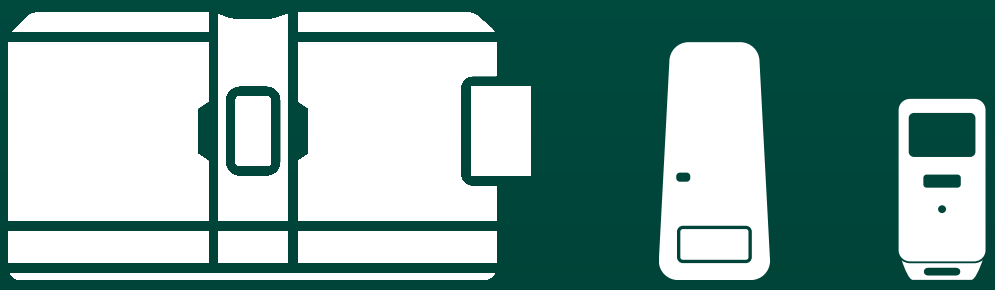
RANDOX

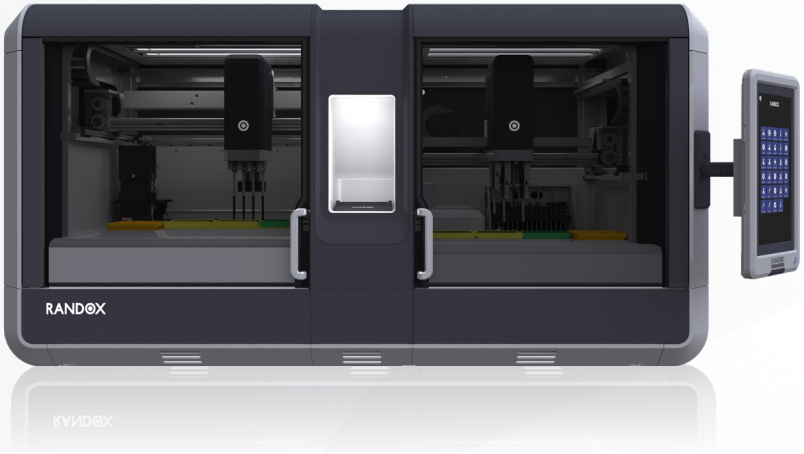
COVID-19 TESTING PLATFORMS



DISCOVERY | EVIDENCE INVESTIGATOR | VIVALYTIC


BOSCH
Hi. Please scan sample code to begin.
vivalytic


RANDOX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CORONAVIRUS

AVAILABLE ON THE DISCOVERY, EVIDENCE INVESTIGATOR & VIVALYTIC

Randox has developed a range of new tests for COVID-19 (SARS-CoV-2) targeting genes in line with WHO & CDC recommendations. Utilising Patented Biochip Technology, with results available from the Vivalytic, Evidence Investigator and Randox Discovery, capable of detecting both SARS-CoV-2 and Sarbecovirus (confirmatory target), to report SARS-CoV-2 positive patient samples.

Vivalytic

Point of Care Analyser

2.5 hours

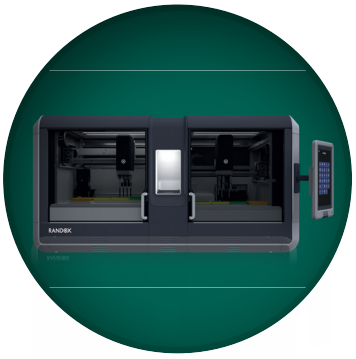
All in One Molecular Platform

Evidence Investigator

Semi-Automated Analyser

< 5 hours

Capable of processing 54 patient samples simultaneously



Discovery

Multiple Laboratories | One Fully Automated, Benchtop Analyser

3 hours

Consolidating Nucleic Acid Extraction,
Multiplex PCR & Biochip Detection

EXTENDED CORONAVIRUS & VRI ARRAY

AVAILABLE ON THE EVIDENCE INVESTIGATOR & VIVALYTIC

Six strains of coronavirus including SARS-CoV-2 are detected on both the Extended Coronavirus & Viral Respiratory Infection arrays. The wider panel delivers a more comprehensive respiratory screen allowing differentiation between COVID-19 and other respiratory pathogens with similar symptoms, ultimately enabling better treatment decisions to be made.

SAMPLE TYPE

Nasopharyngeal Swab

SAMPLE VOLUME

Vivalytic	300µl Clinical Sample
Evidence Investigator	5µl of Nucleic Acid required for PCR detection
Discovery	*In Development

VIRUSES

SARS-CoV-2 (COVID-19)	Adenovirus A/B/C/D/E
Sarbecovirus (SARS, SARS like, SARS-CoV-2)	Enterovirus A/B/C
Coronavirus 229E/NL63	Influenza A
Coronavirus OC43/HKUI	Influenza B
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	Rhinovirus A/B

ORDERING INFORMATION

EV4418	Investigator	Extended Coronavirus Array
F09G300382	Vivalytic	Viral Respiratory Infections Array

SARS-COV-2 ARRAY

2-PLEX ARRAY DETECTING & CONFIRMING COVID-19

The Io-plex test detects both SARS-CoV-2 and Sarbecovirus (confirmatory target), to report SARS-CoV-2 positive patient samples.

SAMPLE TYPE

Nasopharyngeal Swab

SAMPLE VOLUME

Vivalytic	300µL Clinical Sample
Evidence Investigator	5µl of Nucleic Acid required for PCR detection
Discovery	*In Development

VIRUSES

SARS-CoV-2 (COVID-19)	Sarbecovirus (SARS, SARS like, SARS-CoV-2)

ORDERING INFORMATION

F09G300599	Vivalytic	2-Plex Array (COVID-19)
EV4432	Investigator	SARS-CoV-2 Array
RDC1002/A	Discovery	2-Plex Array (COVID-19) Lyo Cartridge
RDC10002/B	Discovery	2-Plex Array (COVID-19) Components

SARS-COV-2 (COVID-19) RAPID TESTING

SARS-COV-2 (COVID-19) IS A RAPID REAL-TIME PCR TEST CARTRIDGE

SARS-CoV-2 (COVID-19) is a rapid real-time PCR test cartridge, available on the Vivalytic providing a clear and concise result in 45 minutes. This enables the patient to take the recommended safety precautions.

SAMPLE TYPE

Nasopharyngeal or Oropharyngeal Swab

SAMPLE VOLUME

Vivalytic	300µl Clinical Sample

VIRUSES

SARS-CoV-2 (COVID-19)

ORDERING INFORMATION

RUO: F09G300413	Vivalytic	SARS-CoV-2 Rapid Test
CE: F09G300411	Vivalytic	SARS-CoV-2 Rapid Test

SARS-COV-2 (COVID-19) POOLING TEST

DETECTING SARS-COV-2 FROM UP TO 5 POOLED SAMPLES SIMULTANEOUSLY

A rapid CE marked real-time PCR test cartridge, providing clear and concise results in 39 minutes, direct at the point of care. Testing up to 5 patient samples at one time, supporting health clinicians in using fewer testing resources.

SAMPLE TYPE

Nasopharyngeal or Oropharyngeal Swab

SAMPLE VOLUME

Vivalytic	750µl Clinical Sample

VIRUSES

SARS-CoV-2 (COVID-19)

ORDERING INFORMATION

RUO: F09G300593	Vivalytic	SARS-CoV-2 Pooling Test
CE: F09G300587	Vivalytic	SARS-CoV-2 Pooling Test

SARS-COV-2 IGG (RBD & NP) ARRAY

UNIQUELY MEASURING ANTIBODIES REACTIVE TO BOTH RBD AND NP

The qualitative detection of IgG antibodies reactive to Spike Receptor Binding Domain (RBD) and Nucleocapsid Protein (NP), identifying individuals with an adaptive immune response to SARS-CoV-2 indicative of recent or prior infection.

SAMPLE TYPE

Human serum and plasma

SAMPLE VOLUME

Evidence Investigator	10µl

ANTIGENS

Spike Receptor Binding Domain (RBD)	Nucleocapsid Protein (NP)

ORDERING INFORMATION

EV4447	Evidence Investigator	SARS-CoV-2 IgG (RBD & NP) Array
EV4448	Evidence Investigator	SARS-CoV-2 IgG (RBD & NP) Array Control Kit

RANDOX DISCOVERY

POWER OF AUTOMATION

Randox Discovery is comprised of three interconnected modules each which operate independently performing different aspects of the diagnostic testing process. Each module is separated by a physical barrier to prevent contamination and is accessible via a door. The workflow process runs from right to left and is compatible with lean working principles.

MODULE III
Biochip Hybridisation & Detection

Module III is used in both immunoassay & molecular workflows and is responsible for hybridisation and subsequent detection using patented biochip technology. The detection camera uniquely moves between sample cartridges to detect biochip chemiluminescence.

MODULE II
Multiplex PCR

Module II is responsible for amplification of the extracted nucleic acid by End Point PCR. UV light is used to sterilise the module and reduce the risk of crossover contamination.

MODULE I
Nucleic Acid Extraction

Module I is responsible for DNA/RNA extraction. After extraction the sample is automatically transferred to Module II. Before transfer, Module I detects the presence of Module II cartridges using a unique vision system.

RANDOX DISCOVERY

MULTIPLE LABORATORIES | ONE FULLY AUTOMATED, BENCHTOP ANALYSER

The Randox Discovery is an exciting and disruptive molecular & immunoassay diagnostic analyser capable of consolidating the normal workload of multiple laboratories into one compact benchtop platform.

Rapid turnaround time. 3 hours to first batch of results with results for subsequent batches every hour after

Capable of processing 16 samples per batch, 48 samples in 5 hours and 64 samples in complete working day

Simple and easy to use. Intuitive user interface guides the operator through the entire testing process

Fully automated platform increasing operator walkaway time. A single operator is all that's required to run up to 3 Discovery analysers

Capable of performing nucleic acid extraction, multiplex PCR & biochip hybridization & detection

BOSCH | vivalytic

VIVALYTIC

THE ALL IN ONE MOLECULAR SOLUTION

BOSCH VIVALYTIC

POINT OF CARE ANALYSER

Randox is bringing molecular diagnostics to point of care testing enabling faster time to result. Powered by Randox Biochip Technology, Vivalytic - the universal diagnostic platform for the point of care.

- Turnaround time: 3 hours
- Closed system
- Point of care platform
- Fully automated
- Detection from clinical specimen
- Suitable for both non-laboratory & laboratory settings

RANDOX

EVIDENCE INVESTIGATOR

Adaptable, Efficient & Comprehensive

EVIDENCE INVESTIGATOR

SEMI-AUTOMATED ANALYSER

The Evidence Investigator is a compact semi-automated benchtop analyser. It is a perfect fit for medium throughput laboratories seeking maximum use of bench space without compromising on the volume of samples processed.

Estimated turnaround time: Less than 5 hours

Medium to high throughput (54 samples and reporting 540 results in less than 5 hours)

Detection from nucleic acid

Batch testing

Suitable for laboratory setting

Comprehensive test menu

QNOSTICS

WHOLE PATHOGEN QUALITY CONTROL FOR SARS-COV-2

Qnostics, a world leading manufacturer of QC solutions for molecular infectious disease testing has developed a range of products designed to support the validation, verification and performance monitoring of molecular assays used in the testing of SARS-CoV-2.

WHY CHOOSE QNOSTICS?

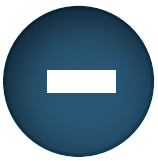
Qnostics controls contain the entire SARS-CoV-2 genome including CDC and WHO consensus sequences, meaning they are compatible with the majority of commercial and in-house assays.

Whole pathogen controls are the ideal material for full-process validation, monitoring the testing process from extraction to amplification and detection ensuring ultimate quality assurance in laboratories.

Quantified by digital PCR, ensuring reproducibility and metrological traceability enabling laboratories to meet their daily QC accreditation requirements.

As third party controls, an independent, unbiased assessment of assay performance is ensured in line with ISO 15189:2012 regulatory requirements.

Qnostics controls are manufactured under ISO 13485 guidelines to ensure quality and traceability.



Negative control available containing human cells/nucleic acids and therefore can be used as part of assay validation.

SARS-COV-2 Q CONTROLS

TARGET PATHOGEN – SARS-COV-2 (COVID-19)

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

Target – Whole Pathogen

Matrix – Transport Medium

Format – Liquid Frozen

Stability – Single use. Once thawed use immediately.

Regulatory Status – CE, RUO

CATALOGUE NUMBER	PRODUCT DESCRIPTION	PACK SIZE
SCV2QC	SARS-CoV-2 Q Control	5 x 0.5 ml
TMNQC	Negative Q Control	5 x 0.5 ml

SARS-COV-2 ANALYTICAL Q PANEL

TARGET PATHOGEN – SARS-COV-2 (COVID-19)

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

Target – Whole Pathogen

Matrix – Transport Medium

Format – Liquid Frozen

Stability – Single use. Once thawed use immediately.

Regulatory Status – CE, RUO

CATALOGUE NUMBER	PRODUCT DESCRIPTION	PACK SIZE
SCV2AQP	SARS-CoV-2 Analytical Q Panel	9 x 0.5 ml

SARS-COV-2 MOLECULAR Q PANEL

TARGET PATHOGEN – SARS-COV-2 (COVID-19)

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

Target – Whole Pathogen

Matrix – Transport Medium

Format – Liquid Frozen

Stability – Single use. Once thawed use immediately.

Regulatory Status – CE, RUO

CATALOGUE NUMBER	PRODUCT DESCRIPTION	PACK SIZE
SCV2MQP	SARS-CoV-2 Molecular Q Panel	4 x 0.5 ml

QCMD

MOLECULAR EQA SOLUTIONS FOR SARS-COV-2

QCMD provide two EQA programmes for SARS-CoV-2. Each programme is designed to evaluate a laboratory's ability to detect SARS-CoV-2 using routine molecular methods and will provide an opportunity to assess performance against an international peer group.

WHY CHOOSE QCMD?

The availability of whole pathogen samples containing the entire viral genome, ensures compatibility with the majority of commercial & in-house assays targeting the CDC and WHO consensus sequences.

EQA samples are designed to mimic the patient sample and assess the full testing process from extraction to amplification and detection.

An individual report is received after each challenge, summarising laboratory performance in comparison to an international peer group.

IT EQA Management System (ITEMS) provides an online tool to easily manage all EQA activities from programme registration to submission of results and provision of EQA reports.

Samples containing SARS-CoV-2 are inactivated and not infectious ensuring safe handling of material.

QCMD 2020

SARS-COV-2 EQA STUDY (SCV2)

The SARS-CoV-2 programme is designed to assess the ability of laboratories to detect SARS-CoV-2 at clinically relevant levels, near the Limit of Detection (LOD) and to assess the specificity of the assay in the presence of other coronaviruses. Two flexible participation options are available including; a single challenge format comprising 10 samples or a two-challenge format comprising 5 samples per challenge.

Target – Whole Pathogen

Matrix – Transport Medium

Format – Liquid Frozen

Stability – Single use. Once thawed use immediately.

Regulatory Status – CE, RUO

FEATURE	AVAILABLE FORMAT(S)	
Catalogue Number	QAV204215_1	QAV204215_2
Number of Challenges	1	2
Number of Samples per Challenge	10	5
Distribution / Testing Period	Q4	Q3 and Q4

SPECIFICATIONS

Sample NA Target Source – Cultured and/or clinical material

Target Range – Covers the clinical range

Matrix – Transport Medium

Sample Volume – 1 ml

Analysis Type – Qualitative

Format – Liquid Frozen

QCMD 2020

2020 RESPIRATORY I PLUS (RESPIPLUS)

The new RESPIplus EQA programme covers SARS-CoV-2 in addition to other respiratory pathogens including Influenza A, Influenza B and Respiratory Syncytial Virus (RSV) and is ideal for laboratories using multiplex and/or cartridge based molecular systems. The programme is designed to assess the ability of molecular workflows in the detection and differentiation of SARS-CoV-2 in combination with other respiratory pathogen targets.

FEATURE	AVAILABLE FORMAT(S)
Catalogue Number	QAV204216_1
Number of Challenges	1
Number of Samples per Challenge	10
Distribution / Testing Period	Q4

SPECIFICATIONS

Sample NA Target Source – Cultured and/or clinical material

Target Range – Covers the clinical range

Matrix – Transport Medium

Sample Volume – 1 ml

Analysis Type – Qualitative

Format – Liquid Frozen

NOTES

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