Ortho Clinical Diagnostics

Because Every Test Is A Life™

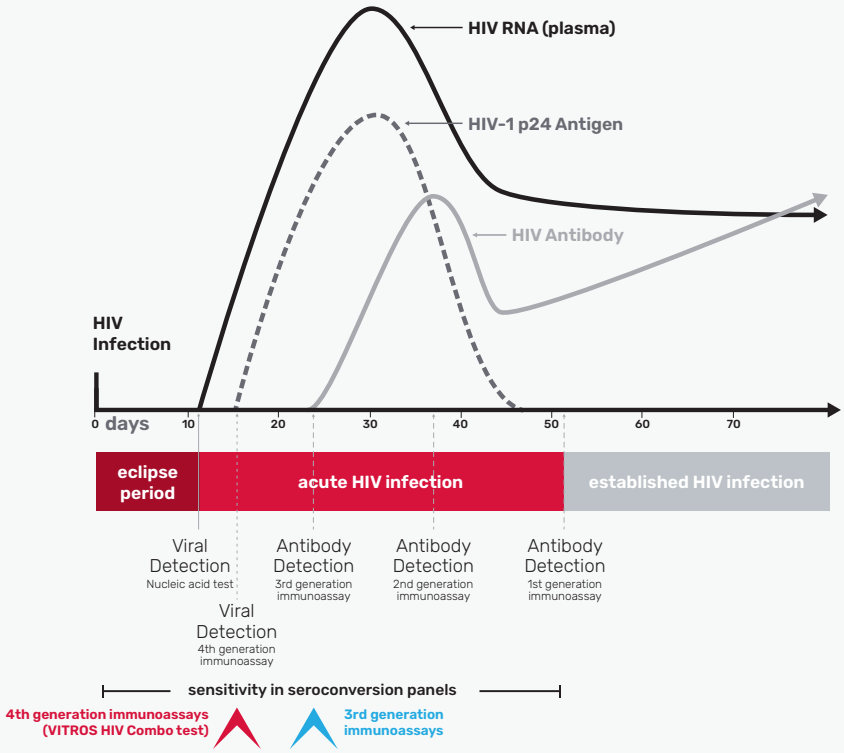
VITROS® HIV Combo Test

You deliver more than results. You deliver trust.

VITROS HIV Combo Test* provides early detection of acute HIV infection[1] with class-leading[2] fourth-generation antigen sensitivity combined with uncompromised specificity.

*VITROS® Immunodiagnostic Products HIV Combo Reagent Pack, Calibrator and Controls.

Sequence of Appearance of Laboratory Markers for HIV Infection[3]



Earlier detection.[3] Improved diagnosis and prevention.

VITROS HIV Combo, a 4th generation test, detects HIV infection earlier than 3rd generation tests.[3]

In 2014, the Centers for Disease Control and Prevention and the Association for Public Health Laboratories updated recommendations to fourth-generation tests for initial HIV screening.[3] Fourth-generation tests simultaneously detect HIV-1 and 2 IgM/IgG antibodies, as well as the p24 antigen. Compared to third-generation HIV tests, which only detect antibodies, p24 antigen detection allows fourth-generation assays to detect an acute HIV infection approximately 7-11 days earlier.[3,4]

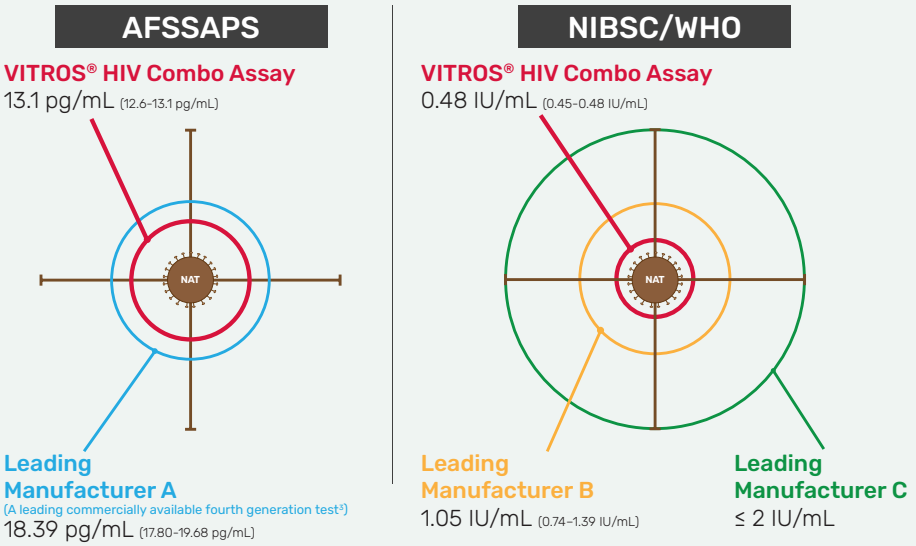
- The VITROS HIV Combo Test became reactive earlier for five of 34 seroconversion panels (agreement for 28 of 34 panels) when compared to a leading commercially available fourth-generation Ag/Ab test.[5]
- Seroconversion panels are a group of serial bleeds from plasma donors during seroconversion. They are intended for use by manufacturers and clinical laboratories to evaluate assay sensitivity.

Seroconversion panel data shows that the VITROS HIV Combo Test delivers even earlier detection than a leading fourth-generation test.[5]

Build trust with performance.

With class-leading antigen sensitivity that doesn't sacrifice specificity, the VITROS HIV Combo Test delivers the utmost confidence in results and can help save cost, time and labor in repeat and confirmatory testing.[1]

- Analytical sensitivity shows a state-of-the-art limit of 0.48 IU/mL NIBSC/WHO and 13.1 pg/mL AFSSAPS[1].
- Clinical specificity was calculated as 100% (CI 99.39 - 100.00%) for adult low risk population[1]. The specificity of the VITROS HIV Combo test for the donor population was calculated as 99.84% (5069/5077) exact 95% CI (99.69-99.93%)[1].



Not drawn to scale.
NAT does not measure p24 antigen and is shown above for relative sensitivities only.

Detection of HIV-1 viral nucleic acid with Nucleic Acid Test (NAT) remains the most sensitive method in identifying acute HIV-1 infection but its use is not widespread due to associated cost, time and labor.

AFSSAPS: French Health Products Safety Agency
NIBSC: The National Institute for Biological Standards and Control
WHO: World Health Organization

A combination you can count on for your patients and your lab.

The performance of the VITROS HIV Combo Test is enhanced by the proprietary technologies and benefits only available on VITROS Systems:

INTELLICHECK® Technology monitors, verifies and documents diagnostic checks throughout sample assay processing. This prevents reporting of results that may be affected by exceptions.

MicroSensor technology detects endogenous interferences and flags affected results without the use of reagents or extra consumables. This verifies the integrity of the processed sample.

MicroWell technology combined with our enhanced chemiluminescence detection technology improves signal detection with outstanding precision and wide dynamic range.

VersaTip technology is designed to eliminate sample carryover and cross-contamination using disposable tips (for samples and reagents on VITROS® ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS® 5600/XT 7600 Integrated Systems).

Operational simplicity with the ability to load while running and excellent reagent/calibration stability.

Seamless integration into VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems.

With the addition of the new VITROS® HIV Combo Controls, we solidify our commitment to help our customers achieve results they can trust and instill confidence in the decisions your clinicians make for the patients you serve.

Comprehensive Infectious Disease Immunodiagnostic Menu of Assays

- Anti-HIV 1+2
- Anti-HCV
- Anti-HBc
- Anti-HBc IgM
- Anti-HBe
- Anti-HBs
- Anti-HAV IgM
- Anti-HAV Total
- Anti-HTLV I/II
- Anti-*T.Cruzi*
- CMV IgG
- CMV IgM
- HBeAg
- HBsAg ES
- Confirmatory HBsAg ES
- HIV Combo
- Rubella IgG
- Rubella IgM
- Toxoplasma IgG
- Toxoplasma IgM
- Syphilis

Ordering Information

Product Name			Catalog Code
VITROS Immunodiagnostic Products HIV Combo Reagent Pack			684 2779
VITROS Immunodiagnostic Products HIV Combo Calibrator			684 2780
Product Name	**Kit Contents**	**Volume**	**Catalog Code**
VITROS® HIV Combo Controls (Negative, Anti-HIV-1, Anti-HIV-2)	3 sets of ready-to-use tubes - 9 tubes in 1 kit	4 mL in each tube	691 2255
VITROS® HIV Combo Controls (Anti-HIV-1 group O)	3 ready-to-use tubes in 1 kit	4 mL in each tube	691 2259
VITROS® HIV Combo Controls (HIV p24 Antigen)	9 Glass vials in 1 kit	1.2 mL in each vial	691 2257

Let's Get Started Contact your local Ortho Clinical Diagnostics representative to bring the early detection capabilities of the VITROS HIV Combo Test to your lab.

1. VITROS® HIV Combo Test Instructions for Use. Pub. No. GEM1255_XUS_EN.
2. Based on NIBSC/AFSSAPS standards data from three other 4th generation manufacturers' assay Instructions for Use.
3. Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Available at http://stacks.cdc.gov/view/cdc/23447. Published June 27, 2014.
4. Mitchell E.O., Stewart G, Bajzik O, Ferret M, Bentsen C, Shriver M.K. (2013). Performance comparison of the 4th generation Bio-Rad Laboratories GS HIV Combo Ag/Ab EIA on the EVOLIS™ automated system versus Abbott ARCHITECT HIV Ag/Ab Combo, Ortho Anti-HIV 1 + 2 EIA on VITROS ECi and Siemens HIV-1/O/2 enhanced on Advia Centaur. *J Clin Virol.* 2013;58:e79-e84.
5. Data on file.

Ortho Clinical Diagnostics is a global leader of in vitro diagnostics dedicated to improving and saving lives through innovative laboratory testing and blood-typing solutions. We never stop innovating to offer streamlined, sustainable laboratory solutions that deliver fast, accurate, reliable test results to support exceptional patient care. **OrthoClinicalDiagnostics.com**

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