

RX IMOLA

A fully automated clinical chemistry analyser



A COMBINED THROUGHPUT OF 560 TESTS PER HOUR

THE RX IMOLA DELIVERS HIGH QUALITY TESTING FOR RESULTS YOU CAN TRUST



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BENEFITS



TEST MENU & CONSOLIDATION

Our extensive dedicated test menu comprises routine chemistries, lipids, antioxidants, cardiac and diabetes testing allowing laboratories to expand their testing capabilities while reducing additional costs associated with sending samples to be tested externally.

Direct, on-board, HbAIc testing capabilities provide many time saving benefits in the laboratory. As there is no pre-treatment step required HbAIc tests can be performed immediately, QC & Calibration checks are quicker, and offline calculations are not needed enabling faster recovery times.



ACCURATE RESULTS

Dual reagent probes with liquid level sensors and bubble detection minimise carry over increasing accuracy. Serum indices check the integrity of patient samples, flagging if samples are deemed icteric, haemolytic or lipaemic. Dual 5 speed stirrers are optimised for each assay to ensure highly accurate results.



QUALITY CONTROL

Providing simple, operational and testing efficiency, 6 different calibration options increase confidence with optimum algorithms being used to achieve the most accurate results. Users can view QC history with automatically generated Levey-Jennings Charts, Mean values, QC statistics and up to 10 user defined multi - rules designed to increase the probability of error detection and reduce false rejections.



FLEXIBILITY & VERSATILITY

12 wavelengths generated via diffraction grating (340-800nm) ensure a multitude of chemistries are possible on one system. The RX imola is capable of running monochromatic, bi-chromatic, endpoint, kinetic, ISE, sample blanking and reagent blanking assays. A cooled reagent carousel, with 60 positions, allows on-board storage without compromising stability.



UNRIVALLED PERFORMANCE

90 Pyrex[®] cuvettes with cuvette check function ensures only clean and viable reaction vessels are used. 5 speed mixing arms eliminate foaming and ensure adequate mixing of latex enhanced immunoturbidimetric assays. The continuous STAT loading hatch allows emergency samples to be analysed quickly and easily at any time.



COST SAVINGS

Minimal maintenance required with just 2 preventative maintenance services per year for reduced downtime. Intuitive user-friendly software ensures that minimal training is required. The RX imola delivers on economic efficiencies with low water consumption of only 18L per hour providing comprehensive testing for rapid and accurate results.

SYSTEM OVERVIEW

REAGENT CAROUSEL

60 reagent positions for 20ml, 50ml and 100ml bottles, all cooled between 8-15°C. Our smart reagent inventory management system with automatic barcode functionality ensures instant recognition of reagents. Randox offers a wide range of dedicated, high performing and unique reagents.

DUAL STIRRERS

Dual 5 speed rotating stirrers rinsed with purified water. The option of different mixing speeds ensure each reagent and sample are at optimum viscosity to enable accurate and precise measurement.

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WASH STATION

An 8 stage washing process with acid, alkali and pure water wash steps ensures cuvettes are thoroughly cleaned before each test. Liquid level sensors prevent cuvette overflows.



SAMPLE CAROUSEL

The emergency loading port allows run interruption for STAT sample processing. 72 positions are contained within the outer ring of the carousel for normal and STAT samples with 20 positions available in the inner ring for QC and calibrators. Barcode sample identification ensures accurate matching of patient identification to specimen.

PERMANENT CUVETTES

With 90 permanent Pyrex[®] cuvettes, the RX imola reduces downtime and ongoing consumable costs associated with changing disposable or semi-disposable cuvettes. Permanent cuvettes offer a lifespan of up to 5 years ensuring stability and accuracy of patient results.

ISE UNIT

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Providing cost savings, the RX imola has a built in ISE unit for direct measurements of sodium, potassium and chloride. The direct ISE approach requires no dilution steps to be carried out limiting possible sources of inprecision.

04

THE RX SERIES TEST MENU



AUTOIMMUNE:

Complement Component 3 Complement Component 4 CRP CRP Full Range (0.3-160mg/l) CRP High Sensitivity IgA IgE IgG IgM Rheumatoid Factor

BASIC METABOLIC PROFILE:

Calcium CO₂ Total Chloride Creatinine Glucose Potassium Sodium Urea

BONE PROFILE:

Alkaline Phosphatase Calcium Phosphorus Total Protein

CARDIAC:

Cholesterol CK-MB CK-NAC CRP CRP Full Range (0.3-160mg/l) CRP High Sensitivity Direct HDL Cholesterol Direct LDL Cholesterol Homocysteine Lipoprotein (a) sdLDL Triglycerides

COMPREHENSIVE METABOLIC PROFILE:

Albumin Alkaline Phosphatase ALT AST (GOT) Direct Bilirubin Calcium Chloride CO² Total Creatinine Glucose Lactate Potassium Sodium Total Bilirubin Total Protein Urea

DIABETES:

Cholesterol Creatinine Cystatin C Direct HDL Cholesterol Direct LDL Cholesterol Fructosamine Glucose Glycerol HbAIc (Direct) HbAIc/Hb (Indirect) Microalbumin NEFA (Non-Esterified Fatty Acids) Ranbut (D-3-Hydroxybutyrate) Total Protein Triglycerides Urinary Protein

ELECTROLYTES:

Calcium Chloride (Nondirect) CO₂ Total Magnesium Potassium (Nondirect) Sodium (Nondirect)

HAEMOLYTIC ANAEMIA:

G-6-PDH Haptoglobin LDH

HEPATIC FUNCTION:

Albumin Aldolase Alkaline Phosphatase ALT Ammonia AST (GOT) Bile Acids Cholinesterase Complement Component 3 Complement Component 4 Direct Bilirubin Gamma GT GLDH Glycerol Haptoglobin IgA IgG IgM Iron (UIBC) LDH Total Bilirubin Total Protein Transferrin Transthyretin (Prealbumin)

INFLAMMATION AND

INFECTION: ASO CRP Lactate Rheumatoid Factor

LIPIDS:

Apolipoprotein A - I Apolipoprotein AII Apolipoprotein B Apolipoprotein CII Apolipoprotein CII Apolipoprotein E Cholesterol Direct HDL Cholesterol Direct LDL Cholesterol Lipoprotein (a) sdLDL Triglycerides

NEONATAL SCREENING:

CRP CRP Full Range (0.3-160mg/l) CRP High Sensitivity IgE Transthyretin (Prealbumin)

NEUROLOGICAL

DISORDERS (CSF): IgA IgG IgM

NUTRITIONAL STATUS:

Albumin Copper Ferritin Iron Iron (UIBC)

Product availability may vary from country to country. Please check with your local Randox representative.

Lipase Magnesium Potassium TIBC Transferrin Transferrin (Prealbumin) Zinc

PANCREATIC

FUNCTION: Amylase Glucose LDH Lipase Pancreatic Amylase

RENAL FUNCTION:

Albumin Ammonia Beta-2 Microglobulin Calcium Chloride Creatinine Cystatin C HbAIc (Direct) HbAIc/Hb (Indirect) lgG LDH Magnesium Microalbumin Potassium Sodium Phosphorus (Inorganic) Urinary Protein Urea Uric Acid



VETERINARY

Albumin Alkaline Phosphatase ALT (GPT) Aldolase Ammonia Amylase AST (GOT) Bile Acids Bilirubin Calcium Chloride

- Cholesterol Cholinesterase (Butyryl) CK-NAC CO₂ Total Copper Creatinine Canine CRP Fructosamine Gamma - GT GLDH Glucose
- Glycerol Iron (UIBC) Lactate Lactate Dehydrogenase LDL Lipase Magnesium NEFA (Non-Esterified Fatty Acids) Phosphorus (Inorganic) Potassium Ranbut (D-3-Hydroxybutyrate)
- Ransel (Glutathione Peroxidase) Ransod (Superoxide Dismutase) Sodium Total Protein Triglycerides Urea Uric Acid Urinary protein Zinc



THERAPEUTIC DRUGS: Phenobarbital Valproic Acid DRUGS OF ABUSE: Ethanol



SPECIFIC PROTEINS:

Apolipoprotein A-I Apolipoprotein All Apolipoprotein B Apolipoprotein CII Apolipoprotein CIII Apolipoprotein E ASO Beta-2 Microglobulin Complement Component 3 Complement Component 4 CRP CRP Full Range (0.3-160mg/l) CRP High Sensitivity Cystatin C Ferritin Fructosamine Haptoglobin HbA1c (Direct) HbA1c/Hb (Indirect) IgA IgE IgG IgM Lipoprotein (a) Microalbumin Rheumatoid Factor sTfR Transthyretin (Prealbumin) Transferrin

ANTIOXIDANTS:

Albumin Bilirubin Ferritin Glutathione Reductase Ransel (Glutathione Peroxidase) Ransod (Superoxide Dismutase) TIBC

RESEARCH

Total Antioxidant Status Transferrin Uric Acid

FOOD AND WINE TESTING: Acetic Acid Ammonia Copper Ethanol Glucose/Fructose Malic Acid Potassium TAS

Product availability may vary from country to country. Please check with your local Randox representative.

SOFTWARE

The RX imola incorporates Windows[®] 10 based software. This intuitive software is easy for users to navigate, enhancing productivity requiring minimal training. The main screen links to a number of tabs including: Quality Control, Parameter, Calibration and Maintenance, allowing for simple access to information and straight forward selection of the operations required. Secure remote diagnostics saves money and time by allowing access to expert technical and applications staff anytime, anywhere. LIMS (Laboratory Information Management System) connectivity is easily achievable via ASTM standard.

Run	65 I	Parameter (F6)	Calibration	. m 1		QC (F8)	1	System	100	Ma	inte (F10)	11	EL SH	UTDOV
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	Run Mo	nitor						т	ime at run	started			18:00	2
IRU	37.0 c	Halogen 2 Min.	Decred No.	4				E	stimated t	time at sa	imple comp	lete	18:11	5
ino	01.0 0	malogen i wint	Roana No. 1					E	stimated f	time at ru	n end		18:3	2
os	PID	SID	Method	R1	S	M1	01	R2	M2	02	Result	CN	Error	
6		R94001601011	BUT2PB	•	•	•	•	•	•	•	0.56	52		
6		R94001601011	BUT3PB		•		•	•	•	•	0.53	53		
7		R94001701011	BUT1PB	•	•	•	•	•	•	•	0.75	54		
7		R94001701011	BUT2PB							×.	0.86	55		
7		R94001701011	BUT3PB	•	•	•	•	•	•	•	0.80	56		
8		R94001801011	BUT1PB		•		*	•		*1	0.97	57		
8		R94001801011	BUT2PB	•	•	•	•	•	•	•	1.14	58		
8		R94001801011	BUT3PB								1.06	59		
9		R94001901011	BUT1PB	•	•	•	•	•	•	•	1.15	60		
9		R94001901011	BUT2PB		•	•	•	•	•	•	1.43	61		
9		R94001901011	BUT3PB	•	•		•	•	•	•	1.31	62		
10		R94002001011	BUT1PB	*							1.28	63		
10		R94002001011	BUT2PB	•	•	•	•	•	•	•	1.24	64		
10		R94002001011	BUT3PB	*	•		*			•	1.24	65		
1		R94002101011	BUT1PB	•	•	•	•	•	•	•	0.32	66		
1		R94002101011	BUT2PB	*							0.30	67		
1		R94002101011	BUT3PB	•	•	•	•	•	•	•	0.30	68		
2		R94002201011	BUT1PB	•	•	•	•	•	•	•	1.23	69		
12		R94002201011	BUT2PB	*	•	•	*	•	•	•	1.21	70		
22		R94002201011	BUT3PB	*	•			•			1.22	71		
23		R94002301011	BUT1PB	•	•	•	•	•	•	•	0.01	72		
23		R94002301011	BUT2PB	*	•		•	•		*	0.00	73		
23		R94002301011	BUT3PB	•	•	•	•	•	•	•	0.00	74		-

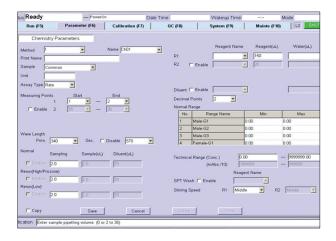
REPORTS

The operator can search for previous reports and view real time results status, including time left until completion. The RX imola has a high capacity storage of up to 30,000 patient reports.

us R	eady	- Po	werOn		Date 1	Time		Wakeup	Time -:	Mode		
Ru	ın (F5)	Parameter (F	5)	Calibration	(F7)	QC (F	8)	System (F	9) Mair	nte (F10)	EL SHUTDO	ΜN
	Invento	iry										
los	Name	Туре	Lot	Size	Vol(mL)	Tests	Method	Total	Valid	Stability	^	
11												1
2												
13												
4												
15	DLDL	R1	957	50mL	48.1		DLDL	291	08/31/2017		AHQLB7800	
6	GLUPAP	R1	439	50mL	45.8		GLUPAP	235	11/30/2017	/	ATC787804(
8	CREAT	R1	331	50mL	45.7		CREAT	338	04/30/2019		AP97B94046	
18	CREAT	R1	331	50mL	45.7		CREAT	338	04/30/2019	-6	AP97894046	
10	TRIGS	R1	189	50mL	48.2		TRIGS	247	03/31/2019		BM59B9304(
1	CREAT	R1 R2	332		24.9		CREAT	338	04/30/2019		AP98C94001	
2												
3												
14	DHDL	R1	923	50mL	48.0		DHDL	355	05/31/2017	-14	AGPNB7501	
15	URIC	R1	255	50mL	42.6		UA	258	09/30/2017	-14	BO73B79008	
6												
17	CAL 1S	R1	167	50mL	41.5		CAL1S	251	07/31/2018	18	CE4NB8702;	
18	ALB	R1	115	50mL	39.4		ALB	167	05/31/2018	-8	A237B85047	
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			an				Cance	a 🚺	Delete			
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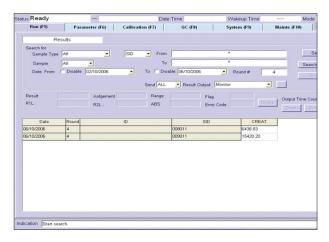
REAGENT INVENTORY

Remaining reagent volume is automatically calculated on-board alongside the number of tests available and stability of the reagents. Should insufficient volume remain for any reagent, an alert will appear, allowing the operator to resolve the situation.



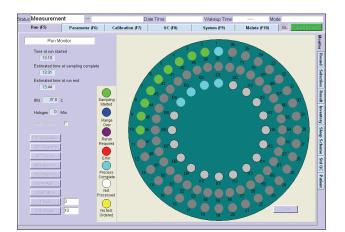
CHEMISTRY PARAMETERS

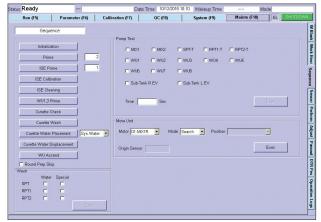
The chemistry parameters screen enables pre-sample dilution to be set up and re-running of assays as required. The user may set up to 20 different test profiles and define the order of analysis.



RESULTS

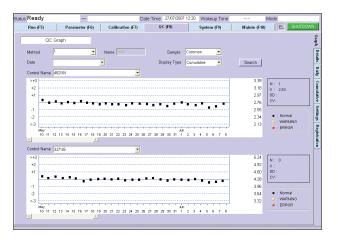
Results are easily retrievable via various search options, like sample type, date or sample category etc. Laboratory staff can download and print results or transmit results to the LIMS system for all relevant clinicians to view.





RUN MONITOR

This screen indicates the number of tests and time left until completion. STAT samples may be added without disturbing existing runs.



MAINTENANCE

Less than 5 minutes daily maintenance is required.



CALIBRATION

The software displays the current valid calibration for each assay installed, the reagent blank absorbance and the calibration check interval. There are 6 calibration models available: Factor, Linear, Point to point, Log-logit, Exponential and Spline.

QUALITY CONTROL

The QC screen generates Levey-Jennings charts and calibration curves allowing a visual performance assessment plus easy identification of QC errors and emerging trends. QC multi rules can be applied to ensure high error detection and minimal false rejection.

FEATURES AT A GLANCE

Providing excellence in clinical chemistry, the RX imola fully automated system combines robust hardware and intuitive software with a wide range of unique and innovative features.



Liquid level sensor, crash, bubble and clot detection



Low water consumption of just 18 litres per hour



Versatile reagent carousel with 60 cooled positions



Unique loading hatch allows emergency samples to be analysed quickly and easily at any time



90 permanent Pyrex[®] cuvettes with innovative cuvette check functionality which optimises analyser performance



Universal sample carousel with 72 positions and 20 cooled control and calibrator positions



Dual 5 speed stirrers enabling mixing to be optimised for each assays requirements



Sleep and auto start functionality and automatic re-runs of sample for faults detected



Maximum of 5 minutes daily maintenance required

ORDERING & CUSTOMER SUPPORT

In choosing to purchase the RX imola from Randox you are partnering with a company that has over 40 years' experience in the IVD industry and clinical chemistry analyser placements in over 120 countries worldwide. Customers needs vary and Randox sales staff and distributor partners will work with your laboratory to create a bespoke package to suit your requirements. Randox Laboratories provide customers with an unrivalled technical support service.

ORDERING INFORMATION

RX imola analyser

RX4900

For more information contact your local representative, or email us at: <u>theRXseries@randox.com</u>

SPECIFICATIONS

PHYSICAL DIMENSIONS

Height	690 mm, 27in
Depth	582 mm, 23in
Width	970 mm, 38in
Weight	I 50 kg, 33 l lbs

PERFORMANCE CHARACTERISTICS

Thusushaut	400 photometric tests per hour, 240 ISE tests per hour.
Throughput	Combined throughput of 560 tests per hour
Analyser accreditation	CE marking in compliance with In Vitro Diagnostic Medical Device Directive 98/79/EC,
	FDA 510k cleared and UL certification
Analyser type	Compact fully automated random access bench top clinical analyser
Assourt asts	Endpoint, kinetic, biochromatic, turbidmetric, sample blanking, reagent
Assay tests	blanking and ISE
Maintenance	Daily maintenance-less than 5 minutes. No rear access required. Simple twice yearly
	preventative maintenance service
Data management	Storage of up to 30,000 patient reports, search facility, test counter
Test channels	60 photometric channels, 3 direct ISE tests - sodium, potassium and chloride
Sleep mode	User defined sleep mode capabilities with automatic wash and instrument prep

REAGENT & SAMPLE SYSTEM

	Removable tray with 60 cooled positions
Reagent capacity	(30 positions for 100 or 50ml bottles and 30 positions for 20ml bottles)
Reagent cooling	8-15°C
Reagent identification	Automatic barcode reagent identification
Reagent inventory	Calculation of remaining reagent volume and tests available, alert for shortage, expired reagent and expired calibration
Reagent pipette	Dedicated twin reagent micropipette with liquid level sensor and crash detection, rinsed inside and outside with purified water
Sample addition	Immediate sampling interruption for addition of samples via removable panel
Sample capacity	Removable tray with 72 positions for samples, 20 cooled position for controls and calibrators
Sample dead volume	I50μl in standard or primary tubes, I00μl in paediatric cups
Sample dilution	Pre-dilution and automatic re-assay with diluted, reduced or increased sample volume. Dilution mixture 100-350µl consisting of 2-35µl of sample and 20-350µl of diluent
Sample identification	Barcode sample identification
Sample pipette	Dedicated sample micropipette with liquid level sensor, crash detection, bubble detection and 4 levels of clot detection. Rinsed inside and outside with purified water
Sample tube Size	Multiple primary tube sizes (diameter 13 to 16mm, height 75 to 100 mm), paediatric cups
Sample type	Serum, Plasma, Urine, Supernatant & Whole Blood

Sample volume	2 to 35µl (0.1µl increments)
STAT sampling	Immediate STAT sampling interruption

REACTION SYSTEM

Minimum reaction volume	Ι 50μΙ
Stirring speed	Dual 5-speed rotating stirrers rinsed with purified water
Stirring system	Paddle type rotating stirrer cleaned with purified water
Temperature	37°C±0.3
Cuvettes	90 reusable Pyrex [®] cuvettes with 5-year lifespan, min volume 150μl, Max volume 450μl, 8-stage cuvette washing system
Cuvette size	8(W) × 6.23(D) × 30(H) mm
Cycle time	9 seconds
Water consumption	I8L per hour
Water requirements	NCCLS type 1 or 2 purified water supply at pressure [0.15-0.34Mpa]

OPTICAL SYSTEM

Detector method	Direct absorbance in cuvette (bichromatic and monochromatic)
Detection principal	12 wavelengths: 340, 380, 415, 450, 510, 546, 570, 600, 660, 700, 750 and 800 nm
ISE tests	Integrated ISE unit
Light source	Halogen tungsten lamp (air-cooled, 6 months service life)

CALIBRATION & QC

	Interactive Levey-Jennings Charts, Daily, Monthly and Batch QC with
Quality control	data archiving, Automatic QC and Automatic calibration
	Factor, Linear, point to point, spline, log-logit and exponential.
Calibration principal	Up to 7 calibrators per test

POWER & CONNECTIVITY

Input voltage	100 - 240 Vac
Power consumption	<900 VA
UPS requirements	1230 W (analyser and PC)
LIMS connectivity	Bi-directional; ASTM standard (RS232 connection)

OPERATING SYSTEM

Operator interface	15'' LCD display and printer externally connected. Windows® based user
	Interface 100-249 VAC, 1230 Watt approx

THE RX SERIES





RX MISANO

RX MONACO

A semi-automated clinical chemistry analyser with the ability to run flow cell or cuvette mode. The RX misano offers 9 wavelengths spanning 340 - 700nm. A large 7" touch screen monitor responsive even when wearing lab gloves allows the user to easily navigate through the testing screens of the analyser. USB port allows users to import Randox-defined test menus and export patient, QC and calibration results. The RX monaco is a fully automated, cost effective solution for low to mid volume clinical chemistry testing offering the ultimate in convenience, performance and confidence. At optimal configuration, the RX monaco performs 170 tests per hour, providing cost effective, high quality testing for small to medium sized laboratories. The RX series test menu allows for complete consolidation of routine and specialised testing onto one efficient, easy to use platform.



RX DAYTONA+

The RX daytona+ is a bench-top, fully automated, random access clinical chemistry analyser capable of performing 270 photometric tests per hour, or 450 tests per hour including ISE. The most versatile analyser in its class, the RX daytona+ combines robust hardware and intuitive software with the world leading RX series test menu including routine & specialised testing and emergency STAT sampling for unrivalled performance.

RX MODENA

A fully automated, random access, floor standing clinical chemistry analyser with a photometric throughput of 800 test per hour, increasing to 1200 including ISE. There are 13 wavelengths spanning 340-800nm and a fully automated onboard, haemolysis function for running direct HbA1c. Accurate results are supported by liquid level, clot, and crash detection. The operating system utilises a modern touchscreen interface and Windows 10 icon based software.

RANDOX - A GLOBAL DIAGNOSTIC SOLUTIONS PROVIDER

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

REAGENTS

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

INTERNAL QUALITY CONTROL

Acusera third party quality controls are made using the highest quality material of human origin, ensuring they react like a real patient sample. With more than 390 analytes available across the Acusera range we can uniquely reduce the number of controls required while reducing costs and time. Our product range includes clinical chemistry, immunoassay, urine, immunology and more. Qnostics molecular controls for infectious disease testing are designed to meet the demand of today's molecular diagnostics laboratory while effectively monitoring the entire testing process. Our whole pathogen molecular controls comprise hundreds of characterised viral, bacterial and fungal targets.

EXTERNAL QUALITY ASSESSMENT

RIQAS is the world's largest international EQA scheme with more than 50,000 participants worldwide. 39 comprehensive, yet flexible programmes cover a wide range of clinical diagnostic testing including chemistry, immunoassay, cardiac, urine, serology and more. Our programmes benefit from a wide range of concentrations, frequent reporting, rapid feedback and user-friendly reports. QCMD, our range of EQA programmes for molecular infectious disease testing, features a whole pathogen matrix making them a true test of patient sample analysis. With access to over 90 programmes including blood borne viruses, respiratory diseases, multipathogen infections and more, there is something for every laboratory.

EVIDENCE SERIES



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

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