

GeneXpert® Dx

Reference Guide



In Vitro Diagnostic Medical Device

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 **Cepheid**
A better way.

Starting up the system

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**



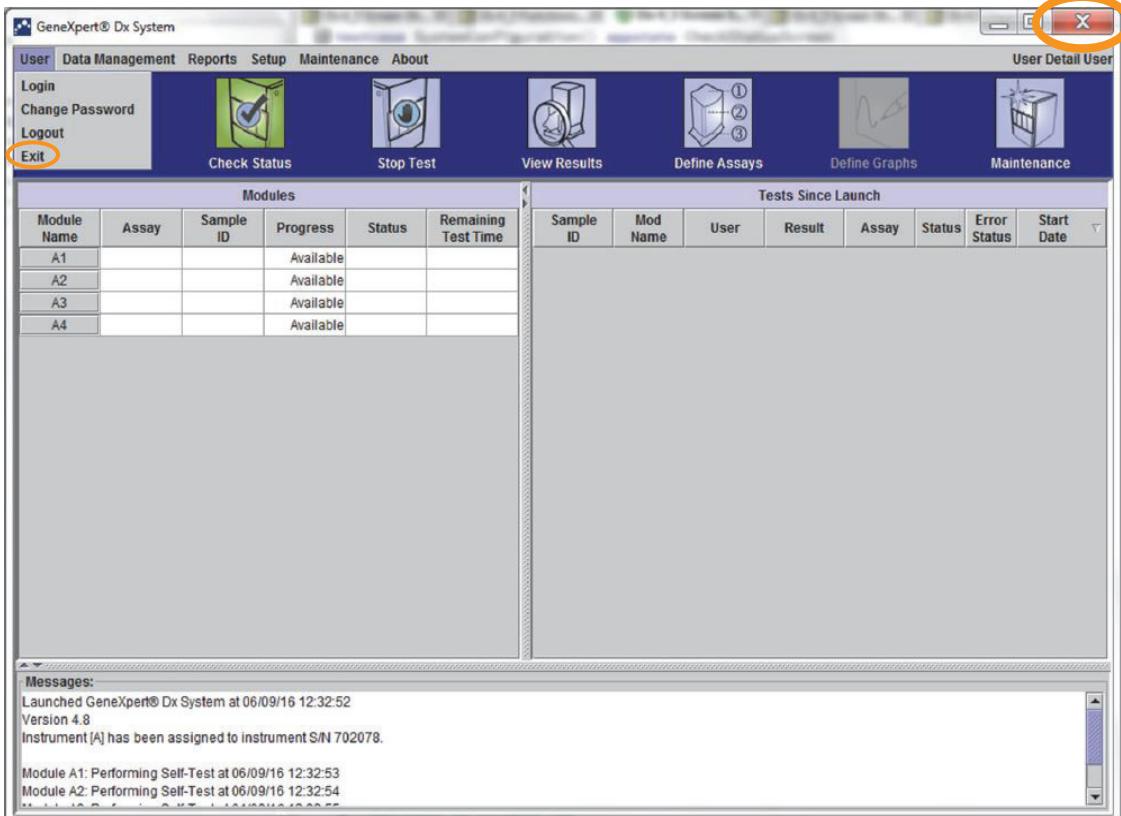
4. The GeneXpert® Dx software starts automatically. Enter user name and password if applicable.

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 GX 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 verify the correct information for the following sections (if applicable):

- Patient ID
- Sample ID

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

The screenshot shows the "Create Test" dialog box. It contains fields for Patient ID (Patient ID) and Sample ID (234567). There are dropdown menus for Select Assay (Xpert Assay 1), Select Module (A2), Reagent Lot ID, Expiration Date (YYYY/MM/DD), Cartridge S/N, Test Type (Specimen), and Sample Type (Other). A Notes section and a "Start Test" button at the bottom are also visible. Two orange arrows point from the text in step 3 to the "Patient ID" and "Sample ID" fields.

5. Load the cartridge in the module with the blinking green light.

Close the module door until the green light stops blinking.



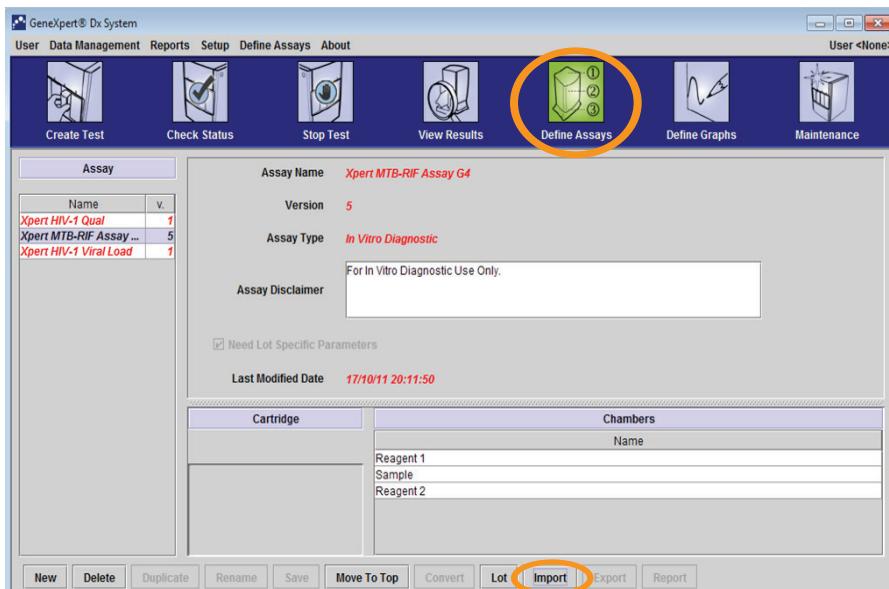
Loading Assay Definition File (ADF)

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.

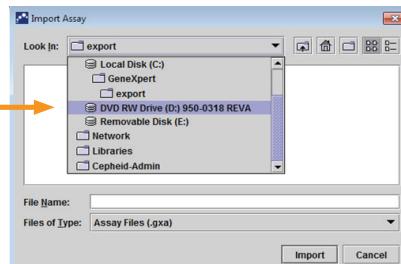


2. Click **Define Assays**.



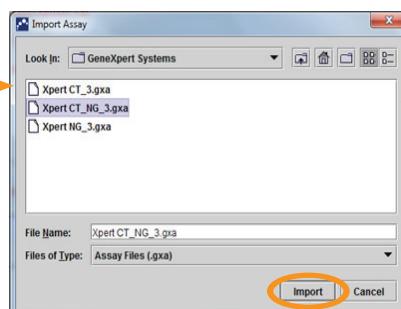
3. Click on **Import**.

4. Select the DVD drive.



5. Select **GeneXpert Systems** folder.

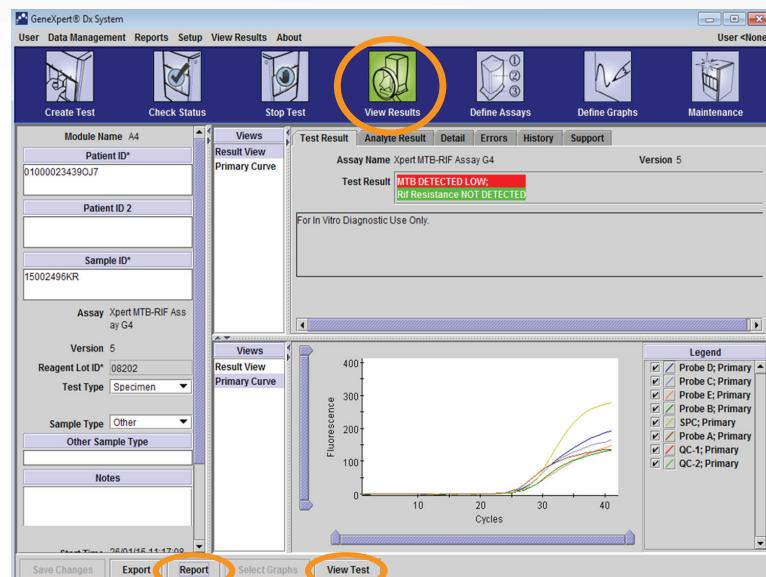
6. Select the .gxa file.



7. Click on **Import**.

View Results and Generate/Print a Report

Click on View Results.



Click on Report.

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

Analyte Result	
<input type="checkbox"/>	Detail
<input type="checkbox"/>	Melt Peaks
<input checked="" type="checkbox"/>	Error Details
<input type="checkbox"/>	Troubleshoot
<input type="checkbox"/>	Messages
<input type="checkbox"/>	History
<input checked="" type="checkbox"/>	YB12163291 C1
<input type="checkbox"/>	YB12155744 C1
<input type="checkbox"/>	YB12209003 D3
<input type="checkbox"/>	YB12167238 D3
<input type="checkbox"/>	YB12167017 D1
<input type="checkbox"/>	YB12163257 RPT C1
<input type="checkbox"/>	YB12163291 C1
<input type="checkbox"/>	YB12155744 C1
<input type="checkbox"/>	YB12142448 C1
<input type="checkbox"/>	YB12146427 D3
<input type="checkbox"/>	YB12137044 D3
<input type="checkbox"/>	YB12137099 B4
<input type="checkbox"/>	YB12087001 A3
<input type="checkbox"/>	YB12089952 D1
<input type="checkbox"/>	YB12081589 D3
<input type="checkbox"/>	YB12074248 B4
<input type="checkbox"/>	YB12081519 A3
<input type="checkbox"/>	YB12021632 D1
<input type="checkbox"/>	YB12033754 D3

Generate Report File Preview PDF Close

Test Report

Patient ID: 010000234390J7
Patient ID 2:
Sample ID: 15002496KR
Test Type:
Sample Type: Specimen

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic

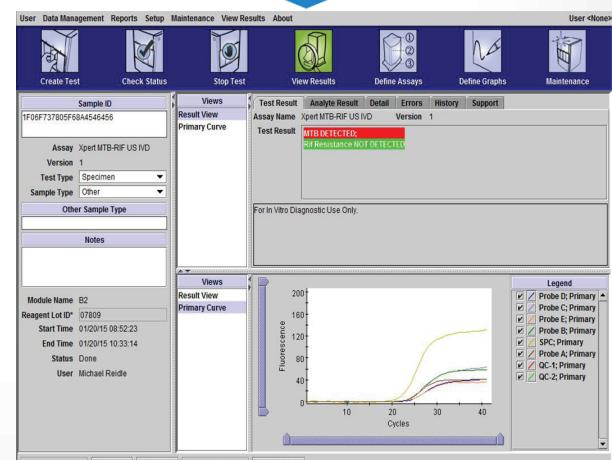
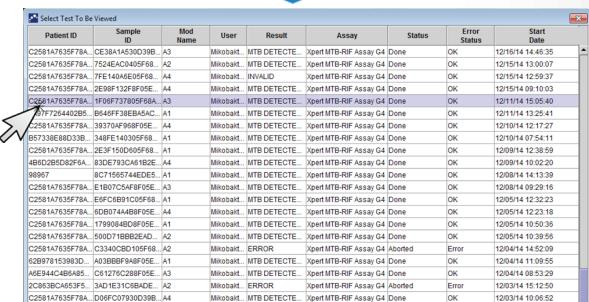
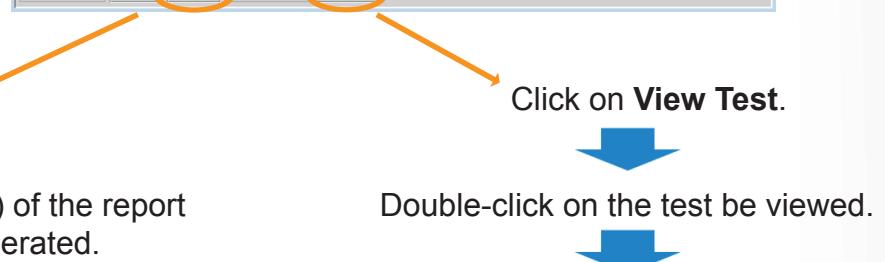
Test Result: MTB DETECTED LOW; Rif Resistance NOT DETECTED

Test and Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	27.6	193	POS	PASS
Probe C	27.5	165	POS	PASS
Probe E	28.4	148	POS	PASS
Probe B	28.0	132	POS	PASS
SPC	28.0	277	NA	PASS
Probe A	26.8	135	POS	PASS
QC-1	0.0	0	NEG	PASS
QC-2	0.0	0	NEG	PASS

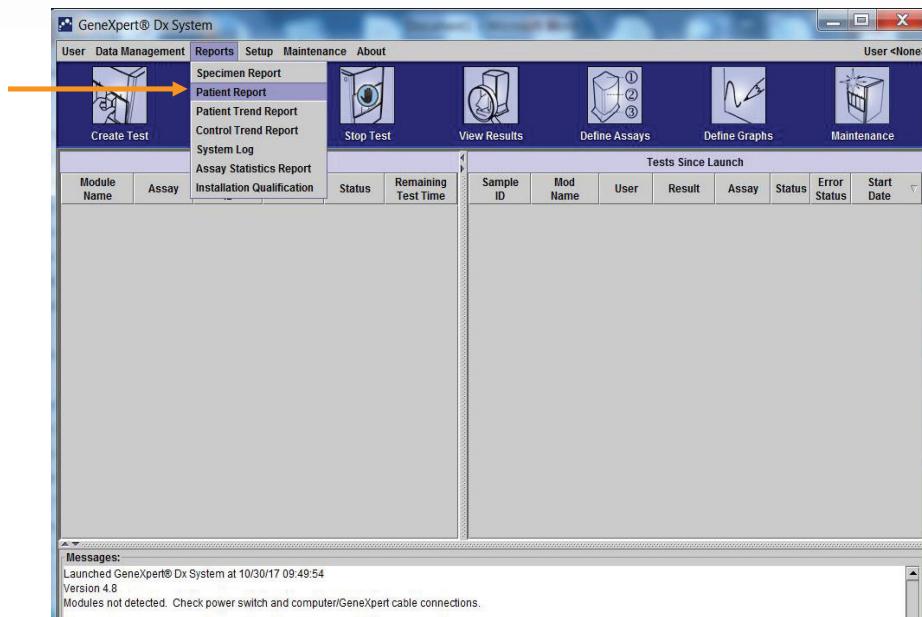
User: Mikrobakteriologijas Lab
Status: Done Start Time: 26/01/15 11:17:08
Expiration Date: 15/05/16 End Time: 26/01/15 12:57:46
S/W Version: 4.4a Instrument S/N: 702365
Cartridge S/N: 300008671 Module S/N: 630365
Reagent Lot ID*: 08202 Module Name: A4
Notes: Error Status: OK

Errors
<None>

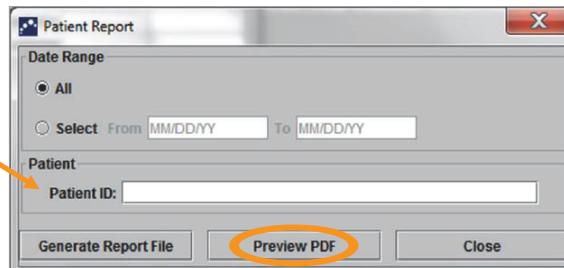


Patient ID Report (if applicable)

1. Select Patient Report



2. Enter the patient ID.

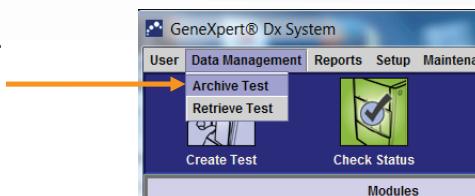


3. Click Preview PDF..



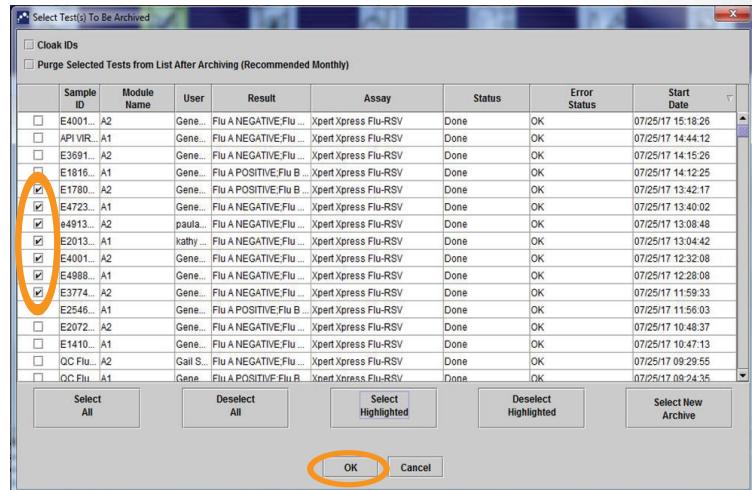
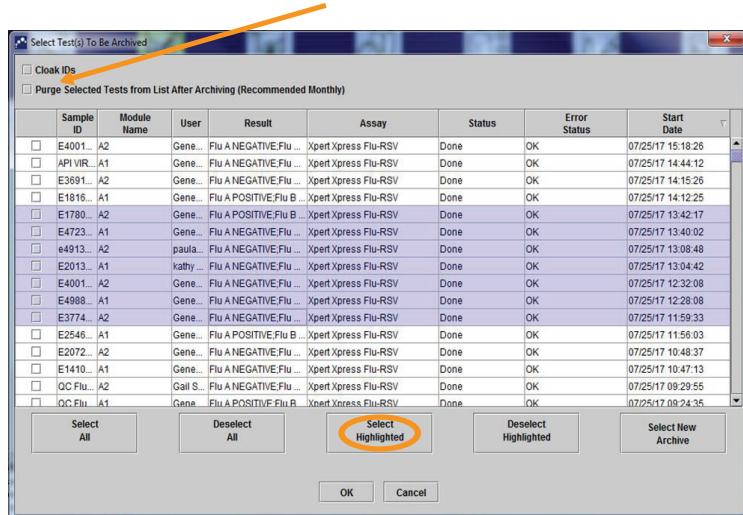
Archiving and Purging

1. Select Data Management and Archive Test.

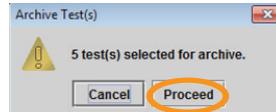


2. Highlight the tests to be archived. Click **Select Highlighted**, then click **OK**.

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

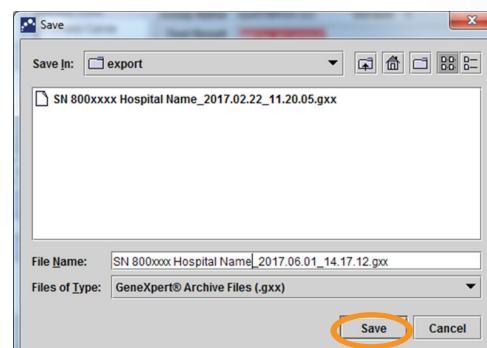


3. Click **Proceed**.



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**.

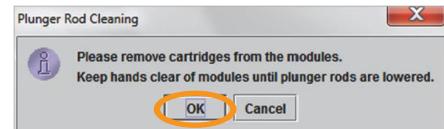
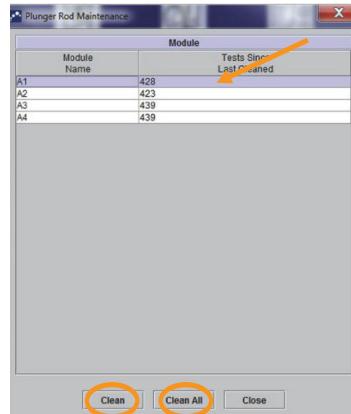
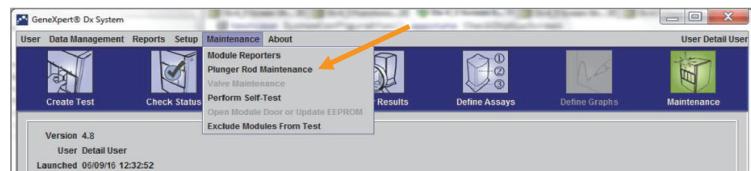
6. Copy archived data file to an external location.

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:

Technical Assistance

- Before contacting Cepheid Technical Support, collect the following information:
 - Product name
 - Lot number
 - Serial number of the System
 - Error messages (if any)
 - Software version and, if applicable, Computer Service Tag number
- Log your complaint online: <http://www.cepheid.com/us/support>

Technical Support Directory

Region	Telephone	Technical Support Email
US	+ 1 888 838 3222	techsupport@cepheid.com
Australia and New Zealand	+ 1800 130 821 (AU) + 0800 001 028 (NZ)	techsupportANZ@cepheid.com
Brazil and Latin America	+ 55 11 3524 8373	latamsupport@cepheid.com
China	+ 86 021 5406 5387	techsupportchina@cepheid.com
France	+ 33 563 825 319	support@cepheideurope.com
Germany	+ 49 69 710 480 480	support@cepheideurope.com
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