WANTAI

Rapid Test for Antibody to Hepatitis C Virus (Colloidal Gold Device)

FOR SERUM / PLASMA / WHOLE BLOOD SAMPLES

INSTRUCTIONS FOR USE

Catalog No. WJ-1310

INTENDED USE

This test is a single use, rapid device intended for qualitative detection of antibodies to hepatitis C virus (HCV) in human serum/ plasma/ whole blood samples. It is intended for use in medical institution as an aid for the diagnosis and management of patients related to infection with HCV and for screening of blood donors, or blood products as well.

SUMMARY

Hepatitis C virus (HCV) is an envelope, single stranded positive sense RNA (9.5 kb) virus belonging to the family of Flaviviridae. Six major genotypes and series of subtypes of HCV have been identified. Isolated in 1989, HCV is now recognized as the major cause for transfusion associated non-A, non-B hepatitis. The disease is characterized with acute and chronic form although more than 50% of the infected individuals develop severe, life threatening chronic hepatitis with liver cirrhosis and hepatocellular carcinomas.

Serological evidence of HCV infection may be obtained by testing for HCV antigens or antibodies in serum of individuals suspected of hepatitis C infection. Antibodies to HCV can be detected throughout virtually the total infection period. Therefore, the use of highly sensitive antibody assays is the primary approach in serodiagnosis of HCV infection.

PRINCIPLE OF THE ASSAY

This test employs chromatographic lateral flow device in a strip format. Colloidal gold conjugated recombinant antigens (Au-Ag) corresponding to HCV core, NS3/4 and NS5 regions are dry-immobilized at the end of nitrocellulose membrane strip. HCV antigens are bond at the Test Zone (T) and rabbit anti-HCV monoclonal antibodies are bond at the Control Zone (C). When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in sample, HCV antibodies will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) zone where they are captured by the HCV antigens generating a visible red line. If there are no HCV antibodies in sample, no red line is formed in the Test Zone (T).The gold conjugate will continue to migrate alone until it is captured in the Control Zone(C) by the rabbit anti-HCV antibodies aggregating in a red line, which indicates the validity of the test.

COMPONENTS

10 Tests

- 10 Test Cassettes;
- 3ml×1 vial of Sample Diluent;
- 1 Package Insert.

Materials required but not provided: clock or timer, safety lancets, alcohol prep-pad, micro pipette, disposable pipette tips, specimen collection container, centrifuge, biohazard waste container, sterile gauze or cotton.

SPECIMEN COLLECTION AND STORAGE

- Serum, plasma or whole blood samples can be used for this test. Plasma or whole blood can be collected with an anticoagulant, e.g. EDTA, citrate, heparin, etc. Whole blood can be collected from venous blood or fingertip blood.
- Samples containing suspended fibrin or aggregates, severe hemolysis samples (hemoglobin >400mg/L) cannot be used for this test. Icteric samples (bilirubin <1.71mmol/L) and hyperlipemia samples (triglyceride <170mmol/L) can be used for this test.
- Serum and plasma samples can be stored at 2-8°C for 7 days, If not required for testing soon, should be frozen at -15°C or lower for long term storage, and avoid more than 2 times of multiple freeze-thaw cycles. Allow samples to reach room temperature (about 30 minutes) and mix well before testing.
- Whole blood samples should be tested immediately after collection, cannot be used for testing after long time storage.

STORAGE AND STABILITY

This test can be stored at room temperature (2-30°C, do not freeze!) for 18 months from the date of manufacture (see label on the pouch). Cassettes must be used within 20 minutes at room temperature after opening the pouch, avoid exposure in humid air for long time.

PRECAUTIONS AND SAFETY

This test is for *In Vitro Use Only* IVD

FOR PROFESSIONAL USE ONLY

- All the waste and sample should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
- Allow the test cassette to reach room temperature (appropriately 30 minutes) before opening the pouch.
- Once taking the cassette out of the pouch, carry out your testing as early as possible (no more than 20 minutes) to avoid moisture. The nitrocellulose membrane can absorb water, which can affect the test chromatography performance.
- Add too much or not enough sample into sample well on Cassette could affect the test results.
- Make sure that the cassette is placed on flat surface during the testing.
- To obtain accurate assay results, the test results should be read at 10-15 minutes. The results obtained after 15 minutes is invalid. Do not read the results in dim light.
- Make sure that the test is within the indicated validity.
- Do not use beyond expiration date.
- If automatic pipette is used, calibrate it frequently to assure the accuracy of dispensing. Use different disposal pipette tips for each specimen in order to avoid cross-contaminations.
- Do not modify the test procedure.
- Do not reuse the test cassettes. Autoclave before disposal.
- A test giving an invalid result should be repeated.
- Blood that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.

PROCEDURE

1. Pipette 50µl of serum, plasma or whole blood into the sample well (S) on the cassette.
2. Immediately add 1 drop (about 50µl) of sample diluent buffer.
3. Place the cassette on flat surface and read the results within 15 minutes.

INTERPRETATION OF RESULTS

Quality Control: One red band will always appear in the Control Zone (C) indicating the validity of the test. If no red band appears, the test is invalid - discard the test and repeat with new sample and new cassette.

Positive Results: One red band in the Test Zone (T) indicates that antibodies to HCV have been detected with this test.

Negative Results: No red band appears within 15 minutes in the Test Zone (T) indicating that no antibodies to HCV have been detected with this test. However, this does not exclude the possibility from infection with HCV.

POSITIVE **NEGATIVE** **INVALID**

The positive result obtained with this HCV rapid test alone cannot be the final diagnosis of HCV infection. Any positive result must be interpreted in conjunction with the patient clinical history and another laboratory testing results. Follow-up and supplementary testing of any positive samples with other analytical system (e.g. ELISA or PCR) is required to confirm any positive result.

PERFORMANCE CHARACTERISTICS

Total 1002 serum samples were tested with this HCV rapid test and compared with a reference kit. The results show that 16 samples were inconsistent between this rapid test and the reference kit, the positive accordance rate is 99.43%, negative accordance rate is 97.25%, total accordance rate is 98.40%, Kappa value is 0.97. Then the 16 samples were tested again with third-party kit, the results show that 8 out of 16 samples were consistent with this HCV rapid test.

No cross reactivity was observed with specimens from patients infected with HIV, TP, HAV, HBV and HEV.

LIMITATIONS

- Negative results do not exclude the possibility of HCV exposure or infection. Infection through recent exposure (seroconversion) to HCV may not be detectable. For positive results, band intensity cannot be used to evaluate the HCV antibody levels. A test giving an invalid result should be repeated.
- If, after retesting of the initially reactive samples, the test results are negative, these samples should be considered as non-repeatable (false positive) and interpreted as negative. As with many very sensitive rapid diagnostic tests, false positive results can occur due to the several reasons, most of which are related but not limited to the quality of the sample and exposition of the test to humidity. For more information contact Beijing Wantai technical support for further assistance.
- This rapid test is intended ONLY for testing of individual serum, plasma or whole blood samples. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
- This is a qualitative assay and the results cannot be used to measure antibodies concentrations.

REFERENCES

1. Alter HJ., Purcell RH, Holland PV, et al. (1978) Transmissible agent in non-A, non-B hepatitis. Lancet I: 459-463
2. Choo Q-L,Weiner AJ, Overby LR, Kuo G, Houghton M. (1990) Hepatitis C Virus: the major causative agent of viral non-A, non-B hepatitis. Br Med Bull 46: 423-441

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