HAV IgG/IgM Test Device
Package Insert

Cat: IHA-422
Version: 03
Specimens: Whole blood/Serum/Plasma
Effective Date: 2024-07

For professional *in vitro* diagnostic use only.

INTENDED USE

The HAV IgG/IgM Test Device (Whole blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM to Hepatitis A Virus (HAV) in whole blood, serum or plasma.

SUMMARY

Hepatitis A is an acute, usually self-limiting disease of the liver caused by hepatitis A virus (HAV). HAV is transmitted from person to person, primarily by the faecal-oral route. The incidence of hepatitis A is closely related to socioeconomic development, and seroepidemiological studies show that prevalence of anti-HAV antibodies in the general population varies from 15% to close to 100% in different parts of the world. One step HAV IgG/IgM Test is a simple, visual qualitative test that detects Hepatitis A Virus antibodies in human Whole Blood /Serum / Plasma. The test is based on immunochromatography and can give a result within 15 minutes.
The HAV IgG/IgM Test Device (Whole blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of IgG and IgM antibodies to HAV in serum or plasma.

PRINCIPLE

The HAV IgG/IgM Test Device (Whole blood/Serum/Plasma) is a qualitative membrane strip based immunoassay for the detection of Hepatitis A Virus IgG and IgM in Whole Blood /Serum / Plasma. The test device consists of: 1) a burgundy colored conjugate pad containing HAV recombinant envelope antigens conjugated with Colloid gold (HAV conjugates) and rabbit IgG-gold conjugates,2) a nitrocellulose membrane strip containing test band (IgG and IgM band) and a control band (C band). The IgG and IgM bands is pre-coated with the antibody for the detection of IgG and IgM anti-HAV and the C band is pre-coated with goat anti rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgG or IgM anti-HAV if present in the specimen will bind to the HAV conjugates. The immunocomplex is then captured by the reagent coated on the IgG or IgM band, forming a burgundy colored IgG or IgM band, indicating a HAV IgG/IgM positive test result and suggesting a fresh infection. Absence of any IgG or IgM band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on the IgG or IgM band. Otherwise, the test result is invalid and the specimen must be retested with another device.

KIT COMPONENTS

Individually packed Test Devices	Each strip contains a colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
Disposable pipettes	For adding specimens use.
Buffer	Phosphate buffered saline and preservative
Package insert	For operation instruction.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device 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 Test Device (Whole blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.

- To collect **Fingerstick Whole Blood specimens:**
  Wash the patient's hand then allow to dry. Massage the hand without touching the puncture. 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 device by using a **capillary tube or hanging drops.**
- 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. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days 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 federal regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test devices
- Buffer
- Disposable specimen droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for plasma only)
- Disposable heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
- Lancets (for fingerstick whole blood only)
- Timer

DIRECTIONS FOR USE

Allow the test device, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
3. Transfer 1 drops (approximately 5μL) of Whole blood/ serum/plasma and 2-3drop buffer (approximately 80-120μL) to the sample pad of the strip with a disposable pipette in the kit, and then start the timer.
4. As the test begins to work, you will see color move across the membrane. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT:



IgG Positive:* The colored line in the control line region (C) appears and a colored line appears in test line region 1 (T1). The result is positive for HAV specific-IgG and is probably indicative of secondary HAV infection.



IgM Positive:* The colored line in the control line region (C) appears and a colored line appears in test line region 2 (T2). The result is positive for HAV specific-IgM antibodies and is indicative of primary HAV infection.



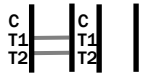
IgG and IgM Positive:* The colored line in the control line region (C) appears and two colored lines should appear in test line regions 1 and 2 (T1 and T2). The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary HAV infection.

NEGATIVE RESULT:



The colored line in the control line region (C) appears. No line appears in test line regions 1 or 2 (T1 or T2).

INVALID RESULT:



Control line (C) falls to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration IgG and IgM antibodies to HAV present in the specimen. Therefore, any shade of colored in the test regions (IgG or IgM) should be considered positive.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. This reagent is designed for the qualitative screening test. Concentration of HAV- IgG or IgM cannot be determined by this qualitative test.
2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.
3. Negative result may occur when detecting short-term infected samples, indicate that the specific antibodies of HAV does not exist or the concentration is below detection limit. If HAV infection is still suspected, the sample should be collected 1-2 weeks later and carry the parallel detection with the first sample.
4. Results of patients who used to receive immunosuppressive therapy or with immune function damage may have a low serology reference value.
5. IgM antibody can be found not only in the primary infection, but also in the secondary infection of HAV.
6. Positive results of the patients who used to receive blood transfusions or other blood products therapy, should be analyzed cautiously.
7. Abnormal results may occur according to operator error or drug use. If HAV infection is still suspected, the sample should be collected later and carry the parallel detection with the first sample.

PERFORMANCE CHARACTERISTICS

Clinical trial results

A clinical evaluation was conducted on 1040 samples comparing the results obtained using the The HAV IgG/IgM Test Device (Whole blood/Serum/Plasma)and other commercially available HAV tests.

Table: HAV IgG Test vs. commercial HAV Test

Relative Sensitivity: 99.7% (98.2%-100%)*
Relative Specificity: 99.6% (98.9%-99.9%)*
Overall Agreement: 99.6% (99.1%-99.9%)*
***95% Confidence Interval**

		HAV Test +	HAV Test -	Total
Other HAV test	+	314	1	315
	-	3	774	777
		317	775	1092

Table: HAV IgM Test vs. commercial HAV Test

Relative Sensitivity: 98.5% (96.2%-99.6%)*
Relative Specificity: 99.2% (98.3%-99.7%)*
Overall Agreement: 99.0% (98.2%-99.5%)*
***95% Confidence Interval**

		HAV Test +	HAV Test -	Total
Other HAV test	+	259	4	263
	-	6	771	777
		265	775	1040

PRECISION

Intra Assay

Within-run precision has been determined by using 15 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified 99.5% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same three specimens: a negative, a low positive and a high positive. Three different lots of the HAV IgG/IgM Test Device (Whole blood/Serum/Plasma) have been tested using negative, low positive and high positive specimens. The specimens were correctly identified 99.5% of the time.

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