GeneXpert® Dx

Reference Guide

Cepheid®
A better way.

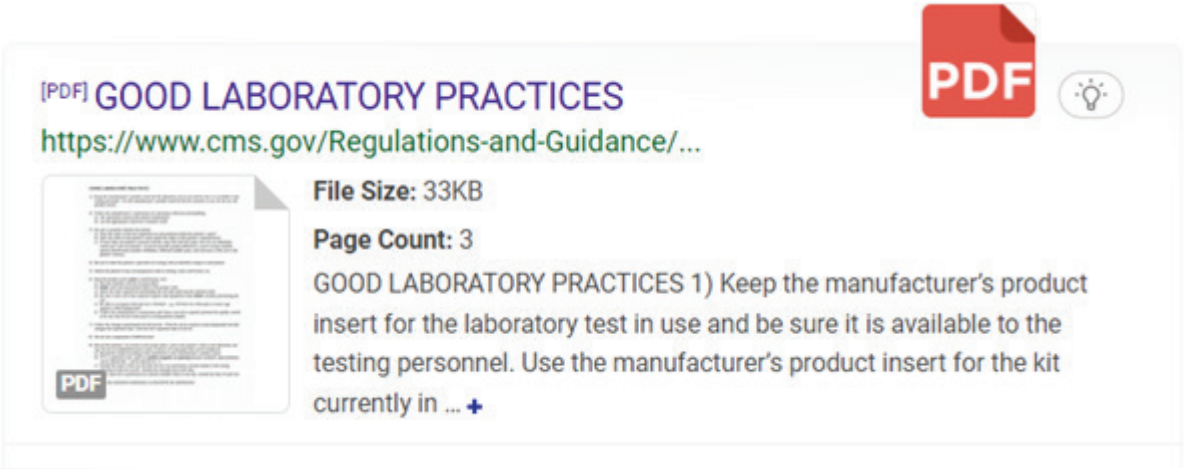
CE IVD *In Vitro* Diagnostic Medical Device

Good Laboratory Practice

Real Time Polymerase Chain Reaction (RT-PCR) is a standard laboratory testing method that is used to select a specific sequence of DNA or RNA. This segment is amplified exponentially which creates billions of detectable copies. This technique has become an important tool in clinical laboratories for the detection of infectious pathogens at extremely low levels. This highly sensitive technique makes RT-PCR highly susceptible to cross-contamination, particularly from sample to sample transfer, if proper clean molecular technique is not used. Implementation of safeguards and strict adherence to robust protocols is often sufficient to ensure that cross-contamination in the molecular laboratory is a rare event.

Follow general CMS guidance for good laboratory practice

CMS.gov Centers for Medicare & Medicaid Services



Preventing Cross Contamination

Use of Personal Protective Equipment (PPE)

Gloves: Change gloves after touching a sample. The outside of the sample harbors much of the sample DNA/RNA that transfers to the surface of gloves.

Lab coats: Wear a lab coat while processing samples. Wearing lab coats will prevent the transfer of sample DNA/RNA to other areas of the room.

Eye/face protection: Wear surgical masks, face shields, or other physical barriers, like a splash shield for procedures with a high likelihood of generating droplets or aerosols.

Cleaning

Bleach: Use a final concentration of 1:10 dilution of 5% household chlorine bleach (used within 1 day of preparation). Final active chlorine concentration should be 0.5%.

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

- Disposable lint-free wipes
- Disposable paper towels

Reagent Storage

Store reagents according to their expected storage conditions in the Information for Use. In addition, cartridges should be kept in their original boxes with the lid shut.

Sample Setup

Dirty area (work area): Area where samples and controls are processed.

Clean area (loading area): Area where the prepared cartridge is loaded onto the instrument.

Cartridge Disposal

Used cartridges may contain potentially infectious materials, as well as highly amplified PCR target(s). **Do not open or attempt to alter any part of the cartridge for disposal**.

Each state has different regulations for classifying regulated medical waste (RMW). The first step to safe biohazard waste disposal is to check with your state's Department of Health to learn the specific regulations you'll need to follow.

Maintenance

Instrument maintenance is required to be performed according to the user guide or operator manual. Some of the maintenance is described in this reference guide, however not all requirements are covered.

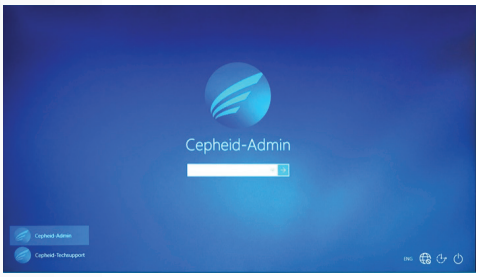
Starting up the system

See the GeneXpert Dx System Operator Manual or Assay Instructions for Use for detailed information..

1. Turn the power switch on the instrument to the **ON** position.
   The blue light on the front panel will light up.

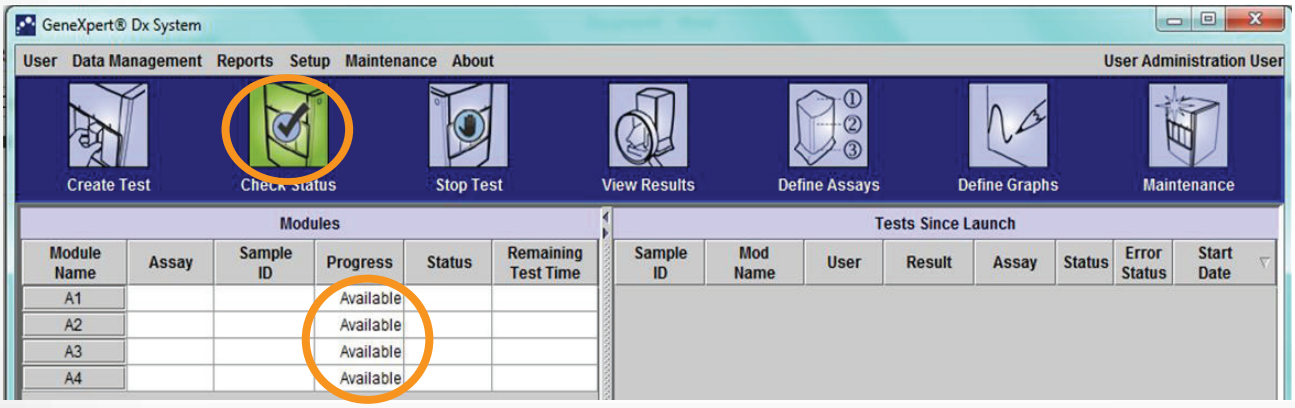
2. Turn the computer ON.

3. User-Account: **Cepheid-Admin**
   Password: **cphd**



4. The GeneXpert Dx software starts automatically. Enter user name and password if applicable.

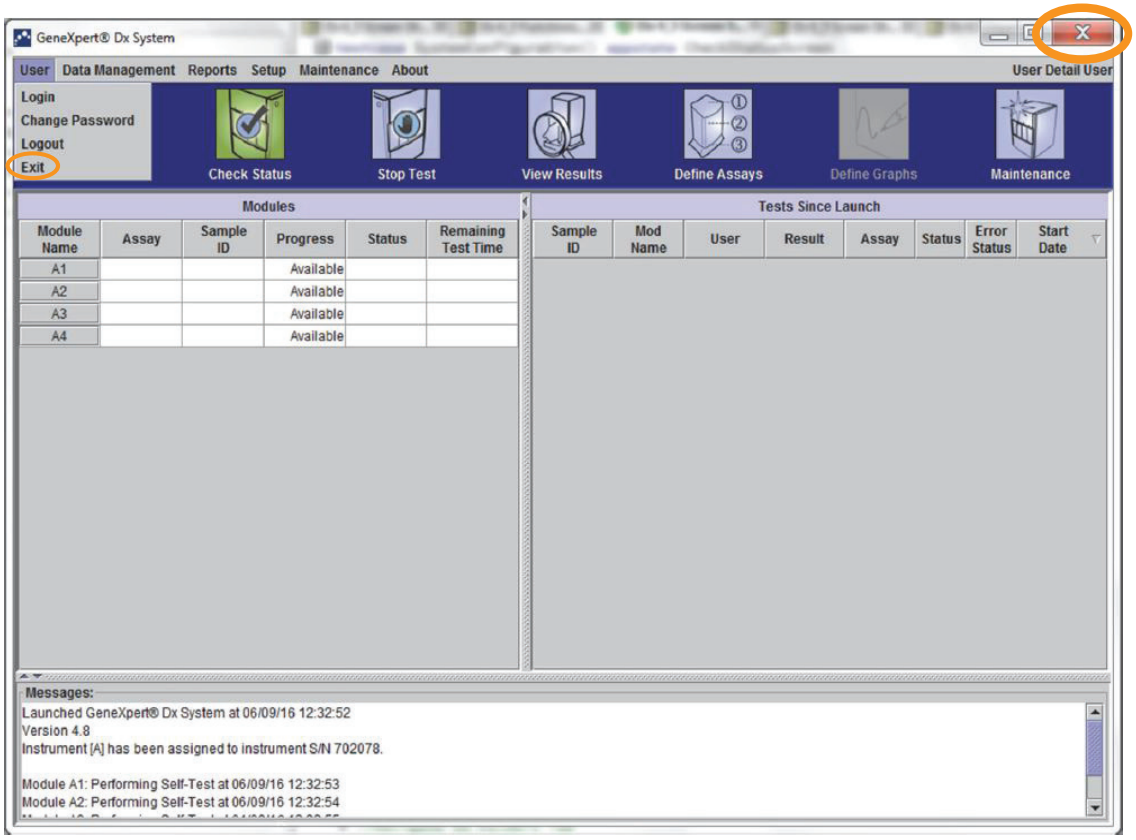
5. In the **Check Status** screen, verify that all the modules are **available**.



Shutting down the system

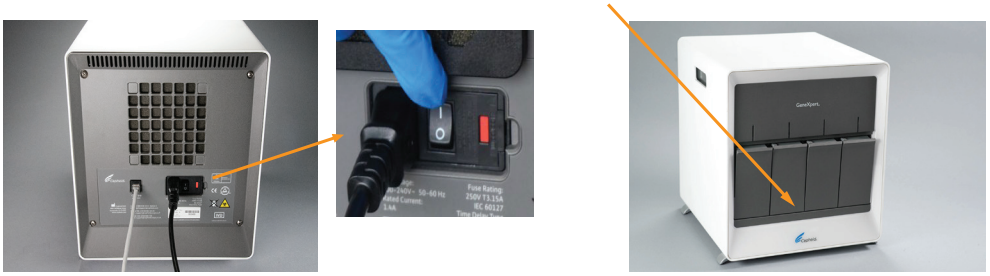
Note: Restart the system once per week.
When performing this task, make sure no tests are running.

1. Exit the GeneXpert Dx software.



2. Turn the computer OFF through the Windows home button.

3. Turn the power switch on the instrument to the **OFF** position.
   The blue light on the front panel will turn off.



Note: Wait 2 minutes before restarting the system.

Common GeneXpert Dx Menus

See Appendix A of the Operator Manual for the complete list

User

- Login
- Change Password
- Logout
- Exit

Data Management

- Archive Test
- Retrieve Test

Reports

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

Setup

- User Administration (Create/Edit Users)
- User Type Configuration
- System Configuration
- Assign Instrument Letter

Maintenance

- Module Reporters
- Plunger Rod Maintenance
- Valve Maintenance
- Perform Self-Test
- Open Module Door or Update EEPROM
- Exclude Modules from Test command

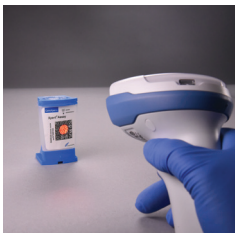
About

- About GeneXpert Dx System

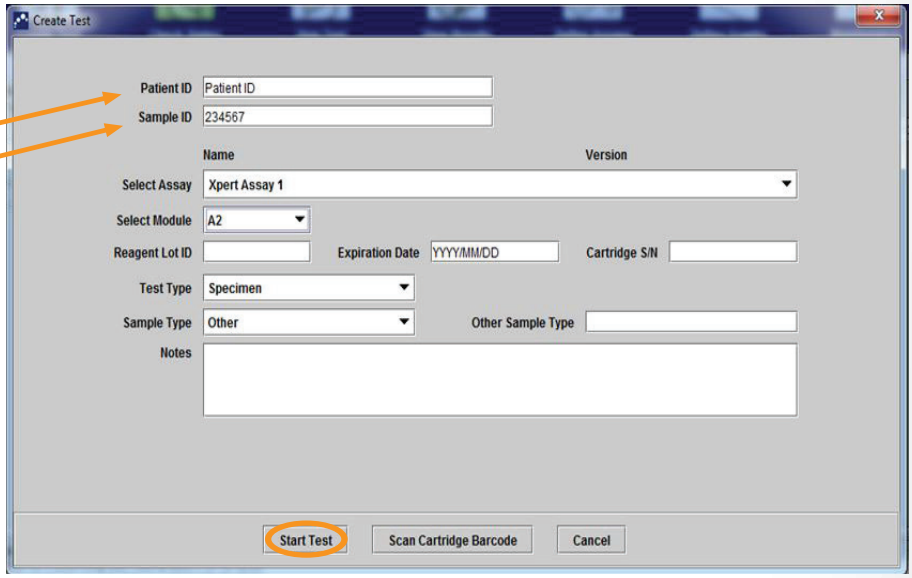
Creating A Test

1. Click on **Create Test** from the main menu of the GeneXpert® Dx

2. Enter or scan the Sample ID and Patient ID (if applicable).
   Scan the barcode on the cartridge.



3. Enter or verifiy the correct information for the following sections (if applicable):
   - Patient ID
   - Sample ID



4. Click on **Start Test** to begin test.

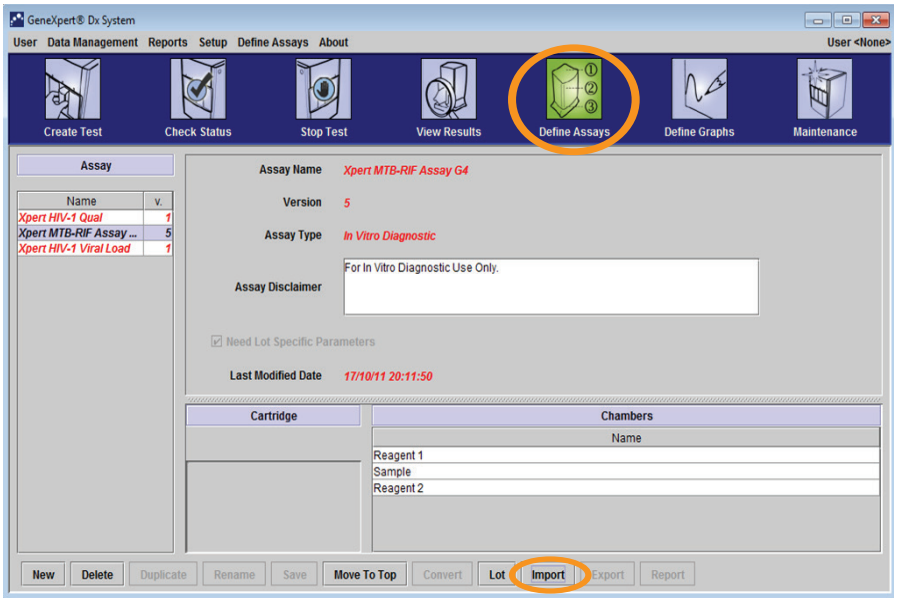
5. Load the cartridge in the module with the blinking green light.
   Close the module door until the green light stops blinking.

Loading Assay Definition File (ADF)

Note: Importing of the Assay Definition File (ADF), located in the kit, is required only when adding a new assay for the first time or when an assay has been updated.

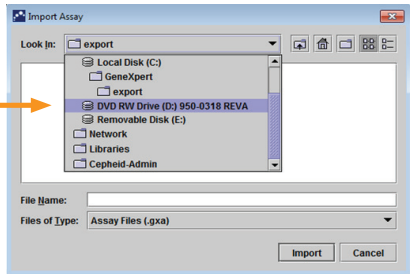
1. Insert the assay definition CD, located in the kit, into the computer's DVD drive.

2. Click **Define Assays.**



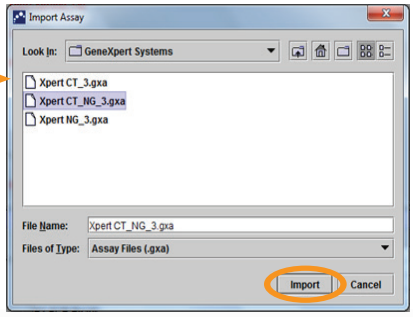
3. Click on **Import**.

4. Select the DVD drive.



5. Select **GeneXpert Systems** folder.

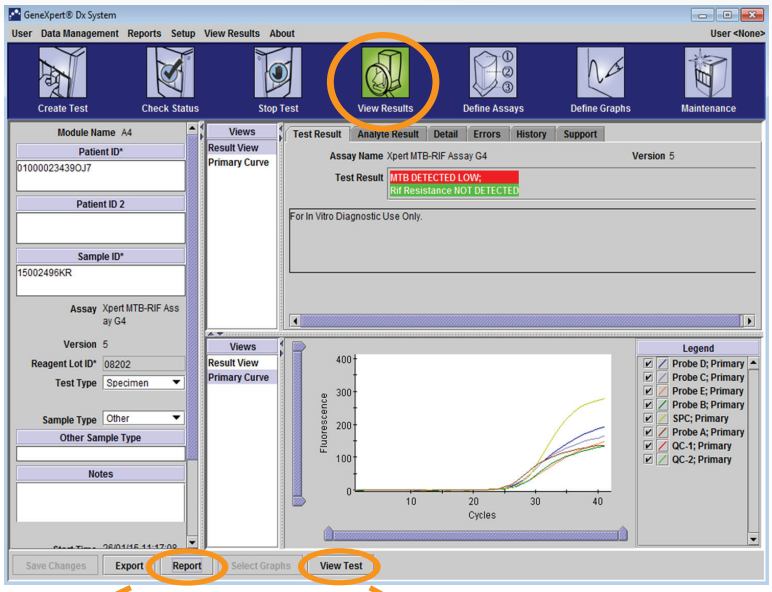
6. Select the .gxa file.



7. Click on **Import**.

View Results and Generate/Print a Report

Click on **View Results**.

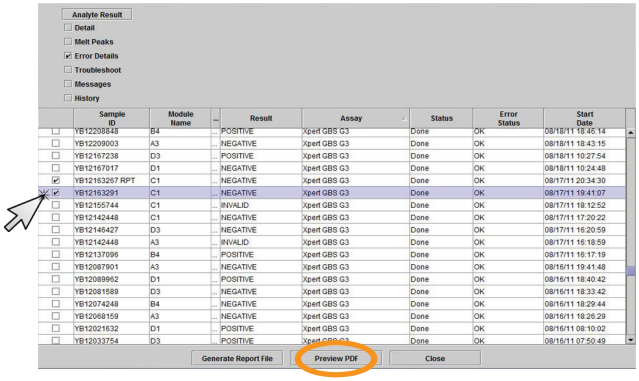


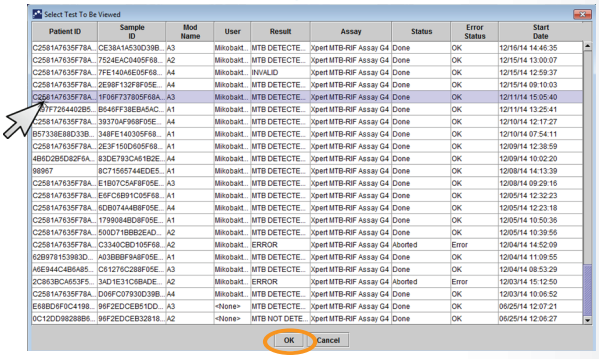
Click on **Report**.

Click on **View Test**.

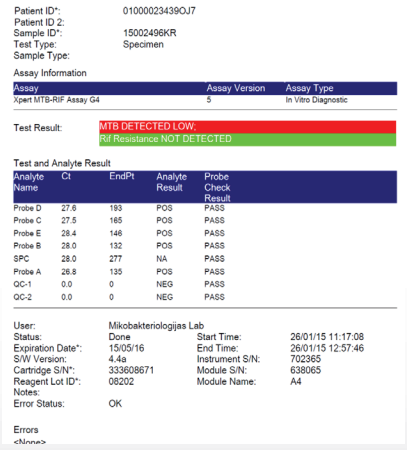
Click on the checkbox(es) of the report to be printed or generated.

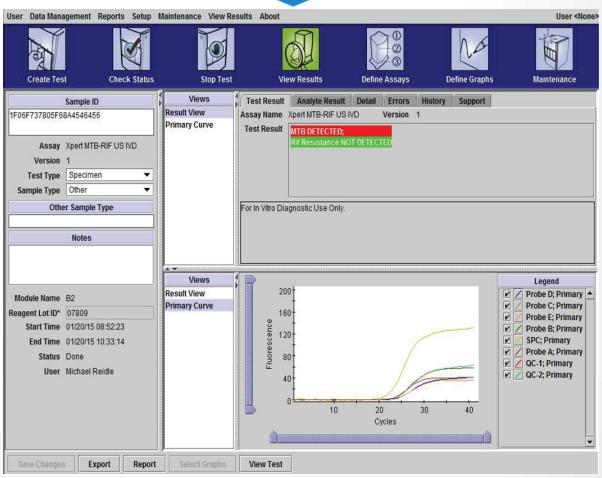
Double-click on the test be viewed.





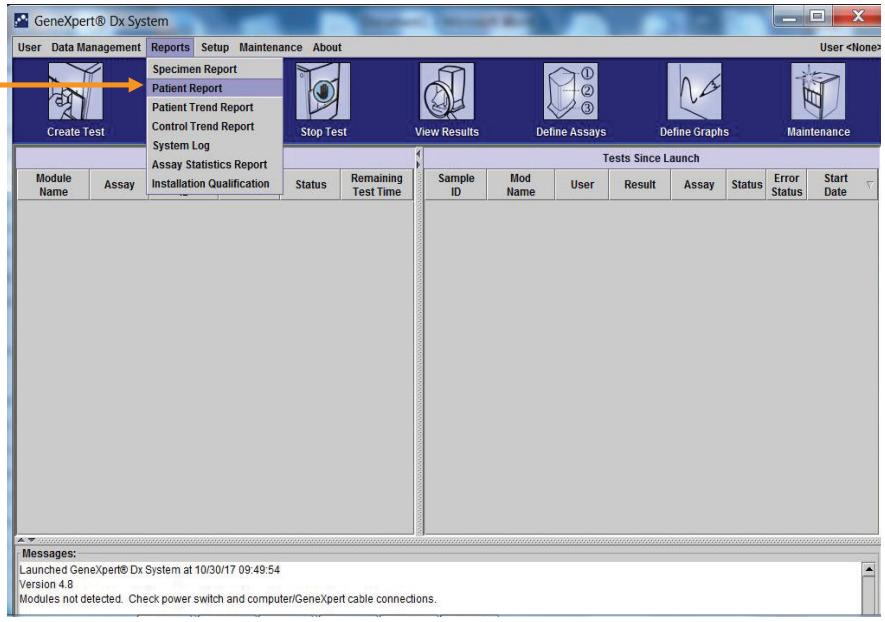
Test Report





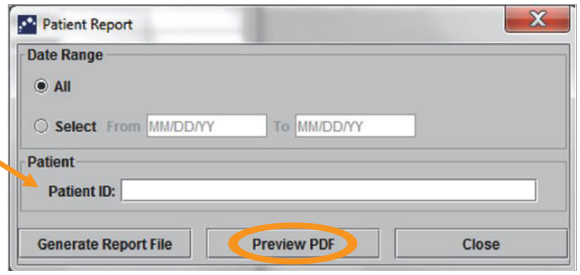
Patient ID Report (if applicable)

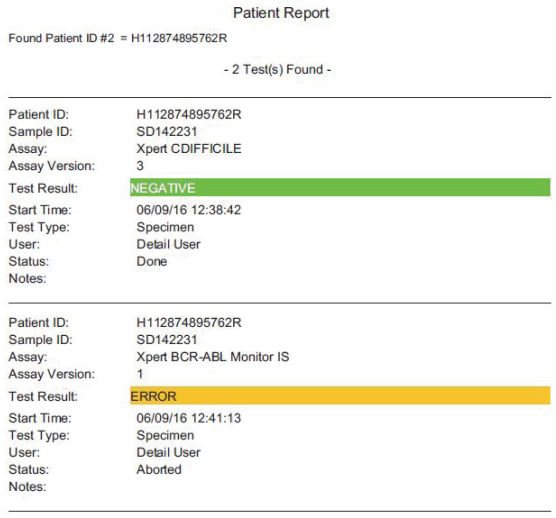
1. Select **Patient Report**



2. Enter the patient ID.

3. Click **Preview PDF.**.





Patient Report

Found Patient ID #2 = H112874895762R

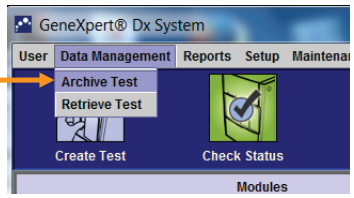
- 2 Test(s) Found -

Patient ID:	H112874895762R
Sample ID:	SD142231
Assay:	Xpert CDIFFICILE
Assay Version:	3
Test Result:	NEGATIVE
Start Time:	06/09/16 12:38:42
Test Type:	Specimen
User:	Detail User
Status:	Done
Notes:	

Patient ID:	H112874895762R
Sample ID:	SD142231
Assay:	Xpert BCR-ABL Monitor IS
Assay Version:	1
Test Result:	ERROR
Start Time:	06/09/16 12:41:13
Test Type:	Specimen
User:	Detail User
Status:	Aborted
Notes:	

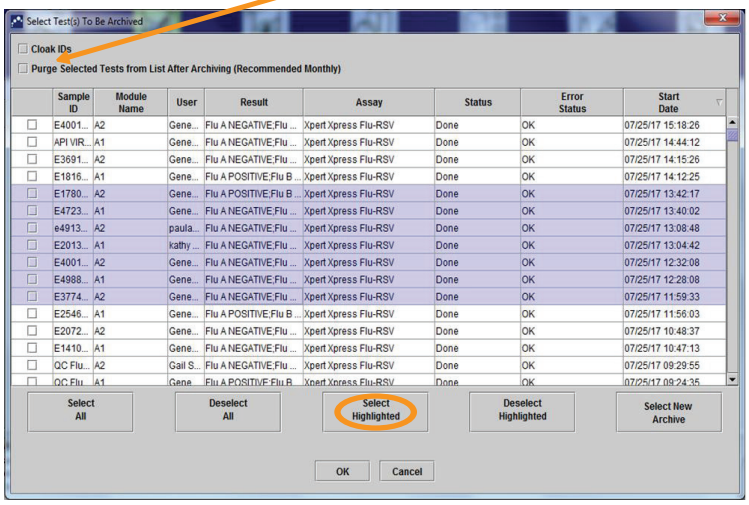
Archiving and Purging

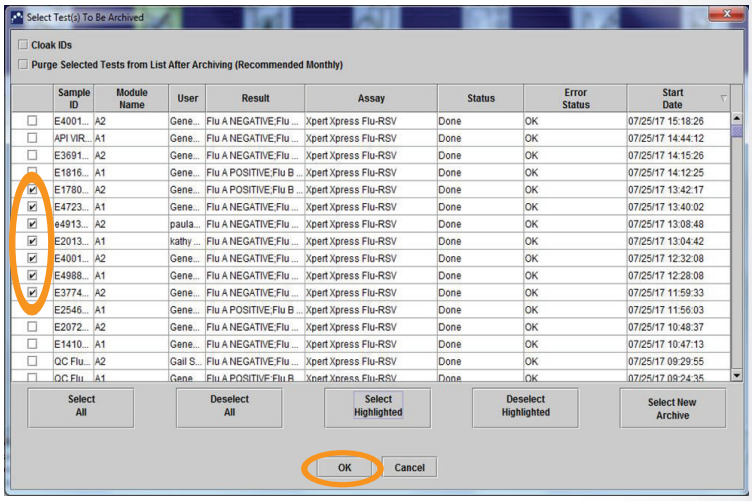
1. Select **Data Management** and **Archive Test**.



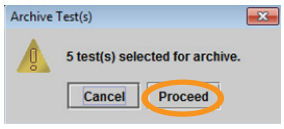
2. Highlight the tests to be archived. Click **Select Highlighted**, then click **OK**.

Note: Check **Purge** to remove archived tests from the database.



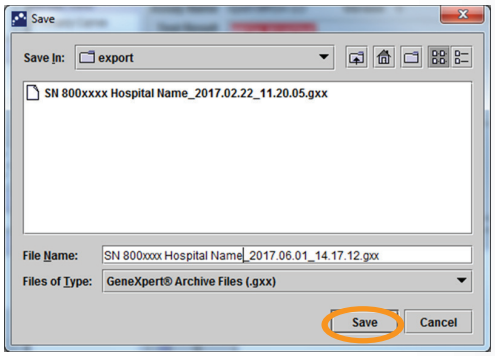


3. Click **Proceed**.



The file name is generated automatically.

4. Click **Save**.



5. Click **OK**.

The archived file can be found in the folder C:\GeneXpert\export

Note: If **Purge Selected Tests** was checked, confirm the selection by clicking **Yes**.

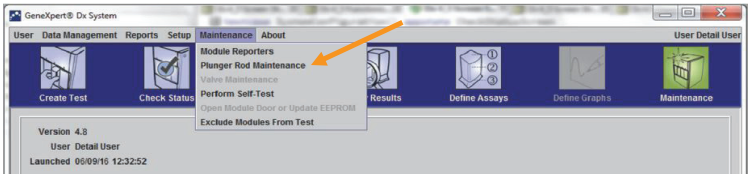
6. Copy archived data file to an external location.

Cartridge Bay and Plunger Rod Cleaning

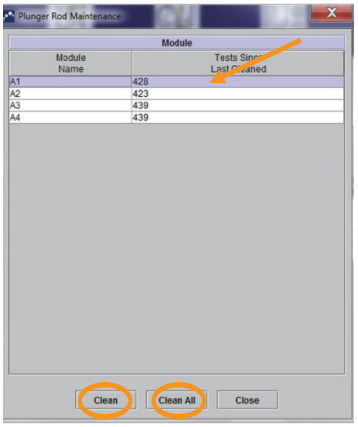
Required Materials

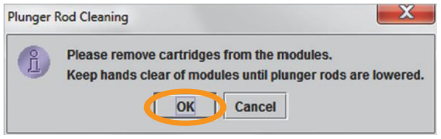
- 1:10 dilution of household chlorine bleach prepared within the same day.
  Final Active Chlorine concentration should be 0.5%, regardless of the household bleach concentration in your country
- 70% ethanol or denatured ethanol (70% ethanol containing 5% methanol and 5% isopropanol)
- Lint-free wipes

1. Remove cartridge(s) from the module(s).
2. Click on **Maintenance** on the Menu Bar, select **Plunger Rod Maintenance**.



3. Select the module(s) to be cleaned and then select **Clean** or **Clean All.**
4. Click **OK**.





5. The plunger rod(s) in the selected module(s) lower(s) into the cartridge bay(s).
6. To clean:
   A. Thoroughly moisten a lint-free wipe with a 1:10 solution of household chlorine bleach.
   B. Vigorously wipe the plunger rod with the lint-free wipe. Using the same lint-free wipe, wipe the walls, ceiling, corners and edges of the cartridge bay, then wipe the inside of the door and the top lip of the door and discard the lint-free wipe.
   C. Wait 2 minutes after wiping with the bleach solution.
   D. Repeat steps A-C twice more, using a new lint-free wipe each time.
   E. Wait 2 minutes after wiping with the bleach solution.
   F. Thoroughly moisten a lint-free wipe with the 70% ethanol solution.
   G. Repeat step B.

7. Once cleaning is completed, click **Move Up**.
8. Click **Close.**

Refer to the Operator Manual for additional Maintenance requirements/tasks.

Notes:

mpower

The molecular revolution is here.

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