

Fact Sheet for Patients: Understanding the Prodesse ProFlu-ST Assay Results

October 27, 2009

An emergency has been declared by the Secretary of Health and Human Services because of the 2009 outbreak caused by the 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 Prodesse ProFlu-ST Assay to help diagnose 2009 H1N1 influenza infection. 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authorization will terminate on April 26, 2010, when the emergency has ceased to exist, or when the authorization has been revoked, whichever is earlier.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 Prodesse ProFlu-ST Assay.

Why was my sample tested using the Prodesse ProFlu-ST Assay?

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. 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 person to person. Like seasonal flu, the 2009 H1N1 flu in humans can vary in severity from mild to severe.

What is the Prodesse ProFlu-ST Assay?

The Prodesse ProFlu-ST Assay is a test performed to detect 2009 H1N1 influenza virus in a nasopharyngeal swab specimen. The FDA has not cleared or approved this test and there are no FDA cleared or approved tests that can identify the 2009 H1N1 flu virus. Based on the data submitted to FDA, FDA has granted an Emergency Use Authorization for the ProFlu-ST Assay.

What are the known risks and benefits of the Prodesse ProFlu-ST Assay?

Besides minimal potential discomfort during sample collection, there is a very small risk of an incorrect result. (See next paragraph for more information). The results of this test from nasopharyngeal swabs (NPS), along with other information, are intended to 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 for the 2009 H1N1 influenza virus, 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. There is a small chance of an incorrect positive test result (false positive) or an incorrect negative test result from a patient infected with the 2009 H1N1 flu virus (false negative). 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 causing 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 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.