Transport Medium
Negative Q Control 02

TMNQC02-A

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⚠ The following instructions must be read before using this product

CE

Intended Use

Qnostics' Transport Medium Negative Q Controls are controls that can be used to help establish the Specificity (false positivity) of molecular assays.

Transport Medium Negative Q controls help laboratories validate assays, equipment and reagents, to assess specificity and contamination issues

Principles of the Panel

The Panel is manufactured under ISO standard 13485: 2016 compliant systems. The Matrix Negative Q Controls consist of, transport medium containing background human cells, which has been tested and found to be below the Limit of Detection for SCV2 nucleic acids.

Product Description and Performance Characteristics

The panel consists of 5 x 0.5ml samples provided as liquid-frozen in a 'single–use' tube format and must be processed immediately after thawing.

Table 1: Panel Components and Characteristics

Sample Code	Target Concentration	Number of vials
TMQC02-NQ	Negative	5

Important Note: For further information on the pathogens verified as below the limit of detection please contact info@qnostics.com

Warnings and Precautions

The Panel has been screened and shown to be below the limit of detection for major pathogens associated with clinical samples in transport medium. The Panel should still 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 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.

All samples within the panel are intended for single use only. After thawing and testing any surplus material must be disposed of according to laboratory procedures.

Limitations

The panel **must not** be used as a substitute for assay process controls provided by the manufacturer of the molecular assay.

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
IVD	In Vitro Diagnostic device		Manufacturer

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