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

REF IHAGM-325	English

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

【INTENDED USE】
The HAV IgG/IgM Combo Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of IgG and 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 HAV IgG/IgM Combo Rapid Test Cassette is to be used to detect IgG and IgM antibodies to HAV in less than 20 minutes by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

【PRINCIPLE】
The test is base on a proprietary technology that combines the principles of immune-chromatography and fluid dynamics. The HAV IgG test has the recombinant mouse anti-human IgG immobilized on the membrane within the test zone. During the test the serum or plasma add on the sample port(S) reacts with mouse anti-human IgG on the membrane first. The HAV IgM test has the recombinant mouse anti-human IgM immobilized on the membrane within the test zone. During the test the serum or plasma add on the sample port(S) reacts with mouse anti-human IgM on the membrane first. The buffer run upward from buffer well (B), HAV antigen reacts to particle coated with mouse anti-HAV migrates through the test zone, the HAV antigens are captured by the HAV antibody in the first step. 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 anti-HAV antibody particles and mouse anti-human IgG on the membrane of HAV IgG rapid test.
The test cassette contains anti-HAV antibody particles and mouse anti-human IgM 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】
1. The HAV IgG/IgM Combo Rapid Test Cassette can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non hemolyzed specimens.
3. 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.
4. 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.
5. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

【MATERIALS】

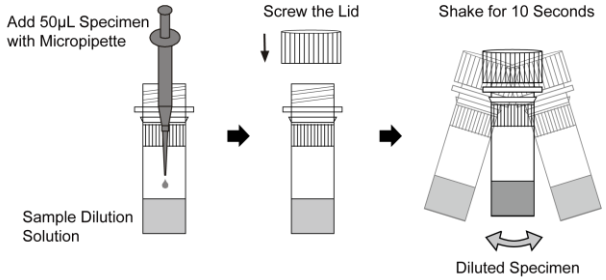
Materials provided

- Test cassettes
- Buffer
- Procedure card
- Droppers
- Sample dilution tubes
- Package insert

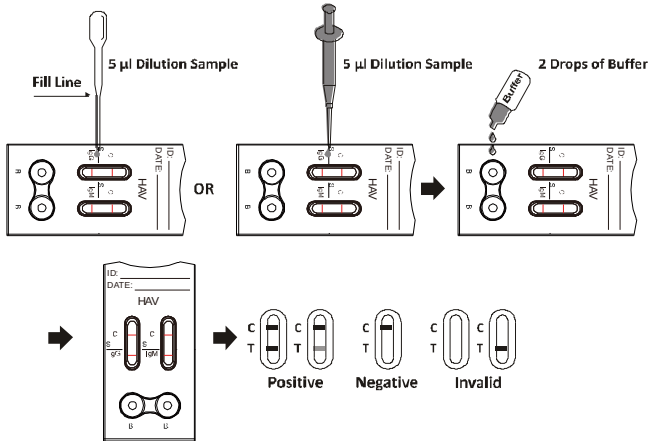
Materials required but not provided

- Specimen collection containers
- Micropipette
- Centrifuge
- Timer

【DIRECTIONS FOR USE】
Sample dilution: Use micropipette to add 50ul specimen into the sample dilution tube. Screw the lid tightly and turn it upside down mildly for 10 seconds to ensure the solution mixed well. Use the diluted sample as specimen for testing. See instruction below.



Testing Procedures
1. Remove the test cassette from sealed pouch and used it within one hour. Best results will be obtained if the assay is performed immediately after opening foil pouch.
2. Absorb the sample from **sample dilution bottle with 5ul droppers**, then transfer **1 drop of the dilution sample** (5ul) to the sample port (S) which part have been marked respectively. Or using micropipette add 5ul dilution sample into the sample port (S) which part have been marked.
3. Add **2 drops of buffer** (approx. 80ul) into the buffer well (B) of the test cassette, start the time.
4. Wait for the colored line(s) to appear. Read the result at 20 minutes, do not interpret the result after 30 minutes.



【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 serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The HAV IgG/IgM Combo Rapid Test Cassette is limited to the qualitative detection of anti-HAV IgG and 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 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.

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

【PERFORMANCE CHARACTERISTICS】

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

IgG Results

Method		ELISA		Total Results
HAV IgG/IgM Combo Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	80	5	85
	Negative	5	519	524
Total Results		85	524	609

Relative Sensitivity: 94.1% (95%CI*: 86.8%-98.1%) *Confidence Intervals
Relative Specificity: 99.0% (95%CI*: 97.8%-99.7%)
Overall Accuracy: 98.4% (95%CI*: 97.0%-99.2%)

IgM Results

Method		ELISA		Total Results
HAV IgG/IgM Combo Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	118	4	122
	Negative	6	466	472
Total Results		124	470	594

Relative Sensitivity: 95.2% (95%CI*: 89.8%-98.2%) *Confidence Intervals
Relative Specificity: 99.1% (95%CI*: 97.8%-99.8%)
Overall Accuracy: 98.3% (95%CI*: 96.9%-99.2%)

【BIBLIOGRAPHY】

1. Minor P. Picornaviridae. In: Francki RIB, Fauquet CM, Knudson DL, et al., eds. Classification and nomenclature of viruses (Arch Virol Supp 2). Wien: Springer-Verlag,1991: 320-326.
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

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

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