|  |
| --- |
| GeneXpert Xpress SARS-CoV-2 Assay Quality Control |
| **Purpose** | This procedure provides instructions for Quality Control procedures required for the Xpert Xpress SARS-CoV-2 Assay.  |
| **Policy Statements** | This procedure applies to all employees that work in microbiology. |
| **Sample** | **New Lot/Shipment and 30 day Quality control:*** SeraCare Accuplex SARS-CoV-2 – Positive Controls
* SeraCare Accuplex SARS-CoV-2 – Negative Controls

**Wipe test control (monthly):*** Culturette swab collected and transferred into UTM

**Instrument Performance Verification after repairs:*** One known positive and one known negative patient sample OR Positive and Negative External Controls
 |
| Frequency | -Every 30 days -Receipt of new shipments-Receipt of new lots-Drift in results (e.g., increasing/decreasing positivity rates)-Potential contamination (negative control)-After drastic system maintenance-Wipe testing: Monthly  |
| **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*
 |
| **Materials** |

|  |  |  |
| --- | --- | --- |
| Reagents | Supplies | Equipment |
| * SeraCare AccuPlex SARS-Cov-2 Reference Material Kit (Catalog No. 0505-0126)
* 10% bleach
* 70% ethanol

Store controls at 2-8°C. Vials are stable until the printed expiry. | * UTM
* Culturette swabs
* Xpert Xpress SARS-CoV-2 Assay cartridges
* Transfer pipettes
* Sample racks
* Cartridge transfer tray
* Absorbent biohazard squares
* Gloves

Store kits at 2-28°C. Kits are stable until the expiration date printed on the outer box.  | * Biosafety Hood
* Cepheid GeneXpert Instrument and computer
* Printer
 |

 |
|
| **Procedure** | **New Lot/Shipment and Daily Quality control:**1. Clean hood and supplies: 10% bleach followed by 70% ethanol.
2. Change gloves.
3. Let one positive (red cap) and one negative (clear cap) QC vial come to room temperature before use.

**NOTE:** Each QC vial can be used up to five (5) times.**NOTE:** label control vials with open date.1. Obtain two test cartridges.
2. Label cartridges for the positive and negative controls.

**NOT**E: Set up the positive control first.1. Vortex controls 5 -10 seconds before use.

**NOTE:** change gloves in between set up of the positive and negative controls1. Run samples as patient samples. (see Xpert Xpress SARS-CoV-2 Assay procedure)

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

**NOTE:** Before reporting patient results, all controls must yield valid results.**NOTE:** Rotate modules for QC testing**Wipe test:**1. Label a UTM tube for wipe testing.
2. Dip a culturette swab into the UTM to moisten.
3. Swab the processing hood surface, counter around the GeneXpert instrument (including the keyboard, mouse, and scanner), and door handles on the instrument.
4. With an absorbant pad covering the top, break swab off into a UTM tube.
5. Process and run as a patient sample.
6. Document testing in the SARS-CoV-2 QC binder.

**NOTE:** 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.
	1. Reports will print automatically.
2. Review reports for results of INVALID, ERROR, NO RESULT or SARS-CoV-2 PRESUMPTIVE POS and repeat testing if necessary.

**Valid QC Results:**Xpert Xpress SARS-CoV-2 Assay:1. SeraCare AccuPlex SARS-CoV-2 Positive Control: **SARS-CoV-2 Detected**
2. SeraCare AccuPlex SARS-CoV-2 Negative Control: **SARS-CoV-2 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.

**Desirable Wipe testing Results:**Wipe test control: **SARS-CoV-2 Not Detected**, No Ct values for E and N2 genes**Reasons to retest:**1. A **SARS-CoV-2 PRESUMPTIVE POSITIVE** result. This may indicate:
	1. SARS-CoV-2 nucleic acids may be present (likely near the limit of detection).
	2. Human or Bat SARS nucleic acids may be present.
2. An **INVALID** result (SPC failure). This may indicate:
	1. The sample was not properly processed.
	2. PCR was inhibited.
	3. The sample was not properly collected.
3. An **ERROR** result. This may indicate:
	1. Probe Check Control failure.
	2. System component failure.
	3. The maximum pressure limit was exceeded.
4. **NO RESULT**:
	1. This result indicated that insufficient data were collected. (e.g. test stopped while in progress or power failure occurred.)

**NOTE:** The same QC vials can be used to retest if their integrity is not in question.**NOTE:** Record any failures, errors and repeat testing in the “GeneXpert Maintenance and Problem Logs” binder.**NOTE:** If there is a QC failure or unexpected results, document observation and correction action. Report QC problems that cannot be resolved to the Technical Specialist. For repeated failures contact Cepheid Technical Support. Do not report patient results until problem is resolved.**NOTE:** If Wipe Test Control results are positive, notify the Technical Specialist, decontaminate the space, recollect a swab and retest. Upon secondary failure discuss expanded testing with the Technical specialist  |
| **References** | 1. Xpert Express SARS-CoV-2 Package Insert, 3023562, Rev C, April 2020. In. Sunnyvale, CA: Cepheid.
2. AccuPlex SARS-CoV-2 Reference Material Kit Package Insert, 13668US-01, March 2020. In. Milford, MA: SeraCare.
 |
| **Historical Record** |  |  |  |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Julie Laramie | 4/13/2020 | Initial Version |
| 2 | Julie Laramie | 6/15/2020 | Changed QC to every 30 days  |
|  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |
| **Archived by:** |  | **Archived Date:** |  |