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HIV 1/2 Test Cassette (Whole Blood)

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

For professional in vitro test use only.

Intended Use

The SMI One-Step HIV 1/2 Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) type-1 and/or type-2 in serum, plasma or whole blood.

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 a 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 -2 elicit an 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 the differences in their biological characteristics, serological activities and genome sequences of HIV-1 and -2 show strong antigenic cross-reactivity (5, 6). Most HIV-2 positive sera can be identified by using HIV-1 based serological tests. This is a rapid test to qualitatively detect the presence of antibody to HIV-1 and/or -2 in serum, plasma or whole blood. The test utilizes a combination of multiple recombinant HIV proteins coated particles and multiple recombinant HIV proteins to selectively detect antibody to the HIV-1 and HIV-2 in the specimen.

Principle

This HIV 1/2 test is a qualitative, membrane-based immunoassay for the detection of antibody to HIV in serum, plasma or whole blood. The membrane is coated with recombinant HIV antigens on the test line region of the cassette. When a sample is applied at one end of the membrane, it reacts with recombinant HIV antigen coated particle that has already been applied to the specimen pad at the same end. 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 Serum, Plasma or Whole Blood 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 Serum, Plasma or Whole Blood does not contain the anti-HIV antibodies, showing a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

Reagents

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

Precautions

- For professional *in vitro* 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 disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protectors when specimens are assayed.
- Humidity and temperature can adversely affect results.

Storage & Stability

Store as packaged in the sealed pouch at room temperature. The test Device is stable through the expiration date printed on the label of the pouch. The test Device must remain in the sealed pouch until use. The buffer should be stored at 4-30℃. **DO NOT FREEZE.** Do not use beyond the expiration date.

Materials

Materials provided:

- Test Device
- Instructions
- 20uL transfer pipette (for whole blood)
- Buffer

Materials required but not provided:

- Centrifuge (for serum or plasma)
- 10uL transfer pipette (for serum or plasma)
- Timer

Specimen Collection & Preparation

- The SMI One-Step HIV 1/2 test can be performed using serum, plasma or whole blood.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- 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℃ for up to 3 days. For long-term storage, serum or plasma specimens should be kept below -20℃.
- 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 for transportation of etiologic agents.

Directions for Use:

Allow test device, buffer, serum, plasma or whole blood specimen, and/or controls to equilibrate to room temperature (15-30℃) prior to testing.

1. Remove the cassette from the sealed 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 cassette on a clean and level surface. Transfer 10µl of serum or plasma or 20µl of whole blood to the sample well (labeled S) of the cassette and allow it to soak in for 1 minute.
3. Add 1 drop (approximately 30µl) of buffer to the sample well and start the timer.
4. Wait for the red or pink line(s) to appear. The test line should be read around 10 minutes.

Note: Low titers of anti-HIV 1/2 antibodies might result in a faint line appearing in the test region (T) after a prolonged time. Do not interpret the result after 20 minutes.

Interpretation of Results:

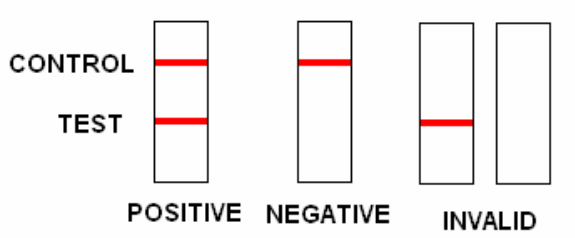
(Please refer to the illustration)

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).

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

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 cassette. If the problem persists, discontinue using the test kit immediately and contact your distributor.

NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of anti-HIV 1/2 antibodies present in the specimen. However, neither the quantitative value nor the rate of increase in anti-HIV 1/2 antibodies can be determined by this qualitative test.



Quality Control

A procedural control is included in the test. A red or pink line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

Limitations

1. This One-Step HIV 1/2 test cassette is for *in vitro* use only. The test should be used for the detection of antibodies to HIV in serum, plasma or whole blood.
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 -2 infections.
3. For confirmation, further analysis of the specimens should be performed, such as ELISA and/or western blot analysis. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. 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 infections.

Performance Characteristics

METHOD COMPARISON: Clinical evaluation was conducted comparing the results obtained using the *AZOG* One-Step HIV 1/2 Test Device (the AZOG test was the precursor to the current SMI test) to FDA approved HIV-1/2 ELISA assay test kits. The study included 94 specimens: both assays identified 54 negative, 25 HIV-1 positive and 12 HIV-2 positive results. The results demonstrated 100% overall agreement (for a percent concordance of $\geq$ 99%) of the *AZOG* One-Step HIV 1/2 Test Device (Serum/Plasma/Whole Blood) when compared to FDA approved HIV-1/2 ELISA Test.

Reference HIV-1/2 ELISA Method

		HIV-1 Positive	HIV-2 Positive	Negative
AZOG Method	Positive	25	12	0
	Negative	0	0	54

SENSITIVITY AND SPECIFICTITY:
The *AZOG* One-Step HIV 1/2 Test Device (precursor to the SMI test) demonstrated a sensitivity of 100% on HIV-1 and HIV-2 samples and a specificity of 100%.

Bibliography

1. Chang, SY, Bowman, BH, Weiss, JB, Garcia, RE 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 transactivator (tat) gene*. Nature (1987) 328:548-550
3. Caetano JA *Immunologic aspects of HIV infection*. Acta Med Port (1991) 4 Suppl 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, JL and Mullins, C. *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 Dondero, TJ, Jr. *HIV-2 and natural protection against HIV-1 infection.* Science (1996) 272:1959-1960.