

Fact Sheet for Patients: Understanding 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 2009 outbreak caused by the 2009 H1N1 influenza 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 IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay to test for the presence of 2009 H1N1 influenza virus in clinical respiratory specimens. 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.

Why was my sample tested using the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay?

Your sample was tested using the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay because you may have been infected with 2009 H1N1 influenza virus. This test could help to determine whether you are infected. The results of this test, along with other information, may also help your doctor take better care of you.

What is 2009 H1N1 influenza?

The 2009 H1N1 influenza is a respiratory disease caused by type A influenza virus. Human cases of 2009 H1N1 influenza 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 can spread from person to person. Like seasonal influenza, the 2009 H1N1 influenza in humans can vary in severity from mild to severe.

What is the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay?

The IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay is a test performed to detect the 2009 H1N1 influenza virus. The FDA has not cleared or approved this test and there are no FDA cleared or approved tests that can identify the 2009 H1N1 influenza virus. Based on the data submitted to FDA, FDA has granted an Emergency Use Authorization for the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay.

What are the known and potential risks and benefits of the IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay?

Besides minimal potential discomfort during sample collection, there is a very small risk of a reported incorrect result (see next paragraph for more information). The results of this test, 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 influenza?

Yes, although there is a very small chance that this test can give a result that is wrong. There is a small chance of an incorrect positive test result (false 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 influenza?

Most, but not all, people with 2009 H1N1 influenza 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 can give a negative result that is wrong (called a false negative) meaning you could possibly still have influenza even though the test is negative. Therefore, while a negative test most likely means you don't have influenza, your doctor must consider the test result together with all other aspects of your illness in deciding how to treat you.