HEV IgG/IgM Rapid Test Cassette (Serum/Plasma) Package Insert

REF IHE-302
English

A rapid test for the qualitative detection of antibodies (IgG and IgM) to Hepatitis E Virus in human serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The HEV IgG/IgM Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG/IgM) to Hepatitis E virus (HEV) in human serum or plasma.

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

The HEV IgG/IgM Rapid Test Cassette (Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of HEV antibodies in serum or plasma. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with HEV antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to HEV, a colored line will appear in IgG test line region. In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM. HEV IgM antibodies, if present in the specimen, reacts with the anti-human IgM and the HEV antigen-coated particles in the test cassette, and this complex is captured by the anti-human IgM, forming a colored line in IgM test line region. Therefore, if the specimen contains HEV IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains HEV IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain HEV antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test cassette contains HEV antigen particles, mouse anti-human IgM and mouse anti-human IgG on the membrane.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. The HEV IgG/IgM Rapid Test Cassette (Serum/Plasma) can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma 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 federal regulations covering the transportation of etiologic agents.

MATERIALS

Materials provided

- Test Cassettes
- Droppers
- Package Insert
- Buffer

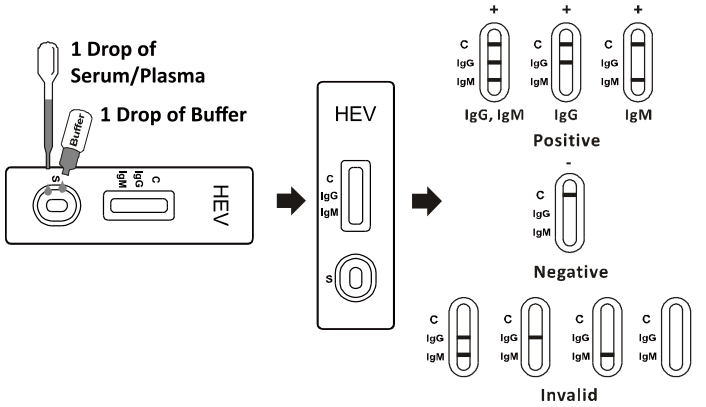
Materials required but not provided

- Specimen Collection Containers
- Centrifuge
- Timer

DIRECTIONS FOR USE

Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test cassette from sealed pouch and used it as soon as possible. Best results will be obtained if the assay is performed immediately after opening foil pouch.
2. Hold the dropper vertically and transfer **1 drop of serum/plasma (approx. 25 µL)** to the sample well (S) of the test cassette.
3. Add **1 drop of buffer (approx. 40 µL)** into the sample well (S) of the test cassette, start the timer.
4. Wait for the colored line(s) to appear. Read the results at **15 minutes**; do not interpret after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

IgG and IgM POSITIVE:* Three colored lines appear. One colored line should be in the control region (C) and another two colored lines should be in IgG test line region and IgM test line region. The color intensities of the lines do not have to match.

IgG POSITIVE:* Two colored lines appear. One colored line should be in the control line region (C), and a colored line appears in IgG test line region.

IgM POSITIVE:* Two colored lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region.

***NOTE**: The intensity of the color in the IgG and/or IgM test line region (T) will vary depending on the concentration of HEV antibodies present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the IgG and IgM test regions.

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

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit.

LIMITATIONS

1. 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 and IgM antibody levels. A test giving an invalid result should be repeated.
2. 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.
3. This kit is intended ONLY for testing of individual sample. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
4. This is a qualitative assay and the results cannot be use to measure antibodies concentrations.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The HEV IgG/IgM Rapid Test Cassette (Serum/Plasma) was compared with a leading commercial ELISA HEV IgG/IgM test; the results show that the HEV IgG/IgM Rapid Test Cassette (Serum/Plasma) has a high sensitivity and specificity.

IgG Result

Method		EIA		Total Results
HEV IgG/IgM Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	18	2	20
	Negative	2	150	152
Total Results		20	152	172

Relative Sensitivity: 90.0% (95%CI*: 68.3%-98.8%)
Relative Specificity: 98.7% (95%CI*: 95.3%-99.8%)
Accuracy: 97.7% (95%CI*: 94.2%-99.4%) *95% Confidence Intervals

IgM Result

Method		EIA		Total Results
HEV IgG/IgM Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	
	Positive	28	3	31
	Negative	2	204	206
Total Results		30	207	237

Relative Sensitivity: 93.3% (95%CI*: 77.9%-99.2%)
Relative Specificity: 98.6% (95%CI*: 95.8%-99.7%)
Accuracy: 97.9% (95%CI*: 95.1%-99.3%) *95% Confidence Intervals

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IVD	*In vitro* diagnostic medical device
2°C 30°C	Temperature limit
	Do not use if package is damaged and consult instructions for use
EC REP	Authorized representative in the European Community/European Union
REF	Catalogue number
Σ	Contains sufficient for <n> tests
	Use-by date
LOT	Batch code
	Manufacturer
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Caution

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Number: 146560003
Revision date: 2023-09-21