Qnostics

Molecular Controls for Infectious Disease Testing

RANDOX

Contents

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
Our range of positive run, whole pathogen, third party controls are designed to monitor assay performance on a daily 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' analytical measuring 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	•	•	•	•	•

Q Controls

Independently manufactured, these positive and 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 supplied in an unassayed, liquid frozen 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

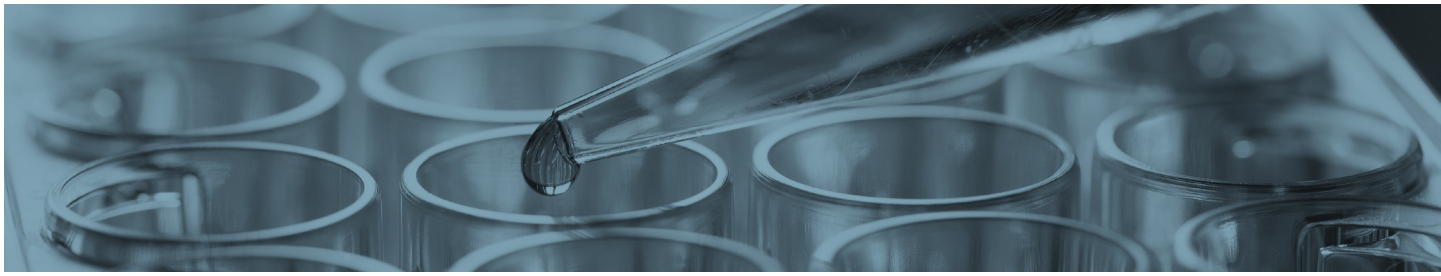
Product Code	Product Description	Pack Size
ADVMQC01-A	ADV Medium Q Control CE	5 x 1 ml
ADVMQC01-B	ADV Medium Q Control RUO	5 x 1 ml

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). Available in a choice of three levels (low, medium and high) depending on your laboratory requirements.

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

Product Code	Product Description	Pack Size
BKVHQC01-B	BKV High Q Control RUO	5 x 1 ml
BKVMQC01-A	BKV Medium Q Control CE	5 x 1 ml
BKVMQC01-B	BKV Medium Q Control RUO	5 x 1 ml
BKVLQC01-B	BKV Low Q Control RUO	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

Product Code	Product Description	Pack Size
CMVMQC01-A	CMV Medium Q Control CE	5 x 1 ml
CMVMQC01-B	CMV Medium Q Control RUO	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). Available in a choice of three levels low, medium and high depending on your laboratory requirements.

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

Product Code	Product Description	Pack Size
EBVHQC01-B	EBV High Q Control RUO	5 x 1 ml
EBVMQC01-A	EBV Medium Q Control CE	5 x 1 ml
EBVMQC01-B	EBV Medium Q Control RUO	5 x 1 ml
EBVLQC01-B	EBV Low Q Control RUO	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

Product Code	Product Description	Pack Size
HSV1MQC01-A	HSV1 Medium Q Control CE	5 x 1 ml
HSV1MQC01-B	HSV1 Medium Q Control RUO	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

Product Code	Product Description	Pack Size
HSV2MQC01-A	HSV2 Medium Q Control CE	5 x 1 ml
HSV2MQC01-B	HSV2 Medium Q Control RUO	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

Product Code	Product Description	Pack Size
JCVMQC02-A	JCV Medium Q Control CE	5 x 1 ml
JCVMQC02-B	JCV Medium Q Control RUO	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

Product Code	Product Description	Pack Size
PCPMQC01-C	PCP Medium Q Control RUO	5 x 0.25 ml

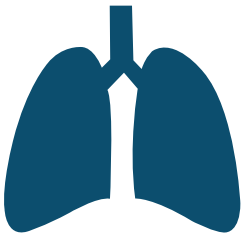
Varicella Zoster Virus (VZV) Control

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

Product Code	Product Description	Pack Size
VZVMQC01-A	VZV Medium Q Control CE	5 x 1 ml
VZVMQC01-B	VZV Medium Q Control RUO	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.

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

Product Code	Product Description	Pack Size
ADVMQC01-A	ADV Medium Q Control CE	5 x 1 ml
ADVMQC01-B	ADV Medium Q Control RUO	5 x 1 ml

Influenza A Virus (INFA) Control

Single plex, 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

Product Code	Product Description	Pack Size
INFAMQC01-A	INFA Medium Q Control CE	5 x 1 ml
INFAMQC01-B	INFA Medium Q Control RUO	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

Product Code	Product Description	Pack Size
INFBMQC01-A	INFB Medium Q Control CE	5 x 1 ml
INFBMQC01-B	INFB Medium Q Control RUO	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

Product Code	Product Description	Pack Size
PINFMQC01-A	PINF Medium Q Control CE	5 x 1 ml
PINFMQC01-B	PINF Medium Q Control RUO	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

Product Code	Product Description	Pack Size
RSVAMQC01-A	RSV A Medium Q Control CE	5 x 1 ml
RSVAMQC01-B	RSV A Medium Q Control RUO	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

Product Code	Product Description	Pack Size
RTXMQC01-D	Respiratory Triplex Control RUO	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

Product Code	Product Description	Pack Size
RVMQC01-A	RV Medium Q Control CE	5 x 1 ml
RVMQC01-B	RV Medium Q Control RUO	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 individual infectious disease assays, in a linear progression. Analytical Q Panels are intended for use in the validation and verification of new assays with the main purpose of helping to ensure assays are linear throughout the dynamic range.

In addition, Analytical Q Panels will support a laboratory's accreditation requirements, in line with ISO 15189:2012.

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 and BKV.

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

Product Code	Product Description	Pack Size
ADVAQP01-B	ADV Analytical Q Panel RUO	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 six 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 – 6
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

Product Code	Product Description	Pack Size
BKVAQP01-B	BKV Analytical Q Panel RUO	6 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

Product Code	Product Description	Pack Size
CMVAQP02-B	CMV Analytical Q Panel RUO	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

Product Code	Product Description	Pack Size
EBVAQP03-B	EBV Analytical Q Panel RUO	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

Product Code	Product Description	Pack Size
HHV6AQP02-B	HHV6 Analytical Q Panel RUO	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

Product Code	Product Description	Pack Size
HSV1AQP01-B	HSV1 Analytical Q Panel RUO	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

Product Code	Product Description	Pack Size
HSV2AQP01-B	HSV2 Analytical Q Panel RUO	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 seven individual levels, linearity is accurately assessed throughout the assay's measuring range.

Target Pathogen – JC Virus (JCV)
Target Genotype – Type 1A
Matrix – Plasma
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

Product Code	Product Description	Pack Size
JCVAQP03-B	JCV Analytical Q Panel RUO	7 x 0.5 ml

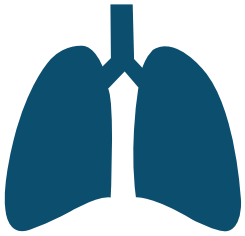
Varicella Zoster Virus (VZV) Analytical Q Panel

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

Product Code	Product Description	Pack Size
VZVAQP02-C	VZV Analytical Q Panel RUO	10 x 1 ml

Analytical Q Panels for Respiratory Infection Testing



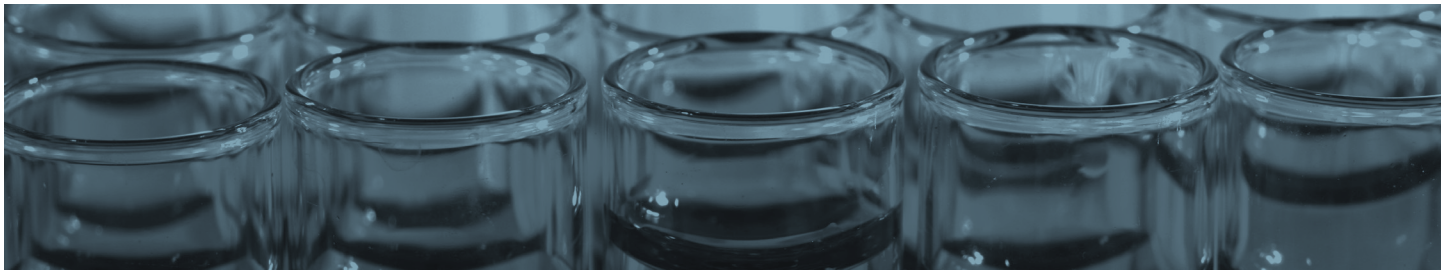
Respiratory tract infections (RTIs) are common conditions, affecting both the upper and lower respiratory tract. For the young, the elderly and the immunocompromised, RTIs can be a significant health threat if not managed effectively. The Analytical Q Panel range covers a range of common viral pathogens.

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

Product Code	Product Description	Pack Size
INFAAQP01-B	INFA Analytical Q Panel RUO	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

Product Code	Product Description	Pack Size
INFBAQP01-B	INFB Analytical Q Panel RUO	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 six 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 – 6
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

Product Code	Product Description	Pack Size
PINFAQP01-B	PINF Analytical Q Panel RUO	6 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

Product Code	Product Description	Pack Size
RSVAAQP01-B	RSV A Analytical Q Panel RUO	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

Product Code	Product Description	Pack Size
RSVBAQP01-B	RSV B Analytical Q Panel RUO	8 x 0.5 ml

Rhinovirus (RV) Analytical Q Panel

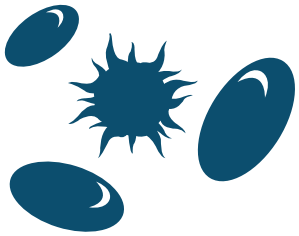
Dedicated Analytical Q Panel for monitoring the performance of molecular assays used in the detection of Rhinovirus (RV). Comprising seven individual levels, linearity is accurately assessed throughout the assay's measuring range.

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

Product Code	Product Description	Pack Size
RVAQP01-B	RV Analytical Q Panel RUO	7 x 0.5 ml

Analytical Q Panels for Blood Borne Virus Testing

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



Parvovirus B19 (B19) Analytical Q Panel

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

Target Pathogen – Parvovirus B19 (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

Product Code	Product Description	Pack Size
B19AQP02-C	B19 Analytical Q Panel RUO	9 x 1.5 ml

Whole pathogen controls designed to monitor the entire testing process

Molecular Q Panels

Molecular Q Panels generally 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 were 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 Q-Panel designed to be used immediately minimising the risk of contamination
Shelf Life – Up to 2 years from date of manufacture

Product Code	Product Description	Pack Size
ADVMQP01-A	ADV Molecular Q Panel CE	4 x 1 ml
ADVMQP01-B	ADV Molecular Q Panel RUO	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 Q-Panel designed to be used immediately minimising the risk of contamination
Shelf Life – Up to 2 years from date of manufacture

Product Code	Product Description	Pack Size
BKVMQP01-A	BKV Molecular Q Panel CE	4 x 1 ml
BKVMQP01-B	BKV Molecular Q Panel RUO	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 Q-Panel designed to be used immediately minimising the risk of contamination
Shelf Life – Up to 2 years from date of manufacture

Product Code	Product Description	Pack Size
CMVMQP01-A	CMV Molecular Q Panel CE	4 x 1 ml
CMVMQP01-B	CMV Molecular Q Panel RUO	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 Q-Panel designed to be used immediately minimising the risk of contamination
Shelf Life – Up to 2 years from date of manufacture

Product Code	Product Description	Pack Size
EBVMQP01-A	EBV Molecular Q Panel CE	4 x 1 ml
EBVMQP01-B	EBV Molecular Q Panel RUO	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 Q-Panel designed to be used immediately minimising the risk of contamination
Shelf Life – Up to 2 years from date of manufacture

Product Code	Product Description	Pack Size
HHV6MQP01-B	HHV6 Molecular Q Panel RUO	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 Q-Panel designed to be used immediately minimising the risk of contamination
Shelf Life – Up to 2 years from date of manufacture

Product Code	Product Description	Pack Size
HSV1MQP01-A	HSV1 Molecular Q Panel CE	4 x 1 ml
HSV1MQP01-B	HSV1 Molecular Q Panel RUO	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 Q-Panel designed to be used immediately minimising the risk of contamination
Shelf Life – Up to 2 years from date of manufacture

Product Code	Product Description	Pack Size
HSV2MQP01-A	HSV2 Molecular Q Panel CE	4 x 1 ml
HSV2MQP01-B	HSV2 Molecular Q Panel RUO	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 Q-Panel designed to be used immediately minimising the risk of contamination
Shelf Life – Up to 2 years from date of manufacture

Product Code	Product Description	Pack Size
JCVMQP02-A	JCV Molecular Q Panel CE	4 x 1 ml
JCVMQP02-B	JCV Molecular Q Panel RUO	4 x 1 ml

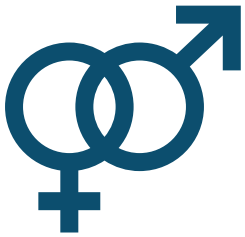
Varicella Zoster Virus (VZV) Molecular Q Panel

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 Q-Panel designed to be used immediately minimising the risk of contamination
Shelf Life – Up to 2 years from date of manufacture

Product Code	Product Description	Pack Size
VZVMQP01-A	VZV Molecular Q Panel CE	4 x 1 ml
VZVMQP01-B	VZV Molecular Q Panel RUO	4 x 1 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 (CT) Molecular Q Panel

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

Target Pathogen – *Chlamydia trachomatis* (CT)
Matrix – Transport Medium
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

Product Code	Product Description	Pack Size
CTMQP01-C	CT Molecular Q Panel RUO	4 x 1 ml

Neisseria gonorrhoea (NG) Molecular Q Panel

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

Target Pathogen – *Neisseria gonorrhoea* (NG)
Matrix – Viral Transport Medium
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

Product Code	Product Description	Pack Size
NGMQP01-C	NG Molecular Q Panel RUO	4 x 1 ml

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

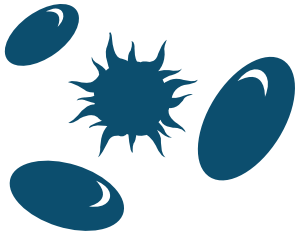
Dedicated Molecular Q Panel for monitoring the performance of molecular assays used in the detection of *Chlamydia trachomatis* & *Neisseria gonorrhoea* (CT/NG). This panel contains four samples including a negative, high, medium and low, designed to cover the clinical range.

Target Pathogen – *Chlamydia Trachomatis* & *Neisseria Gonorrhoea* (CT/NG)
Matrix – Transport Medium
Stability – Single use Q-Panel designed to be used immediately minimising the risk of contamination
Shelf Life – Up to 2 years from date of manufacture

Product Code	Product Description	Pack Size
CTNGMQP01-C	CT/NG Molecular Q Panel RUO	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), Hepatitis A Virus (HAV) and Hepatitis E Virus (HEV).



Parvovirus B19 (B19) Molecular Q Panel

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

Target Pathogen – Parvovirus B19 (B19)
Target Genotype – Type 1a
Matrix – Plasma
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

Product Code	Product Description	Pack Size
B19MQP01-C	B19 Molecular Q Panel RUO	4 x 1.5 ml

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 Q-Panel designed to be used immediately minimising the risk of contamination
Shelf Life – Up to 2 years from date of manufacture

Product Code	Product Description	Pack Size
HAVMQP02-C	HAV Molecular Q Panel RUO	4 x 0.6 ml

Molecular Q Panels for Gastrointestinal Infection Testing

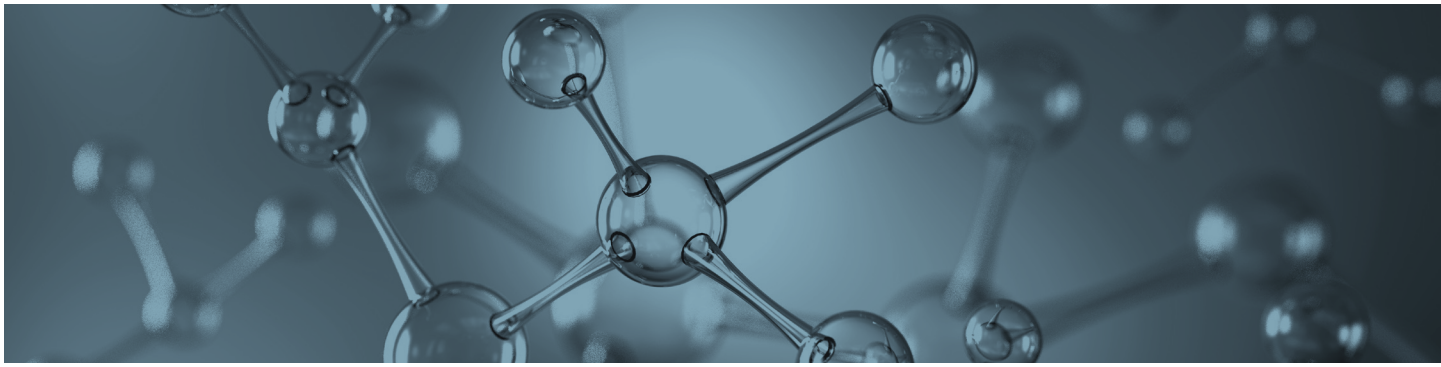
Gastroenteritis can be caused by a wide variety of viruses and is often associated with severe inflammation of the gastrointestinal tract involving both the stomach and small intestine. This results in acute diarrhoea and vomiting. Diagnosis is primarily based on clinical symptoms, but laboratory diagnosis 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 Q-Panel designed to be used immediately minimising the risk of contamination
Shelf Life – Up to 2 years from date of manufacture

Product Code	Product Description	Pack Size
NVGIMQP01-C	Norovirus GI Molecular Q Panel RUO	3 x 1 ml
NVGIIMQP01-C	Norovirus GII Molecular Q Panel RUO	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 were 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 Meningitis / Encephalitis (ME)

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.

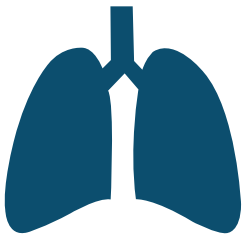
Meningitis / Encephalitis (ME) Evaluation Panel

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

Product Code	Product Description	Pack Size
MEEP01-C	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. The Respiratory Infection Evaluation Panel combines INF A, INF B, RSV and seasonal flu.

Respiratory Infection Testing Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. The Respiratory Infection Evaluation Panel comprises five viral targets at medium sample concentration, and a negative.

Target Pathogens – INFA - H1N1, INFA - H3N2, INFB - Victoria, RSV - Type A, RSV - Type B
Matrix – Transport Medium
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

Product Code	Product Description	Pack Size
RESPEP01-C	Respiratory Evaluation Panel RUO	6 x 1 ml
RESPEP01-X	Respiratory Evaluation Panel CE	6 x 1 ml

Evaluation Panels for Fungal Infections

The treatment and management of patients with compromised immune systems has seen important developments in recent years. As a result the healthcare and management of immunocompromised patients has greatly improved. However, pathogen infection remains a significant contributor to morbidity and mortality in these patients. A number of opportunistic parasitic pathogens are of concern in the management of immunocompromised patients including Candida spp. and Aspergillus spp. The Fungal Evaluation Panels cover a wide range of fungal targets allowing effective assay validation.

Candida (Candida spp) Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. This Fungal Evaluation Panel comprises three fungal targets relating to Candida spp. High and medium concentrations are provided in addition to a negative sample.

Target Pathogens – *Candida albicans, Candida glabrata, Candida krusei*
Matrix – Serum
Panel Members – 7 (High, Medium & 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

Product Code	Product Description	Pack Size
CANEP01-C	Candida Evaluation Panel RUO	7 x 0.5 ml

Aspergillus (Aspergillus spp) Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. This Fungal Evaluation Panel comprises two fungal targets relating to Aspergillus spp. High and medium concentrations are provided in addition to a negative sample.

Target Pathogens – *Aspergillus fumigatus, Aspergillus terreus*
Matrix – Serum
Panel Members – 5 (High, Medium & 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

Product Code	Product Description	Pack Size
ASPEP01-C	Aspergillus Evaluation Panel RUO	5 x 0.5 ml

Evaluation Panels for Gastrointestinal Infections

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. Evaluation Panels are available for a wide range of viral, bacterial and fungal 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 – Faecal Matrix
Panel Members – 6 (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

Product Code	Product Description	Pack Size
GENVEP01-C	Gastroenteritis Evaluation Panel (Viral) RUO	6 x 1 ml

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)
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

Product Code	Product Description	Pack Size
GENBEP01-C	Gastroenteritis Evaluation Panel (Bacterial-Parasite) RUO	10 x 1 ml

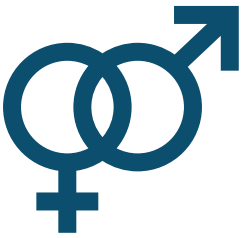
Gastroenteritis Evaluation Panel (Pathogenic E.coli)

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)
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

Product Code	Product Description	Pack Size
GENEEP01-C	Gastroenteritis Evaluation Panel (Pathogenic E. coli) RUO	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

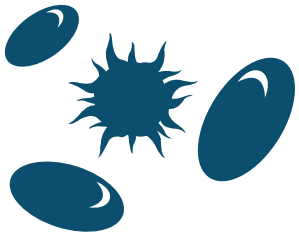
Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. The STI Panel comprises nine targets.

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

Product Code	Product Description	Pack Size
STIEP01-C	STI Evaluation Panel RUO	10 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 Pathogens – 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

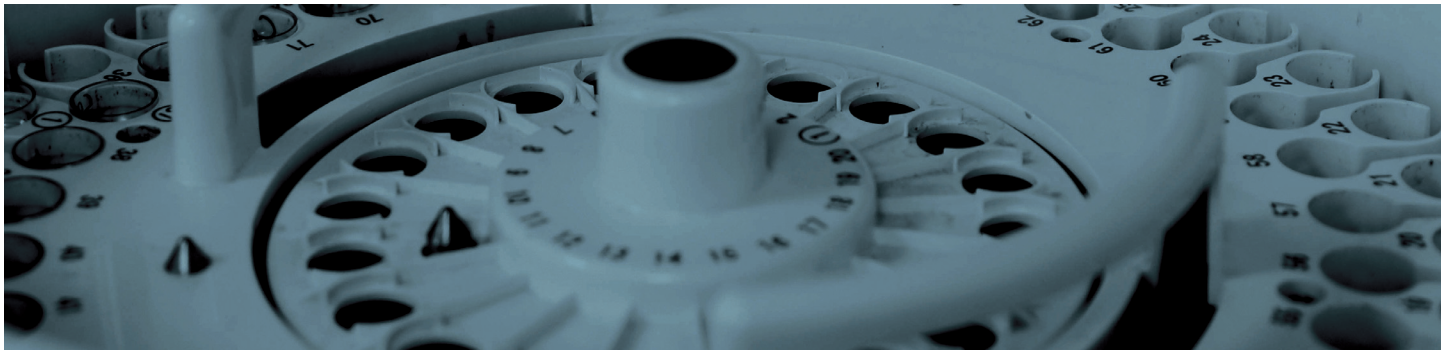
Product Code	Product Description	Pack Size
HBVGTEP01-C	HBV Genotype Evaluation Panel RUO	6 x 1.2 ml

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 of HBV A (medium) and a negative are also included.

Target Pathogens – Types A and D
Target Genotype – Whole Pathogen
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

Product Code	Product Description	Pack Size
HBVDNAEP01-C	HBV Evaluation Panel RUO	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 Pathogens – 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

Product Code	Product Description	Pack Size
HCVGTEP01-C	HCV Genotype Evaluation Panel RUO	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 negative sample is also included.

Target Pathogens – 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

Product Code	Product Description	Pack Size
HCVRNAEP01-C	HCV Evaluation Panel RUO	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 of gg3c (medium) is also included.

Target Pathogens – 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

Product Code	Product Description	Pack Size
HEVEP01-C	HEV Evaluation Panel RUO	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 Pathogen – 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

Product Code	Product Description	Pack Size
HIVRNAEP01-C	HIV1 Evaluation Panel RUO	8 x 1.2 ml

Evaluation Panels for HIV Dried Blood Spot

HIV1 Drug Resistance genotyping is an essential component of the WHO Global Drug Resistance Prevention and Assessment Strategy. Plasma is considered the most appropriate specimen type however its use may not be feasible in remote areas. An alternative specimen type is dried blood spots as the filter paper used is easily obtained and the viral RNA is stable over longer periods.

Human Immunodeficiency Virus (HIV) Dried Blood Spot Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. This panel has been designed to be representative of clinical human specimens. The cards represent high positive, low positive, and negative samples.

Target Pathogen – Human Immunodeficiency Virus 1 (HIV1)
Matrix – Whole blood
Panel Members – 3 cards, 5 spots
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

Product Code	Product Description	Pack Size
HIVDBSEP01-C	HIV Dried Blood Spot Evaluation Panel RUO	3 x 1 card

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 final report from previous QCMD distribution – however, they are 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.

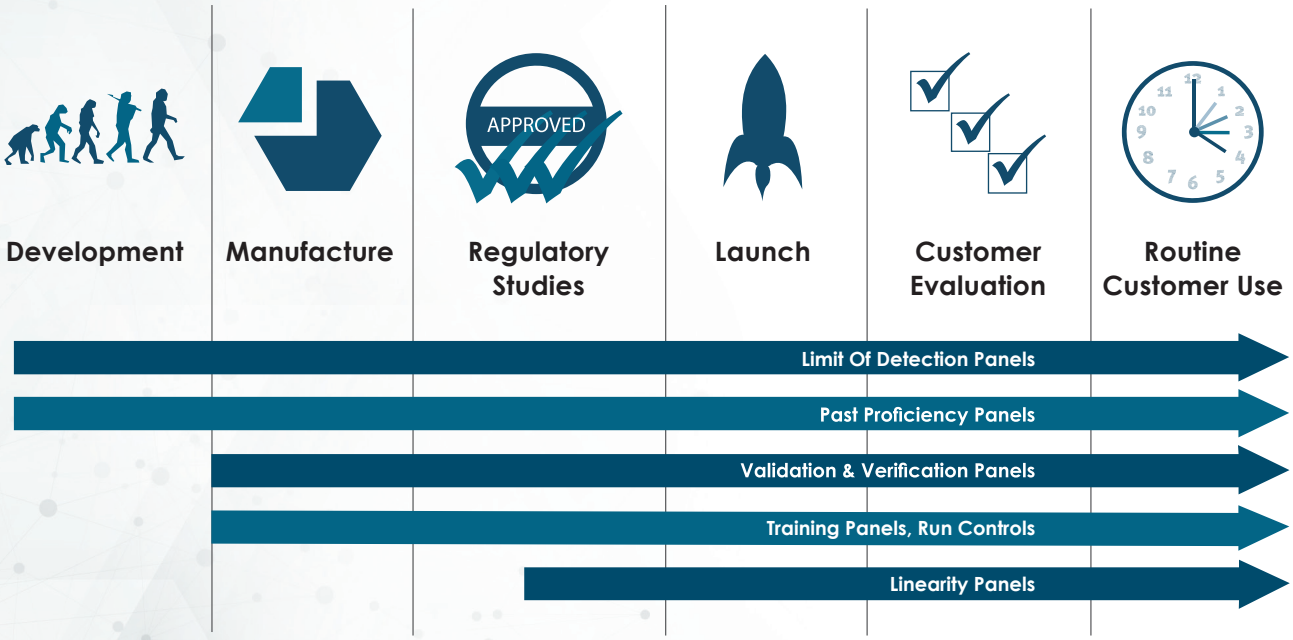
There is a wide range of QCMD Past Panels available including; Adenovirus, BK Virus, Cytomegalovirus, Epstein Barr Virus, Hepatitis A, Hepatitis B, Influenza A & B, Norovirus, Rhinovirus, Varicella-Zoster Virus and much more.

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.

Index by Disease State

Transplant Associated Diseases	Q Control	Analytical Q Panel	Molecular Q Panel	Evaluation Panels
	Page Number	Page Number	Page Number	Page Number
Adenovirus (ADV)	3	10	18	
BK Virus (BKV)	3	10	18	
Cytomegalovirus (CMV)	4	11	19	
Epstein-Barr Virus (EBV)	4	11	19	
Human Herpes Virus 6 (HHV6)		11	19	
Herpes Simplex Virus 1 (HSV1)	4	12	20	
Herpes Simplex Virus 2 (HSV2)	5	12	20	
JC Virus (JCV)	5	12	20	
Pneumocystis pneumonia (PCP)	5			
Varicella Zoster Virus (VZV)	6	13	21	

Respiratory Infection Testing				
	Page Number	Page Number	Page Number	Page Number
Adenovirus (ADV)	6			
Influenza A Virus (INFA - H1N1)	7	13		25
Influenza A Virus (INFA - H3N2)				25
Influenza B Virus (INFB - Victoria)	7	14		25
Parainfluenza Virus (PINF)	7	14		
Respiratory Syncytial Virus A (RSV A)	7	14		25
Respiratory Syncytial Virus B (RSV B)		15		25
Rhinovirus (RV)	8	15		

Blood Borne Virus				
	Page Number	Page Number	Page Number	Page Number
Parvovirus B19 (B19)		16	22	
Hepatitis A Virus (HAV)			23	
Hepatitis B Virus (HBV) Genotypes				29
Hepatitis B Virus (HBV)				29
Hepatitis C Virus (HCV) Genotypes				30
Hepatitis C Virus (HCV)				30
Hepatitis E Virus (HEV)				30
Human Immunodeficiency (HIV1)				31

Sexually Transmitted Infections				
	Page Number	Page Number	Page Number	Page Number
Chlamydia Trachomatis (CT)			21	
Neisseria Gonorrhoea (NG)			21	
Trichomonas vaginalis				28
Mycoplasma genitalium				28
Mycoplasma hominis				28
Ureaplasma urealyticum				28
Gardnerella vaginalis				28
Neisseria gonorrhoea				28
Chlamydia trachomatis (LGV)				28
Chlamydia trachomatis (LGV) transport				28
Chlamydia trachomatis (SW)				28

Index by Disease State

Gastrointestinal Infection Testing	Q Control	Analytical Q Panel	Molecular Q Panel	Evaluation Panels
	Page Number	Page Number	Page Number	Page Number
Norovirus GI			23	27
Norovirus GII			23	27
Adenovirus Type 41				27
Rotavirus				27
Astrovirus				27
Sapovirus				27
Campylobacter jejuni				27
Campylobacter lari				27
Clostridium difficile 027				27
Shigella flexneri				27
Salmonella enteritidis				27
Yersinia enterolitica				27
Giardia lamblia				27
Cryptosporidium parvum				27
Entamoeba histolytica				27
Plesiomonas shigelloides				27
E.coli 0157				28
Shiga toxin-producing *E.coli*				28
Enterotoxigenic *E.coli*				28

Meningitis / Encephalitis (ME)	Q Control	Analytical Q Panel	Molecular Q Panel	Evaluation Panels
	Page Number	Page Number	Page Number	Page Number
Escherichia coli (E.coli)				25
Haemophilus influenzae				25
Listeria monocytogenes				25
Neisseria meningitidis				25
Streptococcus agalactiae				25
Streptococcus pneumoniae				25
Cytomegalovirus				25
Enterovirus				25
Herpes Simplex Virus 1				25
Herpes Simplex Virus 2				25
Human Herpes Virus 6				25
Human Parechovirus				25
Varicella Zoster Virus				25
Cryptococcus neoformans / gattii				25

Fungal Infections	Q Control	Analytical Q Panel	Molecular Q Panel	Evaluation Panels
	Page Number	Page Number	Page Number	Page Number
Candida albicans				26
Candida glabrata				26
Candida krusei				26
Aspergillus fumigatus				26
Aspergillus terreus				26

HIV Dried Blood Spot	Q Control	Analytical Q Panel	Molecular Q Panel	Evaluation Panels
	Page Number	Page Number	Page Number	Page Number
Human Immunodeficiency Virus 1 (HIV1)				31

Index by Pathogen

	Q Control	Analytical Q Panel	Molecular Q Panel	Evaluation Panels
Adenovirus (ADV)	•	•	•	•
Aspergillus fumigatus				•
Aspergillus terreus				•
Astrovirus				•
B19 (Parvovirus B19)		•	•	
BK Virus (BKV)	•	•	•	
Campylobacter jejuni				•
Campylobacter lari				•
Candida albicans				•
Candida galbrata				•
Candida krusei				•
Chlamydia trachomatis (CT)			•	•
Chlamydia trachomatis (LGV)				•
Chlamydia trachomatis (SW)				•
Clostridium difficile 027				•
Cryptococcus neoformans / gattii				•
Cryptosporidium parvum				•
CT / NG			•	•
Cytomegalovirus (CMV)	•	•	•	•
Entamoeba histolytica				•
Enterotoxigenic *E. coli* (ETEC)				•
Enterovirus				•
Epstein-Barr Virus (EBV)	•	•	•	
Escherichia coli				•
Gardnerella vaginalis				•
Giardia lamblia				•
Haemophilus influenzae				•
Hepatitis A Virus (HAV)			•	
Hepatitis B Virus (HBV)				•
Hepatitis C Virus (HCV)				•
Hepatitis E Virus (HEV)				•
Herpes Simplex Virus 1 (HSV1)	•	•	•	•
Herpes Simplex Virus 2 (HSV2)	•	•	•	•
HIV (Dried Blood Spot)				•
Human Herpes Virus 6 (HHV6)		•	•	•
Human Immunodeficiancy Virus 1 (HIV1)				•
Human Parechovirus				•
Influenza A (INFA)	•	•		•
Influenza A Virus subtype H1N1 (INFA (H1N1))				•
Influenza A Virus subtype H3N2 (INFA (H3N2))				•
Influenza B (INFB) (Victoria)	•	•		•
JC (John Cunningham) Virus (JCV)	•	•	•	
Listeria monocytogenes				•

Index by Pathogen

	Q Control	Analytical Q Panel	Molecular Q Panel	Evaluation Panels
Mycoplasma genitalium				•
Mycoplasma hominis				•
Neisseria gonorrhoea (NG)			•	•
Neisseria meningitidis				•
Norovirus GI			•	•
Norovirus GII			•	•
Parainfluenza (PINF)	•	•		
Plesiomonas shigelloides				•
Pneumocystis pneumonia (PCP)	•			
Respiratory Syncytial Virus (RSV)				•
Respiratory Syncytial Virus A (RSV A)	•	•		•
Respiratory Syncytial Virus B (RSV B)		•		•
Rhinovirus (RV)	•	•		
Rotavirus				•
Salmonella enteritidis				•
Sapovirus				•
Shiga toxin-producing *E. coli* (STEC)				•
Shigella flexneri				•
Streptococcus agalactiae				•
Streptococcus pneumoniae				•
Trichomonas Vaginalis				•
Ureaplasma urealyticum				•
Varicella Zoster Virus (VZV)	•	•	•	•
Yersinia enterocolitica				•

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