FDA Clears the Focus Diagnostics Simplexa™ Flu A/B & RSV Direct Test to Include Eight Circulating Influenza Viruses

December 9, 2014

CYPRESS, Calif. and MADISON, N.J., Dec. 9, 2014 /PRNewswire/ -- As the 2014-2015 flu season begins, Focus Diagnostics, the products business of Quest Diagnostics (NYSE: DGX), today announced that its Simplexa™ Flu A/B & RSV Direct Kit has received FDA clearance for eight additional influenza strains. These strains may pose significant potential health risks and may be circulating this winter. The FDA, which granted 510(k) clearance to the test kit originally in July 2012, cleared additional analytical reactivity to include Flu A H7N9 and H3N2v, among other strains, based on studies that demonstrated the test's analytical performance.

"Influenza viruses constantly evolve, and virus subtypes can quickly develop and infect large populations. It is vital that the tests can detect the recently circulating and geographically diverse strains," said Hollis (Holly) J. Batterman, MD, medical director, infectious diseases, Focus Diagnostics.

"The studies we've performed with our Simplexa Influenza/RSV assay reflect our commitment to making sure health care providers have access to molecular infectious disease tests that are highly robust and use the most innovative technologies. We are particularly gratified that we can offer testing for recently circulating influenza viruses before this year's flu season is in full swing," added Dr. Batterman.

Seasonal influenza epidemics occur primarily during the winter in temperate climates and year round in tropical climates. According to the Centers for Disease Control and Prevention (CDC), flu activity most commonly peaks in the United States between December and February.

The Simplexa Flu A/B & RSV Direct kit on the 3M Integrated Cycler is a real-time RT-PCR molecular test that was 510(k) cleared by the FDA in July 2012 for the *in vitro* qualitative detection and differentiation of influenza A virus, influenza B virus and respiratory syncytial virus (RSV) RNA in nasopharyngeal swabs from patients with signs and symptoms of respiratory tract infection in conjunction with clinical and epidemiological risk factors. Simplexa Flu A/B & RSV Direct was one of the first to be FDA cleared for molecular detection of influenza A, B and respiratory syncytial virus. The performance characteristics of the test with clinical specimens that are positive for novel avian influenza have not been established.

The test kit with the eight additional strains is now available directly in the United States and internationally through the global distribution network of Focus Diagnostics. Classified as CLIA moderate complexity, the test can report results in about an hour through a proprietary process that eliminates nucleic acid extraction, a time consuming technique typically employed by molecular tests.

Influenza viruses constantly change, causing the regular appearance of novel strains. The additional eight strains for which FDA cleared analytical reactivity are: H7N9, H3N2 (both the Minnesota and Indiana strains) as well as H1N1 (2011), H3N2 (the Ohio and Texas strains) and influenza B (Brisbane and Wisconsin strains). Of particular concern are the novel avian influenza A strain H7N9, which can cause death in as many as one third of infected patients, and the H3N2v, which infects humans more easily than other swine influenza virus, according to the CDC.

"Timely diagnosis is critical to effective management of infectious diseases like influenza. By providing fast, reliable results in about an hour, our Simplexa platform helps physicians quickly diagnose and treat patients," said Michelle Tabb, PhD, vice president of research and development for Focus Diagnostics. "These changes to our Simplexa test reflect our vision to develop high quality molecular tests that deliver critical insights to improve outcomes and empower better health."

Influenza occurs globally, affecting an estimated 5%–10% of adults and 20%–30% of children, according to the World Health Organization.

About Focus Diagnostics and Simplexa™
Focus Diagnostics, Inc., a business of Quest Diagnostics, develops and manufactures the Simplexa line of molecular test products operating on the Integrated Cycler, a compact, portable testing platform, as part of a global collaboration with 3M. Simplexa was the first test kit to be FDA cleared for aiding in the detection and differentiation of the 2009 H1N1 influenza virus in May 2010. Additional Simplexa tests aid in the detection and differentiation of *Clostridium difficile* and HSV 1 & 2. The Simplexa/3M technology has won several industry awards for medical innovation, including prestigious Medical Design Excellence Awards in 2012 and 2011. In addition to Simplexa, Focus Diagnostics' products sold worldwide include HerpeSelect™ type-specific HSV serology and West Nile Virus DxSelect™. To learn more or to order Simplexa and other Focus Diagnostics tests, please contact Focus Diagnostics at 800-838-4548 or visit www.Focusdx.com.

About Quest Diagnostics
Quest Diagnostics is the world's leading provider of diagnostic information services needed 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 QuestDiagnostics.com.

About 3M
3M captures the spark of new ideas and transforms them into thousands of ingenious products. The 3M culture of creative collaboration inspires a never-ending stream of powerful technologies that make life better. 3M is the innovation company that never stops inventing. With $31 billion in sales, 3M employs 89,000 people worldwide and has operations in more than 70 countries. For more information, visit www.3M.com or follow @3MNews on Twitter.

Contacts:
Wendy Bost, Quest Diagnostics (Media): 973-520-2800
Dan Haemmerle, Quest Diagnostics (Investors): 973-520-2900

Logo - http://photos.prnewswire.com/prnh/20130717/NY48934LOGO

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/fda-clears-the-focus-diagnostics-simplexa-flu-ab--rsv-direct-test-to-include-eight-circulating-influenza-viruses-300006871.html

SOURCE Quest Diagnostics