EnCore Biomedicals

EnSure HEV IgM Test

Rapid Diagnostics Test for HEV IgM

Store at 2°c to 30°c

INTENDED USE

The HEV IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of anti-hepatitis E virus (HEV) IgM in human serum or plasma. It is intended to be used as a screening test by professionals and provides a preliminary test result to aid in the diagnosis of infection with HEV. Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgment of the health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY

Hepatitis E, a major form of enterically transmitted hepatitis, is widespread in many developing countries but is currently considered an emerging threat to other parts of the world. HEV is a non-enveloped, positive-sense, single-stranded RNA virus is currently classified within the family Caliciviridae. It is mainly transmitted through fecal- oral route. At least four major genotypes of HEV have been recognized: genotypes 1 and 2 are restricted to humans while genotypes 3 and 4 can infect both humans and animals. Antibody responses peak at about one month after initial infection. Antiviral IgM is detected in >90% of patients and persists for 3 months. Anti-HEV IgM is also a well-established marker of recent infection and is the most convenient one for diagnosis. Reliable techniques for anti-HEV IgM detection such as immunofluorescence and immune electron microscopy (IEM) have been developed. However, these techniques require labor-intensive procedures that are not available to many laboratories. The HEV IgM Rapid Test is designed to detect anti-HEV IgM in human serum or plasma. It can be performed within 15 minutes by minimally skilled personnel without laboratory equipment.

PRINCIPLE OF THE ASSAY

The HEV IgM Rapid Test is a lateral flow chromatographic immunoassay. The test strip in the cassette device consists of: a colored conjugate pad containing HEV antigens conjugated with colloidal gold (HEV conjugates) and a control antibody conjugated with colloidal gold, a nitrocellulose membrane strip containing a test line (T line) and a control line © line). The Test line is pre-coated with monoclonal anti-human IgM antibody, and the Control line is pre-coated with a control line antibody. When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. Anti-HEV IgM if present in the specimen will bind to the HEV conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM forming a colored Test line, indicating a HEV IgM positive test result and suggesting an acute infection. Absence of the test line suggests a negative result.

PACKAGE CONTAINS

1. Each Pouch contents: Test Cassette, Desiccant.
2. Sample dropper
3. 1 Assay buffer bottle
4. 1 instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. Calibrated Micropipette
3. Disposable Gloves

WARNINGS AND PRECAUTIONS

For in vitro Diagnostic Use

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

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

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

SPECIMEN COLLECTION

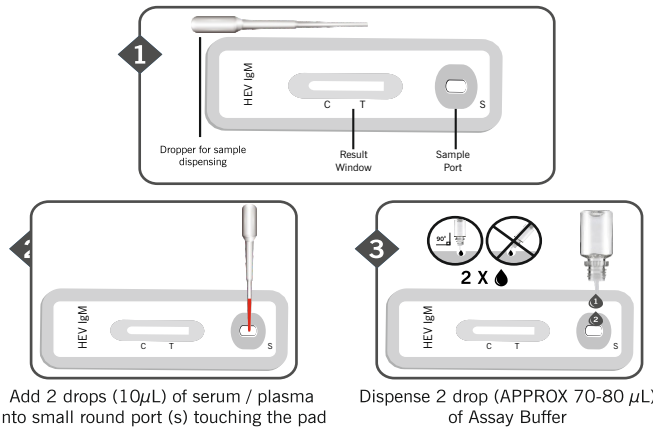
Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma/Serum

1. Collect blood specimen into collection tube containing EDTA, citrate or heparin for plasma or collection tube containing no anticoagulants for serum by venipuncture.
2. To make plasma specimen, centrifuge collected specimens and carefully withdraw the plasma into a new pre-labeled tube.
3. To make serum specimen, allow blood to clot, then centrifuge collected specimens and carefully withdraw the serum into a new pre-labeled tube. Store specimens at 20° C, if not tested immediately. The specimens can be stored at 20° C for up to 5 days. The 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, gross hemolysis or turbidity in order to avoid interference with result interpretation.

TEST PROCEDURE

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the test, and silica gel pouch. Check the color of the silica gel. It should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.
3. Add 2 drops (10 μL) of serum / plasma into the sample well S
4. Then add 2 drops (approximately 70-80 μL) of Assay buffer immediately.
5. Results can be read at 15 minutes. Don't read results after 20 minutes.



Add 2 drops (10μL) of serum / plasma into small round port (s) touching the pad

Dispense 2 drop (APPROX 70-80 μL) of Assay Buffer

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INTERPRETATION OF ASSAY RESULT

NEGATIVE : A colored line appears at control region 'C' only.

POSITIVE: A distinct colored lines appears at control region 'C' and at test region 'T'

The appearance of any burgundy color in the Test line, regardless of intensity, must be considered as presence of the HEV IgM

INVALID: The test should be considered invalid if,

A) No line appears at 'C', 'T' region

B) No line appears at 'C' region and line appear at 'T' region.

PERFORMANCE CHARACTERISTICS

Internal Evaluation:

In an in-house study, total 210 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 98.36 % (i. e. 60/61) and the relative specificity was 99.33% (i. e. 150/151). The results are summarized in the following table:

Sample	Total Number of samples tested	Rapid HEV IgM Test		Sensitivity (%)	Specificity (%)
		Positive	Negative		
HEV IgM Positive Serum Samples	30	29	1	98.36%	
HEV IgM Positive Plasma Samples	30	30	-		
Negative Human Serum	75	1	74		99.33%
Negative Human Plasma	75	-	75		

LIMITATIONS

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of anti-HEV IgM in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The HEV IgM Rapid Test is limited to the qualitative detection of anti-HEV IgM in human serum or plasma. The intensity of the test line does not have a linear correlation with the antibody tiler in the specimen.
3. A negative or non-reactive result for an individual subject indicates absence of detectable anti-HEV IgM. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with HEV.
4. A negative or non-reactive result can occur if the quantity of the anti-HEV 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. Some specimens containing unusually high of heterophile antibodies or rheumatoid factor may affect expected results.
6. Infection may progress rapidly. If the symptoms persist and the result from HEV IgM Rapid Test is negative or non-reactive, it is recommended to test with an alternative test method such as ELISA or PCR.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

DISCLAIMER

All precaution shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results. This test provides presumptive diagnosis of HEV IgM infection. A confirmed HEV IgM infection diagnosis should only be made by a physician after all clinical and laboratory Findings have been evaluated.

REFERENCES

1. Evaluation of a new rapid immunochromatographic assay for serodiagnosis of acute Hepatitis E infection, Am. J. Trop. Med. Hyg., 73(5), 2005, p: 942-946.
2. A Rapid Immunochromatographic Assay for Hepatitis B Virus Screening, Lau D. T., et. al., Journal of Viral Hepatitis, Vol. 10, No. 4, July 2003, p.: 331-334.
3. Hepatitis E Virus: A Review, P. Vasickova, et. al., Veterinarni Medicina, 52, 2007 (9): 365-384. 4. Hepatitis E Virus Infection Diagnosed by Serology: A Report of Cases at the San Lazaro Hospital, Manila, Nina Gloriani-Barzaga, et. al., College of Public Health, University of Phillippines, Manila.
5. The Role of Hepatitis E Virus Infection Among Patients With Acute Viral Hepatitis in Southern Saudi Arabia, Bandar Al-Knawy, et. al., Annals of Saudi Medicine, Vol. 17, No. 1, 1997.
6. Hepatitis E Virus Coinfection with Hepatropic Viruses in Egyptian Children, Maysaa El sayed Zaki, et. al., J. Microbiol immunol Infect. 2008; 41:254-258.

SYMBOL KEY

IVD	In Vitro Diagnostic Use	2°C 30°C	Temperature limitation
	Manufacturer	2	Single Use
	Manufacturing Date	Σ	Number of tests in the pack
	Expiry Date		Do not use if pouch or kit damaged
LOT	Lot Number	i	Read package insert before use

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