DRG® One Step Anti-HIV (1&2) (RAP-4578)

Revised 19 April 2010

INTENDED USE

THE ONE STEP ANTI-HIV(1&2) TEST IS A COLLOIDAL GOLD ENHANCED, RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY 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 One Step 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 1 to 15 minutes.

PRINCIPLE OF THE PROCEDURE

The assay starts with a sample applied to the sample well. A recombinant HIV antigen conjugated to colloidal gold embedded in the sample pad reacts with the HIV antibody present in blood, serum or plasma forming conjugate/HIV antibody complex. As the mixture is allowed to migrate along the test strip, the conjugate/HIV antibody complex is captured by recombinant HIV antigen immobilized on a membrane forming a colored test band in the test region. A negative sample does not produce a test band due to the absence of colloidal gold 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. This control band is the result of colloidal gold conjugate binding to the anti-HIV antibody immobilized on the membrane. The control band indicates that the colloidal gold conjugate is functional.

REAGENTS AND MATERIALS SUPPLIED

Each Kit contains:

- 25 Test cards /50 test strip individually foil pouched with a desiccant
- 1 bottle of Sample Diluent
- 1 Package Insert
- Sample dispensing plastic droppers with each test pouch.(for card only)

MATERIALS REQUIRED BUT NOT PROVIDED

- Positive and negative controls

STORAGE AND STABILITY

The kit must be stored at 2 - 30°C.

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WARNINGS AND PRECAUTIONS

1. ALL positive results must be confirmed by an alternate 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 one kit lot to another.

SAMPLE COLLECTION

Whole Blood

1. Collect whole blood specimens following regular clinical laboratory procedures.
2. Heparinized capillary tubes must be used for collecting whole blood samples. Do not use hemolyzed blood samples.
3. Whole blood specimens should be used immediately after collection.

Serum or plasma

1. Collect serum or plasma specimens following regular clinical laboratory procedures.
2. Storage: A specimen should be refrigerated if not used the same day of collection. Specimens should be frozen if not used within 3 days of collecting. Avoid freezing and thawing the specimens more than 2-3 times before using. 0.1% of sodium azide can be added to specimen as preservative without affecting the results of the assay.

ASSAY PROCEDURE

Do not open pouch until you are ready to test the sample.

For test cards:

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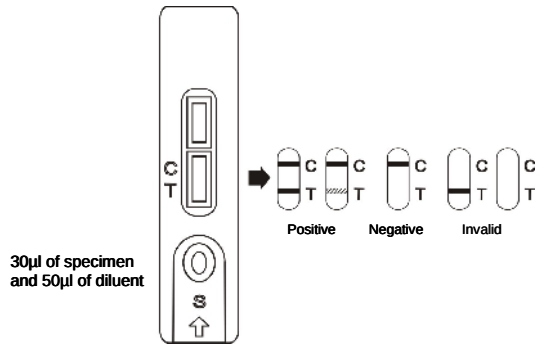
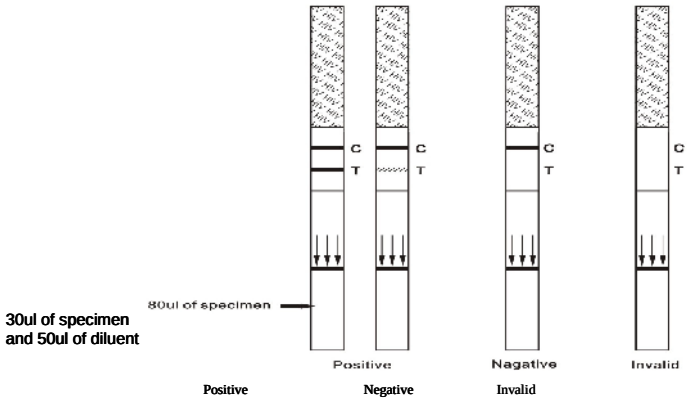
1. Bring all reagents and specimens to room temperature.
2. Remove the test card from the foil pouch and place on a clean dry surface.
3. Identify the test card for each specimen or control.
4. Dispense 30µl（1 drop） of the specimen or control into the sample well on the card using the plastic dropper. Then dispense 50µl（1 drop） of sample diluent.
5. Interpret test results at 15 minutes.



For test strips:

1. Bring all reagents and specimens to room temperature.
2. Remove the test strip from the foil pouch and place on a clean dry surface.
3. Identify the test strip for each specimen or control.
4. Apply 30µl of specimen to the sample pad behind the (↓↓↓) mark at the bottom of test strip. Then dispense 50µl (1 drop) of sample diluent.
5. Interpret test results at 15 minutes.



Caution: Use a clean pipette or tip for every sample to avoid cross-contamination.

6. A positive result may be interpreted early, however read any negative at 15 minutes to ensure sample is negative and not a low concentration of the anti-HIV antibody**. Do not interpret the result after 20 minutes**.

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It is recommended to run a known positive control and negative control in each performance to ensure the assay procedure.

Notes:

1. *The positive results could appear as soon as 1 minute for a sample with high levels of HIV antibodies.*
2. *Do not interpret result after 20 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

   In an in-house laboratory study, 63 confirmed negative whole blood samples were evaluated with One Step Anti-HIV (1&2) Test using EIA and Western Blot as reference tests. The study gave 100% specificity for the test.

2. Sensitivity

   In the above-mentioned study, One Step Anti-HIV (1&2) Test was evaluated with 32 confirmed whole blood positive samples. The sensitivity of One Step Anti-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 not hemolyzed and that are with good fluidity can be used in this test.
2. Fresh samples are best but refrigerated samples can be used. Frozen samples can not be used.
3. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.

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