ANTI HIV – 1/2 Triline Card

IMMUNOPAK

Last update 24-11-2014

INTENDED USE:
The HIV-1/HIV-2 test is a solid phase immunochromatographic assay for the qualitative detection of antibodies against HIV-1 and HIV-2 in human serum/plasma.

INTRODUCTION:
HIV-1 has been isolated from patients with AIDS and AIDS related complex, and from healthy persons with high potential risk of developing AIDS. Patients with HIV-2 are found primarily in parts of West Africa.HIV-1 and HIV-2 are similar in their morphology, cell tropism, host interaction and genetic structure Serological studies have determined that HIV-1 and HIV-2 have multiple common epitopes in core antigens but much less in the envelope antigens.

PRINCIPLE:
Rapid HIV 1 & 2 Test employs chromatographic lateral flow device in a cassette format. Colloidal gold conjugated recombinant antigens (Au-Ag) corresponding to HIV-1 (gp120 + gp41) and HIV-2 (gp-36) are dry-immobilized at the end of nitrocellulose membrane strip. HIV 1 & 2 antigens are bound at the Test Zone (T1 & T2) respectively. Goat Anti-Mouse IgG antibodies are bound at the Control Zone(C). When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If there are HIV- 1 or HIV-2 antibodies in sample, they will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T1 or T2) where they are captured by the HIV 1 or 2 antigens generating a visible purple line. If there are no HIV 1 or HIV 2 antibodies in sample, no purple line is formed in the Test Zone (T).The gold conjugate will continue to migrate alone until it is captured in the Control Zone (C) by the Goat Anti Mouse IgG antibodies aggregating in a purple line, which indicates the validity of the test.

SPECIMEN COLLECTION & STORAGE:
1. The test must be performed using human serum/plasma.
2. If specimens are not immediately tested they should be refrigerated at 4-8ºC.For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use.
3. Specimens containing precipitates may yield inconsistent test results. Such specimens must be clarified prior to assaying.

TEST PROCEDURE:
1. Remove the test device from the foil pouch, and place it on a flat, dry surface.
2. Holding the sample dropper above the test disk, slowly add 1 drop (10µl) of sample in to the sample well, then add 2 drops of assay diluent (about 75 µl).
3. As the test begins to work, you will see purple color moving across the result Window in the center of the Test Disk.
4. **Interpret test results at 15 to 20 minutes. Do not interpret test result beyond 20 minutes.**

PRECAUTION:
1. The HIV-1/HIV-2 Test devices should be stored at 4 to 30°C. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration.
2. Specimen with extremely high concentrations of red blood cells, fibrin should be recentrifuged before use.

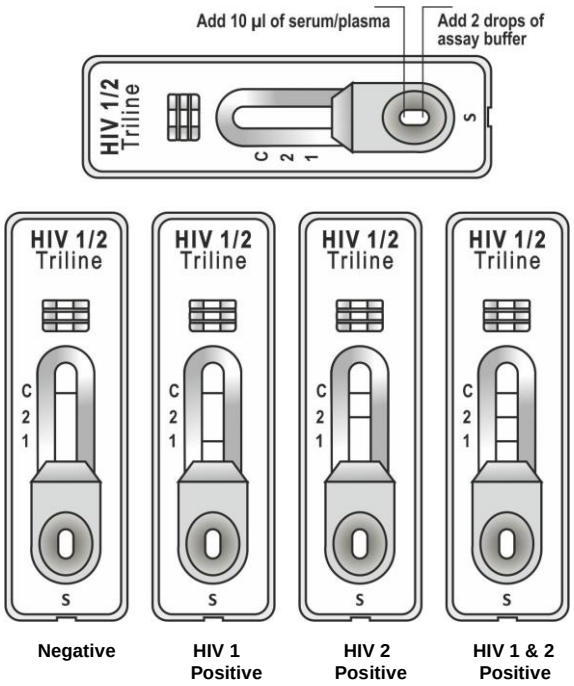
PRESENTATION:

	50 Test
Disposable test cards	50 Card
Assay diluent	1

The Shelf life or expiry of the card is printed on the pouch.

IMPORTANT NOTE:

Please dispense accurately 10µl of Serum Sample with Micropipette or the Sample Dropper provided and add 2 drops of Assay Buffer to avoid False Results and Back Flow.



INTERPRETATION OF RESULTS:
Negative: Only one colored band appears on the control (C) region. No apparent band on the test (T2 and T1) region.

HIV 1 Positive: In addition to a purple colored control (C) band, a distinct darker purple colored band will appear in the test (T1) region. A light purple color band might appear in the T2 region.

HIV 2 Positive: In addition to a purple colored control (C) band, a distinct darker purple colored band will appear in the test (T2) region. A light purple color band might appear in the T1 region.

Both HIV 1 and 2 Positive: In addition to a purple colored control (C) line, a distinct purple colored band will appear in both of the (T1 and T2) region at the same time.

Invalid: A total absence of color in both regions or no colored line appears in the control (C) region is an indication of procedure error and/or test reagent deterioration.

PERFORMANCE EVALUATION:
No standards for performance have yet been established for HIV rapid assays. The HIV-1/HIV-2 test has been tested against a commercially available HIV panel with a commercially available ELISA HIV assay. All samples in the HIV panel detected as positive by the ELISA assay were also detected by Reckon HIV-1/HIV-2 as positive. No cross reactivity or interference was detected from other antigens, lipemic, or icteric samples.

CLINICAL TRIALS:
To establish the sensitivity and specificity of Reckon Diagnostics Anti-HIV (1+2) Serum/Plasma test kit, 505 clinic samples were studied. Another commercially available qualitative test kit was used to compare with Reckon Diagnostic Anti-HIV serum test kit for relative sensitivity and specificity in 505 samples. Only 3 samples were discordant. In turn, the agreement is 99.4%.

LIMITATIONS:
1. Although a positive result may indicate infection with HIV-1 or HIV- 2 virus, a diagnosis of HIV infection can only be made on clinical grounds, if an individual meets the case definition for HIV infection established by the Centers for disease Control. For samples repeatedly testing positive, more specific supplemental tests must be performed. Immunochromatographic testing alone can not be used to diagnose HIV infection even if the antibodies against HIV-1/HIV-2 are present in patient specimen. A Negative result at any time does not preclude the possibility of HIV-1/HIV-2 infection.
2. The HIV-1/2 rapid test is only used for the HIV antibodies screening test, the final diagnosis of HIV infection should be definite by the confirmation test.
3. A “Hook Effect “may be seen with very strong positive samples to weaken the color intensity of test bands. Dilute the sample 5 to 10 times can help improve this sample specific effect.

REFERENCES:
1. Caetano JA immunologic aspects of HIV infection. Acta Med Port (1991) a Suppl 1:52S-58S.
2. Janssen, RS, Satten, GA, Stramer, SL, Rawal, BD, Obrien, T R,Weiblen.BJ,Hecht,FM.
3. Jack, N, Cleghorn, FR, Kahn, JO, Chesney, MA and Busch MP. New testing stra Tegy to detect early HIV-1 infection for use in incidence estimates and for clinical and prevention purpose. JAMA (1998)280(1):42-48.
4. Lee Ratner, William Haseltine, Roberto Patarca, etc.: Complete nucleotide sequence of the AIDS virus, HTL V-lll. Nature VOL.313, 24 January 1985.

3/7, B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnostics.com
Phone: +91·265·2281631
Email: mail@reckondiagnostics.com

RECKON DIAGNOSTICS P. LTD.