CE IVD

HAV IgG/IgM Rapid Test Kit (Colloidal Gold)

PRODUCT NAME
HAV IgG/IgM Rapid Test Kit(Colloidal Gold)

SPECIFICATION
25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE
The HAV IgG/IgM Rapid Test is a lateral flow chromatographic immunoassayfor the qualitative detection and differentiation of antibodies (IgG and IgM)to Hepatitis A virus (HAV) in human serum, plasma or whole blood. It isintended to be used as a screening test by professionals and provide apreliminary test result to aid in the diagnosis of HAV infection.

INTRODUCTION AND CLINICAL SIGNIFICANCE
First isolated in 1973, hepatitis A virus (HAV) is a non-enveloped RNA virusof the family Picornaviridae, genus Hepatovirus. Its transmission occursprimarily through serial transmissions from person to person by the fecal-oral route. However, HAV can also be contracted from contaminated water,close personal contact, sexual contact, and illicit drug use. Infection ischaracterised by rapid onset following an incubation period ofapproximately 28 days (15-50 days), which is followed by a rapid onset ofsymptoms. Signs and symptoms can include nausea, vomiting, diarrhea,dark urine, jaundice, fever, headaches, weight loss and abdominal pain. Thelikelihood of symptoms increases with age. Normally, acute illness does notlast more than two months. There is no chronic viral shedding and nochronic stage of the disease, though recurrences, acute fulminant hepatitisand other complications may occur. Anti-HAV IgM are detectable at orprior to the onset of clinical illness and decline in about 3 to 6 months. Anti-HAV IgG appear soon after IgM, persist for years after infection and conferlifelong immunity. The presence of anti-HAV IgG and the absence of anti-HAV IgM can be used to differentiate between past and current infections.IgM assays can detect antibodies in individuals recently administeredhepatitis A vaccine for a short period of time. However, lowerconcentrations detected 4 to 6 months after the onset of infection typicallydo not produce a positive test result.
The HAV IgG/IgM Rapid Test detects and differentiates anti-HAV IgG from anti-HAV IgM in human serum, plasma or whole blood after 15 minutes and can be performed by minimally-skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE
The HAV IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay.The test cassette consists of: 1) a burgundy conjugate pad containing HAVantigens conjugated with colloidal gold (HAV Ag conjugates) and controlantibodies conjugated with colloidal gold, 2) a nitrocellulose membranestrip containing two test lines (M and G) and a control line (C). Mouse anti-human IgM are pre-coated on the line 'M', mouse anti-human IgG areprecoated on the line 'G' and control antibodies are pre-coated on the line(C). When an adequate volume of specimen and buffer is dispensed into thesample well (S) and buffer well (B) respectively, the specimen migrates bycapillary action along the test cassette. If anti-HAV IgM are present in the specimen, they bind to the HAV Ag conjugates. The immunocomplexes arethen captured on the membrane by the pre-coated mouse anti-human IgM,forming a burgundy line 'M', indicating an HAV IgM positive test result. Ifanti-HAV IgG are present in the specimen, they also bind to the HAV Agconjugates. The immunocomplexes are then captured on the membrane bythe pre-coated mouse anti-human IgG, forming a burgundy line 'G',indicating an HAV IgG positive test result. The absence of both test lines (Mand G) suggests a negative result.
The test contains an internal control (C) which should always exhibit a burgundy line of the immunocomplex of control line antibodies, regardless of the colour development of the test lines (M and G). Otherwise, the test result is invalid and the specimen should be retested with another test cassette.

REAGENTS AND MATERIALS SUPPLIED
- HAV IgG/IgM Rapid Tests (incl. desiccant)
- capillary tubes (5 µL)
- Buffer
- package insert

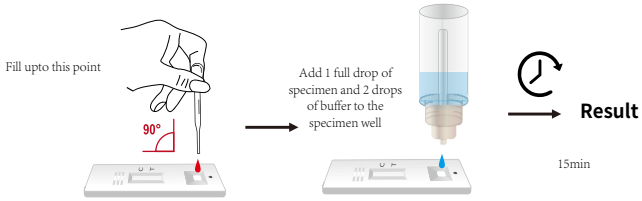
ADDITIONAL MATERIALS REQUIRED
- Clock or timer
- Lancing device (for whole blood testing)

STORAGE AND STABILITY
All reagents are ready to use as supplied. Store unused test cassettesunopened at 2-30°C. If tests are stored at 2-8°C, ensure that they arebrought to room temperature before opening. The test cassette is stableuntil the expiration date printed on the sealed foil pouch. Do not freeze testkits or expose them to temperatures over 30°C.

WARNINGS AND PRECAUTIONS
•For professional in-vitro diagnostic use only.
•Carefully read through the test procedure prior to testing.
•Do not use the test after the expiration date indicated on the package.
•Do not use the test if the foil pouch is damaged.
•Do not reuse tests.
•Do not add samples to the reaction area (result area).
•In order to avoid contamination, do not touch the reaction area (resultarea).
•Do not substitute or mix components from different test kits.
•Do not use hemolysed specimens for testing.
•Do not eat, drink or smoke in the area where specimens and test kits arehandled.
•Wear protective clothing such as laboratory coats, disposable gloves andeye protection when specimens are being assayed. Wash handsthoroughly after performing the test.
•Handle all specimens as if they contain infectious agents. Observeestablished precautions for microbiological risks throughout all procedures and standard guidelines for the appropriate disposal ofspecimens.
•The test results should be read at 15 minutes after the specimen isapplied to the sample well of the test cassette. Reading the results aftermore than 20 minutes may give erroneous results.
•Do not perform the test in a room with strong air flow, i.e. an electric fanor strong air-conditioning.

SPECIMEN COLLECTION PREPARATION
Consider any materials of human origin as infectious and handle them usingstandard biosafety procedures. Do not use hemolysed blood for testing.
Plasma
•Collect a blood specimen into a collection tube (containing EDTA, citrateor heparin) by venipuncture.
•Separate plasma by centrifugation.
•Carefully withdraw the plasma into a new pre-labeled tube.
Serum
•Collect blood specimen into a collection tube (containing noanticoagulants) by venipuncture.
•Allow the blood to clot.
•Separate serum by centrifugation.
•Carefully withdraw the serum into a new pre-labeled tube.
Test specimens as soon as possible after collection. Specimens can be stored at 2-8°C for up to 5 days if they are not to be tested immediately. Specimens should be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, haemolysis or turbidity in order to avoid interference with result interpretation.
Blood
Drops of whole blood can be obtained by either fingertip puncture or venipuncture. Collect a blood specimen into a collection tube (containing EDTA, citrate or heparin).
Whole blood specimens should be refrigerated (2-8°C) if they are not tested immediately. Specimens must be tested within 24 hours of collection.

TEST PROCEDURE
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C)prior to testing.
1.When you are ready to test, open the pouch and remove the testcassette. Place it on a clean, level surface.
2.Label the test cassette with the specimen ID number.
3.Using a squeezing motion, fill the capillary tube with serum, plasma or whole blood. Do not exceed the specimen line. The volume of the specimen is approximately 5 µL. **For maximum precision, transfer the specimen using a pipette capable of delivering 5 µL volumes.**



4.Holding the capillary tube vertically, dispense the entire specimen intothe center of the sample well (S), making sure that there are no airbubbles.
5.Immediately add 2 drops (approximately 60-80 µL) of Buffer into the buffer well (B), holding the bottle vertically. Start the timer.
6.Read test results after 15 minutes. Positive results may be visible in as little as 1 minute. Do not read results after more than 20 minutes. To avoid confusion, discard the test cassette after interpreting the result.

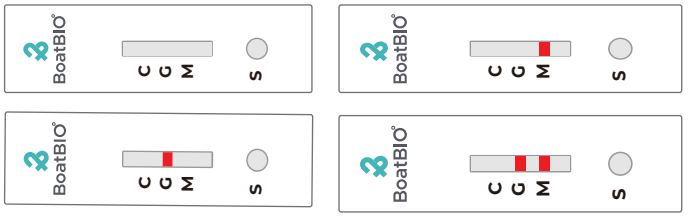
RESULT INTERPRETATION
Positive/reactive for IgM:
A coloured line develops in the control line region (C)and a coloured line develops in the test lineregion (M) for IgM. The test result indicates the presence of anti-HAV IgM.
Positive/reactive for IgG:
A coloured line develops in the control line region (C)and a coloured line develops in the test lineregion (G) for IgG. The test result indicates thepresence of anti-HAV IgG.
Positive/reactive for IgG and IgM:
In addition to the control line (C), a coloured line develops in each test line region: (G) for IgG and (M) for IgM. The test result indicates the presence of anti-HAV IgM and IgG.
Negative/non-reactive:
Only the control line (C) appears. The absence of the test lines (G) and (M) indicates that no detectable anti-HAV IgG or IgM are present in the specimen.
Invalid
If no control line (C) appears, the assay is invalid regardless of any color development of the test lines (G) and (M). Repeat the assay with a new test cassette.
Results from any test which has not produced a control line at the specified reading time must be discarded.
Please 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.
Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for the control line failure.

Positive/reactive for IgM

Positive/reactive for IgG

Positive/reactive for IgG and IgM

Negative



Invalid

QUALITY CONTROL

Internal Control:

A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Control:

The use of external positive and negative controls is recommended to assure the proper performance of the assay.

LIMITATIONS

•The sections 'Test Procedure' and 'Result Interpretation' must befollowed closely when testing for the presence of anti-HAV antibodies inserum, plasma or whole blood from individual subjects. Failure to followthe procedure may lead to inaccurate results.

•The HAV IgG/IgM Rapid Test is limited to the qualitative detection of anti-HAV antibodies in human serum, plasma or whole blood. The intensity ofthe test line has no linear correlation with the antibody titer in thespecimen.

•A negative or non-reactive test result does not preclude the possibility ofexposure to, or infection with, HAV. A negative or non-reactive result canoccur if the HAV antibody titer present in the specimen is below thedetection level of the assay or if anti-HAV antibodies were not yetpresent during the stage of disease in which the sample was collected.

•Unusually high titers of heterophile antibodies or rheumatoid factor(>2,500 IU/mL) may affect results.

•The results obtained with this test should only be interpreted inconjunction with other diagnostic procedures and clinical findings.

EXPECTED VALUES

Approximately 1.5 million clinical cases of hepatitis A occur worldwide annually, but the rate of infection is probably as much as ten times higher. Incidence rate is strongly related to socioeconomic indicators, access to safe drinking water and vaccination. In less developed countries with poor sanitary and hygienic conditions, HAV is endemic and most persons become infected in early childhood. The highest prevalence of HAV is in some areas of Africa, Asia and Central and South America, where seroprevalence can reach up to 90%. In most developed regions, such as North America, Western Europe, Australia and Japan, infection rates in children are generally low.

EXPECTED VALUES

Clinical Performance of the HAV IgG/IgM Rapid Test (IgM)

A total of 65 samples from susceptible subjects were tested by with the HAV IgG/IgM Rapid Test and with a commercially available HAV IgM EIA. The results are presented in the following table:

HAV IgG/IgM Rapid Test (IgM)			
HAV IgM EIA	Positive	Negative	Total
Positive	15	0	15
Negative	0	50	50
Total	15	50	65

Relative sensitivity: >99%
Relative specificity: >99%
Overall agreement: >99%

Clinical Performance of the HAV IgG/IgM Rapid Test (IgG)

A total of 100 samples from susceptible subjects were tested with the HAV IgG/IgM Rapid Test and with a commercially available HAV IgG reference test. The results are presented in the following table:

HAV IgG/IgM Rapid Test (IgG)			
HAV IgG reference test	Positive	Negative	Total
Positive	75	1	76
Negative	0	24	24
Total	75	25	100

Relative sensitivity: 98.7%
Relative specificity: >99%
Overall agreement: 99%

Cross-reactivity

Specimens from other infectious diseases and immunomarkers were tested for cross-reactivity with the HAV IgG/IgM Rapid Test. The results showed that the following specimens did not cross-react with the HAV IgG/IgM Rapid Test:

Specimen	Sample size	HAV IgG/IgM Rapid Test (reactivity)
Dengue positive serum	6	Negative
HCV positive serum	6	Negative
HIV positive serum	6	Negative
Syphilis positive serum	6	Negative
TB positive serum	6	Negative
H. pylori positive serum	6	Negative
HBsAg positive serum	6	Negative
ANA positive serum	6	Negative
HAMA positive serum	4	Negative
RF positive serum (≤2,500 IU/mL)	3	Negative

Interference

Common substances such as fever medications, anticoagulants and blood components may affect the performance of the HAV IgG/IgM Rapid Test. Potential interference effects were studied by spiking selected substances into three levels of HAV standard controls. The results demonstrate that at the concentrations tested, the substances studied do not affect the performance of the HAV IgG/IgM Rapid Test.

Note: -: Negative; +: Weak positive; +++: Strong Positive

Interfering Substances	HAV IgG reactivity			HAV IgM reactivity		
	Negative	Weak positive	Strong positive	Negative	Weak positive	Strong positive
Serum matrix	-	+	+++	-	+	+++
Bilirubin 20 mg/dL	-	+	+++	-	+	+++
Hemoglobin 2 g/L	-	+	+++	-	+	+++
Glucose 55 mmol/L	-	+	+++	-	+	+++
Salicylic acid 1.45 mmol/L	-	+	+++	-	+	+++
Heparin3,000 U/L	-	+	+++	-	+	+++
EDTA 3.4 μmol/L	-	+	+++	-	+	+++
Sodium citrate 1.27%	-	+	+++	-	+	+++

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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