<table>
<thead>
<tr>
<th><strong>Lab Dept:</strong></th>
<th>Microbiology/Virology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Name:</strong></td>
<td>RSV &amp; INFLUENZA A, B PCR</td>
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</table>

**General Information**

<table>
<thead>
<tr>
<th><strong>Lab Order Codes:</strong></th>
<th>RIP</th>
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<tbody>
<tr>
<td><strong>Synonyms:</strong></td>
<td>Influenza A, B and RSV PCR; Respiratory viruses, RSV and Influenza A, B PCR; PCR for RSV and Influenza A, B</td>
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<tr>
<td><strong>CPT Codes:</strong></td>
<td>87631 – Respiratory virus, multiplex amplified probe, 3-5 targets</td>
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<tr>
<td><strong>Test Includes:</strong></td>
<td>Rapid detection of influenza virus types A and B and RSV in upper respiratory tract infections by RT-PCR (Reverse Transcription Polymerase Chain Reaction).</td>
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**Logistics**

<table>
<thead>
<tr>
<th><strong>Lab Testing Sections:</strong></th>
<th>Microbiology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phone Numbers:</strong></td>
<td>MIN Lab: 612-813-5866</td>
</tr>
<tr>
<td></td>
<td>STP Lab: 651-220-6555</td>
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<tr>
<td><strong>Test Availability:</strong></td>
<td>Specimens accepted daily, 24 hours</td>
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<tr>
<td><strong>Turnaround Time:</strong></td>
<td>45 minutes</td>
</tr>
<tr>
<td><strong>Special Instructions:</strong></td>
<td>• Requisition must state <strong>specific site</strong> of specimen and <strong>date/time of collection</strong>.</td>
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**Specimen**

| **Specimen Type:** | Flocked Nasopharyngeal (NP) swabs in Universal Transport Media (UTM), Flocked nasal swabs in UTM |
**Container:**
NP Swabs

CHC #: 32788 Swab, flocked Sterile 3mL

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**Nasal Swabs:**

CHC #: 32720 Kit, Spec Collection Swab Cup

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**Volume:**
1 Nasopharyngeal (NP) SWAB: 1 Nasal Swab

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**Collection:**

**Nasopharyngeal swabs:**

1. Open the package that contains the swab and transport medium tube. Set the tube aside before collecting the specimen.
2. Open the swab wrapper and remove the swab, taking care not to touch the tip of the swab to any surface.
3. Hold the swab in your hand, pinching in the middle of the swab shaft on the scoreline.
4. Gently insert the swab into the nostril until you touch the posterior nasopharynx. Rotate the swab several times.
5. Remove the cap from the tube. Insert the swab into the transport medium.
6. Break the swab shaft against the side of the tube at the scoreline. Avoid splashing contents on the skin. Wash with soap and water if exposed.
7. Replace the cap on the tube and close tightly for transport to the lab.

Nasal swabs:
1. Open the package that contains the swab and transport medium tube. Set the tube aside before collecting the specimen.
2. Open the swab wrapper and remove the swab, taking care not to touch the tip of the swab to any surface.
3. Hold the swab in your hand, pinching in the middle of the swab shaft on the scoreline.
4. Rotate the swab against the inside of the nostril for 3 seconds while applying pressure with a finger to the outside of the nostril. Do not insert the swabs more than 1-1.5 cm.
5. Repeat Step 4 on the other nostril with the same swab. To avoid specimen contamination, do not touch the swab tip to anything after collecting the specimen.
6. Remove the cap from the tube. Insert the swab into the transport medium.
7. Break the swab shaft against the side of the tube at the scoreline. Avoid splashing contents on the skin. Wash with soap and water if exposed.
8. Replace the cap on the tube and close tightly for transport to the lab.

Transport/Storage: Transport to the laboratory immediately to maintain specimen integrity. Specimens can be stored at room temperature for 24 hrs or refrigerated temperatures (2-8°C) for 7 days.

Sample Rejection: Samples collected with any other swab or collection device other than listed above; improperly labeled samples, leaking containers. If an unacceptable specimen is received, the patient’s caregiver will be notified and another specimen will be requested before the specimen is discarded.

Interpretive

Reference Range: Negative
Limitations:

- The performance of the Xpert Xpress Flu/RSV Assay was validated using the procedures provided in the package insert. Modifications to the procedures may alter the performance of the test.
- Results from the Xpert Xpress Flu/RSV Assay should be interpreted with other laboratory and clinical data available to the clinician.
- Erroneous test results might occur from improper specimen collection; failure to follow the recommended sample collection, handling, and storage procedures; technical error; sample mix-up; or because the number of organisms in the specimen is too low to be detected by the test. Careful compliance with the instructions in this insert is necessary to avoid erroneous results.
- Negative results do not preclude influenza virus or RSV infection and should not be used as the sole basis for treatment or other patient management decisions.
- Results from analytical studies show potential for competitive inhibition in specimens with two different viruses.
- When using the Xpert Xpress Flu/RSV Assay in the Flu Only mode, in the event of a mixed infection one of two infections may be reported as NEGATIVE.
- Results from the Xpert Xpress Flu/RSV Assay 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.
- If the virus mutates or there are other sequence changes in the target region, influenza virus and/or RSV may not be detected, or may be detected less predictably.
- Positive and negative predictive values are highly dependent on prevalence. The performance may vary depending on the prevalence of the different viruses and population tested.
- This test is a qualitative test and does not provide the quantitative value of detected organism present.
- This test has not been evaluated for patients without signs and symptoms of influenza or RSV infection.
- This test has not been evaluated for monitoring treatment of influenza or RSV infection.
- This test has not been evaluated for screening of blood or blood products for the presence of influenza or RSV.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- The effect of interfering substances has only been evaluated for those listed within the labeling. Interference by substances other than those described can lead to erroneous results.
- Cross-reactivity with respiratory tract organisms other than those described herein can lead to erroneous results.
- This assay has not been evaluated for immunocompromised individuals.
- Recent patient exposure to FluMist® or other live attenuated influenza vaccines may cause inaccurate positive results.
Although this test has been shown to detect A/H1N1 (pre-2009 pandemic), A/H7N9 (detected in China in 2013) and A/H3N2v viruses cultured from positive human respiratory specimens, the performance characteristics of this device with clinical specimens that are positive for the A/H1N1 (pre-2009 pandemic), A/H7N9 (detected in China in 2013) and A/H3N2v viruses have not been established.

This test is not intended to differentiate RSV subgroups, Influenza A subtypes or Influenza B lineages. If differentiation of specific RSV or influenza subtypes is required, additional testing may be necessary.

**Methodology:**
Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) and Real-time PCR.

**References:**

**Updates:**
- 12/22/2016: Removed BAL as an acceptable specimen type; discontinued influenza A subtyping.
- 10/01/2019: Change Methodology for Cepheid GeneXpert