



TEST: HIV-1/2 ANTIBODIES PLUS ANTIGEN – FOURTH GENERATION

PRINCIPLE:

This test is an *in vitro* immunoassay (ELISA) for the simultaneous qualitative detection of antibodies to human immunodeficiency virus type 1 in human serum. This test also detects the presence of HIV p24 antigen in human serum. Positive results indicate the presence of either HIV-1 or 2 antibodies and/or p24 antigen.

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.

The HIV-2 virus is similar to the HIV-1 virus in morphology, cell tropism, interaction with CD4 cellular receptor, *in vitro* cytopathic effect on CD4 cells, overall genomic structure and its ability to cause AIDS. HIV-2 is transmitted by sexual contact, by exposure to blood or certain blood products or from an infected mother to her fetus or child.

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 patient's specimen by HIV-1 and HIV-2 Western Blot or other confirmatory method to prove that HIV antibodies are indeed present.

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 2-8°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 Linked Immunosorbent Assay (ELISA).

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

Turnaround Time: One Week