

**FACT SHEET FOR PATIENTS:
UNDERSTANDING RESULTS FROM THE LYRA™ INFLUENZA A SUBTYPE H7N9
ASSAY TEST**

February 14, 2014

What is the Lyra™ Influenza A Subtype H7N9 Assay?

The Lyra™ Influenza A Subtype H7N9 Assay is a laboratory test designed to detect the H7N9 virus. Unlike most other influenza tests available for clinical use, this test has not been cleared or approved by the Food and Drug Administration (FDA). However, the FDA has determined that this test can be used under an Emergency Use Authorization (EUA) based on data submitted by Quidel Corporation, which makes this test.

What is an Emergency Use Authorization (EUA)?

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, FDA authorized the emergency use of the Lyra™ Influenza A Subtype H7N9 Assay to test for the presence of the influenza A (H7N9) virus (detected in China in 2013) in clinical respiratory samples. Use of this test is authorized under an EUA only for the duration of the threat of emergency, unless it is revoked sooner.

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 Lyra™ Influenza A Subtype H7N9 Assay.

Why was my sample tested using the Lyra™ Influenza A Subtype H7N9 Assay?

The sample(s) collected to test for the H7N9 influenza virus should be taken from your nose or nasopharynx. The sample(s) collected was tested using the Lyra™ Influenza A Subtype H7N9 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 (February 14, 2014). However, public health officials have determined that this virus has the potential to change in ways that could allow it to spread more readily from human to human. This potential poses risks for a

public health emergency. 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 Lyra™ Influenza A Subtype H7N9 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?

Updates about H7N9 flu or significant new findings observed during the course of the emergency use of this test will be made available at <http://www.cdc.gov/flu/avianflu/h7n9-virus.htm>.

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