



## Transport Medium Negative Q Control 02

TMNQC02-B

### 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' Transport Medium Negative Q Controls are for research use only and intended to help laboratories monitor their molecular assays on a run to run basis within customer derived limits.

All laboratory assays exhibit some degree of variation or error (systemic or random) in their daily performance. What is important is that the laboratory understands what variation is acceptable and how that variation can be monitored and managed in the laboratory setting.

The controls, combined with appropriate laboratory Statistical Process Control (SPC) have proven to be very effective in the monitoring of laboratory assay performance, assay variation and the monitoring of assay reagents lots.

#### Principles of the Panel

The panel is manufactured under ISO standard 13485: 2016 compliant systems.

The Panels are suitable for use with the majority of commercial and in-house molecular methods and will give a negative result to all pathogens.

#### Product Description and Performance Characteristics

The panel consists of 5 x 0.5 ml samples of Transport Medium negative controls (see Table 1). The panels are 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
TMNQC02-NQ	Negative	5

#### Warnings and Precautions

The panel contains no pathogenic material but should 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.
- 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.

**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](mailto: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. 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.

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, 3<sup>rd</sup> 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'.



Product Code



Single use only



Temperature limitations



Contains sufficient for "N" tests



Batch code



Attention, consult instructions for use



Expiry date (last day of month)



Biohazard



Research Use Only



Manufacturer