



## **FDA Issues Another Emergency Use Authorization for Commercial H1N1 Flu Test to Quest Diagnostics' Focus Diagnostics**

Test runs on the 3M Integrated Cyclor;  
Reflects first Simplexa™ branded molecular test kits from Focus Diagnostics

**Madison, N.J., – October 16, 2009** – The U.S. Food and Drug Administration (FDA) today issued a second emergency use authorization (EUA) to Focus Diagnostics, the infectious disease diagnostics business of Quest Diagnostics Incorporated (NYSE:DGX), for its 2009 H1N1 influenza virus test. With the EUA, Focus Diagnostics is the only company in the U.S. to offer test kits for detecting the pandemic 2009 H1N1 virus that the FDA has authorized for emergency use by CLIA high-complexity labs, which include certain hospital and regional labs. The test allows clinicians to quickly and definitively identify infected patients, differentiating from those who have similar symptoms.

The new EUA authorizes Focus Diagnostics to market and offer its Simplexa™ Influenza A H1N1 (2009) test for use on the 3M™ Integrated Cyclor from 3M (NYSE:MMM) to CLIA high complexity laboratories for the duration of the emergency. The 3M Integrated Cyclor is a microfluidic molecular diagnostic testing system and is not FDA cleared or approved. Used on the 3M platform, the test can provide increased capacity for 2009 H1N1 influenza virus testing to a wide range of CLIA high complexity laboratories, including many hospitals, coping with a surge in testing demand.

The new test offering is one outgrowth of an exclusive global distribution agreement formed between Focus Diagnostics and 3M under which Focus will develop and offer its first line of molecular diagnostic test kits, to be sold under the Simplexa brand name, on the 3M Integrated Cyclor. The 2009 H1N1 influenza test kit is the first offering from the Simplexa product line, and the company plans to launch additional Simplexa test kits on the 3M Integrated Cyclor for infectious diseases in 2010.

“FDA’s EUA for our new Simplexa H1N1 test on the 3M Integrated Cyclor is a major advance for 2009 H1N1 influenza testing,” said Jon R. Cohen, M.D., senior vice president and chief medical officer, Quest Diagnostics. “Until now, many CLIA high complexity labs didn’t have the technology, space or expertise to perform molecular testing for the 2009 H1N1 flu virus. Our relationship with 3M means that not only will more labs be able to perform this type of testing, but they will also be able to fulfill higher levels of testing demand. Expanded lab capability may be critical to the nation’s management of increased 2009 H1N1 testing this winter.”

“Our exceptional collaboration with Focus Diagnostics underscores 3M’s commitment to leading the industry in introducing new technologies in clinical diagnostics,” said Debra Rectenwald, vice president, general manager, 3M Infection Prevention Division. “We are excited that Focus Diagnostics will be able to implement a real-time molecular technology that can improve the speed and meet the demand for H1N1 testing.”

Quest Diagnostics’ Focus Diagnostics has a track record of being first to market with new laboratory testing services for emerging infectious diseases. On July 24, 2009, FDA announced that it had issued its first emergency use authorization for a commercial 2009 H1N1 influenza virus test to Focus Diagnostics for a laboratory developed test it had launched in May 2009. This EUA was issued for the test running on equipment from Roche and Applied Biosystems.

The Focus Diagnostics Simplexa™ Influenza A H1N1 (2009) test, which employs real-time polymerase chain reaction (PCR), qualitatively detects RNA of the 2009 H1N1 flu virus in a patient’s nasal or nasopharyngeal specimens. The test targets a separate region of the hemagglutinin gene of the 2009 H1N1 influenza virus to differentiate the presence of the 2009 H1N1 flu virus from seasonal human influenza A virus.

The 3M Integrated Cyclor is an instrument offering real-time polymerase chain reaction (PCR) technology that provides results in 30-75 minutes. The compact instrument utilizes advanced data management software to help laboratories

process, store and transfer data quickly and effectively. In addition, the instrument has a small laboratory footprint at approximately 12 inches high and 12 inches deep, and can process up to 96 samples per run.

“Our reference laboratories typically report results within 24 hours of receipt of specimen,” said John G. Hurrell, PhD, vice president and general manager, Focus Diagnostics. “With the Simplex test on the 3M Integrated Cyclor, a typical CLIA high-complexity laboratory can generate results within hours, considerably reducing time spent to send a specimen to an outside lab. Faster turnaround time can aid in clinical management of the patient and allow hospitals to segregate infected patients from other high-risk individuals.”

Quest Diagnostics performs H1N1 flu testing using the Focus Diagnostics test authorized for emergency use by FDA in July at its Focus Diagnostics laboratory in Cypress, CA, as well as at its Nichols Institute laboratories in San Juan Capistrano, CA, and Chantilly, VA, and its Specialty Laboratory in Valencia, CA.

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 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 and 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. An EUA only authorizes use for the duration of the declaration of emergency, which is currently set to 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, 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™ 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).

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