MTB Rifampicin-resistant Q Control 01

MTBRQC01-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' *Mycobacterium tuberculosis* (MTB) Rifampicin-resistant Q Controls are for research use only and intended to help laboratories develop their molecular assays and monitor performance on a run to run basis from extraction phase, through amplification, to detection.

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. Qnostics' controls, combined with appropriate statistical process controls have proven to be very effective in the monitoring of laboratory assay performance, assay variation and the monitoring of assay reagents lots. They also help support a laboratory's regulatory requirements under the standard ISO 15189 or equivalent and help ensure the reliability of test results.

Principles of the Panel

The panel is manufactured under ISO standard 13485compliant systems. The samples were prepared by making a quantitated dilution of whole rifampicin-resistant *Mycobacterium tuberculosis* material into synthetic sputum containing background human cells which was tested and found to be negative for *Mycobacterium* nucleic acids (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.

The Panels are suitable for use with the majority of commercial and in-house molecular methods and are will give a positive result for *M. tuberculosis* and rifampicin resistance. 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 5 x 1ml positive samples (see Table 1). The panels are provided as liquid-frozen in a 'single–use' tube format and must be extracted immediately after thawing. The target concentration of the panel has been designed to be within the dynamic range of most molecular assays and are consistent within each lot and across batches.

Table 1: Panel Components and Characteristics

Sample Code	Target Concentration (CFU/ml)	Number of vials
MTBRQC01-QC	400	5

IMPORTANT NOTE: The panel has **no assigned value.** The value provided in Table 1 is specific to the Qnostics' reference assay used for the qualification of the panel. The actual sample quantification 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). It is the responsibility of the end user to establish their own target range and limits for the panel using their laboratory's molecular procedures for their specific molecular diagnostic assay and appropriate statistical control.

Warnings and Precautions

The panel contains whole *Mycobacterium tuberculosis* 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 MTB 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 MTB 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. 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.

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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