HAV IgG/IgM Rapid Test

Cat. No.:DTS649
Pkg.Size:

Intended use

CD HAV IgG/IgM Rapid Test is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to Hepatitis A virus in human serum or plasma. This test provides only a preliminary test result. Therefore, isolation of virus, PCR and RT-PCR, more specific alternative diagnosis method must be used in order to obtain a confirmation of Hepatitis A virus infection.

General Description

Hepatitis A is caused by infection with the hepatitis A virus (HAV), a nonenveloped RNA agent that is classified as a picornavirus. Hepatitis A is an acute infectious disease of the liver. It can be serious for older people and people who already have liver disease. Death is possible, although very rare. The incubation period of hepatitis A is 15~50 days, with an average of 28 days. The illness caused by HAV infection typically has an abrupt onset of signs and symptoms that include fever, malaise, anorexia, nausea, and abdominal discomfort, followed several days later by dark urine and jaundice. Hepatitis A is spread through feces. People can get infected through close contact with an infected person and eating contaminated food or drinking contaminated water.

Principle Of The Test

CD HAV IgG/IgM Rapid Test is designed to simultaneously detect and differentiate IgG and IgM antibodies to Hepatitis A virus in human serum or plasma.
CD HAV IgG/IgM test device has 3 pre-coated lines, “G” (HAV IgG Test Line), “M” (HAV IgM Test Line) and “C” (Control Line) on the surface of the membrane. All three lines in result window are not visible before applying any samples. The “Control Line” is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. A purple “G” and “M” lines will be visible in the result window if there are enough IgG and/or IgM antibodies to Hepatitis A virus in the sample. If IgG and/or IgM antibodies to Hepatitis A virus are not present in the sample, there is no color appearance in “G” and/or “M”.

Reagents And Materials Provided

1. CD HAV IgG/IgM kit contains following items to perform the assay.
① Test devices individually foil pouched with a desiccant
② Assay diluent (5ml/vial)
③ 5μl capillary pipette
④ Instruction for use
2. Active ingredients of main components
① 1 test device included ; Gold Conjugates (as main component) : Mouse monoclonal anti-Hepatitis A Virus-gold colloid (1±0.2), Test line “G” (as main component) : Mouse monoclonal anti-human IgG (4±0.8), Test line “M” (as main component) : Mouse monoclonal anti-human IgM (4±0.8), Control line (as main component) : Goat anti-mouse IgG) (8±1.6)
② Assay buffer include ; 100 mM Phosphate buffer, Tween 20 (0.1%), Sodium azide (0.01%)

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Specimen Collection And Preparation

1. Specimen Collection and Storage
① Serum or plasma samples may be used with this test.
② **[Serum]** Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
[Plasma] Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
③ If serum or plasma specimens are not tested immediately, they should be refrigerated at 2~8℃ For storage period longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1~30℃) prior to use.
④ Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
2. Precaution
① Anticoagulants such as heparin, EDTA, and citrate do not affect the test result.
② As known relevant interference, hemolytic samples, rheumatoid factorscontained samples and lipaemic, icteric samples can lead to impair the test results.
③ Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.

Assay Procedure

1. Allow all kit components and specimen to room temperature prior to testing.
2. Remove the test device from foil pouch, place it on a flat, dry surface.
3. **[Using a capillary pipette]** With a 5µl capillary pipette, add 5µl of serum or plasma specimen drawn to black line into the square sample well marked “S”. OR,
[Using a micropipette] Add 5µl of serum or plasma specimen into the square sample well marked “S”.
4. Add 4 drops of assay diluent to the assay diluent well round shaped.
5. Interpret test results at 20 minutes.
Caution : In case that color intensity of test line show very faint at 20 minutes, wait until 40 minutes and then check the test line again in order to get accurate result.

Quality Control

The “Control Line” is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

Interpretation of Results

1. **Negative**
The control line is only visible on the test device. No IgG and IgM antibodies were detected.

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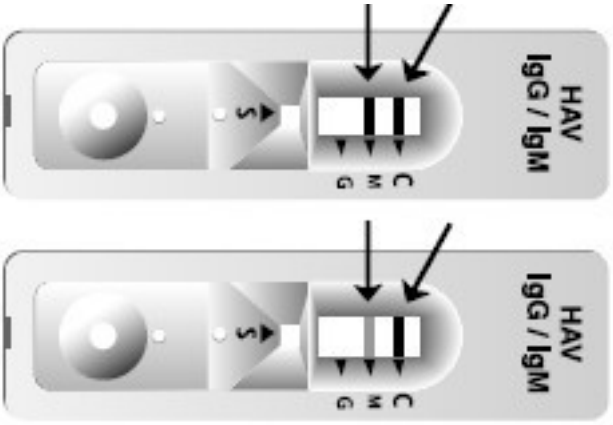
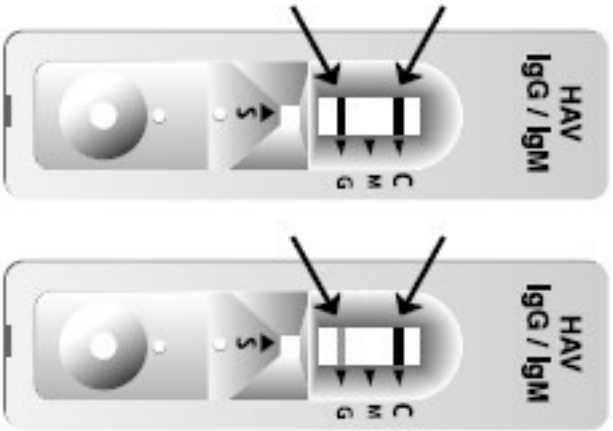
2. **IgM Positive**

The control line (C) and IgM line (M) are visible on the test device. This is positive for IgM antibodies to HA virus.



3. **IgG Positive**

The control line (C) and IgG line (G) are visible on the test device. This is positive for IgG antibodies.



4. **IgG and IgM Positive**

The control line (C), IgM (M) and IgG line (G) are visible on the test device. This is positive for both IgM and IgG antibodies.

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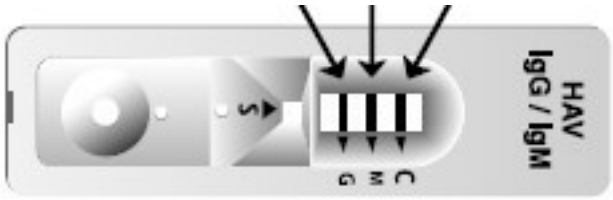

5. **Invalid**

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Repeat the test using a new test device.

Specific Performance Characteristics

The performance of the CD HAV IgG/IgM Rapid test was evaluated with commercial HAV IgM Rapid test. We used 125 samples for positive and 150 samples for negative. We found the relative sensitivity is 97.6% (122/125), the relative specificity is 98.0% (147/150). The results are summarized in the following tables.

		CD BIOLINE HAV IgG/IgM Rapid		Commercial HAV IgM Rapid test		Total
		Positive	Negative	Positive	Negative	
Confirmed by ELISA	Positive Specimens	122	3	104	21	125
	Negative Specimens	147	3	131	19	150
Sensitivity		97.6 % (122/125)		83.2 % (104/125)		
Specificity		98.0 % (147/150)		87.3 % (131/150)		

Precautions

1. For best results, strict adherence to these instructions is required.
2. All specimens should be handled as being potentially infectious.
3. The test device should be stored at room temperature. Do not store at refrigerator.
4. The test device is sensitive to humidity as well as to heat.
5. Do not open or remove test device from individually sealed pouches until immediately before their use. Perform the test immediately after removingthe test devices from the foil pouch.

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6. Do not use it beyond the expiration date. The shelf-life of the kit is as indicated on the outer package.
7. Do not use the test kit if the pouch is damaged or the seal is broken.
8. The components (test device and assay diluent) in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.
9. The assay diluent contains low concentration of sodium azide as a preservative. Sodium azide is toxic and should be handled carefully to avoid ingestion and skin contact.

Warnings

1. DO NOT RE-USE test device.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.
8. The instruction must be followed exactly to get accurate results.

Limitations

1. This test detects the presence of antibodies to Hepatitis A virus in the specimen and should not be used as the sole criterion for the diagnosis of Hepatitis A virus infection.
2. The diagnosis of acute Hepatitis A virus infection is confirmed during the acute or early convalescent phase of infection by the presence of IgM anti-Hepatitis A virus in serum or plasma. IgM anti-Hepatitis A virus generally disappears within 6 months after the onset of symptoms. IgG anti-Hepatitis A virus appears in the convalescent phase of infection, remains for the lifetime of the person, and confers enduring protection against disease.
3. The presence of total anti-Hepatitis A virus and absence of IgM anti-Hepatitis A virus indicates immunity consistent with either past infection or vaccination.
4. Persons who test positive for IgM anti-Hepatitis A virus more than 1 year after infection have been reported, as have likely false-positive tests for persons without evidence of recent Hepatitis A virus infection.
5. A negative result can occur if the quantity of the IgG and/or IgM anti-Hepatitis A virus 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.
6. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
7. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.

REFERENCES

1. Nainan OV, Xia G, Vaughan G, Margolis HS. Diagnosis of hepatitis a virus infection: a molecular approach.Clin Microbiol Rev. 2006 Jan;19(1):63-79.
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3. Zoni R, Zanelli R, Riboldi E, Bigliardi L, Sansebastiano G. Investigation on virucidal activity of chlorine dioxide. experimental data on feline calicivirus, HAV and Coxsackie B5.J Prev Med Hyg. 2007 Sep;48(3):91-5.

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