HIV 1/2 Rapid Cassette Test

(Whole Blood/Serum/Plasam)

INTENDED USE

The HIV 1/2 One Step Rapid Test is a rapid immunoassay for the qualitative detection of Human Immunodeficiency Virus (HIV) type-1 and/or type-2 in whole blood,serum or plasma.

INTRODUCTION

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). Of all the HIV types, HIV type 1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy people with a high risk for developing AIDS and HIV type 2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals. Both HIV-1 and -2 elicit immune responses in human. Testing human whole blood, serum or plasma for the presence of HIV antibodies has proven an effective aid in determining whether an individual has been exposed to HIV and in screening blood products for possible HIV contamination.

PRINCIPLE

The HIV 1/2 One Step Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The membrane is coated with recombinant HIV antigens on the test line region of the device. When a specimen is applied at one end of the membrane, it reacts with HIV antigen coated gold conjugate in the test. The mixture then migrates chromatographically by capillary action and reacts with the recombinant HIV antigens on the membrane in the test line region.

If the whole blood, serum or plasma contains antibodies to HIV-1 or HIV-2, a coloured line will appear in the test line region, showing a positive result. The absence of the coloured test line indicates that the whole blood,serum or plasma does not contain the anti-HIV antibodies, showing a negative result. A coloured line will always appear at the control line region to serve as a procedural control.

This indicates if the proper volume of specimen has been added and that membrane wicking has occurred.

PRODUCT CONTENTS

The HIV 1/2 One Step Rapid Test contains HIV antigen coated particles and HIV antigens coated on the membrane.

MATERIALS SUPPLIED

1.Test device 2 Pipette dropper 3.Desiccant 4.Buffer 5.Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Specimen collection containers.
3. Lancets (for fingerstick whole blood only)
4. Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
5. Centrifuge (for plasma only)

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C.

If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re- use under any circumstances.
5. Handel all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
7. Humidity and temperature can adversely affect results

SPECIMEN COLLECTION

1. Use either whole blood, serum or plasma.

To collect Fingerstick whole Blood Specimens:

Wash the patients' hand with soap and warm water or clean with an alcohol swab

Puncture the skip with a sterile lancet. Wipe away the first sign of blood

Gently form a rounded drop of blood over the puncture site and add the fingerstick whole blood specimen to test device **using a capillary tube**

Touch the end of capillary tube to blood until filled to approximately 50ul

Place the bulb onto the top end of the capillary tube dispense the whole blood into the specimen well (s) of the test device.

Add the fingerstick whole blood specimen to the test device by **using hanging drops:**

Position the patient's finger so that the drop of blood is just abobe the specimen well (s) of the test device

Allow 2 hanging drops of fingerstick whoel blood to fall into the specimen well (s) of the test device, or move the patient's finger so that the hanging drop touches the specimen (s) . Avoid touching the finger directly to the specimen we (s).

2. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
4. Specimens may be stored at 2-8°C for up to 3 days, prior to testing.
5. For long term storage, specimens should be kept below -20°C.
6. Bring specimens to room temperature prior to testing.
7. Frozen specimens must be completely thawed and mixed well prior to testing.
8. Specimens must not be repeatedly frozen and thawed.
9. If specimens are to be shipped, they should be packed in compliance with local regulations for transportation of aetiological agents.

TEST PROCEDURE

Allow the test, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test on a clean and level surface.

For Serum or Plasma:

Hold the dropper vertically and transfer 1 full drops of serum or plasma (approx. 25 µl) and start the timer. Avoid air bubbles. See illustration below.

For Venipuncture Whole Blood specimens:

Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50ul) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 25ul) and start the time. See illustration below.

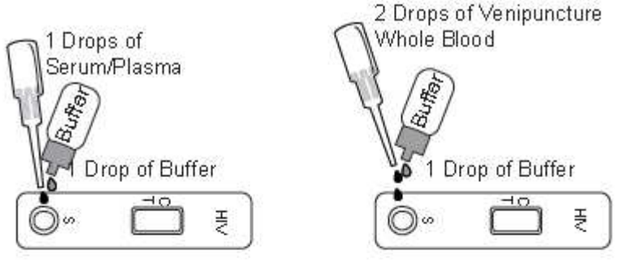
For Fingerstick Whole Blood specimens:

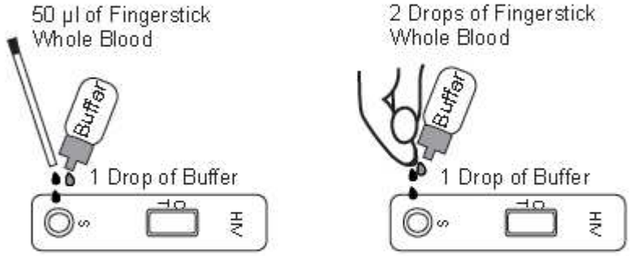
To use a capillary tube: Fill the capillary tube and transfer approximately 50ul of fingerstick whole blood specimen into the specimen well (S) of the test device, then add 1 drop of buffer (approximately 25ul) and start the timer. See illustration below.

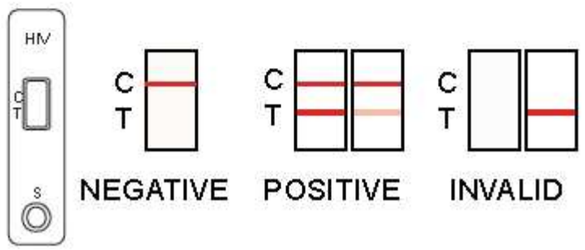
To use hanging drops: Allow 2 hanging drops of fingerstick whole blood specimen (approximately 50ul) to fall into the center of the specimen well (s) of the test device, then add 1 drop of buffer (approximately 25ul) and start the timer. See illustration below

3. Wait for the coloured line(s) to appear. Read results in 15 minutes. *Do not interpret the result after 15 minutes.*

INTERPRETATION OF RESULTS







Positive: Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

Negative: One coloured line appears in the control line region(C). No line appears in the test line region (T).

Invalid: Control line fails to appear.

QUALITY CONTROL

The control line in the control zone is a built-in procedural control in the Test. The control line appearing as specified indicates that the test is properly performed and reagents are functional.

LIMITATIONS

1. The Test is for *in vitro* use only.

2. The Test is a qualitative test.

3. The test is an aid to clinical diagnosis of HIV infection. As with all diagnostic tests, however, result from the Test should not be used as the only basis for a definite diagnosis.

4. The test result should be interpreted together with all other clinical and laboratory findings by a physician before a definite diagnosis can be reached.

5. The positive results should be confirmed by independent confirmatory tests.

6. In cases where the test result is negative while clinical symptoms persist, further consultation with a physician and additional tests of other methods should be followed. A negative result at any time does not preclude the possibility of HIV -1 and/or -2 infection.

Optimal assay performance requires strict adherence to the assay procedures described in this insert sheet. Deviations may lead to aberrant results.

PERFORMANCE CHARACTERISTICS

Sensitivity: The test has been compared with a leading commercial HIV EIA test using clinical specimens. Results showed the HIV rapid device is very sensitive to HIV 1 and/or HIV 2 antibodies.

Specificity: The specificity is comparable to a leading commercial HIV EIA test. The test is highly specific for anti-HIV-1 and/or -2 when compared to a leading commercial HIV EIA test.

The HIV One Step Rapid Test vs. EIA test

Method		EIA		Total
HIV	Results	Positive	Negative	Results
Test	Positive	204	3	207
Device	Negative	0	200	200
Total Results		204	203	407

Relative sensitivity:100%

Relative specificity: 98.5%

Accuracy: 99.0%

REFERRENCE

1. Janssen, RS, Satten, GA, Stramer, SL, Rawal, BD, O'Brien, TR, Weiblen, BJ, Hecht, FM, Jack, N, Cleghorn, FR, Kahn, JO, Chesney, MA and Busch MP. New testing strategy to detect early HIV-1 infection for use in incidence estimates and for clinical and prevention purposes. JAMA (1998) 280(1): 42-48.

2. Vasudevachari M.B., et al. Principles and Procedures of Human Immunodeficiency Virus Serodiagnosis. In Noel R. Rose, et al. (ed.), Manual of Clinical Laboratory Immunology. P. (1997) 788-801. ASM Press. Wash. D.C.