

FACT SHEET FOR PATIENTS:
UNDERSTANDING RESULTS FROM THE CDC HUMAN INFLUENZA VIRUS REAL-TIME RT-PCR DIAGNOSTIC PANEL-INFLUENZA A/H7 (EURASIAN LINEAGE) ASSAY

April 22, 2013

The Secretary of Health and Human Services (HHS) has declared circumstances exist to allow emergency use of diagnostic tests for detection of the avian influenza A(H7N9) virus because of the significant *potential* for a public health emergency involving this virus. Therefore, the Food and Drug Administration (FDA) authorized the emergency use of the Centers for Disease Control and Prevention (CDC) Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay to test for the presence of the H7N9 influenza virus in clinical respiratory samples. Use of this test is authorized under an Emergency Use Authorization (EUA) only for the duration of the threat of emergency, unless it is revoked sooner.

The sample(s) collected to test for the H7N9 influenza virus should be taken from either your upper respiratory tract (such as your nose or throat), or your lower respiratory tract (such as your lungs). 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 CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay.

What is the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay?

The CDC Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay is a laboratory test designed to detect the H7N9 virus. The FDA has not cleared or approved this test, and there are no FDA cleared or approved tests that can identify the H7N9 virus. However, based on data submitted by CDC, FDA has determined that this test can be used for emergency use under an EUA.

Why was my sample tested using the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay?

The sample collected was tested using the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay to help determine whether you are infected with the H7N9 virus and may help your doctor take better care of you. The test results could also help public health officials to identify and limit the spread of this virus in your community.

What is H7N9 flu?

The H7N9 flu is a respiratory disease caused by a novel (new) influenza virus called “H7N9”. Human cases of H7N9 virus infection have been identified in China but there has been no sustained human to human transmission in China. No human cases of H7N9 have been confirmed in the United States at the time of this EUA issuance (April 22, 2013). However, public health officials have determined that this virus has the potential to change in ways that could allow it to spread from human to human. And this potential poses risks for a public health emergency that could affect national security or the health and security of United States citizens living abroad. As with seasonal flu, H7N9 flu in humans could vary in severity from mild to severe.

What are the known risks and benefits of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay?

Besides minimal potential discomfort during sample collection, there is a very small risk that the test result reported is incorrect (see next paragraphs for more information). The benefit of having this test is that the results of this test, along with other information, can help your doctor take better care of you. Also, knowing your test results would help you to take precautions to prevent the spread of the virus to your family or others.

If this test is positive, does that mean that I have H7N9 flu?

If you have a positive test, it is very likely that you have H7N9 flu. 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 H7N9 flu?

If you have a negative test, you probably do not have H7N9 flu and are sick with something else. There is a very small chance that this test can give a result that is wrong (false negative), meaning you could possibly still have H7N9 flu even though the test is negative. A false negative result might cause any or all of the following: delayed treatment, potential lack of treatment, or stopping your antiviral medication too soon. However, to avoid a false negative result affecting your care, your doctor should not change your medical care solely based on a negative result, and instead, consider all other aspects of your illness along with your test result in deciding how to treat you.

How can I learn more?

Information about H7N9 flu and any significant new findings observed during the course of the emergency use of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay will be made available at <http://www.cdc.gov/flu/avianflu/h7n9-virus.htm>.

Please also contact your doctor, if you have any questions.