4th Generation Test

GS HIV Combo Ag/Ab EIA

Detecting Acute HIV Infection
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.

**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%.

**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.
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### 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 37°C**

#### Sample/Reagent Addition Monitoring

<table>
<thead>
<tr>
<th>Color of well BEFORE dispensing</th>
<th>Color of well AFTER dispensing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WASH</strong></td>
<td></td>
</tr>
<tr>
<td><strong>100 µL of Conjugate 2</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Incubate for 30 minutes at room temperature (18-30°C)</strong></td>
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</tbody>
</table>

#### WASH

- **80 µL of Working TMB Solution**
- **Incubate for 30 minutes at room temperature (18-30°C)**
- **100 µL Stopping Solution**

#### 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**

**Ordering Information**

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<tr>
<th>Catalog No.</th>
<th>Description</th>
<th>Tests</th>
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<td>26217</td>
<td>GS HIV Combo Ag/Ab EIA (2 plates)</td>
<td>192</td>
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<tr>
<td>26218</td>
<td>GS HIV Combo Ag/Ab EIA (10 plates)</td>
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