



FACT SHEET FOR HEALTHCARE PROVIDERS:

INTERPRETING TEST RESULTS OBTAINED WITH THE CDC swH1N1 (SWINE) INFLUENZA VIRUS REAL-TIME RT-PCR DETECTION PANEL ON THE JOINT BIOLOGICAL AGENT IDENTIFICATION AND DIAGNOSTIC SYSTEM (JBAIDS) INSTRUMENT

August 24, 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 CDC swH1N1 (swine) Influenza Virus Real-time RT-PCR Detection Panel on the Joint Biological Agent Identification and Diagnostic System (JBAIDS) Instrument (rRT-PCR Swine Flu Panel on JBAIDS) to test for the presence of the 2009 H1N1 influenza virus in clinical specimens collected via nasopharyngeal swabs (NPS) and in culture 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authorization will terminate on April 26, 2010, when the emergency has ceased to exist, or when the authorization has been revoked, whichever is earlier.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 rRT-PCR Swine Flu Panel on JBAIDS.

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 be used on the Applied Biosystems (ABI) 7500 Fast Dx instruments. To augment existing testing capacity and provide 2009 H1N1 Influenza testing capability to Department of Defense (DoD) sites, most of which currently do not have PCR capability on the ABI 7500 Fast Dx instruments, but are currently equipped with the JBAIDS instruments, FDA has authorized the emergency use of the rRT-PCR Swine Flu Panel on JBAIDS 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 rRT-PCR Swine Flu Panel on JBAIDS should be ordered only to diagnose 2009 H1N1 influenza virus infection. Specimen collection should be conducted according to the manufacturer's instructions for the specimen collection device and sent to a JBAIDS qualified DoD 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 rRT-PCR Swine Flu Panel on JBAIDS 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 “*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 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 rRT-PCR Swine Flu Panel on JBAIDS 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:

JBAIDS Operators Help Line / Technical Assistance:

JBAIDS Training School
2507 Kennedy Circle
Bldg 110
Brooks City Base, TX 78235
JBAIDSSwFlu@amedd.army.mil
DSN: 240-3248 or Commercial: 210-536-3248

Healthcare providers will be contacted by the DoD’s Joint Project Management Office, Chemical Biological Medical Systems (CBMS), in the event of any significant new findings observed during the course of the emergency use of the rRT-PCR Swine Flu Panel on JBAIDS.

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/guidance/>.

