Focus Diagnostics Launches 2009 H1N1 Flu Test Kit to Commercial Laboratories in the U.S.

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First test for detecting the new virus to be authorized by FDA for use by CLIA high-complexity labs during pandemic emergency

CYPRESS, Calif., Aug. 20 /PRNewswire-FirstCall/ -- Focus Diagnostics, the infectious disease diagnostics business of Quest Diagnostics Incorporated (NYSE: DGX), today announced that its Influenza A H1N1 (2009) Real Time RT-PCR test is now available as a test kit for use by "high complexity" clinical laboratories in the U.S. The test qualitatively detects the RNA of the 2009 H1N1 influenza virus ("pandemic virus") from a patient's nasal, nasopharyngeal or throat specimen. In combination with clinical and epidemiological assessments, the test aids physicians in diagnosing patients infected with the pandemic virus rather than other influenza A strains.

"The availability of a quality test kit authorized by FDA for use during the pandemic emergency will contribute to the nation's capacity for accurate testing for the 2009 H1N1 influenza virus," said John Hurrell, Ph.D., vice president and general manager, Focus Diagnostics. "Expanded testing for this new virus could be critically important in aiding clinicians in determining which influenza A virus is causing a patient's illness should there be a surge in testing demand during the fall and winter flu season."

On July 24, the U.S. Food and Drug Administration ("FDA") announced it had granted emergency use authorization ("EUA") to the Focus Diagnostics test, the first granted to a commercial test for detecting the 2009 H1N1 influenza virus. On August 17, FDA informed Focus Diagnostics that it had issued an amended EUA for the company's test to reflect labeling clarifications regarding the contents of the test kit. According to the EUA, the test may be performed in laboratories certified under the U.S. Clinical Laboratory Improvement Amendments ("CLIA") to perform high-complexity tests and operating certain equipment.

In April 2009, the FDA granted two EUAs in connection with the CDC's RT-PCR diagnostic panel used by public health labs in the U.S. to detect the 2009 H1N1 influenza virus infection. In its EUA application to the FDA, Focus Diagnostics presented data involving more than 100 clinical specimens indicating that the Focus Diagnostics test agreed 100% with the CDC's RT-PCR test in identifying specimens as positive or negative for the pandemic virus.

For more information about Quest Diagnostics and influenza testing options, please visit www.FocusDx.com or www.QuestDiagnostics.com/2009H1N1.

About the Influenza A H1N1 (2009) Real Time RT-PCR test

The Focus Diagnostics test uses reverse transcriptase polymerase chain reaction, or RT-PCR, to amplify viral RNA to make it detectable in a specimen. It targets two separate regions of the hemagglutinin ("H1") gene of the 2009 H1N1 influenza virus to differentiate the presence of the pandemic virus from seasonal human influenza A virus. If RNA of Influenza A virus and the 2009 Influenza H1 gene are detected, the specimen is reported as positive for 2009 H1N1 influenza infection. The expected turnaround time for reporting a result is within approximately 24 hours of receipt of a specimen by the Focus Diagnostics laboratory in Cypress, California.

About the FDA's Emergency Use Authorization

The FDA has not cleared or approved any tests for the identification of the 2009 H1N1 influenza virus. The EUA authority allows the FDA, based on the evaluation of available data, to authorize the use of unapproved or uncleared medical products or unapproved or uncleared uses of approved or cleared medical products following a determination and declaration of emergency, provided certain criteria are met. In the case of the Influenza A H1N1 (2009) Real Time RT-PCR, the FDA has only authorized its use for the duration of the declaration of emergency, which is currently set to expire on April 26, 2010, unless it is terminated, revoked sooner or renewed. Only CLIA high-complexity laboratories operating certain equipment are permitted to perform the test under the EUA.

About Focus Diagnostics

Focus Diagnostics, Inc. is an infectious disease diagnostics company, providing infectious disease reference laboratory services to hospitals and laboratories nationwide, and manufacturing and distributing diagnostic products worldwide. Focus Diagnostics develops innovative tests and products to assist physicians in diagnosing infectious diseases, and often provides the first diagnostic tests in the U.S. for emerging diseases, such as West Nile Virus and SARS. HerpeSelect type-specific HSV serology and West Nile Virus DxSelect(TM) are top-selling Focus Diagnostics products used in laboratories worldwide. Focus Diagnostics is a wholly owned subsidiary of Quest Diagnostics.

Focus Diagnostics has collaborated with the U.S. Centers for Disease Control and Prevention, the World Health Organization and other public health agencies to help identify and develop diagnostic tests for emerging infectious diseases. Focus Diagnostics was instrumental in developing the first laboratory developed test for West Nile virus after it was identified in New York in 1999. Focus Diagnostics also introduced the first laboratory developed test for SARS and one of the first FDA-cleared serological test kits for Lyme disease. Visit www.focusdx.com for additional information.

About Quest Diagnostics

Quest Diagnostics is the world's leading provider of diagnostic testing, information and services that patients and doctors need to make better healthcare decisions. The company offers the broadest access to diagnostic testing services through its network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a pioneer in developing innovative diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional company information is available at www.QuestDiagnostics.com.

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