You deliver more than results.

You deliver trust.

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

Inspiring confidence in the results your laboratory provides.

VITROS® HIV Combo test

Ortho Clinical Diagnostics

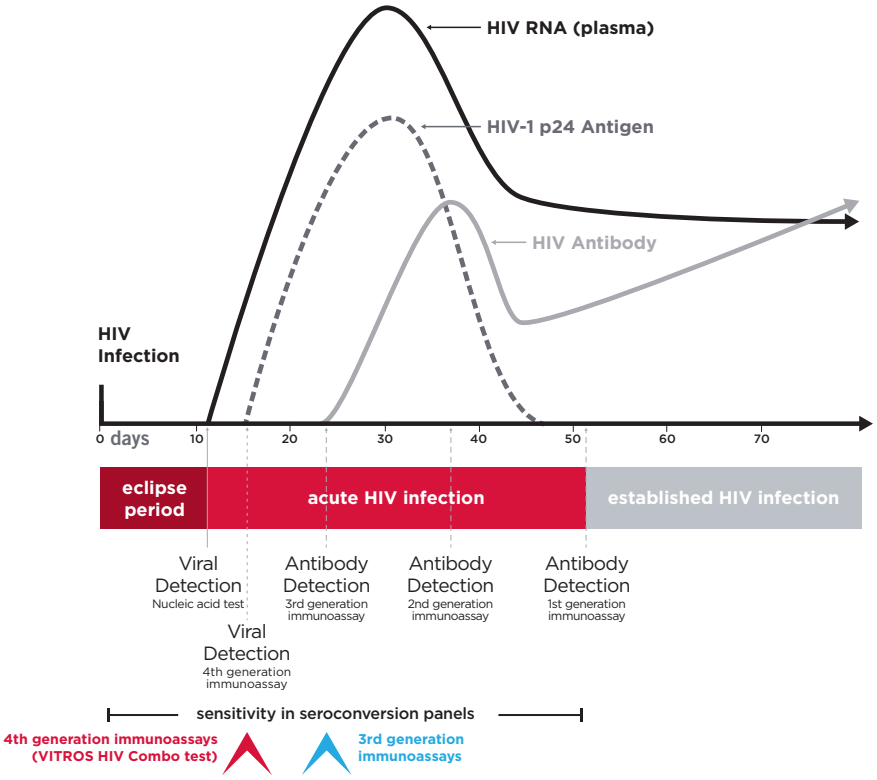
*VITROS® Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator.
Product availability subject to local regulatory requirements.

Earlier detection.[3] Improved diagnosis and prevention.

VITROS HIV Combo, a 4th generation test, detects HIV-1 infection earlier than 3rd generation tests.[3]

In 2014, the CDC (Centers for Disease Control and Prevention) and the APHL (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]

Sequence of appearance of laboratory markers for HIV-1 infection[3]



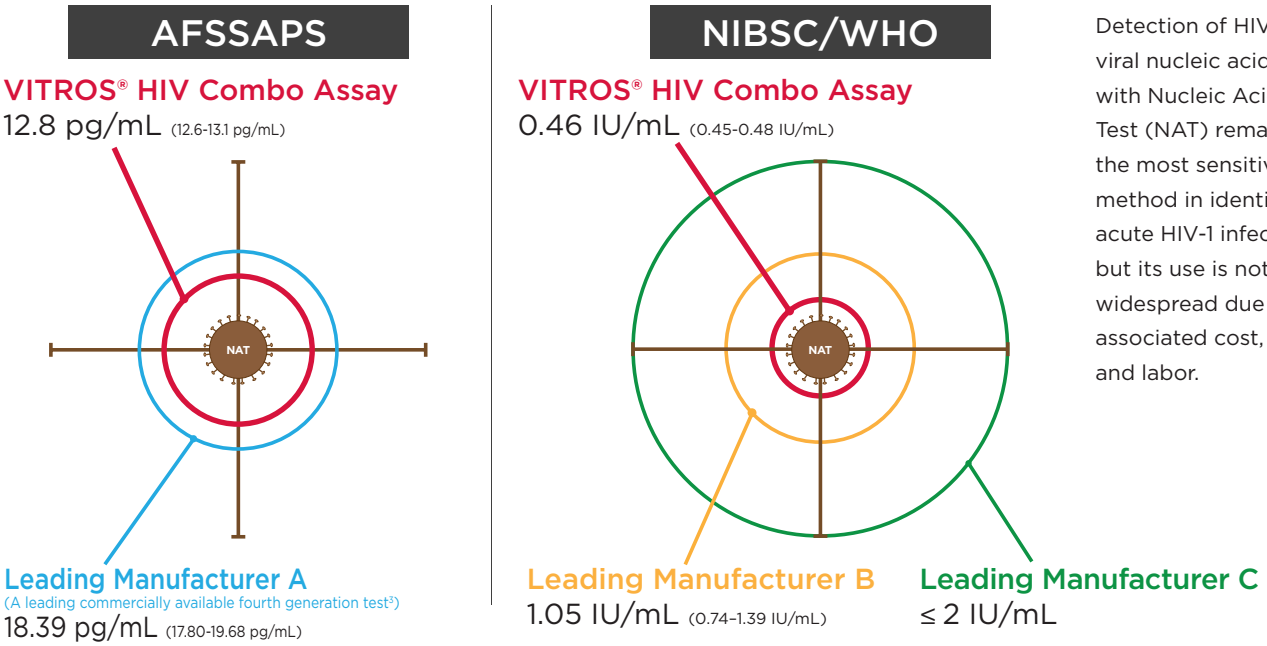
Seroconversion panel data shows that the VITROS HIV Combo test delivers even earlier detection than a leading fourth-generation test.

The VITROS HIV Combo test became reactive earlier for six of 32 seroconversion panels (agreement for 25 of 32 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.

Build trust with performance.

With class-leading[2] antigen sensitivity that doesn't sacrifice specificity, The VITROS HIV Combo test delivers the utmost confidence in results and can save, cost, time and labor in repeat and confirmatory testing.[3]



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.

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

- Analytical sensitivity shows a state-of-the-art[2] limit of 0.46 IU/mL (range 0.45-0.48 IU/mL) NIBSC/WHO and 12.8 pg/mL (range 12.6 - 13.1 pg/mL) AFSSAPS[1]
- Clinical specificity was calculated as 99.58% (CI 99.38%-99.73%) for adult low risk population.[1]

1. VITROS HIV Combo test Instructions for Use, GEM1256_US_EN, Version 1.0.
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, Bensten C, Shriver M.K. (2013). Performance comparison of the 4th generation Bio-Rad LaboratoriesGS HIV Combo Ag/Ab EIA on the EVOLISTMautomated system versusAbbott ARCHITECT HIV Ag/Ab Combo, Ortho Anti-HIV 1 + 2 EIA onVitros ECi and Siemens HIV-1/O/2 enhanced on Advia Centaur. Journal of Clinical Virology 58S (2013) e79– e84
5 Data on file

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 effected results without the use of reagents or extra consumables. This verifies the integrity of processed sample.
- MicroWell technology combined with our Enhanced Chemiluminescence Detection Technology improves signal detection with outstanding precision, sensitivity and a wide dynamic range.
- VersaTip technology is designed to eliminate sample carryover and cross-contamination using disposable tips (for samples and reagents on VITROS® 3600 Immunodiagnostic Systems).
- VITROS Systems deliver operational simplicity with the ability to load while running and excellent reagent/calibration stability.
- Seamless integration into VITROS 3600 Immunodiagnostic Systems.

COMPREHENSIVE INFECTIOUS DISEASE IMMUNODIAGNOSTIC MENU OF ASSAYS

Anti-HIV 1+2	Anti-HBe	HBeAg	HIV Combo
Anti-HCV	Anti-HBs	HBsAg	
Anti-HBc	Anti-HAV IgM	HBsAg Confirmatory	
Anti-HBc IgM	Anti-HAV Total	Rubella IgG	

ORDERING INFORMATION

VITROS® Immunodiagnostic Products HIV Combo Reagent Pack	684 2781
VITROS® Immunodiagnostic Products HIV Combo Calibrator	684 2782

BIO-RAD CONTROLS RECOMMENDED

Controls containing suitable levels of anti-HIV-1, anti-HIV-2, anti-HIV-1 group O, and HIV p24 antigen are recommended for use with the VITROS 3600 Immunodiagnostic System. The following controls have been tested and found suitable for use:

Bio-Rad VIROCLEAR® negative control	Dropper Bottle: One 5 mL Tubes: Ten 4 mL	00106 (1 x 5 mL) or 00112 (10 x 4 mL)
Bio-Rad VIROTROL® I anti-HIV-1 positive control	Dropper Bottle: One 5 mL Tubes: Ten 4 mL	00100E (1 x 5 mL) or 00101E (10 x 4 mL)
Bio-Rad VIROTROL® HIV-2 anti-HIV-2 positive control	Dropper Bottle: One 5 mL	00105C (1 x 5 mL)
Bio-Rad VIROTROL® HIV-1 gO anti-HIV-1 gO positive control	Tube: One 4 mL Tubes: Five 4 mL	00113x (1 x 4 mL) or 00113 (5 x 4 mL)
Bio-Rad VIROTROL® HIV-1 Ag p24 antigen positive control	Dropper Bottle: One 5 mL	00108A (1 x 5 mL)