



Qnostics

Respiratory Target Multiplex

Product codes:

- **RTX1QC01-B**
- **RTX2QC01-B**
- **RTX3QC01-B**
- **RTX4QC01-B**
- **RTX5QC01-B**
- **TMQC01-B**

Technical Note

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Multiplex molecular diagnostics of respiratory microbes

Seasonal respiratory infections remain one of the highest causes of sickness across all age groups and given that the clinical presentation of different respiratory microbes can be very similar it is extremely difficult to determine the causative agent purely on the clinical symptoms. As a result, the use of targeted multiplex molecular diagnostic assays which enable the simultaneous detection and determination of different respiratory microbes have become increasingly important in patient and public health management as well as surveillance monitoring of seasonal respiratory microbial infections.

Intended use of the RTX

The RTX range of external quality control products are intended to support the use of respiratory multiplex molecular assays:

- Supporting the validation of the multiplex assay performance in line with the laboratory's internal quality plan
- As a daily external positive process control.
- **Note:** a negative process control is also available if required (TMNQC02)
- Monitoring the change of assay change reagent batches / lots
- Verification after assay test system maintenance and/or after software upgrades.
- As a training aid for staff competency assessment

RTX Product Description

The Qnostics' Respiratory Target Multiplex (RTX) range consists of 5 independent control products covering a total of 20 different respiratory microbes. Each RTX product is a combination of four respiratory microbes in a physiological transport media containing background human cells. Each RTX product consists of 5 x 0.7 ml samples, positive for four respiratory targets in a single vial and respiratory microbes covered in each are as follows:

- **RTX1:** Influenza A (H1 pdm09), Respiratory Syncytial Virus A, Influenza B (Victoria) and SARS-CoV-2
- **RTX2:** Parainfluenza virus 1, Adenovirus (Type 1), *Mycoplasma pneumoniae* and Coronavirus OC43.
- **RTX3:** Parainfluenza virus 2, Human Metapneumovirus, Enterovirus A16 and Coronavirus 229E.
- **RTX4:** Parainfluenza virus 3, Rhinovirus 16, *Legionella pneumophila* and Coronavirus NL63.
- **RTX5:** Parainfluenza virus 4, Enterovirus D68, Adenovirus (Type 14) and Respiratory Syncytial Virus B

Table 1: Summary guide to the content of the 5 RTX products.

| Product Code | Positive for the following Targets | | | |
|-----------------|------------------------------------|--------|-----------------------|---------|
| RTX1QC01 | INFA H1N1 pdm09 | RSV A | INFB Victoria | SCV2 |
| RTX2QC01 | PINF 1 | ADV 1 | <i>M. pneumoniae</i> | CV OC43 |
| RTX3QC01 | PINF 2 | hMPV | EV A16 | CV 229E |
| RTX4QC01 | PINF 3 | RV 16 | <i>L. pneumophila</i> | CV NL63 |
| RTX5QC01 | PINF 4 | EV D68 | ADV 14 | RSV B |

IMPORTANT NOTE: The RTX Products have **no assigned values** and should not be used as a replacement for the controls the manufacturer may provide with the assay. The RTX products should always be used in line with the QC requirements recommended by the molecular assay manufacturer and any regional regulatory requirements. All relative quantitation data (Cycle Threshold values) provided are for information purposes only and are dependent on the nucleic acid extraction / molecular assay system used (see Limitations). It is therefore the responsibility of the end user to establish their own results for each of the RTX products using their laboratory's molecular procedures.

Performance Characteristics

The Qnostics' Respiratory Target Multiplex (RTX) products were designed for use with a range of molecular multiplex respiratory assays including the following:

- Cepheid Xpert® Xpress SARS-CoV-2/Flu/RSV assay
 - **Only RTX1QC01 applicable**
- BIOFIRE® Respiratory Panel 2.1 *plus*
- Qiagen QIAstat-Dx® Respiratory SARS-CoV-S Panel

Table 2: RTX1QC01 Performance on Cepheid Xpert® Xpress

| RTX1 Targets | Qualitative Result | Target C _t Values | Xpert® Xpress FLU/RSV |
|--------------|------------------------------------|------------------------------|-----------------------|
| Influenza A | Positive Flu A1 Positive Flu A2 | 32.0-35.0 | FLU A1 33 |
| | | | FLU A2 34 |
| Influenza B | Positive Flu B | 32.0-35.0 | FLU B 34 |
| RSV A | Positive RSV | 32.0-35.0 | RSV 32 |
| SARS CoV 2 | Positive E Positive N2 | 25.0-30.0 | E 27 |
| | | 35.0-40.0 | N2 39 |

Table 3: RTX Performance on Qiagen QIAstat-Dx

| Product Code | QIAstat-Dx® results (Qualitative) | | | |
|-----------------|---|--|--|--|
| RTX1QC01 | INFA pdm09 ⁽¹⁾ Positive C _t : 37 / 35 | RSV A Positive C _t : 35 | INFB Victoria Positive C _t : 35 | SCV2 Positive C _t : 33 |
| RTX2QC01 | PINF 1 Positive C _t : 28 | ADV 1 Positive C _t : 30 | <i>M. pneumoniae</i> Positive C _t : 33 | CV OC43 Positive C _t : 33 |
| RTX3QC01 | PINF 2 Positive C _t : 33 | hMPV Positive C _t : 28 | EV A16 ⁽²⁾ Positive C _t : 27 | CV 229E Positive C _t : 35 |
| RTX4QC01 | PINF 3 Positive C _t : 28 | RV 16 ⁽²⁾ Positive C _t : 32 | <i>L. pneumophila</i> Positive C _t : 26 | CV NL63 Positive C _t : 33 |
| RTX5QC01 | PINF 4 Positive C _t : 30 | EV D68 ⁽²⁾ Positive C _t : 30 | ADV 14 Positive C _t : 34 | RSV B Positive C _t : 32 |

Notes ⁽¹⁾ There are two targets for INF A, a general INF A reaction and a specific H1 pdm09 reaction. ⁽²⁾ The assay does not distinguish between EV and RV

Table 4: RTX Performance on BioFire Respiratory Panel 2.1 *plus*

| Product Code | BioFire® Respiratory Panel 2.1 <i>plus</i> results (Qualitative) | | | |
|-----------------|--|-----------------------------------|---------------------------------------|---------------------|
| RTX1QC01 | INFA pdm09 ⁽¹⁾ Positive | RSV A Positive | INFB Victoria Positive | SCV2 Positive |
| RTX2QC01 | PINF 1 Positive | ADV 1 Positive | <i>M. pneumoniae</i> Positive | CV OC43 Positive |
| RTX3QC01 | PINF 2 Positive | hMPV Positive | EV A16 ⁽²⁾ Positive | CV 229E Positive |
| RTX4QC01 | PINF 3 Positive | RV 16 ⁽²⁾ Positive | <i>L. pneumophila</i> Not in assay | CV NL63 Positive |
| RTX5QC01 | PINF 4 Positive | EV D68 ⁽²⁾ Positive | ADV 14 Positive | RSV B Positive |

Notes This assay does not provide values, just qualitative positive or negative results.