HIV (1/2 Triline) Card

(Serum/Plasma)

IMMUNOPAK

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Ref. RDT-HIC.103, 50 Test

INTENDED USE

The HIV 1/2 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 Triline card employs chromatographic lateral flow test 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 region (T1 & T2) respectively. Goat Anti-Mouse IgG antibodies are bound at the Control region(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 an antibody-antigen-colloidal gold complex. These complexes will continue to migrate along the strip until the Test region (T1 or T2) where they are captured by the HIV 1 or 2 antigens generating a visible pink-purple line. If there are no HIV 1 or HIV 2 antibodies in sample, no pink-purple line is formed in the Test region (T1 or T2).The gold conjugate will continue to migrate alone until it is captured in the Control region (C) by the Goat Anti Mouse IgG antibodies aggregating in a pink-purple line, which indicates the validity of the test.

PRESENTATION

	50Test
HIV (1/2 Triline) cards	50 Cards
Assay buffer	1 Vial

PRECAUTION

1. The HIV-1/2 test card 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 re-centrifuged before use.

STORAGE AND STABILITY

HIV 1/2 test card should be stored at 2°C-40°C. The card may be stored at room temperature but not exceeding 40°C in the original sealed pouch. The shelf life or expiry of the card is printed on the pouch as well as on the carton label. The test kit should be kept away from direct sunlight, moisture and heat.

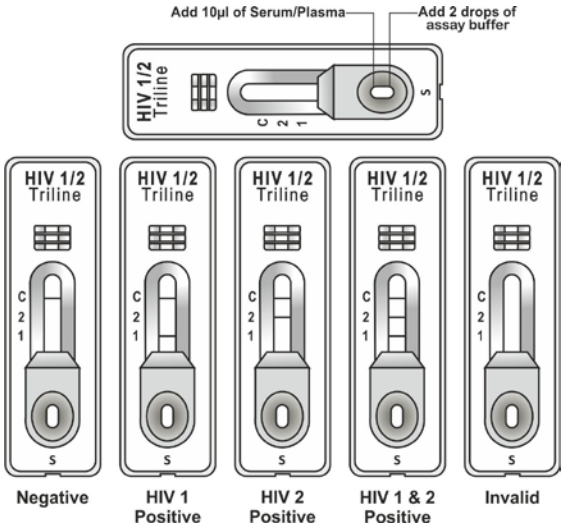
SPECIMEN COLLECTION AND STORAGE

1. The test must be performed using human serum/plasma.
2. If specimens are not immediately tested they should be refrigerated at 2°C-8°C. For storage period 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. Allow the test, specimen and/or control to room temperature prior to testing.
2. Remove one test card from the pouch and place it on a clean, flat surface.
3. With the help of the **Dropper** provided, add one drop of serum/plasma (approx. 10µl) into the sample well, alternatively 10 µl of serum/plasma may be delivered in the sample well if using a **Micropipette.**
4. Add 2 drops (60 µl) of assay buffer (Diluent) into the sample well of the test device. **(If needed add one more drop of assay buffer).**
5. As the test begins to work, you will see pink-purple color moving across the result window in the center of the Test cassette.
6. **Interpret test results at 15 to 20 minutes. Do not interpret test result beyond 20 minutes.**

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 pink-purple line appears on the control (C) region. No apparent line on the test (T1 and T2) region.

HIV 1 Positive: In addition to a pink-purple control (C) line, a distinct pink-purple line will appear in the test (T1) region.

HIV 2 Positive: In addition to a pink-purple control (C) line, a distinct pink-purple line will appear in the test (T2) region.

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

Invalid: A total absence of pink-purple line in both regions or no pink-purple line appears in the control (C) region is an indication of procedure error and/or test reagent deterioration. Repeat the test with a new cassette.

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.

SENSITIVITY & SPECIFICITY

To establish the sensitivity and specificity of Reckon Diagnostics Anti-HIV (1/2) Triline (Serum/Plasma) test kit, 905 clinical 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 905 samples. Only 2 samples were discordant. In turn, the agreement is 99.8%.

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

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