dialog will display. See Figure 5-51.

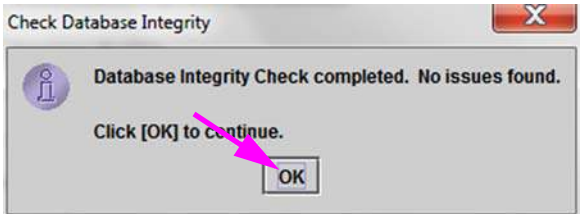


Figure 5-51. Check Database Integrity Completed Dialog Box

5. Select **OK**.
6. Select **Cancel** to close the Database Management window.

This completes the procedure for managing the database. If there are no additional changes, exit the GeneXpert Dx software and return to the Xpress software. See Section 5.10.

5.8 Purging Tests from the Database

Tests may be purged from the active database after they have been archived (see Section 5.6, Archiving the Tests for details).

Important

When tests have been archived, they have not been permanently deleted from the computer. They have been removed from the main system database and saved to an archive file when the Purge Selected Tests from List After Archiving (Recommended Monthly) option has been selected. Tests may be retrieved from the archive file if needed for later use. See Section 5.6.1, Retrieving Data from an Archive File.

5.9 Connecting to the Printer with a Direct USB Connection

If the wireless connection between the Xpress computer and printer is not functional, try troubleshooting the issue with the steps in Section 6.18.2, Troubleshooting Wireless Printer Connection. It is also possible to establish a direct USB connection with the printer. Connect the USB cable provided with the printer to a USB port on the computer. This may require removing either the LIS dongle (if used) or the barcode scanner while printing.

5.9.1 Connecting to the Printer with a Direct USB Connection with Windows 7

1. Select the Windows Start button and select **Devices and Printers** in the right panel of the start menu.
2. From the Control panel, locate and select on **View devices and printers**. See Figure 5-56.

Figure 5-52. Windows Control Panel

3. Right-select on any existing Cepheid Xpress printer and select **Remove this device**. See Figure 5-53.

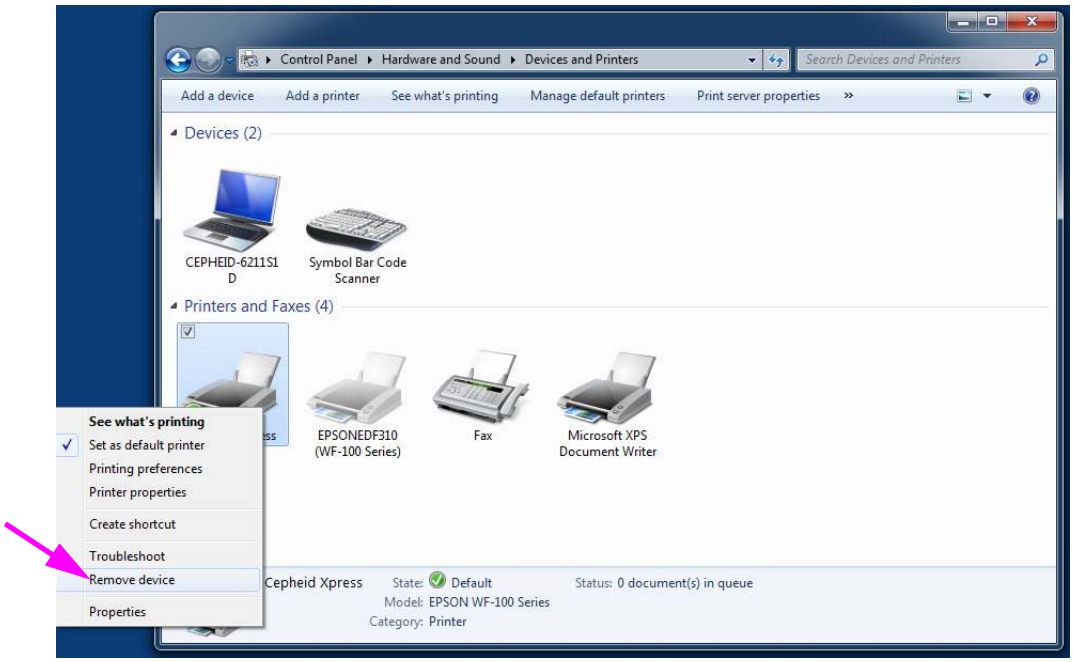


Figure 5-53. Devices and Printers Window - Remove device

4. After the existing Cepheid Xpress printer is removed, unplug the scanner and replace it with the USB printer cable
5. Windows will automatically begin installing device driver software for the printer.
6. After the installation is complete, a WF-100 series printer will show up under Printers and Faxes.

7. Right-select on the WF-100 series printer and select **Printer Properties**. See Figure 5-58.

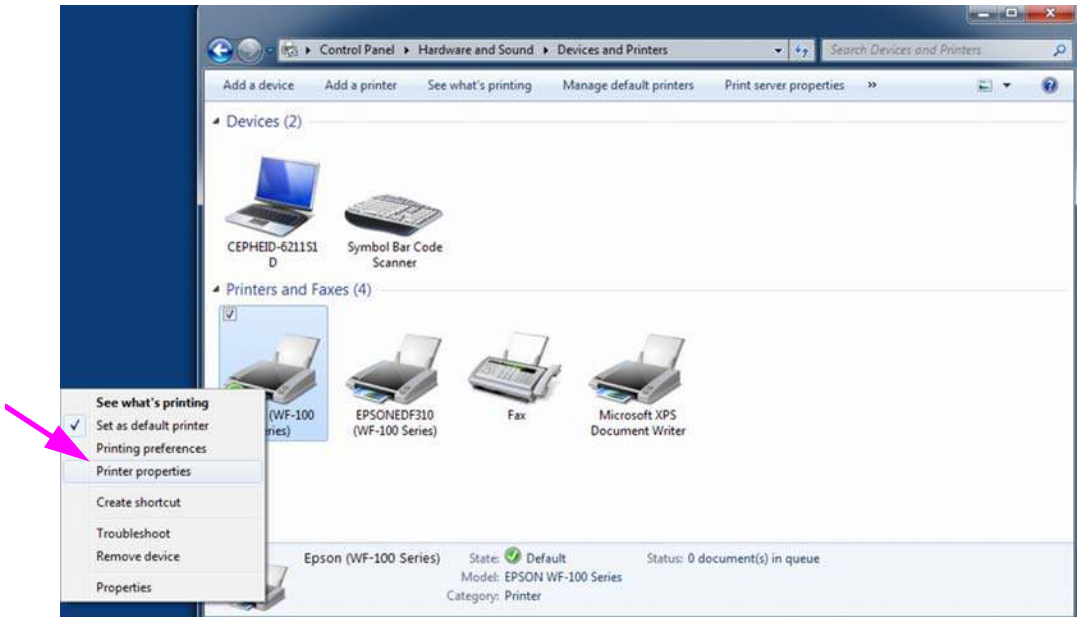


Figure 5-54. Devices and Printers Window Showing the Printer Properties Popup

8. Change the device name to **Cepheid Xpress** and select **OK**. See Figure 5-59.

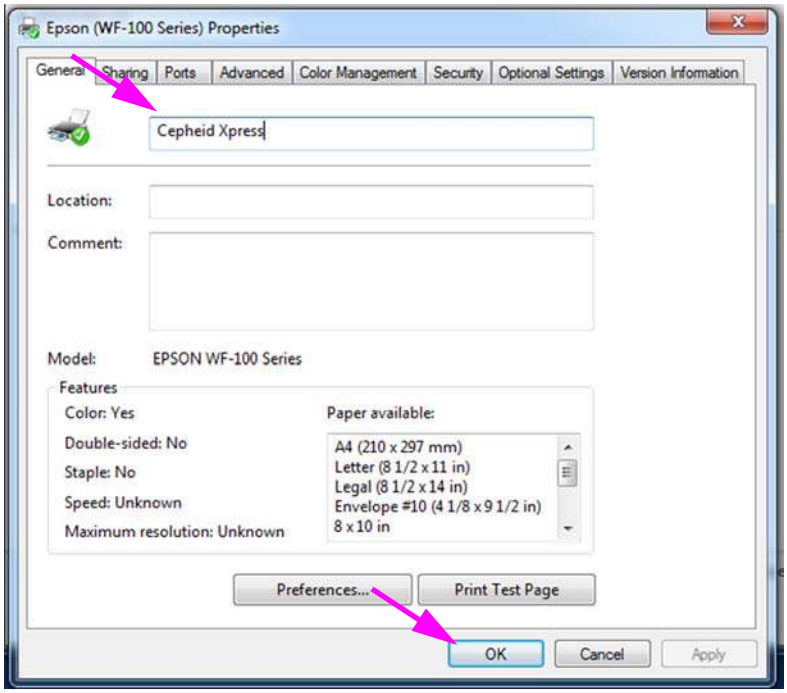


Figure 5-55. Printer Properties Window Showing the General Tab

9. Right-select on the printer and select **Set as default printer**.

10. A green check mark will display on the Cepheid Xpress printer indicating that it is set as the default printer.

This completes the procedure for connecting the printer with a USB cable. If there are no additional changes, exit the GeneXpert Dx software and return to the Xpress software. See Section 5.10.

5.9.2 Connecting to the Printer with a Direct USB Connection with Windows 10

1. Select the Options button in the lower right of the screen. From the Options panel, locate and select **All settings**. See Figure 5-56.

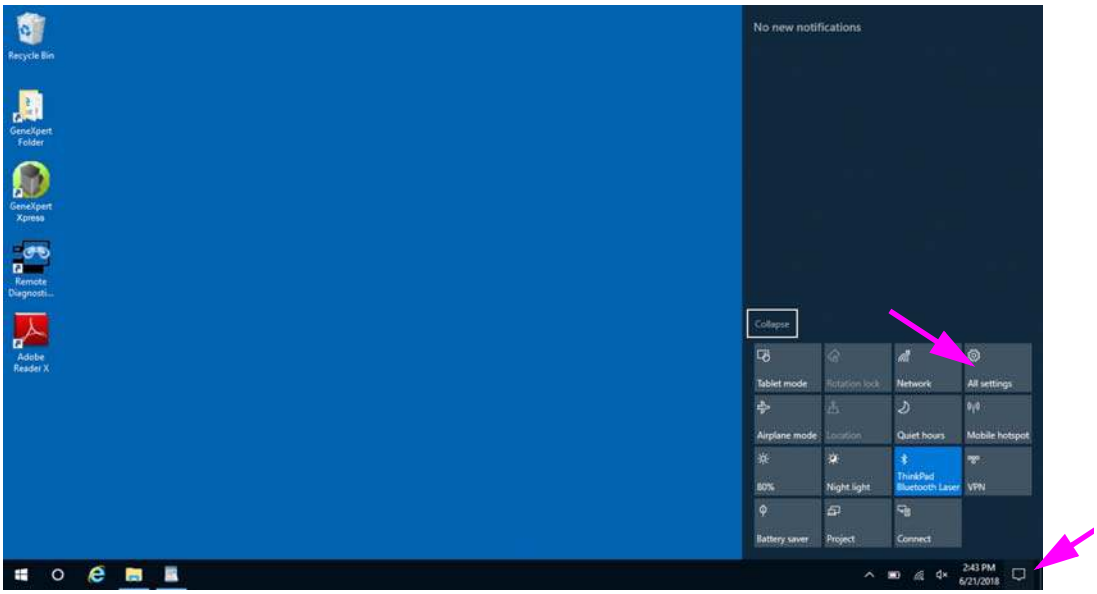


Figure 5-56. Windows Options Panel

2. Select **Devices**. See Figure 5-57.

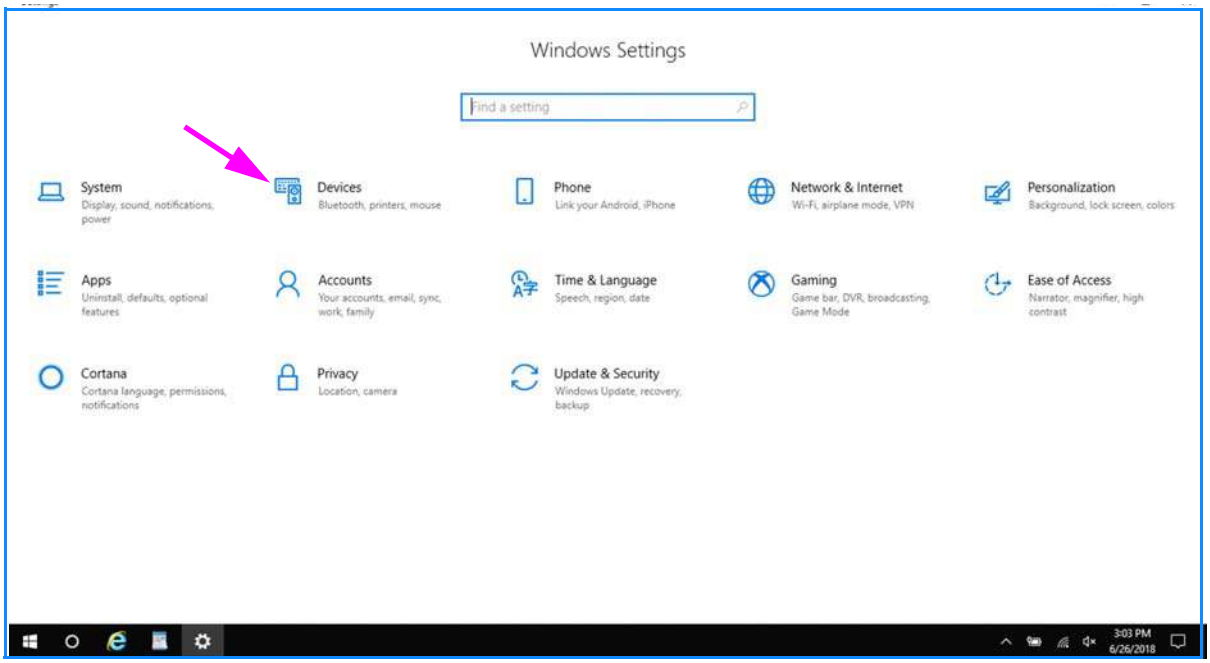


Figure 5-57. Windows Settings - Devices

3. Select **Printers & scanners** from the list on the left of the screen. See Figure 5-59.
4. Click Cepheid Xpress in the list of printers and Select **Remove device.** Select **Yes** from the confirmation popup window. After the existing Cepheid Xpress printer is removed, unplug the scanner and replace it with the USB printer cable.
5. Windows will automatically begin installing device driver software for the printer.
6. After the installation is complete, a WF-100 series printer will show up under Printers and Scanners.
7. Click on the WF-100 series printer and select **Manage**. The Manage your device window appears. Select **Printer properties.**
8. Change the device name to **Cepheid Xpress** and select **OK**. See Figure 5-58.

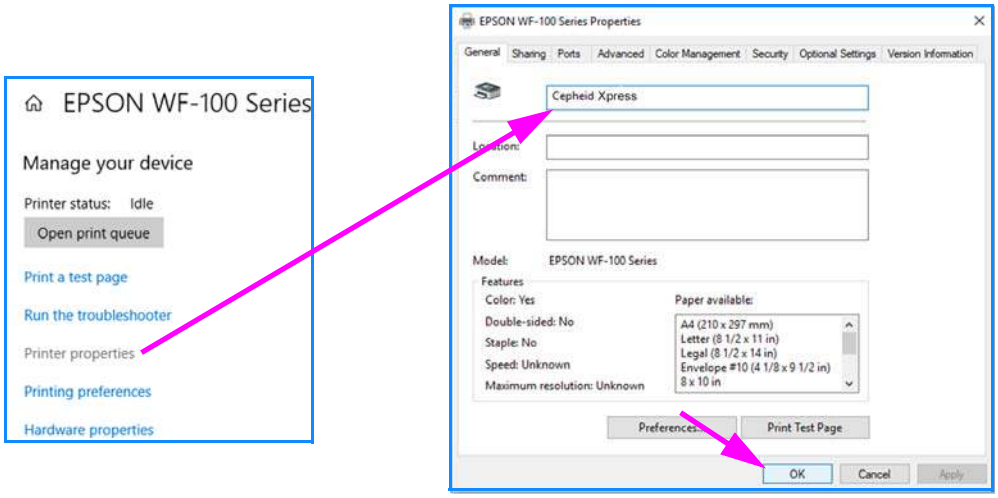


Figure 5-58. Manage your device Window Showing the Printer Properties Popup

Click on the check mark next to Let Windows manage my default printer to deselect it. See Figure 5-59.

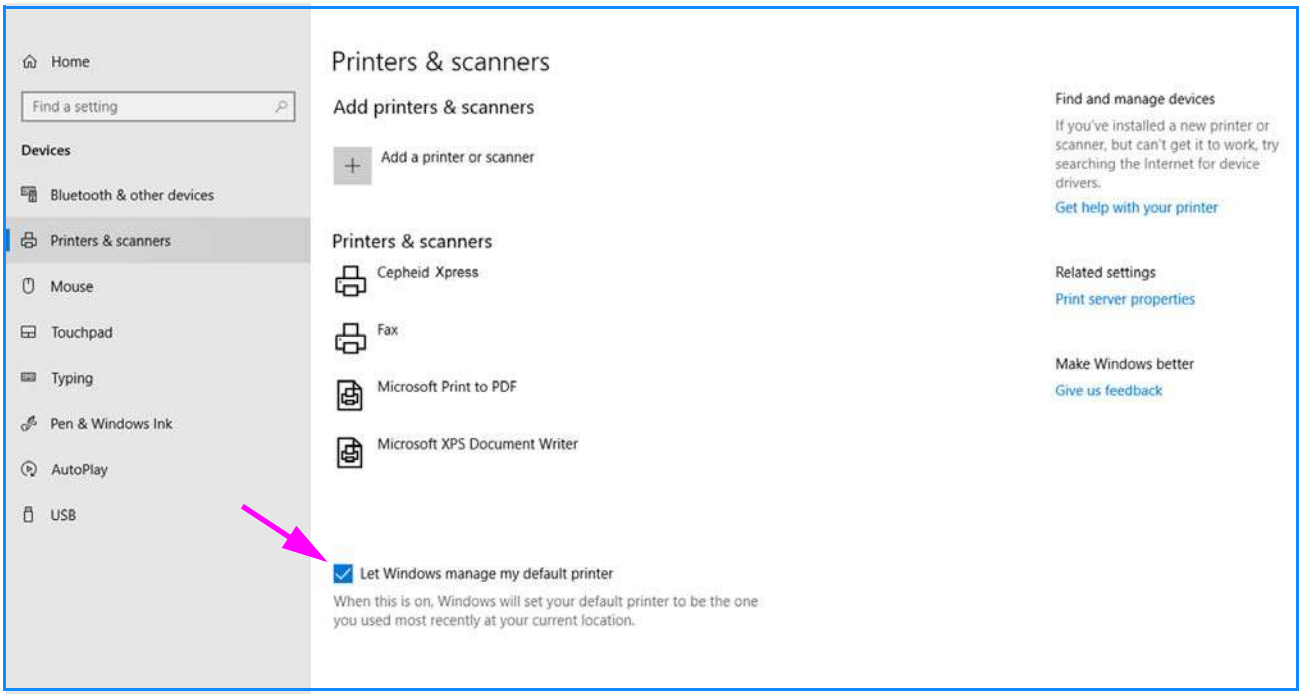


Figure 5-59. Printer &scanners Window Showing Let Windows manage my default printer

9. Select the **Cepheid Xpress** printer and select **Manage**. Select **Set as default**.
10. The printer will now display Default under the name.

This completes the procedure for connecting the printer with a USB cable. If there are no additional changes, exit the GeneXpert Dx software and return to the Xpress software. See Section 5.10.

5.10 Returning to the GeneXpert Xpress Software

5.10.1 Exiting the GeneXpert DX Software

1. To exit the GeneXpert Dx software, select **Exit** under the **User** menu on the GeneXpert Dx System window. See Figure 5-60.

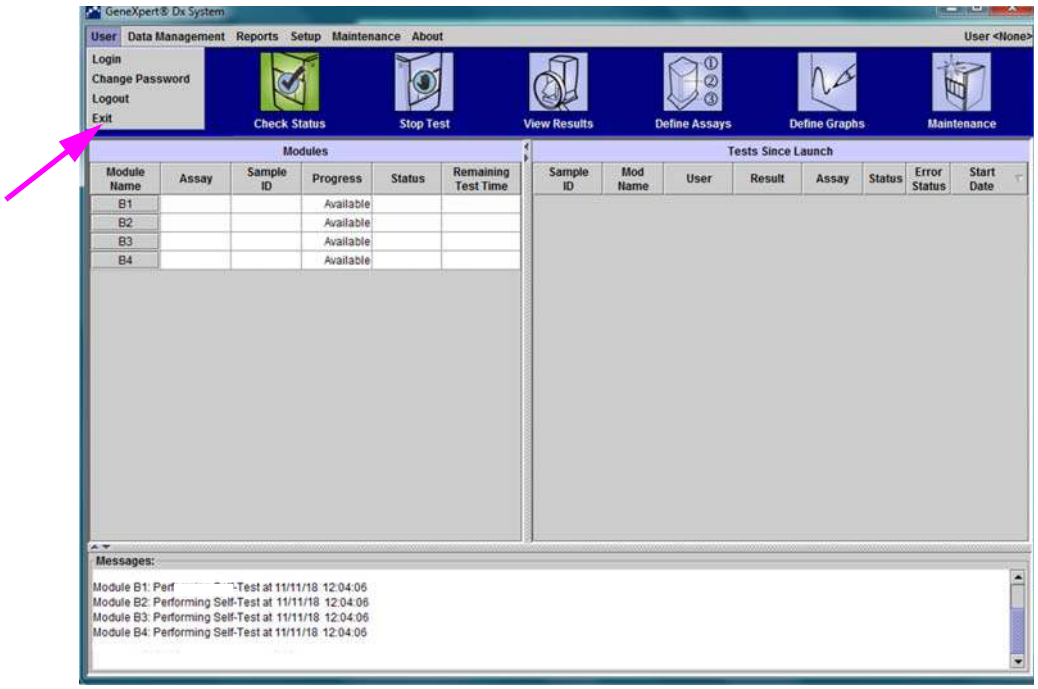


Figure 5-60. GeneXpert Dx System Window Showing the User Menu Item

2. If an archive is overdue, the **Test Archive Reminder** dialog box displays. See Figure 5-61. Select **No**.

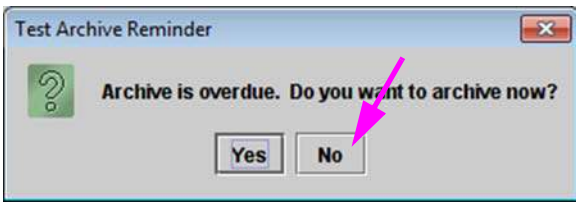


Figure 5-61. Test Archive Reminder Dialog Box

3. The Database Management dialog box displays on top of the GeneXpert Dx System window. See Figure 5-62. Select **No** in the Database Management dialog box.

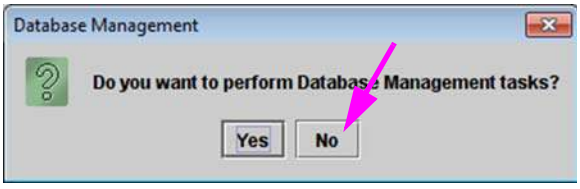


Figure 5-62. Database Management Dialog Box

4. The GeneXpert System window closes and the Windows desktop is displayed. See Figure 5-63.

5.10.2 Starting the GeneXpert Xpress Software

1. Start the GeneXpert Xpress software by double-tapping the **GeneXpert Xpress** icon located on the Windows desktop. See Figure 5-63 for Windows 7 or Figure 5-64 for Windows 10.

Figure 5-63. Windows Desktop (Laptop Mode) Showing the GeneXpert Xpress Icon

Figure 5-64. Windows Desktop (Laptop Mode) Showing the GeneXpert Xpress Icon

The GeneXpert Xpress Software splash screen momentarily displays, followed by the GeneXpert Xpress Software Welcome page (see Figure 5-65).

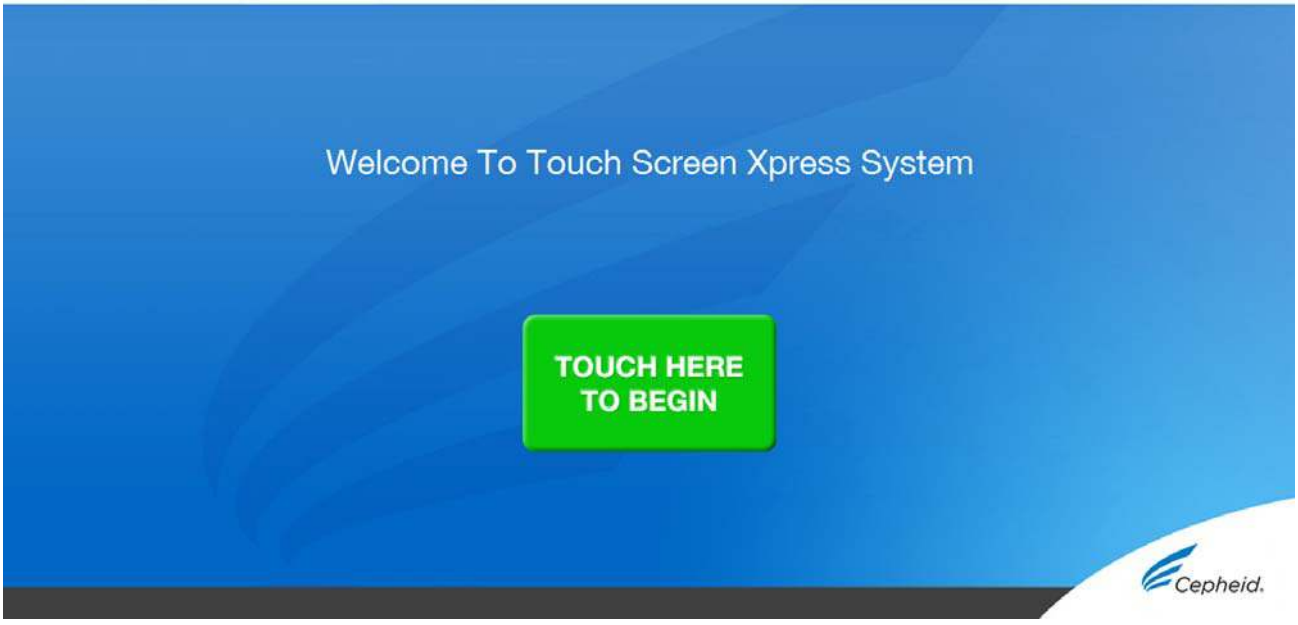


Figure 5-65. Welcome Screen

After you touch the **TOUCH HERE TO BEGIN** button, the **Home** screen displays with **New Test** and **View Previous Tests** buttons. See Figure 5-66.

Note If a log-in is required, the sign-in screen will display before the Home screen displays. Then after logging in, the Home screen displays with **RUN NEW TEST** and **VIEW PRVIOUS TESTS** buttons.

Note It may take 2 to 3 minutes for the software to load. Please wait.

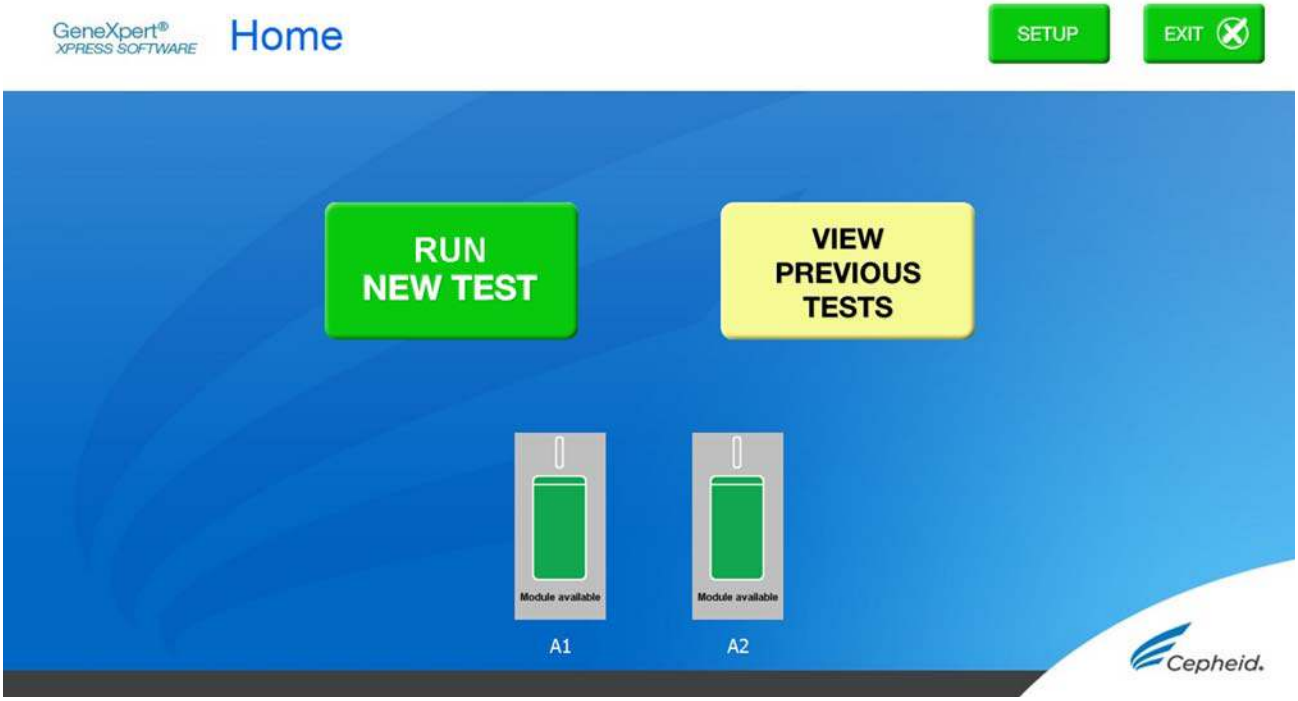


Figure 5-66. New Test and View Previous Tests Screen

6 Maintenance

This chapter describes the maintenance to be performed on the GeneXpert Xpress system.

Note The actions described in this chapter are intended for the administrative user and may not be available to all users.

Note Use the GeneXpert Dx software to perform the activities described in this chapter. If assistance is required, contact Cepheid Technical Support. See the Technical Assistance section in the Preface for contact information.

6.1 Maintenance Tasks

Although the system is designed to prevent cross-contamination and ensure accurate results, the instrument can be checked and cleaned periodically as a precautionary measure. Table 6-1 lists the basic maintenance tasks that can be performed.

Table 6-1. Maintenance Tasks and Frequency

Task	Frequency	Section
Power down the GeneXpert Xpress instrument	Weekly	Section 6.3
Power down the GeneXpert Xpress computer	Weekly	Section 6.3
Archive tests	Monthly	Section 5.6
Purge tests	Monthly	Section 5.8
Replace the fan filters	Monthly	Section 6.10
Clean plunger rod and cartridge bay	Quarterly	Section 6.9
Clean the instrument surfaces	Quarterly	Section 6.6
Perform annual instrument maintenance	Annually	Section 6.11
Print system log report	As necessary	Section 6.15
Back up database	As necessary	Section 5.7.1

6.2 Maintenance Log

Complete the maintenance log shown in Figure 6-1 daily or whenever maintenance tasks are performed on the system. Copies of this monthly log may be made to use, as required. There is an electronic version of this file available and can be used for monthly records. The electronic version of this file is a pdf file that can be filled in and saved using Adobe Reader or Adobe Acrobat.

GeneXpert Xpress® System Maintenance Log

Name of Institution

GeneXpert Serial Number:

Month and Year of Activities:

Last Calibration Date:

Last Calibration Check Date:

Installation Date:

Instructions:
1. For each maintenance activity listed below check the box(es) under the day of the month that the activities were performed and enter your initials (2 characters maximum) in the bottom row.
2. Save the file after entering the data. We recommend saving one file each month for a complete record of activities.

Daily Maintenance	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean work area	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Close all module doors	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Discard used cartridges	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Weekly Maintenance																															
Power down the GeneXpert Xpress instrument[1]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Power down the GeneXpert Xpress computer[1]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Monthly Maintenance																															
Archive Tests[2]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Purge tests[2]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Replace the fan filters[1]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Quarterly Maintenance																															
Clean plunger rod and cartridge bays[1]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Clean Instrument surfaces[1]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Yearly Maintenance																															
Perform annual instrument maintenance[1]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
As Necessary																															
Print system log report[1]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Back up database[2]	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Technician Initials (Two Letters)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

1. Refer to Chapter 6 (Maintenance) in the Xpress Users Guide for detailed procedure.
2. Refer to Chapter 5 (Administrative Tasks) in the Xpress Users Guide for detailed procedure.

Reference: GeneXpert Xpress Users Guide (P/N 301-6994, Rev. C)

Cepheid®

301-7393 Rev. B December 2018

Figure 6-1. Maintenance Log

6.3 Power Down the System

The GeneXpert Xpress instrument and computer should be powered down once per week to refresh the system. This action clears out unwanted temporary files and guards against computer memory corruption to prevent a malfunction of the system.

To exit the GeneXpert Dx software, see Section 5.10.1, Exiting the GeneXpert DX Software. Power down the computer, Then turn off the GeneXpert Xpress Instrument, (See Figure 6-2) wait two minutes, then restart the instrument and computer (See Section 3.1, Starting the GeneXpert Xpress II and GeneXpert Xpress Software or Section 4.1, Starting the GeneXpert Xpress IV and GeneXpert Xpress Software).

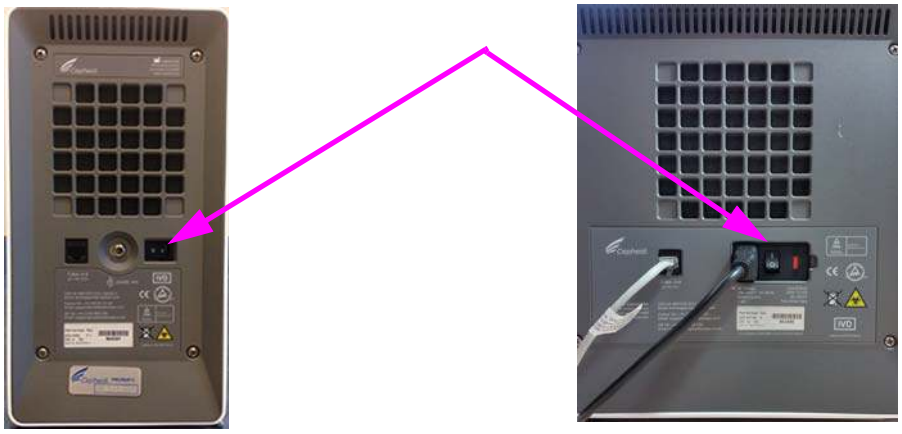


Figure 6-2. Power Switches for the GeneXpert Xpress II and GeneXpert Xpress IV

6.4 Guidelines for Cleaning and Disinfecting

Cleaning and disinfecting system components is crucial for proper system maintenance. Disinfection is a chemical reaction. As a chemical reaction, it is affected by many factors including the concentration of the disinfectant, contact time, temperature, nature of the microbes present, amount of organic residue, surface properties, etc. With any disinfectant, it is crucial that the entire area to be disinfected be in contact with the disinfecting solution.

General guidelines for routine surface cleaning are:

- Use only 70% ethanol or denatured ethanol (70% ethanol containing 5% methanol and 5% isopropanol).

General guidelines for cleaning combined with disinfection are:

- Use a final concentration of 1:10 dilution of household chlorine bleach (used within 1 day of preparation).
- Use sufficient disinfectant (bleach solution) and spread the disinfectant evenly. The entire surface should be wet to completely disinfect the surface.
- Allow a minimum of two minutes contact time. More than five minutes is not recommended.

- Remove remaining bleach residue with 70% ethanol or denatured ethanol (70% ethanol containing 5% methanol and 5% isopropanol).

Caution

Failure to remove bleach residue from the system may cause damage to the instrument components. Always perform a wipe down with ethanol after using bleach.

- Repeat the cleaning and disinfection with bleach three times (two minutes contact time for each bleach application) followed by a final wipe with ethanol to remove bleach residue.

6.5 Cleaning the Work Area

Clean the work area daily using good laboratory practices to avoid contamination of specimens or reagents. Follow your institution's guidelines for cleaning the work area.

6.6 Close Module Doors

Check that all module doors are closed daily to avoid contamination of the modules.

6.7 Discard Used Cartridges

Discard used cartridges from the GeneXpert Xpress modules and on the surrounding work surfaces. Follow your institution's standard practices for disposal. See Section 2.4, Chemical Safety and Section 2.3, Biological Hazard Safety for additional information regarding cartridge disposal.

6.8 Cleaning the Instrument Surfaces

Clean the instrument surfaces quarterly (every three months) with ethanol. All outside surfaces of the instrument housing should be cleaned including the top, sides, and outside door of the module.

Before cleaning the instrument surfaces, read Section 6.4, Guidelines for Cleaning and Disinfecting.

The materials required for this procedure are:

- 70% ethanol or denatured ethanol (70% ethanol containing 5% isopropanol and 5% methanol).

Caution

Do not use 70% isopropyl alcohol for cleaning the instrument surfaces. Isopropyl alcohol can degrade system components.

- A final concentration of 1:10 dilution of household chlorine bleach (used within 1 day of preparation).

Important

Use the bleach solution only in the event of a spill. Wipe down the affected surface(s) with bleach three separate times. Leave the bleach on the instrument surfaces for two minutes each time before wiping the surfaces with ethanol to remove the bleach residue.

- Lint-free wipes or paper towels
- Disposable gloves
- Eye protection

Biological Risks

Wear disposable gloves, eye protection and other personal protective equipment (PPE) mandated by your institution's safety policies while performing this cleaning procedure. Wearing PPE prevents exposure to chemical and biologically hazardous materials.

6.8.1 Quarterly Maintenance

Warning

Shut down the GeneXpert Xpress completely when cleaning the instrument surfaces.

Important

Do not remove the instrument covers or use a vacuum cleaner inside the instrument at any time. Remove debris from exterior instrument surfaces using lint-free wipes or paper towels moistened with ethanol or bleach as described in the following procedure.

For routine cleaning of the instrument surfaces:

1. Thoroughly moisten a lint-free wipe or paper towel with the 70% ethanol solution.
2. Wipe all surfaces outside the instrument. Change lint-free wipes or paper towels frequently while wiping.
3. Move the GeneXpert Xpress instrument and wipe the table surfaces underneath and around the instrument. Change lint-free wipes or paper towels frequently while wiping.
4. Discard used wipes or paper towels according to your standard laboratory procedure.

6.8.2 In Case of Spill

Clean affected exterior instrument surfaces in the event of a spill.

Important

If it is suspected that a spill has affected the interior of the instrument, do not remove any of the exterior instrument covers. Instead, shut down the instrument and contact Cepheid Technical Support for assistance.

To clean the affected instrument surfaces:

1. Thoroughly moisten a lint-free wipe or paper towel with the 1:10 bleach solution.
2. Wipe affected surfaces on the instrument. Change wipes or paper towels frequently while wiping.
3. Allow the bleach solution to remain on the surfaces at least two minutes but no longer than five minutes.
4. Repeat Step 1 through Step 3 two more times for a total of three times.
5. Thoroughly moisten a lint-free wipe or paper towel with the 70% ethanol solution.
6. Wipe affected surfaces on the instrument. Change wipes or paper towels frequently while wiping.
7. Discard used wipes or paper towels according to your standard laboratory procedure.

6.9 Cleaning the Plunger Rods and Cartridge Bays

Clean and disinfect the plunger rods and cartridge bays quarterly (every three months), in the event of a spill, or if a negative control yields a positive result.

Before cleaning the plunger rods and cartridge bays, read Section 6.4, Guidelines for Cleaning and Disinfecting.

The materials required for this procedure are:

- A final concentration of 1:10 dilution of household chlorine bleach (used within 1 day of preparation)

Important

Perform the bleach wipe-down three separate times on the interior surfaces of the cartridge bay, allowing the bleach to remain on the surfaces for two minutes after each wipe. After the final two minutes, remove the bleach residue by thoroughly wiping the cartridge bay and plunger rod with ethanol.

- 70% ethanol or denatured ethanol (70% ethanol containing 5% isopropanol and 5% methanol)

Caution

Do not use 70% isopropyl alcohol for cleaning the cartridge bay and plunger rod. Isopropyl alcohol can degrade polycarbonate plastics.

- Lint-free wipes or paper towels
- Disposable gloves
- Eye protection

Biological Risks

Wear disposable gloves, eye protection and other personal protective equipment (PPE) mandated by your institution's safety policies while performing this cleaning procedure. Wearing PPE prevents exposure to chemical and biologically hazardous materials.

To clean the plunger rod(s) and cartridge bay(s):

1. Remove cartridge(s) from the module(s) to be cleaned.
2. In the GeneXpert Dx System window, click the **Maintenance** icon (see Figure 6-3). The **Maintenance** screen is displayed.
3. Click on **Maintenance** on the Menu Bar (see Figure 6-3), select **Plunger Rod Maintenance**. The **Plunger Rod Maintenance** dialog box is displayed. See Figure 6-4.

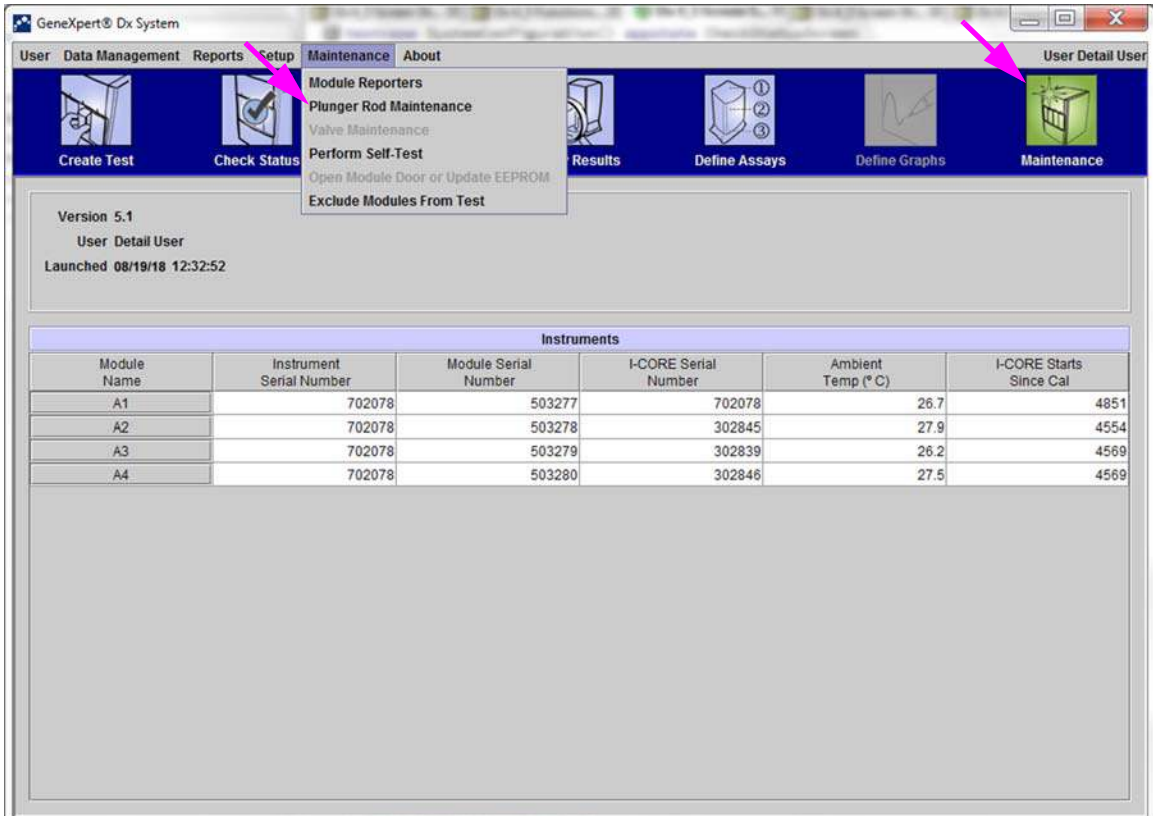


Figure 6-3. GeneXpert Dx System Window

Figure 6-4. The Plunger Rod Maintenance Dialog Box

Note

For efficient cleaning of the cartridge bay(s) and plunger rod(s), choose the **Clean All** option, which lowers all plunger rod(s), allowing the cleaning of all modules simultaneously.

4. In the **Module** table, select the module(s) to be cleaned and then select **Clean** or **Clean All** (see Figure 6-4). The Plunger Rod Cleaning dialog box is displayed (see Figure 6-5).

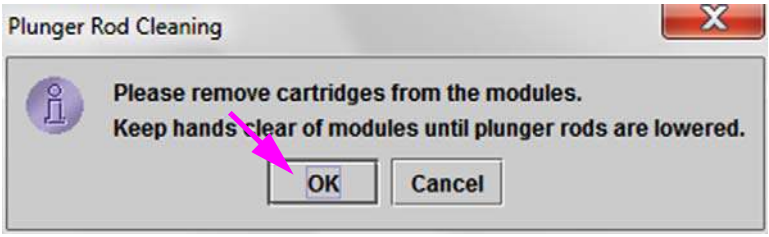


Figure 6-5. Plunger Rod Cleaning Dialog Box

5. Ensure that there are no cartridges in any of the modules, and click **OK**.
6. In the Plunger Rod Maintenance dialog box, the **Clean** button name changes to **Move Up** (if the **Clean All** button is clicked, it changes to **Move Up All**). In the instrument, the plunger rod(s) in the selected module(s) (or all modules if the **Clean All** button is clicked) lowers into the cartridge bay(s). See Figure 6-6.

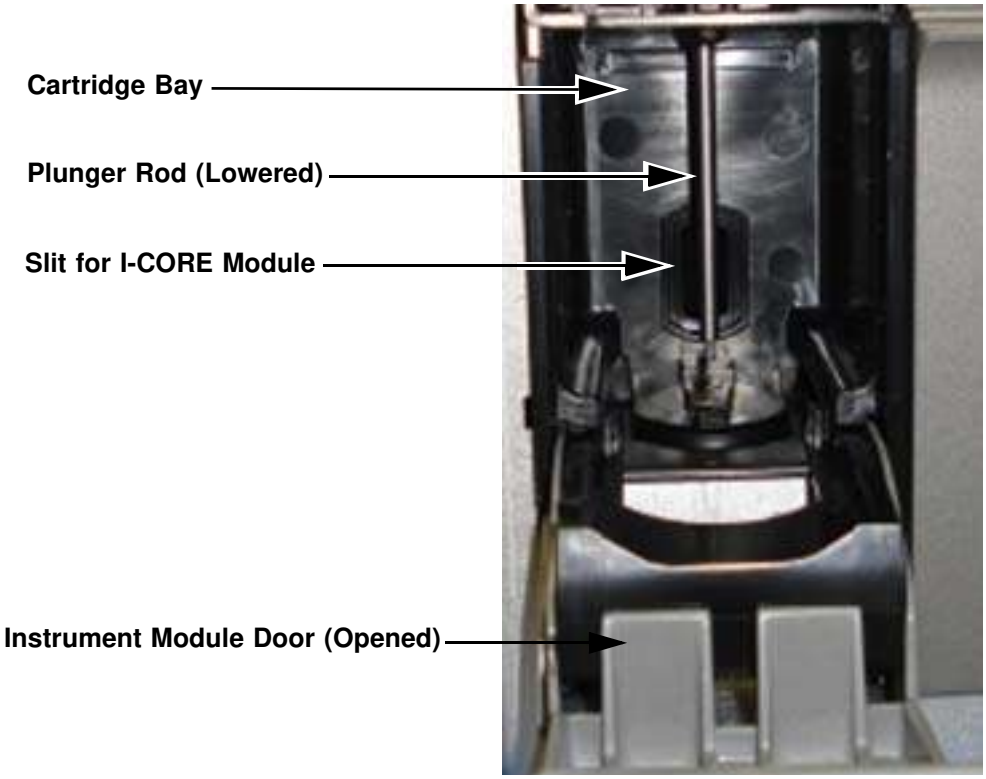


Figure 6-6. Plunger Rod Lowered into Cartridge Bay

7. Clean the plunger rod(s) and cartridge bay(s) as follows:

   A. Thoroughly moisten a lint-free wipe or paper towel with a 1:10 solution of household chlorine bleach.

   B. Vigorously wipe the plunger rod with the lint-free wipe or paper towel. Wipe hard enough to remove the black debris that accumulates on the plunger rod.

      Using the same lint-free wipe or paper towel, wipe the walls, ceiling, corners and edges of the cartridge bay, then wipe the inside of the door and the top lip of the door and discard the lint-free wipe or paper towel.

Caution

Getting liquid inside the I-CORE module can damage the module. Do not touch the slit on the I-CORE module where the cartridge reaction tube is inserted (see Figure 6-6).

Caution

Do not allow the bleach to remain on any surface for more than five minutes.

   C. Wait 2 minutes after wiping with the bleach solution.

D. Use a new lint-free wipe or paper towel thoroughly moistened with the 1:10 bleach solution and wipe the plunger rod, walls, ceiling, corners and edges of the cartridge bay, then wipe the inside of the door and the top lip of the door and discard the wipe.

E. Wait 2 minutes after wiping with the bleach solution.

F. Using another new lint-free wipe or paper towel thoroughly moistened with the 1:10 bleach solution, wipe the plunger rod, walls, ceiling, corners and edges of the cartridge bay. Wipe the inside of the door and the top lip of the door and discard the lint-free wipe or paper towel.

G. Wait 2 minutes after wiping with the bleach solution.

H. Thoroughly moisten a lint-free wipe or paper towel with the 70% ethanol solution.

I. Use the lint-free wipe or paper towel thoroughly moistened with the 70% ethanol solution to remove all residual bleach. Wipe the plunger rod, walls, ceiling, corners and edges of the cartridge bay, then wipe the inside of the door and the top lip of the door and discard the lint-free wipe or paper towel.

8. After the plunger rod(s) and cartridge bay(s) have been cleaned, return to the Plunger Maintenance dialog box and select the **Move Up** button. The plunger rod(s) move(s) back up to the resting position.
9. Click **Close** to close the Plunger Maintenance dialog box.
10. Manually close the instrument module door(s).
11. This completes the procedures for cleaning the plunger rod(s) and cartridge bay(s).

6.10 Cleaning and Replacing the Fan Filters

6.10.1 GX-II and GX-IV Fan Filters

Note

In order to minimize system downtime, Cepheid recommends that you have a spare fan filter available to swap with the dirty fan filter being cleaned. After removing the fan filter, it may be cleaned and re-used the next time that a fan filter is removed for cleaning.

Clean the fan filters monthly or more frequently, if necessary. There is one fan filter on both the GeneXpert Xpress II and the GeneXpert Xpress IV instruments. Location of the fan filters is on the back of the instruments (see Figure 6-7). The materials needed for the procedure are as follows:

- Replacement fan filters:
  - GeneXpert Xpress II - Filter Part Number: 001-1271
  - GeneXpert Xpress IV - Filter Part Number: 001-1537

- Paper towels
- Water
- Disposable gloves

Important

The GeneXpert Xpress instrument and computer must be powered down prior to performing the fan filter cleaning described below. This procedure must be performed on a monthly basis.

1. Make sure all tests have finished running before attempting to move the instrument.
2. Turn off the GeneXpert Xpress II or IV instrument and the computer following the instructions in Section 6.3, Power Down the System.

Note

If needed, gently move the instrument when performing the following procedure for fan filter cleaning.

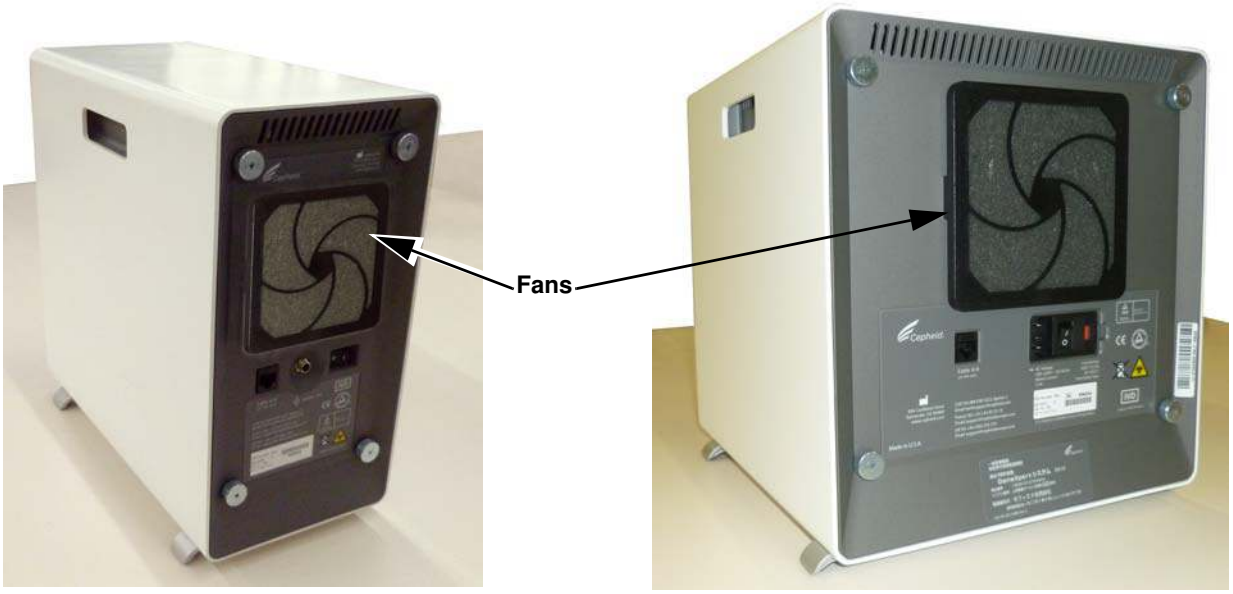
Warning

See the weights table in Section B.2, General Specifications for GeneXpert Instrument weights. Use care when moving the instrument. Do not attempt to lift the instrument without proper safety training and assistance. Lifting or moving the instrument without proper training and assistance can cause personal injury, damage the instrument, and void your warranty.

Caution

Be careful not to drop the instrument.

3. Reposition the instrument so the fan filter can be easily accessed. See Figure 6-7.



GeneXpert Xpress II

GeneXpert Xpress IV

Figure 6-7. GeneXpert Xpress II and GeneXpert Xpress IV Instruments Positioned for Access to Fans

4. Gently take the fan filter guard off by unsnapping the guard from the fan housing (see Figure 6-8) and place it aside for the remainder of the procedure for filter removal and cleaning.

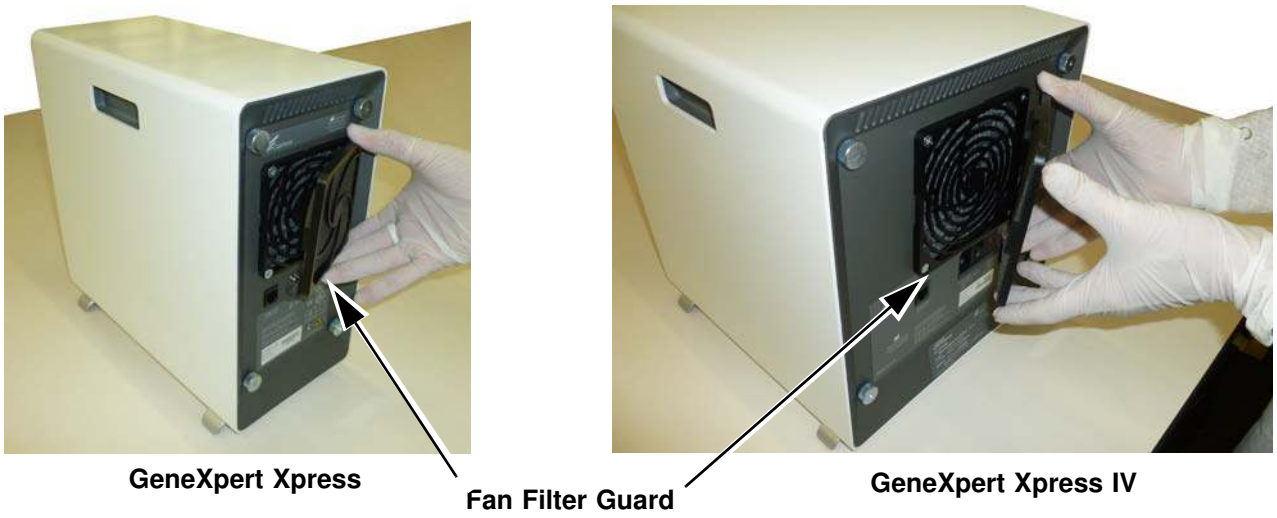


Figure 6-8. Removing Fan Filter Guard

5. Remove the dirty filter for cleaning. See Figure 6-9.

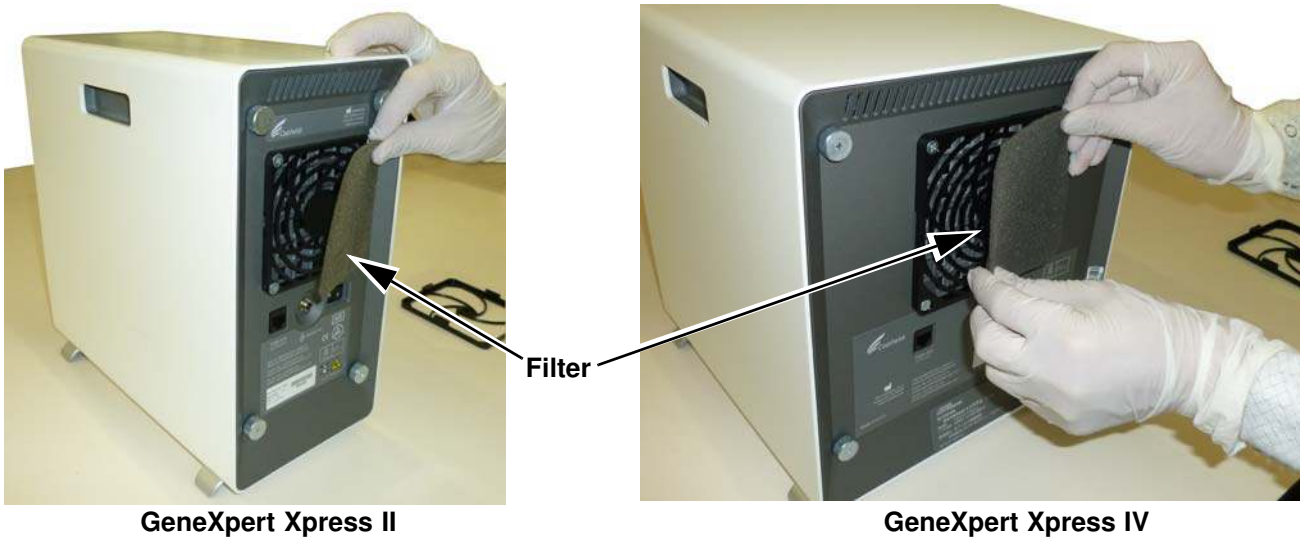


Figure 6-9. Filter Removal

6. Place a clean filter into the fan filter guard.
7. Position the fan filter guard and filter into place as a unit. Press the sides of the guard firmly onto the fan housing until the grip snaps securely onto the fan. Press the bottom of the guard until the grip snaps securely onto the fan. See Figure 6-10.

GeneXpert Xpress II: Pressing the Bottom into Place

GeneXpert Xpress IV: Pressing the Sides into Place

Figure 6-10. Installing the Fan Filter Guard

8. Clean the old filter by washing it. Place this cleaned filter between two paper towels and allow it to air-dry.

Caution

Never wash a fan filter and then put it back onto the system immediately. The fan filter must be completely dry before installing it onto the system.

9. After the filter is dry, store it to use the following month, when you next remove the filter for cleaning.
10. In the maintenance log (see Figure 6-1), fill in the date of the fan filter cleaning and keep it for your records.

6.11 Annual Instrument Maintenance

Calibration of the GeneXpert Xpress instrument is not required during the initial system startup. Cepheid performs all of the necessary calibrations before the system is shipped. However, Cepheid recommends that the system be checked for proper calibration on an annual basis. Based upon the usage and care of each system, calibration checks may be recommended more frequently. The system is designed to measure module performance with the internal assay controls. In the event of a module failure, the replacement module provided will have been calibrated prior to shipment.

The Cepheid Field Service Engineer or customer will perform the calibration checks during annual maintenance or by the field service engineer if responding to a module failure. Contact Cepheid Technical Support for information about calibration. See the Technical Assistance section in the Preface for contact information.

6.12 Using Module Reporters

Cepheid Technical Support may ask you to use the Module Reporters tool when investigating the source of possible module-related problems. The Module Reporters tool is also used to check the last date of calibration for the modules. It provides calibration information and other data, shown in Figure 6-11.

To view the Module Reporters, go to the Maintenance screen. Click on **Maintenance** on the menu bar and select **Module Reporters**. The Module Reporters window displays. See Figure 6-11.

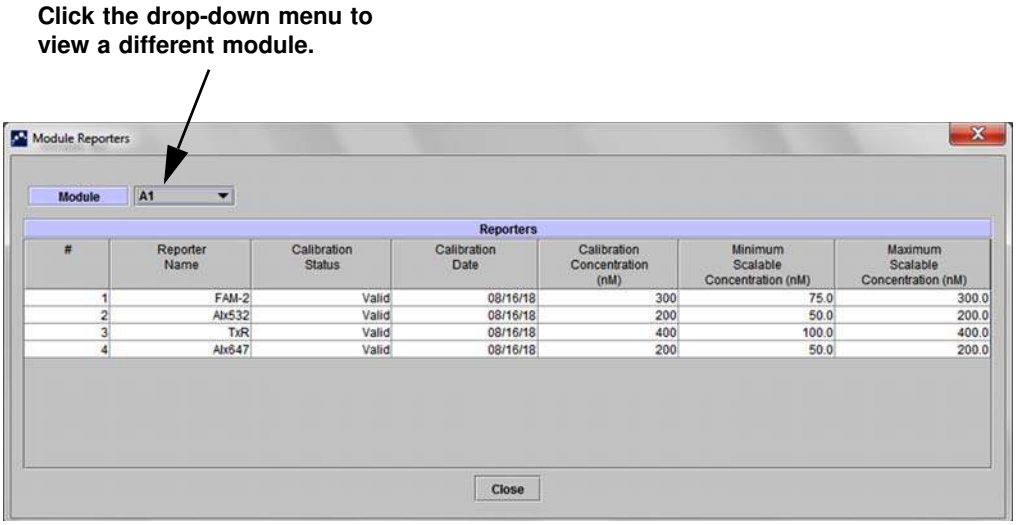


Figure 6-11. Module Reporters Window

6.13 Performing a Manual Self-Test

Note **No tests can be running in the GeneXpert Xpress when performing a manual self-test.**

The GeneXpert Xpress automatically performs a self-test during startup. However, a self-test can be manually initiated on any of the modules to reset and check for hardware failure problems.

To start the self-test:

1. Remove cartridges from the modules to be checked.

2. In the GeneXpert Dx System window, click the **Maintenance** icon. The Maintenance screen displays. See Figure 6-14.
3. Click on **Maintenance** on the menu bar and select **Perform Self-Test.** The Module Self-Test dialog box displays. See Figure 6-12.

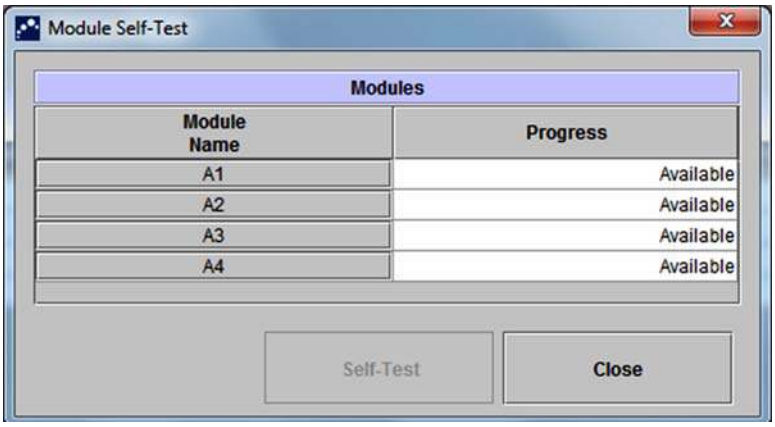


Figure 6-12. Module Self-Test Dialog Box

4. Select the module to be checked.
5. Click **Self-Test**. The Self-Test dialog box displays. See Figure 6-13.

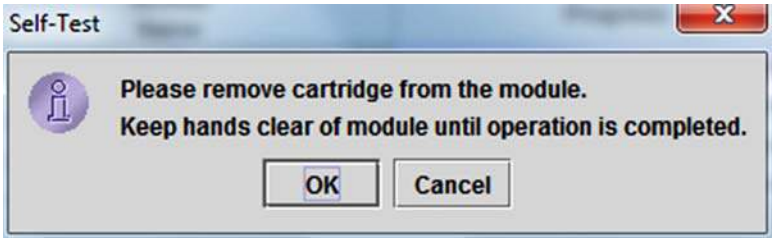


Figure 6-13. Self-Test Dialog Box

6. Follow the instructions in the Self-Test dialog box and click **OK**.
7. When the self-test finishes, the software changes the progress to **Available**, indicating the self-test passed. If the message indicates the self-test failed, contact Cepheid Technical Support. See the Technical Assistance section in the Preface for the contact information.

6.14 Excluding Modules from Test

Modules may be excluded from testing, if desired, by following the instructions in this section. Modules that are excluded will be listed as **Disabled**, and will not be used by the system to run tests.

To exclude modules from a test:

1. In the GeneXpert Dx System window, click the **Maintenance** icon. The Maintenance screen displays. See Figure 6-14.
2. Click on **Maintenance** on the menu bar and select **Exclude Modules From Test**. The Exclude Modules From Test dialog box displays. See Figure 6-15.

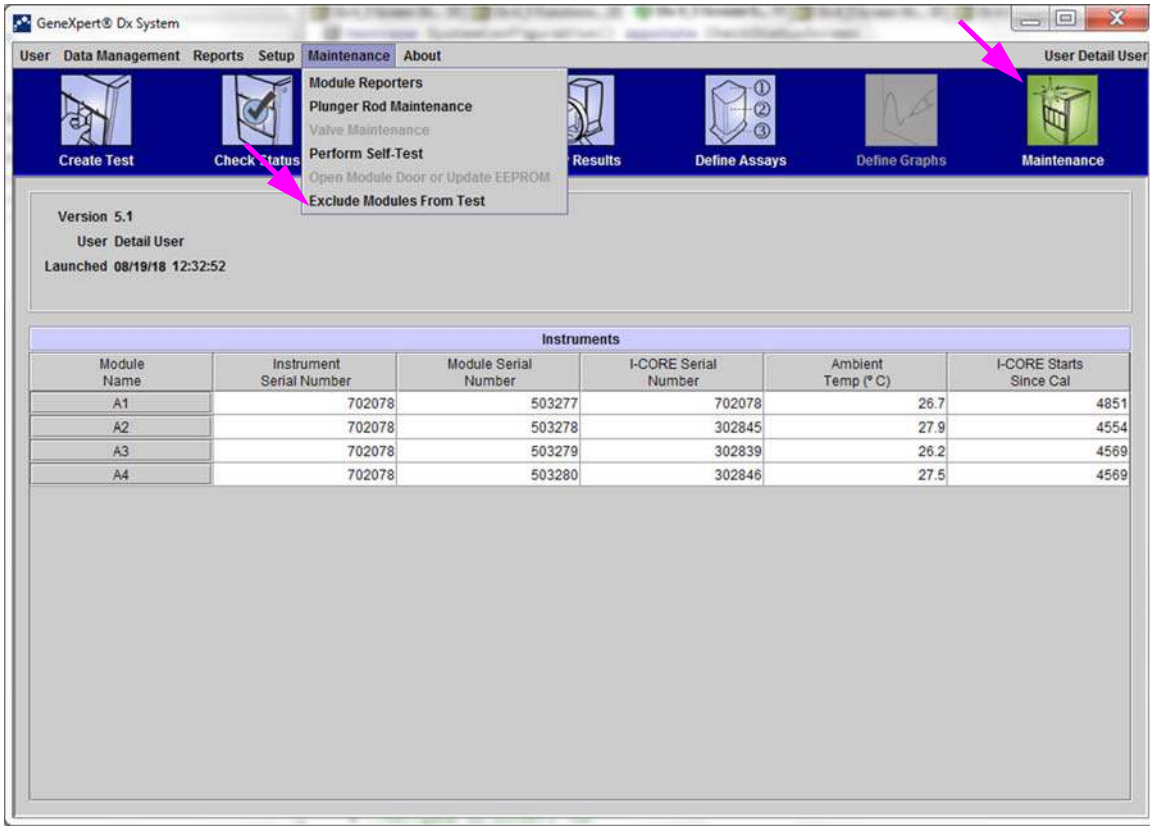


Figure 6-14. GeneXpert Dx System Window

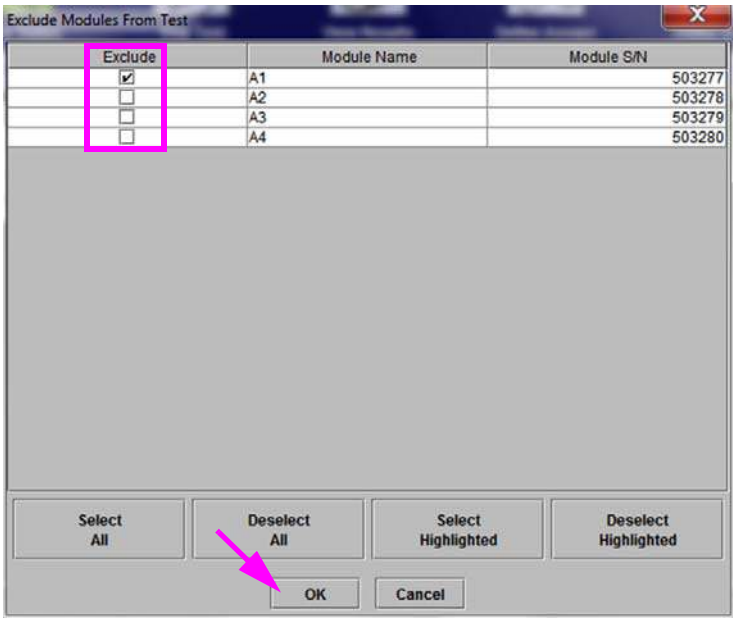


Figure 6-15. Exclude Modules From Test Dialog Box

3. Select the module(s) to be excluded from test by clicking on the adjacent check box.
4. Press the **OK** button to save changes to the Exclude Modules From Test dialog box (see Figure 6-15).

   Press the **Cancel** button to cancel changes.

6.15 Generating the System Log Report

The System Log reports can be used to provide incidents of instrument module self-tests and errors to Cepheid when a module failure has been encountered.

1. In the GeneXpert Dx System window, click **Reports** on the menu bar, and then click **System Log**. The System Log Report window displays. See Figure 6-16.

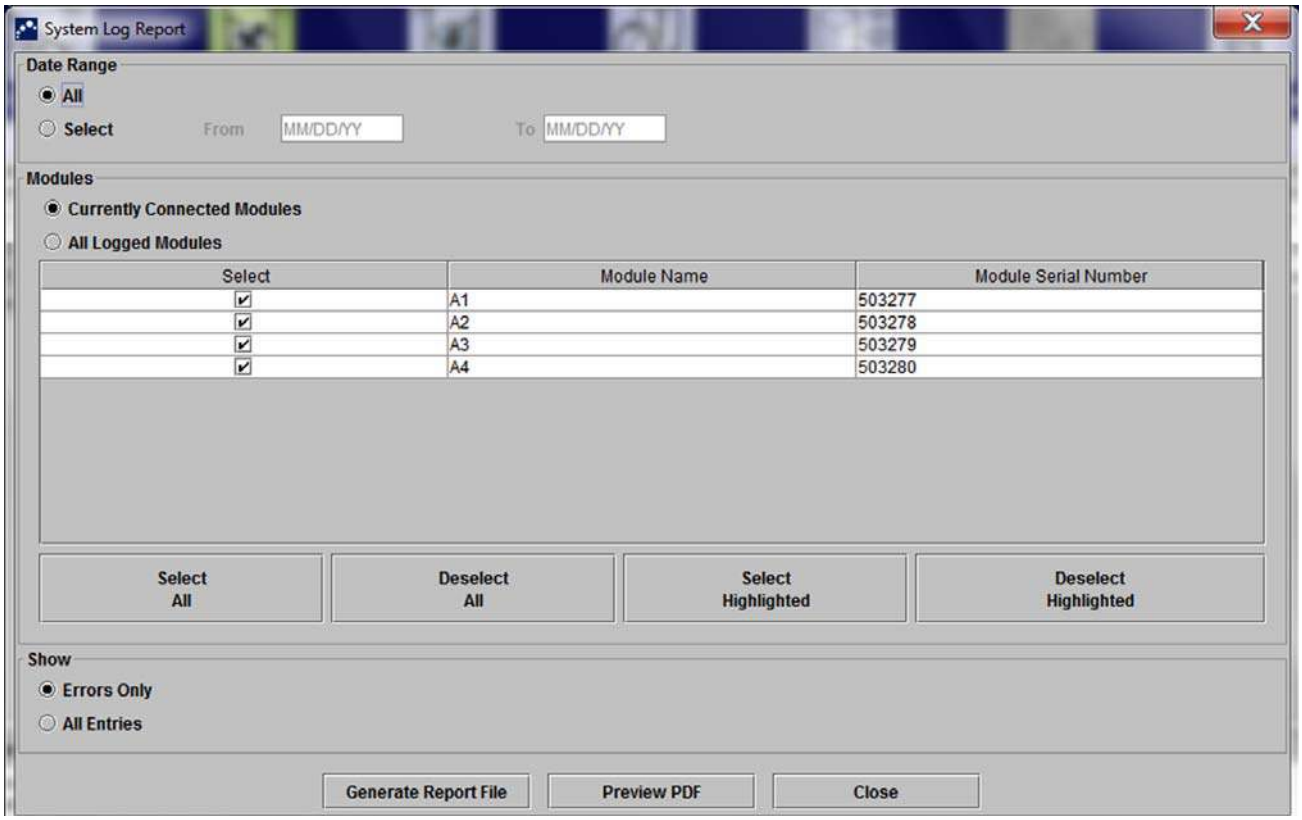


Figure 6-16. System Log Report Window

2. Specify the following criteria to view the trends of interest:

   - **Date Range:**
     - **All**—Select to include all of the records.
     - **Select**—Select to filter the records by specifying a range of dates. Entries older than 1 year are automatically removed.
   - **Modules:**
     - **Currently Connected Modules**— Displays modules that are connected to the system and are currently shown on Check Status screen. This is the default option.
     - **All Logged Modules**—Displays all modules which have self-test or error entries in this system database within the last 1 year. This allows technical support to obtain self-test/error entries for a module that is no longer connected to the system.

       A list of modules is displayed in the table. Select the module to be included in the system by selecting the individual modules one-by-one, or by using one of the following buttons:

       - **Select All**—Selects every module shown in the table by checking all check boxes.

- **Deselect All**—Deselect every Module by clearing all check boxes.
- **Select Highlighted**—Selects the row(s) highlighted by the mouse.
- **Deselect Highlighted**—Deselect the highlighted rows and clear the check boxes.

- **Show:**
  - **Errors Only**—Displays only error entries in the generated report file.
  - **All Entries**—Displays all self-test entries and error entries in the report.

3. When you finish selecting the log criteria, click one of the following buttons:
   - **Generate Report File**—Creates a PDF file and saves it to the location you specify.
     - Click the **Generate Report File** button on the System Log Report screen (see Figure 6-16) to create the PDF file of the test report. The Generate Report File dialog box will display, which enables a file to be saved to a specified location. Click **Save** after navigating to the specific location.
     - Optionally, to print the report, go to the saved location, open the test report and print it. A test report similar to the test report shown in Figure 6-17 will be printed.
   - **Preview PDF**—Creates a PDF file and displays the file in the Adobe Reader window. See Figure 6-17. The PDF file can be saved and printed from the Adobe Reader software.
4. After printing the System Log report, click **Close** to close the System Log Report window.

GeneXpert PC 07/09/18 12:59:42

System Log Report

– Selection Criteria –

Date Range: All

Modules: Currently Connected Modules
Module A1,A2,A3,A4.

Show: Errors Only

User: Detail User

Module Name	Instrument S/N	Module S/N
A1	702078	503277

#	Description	Detail	Time	Version
1	Self-test error	Error 4001: A problem with the memory of the I-CORE was detected	07/09/18 12:58:20	4.7

Module Name	Instrument S/N	Module S/N
A2	702078	503278

<No Data Available>

Module Name	Instrument S/N	Module S/N
A3	702078	503279

<No Data Available>

Module Name	Instrument S/N	Module S/N
A4	702078	503280

<No Data Available>

If there is an issue with an instrument, contact Technical Support.

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Figure 6-17. An Example of a System Log Report

6.16 Replacing Instrument Parts

Caution

Do not attempt to replace the power cord or Ethernet cable using non-approved parts. Using incompatible parts can damage the instrument, cause performance problems or cause loss of data.

You can replace the following GeneXpert Xpress instrument parts:

- Power cord for GeneXpert Xpress IV(Part Number: 100-1375)
- Ethernet cable (Part Number: 700-0555)
- DC Adapter Power Supply for GeneXpert Xpress II (Part Number: 100-3632)
- Power Cord for GeneXpert Xpress IV (Part Number: 100-3717)

You can obtain the power cord, Ethernet cable, and DC adapter power supply from Cepheid. See the Technical Assistance section in the Preface for the contact information.

6.17 Repairing the Instrument

Warning

Do not attempt to open or remove the instrument covers. Doing so can expose you to electrical hazards and cause injuries or death.

Warning

Do not attempt to open or remove the instrument covers. Do not attempt to modify or repair the system. Improper repairs and incorrect part replacements can cause injury, damage the instrument, and void your warranty.

To protect your warranty and for proper operation, the GeneXpert Xpress should be serviced only by an authorized Cepheid representative. If the instrument is not working correctly, contact Cepheid Technical Support. See the Technical Assistance section in the Preface for the contact information. When you call Cepheid Technical Support, be prepared to supply the serial number of your instrument. You can find the serial number label on the back side of the instrument.

6.18 Troubleshooting

This section lists the possible problems or error messages you might encounter. The topics are as follows:

- Section 6.18.1, Hardware Problems
- Section 6.18.2, Troubleshooting Wireless Printer Connection
- Section 6.18.4, Error Messages

6.18.1 Hardware Problems

Table 6-2 lists the possible hardware problems you might encounter. To contact Cepheid Technical Support, see the Technical Assistance section in the Preface for the contact information.

Table 6-2. Hardware Problems

Problem	Possible Cause	Solution
The system does not start.	The instrument is not connected to the power outlet.	Check the instrument power connections.
Module not detected.	Network cable not connected or incorrect cable installed. Software launched before instrument turned on. The IP address is not assigned correctly.	Connect network cable (Cepheid P/N 700-0555). Exit software and relaunch with instrument powered on. Change IP Address
Hardware failure.	Using software version less than 4.0 with 6-color instrument.	Turn system off and update software.
Barcode scanner failure.	Symbology unsupported. Scanner barcode cable not plugged in.	GeneXpert Dx software supports Code 39, Codebar, Code 128 (A, B and C) linear barcode symbologies and Interleave 2 of 5. Unplug scanner and replug into computer.
The cartridge is stuck inside the instrument module.	Module mechanical failure.	To remove the cartridge: • In the GeneXpert Dx System window, click **Maintenance** on the toolbar. • On the Maintenance menu, click **Open Module Door or Update EEPROM**. • Select the module. • Click **Open Door** to open the module door. If the door does not open, cycle the instrument power and repeat the above steps.

Table 6-2. Hardware Problems (Continued)

Problem	Possible Cause	Solution
The instrument module red light is flashing.	Module mechanical failure.	Confirm no cartridge is in the module. Perform a self-test manually (Section 6.13, Performing a Manual Self-Test). If the error recurs, contact Cepheid Technical Support.
Test report is not printed at the end of run.	Printer off line. Printer out of paper and/ or toner.	Check: • Printer on-line. • Paper present. • Toner OK.
Unable to create a test.	Modules not available. No assay selected. Module not calibrated for reporters used in assay. The ambient temperature of the module is above 55 °C.	Check that assay is selected. Calibrate with assay dyes. Check that the modules are not disabled. Check module temperature in Maintenance screen. If your room is in the recommended temperature range and the module is above 55 °C, contact Cepheid Technical Support.
Unable to start test.	Reporters out of calibration.	Check module reporters in maintenance window: Reporter for assay are present. Calibration status is valid.

6.18.2 Troubleshooting Wireless Printer Connection

Check if the wireless capability is disabled on the computer. For a Windows 7 computer, see Section 6.18.2.1, Troubleshooting Wireless Printer Connections for Windows 7. for a Windows 10 computer, see Section 6.18.2.2, Troubleshooting Wireless Printer Connections for Windows 10.

6.18.2.1 Troubleshooting Wireless Printer Connections for Windows 7

1. f the wireless capability is disabled on the Tablet, the **f12** key on the keyboard will display an amber light.
2. Press and hold the **fn** key at the same time as pressing the **f12** key to enable the wireless capability.
3. The amber light will no longer appear.

Check if the Cepheid Xpress printer is no longer default printer.

1. Select the Windows **Start** button >**Devices and Printers** in the right panel of the start menu.
2. Right click on the **Cepheid Xpress** printer and select **Set as default printer**.

3. A green check mark will display on the Cepheid Xpress printer indicating that it is set as the default printer.

6.18.2.2 Troubleshooting Wireless Printer Connections for Windows 10

1. If the wireless capability is disabled on the computer, the indicator on the outer lid of the computer will be off.
2. Press and hold the **fn** key at the same time as pressing the **f8** key to enable the wireless capability.
3. The indicator light on the outer lid of the computer will be green.

Check if the Cepheid Xpress printer is no longer default printer.

1. Select the **Options** button >**All settings> Devices> Printers & scanners**.
2. Click on the **Cepheid Xpress** printer >**Manage** and select **Set as default**.
3. The word Default will display under Cepheid Xpress.

6.18.3 Re-installing Wireless Printer and Drivers

1. Exit the Xpress software. See Section 3.8, Exiting the Software and Turning Off the System or Section 4.8, Exiting the Software and Turning Off the System.
2. Connect a DVD drive with the Laptop via a USB cable as show in Figure 5-30 of Section 5.5.1, The DVD Drive.
3. Power on the EPSON WF-100 printer.
4. On the printer's control panel, press the **OK** button to select Wi-Fi Setup.
5. Press the **Next** button until you see Wi-Fi Direct Setup and press the **OK** button.
6. Press the **OK** button to proceed for Connection Setup.
7. Again, Press **OK** to proceed.
8. Press **OK** again to proceed further and you will be prompted with a screen where you will see the Network SSID and Password to connect the Wireless printer to the computer. Please make a note of this SSID and Password.
9. On the computer, select the SSID from the Wi-Fi display panel and enter the password noted earlier to connect to the printer. See Figure 6-18.

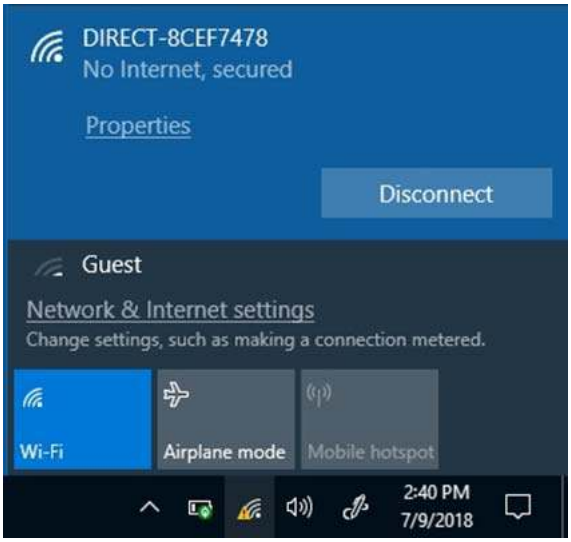

Figure 6-18. Wi-Fi Display Panel

10. Insert the EPSON WF-100, installation CD (shipped in the printer box) in the DVD drive.
11. When the Select to choose what happens to this disk pop up windows appears click on it and select **Run SETUP.exe**.
12. Click **Yes** to the pop up window, Do you want to allow this app to make changes to your device?.
13. Click **Accept** to agree with the license terms.
14. Select **Epson drivers and utilities**.
15. Click **Install**.
16. After the installation is complete, select **Next**.
17. Select **The Printer is already on my wireless network** and click **Next**.
18. In the firewall window, check the **Allow Access** option and select **Next**.
19. Select the printer **WF-100 Series**, and select **Next.**
20. On the next screen, select the **Print Test Page** button to print a page and confirm the installation of the printer is complete. Once the test page is printed, click **Next**.
21. Select **Exit** to close the setup
22. Follow the instructions in Section 5.9, Connecting to the Printer with a Direct USB Connection starting from step 7 to change the name of the printer.
23. When finished, remove CD and the DVD drive. Plug in the scanner if removed.
24. Log into the Xpress application. See Section 5.10, Returning to the GeneXpert Xpress Software.

6.18.4 Error Messages

This section describes the location of the error messages. To contact Cepheid Technical Support, see the Technical Assistance section in the Preface for the contact information.

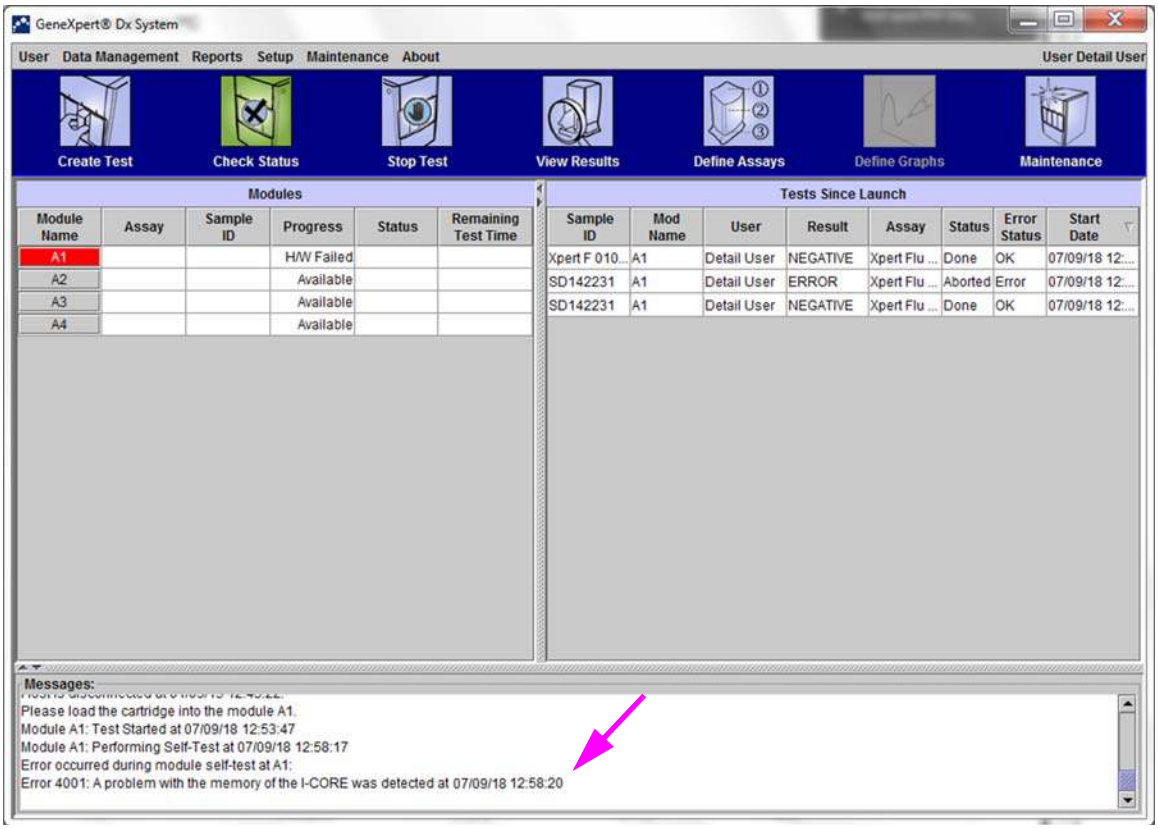

Figure 6-19. GeneXpert Dx System - Check Status Window

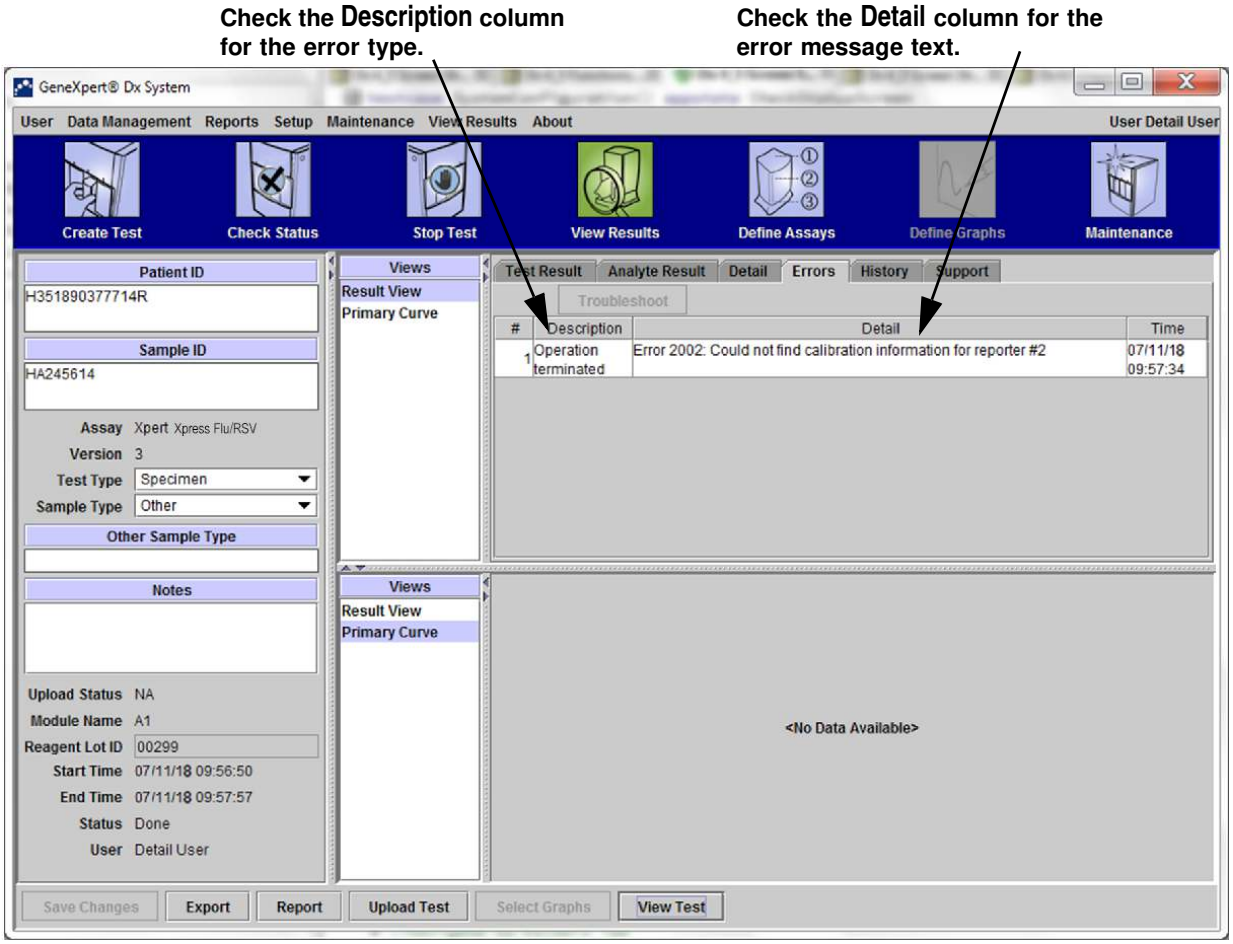

Figure 6-20. GeneXpert Dx System - View Results Window - Errors Tab

A Optional Computer Setup and Usage

This appendix provides information on changing the screen orientation from tablet mode to laptop mode and using the optional computer stand.

- Section A.1, Windows 10 - Changing Screen Orientation/Mode to Laptop
- Section A.2, Windows 10 - Changing Screen Orientation/Mode to Tablet
- Section A.3, Windows 7 Computer - Changing Screen Orientation/Mode
- Section A.4, Windows 7 Computer - Computer Stand Usage in Tablet Mode

A.1 Windows 10 - Changing Screen Orientation/Mode to Laptop

The computer is shipped closed, with the LCD screen facing to the inside. However the screen configuration is set to Tablet mode.

Figure A-1. Computer, Shown Closed, as Shipped

1. To change the computer to laptop mode open the cover if it is not already open, as shown in Figure A-2. Power up the laptop if needed. See Section 3.1, Starting the GeneXpert Xpress II and GeneXpert Xpress Software or Section 4.1, Starting the GeneXpert Xpress IV and GeneXpert Xpress Software.

Figure A-2. Computer Shown in Laptop Mode

2. Exit the Xpress program but do not turn off the computer, (see Section 3.8, Exiting the Software and Turning Off the System or Section 4.8, Exiting the Software and Turning Off the System).

3. When you are at the desktop, touch the **Options** button on the lower right corner of the Windows desktop. See Figure A-3.

Figure A-3. Options Button Location on Windows 10 Desktop

4. In the popup window, touch **Tablet** to turn off the tablet screen mode. See Figure A-4. The Tablet mode button will turn gray.

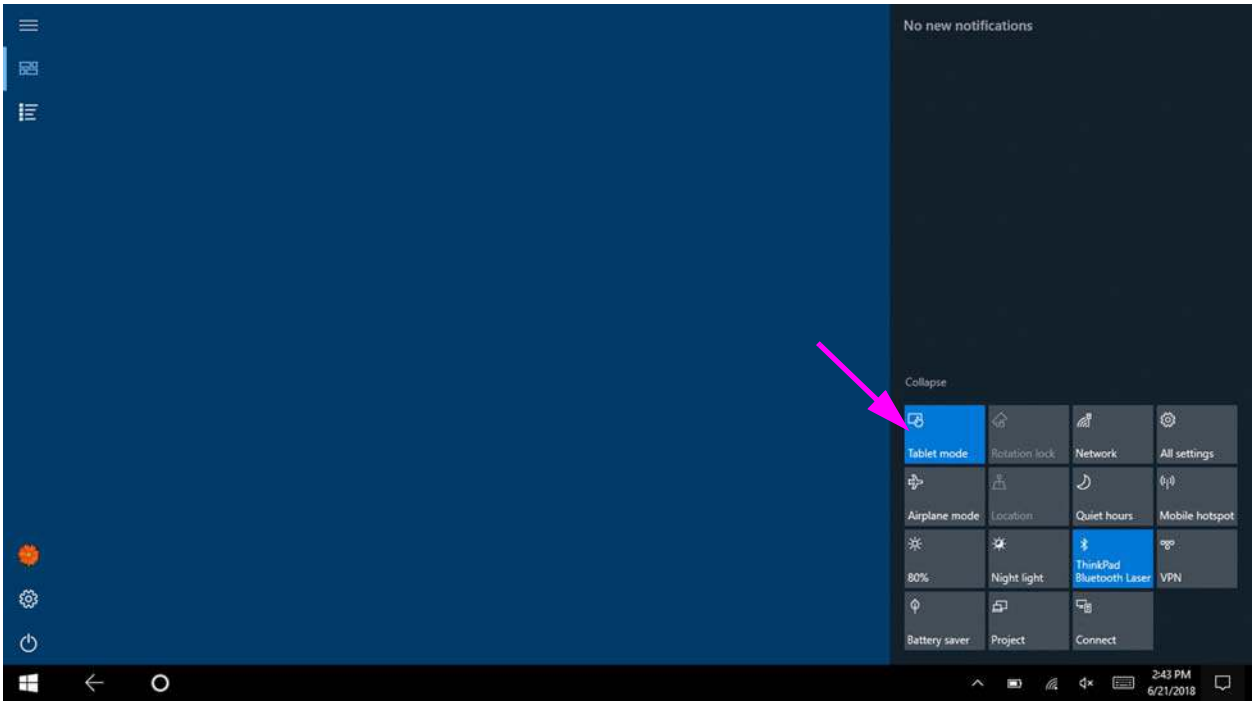

Figure A-4. Options Menu Showing the Tablet Button

A.2 Windows 10 - Changing Screen Orientation/Mode to Tablet

1. Open the laptop top until is 360 degrees from the closed position.
2. If required, exit the Express program, (see Section 3.8, Exiting the Software and Turning Off the System orSection 4.8, Exiting the Software and Turning Off the System) or the GeneXpert Dx program. See Section 5.10.1, Exiting the GeneXpert DX Software.
3. When you are at the desktop, touch the **Options** button on the lower right corner of the Windows desktop. Then touch the Tablet mode button. The button will turn blue. See Figure A-5.

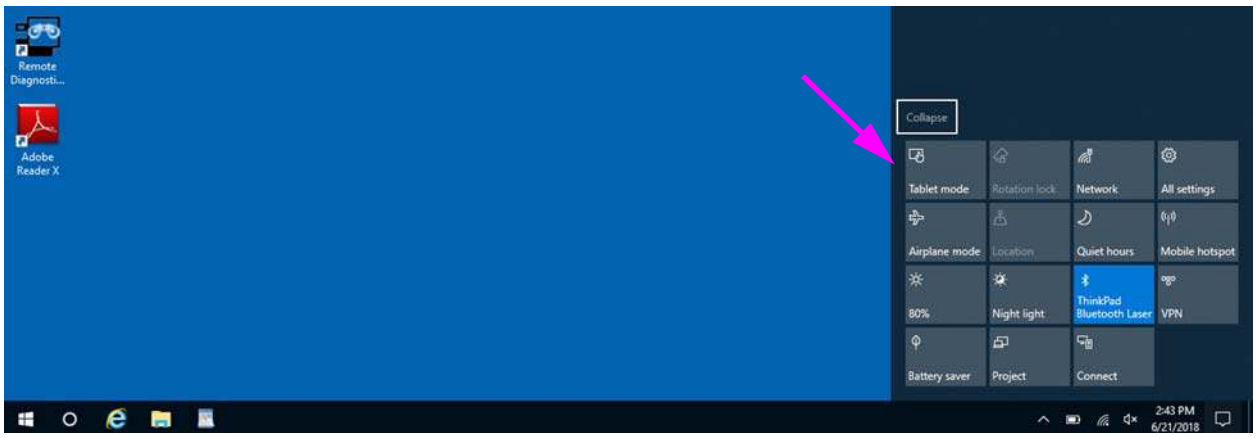

Figure A-5. Options Menu Showing the Tablet Button Off

A.3 Windows 7 Computer - Changing Screen Orientation/Mode

The computer is shipped in tablet mode with the LCD screen facing up. See Figure A-1.

Figure A-6. Computer, Shown in Tablet Mode, as Shipped

To change the computer to laptop mode, as shown in Figure A-2, Power up the laptop, if needed. See Section 3.1, Starting the GeneXpert Xpress II and GeneXpert Xpress Software or Section 4.1, Starting the GeneXpert Xpress IV and GeneXpert Xpress Software.

There are two methods for changing the orientation of the screen, either press the **Ctrl**, **Alt** and **Page up** buttons on the keyboard at the same time or:

Figure A-7. Computer Shown in Laptop Mode

1. Touch the **Start** button on the lower left corner of the Windows desktop. See Figure A-3.

Figure A-8. Start Button Location on Windows 7 Desktop

2. When the menu appears, select **Control Panel** (see Figure A-4). The Control Panel screen is displayed. See Figure A-10.

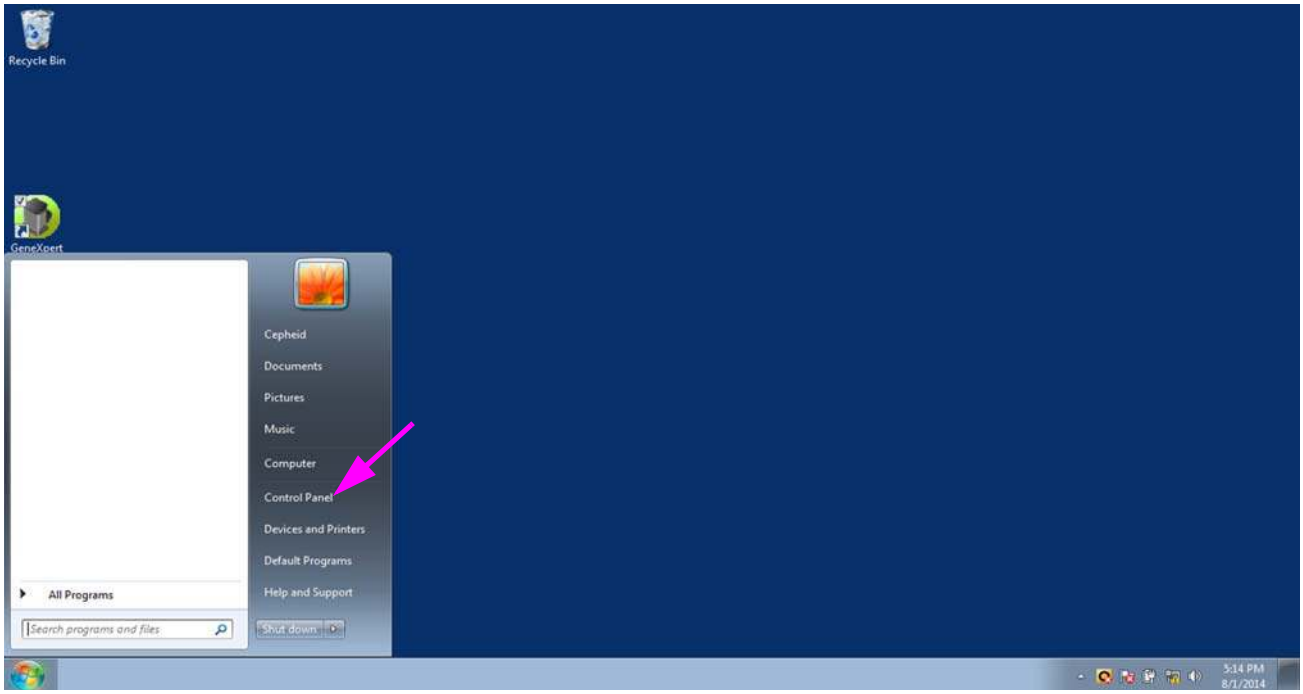

Figure A-9. Start Button Menu Showing Control Panel

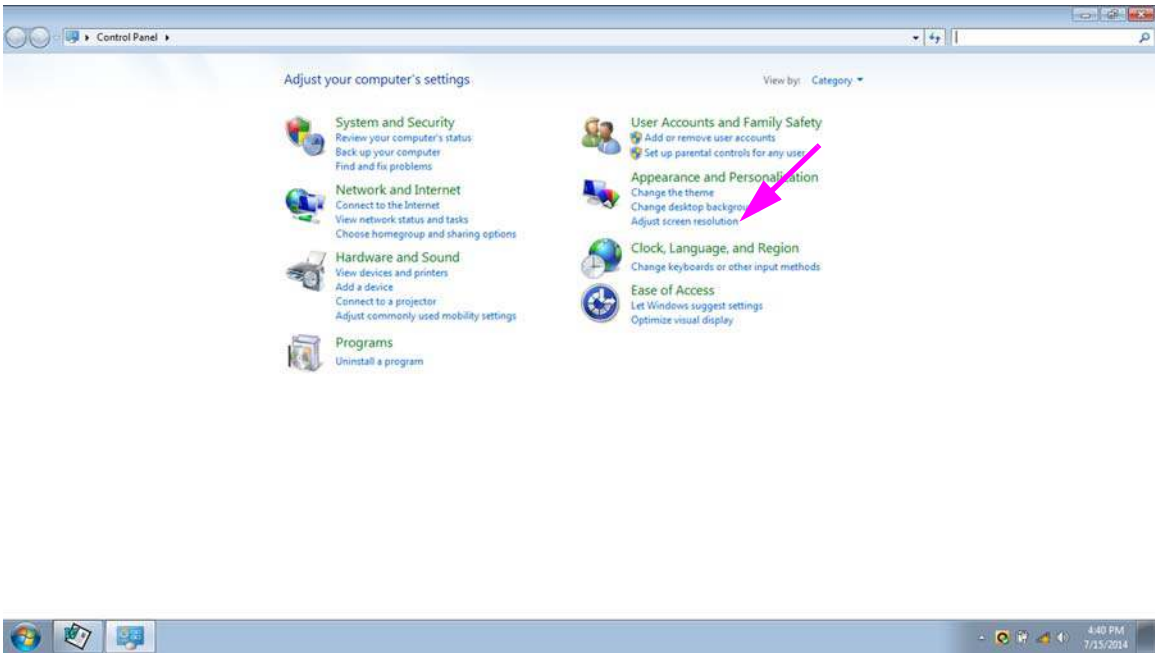

Figure A-10. Control Panel menu, showing Adjust Screen Resolution Menu Item

3. On the Control Panel screen, locate the **Appearance and Personalization** options and touch **Adjust screen resolution**. See Figure A-10.
4. When the Screen Resolution window is displayed, touch the **Orientation** drop-down menu and choose **Landscape .** See Figure A-11.
5. Touch the **Apply** button and then the **OK** button. On the next dialog box, quickly touch **Keep Change**.

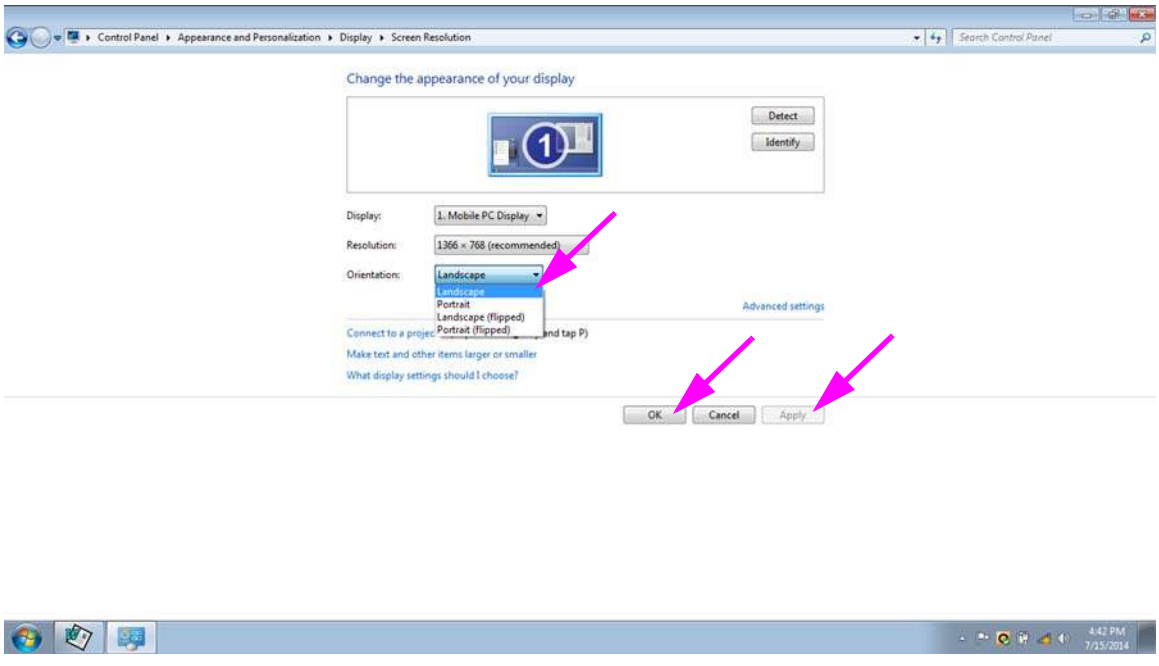

Figure A-11. Screen Resolution Window

Figure A-12. Computer with Screen Rotated to Laptop Mode

6. Open the computer and rotate the screen 180 degrees as shown in Figure A-12.

Caution

Before rotating the screen, be sure it is perpendicular to the keyboard and gently rotate the screen counterclockwise to rotate the screen from tablet to laptop mode, clockwise to rotate the screen from laptop to tablet mode. Applying too much pressure when rotating the screen may damage the laptop.

Note

To change the orientation to tablet mode, follow the instructions above but select **Landscape (flipped)** on the Screen Resolution Window, See Figure A-11. Rotate the screen and lower it over the keyboard as shown in Figure A-1.

A.4 Windows 7 Computer - Computer Stand Usage in Tablet Mode

The computer stand can be used when the computer is in tablet mode.

The height of the stand is adjustable, by first pushing down on the front of the stand and pulling the height adjustment lever out from the left side of the stand. Move the stand to the desired height. Release the height adjustment lever to secure the stand in the new position. Figure A-13 shows the computer stand without the computer on it. The stand and computer are shown in Figure A-14.

Figure A-13. Computer Stand Without Computer

Figure A-14. Computer Stand with Computer in Tablet Mode

B Performance Characteristics and Specifications

This chapter presents the GeneXpert Xpress performance characteristics and specifications. The topics are as follows:

- Section B.1, Instrument Classification
- Section B.2, General Specifications
- Section B.3, Operational Environmental Parameters
- Section B.4, Environmental Conditions - Storage and Transport
- Section B.5, Sound Pressure
- Section B.6, Product Energy Consumption Information

B.1 Instrument Classification

The GeneXpert Xpress is:

- An Industrial Scientific Medical Device (ISM) instrument, medium-sized, for industrial and laboratory use.
- Designed for stationary operation.
- Intended for worldwide use.
- Intended for evaluating preprocessed biological material.

B.2 General Specifications

B.2.1 General Specifications for GeneXpert Xpress Instruments

The GeneXpert Xpress instruments have the following specifications:

- **Dimensions and Weight:**

Table B-1. Dimensions and Weight

Instrument	Width	Height	Depth	Weight
GX-II	16.3 cm (6.4 in)	30.7 cm (12.1 in)	29.7 cm (11.7 in)	6.5 kg (15 lb)
GX-IV	28.2 cm (11.1 in)	30.5 cm (12 in)	29.7 cm (11.7 in)	11.4 kg (25 lb)

- **Power Supply:** Auto-ranging
- **Rated AC Voltage Range:** 100–240 V~, 50–60Hz
- **Mains Supply Fluctuations:** Up to ± 10% of the nominal voltage
- **Transient Over-Voltages:** Up to 2500 V peak (impulse withstand category II)
- **Rated Current and Fuse Rating:**

Table B-2. Rated Current and Fuse Rating

Instrument	Rated Current	Fuse Rating
GX-II	1.5A @ 100V~ (AC Adapter Output 2.5A @ 24Vdc)	No serviceable fuse
GX-IV	1.4A @ 100V~	250V~ T3A (IEC 60127 time-delay type)

B.3 Operational Environmental Parameters

Your laboratory must meet the following requirements:

- **General Environment:** Indoor only
- **Pollution Degree:** 2
- **Operating Temperature:** 15–30 °C
- **Operating Temperature Required for Maximum Thermal Ramp Rates:** 20–25 °C
- **Relative Humidity:** 20%–80%, non-condensing

Place the GeneXpert Xpress away from heat and air conditioning ducts. Do not place the instrument directly under an air vent or in direct sunlight. Always keep the instrument module doors closed when not in use.

B.4 Environmental Conditions - Storage and Transport

The required storage conditions are as follows:

- **Temperature:** -30 °C to +45 °C
- **Humidity:** 0%–95% relative humidity, non-condensing

B.5 Sound Pressure

The sound pressure specifications are as follows:

- **Audible Sound Pressure Range:** < 85 dB (reference level 20 µPa)
- **Ultrasonic Sound Pressure Between 20kHz to 100kHz:** < 94.5 dB SPL (reference level 20 µPa)
- **Maximum Sound Pressure:** Contained in the 40 kHz one-third octave bands

B.6 Product Energy Consumption Information

Supplier Name	Supplier Model Identifier	Energy Efficiency Class	On Mode Power Consumption (W)	Annual Energy Consumption (KWh)	Standby Power Consumption (W)
Cepheid	GeneXpert GX-II	G	85	372	71
Cepheid	GeneXpert GX-IV	G	100	489	83

C Norton Security AntiVirus Software

Important **This appendix only applies to systems running Windows 7 software.**

This appendix describes the operation of the Norton Security AntiVirus software and applies to users that have their GeneXpert Xpress system computer connected to the Internet.

The GeneXpert Xpress computer running Windows 7 comes pre-installed with Norton Security AntiVirus software to maintain a secure working environment.

Important **The antivirus software comes installed with a 1 year license, and will automatically update virus definitions if the computer is connected to the Internet.**

Note The user will receive a warning on startup if the Norton Security AntiVirus software is expiring soon or has expired.

Note During activation of a new antivirus installation, the computer must be connected to the Internet or activation will not complete. If necessary, please contact Cepheid Technical Support. See the Technical Assistance in the Preface for contact information.

C.1 Norton Security AntiVirus and GeneXpert Xpress

The Norton Security AntiVirus software comes preconfigured to operate in silent mode. This means that interruptions may occur if a virus or malware is detected. By default, Norton Security removes any security risks from your computer and quarantines them. If an error occurs, contact Cepheid Technical Support.

C.2 Viewing Norton Security AntiVirus Status

To ensure that the Norton Security AntiVirus software is functioning correctly, look for the Norton icon in the Windows 7 system tray. See Figure C-1. If the Norton Security icons are not visible in the system tray, open the Norton Security software using the desktop icon to make them display.

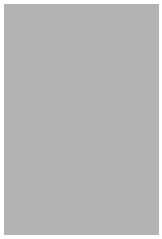

Figure C-1. Norton Security Icon in Windows 7 System Tray

If the Norton software is disabled, the license may have expired. In that case, contact your administrator.

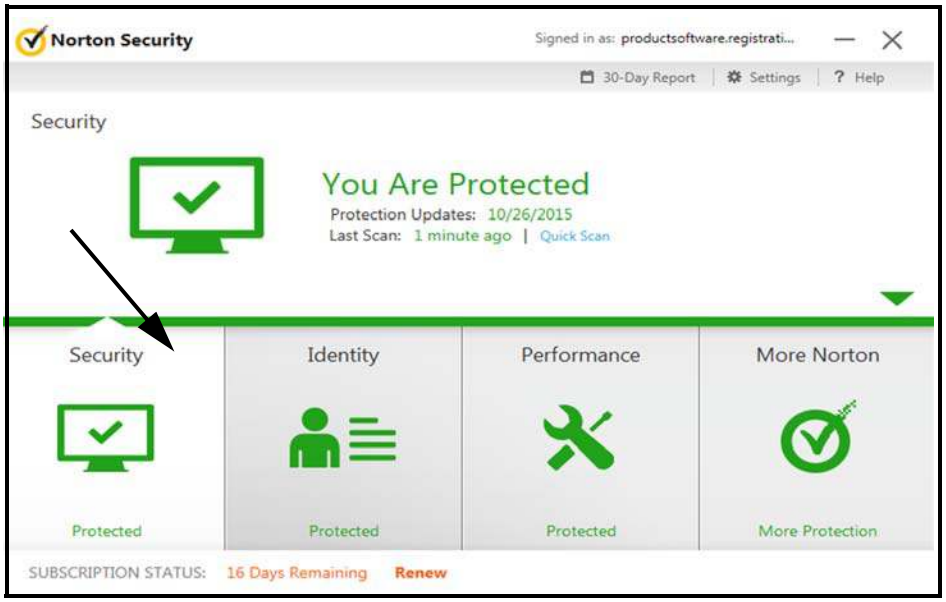

Figure C-2. Norton Security Main Screen

C.3 Full System Antivirus Scans

The software will automatically perform full system scans once a month at a time when the GeneXpert Xpress software is not running. If the GeneXpert Xpress software is continuously running, Cepheid recommends closing it monthly to allow the Norton Security full system scan to execute. To do so, close the GeneXpert Xpress software and leave the computer turned on and logged in to Windows overnight.

Manual Scan

Alternatively, you can manually perform the full system scan monthly. To perform a manual scan, follow these steps:

1. Open the Norton Security software using the desktop icon.
2. Click the green **Security** icon and then click **Run Scans**. See Figure C-3.

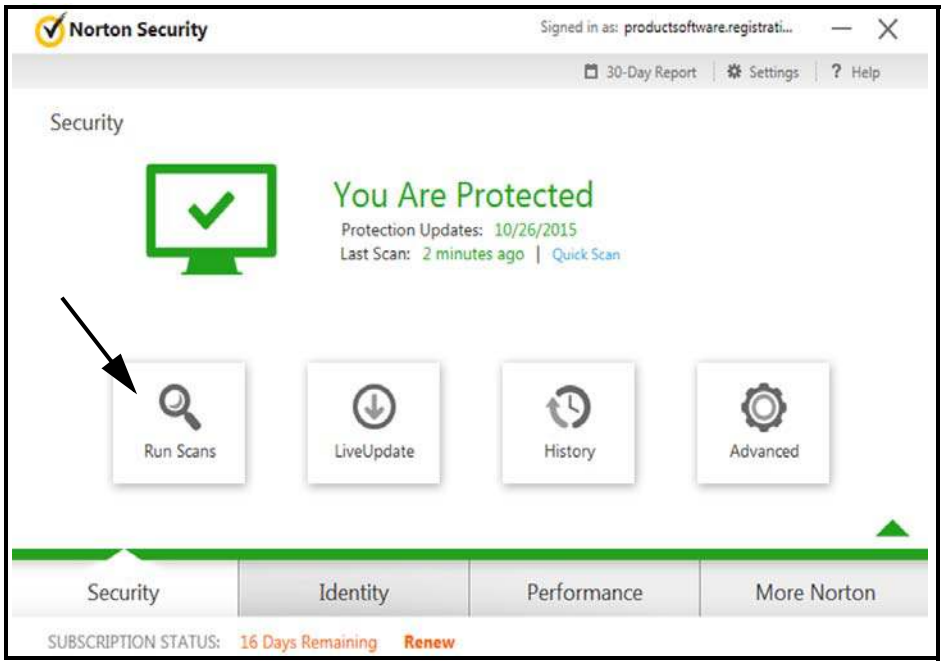

Figure C-3. Performing a Manual Scan

3. The Scans screen is displayed. See Figure C-4. Select the **Full System Scan** button and then click **Go**. The full system scan will begin.

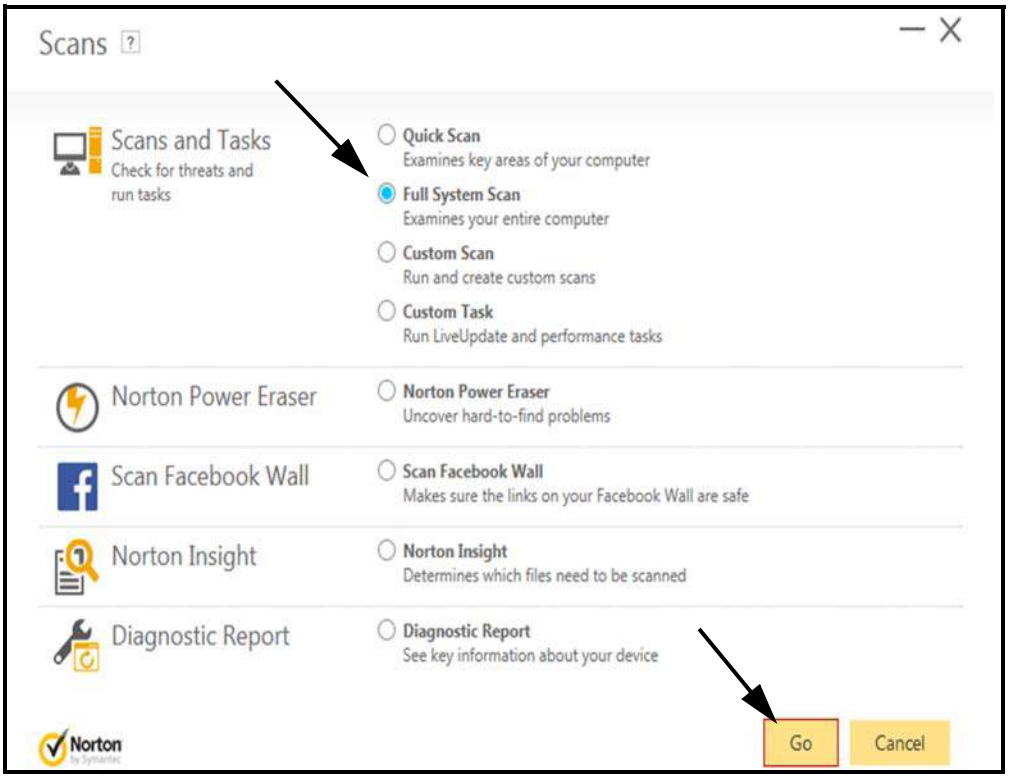

Figure C-4. Scans Screen

C.4 Creating a Custom Scan Interval

C.4.1 Changing the Scan Interval

It is also possible to change the full scan interval from its default of monthly.

Note Cepheid does not recommend increasing the scan interval to longer than monthly.

1. Open the Norton Security software using the desktop icon.
2. Click the green **Security** icon and then click **Run Scans** from the menu item underneath. See Figure C-5.

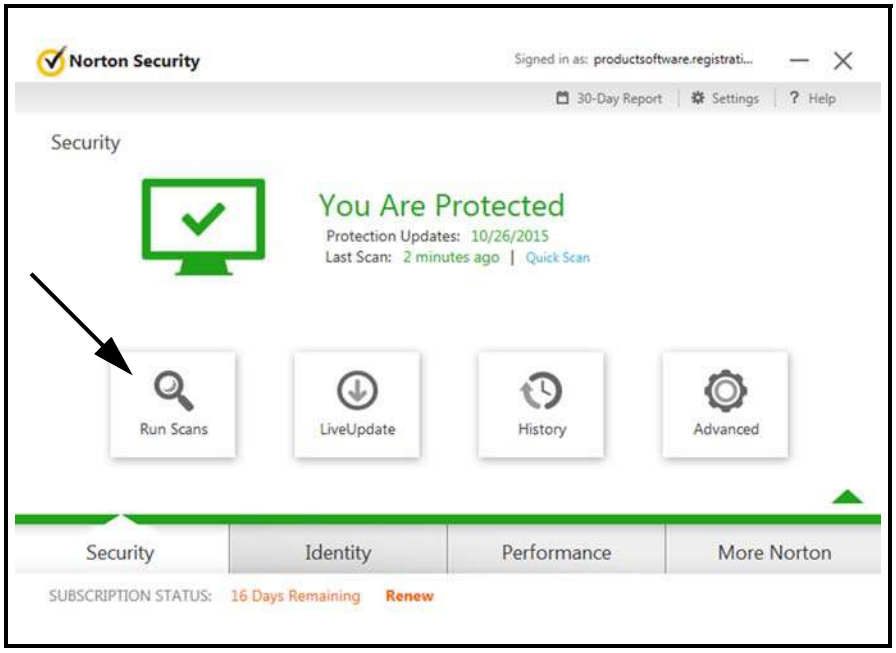

Figure C-5. Performing a Custom Manual Scan

3. The **Scans** screen is displayed (see Figure C-6). Select the **Custom Scan** button and then click **Go**. A new Scans screen is displayed. See Figure C-7.

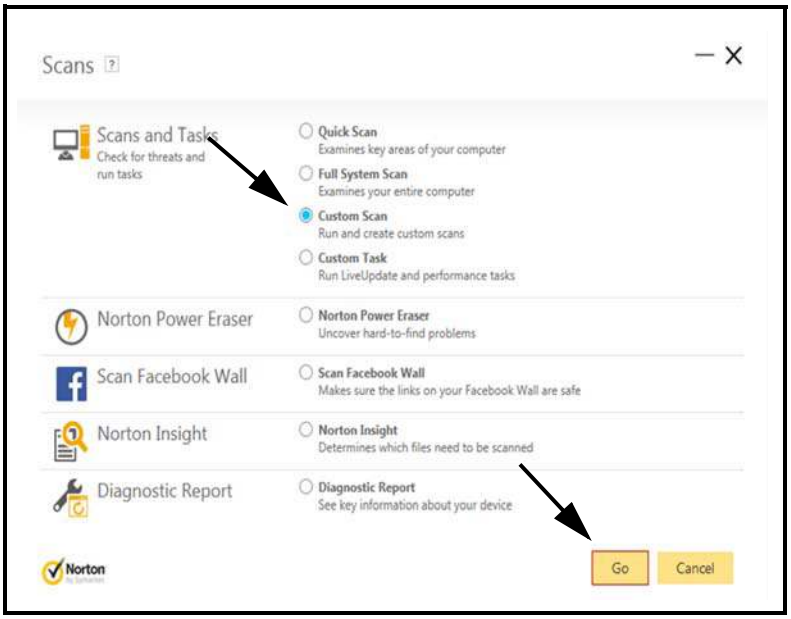

Figure C-6. Scans Screen

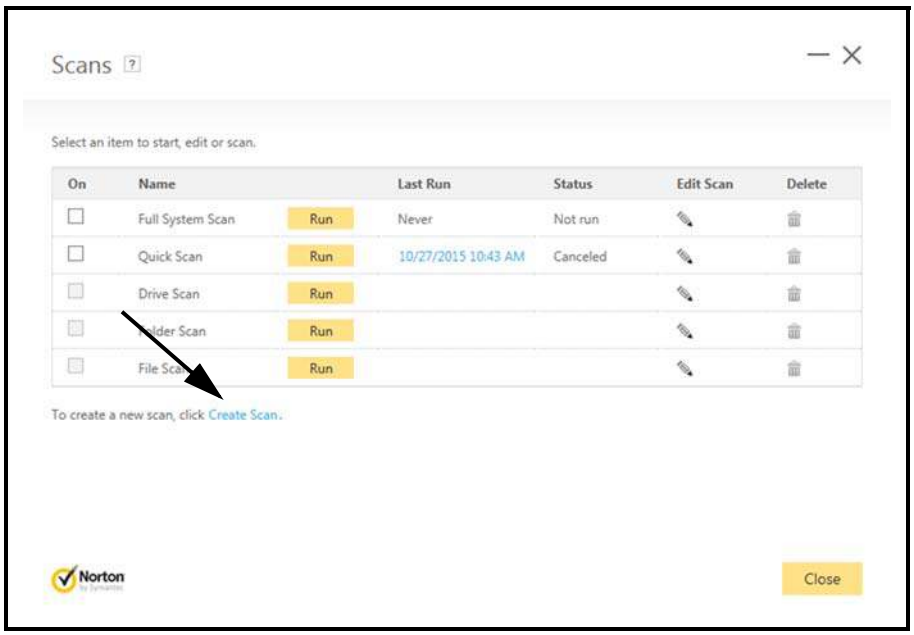

Figure C-7. Scan Screen Showing Create Scan Button

4. On the Scans screen, click the **Create Scan** at the bottom of the screen. The **New Scan** screen is displayed. See Figure C-8.

5. **Step 1. Scan Items:** When the **New Scan** screen displays (see Figure C-8) enter a name for the scan you wish to create in the **Scan Name** field at the top of the screen. A custom scan cannot be created without a name entered in this field.

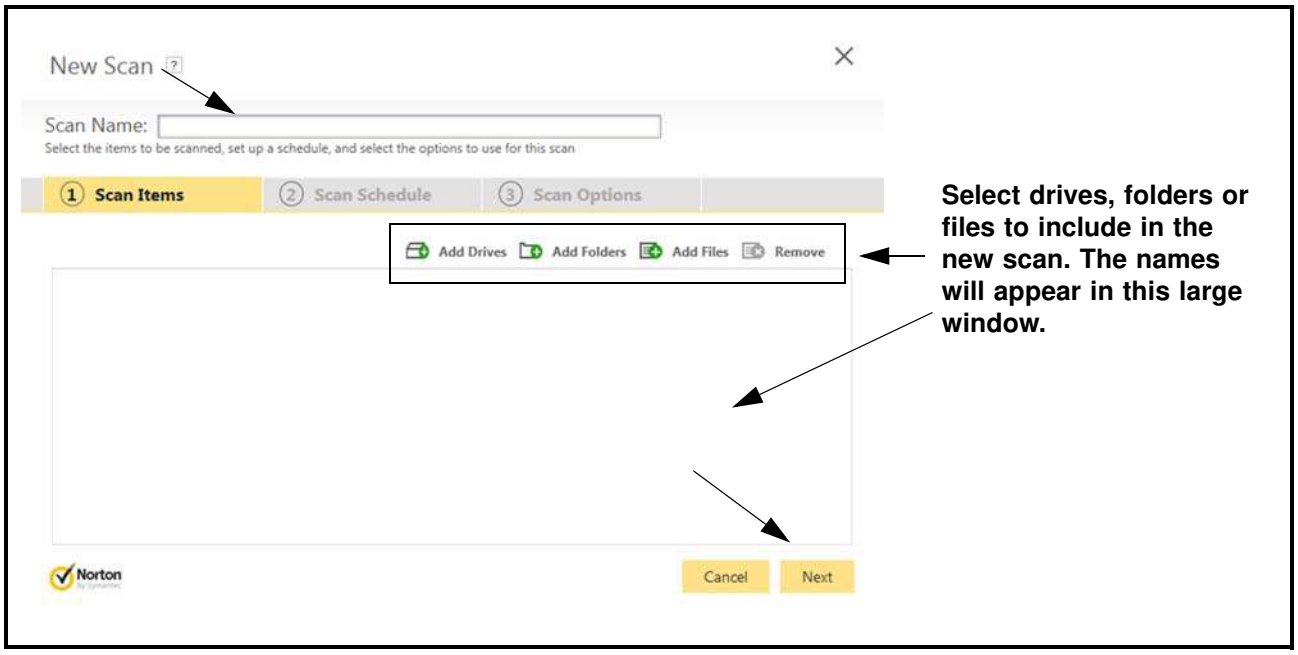

Figure C-8. New Scan Screen

6. Select any drives, folders or files to add to the special scan and then click the **Next** button to move to the next screen.

7. **Step 2. Scan Schedule:** On this screen (see Figure C-9), you will set up the scan schedule or interval.

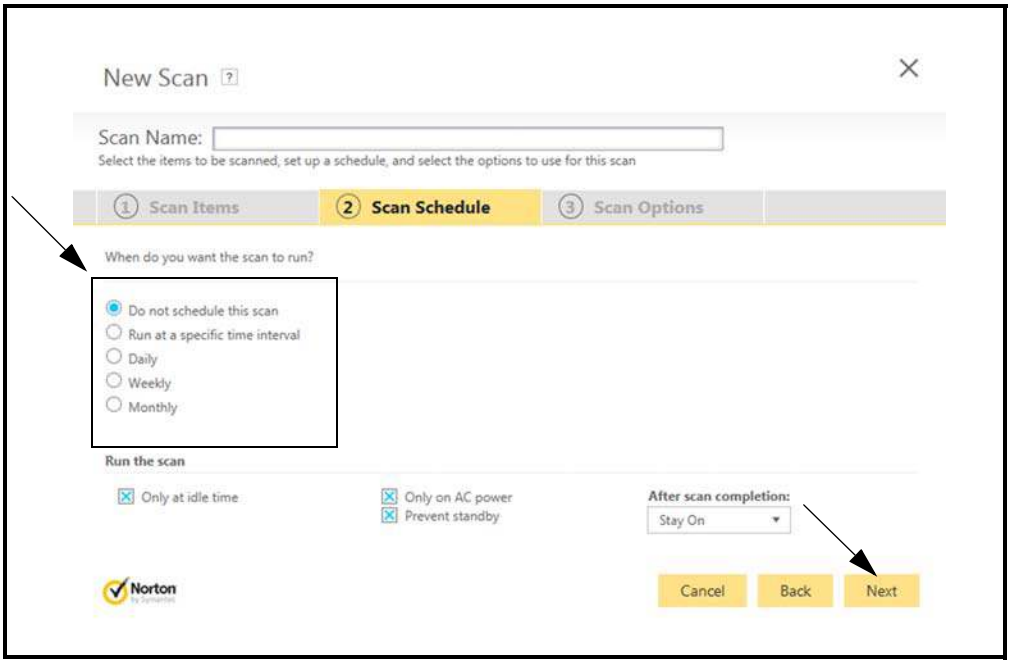

Figure C-9. Scan Schedule Screen

8. Choose from the items listed under the **When do you want the scan to run?** location and select the **Next** button. The Scan Options screen is displayed. See Figure C-10.

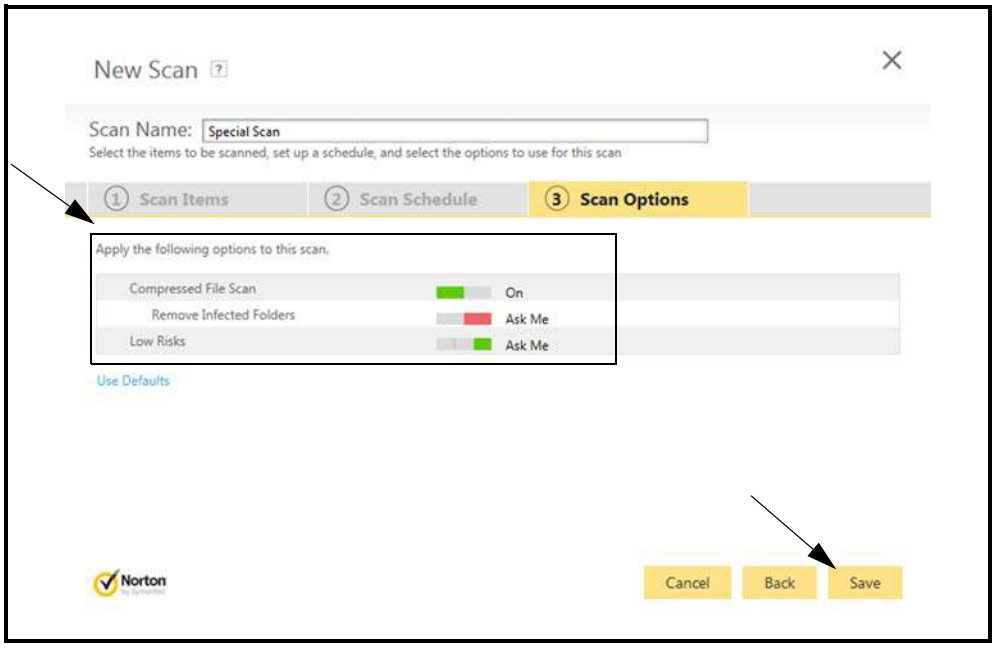

Figure C-10. Scan Options Screen

9. **Step 3. Scan Options:** On this screen, set any options for the new scan setup you have created. After choosing any options from those presented, click **Save**.

C.4.2 Running a Custom Scan

1. To run your newly-created custom scan, select the green **Security** icon and then select **Run Scans** (see Figure C-11). The Scans screen is displayed. See Figure C-12.

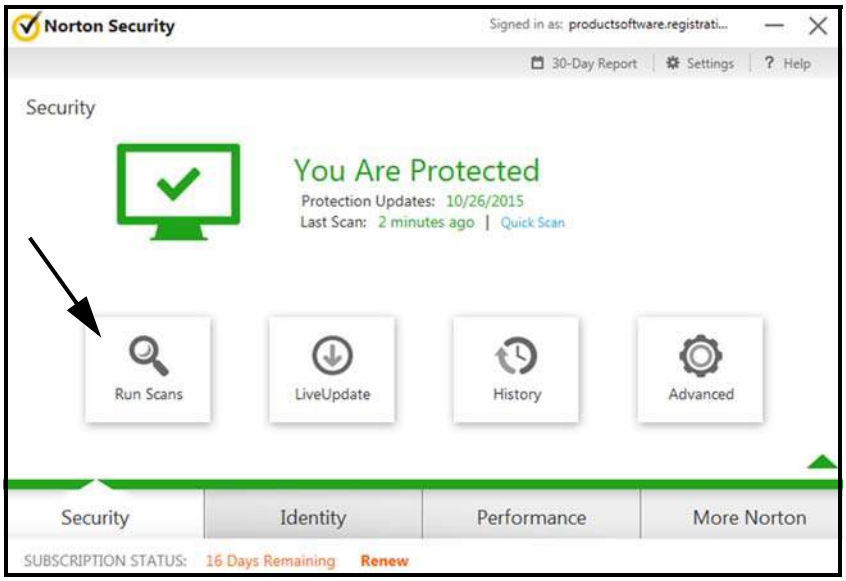

Figure C-11. Running a Special Scan

2. On the Scans screen, select **Custom Scan** and then select **Go** (see Figure C-12). A new Scans screen is displayed. See Figure C-13.

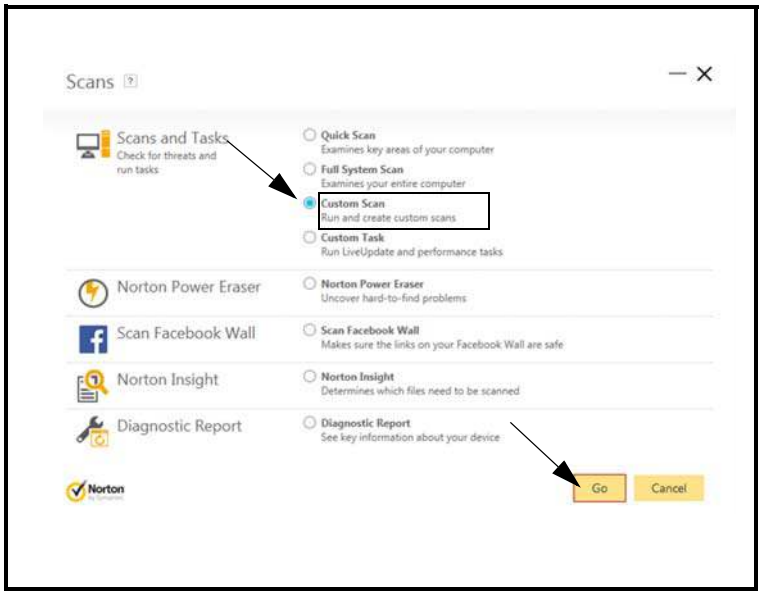

Figure C-12. Scans Screen

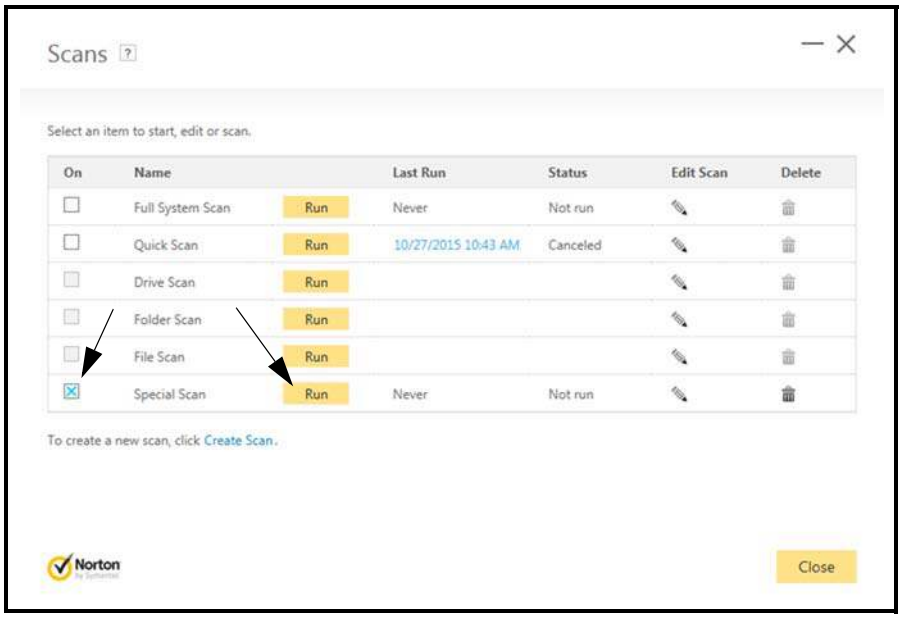

Figure C-13. Scan Screen, Showing the Special Scan

3. On this screen, locate the new scan (see Figure C-13). In the example shown, **Special Scan** is the last item on the list of available scans. Click the **Run** button on this line and the scan will begin.

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