HAV IgM Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for Use

A lateral flow immunochromatographic assay for the qualitative detection of IgM antibody to Hepatitis A virus (HAV) in human whole blood ,serum or plasma.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION

1T/box,10T/box,20T/box,25T/box,40T/box,50T/box

INTENDED USE

The HAV IgM Rapid Test Cassette (Colloidal Gold) is a lateral flow immunochromatographic assay for the qualitative detection of IgM antibody to Hepatitis A virus (HAV) in human whole blood， serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HAV. The test is recommended for professional use only. All results must be interpreted together with other clinical information available to the physician.

SUMMARY

Hepatitis A virus (HAV) is a kind of RNA virus, which belongs to the family of Picornavirus. HAV showed a spherical particles shape with 27 nm in diameter, icosahedral symmetry consisted of 32 shell particles, containing linear single-strand RNA. Hepatitis A is a kind of intestinal infectious disease caused by hepatitis A virus (HAV) with a worldwide distribution. Children and adolescents are most likely to be infected, and the peak incidence is in winter and spring. Hepatitis A is the most common type of acute viral hepatitis, mainly spread by fecal-oral route. The incubation period of hepatitis A virus is 15 to 45 days, HAV- IgM antibody can be detected in serum a short time later after infected, continue to rise very rapidly, peaking in about 2 weeks, decreasing gradually, disappear in 8 weeks. While HAV-IgG antibody appear later than IgM and will persistent for a long time. Detection of HAV- IgM antibody can diagnose HAV infection in early stage for its simple, fast, and high specificity. Both the immunological detection and virus nucleic acid detection can be used as the basis for laboratory diagnosis of hepatitis A virus.

TEST PRINCIPLE

The test utilizes antibodies including a recombinant protein rabbit anti-HAV polyclonal antibody and mouse anti-human monoclonal antibody on the nitrocellulose membrane with colloidal gold marked HAV antigen as a mark tracer. The reagent is used to detect the HAV IgM antibody in serum/plasma according to the principle of double antibody sandwich method and gold immunochromatography assay. The sample mixing up HAV antibody – marker move along the membrane to the T line, and form the T line when the sample contains HAV-IgM antibody, which a positive result. Conversely, it is a negative result.

REAGENTS AND MATERIALS PROVIDED

Test devices. Each test strip is packed in a foil pouch with a package of desiccant.
Dropper
Instruction for use.
Assay buffer.

MATERIALS REQUIRED BUT NOT PROVIDED

Clock or Timer
Pipette capable of delivering 1.5μl volumes with a precision better than 3%
（Optional Accessories: Sampling Ring ）

PRECAUTIONS

1. For IN VITRO diagnose only.
2. Do not use after the expiration date. The test should remain in the sealed pouch until use.
3. Do not mix components from kits with different lot number. The test result is invalid over 20 minutes.
4. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.
5. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.
6. Patients used to receive monoclonal antibodies therapy may have human anti-mouse antibodies (HAMA) in blood, which does not apply to the detection of this reagent. Other detection method is suggested.
7. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.
8. Dispose the used kit after decontamination of all liquids or solid wastes by following the local law or laboratory rule.

STORAGE AND STABILITY

Store the kit in cool and dry places at a temperature between 2-30°C. **Do not freeze.** The shelf-life of the kit under these storage conditions is 24 months.

SPECIMEN COLLECTION AND HANDLING

1.HAV IgM Rapid Test Cassette can be performed using whole blood,serum or plasma.
2.Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3.Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Samples may be stored at 2-8°C for 1 week prior to assay, and at -20°C for 2 years. Frozen refrigerated samples should be recovered to room temperature before detection and thoroughly mixed. Repeat freeze and thaw for no more than 3 times. Samples that exhibiting visible precipitates, stink or muddy should not be used.
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 national regulations covering the transportation of etiologic agents.

ASSAY PROCEDURE

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (10°C-30°C) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened.

1. Take off the outer packing, put the cassette onto the desk with the sample adding area of the cassette.
2. Whole blood,Serum/Plasma: Drop 1.5μl whole blood,serum/plasma vertically onto the membrane. The pipette tip of micro pipette or sample loop is required to touch the membrane gently for an accurate operation when the sample is added.
3. Add about 2 drops of (80μl-100μl) sample buffer onto the sample pad of strip. Observe the test results immediately within 15-20 minutes, the result is invalid over 20 minutes.

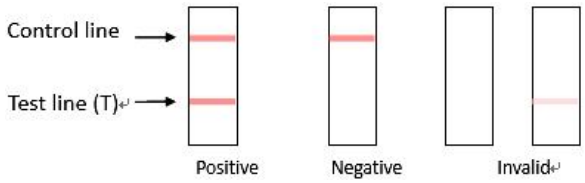
INTERPRETATION OF ASSAY RESULT

(Please refer to the illustration)

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered as an internal 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.

PERFORMANCE CHARACTERISTICS

1. Using internal and national quality control samples:

Negative specificity: The results should all be negative when detecting 10 kits of HAV-IgM negative quality control samples.

Positive specificity: The results should all be positive when detecting 10 kits of IgM positive quality control samples.(Including strong, medium and weak positive samples)

Limit of detection: The results should all be positive when detecting the internal quality control samples or the diluted national HAV- IgM positive quality control samples with the diluents rate at 1:8.

Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the precision control samples by 10 kits of the same batch.

2. Clinical trial results

A clinical evaluation was conducted on 1040 samples comparing the results obtained using the Diagnostic Kit for IgM Antibody to Hepatitis A Virus (Colloidal Gold) and other commercially available HAV tests.

HAV IgM Rapid Test	Reference Product			Total
	Positive	Negative		
Positive	259	6		265
Negative	4	771		775
Total	263	777		1040

3. Analytical sensitivity: 1000 mol/L bilirubin, 5.65mmol/L triglyceride, 6.5g/L hemoglobin has no effect on the detection result. The reagent is not affected by the rheumatoid factor, antinuclear antibodies.

The addition of HEV、HBV、HCV、TP and HIV showed no cross-reactivity.

LIMITATIONS OF TEST

1. This reagent is designed for the qualitative screening test. Concentration of HAV-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. Sensitivity can be lowered by the competition between high titers of HAV-IgG and HAV-IgM antibody to the antigen binding site. Results of this kind of samples should be analyzed cautiously.
4. 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.
5. Results of patients who used to receive immunosuppressive therapy or with immune function damage may have a low serology reference value.
6. IgM antibody can be found not only in the primary infection, but also in the secondary infection of HAV.
7. Positive results of the patients who used to receive blood transfusions or other blood products therapy, should be analyzed cautiously.
8. 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.

Code:GKPD032-1 Effective date: May 27, 2024

Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃-30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Manufacturer:
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