

GeneXpert® Xpress System



User's Guide

Xpress Software Version 6.3



302-1442, Rev. D November 2020

Preface

About This Guide

The *GeneXpert Xpress 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 anti-virus software and its operation is also included.

Read the entire manual and become familiar with the safety information before you start to operate the system. Using the system without reading the manual can result in serious injury, damage to the system, invalid results, or loss of data.

Safety Information

[Chapter 2](#) (Safety) in this manual provides important safety information that you should use when operating the GeneXpert Xpress system. Read and understand the safety information thoroughly before you begin operating the system. 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 special 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 302-1345)
- Assay Quick Reference Instructions (P/N varies, specific to the assay being run)
- Assay Package Insert (P/N varies, specific to the assay being run)

GeneXpert Xpress System

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“**Customer**” means the original party that obtained the Instrument from Cepheid, and not any subsequent purchasers.

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Not all products described in this Manual are available in all countries.

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**Warning**

This product can expose you to chemicals including Nickel, which is known to the State of California to cause cancer or birth defects or other reproductive harm. For more information, visit www.P65Warnings.ca.gov.

Table of Symbols

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

Symbol	Meaning
	<i>In vitro</i> diagnostic medical device
	CE marking—European Conformity
	Do not reuse
	Consult instructions for use
	Manufacturer
	Separate collection for electrical and electronic equipment waste per Directive 2002/96/EC in the European Union.
	This type of warning label indicates a potential biological hazard risk. Biological samples such as tissues, body fluids, and blood of humans and/or animals have the potential to transmit infectious diseases. Follow your local, state/provincial, and national safety regulations for handling and disposing the samples.
	This type of warning label indicates that hazardous high voltage sections are present in the electrical system in the GeneXpert Xpress. Do not remove covers with this warning label.
	This type of symbol indicates a Warning or Caution for which there is no other identified symbol. Read the instructions following the symbol to avoid injury or equipment damage.

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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, hub serial number

Region
US
Telephone: +1 888.838.3222, Option 2
Email: TechSupport@cepheid.com

Contact information for other Cepheid offices is available on our website at www.cepheid.com or www.cepheidinternational.com under the **SUPPORT** tab. Select the **Contact Us** option.



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1 Introduction

This chapter provides an overview of the GeneXpert Xpress system. The topics are:

- [Section 1.1, Intended Use](#)
- [Section 1.2, Software Installation](#)
- [Section 1.3, System Components](#)
- [Section 1.4, LIS Uploads and Downloads](#)
- [Section 1.5, Anti-virus Software](#)
- [Section 1.6, Network Connection](#)
- [Section 1.7, Windows® User Accounts](#)
- [Section 1.8, Software Buttons, Icons and Symbols](#)
- [Section 1.9, Creating Patient/Sample IDs](#)

Note The GeneXpert Xpress system is designed for touchscreen operation.

Note GeneXpert Xpress software version 6.3 supports Microsoft® Windows®10 operating systems. All screens shown in this guide are from GeneXpert Xpress software version 6.3 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, call Cepheid Technical Support. See the [Technical Assistance](#) section in the [Preface](#) for the contact information.

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 at a Glance](#).

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 system, and void your warranty.

Do not install non-approved software.

DO NOT turn off the GeneXpert instrument or the GeneXpert Xpress hub 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.

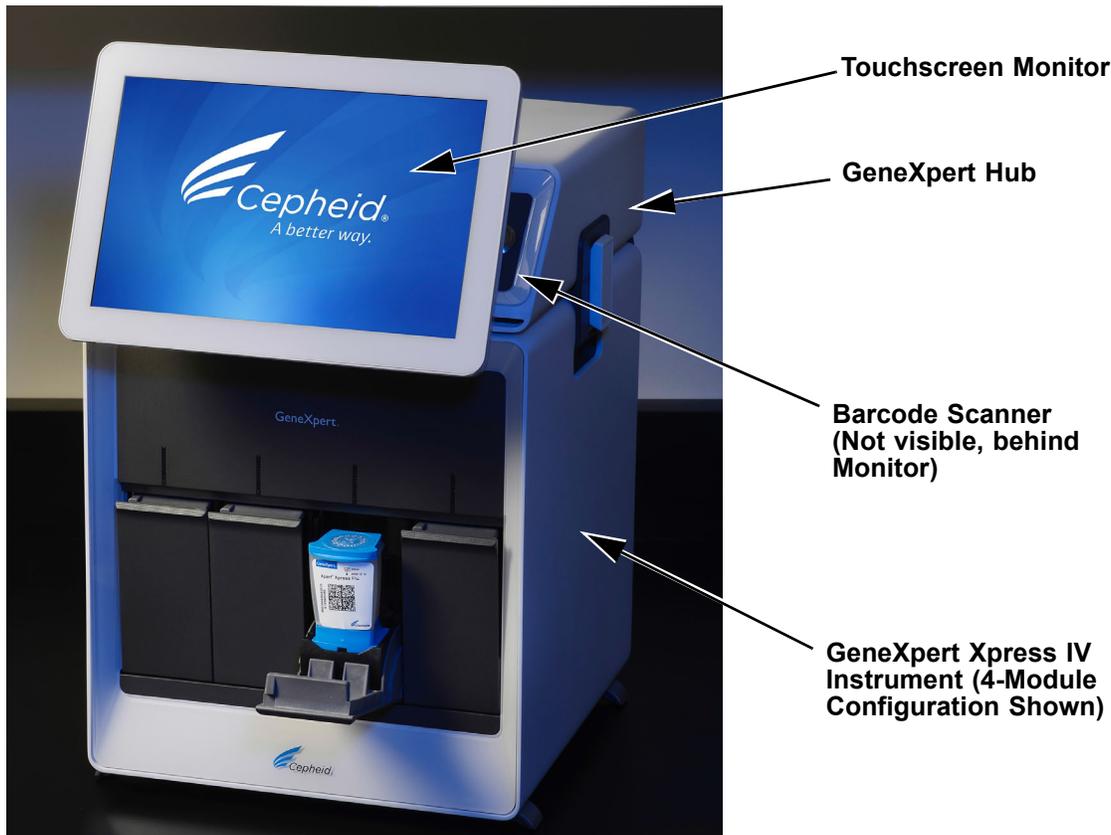


Figure 1-1. GeneXpert Xpress System at a Glance

Note

Refer to Chapter 3 of this manual for details on the operation of the system.

Table 1-1. GeneXpert Xpress System at a Glance

Component	Definition
Touchscreen Monitor	The touchscreen is used to make selections in the software.
GeneXpert Hub	The GeneXpert hub includes a computer which runs the Xpress Software that communicates with the GeneXpert modules. The GeneXpert hub has an attached barcode reader and touchscreen.
Barcode Scanner	Allows you to scan the user ID, patient ID (optional) and the specimen's sample ID barcode, and the cartridge barcode, which enters the cartridge type (e.g., Xpress Flu) and settings into the system.
GX-IV Instrument	The instrument can contain up to four modules. A sample-prepped cartridge is inserted into a module where the sample is processed for detection of a specific genetic sequence or organism.

1.4 LIS Uploads and Downloads

GeneXpert Xpress supports both LIS uploads and downloads, with or without the use of a Data Management system. See [Section 3.9](#) for information on operating with LIS or Point-of-Care Testing (POCT) connectivity and [Section 4.10](#) for information on host management and settings.

Point-of-Care Testing is defined as medical diagnostic testing at or near the point of care, meaning near the patient at the time of the test.

Please contact your local IT/LIS administrator first for assistance in configuring your system for LIS uploads/downloads or connecting the Ethernet adapter. Refer to the *GeneXpert Xpress System Getting Started Guide* (P/N 302-1345) for further information about connecting the Ethernet adapter.

For assistance, call Cepheid Technical Support. See the [Technical Assistance](#) section in the [Preface](#) for the contact information

Note

Cepheid recommends to always confirm that LIS uploaded or downloaded 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 Anti-virus Software

The GeneXpert Xpress system running Windows 10 ships with Windows Defender Anti-virus to protect against viruses that could cause data corruption or disrupt normal functionality. Because Windows Defender Anti-virus comes bundled with Windows 10 and is updated and maintained automatically with the operating system, Cepheid does not recommend using additional anti-virus software for the GeneXpert Xpress system computer running Windows 10.

Caution



If Bitlocker is enabled (see [Section 4.12](#)), it is the customer's responsibility to maintain the encryption key so that it is not forgotten or misplaced. For more information, visit <https://www.microsoft.com>.

1.6 Network Connection

Caution



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

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

1.7 Windows[®] User Accounts

The GeneXpert Xpress system 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.

See [Table 4-1](#) for a description of User Types and permissions for GeneXpert Xpress.

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 1-2. Software Buttons, Icons and Symbols

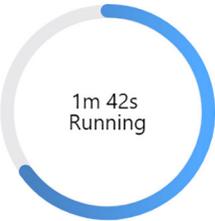
Symbol	Definition
	Home - Go to the Home screen.
	RESULTS - Displays a list of any tests previously run.
	QC - Navigates to the Quality Control page,
	User Menu - Displays system notifications (if any) and user options to Change a Password , Logout or Exit the GeneXpert Xpress Software. Also provides an About selection to show the software version, Cepheid email addresses and a link to the complete software License .
	Available - Indicates a module that is available to run a test.
	Indicates a module with test in progress.
 PID-7035 Module A1	Indicates a module available after a test has completed (with Patient ID displayed).
	CANCEL TEST - Cancel a test being created (before the test starts running)

Table 1-2. Software Buttons, Icons and Symbols (Continued)

Symbol	Definition
	Stop Test - Stops a test currently running.
	Report - Displays a PDF of the test shown onscreen (located on the Test Completed screen).

1.9 Creating Patient/Sample IDs

Character limits for a Sample ID is 25 characters; a Patient ID limit is 32 characters.

Do not use the following symbols in the Patient ID and Sample ID fields: | : * " < > / \ ?

If invalid characters are manually entered or scanned, there will be a software notification to the user.

2 Safety

This chapter describes the possible safety hazards found in the GeneXpert Xpress system. It is imperative that you follow the precautions in this chapter for safe operation. The topics are as follows:

- [Section 2.1, Electrical Symbols on the Hub and Instrument](#)
- [Section 2.2, Electrical Safety](#)
- [Section 2.3, Biological Hazard Safety](#)
- [Section 2.4, Chemical Safety](#)
- [Section 2.5, Environmental Data](#)
- [Section 2.6, Barcode Scanner](#)

Caution



If the GeneXpert Xpress system is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Warning



See the System Dimensions and Weights table in Appendix A for the GeneXpert Xpress system weights. Use care when unpacking the hub or 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.

2.1 Electrical Symbols on the Hub and Instrument

Table 2-1 lists the electrical symbols that you will find on the GeneXpert Xpress system.

Table 2-1. Electrical Symbols on the Hub and Instrument

Label	Description
I	Indicates the ON position of the main instrument and hub power switches.
O	Indicates the OFF position of the main instrument and hub power switches.
~	Indicates the designated instrument or hub connector either receives or delivers alternating current or voltage.
	Indicates the rating of the fuse (such as 250V T2A) protecting the unit.
	Indicates a location of the chassis ground connection.

2.2 Electrical Safety

Warning



ELECTRICAL HAZARD: Do not attempt to open or remove the hub or 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 hub or instrument, unplug the hub and instrument and contact Cepheid Technical Support for instructions.

Warning



ELECTRICAL HAZARD: Do not replace the provided AC power cable with an inadequately rated substitute power cable.

The GeneXpert Xpress hub and instrument enclosures are 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.

Biological Risks



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 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.

2.6 Barcode Scanner

Caution



This device emits IEC Class 1M LED light. Do not view directly with optical instruments.

The SE3307 imager engine meets the accessible LED light limits for an IEC Class 1M LED product. Complies with EN/IEC 62471 (for LED devices).



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.

3 Operation

This chapter describes how to run tests using the GeneXpert Xpress system, in the normal system configuration as shipped from Cepheid. The topics are:

- [Section 3.1, Starting the GeneXpert Xpress System](#)
- [Section 3.2, Using the Virtual Keyboard](#)
- [Section 3.3, Running a Test Using the GeneXpert Xpress Software](#)
- [Section 3.4, Starting a Test While Another Test is Running](#)
- [Section 3.5, Viewing Previous Test Results](#)
- [Section 3.6, User Menu Functions](#)
- [Section 3.7, Exiting the Software and Turning Off the System](#)
- [Section 3.8, Quality Control Lockout \(Optional\)](#)
- [Section 3.9, Operating with Host \(LIS or POCT\) Connectivity](#)
- [Section 3.10, Error Handling](#)
- [Section 3.11, The About and License Screens](#)

Note

The GeneXpert Xpress instrument is available in either a 2-module or 4-module configuration within the GeneXpert IV instrument. This chapter describes and shows screens for a 4-module configuration instrument. In a 2-module configuration instrument, two of the modules are replaced by blank panels, but the operation will be the same, except for the number of modules available to the user.

In this configuration:

- All cables have been connected as described in the *GeneXpert Xpress System Getting Started Guide* (P/N 302-1345).
- An Administrator account has been created, which allows for initial login to the GeneXpert Xpress system (see [Section 4.1, Powering Up the GeneXpert System](#)).

See [Table 4-1](#) for a description of User Types and permissions for GeneXpert Xpress.

An administrator must perform the setup instructions shown in [Chapter 4, Administrative Tasks](#), before the GeneXpert Xpress IV instrument is used to run tests.

For information on signing in, see [Section 3.6, User Menu Functions](#).

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

- *GeneXpert Xpress Getting Started Guide* (P/N 302-1345), shipped with the system.
- Assay Quick Reference Guide, shipped with the assay lot.

3.1 Starting the GeneXpert Xpress System

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** (I) position (see [Figure 3-1](#)). After power to the hub has been turned on, the blue light on the front of the instrument will be **ON**.

Note

The instrument must be powered up first, before the GeneXpert hub or the Xpress software will not recognize the instrument being connected.

2. Turn on the GeneXpert hub. The power switch is located on the back of the GeneXpert hub. Press the switch to the **ON** (I) position (see [Figure 3-1](#)). After power has been turned on, the blue light on the right front panel of the GeneXpert hub will be **ON**.

Note

The power cord going from the outlet on the GeneXpert Xpress hub is has power regardless of the state of the switch on the GeneXpert Xpress back panel. The power switch on the instrument does not need to be turned on to power up the GeneXpert Xpress hub.

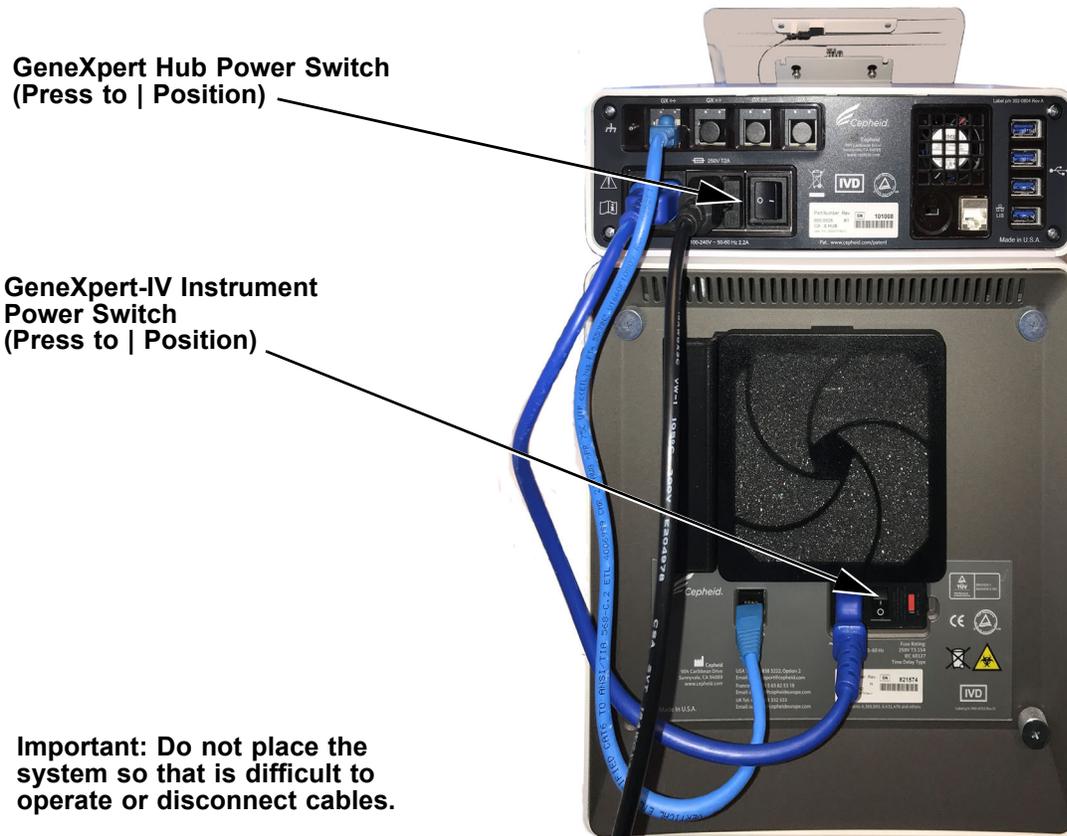
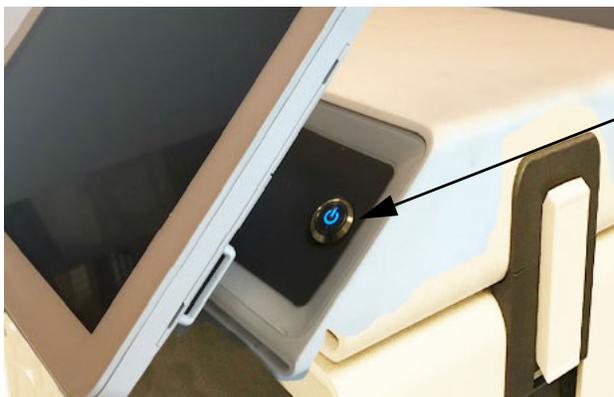


Figure 3-1. Rear of GeneXpert Xpress System, showing Power Switches



Note: It is only necessary to press the blue GeneXpert hub power indicator/switch when powering down (not when powering up).

Figure 3-2. GeneXpert Computer Power Indicator/Switch (Right Front of System)

3. Wait until the system boots. The Windows Opening screen will appear (see [Figure 3-3](#)). Swipe up anywhere on the screen, (as indicated by the dashed arrow) to display the login field.



Figure 3-3. Windows Opening Screen

Caution



You must log on using the preconfigured account. If you log on using a different user name and profile, the login will fail.

4. The Windows Login screen appears (see [Figure 3-4](#)).

5. On the Windows Login screen (see [Figure 3-4](#)), enter the password and touch the **arrow** to the right of the **Password** field.

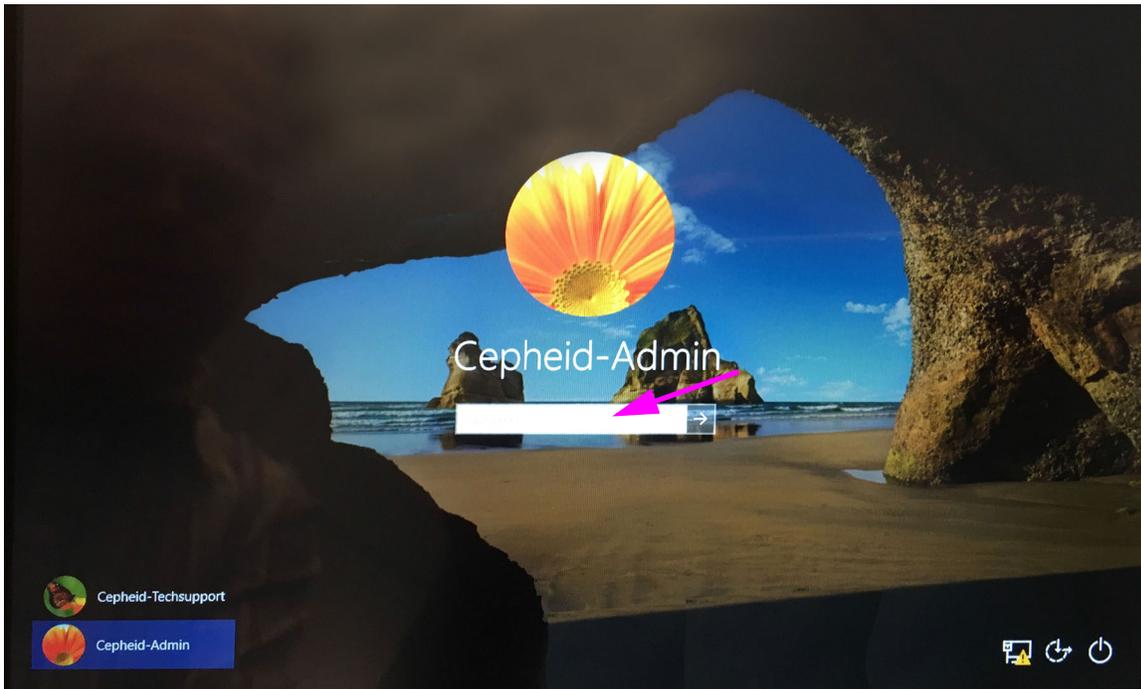


Figure 3-4. Windows Login Screen

6. When you touch the login field, the virtual keyboard appears (see [Figure 3-5](#)).

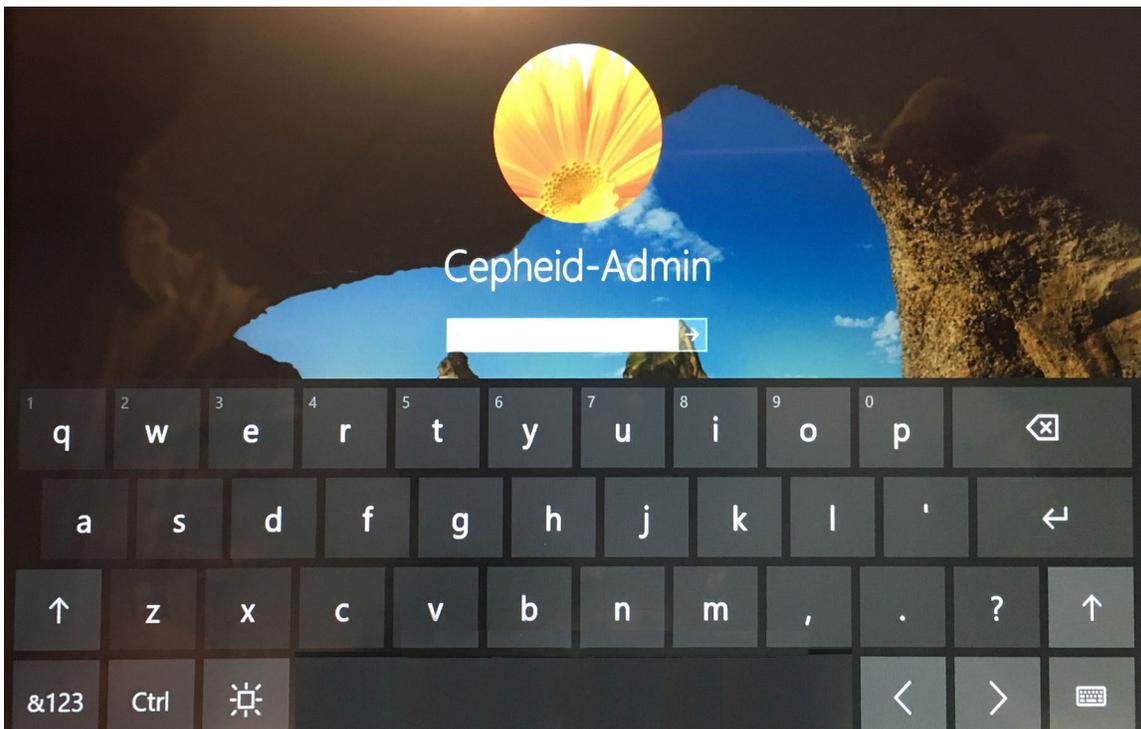


Figure 3-5. Windows Login Screen with Keyboard

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

The GeneXpert Xpress software starts automatically on system startup.

A GeneXpert Xpress icon on the Windows desktop allows for manual software initiation. See [Figure 3-6](#).



Figure 3-6. GeneXpert Xpress System Shortcut Icon

7. The GeneXpert Xpress software launches.

3.2 Using the Virtual Keyboard

This section provides information on using the virtual keyboard which appears onscreen when you are entering information, such as a Sample ID or a Patient ID (when you cannot scan a barcode), or perhaps when you want to change a password.

Touching a screen entry field will cause the virtual keyboard to appear (see [Figure 3-7](#)).

To close the keyboard, touch the **X** in the upper right of the keyboard.

Note There may be times when the virtual keyboard covers or hides an input button such as **CONFIRM** or **OK**, which are needed to complete an action. To access a hidden button, touch the X button to close the keyboard.

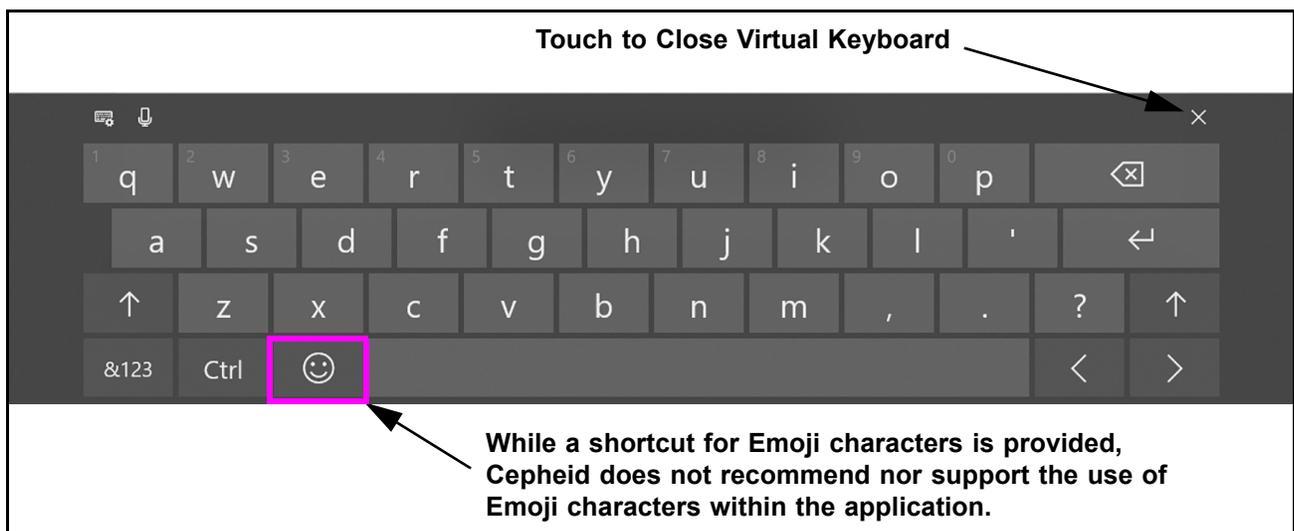


Figure 3-7. Virtual Keyboard Operation

3.3 Running a Test Using the GeneXpert Xpress Software

Note The login in this section can be by any user.

1. After logging into Windows with your credentials, the Xpress software launches, with the display of the Xpress Login screen (see [Figure 3-8](#)).
2. Touch the **User Name** field, and the virtual keyboard appears.
3. Enter your **User Name** and **Password** in the provided fields, and then touch the **X** button at the far right of the keyboard. The keyboard disappears, and the **LOGIN** button is visible. Touch the **LOGIN** button to complete the login process.

Note If you need assistance with either your **User Name** or **Password**, contact your system administrator.

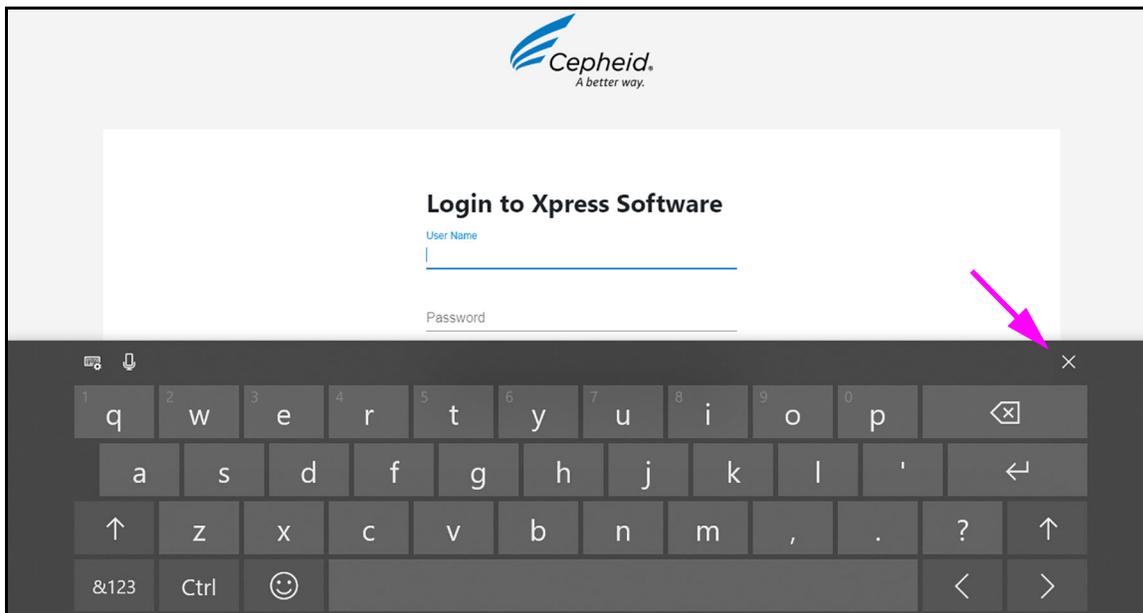


Figure 3-8. Login to Xpress Software Screen

4. After login is complete, dialog boxes appears, asking if you wish to perform database tasks and also, if you want to archive tests.
5. If you reply **NO** to each of these questions, the Xpress Home screen, with the **NEW TEST** button, appears (see [Figure 3-9](#)).

The instrument is now initialized and ready to run tests (see [Section 3.3.1](#)).

3.3.1 Starting a Test

Caution

Maintain at least 15 to 20 cm (6 to 8 inches) of clearance on each side of the GeneXpert Xpress system. Do not block the fan exhaust or air intake on the instrument or hub. The lack of proper ventilation can cause the instrument or GeneXpert hub to malfunction.

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

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 is an example. Other assays may have minor differences. Refer to the package insert for specific instructions.

When the Home screen appears, you will see the modules available (Module A1, Module A2, etc.) for running a test. At the top of the screen, you can touch **RESULTS** (which displays any previous test results) or **QC** (to run Quality Control tests).

1. Touch the **NEW TEST** button on the Home screen (see [Figure 3-9](#)). The Patient Information screen is displayed if the system is configured to use Patient ID (see [Figure 3-11](#)).

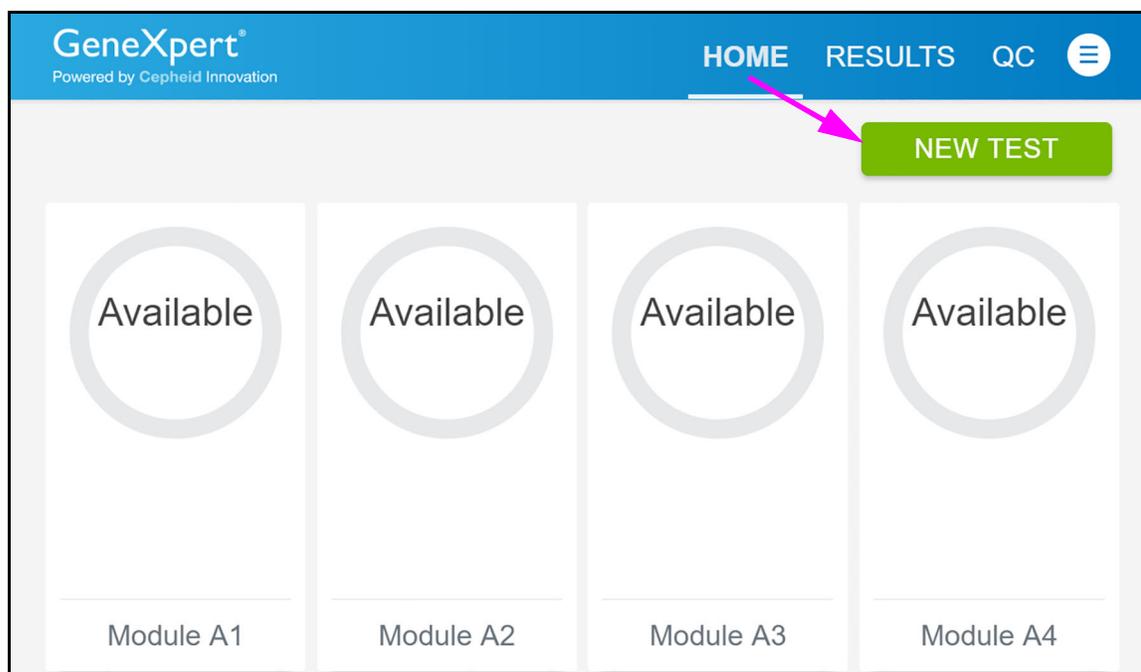


Figure 3-9. Home Screen (GX-IV, Four-Module Configuration Shown)

3.3.2 Entering the Patient ID

This section describes the method for entering the Patient ID into the system, either by scanning a barcode or entering the ID manually using the virtual keyboard.

On the Patient Information screen, enter the Patient ID (character limit is 32).

Do not use the following symbols in this area: | : * “ < > / \ ?

If invalid characters are manually entered or scanned, there will be a software notification to the user.

Note

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

The Patient ID barcode can be scanned using the integrated barcode scanner, (see [Section 3.3.2.1](#)), or, if the barcode is unreadable or non-existent, the Patient ID number can be entered manually (see [Section 3.3.2.2](#)).

Note

During test preparation, the header across the top of the screen displays the progression of steps, to be performed, such as **Sample, Cartridge, Preparation and Loading**, etc.

3.3.2.1 Scan the Patient ID

1. If there is a Patient ID barcode, scan it using the integrated barcode scanner located behind the right side of the touch screen. Position the barcode about 4 inches away from the right side of the scanner (about 3 inches from the right side of the monitor) (see [Figure 3-10](#)).



Figure 3-10. Integrated Barcode Scanner

2. Verify that the Patient ID you have scanned is correct. If it does not match, touch the **CLEAR** button and rescan the Patient ID.

If it is correct, touch the **CONTINUE** button and the Confirm Patient Information screen appears (see [Figure 3-12](#)).

3.3.2.2 Enter the Patient ID Manually

1. To enter the **Patient ID** manually, touch **Patient ID** and manually enter the Patient ID number using the virtual keyboard which appears onscreen (see [Figure 3-11](#)).
2. Verify that the Patient ID you have entered is correct. If it is correct, touch the **CONTINUE** button. If it does not match, touch the **CLEAR** button and manually re-enter the Patient ID.
3. When you are done, touch **CONTINUE** and the Confirm Patient Information screen appears (see [Figure 3-12](#)).

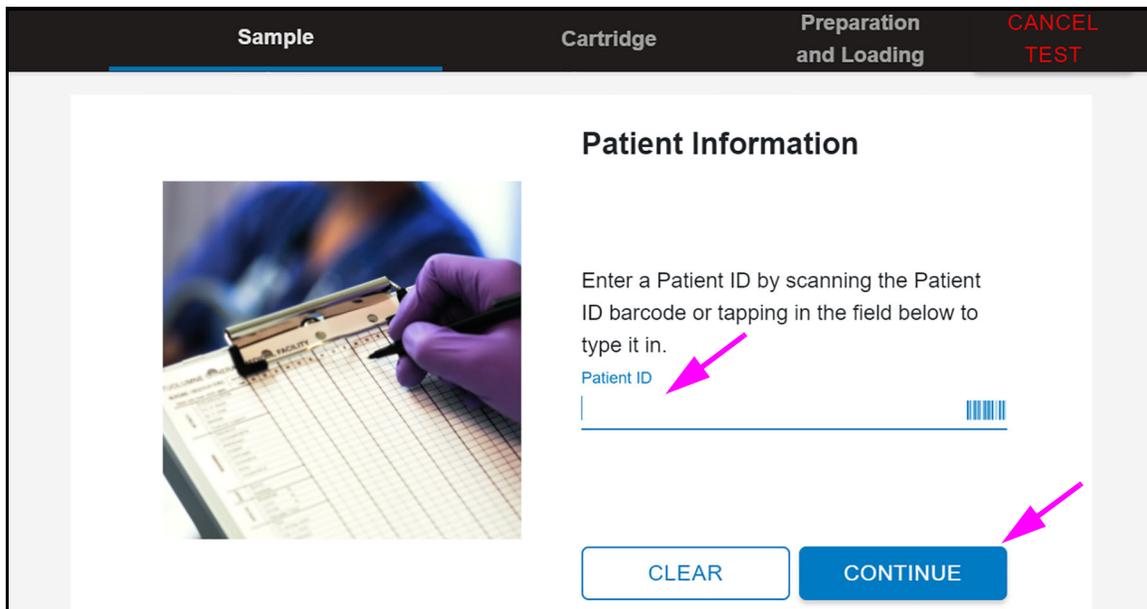


Figure 3-11. Patient Information Screen

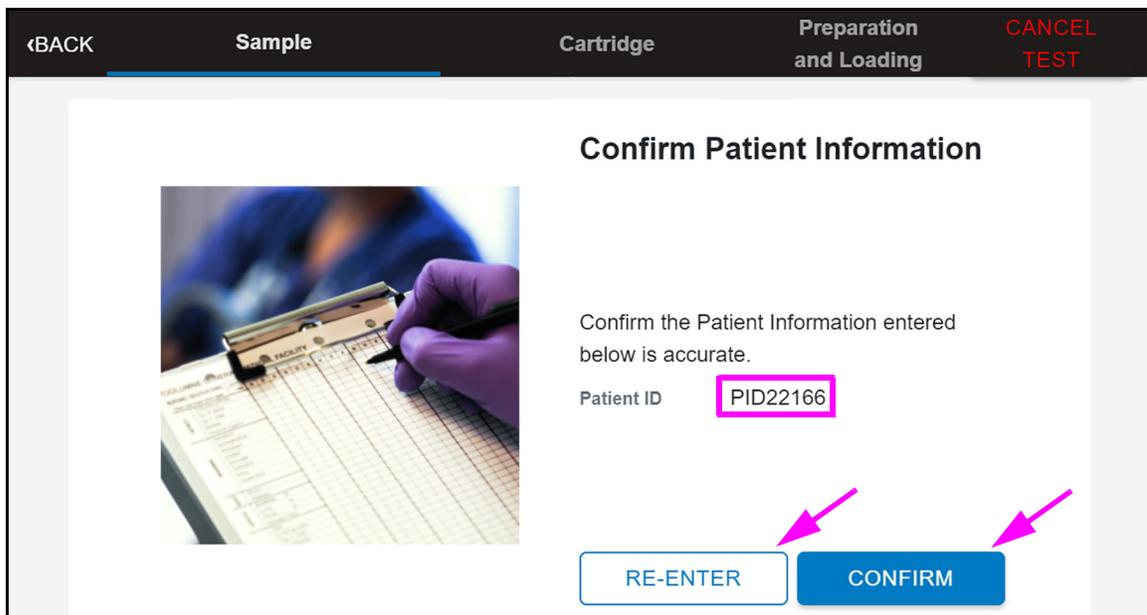


Figure 3-12. Confirm Patient Information Screen

4. On the Confirm Patient Information screen, verify the Patient ID number displayed is correct, and touch **CONFIRM**. The Sample ID screen appears (see [Figure 3-15](#)).

If the Patient ID number is not correct, touch **RE-ENTER** to return to the Patient Information screen and re-scan or manually enter the correct patient ID number.

3.3.3 Entering the Sample ID

This section describes the method for entering the Sample ID into the system, either by scanning a barcode, entering the ID manually using the virtual keyboard, or having the system assign a random Sample ID.

On the Patient Information screen, enter the Sample ID (character limit is 25 characters).

Do not use the following symbols in this area: | : * “ < > / \ ?

If invalid characters are manually entered or scanned, there will be a software notification to the user.

Note

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

The Sample ID number can be scanned using the integrated barcode scanner, located behind the right side of the touch screen (see [Section 3.3.3.1](#)).

If there is no barcode, or if it cannot be scanned, enter the Sample ID number manually (see [Section 3.3.3.2](#)).

If desired, the Xpress system can assign a Sample ID, instead of scanning or entering it manually (see [Section 3.3.3.3](#)).

3.3.3.1 Scan the Sample ID

1. Scan the Sample ID barcode using the barcode scanner. Hold the sample about four inches (10 cm) away from the right side of the scanner (about three inches (7.5 cm) from the right side of the monitor) as shown (see [Figure 3-13](#)).

Note

The barcode scanner will project a locating feature to assist in centering the barcode in the scan region.



Figure 3-13. Correct Placement for Scanning a Sample

2. After a successful scan, the Confirm Sample ID screen appears (see [Figure 3-16](#)). Verify that the Patient/Sample ID on the Confirm Sample ID screen matches the Sample ID on the sample. If it matches, touch the **CONTINUE** button. If it does not match, touch the **RE-ENTER** button, which automatically clears the Sample ID. Manually enter the correct Sample ID.

3.3.3.2 Enter the Sample ID Manually

1. If there is no barcode present, or if the barcode will not scan, touch the Sample ID entry area (see [Figure 3-15](#)), and enter the Sample ID using the virtual keyboard which appears onscreen.

To make the keyboard disappear, touch the **X** in the upper right corner of the keyboard (see [Figure 3-16](#)). See [Section 3.11](#) for additional information about the keyboard operation.

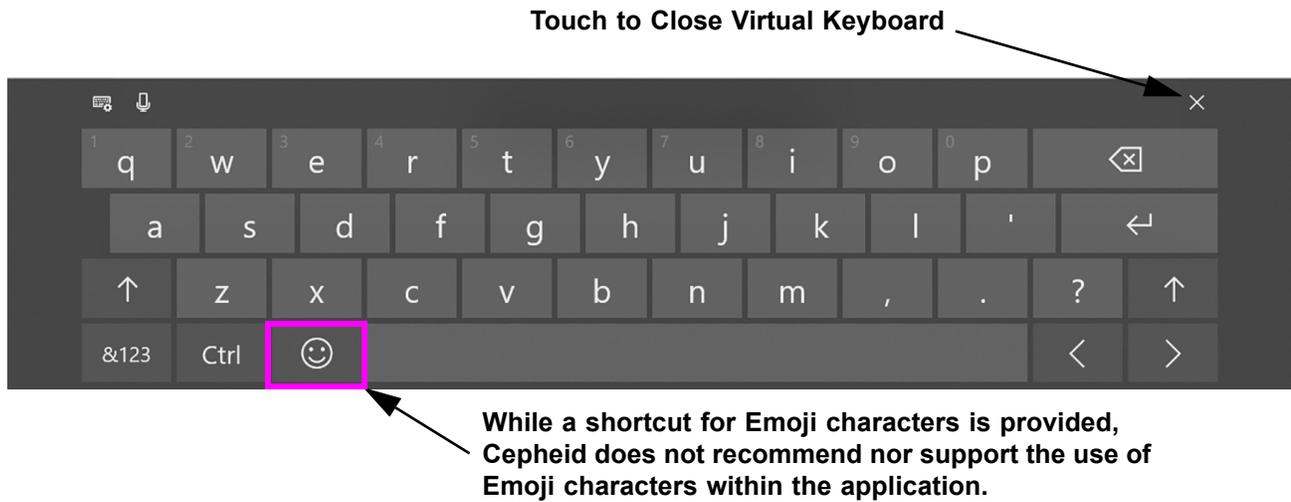


Figure 3-14. Virtual Keyboard

2. Verify that the Sample ID you have entered is correct (see Figure 3-15). If it does not match, touch the **CLEAR** button and manually re-enter the Sample ID.
3. Touch **CONTINUE** when you are done. The Confirm Sample ID screen appears (see Figure 3-16).



Figure 3-15. Sample ID Screen

4. On the Confirm Sample ID screen (see Figure 3-16), verify that the Sample ID matches the Sample ID on the sample. If it matches, touch the **CONFIRM** button. If it does not match, touch the **RE-ENTER** button, re-enter the Sample ID and touch the **CONFIRM** button.



Figure 3-16. Confirm Sample ID Screen

3.3.3.3 Have Xpress Assign a Random Sample ID Automatically

If desired, your Xpress system can assign a Sample ID, instead of you scanning or manually entering the number, using the following steps.

1. When the Sample ID screen appears, simply touch the **CONTINUE** button once.

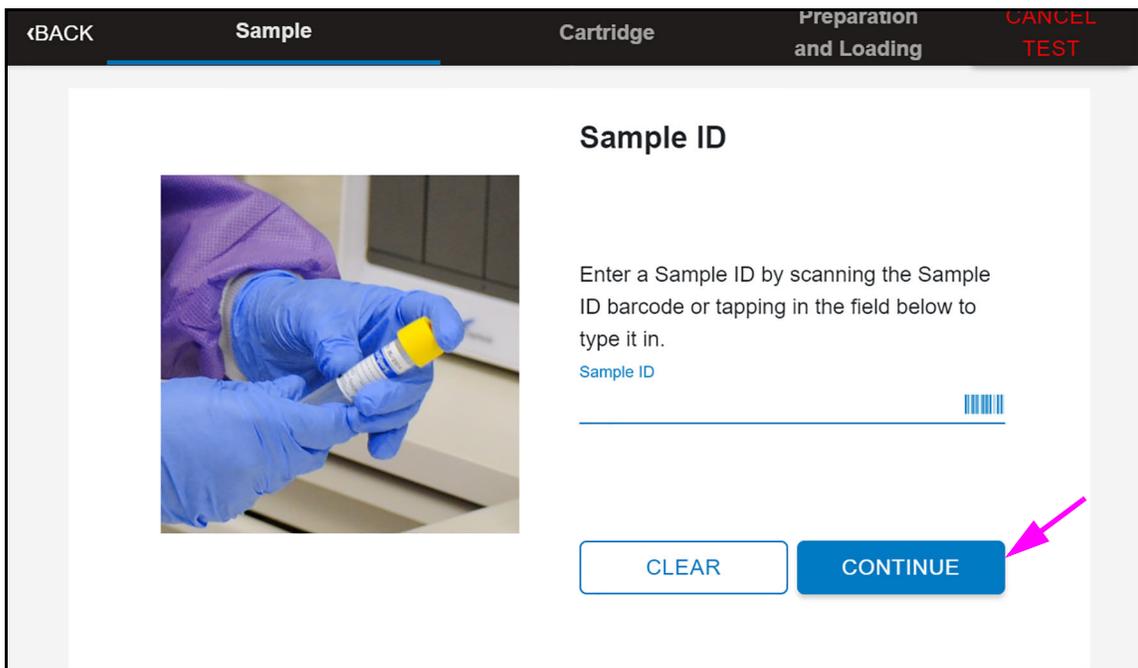


Figure 3-17. Sample ID Screen

2. The Confirm Sample ID screen appears (see [Figure 3-18](#)).
3. On the Confirm Sample ID screen (see [Figure 3-18](#)), the generated Sample ID is displayed. If you do not wish to use the Sample ID shown, touch the **RE-ENTER** button to return to the previous screen.

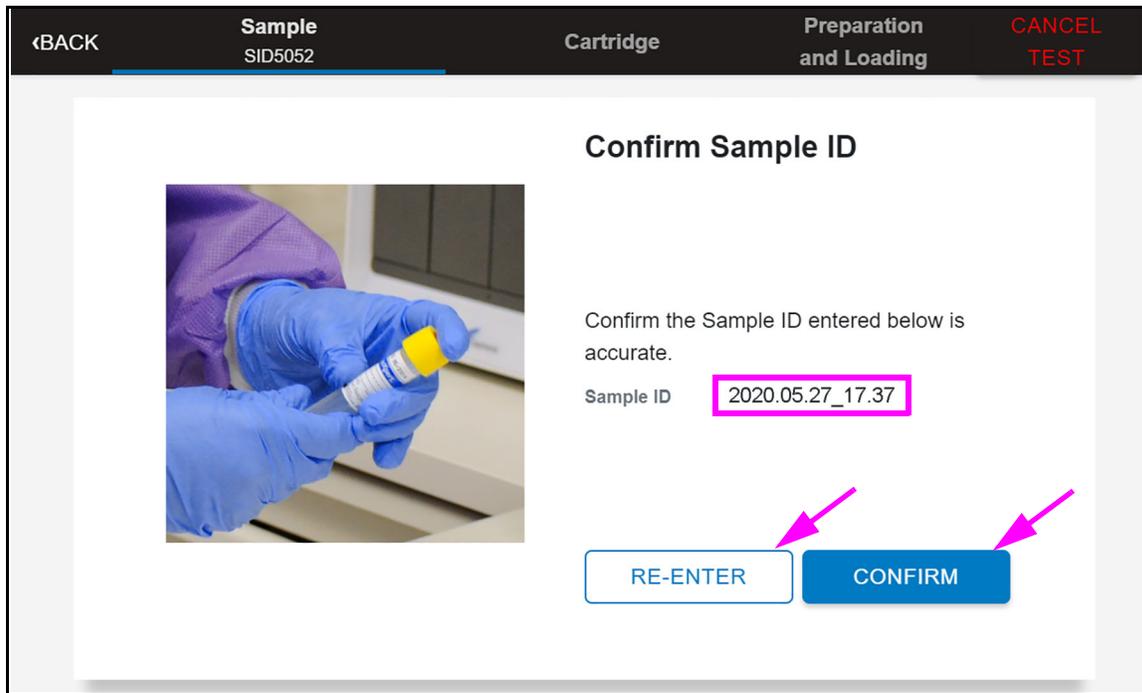


Figure 3-18. Confirm Sample ID Screen

4. After confirming that the Patient ID and Sample ID are correct, touch **CONFIRM**. The Scan Cartridge Barcode screen will be displayed (see [Figure 3-19](#)).

3.3.4 Scan Cartridge Barcode

This section describes the method for scanning a cartridge barcode into the system, with additional instructions for combinatorial assays.

Biological Risks



In the following steps, cartridges should be kept upright when handling or scanning. Do not rotate or tip the cartridge, because damage to the contents or injury to personnel may occur.

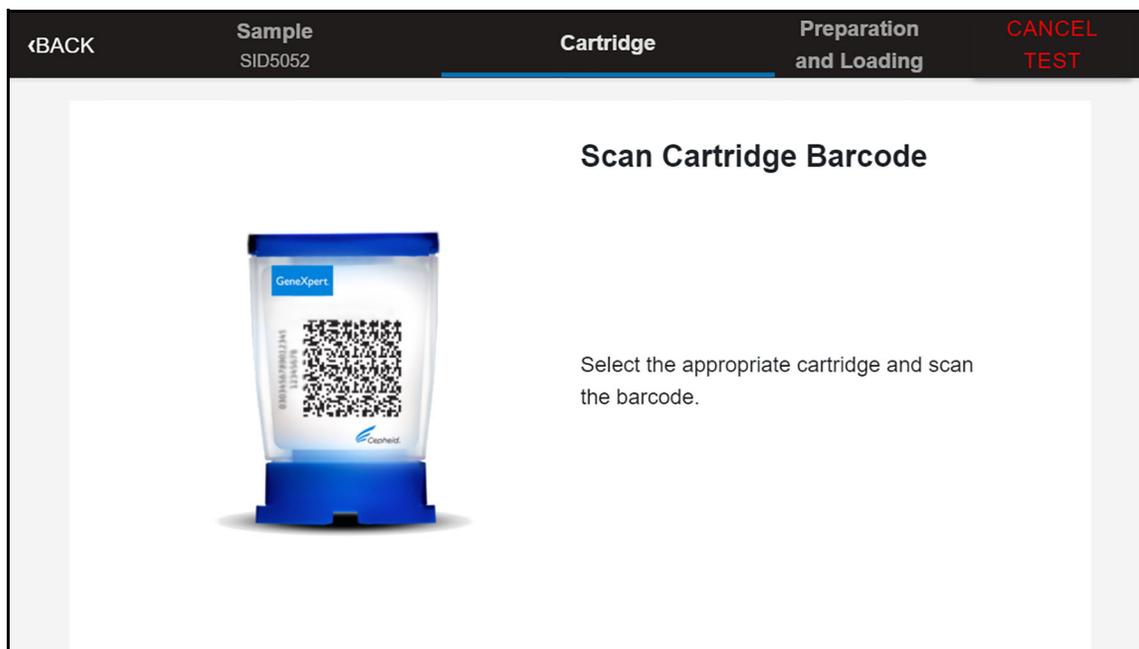


Figure 3-19. Scan Cartridge Barcode Screen

1. Select the appropriate cartridge with the sample and use the integrated barcode scanner to scan the cartridge barcode.
2. Hold the cartridge about 4 inches away from the right side of the scanner (about 3 inches from the right side of the monitor) as shown (see [Figure 3-20](#)).

Note

The barcode scanner will project a locating feature to assist in centering the barcode in the scan region.



Figure 3-20. Correct Placement for Scanning a Cartridge

Combinatorial Assays Only

Note

For combinatorial assays, such as Flu, RSV and Flu/RSV, select the correct test, and then touch the **CONFIRM** button (see [Figure 3-21](#) as an example).

Make the appropriate selection from the Select Test menu, as shown in [Figure 3-21](#).

- Flu A, Flu B and RSV: Select **Xpert Xpress Flu-RSV**
- Flu A and Flu B only: Select **Xpert Xpress_Flu**
- RSV only: Select **Xpert Xpress_RSV**

Only the test result for the assay selected at this step will be collected once the test is started. Flu A, Flu B, and RSV results will only be collected if the Xpert Xpress Flu-RSV assay is selected.

Confirm the selected test from the Select Test menu, as shown in [Figure 3-21](#).

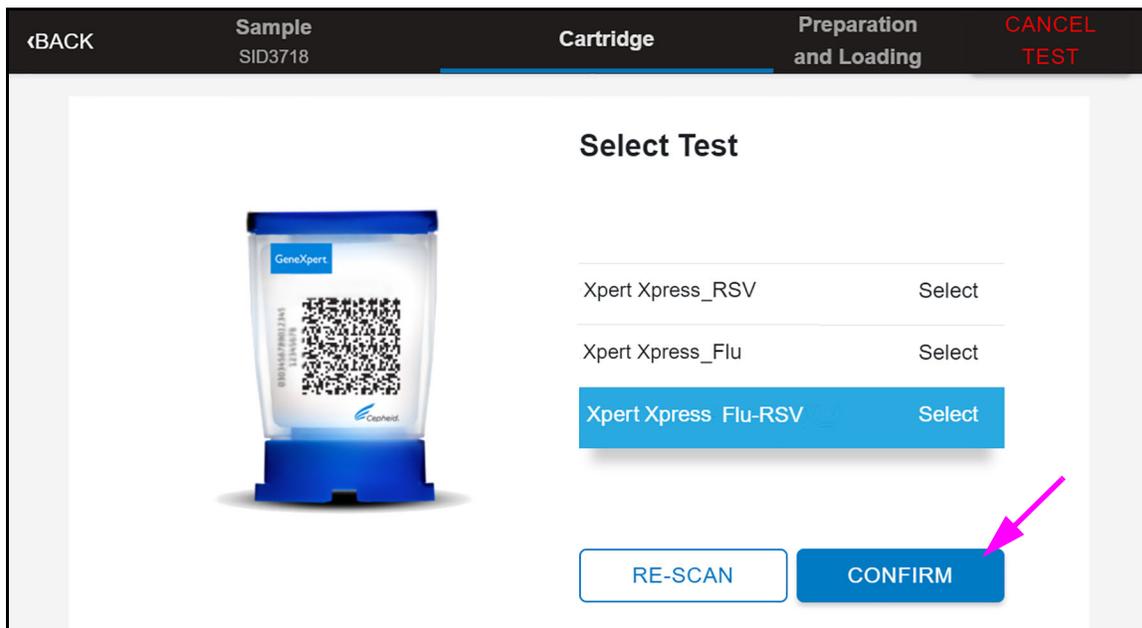


Figure 3-21. Select Test Screen (for Combinatorial Assays only)

3. After scanning, the Confirm Test Information screen appears (see [Figure 3-22](#)).
4. Verify that the correct cartridge has been scanned and that the assay name shown on the Confirm Test Information screen matches the assay name on the cartridge.

If it does not match, touch the **RE-SCAN** button and scan the correct cartridge barcode.

5. After you have a match, touch the **CONFIRM** button. The Login screen appears if a user has not previously logged in (see [Figure 3-23](#)).

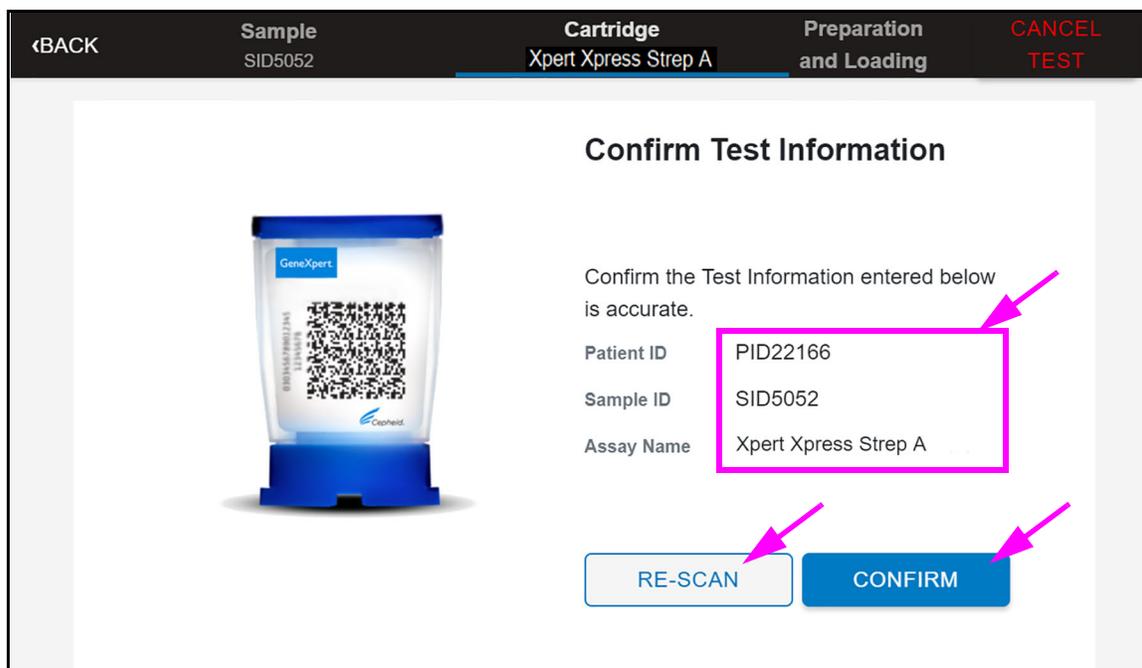


Figure 3-22. Confirm Test Screen

6. On the Login screen, touch the **User Name** entry area.

Depending on the system configuration, the **User Name** can be scanned or entered manually.

- A. If scanning, use the barcode scanner to scan the barcode containing the **User Name** and **Password** information.
- B. If the virtual keyboard appears when you touch the **User Name** field, use the following steps to enter your credentials.
 - 1) Enter your **User Name**.
 - 2) Scroll down and enter your user **Password**.

Note

If you need assistance with either your **User Name** or **Password**, contact your system administrator.

- 3) When you have entered your **User Name** and **Password**, touch the **X** in the upper right of the virtual keyboard. The virtual keyboard will disappear and the **LOGIN** button will be visible at the bottom of the screen.
7. Touch the **LOGIN** button to continue.

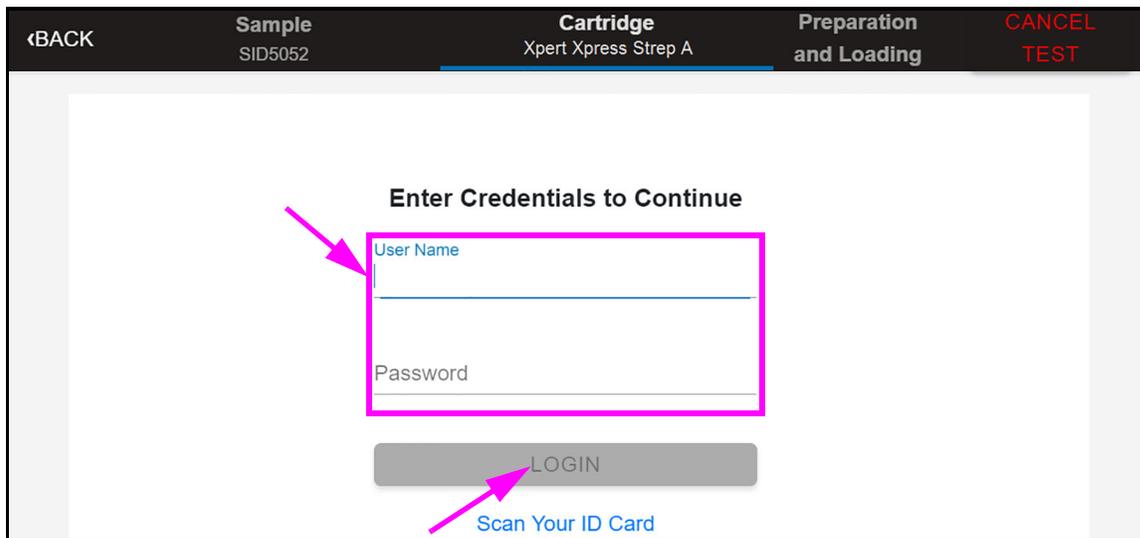


Figure 3-23. Login Screen

8. The Cartridge Preparation screen will be displayed (see Figure 3-24). A video clip will appear showing the cartridge preparation steps. 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.

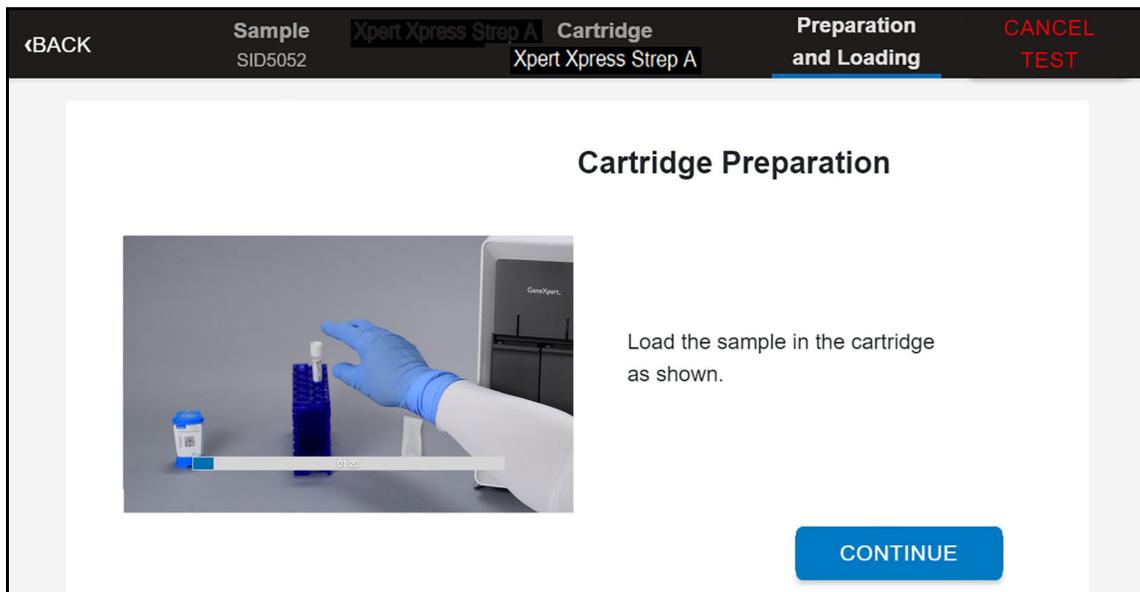


Figure 3-24. Cartridge Preparation Screen

3.3.5 Loading a Cartridge into a Module and Starting a Test

This section describes how to load a cartridge into an available module and start a test.

1. After the cartridge has been prepared, touch the **CONTINUE** button on the Cartridge Preparation screen (see Figure 3-24) to halt the video clip. The Load Cartridge into Module screen will be displayed (see Figure 3-25).

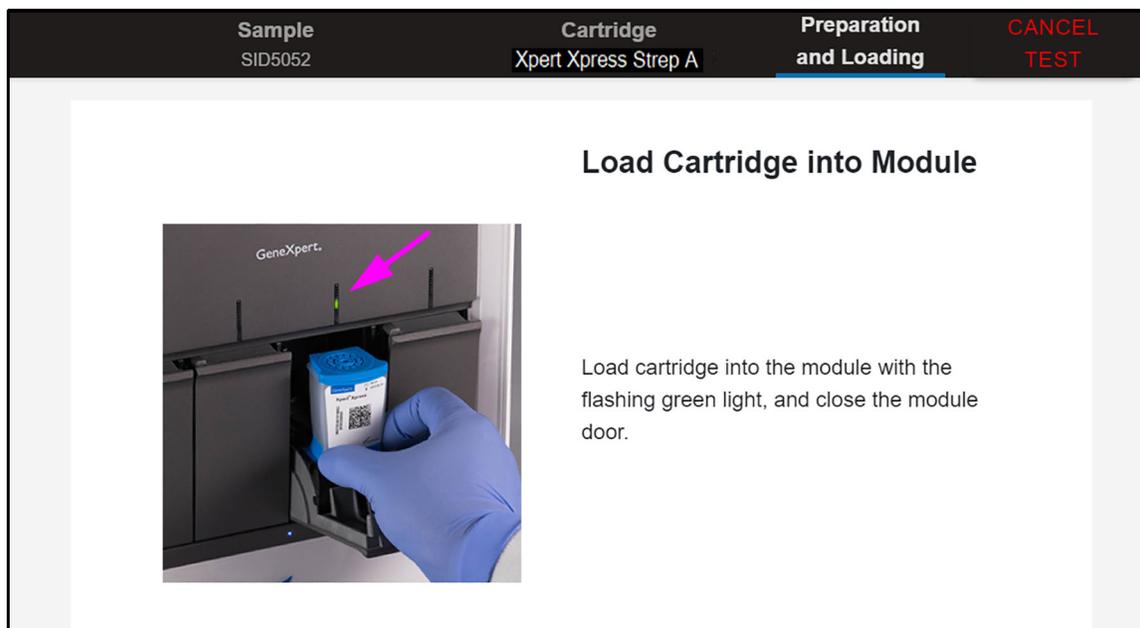


Figure 3-25. Load Cartridge to Module Screen

2. When the Load Cartridge into Module screen is displayed (see [Figure 3-25](#)), open the instrument module door below the module with the flashing green light.
3. Place the cartridge on the module bay floor (see [Figure 3-26](#)). The cartridge label should face out.



Figure 3-26. Cartridge Inserted into Module

4. Press the module door closed, ensuring that the door is completely closed. The door will latch and the flashing green light will turn solid green. As soon as the cartridge is loaded, the Test Loading screen will be displayed (see [Figure 3-27](#)) showing that the cartridge is being loaded, with a succession of blue indicator dots progressing.

Note

If necessary, touch the **STOP TEST** button to cancel a test while it is loading. Note that you will not get a test result from a canceled test.

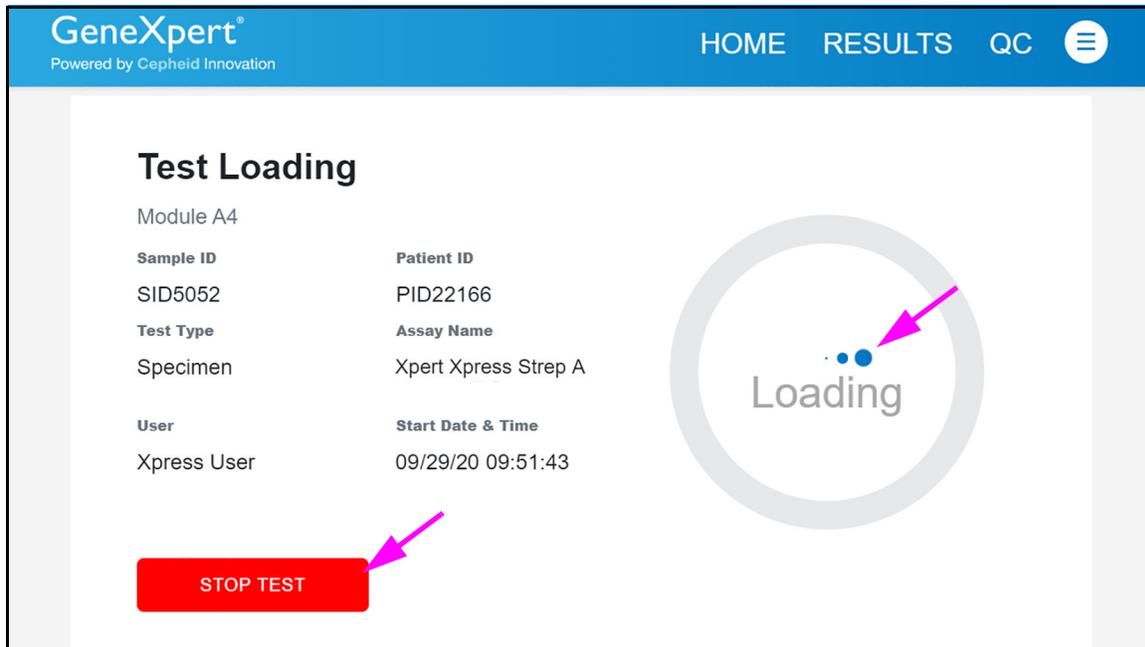


Figure 3-27. Test Loading Screen showing Cartridge Loading

- After the test has loaded, the Test Running screen appears, showing a blue circular graphic indicator at the right side of the screen, indicating the progress of the test and the time remaining until a test result is available (see [Figure 3-28](#)).

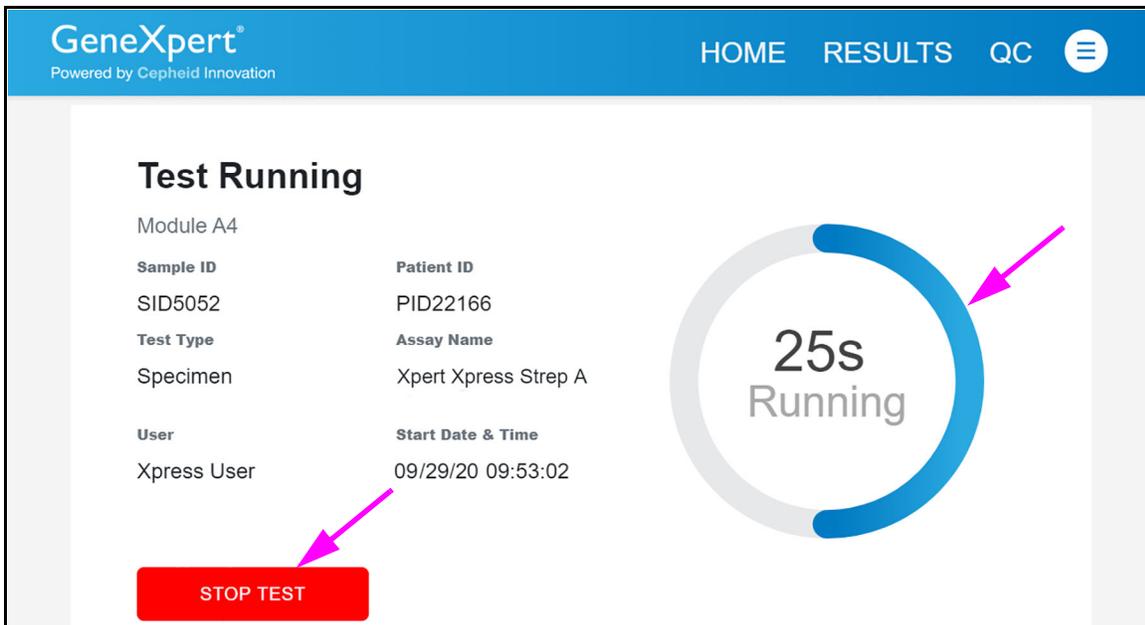


Figure 3-28. Test in Progress Screen showing Test Time Remaining

Note

If necessary, touch the **STOP TEST** button to stop a test in progress. Note that you will not get a test result from a canceled test.

Note

At this point, while a test is running, another test can be started by returning to the Home screen. To start an additional test, see [Section 3.4, Starting a Test While Another Test is Running](#).

- When a test completes, the Test Completed screen appears (see [Figure 3-29](#)).

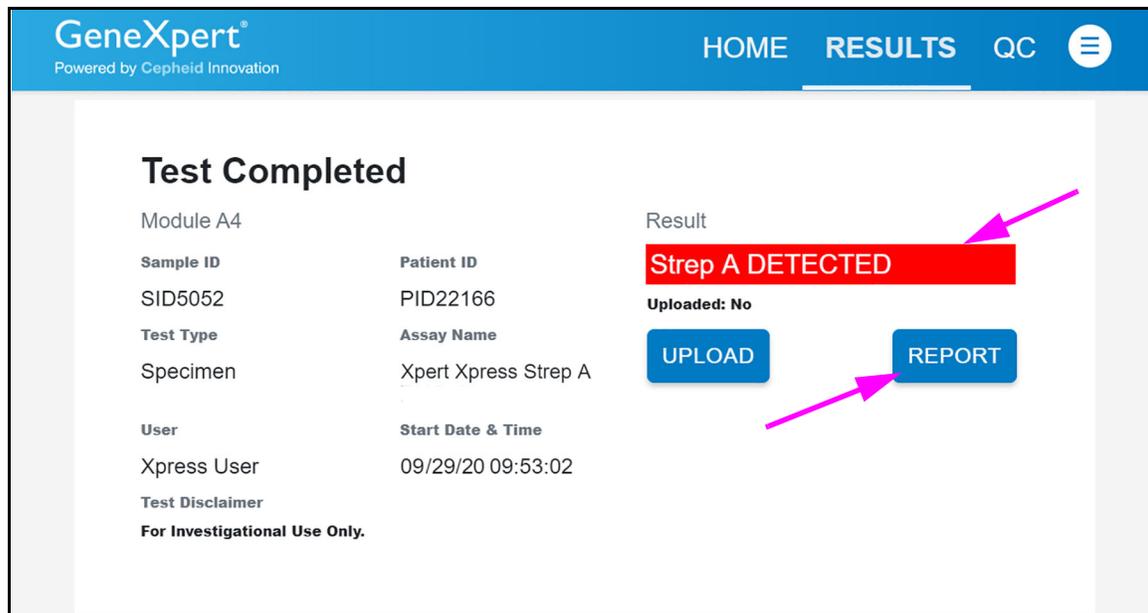


Figure 3-29. Test Completed Screen

- Open the module door, remove the used cartridge, and properly dispose of the cartridge according to your institution's hazardous waste disposal guidelines.
- The Test Completed screen shows results for the completed test (see [Figure 3-29](#)).
- To view a complete test report of the test just completed, touch the **REPORT** button on the Test Completed screen.

The Report Viewer screen then appears (see [Figure 3-30](#)), displaying the report which can be saved, or printed to any wired or network printer, as desired.

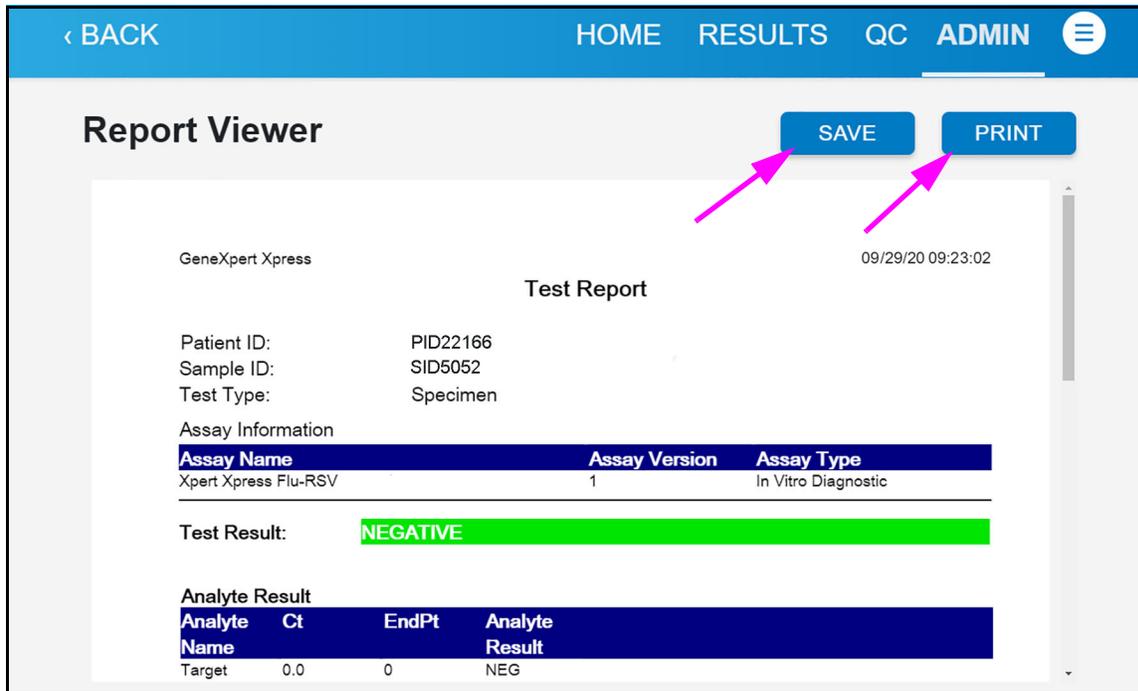


Figure 3-30. Screen showing Test Report of Test Just Completed (Partial View shown)

Note

If the option to print the results was selected, a screen indicating the print was successful will display.

After saving and/or printing the test results, touch the **HOME** button to return to the Home screen. From the Home screen you can touch **RESULTS** to view the results of the tests previously run (see [Section 3.5](#)).

This completes the running a test procedure using the GeneXpert Xpress system

If any error messages occur while running the test, see [Section 3.10, Error Handling](#).

3.4 Starting a Test While Another Test is Running

Additional tests may be started when another test is in progress by following the steps in this section.

Note

The total number of tests that can be running at one time is only limited by the number of available modules in the GeneXpert instrument.

1. Touch the **HOME** button on the Test Running screen (see [Figure 3-31](#)).

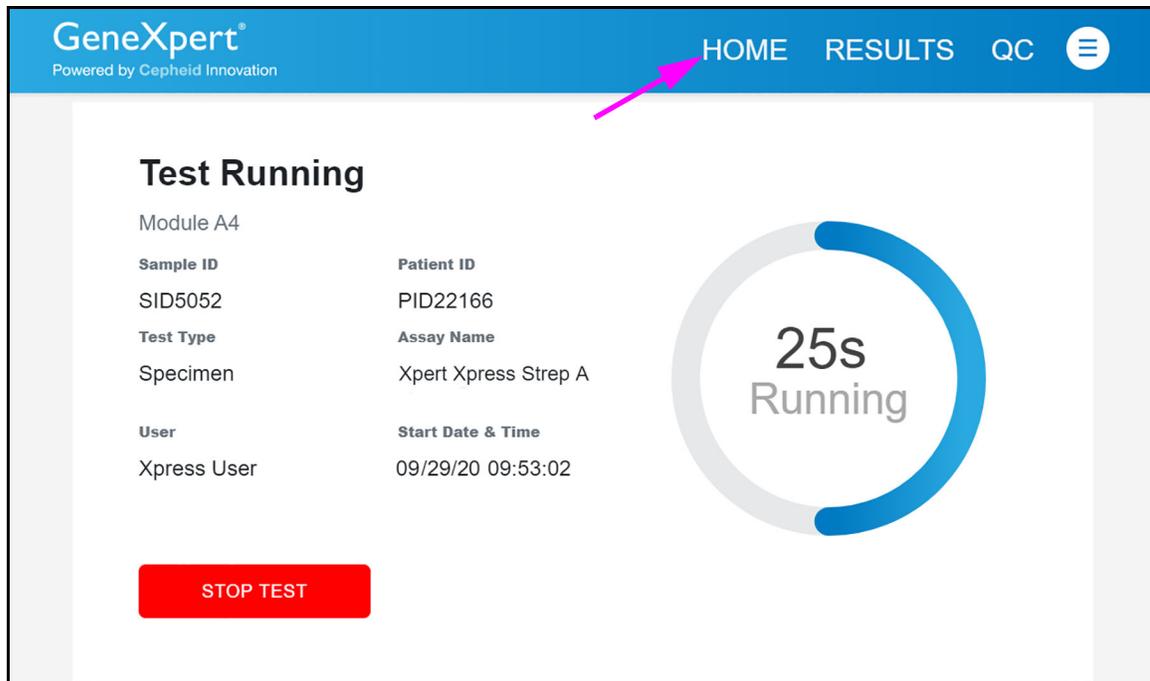


Figure 3-31. Test Running Screen - Going to the Home Screen to Start a New Test

2. The Home screen appears. In this example, the current test is running and three modules are available for additional tests to be started.

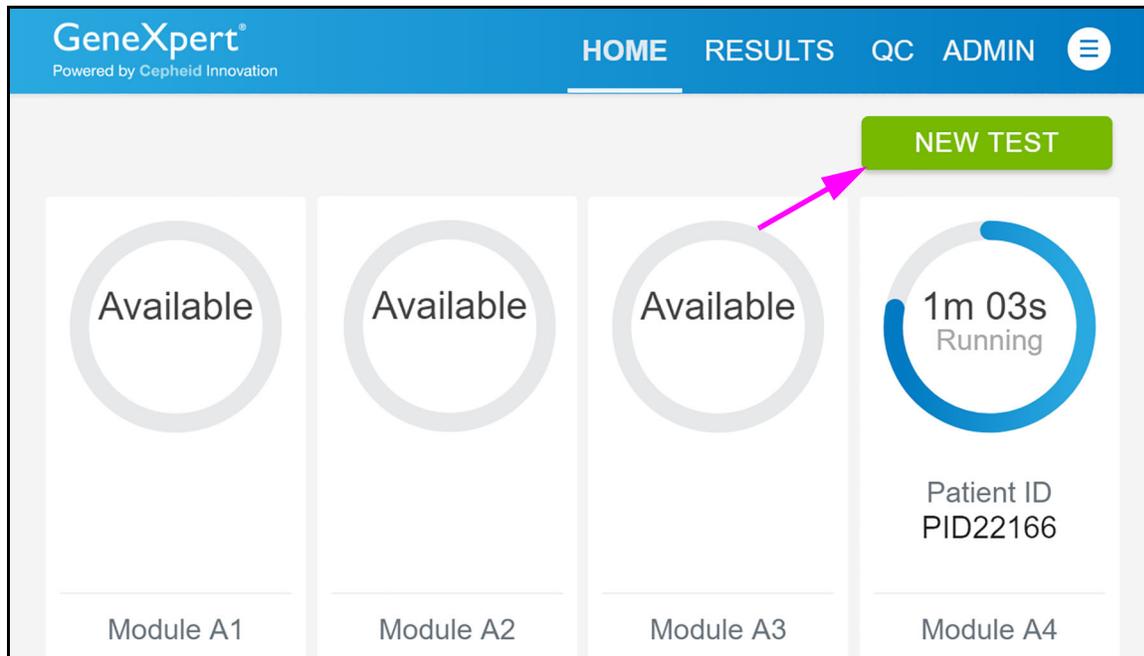


Figure 3-32. Home Screen, showing Three Available Modules

3. Touch the **NEW TEST** button on the Home screen (see [Figure 3-32](#)).
4. You can now perform the same steps required for a standard test, as described in [Section 3.3.2](#)).
5. After a second test has started, touch the **HOME** button. The module(s) in use will appear with a circular progress indicator around each test (see [Figure 3-33](#)).

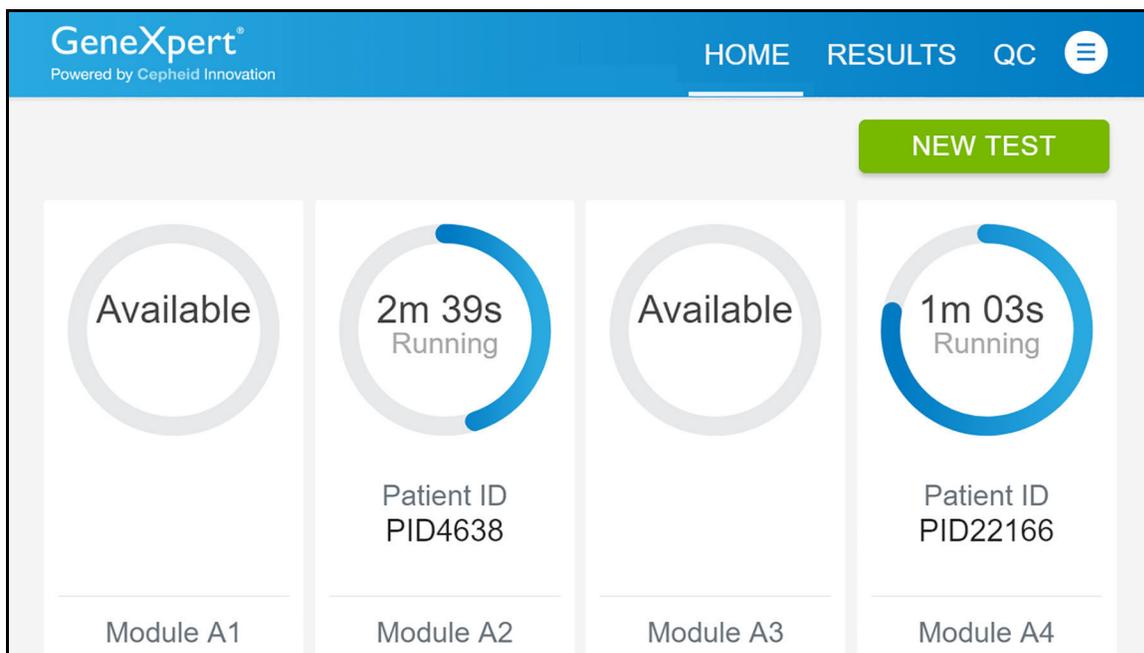


Figure 3-33. Home Screen showing Two Tests Running

- After a test has completed, the module icon text will change to **Complete** (see [Figure 3-34](#)).

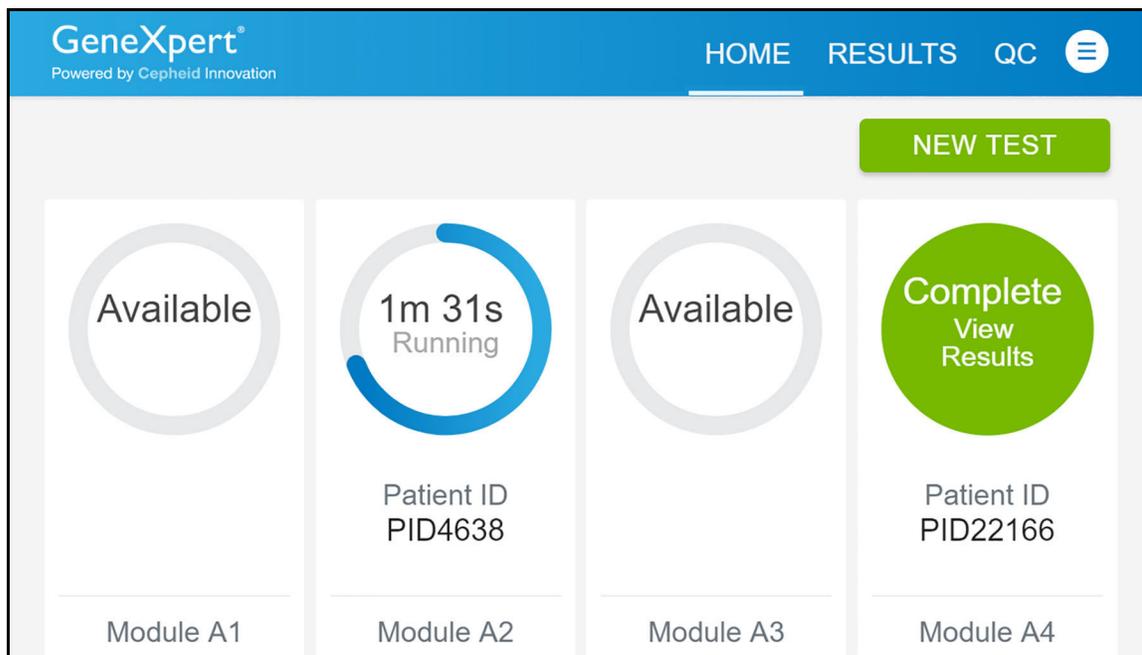


Figure 3-34. Home Screen with One of Two Tests Completed

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

3.5 Viewing Previous Test Results

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

- Touch the **RESULTS** button on the Home screen (see [Figure 3-35](#)).

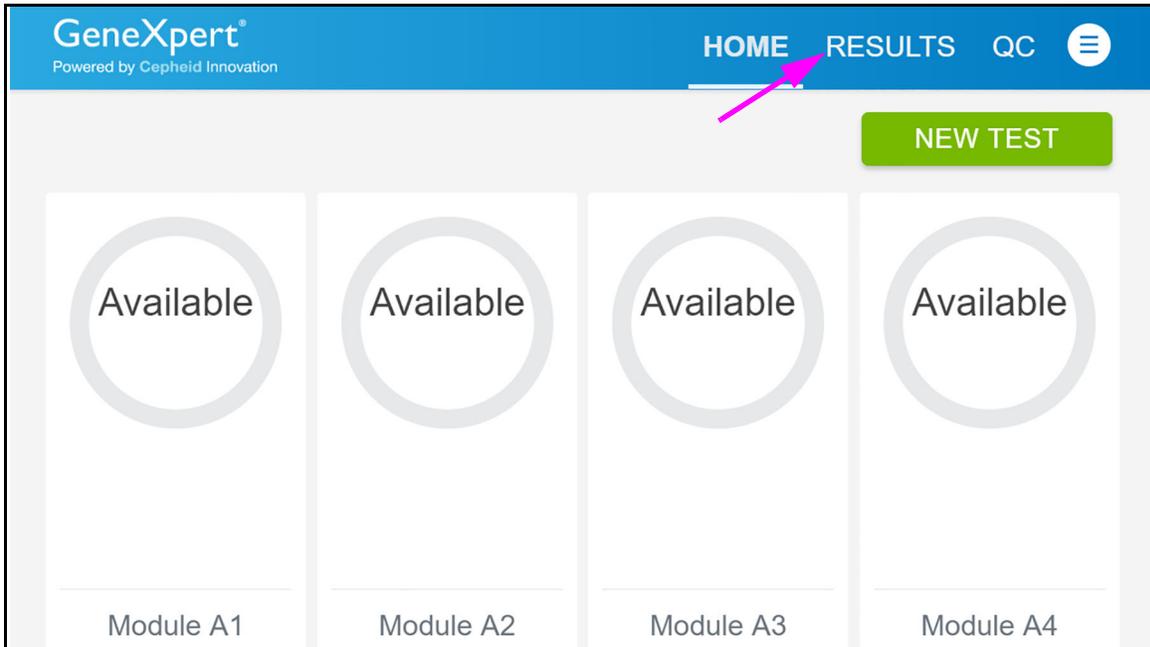


Figure 3-35. Home Screen (GX-IV, Four-Module Configuration Shown)

2. The Results screen is displayed (see Figure 3-36) showing a listing of tests previously run on the system.

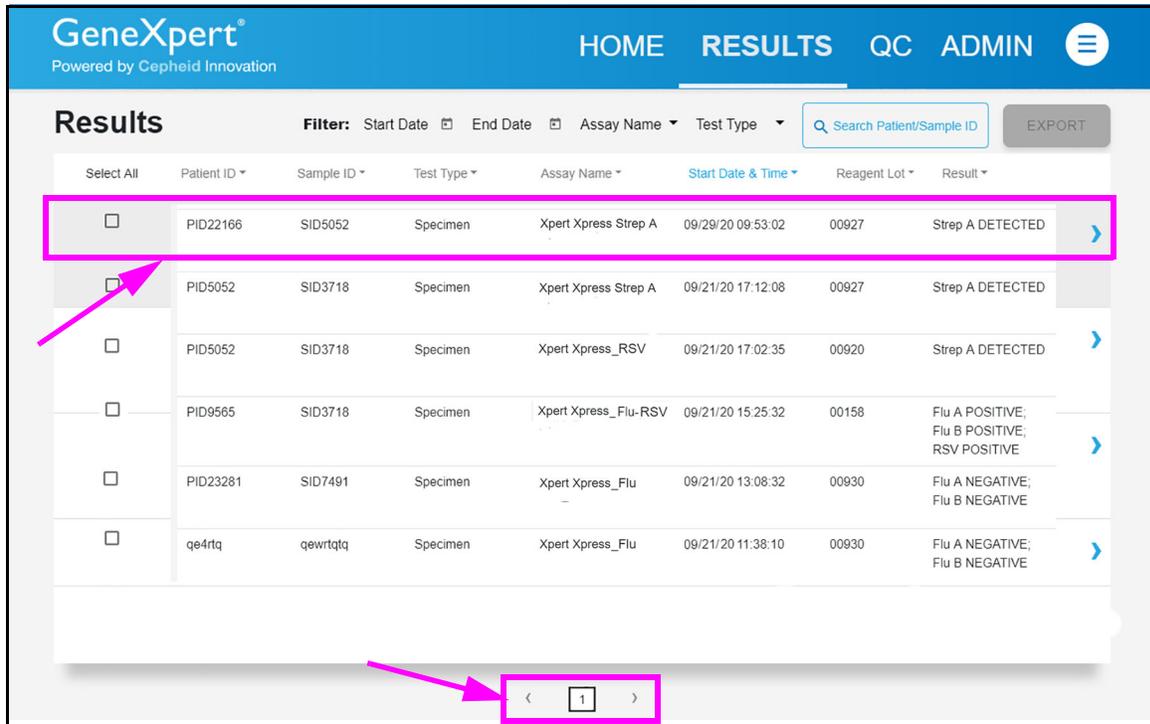


Figure 3-36. Results Screen showing a Listing of Previous Test Results Completed

- On the Results screen, tests are arranged, by default, in order by the date and time that a test was run. Touch the numbered page buttons at the bottom of the screen (see [Figure 3-36](#)) to navigate through the results if there is more than one page of results.

Note

The Patient ID and Sample ID columns are configurable so that either or both are visible, depending on the administrator's configuration. The filters on top of the column allow filtering by **Start Date**, **End Date**, **Assay Name** and **Test Type**, or by searching by the **Patient** or **Sample ID** number.

- After finding the desired test result, touching that particular test will open the Test Completed screen of the selected test (see [Figure 3-37](#)).

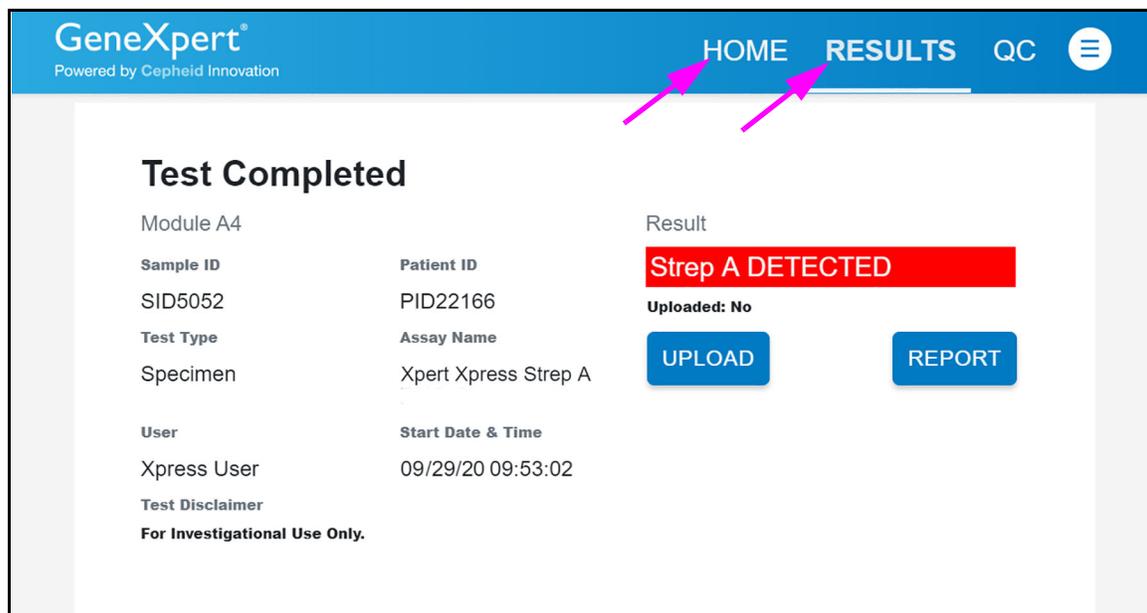


Figure 3-37. Test Completed Screen

- After viewing the results, touch the **HOME** button to return to the Home screen and run additional tests or touch the **RESULTS** button to return to the Results screen and view additional tests.

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

This completes the procedure for viewing previous test results.

3.6 User Menu Functions

The **User Menu** icon is located in the upper right corner of the screen (see [Figure 3-38](#)).

Touch the **User Menu** icon, and a drop-down menu appears. The drop-down menu identifies the user currently logged into the system, as well as notifications (if any). In addition, there are choices of **Change Password** (of the logged-in user), **About** (details of the Xpress software), **Logout** (of the present user) and **Exit**, which exits the Xpress software (see [Figure 3-39](#)).

3.6.1 Log In and Log Out

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

To log In:

1. Follow [Section 3.1, Starting the GeneXpert Xpress System](#) to get to the Home screen (see [Figure 3-38](#)).

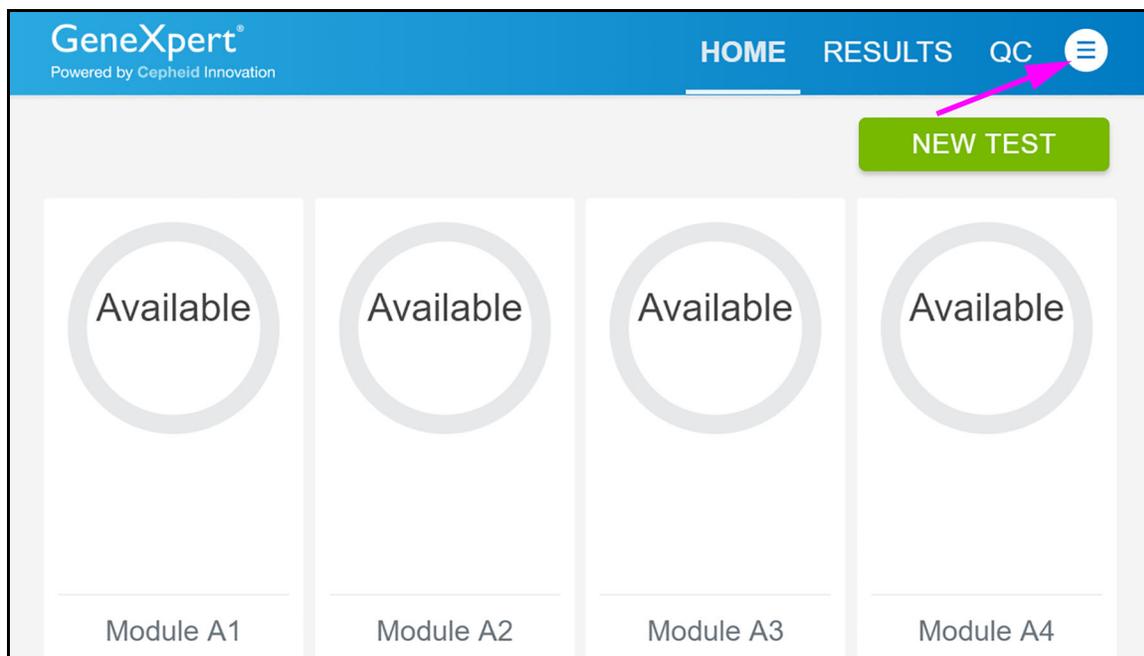


Figure 3-38. Home Screen (GX-IV, Four-Module Configuration Shown)

2. On the Home screen, touch the **User Menu** icon in the upper right corner of the screen. The **User Menu** appears (see [Figure 3-39](#)). Touch the **Login** entry.

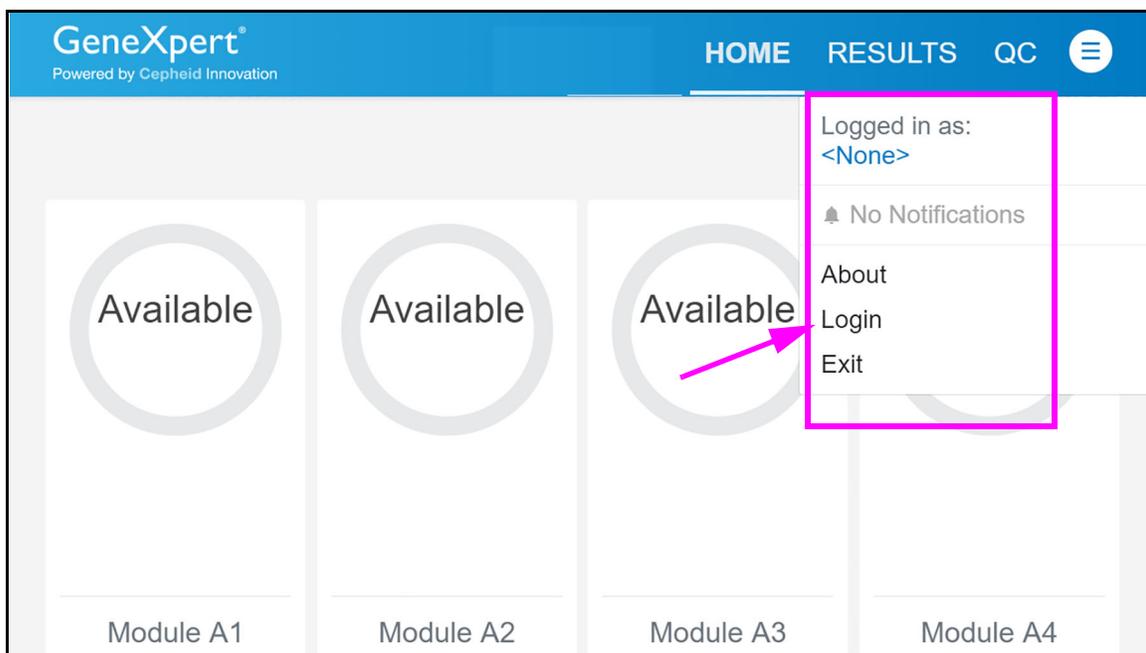


Figure 3-39. The Xpress User Menu

- If the **Login with Institutional ID** choice has not been selected by the administrator, login must be made using the virtual keyboard and the Login to GeneXpert Xpress Software screen will be displayed (see [Figure 3-40](#)).
- If the **Login with Institutional ID** choice has been selected by the administrator, login must be made using an ID card with barcode and the Scan Your ID Card to Continue screen will be displayed (see [Figure 3-41](#)).

3.6.1.1 Manual Login using the Virtual Keyboard

This section describes the steps necessary to log in manually, using the virtual keyboard on the touchscreen.

Note

To login with an Institutional Login (barcode) see [Section 3.6.1.2](#).

1. After touching the Login entry on the **User Menu**, the Login to GeneXpert Xpress Software screen will be displayed (see [Figure 3-40](#)).

Touch the **User Name** entry field, and the virtual keyboard appears.

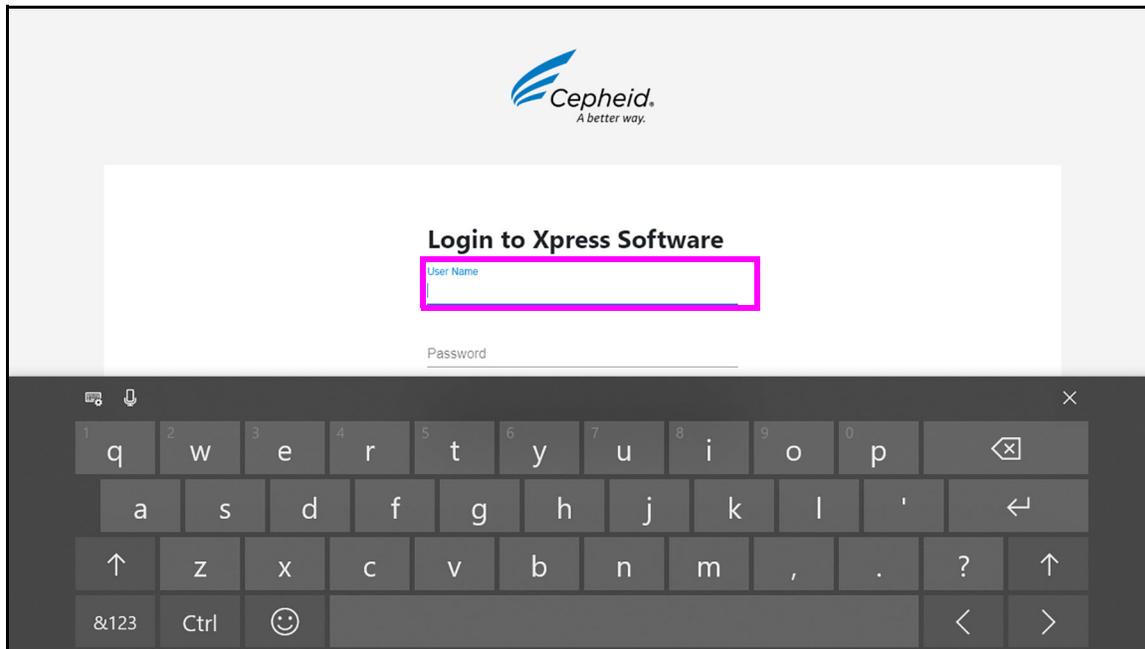


Figure 3-40. Login to Xpress Software Screen

2. Enter your **User Name**.
3. Scroll down and enter your user **Password**.
4. When you are finished entering your **User Name** and **Password**, touch the **X** in the upper right of the virtual keyboard. The virtual keyboard will disappear and the **LOGIN** button will be visible at the bottom of the screen.
5. Touch the **LOGIN** button and the Home screen appears.

3.6.1.2 Institutional ID Login

This section describes the steps necessary to log in using a barcode on an Institutional ID. To login using an Institutional ID, an administrator must first select that option in the General Settings screen (see [Section 4.8.1](#)).

Note

To login manually, using the virtual keyboard, see [Section 3.6.1.1](#).

1. After touching the **Login** entry on the **User Menu**, the Login to GeneXpert Xpress System - Scan Your ID Card screen will be displayed (see [Figure 3-41](#)) if your administrator has previously selected that ID Card scanning option.

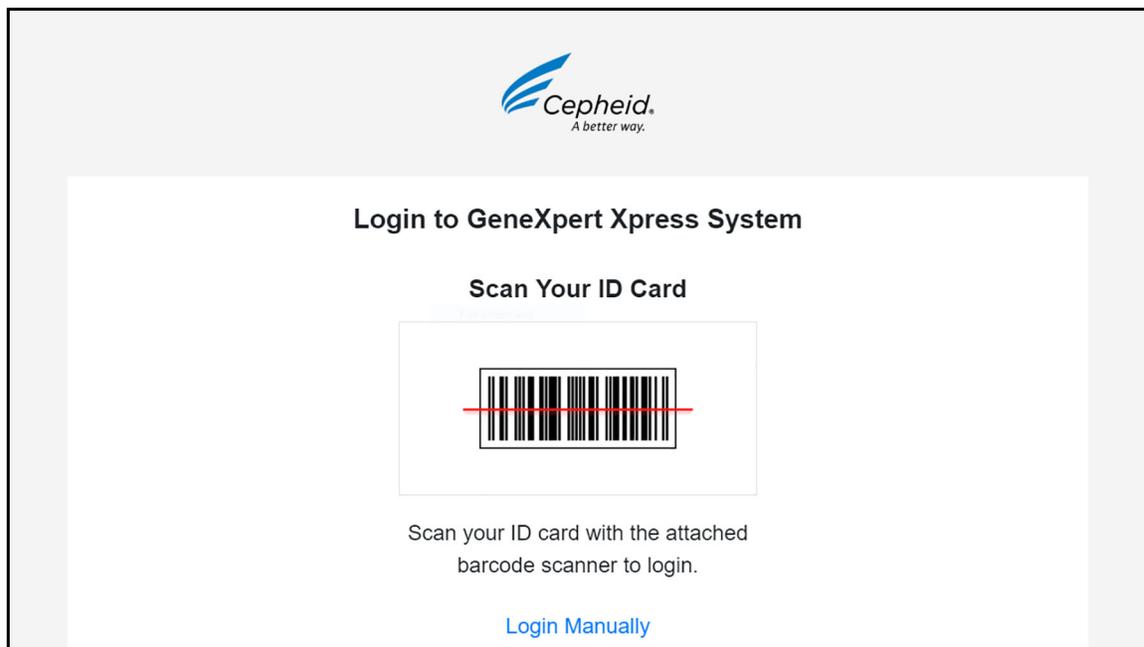


Figure 3-41. Login to GeneXpert Xpress System Screen

2. Using the integrated barcode scanner, scan your ID card. The Home screen appears.

To Log Out:

1. Locate the **User Menu** icon, which is located in the upper right corner of any screen (see [Figure 3-42](#)). In this example, the Home screen is shown.

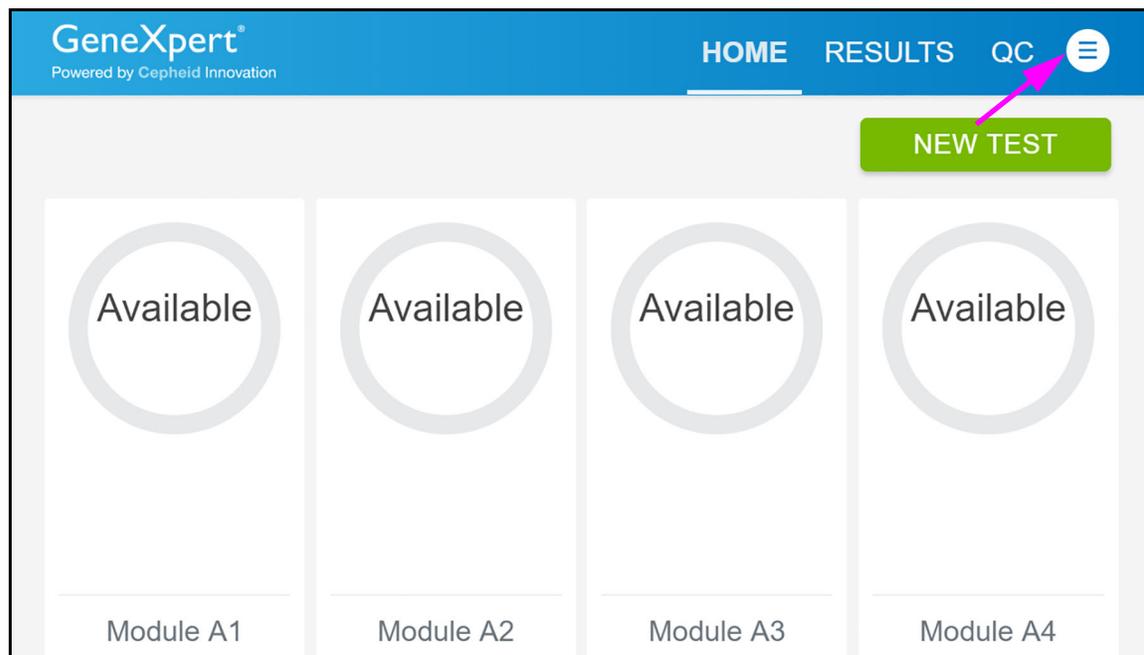


Figure 3-42. Home Screen showing the User Menu Icon

2. Touch the **User Menu** icon, and a drop-down menu appears (see [Figure 3-43](#)).

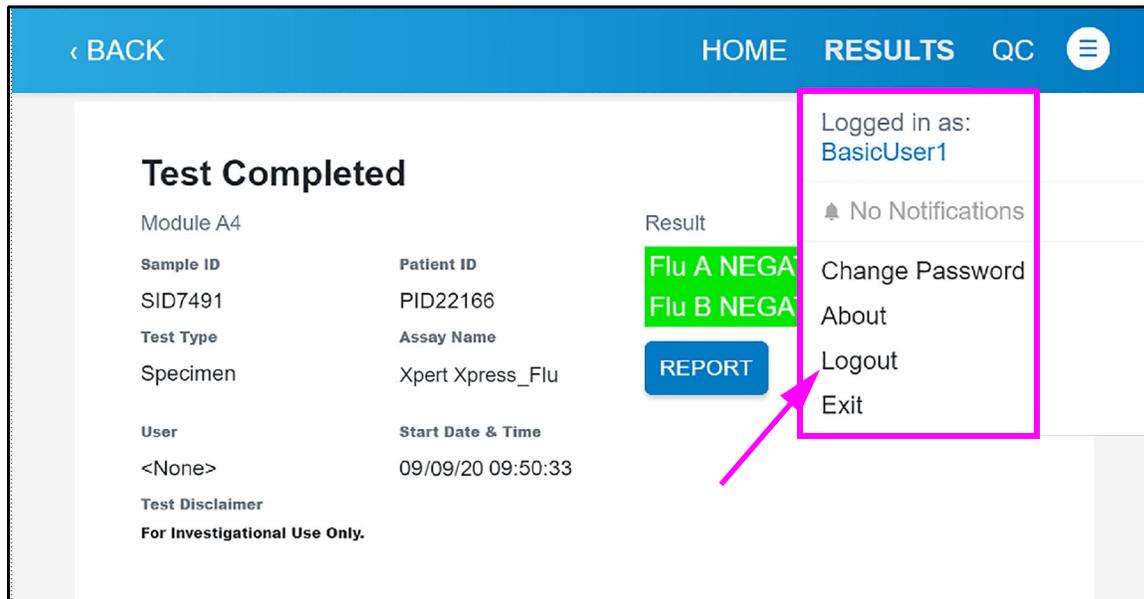


Figure 3-43. Test Completed Screen with User Drop-Down Menu

3. When you are finished with a session, touch **Logout** to log out of the system. You will be logged out and the screen will return to the Login screen (see [Figure 3-23](#)).

Note You should log out if you are going to be away from the system for an extended period of time. Logging out prevents the software from recording other users' activities under your account.

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

Note A second user can start a separate test if a test is in progress. The first user must log off, the second user then will log in and start an additional test following the steps in [Section 3.4, Starting a Test While Another Test is Running](#)

3.6.2 Changing Your Password

The method for changing a password varies, depending on whether or not the GeneXpert Xpress system is connected to a Data Manager. If your Xpress system is **not connected** to a Data Manager, follow the procedure in this section.

To change your **own** password, touch the **User Menu** icon. Touch **Change Password** on the drop-down menu. The Change Password screen appears (see [Figure 3-44](#)).

Important If your Xpress system is connected to a Data Manager, a user password cannot be changed locally by either the user or an administrator. If a Data Manager is being utilized, contact the administrative department, requesting a password change.

Note Only an Administrator can change **another user's** password. To do this, the Administrator must do so through the Admin User Management screen, and not through this Change Password screen.

Important

If a password is changed locally by either the user or an Administrator, and the Xpress system is later connected to a Data Manager, the new password will not be recognized. In this case, the previous password will still be active.

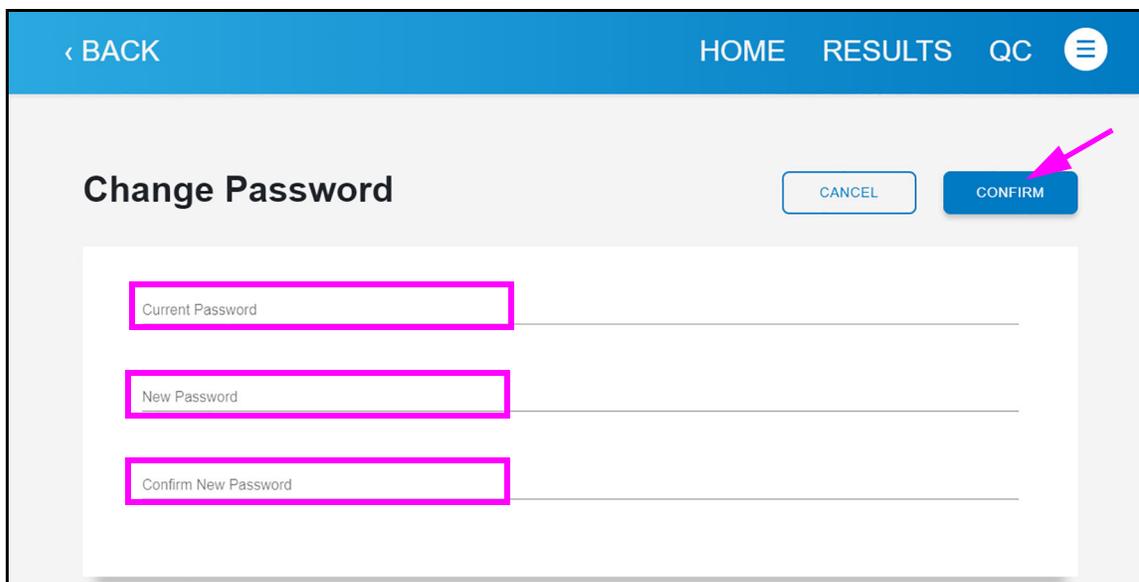


Figure 3-44. Change Password Screen

1. On the Change Password screen, touch the **Current Password** entry area and the virtual keyboard will appear. Enter your **Current Password**. Touch **New Password** and enter your new password. Touch **Confirm New Password** and enter your new password a second time.

Note

Passwords cannot contain spaces and the length should be between 6 and 32 characters.

2. When you are done, touch **CONFIRM** at the upper right of the screen, and you will be returned to your previous screen, such as **Home**, **Test Completed**, etc., and your new password will be active.

3.7 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 on the Home screen.
If you are on one of the test screens (but not actually running a test), or in one of the View Test Result screens, touch the **HOME** button in the upper part of the screen.
From the Home screen, touch the **User Menu** icon (see [Figure 3-45](#)). A drop-down menu will be displayed (see [Figure 3-46](#)).

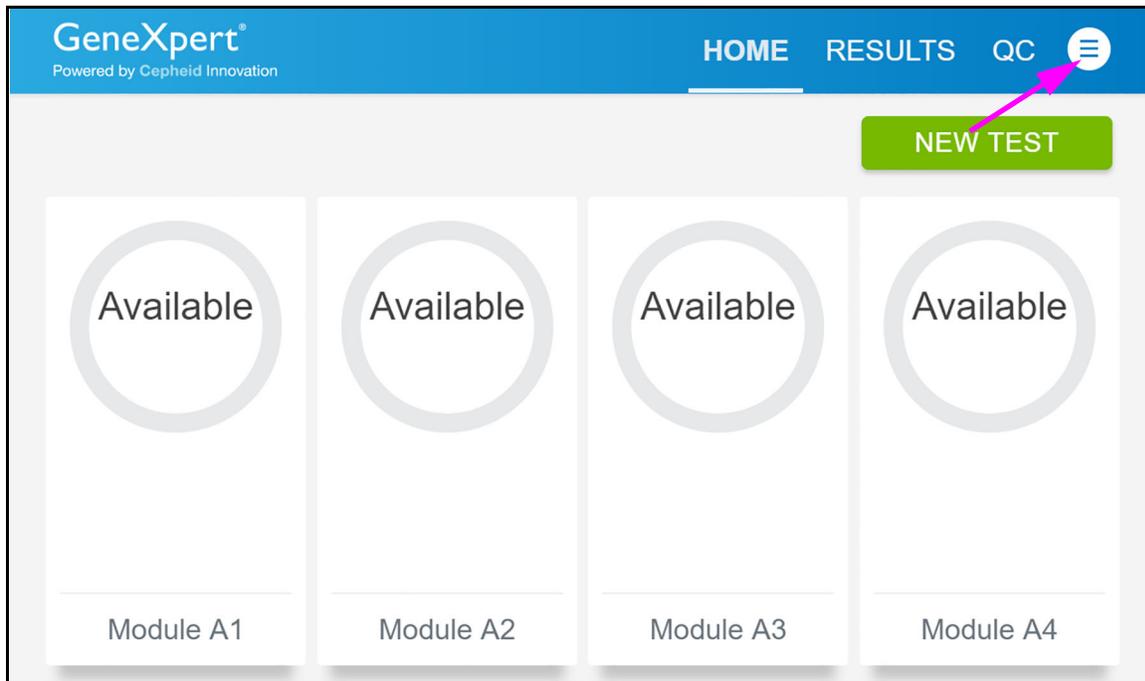


Figure 3-45. Home Screen showing the User Menu Icon

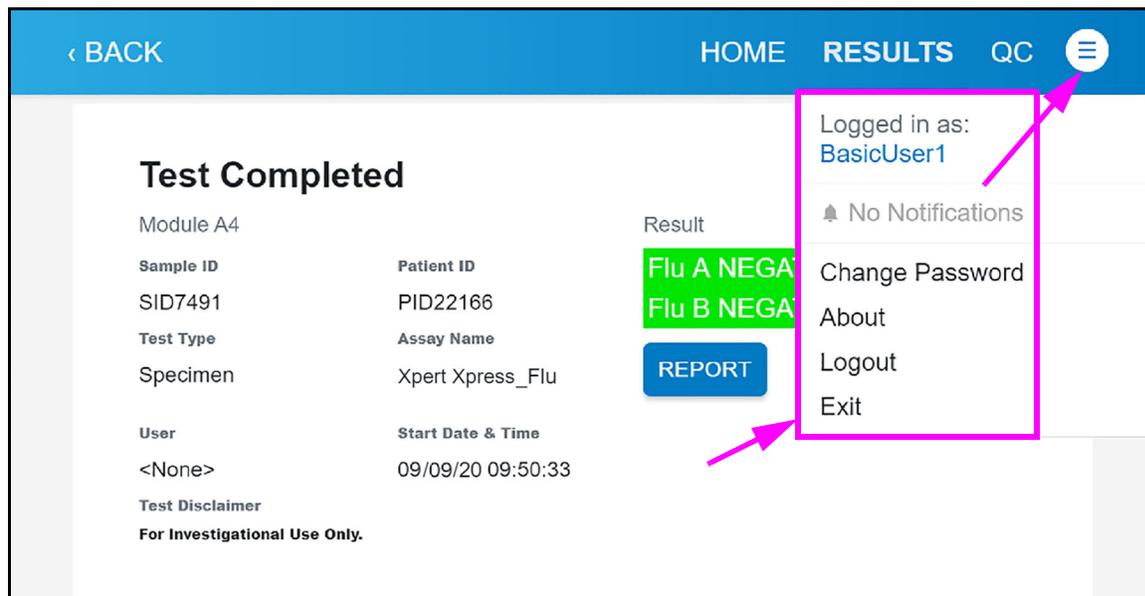


Figure 3-46. Home Screen showing User Drop-Down Menu, with Exit Selected

2. Using the drop-down menu, touch **Exit**. A Confirm screen appears, asking if you are sure you wish to exit. Select **YES** to exit the software, and return to the Windows desktop. If you do not want to exit the software, select **NO**.
3. Press the blue power switch on the right front of the GeneXpert hub (see [Figure 3-47](#)). The GeneXpert hub computer will turn off.



Figure 3-47. GeneXpert Xpress Hub, showing Blue Power Switch

4. Wait 10 seconds for Windows to shut down, and power down the GeneXpert hub using the power switch located on the back of the GeneXpert hub. Press the switch to the **OFF** (○) position (see [Figure 3-48](#)).



Figure 3-48. GeneXpert Xpress Hub Power Switch (Rear of Hub)

5. Turn off the GeneXpert IV instrument. The power switch is located on the back of the instrument. Press the switch to the **OFF** (○) position (see [Figure 3-49](#)).

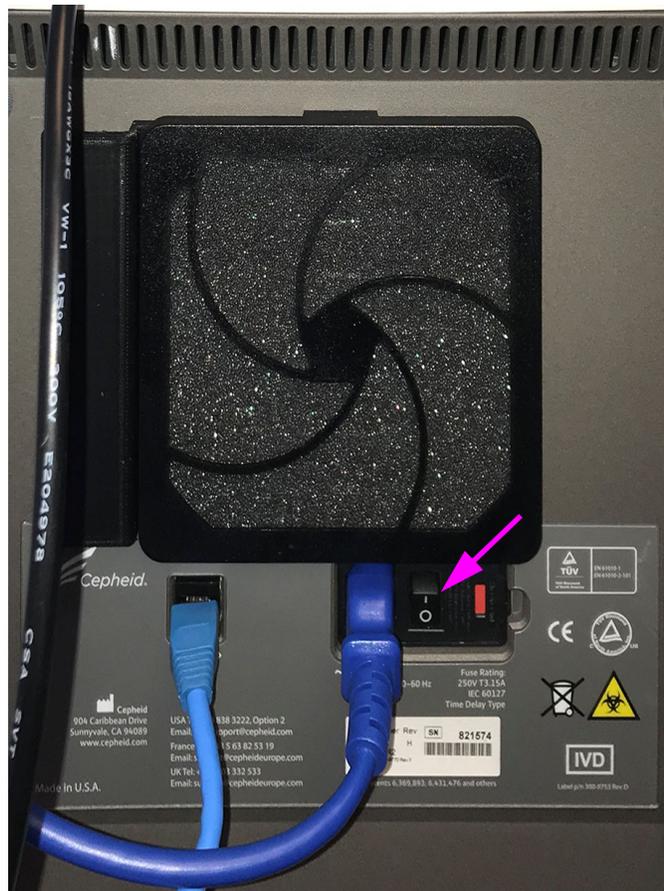


Figure 3-49. Turn OFF the Instrument

The GeneXpert Xpress system is now shut down. To run tests later, see [Section 3.1, Starting the GeneXpert Xpress System](#).

3.8 Quality Control Lockout (Optional)

3.8.1 Quality Control

Quality Control tests can be run at any time; the lockout feature does not need to be enabled, however, the result will not be saved in the QC Summary history.

Touch the **QC** button at the top of the screen to view the Quality Control Summary screen begin a quality control test or to view the Select Quality Control page (see [Figure 3-50](#)).

The Quality Control screen provides the choice of running either a positive or negative test, running a proficiency test, viewing the summary page or returning to the Home screen.

To run a positive or negative test, touch the appropriate button on the screen. See [Section 3.8.3, Running a Quality Control Test](#).

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



Figure 3-50. Select Quality Control Type Screen

The summary page will display important information about the QC status for assays (see [Figure 3-51](#)).

Note

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

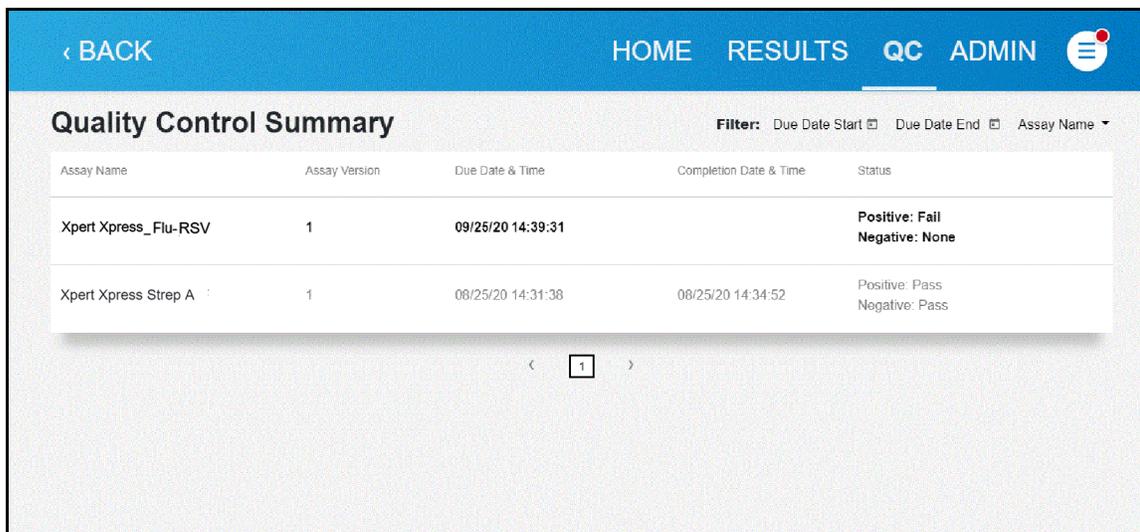


Figure 3-51. Quality Control Summary Screen

3.8.2 Quality Control Lockout

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

If the QC lockout feature is set so that QC must be run at regular intervals, reminders 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. Acknowledge the reminder to close the reminder window to proceed.

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.

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

3.8.3 Running a Quality Control Test

1. Touch the **QC** button on the Home screen (see [Figure 3-52](#)). The Quality Control screen is displayed (see [Figure 3-53](#)).

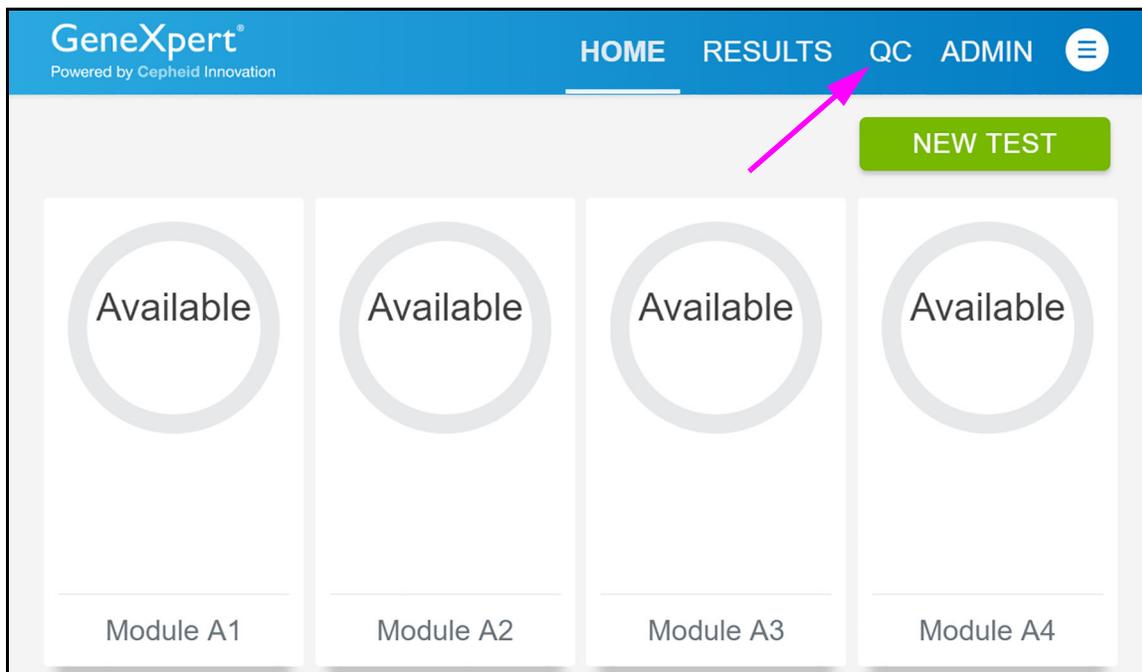


Figure 3-52. Home Screen (GX-IV, Four-Module Configuration Shown)

- On the Quality Control screen, select either **POSITIVE** or **NEGATIVE** for the control type that will be tested. In the following example, touch **RUN QC POSITIVE TEST** (see [Figure 3-53](#)). The Sample ID screen appears (see [Figure 3-54](#)).



Figure 3-53. Quality Control Screen

3.8.4 Entering the Sample ID

Touch the sample ID field to display the keyboard and enter **Negative Control** if running a negative control or **Positive Control** if running a positive control test.

Touch **CONTINUE** when you are done. The Confirm Sample ID screen appears (see [Figure 3-55](#)).



Figure 3-54. Sample ID Screen

1. Verify that the Sample ID on the Confirm Sample ID screen (see [Figure 3-55](#)) matches the Sample ID entered on the Sample ID screen (Positive Control or Negative Control). If it matches, touch the **CONFIRM** button. If it does not match, touch the **RE-ENTER** button, re-enter the Sample ID and touch the **CONTINUE** button.



Figure 3-55. Confirm Sample ID Screen

2. The Scan Cartridge Barcode screen appears (see [Figure 3-56](#)).

Biological Risks



In the following steps, cartridges should be kept upright when handling or scanning. Do not rotate or tip the cartridge, because damage to the contents or injury to personnel may occur.

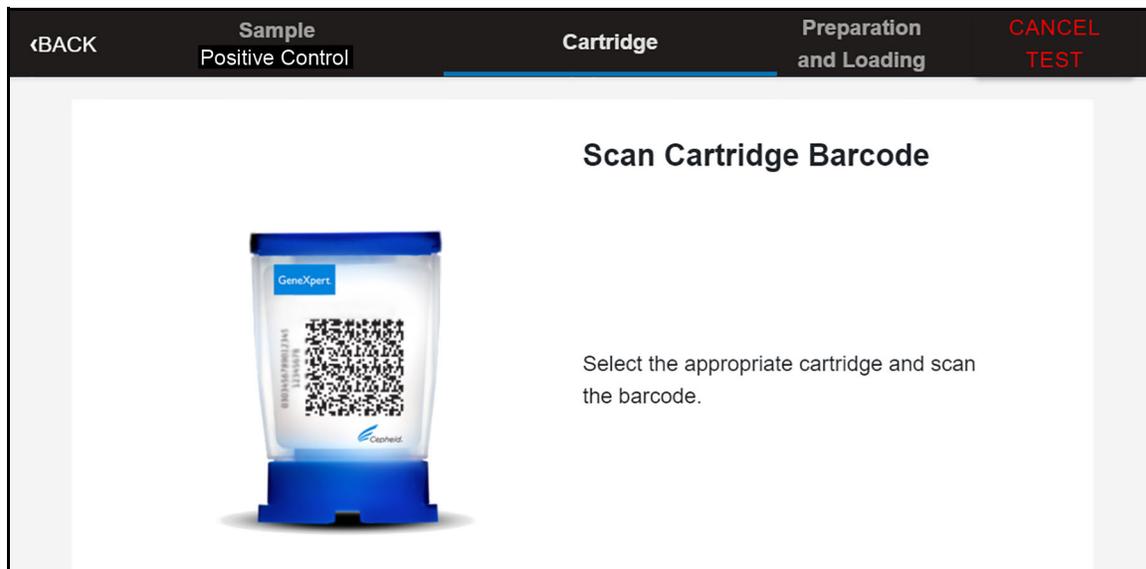


Figure 3-56. Scan Cartridge Barcode Screen

- Scan the barcode. After scanning the barcode, the Confirm Test Information screen appears (see Figure 3-57).

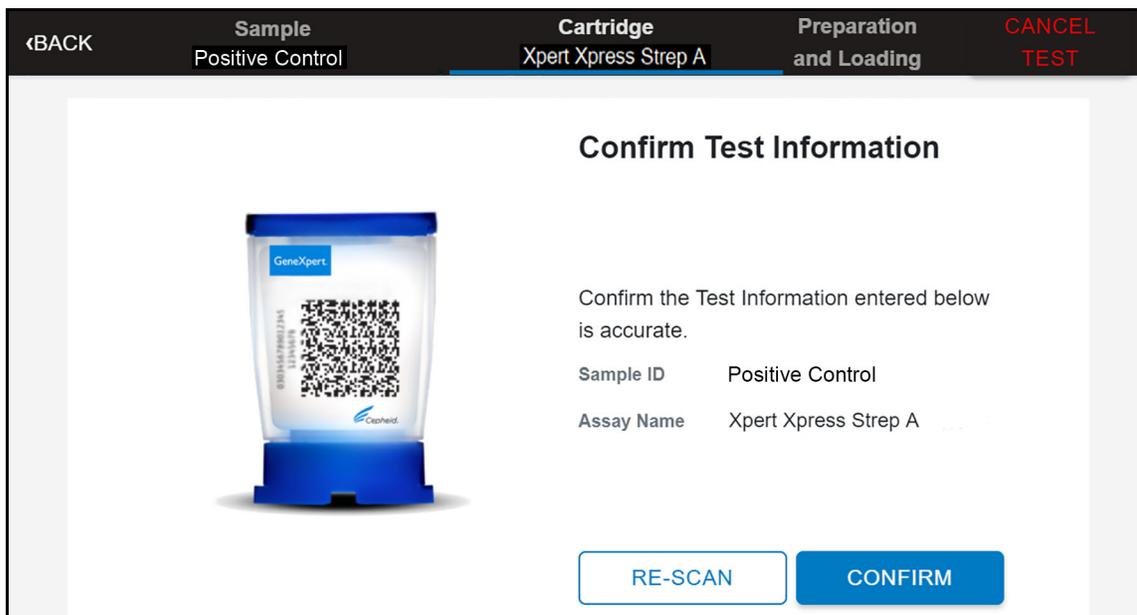


Figure 3-57. Confirm Test Information Screen

- Verify that the correct cartridge has been scanned and that the assay name shown on the Confirm Test Information screen matches the assay name on the cartridge.

If it does not match, touch the **RE-SCAN** button and scan the correct cartridge barcode.

After you have a match, touch the **CONTINUE** button. The Confirm Quality Control Test screen appears (see Figure 3-58).

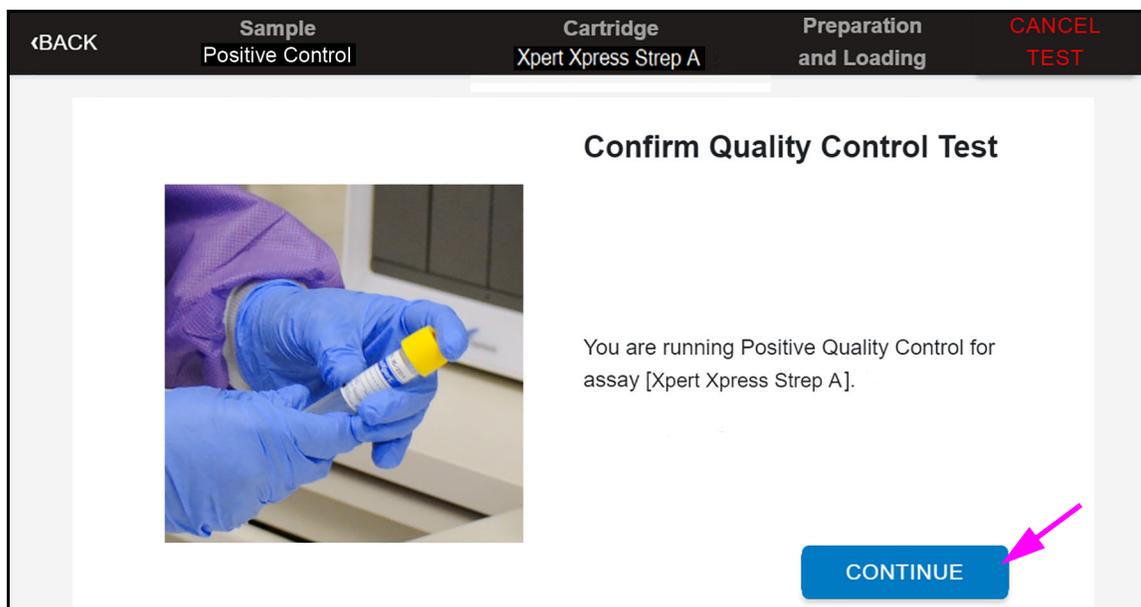


Figure 3-58. Confirm Quality Control Test Screen

- After confirming that the test information is correct, touch **CONTINUE**. Depending on settings, the Login screen may be displayed (see [Figure 3-60](#)).

Note

In General Settings, there is a **Login to Start Test** configuration which can be altered to change when a user needs to login to start a test.

- If the Login screen is displayed, enter your **User Name** and **Password**.

Combinatorial Assays Only

For Combinatorial assays only, an additional screen will appear at this time, where you must select the appropriate test from those tests listed on the screen.

Note

If QC lockout is enabled, a positive and negative control for each ADF is required.

Note

For assays with combinatorial assays, such as Flu, RSV and Flu/RSV, select the correct test, then touch the **CONFIRM** button (see [Figure 3-59](#) as an example).

Make the appropriate selection from the Select Test menu, as shown in [Figure 3-59](#).

- Flu A, Flu B and RSV: Select **Xpert Xpress Flu-RSV**
- Flu A and Flu B only: Select **Xpert Xpress_Flu**
- RSV only: Select **Xpert Xpress_RSV**

Only the test result for the assay selected at this step will be collected once the test is started. Flu A, Flu B, and RSV results will only be collected if the Xpert Xpress Flu-RSV assay is chosen. Confirm the selected test from the Select Test menu, as shown in [Figure 3-59](#).

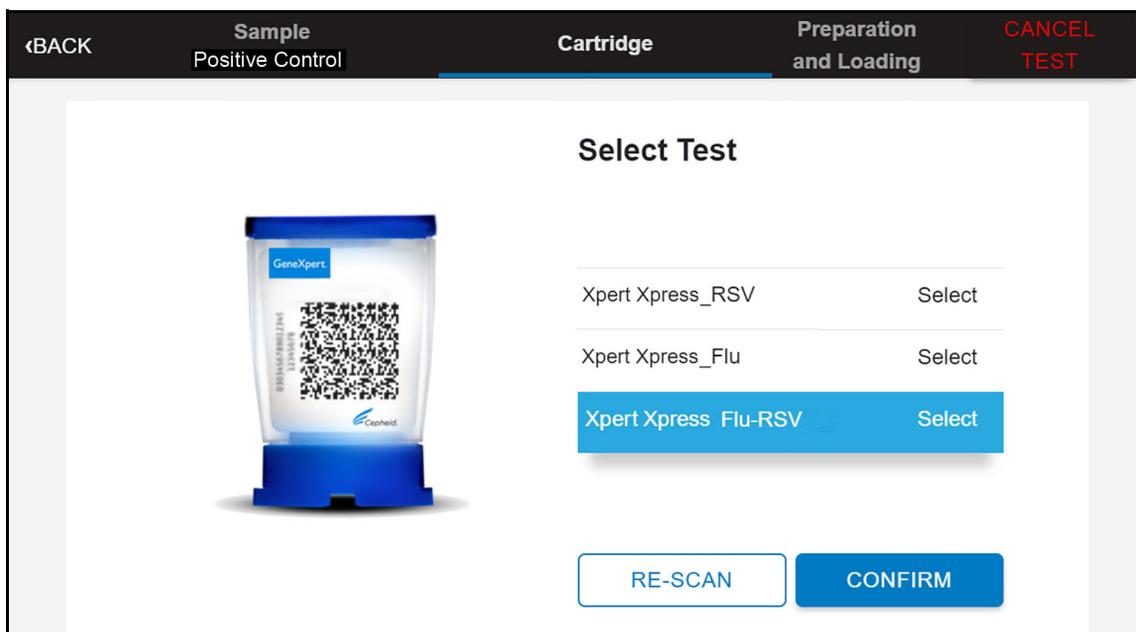


Figure 3-59. Select Test Screen (for Combinatorial Assays only)

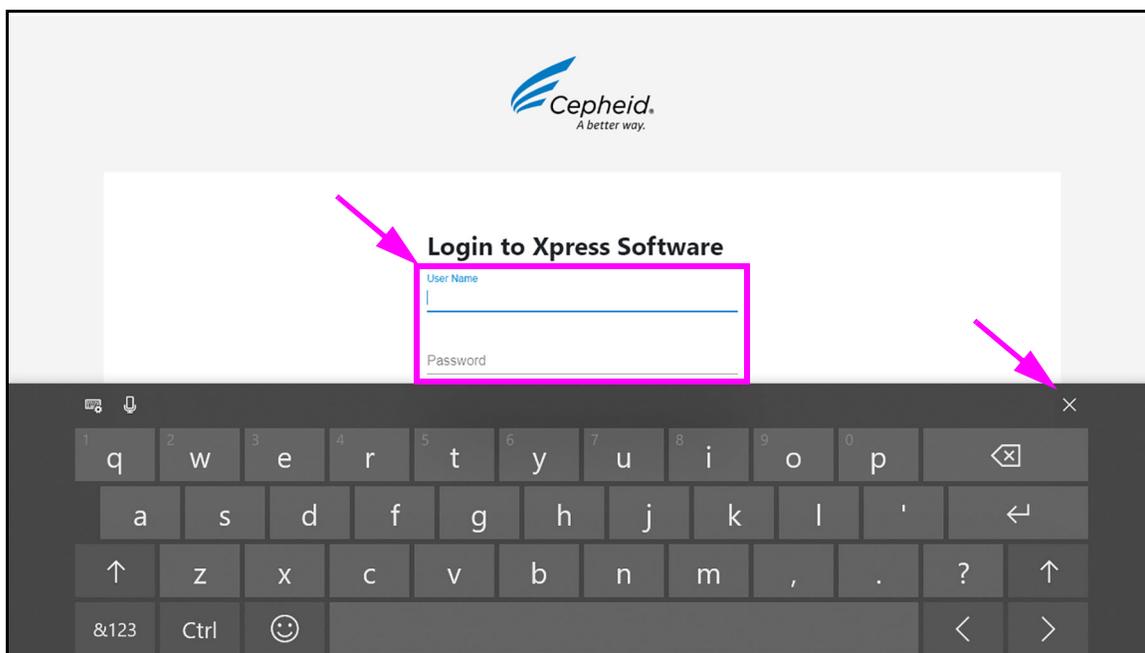


Figure 3-60. Login Screen

7. The Cartridge Preparation screen will be displayed (see [Figure 3-61](#)). A video clip will appear showing the cartridge preparation steps. 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.

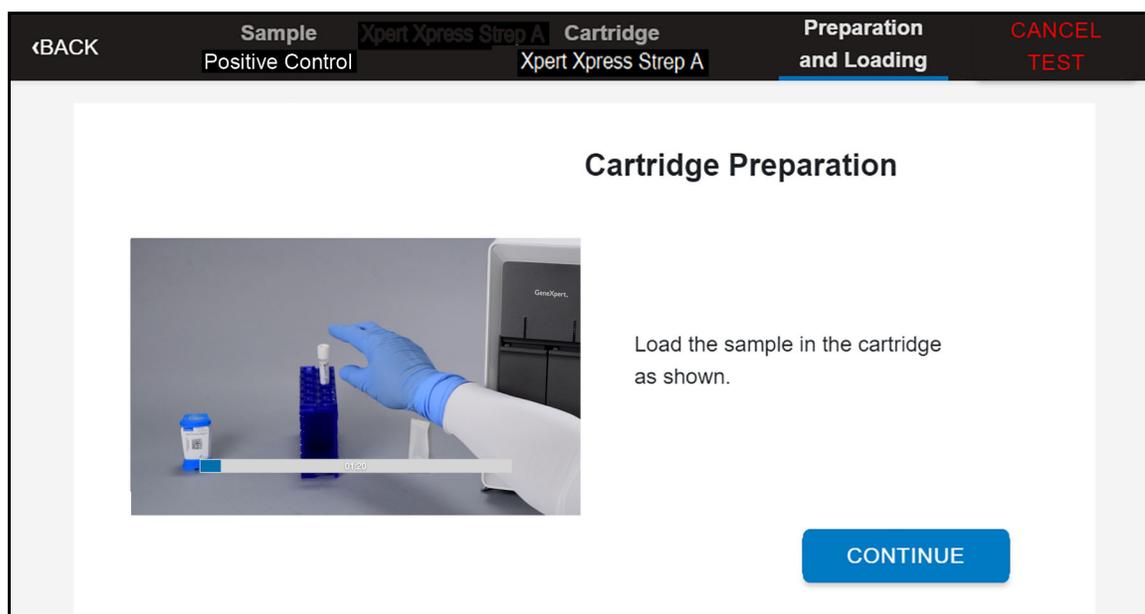


Figure 3-61. Cartridge Preparation Screen

8. After the cartridge has been prepared, touch the **CONTINUE** button on the Cartridge Preparation screen (see [Figure 3-61](#)) to halt the video clip. The Load Cartridge into Module screen will be displayed (see [Figure 3-62](#)).

11. Press the module door closed, ensuring that the door is completely closed. The door will latch and the flashing green light will turn solid green. As soon as the cartridge is loaded, the Test Loading screen will be displayed (see [Figure 3-64](#)) showing that the cartridge is being loaded.

Note

If necessary, touch the **STOP TEST** button to stop/cancel a test now, while it is loading, or later when the test is in progress. Note that you will not get a test result from a canceled test.

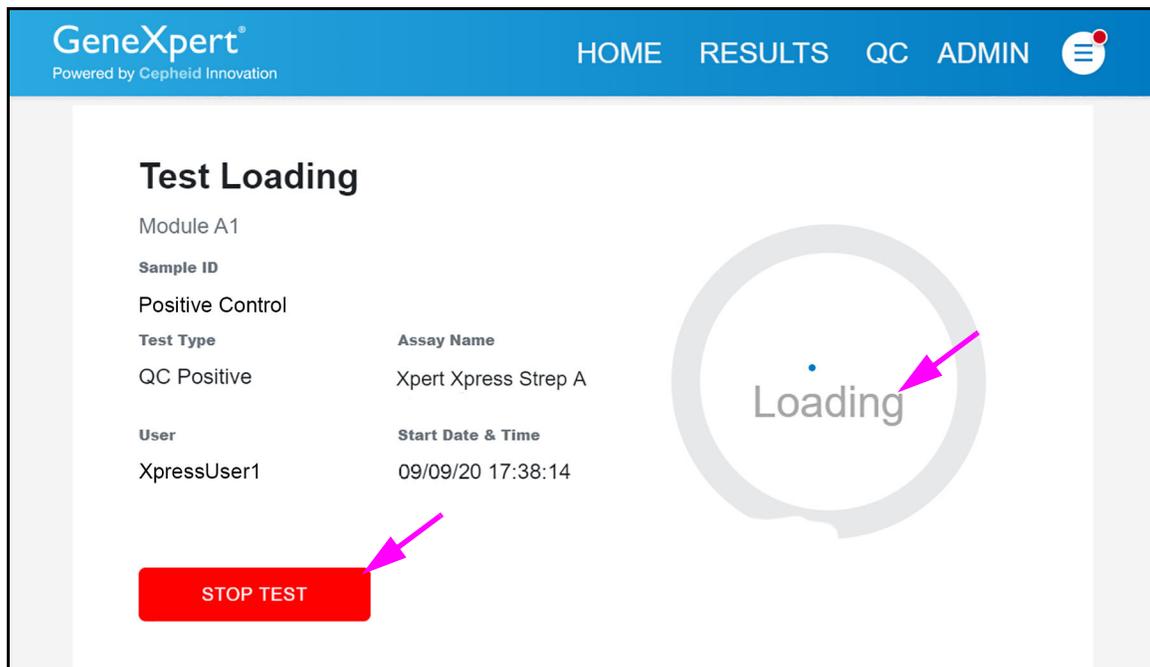


Figure 3-64. Test Loading Screen showing Cartridge Loading

12. After the test has loaded, the Test Running screen appears, showing a blue circular graphic indicator at the right side of the screen, indicating the progress of the test and the time remaining until a test result is available (see [Figure 3-65](#)).

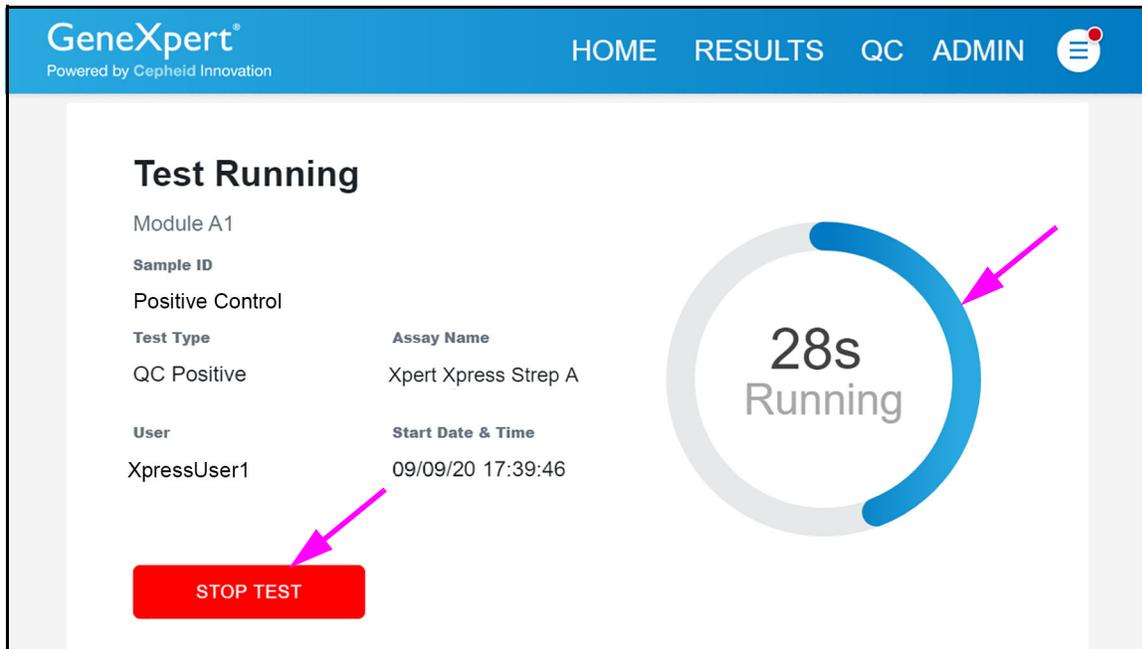


Figure 3-65. Test in Progress Screen showing Test Time Remaining

13. When a test completes, the QC Test Result screen appears (see [Figure 3-66](#)). The QC Test Result screen shows results for the completed QC tests.
14. Open the module door, remove the used cartridge, and properly dispose of the cartridge according to your institution’s hazardous waste disposal policies.

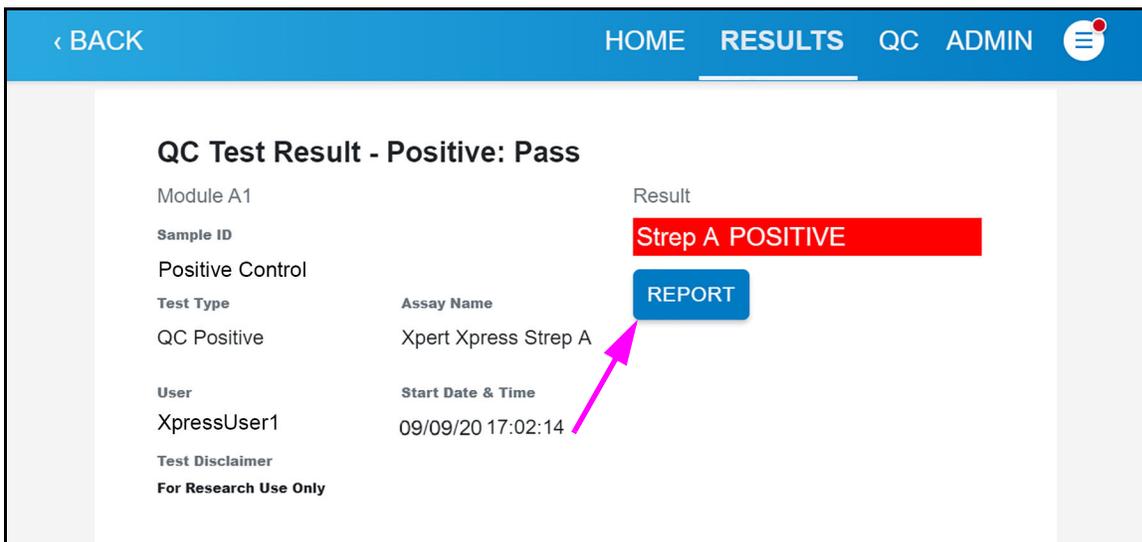


Figure 3-66. QC Test Result - Positive Pass Screen

15. Test the second control tube. Repeat [Step 1](#) in [Section 3.8.3](#) through [Step 14](#) in [Section 3.8.4](#) with the second control tube. In this example, the first test is with the positive control (see [Figure 3-66](#)), therefore the second test is with the negative control (see [Figure 3-67](#)).

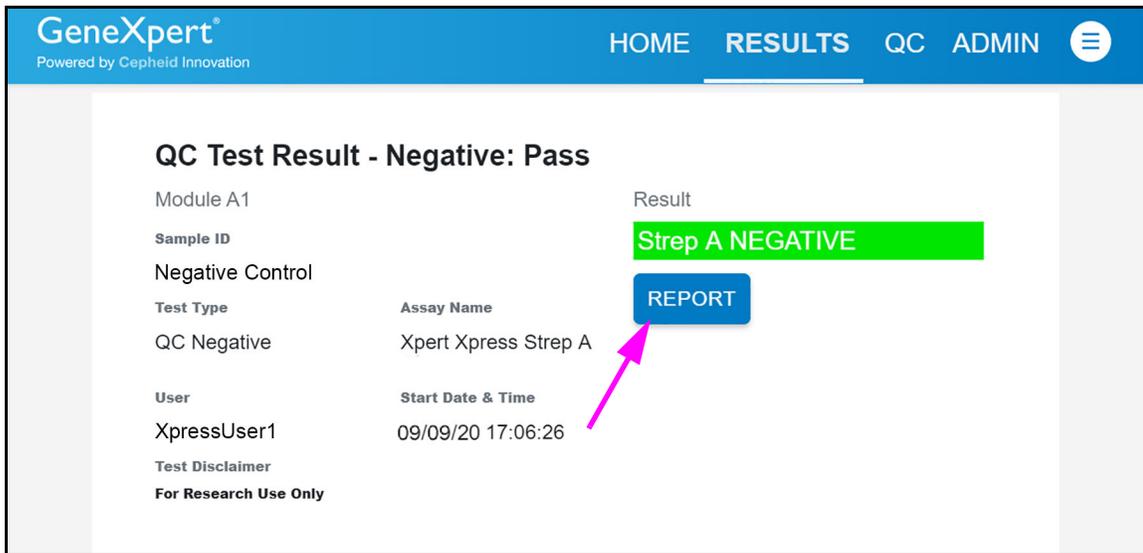


Figure 3-67. QC Test Result - Negative Pass Screen

16. To view a complete test report of the test just completed, touch the **REPORT** button on the QC Test Result screen.

The Report Viewer screen then appears (see [Figure 3-68](#)), displaying the report which can be saved, or printed to any wired or network printer, as desired.

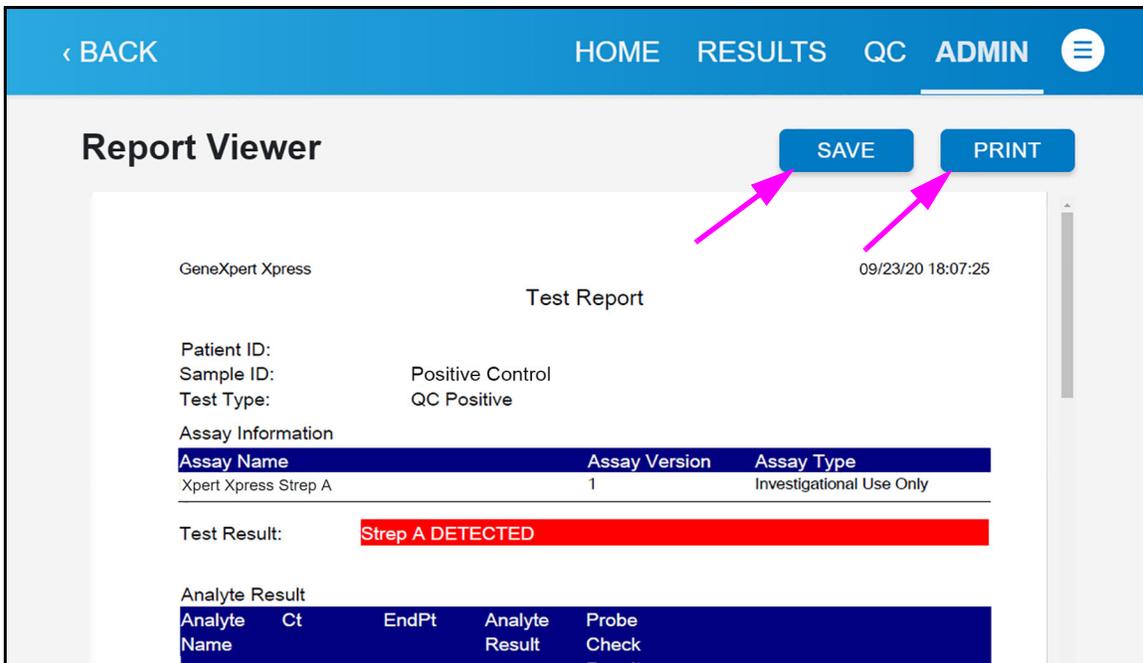


Figure 3-68. Screen showing Test Report of Test Just Completed (Partial View shown)

Note

If the option to print the results was selected, a screen indicating the print was successful will display.

17. After viewing and/or printing the test results, touch the **HOME** button to return to the Home screen. From the Home screen you can touch **RESULTS** (in the top banner) to view the results of the tests previously run (see [Section 3.5](#)).

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

If any error messages occur while running the test, see [Section 3.10, Error Handling](#).

3.9 Operating with Host (LIS or POCT) Connectivity

This section provides instructions on how to use the GeneXpert Xpress system host interface to:

- Create a test from a downloaded test order and upload the result (see [Section 3.9.1](#))
- Upload a test result ([Section 3.9.2, Uploading a Test Result to the Host](#))

Note

Beyond the routines described in this section when operating with LIS connectivity, an Admin has additional capabilities for performing queries and managing host test orders, as described in [Section 4.11](#).

Caution



Cepheid recommends to always confirm that LIS uploaded results match GeneXpert Xpress test results after any changes to the GeneXpert Xpress or host system, including (but not limited to) changes to the following:

- GeneXpert Xpress software version
 - GeneXpert Xpress Host Communication Settings
 - Host middleware software or configuration changes
 - LIS software or configuration changes
-

3.9.1 Creating a Test with Host Connectivity

When host connectivity is enabled, the GeneXpert Xpress system periodically queries all test orders from the host. Depending on the Host Communication settings (see [Section 4.10.3](#)), test orders will be automatically downloaded from the host when a test is initiated.

Procedure

1. If configured, enter the Patient ID as described in [Section 3.3.2](#).
2. Enter the Sample ID as described in [Section 3.3.3](#).

Note

If there are test orders available from the host, there should be samples on hand for the tests ordered.

3. The system checks for a matching host order.
 - A. If no order is found, the following screen appears (see [Figure 3-69](#)).

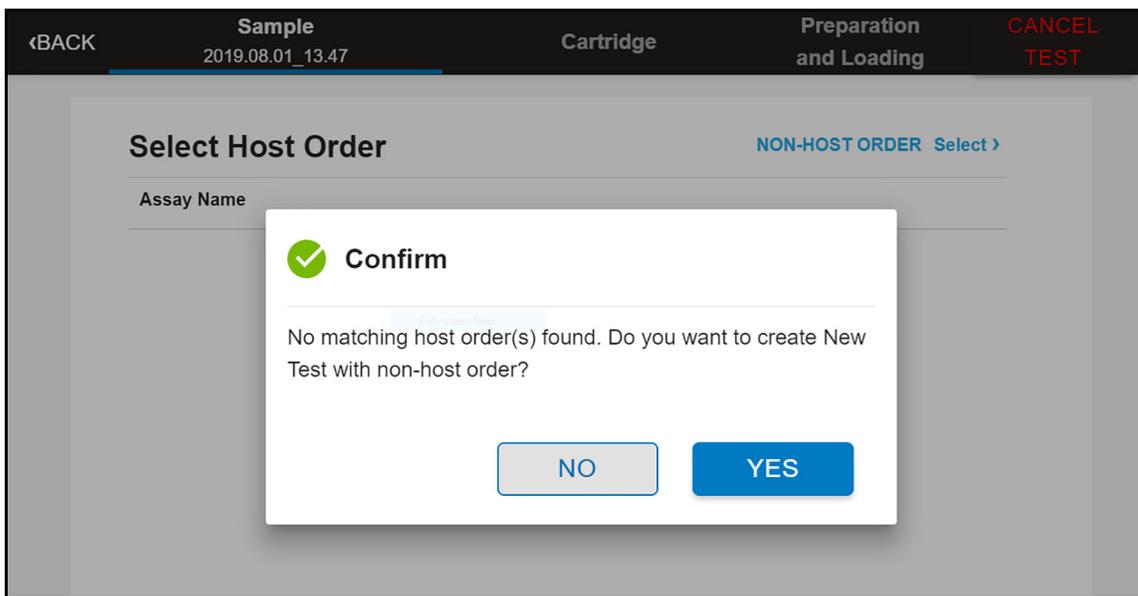


Figure 3-69. No Matching Orders Found Dialog Box

- A. If you answer **NO**, you will be returned to the Home screen. Start another test by touching the **NEW TEST** button. Perform the routine beginning with [Step 1](#) of this procedure, by scanning a different Patient ID and Sample ID.
- B. If you answer **YES**, then you can scan the cartridge and order a non-host order test, as described in [Section 3.3.4](#) and [Section 3.3.5](#).

Note

The workflow in your laboratory will determine how a test is created.

4. When you scan a Patient ID and a Sample ID, and the order is in the system, the Select Host Order screen appears (see [Figure 3-70](#)), and the host order(s) appears on the screen.

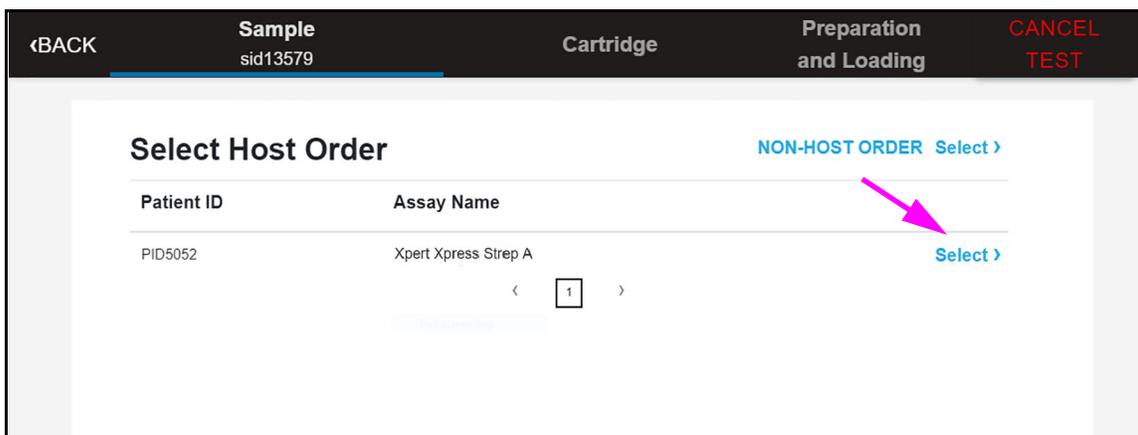


Figure 3-70. Select Host Order Screen

5. Touch the **Select** button at the right of the host order (see [Figure 3-70](#)).

6. The Scan Cartridge Barcode screen will automatically display a prompt to scan the barcode on the cartridge. This prompt confirms that the correct assay will be run. The reagent lot ID, expiration date, and cartridge serial number are processed. Refer to [Section 3.3.4](#) for instructions on scanning a cartridge barcode. This order will be removed from the list of new orders.
7. Insert the specimen and reagents into the cartridge according to the assay-specific package insert.
8. Load the cartridge, and close the module door by performing the steps starting with [Section 3.3.5](#).

Note The Test Completed screen will vary slightly from that shown in [Figure 3-29](#).

3.9.2 Uploading a Test Result to the Host

Note You cannot change the Patient ID, Patient ID 2, Patient Name, Sample ID, or the assay if it is selected from a host downloaded test order.

Test results can be uploaded to the host either automatically or manually.

1. After the test is completed, the result will be automatically uploaded, as determined by the host communication settings (see [Section 4.10.3](#)).
2. The Upload Status is shown in the Test Information area of the View Result window (see [Figure 3-71](#)).

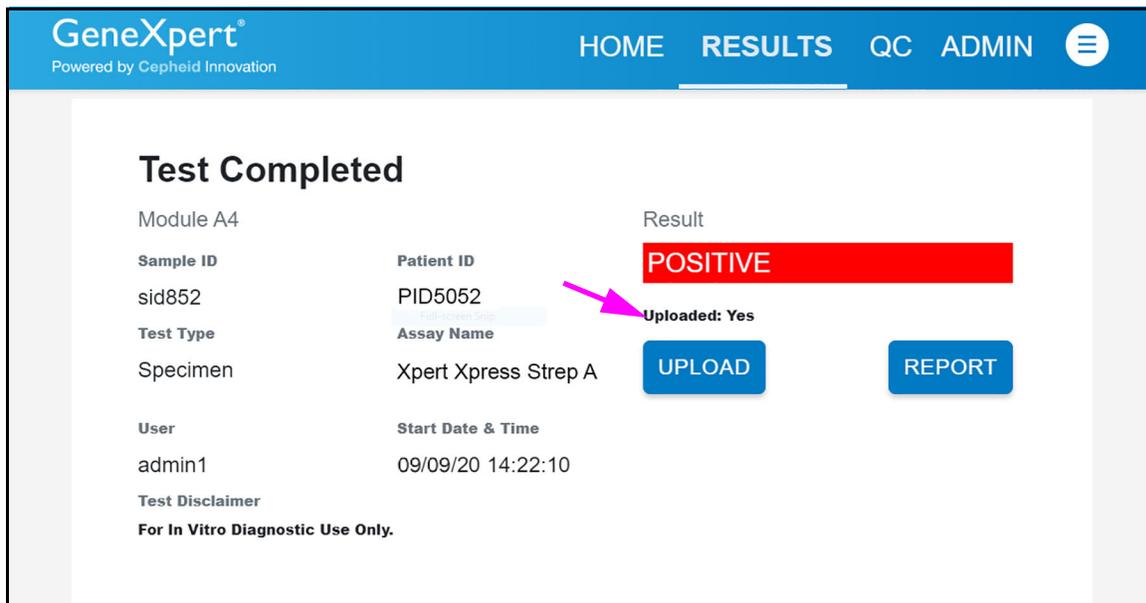


Figure 3-71. Test Upload Status shown on the Test Completed Screen

3.9.2.1 Manually Uploading a Test Result to the Host

If a test has not been automatically uploaded, it can be manually uploaded by touching **UPLOAD** on the Test Completed screen (see [Figure 3-72](#)). The individual test result will be uploaded to the host.

Note You can manually upload a test result even if **Automatic Result Upload** is enabled.

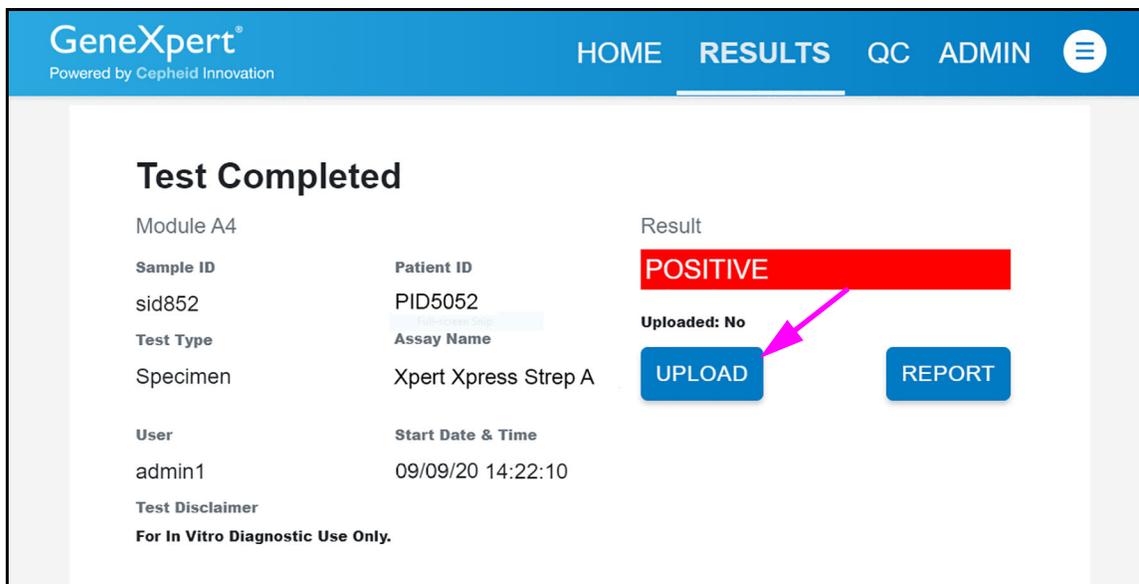


Figure 3-72. Touch UPLOAD to Upload the Test Result to the Host

The possible host upload statuses are:

- **Uploaded: No**—this result has not been uploaded.
- **Uploaded: Yes**—this result has been received by the host.

Note If an attempt to exit the software is made while results are uploading, the software will alert the user.

Note Each test can be uploaded individually from the Test Completed screen.

3.9.2.2 Uploading a QC Result to the Host

QC results can be automatically uploaded to the host, depending on the settings for **Automatic Result Upload**. In addition, a QC result can be manually uploaded, as described in [Section 3.9.2.1, Manually Uploading a Test Result to the Host](#).

Note If there are problems with host connectivity, see [Section 4.10.3, Host Communication Settings](#) and [Section 5.19.1, User Lockout Problems](#).

3.10 Error Handling

This section describes how to handle any errors that may occur when using the GeneXpert Xpress system. An example of an error that may occur is shown below.

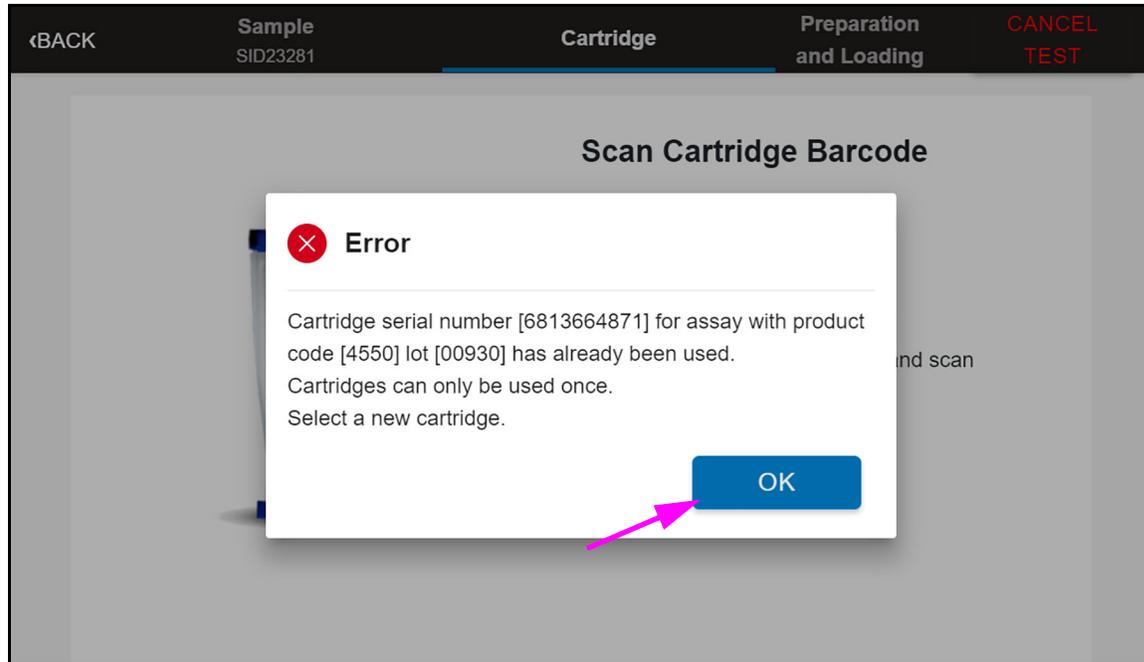


Figure 3-73. Cartridge Already Used Error Screen

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

For any error messages that may appear on-screen, follow the instructions on the screen.

3.11 The About and License Screens

This section describes the use of the **User Menu** of the GeneXpert Xpress software to display the About and License screens. The About and License screens allow you to display and read the software license information.

1. To access the About and License screens, you can be on the Home screen or any screen which has a blue banner at the top.
2. From the Home screen, touch the **User Menu icon** (see [Figure 3-74](#)). A drop-down menu will be displayed (see [Figure 3-75](#)).

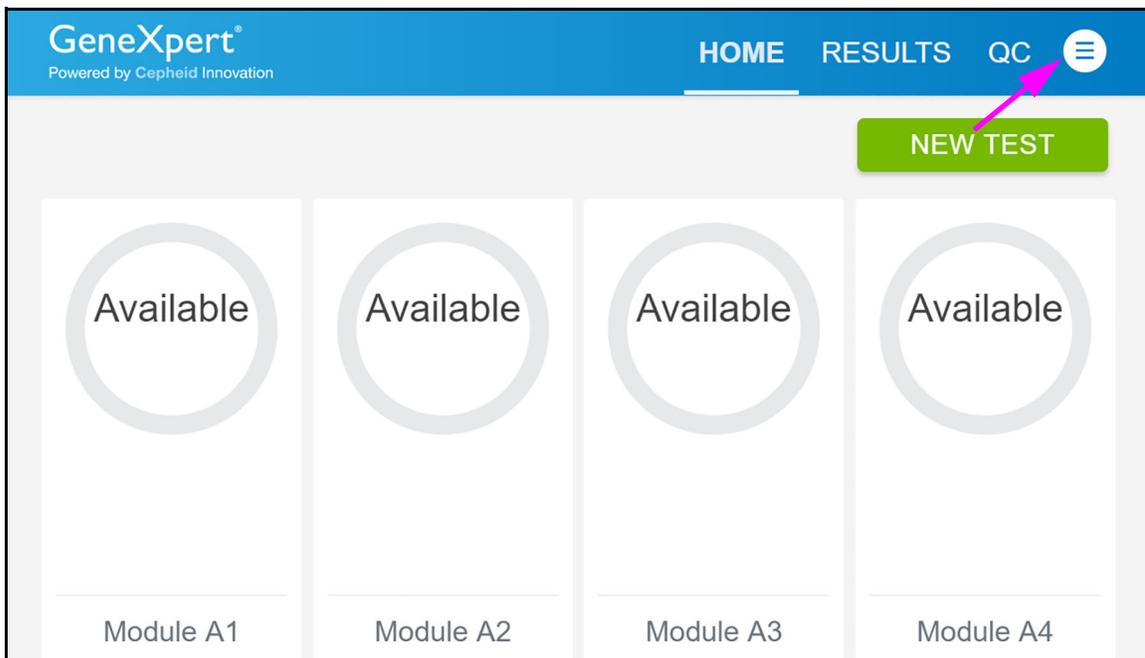


Figure 3-74. Home Screen

3. On the **User Menu**, touch the About menu item (see [Figure 3-75](#)).

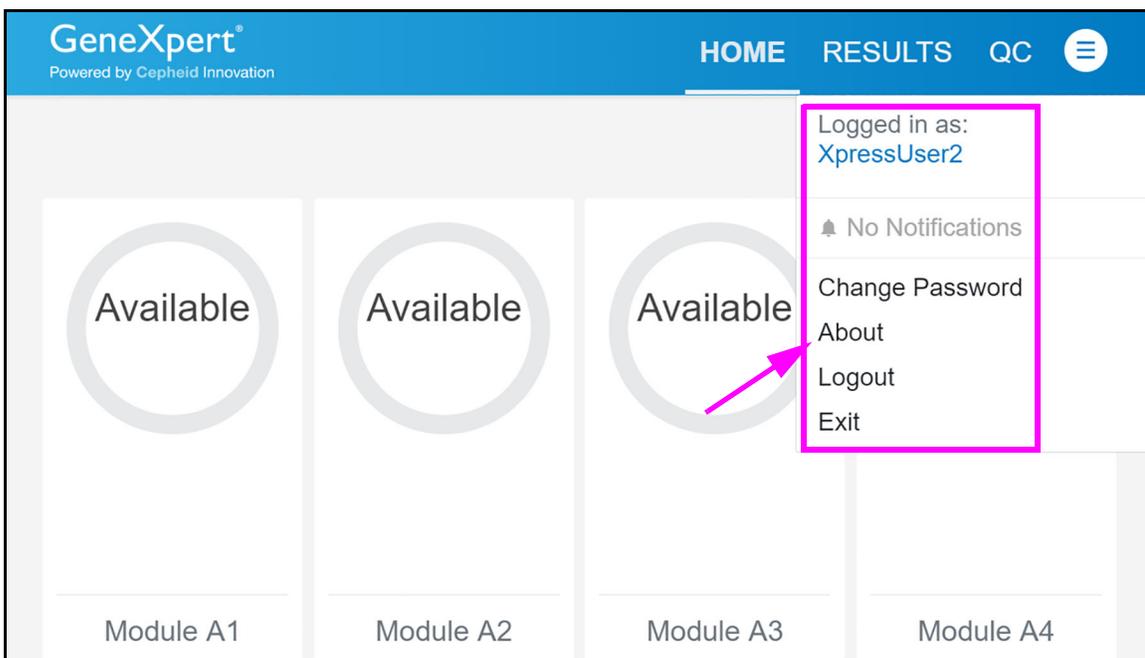


Figure 3-75. Home Screen, showing User Drop-Down Menu and About Selection

The About screen appears (see [Figure 3-76](#)), which shows the current software version, the POC serial number and Cepheid technical support contact information.

Each Xpress system will have its own unique POC serial number. The serial number may need to be entered into the Data Manager, to allow bi-directional communications.

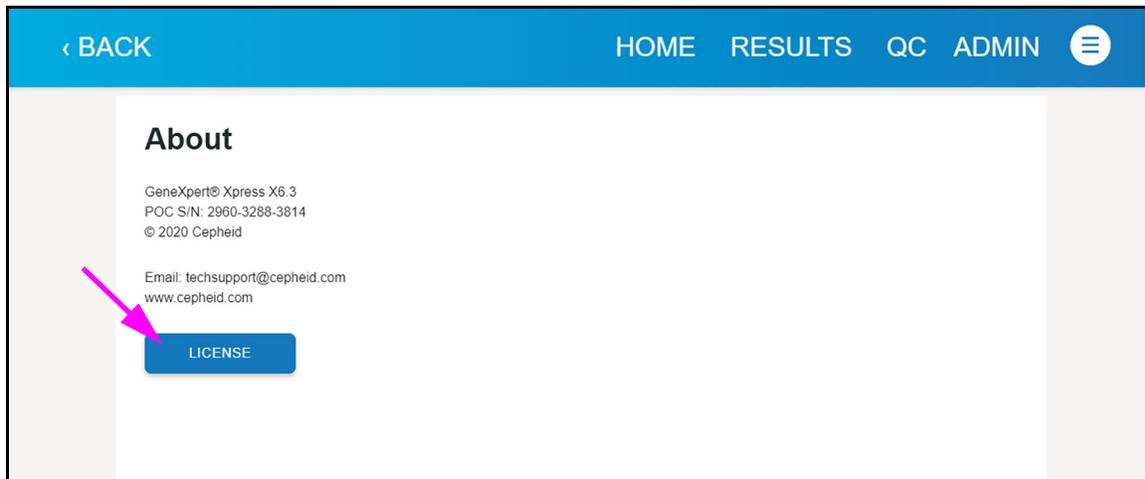


Figure 3-76. About Screen

4. On the About screen (see [Figure 3-76](#)), touch **LICENSE** to view the software license agreement. The License Information screen is displayed (see [Figure 3-77](#)).

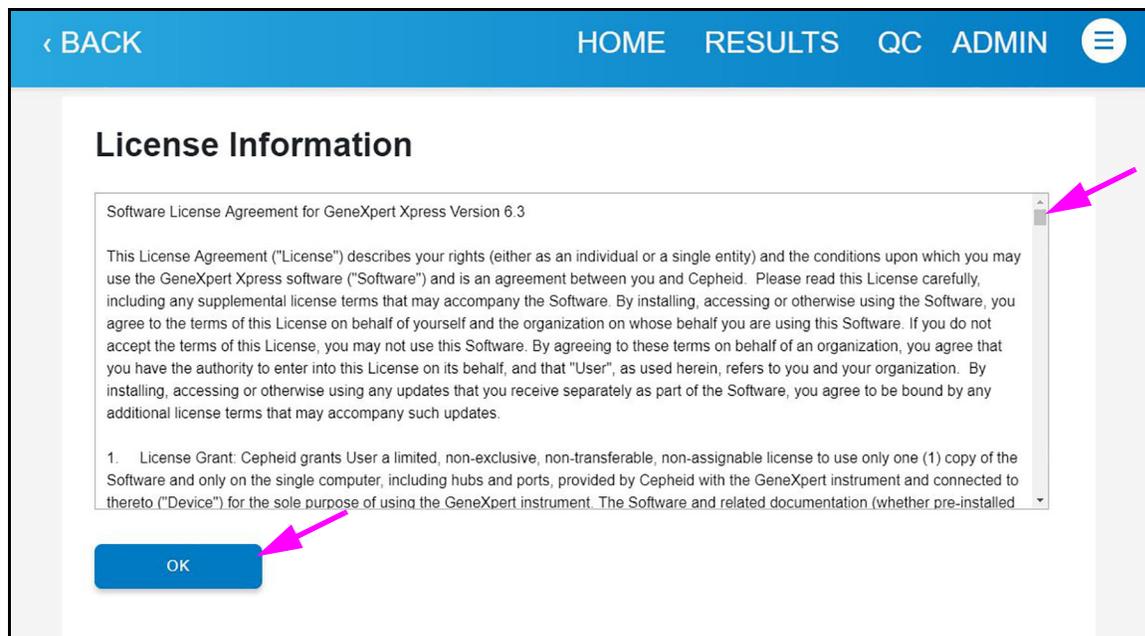


Figure 3-77. License Information Screen

5. On the License Information screen (see [Figure 3-77](#)), you can read the software license agreement for GeneXpert Xpress. Use the scroll bar on the right to scroll down to read the entire agreement.
6. To return to the About screen, touch the **OK** button.
To return to the Home screen, touch the **HOME** button at the top of the screen.

4 Administrative Tasks

This chapter explains how to run administrative tasks for the GeneXpert Xpress system. The topics are as follows:

- [Section 4.1, Powering Up the GeneXpert System](#)
- [Section 4.2, Starting the GeneXpert Xpress Software](#)
- [Section 4.3, Xpress Home Screen - Accessing Admin Functions](#)
- [Section 4.4, Administration Tasks](#)
 - [Section 4.4.1, Reports](#)
 - [Section 4.4.2, Instrument](#)
- [Section 4.5, Manage Users](#)
- [Section 4.6, Data Management Tasks](#)
 - [Section 4.6.1, Retrieving Tests](#)
 - [Section 4.6.2, Archiving Tests](#)
 - [Section 4.6.3, Retrieving Data from an Archive File](#)
 - [Section 4.6.4, Purging Tests from the Database](#)
 - [Section 4.6.5, Database Management](#)
 - [Section 4.6.5.1, Backing Up the Database](#)
 - [Section 4.6.5.2, Restoring the Database](#)
 - [Section 4.7, Managing Assays](#)
- [Section 4.8, System Configuration](#)
 - [Section 4.8.1, General Settings](#)
 - [Section 4.8.2, Folders](#)
 - [Section 4.8.3, QC Lockout Settings](#)
 - [Section 4.8.4, Archive Settings](#)
 - [Section 4.8.5, Configuring the Barcode Scanner](#)
- [Section 4.9, Setting the IP Address for Instrument Communication](#)
- [Section 4.10, Host \(LIS\) Management and Settings](#)
 - [Section 4.10.1, Managing Host Orders](#)
 - [Section 4.10.2, Host Test Code Settings](#)
 - [Section 4.10.3, Host Communication Settings](#)

- Section 4.11, Operating with Host (LIS) Connectivity (Admin Only)
 - Section 4.11.1, Creating a Test with Host Connectivity
 - Section 4.11.2, Uploading a Test Result to the Host

Note

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

4.1 Powering Up the GeneXpert System

This section describes how to log onto the Xpress 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** (I) position. After power has been turned on, the blue light on the front of the instrument will be **ON**.
2. Turn on the hub computer. The power switch is located on the back of the hub. Press the switch to the **ON** (I) position. After power has been turned on, the blue light on the right front panel of the hub will be **ON**.
3. Wait for the system to boot. The Windows Opening screen appears (see [Figure 4-1](#)). Swipe up anywhere on this screen, (as indicated by the dashed arrow) to display the login screen.



Figure 4-1. Windows Opening Screen

4. The Windows Login screen appears. See [Figure 4-2](#).

The GeneXpert Xpress computer is configured with two Windows accounts. The **Cepheid-Admin** account is for administrator tasks such as software updates, system configuration and normal operation; and the **Cepheid-Techsupport** account is for use only by Cepheid Technical Support See [Figure 4-2](#)).

Note

The system may come up initially in the **Cepheid-Techsupport** account configuration. If so, touch the **Cepheid-Admin** button at the bottom of the screen (see [Figure 4-2](#)).

Caution

You must log on using the preconfigured account. If you log on using a different user name and profile, the login will fail.

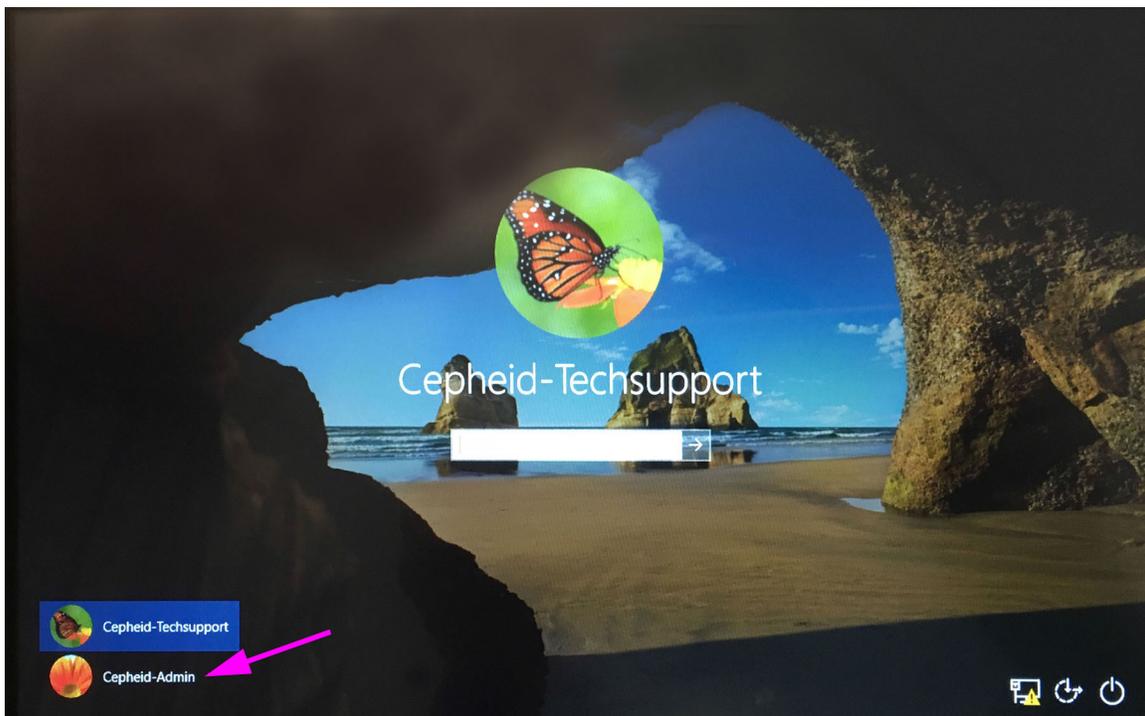


Figure 4-2. Windows Login Screen

5. On the Windows Login screen, touch the **Cepheid-Admin** icon in the lower left corner of the screen (see [Figure 4-2](#)).
6. The **Cepheid-Admin** login screen appears (see [Figure 4-3](#)).

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**

7. On the Cepheid-Admin login screen (see [Figure 4-2](#)), enter the password and touch the **arrow** to the right of 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, enter the assigned password for future logins (see [Figure 4-3](#)).

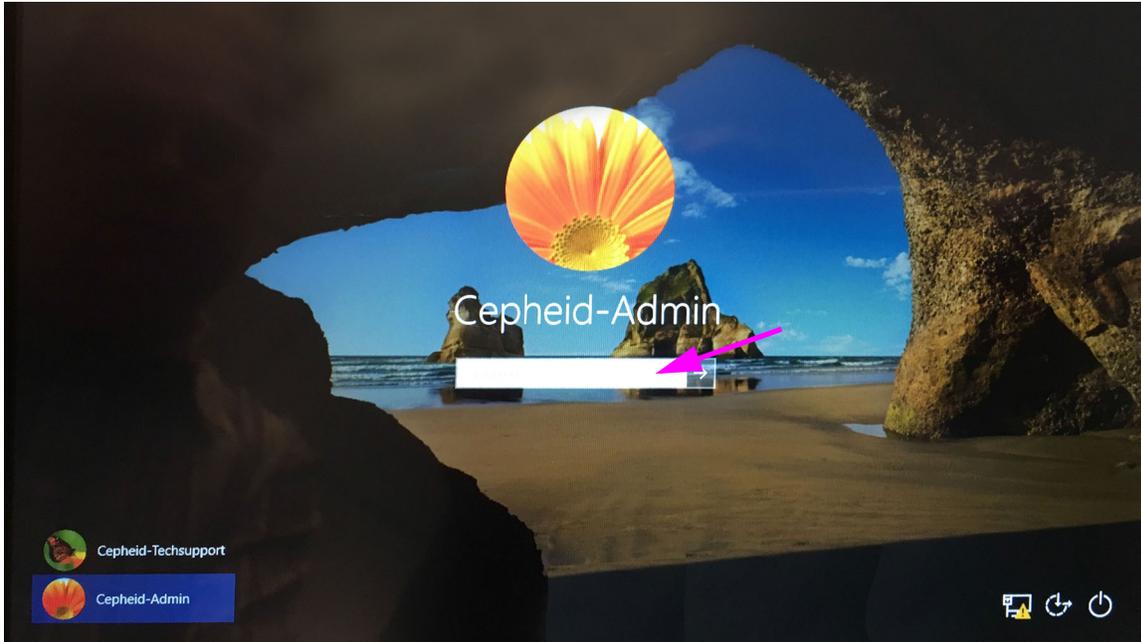


Figure 4-3. Cepheid-Admin Login Screen

8. Touch the login field, and the virtual keyboard appears (see [Figure 4-4](#)).

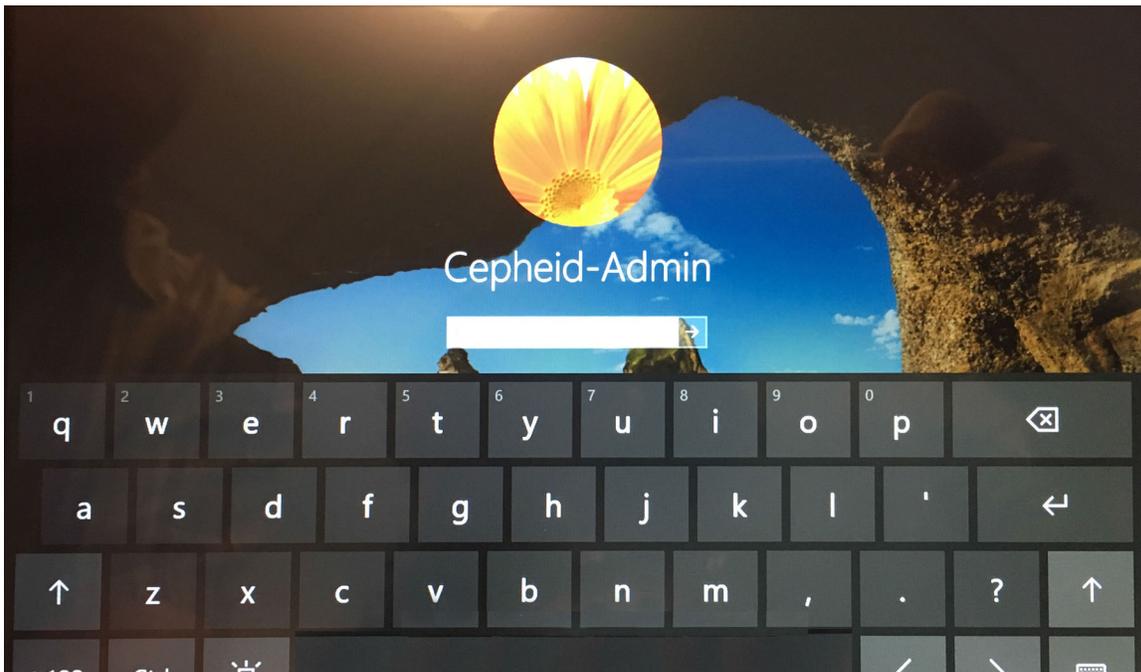


Figure 4-4. Cepheid-Admin Login Screen with Virtual Keyboard

Note

On the initial login to the Xpress system for the **Cepheid-Admin** account, after entering the **cphd** password, a prompt will be immediately displayed to change the password. Follow the on-screen instructions to change the password. Enter the old password (**cphd**) for the account then enter the new password two times. Remember to record and store the new password information in a safe location.

After the first login to the system, there will be no additional prompts to change the password.

Caution

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

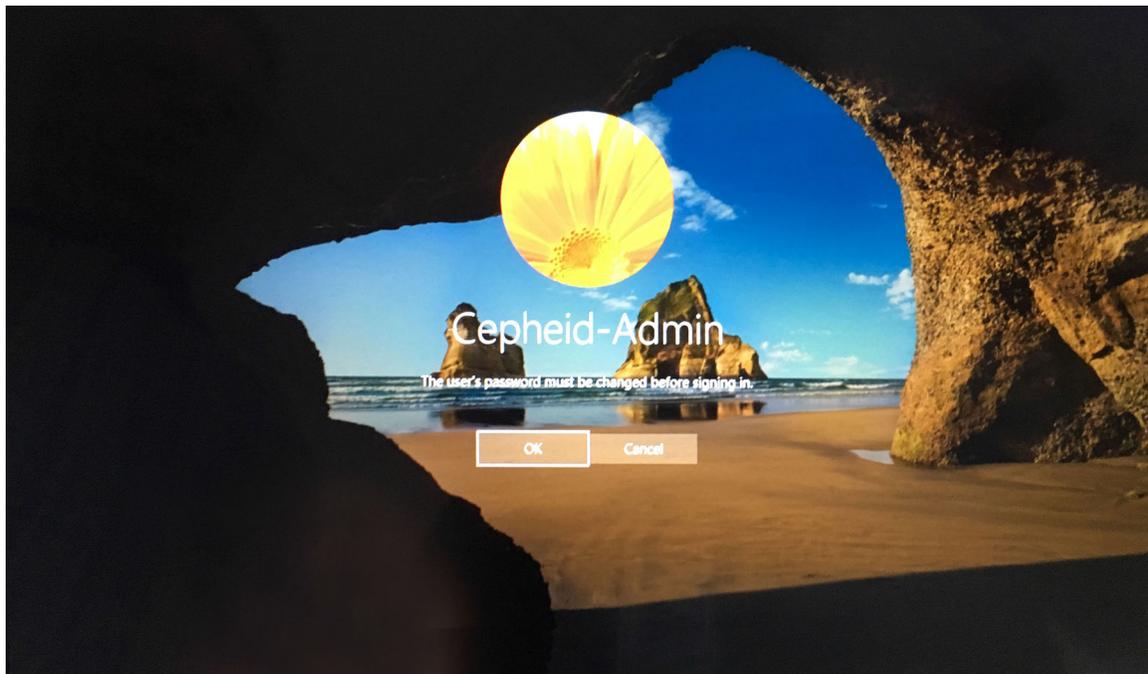


Figure 4-5. Change Password Screen

9. The Windows Password Dialog box is displayed (see [Figure 4-6](#)). In the first space provided, enter **cphd**, or if previously changed, your **old password**.

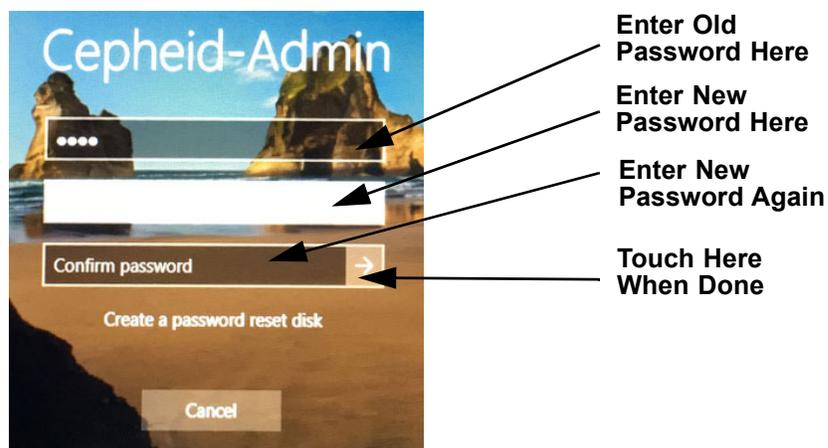


Figure 4-6. Windows Password Dialog Box

10. Enter your **new password** in the next box.
11. Enter your **new password** once more in the next box to confirm your entry.
12. Touch the **arrow** button at the right of the **Confirm password** field.

Note

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

13. A confirmation screen appears (see [Figure 4-7](#)).

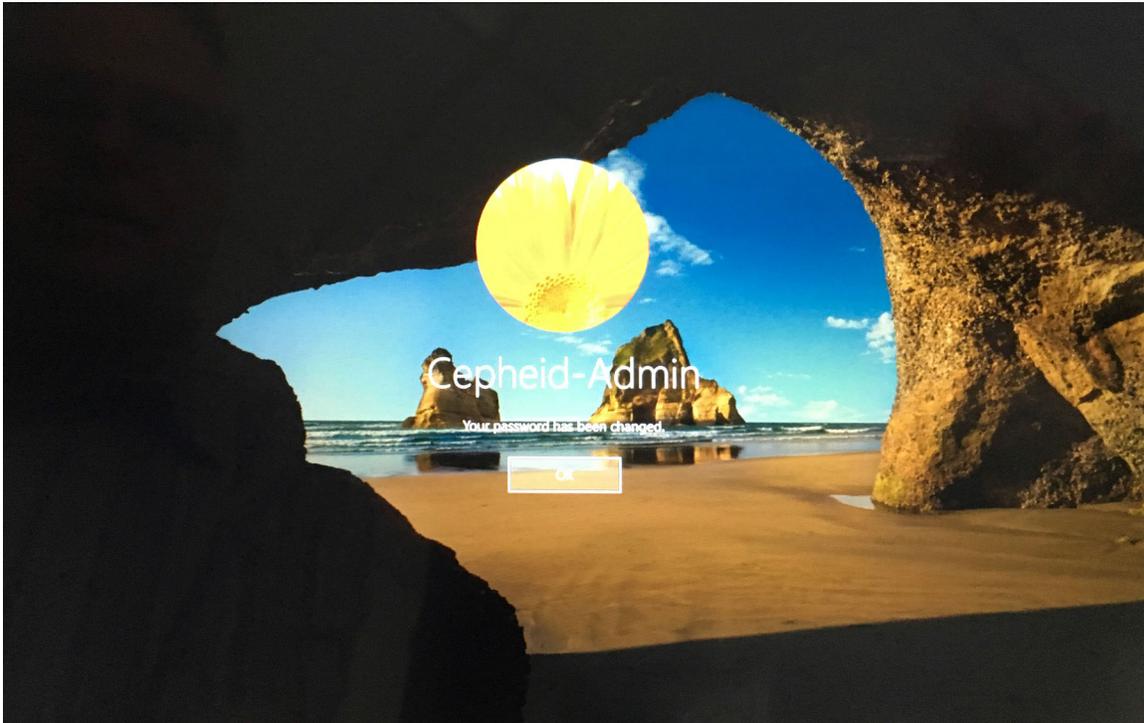


Figure 4-7. Password Confirmation Screen

14. Touch **OK** to complete the changing of password operation (see [Figure 4-7](#)).

The GeneXpert Xpress software launches.

15. The GeneXpert Xpress software starts automatically on system startup.

A GeneXpert Xpress icon on the Windows desktop allows for manual software initiation. See [Figure 4-8](#).



Figure 4-8. GeneXpert Xpress System Shortcut Icon

4.2 Starting the GeneXpert Xpress Software

1. After logging into Windows with administrator credentials, the Xpress software launches, with the display of the Xpress Login screen (see [Figure 4-9](#).)
2. Touch the **User Name** field, and the virtual keyboard appears.
3. Enter your User Name and Password in the provided fields, and then touch the **X** button at the far right of the keyboard. The keyboard disappears, and the **LOGIN** button is visible. Touch the **LOGIN** button to complete the login process.

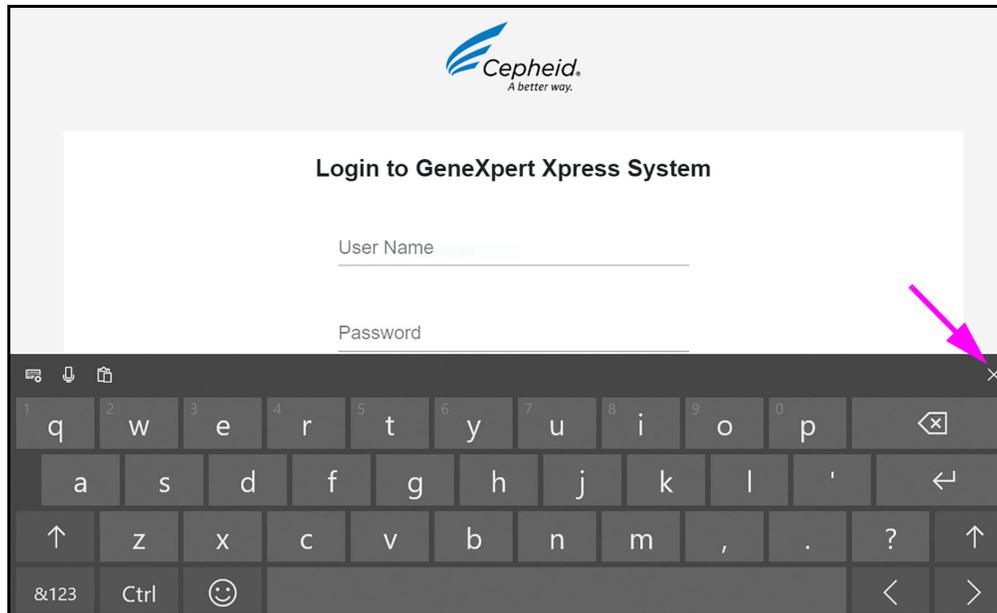


Figure 4-9. Login to GeneXpert System Screen

4. After login is complete, the Xpress Home screen appears (see [Figure 4-10](#)).

4.3 Xpress Home Screen - Accessing Admin Functions

When the Home screen appears, you will see the modules available (Module A1, Module A2, etc.) for running a test.

At the top of the screen, you can touch **RESULTS** (which displays any previous test results), **QC** (to run Quality Control tests) and **ADMIN** (to access Administration functions). This chapter's primary focus will be on the functions available to an administrator.

To access the main Administration screen, touch the **ADMIN** button on the Home screen (see [Figure 4-10](#)).

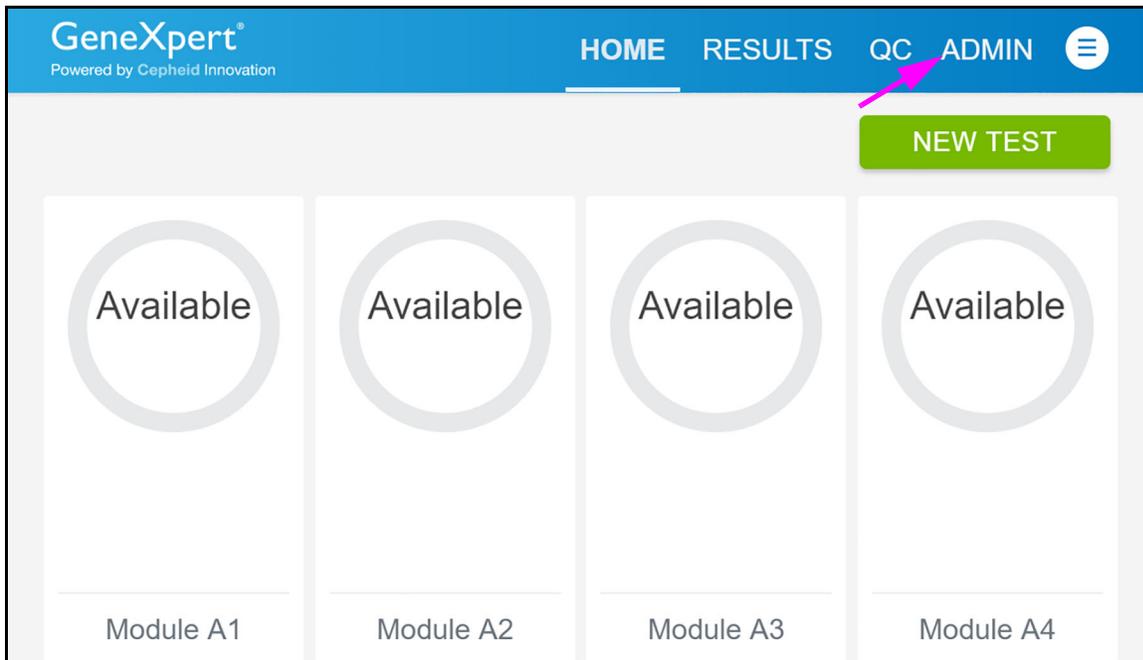


Figure 4-10. Xpress Home Screen

The Admin screen is displayed (see [Figure 4-11](#)). This screen shows a menu of the various functions available to an administrator.

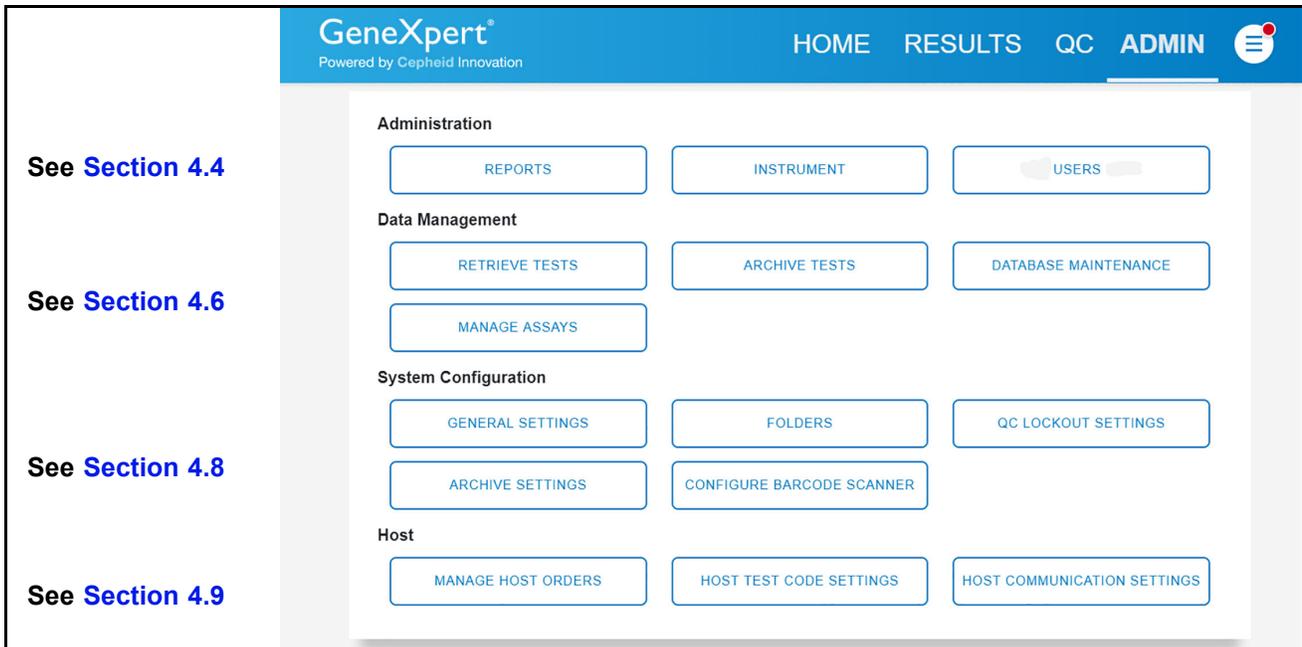


Figure 4-11. Admin Screen

4.4 Administration Tasks

Administration functions available to an administrator: Touch the **REPORTS** button to view the Reports menu (see [Figure 4-12](#)).

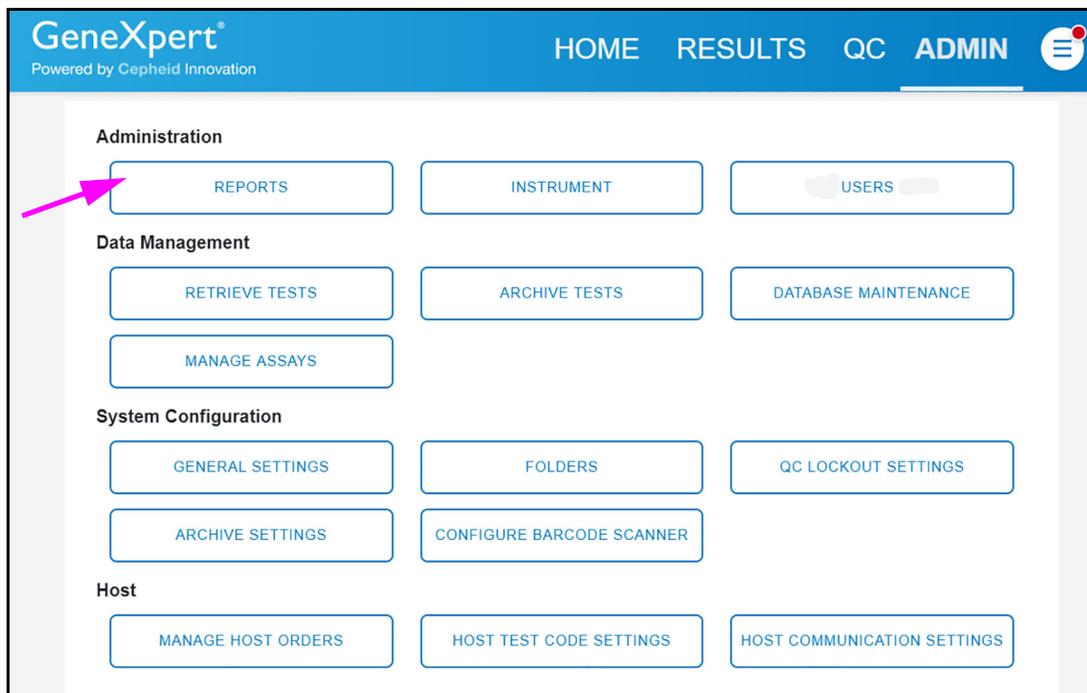


Figure 4-12. Reports Selected on the Administration Screen

4.4.1 Reports

When the Reports screen appears, the **SYSTEM LOG** and the **INSTALLATION QUALIFICATION** report buttons for the system are available (see [Figure 4-13](#)).

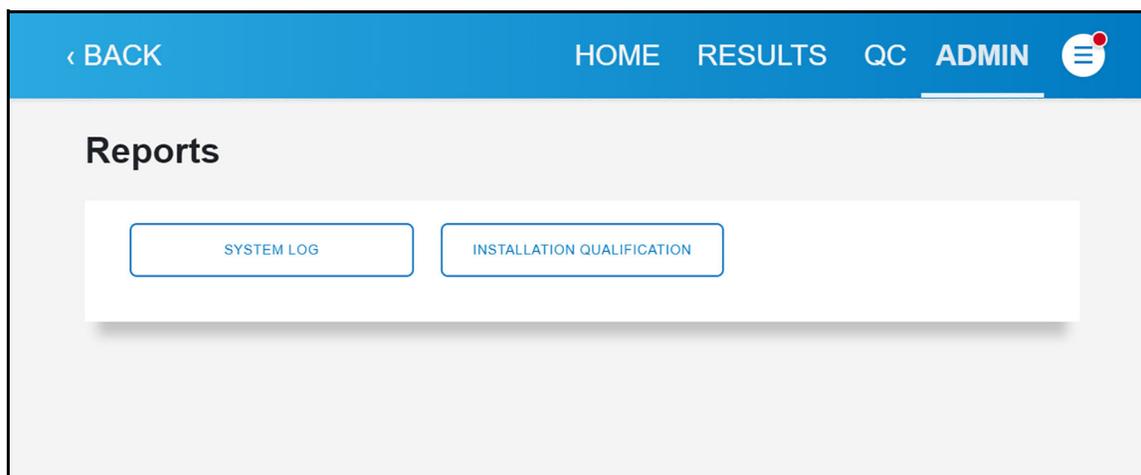


Figure 4-13. Reports Screen

4.4.1.1 System Log

On the Reports screen, touch the **SYSTEM LOG** button. The System Log screen appears (see [Figure 4-14](#)).

The report shows the installed modules in the instrument, and the report can be used to provide incidents of instrument module self-tests and error to Cepheid when a module failure has been encountered.

1. Specify the following criteria to view the trends of interest:
 - **Date Range:**
 - **All**—Select to include all of the records.
 - **Date Range**—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 the Instrument 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(s) to be included in the report 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.
 - **Select Individual Modules**—Touch each module check box individually that you wish to include.
 - **Deselect All**—Deselect every module by clearing all 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.

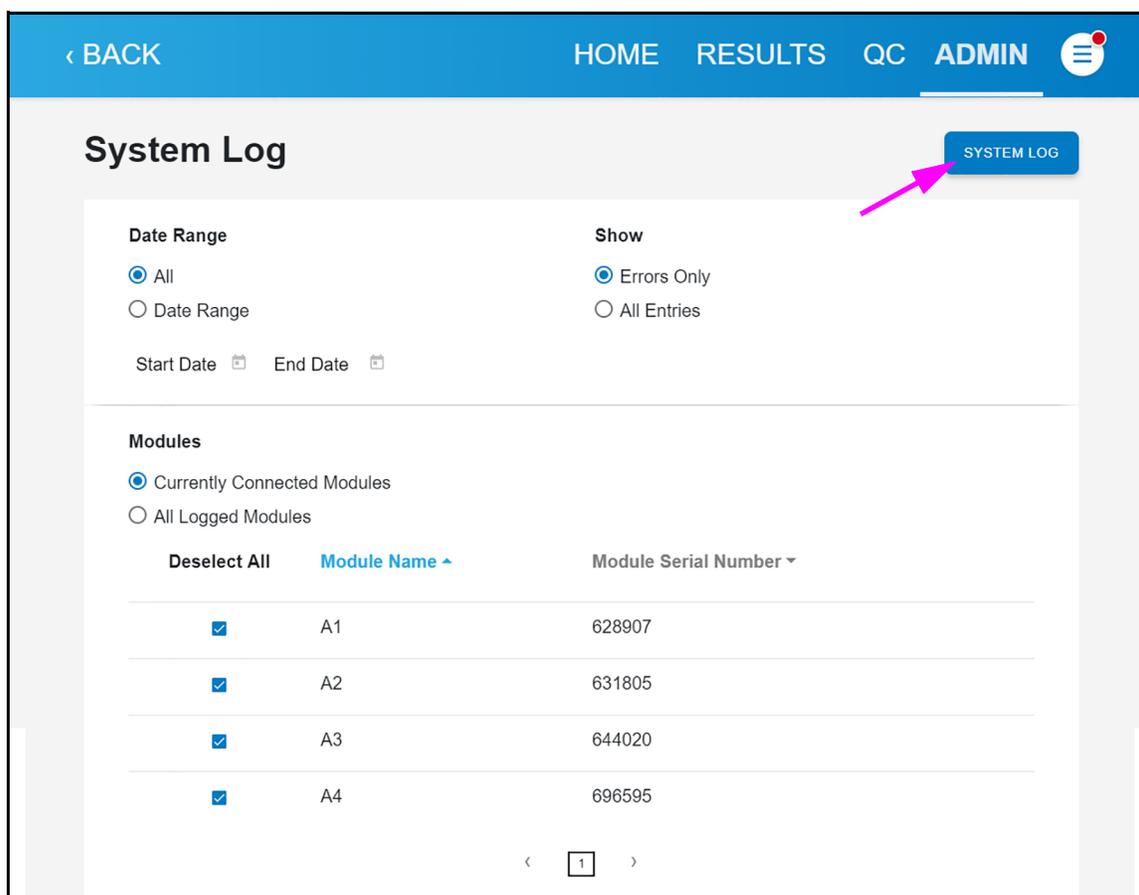


Figure 4-14. System Log Screen

2. To generate a report, touch the **SYSTEM LOG** button on the System Log screen (see [Figure 4-14](#)).
3. The System Log Report appears. From this screen, scroll down to view the entire report, or touch the **Print** icon at the top of the screen to create a .pdf file of the report (see [Figure 4-15](#)).

A dialog box will appear, which enables a file to be saved to a specified location.

GeneXpert Xpress 09/16/20 11:37:15

System Log Report

- Selection Criteria -
Date Range: All
Modules: Currently Connected Modules
Module A1,A2,A3,A4.
Show: Errors Only
User: <None>

Module Name	Instrument S/N	Module S/N
A1	810379	628907
<No Data Available>		

Module Name	Instrument S/N	Module S/N
A2	810379	631805
<No Data Available>		

Module Name	Instrument S/N	Module S/N
A3	810379	644020
<No Data Available>		

Module Name	Instrument S/N	Module S/N
A4	810379	696595
<No Data Available>		

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

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Figure 4-15. System Log Report

4.4.1.2 Installation Qualification Report

On the Reports screen, touch the **INSTALLATION QUALIFICATION** button and the Installation Qualification Report appears (see [Figure 4-16](#)).

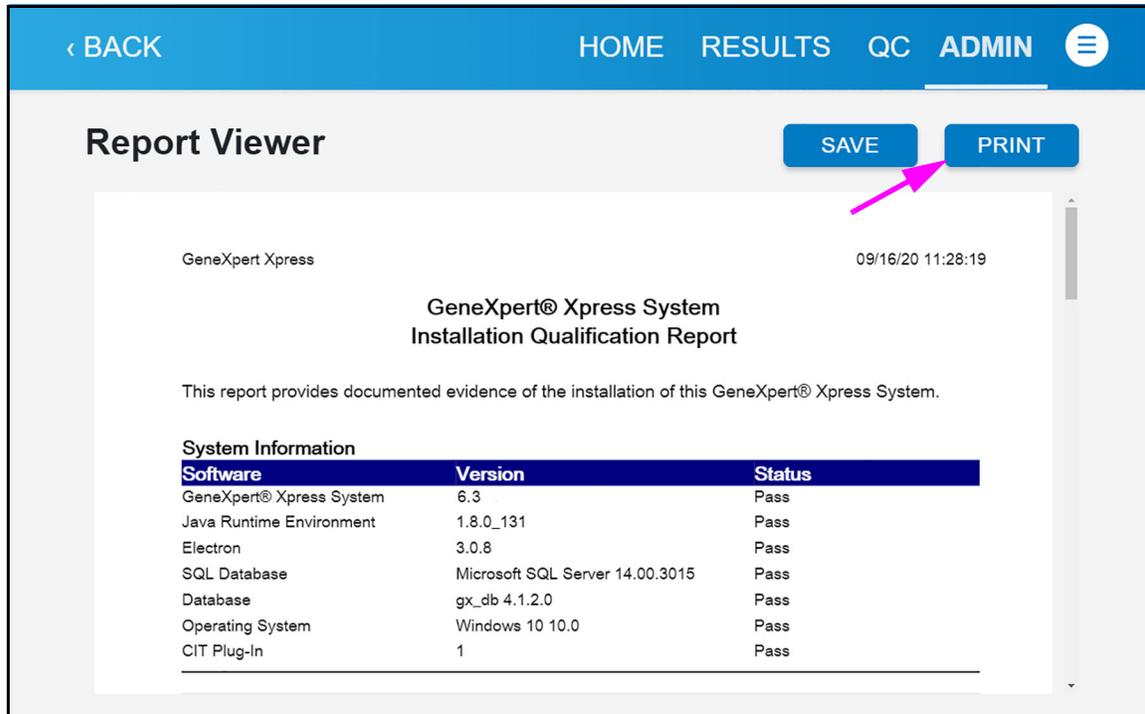


Figure 4-16. Installation Qualification Report - Initial, Partial View

Touch the **PRINT** icon on this report screen to send a copy to the printer or to create a .pdf version of the file (see [Figure 4-17](#) and [Figure 4-18](#)), or touch **SAVE** to save a copy.

POC S/N

The Installation Qualification Report also shows the POC S/N ([Figure 4-17](#)). This POC S/N (Point-of-Care Serial Number) is the unique identifier of your GeneXpert Xpress system, and is used by the POCC to communicate with your Xpress system when it is connected to a Data Manager.

GeneXpert Xpress
09/16/20 11:30:52

GeneXpert® Xpress System Installation Qualification Report

This report provides documented evidence of the installation of this GeneXpert® Xpress System.

System Information

Software	Version	Status
GeneXpert® Xpress System	X6.3	Pass
Java Runtime Environment	1.8.0_131	Pass
Electron	3.0.8	Pass
SQL Database	Microsoft SQL Server 14.00.3015	Pass
Database	gx_db 4.1.2.0	Pass
Operating System	Windows 10 10.0	Pass
CIT Plug-In	1	Pass

PCC S/N
5721-7446-3461

Instrument Information

Instrument A

Instrument S/N	Gateway Firmware
810379	2.0.18

Module Name	Module S/N	Module Firmware	Internal Temp °C	Status
A1	628907	3.3.4	30.98	Pass
A2	631805	3.3.4	31.35	Pass
A3	644020	3.3.4	28.75	Pass
A4	696595	3.3.4	27.82	Pass

Available Assays

Assay Name	Version	Assay Type
Xpert Xpress Flu	1	In Vitro Diagnostic
Xpert Xpress Flu-RSV	1	In Vitro Diagnostic
Xpert Xpress Strep A	1	In Vitro Diagnostic

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Figure 4-17. Installation Qualification Report - Page 1 of 2

GeneXpert Xpress

09/16/20 11:30:52

GeneXpert® Xpress System Installation Qualification Report

Installation of networked instruments complies with the setup requirements specified in the GeneXpert® Xpress System Operator Manual, 'Installation' section.

Verified by	Date
-------------	------

This IQ is acceptable if all System Information and Instrument Information are listed as 'Pass'. All instrument modules that are listed as 'Pass' are available for use.

Acceptance: Acceptable Not Acceptable

Performed by	Date
--------------	------

Reviewed and approved by	Date
--------------------------	------

Figure 4-18. Installation Qualification Report - Page 2 of 2

4.4.2 Instrument

Touch the **INSTRUMENT** button to view the Instrument screen (see [Figure 4-19](#)).

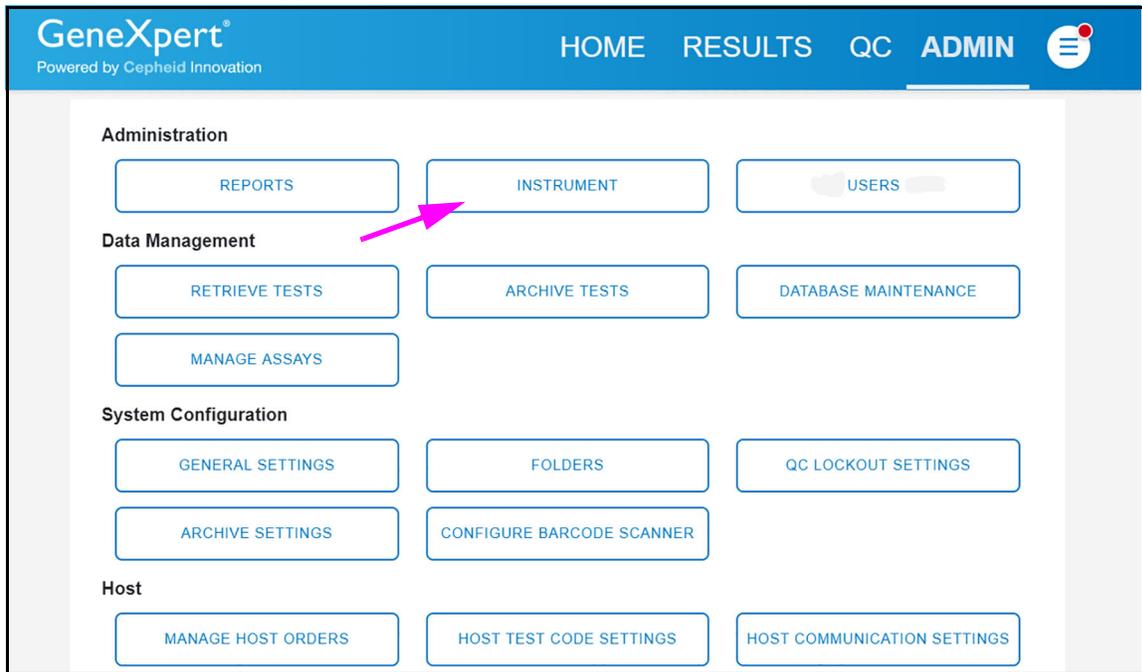


Figure 4-19. Instrument Selected on the Administration Screen

The Instrument screen shows the available modules. Additional buttons on this screen allow the exclusion of modules from test or for plunger rod maintenance (see [Chapter 5](#) for detailed maintenance descriptions).

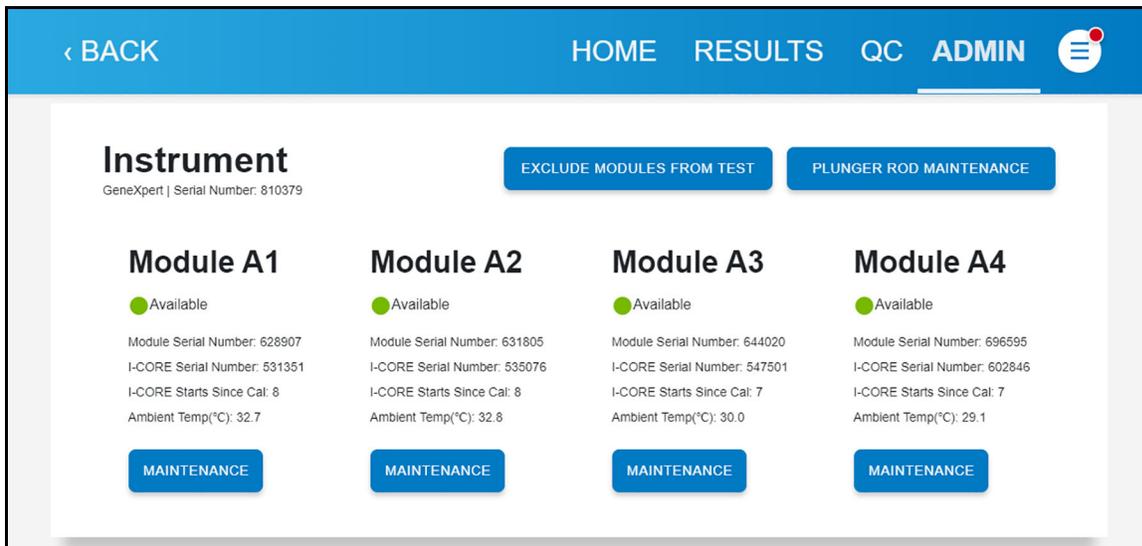


Figure 4-20. Instrument Screen

4.5 Manage Users

This section describes user roles, functions, requirements and how to view user list and how to add or change users on the system.

4.5.1 User Functions by Roles

The following table lists the functions that different user roles can perform.

Table 4-1. User Functions by Roles

User Role	Run Test	View Results	Perform Maintenance	Perform Administrative and System Functions
Xpress User	Yes	Yes	Limited	No
Administrator	Yes	Yes	Yes	Yes

4.5.2 User Name Requirements

When a new user is created, either locally or through a Data Manager, the User Name and Password must meet certain requirements.

If a user name does not meet the requirements shown in this section, the Xpress system will reject that particular User and they will not be included on the Xpress User List. All other validated users will be included on the Xpress User List. The Data Manager may sometimes refer to a User as an Operator.

- **User Name:** A user name is required. A user name should have a minimum of 6 characters and a maximum of 128 characters. The User name cannot contain spaces, and cannot contain any of the following characters: | : * " < > / \ ?
- **User Password:** A user password is required, and cannot contain spaces
- **User Expiration Date:** This date usually refers to the end of a one-year period after user certification was granted. User's expiration date should not be empty when the user is being managed by a Data management system.

Note

If users are managed locally (not through a Data Manager), a user expiration date is not required.

- **User Permission Level:** A user permission level should be entered as either 1 or 4
 - **Permission level 1:** is an Administrator User
 - **Permission level 4:** is an Xpress User
- **Name Duplication:** The User name should not be duplicated

Note

The User ID and Institutional ID will be the same when receiving from a data manager. A data manager sometimes refers to users as operators. When the operator information is received from a data manager, the user ID and the institutional ID will be the same when logging onto the Xpress system.

4.5.3 Viewing the User List

Prior to viewing the User List, if the user is list-managed by a sata manager, the list must be selected to be downloaded, using the settings on the Host Communication Settings screen. Use the steps in this section to set up that download.

1. Touch **ADMIN** from any user screen and the Administrator screen appears (see [Figure 4-21](#)).

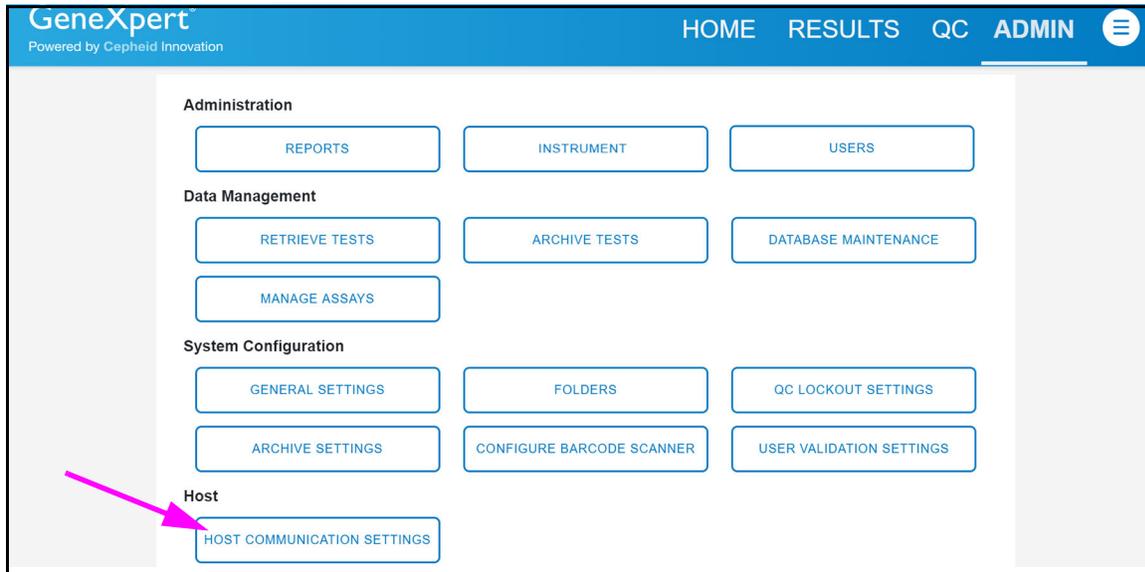


Figure 4-21. Administration Screen

2. Touch the **HOST COMMUNICATION SETTINGS** button and the Host Communications screen appears (see [Figure 4-22](#)).

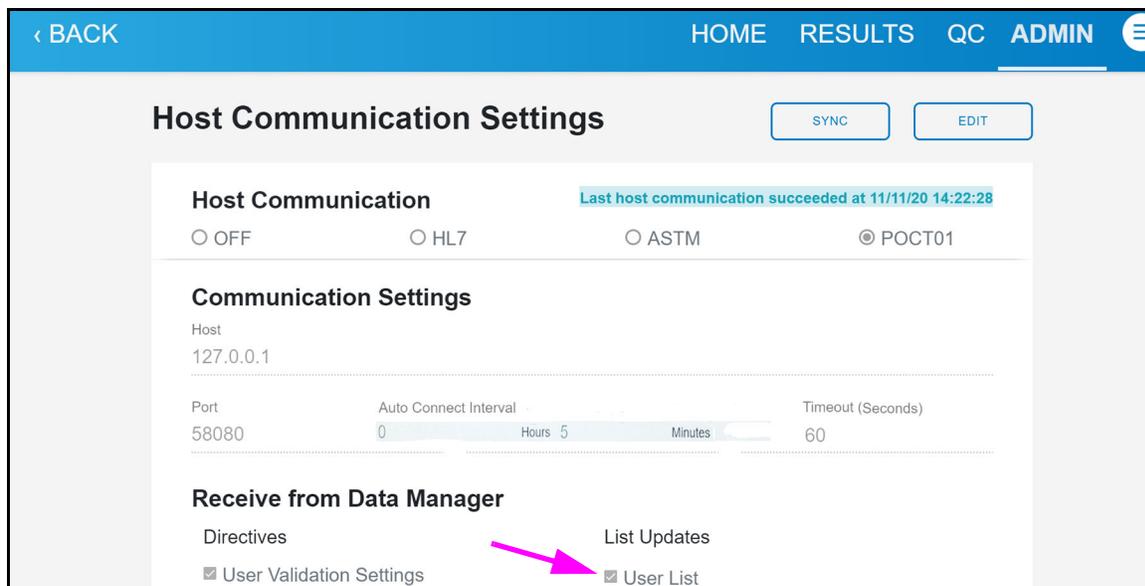


Figure 4-22. Host Communication Settings Screen

- At the bottom of this screen, touch the **User List** check box, under the **Receive from Data Manager** section. Checking this box will tell the Data Manager to include the User List when it performs the next download.

When the Xpress system is connected to a Data Manager, the user list cannot be managed on the local Xpress system. All user information must be added to the Data Manager by the system administrator, and the user list will then be automatically downloaded to the Xpress system.

Note

If the system was previously not configured to receive User list updates (the User List box was not checked) but then is later changed to receive user list updates, the existing user list will be overwritten by the new user list when it is sent from the data manager.

Note

Cepheid has tested that 6,000 users can be received from the data manager, but it could receive more. If more are sent there may be performance issues.

Note

When receiving a user list from a data manager, the system will receive only validated users that have been entered into the data manager. Refer to [Section 4.5.2](#) for the user information requirements that must be added to the data manager in order for the Xpress system to receive the user information from the data manager.

Note

If a user name does not appear on the User List, but has been added to the data manager, please see [Section 5.19.3](#), the POCT troubleshooting section.

- Return to the Administration screen (see [Figure 4-23](#)). Touch the **USERS** button. The Users screen appears (see [Figure 4-24](#)).

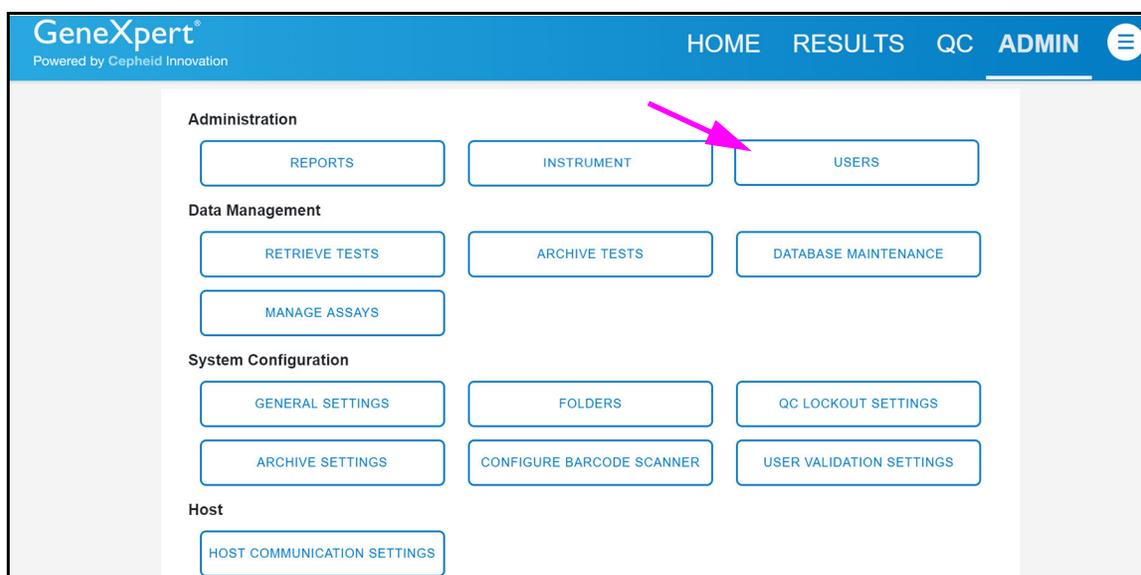


Figure 4-23. Administrator Screen, showing the USERS Button

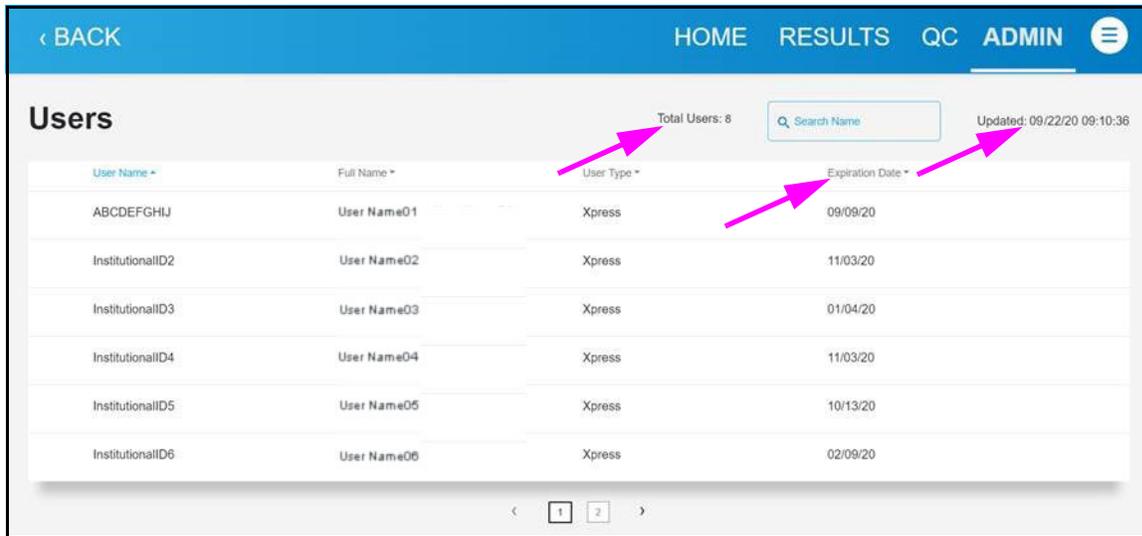


Figure 4-24. Users Screen, showing the List of Active Users

- The Users Screen (see [Figure 4-24](#)) displays **User Name**, **Full Name**, **User Type** and **Expiration Date**. If any user information needs to be updated it must be done on the data manager.

The Expiration date will be set on the data manager and received and stored on the Xpress system. For more information about the User expiration date, see [Section 4.5.5.2](#).

The User screen displays the number of **Total Users** that were received by the data manager and stored on the Xpress system

The User screen shows the date and time the user list was last updated by the data manager.

Note Each User List update event will update all user information. If the user expiration date is changed by the system administrator to a different date, then that new date will also be displayed when the user list is next accessed.

Note When the data manager sends an updated user list to the Xpress system, all information will be updated. If the user is removed from the user list on the data manager then the user will be removed from the user list on the Xpress system.

4.5.4 Adding and Removing Users

This section describes how to add and remove users in the system, either locally or through a data management system.

4.5.4.1 Locally

This section describes how to add users on the system locally, without host (POCT) communication.

Note

When users are managed using a Data Management system, they cannot be managed locally on the system. To manage users remotely, see [Section 4.5.5, Users in a Data Management System](#).

Important

When users are added locally and the system is later connected to a Data Management (DM) system, those local users will be removed when the user list is updated. It will be necessary to have the system administrator add those users again, using the DM.
If a user is added to a DM system and the Xpress system is later disconnected from the DM, the user list that is then viewed locally will be the last list that was downloaded from the DM.

Using the Administrator screen, touch the **USERS** button (see [Figure 4-25](#)).

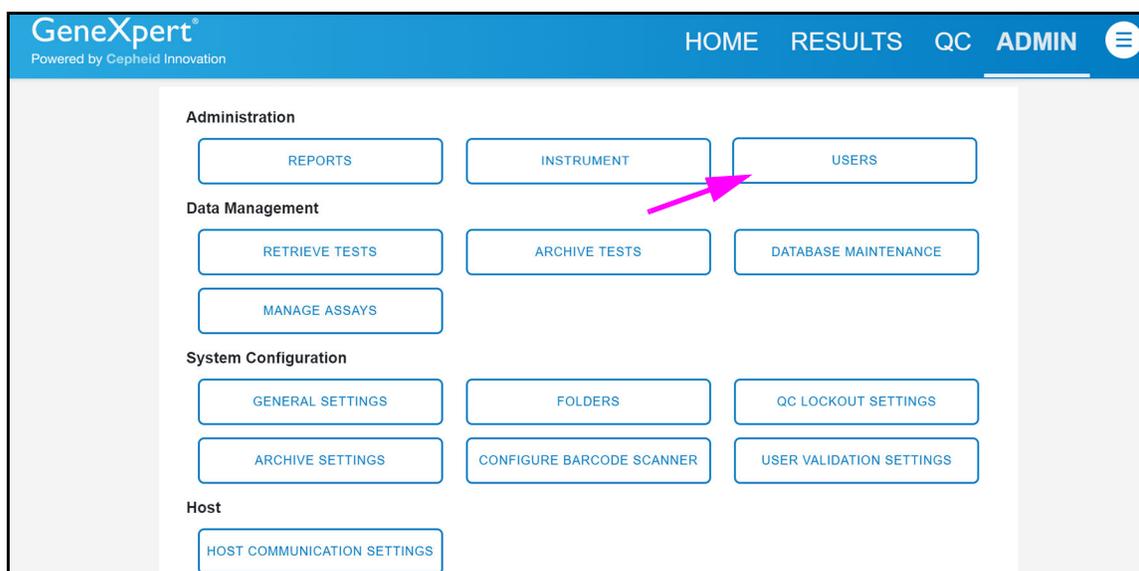


Figure 4-25. USERS Selected on the Administration Screen

- The Users screen appears (see [Figure 4-26](#)). Touch the **ADD USER** button.

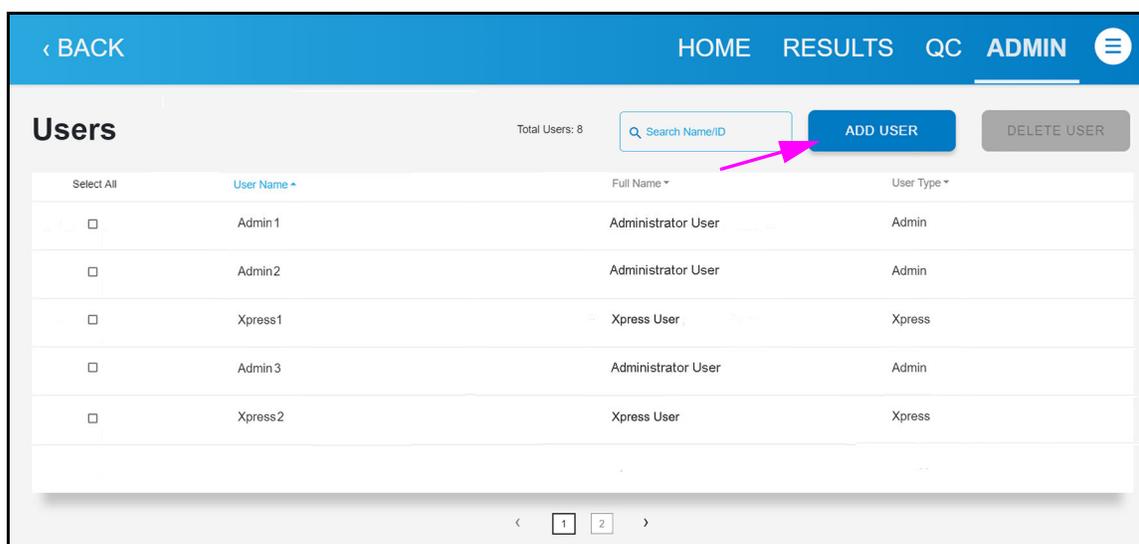


Figure 4-26. Users Screen

7. The Add User screen appears (see [Figure 4-27](#)). On this screen, enter the full name of the user to be added, as well as their password. Re-enter the password as confirmation. Ensure the user name conforms to the requirements stated in [Section 4.5.2](#).
8. Enter the User type (Admin or Xpress) from the drop-down menu at the bottom right of the screen (see [Figure 4-27](#)).

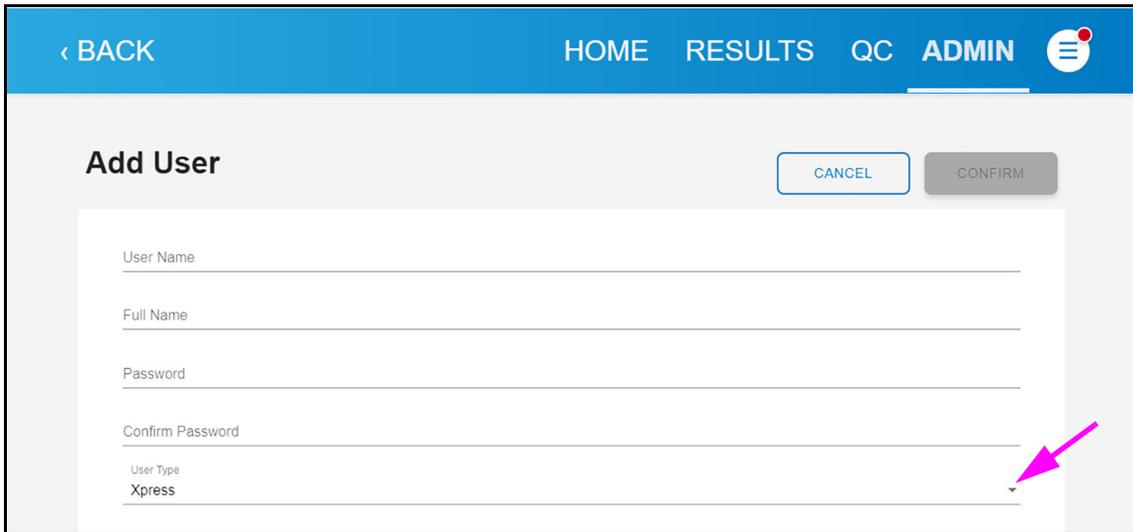


Figure 4-27. Add User Screen

9. When all user information on this screen has been entered, touch the **CONFIRM** button (see [Figure 4-28](#)).

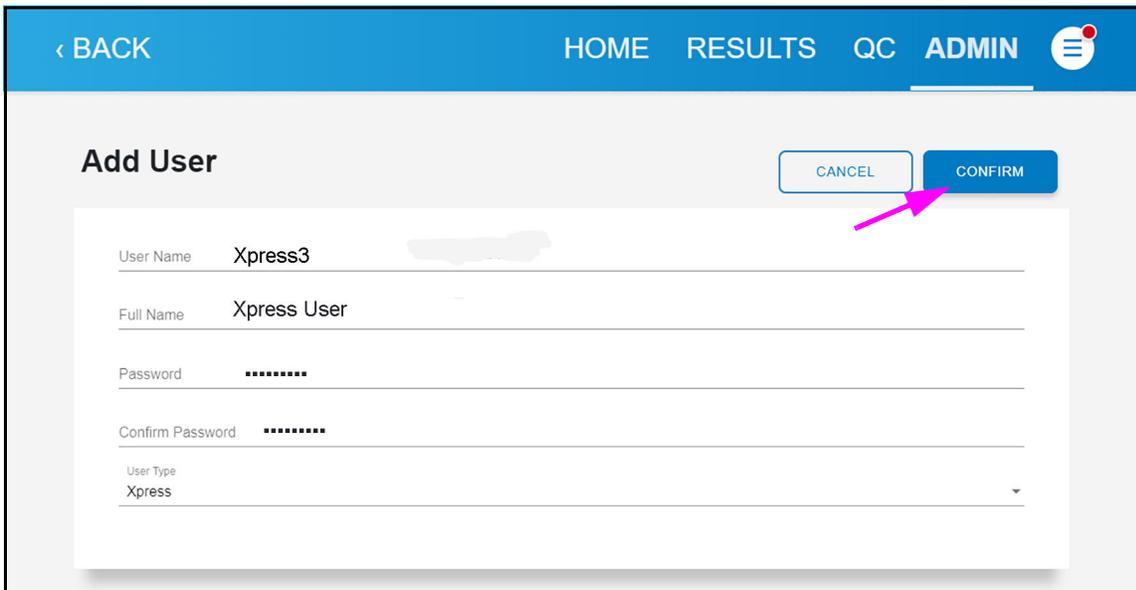


Figure 4-28. Add User Screen - Confirmation

10. Return to the Users screen. The added user now appears on screen (see [Figure 4-28](#)).

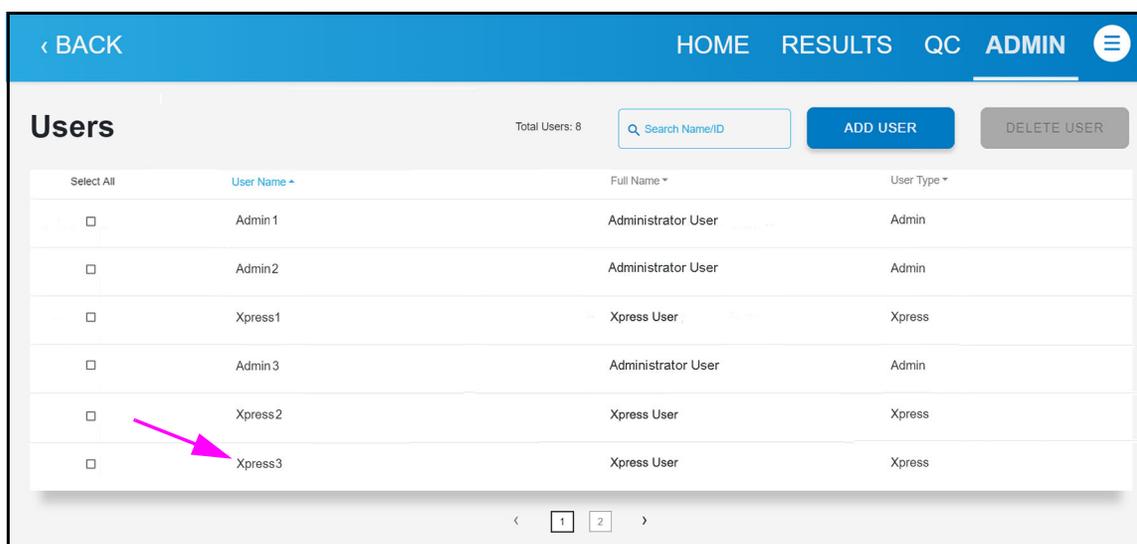


Figure 4-29. Users Screen, showing Added User

This completes the addition of a new user.

4.5.5 Users in a Data Management System

This Section will explain the behavior when the system is configured to receive User Lists from a Data Manager.

When using a data management system, all user additions and changes are done by the system administrator, remotely, using the Data Manager. Users cannot be added or changed locally.

Note If users are managed locally on the system (without POCT communication), see [Section 4.5.4](#).

Important When users are added locally and the system is later connected to a Data Management (DM) system, those local users will be removed when the user list is updated. It will be necessary to have the system administrator add those users again, using the DM. If a user is added to a DM system and the Xpress system is later disconnected from the DM, the user list that then appears locally will be the last list that was downloaded from the DM.

See [Table 4-1](#) for a description of User Types and permissions for GeneXpert Xpress.

4.5.5.1 User Validation Management through a Data Manager

This section tells how to select and view User Validation Settings from a Data Manager. User Validation Settings allow a data manager to manage user's expiration dates, and the behavior the system uses when expired users are encountered, such as allowing an expired user to log on, warning an expired user, or locking out an expired user.

1. From any screen, touch **ADMIN** to access the Administrator screen. When the screen appears, touch **HOST COMMUNICATION SETTINGS** (see [Figure 4-30](#)). The Host Communication Settings screen appears (see [Figure 4-33](#)).

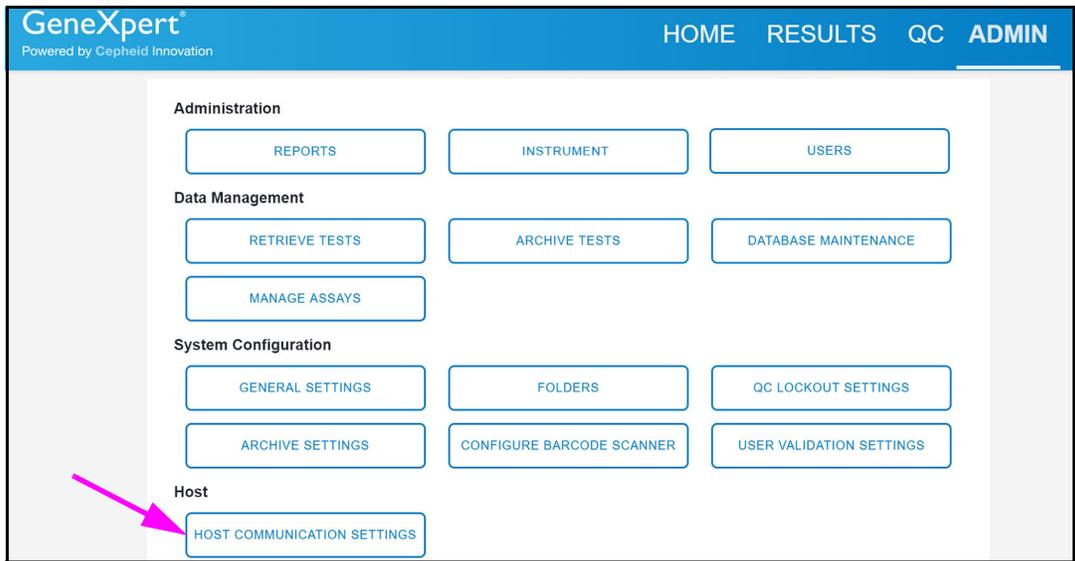


Figure 4-30. Admin Screen, Showing the HOST COMMUNICATION SETTINGS Button

2. To allow a system to receive User Validation Settings from a data manager, touch the **User Validation Settings** check box at the bottom of the screen (see [Figure 4-31](#)). When this box is checked the Xpress system will receive and store User Validation Settings from the data manager.

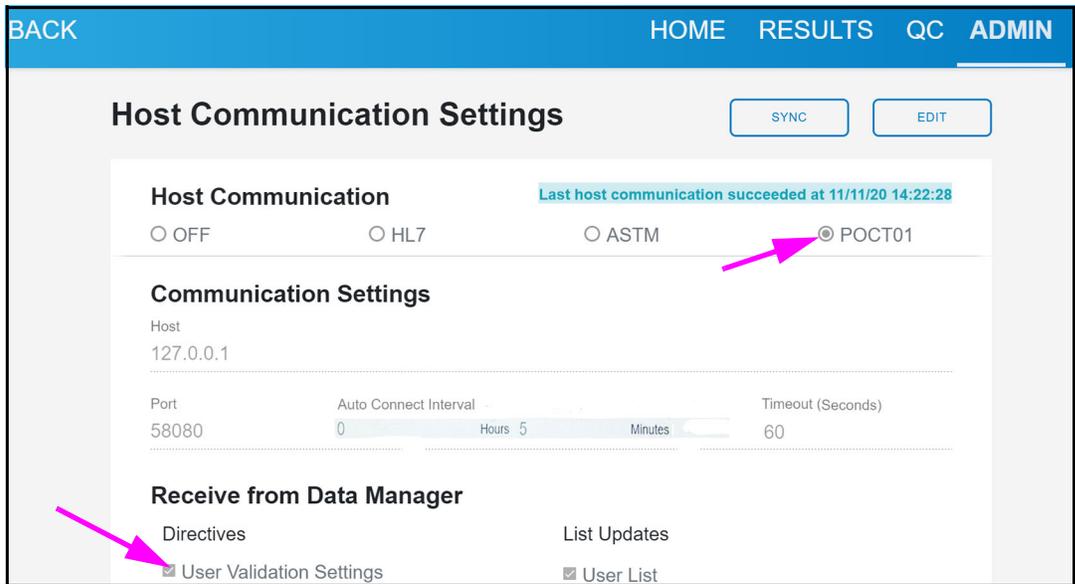


Figure 4-31. Host Communication Settings Screen

Note

When POCT01 is selected on the Host Communication screen (see [Figure 4-31](#)), the User Validation settings button will appear on the Administrator Screen.

3. From any screen, touch **ADMIN** to access the Administrator screen.
4. On the Administrator screen, touch **USER VALIDATION SETTINGS** (see [Figure 4-32](#)). The User Validation Settings screen appears (see [Figure 4-33](#)), showing the active option selected. See [Section 4.5.5.2](#) for a definition of the three options available.

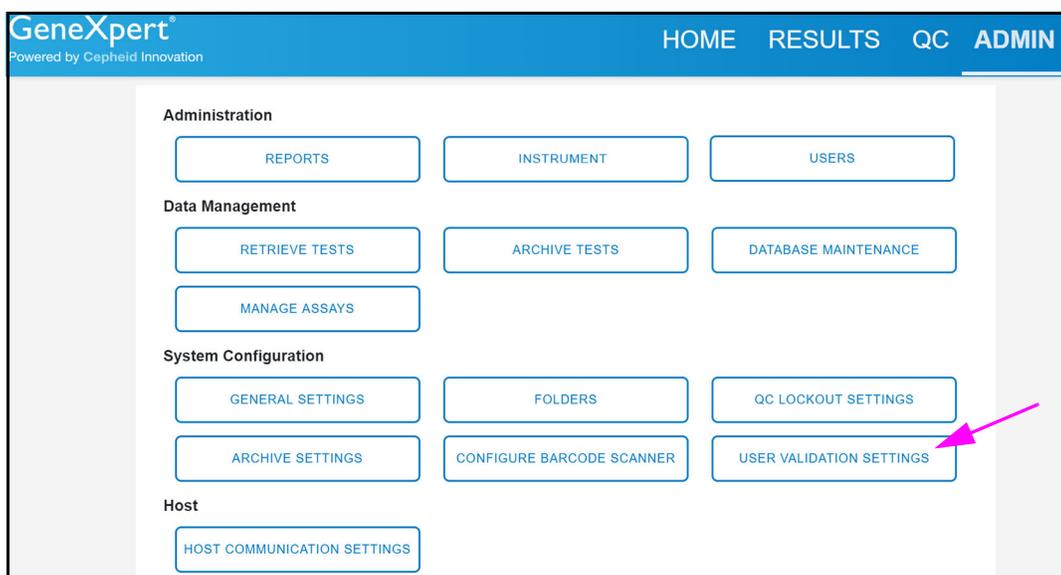


Figure 4-32. Admin Screen, showing the USER VALIDATION SETTINGS Button

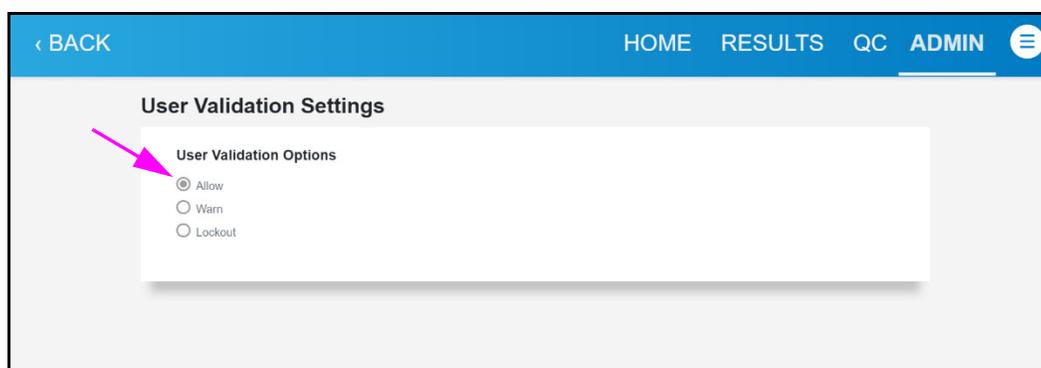


Figure 4-33. User Validation Settings Screen

Note

The **User Validation Options** on the User Validation Settings screen can only be edited on the Data Manager. Locally, the Administrator can only view (not change) the User Validation Options that were sent from the Data Manager to the Xpress system.

4.5.5.2 User Validation Options - Descriptions

User Validation Options information gets pushed down to the Xpress system from the Data Manager, and this information manages the login access of the users. User login access is determined by their individual expiration dates, which is usually based on a user's credential status.

The three **User Validation Options** are:

- **Allow:** If the User Validation setting is set to **Allow**, anyone on the User List that was received from the Data Manager may log in, regardless of their expiration status. If a User on the User List is expired, they can still log in (based on how the system administrator has set it up). See the system administrator for additional information

- **Warn:** If the User Validation setting is set to **Warn**, and a user who is expired attempts to log in, a message will appear, stating that they expired on a particular date, and asking if they still want to continue (see [Figure 4-34](#)). The warning serves as a reminder that the user needs to complete their compliance training, but if it's urgent they can continue. See the System Administrator for additional information.



Figure 4-34. Example Message when User List is Set to Warn Expired Users

- **Lockout:** When the User Validation setting is set to **Lockout** (the default setting) and an expired user attempts to login, the user will receive an error message (see [Figure 4-35](#)), informing them that they are not allowed to login to the Xpress system. See the System administrator for additional information.

Note

The default User Validation setting is set to **Lockout**. This must be changed on the Data Manager if the Administrator wishes it changed to a different setting, such as **Allow** or **Warn**.



Figure 4-35. Example Message when User List is Set to Lockout Expired Users

4.6 Data Management Tasks

On the Admin screen, touch the **RETRIEVE TESTS** button to retrieve tests that have been previously archived (see [Figure 4-36](#)).

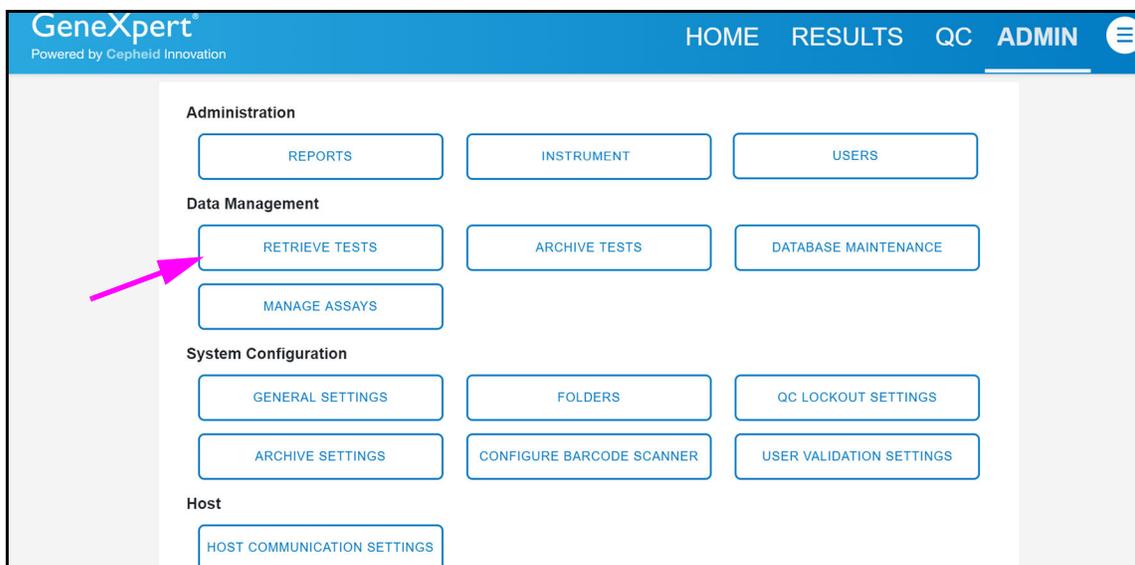


Figure 4-36. Admin Screen

4.6.1 Retrieving Tests

Touch the **RETRIEVE TESTS** button and the Open dialog box appears (see [Section 4.6.3](#) for detailed information and screens).

4.6.2 Archiving Tests

Archiving tests allows you to move your data and, if desired, free up space in the database. You can archive multiple tests at one 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(s) and saves the data in an .nxx file.

On the Admin screen, touch the **ARCHIVE TESTS** button to archive the tests in the database (see [Figure 4-37](#)).

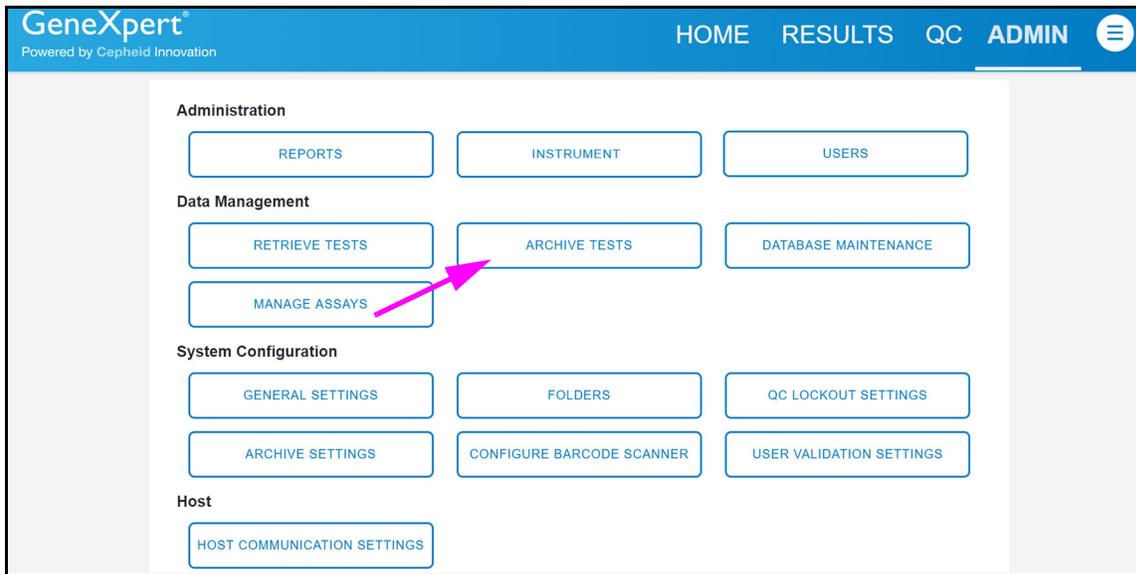


Figure 4-37. Admin Screen

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.

In addition, tests can be selected to be purged (removal of original, large files) from the database after archiving (see Figure 4-38).

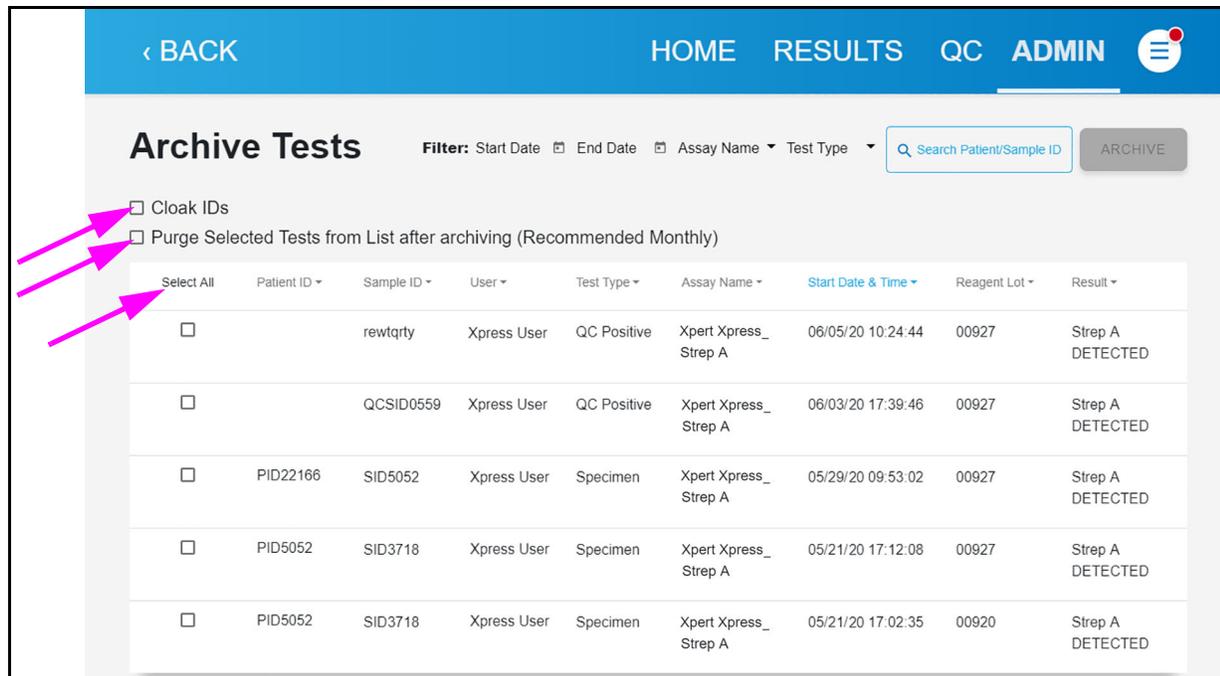


Figure 4-38. Archive Tests Screen - View 1

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.**

Select any tests to be excluded from the archive by touching the **Check Box** at the left of the test (see [Figure 4-39](#)).

In addition, touching the **Select All** button will select all listed tests for archiving.

The screen will change to indicate the selected tests with a white check mark on a blue **Check Box** (see [Figure 4-40](#)). The **Select All** button has now changed to **Deselect All**.

Touch **Deselect All** to clear the check marks from all the selected tests.

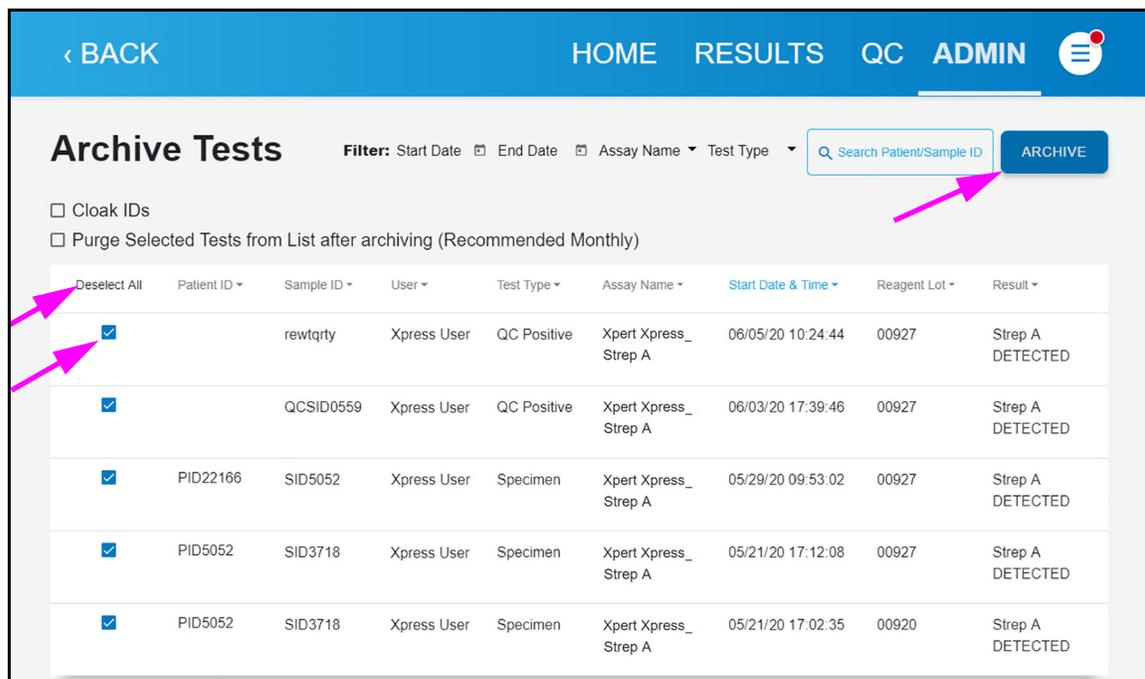


Figure 4-39. Archive Tests Screen - View 2

After selecting the test(s) to be archived, touch **ARCHIVE**.

A confirmation box appears (see [Figure 4-40](#)), showing the number of tests to be archived. Touch **OK** to begin the archiving process.

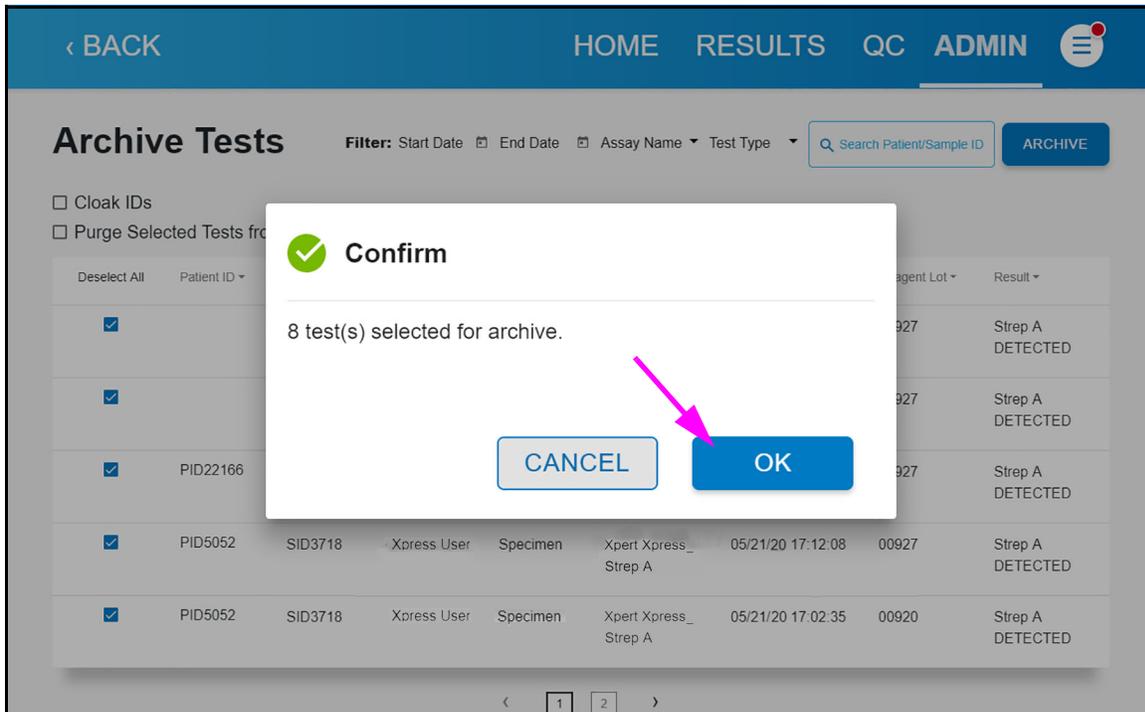


Figure 4-40. Archive Confirmation Screen

After archiving completes, an Information box appears (see Figure 4-41), showing the number of tests archived and the archived file path.

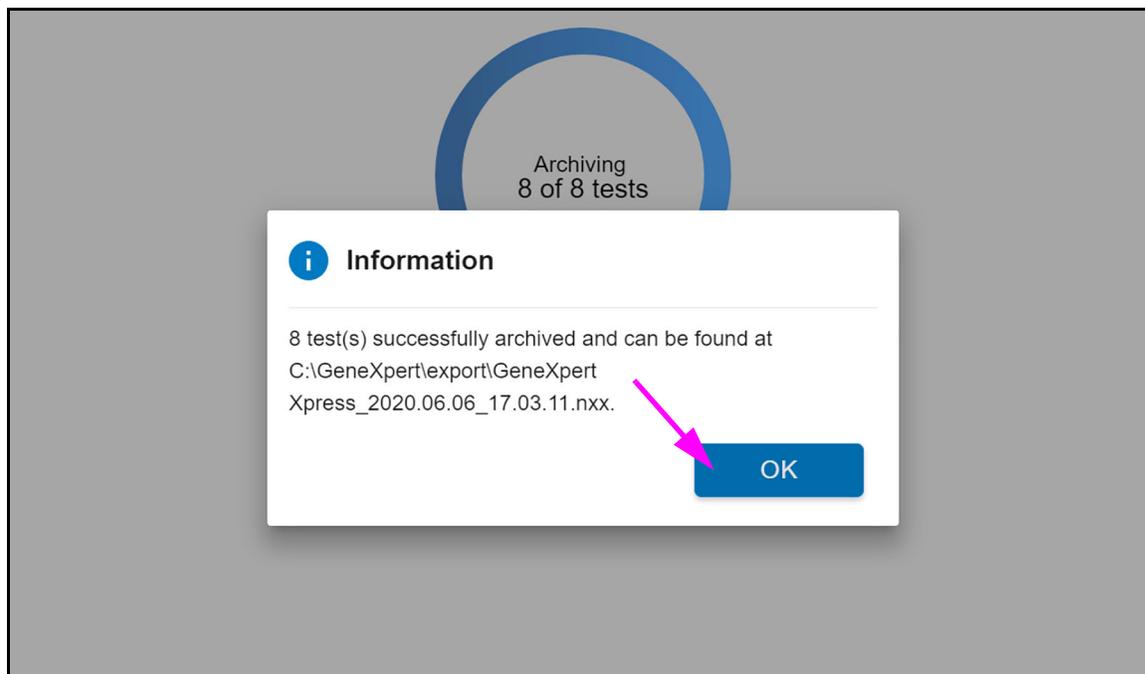


Figure 4-41. Archive Information Screen

Touch **OK** to close this window.

4.6.3 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. On the Admin screen, touch **RETRIEVE TEST**. The Open dialog box appears (see [Figure 4-42](#)).

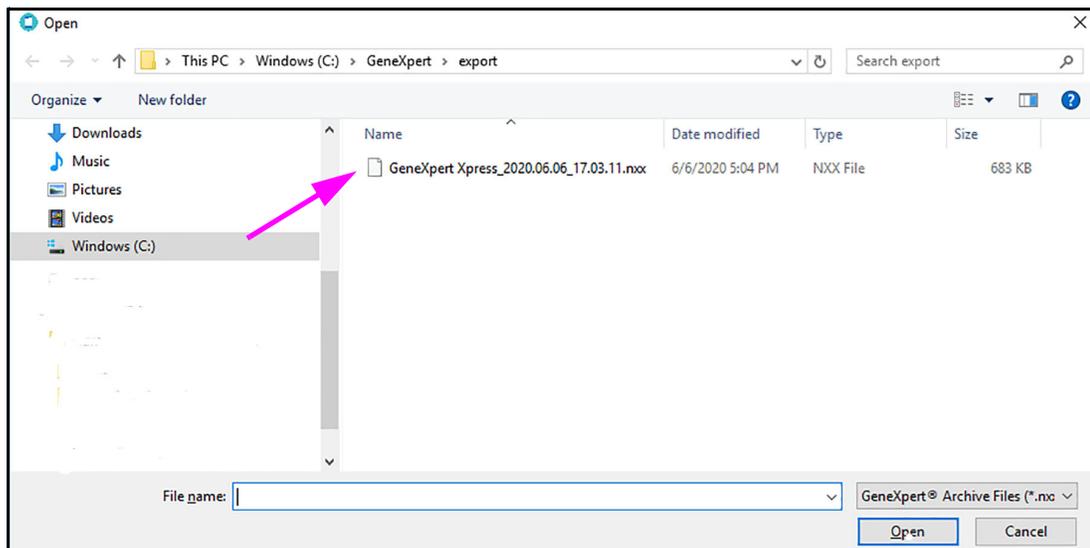


Figure 4-42. Archive Open Dialog Screen

2. Locate and select the archive file, and then touch **Open** to retrieve the selected test(s) from the old or new archive files (see [Figure 4-43](#)),

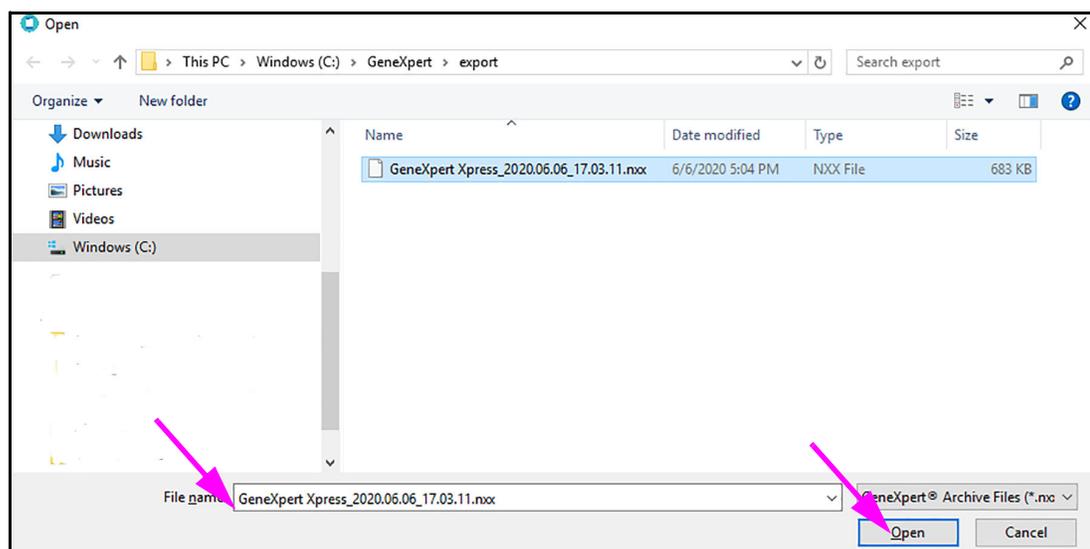


Figure 4-43. Archive Confirmation Screen

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. Touch **OK**.

- The Retrieve Tests screen appears (see [Figure 4-44](#)). The tests that already exist in the current database appear in red text.
Touch **BACK** to leave this screen without retrieving any archived tests.

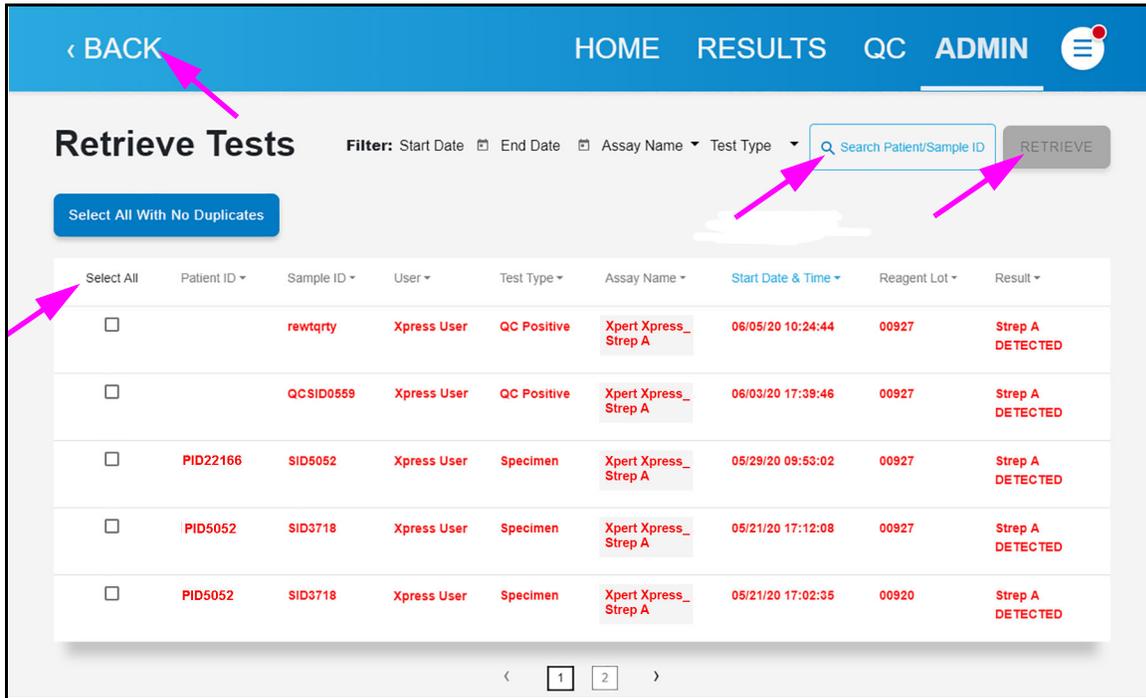


Figure 4-44. Retrieve Tests Screen

The Retrieve Tests screen shows the tests previously run, with test information, including Patient ID, Sample ID, etc. By default, the most recent test are displayed first. A search function is provided, to search by Patient or Sample ID.

- Select the tests you want to retrieve. You can select the individual tests one-by-one by touching the check boxes at the left of the filename, or touching **Select All** to choose all results in the list.
- Touch **RETRIEVE** to retrieve the selected test(s). A confirmation screen appears. Touch **YES** to continue with the retrieval. The selected test(s) are retrieved and a message appears and confirms that the tests are retrieved.
Touch **NO** to not retrieve the selected test(s) from the database.

4.6.4 Purging Tests from the Database

Tests may be purged from the active database after they have been archived (see [Section 4.6.2, Archiving Tests](#) for details).

Note

Host communication cannot be enabled while purging tests.

Caution

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 4.6.3, Retrieving Data from an Archive File](#).

4.6.5 Database Management

The database is a history file of previously-run tests, showing patient information, sample information, test type and results, system configuration, Assay Definition Files, User Administration, etc.

It is recommended that a database backup be created whenever there is a change to the system configuration. This file should be stored outside of the GeneXpert Xpress hub in case of computer replacement, where the backup will be restored onto the new computer.

These stored results can be managed by archiving to save storage space, purging (removal or deletion) if no longer needed, or restored from the archive if the original version of the test is required.

Note

Database management cannot be performed while host communication is enabled. The user must disable host communication to perform database maintenance.

To perform these tasks, access the Admin screen. Touch the **DATABASE MAINTENANCE** button (see [Figure 4-45](#)). The Database Management screen appears (see [Figure 4-48](#)).

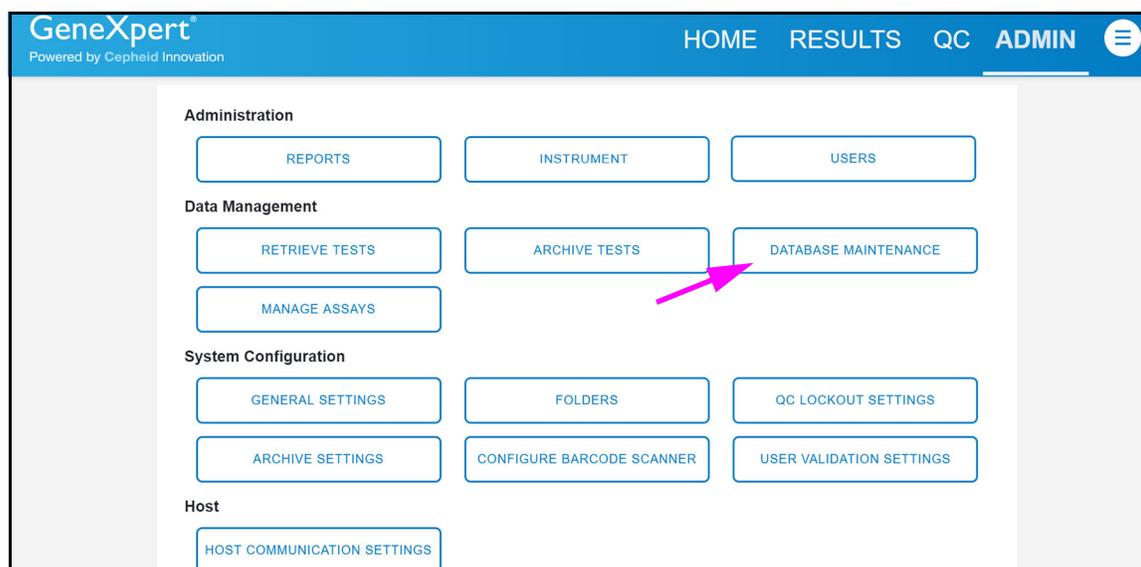


Figure 4-45. Admin Screen

On the Database Maintenance screen the Administrator can perform database tasks, such as backing up the database or restoring the database from a backup.

4.6.5.1 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. Touch **DATABASE BACKUP** on the Database Maintenance screen (see [Figure 4-46](#)).

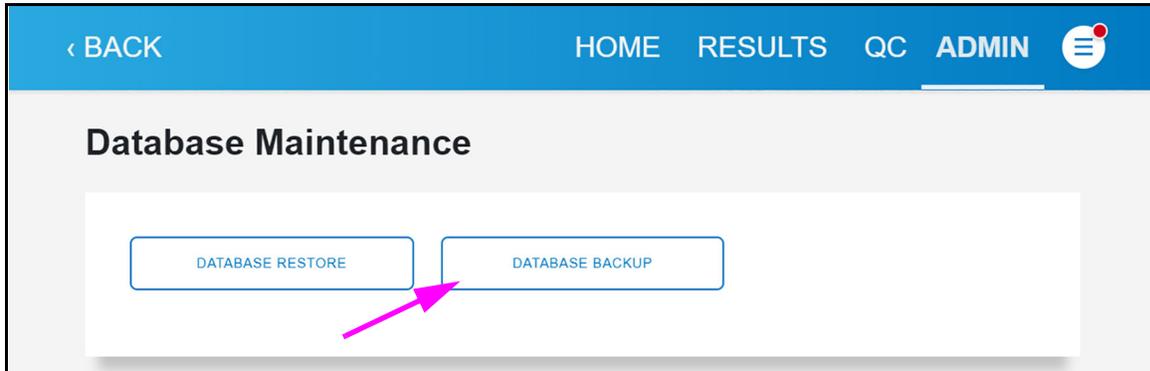


Figure 4-46. Database Maintenance Screen

A screen appears with the default database filename.

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 touch **Save** to continue with the backup routine (see [Figure 4-47](#)). The backup process creates a .zip file in the location you specified.

Caution



The default database backup location is the Backup folder which is located on the GeneXpert hub hard drive. To guard against loss of data, the files in the Backup folder should be periodically copied to a different computer or server. If the GeneXpert hub is connected to a network, it is possible to back up the files directly to a server.

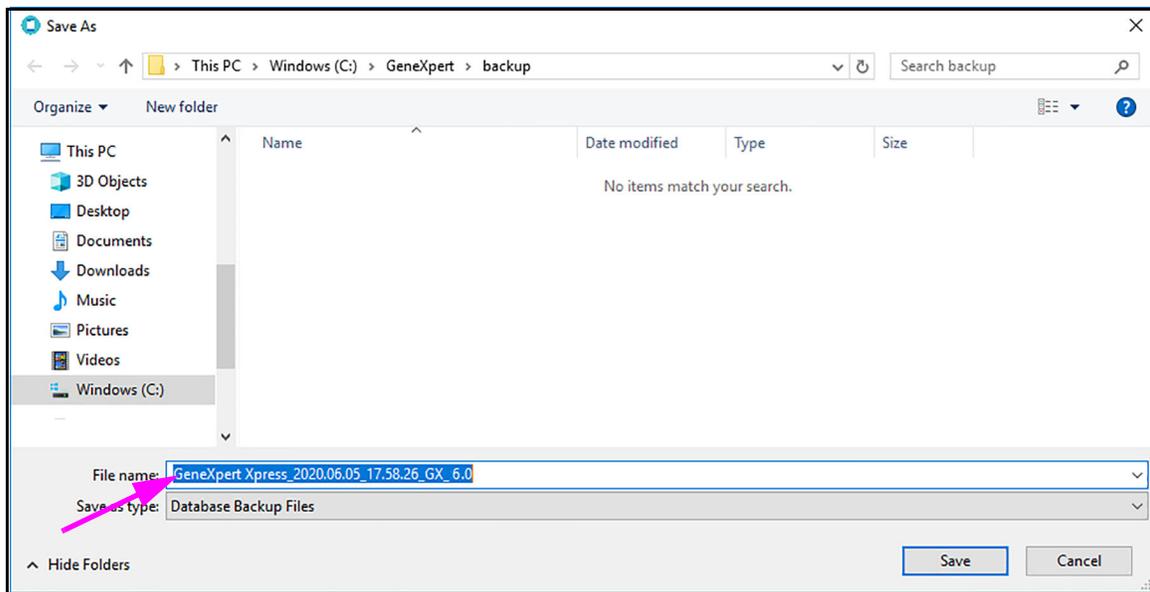


Figure 4-47. Database Backup Screen, showing Default Filename

4.6.5.2 Restoring the Database

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, restore the database, and then retrieve the data from the archive file.

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.

To restore the database:

1. Touch **DATABASE RESTORE** on the Database Maintenance screen (see [Figure 4-48](#)).

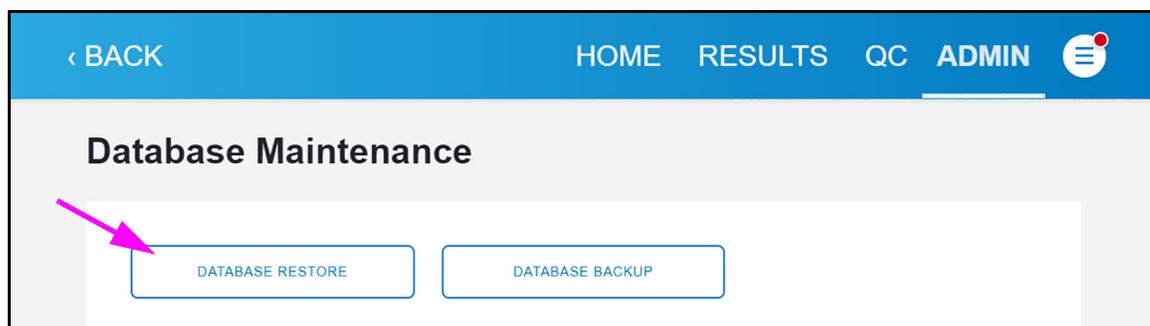


Figure 4-48. Database Maintenance Screen

2. A screen appears, asking if you want to create a backup of your current database before proceeding. Choose **YES** or **NO**.
 - A. If you choose **NO**:
 - 1) An advisory screen appears, stating “Database Restore will **OVERWRITE** your current database with a backup database.” Touch **CONFIRM** to acknowledge the message and continue (see [Figure 4-49](#)).

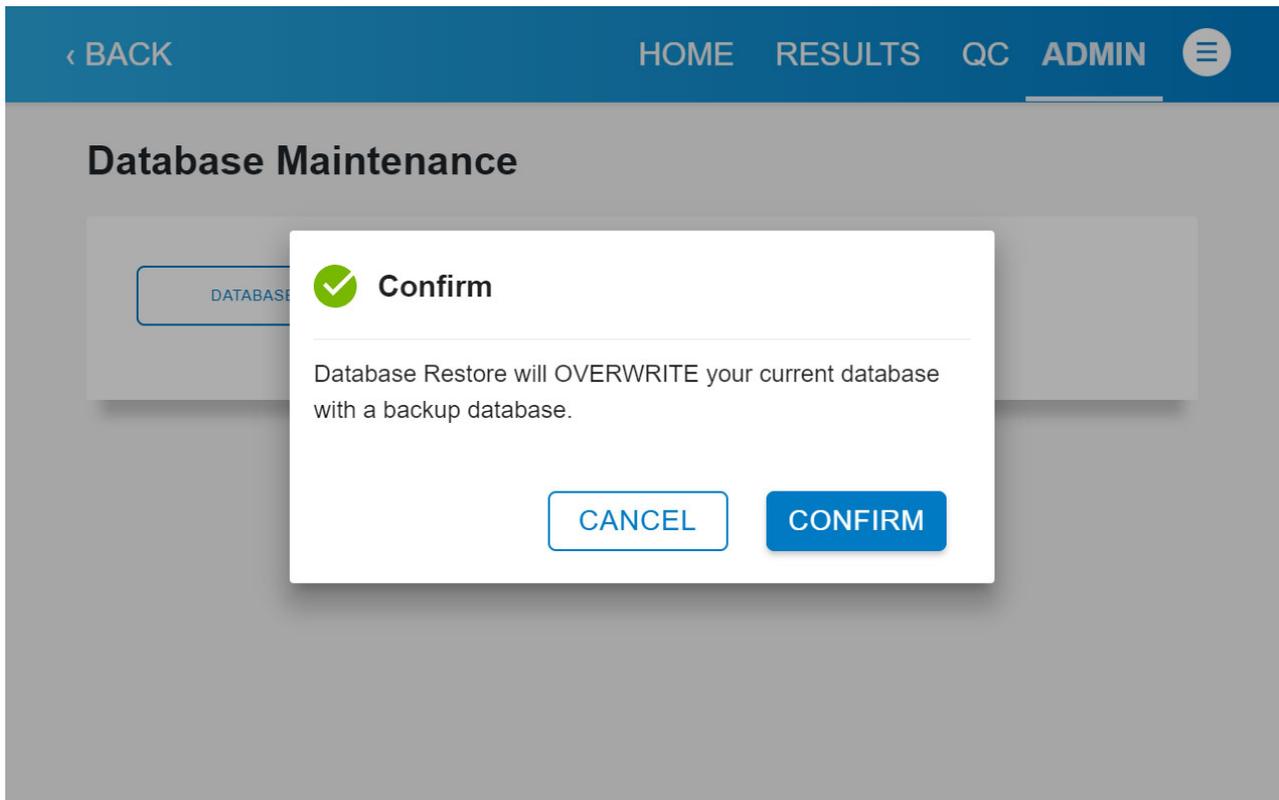


Figure 4-49. Database Restore Confirmation Advisory

- 2) A screen will appear with a listing of database backup files.
- 3) Select a database backup file from the available listings in the upper window, and it will appear in the **File name:** field bottom of the screen (see [Figure 4-50](#)).

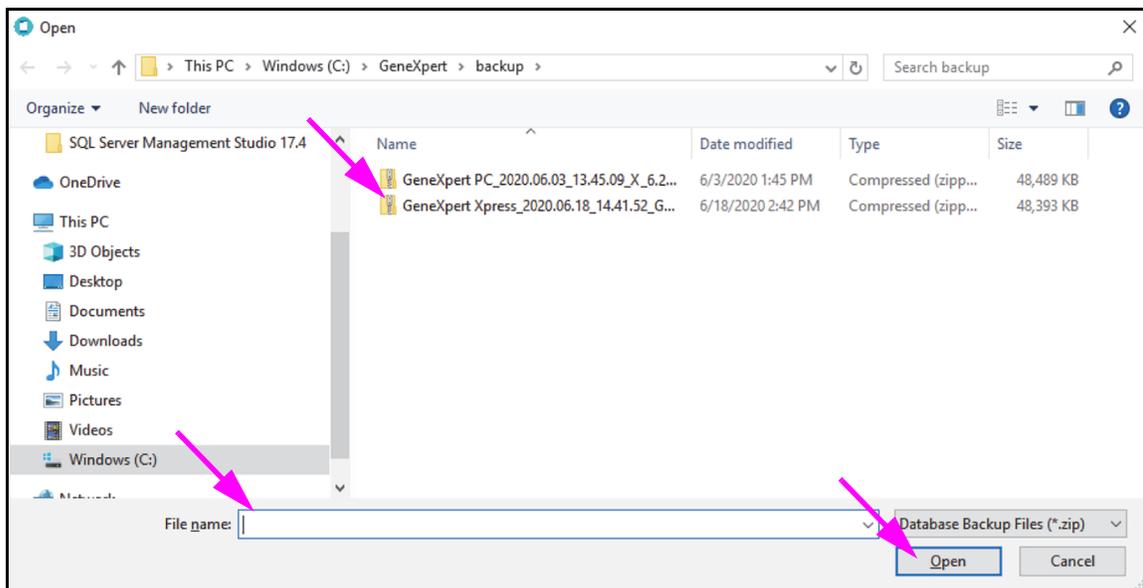


Figure 4-50. Database Backup File Folder

- 4) Touch **Open** at the bottom of the screen.
- 5) The Database restoration begins. When the restoration is complete, a message advises that the software will now shut down (see [Figure 4-51](#)).

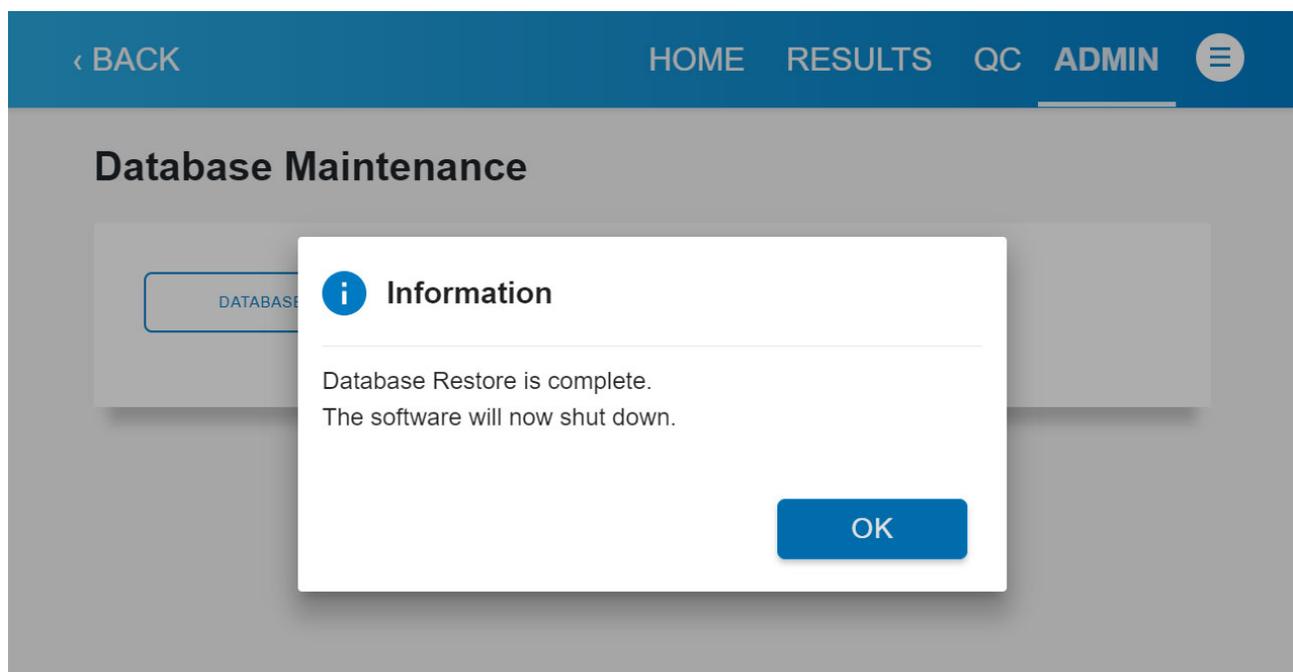


Figure 4-51. Database Restore Completion Advisory

- A. If you choose **YES**:
 - 1) A screen appears where you will select a database backup file from the listings in the upper window. The file then appears in the **File name:** field. Touch **Save**. (see [Figure 4-52](#)).

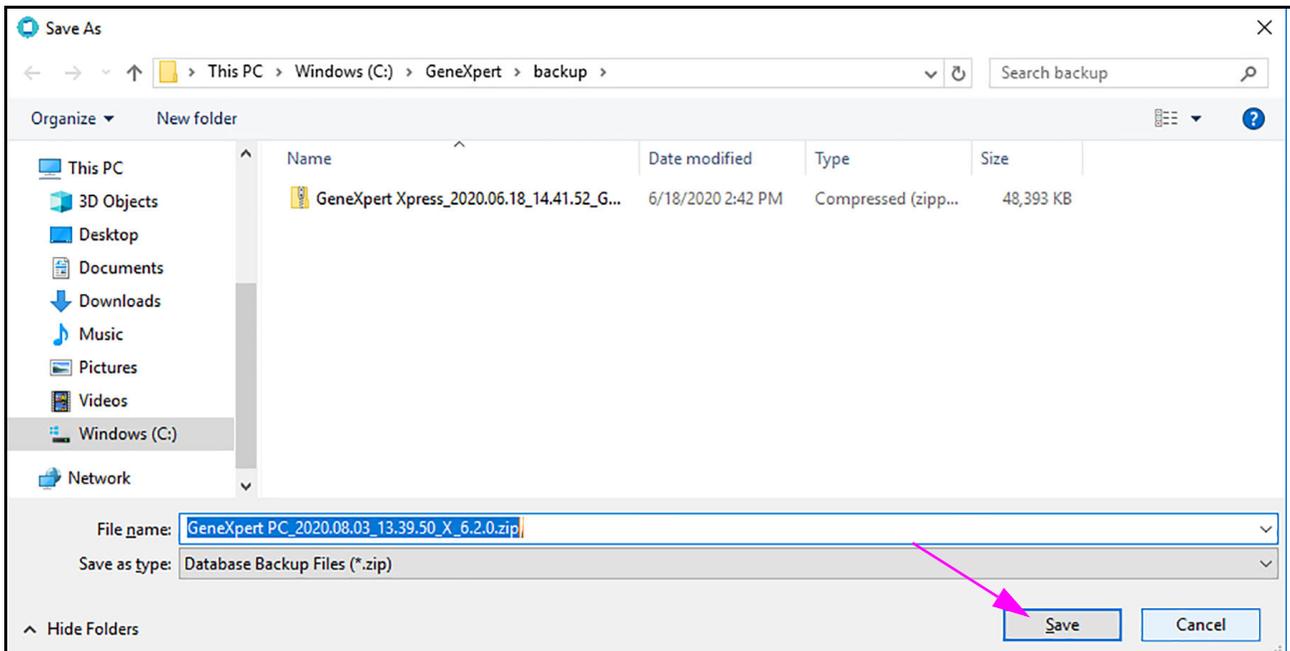


Figure 4-52. Database Backup File Folder

- 2) Database backup will begin, and when it is done an advisory screen appears stating that database backup is complete. Touch **OK** to continue (see Figure 4-53).

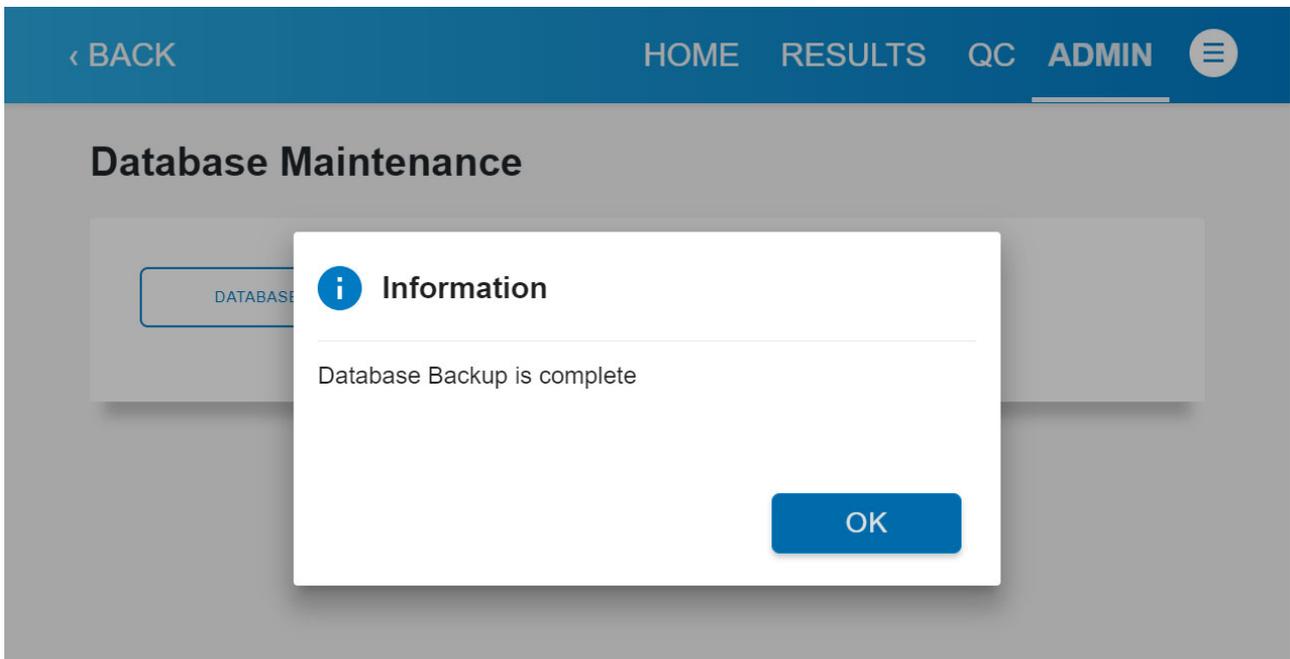


Figure 4-53. Database Backup is Complete Advisory

- 3) A new advisory screen appears, stating that “Database Restore will **OVERWRITE** your current database with a backup database.” Touch **CONFIRM** to acknowledge the message and continue (see Figure 4-53).

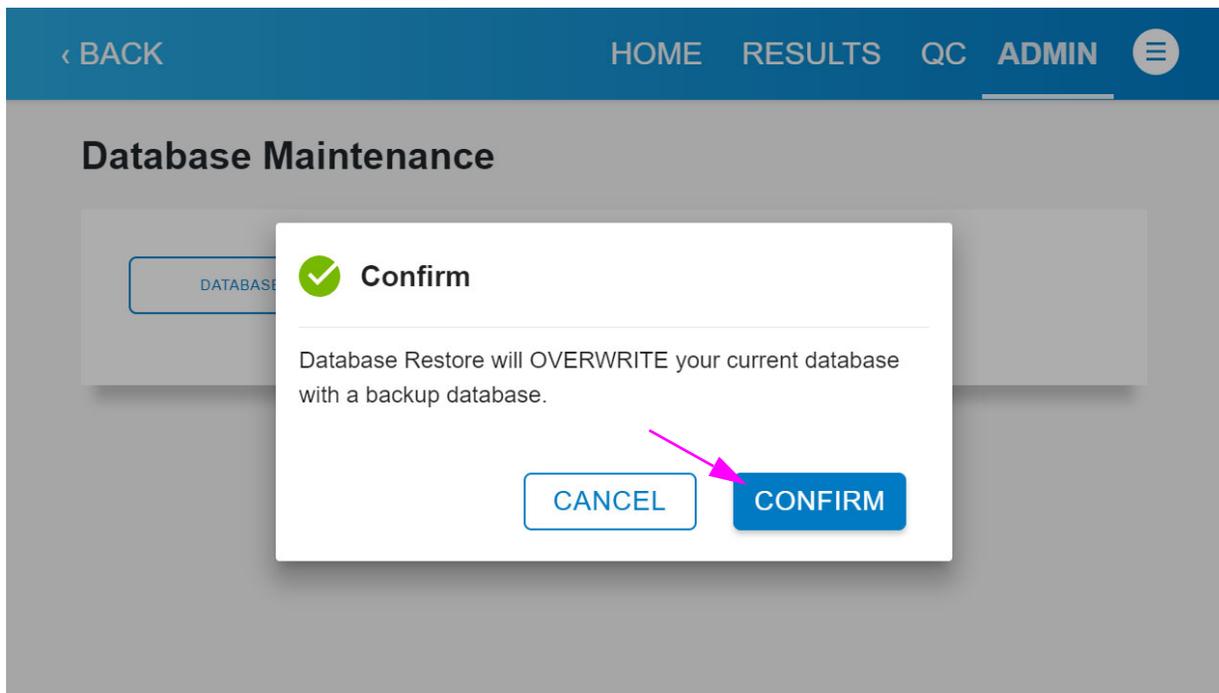


Figure 4-54. Database Restore Overwrite Advisory

- 4) A new filename screen appears. Select a file from the backup listing, and touch **Open** (see [Figure 4-55](#)).

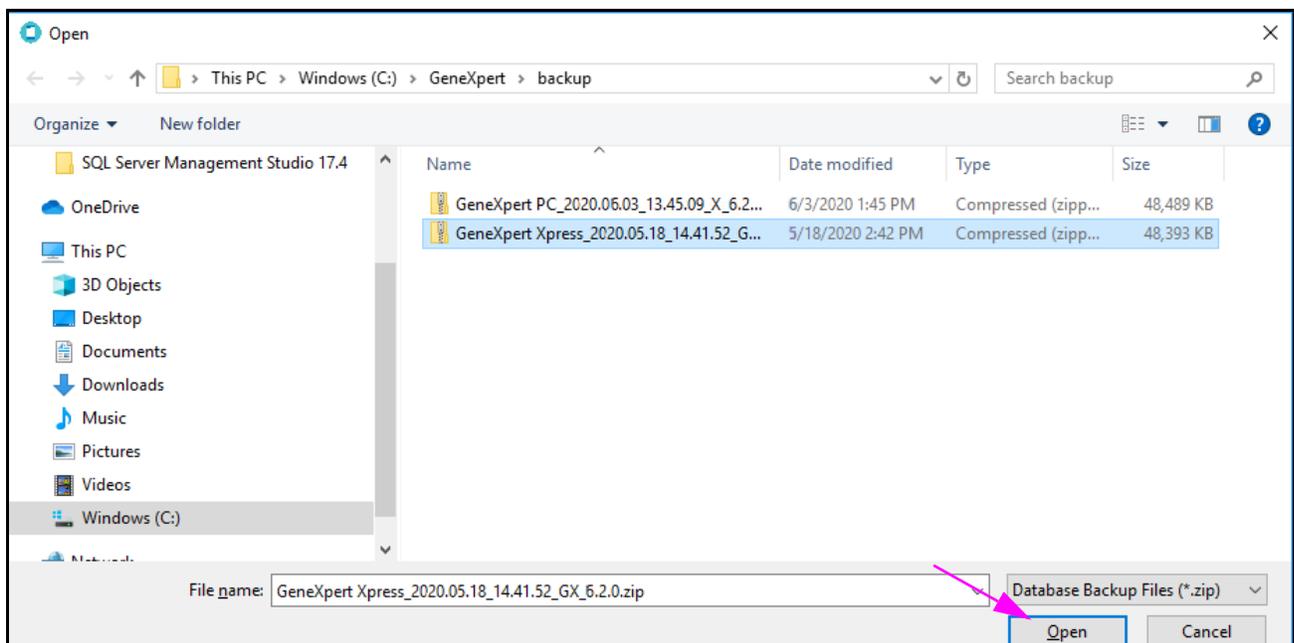


Figure 4-55. Database Backup File Folder

- 5) The Restore in Progress screen appears, and when it is complete, another information screen appears, with an advisory that the software will now shut down (see [Figure 4-56](#)). Touch **OK** to confirm.

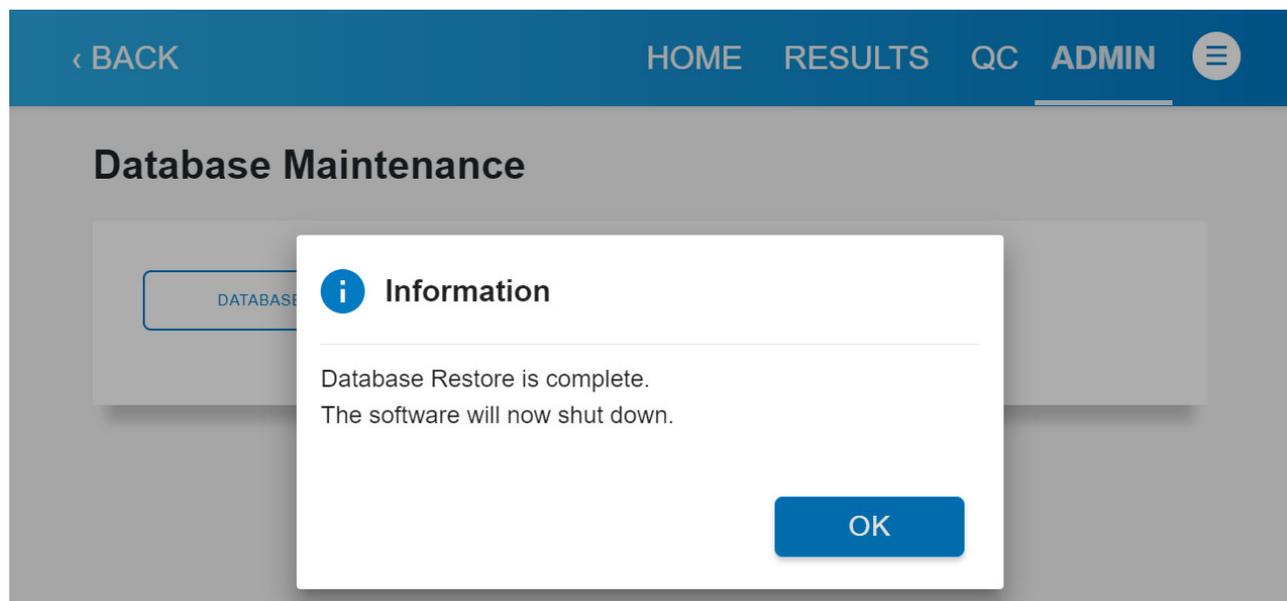


Figure 4-56. Database Restore Completion Advisory

4.7 Managing Assays

An assay definition contains a series of programmed steps that the GeneXpert Xpress system uses to perform sample preparation, amplification and detection procedures. As described in this section, assay definition files can be imported by either using the CD that is supplied with the assay kit, or downloaded from the Cepheid website.

4.7.1 Importing Assay Definitions from the CD

In vitro diagnostic assay definition (.gxa/.nxa) files are included on the CD that is shipped with the assay kit and imported into the software as described in this section. Assay definitions that are no longer in use can also be deleted (also described in this section).

On the Admin screen, touch the **MANAGE ASSAYS** button (see [Figure 4-57](#)) to import or delete assay definition files from the system.

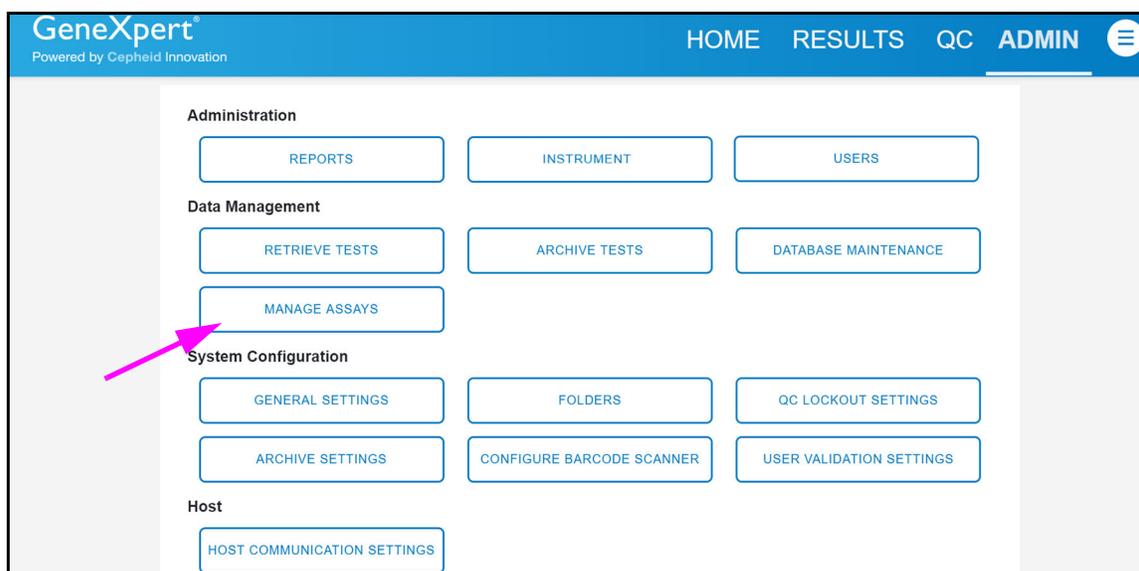


Figure 4-57. Admin Screen

The Manage Assays screens appears, showing a list of the assays installed on the system (see [Figure 4-58](#)).

4.7.1.1 Delete Assay(s)

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 Manage Assays window (see [Figure 4-58](#)), select the **Check Box** at the left corresponding to the assay to be deleted, and touch the **DELETE ASSAY** button at the right. A Confirm screen appears (see [Figure 4-58](#)).

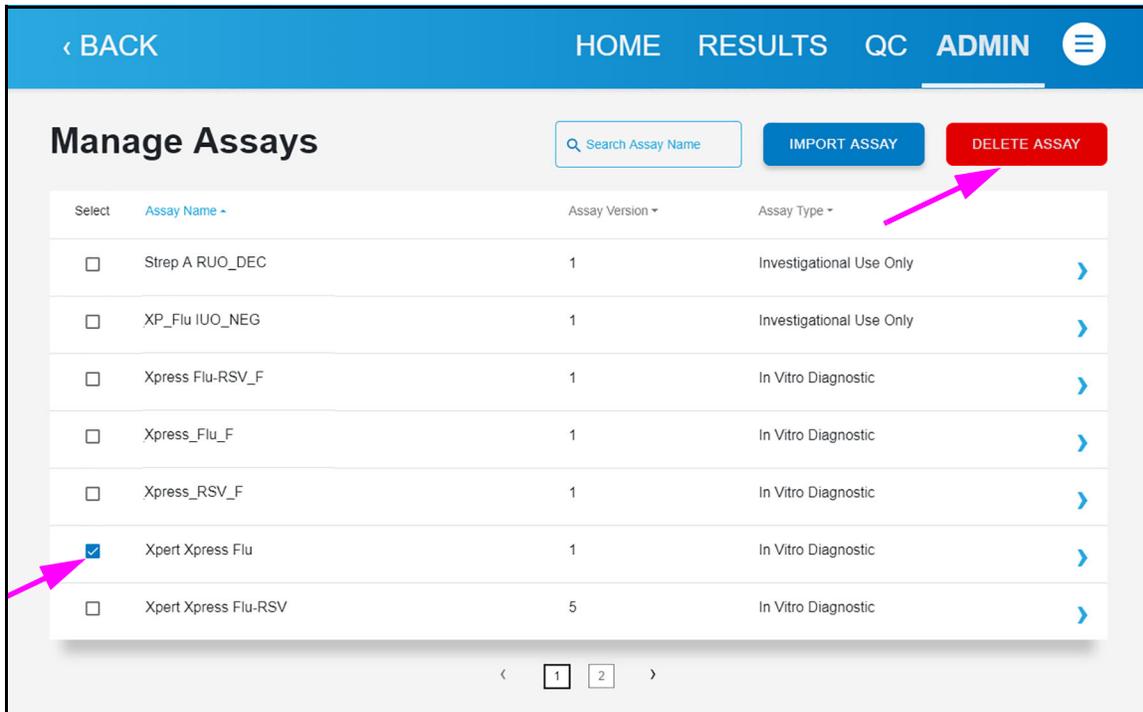


Figure 4-58. Manage Assays Screen

2. Touch **YES** on the Confirm message to delete the assay definition. The assay definition file will be deleted and is removed from the list of assays.

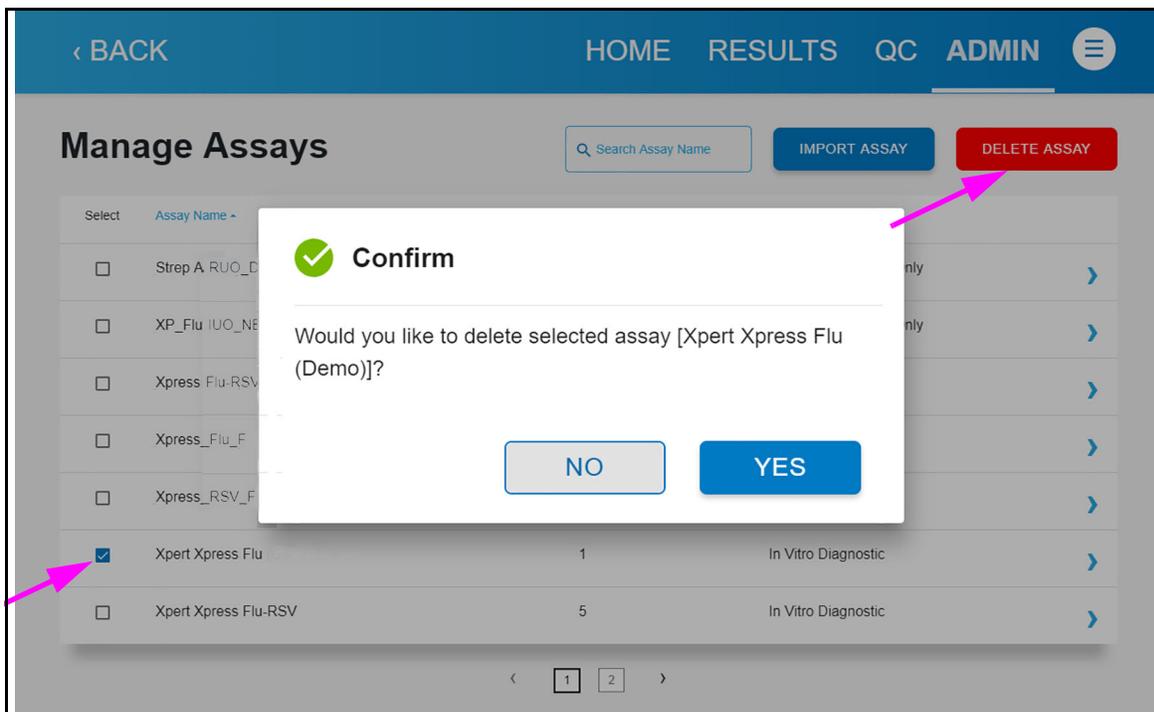


Figure 4-59. Manage Assays Screen

4.7.1.2 Connecting a DVD Drive to the Xpress System

This section describes how to connect the DVD drive supplied with the system to import assay definitions from the CDROM.

1. Locate the DVD drive. The DVD drive is shipped in the accessories box and is labeled as an item to save.

Note

If the DVD drive has been misplaced and cannot be found, contact Cepheid Technical Support for assistance. See the Technical assistance section in the Preface for the contact information.

2. Plug the DVD drive into one of the available USB ports on the rear of the hub.
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 CDROM.

4.7.1.3 Importing Assay Definition

Note

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

1. To import new assay definitions, touch the **MANAGE ASSAYS** button on the Admin screen (see [Figure 4-57](#)).
2. The Manage Assays screen appears (see [Figure 4-60](#)). To import an assay into the system, touch the **IMPORT ASSAY** button.

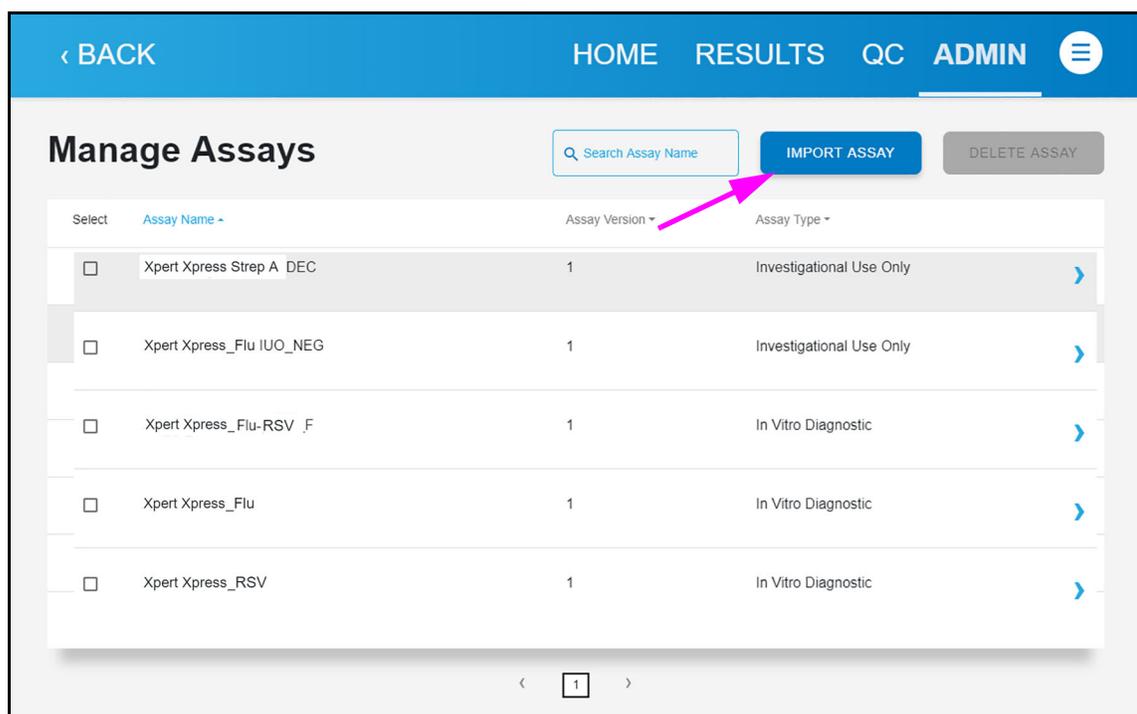


Figure 4-60. Manage Assays Screen, showing the Import Assay Function

3. Navigate to the DVD and to the folder containing ADF files. A screen appears where you will locate the assay definition file to be imported. Locate and touch the assay definition (.gxa) file (see [Figure 4-61](#)).

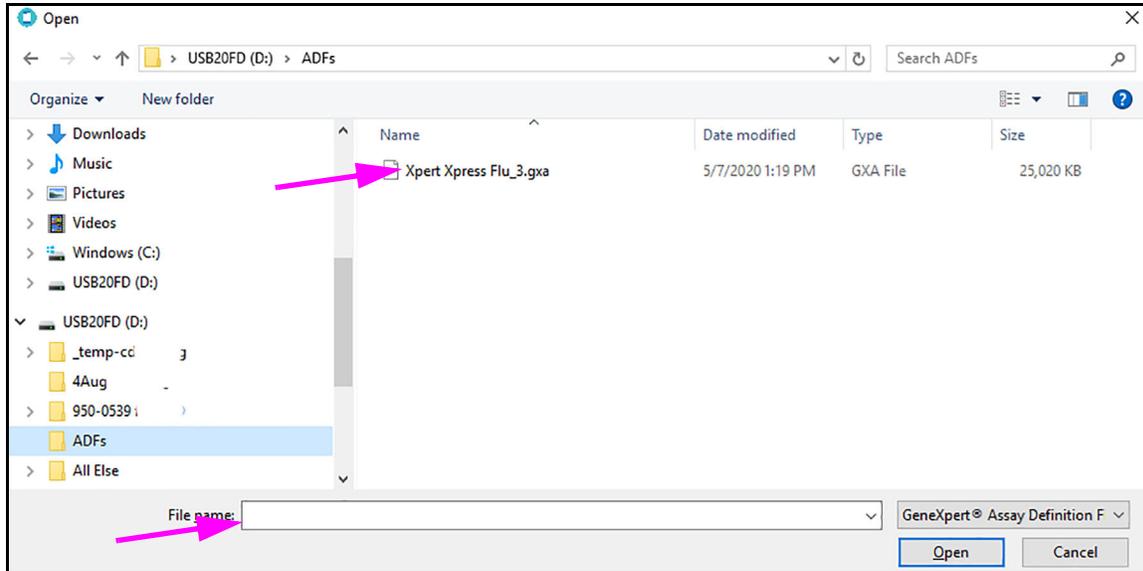


Figure 4-61. File Screen, showing the Assay File to be Imported

4. The assay name appears in the filename field (see [Figure 4-62](#)). Touch **Open** to import the file into the system.

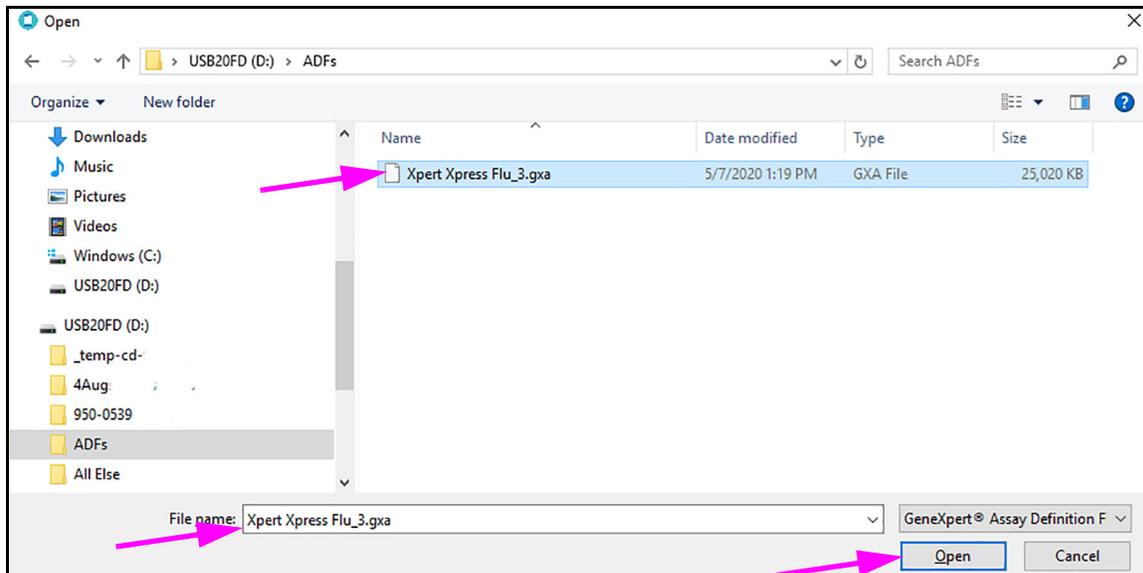


Figure 4-62. File Screen, showing the Assay File to be Imported

5. The new assay name and version number appear in the Assay list.
6. If you need to import additional assay definition files from the same CD, repeat [Step 3](#) through [Step 5](#).

Note

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

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

4.7.2 Downloading ADFs and PIs from the Cepheid Website

To download assay definition files from the Cepheid website:

1. With an Internet capable computer, navigate to www.cephheid.com/import.
2. Under the **Tests** menu, select the product that you need to import the ADF for.
3. Scroll down to the Product **Resources** section.
4. Click on **ADF Import Instructions** to download the complete set of instructions for downloading ADF files and package inserts.
5. Read and follow the *Assay Import Instructions* to download the ADF and package insert and to install the ADF onto your GeneXpert Xpress System.

Note Assay Import Instructions are available in multiple languages.

Note If your system is connected to an LIS or HIS network, you must update your host test codes (after the assay definition file installation), in order to download tests to the system and/or upload test results from the system to the LIS or HIS network. For instructions on updating host test codes, see [Section 4.10.2](#).

4.8 System Configuration

System Configuration in the following section includes general system preference settings, folder path locations and naming, QC lockout settings, archive interval settings and configuring the barcode scanner. On the Admin screen, touch **GENERAL SETTINGS** (see [Figure 4-63](#)). The General Settings screen appears (see [Figure 4-64](#))

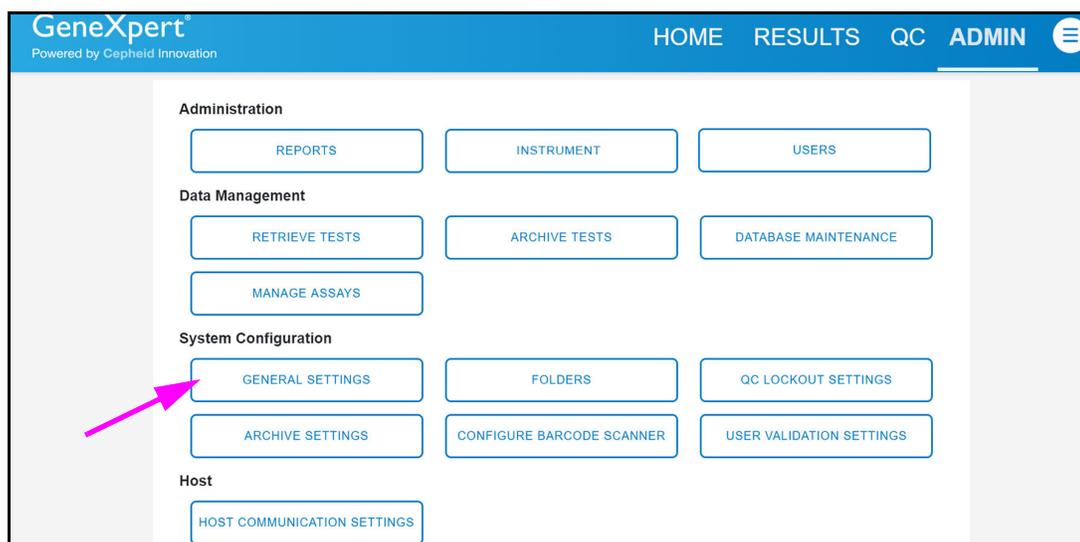


Figure 4-63. Admin Screen

4.8.1 General Settings

On the General Settings screen, the Administrator can set the date and time format, Patient Information characteristics, Institutional ID login requirements, and audio reminder notifications.

Touching the check box to the left of Institutional ID will prompt the user to log in to the system using the barcode scanner, rather than entering a **User Name** and **Password** using the virtual keyboard.

Require Start Test Login determines if the Login screen appears when a new test is initiated. The user can select **Never**, **Always**, or choose **Start Test Login Timeout** and select a value in minutes from the drop-down menu.

To edit any entries on this screen, touch **EDIT**, make any desired changes and touch **CONFIRM** when you are finished.

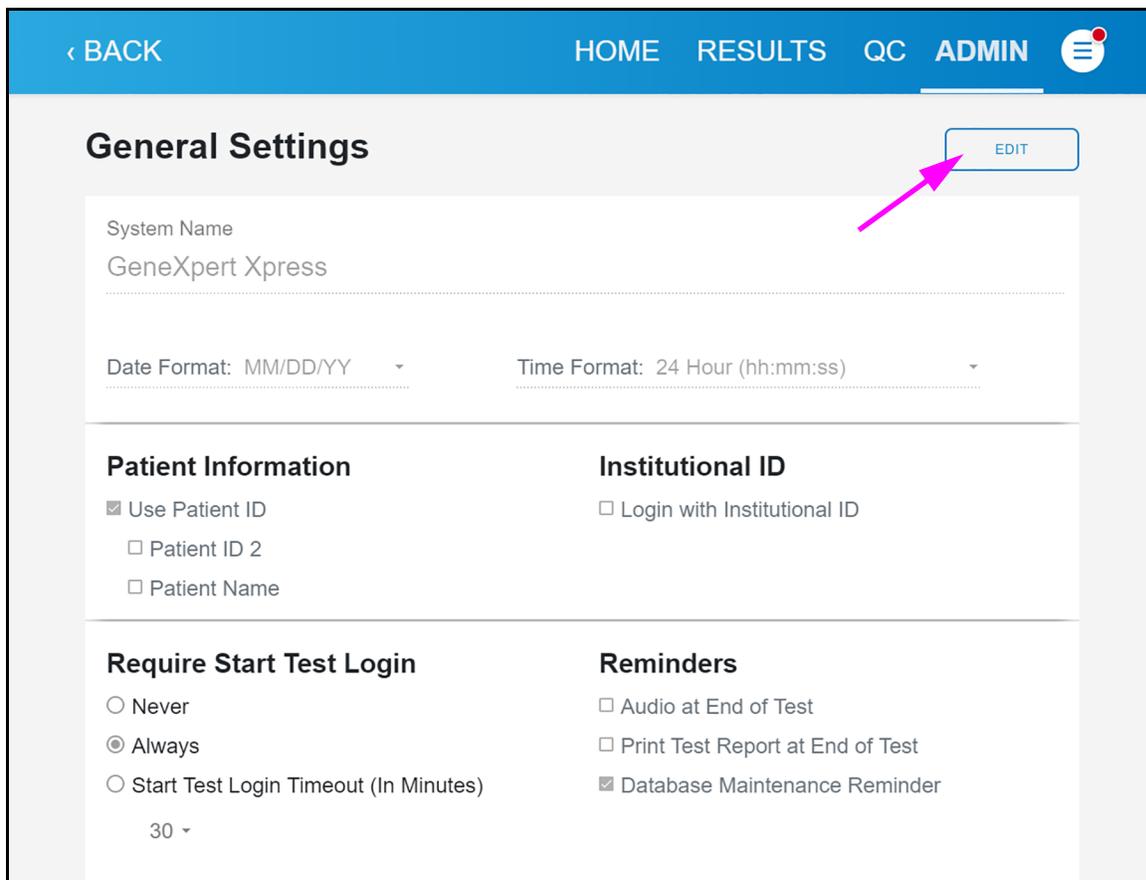


Figure 4-64. General Settings Screen

4.8.2 Folders

The **FOLDERS** screen displays the default location for the Export, Report, Backup and Database folders. To access this menu to make changes in the folder locations, touch the **FOLDERS** button on the Admin screen (see [Figure 4-65](#)).

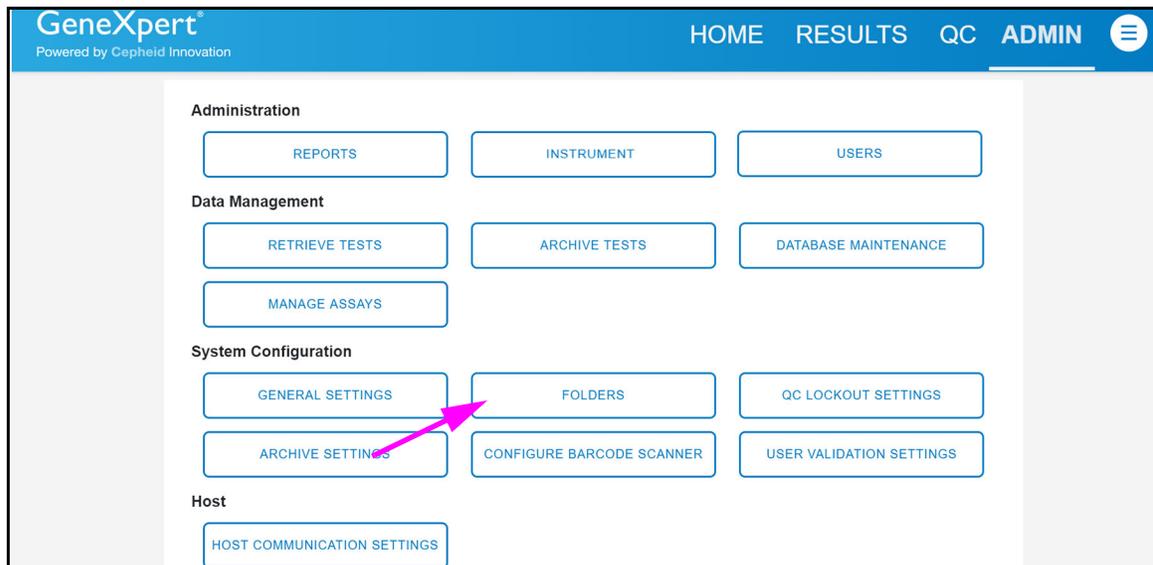


Figure 4-65. Admin Screen

The Folders screen appears (see [Figure 4-66](#)). Touch the **EDIT** button, and make any changes to the default folder locations shown. Touch **CONFIRM** when you are finished.

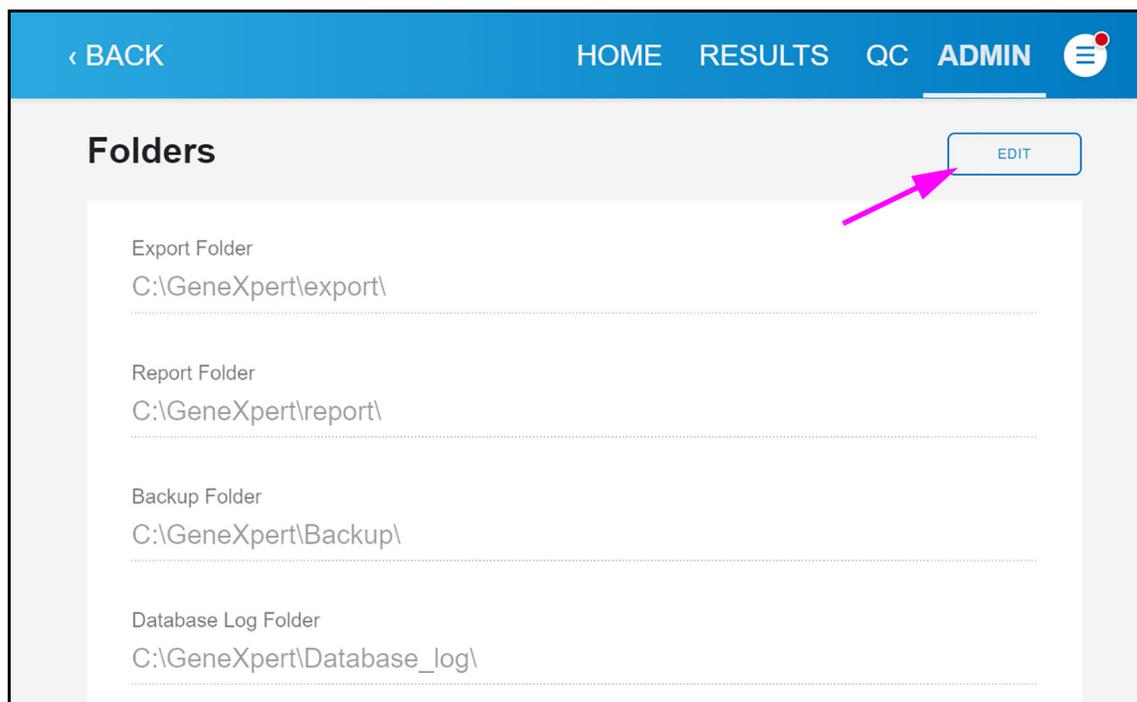


Figure 4-66. Folders Screen

4.8.3 QC Lockout Settings

The QC lockout feature allows an administrator to prevent a specific assay from running patient samples until the applicable Quality Controls (QC) assay have been run and produce valid results. The QC assay can be specified to be run at required intervals or at the beginning of a new lot of cartridges.

Use the QC Lockout Settings screen to change the settings for QC Lockout.

On the Admin screen (see [Figure 4-67](#)) touch **QC LOCKOUT SETTINGS** to display the QC Lockout Settings screen (see [Figure 4-68](#)).

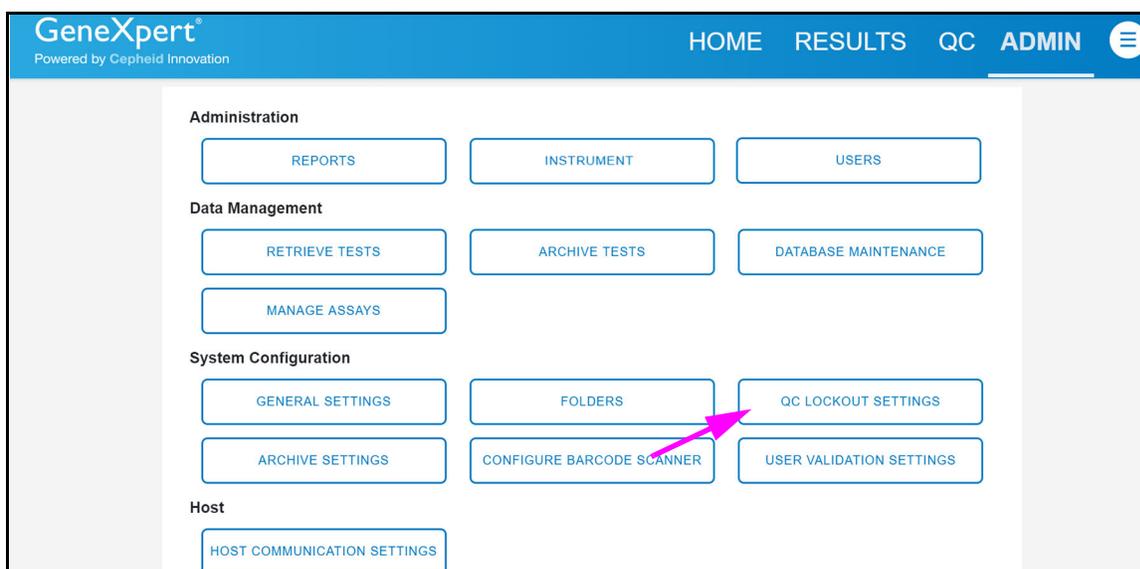


Figure 4-67. Admin Screen

Use the QC Lockout Settings screen (see [Figure 4-68](#)) to enable or disable QC Lockout for all assays, make any changes in the frequency of QC Lockout, choose between Assay-based or Reagent Lot-based lockouts, change the Lockout frequency setting, the reminder notification for the upcoming QC tests (in hours) and the expiration period of QC Notifications.

Assay Based: Refers to the lockout of a specific Assay (such as Flu or Strep A).

Reagent Lot Based: Refers to lockout of each reagent lot.

Touch the **EDIT** button, and make any changes to the settings shown (see [Figure 4-69](#)).

Under **Quality Control Lockout**, touch the **Enable QC Lockout for All Assays** check box to select **Once**, **Daily**, **Weekly** or **Monthly** from the **Frequency** drop-down menu.

Under **Notification Settings**, select the time interval from the **Reminder for upcoming QC tests in hours** drop-down menu.

To delete QC reminders: Under **Expire QC Notifications**, touch the check box, and then select the expiration time interval using the drop-down menu at **Delete QC Reminders**.

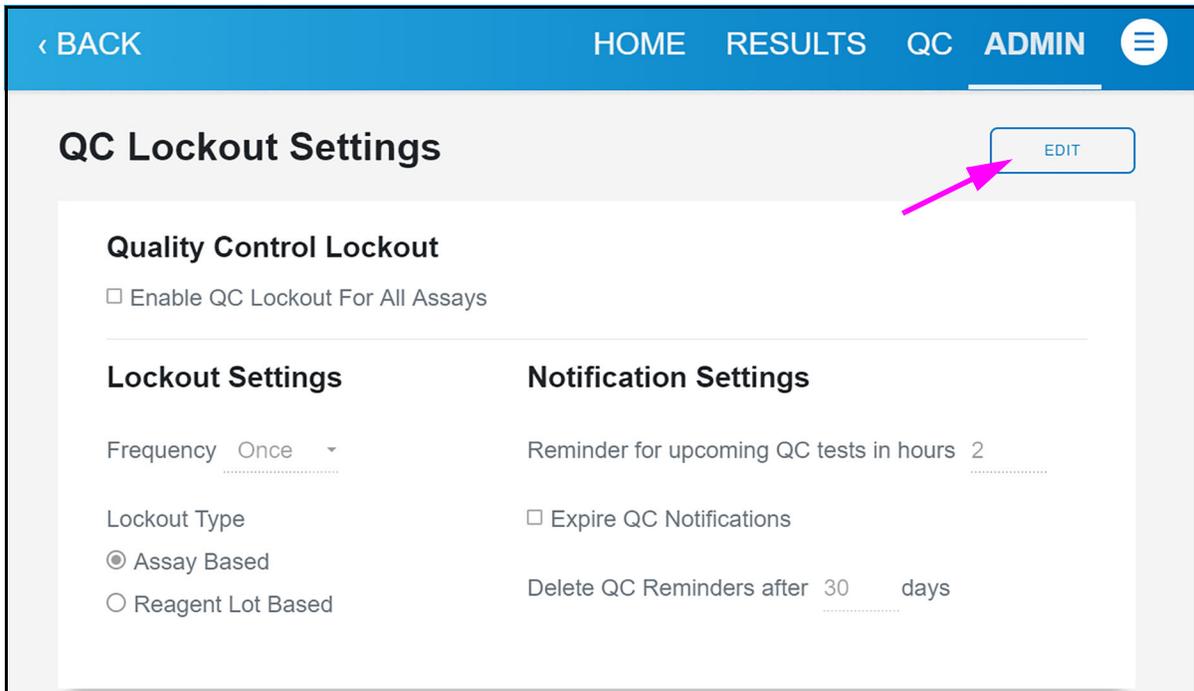


Figure 4-68. QC Lockout Settings Screen

Touch **CONFIRM** when you are finished.

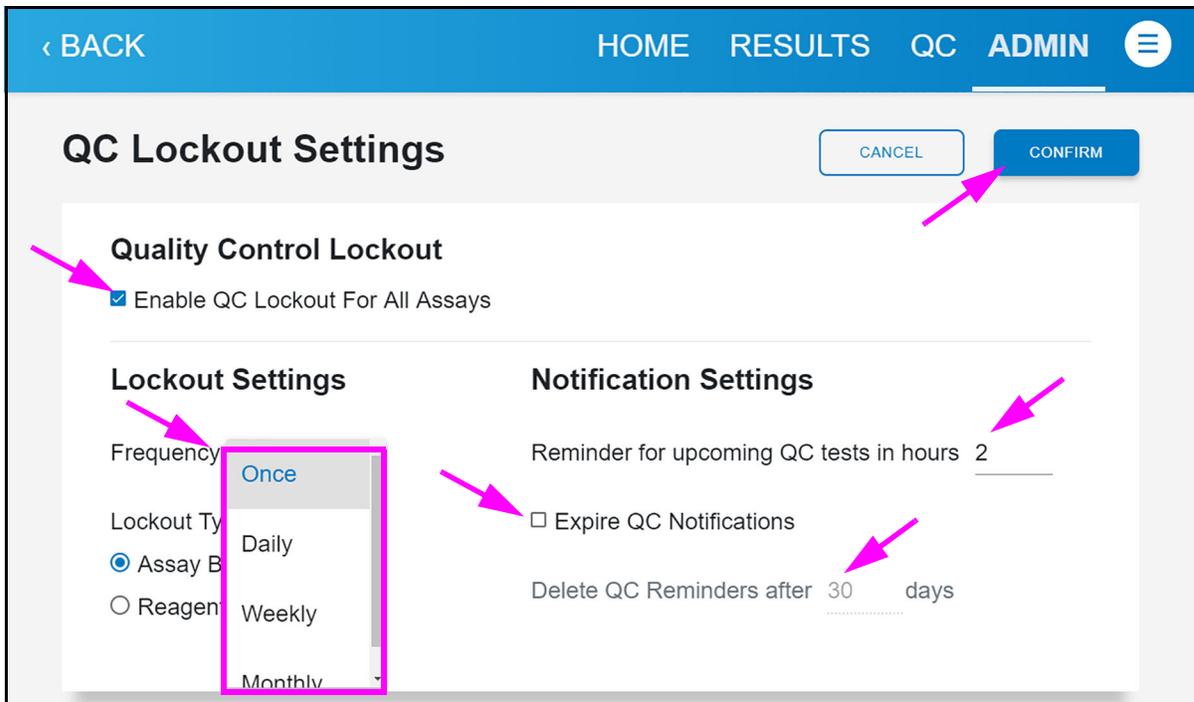


Figure 4-69. QC Lockout Settings Screen - Showing Drop Down Menu Selections

4.8.4 Archive Settings

Use the Archive Settings screen to change the Archive Test Results time settings. On the Admin screen (see [Figure 4-70](#)) touch **ARCHIVE SETTINGS** to display the Archive Settings screen (see [Figure 4-71](#)).

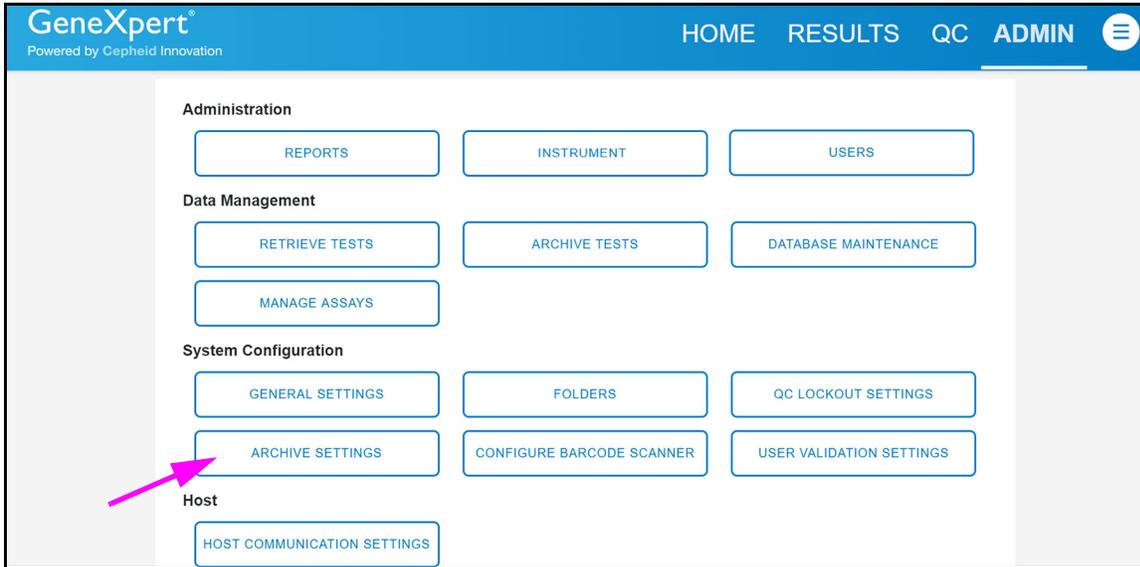


Figure 4-70. Admin Screen

Choose between Manual archiving and Manual archiving with reminders, which can be changed between the default weekly period to monthly (see [Figure 4-71](#)).

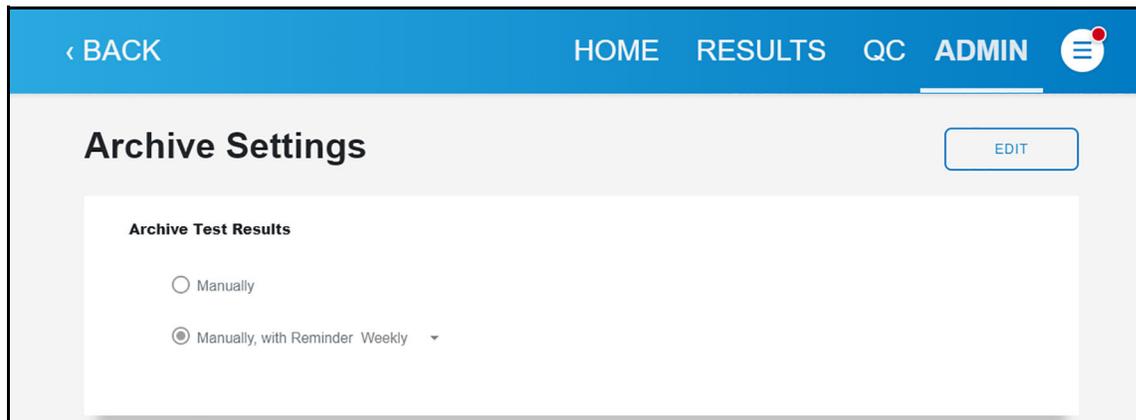


Figure 4-71. Archive Settings Screen

4.8.5 Configuring the Barcode Scanner

Use the following section to scan a configuration barcode to configure the barcode scanner. On the Admin screen (see [Figure 4-72](#)) touch **CONFIGURE BARCODE SCANNER** to display the Configure Barcode Scanner screen (see [Figure 4-74](#)).

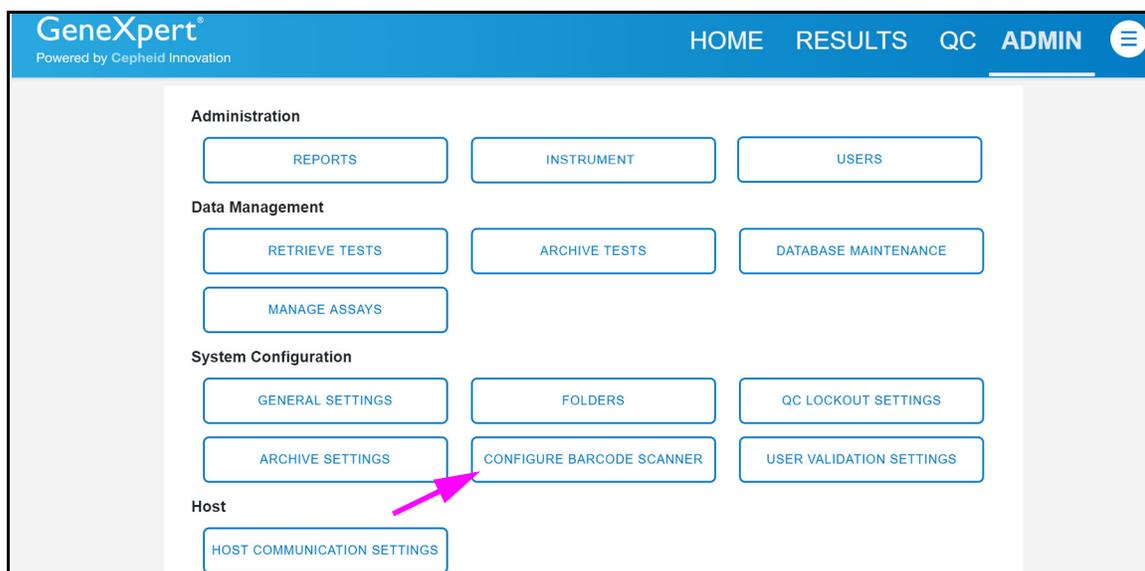


Figure 4-72. Admin Screen

Should it be necessary to reconfigure the scanner, if it is replaced or otherwise mis-configured, perform these steps:

1. Print the matrix shown in [Figure 4-73](#).



Figure 4-73. Matrix to Scan to Reconfigure the Barcode Scanner

2. Using the Configure Barcode Scanner screen, touch the **ENABLE SCANNER** button.
3. Scan the “Configuration Data Matrix” barcode printed from [Figure 4-73](#), to reconfigure the scanner.

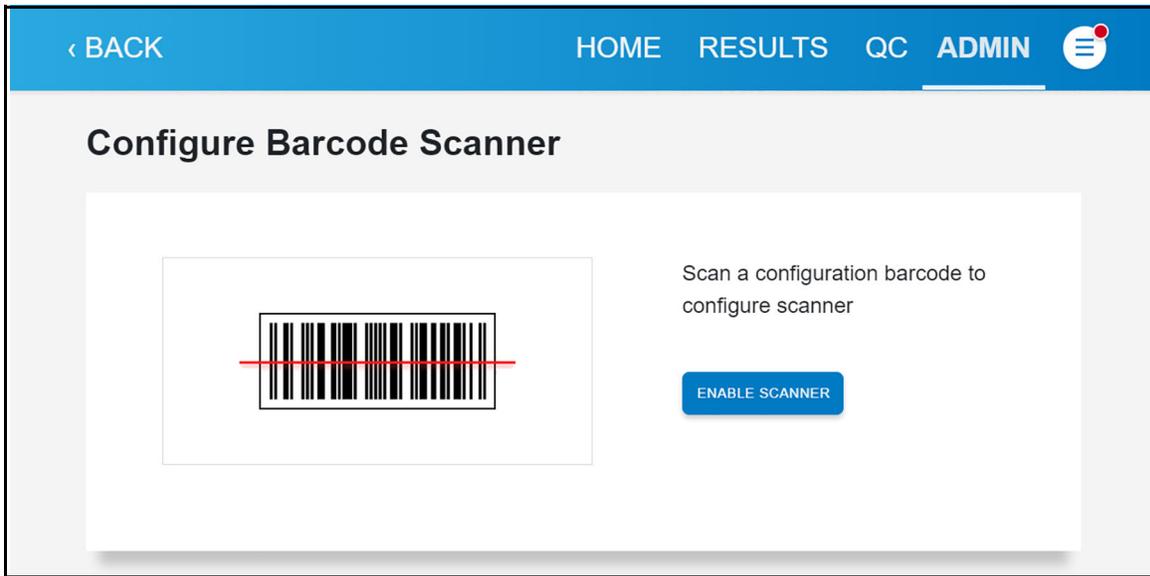


Figure 4-74. Configure Barcode Scanner Screen

4.9 Setting the IP Address for Instrument Communication

Note

To perform the steps in this section, you must either be logged on as **Cepheid-Admin** or you need to enter the **Admin** password.

The GeneXpert hub is already configured with the correct IP address when the GeneXpert Xpress system is shipped. If it needs to be reset:

1. Log onto the system as **Cepheid-Admin** or enter the **Admin** password when requested to do so.
2. On the Windows taskbar, touch the **Windows** icon.
3. Select the **Settings** icon (the gear). The Windows Settings screen appears (see [Figure 4-75](#)).



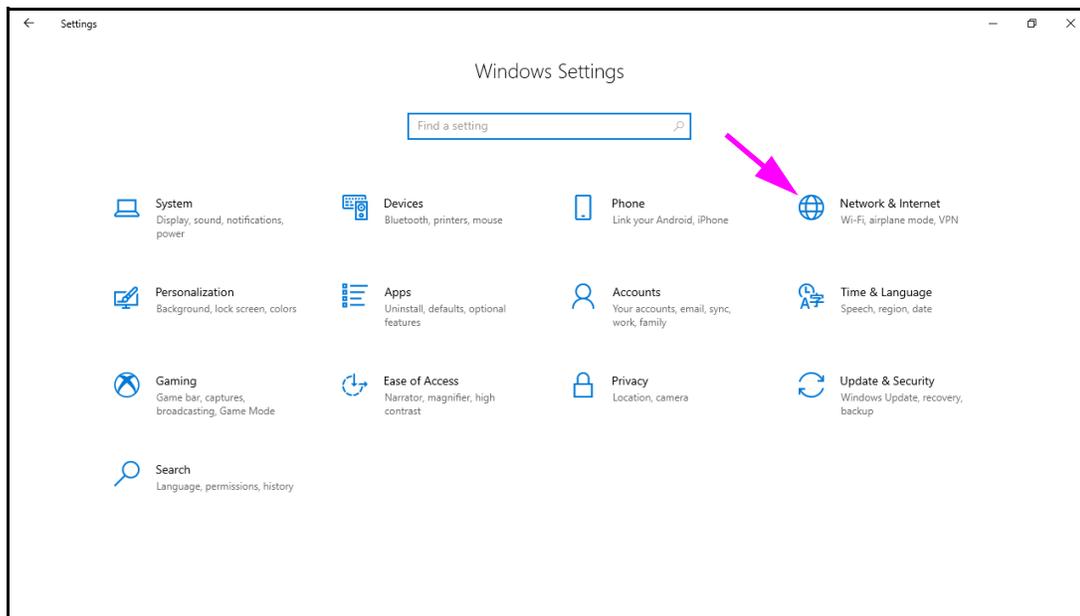


Figure 4-75. All Control Panel Items Window—Category View

4. Touch **Network & Internet**. The **Network & Internet** screen appears (see [Figure 4-76](#)).
5. Touch **Ethernet** on the left panel.

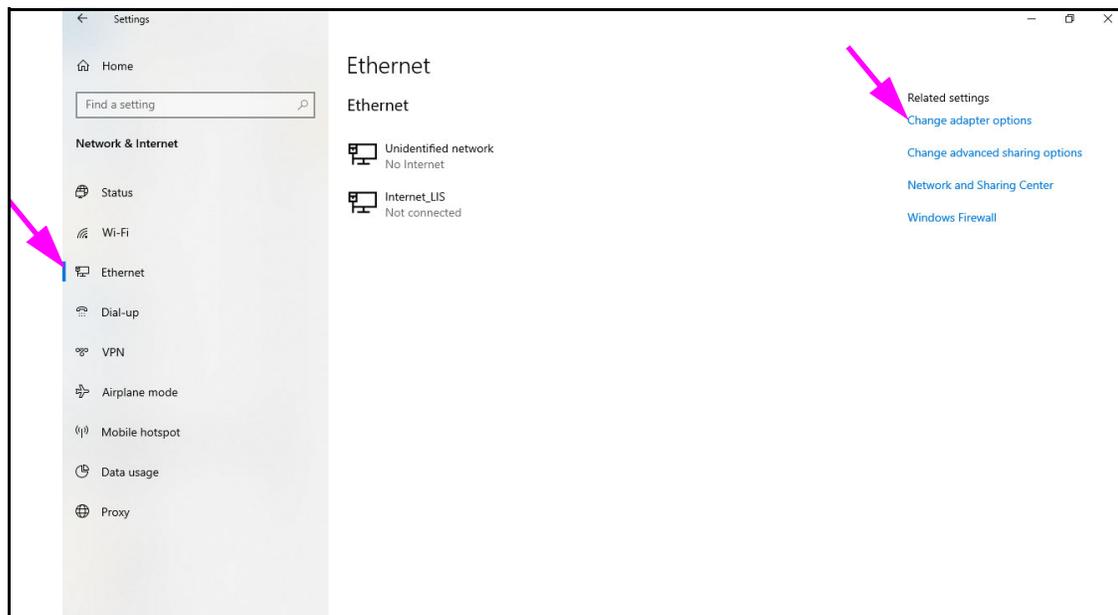


Figure 4-76. Network and Sharing Center Screen

6. Touch **Change Adapter Options** on the right panel (see [Figure 4-76](#)). The Network Connections screen appears (see [Figure 4-77](#)).

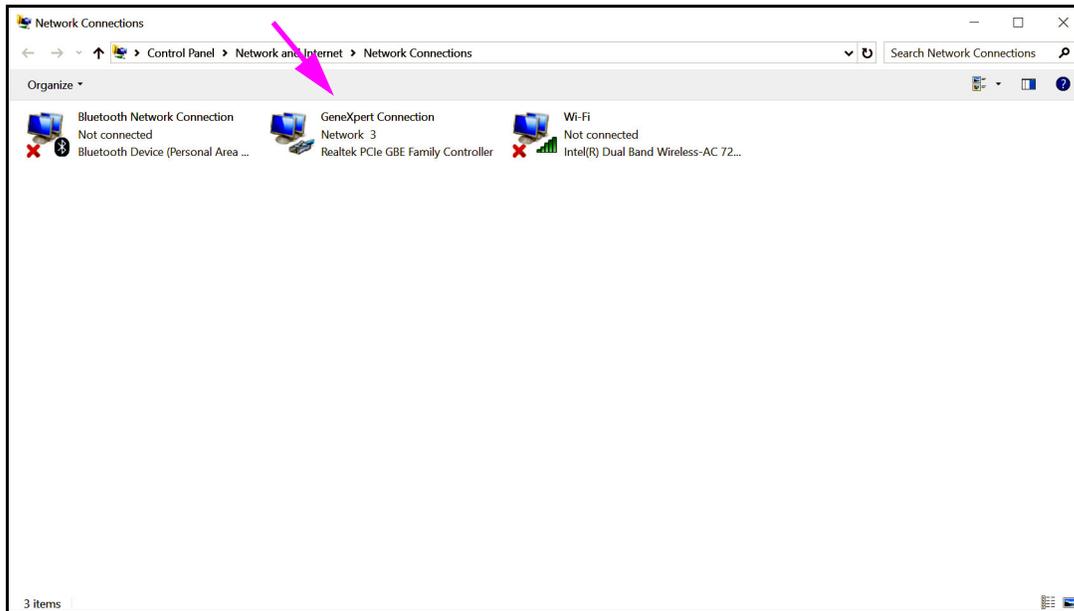


Figure 4-77. Network Connections Screen

7. Touch and hold the **GeneXpert Connection** entry. A drop-down menu appears (see Figure 4-78).

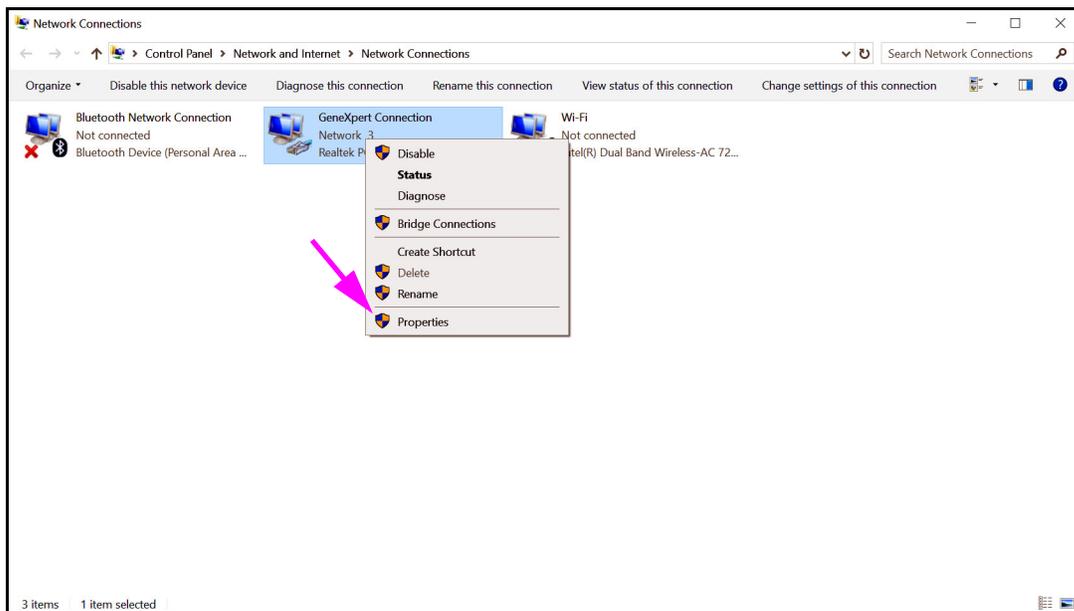


Figure 4-78. Network Connections Screen with Drop-Down Menu

8. Select **Properties** from the drop-down menu. The screen shown in Figure 4-79 is displayed.

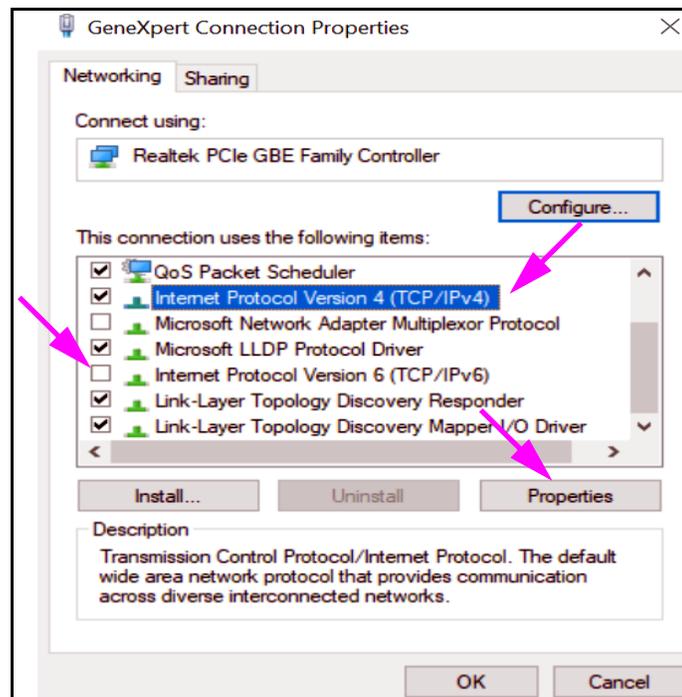


Figure 4-79. GeneXpert Connection Properties Screen

9. On the GeneXpert Connection Properties Screen (shown in [Figure 4-79](#)) uncheck the box next to **Internet Protocol Version 6 (TCP/IPv6)**. Touch **Internet Protocol Version 4 (TCP/IPv4)**, and then touch **Properties**. The Internet Protocol Version 4 (TCP/IPv4) Properties screen appears.

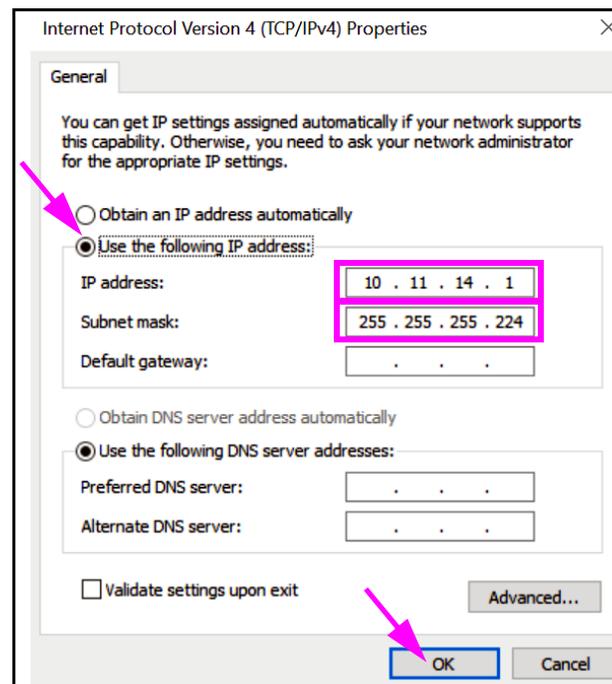


Figure 4-80. Internet Protocol Version 4 (TCP/IPv4) Properties Screen

10. On this screen, touch **Use the following IP address** (see [Figure 4-80](#)):
11. Enter:
IP Address: **10 . 11 . 14 . 1**
Subnet Mask: **255 . 255 . 255 . 224**
12. After you have verified that all numbers are entered correctly, touch **OK** to close the GeneXpert Connection Properties window.
13. Touch **Close** to close the GeneXpert Connection Properties window.
14. Touch the **X** in the right corner of the window to close the Control Panel window.
15. Return to the GeneXpert Xpress Home screen and touch the **User Menu** icon in the upper right corner of the screen to exit the software.
16. Restart the system.

4.10 Host (LIS) Management and Settings

4.10.1 Managing Host Orders

Use the Manage Host Orders screen to cancel or change the status of host orders.

On the Admin screen (see [Figure 4-81](#)), touch **MANAGE HOST ORDERS** to display the Manage Host Orders screen (see [Figure 4-82](#)).

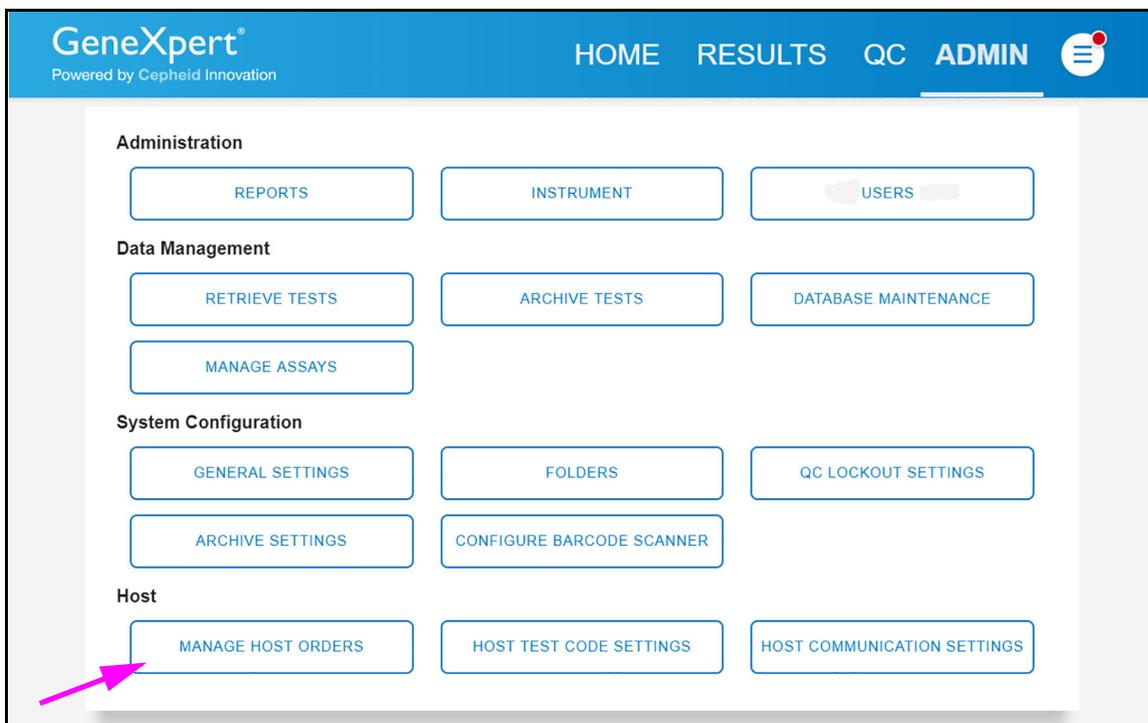


Figure 4-81. Admin Screen

On the Manage Host Orders screen, the administrator can perform a manual query of host orders, expired results (pending upload for tests that should no longer be uploaded to the host), reset the communications buffer (clear the data between the GeneXpert Xpress system and the host), cancel orders, and delete canceled orders (see [Figure 4-82](#)).

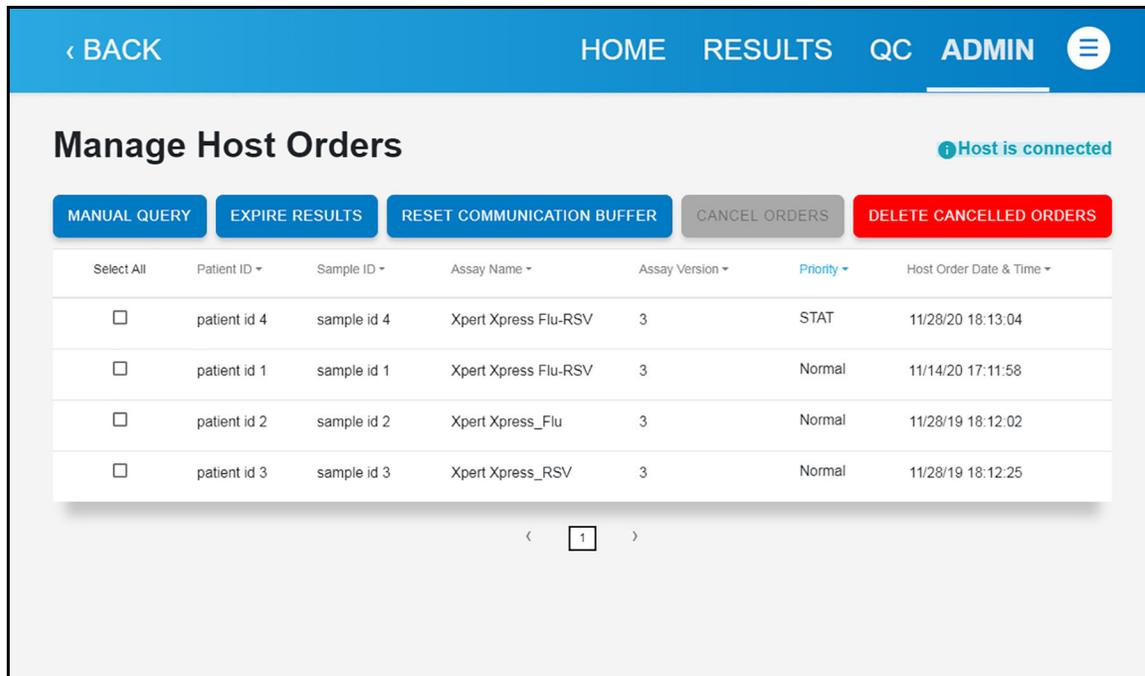


Figure 4-82. Manage Host Orders

The buttons on the Host Orders Screen are:

- **MANUAL QUERY**—Allows a manual query of the host for any new orders. During the manual query, the **MANUAL QUERY** button becomes the **ABORT QUERY** button. Wait until the query is completed or touch the **ABORT QUERY** button to cancel the operation.
- **EXPIRE RESULTS**—Touch to change **Upload - Pending** and **Review** to **Expired**.
- **CANCEL ORDERS**-Touch to flag the selected orders for cancellation.
- **RESET COMMUNICATION BUFFER**—To clear the data between the GeneXpert Xpress and the host. This is useful to remove data during host communication testing.
- **DELETE CANCELLED ORDERS**—Touch to delete the flagged canceled orders. This is useful to remove redundant orders during host communication testing.

4.10.2 Host Test Code Settings

Use the Host Test Code Settings screen for configuring the Host Test Codes used by your LIS system.

On the Admin screen (see Figure 4-83), touch **HOST TEST CODE SETTINGS** to display the Host Test Code Settings screen (see Figure 4-84).

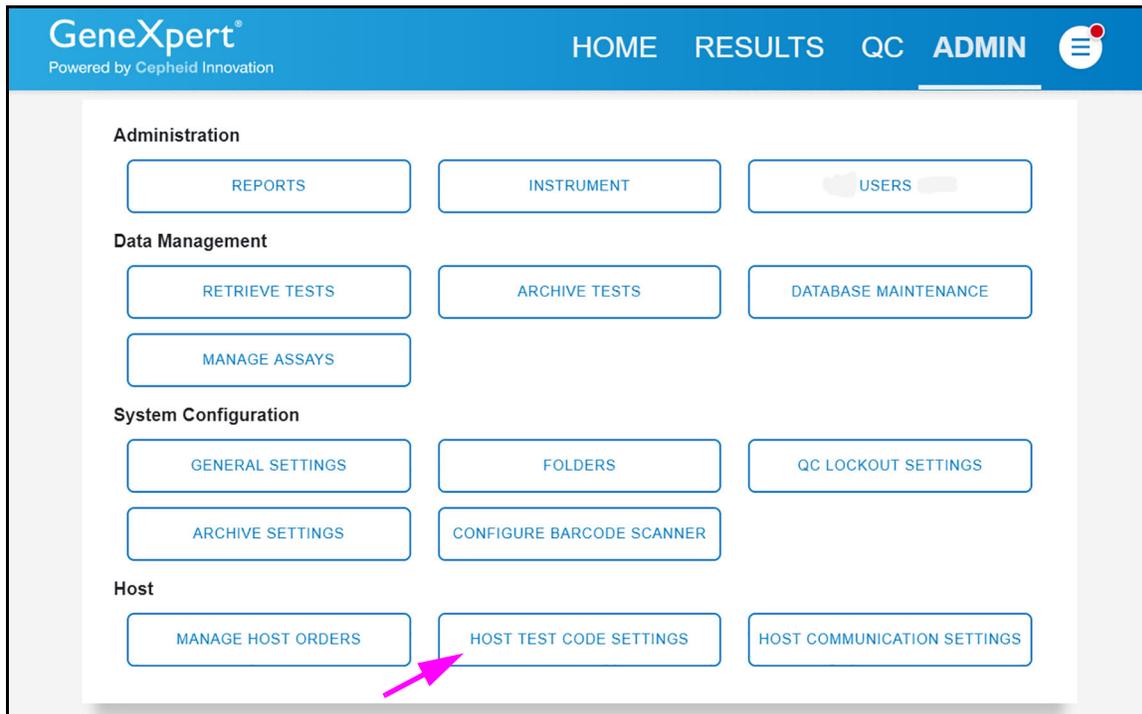


Figure 4-83. Admin Screen

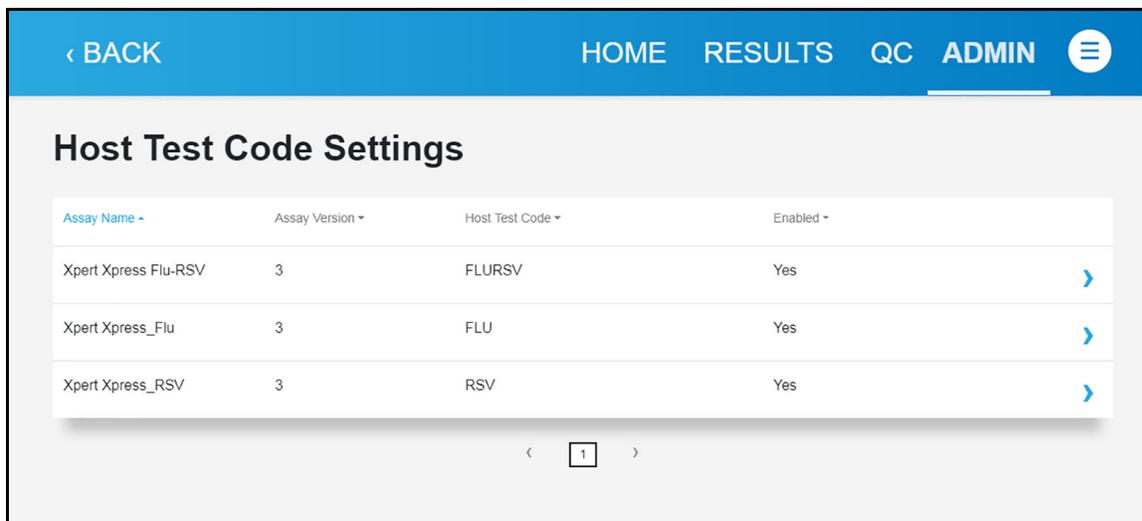


Figure 4-84. Host Test Code Settings

4.10.2.1 Using the Host Test Code Screen

This screen allows the host administrator to type in the test code that was entered into the host, so it can be translated into the GeneXpert Xpress system for test order processing and result reporting.

- **Enabled**—Indicates if the assay has been set up for test order download and result reporting.
- **Assay Name**—Assay name available for host connectivity.
- **Assay Version**—Assay version available for host connectivity.
- **Host Test Code**—the test code which the host used for download of test order and upload of test result.

Important

You cannot edit the test code for old versions of an assay. If you update the test code, the update will only apply to the new version of the assay; therefore, you must change the test code before upgrading an assay.

Caution



Be careful to not use the same test code for tests from two different assays.

Touch **CONFIRM** to save the changes. Close the screen.

4.10.3 Host Communication Settings

The Host Communications Settings screen displays the current communication settings which can be changed, if needed.

On the Admin screen (see [Figure 4-83](#)) touch **HOST COMMUNICATIONS SETTINGS** to display the Host Communications Settings screen (see [Figure 4-86](#)).

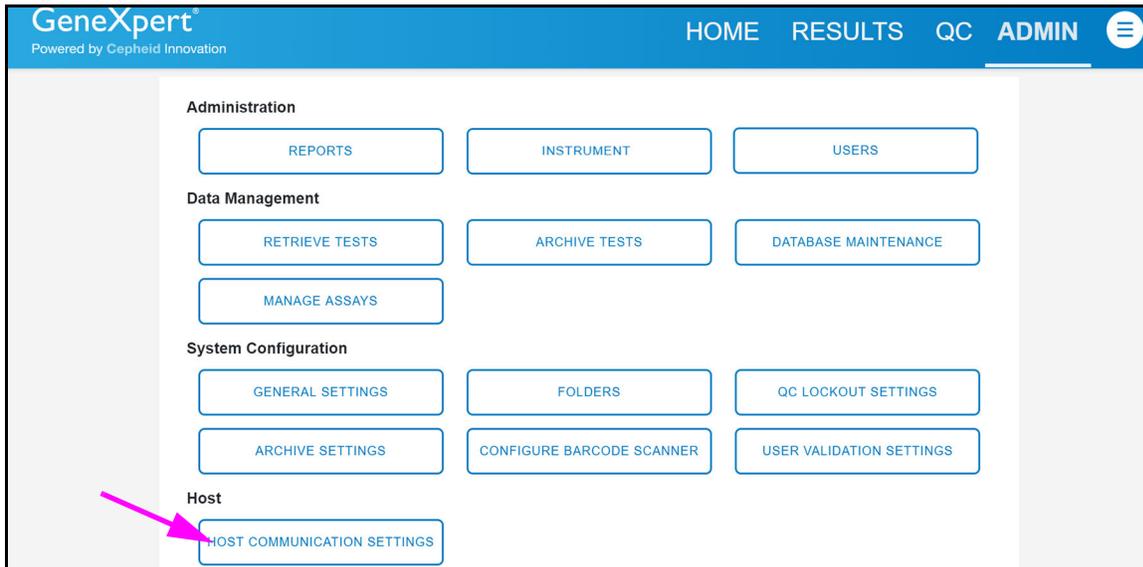


Figure 4-85. Admin Screen

On the Host Communications screen, the administrator can enable or disable host LIS or Data Manager communication, set up communication settings including changing the host ID name, changing protocol between HL7 and ASTM, POCT01, and choose to run Xpress as either a server or client, as described below.

In addition, settings are provided for automatic host Query after Sample ID scan, automatic test order downloading and result uploading, and choosing instrument specimen identification.

The Host Communications screen also displays the server IP address and port settings. To change any of these setting, touch **EDIT**, make any changes, and touch **CONFIRM** when you are done (see [Figure 4-86](#)). For assistance, call Cepheid Technical support. See the Technical Assistance section in the [Preface](#) for the contact information.

When a Host is connected, the status in the right side of the screen will display in blue that a Host is Connected (see [Figure 4-86](#)). If the Host is disconnected, the display will appear in red stating that the Host is disconnected (see [Figure 4-87](#)). If this is unexpected, please see [Section 5.19](#).

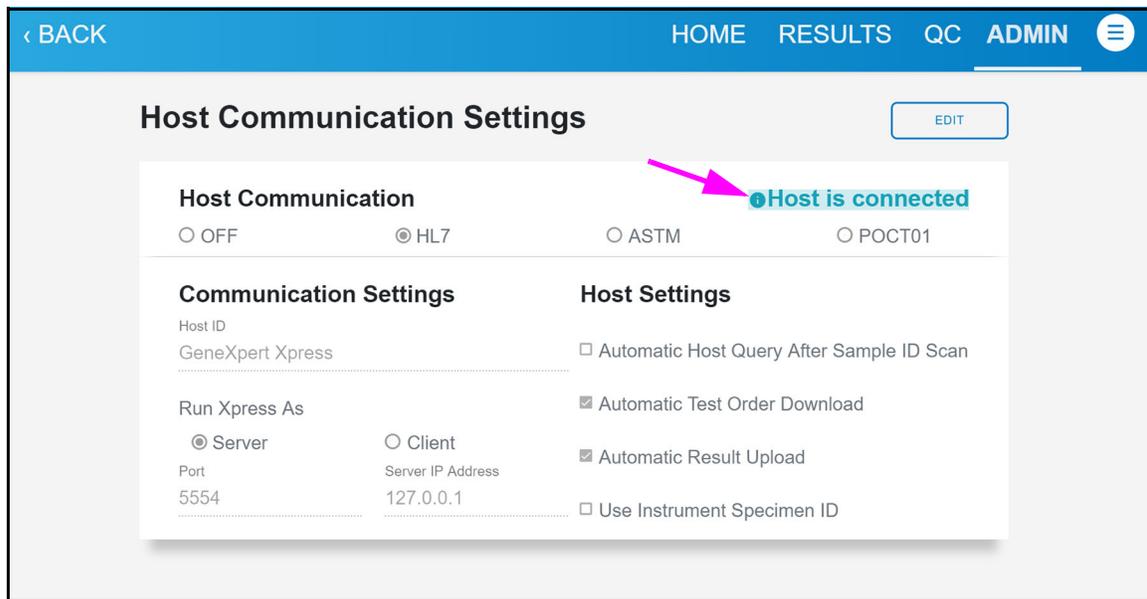


Figure 4-86. Host Communications Settings - Host is Connected

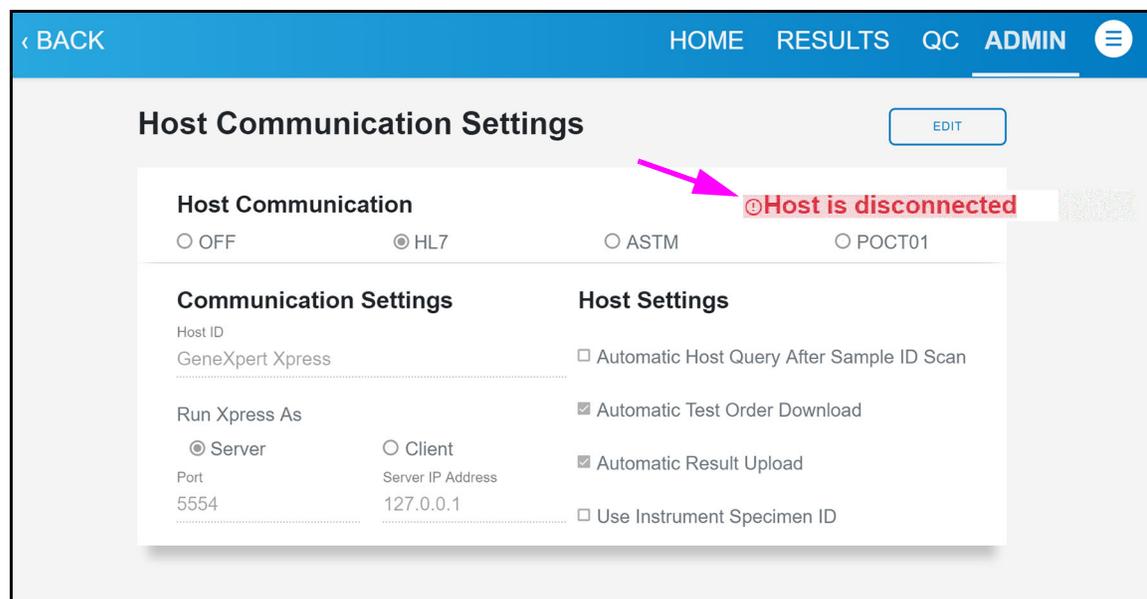


Figure 4-87. Host Communications Settings - Host is Disconnected

Note

If the LIS is being enabled on a new system, there will be no assays shown.

Caution



Within the hospital or laboratory network, each GeneXpert Xpress system should have a unique system name, which is used for host communication. The System Administrator should control the process for defining system names.

Host (LIS) Settings Descriptions

Use the following settings to configure the communication between the GeneXpert Xpress software and a Laboratory Information System (LIS):

Host Communication

- **Enable Host Communication**—Select to enable the GeneXpert Xpress software connected to a host. Clear to disable the host communication.

Host Settings

- **Automatic Host Query After Sample ID Scan**—Select to enable the GeneXpert Xpress system to query for test orders associated with the scanned or entered Sample ID.
- **Automatic Test Order Download**—Select to enable the GeneXpert Xpress system to periodically query all test orders from the host.

Caution



If the Host is connected to multiple GeneXpert Xpress systems, you may want to:

- **Use Automatic Host Query After Sample ID Scan instead of Automatic Test Order Download to minimize duplicate orders to multiple GeneXpert Xpress systems.**
 - **The host should download order to a specific GeneXpert Xpress system.**
 - **If orders are sent to multiple GeneXpert Xpress systems, the host should cancel pending orders when completed result is received.**
-

- **Automatic Result Upload**—As soon as the test is completed, the results are uploaded.
 - **Use Instrument Specimen ID**—Select to enable the GeneXpert Xpress system to generate a unique specimen ID, which is returned to the host. The Instrument Specimen ID is a unique ID for this sample. It should be stored in the host and used for future communication for this sample. This option is applicable if the facility does not provide unique sample identification.
If the facility provides unique sample identification, this setting should be disabled.
 - **Communication Settings**—Select or clear the following check boxes:
 - **Protocol**—Select **HL7**—compatible or **ASTM**—compatible protocol.
-

Note

HL7 or ASTM protocols can be used to connect to data manager software for test orders and result entry only.

- **Run Xpress As** - radio button with options: Server and Client (default).
 - **Server IP Address**—Only integers and characters are allowed. The system only accepts valid IPv4 addresses (Format #.#.#.#). Required field.
 - **Port #**—The port number is between 1024 to 65535 with default as blank. Entries in this field will always be ASCII numeric. Required field.
-

Caution



The network port that is dedicated for the GeneXpert Xpress GX-IV instrument should not be used for the host connection. The second NIC available on each GeneXpert Xpress computer should be used to connect the GeneXpert Xpress system to the host.

- **Host ID**— Type in a unique host name to identify an LIS or Data Management system (DM) that is connected to the GeneXpert Xpress system. The maximum number of characters is 20.

Host (POCT) Communication Settings Descriptions

Use the following settings to configure the communication between the GeneXpert Xpress software and a Laboratory Information System (LIS):

- **Host Communication**
 - **Enable Host Communication**—Select to enable the GeneXpert Xpress software connected to a host. Clear to disable the host communication.

The status of the last host communication is displayed on the right side of the Host Communications Screen (see [Figure 4-88](#)). This Status will state when the last host communication was successful, and can be useful in determining if ongoing communication is successful. If this status displays that the host communication was not successful, please see [Section 5.19.1](#) for LIS troubleshooting.

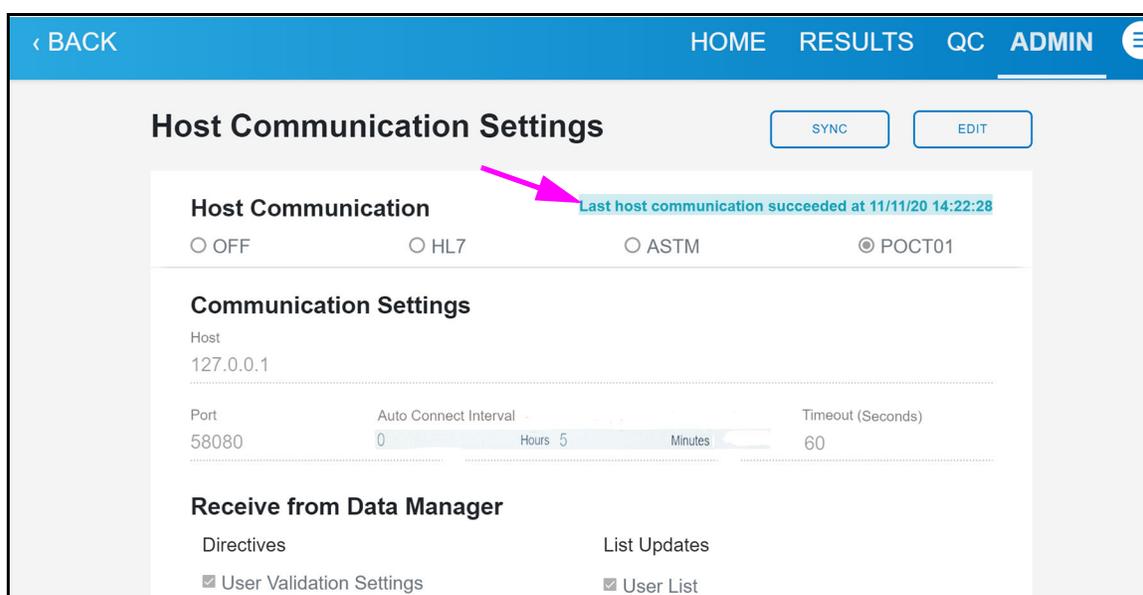


Figure 4-88. Host Communications Settings - Last Communication Message

- **Communication Settings**—Select or clear the following check boxes:
 - **Host ID**— Type in a unique host name to identify a Data Management system (DM) that is connected to the GeneXpert Xpress system. The maximum number of characters is 20.
 - **Port #**—The port number is between 1024 to 65535 with default as blank. Entries in this field will always be ASCII numeric. Required field.

Caution



The network port that is dedicated for the GeneXpert Xpress GX-IV instrument should not be used for the host connection. The second NIC available on each GeneXpert Xpress computer should be used to connect the GeneXpert Xpress system to the host.

- **Auto Connect Interval**— The Auto Connect Interval sets the time interval used by the GeneXpert Xpress system to automatically reach out to the Data Management System to receive data. The Auto Connect Interval default is one hour. The interval range can be adjusted to between 5 minutes and 24 hours.
- **Timeout** - The Timeout is how much time the GeneXpert Xpress will use when attempting to communicate with the Data Management System. The Timeout default is 60 seconds, and the timeout range can be adjusted to between 30 and 60 seconds before the communication is terminated.
- **Receive from Data Manager** - Select the following to receive data from the Data Management System
 - **User Validation Settings** - When this is selected, the GeneXpert Xpress can receive User Validation Settings from the Data Management System. See [Section 4.5.5.2](#) for a description of the three User Validation Settings.
 - **User List** - When this is selected the GeneXpert Xpress can receive the User List (which includes the name and expiration status of each user) from the Data Management system. The User List will be automatically downloaded at the interval shown in the **Auto Connect Interval** field. To override this preset time interval and receive the User List on demand, touch the **SYNC** button on the Host Communication Settings screen

Caution



Do not use **Reset Communication Buffer** (discussed below) during normal operation; otherwise, you will have to re-download orders and re-upload results.

4.11 Operating with Host (LIS) Connectivity (Admin Only)

This section provides instructions on how to use the GeneXpert Xpress system host interface to:

- Create a test from a downloaded test order and upload the result (see [Section 4.11.1](#))
- Upload a test result ([Section 4.11.2, Uploading a Test Result to the Host](#))
- Troubleshoot Host Connectivity ([Section 5.19.1, User Lockout Problems](#))

Caution



Cepheid recommends to always confirm that LIS uploaded results match GeneXpert Xpress test results after any changes to the GeneXpert Xpress or host system, including (but not limited to) changes to the following:

- GeneXpert Xpress software version
- GeneXpert Xpress Host Communication Settings
- Host middleware software or configuration changes
- LIS software or configuration changes

4.11.1 Creating a Test with Host Connectivity

When host connectivity is enabled, the GeneXpert Xpress system periodically requests new orders, and test orders can be automatically downloaded from the host.

An Admin can perform manual queries of new orders from the Manage Host Orders screen and can also view new test orders from the Manage Host Orders screen which have been automatically downloaded from the host.

Any user can scan or manually enter the Sample ID to perform host query for orders for a specific Sample ID.

The workflow in your laboratory will determine how a test is created.

Select Host Order Screen

When any user scans a sample and the order is in the system, the Select Host Order screen appears (see [Figure 4-89](#)), and the host order appears on the screen.

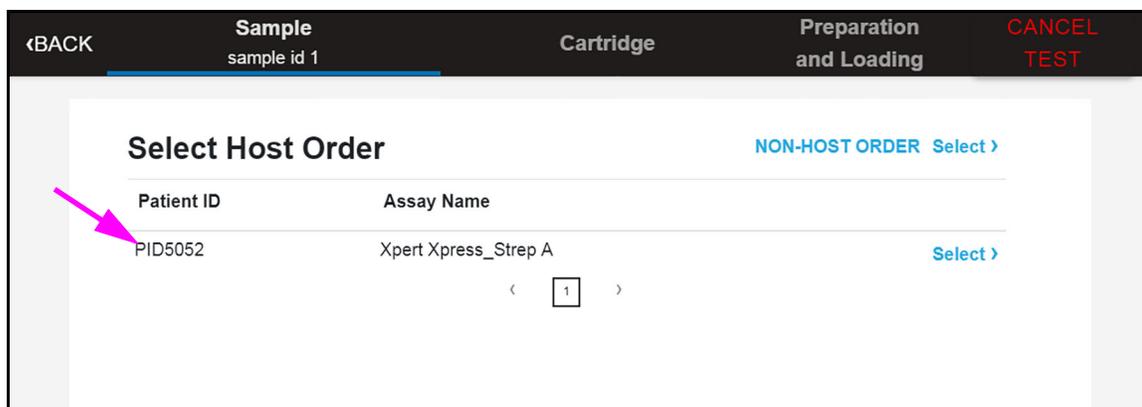


Figure 4-89. Select Host Order Screen

Manage Host Orders Screen

To perform a manual query of Host Orders, touch **ADMIN** on the Home screen, and the Administration screen appears. Touch **MANAGE HOST ORDERS** at the bottom of the screen, and the Manage Host Orders screen appears (see [Figure 4-90](#)).

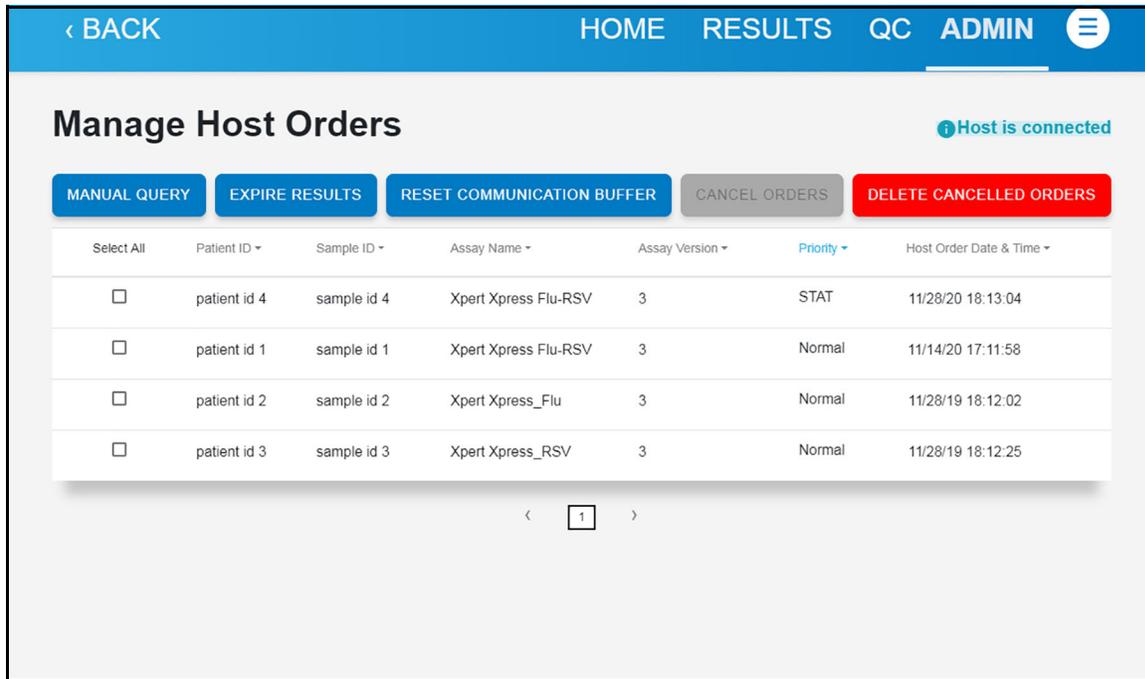


Figure 4-90. Manage Host Orders Screen

- **Patient ID**—Patient ID for each test order (If **Use Patent ID** is configured).
- **Sample ID**—Sample ID for each test order.
- **Assay Name**—Assay name for each test order.
- **Assay Version**—Assay version number for each test order.
- **Priority**—Indicates whether it is **STAT** priority or **Normal** priority.
- **Host Order Date & Time**—Date and Time downloaded by the host or created by the GeneXpert Xpress as date and time received.
- **CANCEL ORDERS** button—Flags a selected order for cancellation.
- **DELETE CANCELLED ORDERS** button—Deletes the flagged order(s).
- **EXPIRE RESULTS** button—Changes **Upload - Pending** and **Review** to **Expired**.
- **MANUAL QUERY** button—Allows manual query of the host for any available new orders.

Note

To accept an order from the host, the test code for the assay must be set up by the host administrator. See [Section 4.10.2, Host Test Code Settings](#) for details.

4.11.1.1 Creating a Test by Selecting from a List of Test Orders Downloaded by the Host Automatically

1. In the **Host Communication Settings** tab of the System Configuration dialog, touch **Automatic Test Order Download** check box to select and enable this function. See [Figure 4-91](#).

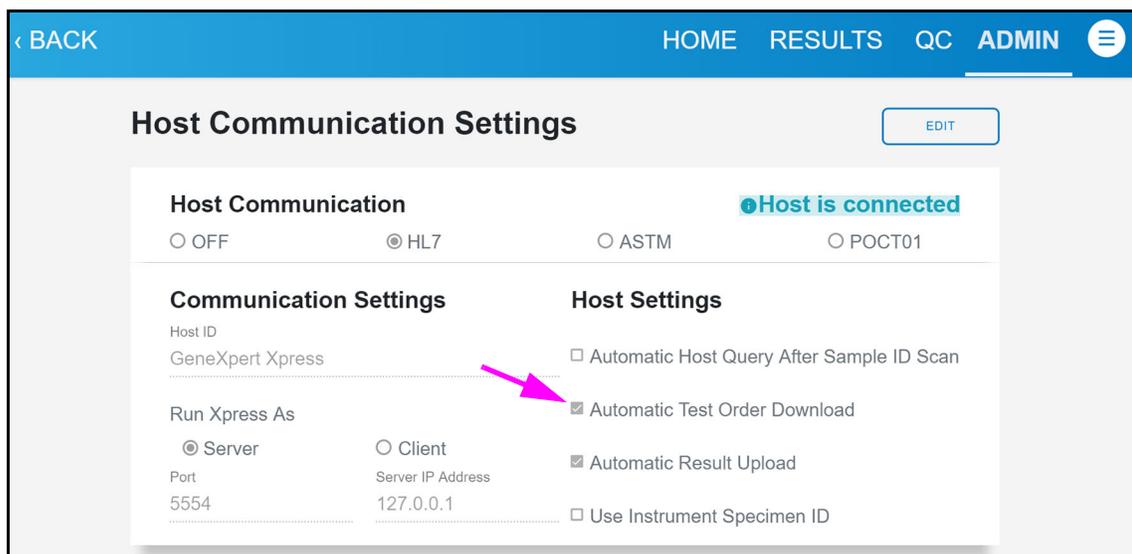


Figure 4-91. Automatic Test Order Download Selected

- The GeneXpert Xpress periodically queries all test orders from the host. The period is fixed in the software as 1 minute.

Note

If there are test orders from the host, there should be samples on hand for the tests ordered.

2. On the GeneXpert Xpress Home screen, touch **NEW TEST**.
3. Scan or enter the optional Patient ID, Patient ID 2, Patient Name, if enabled.

Do not use the following symbols in this area: | @ ^ ~ \ & / : * ? " < > ' \$ % ! ; () - .

If invalid characters are manually entered or scanned, there will be a software notification to the user (see [Section 3.3.2.1](#)).

The Scan Sample ID Barcode screen appears.

4. Scan the Sample ID barcode on the specimen container using the barcode scanner, as described in [Section 3.3.3.1](#)).
5. The Select Host Order screen appears, showing the test order corresponding to the Sample ID scanned. Select the order by touching **Select** on the right side of the screen (see [Figure 4-92](#)).

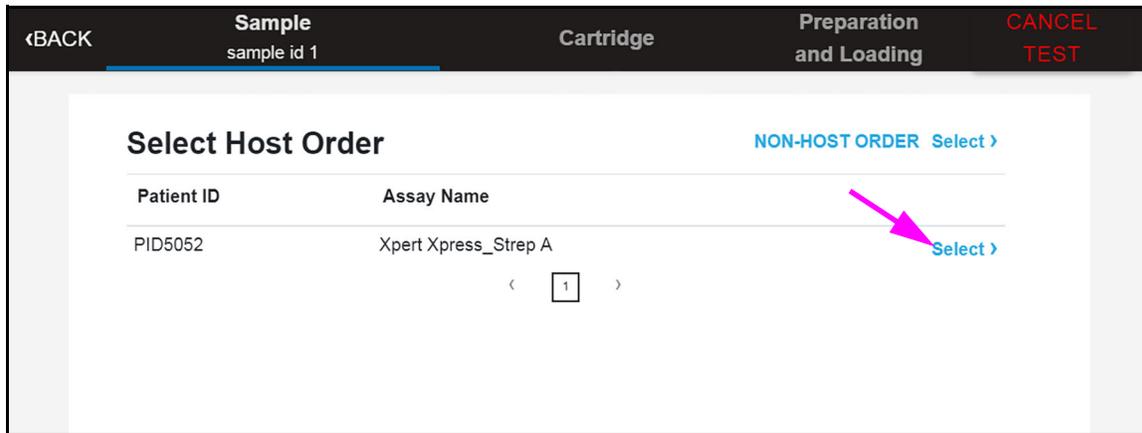


Figure 4-92. Select Host Order Screen

6. The Scan Cartridge Barcode screen will automatically display a prompt to scan the barcode on the cartridge. This confirms that the correct assay will be run. Reagent lot ID, expiration date, and cartridge serial number are processed. See [Section 3.3.4](#) for instructions on scanning a cartridge barcode.
7. The order for this Patient ID and Sample ID will be removed from the list of new orders.
8. Insert the cartridge with the specimen and reagents according to the assay-specific package insert.
9. Load the cartridge, and close the module door by performing the steps starting with [Section 3.3.5](#).

Note

You cannot change the Patient ID, Patient ID 2, Patient Name, Sample ID, or the assay if it is selected from a host downloaded test order.

4.11.1.2 Creating a Test by Manually Requesting Test Orders and Selecting From the List of Test Orders

You can manually request new test orders from the host by touching the **Manual Query** button on the Manage Host Orders screen. After orders are downloaded from the host, proceed as instructed in [Section 4.11.1.1, Creating a Test by Selecting from a List of Test Orders Downloaded by the Host Automatically](#).

4.11.1.3 Creating a Test by Querying the Host with Sample ID

1. In the **Host Communication Settings** tab of the System Configuration dialog, the Admin must touch the **Automatic Host Query After Sample ID Scan** check box to select and enable this function. See [Figure 4-93](#).
When this function is checked and later, if a new test is started, when the **Sample ID** is scanned (or entered), the data manager will be queried. If an existing test order is found by the data manager, the test order will be automatically downloaded from the LIS to the Xpress system for processing.

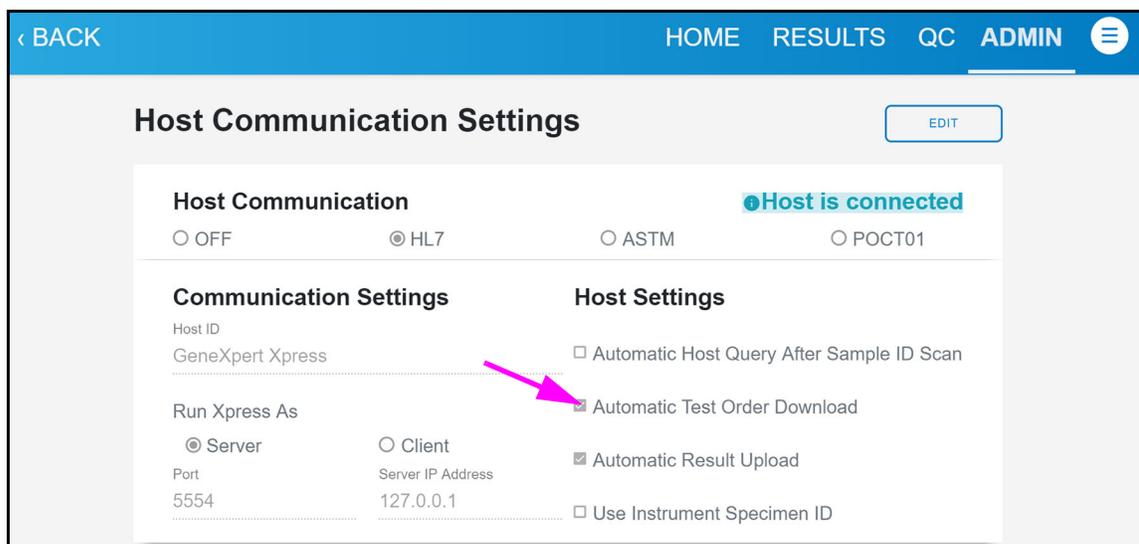


Figure 4-93. Select Host Query

2. On the GeneXpert Xpress Home screen, touch **NEW TEST**. Depending on the setup, the Scan Sample ID Barcode screen appears (see [Section 3.3.3](#)).
3. Scan the sample ID barcode on the specimen container (see [Figure 3-10](#)).
4. Test orders for this Sample ID are downloaded from the host and are displayed in the **Select Host Order** screen which can be sorted by touching the header.

Note Other downloaded orders for different samples will not be displayed in the order table.

5. Select an order from the table. This will select the assay according to the test order.

Note If only one order matches the given Sample ID, this order will be automatically displayed.

6. The Scan Cartridge Barcode screen will automatically display a prompt to scan the barcode on the cartridge. This confirms that the correct assay will be run. Reagent lot ID, expiration date, and cartridge serial number are processed. See [Section 3.3.4](#) for instructions on scanning a cartridge barcode.

The order for this Patient ID and Sample ID will be removed from the list of new orders.

7. Insert the cartridge with the specimen and reagents according to the assay-specific package insert.
8. Load the cartridge, and close the module door by performing the steps starting with [Section 3.3.5](#).

4.11.1.4 Aborting a Query

During the Manual Query, the user touches the Manual Query button and the application queries the LIS for all new orders (see [Figure 4-94](#)).

While the query is being performed, the button shall change to be **ABORT QUERY**.

If the query completes normally, the database's LIS test orders shall be updated appropriately, with valid new orders being inserted and valid cancellations applied. The button shall return to **MANUAL QUERY** button.

To start a test or close the dialog box, wait until the query is completed or touch the **Abort Query** button to cancel the operation.

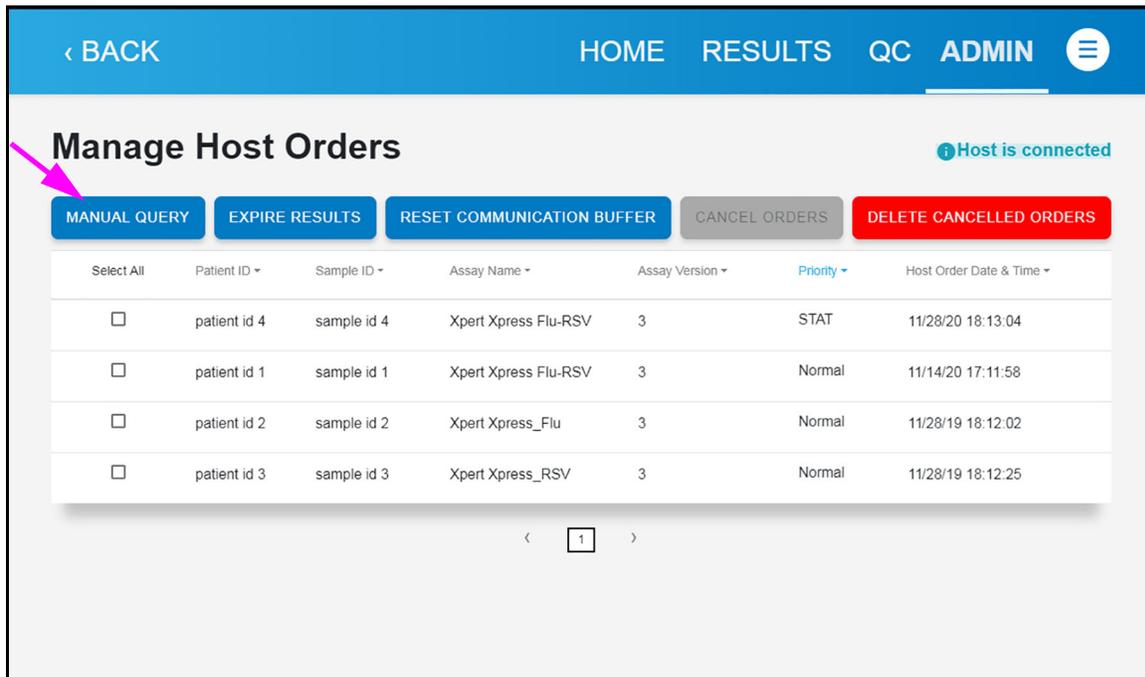


Figure 4-94. Manage Host Orders Screen, showing the Manual/Abort Query Button

4.11.1.5 Deleting a Host Downloaded Test Order

Occasionally, you may need to delete an order downloaded from the host.

1. Select individual orders from the Manage Host Orders screen using the check boxes at the left of the order, or **Select All** in the far left heading to select every order on the screen (see [Figure 4-95](#)).
2. Touch the **CANCEL ORDERS** button.

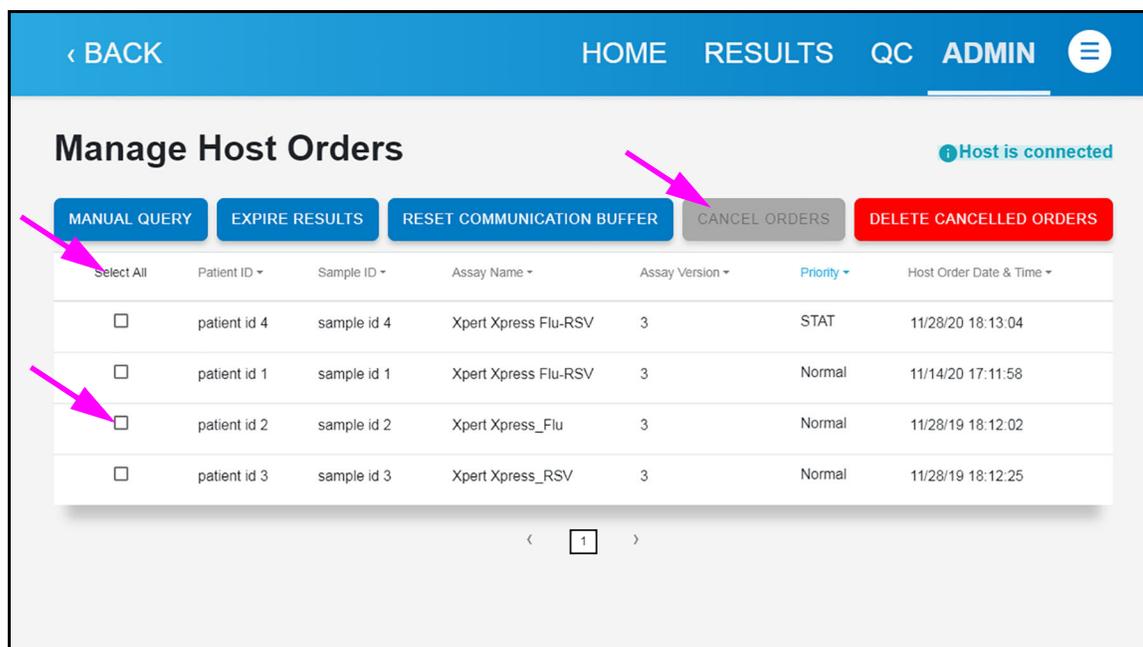


Figure 4-95. Deleting a Host Downloaded Test Order

3. A new screen appears. You have the option of deleting canceled host orders that are more than 6 days old, or deleting all canceled host orders. Select a delete option and touch **OK** or **CANCEL**.

4.11.2 Uploading a Test Result to the Host

Test results can be uploaded to the host either automatically or manually.

Note Be aware that only Patient Results, Quality Control Results and Proficiency Test Results can be auto-uploaded when POCT01 or LIS are enabled.

4.11.2.1 Switching Protocols - Resulting Upload Behavior

This section describes the behavior when a user switches from one protocol to another (HL7/ASTM to POCT or from POCT to HL7/ASTM).

- If a test is run and HL7 or ASTM is turned off and then turned on:
 - If the test has a host code it can be manually uploaded.
 - if the host code is not defined, it cannot be uploaded to the LIS.
- If a test is run while HL7 or ASTM is turned on and then is switched to POCT01, the test result will be automatically uploaded to the data manager.
- If a test is run with no protocol selected, and then POCT01 is switched on, the result can be **manually** uploaded but will not be **automatically** uploaded.

4.11.2.2 Automatically Uploading the Test Result to the Host

1. In the **Host Communication Settings** tab of the System Configuration dialog, touch **EDIT** and select the **Automatic Result Upload** check box so the result will be uploaded as soon as the test is completed. See [Figure 4-96](#).

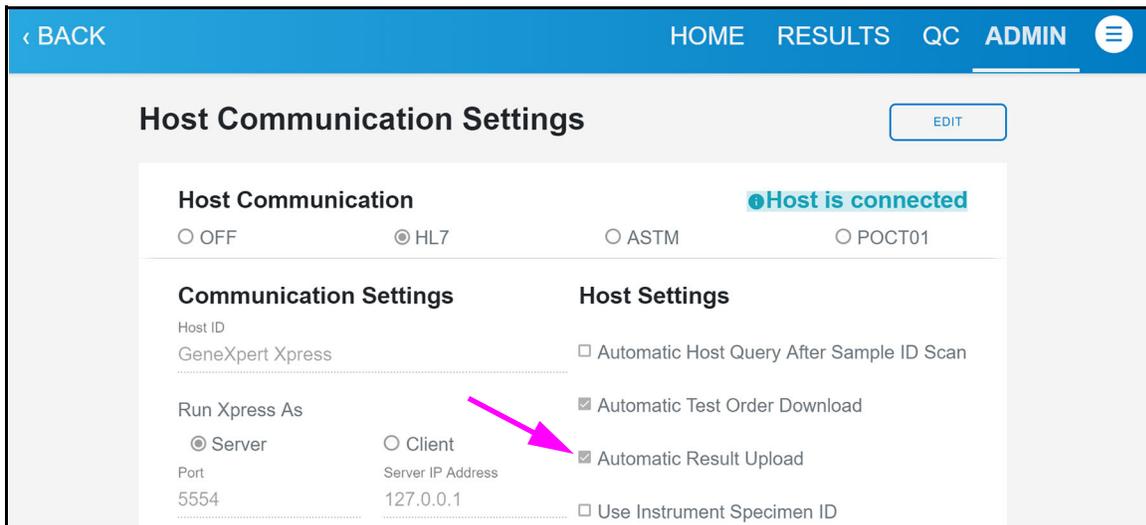


Figure 4-96. Automatic Result Upload

2. After the test is completed, the result will be automatically uploaded. The Upload Status is shown in the Test Information area of the View Result window (see [Figure 4-97](#)).

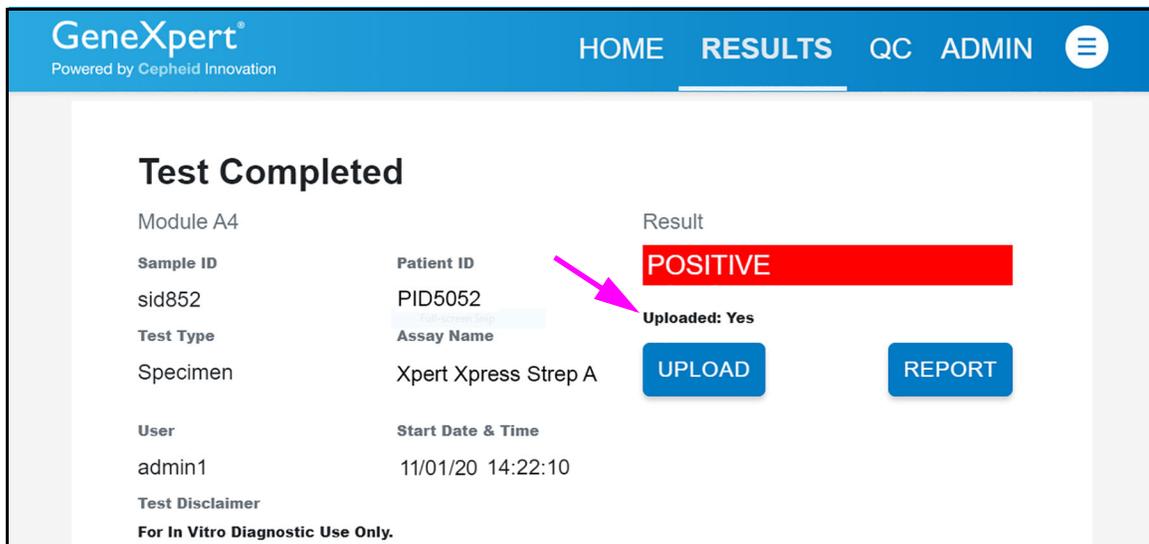


Figure 4-97. Test Upload Status shown on the Test Completed Screen

4.11.2.3 Manually Uploading a Test Result to the Host

Touch **UPLOAD** on the Test Completed screen (see Figure 4-97). The individual test result will be uploaded to the host, then on to the LIS. The test result will then appear on the patient chart or record (see Figure 4-98).

Note

You can manually upload a test result even if **Automatic Result Upload** is enabled.

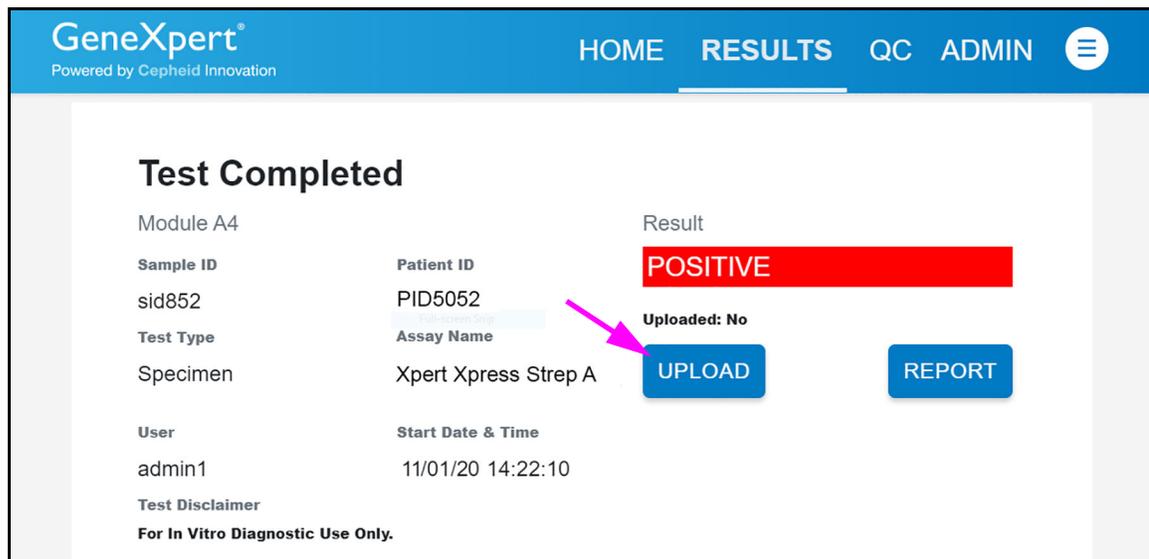


Figure 4-98. Touch **UPLOAD** to Upload the Test Result to the Host

The possible host uploaded statuses are:

- **Uploaded: No**—this result has not been uploaded.
- **Uploaded: Yes**—this result has been received by the host.

Note If an attempt to exit the software is made with results in the uploading status, the software will alert the user.

Note Each test can be uploaded individually from the Test Completed screen.

4.11.2.4 Uploading a QC Result to the Host

Results that are automatically uploaded (only when POCT01 is enabled, not HL7 or ASTM) include patient results, Quality Control (QC) results and Proficiency Test (PT) results.

Regardless of the setting for **Automatic Result Upload**, a QC result must be manually uploaded. See [Section 4.11.2.3, Manually Uploading a Test Result to the Host](#).

Note If there are problems with host connectivity, see [Section 5.19, Troubleshooting](#) and [Section 5.19.1, User Lockout Problems](#).

4.12 Disk Encryption

This section provides information about enabling BitLocker Drive Encryption on the Xpress system.

BitLocker is an encryption system designed to prevent most offline attacks and malware. It is essential for you to use this feature to protect your data and keep confidential information secure. The procedure for Enabling BitLocker Drive Encryption in Windows 10 is included below.

Note Before you begin, please be aware that encrypting your entire hard disk can be a long process. You will be able to use your computer while encryption takes place in the background, but you will eventually need to restart your computer. Save files frequently and plan accordingly.

Note Cepheid has validated BitLocker disk encryption on GeneXpert computers running Windows 10. Customers are responsible for enabling BitLocker and setting the recovery key.

Depending on whether or not your system has a Trusted Platform Module (TPM) installed, use one of the two procedures shown below:

Systems without a Trusted Platform Module

If your system does not include a Trusted Platform Module (TPM) chip, you will not be able to turn on BitLocker in Windows 10. You can still use encryption, but you will need to use the Local Group Policy Editor to enable additional authentication at startup. Follow the steps in this section to set up encryption.

1. Touch and hold the **Windows** button. When the menu appears, touch the **Run** button. A dialog box opens. Touch the entry field and the virtual keyboard appears. In the Windows dialog box type **gpedit.msc** and touch **OK**.
2. Under Computer Configuration, expand **Administrative Templates**.

3. Expand **Windows Components**.
4. Expand **BitLocker Drive Encryption** and **Operating System Drives**.
5. On the right side, touch and hold **Require additional authentication at startup**.
6. Touch **Enabled**.
7. Touch to check the **Allow BitLocker without a compatible TPM (requires a password or a startup key on a USB flash drive)** option.
8. Touch **OK** to complete this process.

System with a Trusted Platform Module

If your system includes a Trusted Platform Module (TPM) , follow the steps in this section to set up encryption.

1. From the Windows desktop, touch **Start>Windows System>File Explorer>This PC**. (see Figure 4-98).
2. Touch and hold **Devices and drives** (see Figure 4-98).

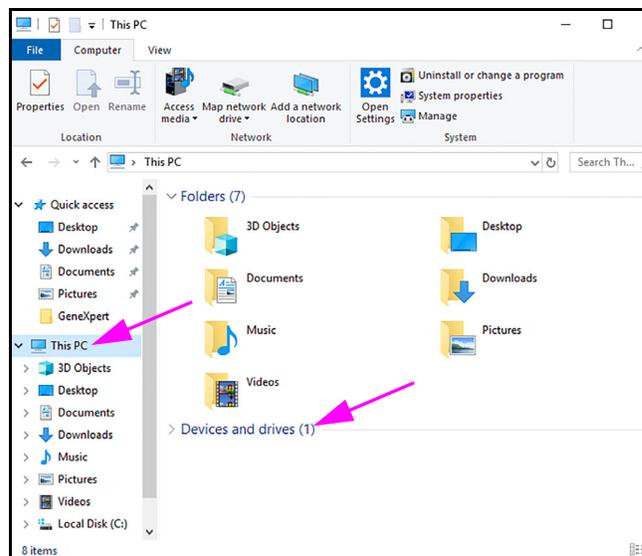


Figure 4-99. Start Menu with This PC Selected

3. When the menu appears, touch **Turn on BitLocker** (see Figure 4-100).

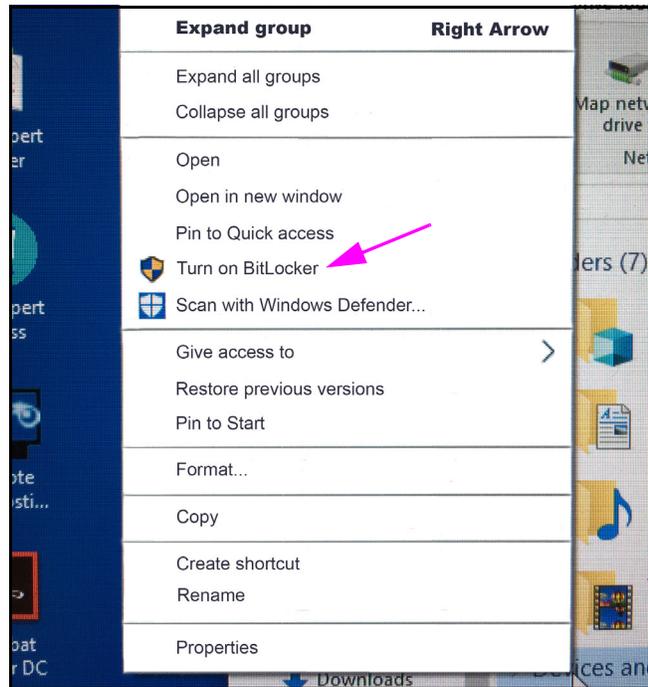


Figure 4-100. Turn on BitLocker Selected

4. The BitLocker configuration screen appears. Insert a flash drive into an open USB port.
5. Touch **Enter a password** to unlock your drive (see Figure 4-100). This is important to ensure you can boot the system even if you lose the recovery key.

Note

Cepheid recommends a password of 10 characters minimum with a combination of upper/lower case letters, numbers, and symbols.

6. Save the recovery key to the USB flash drive and print the recovery key.
7. Remove and safely store the USB flash drive. Archive the recovery key with your IT department.

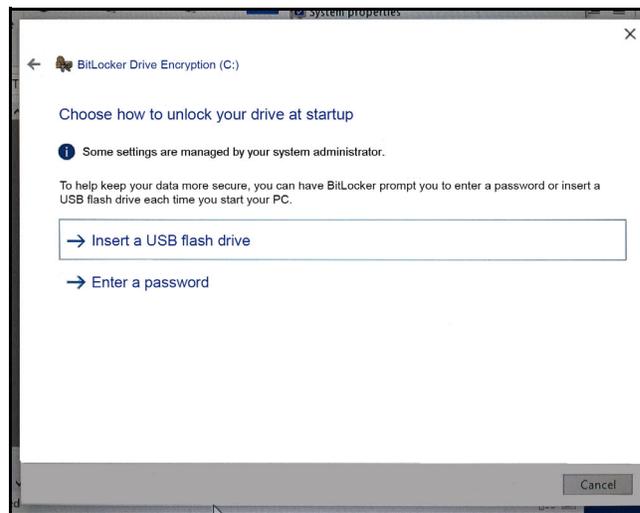


Figure 4-101. Choose Unlock Method for Flash Drive

Important

If BitLocker is enabled, it is the customer's responsibility to maintain the recovery key if it is forgotten or misplaced. For more information, visit <https://www.microsoft.com>.

8. Select by touching **New encryption mode** (recommended for the fixed drive on the Xpress hub system).
9. Touch to check the box next to **Run BitLocker system check**.
10. Restart your computer.
11. Enter your password when prompted.
12. After logging into Windows, you can check the status of encryption as follows:
 - A. Touch **Start > File Explorer > This PC**.
A padlock emblem now appears on the system drive.
 - B. Select the drive by touching and hold the drive, then touch **Manage BitLocker**.
 - C. Confirm the current status, which should be **C: BitLocker Encrypting**

Note

You can continue using your computer while encryption takes place in the background. You will be notified when it is complete.

Once BitLocker Encryption is finished, all content and communications will be secured.

5 Maintenance

This chapter describes the maintenance to be performed on the GeneXpert Xpress system. The topics are:

- [Section 5.1, Maintenance Tasks](#)
- [Section 5.2, Maintenance Log](#)
- [Section 5.3, Power Down the System](#)
- [Section 5.4, Guidelines for Cleaning and Disinfecting](#)
- [Section 5.5, Cleaning the Work Area](#)
- [Section 5.6, Close Module Doors](#)
- [Section 5.7, Discard Used Cartridges](#)
- [Section 5.8, Cleaning the Instrument and Hub Surfaces](#)
- [Section 5.9, Cleaning the Plunger Rods and Cartridge Bays](#)
- [Section 5.10, Cleaning the I-CORE](#)
- [Section 5.11, Cleaning and Replacing the GX-IV Fan Filter](#)
- [Section 5.12, Annual Instrument Maintenance](#)
- [Section 5.13, Using Module Reporters](#)
- [Section 5.14, Performing a Manual Self-Test](#)
- [Section 5.15, Excluding Modules from Testing](#)
- [Section 5.16, Generating the System Log Report](#)
- [Section 5.17, Replacing Hub and Instrument Parts](#)
- [Section 5.18, Repairing the Hub or Instrument](#)
- [Section 5.19, Troubleshooting](#)

Note

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

5.1 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 5-1](#) lists the basic maintenance tasks that can be performed.

Table 5-1. Maintenance Tasks and Frequency

Task	Frequency	Section
Power down the GeneXpert Xpress System	Weekly	Section 5.3
Clean the fan filters	Weekly	Section 5.11
Clean the I-CORE using the I-CORE Cleaning brush	As necessary	Section 5.10
Replace the fan filters	Quarterly	Section 5.11
Clean plunger rod and cartridge bay	Quarterly	Section 5.9
Clean the instrument and hub surfaces	Quarterly	Section 5.8
Perform annual instrument maintenance	Annually	Section 5.12
Print system log report	As necessary	Section 5.16

5.2 Maintenance Log

Complete the maintenance log shown in [Figure 5-1](#) 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 on the User Guide DVD 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.

5.3 Power Down the System

The GeneXpert instrument and hub 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 Xpress software, see [Section 3.7, Exiting the Software and Turning Off the System](#). Power down the computer, wait two minutes, then restart the computer.

Important

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

- To exit the software, you must be on the Home screen.
If you are on one of the test screens (but not actually running a test), or in one of the View Test Result screens, touch the **HOME** button in the upper part of the screen.
- Power down the system using the procedure in [Section 3.7, Exiting the Software and Turning Off the System](#).

To run tests later, see [Section 3.1, Starting the GeneXpert Xpress System](#).

GeneXpert® Xpress System Maintenance Log

Name of Institution

GeneXpert Serial Number:

Month and Year:

Last Calibration Check Date:

Installation Date:

Instructions:

1. Enter the name of your institution, GeneXpert Serial Number, current Month and Year, Last Calibration Check date, and Installation Date in the fields above.
2. 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.
3. Save the file after entering the data. We recommend saving one file each month for a complete record of activities.

	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
Daily Maintenance	<input type="checkbox"/>																														
Clean work area	<input type="checkbox"/>																														
Close all module doors	<input type="checkbox"/>																														
Discard used cartridges	<input type="checkbox"/>																														
Weekly Maintenance	<input type="checkbox"/>																														
Power down the GeneXpert Xpress Instrument ²	<input type="checkbox"/>																														
Power down the GeneXpert Xpress Hub ²	<input type="checkbox"/>																														
Clean instrument fan filter	<input type="checkbox"/>																														
Monthly Maintenance	<input type="checkbox"/>																														
Archive tests ²	<input type="checkbox"/>																														
Purge tests ²	<input type="checkbox"/>																														
Quarterly Maintenance	<input type="checkbox"/>																														
Clean plunger rod and cartridge bays ¹	<input type="checkbox"/>																														
Clean instrument and hub surfaces ¹	<input type="checkbox"/>																														
Replace instrument fan filters ¹	<input type="checkbox"/>																														
Yearly Maintenance	<input type="checkbox"/>																														
Check annual instrument maintenance ¹	<input type="checkbox"/>																														
As Necessary	<input type="checkbox"/>																														
Clean I-CORE Using I-CORE ¹ cleaning brush	<input type="checkbox"/>																														
Print system log report ¹	<input type="checkbox"/>																														
Back up database ²	<input type="checkbox"/>																														
Technician Initials (Two Letters)																															



1. Refer to Chapter 5 (Maintenance) in the Operator Manual for detailed procedure.
 2. Refer to Chapter 3 (Operating Instructions) in the User's Guide for detailed procedure.
 These are minimum recommendations for cleaning. Your institution may require that maintenance be performed on a more frequent basis.
 Reference: GeneXpert GX Dx Operator Manual (PN 302-1442, Rev. D)

Figure 5-1. Maintenance Log

5.4 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.

Note Maintenance procedures may be performed more frequently according to your environmental conditions.

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).

Note Final active chlorine concentration should be 0.5% regardless of the household bleach concentration in your country.

Caution



Do not to spray any cleaning fluids directly on the hub or instrument. Begin by spraying the bleach/alcohol onto a clean wipe, then wipe the hub or instrument.

- 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 eight 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.

Note An optical brush should be used for frequent I-CORE cleaning depending on your environment. Please contact your local representative to determine the frequency of cleaning the optical lens. See [Section 5.10.1, Lens Cleaning Procedure](#) for how to perform the optical cleaning.

5.5 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.

5.6 Close Module Doors

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

5.7 Discard Used Cartridges

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

5.8 Cleaning the Instrument and Hub Surfaces

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

Before cleaning the instrument and hub surfaces, read [Section 5.4, 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 and hub surfaces. Isopropyl alcohol can degrade system components.

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

Note

Final active chlorine concentration should be 0.5% regardless of the household bleach concentration in your country.

Caution



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 and hub surfaces for two minutes each time before wiping the surfaces with ethanol to remove the bleach residue.

- Lint-free wipes
- 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.

5.8.1 Quarterly Maintenance

Warning



Shut down the GeneXpert Xpress system completely when cleaning the instrument and hub surfaces.

Important

Do not remove the instrument or hub covers or use a vacuum cleaner inside the instrument or hub at any time. Remove debris from exterior instrument and hub 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 and hub surfaces:

1. Thoroughly moisten a lint-free wipe or paper towel with the 70% ethanol solution.
2. Wipe all surfaces outside the instrument and hub. Change lint-free wipes or paper towels frequently while wiping.
3. Move the GeneXpert 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

5.8.2 In Case of Spill

Clean affected exterior instrument and hub 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 and hub surfaces:

1. Thoroughly moisten a lint-free wipe or paper towel with the 1:10 bleach solution.
2. Wipe affected surfaces on the instrument and hub. 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 eight 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 and hub. Change wipes or paper towels frequently while wiping.
7. Discard used wipes or paper towels according to your standard laboratory procedure.

5.9 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.

Important

Do not perform plunger rod maintenance when tests are in progress. If plunger maintenance is started while tests are in progress and a module where plunger maintenance is being performed (syringe rod lowered) becomes unavailable to complete the maintenance (raise syringe rod), the GeneXpert Xpress software must be restarted after tests complete.

Before cleaning the plunger rods and cartridge bays, read [Section 5.4, 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. Touch the **ADMIN** button on the Home screen (see [Figure 5-2](#)).

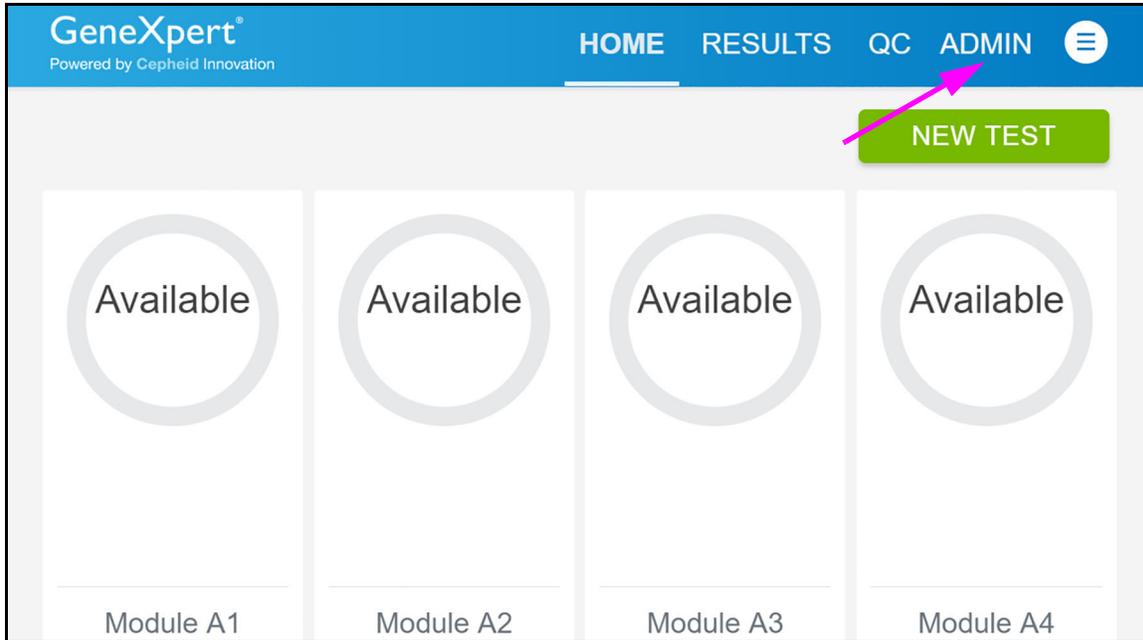


Figure 5-2. Home Screen (GX-IV, Four-Module Configuration Shown)

The Administration screen is displayed (see [Figure 5-3](#)). This screen shows a menu of the various functions available to an administrator.

Touch the **Instrument** button to view the Instrument screen (see [Figure 5-4](#)).

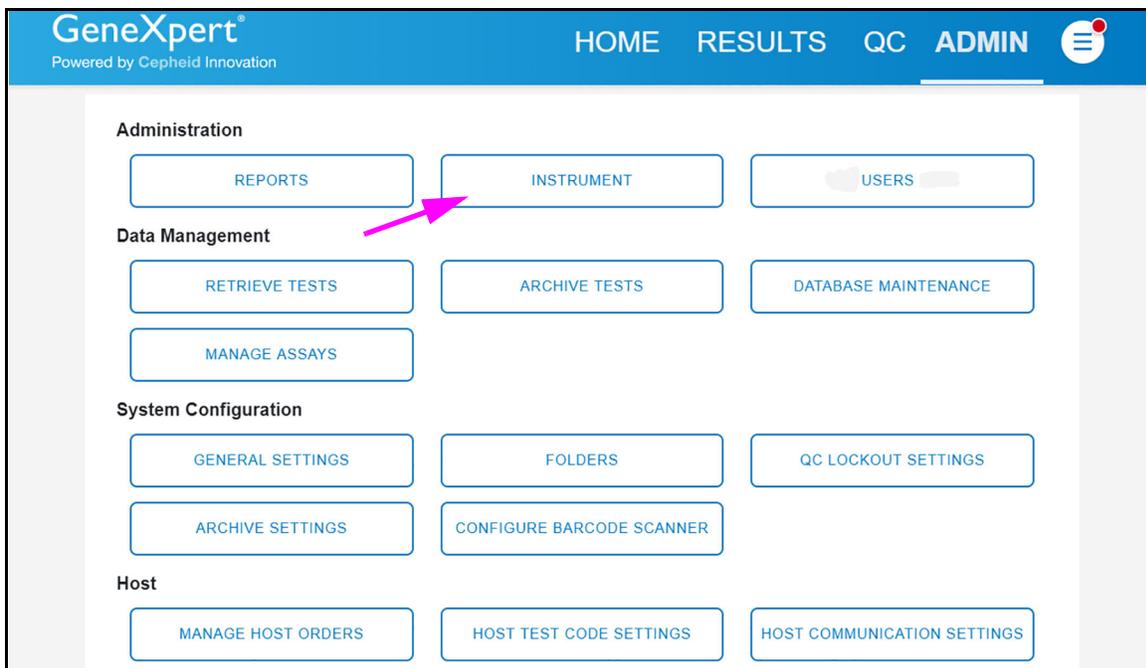


Figure 5-3. Instrument Selected on the Administration Screen

- On the Instrument screen, touch the **PLUNGER ROD MAINTENANCE** button (see [Figure 5-4](#)). The Plunger Rod Maintenance screen is displayed (see [Figure 5-5](#)).

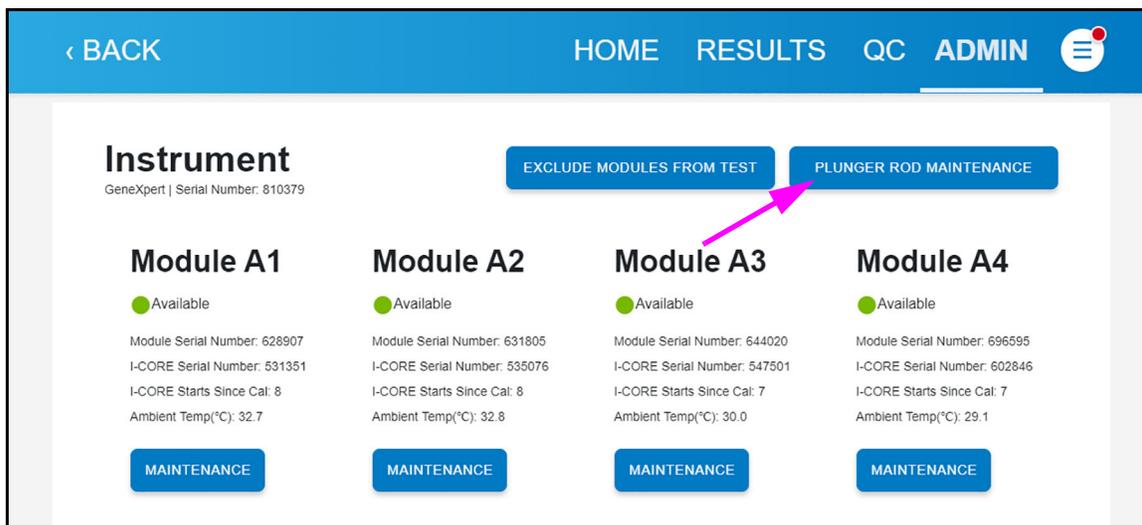


Figure 5-4. Instrument Screen

- On the Plunger Rod Maintenance screen (see [Figure 5-5](#)), touch the check box at the left of the module to be cleaned.

Note

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

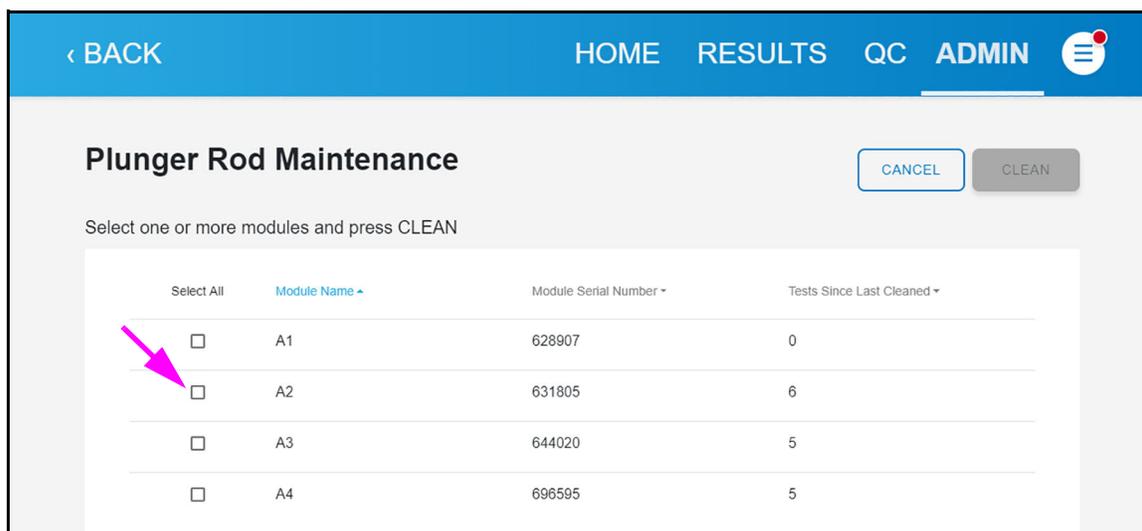


Figure 5-5. Plunger Rod Maintenance Screen

In this example, **Module A2** is selected (see [Figure 5-6](#)).

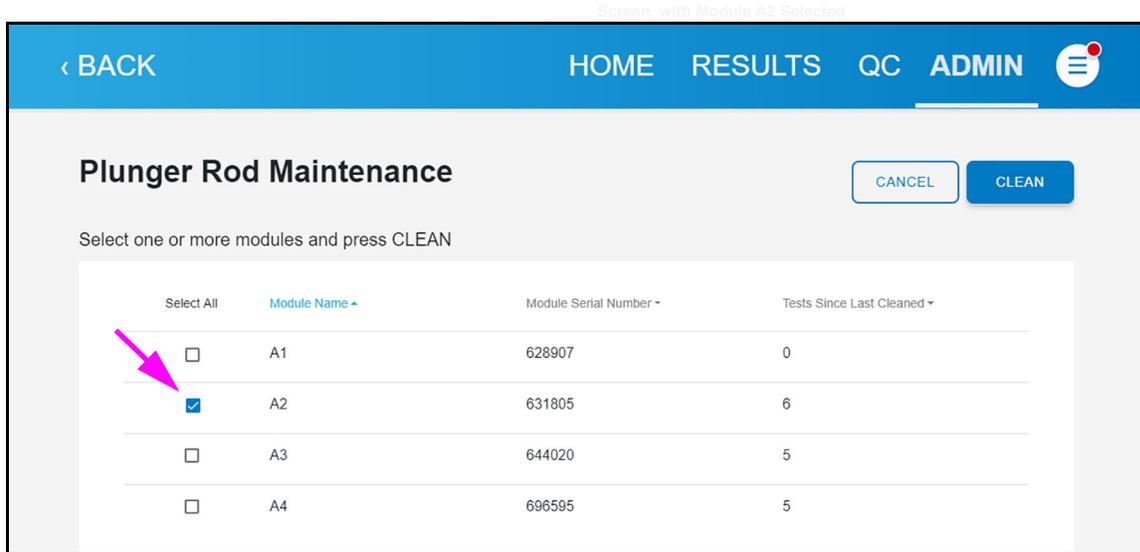


Figure 5-6. Plunger Rod Maintenance Screen, with Module A2 Selected

- After module selection is complete (see [Figure 5-6](#)), touch the **CLEAN** button. A new screen appears (see [Figure 5-7](#)) with instructions to open the selected module door and remove any cartridges from the module(s).

Important

Keep hands clear of modules until the plunger rods are lowered.

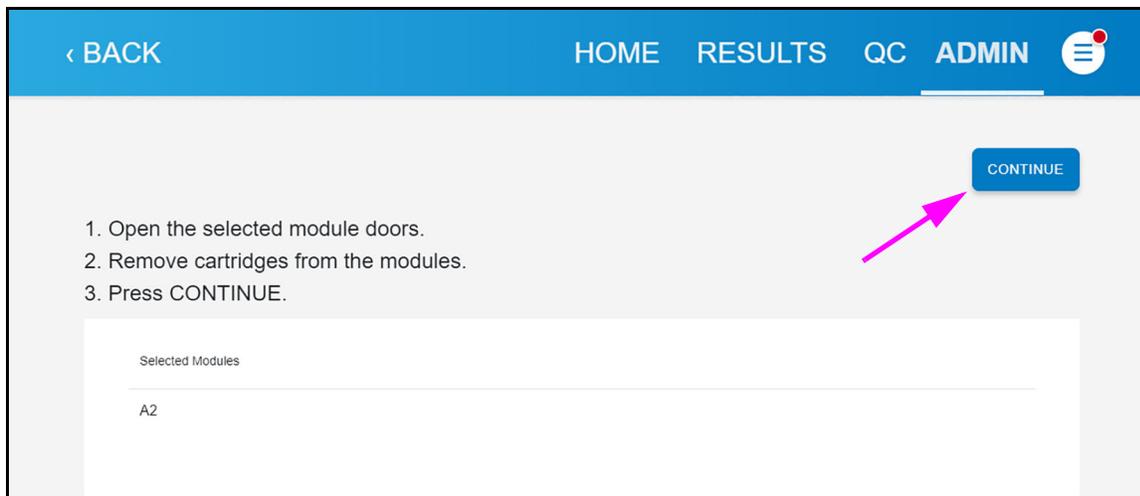


Figure 5-7. Cartridge Removal Instruction Screen

- After any cartridges have been removed, touch the **CONTINUE** button. A new screen appears (see [Figure 5-8](#)) with instructions to clean the plunger rod(s) and module bay(s).

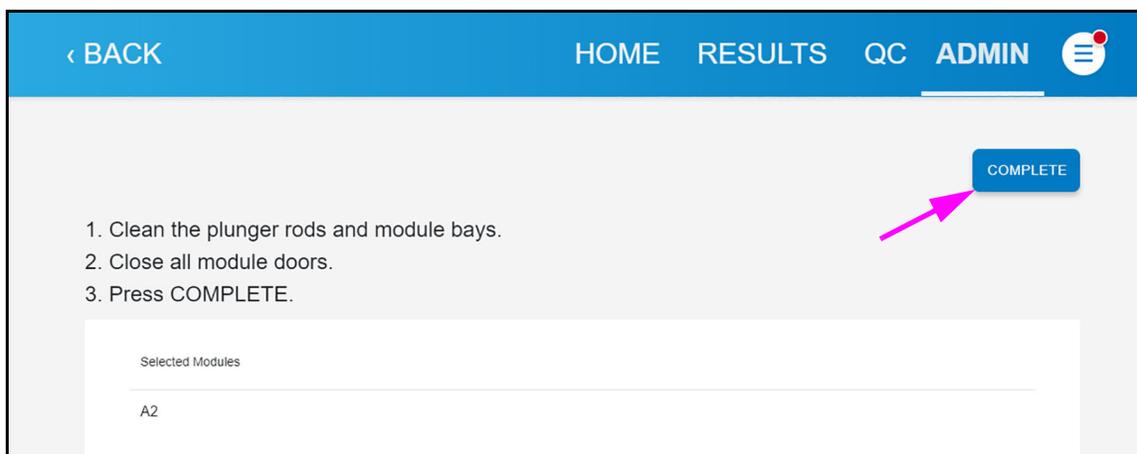


Figure 5-8. Plunger Rod Cleaning Instruction Screen

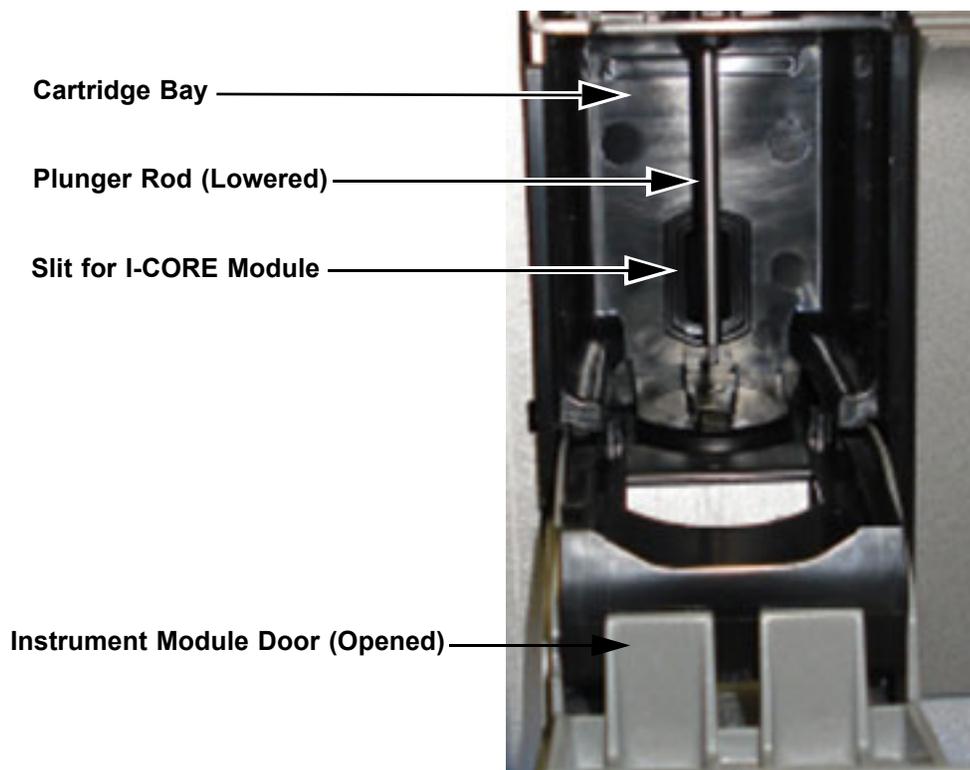


Figure 5-9. Plunger Rod Lowered into Cartridge Bay

7. Clean the plunger rod(s) and cartridge bay(s) as follows:
 - A. Thoroughly moisten a lint-free wipe with a 1:10 solution of household chlorine bleach.

Caution



Do not use a spray bottle to clean inside the cartridge bay. Getting bleach solution inside the I-CORE module can damage the module.

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

Using the same lint-free wipe, 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.

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 5-9](#)).

Caution



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

- C. Wait 2 minutes after wiping with the bleach solution.
 - D. Use a new lint-free wipe 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 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.
 - G. Wait 2 minutes after wiping with the bleach solution.
 - H. Thoroughly moisten a lint-free wipe with the 70% ethanol solution.
 - I. Use the lint-free wipe 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.
8. After the plunger rod(s) and cartridge bay(s) have been cleaned, return to the Plunger Rod Cleaning Instructions screen (see [Figure 5-7](#)) and touch the **COMPLETE** button. The plunger rod(s) move(s) back up to the resting position.

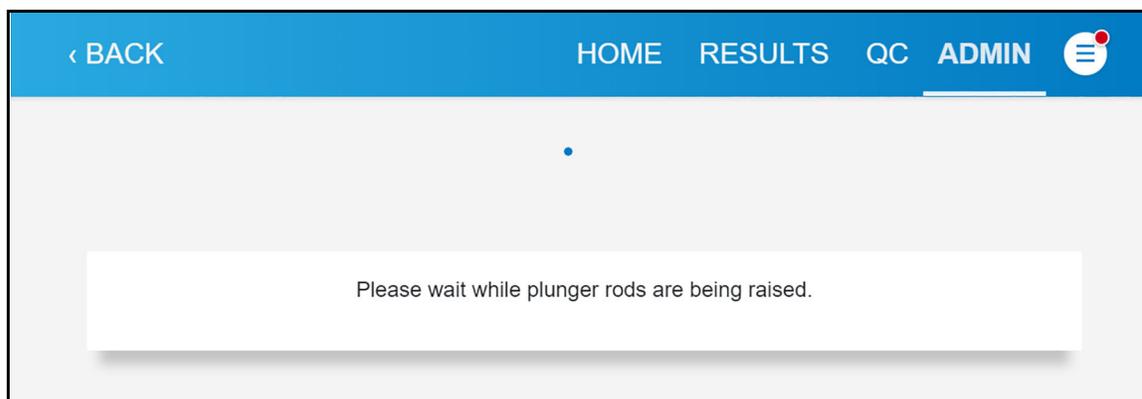


Figure 5-10. Plunger Rod Repositioning Advisory Screen

9. Manually close the instrument module door(s).
10. After the plunger rods complete their repositioning, the plunger rod cleaning complete advisory screen appears. Touch **OK** to acknowledge.
11. The Instrument screen appears (see [Figure 5-11](#)) Touch the **HOME** button to return to the Home screen.

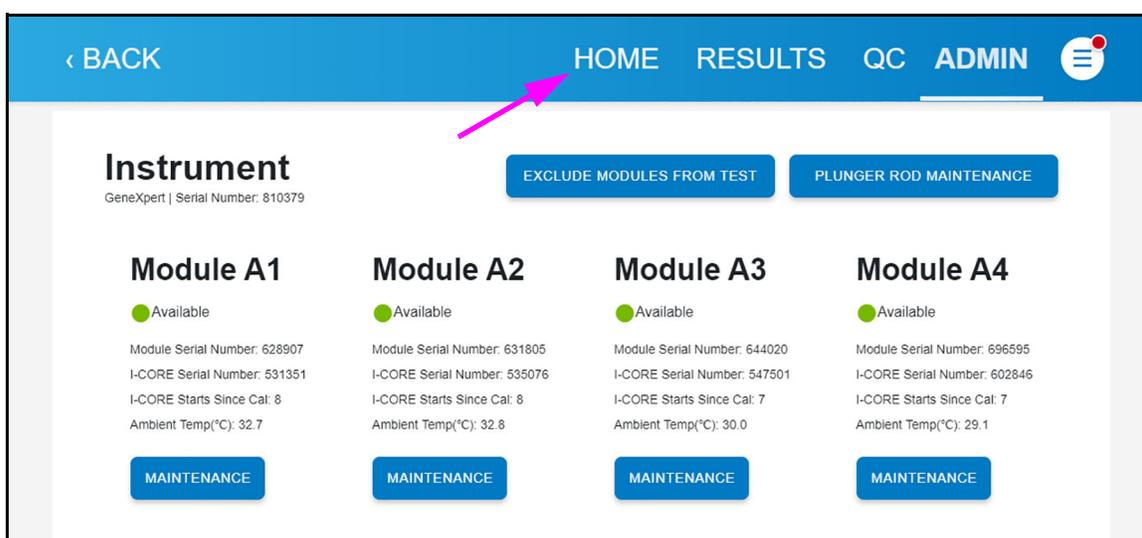


Figure 5-11. Instrument Screen

This completes the procedures for cleaning the plunger rod(s) and cartridge bay(s).

5.10 Cleaning the I-CORE

Perform this I-CORE cleaning procedure as necessary. If you operate the system in an area with high pollution, dust or smoke, you will need to clean more frequently. This procedure describes the method for removing dust and tube debris from the surface of rod lenses of the excite and detect blocks for GeneXpert Xpress modules.

Materials Required or Recommended for Cleaning

- GX Cleaning Kit (700-6519S)
- Disposable gloves

Estimated Cleaning Time: 30 Seconds per module.

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.

5.10.1 Lens Cleaning Procedure

1. Select the module to be cleaned and manually open the door of the module.
2. If necessary, remove the cartridge from the module.

Biological Risks



Remove the cartridge from the GeneXpert Xpress modules prior to cleaning. Failure to remove a cartridge could result in personnel being exposed to biological hazards and/or liquid biological materials spilling into the instrument and causing damage to the instrument.

3. Locate the brush provided in the GX Cleaning kit (see [Figure 5-12](#)).

Nylon Bristles

Shank Insertion Shoulder



Figure 5-12. Lens Cleaning Brush (300-8330)

Note

The brush is designed so that it will easily insert into the I-CORE slit and make contact with the rod lenses of the excite and detect blocks.

Biological Risks



Make sure you wear disposable gloves for the cleaning process. Wearing gloves prevents you from being exposed to biologically hazardous materials.

4. Wearing disposable gloves, insert the brush into the I-CORE slit in a tilted manner up to the shank insertion shoulder, as shown in Figure 9-7.

Note

Make sure that all the bristles are fully inserted (up to the shoulder of the plastic shank of the brush) so that it does not cause unnecessary damage to the brush.

Caution

Do not insert any objects into the I-CORE slit except the provided brush. Inserting any other object may damage the I-CORE.

Caution

Do not apply any solution (such as ethanol or bleach) onto the brush bristles. The brush must be completely dry when inserting it into the I-CORE slit.

Important

The brush is intended for single-use and should not be used on more than one module. Use a new brush for each module to be cleaned.

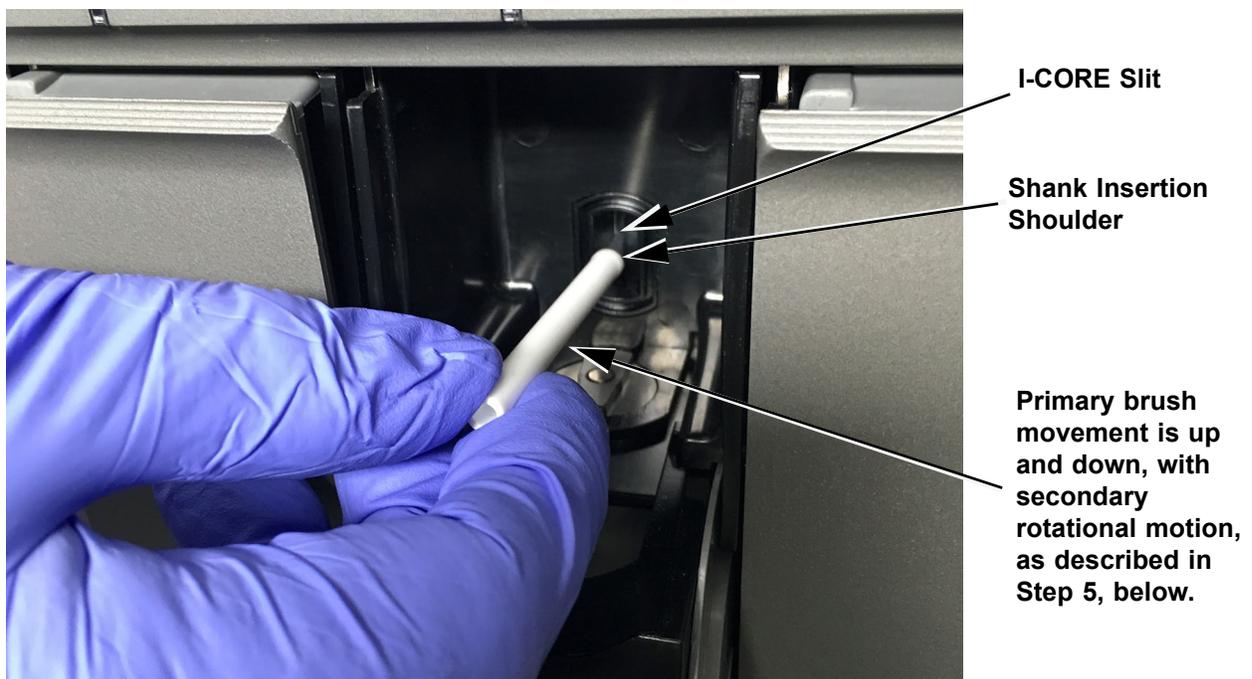


Figure 5-13. Inserting the Cleaning Brush into the I-CORE Slit

5. Insert the brush into the I-CORE slit completely up to the plastic shank (shoulder) of the brush. Hold the brush firmly in the I-CORE slit, and perform cleaning of the rod lenses as described below. The entire cleaning process should take approximately 30 seconds per module.

Note

Cleaning is done by moving the brush in an up and down direction within the I-CORE slit. Brush rotation, even if it has to be done, is not the main action that results in optics cleaning.

- A. Begin by brushing from the top of the I-CORE slit to the bottom, making sure to

apply a uniform pressure when brushing from the top to the bottom of the I-CORE slit. This will ensure that most of the tube debris and dust is brushed off from the surface of the lenses.

- B. Rotate the brush from left to right and back again, approximately 180°.
 - C. Brush once more from the top of the I-CORE slit to the bottom.
 - D. Rotate the brush again from left to right and back again, approximately 180°.
 - E. Finally, brush again from the top of the I-CORE slit to the bottom.
6. When lens cleaning is complete, remove and discard the used brush and gloves as hazardous waste.

Biological Risks



Dispose of gloves and brushes according to your institution's safety policies and procedures for hazardous waste.

5.11 Cleaning and Replacing the GX-IV Fan Filter

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 filter weekly or more frequently, if necessary if you operate the instrument in an area with high pollution, dust or smoke. Replace the fan filter quarterly, or more frequently if necessary. There is one fan filter on the GeneXpert Xpress instrument. Location of the fan filter is on the back of the instrument (see [Figure 5-14](#)). The materials needed for the procedure are as follows:

- Replacement Fan Filter Part Number: 001-1537
- Paper towels
- Water
- Disposable gloves

Important

The GeneXpert Xpress instrument and hub 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 instrument and the GeneXpert hub, following the instructions in [Section 5.4, Guidelines for Cleaning and Disinfecting](#).

Note

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

Warning

See the weights table in [Section A.2, General Specifications for the GeneXpert Xpress System](#) for weights. Use care when moving the system. Do not attempt to lift the system without proper safety training and assistance. Lifting or moving the system without proper training and assistance can cause personal injury, damage the GeneXpert Xpress hub or instrument, and void your warranty.

Caution

Be careful not to drop the GeneXpert Xpress system.

3. Reposition the instrument so the fan filter can be easily accessed (see [Figure 5-14](#)).

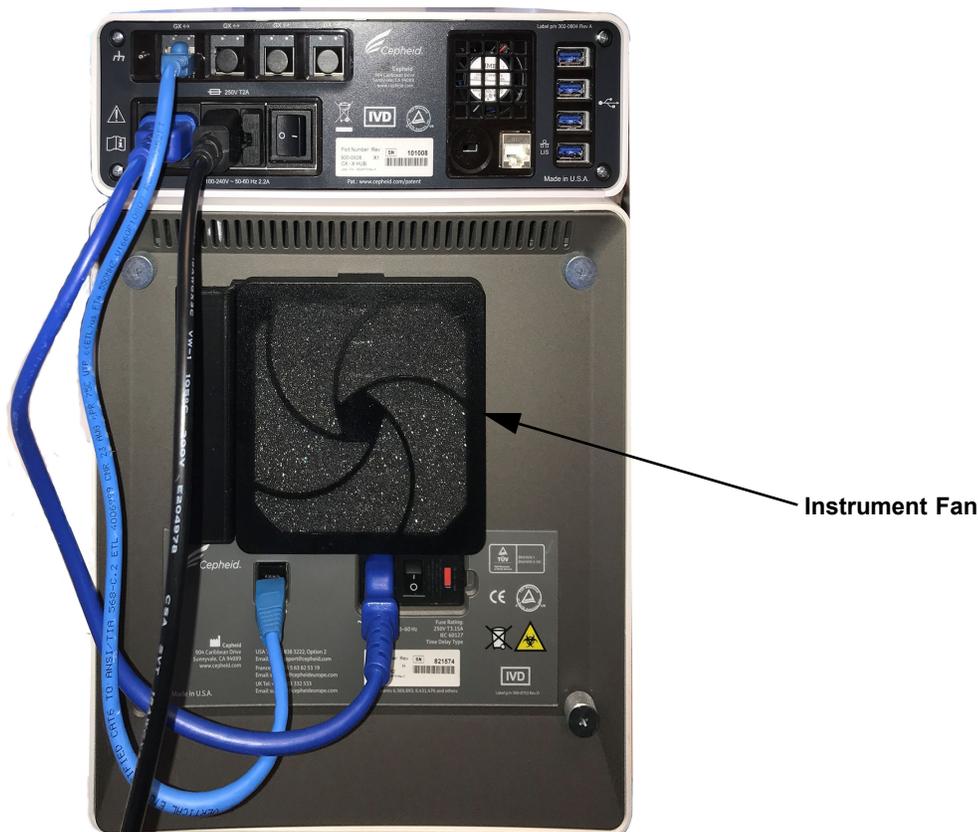


Figure 5-14. GeneXpert Xpress IV Instrument Positioned for Access to Fans

4. Gently take the fan filter guard off by unsnapping the guard from the fan housing (see [Figure 5-15](#)) and set it aside for the remainder of the procedure for filter removal and cleaning.



Fan Filter Guard

Figure 5-15. Removing Instrument Fan Filter Guard

5. Remove the dirty filter for cleaning (see [Figure 5-16](#)).



Filter

Figure 5-16. Instrument 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 5-17](#)).

**Pressing the Fan Guard
Sides into Place**

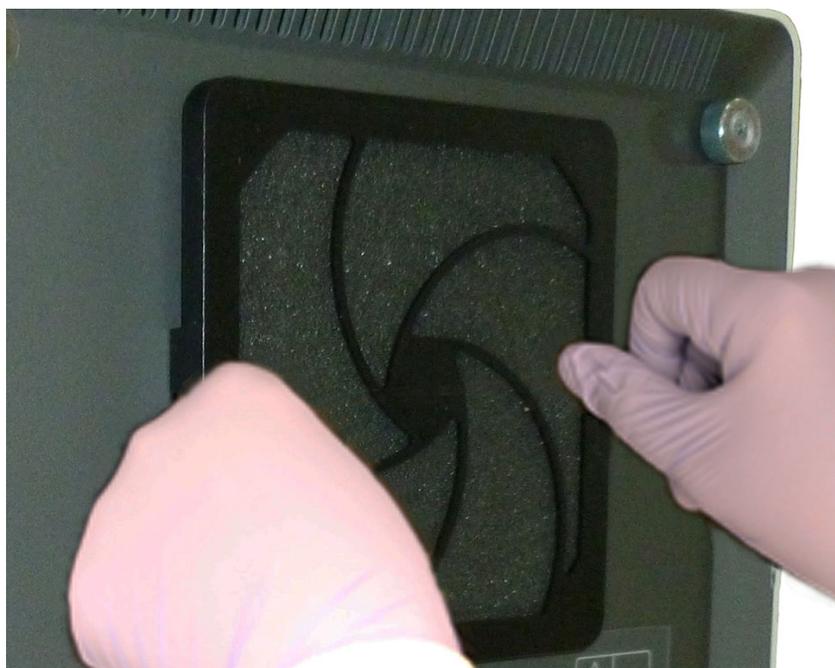


Figure 5-17. Installing the Instrument Fan Filter Guard Sides

8. Press the bottom guard of the filter into place (see [Figure 5-17](#)).

**Pressing the Fan Guard
Bottom into Place**

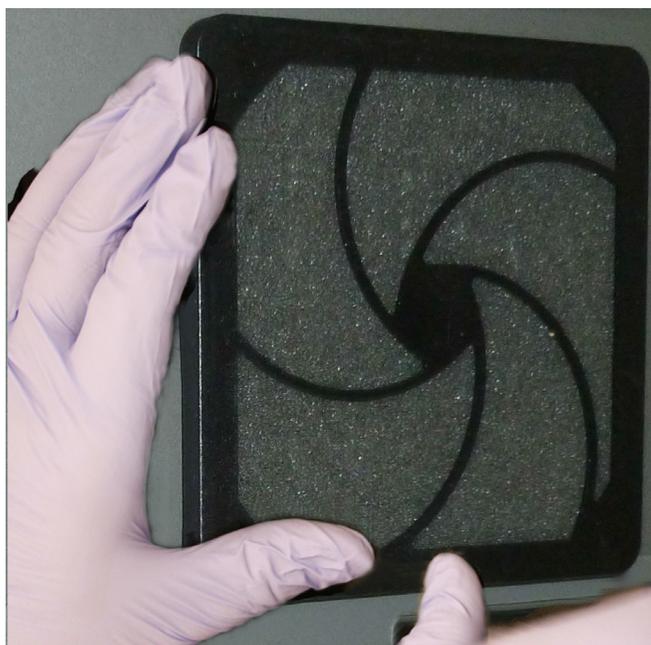


Figure 5-18. Installing the Instrument Fan Filter Guard Bottom

9. 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.

10. After the filter is dry, store it to use the following month, when you next remove the filter for cleaning.
11. In the maintenance log (see [Figure 5-1](#)), fill in the date of the fan filter cleaning and keep it for your records.

5.12 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 from the point of initial use. 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 replacement, the replacement module provided will have been calibrated prior to shipment.

A GeneXpert operator or Field Service Engineer with Administrator user permissions can perform calibration checks during annual maintenance. Contact Cepheid Technical Support for information about calibration checks. See the [Technical Assistance](#) section in the [Preface](#) for contact information.

5.13 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 5-20](#).

1. To view the Module Reporters of a particular module, go to the Instrument screen (see [Figure 5-19](#)). Touch the **MAINTENANCE** button for the module desired. The Module Maintenance screen with Module Reporters appears (see [Figure 5-20](#)).

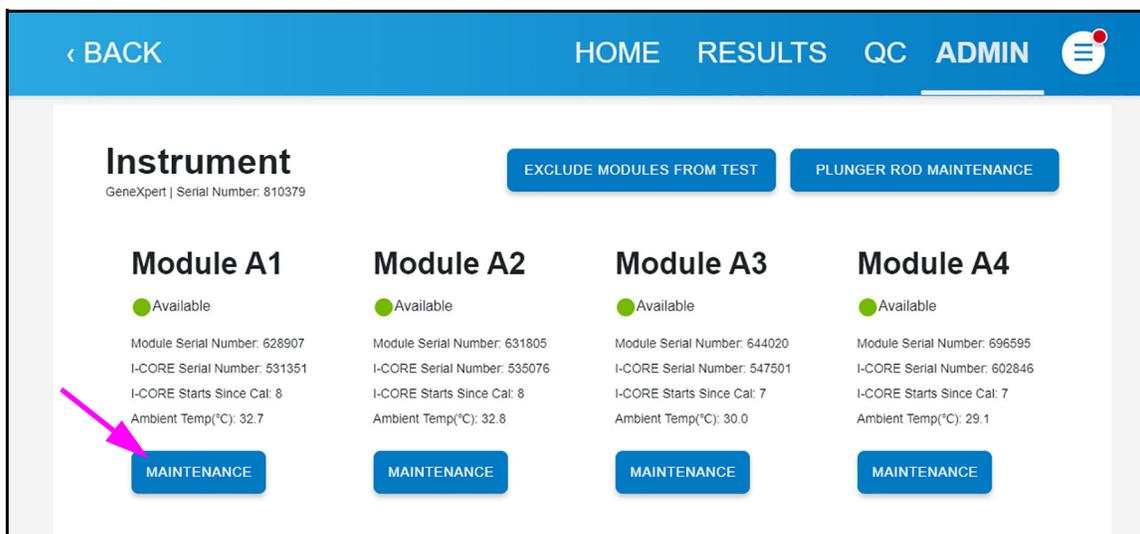


Figure 5-19. Instrument Screen

- The Module Reporter names are shown in the far-left column.

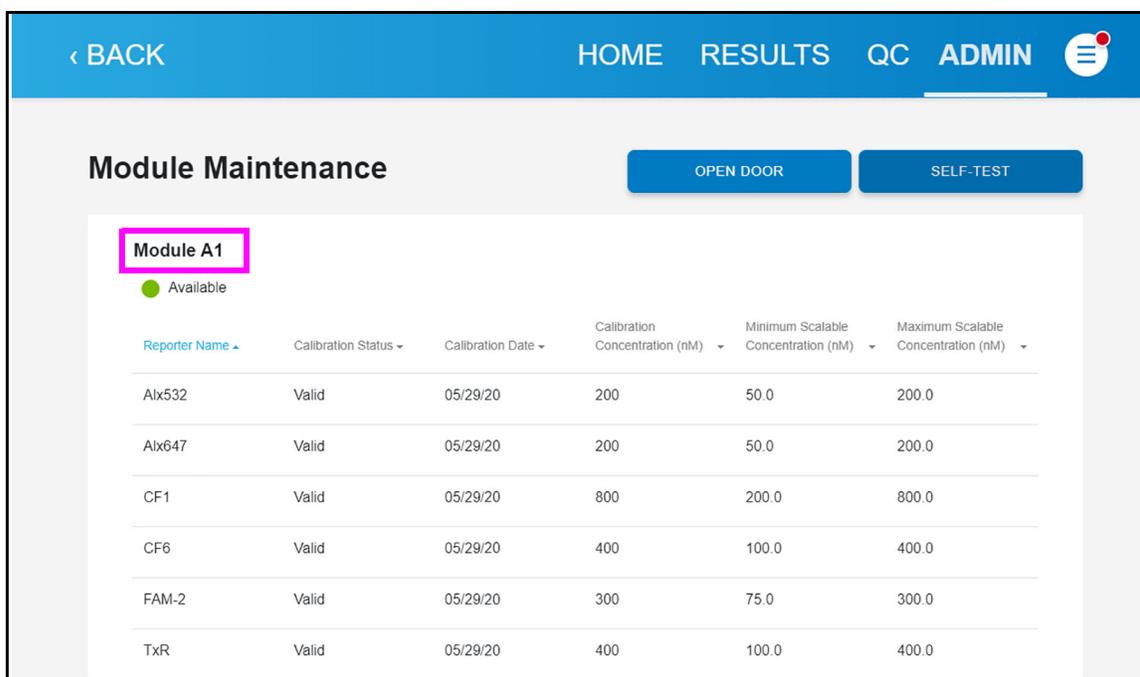


Figure 5-20. Module Maintenance Screen, showing Module Reporters

- Return to the Instrument screen to select and view a different module.

5.14 Performing a Manual Self-Test

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

The GeneXpert Xpress system 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. Go to the Instrument screen (see Figure 5-21). Touch the **MAINTENANCE** button for the module desired for the self-test (**Module A1** is used in this example). The Module Maintenance screen appears (see Figure 5-22).

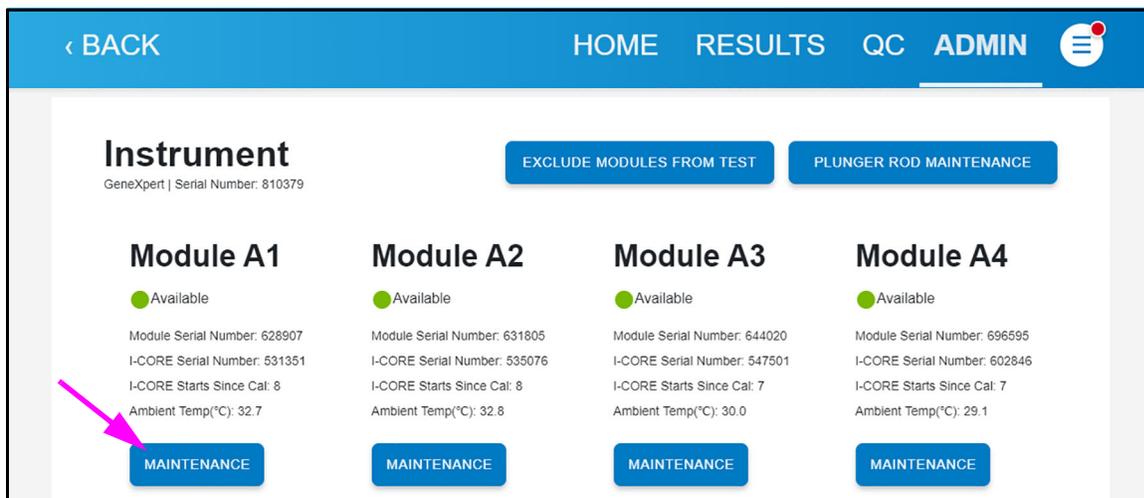


Figure 5-21. Instrument Screen

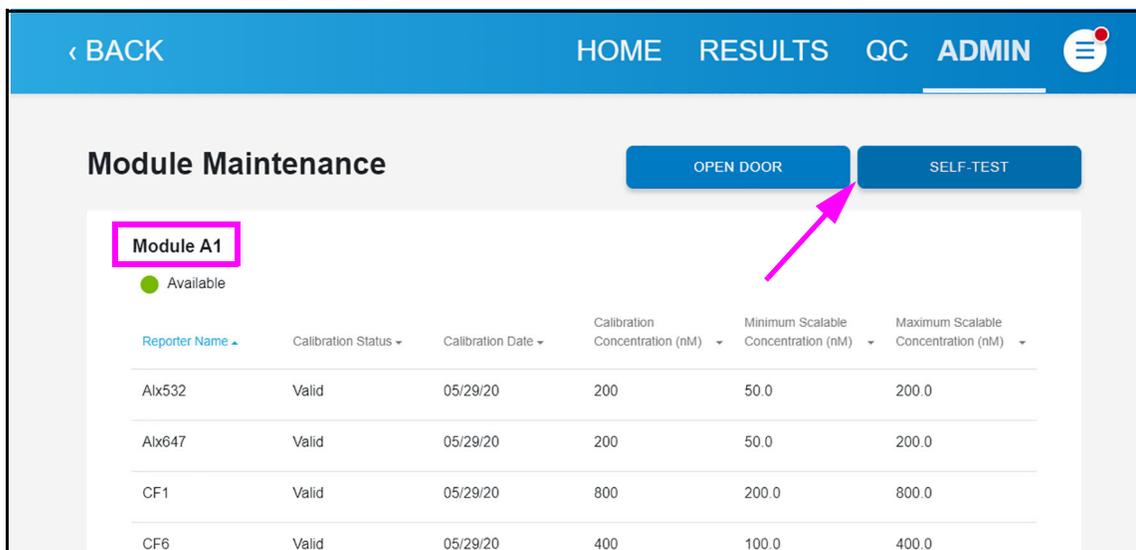


Figure 5-22. Module Maintenance Screen, showing Module Reporters

Note

If necessary, return to the Instrument screen to select and view a different module.

3. Touch **SELF-TEST**. The Self-Test Confirm dialog box appears (see Figure 5-23).

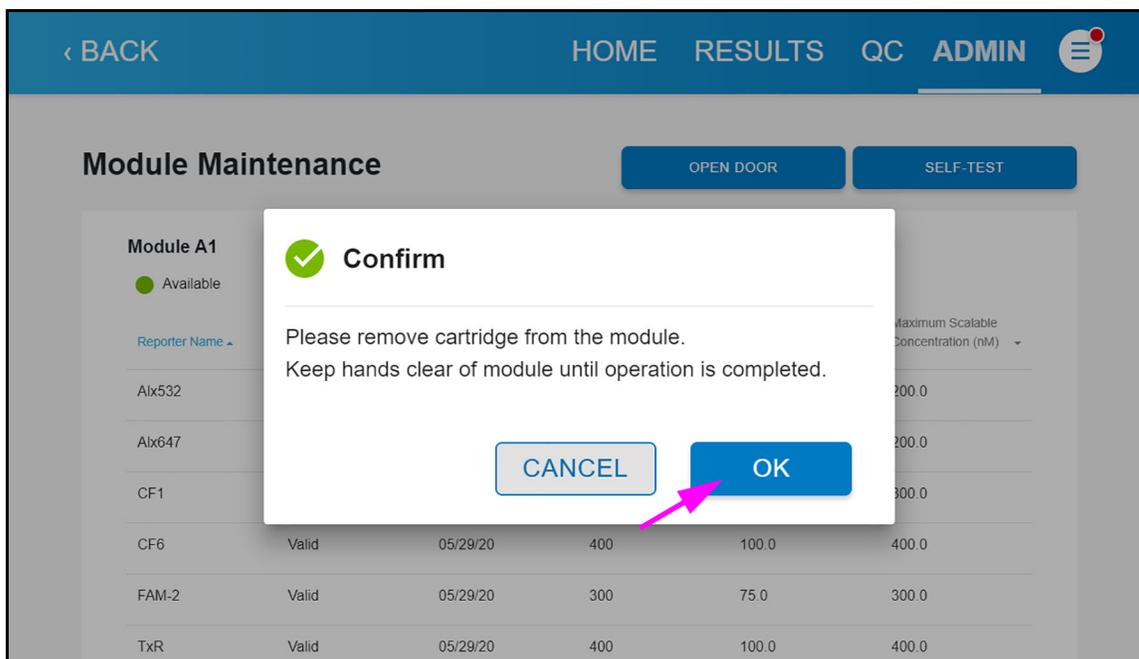


Figure 5-23. Self-Test Confirmation Dialog Box

4. Follow the instructions in the Self-Test Confirm dialog box and touch **OK**.

- When the self-test finishes, the software changes the progress to **Available** (see [Figure 5-23](#)), indicating the self-test passed. If a message appears indicating the self-test failed, contact Cepheid Technical Support. See the [Technical Assistance](#) section in the [Preface](#) for the contact information.

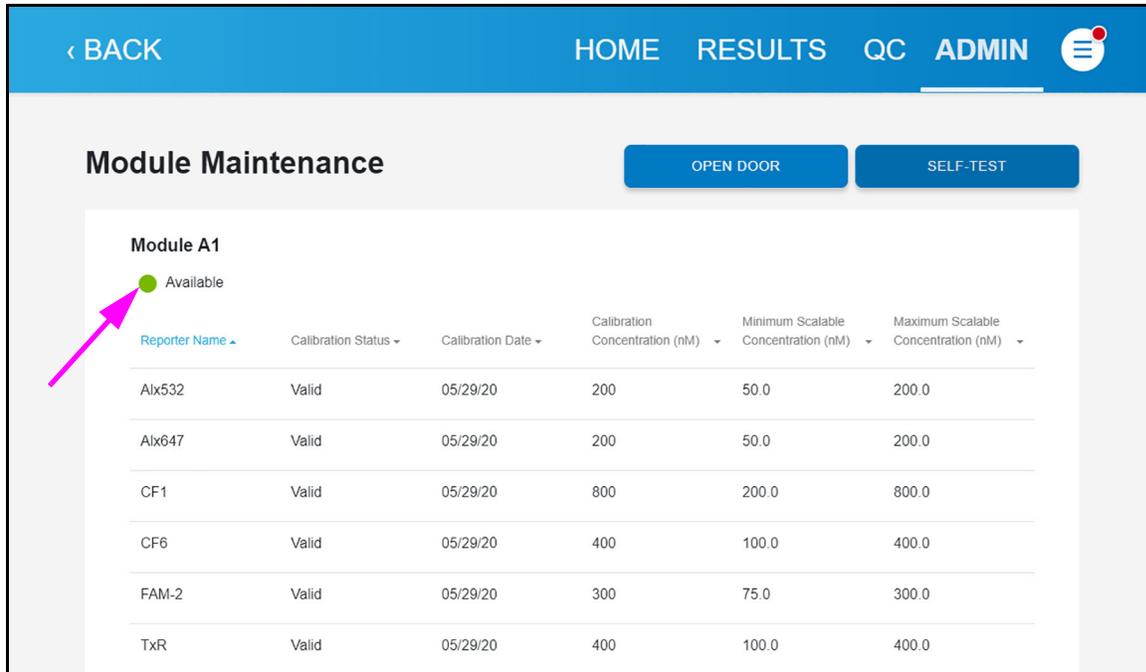


Figure 5-24. Module Maintenance Screen, showing Module Available

5.15 Excluding Modules from Testing

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:

- Go to the Instrument screen (see [Figure 5-25](#)). Touch the **EXCLUDE MODULES FROM TEST** button.

The Exclude Modules from Test screen appears (see [Figure 5-26](#)).

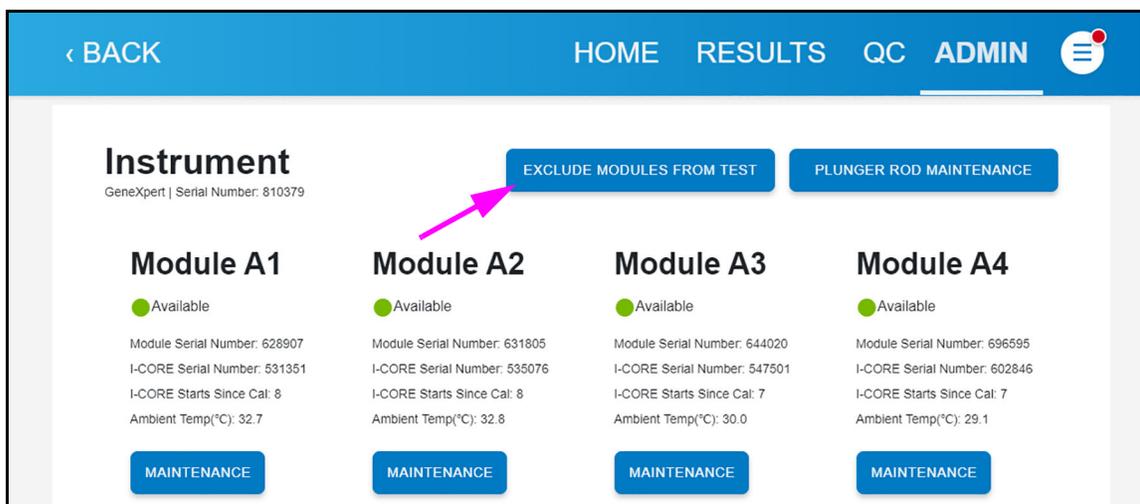


Figure 5-25. Instrument Screen

2. Select the module(s) to be excluded from test by touching the check box at the left of the desired module (see Figure 5-26). The module will be shown as **Disabled**. Press the **CANCEL** button to cancel changes.
3. Touch the **CONFIRM** button to save changes to the Exclude Modules From Test screen. The Instrument screen appears.

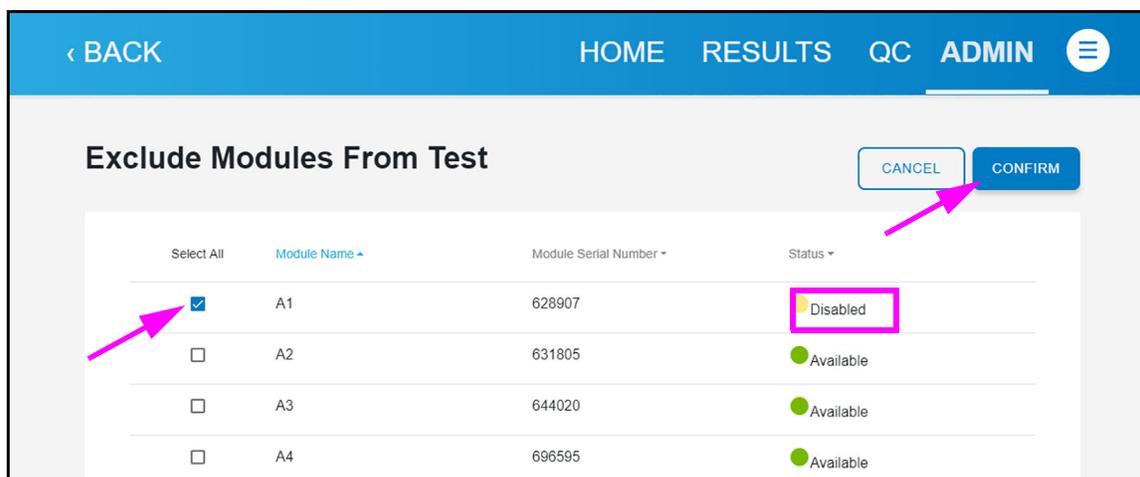


Figure 5-26. Module Maintenance Screen, showing Module Reporters

4. The Instrument screen appears. Touch **HOME** on the Instrument screen to return to the Home screen.

5.16 Generating the System Log Report

The System Log report can be used to provide incidents of instrument module self-tests and errors to Cepheid when a module failure has been encountered (see [Section 4.4.1.1](#)).

5.17 Replacing Hub and 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 IV instrument parts:

- Ethernet Cable, 20 Inch (GeneXpert Xpress hub to GX - IV) (P/N 100-5654)
- Power Cord, 72 Inch (for GeneXpert Xpress) (P/N 100-3717)
- Power Cord, 18 Inch (GeneXpert Xpress hub to GX - IV) (P/N 100-5653)
- Fan Filter, GeneXpert GX-IV (P/N 001-1537)

You can obtain the power cords and Ethernet cables from Cepheid. See the [Technical Assistance](#) section in the [Preface](#) for the contact information.

5.18 Repairing the Hub or Instrument

Warning



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

Warning



Do not attempt to open the hub or instrument covers. Do not attempt to modify or repair the GeneXpert Xpress 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 system should be serviced only by an authorized Cepheid representative. If the system 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 numbers of your system. You can find the serial number labels on the back side of the hub and instrument.

5.19 Troubleshooting

This section lists the possible hardware problems you might encounter.

[Table 5-2](#) 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 5-2. 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.
Screen does not automatically light up after system power on.	Touchscreen is powered off.	Press power button on the back of the touchscreen to power on the screen.
Module(s) 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 100-5654). Exit the software and relaunch with the instrument powered on. Change the IP Address setting by performing the steps provided in Section 4.9
The cartridge is stuck inside the instrument module.	Module mechanical failure.	To remove the cartridge: <ul style="list-style-type: none"> • Touch the ADMIN button at the top of any screen. • On the Instrument screen, touch the MAINTENANCE button for the module you wish to access. • On the Module Maintenance screen, touch the OPEN DOOR button to open the module door on the selected module. If the door does not open, cycle the instrument power and repeat the above steps.
The instrument module red light is flashing.	Module mechanical failure.	Confirm no cartridge is in the module. Perform a self-test manually (Section 5.14, Performing a Manual Self-Test). If the error recurs, contact Cepheid Technical Support.
Unable to create a test.	Modules not available. No assay selected. The ambient temperature of the module is above 55 °C. Barcode is not detected.	Check that the modules are not disabled. Check that assay is selected. 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. Barcode reader may need reconfiguration. (See Section 4.8.5). Check that the barcode reader is functional.

5.19.1 User Lockout Problems

There may be an occasion when all users on site cannot log onto the system and are locked out. This can be the result of all available users forgetting their passwords, or a software malfunction. Whatever the reason, there is a "back-door" option available as a remedy, by contacting Cepheid Technical Support. See the [Technical Assistance](#) section in the [Preface](#) for the contact information.

5.19.2 Troubleshooting the LIS Interface

[Table 5-3](#) lists the possible system configuration problems you might encounter. To contact Cepheid Technical Support, see the [Technical Assistance](#) section in the [Preface](#) for the contact information.

Table 5-3. System Configuration Problems

Problem	Cause	Solutions
Cannot edit test code for old versions of an assay. If the LIS Administrator updates the test code, it will only apply to the new version of the assay.	Upgrade of assay to new version.	Change the test code prior to upgrade of assay.
Upload of test results shows incorrect System Name.	Incorrect system name.	<ul style="list-style-type: none"> • LIS interface to check for incorrect instrument system name. • LIS Administrator to control process for defining system name.
User error in selecting the assay when defining test codes.	User error in selecting the assay.	LIS Administrator to configure correct test code.

5.19.3 Troubleshooting the POCT Interface

[Table 5-3](#) lists some possible system configuration problems you might encounter, but you may encounter issues not listed here. To contact Cepheid Technical Support, see the [Technical Assistance](#) section in the [Preface](#) for the contact information.

Note

See [Section 5.19.4](#) for information on how to access the POCT communication log, which can aid in POCT communication troubleshooting issues.

Note

See [Section 5.19.5](#) for information on how to perform troubleshooting steps remotely.

Table 5-4. System Configuration Problems

No.	Problem	Cause	Solutions
1.	The GeneXpert Xpress is dropping the connection.	<p>The connection interval set up on the DM is connecting too quickly after previous communication, or</p> <p>The host connection was changed on the Xpress Host Communication screen, or</p> <p>The connection is routed over a different gateway, or</p> <p>The assigned port is being blocked on the network, or</p> <p>The assigned port is duplicated on another device</p>	<ol style="list-style-type: none"> 1. Verify that POCT01 Protocol is enabled in GeneXpert Xpress Host Connectivity Settings. 2. Check the Ethernet cable. Are both ends of the cable connected correctly? 3. Check to see if other devices (other than GX) in your lab are having intermittent connectivity issues. 4. Contact your IT department to see if there is a network problem. 5. Check Windows Defender for malware. 6. Verify if the DM has assigned the port to another connection. 7. Check if the DM driver was updated, which could change configuration and cause an out of sync condition. 8. Review the Xpress event viewers logs and see if there is a connection lockout.
2.	The GeneXpert Xpress states that communication is failing on the Host Communication screen.	<p>The device has not been added to the Data Manager, or</p> <p>Windows firewall is blocking the port, or</p> <p>The device is not physically connected to the wall Ethernet jack, or</p> <p>Host Communication settings are not correct on the GeneXpert Xpress, or</p> <p>The serial number of the GX may have been entered in the DM incorrectly.</p>	<ol style="list-style-type: none"> 1. Examine the host communication screen settings to ensure they are correct. 2. Verify that the GX Xpress is on the network. 3. Look in the DM software to see if the device has been added. 4. Look in the DM software to make sure the GX serial number is correct. 5. Review the Xpress event viewer logs to see if an error message indicates if the device is not set up in the DM. 6. Review the Xpress event viewer logs and see if an error message matches the serial number on the DM. 7. Confirm that the network cable is connected securely from the GeneXpert to the wall jack. 8. Confirm (with your IT network engineer's assistance) that the network jack is enabled. 9. Confirm (with your IT network engineer's assistance) that the port for the POC DM is not blocked.

Table 5-4. System Configuration Problems (Continued)

No.	Problem	Cause	Solutions
3.	Test results from the GX are not being sent by the GX to the DM.	DM never sends a request observation message, or There is a GX computer Ethernet issue, or There is a network issue, or There are incorrect host communication settings	<ol style="list-style-type: none"> 1. Check the Ethernet connection of your GX system. 2. Ensure the Host Communication settings on the GX are correct. 3. Review the Xpress event viewer logs and see if results have been sent.
4.	One or more GX instruments are not getting updated user lists.	The GX instrument(s) are in a DM group without an associated GX user list, or The DM has a GX user list for the group, but the DM is not configured to send the user list	<ol style="list-style-type: none"> 1. Check that the group the GX is assigned to on the DM is associated with a user list 2. Check that the DM is configured to send user lists to the GX group.
5.	User validation settings for Lockout , Warn and Allow are not showing up in the GX.	The DM is not sending the validation settings, or There is no connection between the DM and the GX, or The DM is sending invalid User Validation settings.	<ol style="list-style-type: none"> 1. See troubleshooting steps for issue No. 1 above. 2. Review the Xpress Windows event viewer User Validation Setting error messages.
6.	The user list is not showing all the expected users on the GX.	Unsupported or invalid character for the user information.	Review the Xpress event viewer logs. See if there is an error message regarding the operator list.
7.	The GX shows that a result was sent but it is not showing in the EMR.	The DM has possibly sent a false result receipt acknowledgment to the GX.	<ol style="list-style-type: none"> 1. Review Xpress event viewer logs and confirm that the DM sent a result receipt acknowledgment to the GX. 2. User needs to contact DM's support to determine why there was a false result receipt acknowledgment.
8.	Manual Sync is not updating.	The user tries to manually sync when there is another conversation in progress.	<ol style="list-style-type: none"> 1. Wait several seconds and try to manually sync again. 2. See troubleshooting steps for problem No.1 above.
9.	A device setting that a user expects to send to the GX is not updating.	The Xpress does not support that specific device setting.	Review windows event error logs for an expected device setting that is not enabled.
10.	Host is disconnected.	The POCT settings are invalid.	<ol style="list-style-type: none"> 1. Check device settings on the Host Communication screen. 2. Check the error logs for an error that gives an invalid POCT01 setting error, and the reason why. 3. Use troubleshooting steps Nos. 1 and 2.
11.	Manual Upload of test result is not transmitting to the DM.	The result may have already been uploaded.	<ol style="list-style-type: none"> 1. Verify if the host connection is working. 2. Verify result upload status in GX. 3. Ask the POC LIS administrator to verify the result transmission received in DM.

5.19.4 Accessing Windows Event Logs for POCT Troubleshooting

This section describes how to access the POCT communication log that can aid in POCT communication troubleshooting issues.

To Access the Windows Event Logs:

1. Touch and hold the Windows **Start** button. The Start menu appears (see [Figure 5-27](#)).
2. On the **Start** menu, touch **Event Viewer** to display the screen.

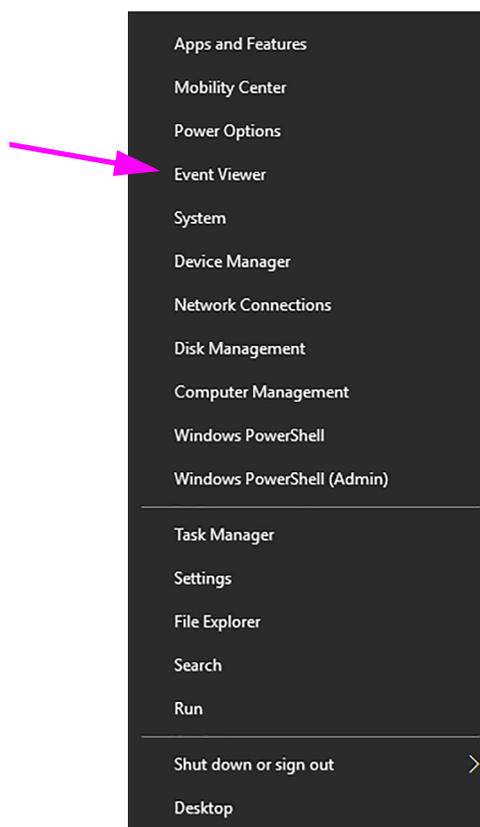


Figure 5-27. Windows Start Screen

Note

It may take a short time for the Event Viewer to be fully loaded (screen shown below is fully loaded). During the loading time under Summary of Administrative Events, it will display **reading data, please wait**.

3. The Event Viewer screen appears (see [Figure 5-28](#)). To view logs:
 - A. Touch the folder **Applications and Services Logs** to expand the folder.

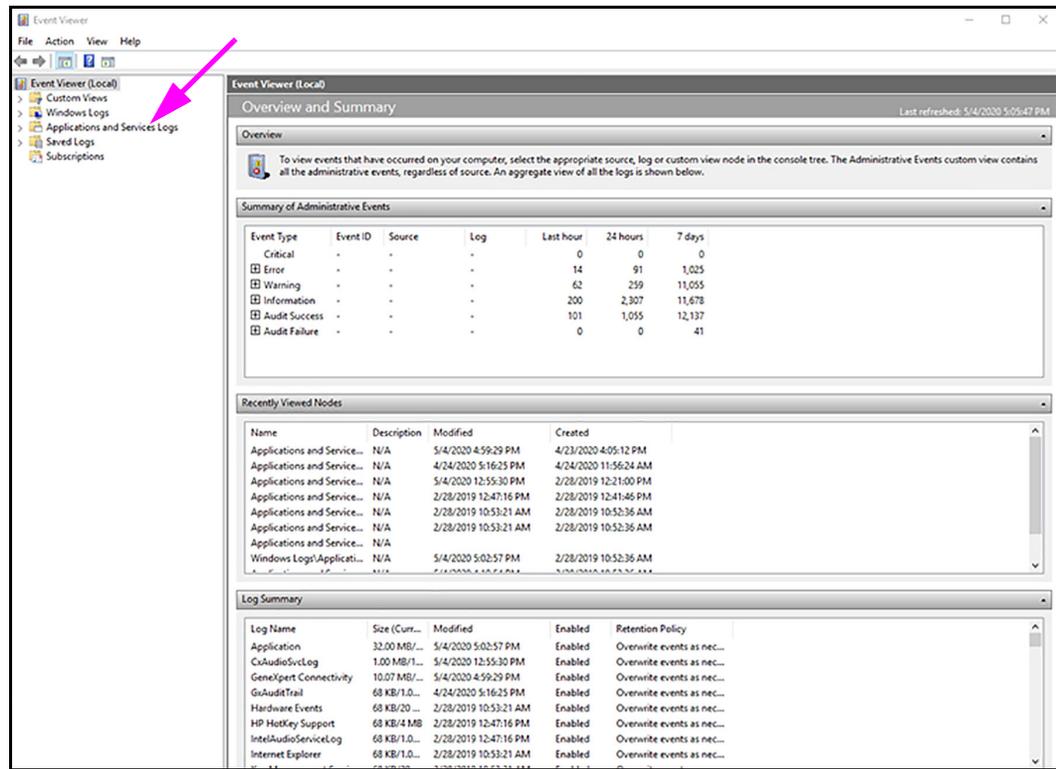


Figure 5-28. Event Viewer Screen

B. On the expanded folder view, touch and hold **GeneXpert Connectivity** (see Figure 5-29).

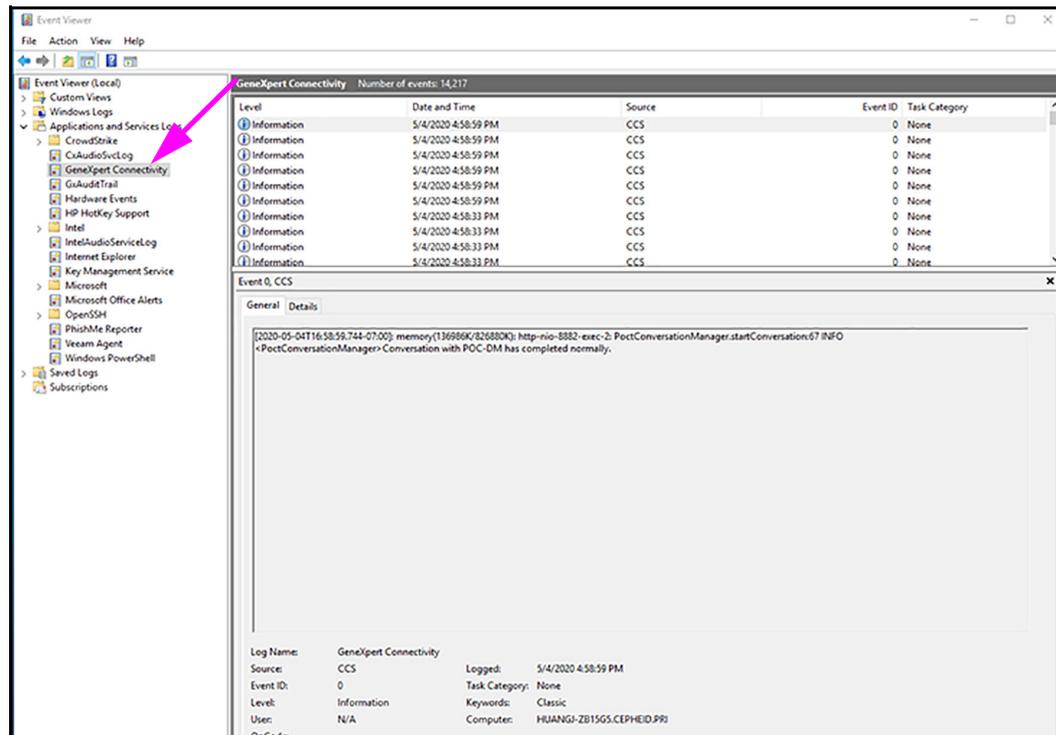


Figure 5-29. Application and Service Logs Folder - Expanded

- C. The GeneXpert Connectivity screen appears (see [Figure 5-30](#)).
- D. Touch **Filter Current Log**.

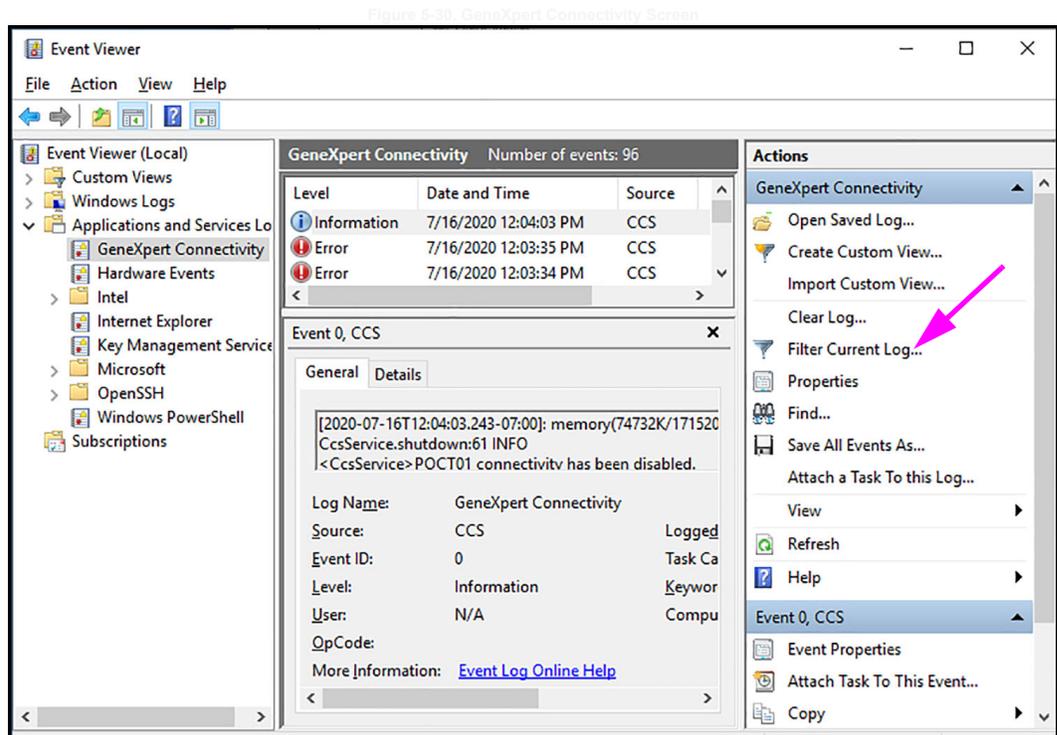


Figure 5-30. GeneXpert Connectivity Screen

4. Configure the filter as desired.
5. Touch **OK**.
6. Touch and hold **GeneXpert Connectivity**.
7. Touch **Save Filtered Log File As...**
8. The Windows Save As screen appears (see [Figure 5-31](#)). On this screen, locate the folder to save the file, and then enter a filename using the virtual keyboard (the keyboard appears when you touch the filename entry field).
9. Specify a desired location and filename, and touch the **SAVE** button.

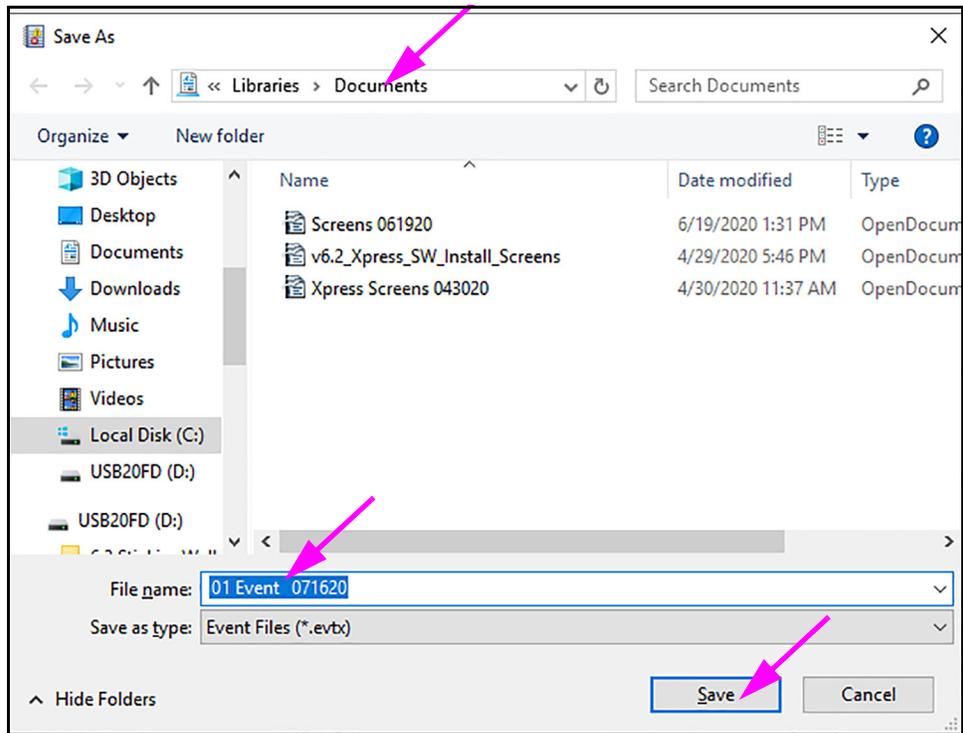


Figure 5-31. Display Information Screen

10. On the **Display Information** prompt, touch **Display Information for these languages**.
11. Touch **OK**.
12. Touch and hold **GeneXpert Connectivity**.
13. Touch **Clear Filter**.

5.19.5 Performing Troubleshooting Issues Remotely

There may be times when you want to remote into your device to perform troubleshooting steps for an issue. Below are steps to connect remote into the device.

Note

The following instructions assume that your device has been set up on the network by your IT department. Please contact your IT department if you need to connect devices to the network.

1. On the Xpress system, perform this one time set up:
 - A. Navigate to **Setting > System > Remote Desktop**.
 - B. Touch **Enable Remote Desktop** to turn it on.
 - C. Touch **Confirm** when prompted.
 - D. Optional Step: Under **Advanced settings**, touch **Require computers to use Network Level Authentication to connect**.

2. On an Administrator system, perform this first time setup per remote machine:
 - A. In Windows Search look up **Remote Desktop Connection**.
 - B. Click to launch **Remote Desktop Connection** from the search result.
 - C. Click **Show Options**. Perform the following steps:
 - 1) For **Computer**, either an IP address or computer name may be entered.
 - 2) For **User name**, enter the user name of the account you wish to access.
 - 3) Optional Step: Check mark **Allow me to save Credentials** so that this connection will be saved for easy access at a later time.
 - D. Click **Connect**.
 - E. Enter the password of the remote machine.
 - F. Click **Remember Me** to save the password.
 - G. Click **OK**.
 - H. You may be prompted by a Windows pop up message **The identity of the remote computer cannot be verified. Do you want to connect anyways?**
Click **Yes**. Optionally you may also click the Check box for **Don't ask me again for connections to this computer**.
3. On an Administrator System, perform these steps on subsequent connects, after the first time setup:
 - A. In Windows Search look up "**Remote Desktop Connection**"
 - B. Click to launch **Remote Desktop Connection** from search result.
 - C. Select previously connected computers from the drop-down menu choices.
 - D. Click **Connect**.
 - E. Depending on if login credentials were saved on the initial set up, this should allow the administrator to be connected. Otherwise follow the on screen prompt similar to first time setup.

A Performance Characteristics and Specifications

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

- [Section A.1, Instrument Classification](#)
- [Section A.2, General Specifications for the GeneXpert Xpress System](#)
- [Section A.3, Operational Environmental Parameters](#)
- [Section A.4, Environmental Conditions - Storage and Transport](#)
- [Section A.5, Sound Pressure](#)
- [Section A.6, Product Energy Consumption Information](#)

A.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 evaluating preprocessed biological material.

A.2 General Specifications for the GeneXpert Xpress System

The GeneXpert Xpress system has the following specifications:

- **Dimensions and Weight:**

Table A-1. System Dimensions and Weights

	Width	Height	Depth	Weight
GX-IV	28.2 cm (11.1 in)	30.5 cm (12 in)	29.7 cm (11.7 in)	11.4 kg (25 lb)
GeneXpert Hub	29.21 cm* (11.5 in)	14 - 15.9 cm ** (5.5 - 6.25 in)	38 - 43 cm (15 - 17 in)	4.9 kg (10.7 lb)
Overall Xpress System	29.21 cm* (11.5 in)	44.5 - 46.36 cm ** (17.5 - 18.25 in)	38 - 43 cm** (15 - 17 in)	16.3 kg (35.7 lb)

*Includes hub to instrument side mounting clamps

**Height and depth varies, depending on the tilt of the adjustable hub monitor

- **Power Supply:** Auto-ranging
- **Rated AC Voltage Range:** 100–240 V~, 50–60Hz Earth Grounded Outlet
- **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 A-2. Rated Current and Fuse Rating

Rated Current	Fuse Rating
2.2A @ 100V~	250V~ T2A (IEC 60127 time-delay type)

A.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

The GeneXpert Xpress system is designed for indoor use only. Place the GeneXpert Xpress system 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.

A.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

A.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

A.6 Product Energy Consumption Information

Table A-3. Product Energy Consumption

Supplier Model Identifier	Energy Efficiency Class	On Mode Power	Annual Energy (KWh)	Standby Power (W)	BTU/hr
GeneXpert IV	G	100	489	83	341
GeneXpert Hub	G	30	155	16	102

