HIV Ab 1/2/O
Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)

**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. 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. HIV-1, HIV-2, and Subtype O all elicit immune responses.

**PRINCIPLE**
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.

**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**
- 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.
- To 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.
- To 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.
**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. Within-run precision has been determined by 10 independent replicates of positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

3. 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 values were correctly identified >99% of the time.

**BIBLIOGRAPHY**


**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**

*Statistical 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 centers 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**

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<tr>
<th>Method</th>
<th>ELISA and/or Western Blot</th>
<th>Total Results</th>
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<tbody>
<tr>
<td>HIV 1/2/O Tri-line Rapid Test Device</td>
<td>Positive 871</td>
<td>Negative 6</td>
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<tr>
<td></td>
<td>Positive 998</td>
<td>Negative 3237</td>
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</table>

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 values were correctly identified >99% of the time.

**ORDERING INFORMATION**

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<td>1168 002</td>
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