CE
IVD

HAV IgM Rapid Test Kit (Colloidal Gold)

PRODUCT NAME
HAV IgM Rapid Test Kit (Colloidal Gold)

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

INTENDED USE
HAV IgM Rapid Test is a single use, rapid device intended for qualitative detection of IgM-class antibodies to hepatitis A virus (HAV) in serum or plasma samples.
It is intended to be used as a screening test and as an aid in the diagnosis of infection with HAV. Any reactive specimen with the HAV IgM Rapid Test must be confirmed with alternative testing method(s) and clinical findings.
For professional use only.

INTRODUCTION
Hepatitis A is a self-limited disease and chronic stage or other complications are rare. Infections occur early in life in areas where sanitation is poor and living conditions are crowded. With improved sanitation and hygiene, infections are delayed and consequently the number of persons susceptible to the disease increases. Because the disease is transmitted through the fecal-oral route in dense populated regions, an outbreak can arise from single contaminated source. The cause of hepatitis A is hepatitis A virus (HAV)-non enveloped positive strand RNA virus with a linear single strand genome, encoding for only one known serotype. HAV has four major, structural polypeptides and it localizes exclusively in the cytoplasm of human hepatocytes. The infection with HAV induces strong immunological response and elevated levels first of IgM and then IgG are detectable within a few days after the onset of the symptoms. The presence of anti-HAV IgM is an important serological marker for early detection and observation of the clinical manifestation of the disease. Increasing levels of anti-HAV IgM are detectable about three weeks after exposure with highest titter after four to six weeks later. Within six months after infection IgM concentration declines to non-detectable levels.

PRINCIPLE
HAV IgM Rapid Test Cassette is based on the principle of agglutinating sera on membrane and utilizes the technique of immunochromatography. The sample pad is coated with HAV antigen. As the test specimen flows through the sample pad assembly of the device, the HAV antigen complex with the HAV specific antibodies in the test specimen. When this complex travels on the conjugated pad which is impregnated with mouse anti-HAV antibody conjugated to colloidal gold, the HAV colloidal gold react with the complex then travels on the membrane due to capillary action. This complex moves further on the membrane to the test region (T) where it is immobilized by anti human IgM antibody coated on the membrane, leading to formation of a pink/purple coloured band. The absence of this band in the test region (T) indicates a negative result. The test contains an internal control (C band) which is coated with goat anti-mouse IgG should exhibit a burgundy colored band regardless of the color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

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

ADDITIONAL MATERIALS REQUIRED
- Clock or timer

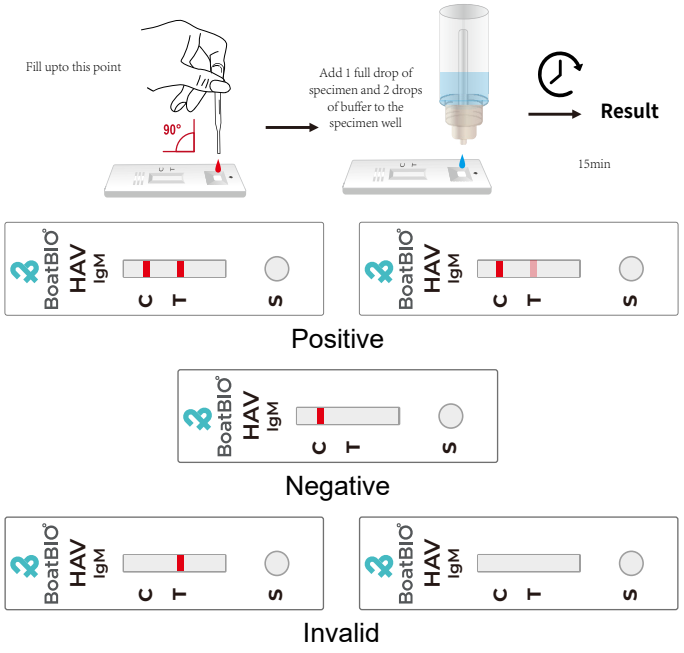
STORAGE AND STABILITY
All reagents are ready to use as supplied. Store unused test device unopened at 4°C-30°C valid for 24 months. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit.

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
1.HAV IgM Rapid Test Cassette (Serum/Plasma) can be performed using either serum or plasma.
2.Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed 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.specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
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 usual regulations for transportation of aetiological agents.

TEST PROCEDURE
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C)prior to testing.
1.Add 1µL serum/plasma specimen in the buffer and mix well.
2.When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface
3.Be sure to label the device with specimen's ID number.
4.Fill the pipette dropper with the specimen. Holding the dropper vertically, dispense 2-3 drops (about 60-90µL) of the diluted specimen into the sample well making sure that there are no air bubbles.and start the timer.
5.Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.

INTERPRETATION OF RESULTS
Positive: If both C and T band are developed ,the test indicates for the presence of IgM anti-HAV in the specimen The result is positive.
Negative: If only the C band is developed, the test indicates that no detectable IgM anti-HAV is present in the specimen. The result is negative.
Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. 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.



QUALITY CONTROL
An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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
1.The test procedure, precautions and interpretation of results for this test must be followed strictly when testing Failure to follow the procedure may give inaccurate results.
2.This test detects the presence of IgM 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.
3.A negative result for an individual subject indicates absence of detectable anti-HAV IgM. However, a negative test result does not preclude the possibility of exposure to or infection with HAV.
4.A negative result can occur if the quantity of the anti-HAV IgM 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.
5.As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS
A total of 425 samples from susceptible subjects were tested by the HAV IgM Rapid Test Cassette and by a commercial EIA test. Comparison for all subjects is showed in the following table:

The HAV IgM Rapid Test Cassette vs. EIA test

HAV IgM Rapid Test			
HAV IgM EIA	Positive	Negative	Total
Positive	203	5	208
Negative	3	214	217
Total	206	219	425
Relative sensitivity: 98.5%Relative specificity: 97.7%Accuracy: 98.1%			

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

Ningbo BESTest Bio-technology Co.,Ltd.
Address: No.80 building, No.777, Qing Feng Road, Cicheng Town,Jiangbei District, Ning Bo, Zhejiang, China 315033
Tel: 0086 571 2799 8736

EC REP **CMC MEDICAL DEVICES & DRUGS S.L**
Address: C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain
Tel: +34951214054
Email - info@cmcmedicaldevices.com