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GeneXpert Quality Control and Maintenance	Origination: 01/2014 Version: 1

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.

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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/manufacture'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

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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% Ethyl Alcohol (Ethanol)
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% ethanol.

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% ethanol.
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.

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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% ethanol.
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

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1. Cepheid GeneXpert Dx System Operator Manual

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GeneXpert Quality Control and Maintenance.doc



GeneXpert Maintenance

GX Serial Number: 800832

Last Calibration Date: January 20, 2014

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% Ethanol																															
- Keep module doors vertical																															
- Throw away used cartridges																															
- 2 inches clear around GX																															
-Disinfect BD Affirm with 10% Bleach																															
-Disinfect BD Affirm with 10% Ethanol																															
Technologist Initials																															

Weekly 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
- Wipe UV bulb with alcohol wipe																															
- Reboot GX Instrument																															
- Reboot Computer																															
Technologist Initials																															

Monthly 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
- 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	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
Site Failure																															
IQ Report before/after service																															

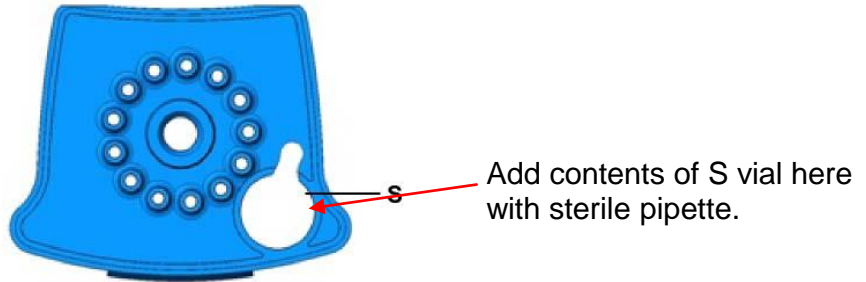
Corrective Action: _____

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

Clean the work areas with 10% bleach followed by 70% ethanol.

Preparing the Cartridge

1. Obtain liquid or soft stool sample.
2. Go under biohazard hood
3. Open kit and label the cartridge with the sample ID.
4. Obtain sterile swab.
5. Vortex stool sample.
6. Place swab in stool, swirl off excess.
7. Place swab in S vial, break off swab, close lid and vortex.
8. Open cartridge lid.
- 9.



10. Close the cartridge lid.
11. **CHANGE GLOVES BEFORE CONTINUING TO NEXT STEP!**
12. Keep cartridge in an upright position. Load Cartridge on instrument within 15 minutes.

Starting the Test

1. In the GeneXpert Dx System window, click **Create Test**.
2. In the **Patient ID Barcode** field, enter the Patient's Last Name
3. Scan the barcode on the Xpert C. *difficile* Assay cartridge.
4. In the **Sample ID** box, type the sample ID (e.g. SM0000).
5. In the **Notes** box, scan/enter your personal identification barcode.
6. Click **Start Test**.
7. Open the instrument module door with the blinking green light and load the cartridge.
8. Close the door. Test will take 47 minutes.

Reporting

1. Review your report to ensure that all checks passed.
2. Log into Meditech and go into Enter Results on the Specimen Desktop.
3. Enter SM#, type E in the Result field to go to page 2, enter organism code as **NEGCDT** for negative samples and **POSCDT** for positive samples.
4. Click on page 3 for all samples. If result is positive enter canned comment **SMART** and the patient location with the interpretation.
5. File Result.
6. Enter positive patients in the CCI for **ZCONCDIFF** under Empiric Isolation.
7. SmartWeb the nurse for all positive samples.
"Please check isolation status of patient [John Doe in Rm 123](#)"

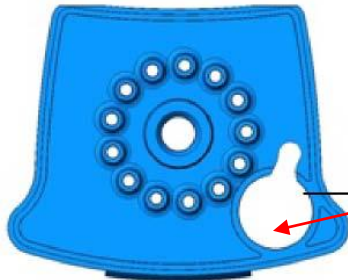
Specimen Retention

Send all completed samples to microbiology.

Clean the work areas with 10% bleach followed by 70% ethanol.

Preparing the Cartridge

1. Obtain patient swab
2. Open kit and label the cartridge with the sample ID.
3. Rub swabs together (if two swabs are received)
- 4.



Add swab here and break off. Make sure the swab falls into the chamber

5. Close the cartridge lid.
6. **CHANGE GLOVES BEFORE CONTINUING TO NEXT STEP!**
7. Keep cartridge in an upright position. Load Cartridge on instrument within 15 minutes.

Starting the Test

1. In the GeneXpert Dx System window, click **Create Test**.
2. In the **Patient ID Barcode** field, enter the Patient's Last Name.
3. Scan the barcode on the Xpert™ GBS Assay cartridge.
4. In the **Sample ID** box, type the sample ID (e.g. SM0000).
5. In the **Notes** box, scan your personal identification barcode.
6. Click **Start Test**.
7. Open the instrument module door with the blinking green light and load the cartridge.
8. Close the door. Test will take 52 minutes.

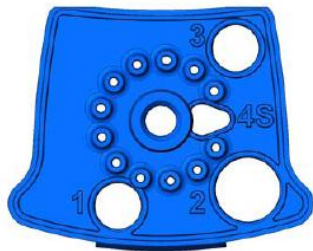
Reporting

1. Review your report to ensure that all checks passed. If the result is **INVALID**, **ERROR**, or **NO RESULT** repeat testing. Obtain another cartridge. Prepare the cartridge using;
 - the second swab (if you received a two swab collection kit)
 - the liquid from the S chamber (if present)
 - the swab out of the S chamber (if only one swab was received.)
2. Log into Meditech and go into Enter Results on the Specimen Desktop.
3. Enter SM#, type E in the Result field to go to page 1, enter **NEGGBS** for negative samples and **POSGBS** for positive samples.
4. Click on page 2.
5. File Result.

Clean the work areas with 10% bleach followed by 70% ethanol.

Preparing the Cartridge

1. Obtain patient sample
2. Open kit and label the cartridge with the sample ID.
3. Add Reagents 1-3 to their respective chambers.
4. Add 140µL of both Reagent 4 and the sample to chamber 4S.



- 1= Binding Reagent
- 2= Wash Reagent
- 3= Elution Reagent
- 4S = Lysis Reagent and Sample

Figure 1. Xpert EV cartridge (top view).

5. Close the cartridge lid.
6. **CHANGE GLOVES BEFORE CONTINUING TO NEXT STEP!**
7. Keep cartridge in an upright position. Load Cartridge on instrument within 15 minutes.

Starting the Test

1. In the GeneXpert Dx System window, click **Create Test**.
2. In the **Patient ID Barcode** field, enter the Patient's Last Name.
3. Scan the barcode on the Xpert™ EV Assay cartridge.
4. In the **Sample ID** box, type the sample ID (e.g. SM0000).
5. In the **Notes** box, scan your personal identification barcode.
6. Click **Start Test**.
7. Open the instrument module door with the blinking green light and load the cartridge.
8. Close the door. Test will take 2 hours and 32 minutes.

Reporting

1. Review your report to ensure that all checks passed. If the result is INVALID, ERROR, or NO RESULT repeat testing. Notify the patient care area of the delay in testing. **If the sample does not give a result two times in a row, freeze the sample for two hours. Thaw the sample and then repeat testing.**
2. Log into Meditech and go into Enter Results on the Specimen Desktop.
3. Enter SM#, type E in the Result field to go to page 1, enter **NEGEV** for negative samples and **POSEV** for positive samples.
4. Click on page 2. If result is positive enter canned comment **CALD**.
5. Call the patient nurse with the result and document the name of the person taking the result.
6. File Result.