HIV 1.2 Rapid Test Cassette
(Whole Blood/Serum/Plasma)
Package Insert

REF IHI-402	English

A rapid test for the diagnosis of Human Immunodeficiency Virus to detect antibodies to HIV type 1 and type 2 qualitatively in human whole blood, serum or plasma.
For professional in vitro diagnostic use only.

【INTENDED USE】

The HIV1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) type 1 and type 2 in human whole blood, serum or plasma to aid in the diagnosis of HIV infection.

【SUMMARY】

Human immunodeficiency virus (HIV) infection is one of the main causes of morbidity and mortality worldwide, with most of the disease concentrated in sub-Saharan Africa. As the infection often takes hold in adults who are in the prime of their economic productivity, HIV infection has dramatically altered the economies of many countries. [1]
HIV includes a diverse collection of viruses, including HIV type 1 (HIV-1) and HIV-2. HIV-1 is more prevalent and more pathogenic than HIV-2 and is responsible for the vast majority of the global pandemic. [1] The HIV virus is a retrovirus that is able to integrate a DNA copy of the viral genome into the DNA of the host cells.[2]
The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HIV 1 and/or HIV 2 in whole blood, serum or plasma specimen. The test utilizes latex conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1.2 in whole blood, serum or plasma.

【PRINCIPLE】

The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibodies to HIV 1.2 in whole blood, serum or plasma. The membrane is pre-coated with recombinant HIV antigens. During testing, the whole blood, serum or plasma specimen reacts with HIV antigen coated particles in the test. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with recombinant HIV antigen on the membrane in the test line region. If the specimen contains antibodies to HIV 1 and/or HIV 2, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain HIV 1 and/or HIV 2 antibodies, a colored line will not appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains HIV 1.2 recombinant antigens coated particles and HIV 1.2 recombinant antigens coated on the membrane.

【PRECAUTIONS】

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or tests are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use after the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using Whole Blood (from venipuncture or fingerstick), serum or plasma.
- To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:
    - Touch the end of the capillary tube to the blood until filled to approximately 50 μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
  - Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
    - Position the patient's finger so that the drop of blood is just above the specimen well of the test Cassette.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen well on the test Cassette, or move the patient's finger so that the hanging drop touches the center of the specimen well. Avoid touching the finger directly to the specimen well.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.
- Plasma can be obtained by centrifugation for 3 minutes 3000 rpm or by static anticoagulant tube to supernatant.

【MATERIALS】

Materials provided

•Test cassettes •Droppers •Buffer •Package insert
•Sterile lancets (optional) •Alcohol pads (optional) •Capillary tubes (optional)

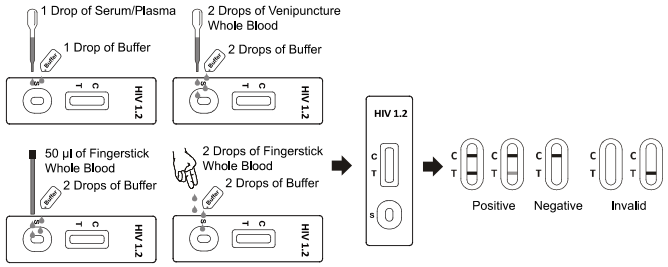
Materials required but not provided

•Specimen collection containers •Timer •Centrifuge

【DIRECTIONS FOR USE】

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

1. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the Cassette on a clean and level surface.
   For **Serum or Plasma** specimen: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 μL) to the specimen well (S), then **add 1 drop of buffer** (approximately 40 μL),and start the timer, see illustration below.
   For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 μL) to the specimen well (S), then **add 2 drops of buffer** (approximately 80 μL), and start the timer. See illustration below.
   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube **and transfer approximately 50μL of fingerstick whole blood specimen** to the specimen well (S) of test Cassette, then **add 2 drops of buffer** (approximately 80 μL) and start the timer. See illustration below.
   - To use hanging drops: Allow **2 hanging drops of fingerstick whole blood specimen** (approximately 50 μL) to fall into the specimen well (S) of test Cassette, then **add 2 drops of buffer** (approximately 80 μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after **20 minutes**.
   Note: It is suggested not to use the vial buffer beyond 6 months after opening the vial.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:*Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T).
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of HIV antibodies present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test Cassette immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this test; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of HIV antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in HIV antibodies can be determined by this qualitative test.
2. The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of HIV antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HIV infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of HIV infection.

【EXPECTED VALUES】

The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial EIA or CMIA HIV kit. The correlation between these two systems is 99.9%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial EIA HIV test, other rapid test or CMIA using clinical specimens. The results show that the relative sensitivity of the HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) is >99.9% and the relative specificity is 99.9%.

Method			HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma)		Agreement
	Result		Positive	Negative	
Predicated Test (EIA or CMIA)	Positive	HIV-1	403	1	99.8% (403/404)
		HIV-2	100	0	>99.9% (100/100)
		Subtype	42	0	>99.9% (42/42)
		Total	545	1	99.8% (545/546)
	Negative	Blood Donations	0	1000	>99.9% (1000/1000)
		Pregnant Women	0	200	>99.9% (200/200)
		Clinical Negative	0	201	>99.9% (201/201)
		Total	0	1401	>99.9% (1401/1401)
Total Result			545	1402	99.9% (1946/1947)

Relative sensitivity: 99.8% (95%CI*: 99.0%~>99.9%);
Relative specificity:100% (95%CI*: 99.8%~100%);
Accuracy: 99.9% (95%CI*: 99.7%~>99.9%). *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: a negative, a low positive, a middle positive and a high positive. One Lot of the HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested over a 10-day period using negative, low positive, middle positive and high positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: a negative, a low positive, a middle positive and a high positive. Three

different lots of the HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested over a 3-day period using negative, low positive, middle positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-Syphilis, anti-EBV, CEA, AFP, PSA, CA15-3, CA19-9, CA125, anti-HAV IgM, anti-HCV, anti-RF, anti-*H.pylori*, anti-CMV IgG, anti-Rubella IgG, anti-TOXO IgG, anti-HSV 1 IgG and anti-HSV 2 IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to HIV negative and positive specimens.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2 g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin:1100 mg/dL
Bilirubin: 1 g/dL	Oxalic Acid: 600 mg/dL

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

1. Deeks, S., Overbaugh, J., Phillips, A. et al. HIV infection. Nat Rev Dis Primers 1, 15035 (2015). https://doi.org/10.1038/nrdp.2015.35
2. Salehi B, Kumar N V A, Şener B, et al. Medicinal plants used in the treatment of human immunodeficiency virus[J]. International journal of molecular sciences, 2018, 19(5): 1459.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests	2°C–30°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE 2934

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Statement: Information about manufacturer of lancet and alcohol pad is placed on the packaging.

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