HAV IgM Rapid Test Kit

Instruction for use

【Product Name】HAV IgM Rapid Test Kit

REF A10075001B, A10075001C, A10075001D, A10075001E

【Specification】1 test/kit, 5 tests/kit, 10 tests/kit, 25 tests/kit

【Intended Use】

The HAV IgM Rapid Test Kit is a colloidal gold immunochromatography intended for the qualitative detection of IgM antibodies to Hepatitis A in human whole blood, serum or plasma in vitro. It provides an aid in the diagnosis of infection with Hepatitis A.

【Summary】

Hepatitis A is a highly contagious liver infection caused by the hepatitis A virus. It is transmitted through the consumption of contaminated food or water, or through close contact with an infected person. Symptoms of hepatitis A include fatigue, nausea, abdominal pain, and jaundice (yellowing of the skin and eyes). The illness is usually self-limiting and most people recover fully without complications. However, in some cases, it can cause severe liver damage and even lead to death. Vaccination is available to prevent hepatitis A, and practicing good hygiene, such as thorough handwashing, can also help reduce the risk of infection.

【Test Principle】

The test is a sandwich immunoassay. If there are HAV IgM antibodies in the sample, it will be combined with colloidal gold labeled HAV antigen, form a complex. Under the action of chromatography, the complex flows on the nitrocellulose membrane. Then, the complex will combine to human anti-HAV monoclonal IgM antibodies (T line) coated on the nitrocellulose membrane. The control line (C line) must appear in the control area of the Cassette for the result to be valid. The colored lines will appear in the test line area, indicating a positive result.

【Main Components】

Materials Provided:

Specification / Material	1 test/kit	5 tests/kit	10 tests/kit	25 tests/kit
Test Cassette	1	5	10	25
Sample Diluent	1	1	1	1
Disposable Pipettes	1	5	10	25
Instruction for Use	1	1	1	1

Materials Optioned:

1. Alcohol pad
2. Safety lancet

Materials Required but Not Provided:

1.Timer
2.Tube rack for specimens
3.Any necessary personal protective equipment

【Storage Conditions and Validity】

1.This product should be stored in a dark and dry place at 2~30℃.The validity period of the kit is 24 months.
2.After unpacking the aluminum foil bag of the test Cassette, It should be used in the specified environment (Temperature 2-35°C,Humidity 40%-90%) within 1 hour.
3.Please see label for the information about the date of manufacture and shelf life.

【Samples Collection Handing】

1. This kit is used to detect human serum/plasma/whole blood samples. The plasma and whole blood samples are recommended to use EDTA, heparin or sodium citrate for anticoagulation. Other body fluids and samples may not get accurate results.

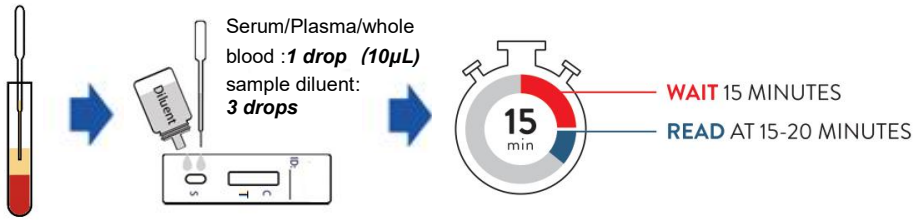
2. After the blood samples are collected, if they cannot be tested in time, the serum/plasma should be stored at 2-8°C for 7 days.The sample can be stored for 30 days under -15°C. The whole blood samples should not be frozen and can be stored for 3 days at 2-8°C.

【Test Method】

1. Read the instructions for use completely before testing.
2. Before use, take out the reagents and specimens, places the reagent on a flat table and balance them to room temperature (18-25°C).
3. The operators take the test Cassette out of the packaging bag and place it on the platform table.
4. Add the specimens

For serum, plasma or venous whole blood samples

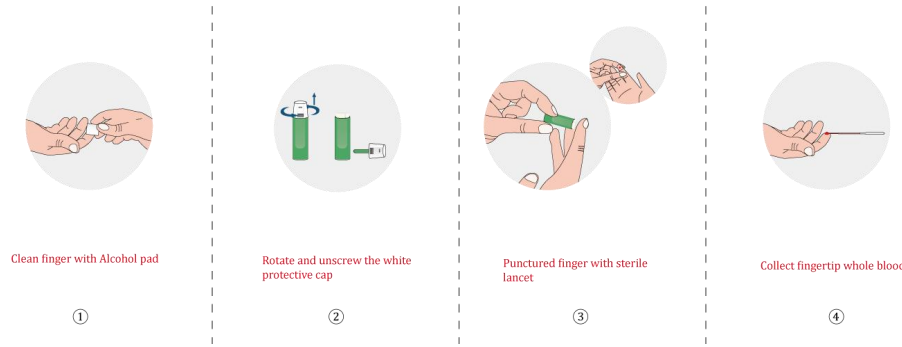
a.Collect and process blood samples according to standard operating procedures to obtain serum/plasma/venous whole blood samples.
b.The operator uses a disposable pipette to absorb 1 drop (10 μL) of the serum, plasma,venous whole blood sample,add it to the sample well.Immediately add 3 drops of sample diluent to the sample well. After finish adding sample,the operators start timing and keep it react for 15 minutes.

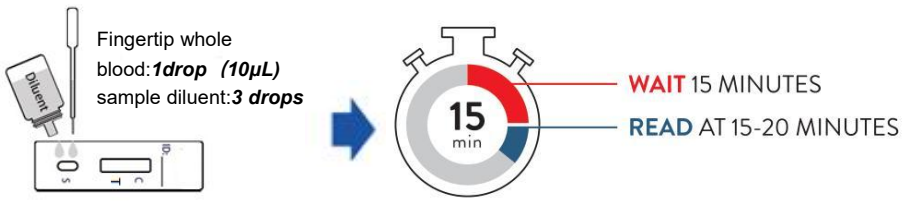


For fingertip whole blood samples

a.Clean the puncture site with the alcohol pad
b.After the alcohol is dried, the fingertips are punctured with safety lancet to form blood droplets
c.The operator uses a disposable pipette to absorb 1 drop (10 μL) of fingertip whole blood sample,Immediately add 3 drops of sample diluent to the sample well.After finish adding sample, the operators start timing and keep it react for 15 minutes.

NOTE：After the formation of blood drops, should wipe the first drop of blood before using a disposable pipette dropper to take fingertip blood samples.





【Interpretation of Test Results】

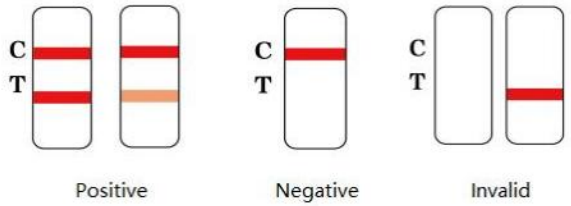
Negative (-):

Only a red line appears in the quality control area (C) and there is no red line in the test area(T). The results indicate that there is no HAV IgM antibody in the sample.

Positive (+):

Two red lines appear, one in the quality control area (C) and one in the test area (T) .The results indicate that there is HAV IgM antibody in the sample.If any Positive, there is currently a suspicion of question of hepatitis A virus infection. Perform another test or to confirm the result.

Invalid: There is no red line in the quality control area(C) which indicates that the operating process is incorrect or the reagent has been damaged. In this case, the medical staff should carefully read the instructions again and retest with new reagents.



【Reporting of Results】

Positive test:

Control line and test line appear on the membrane. The lower the antibody concentration is, the weaker the test line is.

Negative test:

Only the control line appears on the membrane. The absence of a test line indicates a negative result.

Invalid:

There should always be a control line in the control region regardless of test result. If control line is not seen, the test is considered invalid. Repeat the test using a new test device.

Note: *It is normal to have a slightly lightened control line with very strong positive samples as long as it is distinctly visible.*

【Limitation of the test】

1. The kit can be used for the detection of human serum,plasma or whole blood samples.The reliability of the determination of this substance in other types of samples has not been fully confirmed.
2. Positive test results do not rule out co-infections with other pathogens.
3. Results of hepatitis A virus test should be correlated with the clinical history and other data available to the clinician evaluating the patient.
4. A false-negative test result may occur if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of hepatitis A virus infection.
5. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.

【Performance Characteristics】

1. **Sensitivity and Specificity**

The clinical performance of HAV IgM Rapid Test Kit was evaluated in comparison to HAV IgM test using clinical specimens. The results are shown in the following tables.

For serum samples

HAV IgM Rapid Test Kit	Commercial HAV IgM test		
	Positive	Negative	Total
Positive	104(a)	3(b)	107(a+b)
Negative	3(c)	98(d)	101(c+d)
Total	107(a+c)	101(b+d)	208(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	97.20%	92.02%~99.42%	
Clinical specificity	97.03%	91.56%~99.38%	
Total coincidence rate	97.12%	93.83%~98.93%	

For plasma samples

HAV IgM Rapid Test Kit	Commercial HAV IgM test		
	Positive	Negative	Total
Positive	107(a)	2(b)	109(a+b)
Negative	3(c)	80(d)	83(c+d)
Total	110(a+c)	82(b+d)	192(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	97.27%	92.24%~99.43%	
Clinical specificity	97.56%	91.47%~99.70%	
Total coincidence rate	97.40%	94.03%~99.15%	

For whole blood samples

HAV IgM Rapid Test Kit	Commercial HAV IgM test		
	Positive	Negative	Total
Positive	125(a)	2(b)	127(a+b)
Negative	4(c)	76(d)	80(c+d)
Total	129(a+c)	78(b+d)	207(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	96.90%	92.25%~99.15%	
Clinical specificity	97.44%	91.04%~99.69%	
Total coincidence rate	97.10%	93.80%~98.93%	

2. **Cross-reactivity**

The HAV IgM Rapid Test Kit does not cross with the IgM antibody of following common Potential Cross-Reactants.

S.N.	Potential Cross-Reactant	S.N.	Potential Cross-Reactant
1	West Nile virus	7	Leptospirosis
2	Japanese encephalitis virus	8	Cytomegalovirus
3	Saint Louis encephalitis virus	9	Chikungunya virus
4	Yellow fever virus	10	Eastern equine encephalitis virus
5	Epstein Barr virus	11	Measles virus
6	Borrelia burgdorferi	12	

3. **Interfering substances**

The concentrations of triglycerides 40mmol/L, hemoglobin 2g/L, rheumatoid factor 1000IU/mL, bilirubin 350μmol/L and HAMA 600ng/mL have no effect on the test results.

【Precautions】

1. After opening the package, the kit should be ready for use as soon as possible and avoid placing it in a high temperature (over 30°C) and high humidity environment for a long time.
2. All samples (whole blood, serum and plasma) and test Cassettes after use should be considered potentially dangerous and should be treated as infectious materials, and the waste should be disposed of in accordance with the regulations of the hospital or environmental protection department.
3. The test strips with any color lines before the test should not be used and the reagents with damaged packaging bags or invalid seals should not be used.
4. The kit is for in vitro diagnostic use only.The kit is for single-use,please do not use the product after it expires.

【Bibliography】

1. Bhalla P, Chadha S, Bhalla A, Singhal S, Kakkar N, Gupta S. Evaluation of the Typhidot IgM rapid test in the diagnosis of typhoid fever among pediatric patients. Indian J Med Microbiol.
2. House DR, Karpowicz L, Batchelor R, et al. Evaluation of a commercial Salmonella typhi IgM rapid test kit for laboratory diagnosis of typhoid fever. J Clin Microbiol.

3. Wijedoru L, Mallett S, Parry CM. Rapid diagnostic tests for typhoid and paratyphoid (enteric) fever. Cochrane Database Syst Rev.
4. Naik DG, Tilak R, Kunwar A, et al. Comparative evaluation of widal test with blood culture in the diagnosis of typhoid fever. J Clin Diagn Res.

【Index of Symbols】

IVD	In vitro diagnostic medical device		Do not re-use
	Do not use if package is damaged and consult instructions for use		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
30°C 2°C	Temperature limit	LOT	Batch code
	Use-by date		Keep dry
	Keep away from sunlight	REF	Catalog number
	Date of manufacture	Σ	Contains sufficient for <n> tests

【Basic Information】

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