Insight | HBeAb

DEVICE

Rapid Competitive Immunochromatographic Assay for the detection of HBeAb in human serum

DEVICE

INTENDED USE

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

SUMMARY

After treatment, in the recovery phase following acute Hepatitis B infection, HBeAg becomes negative. Antibodies to the 'e' antigen (HBeAb) normally appears a few weeks after HBeAg is no longer detectable. The presence of HBeAb generally indicates that the patient is recovering from the acute stage of the illness. INSIGHT HBeAb detects the presence of HBeAb in human serum and helps determine whether the HBV infection is resolved. Presence of HBeAb suggests low or missing infectivity and serves as a measure of patient infectivity. In monitoring the cause of accute and chronic HBV infections, the occurence of HBeAb and disappearance of HBeAg are of prognostic value.

PRINCIPLE

INSIGHT HBeAb is based on the principle of agglutination of antibodies/ antisera with respective antigen in a competitive immuno-chromatography format along with use of nano gold particles as agglutination. The conjugate pad is impregnated with three components - Agglutinating sera for HBeAg conjugated to colloidal gold, HBeAg and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, HBeAg complexes with the HBeAb present in the test specimen and the Agglutinating sera for HBeAg - colloidal gold conjugate 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 not immobilized by Agglutinating sera for HBeAg coated on the membrane, forming no band. The absence of this band in the test region (T) indicates a positive result.

In absence of HBeAb in the test specimen, Agglutinating sera for HBeAg - colloidal gold conjugate, binds to HBeAg and along with rabbit globulin - colloidal gold conjugate moves further on the membrane to the test region (T) where it is immobilized by Agglutinating sera for HBeAg coated on the membrane, forming a pink/purple coloured band indicating 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 HBeAb kit contains individual pouches each containing a
   1. DEVICE: Membrane test assembly impregnated with colloidal gold conjugated to the Agglutinating sera for HBeAg, rabbit globulin, HBeAg, Agglutinating sera for HBeAg 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

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. 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 HBeAb 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 INSIGHT HBeAb 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). 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 HBeAb 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 HBeAb. This concludes that the active stage of HBeAb infection is almost over and the risk of being contagious is greatly reduced.

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 HBeAb device.

PERFORMANCE CHARACTERISTICS

The sensitivity of INSIGHT HBeAb is ~4ncu/ml.

REMARKS

1. The deliberate slow reaction kinetics of INSIGHT HBeAb 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 HBeAb 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. HBeAb is not detectable in infections caused by non-HBeAg producing HBV mutants. Investigation for HBeAg and HBeAb is a ppropriate only in HBsAg positive sera. Few carriers having low concentrations of HBsAg may be negative for HBeAg and HBeAb.

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 AD, et. al., J. Infect. Dis. 1999 Feb; 179(2): 489-92.
8. Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

	Temperature Limitation		Consult Instructions for use		Date of Manufacture		Do not reuse
	Manufacturer	IVD	*In vitro* 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		

TULIP DIAGNOSTICS (P) LTD.

PS

GITANJALI, TULIP BLOCK, DR. ANTONIO DO REGO BAGH, ALTO SANTACRUZ, BAMBOLIM COMPLEX P.O., GOA-403 202, INDIA. Website: www.tulipgroup.com

PLOT NOS. 92/96, PHASE II C, VERNA IND. EST., VERNA, GOA-403 722, INDIA.

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