FDA Grants First Authorization of a Commercial 2009 H1N1 Flu Test for use During Pandemic Flu Emergency to Quest Diagnostics' Focus Diagnostics Business

July 24, 2009

MADISON, N.J., July 24 /PRNewswire-FirstCall/ -- Quest Diagnostics Incorporated (NYSE: DGX), the world's leading provider of diagnostic testing, information and services, today announced that the U.S. Food and Drug Administration (FDA) has granted an emergency use authorization to the company's Focus Diagnostics business for its test for detecting the 2009 H1N1 influenza virus (the "pandemic flu virus"), a strain of influenza A virus initially referred to as the swine flu virus.

The Influenza A H1N1 (2009) Real Time RT-PCR test is the first commercial lab test to be granted an emergency use authorization by the FDA for testing for the 2009 H1N1 influenza virus. It is also the first test to qualitatively detect RNA of the pandemic flu virus in a patient's nasal or nasopharyngeal specimens. The test targets two separate regions of the hemagglutinin gene of the 2009 H1N1 influenza virus to differentiate the presence of the pandemic virus from seasonal human influenza A virus. Turnaround time for reporting results is typically within 24 hours of receipt of specimen.

"This emergency use authorization means that the Influenza A H1N1 (2009) Real Time RT-PCR, when combined with clinical and epidemiological assessments, can aid physicians in diagnosing patients infected with the 2009 H1N1 influenza virus versus other influenza A virus strains," said Jon R. Cohen, M.D., senior vice president and chief medical officer, Quest Diagnostics. "This capability could be critically important in aiding clinicians in determining which Influenza A virus is causing an infection should there be a surge in flu cases during the fall and winter flu season. We will continue to work closely with public health officials, who have done an outstanding job managing the pandemic, to mitigate its effect on public health."

Quest Diagnostics' Focus business, which has a track record of being first to market with new laboratory testing services for emerging infectious diseases, developed and, in May 2009, launched the laboratory developed test to help offload an expected backlog of testing from public health laboratories. In the U.S., public health labs employ the CDC's rRT-PCR test, which the FDA authorized for emergency use in April 2009. Public health labs may use the CDC test to determine if certain high-risk patients who test positive for influenza A virus by commercial tests are infected with the pandemic flu virus.

Since Focus Diagnostics began to perform its laboratory developed test at its Cypress, CA, laboratory two months ago, orders placed by physicians for patients suspected of being infected with the 2009 H1N1 influenza virus increased dramatically before peaking in late June. While test volume has since declined, it remains more than 30 times higher than the company's typical rate of influenza virus testing in July.

Of those samples tested by Focus Diagnostics, approximately three fourths for patients between the ages of five and 20 years have tested positive for the 2009 H1N1 influenza virus. By comparison, positivity rates in adults 21 to 40 years of age have averaged approximately 49 percent over the past two months. Adults 41 to 60 years of age have experienced positivity rates of 36 percent, while those 61 to 80 years of age have experienced positivity rates of approximately 14 percent.

"Our data are consistent with CDC data suggesting that this pandemic flu virus is disproportionately affecting children and young adults, as compared to older adults," Jay M. Lieberman, M.D., medical director, Focus Diagnostics, said. "In fact, almost 60 percent of all positive results identified by our test have been in children 18 or younger.

"In addition, our data, consistent with CDC data, reveal that not only has this pandemic virus not faded away, it is behaving differently than the seasonal flu, which is typically absent during the summer months in the Northern Hemisphere," Dr. Lieberman continued. "When you also factor in the rapid global spread of the virus, particularly the increasing number of cases in certain countries in the Southern Hemisphere, it appears increasingly likely that this novel H1N1 virus could be a major influenza strain circulating in the U.S. this flu season."

Quest Diagnostics is currently in the process of validating the test at a number of its CLIA high complexity laboratories around the U.S. capable of performing the test in compliance with the emergency use authorization. The Quest Diagnostics Focus laboratory in Cypress, CA, currently is the only laboratory performing this test.

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

About the FDA's Emergency Use Authorization

The U.S. Secretary of Health and Human Services has declared a public health emergency because of the outbreak of the pandemic flu virus. The FDA, in response to requests from the CDC, has issued emergency use authorizations to make important diagnostic and therapeutic tools available to public health and medical personnel in order to identify and respond to the 2009 H1N1 influenza virus under certain circumstances.

The FDA has not cleared or approved any tests for the identification of the 2009 H1N1 influenza virus. The emergency use authorization 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.

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.

Contacts:
Wendy Bost (Media): 973-520-2800
Laure Park (Investors): 973-520-2900

SOURCE Quest Diagnostics Incorporated