HV1.2.O Rapid Test Cassette Single Use Kit (Whole Blood/ Serum/Plasma)

Package Insert

REF IHI-T402H	English

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

【INTENDED USE】

The HIV 1.2.O 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,type 2 and subtype O in whole blood, serum or plasma to aid in the diagnosis of HIV infection.

【SUMMARY】

HIV (Human Immunodeficiency Virus) is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from the 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-1 consists of Subtype M and Subtype O. Highly divergent strains of HIV-1 were first recognized 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 characters, serological activities and genome sequences, HIV-1, HIV-2, and Subtype O show strong antigenic cross-reactivity.5,6

The HIV 1.2.O Rapid Test Cassette (Whole Blood/Serum/ Plasma) is a rapid test to qualitatively detect the presence of antibodies to HIV type 1, type 2, and/or Subtype O in whole blood, serum or plasma specimen.

【PRINCIPLE】

The HIV 1.2.O Rapid Test Cassette(Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibodies to HIV-1, HIV-2, and Subtype O in whole blood, serum or plasma. The membrane is pre-coated with recombinant HIV antigens in the test line regions, T1 and T2. The T1 test line is pre-coated with HIV-1 and Subtype O antigen and the T2 test line is pre-coated with HIV-2 antigen. During testing, the whole blood, serum or plasma specimen reacts with HIV antigen coated particles in the test strip. 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 Subtype O, or HIV-2, one colored line will appear in the test line region; if the specimen contains antibodies to HIV-1 and/or Subtype O, and HIV-2, two colored lines will appear in the test line region. Both indicate a positive result. However, due to possible cross-reactivity, HIV-1, HIV-2 or Subtype O single seropositivity may lead in some cases to appearance of two test lines. If the specimen does not contain HIV-1, Subtype O, and/or HIV-2 antibodies, no colored line will 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.

【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 test cassettes 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.

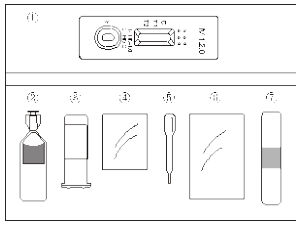
【STORAGE AND STABILITY】

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.

【MATERIALS】

The small pouch contains:

1. Test cassette



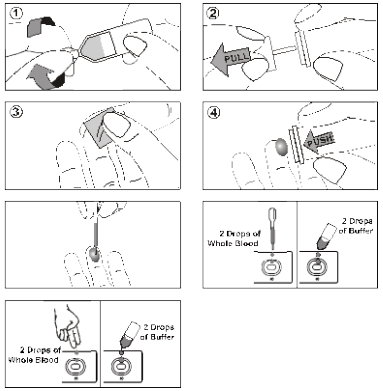
The large pouch contains:

2. Buffer
3. Sterile lancet
4. Alcohol swab
5. Disposable dropper
6. Package insert
7. band-aid

【DIRECTIONS FOR USE】

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

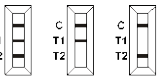
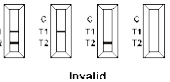
Open the small pouch, remove the test cassette and place it on a clean and level surface. Best results will be obtained if the assay is performed within one hour.



1. Open the large pouch, remove the buffer vial, sterile lancet and other materials. Twist off the tab of the buffer vial without squeezing. Then place it on a clean and level surface.
2. Carefully pull off the sterile lancet cap.
3. Use the provided alcohol swab to clean the puncture site.
4. Push the sterile lancet firmly into the chosen site. Let a large drop of free-flowing blood collect at the puncture site. To increase blood flow, use the thumb and forefinger to gently apply pressure around the puncture site.
5. Add the blood specimen to the test cassette using either the disposable dropper included in the large pouch or hanging drops.
   To use the **disposable dropper**:
   Hold the dropper vertically, aspirate the blood from puncture site and dispense **2 drops of whole blood** from the dropper in the specimen well (S) on the test cassette, then add **2 drops of buffer** and start the timer. Avoid touching the dropper directly to the finger.
   OR
   To use **hanging drops**:
   Turn the hand over and allow **2 hanging drops of whole blood** to fall into the center of the specimen well (S) of the test cassette. **DO NOT TOUCH THE SPECIMEN WELL (S) WITH FINGER.** Then add **2 drops of buffer** into the specimen well (S) and start the timer.
6. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.

NOTE: This test can also be run with serum/plasma specimens according to the following instructions: Add **1 drop of serum or plasma (approximately 25 µL)** to the specimen well (S) of the test cassette, then add **1 drop of buffer**, and start the timer. Read results at 10 minutes. Do not interpret results after 20 minutes.

【INTERPRETATION OF RESULTS】

 Positive	**POSITIVE** **Two or three distinct colored lines appear.** One line should always appear in the control line region (C), and another one or two apparent colored line(s) should appear in the test line region(s) (T1 and/or T2). The intensity of the color in the test line region (T1 and T2) will vary depending on the concentration of HIV antibodies present in the specimen. Therefore, any shade of color in the test line region (T1 and/or T2) should be considered positive.
 Negative	**NEGATIVE** **One colored line appears in the control region (C).** No apparent colored lines appear in the test line regions (T1 and T2).
 Invalid	**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 cassette. If the problem persists, discontinue using the test kit 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 cassette; 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.O 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.O 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. For confirmation, further analysis of the specimens should be performed according to local health authorities' guidelines, such as ELISA and/or Western Blot analysis.
4. As with all rapid test cassettes, 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.
6. Due to possible cross reactivity, the appearance of lines in both T1 and T2 does not necessarily indicate co-infection from HIV-1, HIV-2 and Subtype O.
7. 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.O Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial HIV EIA test. The correlation between these two systems is 99.9%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

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

Method		ELISA		Total Result
HIV 1.2.O Rapid Test cassette (Whole Blood/Serum/Plasma	Results	Positive	Negative	
	Positive	148	2	150
	Negative	0	1728	1728
Total Result		148	1730	1878

Relative sensitivity: >99.9% (95%CI*: 98.0%~100.0%);
Relative specificity: 99.9% (95%CI*: 99.6%~100.0%);
Accuracy: 99.9% (95%CI*: 99.6%~100.0%). *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values 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 medium positive and a high positive. Three different lots of the HIV 1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested over a 3-day period using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The HIV1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by HAMA, RF, HBsAg, HBsAb, HbeAg, HBeAb, HBcAb, HCV, Syphilis, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interference studies

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: 2g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin 1.1g/dL
Bilirubin: 1g/dL	Oxalic Acid: 600mg/dL

【BIBLIOGRAPHY】

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Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalog #
2°C 30°C	Store between 2-30°C	LOT	Lot Number		

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