Arbor Vita Corporation's A/H7N9 Influenza Rapid Detection Test Authorized for Emergency Use by FDA

FREMONT, California, May 21, 2014

A new strain of the avian influenza virus appeared in China in 2013. This particular `bird flu', influenza A/H7N9 virus (detected in China in 2013), kills one in three people infected. In two successive and increasing waves, this virus has moved across China and crossed the Chinese border into Hong Kong, Taiwan and Malaysia[1]. According to CDC it is possible that the virus can appear in the US[2]. This past week, another case of influenza A /H7N9 virus was reported in Hong Kong.

This virus caught the attention of the US government and Swiss government because of its pandemic lethal potential. Rapid, simple, and affordable detection is a critical defense against such a threat. Arbor Vita Corporation (AVC), a privately held company, announced today that the United States Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for their AVC A/H7N9 Influenza Rapid Test for the presumptive detection of the influenza A /H7N9 virus (detected in China in 2013) in patients with signs and symptoms of respiratory infection in conjunction with epidemiological risk factors".

The US Navy approached Arbor Vita in the spring of 2013 to develop a simple, yet accurate test to detect the influenza A/H7N9 virus. Arbor Vita had demonstrated success in developing similar test for the influenza A/H5N1 virus. The Navy specified that the test be simple enough for non-laboratory personnel to use in field conditions. The alarming spread of the virus necessitated that such a test be available.

Arbor Vita's collaborators at the US Navy, Swiss Armed Forces (Spiez Laboratory) and the University of Hong Kong evaluated AVC A/H7N9 Influenza Rapid Test. "We have confirmed that Arbor Vita's test can detect human H7N9 viruses. The dual testing system – Influenza A virus and A/H7N9 virus – clearly has a great advantage." says Dr. Leo Poon, associate professor at Centre of Influenza Research and School of Public Health, University of Hong Kong.

"We are delighted to participate to make this surveillance tool available for pre-pandemic setting to help prevent a lethal pandemic," says Colonel Sergei Bankoul, MD, Senior Consultant to the Swiss Surgeon General.

Viruses are small infectious agents that replicate only inside the living cell of other organisms. They are the source of such illnesses as the flu and HIV. When viruses transmit unchecked between many members of a population it leads to a pandemic such as those of measles, smallpox or influenza. The influenza pandemic of 1918 resulted in 100 million deaths per year in Europe, North America and Asia. Viruses are constantly mutating producing more or less

virulent strains with differing abilities of transmission between hosts. The 21st century has seen increased population densities and increased interactions between widely separated populations. The lethal potential of an unchecked virus is enormous. This is what makes the technology being developed at Arbor Vita so important.

Access to the influenza A/H7N9 virus proved to be difficult but possible with help from Dr. Leo Poon. Cases of influenza A/H7N9 virus around the Lunar New Year mushroomed as people travelled to visit each other bringing live chickens as presents from affected areas and spreading the virus inside and outside of China. "The AVC A/H7N9 Influenza Rapid Test is a potent early surveillance tool. This test is suitable for early screening in strategic locations. Early detected infections are then confirmed by molecular tests, such as PCR in large reference laboratories," says Dr. Peter Lu, Chief Executive Officer of Arbor Vita Corporation.

This test is intended for use by the DoD network laboratories in the U.S. or outside the U.S., or other U.S. government laboratories outside the U.S. for testing of U.S. citizens living and traveling abroad in China and other affected areas and for U.S. Military, Department of State, and other U.S. governmental agency personnel stationed or working in China and other affected areas who may be potentially exposed to influenza A/H7N9 virus (detected in China 2013), or by foreign laboratories

"We are proud and excited to receive FDA's authorization under an EUA for the first rapid test able to diagnose patients suffering from this deadly respiratory infection. We applaud the FDA's efforts to authorize the test. This test may prove to be critical at containing a potential avian influenza pandemic" concludes Dr. Peter Lu.

This test has been authorized by the FDA under Emergency Use Authorization. This test has not been FDA approved or cleared. This test has been authorized for use by the DoD network laboratories for use in the US and outside the US, other US government laboratories outside the US, or foreign laboratories. This test has been authorized only for the detection of influenza A/H7N9 (detected in China 2013) and not for the detection of any other viruses or pathogens. This test is only authorized for the duration of the HHS declaration of emergency that justifies this authorization, unless the authorization is revoked sooner.

1. http://www.cdc.gov/flu/news/h7n9-case-malaysia.htm
2. CDC FAQ site: http://www.cdc.gov/flu/avianflu/h7n9-faq.htm#human-cases
3. Qi X, Qian Y, Bao C, Guo X, Cui L, Tang F, et al. Probable person to person transmission of novel avian influenza A (H7N9) virus in Eastern China, 2013: epidemiological investigation. BMJ 6 August 2013;347:f4752
4. Kannan Tharakaraman, Akila Jayaraman, et al. Receptor Binding of the Influenza A Virus H7N9 Hemagglutinin, Cell, Volume 153, Issue 7, 20 June 2013, Pages 1486-1493

About Arbor Vita Corporation:

Arbor Vita Corporation (AVC) is a privately held company committed to making a difference by enabling early and accurate diagnosis and treatment of disease. The company has products on the market or in clinical studies to address global health challenges in the areas of HPV-induced cancer, infectious disease and proteomic research.

Arbor Vita Corporation Contact:

Evelyne Gaillard
evelyne.gaillard@arborvita.com