Atlas Link (Beijing) Technology Co., Ltd

One Step Hepatitis B Surface Antigen （HBsAg ）Rapid Test

Instructions For Use

Format: Cassette
Catalog Number: HBV212
Specimen: Serum/Plasma

CE 2265

* Please carefully read the instructions before use

INTENDED USE

One Step Hepatitis B Surface Antigen (HBsAg) Rapid Test is a rapid and convenient immunochromatographic assay for qualitative detection of HBsAg in human whole blood, serum or plasma sample at or above a level of 1 ng/ml. It is intended for professional use as an aid in diagnosis of Hepatitis B virus (HBV) infection. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test

SUMMARY AND PRINCIPLE OF THE ASSAY

Hepatitis B virus (HBV) is partially double-stranded DNA that causes acute or chronic hepatitis. The viral particles are transmitted through exposure of infectious body fluids or blood, blood transfusion, and use of contaminated needles or syringes. Chronic hepatitis may progress to severe outcomes, including cirrhosis and liver cancer (heptatocellular carcinoma). The virus is divided into four major serotypes (adr, adw, ayr, ayw) based on antigenic epitopes presented on its envelope proteins.

Hepatitis B surface antigen (HBsAg) is the first marker to appear in the blood in acute hepatitis B, being detected 1 week to 2 months after exposure and 2 weeks to 2 months before the onset of symptoms. Three weeks after the onset of acute hepatitis almost half of the patients will still be positive for HBsAg. In the chronic carrier state, the HBsAg persists for long periods with no seroconversion to the corresponding antibodies.The most commonly used diagnostic and blood screening markers sought is HBsAg. An individual positive for HBsAg is considered to be infected with HBV and is therefore potentially infectious.

One Step HBsAg test is an antigen-capture immunochromatographic assay, detecting presence of HBsAg in blood samples. Monoclonal antibodies specifically against HBsAg are 1) conjugated with colloidal gold and deposited on conjugate pad and 2) immobilized on test line on the nitrocellulose membrane. When blood sample is added, it rehydrates the gold-antibody conjugate and the HBsAg, if any in samples, interact with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate toward test window until the Test Zone (T) where they are captured by immobilized antibodies, forming a visible red line (Test band, indicate positive results). If HBsAg are absent in the sample, no red line will appear in the Test Zone (T).

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a colored control line in the Control Zone is an indication of an invalid result.

One Step HBsAg Test detects HBsAg for major serotypes (adr, adw, ayr, ayw) at concentrations of 1.0 ng/ml.

PACKAGE CONTENTS

- Pouch contents: Test Cassette, Sample dropper, Desiccant
- Test instruction

OTHER REQUIRED MATERIALS (NOT PROVIDED)

- Gloves
- Clock or timer

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

SPECIMEN PREPARATION

- For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
- For plasma samples, collect blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
- The blood may be stored at 2ºC to 8ºC for up to three days if the tests cannot be performed immediately. Ensure that the blood samples should be allowed to attain room temperature prior to use.

TEST PROCEDURES

1

Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.

2

Holding the sample dropper vertically, add three full drops (120 µl) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device

3

Read the result in 10 minutes. Read results as shown under interpretation of Results.

NOTE: Specimens with high concentrations of HBsAg may produce positive result in as little as 1 minute. Confirm negatives in 20 minutes.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATIONS

Negative
A pink colored band appears only at the control region (C) , indicating a negative result for HBV infections.

Positive
A clear pink control band (C) band (T) appear, indicating a HBV infections.

Invalid
No visible band at the control region (C). Repeat with a new test device. If test still fails, please contact the distributor with the lot number

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- This product is an *in vitro* diagnostic test designed for professional use only.
- Humidity and temperature can adversely affect results.
- The instruction for use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting HBsAg, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Analytic Sensitivity

One Step HBsAg Test detects HBsAg for major serotypes (adr, adw, ayr, ayw) at concentrations of 1.0 ng/ml.

2. Analytic Specificity

The effect of seromarkers associated with unrelated medical conditions on the specificity of the one Step HBsAg Test was assessed using a panel of specimens. The seromarkers studied were: HCV samples, Dengue samples, the haemolytic samples, rheumatoid factors-contained samples, HIV samples, anti-CMV positive, anti-EBV positive, anti-HSV positive, anti-HAV positive, non-viral liver diseases (non-alcoholic steatohepatosis, fatty liver, drug-induced hepatotoxicity) , rubella antibody positive, syphilis serology positive, anti-nuclear antibody positive, C-reactive protein (CRP) positive, antistreptolysin O titre (ASOT) positive. The results demonstrated that One Step HBsAg Test kits have no cross-reactivity with these specimens.

3. Diagnostic Sensitivity and Specificity

Total 554 positive samples were tested 553 positive by HBsAg Test and CE marked Wantai HBsAg EIA; the one (No.216 from ChongYi) tested negative by both HBs Ag Rapid Test and Wantai HBsAg EIA, was further confirmed positive by PCR. The serotype of the false negative sample was unknown. The diagnostic sensitivity of HBsAg Rapid Test was 99.82% (553/554) and could identify the 4 HBV serotypes.

Table 1 Summary of Diagnostic Sensitivity of HBsAg Rapid Test

Serotype	Results of HBs Antigen Rapid Test		Results of CE Marked Wantai HBsAg EIA		Subtotal
	Positive	Negative	Positive	Negative	

adw2	118	0	118	0	118
ayw1	33	0	33	0	33
adr	5	0	5	0	5
ayw2	3	0	3	0	3
ayr	1	0	1	0	1
ayw3	1	0	1	0	1
Unknown serotype	392	1	392	1	393
Subtotal	553	1	553	1	554

Of the 1752 samples, 1750 were tested negative, 2 tested positive (both from blood donors) by HBsAg Rapid Test. All the results which showed inconsistent with CE marked Wantai HBsAg EIA were further confirmed negative by PCR. The diagnostic sensitivity of HBsAg Rapid Test was 99.89% (1750/1752), false positive rate is 0.11% .

Table 2 Summary of Diagnostic Specificity of HBsAg Rapid Test

	Results of HBsAg Rapid Test		Results of CE Marked Wantai HBsAg EIA		Subtotal
	Negative	Positive	Negative	Positive	
Blood Donors	1114	2	1113	3	1116
200 clinical specimens	200	0	200	0	200
200 Pregnant Women	200	0	200	0	200
236 potentially interfering samples	236	0	236	0	236
Subtotal	1750	2	1749	3	1752

4. Inteference Study

The following substances and conditions were found not to interfere with the test. List of potentially interfering chemical analytes and concentrations tested are as follow:

Interfering compounds or factors		With Interfering compound added			Without interfering compound		
Name	Spiked final Conc.	Negative serum	HBsAg positive serum (1ng/ml)	HbsAg positive serum (5ng/ml)	Negative serum	HBsAg positive serum (1ng/ml)	HbsAg positive serum (5ng/ml)
Chemical analytes							
Acetaminophen	200 ug/ml	-	+	+	-	+	+
Acetylsaclicylic Acid	200 ug/ml	-	+	+	-	+	+
Amikacin	200 ug/ml	-	+	+	-	+	+
Ascorbic acid	200 ug/ml	-	+	+	-	+	+
Aspartame	200 ug/ml	-	+	+	-	+	+
Atropine Sulfate	200 ug/ml	-	+	+	-	+	+
Benzoic Acid	200 ug/ml	-	+	+	-	+	+
Caffeine	200 ug/ml	-	+	+	-	+	+
Deoxyephedrine	200 ug/ml	-	+	+	-	+	+
Dextromethorphan	200 ug/ml	-	+	+	-	+	+
EDTA	800 ug/ml	-	+	+	-	+	+
Gentesic acid	200 ug/ml	-	+	+	-	+	+
Histamine	200 ug/ml	-	+	+	-	+	+
Methaqalone	200 ug/ml	-	+	+	-	+	+
Pendimetrazine	200 ug/ml	-	+	+	-	+	+
Penicillin G	200 ug/ml	-	+	+	-	+	+
Quinine	200 ug/ml	-	+	+	-	+	+
Ranitidine	200 ug/ml	-	+	+	-	+	+
Sodium Salicylate	200 ug/ml	-	+	+	-	+	+
Tryptophan	200 ug/ml	-	+	+	-	+	+
Tetracycline	200 ug/ml	-	+	+	-	+	+
Tetrahydrozoline	200 ug/ml	-	+	+	-	+	+
Ethanol	1%	-	+	+	-	+	+
Methanol	1%	-	+	+	-	+	+
Heparin	1%	-	+	+	-	+	+
Citrate	3.2%	-	+	+	-	+	+
Biological analytes							
Albumin	2 mg/ml	-	+	+	-	+	+
Glucose	2 mg/ml	-	+	+	-	+	+
Bilirubin	2 mg/ml	-	+	+	-	+	+
Hemoglobin	2 mg/ml	-	+	+	-	+	+

REFERENCES

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4. Cho EW, Park JH, Yoo OJ, Kim KL. Translocation and accumulation of exogeneous hepatitis B virus preS surface proteins in the cell nucleus. *J Cell Sci*(2001). 114 (Pt 6):1115-1123.
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INDEX OF SYMBOLS

	Do not reuse	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Temperature limitation	Σn	Contains sufficient for < n > tests
	Caution	REF	Catalog number
	Manufacturer		Consult instructions for use
EC REP	Authorised representative in the European community	CE	CE Mark

MANUFACTURER CONTACT INFORMATION

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