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| GeneXpert Maintenance and Troubleshooting |
| **Purpose** | This procedure provides instructions for maintenance tasks performed on the GeneXpert system.  |
| **Policy Statements** | This procedure applies to technical staff performing testing on the GeneXpert. |
| **Special Safety Precautions** | Microbiologists/virologists are subject to occupational risks associated with specimen handling. Refer to the safety policies located in the safety section of the *Microbiology*and *Virology Policy Manual***:**1. *Biohazard Containment*
2. *Safety in the Microbiology/Virology Laboratory*
* *Biohazardous Spills*
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| **Materials** |

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| Reagents | Supplies | Equipment |
| * Household bleach
* 70% ethanol
* Extran diluted to 5%
 | * Lint free wipes
* Cloth Wipes
* Squirt Bottle
 | * Fan filters
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| **Procedure** | **Daily Maintenance****Make 10% beach dilution daily:**1. Combine 50mL bleach with 450mL DIH2O in a 500mL squirt bottle.**Clean GeneXpert work area (hood and counter) at beginning of shift:** 1. Wipe with 10% bleach.
2. Wait 2 minutes.
3. Follow with 70% ethanol.

**Discard used cartridges****Close all module doors** **Check printer paper****Restock supplies****Check filter % on hood****Review GeneXpert results and Problem Logs****Clean GeneXpert work area (hood and counter) at end of shift:**1. Wipe with 10% bleach dilution.
2. Wait 2 minutes.
3. Follow with 70% ethanol.

**Weekly Maintenance****Power down the GeneXpert instrument and computer:** 1. Shut down the computer from the start menu first, then switch off the instrument (CBA).
2. Wait 5 minutes.
3. Power on the analyzer before turning the computer back on (ABC).

**Monthly Maintenance** **Archive and Purge tests:**1. Log into the system.
2. In the GeneXpert System window, on the **Data Management** menu, click **Archive Test.**
3. Select the tests to be archived from the previous month.
4. Select **Purge selected Tests from List After Archiving**.
5. Click **OK** and confirm the archive and purge request.
6. Click **Proceed**.
7. Select the folder in which to store the archive (**.gxx or .nxx**) file.
	1. Windows (C:) -> GeneXpert -> Export
8. Rename the file according to the **month and year of the results that are being archived**.
	1. NOTE: leave as a (.gxx or .nxx) file
9. Click **Save**.
10. The Archive Test(s) dialog box will be displayed once archiving is complete. Click **OK**.
11. The Purge Tests(s) dialog box will appear. Click **Yes** to confirm.

**Replace Fan Filters:**1. Power down the computer first and then the analyzer.
2. Gently take the fan filter guards off by unsnapping the guard from the fan housing.
3. Remove dirty filter.
4. Run the filter under water, set on paper towels, and allow to air dry overnight.
5. Place a clean filter into the fan filter guards.
6. Position the fan filter guard and filter into place as a unit.
7. Press the sides and bottom of the guard firmly onto the fan housing until the grip snaps securely onto the fan.

**Quarterly Maintenance** **Clean plunger rod and cartridge bays:**1. Ensure that there are no cartridges in any of the modules.
2. In the GeneXpert System window, click the **Maintenance** icon
3. Click on **Maintenance** on the Menu Bar, select **Plunger Rod Maintenance**.
4. Click on **Clean All** in the dialog box.
5. The Plunger Rod cleaning dialog box will be displayed – click **OK.**
6. Clean the plunger rods and cartridge bays:
	1. Thoroughly moisten a lint-free wipe with 10% bleach dilution.
	2. Vigorously wipe the plunger rod with the lint-free wipe.

NOTE: Wipe hard enough to remove the black debris that accumulate on the rod. * 1. Using the same wipe: wipe the walls, ceiling, corners and edges of the cartridge bay, then wipe the inside of the door and top lip of the door.
	2. Discard the wipe.
	3. Wait 2 minutes.
	4. Using a new lint-free wipe, complete the cleaning process again.
	5. Wait 2 minutes.
	6. Using a new lint-free wipe, complete the cleaning process again.
	7. Wait 2 minutes
	8. Thoroughly moisten a lint-free wipe with 70% ethanol.
	9. Use the lint-free wipe to remove all residual bleach by following the same cleaning process as listed above.
	10. Once all plunger rods and cartridge bays have been cleaned, return to the Plunger Maintenance dialog box and select the **Move Up** button.
	11. Click **Close** to close the Plunger Maintenance dialog box.
	12. Make sure all module doors in the instrument are shut.

**Clean instrument surfaces:** 1. Wipe with 70% ethanol.

**Yearly Maintenance** **Perform annual instrument maintenance:**Cepheid recommends that the system be checked for proper calibration on anannual basis. Based upon the usage and care of each system, calibration checks may berecommended more frequently. Request Xpert check kit 2 months prior to calibration expiration (12 months from last calibration check date). Contact Tech Support or Field Specialist (Carolyn.Anderson@cepheid.com).The Cepheid Field Service Engineer or customer will perform the calibration checksduring annual maintenance or by the field service engineer if responding to a modulefailure. **As Necessary** **Generate a system log report:**The System Log reports can be used to provide incidents of instrument module self-testsand errors to Cepheid when a module failure has been encountered.To generate a system log report:1. In the GeneXpert Dx System window, click **Reports** on the menu bar, and then click **System Log**.
2. Specify the following 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 (allows technical support to obtain self-test/error entries for a module that is no longer connected to the system).
1. A list of modules is displayed in the table. Select the module to be included in the system by selecting the individual modules one-by-one, or by using one of the available buttons.
2. Select the preference for **Show:**
* **Errors Only**—Displays only error entries in the generated report file.
* **All Entries**—Displays all self-test entries and error entries in the report.
1. When you finish selecting the log criteria, click one of the following buttons:
* **Generate Report File**—Creates a PDF file and saves it to the location you specify.
* Click the **Generate Report File** button on the System Log Report screen (see to create the PDF file of the test report. The Generate Report File dialog box will appear, which enables a file to be saved to a specified location. Click **Save** after navigating to the specific location.
* **Preview PDF**—Creates a PDF file and displays the file in the Adobe Reader window. The PDF file can be saved and printed from the Adobe Reader software.
1. After printing the System Log report, click **Close** to close the System Log Report window.

**Back up database:**The entire database should be backed up periodically and stored on a different computer or on a different storage medium. To back up the database:1. Select **Database Backup** on the Database Management window.
2. Click **Proceed**.
3. Locate and select the folder in which you want to store the backup file, type a name for the backup file (or use the default file name), and then click **Save.**
* The backup process creates a .zip file in the location you specified.

**Discarding Unused Cartridges:** GeneXpert cartridges for any assay should not be used for testing if any of the following are true: * Cartridge appears wet or has leaked
* Cartridge has white precipitate around the top when closed or open
* The lid seal has been broken
* The reaction tube has been damaged
* It has been dropped after removed from packaging
* It has been dropped or shaken after sample has been added

**NOTE:** These cartridges are considered reactive prior to use.1. Place unused cartridges in the blue bin labeled “unusable cartridges” found in rapid molecular. (These cartridges will be submitted to Cepheid tech support for a credit.)
2. Once credited, place unused cartridges in large white bucket with lid and label with green Hazardous Waste label as follows: “**GeneXpert cartridges- D003 Reactive”**.
3. When white bucket is full, contact Safety Specialist (Denis Deutsch) by email to request a pick up by West Bay.

**Cleaning up cartridge spills**GeneXpert cartridges that tip over when open may spill reagents and/or sample:* The area effected must be cleaned
* The spill must **NOT** be cleaned with a 10% dilution
1. Clean the spill with 5% diluted extran followed by 70% ethanol.

NOTE: see the procedure below for 5% Extran prep1. Dispose of the cartridge(s) according to the procedure above.

 **Making 5% Extran**1. Combine 475 mL DI H2O and 25 mL Extran 300 in a 500 mL squirt bottle.
2. The working solution expires in 1 year.

 **Making 70% ethanol** 1. Combine 350 mL 100% Dehydrant and 150 mL DI H2O in a 500 mL squirt bottle.
2. The working solution expires in 1 year.
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| **Troubleshooting** | Instrument errors should be addressed in real time. Use the instrument manual on the desk top to investigate appropriate actions based on error codes. See some detailed notes for frequently encountered errors below: **Error 2025: Plunger Error**1. Remove the cartridge and restart the test in the same module, using the same cartridge.
2. If the error persists, try moving the cartridge to a different module.
	1. If Error resolved in new module, disable the faulty module.
	2. If error persists, set up the test again with a new cartridge.

**Error 2037: Cartridge Integrity** 1. Remove and inspect cartridge for damage.
	1. If damaged, set up the test again with a new cartridge.
	2. If not damaged, restart the test with the same cartridge.
		1. If error persisted, restart the test with a new cartridge.

See [MC 9.01.R1 GeneXpert Error Chart for reference](MC%209.01.R1%20GeneXpert%20Error%20Chart.docx).**NOTE:** Record all errors in the problem log.  |
| **Result Reporting** | Record completion of maintenance tasks on the Rapid Molecular Maintenance and Rapid Molecular Daily Maintenance Logs.  |
| **References** | 1. GeneXpert Dx System Operator Manual: Software Version 4.8, 3010045, Rev. K. In. Sunnyvale, CA: Cephied Inc.; 2016.
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| **Historical Record** |  |  |  |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Julie Laramie/Helen Stefan  | 4/16/2018 | Initial Version |
| 2 | Jamie Berg / Julie Laramie | 5/11/2020 | -Added discarding of unused cartridges -Updated daily maintenance tasks |
| 3 | Julie Laramie | 8/31/2020 | Added cleaning of cartridge spills, 5% extran prep, 70% ethanol prep |
|  | 4 | Julie Laramie/Jamie Berg | 4/19/2021 | Added trouble shooting section and error reference.  |  |  |
|  |  |  |  |
| **Archived by:** |  | **Archived Date:** |  |