



Ortho Clinical Diagnostics Receives FDA Approval for First Anti-HIV 1+2 Test for Use on Random Access, Integrated Laboratory Testing System

-- Results Available in Less Than 50 Minutes, Helping Laboratories Improve Staff Efficiency and Increase Productivity --

RARITAN, N.J. (Oct. 14, 2009) - Ortho Clinical Diagnostics today announced U.S. Food and Drug Administration (FDA) approval of a diagnostic assay for the detection of antibodies to human immunodeficiency virus (HIV) types 1+2 (Anti-HIV 1+2) for use on the VITROS[®] 5600 Integrated and VITROS[®] 3600 Immunodiagnostic Systems. This is the first HIV diagnostic assay approved for an integrated system in the United States, allowing laboratories to run HIV and other routine tests on a single testing platform and eliminating the need for expensive batch testing of multiple patient samples.

"By providing a fast, cost-effective and reliable method for testing HIV, the VITROS[®] Anti-HIV 1+2 Assay will help enhance the clinical laboratory's ability to adhere to the Centers for Disease Control and Prevention (CDC) HIV screening guidelines, while at the same time increasing the lab's productivity and efficiency," said Mike Samoszuk, M.D., Chief Medical Officer, Ortho Clinical Diagnostics. "This approval underscores Ortho Clinical Diagnostics' continuing commitment to providing clinical laboratories with tests that help detect diseases earlier for better patient outcomes."

The CDC recommends routine screening for people between the ages of 13 and 64 during annual check-ups, pregnant women either before or during pregnancy, and newborns. Currently, more than 230,000 people living with HIV in the U.S. are unaware they have the disease, increasing the need for routine screening.¹ HIV screening plays an invaluable role in early disease detection, prevention and treatment.

The VITROS[®] Anti-HIV 1+2 Assay is an *in vitro* diagnostic immunoassay for the qualitative detection of HIV 1+2 in human serum and plasma. It provides physicians with a reliable and quick test for HIV, a virus that causes acquired immunodeficiency syndrome (AIDS) and can lead to death. It may also be used to screen for HIV in pregnant women to identify neonates who are at high risk of acquiring HIV during the perinatal period.² Being aware of a mother's HIV status enables physicians to prevent mother-to-child HIV transmission by providing antiretroviral treatment to both mothers and their babies.

Following the recent approval of the VITROS[®] Anti-HCV Assay for the qualitative detection of immunoglobulin G antibody to hepatitis C virus in human serum and plasma, the approval of the VITROS[®] Anti-HIV 1+2 Assay marks another important milestone in the launches of Ortho Clinical Diagnostics' clinical laboratory testing platforms. Since the launches of the VITROS[®] 5600 Integrated and VITROS[®] 3600 Immunodiagnostic Systems at the end of 2008, 112 assays have been released. Approval of the complete VITROS[®] Menu of 114 assays is expected by mid-2010.

Ortho Clinical Diagnostics' broad, world-class menu of immunoassays covers major disease states including cardiology, oncology, endocrinology, infectious disease, thyroid, metabolic conditions and anemia. The company's VITROS[®] assay menu covers up to 90 percent of the top 100 assays and 99 percent of laboratory test volume, with numerous other assays in development. Upon full menu approval, only Ortho Clinical Diagnostics' VITROS[®] 5600 Integrated System will offer a complete infectious disease testing menu in the U.S., including HIV and rubella, in addition to a comprehensive menu of routine assays that can be run on a single platform.

About HIV

Human immunodeficiency virus (HIV) is a retrovirus that affects the immune cells of infected people by destroying certain white blood cells, called T-cells, which the body relies on to fight infection.² When opportunistic infections develop³ (e.g., tuberculosis) or when the immune system is suppressed below a specific level, HIV-infected people are considered to have AIDS.⁴

About the VITROS[®] 5600 Integrated System

The VITROS[®] 5600 Integrated System is a high-capacity system that integrates clinical chemistry and immunoassay testing on one platform using innovative Sample Centered Processing. The VITROS[®] 5600 Platform is smaller than many other systems and does not have any water or drainage requirements, making the most of limited lab space while allowing flexibility in instrument location.

About the VITROS® 3600 Immunodiagnostic System

The VITROS® 3600 Immunodiagnostic System is a high-capacity immunoassay system with Intelligent Sample Management for routine and specialty testing. The VITROS® 3600 Immunodiagnostic System offers a broad menu of 47 immunoassays, covering disease states such as cardiology, oncology, endocrinology, infectious disease, thyroid, metabolic conditions and anemia.

About Ortho Clinical Diagnostics

Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company, 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. For more information, visit www.orthoclinical.com.

¹ The National Institute of Allergy and Infectious Diseases, "HIV/AIDS Testing and Diagnosis." Available at: <http://www3.niaid.nih.gov/topics/HIVAIDS/Understanding/diagnosis.htm>. Accessed October 7, 2009.

² Centers for Disease Control and Prevention (CDC), "HIV Basic Facts." Available at: <http://www.cdc.gov/hiv/topics/basic/index.htm#hiv>. Accessed October 8, 2009.

³ U.S. National Library of Medicine, "HIV Infection." Available at: <http://www.nlm.nih.gov/medlineplus/ency/article/000602.htm>. Accessed October 8, 2009.

⁴ Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. 2006 Disease Profile, 2008. Available at: http://www.cdc.gov/nchhstp/Publications/docs/2006_Disease_Profile_508_FINAL.pdf. Accessed October 7, 2009.