



## 2009 H1N1 Flu Test From Quest Diagnostics Now CE Marked For International Distribution Under The Simplexa(TM) Brand Name

November 18, 2009

### **Simplexa(TM) molecular RT-PCR test runs on the 3M Integrated Cyclor; employs RT-PCR technologies comparable to 2009 H1N1 flu test used by World Health Organization**

MADISON, N.J., Nov. 18 /PRNewswire-FirstCall/ -- Quest Diagnostics Incorporated (NYSE: DGX), the world's leading provider of diagnostic testing, information and services, today announced that the Simplexa Influenza A H1N1 (2009) test developed by its Focus Diagnostics business has been CE marked and is now available as a test kit for distribution to approximately 35 countries in Europe. Focus Diagnostics is showcasing the test at MEDICA 2009, November 18 to 21, 2009, at the Dusseldorf Fair Trade Centre, Hall 3, Stand D20, Booth 2 (American Pavilion).

"As the influenza A(H1N1) 2009 virus continues to spread across the globe, it is imperative that clinicians have access to reliable tests for quickly and definitively identifying infected patients," said Harald Kessler, M.D., professor and head of the research unit "Molecular Diagnostics", Medical University of Graz, Austria. "The new Simplexa assay may contribute to a fast and reliable option for generating 2009 H1N1 virus test results in molecular laboratories throughout Europe and many other regions. Fast turnaround time can aid in clinical management of patients and allow hospitals to segregate infected patients from other high-risk individuals."

The Focus Diagnostics Simplexa(TM) Influenza A H1N1 (2009) test employs real-time reverse transcription polymerase chain reaction (RT-PCR) to qualitatively detect the 2009 H1N1 flu virus in a patient's nasal or nasopharyngeal specimens. The test targets a region of the hemagglutinin gene of the 2009 H1N1 influenza virus specifically to detect the presence of 2009 H1N1 influenza RNA, thereby differentiating it from seasonal human influenza A viruses. The World Health Organization (WHO), which provides guidance for countries managing the pandemic, states that RT-PCR is the "only rapid diagnostic test for which a positive result is accepted as confirmation" of human infection with the 2009 H1N1 pandemic virus.(1)

The Focus Diagnostics Simplexa(TM) Influenza A H1N1 (2009) test is an outgrowth of an exclusive global distribution agreement between Focus Diagnostics and 3M (NYSE: MMM) under which Focus will develop and offer molecular diagnostic test kits, to be sold under the Simplexa brand name, on the 3M Integrated Cyclor. The 3M Integrated Cyclor supports real-time polymerase chain reaction (PCR) technology and employs advanced data management software to help laboratories process, store and transfer data quickly and effectively. It can process up to 96 samples per run, and provides results in 30 to 85 minutes, depending on the test's parameters. It has a small laboratory footprint, at approximately 31 centimeters (12 inches) high and 31 centimeters long.

The Simplexa Influenza A H1N1 (2009) test, which was launched in October 2009, is the first offering from the Simplexa product line. Focus Diagnostics plans to launch additional Simplexa test kits on the 3M Integrated Cyclor for infectious diseases in 2010, pending required regulatory clearances.

Quest Diagnostics' Focus Diagnostics has a track record of being first to market with new laboratory testing services for emerging infectious diseases. The company introduced a 2009 H1N1 flu test approximately two weeks after the U.S. Department of Health and Human Services declared a pandemic emergency in the U.S. in late April. The U.S. Food and Drug Administration (FDA), the regulatory body that oversees diagnostic testing in the U.S., granted emergency use authorizations to Focus Diagnostics for its first test as well as its new Simplexa test.

"Expanded influenza capability could be critically important as the pandemic virus continues its spread globally," said John G. Hurrell, PhD, vice president and general manager, Focus Diagnostics. "Our Simplexa test affords many hospital, health clinic and reference laboratories the ability to quickly produce results, even when faced with high volumes of testing, using a compact, reliable molecular device."

To order the test, please contact Focus Diagnostics at 800-445-0185 (U.S.) or +49-6026-9499540 (Europe). You may also email us at [H1N12009@focusdx.com](mailto:H1N12009@focusdx.com). For more information about Quest Diagnostics and influenza testing options, please visit [www.QuestDiagnostics.com/2009H1N1](http://www.QuestDiagnostics.com/2009H1N1) or [www.FocusDx.com/2009H1N1](http://www.FocusDx.com/2009H1N1).

#### *About the FDA's Emergency Use Authorization*

The FDA has authorized Focus Diagnostics to market and offer its Simplexa(TM) Influenza A H1N1 (2009) test for use on the 3M(TM) Integrated Cyclor to CLIA high-complexity laboratories for use during the emergency. The 3M Integrated Cyclor is a microfluidic molecular diagnostic testing system and is not FDA cleared or approved. This Simplexa(TM) Influenza A H1N1 (2009) test has not been FDA cleared or approved. This test has been authorized by FDA under an Emergency Use Authorization. This test is only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Act, 21 U.S.C. section 360bbb-3(b)(1). The declaration of emergency will expire on April 26, 2010, unless it is terminated or 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. 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](http://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](http://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](http://www.3M.com).

(1) "WHO European guidance for influenza surveillance in humans," World Health Organization, 2009.

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