HOMEMED HIV 1/2
RAPID TEST KIT

HOMEMED

For in vitro diagnostic use by healthcare professionals only.

INTENDED USE

The HOMEMED HIV 1/2 Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in whole blood, serum or plasma, to aid in the diagnosis of HIV infection. This test is a **SCREENING** test only. All positive results should be confirmed. For healthcare professional use only.

BACKGROUND

The human immunodeficiency virus (HIV) is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). 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 a potential high risk for developing AIDS.[1] HIV-1 consists of Subtype M and Subtype O. Highly divergent strains of HIV-1 were first recognised in 1990 and grouped provisionally as Subtype O, as this variation has similar glycoprotein markers to HIV-1 but a slight variation to the protein marker. Although rarely compared to HIV-1 and HIV-2, infections caused by Subtype O have so far been identified in Africa (Cameroon), France and Germany. HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals.[2] HIV-1, HIV-2 and Subtype O all elicit immune responses.[3] Detection of HIV antibodies in serum, plasma or whole blood 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, HIV-2 and Subtype O show strong antigenic cross-reactivity.[5,6] Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.
The HOMEMED HIV 1/2 Rapid Test Kit is a rapid test to qualitatively detect the presence of antibodies to HIV-1, HIV 2 and/or HIV-1 (O) in whole blood, serum or plasma specimens. The test kit comes with all essential accessories to perform the test.

PRINCIPLE

The HOMEMED HIV 1/2 Rapid Test Kit detects antibodies to HIV-1/HIV-2 in whole blood, serum or plasma, through visual interpretation of colour development on the internal strip. Recombinant HIV antigens are immobilised on the test region of the membrane. During testing, the specimen reacts with the HIV antigen conjugated to coloured particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there are sufficient HIV-1/HIV-2 antibodies in the specimen, a coloured line will form at the test line region of the membrane. The presence of this coloured line indicates a positive test result, while its absence indicates a negative test result. The appearance of a coloured line at the control line region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS AND MATERIALS

The small pouch contains	**The large pouch contains**
1 HIV Test Device	1 Buffer
	1 Disposable pipette
	1 Sterile safety lancet
	1 Alcohol swab

PRECAUTIONS

For *in vitro* diagnostic use only.

- Do not use after expiration date, indicated on the package. Do not use the test if the foil pouch is damaged.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens or kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing 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 being tested.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

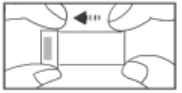
- The kit should be stored at 2-30°C until the expity date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Do not use beyond the expiration date.
- Kits should be kept out of direct sunlight.
- The product is humidity-sensitive and should be used immediately after opened.
- Any test in an improperly sealed pouch should be discarded.

PROCEDURE

IMPORTANT: Test kit, specimen and/or controls should be brought to room temperature (15-30°C) prior to testing. Do not open pouch until ready to perform the test.

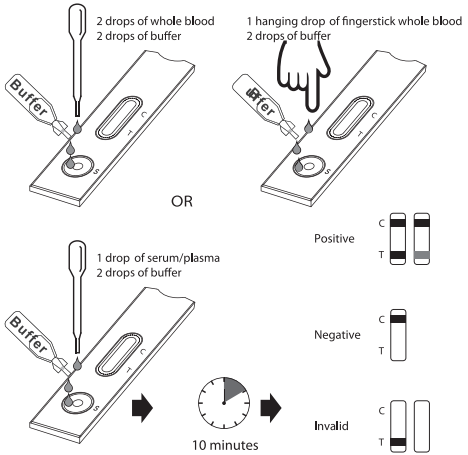
1. Open the small pouch, remove the test device and place it on a clean and level surface.
2. Open the large pouch and remove the buffer ampule, disposable pipette, sterile safety lancet and alcohol swab.
3. Clean the puncture site with the alcohol swab provided.
4. Twist off the cap of the buffer ampule.

5. Carefully remove the cap from the safety lancet. Push the safety lancet firmly against the puncture site until it pricks the finger.



6. **Using whole blood:**
   Transfer 2 drops of whole blood to the specimen well (S) of the device with the provided disposable pipette, then add 2 drops of buffer and start the timer.
   OR
   Allow 1 hanging drop of fingerstick whole blood to fall into the center of the specimen well (S) of the test device, then add 2 drops of buffer and start the timer. Be careful not to touch the specimen well (S) with the finger.

   Using serum/plasma:
   Transfer 1 drop of serum/plasma to the specimen well (S) of the device with the provided disposable pipette, then add 2 drops of buffer and start the timer.
7. Avoid trapping air bubbles in the specimen well (S) and do not add any solution to the result area. As the test begins to work, colour will migrate across the membrane.
8. Wait for the coloured lines to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Refer to the illustration above)

Positive: Two coloured lines appear. One line appears in the control line region (C), and another line 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.

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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Note:

- The colour intensity of the control- and test lines may vary. Any colour change in the test line region should be interpreted as positive, provided a control line is present.
- All positive test results should be confirmed by an alternate method.

QUALITY CONTROL

- Internal procedural controls are included in the test. A coloured 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.
- External controls are not supplied with this kit. 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 OF THE TEST

1. The HOMEMED HIV 1/2 Rapid Test Kit is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HIV in human whole blood, serum or plasma. Neither the quantitative value nor the rate of increase in HIV antibody concentration can be determined by this qualitative test.
2. The HOMEMED HIV 1/2 Rapid Test Kit will only indicate the presence of antibodies to HIV in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1 / HIV-2 infection.
3. For confirmation, further analysis of the specimens should be performed, such as ELISA and/or Western Blot analysis.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. This test is intended for screening purposes only. Results should not be used to determine the serotype of HIV infections.

EXPECTED VALUES

The HOMEMED HIV 1/2 Rapid Test Kit has been compared with leading commercial HIV ELISA tests. The correlation between these two systems is 99.8%.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The HOMEMED HIV 1/2 Rapid Test Kit has correctly identified specimens of a panel and has been compared to leading commercial ELISA HIV tests using clinical specimens. The results show that the relative sensitivity of the HOMEMED HIV 1/2 Rapid Test Kit (Whole Blood/Serum/Plasma) is 99.9% and the relative specificity is 99.9%.

Method		EIA(ELISA)		Total Results
HOMEMED HIV 1/2 Rapid Test Kit	Results	Positive	Negative	
	Positive	871	6	877
	Negative	1	2449	2450
Total Results		872	2455	3327

Relative Sensitivity: >99.9% (99.4%-100.0%)*
Relative Specificity: >99.8% (99.5%-99.9%)*
Overall Agreement: >99.8% (99.6%-99.9%)*
*95% Confidence Interval

LITERATURE REFERENCES

1. Chang SY, Bowman BH, Weiss JB, Garcia RE and White TJ. *The Origin of HIV-1 isolate HTLV-IIIB.* Nature (1993) 3:363:466-9.
2. Arya SK, Beaver B, Jagodzinski L, Ensoli B, Kanki PJ,Albert J, Fenyo EM, Biberfeld G, Zagury JF and Laure F. *New human and simian HIV-related retroviruses possess functional transactivator (tat) gene.* Nature (1987) 328:548-550.
3. Caetano JA. *Immunologic aspects of HIV infection.* Acta Med Port (1991) 4 Suppl 1:52S-58S.
4. 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.
5. Travers K, Mboup S, Marlink R, Gueye-Nidaye A, Siby T, Thior I, Traore I, Dieng-Sarr A, Sankale JL and Mullins C. *Natural protection against HIV-1 infection provided by HIV-2.* Science (1995) 268:1612-1615.
6. Greenberg AE, Wiktor SZ, DeCock KM, Smith P, Jaffe HW and Dondero TJ Jr. *HIV-2 and natural protection against HIV-1 infection.* Science (1996) 272:1959-1960

GLOSSARY OF SYMBOLS

Σ 1	Catalog number	2°C 30°C	Temperature limitation
i	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse

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