|  |
| --- |
| GeneXpert Xpert Enterovirus (EV) Assay Quality Control |
| **Purpose** | This procedure provides instruction for Quality Control procedures required for the Xpert EV Assay. |
| **Policy Statements** | This procedure applies to Microbiologists who perform testing in the Rapid Molecular area. |
| **Materials** |  |  |  |  |
|  | **Reagents** | **Supplies** | **Equipment** |
|  | * Microbiologics Enterovirus (EV) Positive & Negative Control 8190
* Tris-EDTA (TE) buffer
* 10% bleach
* 70% ethanol
 | * Xpert Enterovirus cartridges
* Nuclease-Free Water
* Transfer pipettes
* Pipette tips
* Sample racks
* Cartridge transfer tray
* Absorbent biohazard squares
* Culturette swabs
* 200 uL extended pipette tips
* 15 ml conical tubes
 | * Biosafety Hood
* Cepheid GeneXpert Instrument and computer
* Printer
* Pipettes
 |
| **Sample** | **New Lot/Shipment and Monthly Quality control:*** Microbiologics Enterovirus (EV) negative controls
* Microbiologics Enterovirus (EV) positive controls

**Wipe test control (monthly):*** Culturette swab collection and placed into tris-EDTA (TE) buffer

**Instrument Performance Verification after repairs:*** One known positive and one known negative patient sample OR Positive and Negative External Controls
 |
| **Special Safety Precautions** | Microbiologists are subject to occupational risks associated with specimen handling. Refer to the safety policies located in the safety section of the *Microbiology Procedure Manual***.**1. [*Biohazard Containment*](file:///G%3A%5CLab%20Procedures%5CMicrobiology%5C1NEW%20Micro%20Procedure%20Manual.%20%28same%20as%20in%20Starnet%29%5CMCVI%203%20Safety%5CMCVI%203.1%20Biohazard%20Containment.docx)
2. [*Biohazardous Spills*](file:///G%3A%5CLab%20Procedures%5CMicrobiology%5C1NEW%20Micro%20Procedure%20Manual.%20%28same%20as%20in%20Starnet%29%5CMCVI%203%20Safety%5CMCVI%203.4%20Biohazardous%20Spills.docx)
3. [*Safety in the Microbiology Laboratory*](file:///G%3A%5CLab%20Procedures%5CMicrobiology%5C1NEW%20Micro%20Procedure%20Manual.%20%28same%20as%20in%20Starnet%29%5CMCVI%203%20Safety%5CMCVI%203.2%20Safety%20in%20the%20Microbiology%20Lab.docx)
 |
| **Storage** | * Store kits at 2-28°C. Kits are stable until the expiration date printed on the outer box.
* Store controls at 2-25°C. Swabs are stable until the expiration date printed on the package.
 |
| **Quality Control** | **Perform QC:*** Every 30 days
* Receipt of new shipments
* Receipt of new lots
* Drift in results (e.g., unexpected significantly increasing/decreasing positivity rates)
* Potential contamination (negative control)
* After drastic system maintenance
* Wipe testing: Monthly

**New Lot/Shipment and Monthly Quality control:**1. Obtain a positive and negative control and nuclease-free water.
2. Aliquot 3 ml nuclease-free water into 2 15 ml conical tubes (3 ml into each tube).
3. Clean hood and supplies: 10% bleach dilution followed by 70% ethanol.
4. Change gloves.
5. Obtain two test cartridges.
6. Label cartridges and conical tubes for the positive and negative controls.

**NOTE:** Set up the positive control first.1. Insert the swab into the nuclease-free water and break shaft off using and absorbent biohazard pad) orange as a barrier on the top of the tube.
2. Vortex the vial for 10 seconds.
3. Change gloves in-between processing of controls AND before moving to the instrument.
4. Run cartridges as patient samples. (see GeneXpert Xpert EV procedure)

**NOTE:** Under the “Test Type” field select “Positive Control 1” or “Negative Control 1”.1. Clean hood with 10% bleach dilution followed by 70% ethanol.
2. Document QC in the GeneXpert Assay binder.

**NOTE:** Before reporting patient results, all controls must yield valid results.**NOTE:** Rotate modules for QC testing.**Wipe test:**1. Aliquot 500 uL TE buffer into a cryovial.
2. Dip a culturette swab in the TE buffer and swab the processing hood surface, counter around the GeneXpert instrument (including the keyboard, mouse, and scanner), and door handles on the instrument.
3. Break swab off into the cryovial using an absorbent biohazard pad (orange) as a barrier on the top of the tube.
4. Process and run as a patient sample.
5. Document testing in the GeneXpert EV QC binder.

**NOTE:** In the event of positive result notify the tech specialist, decontaminate, and re-test. |
| **Procedure** | **Reviewing results:**1. Ensure that the printer is turned on.
	1. Reports will print automatically.
2. Review reports for valid QC results or any reason to retest

**Reasons to retest:**1. An **INVALID** result. This may indicate:
	1. The sample was not properly processed.
	2. PCR was inhibited.
2. An **ERROR** result. This may indicate:
	1. The reaction tube was filled improperly.
	2. A reagent probe integrity problem was detected.
	3. The maximum pressure limit was exceeded.
	4. A valve positioning error was detected.
3. **NO RESULT**:
	1. This result indicated that insufficient data were collected. (e.g. test stopped while in progress or power failure occurred.)

**NOTE:** if retesting is required, obtain a new vial of QC material**Valid Results:*** Microbiologics Enterovirus (EV) positive control: Enterovirus positive
* Microbiologics Enterovirus (EV) negative control: Enterovirus negative

**Desirable Results:*** Wipe test control: Enterovirus Negative

**NOTE:** Record any failures, errors, and repeat testing in the “GeneXpert Maintenance and Problem Log” **NOTE:** If there is a QC failure, document observation and correction action. Report QC problems that cannot be resolved to the tech specialist. For repeated failures contact Cepheid Technical Support. Do not report patient results until problem is resolved. |
| **References** | 1. Xpert EV Package Insert, 300-5052, Rev. H, October 2012. Sunnyvale, CA: Cepheid.
2. CAP Microbiology Checklist, College of American Pathologists, 325 Wakegan Road, Northfield, IL 60093-2750, 08/17/2016.
 |
|  |  |
| **Training Plan/ Competency Assessment** | **Training Plan** | **Initial Competency Assessment** |
| 1. Employee must read the procedure.
2. Employee will observe trainer performing the procedure.
3. Employee will demonstrate the ability to perform procedure, record results and document corrective action after instruction by the trainer.
 | 1. Direct observation.
 |
|  |  |
| **Historical Record** |  |  |  |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Julie Laramie / Matthew Meyer | 5/25/2020 | Initial Version |
| 2 | Susan DeMeyere/ Jamie Berg | 3/18/2022 | Change to Microbiologics controls |
|  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |