BLEED TRIM FOLD

Test your health

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INSTRUCTIONS FOR USE

CE 0483

PRIMA® HOME TEST

HIV 1/2 TEST

Rapid immunochromatographic manual self test for the qualitative detection of antibodies to human immunodeficiency virus 1 and 2 (HIV-1/HIV-2) in human capillary blood to assist the identification of HIV infection

HIV AND AIDS

The human immunodeficiency virus (HIV) is a pathogen which attacks and suppresses the immune system by affecting in particular white blood cells. HIV infections can be caused by two similar retroviruses, HIV-1 or HIV-2. HIV-1 causes most HIV infections worldwide, while HIV-2 causes many HIV infections in West Africa. The possible transmission pathways for HIV are:

- Sexual: through sexual intercourses not protected by an effcient 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). AIDS is a syndrome that can occur in people with HIV even several years after becoming infected and identifies an advanced clinical stage of HIV infection. The onset of AIDS can be avoided by taking appropriate antiretroviral therapies early on.

RISK FACTORS

Behaviours and conditions that put people at greater risk of contracting HIV include:

- having condomless anal or vaginal sex;
- having another sexually transmitted infection (STI) such as syphilis, herpes, chlamydia, gonorrhoea or bacterial vaginosis;
- haring contaminated needles, syringes, other equipment or solutions when injecting drugs or medicines;
- eceiving unsafe injections, blood transfusions, tissue transplantation or medical procedures that involve unsterile cutting or piercing;
- experiencing accidental needle stick injuries, including among health workers.

TEST PRINCIPLE AND INTENDED USE

HIV 1/2 TEST is a manual immunochromatographic device for self-testing. The gp41 antigens for HIV-1 and gp36 for HIV-2, together with colloidal gold nanoparticles, are the active components of the test. During the test, anti-HIV-1 and anti-HIV-2 antibodies, if present in the capillary blood sample, react with the gp41 and gp36 antigens bound to the gold nanoparticles present in the gold pad of the test. The mixture chromatographically migrates upwards into the strip membrane by capillary action due to the addition of the diluent, and interacts with the line region of the test, where the gp41 and gp36 antigens are again fixed, resulting in the appearance of a coloured line. If anti-HIV-1 and anti-HIV-2 antibodies are not present in the sample (capillary blood), no coloured line will appear in the test line region, indicating a negative result. As a procedural control, a coloured line will always appear at the control line, due to the interaction of gold nanoparticle-bound immunoglobulins with the anti-immunoglobulins fixed on the control line, indicating that the test procedure has been performed correctly and that the test components and reagents have worked as intended. HIV 1/2 TEST is a quick and simple tool for the identification of HIV infection.

F.A.Q. – QUESTIONS AND ANSWERS

DO NOT TAKE ANY DECISION OF MEDICAL RELEVANCE WITHOUT FIRST CONSULTING YOUR MEDICAL PRACTITIONER OR HIV CENTERS ON THE TERRITORY AFTER PERFORMING THE TEST.

WHEN CAN THE TEST BE PERFORMED?

The test can be carried out by anyone who has been or suspects to have been exposed to the virus (refer to the risk factors mentioned above), people with HIV symptoms (non-specific such as fever, fatigue, dermatitis, sore throat, joint pain and increased lymph node volume), 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.

WHAT ARE THE TEST PERFORMANCES?

To assess the performance, a clinical evaluation was performed by comparing the results obtained against the laboratory's reference method.

Table 1.

	REFERENCE METHODS		
HIV 1/2 TEST	NEGATIVE	POSITIVE	n.
NEGATIVE	1520	4	1524
POSITIVE	5	560	565
n.	1525	564	2089

Confusion matrix showing results of PRIMA device in comparison with the results of the reference method.

On the base of the above results and considering the Wilson 95% Confidence Interval, the values of sensitivity and specificity of HIV 1/2 Test are the following:
Sensitivity = 99.3% (560/564), Wilson 95% CI: 97.8-99.7%
Specificity = 99.7% (1520/1525), Wilson 95% CI: 99.2-99.9%

CROSS-REACTIVITY AND INTERFERING SUBSTANCES TESTED

To determine the effects of possible interferences, the substances listed in Table 2 were added to HIV Positive and HIV Negative plasma samples at the concentrations listed below. No interference was found associated with HIV 1/2 TEST.

Table 2.

SUBSTANCE	CONCENTRATION
Albumin	5.0 g/dL
Total proteins	8.69 g/dL
Direct bilirubin	2.76 mg/dL
Total bilirubin	5 mg/dL
Total cholesterol	174 mg/dL
HDL cholesterol	70 mg/dL
LDL cholesterol	102.5 mg/dL
Triglycerides	317.5 mg/dL

SUBSTANCE	CONCENTRATION
Glucose	125 mg/dL
Uric acid	12.75 mg/dL
Hemoglobin	2000 mg/dL
Isopropanol	35% v/v
Ethanol	1% v/v
Ascorbic acid	20 mg/dL
Caffeine	10.8 mg/dL

ACTIVE SUBSTANCE	CONCENTRATION
Acetylsalicylic acid	3.0 mg/dL
Paracetamol	15.6 mg/dL
Ibuprofen	21.9 mg/dL
Amoxicillin	5.4 mg/dL
Ceftriaxone	1.11 mg/dL
Levofloxacin	84.0 mg/dL
Tetracycline	2.4 mg/dL

No cross-reaction was observed with Adenovirus IgG, Parainfluenza IgG, RSV IgM, Enterovirus IgG, Rubella IgG, Toxoplasma IgG, Haemophilus influenzae IgG, SARS IgG, MERS IgG, Adenovirus IgM, Bordetella pertussis IgG, Influenza A IgG, Influenza B IgG, Legionella IgG, Antinuclear Antibodies (ANA), Chlamydia pneumoniae IgG/IgA, Cytomegalovirus (CMV) IgG, Herpes Simplex Virus (HSV) IgG, Hepatitis B Virus(HBV) Ig, Treponema pallidum (Syphillis) Ig.

WHAT IS THE DIFFERENCE BETWEEN HIV AND AIDS?

Being HIV-positive, i.e. having the specific antibodies for HIV in your blood, does not mean you have AIDS. HIV is a virus that attacks the cells of the immune system, progressively weakening it. AIDS (Acquired Immunodeficiency Syndrome) is the advanced stage of HIV infection, in which the immune system is so compromised that the body can no longer defend itself against infection and disease. Having AIDS means being more vulnerable to serious infections and some forms of cancer. When a person is infected with HIV, he or she may have no symptoms for many years, but the virus continues to damage the immune system. However, anti-retroviral drugs available today can control HIV infection, preventing or delaying the development of AIDS and allowing those affected to live long and healthy lives.

DOES HIV 1/2 TEST DETECT OTHER DISEASES?

No. HIV 1/2 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. The target antigens of these antibodies are gp41 for HIV-1, and gp36 for HIV-2. HIV 1/2 TEST cannot be used to detect other sexually transmitted infections.

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

No. HIV 1/2 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.

If you need additional information, assistance or would like to report a problem, please contact us at support@primalabsa.ch. In case of serious incidents occured in relation to the device please inform the local health authority and manufacturer. You are advised to contact your local HIV associations for counselling services.

BIBLIOGRAPHY

1. https://www.who.int/health-topics/hiv-aids/#tab=tab_1
2. Branson BM, Owen SM, Wesolowski LG, et al. CDC. Laboratory Testing for the Diagnosis of HIV Infection:Updated Recommendations. https://dx.doi.org/10.15620/cdc.23447
3. Hurt CB, Nelson JAE, Hightow-Weidman LB, Miller WC. Selecting an HIV test: a narrative review forclinicians and researchers. Sex Trans Dis 2017; 44:739-746
4. Centers for Disease Control and Prevention, HIV Testing, https://www.cdc.gov/hiv/testing/
5. Jamil MS, Eshun-Wilson I, Witzel TC, Siegfried N, Figueroa C, Chitembo L, Msimanga-Radebe B, et al. Examining the effects of HIV self-testing compared to standard HIV testing services in the general population: A systematic review and meta-analysis. EClinicalMedicine. 2021; 7;38:100991
6. Taylor D, Durrigon M, Davis H, Archibald C, Konrad B, Coombs D, Gilbert M et al. 2015. Probability of a false-negative HIV antibody test result during the window period: a tool for pre- and post-test counselling. Int J STD AIDS 2015; 26(4):215-24

MEDICAL DEVICES INSIDE THE KIT

STERILE R
Lancet
CE 0197 *Huaian Tianda Medical Instruments Co., Ltd., No.106 East Songjiang Road,Huaiyin, Economic&Technological Development Zone, 223300 - Huaian City, Jiangsu - P. R. China*
EC REP *Riomavix Sociedad Limitada Calle de Almansa 55, 1D Madrid 28039, Spain*

Alcohol cleansing gauze
CE *Phoenix Innovative Healthcare Manufacturers Pvt. Ltd. EL-209, Shil Mahape Road, Electronic Zone, MIDC, TTC Industrial Area, Mahape, Navi Mumbai 400 710 MH I India*
EC REP *Advena Ltd., Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013. Malta*

SIMBOLOGY

- IVD — *In vitro diagnostic medical device*
- *Read the instructions for use carefully*
- STERILE R — *Sterilised by radiation*
- EC REP — *Authorised Representative in the European Community*
- UDI — *Unique Device Identification*
- *Not for near patient testing*
- +4°C +30°C — *Temperature limits*
- *Do not reuse*
- *Sufficient for <n> tests*
- *Use by (last day of the month)*
- *Intended for self-testing*
- REF — *Product code*
- LOT — *Product batch*
- CE — *EC marking*
- *Manufacturer*
- *Importer*

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A summary of safety and performance (SSP) for this device is available at https://ec.europa.eu/tools/eudamed. This is the SSP location after the launch of European Database on Medical Devices. Search for the device using the UDI-DI provided on the outer packaging of the device.

LIMITATIONS

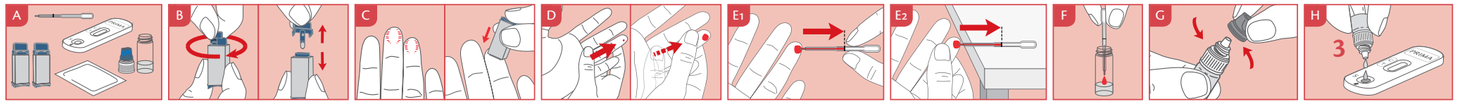
1. This test is not to be used for monitoring and donor screening.
2. The use of this test is not recommended under 16 years of age.
3. This test may not detect HIV infections that have occurred within the last 3 months.
4. HIV 1/2 TEST only indicates the presence of antibodies to HIV. Not to be used as the sole criteria for the diagnosis of HIV infection or treatment. A negative result does not at any time preclude the possibility of HIV infection.
5. HIV 1/2 TEST is not intended for therapeutic follow-up with patients receiving antiretroviral therapy.
6. ***Situations that can lead to "false positive" results*** (the test incorrectly indicates a positive result even if the anti-HIV antibodies are not present): 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.
7. ***Situations that can lead to"false negative" result*** (the test incorrectly indicates a negative result even if the anti-HIV antibodies are present in the sample) are also possible in case the level of antibodies is below the limit of detection, this may be particularly relevant for HIV-1 groups O, N and P (prevalence of these HIV 1 groups worldwide: about 1%). The main consequences of a false negative result are: a delay in receiving the proper therapy, transmission of the virus to other persons. 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.
8. The test is not intended for professional use or near-patient testing.
9. The use of antiretroviral therapies (such as PrEP or PEP) and immunosuppressive drugs may affect anti-HIV antibody levels, reducing the detectability of the infection. It is recommended to consult your physician for alternative tests.

CONTRA-INDICATIONS

People suffering from haemophilia or taking anticoagulants could have an excessive bleeding after the fingerprick.

PRECAUTIONS

1. **In vitro diagnostic device for individual use.**
2. **Read these instructions carefully before testing. The test is reliable if the instructions are followed properly.**
3. **Follow the procedure exactly, using only the specified amount of blood and diluent.**
4. **Keep the test out of the reach of children.**
5. **Do not use the test after the expiry date or if the packaging and/or internal components are damaged.**
6. **Store the test components at a temperature of +4 °C to +30 °C. Do not freeze.**
7. **Only use the test and its components once. Avoid eye/skin contact with the test fluid.**
8. **The test is for external use only. DO NOT SWALLOW.**
9. **After use, dispose of all components in accordance with local regulations. Ask your pharmacist for advice.**
10. **Using the test on another person: if you perform the test on someone else (e.g. family members, caregivers or partners), this should only be done at home. Handle all blood samples as potentially infectious. Always wear new disposable gloves, a mask, and eye protection. Avoid direct contact with blood. Dispose of all used components safely; do not reuse any part of the test. In case of contact with eyes, mouth, or mucous membranes, rinse immediately with plenty of water and seek medical advice without delay. This test is not intended for use in professional healthcare or near-patient settings.**
11. **No medically significant action should be taken without consulting your doctor first. A definitive diagnosis can only be made by a doctor after a joint evaluation of the clinical information and the results from further tests.**
12. **HIV 1/2 TEST is only able to detect HIV infection and cannot be used for the detection of other sexually transmitted infections.**
13. **Do not confuse/mix components of this kit with components of other kits.**



CONTENT

- 1 hermetically sealed aluminium pouch containing: 1 HIV 1/2 TEST cassette, 1 desiccant bag.
- 1 dropper vial containing the HIV 1/2 TEST DILUENT sufficient for 1 test.
- 1 capillary pipette for collecting the blood sample.
- 2 sterile lancets.
- 1 alcohol cleansing gauze.
- 1 instruction leaflet.

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

NOTE: - Only open the sealed aluminium pouch prior to performing the test.
- The desiccant bag must not be used. Discard it, without opening it, by deposing of it together with the household waste.
- Items needed and not provided: an instrument for measuring time (e.g. stopwatch, clock).

TEST PROCEDURE

ATTENTION: Read the entire procedure before performing the test!

1) Wash hands with soap and warm water, rinse with clean water and dry.
Note: The use of warm water facilitates capillary blood sampling as it induces vasodilation.
2) Prepare the necessary material as follows: open the aluminium sachet, only take out the cassette and throw away the desiccant bag. Open the plastic sachet containing the pipette and use the provided gauze to clean the puncture site. Allow the area to air dry and unscrew the white cap from the diluent bottle. **–FIG. A**
3) Remove the protective cap from the lancet by carefully rotating it 360° without pulling it. Pull out and discard the released cap. **–FIG. B**
4) Position the hand downward and gently massage from the palm to the chosen phalanx repeatedly to improve blood flow: middle or ring fingers are recommended - avoid the fifth finger. The puncture should be made slightly off-center, in the fleshy area of the thickest part of the phalanx. Press the lancet perpendicular to the fingertip, on the side from which the cap was removed, while keeping it firmly between the fingers. **–FIG. C**
The tip of the lancet automatically retracts safely after use. If the lancet does not work properly, use the second one provided. If the latter is not necessary, it can be disposed of without special precautions.
Note: make a single puncture. Do not perform an immediate double sticking at the same site.
5) Wipe away the first drop of blood and allow another drop to form, by keeping your hand downward and continue to massage the finger until the specimen volume is adequate. **–FIG. D**
6) Pick up the pipette **without pressing the bulb**. Two withdrawal methods are suggested:
–FIG. E1: hold the pipette at a slight incline without squeezing the bulb and place it in contact with the blood droplet, it will enter on its own by capillary action. Remove the pipette when it reaches the black line. If there is not enough blood, continue massaging the finger until the line is reached.
–FIG. E2: place the pipette on a flat, clean surface, allowing the tip to protrude, at which point the drop of blood should come into contact with the pipette, it will enter on its own by capillary action. Move your finger away when it reaches the black line. If there is not enough blood, continue massaging the finger until the line is reached.
Avoid, as far as possible, breaking contact between the blood and the pipette so as to prevent the formation of air bubbles.
7) Deposit the collected blood into the dropper vial, previously opened, by squeezing the bulb of the pipette. **–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.
8) Unscrew the blue cap from the dropper vial (leave the white cap tightly screwed on). **–FIG. G**
Solution must be used immediately. Deposit **3 drops** into the well indicated on the cassette (S). **–FIG. H**
Note: if the dispensed drops contain air bubbles, add another drop to the sample well. Wait 2-3 seconds between each drop of solution.
9) Wait **10 minutes** and then interpret the results as follows. Do not move the device while waiting.

RESULTS INTERPRETATION

READ THE RESULTS AT 10 MINUTES. DO NOT READ THE RESULTS AFTER 15 MINUTES.

POSITIVE*

Two coloured lines appear in the results window in the T (Test) and C (Control) regions.

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

***NOTE:** The colour intensity in the control and test line regions may vary (as can be seen in the pictures). Therefore, any colour intensity in the region of the T line must be considered positive.

WHAT TO DO?
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.

NEGATIVE

Only one coloured line appears next to the C (Control) mark.

This result means that HIV-1 and HIV-2 antibodies are not present or are present in very low concentrations, which cannot be detected by this diagnostic test.

WHAT TO DO?
If the result is negative, the test did not identify the presence of antibodies to HIV-1 and HIV-2. This result may indicate that HIV infection has not occurred or is at an early stage where specific antibodies have not been yet developed. 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.

INVALID

No line appears at the C (Control) mark.

The most likely reason for an invalid result is that the procedure has not been performed correctly. Review the procedure and repeat the test with a new device and a new sample.

REVISIONS

REVISION	DATE	CHANGES
2.0	03/2026	New registered office of PRIMA Lab SA