Ortho Clinical Diagnostics

FDA Expands Use for Ortho's VITROS® HIV Combo Test: Menu Milestone for VITROS® XT 7600 Integrated System

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Entire Ortho-created menu of assays now available on Ortho's latest-generation analyzer

Ortho Clinical Diagnostics, a global leader of in vitro diagnostics, announced that its VITROS® Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator (VITROS® HIV Combo test) has been granted pre-market approval by the U.S. Food and Drug Administration for use on Ortho's VITROS® XT 7600 Integrated System.

This FDA clearance means that all of Ortho's assays cleared or approved for use in the United States are now available on the VITROS XT 7600 Integrated System, Ortho's latest-generation analyzer that combines the company's proprietary MicroSlide technology with sophisticated digital imaging capabilities and the potential to perform two commonly paired tests simultaneously, features that make a lab's test results even more powerful than before.

> ***"The availability of the VITROS HIV Combo Test on the VITROS XT 7600 Integrated System is a huge win for our customers," said Heidi Casaletto, Ortho's head of portfolio strategy and marketing. "The synergy of the two working together, especially when combined with our MicroSlides that can perform two tests on the same slide at the same time, lets customers leverage the bulk of our portfolio on our most advanced system. And our customers get this benefit less than a year after the VITROS XT 7600 Integrated System initially hit the U.S. market."***

The VITROS XT 7600 Integrated System, which was introduced to the U.S. market in November, also can run several MicroTip Partnership Assays (MPAs), which are validated third-party assays that run on Ortho systems. Ortho is working with its strategic partners to bring the remaining third-party assays in Ortho's assay portfolio to the VITROS XT 7600 Integrated System soon.

VITROS HIV Combo, a fourth-generation test, detects both HIV-1 and HIV-2 antibodies (Ab) and the p24 antigen (Ag). By detecting the antigen itself, rather than only the antibodies to the antigen. Ortho's VITROS HIV Combo detects HIV-1 acute infection earlier than previous generations of tests.1

In addition, Ortho's assay 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.2 This result indicated that Ortho's assay performance is very competitive in shortening the diagnostic window (the time between HIV infection and detection) – a valuable attribute in HIV testing.

According to the World Health Organization, 37 million people worldwide are living with HIV today.3 Starting treatment as soon as possible after infection can help avert millions of AIDS-related deaths and new infections.

VITROS HIV Combo is enhanced by a combination of proprietary technologies and benefits available on all Ortho's VITROS Systems, including MicroWell technology and INTELLICHECK® Technology, which provides laboratories with the accuracy needed to have complete trust in their results.

About VITROS® Systems

The VITROS® Chemistry, Immunodiagnostic and Integrated Systems from Ortho Clinical Diagnostics are 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 cdc.gov

2 VITROS HIV Combo Instructions for Use

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

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