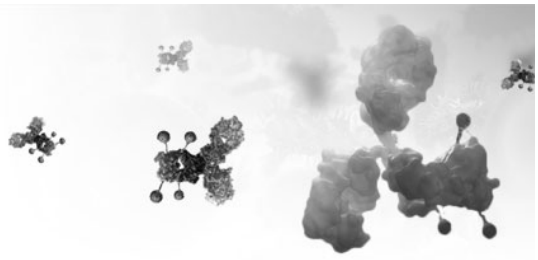

HIV 1&2 Rapid Test (DTS553)

This product is for research use only and is not intended for diagnostic use.

PRODUCT INFORMATION

Size	40T

Intended Use

The HIV 1/2 Rapid Test is a rapid immunochromatography assay for the qualitative detection of antibodies to HIV 1/2 virus in human serum, plasma and whole blood.

Principles of Testing

HIV 1/2 utilizes the principle of immunochromatography, a unique two site immunoassay on a membrane. In HIV 1/2, a mixture of highly purified recombinant antigen of gp 41, recombinant p24 combined to subtype O specific synthetic peptide, representing HIV-1 and recombinant gp 36 representing HIV-2 are coated on the membrane in the test region and anti-rabbit antiserum in the control region. As the test sample flows through the membrane assembly within the test device, the colored - HIV 1/2 specific recombinant antigen-colloidal gold conjugate complexes with HIV antibodies in the sample. This complex moves further on the membrane to the test region where it is immobilized by the HIV 1/2 Specific recombinant antigens coated on the membrane leading to formation of the colored band which confirms a positive test results. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any along with rabbit IgG colloidal gold conjugate move further on the membrane and are subsequently immobilized by the anti-rabbit antibodies coated on the membrane at the control region, forming a colored band. This control band serves to validate the test results.

Reagents And Materials Provided

HIV kit has the following components:
A. 40 individually pouched devices comprising of:
1. Test Device: Comprising of HIV 1/2 specific recombinant antigen-colloidal gold conjugate, Rabbit IgG-colloidal gold conjugate,
membrane assembly predispensed, with HIV 1/2 specific recombinant antigen and anti rabbit antiserum coated at the test region

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and the control region respectively.

2. Disposable Plastic Dropper.

3. Desiccant Pouch.

B. Sample Running Buffer : 2 bottles. (0.1 M Tris buffer with 1.5% Tween 20 and 0.1 % Sodium azide)

Storage

The sealed pouches in the test kit and the sample running buffer may be stored between 4°C to 30°C for the duration of the shelf life as indicated on the pouch and the vial. After first opening of the sample running buffer vial, the buffer is stable until the expiration date, if kept at 4°C to 30°C. Do not freeze the kit or components.

Specimen Collection And Preparation

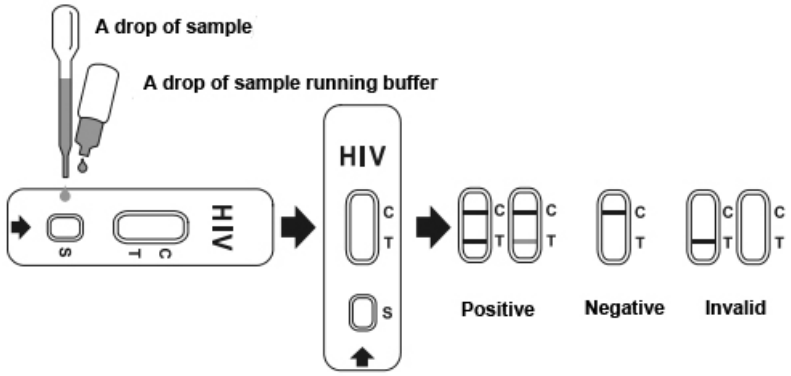
Whole blood sample: using finger, ear lobe peripheral blood or venous blood, blood samples without anticoagulant treatment should be uesd immediately. Anticoagulation should be used within 24h.

Assay Procedure

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the device. Once opened, the device must be used immediately.
3. Add one drop of sample (25 ul) using the sample dropper provided, in the well marked "S".
4. Add a drop of sample running buffer (40 ul) in the well marked "S".

Interpretation Of Results

At the end of 15 minutes read the results as follows:
Negative: Only one colored band appears on the control region'C'.
Positive: In addition to the control band, a distinct colored band also appears on the test region 'T'.
The test should be considered invalid if neither the test band not the control band appears. Repeat the test with a new device.



Precision

Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive HIV samples.

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No variations were found in the outcome of the different tests.

Precautions

1. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Sample running buffer contains sodium azide (0.1%). Avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.
7. If the pouch of the test device is damaged, discard the device and take a new one for the test.
8. For professional use only, not to be used by the general public.
9. Negative result may not have detected recently acquired HIV infection.
10. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of
registered medical practitioner.

Limitations

1. The test detects the presence of antibodies to HIV in the specimen and hence should not be used as the sole criterion for the
diagnosis HIV infection.
2. As with all diagnostic tests, the result must be correlated with clinical findings. If the test result is negative and suspicion stillexists, additional follow-up testing using other clinical methods is recommended.
3. A negative result at any time does not preclude the possibility of exposure to or infection with HIV.
4. A positive test result, even a weak positive, must be verified with a confirmation test.

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