CE

Insight | HEV-IgM

DEVICE

Rapid Immunochromatographic Assay for the detection of IgM antibodies to HEV in human serum / plasma

DEVICE

INTENDED USE
INSIGHT HEV-IgM is a rapid, self-performing, immunochromatographic assay for the detection of IgM antibodies to Hepatitis E virus in human serum / plasma.

SUMMARY
Hepatitis E is caused by infection with the hepatitis E virus, a non-enveloped, single-stranded RNA virus. HEV is transmitted via the faecal-oral route. Hepatitis E is a waterborne disease, and contaminated water or food supplies have been implicated in major outbreaks. Hepatitis E virus causes acute sporadic and epidemic viral hepatitis. However, prolonged viraemia or faecal shedding are unusual and chronic infection does not occur. But, Hepatitis E is known to be fatal among pregnant women especially in the third semester. IgM antibodies to HEV are produced at an early stage of HEV infection and persist during the acute clinical illness. INSIGHT HEV-IgM, a rapid test for the detection of IgM antibodies to Hepatitis E virus in human serum or plasma enables diagnosis of the early and acute stage of infection.

PRINCIPLE
INSIGHT HEV-IgM is based on the principle of agglutination of antibodies/ antisera with respective antigen in an immuno-chromatography format along with use of nano gold particles as agglutination. The conjugate pad is impregnated with two components - HEV antigen conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the HEV antigen colloidal gold conjugate complexes with the HAV specific antibodies 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 Agglutinating sera for Human IgM 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 HEV- IgM kit contains individual pouches each containing a
   1. DEVICE : Membrane test assembly impregnated with HEV antigen colloidal gold conjugate, rabbit globulin-colloidal gold conjugate, Agglutinating sera for Human IgM and Agglutinating sera for rabbit globulin at the respective regions.
   2. Desiccant pouch.
   3. PIPETTE : Sample applicator.

B. BUF : Sample running buffer.

C. Package insert.

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OPTIONAL MATERIAL REQUIRED
Variable volume precision micropipettes, test tube (12 x 75 mm), 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. Sample Running buffer contains Sodium Azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing.
8. 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 HEV-IgM uses human serum / plasma 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. Whole blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate can be used.
6. If serum is to be used as specimen, allow blood to clot completely. Centrifuge to obtain clear serum.
7. Repeated freezing and thawing of the specimen should be avoided.
8. Do not use viscous/turbid, lipaemic, hemolysed, clotted and contaminated serum/plasma specimens.
9. 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 HEV-IgM 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. Using a micropipette, pipette out 5 µl of the specimen and dispense into a test tube. Then pipette out 250 µl of the sample running buffer and dispense to the test tube (1:50 dilution). Mix well. This is the test specimen.
8. Holding the applicator vertically, carefully dispense exactly three drops of the test specimen into the specimen port (S). Alternatively, using a micropipette, carefully dispense exactly 150 µl of test specimen into the specimen port (S).
9. Start the stopwatch. Read the results at the end of 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 © This indicates absence of IgM antibodies to HEV.

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 IgM antibodies to HEV.

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 HEV-IgM device.

PERFORMANCE CHARACTERISTICS

The sensitivity of INSIGHT HEV-IgM is ~1 ncu/ml.

REMARKS

1. The deliberate slow reaction kinetics of INSIGHT HEV-IgM 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 HEV-IgM 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. In some studies it has been reported that low titre IgM antibodies to HEV may persist for about 4 months post infection. Therefore, in endemic areas, samples positive yet with low signal intensity should be interpreted with caution, preferably in light of patient history.

6. Anti HEV IgM is detectable in about 80 percent of the HEV infections. Hence, absence of anti HEV IgM does not rule with certainty unlying accute Hepatitis. Since anti HEV is usually present for six to seven weeks post infection and diminishes after three months its presence is proof of recent 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.

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SYMBOL KEYS

Temperature Limitation	Consult Instructions for use	Date of Manufacture	Do not reuse
Manufacturer	*In vitro* Diagnostic Medical Device	This side up	Production site
Use by	Catalogue Number	Device	Sample running buffer
Contains sufficient for <n> tests	Batch Number / Lot Number	Disposable Plastic Sample Applicator	Authorised Representative in the European Community

TULIP DIAGNOSTICS (P) LTD.

PS

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EC REP

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