Sbio HBeAb Test

Rapid Competitive Test for detection of HBeAb in human serum

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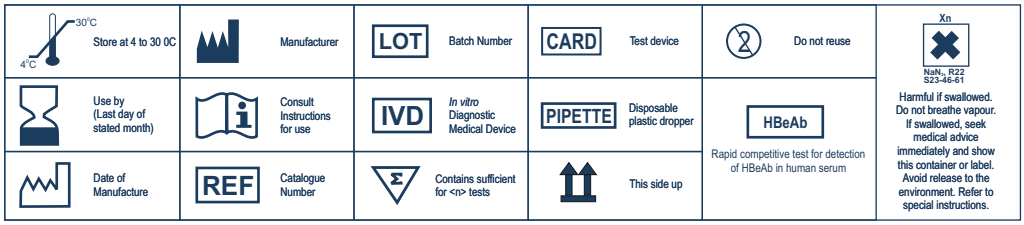

INTENDED USE

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

SUMMARY

HbcAb is the first detectable antibody to appear around 8 weeks after infection with HBV. Hence it is an early indicator of acute infection. Hbc antibodies do not neutralize the virus. HbcAb persists in the serum even after infection with HBV has been overcome. SBio HBcAb Test detects the presence of HBcAb in human serum hence it is a life long marker which represents past exposure as well as active infection in the acute and chronic stages. It is a good marker for post HBV infection for estimating prevalence of infection.

PRINCIPLE

SBio HBcAb Test is based on the principle of agglutinating sera on membrane and utilizes the technique of competitive immunochromatography. The conjugate pad is impregnated with three components - Anti HBcAg monoclonal antibody conjugated to colloidal gold, HBcAg and mouse IgG conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, HBcAg complexes with the HBcAb present in the test specimen and the Anti HBcAg monoclonal antibody colloidal gold conjugate 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 not immobilized by Anti HBcAg monoclonal antibody coated on the membrane, forming no band. The absence of this band in the test region (T) indicates a positive result.

In absence of HBcAb in the test specimen, Anti HBcAg monoclonal antibody colloidal gold conjugate, binds to HBcAg and along with mouse IgG colloidal gold conjugate moves further on the membrane to the test region (T) where it is immobilized by Anti HBcAg monoclonal antibody coated on the membrane, forming a pink/purple coloured band indicating 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 HBcAb Test kit contains individual pouches each containing a
   1. Device: Membrane test assembly impregnated with colloidal gold conjugated to anti HBcAb monoclonal and mouse IgG antibodies, HBcAg, anti HBcAg (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) Do not reuse the test device. (4) Read the instructions carefully before performing the test. (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 HBcAb 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. To obtain a good serum 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 HBcAb 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 100 µl 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:

Two pink/purple coloured bands appear at the Control Region (C) and Test Region (T). This indicates absence of HBcAb in the specimen.

Positive Result:

Only one pink/purple coloured band appears at the Control Region (C). This indicates that the specimen contains detectable amount of HBcAb.

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 HBcAb Test device.

PERFORMANCE CHARACTERISTICS

The sensitivity of SBio HBcAb Test is ~4ncu/ml.

REMARKS

1. The deliberate slow reaction kinetics of SBio HBcAb 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 15 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 HBcAb 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. Lack of detectable HBcAb in samples can be due to its binding to immune complexes in vivo. High anti HBC titres in negative HBsAg individuals suggests chronic Hepatitis B infection.

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

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