|  |
| --- |
| GeneXpert Xpress MVP Assay Quality Control |
| **Purpose** | This procedure provides instructions for Quality Control procedures required for the Xpert Xpress MVP Assay.  |
| **Policy Statements** | This procedure applies to all employees that work in microbiology that perform Quality Control. |
| **Sample** | **New Lot/Shipment and Monthly Quality control:*** Microbiologics 8255 Multiplex Vaginal Control Panel-positive and negative controls

**Wipe test control (monthly):*** Swab collected with an Xpert Swab Specimen Collection Kit

**Instrument Performance Verification after repairs:*** One known positive and one known negative patient sample OR Positive and Negative External Control swabs
 |
| Frequency | -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  |
| **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**Policy Manual***:**1. Biohazard Containment
2. Safety in the Microbiology Laboratory
* Biohazardous Spills
 |
| **Materials** |

|  |  |  |
| --- | --- | --- |
| Reagents | Supplies | Equipment |
| * Microbiologics 8255 Multiplex Vaginal Panel-positive and negative controls
* Household bleach
* 70% ethanol
 | * Xpert Swab Specimen collection kits
* Xpert Xpress MVP cartridges
* Transfer pipettes
* Simple racks
* Cartridge transfer tray
* Absorbent biohazard squares
 | * Biosafety Hood
* Cepheid GeneXpert Instrument and computer
* Printer
 |

 |
|
| **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.
 |
| **Procedure** | **New Lot/Shipment and Monthly Quality control:**1. Clean hood and supplies: 10% bleach dilution followed by 70% ethanol.
2. Change gloves.
3. Obtain Microbiologics Multiplex Vaginal Panel Pos/neg controls, two test cartridges and two Xpert Swab Specimen Collection sample tubes.
4. Label cartridges and collection tubes for the positive and negative controls, write prep date (exp. 1 day).
5. Setting up the positive control first, open the control swab.
6. Insert the swab into the collection tube, lift it up (about 2cm from the bottom), and break the shaft off using an absorbent biohazard pad (orange) as a barrier on the top of the tube.
7. Vortex the vial for 10 seconds.
8. Using the included kit pipet, transfer Swab Specimen Collection kit media into the proper cartridge.
9. Change gloves in-between processing of controls AND before moving to the instrument.
10. Run cartridges as patient samples (See GeneXpert Xpress MVP Assay procedure) labeled under the “Test Type” field select “Positive Control 1” or “Negative Control 1”.
11. Clean hood with 10% bleach dilution followed by 70% ethanol.
12. Document QC in the GeneXpert Assay binder.
* All controls must yield valid results before reporting patient results.
* Rotate modules for QC testing.

**Wipe test:**1. Obtain an Xpert Swab Specimen Collection Kit. Label the pink capped tube for wipe testing. Using the small swab from the kit, wet the swab in transport media and swab the processing hood surface, counter around the GeneXpert instrument (including the keyboard, mouse, and scanner), and door handles on the instrument.
2. Break swab off into the pink capped tube using an absorbent biohazard square as a barrier.
* The SAME pink capped tube can be used for CTNG and TV wipe testing.
1. Process and run as a patient sample.
2. Document testing in the GeneXpert QC binder.
3. In the event of positive result notify the tech specialist, decontaminate, and re-test.
 |
| **Interpretation and Documentation** | 1. Ensure that the printer is turned on. Reports will print automatically.
2. Click on **View Results** on the top drop-down menu bar and select **View Test**.
3. Select the result you would like to review: Click **OK**.

**Valid Results:*** **Microbiologics Multiplex Vaginal positive control:** BV Positive, Candida group Detected, Candida glab/krus Detected, TV Detected
* **Microbiologics Multiplex Vaginal negative control**: BV Negative, Candida group Not Detected, Candida glab/krus Not Detected, TV Not Detected
* **Wipe test control:** BV Negative, Candida group Not Detected, Candida glab/krus Not Detected, TV Not Detected
	1. NOTE: SPC does not need to pass for a positive result to be valid.
	2. NOTE: SPC does need to pass for a negative result to be valid.

**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.)

Record any failures on the “GeneXpert Service and Error Log” log. 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 Xpress MVP Package Insert, 301-8994, Rev. E, October 2022Sunnyvale, CA: Cepheid.
2. CAP Microbiology Checklist, College of American Pathologists, 325 Wakegan Road, Northfield, IL 60093-2750, 08/17/2016.
3. Microbiologics. Instructions for Use: Helix Elite Molecular Standards (Inactivated Swabs) Products, PI.2252 Rev D. St. Cloud, MN, 2019.
 |
| **Historical Record** |  |  |  |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Susan DeMeyere | 6/6/2023 | Initial Version |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |