WANTAI

Rapid Test for Hepatitis B Virus Surface Antigen (Colloidal Gold Device)

FOR SERUM / PLASMA / WHOLE BLOOD SAMPLES

INSTRUCTIONS FOR USE

Catalog No. WJ-1110

INTENDED USE

This test is a chromatographic immunoassay for qualitative detection of the surface antigen of hepatitis B virus (HBsAg) in human serum, plasma or whole blood samples. It is intended for use in medical institution as an aid for diagnosis and management of patients related to infection with hepatitis B virus as well for screening of blood donors or blood products.

SUMMARY

Hepatitis B virus (HBV) is an enveloped; double-stranded DNA virus belonging to the Hepadnaviridae family and is recognized as the major cause of blood transmitted hepatitis together with hepatitis C virus (HCV). Infection with HBV induces acute or chronic liver diseases and in some cases that can lead to cirrhosis and carcinoma of the liver. Hepatitis B surface antigen or HBsAg, which was previously described as Australia antigen is the most important protein of the envelope of Hepatitis B Virus. The surface antigen contains the determinant “a”, common to all known viral subtypes, immunologically distinguished in two distinct subgroups (ay and ad). HBV has 10 major serotypes and four HBsAg subtypes have been recognized (adw, ady, ayw, and ayr). HBsAg can be detected 2 to 4 weeks before the ALT levels become atypical and 3 to 5 weeks before symptoms develop.

PRINCIPLE OF THE ASSAY

This HBsAg rapid test employs chromatographic lateral flow device. Colloidal gold conjugated monoclonal antibodies reactive to HBsAg (sAb-Au) are dry-immobilized onto a nitrocellulose membrane strip. When the sample is added, it migrates by capillary diffusion trough the strip rehydrating the gold conjugate. If present, HBsAg will bind with the gold conjugated antibodies forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by anti-HBs antibodies immobilized there and a visible red line appears. If there is no HBsAg in sample, no red line will appear in the Test Zone (T). The gold conjugate will continue to migrate alone until is captured in the Control Zone (C) from immobilized goat anti-mouse IgG antibody and aggregating in a red line, which indicates the validity of the test.

COMPONENTS

10 Tests

- 10 Test Cassettes;
- 6ml×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 should 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 (about 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.
- The results obtained after 30 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

For whole blood sample:

1. Pipette 40µl of whole blood into the sample well (S) on the cassette.
2. Add 1 drop of sample diluent buffer.
3. Place the cassette on flat surface and read the results within 30 minutes.

For serum or plasma sample:

1. Pipette 80µl of serum or plasma into the sample well (S) on the cassette.
2. Place the cassette on flat surface and read the results within 30 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 control 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 HBsAg have been detected with this test.

Negative Results: No red band appears within 30 minutes in the Test Zone (T) indicating that no HBsAg have been detected with this test. However, this does not exclude the possibility from infection with HBV.

POSITIVE **NEGATIVE** **INVALID**

The positive result obtained with this test alone cannot be the final diagnosis of HBV 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

In a clinical evaluation of the performance of this HBsAg rapid test, using 3254 confirmed negative and 437 confirmed positive samples, the sensitivity was 99.54% (435/437) and the specificity was 99.56% (3240/3254).

The analytical sensitivity of this HBsAg rapid test is 1ng/ml (reference standards provided from the Reference Laboratory for Immunology Product under the Ministry of Health, China).

The overall agreement with the reference ELISA test is 100% (57/57).

No cross reactivity was observed with specimens from patients infected with HAV, HCV, HIV, HTLV, CMV and TP.

LIMITATIONS

- Negative results do not exclude the possibility of HBV exposure or infection. Infection through recent exposure (seroconversion) to HBV may not be detectable. For positive results, band intensity cannot be used to evaluate the HBsAg 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 exposure 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 antigen concentration.

REFERENCES

1. Krugman, S. and Giles, J.P. (1973). Viral hepatitis, type B (MS-2-Strain). Further observation on natural history and prevention. N. Engl. J. Med., 288, 755
2. Krugman, S., Overby, L.R. et al. (1979). Viral hepatitis B. Studies on natural history and prevention re-examined. N. Engl. J. Med., 300, 101
3. Piet, M.P, Chin, S. et al. (1990). The use of tri (n-butyl) phosphate detergent mixtures to inactive hepatitis virus and human immunodeficiency virus in plasma and plasma’s subsequent fractionation. Transfusion, 30, 591
4. Blumerg B.S., Suinick A.I., London W.T.. Hepatitis and leukemia: their relation to Australia antigen. Bull.N.Y.Acad.Med.. 44:1566, 1968
5. Boniolo A., Dovis M., Matteja R.. The use of enzyme-linked immunosorbent assay for screening hybridoma antibodies against hepatitis B surface antigen. J.Immunol.Meth.. 49:1,1982
6. Caldwell C.W., Barpet J.T.. Enzyme immunoassay for hepatitis B and its comparison to other methods. Cli.Chim.Acta 81: 305, 1977

Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.
No.31 Kexueyuan Road, Changping District, Beijing 102206, China
Tel: +86-10-59528888; Fax: +86-10-89705849
Email: wtexport@ystwt.com; Website: www.ystwt.com