HEV-IgG Rapid test

Catalog No.: BG701C

INTENDED USE

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

SUMMARY

Hepatitis E virus (HEV) is a non-enveloped, single- stranded RNA virus identified in 1990. Infection with HEV induces acute or sub-clinical liver diseases similar to hepatitis A. HEV infections, endemic and frequently epidemic in developing countries, is seen also in developed countries in a sporadic form with or without a history of traveling to endemic area. The overall case-fatality is 0.5~3%, and much higher (15~25%) among pregnant women. A hypothesis that
HEV infection is a zoonosis was presented in 1995. Then a swine HEV and later an avian HEV were identified and sequenced separately in 1997 and 2001. Since then, HEV infection include anti-HEV, viremia and feces excretion of HEV was seen in a wide variety of animals, i.e., swine, rodents, wild monkeys, deer, cow, goats, dogs and chicken in both the developing and developed countries. A direct testimony was reported that the consumption of uncooked dear meat infected with HEV led to acute hepatitis E in human. And HEV genome sequences can be detected in pork livers available in the supermarkets in Japan.
With the discovery of conformational epitopes in HEV, HEV serology was further explored and understood. The phenomenon of long-lasting and protective antibodies to HEV was observed which greatly enhance the understanding to the diagnosis, epidemiology, zoonosis-related studies and vaccine development.

PRINCIPLE OF THE ASSAY

This test employs chromatographic lateral flow device in a cassette format.Colloidal gold conjugated recombinant antigens (Au-Ag) corresponding to HEV antigens are dry-immobilized at the end of nitrocellulose membrane strip.Anti-human IgG (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, HEV IgG 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 IgG (anti-μ chain) generating a visible red line. If there are no HEV IgG 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 HEV IgM colloidal gold rapid test strips, each placed in white plastic cassette and packed in foil pouch, Instructions for Use, 5ml×1 dilution tubes.
Materials required but not provided: Safety lancet, alcohol Prep-Pad, Disposable Pipette, clock or timer, specimen collection container, centrifuge, biohazard waste container

SPECIMEN COLLECTION

Wash your hands with soap and warm water. Choose a puncture site on the fingertip. Clean the fingertip with Alcohol Prep Pad. Place a Safety Lancet on a selected puncture site. Forcefully press the tip of the Safety Lance against your fingertip. Wipe away the first drop of blood with sterile gauze or cotton. Using Disposable Pipette, collect blood from the puncture site. Alternatively - draw blood following laboratory procedure for obtaining venous blood.

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 15-20 minutes. Results obtained after 20 minutes can lead to incorrect interpretation.
• Detection of high rate diluted samples (e.g. quality control materials diluted more than 100 times), please directly dispense 50μL diluted samples for testing.
• 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.

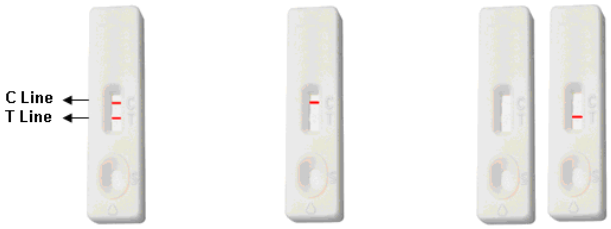
ASSAY PROCEDURE

Allow the test cassette to reach room temperature (appropriately 30minutes) before opening the pouch. Add one drop (approximately 50μL) serum/plasma sample into the sample dilution tube by using the sample dispenser and mix completely. Open the pouch and pipette 50μL diluted sample into the sample well. Avoid dropping

sample in the observation window. Do not allow the sample to overflow.
Place the cassette on flat surface and read the results within15-20 minutes. DO NOT INTERPRET RESULT AFTER 20 MINUTES.

RESULTS

Quality Control: One red line will always appear next to the Control Zone(C) indicating the validity of the test. If no red line 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 IgG antibodies to HEV have been detected using this HEV IgG Rapid Test.
Negative Results: No red line appears within 10 minutes next to the Test Zone (T) indicating that no IgG antibodies to HEV have been detected with this HEV IgG Rapid Test. However, this does not exclude the possibility from infection with HEV.



POSITIVE NEGATIVE INVALID

The positive result obtained with this HEV IgG Rapid Test alone cannot be the final diagnosis of HEV. Any positive result must be interpreted in onjunction with the patient clinical history and another laboratory testing 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 HEV exposure or infection. Infection through recent exposure (seroconversion) to HEV may not be detectable. For positive results, line intensity cannot be used to evaluate the HEV IgG antibody levels. A test giving an invalid result should be repeated.
• If, after retesting of the initially reactive samples, the test results are negative, these samples should be considered as non-repeatable (false positive) and interpreted as negative. 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 the sample and exposition of the test to humidity. For more information contact Bioneovan technical support for further assistance.
• This kit is intended ONLY for testing of individual samples. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
• This is a qualitative assay and the results cannot be used to measure antibodies concentrations.