

ONE STEP Anti-HIV(1&2) Tri-line Test

(Whole Blood/Serum/Plasma)

FOR IN VITRO DIAGNOSTIC USE

INTENDED USE

THE ADVANCED QUALITY™ ONE STEP ANTI-HIV(1&2) TRI-LINE 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(1&2) 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 Advanced Quality One Step Anti-HIV(1&2) Tri-line Test is a simple, visual qualitative test that detects antibodies in human 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 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 line in the test region. A negative sample does not produce a test line 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 line in the control region appears at the end of test procedure regardless of test result. This control line is the result of colloidal gold conjugate binding to the anti-HIV antibody immobilized on the membrane. The control line indicates that the colloidal gold conjugate is functional.

Two test lines are coated on the membrane; on T1 region recombinant gp41, p24, and gp120 are immobilized; most of HIV I or HIV II infected samples give positive results on T1 region; On T2 region a recombinant gp36 is coated, which is HIV II specific, and a positive result appearing on T2 region indicates a HIV positive samples.

The ADVANCED QUALITY™ Anti-HIV(1&2) Tri-line Test is a immunochromatographic (rapid) test for the qualitative detection of antibodies of all isotypes (IgG,IgM,IgA) specific to HIV-1 including subtype O and HIV-2 simultaneously, in human whole blood, serum or plasma.

REAGENTS AND MATERIALS SUPPLIED

- Test cards/ test strips individually foil pouched with a desiccant
- Sample diluent

- Package Insert
- Sample dispensing plastic dropper with each test pouch.(for card only)

MATERIALS REQUIRED BUT NOT PROVIDED

- Pipettes to transfer specimen.
- Positive and negative controls

STORAGE AND STABILITY

1. Store unused kit at 2 - 30°C.
2. Store test cards/strips at 2 - 30°C and away from direct sunlight.

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 AND STORAGE

Whole Blood:

1. Collect whole blood specimens following regular clinical laboratory procedures.
2. Heparinized capillary tubes treated with anticoagulant must be used for collecting blood samples.
3. Whole blood specimens should be used immediately after collection.

Serum or Plasma:

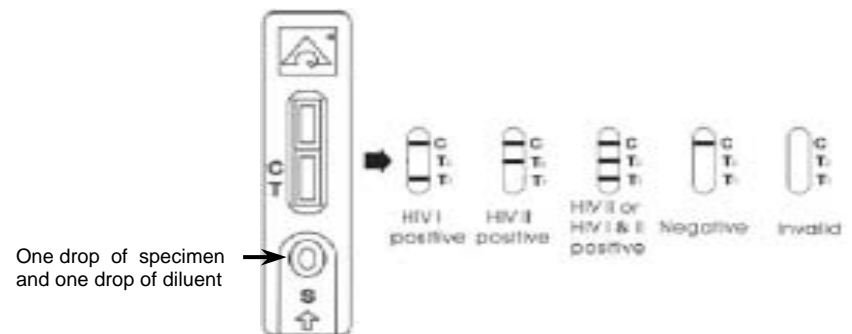
1. Collect serum or plasma specimens following regular clinical laboratory procedures.
2. Storage: A specimen should be refrigerated if not used the same day of collection. Specimens should be frozen if not used within 3 days of collecting. 0.1% of sodium azide can be added to specimen as preservative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

ASSAY PROCEDURE

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

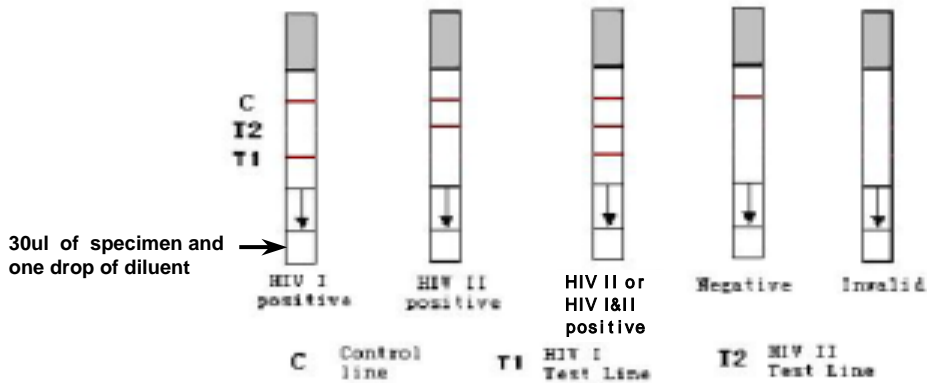
For test cards:

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 one drop (30µl) of the specimen or control into the sample well on the card Using the plastic dropper provided, then add one drop of sample diluent into the same well.
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 at least 30µl of specimen to the sample pad behind the (↓↓↓) mark at the bottom of test strip, then add one drop of sample diluent at the same place.
5. Interpret test results at 15 minutes.



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

NOTE: 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.**

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

READING THE TEST RESULTS

1. **Positive:** Control line and at least one test line appear on the membrane. The appearing of T1 test line indicates a HIV I positive result, the appearing of T2 test line indicates a HIV II positive result, the appearing of both T1 and T2 test lines indicate a HIV II or HIV I&II positive result. The lower the antibody concentration is, the weaker the test line is.
Regarding the positive results for HIV-1 and HIV-2 in one patient, it is possible for reason as follows:
 - 1) There is the homology in the amino acid sequence of HIV type-1 and type-2.
 - 2) So, it is possible that the test results appear the positive results for HIV-1 and HIV-2 in one patient, simultaneously.
2. **Negative:** Only the control line appears on the membrane. The absence of a test line indicates a negative result.

3. **Invalid:** There should always be a control line in the control region regardless of test result. If control line 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 line 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 samples were evaluated with Advanced Quality One Step Anti-HIV(1&2) Tri-Line Test using EIA and Western Blot as reference tests. The study gave 100% specificity for the test.

2. Sensitivity

In the above-mentioned study, Advanced Quality One Step Anti-HIV(1&2) Tri-Line Test was evaluated with 32 confirmed positive samples. The sensitivity of Advanced Quality One Step Anti-HIV(1&2) Test was found to be 100% relative to consensus with EIA results, supported by Western Blot assay.

WARNINGS

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 and frozen samples can be used.
3. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.

LIMITATIONS OF THE TEST

Although a positive result may indicate infection with HIV-1 or HIV-2 virus, a diagnosis of AIDS can only be made on clinical grounds, if an individual meets the case definition for AIDS established by the Centers for Disease Control. For samples repeatedly tested positive, more specific supplemental tests must be performed. Immunochromatographic testing alone cannot be used to diagnose AIDS even if the antibodies against HIV-1/HIV-2 are present in a patient specimen. A negative result at any time does not preclude the possibility of HIV-1/HIV-2 infection.

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