HEV IgG/IgM Rapid Test

For detection of Hepatitis E Virus antibodies in Human Serum, Plasma or Whole Blood.

IVD *In-vitro diagnostic use only* *Not reuse*

Introduction

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 in1997 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.

Intended Use

This test is a single use, rapid device intended for qualitative detection of IgG/IgM-class antibodies to hepatitis E virus (HEV)

in serum, plasma or whole blood 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

Principle

The One Step HEV IgG/IgM Test is a qualitative membrane strip based immunoassay for the detection of Hepatitis E Virus antibodies (IgG and IgM) in Whole Blood /Serum / Plasma. The test device consists of: 1) a burgundy colored conjugate pad containing HEV recombinant envelope antigens conjugated with Colloid gold (HEV conjugates) and rabbit IgG-gold conjugates,2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band (C band). The T1 band is pre-coated with the antibody for the detection of IgM anti-HEV, T2 band is coated with antibody for the detection of IgG anti-HEV, and the C band is pre-coated with goat anti rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgG anti-HEV, if present in the specimen, will bind to the HEV conjugates. The immunocomplex is then captured by the reagent pre-coated on the T2 band, forming a burgundy colored T2 band, indicating a HEV IgG positive test result and suggesting a recent or repeat infection. IgM anti-HEV if present in the specimen will bind to the HEV conjugates. The immunocomplex is then captured by the reagent coated on the T1 band, forming a burgundy colored T1 band, indicating a HEV IgM positive test result and suggesting a fresh infection. Absence of any T bands (T1 and T2) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

Materials Included and Active Ingredients

1) HEV IgG/IgM test kit contains the following items to perform the assay.

- HEV IgG/IgM test device foil pouched with a desiccant
- Disposable dropper capable of delivering 15 µL sample volume (may not provided)
- Assay diluents
- Instruction for use

Kit Precautions and Storage Instructions

1) For best results, adhere to instructions provided
2) All specimens should be handled as potentially infectious
3) The test device should be stored at room temperature
4) The test device is sensitive to humidity as well as heat
5) Do not use beyond expiration date
6) Do not use test kit if pouch is damaged or seal is broken
7) Use test device immediately after removing from the pouch
8) The components (test device and assay diluents) in this kit HEVe been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
9) Store kit at room temperature (2 -30 ^{o}C). Do not expose the kit to temperature over 30 ^{o}C.

Warnings

1) For in vitro diagnostic use only. DO NOT RE-USE test device
2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
3) Do not eat or smoke while handling specimens
4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
5) Avoid splashing or aerosol formation
6) Clean up spills thoroughly using an appropriate disinfectant
7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
8) Do not mix with other specimens.

Specimen Collection, Storage and Precautions

1) Serum (S): Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant .
2) Plasma (P): Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
3) Whole Blood (WB): Collect the whole blood by lancing devices. WB can be delivered by pipette directly to the test card.
4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8°C. For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30°C) prior to use.
5) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
6) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test results.
7) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.
8) As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.

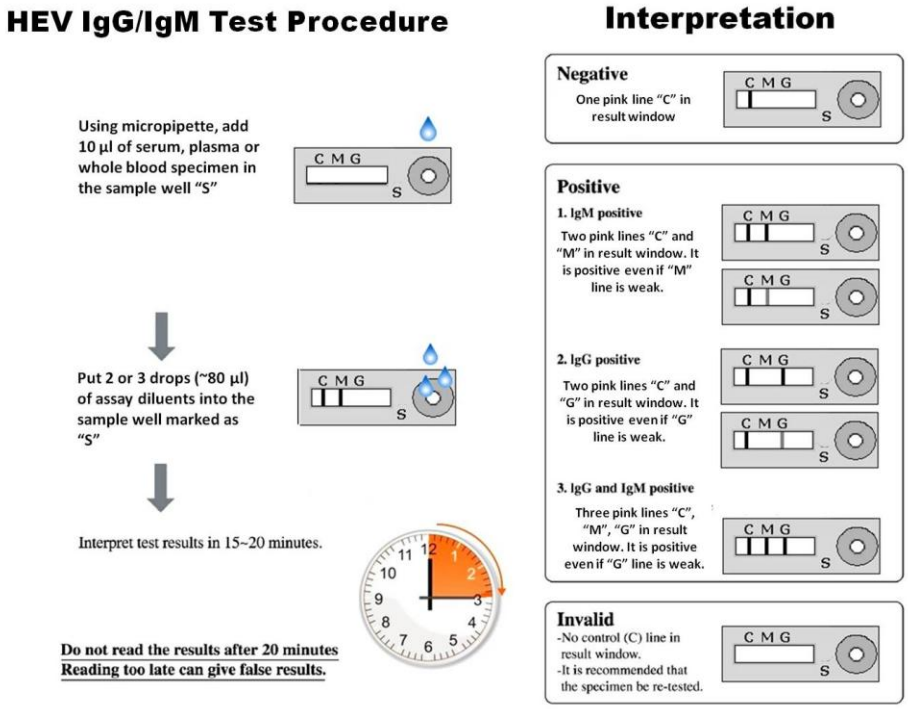
Test Procedure (Refer to Figure)

1) Allow all test components and specimen to come to room temperature prior to testing
2) Remove the test device from the foil pouch, and place it on a flat, dry surface
3) With a micropipette (not provided) or a disposable dropper, add about 10 µL of serum/ plasma or whole blood specimen into the sample well marked "S**"; Allow about 30 seconds for the specimen to be absorbed totally**.
4) Add 3 drop of diluents buffer to the sample well.
5) As the test begins to work, you will see red color move across the result window in the center of the test device.

6) Interpret test results at 15-20 minutes. Caution: Do not read test results after 20 minutes. Reading too late can give false results.

Interpretation of Test Results (Refer to Figure)

Interpretation of the test (Refer to figure)
Negative
The control line is only visible on the test device. No IgG and IgM antibodies were detected.
IgM Positive
The control line (C) and IgM line (M) are visible on the test device. This is positive for IgM antibodies to HEV
IgG Positive
The control line (C) and IgG line (G) are visible on the test device. This is positivefor IgG antibodies to HEV.
IgG and IgM Positive
The control line (C), IgM (M) and IgG line (G) are visible on the test device. This is positive for both IgM and IgG antibodies to HEV.
Invalid
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Repeat the test using a new test device.



Limitations of the Test

1. The One Step HEV IgG/IgM Test is for in vitro diagnostic use only. The test should be used for the detection of HEV antibodies in Whole Blood /Serum / Plasma specimens only. Neither the quantitative value nor the rate of increase in HEV antibodies can be determined by this qualitative test.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of HEV infection.

Internal Quality Control

The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required

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