



FDA Clears the Focus Diagnostics Simplexa™ Flu A/B & RSV Direct Test to Include 53 New Virus Strains for the 2015-2016 Flu Season

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Molecular test from Quest Diagnostics' products business is cleared to identify 92 influenza and respiratory syncytial virus strains, more than any other FDA-cleared molecular test

CYPRESS, Calif. and MADISON, N.J., Oct. 6, 2015 /PRNewswire/ -- In advance of the 2015-2016 flu season, Focus Diagnostics, the products business of Quest Diagnostics (NYSE: DGX), today announced that its Simplexa™ Flu A/B & RSV Direct Kit has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for 46 additional influenza A and influenza B virus strains and 7 additional respiratory syncytial virus (RSV) strains.



The FDA granted 510(k) initial clearance to the Simplexa test kit for select virus strains in July 2012 and clearance of some additional strains in 2014. With the recent clearance, the Simplexa test can detect a total of 92 influenza and RSV virus strains, more than any other FDA-cleared molecular test kit. These include all four influenza strains the World Health Organization recommends be included in vaccines during the northern hemisphere's 2015-2016 influenza season: A/Switzerland/9715293/2013 (H3N2)-like virus; A/California/7/2009 (H1N1)-like virus, B/Phuket/3073/2013-like virus and B/Brisbane/60/2008-like virus.

In addition, the 46 new influenza strains include 20 avian influenza A and two swine influenza virus strains. These may be increasingly important to detect, as avian and swine influenza viruses can carry over into human populations.

"With the influenza virus constantly evolving year after year and the potential to infect large populations, it's critical that physicians have access to tests to aid the detection of newly circulating and geographically diverse strains," said Michelle Tabb, PhD, vice president of research and development for Focus Diagnostics. "We are particularly gratified that we have validated recently circulating influenza viruses – including the Switzerland, California, Phuket and Brisbane strains – before this year's flu season takes off, and that we have expanded our avian influenza detection claims."

Influenza occurs globally, affecting an estimated 5%-10% of adults and 20%-30% of children, according to the World Health Organization statistics. According to the Centers for Disease Control and Prevention (CDC), most seasonal flu activity in the Northern Hemisphere occurs between October and May, with peak season in the United States between December and February.

The Simplexa Flu A/B & RSV Direct kit on the 3M Integrated Cyclor is a real-time RT-PCR molecular test 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. It was one of the first tests to be FDA cleared for combined molecular detection of influenza A, B and respiratory syncytial virus. 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.

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 Cyclor, 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 influenza A, influenza B and RSV, Clostridium difficile, Group A Strep and HSV 1 & 2. The Simplexa/3M technology has won several industry awards for medical innovation, including winning the prestigious Gold-level Medical Design Excellence Award and Bronze level Edison award. 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 empowers people to take action to improve health outcomes. Derived from the world's largest database of clinical lab results, our diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve health care management. Quest annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our 45,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives. www.QuestDiagnostics.com.

About 3M

3M is a science-based company with a culture of creative collaboration that inspires powerful technologies, making life better. With \$32 billion in sales,

3M employs 90,000 people worldwide and has operations in more than 70 countries. For more information, visit www.3M.com or follow @3MNewsroom on Twitter.

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