HIV 1/2
Human Immunodeficiency Virus Rapid Test Device
Package Insert

Cat: IHI-402 **Specimens:** Whole Blood/Serum/Plasma
Version: 02 **Effective Date:** 2015-02

For professional *in vitro* diagnostic use only.

INTENDED USE

The HIV 1/2 Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV 1 and/or HIV 2 in whole blood, serum or 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 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 2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals.[2] Both HIV 1 and HIV 2 elicit immune response.[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 of the differences in their biological characters, serological activities and genome sequences, HIV 1 and HIV 2 show strong antigenic cross-reactivity.[5,6] Most HIV 2 positive sera can be identified by using HIV 1 based serological tests.

The HIV 1/2 Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HIV 1 and/or HIV 2 in whole blood, serum or plasma specimen. The test utilizes latex conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1/2 in whole blood, serum or plasma.

PRINCIPLE

The HIV 1/2 Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibodies to HIV 1/2 in whole blood, serum or plasma. The membrane is pre-coated with recombinant HIV antigens. 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 HIV 2, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain HIV 1 and/or HIV 2 antibodies, a colored line will not 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.

STORAGE AND STABILITY

The kit can be stored 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.

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 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.

SPECIMEN COLLECTION AND PREPARATION

- The HIV 1/2 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.
  - 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 Fingersitck Whole Blood specimen to the test device by using a capillary tube or hanging drop.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed 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 federal regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test devices
- Buffer
- Disposable specimen droppers
- Package insert

Materials Required But Not Provided

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

DIRECTIONS FOR USE

Allow the test device, specimen, buffer, and/or controls to equilibrate to 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.
   Hold the dropper vertically and transfer 2 drops of specimen (approximately 80 μL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 μL) and start the timer.
3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret results after 20 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT:

* A colored band appears in the control band region (C) and another colored band appears in the T band region.

NEGATIVE RESULT:

One colored band appears in the control band region (C). No band appears in the test band region (T).

INVALID RESULT:

Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of HIV antibodies present in the specimen. Therefore, any shade of colored in the test region (T) should be considered positive.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive 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.

LIMITATION

1. The HIV 1/2 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 whole blood, serum or plasma. Neither the quantitative value or the rate of increase in HIV antibody concentration can be determined by this qualitative test.
2. This test 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 and/or 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. If the test result is negative and clinical symptoms persist, additional follow up tests using other clinical methods are recommended. A negative result at any time does not preclude the possibility of HIV 1 and/or HIV 2 infection.

EXPECTED VALUES

The HIV 1/2 Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) has been compared with a leading commercial HIV EIA test. The correlation between these two systems is 99.8%.

PERFORMANCE CHARACTERISTICS

Sensitivity

The HIV 1/2 Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) has been tested by anti-HIV 1 low titer performance panel, anti-HIV 2 performance panel and anti-HIV 1 seroconversion panel (Boston Biomedica, Inc.). And it has also been compared with leading commercial EIA HIV test on clinical specimens. The results show that HIV 1/2 Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is very sensitive to HIV 1 and/or HIV 2 antibodies.

Specificity

The specificity of the test is comparable to a leading commercial HIV EIA test. The HIV 1/2 Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is highly specific for anti-HIV 1 and/or HIV 2 compared to a leading commercial HIV EIA test.

Method		EIA		Total Results
HIV 1/2 Rapid Test Device	Results	Positive	Negative	
	Positive	554	4	558
	Negative	0	1159	1159
Total Results		554	1163	1717

Relative Sensitivity: 99.9% (99.3%-100.0%)*Relative Specificity: 99.6% (99.1%-99.9%)*
Relative Accuracy: 99.8% (99.4%-99.9%)* * 95% Confidence Interval

Precision

Intra Assay

Within-run precision has been determined by using 15 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified 99.5% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same three specimens: a negative, a low positive and a high positive. Three different lots of the HIV 1/2 Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using negative, low positive and high positive specimens. The specimens were correctly identified 99.5% of the time.

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