

Abbott

Determine

HIV-1/2 Ag/Ab Combo

Subject Information Notice

Size: 13cm x 22.5cm



PMS 303 U
Dark Blue

PN: IN06732532

Rev: 4

Date of Last Revision:

4.9 2021/06/29

INFORMATION YOU SHOULD KNOW about HIV and the DETERMINE™ HIV-1/2 Ag/Ab COMBO.

It is very important for you to read this brochure before you are tested for HIV.

It will provide you with the following information:

- *What should you know before you are tested for HIV?*
- *What should you know about HIV and AIDS?*
- *How can you become infected with HIV?*
- *How can you avoid HIV infection?*
- *Why should you get an HIV test?*
- *What should you know about your options for HIV testing?*
- *What should you know about the Determine™ HIV-1/2 Ag/Ab Combo assay rapid tests and how they are done?*
- *What should you know about your test results?*
- *Where can you get more information about HIV and AIDS?*

WHAT SHOULD YOU KNOW before YOU ARE TESTED for HIV?

Read this brochure carefully. If you have any further questions, or do not understand something, make sure that you ask your healthcare provider to explain it to you. Your healthcare provider is the best person to answer your questions about HIV, the Determine HIV-1/2 Ag/Ab Combo assay, and other testing options that are available to you. You have a choice of the type of test to be used. Depending on what type of HIV test you choose, an appropriate sample will be taken and checked for HIV antibodies and p24 antigen. If HIV antibodies or p24 antigen are found in your body, that means that you have been infected with HIV, which is the virus that causes AIDS.

WHAT SHOULD YOU KNOW about HIV and AIDS?

HIV stands for Human Immunodeficiency Virus. HIV causes AIDS (Acquired Immunodeficiency Syndrome). Many people are infected with HIV and do not have any sign of illness for many months or years. When a person becomes infected with HIV, the virus begins to attack his or her immune system, which is the body's defense against illness. As a result, that person becomes ill more and more often. When his or her body loses the ability to fight diseases, that person is said to have AIDS. People with AIDS become very sick with serious illnesses and cancers, and often will die from these illnesses.

HOW CAN YOU BECOME INFECTED with HIV?

HIV is passed on through contact with blood, semen, vaginal fluids, or the breast milk of an infected person. Contact can come from unsafe sex. It can also come from exposure to blood through the sharing of used syringes or needles. Infected women can pass the virus to their babies during pregnancy, childbirth, and breast feeding. It is also possible to become infected with HIV through a blood transfusion, although this is now very rare. People do not become infected with HIV through everyday casual contact with people at school,

work, home, or anywhere else. The virus is not spread from contact with sweat, tears, saliva, or a casual kiss from an infected person (deep, or "French" kissing is not advised). Nor can people become infected from contact with forks, cups, clothes, phones, toilet seats, or other things used by someone who is infected with HIV. People do not become infected from eating food prepared by an HIV-infected person. People have not become infected with HIV through insect bites.

HOW CAN YOU AVOID HIV INFECTION?

The best way to avoid getting HIV is to avoid activities that would allow the virus to be passed to you. You can reduce the risk of becoming infected with HIV by the following:

- *The only way to avoid sexual exposure to HIV is to have sex with an uninfected partner or to abstain.*
- *If you are not certain that your sex partner is uninfected, you should use a latex condom correctly every time you have sex.*
- *Do not share needles or syringes.*

WHY SHOULD YOU GET an HIV TEST?

You may have been infected with HIV and not know it. It can take many years before someone infected with HIV develops AIDS. There are no visible signs to tell you if you have been infected with HIV. The only way to be confident that you are not infected with HIV is to get an HIV test. If you learn that you are infected with HIV, you can take steps to avoid activities that will pass it on to others. It is important to find out if you are infected with HIV so that you can receive good medical care. Although there is presently no cure for AIDS, there are new treatments and medications for HIV infection that can help you live a longer and healthier life.

WHAT SHOULD YOU KNOW about your OPTIONS for HIV TESTING?

The Determine HIV-1/2 Ag/Ab Combo assay can give you a rapid HIV test result in approximately 20 minutes. A rapid test is ideal for those situations where speed is critical, such as in an emergency room. There are other HIV tests available, if the test results are not needed right away. These tests may use a sample of your blood, fluid from your mouth, or a urine sample, but the result may not be available for 1-2 weeks.

WHAT SHOULD YOU KNOW about the DETERMINE™ HIV-1/2 Ag/Ab ASSAY and HOW IT IS DONE?

The Determine HIV-1/2 Ag/Ab Combo assay is a fast and accurate test that provides easy-to-read test results in 20 minutes. The Determine HIV-1/2 Ag/Ab Combo assay is used to look for p24 antigen or antibodies in a sample of your blood.

The p24 viral capsid (core) protein, common (but not identical) to both HIV-1 or HIV-2 is detectable in blood earlier than HIV antibody during acute infection.^{1,2,3}

It appears early after infection and is typically associated with high levels of viremia, during which the individual is highly infectious.⁴ Combined antigen and antibody tests should provide earlier detection of HIV infection than that afforded by antibody-only tests.

Once you decide to use the Determine HIV-1/2 Ag/Ab Combo assay, your healthcare provider will either prick your finger and take a drop of blood or take a tube of blood from your vein and perform the test while you wait. He or she will give you the test results during the same visit. The Determine HIV-1/2 Ag/Ab Combo assay is very accurate; however, additional testing is necessary to confirm a reactive result. For more detail, you can ask your healthcare provider to give you complete information about the Determine HIV-1/2 Ag/Ab Combo assay.

WHAT SHOULD YOU KNOW about your TEST RESULTS after HAVING the DETERMINE™ HIV-1/2 Ag/Ab ASSAY?

A Negative result means that HIV antibodies or p24 antigen were not detected in your blood at the time of testing. However, this does not completely rule out the possibility of infection with HIV. If, in the last 3 months, you have had any of the contacts described in the “How can you become infected with HIV?”

Section above, there is a possibility that you may still be infected with HIV. HIV antibodies may not appear until a few months after infection with the virus. A very recent infection may not produce enough p24 antigen or antibodies to be detected by this test.

Ask your healthcare provider if you should consider getting tested again in the next 3 to 6 months to be sure that you are not infected. However, if you are certain that you have not had any of the contacts that could transmit HIV in the 3 months before your HIV test, a Negative test result means you were not infected with HIV at the time of testing. Ask your healthcare provider to help you understand what your test results mean for you.

A Preliminary Positive test result suggests that your blood may contain HIV antibodies or p24 antigen. This result, however, must be confirmed by another test. If you have participated in an HIV vaccine study, you should inform the person giving you the test. Until your HIV test is confirmed, you should be careful to avoid activities that might spread HIV. If your test result is confirmed positive (HIV-infected), new treatments can help you maintain your health.

Some people who test positive for HIV infection stay healthy for many years. Even if you become ill, there are medications that can help to slow down the virus and maintain your immune system. You should tell your doctor that you are HIV positive, so that he or she can watch your health closely. You must take steps to protect others by practicing safe sex and by informing your past and present partners about your HIV test result.

WHERE CAN YOU GET MORE INFORMATION about HIV and AIDS?

If you have any questions or want additional information, ask your healthcare provider or contact your local health department. You can also call the National AIDS Hotline at 1-800-CDC-INFO (1-800-232-4636) to talk with an HIV specialist. They can give you quick, private answers at any time, day or night. Other AIDS service organizations near you can also provide information, education, and the help you may need.

References:

1. Centers for Disease Control and Prevention (CDC) *Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings. MMWR 1988; 37(24):377-388.*
2. Louie B, Wong E, Klausner JD, Liska S, Hecht F, Dowling T, Obeso M, Phillips SS and Pandori MW (2008) Assessment of rapid tests for detection of Human Immunodeficiency Virus-specific antibodies in recently infected individuals. *Journal of Clinical Microbiology 46(4): 1494-1497.*
3. Lyons MS, Lindsell CJ, Hawkins DA, Raab DL, Trott AT and Fichtenbaum CJ (2008) Contributions to early HIV diagnosis among patients linked to care vary by testing venue. *BMC Public Health 8:220*
4. Gürtler LG, Hauser PH, Eberle J, et al. A New Subtype of Human Immunodeficiency Virus Type 1 (MVP-5180) from Cameroon. *Journal of Virology. 1994; 68(3):1581-1585.*