

 **ADVANCED QUALITY™ One Step Anti-HIV(1&2) Test**
(Whole blood / Serum / Plasma)

FOR IN VITRO DIAGNOSTIC USE

INTENDED USE

THE ADVANCED QUALITY™ ONE STEP ANTI-HIV(1&2) TEST IS A COLLOIDAL GOLD ENHANCED, ONE STEP 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 Advanced Quality 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 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 cards 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

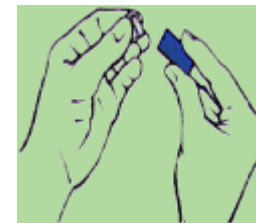
1. Bring the HIV test device, sample diluent, alcohol swab, safety lancet, plastic tube.
2. Remove test card from the sealed pouch.
3. Read the instruction for safety lancet.

Instruction for safely lancet

1. BEFORE YOU BEGIN

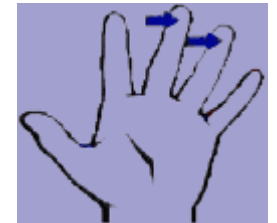
- Wash hands with soap and warm water and dry thoroughly.
- Lay out the lancets, open alcohol prep pad, sterile gauze pad, and bandage.

2. REMOVE CAP FROM LANCET



Remove plastic cap from lancet. Once the cap is removed do not touch the exposed surface of the lancet until you are ready to use.

3. CLEAN SELECTED FINGER



Choose either the middle or ring finger of your non-dominant hand. To help increase blood flow rub hands together for 10 seconds, then allow hand to hang at your side for 30 seconds.

4. CHOOSE AND CLEAN SELECTED FINGER 5. PLACE HAND ON FLAT SURFACE



Use alcohol prep to further clean the finger.



Place the chosen hand with the palm side up on a flat surface or table. Place the lancet slightly off center near the tip of your finger (do not use exact center).

6. PRESS LANCET FIRMLY ON FINGER 7. GENTLY MILK HAND AND FINGER



Hold lancet steady against your finger. Press lancet firmly against your finger. Observe the finger to see if blood is flowing.



Holding hand downward, gently milk hand starting at the wrist and working down to the base of the finger to produce blood. DO NOT squeeze just the finger as this blocks blood flow.

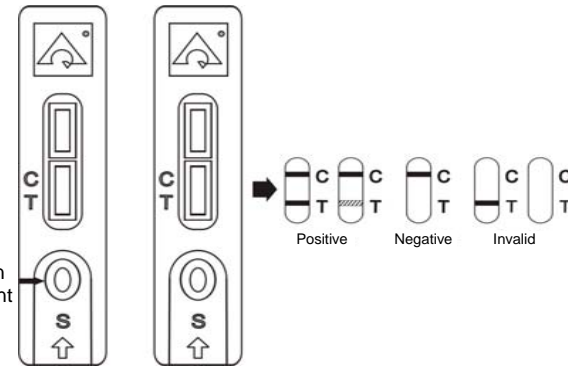
Note: Whole blood, serum or plasma collected following regular clinical Laboratory Procedures can be used for this test.

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 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.



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

Clinical studies were done to evaluate the performance of Advanced Quality One Step 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 Advanced Quality One Step HIV 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, Advanced Quality One Step Anti-HIV(1&2) Test was evaluated with 64 confirmed positive serum samples (32 samples each

in USA and Canada). 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.

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.

BIBLIOGRAPHY

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