

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 moderate complexity medical device for use with serum, plasma, or whole blood. The manufacturer intends to seek a CLIA waiver for use with whole blood specimens.
- 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 third-generation laboratory HIV antibody tests, but three to four days after fourth-generation laboratory antigen/antibody HIV tests.¹
- 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 4th generation antigen/antibody immunoassays, p24 antigen assays and RNA.^{d, 2-4}
- An international study suggests that there is lower specificity for the antigen component of the test (98.3%) than for the antibody component (99.2%).^{d, 3}
- Determine Combo can become reactive earlier after infection than the Western blot, so testing after a reactive test result needs to be able to detect acute infections if the Western blot is negative or indeterminate.
- As of April 2014, data are insufficient to recommend use of this test as the initial assay in the [proposed laboratory algorithm.](#)

^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

1. Masciotra S, Luo W, Youngpairoj AS, et al. Performance of the Alere Determine HIV-1/2 Ag/Ab Combo Rapid Test with specimens from HIV-1 seroconverters from the US and HIV-2 infected individuals from Ivory Coast. *Journal of clinical virology : the official publication of the Pan American Society for Clinical Virology*. Aug 1 2013.
2. Laperche S, Leballais L, Ly TD, Plantier JC. Failures in the detection of HIV p24 antigen with the Determine HIV-1/2 Ag/Ab Combo rapid test. *The Journal of infectious diseases*. Dec 15 2012;206(12):1946-1947; author reply 1949-1950.
3. Rosenberg NE, Kamanga G, Phiri S, et al. Detection of acute HIV infection: a field evaluation of the determine(R) HIV-1/2 Ag/Ab combo test. *The Journal of infectious diseases*. Feb 15 2012;205(4):528-534.

4. Kilembe W, Keeling M, Karita E, et al. Failure of a novel, rapid antigen and antibody combination test to detect antigen-positive HIV infection in African adults with early HIV infection. *PloS one*. 2012;7(6):e37154.