



FACT SHEET

Rapid Diagnostic Testing for Influenza: Information for Clinical Laboratory Directors

Rapid Diagnostic Tests for Influenza

The availability and use of commercial influenza rapid diagnostic tests by laboratories and clinics have substantially increased in recent years.

- Influenza rapid diagnostic tests are screening tests for influenza virus infection.
- They can provide results within 15 minutes.
- More than 10 rapid influenza tests have been approved by the U.S. Food and Drug Administration (FDA) (see [Influenza Diagnostic Table](#)).
- Rapid tests differ in some important respects:
 - Some can identify influenza A and B viruses and distinguish between them.
 - Some can identify influenza A and B viruses but cannot distinguish between them.
 - Some tests are waived from requirements under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
 - Most tests can be used with a variety of specimen types (see [Influenza Diagnostic Table](#)), but the accuracy of the tests can vary based on the type of specimen collected (for example throat swab versus nasal swab).
- FDA approval is based upon specific specimen types.
- The rapid tests vary in terms of sensitivity and specificity when compared with viral culture or RT-PCR. Product insert information and research publications indicate that:
 - Sensitivities are approximately 50-70%
 - Specificities are approximately 90-95%
- Specimens to be used with rapid tests generally should be collected as close as is possible to the start of symptoms and usually no more than 4-5 days later in adults. In very young children, influenza viruses can be shed for longer periods; therefore, in some instances, testing for a few days after this period may still be useful.

Accuracy Depends Upon Prevalence

The positive and negative predictive values vary considerably depending upon the prevalence of influenza in the community.

- False-positive (and true-negative) influenza test results are more likely to occur when disease prevalence is low, which is generally at the beginning and end of the influenza season.
- False-negative (and true-positive) influenza test results are more likely to occur when disease prevalence is high, which is typically at the height of the influenza season.

Clinical Considerations of Testing When Influenza Prevalence is Low

When disease prevalence is relatively low, the positive predictive value (PPV) is low and false-positive test results are more likely. By contrast, when disease prevalence is low, the negative predictive value (NPV) is high, and negative results are more likely to be true.

If Flu Prevalence is...	And Specificity is...	Then PPV is...	False Pos. rate is...
VERY LOW (2.5%)	POOR (80%)	V. POOR (6-12%)	V. HIGH (88-94%)
VERY LOW (2.5%)	GOOD (98%)	POOR (39-56%)	HIGH (44-61%)
MODERATE (20%)	POOR (80%)	POOR (38-56%)	HIGH (44-62%)
MODERATE (20%)	GOOD (98%)	GOOD (86-93%)	LOW (7-14%)

The interpretation of positive results should take into account the clinical characteristics of the case. If an important clinical decision is affected by the test result, the rapid test result should be confirmed by another test, such as viral culture or polymerase chain reaction (PCR).

Clinical Considerations of Testing When Influenza Prevalence is High

When disease prevalence is relatively high, the NPV is low and false-negative test results are more likely. When disease prevalence is high, the PPV is high and positive results are more likely to be true.

If Flu Prevalence is...	And Specificity is...	Then PPV is...	False Pos. rate is...
MODERATE (20%)	POOR (50%)	MODERATE (86-89%)	MODERATE (11-14%)
MODERATE (20%)	HIGH (90%)	V. GOOD (97-99%)	V. LOW (2-3%)
HIGH (40%)	POOR (50%)	MODERATE (70-75%)	MODERATE (25-30%)
HIGH (40%)	HIGH (90%)	V. GOOD (93-94%)	LOW (6-7%)

The interpretation of negative results should take into account the clinical characteristics of the patient. If an important clinical decision is affected by the test result, then the rapid test result should be confirmed by another test, such as viral culture or PCR.

Selecting Tests

Many factors should be considered when selecting a test, including the following:

- Tests with high sensitivity and specificity will provide better positive and negative predictive values.
- Types of specimens that provide the most accurate results.

Information about these characteristics can be found in product inserts and scientific articles, and by contacting the manufacturer.

Changes in Recommended Procedures Can Affect Test Results

Modification by the user can affect test performances and increase false-positive and/or false-negative rates. Such modifications include

- Using specimens for which the test is not optimized
- Using swabs that did not come with the rapid test kits [unless recommended (see table)].

When Is Use of Rapid Diagnostic Tests Beneficial?

- Testing during an outbreak of acute respiratory disease can determine if influenza is the cause.
- During influenza season, testing of selected patients presenting with respiratory illnesses compatible with influenza can help establish whether influenza is present in a specific patient population and help health-care providers determine how to use their clinical judgment for diagnosing and treating respiratory illness. (Testing need not be done for all patients.)

- Otherwise, rapid tests do not address the public health need for influenza virus isolated that can only be obtained through the collection of specimens for viral culture. Influenza virus isolates are essential for determining the match between circulating influenza viruses and those viruses contained in the vaccine and for aiding in the selection of new vaccine strains.

Influenza Diagnostic Table

Procedure	Influenza Types Detected	Acceptable Specimens	Time for Results	Rapid result available
Viral culture	A and B	NP swab ² , throat swab, nasal wash, bronchial wash, nasal aspirate, sputum	3-10 days ³	No
Immunofluorescence DFA Antibody Staining	A and B	NP swab ² , nasal wash, bronchial wash, nasal aspirate, sputum	2-4 hours	No
RT-PCR⁵	A and B	NP swab ² , throat swab, nasal wash, bronchial wash, nasal aspirate, sputum	2-4 hours	No
Serology	A and B	paired acute and convalescent serum samples ⁶	2 weeks or more	No
Enzyme Immuno Assay (EIA)	A and B	NP swab ² , throat swab, nasal wash, bronchial wash	2 hours	No
Rapid Diagnostic Tests				
3M™ Rapid Detection Flu A+B Test (3M)	A and B	NP ² swab/aspirate; Nasal wash/aspirate	15 minutes	Yes
Directigen Flu A⁷ (Becton-Dickinson)	A	NP ² wash/aspirate/swab; throat swab	less than 15 minutes	Yes
Directigen Flu A+B^{7,9} (Becton-Dickinson)	A and B	NP ² wash/aspirate/swab; lower nasal swab; throat swab; bronchioalveolar lavage	less than 15 minutes	Yes
Directigen EZ Flu A+B^{7,9} (Becton-Dickinson)	A and B	NP ² wash/aspirate/swab; lower nasal swab; throat swab; bronchioalveolar lavage	less than 15 minutes	Yes
BinaxNOW Influenza A&B^{8,9} (Inverness)	A and B	Nasal wash/aspirate, NP swab ²	less than 15 minutes	Yes
OSOM® Influenza A&B⁹ (Genzyme)	A and B	Nasal swab	less than 15 minutes	Yes
QuickVue Influenza Test^{4,8} (Quidel)	A and B	NP swab ² , nasal wash, nasal aspirate	less than 15 minutes	Yes
QuickVue Influenza A+B Test^{8,9} (Quidel)	A and B	NP swab ² , nasal wash, nasal aspirate	less than 15 minutes	Yes

SAS FluAlert^{7,9} (SA Scientific)	A and B	Nasal wash/aspirate	less than 15 minutes	Yes
TRU FLU^{7,9} (Meridian Bioscience)	A and B	Nasal wash/swab, NP aspirate/swab	15 minutes	Yes
XPECT Flu A&B^{7,9} (Remel)	A and B	Nasal wash, NP swab ² , throat swab	less than 15 minutes	Yes

1. List may not include all test kits approved by the U.S. Food and Drug Administration.
2. NP = nasopharyngeal.
3. Shell vial culture, if available, may reduce time for results to 2 days.
4. Does not distinguish between influenza A and B virus infections.
5. RT-PCR = reverse transcriptase polymerase chain reaction.
6. A fourfold or greater rise in antibody titer from the acute- (collected within the 1st week of illness) to the convalescent-phase (collected 2-4 weeks after the acute sample) sample is indicative of recent infection.
7. Moderately complex test – requires specific laboratory certification.
8. CLIA-waived test. Can be used in any office setting. Requires a certificate of waiver or higher laboratory certification.
9. Distinguishes between influenza A and B virus infections.

Disclaimer: Use of trade names or commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention or the Department of Health and Human Services.

Additional Information

- A listing of state and local health departments is available at www.cdc.gov/doc.do/id/0900f3ec80226c7a#states

For more information, visit www.cdc.gov/flu or call the CDC Flu Information Line at (800) CDC-INFO (English and Spanish) or (800) 243-7889 (TTY).