Qnostics

Meningitis/Encephalitis Evaluation Panel 01

MEEP01-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

Intended Use

Qnostics' Meningitis / Encephalitis Evaluation Panels are for research use only and intended to help laboratories verify their qualitative molecular assay procedure's ability to detect nucleic acids from pathogens associated with meningitis and encephalitis.

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

Principles of the Panel

The panels are manufactured to ISO standard 13485:2016 compliant systems. The samples were produced by making quantitative dilutions of whole pathogen into transport media which was tested and found to be negative for the pathogens listed in Tables 1, 2 & 3. Samples are representative of clinical human specimens and are traceable to an internal reference preparation in line with the requirements of ISO 17511:2003.

The panels are suitable for use with the majority of qualitative commercial and in-house molecular methods and the samples are external controls with known performance on the BioFire FilmArray® platform. 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 3 boxes containing 14 x 0.25ml samples, (see Tables 1, 2 & 3). The panels are provided as liquid-frozen in a 'single–use' tube format and must be processed immediately after thawing. The target concentrations of the panel have been designed to allow pooling of up to five pathogens. Pooling five pathogens will give a positive reading for all five pathogens in most compatible molecular assays. The panels are consistent within each lot and across batches.

Table 1: Panel Components and Characteristics: Box 1 of 3

Sample Code	Sample Description
Sample 1.1	Escherichia coli K1
Sample 1.2	Cytomegalovirus AD169
Sample 1.3	Enterovirus (Coxsackie B3)
Sample 1.4	Streptococcus pneumoniae
Sample 1.5	Human Herpes Virus 6 A

Table 2: Panel Components and Characteristics: Box 2 of 3

Sample Code	Sample Description
Sample 2.1	Herpes Simplex Virus 1 (95-1906)
Sample 2.2	Neisseria meningitidis
Sample 2.3	Streptococcus agalactiae
Sample 2.4	Cryptococcus gattii

Table 3: Panel Components and Characteristics: Box 3 of 3

Sample Code	Sample Description
Sample 3.1	Haemophilus influenzae
Sample 3.2	Herpes Simplex Virus 2 (09)
Sample 3.3	Varicella Zoster Virus (9/84)
Sample 3.4	Listeria monocytogenes
Sample 3.5	Human Parechovirus 3

IMPORTANT NOTE: The panel members have **no assigned value** and are intended for the qualitative detection of pathogens associated with meningitis and encephalitis. The performance of any pathogen combination is specific to the workflow employed. Any combination, not previously characterised, must be validated to ensure that there is no inhibition of positive results or no issues with specificity caused by combining targets.

Warnings and Precautions

The panel contain whole pathogen 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.

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, 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.
- Samples can be analysed separately or combined using a pooling strategy in line with the molecular detection system used.
  - E.g. BioFire technical note FLM1-PRT-0245
- If samples are to be pooled. The total dilution of the samples should not be greater than a factor of 1 in 5.
- 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 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.
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 panel **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 a reference material. The laboratory needs to establish its own target results using the panel for their 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).

Centers for Disease Control (CDC). Recommendations for the prevention of HIV transmission in healthcare settings. MMWR 1987; 36, Supplement no. 2S.

Centers for Disease Control (CDC). Update: Universal guidelines for the prevention of transmission of human immunodeficiency virus, hepatitis B virus and other blood borne pathogens in health-care settings. MMWR; 37:377-388

Centers for Disease Control (CDC). Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to healthcare and public-safety workers. MMWR 1989; 38(S6):1-36.

Symbols

Symbols used in the labelling of this product comply with BS EN ISO 15223-1:2016 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

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