



Focus Diagnostics Receives FDA Clearance to Market Plexus HerpeSelect

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CYPRESS, Calif., March 5 /PRNewswire-FirstCall/ -- Focus Diagnostics, Inc., a wholly owned subsidiary of Quest Diagnostics Incorporated, (NYSE: [DGX](#) - [News](#)), today announced it has received FDA 510k clearance to market its new Plexus(TM) HerpeSelect® 1 and 2 IgG test kit, the first multiplex type-specific HSV serology panel using xMAP® technology from Luminex Corporation. Focus Diagnostics' HerpeSelect, available since 2000 in ELISA and Immunoblot formats, accurately distinguishes HSV type-1 and type-2 antibodies, assisting physicians in their choice of treatment and patient counseling. HerpeSelect is the leading type-specific HSV serology product worldwide. The new Plexus HerpeSelect assay demonstrated comparable performance to HerpeSelect ELISA in clinical trials. Plexus HerpeSelect is the first in a new line of multiplex infectious disease assays being developed by Focus Diagnostics that are designed to match physician-ordering patterns for diagnosing specific infections. Focus Diagnostics plans to add additional multiplex antibody and antigen detection panels to the Plexus Multi-Analyte Diagnostics product line.

Plexus HerpeSelect provides laboratories with a complete HSV serology profile from a single specimen, in a single assay, using Luminex® instrumentation. Laboratories that have a Luminex instrument system in place can expand their test menu to include the HerpeSelect 1 and 2 serology panel. Like all HerpeSelect products, the Plexus assay uses glycoprotein G -- gG1 and gG2 -- the antigens corresponding to HSV-type 1 and 2, respectively. The Luminex xMAP technology uses laser optics similar to flow cytometry and an array of fluorescent dye-labeled beads to simultaneously detect multiple targets in the same specimen. Together, Plexus and Luminex offer laboratories facing an ongoing shortage of qualified staff the opportunity for greater productivity using fewer resources.

"We see multiplex testing as a common-sense approach that will be applied to other future products," said John Hurrell, General Manager, Focus Diagnostics' HerpeSelect is the first Plexus product that extends our premier product brand into laboratories seeking to increase productivity. We are excited about the prospect of improving laboratory medicine and offering physicians more rapid and accurate clinical information."

Just half a dozen years ago, genital herpes infections were increasing dramatically with no reliable means for detecting the viral infection. Transmission occurs 70% of the time in the absence of symptoms, and symptoms are often misdiagnosed. Perhaps most disturbing is the increased risk of acquiring HIV for individuals infected with HSV-2, and the risk to neonates if the mother is shedding virus during vaginal birth. Today more than 50 million individuals in the U.S. are infected and 90% are unaware they have the disease. More than one million people are newly infected each year. While herpes is not curable, antiviral treatments offer patients or their partners a reduced risk of acquiring or transmitting HSV-2.

Focus Diagnostics has been involved in the global research and development of type-specific herpes diagnostic products for well over a decade. Focus Diagnostics' HerpeSelect type-specific HSV serology products entered the clinical laboratory market in 2000 and provided laboratories with the first reliable tools to accurately test for HSV-1 and HSV-2 antibodies. Publications from professional organizations, such as the Centers for Disease Control and Prevention (CDC -- Sexually Transmitted Diseases Treatment Guidelines, 2006) and American College of Obstetrics and Gynecology (ACOG Practice Bulletin: Clinical Management Guidelines for Obstetricians- Gynecologists No. 57, Nov. 2004), now reference the importance of type-specific HSV serology testing in providing an accurate diagnosis of genital herpes.

About Focus Diagnostics, Inc.

Focus Diagnostics, Inc. is an infectious disease diagnostics company, providing reference laboratory services to hospitals and laboratories nationwide and manufacturing and distributing diagnostic products worldwide. Focus Diagnostics develops innovative products for diagnosing infectious diseases, and often provides the first commercially available diagnostic tests in the U.S. for emerging diseases such as West Nile Virus and SARS. HerpeSelect® type-specific HSV serology and West Nile Virus DxSelect(TM) are top-selling Focus Diagnostics products used in laboratories worldwide. Focus Diagnostics was acquired in July 2006, by Quest Diagnostics, and is a wholly owned subsidiary of Quest Diagnostics, Incorporated. Visit <http://www.focusdx.com> for additional information.

About Quest Diagnostics, Incorporated

Quest Diagnostics is the 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 national 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 new diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional company information is available at: <http://www.questdiagnostics.com>.

The statements in this press release that are not historical facts or information may be forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause actual results and outcomes to be materially different. Certain of these risks and uncertainties may include, but are not limited to, competitive environment, changes in government regulations, changing relationships with customers, payers, suppliers and strategic partners and other factors described in the Quest Diagnostics Incorporated 2006 Form 10-K and subsequent SEC filings.

Source: Focus Diagnostics, Inc.