

Fact Sheet for Healthcare Providers: Interpreting IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay Results

March 24, 2010

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 IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay to test for the presence of the 2009 H1N1 influenza virus in clinical respiratory specimens under an Emergency Use Authorization (EUA). This authorization will terminate on April 26, 2010, unless (1) it is revoked sooner, (2) the declaration of emergency is terminated sooner, or (3) the declaration of emergency is renewed for a longer term. 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 IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay.

At this time, there are no FDA-approved or cleared tests that identify the existence of the 2009 H1N1 influenza virus in clinical specimens. Previously, the FDA granted Emergency Use Authorization for other tests intended to detect 2009 H1N1 influenza virus, see <http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm> for more information. To augment current testing capacity, FDA has authorized the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay to detect 2009 H1N1 influenza virus infections. Current information on 2009 H1N1, 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 IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay should be ordered only to detect 2009 H1N1 influenza virus infection in patients with signs and symptoms of respiratory infection. This test is authorized for use with upper respiratory tract specimens (such as nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal/throat swabs (NPS/TS)). 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 IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay indicates that the patient has been 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 on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel*" 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 IMDx 2009 Influenza A H1N1 Real-Time RT-PCR 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 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 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 decisions. A negative result from the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR 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 IntelligentMDx, Inc. in the event of any significant new findings observed during the course of the emergency use of the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay.