



Two Point of Care Tests From Quest Diagnostics Receive FDA 510(k) Clearance

November 1, 2007

First step for performing important diagnostics in physician offices

MADISON, N.J., Nov. 1 /PRNewswire-FirstCall/ -- Quest Diagnostics Incorporated (NYSE: DGX), the nation's leading provider of diagnostic testing, information and services, today announced that its HemoCue and Focus Diagnostics subsidiaries have received FDA 510(k) clearance for two new point of care tests. The HemoCue(R) White Blood Cell (WBC) Analyzer is a whole-blood test performed on finger-stick samples that assists physicians diagnosing infection, inflammation, bone marrow failure, autoimmune diseases, drug toxicity, leukemic neoplasia and many other medical conditions now routinely tested for by reference laboratories. The company also received FDA clearance for Focus Diagnostics' HerpeSelect(R) Express(TM) HSV-2, a test for aiding in the diagnosis of the herpes simplex type-2 virus, the primary cause of genital herpes. This is the first step in the regulatory process that allows the companies to market the products and file for CLIA waivers, which would enable the tests to be used in a much larger segment of physician offices. The \$6 billion market for point of care tests is growing an estimated eight percent to ten percent a year.

"The HerpeSelect Express HSV-2 test and HemoCue WBC Analyzer are important technologies that underscore the growing importance of point of care tests as complements to laboratory-based diagnostics," said Joyce G. Schwartz, M.D., vice president and chief laboratory officer, Quest Diagnostics. "These two tests could markedly change the speed of diagnosing infections, allowing physicians to make immediate treatment decisions for their patients."

The HemoCue WBC Analyzer provides a count of a patient's white blood cells in as few as three minutes using a blood sample taken from the patient's finger tip. Unlike conventional methods which measure red and total blood cell counts, the HemoCue WBC Analyzer is the first point of care device to produce quantitative results of a patient's white blood cells.

Changes in white blood cell counts can help physicians detect numerous conditions and disorders. With 510(k) clearance for marketing, physicians who operate CLIA-certified moderately complex laboratories now may use the HemoCue WBC Analyzer to quickly produce results during a single office visit. HemoCue plans to apply for CLIA waiver for the HemoCue WBC Analyzer shortly, which if granted, would permit physicians to offer the test in CLIA-waived laboratories, which are far more prevalent than moderately complex laboratories. The Analyzer is available worldwide.

The HerpeSelect Express HSV-2 test is designed to be simple enough for use in clinics and other point of care settings, and can produce results within fifteen minutes. The ability of physicians to provide counsel on treatment options and lifestyle changes during a single office visit can benefit patients who are anxious about their test results or who may be unwilling or unable to return for a second visit to learn their results. The prevalence of herpes has increased dramatically in the last three decades because it is often transmitted without the knowledge of the infected individual or the uninfected partner. Today more than 50 million individuals in the U.S. are infected and 90 percent are unaware they have the disease. Focus Diagnostics plans to apply for CLIA-waived status for the test within the next two weeks.

With FDA 510(k) clearance, manufacturers may market their diagnostic device for use in moderately complex laboratories, as defined by the Clinical Laboratory Improvement Amendments (CLIA), which establish standards for diagnostic testing in the U.S. 510(k) clearance also enables manufacturers to submit the test for review by the FDA for CLIA-waived status. A test that is CLIA waived fulfills certain criteria, such as ease of use, that make it suitable for operation by non-laboratory trained staff in physician offices and clinics.

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(R) type-specific HSV serology and West Nile Virus DxSelect(TM) are top-selling Focus Diagnostics products used in laboratories worldwide. Focus Diagnostics is a wholly owned subsidiary of Quest Diagnostics Incorporated. Visit www.focusdx.com for additional information.

About HemoCue AB

HemoCue, a Quest Diagnostics company, is a leading global company in a field of diagnostics known as near patient, or point of care, testing. In 1982, HemoCue introduced the first system making accurate hemoglobin testing possible in near patient settings. Since then, HemoCue has sold more than 250,000 systems worldwide and sells more than 100 million cuvettes annually. The company also manufactures point of care tests for glucose and urine albumin. The company has wholly owned subsidiaries in England, Finland, Germany, the Netherlands, Switzerland and the U.S., with franchises and third-party distributors generating revenue in more than 100 countries. Quest Diagnostics acquired HemoCue in 2007. HemoCue is based in Angelholm, Sweden. Additional information is available at www.hemocue.com.

About Quest Diagnostics

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 www.questdiagnostics.com.

This communication contains certain forward-looking statements. These forward-looking statements, which may include, but are not limited to, statements concerning the proposed acquisition, are based on management's current expectations and estimates and involve risks and uncertainties that could cause actual results or outcomes to differ materially from those contemplated by the forward-looking statements. Certain of these risks and uncertainties may include, but are not limited to the risks and uncertainties described in the Quest Diagnostics Incorporated 2006 Form 10-K and subsequent filings.

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CONTACT: Investors: Laure Park, +1-973-520-2900, or Media: Wendy Bost,
+1-973-520-2800, both of Quest Diagnostics Incorporated /
Web site: <http://www.questdiagnostics.com>
<http://www.hemocue.com>
<http://www.focusdx.com> /