



## Focus Diagnostics and 3M Launch FDA-Cleared Simplexa™ Test on 3M™ Cyclor for Molecular Influenza and Respiratory Virus Testing by Moderate Complexity Healthcare Facilities

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### First moderate-complexity Simplexa™ assay developed through funding by U.S. Department of Health and Human Services' BARDA BAA program for public health preparedness

CYPRESS, Calif. and SAINT PAUL, Minn., Oct. 9, 2012 /PRNewswire/ -- Focus Diagnostics, a business of Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic testing, information and services, and 3M, a global diversified technology company (NYSE: MMM), today announced that the U.S. Food and Drug Administration (FDA) has provided 510(k) clearance and CLIA moderate-complexity categorization to the Simplexa Flu A/B & RSV Direct test on the 3M™ Integrated Cyclor.

The new test aids in the qualitative detection and differentiation of RNA of influenza A and B viruses and respiratory syncytial virus (RSV), common causes of respiratory illness. Focus Diagnostics, maker of the Simplexa™ brand of molecular test kits, and 3M™, maker of the 3M Integrated Cyclor technology, developed the test through an exclusive global collaboration. The collaboration, formed in 2009, has produced several Simplexa molecular tests, including the first FDA-cleared commercial test for the influenza A H1N1 (2009) virus.

The Simplexa Flu A/B & RSV Direct molecular test is the first moderate-complexity molecular test from the Focus Diagnostics' Simplexa product line, significantly broadening potential clinical access to the Simplexa/3M technology. Moderate complexity laboratories, defined by the Clinical Laboratory Improvement Amendments (CLIA), include certain types of physician's offices, community hospitals, health clinics and integrated delivery networks. These facilities typically lack the personnel and technology to perform high-complexity molecular diagnostic tests. Since the test can be performed in these moderate complexity labs, patient results may be obtained readily to help speed therapeutic decisions.

"The future of influenza and all respiratory virus testing is molecular diagnostics, given its potential for high sensitivity and fast reporting of test results, which are essential for patient management," said Jay M. Lieberman, M.D., medical director, infectious diseases, for Quest Diagnostics and Focus Diagnostics. "The clearance and moderate complexity categorization of the Simplexa test on the 3M Integrated Cyclor signifies an important step forward in expanding access to near-patient molecular testing, potentially helping clinicians to make better decisions for their patients."

The new Simplexa test was developed with funding from The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services. It supports the development of new technologies with potential to be effective medical countermeasure products for public health emergency threats. BARDA awarded a \$5.9 million contract for the test's development.

"We are pleased to be part of this development that brings near-patient quality molecular testing to localized healthcare settings, and see it as evidence that public-private collaborations can produce important medical technologies," said Tom Cole, global marketing manager for 3M Infection Prevention Division. "The availability of this test to a broad swath of healthcare professionals in the U.S. will no doubt advance the diagnosis and management of many patients this coming Flu/RSV season."

Influenza and RSV are contagious respiratory illnesses caused by viral infections. While influenza and RSV produce relatively mild disease in most healthy individuals, they may cause severe respiratory disease or death in certain populations, including young children and older adults.

#### Simplexa Flu A/B & RSV Direct test on the 3M™ Integrated Cyclor

The Simplexa Flu A/B & RSV test kit is intended for use on the 3M Cyclor for the *in vitro* qualitative detection and differentiation of RNA of influenza A and B viruses and the respiratory syncytial virus (RSV) in nasopharyngeal swabs. The test does not require the time-consuming nucleic extraction process required by many molecular tests, and can be performed and produce results within an hour.

The Simplexa Flu A/B & RSV Direct is now available in the United States. It was CE marked for distribution in Europe in 2011.

#### About Focus Diagnostics and Simplexa™

Focus Diagnostics, a business of Quest Diagnostics, develops and manufactures the Simplexa line of molecular test products operating on the 3M™ Integrated Cyclor, a compact, portable testing platform, as part of an exclusive global collaboration with 3M (MMM). 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*, *Bordetella pertussis* and *parapertussis*, Cytomegalovirus, Epstein Barr virus and BK virus. The Simplexa/3M technology has won two several industry awards for medical innovation, including prestigious Medical Design Excellence Awards (MDEA) 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 about or order Simplexa and other Focus Diagnostics tests, please contact Focus Diagnostics at 800-445-0185 (U.S.) or +49-6026-9499540 (Europe), or visit [www.Focusdx.com](http://www.Focusdx.com).

#### About 3M

3M captures the spark of new ideas and transforms them into thousands of ingenious products. Our 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 \$30 billion in sales, 3M employs 84,000 people worldwide and has operations in more than 65 countries. For more information, visit [www.3M.com](http://www.3M.com) or follow [@3MNews](https://twitter.com/3MNews) on Twitter.

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