

Test Name:	GS HIV Combo Ag/Ab EIA
Test Methodology:	Enzyme immunoassay for the simultaneous detection of HIV p24 antigen and antibodies to HIV-1 and HIV-2.
Test to be Performed:	HIV Combo EIA
CPT:	87389
Reflex Testing Criteria:	Repeatedly reactive results are reflexed to HIV Geenius test to distinguish between HIV-1 and HIV-2. Discordant results are reflexed to HIV-1 Qualitative test.
Pre-Approval Required:	N/A
Accepted Specimens:	Serum (serum tube or SST)
Specimen Stability:	Samples should be tested within 7 days of collection. Samples may be stored for up to 2 days at room temperature. Optimum storage: 2-8°C. For samples that require longer than 7 days storage, serum must be removed from the red cells and stored at -20°C or below. Samples should not be used if they have more than 4 freeze-thaw cycles.
Storage/Transport Conditions:	Specimens should be stored and transported at 2-8°C. Sufficient frozen cold packs in an insulated cooler can be used to maintain this temperature.  Specimens may be transported at room temperature (15-25°C) if delivered to the lab within 48 hours from collection time.
Turnaround Time:	7 business days
Reference Range:	Non-reactive
Comments:	A negative test result does not preclude the possibility of exposure to or infection with HIV-1 and/or HIV-2.  All specimens with a preliminary positive result from any rapid HIV test conducted in a CLIA-waived setting will be tested using the HIV Combo EIA as the first step of the Laboratory HIV Testing Algorithm.