

 **ADVANCED QUALITY™ Rapid Anti-HCV Test**
(Serum / Plasma)

FOR IN VITRO DIAGNOSTIC USE

INTENDED USE

THE ADVANCED QUALITY™ RAPID ANTI-HCV TEST IS A COLLOIDAL GOLD ENHANCED, RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS (HCV) IN HUMAN 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 general method of detecting infection with HCV 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-HCV 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 15 minutes.

PRINCIPLE OF THE PROCEDURE

The assay starts with a sample applied to the sample well and add provided sample diluent immediately. The HCV antigen -colloidal gold conjugate embedded in the sample pad reacts with the HCV antibody present in serum or plasma sample forming conjugate/HCV antibody complex. As the mixture is allowed to migrate along the test strip, the conjugate/HCV antibody complex is captured by an antibody-binding protein A immobilized on a membrane forming a colored test band in the test region. A negative sample does not produce a test line due to the absence of colloidal gold conjugate/HCV antibody complex. The antigens used in the test are recombinant proteins corresponding to highly immunoreactive regions of HCV. 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 a anti-HCV antibody immobilized on the membrane. The control line indicates that the colloidal gold conjugate is functional. The absence of the control band indicates that the test is invalid.

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.

SAMPLE COLLECTION AND STORAGE

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.

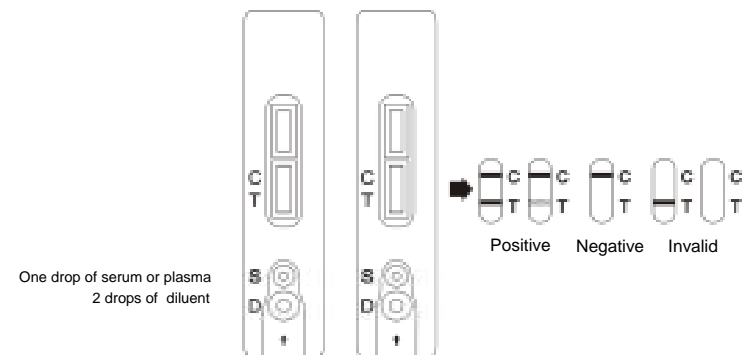
BEFORE TESTING

1. Bring the device, sample diluent, and specimens to room temperature.
2. Remove test card from the sealed pouch.

ASSAY PROCEDURE

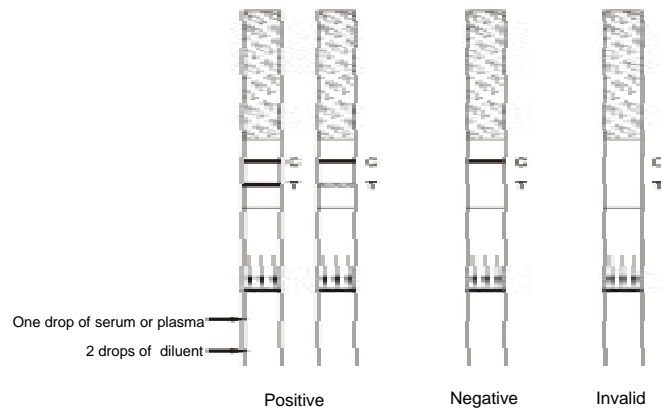
For test cards:

1. Dispense 1 drop(10µl) of serum or plasma 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 (10µl) of serum or plasma to the upper edge of the sample pad of the test strip using the plastic dropper provided according to the figure.
2. Add two drops of Sample Diluent to the lower edge of the sample pad after the specimen is added.
3. Interpret test results at 15 minutes.



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 HCV 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.

PERFORMANCE CHARACTERISTICS

1. Specificity:

The specificity of the Advanced Quality Rapid Anti-HCV Test is based on clinical studies using confirmed negative serum samples from blood bank and hospital patients in USA (66 samples) and China (90 samples). The studies were performed comparing the results from Advanced Quality Rapid Anti-HCV test and that from Abbott's ELISA as a reference test. The overall specificity was found to be 97 - 99%.

2. Sensitivity:

In the same studies mentioned above, Advanced Quality Rapid Anti-HCV Test was evaluated with 61 confirmed positive serum samples (USA: 31 samples and China: 30 samples). All 61 samples were found reactive.

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.
3. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.

BIBLIOGRAPHY

1. Choo Q-L, Weiner AJ, Overby LR, Kuo G, Houghton M. Hepatitis C virus: the major causative agent of viral non-A, non-B hepatitis. *Br Med Bull* 1990;46:423-41.
2. Alter HJ, Purcell RH, Shih JW, Melpolder JC, Houghton M, Choo Q-L, Kuo G. Detection of antibody to hepatitis C virus in prospectively followed transfusion recipients with acute and chronic non-A, non-B hepatitis. *A Engl J Med* 1989;321: 1494-500.
3. Esteban JI, Gonzalez A, Hernandez JM et al. Evaluation of antibodies to hepatitis C virus in a study of transfusion-associated hepatitis. *N Engl J Med* 1990;323:1107-12.
4. Alter HJ, Holland PV, Morrow AG et al. Clinical and serological analysis of transfusion-associated hepatitis. *Lancet* 1975;2:838-41.