HAV IgG/IgM Rapid Test (S/P/WB)

Cat. No.: HAV 260

1. INTENDED USE

The HAV IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection and differentiation of antibodies (IgG and IgM) to Hepatitis A virus (HAV) in human serum, plasma or whole blood. It is intended to be used as a screening test by professionals and provide a preliminary test result to aid in the diagnosis of HAV infection.

2. SUMMARY AND PRINCIPLE OF THE ASSAY

HAV, a positive-sense RNA virus, is a unique member of the family *Picornaviridae*. HAV is highly contagious and is primarily transmitted from person-to-person by the fecal-oral route either through person to person contact or consumption of contaminated food or water. Although hepatitis A is not ordinarily a sexually transmitted disease, the infection rate is high among men who have sex with men due to oral-anal contact.

The presence of anti-HAV IgM in blood samples suggests an acute or recent HAV infection. In most infected individuals, anti-HAV IgM rapidly increases in titer over a period of 4-6 weeks post infection and then declines to non-detectable levels within 3 to 6 months. Anti-HAV IgG can be detected at the onset of symptoms and remain elevated throughout an individual's life. Protective immunity from an infection with HAV is indicated by an anti-HAV IgG level ≥20-33 mIU/mL, though the presence of anti- HAV IgG ≥ 20-33 mIU/mL does not necessarily ensure protection from a future HAV infection. A patient without protective levels of anti-HAV IgG (< 20-33 mIU/mL) is considered at risk of acquiring an HAV infection.

The HAV IgG/IgM Rapid Test is a lateral flow immunoassay for the qualitative detection and differentiation of anti-HAV IgG and IgM in serum, plasma or whole blood. It can be performed within 15 minutes by minimally skilled personnel without the use of laboratory equipment.

3. PACKAGE CONTENTS

1) Pouch contents: Test Cassette, Desiccant.
2) 5 µl capillary tube
3) Buffer
4) Test instruction.

4. WARNINGS AND PRECAUTIONS

1) For professional in vitro diagnostic use only.
2) Do not reuse.
3) Do not use if the pouch seal or its packaging is compromised.
4) Do not use after the expiration date shown on the pouch.
5) Do not mix and interchange different specimens.
6) Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.
7) Wash hands thoroughly after finishing the tests.
8) Do not eat, drink or smoke in the area where the specimens or kits are handled.
9) Clean up spills thoroughly with appropriate disinfectants.
10) Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
11) Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
12) Keep out of children's reach.

5. SPECIMEN PREPARATION

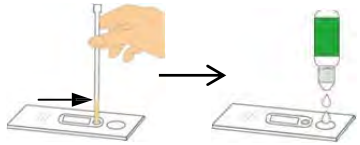
1) The HAV IgG/IgM test is performed on human serum, plasma or whole blood.
2) For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
3) For plasma samples, collect blood in a tube containing anticoagulant.
4) Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
5) Test specimens as soon as possible after collecting. If not tested immediately, store specimens at 2- 8°C for up to 5 days. For longer storage, specimens should be kept frozen at -20°C.
6) For whole blood samples, collect blood in a tube containing anticoagulant.
7) Whole blood specimens should be stored at 2-8°C if not tested immediately. The specimens must be tested within 24 hours of collection.
8) Do not use heat-inactive specimens.

6. TEST PROCEDURE

1) Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a level surface.
2) Using micropipette, add 5 µL of serum, plasma or whole blood into the sample well marked "S".

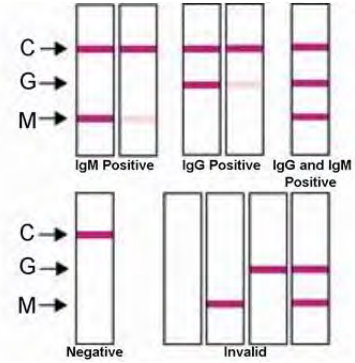
OR

Using capillary tube, add 5 µL of serum, plasma or whole blood into the sample well marked "S". Fill the capillary tube with specimen not exceeding the specimen line. The volume of the specimen is approximately 5 µL.



3) Immediately add 2 drops (approximately 60-80 µL) of sample diluent into the buffer well (B well) with the bottle positioned vertically.
4) Read the result in 15 minutes, following instructions under the "Result Interpretations" section
5) Do not read results after 20 minutes.

7. RESULT INTERPRETATIONS



Negative

If only the C line develops, the test indicates that anti-HAV antibodies are not detected in the specimen. The result is negative or non-reactive.

Positive

1) In addition to the presence of the C line, if only the G line develops, the test result indicates the presence of anti-HAV IgG; the result is HAV IgG positive or reactive.
2) In addition to the presence of the C line, if only the M line develops, the test indicates the presence of anti-HAV IgM. The result is HAV IgM positive or reactive.
3) In addition to the presence of C line, if both the G and M lines develop, the test indicates the presence of anti-HAV IgG and anti-HAV IgM. The result is HAV IgG and HAV IgM positive or reactive.

Invalid

If no C line develops, the assay is invalid regardless of any color development on the test lines (G and M) as indicated below. Repeat the assay with a new device.

8. STORAGE AND STABILITY

1) Test device in the sealed pouch can be stored at 2-30°C up to the expiration date. Do not freeze the test device.
2) The test device should be kept away from direct sunlight, moisture and heat.

9. PERFORMACE CHARACTERISTICS

1) Analytical Sensitivity of IgG Detection

The 2nd WHO International Standard for HAV (NIBSC 97/646) was reconstituted in water to 98 IU/mL and diluted with negative serum to concentrations of 40, 50, 60, 70, 80, 90, and 100 mIU/mL. Thirty repeats were tested on the HAV IgG/IgM Rapid Test. Defined as the 93% detection level, the limit of detection, or sensitivity, of the HAV IgG/IgM Rapid Test for the G test line is 70 mIU/mL.

HAV IgG (mIU/mL)	40	50	60	70	80	90	100
Number Positive	0	3	11	28	30	30	30

Number Negative	30	27	19	2	0	0	0

N=30, analytical sensitivity at 70 mIU/mL = 28/30 x 100% = 93%

2) Accuracy of IgG Detection

A total of 200 clinical specimens were collected and tested with the HAV IgG/IgM Rapid Test and by a commercial anti-HAV IgG/IgM rapid test. Comparison for all subjects is shown in the following table:

Reference		HAV IgG/IgM Rapid Test		Total
		Positive	Negative	
Commercial test	Positive	125	0	125
	Negative	4	71	75
Total		129	71	200

Relative Sensitivity: 100%, Relative Specificity: 94.7%, Overall Agreement: 98.0%

3) Accuracy of IgM Detection

A total of 306 specimens were collected and tested with the HAV IgG/IgM Rapid Test and by a commercial anti-HAV IgM ELISA. Comparison for all subjects is shown in the following table:

		HAV IgG/IgM Rapid Test		Total
		Positive	Negative	
Commercial test	Positive	91	5	96
	Negative	7	203	210
Total		98	208	306

Relative Sensitivity: 94.8%, Relative Specificity: 96.7%, Overall Agreement: 96.1%

4) Performance on Boston Biomedica Inc (BBI) Anti-HAV Seroconversion Panel

The performance of the HAV IgG/IgM Rapid Test was evaluated using the BBI Anti-HAV Seroconversion Panel (PHT903). The results are shown in the following table:

BBI Reference Panel: HAV ELISA		HAV IgG/IgM Rapid Test
Type	Number	Agreement
IgG HAV Positive	10	10 (100%)
IgG HAV Negative	5	5 (100%)
IgM HAV Positive	10	10 (100%)
IgM HAV Negative	5	5 (100%)

5) Positive Rate on the Random Clinical Specimens

990 random, clinical specimens were tested with the HAV IgG/IgM Rapid Test. The positive rate was 70.4% for IgG anti-HAV and 4.6% for IgM anti-HAV.

6) Cross-Reactivity

No false positive anti-HAV IgG and IgM results were observed on 4-10 specimens from the following disease states or special conditions, respectively:

HBV	HCV	HEV	HIV	hCG
Dengue	H. pylori	Malaria	TB	T. pallidum
Typhoid	ANA	HAMA	RF (up to 1,000 IU/mL)	

7) Interference

Common substances (such as pain and fever medication and blood components) may affect the performance of the HAV IgG/IgM Rapid Test. This was studied by spiking these substances into negative, anti-HAV IgG positive and IgM positive specimens, respectively. The results demonstrate that at the concentrations tested, the substances studied do not affect the performance of the HAV IgG/IgM Rapid Test.

List of potentially interfering substances and concentrations tested:

1. Albumin	60 g/L	6. Hemoglobin	2 g/L
2. Bilirubin	20 mg/dL	7. Heparin	3,000 U/L
3. Creatinine	440 µmol/L	8. Salicylic acid	4.5 mmol/L
4. EDTA	3.5 µmol/L	9. Sodium citrate	3.5%
5. Glucose	55 mmol/L		

10. LIMITATIONS OF TEST

1) The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of antibodies to HAV in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may lead to inaccurate results.

2) The HAV IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to HAV in human serum, plasma or whole blood. The intensity of the test line does not have linear correlation with the antibody titer in the specimen.

3) A negative or non-reactive test result does not preclude the possibility of exposure to or infection with HAV. A negative or non-reactive result can occur if the titer of HAV antibodies present in the specimen is below the level detectable by the assay or if HAV antibodies were not present during the stage of disease in which the sample was collected.

4) A negative result does not rule out an acute infection with HAV. Samples collected too early in the course of an infection may not have detectable levels of IgM.

Infection may progress rapidly. If the symptoms persist, while the result from HAV IgG/IgM Rapid Test is negative or non-reactive, it is recommended to test with an alternative test method or re-test the patient a few days later.

5) Unusually high titers of heterophile antibodies or rheumatoid factor (≥1,000 IU/mL) may affect expected results.

6) Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

11. REFERENCES

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