

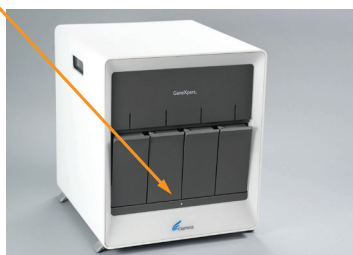
GeneXpert[®] Dx

Reference Guide

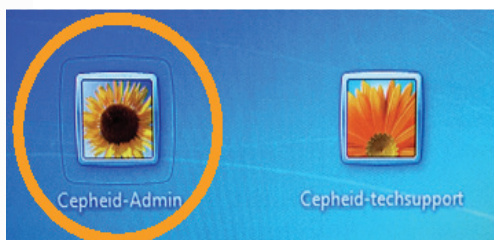


Starting up the system

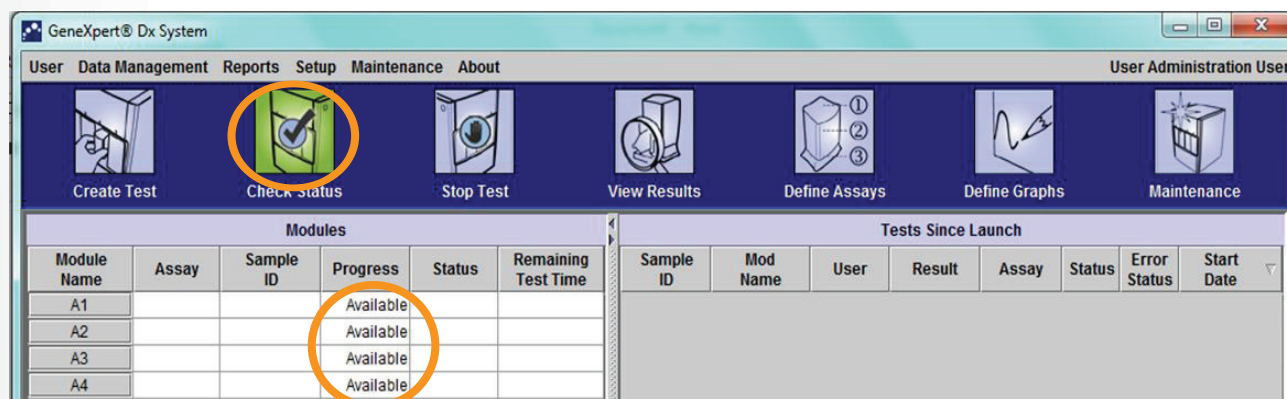
1. Turn the power switch on the instrument to the **ON** position.
The blue light on the front panel will light up.



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**.

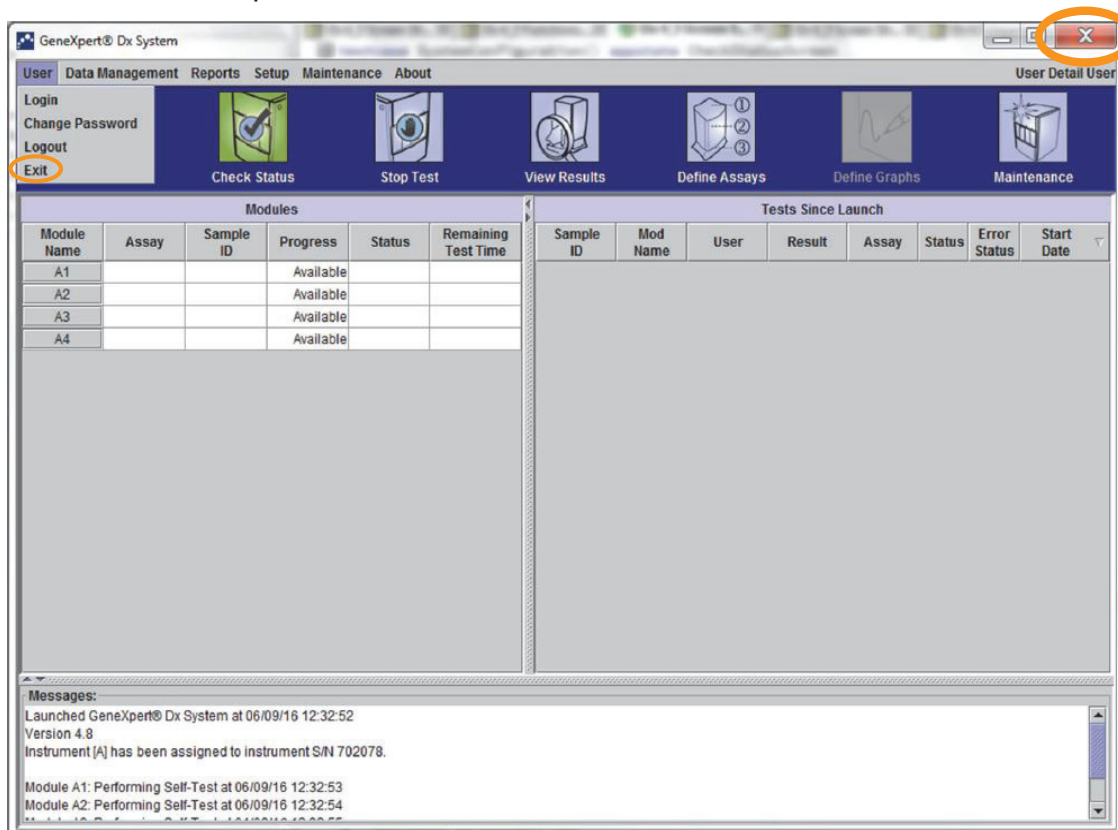


Shutting down the system

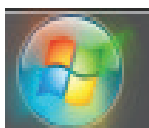
Note: Restart the system once per week.

When performing this task, make sure no tests are running.

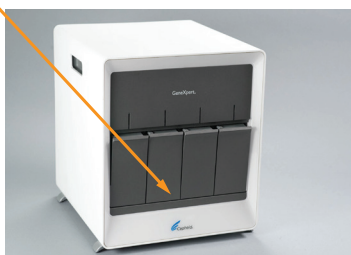
1. Exit the GeneXpert® Dx software.



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

A screenshot of the 'Create Test' dialog box in the GeneXpert software. The dialog box has a title bar that says 'Create Test'. It contains several input fields and dropdown menus. The 'Patient ID' field is empty, and the 'Sample ID' field contains '234567'. The 'Select Assay' dropdown is set to 'Xpert Assay 1'. The 'Select Module' dropdown is set to 'A2'. The 'Reagent Lot ID' field is empty, and the 'Expiration Date' field is set to 'YYYY/MM/DD'. The 'Cartridge S/N' field is empty. The 'Test Type' dropdown is set to 'Specimen'. The 'Sample Type' dropdown is set to 'Other', and the 'Other Sample Type' field is empty. There is a 'Notes' text area at the bottom. At the bottom of the dialog box are three buttons: 'Start Test' (highlighted with an orange circle), 'Scan Cartridge Barcode', and 'Cancel'. Two orange arrows point from the 'Patient ID' and 'Sample ID' labels in the list to their respective input fields in the dialog box.

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.



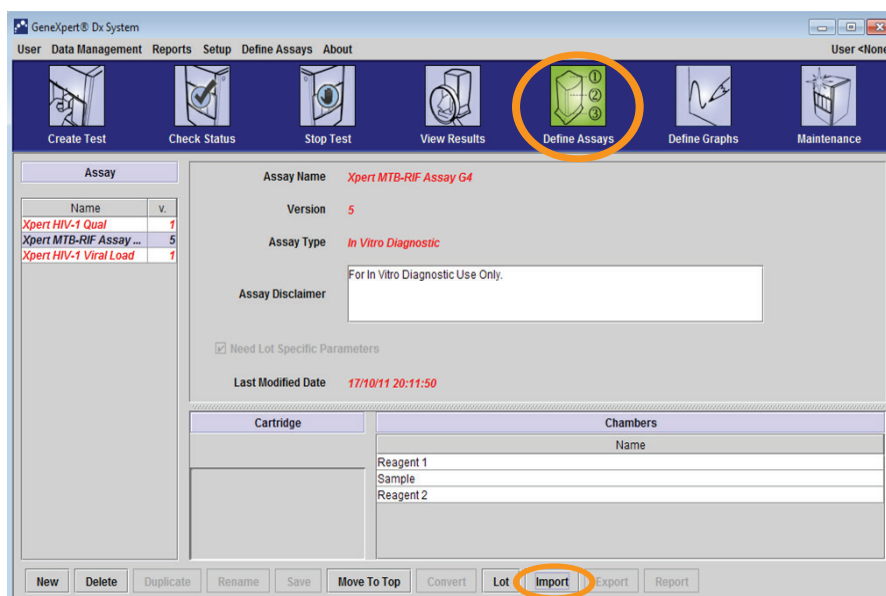
Loading Assay Definition File (ADF)

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.

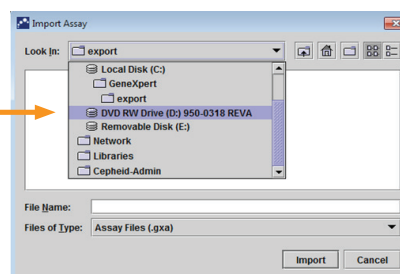


2. Click **Define Assays**.



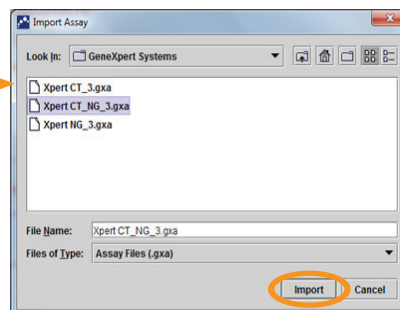
3. Click on **Import**.

4. Select the DVD drive.



5. Select **GeneXpert Systems** folder.

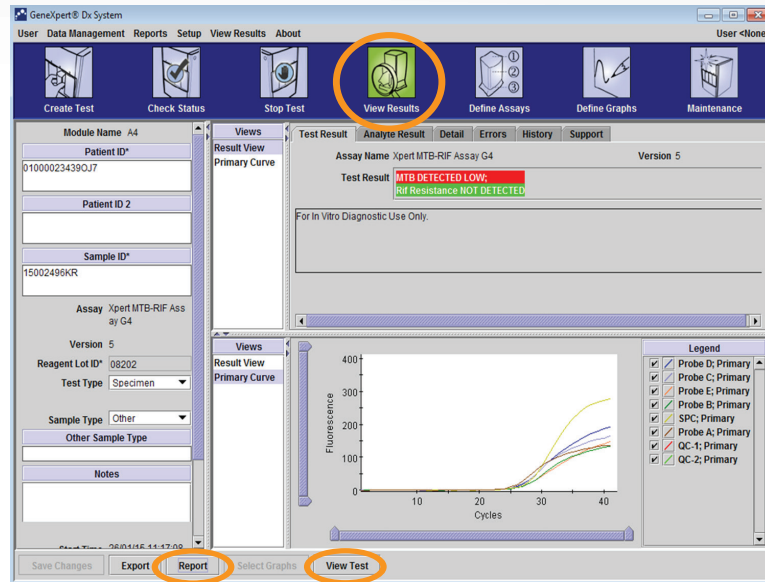
6. Select the .gxa file.



7. Click on **Import**.

View Results and Generate/Print a Report

Click on **View Results.**

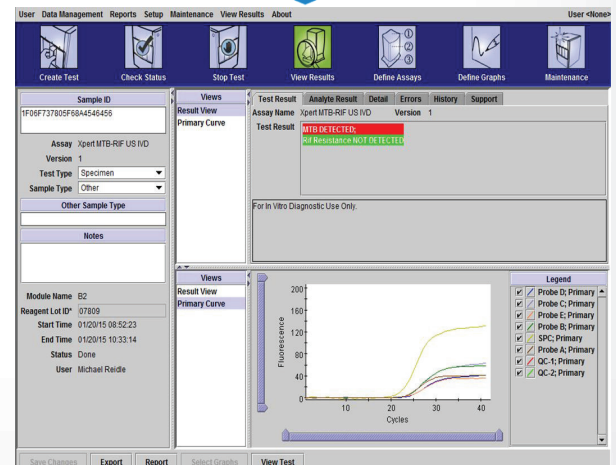
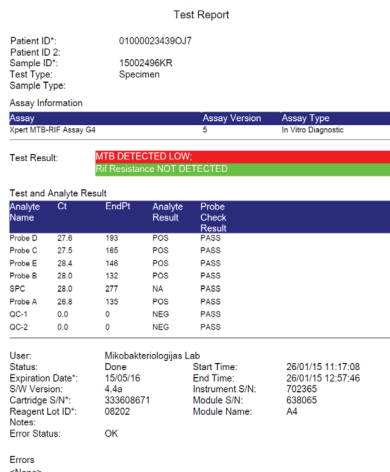
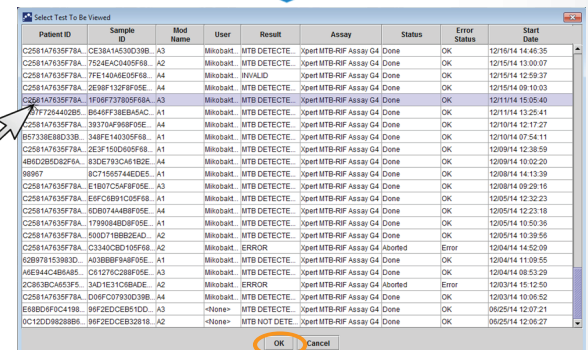
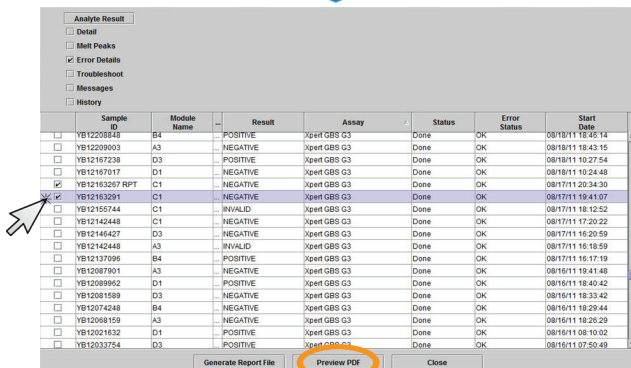


Click on **Report.**

Click on **View Test.**

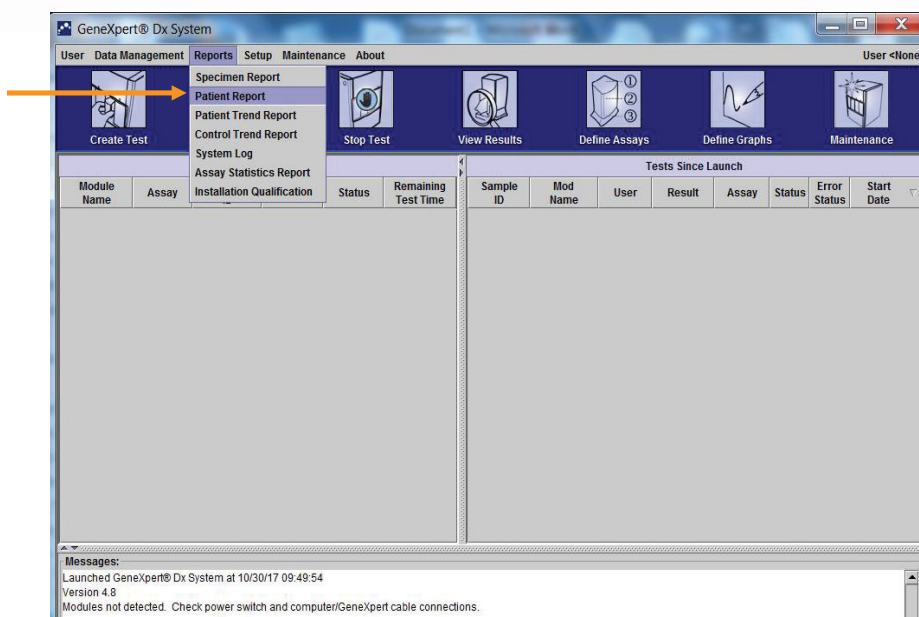
Click on the checkbox(es) of the report to be printed or generated.

Double-click on the test to be viewed.



Patient ID Report (if applicable)

1. Select Patient Report



2. Enter the patient ID.

Patient Report

Date Range

☒ All
☐ Select From MM/DD/YY To MM/DD/YY

Patient

Patient ID:

Generate Report File Preview PDF Close

3. Click Preview PDF..



Patient Report

Found Patient ID #2 = H112874895762R

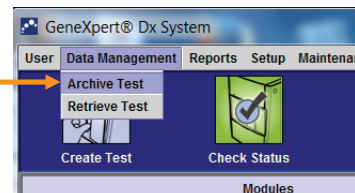
- 2 Test(s) Found -

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:	

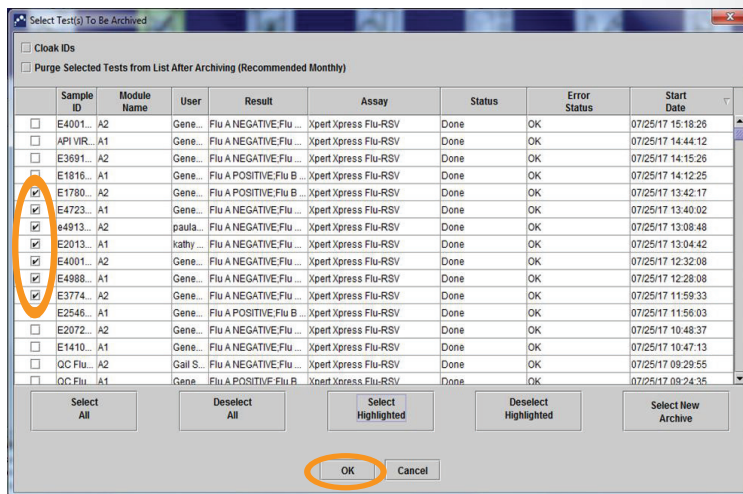
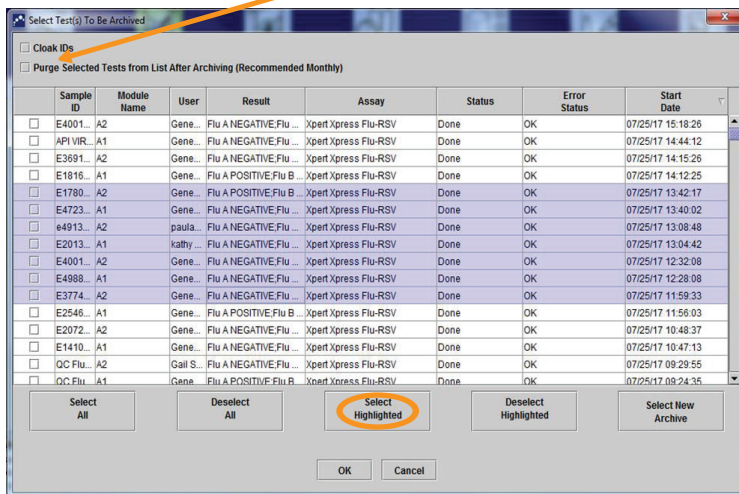
Archiving and Purging

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

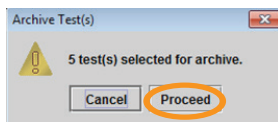


2. Highlight the tests to be archived. Click **Select Highlighted**, then click **OK**.

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

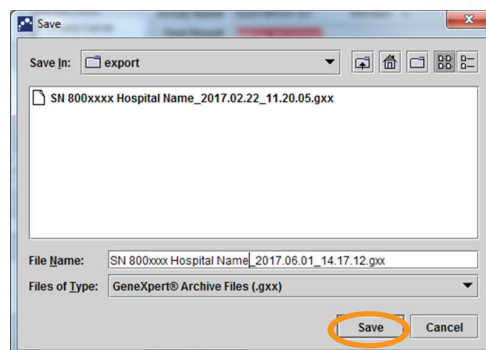


3. Click **Proceed**.

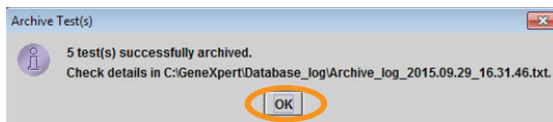


The file name is generated automatically.

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**.

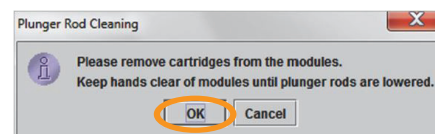
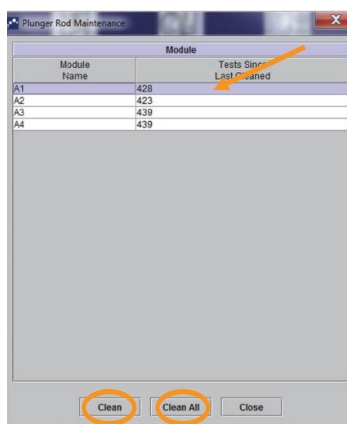
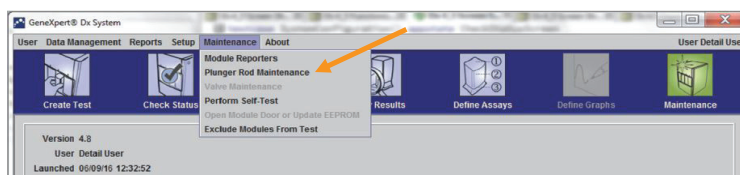
6. Copy archived data file to an external location.

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:

[illegible]

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
India, Bangladesh, Bhutan, Nepal, and Sri Lanka	+ 91 11 48353010	techsupportindia@cepheid.com
Italy	+ 39 800 902 567	support@cepheideurope.com
South Africa	+ 27 861 22 76 35	support@cepheideurope.com
United Kingdom	+ 44 3303 332 533	support@cepheideurope.com
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