

Rapid Anti-HIV(1&2) TEST

(Whole Blood/Serum/Plasma)

FOR IN VITRO DIAGNOSTIC USE ONLY

INTENDED USE

THE RAPID ANTI-HIV(1&2) TEST IS A COLLOIDAL GOLD ENHANCED, RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFFICIENCY VIRUS (HIV) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS A SCREENING TEST, AND ALL POSITIVES MUST BE CONFIRMED USING AN ALTERNATE TEST SUCH AS WESTERN BLOT. THE TEST IS INTENDED FOR HEALTHCARE PROFESSIONAL USE ONLY.

SUMMARY

The human immunodeficiency virus (HIV) is the causative agent of acquired immune deficiency syndrome (AIDS). The general method of detecting infection with HIV is to observe the presence of antibodies to the virus by an EIA method followed by confirmation with Western Blot. The Rapid Anti-HIV(1&2) Test is a simple, visual qualitative test that detects antibodies in human whole blood serum or plasma. The test is based on immunochromatography and can give a result within 15 minutes.

PRINCIPLE OF THE PROCEDURE

The assay starts with a sample applied to the sample well and add provided sample diluent immediately. The HIV antigen -colloidal gold conjugate embedded in the sample pad reacts with the HIV antibody present in serum or plasma sample forming conjugate/HIV antibody complex. As the mixture is allowed to migrate along the test strip, the conjugate/HIV antibody complex is captured by a second antibody immobilized on the membrane forming a colored test band in the test region. A negative sample does not produce a test band due to the absence of conjugate/HIV antibody complex. The antigens used in the conjugate test are recombinant proteins that correspond to highly immunoreactive regions of HIV1 and HIV2. A colored control band in the control region appears at the end of test procedure regardless of test result. The control band indicates that the colloidal gold conjugate is functional.

REAGENTS AND MATERIALS SUPPLIED

- Test card individually foil pouched with a desiccant
- Plastic dropper
- Sample Diluent
- Safety lancet
- Alcohol swab
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Positive and negative controls

STORAGE AND STABILITY

The kit must be stored at 2 - 30°C.

WARNINGS AND PRECAUTIONS

1. All positive results must be confirmed by an alternative method.

2. Treat all specimens as though potentially infectious. Wear gloves and protective clothing when handling specimens.
3. Devices used for testing should be autoclaved before disposal.
4. Do not use kit materials beyond their expiration dates.
5. Do not interchange reagents from different lot of kit.

BEFORE TESTING

1. Bring the HIV test device, sample diluent, alcohol swab, safety lancet, plastic tube.
2. Remove test card from the sealed pouch.

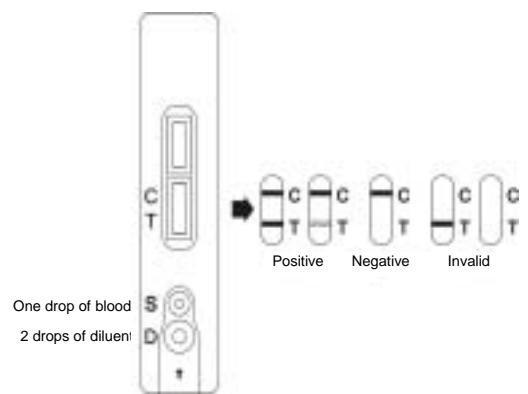
SPECIMEN COLLECTION

1. Clean the area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce with the safety lancet.

Note: Whole blood, serum or plasma collected following by regular clinical Laboratory procedures can also be used for this test.

ASSAY PROCEDURE

1. With the plastic tube to collect blood.
2. Dispense one drop of blood to the "S" well of the test card using the plastic dropper according to the figure.
3. Add three drops of Sample Diluent to the "D" well immediately after the specimen is added.
4. Interpret test results at 15 minutes.



READING THE TEST RESULTS

1. **Positive:** Both purplish red test band and purplish red control band appear on the membrane. The lower the antibody concentration, the weaker the test band.
2. **Negative:** Only the purplish red control band appears on the membrane. The absence of a test band indicates a negative result.
3. **Invalid:** There should always be a purplish red control band in the control region regardless of test result. If control band is not seen, the test is considered invalid. Repeat the test using a new test device.

Note: It is normal to have a slightly lightened control band with very strong positive samples as long as it is distinctly visible.

PERFORMANCE CHARACTERISTICS

1. Specificity

Clinical studies were done to evaluate the performance of the Rapid Anti-HIV(1&2) Test In USA and Canada. In both studies, 119 confirmed negative serum samples (USA: 63 samples and Canada: 56 samples) were tested by the Rapid Anti-HIV(1&2) Test using EIA and Western Blot as reference tests. Both studies gave 100% specificity for the test.

2. Sensitivity

In both the studies mentioned above, the Rapid Anti-HIV(1&2) Test was evaluated with 64 confirmed positive serum samples (32 samples each in USA and Canada). The sensitivity of the Rapid HIV(1&2) Test was found to be 100% relative to consensus with EIA results, supported by Western Blot assay.

LIMITATIONS

1. Only samples that are clear and with good fluidity can be used in this test.
2. Fresh samples are best but frozen samples can be used. If a sample has been frozen, it should be allowed to thaw in a vertical position. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.

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