

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

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

INTENDED USE

The HAV Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of IgG antibody to Hepatitis A virus (HAV) in serum or plasma.

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 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 Rapid Test Cassette is to be used to detect IgG antibody to HAV in less than 20 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 test has the recombinant mouse anti-human IgG immobilized on the membrane within the test zone. During the test the serum or plasma added on the sample port(S) reacts with mouse anti-human IgG on the membrane first. The buffer runs 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 a positive result when the test zone forms 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.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- 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 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 Rapid Test Cassette can be performed using serum or plasma.
- 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.
- 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.

MATERIALS

Materials provided

- Test cassettes
- Droppers
- Package insert
- HAV buffer
- Sample dilution tube

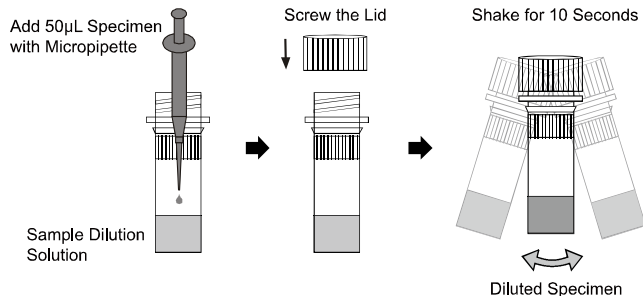
Materials required but not provided

- Specimen collection containers
- Centrifuge
- Timer

DIRECTIONS FOR USE

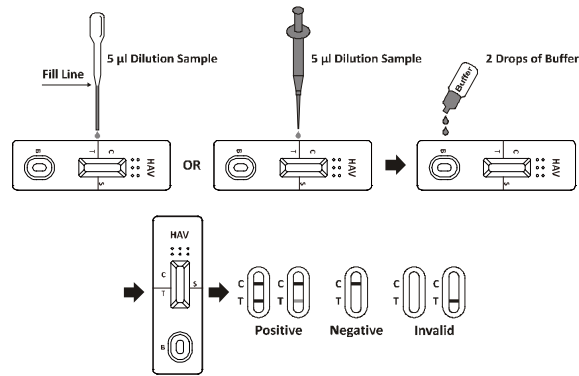
1. Sample Dilution

Use micropipette to add 50µL specimen into the sample dilution tube. Screw the lid tightly and shake it for 10 seconds to ensure the solution could be well mixed. Use the diluted sample as specimen for testing. See instruction below.



2. Testing Procedures

- 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.
- Hold the dropper vertically, draw the diluted specimen from sample dilution bottle up to the fill line marked on the dropper as shown in illustration below (approx. 5µL), transfer the diluted specimen to the **sample area (S)** which has been marked on the test cassette. Or use micropipette to add 5µL diluted specimen into the **sample area (S)** which has been marked.
- Add 2 drops of buffer (approx. 80µL) into the **buffer well (B)** marked on the test cassette, start the timer. See illustration below.
- 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 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

- The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of anti-HAV IgG in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
- The HAV Rapid Test Cassette is limited to the qualitative detection of anti-HAV IgG in human serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
- A negative result for an individual subject indicates absence of detectable anti-HAV IgG. However, a negative test result does not preclude the possibility of exposure to or infection with HAV.
- A negative result can occur if the quantity of the anti-HAV IgG 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.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

EXPECTED VALUES

The HAV IgG Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial HAV EIA test. The correlation between these two systems is 98.4%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

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

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

Relative Sensitivity: 94.1% (95%CI*: 86.8%-98.1%)

Relative Specificity: 99.0% (95%CI*: 97.8%-99.7%)

Overall Accuracy: 98.4% (95%CI*: 97.0%-99.2%)

*Confidence Intervals

BIBLIOGRAPHY

- 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.
- Keeffe EB. Clinical approach to viral hepatitis in homosexual men. Med Clin North Am. 1986;70(3):567-86.
- 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		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged				