

Fact Sheet for Healthcare Providers: Interpreting the Prodesse ProFlu-ST Assay Results

October 27, 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 (previously referred to by some 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 Prodesse ProFlu-ST Assay under an Emergency Use Authorization (EUA). The Prodesse ProFlu-ST Assay detects 2009 H1N1 influenza viral RNA in nasopharyngeal swab (NPS) specimens; interpretation of test results utilizes an algorithm: a positive result for 2009 H1N1 influenza virus and concurrent negative results for seasonal influenza A/H1 and A/H3 using the Prodesse ProFlu-ST Assay indicate that the patient is infected with the 2009 H1N1 influenza virus.

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authorization will terminate on April 26, 2010, when the emergency has ceased to exist, or when the authorization has been revoked, whichever is earlier.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 Prodesse ProFlu-ST Assay.

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 and the Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR test to be used on the Applied Biosystems (ABI) 7500 Real-time PCR instruments. To augment existing testing capacity and provide 2009 H1N1 influenza testing capability to clinical laboratories that have certificates under CLIA to perform high complexity tests, some of which currently do not have PCR capability on the ABI 7500 instruments, but are currently equipped with the Cepheid SmartCycler II real-time PCR instruments, FDA has authorized the emergency use of the Prodesse ProFlu-ST Assay to detect 2009 H1N1 influenza infection aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results. 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 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 Prodesse ProFlu-ST Assay should be ordered only to diagnose 2009 H1N1 influenza virus infection in patients who are diagnosed with influenza A. This test is authorized for use with nasopharyngeal swab (NPS) specimens only. Specimen collection should be conducted according to the manufacturer's instructions for the specimen collection device and sent to a laboratory that has certificate under CLIA to perform high complexity tests 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 Prodesse ProFlu-ST Assay and concurrent negative results for seasonal influenza A/H1 and A/H3 indicate that the patient is infected with the 2009 H1N1 influenza virus. The assay result 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 “*Interim Guidance on Antiviral Recommendations for Patients with Confirmed or Suspected Swine Influenza A (H1N1) Virus Infection and Close Contacts*” at <http://www.cdc.gov/h1n1flu/guidance/>.

The Prodesse ProFlu-ST Assay has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, the risks 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 of 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 of 2009 H1N1 influenza virus from the Prodesse ProFlu-ST Assay 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 that 2009 H1N1 influenza virus infection is likely, and diagnostic tests for other causes of acute respiratory illness are negative.

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Healthcare providers will be contacted by Gen-Probe Prodesse, Inc. in the event of any significant new findings observed during the course of the emergency use of the Prodesse ProFlu-ST Assay.