

Technical Bulletin

Detailed information concerning methodology, specimen requirements, and reference ranges on new and specialized tests

• Test Name:	Human Immunodeficiency Virus, Type 1 & Type 2 Plus Group O Antibody Screen (HIV-1/HIV-2)
• Test Order Number:	3970
• CPT code:	86703
• Department:	ACM Medical Laboratory at Elmgrove - Chemistry (400)
• Testing Schedule:	Monday - Friday
• Specimen Requirement:	1 SST serum separator (barrier) red/gray top tube
• Reference Range:	Nonreactive
• Methodology:	ELISA (Enzyme Immunoassay)
• Turn-Around-Time	24-48 hours

Clinical Significance: Available data indicates that acquired immunodeficiency syndrome (AIDS) is caused by a virus transmitted by sexual contact, exposure to blood (including sharing contaminated needles and syringes) or certain blood products, or transmitted from an infected mother to her fetus or child during the perinatal period¹. Human Immunodeficiency Virus Type 1 (HIV-1) has been isolated from nearly 90% of patients with AIDS and AIDS- related complex (ARC), and from persons at high risk for AIDS.

In 1986, a second type of virus HIV-2 was isolated from patients in West Africa. Although other sporadic cases have been found retrospectively, in other parts of the world, HIV-2 infection appears to be endemic only in West Africa. EIA test methods for HIV-1&2 are required for blood donor screening. Only 31 cases of HIV-2 infection have been documented in the United States, thus only HIV-1 testing is usually performed on patients.²

Method: The HIV-1/HIV-2 Plus O EIA is an enzyme-linked immunosorbant assay (ELISA) for the qualitative determination of antibody to HIV-1, HIV-2 and HIV-1 Group O in human serum or plasma. A diluted specimen is added to a microtiter well coated with purified gp160 and p24 recombinant proteins derived from HIV-1, gp36 peptide, and a synthetic polypeptide mimicking an artificial HIV-1 group O specific epitope. The wells are incubated and then washed. A conjugate solution, containing peroxidase-conjugated antigens, is added to the wells and then incubated. If HIV-1 and/or HIV-2 antibody is present, it will bind to the antigen coated on the well and to the peroxidase-conjugated antigens in the conjugate. The antigen-antibody-antigen complexes remain bound to the well during the subsequent wash step, which will remove any unbound materials.

A blue-green color develops in proportion to the amount of HIV antibody present in the sample. The optical absorbance of specimens and controls is determined spectrophotometrically at a wavelength of 450nm.³

Clinical Interpretation:

HIV-1, 2 Negative

Specimens with absorbance values less than the cutoff value are considered non-reactive and are considered negative for the HIV-1, HIV-2, and HIV-1 Group O antibodies. Further testing is not required.

Specimens found repeatedly reactive by EIA and negative by HIV-1 Western Blot and negative for HIV-2 EIA are considered **negative** for the HIV-1, HIV-2, and HIV-1 Group O antibodies.

Repeatedly Reactive

Specimens with absorbance values equal to or greater than the cutoff value are repeated in duplicate. If, after repeat testing, the absorbance value of either of the duplicates is greater than or equal to the cutoff value, the specimen is considered repeatedly reactive. **Repeatedly reactive results are subjected to confirmatory testing** by Western Blot prior to reporting.

Specimens found repeatedly reactive by EIA and positive by HIV-1 Western Blot are considered **positive for antibodies to HIV-1**.

HIV-1 Positive

Specimens found repeatedly reactive by EIA, negative or indeterminate by HIV 1 Western Blot, positive HIV-2 EIA and HIV-2 Western Blot are considered **positive for antibodies to HIV-2**.

HIV-2 Positive

Specimens found repeatedly reactive by EIA, indeterminate by HIV 1 Western Blot, and negative for HIV-2 EIA are considered **Indeterminate for antibodies to HIV-1**.

Indeterminate

Nonspecific EIA reactions have been seen in some samples from people who, due to prior pregnancy, blood transfusion, or other exposure, have antibodies to the human cells or the media (H9/HTLVIIIB) in which the HIV-1 virus is grown for assay production.⁴

References:

1. Centers for Disease Control and Prevention, Revised Guidelines for HIV Counseling, Testing, and Referral and Revised Recommendations for HIV Screening of Pregnant Women, November 9, 2001, MMWR 2001; **50** (No. RR-19); [pp. 1-110].
2. Centers for Disease Control and Prevention, unpublished data, 1992.
3. Genetic Systems™ HIV-1/HIV-2 Plus O EIA, insert, August. 2003.
4. Kuhn, P. et. al, HLA DR4 Antibodies Cause Positive HTLV-III Antibody ELISA Results. Lancet, 1985; 1222-1223.

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