GeneXpert[®] Dx [™] Reference Guide





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



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.

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

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.

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		Mod	lules		_	1		Te	ests Since L	aunch				
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	5		Available											
A1			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.

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	erforming Sel		9/16 12:32:53 9/16 12:32:54											100

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.

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Common GeneXpert Dx Menus

See Appendix A of the Operator Manual for the complete list

GeneXpert® Dx System

User Data Management Reports Setup Maintenance About

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.



	Create Test		Rectarded International			
3. Enter or verifiy the correct information for the following	Patient ID Sample ID	Patient ID				
sections (if applicable):	Sample io	Name		Version		
Patient ID	Select Assay	Xpert Assay 1			•	
Sample ID	Select Module	A2 🔻				
	Reagent Lot ID	Expiration	Date YYYY/MM/DD	Cartridge S/N		
	Test Type	Specimen	•			
4. Click on Start Test to begin test.	Sample Type Notes	Other	▼ Other Samj	ple Type		
		Start Test	Scan Cartridge Barcode	Cancel		

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

Close the module door until the green light stops blinking.



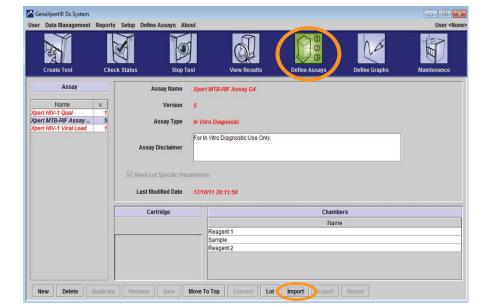
Loading Assay Definition File (ADF)

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.

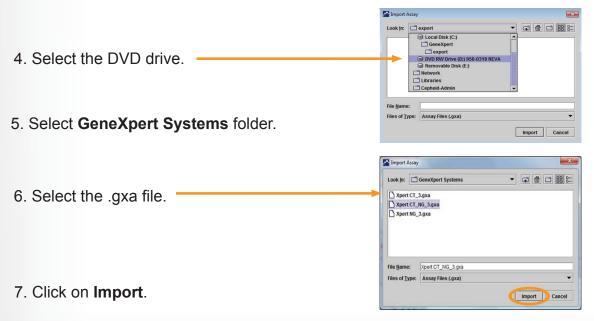
1. Insert the assay definition CD, located in the kit, into the computer's DVD drive.



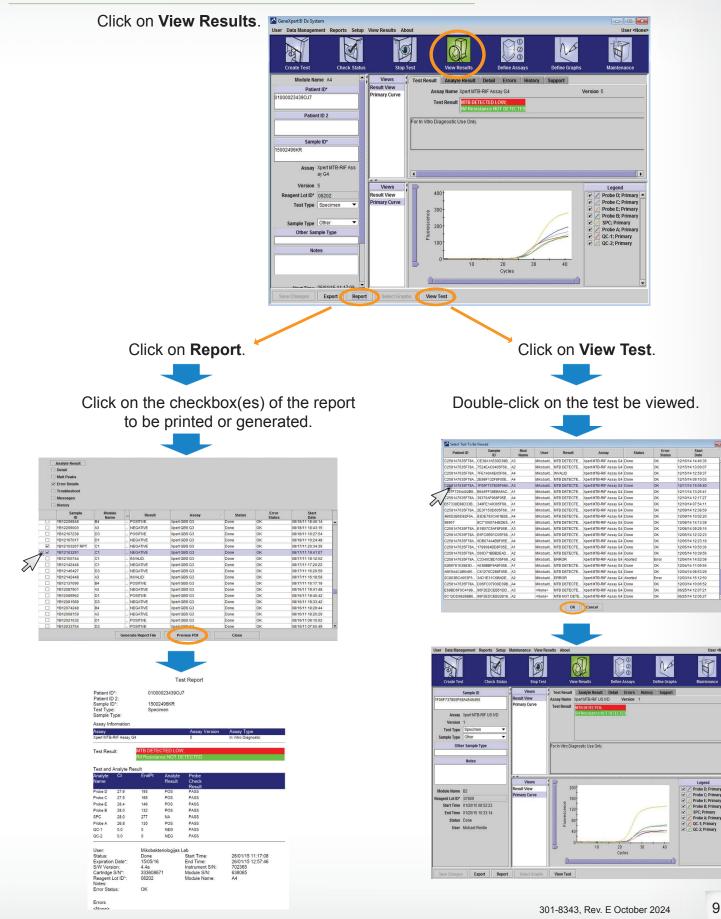
2. Click Define Assays.



3. Click on Import.



View Results and Generate/Print a Report



Patient ID Report (if applicable)

1. Select Patient Report	GeneXpert® Dx	System		Income Name			_ D _ X
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		Specimen Report Patient Report	To	A		n G	Î
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	Module	Assay Statistics Report ay Installation Qualification	Statue Remaining	Sample Mod	Tests Since	r r	Error Start
	Name Ass	ay installation Qualification	Status Test Time	ID Name	User Result	Assay Status	Status Date
	Messages:						
	Version 4.8	9 Dx System at 10/30/17 09:49:54					
	Modules not detected.	Check power switch and compu	iter/GeneXpert cable connecti	ons.			
2 Enter the nationt ID	Patient Repo	rt		X	<u>S</u>		
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	O Select Fro		o MM/DD/YY				
	Patient						
	Patient ID:]			
2. Oliok Browiew BDE	Generate Rep	port File	view PDF	Close			
3. Click Preview PDF.	Generate Rep	Pre	view PDF	Close			
		_					
		Patien	t Report				
	Found Patient ID #2	= H112874895762R					
		- 2 Test(s) Found -				
	Patient ID:	H112874895762R			<u></u>		
	Sample ID:	SD142231					
	Assay: Assay Version:	Xpert CDIFFICILE 3					
	Test Result:	NEGATIVE					
	Start Time: Test Type:	06/09/16 12:38:42 Specimen					
	User: Status:	Detail User Done					
	Notes:	Done					
	Patient ID:	H112874895762R			- 63		
	Patient ID: Sample ID:	SD142231					
	Assay: Assay Version:	Xpert BCR-ABL Monitor 1	IS				
	Test Result:	ERROR					
	Start Time: Test Type:	06/09/16 12:41:13 Specimen					
	User:	Detail User					
	Status: Notes:	Aborted					
	0755 U						

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.

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Sample ID	e	Module Name	User	Result	Assay	Status		Error Status	Start Date	-	Sam		User	Result	Assay	Statu	5	Error Status	Start Date
E4001				Flu A NEGATIVE;Flu		Done	ок		07/25/17 15:18:26		100 C 17 C 17 C 17 C 1		0.0000000000000000000000000000000000000	Flu A NEGATIVE;Flu	ALL STOLEN AND A PARTY OF A LATTAC	Done	ок		07/25/17 15:18
API VIR				Flu A NEGATIVE; Flu		Done	ок		07/25/17 14:44:12		API VI				Xpert Xpress Flu-RSV	Done	ок		07/25/17 14:44
E3691				Flu A NEGATIVE; Flu	1 - 24	Done	ОК		07/25/17 14:15:26		E369		Gene		Xpert Xpress Flu-RSV	Done	OK		07/25/17 14:15
E1816	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			Flu A POSITIVE;Flu B		Done	ок		07/25/17 14:12:25		E1816	100 J 100 L	10120000000000		Xpert Xpress Flu-RSV	Done	ок		07/25/17 14:12
E1780				Flu A POSITIVE; Flu B .		Done	OK		07/25/17 13:42:17		E1780		Gene		Xpert Xpress Flu-RSV	Done	OK		07/25/17 13:42
E4723				Flu A NEGATIVE;Flu		Done	OK		07/25/17 13:40:02		E4723		Gene		Xpert Xpress Flu-RSV	Done	OK		07/25/17 13:40
e4913				Flu A NEGATIVE;Flu		Done	OK		07/25/17 13:08:48		e4913		paula.		Xpert Xpress Flu-RSV	Done	OK		07/25/17 13:08
E2013 E4001				Flu A NEGATIVE; Flu		Done	OK OK		07/25/17 13:04:42		E2013		kathy		Xpert Xpress Flu-RSV Xpert Xpress Flu-RSV	Done	OK OK		07/25/17 13:04
E4001				Flu A NEGATIVE;Flu Flu A NEGATIVE;Flu		Done	OK OK		07/25/17 12:32:08	I I I I I I I I I I I I I I I I I I I	E400*		Gene		Xpert Xpress Flu-RSV Xpert Xpress Flu-RSV	Done	OK OK		07/25/17 12:32
E4988				Flu A NEGATIVE; Flu Flu A NEGATIVE; Flu	Xpert Xpress Flu-RSV Xpert Xpress Flu-RSV	Done	OK		07/25/17 12:28:08 07/25/17 11:59:33		E4988	tore and the	Gene	Flu A NEGATIVE; Flu		Done	OK		07/25/17 12:28
E2546	1000			Flu A POSITIVE; Flu B		Done	OK		07/25/17 11:59:33		E2546			and the second se	. Xpert Xpress Flu-RSV	Done	OK		07/25/17 11:59
E2040	-			Flu A NEGATIVE; Flu		Done	OK		07/25/17 10:48:37		E2072				Xpert Xpress Flu-RSV	Done	OK		07/25/17 10:48
E1410			10.000	Flu A NEGATIVE; Flu		Done	OK		07/25/17 10:47:13						Xpert Xpress Flu-RSV	Done	OK		07/25/17 10:48
QC Flu			- Contraction	Flu A NEGATIVE;Flu	and the second se	Done	OK		07/25/17 09:29:55						Xpert Xpress Flu-RSV	Done	OK		07/25/17 09:29
QC Flu				Flu A POSITIVE Flu B		Done	OK		7/25/17 09:24:35						Xnert Xnress Flu-RSV	Done	OK		07/25/17 09:24
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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**.



	Module	
Module Name	Tests Since Last O caned	
1	428	
2	423	
1 2 3 4	439	
4	439	
	(Chan A) Chan	Plunger Rod Cleaning Please remove cartridges from the modules. Keep hands clear of modules until plunger rods are lowere OK Cancel

- 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:	
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