XIII. Waived Influenza A+B Test			
A. Clinical Usage B. Test Principle C. Patient Preparation D. Supplies			
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A. Policy and Clinical Usage
The laboratory and designated nursing staff perform waived Influenza testing. The influenza test is a rapid one step, visual test for the qualitative detection of influenza type A and type B antigens directly from nasal swab and nasopharyngeal swabs. The test is intended for the use as an aid in the rapid differential diagnosis of acute influenza type A and type B viral infections. The test is not intended to detect influenza C antigens.

Influenza is a highly contagious, acute viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single strand RNA viruses known as influenza viruses. There are three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and are associated with the most serious epidemics. Type B viruses produce a disease that is generally milder than that caused by Type A. Type C viruses can circulate simultaneously, but usually one type is dominant during a given season.

B. Test Principle
The influenza A+B test involves extraction of Influenza A and B virus antigens employing a monoclonal antibody technique. An extraction of the patient's viral particles is disrupted, exposing the internal viral nucleoproteins. A test strip is placed in the extraction tube where nucleoproteins in the specimen react with the reagents in the test strip.

Extractions containing antigens for Influenza A and B react with the monoclonal antibodies resulting in a pink-to red test line along with a blue procedural control line, indicating a positive test result in separate specified areas.

C. Patient Preparation:
None. Prior to collecting the specimen, two patient identifiers must be used to accurately identify the patient.

D. Supplies/ Materials Required

QuickVue Influenza A+ B test kit

Test strips	Extraction solution
Extraction Tubes	Disposable droppers
Positive Type A control swab	Positive Type B control swab
Negative control swab	Package Insert
Procedure Card	Sterile Nasal Swabs
Timer	PPE Gloves and Gown

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E. Storage F. Specimen Collection G. Quality Control and Confirmatory Testing			
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E. Storage and Stability
Store test kit at 15-30° degrees centigrade (room temperature), out of direct sunlight. Do not freeze. The test kit is stable until the date imprinted on the box label and/or foil pouch. Do not use past the expiration date.

F. Specimen Type and Collection
1. Proper specimen collection, storage, and transport are critical to the performance of the test.
2. For best performance, use only the swabs supplied with the kit.
3. Wash hands apply gloves and gown. Identify the patient using two patient identifiers.
4. Obtain as much secretion as possible.
5. Insert the sterile swab into the nostril that presents the most secretion under visual inspection.
6. Gently push the swab until resistance is met less than one inch into the nostril.
7. Using gently rotate the swab a few times against the nasal wall.
8. 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.
9. Specimens may be stored in a clean closed container for up to 8 hours prior to testing, but immediate testing is recommended.

G. 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.

Quidel QuickVue Influenza A+B test contains a built-in control feature on the test strip. The manufacturer's recommendation is to document these built-in procedural controls for each patient. Positive and negative controls will be performed with every new lot number or shipment, and every 25 tests or monthly (whichever comes first).

If controls do not perform as described in the Procedure:
1. If no distinct blue procedural Control line develops at 10 minutes, then the test is considered invalid.
2. Check the expiration date on the kit.
3. Repeat using a new test device and/or call Quidel technical support at 1-800-874-1517.

Evaluation of test performance and Confirmatory Testing
Performance of the test and the test device will be evaluated annually or as needed by:
1. Viral culture of positive test results for surveillance as recommended by the Public Health Laboratory of East Texas.
2. Viral culture of all negative Influenza A-B when VTM (Viral Transport Media) is available.

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H. Test Procedure			
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H. Test Procedure

Step	Action
1	Wash hands. PPE Gloves and Gown must be worn during this procedure.
2	Check the expiration on each test package or outer box before using. Do not use past the expiration date. Make sure controls have been run. Read the manufacturer's instructions before performing the test.
3	Label the required number of test devices with the patient's name and control identification.
4	Bend over the tab on the extraction reagent solution and dispense the solution into the Extraction tube to dissolve the contents.
5	Gently swirl the extraction tube to dissolve the contents.
6	Place the patient swab with the sample into the extraction tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the extraction tube.
7	Leave the swab in the extraction tube for one minute.
8	Roll the swab head against the inside of the extraction tube as you remove it. Place the used swab in a biohazard container.
9	Place the test strip into the extraction tube with the arrows on the strip pointing down. Do not handle or move the test strip until the test is completed and ready for reading (10 minutes).
10	Read the result at 10 minutes. Some positive results may appear sooner, but do not read the result after 10 minutes.
11	Discard strips and extraction tube in a biohazardous container. Remove gloves, discard, and wash hands.

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I. Interpretation J. Reporting of Results			
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I. Interpretation of Results
Test results are interpreted based on the presence or absence of a pink band in the **test** areas and a blue band in the **control regions** of the test strip. The interpretation should be performed at the end of the reaction time.

Positive Result:
At 10 minutes the background color should clear to white, and **ANY** shade of a pink-to red test line forms, either above or below the blue control line **AND** the appearance of a blue procedural control line indicates the presence of influenza A and or B viral antigen. Hold the test strip with the errors pointing down.

1. If the pink/red line is **above** the control line the test results are positive for Influenza A.
2. If the pink/red line is **below** the control line, the test results are positive for Influenza B.

Negative Result: At ten minutes, the appearance of ONLY the blue procedural control line indicates the sample is negative for Influenza A and B viral antigen.

Invalid: The results are invalid if the blue procedural line does not appear, even if any shade of pink/red test line appears. **The result is considered invalid and not reported.** If at 10 minutes the background does not clear and it interferes with the reading of the test, the results are considered invalid.
Notify Provider and request repeat testing.
Contact the Provider and send a specimen to the reference lab.

1. Use only the applicator provided by the reference laboratory.
2. Place the swab back into the paper wrapper, and label with the patient's name, case number, and date.

J. Report results

1. Fax the report to Med Clinic and the patient's unit.
2. Leave a copy of the report in the Laboratory.
3. Negative results do not rule out the presence of Influenza A/B

Additional testing may be required if requested by the Provider.
Negative results will be confirmed with a viral culture for follow-up testing when media is available and as recommended by the Center for Disease Control and Texas Public Health Department.
Viral Transport Media may be obtained from:

1. Cherokee County Health Department
   903-683- 6191
   510 E. Commerce, Jacksonville, Texas

2. Public Health Laboratory PHLET
   1-903-877-5071
   Health Center Street (UT Health Center Complex) Tyler, Texas.

RUSK STATE HOSPITAL

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K. Limitations			
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K. Limitations

1. The kit is to be used for the qualitative detection of Influenza A and B antigen from nasal swab specimens.
2. A negative test result may occur if the level of antigen is below the detection limit of the test.
3. Failure to follow the test procedure and interpretations of the test results may adversely affect the test performance and/or invalidate the test result.
4. Results must be evaluated in conjunction with other clinical data available to the Provider.
5. Negative test results do not rule out possible other non-influenza viral infections.
6. Positive test results do not rule out co-infections with other pathogens.
7. Individuals who receive the nasally administered influenza A vaccine may have positive test results for up to three days after vaccination.
8. Monoclonal antibodies may fail to detect, or detect with less sensitivity, Influenza viruses that have undergone minor amino acid changes in the target epitope region.

Citation(s):

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