ASSURE HEV IgM

RAPID TEST

Instructions For Use

CE

REVISION DATE: 2016-07
MDH0011-ENG-7

Note Changes Highlighted

REF 43160-020 (20 tests kit)

TRADE NAME AND INTENDED USE

The **MP Diagnostics ASSURE HEV IgM Rapid Test** is an immunochromatographic test device intended for the rapid detection of IgM antibodies to Hepatitis E virus (HEV) in human serum, plasma or whole blood. It is intended as a clinical diagnostic test for diagnosing infection with Hepatitis E.

INTRODUCTION

Hepatitis E is known as enterically transmitted non-A non-B hepatitis (ET-NANB) and the etiological agent for this disease has been well established as a non-enveloped, positive sense, single stranded RNA virus named as hepatitis E virus (HEV) (1-3). Although the disease is self-limiting with a mortality rate of 1 to 3% in general adult populations, hepatitis E in pregnant women can take more severe forms with a case fatality rate up to 20%, especially during the third trimester (4). Increasing evidence suggests that this hepatitis occur not only in developing areas such as Central and South Asia, North and West Africa, Middle East and in Mexico, but also in industrialized nations and areas including the US, Japan and Europe. Hence, the disease might be more widespread than previously recognized (5-6).

As current available tools for the detection of the disease remain mostly laboratory-based requiring trained personnel and equipment, a simple rapid test that enables an early detection at the point of care where laboratory facilities are not readily accessible is, therefore, an unmet need for the management of hepatitis E. The **MP Diagnostics ASSURE HEV IgM Rapid Test** is developed to address such a need. The new test is a reverse-flow immunochromatographic test (7) and uses immobilized mouse anti-human IgM antibodies for capturing the IgM antibodies in the test samples. The presence of the captured IgM antibody specific to HEV is detected by the colloidal gold-labeled recombinant protein (9-10).

DESCRIPTION OF SYMBOLS USED

The following are graphical symbols used in or found on MP Diagnostics products and packaging. These symbols are the most common ones appearing on medical devices and their packaging. Some of the common symbols are explained in more detail in the European and International Standard EN ISO 15223: 2012.

	Use by *Synonym for this :* Expiry Date	IVD	*In vitro* diagnostic medical device
LOT	Batch Code *Synonyms for this are:* Lot Number Batch Number	REF	Catalogue Number
	Temperature Limitation		Attention. See Instructions for Use
	Manufacturer	EC REP	Authorised Representative in the European Community
Σ	Contains sufficient for <n> tests		Consult Instructions for Use
	Do not reuse		

CHEMICAL AND BIOLOGICAL PRINCIPLES OF THE PROCEDURE

MP Diagnostics ASSURE HEV IgM Rapid Test is an IgM capture solid-phase immunochromatographic assay. All antibodies of IgM class, when present in the test sample, can be captured by anti-human IgM antibodies immobilized on the membrane. The presence of HEV specific IgM antibodies can be differentially detected by a colloidal gold-labeled HEV antigen immobilized within the device, and can be visualized as pink/purple lines after assay. In addition, immobilized rabbit IgG antibodies which can be recognized by colloidal gold-labeled anti-rabbit IgG antibodies were used as a control for proper function of the reagents.

KIT COMPONENTS

DEVICE	MP Diagnostics ASSURE HEV IgM Rapid Test devices in individually sealed pouches with desicant. Store at 2°C - 28°C	20 devices
BUFFER	CHASE BUFFER containing 0.02% thimerosal and 0.01% Triton-X 100. Store at 2°C - 28°C	1 bottle (5 ml)
APPLICATOR	SAMPLE APPLICATOR Twenty plastic samples applicators, each with marks at 25µl and 35µl	20 pieces
	Instructions For Use	1 copy

HEALTH AND SAFETY INFORMATION

1. In case of an accident or contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Consult a physician immediately in the event that contaminated materials are ingested or come in contact with open lacerations, or other breaks in the skin.
3. Wipe any spills of sera, plasma or blood promptly with 1% sodium hypochlorite solution.
4. Autoclave all used and contaminated materials at 121°C, 15 p.s.i. for 30 minutes before disposal. Alternatively, decontaminate materials in 5% sodium hypochlorite solution for 30-60 minutes before disposal in biohazard waste-bags.

Pursuant to EC regulation 1272/2008 (CLP), hazardous components are classified and labelled as follows:

Component:	**Chase Buffer**
Signal Word:	**Warning**
Pictogram:	
Hazard Statements:	H319 Causes serious eye irritation.
Precautionary Statements:	P264 Wash hands thoroughly after handling. P280 Wear protective gloves/protective clothing/ eye protection/face protection.
Supplemental Statements:	EUH 210 Safety Data Sheet is available on request
Contains:	1% Triton X-100

ANALYTICAL PRECAUTIONS :

1. For *in vitro* diagnostic use only.
2. For Professional use only
3. Please refer to the product labelling for information on potentially hazardous components
4. Gloves must be worn.
5. Optimal assay performance requires **STRICT ADHERENCE** to the assay procedure described in this Instructions For Use. Deviations from the procedure may lead to aberrant results.
6. Do not interchange reagents between kit lots.
7. Do not use kit components beyond the expiry date printed on the kit box.
8. Reagents supplied should not present a hazard to health if used in accordance to the instructions stated.
9. For best results allow all reagents and samples to reach room temperature (25°C ± 3°C) before use.

STORAGE

1. Store entire kit at 2°C - 28°C. Test devices should be kept sealed until use.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Lancets
2. Alcohol swabs

SAFETY PRECAUTIONS

1. Autoclave all used and contaminated materials at 121°C, 15 p.s.i. for 30 minutes before disposal. Alternatively, decontaminate materials in 5% sodium hypochlorite solution for 30-60 minutes before disposal in biohazard waste-bags.
2. Wipe any spills of sera, plasma or blood promptly with 1% sodium hypochlorite solution.

SPECIMEN COLLECTION

Whole blood can be collected in anti-coagulant containing tubes and used as outlined in the assay procedure immediately or stored at 2°C to 8°C for not more than 48 hours before use.

Serum / plasma samples should be stored at 2°C to 8°C if the test is to be run within 7 days of collection or frozen at -20°C or colder if the test is to be delayed for more than 7 days. Clear, non-hemolyzed samples are preferred. Lipemic, icteric or contaminated (particulate) samples should be filtered (0.45µm) or centrifuged before testing.

Samples can be inactivated but this is not a requirement for optimal test performance.

Inactivate as follows:
1. Loosen cap of sample container.
2. Heat-inactivate sample at 56ºC for 30 minutes in a water bath.
3. Allow sample to cool down before retightening cap.
4. Sample can be stored frozen until analysis.

Repeated freeze-thawing of the sample is not recommended.

ASSAY PROCEDURE

IMPORTANT : Strict adherence to the assay procedure will ensure optimal assay performance. Deviations from the procedure may lead to aberrant results.

Note: Allow the kit to warm to room temperature before running the assay. If precipitates are found in the Chase Buffer reagent, shake the bottle vigorously and allow to warm up further. Omit this step if the kit is stored at 18 to 28°C.

1. Label the test device with the sample name.
2. Proceed with the appropriate assay procedure as diagrammed below.
3. When drawing whole blood, wipe finger tip with alcohol swab, let dry, and prick with lancet. Face the pricked finger tip upwards. Draw the blood with the provided sample applicator to the 35 µl mark (apply slight pressure to the bulb section before drawing blood). Dispense the sample completely into the square well.

Diagram 1: Assay for serum or plasma

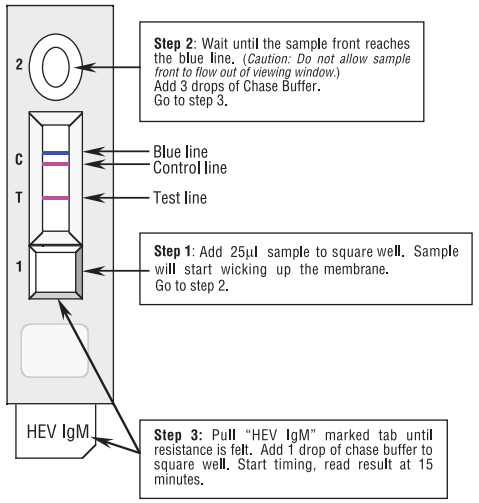
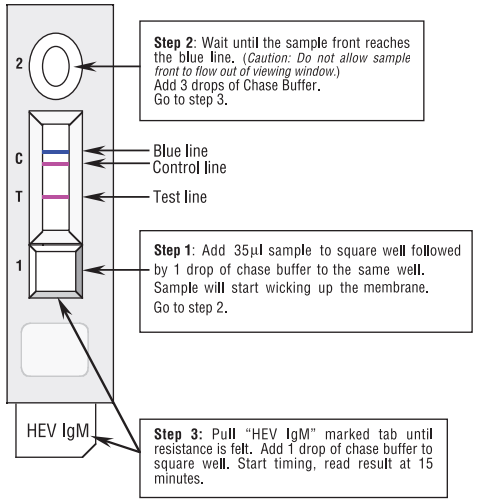


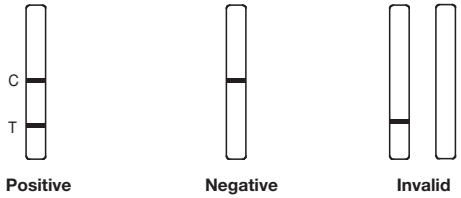
Diagram 2: Assay for whole blood



QUALITY CONTROL

1. Running of the positive and negative controls (not included) is optional.
2. Control line contains a blue dye which is the only line visible before running the assay. This line will disappear at the end of the assay.
3. If the control line at the position C does not become visible, the test is invalid. Positive samples will have additional colored band at position T.

INTERPRETATION OF RESULTS



Colored bands will appear at the marked positions "C" or "T" with the following interpretations:

1. **Positive** for HEV IgM antibodies if colored bands appear at the Test line (T) and Control line (C). Any intensity of band should be considered as a positive.
2. **Negative** for HEV IgM antibodies if only the Control line (C) is visible through the viewing window.
3. **Invalid** if the Control line (C) is absent. If this occurs, the assay should be repeated using a new device.

LIMITATION OF PROCEDURE

Optimal assay performance requires strict adherence to the assay procedure described. Deviation from the procedure may lead to aberrant results. A NEGATIVE result does not exclude the possibility of exposure to or infection with HEV.

PERFORMANCE

Specificity and Sensitivity

The performance of ASSURE HEV IgM Rapid Test was evaluated with over 582 blood samples, of which 277 hepatitis E positive sera and 305 serum samples from healthy donors. The sensitivity and specificity of ASSURE HEV IgM Rapid Test was found to be 100% (277/277) and 95.41% (291/305) respectively (Table 1).

Table 1: Summarized Data

Serum group and patient status	No. of positive & Performance %
Sera from patients with:	
Hepatitis E	277/277
Total Sensitivity	**100.00%**
	(95% CI: 98.68 to 100.00)
Healthy donors	291/305
Total Specificity	**95.41%**
	(95% CI: 92.42 to 97.47)
Total Positive Predictive Value (PPV)	**95.19%**
	(95% CI: 92.06 to 97.35)
Total Negative Predictive Value (NPV)	**100.00%**
	(95% CI: 98.74 to 100.00)

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LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer makes no expressed warranty other than that the test kit will function as an *in vitro* diagnostic assay within the specifications and limitations described in the Instructions For Use when used in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied, including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any other purposes. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product. The manufacturer shall not be liable to the purchaser or third parties for any damage, injury or economic loss howsoever caused by the product in the use or in the application thereof.

TECHNICAL PROBLEMS / COMPLAINTS

Should there be a technical problem / complaint:

1. Note the kit lot number and the expiry date.
2. Retain the kit and the test device.
3. Contact the nearest MP Biomedicals office or your local distributor.

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