RapidTech Plus HIV 1+2

INTENDED USE

The RapidTech Plus HIV 1+2 Test is a qualitative test for the detection of antibodies to Human Immunodeficiency Virus Type I and 2 (HIV-1+2) in serum specimen.

SUMMARY

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). A lipid envelope that is derived from host cell membrane surrounds the virus. 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 of developing AIDS. HIV-2 has been isolated from West African AIDS patients and from seropositive aymptomatic individuals. Both HIV-1 and -2 elicit immune response. Detection of HIV antibodies in 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. A test is considered positive when an assay such as ELISA, if a or western blots is reactive. Despite the differences in their biological characteristics serological activities and genome sequences, 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 RapidTech Plus HIV 1+2 Test is a rapid test to qualitatively detect the presence of antibody to HIV-1 and/or HIV-2 in serum or plasma specimens. The test utilizes a combination of protein A-colloidal gold conjugate and multiple recombinant HIV proteins to selectively detect antibody to the HIVs in serum or plasma. The genes for envelope protein (gp36/41) encode the recombinant HIV proteins used in the test kits.

This test is designed as an **initial screening test** for HIV-1+2 antibodies. All positive specimens must be confirmed with Western Blot or other qualified EIA assays.

PRINCIPLE

This assay is a chromatographic immunoassay (CIA), containing filter membrane coated with HIV-1 and 2 specific antigens and coloured gold colloidal reagents labeled with HIV-1 and 2 specific antigens. There are two regions, test region and control region, an the membrane of the test strip. The T line, a purple colour band in the test region of membrane, will be developed rapidly (from 30 seconds to 15 minutes) when antibodies to HIV-1 and/or 2 are present in the specimen. If antibodies to HIV-1 and/or 2 are not present, no T line will be developed in the test region. The C line, a purple colour band In the control region of the test, should always appear regardless of the presence of antibodies to HIV-1 + 2, serving as an internal qualitative control of the test system.

REAGENT AND MATERIALS SUPPLIED

1. RapidTech Plus HIV 1+2 test cards
2. Reaction buffer.

STORAGE CONDITIONS

The kit should be stored at refrigeration (2º to 8ºC) or room temperature (l5º to 30ºC) in the sealed pouch with a desiccant packet for the duration of the shelf life. Freeze or expose the kit and the Reaction Buffer to temperatures over 30°C may cause malfunction.

SPECIMEN COLLECTION

Following standard clinical procedure to collect specimen. Only plasma specimen from EDTA anticoagulated blood should be used. Serum specimens can be stored at room temperature (18º to 25ºC) for 4 hours, at 2º to 8ºC for 48 hours, and longer at –20ºC or lower temperature. Repeated freezing and thawing specimens are not recommended for this assay.

Any sediment in specimens should be removed by centrifugation. Avoid using any turbid or hemolysed specimens.

PRECAUTION

1. Handle all specimens with caution as they may be capable of transmitting infection.
2. Do not pipette by mouth.
3. Do not smoke, eat or drink in areas where specimens are handling.
4. Wear disposable gloves while handling specimens and thoroughly wash hands afterwards.

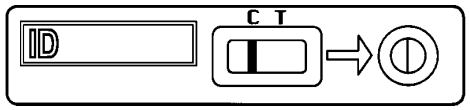
TEST PROCEDURE

Test device together with patient's whole blood, serum sample, control or reference materials should be brought to room temperature (18º to 30ºC) prior to testing.

1. Remove the test device from its protective pouch. Label the device with patient or control identifications
2. Add 1 drop, about 40 µL plasma or serum into the sample well. Allow the specimen to be absorbed completely.
3. Add 6 free falling drops of Reaction Buffer from the Reaction Buffer squeeze bottle
4. Read results in 15 minutes. Do not interpret test results after 30 minutes.

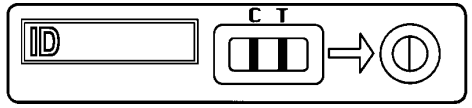
INTERPRETATION OF RESULTS

NEGATIVE: Only one red coloured band appears on the control line region. No apparent red coloured band on the test line region.



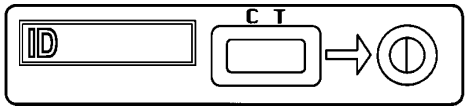
Negative

POSITIVE: In addition to the control band, a distinct red coloured band also appears on the test line region.



Positive

INVALID: When no coloured bands appear on either region, the test should be voided since an improper test or deterioration of reagents probably occurred.



Invalid

QUALITY CONTIOL

The procedural control is included in the test. A coloured band appearing on the control region of the membrane indicates proper performance and reactive reagents.

LIMITATIONS

1. This HIV rapid test is for in vitro use only. This test should be used for the detection of antibodies to HIV in serum or plasma samples
2. This kit is not recommended for testing pooled specimen or other body fluids other than plasma and serum specimen.
3. This kit is not recommended for blood transfusion testing. More sensitive method, such as ELISA, should be used for this purpose.
4. This assay alone cannot be used to diagnose AIDS even if the antibodies against HIV-1 + 2 are present. For repeatedly reactive specimens, it is recommended that more specific supplemental tests and clinical evaluation on patient's situation should be done before making a final diagnosis.
5. A negative test result at any time does not preclude the possibility of exposure to, or infection with HIV-1+2.

PERFORMANCE CHARACTERISTICS

Sensitivity

RapidTech Plus HIV1+2 test has passed Anti-HIV 1 low Titer Performance Panel (PRB106), Anti-HIV 1 Seroconversion Panel J (PRB910), and Anti-HIV-2 Performance Panel (PRF202) from Boston Biomedica, Inc. and has also been compared with leading commercial EIA HIV test on clinical samples. The result show that rapid test is very sensitive to HIV-1 and/or -2 antibodies.

Specificity

Genes for the glycoproteins on the viral envelope (gp36/41) encode the recombinant antigen used in the HIV rapid test. The HIV rapid test is highly specific for anti-HIV-1 and/or HIV-2 comparable to a leading commercial EIA HIV test with a relative specificity of 99.1%.

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens containing negative, low positive and high positive samples. The negative and positive values were correctly identified 99.55 of the time.

Inter-Assay

Between-run precision has been determined by using the same three specimens of negative, low positive and high positive of antibodies to HIV in 15 independent assays and with three different lots of HIV rapid test reaction cards over a 3 month period. The negative and positive values were correct 99.5% of the time.

REFERENCES

1. Popovic M, et al, Detection, isolation, and continuous production of cytopathic retroviruses (HTLV-111) from patients with AIDS and pre-AIDS. Science 1984; 497-500.
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4. Clavel F, HIV-2. the West African AIDS virus. AIDS 1987; 1: 135-140.
5. Plot P, et al., AIDS, An intemauonal perspective, Science 1988; 239: 573- 579.
6. Provisional Public Health Service Interagency recommendations for screening donated blood and plasma for antibody to the virus causing Acquired Immunodeficiency Syndrome, MNW 34:1-5.

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