| | |
|---|---|
| **Policy Statement** | The proper quality control and maintenance procedures of the Cepheid GeneXpert ensure that the laboratory will obtain accurate results from specimen analysis. |
| **Purpose** | The procedure provides the appropriate steps to complete, quality control, calibration and maintenance. |
| **Scope** | This procedure applies to testing personnel authorized to perform testing utilizing the GeneXpert. This group includes, but is not limited to Medical Technologists, Medical Technologists II, and Clinical Lead Technologists. |
| **Responsibility** | All the above personnel are responsible for following this procedure without exception. In addition, testing personnel are also responsible for evaluating the results and taking proper remedial action. |

## Quality Control (QC)

### Performing QC

QC specimens for the GeneXpert are chosen based on the requirements of the assay. Specimens are stored and utilized according to the manufacturer's guidelines. QC specimens are analyzed by associates that normally perform patient testing. Testing follows normal test procedures, unless sample preparation requires additional steps.

### Utilizing KWIK-STIK™ QC Sets

KWIK-STIK™ devices contain a lyophilized pellet of a single strain of microorganism. KWIK-STIK™ devices are utilized for the C difficile and GBS assays. The following steps should be used to activate the device.

1. Tear open pouch at notch and remove the KWIK-STIK™.
2. Tear off the Pull-Tab portion containing the lot information. Attach to the appropriate form.
3. Pinch just below the fluid meniscus of the ampule found in the cap to release the hydrating fluid.
4. Hold vertically and tap to facilitate flow of fluid through the shaft into the bottom of the unit containing the pellet.
5. Crush the pellet and mix in fluid using a pinching action.
6. Heavily saturate the swab in the hydrated suspension.

7. Proceed with the test by following the directions found in the specific assay procedure.

**Utilizing Other Types of QC**
Other types of QC specimens are appropriate for the GeneXpert. The EV Assay utilizes Acrometrix® OptiQual QC. It is also acceptable to utilize external organism control from microbiology and known patient samples for all of the assays. The use of these other types must be approved by a Clinical Lead Technologist prior to testing. All of these types of QC specimens are performed using the same procedures as patient samples. Steps are outlined in the specific assay procedures.

**Frequency of QC**
Each assay performed on the GeneXpert includes electronic/procedural/built-in internal controls. Studies using external controls have been performed to validate these internal controls. With this validation, daily QC is not required. QC is performed monthly, with each new lot or shipment, after major system maintenance and after software upgrades. QC can also be utilized in trouble-shooting procedures where indicated. New lot verification requires a sample of the same matrix (*e.g.* known patient sample), where applicable.

**QC Acceptability**
All QC results should be reviewed by the performing technologist for acceptability. Acceptability is defined as achieving the expected/manufacturer's result. See *QC Corrective Action* for guidance on how to proceed if QC is not acceptable.

**QC Corrective Action**
When testing QC specimens it is expected to that the manufacturers' results will be achieved. In the event that the appropriate results are not achieved notify the Clinical Lead Technologist. The following steps should be completed.

- Halt patient testing with the specified lot number
- Repeat testing with another QC specimen
- Repeat testing with an alternative QC specimen or known patient sample
- Contact the vendor Technical Support Hotline

**QC Review**
Monthly QC is reviewed by the Clinical Lead Technologist or designee. Review is not required prior to patient testing.

## Maintenance

Maintenance procedures help to prevent cross-contamination and ensure a secure data base. This includes daily, weekly, monthly and calibration maintenance. Perform the

appropriate maintenance as noted on the maintenance chart or when alerted by the instrument. Record all maintenance on the appropriate charts when completed.

**Supplies**

1. Cepheid GeneXpert Analyzer
2. 10% Bleach (freshly prepared)
3. 70% Isopropyl Alcohol (Isopropanol)
4. Sterile Cotton tipped applicators (swabs)
5. Kimwipes
6. Gloves
7. Removable thumb drive for data backup

**Daily Maintenance**

Disinfect instrument surface with Kimwipes by wiping down the outside of the instrument and module doors. Disinfection should be completed with 10% bleach followed by 70% isopropanol.

**Weekly Maintenance**

Reboot GeneXpert and computer.

**Monthly Maintenance**

## *Disinfect Cartridge Bays*

1. Wet a sterile cotton tipped applicator and Kimwipe with 10% bleach solution.
2. Remove any excess solution.
3. Open the instrument module door.
4. Wipe the surfaces inside the cartridge bay with the swab/ Kimwipe. The swab should be used for corners and hard to reach areas.
   *Note:* Do not touch the slit on the I-CORE module into which the cartridge reaction tube is inserted.
5. Wait 10 minutes.
6. Wet a new swab/Kimwipe with the 70% isopropanol.
7. Remove any excess solution.
8. Wipe the same surfaces with the new swab/Kimwipe.
9. Repeat steps 6-8.
10. Close the instrument module door.
11. Repeat steps 1-10 for each cartridge bay. Use fresh swab/Kimwipe with each module.

## *Disinfect Syringe Plungers*

1. Choose Maintenance on the toolbar.
2. Choose Plunger Maintenance.
3. Select the module that you want to clean and choose Clean.

*Note:* The plunger rod will lower into the cartridge bay.

4. Wet a Kimwipe with 10% bleach solution.
5. Remove any excess solution.
6. Wipe the plunger rod with the Kimwipe.
   *Note:* Use a fresh Kimwipe for each plunger rod.
7. Wait 5 minutes.
8. Wet a new Kimwipe with the 70% isopropanol.
9. Remove any excess solution.
10. Wipe the plunger rod with the Kimwipe.
11. Repeat steps 8-10.
12. Chose Move Up. The plunger rod moves back into its resting position.
13. Repeat steps 3-12 for each module.

### *Archive and Backup Data*

1. Choose the Data Management icon.
2. Choose Archive test.
3. Select the tests to be archived.
4. Choose Archive. (Usually the previous months results of a particular test.)
5. Choose Proceed.
6. Save results in C:Genexpert/Export/Month Year.gxx.
   *For example:* In the month October, archive September under C:Genexpert/Export/October 2014.gxx
7. Save this file to the removable thumb drive as well.
   *Note:* Archived results are maintained on the analyzer computer and the laboratory server.

### *Clean Fan Filters*

1. In the back of the GX, remove and clean/ wash/ dry the filters of dust particles.
2. Replace the fan filters.

**Calibration Maintenance**

The instrument should be calibrated annually or after 2000 tests/module. Annual maintenance is completed with a kit provided by the vendor. The procedure should be performed as defined in the provided instructions.

## Supporting Documents

CORE 6600 F GeneXpert Quality Control
CORE 6600 Fa GeneXpert Maintenance Log
CORE 6605 R Xpert C difficile Assay
CORE 6610 R Xpert GBS Assay
CORE 6625 R Xpert EV Assay

## References

1. Cepheid GeneXpert Dx System Operator Manual

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# GeneXpert Maintenance

GX Serial Number: __800832_____

Last Calibration Date: _____

Month: _____ Year: _____

Monthly Review: _____
Date: _____

| **Daily Maintenance** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| - Decontamination of BSC* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Allow BSC to run for 15 minutes | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Check Airflow of BSC + | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Run UV light for 15 minutes | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Clean GeneXpert work area * | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Disinfect with 10% Bleach * | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Disinfect with 70% Alcohol * | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Keep module doors vertical | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Throw away used cartridges | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - 2 inches clear around GX | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Technologist Initials | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Weekly Maintenance** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Check of biohazard hood UV light | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Wipe UV bulb with alcohol wipe | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Reboot GX Instrument | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Reboot Software and Computer | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Technologist Initials | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Monthly Maintenance** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Archive Runs | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Delete Runs | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Save archived data to network | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Disinfect GX surfaces | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Disinfect Cartridge Bay Interior | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Disinfect Plunger Rod | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Clean fan filters monthly | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - Disinfect lower plenum of hood | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Technologist Initials | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **As Required** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Site Failure | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| IQ Report before/after service | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Corrective Action: _____

* BSC = Biological Saftey Cabinet, Cleaning/Disinfecting should be done with 10% bleach followed by 70% Alcohol + The accepatble range for the biohazard Mag Gauge is 0.8-1.1 inches.

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# Monthly GeneXpert QC or Lot Verification – C. *difficile*, Group B Strep, and Enterovirus

Perform testing on appropriate QC, KWIK-STIK™ Set or known patient as applicable. QC should be performed monthly and with each new lot number. Retain a copy of the run report from the GeneXpert System and all information received with the QC set.

## C. *difficile*

Kit Lot Number _____ Exp. Date _____

| ATCC 70057™ | | ATCC 9689™ | |
|---|---|---|---|
| Place sticker here | | Place sticker here | |
| Expected Result | Negative | Expected Result | Positive |
| Result Received | | Result Received | |

## Group B Strep

Kit Lot Number _____ Exp Date _____

| ATCC4356™ | | ATCC12401 E3™ | | ATCC12401 E5™ | | ATCC12401 E7™ | |
|---|---|---|---|---|---|---|---|
| Place sticker here | | Place sticker here | | Place sticker here | | Place sticker here | |
| Expected Result | Negative | Expected Result | Positive | Expected Result | Positive | Expected Result | Positive |
| Result Received | | Result Received | | Result Received | | Result Received | |

Known Patient Accession Number: _____ Original Kit Lot #: _____ Expected Result: _____ Result Received: _____

## Enterovirus

Kit Lot Number _____ Exp. Date _____

| EV Neg | | EV Low | |
|---|---|---|---|
| Lot # | | Lot # | |
| Expected Result | Negative | Expected Result | Positive |
| Result Received | | Result Received | |

Corrective Action: _____

_____

_____

_____

Technologist Performing Testing: _____ Date: _____

Reviewed by: _____