



HIV 1/2 Human Immunodeficiency Virus Rapid Test Device (Serum / Plasma)

A rapid test for the qualitative detection of antibodies to human Immunodeficiency Virus-1 and/or 2 in serum or plasma.

For In-vitro diagnostic use only

INTENDED USE

The HIV 1/2 Rapid Test Device (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Human Immunodeficiency Virus (HIV) type-1 and/or type-2 in serum or plasma.

SUMMARY

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virus 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 a high potential risk for developing AIDS. HIV-2 has been isolated from West Africa AIDS patients and from seropositive asymptomatic individual. Both HIV-1 AND -2 elicit an immune response. Detection of HIV antibodies in whole blood, serum or plasma 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. Despite the difference in their biological characteristics, serological activities and genome sequences of HIV-1 and -2 show strong antigenic cross-reactivity. Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.

The HIV 1/2 Rapid Test Device (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HIV-1 and/or -2 in serum or plasma specimen. The test utilizes a combination of protein A coated particles and multiple recombinant HIV proteins to selectively detect antibody to the HIV-1 and HIV-2 in serum or plasma.

PRINCIPLE

The HIV 1/2 Rapid Test Device (Serum/Plasma) is a qualitative, membrane-based immunoassay for the detection of antibodies to HIV in serum or plasma. The membrane is coated with recombinant HIV antigens on the test line region of the device. When the serum

or plasma specimen is applied at one end of the membrane, it reacts with Anti-Human IgG Monoclonal antibody coated particles. The mixture then migrates chromatographically towards the other end of the membrane and reacts with the recombinant HIV antigens on the membrane in the test line region. If the Plasma or serum contains antibodies to HIV-1 or HIV-2, a colored line will appear in the test line region, showing a positive result. The absence of the colored line indicates that the Plasma or serum does not contain the anti-HIV antibodies, showing a negative result. A colored line will always appear in the control region to serve as a procedural control indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains protein A coated particles and HIV antigens coated on the membrane.

PRECAUTIONS

For in-vitro diagnostic use only. Do not use after expiration date. Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as though they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposable capillary tubes. Wear protective clothing such as laboratory coats, disposable gloves and eye protectors when specimens are assayed. Humidity and temperature can adversely affect results.

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.

SPECIMEN COLLECTION AND PREPARATION:

The HIV (1/2) Test Device (Serum/Plasma) can be performed using serum or plasma. Only use sodium heparin or lithium heparin tubes to collect plasma specimens. Do not use EDTA collection tubes.

1. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
2. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
3. 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.
4. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

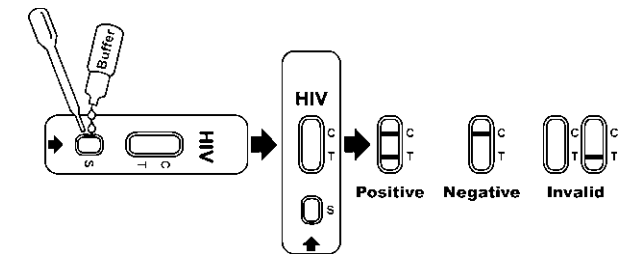
Test devices
Disposable specimen droppers
Buffer
Package insert

Materials Required But Not Provided:

Specimen collection containers
Centrifuge
Timer

DIRECTIONS FOR USE

1. Allow test device, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. 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.
3. Place the test device on a clean and level surface.
4. Hold the dropper vertically and transfer 1 drop of serum or plasma (approx. 25 µl) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 25 µl) and then start the timer. Avoid trapping air bubbles in the specimen well (S). Please see the illustration below.
5. Wait for the red line(s) to appear. The result should be read at 10 minutes. Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: * Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

*NOTE: The intensity of the red color in the test line region (T) may vary depending on the concentration of anti-HIV 1/2 antibodies present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: If no red line appears at control line region (C), the result is invalid and should be repeated. If the problem persists, contact your local distributor or supplier.

Quality control

Internal procedural controls are included in the test. A red line appearing in line control region (C) is considered 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 Rapid Test Device (Serum / Plasma) is for in vitro use only. The test should be used for the detection of antibodies to HIV in serum or plasma specimen.
2. The HIV 1/2 Rapid Test Device (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 and/or-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 -2 infection.

EXPECTED VALUES:

The HIV1/2 Rapid Test Device (Serum / Plasma) has been compared with a leading commercial HIV EIA test. The correction between these two systems is 99%.

PERFORMANCE CHARACTERISTICS

Sensitivity

The HIV 1/2 Rapid Test Device (Serum / Plasma) has passed Anti-HIV1 Low Titer Performance Panel (PRB 106), Anti-HIV1 Seroconversion Panel (PRB610, and Anti-HIV2 Performance Panel (PRF 202) (Boston Biomedica, Inc.). It has also been compared with a leading commercial HIV EIA test using clinical specimens. The results show that HIV 1/2 Rapid Test Device (Serum / Plasma) is very sensitive to HIV 1 and/or HIV2 antibodies.

Specificity

The recombinant antigen used in the HIV1/2 Rapid Test Device (Serum / Plasma) is encoded by genes for the glycoproteins on the viral envelope. The HIV 1/2 Rapid Test Device (Serum / Plasma) is highly specific for anti-HIV-1 and/or-2 compared to a leading commercial HIV EIA test.

HIV Reference Method		
Method	EIA	Total Results

HIV1/2 Test Device	Results	Positive	Negative	
	Positive	75	25	100
	Negative	2	992	994
Total Results		77	1017	1094

Relative Sensitivity: 97.4%
 Relative Specificity: 97.5%
 Accuracy: 97.5%

Precision

Intra-Assay

Within-run precision has been determined by 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 Rapid Test Device (Serum/Plasma) have been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 99.5% of the time.

BIBLIOGRAPHY:

1. Chang, SY, Bowman, BH, Weiss, JB, Garcia, RF and White, TJ. The origin of HIV-1 isolate HTLV-IIIb. Nature (1993)3/363:466-9
2. 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 Tran activator (tat) gene. Nature (1987) 328:548-550
3. Caetano JA Immunologic aspects of HIV infection. Acta MedPort (1991) 4Suppl 1:52S-58S
4. 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
5. Travers, K, Mboup, S, Marlink, R, Gueye-Nidaye, A, Siby, T, Thior, I, Traore, I, Dieng-Sarr, A, Sankale, Ji and Mullins, . Natural protection against HIV-1 infection provided by HIV-2. Science(1995) 268:1612-1615
6. Greenberg, AE, Wiktor, SZ, DeCock, KM, Smith, P, Jaffe HW and Donrero, TJ, Jr. HIV-2 nad natural protection against HIV-1 infection. Science (1996) 272:1959-1960

ATLAS MEDICAL

**William James House, Cowley Rd,
 Cambridge, CB4 4WX, UK
 Tel: ++44 (0) 1223 858 910**

Fax: ++44 (0) 1223 858 524

PPI123A01

Revision C (06.011.2006)