Anti-HIV (1&2) Rapid Test

(Whole Blood/Serum/plasma)

FOR IN VITRO DIAGNOSTIC USE

This package insert must be read carefully prior to use. Package insert instructions must be carefully followed. Reliability of test results cannot be guaranteed if there are any deviations from the instructions in this package insert.

【INTENDED USE】

The iCARE Anti-HIV (1&2) Rapid Test is a colloidal gold enhanced, rapid immunochromatographic test for the qualitative detection of antibodies to human immunodeficiency virus (HIV) in human whole blood, serum, or plasma. This test is a screening test, and all positives must be confirmed using an alternate test such as western blot. The test is intended for healthcare professional use only.

【SUMMARY】

The human immunodeficiency virus (HIV) is the causative agent of acquired immune deficiency syndrome (AIDS). The general method of detecting infection with HIV is to observe the presence of antibodies to the virus by an EIA method followed by confirmation with Western Blot. The iCARE Anti-HIV (1&2) Rapid Test is a simple, visual qualitative test that detects antibodies in human whole blood, serum, or plasma. The test is based on immunochromatography and can give a result within 20 minutes.

【PRINCIPLES OF THE TEST PROCEDURES】

The test starts with a sample applied to the sample well. A recombinant HIV antigen conjugated to colloidal gold embedded in the sample pad reacts with the HIV antibody present in whole blood, serum or plasma forming conjugate/HIV antibody complex. As the mixture is allowed to migrate along the test strip, the conjugate/HIV antibody complex is captured by recombinant HIV antigen immobilized on a membrane forming a colored test band in the test region. A negative sample does not produce a test band due to the absence of colloidal gold conjugate/HIV antibody complex. The antigens used in the conjugate test are recombinant proteins that correspond to highly immunoreactive regions of HIV1 and HIV2. A colored control band in the control region appears at the end of test procedure regardless of test result. This control band is the result of colloidal gold conjugate binding to the anti-HIV antibody immobilized on the membrane. The control band indicates that the colloidal gold conjugate is functional.

【MATERIALS PROVIDED】

FOR CARD TEST

- Test card individually foil pouched with a desiccant……..40
- Sample diluent (5ml)…….2
- Plastic dropper……..……..40
- Package insert……..……..…...1

FOR STRIP TEST

- Test strip individually foil pouched with a desiccant……..…..50
- Sample diluent (5ml)…… ……..……...2
- Package insert……..….1

【MATERIALS REQUIRED BUT NOT PROVIDED】

- Timer or stopwatch, pipettes
- Blood collection devices

- Biohazard disposal container
- Disposable gloves

【STORAGE AND STABILITY】

The kit has a 24-month shelf-life from the date of manufacture. Store the unused kits at 2℃-30℃. If stored refrigerated, ensure that the sealed pouch is brought to room temperature (15℃-30℃) before opening for testing. The sample diluent should be used within 8 weeks after opening.

【WARNINGS AND PRECAUTIONS】

1. ALL positive results must be confirmed by an alternate method.
2. Treat all specimens as though potentially infectious. Wear gloves and protective clothing when handling specimens.
3. Devices used for testing should be autoclaved before disposal.
4. Do not use kit materials beyond their expiration dates.
5. Do not interchange reagents from one kit lot to another.
6. Do not re-use the test cards or any single use accessories.

【SAMPLE COLLECTION】

FINGERSTICK WHOLE BLOOD

1. Using an antiseptic alcohol swab. Clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad. Using a sterile lancet, puncture the skin just off the center of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
2. Pick up an unused specimen collection plastic dropper to collect the drop of blood.

VENIPUNCTURE WHOLE BLOOD

1. Using standard venous phlebotomy procedure, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA, heparin, or sodium citrate. Other anticoagulants have not been tested and may give an incorrect result. If the specimens are not tested at the time of collection, the whole blood can be stored at 2℃-8℃ for 3 days. Before testing, mix the blood tube gently by inversion several times to ensure a homogeneous sample.
2. Pick up an unused specimen collection plastic dropper to collect the drop of blood.

SERUM OR PLASMA

1. SERUM

   Use the standard venous phlebotomy procedure to collect a whole blood sample by a tube **NOT** containing any of the following anticoagulants: EDTA, heparin, or sodium citrate. Leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.

2. PLASMA

   Use the standard venous phlebotomy procedure to collect a whole blood sample by a tube containing any of the following anticoagulants: EDTA, heparin, or sodium citrate. And then centrifuge blood to get a plasma specimen.

Note:

1. If serum or plasma specimens are not tested immediately, they should be refrigerated at 2℃-8℃. For storage period longer than 7 days, freezing is recommended. They should be brought to room temperature before testing.
2. Serum or plasma specimens containing a precipitate may yield inconsistent test result. Such specimens must be clarified before testing.
3. Avoid frequent (more than 3 times) thaw-and-freeze of specimens.
4. 0.1% sodium azide can be added to the specimen as a preservative without affecting the results of the test.

5. Shipped specimens should be packed in compliance with federal and international regulations covering the transportation of etiologic agents.

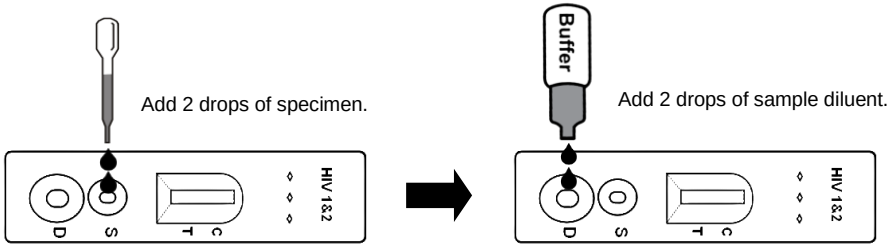
【TEST PROCEDURES】

Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 1 hour.

1. Bring all reagents and specimens to room temperature.
2. Remove the test from the foil pouch and place on a clean dry surface.
3. Identify the test for each specimen or control.

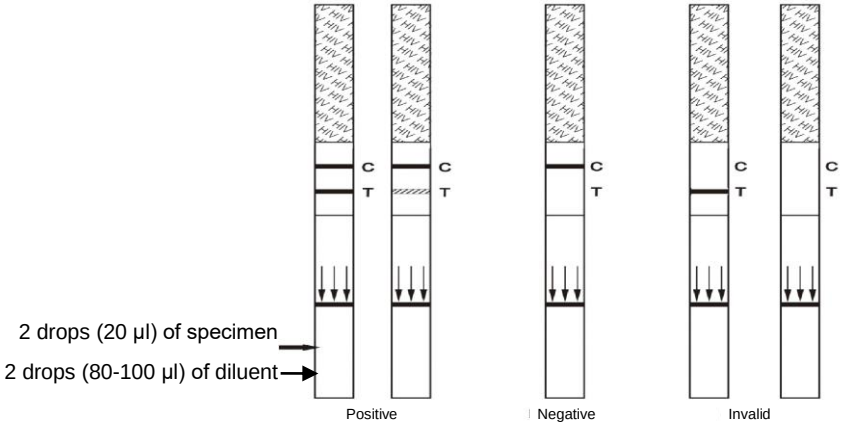
FOR TEST CARDS:

1. Add 2 drops (20μl) of the specimen or control into the sample well on the card using the plastic dropper. Then add 2 drops (80-100 μl) of sample diluent.
2. Interpret test results at 15~20 minutes. Do not read results after 20 minutes.



FOR TEST STRIPS:

1. Add 2 drops (20μl) of specimen to the sample pad behind the (↓↓↓) mark at the bottom of test strip. Then add 2 drops (80-100 μl) of sample diluent.
2. Interpret test results at 15~20 minutes.

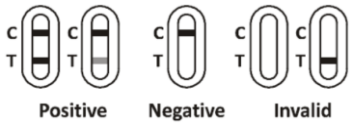


Caution: Use a clean pipette or tip for every sample to avoid cross-contamination.

NOTE:

1. *A positive result may be interpreted early, however read any negative at 15 minutes to ensure sample is negative and not a low concentration of the anti-HIV antibody**. Do not interpret the result after 20 minutes***.
2. *The positive results could appear as soon as 1 minute for a sample with high levels of HIV antibodies.*
3. *No test provides absolute assurance that a specimen does not contain low levels of HIV antigen and/or antibodies to HIV-1/2 such as those present at a very early stage of infection. A negative result does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2 viruses.*

【INTERPRETATION OF TEST RESULTS】



1. *Positive:* Both purplish red test band and purplish red control band appear on the membrane.
2. *Negative:* Only the purplish red control band appears on the membrane. The absence of a test band indicates a negative result.
3. *Invalid:* There should always be a purplish red control band in the control region regardless of test result. If control band is not seen, the test is considered invalid. Repeat the test using a new test device.

Note: *It is normal to have a slightly lightened control band with very strong positive samples as long as it is distinctly visible.*

【PERFORMANCE CHARACTERISTICS】

1. Specificity: 100%

   In an in-house laboratory study, 63 confirmed negative whole blood samples were evaluated with iCARE^{TM} Anti-HIV (1&2) Rapid Test using EIA and Western Blot as reference tests. The study gave 100% specificity for the test.

2. Sensitivity: 100%

   In the above-mentioned study, iCARE^{TM} Anti-HIV (1&2) Rapid Test was evaluated with 32 confirmed whole blood positive samples. The sensitivity of iCARE^{TM} Anti-HIV (1&2) Rapid Test was found to be 100% relative to consensus with EIA results, supported by Western Blot assay.

【LIMITATIONS】

1. Only samples that are not hemolyzed and that are with good fluidity can be used in this test.
2. Fresh samples are best but refrigerated and frozen samples can also be used after thawing and balancing to the room temperature. However for whole blood, frozen samples cannot be used.
3. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.
4. Although a positive result may indicate infection with HIV-1 or HIV-2 virus, a diagnosis of AIDS can only be made on clinical grounds, if an individual meets the case definition for AIDS established by the Centers for Disease Control. For samples repeatedly tested positive, more specific supplemental tests must be performed. Immunochromatographic testing alone cannot be used to diagnose AIDS even if the antibodies against HIV-1/HIV-2 are present in a patient specimen.

【BIBLIOGRAPHY】

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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.

【INDEX OF SYMBOLS】

	Consult instruction for use	IVD	For *in vitro* diagnostic use only	REF	Catalog number		Temperature limit
LOT	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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