



FACT SHEET FOR PATIENTS:

UNDERSTANDING 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

An emergency has been declared by the Secretary of Health and Human Services because of the 2009 outbreak caused by a 2009 H1N1 flu virus. This virus has also been 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 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 2009 H1N1 flu virus in clinical respiratory specimens collected via nasopharyngeal swabs (NPS) and in viral culture. 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authorization will terminate on April 26, 2010, when the emergency has ceased to exist, or when the authorization has been revoked, whichever is earlier.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 this 2009 H1N1 influenza virus test when used with the JBAIDS instrument.

Why was my sample tested using the rRT-PCR Swine Flu Panel on JBAIDS?

There are no FDA cleared or approved tests that can identify the 2009 H1N1 flu virus. FDA has granted Emergency Use Authorization for use of the rRT-PCR Swine Flu Panel on JBAIDS. Your sample was tested using this test because you may have been infected with the 2009 H1N1 flu virus. This test could help to determine whether you are infected so that public health officials could quickly identify a case and limit its spread. The results of this test, along with other information, may also help your doctor take better care of you.

What is 2009 H1N1 flu?

The 2009 H1N1 flu is a respiratory disease caused by type A influenza virus. Human cases of 2009 H1N1 flu virus infection have been identified in the United States and internationally. The Centers for Disease Control and Prevention (CDC) has determined that this virus is contagious and is spreading from human to human. Like seasonal flu, the 2009 H1N1 flu in humans can vary in severity from mild to severe.

What is a 2009 H1N1 Influenza Test?

The rRT-PCR Swine Flu Panel on JBAIDS is believed to be a good test to detect the 2009 H1N1 flu virus. The FDA has not cleared or approved this test. The FDA has agreed that we can use this 2009 H1N1 influenza test under an Emergency Use Authorization. We don't know for sure if this test can identify all people who may get sick with 2009 H1N1 flu.

What are the known risks and benefits of a 2009 H1N1 Influenza Test?

The results of this test from nasopharyngeal swabs, along with other information, can help your doctor take better care of you. Knowing your test results may help you to prevent the spread of the virus to your family or others.

If this test is positive, does that mean that I have 2009 H1N1 flu?

Yes, although there is a very small chance that this test can give a result that is wrong (false positive). If your result from this test is positive, your doctor may decide how to care for you based on the test results along with other factors.

If this test is negative, does that mean that I do not have 2009 H1N1 flu?

Most, but not all, people with 2009 H1N1 flu will have a positive test. Therefore, if your test is negative, something else may be responsible for your illness. However, there is a small chance that this test can give a negative result that is wrong (called a false negative), meaning you could possibly still have flu even though the test is negative. Therefore, while a negative test most likely means you don't have flu, your doctor must consider the test result together with all other aspects of your illness in deciding how to treat you.

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

