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| GeneXpert Xpress SARS-CoV-2/Flu/RSV Assay Quality Control |
| **Purpose** | This procedure provides instructions for Quality Control procedures required for the Xpert Xpress SARS-CoV-2/Flu/RSV Assay.  |
| **Policy Statements** | This procedure applies to all employees that work in microbiology. |
| **Sample** | **New Lot/Shipment and Monthly Quality control:*** ZeptoMetric NATtrol Flu/RSV/SARS-CoV-2 External Run Controls
* NATFRC-6C: Positive Controls
* VTM: Negative Controls

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

**Instrument Performance Verification after repairs:*** One known positive and one known negative patient sample OR Positive and Negative External Control Material
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| 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*
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| **Materials** |

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| Reagents | Supplies | Equipment |
| * ZeptoMetrix Positive Control (NATFRC-6C)
* VTM (negative QC)
* Household bleach
* 70% ethanol
 | * Culturette swabs
* Xpert Xpress SARS-CoV-2/Flu/RSV Assay cartridges
* Transfer pipettes
* Sample racks
* Cartridge transfer tray
* Absorbent biohazard squares

Store kits at 2-28°C. Kits are stable until the expiration date printed on the outer box. Store controls at 2-8°C. Stable until the expiration date printed on the package. | * Biosafety Hood
* Cepheid GeneXpert Instrument and computer
* Printer
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| **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 a positive control and a VTM aliquot for the negative control.
4. Label cartridges for the positive and negative controls.

**NOTE:** Set up the positive control first.1. Set up as you would a patient sample.
2. Change gloves in-between processing of controls AND before moving to the instrument.
3. Run cartridges as patient samples. (see Xpert Xpress SARS-CoV-2/Flu/RSV Assay 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. Label a VTM tube for wipe testing.
2. Dip a culturette swab into the VTM 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 absorbent pad covering the top, break swab off into a VTM tube.
5. Process and run as a patient sample.
6. Document testing in the GeneXpert 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. 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**.
4. Review result interpretations and amplification curves for exponential growth.
	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.
5. Click on the **Errors** tab to ensure no errors occurred during testing. (Section 9.18.2 in Operator Manual provides error code descriptions)

**Reasons to retest:**1. An **INVALID** result (SPC failure). This may indicate:
	1. The sample was not properly processed.
	2. The sample was not properly collected.
	3. PCR was inhibited.
2. An **ERROR** result. This may indicate:
	1. Probe Check failure.
	2. System component failure.
	3. No sample or too little of sample added.
	4. Maximum pressure limits were exceeded.
3. **NO RESULT**:
	1. This result indicated that insufficient data were collected (e.g. test stopped while in progress or power failure occurred).

**NOTE:** Record any failures on the “GeneXpert Service and Error Log” log. **Valid Results:**Positive control: SARS-CoV-2 POSITIVEFlu A POSITIVE Flu B POSITIVERSV POSITIVE Negative Control: SARS-CoV-2 NEGATIVEFlu A NEGATIVEFlu B NEGATIVERSV NEGATIVE**Desirable Results:*** Wipe test control: no analytes detected

**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. |
| **References** | 1. Xpert Xpress SARS-CoV-2/Flu/RSV Package Insert, 302-4421, Rev. A, September, 2020. Sunnyvale, CA: Cepheid.
2. ZeptoMetrix NATtrol Flu/RSV/SARS-CoV-2 External Run Controls Package Insert, ZMC-PI-0029, Rev. 01, August, 2020. Buffalo, NY: ZeptoMetrix.
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| **Historical Record** |  |  |  |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Julie Laramie | 11/01/2020 | Initial Version |
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| **Archived by:** |  | **Archived Date:** |  |