CE

Insight | HAV-IgM

DEVICE

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

DEVICE

INTENDED USE

INSIGHT HAV-IgM is a rapid, self-performing, immnochromatographic assay for the detection of IgM antibodies to Hepatitis A virus in human serum or plasma.

SUMMARY

Hepatitis A is a liver disease caused by the Hepatitis A virus (HAV). It is a food and waterborne disease that is primarily transmitted by the faecal / oral route. HAV infects hepatocytes, causes elevation of liver enzymes and inflammation of the liver. The virus particles are released into the bile duct and excreted in faeces. The presence of virus in the blood is detected 2-4 weeks after infection. IgM antibodies to HAV are produced at an early stage of HAV infection and persist during the acute phase of the disease. Detection of anti HAV-IgM is confirmatory for the diagnosis of recent Hepatitis A.
INSIGHT HAV-IgM, a rapid test for the detection of IgM antibodies to Hepatitis A virus in human serum or plasma enables diagnosis of the early and acute stage of infection.

PRINCIPLE

INSIGHT HAV-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 - HAV 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 HAV 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 HAV-IgM kit contains individual pouches each containing a
   1. DEVICE: Membrane test assembly impregnated with HAV antigen colloidal gold conjugate, Agglutinating sera for 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.

REF	10501010
Σ	10

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

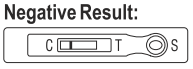
1. INSIGHT HAV-IgM uses human serum / plasma as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2-8°C for maximum up to 24 hours.
4. Refrigerated 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 HAV-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 sample applicator vertically, carefully dispense exactly three drops of the test specimen into the specimen port (S). Alternatively, using a micropipette, carefully dispense exactly 75 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 HAV.

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 HAV.

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 HAV-IgM device.

PERFORMANCE CHARACTERISTICS

In an in-house study, the performance of two different lots of INSIGHT HAV-IgM was evaluated using a panel of 21 clinically positive specimen and 60 clinically negative specimen obtained from different hospitals and laboratories in comparison with a commercially available HAV-IgM ELISA kit. The results of the evaluation are as follows:

Specimen Data	Total No.	ELISA	INSIGHT HAV-IgM	Sensitivity	Specificity
Specimen HAV-IgM Positive	21	21	21	100%	NA
Specimen HAV-IgM Negative	60	60	58	NA	93.5%

REMARKS

1. The deliberate slow reaction kinetics of INSIGHT HAV-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 HAV-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 HAV 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. Approximately ten days after the onset of illness anti HAV IgG is also present.
7. Anti HAV IgG transferred from mother via placenta remains detectable in infant for more than one year. Anti HAV IgM persists for two to six months after onset of illness.

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. Genetic Variability of Hepatitis A Virus, Mauro Costa-Mattioli, et. al., Journal of General Virology (2003), 84, 3191-3201.
2. Genetic Analysis of Hepatitis A Virus Strains Recovered From the Environment and From Patients with Acute Hepatitis, Sonia Pina, et. al., Journal of General Virology (2001), 82, 2955-2963.
3. Diagnosis of Hepatitis A Virus Infection: A Molecular Approach, Omana V. Nainan, et. al., Clinical Microbiology Reviews, Jan. 2006, p.: 63-79.
4. Detection of Poliovirus, Hepatitis A Virus and Rotavirus From Sewage and Water Samples, Leera Kittigul, et. al., Southeast Asian J. Trop. Med. Public Health, Vol. 31, No. 1, March 2000.
5. Prevention of Hepatitis A Infection, Mehdi Saberifiroozi, Hepatitis Monthly 2005; 5(1): 19-27.
6. Iraq: A hot Zone for HAV Infection? Seyed-Moayed Alavian, Hepatitis Monthly 2005; 5(3): 53-56.
7. Hepatitis A Virus: A Major Global Public Health Problem, Especially in Developing Countries, Hepatitis Monthly 2005; 5(4): 145-149.
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	BUF	Sample running buffer
	Contains sufficient for <n> tests	LOT	Batch Number / Lot Number	PIPETTE	Disposable Plastic Sample Applicator	EC REP	Authorised Representative in the European Community

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.

EC REP

CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain

1117/VER-01