

PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC81100 – GeneXpert Dx System Maintenance	Policy Number: 29-10-V1
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s):	
Effective Date: 19/01/2021	Next Review Date: 19/01/2023
Issuing Authority: Director of Health Services	Date Approved: 19/01/2021
Accreditation Canada Applicable Standard: N/A	

GUIDING PRINCIPLE:

Although the GeneXpert Dx System is designed to prevent cross-contamination and ensure accurate results, the instrument should be checked and cleaned periodically as a precautionary measure.

PURPOSE/RATIONALE:

This standard operating procedure describes the daily, weekly, monthly and as-required maintenance requirements for the GeneXpert Dx System.

SCOPE/APPLICABILITY:

This procedure applies to Medical Laboratory Technologists processing specimens using the GeneXpert Dx System.

REAGENTS and/or MEDIA:

- 10% sodium hypochlorite solution (prepared within 1 day)
- 70% isopropyl alcohol
- Accel TB wipes

SUPPLIES:

- Orange biohazard wipes or paper towels
- Gauze squares
- Kimwipes

EQUIPMENT

- GeneXpert Dx System

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SPECIAL SAFETY PRECAUTIONS:

Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potential infectious materials or cultures.

- Ensure that appropriate hand hygiene practices be used.
- Lab gown must be worn when performing activities with potential pathogens.
- Gloves must be worn when direct skin contact with infected materials is unavoidable.
- Eye protection must be used when there is a known or potential risk of exposure of splashes.
- All procedures that may produce aerosols, or involve high concentrations or large volumes should be conducted in a biological safety cabinet (BSC).
- The use of needles, syringes and other sharp objects should be strictly limited.

All patient specimens are assumed to be potentially infectious. Routine Practices must be followed. Since viable micro-organisms are used, all cultures must be handled with appropriate precautions. All equipment in contact with cultures should be decontaminated by appropriate methods.

QUALITY CONTROL:

- Record all actions and results of maintenance checks on MIC81110-Maintenance Record-GeneXpert

PROCEDURE INSTRUCTIONS:

Step	Action
Daily GeneXpert Maintenance	
1	Disinfect work area: <ul style="list-style-type: none">• Thoroughly wipe all interior surfaces of the biosafety cabinet, chair, laptop keyboard, barcode scanner and bench tops with Accel TB wipes

Step	Action
Weekly GeneXpert Maintenance	
1	Reboot the GeneXpert instrument, software and laptop: <ul style="list-style-type: none">• Wait for the instrument to finish all processes and ensure all cartridges are removed from the modules• Quit the GeneXpert Dx System software: On the User menu, click Exit• If the Test Archive Reminder dialogue box appears, select NO• Log off and power down the laptop• Turn OFF the power to the GeneXpert. The power switch is located at the back of the instrument. Wait 2 minutes• Turn ON the power to the GeneXpert• Power up the laptop. The password on the laptop is covid19• Select the GeneXpert software. Enter the username admin1 and the password covid19• If the Test Archive Reminder dialogue box appears, select NO

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Step	Action
Monthly GeneXpert Maintenance	
1	<p>Disinfect GeneXpert surfaces:</p> <ul style="list-style-type: none"> • Dampen gauze square with the 10% sodium hypochlorite solution and wipe the instrument surfaces (instrument top, sides, back and doors) • Wait 5 minutes • Dampen gauze square with 70% isopropyl alcohol and wipe the instrument surfaces • Repeat a second time with new gauze square
2	<p>Disinfect cartridge bay interior:</p> <ul style="list-style-type: none"> • Open all module doors • Dampen a Kimwipe with the 10% sodium hypochlorite solution • Wipe the surfaces inside the cartridge bay, the inside of the door and the top lip of the door with the Kimwipe • Do NOT touch the slit at the back • Wait 5 minutes • Dampen a Kimwipe with 70% isopropyl alcohol • Wipe the same surfaces with the Kimwipe • Repeat a second time with a new Kimwipe • Close the module door and repeat for all modules in the instrument
3	<p>Disinfect plunger rod:</p> <ul style="list-style-type: none"> • In the GeneXpert Dx System menu, click Maintenance on the toolbar • From the Maintenance menu, click Plunger Rod Maintenance. The Plunger Rod Maintenance dialog box appears • In the Module table, click Clean All to clean all modules simultaneously. The Plunger Rod Cleaning dialog box appears • Follow the directions in the dialog box, and then click OK • The plunger rods will lower in each module • Dampen Kimwipes with the 10% sodium hypochlorite solution (one for each plunger rod to be cleaned) • Gently wipe each plunger rod with one of the Kimwipes. Use a fresh Kimwipe for each plunger rod • Wait 5 minutes • Dampen Kimwipes with 70% isopropyl alcohol (one for each plunger rod to be cleaned) • Wipe each plunger rod with one of the Kimwipes. Use a fresh Kimwipe for each plunger rod • Repeat a second time with a new Kimwipe • In the Plunger Rod Maintenance dialogue box, click Move Up All and the plunger rods will move back up to the resting position
4	<p>Clean fan filters:</p> <ul style="list-style-type: none"> • Quit the GeneXpert System software: On the User menu, click Exit • Log off and power down the laptop • Turn OFF the power to the GeneXpert • Gently slide the instrument around so that you can easily access the filter cover(s) and gently take the fan filter and guard off the housing

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	<ul style="list-style-type: none"> Wash the filter in running tap water to remove dust buildup. Place the filter between 2 orange wipes or paper towels to dry Install the clean, dry filter in the fan guard and replace the guard onto the fan assembly Repeat this procedure for the remaining fan filters if applicable Turn ON the power to the GeneXpert Power up the laptop. The password on the laptop is covid19 Selected the GeneXpert software. Enter the username admin1 and the password covid19
5	<p>Archive tests:</p> <ul style="list-style-type: none"> In the GeneXpert Dx System menu, click Data Management From the Data Management menu, click Archive Test. The Select Test to Be Archived dialogue box appears Click Select All and then click OK Click Proceed. The file name is generated automatically Click SAVE, then click OK
6	<p>Database management:</p> <ul style="list-style-type: none"> Insert the correct removable drive into the USB port On the User menu, click Exit. When asked Do you want to perform Database Management tasks, select Yes Select Database Backup, and then click Proceed From the Save In drop down menu, select the removable drive and then select Save

Step	Action
Yearly GeneXpert Maintenance	
1	<p>Calibration of the GeneXpert:</p> <ul style="list-style-type: none"> Cepheid will notify Microbiology of the need to re-calibrate the modules at the appropriate time

Step	Action
As-Required GeneXpert Maintenance	
1	<p>Checking the test version in the GeneXpert:</p> <ul style="list-style-type: none"> On the CD that came with the kit, the version number is underneath the name of the test, at the top In the GeneXpert Dx System window, click Define Assays. The Define Assays window appears In the Assay list (on the left side of the window), verify that the assay definition you want to use is present. Cartridges will not run with an assay version that does not match the cartridge barcode information If the assay is not listed, import the assay definition file as below
2	<p>Importing assay definition files on the GeneXpert Dx System:</p> <ul style="list-style-type: none"> Connect the portable DVD WRITER to the laptop using the USB cable Insert the CD that came with the kit into the portable DVD WRITER In the GeneXpert Dx System window, click Define Assays on the menu bar. The Define Assays window appears

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- Click **Import**. The Import Assay dialog box appears
- In the Import Assay dialog box, under the **Look In** drop down box, select the DVD drive
- Click on the GeneXpert System folder; click **Open** to view the list of applicable assay definition files
- Locate and select the assay definition (.gxa) file and then click **Import**
- The new assay name and version number appear in the Assay list (on the left side of the window) and details appear to the right of the list

REFERENCES:

1. Cepheid GeneXpert. *Dx System User Manual*. 301-0045, Rev.C, June 2012

APPROVAL:

Date

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	28 May 20	Initial Release	L. Steven

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