HAV IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF IHAGM-425	English

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

【INTENDED USE】

The HAV IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Hepatitis A virus (HAV) in whole blood, 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 HAV IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is to be used to detect IgG and 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 HAV IgG 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 IgG coated particles in the test. The HAV 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 IgG particles and HAV antigen on the membrane of HAV IgG rapid test.

The test cassette contains mouse anti-human IgM particles and HAV antigen on the membrane of HAV IgM rapid test.

【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 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 IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) 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 cassette.
- 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 the specimens have been collected. 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 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.

【MATERIALS】

Materials provided

• Test Cassettes • Droppers • Buffer • Package Insert

Materials required but not provided

• Specimen collection containers • Centrifuge • Timer

For fingerstick whole blood

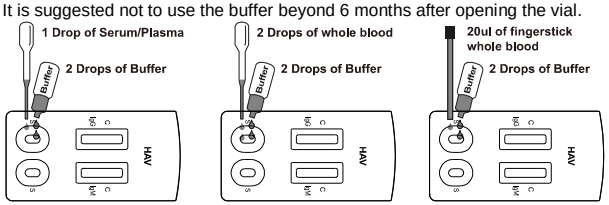
• Lancets • Heparinized capillary tubes and dispensing bulb

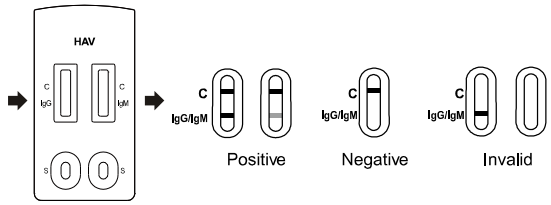
【DIRECTIONS FOR USE】

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 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 10µL) to each **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 each **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 each **specimen well(S)** of test cassette, 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 above)

POSITIVE:* Two distinct 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 line region (T) will vary depending on the concentration of HAV IgG or 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 Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of anti-HAV IgG or anti-HAV IgM in whole blood, serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The HAV IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is limited to the qualitative detection of anti-HAV IgG and IgM antibodies in human whole blood, 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 IgG and 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 IgG or 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.

【EXPECTED VALUES】

The HAV IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial ELISA HAV test. The correlation between these two systems is over 98%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The HAV IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with a leading commercial ELISA HAV test; the results show that the HAV IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity.

IgG Results

Method		ELISA		Total Results
HAV IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	371	3	374
	Negative	8	316	324
Total Results		379	319	698

Relative Sensitivity: 97.9% (95%CI*: 95.5%-99.0%) *Confidence Intervals
Relative Specificity: 99.1% (95%CI*: 97.3%-99.8%)
Overall Accuracy: 98.4% (95%CI*: 97.2%-99.2%)

IgM Results

Method		ELISA		Total Results
HAV IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	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%)

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 IgG/IgM Combo Rapid Test Cassette (Whole blood/Serum/Plasma) 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 IgG/IgM Combo Rapid Test Cassette (Whole blood/Serum/Plasma) 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 IgG/IgM Combo Rapid Test Cassette (Whole blood/Serum/Plasma) 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.

Index of Symbols

IVD	For in vitro diagnostic use only	Σ	Tests per kit	EC REP	Authorized Representative
2°C 30°C	Store between 2-30°C		Use by		Do not reuse
	Do not use if package is damaged	LOT	Lot Number	REF	Catalog #
	Manufacturer		Consult Instructions For Use		

Hangzhou AllTest Biotech Co.,Ltd.
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Number: 146163400
Effective date: 2019-12-19