# HAV-IgM Rapid test Cassette

Catalog No.:BG601C

## INTENDED USE

This test is a single use, rapid device intended for qualitative detection of IgM-class antibodies to hepatitis A virus (HAV)in serum, plasma samples. It is intended to be used in clinical laboratories for diagnosis of acute hepatitis A and management of patients related to infection with hepatitis A virus.

## SUMMARY

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 OF THE ASSAY

This test employs chromatographic lateral flow device in cassette format. Colloidal gold conjugated recombinant antigens (Au-Ag) corresponding to HAV antigens are dry-immobilized at the end of nitrocellulose membrane strip. Anti-human IgM (anti-μ chain) are bond at the Test Zone (T) and goat anti-mouse IgG antibodies are bond at the Control Zone (C). When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in sample, HAV IgM antibodies will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by anti-human IgM (anti-μ chain) generating a visible red line. If there are no HAV IgM antibodies in sample, no red line is formed in the Test Zone (T). The gold conjugate will continue to migrate alone until it is captured in the Control Zone(C) by the goat anti-mouse IgG antibodies aggregating
in a red line, which indicates the validity of the test.

## COMPONENTS

Forty tests/kit
40 HAV IgM colloidal gold rapid test strips, each placed in white plastic cassette and packed in foil pouch, instructions for use, 1 ×6 ml vial of sample diluents. Materials required but not provided: clock or timer, safety
lancets, alcohol prep-pad, disposable pipettes, specimen collection container, centrifuge, biohazard waste container, sterile gauze or cotton.

## SPECIMEN COLLECTION

-Serum/plasma samples:
Fresh serum or plasma samples can be used. No special patient preparation required. Care should be taken to ensure blood full clotting and any visible particulate matter in the sample should be removed by centrifugation or filtration. Avoid the use of highly hemolytic, turbid, microorganism contaminated samples or samples stored for over 30days at2-8 ℃. Store samples at 2-8 ℃. Samples not required for assay within 3 days should be stored frozen (-20 ℃ or lower). Avoid sample deterioration by multiple freeze-thaw cycles.
-Plasma: Collect whole blood into a collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture. Separate the plasma by centrifugation.
-Serum: Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture. Allow the blood to clot. Separate by centrifugation.
The original samples cannot be tested directly, must be diluted with sample diluents before testing!

## STORAGE AND STABILITY

This test can be stored at room temperature (2-30 ℃, do not freeze!) for 24 months from the date of manufacture (see label on strip pouch). Use immediately after opening.

## PRECAUTIONS AND SAFETY

This test is for In Vitro Use only
FOR PROFESSIONAL USE ONLY
• All the waste and sample should be treated in case of transmitting disease and must be properly disinfected(autoclaving is preferred) before disposal.
• Once taking the cassette out of the pouch, carry out your testing as early as possible (no more than 20 minutes) to avoid moisture. The nitrocellulose membrane can absorb water, which can affect the test chromatography
Performance.
• To obtain accurate assay results, the test results must be read within 10 minutes. Results obtained after 10 minutes can lead to incorrect interpretation
• Make sure that the test is within the indicated validity.
• If automatic pipette is used, calibrate it frequently to assure the accuracy of dispensing. Use different disposal pipette tips for each specimen in order to avoid Cross-contaminations.
• Do not modify the test procedure.

• Do not reuse the test cassettes. Autoclave before disposal.
• A test giving an invalid result should be repeated.
• Blood that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.

## ASSAY PROCEDURE

1. Allow the test cassette to reach room temperature (appropriately 30minutes) before opening the pouch.
2. Add 10μL serum or plasma sample into the sample well, then add 100 μL of sample dilution immediately
3. Open the pouch and pipette 80μl of diluted sample into the sample window (S). Avoid dropping sample in the observation window. Do not allow the sample to overflow.
4. Place the cassette on flat surface and read the results within15-20 minutes.

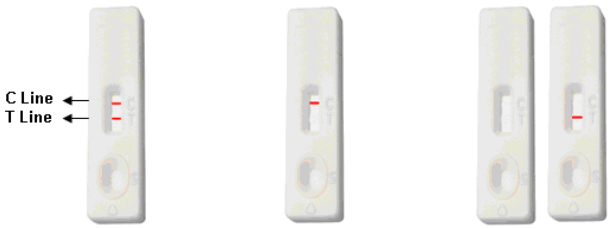
A positive test line may appear after 20 minutes - this is a False Positive Result - do not read the results after 10minutes.

## RESULTS

Quality Control: One red line will always appear next to the Control Zone(C) indicating the validity of the test. If no redline appears, the test is invalid - discard the test and repeat with new sample and new cassette. Positive Results: One red line next to the Test Zone (T) indicates that IgM antibodies to HAV have been detected using this HAV IgM Rapid Test.

Negative Results: No red line appears within 20 minutes next to the Test Zone (T) indicating that no IgM antibodies to HAV have been detected with this HAV IgM Rapid Test.

However, this does not exclude the possibility from infection with HAV.




POSITIVE NEGATIVE INVALID

The positive result obtained with this HAV IgM Rapid Test alone cannot be the final diagnosis of HAV. Anypositive result must be interpreted in conjunction withthe patient clinical history and another laboratorytesting results. Follow-up and supplementary testing of any positive samples with other analytical system (e.g. ELISA, WB) is required to confirm any positive result.

## LIMITATIONS

Negative results do not exclude the possibility of HAVexposure orinfection. Infection through recent exposure(seroconversion) to HAV may not be detectable. Forpositive results, line intensity cannot be used to evaluate the HAV IgM antibody levels. A test giving an invalid resultshould be repeated.

• If, after retesting of the initially reactive samples, the testresults arenegative, these samples should be consideredas non-repeatable (false positive) and interpreted asnegative. As with many very sensitive rapid diagnostic tests,false positive results can occur due to the several reasons,most of which are related but not limited to the quality of thesample and exposition of the test to humidity. For more information contact BIONEOVAN.CO, .LTD technical support forfurther assistance.

• This kit is intended ONLY for testing of individual samples.Do not use it for testing of cadaver samples, saliva, urine orother body fluids, or pooled (mixed) blood.

• This is a qualitative assay and the results cannot be used tomeasure antibodies concentrations.

## REFERENCES

1. J.V. PARRY, (1981). Hepatitis A infection: guidelines for development
of satisfactory assays for laboratory diagnosis. The Institute of Medical
Laboratory Sciences 38, 303-311.
2. Lindberg J., Frosner G., Hansson B.G. et al. Serologic markers ofhepatitis A and B in chronic active hepatitis. Scandinavian Journal of
Gastroenterology, 13:525-527, 1978.
3. Battegay M, Gust ID, and Fein stone SM. Hepatitis A virus. In: Mandell
GL, Bennett JE, and Dolin R, eds. Principles and Practice of Infectious
Diseases, 4th ed. New York, Churchill Livingstone, 1995:1636-1656.
4. Berge JJ et al. The cost of hepatitis A infections in Americanadolescents and adults in 1997.Hepatology, 2000, 31(2): 469-473.
5. Burke DS, Graham RR, and Heisey GB. Hepatitis A virus in primatesoutside captivity. Lancet, 1981, 2:928.45(RR15):1-30.