

TEST: HIV-1 ANTIBODY**PRINCIPLE:**

This test is an in vitro immunoassay (EIA) for the qualitative detection of antibodies to human immunodeficiency virus type 1 in human serum or plasma.

Human immunodeficiency virus type 1 (HIV-1) is the first discovered AIDS virus. HIV-1 is transmitted by sexual contact, by exposure to blood or certain blood products or from an infected mother to her fetus or child. The prevalence of HIV-1 antibodies in AIDS and AIDS-related complex (ARC) patients and persons at risk is high and the virus can be isolated from nearly 90% of all seropositive individuals. Use of recombinant DNA derived antigens corresponding to three viral proteins HIV-1 core and envelope and HIV-2 envelope allows for the detection of anti-HIV-1 and/or anti-HIV-2 positive specimens.

A specimen found to be initially reactive should be retested in duplicate using a sample from the original source. Reactivity in either or both of these duplicate tests (repeatable reactive) is highly predictive of the presence of HIV-1 and /or HIV-2 antibodies in people at increased risk for HIV infection. However, because of possible non-specific reactions due to other causes, particularly when testing low prevalence populations (e.g. blood donors), it is appropriate to further test the patients specimen by HIV-1 and HIV-2 Western Blot or other confirmatory method to prove that HIV antibodies are indeed present.

The HIV-1/HIV-2 (rDNA) EIA method dilutes the specimen in a specimen diluent that is incubated with a polystyrene bead coated with Recombinant HIV-1 env and gag and HIV-2 env proteins. If the specific antibody is present it reacts with the antigens on the coated bead. After removal of the unbound materials and washing of the bead, specific immunoglobulins remaining bound to the solid phase are detected by incubating the bead-antigen complex with a solution containing HIV-1 gag and env together with HIV-2 env Recombinant proteins labeled with horseradish peroxidase (HRPO) also known as the conjugate. Unbound enzyme conjugate is then removed and the beads are washed. Next, o-Phenylenediamine (OPD) solution containing hydrogen peroxidase is then added to the bead and after incubation a yellow-orange color develops in proportion to the amount of HIV-1 and /or HIV-2 antibodies which is bound to the bead. The enzyme reaction is stopped with 1 N Sulfuric Acid and the intensity of the color development is read using the spectrophotometer.

SPECIMEN REQUIREMENTS:

2ml serum collected in a red top tube with no additive or in a serum separator tube (gel barrier). Serum should be separated from the clot as soon as possible to avoid hemolysis. Store at 2-10°C up to one week. If testing is further delayed, sera should be frozen at 20°C or lower. Avoid repeat freeze-thaw cycles.

METHOD: Enzyme Immunoassay (EIA)

REFERENCES:

1. Feorino, P.M., Jaffe, H.W., Palmer, E. *et al.* Transfusion-associated acquired immunodeficiency syndrome: evidence for persistent infection in blood donors. *New Engl J Med* 1985;312 (20):1293-6.
2. Sheehan, C. *Clinical Immunology: Principles and Laboratory Diagnosis*, 1990

Normal Range: Non-reactive for HIV-1 Ag

Turnaround Time: One Week