

GeneXpert Dx System



Operator Manual

Software Version 4



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Preface

About this manual

The *GeneXpert® Dx System Operator Manual* provides instructions on the safe use of the GeneXpert Dx System. Read the entire manual and become familiar with the safety information before you start to operate the instrument. Using the instrument without reading the manual or without proper training can result in serious injury, damage to the instrument, invalid results, or loss of data.

The software-related instructions in this operator manual assume you have basic computer skills. You should be familiar with the Microsoft® Windows® graphical user interface. If you do not have these skills, refer to the documentation for Windows.

Safety information

Chapter 9 in this manual provides important safety information that you should use when operating the GeneXpert instrument. Read and understand the safety information thoroughly before you begin operating the instrument.

Make sure you follow the precautionary statements presented in this manual:

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



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

Highlights information that is critical for the completion of a task or the optimal performance of the system.

Note: Identifies information that applies only in special cases.

Assistance

For assistance, contact Cepheid using one of the following contact details. Make sure you provide the instrument serial number when you call or email.

North America

For technical support, use the following contact details:

Tel: +1.888.838.3222

Email: techsupport@cepheid.com

You can reach Cepheid Technical Support by telephone Monday through Friday, from 5 A.M. to 5 P.M. Pacific time.

For general information, use the following contact details:

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Sunnyvale, CA 94089-1189
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Fax: +1.408.541.4192

European Union

For technical support, use the following contact details:

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Authorized Representative

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France

Tel: +33.563.82.53.00

Fax: +33.563.82.53.01

Email: cepheid@cepheideurope.fr

Other locations

Contact your local Cepheid office. Contact information for Cepheid offices is available at www.cepheid.com or www.cepheidinternational.com.

Chapter 1 Introduction—Use and Function

The GeneXpert Dx System automates and integrates sample preparation, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time Polymerase Chain Reaction (PCR). The system is suited for *in vitro* diagnostic applications that require hands-off processing of patient samples (specimens) and provides both summarized and detailed test results data in tabular and graphic formats.

This chapter provides an overview of the GeneXpert Dx System. The topics are as follows:

- Four Models of GeneXpert Instruments (Section 1.1)
- System Components (Section 1.2)
- GeneXpert Cartridges (Section 1.3)
- GeneXpert Dx System Software (Section 1.4)
- Workflow Overview (Section 1.5)
- Before You Begin (Section 1.6)

1.1 Four Models of GeneXpert Instruments

There are four different GX R2 instruments:

- The GX-I R2 instrument consists of one module (or one site) to process one sample (Figure 1-1).
- The GX-II R2 instrument consists of two modules. Each module processes one sample (Figure 1-2)
- The GX-IV R2 instrument consists of up to four modules. Each module processes one sample (Figure 1-3). Up to four GeneXpert IV instruments can be connected to one computer.
- The GX-XVI R2 instrument consists of up to sixteen modules. Each module processes one sample (Figure 1-4).

1.2 System Components

- **GeneXpert instrument**—Accepts the GeneXpert cartridges that you load into the instrument, lyses the samples in the cartridges, releases the nucleic acids, and amplifies the target sequences. Because the system allows you to control the modules independently, you can process different samples using different assay definitions in the same instrument at the same time.
- **Desktop or laptop computer**—Allows you to run the GeneXpert Dx System software and hosts the GeneXpert Dx System results database. The software allows you to select the assay definitions, monitor the test process, view the results, and export selected data to downstream software, such as Microsoft® Excel, for additional analysis. The

software also allows you to archive and retrieve the results data and manage the database.

- **Barcode scanner**—Facilitates data entry in the system.

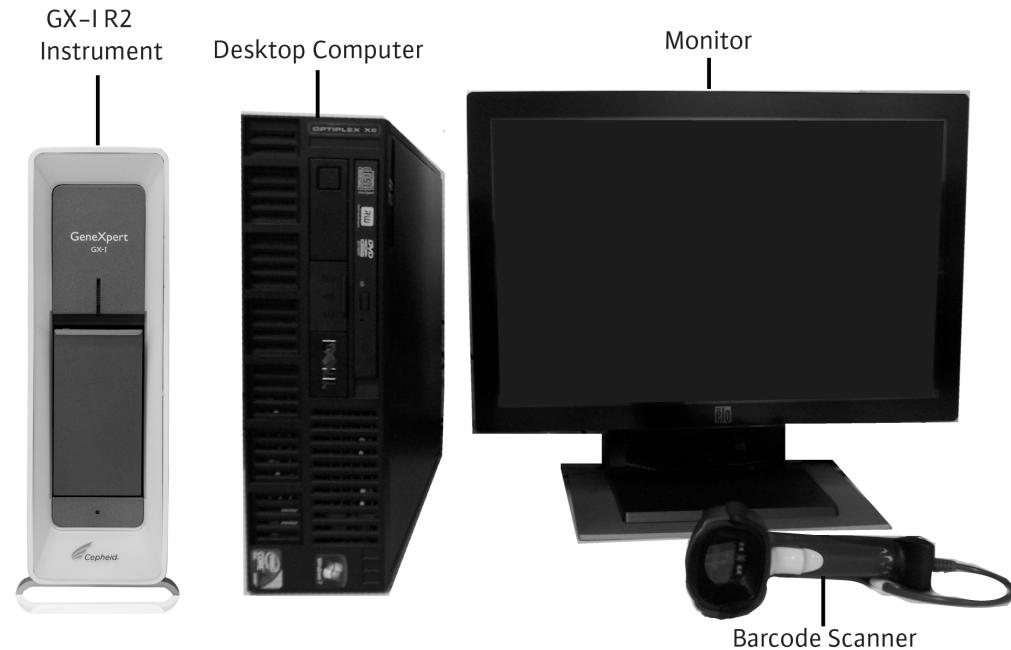


Figure 1-1. GX-I R2 Dx System hardware components (shown with the desktop computer)



Figure 1-2. GX-II R2 Dx System hardware components (shown with the desktop computer)

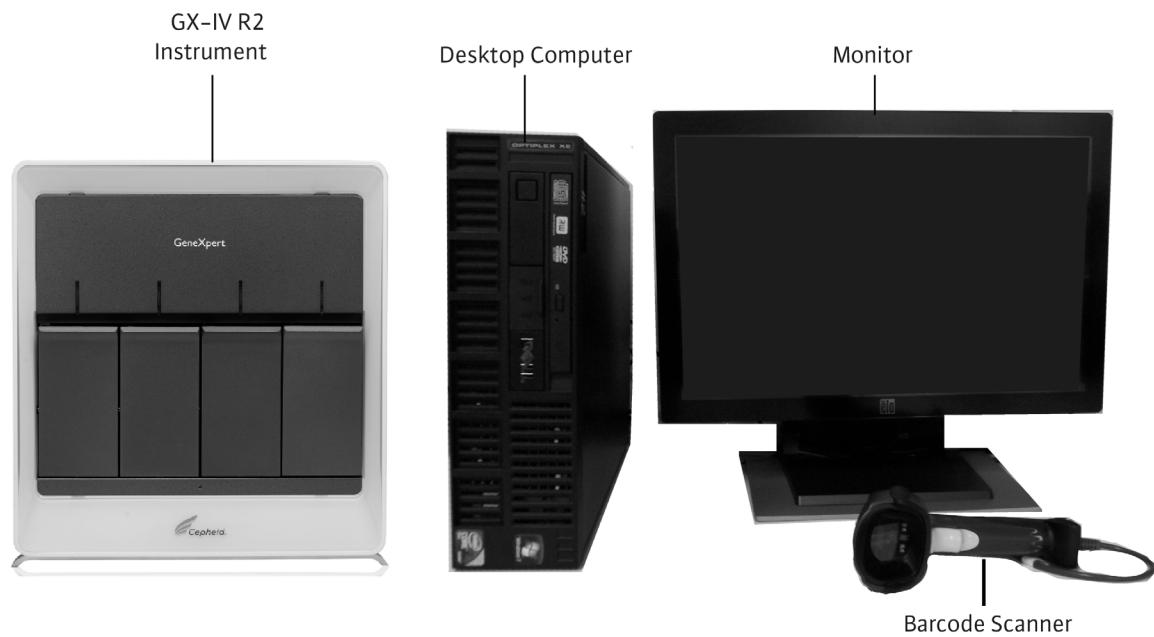


Figure 1-3. GX-IV R2 Dx System hardware components (shown with the desktop computer)

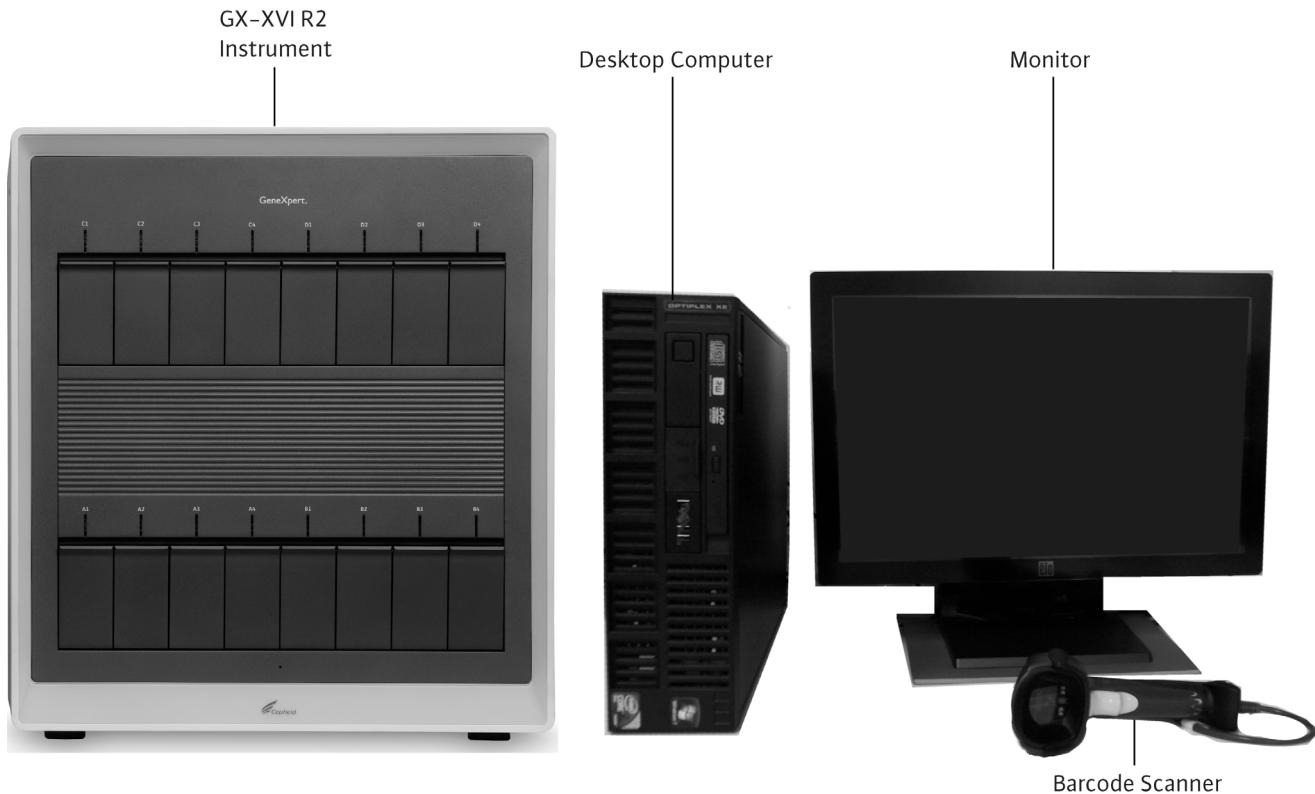


Figure 1-4. GX-XVI R2 Dx System hardware components (shown with the desktop computer)

1.3 GeneXpert Cartridges

The samples are prepared and processed in single-use, assay-specific GeneXpert cartridges (Figure 1-5). You insert the sample and applicable reagents into a cartridge and then load the cartridge into one of the available instrument modules.

The cartridges are not supplied with the system and must be purchased separately. For ordering information, contact Cepheid. See the Assistance section in the Preface for the contact information.



Figure 1-5. GeneXpert cartridge

1.4 GeneXpert Dx System Software

The GeneXpert Dx System software is installed on the supplied computer and can accommodate a variety of applications. This section describes the software features that are for *in vitro* diagnostic use.

1.4.1 Features for *in vitro* diagnostic use

The GeneXpert Dx System software allows you to perform the following tasks for *in vitro* diagnostic use (Figure 1-6):

- **Administrative tasks**—Configure the system to accommodate your organization's preferences, define system users and set up permissions (access privileges), import or delete *in vitro* diagnostic assay definitions, generate external control trend reports, and manage the test data in the database.
- **Test tasks**—Create and start an *in vitro* diagnostic test, stop a test in progress, monitor a test in progress, view the test results, edit test information, and generate test reports.
- **Maintenance tasks**—Perform a self-test manually for troubleshooting and check the calibration and test counts.

For a summary of the workflows for *in vitro* diagnostic use, see Section 1.5.

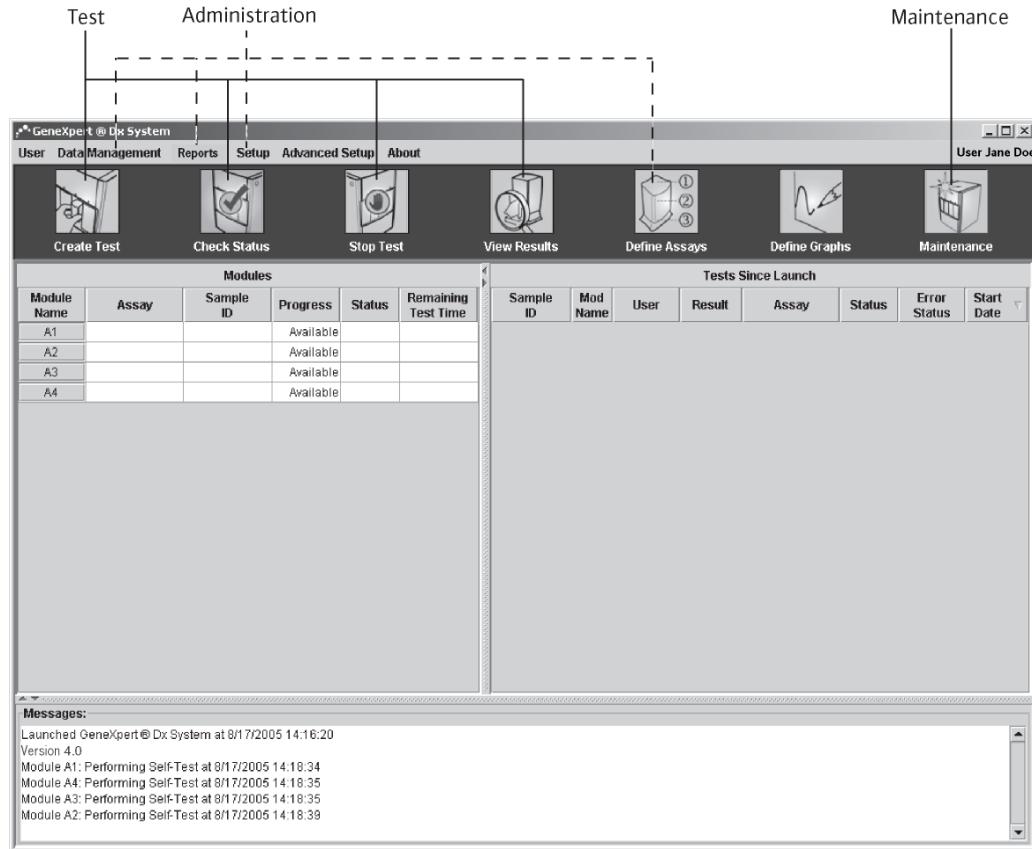


Figure 1-6. GeneXpert Dx System software features that are intended for *in vitro* diagnostic use

1.5 Workflow Overview

The GeneXpert Dx System workflow covers the following tasks:

- Installation and setup (Section 1.5.1)
- Test process (Section 1.5.2)

1.5.1 Installation and setup workflow

Table 1-1 lists the tasks for installing and setting up the GeneXpert Dx System. Note that although you can import *in vitro* diagnostic assay definition files, the GeneXpert Dx System software does not allow you to modify the assay definitions.

Table 1-1. Workflow for installing and setting up the system

Step	Task	Section
1.	Install the GeneXpert Dx instruments.	Section 2.4
2.	Set up the computer.	Section 2.5
3.	Start the software.	Section 2.6
4.	(Optional) Assign instrument letters.	Section 2.7
5.	Define users and permissions.	Section 2.8
6.	Configure the system.	Section 2.9
7.	Verify proper installation and setup.	Section 2.10
8.	(Optional) Import assay definition files.	Section 2.11

After the system is installed and running, you can perform the following tasks:

- Add new users (Section 2.8.3.2)
- Install additional GeneXpert instruments (Section 2.4.2)

1.5.2 Test workflow

Table 1-2 lists the tasks for processing a specimen sample using the GeneXpert Dx System. Note that although you can import *in vitro* diagnostic assay definition files, the GeneXpert Dx System software does not allow you to modify the assay definitions (Section 1.4). For systems connected to Host, see Chapter 6 for test workflow.

Table 1-2. Typical test workflow

Step	Task	Section
1.	Start the GeneXpert Dx System.	Section 5.3
2.	Check the list of assays available. Import the assay definition files if necessary.	Sections 5.4 and 2.11
3.	Create a test.	Section 5.5
4.	Start the test.	Section 5.5
5.	Load a cartridge into an instrument module.	Section 5.6
6.	Monitor the test progress.	Section 5.8
7.	View the test results.	Section 5.10
8.	Manage the test results data.	Section 5.15
9.	Maintain the system.	Chapter 10

Figure 1-7 is a graphical overview of the test workflow.

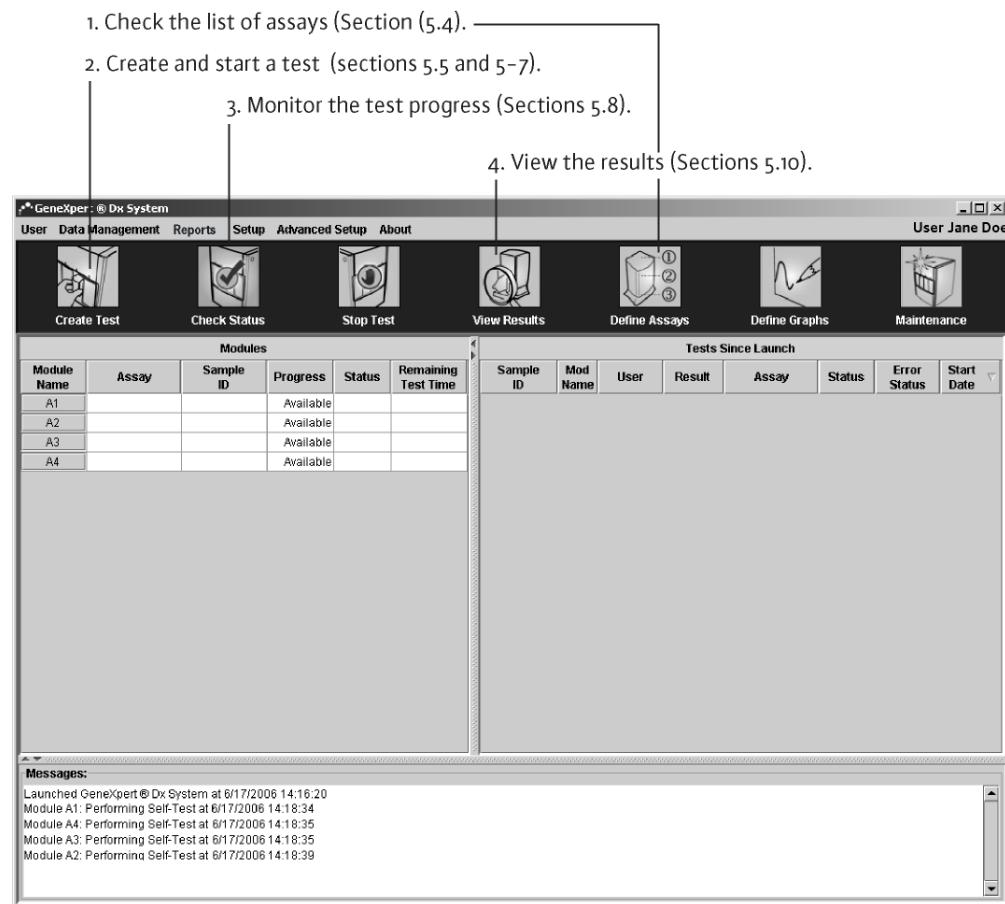


Figure 1-7. GeneXpert Dx System window and the typical test workflow

1.6 Before You Begin

Make sure you read the entire manual and become familiar with the safety information in Chapter 9 before you start to operate the instrument. Using the instrument without reading the manual or without proper training can result in serious injury, damage to the instrument, or loss of data.

Chapter 2 Installation—Procedures and Special Requirements

This chapter describes how to install and set up the system. Except when noted, the procedures in this chapter are for the GeneXpert Dx System administrator or equivalent personnel. The topics are as follows:

- GeneXpert Dx System Package Contents (Section 2.1)
- Antivirus Software (Section 2.2)
- Required Materials for Use with the System (Section 2.3)
- Installing the GeneXpert Instruments (Section 2.4)
- Setting Up the Computer (Section 2.5)
- Starting the Software (Section 2.6)
- Assigning Instrument Letters (Section 2.7)
- Defining Users and Permissions (Section 2.8)
- Configuring the System (Section 2.9)
- Verifying Proper Installation and Setup (Section 2.10)
- Managing Assay Definitions and Lot-Specific Parameters (Section 2.11)
- Restarting the System (Section 2.12)
- Uninstalling or Reinstalling GeneXpert Dx System Software (Section 2.13)

2.1 GeneXpert Dx System Package Contents

The GeneXpert Dx System package contains the following:

- GeneXpert instrument
- Desktop or laptop computer, preloaded with the GeneXpert Dx Software and other required software
- Network switch (included if you have two or more instruments)
- 2D barcode scanner
- Power cord, type: IEC-320-13, 10A/125V North America, 10A/250V International (for GX-IV R2 and GX-XVI R2)
- DC Adapter Power cable (for GX-I R2 and GX-II R2)
- CAT-5 Ethernet® crossover cable
- *GeneXpert Dx System Operator Manual*

Caution



Use only the components included in the package. Do not replace any of the components, such as the computer. Using non-approved replacement components can produce invalid results, cause loss of data, or damage other system components.

2.2 Antivirus Software

Caution



Do not connect the GeneXpert Dx System computer to the Internet. Doing so can introduce computer viruses and corrupt the results data.

If you plan to connect the computer to a local area network, Cepheid strongly recommends that you install the supplied Norton AntiVirus™ software. To install Norton AntiVirus, insert the Norton AntiVirus CD in the computer CD-ROM drive. The installation process should start automatically. Follow the instructions in the installation window to install and activate the software. See also the Norton AntiVirus User Guide.

Caution



The GeneXpert Dx System computer is set up to use Windows® Firewall so you can leave Windows Firewall turned on. Do not turn on or use other non-Windows firewall products. Doing so can prevent data collection.

2.3 Required Materials for Use with the System

The following items are required for use with the GeneXpert Dx System but are not included in the package:

- Assay-specific GeneXpert cartridges
- Assay-specific requirements (refer to the assay package insert or your local and national regulatory guidelines)
- Surge protector
- Printer

To order the GeneXpert cartridges or printer, contact Cepheid. See the Assistance section in the Preface for the contact information.

2.4 Installing the GeneXpert Instruments

Caution



Version 2.1 (or above) software is required for 6-color GeneXpert Dx System and modules. To avoid hardware failures, GeneXpert Dx 2.1 (or above) software must be installed BEFORE connecting and powering up a 6-color instrument or upgrade modules.

Warning



See weights table in Section 4.2 for GeneXpert instrument weights. Use care when unpacking the instrument. Do not attempt to lift the instrument without proper safety training and assistance. Lifting or moving the instrument without proper training and assistance can cause personal injury, damage the instrument, and void your warranty.

Important

Before you install the instrument, read chapters 4 and 8 to become familiar with the system specifications and requirements.

2.4.1 To Install a instrument

1. Unpack the system and make sure the package contains the items in Section 2.1.
2. Place the instrument on a hard, sturdy, level surface. Make sure the power cord connection and the power switch (on the back side) are easily accessible.

Caution



Provide at least 5 cm (2 in) of clearance on each side of the instrument. Do not block the fan exhaust on the lower back side or the air intake on the upper back side. The lack of proper ventilation can cause the instrument to malfunction.

3. Connect one end of the supplied Ethernet cable to the network port on the back side of the computer (depending on the GX R2 model, see Figure 2-1, or 2-2, or 2-3, or 2-4). A label indicates that the port is for use with the GX R2 instrument.

Important

Use the supplied Ethernet cable to connect the GeneXpert instrument and the computer. If the cable is missing or you need an additional cable, contact Cepheid Technical Support. See the Assistance section in the preface for the contact information. See Section 10.9 for the part number.

Caution



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

Note: The computer supplied with the GeneXpert instrument should have been set to the correct IP address before it left the factory, but if the computer is not communicating with the instrument, perform the steps shown in the following sidebar titled “How to Set the IP Address”.

How to Set the IP Address

1. Select Start -> Control Panel -> Network and Internet Connections.
2. Under or pick a Control Panel icon click on Network Connections.
3. Right-click on GeneXpert Connection and select Properties from the pop up menu.
4. Highlight Internet Protocol (TCP/IP) and then click on Properties.
5. Select “Use the following IP address:”.
6. Enter:
IP Address: 10 . 11 . 14 . 1
Subnet Mask: 255 . 255 . 255 . 224
7. After you have verified that all numbers are entered correctly, click OK or Close to close the GeneXpert Connection properties windows.

4. Connect the other end of the Ethernet cable to the network port on the lower back panel of the instrument (Figure 2-1, or 2-3, or 2-4).
5. Connect the supplied power cords (or DC adapter power cable) to the instrument and the computer, and then connect the power cords to a surge protector.

Caution



Make sure the surge protector is connected to a properly grounded circuit. Using a non-grounded circuit can cause damage to the instrument.

6. Turn on the instrument. The small blue light on the front of the instrument turns on.
7. Now, perform the steps given in Section 2.5 (Setting Up the Computer), or if you are setting up multiple instruments, perform the steps given in Section 2.4.2 (To Install additional instruments).

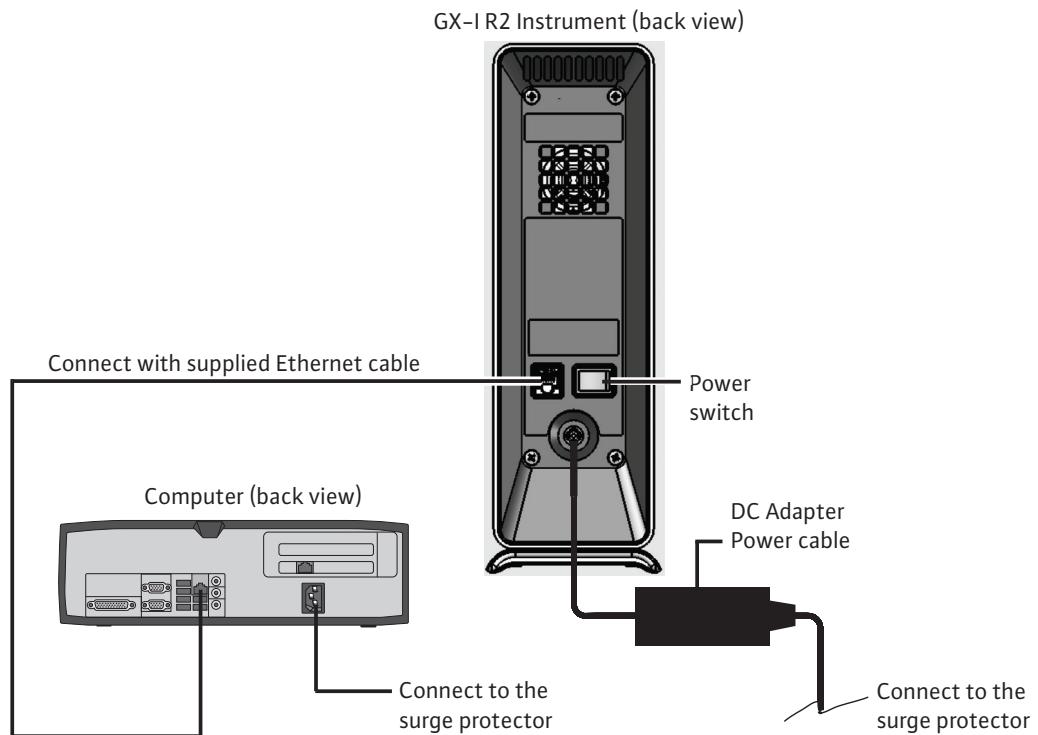


Figure 2-1. Connecting the GX-I R2 instrument to the computer

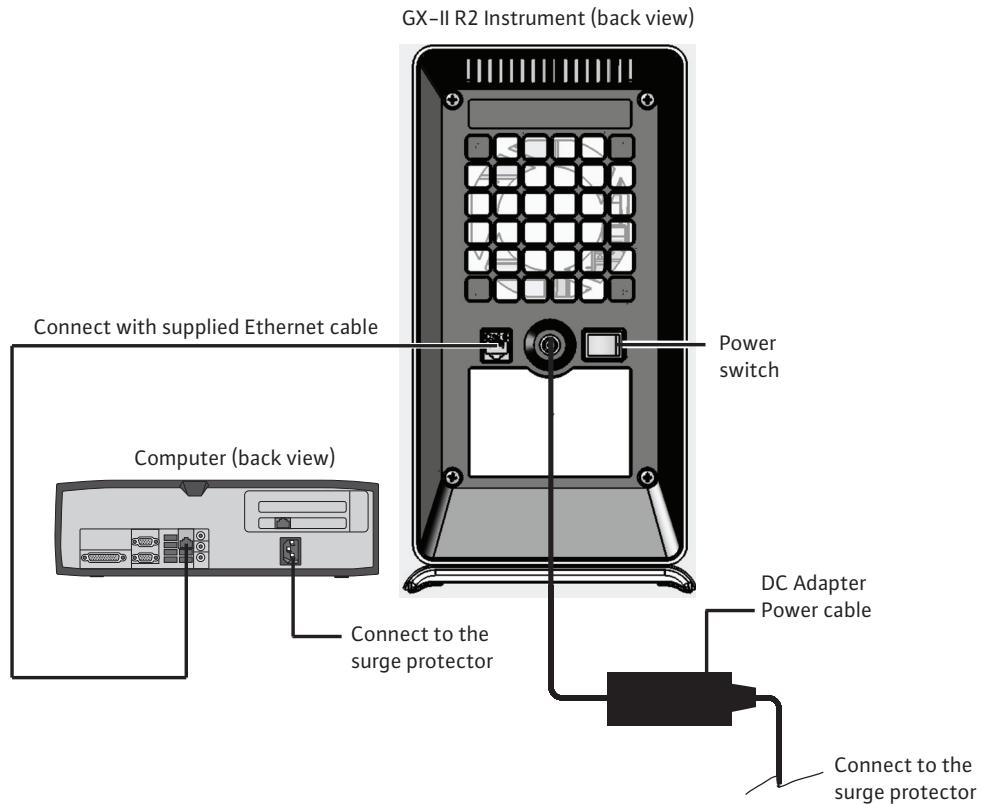


Figure 2-2. Connecting the GX-II R2 instrument to the computer

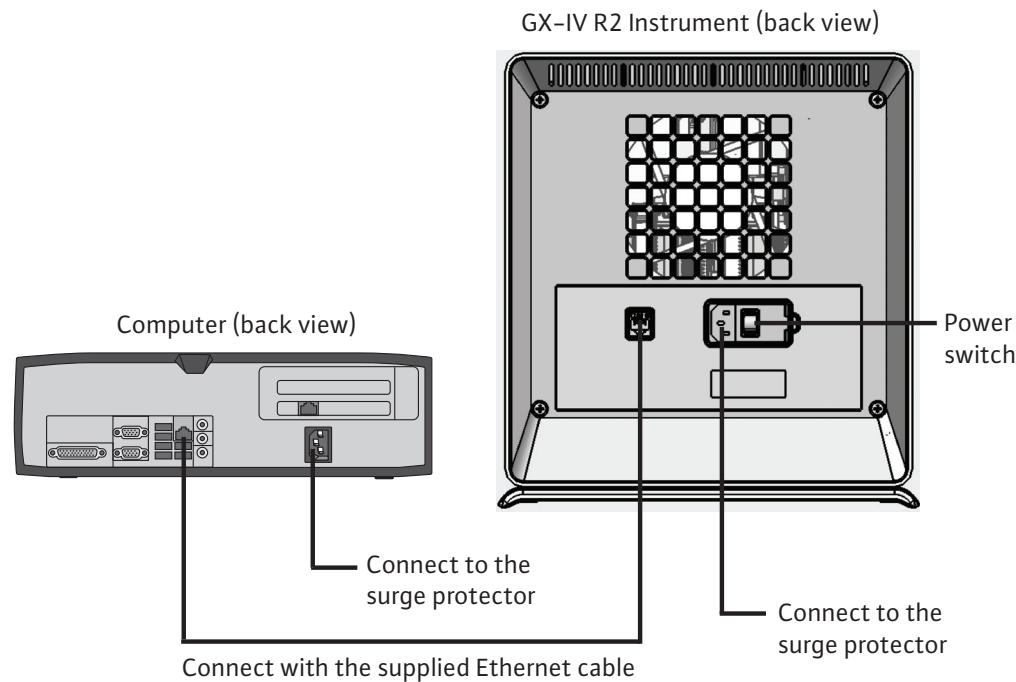


Figure 2-3. Connecting the GX-IV R2 instrument to the computer

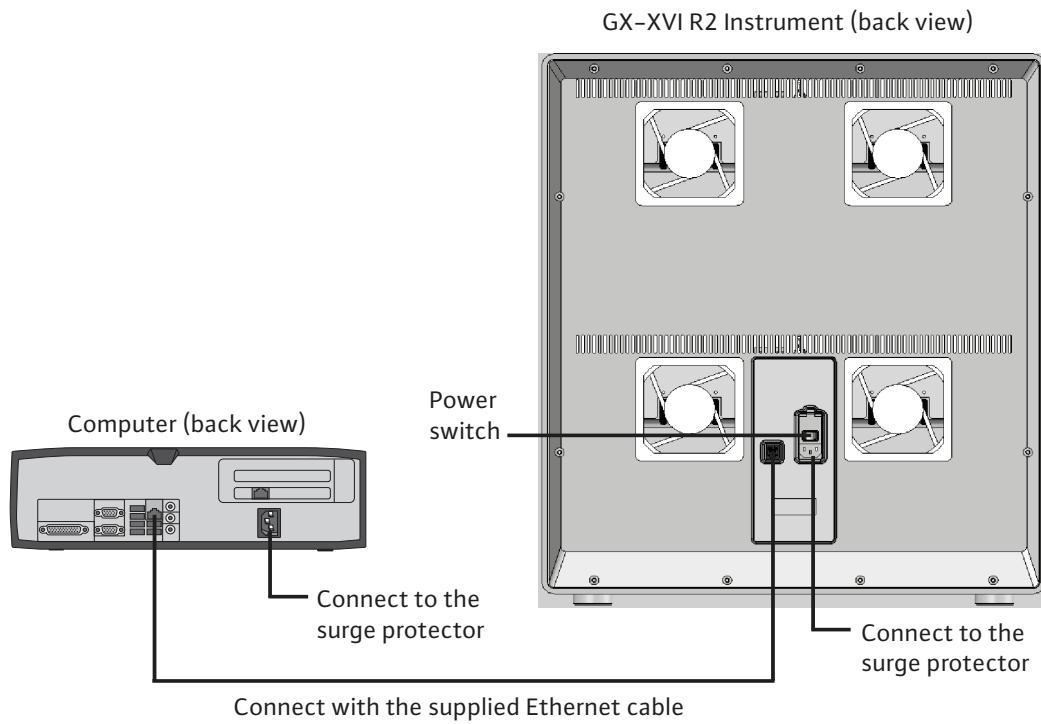


Figure 2-4. Connecting the GX-XVI R2 instrument to the computer

2.4.2 To Install additional instruments

Caution



Before you install additional instruments, make sure the GeneXpert Dx System software is not running.

Caution



Version 4.0 (or above) software is required for 6-color GeneXpert Dx System and modules. To avoid hardware failures, GeneXpert Dx 4.0 software (or above) must be installed BEFORE connecting and powering up a 6-color instrument or upgrade modules.

Note: You do not have to turn off the computer to connect additional instruments.

You can connect up to four GX-I, GX-II, or GX-IV R2 instruments to a single computer. In the multiple-instrument setup, connect the computer to the supplied network switch, and then connect the instruments to the switch (Figure 2-5).

1. Unpack the additional instrument(s), power cords, network switch, and Ethernet cables.

2. If the GeneXpert Dx Software is currently running, quit the software.

See GX System Note that is supplied with the computer.

3. Disconnect the Ethernet cable from the back of the previously installed instrument. Keep the Ethernet cable connected to the computer.

4. Connect the free end of the Ethernet cable in step 3 to any of the available ports in the network switch. The Ethernet cable should connect the computer and the network switch.

5. Using a second Ethernet cable, connect the additional instrument to any available port in the network switch. One end of the Ethernet cable connects to the network port on the back of the instrument, the other end connects to a free port of the network switch.

6. Repeat step 5 to connect additional instruments to the network switch.

7. Connect the supplied power cord to the additional instrument, and then connect the power cord into a surge protector. Repeat this step for each additional instrument.

8. Leave the instruments OFF until the computer is setup.

9. Now, perform the steps given in Section 2.5 (Setting Up the Computer).

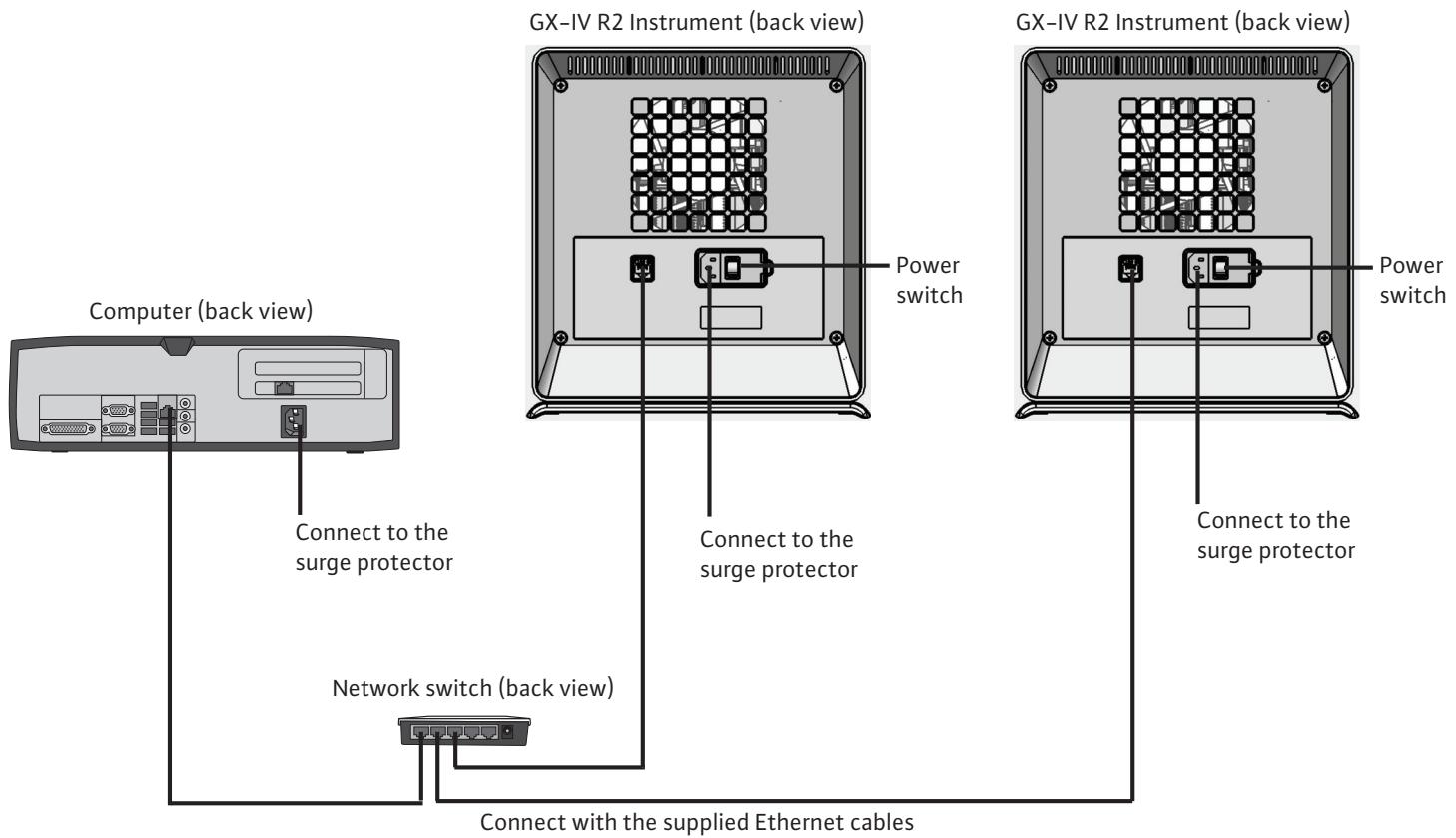


Figure 2-5. Connecting multiple GX-IV R2 instruments to the computer

2.5 Setting Up the Computer

After you install the instrument(s), you need to do the following:

Important

Connect the barcode scanner directly to the computer USB port. Do not use a USB hub.

1. Turn on the computer (if you have not already done so).
2. Log on to Windows using the preconfigured account that has administrator privileges.

Caution



Make sure you are logged on using the preconfigured account. If you log on using a different user name and profile, the power management settings will be incorrect.

You must log on as the Cepheid user to operate the system. When logging on, use the following:

- **User name:** Cepheid
 - **Password:** cphd
3. Confirm that the GeneXpert Dx System software is installed. Check that the GeneXpert Dx shortcut icon is on the Windows desktop (Figure 2-6).



Figure 2-6. GeneXpert Dx System shortcut icon

4. Select the correct computer power management setting to ensure the proper operation of the system (Section 2.5.1).
5. Set the computer date and time to ensure accurate time-stamping when the system is in use (Section 2.5.2).

2.5.1 Selecting the power management setting

The computer is already configured with the correct power management software. If it needs to be reset:

1. Open the Control Panel window. To do this, on the Windows desktop, click Start, and then click **Control Panel**.
2. Select Performance and Maintenance option, and then double-click **Power Options** icon. The Power Options Properties dialog box appears (Figure 2-7).

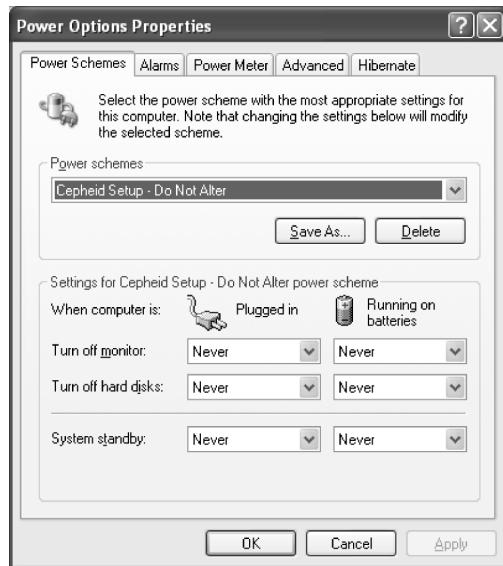


Figure 2-7. Power Options Properties dialog box for desktop computers

3. In the Power schemes list, select Cepheid Setup- Do Not Alter.
4. In the settings for CepheidSetup - do not alter power scheme area, select Never for all the conditions when the computer is connected to the power outlet and, if the computer is a laptop, when it is running on batteries.
5. Click Apply to apply the settings.
6. Click Hibernate tab and make sure Hibernate is disabled (Figure 2-8).

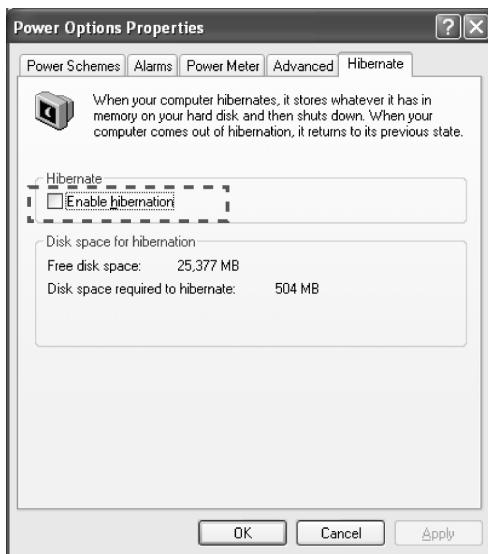


Figure 2-8. Power Options Properties dialog box (Hibernate)

If Hibernate is not disabled, click the checkbox adjacent to **Enable hibernation** to uncheck the box. Click **Apply** and then click **OK** to save the settings and close the Power Options Properties dialog box.

2.5.2 Setting the Local Date and Time

1. Click Start, and then click Control Panel.
2. Double-click Date and Time icon. The Date and Time Properties dialog box appears (Figure 2-9).

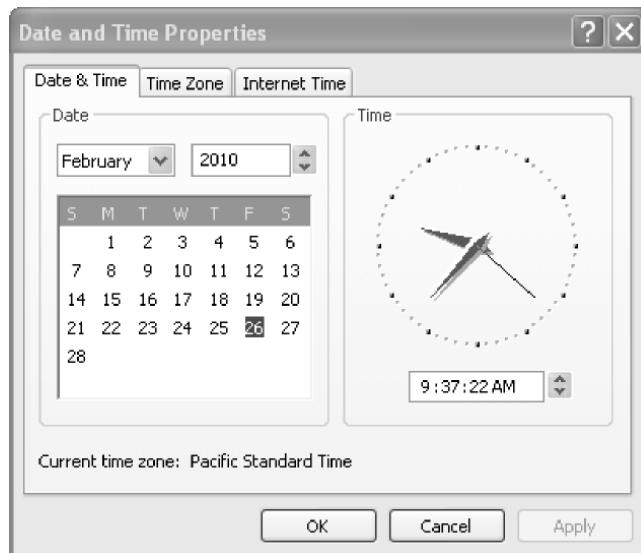


Figure 2-9. Date and Time Properties dialog box

3. In the Date & Time tab, set the correct local date and time.
4. In the Time Zone tab, select the correct local time zone.
5. Click OK to save the changes and close the dialog box.

Caution



Do not change when test is in progress.

6. In the Internet Time tab, disable **Automatically synchronize with an Internet time server** by deselecting the adjacent checkbox (Figure 2-10).

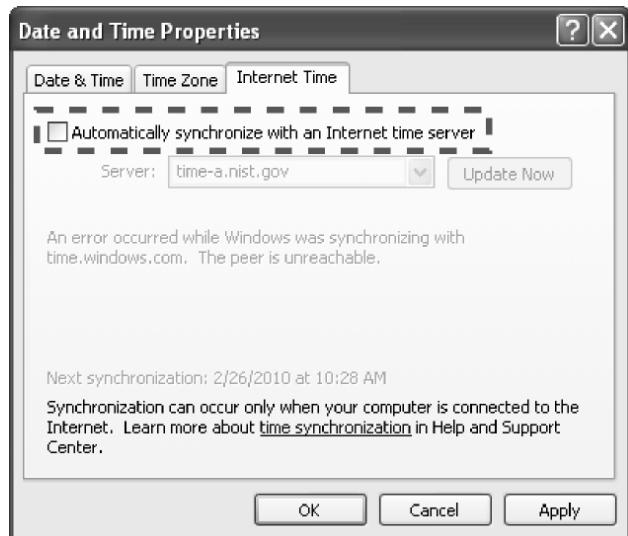


Figure 2-10. Internet Time tab

- Click **Apply**, and then click **OK** to save the settings and close the Date and Time Properties dialog box.

2.6 Starting the Software

After you install the system and set up the computer, the Desktop PC enables Auto-Start of GeneXpert Dx application upon logging into Windows User Account.

The first time you start the software, you do not have to provide a user name and password. After you define the administrator profile (Section 2.8), the software will ask you for a user name and password each time you start the software (Section 5.2.3).

As the software is starting, the green light above each module door flashes briefly, then turns off. The first time you start the software after installation, an Assign Instrument Letter confirmation dialog box appears (Figure 2-12). After automatic instrument letter assignment, and every time you start the software thereafter, the GeneXpert Dx System window appears without the Assign Instrument Letter confirmation dialog box.

Note: Whenever you exit the GeneXpert application, without powering down, you will have to manually double-click on the GeneXpert Dx icon to restart the application.

You can do this in one of two ways:

On the Windows desktop, double-click the GeneXpert Dx icon (Figure 2-6).

or

On the Windows desktop, click **Start**, point to **All Programs**, point to **Cepheid**, and then click **GeneXpert Dx**.

Important **Do not load any new version of Microsoft® SQL applications.**

Important If calibration reminder (Figure 2-11) is displayed, schedule a calibration; contact Cepheid Technical Support.

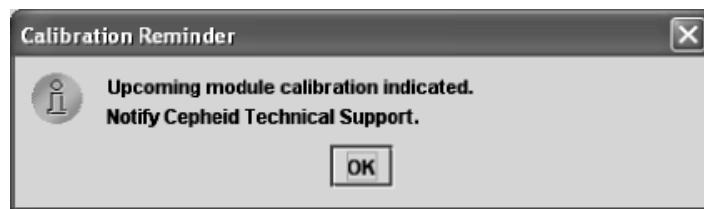


Figure 2-11. Calibration Reminder dialog box

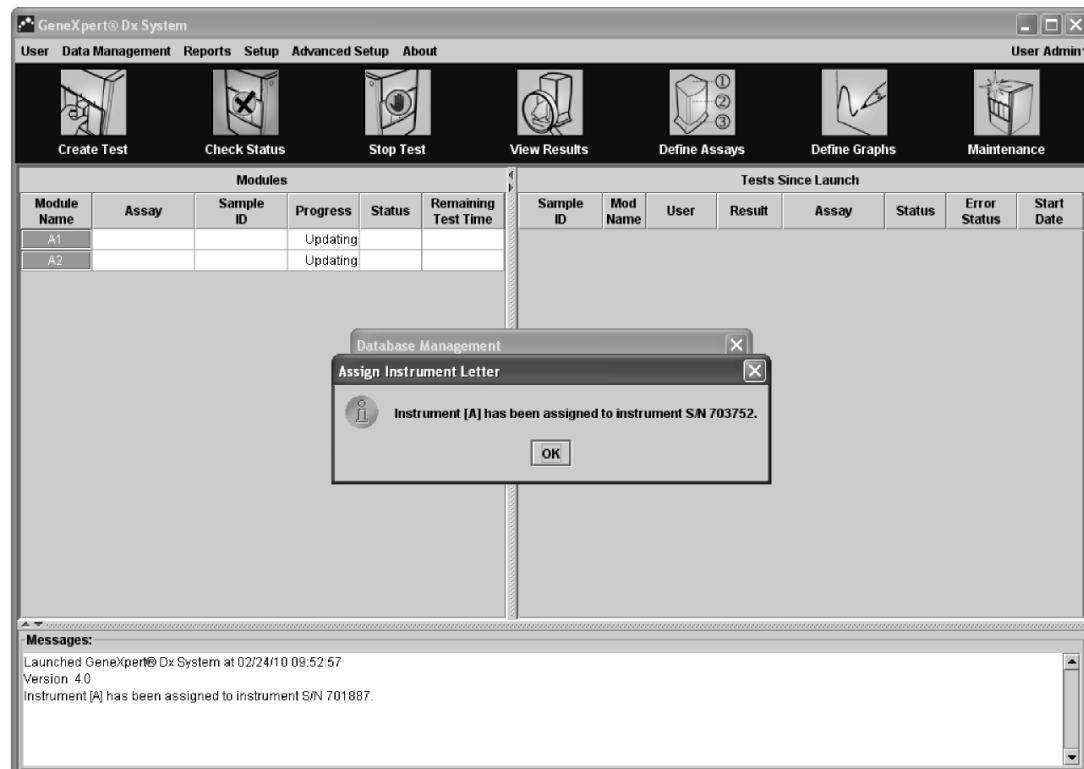


Figure 2-12. GeneXpert System window—Assign Instrument Letter dialog box

8. Click OK in the Assign Instrument Letter dialog box (Figure 2-12).

The Assign Instrument Letter dialog box disappears (Figure 2-15).

2.7 Assigning Instrument Letters

2.7.1 To Assign instrument letters (GX-I R2, GX-II R2, and GX-IV R2 instruments)

Note: This section describes tasks that only the GeneXpert Dx System administrator and users with the appropriate privileges can perform.

The first time you start the software after installation, the software will automatically assign instrument letters. By default, the software automatically assigns a letter (A, B, C or D) to identify each instrument connected to the computer. In addition, the software also assigns a number (1, 2, 3 or 4) to each module that is installed, from left to right. For example, A1 is the first or left-most module of the A instrument. The instrument and module identification appears in the Module Name column in all the software windows.

To change the instrument letter assignment:

1. In the GeneXpert Dx System window, click **Setup** in the menu bar, and then select **Assign Instrument Letter**. The Assign Instrument Letter dialog box appears (Figure 2-13).

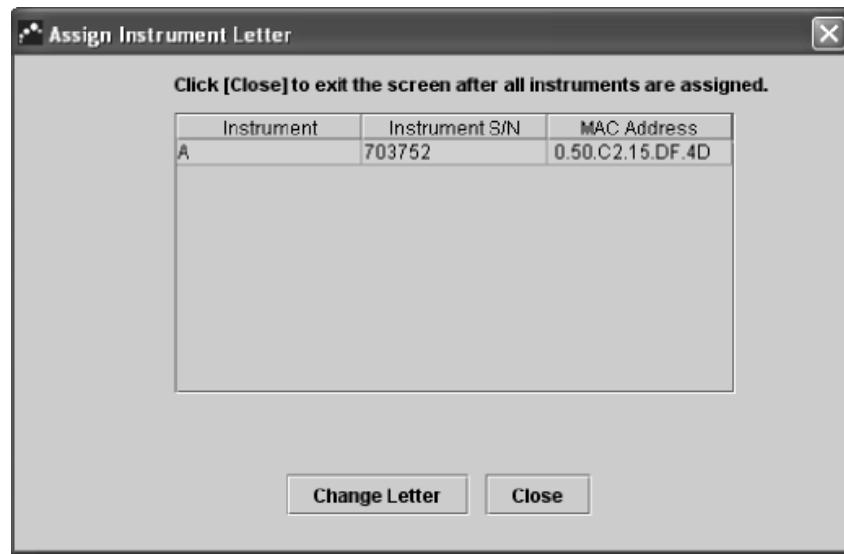


Figure 2-13. Assign Instrument Letter dialog box

2. In the Assign Instrument Letter dialog box, select the instrument, and then click **Change Letter**. The Change Letter dialog box appears (Figure 2-14). Select the letter you want for the instrument, and then click **OK**.

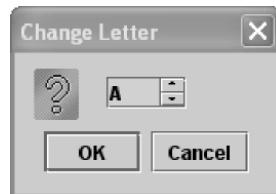


Figure 2-14. Change Letter dialog box.

3. To view the letter assignment at any time, in the GeneXpert Dx System window (Figure 2-15), on the Setup menu, click **Assign Instrument Letter**.

Note: Because the instruments do not have letter indicators, you might want to physically label each instrument according to its letter assignment.

Figure 2-15 is an example of the GeneXpert System window after assigning instrument letters to a GX-IV R2.

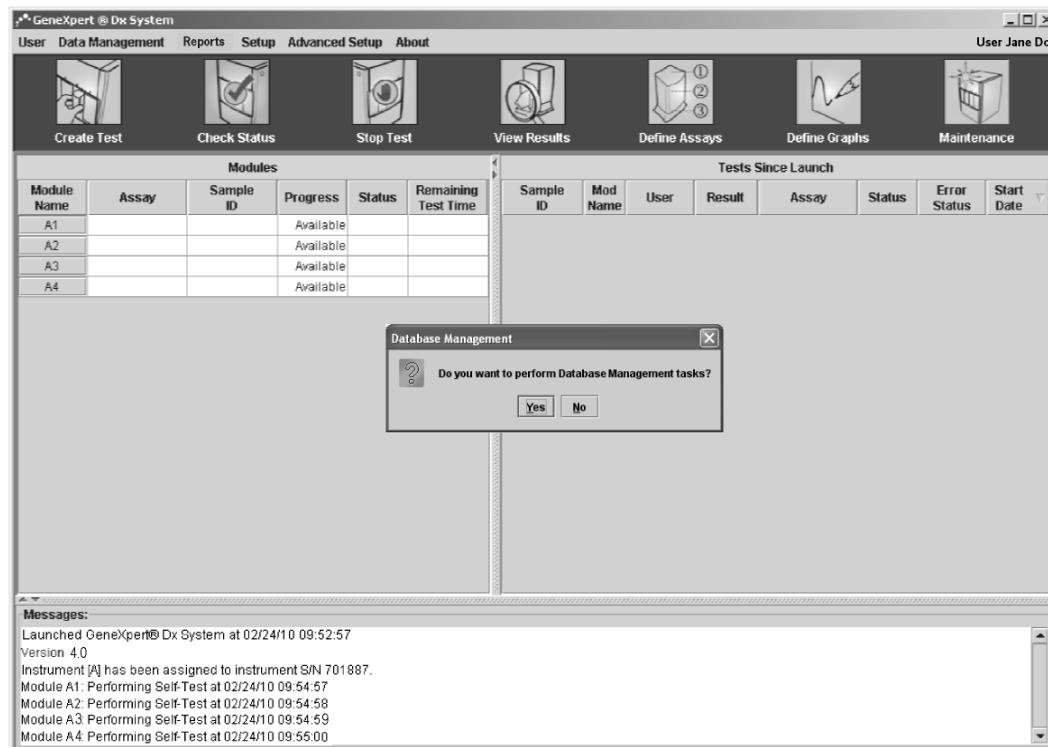


Figure 2-15. GeneXpert System window—Database Management dialog box

The Database Management dialog box appears on top of the GeneXpert Dx System window (Figure 2-15).

4. If you do not want to perform database management tasks, perform the steps in Section 5.3.2.

If you want to perform database management tasks, perform the steps in the Section 5.3.3.

Now you are ready to configure the software and additional computer components. For details, see Section 2.8, “Defining Users and Permissions.”

2.7.2 To Assign instrument letters (GX-XVI R2 instruments)

Note: Only GeneXpert Dx System administrator and users with the appropriate privileges can assign instrument letters.

The GeneXpert Dx System software automatically assigns a letter (A, B, C or D) to identify each quadrant of the GX-XVI R2 instrument connected to the computer. Figure 2-16 shows how each quadrant of the GX-XVI R2 is seen by the system.

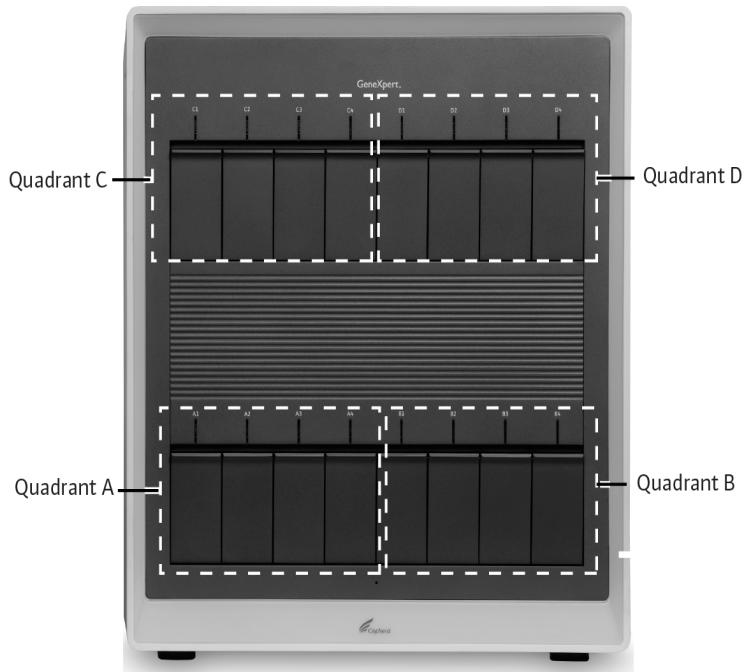


Figure 2-16. GX-XVI R2 quadrant assigned letter (A to D)

In addition to assigning instrument letters, the software also assigns a number (1, 2, 3 or 4) to each module that is installed. For example, C1 is the first or left-most module of the C instrument (quadrant C). The instrument and module identification appears in the Module Name column in all the software windows.

2.7.2.1 Viewing letter assignment (GX-XVI R2 instruments)

The first time you start the software after installation, the software will automatically assign instrument letters (Figure 2-17).

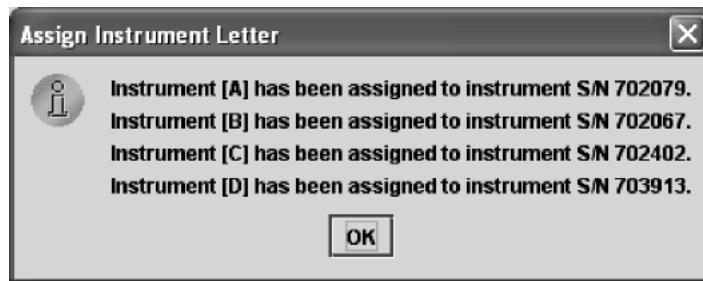


Figure 2-17. Assign Instrument Letter dialog box

To ensure that letter assignments match the GX-XVI R2 instrument, perform the following steps:

1. In the GeneXpert Dx System window, click **Setup** in the menu bar, and then select **Assign Instrument Letter**. The Assign Instrument Letter dialog box appears (Figure 2-18).

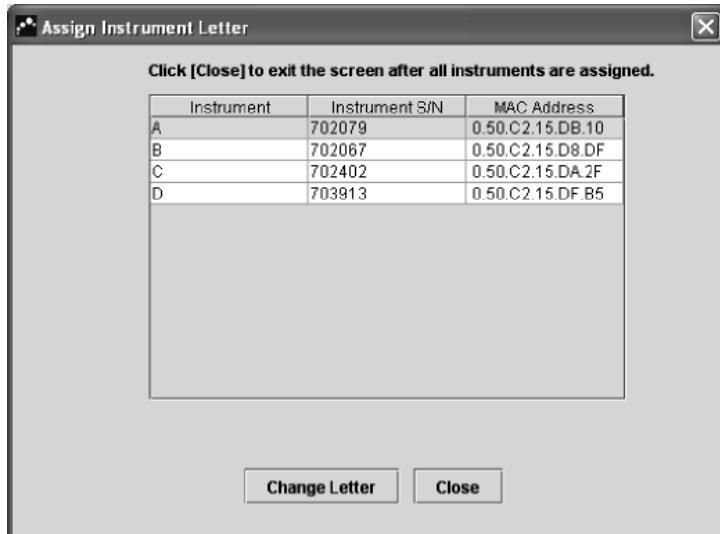


Figure 2-18. Assign Instrument Letter dialog box after assigning and instrument letter

At the same time, the green LED indicators of four modules that comprise the selected quadrant will flash.

2. To change the assignment letter, click **Change Letter** in the Assign Instrument Letter dialog box (Figure 2-18). The Change Letter dialog box appears (Figure 2-19). Select the letter you want for the instrument by using the up and down arrows of the Change Letter dialog box. Select the letter that corresponds to the quadrant defined by the four flashing modules. For example, if the upper left set of modules (Quadrant C in Figure 2-16) is flashing, select **C** as the next letter.

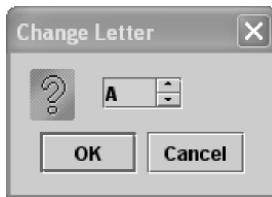


Figure 2-19. Change Letter dialog box.

3. After changing the assignment letter, click **OK**.

The changed assignment letter will be displayed in the table in the Assign Instrument Letter dialog box (Figure 2-18).

4. Click **Close** to dismiss the Assign Instrument Letter dialog box.

5. Continue to assign instrument letters until all four quadrants are correctly assigned to the letters A, B, C, and D.

Note: Because the instruments do not have letter indicators, you might want to physically label each instrument according to its letter assignment.

Figure 2-20 is an example of the GeneXpert DX System window after assigning instrument letters to a GX-XVI R2.

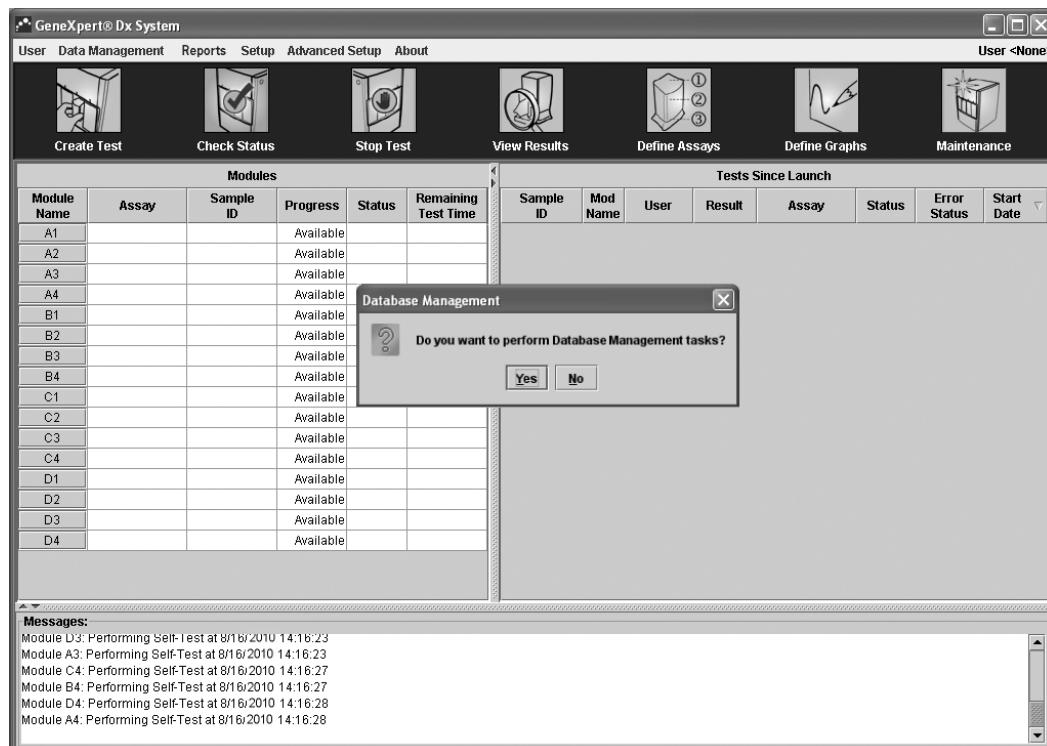


Figure 2-20. GeneXpert System window

The Database Management dialog box appears on top of the GeneXpert Dx System window (Figure 2-20).

6. If you do not want to perform database management tasks, perform the steps in Section 5.3.2.

If you want to perform database management tasks, perform the steps in the Section 5.3.3.

Now you are ready to configure the software and additional computer components. For details, see Section 2.8, “Defining Users and Permissions.”

2.8 Defining Users and Permissions

Before you start to use the GeneXpert Dx System software, you should define the GeneXpert Dx System administrator and other system users. All the administrator functions are accessible from the Setup menu in the GeneXpert Dx System window (Figure 2-15).

2.8.1 User types

The GeneXpert Dx System allows you to set up task permissions for different user types: Basic and Detail. As the system administrator, you can use this feature to limit access to the software functions based on your organization's policies. For example, you might want to set up the policy presented in Table 2-1.

Table 2-1. Example user permission policy for *in vitro* diagnostic use

User type	Run test	View results	Perform maintenance	Perform Admin and system functions
Basic	Yes	Summary only	No	No
Detail	Yes	All details	Limited	No
Administrator*	Yes	All details	All	Yes

*The Administrator user type has permissions to perform all the tasks and the permissions cannot be changed.

2.8.2 Specifying user permissions

To specify permitted tasks for each user type, in the GeneXpert Dx System window, on the **Setup** menu, click **User Type Configuration**. The User Type Configuration dialog box appears and displays a permissions table.

- To allow a user type to perform certain tasks, select the task check boxes in the user type column. See Table 2-2 for a complete list and description of the tasks.
- To remove a permission, clear the task check box in the user type column.
- To return all three user types to the default permission selections, click **Reset to Default**.

When you are finished specifying the permissions, click **OK** to save the changes and close the dialog box.

Table 2-2 lists the tasks as they appear in the User Type Configuration dialog box. The table provides a description of each task.

Table 2-2. User task descriptions

Task	Description
Create/Start Test	Allows you to create and start an <i>in vitro</i> diagnostic test (sections 5.5 and 5.7).
Stop One Test or All Tests	Allows you to stop one or more tests in progress (Section 5.9).
Edit Tests	Allows you to edit the <i>in vitro</i> diagnostic test information (Section 5.11).
Delete Tests	Allows you to delete a test from the database (Section 5.15.1).
Delete Assay and Lot Specific Parameters	Allows you to delete an assay definition or lot-specific parameter (Section 2.11).
Import Assay Definition and Lot Specific Parameters	Allows you to import assay definition (.gxa) and lot-specific parameter (.gxr) files (Section 2.11).
Archive Test	Allows you to archive and delete (optional) test data (Section 5.15.1).
Retrieve Test	Allows you to retrieve test data from the test archives (Section 5.15.2).
Backup Database	Allows you to back up the database (Section 5.16.1).
Restore Database	Allows you to restore the database (Section 5.16.2).
Compact DB and Run Database Integrity Check	Allows you to compact the database and run data integrity checks (Section 5.16.3).
View Specimen and Patient reports	Allows you to display an overview of the test results for the selected specimen in the database, and display test results for samples for one patient according to the Patient ID in the database.
View Control Trend and Assay Statistics reports	Allows you to create and display the external-control trend reports (Section 7.4), and display a report showing the number of tests performed for each assay over a period of time with monthly breakdown values.
View System Log	Allows you to create and display a report about recent self-tests and instrument errors.
Edit System Configuration	Allows you to modify the system configuration information (Section 2.9).
Assign Instrument Letter	Allows you to change the instrument letter assignment (Section 2.7).
View IQ Report	Allows you to view the installation qualification report (Section 2.10).
View Module Reporter	Allows you to display the reporters available in a module.
Run Plunger Maintenance	Allows you to lower the plunger in the instrument for cleaning (Section 10.4).

Table 2-2. User task descriptions (Continued)

Task	Description
Run Valve Maintenance	For service use only. Do not use this function without guidance from Cepheid Technical Support.
Run Self-Test	Allows you to perform an instrument module self-test (Section 10.7).
Open Door	Allows you to unlock and open an instrument module door and update cross-platform ICORE EEPROM format.
View About Box	Allows you to display the About window and view the software version number and copyright information.

2.8.3 Managing users

As the GeneXpert Dx System administrator, you can add users to the system and categorize them as different user types, edit the user profiles, or remove users from the system.

2.8.3.2 Adding new users

Important **The first user you add must be the administrator. Having the administrator profile allows you to add other users and configure the system.**

Note: Until you define the administrator profile, anyone using the software has full access to all of the tasks (except create a test).

To add users:

1. In the GeneXpert Dx System window (Figure 2-15), on the Setup menu, click User Administration. The User Administration dialog box appears (Figure 2-21).

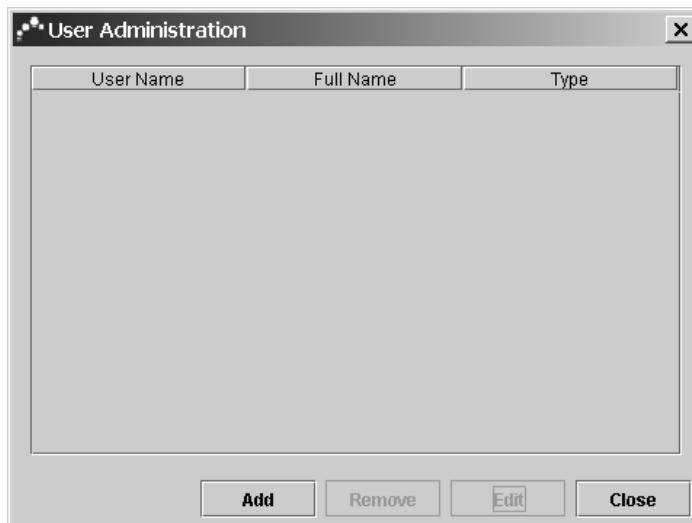


Figure 2-21. User Administration dialog box

2. Click **Add**. The Add User dialog box appears (Figure 2-22).
3. In the **User Name** box, type a unique user name containing 6 to 10 characters that can include spaces. For example, the first user you should add is the administrator, so type Admin (or an equivalent name).
4. (Optional) In the **Full Name** box, type the full or actual name of the user. For example, if the administrator is David Jones, type David Jones. The full name can contain a maximum of 32 characters. Do not use special characters, such as the quotation marks (""). If you do not provide a name, the software will automatically insert the user name in this box. This name appears in the test reports.
5. In the **Password** and **Confirm Password** boxes, type the password for the user. The password must contain 6 to 10 characters.
6. In the **User Type** list, select the type you want to categorize the user (Section 2.8.1).
7. When you are finished, click **OK** to save the changes and close the dialog box.

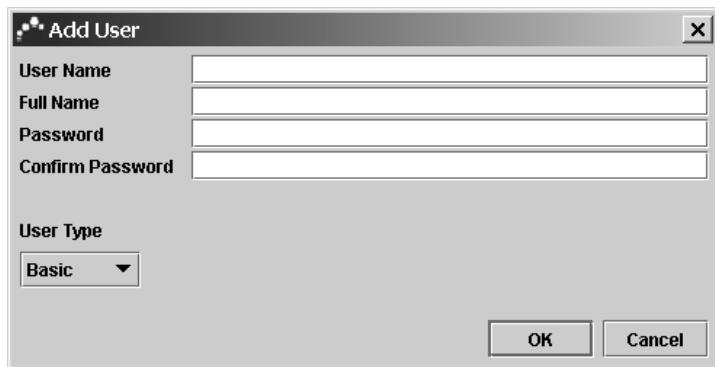


Figure 2-22. Add User dialog box

2.8.3.3 Editing user profiles

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

1. In the User Administration dialog box (Figure 2-21), in the **User Name** column, select the user you want to edit.
2. Click **Edit**. The Edit User dialog box appears (Figure 2-23).
3. Revise the information as desired, and then click **OK** to save the changes and close the dialog box.

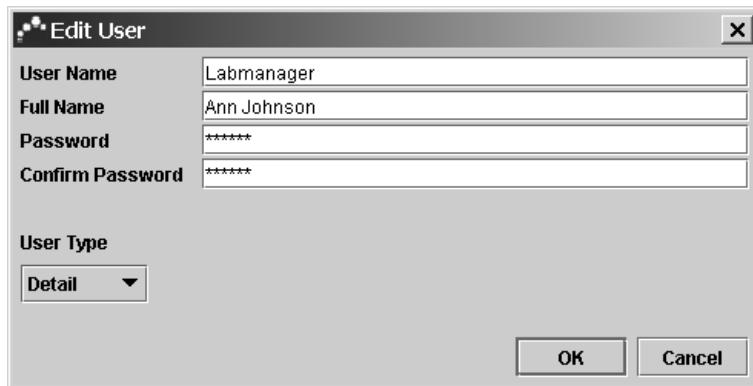


Figure 2-23. Edit User dialog box

2.8.3.4 Removing users

To remove a user, in the User Administration dialog box (Figure 2-21), select the user, and then click **Remove**. Click **Close** to save the change and close the dialog box.

Note: When you remove a user, the tests created by that user will remain in the database.

2.9 Configuring the System

Using the System Configuration function, you can specify the following:

- a name for the system (**General** tab)
- the date and time formats (**General** tab)
- options for creating a test (**General** tab)
- control of how the archive reminder is performed (**Archive Settings** tab)
- default folder paths for the exported test data, reports, and other information (**Folders** tab)
- LIS interface (**Host Communication Settings** tab)

2.9.1 General tab

1. In the GeneXpert Dx System window (Figure 2-15), click **Setup** on the menu bar, then click **System Configuration**. The System Configuration dialog box and the **General** window appears (Figure 2-24).

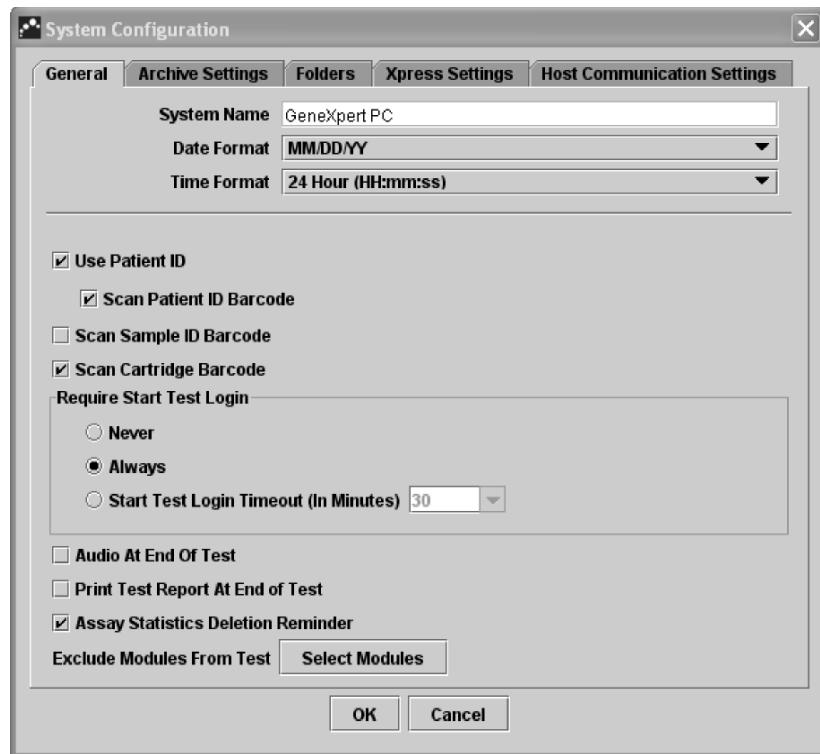


Figure 2-24. System Configuration dialog box (General window)

2. Provide the requested information for the **General** tab as follows:

- **System Name** box—Type a unique name for your system. The system name will be displayed in all of the reports.
- **Date Format** list—Select the format in which you want to display the month, day, and year.
- **Time Format** list—Select the 24-hour or the 12-hour format.
- **Use Patient ID**—If Patient ID is enabled, you also can select and use Patient ID barcode. Patient ID is available in Create Test and View Results.
- **Scan Patient ID Barcode**—Select to enable the software to prompt you to scan the Patient ID barcode. Clear the check box if you do not want the software to prompt you for the Patient ID barcode.
- **Scan Sample ID Barcode**—Select to enable the software to prompt you to scan the Sample ID barcode. Clear the check box if you do not want the software to prompt you for the Sample ID barcode.
- **Scan Cartridge Barcode**—Select to enable the software to automatically prompt you to scan the cartridge barcode (recommended). Clear the check box if you do not want the software to prompt you for the cartridge barcode.
- **Require Start Test Login**—This option allows the system administrator to configure if Start Test Login is required for traceability of the person who started a test and the period for the Start Test Login.

The options provided to the administrator are:

- **Never**
- **Always** – This option is the default.
- **Start Test Login Timeout (In Minutes)**

If this option is **Never**, Start Test Login dialog box is never displayed when the **Start Test** button is pressed in the Create Test window.

If this option is **Always**—Start Test Login dialog box is always displayed if there is a custom-defined user.

If this option is **Start Test Login Timeout (In Minutes)** and if there is a custom-defined user, the system monitors the time lag since the most recent user login or Start Test Login. After this amount of time elapses and the user presses the **Start Test** button in Create Test window, then the Start Test Login dialog box appears.

The timeout counter will be reset when any user logs in.

Time In Minutes

The user can select from 1 to 60 minutes using the drop-down list or enter a value in the same range. The default is 30 minutes.

3. Select or clear the following check boxes:

- **Audio At End of Test**—If the user turns on the audio option, a short tone will be provided at the end of the test. This uses the Windows default beep sound and settings.
- **Print Test Report At End of Test**—Option to allow a test report to be automatically printed to the Windows system default printer in the default format.
Note: If the printer is out of paper, the test report is still there even though the report is not printed. Load paper into the printer and manually print the test report.
- **Assay Statistics Deletion Reminder**—The user can enable or disable the Assay Statistics Deletion Reminder. Default is enabled.
- **Exclude Modules From Test**—Modules that are excluded will be listed as “Disabled”, and will not be used by the system to run tests.

To exclude modules from a test:

1. On the **General** window of the System Configuration dialog box (Figure 2-24), click **Select Modules**. The Exclude Modules From Test dialog box appears (Figure 2-25).

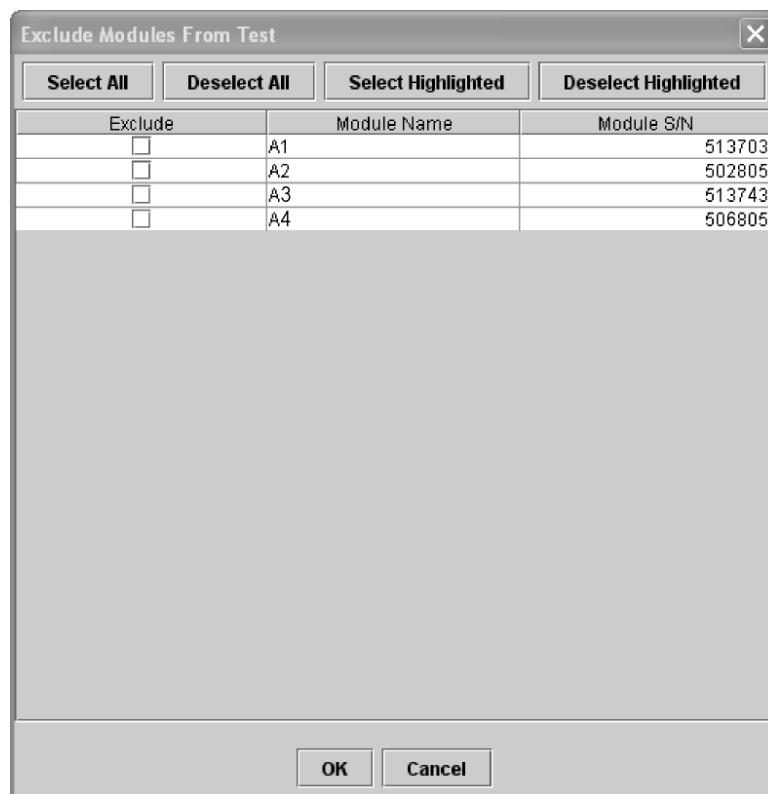


Figure 2-25. Exclude Modules From Test dialog box

2. Select the module(s) you want to exclude for a test by clicking on the adjacent checkbox.
3. Press the **OK** button to save changes to the Exclude Modules From Test dialog box (Figure 2-25).

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

2.9.2 Archive Settings tab

This tab provides the settings that control how archive reminder is performed.

You can select how often you would like to be reminded to archive your files: Never, Weekly, or Monthly.

1. In the GeneXpert Dx System window (Figure 2-15), click **Setup** on the menu bar, then click **System Configuration**.
2. Select the **Archive Settings** tab. The Archive Settings window appears (Figure 2-26).

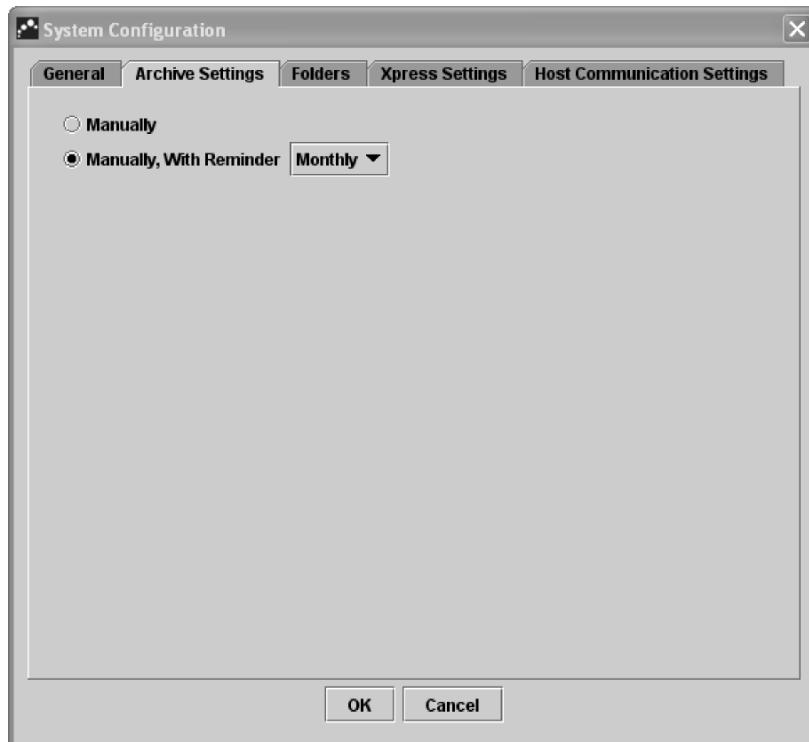


Figure 2-26. System Configuration dialog box (Archive Settings window)

3. Select the desired options:

- **Manually**—If this option is selected, archiving has to be performed manually by the user, at the user's convenience, and will follow the manual archive process.

Manually, With Reminder—If this option is selected, a reminder will be displayed if the user has Archive Test privilege. This reminder is not displayed for the users who do not have Archive Test privilege.

The user can choose to receive reminders weekly or monthly. The default will be weekly.

The system will attempt to remind the user to perform an overdue archive if the last archive was performed in the last week or the last month (depending on the reminder period selected). The last week or the last month is defined as being the

day prior to the first day of the current week/month. The first day of a week is considered to be Monday. The first day of a month is the first of each month. In such an event, the reminder is displayed to the user when:

- GeneXpert application starts
- GeneXpert application normally terminates
- user logs in (excluding start test login)

If the user accepts the archive-reminder prompt, the Archive Test dialog will be shown immediately.

If the user dismisses the reminder prompt, the software will proceed normally, and the user will be reminded next time the reminder criteria are met.

2.9.3 Folders tab

1. In the GeneXpert Dx System window (Figure 2-15), click **Setup** on the menu bar, then click **System Configuration**.
2. Click the **Folders** tab. The Folders window appears (Figure 2-27).

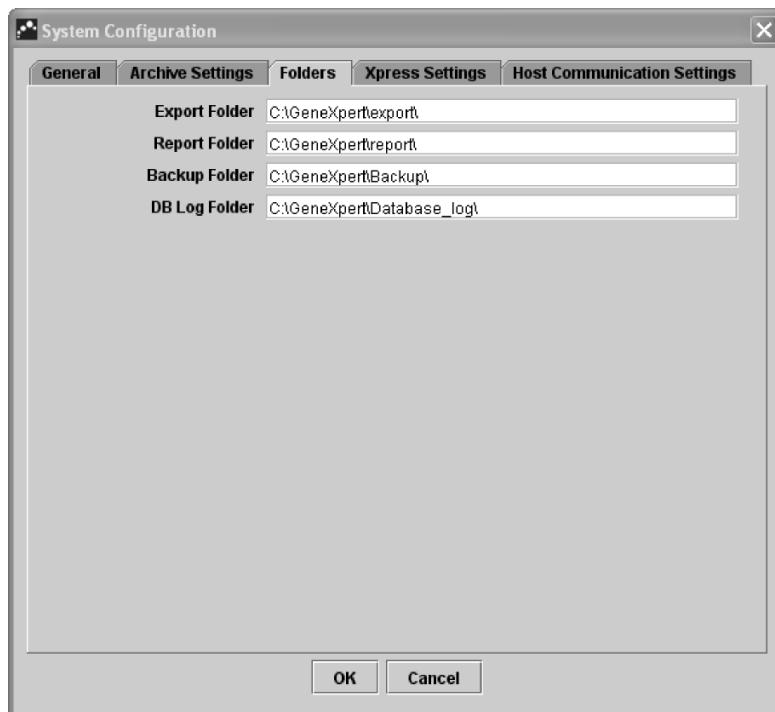


Figure 2-27. System Configuration dialog box (Folders window)

3. Provide the requested information for the **Folders** tab as follows:
 - **Export Folder** box—Type the path to the folder in which all of the exported test data will reside. Alternatively, you can use the default path supplied.
 - **Report Folder** box—Type the path to the folder in which all of the reports will reside. Alternatively, you can use the default path supplied.

- **Backup Folder** box—Type the path to the folder in which the backup database will reside. Alternatively, you can use the default path supplied.
 - **DB Log Folder** box—Type the path to the folder in which the database log files will reside. Alternatively, you can use the default path supplied.
4. Click OK to save the changes and close the window.

2.9.4 Host Communication Settings tab

1. In the GeneXpert Dx System window (Figure 2-15), click Setup on the menu bar, then click System Configuration.
2. Click the Host Communication Settings tab. The Host Communication Settings window appears (Figure 2-28).

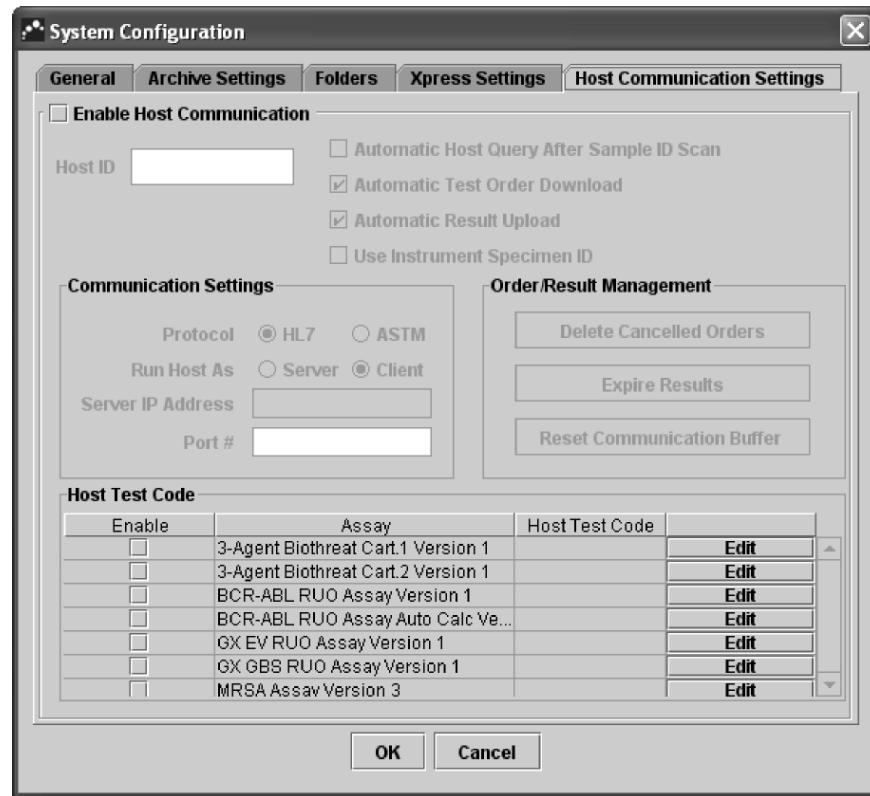


Figure 2-28. System Configuration dialog box (Host Communication Settings window)

3. See Chapter 6 for details on how to enable and configure the communication between the GeneXpert Dx software and a Host or Laboratory Information System (LIS).

2.10 Verifying Proper Installation and Setup

Note: This section describes tasks that all users with the appropriate permissions can perform (Section 2.8).

After you finish installing the instrument, setting up the computer, defining the users and permissions, and configuring the system, you should verify that the system is properly installed and set up. To do this:

1. In the GeneXpert Dx System window, on the Reports menu, click **Installation Qualification**. The Adobe® Reader® window appears and displays the GeneXpert Dx System Installation Qualification Report (Figure 2-29).
2. Print the report. If the computer is not connected to a printer, save the file to a location where you can print the report.
3. Review the following sections in the report:
 - **System Information**—Check that the Status column displays Pass in each row.
 - **Instrument Information**—For each instrument connected to the computer, the report shows the instrument serial number, the firmware installed, and the status of each operational module. If an Out of Calibration message or a Not Available message is shown, call Cepheid Technical Support. See the Assistance section in the preface for the contact information.
 - **Available Assays**—Check the assays in the list. If the No Assays message is shown, see the instructions provided with your *in vitro* diagnostics assay kit and section 2.11.1 for instructions on how to import assay definition files. If the No Assays message is shown after you import the assay definition files, call Cepheid Technical Support. See the Assistance section in the Preface for the contact information.
4. Sign the Installation Qualification Report, and then fax it to Cepheid Technical Support. See the Assistance section in the Preface for the contact information.

GeneXpert PC

06/07/10 14:21:42

GeneXpert® Dx System Installation Qualification Report

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

System Information

Software	Version	Status
GeneXpert® Dx System	4.0	Pass
Java Runtime Environment	1.6.0_05	Pass
GX_Utils.DLL	0.8.3.0	Pass
SQL Database	2005 - 9.00.4035.	Pass
Database	gx_db 1.4.17.0	Pass
Operating System	Windows XP 5.1 Service Pack 3	Pass
CIT Plug-In	1	Pass

Instrument Information

Instrument A

Instrument S/N	Gateway Firmware
703754	2.0.18

Module Name	Module S/N	Module Firmware	Internal Temp °C	Status
A1	601261	2.0.0	24.9	Pass
A2	601260	2.0.0	25.3	Pass
A3	601221	2.0.0	26.4	Pass
A4	601154	2.0.0	26.2	Pass

Shaded Modules = ICORE Starts exceeds 2000 or Reporter is out of calibration.

Available Assays

Assay Name	Version	Assay Type
Xpert EV	2	In Vitro Diagnostic
Xpert GBS	1	In Vitro Diagnostic
Xpert MRSA	3	In Vitro Diagnostic
BCR-ABL RUO Assay	1	Research Use Only
BCR-ABL RUO Assay Auto Calc	2	Research Use Only
GX EV RUO Assay	1	Research Use Only
GX GBS RUO Assay	1	Research Use Only
MRSA Assay	3	Research Use Only
MRSA_SA SSTI Assay	1	Research Use Only

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Figure 2-29. Example Installation Qualification Report in the Adobe Reader window

2.11 Managing Assay Definitions and Lot-Specific Parameters

Note: This section describes tasks that all users with the appropriate permissions can perform (Section 2.8).

An assay definition contains a series of programmed steps that the GeneXpert Dx System uses to perform sample preparation, amplification, and detection procedures. You can obtain *in vitro* diagnostic assay definition (.gxa) files from Cepheid and import them into the software (Section 2.11.1). You can also delete assay definitions that are no longer in use (Section 2.11.2).

Some assay definitions require lot-specific parameters to determine the test results. The 2D cartridge barcodes contain the lot-specific parameter information that is automatically imported when you scan the barcode. If, for some reason, the barcode scanner is not working or is not available, you can supply the lot-specific parameter information manually by importing the .gxr file (Section 2.11.3). You can also delete lot-specific parameter information that is no longer in use (Section 2.11.4).

2.11.1 Importing assay definitions

Note: Although you can import *in vitro* diagnostic assay definitions, the GeneXpert Dx System software does not allow you to modify the assay definitions.

To import new assay definitions:

1. In the GeneXpert Dx System window, click **Define Assays** on the menu bar. The Define Assays window appears. Figure 2-31 shows the Define Assay window for the GeneXpert Dx System administrator. The window for Detail and Basic users has fewer functions.
2. Click **Import**. The Import Assay dialog box appears (Figure 2-30).

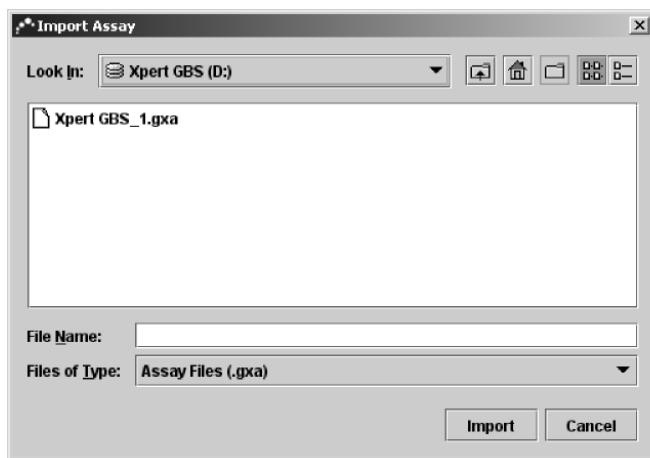


Figure 2-30. Import Assay dialog box

3. Locate and select the assay definition (.gxa) file, and then click **Import**. The new assay name and version number appear in the Assay list (on the left side of the window) and details about the assay appear to the right of the list.

4. Check the assay name and version number to make sure you have imported the correct assay definition.

2.11.2 Deleting assay definitions

1. To delete an assay definition file, in the Define Assays window (Figure 2-31), select the assay name in the Assay list (on the left side of the window), and then click **Delete**. A confirmation message appears.
2. Click **Yes** to delete the assay definition.

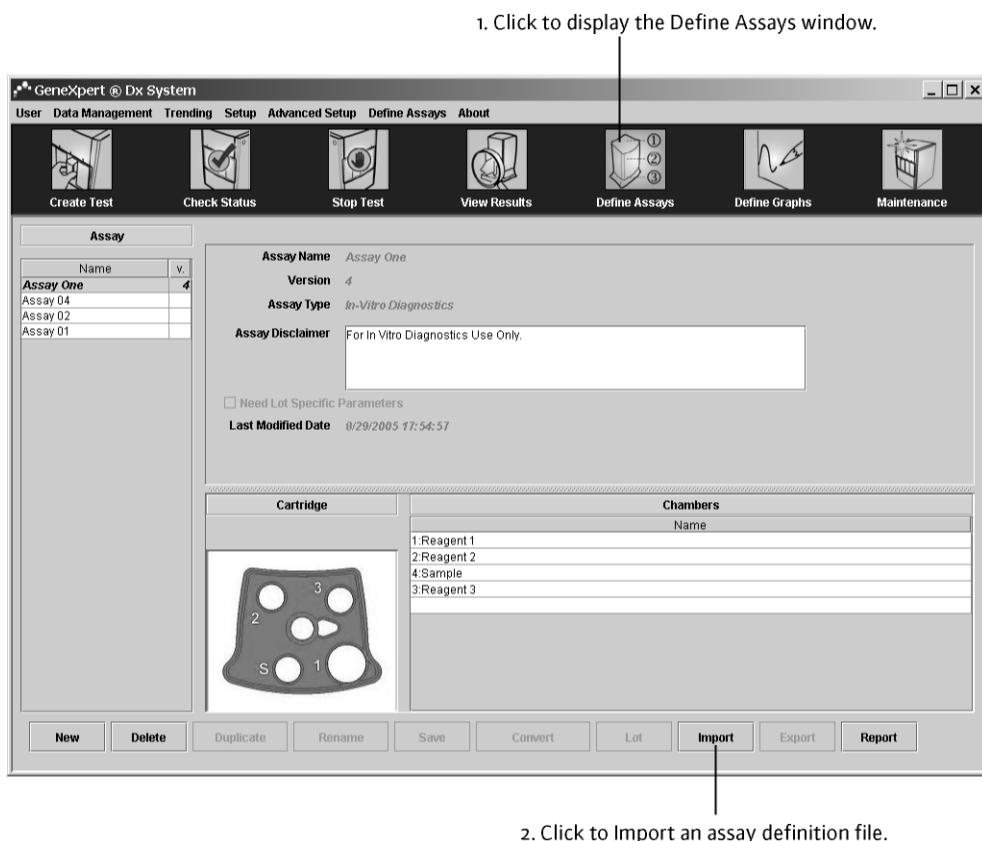


Figure 2-31. GeneXpert Dx System – Define Assays window (administrator view)

2.11.3 Importing lot-specific parameters manually

To import lot-specific parameters manually:

1. In the Define Assays window (Figure 2-31), select the assay name in the Assay list (on the left side of the window).
2. Click **Lot**. The Reagent Lot Specific Parameters dialog box appears (Figure 2-32).
3. Click **Import**. The Import Reagent Lot Specific Parameters dialog box appears.
4. Locate and select the .gxr file, and then click **Open**. The new lot number appears in the Reagent Lot Specific Parameters dialog box.
5. Click **Scan** to scan a cartridge barcode of a lot be imported.

6. Click **Close** in the Reagent Lot Specific Parameters dialog box to return to the Define Assays window.

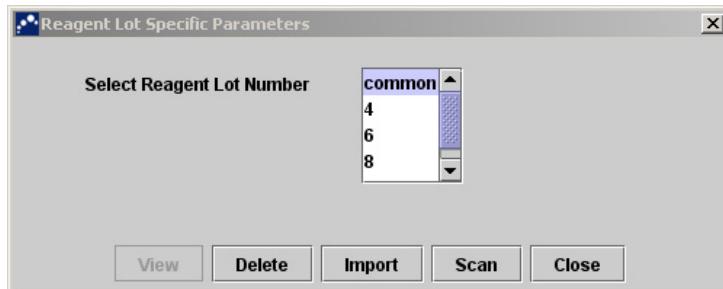


Figure 2-32. Reagent Lot Specific Parameters dialog box

2.11.4 Deleting lot-specific parameters

To delete lot-specific parameters:

1. In the Define Assays window (Figure 2-31), click **Lot**. The Reagent Lot Specific Parameters dialog box appears (Figure 2-32).
2. Select the lot number you want to delete, and then click **Delete**. A confirmation message appears.
3. Click **OK** to delete the lot-specific parameters.
4. Click **Close** to dismiss the Reagent Lot Specific Parameters dialog box.

2.11.5 Creating an assay definition report

To create a report for an assay definition, in the Define Assays window (Figure 2-31), click **Report**.

For predefined factory assays, the software creates a PDF file containing the assay information and displays the file in the Adobe Reader window.

2.12 Restarting the System

Note: This section describes tasks that all user types can perform.

Under some troubleshooting scenarios (Chapter 11), you might need to restart the system. To do this:

1. Make sure the instrument is not in the middle of processing a sample. You should wait for the instrument to finish all processes before restarting the system.
2. Remove the cartridges from the instrument modules.
3. Quit the GeneXpert Dx System software. To do this, on the **User** menu, click **Exit**.

If an archive is overdue, the Test Archive Reminder dialog box appears (Figure 2-33).

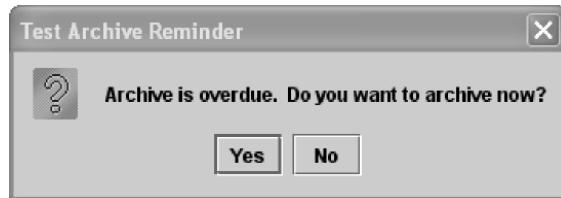


Figure 2-33. Test Archive Reminder dialog box

4A. If you do not want to archive:

- a. Click **No** in the Test Archive Reminder dialog box (Figure 2-33). The Database Management dialog box (Figure 2-34) appears on top of the GeneXpert Dx System window.

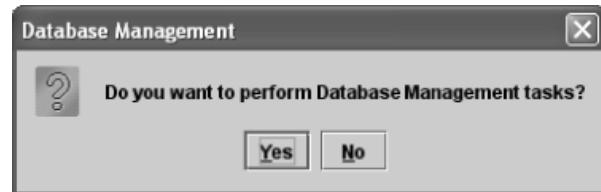


Figure 2-34. Database Management dialog box

- b. Click **No** in the Database Management dialog box (Figure 2-34). GeneXpert Dx System software closes.

OR

4B. If you want to archive:

- a. Click **Yes** in the Test Archive Reminder dialog box (Figure 2-33). The Select Test(s) To Be Archive dialog box appears (Figure 2-35).

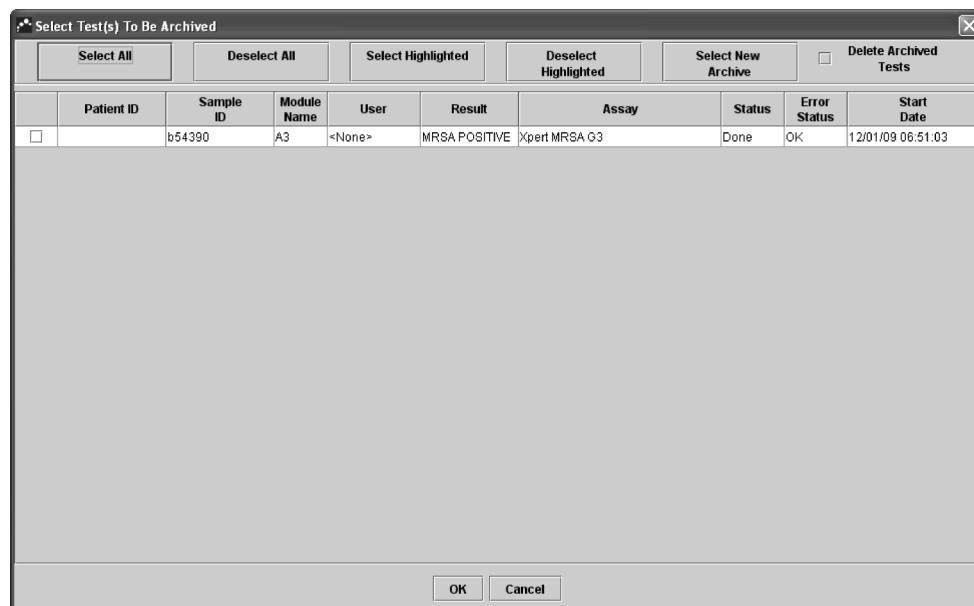


Figure 2-35. Select Test(s) To Be Archived dialog box

- b. Perform steps 2 through 6 in the procedure in Section 5.15.1 (Archiving the tests).

When you are finished with the archive, the Database Management dialog appears (Figure 2-34).

- c. Click No.

The GeneXpert Dx System software closes.

5. Turn off the instrument.
6. Wait a few minutes.
7. Turn on the instrument.
8. Start the GeneXpert Dx System software (Section 2.6).

The Database Management dialog box appears on top of the GeneXpert Dx System window (Figure 2-15 or Figure 2-20).

9. If you Do Not want to perform database management tasks, perform the steps in Section 5.3.2.

If you want to perform database management tasks, perform the steps in the Section 5.3.3.

2.13 Uninstalling or Reinstalling GeneXpert Dx System Software

The GeneXpert Dx System software is already installed on the supplied computer. If the software becomes corrupted, or if you experience a system failure, do not attempt to reinstall the software. Call Cepheid Technical Support for assistance to minimize the chance of permanent data loss. See the Assistance section in the Preface for the contact information.

Chapter 3 Principles of Operation

This chapter explains how the GeneXpert Dx System works. The topics are as follows:

- System Operation Overview (Section 3.1)
- GeneXpert Dx Instrument (Section 3.2)
- GeneXpert Cartridge (Section 3.3)
- I-CORE Module (Section 3.4)
- Heating and Cooling Mechanisms (Section 3.5)
- Optical System (Section 3.6)
- System Calibration (Section 3.7)

3.1 System Operation Overview

Each GeneXpert Dx module processes one sample. You insert the sample and applicable reagents into a GeneXpert cartridge, create a test (Section 5.5), load the cartridge into an available instrument module (Section 5.6), and then start the test (Section 5.7). During the test, the system performs the following steps:

1. Moves the sample and reagents into different chambers in the cartridge for sample preparation.
2. Hydrates the reagent beads.
3. Performs probe checks to ensure that the sample preparation is successful (only if the assay definition requires this step).
4. Moves the sample and reagent mixture into the reaction tube.
5. Starts the PCR cycles and real-time detection.

3.2 GeneXpert Dx Instrument

Each instrument module contains the following components that enable automated sample processing in the cartridge and filling of the tube with the sample-reagent mixture for PCR:

- **Valve drive**—Rotates the cartridge valve body to address the different cartridge chambers.
- **Syringe pump drive**—Dispenses fluids into the different cartridge chambers.
- **Ultrasonic horn**—Lyses the sample (if applicable).
- **I-CORE[®] module**—Performs PCR amplification and detection.

A cartridge loading and unloading mechanism assures the proper movement of the cartridge in the instrument. In addition, the system is designed to perform a self-test before each test starts to verify that the system is functioning properly.

3.3 GeneXpert Cartridge

The disposable, single-use GeneXpert Dx cartridge holds the samples and reagents that you want to process in the GeneXpert Dx System. Each cartridge consists of the following components (Figure 3-1):

- **Processing chambers**—Hold samples, reagents, processed sample, and waste solutions. One chamber is designated as an air chamber to equilibrate pressures within the cartridge.
- **Valve body**—Rotates and allows fluid to move to different cartridge chambers and to the reaction tube. Within the valve body, the specimen is isolated, PCR inhibitors are removed, and specimens are ultrasonically lysed (if applicable). After the sample is processed, it is mixed with PCR reagents and moved into the integrated reaction tube.
- **Reaction tube**—Enables rapid thermal cycling and optical excitation and detection of the tube contents. The reaction tube is automatically inserted into the I-CORE module when the cartridge is loaded into the instrument.

The cartridge is designed to keep the reagent contained within the cartridge. It is a closed-system vessel.

The GeneXpert cartridges are not supplied with the system. To order the assay-specific cartridges, contact Cepheid. See the Assistance section in the Preface for the contact information.

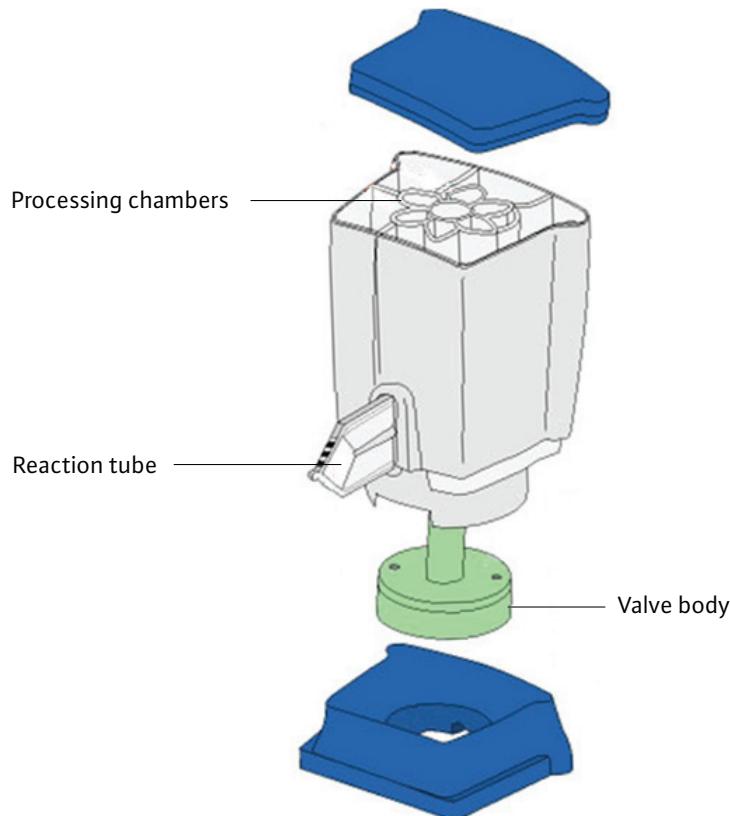


Figure 3-1. GeneXpert cartridge components

3.4 I-CORE Module

The I-CORE (Intelligent Cooling/Heating Optical Reaction) module is the hardware component within each instrument module that performs PCR amplification and fluorescence detection. As part of the cartridge load process, the reactor tube is inserted into the ICORE module (Figure 3-2). The sample and reagent mixture are pushed from the cartridge into the reaction tube. During the amplification process, the I-CORE heater heats up and the fan cools down the reaction tube contents. The optical blocks excite the dye molecules and detect the fluorescence emitted.

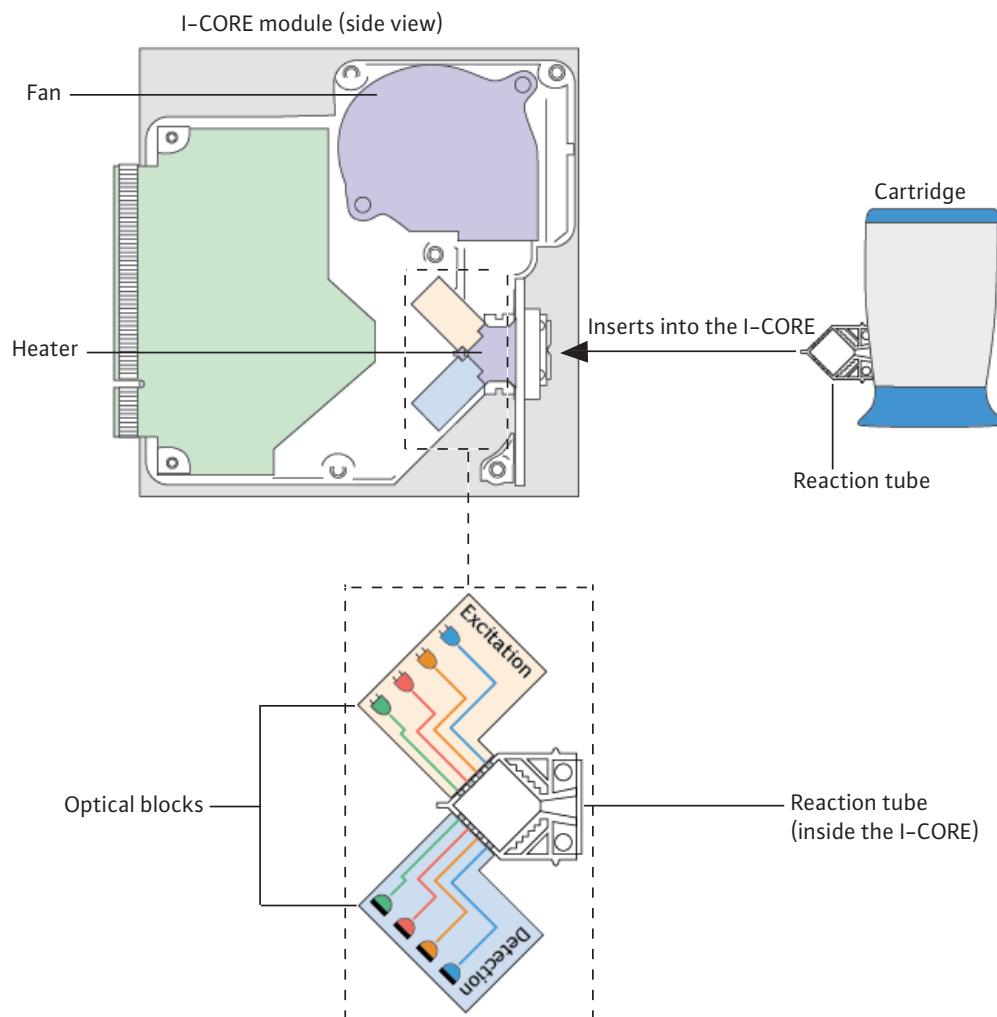


Figure 3-2. I-CORE module

3.5 Heating and Cooling Mechanisms

Within the I-CORE, the heater consists of two ceramic plates that have high thermal conductivity to assure temperature uniformity and rapid heat transfer (Figure 3-2). Resistive heater elements are deposited on the ceramic plates using thick film technologies and a thermistor attached directly to each plate monitors its temperature. A high-efficiency fan cools the reaction tube contents by moving ambient air across the heater plates. During thermocycling, the instrument firmware controls the temperature inside the instrument module. The firmware incorporates a control loop to ensure rapid heating of the plates while minimizing the temperature overshoot around the desired target temperature.

3.6 Optical System

Within the I-CORE, the optical system consists of two blocks (Figure 3-2):

- **Six-color excitor module**—Contains high intensity light-emitting diodes (LEDs) to excite the reporter dye molecules.
- **Six-color detector module**—Contains silicon photodetectors and filters to detect the six spectral bands.

The optical blocks are positioned within the I-CORE such that their apertures mate with the optical windows of the reaction tube, allowing excitation and emission detection of the reaction mixture. By using probes labeled with different fluorescent reporter dyes, up to six targets can be detected simultaneously in a single reaction tube. The emission spectra of fluorescent dyes can overlap, and a particular dye could produce signal in more than one channel. To compensate for the spectral overlap, the system uses appropriate calibration and data analysis algorithms to determine the concentrations of each reporter dye. Table 3-1 shows the excitation and detection spectral bands for the six channels.

Table 3-1. GeneXpert System excitation and emission ranges (6-color)

Optical channel	Excitation (nm)	Emission (nm)	Calibrated reporter dyes
1	375-405	420-480	CF 1
2	450-495	510-535	FAM
3	500-550	565-590	Alexa Fluor® 532
4	555-590	606-650	Texas Red®
5	630-650	665-685	Alexa Fluor 647®
6	630-650	>700	CF 6

A four-color optical system is an older version I-CORE. Table 3-2 lists the excitation and emission ranges for the four-color optical system.

Table 3-2. GeneXpert System excitation and emission ranges (4-color)

Optical channel	Excitation (nm)	Emission (nm)	Calibrated reporter dyes
1	450–495	510–527	FAM
2	500–550	565–590	Alexa Fluor® 532
3	555–590	606–650	Texas Red®
4	630–650	670–750	Alexa Fluor 647®

3.7 System Calibration

The thermal reaction chamber thermistors are calibrated to $\pm 1.0\text{ }^{\circ}\text{C}$ using National Institute of Standards and Technology (NIST)-traceable standards. During the manufacturing process, the temperature of the heating system is measured at two temperatures: $60\text{ }^{\circ}\text{C}$ and $95\text{ }^{\circ}\text{C}$. Calibration coefficients that correct for small errors in the raw thermistor readings of the heaters are stored in the memory of each I-CORE module.

The optical system is calibrated using standard concentrations of individual unquenched fluorescent dye-oligos. For each optical channel, the signal produced by a tube alone (the blank signal) is subtracted from the raw signal produced by the dye-oligo standard to determine the spectral characteristics. Using the individual spectral characteristics of the pure dye-oligos, signals from an unknown mixture of dye-oligos can be resolved into corrected signals for the individual dye-oligos in the mixture.

Chapter 4 Performance Characteristics and Specifications

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

- Instrument Classification (Section 4.1)
- General Specifications (Section 4.2)
- Thermal Performance Parameters (Section 4.3)
- Operational Environmental Parameters (Section 4.4)
- Environmental Conditions for Storage and Transport (Section 4.5)
- Sound Pressure (Section 4.6)
- European Union Directives (Section 4.7)
- Product Energy Consumption Information (Section 4.8)

4.1 Instrument Classification

The GeneXpert Dx System is:

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

4.2 General Specifications

The GeneXpert Dx instrument has the following specifications:

- Dimensions:

GX-I R2	9.4 cm (3.7 in) wide, 30.5 cm (12 in) high, 29.7 cm (11.7 in) deep
GX-II R2	16.3 cm (6.4 in) wide, 30.7 cm (12.1 in) high, 29.7 cm (11.7 in) deep
GX-IV R2	28.2 cm (11.1 in) wide, 30.5 cm (12 in) high, 29.7 cm (11.7 in) deep
GX-XVI R2	71.1 cm (28 in) wide, 65.8 cm (25.9 in) high, 33.8 cm (13.3 in) deep

- **Weight:**

GX-I R2	4 kg (9 lb)
GX-II R2	6.5 kg (15 lb)
GX-IV R2	11.4 kg (25 lb)
GX-XVI R2	57 kg (125 lb)

- **Power supply:** Auto-ranging
- **Rated AC voltage range:** 100–240 V~, 50–60Hz
- **Mains supply fluctuations:** Up to \pm 10% of the nominal voltage
- **Transient over-voltages:** Up to 2500 V peak (impulse withstand category II)
- **Rated Current:**

GX-I R2	2.5A @ 24V
GX-II R2	2.5 A @ 24V
GX-IV R2	1.4A @ 100V~
GX-XVI R2	6.16A @ 100V~

- **Fuse Rating:**

GX-I R2	No servicable fuse
GX-II R2	No servicable fuse
GX-IV R2	250V~ T3A (IEC 60127 time-delay type)
GX-XVI R2	250V~ T6.3A (IEC 60127 time-delay type)

4.3 Thermal Performance Parameters

The thermal performance parameters of the system are as follows:

- **Heating ramp rates (max.):** 10 °C/sec from 50 °C to 95 °C
- **Cooling ramp rates (max.):** 2.5 °C/sec from 95 °C to 50 °C
- **Temperature duration accuracy:** \pm 1.0 sec from programmed time
- **Temperature accuracy:** \pm 1.0 °C from 60 °C to 95 °C

4.4 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:** 10%–95%, non-condensing

Place the GeneXpert Dx instrument 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.

4.5 Environmental Conditions for Storage and Transport

The required storage conditions are as follows:

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

4.6 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

4.7 European Union Directives

The GeneXpert Dx System complies with the following standards for laboratory equipment:

- IVD In-Vitro Device Directive 98/79/EC
- EMC Directive 2004/108/EC
- Low Voltage Directive 2006/95/EC
- WEEE Directive 2002/96/EC
- Energy Labeling Directive 2010/30/EU

4.8 Product Energy Consumption Information

Supplier Name	Supplier Model Identifier	Energy Efficiency Class	On Mode Power Consumption (W)	Annual Energy Consumption (KWh)	Standby Power Consumption (W)
Cepheid	GeneXpert I R2	G	61	263	58
Cepheid	GeneXpert II R2	G	85	372	71
Cepheid	GeneXpert IV R2	G	100	489	83
Cepheid	GeneXpert XVI R2	G	270	1168	170

Chapter 5 Operating Instructions

This chapter explains how you use the GeneXpert Dx System to run an *in vitro* diagnostic (IVD) test and manage the results data. The topics are as follows:

- Typical Workflow (Section 5.1)
- Getting Started (Section 5.2)
- Starting the GeneXpert Dx System (Section 5.3)
- Checking the List of Available Assay Definitions (Section 5.4)
- Creating a Test (Section 5.5)
- Loading a Cartridge into an Instrument Module (Section 5.6)
- Starting the Test (Section 5.7)
- Monitoring the Test Process (Section 5.8)
- Stopping a Test in Progress (Section 5.9)
- Viewing the Test Results (Section 5.10)
- Editing the Test Information (Section 5.11)
- Generating Test Result Reports (Section 5.12)
- Exporting the Test Results (Section 5.13)
- Uploading Test Results to Host (Section 5.14)
- Managing the Test Results Data (Section 5.15)
- Performing the Database Management Tasks (Section 5.16)
- Deleting a Test (Section 5.17)
- Viewing and Printing Reports (Section 5.18)

5.1 Typical Workflow

Table 5-1 shows the typical workflow for processing a specimen sample using the GeneXpert Dx System.

Table 5-1. Typical workflow for processing a specimen.

Step	Task	Section
1.	Start the GeneXpert Dx System.	Section 5.3
2.	Perform Database Management Tasks.	Section 5.3.1
3.	Check the list of assays available. Import the assay definition files if necessary.	Sections 5.4 and 2.11
4.	Prepare the assay-specific GeneXpert cartridge	See the Package Insert that is shipped with the cartridge.
5.	Create a test.	Section 5.5
6.	Load a cartridge into an instrument module.	Section 5.6
7.	Start the test.	Section 5.7
8.	Monitor the test progress.	Section 5.8
9.	View the test results.	Section 5.10
10.	Generate test result reports.	Section 5.12
11.	Export the test results.	Section 5.13
12.	Manage the test results data.	Section 5.15

5.2 Getting Started

This section describes the basic system tasks.

- Powering the instrument on and off (Section 5.2.1)
- Starting and ending the software (Section 5.2.2)
- Logging on (Section 5.2.3)
- Logging off (Section 5.2.4)
- Changing your password (Section 5.2.5)
- Using the system window (Section 5.2.6)

5.2.1 Powering the instrument on and off

The power switch is located on the lower back side of the instrument. From the front of the instrument, you can reach the switch from the right side.

To turn on the instrument, press the switch to the on position (**I**). To turn off the instrument, press the switch to the off position (**O**).

Important **Cepheid recommends powering down the instrument and computer a minimum of once per week.**

5.2.2 Starting and ending the software

This section explains how to start and end the GeneXpert Dx System software. You should always:

- Turn on the instrument before you start the software.
- End a software session before you turn off the instrument.

5.2.2.1 Starting the software

You can start the software in one of two ways:

- On the Windows desktop, double-click the GeneXpert Dx icon (Figure 5-1, item a).
or
- On the Windows desktop, click **Start**, point to **All Programs**, point to **Cepheid**, and then click **GeneXpert Dx** (Figure 5-1, item b).

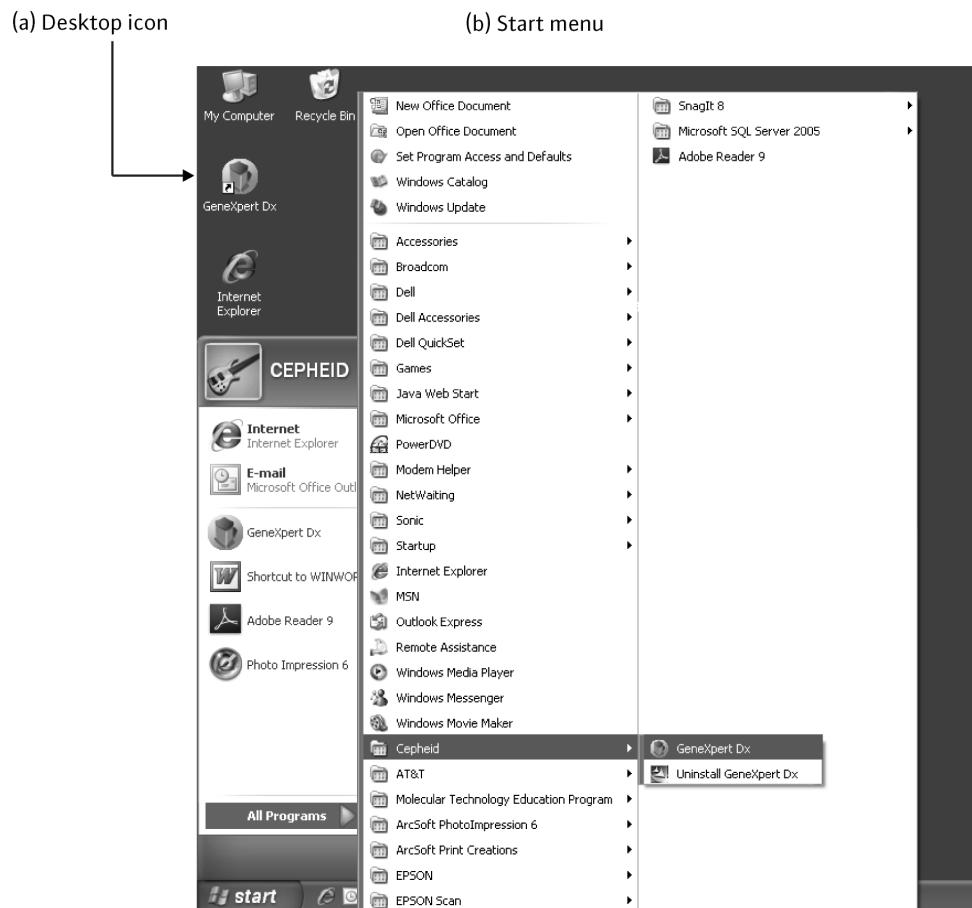


Figure 5-1. Methods of starting the software

Each time you start the software, the Login dialog box appears and asks for a user name and password (Figure 5-2). In the **User Name** box, type your GeneXpert Dx System user name. In the **Password** box, type your password. Click **OK** to log on and start the software.



Figure 5-2. Login dialog box

Important If the Login dialog box does not appear during the software startup, contact your GeneXpert Dx System administrator.

Note: If you forget your password, contact your GeneXpert Dx System administrator. If you are the GeneXpert Dx System administrator and you forget your password, contact Cepheid Technical Support. See the Assistance section in the preface for the contact

information. Cepheid Technical Support will supply a temporary password to allow you to log on and change the password. The temporary password expires after 1 day.

5.2.2.2 Ending the software session

To end the GeneXpert Dx System software session, in the GeneXpert Dx System window (Figure 5-8), on the **User** menu, click **Exit** (Figure 5-3).



Figure 5-3. User menu (Exit)

The Database Management dialog box appears on the top of the GeneXpert Dx System window. Perform or not perform the desired Database Management Tasks. See Section 5.3.1 for details.

After you completed Database Management Tasks, click **Cancel** and the software ends. You can now turn off the instrument.

5.2.3 Logging on

To log on to the software while the software is running, on the **User** menu, click **Login** (Figure 5-4).

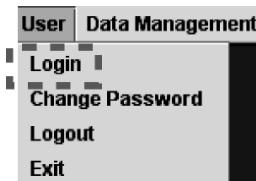


Figure 5-4. User menu (Login)

5.2.4 Logging off

To log off the software, in the GeneXpert Dx System window, on the **User** menu, click **Logout** (Figure 5-5).

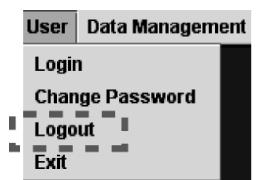


Figure 5-5. User menu (Logout)

The GeneXpert Dx System window changes to the No User mode. You should log off if you will be away from the system for an extended period. Logging off prevents the software from recording other users' activities under your account.

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

5.2.5 Changing your password

To change your GeneXpert Dx System software password:

1. In the GeneXpert Dx System window, on the User menu, click **Change Password** (Figure 5-6).

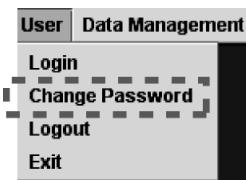


Figure 5-6. User menu (Change Password)

The Change Password dialog box appears (Figure 5-7).



Figure 5-7. Change Password dialog box

2. In the **Current Password** box, type your current password.
3. In the **New Password** and **Confirm New Password** boxes, type your new password.
4. Click **OK** to save the change and close the dialog box.

5.2.6 Using the system window

When you start the GeneXpert Dx System software, the GeneXpert Dx System Check Status window appears. Figure 5-8 shows an example of the GeneXpert Dx System window.

Depending on the permissions you have, the window in Figure 5-8 might vary slightly. For information about your user profile and permissions, see your GeneXpert Dx System administrator.

When you click Check Status, View Results, Define Assays, or Maintenance on the menu bar, the window contents change and a new menu appears on the menu bar. For example,

if you click View Results, the View Results window displaces the current window contents. In addition, the View Results menu appears on the menu bar so that you have the option of accessing the View Results functions from the menu.

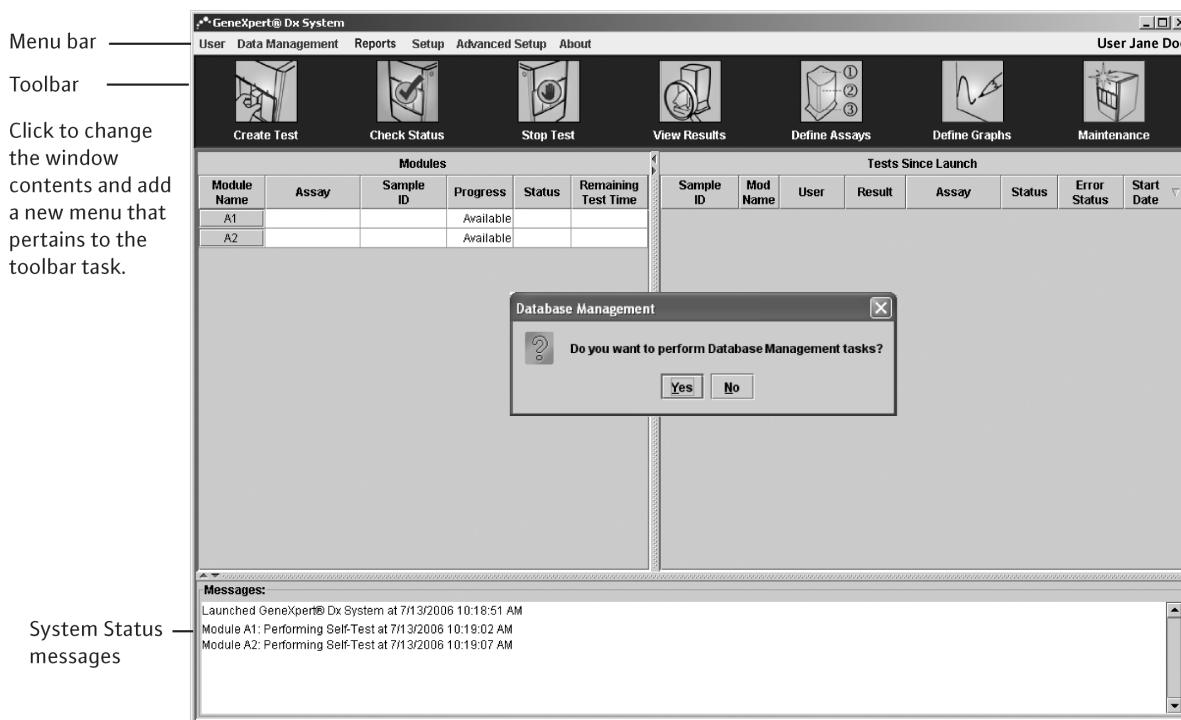


Figure 5–8. GeneXpert Dx System window

5.3 Starting the GeneXpert Dx System

Important You should always turn on the instrument before you start the software.

To start the GeneXpert Dx System:

1. Make sure the instrument modules are empty. Open the module doors and remove any cartridges remaining from previous tests.
2. If you have not already done so, turn on the GeneXpert Dx instrument (Section 5.2.1).
3. If you have not already done so, turn on the computer.
4. Start the software (Section 5.2.2.1). The Login dialog box appears (Figure 5–2).
5. Log on using your user name and password (Section 5.2.3). The GeneXpert Dx System window appears (Figure 5–8). Depending on the permissions you have, the GeneXpert Dx System window might vary slightly from Figure 5–8.

5.3.1 Database Management Tasks

The Database Management dialog box (Figure 5-9) appears on top of the GeneXpert Dx System window.

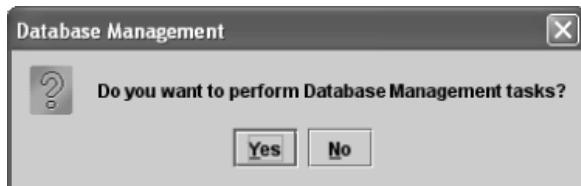


Figure 5-9. Database Management dialog box

If you DO NOT want to perform database management tasks, perform the steps in Section 5.3.2.

If you want to perform database management tasks, perform the steps in the Section 5.3.3.

5.3.2 Not performing database management tasks

1. Click No in the Database Management dialog box (Figure 5-9).

The Database Management dialog box disappears from the GeneXpert Dx System window.

5.3.3 Performing database management tasks

1. Click Yes in the Database Management dialog box (Figure 5-9). The Database Management dialog box appears in the GeneXpert Dx System window.

Note: Depending on the user's privileges, you may not see all (or any) of the four options in the Database Management dialog box (Figure 5-10).

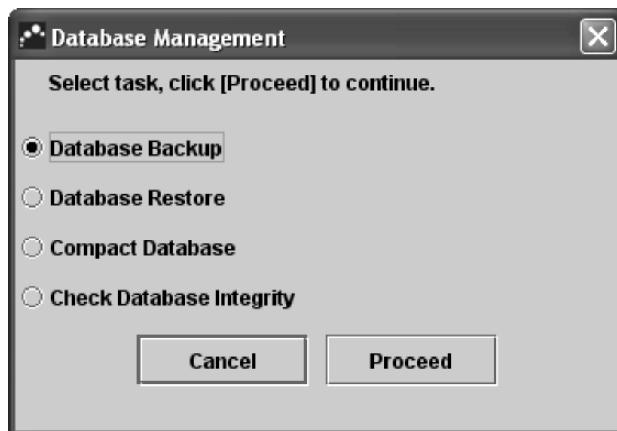


Figure 5-10. Database Management dialog box

2. Select the applicable button for the database management tasks you desire (i.e., Database Backup, Database Restore, Compact Database, or Check Database Integrity).

See Section 5.16 (Performing the Database Management Tasks) for details on how to perform each of the database management tasks.

3. Click the **Proceed** button (Figure 5-10) to start performing the desired database management task.
4. After the database management task is completed a confirmation dialog box appears. Click **OK**, and then the **Cancel** button in the Database Management dialog box.

The Database Management dialog box disappears from the GeneXpert Dx System software window.

5.3.4 Test Archive Reminder

If an archive is overdue, the Test Archive Reminder dialog box appears (Figure 5-11).

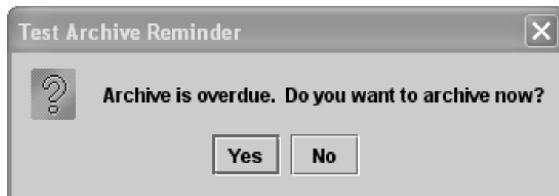


Figure 5-11. Test Archive Reminder dialog box

1A. If you do not want to archive:

- Click **No** in the Test Archive Reminder dialog box (Figure 5-11). The Test Archive Reminder dialog box disappears from the GeneXpert Dx System window.

or

1B. If you want to archive:

- Click **Yes** in the Test Archive Reminder dialog box (Figure 5-11). The Select Test(s) To Be Archive dialog box appears (Figure 5-12).

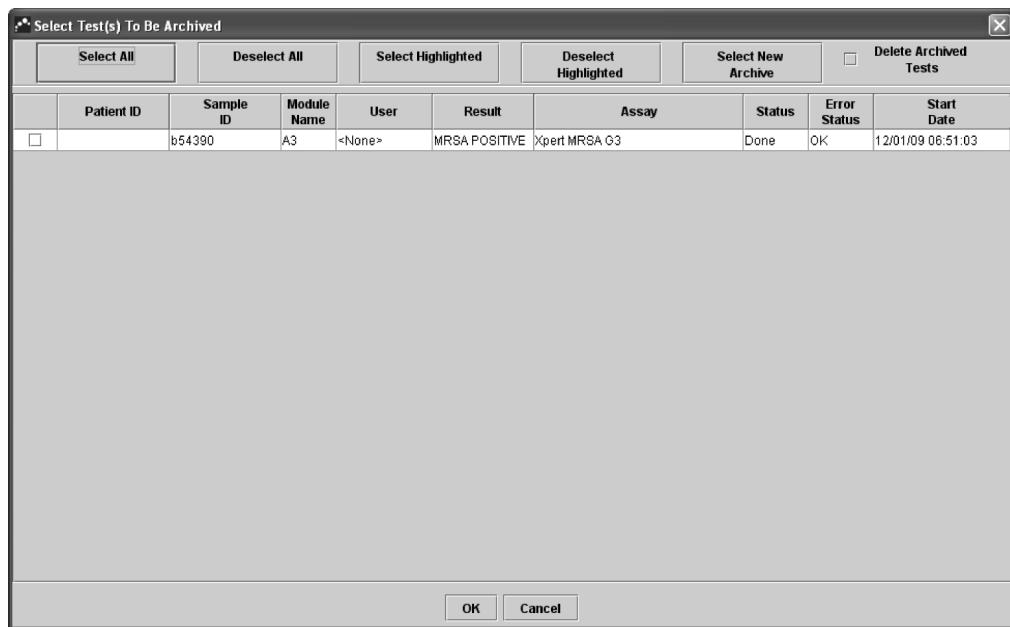


Figure 5-12. Select Test(s) To Be Archived dialog box

2. Perform steps 2 through 6 in the procedure in Section 5.15.1 (Archiving the tests).

5.4 Checking the List of Available Assay Definitions

Before starting an *in vitro* diagnostic test, you should check that the assay definition you want to use is already loaded in the software. To do this:

1. In the GeneXpert Dx System window, click **Define Assays**. The Define Assays window appears (Figure 5-13).
2. In the **Assay** list (on the left side of the window), verify that the assay definition you want to use is present. Cartridges will not run with an assay version that does not match the cartridge barcode information. Make sure you are using the latest version of the assay definition.
3. If the assay is not listed, import the assay definition file (Section 2.11.1). You must have permission to import assay definitions. If you do not have such permission, contact your GeneXpert Dx System administrator.

1. Click to display the Define Assays window.

2. Verify that the assay you want is present.

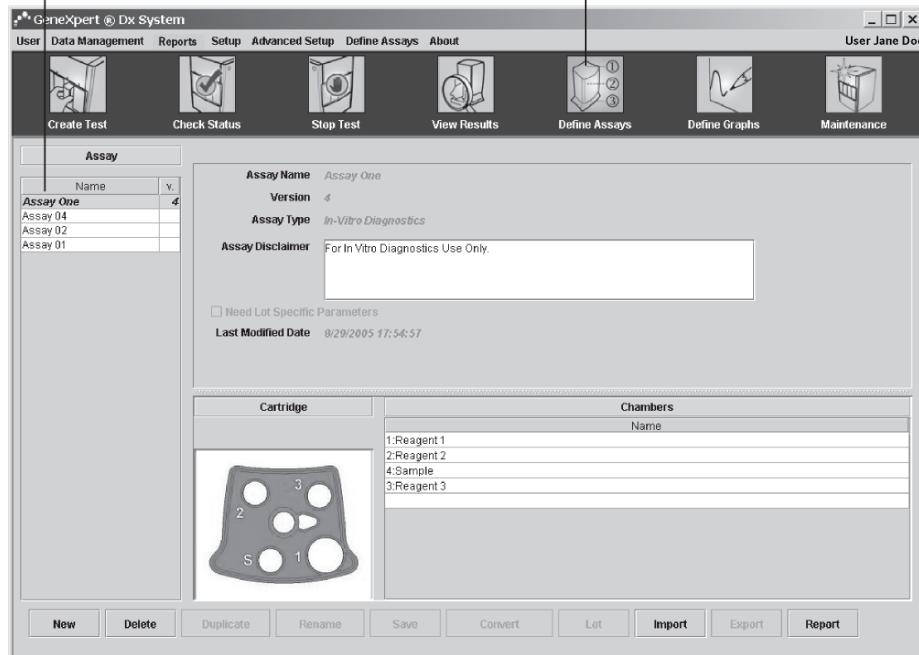


Figure 5-13. GeneXpert Dx System – Define Assays window

5.5 Creating a Test

Caution  The information you provide in the Create Test dialog box is automatically saved when you start the test. If you close the Create Test dialog box before you start the test, all information will be lost.

Note: This section assumes that your GeneXpert Dx System administrator has configured the system to not use Patient ID, to allow Sample ID and cartridge barcode scanning, and to require login at start up (Section 2.9). Scanning the Sample ID and cartridge label reduces typing errors and helps ensure that the Sample ID and test results are properly linked. If the barcode scanning options are not turned on, you can provide the Sample ID and assay information manually.

Important If you are using manual entry, ensure that the Sample ID is entered correctly.

When you create a test, you are creating a record of how a specimen is processed. The record includes the assay information, instrument module ID, and test type. To create a test:

1. In the GeneXpert Dx System window, click **Create Test** on the menu bar. The Scan Sample ID Barcode dialog box appears (Figure 5-14).

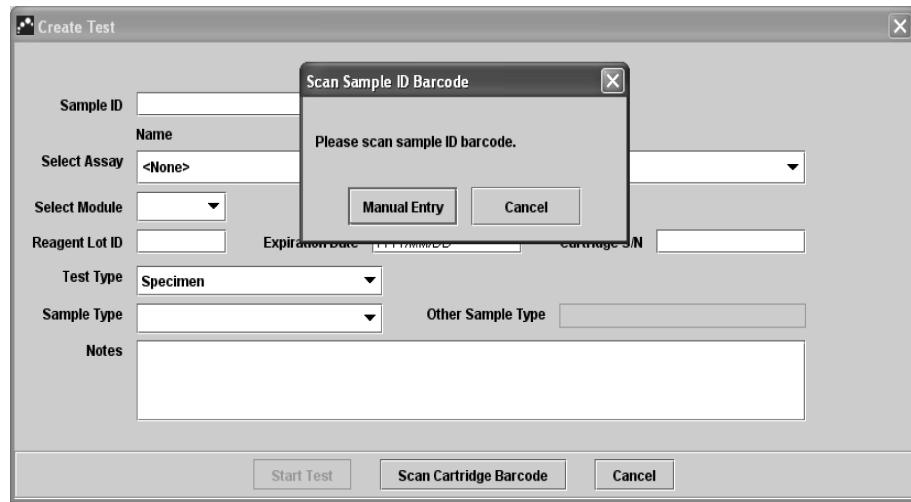


Figure 5-14. Create Test window and Scan Sample ID Barcode dialog box

2. Scan the Sample ID barcode using the supplied barcode scanner. The Scan Cartridge Barcode dialog box appears (Figure 5-15).

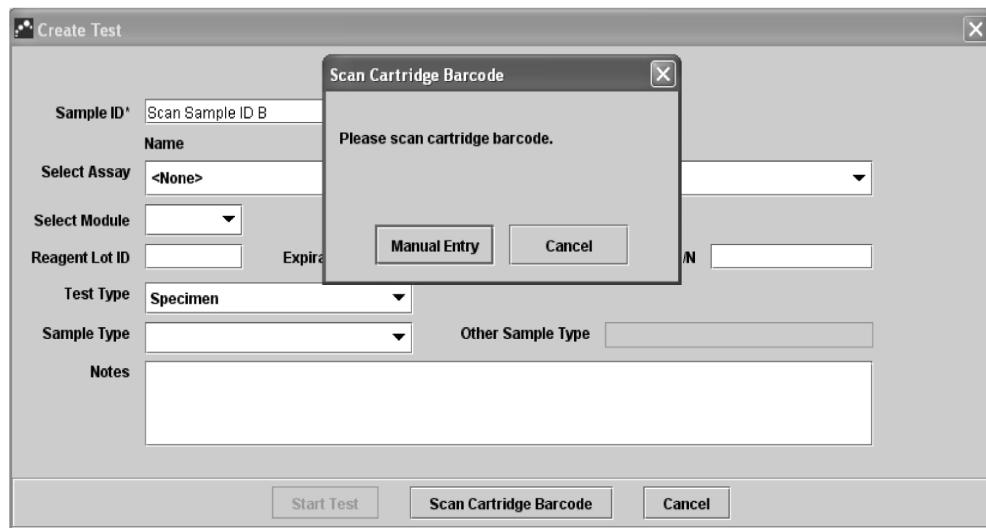
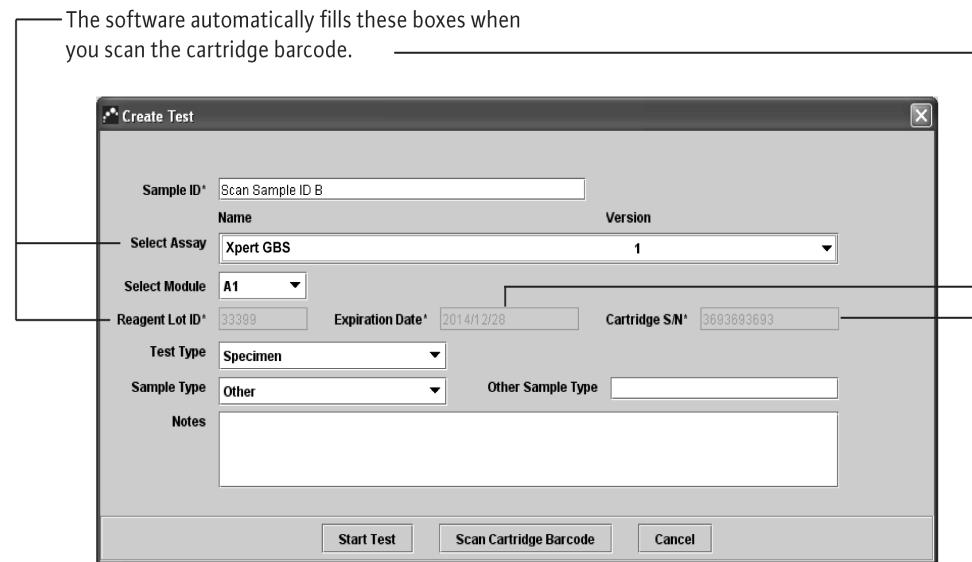


Figure 5-15. Scan Cartridge Barcode dialog box

3. Scan the cartridge barcode using the supplied barcode scanner. The Create Test dialog box appears as shown in Figure 5-16. Note that the software automatically fills the required information in the Create Test window.

Important To ensure the accuracy of test results, be sure to use the same cartridge in the test.

Important If you see multiple assays in the drop-down menu, select the desired assay.



* Note: The asterisks adjacent to Sample ID, Reagent Lot ID, Expiration Date, and Cartridge SN indicate the data was scanned in.

Figure 5-16. Create Test dialog box with the Sample ID, Test Type, and Notes boxes shown

4. (Optional) In the **Select Module** list, select the available instrument module. By default, the software displays the module that is least used.
Only modules with the correct calibration and that are not busy running another test will be selectable. You can change the selected module by clicking on the drop down menu.
5. (Optional) Type the **Sample ID** (if not scanned previously). Sample IDs cannot include the following characters: /, \, ;, *, ?, “, <, > or |.
6. Select the **Test Type** (Specimen or External Controls)
7. Type information about the test in the **Notes** box.

Note: Cepheid barcode scanner has been qualified to be used with Code 39, Code 128A, B, or C and 2-D data matrix symbologies.

Caution  Make sure you scan or type the correct **Sample ID** or **Patient ID**. The **Sample ID** or **Patient ID** is associated with the test results and is shown in the **View Results** window and all the reports.

5.6 Loading a Cartridge into an Instrument Module

Caution  Do not load a GeneXpert cartridge that has been dropped or shaken after you have inserted the sample and reagents. Dropping or shaking the cartridge can cause invalid results. Bent or broken reaction tubes can also produce invalid results. Do not re-use spent cartridges.

Caution  Always pick up the cartridge by its body. Do not pick up the cartridge by the protruding reaction tube (Figure 5-17).

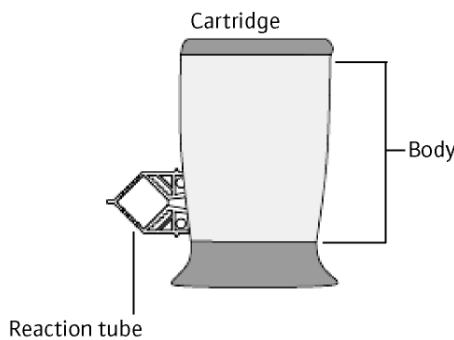


Figure 5-17. Cartridge and reaction tube

This section assumes that you have inserted the specimen and reagents into the GeneXpert cartridge. See the assay-specific package insert or quality-control labeling document for instructions.

5.7 Starting the Test

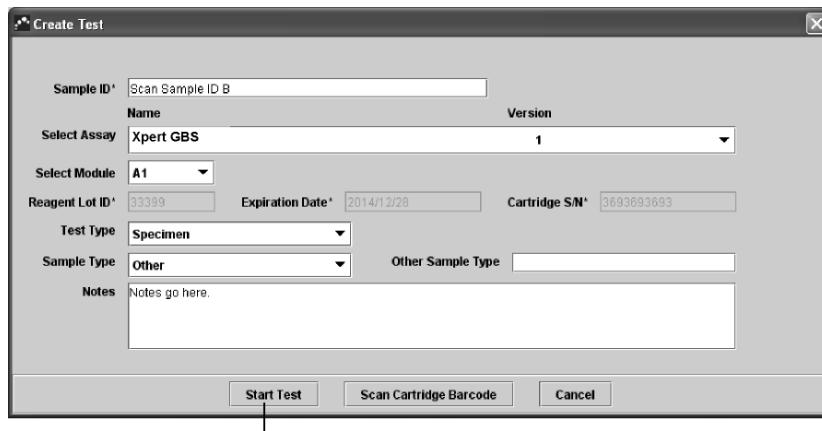
Caution  **Do not run other software while a test is in progress. Doing so might interfere with the test process and cause the loss of data.**

Note: If you log out while a test is in progress, the system will continue to finish the test and save the results.

To start the test:

1. In the Create Test dialog box (Figure 5-18), click **Start Test**. The software asks for your password.

Note: If your user name is not displayed, type your user name and password.



Click to start the test.

Figure 5-18. Create Test dialog box ready to start test

2. Type your password, and then click **OK**. In the Check Status window, the instrument module progress changes to Waiting. The green light above the instrument module door flashes.
3. Open the instrument module door.
4. Place the cartridge on the module bay floor (Figure 5-19). The cartridge label should face out. Make sure the cartridge sits level on the bay floor and is positioned at the heel of the bay.
5. Close the instrument module door all the way. The door locks and the green light stops flashing and stays on. The test starts.

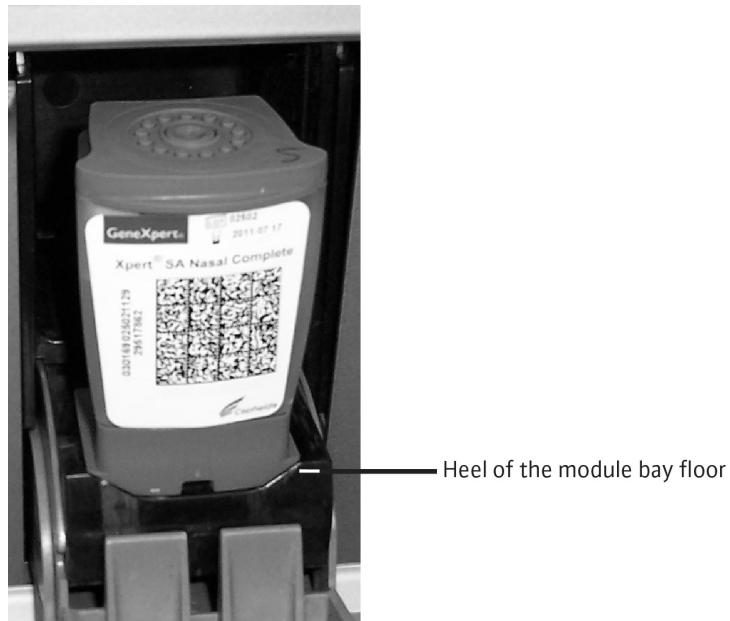


Figure 5-19. GeneXpert cartridge, positioned at the heel of the module bay floor

During the first few minutes after you start the test, the system moves the cartridge contents and rehydrates the reagent beads. If applicable to the assay definition, the system also performs a probe check to see if the master mix is reconstituted properly and that the probes are present in the master mix.

- If the probe check fails, the test will abort. You can check the error message to review the cause of the probe check failure (Chapter 11).
- If the probe check passes, the test continues.

When the test finishes, the instrument module door unlocks and the green light turns off. In the GeneXpert Dx System window, the Progress column in the Modules area shows the module is available.

5.8 Monitoring the Test Process

You can monitor the test process or other status indicators in the following areas of the Check Status window (Figure 5-20):

- **Modules**—Displays the assay definition used, the Sample ID, the progress or phase of the test (for example, 3/45 means the test is on the third PCR cycle out of 45 cycles), the status of the test phase, and the amount of time remaining until the end of the test. If the Status column displays Error or Warning, look in the Messages area of the window for a description of the problem.
- **Messages**—Displays the date and time you started the software, the software version number, and any error messages that were encountered since the software started.

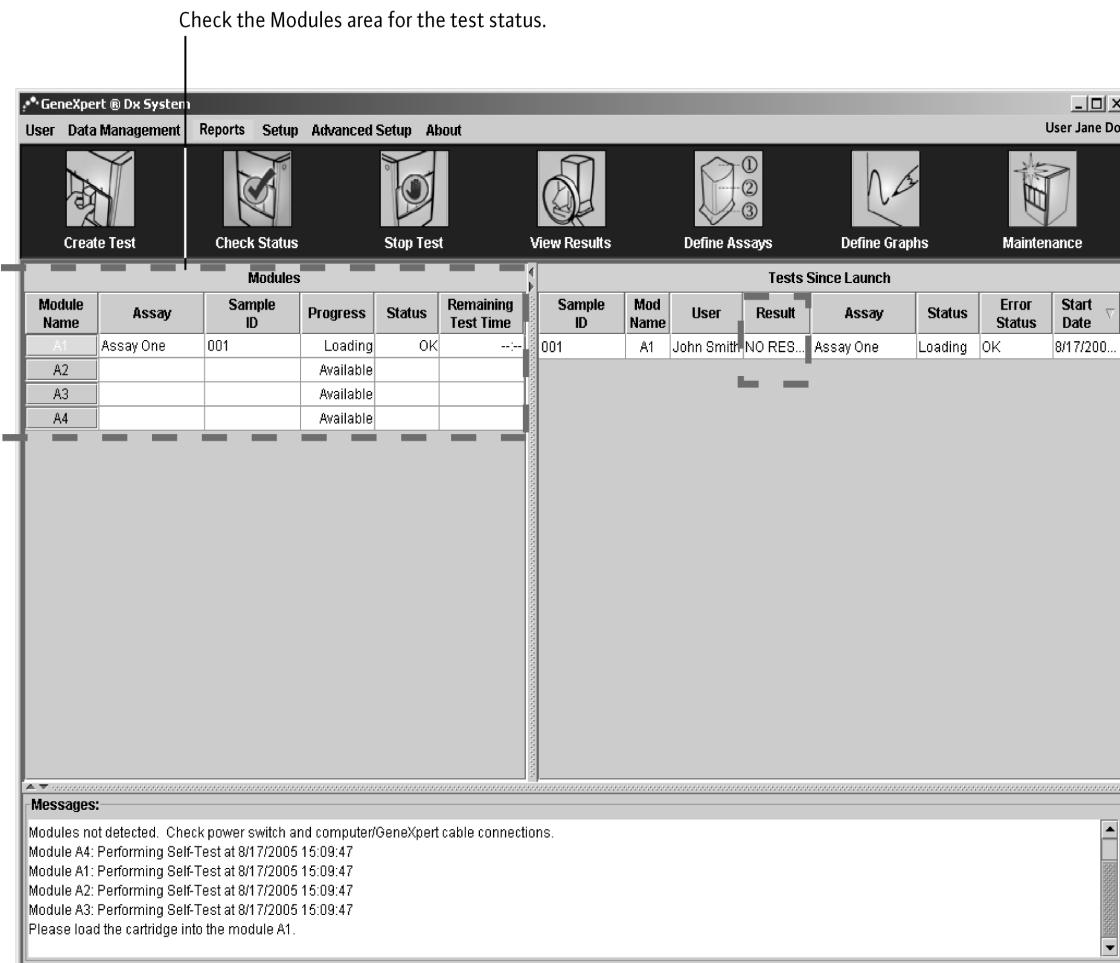


Figure 5-20. GeneXpert Dx System—Check Status window, displaying the status of a run in progress

When a test is in progress, “NO RESULT” is shown in the Result column.

Note: When the right side of the screen displays “Tests Since Launch” it means tests since the most current launch of the GeneXpert Dx System software.

5.9 Stopping a Test in Progress

Caution After you stop a test in progress, the system halts the sample processing activities and terminates data collection. Do not reuse the cartridge.



To stop a test that is currently in progress, in the GeneXpert Dx System window, click Stop Test on the menu bar. The Stop Test dialog box appears (Figure 5-21). You can do one of the following:

- **Stop individual tests**—Select the tests you want to stop, and then click Stop. The confirmation dialog box appears. Click Yes to confirm or click No to cancel.
- **Stop all tests in progress**—Click Select Running to select all tests currently in progress, and then click Stop. The confirmation dialog box appears. Click Yes to confirm or click No to cancel.
- To clear all of the test selections, click Deselect All.
- Click Cancel to dismiss the Stop Test dialog box.

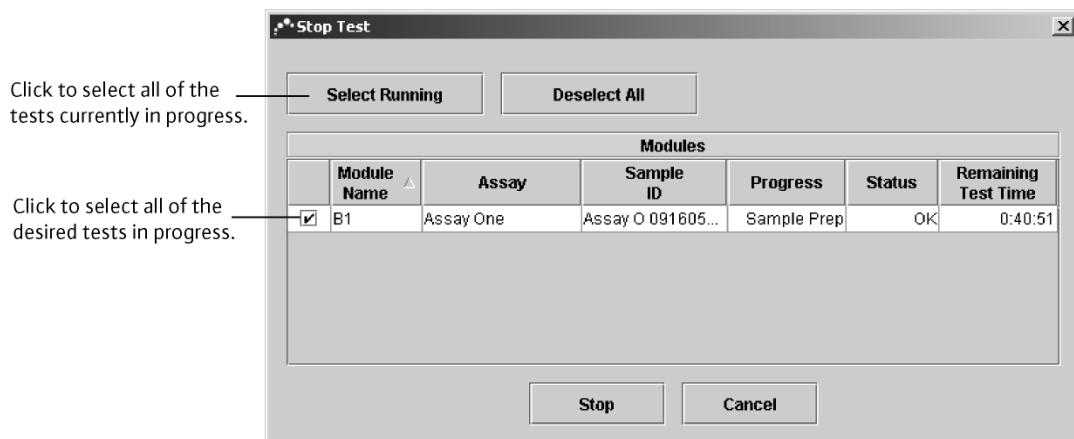


Figure 5-21. Stop Test dialog box

5.10 Viewing the Test Results

You can display and view the test results in the View Results window (Section 5.10.1). The features in the View Results window vary by user type:

- Basic users (Section 5.10.2)
- Detail users and the administrator (Section 5.10.3)

5.10.1 Displaying the test results

To select and display the test results:

1. In the GeneXpert Dx System window, click View Results on the menu bar. The View Results window appears (Figure 5-22).

Note: The View Results window displays different features for different user types. Section 5.10.2 describes the View Results window for the Basic users. Section 5.10.3 describes the View Results window for the Detail users and the administrator.

Figure 5-22 shows a View Results window for Detail users and the administrator.

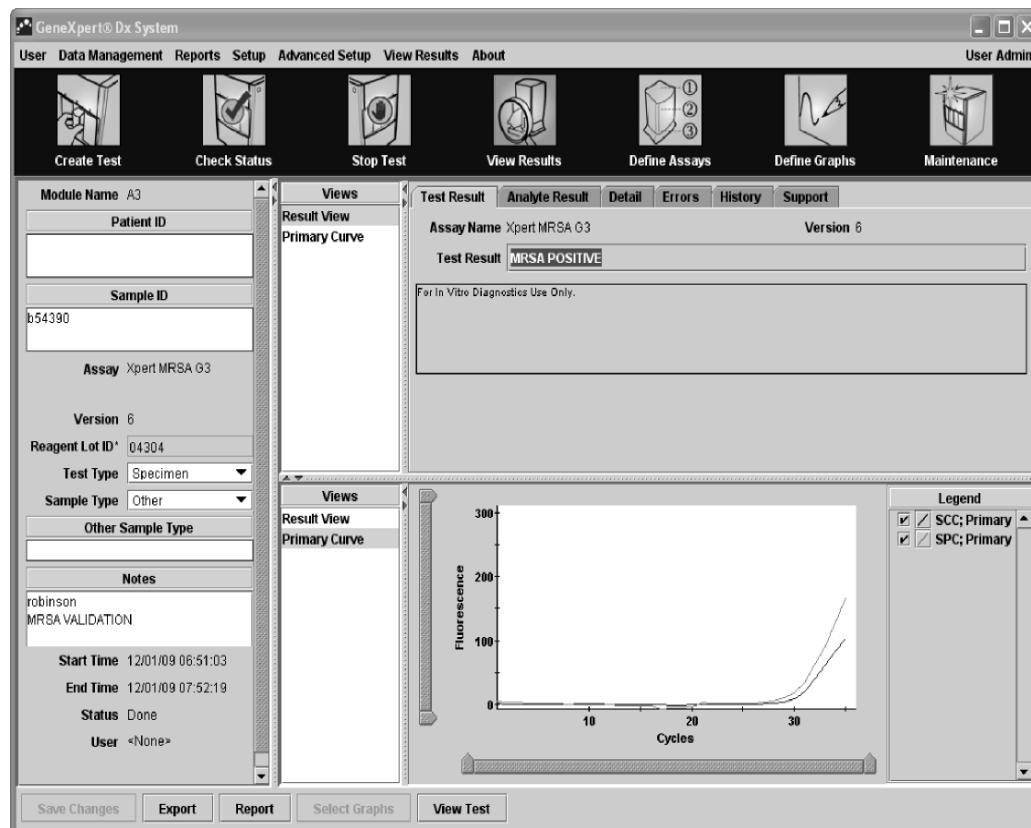


Figure 5-22. GeneXpert Dx System—View Results window (Detail and Admin view)

2. To select a test, click View Test.

The Select Test To Be Viewed dialog box appears (Figure 5-23).



Figure 5-23. Select Test to be Viewed dialog box

Caution



Sometimes only part of the result information is shown in the Result column of the Select Test to be Viewed dialog box. To see the rest of the result information, move the mouse's cursor over the Result column.

3. Select the test of interest. To sort the list of tests by a column, click the column heading.
4. Click **OK**. The results of the selected test appear in the View Results window.

The test is displayed.

5.10.2 Basic user view

Figure 5-24 shows the View Results window for Basic users. The window contains three tabs: Results, Errors, and Support.

5.10.2.1 Results tab

The **Results** tab displays the following information for a test (Figure 5-24):

- **Patient ID** (If Use Patient ID is enabled. It is user editable)
- **Sample ID** (user editable)
- **Assay**—Assay name
- **Version**—The assay version number
- **Result**

The test Results shown in the Basic View Results will be expanded to display all lines for multiple line results to support the maximum number of results for organism,

genotyping, or % ratio assays. If the expansion is such that other information will no longer fit on the window, a scroll bar will allow viewing of the other information.

- **User**—Operator name
- **Sample Type**—Editable, using drop down list of assay specific sample types.
- **Other Sample Type**—Same behavior as described for Create Test dialog.
- **Notes** (user editable)
- **Start Time**—test start date and time stamp
- **End Time**—test end date and time stamp
- **Status**— test status
- **Upload Status** (if Host Interface is enabled)
- **Disclaimer**—This disclaimer states any limitations or additional information for the assay test.

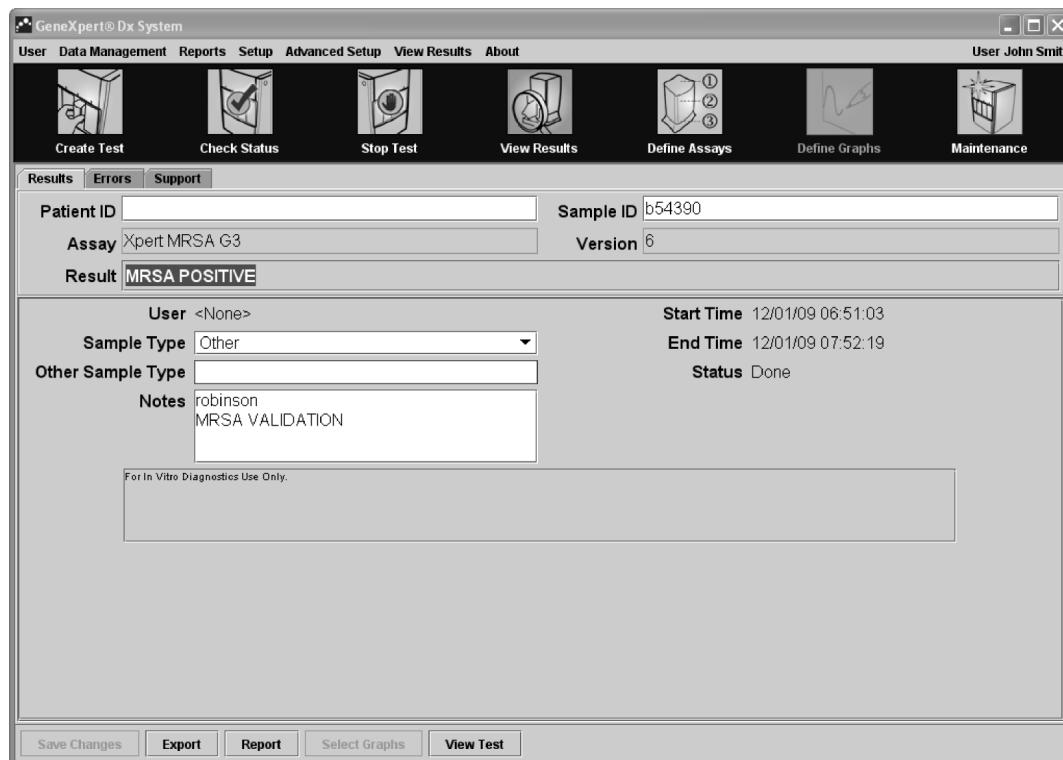


Figure 5-24. GeneXpert Dx System, View Results window —Results tab (Basic users view)

5.10.2.2 Errors tab

The **Errors** tab lists the errors encountered during the test process and provides the following information (Figure 5-25):

- **#**—The number that indicates the sequence in which the errors appeared during the test.
- **Description**—The error message category.
- **Detail**—The error message text.
- **Time**—The time at which the error occurred.

See Chapter 11 for a description of the error messages and the possible causes and potential solutions to the errors.

If there were no errors during the test, the Errors tab displays a blank table.

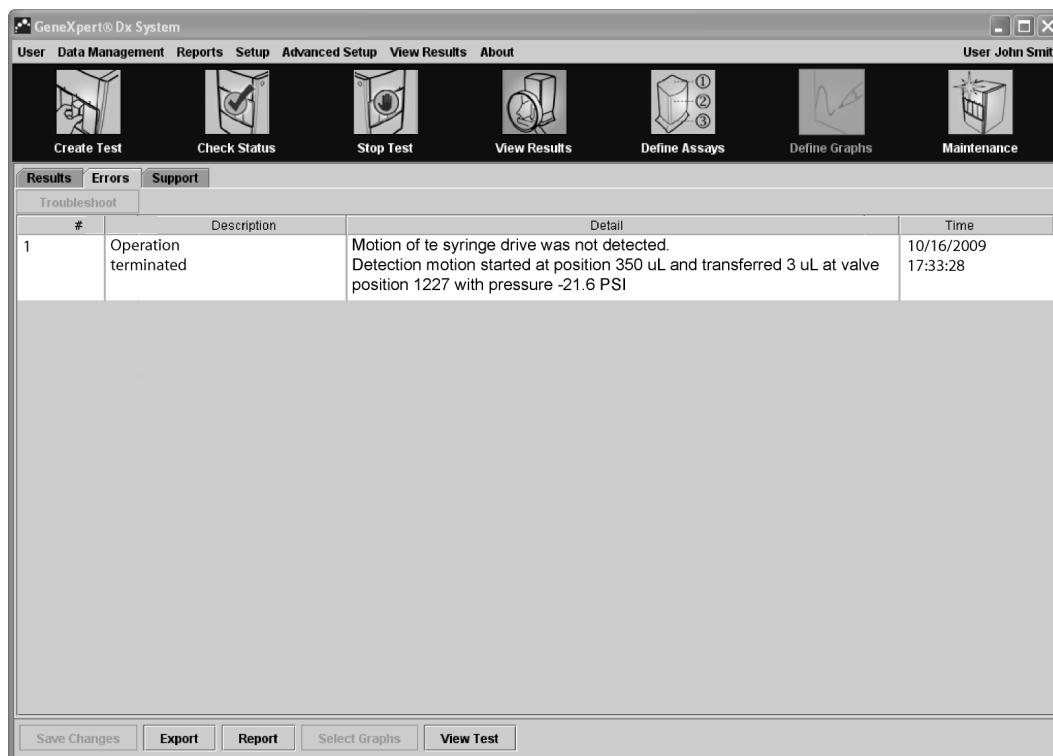
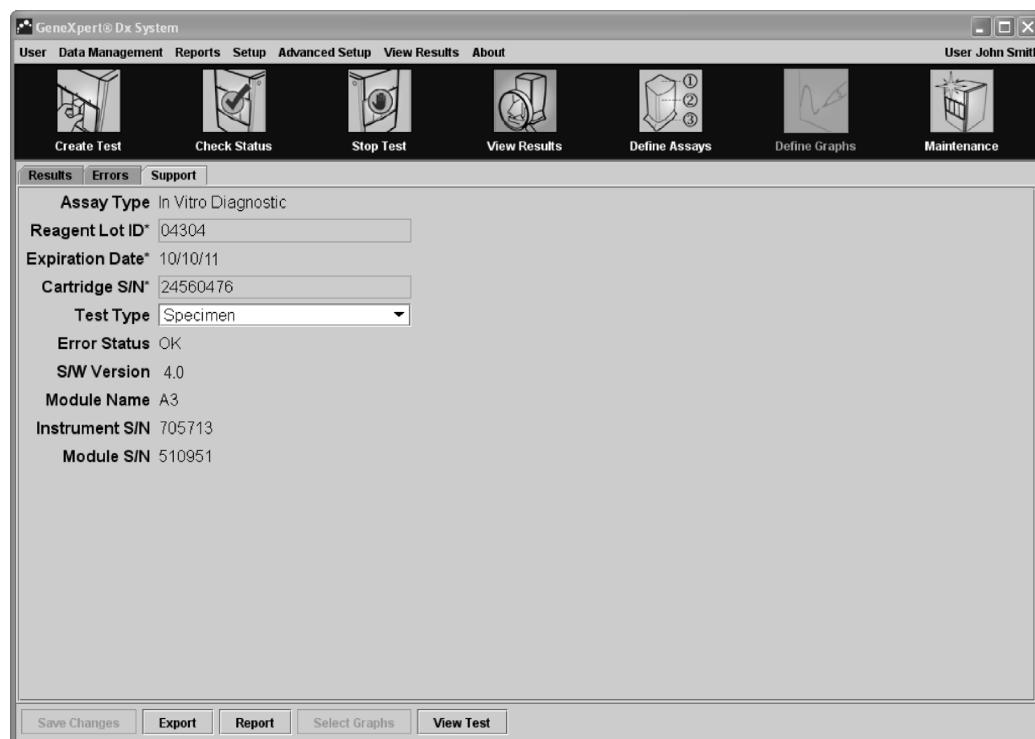


Figure 5-25. GeneXpert Dx System, View Results window—Errors tab (Basic users view)

5.10.2.3 Support tab

- The **Support** tab displays the following information for a test (Figure 5-26):
 - **Assay Type**
 - **Reagent lot ID** (it is not editable if the associated assay is a factory assay that required lot specific parameters or the cartridge barcode is scanned)
 - **Expiration Date**—Cartridge expiration date
 - **Cartridge S/N**—cartridge serial number. It is not editable if the cartridge barcode is scanned
 - **Test Type** (user editable)
 - **Error Status**—test error status (OK, Error or Warning)
 - **S/W Version**
 - **Module Name**
 - **Instrument S/N**
 - **Module S/N**



* Note: The asterisks adjacent to Reagent Lot ID, Expiration Date, and Cartridge S/N indicate the data was scanned in.

Figure 5-26. GeneXpert Dx System, View Results window—Support tab (Basic users view)

5.10.3 Detail user and administrator view

Figure 5-27 shows the View Results window for Detail users and the administrator. The window is divided into four areas:

- **Test information area**—Displays information provided when you created the test, including the module used in the test, the Patient ID (if it is enabled), Sample ID, assay information, and cartridge information. You can edit and save the Patient ID or Sample ID, Test Type information, Sample Type, Other Sample Type, and text in the Notes box (Section 5.11).
- **Views area**—Allows you to arrange the display of the Results and Growth curve areas. For example, you can display the growth curve area above the results area.
- **Results area**—Allows you to view the information in the following tabs: Test Result, Analyte Result, Detail, Errors, History, and Support.
- **Growth curve area**—Displays a graph that plots the number of cycles on the X-axis and the fluorescence units on the Y-axis for each analyte. The graph reflects the curve analysis specified in the assay definition (primary, second derivative, or the combination). Using this graph, you can visually inspect the rate at which the fluorescence signal increases.

To display or hide an analyte graph, select the analyte name in the graph legend to the right of the graph. In addition, you can change the magnification of the graph in the X or Y direction by dragging the horizontal or vertical slider next to the X- or Y-axis.

5.10.3.1 Test Result tab

- The Test Result tab of the Result View displays the following information for a test (Figure 5-27):
 - **Assay Name and Version**
 - **Test Result**
 - Disclaimer—This disclaimer states any limitations or additional information for the assay test.

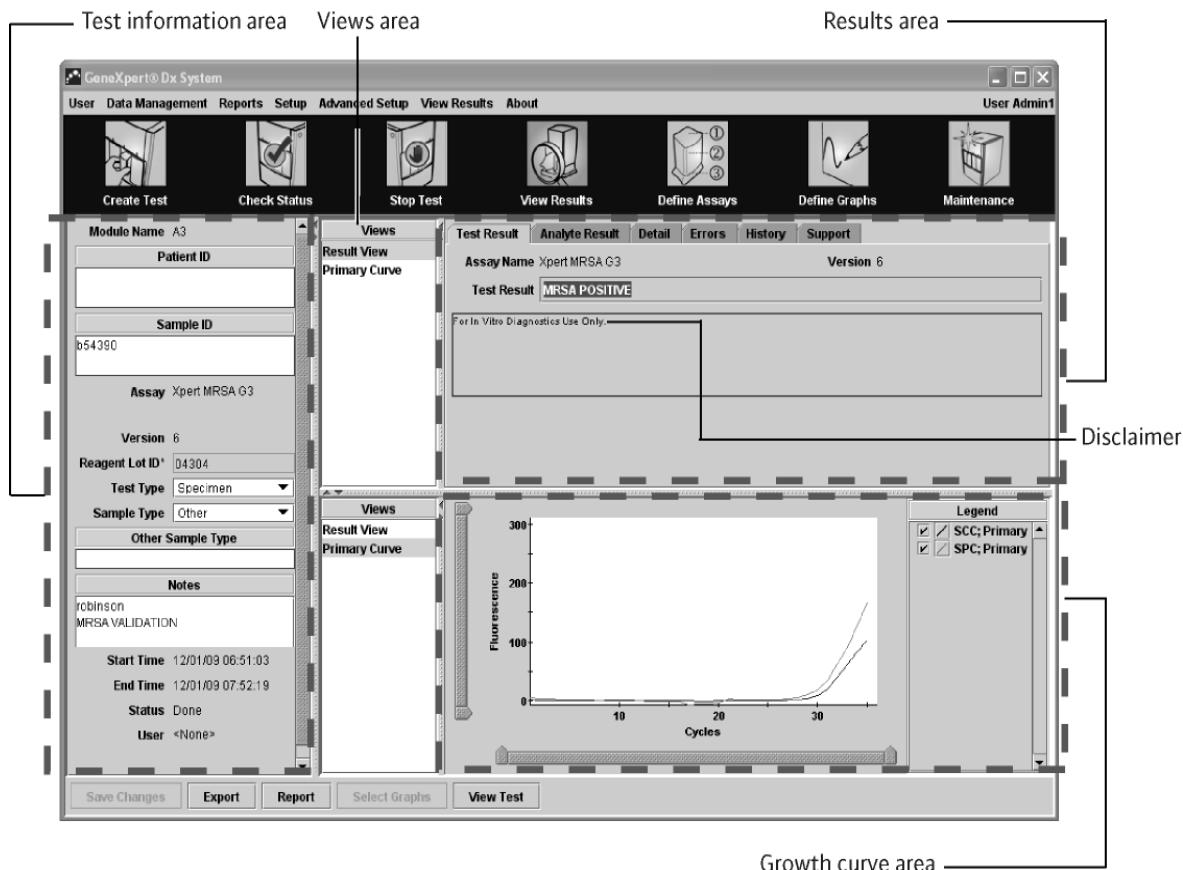


Figure 5-27. GeneXpert Dx System, View Results window—Test Result tab (Detail users and administrator view)

5.10.3.1 Analyte Result tab

The **Analyte Result** tab displays the following information in tabular form (Figure 5-28).

- **Analyte Name**—The analyte that was tracked during the test process. The possible analytes are the name of the test target, IC (internal control), or SPC (sample processing control), and EC (endogenous control).
- **Ct**—The first cycle in which the fluorescence signal reaches a specified threshold. The threshold cycle (Ct) is determined from the growth curve (Primary Curve and Combination Curve), or the second derivative of the growth curve (2nd Deriv).
- **EndPt**—The endpoint value of the growth curve in fluorescence units.
- **Analyte Result**—The result for each analyte processed. The results are displayed after the test is finished.
- **Probe Check Result**—The result of the probe check, the process that verifies presence and integrity of the probes in the master mix. Possible values are PASS, FAIL, and NA if the assay does not include a probe check. The probe check passes if the measured fluorescence values together meet the predetermined validated acceptance criteria.

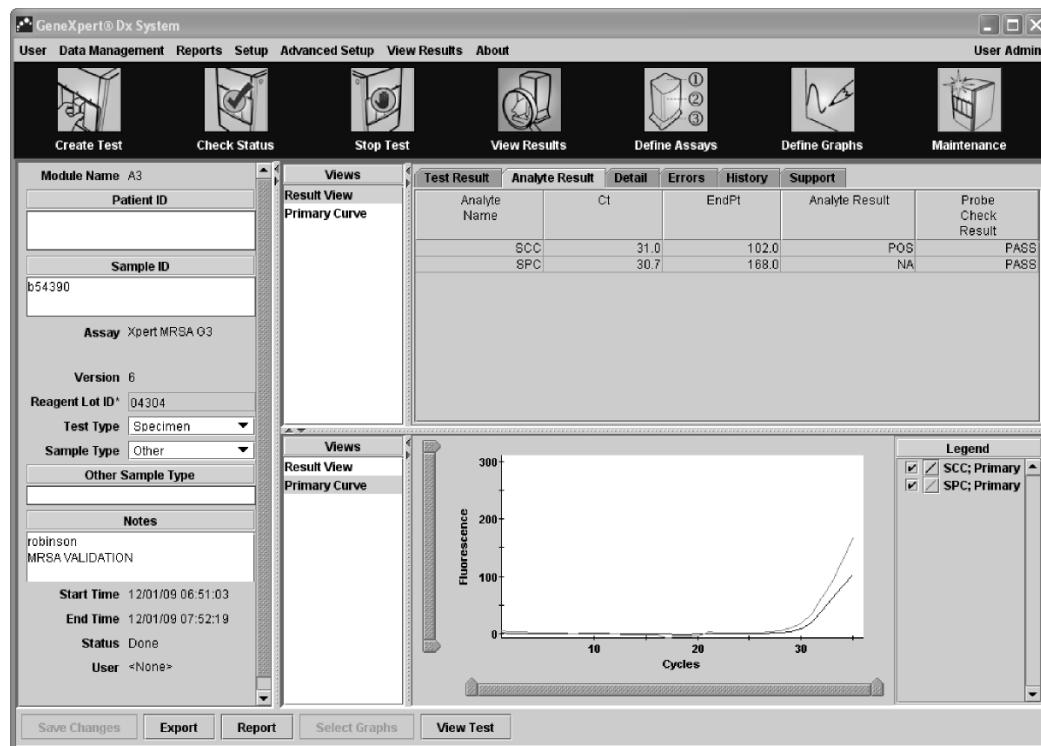


Figure 5-28. GeneXpert Dx System, View Results window —Analyte Result tab (Detail users and administrator view)

5.10.3.2 Detail tab

The Detail tab displays the detailed probe check results if the assay specified the use of a probe check (Figure 5-29). In addition, the second derivative peak height value (for the combination curve), melt peaks, and curve fit result are available if the assay definition specified their use.

As shown in Figure 5-29, the Detail tab of the Result View provides following miscellaneous data for a test results:

- **Analyte Name**
- **Prb Chk 1**—Probe check 1 optics reading
- **Prb Chk 2**—Probe check 2 optics reading
- **Prb Chk 3**—Probe check 3 optics reading
- **Probe Check Result**—Pass or Fail
- **2nd Derivative Peak Height**
- **Melt Peak 1** (shown if assay uses this)
- **Melt Peak 2** (shown if assay uses this)
- **Melt Peak 3** (shown if assay uses this)
- **Curve Fit** (shown if assay uses this)

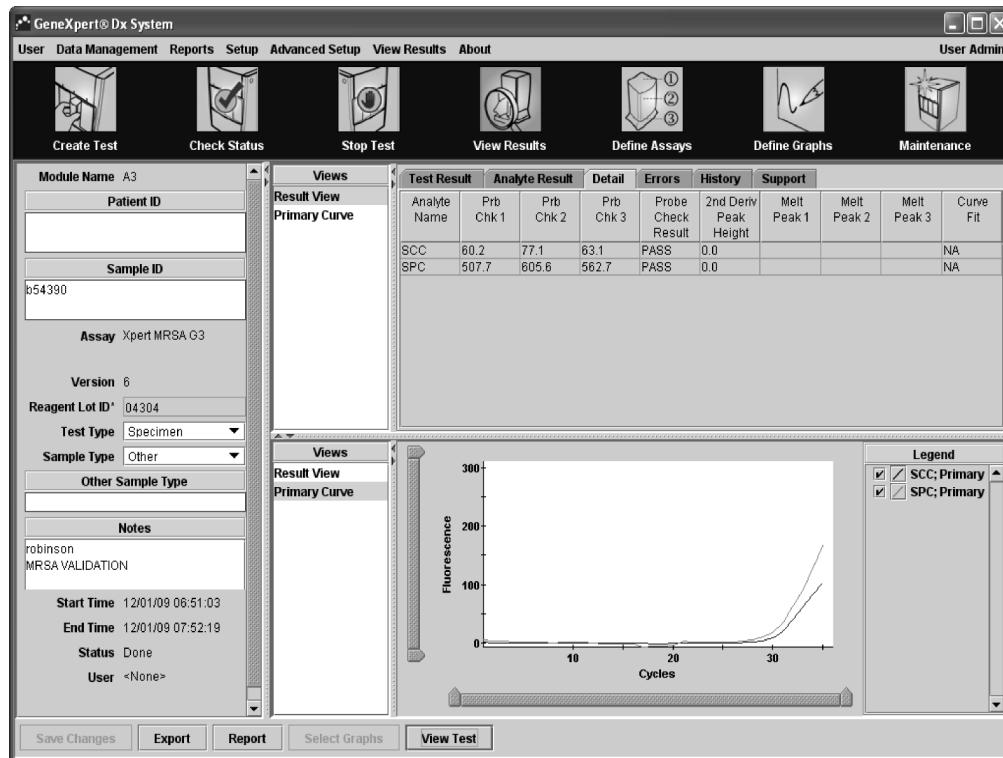


Figure 5-29. GeneXpert Dx System – View Results window—Detail tab (Detail users and administrator view)

5.10.3.3 Errors tab

The **Errors** tab lists the errors encountered during the test process and provides the following information (Figure 5-30):

- #—The number that indicates the sequence in which the errors appeared during the test.
- **Description**—The error message category.
- **Detail**—The error message text.
- **Time**—The time at which the error occurred.

See Chapter 11 for a description of the error messages and the possible causes and potential solutions to the errors.

If there were no errors during the test, the Errors tab displays a blank table.

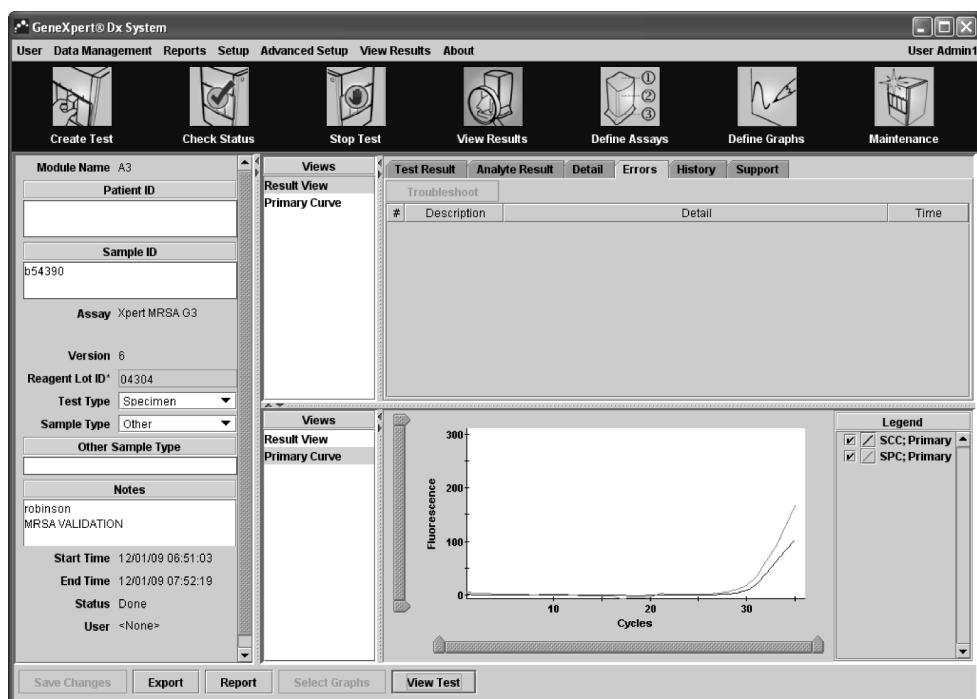


Figure 5-30. GeneXpert Dx System – View Results window—Errors tab (Detail users and administrator view)

5.10.3.4 History tab

The History tab displays a log of revisions made to the test information (Figure 5-31). The log includes the original information, the revised information, the user who revised the information, and the date and time of the revision.

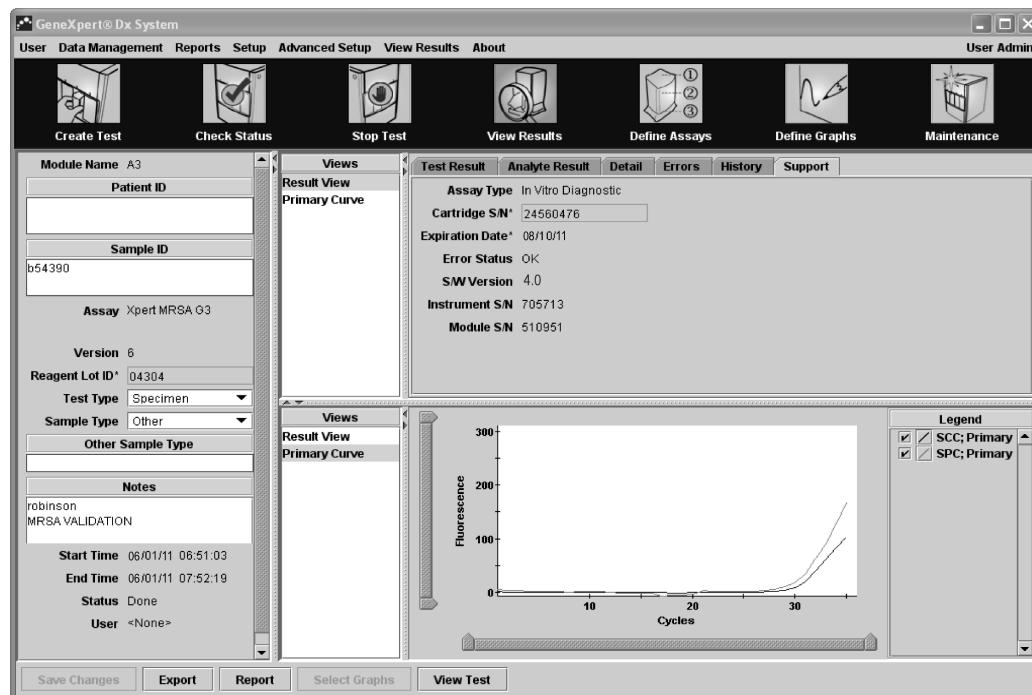


Figure 5-31. GeneXpert Dx System, View Results window—History tab (Detail users and administrator view)

See Section 5.11 (Editing the Test Information) for instructions on how to edit information in the View Results window and save the change(s) into the History tab window.

5.10.3.5 Support tab

- The **Support** tab for the Detail users and administrators displays the following information for a test (Figure 5-32):
 - Assay Type**
 - Cartridge S/N**—cartridge serial number. It is not editable if the cartridge barcode is scanned
 - Expiration Date**—Cartridge expiration date
 - Error Status**—test error status (OK, Error or Warning)
 - S/W Version**
 - Instrument S/N**
 - Module S/N**



* Note: The asterisks adjacent to Cartridge S/N and Expiration Date indicate the data was scanned in.

Figure 5-32. GeneXpert Dx System, View Results window—Support tab (Detail users and administrator view)

5.11 Editing the Test Information

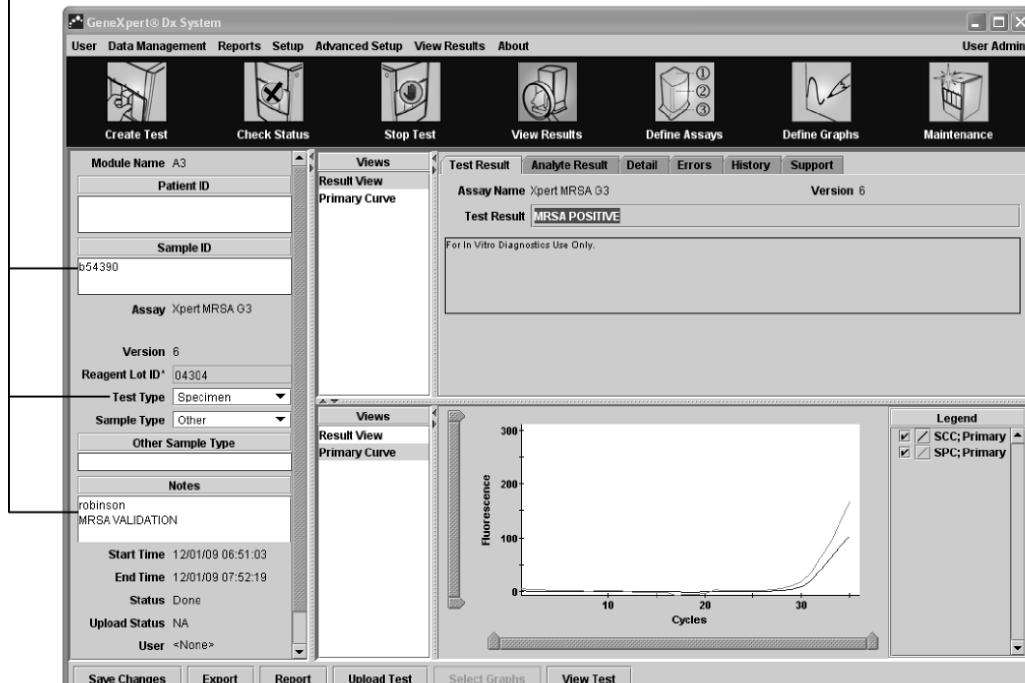
Caution  Make sure you scan or type the correct Sample ID and Patient ID. The Sample ID and Patient ID is associated with the test results and is shown in the View Results window and all the reports.

For each test, you can edit the Patient ID (if it is enabled), Sample ID, Test Type, Sample Type, Other Sample Type, and Notes. To do this:

1. In the View Results window (Figure 5-24 or 5-27), edit the Sample ID, Test Type, or Notes (Figure 5-33).

Sample IDs cannot include the following characters: /, \, ;, *, ?, “, <, > or |.

1. Edit the information in the boxes.



2. Click to save changes.

Figure 5-33. GeneXpert Dx System—View Results window (Detail users and administrator view)

To demonstrate the History tab feature:

1. In the GeneXpert Dx System window, click View Results on the menu bar. The Test Result tab window is displayed (Figure 5-34).

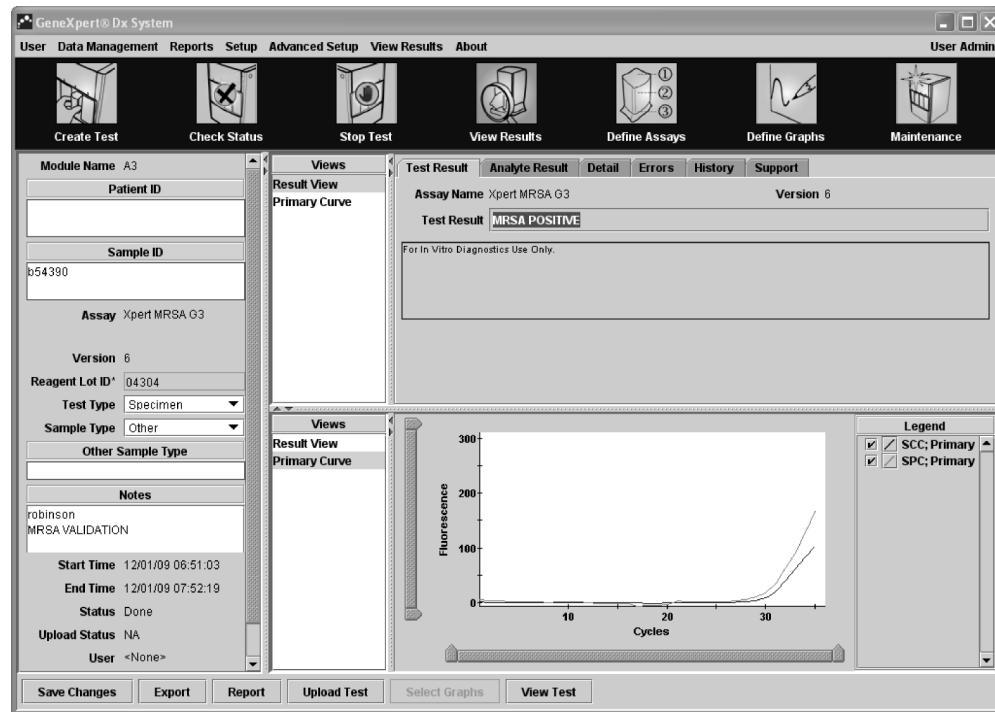


Figure 5-34. GeneXpert Dx System, View Results window—(Detail users and administrator view)

2. Click the **History** tab in the View Results screen. The history window is displayed (Figure 5-35).

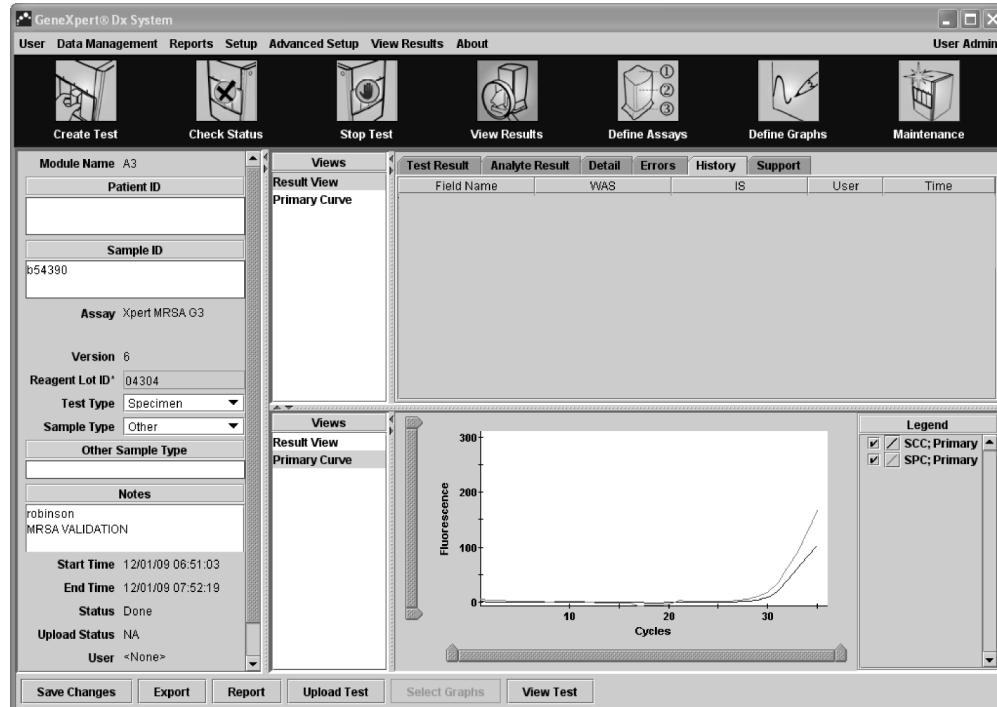


Figure 5-35. GeneXpert Dx System, History tab window selected

3. Change Test Type to Negative Control as shown in Figure 5-36.

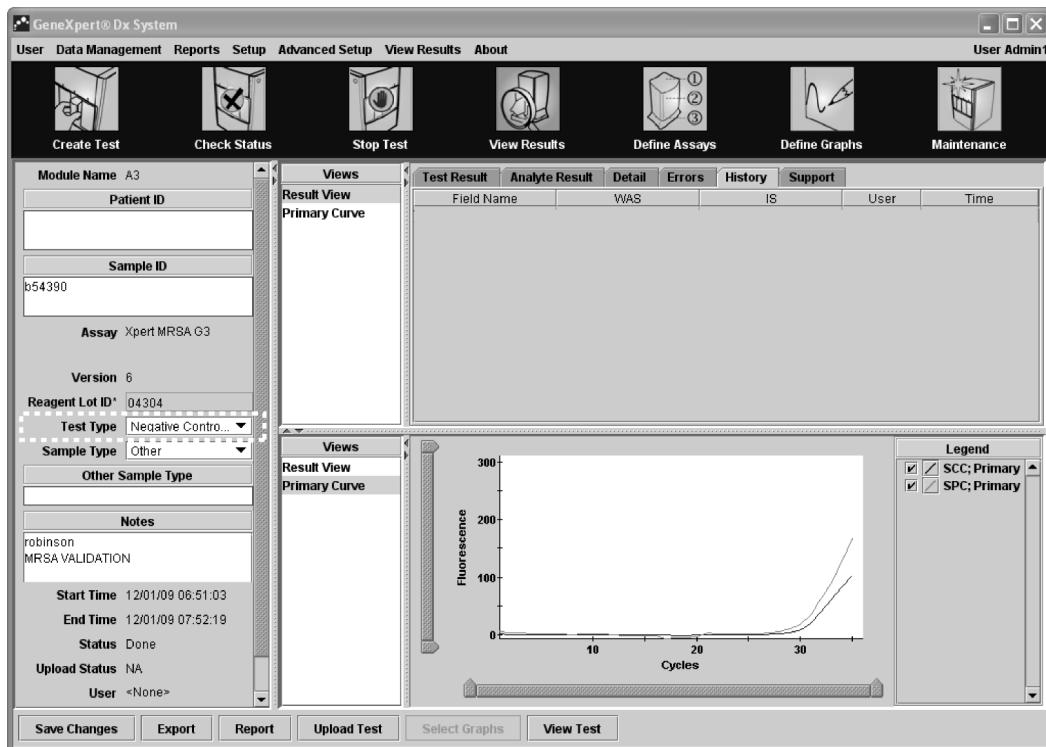


Figure 5-36. GeneXpert Dx System, View Results window—Test Type changed from Specimen to Negative Control

4. Click **Save Changes** button located at the bottom of the View Results window (Figure 5-36). The Save Test dialog box appears (Figure 5-37).

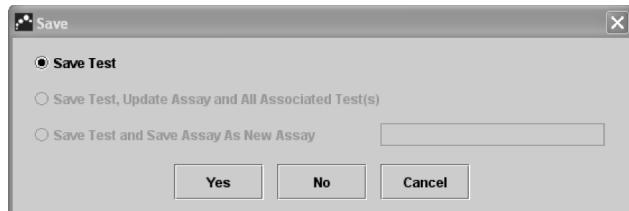


Figure 5-37. Save Test dialog box

5. Click **Yes** to save the changes and proceed. The software tracks the change history (Figure 5-38). If you are a Detail user or the administrator, you can view the changes in the History tab (Section 5.10.3.4).

Click **No** to not save changes and proceed.

Click **Cancel** to not proceed and stay in the same window.

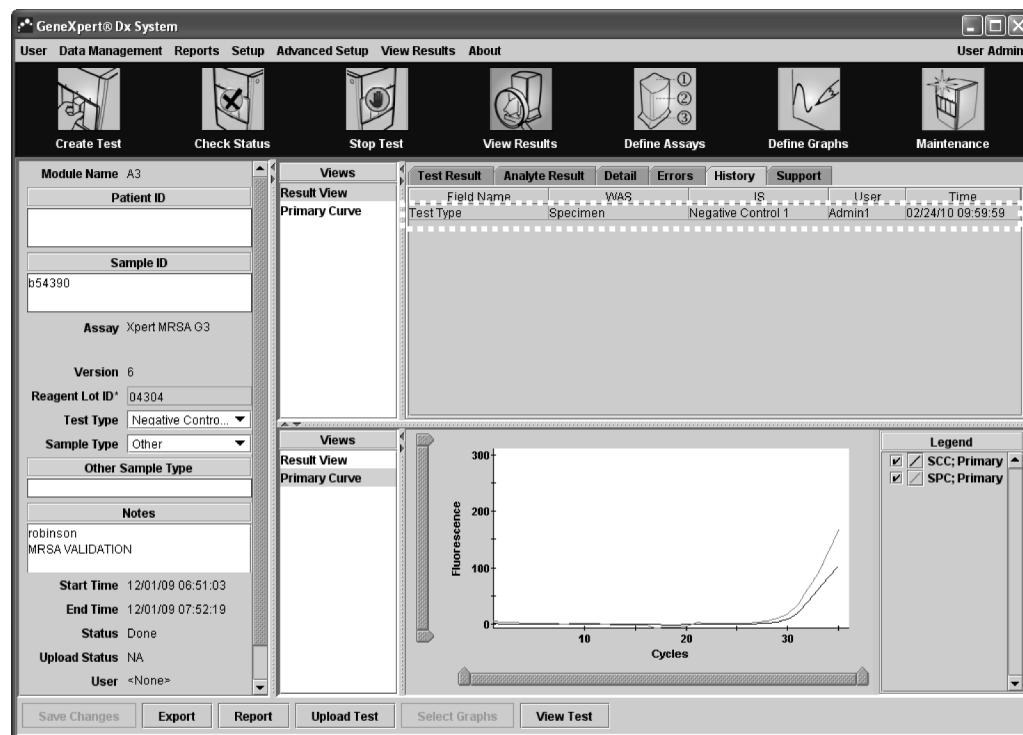


Figure 5-38. History tab window showing change from Specimen to Negative Control test type

5.12 Generating Test Result Reports

To generate a PDF file containing the test results, in the View Results window (Figure 5-27), click **Report**.

For Basic users, the software creates a PDF file and displays the file in the Adobe Reader window. You can save and print the PDF file from the Acrobat software. For instructions on how to use Acrobat, see the Acrobat user documentation.

For Detail users and the administrator, the software displays the Test Report dialog box (Figure 5-39). Select the information you want to include and the tests of interest, and then click one or both of the following buttons:

- **Generate Report File**—Creates a PDF file and saves it in the default location (Section 2.9) or a location you specify.
- **Preview PDF**—Creates a PDF file and displays the file in the Adobe Reader window. You can save and print the PDF file from the Acrobat software. For instructions on how to use Acrobat, see the Acrobat user documentation.

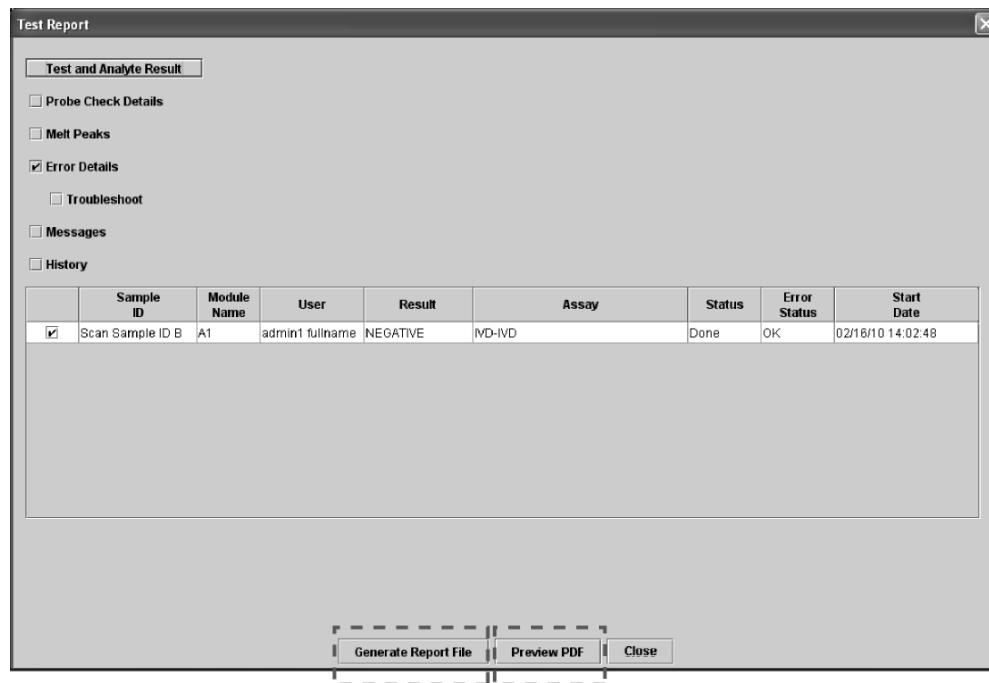


Figure 5-39. Test Report dialog box (Detail user and administrator only)

Caution

Sometimes only part of the result information is shown in the Result column of the Test Report dialog box. To see the rest of the result information, move the mouse's cursor over the Result column.



If **Print Test Report At End of Test** is enabled, the report will automatically print after the test is completed (see Section 2.9).

5.13 Exporting the Test Results

To export the test results to a comma-separated value (.csv) file, in the View Results window (Figure 5-24 or 5-27), click **Export**.

For Basic users, the Result Export dialog box appears (Figure 5-41). Locate and select the folder to which you want to export the file, type a file name, and then click **Save**.

For Detail users and the administrator, the Export Data dialog box appears (Figure 5-40).

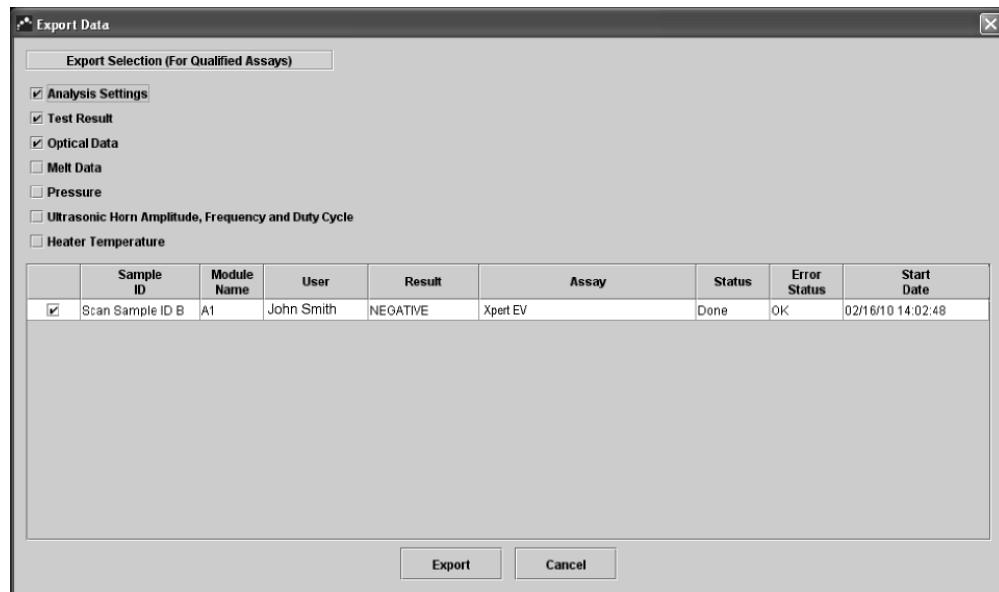


Figure 5-40. Export Data dialog box (Detail users and administrator only)

Select the test results and the associated information you want to export, and then click **Export**. The Result Export dialog box appears (Figure 5-41). Locate and select the folder to which you want to export the file, type a file name, and then click **Save**.

Note: When a report file is exported, the software will remember the last directory used.

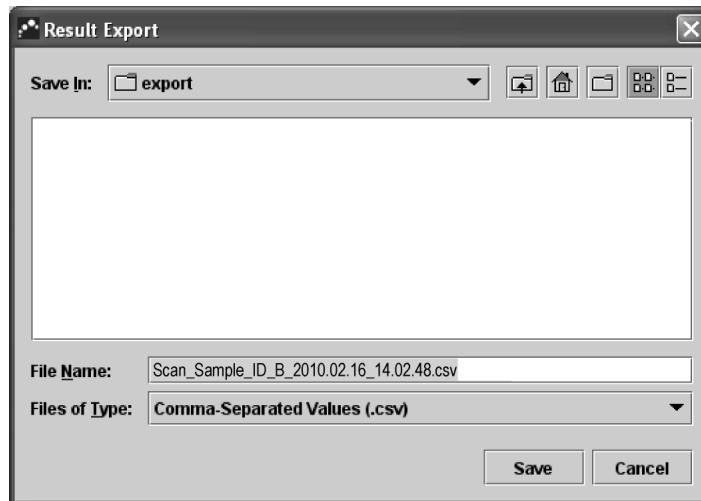


Figure 5-41. Result Export dialog box

5.14 Uploading Test Results to Host

If your Host connectivity is enabled, the **Upload Test** button (Figure 5-42) is available for use to select test(s) for uploading to the Host. For details, see Chapter 6 (Operating with Host Connectivity).Operating Instructions

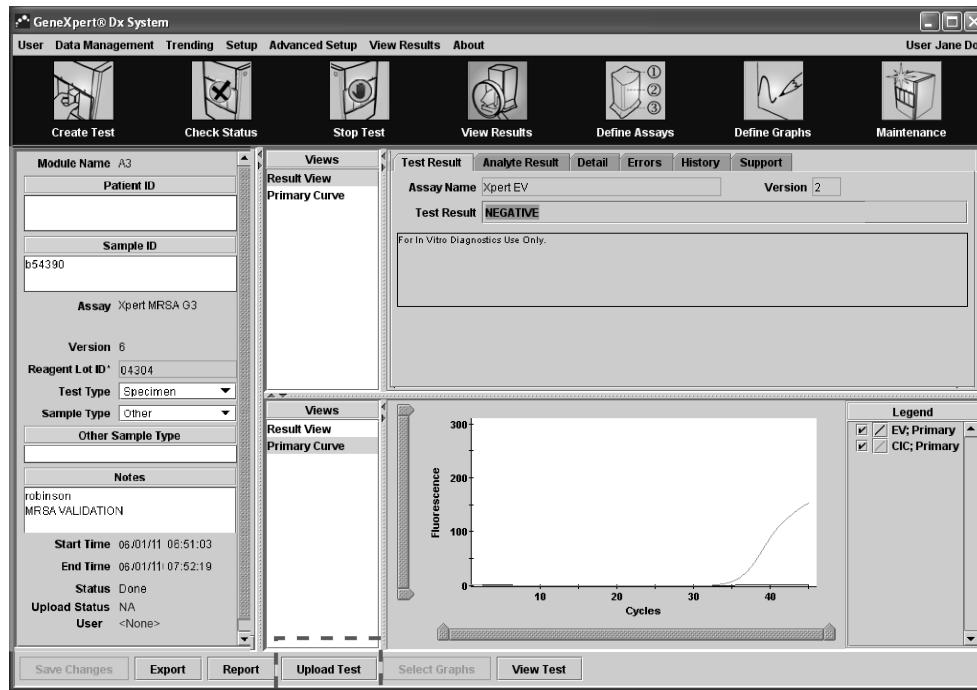


Figure 5-42. Upload test results to the Host

5.15 Managing the Test Results Data

The GeneXpert Dx System includes a database that stores all of the saved test results. You can:

- manage the test result data:
 - Archive tests and then delete archived tests to save database space (Section 5.15.1).
 - Retrieve tests from an archived file (Section 5.15.2).
- perform database management tasks (only during system startup and shutdown):
 - Back up the database (Section 5.16.1).
 - Restore the database (Section 5.16.2).
 - Compact the database (Section 5.16.3).
 - Check the integrity of the database (Section 5.16.4).

The GeneXpert Dx System administrator specifies whether you have the permissions for the data management tasks (Section 2.8). See your GeneXpert Dx System administrator to adjust the permissions to meet your requirements.

5.15.1 Archiving the tests

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

Caution

Some e-mail filters may block files with .gxx extensions. Change extension if required.



To archive the test data:

1. In the GeneXpert Dx System window, on the Data Management menu, click Archive Test. The Select Test(s) To Be Archived dialog box appears (Figure 5-43).



Figure 5-43. Select Test(s) To Be Archived dialog box

2. Select the tests you want to archive. You can select the individual tests one-by-one, or select a large number of tests by clicking one of the following:

Note: You can also hold “Shift” or “Ctrl” to highlight continuous and discontinuous multiple tests in the Archive Tests dialog window.

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

Click Deselect All to clear all of the test selections in the window. Click Deselect Highlighted to clear the tests you highlighted.

To free up space, select the **Delete Archived Tests** check box. The selected tests will be archived and then removed from the database.

3. Click OK. A message appears and asks you to confirm the archive request.
4. Click Proceed. The Save dialog box appears.

5. Locate and select the folder in which you want to store the archive (.gxx) file, type a name for the archive file, and then click **Save**.
6. If you selected the **Delete Archived Tests** option, a confirmation dialog box appears. Click **Yes** to confirm.

5.15.2 Retrieving data from an archive file

Caution



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

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

1. In the GeneXpert Dx System window, on the **Data Management** menu, click **Retrieve Test**. The Open dialog box appears.
2. Locate and select the archive (.gxx) file, and then click **Open**. The Select Test(s) To Be Retrieved From dialog box appears (Figure 5-44). The tests that already exist in the current database appear in red text.

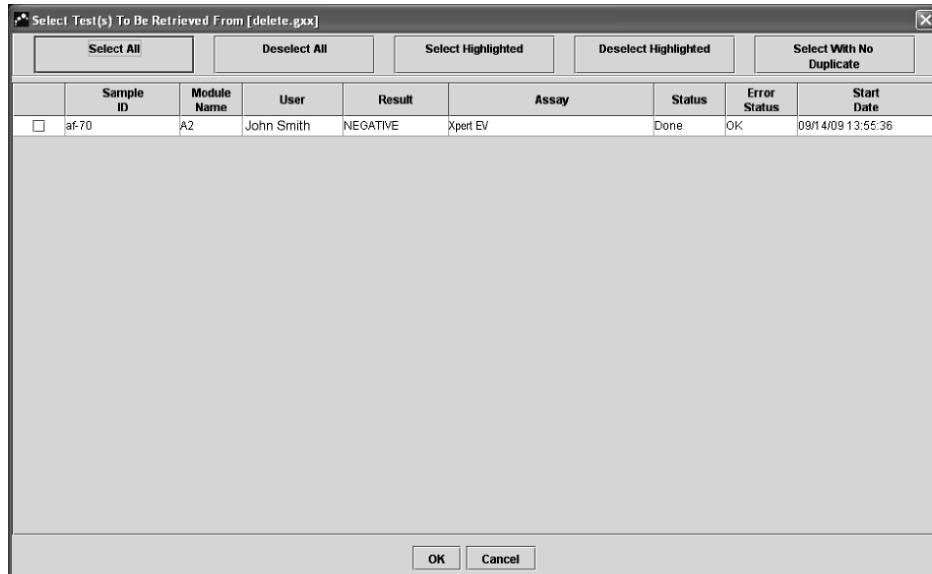


Figure 5-44. Select Test(s) To Be Retrieved dialog box

3. Select the tests you want to retrieve. You can select the individual tests one-by-one, or select multiple tests by clicking one of the following:
 - **Select All**—Selects all of the tests in the table.
 - **Select Highlighted**—Selects the tests you highlighted.
 - **Select With No Duplicate**—Selects only the tests that do not exist in the current database.

Click **Deselect All** to clear all of the selections in the dialog box. Click **Deselect Highlighted** to clear the tests you highlighted.

4. Click **Retrieve Test(s)**. A message appears and asks you to confirm the retrieval.
5. Click **Proceed**. A message appears and confirms that the tests are retrieved.

5.16 Performing the Database Management Tasks

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

- Back up the database (Section 5.16.1).
- Restore the database (Section 5.16.2).
- Compact the database (Section 5.16.3).
- Check the integrity of the database (Section 5.16.4).

The GeneXpert Dx System administrator specifies whether you have the permissions for the data management tasks (Section 2.8). See your GeneXpert Dx System administrator to adjust the permissions to meet your requirements.

After starting up or shutting down the system, the Database Management dialog box appears on top of the GeneXpert Dx System window (Figure 5-45).

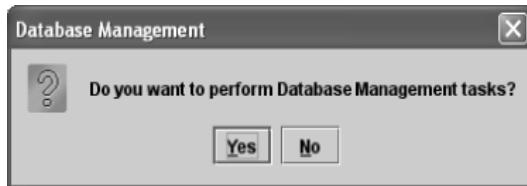


Figure 5-45. Database Management dialog box

1. Click Yes on the Database Management dialog box (Figure 5-45). The Database Management dialog box appears (Figure 5-46).

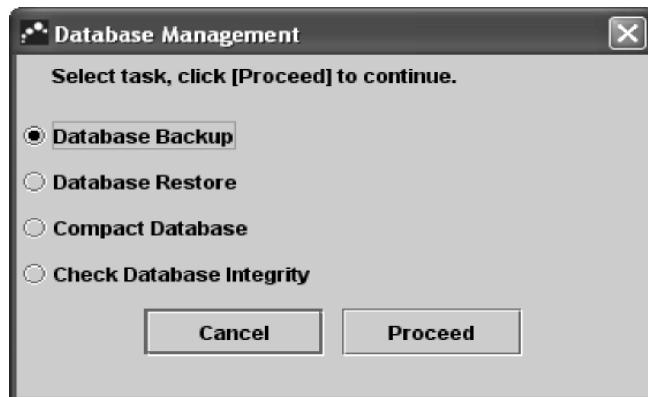


Figure 5-46. Database Management dialog box

5.16.1 Backing up the database

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

To back up the database:

1. Select **Database Backup** on the Database Management dialog box (Figure 5-46).
2. Click **Proceed**.
3. Locate and select the folder in which you want to store the backup file, type a name for the backup file, and then click **Save**. The backup process creates a Zip file in the location you specified. Depending on the amount of data in the database, the backup process might take some time. When the backup process is finished, a process completion message appears.

5.16.2 Restoring the database

Caution



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

You can restore the entire database using the backup database file. Because the restore process overwrites the data in the current database, you should first archive any test data you want to retain (Section 5.15.1), restore the database, and then retrieve the data from the archive file (Section 5.15.2).

To restore the database:

1. Select **Database Restore** on the Database Management dialog box (Figure 5-46).
2. Click **Proceed**. The Database Restore confirmation dialog box appears (Figure 5-47).

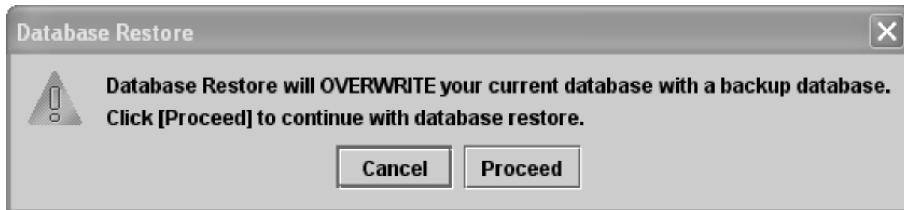


Figure 5-47. Database Restore confirmation dialog box

3. Click **Proceed** in the Database Restore confirmation dialog box to continue, or click **Cancel** to discontinue.
4. Locate and select the backup (.zip) file, and then click **Open**. A dialog box appears asking if you want to back up the current database before restoring. (Recommended.)
5. Click **Proceed** to create a backup or click **Cancel** to skip this step. Depending on the amount of data in the database, the restore process might take some time. When the restoration process is finished, a process completion message appears.
6. Click **OK** to close the GeneXpert Dx System software application.

7. If desired, restart the GeneXpert Dx System software. For details on starting the software, see Section 5.3, “Starting the GeneXpert Dx System.”

5.16.3 Compacting the database

You can compact the database periodically to ensure efficient use of the space in the database and to save hard disk space.

To compact the database:

1. Select **Compact Database** on the Database Management dialog box (Figure 5-46).
2. Click **Proceed**.

The Compact Database confirmation dialog box appears (Figure 5-48).

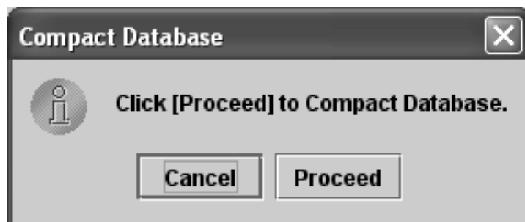


Figure 5-48. Compact Database confirmation dialog box

3. Click **Proceed** to compact the database.

When the database is successfully compacted, the Compact Database complete dialog will appear (Figure 5-49).



Figure 5-49. Compact Database completed dialog box

4. Click **OK**.

Note: In addition to compacting the database, you can also save space by deleting data after archiving. For details on deleting archived tests, see Section 5.15.1.

5.16.4 Checking the integrity of the database

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

1. Select **Check Database Integrity** on the Database Management dialog box (Figure 5-46).
2. Click **Proceed**.

The Check Database Integrity confirmation dialog box appears(Figure 5-50), asking you to confirm the check request.



Figure 5-50. Check Database Integrity confirmation dialog box

3. Click **Proceed** to start the integrity check. If the software finds integrity errors, a message alerts you. Click **Proceed** to repair the database.

When the check database integrity is successfully completed, the Check Database Integrity complete dialog will appear (Figure 5-51).



Figure 5-51. Check Database Integrity completed dialog box

4. Click **OK**.

5.17 Deleting a Test

You are allowed to delete a test after archiving a test (see Section 5.15.1 for details).

5.18 Viewing and Printing Reports

The **Reports** menu (Figure 5-52) provides the following menu options:

- Specimen Report
- Patient Report
- Control Trend Report
- System Log
- Assay Statistics Report
- Installation Qualification

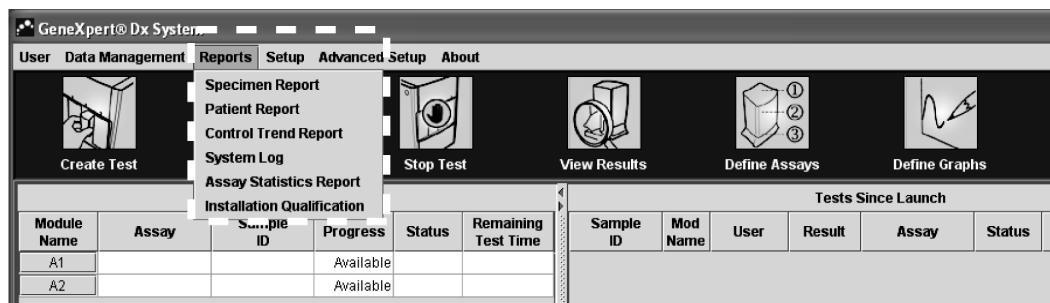


Figure 5-52. GeneXpert Dx System—Reports drop-down menu

5.18.1 Specimen Report

The Specimen Report provides you with an overview of the test results for the selected specimen in the database. This menu item is available to privileged users.

To view the specimen report:

1. In the GeneXpert Dx System window, on the Reports menu (Figure 5-52), click Specimen Report. The Specimen Report dialog box appears (Figure 5-53).

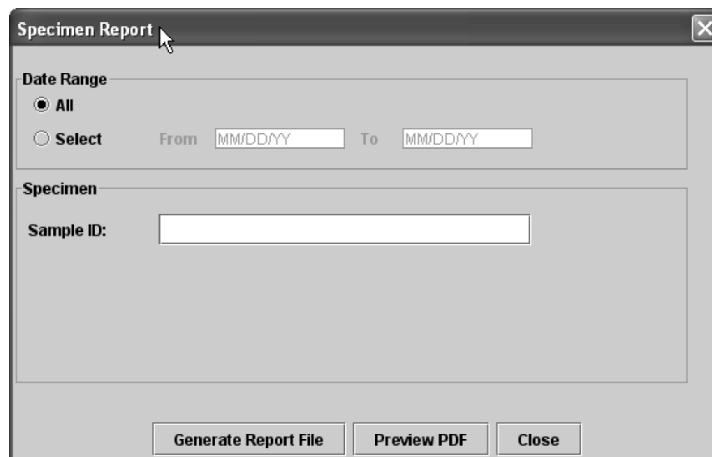


Figure 5-53. Specimen Report dialog box

2. Specify the following criteria to view the specimen report of interest:
 - **Date Range**—Click **All** to view all dates or click **Select** to view report(s) for a specific date range.
 - **Sample ID**—You can enter the exact sample ID, a single-character wildcard ‘?’ combined in exact characters or a multiple-character wildcard ‘%’ with or without exact characters.
3. When you finish selecting the criteria, click one or both of the following buttons:
 - **Generate Report File**—Creates a PDF file and saves it to the location you specify.
 - **Preview PDF**—Creates a PDF file and displays the file in the Adobe Reader window (Figure 5-54). You can save and print the PDF file from the Reader software.

Specimen Report

- Selection Criteria -

Date:	All
Sample ID:	%

Found Sample ID #1 = 01000462 jones

- 1 Test(s) Found -

Patient ID:	
Sample ID:	01000462 jones
Assay:	Xpert MRSA-SA BC G2
Assay Version:	2
Test Result:	MRSA NEGATIVE; SA NEGATIVE
Start Time:	01/11/10 08:28:27
Test Type:	Specimen
User:	GX User
Status:	Done
Notes:	Jones, Pankie M Aer

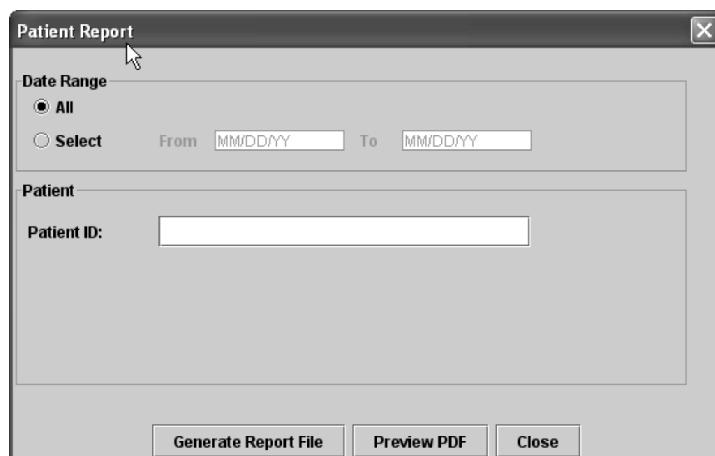
Figure 5-54. Example Specimen Report

5.18.2 Patient Report (if enabled)

The Patient Report provides test results for samples for one patient according to the Patient ID in the database. This menu item is available to privileged users.

To view the patient report:

1. In the GeneXpert Dx System window, on the Reports menu (Figure 5-52), click **Patient Report**. The Patient Report dialog box appears (Figure 5-55).

**Figure 5-55.** Patient Report dialog box

2. Specify the following criteria to view the patient report of interest:
 - **Date Range**—Click **All** to view all reports or click **Select** to view report(s) for a specific date range.
 - **Patient ID** – the user can enter the exact patient ID, a single-character wildcard ‘?’ combined in exact characters or a multiple-character wildcard ‘%’ with or without exact characters.
3. When you finish selecting the criteria, click one or both of the following buttons:
 - **Generate Report File**—Creates a PDF file and saves it to the location you specify.
 - **Preview PDF**—Creates a PDF file and displays the file in the Adobe Reader window (Figure 5-56). You can save and print the PDF file from the Reader software.

GeneXpert PC 03/04/10 12:36:40

Patient Report

- Selection Criteria -

Date:	All
Patient ID:	%

Found Patient ID #1 =

- 1 Test(s) Found -

Patient ID:	23530876
Sample ID:	b54390
Assay:	Xpert MRSA G3
Assay Version:	6
Test Result:	MRSA POSITIVE
Start Time:	12/01/09 06:51:03
Test Type:	Positive Control 1
User:	<None>
Status:	Done
Notes:	robinson MRSA VALIDATION

Figure 5-56. Example Patient Report

5.18.3 Control Trend Report

See Section 7.4 (Control Trend Reports).

5.18.4 System Log

See Section 10.8 (Generating the System Log Report).

5.18.5 Assay Statistics Report

An Assay Statistics Report is a report showing the number of tests performed for each assay over a period of time with monthly breakdown values.

To view the assay statistics report:

1. In the GeneXpert Dx System window, on the **Reports** menu (Figure 5-52), click **Assay Statistics Report**. The Assay Statistics Report dialog box appears (Figure 5-57).

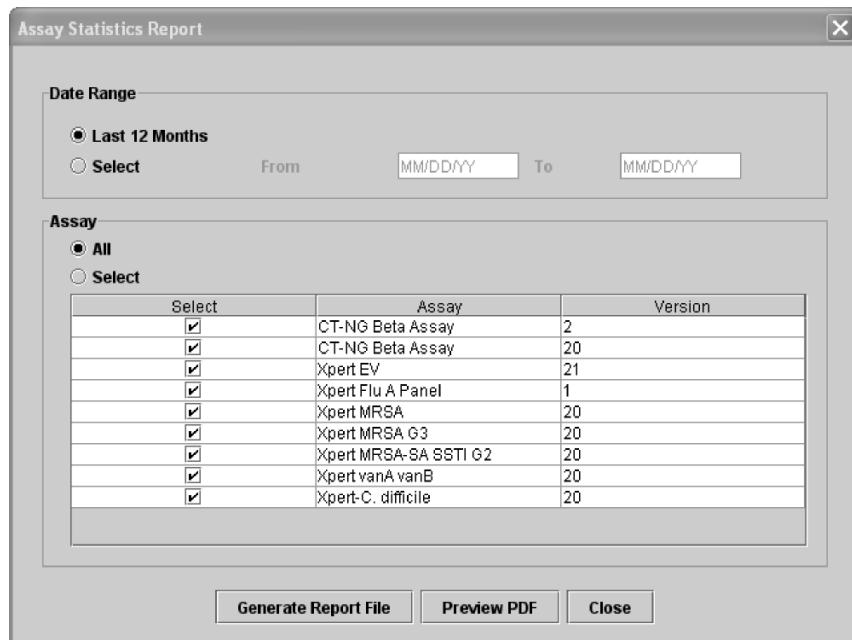


Figure 5-57. Assay Statistics Report dialog box

2. Specify the following criteria to view the assay statistics of interest:
 - **Date Range**—Select Last 12 Months or select for a specific date range.
 - **Assay**—Select **All** to select all the listed assays or **Select** to select a specific assay.
3. When you finish selecting the assay(s), click one or both of the following buttons:
 - **Generate Report File**—Creates a PDF file and saves it to the location you specify.
 - **Preview PDF**—Creates a PDF file and displays the file in the Adobe Reader window (Figure 5-58). You can save and print the PDF file from the Reader software.

Cepheid Tech Support	03/05/10 15:15:34	
Assay Statistics Report		
- Selection Criteria -		
Date Range:	From 03/06/09 To 03/05/10	
<hr/>		
Assay Name	Version	Number of Tests
Xpert EV	21	1
Start Date	End Date	Number of Tests
03/06/09	03/31/09	0
04/01/09	04/30/09	0
05/01/09	05/31/09	0
06/01/09	06/30/09	0
07/01/09	07/31/09	0
08/01/09	08/31/09	0
09/01/09	09/30/09	0
10/01/09	10/31/09	0
11/01/09	11/30/09	1
12/01/09	12/31/09	0
01/01/10	01/31/10	0
02/01/10	02/28/10	0
03/01/10	03/05/10	0

Figure 5-58. Example Assay Statistics Report

5.18.6 Installation Qualification

See Section 2.10 (Verifying Proper Installation and Setup).

Chapter 6 Operating with Host Connectivity

This chapter provides instructions on how to use the GeneXpert Host interface to:

- Enable and configure Host Communication (Section 6.1)
- Configure Assay for order and result upload (Section 6.2)
- Create a test from downloaded test order (Section 6.3)
- Upload a test result (Section 6.4)
- Troubleshoot Host Connectivity (Section 6.5)
- Troubleshoot the LIS Interface (Section 6.6)

6.1 Enabling and Configuring Host Communication

1. In the GeneXpert Dx System window, click **Setup** on the menu bar, then click **System Configuration**. The System Configuration dialog box and the **General** window appears (Figure 6-1).

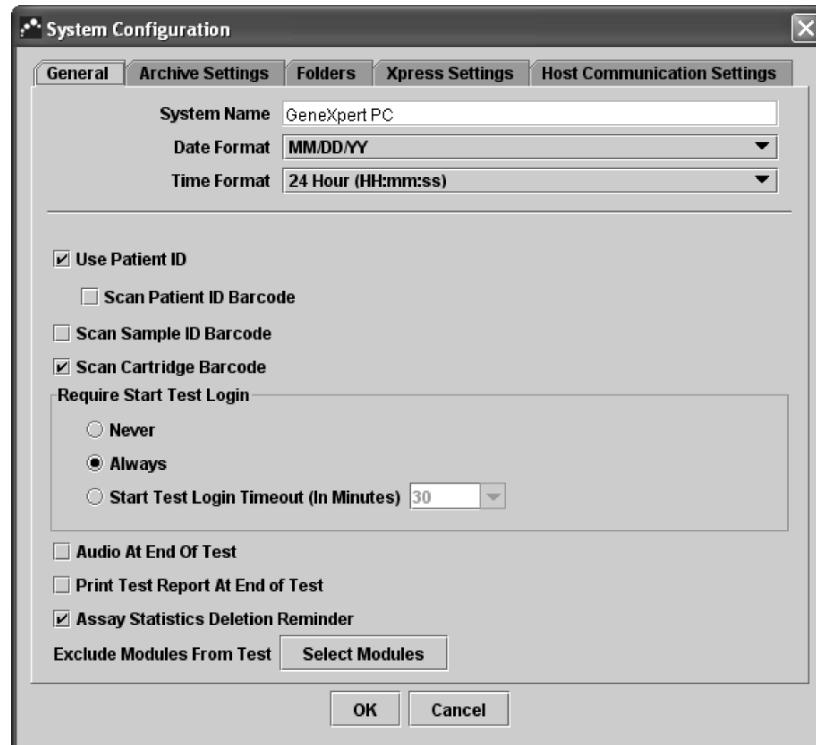


Figure 6-1. System Configuration dialog box (General window)

Important Within the hospital or laboratory network, each GeneXpert system should have a unique system name, which is used in the communication. The LIS Host administrator should control the process for defining System Name.

- Click the **Host Communication Settings** tab. The Host Communication Settings window appears (Figure 6-2).

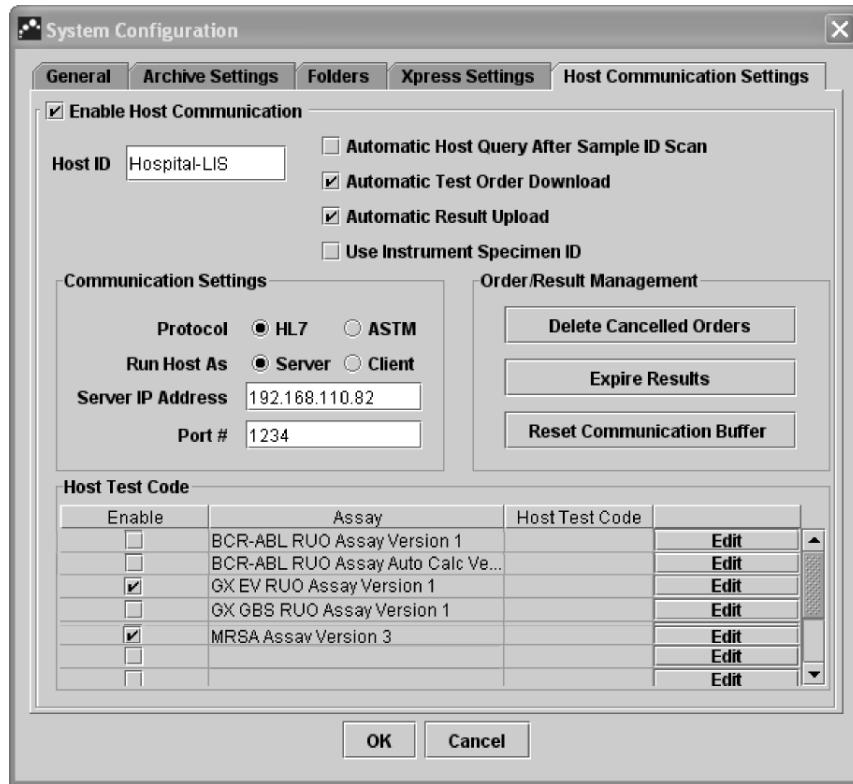


Figure 6-2. Host Communication Settings window

- Provide the settings to configure the communication between the GeneXpert Dx software and a Laboratory Information System (LIS):
 - Enable Host Communication**—Select to enable the GeneXpert Dx software connected to a Host. Clear to disable the Host communication.
 - Host ID**—Type in unique Host name to identify an LIS or Data Management System (DMS) that is connected to this GeneXpert system. The maximum number of characters is 20.
 - Automatic Host Query After Sample ID Scan**—Select to enable the GeneXpert system to query for test orders associated to the scanned or entered Sample ID.
 - Automatic Test Order Download**—Select to enable the GeneXpert system to periodically query all test orders from the Host.

Caution	If the Host is connected to multiple GeneXpert Systems, you may want to:
	<ul style="list-style-type: none"> - Use Automatic Host Query After Sample ID Scan instead of Automatic Test Order Download to minimize duplicate orders to multiple GeneXpert systems. - The Host should download order to a specific GeneXpert System. - If orders are sent to multiple GeneXpert systems, the Host should cancel pending orders when completed result is received. <ul style="list-style-type: none"> - Automatic Result Upload—As soon as the test is completed, the results are uploaded. - Use Instrument Specimen ID—Select to enable the GeneXpert 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. <p>If the facility provides unique sample identification, this setting should be disabled.</p> <ul style="list-style-type: none"> • Communication Settings box—Select or clear the following check boxes: <ul style="list-style-type: none"> - Protocol—Select HL7-compatible or ASTM-compatible protocol. - Run Host As—For socket connection between the two systems. Select to run the Host as a Server or a Client. - Server IP Address— If run Host as Server option is selected, an IP address with 4-part value (N.N.N.N) should be entered. The value should match the IP address of the Host server. N is between 0-255. If run Host as Client option is selected, the IP address of the network card available for Host connectivity is displayed. - Port #— The port number should be between 1024 to 65535.
Important	The network port that is dedicated for the GeneXpert instrument should not be used for the Host connection. The second NIC available on each GeneXpert computer should be used to connect the GeneXpert system to the Host.
Caution	<ul style="list-style-type: none"> • Order/Result Management—Click the appropriate buttons: <ul style="list-style-type: none"> - Delete Cancelled Orders—Click to delete cancelled orders. This is useful to remove redundant orders during Host communication testing. - Expire Results—Click to expire results pending upload for tests that should no longer upload to the Host. <p>Do not use Reset Communication Buffer (discussed below) during normal operation; otherwise, you will have to re-download order and re-upload results.</p> <ul style="list-style-type: none"> - Reset Communication Buffer—To clear the data between the GeneXpert system and the Host. This is useful to remove data during Host communication testing.

- **Host Test Code** table—This look up table allows the Host administrator to enter the test code known in the Host to be translated into the GeneXpert system for test order processing and result reporting.
 - **Enable**—Indicates if the assay has been set up for test order download and result reporting.
 - **Assay**—Assay name available for Host connectivity.
 - **Host Test Code**—the test code which the Host used for download of test order and upload of test result.

Caution  **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.**

- **Edit**—Click **Edit** button to change the setting and enable assay. The Edit Test dialog will appear.

6.2 Configuring Assay for Order and Result Upload

Caution  **In order to perform the required assay, the same test code should be entered both in the Host and the GeneXpert system.**

Caution  **Do not change test orders until all test results have been uploaded.**

6.2.1 To configure a single-result assay for order and result upload

1. In the **Host Test Code** table section of the Host Communication Settings window (Figure 6-2), click the desired appropriate **Edit** button to change the setting. The Define Test Code dialog box appears (Figure 6-3).

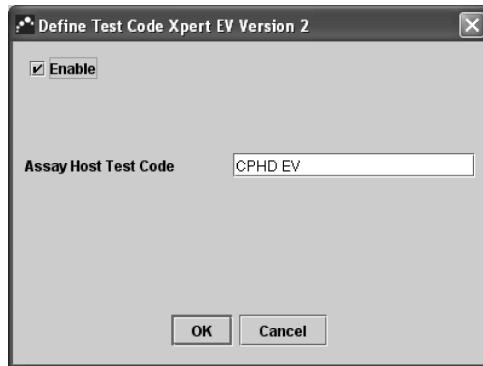


Figure 6-3. Define Test Code dialog box for a single-result assay

2. Click the **Enable** checkbox to allow the Host to download test orders and GeneXpert system to upload results to the Host, using the defined assay test code.

3. In the **Assay Host Test Code** field of the Define Test Code dialog box, type in the same test code that was entered in the Host system (the test code entered for the GeneXpert Dx System must be the same as the test code entered for Host system). You can type in 1 to 15 characters.
4. Click **OK** to save the setting for this assay. The software will check for uniqueness of the test code before saving.

Note: Cepheid recommends that you use the same test code for the new version of the same assay. However, if you want to change the test code of the current assay, make the change before importing the next version.

6.2.2 To configure a multiple-result assay for order and result upload

The multiple-result assay provides results for multiple organism and genes.

1. In the **Host Test Code** table section of the Host Communication Settings window (Figure 6-2), click the desired appropriate **Edit** button to change the setting. The Define Test Code dialog box appears (Figure 6-3).
 2. Click the **Enable** checkbox to allow the Host to download test orders and the GeneXpert system to upload results to the Host, using the defined assay test code.
 3. In the **Assay Host Test Code** field, type in the same test code that was entered in the Host system (the test code entered for the GeneXpert Dx System must be the same as the test code entered for Host system). You can type in 1 to 15 characters.
- The result names reported by the assay are listed in the **Result Name** field (Figure 6-4).
4. Type in the result test code in the **Result Test Code** field (Figure 6-4) corresponding to each result name that can be reported by this assay.

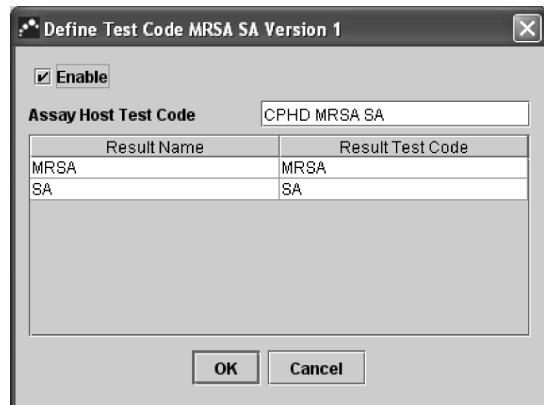


Figure 6-4. Define Test Code dialog box for a multi-result assay

5. Click **OK** to save the changes and close the window.

6.3 Creating a Test with Host Connectivity

When the Host Connectivity is enabled, test orders can be automatically downloaded from the Host by:

- The GeneXpert system periodically requesting new orders
- Manual queries by GeneXpert user of new orders from the Create Test dialog box
- Scanning or entering the Sample ID to perform Host query for orders for a specific Sample ID

The workflow in your laboratory will determine how you will create a test.

Additional areas are available in Create Test dialog (Figure 6-5).

The screenshot shows the 'Create Test' dialog box. At the top, there is a table titled 'Host Test Order Table' with four columns: 'Sample ID', 'Assay', 'STAT', and 'Order Time'. The table contains four rows of data for 'Patient 1' with different assay details and order times. To the right of the table are four 'Delete' buttons. Below the table is a large empty text area with scroll bars. To the right of this area is a 'Manual Query' button. The main body of the dialog contains several input fields: 'Sample ID' (text box), 'Name' (text box) and 'Version' (text box), 'Select Assay' (dropdown menu showing '<None>'), 'Select Module' (dropdown menu), 'Reagent Lot ID' (text box), 'Expiration Date' (text box with placeholder 'YYYY/MM/DD'), 'Cartridge S/N' (text box), 'Test Type' (dropdown menu showing 'Specimen'), 'Sample Type' (dropdown menu), 'Other Sample Type' (text box), and a 'Notes' text area. At the bottom are three buttons: 'Start Test', 'Scan Cartridge Barcode', and 'Cancel'.

Figure 6-5. Create Test window with Host Test Order Table

- **Host Test Order Table** - New orders are shown in the table which can be sorted by clicking the header. The table contains:
 - **Sample ID**—Sample ID(s) for each test order.
 - **Assay**—Assay name and version number for each test order.
 - **STAT**—Indicates whether it is STAT priority or Normal priority.
 - **Order Time**—Time downloaded by the Host or created by the GX as time received.
 - **Delete** —Allows an order to be cancelled.

- **Host Query Status**—Displays the current status for query for new orders.
- **Manual Query** button—Allows manual query of the Host for any available new orders.

Note: To accept order from the Host, the test code for the assay must be setup by the Host administrator. See Section 6.2 for details.

6.3.1 To create a test by selecting from a list of test orders downloaded by the Host automatically

1. In the **Host Communication Settings** tab, click on the **Automatic Test Order Download** checkbox to select and enable this function (Figure 6-6).

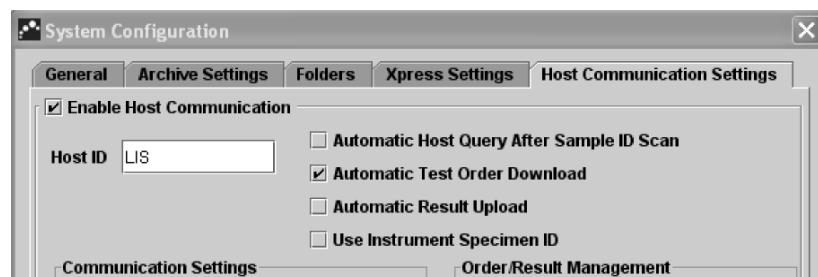


Figure 6-6. Automatic Test Order Download selected

2. The GeneXpert Dx System periodically queries all test orders from the Host.

The **Create Test** button is shown with a Plus (+) sign, indicating new orders to be filled (Figure 6-7).



Figure 6-7. Menu bar indicating plus sign on Create Test button

3. Select the **Scan Sample ID Barcode** in the **General** window.
4. Select the **Scan Cartridge Barcode** in the **General** window.
5. Click **OK**.
6. Click **Create Test**. The Scan Sample ID Barcode dialog box appears (see Figure 5-14 in Section 5.5).
7. Scan or enter the optional Patient ID.
8. Scan the sample barcode on the specimen container (see Section 5.5).
9. New orders for this optional Patient ID and Sample ID are shown in the **Host Test Order Table** section of the Create Test window, which can be sorted by clicking the table header.
10. Select an order from the table. This will select the assay according to the test order.

11. The Scan Cartridge Barcode dialog will automatically display to prompt you 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 and transferred.
12. The order for this Patient ID and Sample ID will be removed from the list of new orders.
13. Insert the cartridge with the specimen and reagents according to the assay-specific package insert. See Section 5.6.
14. Start the test, load the cartridge, and close the module door by performing steps given in Section 5.7.

Note: You cannot change the Patient ID, Sample ID, or the assay if it is selected from an Host downloaded test order.

Note: If only one order matches the given Patient ID and Sample ID, this order will be automatically selected.

6.3.2 To create 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 clicking **Manual Query** button. After orders are downloaded from the Host, proceed as instructed in Section 6.3.1.

6.3.3 To create a test by querying the Host with Sample ID

1. In the **Host Communication Settings** window, click on the **Automatic Host Query After Sample ID Scan** checkbox to select and enable this function (Figure 6-8).

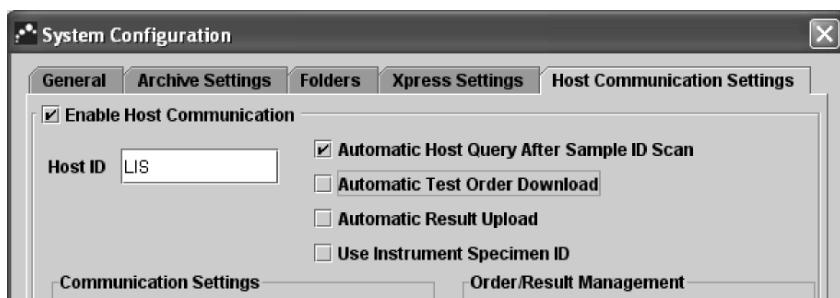


Figure 6-8. Host Query selected

2. Select the **Scan Sample ID Barcode** in the **General** window.
3. Select the **Scan Cartridge Barcode** in the **General** window.
4. Click **Create Test**. The Scan Sample ID Barcode dialog box appears (see Figure 5-14 in Section 5.5).
5. Scan the sample barcode on the specimen container (see Section 5.5).
6. Test orders for this Sample ID are downloaded from the Host and are displayed in the **Host Test Order Table** which can be sorted by clicking the header.

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

7. 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 selected.

8. The Scan Cartridge Barcode dialog will automatically display and prompt you to scan the barcode on the cartridge. This confirms that the correct assay will be run. The reagent lot ID, expiration date, and cartridge serial number are processed and transferred.
9. Insert the cartridge with the specimen and reagents according to the assay-specific package insert (see Section 5.6).
10. Start the test, load the cartridge, and close the module door by performing steps given in Section 5.7.

6.3.4 To Abort Query

During the Manual Query described in Section 6.3.2 or Host Query described in Section 6.3.3, the **Manual Query** button becomes the **Abort Query** button (Figure 6-9). To start a test or close the dialog box, wait until the query is completed, or click **Abort Query** to cancel the operation.

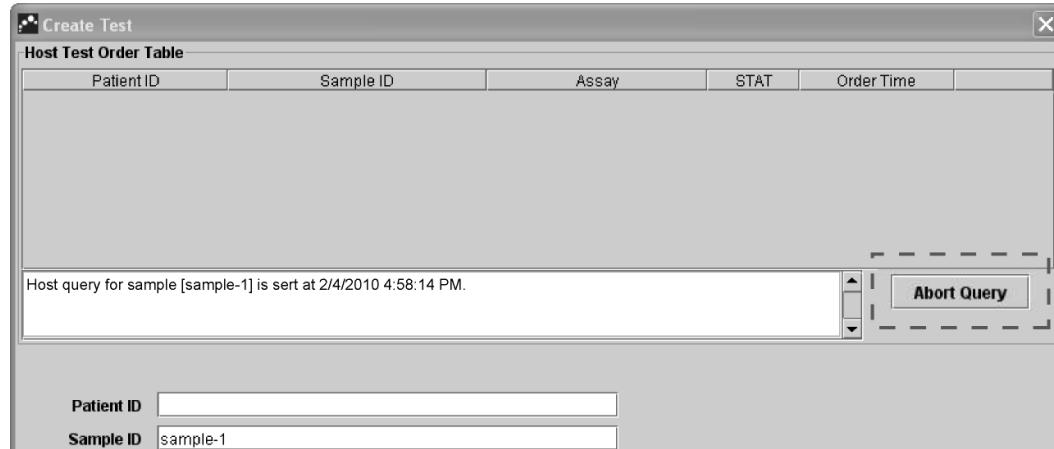


Figure 6-9. Create Test window showing the Abort Query button

6.3.5 To delete an Host downloaded test order

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

1. Select the order from the **Host Test Order Table**.
2. Click **Delete** button on the same row (Figure 6-10).

Sample ID	Assay	STAT	Order Time	
Patient 1	Xpert MRSA-SA SSTI G2 Version 20	Normal	07/30/09 11:00:14	Delete
Patient 1	Xpert MRSA-SA BC G2 Version 20	Normal	07/30/09 11:00:15	Delete
Patient 1	Xpert vanA vanB Version 20	Normal	07/30/09 11:00:17	Delete
Patient 1	Xpert GBS	Normal	02/09/10 13:30:14	Delete

Figure 6-10. Deleting an Host download test order

3. A confirmation dialog is shown. Click to confirm the deletion.
 - The order will be removed from the table.
 - The Host will be informed.

6.4 Uploading a Test Result to the Host

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

6.4.1 To automatically upload the test result to the Host

1. In the **Host Communication Settings** window, click the **Automatic Result Upload** checkbox so the result will be uploaded as soon as the test is completed (Figure 6-11).

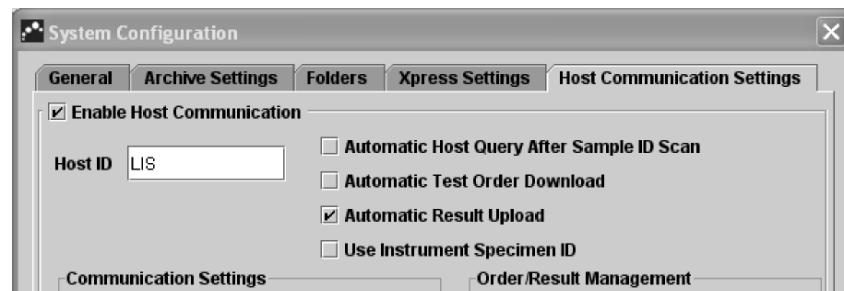


Figure 6-11. Automatic Result Upload

2. Click **OK**. Upload status is shown in the Test Information area of the View Result window.

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 (Figure 6-12).

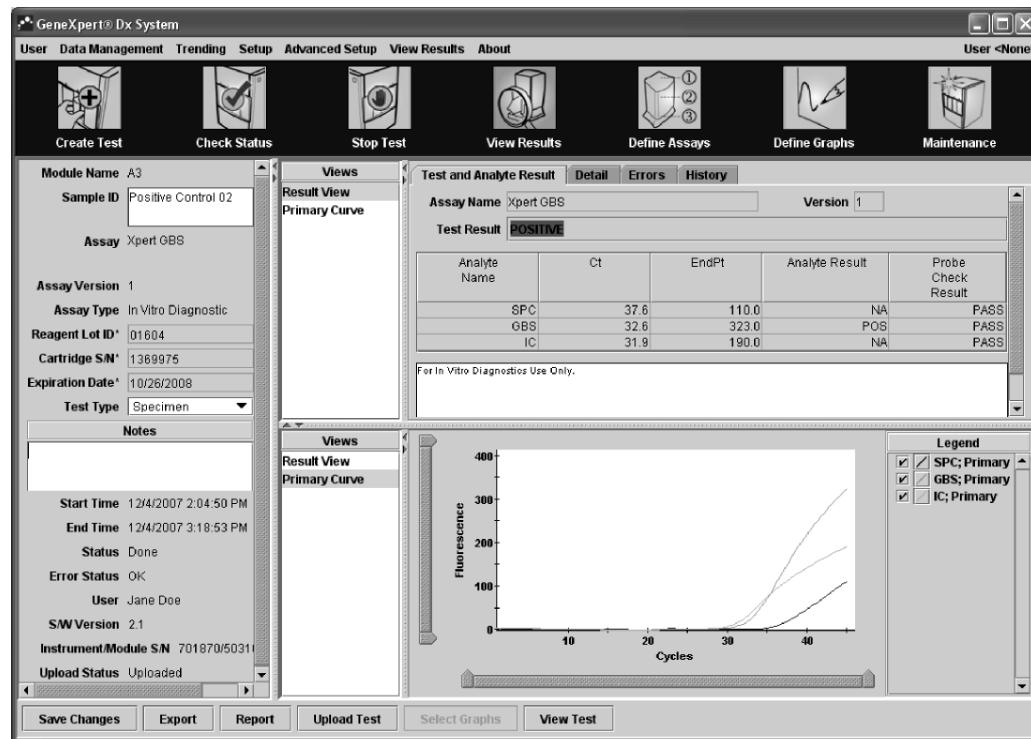


Figure 6-12. Host Upload shown in the Test Information area of the View Result window

6.4.2 To manually upload a test result to the Host

1. In the **Host Communication Settings** window, make sure **Automatic Result Upload** is deselected or disabled (Figure 6-11).
2. Click **Upload Test** in the View Results window (Figure 6-12). The Select Test(s) To Be Uploaded To Host window appears, displaying completed tests (Figure 6-13).



Figure 6-13. Select Test(s) To Be Uploaded To Host window

The possible Host uploaded statuses are:

- Upload-pending – this result has not been uploaded. If you exit the software with Upload-pending status, the software will remind you.
- Uploading – this result is being uploaded.
- Re-Uploading – this result has been uploaded previously and currently being up uploaded.
- Uploaded – this result has been received by the Host.
- Review – this is an external control and it should be reviewed before manually uploading.
- Expired – test has not been uploaded and will not be reminded by the system when exiting the software.

Note: If you attempt to exit the software with results in the upload pending, uploading or re-uploading status, the software will remind you.

3. Select the test you want to upload. You can select the individual tests one-by-one, or select a large number of tests (up to 100 tests) by clicking one of the following:
 - **Select All** – Selects all of the tests in the table.
 - **Select Highlighted** – Selects the tests you highlighted.
 - **Select All Pending** – Selects only the tests that have not been uploaded before.
4. Click **Deselect All** to clear all of the test selections in the window. Click **Deselect Highlighted** to clear the tests you highlighted.
5. Click **Upload**. A message appears and asks you to confirm the upload request.

6. Click **Close**.

6.4.3 To upload an external control result to the Host

Regardless of the setting for **Automatic Result Upload**, external control result is manually uploaded. See Section 6.4.2 (To manually upload a test result to the Host).

6.5 Troubleshooting Host Connectivity

6.5.1 Host connectivity indicator

When the software starts, Host connectivity is automatically established if it is enabled. The **Check Status** button is shown as normal (Figure 6-14).



Figure 6-14. Check Status button normal (check mark symbol)

If during the operation the Host connectivity is interrupted, the **Check Status** button will change to an “X” sign and a message is displayed in the Messages area of the Check Status window (Figure 6-15). Contact your Host administrator to re-establish the connection.

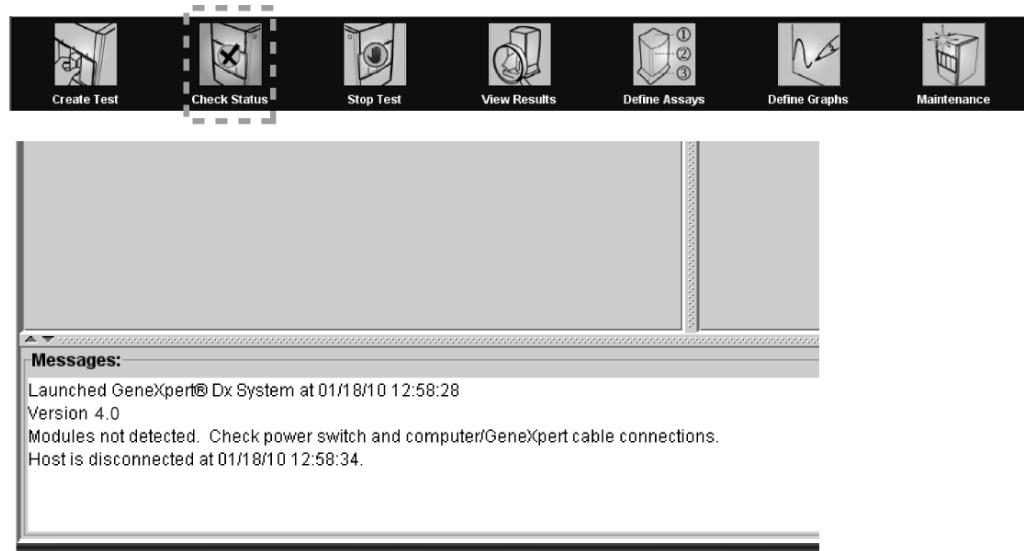


Figure 6-15. Check Status button symbol changed to X and Messages displayed

6.5.2 Host communication buffer

If the communication between the GeneXpert system and the Host is slow, the data may be filling up in the communication buffer. When the communication buffer is at and above 75%, the system will stop uploading result and provide warning to the user in the Check Status screen.

When you click the **Upload Result** button in the View Results screen before the Host connection is established or when communication buffer is filled up, the Upload Result To Host dialog box appears (Figure 6-16).

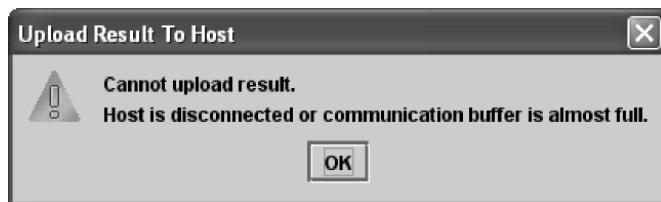


Figure 6-16. Upload Result To Host dialog box

6.6 Troubleshooting the LIS Interface

6.6.1 System configuration problems

Table 6-1 lists the possible system configuration problems you might encounter. To contact Cepheid Technical Support, see the Assistance section in the Preface for the contact information.

Table 6-1. System configuration problems

Problem	Cause	Solution
Cannot Edit Test Code for old versions of an assay, if LIS Admin updates test code it will only apply to new version of the assay.	Upgrade of assay to new version.	Change the test code prior to upgrade of assay.
Upload of test results with duplicate System Name cannot tell which instrument results came from.	Duplicate System Name.	<ol style="list-style-type: none"> System Name must be Unique. LIS Interface to check for duplicate instrument system names. LIS Admin to control process for defining System name.
User Error in Selecting the Assay when defining Test Codes.	User Error in Selecting the Assay.	LIS Admin to configure correct test code; for example, CPT code for test or Abbreviate Assay Name.

6.6.2 Order management problems

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

Table 6-2. Order management problems

Problem	Cause	Solution
Multiple system receive same test order – both assign ISID .	Test order sent to multiple GX systems in parallel.	<ol style="list-style-type: none"> 1. Operator to cancel test order. 2. LIS Admin to switch to Host Query configuration instead of Query All. 3. Prevent the LIS from downloading to multiple systems.
Test Orders Downloaded to Incorrect GX System.	Duplicate System Name.	<ol style="list-style-type: none"> 1. System name must be Unique. 2. LIS Interface to check for duplicate instrument system name. 3. LIS Admin to control process for defining System name.
Incorrect Assay is run.	User Error in entering the Host Test Code.	<ol style="list-style-type: none"> 1. Verify that the test code in test order table is active in GX configuration. 2. LIS Admin to configure correct test codes.
Moderate complexity user runs a high complexity assay.	Query all gives GX and SC test orders.	If your facility has both GeneXpert and Smart Cyclers Interface to LIS, then use unique test code (do not repeat test codes across different systems).

6.6.3 Result management problems

Table 6-3 lists the possible result management problems you might encounter. To contact Cepheid Technical Support, see the Assistance section in the Preface for the contact information.

Table 6-3. Result management problems

Problem	Cause	Solution
LIS asks for all results on specific specimen ID.	Request for upload only includes specimen ID.	LIS Interface to setup proper handling of duplicate result upload; for example, take the latest result.
Upload duplicate test results.	User uploads test results that have previously been uploaded.	LIS Admin to administer proper handling of duplicate result upload.
Re-upload confirmation pass or fail.	Re-upload fails.	Interface to address failed attempt to re-upload result.

Chapter 7 Calibration and Quality Control

This chapter describes the following:

- Calibration (Section 7.1)
- Quality Control (Section 7.2)
- External Quality Control (Section 7.3)
- Control Trend Reports (Section 7.4)

7.1 Calibration

You do not need to calibrate the GeneXpert Dx instrument. Cepheid performs all of the necessary calibrations before you receive the system. However, Cepheid recommends that the instrument be recalibrated after 1 year of use, based on the initial installation date (or based on the previous calibration for subsequent years) or at 2,000 tests per instrument module, whichever comes first. See Section 10.5 to determine the date or number of tests since last calibration. To schedule a calibration, contact Cepheid Service Support. See the Assistance section in the preface for the contact information.

7.2 Quality Control

Quality control is an important part of *in vitro* diagnostic testing because it ensures you are performing the tests correctly and that your GeneXpert Dx System is working properly. The GeneXpert Dx System automatically performs internal quality control for each sample. During each test, the system uses one or more of the following controls:

- **Sample-processing control (SPC)**—Ensures a sample was correctly processed. The sample-processing control is included in the cartridge and is processed with the sample and the DNA is detected by a PCR assay.
- **Internal control (IC)**—Verifies the performance of the PCR reagents and prevents a false negative result. The internal control PCR assay assesses if there is any inhibition, possibly by components, in the test sample. The internal control is provided in the cartridge and should be positive in a negative sample.
- **Endogenous control (EC)**—Normalizes targets and ensures sufficient sample is used in the test. Because of its low variability, the endogenous control can also be used to indicate sample-inhibitor contamination. The endogenous control is taken from the specimen sample.

In addition to the controls, the GeneXpert Dx instrument performs a probe check during the first stage of the test. A probe check verifies the presence and the integrity of the labeled probes. A probe-check status of Pass indicates that the probe check results meet the acceptance criteria.

7.3 External Quality Control

External controls may be used in accordance with local, state, or federal accrediting organization as applicable. External controls can be trended if you assign an external control test type when you create the test. For additional information, see the quality label or package insert for the specific assay.

7.4 Control Trend Reports

You can use the Control Trend reports to verify the quality of the system or the reagents. For example, you can generate a negative-control trend report to check for cross-contamination. You can also generate other external-control trend reports to check for reagent degradation.

To view the control trends, in the GeneXpert Dx System window on the Reports menu, click **Control Trend Report**. The Control Trend Report dialog box appears (Figure 7-1). Specify the following criteria to view the trends of interest:

- **Date Range**—Select **All** to include all of the tests or filter the tests by specifying a range of dates. Control trending is not available for % Ratio quantitative assays.
- **Assays**—Select an assay in the list to filter by assay definition.
- **Reagent Lot Number**—Select a lot number to filter by the reagent lot number.
- **Test Types**—Select the external-control trend types to be trended.
- **Select Analyte button**—Select the analytes.
- **Data Type**—Select the **Cycle Threshold** and **End Point** data to be trended.

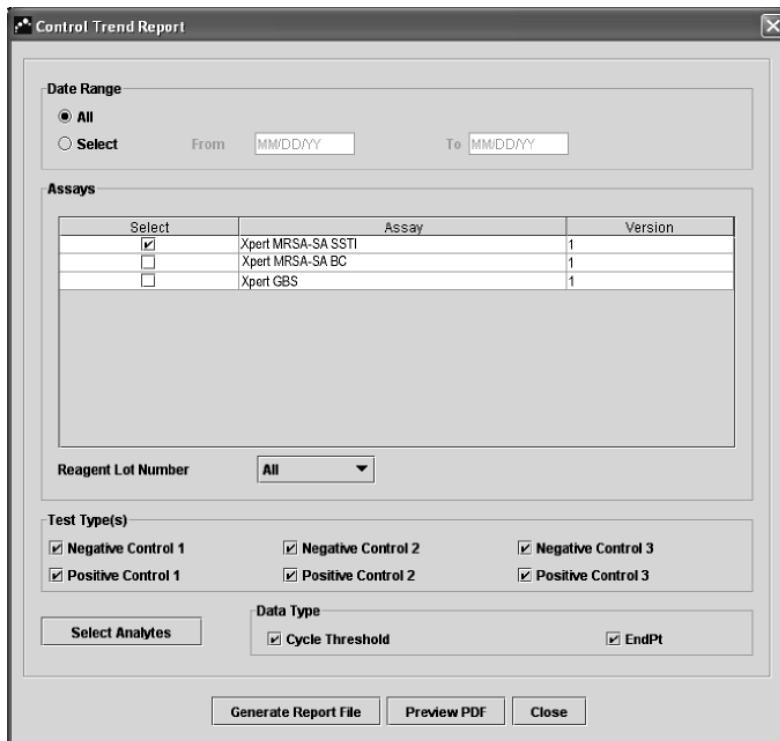


Figure 7-1. Control Trend Report dialog box.

When you finish selecting the trend criteria, click one or both of the following buttons:

- **Generate Report file**—Creates a PDF file and saves it to the location you specify.
- **Preview PDF**—Creates a PDF file and displays the file in the Adobe Reader window (Figure 7-2). You can save and print the PDF file from the Reader software.

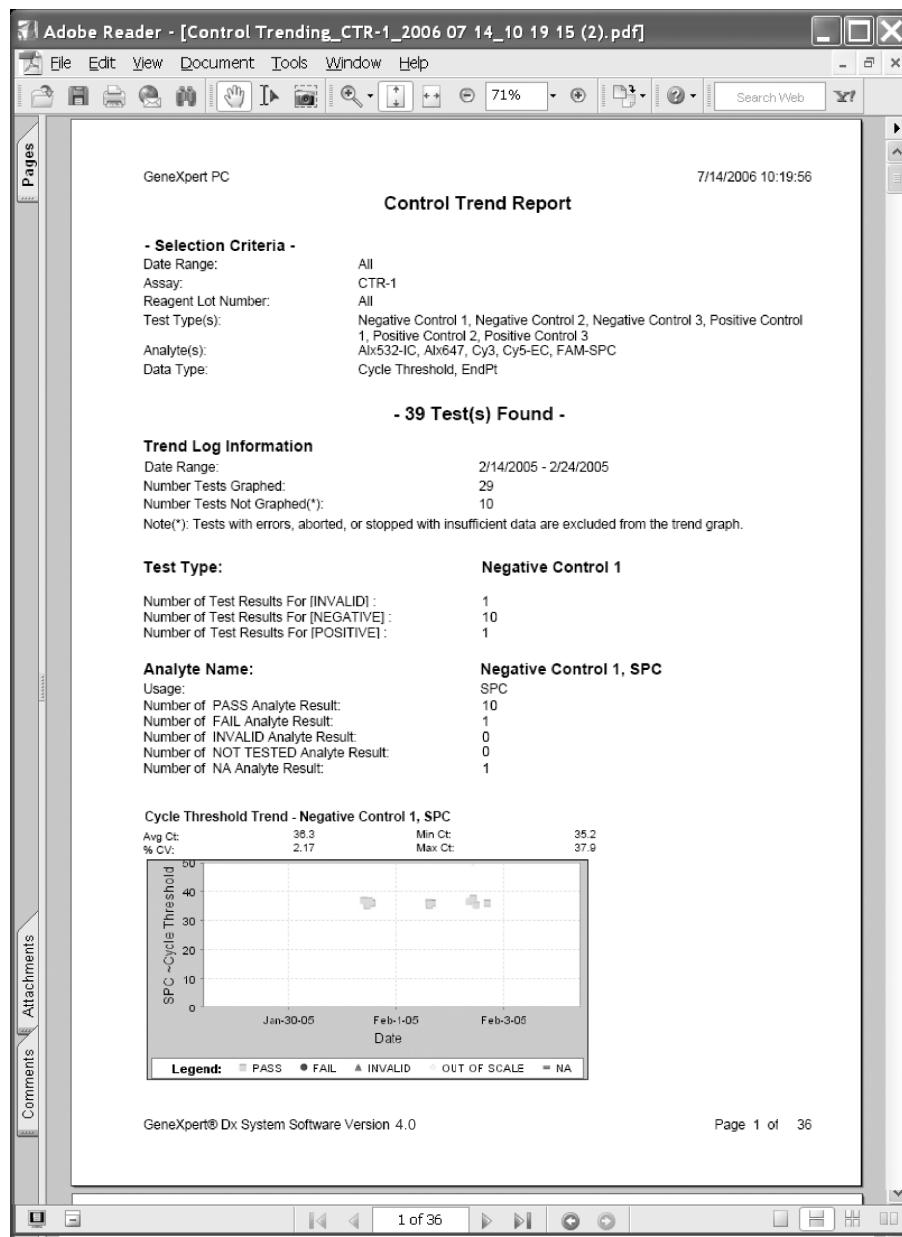


Figure 7-2. An example Control Trend Report in the Adobe Reader window.

Note: The Control Trend Report will show Ct=0 as “out of scale”.

Chapter 8 Precautions and Limitations

You should be aware of the following system precautions and limitations to ensure proper operation and results:

- Laboratory (Section 8.1)
- Instrument and Software (Section 8.2)
- Cartridge (Section 8.3)
- Assay (Section 8.4)

8.1 Laboratory

Before you install the GeneXpert Dx System, make sure your laboratory meets the environmental requirements specified in Chapter 4.

8.2 Instrument and Software

Be sure to do the following:

- Place the GeneXpert Dx instrument in a sheltered environment because it is designed for indoor use only.
- Provide at least 5 cm (2 in) of clearance on each side of the instrument to ensure adequate ventilation.
- Do not place the GeneXpert instrument close to the vents of other instruments or air handling units.
- Connect the GeneXpert Dx System to a surge protector and a properly grounded AC circuit. See Chapter 4 for the electrical requirements.
- Use the GeneXpert Dx System for *in vitro* diagnostic applications only.

While a test is in progress:

- Do not move the instrument.
- Do not run other software.
- Do not change the date and time, while a test is in progress.

8.3 Cartridge

The GeneXpert cartridges are designed for single use only. To prevent cross-contamination and biologically hazardous situations, use each cartridge only once.

8.4 Assay

For each test, be sure to follow the instructions in the assay-specific package insert, which specifies the test requirements.

Chapter 9 Safety Hazards

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

- General Safety Precautions (Section 9.1)
- Moving the Instrument (Section 9.2)
- Safety Labels on the Instrument (Section 9.3)
- Electrical Safety (Section 9.4)
- Chemical Safety (Section 9.5)
- Biological-Hazard Safety (Section 9.6)
- Environmental Data (Section 9.7)

9.1 General Safety Precautions

Before you start to use the GeneXpert Dx System, make sure you read this operator manual entirely and are familiar with the safety information. Using controls, making adjustments, or performing procedures other than those specified in this manual can result in exposure to hazards that can cause injury to personnel or damage to the system.

Protection provided by the equipment may be impaired if the equipment is used with accessories not provided or recommended by the manufacturer, or used in a manner not specified by the manufacturer. Do not use the equipment in hazardous atmospheres or with hazardous materials for which the equipment is not designed.

9.2 Moving the Instrument

Because of the GeneXpert Dx instrument's weight (see Weight in Section 4.2), do not attempt to lift the instrument without proper safety training and assistance.

Warning



Lifting or moving the instrument without proper training and assistance can cause personal injury, damage the instrument, and void your warranty.

9.3 Safety Labels on the Instrument

Table 9-1 lists the electrical labels that you might find on the GeneXpert Dx instrument.

Table 9-1. Electrical safety labels on the instrument.

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

Table 9-2 lists other safety labels that you might find on the GeneXpert Dx instrument.

Table 9-2. Other safety labels on the instrument.

Label	Description
!	Indicates that you should consult the operator manual for further information and to proceed with appropriate caution.
!	Indicates a potential biological hazard risk. Biological samples such as tissues, body fluids, and blood of humans and other animals have the potential to transmit infectious diseases. Follow your local, state/provincial, and national safety regulations for handling and disposing of the samples.

9.4 Electrical Safety

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



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

9.5 Chemical Safety

- Follow standard laboratory safety procedures for working with chemicals.
- Consult your institution's environmental waste personnel on proper disposal of used cartridges, unused reagents, and disposal of instruments. This material may exhibit characteristics of federal EPA Resource Conservation and Recovery Act (RCRA) hazardous waste requiring specific disposal requirements. Check state and local regulations as they may differ from federal disposal regulations. Institutions outside the USA should check their country hazardous waste disposal requirements
- Material Safety Data Sheets (MSDS) 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.

9.6 Biological-Hazard Safety

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 universal precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention and the Clinical Laboratory Standards Institute (formerly National Committee for Clinical Laboratory Standards).

9.7 Environmental Data

- Recyclability of GeneXpert System: the WEEE mark is affixed to Cepheid electronic products.
- Recyclability of packaging materials: many of the shipping packaging components can be recycled.
- Additional information on the above, including EU and country directives concerning packaging, energy consumption, RoHS, REACH, Prop. 65, etc. can be found on the Cepheid website.

Chapter 10 Service and Maintenance

This chapter describes the basic maintenance procedures for the GeneXpert Dx instrument. The topics in this chapter are as follows:

- Maintenance Tasks (Section 10.1)
- Disinfecting the Instrument Surfaces (Section 10.2)
- Disinfecting the Cartridge Bay (Section 10.3)
- Disinfecting the Plunger Rod (Section 10.4)
- Calibrating the Instrument (Section 10.5)
- Using Module Reporters (Section 10.6)
- Performing a Manual Self-Test (Section 10.7)
- Generating the System Log Report (Section 10.8)
- Replacing Instrument Parts (Section 10.9)
- Repairing the Instrument (Section 10.10)

10.1 Maintenance Tasks

Although the system is designed to prevent cross-contamination and ensure accurate results, you should check and clean the instrument periodically as a precautionary measure. Table 10-1 lists the basic maintenance tasks you can perform.

Table 10-1. Maintenance tasks and frequency.

Task	Frequency	Section
Disinfect the instrument surfaces.	Monthly	Section 10.2
Disinfect the cartridge bay interior.	Monthly	Section 10.3
Disinfect the syringe plunger rod.	Monthly	Section 10.4
Calibrate the instrument.	Annually, 2000 tests/module, or as indicated by the Xpert Check software	Section 10.5
Check module reporter calibration.	When requested by Cepheid Technical Support	Section 10.6
Perform a self-test manually.	As necessary	Section 10.7

10.2 Disinfecting the Instrument Surfaces

You should disinfect the instrument surfaces monthly or more frequently if necessary. The materials you need for the procedure are as follows:

- 10% bleach (prepared within 1 week)
- 70% alcohol
- Paper towels
- Latex gloves
- Eye protection

Warning



Make sure you wear latex gloves and eye protection for the cleaning procedure. Wearing gloves and eye protection prevents you from being exposed to chemical and biologically hazardous samples.

To clean the instrument surfaces:

Warning



Be careful where you use or spray cleaning solution on the instrument. Do not allow any cleaning solution to spill near AC power components.

1. Dampen a paper towel with the 10% bleach solution.
2. Wipe the instrument surfaces thoroughly with the paper towel.
3. Dispose of the used paper towel according to your standard laboratory procedure.
4. Wait 10 minutes.
5. Dampen a paper towel with the 70% alcohol solution.
6. Wipe the instrument surfaces with the paper towel.
7. Dispose of the used paper towel according to your standard laboratory procedure.
8. Repeat steps 5 through 7.

10.3 Disinfecting the Cartridge Bay

You should disinfect the cartridge bay monthly or more frequently if necessary. The materials you need for the procedure are as follows:

- 10% bleach (prepared within 1 week)
- 70% alcohol
- Cotton or Dacron® swabs
- Latex gloves
- Eye protection

Warning



Make sure you wear latex gloves and eye protection for the cleaning procedure. Wearing the gloves and eye protection prevents you from being exposed to chemical and biologically hazardous samples.

To disinfect the cartridge bay:

1. Dip a swab into the 10% bleach solution. Press the swab against the inside wall of the container to remove excess solution.
2. Open the instrument module door.

3. Wipe the surfaces inside the cartridge bay with the swab. Do not touch the slit on the I-CORE module into which the cartridge reaction tube is inserted.

Caution

Getting liquid inside of the I-CORE module can damage the module.

4. Wait 10 minutes.
5. Dip a new swab into the 70% alcohol solution. Press the swab against the inside wall of the container to remove excess solution.
6. Wipe the same surfaces with the new swab.
7. Repeat steps 5 and 6 two times.
8. Close the instrument module door.

10.4 Disinfecting the Plunger Rod

You should disinfect the plunger rod monthly or more frequently if necessary. The materials you need for the procedure are as follows:

- 10% bleach (prepared within 1 week)
- 70% alcohol
- Cotton or Dacron® swabs
- Paper towels
- Latex gloves
- Eye protection

Warning

Make sure you wear latex gloves and eye protection for the cleaning procedure. Wearing the gloves and eye protection prevents you from being exposed to chemical and biologically hazardous samples.

To disinfect the plunger rod:

1. Remove cartridges from the modules you want to clean.
2. In the GeneXpert Dx System window, click Maintenance on the menu bar. The Maintenance window appears (Figure 10-1).

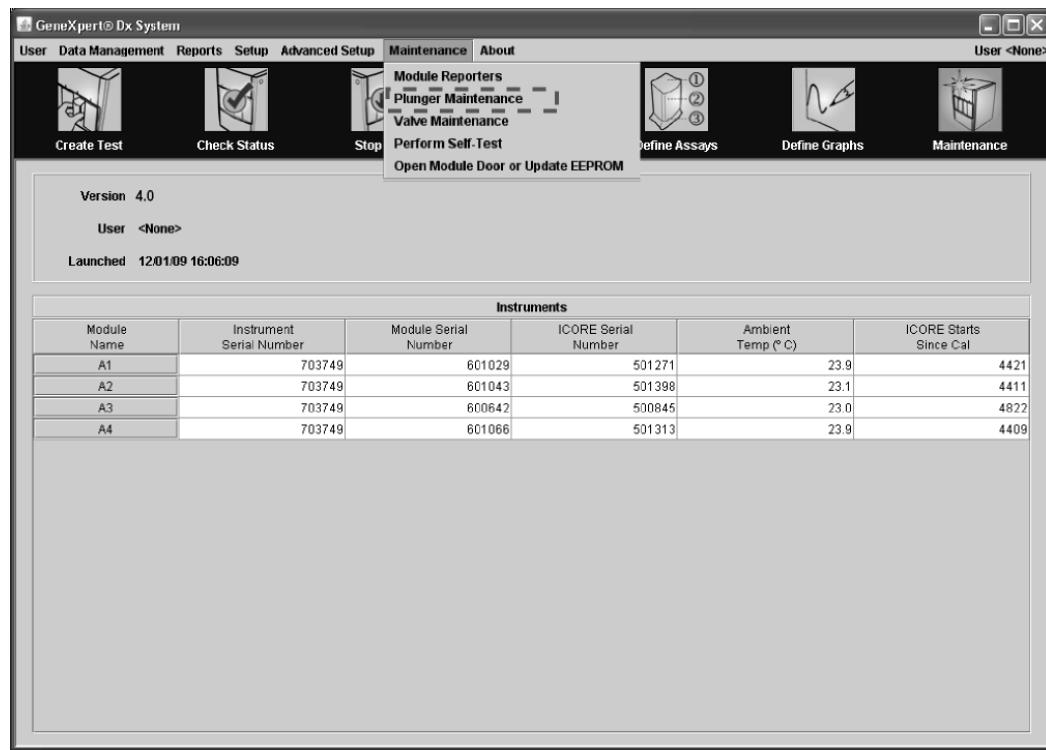


Figure 10-1. Maintenance window

3. On the Maintenance menu, click Plunger Maintenance. The Plunger Maintenance dialog box appears (Figure 10-2).

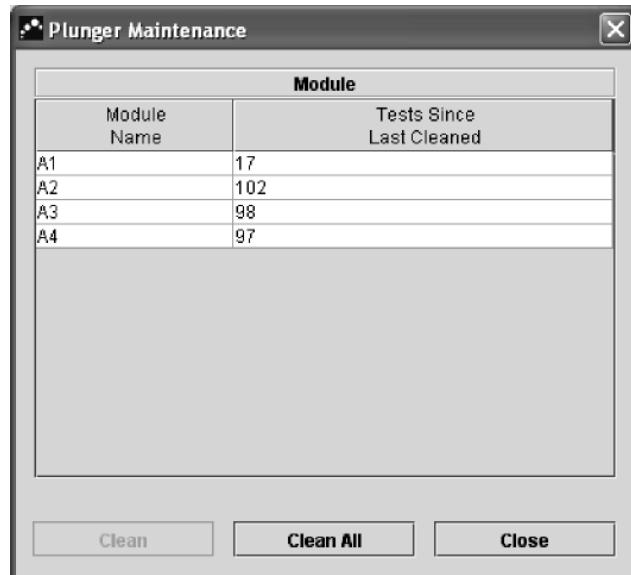


Figure 10-2. Plunger Maintenance dialog box

4. In the **Module** table, select the module you want to clean, and then click **Clean** or select **Clean All** to clean all modules simultaneously. The Plunger Cleaning dialog box appears (Figure 10-3).

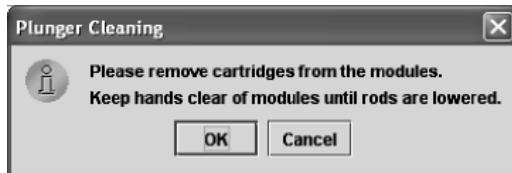


Figure 10-3. Plunger Cleaning dialog box

5. Follow the directions in the Plunger Cleaning dialog box, then click **OK**.

In the Plunger Maintenance dialog box, the **Clean** button changes to **Move Up** (if you clicked **Clean All** button, it changes to **Move Up All**). In the instrument, the plunger rod in the selected module (or all modules if you clicked **Clean All** button) lowers into the cartridge bay (Figure 10-4).

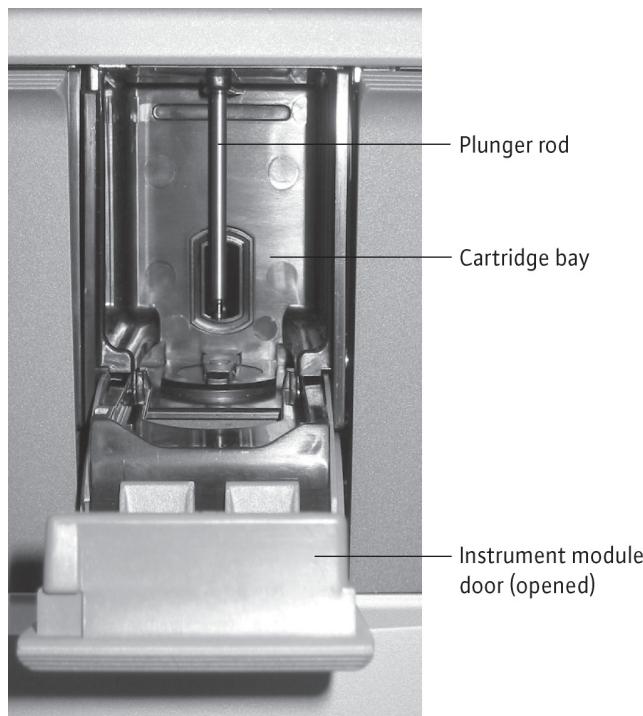


Figure 10-4. Plunger rod, lowered into the cartridge bay

6. Dip a number of swabs in the 10% bleach solution. Press the swabs against the inside wall of the container to remove excess solution.
7. Wipe the plunger rods with the swabs. Use a fresh swab for each plunger rod.
8. Wait 5 minutes.

9. Dip a number of swabs into the 70% alcohol solution. Press the swabs against the inside wall of the container to remove excess solution.
10. Wipe the plunger rods with the swabs. Use a fresh swab for each plunger rod.
11. Repeat steps 9 and 10 two times.
12. In the Plunger Maintenance dialog box, click **Move Up** (or **Move Up All**). The plunger rod moves back up to its resting position.
13. Click **Close** to dismiss the Plunger Maintenance dialog box.

10.5 Calibrating the Instrument

You do not need to calibrate the GeneXpert Dx instrument. Cepheid performs all of the necessary calibrations before you receive the system. However, Cepheid recommends that the instrument be recalibrated after 1 year of use, based on the initial installation date (or based on the previous calibration for subsequent years) or at 2,000 tests per instrument module, whichever comes first.

The system monitors the number of tests since last calibration. Contact Cepheid Technical Support to schedule a calibration when a calibration reminder is displayed. See the Assistance section in the preface for the contact information.

1. To check whether the instrument requires calibration, in the Maintenance window (Figure 10-1), look at the **ICORE Starts Since Cal** column. On the maintenance menu, click **Module Reporters**. The Module Reporters dialog box appears (Figure 10-5).
2. Check the calibration date. If needed, contact Cepheid Technical Support to schedule a calibration. See the Assistance section in the preface for the contact information.

10.6 Using Module Reporters

Cepheid Technical Support may ask you to use the Module Reporters tool when investigating the source of possible module-related problems. It provides calibration information and other data, shown in Figure 10-5.

To view the Module Reporters, on the Maintenance screen choose **Maintenance > Module Reporters**. The Module Reporters window appears.

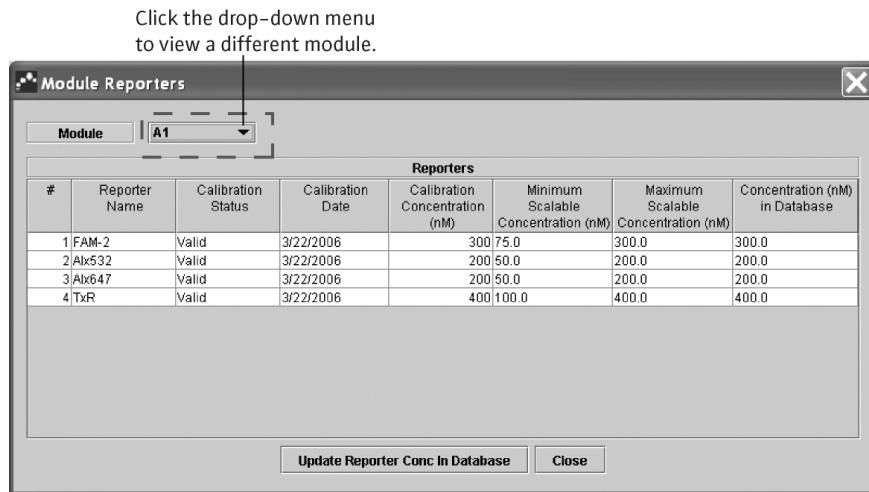


Figure 10-5. Module Reporters dialog box

10.7 Performing a Manual Self-Test

The GeneXpert Dx System automatically performs a self-test during startup. However, you can initiate a self-test manually to check for hardware failure problems.

To start the self-test:

1. Remove cartridges from the modules you want to check.
2. In the GeneXpert Dx System window, click Maintenance on the menu bar. The Maintenance window appears (Figure 10-1).
3. On the Maintenance menu, click Perform Self-Test. The Module Self-Test dialog box appears (Figure 10-6).

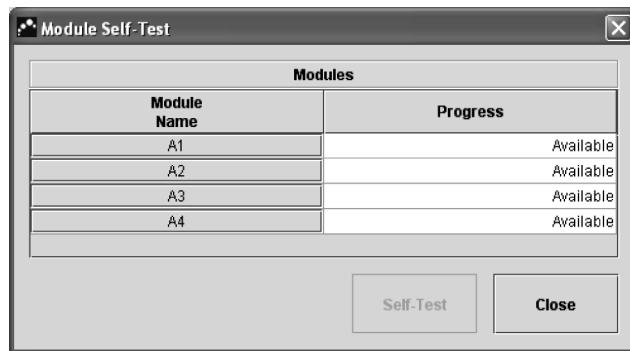


Figure 10-6. Module Self-Test dialog box

4. Select the module you want to check.

5. Click **Self-Test**. The Self-Test dialog box appears (Figure 10-7).

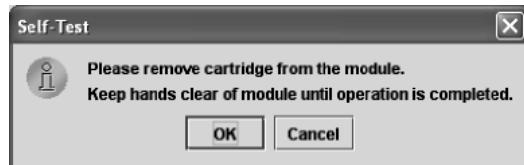


Figure 10-7. Self-Test dialog box

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

10.8 Generating the System Log Report

You can use the System Log reports to provide incidents of instrument module self-tests and errors to Cepheid when you have encountered module failure.

1. In the GeneXpert Dx System window, click **Reports** on the menu bar, and then click **System Log**. The System Log Report dialog box appears (Figure 10-8).



Figure 10-8. System Log Report window

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

- **Date Range:**

- **All**—Select to include all of the records.
- **Select**—Select to filter the records by specifying a range of dates. Entries older than 1 year are automatically removed.

- **Modules:**

- **Currently Connected Modules**— Displays modules that are connected to the system and are currently shown on Check Status screen. This is the default option.
- **All Logged Modules**—Displays all modules which have self-test or error entries in this system database within the last 1 year. This allows technical support to obtain self-test/error entries for a module that is no longer connected to the system.

A list of modules is displayed in the table.

Select the module to be included in the system by selecting the individual modules one-by-one, or by using one of the following buttons:

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

- **Show:**

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

3. When you finish selecting the log criteria, click one or both of the following buttons:

- **Generate Report file**—Creates a PDF file and saves it to the location you specify.
- **Preview PDF**—Creates a PDF file and displays the file in the Adobe® Reader window (Figure 10-9). You can save and print the PDF file from the Reader software.

GeneXpert PC

12/3/2007 08:52:01

System Log Report

- Selection Criteria -

Date Range: All

Modules: Currently Connected Modules
Module B1,B2,B3,B4.

Show: Errors Only

User: Jane Doe

Module Name	Instrument S/N	Module S/N
B1	702324	600016
<No Data Available>		

Module Name	Instrument S/N	Module S/N
B2	702324	600027
<No Data Available>		

Module Name	Instrument S/N	Module S/N
B3	702324	600024
<No Data Available>		

Module Name	Instrument S/N	Module S/N
B4	702324	600028
<No Data Available>		

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

Figure 10-9. An example of System Log Report in the Adobe Reader window

10.9 Replacing Instrument Parts

Caution

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

You can replace the following GeneXpert Dx instrument parts:

- Power cord (part number 100-1375)
- Ethernet cable (part number 700-0555)
- DC Adapter Power cable, for GX-I R2 and GX-II R2 (part number 100-3632)

You can obtain the power cord, Ethernet cable, and DC Adapter Power cable from Cepheid. See the Assistance section in the preface for the contact information.

10.10 Repairing the Instrument

Warning

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

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

Chapter 11 Troubleshooting

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

- Hardware Problems (Section 11.1)
- Error Messages (Section 11.2)

11.1 Hardware Problems

Table 11-1 lists the possible hardware problems you might encounter. To contact Cepheid Technical Support, see the Assistance section in the Preface for the contact information.

Table 11-1. Hardware problems

Problem	Possible cause	Solution
The system does not start.	The instrument is not connected to the power outlet.	Check the instrument power connections.
Module not detected.	Network cable not connected or incorrect cable. Software launched before instrument turned on. The IP address is not assigned correctly.	Connect network cable (Cepheid P/N 700-0555). Exit software and relaunch with instrument powered on. Change IP Address Setting by performing the steps provided in Section 2.4 in the sidebar titled “How to Set the IP Address”.
Hardware failure.	Using software version less than 4.0 with 6-color instrument.	Turn system off and update software.
Barcode scanner failure.	Symbology unsupported. Scanner barcode cable not plugged in.	GeneXpert software supports Code 39, Codabar, Code 128A, B, or C, and 2-D data matrix symbologies. Unplug scanner and replug into computer.
The cartridge is stuck inside the instrument module.	Module mechanical failure.	To remove the cartridge: <ol style="list-style-type: none">1. In the GeneXpert Dx System window, click Maintenance on the toolbar.2. On the Maintenance menu, click Open Module Door.3. Select the module.4. Click Open_Door to open the module door. If the door does not open, cycle the instrument power and repeat the above steps.

Table 11-1. Hardware problems (Continued)

Problem	Possible cause	Solution
The instrument module red light is flashing.	Module mechanical failure.	Confirm no cartridge is in the module. Perform a self-test manually (Section 10.7). If the error recurs, contact Cepheid Technical Support.
Test report is not printed at the end of run.	<ul style="list-style-type: none"> • Printer off line. • Printer out of paper and toner. 	Check: <ul style="list-style-type: none"> • Printer on-line. • Paper present. • Toner OK.
Creating a test.	<ul style="list-style-type: none"> • Modules not available. • No assay selected. • Module not calibrated for reporters used in assay. • The ambient temperature of the module is above 55 °C. 	Check that assay is selected. Calibrate with assay dyes. Check that the modules are not disabled. Check module temperature in Maintenance screen. If your room is in the recommended temperature range and the module is above 55 °C, contact Cepheid Technical Support.
Unable to start test.	<ul style="list-style-type: none"> • Reporters out of calibration. 	Check module reporters in maintenance window: <ol style="list-style-type: none"> 1. Reporter for assay are present. 2. Calibration status is valid.

11.2 Error Messages

This section lists the error messages and provides possible causes and solutions. The error messages are grouped by the categories shown in the software:

- **Run-time error**—Errors that occur during a test (Section 11.2.1).
- **Operation terminated**—Errors that abort a test (Section 11.2.2).
- **Cartridge loading**—Errors that occur during a cartridge loading process (Section 11.2.3).
- **Self-test**—Errors that occur during the self-test process (Section 11.2.4).
- **Post-run analysis**—Errors that occur during the data reduction process (Section 11.2.5).

You can view all of the errors in the Check Status window (Figure 11-1). Details for test-specific errors are also shown on the Errors tab of the View Results window (Figure 11-2).

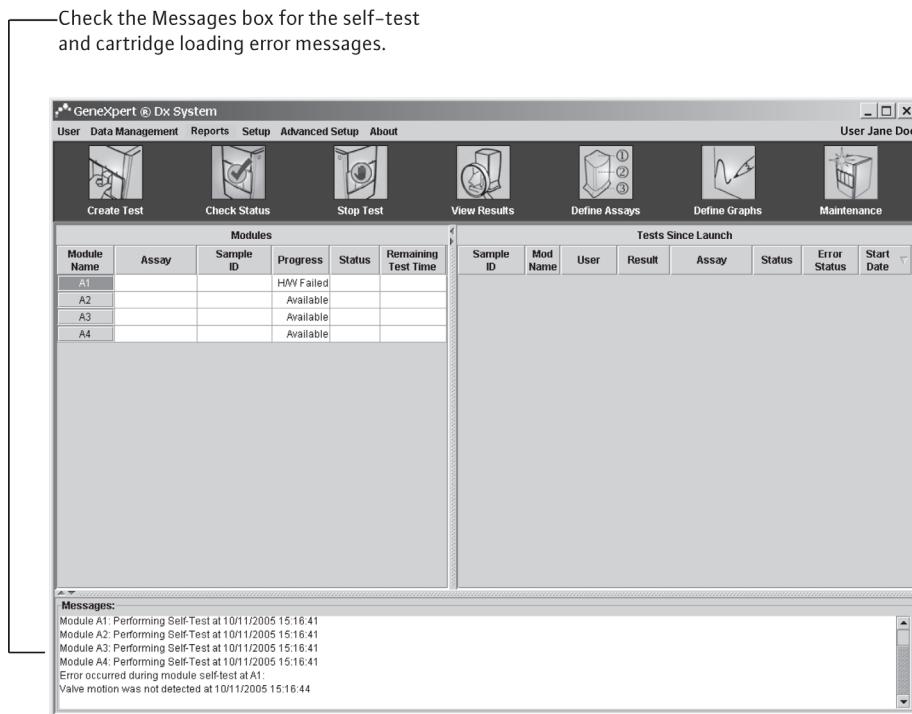


Figure 11-1. GeneXpert Dx System – Check Status window

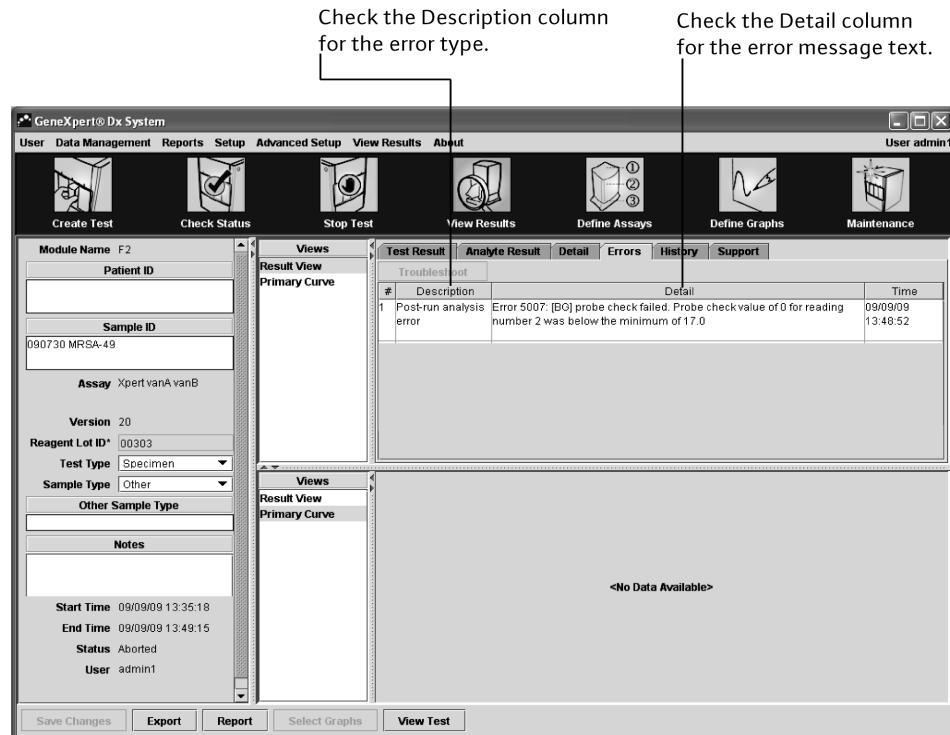


Figure 11-2. GeneXpert Dx System – View Results window – Errors tab (Detail users and administrator view)

11.2.1 Run-time error

Table 11-2 lists errors that might appear during a test that is not aborted. Although the system was able to finish the test and save the results, some non-critical errors occurred and require your attention. These error messages appear in the View Results window (Figure 11-2). To contact Cepheid Technical Support, see the Assistance section in the Preface for the contact information.

Table 11-2. Errors that occurred during a test that is not aborted

Error code	Error message	Possible causes	Solution
1001	The actual temperature n °C has drifted too far away from the setpoint of m °C. (n and m are temperature values that the software displays. The values can vary.)	A heater component or a related component failed. Environment temperature is too warm. Fan Failure.	Report the temperature value in the error message to Cepheid Technical Support. Check room temperature. Check fans are functional and fan filters are clean.
1002	The temperature difference of n °C exceeds the limit of m °C. The temperatures for heaters A and B are p °C and q °C. (n, m, p, and q are temperature values that the software displays. The values can vary.)	The difference between the temperatures of the two thermistors has exceeded the acceptable difference of 5 °C.	Call Cepheid Technical Support.
1004	The internal instrument temperature n °C was out of range of m ₁ °C to m ₂ °C. (n, m ₁ , and m ₂ are temperature values that the software displays. The values can vary.)	One or more of the following might have caused the error: <ul style="list-style-type: none">• The ambient temperature is not within the required range.• The environmental conditions do not meet the requirements.• The ambient temperature sensor failed.• Broken or dirty fans	Check the following: <ul style="list-style-type: none">• The instrument has at least 5 cm (2 in) of clearance on each side.• The laboratory environmental conditions meet the requirements specified in Chapter 4.• Fans are moving.• Clean fan filters. If the instrument meets all the requirements and the error persists, call Cepheid Technical Support.
1005	Optic signal of n from detector #m using LED #p exceeded the limit of q. (n, m, p, and q are values that the software displays. The values can vary.)	One or more of the following might have caused the error: <ul style="list-style-type: none">• The signal from the reporter is too high.• The door is not closed properly.• A hardware component failed.	Try one or more of the following solutions: <ul style="list-style-type: none">• Use a different cartridge.• Make sure the door is closed completely. If the error recurs, call Cepheid Technical Support and provide the information presented in the error message.

Table 11-2. Errors that occurred during a test that is not aborted (Continued)

Error code	Error message	Possible causes	Solution
1006	Detector #n dark signal of m exceeded the limit of p. (n, m, and p are values that the software displays. The values can vary.)	The detector or the electronics failed.	Call Cepheid Technical Support and provide the information presented in the error message.
1007	The n V power supply was detected to be m V. (n and m are voltage values that the software displays. The values can vary.)	The power supply voltage is out of range.	Record the information in the error message. If the error recurs in multiple runs, call Cepheid Technical Support.
1017	The measured temperature of the optical system was n °C which was not within the acceptable range of m ₁ °C to m ₂ °C. (n, m ₁ , and m ₂ are temperature values that the software displays. The values can vary.)	One or more of the following might have caused the error: <ul style="list-style-type: none">• The optical block thermistor failed.• The ambient temperature is too high.	Rerun the test. If the error recurs, call Cepheid Technical Support.
1018	A valve positioning error of n count(s) was detected at the end of the run. (n is a value that the software displays. The value can vary.)	A valve component failed. Cartridge integrity compromised.	Rerun the test. If the error recurs, call Cepheid Technical Support.

11.2.2 Operation terminated

Table 11-3 lists errors that might appear when a test is aborted (Table 11-3). The operation-terminated error messages appear in the View Results window (Figure 11-2). To contact Cepheid Technical Support, see the Assistance section in the Preface for the contact information.

Table 11-3. Errors that might appear when a test is aborted

Error code	Error message	Possible causes	Solution
2003	Module is already running a test with test ID n while performing command ID m. (m and n are ID numbers that the software displays. The number can vary.)	Software communication failed.	Call Cepheid Technical Support.

Table 11-3. Errors that might appear when a test is aborted (Continued)

Error code	Error message	Possible causes	Solution
2005	Motion of the syringe drive was not detected. Detected motion started at position n μ l and transferred m μ l at valve position p with pressure q PSI. (n, m, p, and q are values that the software displays. The values can vary.)	A syringe stall was detected.	<p>Try one or more of the following solutions:</p> <ul style="list-style-type: none"> • Use a new cartridge. • Restart the system. See Section 2.12 for instructions. <p>If the error persists, call Cepheid Technical Support.</p>
2006	Valve motion was not detected. Valve started at position n. Last detected at position m. (n and m are values that the software displays. The values can vary.)	The valve drive failed. Improper interface between cartridge and valve body.	<p>Try one or more of the following solutions:</p> <ul style="list-style-type: none"> • Open the module and reposition the cartridge. • Use a new cartridge. • Restart the system. See Section 2.12 for instructions. <p>If the error persists, call Cepheid Technical Support.</p>
2008	Syringe pressure reading of n PSI exceeds the protocol limit of m PSI. (n and m are pressure values that the software displays. The values can vary.)	One or more of the following causes might have caused the error: <ul style="list-style-type: none"> • The filter is clogged by debris in sample. • Pressure sensor failed. 	<p>Try one or more of the following solutions:</p> <ul style="list-style-type: none"> • Use a new cartridge. • Run a cartridge containing buffer only. <p>If the error persists, call Cepheid Technical Support.</p>
2009	Syringe pressure reading of n PSI is below the protocol limit of m PSI. (n and m are pressure values that the software displays. The values can vary.)	The filter is clogged.	<p>Try one or more of the following solutions:</p> <ul style="list-style-type: none"> • Use a new cartridge. • Run a cartridge containing buffer only. <p>If the error persists, call Cepheid Technical Support.</p>
2012	An inaccurate valve move to position n was detected. The valve was detected to stop at position m. (n and m are values that the software displays. The values can vary.)	A component of the valve drive failed.	Use a new cartridge. If the error persists, call Cepheid Technical Support.

Table 11-3. Errors that might appear when a test is aborted (Continued)

Error code	Error message	Possible causes	Solution
2014	The digital temperature reading of n for Thermistor A/Thermistor B/Ambient Thermistor/Optic Thermistor was not within the acceptable range of m1 to m2. (n, m1, and m2 are temperature values that the software displays. The values can vary.)	The heater A/heater B/module's/optical block thermistor failed.	<p>Check the following:</p> <ul style="list-style-type: none"> • The ambient temperature • The internal temperature of the instrument • Two inches of clearance, refer to Chapter 2 (Installation) <p>If the ambient and internal temperatures are within the acceptable range and you continue to see the error message, call Cepheid Technical Support.</p>
2016	The system was unable to find the valve home position.	The valve position sensor failed.	<p>Perform self-test and try again with another cartridge.</p> <p>If the error persists, call Cepheid Technical Support.</p>
2017	The door latch sensor is still on after a cartridge eject operation.	<p>One or more of the following might have caused the error:</p> <ul style="list-style-type: none"> • A syringe component failed. • The door or a related component failed. • The door sensor failed. 	<p>To remove the cartridge:</p> <ol style="list-style-type: none"> 1. In the GeneXpert Dx System window, click Maintenance on the toolbar. 2. On the Maintenance menu, click Open Module Door. 3. Select the module. 4. Click Open Door to open the module door. <p>After you remove the cartridge, restart the system. See Section 2.12 for instructions.</p>
2022	Failed to get to desired temperature of n °C. The temperature reached m °C. (n and m are temperature values that the software displays. The values can vary.)	Environmental temperature is above or below the acceptable range.	<p>Check the following:</p> <ul style="list-style-type: none"> • The ambient temperature • The internal temperature of the instrument • Two inches of clearance, refer to Chapter 2 (Installation) <p>If the ambient and internal temperatures are within the acceptable range and you continue to see the error message, call Cepheid Technical Support.</p>
2024	An ultrasonic horn failure occurred with n% duty cycle, m Hz and actual p% amplitude. Setpoint amplitude was q%. (n, m, p, and q are values that the software displays. The values can vary.)	The ultrasonic horn failed.	<p>Use a new cartridge.</p> <p>If the problem persists, call Cepheid Technical Support.</p>

Table 11-3. Errors that might appear when a test is aborted (Continued)

Error code	Error message	Possible causes	Solution
2026	The ultrasonic horn current was detected to be out of the normal range.	The ultrasonic horn failed.	Call Cepheid Technical Support.
2032	The ultrasonic horn could not be tuned properly. The tuning frequency value was n Hz. (n is a value the software displays. The value can vary.)	The ultrasonic horn failed.	Use a new cartridge. If the problem persists, call Cepheid Technical Support.
2034	The optical signal from Detector n/LED n did not reach the expected value. Expected value=m, Actual value=p. (n, m, and p are values that the software displays. The values can vary.)	One or more of the following might have caused the error: <ul style="list-style-type: none">• The LED is not working.• The detector is not working.• The associated circuit is experiencing problems.	Restart the test. If the error recurs, restart the system. See Section 2.12 for instructions. If the error persists, call Cepheid Technical Support.
2035	An ultrasonic failure occurred with n% duty cycle, m Hz and actual p% amplitude. Setpoint amplitude was q%. (n, m, p, and q are values that the software displays. The values can vary.)	One or more of the following might have caused the error: <ul style="list-style-type: none">• Cartridge issue• Dirt on the horn surface• The ultrasonic horn failed.	Restart the test. If the error recurs, restart the system. See Section 2.12 for instructions. If the error persists, call Cepheid Technical Support.
2126	Module was reset.	Intermittent power supply failure. Power supply cable or connector failure.	Restart system. If problem persists, call Cepheid Technical Support.
2127	Module communication loss was detected.	Ethernet cable between PC and GX instrument. Communication cable between gateway and GX Module.	Unplug and replug instrument ethernet cable, then restart system. If problem persists, call Cepheid Technical Support.

11.2.3 Cartridge loading

Table 11-4 lists errors that might appear during a cartridge loading process. The cartridge-loading error messages appear in the Check Status window (Figure 11-1).

Because the software performs some self-test procedures during the loading process, some of the error messages that appear during loading process are identical to the self-test error messages. See Section 11.2.4 for the list of those messages. To contact Cepheid Technical

Support, see the Assistance section in the Preface for the contact information.

Table 11-4. Errors that might appear during the cartridge loading process

Error code	Error message	Possible causes	Solution
2011	Unable to initialize pressure sensor to n. Sensor value of m was obtained. (n and m are pressure values that the software displays. The values can vary.)	The force sensor failed.	Restart the test. If the error recurs, restart the system. See Section 2.12 for instructions. If the error persists, call Cepheid Technical Support.
2018	Attempt to load a cartridge while the door is still closed.	One of the following might have caused the error: <ul style="list-style-type: none">• The valve motor failed.• A syringe component failed.• The door-latch sensor failed.	Restart the system. See Section 2.12 for instructions. Open door. If the error recurs, call Cepheid Technical Support.
2025	One of the following messages is displayed: <ul style="list-style-type: none">• The system failed to find the plunger home position. Plunger moved down looking for ADC = n. ADC value m was detected and stall occurred.• The system failed to find the plunger home position. Upward move with minimum force value of n was completed without reaching force value less than m. (n and m are values that the software displays. The values can vary.)	The plunger components or the force sensor failed.	To determine if the error is caused by a failed instrument module or a bad cartridge: <ol style="list-style-type: none">1. Restart the test using the same cartridge and load it into the same instrument module.2. If the error recurs, restart the test using the same cartridge but load it into a different instrument module. If the test progresses successfully in the new module, the previous module requires repair. Call Cepheid Technical Support.3. If the error occurs in the second instrument module, restart the test using a new cartridge and load it into the original module. If the test progresses successfully, the previous cartridge was bad. If the error persists, call Cepheid Technical Support.
2037	The cartridge integrity test failed at valve position <n>. The pressure change of f.ff PSI did not exceed the requirement of f.ff PSI. The pressure increased from f.ff PSI to f.ff PSI during the test.	The cartridge integrity test failed.	Restart the system. See Section 2.12 for instructions. Open door. If the error recurs, call Cepheid Technical Support.

11.2.4 Self-test

Table 11-5 lists errors that might appear during the self-test process. The self-test error messages appear in the Check Status window (Figure 11-1). To contact Cepheid Technical Support, see the Assistance section in the Preface for the contact information.

Table 11-5. Error messages that might appear during the self-test process

Error code	Error message	Possible causes	Solution
4001	A problem with the memory of the I-CORE was detected.	A hardware component failed.	<p>Restart the system. See Section 2.12 for instructions.</p> <p>Open door, select module, and update EEPROM.</p> <p>If the error recurs, call Cepheid Technical Support.</p>
4002	A problem with the main memory of the GeneXpert module was detected.	A hardware component failed.	<p>Restart the system. See Section 2.12 for instructions.</p> <p>If the error recurs, call Cepheid Technical Support.</p>
4003	A problem of the ultrasonic horn system was detected.	The ultrasonic drive circuitry failed.	<p>Restart the system. See Section 2.12 for instructions.</p> <p>If the error recurs, call Cepheid Technical Support.</p>
4004	Valve motion was not detected.	A component of the valve drive failed.	<p>Remove any cartridges from the module, and then restart the system.</p> <p>If the error recurs, perform a self-test manually (Section 10.7). If the error persists, call Cepheid Technical Support.</p>
4006	Syringe drive movement was not detected.	<p>The stall sensor failed during cartridge loading because:</p> <ul style="list-style-type: none"> • The cartridge was not positioned correctly. • A component of the syringe drive failed. 	<p>Restart the system. See Section 2.12 for instructions.</p> <p>If the error persists, call Cepheid Technical Support.</p>
4008	The n-V power supply was detected to be m V. (n and m are voltage values that the software displays. The values can vary.)		<p>Restart the system. See Section 2.12 for instructions.</p> <p>If the error persists, call Cepheid Technical Support.</p>
4009	Heater A operation was not verified. Measured temperature changed from n °C to m °C. (n and m are temperature values that the software displays. The values can vary.)	A heater A component failed.	<p>Perform self-test.</p> <p>If the error persists, call Cepheid Technical Support.</p>

Table 11-5. Error messages that might appear during the self-test process (Continued)

Error code	Error message	Possible causes	Solution
4010	Cooling fan operation was not verified. Measured temperature of n °C exceeded the limit of m °C. (n and m are temperature values that the software displays. The values can vary.)	A cooling component failed.	Make sure that the air vents are not blocked. The instrument must have at least 5 cm (2 in) of clearance on each side. Perform self-test. If the error recurs, call Cepheid Technical Support.
4011	The reported dark value of n for detector m was too high. (n and m are values that the software displays. The values can vary.)	The module door was not closed completely, or a hardware component failed.	Make sure the module door is closed completely. If the error recurs, record the value in the error message, and then call Cepheid Technical Support.
4012	Heater B operation was not verified. Measured temperature changed from n °C to m °C. (n and m are temperature values that the software displays. The value can vary.)	A heater B component failed.	Perform self-test. If the error persists, call Cepheid Technical Support.
4013	An inaccurate valve move was detected. The valve was programmed to stop at position n but stopped at position m. (n and m are position values that the software displays. The values can vary.)	A valve error has occurred.	Remove any cartridge from the module. Perform a self-test manually (Section 10.7). If the error recurs, call Cepheid Technical Support.
4014	The optical signal from Detector n/LED n did not reach the expected value. Expected value = m, Actual value = p. (n, m, and p are optical signal values that the software displays. The values can vary.)	An optics component failed.	Call Cepheid Technical Support.
4015	The measured temperature of the optical system is n which was not within the acceptable range of m ₁ to m ₂ . (n, m ₁ , and m ₂ are temperature values that the software displays. The values can vary.)	An optical block thermistor failed.	Restart the system. See Section 2.12 for instructions. If the error recurs, call Cepheid Technical Support.
4016	GX module program corruption. Unable to continue the test	1) Possible RAM failure 2) Possible EMI 3) Firmware defect	Call Cepheid Technical Support.

Table 11-5. Error messages that might appear during the self-test process (Continued)

Error code	Error message	Possible causes	Solution
4017	The digital temperature reading of n for Thermistor A/Thermistor B/Ambient Thermistor/Optic Thermistor was not within the acceptable range of m1 to m2. (n, m1, and m2 are temperature values that the software displays. The values can vary.)	The heater A/heater B/module's/optical block thermistor failed.	Restart the system. See Section 2.12 for instructions. If the error recurs, call Cepheid Technical Support.
4019	The optical ramp test for LED n resulted in non-monotonic results at DAC setting of nnn. The reference detector readings were nnn and nnn.	LED is broken.	Restart the system. See Section 2.12 for instructions. If the error recurs, call Cepheid Technical Support.

11.2.5 Post-run analysis

Table 11-6 lists errors that might appear during the post-run analysis (data reduction) process. The post-run analysis error messages appear in the View Results window (Figure 11-2). To contact Cepheid Technical Support, see the Assistance section in the Preface for the contact information.

Table 11-6. Data reduction errors

Error code	Error message	Possible causes	Solution
5001	Unable to verify positive analyte [x] using curve fitting. (x is the analyte name)	A component of the cartridge is defective, causing the positive growth curve to have an abnormal shape.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.
5002	Failed to verify valid amplification curve for reporter. The shape factor of n was below the minimum of m. (n and m are values that the software displays. The values can vary.)	A component of the cartridge is defective, causing the positive amplification curve to have an abnormal shape.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.
5003	Failed to verify valid amplification curve for reporter. The shape factor of n was higher than the maximum of m. (n and m are values that the software displays. The values can vary.)	A component of the cartridge is defective, causing the positive amplification curve to have an abnormal shape.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.
5004	Failed to verify valid amplification curve for reporter. The normalized sum of errors of n was greater than the limit of m. (n and m are values that the software displays. The values can vary.)	A component of the cartridge is defective, causing the positive amplification curve to have an abnormal shape.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.
5005	Failed to verify valid amplification curve for reporter. The slope to vertical scaling ratio of n was higher than the limit of m. (n and m are values that the software displays. The values can vary.)	A component of the cartridge is defective, causing the positive amplification curve to have an abnormal shape.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.
5006	X probe check failed. Probe check value of n for reading number m was above the maximum of p. (x is the analyte name, n, m, and p are values that the software displays. The values can vary.)	One or more of the following might have caused the error: <ul style="list-style-type: none"> • An incorrect amount of reagent was inserted into the cartridge. • The reagent is bad. • Fluid transfer failed. 	Check the following: <ul style="list-style-type: none"> • Reagents are added to the cartridge correctly. • Cartridges were stored correctly. Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.

Table 11-6. Data reduction errors (Continued)

Error code	Error message	Possible causes	Solution
5007	X probe check failed. Probe check value of n for reading number m was below the minimum of p. (x is the analyte name, n, m, and p are values that the software displays. The values can vary.)	One or more of the following might have caused the error: <ul style="list-style-type: none">• An incorrect amount of reagent was inserted into the cartridge.• The reagent is bad.• Fluid transfer failed.• The sample was processed incorrectly in the cartridge.	Check the following: <ul style="list-style-type: none">• Reagents are added to the cartridge correctly.• Cartridges were stored correctly. Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.
5008	X probe check failed. Probe check delta value n between reading number m and reading number p was below the minimum of q. (x is the analyte name, n, m, and p are values that the software displays. The values can vary.)	One or more of the following might have caused the error: <ul style="list-style-type: none">• An incorrect amount of reagent was inserted into the cartridge.• The reagent is bad.• Fluid transfer failed.	Check the following: <ul style="list-style-type: none">• Reagents are added to the cartridge correctly.• Cartridges were stored correctly. Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.
5009	X probe check failed. Probe check delta value n between reading number m and reading number p was above the maximum of q. (x is the analyte name, n, m, and p are values that the software displays. The values can vary.)	One or more of the following might have caused the error: <ul style="list-style-type: none">• An incorrect amount of reagent was inserted into the cartridge.• The reagent is bad.• Fluid transfer failed.	Check the following: <ul style="list-style-type: none">• Reagents are added to the cartridge correctly.• Cartridges were stored correctly. Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.
5010	Unable to verify positive analyte [x] using curve fitting. X readings were available, but the minimum number of readings required is y. (x is the analyte name; y is a value software displays)	A component of the cartridge is defective, causing the positive growth curve to have an abnormal shape.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.
5011	Signal loss detected in the amplification curve for analyte [analyte [x]]. n decrease in signal with m% decrease at cycle p. (X is the analyte name; n, m, and p are values that the software displays. The values can vary.)	Loss of tube pressure.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.

Appendix A Quick Reference

This appendix provides a quick reference of the software menus and commands. In the GeneXpert Dx System window, the menus are as follows:

- User (Section A.1)
- Data Management (Section A.2)
- Reports (Section A.3)
- Setup (Section A.4)
- About (Section A.5)

Main menu bar tasks are as follows:

- Create Test (Section A.6)
- Stop Test (Section A.7)
- View Results (Section A.8)
- Define Assays (Section A.9)
- Maintenance (Section A.10)

A.1 User

Command	Description
Login	Logs you on to your GeneXpert Dx System account.
Change Password	Changes your password.
Logout	Logs you out of your GeneXpert Dx System account.
Exit	Exits the GeneXpert Dx System software.

A.2 Data Management

Command	Description
Archive Test	Archives the tests you select.
Retrieve Test	Retrieves the tests you select.

A.3 Reports

Command	Description
Specimen Report	Displays an overview of the test results for the selected specimen in the database.
Patient Report	Displays test results for samples for one patient according to the patient ID in the database.
Control Trend Report	Displays and prints the external-control trend reports.
System Log	Displays and prints the log of module self-test and module errors.
Assay Statistics Report	Displays a report showing the number of tests performed for each assay over a period of time with monthly breakdown values.
Installation Qualification	Displays and prints the installation qualification report.

A.4 Setup

Command	Description
User Administration	Adds users, removes users, or edits user information.
User Type Configuration	Specifies the user type permissions.
System Configuration	Specifies the system name, date format, time format, and destination folders for exported files, reports, database logs. You can also specify other system settings.
Assign Instrument Letter	Assigns an ID to each instrument and instrument module.

A.5 About

Command	Description
About GeneXpert Dx System	Displays the software copyright and version number.

A.6 Create Test

Command	Description
Scan Patient ID	Use the barcode scanner to enter the Patient ID.
Scan Sample ID	Use the barcode scanner to enter the Sample ID.
Manual entry	Use to manually enter the Patient ID, Sample ID, or cartridge information.
Scan Cartridge Barcode	Use the scanner or choose Manual Entry to enter the cartridge barcode.
Start Test	Begin the test.
Cancel	Closes the dialog box, discarding the new test.

A.7 Stop Test

Command	Description
Select Running	Selects all tests in progress.
Deselect All	Clears all selections.
Stop	Stops selected tests.
Cancel	Closes the dialog box.

A.8 View Results

Command	Description
Save Changes	Saves changes you make in the Patient ID, Sample ID, Test Type, Sample Type, Other Sample Type, and Notes boxes.
Export	Exports the selected results to a .csv file.
Report	Saves the results in a PDF file.
Upload Test	Upload selected results to LIS.
View Test	Displays list of tests that can be viewed.

A.9 Define Assays

Command	Description
Delete	Deletes the assay definition file (.gxa) you select.
Move to Top	Moves the currently selected assay to top of the assay list.
Lot	Manages lot-specific parameters for the selected assay definition.
Import	Imports an assay definition into the database.
Report	Displays or saves the assay definition in a PDF file.

A.10 Maintenance

Command	Description
Module Reporters	Displays optical calibration information about the instrument module.
Plunger Maintenance	Lowers the syringe plunger rod for cleaning.
Valve Maintenance	Checks the valve drive.
Perform Self-Test	Performs the self-test to check the system functions.
Open Module Door or Update EEPROM	Opens the module door to eject a stuck cartridge and update cross-platform ICORE EEPROM format.

Appendix B Glossary

.gxa file—an assay definition file.

.gxr file—a lot-specific parameter file.

.gxx file—an archive file that contains multiple tests.

assay definition—a series of programmed steps to perform sample preparation, amplification, and detection procedures.

curve fit—the determination of a curve that fits a specified set of data points on a graph.

cycle threshold (C_t)—the first cycle in which the fluorescence reaches a specified threshold. The C_t can be determined by analyzing the growth curve (Primary Curve) or the second derivative of the growth curve (2nd Deriv).

data reduction—the process in which the system analyzes the raw data based on the settings in the assay definition to determine the test result.

DMS (Data Management System)—could be a stand-alone small scale information system or compliment an LIS in the same facility. A DMS is a software application which handles receiving, processing and storing information.

endogenous control—a control (gene) taken from the test sample and used to normalize targets and to ensure sufficient sample is used in the test. Because of its low variability, the endogenous control can also be used to indicate sample-inhibitor contamination.

endpoint—the fluorescence reading for the last cycle of a thermal cycling protocol.

amplification curve—a graph that plots the number of PCR cycles against fluorescence detected. A real-time **amplification** curve has three distinct phases: baseline, log-linear, and plateau. The increase in fluorescence is proportional to the amount of amplicon generated and can be used to define the cycle threshold.

instrument module—an individual hardware component within which fluidic and thermocycling protocols occur. Each module consists of a bay for holding a cartridge, a syringe drive, a valve drive, an ultrasonic horn, and an I-CORE module.

internal control (IC)—a control that verifies the performance of the PCR reagents and prevents a false negative result. The internal control PCR assay assesses if there is any inhibition, possibly by components in the test sample. The internal control should be positive in a negative sample.

LIS (Laboratory Information System)—is a software application which handles receiving, processing, and storing information generated by medical laboratory processes. These systems often must interface with instruments and other information systems, such as hospital information systems (HIS). An LIS is highly configurable application which is customized to facilitate a wide variety of laboratory workflow models.

lot-specific parameters (LSP)—information about a reagent lot that is required by some assay definitions to determine the test results. The lot-specific parameters are included in the GeneXpert cartridge 2D barcodes and in the lot-specific parameter (.gxr) files.

manual entry—manually enter the sample ID.

module—see instrument module.

primary curve—a plot of fluorescence vs. cycle number. A real-time growth curve should have three distinct phases: baseline, log-linear and plateau. The increase in fluorescence is proportional to the amount of amplicon generated and can be used to define the cycle threshold.

probe check—a stage during the test that checks for the presence and the integrity of the labeled probes.

protocol—an assay command that defines the thermal cycling and optical data collection parameters for an assay.

reporter—a fluorescent dye or dye complex used to detect specific amplification products.

sample processing control (SPC)—a control that ensures a sample was correctly processed. The sample-processing control is processed with the sample and its DNA is detected by a PCR assay.

site—see instrument module.

system log—a report of incidents of instrument module self-tests and errors.

test—the laboratory process used to determine the presence of a substance and measure the amount of that substance. In the GeneXpert Dx System software, a test is a record of how a specimen is processed. The record includes the instrument module ID, the assay information, sample ID, test type, and notes about the test.

test type—the sample that is designated as a specimen, positive control, or negative control in the test.

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