HAV IgG/IgM Device (2-30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADHAV3	20 Tests

Intended Use:
The HAV IgG/IgM Device 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 picornaviridae. Its transmission depends primarily on serial transmission from person to person by the faecal-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.

Test Principle:
The test has recombinant anti-human IgG and anti-human IgM immobilized on the membrane in two distinct test regions. During the test serum or plasma is added to the sample area within the test regions and any anti-HAV IgM or anti-HAV IgG antibodies present in the sample are captured by the anti-human IgG or anti-human IgM coated there. Buffer is added to the buffer well and as it migrates upward HAV antigen reacts with particles coated with mouse anti-HAV. In the test regions the HAV antigen also reacts with the sample HAV antibodies captured in the first step. A positive result is indicated when a coloured line forms in the IgG and/or IgM test line region, no coloured line in the test regions indicates a negative result. To serve as a procedural control, a coloured line should always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Reagents:
The test device contains anti-HAV antibody particles and mouse anti-human IgG on the membrane of HAV IgG rapid test.
The test device contains anti-HAV antibody particles and mouse anti-human IgM on the membrane of HAV IgM rapid test.

Materials Provided
Individually pouched test devices
Droppers
HAV Buffer
Sample dilution tube
Instructions for Use sheet

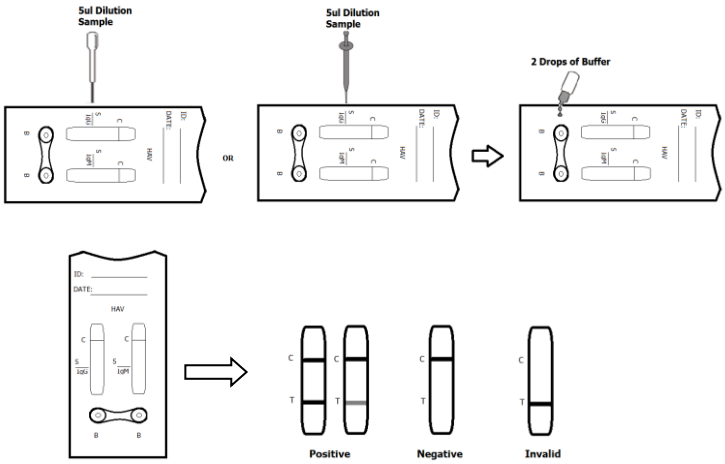
Materials not provided: Timer, specimen collection container, centrifuge

Precautions:
- For professional in vitro diagnostic use only. Do not use after the date. expiry
- The test should remain in the sealed pouch until ready to use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- 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 until the expiry date printed on the sealed pouch.
- **DO NOT FREEZE**.
- Do not use beyond the expiry date.

Specimen Collection and Preparation:
1. The HAV IgG/IgM test can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, no haemolysed 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.

Assay Procedure:
Bring tests and specimens to room temperature (15-30°C) before use.
1. Sample dilution: Add 50µl sample to the sample dilution bottle. Cap the bottle and invert several times to ensure the solution is well mixed.
2. Remove the test cassette from sealed pouch and use it within one hour. Best results will be obtained if the assay is performed immediately after opening foil pouch.
3. Withdraw a portion from the sample dilution bottle using a 5µl dropper, then transfer 1 drop of the diluted sample (5µl) to the sample area which is marked on the device. Or transfer 5µl of diluted sample to the sample area using a pipette.
4. Add 2 drops of buffer (approx. 80µl) into the buffer well (B) of the test device, start the timer.
5. Read the result at 20 minutes, do not interpret any results after 30 minutes.



Interpretation of Results:
Positive: Two distinct coloured lines appear. One coloured line should be in the control region (C) and another coloured line should be in the test region (T).
NOTE: The intensity of the colour 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 colour in the test region (T) should be considered positive.

Negative: One coloured line appears in the control region (C). No apparent coloured 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Quality Controls:
A procedural control is included in the test. A coloured 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 of the Test:
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 Device 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 quality 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.

Performance Characteristics:
The HAV IgG/IgM Device has been compared with a leading commercial HAV EIA test. The correlation between these two systems is > 98%.
Sensitivity and Specificity: The HAV IgG/IgM Device was compared with a leading commercial ELISA HAV test; the results show that the HAV IgG/IgM Device has a high sensitivity and specificity.
IgG Results

Method		EIA		Total Results
HAV IgG/IgM Device (Serum/Plasma)	Results	Positive	Negative	
	Positive	80	5	85
	Negative	5	519	524
Total Results		85	524	609

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

IgM Results

Method		EIA		Total Results
HAV IgG/IgM Device (Serum/Plasma)	Results	Positive	Negative	
	Positive	118	4	122
	Negative	6	466	472
Total Results		124	470	594

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

References:

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.

Glossary of Symbols:

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

CE

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