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| GeneXpert Xpress SARS-CoV-2, Flu and RSV Assay | | | | | |
| **Purpose** | This procedure provides instructions for performing the Xpert Xpress SARS-CoV-2, Flu and RSV assay on the Cepheid GeneXpert system. | | | | |
| **Policy Statements** | This procedure applies to all technical staff performing testing on the GeneXpert. | | | | |
| **Principle and Clinical Significance** | The Xpert Xpress Flu and Flu-RSV Assay is intended to aid in the diagnearlyosis of SARS-CoV-2 (COVID-19), Influenza (Flu) and Respiratory Syncytial virus (RSV) in patients with signs and symptoms of respiratory infection. The results are intended to be used in conjunction with clinical and epidemiological risk factors.  An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) on December 31, 2019.Chinese authorities identified a novel coronavirus (2019-nCoV), which has since spread globally, resulting in a pandemic of coronavirus disease 2019 (COVID­19). COVID-19 is associated with a variety of clinical outcomes, including asymptomatic infection, mild upper respiratory infection, severe lower respiratory disease including pneumonia and respiratory failure, and in some cases, death. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.  Influenza is a contagious viral infection of the respiratory tract. Transmission of the flu is primarily airborne, and the peak of transmission typically occurs in the winter months. Symptoms commonly include fever, chills, headache, malaise, cough, and sinus congestion. Gastrointestinal symptoms (i.e., nausea, vomiting or diarrhea) may also occur, primarily in children, but are less common. Symptoms generally appear within two days of exposure to an infected person. Pneumonia may develop as a complication due to influenza infection, causing increased morbidity and mortality in pediatric, elderly, and immunocompromised populations.  Influenza viruses are classified into types A, B, and C. Influenza A is the most common type of influenza virus in humans, and is generally responsible for seasonal flu epidemics and potentially pandemics. Influenza A viruses can also infect animals such as birds, pigs, and horses. Infections with influenza B virus are generally restricted to humans and less frequently cause epidemics. Influenza A viruses are further divided into subtypes on the basis of two surface proteins: hemagglutinin (H) and neuraminidase (N). Seasonal flu is normally caused by subtypes H1, H2, H3, N1 and N2. In addition to seasonal flu, a novel H1N1 strain was identified in humans in the United States in early 2009.  Respiratory Syncytial Virus (RSV), a member of the *Pneumoviridae* family (formerly *Paramyxoviridae*), consisting of two strains (subgroups A and B) is also the cause of a contagious disease. RSV primarily affects infants, and the elderly who are immunocompromised. The virus can remain infectious for hours on countertops and toys and can cause both upper respiratory infections, such as colds, and lower respiratory infections manifesting as bronchiolitis and pneumonia. By the age of two years, most children have already been infected by RSV and because only weak immunity develops, both children and adults can be reinfected. Symptoms appear four to six days after infection and are usually self-limiting, lasting approximately one to two weeks in infants. In adults, infection lasts about 5 days and presents as symptoms consistent with a cold, such as rhinorrhea, fatigue, headache, and fever. The RSV season mirrors influenza somewhat as infections begin to rise during the fall through early spring.  The Xpert Xpress SARS-CoV-2/Flu/RSV test is a molecular *in vitro* diagnostic test that aids in the detection and differentiation of RNA from Flu A, Flu B, RSV and SARS-CoV-2 virus and is based on widely used nucleic acid amplification technology. The Xpert Xpress SARS-CoV-2/Flu/RSV test contains primers and probes and internal controls used in RT­PCR for the *in vitro* qualitative detection and differentiation of RNA from Flu A, Flu B, RSV and SARS-CoV-2 virus in upper respiratory specimens.  **Principle of the Procedure**  The Xpert Xpress SARS-CoV-2/Flu/RSV test is an automated *in vitro* diagnostic test for qualitative detection and differentiation of RNA from Flu A, Flu B, RSV and SARS-CoV-2 virus. The Xpert Xpress SARS-CoV-2/Flu/RSV test is performed on GeneXpert Instrument Systems.  The GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real-time PCR and RT-PCR assays.  The Xpert Xpress SARS-CoV-2/Flu/RSV test includes reagents for the detection of RNA from Flu A, Flu B, RSV and SARS-CoV-2 virus in either nasopharyngeal swab, nasal swab, or nasal wash/ aspirate specimens. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert instrument. The SPC is present to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the RT-PCR reaction. The SPC also ensures that the RT-PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the RT-PCR reagents are functional. The PCC verifies reagent rehydration, PCR tube filling, and confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability.  The nasopharyngeal swab, nasal swab, or nasal wash/ aspirate specimen is collected and placed into a transport tube containing 3 mL of viral transport medium. The specimen is briefly mixed by rapidly inverting the collection tube 5 times. Using the supplied transfer pipette, the sample is transferred to the sample chamber of the Xpert Xpress SARS-CoV-2/Flu/RSV cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Instrument System platform, which performs hands-off, automated sample processing, and real-time RT-PCR for detection of viral RNA. | | | | |
| **Test Code** | **FLVD**: SARS-CoV-2 and Flu  **FLRVD**: SARS-CoV-2, Flu, and RSV | | | | |
| **Sample** | 1. **Acceptable specimens:**  * Nasopharyngeal (NP) swabs: Mini-tip flocked swabs placed in 3mL UTM * Nasal swabs: Flocked swabs placed in 3mL UTM  1. **SDES codes/Specimen type:**  * **NP** – Nasopharyngeal Swab * **NARE –** Nasal Swab  1. **Specimen Collection and Transport:**  * Refer to *Lab Test Directory* on StarNet  1. **Specimen assessment:**  * Refer to the policy MCVI 2.1 *Specimen Rejection Criteria*  1. **Specimen Storage**  * Specimens should be refrigerated (2–8 °C) up to seven days until testing is performed * Specimens can be stored at room temperature (15–30 °C) for up to 24 hours if required | | | | |
| **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 | | * Household bleach * 70% ethanol | * Xpert Xpress SARS-Cov-2/Flu/RSV Assay cartridges * Transfer pipettes * Sample racks * Cartridge transfer tray * 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 | | | | | |
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| **Calibration** | Annual “Xpert Check Kit” calibration performed by Cepheid. | | | | |
| **Quality Control** | **Daily Quality Control:**  Once an Xpert cartridge has been loaded and before the sample processing steps begin, the software checks the optics, the readiness of the module’s mechanical components, and the ambient temperature of the module to assure proper performance of PCR, and the physical integrity of the cartridge.  Each test includes a Sample Processing Control (SPC) and a Probe Check Control (PCC).   * **Sample Processing Control (SPC) –** Ensures that the sample was processed correctly. The SPC verifies that sample processing is adequate. Additionally, this control detects sample-associated inhibition of the real-time PCR assay, ensures that the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction, and that the PCR reagents are functional. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria. * **Probe Check Control (PCC) –** Before the start of the PCR reaction, the GeneXpert System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability. The PCC passes if it meets the validated acceptance criteria.   **External Quality Control:**   * Perform QC using external positive and negative controls every day patient testing is performed. Record results in the GeneXpert assay binder on the Log. * See IQCP document. * See Quality Control Procedure.   **New Lot/Shipment Quality control:**   * Perform QC using external positive and negative controls with each new lot or shipment before putting into service. Record results in the GeneXpert assay binder on the Log. * See Quality Control Procedure   **Wipe testing control:**   * Perform wipe testing every 30 days to monitor for contamination. * See Quality Control Procedure.   **NOTE:** External quality control may be performed on an as needed basis if certain circumstances arise. Examples include:   * Drift in results (e.g., increasing/decreasing positivity rates) * Potential contamination (negative control) * After drastic system maintenance | | | | |
| **Procedure** | **Cartridge preparation:**   1. Clean hood with10% bleach dilution (made daily) followed by 70% ethanol. 2. Change gloves. 3. Obtain an Assay cartridge, transfer pipette, and sample transport tube to be tested. 4. Label the side of the cartridge with a bar-coded foot-label. 5. Open the cartridge lid. 6. Mix the sample by vortexing for 10 seconds. 7. Open the transport tube lid and draw up specimen in the transfer pipette by completely squeezing the top bulb until it is flat, place the pipette into the VTM, and release the top bulb to slowly fill the pipette. See the **Figure 1** below.     **Figure 1: Sample Transfer Pipette**   1. Insert the pipette to the bottom of the well in the cartridge (see **Figure 2**)and empty the pipette’s content into the cartridge.   **NOTE:** Take care to dispense the entire volume of liquid into the Sample Chamber. False negative results may occur if insufficient sample is added to the cartridge.    **Figure 2: Test Cartridge**   1. Close the cartridge lid, and set onto the transfer tray. 2. Change gloves and proceed to prepare additional samples or start the test.   **NOTES:**  -Hood surfaces must be cleaned between samples with 10% bleach dilution followed with 70% ethanol if there were any splashes, spills, or uncertainty of cleanliness.  -\*\*Start the test within 30 minutes of adding the sample to the cartridge  **Starting the test:**   1. Ensure clean gloves are on before stepping to the computer work space. 2. If instrument and computer are turned off: start up the instrument by flipping the power switch located in the back of the instrument. Turn on the computer next. 3. Log onto the appropriate Windows account:    1. User: lab1    2. Password: labstaff4 4. The GeneXpert software will launch automatically. If it doesn’t double-click the GeneXpert Dx software shortcut icon on the desktop. 5. Log onto the software.    1. User: First 6 letters of your first and last name (combined)    2. Password: First 6 letters of your first and last name (combined) 6. In the GeneXpert System window, click **Create Test.** 7. Navigate to the **Sample ID** box. Scan or type in the sample ID. 8. Scan the barcode on the cartridge.   NOTE: if the barcode on the cartridge does not scan, then repeat the test with a new cartridge.   1. If prompted, select the appropriate assay from the **Select Assay MENU.**    1. Select “Xpert Xpress SARS-CoV-2/Flu/RSV” 2. Select the appropriate test type for samples or controls. 3. Enter additional information in the “notes” field (day of QC, collect date, etc.) if needed. 4. Click **Start Test**. 5. Enter your username and password, if requested. 6. Open the instrument module door with the blinking green light.   **NOTE:** when setting up for testing you may opt to use any available module.   1. With the barcode facing towards you, set the cartridge into the module and close the door. 2. Wait for the test to start and the light to stop blinking. The test will run for approximately 42 minutes. 3. Remove the cartridge when testing is finished (the light will be off and the system will release the door lock). 4. Dispose of used cartridges into bio-bags and place into biohazard sharps bins. 5. Clean any equipment used (pipettes, racks, transfer tray, etc.), hood, and counters (including keyboard, scanner, and mouse) at the end of the day.   **NOTE:** Sample processing, testing, and cleaning should follow a unidirectional work-flow to avoid contamination. | | | | |
| **Interpretation/ Results** | 1. Click on **View Results** on the top drop-down menu bar and select **View Test**. 2. Select the result you would like to review: Click **OK**.    1. The results reported are interpreted automatically by the GeneXpert Instrument System. 3. If required, review result interpretations and amplification curves for exponential growth. See **Figure 3**.    1. **NOTE:** SPC does not need to pass for a positive result to be valid.    2. **NOTE:** the SPC does need to pass for a negative result to be valid. 4. Click on the **Errors** tab to ensure no errors occurred during testing. (Section 9.18.2 in Operator Manual provides error code descriptions)   **Figure 3: Amplification curves**    **Influenza Interpretation notes:**   1. The Xpert Xpress SARS-CoV-2/Flu/RSV Assay has two channels (Flu A 1 and Flu A 2) to detect most influenza A strains. 2. All influenza A strains detected by the Xpert Xpress Flu or Flu/RSV Assay are reported as **Flu A POSITIVE**.   **NOTE:** Either the Flu A 1 or Flu A 2 channel need to be positive in order for a **Flu A POSITIVE** test result to be reported.   1. **Table 1** below lists all the possible test results for Flu A.   **Table 1: Possible Flu A Results**     1. **Table 2** below lists possible results and interpretations.   **Table 2: SARS-CoV-2Flu/RSV Instrument Results and Interpretations**   |  |  | | --- | --- | | **Result** | **Interpretation** | | **SARS-CoV-2 POSITIVE** | The SARS-CoV-2 target nucleic acids are detected.   * The SARS-CoV-2 signal has a Ct within the valid range and endpoint above the minimum setting * SPC: NA (not applicable); SPC is ignored because SARS-CoV-2 target amplification occurred. * Probe Check: PASS; all probe check results pass. | | **Flu A POSITIVE\*\*** | The Flu A signal for either the Flu A1 nucleic acid target or the Flu A2 nucleic acid target or signals for both nucleic acid targets has a Ct within the valid range and endpoint above the threshold setting.   * SPC – NA; SPC is ignored because the Flu A target amplification occurred. * Probe Check – PASS; all probe check results pass. | | **Flu B POSITIVE\*\*** | The Flu B signal has a Ct within the valid range and endpoint above the minimum setting.   * SPC: NA; SPC is ignored because Flu B target amplification occurred. * Probe Check: PASS; all probe check results pass. | | **RSV POSITIVE** | The RSV signal has a Ct within the valid range and endpoint above the minimum setting.   * SPC: NA; SPC is ignored because RSV target amplification occurred. * Probe Check: PASS; all probe check results pass | | **SARS-CoV-2 NEGATIVE**  **Flu A NEGATIVE**  **Flu B NEGATIVE**  **RSV NEGATIVE** | SARS-CoV-2 target RNA is not detected; Flu A target RNA is not detected; Flu B target RNA is not detected; RSV target RNA is not detected.   * SARS-CoV-2, Flu A, Flu B and RSV target RNAs are not detected. * SPC – PASS; SPC has a Ct within the valid range and endpoint above the minimum setting. * Probe Check – PASS; all probe check results pass. | | **INVALID** | SPC does not meet acceptance criteria. Presence or absence of the target RNAs cannot be determined. Repeat testing.   * SPC: FAIL; SPC and SARS-CoV-2, Flu A, Flu B and RSV signals do not have a Ct within valid range and endpoint is below minimum setting. * Probe Check – PASS; all probe check results pass. | | **ERROR** | Presence or absence of SARS-CoV-2, Flu A, Flu B and RSV nucleic acids cannot be determined. Repeat test according to the Retest Procedure below.   * SARS-CoV-2: NO RESULT * Flu A: NO RESULT * Flu B: NO RESULT * RSV: NO RESULT * SPC: NO RESULT * Probe Check: FAIL1; all or one of the probe check results fail\*   \*If the probe check passes, the error is caused by the maximum pressure limit exceeding the acceptable range, no sample added, or by a system component failure. | | **NO RESULT** | Presence or absence of SARS-CoV-2, Flu A, Flu B and RSV nucleic acids cannot be determined. Repeat test according to the Retest Procedure bekiw. A **NO RESULT** indicates that insufficient data were collected. For example, the operator stopped a test that was in progress.   * SARS-CoV-2: NO RESULT * Flu A: NO RESULT * Flu B: NO RESULT * RSV: NO RESULT * SPC: NO RESULT * Probe Check: NA | | If the SPC is negative and the results for any of the targets are positive, the results for all targets are considered valid. | |   **\*\*If sample is positive for BOTH Flu A and B, repeat testing.** If repeat testing yields the same results – report sample as a dual positive  **Reasons to retest the original sample:**   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). 4. A dual positive result was obtained upon initial testing   **Retesting procedure:**   1. Call provider to notify if result reporting will exceed the 1 hour turnaround time.   **NOTE:** Document who you called and the date/time in the problem log and on the results sheet.   1. Obtain the original sample and a new cartridge. 2. Retest the sample according to the instructions in this SOP. 3. Report results according to **Table 3** below.   **Table 3: Retesting results and interpretation**   |  |  |  | | --- | --- | --- | | **Initial result** | **Repeat Result** | **Report** | | **INVALID** | INVALID | Unresolved | | VALID | Valid results | | **ERROR** | ERROR or INVALID | Unresolved | | VALID | Valid results | | **NO RESULT** | NO RESULT, ERROR or INVALID | N/A – repeat testing | | **Dual Positive (Flu A and Flu B)** | Dual Positive (matches) | Report dual positive | | Single positive | Consult Technical Specialist or Technical Director |  1. See the instructions below for reporting unresolved results.   **NOTE:** Record any failure, errors, and repeat testing on the “GeneXpert Service and Error Log” log. | | | | |
| **Result Reporting** |  | | | | |
|  | **NOTE:** Negative results **will** auto file, SARS-CoV-2 Positive, Dual Flu A/B Positive, and Invalid (Unresolved) results will **not** auto file   1. Log into Sunquest Laboratory to release results. 2. Select **Result Entry** from menu options. 3. In the Configuration field select CGX from the dropdown box. 4. Click on the **Result** button located in the lower right corner to populate the transmitted results. 5. Review messages located on the top and results. Compare results to the GeneXpert report. 6. Record provider notification if reporting:    1. Positive SARS-CoV-2 Results    2. Unresolved Results (See Reporting Invalid (unresolved) Results) 7. Check the release box. 8. Click **Save** button located on the lower left corner. Click **Accept** when the “Verify Release Destination” window opens.   **NOTE:** All samples will automatically have the following result comment attached: **SARS4** “The Xpert Xpress SARS-CoV-2/Flu/RSV Assay was issued an Emergency Use Authorization (EUA) by the FDA on September 24, 2020.”   1. At the end of the shift call a completed worksheet check results, and staple to GeneXpert Report. Place in the GeneXpert SARS-CoV-2/Flu/RSV result binder. 2. Store samples in fridge:    1. Put in rack according to **day of the week**    2. **Mark positive samples with X** on the cap, and write results on the tube. 3. **Write results on a large patient label** and place in the bin by printer. 4. Discard old samples after 7 days.   **NOTE:** St. Paul lab is to send positive samples and labels to Mpls | | | | |
| **Critical Results** | No critical result values. | | | | |
| **Reporting confirmed Flu A and Flu B dual positive results** | 1. Log into Sunquest to release results. 2. Select Result Entry from Menu options 3. In the Configuration field select CGX from the dropdown box. 4. Click on the  button located in the lower right corner to populate the transmitted results. 5. Review messages located on the top and results. Compare results to the GeneXpert report. | | | | |
| **Reporting Invalid (unresolved) Results** | 1. Notify the care provider of the unresolved result. 2. Log into Sunquest to release results. 3. Select Result Entry from Menu options 4. In the Configuration field select CGX from the dropdown box. 5. Click on the  button located in the lower right corner to populate the transmitted results. 6. Review messages located on the top and results. Compare results to the GeneXpert report. 7. The result will be reported as **unresolved** (UNRE) and the following code SIA will automatically append: “This sample is inhibitory to amplification and the results are inconclusive. Consider repeat collection if clinically indicated.” 8. Add the code CAL to one of the results, press tab, enter semi-colon record who the result was relayed to and the date/time. 9. Check the release box. 10. Click  button located on the lower left corner. Click  when the “Verify Release Destination” window opens. | | | | |
| **Correcting Results** | 1. Open Result Entry, select the Manual resulting mode (top left corner), from the configuration drop down select the appropriate test. Click  in the lower right corner. 2. Enter the Specimen ID, enter Tab and click Yes to modify the result. 3. Change the incorrect result. The corrected result comment will automatically append. Add the CAL comment, press tab, enter a semi-colon and record who was called and the time/date.      1. Click . Click  when the “Verify Release Destination” window opens. | | | | |
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| **Limitations** | * Performance of the Xpert Xpress SARS-CoV-2/Flu/RSV test has only been established in nasopharyngeal swab specimens. Use of the Xpert Xpress SARS-CoV-2/Flu/RSV test with other specimen types has not been assessed and performance characteristics are unknown. * Nasal swabs (self-collected under supervision of, or collected by, a healthcare provider) and nasal wash/aspirate specimens are considered acceptable specimen types for use with the Xpert Xpress SARS-CoV-2/Flu/RSV test but performance with these specimen types has not been established. * As with any molecular test, mutations within the target regions of the Xpert Xpress SARS-CoV-2/Flu/RSV test could affect primer and/or probe binding resulting in failure to detect the presence of virus or the virus being detected less predictably. * This test cannot rule out diseases caused by other bacterial or viral pathogens. * The performance of this test was validated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the test. * Erroneous test results might occur from improper specimen collection; failure to follow the recommended sample collection, handling, and storage procedures; technical error; or sample mix-up. Careful compliance with the instructions in this insert is necessary to avoid erroneous results. * False negative results may occur if virus is present at levels below the analytical limit of detection. * Negative results do not preclude SARS-CoV-2, influenza or RSV infection and should not be used as the sole basis for treatment or other patient management decisions. * Results from the Xpert Xpress SARS-CoV-2/Flu/RSV test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient. * Viral nucleic acid may persist *in vivo*, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious or are the causative agents for clinical symptoms. * This test has been evaluated for use with human specimen material only. * This test is a qualitative test and does not provide the quantitative value of detected organism present. * This test has not been evaluated for monitoring treatment of infection. * This test has not been evaluated for screening of blood or blood products for the presence of SARS-CoV-2, influenza or RSV. * The effect of interfering substances has only been evaluated for those listed within the labeling. Interference by substances other than those listed in the instructions foruse can lead to erroneous results. * Results from analytical studies with contrived co-infected samples showed potential for competitive interference when SARS-CoV-2, Flu or RSV was present at 1X LoD levels. * Cross-reactivity with respiratory tract organisms other than those described herein can lead to erroneous results. * Recent patient exposure to FluMist® or other live attenuated influenza vaccines may cause inaccurate positive results. * As the Xpert Xpress SARS-CoV-2/Flu/RSV test does not differentiate between the N2 and E gene targets, the presence of other coronaviruses in the B lineage, *Betacoronavirus* genus, including SARS-CoV-1 may cause a false positive result. None of these other coronaviruses is known to currently circulate in the human population. * This test is not intended to differentiate RSV subgroups, influenza A subtypes or influenza B lineages. If differentiation of specific RSV or influenza subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required. * This test has not been FDA cleared or approved. * This test has been authorized by FDA under an EUA for use by authorized laboratories. * This test has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV), and not for any other viruses or pathogens. * This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. | | | | |
| **Method Performance Specifications** | According to the manufacturer (per the package insert) – see **Table 4** below.  **Table 4: Overall specifications for NP specimens** | | | | |
| **References** | Xpert Xpress SARS-CoV-2/Flu/RSV Package Insert, 302-4421, Rev. A, September, 2020. Sunnyvale, CA: Cepheid.  Influenza (Flu) Atlanta, GA: Centers for Disease Control and Prevention; 2019 [Available from: <https://www.cdc.gov/flu/index.htm>.]  Respiratory Syncytial Virus Infection (RSV) Atlanta, GA: Centers for Disease Control and Prevention; 2018 [Available from: <https://www.cdc.gov/rsv/index.html>.]  Zou L, Ruan F, Huang M, et al. SARS-CoV-2 viral load in upper respiratory specimens of infected patients. 2020.  Xu X-W, Wu X-X, Jiang X-G, et al. Clinical findings in a group of patients infected with the 2019 novel coronavirus (SARS-Cov-2) outside of Wuhan, China: retrospective case series. 2020;368.  Lai C-C, Shih T-P, Ko W-C, Tang H-J, Hsueh P-RJIjoaa. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and corona virus disease-2019 (COVID-19): the epidemic and the challenges. 2020:105924. | | | | |
| **Alternate Methods** | 1. Flu/RSV PCR in house 2. SARS-CoV-2 PCR in house or send out 3. Respiratory Panel testing | | | | |
| **Proficiency Testing** | CAP:  ID3, 3 shipments with 5 samples (Flu/RSV)  COV2, 2 shipments with 3 samples (SARS-CoV-2) | | | | |
| **Training Plan/ Competency Assessment** | **Training Plan** | | | **Initial Competency Assessment** | |
| 1. Employee must read the procedure. 2. 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 | 11/01/2020 | | Initial Version |
|  |  |  | |  |
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|  |  |  | |  |
| **Archived by:** |  | **Archived Date:** | |  |