HIV 1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma) Instructions for use

RightSign®

REF IHIV-C42	English

A rapid test for the diagnosis of human immunodeficiency virus for the qualitative detection of antibodies against HIV type 1, type 2 and subtype O in whole blood, serum or plasma. For in vitro diagnostic use only.

【INTENDED USE】

The HIV 1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma) is a chromatographic immunoassay for the rapid and 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 causative agent of acquired immunodeficiency syndrome (AIDS). The virion is surrounded by a lipid membrane which originates from the cell membrane of the host cell. There are several viral glycoproteins on the envelope. Each virus contains two copies of positive-stranded genomic RNAs. Human immunodeficiency virus type 1 (HIV-1) infection occurs throughout the body and can have dramatic physical effects, such as neurocognitive impairment in the central nervous system.[1] HIV-1 has been isolated in patients with AIDS and AIDS complex and in healthy people at high potential risk of AIDS.[2] HIV-1 consists of subtype M and subtype O. Very different strains of HIV-1 were first identified in 1990 and provisionally grouped as subtype O. This variant has similar glycoprotein markers to HIV-1, but only a slight difference in the protein marker. Infections caused by subtype O are rare compared to HIV-1 and HIV-2 infections. So far, they have been found in Africa (Cameroon), France and Germany. HIV-2 has been isolated in West African AIDS patients and in seropositive asymptomatic individuals.[3] Both HIV-1, HIV-2 and subtype O trigger immune responses.[4] The detection of HIV antibodies in serum, plasma or whole blood is the most efficient and common method to determine whether a person has been infected with HIV and to test blood and blood products for HIV. Despite the differences in their biological properties, serological activities and genome sequences of HIV-1, HIV-2 and subtype O show strong antigenic cross-reactivity.

The HIV 1.2.O Rapid test Cassette (Whole Blood/Serum/Plasma) is a rapid test for the qualitative detection of antibodies against HIV type 1, type 2 and/or subtype O in whole blood, serum or plasma samples.

【PRINCIPLE】

The HIV 1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of antibodies against 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 region 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 the test, the whole blood, serum or plasma sample 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 sample contains antibodies against HIV-1 and/or subtype O or HIV-2, a coloured line appears in the test line region. If the sample contains antibodies against HIV-1 and/or subtype O as well as HIV-2, two coloured lines appear in the test line region. Both options indicate a positive result. Due to possible cross-reactivity of HIV-1, HIV-2 or subtype O seropositivity, two test lines may occur in some cases. If the sample does not contain HIV-1, subtype O and/or HIV-2 antibodies, no coloured line appears in the test region, which indicates a negative result. To serve as a procedure control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and that the membrane had the intended capillary action.

【REAGENTS】

The test contains recombinant HIV type 1, type 2 and subtype O coated particles and HIV type 1, type 2 and subtype O recombinant antigens applied to the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after expiration date indicated on the package.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Do not use the test if its foil pouch is damaged.
- Handle all specimens as if they containinfectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protectionwhen specimens are assayed.
- The used testing materials should be discarded in accordancewith local, state and/or federal regulations.
- Testing should be performed within one hour after opening the pouch. A relative humidity >60% and a temperature > 30 ℃ can particularly affect the results.

【STORAGE AND STABILITY】

Store in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable until the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until use. Once opened, the bottle of buffer solution can be stored for 1.5 months at room temperature or refrigerated (2-30 °C). DO NOT FREEZE. Do not use after the expiry date.

【SPECIMEN COLLECTION AND PREPARATION】

- The HIV 1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma) can be used with whole blood (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 whole blood sample into the test cassette using a capillary tube:
    - Add blood to the end of the capillary tube until it is filled to about 50 µl. Avoid air bubbles.
    - Place the plunger on the top of the capillary tube and then squeeze it to dispense all the blood into the specimen well of the test cassette.
  - Collection of whole blood samples by venipuncture:
    - Collection tubes containing anticoagulants such as K2EDTA, K3EDTA, potassium citrate, lithium heparin, sodium oxalate, sodium heparin and sodium citrate are suitable.
- Preparation of serum/plasma samples:
  - Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-haemolysed samples.
- Testing should be performed immediately after specimen collection. Do not leave the samples at room temperature over a long period of time. Serum and plasma samples can be stored at 2-8 °C for up to 3 days. For long-term storage, the samples 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 samples. 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 totesting. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be transported, they should be packed in compliance with local regulations.

【MATERIALS】

Materials Provided

- Test cassettes
- Buffer (0.02% NaN3 + 0.025% Kanamycinsulfate)
- Pipettes
- Package insert

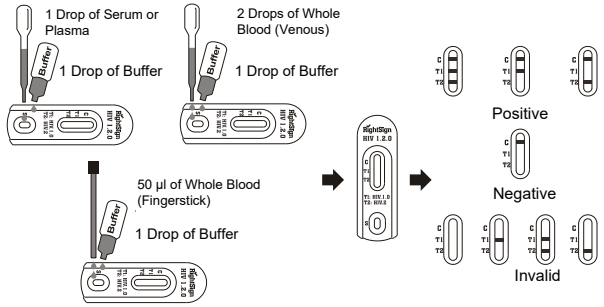
Materials required but not provided

- Collection tubes
- Lancets (only for fingerstick)
- Centrifuge (Serum/Plasma)
- Timer
- Heparinised sample capillaries and dosing flasks (only for fingerstick)

【TEST PROCEDURE】

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean, level surface.
   Serum or plasma samples: Hold the pipette vertically and add **1 drop of serum or plasma** (approx. 25 µl) to the specimen well, then add **1 drop of buffer** (approx. 40 µl) and start the timer. See illustration below.
   Whole blood sample (venipuncture): Hold the pipette vertically and add **2 drops of whole blood** (approx. 50 µl) to the specimen well. **Then add 1 drop of buffer** (approx. 40 µl) and start the timer. See illustration below.
3. Whole blood sample (fingerstick): Fill the capillary tube and add approximately 50 µl whole blood to the specimen well. Then add 1 drop of buffer (approx. 40 µl) and start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(See illustration above)

POSITIVE:* Two or three coloured lines appear. One line should always appear in the control line region (C), and one or two more lines should appear in the test line region (T1 and/or T2) .

*** NOTE:** The intensity of the colour in the test region (T1 and/orT2) may vary depending on the concentration of the HIV antibodies present in the specimen. Therefore, any shade of colour in the test region (T1 and/or T2) should be considered positive.

NEGATIVE: One coloured line appears in the control region (C). No apparant lines appear in the test region (T1 and T2).

INVALID: The control line fails to appear. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band 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.

【QUALITY CONTROL PROCEDURES】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; 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 intended for in vitro diagnostic use only. The test should only be used for the detection of HIV antibodies in whole blood, serum or plasma samples. Neither the quantitative value nor the rate of increase of 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 sample and should not be used as the sole criterion for the diagnosis of HIV infection.
3. For confirmation, further analysis of the samples should be performed according to the guidelines of the local health authorities.
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. The results are not intended to determine the serotype of HIV infection.
6. Because of possible cross-reactivity, the appearance of lines in both T1 and T2 does not necessarily indicate co-infection of 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) was compared with a commercial HIV ELISA test. The correlation between these two systems is 99.6%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The HIV 1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma) correctly identified seroconversion panel samples and was compared to a leading commercial ELISA HIV test using clinical samples. 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			HIV 1.2.O-Rapid Test Cassette		Correlation
	Results		Positive	Negative	
ELISA	Positive	HIV-1	360	0	>99.9% (360/360)
		HIV-2	100	0	>99.9% (100/100)
		HIV-1 Serotypes A-K (non-B-subtypes)	40	0	>99.9% (40/40)
		Total	500	0	>99.9% (500/500)
	Negative	Blood donations	2	1498	99.9% (1498/1500)
		Clinical negative	0	200	>99.9% (200/200)
		Negative samples from pregnant women	0	200	>99.9% (200/200)
		Possibly interfering samples	0	100	>99.9% (100/100)
		Total	2	1998	99.9% (1998/2000)
Total Result			502	1998	99.9% (2498/2500)

Relative sensitivity =500/500= >99.9% (95%CI*: 99.4%~100.0%)
Relative specificity =1998/(1998+2)=99.9%(95%CI*: 99.6%~100%)
Accuracy =(500+1998)/(500+2+1998)=99.9%(95%CI*: 99.7%~99.99%)
* Confidence intervals

Serum vs. Plasma

Sensitivity in seropositive paired serum and plasma samples

A total of 60 serum and plasma seropositive pairs were tested with the HIV1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma).

There was a good correlation of test results between serum and plasma with HIV seropositive samples.

Sample type	Number of samples tested	Correlation (HIV 1.2.O Rapid Test)
Paired Serum	60	>99.9%(60/60)
Paired Plasma	60	>99.9%(60/60)

Specificity in seronegative paired serum and plasma samples

A total of 130 seronegative paired serum and plasma from healthy volunteers were tested with HIV 1.2.O Rapid Test Cassettes (Whole Blood/Serum/Plasma).

There was a good correlation of test results between serum and plasma with HIV seronegative samples.

Sample type	Number of samples tested	Correlation (HIV 1.2.O Rapid Test)
Paired Serum	130	>99.9%(130/130)
Paired Plasma	130	>99.9%(130/130)

Accuracy

Intra Assay

Within-run precision was determined using 10 replicates of four samples: one negative, one low, one medium and one high. The negative, low positive, medium positive and high positive values were correctly detected > 99% of the time.

Inter Assay

Inter-run precision was determined by 10 replicates of four samples: one negative, one HIV-1 low positive, one HIV-1 medium positive and one HIV-2 positive. Three different batches of the HIV 1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma) were tested with negative, HIV-1 low positive, intermediate HIV-1 samples and HIV-2 positive samples. The samples were correctly identified in more than 99% of the cases.

Cross-reactivity

The HIV1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma) was tested with positive HBc, HBs, HCV,HLTV I / II, HEV, rheumatoid factor (RF), CMV, EBV, malaria, SYP and HSV samples. The results showed no cross-reactivity.

Interference Studies

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

Acetaminophen: 20 mg/dL
Acetylsalicylic acid: 20 mg/dL
Ascorbic acid: 2g/dL Creatine: 200 mg/dL Bilirubin: 1g/dL
Caffeine: 20 mg/dL
Gentisic acid 20 mg/dL
Albumin: 2 g/dL
Haemoglobin 1.1g/dL
Oxalic acid: 600mg/dL

None of the substances in the tested concentration caused interference with the test.

【LITERATURE REFERENCES】

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4. Caetano JA Immunologic aspects of HIV infection. Acta Med Port (1991) 4 Suppl 1:52S-58S
5. Sholukh AM, et al. Defense-in-depth by mucosally administered anti-HIV dimeric IgA2 and systemic IgG1 mAbs: complete protection of rhesus monkeys from mucosal SHIV challenge. Vaccine. 2015;33:2086–2095.
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Index Of Symbols

	Read instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	*In vitro diagnostic medical device*		Use by		Do not reuse
2°C 30°C	Store between 2-30	LOT	Batch Code	**REF**	Catalog number
	Do not use if the package is damaged				

Manufacturer
Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou, P. R. China

CE 1434

EC REP
Shanghai International
Holding Corp. GmbH (Europe)
Eiffestrasse 80,
20537 Hamburg, Germany

Reference number: RP5346100
Effective date: 2020-09-15