SPECTRUM

The Creative Approach To Bioscience

HIV Ab 1/2/O

Tri-line Human Immunodeficiency Virus Rapid Test Device
(Whole Blood/Serum/Plasma)

REF: 1168 001 25 test
REF: 1168 002 50 test

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

INTENDED USE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV-1, HIV-2, and Subtype O in whole blood, serum or plasma 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 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 crossreactivity. 5,6 Most HIV-2 positive sera can be identified by using HIV-1 based serological tests. The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibodies to HIV-1, HIV-2, and/or Subtype O in whole blood, serum or plasma specimen.

PRINCIPLE

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (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 the mixture of HIV-1 envelope and core antigens and HIV-2 envelope antigen that are coated on colored 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. 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Do not eat, drink or smoke in the area where the 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.
- 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 device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (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 new sterile lancet for each person. 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 device 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 into the specimen well (S) of the test device.
  - Add the Fingerstick Whole Blood specimen to the test device by using **hanging drops**:
    - Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, nonhemolyzed specimens.
- Testing should be performed immediately after specimen collection. 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.

MATERIALS

Materials Provided

- Test devices
- Droppers
- Buffer
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Centrifuge
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

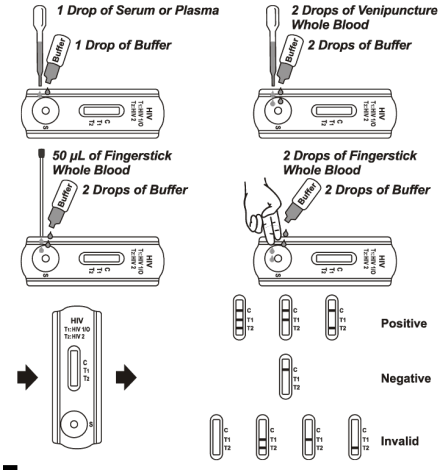
Allow the test device, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
   For **Serum or Plasma** specimens: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µL) and start the timer. See illustration below. For **Venipuncture Whole Blood** specimens: Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50 µL) to the specimen well (S) of the test device,

then add 2 drops of buffer (approximately 80 µL) and start the timer. See illustration below. For **Fingerstick Whole Blood** specimens:

- To use a capillary tube: Fill the capillary tube and **transfer approximately 50 µL of fingerstick whole blood specimen** to the specimen well (S) of the test device, 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 center of the specimen well (S) on the test device, **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 read results after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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).

****NOTE:*** 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: **One colored line appears in the control region (C).** No apparent colored lines appear in the test line regions (T1 and T2).

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.

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 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.

LIMITATION

1. The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) 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 HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) 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, and/or Subtype O 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.
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 nor can it identify the serotype.

EXPECTED VALUES

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) has been compared with leading commercial HIV ELISA tests and/or Western Blot. The correlation between these two systems is 99.8%.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) was evaluated in a multi-center field study, a blood donation center as well as an in-house clinical study. The multi-center study included 1,640 specimens from different countries. There were 1,000 specimens from the blood donation center, and the in-house clinical study included 687 specimens and an HIV Performance Panel that was purchased from a commercial source. The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) was compared to leading commercial ELISA HIV tests and/or Western Blot. Of the 3,327 total specimens, 872 were found positive and 2,455 specimens were found negative by ELISA and/or Western Blot. The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) showed 99.9% relative sensitivity, and 99.8% relative specificity compared to ELISA and/or Western Blot.

HIV 1/2/O Tri-line Rapid Test Device vs. ELISA and/or Western Blot

Method		ELISA and/or Western Blot		Total Results
HIV 1/2/O Tri-line Rapid Test Device	Results	Positive	Negative	
	Positive	871	6	877
	Negative	1	2449	2450
Total Results		872	2455	3327

Relative Sensitivity: 99.9% (99.4-100 %)* Relative Specificity: 99.8% (99.5-99.9%)*
Relative Accuracy: 99.8% (99.6-99.9%)* * 95% Confidence Interval

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, 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 10 independent assays on the same four specimens: a negative, a low positive, medium positive and a high positive. Three different lots of the HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. 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.
2. Chang SY, Bowman BH, Weiss JB, Garcia RE and White TJ. The Origin of HIV-1 isolate HTLVIIIB. Nature (1993) 3:363:466-9.
3. 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.
4. 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.
5. 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.
6. Caetano JA. Immunologic aspects of HIV infection. Acta Med Port (1991) 4 Suppl 1:52S-58S.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
1168 001 1168 002	25 test 50 test

Egyptian Company For Biotechnology (S.A.E.)
Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
Tel: +2 02 4665 1848 - Fax: +2 02 4665 1847
E-mail: info@spectrum-diagnostics.com
www.spectrum-diagnostics.com