

# Ortho Clinical Diagnostics

## FDA Approves Ortho Clinical Diagnostics VITROS® Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator on the VITROS® 3600 Immunodiagnostic System

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### New Test Expands Infectious Disease Assay Menu

Ortho Clinical Diagnostics (Ortho), a global leader of in vitro diagnostics, announced that its VITROS Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator (VITROS® HIV Combo test) received approval from the U.S. Food and Drug Administration for use on Ortho's VITROS 3600 Immunodiagnostic System.<sup>1</sup>

VITROS HIV Combo, a fourth-generation test, detects both HIV-1 and HIV-2 antibodies (Ab) and the p24 antigen (Ag), enabling HIV-1 acute infection detection earlier than third-generation tests.<sup>2</sup>

According to estimates by the World Health Organization (WHO), 37 million people worldwide are living with HIV today.<sup>3</sup> Starting antiretroviral treatment as soon as possible after diagnosis can help avert millions of AIDS-related deaths and new infections.<sup>2</sup> According to the U.S. Centers for Disease Control and Prevention, identifying patients in the early stages of infection is crucial.<sup>2</sup>

"Ortho is committed to expanding its assay menu and improving laboratory workflow efficiencies for its customers," said Robert Yates, Ortho's chief operating officer. "With the launch of the VITROS HIV Combo test, laboratories can help provide earlier detection of HIV, while operating efficiently."

The clinical and technical performance of the VITROS HIV Combo test on VITROS® Systems was evaluated during routine use at three external testing laboratories in the US and at Ortho's research and development laboratories. This assessment confirmed that the test provides competitive sensitivity and specificity when compared to a leading commercially available fourth-generation test.<sup>4</sup>

In the comparison studies, assay sensitivity was evaluated on seroconversion panels. The VITROS HIV Combo test showed earlier detection of acute HIV infection in six of 32 seroconversion panels (agreement for 25 of 32 panels) when compared to a leading commercially available fourth-generation Ag/Ab test, indicating that the assay performance is very competitive in shortening the diagnostic window (the time between HIV infection and detection) - a valuable attribute in HIV testing.

The test's excellent p24 sensitivity with uncompromised specificity is enhanced by a combination of proprietary technologies and benefits only available on VITROS Systems:

- MicroWell technology combined with our Enhanced Chemiluminescence Detection Technology improves signal detection with outstanding sensitivity, precision and a wide dynamic range.
- The Intellicheck® Technology with its suite of quality checks, including MicroSensor technology detects endogenous interferences; SMART Metering and VersaTip technology which helps exclude carryover and cross-contamination using disposable tips.

These provide laboratories the accuracy needed to have the utmost trust in their results.

Ortho plans to file Premarket Approval (PMA) supplements for the use of the VITROS HIV Combo test on the VITROS® ECi/ECiQ Immunodiagnostic Systems, and the VITROS® 5600 Integrated System.

### About The VITROS® Systems

The VITROS® Chemistry, Immunodiagnostic and Integrated Systems from Ortho Clinical Diagnostics is a portfolio of products and patented enabling technologies that help clinical laboratories diagnose, monitor and treat disease. VITROS Systems are engineered to help clinical laboratories with organizational, operational and economic challenges.

### About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics is a global leader of in vitro diagnostics serving the global clinical laboratory and immunohematology communities. Across hospitals, hospital networks, blood banks, and labs in more than 125 countries and territories, Ortho's high-quality products and services enable health care professionals to make better-informed treatment decisions. Ortho brings sophisticated testing technologies, automation, and information management and interpretation tools to clinical laboratories around the world to help them run more efficiently and effectively and improve patient care. For the immunohematology community, Ortho's blood typing products help ensure every patient receives blood that is safe, the right type and the right unit. Ortho's purpose is to improve and save lives with diagnostics, and it does that by reimagining what's possible. This is what has defined Ortho for more than 75 years, and it's what drives Ortho forward.

1. The VITROS HIV Combo test is not currently approved or available in the United States for use on VITROS 5600 Integrated System & VITROS ECi/ECiQ Immunodiagnostic System

2. <http://www.cdc.gov/std/treatment/2010/hiv.htm>

3. <http://www.who.int/hiv/en/>

4. Data on file.

VITROS® is a trademark of Ortho Clinical Diagnostics.

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