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# **DESCRIPTION OF PROCEDURE REVISION**

Name of procedure:

AHC.M992 Cepheid GeneXpert® Dx System Maintenance with Form: AG.F408 GeneXpert System Preventive Maintenance Log

**Description of change(s):** 

Added Addendum B : Delete Host Orders to the SOP Added to Weekly maintenance on Maintenance log, AG.F408

Document your compliance with this training update by taking the quiz in the MTS system.



# **GeneXpert System Preventive Maintenance Log**

Shady Grove Medical Center 

White Oak Medical Center

Month:	Year:
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Instrument Serial Number:

To clean or disinfect a surface, wipe it with a 1:10 dilution of household chlorine bleach solution and then wipe again with 70% ethanol or isopropyl alcohol.

Frequency	Task	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Clean Work Area						6	0.																								
Daily	Close all Module Doors							~	2																							
	Discard Used Cartridges									20																						
	Tech code										V																					
Weekly	Delete Host Orders	Date	e:		Т	ech:			Da	te:	~	K Te	ch:			Date	e:		Т	ech:			Date	e:		Т	ech:					
Weekiy	Power down the GeneXpert Computer	Date	e:		Т	ech:			Da	te:		∕∕ Te	ecn <sup>.</sup>	K.		Date	e:		Т	ech:			Date	e:		Т	ech:					
	Power down the GeneXpert Instrument	Date	e:		Т	ech:			Da	te:		Te	ech:	$\diamond$	Ż	Date	e:		Т	ech:			Date	e:		Т	ech:					
Monthly	Archive Tests	Date	Date: Tech:											° C	<u>Cy</u>																	
	Purge Tests	Date	e:		Т	ech:										<u> </u>	4															
Quarterly	Replace Fan Filters	Date	e:		Т	ech:																										
Quartony	Clean plunger rod and cartridge bays	□ C	heck	c if qu	larte	rly m	naint	is no	t du	е			lf qu Date	iarte e per	rly m form	aint. ed:	is dı	ue, th	en:	Т	ech											
Weekly Review by	Clean instrument surface	c	heck	c if qu	larte	rly m	naint	is no	t du	e			lf qu Date	iarte e per	rly m form	aint. ed:	is dı	ıe, th	en:	Т	ech											
	•	Date	e:		Т	ech:			Da	te:		Τe	ech:			Date	e:		T	ech:			Date	e:		Te	ech:					

Supervisory review: \_\_\_\_\_ Date:

AG.F408.2

Revised 6/2023

# AHC.M992 Cepheid GeneXpert® Dx System Maintenance

### Copy of version 2.0 (approved, not yet effective)

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Needed On or Before	7/3/2025	Organization	Adventist HealthCare				
Effective Date	8/1/2023						

#### **Approval and Periodic Review Signatures**

Туре	Description	Date	Version	Performed By	Notes
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Approval	Laboratory Operations Director	7/3/2023	2.0	Robert SanLuis	
Approval	Microbiology Director	6/29/2023	2.0	Vittal Ponraj	M
Approval	Lab Director	11/10/2021	1.0	Nicolas Cacciabeve	
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Approvals and periodic reviews that occurred before this document was added to the MediaLab Document Control system may not be listed.

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**Version History** 

Version Status

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0.0	Retired	First version in Document Control	11/16/2018	7/25/2018	11/10/2021

#### **Linked Documents**

• AG.F408 GeneXpert System Preventive Maintenance Log



Non-Technical SOP

Title	Cepheid GeneXpert® Dx System	n Maintenance
Prepared by	Leslie Barrett	Date: 4/24/2018
Owner	Ron Master	Date: 4/24/2018

Laboratory Approval		
Print Name and Title	Signature	Date
Refer to the electronic signature page for		
approval and approval dates.		
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## 1. PURPOSE

This procedure describes the general maintenance for the Cepheid GeneXpert® Dx System.

#### 2. SCOPE

This procedure applies to the Cepheid GeneXpert® Dx System.

PDD,

## **3. RESPONSIBILITY**

Core Laboratory personnel are responsible for performing daily, weekly, monthly (archiving data excluded), and quarterly tasks.

The Microbiology technical director or designee is responsible for performing data archive, data purging and as needed tasks.

#### 4. **DEFINITIONS**

None

# 5. **PROCEDURE**

## A. Daily Tasks

1. Cleaning the Work Area

Clean the work area daily using good laboratory practices to avoid contamination of specimens or reagents. Wipe surface of BSC first with 10% bleach. Allow to dry and then remove any bleach residue using 70% ethanol.

- Close Module Doors Check that all module doors are closed daily to avoid contamination of the modules.
- 3. Discard Used Cartridges Discard used cartridges from the GeneXpert Dx system modules and on the surrounding work surraces. Place in biohazard trash.

# B. Weekly Tasks

- 1. Delete Host Orders (see Addendum B)
- 2. MAKE SURE ALL TESTS HAVE BEEN COMPLETED. The system may not be shut down while tests are running.
- 3. Power Down the System
  - a. The GeneXpert computer and instrument hould be powered down once per week to refresh the system. This action clear out unwanted temporary files and guards against computer memory corruption to prevent a malfunction of the system.
  - b. To exit the GeneXpert Dx software, in the GeneXpert Dx System window, on the User menu, click Logout.
  - c. Power down the computer
  - d. Power down the instrument
  - e. Wait two (2) minutes, then restart the instrument
  - f. Restart the computer
  - g. Start the GeneXpert program

# C. Monthly Tasks

1. Archiving the Tests

Archiving tests allows you to move your data and, if desired, free up space in the database. You can archive multiple tests at a time. In addition to serving as a safe-keeping mechanism, you can provide the archive files to Cepheid for analysis when troubleshooting. The archive process creates a copy of the test and saves the data in a .gxx file.

To archive the test data:

a. In the GeneXpert Dx System window, on the Data Management menu, click Archive Test. The Select Test(s) To Be Archived dialog box appears.

# Adventist HealthCare

Site: Shady Grove Medical Center, White Oak Medical Center

Title: Cepheid GeneXpert® Dx System Maintenance

	T Guone io	ID	Name	User	Result	Assay	Status	Status	Date
П	1112874895762R	SD142231	A1	Detail User	ERROR	Xpert BCR-ABL Monitor IS	Aborted	Error	06/09/16 12:41:
П	1112874895762R	SD142231	A1	Detail User	NEGATIVE	Xpert CDIFFICILE	Done	ок	06/09/16 12:38:
П	1351890382682T	HG656788	К3	Detail User	HIV-1 DETECTE	HIV-1 Quant IUO CE	Done	ок	06/08/16 15:47:
] n	negative control	negative control	K4	Detail User	HIV-1 NOT DET	HIV-1 Quant IUO CE	Done	ок	06/08/16 15:45:
л н	1351890386682R	FT343558	K2	Detail User	HIV-1 DETECTE	HIV-1 Quant IUO CE	Done	ок	06/08/16 15:42:
П	4351890382682T	HG656788	A2	Administration	HIV-1 DETECTE	HIV-1 Quant IUO CE	Done	ок	06/08/16 14:57
л н	1351890386682R	FT343557	A3	Administration	HIV-1 DETECTE	HIV-1 Quant IUO CE	Done	ок	06/08/16 14:55
л н	1351890377714R	HA245614	A1	Detail User	ERROR	Xpert CDIFFICILE	Done	Error	06/29/16 15:56
и н	4351890377714R	HA245621	A1	Detail User	NO RESULT	Xpert CDIFFICILE	Done	Load Error	06/29/16 15:56
П	1351875882682R	TT555698	B3	Basic User	ERROR	HIV-1 Quant IUO CE	Aborted	Error	09/16/16 14:57
л н	1351890382682R	TG478589	82	Administration	HIV-1 NOT DET	HIV-1 Quant IUO CE	Done	ок	09/16/16 14:52
л н	1351890345682R	CR538763	B4	Administration	MTB NOT DETE	Xpert MTB-RIF US IVD	Done	ок	09/16/16 13:39
л н	139590382682R	KW630987	B3	Administration	MRSA NEGATIV	Xpert SA Nasal Complet	Done	ок	09/16/16 13:38
ПН	1351873382682R	GH487365	A3	Administration	MRSA NEGATIV	Xpert SA Nasal Complet	Done	ок	09/16/16 13:36
л н	1351898782682R	SR543267	A2	Administration	MRSA POSITIVE	Xpert SA Nasal Complet	Done	ок	09/16/16 13:34
	12540002026020	DUMEEROZ	00	Administration	HIDOA NECATIV	Vest C4 Masel Complet	Dees	OK	00146146.42.22

- b. Select the test(s) you want to archive. Click the check box that is adjacent to each test you wan to archive. You can select the individual tests one-by one, or select a large number of tests by clicking one of the following buttons at the bottom of the Select Tests To Be Archived screen:
  - Select All Selects all of the tests in the table.
  - Select Highlighted Selects the tests you highlighted.
  - Select New Archive Selects only the tests that have not been archived before.
  - Note: You can also hold the Shift or Ctrl keys to highlight continuous and discontinuous multiple tests on the Select Tests To Be Archived screen.

After selecting tests on the Select Tests To Be Archived screen, click one of the following buttons to deselect some or all tests:

- Deselect All Deselects all of the test selections in the window.
- Deselect Highlighted Deselects the tests you highlighted.

In addition to selecting the tests to archive, there are two check boxes located near the top of the Select Tests To Be Archived screen that may need to be selected:

- Cloak IDs Select this check box if you want to send Cepheid Technical Support some data in question, but want to hide patient-sensitive information. (This option will not be used unless data is requested by Cepheid Technical support.)
- Purge Selected Tests from List After Archiving (Recommended monthly) Select this check box to free up space on the computer. After the selected tests have been successfully archived, they are removed from the database.
- c. Click OK. A message appears and asks you to confirm the archive request.
- d. Click Proceed. The Save dialog box appears. Click Cancel to not perform the Archive Test operation.
- e. Locate and select the folder in which you want to store the archive (.gxx) file, type a name for the archive file, and then click Save.

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- f. After the files have been archived, the Archive Test(s) dialog box is displayed indicating that the tests have been successfully archived. Click OK.
- h. If you selected the Purge Selected Tests from List After Archiving (Recommended Monthly) option, a Purge Test(s) dialog box appears indicating that the selected test(s) will be deleted from the database. Click Yes to confirm or click No to not delete the selected test(s) from the database.

Cautions:

- The default archive location is the export folder which is located on the • computer hard drive. To guard against loss of data, the files in the export folder should be periodically copied to a different computer or server To configure the archive location, see Section 2.11.2, of the Operator Manual.
- If data is archived and purged from the database, then the archive files will • only include the Patient ID and not the patient demographic data. Therefore, it will not be available again and cannot be used in future connectivity solutions.

# 2. Replace GX-XVI Far Filters

Clean the fan filters more ly or more frequently, if necessary. There are four (4) fan filters which are located on the back of the GXXVI.

- a. Supplies needed
  - Replacement fan filters Filter Part Number: 001-1271 •
  - Paper towels •
  - Water
  - Gloves
- b. MAKE SURE ALL TESTS HAVE FINSHED RUNNING.
- c. Exit the GeneXpert Dx software. In the GeneXpert Dx System window, on the User menu, click Logout.
- d. Turn off the GX-XVI R1 computer and the instrument.
- e. If there is not sufficient rear access to the instrumen (dide the instrument around so you can easily access the filter covers.
- f. Gently take the fan filter guard off by unsnapping the guard from the fan housing, and place it aside for the remainder of the procedure for filter removal and cleaning.
- g. Remove the dirty filter(s) for cleaning.
- h. Place a clean filter into the fan filter guard.
- Position the fan filter guard and filter into place as a unit. Press the sides of i. the guard firmly onto the fan housing until the grip snaps securely onto the fan. Press the bottom of the guard until the grip snaps securely onto the fan.
- Repeat above steps for the remaining fan filters (three additional filters). j.
- k. Clean the old filters by rinsing with tap water. Place each cleaned filter between two paper towels and allow it to air-dry.
- After the filters are dry, store them to use the following month, when you next 1. remove the filters for cleaning.

# **D.** Quarterly Tasks

- 1. Clean Plunger Rod and Cartridge Bay
  - a. Supplies needed

- 1:10 dilution of household chlorine bleach (used within 1 day of preparation)
- 70% ethanol or denatured ethanol (70% ethanol containing 5% isopropanol and 5% methanol)
- Lint-free wipes
- Gloves
- Face protection
- b. Remove cartridge(s) from the module(s) to be cleaned.
- c. In the GeneXpert Dx System window, click the Maintenance icon.
- d. The Maintenance screen is displayed.
- e. Click on **Maintenance** on the Menu Bar, select **Plunger Rod Maintenance**. The **Plunger Rod Maintenance** dialog box is displayed.
- f. In the Module table, select the module(s) to be cleaned and then select Clean or Clean All. The Plunger Rod Cleaning dialog box is displayed.
- g. Ensure that there are no cartridges in any of the modules, and click OK.
- h. In the Plunger Roc Maintenance dialog box, the Clean button name changes to Move Up (if the Clean All button is clicked, it changes to Move Up All). In the instrument, the plunger rod(s) in the selected module(s) (or all modules if the Clean All button is clicked) lowers into the cartridge bay(s).
- i. Clean the plunger rod(s) and cartridge bay(s) as follows:
  - 1) Thoroughly moisten a hrt-free wipe with a 1:10 solution of household chlorine bleach.
  - 2) Vigorously wipe the plunger red with the lint-free wipe. Wipe hard enough to remove the black debris that accumulates on the plunger rod. Using the same lint-free wipe, wipe the walls, ceiling, corners and edges of the cartridge bay, then wipe the insi te of the door and the top lip of the door and discard the lint-free wipe.
  - 3) Wait 2 minutes after wiping with the bleach solution.
  - 4) Use a new lint-free wipe thoroughly moistened with the 1:10 bleach solution and wipe the plunger rod, 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 wipe.
  - 5) Wait 2 minutes after wiping with the bleach solution.
  - 6) Using another new lint-free wipe thoroughly moistened with the 1:10 bleach solution, wipe the plunger rod, walls, ceiling, corners and edges of the cartridge bay. Wipe the inside of the door and the top lip of the door and discard the lint-free wipe.
  - 7) Wait 2 minutes after wiping with the bleach solution.
  - 8) Thoroughly moisten a lint-free wipe with the 70% ethanol solution.
  - 9) Use the lint-free wipe thoroughly moistened with the 70% ethanol solution to remove all residual bleach. Wipe the plunger rod, 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.
- j. After the plunger rod(s) and cartridge bay(s) have been cleaned, return to the Plunger Maintenance dialog box and select the Move Up button. The plunger rod(s) move(s) back up to the resting position.
- k. Click Close to close the Plunger Maintenance dialog box.
- l. Manually close the instrument module door(s).

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- 2. Clean the Instrument Surfaces
  - a. For routine cleaning of the instrument surfaces:
    - 1) Thoroughly moisten a lint-free wipe or paper towel with the 70% ethanol solution.
    - 2) Wipe all surfaces outside the instrument. Change lint-free wipes or paper towels frequently while wiping.
    - 3) Move the GeneXpert instrument and wipe the table surfaces underneath and around the instrument. Change lint-free wipes or paper towels frequently while wiping.
    - 4) Discard used wipes or paper towels into biohazard trash.
  - b. In case of a spill:
    - 1) Thoroughly moisten a lint-free wipe or paper towel with the 1:10 bleach solution.
    - 2) Wipe affected surfaces on the instrument. Change wipes or paper towels frequently while wiping.
    - 3) Allow the bleach solution to remain on the surfaces at least two minutes but no longer than five minutes.
    - 4) Repeat Step 1 through Step 3 two more times for a total of three times.
    - 5) Thoroughly moister a lint-free wipe or paper towel with the 70% ethanol solution.
    - 6) Wipe affected surfaces on the instrument. Change wipes or paper towels frequently while wiping.
    - 7) Discard used wipes or paper towe's into biohazard trash.

# E. As Needed Tasks

1. Print System Log Report (only required if requested by Cepheid Technical Support for troubleshooting a problem)

The System Log reports can be used to provide incidents of instrument module self-tests and errors to Cepheid when a module failure has been encountered.

- a. In the GeneXpert Dx System window, click **Reports** on the menu bar, and then click System Log. The System Log Report window appears
- b. Specify the criteria (Date Range, Modules, Show) to view the trends of interest. Refer to Operators manual for detailed instructions.
- c. When finished selecting the log criteria, click one of the following buttons:
  - Generate Report File—Creates a PDF file and saves it to the location you specify.
  - Preview PDF—Creates a PDF file and displays the file in the Adobe Reader window.
- d. When finished printing, click **Close** to close the report window.
- 2. Back Up Database (only required if system settings are changed) You should back up the entire database periodically and store the backup on a different computer or on a different storage medium. If the computer fails, you can restore the entire database using the backup copy.
  - a. Select Database Backup on the Database Management window.
  - b. Click Proceed.

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- c. Locate and select the folder in which you want to store the backup file, type a name for the backup file (or use the default file name), and then click Save. The backup process creates a .zip file in the location you specified.
- d. The backup process varies, depending on the amount of data in the database and the speed of the computer (older computers may take longer). For large database backups, a progress bar will be displayed. When the backup process is finished, a process completion message appears

### F. Documentation

Tasks performed by laboratory personnel are recorded on the GeneXpert System Preventive Maintenance Log.

### G. Annual Task

Annual instrument maintenance is performed by a Cepheid service engineer.

### H. Interface Communication Issues

Refer to the addendum

### 6. **RELATED DOCUMENTS**

GeneXpert System Preventive Mainter ance Log (AG.F408)

### 7. **REFERENCES**

GeneXpert Dx System Operator Manual, Cepheid, 301-0045, Rev. L August 2017

# 8. **REVISION HISTORY**

Version	Date	Reason for Revision	Revised By	Approved By
0	11/5/21	Header: Changed WAH to WOMC Sections 5 & 9: Added interface communication issue resolution Footer: Updated prefix to AHC	M Sabonis	R Master
1	6/28/23	Added Addendum B- Delete Host Orders AG.F408 updated weekly task	M Sabonis	V Ponraj

# 9. ADDENDA AND APPENDICES

- A. Troubleshooting Interface Communication Issue
- B. Deleting Host Orders

### Addendum A

# **Troubleshooting Interface Communication Issue**

### Host is disconnected or communication buffer is almost full.

If this Cepheid Error message displays, then

Upload	Upload Result To Host		
ġ.	Cannot upload result. Host is disconnected or communication buffer is almost full.		
	ОК		

• Contact LIS support at the site of the instrument issue. If LIS support is not on site, then call Cepheid technical support. They can remote in and address the issue.

## Action for LIS support on site:

Step 1. Enable /disable host

- a. In the GeneXpert software, click on the Stup drop down menu and select System Configuration.
- b. Go to the Host Communication Settings tab. Uncheck Enable Host Communication and click OK at the bottom to close the window.
- c. Exit software and relaunch 30 seconds later.
- d. Go back to Setup and select System Configuration again
- e. Go to the Host Communication Settings tab.
- f. Check Enable Host Communication to reset the LIS connection from the GeneXpert side.
- g. If this doesn't resolve the issue then try recycling Sunquest connection. If recycling Sunquest interface doesn't resolve issue with communication then proceed to Step 2, Clearing ES buffer.

#### Step 2. Clearing ES buffer

- a. To clear out buffer, navigate to C: GeneXpert\LIS\esbuffer\OUT and delete all files present in the out buffer folder.
- b. If still not communicating, then try recycling Sunquest connection.

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### Addendum B

### Instructions on how to **Delete Host Orders** on the Cepheid

Orders for testing on the Cepheid are downloaded to the instrument when you scan the Sunquest barcode (Host query). To configure this, the <u>Cepheid instrument test</u> (cartridge) is associated with one of the individual test on Sunquest.

Example:

Sunquest test	Cepheid Instrument Test ( cartridge)	
INFUA	XFLUABRSV (Influ a/B and RSV)	
INFUB	SARSCOV2FLURSV (Covid, influ A/B and	
	RSV)	
COVNT	COV2PLUS (Covid only)	

1. So if the Sunquest order code is IRCPCR then Sunquest will download the following orders(see below)

	NO.
Sunquest test	Opwnload Cepheid Test ( cartridge)
INFUA	XFWABRSV (Influ a/B and RSV)
INFUB	SARSCOV2FLURSV (Covid, influ A/B and RSV)
COVNT	COV2PLUS (Covid only)
RSV	Not mapped

- 2. When the Cepheid cartridge SARSCOV2FLURSV is scanned for test IRCPCR, Cepheid will grab the "SARSCOV2FLURSV" order. Therefore the two other orders will remain on the Cepheid.
- 3. These remaining tests build up on the Cepheid to a point where the buffer cannot hold any new orders. Therefore when you scan the Sunquest barcode then Cepheid cannot find the order.

To prevent this from happening the HOST TEST ORDERS must be deleted.

### Below are steps on how to delete the orders.

### 1. Select Create Test



2. Click Cancel in the Scan Sample Barcode window



3. Click Delete All Host Test Orug

Delete All Host Tes rders Test Code [XFLUABRSV] cannot be processed. Test Code [XFLUABRSV] cannot be processed 4. Window displays to confirm you want to delete. Click on YUS



- 5. Orders are now deleted.
- 6. Click on Cancel to close window

ample ID	Name	Version
ect Assay	<none></none>	•
ct Module	-	
gent Lot ID	Expiration Date YYYY/MDD	Cartridge S/N
Test Type	Specimen	
ample Type	Other Sample Type	
Notes		

Note: Orders in window once deleted will still display. You will NOT see an empty window after deletion of orders.