RightSign®

HBsAg Rapid Test Cassette (Serum/Plasma)
Package Insert

REF IHBSG-C31	English

A rapid test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) in serum or plasma.
For professional in vitro diagnostic use only.

【INTENDED USE】

The HBsAg Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B Surface Antigen in serum or plasma. HBsAg Rapid Test Cassette (Serum/Plasma) is not intended for blood donors and organs testing.

HBV is a hepatotropic virus which belongs to the Hepadnaviridae family and replicates its DNA genome via a reverse transcriptase mechanism. [1]

The complex antigen found on the surface of HBV is called HBsAg. Previous designations included the Australia or Au antigen. The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. In a typical Hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus.

The HBsAg Rapid Test Cassette is a rapid test to qualitatively detect the presence of HBsAg in serum or plasma specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma.

【PRINCIPLE】

The HBsAg Rapid Test Cassette is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in serum or plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the cassette. During testing, the serum or plasma specimen reacts with the particle coated with anti-HBsAg antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test device contains anti-HBsAg particles and anti-HBsAg coated on the membrane.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used tests, specimens and potentially contaminated materials should be discarded according to the local regulations.
5. The test after open the pouch should be performed in one hour especially the relative humidity >60% and the temperature >30℃ can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

1. The HBsAg Rapid Test Cassette can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. Specimens should be kept below -20°C up to 6month.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials provided

Test cassettes　　Droppers　　Package insert

Materials required but not provided

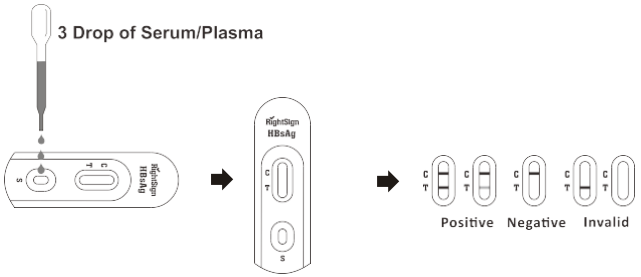
Specimen collection containers　　Centrifuge　　Timer

【DIRECTIONS FOR USE】

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. For Serum or Plasma specimen:

Hold the dropper vertically and transfer **3 drops of serum or plasma (approximately 120 µL)** to the specimen well of test device and start the timer. See illustration below.

3. Wait for the colored line is appeared. The result should be read **at 15~30 minutes.** Do not interpret the result after **30 minutes**.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of HBsAg present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms adequate membrane wicking.

Control standards are not supplied with this kit; however, it is recommended that a positive control (containing 10 ng/ml HBsAg) and a negative control control (containing 0 ng/ml HBsAg) be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The HBsAg Rapid Test Cassette is for professional in vitro diagnostic use only. The test should be used for the detection of HBsAg in serum or plasma specimen. Neither the quantitative value nor the rate of HBsAg concentration can be determined by this qualitative test.
2. The HBsAg Rapid Test Cassette will only indicate the presence of HBsAg in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. The HBsAg Rapid Test Cassette cannot detect less than 1 PEI ng/ml of HBsAg in specimens. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B infection.

【EXPECTED VALUES】

The HBsAg Rapid Test Cassette(Serum/Plasma) has been compared with a leading commercial HBsAg EIA test. The correlation between these two systems is over 98%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity

The HBsAg Rapid Test Cassette (Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 300 ng/ml. All 10 HBsAg subtypes produced positive results on The HBsAg Rapid Test Cassette (Serum/Plasma). The test can detect 1 PEI ng/ml of HBsAg in serum/plasma.

Specificity

Antibodies used for the HBsAg Rapid Test Cassette (Serum/Plasma) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the HBsAg Rapid Test Cassette (Serum/Plasma) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

The results show that the relative sensitivity of the HBsAg Rapid Test Cassette (Serum/Plasma) is 99.8%, and the relative specificity is 99.6%. And more than 30 seroconversion panel have been evaluated with the test.

Method		EIA		Total Results
HBsAg Rapid Test Cassette(Serum/Plasma)	Results	Positive	Negative	
	Positive	424	6	430
	Negative	1	1606	1607
Total Results		425	1612	2037

Relative Sensitivity: 99.8% (95%CI*: 98.7%-100.0%)
Relative Specificity: 99.6% (95%CI*: 99.2%-99.9%)
Accuracy: 99.7% (95%CI*: 99.3%-99.9%)
*Confidence Intervals

The results show that the diagnostic sensitivity of the HBsAg Rapid Test Cassette (Serum/Plasma) is 99.8%, and the diagnostic specificity is 99.6%.

Method		Predicated Result		Total Results
HBsAg Rapid Test Cassette(Serum/Plasma)	Results	Positive	Negative	
	Positive	424	6	430
	Negative	1	1606	1607
Total Results		425	1612	2037

Diagnostic Sensitivity: 99.8% (95%CI*: 98.7%-100.0%)
Diagnostic Specificity: 99.6% (95%CI*: 99.2%-99.9%)
Accuracy: 99.7% (95%CI*: 99.3%-99.9%)
*Confidence Intervals

Precision Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens containing 0ng/ml, 1ng/ml, 7ng/ml and 20ng/ml of HBsAg. The negative and positive values were correctly identified >99.9% of the time.

Inter-Assay

Between-run precision has been determined by using the same four specimens of 0ng/ml, 1ng/ml, 7ng/ml and 20ng/ml of HBsAg in 10 independent assays. Three different lots of the HBsAg Rapid Test Cassette (Serum/Plasma) has been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified >99.9% of the time.

Cross-reactivity

The HBsAg Rapid Test Cassette (Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, H. Pylori, MONO, CMV, Rubella, HCV, HEV and TOXO positive specimens. The results showed no cross- reactivity

Interfering Substances

The HBsAg Rapid Test Cassette (Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed.

Ascoribic acid	20mg/ml	acetoaminophen	20mg/dl
Hemoglobin	1000mg/dl	Aspirin	20mg/dl
Gentistic acid	20mg/dl	Methanol	10%
Oxalic acid	60mg/dl	Creatine	200mg/dl
Bilirubin	1000mg/dl	Albumin	2000mg/dl
Uric acid	20mg/ml	Caffeine	20mg/dl

【BIBLIOGRAPHY】

1. Zoulim F, Lebossé F, Levrero M. Current treatments for chronic hepatitis B virus infections. Curr Opin Virol 2016;18:109-116.
2. Ott, J. J., Stevens. G. A., Groeger, J. & Wiersma, S. T. Global epidemiology of hepatitis B virus infection: new estimates of age-specific HBsAg seroprevalence and endemicity. Vaccine 30, 2212-2219(2012).
3. Shevanthi,N., Mark, T., Elisa, S., etc. Requirements for global elimination of hepatitis B: a modelling study. The Lancet Infectious Diseases, Volume 16, Issue 12, December 2016, Pages 1399-1408.

Index of Symbols

	Consult Instruction for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 36°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

Manufacturer:
Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou, P. R. China

CE 1434

EC REP
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