HAV IgM Rapid Test (Whole Blood/Serum/Plasma) For professional use

ELISURE

IVD REF SIC-RDT-HAV-202029

A rapid test for the qualitative detection of IgM antibodies to Hepatitis A virus in whole blood, serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The HAV IgM Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of IgM antibody to Hepatitis A Virus (HAV) in whole blood, serum or plasma.

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 HAV IgM Rapid Test is to be used to detect anti-HAV IgM in less than 15 minutes by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

PRINCIPLES

The test is base on a proprietary technology that combines the principles of immune-chromatography and fluid dynamics. The test has the recombinant mouse anti-human IgM immobilized on the membrane within the test zone. After specimen is added to the specimen well of the, 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.

MATERIALS

Materials Provided

• Test Cassettes • Droppers • Package Insert • Buffer

Materials Required But Not Provided

• Centrifuge • Time • Specimen Collection Containers
For fingerstick whole blood
• Lancets • Heparinized Capillary Tubes and Dispensing Bulb

WARNINGS AND PRECAUTIONS

Please read all the information in this package 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.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (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

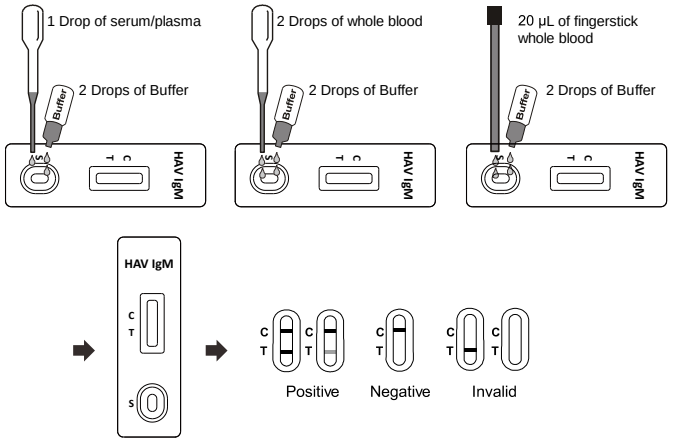
- The HAV IgM Rapid Test can be performed using whole blood, serum or plasma.
- To collect **Fingerstick Whole Blood** specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using a **capillary tube:**
    - Touch the end of the capillary tube to the blood until approximately 20 µL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test.
- 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 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 1 day of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 federal 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.

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it as soon as possible.
2. Place the test 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.
   For **Venipuncture Whole Blood** specimen:
   Hold the dropper vertically and transfer **2 drops of whole blood** (approximately 20 µL) to the **specimen well(S)**, then add **2 drops of buffer** (approximately 80 µL), and start the timer. See illustration below.
   For **Fingerstick Whole Blood** specimen:
   To use a capillary tube: Use the capillary tube and **transfer approximately 20 µL of fingerstick whole blood specimen** to the specimen well(S) of test , 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.



INTERPRETATION OF RESULTS

(Please refer to the illustration)

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 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

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

LIMITATIONS

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of anti-HAV IgM in serum or plasma from individual subjects. Failure to follow the procedures may give inaccurate results.
2. The HAV IgM Rapid Test is limited to the qualitative detection of anti-HAV IgM 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. 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.
7. The hematocrit level of the whole blood can affect the test results. Hematocrit level need to be between 25% and 65% for accurate results.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The HAV IgM Rapid Test was compared with a leading commercial ELISA HAV IgM test; the results show that the HAV IgM Rapid Test has a high sensitivity and specificity:

Method		ELISA		Total Results
	Results	Positive	Negative	
HAV IgM Rapid Test	Positive	111	5	116
	Negative	5	576	581
Total Results		116	581	697

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

Limitation of Detection

The minimum detection level is 1:1000 for HAV IgM positive specimen.

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 HAV IgM Rapid 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 HAV IgM Rapid 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 HAV IgM Rapid 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 20 mg/mL Ascoribic acid, 1000 mg/dL Hemoglobin, 20 mg/dL Gentistic acid, 60 mg/dL Oxalic acid, 30 mg/dL Bilirubin, 20 mg/mL Uric acid, 20 mg/dL acetoaminophen, 20 mg/dL Aspirin, 10% Methanol, 200 mg/dL Creatine, 2000 mg/dL Albumin, 20 mg/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.

INDEX OF SYMBOLS

	Consult instructions for use		Contains sufficient for <n> tests
IVD	*In vitro* diagnostic medical device		Use-by date
	Temperature limit	LOT	Batch code
	Do not use if package is damaged		Manufacturer
REF	Catalogue number		Do not re-use

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Number: M150574102B
Revision date: 2026-07-20