



# Qnostics

Complete Quality Control Solutions for  
SARS-CoV-2 (COVID-19)



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# QNOSTICS | INTERNAL QUALITY CONTROLS

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Qnostics, a world leading manufacturer of QC solutions for molecular infectious disease testing has developed a range of products designed to support the validation, verification and performance monitoring of molecular assays used in the testing of SARS-CoV-2. Whole pathogen controls designed to monitor assay performance on a run to run basis. As true third party controls, assay drift is detected, monitored and managed helping to ensure accurate and reliable results.

# QNOTICS | INTERNAL QUALITY CONTROLS

## Why choose Qnostics

-  Qnostics controls contain the entire SARS-CoV-2 genome including CDC and WHO consensus sequences, meaning they are compatible with the majority of commercial and in-house assays.
-  Whole pathogen controls are the ideal material for full-process validation, monitoring the testing process from extraction to amplification and detection ensuring ultimate quality assurance in laboratories.
-  Quantified by digital PCR, ensuring reproducibility and metrological traceability enabling laboratories to meet their daily QC accreditation requirements.
-  As third party controls, an independent, unbiased assessment of assay performance is ensured in line with ISO 15189:2012 regulatory requirements.
-  Qnostics controls are manufactured under ISO 13485 guidelines to ensure quality and traceability.
-  Negative control available containing human cells/nucleic acids and therefore can be used as part of assay validation.

## SARS-CoV-2 Q Controls

Whole pathogen controls designed to monitor assay performance on a run to run basis. As true third party controls, assay drift is detected, monitored and managed helping to ensure accurate and reliable results.

**Target Pathogen** – SARS-CoV-2 (COVID-19)

**Format** – Liquid Frozen

**Target** – Whole Pathogen

**Stability** – 5 days opened vial stability

**Matrix** – Transport Medium

**Regulatory Status** – CE, RUO

| Thomas Number | Product Description  | Pack Size  |
|---------------|----------------------|------------|
| CHM01P950     | SARS-CoV-2 Q Control | 5 x 0.5 ml |
| CHM01P941     | Negative Q Control   | 5 x 0.5 ml |

## SARS-CoV-2 Analytical Q Panel

Designed to span the analytical measuring range of an assay, allowing assessment of linearity, Limit of Detection (LOD) and Limit of Quantitation (LOQ).

**Target Pathogen** – SARS-CoV-2 (COVID-19)

**Format** – Liquid Frozen

**Target** – Whole Pathogen

**Stability** – 5 days opened vial stability

**Matrix** – Transport Medium

**Regulatory Status** – CE, RUO

| Thomas Number | Product Description           | Pack Size  |
|---------------|-------------------------------|------------|
| CHM01P952     | SARS-CoV-2 Analytical Q Panel | 9 x 0.5 ml |

## SARS-CoV-2 Molecular Q Panel

Four individual levels including a negative are provided spanning the assays' clinical range. Molecular Q Panels may be used to support laboratory training and in the performance assessment and validation of molecular diagnostic assays.

**Target Pathogen** – SARS-CoV-2 (COVID-19)

**Format** – Liquid Frozen

**Target** – Whole Pathogen

**Stability** – 5 days opened vial stability

**Matrix** – Transport Medium

**Regulatory Status** – CE, RUO

| Thomas Number | Product Description          | Pack Size  |
|---------------|------------------------------|------------|
| CHM01P951     | SARS-CoV-2 Molecular Q Panel | 4 x 0.5 ml |

# QNOTICS | INTERNAL QUALITY CONTROLS

## Respiratory Target Multiplex (RTX)

A series of respiratory target multiplex controls are available, enabling the requirements for winter testing strategies to be met. The controls cover a range of viral and bacterial pathogens responsible for an array of respiratory diseases in various patient cohorts, whilst discriminating cold and flu from COVID-19.

### RTX Plus Q Control

**Target Pathogen** – Influenza A (H1N1), Influenza B (Victoria), RSV A, Coronavirus (SARS-CoV-2)

**Target** – Whole Pathogen

**Matrix** – Transport Medium

**Format** – Liquid Frozen

**Stability** – Single use. Once thawed use immediately.

**Regulatory Status** – RUO

| Thomas Number | Product Description | Pack Size |
|---------------|---------------------|-----------|
| CHM01P960     | RTX Plus Q Control  | 5 x 0.6ml |

### RTX2 Q Control

**Target Pathogen** – Parainfluenza I, Adenovirus I, *Mycoplasma pneumoniae*, Coronavirus (OC43)

**Target** – Whole Pathogen

**Matrix** – Transport Medium

**Format** – Liquid Frozen

**Stability** – Single use. Once thawed use immediately.

**Regulatory Status** – RUO

| Thomas Number | Product Description | Pack Size |
|---------------|---------------------|-----------|
| CHM01P959     | RTX2 Q Control      | 5 x 0.6ml |

# QNOSTICS | INTERNAL QUALITY CONTROLS

## RTX3 Q Control

**Target Pathogen** – Parainfluenza 2, Metapneumovirus (A2), Enterovirus (A16), Coronavirus (229E)

**Target** – Whole Pathogen

**Matrix** – Transport Medium

**Format** – Liquid Frozen

**Stability** – Single use. Once thawed use immediately.

**Regulatory Status** – RUO

| Thomas Number | Product Description | Pack Size |
|---------------|---------------------|-----------|
| CHM01P958     | RTX3 Q Control      | 5 x 0.6ml |

## RTX4 Q Control

**Target Pathogen** – Parainfluenza 3, Rhinovirus (16), *Legionella pneumophila*, Coronavirus (NL63)

**Target** – Whole Pathogen

**Matrix** – Transport Medium

**Format** – Liquid Frozen

**Stability** – Single use. Once thawed use immediately.

**Regulatory Status** – RUO

| Thomas Number | Product Description | Pack Size |
|---------------|---------------------|-----------|
| CHM01P957     | RTX4 Q Control      | 5 x 0.6ml |

## RTX5 Q Control

[for paediatric testing]

**Target Pathogen** – Parainfluenza 4, Adenovirus (14), RSV B, Enterovirus (D68)

**Target** – Whole Pathogen

**Matrix** – Transport Medium

**Format** – Liquid Frozen

**Stability** – Single use. Once thawed use immediately.

**Regulatory Status** – RUO

| Thomas Number | Product Description | Pack Size |
|---------------|---------------------|-----------|
| CHM01P956     | RTX5 Q Control      | 5 x 0.6ml |

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