

**FACT SHEET FOR PATIENTS:  
UNDERSTANDING THE FOCUS DIAGNOSTICS INFLUENZA A H1N1 (2009)  
REAL-TIME RT-PCR TEST RESULTS**

July 23, 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 Focus Diagnostics Influenza A H1N1 (2009) Real-Time RT-PCR (Focus Diagnostics Influenza A H1N1 (2009) test) to test for the presence of 2009 H1N1 flu virus in clinical respiratory specimens. 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authorization will terminate on April 26, 2010, when the emergency has ceased to exist, or when the authorization has been revoked, whichever is earlier.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.

**Why was my sample tested using the Focus Diagnostics Influenza A H1N1 (2009) Test?**

There are no FDA cleared or approved tests that can identify the 2009 H1N1 flu virus. FDA has granted Emergency Use Authorization for the Focus Diagnostics Influenza A H1N1 (2009) test. Your sample was tested using this test kit, 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 Focus Diagnostics Influenza A H1N1 (2009) test 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, nasal swabs, throat swabs, or nasal aspirates, 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?**

If this test is negative you may be sick with something that is not 2009 H1N1 flu. There is a small chance that this test can give a result that is wrong (false negative). A false negative result should not affect your care. No changes in your medical care should be solely based on a negative result.

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/>.