



FDA Clears Influenza and Respiratory Virus Test Kit from Quest Diagnostics' Focus Diagnostics Business

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Simplexa(TM) is first molecular test kit that does not require additional testing to confirm flu A, flu B or respiratory syncytial virus (RSV) infection

MADISON, N.J., and CYPRESS, Calif., Dec. 1, 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 Focus Diagnostics Simplexa Flu A/B & RSV test on the 3M(TM) Integrated Cycler. The Simplexa test, developed and manufactured by Quest Diagnostics' Focus Diagnostics business, is intended as an aid in the detection and discrimination of influenza A, influenza B and RSV virus infections.

Other manufacturers' molecular test instructions recommend that negative results for at least one of the viruses be confirmed with culture. Unlike the others, that recommendation is not in the Simplexa Flu A/B RSV instructions. Like the other tests, negative Simplexa test results do not preclude infection with influenza virus or RSV and should not be the sole basis of diagnosis, patient management and other treatment decisions. In addition, the time to perform the Simplexa test following RNA extraction from a specimen takes only about an hour, with results expected to be reported in less than three hours following receipt of a specimen. *

"Influenza and RSV are two leading causes of respiratory tract infections in the U.S. and globally, infecting many millions of patients each year. These viruses sometimes cause severe illness and even death, particularly in infants and young children, older adults and people with underlying health problems," said Jay M. Lieberman, M.D., medical director, infectious diseases, Quest Diagnostics and Focus Diagnostics. "Infection with these viruses can be challenging to diagnose because their signs and symptoms often mimic infection by other respiratory viruses. Our highly sensitive Simplexa test will help physicians quickly and reliably diagnose respiratory illness due to influenza or RSV, to help them better manage their patients."

The Simplexa tests employ real-time reverse transcription (RT) polymerase chain reaction (PCR) to qualitatively detect RNA of the influenza A or B viruses or RSV in a patient's nasal or nasopharyngeal specimens. The Simplexa Flu A/B & RSV test reports if a patient is positive or negative for infection with one or more of the three classes of viruses.

Results of a clinical study presented to the FDA in the 510(k) filing found the Simplexa test performed comparably to predicate devices in detecting the target viruses in patient specimens.

The new test is the second from the Simplexa product line of RT-PCR molecular test kits that run on the 3M integrated Cycler as part of an exclusive global distribution agreement between Focus Diagnostics and 3M (NYSE: MMM). In May 2010, the Simplexa Influenza A H1N1 (2009) test on the 3M Integrated Cycler was the first commercial RT-PCR test to receive FDA clearance for the detection and differentiation of the 2009 H1N1 influenza and other influenza A viruses.

"Our Simplexa test line can empower hospital, urgent care clinics and other labs to perform highly advanced molecular testing close to their patients, for faster reporting of results," said John G. Hurrell, Ph.D., vice president and general manager, Focus Diagnostics. "For many physicians and lab administrators, it will eliminate the time-consuming step of sending a specimen to a reference lab for molecular testing to detect flu and RSV infection."

About Respiratory Viruses

Influenza and RSV are spread through human contact and cause respiratory illness, sometimes severe. RSV can cause colds, bronchiolitis and pneumonia. Twenty five to 40 percent of infants and young children with RSV infection show signs of pneumonia or bronchiolitis, according to the U.S. Centers for Disease Control and Prevention (CDC), which estimates that between 75,000 and 125,000 children less than one year of age are hospitalized each year due to RSV. According to the CDC, highly sensitive RT-PCR tests should be considered for testing for RSV infection, particularly for older children and adults. Influenza is also a major source of respiratory illness. In 2009, a new Influenza A virus, 2009 H1N1, caused more than 12,000 flu-related deaths in the U.S. The American Society for Microbiology recommends PCR or viral culture as the preferred methods for diagnostic testing for influenza.

About the Focus Diagnostics Simplexa Flu A/B & RSV test on the 3M Integrated Cycler

The Focus Diagnostics Simplexa(TM) Flu A/B & RSV assay is intended for use on the 3M Integrated Cycler instrument for the in vitro qualitative detection and discrimination of influenza A virus, influenza B virus, and respiratory syncytial virus (RSV) RNA in nasopharyngeal swabs (NPS) from human patients with signs and symptoms of respiratory tract infection in conjunction with clinical and epidemiological risk factors. This test is intended for use as an aid in the differential diagnosis of influenza A, influenza B, and RSV viral infections in humans and is not intended to detect influenza C.

Negative results do not preclude influenza virus or RSV infection and should not be used as the sole basis for treatment or other patient management decisions. Performance characteristics for influenza A were established during the 2010 influenza season when 2009 H1N1 influenza was the predominant influenza A virus in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

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 <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 <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 <http://www.3m.com/>.

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* This press release was updated on December 15, 2010 to include information in the second paragraph describing the method by which the Simplexa test confirms infection.