Flu A/B PCR (FLUPCR)

SYNONYMS: Xpert® Flu, Influenza A & Influenza B PCR

INTENDED USE
The Cepheid Xpert® Flu Assay, performed on the GeneXpert® Instrument System, is an automated, multiplex real-time RT-PCR assay intended for the in vitro, qualitative detection of influenza A, influenza B, and 2009 H1N1 influenza viral RNA. The Xpert Flu Assay uses nasopharyngeal swab specimens placed into UTM (Universal Transport Media) that were collected from patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. The Xpert Flu Assay is intended as an aid in the diagnosis of influenza.

Performance characteristics for influenza A were established during the 2009–2010 influenza season when 2009 H1N1 was the predominant influenza A virus in circulation. Performance characteristics for influenza A were confirmed when influenza A/H3 and influenza A/2009 H1N1 were the predominant influenza A viruses in circulation (2009–2010, 2010–2011, and 2011–2012). When other influenza A viruses are emerging, performance characteristics may vary.

IMPORTANT:
- The laboratory will contact providers with any positive result.
- Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

METHODOLOGY
- Multiplex real-time PCR and RT-PCR

TEST INCLUDES
The Cepheid Xpert® Flu molecular test evaluates specimens for the presence of the following genes:
- Influenza A Matrix Gene
- Influenza A 2009 H1N1 Hemagglutinin Gene
- Influenza B Hemagglutinin Gene

SPECIMEN REQUIREMENTS

<table>
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<tr>
<th>SPECIMEN</th>
<th>VOLUME</th>
<th>CONTAINER</th>
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<tbody>
<tr>
<td>nasopharyngeal swab</td>
<td>Flocked swab in 3 mL of UTM</td>
<td>Cepheid UTM (Universal Transport Medium) Kit for the Collection and Preservation of Influenza Viruses (kit available from the laboratory includes flocked swab—smaller pediatric swabs available upon request)</td>
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Collection
Specimen should be collected within the first 24–72 hours of onset of symptoms, and no later than 5 days after onset of symptoms. Using infection control precautions:
1. Use a nasopharyngeal flocked swab.
2. The distance from the patient’s nose to the ear gives an estimate of the distance the swab should be inserted.
3. Insert swab into one nostril straight back (not upwards) and back to the nasopharynx and leave in place for a few seconds.
4. Slowly withdraw swab with a rotating motion.
5. Place the tip of the swab into the UTM tube containing 3 mL of Universal Transport Medium and break the shaft at the score line. Discard the handle portion, but be sure to leave the swab tip in the tube.
6. Label the specimen with patient ID and your initials.
Transport & Storage
* Note that the Universal Transport Media (UTM) itself may be stored at room temperature.
* **Specimens should be transported to the laboratory immediately.** If there will be any delay, specimens should be stored and transported at 2–8°C.
* Samples can be stored for up to 72 hours at 2–8°C before processing.

Causes for Rejection
* improper swab storage
* wrong swab type

INTERFERING SUBSTANCES
Potentially interfering substances in the nasopharynx may include, but are not limited to: blood, nasal secretions or mucus, and nasal and throat medications used to relieve congestion, nasal dryness, irritation, or asthma and allergy symptoms, as well as antibiotics and antivirals. Highly viscous samples resulting from the addition of 1.5% (w/v) and 2.5% (w/v) mucin yielded false-negative test results from the Xpert Flu Assay. Inhibition of the Xpert Flu Assay was also observed from the addition of 1% (w/v) mucin, resulting in delayed detection of influenza A, influenza A subtype 2009 H1N1, and influenza B.

REFERENCE RANGE
Not Detected

ADDITIONAL INFORMATION
Influenza, or the flu, is a contagious viral infection of the respiratory tract, which often occurs in the winter. Transmission of influenza is primarily airborne (i.e., coughing or sneezing). 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 individual. Secondary bacterial pneumonia may develop as a complication after an influenza infection, causing increased morbidity and mortality in pediatric, elderly and immunocompromised populations.

Influenza viruses are classified into types A, B, and C, the first two of which cause the most human infections. Influenza A is the most common type of influenza virus in humans, and is generally responsible for seasonal flu epidemics and potentially can cause 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 cause epidemics more rarely. 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 viruses bearing hemagglutinin subtypes H1, H2 or H3, combined with neuraminidase subtypes N1 or N2, e.g., type H3N2. In addition to already circulating seasonal flu viruses, a novel H1N1 strain, which emerged in Mexico, was identified in humans in early 2009.

Active surveillance programs in conjunction with infection control precautions are important components for preventing transmission of influenza. The use of assays that provide rapid results to identify and differentiate the infecting agent in patients infected with seasonal and 2009 H1N1 flu is also an important factor for effective control, proper choice of treatment, and prevention of widespread outbreaks of influenza.

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<tr>
<th>Clinical Sensitivity and Specificity of the Xpert® Flu Assay</th>
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<tr>
<td><strong>NASOPHARYNGEAL (NP) SWAB</strong></td>
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<tr>
<td>Sensitivity</td>
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<td>Specificity</td>
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MEDITECH CODE   FLUPCR
CPT CODES  87502 x 2, 87503 x 1
LABORATORY  Molecular Pathology Department
AVAILABILITY  24 hours a day, 7 days a week
TURNAROUND TIME  90 minutes from receipt to result verification