Qnostics

Molecular Controls for Infectious Disease Testing

RANDOX

Whilst every attempt is made to ensure that information is accurate and up-to-date, some information is subject to change.
Please contact **marketing@randox.com** for current details.

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 molecular Nucleic Acid Amplification Testing (NAAT). The Qnostics product portfolio covers a vast range of characterised viral, bacterial and fungal targets covering a wide range of infectious disease areas including; transplant associated diseases, respiratory infections, blood borne viruses, sexually transmitted diseases, gastrointestinal infections and central nervous system diseases.

A typical molecular workflow consists of an extraction, amplification and/or detection phase, each of which can introduce variation into the test result. The aim of the Qnostics portfolio is to help identify, qualify, and monitor variation throughout the molecular workflow in line with the laboratory's routine quality control and quality assurance processes. Hence Qnostics products can be used support the evaluation, validation and/or verification of new and existing molecular workflows/assays in the laboratory as well as support the daily QC monitoring of assay performance, linearity assessment and staff training requirements.

The relationship between Qnostics product types within a product family, and their intended uses, are illustrated in Figure 1 below. Qnostics' products are manufactured to ISO 13485 compliant systems and are representative of clinical specimens. Where available, the Qnostics products are traceable to an internationally recognised reference material such as a WHO International Standard. Where there are currently no internationally recognised reference materials the products are traceable to an Internal Reference Material in line with the requirements of ISO 17511.

Manufacturers		
Linearity (V&V) LOD/LOQ	Accuracy (V&V) Precision (V&V)	Verification & Validation
End Users		
Linearity (V&V) LOD/LOQ	Accuracy (V&V) Precision (V&V)	Training Internal Quality Controls (QC/QA)

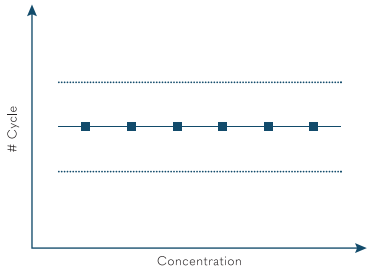
Analytical Q Panels **Molecular Q Panels** **Q Controls**

Figure 1: Relationship between Qnostics product types and intended use.

In addition to the catalogue products which are provided to clinical laboratories, research institutes, and industry, Qnostics has delivered custom QC products and services to IVD assay manufacturers, EQA providers, Pharmaceutical and CRO organisations for over 20 years with the overall aim of supporting them at all stages of the molecular workflow / assay's product life cycle from R&D to in-market customer support.

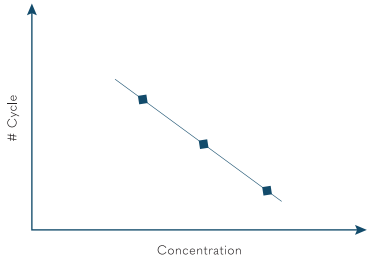
Product Summary

All Qnostics products are designed for the detection of the microbe(s) of interest within the formulated control and can be used within qualitative and/or quantitative molecular workflows / assays. The Qnostics control products are provided 'unassayed' meaning they have no assigned value. Given the extent and diversity of molecular workflows currently in use across different laboratories, it's the responsibility of the end user to establish their own values for each of the Qnostics control materials using their laboratory's routine molecular workflow.



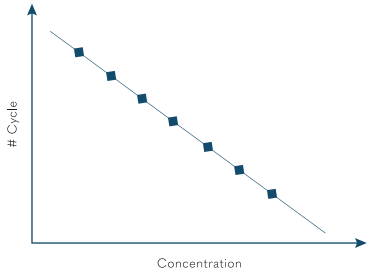
Q Controls

Qnostics' 'Q' Controls are positive run controls intended to help laboratories monitor their molecular diagnostic assay on a run-to-run basis within customer derived limits. These third-party independent external controls will ensure that assay drift is detected, monitored and managed allowing the laboratory to continue to provide accurate and reliable results. They also help support a laboratory's regulatory requirements under the standard ISO 15189.



Molecular Q Panels

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



Analytical Q Panels

Analytical 'Q' Panels are designed to cover the dynamic range of an assay allowing the laboratory to assess the linearity, LOD and LOQ of their assay. Each panel contains a dilution series covering the analytical range of most assays, in a linear progression, all of which should be treated as a patient sample within an assay run.

Evaluation Panels

Evaluation panels are designed to assist laboratories with the development of their molecular assays, establish the assay performance parameters of the molecular method and determine its fitness for purpose. The evaluation panels for blood-borne viruses contain a duplicate vial of one concentration which allows laboratories to assess reproducibility of their workflow for these targets.

Why use third-party controls?

The use of characterised third-party quality controls or Internal Quality Controls (IQC) is important to ensure confidence that laboratories are producing reliable data with minimal errors. Additionally, it provides laboratories with real time monitoring of their assay performance, allowing them to detect any random or systematic error and potential batch-to-batch variation introduced by laboratory reagents. This allows the laboratory to practice preventative, rather than reactive, quality control. The use of third-party controls is also recommended in various national guidelines globally including The United Kingdom Accreditation Service (UKAS), The Clinical and Laboratory Standards Institute (CLSI) and The National Association of Testing Authorities, Australia (NATA).

NOTE: Internal controls provided by the manufacturer of laboratory reagents (e.g. PCR reagents) are not third-party controls and cannot detect batch-to-batch variation of reagents.

QCMD Past Panels

Residual samples from previous QCMD EQA challenges can be used in assay evaluation particularly where there are no equivalent Qnostics products available or the end-user laboratory requires a broader range of microbial strains or subtype to support their evaluation.

QCMD past panel are only available on request and availability is dependent on the stated end-users required intended use.
Note: QCMD past panel samples are NOT IVDD/IVDR products.

The following table is designed to help inform you of 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 development				•	•
Detection of subtypes and strains				•	•
Staff training	•	•	•	•	•
Retest after poor EQA performance	•	•	•	•	•

Benefits

Whole Pathogen Controls

As whole pathogen controls, the Qnostics 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. Additionally, by inclusion of the entire microbial genome, our controls will be compatible with the majority of commercial and in-house NAAT technologies.

True Third Party Controls

All Qnostics controls can be described as true third-party controls thus delivering an independent, unbiased assessments of assay performance whilst helping to meet ISO 15189 regulatory requirements.

Traceability

All controls are traceable to international reference materials and/or international standards, where available in line with the requirements of ISO 17511.

Liquid for Ease-of-Use

All samples are conveniently supplied in a liquid frozen format meaning there is no additional preparation or handling required, reducing the risk of pre-analytical or human errors.

Target Pathogen Provided

Qnostics controls cover the detection of pathogens associated with a wide range of diseases including Blood Borne Viruses, Central Nervous System Diseases, Drug Resistance, Gastrointestinal Diseases, Respiratory Infections, Sexually Transmitted Diseases and Transplant Associated Diseases.

Flexible

The Qnostics range provides solutions to support laboratories in monitoring assay performance on a routine basis as well as assessing Limit of Detection (LOD), Limit of Quantitation (LOQ) and evaluating assay sensitivity and specificity.

Multi-Analyte Pathogen Material

Where appropriate, Qnostics provide multi-pathogen controls designed for use with multiplex assays.

Blood Borne Viruses

The Blood Borne Virus (BBV) group of Qnostics controls consists of pathogens that are detected from the blood. This includes Hepatitis B virus (HBV), Hepatitis C virus (HCV), Human Immunodeficiency virus (HIV), and Parvovirus B19.

	Q Controls	Molecular Q Panels	Analytical Q Panels	Evaluation Panels
Hepatitis B Virus (HBV)	•			•
Hepatitis B Virus Genotype (HBVGT)				•
Hepatitis C Virus (HCV)	•			•
Hepatitis C Virus Genotype (HCVGT)				•
Human Immunodeficiency Virus (HIV)	•			•
Parvovirus B19 (B19)		•	•	

Blood Borne Viruses

Hepatitis B Virus (HBV)

	Q Control	Evaluation Panel	Genotype Evaluation Panel
Target Pathogen	Hepatitis B Virus (HBV)		
Target Genotype	Type A	Types A and D	Types A, B, C, D and H
Matrix	Plasma		
Panel Members	5	8	6
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination.		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	RUO		

Catalogue Code	Product Description	Pack Size
HBVMQC	HBV Molecular Q Control	5 x 1.2 ml
HBVDNAEP	HBV DNA Evaluation Panel	8 x 1.2 ml
HBVGTEP	HBV Genotype Evaluation Panel	6 x 1.2 ml

Hepatitis C Virus (HCV)

	Q Control	Evaluation Panel	Genotype Evaluation Panel
Target Pathogen	Hepatitis C Virus (HCV)		
Target Genotype	Type 1b	Type 1b and 3a	Types 1a, 1b, 2b, 3a, 4a, 5a and 6a
Matrix	Plasma		
Panel Members	5	8	
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	RUO		

Catalogue Code	Product Description	Pack Size
HCVMQC	HCV Molecular Q Control	5 x 1.2 ml
HCVRNAEP	HCV RNA Evaluation Panel	8 x 1.2 ml
HCVGTEP	HCV Genotype Evaluation Panel	8 x 1.2 ml

Human Immunodeficiency Virus (HIV)

	Q Control	Evaluation Panel
Target Pathogen	Human Immunodeficiency Virus (HIV)	
Target Genotype	Type B	Types B and C
Matrix	Plasma	
Panel Members	5	8
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination	
Shelf Life	Up to 2 years from date of manufacture	
Regulatory Status	RUO	

Catalogue Code	Product Description	Pack Size
HIVMQC	HIV Molecular Q Control	5 x 1.2 ml
HIVRNAEP	HIV RNA Evaluation Panel	8 x 1.2 ml

Parvovirus B19

	Molecular Q Panel	Analytical Q Panel
Target Pathogen	Parvovirus B19	
Target Genotype	Type 1a	
Matrix	Plasma	
Panel Members	4	9
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination	
Shelf Life	Up to 2 years from date of manufacture	
Regulatory Status	RUO	

Catalogue Code	Product Description	Pack Size
B19MQP	B19 Molecular Q Panel	4 x 1.3 ml
B19AQP	B19 Analytical Q Panel	9 x 1.3ml

Central Nervous System

Infections of the Central Nervous System (CNS) can occur indirectly via the blood following damage to the blood brain barrier or directly through intraneuronal routes. Encephalitis and meningitis are important CNS infections which can have viral, bacterial or parasitic origins. Viral encephalitis can occur as a result of acute infection or as the consequence of latent infection. Common viral causes include herpes simplex virus (HSV), specific enteroviruses (EV), JC and BK virus, as well as Varicella- Zoster virus (VZV). Bacterial infections within the CNS such as meningitis can be a result of direct infection of the brain or may be due to underlying diseases which can lead to secondary CNS infection. Parasites such as *Toxoplasma gondii* can also cause CNS infections particularly in immunocompromised individuals. In recent years significant advances have been made in understanding CNS pathogenesis with the development of molecular technologies for the diagnosis and monitoring of disease, the introduction of effective treatment therapies and, in some cases, the development of vaccines (e.g. Japanese encephalitis & rabies).

	Q Controls	Molecular Q Panels	Analytical Q Panels	Evaluation Panels
BK Virus (BK)	•	•	•	
Enterovirus (EV)	•			
Herpes Simplex Virus 1 (HSV1)	•	•	•	
Herpes Simplex Virus 2 (HSV2)	•	•	•	
JC Virus (JCV)	•	•	•	
Meningitis / Encephalitis Multiplex (MEX)	•			
Varicella Zoster Virus (VZV)	•	•	•	

BK Virus (BKV)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	BK Virus (BKV)		
Target Genotype	Type 1b-2		
Matrix	Plasma		
Panel Members	5	4	10
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination.		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		

Catalogue Code	Product Description	Pack Size
BKVMQC	BKV Molecular Q Control	5 x 1 ml
BKVMQP	BKV Molecular Q Panel	4 x 1 ml
BKVAQP	BKV Analytical Q Panel	10 x 1 ml

Enterovirus (EV)

	Q Control
Target Pathogen	Enterovirus
Target Genotype	EV Coxsackie B3
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

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

Herpes Simplex Virus 1 (HSV1)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	Herpes Simplex Virus 1 (HSV1)		
Target Genotype	Clinical isolate		
Matrix	Transport Medium		
Panel Members	5	4	8
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		

Catalogue Code	Product Description	Pack Size
HSV1MQC	HSV1 Molecular Q Control	5 x 1 ml
HSV1MQP	HSV1 Molecular Q Panel	4 x 1 ml
HSV1AQP	HSV1 Analytical Q Panel	8 x 1 ml

Central Nervous System

Herpes Simplex Virus 2 (HSV2)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	Herpes Simplex Virus 2 (HSV2)		
Target Genotype	Type 09		
Matrix	Transport Medium		
Panel Members	5	4	10
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		

Catalogue Code	Product Description	Pack Size
HSV2MQC	HSV2 Molecular Q Control	5 x 1 ml
HSV2MQP	HSV2 Molecular Q Panel	4 x 1 ml
HSV2AQP	HSV2 Analytical Q Panel	10 x 1 ml

JC Virus (JCV)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	JC Virus (JCV)		
Target Genotype	Type 1A		
Matrix	Plasma		
Panel Members	5	4	10
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		RUO

Catalogue Code	Product Description	Pack Size
JCVMQC	JCV Molecular Q Control	5 x 1 ml
JCVMQP	JCV Molecular Q Panel	4 x 1 ml
JCVAQP	JCV Analytical Q Panel	10 x 1 ml

Meningitis/Encephalitis Multiplex (MEX1) – *To be released in 2025*

	Q Control
Target Pathogen	*Escherichia coli,* Cytomegalovirus, Enterovirus, *Streptococcus pneumoniae,* Human Herpes Virus 6
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
MEX1QC	MEX1 Q Control	5 x 1 ml

Meningitis/Encephalitis Multiplex (MEX2) – *To be released in 2025*

	Q Control
Target Pathogen	Herpes Simplex Virus 1, *Neisseria meningitidis, Streptococcus agalactiae, Cryptococcus species, Adenovirus Type 7*
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
MEX2QC	MEX2 Q Control	5 x 1 ml

Meningitis/Encephalitis Multiplex (MEX3) – *To be released in 2025*

	Q Control
Target Pathogen	*Haemophilus influenzae,* Herpes Simplex Virus 2, Varicella Zoster Virus, *Listeria monocytogenes,* Human Parechovirus 3
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
MEX3QC	MEX3 Q Control	5 x 1 ml

Varicella Zoster Virus (VZV)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	Varicella Zoster Virus		
Target Genotype	Type 9/84		
Matrix	Transport Medium		
Panel Members	5	4	10
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		

Catalogue Code	Product Description	Pack Size
VZVMQC	VZV Molecular Q Control	5 x 1 ml
VZVMQP	VZV Molecular Q Panel	4 x 1 ml
VZVAQP	VZV Analytical Q Panel	10 x 1 ml

Drug Resistance

The ability of microorganisms to adapt and develop resistance to antimicrobials is a natural and evolutionary trait which they have been employing for thousands of years. There are therefore many examples of drug resistant strains in viral, bacterial and parasitic diseases. It is well recognised however, the lack of antimicrobial stewardship and their availability over-the-counter has accelerated the emergence of drug resistance in the community and let to the emergence of multidrug resistant diseases.

	Q Controls	Molecular Q Panels	Analytical Q Panels	Evaluation Panels
Carbapenemase Resistance *Enterobacterales* (CPE)	•			
Rifampicin Resistant *Mycobacterium tuberculosis* (MTB)	•			
Vancomycin Resistant *Enterococci* (VRE)	•			

Rifampicin Resistant *Mycobacterium tuberculosis (MTB)*

	Q Control
Target Pathogen	*Mycobacterium tuberculosis (MTB)*
Target Genotype	Rifampicin Resistance
Matrix	Synthetic Sputum
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
MTBRQC	MTBR Q Control	5 x 1 ml

Vancomycin Resistant *Enterococci* (VRE)

	Q Control
Target Pathogen	*Enterococcus faecium* and *Enterococcus faecalis*
Target Genotype	*vanA* resistant *E. faecium* and *vanB* resistant *E. Faecali*
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

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

Carbapenemase Resistant *Enterobacterales* (CPE) – *To be released in 2025*

	Q Control
Target Pathogen	Carbapenemase Resistant *Enterobacterales*
Target Genotype	KPC, NDM, VIM, IMP-1 and OXA-48
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
CPEMQC	CPE Q Control	5 x 1 ml

Gastrointestinal Infections

Gastroenteritis can be caused by a wide variety of bacteria, viruses and parasites. It 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 primarily relies on clinical symptoms, however determining the etiological cause is often required to support patient care. In recent years molecular diagnostic techniques such as real-time PCR have also been introduced for the laboratory diagnosis of gastroenteritis, including the ability to simultaneously screen for a wide range of enteric pathogens using multiplex assays. As a result, molecular diagnostic techniques are increasingly being used in the routine laboratory setting for detection, determination and surveillance of a wide range of enteric pathogens.

	Q Controls	Molecular Q Panels	Analytical Q Panels	Evaluation Panels
Clostridium difficile (CD)	•			
Gastroenteritis (Bacterial/Parasitic) (GENB)				•
Gastroenteritis (Pathogenic *Escherichia Coli*) (GENE)				•
Gastroenteritis (Viral) (GENV)				•
Gastroenteritis (Viral) (Multiplex) (GVX)	•			
Norovirus GI/GII duplex (NV)	•			

Clostridium difficile (CD) – *To be released in 2025*

	Q Control
Target Pathogen	*Clostridium difficile*
Target Genotype	Ribotype 027
Matrix	Synthetic Faecal Matrix
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
CDMQC	*C. difficile* Q Control	5 x 1 ml

Gastroenteritis (Bacterial-Parasitic) (GENB)

	Evaluation Panel
Target Pathogen	*Campylobacter jejuni, Campylobacter lari, Clostridium difficile 027, Shigella flexneri, Salmonella enteritidis, Yersinia enterolitica, Giardia lamblia, Cryptosporidium parvum, Entamoeba histolytica and Plesiomonas shigelloides*
Matrix	Synthetic Faecal Matrix
Panel Members	10
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
GENBEP	GENB Evaluation Panel	10 x 1 ml

Gastroenteritis (pathogenic *E. coli*) (GENE)

	Evaluation Panel
Target Pathogen	*E.coli* O157, Shiga toxin-producing *E.coli*, Enterotoxigenic *E.coli*
Matrix	Transport Medium
Panel Members	6
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
GENEEP	GENE Evaluation Panel	6 x 0.5 ml

Gastrointestinal Infections

Gastroenteritis (viral) (GENV)

	Evaluation Panel
Target Pathogen	Norovirus GI, Norovirus GII, Adenovirus Type 41, Rotavirus, Astrovirus, Sapovirus
Matrix	Synthetic Faecal Matrix
Panel Members	6
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
GENVEP	GENV Evaluation Panel	6 x 1 ml

Gastroenteritis Viral Multiplex (GVX)

	Q Control
Target Pathogen	Norovirus GI, Norovirus GII, Adenovirus Type 41, Rotavirus, Astrovirus, Sapovirus
Matrix	Synthetic Faecal Matrix
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
GVXMQC	GVX Molecular Q Control	5 x 0.5 ml

Norovirus GI/GII Q Control

	Q Control
Target Pathogen	Norovirus
Target Genotype	GI and GII
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

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

Respiratory Infections

Respiratory tract infections (RTIs) are the most common cause of symptomatic illness affecting both adults and children each year. These infections can affect both the upper and lower respiratory tract and can range from the common cold to viral or bacterial pneumonia. For the young, the elderly and the immune compromised, RTIs can be associated with significant morbidity and mortality, particularly if they are not managed effectively. RTIs can be caused by many bacterial, viral and fungal pathogens which have nearly indistinguishable physiological symptoms. Difficulty in diagnosis increases the risk of undiagnosed or misdiagnosed infections leading to delayed or inappropriate antimicrobial intervention. The advancement of molecular diagnostic techniques has improved our ability to rapidly determine the causative agents of RTIs and has the potential to improve patient management and antimicrobial stewardship, control of nosocomial transmission and promote targeted therapy.

	Q Controls	Molecular Q Panels	Analytical Q Panels	Evaluation Panels
Adenovirus (ADV)	•	•	•	
Influenza A Virus (INFA)	•		•	
Influenza B Virus (INFB)	•		•	
Mycobacterium tuberculosis (MTB)	•			
Pneumocystis jirovecii pneumonia *(PCP)*	•			
Parainfluenza Virus (PINF)	•			
Respiratory Syncytial Virus A (RSV A)	•		•	
Respiratory Syncytial Virus B (RSV B)			•	
Respiratory Target Multiplex 1 (RTX1)	•			
Respiratory Target Multiplex 2 (RTX2)	•			
Respiratory Target Multiplex 3 (RTX3)	•			
Respiratory Target Multiplex 4 (RTX4)	•			
Respiratory Target Multiplex 5 (RTX5)	•			
Respiratory Target Multiplex 6 (RTX6)	•			
Respiratory Multiplex (RTX)				•
Rhinovirus (RV)			•	
SARS-CoV-2 (SCV2)	•	•	•	

Respiratory Infections

Adenovirus (ADV)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	Adenovirus (ADV)		
Target Genotype	Type 1		
Matrix	Transport Medium		
Panel Members	5	4	8
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		

Catalogue Code	Product Description	Pack Size
ADVMQC	ADV Molecular Q Control	5 x 1 ml
ADVMQP	ADV Molecular Q Panel	4 x 1 ml
ADVAQP	ADV Analytical Q Panel	8 x 1 ml

Influenza A Virus (INFA)

	Q Control	Analytical Q Panel
Target Pathogen	Influenza A Virus (INFA)	
Target Genotype	H1N1	
Matrix	Transport Medium	
Panel Members	5	9
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination	
Shelf Life	Up to 2 years from date of manufacture	
Regulatory Status	CE and RUO	RUO

Catalogue Code	Product Description	Pack Size
INFAMQC	INFA Molecular Q Control	5 x 1 ml
INFAAQP	INFA Analytical Q Panel	9 x 1 ml

Influenza B Virus (INFB)

	Q Control	Analytical Q Panel
Target Pathogen	Influenza B Virus (INFB)	
Target Genotype	Victoria	
Matrix	Transport Medium	
Panel Members	5	7
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination	
Shelf Life	Up to 2 years from date of manufacture	
Regulatory Status	CE and RUO	RUO

Catalogue Code	Product Description	Pack Size
INFBMQC	INFB Molecular Q Control	5 x 1 ml
INFBAQP	INFB Analytical Q Panel	7 x 1 ml

Mycobacterium tuberculosis (MTB)

	Q Control
Target Pathogen	*Mycobacterium tuberculosis* (MTB)
Matrix	Synthetic Sputum
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
MTBQC	*MTB Molecular Q Control*	5 x 1 ml

Pneumocystis jirovecii pneumonia (PCP)

	Q Control
Target Pathogen	*Pneumocystis jirovecii*
Matrix	Saline
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
PCPMQC	PCP Molecular Q Control	5 x 0.5 ml

Parainfluenza Virus (PINF)

	Q Control
Target Pathogen	Parainfluenza Virus (PINF)
Target Genotype	Type 1
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

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

Respiratory Infections

Respiratory Syncytial Virus A (RSVA)

	Q Control	Analytical Q Panel
Target Pathogen	Respiratory Syncytial Virus A (RSVA)	
Target Genotype	Type A	
Matrix	Transport Medium	
Panel Members	5	8
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination	
Shelf Life	Up to 2 years from date of manufacture	
Regulatory Status	CE and RUO	RUO

Catalogue Code	Product Description	Pack Size
RSVAMQC	RSVA Molecular Q Control	5 x 1 ml
RSVAAQP	RSVA Analytical Q Panel	8 x 0.5 ml

Respiratory Syncytial Virus B (RSVB)

	Analytical Q Panel
Target Pathogen	Respiratory Syncytial Virus B (RSVB)
Target Genotype	Type B
Matrix	Transport Medium
Number of Levels	8
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
RSVBAQP	RSVB Analytical Q Panel	8 x 0.5 ml

Respiratory Multiplex 1 (RTX1)

	Q Control
Target Pathogen	Influenza A (H1N1), Influenza B (Victoria), Respiratory Syncytial Virus A (RSV A), Coronavirus (SARS-CoV-2)
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

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

Respiratory Multiplex 2 (RTX2)

	Q Control
Target Pathogen	Parainfluenza 1, Adenovirus 1, *Mycoplasma pneumoniae*, Coronavirus (OC43)
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

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

Respiratory Multiplex 3 (RTX3)

	Q Control
Target Pathogen	Parainfluenza 2, Metapneumovirus (A2), Enterovirus (A16), Coronavirus (229E)
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
RTX3QC	RTX3 Q Control	5 x 0.7 ml

Respiratory Multiplex 4 (RTX4)

	Q Control
Target Pathogen	Parainfluenza 3, Rhinovirus (16), *Legionella pneumophila*, Coronavirus (NL63)
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

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

Respiratory Infections

Respiratory Multiplex 5 (RTX5)

	Q Control
Target Pathogen	Parainfluenza 4, Adenovirus (14), Respiratory Syncytial Virus B (RSV B), Enterovirus (D68)
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

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

Respiratory Multiplex 6 (RTX6)

	Q Control
Target Pathogen	*Bordetella pertussis, Bordetella parapertussis*, Influenza A H3N2, *Chlamydophila pneumoniae*
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

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

Respiratory Multiplex (RTXEP)

	Evaluation Panel
Target Pathogen	**Sample 1** : Influenza A (H1N1), Influenza B (Victoria), Respiratory Syncytial Virus A, SARS-CoV-2 **Sample 2** : Parainfluenza 1, Adenovirus 1, *Mycoplasma pneumoniae*, Coronavirus (OC43) **Sample 3** : Parainfluenza 2, Metapneumovirus (A2), Enterovirus (A16), Coronavirus (229E) **Sample 4** : Parainfluenza 3, Rhinovirus (16), *Legionella pneumophila*, Coronavirus (NL63) **Sample 5** : Parainfluenza 4, Enterovirus (68), Adenovirus (14), Respiratory Syncytial Virus B **Sample 6** : *Bordetella pertussis, Bordetella parapertussis, Influenza A (H3N2), Chlamydophila pneumoniae* **Sample 7** : Negative
Matrix	Transport Medium
Panel Members	7
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

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

Rhinovirus (RV)

	Analytical Q Panel
Target Pathogen	Rhinovirus (RV)
Target Genotype	Type A/16
Matrix	Transport Medium
Number of Levels	7
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
RVAQP	RV Analytical Q Panel	7 x 0.5 ml

SARS-CoV-2 (SCV2)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	Coronavirus (SARS-CoV-2)		
Matrix	Transport Medium		
Panel Members	5	4	9
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		

Catalogue Code	Product Description	Pack Size
SCV2QC	SARS-CoV-2 Q Control	5 x 0.5 ml
SCV2MQP	SARS-CoV-2 Molecular Q Panel	4 x 0.5 ml
SCV2AQP	SARS-CoV-2 Analytical Q Panel	9 x 0.5 ml

Sexually Transmitted Infections

Sexually transmitted infections (STIs) remain a major public health concern throughout the world with some infections reaching epidemic proportions in sexually active groups. As a result, a number of WHO and UN global strategies have been initiated in an attempt to control the spread of STIs. The main preventative cause of infertility, particularly among women, are untreated STIs. Additionally, some STIs remain asymptomatic in men and/or women and can lead to significant reproductive complications and congenital infections. For these reasons, effective population monitoring, diagnosis of symptoms and appropriate treatment is essential to controlling and preventing the spread of these infections in the community. Molecular diagnostic techniques allow for the accurate diagnosis of STIs in patients who present with similar symptoms or asymptomatic patients from high-risk groups allowing early and accurate intervention and treatment.

	Q Controls	Molecular Q Panels	Analytical Q Panels	Evaluation Panels
Chlamydia trachomatis and Neisseria gonorrhoeae (CTNG) (Transport Medium)	•			
Chlamydia trachomatis and Neisseria gonorrhoeae (CTNG) (Urine Matrix)	•			
Human Immunodeficiency Virus (HIV)	•			•
Herpes Simplex Virus 1 (HSV1)	•	•	•	
Herpes Simplex Virus 2 (HSV2)	•	•	•	
Human Papillomavirus (HPV)	•			
Sexually Transmitted Infection (STI)				•
Trichomonas vaginalis and *Mycoplasma genitalium* (TV/MG)	•			

Chlamydia trachomatis and Neisseria gonorrhoeae (CT/NG) (Transport Medium)

	Q Control
Target Pathogen	*Chlamydia trachomatis & Neisseria gonorrhoeae*
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
CTNGTQC	CTNG Q Control (Transport Medium)	5 x 1 ml

Chlamydia trachomatis and *Neisseria gonorrhoeae* (CT/NG) (Urine)

	Q Control
Target Pathogen	*Chlamydia trachomatis & Neisseria gonorrhoeae*
Matrix	Urine
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

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

Human Immunodeficiency Virus (HIV)

	Q Control	Evaluation Panel
Target Pathogen	Human Immunodeficiency Virus (HIV)	
Target Genotype	Type B	Types B and C
Matrix	Plasma	
Panel Members	5	8
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination	
Shelf Life	Up to 2 years from date of manufacture	
Regulatory Status	RUO	

Catalogue Code	Product Description	Pack Size
HIVMQC	HIV Molecular Q Control	5 x 1.2 ml
HIVRNAEP	HIV RNA Evaluation Panel	8 x 1.2 ml

Sexually Transmitted Infections

Herpes Simplex Virus 1 (HSV1)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	Herpes Simplex Virus 1 (HSV1)		
Target Genotype	Clinical Isolate		
Matrix	Transport Medium		
Panel Members	5	4	8
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		

Catalogue Code	Product Description	Pack Size
HSV1MQC	HSV1 Molecular Q Control	5 x 1 ml
HSV1MQP	HSV1 Molecular Q Panel	4 x 1 ml
HSV1AQP	HSV1 Analytical Q Panel	8 x 1 ml

Herpes Simplex Virus 2 (HSV2)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	Herpes Simplex Virus 2 (HSV2)		
Target Genotype	Type 09		
Matrix	Transport Medium		
Panel Members	5	4	10
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		

Catalogue Code	Product Description	Pack Size
HSV2MQC	HSV2 Molecular Q Control	5 x 1 ml
HSV2MQP	HSV2 Molecular Q Panel	4 x 1 ml
HSV2AQP	HSV2 Analytical Q Panel	10 x 1 ml

Human Papillomavirus Virus (HPV)*

	Multiplex Q Control
Target Pathogen	Human Papillomavirus
Target Genotype	Types 16 and 18
Matrix	PreservCyt ™
Panel Members	10
Stability	Single use, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
HPVMQC	HPV Molecular Q Control	10 x 1.2 ml

**Storage at 15-30˚C*

Sexually Transmitted Infection (STI)

	Evaluation Panel
Target Pathogen	Simulated swab: *Chlamydia trachomatis, Trichomonas vaginalis, Mycoplasma genitalium, Ureaplasma urealyticum, Mycoplasma hominis, Gardnerella vaginalis* In urine: *Neisseria gonorrhoeae, Chlamydia trachomatis*
Matrix	Simulated swab or Urine
Panel Members	10
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

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

Trichomonas Vaginalis & Mycoplasma Genitalium (TV/MG)

	Multiplex Q Control
Target Pathogen	*Trichomonas vaginalis* and *Mycoplasma genitalium*
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
TVMGMQC	TVMG Q Control	5 x 1 ml

Transplant Associated Diseases

Advances in transplant medicine, including the development of immunosuppressive agents, has greatly improved the prospects of transplant recipients. However, infection and in particular viral reactivation remain significant contributors to transplant patient morbidity and mortality. Several viruses are of particular concern, these include: adenovirus (ADV), BK virus (BKV), human cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpes virus (HHV6) and JC virus (JCV). Other opportunistic infections such as those caused by the parasite *Toxoplasma gondii* and the fungus *Pneumocystis jirovecii* are also of concern. Advances in molecular diagnostics have allowed accurate pathogen diagnosis prior to transplant and accurate monitoring, particularly of viral load over time, following transplantation. This in turn allows for early and accurate pre-emptive intervention and the commencement of appropriate antiviral drug therapy.

	Q Controls	Molecular Q Panels	Analytical Q Panels	Evaluation Panels
Adenovirus (ADV)	•	•	•	
BK Virus (BKV)	•	•	•	
Cytomegalovirus (CMV)	•	•	•	
Epstein-Barr Virus (EBV)	•	•	•	
Human Herpes Virus 6 (HHV6)		•	•	
JC Virus (JCV)	•	•	•	

Adenovirus (ADV)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	Adenovirus (ADV)		
Target Genotype	Type 1		
Matrix	Transport Medium		
Panel Members	5	4	8
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		

Catalogue Code	Product Description	Pack Size
ADVMQC	ADV Molecular Q Control	5 x 1 ml
ADVMQP	ADV Molecular Q Panel	4 x 1 ml
ADVAQP	ADV Analytical Q Panel	8 x 1 ml

BK Virus (BKV)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	BK Virus (BKV)		
Target Genotype	Type 1b-2		
Matrix	Plasma		
Panel Members	5	4	10
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		

Catalogue Code	Product Description	Pack Size
BKVMQC	BKV Molecular Q Control	5 x 1 ml
BKVMQP	BKV Molecular Q Panel	4 x 1 ml
BKVAQP	BKV Analytical Q Panel	10 x 1 ml

Transplant Associated Diseases

Cytomegalovirus (CMV)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	Cytomegalovirus (CMV)		
Target Genotype	AD169		
Matrix	Plasma		
Panel Members	5	4	9
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		

Catalogue Code	Product Description	Pack Size
CMVMQC	CMV Molecular Q Control	5 x 1 ml
CMVMQP	CMV Molecular Q Panel	4 x 1 ml
CMVAQP	CMV Analytical Q Panel	9 x 1 ml

Epstein-Barr Virus (EBV)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	Epstein-Barr Virus (EBV)		
Target Genotype	B-95		
Matrix	Plasma		
Panel Members	5	4	10
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		

Catalogue Code	Product Description	Pack Size
EBVMQC	EBV Molecular Q Control	5 x 1 ml
EBVMQP	EBV Molecular Q Panel	4 x 1 ml
EBVAQP	EBV Analytical Q Panel	10 x 1 ml

Human Herpes Virus 6 (HHV6)

	Molecular Q Panel	Analytical Q Panel
Target Pathogen	Human Herpes Virus 6 (HHV6)	
Target Genotype	A-GS	
Matrix	Plasma	
Panel Members	4	10
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination	
Shelf Life	Up to 2 years from date of manufacture	
Regulatory Status	RUO	

Catalogue Code	Product Description	Pack Size
HHV6MQP	HHV6 Molecular Q Panel	4 x 1 ml
HHV6AQP	HHV6 Analytical Q Panel	10 x 1 ml

JC Virus (JCV)

	Q Control	Molecular Q Panel	Analytical Q Panel
Target Pathogen	JC Virus (JCV)		
Target Genotype	Type 1A		
Matrix	Plasma		
Panel Members	5	4	10
Stability	Single use, designed to be used immediately after thawing, minimising the risk of contamination		
Shelf Life	Up to 2 years from date of manufacture		
Regulatory Status	CE and RUO		RUO

Catalogue Code	Product Description	Pack Size
JCVMQC	JCV Molecular Q Control	5 x 1 ml
JCVMQP	JCV Molecular Q Panel	4 x 1 ml
JCVAQP	JCV Analytical Q Panel	10 x 1 ml

Other

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

The Qnostics Transport Medium Negative Q Control is a dedicated, negative control for use in monitoring the performance of molecular assays by helping to establish the specificity (false positivity).

	Q Controls	Molecular Q Panels	Analytical Q Panels	Evaluation Panels
Transport Medium Negative (TMN)	•			

Transport Medium Negative (TMN)

	Q Control
Target Pathogen	Negative
Matrix	Transport Medium
Panel Members	5
Stability	Single use, designed to be used immediately after thawing.
Shelf Life	Up to 2 years from date of manufacture
Regulatory Status	RUO

Catalogue Code	Product Description	Pack Size
TMNQC	TMN Q Control	5 x 0.5 ml

QCMD Past Panels

QCMD Past Panels are highly characterised quality assessment materials that have been used in previous QCMD international EQA/PT schemes. Past Panels are helpful in post EQA evaluations and provide an additional source of quality material. Past panels are provided by Qnostics following closure of the EQA cycle. The panels are provided with a summary table and are typically limited in availability.

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 ensure any improvements made after a poor EQA performance are successful.

It is important to note that QCMD Past Panels are intended for EQA purposes, in line with **ISO 17043**. The panels are not intended for use as an IVD control or calibrator. In the absence of 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 are a wide range of QCMD Past Panels available.
Please enquire for more details: marketing@randox.com

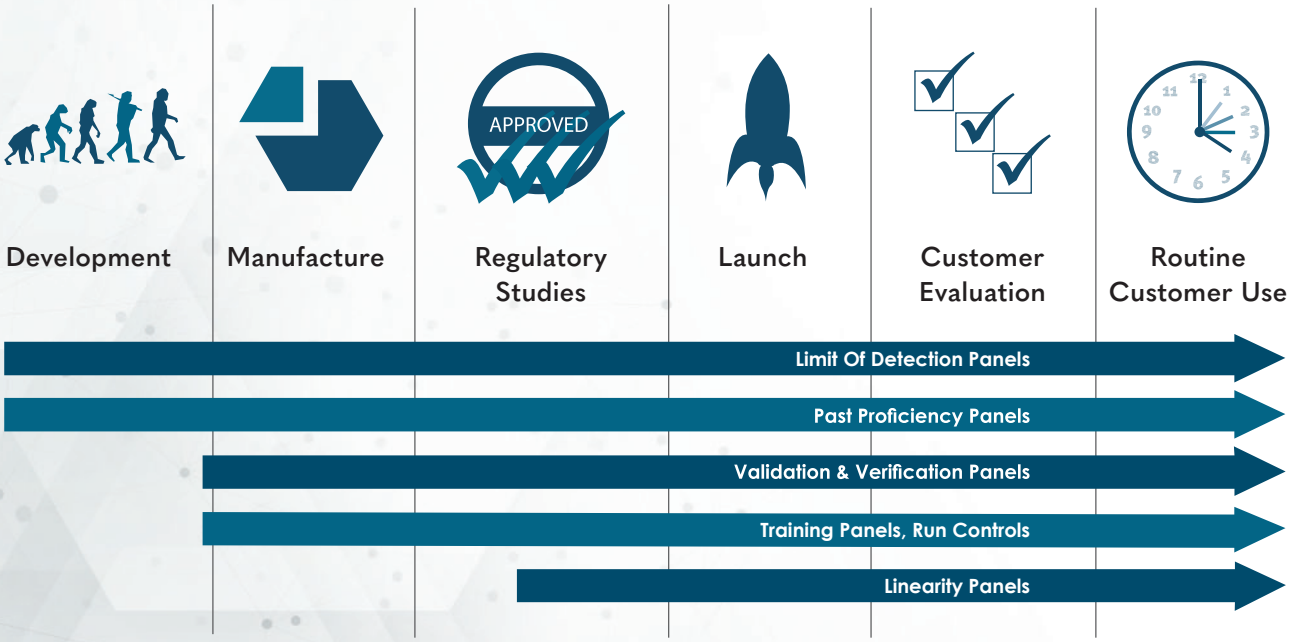
Custom Controls and Service Provision

If you cannot find what you are looking for, we offer custom made Quality Controls, specially designed, to fit all stages of the molecular assay life cycle. Qnostics have a large repository of pathogens associated with human infectious diseases including viral, bacterial, fungal and parasitic targets. These pathogens cover several different infectious disease states including Blood Borne Viruses, Central Nervous System, Drug Resistance, Gastrointestinal, Respiratory, Sexually Transmitted Diseases and Transplant Associated Diseases.

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;



RANDOX | Qnostics

Molecular controls for infectious disease testing

Whole Pathogen Controls

True Third Party Controls

Traceability

Liquid for Ease-of-Use

Target Pathogens Provided

Data Management Made Easy

DO YOU SPEND COUNTLESS HOURS TRACKING AND ANALYSING YOUR QC DATA?

IS YOUR QC DATA STORED ON A LOCAL NETWORK OR COMPUTER?

DO YOU STRUGGLE TO ANALYSE INSTRUMENT OR TARGET PERFORMANCE?

DOES IT TAKE YOU COUNTLESS DAYS MANUALLY CALCULATING YOUR UOM?

Acusera 24•7 can provide your laboratory one location for all your statistical analysis and the management of daily QC activities.

ACUSERA 24•7 | INTERLABORATORY DATA MANAGEMENT

Interactive Charts

User Friendly Reports

Automatic Calculation of UM

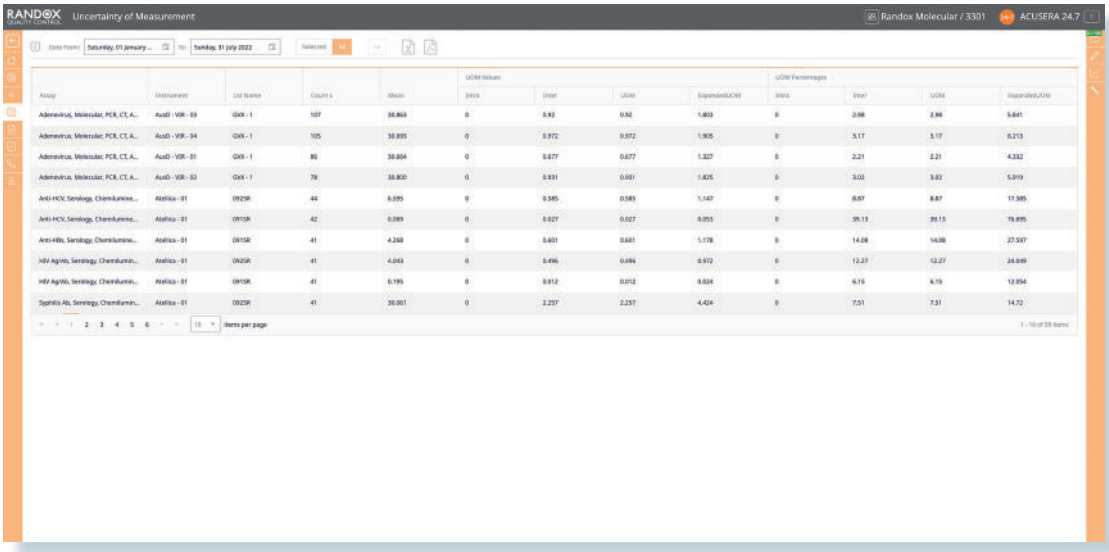
Multi-User Access

Web-Based Software

Levey-Jennings Charts

- Compare targets across multiple analyser's
- Identify trends across multiple: **QC lots / Analyser's / Targets**

Uncertainty of Measurement Report

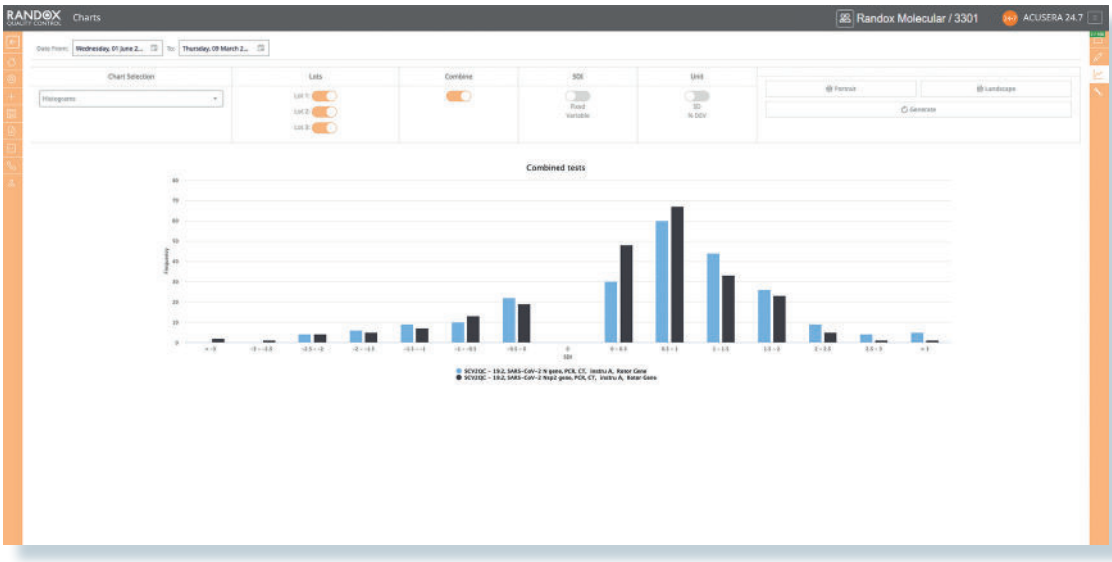


- Automatic calculation of UOM within a dedicated report

Want to find out more information on Acusera 24•7, Randox and how we can help your lab?

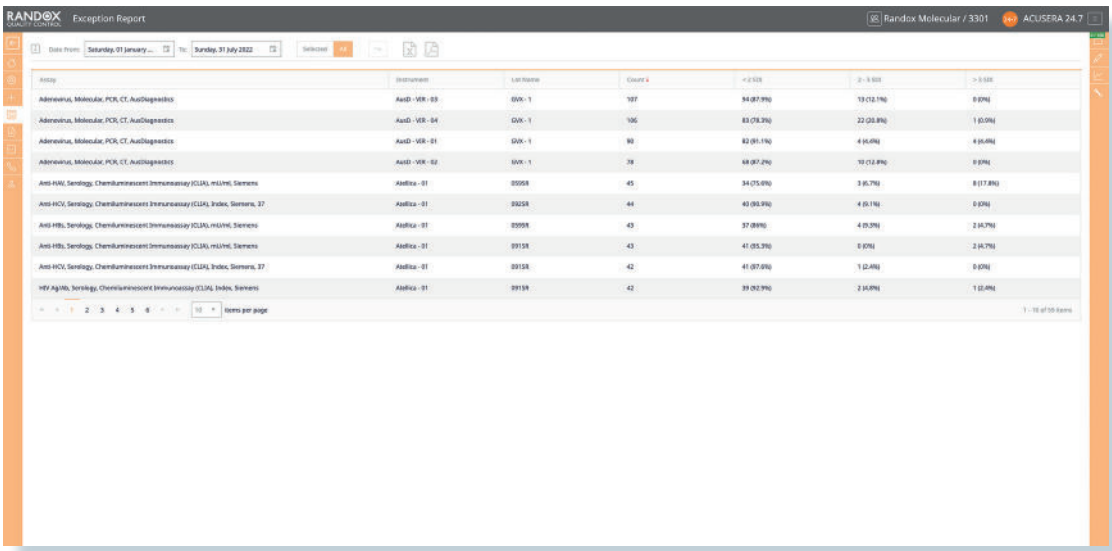
Scan the QR code to find out more

Histogram Chart



- Identify bias within any test system

Exception Report



- Quickly highlight poor performing targets

Pathogen Index

PATHOGEN	Blood Borne Viruses	Central Nervous System	Drug Resistance	Gastrointestinal Infections	Respiratory Infections	Sexually Transmitted Diseases	Transplant Associated Diseases	Compatible with Acusera 24/7
Adenovirus Type 1					•			•
Adenovirus Type 14					•			•
Adenovirus Type 41				•				•
Astrovirus				•				
BK Virus		•					•	•
Bordetella parapertussis					•			•
Bordetella pertussis					•			•
Carbapenemase-resistant *Enterobacterales*			•					
Campylobacter jejuni				•				
Campylobacter lari				•				
Chlamydia trachomatis						•		•
Chlamydophila pneumonia					•			•
Clostridium difficile 027				•				
Coronavirus (229E)					•			•
Coronavirus (NI63)					•			•
Coronavirus (Oc43)					•			•
Coronavirus (Sars-Cov-2)					•			•
Cryptococcus species		•						•
Cryptosporidium parvum				•				
Cytomegalovirus		•					•	•
Entamoeba histolytica				•				
Enterococcus faecalis			•					•
Enterococcus faecium			•					•
Enterotoxigenic *E. coli*				•				•
Enterovirus (A16)					•			•
Enterovirus (Coxsackie B3)		•						•
Enterovirus (D68)					•			•
Epstein-Barr Virus							•	•
Escherichia cK1		•						
Escherichia coli O157				•				
Gardnerella vaginalis						•		
Giardia lamblia				•				
Haemophilus influenzae		•						•
Hepatitis B Virus	•							•
Hepatitis C Virus	•							•
Herpes Simplex Virus 1		•				•		•
Herpes Simplex Virus 2		•				•		•
Human Herpes Virus 6		•					•	•
Human Immunodeficiency Virus	•					•		•

Pathogen Index

PATHOGEN	Blood Borne Viruses	Central Nervous System	Drug Resistance	Gastrointestinal Infections	Respiratory Infections	Sexually Transmitted Diseases	Transplant Associated Diseases	Compatible with Acusera 24/7
Human Papillomavirus						•		•
Human Parechovirus 3		•						•
Influenza A (H1N1)					•			•
Influenza A (H3N2)					•			•
Influenza B (Victoria)					•			•
JC Virus		•					•	•
Legionella pneumophila					•			•
Listeria monocytogenes		•						•
Metapneumovirus (A2)					•			•
Mycobacterium tuberculosis			•		•			•
Mycoplasma genitalium						•		•
Mycoplasma hominis						•		
Mycoplasma pneumoniae					•			•
Neisseria gonorrhoeae						•		•
Neisseria meningitidis		•						•
Norovirus GI				•				•
Norovirus GII				•				•
Parainfluenza 1					•			•
Parainfluenza 2					•			•
Parainfluenza 3					•			•
Parainfluenza 4					•			•
Parvovirus B19	•							•
Plesiomonas shigelloides				•				
Pneumocystis jirovecii pneumonia					•			•
Respiratory Syncytial Virus A					•			•
Respiratory Syncytial Virus B					•			•
Rhinovirus 16					•			•
Rotavirus				•				•
Salmonella enteritidis				•				
Sapovirus				•				•
Shiga toxin-producing E. coli				•				
Shigella flexneri				•				
Streptococcus agalactiae		•						•
Streptococcus pneumoniae		•						•
Trichomonas vaginalis						•		•
Ureaplasma urealyticum						•		
Varicella Zoster Virus		•						•
Yersinia enterocolitica				•				

Randox QC Portfolio

Our expertise in Quality Control have led to us creating market leading products that are tried and trusted by laboratory professionals. Our product portfolio offers high quality diagnostic solutions which offer reliable and rapid diagnosis and we believe that by providing laboratories with these tools, we can improve health worldwide.

Acusera - True third party controls offering complete test menu consolidation

Uniquely combining more than 100 analytes conveniently in a single control, laboratories can significantly reduce costs and consolidate without compromising on quality. As true third party controls, unbiased performance assessment with any instrument or method is guaranteed.

Acusera 24•7 - Online QC software with real-time peer group statistics

Designed for use with the Acusera range of third party controls, the Acusera 24•7 software will help you monitor and interpret your QC data. Access to an impressive range of features, including interactive charts, the automatic calculation of Measurement Uncertainty & Sigma Metrics and live peer group data generated from our extensive database of laboratory participants, ensures Acusera 24•7 is the most comprehensive package available.

RIQAS - Randox international quality assessment scheme

The largest international EQA scheme, used by more than 76,000 laboratory participants in over 140 countries worldwide. Comprising over 360 routine and esoteric parameters in 38 comprehensive and flexible EQA programmes, RIQAS is designed to cover all areas of clinical testing. Each programme benefits from a wide range of concentrations, frequent reporting and informative yet user-friendly reports.

MOLECULAR - IQC & EQA solutions for infectious disease testing

Our complete quality control solutions for molecular infectious disease testing comprise hundreds of characterised viral, bacterial and fungal targets. Covering a wide range of transplant associated diseases, respiratory infections, blood borne viruses, sexually transmitted infections and more, our Molecular IQC and EQA range covers the full laboratory portfolio. Both our product offering are manufactured using only the highest quality material and the availability of whole pathogen samples ensures the performance of the patient sample is mimicked throughout.

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