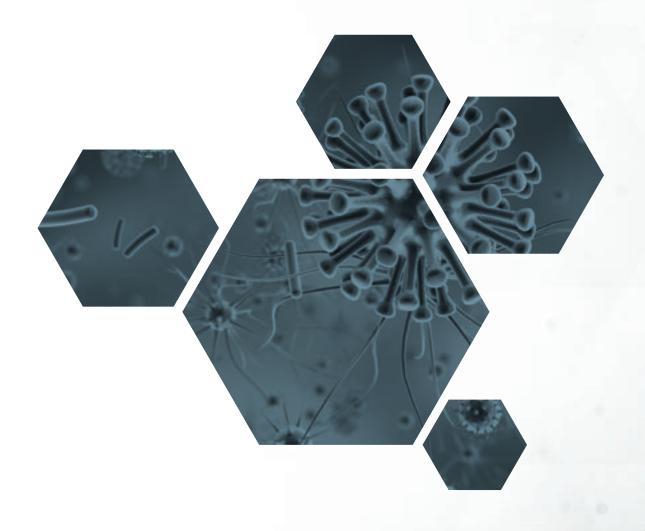


Qnostics

Molecular Controls for Infectious Disease Testing





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Introduction

Qnostics is a leading provider of Quality Control solutions for Molecular Infectious Disease testing. Designed to meet the demands of today's molecular diagnostics laboratory and laboratories carrying out Nucleic Acid Testing (NAT), our range comprises hundreds of characterised viral, bacterial and fungal targets covering a wide range of Transplant Associated Diseases, Respiratory Diseases, Blood Borne Viruses, Sexually Transmitted Infections, Gastrointestinal Infections and Central Nervous System Diseases.

As a provider of complete QC solutions, our products can be used in the daily monitoring of assay performance, linearity assessment, assay evaluation, validation/verification of new assays and staff training.

In addition to clinical and molecular laboratories, Qnostics has, for more than a decade, delivered custom QC products and services to IVD assay manufacturers, EQA providers, Pharmaceutical and CRO organisations with the overall aim of supporting them at all stages of the assay's product life cycle from R&D to in-market customer support.

Q Controls

Ourrange of positive run, whole pathogen, third party controls are designed to monitor assay performance on a routine basis. As true third party controls, assay drift is detected, monitored and managed, helping to ensure accurate and reliable results. The use of third party controls will also help to support ISO 15189:2012 regulatory requirements.

Molecular Q Panels

Molecular Q Panels consist of four individual levels, including a negative, and are intended to evaluate the assays' clinical range. Molecular Q Panels can also be used to support laboratory training and in the assessment and development of molecular diagnostic assays from extraction phase through amplification and finally detection.

Analytical Q Panels

Analytical Q Panels are designed to cover the dynamic range of an assay allowing assessment of the linearity, Limit of Detection (LOD) and Limit of Quantitation (LOQ). Each panel contains a minimum of five samples spanning the dynamic range of the assay in a linear progression.

Evaluation Panels

Evaluation Panels cover a range of genotypes and/or levels, and may be used to evaluate assay characteristics, confirm performance claims and ultimately ensure the assay is fit for purpose. Evaluation Panels may also be used in the validation of clinical assays and the development of new diagnostic tests.

QCMD Past Panels

Samples from previous QCMD EQA challenges may be available for use in assay evaluation and staff training.

The following table is designed to help you choose the most appropriate solution for your needs:

	Q Controls	Molecular Q Panels	Analytical Q Panels	Evaluation Panels	QCMD Past Panels
Daily assay monitoring	•				
Assay verification / validation	•	•	•	•	
Linearity/LOD/LOQ assessment					
Assay evaluation				•	•
Detection of subtypes and strains				•	•
Staff training	•	•	•	•	•
Retest after poor EQA performance	•	•	•	•	•

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Q Controls

Independently manufactured, externally run controls are designed to be treated as a patient sample within an assay run. Helping to support a laboratory's accreditation requirements in line with ISO 15189:2012, Q Controls are available as positive or negative, and are supplied in an unassayed, liquid format delivering accurate and reliable test results.

Benefits

Whole pathogen controls

As whole pathogen controls, the Q Control range is designed to mimic the performance of patient samples and can be used to effectively monitor the performance of the entire testing process including extraction, amplification and detection.

Traceability

All controls are traceable to international reference materials, where available.

Third party control

All Q Controls can be described as true third party controls thus delivering an independent, unbiased assessment of assay performance whilst helping to meet ISO 15189:2012 regulatory requirements.

Liquid for ease-of-use

All samples are conveniently supplied in a liquid frozen format meaning there is no additional preparation or handling required.

Q Controls for Transplant Associated Diseases

Advances in transplant medicine have greatly improved the prospects of transplant recipients. However, pathogen infection and in particular, viral reactivation remain significant contributors to transplant patient morbidity and mortality. The Q Control range covers a number of viruses and fungal pathogens of particular concern, including: HSV, CMV, EBV, ADV, JCV and BKV.



Adenovirus (ADV) Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of Adenovirus (ADV) Type 1.

Target Pathogen – Adenovirus (ADV)

Target Genotype – Type 1 **Matrix** – Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
ADVMQC	ADV Medium Q Control	5 x 1 ml

BK Virus (BKV) Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of BK Virus (BKV).

Target Pathogen – BK Virus (BKV)
Target Genotype – Type 1b-2

Matrix – Plasma

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
BKVMQC	BKV Medium Q Control	5 x 1 ml



Cytomegalovirus (CMV) Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of Cytomegalovirus (CMV).

Target Pathogen – Cytomegalovirus (CMV)

Target Genotype – AD169

Matrix - Plasma

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
CMVMQC	CMV Medium Q Control	5 x 1 ml
•••••		••••••••

Epstein-Barr Virus (EBV) Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of Epstein-Barr Virus (EBV).

Target Pathogen – Epstein-Barr Virus (EBV)

Target Genotype – B-95

Matrix – Plasma

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
EBVMQC	EBV Medium Q Control	5 x 1 ml
•••••		••••••

Herpes Simplex Virus 1 (HSV1) Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of Herpes Simplex Virus 1 (HSV1).

Target Pathogen – Herpes Simplex Virus 1 (HSV1)

Target Genotype – Type 95

Matrix – Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
HSV1MQC	HSV1 Medium Q Control	5 x 1 ml

Herpes Simplex Virus 2 (HSV2) Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of Herpes Simplex Virus 2 (HSV2).

Target Pathogen – Herpes Simplex Virus (HSV2)

Target Genotype – Type 09 **Matrix** – Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
HSV2MQC	HSV2 Medium Q Control	5 x 1 ml

JC Virus (JCV) Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of JC Virus (JCV).

Target Pathogen – JC Virus (JCV)

Target Genotype - Type 1A

Matrix – Plasma

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
JCVMQC	JCV Medium Q Control	5 x 1 ml

Pneumocystis jirovecii pneumonia (PCP) Control

Dedicated, positive control for use in monitoring the performance of molecular assays used in the detection of *Pneumocystis jirovecii pneumonia* (PCP).

Target Pathogen – Pneumocystis jirovecii pneumonia (PCP)

Matrix - Saline

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Catalogue Code	Product Description	Pack Size
PCPMQC	PCP Medium Q Control	5 x 0.25 ml

Varicella Zoster Virus (VZV) Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of Varicella Zoster Virus (VZV).

Target Pathogen – Varicella Zoster Virus (VZV)

Target Genotype – Type 9/84 **Matrix** – Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
VZVMQC	VZV Medium Q Control	5 x 1 ml

Q Controls for Respiratory Infection Testing

Respiratory tract infections (RTIs) are common conditions, affecting both the upper and lower respiratory tract. For the young, the elderly and the immunocompromised, RTIs can be a significant health threat if not managed effectively. The Q Control range covers a range of common viral pathogens including SARS-CoV-2 and a range of Multiplex Respiratory Target Controls which enable a laboratory to monitor the performance of multiple clinically relevant strains from the same control sample.



Adenovirus (ADV) Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of Adenovirus (ADV) Type 1.

Target Pathogen – Adenovirus (ADV)

Target Genotype – Type 1

Matrix – Viral Transport Medium

Stability – Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
ADVMQC	ADV Medium Q Control	5 x 1 ml



Influenza A Virus (INFA) Control

Dedicated, positive run control, dedicated for use in monitoring the performance of molecular assays used in the detection of Influenza A Virus (INFA).

Target Pathogen – Influenza A Virus (INFA)

Target Genotype - H1N1

Matrix - Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
INFAMQC	INFA Medium Q Control	5 x 1 ml
•••••		• • • • • • • • • • • • • • • • • • • •

Influenza B Virus (INFB) Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of Influenza B Virus (INFB).

Target Pathogen – Influenza B Virus (INFB)

Target Genotype – Victoria **Matrix** – Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
INFBMQC	INFB Medium Q Control	5 x 1 ml
•••••		• • • • • • • • • • • • • • • • • • • •

Mycobacterium tuberculosis (MTB) Q Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of Mycobacterium tuberculosis.

Target Pathogen – Mycobacterium tuberculosis (MTB)

Matrix – Synthetic Sputum

Stability – Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Catalogue Code	Product Description	Pack Size
MTBQC	Mycobacterium tuberculosis (MTB) Q Control	5 x 1 ml

Parainfluenza Virus (PINF) Control

Monitor the performance of molecular assays used in the detection of Parainfluenza Virus (PINF) using this dedicated, positive run control.

Target Pathogen – Parainfluenza Virus (PINF)

Target Genotype – Type 1

Matrix - Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
PINFMQC	PINF Medium Q Control	5 x 1 ml
•••••	•••••	• • • • • • • • • • • • • • • • • • • •

Respiratory Syncytial Virus A (RSV A) Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of Respiratory Syncytial Virus A (RSV A).

Target Pathogen – Respiratory Syncytial Virus A (RSV A)

Target Genotype – Type A

Matrix – Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
rsvamqc	RSV A Medium Q Control	5 x 1 ml
••••••		

Respiratory Triplex Control

The Respiratory Triplex Q control is designed to monitor the daily performance of a range of molecular assays including Influenza A, Influenza B and Respiratory Syncytial Virus (RSV). Five positive and five negative samples are conveniently supplied in a single pack reducing the number of individual kits required.

Target Pathogen - Influenza A (H1N1), Influenza B (Victoria), Respiratory Syncytial Virus A (RSV A)

Target Genotype – H1N1, Victoria, RSV A

Matrix – Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
rtxmqc	Respiratory Triplex Control	5 x 0.5 ml (Positive) 5 x 0.5 ml (Negative)

Rhinovirus (RV) Control

This Rhinovirus (RV) dedicated, positive run control is designed for use in monitoring the performance of molecular assays.

Target Pathogen – Rhinovirus (RV)

Target Genotype – Type 16

Matrix - Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Product Description	Pack Size
RV Medium Q Control	5 x 1 ml
	<u> </u>

RTX1 Q Control

Positive run control comprising Influenza, A, Influenza B, RSV and SARS-CoV-2, as a whole pathogen control it is ideal for use with multiplex assays.

Target Pathogen - Influenza A (H1N1), Influenza B (Victoria), Respiratory Syncytial Virus A (RSV A), Coronavirus (SARS-CoV-2)

Matrix - Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
RTX1QC	RTX1 Q Control	5 x 0.7 ml

RTX2 Q Control

Multiplex, positive run respiratory control comprising a range of common viral and bacterial pathogens. As a whole pathogen control, it is suitable for use as a full-process control.

Target Pathogen - Parainfluenza 1, Adenovirus 1, Mycoplasma pneumoniae, Coronavirus (OC43)

Matrix – Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

 $\textbf{Regulatory Status} - \mathsf{RUO}$

Catalogue Code	Product Description	Pack Size
RTX2QC	RTX2 Q Control	5 x 0.7 ml

RTX3 Q Control

Multiplex, positive run respiratory control comprising a range of common viral and bacterial pathogens. As a whole pathogen control, it is suitable for use as a full-process control.

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

Matrix - Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - RUO

Product Description	Pack Size
RTX3 Q Control	5 x 0.7 ml

RTX4 Q Control

Multiplex, positive run respiratory control comprising a range of common viral and bacterial pathogens. As a whole pathogen control, it is suitable for use as a full-process control.

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

Matrix - Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
RTX4QC	RTX4 Q Control	5 x 0.7 ml

RTX5 Q Control

Suitable for use in paediatric testing, Multiplex, positive run respiratory control comprising a range of common viral and bacterial pathogens. As a whole pathogen control, it is suitable for use as a full-process control.

Target Pathogen - Parainfluenza 4, Adenovirus (14), Respiratory Syncytial Virus B (RSV B), Enterovirus (D68)

Matrix – Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

 $\textbf{Regulatory Status} - \mathsf{RUO}$

Catalogue Code	Product Description	Pack Size
RTX5QC	RTX5 Q Control	5 x 0.7 ml

RTX6 Q Control

Multiplex respiratory control comprising a range of common viral and bacterial whole pathogens. As a whole pathogen control, it is suitable for full-process control.

Target Pathogen – Bordetella pertussis, Bordetella parapertussis, Influenza A H3N2, Chlamydophila pneumoniae

Matrix - Viral Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
RTX6QC	RTX6 Q Control	5 x 0.7 ml

SARS-CoV-2 Q Control

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

Target Pathogen – Coronavirus (SARS-CoV-2)

Target Genotype – Whole Pathogen

Matrix – Transport Medium **Stability** – 5 day stability

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE and RUO

Catalogue Code	Product Description	Pack Size
SCV2QC	SARS-CoV-2 Q Control	5 x 0.5 ml

Q Controls for Blood Borne Viruses

Monitoring for the presence of Blood Borne Viruses (BBV) nucleic acid is an essential parameter in guiding clinical treatment and patient outcome. The Q Controls range is designed to monitor the entire molecular workflow from extraction to detection.



Hepatitis B (HBV) Control

Dedicated, positive run Q Control for use in monitoring the performance of molecular assays used in the detection of Hepatitis B (HBV).

Target Pathogen – Hepatitis B Virus (HBV)

Target Genotype – Type A

Matrix – Plasma

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
HBVMQC	HBV Medium Q Control	5 x 1.2 ml

Hepatitis C (HCV) Control

Dedicated, positive run Q control for use in monitoring the performance of molecular assays used in the detection of Hepatitis C (HCV).

Target Pathogen – Hepatitis C Virus (HCV)

Target Genotype - Type 1B

Matrix - Plasma

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
HCVMQC	HCV Medium Q Control	5 x 1.2 ml
ne mag		37.112.111

Human Immunodeficiency Virus 1 (HIV-1) Control

Monitor the performance of molecular assays used in the detection of Human Immunodeficiency 1 (HIV-1) using this dedicated, positive run control.

Target Pathogen – Human Immunodeficiency Virus 1 (HIV-1)

Target Genotype – Type B

Matrix – Plasma

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
HIVMQC	HIV Medium Q Control	5 x 1.2 ml

Q Controls for Exotic Diseases

Using suitable quality control measures is paramount in ensuring quality daily performance of the molecular assay. Exotic diseases are infectious diseases that were previously confined to specific regions globally which are now appearing in new and unexpected areas. With global warming and travelling globally becoming more and more prominent exotic diseases may rise simultaneously as these are believed to be two key factors in their spreading.



West Nile Virus (WNV) Control

West Nile Virus Q Controls are intended to help laboratories monitor their molecular assays on a run to run basis within customer derived limits. The control consists of 5 Medium Positive and 5 Negative samples.

Target Pathogen – West Nile Virus (WNV)

Target Genotype – NY99

Matrix – Plasma

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
WNVMQC	WNV Medium Q Control	5 x 1.5 ml (Positive)
		5 x 1.5 ml (Negative)

Zika Virus (ZV) Control

The Qnostics Zika Virus Q Controls are intended to help laboratories monitor their molecular assays on a run to run basis within customer derived limits. The control consists of 5 Medium Positive and 5 Negative samples.

Target Pathogen – Zika Virus (ZV)
Target Genotype – African

Matrix – Plasma

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
ZVMQC	Zika Virus Medium Q Control	5 x 1.5 ml (Positive) 5 x 1.5 ml (Negative)

Q Controls for Gastrointestinal Infections

There are a number of bacteria, viruses and parasites that cause gastrointestinal infections. In many cases the infection will pass in a number of days.



Norovirus GI/GII Q Control

The Norovirus GI/GII Q control is designed to monitor the daily performance of a range of molecular assays. Five samples positive for genotypes I & II are conveniently supplied in a single pack reducing the number of individual kits required.

Target Pathogen – Norovirus

Target Genotype - Genotypes I and II

Matrix – Transport Medium

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Catalogue Code	Product Description	Pack Size
NVQC	Norovirus GI/GII Q Control	5 x 0.5 ml



Q Controls for Central Nervous System Infections

Infections of the Central Nervous System (CNS) can affect the brain and spinal cord and usually cause swelling of the target area. Consequences of CNS infection can become serious, however, with rapid and correct treatment most cases can be resolved. This further highlights the need for quality testing measures to be put in place.



Enterovirus Q Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of Enterovirus.

Target Pathogen – Enterovirus
Target Genotype – Coxsackie B3
Matrix – Transport Medium

Stability – Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
EVQC	Enterovirus Q Control	5 x 1 ml

Q Controls for Drug Resistance

Drug resistance - or antibiotic resistance - occurs when the germs no longer respond to the antibiotics that have been designed to kill them. If these germs develop resistance to antibiotics they become "drug-resistant", for example vancomycin-resistant-enterococci.



Vancomycin Resistant Enterococci Q Control

Dedicated, positive control samples for use in monitoring the performance of molecular assays used in the detection of Enterococci.

Target Pathogen – Enterococci

Target Genotype – van A resistant E. faecium and van B resistant E. Faecali

Matrix - Transport Medium

Stability – Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Catalogue Code	Product Description	Pack Size
VREQC	VRE Q Control	5 x 0.5 ml

Mycobacterium tuberculosis (MTB) Rifampicin Resistant Q Control

Compatible for use with Cepheid analysers, this whole pathogen positive control is designed to monitor the performance of molecular assays used in the detection of Rifampicin resistant Mycobacterium tuberculosis.

Target Pathogen – Mycobacterium tuberculosis (MTB)

Target Genotype – Rifampicin Resistance

Matrix – Synthetic Sputum

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
MTBRQC	Mycobacterium tuberculosis (MTB) (Rifampicin Resistance) Q Control	5 x 1 ml

Q Controls for Sexually Transmitted Infections

A sexually transmitted infection is passed from one person to another through sexual contact. An infection is when bacteria, virus or parasite enters and grows within the body. There are more than 30 different bacteria, viruses and parasites known to be transmitted.



Chlamydia trachomatis and Neisseria gonorrhoeae (CT/NG) Q Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of Chlamydia trachomatis and Neisseria gonorrhoeae.

Target Pathogen – C. trachomatis & N. gonorrhoeae

Matrix – Transport Medium

Stability – Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Catalogue Code	Product Description	Pack Size
CTNGTQC	CTNG Q Control	5 x 1 ml



Chlamydia trachomatis and Neisseria gonorrhoeae (CT/NG) Q Control

Dedicated, positive run control for use in monitoring the performance of molecular assays used in the detection of Chlamydia trachomatis and Neisseria gonorrhoeae.

Target Pathogen – C. trachomatis & N. gonorrhoeae

Matrix - Urine

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
CTNGUQC	CTNG Q Control	5 x 1 ml

Negative Q Control Range

A negative control otherwise known as the "baseline", should be used in microbiology testing. A negative control does not receive any test or treatment, they simply get observed in their natural state. The laboratory knows there will be a negative result and does not expect any response from the control tes



Synthetic Sputum Negative Q Control

Dedicated, negative control for use in monitoring the performance of molecular assays by helping to establish the specificity (false positivity).

Matrix – Synthetic Sputum & background human cells

Stability – Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
SSPQC	Synthetic Sputum Negative Q Control	5 x 1 ml

SARS-CoV-2 Negative Q Control

Dedicated, negative control for use in monitoring the performance of SARS-CoV-2 molecular assays by helping to establish the specificity (false positivity). This negative control has been designed as part of the Qnostics SARS-CoV-2 range.

Matrix – Transport Medium & background human cells

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Catalogue Code	Product Description	Pack Size
TMNQC	Transport Medium Negative Q Control	5 x 0.5 ml

Transport Medium Negative Q Control

Dedicated, negative control for use in monitoring the performance of molecular assays by helping to establish the specificity (false positivity).

Matrix - Transport Medium & background human cells

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
TMQC	Transport Medium Negative Q Control	5 x 1 ml
••••••		

Synthetic Faecal Matrix Negative Q Control

Dedicated, negative control for use in monitoring the performance of molecular assays by helping to establish the specificity (false positivity).

Matrix – Synthetic Faecal Matrix & background human cells

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
SFMQC	Synthetic Faecal Matrix Negative Q Control	5 x 1 ml

Citrated Plasma Negative Q Control

Dedicated, negative control for use in monitoring the performance of molecular assays by helping to establish the specificity (false positivity).

Matrix - Citrated plasma

Stability - Single use control designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - $\ensuremath{\mathsf{RUO}}$

Catalogue Code	Product Description	Pack Size
PLQC	Citrated Plasma Negative Q Control	5 x 1 ml
	•	

Urine Negative Q Control

Dedicated, negative control for use in monitoring the performance of molecular assays by helping to establish the specificity (false positivity).

Matrix - Urine & background human cells

Shelf Life – Up to 2 years from date of manufacture

Catalogue Code	Product Description	Pack Size
UQC	Urine Negative Q Control	5 x 1 ml



Analytical Q Panels

Each Analytical Q Panel consists of five or more individual samples including a negative and is designed to cover the dynamic range of the assay. Analytical Q Panels are intended for use in the validation and verification of new assays helping to establish the Limit of Detection (LOD) and ensuring the assay is linear throughout the dynamic range.

Benefits

Whole pathogen controls

As whole pathogen controls, the Analytical Q Panel range is designed to mimic the performance of patient samples and can be used to effectively monitor the performance of the entire testing process including extraction, amplification and detection.

Traceability

All Analytical Q Panels are traceable to international reference materials where available.

Clinically relevant range

All Analytical Q Panels comprise a series of samples designed to cover the assays measuring range. Up to 10 different concentrations can be covered in a single Analytical Q Panel, with each panel also including a negative sample.

Liquid for ease-of-use

All samples are conveniently supplied in a liquid frozen format meaning there is no additional preparation or handling required.

Analytical Q Panels for Transplant Associated Diseases

Advances in transplant medicine have greatly improved the prospects of transplant recipients. However, pathogen infection and in particular, viral reactivation remain significant contributors to transplant patient morbidity and mortality. The Analytical Q Panel range covers a number of viruses of particular concern, including: HSV, CMV, EBV, ADV, JCV, BKV and HHV6.



Adenovirus (ADV) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Adenovirus (ADV). Comprising eight individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Adenovirus (ADV)

Target Genotype – Type 1

Matrix – Viral Transport Medium

Number of Levels - 8

Stability – Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
ADVAQP	ADV Analytical Q Panel	8 x 1 ml

BK Virus (BKV) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of BK Virus (BKV). Comprising ten individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – BK Virus (BKV)
Target Genotype – Type 1b-2

Matrix – Plasma Number of Levels – 10

Stability - Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

 $\textbf{Regulatory Status} \text{-} \mathsf{IVD} \text{ and } \mathsf{RUO}$

Catalogue Code	Product Description	Pack Size
BKVAQP	BKV Analytical Q Panel	10 x 1 ml



Cytomegalovirus (CMV) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Cytomegalovirus (CMV). Comprising nine individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Cytomegalovirus (CMV)

Target Genotype - AD169

Matrix – Plasma

Number of Levels - 9

Stability - Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
CMVAQP	CMV Analytical Q Panel	9 x 1 ml
••••••		

Epstein-Barr Virus (EBV) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Epstein-Barr Virus (EBV). Comprising ten individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Epstein-Barr Virus (EBV)

Target Genotype – B-95

Matrix – Plasma

Number of Levels - 10

Stability - Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
EBVAQP	EBV Analytical Q Panel	10 x 1 ml
•••••	•••••	•••••••

Human Herpes Virus 6 (HHV6) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Human Herpes Virus 6 (HHV6). Comprising ten individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Human Herpes Virus 6 (HHV6)

Target Genotype – Type A-GS

Matrix – Plasma

Number of Levels – 10

Stability - Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
HHV6AQP	HHV6 Analytical Q Panel	10 x 1 ml

Herpes Simplex Virus 1 (HSV1) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Herpes Simplex Virus 1 (HSV1). Comprising eight individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Herpes Simplex Virus 1 (HSV1)

Target Genotype – Type 95 **Matrix** – Viral Transport Medium

Number of Levels – 8

Stability - Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

 $\textbf{Regulatory Status} \text{-} \mathsf{IVD} \text{ and } \mathsf{RUO}$

Catalogue Code	Product Description	Pack Size
HSV1AQP	HSV1 Analytical Q Panel	8 x 1 ml
••••••		• • • • • • • • • • • • • • • • • • • •

Herpes Simplex Virus 2 (HSV2) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Herpes Simplex Virus 2 (HSV2). Comprising ten individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Herpes Simplex Virus 2 (HSV2)

Target Genotype – Type 09 **Matrix** – Viral Transport Medium

Number of Levels - 10

Stability - Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
HSV2AQP	HSV2 Analytical Q Panel	10 x 1 ml
•••••	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •

JC Virus (JCV) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of JC Virus (JCV). Comprising ten individual levels, linearity is accurately assessed throughout the assay's measuring range.

 $\textbf{Target Pathogen} - \mathsf{JC} \ \mathsf{Virus} \ (\mathsf{JCV})$

Target Genotype - Type 1A

Matrix - Plasma

Number of Levels – 10

Stability - Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
JCVAQP	JCV Analytical Q Panel	10 x 1 ml

Varicella Zoster Virus (VZV) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Varicella Zoster Virus (VZV). Comprising ten individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Varicella Zoster Virus (VZV)

Target Genotype – Type 9/84 **Matrix** – Viral Transport Medium

Number of Levels – 10

Stability - Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

 $\textbf{Regulatory Status} \text{-} \mathsf{IVD} \text{ and } \mathsf{RUO}$

Catalogue Code	Product Description	Pack Size
VZVAQP	VZV Analytical Q Panel	10 x 1 ml

Analytical Q Panels for Respiratory Infection Testing

Respiratory tract infections (RTIs) are common conditions, affecting both the upper and lower respiratory tract. For the young, the elderly and the immunocompromised, RTIs can be a significant health threat if not managed effectively. The Analytical Q Panel range covers a range of common viral pathogens including SARS-CoV-2.



Influenza A Virus (INFA) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Influenza A Virus (INFA). Comprising nine individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Influenza A Virus (INFA)

Target Genotype - H1N1

Matrix - Viral Transport Medium

Number of Levels -9

Stability – Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO $\,$

Catalogue Code	Product Description	Pack Size
INFAAQP	INFA Analytical Q Panel	9 x 1 ml



Influenza B Virus (INFB) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Influenza B Virus (INFB). Comprising seven individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Influenza B Virus (INFB)

Target Genotype – Victoria **Matrix** – Viral Transport Medium

Number of Levels – 7

Stability - Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
INFBAQP	INFB Analytical Q Panel	7 x 1 ml
•••••	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •

Parainfluenza Virus (PINF) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Parainfluenza Virus (PINF). Comprising nine individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Parainfluenza Virus (PINF)

Target Genotype – Type 1 **Matrix** – Viral Transport Medium

Number of Levels – 9

Stability - Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
PINFAQP	PINF Analytical Q Panel	9 x 1 ml
•••••	•••••	• • • • • • • • • • • • • • • • • • • •

Respiratory Syncytial Virus A (RSV A) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Respiratory Syncytial Virus A (RSV A). Comprising eight individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Respiratory Syncytial Virus A (RSV A)

Target Genotype – Type A **Matrix** – Viral Transport Medium

Number of Levels - 8

Stability – Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
rsvaaqp	RSV A Analytical Q Panel	8 x 0.5 ml

Respiratory Syncytial Virus B (RSV B) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Respiratory Syncytial Virus B (RSV B). Comprising eight individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Respiratory Syncytial Virus B (RSV B)

Target Genotype – Type B

Matrix – Viral Transport Medium

Number of Levels - 8

Stability - Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Product Description	Pack Size
RSV B Analytical Q Panel	8 x 0.5 ml
••••••	• • • • • • • • • • • • • • • • • • • •

Rhinovirus (RV) Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Rhinovirus (RV). Comprising seven individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Rhinovirus (RV)

Target Genotype – Type A16

Matrix – Viral Transport Medium

Number of Levels – 7

Stability – Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
RVAQP	RV Analytical Q Panel	7 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 – Coronavirus (SARS-CoV-2)

Target Genotype – Whole Pathogen

Matrix – Transport Medium **Stability** – 5 day stability

Shelf Life – Single use Q-Panel designed to be used immediately minimising the risk of contamination

Regulatory Status - CE and RUO

Catalogue Code	Product Description	Pack Size
SCV2AQP	SARS-CoV-2 Analytical Q Panel	9 x 0.5 ml

Analytical Q Panels for Blood Borne Virus Testing

The blood borne virus range of Analytical Q Panels comprises Parvovirus B19.



Parvovirus B19 Analytical Q Panel

Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Parvovirus B19. Comprising nine individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – Parvovirus B19
Target Genotype – Type 1a

Matrix – Plasma

Number of Levels – 9

Stability – Single use Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
B19AQP	B19 Analytical Q Panel	9 x 1.5 ml



Whole pathogen controls are the <u>ideal material</u> <u>for full-process validation</u>, from extraction to amplification and detection, to ensure ultimate quality assurance in laboratories.



Molecular Q Panels

Molecular Q Panels comprise four samples including a high, medium, low and a negative sample. Each Molecular Q Panel is designed for use when assessing analytical sensitivity and specificity as a part of new assay validation. They may also be used to assist with staff training and can be used to troubleshoot poor EQA performance.

Benefits

Whole pathogen controls

As whole pathogen controls, the Molecular Q Panel range is designed to mimic the performance of patient samples and can be used to effectively monitor the performance of the entire testing process including extraction, amplification and detection.

Traceability

All Molecular Q Panels are traceable to international reference materials where available.

Clinically relevant range

All Molecular Q Panels comprise four samples including a negative, low, medium and high sample designed to cover the clinical range in a linear progression.

Liquid for ease-of-use

All samples are conveniently supplied in a liquid frozen format meaning there is no additional preparation or handling required.

Molecular Q Panels for Transplant Associated Diseases

Advances in transplant medicine have greatly improved the prospects of transplant recipients. However, pathogen infection and in particular viral reactivation remain significant contributors to transplant patient morbidity and mortality. The Molecular Q Panel range covers a number of viruses of particular concern, including: HSV, HHV6, CMV, EBV, ADV, JCV and BKV.



Adenovirus (ADV) Molecular Q Panel

Dedicated Molecular Q Panel for monitoring the performance of molecular assays used in the detection of Adenovirus (ADV). This panel contains four samples including a negative, high, medium and low, designed to cover the clinical range.

Target Pathogen – Adenovirus (ADV)

Target Genotype - Type 1

Matrix – Viral Transport Medium

Stability - Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
ADVMQP	ADV Molecular Q Panel	4 x 1 ml

BK Virus (BKV) Molecular Q Panel

Dedicated Molecular Q Panel for monitoring the performance of molecular assays used in the detection of BK Virus (BKV). This panel contains four samples including a negative, high, medium and low, designed to cover the clinical range.

Target Pathogen – BK Virus (BKV)
Target Genotype – Type 1b-2

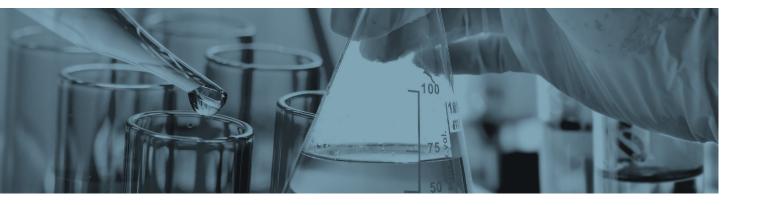
Matrix – Plasma

Stability - Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
BKVMQP	BKV Molecular Q Panel	4 x 1 ml



Cytomegalovirus (CMV) Molecular Q Panel

Dedicated Molecular Q Panel for monitoring the performance of molecular assays used in the detection of Cytomegalovirus (CMV). This panel contains four samples including a negative, high, medium and low, designed to cover the clinical range.

Target Pathogen – Cytomegalovirus (CMV)

Target Genotype - AD169

Matrix – Plasma

Stability - Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
CMVMQP	CMV Molecular Q Panel	4 x 1 ml
•••••		•••••

Epstein-Barr Virus (EBV) Molecular Q Panel

Dedicated Molecular Q Panel for monitoring the performance of molecular assays used in the detection of Epstein-Barr Virus (EBV). This panel contains four samples including a negative, high, medium and low, designed to cover the clinical range.

Target Pathogen – Epstein-Barr Virus (EBV)

Target Genotype – B-95

Matrix – Plasma

Stability - Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
EBVMQP	EBV Molecular Q Panel	4 x 1 ml
•••••		••••••

Human Herpes Virus 6 (HHV6) Molecular Q Panel

Dedicated Molecular Q Panel for monitoring the performance of molecular assays used in the detection of Human Herpes Virus 6 (HHV6). This panel contains four samples including a negative, high, medium and low, designed to cover the clinical range.

Target Pathogen – Human Herpes Virus 6 (HHV6)

Target Genotype – Type A-GS

Matrix – Plasma

Stability - Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
HHV6MQP	HHV6 Molecular Q Panel	4 x 1 ml

Herpes Simplex Virus 1 (HSV1) Molecular Q Panel

Dedicated Molecular Q Panel for monitoring the performance of molecular assays used in the detection of Herpes Simplex Virus 1 (HSV1). This panel contains four samples including a negative, high, medium and low, designed to cover the clinical range.

Target Pathogen – Herpes Simplex Virus 1 (HSV1)

Target Genotype – Type 95 **Matrix** – Viral Transport Medium

Stability - Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
HSV1MQP	HSV1 Molecular Q Panel	4 x 1 ml
••••••		• • • • • • • • • • • • • • • • • • • •

Herpes Simplex Virus 2 (HSV2) Molecular Q Panel

Dedicated Molecular Q Panel for monitoring the performance of molecular assays used in the detection of Herpes Simplex Virus 2 (HSV2). This panel contains four samples including a negative, high, medium and low, designed to cover the clinical range.

Target Pathogen – Herpes Simplex Virus 2 (HSV2)

Target Genotype - Type 09

Matrix – Viral Transport Medium

Stability - Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
HSV2MQP	HSV2 Molecular Q Panel	4 x 1 ml
•••••	•••••	•••••••

JC Virus (JCV) Molecular Q Panel

Dedicated Molecular Q Panel for monitoring the performance of molecular assays used in the detection of JC Virus (JCV). This panel contains four samples including a negative, high, medium and low, designed to cover the clinical range.

Target Pathogen – JC Virus (JCV)

Target Genotype - Type 1A

Matrix – Plasma

Stability – Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
JCVMQP	JCV Molecular Q Panel	4 x 1 ml

Varicella Zoster Virus (VZV) Molecular Q Panel

Dedicated Molecular Q Panel for monitoring the performance of molecular assays used in the detection of Varicella Zoster Virus (VZV). This panel contains four samples including a negative, high, medium and low, designed to cover the clinical range.

Target Pathogen – Varicella Zoster Virus (VZV)

Target Genotype – Type 9/84 **Matrix** – Viral Transport Medium

Stability - Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - CE, IVD and RUO

Catalogue Code	Product Description	Pack Size
VZVMQP	VZV Molecular Q Panel	4 x 1 ml

Molecular Q Panels for Respiratory Infection Testing

In response to the Coronavirus (COVID-19) pandemic, this product has been developed to support the validation, verification and performance monitoring of molecular assays used in the testing of SARS-CoV-2. Accurate and reliable laboratory testing is an essential aspect of COVID-19 disease management and outbreak control.



SARS-CoV-2 Molecular Q Panel

Dedicated SARS-CoV-2 molecular panel which has been designed to assess the performance of SCV2 molecular diagnostic assays from the extraction phase, through amplification to detection. This Molecular Q Panel consists of four samples, including a negative, high, medium and low all of which are designed to cover the clinical range.

Target Pathogen – Coronavirus
Target Genotype – SARS-CoV-2
Matrix – Transport Medium
Stability – 5 day stability

Shelf Life - Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Regulatory Status - CE and RUO

Catalogue Code	Product Description	Pack Size
SCV2MQP	SARS-CoV-2 Molecular Q Panel	4 x 0.5 ml



Molecular Q Panels for Sexually Transmitted Infections

Sexually transmitted infections (STIs) remain a major public health concern globally. STIs are the main preventable cause of infertility, particularly in women. However, some STIs remain asymptomatic before leading to serious reproductive complications and congenital infections, therefore appropriate diagnosis and treatment is essential. The Molecular Q Panel range covers Chlamydia and Gonorrhoea.



Chlamydia trachomatis & neisseria gonorrhoea (CT/NG) Molecular Q Panel

Dedicated Molecular Q Panel for monitoring the performance of molecular assays used in the detection of *Chlamydia trachomatis & Neisseria gonorrhoea* (CT/NG). This panel contains four samples including a negative, high, medium and low, designed to cover the clinical range.

Target Pathogen – Chlamydia Trachomatis & Neisseria Gonorrhoea (CT/NG)

Matrix – Transport Medium

Stability - Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
CTNGMQP	CT/NG Molecular Q Panel	4 x 1 ml

Molecular Q Panels for Blood Borne Virus Testing

The blood borne virus range of Molecular Q Panels comprises a range of pathogens that are classically detected directly from the blood. This includes B19 Virus (B19) and Hepatitis A Virus (HAV).



Hepatitis A Virus (HAV) Molecular Q Panel

Dedicated Molecular Q Panel for monitoring the performance of molecular assays used in the detection of Hepatitis A Virus (HAV). This panel contains four samples including a high, medium, low, and a negative, designed to cover the clinical range.

Target Pathogen – Hepatitis A Virus (HAV)

Target Genotype – Type 1a

Matrix – Plasma

Stability – Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
HAVMQP	HAV Molecular Q Panel	4 x 1.2 ml

Parvovirus B19 Molecular Q Panel

Dedicated Molecular Q Panel for monitoring the performance of molecular assays used in the detection of Parvovirus B19. This panel contains four samples including a negative, high, medium and low, designed to cover the clinical range.

Target Pathogen – Parvovirus B19

Target Genotype - Type la

Matrix – Plasma

Stability - Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
B19MQP	B19 Molecular Q Panel	4 x 1.5 ml

Molecular Q Panels for Gastrointestinal Infection Testing

Gastroenteritis can be caused by a wide variety of viruses and is often associated with severe inflammation of the gastrointestinal tract involving both the stomach and small intestine. This results in acute diarrhoea and vomiting. Diagnosis is primarily based on clinical symptoms, but laboratory diagnosis is often needed in order to support patient care.



Norovirus Molecular Q Panels

Dedicated Molecular Q Panels for monitoring the performance of molecular assays used in the detection of Norovirus GI and Norovirus GII. Each panel contains three samples including a high, medium and low, designed to cover the clinical range.

Target Pathogen – Norovirus GI & Norovirus GII

Target Genotype – Norovirus

Matrix – Viral Transport Medium

Stability – Single use Molecular Q-Panel designed to be used immediately minimising the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
NVGIMQP	Norovirus Gl Molecular Q Panel	3 x 1 ml
NVGIIMQP	Norovirus Gll Molecular Q Panel	3 x 1 ml





Evaluation Panels

Evaluation Panels may be used to evaluate assay characteristics, confirm performance claims and ultimately ensure the assay is fit for purpose. Evaluation Panels may also be used in the validation of clinical assays and the development of diagnostic tests.

Evaluation Panels are available in a variety of formats and cover a range of common genotypes. Using these Evaluation Panels, laboratories can also support their accreditation requirements in line with ISO 15189 or ISO 17025.

Benefits

Whole pathogen controls

As whole pathogen controls, Evaluation Panels are designed to mimic the performance of patient samples and can be used to effectively monitor the performance of the entire testing process including extraction, amplification and detection.

Traceability

All Evaluation Panels are traceable to international reference materials where available.

Clinically relevant

Samples covering a range of common genotypes are provided, ensuring accurate detection by the instrument or method in use.

Liquid for ease-of-use

All samples are conveniently supplied in a liquid frozen format meaning there is no additional preparation or handling required.

Evaluation Panels for Central Nervous System Infections

Multiplex based molecular diagnostic assays offer the ability to detect a wide range of pathogens within a single diagnostic test. Syndromic approaches to test for meningitis allow clinicians to identify the cause of infection often in a near patient, point of care setting where rapid diagnosis aids faster clinical decision making and patient treatment.



Enterovirus Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. This Enterovirus Evaluation Panel comprises 4 targets relating to Enterovirus alongside a negative sample.

Target Pathogens – Enterovirus Serotypes CV-A16, CV-B3, CV-A24 & EV-D68

Matrix - Transport Medium

Stability - Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
EVEP	Enterovirus Evaluation Panel	5 x 1 ml

Meningitis / Encephalitis (ME) Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. This ME Evaluation Panel has been designed with known performance on the BioFire FilmArray platform and is intended to be used with BioFire's verification pooling scheme for the FilmArray ME assay, but may also be used with other molecular diagnostic platforms.

Target Pathogens – Escherichia coli, Haemophilus influenzae, Listeria monocytogenes, Neisseria meningitidis, Streptococcus agalactiae, Streptococcus pneumoniae, Cytomegalovirus, Enterovirus, Herpes Simplex Virus 1, Herpes Simplex Virus 2, Human Herpes Virus 6, Human Parechovirus, Varicella Zoster Virus, Cryptococcus neoformans / gattii

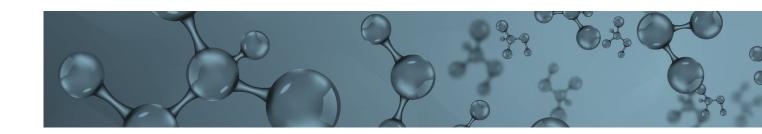
Matrix – Transport Medium

Panel Members – 14

Stability – Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Catalogue Code	Product Description	Pack Size
MEEP	Meningitis / Encephalitis (ME) Evaluation Panel	14 x 0.25 ml



Evaluation Panels for Respiratory Infection Testing

Respiratory tract infections (RTIs) are common conditions, affecting both the upper and lower respiratory tract. For the young, the elderly and the immune compromised, RTIs can be a significant health threat if not managed effectively.



Mycobacterium tuberculosis (MTB) Evaluation Panel Control

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. This MTB Evaluation Panel comprises 3 targets relating to Mycobacterium tuberculosis. High and medium concentrations are provided alongside a negative sample.

Target Pathogens – MTB, M. bovis, Rifampicin (Rif) resistant MTB, Isoniazid (INH) resistant MTB, Negative

Matrix - Synthetic Sputum

Panel Members – 8 (Including a negative)

 $\textbf{Stability} - \textbf{Single use.} \ \textbf{Once thawed, use immediately}$

Shelf Life – up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
MTBEP	Mycobacterium tuberculosis (MTB) Evaluation Panel	8 x 1 ml

RTX Evaluation Panel

Dedicated Evaluation Panel for validating and/or verifying Respiratory assay systems . The RTX Evaluation panel comprises of 6 vials of positive multiplexed controls and a negative sample. With each vial contains 4 pathogens, the RTXEP panel comprises a total of 24 common viral and bacterial whole pathogens.

Target Pathogen – Influenza A H1N1, Influenza B Victoria, Influenza A H3N2, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Enterovirus D68, Enterovirus A16, Rhinovirus 16, SARS-Coronavirus-2, Coronavirus OC43, Coronavirus 229E, Coronavirus NL63, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, Adenovirus 1, Adenovirus 14, Mycoplasma pneumoniae, Metapneumovirus A2, Legionella pneumophila, Bordetella pertussis, Bordetella parapertussis, Chlamydophila pneumoniae, Negative

Matrix – Viral Transport Medium

Stability - Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
RTXEP	RTX Evaluation Panel	7 x 0.7 ml



Evaluation Panels for Gastrointestinal Infections

Gastroenteritis can be caused by a wide variety of pathogens and is often associated with severe inflammation of the gastrointestinal tract involving both the stomach and small intestine. This results in acute diarrhoea and vomiting. Diagnosis is primarily based on clinical symptoms, but laboratory diagnosis is often needed in order to support patient care. Evaluation Panels are available for a wide range of viral, bacterial and parasitic targets.



Gastroenteritis Evaluation Panel (Viral)

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. This Gastroenteritis Panel comprises six viral targets at medium concentration.

Target Pathogen – Norovirus GI, Norovirus GII, Adenovirus Type 41, Rotavirus, Astrovirus, Sapovirus

Matrix - Synthetic Faecal Matrix

Panel Members – 6 (medium positive)

Stability - Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
GENVEP	Gastroenteritis Evaluation Panel (Viral)	6 x 1 ml
<u> </u>	2 40.112 5.11.01.11.2 1.12.4 1.13.1 (1.11.4.1)	

Gastroenteritis Evaluation Panel (Bacterial-Parasite)

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. This Gastroenteritis Panel comprises ten bacterial and parasitic targets at medium concentration.

Target Pathogen – Campylobacter jejuni, Campylobacter lari, Clostridium difficile 027, Shigella flexneri, Salmonella enteritidis, Yersinia enterolitica, Giardia lamblia, Cryptosporidium parvum, Entamoeba histolytica, Plesiomonas shigelloides

Matrix – Synthetic Faecal Matrix

Panel Members – 10 (medium positive)

Stability – Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

 $\textbf{Regulatory Status} \text{-} \mathsf{IVD} \text{ and } \mathsf{RUO}$

Catalogue Code	Product Description	Pack Size
GENBEP	Gastroenteritis Evaluation Panel (Bacterial-Parasite)	10 x 1 ml

Gastroenteritis Evaluation Panel (Pathogenic E.coli)

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. The Pathogenic E.coli Panel comprises three common variants of E.coli at medium concentration.

Target Pathogen – E.coli 0157, Shiga toxin-producing E.coli, Enterotoxigenic E.coli

Matrix - Transport Medium

Panel Members – 6 (medium positive)

Stability - Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
GENEEP	Gastroenteritis Evaluation Panel (Pathogenic E. coli)	6 x 0.5 ml

Evaluation Panels for Sexually Transmitted Infections

Sexually transmitted infections (STIs) remain a major public health concern globally. STIs are the main preventable cause of infertility, particularly in women. However, some STIs remain asymptomatic before leading to serious reproductive complications and congenital infections, therefore appropriate diagnosis and treatment is essential. The STI Evaluation Panel comprises a wide range of bacterial targets.



Sexually Transmitted Infection (STI) Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. The STI Panel comprises nine targets.

Target Pathogens – Trichomonas vaginalis, Mycoplasma genitalium, Mycoplasma hominis, Ureaplasma urealyticum, Gardnerella vaginalis, Neisseria gonorrhoea, Chlamydia trachomatis (LGV) Urine, Chlamydia trachomatis (LGV) transport media, Chlamydia trachomatis (SW) Urine

Matrix - Simulated swab or Urine

Panel Members – 10 (including a negative)

Stability - Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
STIEP	STI Evaluation Panel	10 x 4 ml

Human Papilloma Virus (HPV) Evaluation Panel

Qnostics' Human Papilloma Virus (HPV) Evaluation panel is intended to help laboratories monitor their molecular assay procedures for the detection & determination of HPV.

Target Genotype – Types 16,18 and 45

Matrix – Transport Medium

Panel Members – 6 (including a negative)

Stability - Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Catalogue Code	Product Description	Pack Size
HPVEP	HPV Evaluation Panel RUO	6 x 4 ml

Evaluation Panels for Blood Borne Virus Testing

The Blood Borne Virus range of Evaluation Panels comprises a range of pathogens that are classically detected directly from the blood. This includes HIV, Hepatitis B, Hepatitis C and Hepatitis E.



Hepatitis B (HBV) Genotype Evaluation Panel

Dedicated Evaluation Panels for validating a new assay or instrument to ensure that everything is working as expected. The HBV Genotype Panel comprises five genotypes and a negative sample.

Target Genotype – Types A, B, C, D and H

Matrix – Plasma

Panel Members – 6 (including a negative)

Stability - Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size	
HBVGTEP	HBV Genotype Evaluation Panel	6 x 1.2 ml	

Hepatitis B (HBV) Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. The HBV Evaluation Panel comprises two genotypes at high, medium and low levels. A duplicate sample and a negative are also included.

Target Pathogens – Hepatitis B

Target Genotype – Types A and D

Matrix – Plasma

Panel Members -8

Stability - Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
HBVDNAEP	HBV DNA Evaluation Panel	8 x 1.2 ml



Hepatitis C (HCV) Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. The HCV Evaluation Panel comprises two genotypes at high, medium and low levels, a duplicate sample and a negative are also included.

Target Genotype – Types 1b and 3a

Matrix – Plasma

Panel Members – 8

Stability - Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
HCVRNAEP	HCV RNA Evaluation Panel	8 x 1.2 ml
•••••		

Hepatitis C (HCV) Genotype Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. The HCV Genotype Panel comprises seven genotypes and a negative sample.

Target Genotype – Types 1a,1b, 2b, 3a, 4a, 5a and 6a

Matrix – Plasma

Panel Members - 8

Stability - Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Regulatory Status - RUO

Catalogue Code	Product Description	Pack Size
HCVGTEP	HCV Genotype Evaluation Panel	8 x 1.2 ml
•••••	•••••	••••••

Hepatitis E (HEV) Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. The HEV Evaluation Panel comprises two genotypes at high, medium and low levels, a duplicate sample is also included.

Target Genotype – Types gg3c and gg3f

Matrix – Plasma

Panel Members -7

Stability - Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Catalogue Code	Product Description	Pack Size
HEVEP	HEV Evaluation Panel	7 x 0.6 ml

Human Immunodeficiency (HIV1) Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. The HIV1 Evaluation Panel comprises two genotypes at high, medium and low levels, a negative is also included.

Target Genotype – Types B and C

Matrix – Plasma

Panel Members - 8

Stability - Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Regulatory Status - IVD and RUO

Catalogue Code	Product Description	Pack Size
HIVRNAEP	HIV1 RNA Evaluation Panel	8 x 1.2 ml

Human Papillomavirus (HPV) Evaluation Panel

The HPV evaluation panel comprises 3 genotypes at high and low levels whilst a negative is also included. This evaluation panel is intended to help laboratories develop their molecular assay procedures for the identification of HPV.

Target Genotype – Type 16, Type 18 and Type 45

Matrix – Plasma

Panel Members - 6

Stability - Single use Evaluation Panel designed to be used immediately minimising the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Catalogue Code	Product Description	Pack Size
HPVEP	HPV Evaluation Panel	6 x 4 ml





QCMD Past Panels

QCMD Past Panels are highly characterised quality assessment materials that have been used within previous QCMD international EQA/PT schemes. Past Panels are extremely helpful in post EQA evaluations and provide an additional source of quality material. They are provided with a summary report and they are very limited in number.

Past Panels are used by laboratories who would like to check that their assay is detecting and or discriminating against different strains and subtypes. Alternatively, some labs will use these panels to check that improvements made since a poor EQA performance are successful.

It is important to note that QCMD Past Panels are intended for EQA purposes only, in line with ISO17043. These Past Panels are not intended for use as an IVD control or calibrator.

However, in the absence of suitable IVD materials, Past Panels may be used to support assay verification.

Benefits

- Check laboratory performance, for example, against their previous results or to perform evaluation prior to the next EQA challenge.
- Where there are no alternative materials available, they can be used to support laboratory assay validation/verification in line with the relevant regulatory guidelines.

There is a wide range of QCMD Past Panels available. Please enquire for more details.

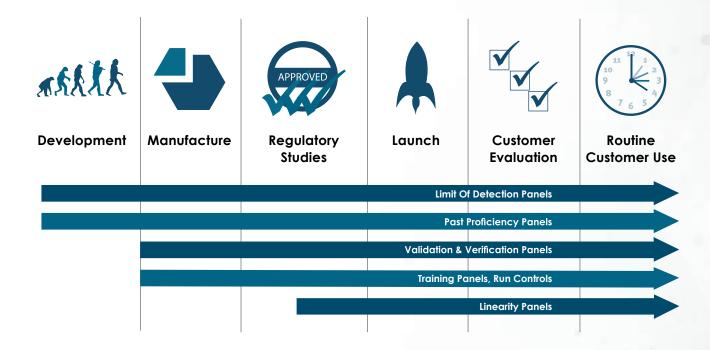


Custom Controls and Service Provision

There are many advantages of working with Qnostics on custom made controls.

- Choose from hundreds of molecular characterised targets
- Targets can be custom made into numerous different formats
- The whole pathogen format accurately mimics clinical samples
- All materials can be provided in a liquid frozen, "ready-to-use" format

Qnostics custom made Molecular Controls are designed to fit all stages of your assay's product life cycle;



A wide range of targets is available including fungal, respiratory pathogens, sexually transmitted infections, transplant associated infections, gastrointestinal infections and blood borne viruses.

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JC Virus [Type 1A]				
Legionella pneumophila	•			
Listeria monocytogenes				
Metapneumovirus [A2]				
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Mycobacterium tuberculosis [m. bovis]	•			•
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Mycobacterium tuberculosis [Rifampicin Resistance]	•			•
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Randox - a global diagnostic solutions provider

Randox has been supplying laboratories worldwide with revolutionary diagnostic solutions for almost 40 years. Our experience and expertise allow us to create a leading product portfolio of high quality diagnostic tools which offer reliable and rapid diagnosis. We believe that by providing laboratories with the right tools, we can improve healthcare worldwide.

Reagents



Randox offers an extensive range of third-party diagnostic reagents which are internationally recognised as being of the highest quality; producing accurate and precise results. At Randox, we re-invest significantly in R&D to ensure we meet the ever-changing needs of the laboratory. Consequently, Randox offer a range of novel and superior performance assays, including: sdLDL-C, Lipoprotein (a), H-FABP, Adiponectin, Copper and Zinc. Applications are available detailing instrument-specific settings for the convenient use of Randox Reagents on numerous clinical chemistry analysers.

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Acusera third party quality controls are made using the highest quality material of human origin, ensuring they react like a real patient sample. With more than 390 analytes available across the Acusera range we can uniquely reduce the number of controls required while reducing costs and time. Our product range includes clinical chemistry, immunoassay, urine, immunology and more.

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RIQAS is the world's largest international EQA scheme with more than 50,000 participants worldwide. 37 comprehensive, yet flexible programmes cover a wide range of clinical diagnostic testing including chemistry, immunoassay, cardiac, urine, serology and more. Our programmes benefit from a wide range of concentrations, frequent reporting, rapid feedback and user-friendly reports.

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In 2002, Randox invented the world's first, Biochip Array Technology, offering highly specific tests, coupled to the highly sensitive chemiluminescent detection, providing quantitative results instantly changing the landscape of diagnostic testing forever. The Randox Evidence Series of multi-analyte immunoanalyser's provide an unrivalled increase in patient information per sample offering diagnostic, prognostic and predictive solutions across a variety of disease areas with a highly advanced clinical and toxicology immunoassay test menu including cardiac, diabetes, drugs of abuse, metabolic and renal markers.

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