HIV 1.2 Rapid Test
(Whole Blood)
Package Insert
For Self-Testing

REF IHI-402H
English

A rapid test for the qualitative detection of antibodies to HIV type 1 and type 2 in human Whole Blood.
For self-testing in vitro diagnostic use.

INTENDED USE

The HIV 1.2 Rapid Test (Whole Blood) 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 to aid in the diagnosis of HIV infection.

SUMMARY

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from host cell membrane. Several viral glycoproteins are on the envelope. Each virus contains two copies of positive-sense genomic RNAs. HIV 1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy people with high potential risk for developing AIDS.[1] HIV 2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals.[2] Both HIV 1 and HIV 2 elicit immune response.[3] Detection of HIV antibodies in serum, plasma is the most efficient and common way to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV.[4] Despite the differences in their biological characteristics, serological activities and genome sequences, HIV 1 and HIV 2 show strong antigenic cross-reactivity.[5,6] Most HIV 2 positive sera can be identified by using HIV 1 based serological tests.

The HIV 1.2 Rapid Test (Whole Blood) is a rapid test to qualitatively detect the presence of antibody to HIV 1 and/or HIV 2 in whole blood specimen. The test utilizes latex conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1.2 in whole blood.

PRINCIPLE

The HIV 1.2 Rapid Test (Whole Blood) is a qualitative, membrane based immunoassay for the detection of antibodies to HIV 1.2 in human whole blood. The membrane is pre-coated with recombinant HIV antigens. During testing, the whole blood specimen reacts with HIV antigen coated particles in the test Cassette. 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, HIV-1 recombinant antigens and HIV-2 recombinant antigens coated on the membrane.

PRECAUTIONS

- For self-testing *in vitro* diagnostic use. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or test are handled.
- Do not use the test if pouch is damaged or has been opened.
- Use the test only once. Do not dismantle and touch the test window of the test cassette.
- The kit must not be frozen or used after the expiration date printed on the package.
- Keep out of the reach of children.
- The used test should be discarded according to local regulations

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.

MATERIALS

Materials Provided

1. Test cassette 2. Buffer 3. Sterile lancet 4. Alcohol pad 5. Capillary dropper 6. Package insert 7. Biosafety Bag

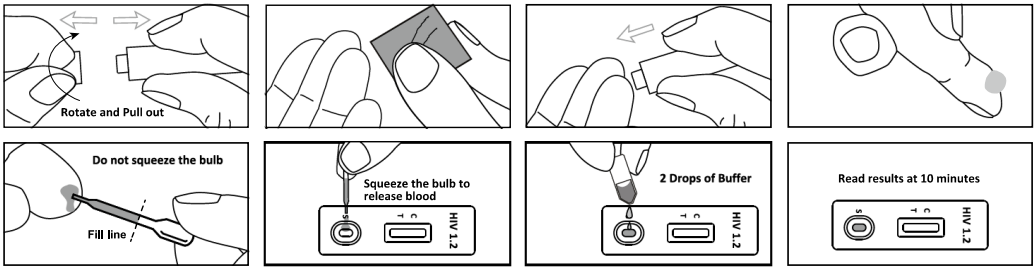
Materials Required But Not Provided

1. Timer

DIRECTIONS FOR USE

Allow the test kit to equilibrate to room temperature (15-30°C) prior to testing.

1. Wash your hands with soap and rinse with clear warm water.
2. Bring the pouch to room temperature before opening it. Open the foil pouch and get out the cassette.
3. Carefully pull off and dispose the released cap of the lancet.
4. Use the provided alcohol pad to clean the fingertip of the middle or ring finger as the puncture site.
5. Press the lancet, on the side from where the cap was extracted; against the fingertip (Side of ring finger is advised). The tip retracts automatically and safely after use.
6. Keeping the hand down, massage the end that was pricked to obtain a blood drop.
7. Without squeezing the capillary dropper bulb, put it in contact with the blood. The blood migrates into the capillary dropper to the line indicated on the capillary dropper.
   You may massage again your finger to obtain more blood if the line is not reached. Avoid air bubbles.
8. Release the blood collected into the sample well(S) of the cassette, by squeezing on the dropper bulb.
9. Wait for the blood to be totally dispensed in the well. Add **2 drops of buffer** into the sample well (S) of the cassette.
10. Wait for the colored line(s) to appear. **Read results at 10 minutes**. Do not interpret the result after 20 minutes.
11. After test is completed, place all the components of the test kit in plastic Biosafety Bag and dispose according to local regulation. Do not reuse any used components of the kit.
12. Wash hands thoroughly after test disposal.



READING THE RESULTS

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.

LIMITATIONS

1. The HIV 1.2 Rapid Test (Whole Blood) is for *in vitro* diagnostic use only.
2. The HIV 1.2 Rapid Test (Whole Blood) will only indicate the presence of HIV antibodies in the whole blood specimen.
3. Although it's rare, false results may occur. If you have concerns that your result may be false, please see a healthcare provider.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. 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.

PERFORMANCE CHARACTERISTICS

Accuracy

The HIV 1.2 Rapid Test (Whole Blood) for self-testing has been compared to a leading commercial HIV ELISA kit using clinical specimens. The results show that the relative sensitivity of the HIV 1.2 Rapid Test (Whole Blood) for self-testing (whole blood) is >99.9% and the relative specificity is 99.7%.

Method		**ELISA**		**Total Results**
HIV 1.2 Rapid Test (Whole Blood)	**Results**	Positive	Negative	
	Positive	508	0	508
	Negative	0	545	545
Total Results		508	545	1053
Relative Sensitivity		>99.9% (95% CI: 99.3%~100%)		
Relative Specificity		>99.9% (95% CI: 99.3%~100%)		
Overall Accuracy		>99.9% (95% CI: 99.7%~100%)		

QUESTIONS & ANSWERS

1. **How can I tell if my test is working?**
   If your test is working you will see a line in the control line area on your test cassette. If there is no line in the control line area, your test did not work, and the test result is invalid. However, the presence of a line in the control line area does not confirm sufficient specimen addition.
2. **Can I get an incorrect or 'false' NEGATIVE result with this test?**
   An incorrect or 'false' NEGATIVE result can occur for any of the following reasons:
   - Incorrectly reading test result.
   - Not following the package insert carefully.
   - If you are on HIV treatment (ARV).
   - If you were very recently infected.
3. **Can I get an incorrect or 'false' POSITIVE result with this test?**
   An incorrect or 'false' POSITIVE result can occur for any of the following reasons:
   - Incorrectly reading test result.
   - Not following the package insert carefully.
   - Having received an HIV vaccine.

MORE INFORMATION

Scan the QR code on the test cassette for more information.

TEST NOW PLATFORM

Scan TEST NOW QR Code below **to report your result** (positive/negative/invalid) and for further information on HIV Self-Test (HIVST).

Note:
The TEST NOW platform is an online one-stop centre that provides HIV-related information including HIVST Kits as well as prevention, treatment and referral services. TEST NOW was developed in collaboration between Malaysia AIDS Foundation (MAF) and MOH.

BIBLIOGRAPHY

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Index of Symbols

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

Hangzhou AllTest Biotech Co.,Ltd.
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