Gastroenteritis Pathogenic *E. coli* Evaluation Panel 01

GENEEP01-D

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⚠ The following instructions must be read before using this product

IVD

Intended Use

Qnostics' Gastroenteritis Pathogenic *E. coli* (GENE) Evaluation Panels are intended to help laboratories develop their molecular assay procedures for the identification of pathogenic *E. coli* gastroenteritis.

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

Principles of the Panel

The Panel is manufactured to ISO standard 13485:2016 compliant systems. The samples were produced by making quantitative dilutions of whole pathogen into transport medium (see Table 1).

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 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 6 x 0.5ml positive samples (see Table 1). The genetic characteristics of samples S01-S05 are shown in Table 2. The Panels are provided as liquid-frozen in a 'single–use' tube format and must be extracted immediately after thawing. The target concentrations of the Panel have been designed to cover the dynamic range of most molecular assays and are consistent within each lot and across batches.

Table 1: Panel Components and Characteristics

Sample Code	Sample Description	Target Ct Values	Number of vials
GENEEP01-S01	Shiga toxin-producing *E. coli* (STEC) 1	31-32	1
GENEEP01-S02	Shiga toxin-producing *E. coli* (STEC) 2	31-32	1
GENEEP01-S03	Enterotoxigenic *E. coli* (ETEC) 1	31-32	1
GENEEP01-S04	Enterotoxigenic *E. coli* (ETEC) 2	31-32	1
GENEEP01-S05	Enterotoxigenic *E. coli* (ETEC) 3	31-32	1
GENEEP01-S06	*E. coli* O157	31-32	1

Table 2: STEC and ETEC (Genotypes)

Sample Code	*Stx 1*	*Stx 2*	*Int*	*hLT*	*hST*	*ST1h*
GENEEP01-S01	+ve	+ve	+ve			
GENEEP01-S02	+ve	+ve	+ve			
GENEEP01-S03				+ve	+ve	+ve
GENEEP01-S04				+ve	+ve	+ve
GENEEP01-S05				+ve	+ve	+ve

IMPORTANT NOTE: The Panel members have **no assigned value.** 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 evaluation procedure, the nucleic acid extraction and molecular assay used (see Limitations). 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 diagnostic assay and appropriate statistical control.

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. 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 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.

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 an absolute reference material. The laboratory needs to establish its own target results using the Panel for their particular molecular assay system.

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		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	