



Qnostics

Molecular Controls for Infectious Disease Testing

Thomas
Scientific

RANDOX



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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

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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q022	ADV Medium Q Control CE	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)

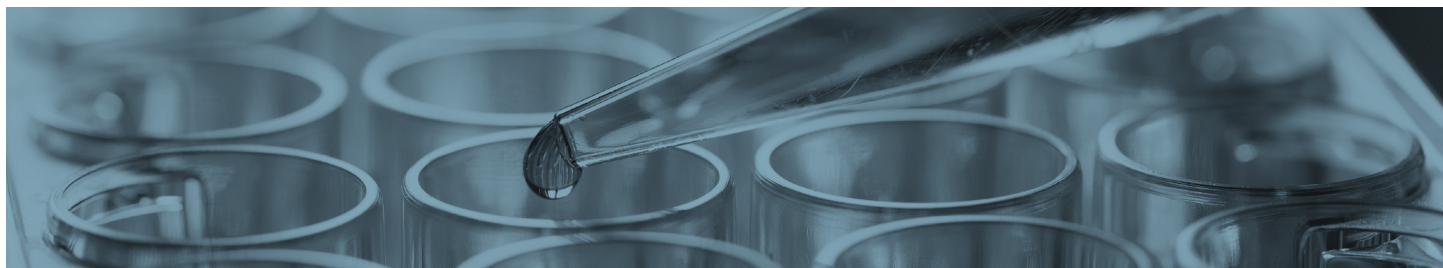
Target Genotype – Type 1b-2

Matrix – Plasma

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

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q017	BKV High Q Control CE	5 x 1 ml
	BKV Medium Q Control CE	5 x 1 ml
	BKV Low Q Control CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q014	CMV Medium Q Control CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q008	EBV High Q Control CE	5 x 1 ml
	EBV Medium Q Control CE	5 x 1 ml
	EBV Low Q Control CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P987	HSV1 Medium Q Control CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P984	HSV2 Medium Q Control CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P977	JCV Medium Q Control CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P968	PCP Medium Q Control IVD	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P936	VZV Medium Q Control CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q022	ADV Medium Q Control CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P981	INFA Medium Q Control CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P979	INFB Medium Q Control CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P966	PINF Medium Q Control CE	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.

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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q018	BKV Analytical Q Panel CE	6 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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q009	EBV Analytical Q Panel CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P993	HHV6 Analytical Q Panel CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P937	VZV Analytical Q Panel CE	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.

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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P963	RSV A Analytical Q Panel CE	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 minimizing the risk of contamination

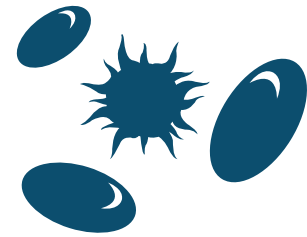
Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P961	RSV B Analytical Q Panel CE	8 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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q020	B19 Analytical Q Panel IVD	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q021	ADV Molecular Q Panel CE	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)

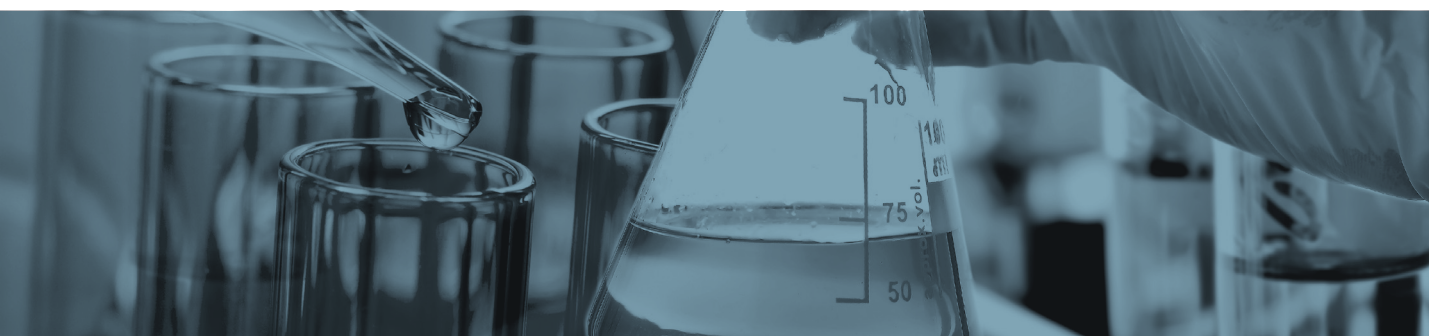
Target Genotype – Type 1b-2

Matrix – Plasma

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

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q016	BKV Molecular Q Panel CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q013	CMV Molecular Q Panel CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q007	EBV Molecular Q Panel CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P986	HSV1 Molecular Q Panel CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P983	HSV2 Molecular Q Panel CE	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

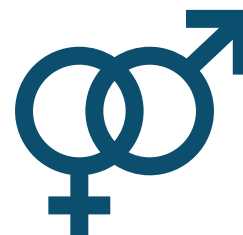
Stability – Single use Q-Panel designed to be used immediately minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P976	JCV Molecular Q Panel CE	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
	CT Molecular Q Panel IVD	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.

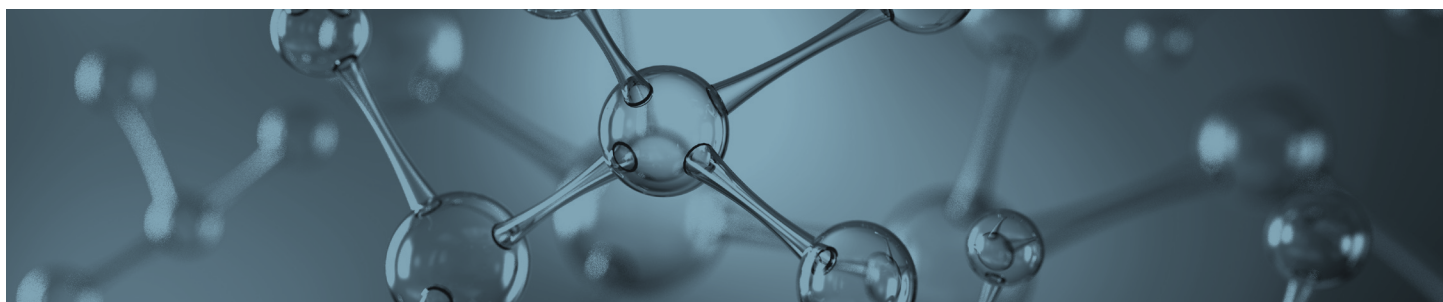
Target Pathogen – *Neisseria gonorrhoea* (NG)

Matrix – Viral Transport Medium

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

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
	NG Molecular Q Panel IVD	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

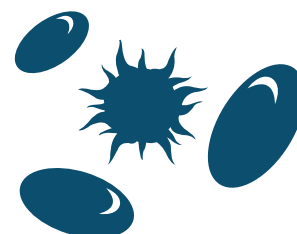
Stability – Single use Q-Panel designed to be used immediately minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q012	CT/NG Molecular Q Panel IVD	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q019	B19 Molecular Q Panel IVD	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 minimizing the risk of contamination

Shelf Life – Up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q001	HAV Molecular Q Panel IVD	4 x 0.6 ml



**Liquid ready-to-use samples
eliminate additional preparation**



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 minimizing the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P975	Meningitis / Encephalitis (ME) Evaluation Panel IVD	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 minimizing the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P964	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 minimizing the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
	Candida Evaluation Panel IVD	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 minimizing the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
	Aspergillus Evaluation Panel IVD	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 minimizing the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q002	Gastroenteritis Evaluation Panel (Viral) CE	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 enterocolitica*, *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 minimizing the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q004	Gastroenteritis Evaluation Panel (Bacterial-Parasite) CE	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

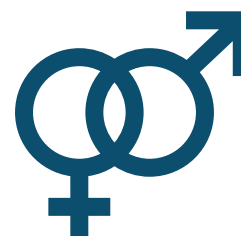
Panel Members – 6 (medium)

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

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q003	Gastroenteritis Evaluation Panel (Pathogenic <i>E. coli</i>) CE	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)

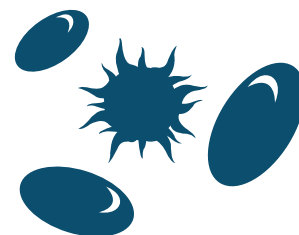
Stability – Single use Evaluation Panel designed to be used immediately minimizing the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P942	STI Evaluation Panel IVD	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 minimizing the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P999	HBV Genotype Evaluation Panel IVD	6 x 1.2 ml



Hepatitis B (HBV) DNA Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. The HBV DNA 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 minimizing the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01Q000	HBV DNA Evaluation Panel IVD	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 minimizing the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P997	HCV Genotype Evaluation Panel IVD	8 x 1.2 ml



Hepatitis C (HCV) RNA Evaluation Panel

Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. The HCV RNA 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 minimizing the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P995	HCV RNA Evaluation Panel IVD	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 minimizing the risk of contamination

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P994	HEV Evaluation Panel IVD	7 x 0.6 ml

Human Immunodeficiency (HIV1) RNA 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 – HIV1 Types B and C

Matrix – Plasma

Panel Members – 8

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

Shelf Life – up to 2 years from date of manufacture

Thomas No.	Product Description	Pack Size
CHM01P990	HIV RNA Evaluation Panel IVD	8 x 1.2 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 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.

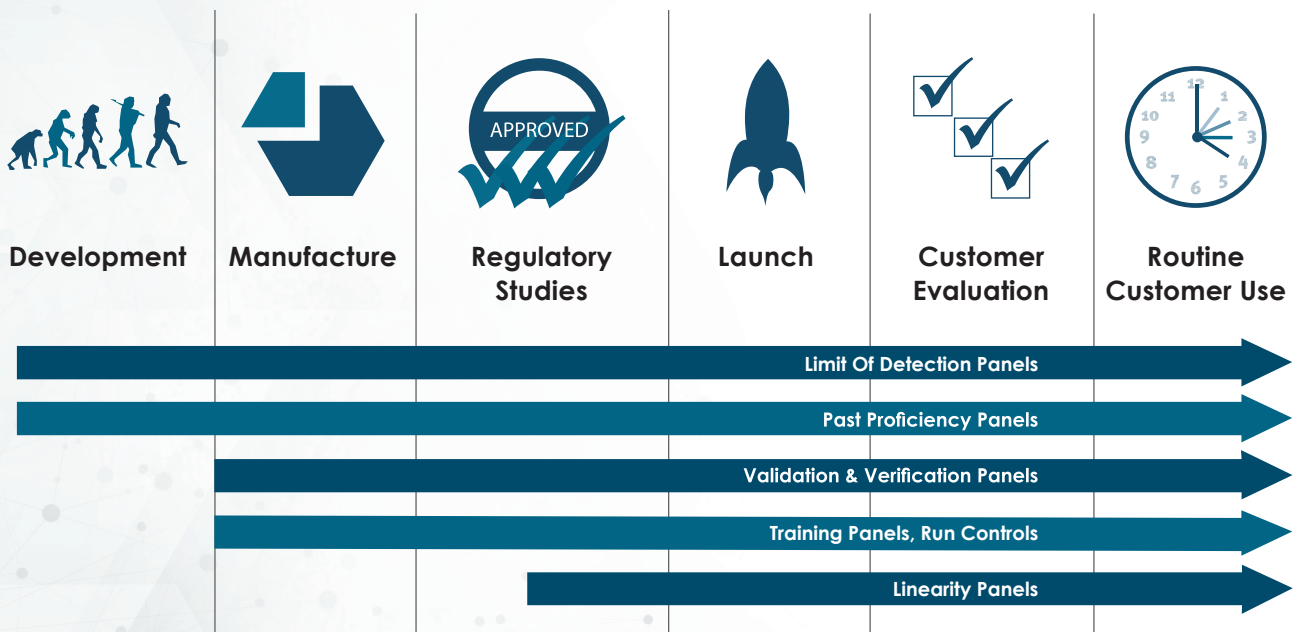


Custom Controls and Service Provision

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

- **Choose from hundreds of molecular characterized 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

	Q Control	Analytical Q Panel	Molecular Q Panel	Evaluation Panels
Transplant Associated Diseases	Page Number	Page Number	Page Number	Page Number
Adenovirus (ADV)	3		14	
BK Virus (BKV)	3	9	14	
Cytomegalovirus (CMV)	4		15	
Epstein-Barr Virus (EBV)	4	9	15	
Human Herpes Virus 6 (HHV6)		10		
Herpes Simplex Virus 1 (HSV1)	4		15	
Herpes Simplex Virus 2 (HSV2)	5		15	
JC Virus (JCV)	5		15	
<i>Pneumocystis pneumonia</i> (PCP)	5			
Varicella Zoster Virus (VZV)	6	10		
Respiratory Infection Testing	Page Number	Page Number	Page Number	Page Number
Adenovirus (ADV)	6			
Influenza A Virus (INFA - H1N1)	7			21
Influenza A Virus (INFA - H3N2)				21
Influenza B Virus (INFB - Victoria)	7			21
Parainfluenza Virus (PINF)	7			
Respiratory Syncytial Virus A (RSV A)		11		21
Respiratory Syncytial Virus B (RSV B)		11		21
Blood Borne Virus	Page Number	Page Number	Page Number	Page Number
Parvovirus B19 (B19)		12	18	
Hepatitis A Virus (HAV)			19	
Hepatitis B Virus (HBV) Genotypes				25
Hepatitis B Virus (HBV)				25
Hepatitis C Virus (HCV) Genotypes				26
Hepatitis C Virus (HCV)				26
Hepatitis E Virus (HEV)				26
Human Immunodeficiency (HIV1)				27
Sexually Transmitted Infections	Page Number	Page Number	Page Number	Page Number
Chlamydia Trachomatis (CT)			17	
Neisseria Gonorrhoea (NG)			17	
<i>Trichomonas vaginalis</i>				24
<i>Mycoplasma genitalium</i>				24
<i>Mycoplasma hominis</i>				24
<i>Ureaplasma urealyticum</i>				24
<i>Gardnerella vaginalis</i>				24
<i>Neisseria gonorrhoea</i>				24
<i>Chlamydia trachomatis</i> (LGV)				24
<i>Chlamydia trachomatis</i> (LGV) transport				24
<i>Chlamydia trachomatis</i> (SW)				24

Index by Disease State

	Q Control	Analytical Q Panel	Molecular Q Panel	Evaluation Panels
Gastrointestinal Infection Testing	Page Number	Page Number	Page Number	Page Number
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Norovirus GII				23
Adenovirus Type 41				23
Rotavirus				23
Astrovirus				23
Sapovirus				23
<i>Campylobacter jejuni</i>				23
<i>Campylobacter lari</i>				23
<i>Clostridium difficile</i> 027				23
<i>Shigella flexneri</i>				23
<i>Salmonella enteritidis</i>				23
<i>Yersinia enterocolitica</i>				23
<i>Giardia lamblia</i>				23
<i>Cryptosporidium parvum</i>				23
<i>Entamoeba histolytica</i>				23
<i>Plesiomonas shigelloides</i>				23
<i>E.coli</i> 0157				24
Shiga toxin-producing <i>E.coli</i>				24
Enterotoxigenic <i>E.coli</i>				24
Meningitis / Encephalitis (ME)	Page Number	Page Number	Page Number	Page Number
<i>Escherichia coli</i> (<i>E.coli</i>)				21
<i>Haemophilus influenzae</i>				21
<i>Listeria monocytogenes</i>				21
<i>Neisseria meningitidis</i>				21
<i>Streptococcus agalactiae</i>				21
<i>Streptococcus pneumoniae</i>				21
Cytomegalovirus				21
Enterovirus				21
Herpes Simplex Virus 1				21
Herpes Simplex Virus 2				21
Human Herpes Virus 6				21
Human Parechovirus				21
Varicella Zoster Virus				21
<i>Cryptococcus neoformans</i> / <i>gattii</i>				21
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<i>Candida glabrata</i>				22
<i>Candida krusei</i>				22
<i>Aspergillus fumigatus</i>				22
<i>Aspergillus terreus</i>				22

Index by Pathogen

	Q Control	Analytical Q Panel	Molecular Q Panel	Evaluation Panels
Adenovirus (ADV)	•		•	•
<i>Aspergillus fumigatus</i>				•
<i>Aspergillus terreus</i>				•
Astrovirus				•
B19 (Parvovirus B19)		•	•	
BK Virus (BKV)	•	•	•	
<i>Campylobacter jejuni</i>				•
<i>Campylobacter lari</i>				•
<i>Candida albicans</i>				•
<i>Candida glabrata</i>				•
<i>Candida krusei</i>				•
<i>Chlamydia trachomatis</i> (CT)			•	•
<i>Chlamydia trachomatis</i> (LGV)				•
<i>Chlamydia trachomatis</i> (SW)				•
<i>Clostridium difficile</i> 027				•
<i>Cryptococcus neoformans</i> / <i>gattii</i>				•
<i>Cryptosporidium parvum</i>				•
CT / NG			•	•
Cytomegalovirus (CMV)	•		•	•
<i>Entamoeba histolytica</i>				•
Enterotoxigenic <i>E. coli</i> (ETEC)				•
Enterovirus				•
Epstein-Barr Virus (EBV)	•	•	•	
<i>Escherichia coli</i>				•
<i>Gardnerella vaginalis</i>				•
<i>Giardia lamblia</i>				•
<i>Haemophilus influenzae</i>				•
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)	•		•	•
Human Herpes Virus 6 (HHV6)		•		•
Human Immunodeficiency Virus 1 (HIV1)				•
Human Parechovirus				•
Influenza A (INFA) (H1N1)	•			•
Influenza A Virus subtype H3N2 (INFA) (H3N2)				•
Influenza B (INFB) (Victoria)	•			•
JC (John Cunningham) Virus (JCV)	•		•	
<i>Listeria monocytogenes</i>				•

Index by Pathogen

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

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