

**FACT SHEET FOR HEALTHCARE PROVIDERS:
INTERPRETING FOCUS DIAGNOSTICS INFLUENZA A H1N1 (2009) REAL-
TIME RT-PCR TEST RESULTS**

July 23, 2009

A public health emergency has been declared by the Secretary of Health and Human Services because of the outbreak of the 2009 H1N1 influenza virus, which is also referred to as swine influenza (H1N1) virus. This fact sheet will refer to the virus as 2009 H1N1 influenza virus. The Food and Drug Administration (FDA) has authorized the emergency use of the Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR to test for the presence of the 2009 H1N1 influenza virus in clinical respiratory specimens (i.e., nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), and nasal aspirates (NA)) under an Emergency Use Authorization (EUA). This authorization will terminate on April 26, 2010, when the emergency has ceased to exist, or when the authorization has been revoked, whichever is earlier. The information in this Fact Sheet is the minimum necessary to inform you of the significant known and potential risks and benefits of the emergency use of the Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR test.

At this time, there are no FDA-approved/cleared tests that identify the existence of the 2009 H1N1 influenza virus in clinical specimens. Previously, the FDA granted Emergency Use Authorization for the Swine Influenza rRT-PCR Detection Panel provided by the CDC. To help with the back log of diagnostic testing at the CDC and other Public Health Laboratories, FDA has authorized the emergency use of the Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR to detect 2009 H1N1 influenza virus infections. Current information on 2009 H1N1 influenza virus, including case definitions and infection control guidelines, is available at <http://www.cdc.gov/h1n1flu/>. All information and guidelines, including those on testing for 2009 H1N1 influenza A virus, may change as we continue to learn more about this disease. Please check CDC's 2009 H1N1 influenza virus website regularly for the most current information.

The Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR test should be ordered only to diagnose 2009 H1N1 influenza virus infection. Although this test is authorized for use with nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), or nasal aspirates (NA), it is strongly recommended that nasopharyngeal or nasal swabs be collected. Specimen collection should be conducted according to the manufacturer's instructions for the specimen collection device and sent to a qualified laboratory for analysis.

What does it mean if the specimen tests positive for the 2009 H1N1 influenza virus?

A positive test for 2009 H1N1 Influenza virus using the Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR indicates that the patient is infected with the 2009 H1N1 influenza virus. The test does not indicate the stage of infection. Laboratory test results should always be considered in the context of clinical observations and epidemiologic data in making a final diagnosis. For guidelines on managing patients please refer to <http://www.cdc.gov/h1n1flu/guidance/> and *Interim Guidance for Infection*

Control for Care of Patients with Confirmed or Suspected Novel Influenza A (H1N1) Virus Infection in a Healthcare Setting” at http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm and “Interim Guidance on Antiviral Recommendations for Patients with Confirmed or Suspected Novel Influenza A (H1N1) Virus Infection and Close Contacts” at <http://www.cdc.gov/h1n1flu/recommendations.htm>

The test has been designed to minimize the likelihood of false positive test results. However, should false positive results occur, risks to patients could include a recommendation for quarantine of household or other close contacts, a recommendation for patient isolation that might limit contact with family or friends, the ability to work, or the ability to receive disease appropriate medical care and therapy, or other unintended adverse effects.

What does it mean if the specimen tests negative for the 2009 H1N1 influenza virus?

Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure are the keys to making patient management and isolation decisions. A negative result from the Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR test should not be interpreted as demonstrating that the patient does not have 2009 H1N1 influenza virus infection, if other aspects of the patient’s clinical presentation or recent epidemiologic exposures indicate 2009 H1N1 influenza virus infection is likely, and diagnostic tests for other causes of acute respiratory illness are negative.

Contact Information:

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Healthcare providers will be contacted by Focus Diagnostics in the event of any significant new findings observed during the course of the emergency use of the Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR test.

Any significant new findings observed during the course of emergency use of a 2009 H1N1 Influenza Test Kit will be made available at <http://www.cdc.gov/h1n1flu/>.