CMV Molecular Q Panel

CMVMQP01-A

GTIN: 5060605500010

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The following instructions must be read before using this product

IVD

CE

2797

Intended Use

Qnostics' Cytomegalovirus (CMV) Molecular Q Panels are intended to help laboratories monitor their molecular assays on a run to run basis within customer derived limits.

The Panels can be used to support laboratory staff training and in the assessment and development of CMV molecular diagnostic assays from extraction phase through amplification to detection.

Principles of the Panel

The Panels are manufactured to ISO standard 13485 compliant systems. The samples were produced by making serial dilutions of whole CMV type AD169 into normal human plasma which was tested and found to be negative for CMV, HCV, HBV and HIV nucleic acids.

Samples are representative of clinical human specimens which are traceable to an internal reference preparation in line with the requirements of ISO 17511 and calibrated to the CMV WHO International Standard (Reference: 09/162)..

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 4 x 1ml samples, 3 positive and 1 negative. Panels are manufactured as a serial log (1:10) dilution (see Table 1). The Panels are provided as liquid-frozen in a 'single–use' tube format and must be extracted immediately after thawing.

Table 1: Panel Components and Characteristics

Sample Code	Serial Log dilution	Number of vials
CMVMQP01-H	High	1
CMVMQP01-M	Medium	1
CMVMQP01-L	Low	1
CMVMQP01-N	Negative	1

IMPORTANT NOTE: It is the responsibility of the end user to establish their own test results and values for each of the Panel members using their laboratory's molecular procedures for their specific molecular diagnostic assay.The Panel members have **no assigned value.** End user Test results and values may vary from end-user laboratory to end user laboratory and are dependent on the evaluation procedure, the nucleic acid extraction and molecular assay used (see Limitations).

Warnings and Precautions

The Panel contains whole CMV 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. Observe the expiration date for the Panels.

If the product is received in an unsatisfactory condition, follow the advice provided within the product Safety Data Sheet (SDS) found on the company website or contact Qnostics for further instructions.

Hazard and Precautionary Statements: H303, H333, P202, P270, P280, P314

Additional Equipment Required but not Provided

The following equipment is not included:

- 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 CMV and, where appropriate, 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 CMV 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 & Handling

The Panel must be stored within the recommended temperature range of -20/-80°C. All samples within the Panel are 'ready to use' after thawing and are intended for single use only. The samples should not be diluted and the re-freezing, repeated thawing or off label storage of the Panel is not recommended as it may lead to variability in the results obtained by the end-user (see limitations of use below).

Limitations

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

It is the responsibility of the end user to establish their own expected results and performance criteria for the product using their specific molecular assay and laboratory procedures in line with its intended use. If the product does not perform in agreement with the end-users established performance criteria, this may be an indication of variation with the molecular assay and should be investigated by the end-user in accordance with their quality management procedures. Common sources of variation within the laboratory include operator error, faulty equipment, and changes in assay reagent lots. If after the investigation the end-user has concerns regarding the performance of the qnostics product they should contact Qnostics for further technical support assistance by email at info@qnostics.com.

References

World Health Organisation (WHO). Laboratory Biosafety Manual, 4th edition – WHO (2020)

ISBN 978-92-4-001131-1 (electronic version)

ISBN 978-92-4-001132-8 (print version).

Symbols

Symbols used in the labelling of this product comply with BS EN ISO 15223-1 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
IVD	In Vitro Diagnostic device		Manufacturer
EC REP	Authorised Representative in the European Community	Test / Tests	Test / Tests
Components	Components	Contents	Contents