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FDA Approves New HIV VITROS Combo Test

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The launch of VITROS HIV Combo test laboratories can help to provide earlier detection of HIV

Ortho Clinical Diagnostics is a global leader of in vitro diagnostics, serving the global clinical laboratory and immunohematology communities.

Ortho announced 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.

The fourth-generation HIV Combo assay detects both HIV-1 and HIV-2 antibodies (Ab) and the p24 antigen (Ag), detecting an HIV-1 acute infection earlier than third-generation assays.

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.

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.

Test findings indicate that the assay performance is competitive and shortens the diagnostic window.

The results of the test, in conjunction with other serological evidence and clinical information, may be used to aid in the diagnosis of HIV-1 and/or HIV-2 infections.

The test’s p24 sensitivity with uncompromised specificity is enhanced by various technologies: MicroWell technology combined with the Enhanced Chemiluminescence Detection Technology that improves signal detection with outstanding sensitivity, precision and a wide dynamic range; and the Intellicheck Technology which includes MicroSensor technology that detects endogenous interferences, and SMART Metering and VersaTIp technology that helps exclude carryover and cross-contamination through 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.