# GeneXpert<sup>®</sup>System with Touchscreen

## ■ 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

NOTE: The instructions here are a summary from the GeneXpert System with Touchscreen Operator Manual and are for reference only. For complete and detailed instructions, refer to the operator manual.

NOTE: These steps must be done in the order below for database synchronization

1. Press the switch on the back of the instrument to the **ON** position. The blue light on the front panel will light up.



2. Press the switch on the back of the touchscreen unit to the **ON** position.



4. Enter your User Name and Password. Touch **Login**.

Login to Cepheid OS	
User Name gxuser	
Password	
Login	
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3. Wait for the system to boot. The software will start in kiosk mode.



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



### Shutting down the system

NOTE: Shut down the system once per week. When performing this task, make sure no tests are running.

1. Touch :> Shutdown



2. After screen turns black, press the switch on the back of the touchscreen unit to the **OFF** position.



3. Press the switch on the back of 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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### **Starting a Test**

1. Touch **Start Test** on the Modules screen.

Cepheid.			Modu	ules Re	esults	Reports	Tasks
		<b>L</b> Ø				Star	rt Test
A1	0	A2	0	A3	0	A4	C
Avail	able	Availa	able	Avail	able	Ava	ailable

3. Scan the barcode on the cartridge then touch **Continue**.



 Verify the information is correct and touch Confirm. Touch (Edit) if not.

Patient ID	Sample ID	Scan Cartridge	Confirm	Load Cartrid
		Cartridge	S/N	
Patient ID		/ 251162	261	
		Reagent I	Lot ID	
Patient ID 2		/ 05464		
		Cartridge	Exp. Date	
Last Name		/ 04/08/2	9	
		Test Nam	0	
First Name		/ DEMO	_ Xpress Flu-RSV v.1	
Sample ID				
2023.02.23_15.24		/		
	Cancel		Back	Co

2. Enter the Patient ID (if applicable), and Sample ID.



4. If prompted, enter your user name and password and touch **Login**.

Cepheid. Aberer wy. Login to Cepheid OS	
User Name gxuser	
Password	
Login	
	C

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



7. Close the module door and wait until the green light stops blinking.

### **Viewing Results and/or Printing a Report**

1. Touch the **Results** tab.

esults				View Report	Actions	Ŧ
Q Search Patient/S	sample ID	I	Select Date Ra	ange	Reset Filte	r
Test Name	▪ Test Ty	pe Y	Q, User ID		Q, Reagent Lot	
Patient ID -	Sample ID -	Test Name *	Completion Date & Time *	User ID -	Result -	
<ul> <li>F5292A2CC449DDE</li> <li>182E7DB60FC592A</li> <li>1C</li> </ul>	29094422BDDAE40 2BF0267C27	Xpert TV v.1	05/13/21 23:34:28	genexpert	TV NOT DETECTED	>
3705C2D14C4E0F7 4E2BA46C3955CBA 5B	5C46818120780159 9D59A3A92	Xpert TV v.1	05/13/21 21:57:33	genexpert	TV NOT DETECTED	>
<ul> <li>EBC887D66681651</li> <li>F2A98D8AB06FF1E</li> <li>C</li> </ul>	0 2D143C21CF140D1 AE4A82A424	Xpert TV v.1	05/13/21 20:55:14	genexpert	TV NOT DETECTED	>
	0BCC46D6AFA3A34 BEBEBA76E0	Xpert C.diff-Epi v.2	05/13/21 20:39:11	genexpert	See Result	>

2. Select the test to be viewed.

Cer	oheid.			Modules	Resul	ts	Reports	s Tasks	:
Res	ults					Viev	v Report	Actions -	•
ş	Q Search Patient/Sar	mple ID			Select Date	Range		Reset Filter	
Test	Name	▪ Test Typ	le	•	Q User ID			Q Reagent Lot	
	Patient ID ~	Sample ID -	Test Name ~		Completion Date & Time ~	U	ser ID *	Result -	
	F5292A2CC449DDB 182E7DB60FC592A 1C	29094422BDDAE40 2BF0267C27	Xpert TV v.1		05/13/21 23:34:28	ge	nexpert	TV NOT DETECTED	>
	3705C2D14C4E0F7 4E2BA46C3955CBA 5B	5C46818120780159 9D59A3A92	Xpert TV v.1		05/13/21 21:57:33	ge	nexpert	TV NOT DETECTED	,***
	EBC887D666816510 F2A98D8AB06FF1E C	2D143C21CF140D1 AE4A82A424	Xpert TV v.1		05/13/21 20:55:14	ge	nexpert	TV NOT DETECTED	, 1
		0BCC46D6AFA3A34 BEBEBA76E0	Xpert C diff-Epi v 2		05/13/21 20:39:11	ge	nexpert	See Result	>
59 Re	sult(s)		IK K	Page 2 of 12	> >I				
01/25/23	13:47:26		)	User: genexpert					*

3. Touch **View Report**. The report opens as a printable PDF.

lodule A1		Xpert Xpress CoV-2 plus v.1	Module A1	Copheid. Test	Report Report R Diagnostic Test	Service D No.	
Patient ID		SARS-CoV-2 NEGATIVE	Patient ID	Test Information			
Sample ID	NEG		Sample ID	Patient D Surrole Rr. MID	Test Type: Sp Completion Time: 120	ecimen	
Test Type	Specimen		Test Type	Test Name: Xpert Xpress CoV-2 plus w1			
Reagent Lot	00100		Reagent Lot	Test Result	Analyte Result	ts	
Start Date & Time	12/02/21 15:49:26		Start Date 5 Time	Results	Analyto Name	Ct	
Completion Date P Time	1202/24 46:40:22		Start Date & Time	SARS-COV-2 NEGATIVE	8 N2	0.0	
completion pare & rime	120221 10.10.32		Completion Date & T		RURP	0.0	
User	Jane Doe		User		SPC	30.2	
Notes	Edit		Notes	Additional Information Use: Jane Boe Instrument Ure 742011 SW Version: 5.3 Module Name: A.3 Module SNR 723450 Respert (url 10) 00100			
est Methodology: RT-PCR Fo ise under the Emergency Usi	r In Vitro Diagnostic Use Only. For Authorization (US).		Test Methodology: RT- use under the Emerger	Cartridge Site 418295645 Cartridge Exp. Dete: 1225/52 System Name: Cartopart System with Text Statu: Dene Dene Statu: One Dene Statu: ON Sate Wannahmer If POS Sate Status Cartopart Status			

### **Archiving and Purging**

1. Touch the **Tasks** tab on the Home screen, then touch **Archive Tests**.

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atabase Maintenance Instrumer	nt Maintenance Technical Support Packag
9.	RE \$

2. Tests are selected by default. Exclude any from the archive by unchecking its left box.

<	Archive Tests		302 /	Archive Reminder S	ettings	Archive (60)
5	Search Patient/Sample	10		🛗 Select Date Range		Reset Filter
Test	Name	▼ Test Type	* Q	User ID	Q, Re	aagent Lot
	Patient ID *	Sample ID ~	Test Name *	Completion Date & Time *	User ID ¥	Result *
<	BB15A9B1343CA6F0 635A67089A31E144	1343CA6F0635A6708 9A31E144	Instrument Functional Test v.4	07/08/21 15:09:47	genexpert admin	NO RESULT
M	1F817F8322C2EB423 BB6E9891D00F26E	B08052BE05DE7224 A72F77A0D	Xpert TV v.1	05/14/21 05:22:30	genexpert	TV NOT DETECT
		1B866223726C909AA 96AB6369	Xpert C.diff-Epi v.2	05/14/21 05:06:57	genexpert	See Result
2		0813178E8FEE21223 B7193425	Xpert C.diff-Epi v.2	05/14/21 05:04:28	genexpert	See Result
		C5E383B02EC9293C D12C3BEED	Xpert C.diff-Epi v.2	05/14/21 04:20:35	genexpert	See Result

3. Touch Archive.

**Check** Purge Selected Tests after archiving.

Note: The file name is generated automatically and can be found in the folder C:\GeneXpert\ export.

Cepheid.	Modules Results Reports	Tasks
< Archive	Confirm Files to Archive	Archive (60)
Search F	60 test(s) selected for archive.	Reset Filter
Test Name	File Location C:\GeneXpert\export\GeneXpert\® System with Touchscreen_2023.01.25_13.03.0	ent Lot
Patient ID *	1.nxx	Result -
BB15A9B13- 635A67089A	Change Location	NO RESULT
☑ 1F817F8322 BB6E9891D	Additional Options	IV NOT DETECTED
8	Cloak Sample ID, Patient ID, Patient ID 2, Patient Name, and Notes Vuge selected tests after archiving (Recommended Monthly)	See Result
- 5	*	See Result
	Cancel Confirm	See Result
60 Result(s)	IC C Page 1 of 12 > >I	1000
01/25/23 13:03:24	User. genexpert	ň

4. Confirm files to be archived and Save files. Then touch OK to close the window.

Confirm Files Durger   Patter   System with Touchscreen 2023 013 fz_130.41 30.xx.   System with Touchscreen 2023 013 fz_130.41 30.xx.   State Sta	Cepheid.	Modules Results Reports Tests X Archive Reminder Settings	Tasks			Cepheid.	M Tests	odules Results	Reports Settings	Tasks Archive (60) Reset Filter
BBEERROTT         Cancel         Confirm         See Result           00 Results)         C4523300020000000000000000000000000000000	C         Search F           Test Name         E           Patient ID =         BB15A9613           GS3A87089A         1F817F8322	Confirm Files to Purge 60 test(s) successfully archived and can be found at C1GeneXpertlexport/GeneXpertle System with Touchscreen_2023.01.25_13.04.13.ncc. A total of 60 test(s) have been selected to be purged. Test(s) can be retrieved if needed. Would you like to continue?	Reset Filter ent Lot Result ~ NO RESULT	C:\GeneXper Locations Local Drive (C.) Reports (R) Reports (R)	Name GeneXpert PC_2021 07 08_13 GeneXpert PC_2021 07 16_16 GeneXpert PC_2021 07 16_16	Test Name Patient ID 0 001540013 001540013 001540013 001540013 001540010 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	60 test(s) successfully purged.		ок	NELO New IT - NO RESULT IV NOT DETECTED See Result
Of Results)         K < Page 1 of 12         XI         File Name         File Type           60 Results)         Ubscreen_black         File Type         GeneXpetB System with Touchscreen_black.0125_13.03.28         GeneXpetB Active File ("nor," goal)         +	BB6E5691D	Cancel Confirm	See Result See Result		GeneXpert PC_2021.00.16_07.	60 Results) 01/25/23 13 04 45	COSE BASINGUE CARRING D13C308EED         Xpert C diff Epr v2           IK         K         Pap           01/25/23 12 04 12         NXXX File	05/1421 0420:35 ge 1 of 12 > >1 generated 550 KB	3	See Result
	60 Result(s) 31/25/23 13:04:30	URAURED ic C Page 1 of 12 > 31 User greenped		File Name GeneXpert® System v	with Touchscreen_2023.01.25_13.03.2	26	File Type GeneXpert® Archive Files (*.nxx, *.goo	) ~		

5. Copy archived data file to an external location, if needed.

### **Cleaning Plunger Rod and Cartridge Bay**

#### CAUTION: Do not spray directly inside the instrument.

Materials Required:

- 70% ethanol or denatured ethanol (70% ethanol containing 5% methanol and 5% isopropanol)
- 1:10 dilution of household bleach (0.5% final chlorine concentration)
- Lint-free wipes
- Institution mandated Personal Protective Equipment (PPE)
- 1. Touch **Tasks** on the Home screen then touch **Instrument Maintenance**.
- 2. On the Instrument screen, touch **Plunger Rod Maintenance**.



- 3. On the next screen, touch the check box of the module to be cleaned then touch **Clean**.
- 4. A new screen appears with instructions to open the selected module door and remove any cartridges from the modules.
- 5. After removing any cartridges, touch **Continue**. A new screen appears with instructions to clean the plunger rods and module bays, touch **Continue**.







- Moisten a lint-free wipe with a 1:10 dilution of household chlorine bleach. Wipe plunger rod and entire cartridge bay interior with diluted bleach 3 times, allowing the bleach to remain for 2 minutes each time.
- 7. Moisten a lint-free wipe with 70% ethanol or denatured ethanol.
- 8. Wipe plunger rod and entire cartridge bay interior with the ethanol solution to remove bleach residue.
- 9. After cleaning, return to the Plunger Rod Cleaning Instructions screen. Manually close module doors and touch **Continue**.
- 10. Touch **OK** to acknowledge cleaning is completed.
- On the Plunger Rod Maintenance screen, touch Cancel and then select Modules to return to the Modules screen.

### Loading Assay Definition File (ADF)

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

(ADFs are available on CD)

1. If using a CD, plug the external DVD drive into the touchscreen unit.

Insert the assay definition file CD into the external DVD drive.

 On the touchscreen, touch : > Settings > Test Menu.

- 3. On the Test Menu screen, touch **Import Test**.
- 4. Navigate to the DVD and to the folder containing the ADF files. Locate and touch the ADF (.gxa/.nxa) file for your instrument. The test name appears in the filename field. *If ADF was downloaded directly from website, navigate to folder where the ADF file was saved.*
- 5. Touch **Open** to import the file into the system.

The new test name and version number appear in the Test list.

Locations	Name	Date Modified	Туре	Size
📇 Local Drive (C:)	In training	07/06/23 09:45:52	File Folder	
요 CDRom Drive (D:)	Xpress SARS-CoV-2_Fu_RSV plut_1 ges	09/14/21 11:08:46	GXA File	6 MB
ile Name		File Type		

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Cepheid.	Modules	Results	Reports	Tasks	1
Settings		_			
General	Reports		Test Menu J		
QC Lockout	Host 		File Locations		
Barcode Scanner	Security				
3/23 11:20:38	User: Genespert1!				

Ce	pheid.	Modules	Results	Reports	Tasks
<	Test Menu			Import Test	Delete Test
\$	Q. Search By Test Name				
	Test Name -	Test Version *	Test Type *		
	Xpert Xpress Flu-RSV	5	In Vitro Diagn	ostic	>
	Xpress SARS-CoV-2_Flu_RSV plus	1	in Vitro Diagn	ostic	>
2 Re	suff(s)				

Notes		





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