



## Focus Diagnostics Receives FDA Clearance for Moderate Complexity Simplexa® HSV 1 & 2 Direct Molecular Test for Aiding the Diagnosis of Encephalitis

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**Quest Diagnostics business launches first HSV PCR for CSF in United States. Test provides results in about 60 minutes.**

MADISON, N.J. and CYPRESS, Calif., March 24, 2014 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information and services, today announced that its Focus Diagnostics products business has received expedited FDA 510(k) clearance and CLIA moderate complexity categorization for its new Simplexa HSV 1 & 2 Direct molecular test on the 3M Integrated Cycler. The test, which is now available for purchase in the United States, is the first molecular test to be cleared by the FDA for the qualitative detection and differentiation of herpes simplex virus 1 (HSV-1) and herpes simplex virus 2 (HSV-2) in cerebrospinal fluid (CSF) from patients suspected of HSV central nervous system (CNS) infection, including encephalitis. The test uses a proprietary process that eliminates nucleic acid extraction, so clinicians can expect results within about an hour after providing a specimen for testing.



Encephalitis is an inflammation of the brain often caused by the herpes simplex or other viruses. The Infectious Diseases Society of America (IDSA) recommends herpes simplex PCR testing on all CSF specimens in patients with encephalitis. HSV encephalitis occurs in all ages and during all seasons, with HSV-1 encephalitis more common in adults and HSV-2 encephalitis more common in newborn infants. Accurate determination of the virus causing encephalitis can influence treatment decisions and outcomes.

The moderate complexity categorization of the Simplexa HSV 1 & 2 Direct molecular test significantly broadens the potential clinical access to the 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.

"Diagnosing encephalitis is a major health challenge because determining the virus causing the condition shapes clinical decision making, yet most diagnostic tools, are slow to perform and may delay therapy," said Kay Myrdal, Vice President and General Manager of Focus Diagnostics. "Our Simplexa HSV 1 & 2 Direct test's ability to rapidly detect and distinguish HSV 1 & 2 in the spinal fluid of a patient suspected of suffering from encephalitis is critically important to clinical treatment decisions. This new assay is an important step in innovations that bring diagnostic insights closer to the patient, to help promote better care and outcomes."

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. Simplexa HSV 1 & 2 Direct is intended to aid in the diagnosis of HSV central nervous system (CNS) infection using CSF from patients suspected of HSV infections of the CNS. Simplexa tests use a proprietary chemistry that eliminates the need for nucleic acid extraction, which involves purifying nucleic acids from a specimen. Nucleic acid extraction is an expensive and time-consuming process requiring specialized equipment and trained personnel.

"The nucleic acid extraction process, used in most commercial molecular test kits, can add approximately 60 to 90 minutes to the total time to result. Focus Diagnostics replaced the extraction process in our Simplexa products with a proprietary chemistry and technology," said Michelle Tabb, Ph.D, Vice President, Research and Development for Focus Diagnostics. "Simplexa HSV 1 & 2 Direct results, like those of other Simplexa Direct test products, are available in about an hour from receiving a specimen for testing. This is a major advantage when dealing with an acute neurological condition like encephalitis."

Simplexa HSV 1 & 2 Direct showed strong performance in clinical studies, with 100% and 98% sensitivity for detection of HSV-1 and HSV-2 respectively. The test was CE marked for distribution to more than 30 countries in Europe in November 2013. For more additional information about Simplexa HSV 1 & 2 Direct and other Simplexa products, please visit Focus Diagnostics' Web site at: [www.focusdx.com](http://www.focusdx.com).

### **About Focus Diagnostics, Inc. and Simplexa®**

Focus Diagnostics, Inc., a business of Quest Diagnostics, develops and manufactures the Simplexa line of molecular test products operating on the 3M Integrated Cycler, a compact, portable testing platform, as part of an exclusive 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, RSV, and *Clostridium difficile*. The Simplexa/3M technology has won 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 800-838-4548 or visit [www.Focusdx.com](http://www.Focusdx.com).

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**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 [QuestDiagnostics.com](http://QuestDiagnostics.com). Follow us at [Facebook.com/QuestDiagnostics](https://Facebook.com/QuestDiagnostics) and [Twitter.com/QuestDX](https://Twitter.com/QuestDX).

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