VITROS<sup>®</sup> Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator

# You deliver more than results. You deliver trust.

The VITROS HIV Combo test provides early detection of acute HIV-1 infection<sup>1</sup> with class-leading<sup>2</sup> 4<sup>th</sup>-generation antigen sensitivity combined with uncompromised specificity.

The VITROS HIV Combo test is designed to inspire confidence in the results your laboratory provides.

Seroconversion panel data shows that the VITROS HIV Combo test delivers even earlier detection than a leading 4<sup>th</sup>-generation assay. The assay became reactive earlier for six of 32 seroconversion panels (agreement for 25 of 32 panels) when compared to a leading commercially available 4<sup>th</sup>-generation Ag/Ab test.<sup>1</sup>

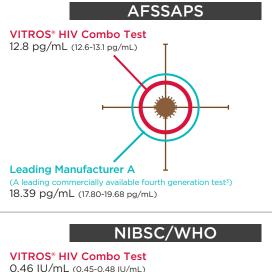
The performance of the VITROS HIV Combo test is enhanced by the proprietary technologies and benefits only available on VITROS Systems: The INTELLICHECK<sup>®</sup>, MicroSensor, and VersaTip technologies.

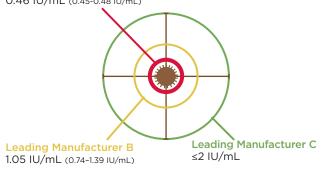
#### VITROS HIV Combo Test Performance Summary<sup>1</sup>

Time to first result	48 minutes	
Sample Volume	80 μL including dead volume	
Calibration Interval	Lot change or every 28 days	
Reagent on-board stability	Up to 12 weeks	
Reagent Type	Liquid Ready to Use	
Specimens Recommended	Serum, Plasma (lithium heparin, sodium heparin, potassium EDTA), SST and PST	

### VITROS HIV Combo Test Antigen Sensitivity Comparison to Several Commercially Available Assays

Analytical sensitivity shows a state-of-the-art\* limit of 0.46 IU/mL NIBSC/WHO and 12.8 pg/mL AFSSAPS<sup>1</sup> based on NIBSC/AFSSAPS standards data from three other 4<sup>th</sup> generation manufacturers' assay Instructions for Use.





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

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.



# 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 carryover and cross-contamination by 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®	Dropper Bottle: One 5 mL	00106 (1 x 5 mL) or
negative control	Tubes: Ten 4 mL	00112 (10 x 4 mL)
Bio-Rad VIROTROL® I	Dropper Bottle: One 5 mL	00100E (1 x 5 mL) or
anti-HIV-1 positive control	Tubes: Ten 4 mL	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	Tube: One 4 mL	00113x (1 x 4 mL) or
anti-HIV-1 gO positive control	Tubes: Five 4 mL	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)

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