Fact Sheet for Health Care Providers:
Interpreting *A/H7N9 Influenza Rapid Test* Results

April 25, 2014

The Secretary of Health and Human Services has declared that circumstances exist that justify authorization of emergency use of *in vitro* diagnostic tests for the detection of the novel influenza A (H7N9) virus because of the significant potential risk for a public health emergency involving this virus. The Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the Arbor Vita Corporation's *A/H7N9 Influenza Rapid Test* to test for the presumptive presence of novel influenza A (H7N9) virus (detected in China in 2013) in nasal swabs from patients with signs and symptoms of respiratory infection. This rapid test is developed to meet special needs of U.S. personnel abroad and in the U.S. at risk for exposure to influenza A (H7N9) virus (detected in China in 2013) or persons infected with influenza A (H7N9) virus (detected in China in 2013). 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 A/H7N9 Influenza Rapid Test.

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, Arbor Vita 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 U.S. public health authorities, the A/H7N9 Influenza Rapid Test should be ordered only to presumptively diagnose influenza A (H7N9) virus (detected in China in 2013) infection. In rare cases of influenza A (H9N2) or A (H10N8) infection, a positive test result may occur. This test is authorized for use with nasal swab specimens. 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.

What does it mean if the specimen tests positive for the novel influenza A (H7N9) virus?

A positive test result from the *A/H7N9 Influenza Rapid Test* indicates that the patient is presumptively infected with the novel influenza A (H7N9) virus (detected in China in 2013). In rare cases of influenza A (H9N2) or A (H10N8) infection, a positive test result may also occur. The test does not indicate the stage of infection. Further laboratory tests should be performed by molecular assay in the context of clinical observations and epidemiologic data in making a final diagnosis.

The *A/H7N9 Influenza Rapid Test* 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: patient isolation that might limit contact with family or friends or the ability to work, the impaired ability to 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.

Current information on the novel influenza A (H7N9) virus, including case definitions, infection control guidelines, and any significant new findings observed during the course of the emergency use of this test is available at http://www.cdc.gov/flu/avianflu/h7n9-virus.htm.

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

A negative test presumes the patient is not infected with the novel influenza A (H7N9) virus but should be confirmed by an FDA-cleared influenza A and B molecular assay. Negative results do not preclude novel influenza A (H7N9) virus 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 *A/H7N9 Influenza Rapid Test* result should not be interpreted as demonstrating that the patient does not have novel 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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