



Ortho-Clinical Diagnostics, Inc. Announces Availability of HTLV-I/II Assay

Assay Completes Infectious Disease Menu, Underscores OCD's Commitment to the Donor Screening Community

RARITAN, NJ -- (Marketwire) -- 03/28/12 -- Ortho Clinical Diagnostics, Inc. (OCD) today announced the availability of the Avioq® HTLV-I/II Microelisa System assay, a new test developed in partnership with Avioq, Inc. to screen blood and organ donations for antibodies to human T-lymphotropic virus (HTLV) type I and II. Screening for antibodies to HTLV-I/II is required by the United States Food and Drug Administration (FDA) for the nearly 16 million blood donations collected in the U.S. each year. (1) HTLV, if left undiagnosed, may cause certain types of conditions, such as a rare form of leukemia and neurological diseases.(1)

"We are proud to introduce the AVIOQ HTLV-I/II Microelisa System assay, which completes our extensive infectious disease assay menu and furthers our longstanding commitment to provide world class products that ensure the safety of blood and plasma supplies," said Tony Hardiman, Director of Worldwide Marketing, Ortho Clinical Diagnostics.

The AVIOQ HTLV-I/II Microelisa System assay is fully compatible with the ORTHO® Summit System platform, offering consistent and reliable performance with minimal add-on assay validation, reducing validation time and assay variation while improving productivity in the lab.

"By providing a fast, cost-effective and reliable screening method for antibodies to HTLV type I and II, OCD is enhancing the donor screening community's ability to adhere to the FDA's testing guidelines, while at the same time protecting patients who receive blood and plasma donations," said Paul Contestable, Principle Scientist, Ortho Clinical Diagnostics.

Ortho Clinical Diagnostics is committed to protecting the safety of the world's blood and plasma supplies. More than 20 years ago, the company introduced the first test for the detection of antibodies to hepatitis C, and has since remained a leader in high-quality solutions to meet rigorous compliance standards and provide blood and blood products that are free from known infectious diseases.

About Human T-Lymphotropic Virus (HTLV)

HTLV is a retrovirus that falls within the same biological category as human immunodeficiency virus (HIV). There are two forms of HTLV infection: HTLV-I and HTLV-II. HTLV-I was first identified in 1980, largely as a consequence of acquired immunodeficiency syndrome (AIDS) research, and is known to be the etiologic agent for adult T-cell leukemia and myelopathy/tropical spastic paraparesis (HAM/TSP), an inflammatory disease of the central nervous system.(2) HTLV-II is a closely related virus to HTLV-I and is associated with neurological disorders resembling HAM/TSP. However, it is not yet clear how the HTLV-II infection is associated with clinical disease.(3)

HTLV-I and HTLV-II viruses are relatively uncommon in the United States, but do occur more frequently in certain populations (Japan and the Caribbean). The infection can persist for a lifetime, but rarely causes major illnesses in most people who are infected.(4)

About Ortho Clinical Diagnostics

Ortho-Clinical Diagnostics, Inc. delivers the high-quality in vitro diagnostic products that give healthcare professionals around the world the knowledge they need to make better treatment decisions sooner. The company serves the global transfusion medicine community with donor screening and blood typing products to help ensure every patient receives blood that is safe, the right type and the right unit. Ortho Clinical Diagnostics also brings sophisticated information management, testing technologies, and automation and interpretation tools to clinical laboratories worldwide to help them run more efficiently and improve patient care.

(1) <http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics#blood-supply>. Accessed July 5, 2011.

(2) <http://patientinfo.ninds.nih.gov/DiseaseInfo.aspx?did=69&dlevel=2>. Accessed September 8, 2010.

(3) H. Vrielink, H.W. Reesink. HTLV-I/II prevalence in different geographic locations. *Trans. Med. Reviews*. Volume 18, Issue 1, Pages 46-57 (January 2004).

(4) [AABB.com](http://www.aabb.org/resources/bct/Pages/bloodfaq.aspx). Blood FAQ. Available at: <http://www.aabb.org/resources/bct/Pages/bloodfaq.aspx>. Accessed August 17, 2010.

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