Hepatitis E Virus Evaluation Panel 01

HEVEP01-C

FOR RESEARCH USE ONLY, NOT FOR USE IN DIAGNOSTIC PROCEDURES

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⚠ The following instructions must be read before using this product

RPBL986_Rev01

Intended Use

Qnostics' Hepatitis E Virus (HEV) Evaluation Panels 01 (HEVEP01-C) are dilution panels to be used for research use only. The Panels are intended for molecular procedures for the identification of HEV nucleic acid.

The Panels can be used to support laboratory staff training and to assess assay performance in HEV molecular assays from extraction phase through amplification to detection.

Principles of the Panel

The Panels are manufactured to ISO standard 13485:2012 compliant systems. The Panel members were produced by making quantitative dilutions of whole HEV (see Table 1) into human plasma.

All Panel members are representative of clinical human plasma specimens which are traceable to an internal reference preparation. The samples are provided as liquid-frozen in a 'single–use' tube format and must be extracted immediately after thawing.

The Panels are suitable for use with the majority of commercial and in-house molecular methods. They can also be used to support the training and monitoring of new operators in line with laboratories quality management requirements.

Product Description and Performance Characteristics

The Panel consists of 7 panel members positive for HEV, 4 positive for HEV type gg3C and 3 positive for HEV type gg3F (Table 1). The Panels are provided in a 'ready to go' single use format at 0.6 ml.

Table 1: Panel Components and Characteristics

Sample Code	Sample type	Target Log_{10} IU/ml	Volume per vial	Number of vials
HEVEP01-S1	HEV gg3C positive	4.0	0.6 ml	1
HEVEP01-S2	HEV gg3C positive	3.7	0.6 ml	1
HEVEP01-S3	HEV gg3C positive	2.7	0.6 ml	1
HEVEP01-S4	HEV gg3C positive	2.0	0.6 ml	1
HEVEP01-S5	HEV gg3F positive	3.7	0.6 ml	1
HEVEP01-S6	HEV gg3F positive	2.7	0.6 ml	1
HEVEP01-S7	HEV gg3F positive	2.0	0.6 ml	1

IMPORTANT NOTE: The values provided in Table 1 are specific to the Qnostics' reference assay used for the qualification of the Panel. The actual panel member quantification values may vary from those reported and are dependent on the analytical procedure, the nucleic acid extraction and molecular assay used. It is the responsibility of the end user to establish their own target results for each of the Panel members using their laboratory's molecular procedures for their specific molecular assay and appropriate statistical control.

For more information and protocols on the utility of this product visit www.qnostics.com

Warnings and Precautions

The Panels are prepared using whole HEV and must only be handled by trained laboratory personnel and in accordance with Good Laboratory Practices, which must include the use of personal protective equipment (PPE). All residual materials must be treated as potentially hazardous and disposed of accordingly. This must be carried out according to the established procedures of the laboratory and in accordance with national and international regulations.

Do not pipette by mouth. Do not eat, drink or smoke when handling the samples or within laboratory spaces.

Additional Equipment Required but not Provided

The following equipment is not included:

- Any Personal Protective Equipment (PPE) - e.g. lab coat and gloves
- Biological safety cabinet
- Nucleic acid extraction kit used in accordance with the manufacturers' instructions
- Molecular Amplification assay specific for HEV and, where used in accordance with the manufacturers' instructions.
- Bench Vortex
- Micro-centrifuge (12-14,000 RPM)
- Calibrated pipettes and sterile barrier filter tips

Procedure

- The Panel must be thawed at room temperature
- Vortex briefly and spin down at 12,000 RPM for 30 seconds before opening the sample tube.
- The samples must then be treated in the same manner to that required by the laboratory for routine specimens, in the normal HEV RNA molecular procedure being assessed.

IMPORTANT NOTICE: Each Panel member is intended for 'single use' ONLY. After thawing and testing any surplus material must be disposed of according to laboratory procedures.

For technical queries please contact info@qnostics.com

Storage

The Panel must be stored within the recommended temperature range of -20/-80°C

All samples within the Panel are intended for single use only. The re-freezing and repeated thawing or off label storage of the Panel is not recommended and may lead to variability in the results obtained.

Limitations

The HEV Panel samples are prepared in pooled human plasma that does not contain additional human cells. This product may not be suitable for assays that require a significant background human cell component.

The HEV Panels **must not** be used as a substitute for assay process controls and / or calibrators (Standards) provided by the manufacturer of the molecular assay.

This product is not an absolute reference material. The laboratory needs to establish its own target results using the HEV for their particular molecular assay system.

These products are labelled as Research Use Only and **cannot be used** as an in vitro diagnostic device for the management of human disease.

References

World Health Organisation (WHO) Laboratory Biosafety Manual, 3rd ed. 2004 ISBN 92 4 154650 6 (LC/NLM classification: QY 25)

Symbols

Symbols used in the labelling of this product comply with BS EN ISO 15223-1:2012 Medical Devices – 'Symbols to be used with medical device labels, labelling and information to be supplied'

REF	Product Code		Single use only
	Temperature limitations	Σ	Contains sufficient for "N" tests.
LOT	Batch code.		Attention, consult instructions for use.
	Expiry date (last day of month).		Biohazard
RUO	Research Use Only		Manufacturer.