XIII. Influenza A+B Test			
Effective: 02/2018	Reviewed:	Revised:	*Discontinue Date:*

A. Policy and Clinical Usage

The laboratory and designated nursing staff perform waived Influenza testing. The influenza test is an in vitro rapid qualitative test that detects influenza type A and type B antigens directly from nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens from patients with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.
Negative test results do not rule out influenza virus infection and should not be used as the sole basis for treatment and management decisions.

Influenza is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted from person to person through aerosol droplets when sneezing and coughing. Common symptoms include high fever, chills, headache, cough, sore throat, and malaise.

The type A influenza virus is more prevalent and is the primary pathogen associated with serious epidemics. Type B produces a disease that is generally not as severe as that caused by Type A. Early differential diagnosis of influenza type A or B can allow for proper treatment with appropriate antiviral therapy while reducing the incidence of inappropriate treatment with antibiotics.

B. Principle

The influenza A & B test involves chemical extraction of viral antigens followed by a solid-phase immunoassay technology for the detection of extracted antigen, influenza A and/or B. In the test procedure, a specimen is collected and placed for one (1) minute into the Extraction Well of the test cassette containing extraction solution, during which time antigen is extracted from disrupted virus particles. The test cassette is then raised, tapped, and laid back down onto a level surface to allow the solution to migrate through the pads containing detector antibodies conjugated to gold dye and then through the test membrane. If influenza antigens are present in the specimen, they will react with anti-influenza antibody coupled to gold dye particles, migrate through the membrane as antigen-antibody-dye complexes, bind to the immobilized anti-influenza antibody on the membrane, and generate a colored line in the Test position (A and/or B) The rest of the sample and unbound/bound dye continue to migrate to the Control line (C position) and forms the internal control.

C. Supplies/ Materials Required

Influenza A& B test cassette
Extraction Reagent/capsule
Timer
Package Insert
PPE Gloves and Gown

D. Storage and Stability
Store test kit at 15-30° degrees centigrade (room temperature) in the original sealed pouch, away from direct sunlight. Kit contents are stable until the expiration date printed on the box or pouch.

Use fresh samples for best performance. Freshly collected samples should be tested immediately. If necessary, swab samples may be stored for up to 4 hours at room temperature or up to 8 hours at 2-8 degrees Celsius (refrigerated). If transport is required, the M4 medium has been tested and shown not to interfere with the performance of the test.

E. Specimen Type and Collection

Good sample collection is the most important first step for an accurate test result. Therefore, follow below instruction carefully to obtain as much secretion as possible.

Nasal Swab Specimen:
1. Use only the flocked swabs supplied with the kit.
2. Wash hands, apply gloves and gown. Identify the patient using two patient identifiers.
3. Gently insert the swab approximately ¼ inch into the anterior nares (just inside the nasal orifice).
4. Rotate the swab a few times against the nasal wall, and repeat in the second nostril, using the same swab.
5. Label the specimen in the patient's presence with the patient's name as it appears on the request, the 679 local case number and the date. Remove gloves, discard, and wash hands.
6. Send specimen to laboratory immediately upon collection.

F. Test Procedure

The test procedure below must be followed to obtain accurate and reproducible results.
Reagents and specimens must be at room temperature for testing.
Do not open foil pouch until you are ready to perform the test.
Several tests may be run at one time.
Label the cassette with the patient identification or control to be tested.
Place test cassette on a level surface.

1. Tear the tab off the Extraction Reagent capsule.
2. Squeeze the Extraction capsule to dispense all of the solution into the Extraction Well of the cassette.
3. Insert the specimen swab on the Swab Stand in the Extraction Well. Rotate swab 3 times to mix the specimen.
4. Incubate 1 minute with the swab in the Extraction Well.
5. Rotate swab 3 times to mix the specimen. Remove and discard the swab.
6. Raise the cassette upright.
7. Let it stand for 1-2 seconds. Gently tap the cassette to ensure that the liquid flows into the hole.
8. Lay the cassette back down onto the flat surface. Start timing.
9. Read results at 15 minutes.

G. Interpretation of Results

Positive:
A reddish purple Control line (C position) and a reddish purple Test line (A or B position) indicate that influenza A or B antigen has been detected. Lines at the A and C positions indicate the presence of Influenza type A viral antigen, and lines at the B and C positions indicate the presence of Influenza type B viral antigen in the specimen. A positive does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype. Determination of a positive result can be made as soon as both a visible Test line (either A or B) and a Control line appear.

Note: The Test line may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen detected. The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test results. Even a light or faint Test line must be interpreted as a positive result.

Negative:
A reddish purple Control line (C position) with no Test line in the A or B position, indicates that Influenza A or B antigen has not been detected. A negative result does not exclude influenza viral infection. Determination of negative results should not be made before 15 minutes.

Invalid:
A reddish purple line should always appear at the Control line (C position). If a line does not form at the Control position in 15 minutes, the test result is invalid and the test should be repeated with a new test cassette. **The result is considered invalid and not reported.**
Notify provider and request repeat testing.

Additional testing may be required if requested by the provider.
Follow-up testing will be performed as recommended by the Center for Disease Control and Texas Public Health Department.

H. Quality Control Rationale and Confirmatory Testing

Rusk State Hospital Lab adheres to the manufacturer's quality control guidelines.
Those certified to perform Influenza testing are responsible for documenting all results as well as corrective action when controls do not perform as expected.

Internal Controls:
Each Influenza A&B Test cassette has built-in controls. The Control line (C position) can be considered as an internal positive procedural control, i.e., a proper amount of sample was used, sample migrated properly, and reagent system worked properly. A distinct reddish purple Control line should always appear if the test has been performed correctly. If the control line does not appear, the test is invalid and a new test should be performed.
A clear background in the Test Result Window is considered an internal negative procedural control. If the test is performed correctly and the cassette is working properly, the background will be clear, providing a distinct result.

External Controls:
Good lab practice includes the use of external controls to ensure proper kit performance. It is recommended that the external controls be performed with every new operator, new lot, or shipment. If controls do not perform as expected, do not use the patient results. Repeat the tests or contact Technical Support @ 1-800-526-2125. The built-in reddish purple Control line indicates only the integrity of the test cassette and proper fluid flow.
Positive and negative controls shall be performed with every new lot number, shipment, and every 25 tests or monthly (whichever comes first).

Performance of testing will be evaluated as needed.
Viral culture of test results shall be sent for surveillance as recommended by the Public Health Laboratory of East Texas.

I. Limitations

1. A negative test result does not exclude infection with influenza A or B. Therefore, the results obtained should be used in conjunction with clinical findings to make an accurate diagnosis. Additional testing is required to differentiate specific flu A and B subtypes.
2. The test detects both viable (live) and non-viable influenza A&B. Test performance depends on the amount of virus (antigen) in the specimen.
3. Individuals who received nasally administered influenza A vaccine may produce positive test results for up to 3 days after vaccination.
4. The performance of this assay has not been evaluated for use in patients without signs and symptoms of respiratory infection.
5. This test cannot rule out diseases caused by other bacterial or viral pathogens.
6. The performance of this test has not been evaluated for immunocompromised individuals.

See package insert for additional details.

Citation(s):

CONSULT Influenza A & B Test. CLIA Complexity: Waived – Company provided pamphlet insert with test kit