FACT SHEET FOR HEALTHCARE PROVIDERS:
INTERPRETING LYRA™ INFLUENZA A SUBTYPE H7N9 ASSAY TEST RESULTS

February 14, 2014

The Secretary of Health and Human Services has declared circumstances exist to justify authorization of the emergency use of in vitro diagnostic tests for the detection of the novel influenza A (H7N9) virus because of the significant potential for a public health emergency involving this virus. The Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the Lyra™ Influenza A Subtype H7N9 Assay to test for the presumptive presence of influenza A (H7N9) virus (detected in China in 2013) in nasal and nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. This EUA will terminate when the Secretary's declaration terminates, 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.

At this time, no FDA-approved/cleared tests that identify the existence of the novel influenza A (H7N9) virus in clinical specimens are available in the United States. Therefore, Quidel Corporation has developed this test to detect influenza A (H7N9) virus (detected in China in 2013) infections. Current information on the novel influenza A (H7N9) virus, including case definitions and infection control guidelines, is available at http://www.cdc.gov/flu/avianflu/h7n9-virus.htm. All information and guidelines, including those on novel influenza A (H7N9) virus laboratory testing, may change as we continue to learn more about this virus. Please check the Centers for Disease Control and Prevention (CDC)'s novel influenza A (H7N9) website regularly for the most current information.

If infection with a novel influenza A (H7N9) virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, the Lyra™ Influenza A Subtype H7N9 Assay test should be ordered only to presumptively diagnose influenza A (H7N9) virus (detected in China in 2013) infection. This test is authorized for use with nasal swab (NS) and nasopharyngeal swab (NPS) specimens. It is strongly recommended that NPS or NS be collected even if other specimens are collected. Specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses, and per the guidance for case investigation and specimen collection (http://www.cdc.gov/flu/avianflu/guidance-labtesting.htm), and according to the manufacturer's instructions for the specimen collection device and sent to a qualified laboratory for analysis.

What does it mean if the specimen tests positive for the influenza A (H7N9) virus (detected in China in 2013)?
A positive test result from the Lyra™ Influenza A Subtype H7N9 Assay indicates that the patient is presumptively infected with the influenza A (H7N9) virus (detected in China in 2013). The test does not indicate the stage of infection. Laboratory test results should always be considered in the context of clinical observations and epidemiologic data in making a final diagnosis. For guidelines on managing patients please refer to "*Interim Guidance for Infection Control Within*

Healthcare Settings When Caring for Confirmed Cases, Probable Cases, and Cases Under Investigation for Infection with Novel Influenza A Viruses Associated with Severe Disease" at http://www.cdc.gov/flu/avianflu/h7n9-infection-control.htm.

The Lyra™ Influenza A Subtype H7N9 Assay has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include any or all of the following: a recommendation for quarantine of household or other close contacts, patient isolation that might limit contact with family or friends, the ability to work, the impaired ability to detect and receive appropriate medical care for the true infection causing the flu like symptoms, unnecessary prescription of an antiviral medication or other therapy, or other unintended adverse effects.

What does it mean if the specimen tests negative for the influenza A (H7N9) virus (detected in China in 2013)?

Negative results do not preclude influenza A (H7N9) virus (detected in China in 2013) infection, and should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure are the keys to making patient management and isolation decisions. A negative Lyra™ Influenza A Subtype H7N9 Assay test result should not be interpreted as demonstrating that the patient does not have influenza A (H7N9) virus (detected in China in 2013) infection. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate influenza A (H7N9) virus (detected in China in 2013) infection is likely, and diagnostic tests for other causes of acute respiratory illness are negative.

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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.