FACT SHEET

Rapid Diagnostic Testing for Influenza: Information for Clinical Laboratory Directors

Background

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

Rapid Diagnostic Tests for Influenza

- Influenza rapid diagnostic tests are screening tests for influenza virus infection.
- They can provide results within 30 minutes.
- More than 10 rapid influenza tests have been approved by the U.S. Food and Drug Administration (FDA) (see 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 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. Product insert information and research publications indicate that:
    - Median sensitivities are approximately 70-75%
    - Median 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.

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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%)

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).