GeneXpert[®] Dx

Beference 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.

ser Data M	lanagement	Reports Set	tup Maintenar	nce Abou	t						U	ser Admin	istration	n Us
Ast						S				Na		A A	D	
Create	Test	Check sta	itus	Stop Te	st	View Results	De	fine Assays	D	efine Graph	s	Maint	enance	
		Mod	ules			1		T	ests Since L	aunch				
Module Name	Assay	Sample ID	Progress	Status	Remaining Test Time	Sample ID	Mod Name	User	Result	Assay	Status	Error Status	Start Date	
A1			Available					do				e - 18		
and the second s			Available											
A2						2								
A2 A3			Available			8								

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.

GeneXpert	® Dx System		1	Concession in which the	and the second	Particular III		Council and	3 m 4 (7 h	posse (b., 1	1.00	-		X
User Data M	lanagement	Reports Se	etup Maintena	ance Abou	t							U	ser Detai	Use
Login Change Pass Logout	word	N		Þ		S				10		A H	D	
Exit		Check S	tatus	Stop Te	st	View Results	0	lefine Assays	D	efine Graph	IS	Maint	enance	
		Мо	dules			1		T	ests Since L	aunch				
Module Name	Assay	Sample ID	Progress	Status	Remaining Test Time	Sample ID	Mod Name	User	Result	Assay	Status	Error Status	Start Date	Ψ
A1			Available								10			
A2			Available											
A3			Available											
A4			Available		1									
Version 4.8 Instrument (A) has been as	signed to ins	09/16 12:32:52 trument S/N 702 9/16 12:32:53								aaannaa			
Module A1: P Module A2: P	erforming Sel	f-Test at 06/09												

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

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	100			**
Patient ID	Patient ID			
Sample ID	234567			
	Name		Version	
Select Assay	Xpert Assay 1			•
Select Module	A2 🔻			
Reagent Lot ID	Expiration Date	YYYY/MM/DD	Cartridge S/N	
Test Type	Specimen 🔻			
Sample Type	Other 💌	Other Sample Type		
Notes				
	Start Test Scan C	Cartridge Barcode C	Cancel	
	Patient ID Sample ID Select Assay Select Module Reagent Lot ID Test Type Sample Type	Patient ID Sample ID Sample ID Select Assay Select Module Reagent Lot ID Test Type Sample Type Notes	Patient ID Patient ID Sample ID 234567 Name Select Assay Xpert Assay 1 Select Module A2 Reagent Lot ID Expiration Date YYYY/MM/DD Test Type Specimen Sample Type Other Other Sample Type Notes	Patient ID Patient ID Sample ID 234567 Name Version Select Assay Xpert Assay 1 Select Module A2 Reagent Lot ID Expiration Date YYYY/MMDD Cartridge S/N Test Type Specimen Sample Type Other Other Sample Type Notes

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)

GeneXpert® Dx System

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.



 File Name:
 Xpert CT_NG_3.gra

 Files of Type:
 Assay Files (.gxa)

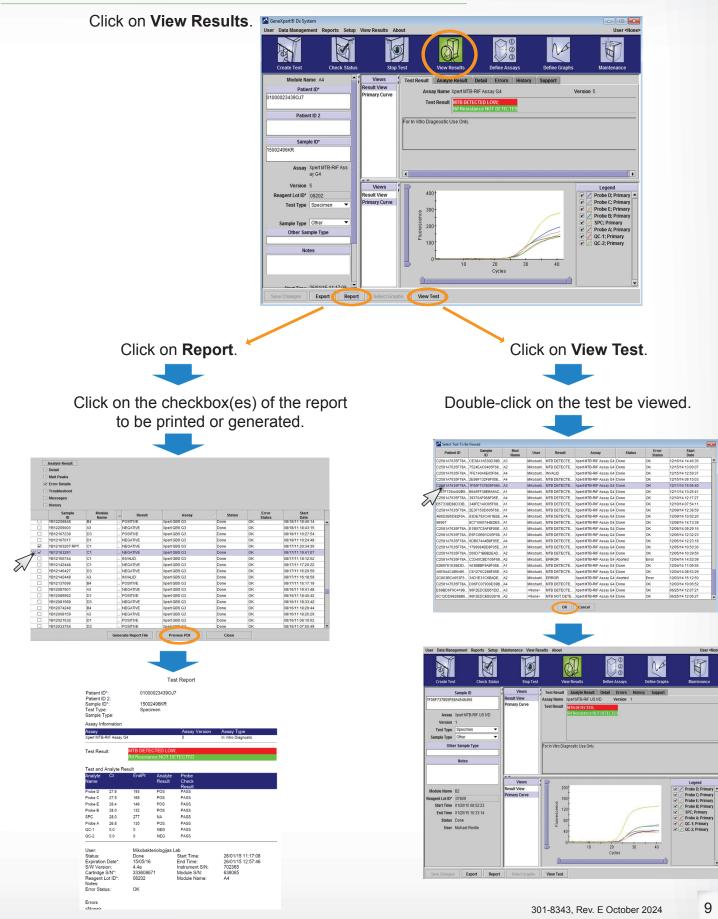
Import Cancel

- - -

er Data Management Reports Setup Define Assays Abou User <No 2. Click Define Assays. 0 2 Create Test Check Statu Stop Test View Re Assay Assay Name Xpert MTB-RIF Assay G4 Name ۷. Version 5 Xpert MTB-RIF Assay ... 5 Assay Type In Vitro Diagnostic For In Vitro Diagnostic Use Only Assay Disclaimer Last Modified Date 17/10/11 20:11:50 Cartridge Chambers Name Reagent 1 ample Reagent 2 Move To Top Convert Lot Import Export Report 3. Click on Import. New Delete Import Assa × Look in: export Cocal Disk (C:) Genexpert
 export
 DVD RW Drive (D:) 950-0318
 Removable Disk (E:) 4. Select the DVD drive. Remova
 Network
 Libraries
 Cepheid-A File Nan Files of <u>Type</u>: Assay Files (.gxa) 5. Select GeneXpert Systems folder. Import Cancel Mark Import Assay Look In: GeneXpert Systems • 🖬 🏠 🗂 🍀 🚝 6. Select the .gxa file. Xpert CT 3.gxa Xpert CT_NG_3.gxa Xpert NG_3.gxa

7. Click on Import.

View Results and Generate/Print a Report



Patient ID Report (if applicable)

1. Select Patient Report	GeneXpert® D	x System		- Marriel Ba		- II	_ D X
	User Data Manage	nent Reports Setup Mainter	ance About				User <nor< td=""></nor<>
		Specimen Report Patient Report		A		Na	The second secon
	Create Test	Patient Trend Report Control Trend Report	Stop Test	View Results	Define Assays	Define Graphs	Maintenance
		System Log Assay Statistics Report				Since Launch	Territer -
	Module As Name	say Installation Qualification	Status Remaining Test Time	Sample Mo ID Nar		sult Assay Statu	s Status Date
	Messages: Launched GeneXper	® Dx System at 10/30/17 09:49:54	4				
	Version 4.8	 Check power switch and complexity 		ctions.			1
2. Enter the nationt ID	Patient Repo	ort			×		
2. Enter the patient ID.	Date Range						
	IIA ®						
	O Select Fi	om MM/DD/YY	To MM/DD/YY				
	Patient						
	Patient ID:						
3. Click Preview PDF.	Generate Re	port File Pre	view PDF	Close			
S. Olicit Teview T DT.							
			t Report				
	Found Patient ID #2	= H112874895762R					
		- 2 Test(s) Found -				
	Patient ID: Sample ID:	H112874895762R SD142231					
	Assay: Assay Version:	Xpert CDIFFICILE 3					
	Test Result: Start Time:	NEGATIVE 06/09/16 12:38:42					
	Test Type: User:	Specimen Detail User					
	Status: Notes:	Done					
	8						
	Patient ID: Sample ID:	H112874895762R SD142231					
	Assay: Assay Version:	Xpert BCR-ABL Monitor	IS				
	Test Result: Start Time:	ERROR 06/09/16 12:41:13					
	Test Type: User:	Specimen Detail User					
	Status: Notes:	Aborted					

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.

ect Test(s) To Be An oak IDs urge Selected Test		After Arc	chiving (Recommende	d Monthly)						oak IDs Irge Selected	d Tests from Li	st After Ar	chiving (Recommende	d Monthly)				
Sample I	Module	User	Result	Assay	Status	I S	Error Status	Start Date	7	Sample	Module	User	Result	Assay	Statu	s	Error Status	Start
E4001 A2		Gene	Flu A NEGATIVE;Flu	Xpert Xpress Flu-RSV	Done	ОК		7/25/17 15:18:26		E4001	A2	Gene	Flu A NEGATIVE;Flu	Xpert Xpress Flu-RSV	Done	ОК		07/25/17 15:18
API VIR A1		Gene	Flu A NEGATIVE;Flu	Xpert Xpress Flu-RSV	Done	OK	07	7/25/17 14:44:12		API VIR	A1	Gene	Flu A NEGATIVE;Flu	Xpert Xpress Flu-RSV	Done	OK		07/25/17 14:44
E3691 A2		Gene	Flu A NEGATIVE;Flu	Xpert Xpress Flu-RSV	Done	OK	07	7/25/17 14:15:26		E3691	A2	Gene	Flu A NEGATIVE;Flu	Xpert Xpress Flu-RSV	Done	OK		07/25/17 14:15
E1816 A1		Gene	Flu A POSITIVE; Flu B	Xpert Xpress Flu-RSV	Done	OK	07	7/25/17 14:12:25		E1816	A1	Gene	Flu A POSITIVE;Flu B .	. Xpert Xpress Flu-RSV	Done	OK		07/25/17 14:12
E1780 A2		Gene	Flu A POSITIVE; Flu B	Xpert Xpress Flu-RSV	Done	OK	07	7/25/17 13:42:17		E1780	A2	Gene	Flu A POSITIVE; Flu B .	Xpert Xpress Flu-RSV	Done	OK		07/25/17 13:42
E4723 A1		Gene	Flu A NEGATIVE;Flu	Xpert Xpress Flu-RSV	Done	ОК		7/25/17 13:40:02		E4723		Gene	Flu A NEGATIVE;Flu	Xpert Xpress Flu-RSV	Done	OK		07/25/17 13:40
e4913 A2				Xpert Xpress Flu-RSV	Done	OK		7/25/17 13:08:48		e4913		-		Xpert Xpress Flu-RSV	Done	OK		07/25/17 13:08
E2013 A1				Xpert Xpress Flu-RSV	Done	OK		7/25/17 13:04:42		E2013			Flu A NEGATIVE; Flu		Done	OK		07/25/17 13:04
E4001 A2				Xpert Xpress Flu-RSV	Done	OK		7/25/17 12:32:08		E4001				Xpert Xpress Flu-RSV	Done	OK		07/25/17 12:32
E4988 A1				Xpert Xpress Flu-RSV	Done	OK		7/25/17 12:28:08		E4988			Flu A NEGATIVE;Flu		Done	OK		07/25/17 12:28
E3774 A2		00/00/00/00/00/00	Flu A NEGATIVE;Flu	Xpert Xpress Flu-RSV	Done	OK		7/25/17 11:59:33		E3774		-	Flu A NEGATIVE;Flu		Done	OK		07/25/17 11:59
E2546 A1				Xpert Xpress Flu-RSV	Done	OK		7/25/17 11:56:03		E2546		-		. Xpert Xpress Flu-RSV	Done	OK		07/25/17 11:56
E2072 A2 E1410 A1				Xpert Xpress Flu-RSV Xpert Xpress Flu-RSV	Done	OK OK		7/25/17 10:48:37 7/25/17 10:47:13		E2072 E1410				Xpert Xpress Flu-RSV Xpert Xpress Flu-RSV	Done	OK OK		07/25/17 10:48
QC Flu A1				Xpert Xpress Flu-RSV	Done	OK		7/25/17 10:47:13		QC Flu			Flu A NEGATIVE; Flu		Done	OK		07/25/17 10:47
QC Flu A1				Xpert Xpress Flu-RSV	Done	OK		7/25/17 09:29:55				_	Flu A POSITIVE Flu B		Done	OK		07/25/17 09:29
Select			Deselect	Select		Deselect				Select			Deselect	Select		Deselect		
All			All	Highlighted		Highlighted		Select New Archive		All			All	Highlighted		Highlighted		Select Net Archive
				OK Cance		re Test(s) 5 test(s)) selected for	or archive.						OK Canc	el			
	3.	C	lick Pr					or archive.					ave	OK Canc				×
	3.	CI	lick Pro			5 test(s)		or archive.				Sav	ve in: 🗀 export	OK Canc				
	Tł	he		oceed. me is gei	Archiv	5 test(s)	cel Proc	er archive.				Sav	ve (n: export SN 800xxxx Hosp Name: SN 80		 _11.20.05.gxx 017.06.01_14			
	Tł 4.	he Cl	file nai	ne is gei ve.	Archiv	5 test(s) Cance Ca	utoma	r archive. Reed		re log 20)15.09.29 1	Sav	re (n: export SN 800xxxx Hosp Name: SN 80 s of Type: Gene2	ital Name_2017.02.22	 _11.20.05.gxx 017.06.01_14	.17.12.9x		

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 Cleaned	
1	428		
2	423		
2 3 4	439		
4	439		
			Plunger Rod Cleaning Please remove cartridges from the modules. Keep hands clear of modules until plunger rods are lower 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.





Not	es:	



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