SBio HBeAg Test

Rapid Test for detection of HBeAg in human serum

REF	90506010
Σ	10 T

30°C / 4°C Store at 4 to 30 °C	Manufacturer	LOT Batch Number	CARD Test 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	HBeAg Rapid test for detection of HBeAg in human serum	
Date of Manufacture	REF Catalogue Number	Σ Contains sufficient for <n> tests	This side up		

INTENDED USE

SBio HBeAg Test is a rapid, immunochromatographic assay for the detection of HBeAg in human serum.

SUMMARY

The hepatitis B 'e' antigen (HBeAg), has been found in the hepatocytes during proliferation of the hepatitis B virus. Its detection is associated with pronounced viral infection and infectivity. After treatment, in the recovery phase following acute Hepatitis B infection, HBeAg becomes negative. HBeAg is generally detectable at the same time as HBsAg and disappears before HBsAg disappears. The presence of HBeAg in chronic infection indicates that HBV is actively reproducing and there is a high possibility of liver damage. In acute infection, HBeAg is generally present in trace amounts and its disappearance indicates accute or chronic Hepatitis B which is in the process of healing. SBio HBeAg Test detects the presence of HBeAg in human serum, thereby giving an assessment of the infectivity and the patient's status.

PRINCIPLE

SBio HBeAg Test is based on the principle of agglutinating sera on membrane and utilizes the technique of immunochromatography. The conjugate pad is impregnated with two components - Anti HBeAg (monoclonal) conjugated to colloidal gold and mouse IgG conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the Anti HBeAg colloidal gold conjugate complexes with the HBeAg in the test specimen and travels on the membrane due to capillary action along with the mouse IgG colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is immobilized by Anti HBeAg (monoclonal) coated on the membrane, leading to formation of a pink/purple coloured band. The absence of this band in the test region (T) indicates a negative result.

The mouse IgG colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the goat anti mouse IgG antibodies coated on the membrane at the control region (C) forming a pink / purple coloured band. This control band acts as a procedural control and serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

A. Each SBio HBeAg Test kit contains individual pouches each containing a
   1. Device: Membrane test assembly impregnated with colloidal gold conjugated to anti HBeAg monoclonal and mouse IgG antibodies, anti HBeAg (monoclonal) and goat anti mouse IgG at the respective regions.
   2. Desiccant pouch.
   3. Sample dropper.

B. Package insert.

OPTIONAL MATERIAL REQUIRED

Variable volume precision micropipettes, stopwatch.

STORAGE AND STABILITY

The sealed pouches in the test kit and the kit components may be stored between 4-30^0 C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.

NOTE

(1) For in vitro diagnostic and professional use only. NOT FOR MEDICINAL USE. (2) Do not use beyond expiry date. (3) Read the instructions carefully before performing the test. (4) Do not reuse the test device. (5) Handle all specimen as if potentially infectious. (6) Follow standard biosafety guidelines for handling and disposal of potentially infectious material. (7) If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.

SPECIMEN COLLECTION AND PREPARATION

1. SBio HBeAg Test uses human serum as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2-8°C for maximum up to 24 hours.
4. Refrigerated specimens must be brought to room temperature prior to testing.
5. If serum is to be used as specimen, allow blood to clot completely. Centrifuge to obtain clear serum.
6. Repeated freezing and thawing of the specimen should be avoided.
7. Do not use viscous/turbid, lipaemic, hemolysed, clotted and contaminated serum specimens.
8. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.

TESTING PROCEDURE

1. Bring the kit components of SBio HBeAg Test device to room temperature before testing.
2. Open a foil pouch by tearing along the “notch”.
3. Remove the testing device and the sample dropper.
4. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. *Once opened, the device must be used immediately.*
5. Label the device with specimen identity.
6. Place the testing device on a flat horizontal surface.
7. Holding the sample dropper vertically, carefully dispense exactly 2 drops of the serum specimen into the specimen port (S). Alternatively, using a micropipette, carefully dispense exactly

100µl of the serum specimen into the specimen port (S).

8. Start the stopwatch. Read the results within 10 minutes. Do not interpret the results beyond 15 minutes.

INTERPRETATION OF RESULTS

Negative Result:

Only one pink / purple coloured band appears at the Control Region (C). This indicates absence of HBeAg in the specimen.

Positive Result:

Two pink / purple coloured bands appear at the Control Region (C) and Test Region (T). This indicates that the specimen contains detectable amount of HBeAg.

Invalid Result:

The test result is invalid if no band appears either at the Control Region (C) or Test Region (T). In such cases, verify the test procedure and repeat the test with a new SBio HBeAg Test device.

PERFORMANCE CHARACTERISTICS

Sensitivity of SBio HBeAg Test is ~1 ncu/ml.

REMARKS

1. The deliberate slow reaction kinetics of SBio HBeAg Test is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
2. Most positive results develop within 10 minutes. However, certain sera sample may take a longer time to flow. Therefore, negatives should be confirmed only at 10 minutes. Do not interpret the results beyond 15 minutes.
3. 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.
4. SBio HBeAg Test should be used as a screening test in clinically suspected cases only, and its results should be confirmed by other supplemental method before taking clinical decisions.
5. HBV infections may also be caused by mutants which do not produce HBeAg.

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. Hepatitis B Virus Immunopathology, Chisari F.V., et. al., Springer Semin Immunopathol, 1995; 17(2-3): 261-81.
2. Hepatitis B Virus Taxonomy and Hepatitis B Virus Genotypes, Schaefer S., et. al., World J. Gastroenterol, 2007, Jan 7;13(1): 14-21.
3. Relevance of Hepatitis B Virus Genome Variability in Organ Transplantation, Samad Amini-Bavil-Olyaee, et. al., Hepatitis Monthly 2007; 7(1): 35-41.
4. Risk Factors in Chronic Hepatitis B Infection: A Case-Control Study, Shahnaz Sali M.D., et. al., Hepatitis Monthly 2005; 5(4): 109-115.
5. Hepatitis B e Antigen-Negative Chronic Hepatitis B, Maryam Vaez Jalali, et. al., Hepatitis Monthly 2006, 6(1): 31-35.
6. Source and Response of Antibody to Hepatitis B Vaccine in Hemodialysis Patients, Zohreh Aminzadeh, et. al., Hepatitis Monthly, 2007; 7(1): 33-34.
7. What Level of Hepatitis B Antibody is Protective?, Jack A.D., et. al., J. Infect. Dis. 1999 Feb; 179(2): 489-92.

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