HIV Ag/Ab 4th Gen. Rapid Home Test
(Whole Blood)

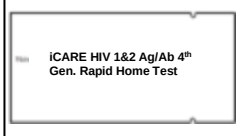
For self-testing
For in vitro diagnostic use only
For Fingertip Whole Blood Specimens
Please read the instructions carefully before use

Instructions for Use

【SPECIFICATION】
1 Test/Kit

【INTENDED USE】
The iCARE Advanced HIV Ag/Ab 4th Gen. Rapid Home Test is a tri-line, serological, lateral flow chromatographic immunoassay for the simultaneous and qualitative detection of human immunodeficiency virus type 1 (HIV-1) p24 antigen, human immunodeficiency virus type 1 antibody and type 2 antibody in human fingertip whole blood specimens to aid in the diagnosis of infection with HIV. The test only provides preliminary analysis results but not critical diagnosis criteria. Any reactive specimen with the iCARE Advanced HIV Ag/Ab 4th Gen. Rapid Home Test must be analyzed and confirmed with alternative testing method(s) and clinical findings. The test is intended for healthcare professional use, self-test, or home test for preliminary screening of HIV infection by layperson. Applications of the test including, screening test for sex transmitted diseases (STD's) among high-risk group of people, regular health examinations, and field screen test for blood bank.

【MATERIALS AND CONTENTS】
Each contains one piece of the following listed accessories in one test kit.



Test Device (with a desiccant)

IFU

Lancet

Alcohol Prep

Sample Diluent

Pipette (30 uL)

Waste Bag

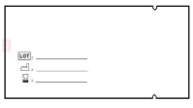
Timer (Materials required but **NOT** provided)

【PREPARATION BEFORE TESTING】

Wash your hands with running water or sanitizer, make sure they are dry and clean before starting the test.

Read the instructions carefully before use.

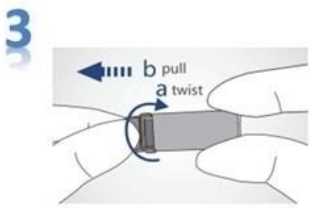
Check all contents of the test kit to make sure that all contents are complete and not damaged.


Check the Expiration Date printed on the foil pouch of the test device, as well as other outer packages.

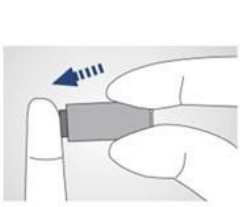
【TEST PROCEDURES】

Tear off to open the Alcohol Prep Pad.

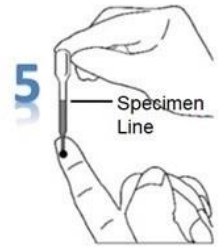
Clean the site area of the finger.



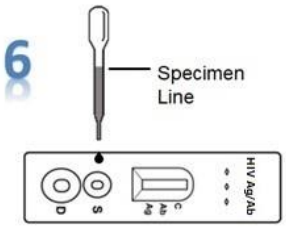
Carefully twist off the protective cap until it is separated from the device.



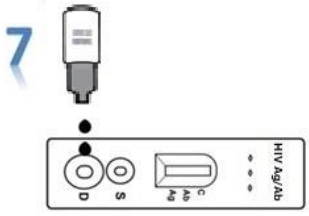
Place the lancet firmly against the puncture site to activate. Do not remove the device until an audible click is heard.



Draw up the blood (30µl) with plastic pipette until reaching specimen line.



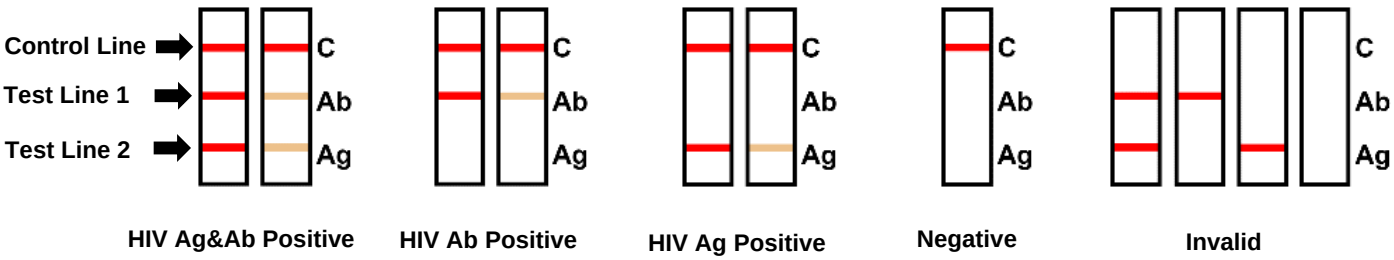
Squeeze out the plastic pipette to add all the blood (30µl) to the "S" well.



Tear off the sealing film and cap the dripper on the sample diluent tube. Then add 2 drops of sample diluent to the "D" well.

Interpret the result at 15 minutes. Don't interpret after 20 minutes.

【INTERPRETATION OF TEST RESULTS】



【SUMMARY】

Human Immunodeficiency Virus type-1 (HIV-1) and type-2 (HIV-2) are enveloped single strand RNA virus that cause acquired immunodeficiency syndrome (AIDS). Current data indicate that the HIV is transmitted through sexual contact, exposure to blood (including sharing contaminated needle and syringe) or certain blood products or from an infected mother to her child during the prenatal period. People with increased risk of HIV infection include intravenous drug users, homosexuals, and hemophiliacs. The presence of HIV-1 p24 antigen indicates fresh infection with HIV-1 virus, and presence of antibodies to HIV- 1/HIV-2 indicates previous exposures to HIV-1/HIV-2 virus.

The iCARE Advanced HIV Ag/Ab 4th Gen. Rapid Home Test utilizes anti-HIV-1 p24 antibody and recombinant HIV antigen immobilized on a membrane to detect HIV-1 p24 antigen, HIV type 1 and HIV type 2 antibodies qualitatively and selectively in human fingertip whole blood specimens.

【TEST PRINCIPLE】

The iCARE Advanced HIV Ag/Ab 4th Gen. Rapid Home Test is a qualitative membrane-based immunoassay for the detection of HIV-1 p24 antigen, HIV type 1 and HIV type 2 antibody in human

fingertip whole blood specimens. The test device consists of: 1) a burgundy-colored pad containing colloidal gold particles coated with recombinant HIV-1 antigen gp41/120, recombinant HIV-2 antigen gp36, and colloidal gold particles coated with monoclonal anti-HIV-1 p24 antibody and 2) a nitrocellulose membrane strip containing two test lines (Ab line and Ag line) and a control line (C). The Ab line is coated with recombinant HIV-1 antigen gp41/120 and recombinant HIV-2 antigen gp36 for the detection of HIV type 1 and HIV type 2 antibodies, and the Ag line is coated with monoclonal anti-HIV-1 p24 antibody for the detection of HIV-1 p24 antigen. When an adequate volume of specimen is added to the specimen well(S) of the device, the specimen migrates by capillary action across the device and interacts with the immobilized antigens respectively. If the specimen contains HIV type 1 and/or HIV type 2 antibodies, a colored line will appear in the Ab line region. If the specimen contains HIV-1 p24 antigen, a colored line will appear in the Ag line region. Absence of any test lines (Ab and Ag) suggests a negative result.

An internal quality control is included in the test, in the form of a colored line appearing in the control line region (C), indicating that the test is functional, and proper and sufficient volume of specimen has been applied to enable migration through the test and control lines, regardless of whether there is a test line or not. If the control line (C) does not appear within the testing time, test result is invalid and the test should be repeated with a new test device.

【STORAGE AND STABILITY】

1. The test kit should be stored at a temperature between 2-30°C. Do not freeze the kit or its components.
2. The shelf life of the kit is as indicated on the outer package (24 months from date of manufacture).
3. This test kit is stable until the expiration date marked on the outer package and foil pouch. Ensure all test components are at room temperature (15-30℃) before use.
4. If the aluminum foil bag is unsealed, the test device should be used as soon as possible and within one hour (15-30℃, humidity ≤80%).

【WARNINGS AND PRECAUTIONS】

1. Read the Instructions for Use (this leaflet) completely before using the product. Follow the instructions carefully. Failure to do so may result in an inaccurate result.
2. The test kit is for single use only, do not reuse any components of the test kit.
3. Guard against moisture, do not open the aluminum foil bag until you are ready to test. Do not use it if the aluminum foil bag is damaged or the test device is damp.
4. Keep out of reach of pet and children.
5. Do not use this test beyond the expiration date printed on the outer package. Always check expiry date before testing.
6. Do not touch the reaction area of the test device.
7. Do not use the kit if the pouch is damaged or not well sealed.
8. The test kit shall be stored in strict accordance with the conditions specified in this manual. Do not freeze the test kit.
9. Apply the drops of test specimen only to the specimen well(S) on the test device.

10. Too many or too few drops of Buffer may result in invalid or incorrect test result.
11. Wear appropriate personal protection equipment and gloves when performing the test, collecting and handling specimens for another individual who need help.
12. Dispose of all used test devices and potentially contaminated materials in the provided waste bag and dispose of according to applicable local laws and regulations.

【LIMITATIONS】

1. The test kit is for in vitro diagnostic use only.
2. The test kit is only used to detect human **Fingertip Whole Blood** specimens, and the results with other specimen tests may be incorrect.
3. The test kit is only used for qualitative testing and does not indicate the number of AIDS Virus in the specimens.
4. Failure to follow the instructions or interpretation of test results may adversely affect test performance and/or invalidate the test results.
5. A negative test result may occur if the level of antigen in a specimen is below the detection limit of the test.
6. Positive test results do not rule out co-infections with other pathogens.

【QUALITY CONTROL】

Internal procedural control is included in the test. A colored line appearing at the control line (C) is an internal control. It indicates that sufficient specimen is added and correct procedural technique is applied.

【PERFORMANCE CHARACTERISTICS】

Clinical performance compared to ELISA: HIV 1/HIV-2 Antibodies

Advanced HIV Ag/Ab 4th Gen. Rapid Home Test	**ELISA**		
	Positive	**Negative**	**Total**
Positive	399	1	400
Negative	1	919	920
Total	400	920	1320

Sensitivity (Positive Percent Agreement): 99.75% = 399/400 (95% CI: 98.60%~99.96%)
Specificity (Negative Percent Agreement): 99.89% = 919/920 (95% CI: 99.39%~99.98%)
Accuracy (Overall Percent Agreement): 99.84% = (399+919)/1320 (95% CI: 99.45%~99.96%)

Clinical performance compared to ELISA: HIV-1 p24 Antigen

Advanced HIV Ag/Ab 4th Gen. Rapid Home Test	**ELISA**		
	Positive	**Positive**	**Total**
Positive	365	1	366
Negative	1	859	860
Total	366	860	1226

Sensitivity (Positive Percent Agreement): 99.72% = 365/366 (95% CI: 98.47%~99.95%)
Specificity (Negative Percent Agreement): 99.88% = 859/860 (95% CI: 99.34%~99.98%)
Accuracy (Overall Percent Agreement): 99.83% = (365+859)/1226 (95% CI: 99.41%~99.96%)

【QUESTION & ANSWER】

1. ***When should I test for my family at home?***
   The test result is a snapshot of your current point in time. Getting tested regularly is the way to know if you have the virus.
2. ***What can affect my test result?***
   Collect specimens according to instructions. Perform the test immediately after collecting the specimen.
3. ***What to do if the test strip is clearly discolored?***
   Pay close attention to the amount of sample diluent (2 drops) that is applied. The capacity of the test strip is limited. If the T-line is very dark and the C-line is weak, the test result is positive. If the C-line (control line) does not appear or the test strip is difficult to read because it is blurry or discolored, please repeat the test according to the instructions.
4. ***I did the test: no control line (C-line).***
   Your test result is invalid. Repeat the test according to the instructions for use.
5. ***I did the test: my result is positive.***
   If the test device shows the control line (C-line) and the test line (ag-line and/or ab-line), meaning your result is positive, you should refer to the recommendations of your local authorities and contact the nearest medical facility. Your test result may be double-checked and the agency will advise you on what to do next.
6. ***I did the test: my result is negative.***
   If the test device clearly shows only the control line (C-line), this may indicate a negative test result. If you experience symptoms such as Fever, cough, sore throat, fatigue, poor appetite, nausea, vomiting, abdominal pain, diarrhea, headache, superficial lymphadenopathy and rash, etc., please consult your family doctor or the nearest health care facility in accordance with the recommendations of your local authorities. Repeat the test if you are not sure.
7. ***I took the test: I am unsure of how to read the result.***
   The result is positive if 2 or 3 horizontal lines (C-line, ag-line and/or ab-line) are visible of the test device. If the test kit clearly shows only the control line (C-line), this may indicate a negative test result. If you are still unsure about reading the results, contact the nearest healthcare facility as recommended by your local authority.
8. ***How can I dispose of the product?***
   Discard the used lancet, sample diluent tube, test device and other waste components into the waste bag and seal the bag mouth. All the used test materials can't be discarded at will. Please dispose of in accordance with the applicable local laws and regulations against medical waste.

【REFERENCES】

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2. Blattner, W., Gallo, R.C. and Temin. H.M. HIV causes AIDS. Science. 241:515, 1988.
3. Curran, J.W., Morgan. W.M., Hardy, A.M., et al. The epidemiology of AIDS: Current status and future prospects. Science 229:1352-1357. 1985.
4. Sarngadharan. M.G., Popovic. M., Bruch, L., Schupback, J., and Gallo, R.C. Antibodies reactive with human T-lymphotropic retroviruses (HTLV-lll) in the serum of patients with AIDS. Science. 224:506-508. 1984.

5. Weber, J.N., Weiss, R.A., Roberts, C., et al. Human immunodeficiency virus infection in two cohorts of homosexual men: Neutralising sera and association of anti-gag antibody with prognosis, Lancet 1:119-124. 1987.
6. Clavel, F., Guetard. D., Brun-Vezinet, F., et al. Isolation of a new human retrovirus from West African patient with AIDS. Science 233:343-346. 1986.
7. J.N. Wasserheit. Epidemiological Synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases, Sexually Transmitted Diseases 1992; 19:61-77.

【INDEX OF SYMBOLS】

	Consult instruction for use		For *in vitro* diagnostic use only		Catalog number		Temperature limit
	Lot number		Use by		Do not reuse		Contains sufficient for <X> tests
	Keep dry		Manufacturer		Date of manufacture		Keep away from sunlight
	Do not use if package is damaged						

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