

| PROGRAM Standard Operating Procedure – Laboratory Services | |
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| Title: MIC70700 – GeneXpert Dx System Maintenance | Policy Number: DRAFT |
| 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 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.

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REAGENTS and/or MEDIA:

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

SUPPLIES:

- Orange biohazard wipes
- Cotton swabs

EQUIPMENT

- GeneXpert Dx System

SPECIAL SAFETY PRECAUTIONS:

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

- 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)

All patient specimens are assumed to be potentially infectious. Universal precautions 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 MIC70711, MIC70712, MIC70713 and MIC70714 – 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 and the bench tops with Accel TB wipes. |

| Step | Action |
|-------------------------------------|---|
| Weekly GeneXpert Maintenance | |
| 1 | Reboot the GeneXpert instrument, software and computer: <ul style="list-style-type: none">Wait for the instrument to finish all processes and remove cartridges from all the modules.Quit the GeneXpert Dx System software: On the User menu, click Exit.Log off and power down the computer.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 computer. The password on the computer is covid19.The software for the GeneXpert Dx System automatically opens. Enter the username admin1 and the password covid19.The message "Do you want to perform Database Management tasks?" appears. Select No and then click OK to log on. |

| Step | Action |
|--------------------------------------|---|
| Monthly GeneXpert Maintenance | |
| 1 | Disinfect GeneXpert surfaces: <ul style="list-style-type: none">Dampen an orange biohazard wipe with the 10% sodium hypochlorite solution and wipe the instrument surfaces.Wait 5 minutes.Dampen an orange biohazard wipe with 70% isopropyl alcohol and wipe the instrument surfaces. Repeat a second time with a new wipe. |

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| 2 | <p>Disinfect cartridge bay interior:</p> <ul style="list-style-type: none">• Open the module door.• Dip a cotton swab into the 10% sodium hypochlorite solution.• Wipe the surfaces inside the cartridge bay with the swab. <p>Do NOT touch the slit at the back.</p> <ul style="list-style-type: none">• Wait 5 minutes.• Dip a swab into 70% isopropyl alcohol.• Wipe the same surfaces with the swab.• Repeat a second time with a new swab.• 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 Maintenance. The Plunger Maintenance dialog box appears.• In the Module table, click Clean All to clean all modules simultaneously. The Plunger Cleaning dialog box appears.• Follow the directions in the Plunger Cleaning dialog box, and then click OK.• Dip 4 swabs into the 10% sodium hypochlorite solution (one for each plunger rod to be cleaned).• Wipe each plunger rod with a swab. Use a fresh swab for each plunger rod.• Wait 5 minutes.• Dip 4 swabs into 70% isopropyl alcohol (one for each plunger rod to be cleaned).• Wipe each plunger rod with a swab. Use a fresh swab for each plunger rod.• Repeat a second time with a new swab.• In the Plunger Maintenance dialogue box, click Move Up All and the plunger rods will move back up to the resting position.• Click Close to diminish the Plunger Maintenance dialogue box. |

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| 4 | <p>Clean fan filter:</p> <ul style="list-style-type: none">• Quit the GeneXpert System software: On the User menu, click Exit.• Log off and power down the computer.• Turn OFF the power to the GeneXpert.• Gently slide the instrument around so you can gain access to the filter cover.• Remove the 4 screws and gently take the fan cover guard off the fan housing and remove the filter.• Wash the filter in running tap water to remove dust buildup and place it between 2 orange wipes to dry it.• Install the clean, dry filter in the guard and replace onto the fan assembly.• Turn ON the power to the GeneXpert.• Power up the computer. The password on the computer is covid19.• The software for the GeneXpert Dx System automatically opens. Enter the username admin1 and the password covid19.• The message "Do you want to perform Database Management tasks?" appears. Select No and then click OK to log on. |
| 5 | <p>Archive runs:</p> <ul style="list-style-type: none">• In the GeneXpert Dx System menu, click Data Management menu, click Archive Test. The Select Test to Be Archived dialogue box appears.• Highlight the tests to be archived and click Select Highlighted. Click OK.• Click Proceed. The file name is generated automatically.• Click SAVE, then click OK |

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

| Step | Action |
|--------------------------------|---|
| As-Required 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 (disregard the number on the left side of the CD). • 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. Make sure you are using the latest version of the assay definition. • If the assay is not listed, import the assay definition file as below. |
| 2 | <p>Importing assay definition files on the GeneXpert Dx systems:</p> <ul style="list-style-type: none"> • Insert the CD that came with the kit into the computer’s DVD drive. • In the GeneXpert Dx System window, click Define Assays on the menu bar. The Define Assays window appears. • 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. |

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Print system log report:

- In the GeneXpert Dx System window, click **Reports** on the menu bar, and then click **System Log**. The System Log Report dialogue box appears.
- Specify the criteria to view the trends of interest:
 - **Date Range:**
 - All – Select to include all of the records.
 - Select – Select to filter the records by specifying a range of dates. Entries older than 1 year are automatically removed.
 - **Modules:**
 - Currently Connected Modules – Displays modules that are connected to the system and are currently shown on Check Status screen. This is the default option.
 - All Logged Modules – Displays all modules which have self-test or error entries in this system database within the last 1 year. This allows technical support to obtain self-test/error entries for a module that is no longer connected to the system.
 - **Show:**
 - Errors Only – Displays only error entries in the generated report file.
 - All Entries – Displays all self-test and error entries in the report.
- When you are finished selecting the log criteria, click one or both 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. You can save and print the PDF file from the Reader software.

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REFERENCES:

- 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 | 25 Apr 20 | Initial Release | L. Steven |
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