

Use of Rapid Influenza Diagnostic Tests for Patients with Influenza-like Illness during the Novel H1N1 Influenza Virus (Swine Flu) Outbreak

Information for Health Care Professionals

May 2, 2009 10:00 PM ET

Background

Rapid influenza diagnostic tests can help in the diagnosis and management of patients who present with signs and symptoms compatible with influenza. Such tests detect seasonal influenza A and B viral nucleoprotein antigens in respiratory specimens. The currently circulating novel H1N1 influenza virus (also referred to as swine flu) is an influenza A virus. Data are not yet available to inform recommendations on the use of rapid influenza diagnostic tests in patients with novel H1N1 virus infection. It is reasonable to assume that rapid diagnostic tests that detect influenza A viral nucleoprotein antigen can detect novel H1N1 flu infection in respiratory specimens as these nucleoprotein antigens are highly conserved across influenza A viruses. However, the sensitivity and specificity of the different rapid tests is not yet known for this novel virus. CDC has received anecdotal reports of false positive and false negative results. Clinicians may consider using rapid diagnostic tests as part of their evaluation of patients with signs and symptoms compatible with influenza, but results should be interpreted with caution. Confirmation of novel H1N1 flu infection can only be made by reverse-transcription polymerase chain reaction (RT-PCR) or viral culture.

Reliability and Interpretation of Rapid Influenza Test Results

The reliability of rapid influenza diagnostic tests depends largely on the conditions under which they are used, and are entirely based on the experience with seasonal influenza.

- For detection of seasonal influenza virus infection, sensitivities of rapid diagnostic tests are approximately 50-70% when compared with viral culture or RT-PCR, and specificities of rapid diagnostic tests for influenza are approximately 90-95%. Sensitivity and specificity of these tests for detection of the novel H1N1 flu virus are unknown.
- False-positive (and true-negative) results are more likely to occur when influenza is uncommon in the community, which is generally at the beginning and end of an outbreak.
- False-negative (and true-positive) results are more likely to occur when influenza is common in the community, which is typically at the height of an outbreak.
- Test sensitivity may vary depending on when in the course of illness the specimen is collected. Respiratory specimens for testing should be collected in the first 4-5 days of illness when viral shedding is greatest.

Given these limitations, the decision of whether or not to test patients with rapid influenza diagnostic tests should be based upon the patient's presenting symptoms, whether or not cases of novel H1N1 have been confirmed in the area, and/or the patient's risk for severe disease or other complications.

- How to interpret a positive test result:

A patient testing positive for influenza B by rapid diagnostic test likely has been infected with seasonal influenza B virus that is continuing to circulate or is a false-positive result. Such a patient is unlikely to have novel H1N1 virus infection.

There are several possibilities when a patient tests positive for influenza A by rapid antigen test:

- The patient might have novel H1N1 virus infection
 - The patient might have seasonal influenza A virus infection **or**
 - The patient might have a false positive test result.
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- Information provided by states and local health authorities should be consulted to determine whether public health authorities are advising that patients who test positive on a rapid influenza antigen test need additional testing. In areas with many new confirmed cases of novel H1N1 flu infection and where community spread of H1N1 is occurring, patients who test positive on a rapid influenza diagnostic test can be treated empirically with antiviral medications if clinically indicated (see guidelines at www.cdc.gov/h1n1flu/recommendations.htm) without further testing.. In areas with no or few confirmed cases of novel H1N1 flu, a nasopharyngeal swab/aspirate or nasal aspirate should be collected and sent to the state public health laboratory for RT-PCR to determine if the patient has H1N1 infection, seasonal influenza A virus infection, or a false-positive test result. Interim guidelines for specimen collection can be found at <http://www.cdc.gov/swineflu/specimencollection.htm>. Interim biosafety guidelines for laboratory workers can be found at: http://www.cdc.gov/h1n1flu/guidelines_labworkers.htm
 - How to interpret a negative result:

Novel H1N1 flu virus infection cannot be excluded when a patient tests negative for influenza A by rapid antigen test. If the patient has an epidemiologic link to a confirmed case (i.e. had close contact with a confirmed case), or has either traveled to or resides in a community where there are one or more confirmed novel H1N1 cases, further testing and treatment should be based upon clinical suspicion, severity of illness, and risk for complications. If there is no epidemiologic link and the patient has mild illness, further testing and treatment are not recommended.