

Ortho Clinical Diagnostics

FDA Approves Expanded Use for Ortho Clinical Diagnostics VITROS® HIV Combo Test

November 28, 2018

New Availability of the VITROS® Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator to Help Labs Using Ortho's VITROS® ECi/ECiQ Immunodiagnostic System to Diagnose HIV Infection

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](#)) received approval from the U.S. Food and Drug Administration for use on Ortho's [VITROS® ECi/ECiQ Immunodiagnostic Systems](#). The VITROS HIV Combo test was previously approved for use on Ortho's [VITROS® 5600 Integrated System](#) and Ortho's [VITROS® 3600 Immunodiagnostic System](#).

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

According to the World Health Organization, 37 million people worldwide are living with HIV today.² Starting treatment as soon as possible after infection can help avert millions of AIDS-related deaths and new infections.

"Early detection of HIV-1 is critical in getting patients into treatment as soon as possible after infection," said Jennifer Paine, Ortho's chief product portfolio and quality, regulatory and compliance officer. "Ortho is proud to be working to deliver our VITROS HIV Combo test to customers worldwide."

The clinical and technical performance of the VITROS HIV Combo test on VITROS® Systems was evaluated at three external testing laboratories in the U.S. and at Ortho's research and development laboratories in Rochester, N.Y. This assessment confirmed that the test provides competitive sensitivity and specificity when compared to a leading commercially available fourth-generation test.

In the comparison studies,³ 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. 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.

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

For more information, visit Ortho on social media: LinkedIn, Twitter, Facebook and Instagram.

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

3. VITROS HIV Combo Instructions for Use

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