PROGRAM Standard Operating Procedure – Laboratory Services

Title: MIC81100 – GeneXpert Dx System Maintenance	Policy Number:
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s):	
Effective Date:	Next Review Date:
Issuing Authority: Director of Health Services	Date Approved:
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 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 Dx System.

SCOPE/APPLICABILITY:
This procedure applies to Medical Laboratory Technologists (MLTs) performing maintenance on 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
- Paper towels
- Gauze squares
- Kimwipes
- USB drive
- Paper towels

EQUIPMENT
- GeneXpert Dx System

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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 MIC81110-Maintenance Record-GeneXpert

PROCEDURE INSTRUCTIONS:

Step	Action
Daily GeneXpert 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 Maintenance	
1	**Reboot the GeneXpert instrument, software, and laptop:** • Ensure all cartridges are removed from the modules • Quit the GeneXpert Dx 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 Maintenance**
1	**Disinfect GeneXpert surfaces:** • 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 dampened with alcohol
2	**Disinfect cartridge bay interior:** • 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 and wipe the surfaces • Repeat a second time with a new Kimwipe dampened with alcohol • Close the module door and repeat for all modules in the instrument
3	**Disinfect plunger rod:** • In the GeneXpert Dx System 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 to be cleaned) and wipe each plunger rod. Use a fresh Kimwipe for each plunger rod • Repeat a second time with a new Kimwipe dampened with alcohol • In the Plunger Rod Maintenance dialogue box, select **Move Up All** and the plunger rods will move back up to the resting position
4	**Clean fan filters:** • Quit the GeneXpert System 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 so that you can easily access the filter cover and gently take the fan filter and guard off the housing • Wash the filter in running tap water to remove dust buildup • 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	**Archive tests:** • In the GeneXpert Dx System 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** • 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

Step	Action
Yearly GeneXpert Maintenance	
1	**Calibration of the GeneXpert:** • Cephid will notify Microbiology of the need to re-calibrate the modules at the appropriate time

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Step	Action
**As-Required GeneXpert Maintenance**
1	**Checking the test version in the GeneXpert:** • Check the version number of the cartridge kit • In the GeneXpert Dx System 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 Dx System:** • 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, **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 box, select the DVD drive • Select on the GeneXpert System 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 (on the left side of the window) and details appear to the right of the list

CROSS-REFERENCES:
- MIC81110-Maintenance Record-GeneXpert

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

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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