

INTENDED USE

INSIGHT HBsAb is a rapid, self-performing, immunochromatographic assay for the detection of HBsAb in human serum.

SUMMARY

Following an HBV infection, HBsAb is generally the last antibodies to appear. Its presence indicates clinical recovery of the patient and subsequent immunity to HBV infection. It is also associated with immunity produced post immunisation. INSIGHT HBsAb detects the presence of HBsAb in human serum and is useful to (a) monitor success of therapy from an acute HBV infection (b) determine past exposure to Hepatitis B surface antigen and (c) testing for immunity to Hepatitis B.

PRINCIPLE

INSIGHT HBsAb is based on the principle of agglutination of antibodies/ antisera with respective antigen in a immunochromatography format along with use of nano gold particles as agglutination. The conjugate pad is impregnated with two components - HBsAg conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the HBsAg- colloidal gold conjugate complexes with the HBsAb in the test specimen and travels on the membrane due to capillary action along with the rabbit-globulin colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is immobilized by HBsAg antigen 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 rabbit globulin-colloidal gold 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 (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 INSIGHT HBsAb kit contains individual pouches each containing a
 1. **DEVICE** : Membrane test assembly impregnated with colloidal gold conjugated to HBsAg and the rabbit globulin, HBsAg antigen and Agglutinating sera for rabbit globulin at the respective regions.
 2. Desiccant pouch.
 3. **PIPETTE** : Sample applicator.
- B. Package insert.

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OPTIONAL MATERIAL REQUIRED

Stopwatch.

STORAGE AND STABILITY

The sealed pouches in the test kit and the kit components may be stored between 4-30° 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. Handle all specimen as if potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
6. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
7. 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

1. INSIGHT HBsAb 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 INSIGHT HBsAb device to room temperature before testing.
2. Open a foil pouch by tearing along the "notch".
3. Remove the testing device and the sample applicator.
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 applicator vertically, carefully dispense exactly **2 drops** 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 HBsAb 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 HBsAb.

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 INSIGHT HBsAb device.

PERFORMANCE CHARACTERISTICS

The sensitivity of INSIGHT HBsAb is ~30mIU/ml.

REMARKS

1. The deliberate slow reaction kinetics of INSIGHT HBsAb 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. INSIGHT HBsAb 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. Presence of anti HBs generally indicates (a) past HBV infection with immunity (b) Hepatitis B immunisation (c) prophylaxis with Hepatitis B immunoglobulin (d) contact with non-infectious HBsAg. In exceptional cases anti HBs and HBsAg may be detectable in serum at the same time.









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.

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SYMBOL KEYS

 Temperature Limitation	 Consult Instructions for use	 Date of Manufacture	 Do not reuse
 Manufacturer	IVD <i>In vitro</i> Diagnostic Medical Device	 This side up	PS Production site
 Use by	REF Catalogue Number	DEVICE Device	
 Contains sufficient for <n> tests	LOT Batch Number / Lot Number	PIPETTE Disposable Plastic Sample Applicator	



PS

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