SBio HBsAg Test

Rapid one step test for the detection of HBsAg in serum, plasma

REF	90201025
Σ	25 T

30°C 4°C Store at 4 to 30 °C	Manufacturer	LOT Batch Number	DEVICE Device	Do not reuse	Xn NaN$_3$, R22 S23-46-61 Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
Use by (Last day of stated month)	Consult Instructions for use	IVD *In vitro* Diagnostic Medical Device	PIPETTE Disposable plastic dropper	HBsAg Rapid one step test for detection of HBsAg in serum, plasma	
Date of Manufacture	REF Catalogue Number	Σ Contains sufficient for <n> tests	This side up		

INTRODUCTION

SBio HBsAg Test is a rapid, qualitative, two site sandwich immunoassay for the detection of Hepatitis B surface antigen, a marker for Hepatitis B infections, in serum/plasma specimen. For professional use.

SUMMARY

Blood containing the Hepatitis B Virus (HBV) is potentially infectious. Hepatitis B surface Antigen (HBsAg), earlier known as Australia antigen, is among the first serological markers that circulate in the blood of infected persons even two to three weeks prior to the appearance of clinical symptoms. The levels of HBsAg are especially elevated during the symptomatic phase and decline thereafter.

Detection of HBV using HBsAg as the marker to screen blood donors is essential to reduce the risk of transmission of Hepatitis B by blood transfusion. HBsAg detection is also useful for screening high risk groups for HBV and for differential diagnosis of Hepatitis infection. SBio HBsAg Test detects the presence of HBsAg in serum/plasma specimens, qualitatively, at concentrations as low as 0.5 ng/ml.

PRINCIPLE

SBio HBsAg Test utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. As the test sample flows through the membrane assembly within the test device, the colored Agglutinating sera for HBsAg-colloidal gold conjugate complexes with the HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized by the Agglutinating sera for HBsAg coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region, forming a colored band. This control band serves to validate the test results. The control band formation is based on the 'Rabbit globulin / Agglutinating Sera for Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band serves to validate the test performance.

REAGENTS AND MATERIALS SUPPLIED

Each individual pouch contains:

1. DEVICE : Contains membrane assembly predispensed with Agglutinating sera for HBsAg-colloidal gold conjugate, rabbit globulin-colloidal gold conjugate, Agglutinating sera for HBsAg and Agglutinating sera for rabbit globulin at the respective regions.
2. PIPETTE : Disposable plastic sample applicator.
3. Desiccant pouch.
4. Package insert.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 4 to 30°C till the duration of the shelf life as indicated on the pouch. DO NOT FREEZE.

WARNINGS

1. The sealed pouches in the test kit may be stored between 4°C To 30°C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.
2. Do not compare the intensity of test lines and the control lines to judge the concentration of HBsAg in the test specimen.
3. Since various tests of HBsAg differ in their performance characteristics and antibody composition, their reactivity patterns may differ.
4. Testing of pooled samples is not recommended.
5. The membrane is laminated with an adhesive tape to prevent surface evaporation. Air pockets or patches may appear, which do not interfere with the test results. Presence of a band at the test region, even if low in intensity or formation, is a positive result.
6. Most positive results develop within 15 minutes. However, certain sera sample may take a longer time to flow. Therefore, negatives should be confirmed only at 30 minutes. Do not read results after 30 minutes.
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
8. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum.

PRECAUTIONS

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use.
2. Do not use beyond expiry date.
3. Read the instruction carefully before performing the test.
4. Handle all specimens as potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum/plasma is preferable, serum/plasma specimen may be stored 2°C To 8°C for upto 24 hours, in case of delay in testing. Do not use haemolysed, turbid or contaminated samples. Turbid samples should be centrifuged and clear supernatant must be used for testing.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the sealed pouches to room temperature. Open the pouch and remove the device, applicator and desiccant. Check the colour of the desiccant. It should be blue. If it has turned colourless

or pink discard the device and use another device. Once opened, the device must be used immediately.

2. Dispense two drops (50µl) of serum/plasma specimen into the sample well 'S' using the applicator provided. Refrigerated specimens must be brought to room temperature prior to testing.
3. At the end of fifteen minutes read the results as follows:

NEGATIVE: A colored band appears at the control region 'C'.

POSITIVE: In addition to the control band, a colored band also appears at the test region 'T'.

INVALID: The test should be considered invalid if no colored band appears on the device. The test should also be considered invalid if a colored band appears only at the test region 'T' and not at the control region 'C'. In such cases, repeat the test with a new device, ensuring that the test procedure has been followed accurately.

PERFORMANCE CHARACTERISTICS

Internal Evaluation-I

In an in-house study, the performance of SBio HBsAg Test was evaluated using a panel of fifty known positives (of varying reactivity) and two hundred known negative specimens in comparison to two licensed ELISA kits - ELISA-I & ELISA-II. The results of the evaluation are as follows:

	TOTAL	SBio HBsAg Test	ELISA I	ELISA II
Number of specimens tested	400	400	400	400
Number of positives	100	100	100	100
Number of negatives	300	298	300	300

Based on this evaluation:
Sensitivity of SBio HBsAg Test: 100%. Specificity of SBio HBsAg Test: 99.3%.

Internal Evaluation-II

SBio HBsAg Test was evaluated with a serial dilution of known concentration of HBsAg positive sample. It was observed that SBio HBsAg Test was able to detect all the dilutions with HBsAg concentration of ≥ 0.5 ng/ml.
Therefore the detection limit of SBio HBsAg Test is 0.5 ng/ml.
With a low titre performance panel (PHA 104) from BOSTON BIOMEDICA Inc., USA, SBio HBsAg Test showed (±) reactivity with a sample that contained as low as 0.3 ng/ml of HBsAg. In the same panel, with another sample of 0.6 ng/ml, SBio HBsAg Test showed (+) reactivity.

Independent External Evaluation

In another independent study, the performance of SBio HBsAg Test was evaluated using a panel of 50 samples; 20 positives & 30 negatives, in comparison with commercially available Immunochromatographic Test (ICT), Enzyme Immunoassay (EIA) and Microparticle Enzyme Immunoassay (MEIA). The results of the evaluation are as follows:

SPECIMEN DATA	TOTAL	SBio HBsAg Test	ICT	EIA
Number of specimens tested	50	50	50	50
No. of Positives	20	19	18	20
No. of Negatives	30	31	32	30

The above study indicates good correlation of the results of SBio HBsAg Test with that of EIA.

LIMITATIONS OF THE TEST

1. Though SBio HBsAg Test is a reliable screening assay, it should not be used as a sole criterion for diagnosis of HBV infection.
2. Interference due to heterophile antibodies, Rheumatoid Factors and other nonanalyte substances in patient's serum, capable of binding antibodies multivalently and providing erroneous analyte detection in immunoassays, has been reported in various studies. Though SBio HBsAg Test uses sufficient amounts of HETEROPHILIC BLOCKING REAGENT (HBR) to inhibit the majority of this interference; nevertheless, some samples with high titers may still express clinically important assay interference. Both laboratory professionals and clinicians must be vigilant to this possibility of antibody interference. Results that appear to be internally inconsistent or incompatible with the clinical presentation should invoke suspicion of the presence of an endogenous artifact and lead to appropriate in vitro investigative action.
3. HBsAg is coded for by the S gene, and the common antigenic epitopes of all subtypes of HBsAg are found in the same 'a' determinant. The antibodies used in SBio HBsAg Test are directed against this 'a' determinant so that all subtypes of HBsAg can be detected. However, a few patients infected with HBV may show negative for HBsAg inspite of a positive test for HBV-DNA or HBV polymerase chain reaction. These rare cases are due to antigenically divergent variants. Therefore, the existence of such variants should be considered before taking clinical decisions.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1) Kim, C. Y., Tillis, J. G. 1973, Purification of Biophysical characterization of Hepatitis A antigen, J. Clin. Invest, 52, May 1973, Pgs. 1176-1186. (2) Kee Myung Lee et.al., Emergence of Vaccine-induced escape mutant of Hepatitis B Virus with Multiple surface gene mutations in a Korean child, J.Korean. Med.Sci., 2001, 16, Pgs 356-361. (3) Koyanagi T et al. Analysis of HBs antigen negative variant of hepatitis B virus: Unique Substitutions, Glu 129 to Asp and Gly 145 to Ala in the surface antigen gene. Med Sci Monit, 2000; 6(6): Pgs1165-1169.

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