

How Accurate is the HIV Antibody Test

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Q. How accurate are the HIV antibody EIA and the HIV antibody Western blot?

When used together, the results from this two-part testing are greater than 99% accurate. The HIV antibody EIA is a screening test and the HIV antibody Western blot is a confirmatory test. Results from an HIV antibody EIA test should never be used alone to report a positive final result.

Q. Do the HIV antibody EIA and HIV antibody Western blot test for HIV-1 and HIV-2?

There are two types of HIV (HIV-1 and HIV-2). Both HIV-1 and HIV-2 have been identified in the United States. The number of known HIV-2 infected persons in the U.S. is less than 100. The estimated number of people in the U.S. infected with HIV-1 is between 650,000 and 900,000.

Some HIV antibody EIA and HIV antibody Western blot assays detect antibody to both HIV-1 and HIV-2. These are referred to as HIV-1/HIV-2 "combination" tests. Some HIV antibody EIA and HIV antibody Western blot assays detect antibody primarily to HIV-1 and secondarily to HIV-2. Others detect antibody primarily to HIV-2 and secondarily to HIV-1.

Q. How accurate are HIV antibody tests in detecting the various subtypes of HIV-1?

HIV-1 is divided into two groups of subtypes. These two groups are referred to as Group M (major) and Group O (outlier). HIV-1 subtypes of Group M vary, depending on their genetic structure. (3) These include subtypes A through I. In the United States, the predominate HIV-1 subtype is B.

Most antibody tests for detecting HIV-1 were developed with the B subtype of the virus. As the genetic composition of a particular virus diverges from the B subtype, the likelihood that the test will be accurate decreases. Most tests, however, do appear to be able to detect antibody to most strains.

Q. What can cause a false-positive result in an HIV antibody EIA test?

There are many reasons for a false-positive EIA result. Some of the more common reasons for a false positive are:

- Contamination: In a laboratory, samples may be placed in the wrong testing well; wells containing negative samples may be contaminated from adjacent positive wells; plate washers may malfunction. In addition, treated blood and blood abnormalities have been implicated in false positive reactions.
- False positive reactions have been reported in 19% of people with hemophilia, 13% of alcoholic patients with hepatitis, and 4% of hemodialysis patients.
- Pregnancy. If this is not her first pregnancy, a woman may react positively when she is, in fact, negative.
- History of injection drug use.
- Cross-reactivity with other retroviruses.

Q. What is the expected false-positive rate for an HIV antibody EIA?

The false-positive rate is 1 to 5 per 100,000 assays.

Q. Can a person test HIV-1 antibody negative but be infected with HIV-1?

Yes. When people develop antibodies to HIV, they "seroconvert" from antibody-negative to antibody-positive. Depending upon the circumstances of infection, it is estimated that the development of antibodies to HIV-1 can take between two weeks to six months. During this interval, sometimes referred to as the "window period," a person may test HIV-1 antibody negative and yet be infected with the virus. This is because his/her immune system has not produced enough antibodies for the test to detect.

Q. What does one do if a test result is "indeterminate?" What causes this?

The term "indeterminate" relative to HIV testing usually refers to the HIV antibody Western blot assay. The HIV antibody Western blot assay is used on two or more specimens found to be reactive by an HIV antibody EIA screening assay. (6) Persons who are not at high risk for HIV infection and do not have symptoms, and yet continue to test indeterminate, usually have a very low probability of being infected with HIV. (7) There are many possible reasons for an indeterminate HIV antibody Western blot assay. Some of these reasons might be:

- Prior blood transfusions, even with non-HIV-1 infected blood
- Prior or current infection with syphilis.
- Prior or current infection with malaria parasites.
- Autoimmune disease (e.g. diabetes, Grave's disease, etc.).
- Infection with other human retroviruses (e.g., HIV-2, HTLV I/II).
- Association with "large animals." Animal trainers and veterinarians are sometimes exposed to viruses which do not cause human disease but may interfere with HIV antibody tests.
- Second or subsequent pregnancies in women.

Whether or not persons who test HIV antibody Western blot indeterminate should be retested depends upon their clinical presentation at the time of testing and what risk factors are present for infection. If a person has an indeterminate Western blot assay for HIV-1, several things can be done. These include:

- Run an alternate HIV antibody "confirmatory" assay on the indeterminate HIV antibody Western blot specimen. The FDA has approved an HIV antibody IFA (immunofluorescent assay) procedure as an equivalent confirmatory test to the HIV antibody Western blot.
- Consider running antibody tests for other human retroviruses (HTLV I/II and HIV-2).
- Run tests to identify the presence of the virus. These tests could include HIV DNA PCR, HIV p24 antigen, and HIV culture. (See below)
- Re-test at 3-month intervals for 6 months.

Q. What is meant by a stable indeterminate result?

"Stable indeterminate" is a term used to describe a situation in which an individual consistently tests indeterminate 6 months or longer from their last possible exposure. The person should be considered HIV negative unless clinical conditions determine otherwise.

Q. Is the HIV PCR (polymerase chain reaction) test more accurate than the HIV antibody EIA and HIV antibody Western blot tests? How?

Sometimes. The HIV DNA PCR test measures something different than the HIV antibody EIA and HIV antibody Western blot assays. The HIV DNA PCR test looks for HIV-1 DNA in the white blood cells of a person, whereas the HIV antibody EIA and HIV antibody Western blot assays measure the immune response to the virus. If a person has a HIV DNA PCR test, the result may be positive even if insufficient antibodies are present for detection by the HIV antibody EIA.