

SPECIMEN SUBMISSION GUIDELINES

HIV Diagnostics and Reference Laboratory, Diagnostics and Countermeasures Branch
Center for Infectious Disease Research, Walter Reed Army Institute of Research
508 Research Drive, Silver Spring, MD 20910

HIV Combo Ag/Ab EIA Test Specification

Test Name: HIV Combo Ag/Ab EIA				
Clinical Significance	Specimen Requirements	Transport/Storage Temperature	Test Approved For	Turn Around Time (After Receipt at HDRL)
<p>Enzyme immunoassay: The Genetics Systems HIV Combo Ag/AB EIA is based on the principle of the sandwich technique for the qualitative detection of HIV-1 p24 Antigen and detection of HIV-1 (Group M and O) and HIV-2 antibodies in human plasma.</p> <p>This 4th generation HIV test has significantly reduced the serological window of detection of HIV infection.</p> <p>Test employed: FDA-approved, commercially available test kit: Bio-Rad GS HIV Combo Ag/Ab EIA</p> <p>Reference Range: Not Detected</p>	<p>4 ml Serum or Plasma left on the SST/PPT tube or aliquoted in a screw top plastic vial</p> <p>Acceptable anticoagulants: EDTA, heparin, sodium citrate, CPD, CPDA-1, ACD</p>	<p>Shipping: Ambient (15 -30°C) Refrigerated (2-8°C) Frozen (-20°C or colder)</p> <p>Test must be performed within 2 days of draw if the specimen is stored and shipped at ambient temperature.</p> <p>Test must be performed within 7 days of draw if stored Refrigerated (2-8°C) and shipped with cold packs.</p> <p>Ship frozen if sample will not be received at HDRL within 48 hours.</p> <p>When shipping frozen, use 2+ lbs. dry ice per day of transport. Shipping on 6 lbs. additional dry ice recommended in case of shipment delay.</p>	<p>FDA approved for Screening for HIV-1 p24 Antigen and antibodies to HIV-1 (group O & M) and HIV-2.</p>	<p>5 business days (Clinical, Force Testing)</p>

Shipping Address: 9100 Brookville Road, BLDG 508, Silver Spring, MD 20910
• Tel: 301-319-3123 • Fax: 301-319-3502