TruQuick™ HEV IgG/IgM 40T

A rapid test for the qualitative detection of antibodies (IgG and IgM) to Hepatitis E Virus in serum or plasma.

REF **TQ5240** IVD **Rx Only**

INTENDED USE
TruQuick HEV IgG/IgM is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG/IgM) to Hepatitis E virus (HEV) in serum or plasma. The results are used with other tests and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST
Hepatitis E Virus (HEV) is a nonenveloped, single- stranded RNA virus identified in 1990. Infection with HEV induces acute or subclinical liver disease 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. 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, ie, swine, rodents, wild monkeys, deer, cow, goats, dogs and chicken in both the developing and developed countries. It was reported that the consumption of uncooked deer meat infected with HEV led to acute hepatitis E in a human. 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 of the diagnosis, epidemiology, zoonosis and vaccine development.

BIOLOGICAL PRINCIPLES
TruQuick HEV IgG/IgM 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, react 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. 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/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: The Test Cassette contains HEV antigen particles and mouse anti-human IgM and mouse anti-human IgG on the membrane.
- Buffer: A buffered solution containing ProClin 300 as a preservative. The Buffer is supplied in a dropper vial ready for use.
- Droppers
- Package insert

MATERIALS NOT PROVIDED
- Specimen collection containers
- Centrifuge
- Timer

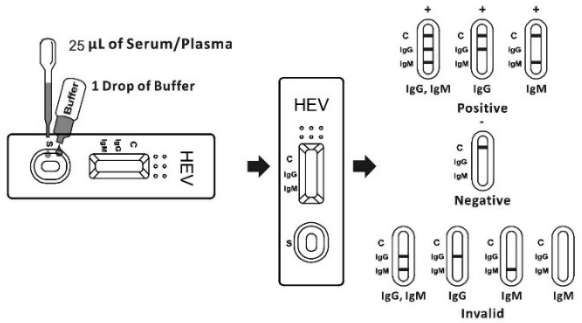
PRECAUTIONS
Please read all the information in this package insert before performing the test.
1. All reagents are for in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.

HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

SHELF LIFE AND STORAGE
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. TruQuick HEV IgG/IgM can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, nonhemolyzed 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 three 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.

TEST PROCEDURE
Allow the test, 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. Using the **25 µL dropper**, transfer 1 drop of sample (25 µL) to the sample well of the Test Cassette.
3. Add 1 drop of Buffer (approx. 40 µL) into the sample well (B) of the Test Cassette and start the timer.
4. 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 lines appear. One colored line should be in the control region (C) and two colored lines should appear, one at the IgG and another at the IgM test line regions. The color intensities of the lines do not have to match.
IgG POSITIVE:* Two 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 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 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 Meridian's Technical Service Department at 800-343-3858 or your local distributor.

QUALITY CONTROL
This test should be performed per applicable local, state, or federal regulations or accrediting agencies.
Internal procedural controls are 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.

External controls are not supplied with this kit; however, it is recommended that positive and negative external controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES
TruQuick HEV IgG/IgM was compared with a leading commercial HEV EIA test. The correlation between these two systems was over 97%.

LIMITATIONS OF THE PROCEDURE
1. Negative results do not exclude the possibility of HEV exposure or infection. Infection through recent exposure (seroconversion) to HEV may not be detectable.
2. 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.
3. If, after retesting of the initially reactive samples, the test results are negative, a sample should be considered as non-repeatable (false positive).
4. If after multiple repeat tests the sample remains nonreactive, it should be interpreted as negative. As with many very sensitive rapid diagnostic tests, false positive results can occur due to the quality of the sample and exposure of the test to humidity.
5. This kit is intended ONLY for testing of patient serum or plasma samples. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
6. This is a qualitative assay and the results cannot be used to measure antibodies concentrations.

SPECIFIC PERFORMANCE CHARACTERISTICS
TruQuick HEV IgG/IgM was compared with a leading commercial ELISA HEV IgG/IgM test; the results show that TruQuick HEV IgG/IgM has high sensitivity and specificity.

IgG Result

Method		EIA		Total Results
	Results	Positive	Negative	
TruQuick HEV	Positive	18	2	20
	Negative	2	150	152
Total Results		20	152	172

Sensitivity: 90.0% (95% CI*: 68.3%-98.8%)
Specificity: 98.7% (95% CI*: 95.3%-99.8%)
Correlation: 97.6% (95% CI*: 94.2%-99.4%) *95% Confidence Intervals

IgM Result

Method		EIA		Total Results
	Results	Positive	Negative	
TruQuick HEV	Positive	28	3	31
	Negative	2	204	206
Total Results		30	207	237

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

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 10 replicates of serum and plasma for four specimens: negative, low positive, medium positive and high positive. The specimens were correctly identified > 99% of the time.
Inter-Assay Precision
Between-run precision was determined by 10 independent assays of the same four serum and plasma specimens: negative, low positive, medium positive and high positive. Three different lots of TruQuick HEV IgG/IgM were used. The samples were correctly identified > 99% of the time.

CROSSREACTIVITY
TruQuick HEV IgG/IgM was tested with samples from patients diagnosed with HAV, HBV, HCV, HIV, HSV, Syphilis, HAMA, RF, Mononucleosis, CMV, Rubella and Toxoplasmosis. There was no crossreactivity with the samples.

TESTS FOR INTERFERING SUBSTANCES
TruQuick HEV IgG/IgM was tested with the following potential interferents. None caused interference at the concentrations tested.

Ascorbic acid 20 mg/mL	Acetaminophen 20 mg/dL
Hemoglobin 1 g/dL	Acetylsalicylic acid 20 mg/dL
Gentisic acid 20 mg/dL	Methanol 10%
Oxalic acid 60 mg/dL	Creatine 200 mg/dL
Bilrubin 1 g/dL	Albumin 2 g/dL
Uric acid 20 mg/mL	Caffeine 20 mg/dL

REFERENCES

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7. Virus from domestic animals in China. J Med Virol. 2002;67:516–521.

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SYMBOL USAGE
You may see one or more of these symbols on the labeling/packaging of this product:
Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	BUF RXN	Reaction Buffer
	Manufacturer		For IVD Performance Evaluation Only
Σ	Contains sufficient for <n> tests	SOLN STOP	Stopping Solution
	Temperature limitation	CONJ ENZ	Enzyme Conjugate
SN	Serial number	CONTROL	Assay Control
TEST	Test Device	REAG	Reagent
	Date of manufacture	BUF WASH	Wash Buffer
BUF	Buffer	⚠	Warning
CONJ	Conjugate	DIL SPE	Specimen Diluent (or Sample Diluent)
SUBS	Substrate	BUF WASH 20X	Wash Buffer Concentration: 20X
RUO	Research Use Only	DET REAG	Detection Reagent
IUO	Investigational Use Only	Rx Only	Prescription Use Only
	Do not use if package is damaged		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.