SBio HAV-IgM Test

Rapid Test for detection of IgM antibodies to HAV in human serum / plasma

REF	90501010
Σ	10 T

30°C / 4°C Store at 4 to 30 °C	Manufacturer	LOT Batch Number	CARD Test device	Do not reuse	Xn NaN_3, R22 S23-46-61 Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
Use by (Last day of stated month)	Consult Instructions for use	IVD *In vitro* Diagnostic Medical Device	PIPETTE Disposable plastic dropper	HAV-IgM Rapid test for IgM antibodies to HAV in human serum/plasma	
Date of Manufacture	REF Catalogue Number	Σ Contains sufficient for <n> tests	This side up		

INTENDED USE

SBio HAV-IgM Test is a rapid, 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.

SBio HAV-IgM Test, 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

SBio HAV-IgM Test is based on the principle of agglutinating sera on membrane and utilizes the technique of immunochromatography. The conjugate pad is impregnated with two components - HAV antigen conjugated to colloidal gold and mouse IgG 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 mouse IgG colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is immobilized by anti human IgM antibody 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 mouse IgG colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the 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 HAV-IgM Test kit contains individual pouches each containing a
   1. Device: Membrane test assembly impregnated with HAV antigen colloidal gold conjugate, mouse IgG colloidal gold conjugate, anti human IgM antibodies and anti mouse IgG antibodies at the respective regions.
   2. Desiccant pouch.
   3. Sample dropper.

B. Sample running buffer.

C. Package insert.

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) 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. (8) 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.

SPECIMEN COLLECTION AND PREPARATION

(1) SBio HAV-IgM Test 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 SBio HAV-IgM 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) 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 dropper 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 (C). 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 SBio HAV-IgM Test device.

PERFORMANCE CHARACTERISTICS

In an in-house study, the performance of two different lots of SBio HAV-IgM Test 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	SBio HAV-IgM Test	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 SBio HAV-IgM 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 HAV-IgM 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) 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

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