



First FDA Clearance of a 2009 H1N1 Test Given to Quest Diagnostics' Focus Diagnostics Business

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Simplexa(TM) molecular RT-PCR test runs on the 3M Integrated Cyclor

MADISON, N.J., and CYPRESS, Calif., May 24, 2010 /PRNewswire via COMTEX/ --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 issued 510(k) clearance to the Simplexa(TM) Influenza A H1N1 (2009) test on the 3M(TM) Integrated Cyclor. The Simplexa test, developed and manufactured by Quest Diagnostics' Focus Diagnostics business, is the first to be cleared by the FDA for use as an aid in the detection and differentiation of influenza A and 2009 H1N1 influenza viral RNA.

The Simplexa Influenza A H1N1 (2009) test runs on the 3M Integrated Cyclor under an exclusive global distribution agreement between Focus Diagnostics and 3M (NYSE: MMM). The test employs real-time reverse transcription (RT) polymerase chain reaction (PCR) to qualitatively detect RNA of the 2009 H1N1 flu virus (2009 H1N1) in a patient's nasal or nasopharyngeal specimens. It reports if a specimen is positive or negative for the presence of 2009 H1N1 or influenza A virus. By comparison, some flu tests, including rapid point-of-care influenza tests, can detect the presence of influenza A, but not differentiate the presence of 2009 H1N1. In addition to 2009 H1N1, influenza A viruses include some seasonal flu subtypes.

"Thankfully, H1N1 is not currently a widespread public health problem, but reliable detection continues to be important to help manage high-risk patients, such as expectant mothers who have flu-like symptoms," said Jay M. Lieberman, M.D., medical director, infectious diseases, Quest Diagnostics and Focus Diagnostics. "Influenza viruses are unpredictable, and reliable tests will be needed, particularly if, as expected, 2009 H1N1 activity again increases later this year."

"Innovation often emerges in response to crisis, and the 2009 H1N1 is no exception," said John G. Hurrell, Ph.D., vice president and general manager, Focus Diagnostics. "When 2009 H1N1 surfaced about a year ago, limitations in traditional flu tests made them unsuitable for dealing with a virus infecting large swaths of the population. These limitations included the sensitivity of rapid tests and the need to ship samples to reference labs with reliable PCR methods. We designed our Simplexa 2009 H1N1 test to overcome these problems by bridging highly reliable PCR with testing technologies that many hospital labs can perform in-house."

"Moreover, FDA clearance of our Simplexa test means hospital and other labs can use our test with confidence since it meets regulatory requirements long term, unlike flu tests authorized for 2009 H1N1 emergency use testing until late June," added Hurrell.

Focus Diagnostics has led the diagnostics industry in the development of new 2009 H1N1 influenza testing technologies. It was the first company to receive emergency use authorization from the FDA for a commercial H1N1 2009 test and the first company to launch a commercial test kit for qualitatively detecting RNA of the H1N1 2009 virus by RT-PCR.

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

About the Focus Diagnostics Simplexa(TM) Influenza A H1N1 (2009) Test

The Focus Diagnostics Simplexa(TM) Influenza A H1N1 (2009) assay is intended for use on the 3M Integrated Cyclor as part of the Microfluidic Molecular System for the in vitro qualitative detection and differentiation of influenza A and 2009 H1N1 influenza viral RNA in nasopharyngeal swabs (NPS), nasal swabs (NS), and nasopharyngeal aspirates (NPA) from human patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

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(R) 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. 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.

About 3M

A recognized leader in research and development, 3M produces thousands of innovative products for dozens of diverse markets. 3M's core strength is applying its more than 40 distinct technology platforms - often in combination - to a wide array of customer needs. With \$25 billion in sales, 3M employs 75,000 people worldwide and has operations in more than 60 countries. For more information, visit www.3M.com.

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