

**FACT SHEET FOR HEALTHCARE PROVIDERS:  
INTERPRETING FOCUS DIAGNOSTICS  
SIMPLEXA™ INFLUENZA A H1N1 (2009) TEST RESULTS**

October 16, 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 SIMPLEXA™ INFLUENZA A H1N1 (2009) Test to test for the presence of the 2009 H1N1 influenza virus in clinical respiratory specimens (i.e., nasopharyngeal swabs (NPS), nasal swabs (NS), and nasopharyngeal aspirates (NPA)) 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authorization will terminate on April 26, 2010, when the emergency has ceased to exist, or when the authorization has been revoked, whichever is earlier.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 SIMPLEXA™ INFLUENZA A H1N1 (2009) 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 has issued EUAs for the CDC Swine Influenza rRT-PCR Detection Panel, the Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR, and the Diatherix Laboratories H1N1-09 Influenza Virus Test. The current EUA authorizes use of the FOCUS DIAGNOSTICS SIMPLEXA™ INFLUENZA A H1N1 (2009) Test on the 3M Integrated Cycler 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 Web site regularly for the most current information.

The FOCUS DIAGNOSTICS SIMPLEXA™ INFLUENZA A H1N1 (2009) 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), or nasopharyngeal aspirates (NPA), 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 result for 2009 H1N1 Influenza virus using the FOCUS DIAGNOSTICS SIMPLEXA™ INFLUENZA A H1N1 (2009) 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 *"Interim Guidance for Infection Control for Care of Patients with Confirmed or Suspected Swine Influenza A (H1N1) Virus Infection in a Healthcare Setting"* and *"Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season"* at <http://www.cdc.gov/h1n1flu/guidance/>.

The SIMPLEXA™ INFLUENZA A H1N1 (2009) Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, the risk to patients

could include any or all of the following: recommendations to limit contact with uninfected persons (including at home or at the workplace), a prescription for antiviral medication or other therapy, the impaired ability to detect and receive appropriate medical care for the true infection causing the flu-like symptoms, 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 only 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 SIMPLEXA™ INFLUENZA A H1N1 (2009) 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:**

Focus Diagnostics, Inc.  
11331 Valley View Ave.  
Cypress, CA 90630  
Contact phone 800-445-0185

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 SIMPLEXA™ INFLUENZA A H1N1 (2009) Test.