Focus Diagnostics Receives FDA Clearance to Add Genital Swab Claim to Moderate Complexity Simplexa™ HSV 1 & 2 Direct Molecular Test

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System from Quest Diagnostics' products business is first FDA-cleared Herpes Simplex Virus 1 and 2 test that uses genital swab or cerebrospinal fluid (CSF) specimen collection

MADISON, N.J. and CYPRESS, Calif., Sept. 3, 2015 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information services, today announced that its Focus Diagnostics products business has received FDA 510(k) clearance to add the genital swab claim to its Simplexa HSV 1 & 2 Direct molecular test on the Integrated Cycler.

The new labeling clearance follows FDA's *de novo* 510(k) clearance and CLIA moderate complexity categorization of the Simplexa HSV 1 & 2 Direct molecular test in March 2014. FDA cleared the test at that time for use with cerebrospinal fluid (CSF) from patients suspected of HSV central nervous system (CNS) infection, including encephalitis, which can be caused by infection with herpes simplex 1 or 2 virus.

Herpes simplex virus type 2 typically causes genital herpes, while herpes simplex virus type 1 typically causes sores around the mouth and lips, although both viruses can cause infection and sores in other locations.

"With nearly one in six adults 49 and younger infected with genital herpes, reliable, speedy diagnosis is key to patient care. The added genital swab claim significantly broadens our test's potential clinical utility as an aid in diagnosing infection with one or both herpes simplex viruses," said Michelle Tabb, Ph.D., vice president, research and development for Focus Diagnostics.

The FDA has granted 510(k) clearance to seven immunodiagnostic tests from Focus Diagnostics for aiding the detection of herpes simplex viruses. In 2000, the FDA cleared the company's first immunoassay test for detecting immunoglobulin G (IgG) of both herpes simplex virus 1 and 2. While the company's FDA-cleared herpes simplex virus IgG tests use venous blood sampling, the FDA also cleared capillary (fingerstick) sampling for a Focus Diagnostic IgG test for herpes simplex virus type 2 in 2007.

The Simplexa Direct test is the first molecular test for herpes simplex viruses from Focus Diagnostics to be FDA cleared, although the company has received FDA 510(k) clearance for six other molecular tests for aiding the diagnosis of infectious diseases, such as Group A Strep and Flu A/B and RSV.

Simplexa tests, designed for use on the 3M Integrated Cycler, employ real-time polymerase chain reaction (PCR) technology to detect DNA or RNA in viruses, bacteria, and other analytes. Like other Simplexa Direct tests, the Simplexa HSV 1 & 2 Direct test is a molecular test that uses a proprietary process that eliminates nucleic acid extraction, providing test results in about an hour.

Categorized as moderate complexity under the Clinical Laboratory Improvement Amendments, the test can be performed in some physician offices, community hospitals, health clinics and integrated delivery networks to perform the test themselves. Molecular tests are typically categorized as high-complexity, under CLIA, and can only be performed in certain reference and complex hospital labs.

The Simplexa HSV 1 & 2 Direct molecular test demonstrated strong performance in clinical studies, and data will be presented at 2015 Annual Meeting of the Association for Molecular Pathology (AMP) meeting November 5-7 in Austin, TX.

For additional information about Simplexa HSV 1 & 2 Direct and other Simplexa products, please visit the Focus Diagnostics' website at: www.focusdx.com.

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 influenza A, influenza B and RSV, Clostridium difficile and HSV 1 & 2. The Simplexa/3M technology has won several industry awards for medical innovation, including twice winning the prestigious Medical Design Excellence 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
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