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	Applicability:	Valley Laboratories

Performing Maintenance on the Cepheid GeneXpert Dx System

PURPOSE

Although the Cepheid GeneXpert Dx System is designed to prevent cross-contamination and ensure accurate results, routine and scheduled maintenance is an important preventative measure. This procedure describes the basic maintenance procedures and maintenance frequency for the GeneXpert Dx System.

POLICY

- This procedure, in addition to the Operator's Manual is to be followed when performing maintenance on the Cepheid GeneXpert Dx System.
- Maintenance is performed on a daily, weekly, quarterly, monthly, annually and as required basis.

EQUIPMENT, REAGENTS AND SUPPLIES

- Cepheid GeneXpert Dx System
- 10% bleach solution (prepared daily)
- 70% reagent alcohol
- · Disposable swabs
- Lint-free wipes (such as Wypall towels)
- · Tap water
- Disposable gloves
- Timer

PROCEDURE

Follow the instructions for basic maintenance of the Cepheid GeneXpert Dx System.

• Refer to GeneXpert Dx System Operator Manual for detailed and additional instructions.

Step	Action
1.	Prior to beginning any maintenance tasks, verify the instrument is not currently in use.
2.	Maintenance is documented during the month using the GeneXpert System Maintenance Log.

· If documenting maintenance using the electronic version of log:

- Check boxes of tasks completed and type first and last initial on the bottom row of the log.
- Save file after entering data.
- Working maintenance log is stored on the Cepheid computer desktop using the following title: [Month Year].
- At the end of the month, verify all maintenance tasks are completed and print the maintenance log for further review.
- Move finished maintenance log to the Completed Maintenance Logs folder and prepare a new maintenance log for next month.

3. **Daily Maintenance:**

- · Disinfect work surfaces / work area.
 - Using a lint-free wipe, wipe surfaces with 10% bleach solution.
 - Wipe over surfaces with 70% reagent alcohol.
- · Ensure module doors are upright when not in use
- · Discard used cartridges in the biohazard waste

4. Weekly Maintenance:

- · Shut down software and computer first.
- · Shut down GeneXpert instrument second.
- Let instrument sit for 2 minutes.
- Turn on GeneXpert instrument.
- · Then, restart computer and software.

5. **Monthly Maintenance:**

- Replace fan filters (total of 4)
 - Instrument & computer must be turned OFF to perform this task.

6. **Quarterly Maintenance:**

- · Disinfect GeneXpert instrument exterior surfaces
 - Dampen a lint-free wipe with 10% bleach solution.
 - Wipe instrument exterior surfaces thoroughly and let sit for 10 minutes.
 - Dampen a lint-free wipe with 70% reagent alcohol and wipe over the surfaces again.
 Repeat this step.
- · Disinfect cartridge bay interior surfaces
 - Dampen a disposable swab with 10% bleach solution.
 - Wipe interior surfaces including sides, bottom and top of cartridge bay and let sit for 10 minutes.
 - **Do not** clean back surface of cartridge bay, which is the slit on the I-CORE module.
 - Dampen a disposable swab with 70% reagent alcohol & wipe over the surfaces again.
 Repeat this step twice.
- Disinfect plunger rod
 - Select Maintenance on the toolbar of GeneXpert Dx System window.
 - Select Clean All on Plunger Maintenance dialog box.
 - Do not select Close while performing maintenance.
 - Follow the directions on the screen and click OK.
 - Dampen a lint-free wipe with 10% bleach solution and wrap wipe around plunger rod,

- wiping up and down.
- Repeat this step for each plunger rod using a new wipe and let sit for 5 minutes.
- Dampen a lint-free wipe with 70% reagent alcohol and repeat cleaning of plunger rod.
 Repeat this step twice.
- Once finished, in Plunger Maintenance dialog box, select **Move Up All** and close.

7. Annual Maintenance:

- · Calibration of the instrument
 - Check annual instrument maintenance refer to Chapter 9 in the Operator Manual for detailed process

8. As Required:

- Archive runs see Appendix A: Archiving and Deleting Runs
- Delete (purge) runs see Appendix A: Archiving and Deleting Runs
- · Manual backup of database to flash drive
 - · Recommended every 3 months
- Print a system log report

RELATED DOCUMENTS

- GeneXpert System Maintenance Log (provided by the manufacturer)
- Operating the Cepheid GeneXpert Dx System
- Performing Maintenance on the Cepheid GeneXpert Dx System Appendix A: Archiving and Deleting Runs
- · Performing an Xpress Flu Assay

REFERENCES

· Cepheid GeneXpert Operator's Manual

All revision dates:

Attachments:

Appendix A: Archiving and Deleting Runs

Approval Signatures

Step Description	Approver	Date
Lab Medical Directors	Kristen Vandewalker: MD	pending
Lab Medical Directors	Andrea Ong: MD	pending
Lab Medical Directors	Hannah Wong: MD	pending
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Lab Medical Directors	Jamie Cassity: MD	pending
Lab Medical Directors	Mary Keohane: MD	pending
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	Lindsey Westerbeck: Dir, Lab	10/15/2019