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PRIMA®

WHAT IS HIV?

The human immunodeficiency virus (HIV) is a pathogen which attacks and suppresses the immune system by affecting in particular white blood cells. The possible transmission pathways for HIV are:

- Sexual: through sexual intercourses not protected by an efficient method of prevention (e.g. condoms);
- Blood: exchange of syringes, transfusions of infected blood;
- Vertical: from mother to baby during pregnancy, at birth and, more rarely, through breastfeeding.

Without taking specific drugs, the HIV virus weakens the immune system leading to the acquired immunodeficiency syndrome (AIDS).

WHAT IS THE AIDS?

AIDS identifies an advanced clinical stage of HIV infection. It is a syndrome that can occur in people with HIV even several years after the infection, when the immune system's efficiency dramatically falls, and the body loses its ability to fight even the most common infections. The AIDS can be prevented by taking antiretroviral therapy at an early stage.

TEST PRINCIPLE & INTENDED USE

HIV 1/2 SELF-TEST is a self-test that is able to specifically detect the presence in a blood sample of anti-HIV 1 and/or 2 antibodies. If the sampled drop of blood contains anti-HIV antibodies, they are captured by the test producing a red-coloured line in the test line region (T). Otherwise, if the sample does not contain such antibodies, no colour will appear in the test line region (T). The absence of colour in the test line region (T) is also possible when the levels of circulating antibodies are below the limit of detection, leading to false negative results, especially for HIV-1 Group O (prevalence of HIV 1 Group O worldwide: 1%). A red-coloured line will always appear in the control line region (C) confirming that the test has correctly operated.
It is recommended to not take any decision of medical relevance after performing this test without first consulting your medical practitioner.

REFERENCES

1. https://www.who.int/health-topics/hiv-aids/#tab=tab_1
2. European Centre for Disease Prevention and Control, HIV/AIDS surveillance in Europe (https://www.ecdc.europa.eu/en/all-topics-zhiv-infection-and-aidssurveillance-and-disease-data/annual-hivaids-surveillance-reports)
3. https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/symptoms-of-hiv
4. Debit et al., "HIV-1 Group O Genotypes and Phenotypes: Relationship to Fitness and Susceptibility to Antiretroviral Drugs"
5. https://www.cdc.gov/hiv/basics/hiv-testing/test-types.html

HIV 1/2 SELF-TEST

PRIMA® HOME TEST

Rapid self-test for the qualitative detection of antibodies to human immunodeficiency virus 1 and 2 (HIV1/HIV2) in whole blood

F.A.Q- QUESTIONS AND ANSWER

Do not take any decision of medical relevance without first consulting your medical practitioner after performing the test.

HOW DOES THE HIV 1/2 SELF-TEST WORK?

The test detects the presence of antibodies to human immunodeficiency virus 1 and 2 (HIV1/HIV2) by means of specific antigens and colloidal gold nanoparticles embedded in the test strip.

WHEN CAN THE TEST BE USED?

HIV 1/2 SELF-TEST can be performed at any time of the day. The test can be carried out by anyone who has been or suspects to have been exposed to the virus, people with HIV symptoms or anyone who wants to be aware of a possible infection. Antibody tests can take 23 to 90 days (window period) to detect HIV infection after an exposure. **HIV 1/2 SELF-TEST is not for use in emergency situations.**

DOES HIV1/2 TEST DETECT OTHER DISEASES?

No. The HIV 1/2 SELF-TEST only detects the presence of antibodies to human immunodeficiency virus 1 and 2 (HIV 1/HIV 2) in the blood sample, which is indicative of virus infection and subsequent immune response. **HIV 1/2 SELF-TEST cannot be used to detect other sexually transmitted infections.**

WHAT IS THE DIFFERENCE BETWEEN HIV AND AIDS?

HIV is a virus that attack the human immune system. Under normal circumstances, immune system cells defend the body against various pathogens - including viruses. However, HIV destroy exactly those cells that should protect the body against it. AIDS is a late consequence of untreated HIV infection. Being HIV positive and having AIDS is not the same thing. The HIV multiplies and damages the immune system until AIDS develops.

CAN THE RESULT BE NOT CORRECT?

The result is correct as long as the instructions are carefully followed. However, the result may not be correct if: the device comes into contact with other liquids before use, if the amount of blood and/or diluent is insufficient, if the number of drops dispensed into the well is incorrect or if the reading time of the result is not respected. The plastic pipette supplied allows to be sure that the volume of collected blood is correct. False positive results (the test incorrectly indicates a positive result even if the anti HIV antibodies are not present) may be due to: *Mycoplasma pneumoniae, Borrelia,* Hepatitis C Virus (HCV), Human T-lymphotropic virus (HTLV), Epstein-Barr Virus/Nuclear Antigen (EBV:EBNA). The main consequences of a false positive result are: the person could experience a strong negative stress and would have to undergo a second unnecessary laboratory test to have the diagnosis confirmed. Due to the lack of samples with very high concentrations of antibodies, the manufacturer cannot exclude the possibility that very high concentrations of antibodies against HIV1/2 in the blood sample could lead to false negative results (the test incorrectly indicates a negative result even if the anti HIV antibodies are actually present). False negative results are also possible in case the level of antibodies is below the limit of detection, this may be particularly relevant for HIV-1 Group O (prevalence of HIV 1 Group O worldwide: 1%). The main consequences of a false negative result are: a delay in receiving the proper therapy, transmission of the virus to other persons.

HOW TO INTERPRET THE TEST IF THE COLOR AND INTENSITY OF THE TEST AND CONTROL LINES ARE DIFFERENT?

The colour and intensity of the lines are not relevant for the interpretation of the results. Refer to the indications and to the images in the section "Results Interpretation" to correctly evaluate the result.

IF READ AFTER 10 MINUTES, IS THE RESULT RELIABLE?

No. The test should be read exactly 10 minutes after the end of the procedure. Results read after 10 minutes may not be correct (false positive results may appear, see question “can the result be not correct” where the consequences of false positive results are explained).

WHAT SHOULD BE DONE IF THE RESULT IS POSITIVE?

If the result is positive, it means that antibodies to HIV 1 and/or HIV 2 are present in the blood sample. You should consult your physician and report the result obtained with this test. **A positive result is not sufficient to indicate the development of HIV infection, the result should be confirmed by your doctor. AVOID ANY ACTIVITY THAT COULD TRANSMIT HIV TO OTHERS until you have received the results of further diagnostic investigations in accordance with your doctor. PROTECT YOURSELF AND OTHERS, ask your doctor for more information on how to prevent the transmission.** False positive results may be obtained due to undesired positive reaction of the test towards other pathogens.

WHAT TO DO IF THE RESULT IS NEGATIVE?

If the result is negative, the test did not identify the presence of antibodies to HIV 1 and HIV 2. This result may mean that HIV infection has not occurred or is at an early stage where specific antibodies have not been yet developed. False negative results may be obtained with patients receiving antiretroviral or cortisone therapy (e.g. conditions of immunosuppression). **If your result is negative but you think you have been exposed or you have symptoms, please contact your doctor to ensure that you are not in the window period (3 months), which is the time required for the development of a detectable amount of HIV antibodies.** Please avoid any activity that may cause HIV transmission to others.

IF THE RESULT IS NEGATIVE, CAN I STOP HAVING PROTECTED SEX?

No. The HIV 1/2 SELF-TEST does not exclude other sexually transmitted disease (such as Herpes, Syphilis, Chlamydia, Gonorrhea, Viral Hepatitis). Moreover, a negative result does not mean that your partner is not HIV infected. **Condoms are the safest way to protect yourself and others.**

WHAT IS THE ACCURACY OF HIV 1/2 SELF-TEST?

The test is very accurate. Evaluation reports show a sensitivity of 99.3% (95% CI: 98.2-99.7%), a specificity of 99.7 (95% CI: 99.2-99.9%) and an overall accuracy of 99.6% (95% CI: 99.2-99.8%) with respect to the laboratory standard test.

CONTENT OF THE KIT

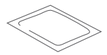
- 1 hermetically sealed aluminium pouch containing:
  1 HIV 1/2 TEST cassette
  1 desiccant bag

Do not open the sealed aluminium bag until just before performing the test. Take care to open it as marked. The desiccant packet must not be used. Dispose of it with household waste without opening it.

- 1 vial with dropper tip containing the HIV 1/2 TEST DILUENT required for 1 test

- 2 sterile lancets for self-drawing blood

- 1 transparent plastic bag containing a pipette for collecting blood



- 1 *antiseptic skin cleanser gauze*

- 1 instructions for use leaflet

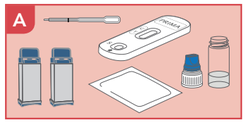
All the mentioned components are packed in a protective plastic bag.

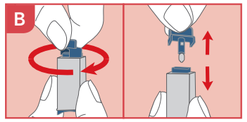
Material required but not supplied: cotton wool, which can be used to remove residual blood drops after the puncture, a device to measure time (i.e. timer, watch).

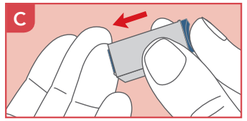
PRECAUTIONS

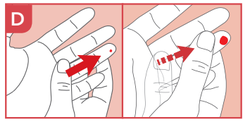
- The HIV 1/2 SELF-TEST is not intended for therapeutic follow-up with patients receiving antiretroviral therapy.
- **Read these instructions for use carefully before testing.** The Test is reliable if the instructions are carefully followed.
- Keep the Test out of the reach of children.
- Do not use the Test after the expiration date or if the packaging is damaged.
- Follow the procedure exactly, using only specified quantities of blood and diluent.
- Store the Test components at a temperature of +4°C to +30°C. Do not freeze.
- Use the Test and the sterile lancet only once.
- The Test is for external use only. DO NOT SWALLOW.
- Not recommended for use by people taking medicines that make the blood thinner (anticoagulants) or people with haemophilia problems.
- After use, dispose of all components according to local regulations, ask your pharmacist for advice.
- This test is only able to detect HIV infection and cannot be used for the detection of other sexually transmitted infections.
- People who use this self-test should consult their doctor prior to making any medical decisions.
- If testing other people, treat blood samples as potentially infected.
- In vitro diagnostic device for individual use.

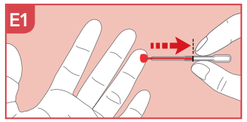
TEST PROCEDURE

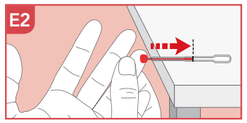


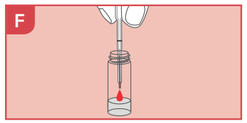


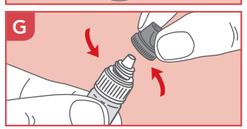


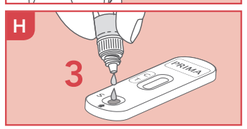












⚠ WARNING: Read the entire procedure carefully before performing the test!

Bring the kit components at room temperature (15-30°C) before testing if the kit was stored refrigerated.

1) Prepare the necessary material as follows: open the aluminium pouch, take out only the test cassette and throw away the desiccant bag. Open the plastic packet containing the pipette and unscrew the white cap from the diluent bottle –FIG. **A**
2) Wash hands with soap and warm water, rinse with clean water and allow to dry. Note: The use of warm water facilitates capillary blood collection as it induces vasodilation.
3) Use the provided gauze to clean the puncture site.
4) Carefully rotate the protective cap of the sterile lancet 360° without pulling it. Extract and discard the released cap. –FIG. **B**
5) Carefully massage the finger chosen for the puncture (the side of the ring finger is recommended). It is important that the massage is done from the palm of the hand to the phalanx, to improve blood flow. Press the open end of the lancet (the side the cap has been extracted from), against the fingertip –FIG. **C**. The tip of the lancet automatically retracts after use. If the lancet does not work properly, discard it and use the second one supplied. If the second one is not required, it can be disposed of without special precautions.
6) Holding the hand down, massage the finger until a large drop of blood forms. It is important to massage from the palm of the hand to the phalanx to improve blood flow. –FIG. **D**
7) Take the pipette **without pressing the bulb**. Two sampling methods are suggested:

   –FIG. **E1**: hold the pipette horizontally **without pressing the bulb** place it in contact with the drop of blood, it will enter the pipette by capillarity. **Move the pipette away when the black line is reached.** If there is not enough blood, continue to massage the finger until the black line is reached.

   –FIG. **E2**: place the pipette on a clean, flat surface with the tip protruding from the shelf, then place the drop of blood in contact with the pipette, it will enter by capillarity. If blood is not sufficient, continue massaging the finger **until the blood has reached the black line**.

   Avoid, as far as possible, to continuously move the tip of the pipette away from the finger in order to prevent the formation of air bubbles.
8) Put the blood collected with the pipette into the opened dropper vial, by pressing on the pipette bulb. –FIG. **F**
   Press the bulb of the pipette 2 or 3 times to make sure all the blood sample is added into the diluent solution. Then place back the screw cap on the dropper vial and mix well.
9) Unscrew the blue cap from the dropper vial (leave the white cap tightly screwed on). –FIG. **G**
10) Deposit 3 drops into the well indicated on the cassette (S). –FIG. **H**
    Note: If the dispensed drop contains air bubbles, add another drop to the well. Wait 3-5 seconds between each drop of diluent.
11) **Read the results at 10 minutes.**

RESULT INTERPRETATION

READ THE RESULTS AT 10 MINUTES.

POSITIVE*

Two coloured lines appear in the reading window next to the C (Control) and T (Test) signs.

This means that the test has detected the presence of HIV 1 and/or HIV 2 antibodies in the sample.

WHAT SHOULD I DO?

Contact your physician and report this result because you are probably sero-positive (specific antibodies have been detected in your blood, indicating the presence of the virus).

*NOTE: The colour intensity in the test line regions may vary depending on the concentration of HIV 1 and/or HIV 2 antibodies present in the sample (as seen in the images). Therefore, any shade of colour in the T line region, even if fainter than those shown in the images, should be considered as a positive result.

Do not take any decision of medical relevance without first consulting your medical practitioner after performing the test.

NEGATIVE

A single-coloured line (of any intensity) appears next to the C (Control) sign. No line appears next to the T (Test) sign.

This means the HIV1 and HIV 2 antibodies are either not present or are present in very low concentrations, not detectable by this diagnostic system.

WHAT SHOULD I DO?

If the result is negative, but you think that you have been exposed to HIV in the last 3 months it is possible that antibodies have not produced yet by your body (window period which is the time required for the development of a detectable amount of HIV antibodies). In this case it is recommended to repeat the test 3 months after the possible exposure and please avoid any activity that may cause HIV transmission to others.

If you have symptoms that can be traced back to HIV contact your doctor anyway.

INVALID

No bands appear or there is a line only next to the T (Test) sign and not next to the C (Control) sign.

In this case it is not possible to interpret the result of the test, which must be considered not valid. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for the absence of the control line (invalid result).

Review the procedure and repeat the test with a new device and a new blood sample.

MEDICAL DEVICE INSIDE THE KIT

STERILE R LANCET

SteriLance Medical (Suzhou) Inc.
No. 68 Litanghe Road
Xiangcheng
Suzhou 215133 - China
CE 0197

EC REP Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

ANTISEPTIC CLEANSER GAUZE: 70% ALCOHOL

Vitrex Medical A/S
Vasekaer 6-8
DK-2730 Herlev
Denmark
CE 2797

SYMBOLS

	Read the instructions before use	IVD	In vitro diagnostic medical device	LOT	Lot number
	Expiry date (last day of the month)	REF	List number		Legal Manufacturer
STERILE R	Sterilised using irradiation	+4°C −30°C	Temperature limits		Do not reuse
EC REP	Authorised Representative in the European Community	n	Sufficient for <n> test	CE	EC Marking