

Alere Determine™ HIV-1/2 Ag/Ab Combo Information Sheet for Testing Programs

- Alere Determine™ HIV-1/2 Ag/Ab Combo (Determine Combo) is a rapid test capable of detecting HIV-1 p24 antigen and HIV-1 and HIV-2 antibodies. The p24 antigen is a part of the HIV virus and can be detected before antibodies develop. If the test is reactive, the Determine Combo indicates whether the reaction is caused by antigen, antibody, or both. [Click here for more information on the Determine HIV-1/2 Ag/Ab Combo test.](#)
- Determine Combo is FDA-approved as a CLIA-waived complexity medical device for fingerstick whole blood. It is also approved as CLIA-moderately complex for use with serum, plasma, or whole blood.
- The sensitivity^a listed in the Determine Combo package insert is 99.9% using serum, plasma, and whole blood.
- The specificity^b listed in the Determine Combo package insert for low risk subjects using all specimen types (serum, plasma, whole blood) is 100.0%, and for high-risk subjects ranges from 98.9% (serum) to 99.7% (whole blood).^c
- CDC studies compared all FDA-approved tests on the same plasma specimens collected from persons during seroconversion, and found that Determine Combo detects infection one to two weeks before other rapid tests, and one to three days before IgG/IgM-sensitive laboratory HIV antibody tests, but three to four days after laboratory antigen/antibody HIV tests.¹ Using simulated whole blood, Determine detects infection two days later than using plasma.²
- Currently there are limited data on the relative sensitivity of Determine Combo or other rapid HIV tests when they are used with whole blood specimens.
- International studies using Determine Combo indicate that antibody sensitivity is comparable to package insert specifications, but that the antigen component did not detect most acute infections detected by laboratory antigen/antibody immunoassays, p24 antigen assays and RNA. ^{d, 3-9}
- In recent reports, specificity has been documented to be 98.9% in plasma¹⁰ and 98.3%-99.9% in whole blood.^{d9,11,12}
- Determine Combo can become reactive earlier after infection than current FDA-approved supplemental antibody tests (antigen or antibody reactivity or both), so HIV-1 nucleic acid testing needs to be conducted after a reactive screening test result, if the supplemental antibody test is negative or indeterminate.
- CDC/APHL laboratory testing guidance, published in June of 2014, recommends that serum/plasma specimens from persons with reactive HIV rapid screening test results are tested with the recommended laboratory algorithm starting with a laboratory antigen/antibody immunoassay.
- Data are insufficient to recommend the use of the Determine Combo as the initial assay in the laboratory algorithm. [Click here to access the updated laboratory testing guideline.](#)

^a Probability that the test result will be reactive if the specimen is a true positive

^b Probability that the test result will be nonreactive if the specimen is a true negative

^c Low risk: from a population with less than 1% prevalence of HIV infection; High risk: clinics with more than 1% prevalence of HIV infection.

^d It is not known whether there is comparable performance between the tests manufactured for use in the United States and the ones used in the international studies that are cited.

References

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