



FACT SHEET

Rapid Diagnostic Testing for Influenza: Information for Health Care Professionals

Background

Rapid diagnostic tests for influenza can help in the diagnosis and management of patients who present with signs and symptoms compatible with influenza. They also are useful for helping to determine whether outbreaks of respiratory disease, such as in nursing homes and other settings, might be due to influenza.

- In general, rapid diagnostic testing for influenza should be done when the results will affect clinical decision making.
- Rapid diagnostic testing can provide results within 30 minutes.

Reliability and Interpretation of Rapid Test Results

The reliability of rapid diagnostic tests depends largely on the conditions under which they are used. Understanding some basic considerations can minimize being misled by false-positive or false-negative results.

- Sensitivities of rapid diagnostic tests are approximately 50-70% when compared with viral culture or reverse transcription polymerase chain reaction (RT-PCR), and specificities of rapid diagnostic tests for influenza are approximately 90-95%.
- False-positive (and true-negative) results are more likely to occur when disease prevalence in the community is low, which is generally at the beginning and end of the influenza seasons.
- False-negative (and true-positive) results are more likely to occur when disease prevalence is high in the community, which is typically at the height of the influenza season.

Minimize False Results

- Use rapid diagnostic tests with high sensitivity and specificity.
- Collect specimens as early in the illness as possible (within 4-5 days).
- Follow manufacturer's instructions, including handling of specimens.
- Consider sending specimens for viral culture to confirm results of rapid tests especially when community prevalence of influenza is low and the rapid diagnostic test result is positive and when the rapid diagnostic test result is negative but disease prevalence is high. (Contact your local or state health department for information about influenza activity).

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-PCR ⁵	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 A ⁷ (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&B ⁹ (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
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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/other.htm#states
- The Association of Public Health Laboratories at www.aphl.org
- The Weekly U.S. Influenza Activity Reports at www.cdc.gov/flu/weekly/fluactivity.htm
- Clinician Outreach and Communication Activity at www.bt.cdc.gov/coca
- CDC flu lab diagnosis information at www.cdc.gov/flu/professionals/labdiagnosis.htm

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).