Qnostics

Gastroenteritis Bacterial/Parasitic Panel 01

GENBEP01-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

RPBL1063_Rev01

Intended Use

Qnostics' Bacterial and Parasitic Gastroenteritis Panel is for research use only and intended to help laboratories develop their nucleic acid based molecular assay procedures for the detection of common causes of bacterial and parasitic gastroenteritis.

The panel can also be used to support laboratory staff training in the molecular assays from extraction phase through amplification to detection.

Principles of Gastroenteritis Panel

The Panel is manufactured to ISO standard 13485:2012 compliant systems. The panel members were produced by making quantitative dilutions of whole pathogen into Synthetic Faecal Matrix (SFM) which has been tested and found to be below the limit of detection for the pathogens listed in Table 1.

All panel members are representative of clinical human specimens and are provided as dilutions in SFM. Each preparation in the Panel is 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 Panel is suitable for use with the majority of commercial and in-house molecular methods. It 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 contains one 1 ml vial for each of the pathogens listed in table 1.

Table 1 - Bacterial / Parasitic Gastroenteritis GENBEP01-C (Panel Components and Characteristics)

Sample ID	Sample Description	Target Ct value	Volume	Matrix
Sample B1	***Campylobacter jejuni***	**29-30**	1 ml	SFM
Sample B2	***Campylobacter lari***	**30-33**	1 ml	SFM
Sample B3	***Clostridium difficile 027***	**29-30**	1 ml	SFM
Sample B4	***Shigella flexneri***	**31-32**	1 ml	SFM
Sample B5	***Salmonella enteritidis***	**31-32**	1 ml	SFM
Sample B6	***Yersinia enterocolitica***	**31-32**	1 ml	SFM
Sample B7	***Giardia lamblia***	**32-35**	1 ml	SFM
Sample B8	***Cryptosporidium parvum***	**32-35**	1 ml	SFM
Sample B9	***Entamoeba histolytica***	**32-35**	1 ml	SFM
Sample B10	***Plesiomonas shigelloides***	**32-35**	1 ml	SFM

IMPORTANT NOTE
The Panel members have **no assigned values**. The Qnostics' reference assay, used for the qualification of the Panel generates values given in Table 1. The actual panel member C_t values may vary from those reported and are dependent on the analytical procedure, the nucleic acid extraction and molecular assay used, as well as the standards used to calibrate and validate the specified molecular procedure. See Limitations of Use.

The panel is provided in a 'ready to go' single use format. The target concentrations of the Panel have been assigned to be within the dynamic range of most molecular assays and are consistent within each lot and across batches.

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.

TECHNICAL ENQUIRIES
For technical queries please contact info@qnostics.com

PROTOCOLS AND PROCEDURES

Warnings and Precautions

The Panel contains 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.

Additional Equipment Required but not Provided

The following equipment is not included:

- Any appropriate Personal Protective Equipment (PPE)- lab coat and gloves
- Biological safety cabinet
- Nucleic acid extraction kit used in accordance with the manufacturers' instructions
- Molecular Amplification assay specific for targets 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 molecular procedure being assessed.

Storage

The Panel must be stored appropriately 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.

References

1. World Health Organisation (WHO) Laboratory Biosafety Manual, 3rd ed. 2004 ISBN 92 4 154650 6 (LC/NLM classification: QY 25)
2. Centers for Disease Control (CDC). Recommendations for the prevention of HIV transmission in healthcare settings.MMWR 1987; 36, Supplement no. 2S.
3. 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
4. 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.

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 an absolute reference material. The laboratory needs to establish its own target results using the Panel 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.

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.