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Owner:	Lindsey Westerbeck: Dir, Lab				
Policy Area:	Lab - Serology				
References:					
Applicability:	Valley Laboratories				
Performing Maintenance on the Cepheid GeneXpert Dx System					

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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

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 Form A: GeneXpert System Maintenance Log.		
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. 		
	NOTE: Although not part of documented daily maintenance, it is important to ensure module doors are upright when not in use and to discard used cartridges in the biohazard waste upon completion of testing.		
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 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
3.	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

- REFERENCES
 - Cepheid GeneXpert Operator's Manual

All revision dates:

Attachments:

Appendix A: Archiving and Deleting Runs Form A: GeneXpert System Maintenance Log

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
Lab Medical Directors	Rowberry Ron: MD	pending
Lab Medical Directors	Jamie Cassity: MD	pending
Lab Medical Directors	Mary Keohane: MD	pending
Lab Medical Directors	Marian Butcher: MD	pending
	Lindsey Westerbeck: Dir, Lab	10/16/2019