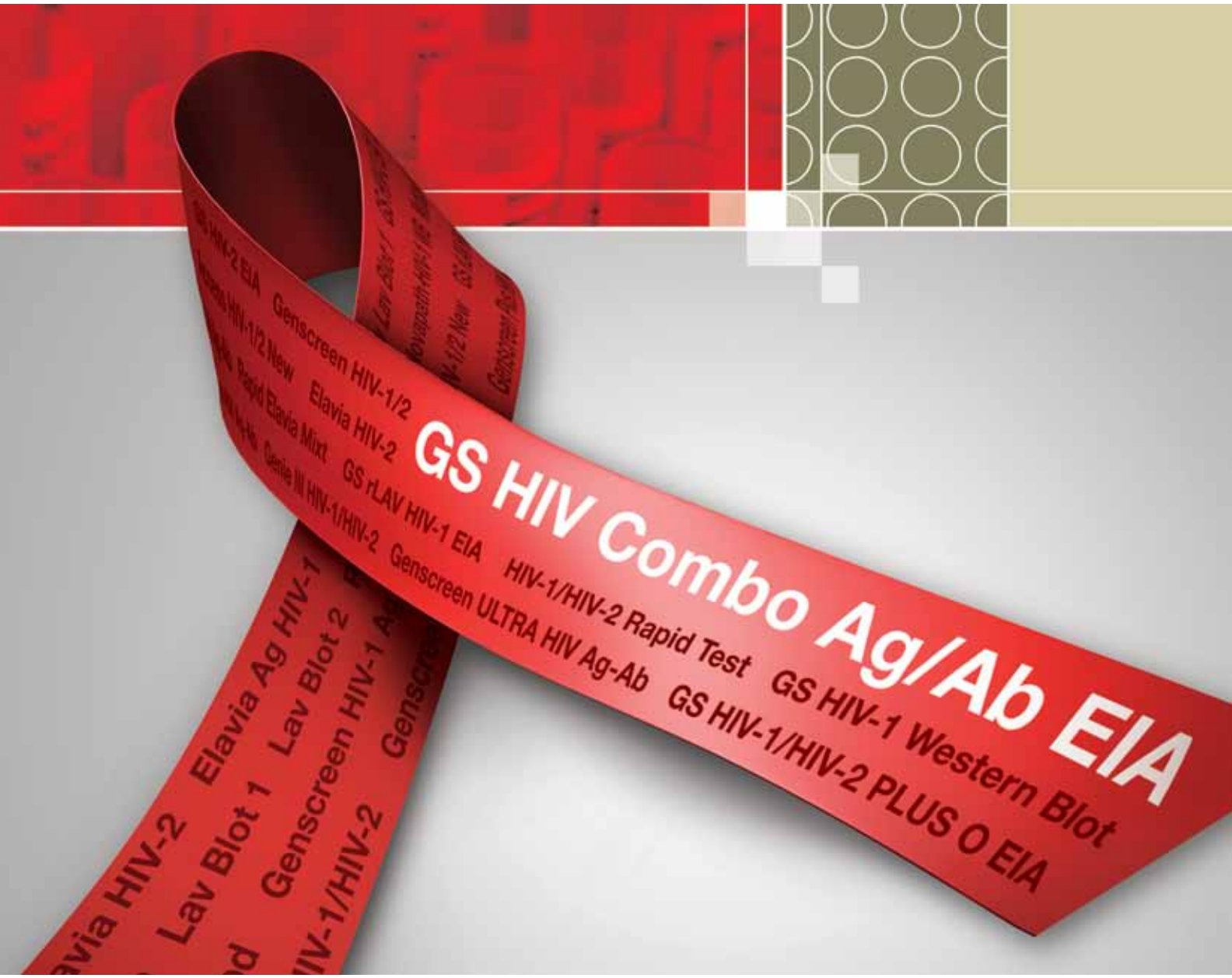



## 4th Generation Test

# GS HIV Combo Ag/Ab EIA

## Detecting Acute HIV Infection

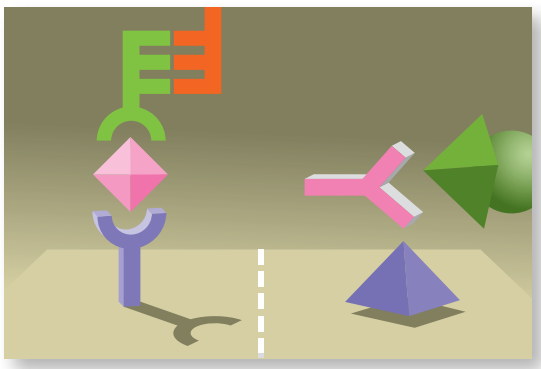
BIO-RAD

# GS HIV Combo Ag/Ab EIA

## Simultaneous Detection of HIV p24 Ag, HIV-1 Ab and HIV-2 Ab

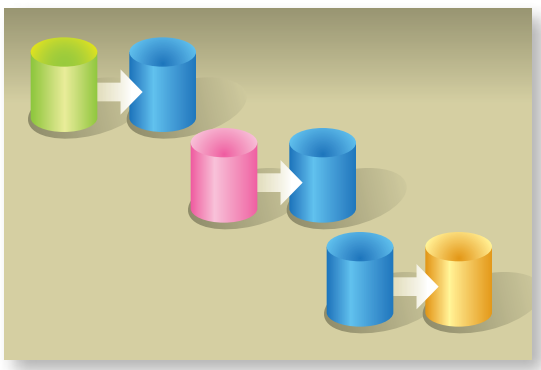
Since the discovery of HIV in 1983, Bio-Rad has delivered more world-class HIV tests than any other company in the world. The 4th generation GS HIV Combo Ag/Ab EIA test is the most recent FDA approved HIV diagnostic test from Bio-Rad Laboratories, for a total of 10 approved or licensed HIV tests in the U.S.

### Features of 4th Generation Combo Assay



Simultaneous antigen/antibody detection

For automated use



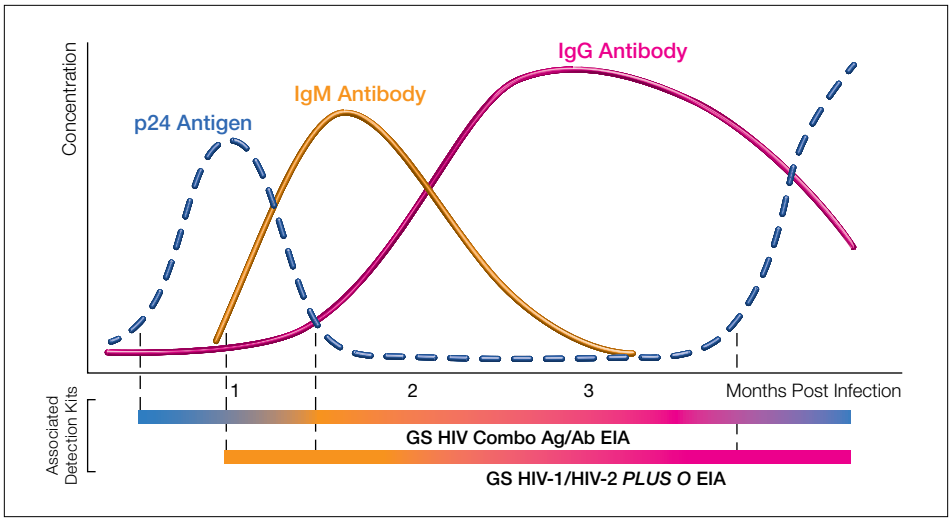
Color changes during protocol steps


Common reagents for all Bio-Rad assays

## Detection of Acute HIV Infection (by Reducing the Seroconversion Detection Window)

Compared to the FDA licensed third generation HIV-1/HIV-2 EIA, the GS HIV Combo Ag/Ab EIA reduced the time to detection of HIV (i.e. window period), with an overall range of 0 to 20 days for the 30 seroconversion panels tested in this study. Therefore, the GS HIV Combo Ag/Ab EIA demonstrated a greater capability of detecting acute HIV infection than either a third generation HIV-1/HIV-2 EIA or an HIV-1 Western blot.

**Window Period and Acute HIV Infection**




## HIV-1 p24 Antigen Analytical Sensitivity

In an internal study, the results demonstrated an antigen sensitivity of 14.78 pg/mL (range of 13.22 – 15.89 pg/mL) on the AFSSAPS standard and an antigen sensitivity of 0.65 IU/mL (range of 0.40 – 1.05 IU/mL) on the WHO standard.

## Detection of All HIV Groups and Variants

Reactivity in HIV-1 (Groups M and O) and HIV-2 positive samples demonstrated that all known HIV groups and variants could be detected.

## Specificity

The specificity of the GS HIV Combo Ag/Ab EIA in low risk populations in this study was 99.87% with a 95% CI of 99.76 – 99.93%.

### *GS HIV Combo Ag/Ab EIA – Closing the window on acute infection with increased specificity and sensitivity.*

**INTENDED USE:** The GS HIV Combo Ag/Ab EIA is an enzyme immunoassay kit for the simultaneous qualitative detection of Human Immunodeficiency Virus (HIV) p24 antigen and antibodies to HIV Type 1 (HIV-1 groups M and O) and HIV Type 2 (HIV-2) in human serum or plasma. This kit is intended as an aid in the diagnosis of HIV-1 and/or HIV-2 infection, including acute or primary HIV-1 infection. The assay may also be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection in pediatric subjects (i.e., children as young as 2 years of age). The GS HIV Combo Ag/Ab EIA is intended for manual use and with the Bio-Rad EVOLIS™ Automated Microplate System.

Results from the GS HIV Combo Ag/Ab EIA cannot be used to distinguish between the presence of HIV-1 p24 antigen, HIV-1 antibody, or HIV-2 antibody in a sample.

**The GS HIV Combo Ag/Ab EIA is not intended for use in screening blood or plasma donors,** as the effectiveness of this test for use in the screening of these donors has not been established. However, in urgent situations, where traditional licensed blood donor screening tests are unavailable or their use is impractical, this assay can be used as a blood donor screening assay.

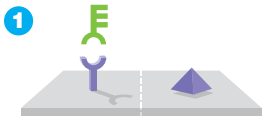
**WARNING:** FDA has approved this test for use with serum and plasma specimens only. Use of this test with specimens other than those specifically approved for use with this test kit may result in inaccurate test results. Results from this assay are to be used in conjunction with clinical findings to establish diagnosis of HIV infection. The performance of this assay has not been established in children younger than 2 years of age.

**CAUTION:** United States federal law restricts this device to sale by or on the order of a physician, or to a clinical laboratory.

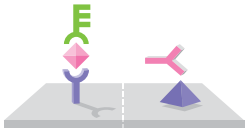
# GS HIV Combo Ag/Ab EIA

## Test Format

- Microplate coated with: monoclonal antibodies and recombinant proteins and peptides

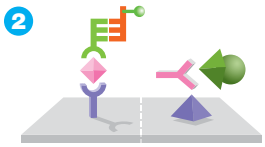


- 25 µL of Conjugate 1



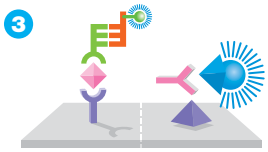
- 75 µL of control or sample
- Incubate for 1 hour at 37ºC

**WASH**

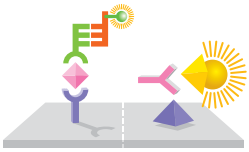


- 100 µL of Conjugate 2
- Incubate for 30 minutes at room temperature (18-30ºC)

**WASH**



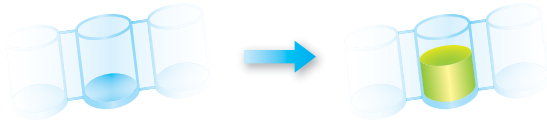
- 80 µL of Working TMB Solution
- Incubate for 30 minutes at room temperature (18-30ºC)

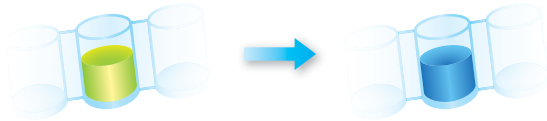


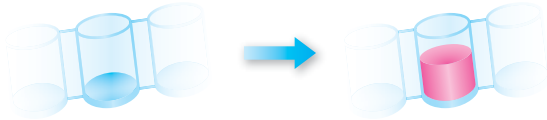
- 100 µL Stopping Solution

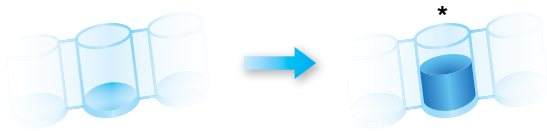
## Sample/Reagent Addition Monitoring

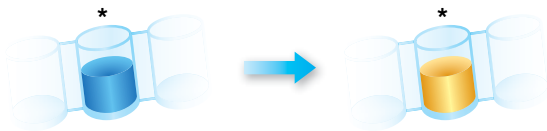
**Color of well BEFORE dispensing** **Color of well AFTER dispensing**










**READ at dual wavelength 450/615-630 nm**

Anti-p24 monoclonal antibodies

HIV-1 Ag (gp 160 recombinant protein and artificial functional consensus polypeptide) + HIV-2 Ag (gp 36 peptide)

Anti-HIV biotinylated polyclonal antibodies

Streptavidin peroxidase conjugate

HIV-1 Ag (gp 41 peptide and artificial functional consensus polypeptide peroxidase conjugate) + HIV-2 Ag (gp 36 peptide) peroxidase conjugate

* Reactive samples after 30 minutes incubation

## Ordering Information

| Catalog No. | Description | |
|---|---|---|
| 26217 | GS HIV Combo Ag/Ab EIA (2 plates) | 192 tests |
| 26218 | GS HIV Combo Ag/Ab EIA (10 plates) | 960 tests |

BIO-RAD

**Bio-Rad Laboratories**

***For further information, please contact the Bio-Rad office nearest you or visit our website at www.bio-rad.com/diagnostics***

*Clinical Diagnostics Group*

***Website*** *www.bio-rad.com/diagnostics* ***U.S.*** *1-800-2BIO-RAD* ***Australia*** *61-2-9914-2800* ***Austria*** *43-1-877-8901* ***Belgium*** *32-9-385-5511* ***Brazil*** *5521-3237-9400* ***Canada*** *1-514-334-4372* ***China*** *86-21-64260808* ***Czech Republic*** *420-241-430-532* ***Denmark*** *+45-4452-1000* ***Finland*** *358-9-804-22-00* ***France*** *33-1-47-95-60-00* ***Germany*** *+49-(0)89-318-840* ***Greece*** *30-210-7774396* ***Hong Kong*** *852-2789-3300* ***Hungary*** *+36-1-459-6100* ***India*** *1-800-180-1224* ***Israel*** *972-3-9636050* ***Italy*** *+39-02-216091* ***Japan*** *81-3-6361-7070* ***Korea*** *82-2-3473-4460* ***Mexico*** *+52 (55) 5488-7670* ***The Netherlands*** *+31-318-540666* ***New Zealand*** *64-9-415-2280* ***Norway*** *47-23-38-41-30* ***Poland*** *48-22-3319999* ***Portugal*** *351-21-472-7700* ***Russia*** *7-495-721-14-04* ***Singapore*** *65-6415-3170* ***South Africa*** *27-11-442-85-08* ***Spain*** *34-91-590-5200* ***Sweden*** *46-8-555-127-00* ***Switzerland*** *41-61-717-95-55* ***Thailand*** *662-651-8311* ***United Kingdom*** *+44-(0)20-8328-2000*