Qnostics

Respiratory Multiplex Evaluation Panel 01

RTXEP01-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' Respiratory Multiplex Evaluation Panel 01 is a panel covering a broad range of respiratory pathogens. The panel consists of 6 positive and 1 negative respiratory control. Each of the positive controls in the panel are a combination of 4 common respiratory pathogens in a single vial.

It is for research use only and intended to help laboratories develop their molecular assays and can assess their performance from extraction phase, through amplification, to detection. It is important to establish assay performance as all 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 respiratory multiplex controls, combined with appropriate laboratory Statistical Process Control can be very effective in the monitoring of laboratory assay performance, assay variation and the monitoring of assay reagents lots. They can also help support a laboratory's regulatory requirements under ISO 15189:2012 or equivalent and help ensure the reliability of test results.

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 0.7ml positive samples and 1 x 0.7ml negative sample (see Table 1). The Panels are provided as liquid-frozen in a 'single–use' format and must be processed immediately after thawing. The target concentrations of the Panel have been designed to be within the dynamic range of most molecular assays and are consistent within each lot and across batches.

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.

Table 1: Panel Components and Characteristics

Sample Code	Sample Description	Number of vials
RTXEP01-S01	**Positive for:** • Influenza A Type H1N1 • Influenza B Type Victoria • Respiratory Syncytial Virus Type A • SARS-CoV-2	**1 x 0.7,ml**
RTXEP01-S02	**Positive for:** • Parainfluenza Type 1 • Adenovirus Type 1 • *Mycoplasma pneumoniae* • Coronavirus Type OC43	**1 x 0.7,ml**
RTXEP01-S03	**Positive for:** • Parainfluenza Type 2 • Metapneumovirus Type A2 • Enterovirus Type A16 • Coronavirus Type 229E	**1 x 0.7,ml**
RTXEP01-S04	**Positive for:** • Parainfluenza Type 3 • Rhinovirus Type 16 • *Legionella pneumophila* • Coronavirus Type NL63	**1 x 0.7,ml**
RTXEP01-S05	**Positive for:** • Parainfluenza Type 4 • Enterovirus Type 68 • Adenovirus Type 14 • Respiratory Syncytial Virus Type B	**1**
RTXEP01-S06	**Positive for:** • *Bordetella pertussis* • *Bordetella parapertussis* • Influenza A Type H3N2 • *Chlamydophila pneumoniae*	**1 x 0.7,ml**
RTXEP01-S07	Below the limit of detection for the targets listed above.	**1 x 0.7,ml**

Note that each of the samples presented in Table 1 are also available in the Q control format, with 5 positive or negative controls per panel. For further information please contact info@qnostics.com

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 the targets in Table 1 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.
- 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'.

	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

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