Rapid Response™

Hepatitis A Virus IgM Test
(Serum/Plasma)

REF HAV-12C40 Product Insert

A rapid test for the qualitative detection of IgM antibodies to Hepatitis A virus in human serum and plasma.

For professional *in vitro* diagnostic use only.

Intended Use

The Rapid Response™ Hepatitis A Virus IgM Test is a rapid chromatographic immunoassay for the qualitative detection of IgM antibodies to Hepatitis A virus (HAV) in serum or plasma specimen.

Summary

HAV is a positive RNA virus, a unique member of picornavirdae[1]. Its transmission depends primarily on serial transmission from person to person by the fecal-oral route. Although hepatitis A is not ordinarily a sexually transmitted disease, the infection rate is high among male homosexuals, as result of oral-anal contact[2,3].
The Rapid Response™ Hepatitis A Virus IgM Test is to be used to detect IgM antibodies to HAV in less than 15 minutes by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

Principle

The test is based on a proprietary technology that combines the principles of immune-chromatography and fluid dynamics. The Rapid Response™ Hepatitis A Virus IgM Test has the recombinant HAV antigen immobilized on the membrane within the test zone. After specimen is added to the specimen well of the cassette, it reacts with mouse anti-human IgM coated particles in the test. It indicates positive result when the test zone form of a colored line, no colored line in the test zone indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Reagents

The test cassette contains mouse anti-human IgM particles and HAV antigen on the membrane of Rapid Response™ Hepatitis A Virus IgM Test.

Precautions

Please read all the information in this product insert before performing the test.

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.

Materials

Materials provided

- Test cassettes
- Buffer
- Droppers
- Product insert

Materials required but not provided

- Lancets
- Centrifuge
- Heparinized capillary tubes and dispensing bulb
- Timer
- Specimen collection containers

Storage and Stability

Store as packaged at room temperature or refrigerated (35.6-86°F; 2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Specimen Collection and Preparation

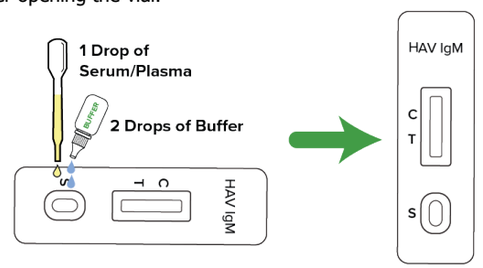
- The Rapid Response™ Hepatitis A Virus IgM Test can be performed using serum or plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 35.6-46.4°F (2-8°C) for up to 3 days. For long term storage, specimens should be kept below -4° F (-20°C).
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

Test Procedure

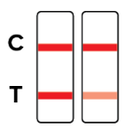
Allow the test cassette, specimen, buffer and/or controls to reach room temperature (59-86°F; 15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.
- For **Serum or Plasma** specimen:
  - Hold the dropper vertically and transfer **1 drop of serum or plasma** (approximately 10 µL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80 µL), and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 15 minutes.** Do not interpret the result after 20 minutes.

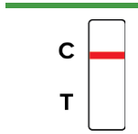
NOTE: It is suggested not to use the buffer, beyond 6 months after opening the vial.



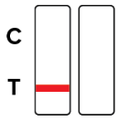
Results Interpretation



POSITIVE:* Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).
***NOTE:** The intensity of the color in the test region (T) will vary depending on the concentration of HAV IgM present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.



NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).



INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Quality Control

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit.

Limitations

1. The Test Procedure and the Test Results Interpretation must be followed closely when testing the presence of anti-HAV IgM in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Rapid Response™ Hepatitis A Virus IgM Test is limited to the qualitative detection of anti-HAV IgM antibodies in human serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-HAV IgM antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with HAV.
4. A negative result can occur if the quantity of the anti-HAV IgM present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

Performance Characteristics

Sensitivity and Specificity

The Rapid Response™ Hepatitis A Virus IgM Test was compared with a leading commercial ELISA HAV test; the results show that The Rapid Response™ Hepatitis A Virus IgM Test has a high sensitivity and specificity.

IgM Results

Method		ELISA		Total Results
Rapid Response™	Results	Positive	Negative	**Results**
Hepatitis A Virus	Positive	111	5	116
IgM Test	Negative	5	576	581
Total Results		116	581	697

Relative Sensitivity: 95.7% (95%CI*: 90.2%-98.6%)
Relative Specificity: 99.1% (95%CI*: 98.0%-99.7%)
Overall Accuracy: 98.6% (95%CI*: 97.4%-99.3%)
*Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens containing negative, low positive, middle positive, high positive of HAV. The negative and positive values were correctly identified 99% of the time.

Inter-Assay

Between-run precision has been determined by using the same four specimens of negative, low positive, middle positive, high positive of HAV in 10 independent assays. Three different lots of the Rapid Response™ Hepatitis A Virus IgM Test has been tested by using negative, low positive, middle positive, and high positive specimens. The specimens were correctly identified 99% of the time.

Cross-reactivity

The Rapid Response™ Hepatitis A Virus IgM Test has been tested by H.pylori, HIV, HBV, HCV, HEV, Syphilis, HAMA, RF, MONO, CMV, Rubella, TOXO positive specimens. The results showed no cross-reactivity.

Interfering Substances

The Rapid Response™ Hepatitis A Virus IgM Test has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed.
In addition, no interference was observed in specimens containing up to 20mg/mL Ascoribic acid, 1000mg/dL Hemoglobin, 20mg/dl Gentistic acid, 60mg/dl Oxalic acid, 30mg/dL Bilirubin, 20mg/mL Uric acid, 20mg/dL acetoaminophen, 20mg/dL Aspirin, 10% Methanol, 200mg/dL Creatine, 2000mg/dL Albumin, 20mg/dL Caffeine.

Bibliography

1. Bohm K , Filomena A , Schneiderhan-Marra N , et al. Validation of HAV biomarker 2A for differential diagnostic of hepatitis A infected and vaccinated individuals using multiplex serology[J]. Vaccine, 2017:S0264410X17311891.
2. Keeffe EB. Clinical approach to viral hepatitis in homosexual men. Med Clin North Am. 1986;70(3):567-86.
3. Ballesteros J, Dal-Re R, Gonzalez A, del Romero J. Are homosexual males a risk group for hepatitis A infection in intermediate endemicity areas? Epidemiol Infect. 1996; 117(1):145-8.

Glossary of Symbols

	Consult instructions for use	Σ	Test per Kit	EC REP	Authorized Representative
35.6°F 2°C / 86°F 30°C	Store between 35.6°F to 86°F		Use by		Do Not Reuse
LOT	Lot Number	IVD	For *in vitro* diagnostic use only	REF	Catalogue #
	Manufacturer		Do not use if package is damaged		

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

CE

BTNX Inc.
722 Rosebank Road,
Pickering, ON L1W 4B2
Canada

Technical Support: 1-888-339-9964