



ADVANCED QUALITY™ Rapid Anti-HIV(1&2) Test
(urine)

FOR IN VITRO DIAGNOSTIC USE

INTENDED USE

THE ADVANCED QUALITY™ 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 URINE. THIS TEST IS A SCREENING TEST, AND ALL POSITIVES MUST BE CONFIRMED USING AN ALTERNATE TEST SUCH AS WESTERN BLOT.

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 Rapid Anti-HIV(1&2) Test is a simple, visual qualitative test that detects antibodies in human urine. The test is based on immunochromatography and can give a result within 15 minutes.

PRINCIPLE OF THE PROCEDURE

The assay starts with a diluent prepared sample applied to the sample well. The HIV antigen -colloidal gold conjugate embedded in the sample pad reacts with the HIV antibody present in urine 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 / test strips individually foil pouched with a desiccant
- Plastic dropper
- Sample Diluent
- 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.

SPECIMEN COLLECTION

1. urine may be used in this test.
2. urine specimens should be refrigerated at 2-8°C up to 3 days.
3. Shipped specimens should be packed in compliance with federal and international regulations covering the transportation of etiologic agents.
4. 0.1% sodium azide can be added to the specimen as a preservative without affecting the results of the assay.

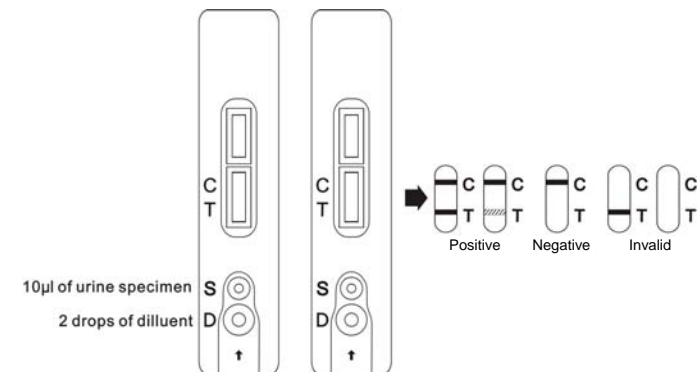
BEFORE TESTING

1. Bring the device/strips, sample diluent, and specimens to room temperature(18~25°C).
2. Remove test card/test strips from the sealed pouch.

ASSAY PROCEDURE

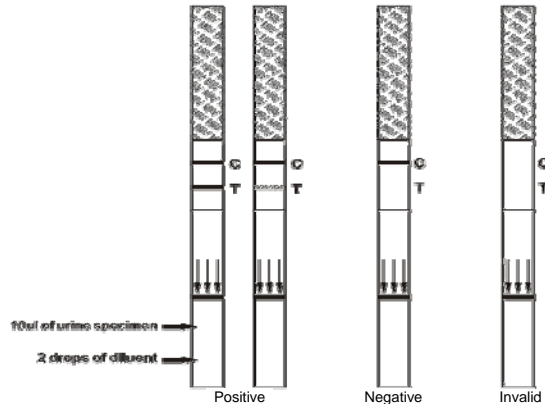
For test cards:

1. Dispense 1 drop (10 µl) of urine specimen to the "S" well of the test card using the plastic dropper provided according to the figure.
2. Add two drops of Sample Diluent to the "D" well *immediately* after the specimen is added.
3. Interpret test results at 15 minutes.



For test strips:

1. Dispense 1 drop (10 µl) of urine specimen to the upper edge of the sample pad of the test strip by using the plastic dropper.
2. Add two drops of Sample Diluent to the lower edge of the sample pad *immediately* after the specimen is added.
3. Interpret test results at 15 minute.



Notes:

1. Applying sufficient amount of sample diluent is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of diluent to sample well.
2. The positive results could appear as soon as 1 minute for a sample with high levels of HIV antibodies.
3. 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.

LIMITATIONS

1. Only samples that are clear and with good fluidity can be used in this test.
2. For research use only.

BIBLIOGRAPHY

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