Title: MIC72100-GeneXpert System Maintenance
Issuing Authority: Director, Laboratory and Diagnostic Imaging Services
Next Review Date:

Type: Laboratory Services Program SOP
Policy Number:
Date Approved:

PROGRAM Standard Operating Procedure – Laboratory Services

Title: MIC72100 – GeneXpert System Maintenance	Policy Number:
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s): NA	
Effective Date:	Next Review Date:
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Accreditation Canada Applicable Standard: NA	

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GUIDING PRINCIPLE:
Although the GeneXpert System is designed to prevent cross-contamination and ensure accurate results, the instrument should be checked weekly and cleaned monthly as a precautionary measure.

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

SCOPE/APPLICABILITY:
This standard operating procedure applies to Medical Laboratory Technologists (MLTs) performing maintenance on the GeneXpert System.

REAGENTS and/or MEDIA:
- 10% sodium hypochlorite
- Clorox bleach wipes
- 70% isopropyl alcohol
- Accel TB wipes

SUPPLIES:
- Orange biohazard wipes
- Paper towels
- Gauze squares
- Kimwipes
- USB drive
- Paper towels

EQUIPMENT:
- GeneXpert System

SPECIAL SAFETY PRECAUTIONS:

Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potentially 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 MIC72110-Maintenance Record-GeneXpert System

PROCEDURE INSTRUCTIONS:

Step	Action
Daily GeneXpert System Maintenance	
1	**Disinfect work area:** • Thoroughly wipe bench top, keyboard and barcode scanner with Accel TB wipes **NOTE:** Do NOT wipe the outer surfaces of the instrument with Accel TB wipes. Accel TB should not come into contact with the instrument
2	**Check printer paper:** • Add paper to the printer if required

Step	Action
Weekly GeneXpert System Maintenance	
1	**Reboot the GeneXpert System instrument, software, and laptop:** • Ensure all cartridges are removed from the modules • Quit the GeneXpert System software: On the **User** menu, select **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. 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**

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Step	Action
Monthly GeneXpert System Maintenance	
1	**Disinfect GeneXpert System surfaces:** • Dampen a gauze square with a 10% sodium hypochlorite solution (or use a Chlorox wipe) and gently wipe the instruments external surfaces (instrument top, sides, back and doors) **NOTE:** Do NOT use Accel TB to clean the GeneXpert • Wait 5 minutes • Dampen a gauze square with 70% isopropyl alcohol and wipe the instrument surfaces • Repeat a second time with a new gauze square dampened with 70% isopropyl alcohol
2	**Disinfect cartridge bay interior:** • Open all module doors • Dampen a Kimwipe with a 10% sodium hypochlorite solution (or use a Chlorox wipe) • Wipe the surfaces inside the cartridge bay (the inside of the door and the top lip of the door) **NOTE:** Do NOT touch the slit at the back • Wait 5 minutes • Dampen a Kimwipe with 70% isopropyl alcohol and wipe the surfaces inside the cartridge bay • Repeat a second time with a new Kimwipe dampened with 70% isopropyl alcohol • Repeat for all modules of the instrument **NOTE:** Use a fresh wipe for each cartridge bay
3	**Disinfect plunger rod:** • In the GeneXpert menu, select **Maintenance** on the toolbar • From the Maintenance menu, select **Plunger Rod Maintenance** • The Plunger Rod Maintenance dialog box appears • In the **Module** table, select **Clean All** to clean all modules simultaneously • The Plunger Rod Cleaning dialog box appears • Follow the directions in the dialog box, and then select **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) and wipe each plunger rod • Repeat a second time with a new Kimwipe dampened with 70% isopropyl alcohol (one for each plunger rod) • In the Plunger Rod Maintenance dialogue box, select **Move Up All** • The plunger rods will move back up to the resting position • When complete, close all module doors

4		**Clean fan filters:** • Quit the GeneXpert software: On the **User** menu, select **Exit** • Log off and power down the laptop • Turn OFF the power to the GeneXpert • Gently slide the instrument around to access the filter cover and gently take the fan filter and guard off the housing • Replace with the clean, backup filters • Wash the dirty filters in running tap water to remove dust buildup and allow to dry • Return the clean, dry fan filters to the plastic bags • 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** • Select the GeneXpert software. Enter the username **admin1** and the password **covid19**
5		**Archive tests:** • In the GeneXpert menu, select **Data Management** • From the Data Management menu, select **Archive Test**. The Select Test to Be Archived dialogue box appears • Select the box at the top of the screen that says: **"Purge Selected Tests from List After Archiving,"** ensure there is a √ in the box • Select **Select All** • Select **OK.** The Archive Test(s) dialogue box appears with the number of tests that are selected for archive • Select **Proceed**. The file name is generated automatically • Select **SAVE** and select **OK** • When the Archive Test is complete, the Purge Test(s) dialogue box will appear saying**: "A total of ___ tests have been selected to be purged. Would you like to continue?** • Select **YES** • The Purge Test(s) dialogue box will appear again letting you know that the archived tests have been successfully purged • Select **OK**
6		**Database management:** • Insert the correct removable drive into the USB port. The USB file box will appear. Select **X** to close • On the **User** menu, select **Exit**. When asked "Do you want to perform Database Management tasks," select **Yes** • The Database Management dialogue box will appear • Select **Database Backup** • Select **Proceed** • The file will automatically be given a name with the current date • From the **Save In** drop down menu, select the removable drive (Transcend D:) and then select **Save** • The Database Backup dialogue box will appear • Select **OK** • Select **X** to exit Database Management • Eject the USB from the laptop and return to the top drawer on TB bench

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Step	Action
Yearly GeneXpert System Maintenance	
1	**Calibration of the GeneXpert System:** • The GeneXpert modules need to be calibrated yearly • Calibration kit and instructions need to be ordered from Cepheid

Step	Action
As-Required GeneXpert System Maintenance	
1	**Checking the test version in the GeneXpert System:** • Check the version number of the cartridge kit • In the GeneXpert window, select **Define Assays** • 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	**Importing assay definition files on the GeneXpert System with CD:** • Connect the portable DVD WRITER to the laptop using the USB cable • Insert the CD from the kit into the portable DVD WRITER • In the GeneXpert window, select **Define Assays** on the menu bar. The Define Assays window appears • Select **Import**. The Import Assay dialog box appears • In the Import Assay dialog box, under the **Look In** drop down menu, select the DVD drive • On the GeneXpert folder, select **Open** to view the list of applicable assay definition files • Locate and select the assay definition (.gxa) file and then select **Import** • The new assay name and version number appear in the Assay list
3	**Importing assay definition files on the GeneXpert System without CD:** • You will need to download the Assay Definition File (ADF) • Go to the website https://www.cepheid.com/en-GB.html • Select **Tests** on the top left-hand side, and find the test you are adding • Go to the **Product Resources** portion on the bottom of the test information page and then select **ADF-Test Name-Download ADF** ⤓ ADF - Xpert Xpress CoV-2 plus Download ADF Software • Insert a USB stick into the computer and drag the ADF file to the stick • Plug the USB stick into the GeneXpert laptop • In the GeneXpert window, select **Define Assays** on the menu bar. The Define Assays window appears • Select **Import**. The Import Assay dialog box appears • In the Import Assay dialog box, under the **Look In** drop down menu, select the USB key with the ADF file • Select the file you are adding and select **Import** • The new assay name and version number appear in the Assay list

CROSS-REFERENCES:

- MIC72110-Maintenance Record-GeneXpert System

REFERENCES:

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

APPROVAL:

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Date

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Director, Laboratory and Diagnostic Imaging Services

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	28 May 20	Initial Release	L. Steven
2.0	17 Oct 22	Procedure reviewed	L. Steven
3.0	01 Oct 24	Procedure reviewed	L. Steven