

## ***FACT SHEET FOR PATIENTS: UNDERSTANDING SWINE INFLUENZA KIT TEST RESULTS***

May 2, 2009

An emergency has been declared by the Secretary of Health and Human Services because of the 2009 outbreak caused by a novel H1N1 flu virus. Novel means that the virus was newly found. This virus has also been referred to as swine influenza (H1N1) virus. This Fact Sheet will refer to the virus as novel influenza A (H1N1) virus. The Food and Drug Administration (FDA) has authorized the emergency use of the Swine Influenza Test Kit to test for the presence of novel H1N1 flu 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authorization will terminate on April 26, 2010, when the emergency has ceased to exist, or when the authorization has been revoked, whichever is earlier.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 Swine Influenza Test Kit.

### **Why was my sample tested using the Swine Influenza Test Kit?**

There are no FDA cleared or approved tests that can identify novel H1N1 flu virus. Therefore, your sample was tested using the Swine Influenza Test Kit because you may have been infected with the novel H1N1 flu virus. This test could help to determine whether you are infected with the novel H1N1 flu virus, 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 novel H1N1 flu?**

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

### **What is the Swine Influenza Test Kit?**

The Swine Influenza Test Kit is believed to be a good test to detect the novel H1N1 flu virus. The FDA has not cleared or approved this test. The FDA has agreed that we can use this test under an Emergency Use Authorization. We don't know for sure if this test can identify all people who may get sick with novel H1N1 flu.

### **What are the known risks and benefits of Swine Influenza Test Kit?**

The results of this test from nasopharyngeal swabs, nasal swabs, throat swabs, dual nasopharyngeal swabs/throat swabs, and 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 novel H1N1 flu?**

Yes, although there is a very small chance that this test can give a result that is wrong (false positive), it is not likely. 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 novel H1N1 flu?**

If this test is negative you may be sick with something that is not novel 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 the emergency use of Swine Influenza Test Kit will be made available at <http://www.cdc.gov/h1n1flu/>.