

RANDOX

## THIRD PARTY CONTROLS

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ACUSERA



## ACUSERA

TRUE THIRD PARTY CONTROLS  
OFFERING COMPLETE TEST MENU CONSOLIDATION



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# BENEFITS

For over 40 years Randox has been shaping the future of clinical diagnostics with our pioneering high quality, cost effective laboratory solutions. With approximately 70% of clinical decisions based on laboratory test results, it is essential that the results provided are accurate and reliable in order to prevent potential misdiagnosis or inappropriate treatment.

Quality Control is our passion; we believe in producing high quality material that can help streamline procedures, whilst saving time and money for laboratories of all sizes and budgets. With an extensive product offering comprising third party quality controls & calibrators, interlaboratory data management, external quality assessment, calibration verification and molecular IQC and EQA for infectious disease testing, you can count on Randox to deliver trustworthy results time and time again. Just ask one of our 60,000 users worldwide.



## Commutability

All Acusera controls are designed to react to the test system in the same manner as the patient sample, helping to meet ISO 15189:2022 requirements whilst reducing inconvenient and costly shifts in QC results when reagent batch is changed.



## Accurate Target Values

Our unique value assignment process utilises thousands of independent labs globally, ensuring availability of highly accurate, robust target values for a wide range of instruments and methods, ultimately eliminating the need to spend time and money assigning in-house.



## True Third Party Controls

Manufactured independently, the Acusera range delivers unbiased performance assessment with any instrument or method, helping to meet ISO 15189:2022 requirements whilst simultaneously eliminating the need for multiple instrument dedicated controls.



## Shelf Life

With a shelf life of up to four years for lyophilised controls and two years for liquid controls, you can benefit from continuity of lot supply whilst reducing the frequency of new lot validation studies, thus saving time and money.



## Consistency

Our superior manufacturing processes ensure stability claims and analyte levels won't differ significantly from lot-to-lot. You can therefore be sure of receiving the same standard of product time and time again.



### Traceability

The values assigned to both our calibrators and control materials are traceable to a recognised reference material or reference measurement procedure meeting ISO 17511 and ISO 18153 requirements.



### Consolidation

Specialising in consolidation, the Acusera range of multi-analyte controls is designed to reduce the number of individual controls required to cover your test menu, ultimately reducing costs, preparation time and storage space.



### Clinically Relevant Levels

The presence of analytes at key decision levels not only helps to ensure accurate instrument performance but maximises laboratory efficiency by eliminating the need for additional low/high level controls at extra expense.



### Reduced Waste

The unrivalled working stability of the Acusera control range helps to keep waste and costs to a minimum.



### Flexible Options

With an extensive range of assayed/unassayed, liquid/lyophilised and single/multi-analyte controls, the Acusera portfolio has a solution to suit all laboratory preferences.



### Custom Controls

Randox is a market leader in the manufacture of customised quality controls designed to meet the individual and unique requirements of even the most specialised laboratories.

For more information about Randox and for our full range of products, please visit [randox.com](http://randox.com), or contact your local Randox representative.

# ISO REQUIREMENTS

Acusera; helping you to meet ISO 15189:2022 requirements.

## Third Party Controls

**“The use of third-party IQC material should be considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer.”**

As true third party controls, the Acusera range has been designed to provide an unbiased, independent assessment of performance. Our Acusera controls have not been manufactured in line with, or optimised for use with any particular reagent, method or instrument.

## Commutability

**“When selecting IQC material, factors to be considered include: the IQC material reacts to the examination method in a manner as close as possible to patient samples.”**

Many Acusera controls are manufactured using 100% human materials, ensuring they behave in the same manner as a patient sample thus providing an accurate reflection of test system performance.

## Clinically Relevant Levels

**“The IQC material provides a clinically relevant challenge to the examination method, has concentration levels at or near clinical decision limits and when possible, covers the measurement range of the examination method.”**

The inclusion of analytes at clinical decision levels will not only eliminate the need to purchase additional low/high level controls but will help to ensure accurate instrument performance.

## Data Management

**“The laboratory shall prevent the release of patient results in the event that IQC fails the defined acceptability criteria. The laboratory shall have a procedure for monitoring the validity of results. ...The resulting data shall be recorded in such a way that trends and shifts are detectable and, where practicable, statistical techniques shall be applied to review the results.”**

Acusera 24•7 provides instant access to an unrivalled range of features including QC multi-rules, interactive charts, live peer group data, automatic calculation of Measurement Uncertainty & Sigma Metrics & our unique dashboard interface, all designed to speed up the review process and provide at-a-glance performance assessment.

## EQA

**“The laboratory shall monitor its performance of examination methods, by comparison with results of other laboratories. This includes participation in EQA programmes appropriate to the examinations and interpretation of examination results, including POCT examination methods.”**

The Randox International Quality Assessment Scheme (RIQAS), is used by more than 55,000 laboratory participants in 134 countries and accredited to ISO 17043. As a result, we have RIQAS users on every continent who are registered for one or more of our 36 flexible EQA programmes, utilising the available data to ensure the quality and reliability of their results.

## Consolidate and Save with Randox Acusera.

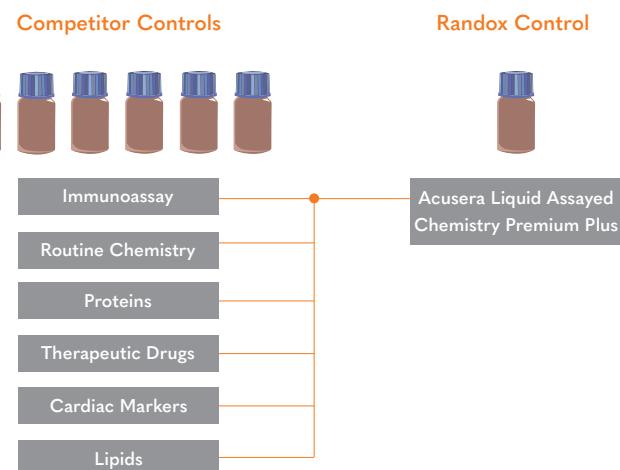
Randox is a leading provider of multi-analyte, true third party controls covering more than 400 analytes. The unique combination of analytes facilitates effective consolidation, helping your laboratory to reduce costs without compromising on performance or quality. Unlike some competitor products, our Acusera Controls are manufactured with analytes present at clinically relevant decision levels, eliminating the need to purchase additional high or low level controls, at extra expense.

### How can consolidating with Randox Acusera benefit you?

With Randox Acusera you could consolidate up to 6 competitor controls into one Acusera control, reducing the amount of storage space required for your QC material, as well as saving valuable time and money for your laboratory. The following examples have been selected to highlight areas where Acusera can help you effectively consolidate your control purchases.

#### Liquid Assayed Chemistry Premium Plus Control

Uniquely combining up to 99 analytes including; routine chemistry, immunoassays, lipids, therapeutic drugs, proteins and cardiac markers in a single vial, you can experience effective consolidation and significant cost savings. The presence of CRP and other proteins at elevated levels will not only help to ensure accurate instrument performance at key decision levels but further reduce the number of individual controls required. - turn to page 23 for more information



#### Competitor Controls



#### Randox Control



#### Immunoassay Premium Plus Control

Impressively covering 55 analytes including tumour markers, therapeutic drugs and routine immunoassay tests, the Acusera Immunoassay Premium Plus control has been uniquely designed to eliminate the need for four or more controls, dramatically reducing costs and time. The added advantage of ultra-low levels of Ferritin, Vitamin B<sub>12</sub> and TSH will help to ensure accurate performance at key decision levels and further reduce the number of controls required. - turn to page 38 for more information

## COMMITMENT TO QUALITY

Randox is committed to quality at every stage of the production process from research and development to customer support. This commitment has been recognised through official accreditation to both national and international standards including UKAS and ISO.

Accreditation to international standards ensures confidence in the quality and consistency of the products and services provided by Randox, and demonstrates compliance to internationally agreed standards.



The United Kingdom Accreditation Service (UKAS) is the only national accreditation body recognised by the government to assess against internationally agreed standards.

RIQAS systems and procedures have been accredited with UKAS approval to **ISO/IEC 17043:2010** "Conformity assessment - General requirements for proficiency testing".

**UKAS**

The International Organisation for Standardisation (ISO) is the largest developer and publisher of international standards in the world. In 2016, Randox was accredited with **ISO13485:2016** approval.



**ISO13485:2016**

**ISO13485:2016** relates to the design/development, manufacture, service and distribution of in vitro diagnostic medical devices, in vitro diagnostic test kits, in vitro diagnostic reagents and in vitro diagnostic analysers.

**ISO13485:2016** highlights the requirements for a quality management system where an organisation needs to prove its ability to provide medical devices and other related services that consistently meet regulatory requirements.

**FDA Cleared**

Many of our quality controls and calibrators are FDA cleared and therefore appropriate for clinical use in the USA. In order for an IVD to be approved for sale in the USA it must not only be safe for use and effective but it must also satisfy the requirements set out in **part 820 title 21** of the Code of Federal Regulations published by the FDA.



**CE Mark**

Many of our Quality Control (QC) products are CE certified and carry the CE mark. CE marking on a product indicates that the product complies with and has satisfied the essential requirements set out by the **In Vitro Diagnostic (IVD) Medical Devices Directive 98/79/EC**. It also demonstrates the fact the product is fit for its intended purpose.

The CE mark is also a declaration from the manufacturer that the product has met all legislation in relation to health and safety and where required, has been assessed in accordance with this legislation.

CE marking is essential for products to be placed on the market and sold in the European Union (EU). It also ensures the free movement of products within the EFTA and EU.

**Canadian  
Medical Device  
Regulations  
from Health  
Canada**

Many Randox products, including our quality controls and calibrators, are **licensed for use in Canada**. Before an IVD device can be sold in Canada, it must meet the requirements set out in the Therapeutic Products Directorate. Health Canada reviews all medical devices to assess their safety, effectiveness and quality before they are authorised for sale.

## RESOURCE HUB

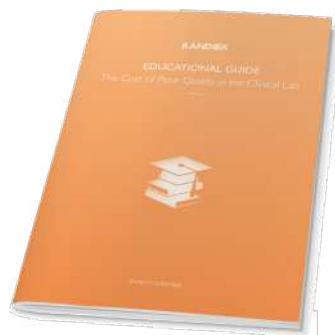
Visit our Resource Hub – [randox.com/resource-hub](http://randox.com/resource-hub) to find a wealth of information to help your laboratory with all your Quality Control requirements, training, accreditation support and so much more.

Have a topic of interest that you're keen on finding out more on, send us an email and request any information we have – [qualitycontrol@randox.com](mailto:qualitycontrol@randox.com)



### Brochures

All Randox Quality Control brochures can be found on this resource hub, whether you're looking for more information on our range of internal quality controls, external quality assessment or interlaboratory data management software – all brochures are available to download.



### Educational Guides

Randox help to support laboratories by providing thought-provoking, market leading insights and multiple laboratory related topics of interest. Our range of educational material includes meeting ISO 15189 accreditation requirements, commutability, how to establish QC reference ranges and many more.



### Videos

We have a range of videos including our promotional video and a full portfolio of educational webinars and tutorials. Find out more on how to interpret RIQAS reports, the role of EQA in QC management, utilising QC software and metrics to help identify performance metrics.



### Posters

Download and print off our range of posters to decorate your work environment, find out the difference between IQC and EQA, using QC multi-rules, monitor your EQA performance and more.

# ANTIOXIDANT CONTROLS

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Free radicals are highly reactive molecules that seek stability by gaining other electrons. In their attempt to do this they often attack nearby molecules, resulting in cellular or systemic damage. Antioxidants act by preventing or slowing the damage caused by these free radicals. A reduction in total antioxidant status has been identified in several disease states, such as cancer and heart disease. Our Acusera Antioxidant Quality Controls are lyophilised for enhanced stability and cover a range of antioxidants ideal for both clinical and research use.

Antioxidant Product Range			
Product Description	Size	Cat No	Page No
Glutathione Peroxidase (Ransel) Control	10 x 1 ml	SC692	09
Glutathione Peroxidase (Ransel) Calibrator	10 x 1 ml	SC10154	09
Glutathione Reductase Control	10 x 5 ml	GR2608	09
Glutathione Reductase Calibrator	10 x 5 ml	GR2609	09
Superoxide Dismutase (Ransod) Control	10 x 1 ml	SD126	09
Total Antioxidant Status (TAS) Control	10 x 5 ml	NX2331	09
Total Antioxidant Status (TAS) Calibrator	10 x 1 ml	NX2332	09



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# ANTIOXIDANTS

## Glutathione Peroxidase (Ransel) Control and Calibrator

A bovine based, whole blood control designed for use in the routine monitoring of accuracy and precision. This product is compatible for use on most clinical chemistry analysers.

- Lyophilised for enhanced stability
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 3 days at 2°C to 8°C
- Single point calibrator

Description	Size	Cat No
Ransel Control	10 x 1 ml	SC692
Ransel Calibrator	10 x 1 ml	SC10154

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## Glutathione Reductase Control and Calibrator

A bovine based control designed for use in the routine monitoring of accuracy and precision. This product is compatible for use on most clinical chemistry analysers.

- Lyophilised for enhanced stability
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 1 days at 2°C to 8°C or 8 hours at 15°C to 25°C

Description	Size	Cat No
Glutathione Reductase Control	10 x 5 ml	GR2608
Glutathione Reductase Calibrator	10 x 5 ml	GR2609

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## Superoxide Dismutase (Ransod) Control

A bovine based, whole blood control designed for use in the routine monitoring of accuracy and precision. This product is compatible for use on most clinical chemistry analysers.

- Lyophilised for enhanced stability
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 10 days at 2°C to 8°C

Description	Size	Cat No
Ransod Control	10 x 1 ml	SD126

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## Total Antioxidant Status (TAS) Control and Calibrator

A human based control designed for use in the routine monitoring of accuracy and precision. This product is compatible for use on most clinical chemistry analysers.

### Control

- Lyophilised for enhanced stability
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 2 days at 2°C to 8°C or 12 hours at 15°C to 25°C

### Calibrator

- Lyophilised for enhanced stability
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 2 days at 2°C to 8°C or 28 days at -20°C
- Single point calibrator

Description	Size	Cat No
Total Antioxidant Status Control	10 x 5 ml	NX2331
Total Antioxidant Status Calibrator	10 x 1 ml	NX2332

# BLOOD GAS CONTROLS

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Blood Gas tests can provide crucial information for medical professionals in acute care environments. As such, the results they produce must be accurate and reliable to ensure correct patient diagnosis and subsequent treatment. Used in both clinical laboratories and at the point-of-care, our Acusera Blood Gas Controls have been designed to ensure ease-of-use and peace of mind. The liquid ready-to-use format ensures that no preparation time is needed and controls can be easily stored both on the ward and in the laboratory at 2°C to 8°C.

# BLOOD GAS

Blood Gas Product Range			
Product Description	Size	Cat No	Page No
Blood Gas Control Level 1	30 x 1.8 ml	BG5001	12
Blood Gas Control Level 2	30 x 1.8 ml	BG5002	12
Blood Gas Control Level 3	30 x 1.8 ml	BG5003	12



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

Blood Gas Control 

Analytes			
Bicarbonate Calcium Chloride	Glucose Lactate pCO <sub>2</sub>	pH pO <sub>2</sub> Potassium	Sodium

Combining 10 parameters including electrolytes and lactate, the Acusera Blood Gas control is designed to meet the demands of today's blood gas analysers. Supplied in convenient, easy to open ampoules and in a liquid ready-to-use format, preparation is kept to an absolute minimum, making this control ideally suited for POC testing. As a true third party control, assayed target values are provided, ensuring unbiased performance assessment.

- Liquid ready-to-use
- Aqueous material
- Suitable for use in POCT
- Stable to expiry date at 2°C to 8°C
- Once opened, controls should be analysed immediately for pH and blood gas analytes; for electrolyte measurements, the control should be analysed within 1 hour of opening

Description	Size	Cat No
Blood Gas Control Level 1	30 x 1.8 ml	BG5001
Blood Gas Control Level 2	30 x 1.8 ml	BG5002
Blood Gas Control Level 3	30 x 1.8 ml	BG5003

# CARDIAC CONTROLS

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The accurate diagnosis of a potentially life threatening cardiac event is essential in order to avoid misdiagnosis and/or incorrect treatment. The Acusera Cardiac Controls have been designed to cover a wide range of cardiac markers at clinical decision levels, eliminating the need for additional low level controls at extra expense. Manufactured from 100% human serum, a matrix similar to that of the patient sample is guaranteed.

Cardiac Product Range			
Product Description	Size	Cat No	Page No
BNP Controls (Beckman)	3 x 1 x 1 ml	CQ10520	15
BNP Controls (Abbott)	3 x 1 x 1 ml	CQ10521	15
BNP Controls (Siemens)	3 x 1 x 1 ml	CQ10522	15
Cardiac Control Ultra Low (Abbott & Roche)	3 x 3 ml	CQ10453	15
Cardiac Control Ultra Low (Siemens)	6 x 1 ml	CQ10428	15
Cardiac Control Level 1 (Siemens)	6 x 1 ml	CQ10429	15
Cardiac Control Level 2 (Siemens)	6 x 1 ml	CQ10430	15
Cardiac Control Level 3 (Siemens)	6 x 1 ml	CQ10431	15
CK-MB Control	10 x 2 ml	CK1212	16
CK-MB Calibrator	10 x 1 ml	CK2393	16
Tri-Level Cardiac Control	3 x 1 ml	CQ3100	16
Tri-Level Cardiac Control	3 x 2 ml	CQ3259	16
Troponin T Control	6 x 3 ml	CQ10450	16



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# CARDIAC

NEW

BNP Control  

Designed for use with in vitro diagnostics assays for the quantitative determination of BNP in human serum and plasma. The Acusera BNP control delivers an unbiased, independent assessment of analytical performance, helping to ensure accurate and reliable patient testing for BNP. Optimised for use on Beckman, Abbott and Siemens systems, these controls are also suitable for other platforms.

- Liquid ready-to-use
- Human based serum
- Stable to expiry date at 2°C to 8°C
- Open vial stability of up to 30 days at 2°C to 8°C

Description	Size	Cat No
BNP Controls (Beckman)	3 x 1 x 1 ml	CQ10520
BNP Controls (Abbott)	3 x 1 x 1 ml	CQ10521
BNP Controls (Siemens)	3 x 1 x 1 ml	CQ10522

Cardiac Control 

Analytes			
Cardiac Ultra Low Troponin I	Cardiac Level 1 NT-proBNP Troponin I	Cardiac Level 2 NT-proBNP Troponin I	Cardiac Level 3 NT-proBNP Troponin I

Delivering an unassayed solution for Troponin I and NT-proBNP testing, the Acusera Cardiac Control is designed for use with Abbott, Roche and Siemens systems. This control provides a full range of clinically relevant testing levels, including High Sensitivity Troponin I.

#### Information in relation to Abbott & Roche Control

- Liquid frozen
- Stable to expiry date at -20°C to -80°C
- Open vial stability of up to 7 days at 2°C to 8°C

#### Information in relation to Siemens Controls

- Liquid frozen
- 4 Clinically relevant levels (including Ultra-Low)
- Stable to expiry date at -20°C to -80°C
- Open vial stability of up to 5 days (Troponin I) and 7 days (NT-proBNP) at 2°C to 8°C

Description	Size	Cat No
Cardiac Control Ultra Low (Abbott & Roche)	3 x 3 ml	CQ10453
Cardiac Control Ultra Low (Siemens)	6 x 1 ml	CQ10428
Cardiac Control Level 1 (Siemens)	6 x 1 ml	CQ10429
Cardiac Control Level 2 (Siemens)	6 x 1 ml	CQ10430
Cardiac Control Level 3 (Siemens)	6 x 1 ml	CQ10431

CK-MB Control and Calibrator 

## Analytes

CK-MB

CK-NAC\*

A dedicated true third party CK-MB control designed for the routine monitoring of both accuracy and precision. Assayed target values and ranges are provided for serum start, substrate start and CK-NAC methods eliminating the need to spend time assigning target values in-house.

- Lyophilised for enhanced stability
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 5 days at 4°C, 8 hours at 25°C and 28 days at -20°C
- Single point calibrator

Description	Size	Cat No
CK-MB Control	10 x 2 ml	CK1212
CK-MB Calibrator	10 x 1 ml	CK2393

\* CK-NAC is not available in the CK-MB Calibrator

Tri-Level Cardiac Control 

## Analytes

CK (Total)	CK-MB (Mass)	Myoglobin	Troponin T
CK-MB (Activity)*	Homocysteine	Troponin I	

The Acusera Cardiac Control was designed for the routine monitoring of accuracy and precision. Assayed, instrument specific values and ranges are provided for 7 common cardiac markers, eliminating the need to spend time assigning target values in-house. The availability of two convenient pack sizes ensures suitability for all laboratory throughputs.

- Lyophilised for enhanced stability
- Human based serum
- Cut off levels for Troponin I and T in-line with international recommendations
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 5 days at 2°C to 8°C or 28 days at -20°C

Description	Size	Cat No
Tri-Level Cardiac Control	3 x 1 ml	CQ3100
Tri-Level Cardiac Control	3 x 2 ml	CQ3259

\* Only available in level 2 and level 3

NEW

Troponin T Control 

True third party control designed for use in the routine monitoring of accuracy and precision of TnT assays.

- Liquid frozen
- Ultra low levels of Troponin T
- Stable to expiry date at -18°C to -24°C
- Open vial stability of up to 7 days at 2°C to 8°C

Description	Size	Cat No
Troponin T Control	6 x 3 ml	CQ10450

# CLINICAL CHEMISTRY CONTROLS

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Our clinical chemistry controls are suitable for a range of integrated analyser systems and methods. To cover all laboratory requirements, our flexible Clinical Chemistry Controls contain up to 100 analytes, delivering effective consolidation and cost savings. Available in a choice of assayed/unassayed, liquid/lyophilised and human/bovine formats, options are available to suit all laboratory sizes and budgets.

Clinical Chemistry Product Range			
Product Description	Size	Cat No	Page No
Aldolase Calibrator	3 x 1 ml	AD5000	19
Aldolase Control Level 2	3 x 1 ml	AD5001	19
Aldolase Control Level 3	3 x 1 ml	AD5002	19
Ammonia Ethanol Control Level 1	6 x 2 ml	EA1366	19
Ammonia Ethanol Control Level 2	6 x 2 ml	EA1367	19
Ammonia Ethanol Control Level 3	6 x 2 ml	EA1368	19
Assayed Chemistry Premium Plus Level 2	20 x 5 ml	HN1530	20
Assayed Chemistry Premium Plus Level 3	20 x 5 ml	HE1532	20
Assayed Chemistry Premium Plus Level 2 & 3	2 x 5 x 5 ml	HS2611	20
Bilirubin Elevated Serum	10 x 3 ml	BE454	20
Bovine Chemistry Assayed Level 1	20 x 5 ml	AL1027	21
Bovine Chemistry Assayed Level 2	20 x 5 ml	AN1026	21
Bovine Chemistry Assayed Level 3	20 x 5 ml	AE1032	21
Clinical Chemistry Calibration Serum Level 2	20 x 5 ml	CAL2350	22
Clinical Chemistry Calibration Serum Level 3	20 x 5 ml	CAL2351	22
Ethanol Calibrator/Control Set	4 x 10 ml	DA2703	22
Glycerol Control	3 x 5 ml	GY1369	22
Liquid Assayed Chemistry Premium Plus Level 1	12 x 5 ml	LAL4213	23
Liquid Assayed Chemistry Premium Plus Level 2	12 x 5 ml	LAN4214	23
Liquid Assayed Chemistry Premium Plus Level 3	12 x 5 ml	LAE4215	23
Liquid Bilirubin Control Level 1	3 x 3 ml	BR10442	24
Liquid Bilirubin Control Level 2	3 x 3 ml	BR10443	24
Liquid Chemistry Premium Plus Level 1	12 x 5 ml	LUL5069	24
Liquid Chemistry Premium Plus Level 2	12 x 5 ml	LUN5070	24
Liquid Chemistry Premium Plus Level 3	12 x 5 ml	LUE5071	24
Multi Calibrator	3 x 2 ml	MC1382	25
Precision Chemistry Premium Plus Level 2	20 x 5 ml	UN1557	25
Precision Chemistry Premium Plus Level 3	20 x 5 ml	UE1558	25
Serum Indices Control	4 x 5 ml	SI10448	26



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# CLINICAL CHEMISTRY

## Aldolase Control and Calibrator

This dedicated Aldolase control is specifically designed to monitor the accuracy and precision of Aldolase on a wide range of chemistry analysers. Supplied in a lyophilised format for enhanced stability, this control and calibrator set comes in a convenient 1ml vial.

- Lyophilised for enhanced stability
- Human based serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of up to 5 days at 2°C to 8°C
- Single point calibrator

Description	Size	Cat No
Aldolase Calibrator	3 x 1 ml	AD5000
Aldolase Control Level 2	3 x 1 ml	AD5001
Aldolase Control Level 3	3 x 1 ml	AD5002

## Ammonia Ethanol Control

This dedicated Ammonia/Ethanol control comes in a highly convenient, liquid ready-to-use format ensuring no preparation is required. As a true third party control, assayed target values are provided, ensuring unbiased performance assessment while eliminating the need for in-house value assignment.

- Liquid ready-to-use
- Aqueous material
- Stable to expiry date at 2°C to 8°C
- Open vial stability of up to 30 days at 2°C to 8°C

Description	Size	Cat No
Ammonia Ethanol Control Level 1	6 x 2 ml	EA1366
Ammonia Ethanol Control Level 2	6 x 2 ml	EA1367
Ammonia Ethanol Control Level 3	6 x 2 ml	EA1368

## Assayed Chemistry Premium Plus Control

Analytes			
<b>Cardiac</b> CK (Total)	<b>Immunoassay</b> Cortisol Folate PSA (Total) T3 (Total) T4 (Free) T4 (Total) TSH Vitamin B <sub>12</sub>	<b>Immunoglobulin M (IgM)</b> Protein (Total) Transferrin	D-3-Hydroxybutyrate γGT GLDH Glucose Iron Iron (TIBC) Iron (UIBC) Lactate Lactate Dehydrogenase (LDH) Lipase Magnesium Osmolality Phosphate (Inorganic) Potassium Sodium Urea Uric Acid (Urate)
<b>Drugs</b> Digoxin Gentamicin Lithium Paracetamol Salicylate Theophylline Tobramycin	<b>Routine Chemistry</b> α-HBDH Acid Phosphatase (Total) Albumin Alkaline Phosphatase (ALP) ALT (GPT) Amylase Amylase (Pancreatic) AST (GOT) Bicarbonate Bile Acids Bilirubin (Direct) Bilirubin (Total) Calcium Chloride Cholinesterase Creatinine		
<b>Electrophoresis</b> α-1-Globulin α-2-Globulin Albumin β-Globulin γ-Globulin	<b>Lipids</b> Apolipoprotein A-1 Apolipoprotein B Cholesterol (HDL) Cholesterol (Total) NEFA Triglycerides		<b>Trace Metals</b> Copper Zinc
	<b>Proteins</b> Immunoglobulin A (IgA) Immunoglobulin G (IgG)		

One of our most popular controls, the Acusera Assayed Chemistry Premium Plus Control, combines a comprehensive 68 analytes in a single vial for maximum efficiency. As a true third party control, assayed instrument, method and temperature specific target values are provided for an extensive range of clinical chemistry analysers, reducing the need to assign values in-house. Also provided are electrophoresis targets as a % breakdown of total protein.

- Lyophilised for enhanced stability
- Human based serum
- Typical Osmolality values: Level 2 is 300 mOsm/kg, Level 3 is 370 mOsm/kg
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of up to 7 days at 2°C to 8°C or 28 days at -20°C

Description	Size	Cat No
Assayed Chemistry Premium Plus Level 2	20 x 5 ml	HN1530
Assayed Chemistry Premium Plus Level 3	20 x 5 ml	HE1532
Assayed Chemistry Premium Plus Level 2 & 3	2 x 5 x 5 ml	HS2611

## Bilirubin Elevated Serum

Analytes		
Bilirubin (Direct)		Bilirubin (Total)

Acusera Bilirubin Elevated Serum is a bovine based serum designed for use in the monitoring of accuracy and precision. This product is suitable for monitoring paediatric bilirubin levels and contains method specific target values and ranges.

- Lyophilised for enhanced stability
- Bovine serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 5 days at 2°C to 8°C

Description	Size	Cat No
Bilirubin Elevated Serum	10 x 3 ml	BE454

# CLINICAL CHEMISTRY

## Bovine Chemistry Assayed Control

Analytes			
<b>Cardiac</b> CK (Total)	<b>Lipids</b> Cholesterol NEFA Triglycerides	Bicarbonate Bile Acids Bilirubin (Direct) Bilirubin (Total) Calcium Chloride Creatinine D-3-Hydroxybutyrate <b>Proteins</b> Protein (Total)	Magnesium Osmolality Phosphate (Inorganic) Potassium Sodium Urea Uric Acid (Urate)
<b>Drugs</b> Lithium			
<b>Immunoassay</b> Cortisol PSA (Total) T3 (Total) T4 (Free) T4 (Total) Vitamin B <sub>12</sub>	<b>Routine Chemistry</b> α-HBDH Acid Phosphatase (Total) Albumin Alkaline Phosphatase (ALP) ALT (GPT) Amylase AST (GOT)	γGT GLDH Glucose Iron Iron (TIBC) Lactate Lactate Dehydrogenase (LDH) Lipase	<b>Trace Metals</b> Copper Zinc

Designed for use in the routine monitoring of accuracy and precision, this comprehensive bovine based, assayed control provides method, instrument and temperature specific values for a unique combination of 44 analytes. Due to its bovine serum matrix and inclusion of common veterinary markers; NEFA, Bile Acids, Lactate and D-3 Hydroxybutyrate, the Acusera Bovine Chemistry Assayed Control delivers a cost effective solution especially suited to veterinary laboratories.

- Lyophilised for enhanced stability
- Bovine based serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of up to 7 days at 2°C to 8°C or 28 days at -20°C
- GLDH is stable for 1 day at 2°C to 8°C and TIBC (AL1027 Only) is stable for 4 days at 2°C to 8°C

Description	Size	Cat No
Bovine Chemistry Assayed Level 1	20 x 5 ml	AL1027
Bovine Chemistry Assayed Level 2	20 x 5 ml	AN1026
Bovine Chemistry Assayed Level 3	20 x 5 ml	AE1032

## Clinical Chemistry Calibration Serum

Analytes			
<b>Cardiac</b> CK (Total)	<b>Routine Chemistry</b> α-HBDH Acid Phosphatase (Total) Albumin Alkaline Phosphatase (ALP) ALT (GPT) Amylase (Pancreatic) Amylase (Total) AST (GOT) Bicarbonate Bile Acids Bilirubin (Direct) Bilirubin (Total)	Calcium Chloride Cholinesterase Creatinine D-3-Hydroxybutyrate γGT GLDH Glucose Iron Iron (TIBC) Lactate Lactate Dehydrogenase (LDH) Lipase	Magnesium Osmolality Phosphate (Inorganic) Potassium Sodium Urea Uric Acid (Urate)
<b>Drugs</b> Lithium			
<b>Lipids</b> Cholesterol Triglycerides			
<b>Proteins</b> Protein (Total)			<b>Trace Metals</b> Copper Zinc

Comprising 40 analytes in a single vial, this multi-analyte, third party calibrator is designed for use with a wide range of clinical chemistry platforms. Assayed, instrument, method and temperature specific values are supplied, ensuring accurate and reliable instrument calibration.

- Lyophilised for enhanced stability
- Human based serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of up to 7 days at 2°C to 8°C or 28 days at -20°C
- Multi-point calibration serum

Description	Size	Cat No
Clinical Chemistry Calibration Serum Level 2	20 x 5 ml	CAL2350
Clinical Chemistry Calibration Serum Level 3	20 x 5 ml	CAL2351

## Ethanol Calibrator/Control Set

Dedicated calibrator and control set designed for the calibration and quality control of the Randox Ethanol assay.

- Liquid ready-to-use
- Human urine
- Stable to expiry date when capped and stored at 2°C to 8°C
- Open vial stability of 28 days at 2°C to 8°C

Description	Size	Cat No
Ethanol Calibrator/Control Set	4 x 10 ml	DA2703

## Glycerol Control

Dedicated Glycerol control for use in the routine monitoring of accuracy and precision. Supplied in a lyophilised format for enhanced stability, this control comes with assayed target values for most major chemistry analysers.

- Lyophilised for enhanced stability
- Human based serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 7 days at 2°C to 8°C

Description	Size	Cat No
Glycerol Control	3 x 5 ml	GY1369

# CLINICAL CHEMISTRY

## Liquid Assayed Chemistry Premium Plus Control



Analytes			
<b>Cardiac</b>	<b>Immunoassay</b>	<b>Proteins</b>	Bile Acids
CK (Total)	$\alpha$ -Fetoprotein (AFP)	$\alpha$ -1-Acid Glycoprotein	Bilirubin (Direct)
Myoglobin	CEA	$\alpha$ -1-Antitrypsin	Bilirubin (Total)
Troponin T	Cortisol	$\beta$ -2-Microglobulin	Calcium
	DHEA Sulphate	Ceruloplasmin	Chloride
<b>Drugs</b>	Folate	Complement C3	Cholinesterase
Amikacin	FSH	Complement C4	Creatinine
Caffeine	hCG	CRP	D-3-Hydroxybutyrate
Carbamazepine	Luteinising Hormone (LH)	Ferritin	$\gamma$ GT
Digoxin	Progesterone	Haptoglobin	GLDH
Ethanol	Prolactin	Immunoglobulin A (IgA)	Glucose
Gentamicin	PSA (Total)	Immunoglobulin E (IgE)	Iron
Lithium	T Uptake	Immunoglobulin G (IgG)	Iron (TIBC)
Paracetamol	T3 (Free)	Immunoglobulin M (IgM)	Lactate
Phenobarbitone	T3 (Total)	Prealbumin	Lactate Dehydrogenase (LDH)
Phenytoin	T4 (Free)	Protein (Total)	Lipase
Salicylate	T4 (Total)	Transferrin	Magnesium
Theophylline	Testosterone		Osmolality
Valproic Acid	TSH		Phosphate (Inorganic)
Vancomycin	Vitamin B <sub>12</sub>		Potassium
			Sodium
<b>Electrophoresis</b>	<b>Lipids</b>		Urea
$\alpha$ -1-Globulin	Apolipoprotein A-1		Uric Acid (Urate)
$\alpha$ -2-Globulin	Apolipoprotein B		
Albumin	Cholesterol (HDL)		<b>Trace Metals</b>
$\beta$ -Globulin	Cholesterol (LDL)		Copper
$\gamma$ -Globulin	Cholesterol (Total)		Zinc
	Lipoprotein (a)		
	Triglycerides		

Uniquely combining up to 99 analytes including; routine chemistry, immunoassays, lipids, therapeutic drugs, proteins and cardiac markers in a single vial, laboratories can experience effective consolidation and significant cost savings. The presence of CRP and other proteins at elevated levels will not only ensure accurate instrument performance at key decision levels but further reduce the number of individual controls required. As a true third party control, assayed target values are provided for most major instruments.

- Liquid frozen
- Human based serum
- Assayed instrument specific target values and ranges
- High levels of CRP and other proteins eliminate the need for multiple controls
- Stable to expiry when stored at -20°C to -80°C
- Open vial stability of up to 7 days at 2°C to 8°C

Description	Size	Cat No	
Liquid Assayed Chemistry Premium Plus Level 1	12 x 5 ml	LAL4213	
Liquid Assayed Chemistry Premium Plus Level 2	12 x 5 ml	LAN4214	
Liquid Assayed Chemistry Premium Plus Level 3	12 x 5 ml	LAE4215	*No claims are made regarding values or stability

NEW

Liquid Bilirubin Control



## Analytes

Bilirubin (Direct)

Bilirubin (Total)

Providing a true third party solution of Bilirubin, this control is designed to deliver an unbiased, independent assessment of performance. Two levels are available covering the required clinically relevant decision levels for neonatal testing and adult liver disease.

- Liquid frozen
- 100% human serum
- Stable to expiry when stored at -20°C to -80°C
- Open vial stability of 7 days at 2°C to 8°C
- Elevated levels of Bilirubin ensure clinical decision levels are met

Description	Size	Cat No
Liquid Bilirubin Control Level 1	3 x 3 ml	BR10442
Liquid Bilirubin Control Level 2	3 x 3 ml	BR10443

## Liquid Chemistry Premium Plus Control



## Analytes

<b>Cardiac</b>	<b>Immunoassay</b>	<b>Proteins</b>	<b>Bilirubin (Direct)</b>
CK (Total)	α-Fetoprotein (AFP)	α-1-Acid Glycoprotein	Bilirubin (Total)
Myoglobin	CEA	α-1-Antitrypsin	Calcium
Troponin T	Cortisol	β-2-Microglobulin	Chloride
<b>Drugs</b>	DHEA Sulphate	Ceruloplasmin	Cholinesterase
Amikacin	Folate	Complement C3	Creatinine
Caffeine	FSH	Complement C4	D-3-Hydroxybutyrate
Carbamazepine	Growth Hormone (GH)	CRP	γGT
Digoxin	hCG	Ferritin	GLDH
Ethanol	Luteinising Hormone (LH)	Haptoglobin	Glucose
Gentamicin	Progesterone	Immunoglobulin A (IgA)	Iron
Lithium	Prolactin	Immunoglobulin E (IgE)	Iron (TIBC)
Paracetamol	Testosterone	Immunoglobulin G (IgG)	Iron (UIBC)
Phenobarbitone	T Uptake	Immunoglobulin M (IgM)	Lactate
Phenytoin	T3 (Free)	Prealbumin	Lactate Dehydrogenase (LDH)
Salicylate	T3 (Total)	Protein (Total)	LAP
Theophylline	T4 (Free)	Transferrin	Lipase
Valproic Acid	T4 (Total)		Magnesium
Vancomycin	TSH		Osmolality
	Vitamin B <sub>12</sub>		Phosphate (Inorganic)
<b>Electrophoresis</b>	<b>Lipids</b>		Potassium
α <sub>1</sub> -Globulin	Apolipoprotein A-1		Sodium
α <sub>2</sub> -Globulin	Apolipoprotein B		Urea
Albumin	Cholesterol (HDL)		Uric Acid (Urate)
β <sub>2</sub> -Globulin	Cholesterol (LDL)		
γ-Globulin	Cholesterol (Total)		
	Lipoprotein (a)		<b>Trace Metals</b>
	Triglycerides		Copper
			Zinc

Comprising 100 analytes in total, the Acusera Liquid Chemistry Premium Plus control is one of the most comprehensive available. Our vast analyte menu allows complete consolidation, eliminating the need to purchase additional controls at extra expense. As an unassayed, third party control it is ideal for monitoring precision on a wide range of laboratory analysers. Presented in a convenient liquid format for ease-of-use, minimal preparation is required.

- Liquid frozen
- Human based serum
- High levels of CRP and other proteins eliminate the need for separate controls
- Stable to expiry date at -20°C to -80°C
- Open vial stability of up to 7 days at 2°C to 8°C
- Typical values provided for all analytes

Description	Size	Cat No
Liquid Chemistry Premium Plus Level 1	12 x 5 ml	LUL5069
Liquid Chemistry Premium Plus Level 2	12 x 5 ml	LUN5070
Liquid Chemistry Premium Plus Level 3	12 x 5 ml	LUE5071

\*No claims are made regarding values or stability

# CLINICAL CHEMISTRY

## Multi Calibrator



Analytes			
Ammonia	Glucose	Glutamate	Lactate

This multi-analyte calibrator is designed for use in the routine monitoring of accuracy and precision. Supplied in a convenient liquid ready-to-use format no preparation is required.

- Liquid ready-to-use
- Human based serum
- Stable to expiry date at 2°C to 8°C
- Once opened stable to expiry date at 2°C to 8°C
- Single point calibrator

Description	Size	Cat No
Multi Calibrator	3 x 2 ml	MC1382

## Precision Chemistry Premium Plus Control



Analytes			
<b>Cardiac</b> CK (Total) Myoglobin Troponin I	Prolactin PSA (Total) T3 (Free) T3 (Total) T4 (Free) T4 (Total) TSH Vitamin B <sub>12</sub>	Ferritin Haptoglobin Immunoglobulin A (IgA) Immunoglobulin E (IgE) Immunoglobulin G (IgG) Immunoglobulin M (IgM) Prealbumin Protein (Total) Transferrin	Cholinesterase Creatinine D-3-Hydroxybutyrate γGT GLDH Glucose Iron Iron (TIBC) Lactate Lactate Dehydrogenase (LDH) LAP Lipase Magnesium Osmolality Phosphate (Inorganic) Potassium Sodium Urea Uric Acid (Urate)
<b>Drugs</b> Carbamazepine Digoxin Gentamicin Lithium Paracetamol Phenobarbitone Phenytoin Salicylate Theophylline Tobramycin Valproic Acid Vancomycin	Apolipoprotein A-I Apolipoprotein B Cholesterol (HDL) Cholesterol (Total) NEFA Triglycerides	Routine Chemistry α-HBDH Acid Phosphatase (Total) Albumin Alkaline Phosphatase (ALP) ALT (GPT) Amylase Amylase (Pancreatic) AST (GOT) Bicarbonate Bile Acids Bilirubin (Direct) Bilirubin (Total) Calcium Chloride	
<b>Immunoassay</b> α-Fetoprotein (AFP) CEA Cortisol Folate hCG	α-1-Acid Glycoprotein α-1-Antitrypsin Ceruloplasmin Complement C3 Complement C4 CRP		<b>Trace Metals</b> Copper Zinc

Our Precision Chemistry Premium Plus control conveniently covers 84 analytes; including a wide range of proteins, lipids and immunoassays making it perfect for consolidation. As an unassayed, third party control it is suitable for use with a wide range of clinical chemistry platforms.

- Lyophilised for enhanced stability
- Human based serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of up to 7 days at 2°C to 8°C or 28 days at -20°C

Description	Size	Cat No
Precision Chemistry Premium Plus Level 2	20 x 5 ml	UN1557
Precision Chemistry Premium Plus Level 3	20 x 5 ml	UE1558

**NEW**

Serum Indices Control

**Analytes**

Haemolysis (H)

Icterus (I)

Lipemia (L)

Designed to be used to monitor an IVD instrument's response in the detection of haemolysed, icteric and lipemic (HIL) samples. This control can be utilised in laboratory interference testing to assist in improving error detection of pre-analytical errors affecting clinical chemistry testing.

- Lyophilised for enhanced stability
- Human based serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 14 days at 2°C to 8°C
- 4 separate levels available including a negative (-) and three positives (+, ++ & +++)

Description	Size	Cat No
Serum Indices Control	4 x 5 ml	SI10448

# COAGULATION AND HAEMATOLOGY CONTROLS

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Our true third party Coagulation and Haematology Controls have been designed to deliver an unbiased assessment of analytical performance, while providing a matrix similar to that of the patient. These multianalyte controls cover the full clinical range in a single control, enabling you to consolidate your test menu, saving both time and money.

# COAGULATION AND HAEMATOLOGY

Coagulation and Haematology Product Range			
Product Description	Size	Cat No	Page No
Coagulation Control Level 1	12 x 1 ml	CG5021	29
Coagulation Control Level 2	12 x 1 ml	CG5022	29
Coagulation Control Level 3	12 x 1 ml	CG5023	29
Haematology Control	3 x 2 x 4.5 ml	HM5162	29



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# COAGULATION AND HAEMATOLOGY

## Coagulation Control

Analytes			
Activated Partial Thromboplastin Time (APTT)	Factor VII	Factor XI	Protein C
Anti-Thrombin III (AT III)	Factor VIII	Factor XII	Protein S
Factor II	Factor IX	Fibrinogen	Prothrombin Time (PT)
Factor V	Factor X	Plasminogen	Thrombin Time (TT)

Our Coagulation Control combines 16 analytes in total, delivering a comprehensive, third party solution for laboratories carrying out both routine and specialised coagulation tests. Comprising a variety of factor assays and basic coagulation tests, the number of individual controls required is reduced, saving costs and time. Assayed method and instrument specific target values & ranges are provided, eliminating the need to spend time assigning target values in-house.

- Lyophilised for enhanced stability
- 100% human material
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of up to 24 hours at 2°C to 8°C

Description	Size	Cat No
Coagulation Control Level 1	12 x 1 ml	CG5021
Coagulation Control Level 2	12 x 1 ml	CG5022
Coagulation Control Level 3	12 x 1 ml	CG5023

## Haematology Control

Analytes			
BASO-X	Mean Platelet Volume (MPV)		
BASO -Y	Monocytes (MONO)		
Basophils (BASO)*	% Monocytes (% MONO)		
% Basophils (% BASO)	Neutrophils (NEUT)		
DIFF-X	% Neutrophils (% NEUT)		
DIFF-Y	Nucleated Red Blood Cells (NRBC)*		
Eosinophils (EOS)	Nucleated Red Blood Cells X (NRBC-X)		
% Eosinophils (%EOS)	Nucleated Red Blood Cells Y (NRBC-Y)		
FSC-X	% Nucleated Red Blood Cells (%NRBC)		
Haematocrit (HCT)	Platelet Distribution Width (PDW)		
Haemoglobin (HGB)	Platelet Large Cell Ratio (P-LCR)		
Haematopoietic Progenitor Cell (HPC)	Plateletcrit (PCT)		
IMIDC	Platelets (PLT)		
IMIRF	Platelets Optical Count (PLT-O)		
Immature Granulocytes (IG)	Red Blood Cells (RBC)		
% Immature Granulocytes (%IG)	Red Blood Cell X (RBC-X)		
Immature Myeloid Information (IMI)	Red Blood Cell Y (RBC-Y)		
Immature Platelet Fraction (IPF)	Red Blood Cell Distribution Width CV (RDW-CV)		
Lymphocytes (LYMPH)	Red Blood Cell Distribution Width SD (RDW-SD)		
% Lymphocytes (% LYMPH)	Red Blood Cells Optical Count (RBC-O)		
Mean Corpuscular Haemoglobin (MCH)	White Blood Cells (WBC)		
Mean Corpuscular Haemoglobin Concentration (MCHC)	White Blood Cells Differential (WBC-D)		
Mean Corpuscular Volume (MCV)			

The Acusera Haematology Control combines an impressive 45 analytes, covering the full blood profile in a convenient liquid ready-to-use format, ultimately increasing productivity and reducing the need for multiple controls. Providing a true third party solution for 5-part WBC differential Sysmex Haematology and Mindray analysers, ensuring unbiased performance assessment.

- Liquid ready-to-use
- 100% Human whole blood
- Barcoded labels enabling quick and easy sample recognition
- Stable for 70 days at 2°C to 8°C
- Open vial stability of 14 days at 2°C to 8°C

Description	Size	Cat No
Haematology Control Tri-Level	3 x 2 x 4.5 ml	HM5162

\*This product may not be suitable for the control of Basophils and NRBC on some Sysmex models

# DIABETES AND WHOLE BLOOD CONTROLS

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This Acusera Diabetes range provides a true third party solution for key tests used in the diagnosis and monitoring of diabetes and haemoglobin variants. Designed for use on multiple platforms, an independent assessment of performance is guaranteed. An extended reconstituted stability of four weeks for many controls will not only keep waste to a minimum but will help to reduce costs. As with all Acusera controls, laboratories can expect to experience reduced preparation time and costs without compromising on consistency or quality.

# DIABETES AND WHOLE BLOOD

Diabetes and Whole Blood Product Range			
Product Description	Size	Cat No	Page No
Fructosamine Control Level 1	3 x 1 ml	FR2994	32
Fructosamine Control Level 3	3 x 1 ml	FR2996	32
Fructosamine Calibrator	3 x 1 ml	FR2993	32
G-6PDH Control Deficient	6 x 0.5 ml	PD2617	32
G-6PDH Control Normal	6 x 0.5 ml	PD2618	32
HbA1c Control Set Level 1 and 2	2 x 2 x 0.5 ml	HA5072	32
HbA1c Calibrator Series	5 x 2 ml, 1 x 8 ml	HA3444	32
Liquid HbA1c Control Level 1	6 x 1 ml	HA10224	33
Liquid HbA1c Control Level 2	6 x 1 ml	HA10225	33
Liquid HbA1c Control Set	2 x 2 x 0.5 ml	HA10155	33



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# DIABETES AND WHOLE BLOOD

## Fructosamine Control and Calibrator

The Acusera Fructosamine control is specifically designed to monitor the accuracy and precision of fructosamine assays. An extended reconstituted stability of 28 days at 2°C to 8°C keeps waste to a minimum and helps to reduce costs.

- Lyophilised for enhanced stability
- Aqueous Based Material
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 28 days at 2°C to 8°C
- Single point calibrator

Description	Size	Cat No.
Fructosamine Control Level 1	3 x 1 ml	FR2994
Fructosamine Control Level 3	3 x 1 ml	FR2996
Fructosamine Calibrator	3 x 1 ml	FR2993

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## G-6-PDH (Glucose-6-Phosphate Dehydrogenase) Control

The Randox Acusera G-6-PDH control is designed specifically to monitor the accuracy and precision of G-6-PDH assays. Two levels of control are available covering both normal and deficient concentration ranges.

- Lyophilised for enhanced stability
- Stabilised red cell haemolysate
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 5 days at 2°C to 8°C

Description	Size	Cat No
G-6-PDH Control Deficient	6 x 0.5 ml	PD2617
G-6-PDH Control Normal	6 x 0.5 ml	PD2618

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## HbA1c Control and Calibrator Series

The Acusera HbA1c control is designed for use in the quality control of HbA1c assays. Assayed instrument and method specific target values and ranges are provided for all major systems and methods including HPLC. A reconstituted stability of 4 weeks keeps waste to a minimum and helps to reduce costs.

### Control

- Lyophilised for enhanced stability
- 100% human whole blood
- Treated in the same manner as a patient sample (requires pre-treatment)
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 28 days at 2°C to 8°C

### Calibrator

- Liquid ready-to-use
- 100% human whole blood
- Treated in the same manner as a patient sample (requires pre-treatment)
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 28 days at 2°C to 8°C
- Multi-point calibrator

Description	Size	Cat No
HbA1c Control Set Level 1 and 2	2 x 2 x 0.5 ml	HA5072
HbA1c Calibrator Series	5 x 2 ml, 1 x 8 ml	HA3444

# DIABETES AND WHOLE BLOOD

## Liquid HbA1c Control

Delivering an assayed QC solution for HbA1c testing, our Acusera Liquid HbA1c control offers a liquid ready-to-use format ideal for both laboratory and POCT testing. Employing our Liquid HbA1c Control in your laboratory could reduce preparation time, whilst the 30 day stability will ultimately minimise waste and costs.

- Liquid ready-to-use
- Human based whole blood
- Suitable for use in POCT
- Treated in the same manner as a patient sample (*requires pre-treatment*)
- Assayed target values are supplied for HPLC
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 30 days at 2°C to 8°C

Description	Size	Cat No
Liquid HbA1c Control Level 1	6 x 1 ml	HA10224
Liquid HbA1c Control Level 2	6 x 1 ml	HA10225
Liquid HbA1c Control Set	2 x 2 x 0.5 ml	HA10155

# IMMUNOASSAY CONTROLS

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As one of the most comprehensive control ranges on the market, the Acusera Immunoassay offering from Randox will streamline QC in any laboratory. With multiple immunoassay controls to choose from, combining up to 55 analytes in a single vial, choice and flexibility is guaranteed. Our unique combination of analytes enables complete test menu consolidation, ultimately reducing costs without compromising on quality or performance. All controls in our Immunoassay range are manufactured from 100% human serum. This matrix ensures the test system will react to the control in the same manner as a patient sample, therefore meeting ISO 15189:2022 requirements while also eliminating shifts in QC target values when reagent batch is changed.

# IMMUNOASSAY

Immunoassay Product Range			
Product Description	Size	Cat No	Page No
AMH Control Level 1	3 x 2 ml	AMH10509	36
AMH Control Level 2	3 x 2 ml	AMH10514	36
AMH Control Level 3	3 x 2 ml	AMH10515	36
AMH Control Level 4	3 x 2 ml	AMH10516	36
Bone Markers (Serum) Control Level 1	6 x 2 ml	SBM10574	36
Bone Markers (Serum) Control Level 2	6 x 2 ml	SBM10587	36
Bone Markers (Serum) Control Level 3	6 x 2 ml	SBM10588	36
Bone Markers (Urine) Control Level 1	3 x 2 ml	UBM10573	36
Bone Markers (Urine) Control Level 2	3 x 2 ml	UBM10589	37
Immunoassay Premium Level 1	12 x 5 ml	IA2638	37
Immunoassay Premium Level 2	12 x 5 ml	IA2639	37
Immunoassay Premium Level 3	12 x 5 ml	IA2640	37
Immunoassay Premium Tri-Level	3 x 4 x 5 ml	IA2633	37
Immunoassay Premium Plus Level 1	12 x 5 ml	IA3109	38
Immunoassay Premium Plus Level 2	12 x 5 ml	IA3110	38
Immunoassay Premium Plus Level 3	12 x 5 ml	IA3111	38
Immunoassay Premium Plus Tri-Level	3 x 4 x 5 ml	IA3112	38
Immunoassay Speciality I Level 1	5 x 2 ml	IAS3113	39
Immunoassay Speciality I Level 2	5 x 2 ml	IAS3114	39
Immunoassay Speciality I Level 3	5 x 2 ml	IAS3115	39
Immunoassay Speciality II Level 1	5 x 1 ml	IAS3117	39
Immunoassay Speciality II Level 2	5 x 1 ml	IAS3118	39
Immunoassay Speciality II Level 3	5 x 1 ml	IAS3119	39
Liquid Immunoassay Premium Tri-Level	3 x 4 x 5 ml	LIA3108	40
Maternal Screening Control Level 1	3 x 1 ml	MSS5024	40
Maternal Screening Control Level 2	3 x 1 ml	MSS5025	40
Maternal Screening Control Level 3	3 x 1 ml	MSS5026	40
PTH Control Level 1	3 x 3 ml	PTH10110	41
PTH Control Level 2	3 x 3 ml	PTH10111	41
PTH Control Level 3	3 x 3 ml	PTH10112	41
Tumour Marker Control Level 2	3 x 2 ml	TU5002	41
Tumour Marker Control Level 3	3 x 2 ml	TU5003	41
Ultra-Low PSA Control	6 x 1 ml	TU10523	41



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

## NEW

Anti-Müllerian Hormone (AMH) Control  

The Randox Acusera AMH control is designed to use as a third party control for the quantitative determination of Anti-Müllerian Hormone (AMH).

- Liquid frozen
- Human based serum
- Available at recommended cut-off values for AMH
- Assayed target values and ranges for a wide range of immunoassay systems
- Stable to expiry date at -20°C to -80°C
- Open vial stability of 30 days at 2°C to 8°C

Description	Size	Cat No
AMH Control Level 1	3 x 2 ml	AMH10509
AMH Control Level 2	3 x 2 ml	AMH10514
AMH Control Level 3	3 x 2 ml	AMH10515
AMH Control Level 4	3 x 2 ml	AMH10516

## NEW

Bone Markers (Serum) Control  

## Analytes

Bone Alkaline Phosphatase (B-ALP)	N-MID Osteocalcin (OC)	Procollagen Type 1 N-Terminal Propeptide (P1NP)
-----------------------------------	------------------------	---

The Randox Acusera Bone Markers (serum) control provides a third party solution for monitoring the performance of bone markers in serum.

- Lyophilised for enhanced stability
- Human based serum
- Assayed target values and ranges for a wide range of immunoassay systems
- Stable to expiry date at 2°C to 8°C
- P1NP and B-ALP are stable for 14 days when reconstituted at 2°C to 8°C, OC is stable for 1-day when reconstituted at 2°C to 8°C

Description	Size	Cat No
Bone Markers (Serum) Control Level 1	6 x 2 ml	SBM10574
Bone Markers (Serum) Control Level 2	6 x 2 ml	SBM10587
Bone Markers (Serum) Control Level 3	6 x 2 ml	SBM10588

# IMMUNOASSAY

NEW

## Bone Markers (Urine) Control



### Analytes

β-2-Microglobulin  
C-Telopeptide\*

Creatinine  
Deoxypyridinoline

Pyridinium Crosslinks  
Pyridinoline\*

N-Telopeptide

The Randox Acusera Bone Markers (urine) control provides a third party solution for monitoring the performance of bone markers in urine.

- Lyophilised for enhanced stability
- Human based urine
- Assayed target values and ranges for a wide range of immunoassay systems
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of up to 14 days at 2°C to 8°C or 28 days at -20°C

Description	Size	Cat No
Bone Markers (Urine) Control Level 1	3 x 2 ml	UBM10573
Bone Markers (Urine) Control Level 2	3 x 2 ml	UBM10589

\*No claims are made regarding value or stability

## Immunoassay Premium Control



### Analytes

17-OH-Progesterone	DHEA-Sulphate	Oestradiol	T3 (Free)
1,25-(OH) <sub>2</sub> -Vitamin D*	Digoxin	Paracetamol	T3 (Total)
25-OH-Vitamin D	Estriol	Phenobarbitone	T4 (Free)
α-Fetoprotein (AFP)	Ethosuximide	Phenytoin	T4 (Total)
ACTH <sup>+</sup>	Ferritin	Primidone	Testosterone
Aldosterone	Folate	Progesterone	Testosterone (Free)*
Amikacin	FSH	Prolactin	Theophylline
Androstenedione	Gentamicin	PSA (Free)	Thyroglobulin
β-2-Microglobulin	Growth Hormone (GH)	PSA (Total)	Tobramycin
C-Peptide	hCG	PTH (Parathyroid Hormone)*	TSH
Carbamazepine	Immunoglobulin E (IgE)	Salicylate	Valproic Acid
CEA	Insulin	Sex Hormone Binding Globulin (SHBG)	Vancomycin
Cortisol	Luteinising Hormone (LH)	T Uptake	Vitamin B <sub>12</sub>

Efficiently combining 52 analytes in total, the Immunoassay Premium Control is designed to cover routine immunoassay testing in a single vial. The additional benefit of clinically relevant concentrations will not only ensure accurate performance at key decision levels, but will also eliminate the need for additional low/high controls at extra expense. As an assayed control, instrument specific target values and ranges are provided for up to 46 analytes, including fertility, thyroid & steroid hormones, kidney function tests, therapeutic drugs and vitamins, saving you time assigning these in-house. Manufactured using 100% human serum, this control is designed to directly mimic a patient sample, reducing costly shifts when reagent batch is changed.

- Lyophilised for enhanced stability
- 100% human serum
- Ferritin and Vitamin B<sub>12</sub> levels suitable for Anaemia monitoring
- Ultra low TSH levels in the level 1 control
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of up to 7 days at 2°C to 8°C, or up to 28 days at -20°C

Description	Size	Cat No
Immunoassay Premium Level 1	12 x 5 ml	IA2638
Immunoassay Premium Level 2	12 x 5 ml	IA2639
Immunoassay Premium Level 3	12 x 5 ml	IA2640
Immunoassay Premium Tri-level	3 x 4 x 5 ml	IA2633

\*Values may not be provided for all levels

\*No claims are made regarding value or stability

Immunoassay Premium Plus Control 

Analytes			
17-OH-Progesterone	CEA	Luteinising Hormone (LH)	T3 (Free)
1,25-(OH) <sub>2</sub> Vitamin D*	Cortisol	Oestradiol	T3 (Total)
25-OH-Vitamin D	DHEA-Sulphate	Paracetamol	T4 (Free)
$\alpha$ -Fetoprotein (AFP)	Digoxin	Phenobarbitone	T4 (Total)
ACTH <sup>+</sup>	Estriol	Phenytoin	Testosterone
Aldosterone	Ethosuximide	Primidone	Testosterone (Free)*
Amikacin	Ferritin	Progesterone	Theophylline
Androstenedione	Folate	Prolactin	Thyroglobulin
$\beta$ -2-Microglobulin	FSH	PSA (Free)	Tobramycin
C-Peptide	Gentamicin	PSA (Total)	TSH
CA 15-3	Growth Hormone (GH)	PTH (Parathyroid Hormone)*	Valproic Acid
CA 19-9	hCG	Salicylate	Vancomycin
CA 125	Immunoglobulin E (IgE)	Sex Hormone Binding Globulin (SHBG)	Vitamin B <sub>12</sub>
Carbamazepine	Insulin	T Uptake	

Impressively covering 55 analytes including tumour markers, therapeutic drugs and routine immunoassay tests, the Acusera Immunoassay Premium Plus control has been uniquely designed to eliminate the need for four or more controls, dramatically reducing costs and time. The added advantage of ultra low levels of Ferritin, Vitamin B12 and TSH will ensure accurate performance at key decision levels and further reduce the number of controls required. Assayed target values are supplied for 49 analytes in this true third party control. Manufactured using 100% human serum, this control is designed to directly mimic a patient sample, reducing costly shifts when reagent batch is changed.

- Lyophilised for enhanced stability
- 100% human serum
- Ferritin and Vitamin B<sub>12</sub> levels suitable for Anaemia monitoring
- Ultra low TSH levels in the level 1 control
- Contains routinely run tumour markers: AFP / CA15-3 / CA19-9 / CA-125 / CEA / PSA / Free-PSA
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of up to 7 days at 2°C to 8°C or 28 days at -20°C

Description	Size	Cat No
Immunoassay Premium Plus Level 1	12 x 5 ml	IA3109
Immunoassay Premium Plus Level 2	12 x 5 ml	IA3110
Immunoassay Premium Plus Level 3	12 x 5 ml	IA3111
Immunoassay Premium Plus Tri-level	3 x 4 x 5 ml	IA3112

<sup>+</sup>Values may not be provided for all levels

\*No claims are made regarding value or stability

# IMMUNOASSAY

## Immunoassay Speciality I Control



### Analytes

1-25-(OH) <sub>2</sub> -Vitamin D 25-OH-Vitamin D Anti-Thyroglobulin (Anti-TG)	Anti-Thyroperoxidase (Anti-TPO) C-Peptide Insulin	Insulin Like Growth Factor-1(IGF-1) Intact PTH (Parathyroid Hormone) Osteocalcin	Procalcitonin
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Covering 10 specialised analytes, the Acusera Immunoassay Speciality I control is designed to complement our standard immunoassay control, meeting the demands of today's modern laboratory. Assayed target values are supplied for all 10 analytes in this true third party control.

- Lyophilised for enhanced stability
- 100% human serum
- Assayed target values and ranges for a wide range of immunoassay systems
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of up to 5 days at 2°C to 8°C or 28 days at -20°C C-Peptide and Procalcitonin are stable for 1 day at 2°C to 8°C IGF-1 is stable for 8 hours at 2°C to 8°C

Description	Size	Cat No
Immunoassay Speciality I Level 1	5 x 2 ml	IAS3113
Immunoassay Speciality I Level 2	5 x 2 ml	IAS3114
Immunoassay Speciality I Level 3	5 x 2 ml	IAS3115

## Immunoassay Speciality II Control



### Analytes

Calcitonin	Gastrin	Procalcitonin	Renin
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Designed for the routine monitoring of more complex, specialised analytes, the Acusera Immunoassay Speciality II control complements our standard immunoassay controls. As a true third party control, assayed target values are supplied and unbiased performance assessment guaranteed.

- Lyophilised for enhanced stability
- 100% human serum
- Assayed target values and ranges for a wide range of immunoassay systems
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 5 days at 2°C to 8°C for Renin, 1 day at 2°C to 8°C for Procalcitonin and 8 hours at 2°C to 8°C for Gastrin and Calcitonin Stable for 28 days at -20°C

Description	Size	Cat No
Immunoassay Speciality II Level 1	5 x 1 ml	IAS3117
Immunoassay Speciality II Level 2	5 x 1 ml	IAS3118
Immunoassay Speciality II Level 3	5 x 1 ml	IAS3119

Liquid Immunoassay Premium Control 

Analytes			
17-OH-Progesterone	Ethosuximide	Paracetamol	T3 (Free)
$\alpha$ -Fetoprotein (AFP)	Ferritin	Phenobarbitone	T3 (Total)
Aldosterone	Folate	Phenytoin	T4 (Free)
Amikacin	FSH	Primidone	T4 (Total)
$\beta$ -2-Microglobulin	Gentamicin	Progesterone	Testosterone
Carbamazepine	Growth Hormone (GH)	Prolactin	Theophylline
CEA	hCG	PSA (Free)	Tobramycin
Cortisol	Immunoglobulin E (IgE)	PSA (Total)	TSH
DHEA-Sulphate	Insulin	Salicylate	Valproic Acid
Digoxin	Luteinising Hormone (LH)	Sex Hormone Binding Globulin (SHBG)	Vancomycin
Estriol	Oestradiol	T Uptake	Vitamin B <sub>12</sub>

The Liquid Immunoassay Premium Control has been designed for use in the routine monitoring of accuracy and precision of multiple instruments. Consolidating up to 44 analytes in a single vial, employing this control can reduce the number of controls required to cover your complete test menu, saving time and money. As a true third party control, assayed values are available for most immunoassay platforms and a wide range of analytes, including hormones, therapeutic drugs and vitamins.

- Liquid frozen
- 100% human serum
- Ferritin and Vitamin B<sub>12</sub> levels suitable for Anaemia monitoring
- Stable to expiry date at -20°C to -80°C
- Open vial stability of up to 7 days at 2°C to 8°C

Description	Size	Cat No
Liquid Immunoassay Premium Tri-Level	3 x 4 x 5 ml	LIA3108

Maternal Screening Control 

Analytes			
$\alpha$ -Fetoprotein (AFP)	Inhibin A	Total $\beta$ -hCG	Unconjugated Oestriol
Free $\beta$ -hCG	PAPP-A		

Delivering an assayed, multi-analyte QC solution for laboratories carrying out maternal screening, the Acusera Maternal Screening control covers a unique combination of analytes, ensuring suitability for both First and Second Trimester screening of Down's syndrome & Spina Bifida. By employing our Maternal Screening Control you could replace up to three competitor controls, ultimately improving efficiency, while reducing costs and preparation time.

- Lyophilised for enhanced stability
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 7 days at 2°C to 8°C

Description	Size	Cat No
Maternal Screening Control Level 1	3 x 1 ml	MSS5024
Maternal Screening Control Level 2	3 x 1 ml	MSS5025
Maternal Screening Control Level 3	3 x 1 ml	MSS5026

# IMMUNOASSAY

## PTH Control

The Acusera PTH Control is an assayed, true third party control designed to complement our Immunoassay range, delivering an unbiased, independant assessment of analytical performance. With an open vial stability of 30 days, waste is kept to a minimum.

- Liquid frozen
- 100% human serum
- Assayed target values and ranges for a wide range of immunoassay systems
- Stable to expiry date at -20°C to -80°C
- Open vial stability of 30 days at 2°C to 8°C

Description	Size	Cat No
PTH Control Level 1	3 x 3 ml	PTH10110
PTH Control Level 2	3 x 3 ml	PTH10111
PTH Control Level 3	3 x 3 ml	PTH10112

## Tumour Marker Control

Analytes			
α-Fetoprotein (AFP)	CA 72-4	CYFRA 21-1	PSA (Free)
β-2-Microglobulin	CA 125	Ferritin	PSA (Total)
CA 15-3	Calcitonin	hCG	Thyroglobulin
CA 19-9	CEA	NSE	

The multi-analyte Acusera Tumour Marker control has been designed for use in the daily monitoring of 15 routine and specialised tumour markers. This true third party control is provided with assayed target values and ranges for all analytes, ensuring an unbiased assessment of performance for a wide range of immunoassay instruments.

- Lyophilised for enhanced stability
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of up to 14 days at 2°C to 8°C

Description	Size	Cat No
Tumour Marker Control Level 2	3 x 2 ml	TU5002
Tumour Marker Control Level 3	3 x 2 ml	TU5003

**NEW**

## Ultra Low PSA Control

The Acusera ultra-low PSA control is intended for use with in vitro diagnostic assays for the quantitative determination of low levels of PSA in human serum and plasma. The control has been optimised for use with Roche systems but is suitable for use across a variety of other platforms.

- Liquid ready-to-use
- Human based serum
- Values for specific instruments are available
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 30 days at 2°C to 8°C

Description	Size	Cat No
Ultra-Low PSA Control	6 x 1 ml	TU10523

# IMMUNOLOGY/ PROTEIN CONTROLS

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The Acusera range of Immunology/Protein Controls has been designed to be both cost effective and convenient. Requiring no preparation or thawing, the liquid ready-to-use format will increase productivity and efficiency in even the most demanding laboratories.

# IMMUNOLOGY/PROTEIN

Immunology/Protein Product Range			
Product Description	Size	Cat No	Page No
β-2-Microglobulin Calibrator	3 x 1 ml	BM10444	44
β-2-Microglobulin Calibrator	3 x 1 ml	BM1362	44
Canine CRP Control Level 2	3 x 1 ml	CP2803	44
Canine CRP Control Level 3	3 x 1 ml	CP2804	44
Liquid CRP Control Level 2	10 x 1 ml	CP2480	44
Liquid CRP Control Level 3	10 x 1 ml	CP2481	44
High Sensitivity CRP Control Level 1	10 x 1 ml	CP2476	44
High Sensitivity CRP Control Level 2	10 x 1 ml	CP2477	44
High Sensitivity CRP Calibrator Series	6 x 2 ml	CP2478	44
CRP Full Range Calibrator	6 x 1 ml	CP2499	44
CSF Control Level 2	10 x 3 ml	CF1500	45
CSF Control Level 3	10 x 3 ml	CF1501	45
Cystatin C Control Level 2	3 x 2 ml	CYS10446	45
Cystatin C Control Level 3	3 x 2 ml	CYS10447	45
Cystatin C Calibrator	5 x 2 ml	CYS10445	45
Cystatin C Control Level 2	3 x 2 ml	CYS5019	45
Cystatin C Control Level 3	3 x 2 ml	CYS5020	45
Cystatin C Calibrator	5 x 2 ml	CYS2699	45
IgE Calibrator Series	6 x 1 ml	IE2492	45
Immunoglobulin Liquid Protein Calibrator	3 x 1 ml	IT3861	46
Liquid CSF Control Level 1	10 x 3 ml	CF10138	46
Liquid CSF Control Level 2	10 x 3 ml	CF10139	46
Specific Protein Calibrator (Liquid)	5 x 1 ml	IT2691	47
Specific Protein Calibrator (Liquid)	5 x 1 ml	IT2692	47
Specific Protein Control Level 1	3 x 1 ml	PS2682	48
Specific Protein Control Level 2	3 x 1 ml	PS2683	48
Specific Protein Control Level 3	3 x 1 ml	PS2684	48
Specific Protein Control Level 1	6 x 3 ml	PS10221	48
Specific Protein Control Level 2	6 x 3 ml	PS10222	48
Specific Protein Control Level 3	6 x 3 ml	PS10223	48
sTfR Control Level 1 & 2	2 x 3 x 1 ml	TF10162	48
sTfR Calibrator	6 x 1 ml	TF10161	48
Xanthochromia Positive Control	6 x 4 ml	XN10505	49
Xanthochromia Negative Control	6 x 4 ml	XN10502	49



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

## β-2-Microglobulin Calibrator

Our dedicated b-2-Microglobulin calibrators are designed for use in the calibration of b-2-Microglobulin assays. With an excellent working stability of 30 days at 2°C to 8°C, waste is kept to a minimum.

- Lyophilised for enhanced stability
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 30 days at 2°C to 8°C or 3 months at -20°C
- Single point calibrator

Description	Size	Cat No
β-2-Microglobulin Calibrator	3 x 1 ml	BM10444
β-2-Microglobulin Calibrator	3 x 1 ml	BM1362

## Canine CRP Control

Dedicated CRP control uniquely designed for use in the quality control of the Randox Canine CRP assay. Supplied in a convenient, liquid ready-to-use format and stable to expiry date, waste and preparation time is kept to an absolute minimum.

- Liquid ready-to-use
- Human CRP in a stabilised protein matrix
- Stable to expiry date at 2°C to 8°C
- Once opened stable to expiry date at 2°C to 8°C

Description	Size	Cat No
Canine CRP Control Level 2	3 x 1 ml	CP2803
Canine CRP Control Level 3	3 x 1 ml	CP2804

## CRP Controls and Calibrator

A choice of two dedicated CRP controls is available, covering elevated and highly sensitive levels of CRP. As true third party controls, assayed target values are provided, ensuring unbiased performance assessment with any instrument or method. Conveniently supplied in a liquid ready-to-use format, no preparation is required.

- Liquid ready-to-use
- 100% human material
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 30 days at 2°C to 8°C
- Multi-point calibrator

Description	Size	Cat No
Liquid CRP Control Level 2	10 x 1 ml	CP2480
Liquid CRP Control Level 3	10 x 1 ml	CP2481
High Sensitivity CRP Control Level 1	10 x 1 ml	CP2476
High Sensitivity CRP Control Level 2	10 x 1 ml	CP2477
High Sensitivity CRP Calibrator Series	6 x 2 ml	CP2478
CRP Full Range Calibrator	6 x 1 ml	CP2499

# IMMUNOLOGY/PROTEIN

## CSF Control

Analytes			
α <sub>1</sub> -Globulin (Electrophoresis)*	β-Globulin (Electrophoresis)*	Glucose	Protein (Total)
α <sub>2</sub> -Globulin (Electrophoresis)*	Chloride	Immunoglobulin G (IgG)	Sodium
Albumin (Electrophoresis)*	γ-Globulin (Electrophoresis)*	Lactate	

Multi-analyte CSF control designed for use in the routine monitoring of both accuracy and precision. As a true third party control, it is compatible for use with a wide range of clinical analysers. Assayed target values are provided, eliminating the need to assign in-house.

- Lyophilised for enhanced stability
- Human based material
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 14 days at 2°C to 8°C

Description	Size	Cat No
CSF Control Level 2	10 x 3 ml	CF1500
CSF Control Level 3	10 x 3 ml	CF1501

\*No claims are made regarding values or stability

## Cystatin C Controls and Calibrators

Dedicated Cystatin C control designed for use in the routine monitoring of both accuracy and precision. Supplied in a convenient, liquid ready-to-use format, no preparation is required. Assayed target values and ranges are provided for this true third party control.

- Liquid ready-to-use
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 30 days at 2°C to 8°C
- Multi-point calibrator

For use with Calibrator CYS10445			For use with Calibrator CYS2699		
Description	Size	Cat No	Description	Size	Cat No
Cystatin C Control Level 2	3 x 2 ml	CYS10446	Cystatin C Control Level 2	3 x 2 ml	CYS5019
Cystatin C Control Level 3	3 x 2 ml	CYS10447	Cystatin C Control Level 3	3 x 2 ml	CYS5020
Cystatin C Calibrator	5 x 2 ml	CYS10445	Cystatin C Calibrator	5 x 2 ml	CYS2699

## IgE Calibrator

Comprising 6 levels, our IgE calibrator series is designed for use in the calibration of IgE immunoturbidimetric assays. With an excellent working stability of 28 days at 2°C to 8°C, waste is kept to a minimum.

- Lyophilised for enhanced stability
- Human IgE in a stabilised matrix
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 28 days at 2°C to 8°C
- Multi-point calibrator

Description	Size	Cat No
IgE Calibrator Series	6 x 1 ml	IE2492

## Immunoglobulin Liquid Protein Calibrator

### Analytes

Immunoglobulin A (IgA)

Immunoglobulin G (IgG)

Immunoglobulin M (IgM)

Calibrator series designed for use in the calibration of IgA, IgG and IgM immunoturbidimetric assays. Suitable for use with the Randox immunoglobulin assays.

- Liquid ready-to-use
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 30 days at 2°C to 8°C
- Single point calibrator

Description	Size	Cat No
Immunoglobulin Liquid Protein Calibrator	3 x 1 ml	IT3861

## Liquid CSF Control

### Analytes

$\alpha$ -1-Globulin (Electrophoresis)*	Chloride	High Sensitivity Immunoglobulin G (hsIgG)	Microalbumin
$\alpha$ -2-Globulin (Electrophoresis)*	$\gamma$ -Globulin (Electrophoresis)*	High Sensitivity Immunoglobulin M (hsIgM)*	Protein (Total)
Albumin (Electrophoresis)*	Glucose	(hsIgM)*	Sodium
$\beta$ -Globulin (Electrophoresis)*	High Sensitivity Immunoglobulin A (hsIgA)*	Lactate	

Providing a true third party solution for the measurement of 14 analytes in Cerebrospinal Fluid (CSF), the new Acusera Liquid CSF Control is designed to deliver an unbiased, independent assessment of analytical performance, helping to ensure accurate and reliable patient testing. With an extended open vial stability of 30 days at 2°C to 8°C, this control will reduce waste, while remaining easy and convenient to use. Two distinct levels are available covering clinically significant ranges.

- Liquid ready-to-use
- Human based material
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 30 days at 2°C to 8°C

Description	Size	Cat No
Liquid CSF Control Level 1	10 x 3 ml	CF10138
Liquid CSF Control Level 2	10 x 3 ml	CF10139

\*No claims are made regarding values or stability

# IMMUNOLOGY/PROTEIN

## Specific Protein Calibrator

Analytes			
Anti-Streptolysin O (ASO) Ceruloplasmin Complement C3 Complement C4	CRP Ferritin Haptoglobin	Immunoglobulin A (IgA) Immunoglobulin G (IgG) Immunoglobulin M (IgM)	Prealbumin Rheumatoid Factor (RF) Transferrin

Multi-analyte calibrator designed for use in the routine calibration of 13 serum proteins including Ferritin, IgA, IgG and IgM. Supplied in a convenient, liquid ready-to-use format with a working stability of 30 days, waste and time are kept to a minimum.

- Liquid ready-to-use
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 30 days at 2°C to 8°C
- Multi-point calibrator

Description	Size	Cat No	
Specific Protein Calibrator (Liquid)	5 x 1 ml	IT2691	<b>FOR USE WITH SAMPLES THAT <u>DO NOT</u> REQUIRE PRE-DILUTION</b>

## Specific Protein Calibrator - Requires pre-dilution

Analytes		
Immunoglobulin A (IgA)	Immunoglobulin G (IgG)	Immunoglobulin M (IgM)

Multi-analyte calibrator designed for use in the routine calibration of 3 serum proteins. Supplied in a convenient, liquid ready-to-use format with a working stability of 30 days, waste and time are kept to a minimum.

- Liquid ready-to-use
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 30 days at 2°C to 8°C
- Multi-point calibrator

Description	Size	Cat No	
Specific Protein Calibrator (Liquid)	5 x 1 ml	IT2692	<b>FOR USE WITH SAMPLES THAT REQUIRE PRE-DILUTION</b>

Specific Protein Control 

Analytes			
$\alpha$ -1-Acid Glycoprotein $\alpha$ -1-Antitrypsin $\alpha$ -2-Macroglobulin $\alpha$ -Fetoprotein (AFP) Albumin Anti-Streptolysin O (ASO) Anti-Thrombin III (AT III)	$\beta$ -2-Microglobulin Ceruloplasmin Complement C3 Complement C4 CRP Ferritin Haptoglobin	Immunoglobulin A (IgA) Immunoglobulin E (IgE) Immunoglobulin G (IgG) Immunoglobulin M (IgM) Kappa Light Chain Lambda Light Chain Lambda Light Chain (Free) <sup>+</sup>	Prealbumin Protein (Total) Retinol Binding Protein (RBP) Rheumatoid Factor (RF) Transferrin

Covering a unique combination of 26 serum proteins, including; Total Kappa and Lambda Light Chains, the Acusera Specific Protein Control could replace as many as three separate controls. Supplied in a user-friendly liquid ready-to-use format with a 30 day open vial stability for all analytes, waste and preparation time are kept to a minimum. Manufactured using 100% human serum, this control is designed to directly mimic a patient sample, reducing costly shifts when reagent batch is changed and ensuring accurate patient testing. Assayed target values and ranges are provided for this true third party control.

- Liquid ready-to-use
- 100% human serum
- Contains both Total Kappa and Lambda Light Chains
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 30 days at 2°C to 8°C

Description	Size	Cat No
Specific Protein Control Level 1	3 x 1 ml	PS2682
Specific Protein Control Level 2	3 x 1 ml	PS2683
Specific Protein Control Level 3	3 x 1 ml	PS2684
Specific Protein Control Level 1	6 x 3 ml	PS10221
Specific Protein Control Level 2	6 x 3 ml	PS10222
Specific Protein Control Level 3	6 x 3 ml	PS10223

<sup>+</sup>Not for use in USA

Soluble Transferrin Receptor (sTfR) Control and Calibrator Series 

Providing a true third party solution for the measurement of Soluble Transferrin Receptor (sTfR), the Acusera control will deliver an unbiased, independent assessment of analytical performance. Designed for use with sTfR assays, this single analyte control saves money on wasted material.

- Lyophilised control
- Human based material
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 28 days at 2°C to 8°C
- Multi-point calibrator

Description	Size	Cat No
sTfR Control Level 1 & 2	2 x 3 x 1 ml	TF10162
sTfR Calibrator	6 x 1 ml	TF10161

## IMMUNOLOGY/PROTEIN

**NEW**

### Xanthochromia Control



#### Analytes

Oxyhaemoglobin

Bilirubin

Designed to deliver a cost-effective, high-quality solution for the testing of Xanthochromia. An unassayed control suitable for use on various UV spectrophotometer analysers.

- Liquid frozen
- Aqueous material
- Stable to for 90 days at -18°C to -24°C or 180 days at -70°C to -90°C
- Open vial stability of up to 2 days at 2°C to 8°C

Description	Size	Cat No
Xanthochromia Positive Control	6 x 4 ml	XN10505
Xanthochromia Negative Control	6 x 4 ml	XN10502

# INFECTIOUS DISEASE CONTROLS (SEROLOGY)

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The Acusera range of serology controls is designed to deliver a cost effective, high quality solution for the analysis of infectious diseases using our multi-marker controls that cover a wide range of testing. These liquid ready-to-use controls come with an unrivalled stability therefore helping laboratories save time and money with added consolidation. Negative controls are also available within our Serology Controls portfolio.

# INFECTIOUS DISEASE (SEROLOGY)

Infectious Disease (SeroLOGY) Product Range			
Product Description	Size	Cat No	Page No
Anti SARS-CoV-2 Controls	2 x 2 x 4 ml	COV10460	52
Anti-SARS-CoV-2 Spike Controls	2 x 2 x 4 ml	COV10533	52
EBV Positive Control	1 x 5 ml	SR10350	52
Lyme Disease Negative Control	1 x 5 ml	SR10345	53
Lyme Disease Positive Control	1 x 5 ml	SR10346	53
HBeAg Positive Control	1 x 5 ml	SR10459	53
HIV-1 P24Ag Positive Control	1 x 5 ml	SR10458	53
Serology Negative Control	6 x 5 ml	SR10351	53
Serology I Positive Control	3 x 5 ml	SR10352	53
Serology II Positive Control	3 x 5 ml	SR10353	53
Serology III Positive Control	3 x 5 ml	SR10354	53
ToRCH Negative Control	6 x 5 ml	SR10347	54
ToRCH IgG Positive Control	3 x 5 ml	SR10348	54
ToRCH IgM Positive Control	3 x 5 ml	SR10349	54



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# INFECTIOUS DISEASE (SEROLOGY)

## Anti-SARS-CoV-2 Controls

Comprising both reactive and non-reactive controls for SARS-CoV-2 total antibodies, the Acusera range is designed to assess the precision of serological assays for COVID-19. As a true third party control, independent performance assessment is guaranteed.

- Liquid ready-to-use
- 100% human serum
- Reactive and non-reactive controls available
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 30 days at 2°C to 8°C

Description	Size	Cat No	
Anti-SARS-CoV-2 Controls	2 x 4 ml (Positive) 2 x 4 ml (Negative)	COV10460	If running the SARS-CoV-2 for spike protein, please be aware that positive control will need to be diluted for spike protein antibodies.

## Anti-SARS-CoV-2 Spike Control

SARS-CoV-2 Spike negative/non-reactive and positive/reactive controls are intended for use with in vitro assays for the determination of spike antibodies to SARS-CoV-2. These controls are unassayed and are suitable for use on various analysers, therefore making them useful in determining the precision of testing systems and allows performance monitoring of multiple test systems.

- Liquid ready-to-use
- 100% human serum
- Reactive and non-reactive controls available
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 30 days at 2°C to 8°C

Description	Size	Cat No
Anti-SARS-CoV-2 Spike Controls	2 x 4 ml (Positive) 2 x 4 ml (Negative)	COV10533

## Epstein Barr Virus (EBV) Control

Analytes		
Epstein Barr Virus (EBV) EBNA IgG	Epstein Barr Virus (EBV) VCA IgG	Epstein Barr Virus (EBV) VCA IgM

The Acusera EBV control is conveniently supplied as liquid ready-to-use and is suitable for use with most immunoassay analysers.

- Liquid ready-to-use
- Human based serum
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 60 days at 2°C to 8°C
- Suitable for use with most immunoassay analysers

Description	Size	Cat No
EBV Positive Control	1 x 5 ml	SR10350

# INFECTIOUS DISEASE (SEROLOGY)

## Lyme Disease (*Borrelia burgdorferi*) Control

### Analytes

*Borrelia burgdorferi* IgG

*Borrelia burgdorferi* IgM

Our control delivers a true third-party solution for the detection of Lyme Disease on most immunoassay analysers. All samples are conveniently supplied in a user-friendly, liquid ready-to-use format.

- Liquid ready-to-use
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 60 days at 2°C to 8°C
- Suitable for use with most immunoassay analysers

Description	Size	Cat No
Lyme Disease Negative Control	1 x 5 ml	SR10345
Lyme Disease Positive Control	1 x 5 ml	SR10346

## Serology Controls

### Analytes

**HBeAg Positive (RUO)**  
HBeAg

Anti-HCV  
Anti-HIV 1 / 2  
Anti-HTLV 1 / 2

**Serology I Positive**  
Anti-HCV  
Anti-HIV 1 / 2  
Anti-HTLV 1 / 2

**Serology II Positive**  
Anti-HAV  
Anti-HBc  
Anti-HBe  
Anti-HBs

**HIV-1 P24 Ag Positive (RUO)**  
HIV-1 P24Ag

HAV IgM  
HBc IgM  
HBeAg  
HBsAg

**Treponema pallidum (Syphilis)**  
IgG

**Serology Negative**  
Anti-HAV  
Anti-HBc  
Anti-HBe  
Anti-HBs

HIV P24Ag  
**Treponema pallidum (Syphilis)**  
IgG

**Serology III Positive**  
HAV IgM  
HBc IgM

The Acusera Serology control range comprises both positive and negative controls for a wide range of pathogens including HIV & Hepatitis, are supplied as liquid ready-to-use and are suitable for use on most immunoassay analysers.

- Liquid ready-to-use
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 60 days at 2°C to 8°C
- Suitable for use with most immunoassay analysers

Description	Size	Cat No
HBeAg Positive Control	1 x 5 ml	SR10459
HIV-1 P24Ag Positive Control	1 x 5 ml	SR10458
Serology Negative Control	6 x 5 ml	SR10351
Serology I Positive Control	3 x 5 ml	SR10352
Serology II Positive Control	3 x 5 ml	SR10353
Serology III Positive Control	3 x 5 ml	SR10354

# INFECTIOUS DISEASE (SEROLOGY)

## ToRCH Controls



Analytes		
<b>ToRCH Negative</b>		
Cytomegalovirus (CMV) IgG	Rubella IgG	Measles IgG
Cytomegalovirus (CMV) IgM	Rubella IgM	Mumps IgG
Epstein Barr Virus (EBV) EBNA IgG	Toxoplasma <i>gondii</i> IgG	Rubella IgG
Epstein Barr Virus (EBV) VCA IgG	Toxoplasma <i>gondii</i> IgM	Toxoplasma <i>gondii</i> IgG
Epstein Barr Virus (EBV) VCA IgM	Anti- <i>Treponema pallidum</i> (Syphilis) IgG	<i>Treponema pallidum</i> (Syphilis) IgG
<i>Helicobacter pylori</i> IgG	Varicella Zoster Virus (VZV) IgG	Varicella Zoster Virus (VZV) IgG
Herpes Simplex Virus 1 (HSV-1) IgG		
Herpes Simplex Virus 1 (HSV-1) IgM		
Herpes Simplex Virus 2 (HSV-2) IgG		
Herpes Simplex Virus 2 (HSV-2) IgM		
Measles IgG		
Mumps IgG		
	<b>ToRCH IgG Positive</b>	<b>ToRCH IgM Positive</b>
	Cytomegalovirus (CMV) IgG	Cytomegalovirus (CMV) IgM
	EBV EBNA IgG	Herpes Simplex Virus 1 (HSV-1) IgM
	<i>Helicobacter pylori</i> IgG	Herpes Simplex Virus 2 (HSV-2) IgM
	Herpes Simplex Virus 1 (HSV-1) IgG	Rubella IgM
	Herpes Simplex Virus 2 (HSV-2) IgG	Toxoplasma <i>gondii</i> IgM

Our ToRCH portfolio includes positive controls for both IgG and IgM antibodies in addition to a negative control. Each control is manufactured using human serum and is suitable for use with most immunoassay analysers. The availability of liquid ready-to-use samples helps to reduce preparation time and the potential for human error.

- Liquid ready-to-use
- Human based serum
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 60 days at 2°C to 8°C
- Suitable for use with most immunoassay analysers

Description	Size	Cat No
ToRCH Negative Control	6 x 5 ml	SR10347
ToRCH IgG Positive Control	3 x 5 ml	SR10348
ToRCH IgM Positive Control	3 x 5 ml	SR10349

# LIPID CONTROLS

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Our Acusera Lipid quality controls have been manufactured from 100% human serum to ensure they are commutable, performing in the same manner as a patient sample with minimal lot to lot value shifts. All of our Lipid Controls contain no stabilisers or preservatives, which may affect the overall performance of the controls. The multi-analyte controls enable test menu consolidation which, along with a four year shelf life from the date of manufacture, ensures minimal waste and helps to reduce costs.

Lipid Product Range			
Product Description	Size	Cat No	Page No
Apolipoprotein Control Level 1	3 x 1 ml	LE5016	57
Apolipoprotein Control Level 2	3 x 1 ml	LE5017	57
Apolipoprotein Control Level 3	3 x 1 ml	LE5018	57
Apolipoprotein Calibrator	3 x 1 ml	LP3023	57
Apolipoprotein Calibrator 2	3 x 1 ml	LP5047	57
Direct HDL/LDL Cholesterol Calibrator (Clearance)	3 x 1 ml	CH2673	57
Lipid Control Level 1	5 x 1 ml	LE2668	58
Lipid Control Level 2	5 x 1 ml	LE2669	58
Lipid Control Level 3	5 x 1 ml	LE2670	58
Lipid Control Level 1	5 x 3 ml	LE2661	58
Lipid Control Level 2	5 x 3 ml	LE2662	58
Lipid Control Level 3	5 x 3 ml	LE2663	58
Lipoprotein (a) Control Level 3	3 x 1 ml	LP3406	58
Lipoprotein (a) Calibrator Series	5 x 1 ml	LP3404	58
sLDL Control Level 1	3 x 1 ml	LE5013	58
sLDL Control Level 2	3 x 1 ml	LE5014	58
sLDL Control Level 3	3 x 1 ml	LE5015	58
sLDL Calibrator	3 x 1 ml	CH5050	58



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# LIPIDS

## Apolipoprotein Control and Calibrators

Analytes		
<b>Apolipoprotein Control</b>	<b>Apolipoprotein Calibrator</b>	<b>Apolipoprotein Calibrator 2</b>
Apolipoprotein A-II Apolipoprotein C-II Apolipoprotein C-III Apolipoprotein E	Apolipoprotein A-I Apolipoprotein B	Apolipoprotein A-II Apolipoprotein C-II Apolipoprotein C-III Apolipoprotein E

The Acusera Apolipoprotein control has been designed for the routine monitoring of 4 esoteric Apolipoprotein analytes. Complementing our Acusera Apolipoprotein control is the Acusera Apolipoprotein Calibrator, which has been designed for use in the calibration of 6 Apolipoprotein assays on a wide range of clinical chemistry analysers.

- Lyophilised for enhanced stability
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Control - reconstituted stability of 7 days at 2°C to 8°C for Apolipoprotein A-II, Apolipoprotein C-II and Apolipoprotein C-III, Apolipoprotein E is stable for 8 hours at 2°C to 8°C All analytes are stable for 4 weeks at -20°C
- Calibrator - reconstituted stability of 7 days at 2°C to 8°C for Apolipoprotein A-II and Apolipoprotein C-II, Apolipoprotein E is stable for 8 hours at 2°C to 8°C All analytes are stable for 4 weeks at -20°C
- Multi-point calibrator

Description	Size	Cat No
Apolipoprotein Control Level 1	3 x 1 ml	LE5016
Apolipoprotein Control Level 2	3 x 1 ml	LE5017
Apolipoprotein Control Level 3	3 x 1 ml	LE5018
Apolipoprotein Calibrator	3 x 1 ml	LP3023
Apolipoprotein Calibrator 2	3 x 1 ml	LP5047

## Direct LDL/HDL Cholesterol Calibrator

Analytes	
Cholesterol (HDL)	Cholesterol (LDL)

The Acusera Direct LDL/HDL Cholesterol Calibrator has been designed for use in the calibration of HDL and LDL Clearance assays on clinical chemistry analysers.

- Lyophilised for enhanced stability
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 5 days at 2°C to 8°C and 1 month at -20°C
- Single point calibrator

Description	Size	Cat No
Direct LDL/HDL Cholesterol Calibrator (Clearance)	3 x 1 ml	CH2673

## Lipid Control

### Analytes

Apolipoprotein A-1  
Apolipoprotein B

Cholesterol (HDL)  
Cholesterol (LDL)

Cholesterol (Total)  
Lipoprotein (a)

Triglycerides

The Randox Acusera Lipid control is supplied with assayed method specific target values and ranges for 7 analytes, covering the complete lipid profile. Unlike with many manufacturers, the material used in the production of the Randox lipid control does not contain preservatives such as Sodium Azide. This ensures a matrix that is compatible with the patient sample and prevents interference with clearance methods of HDL and LDL. Two flexible and convenient pack sizes are available, providing a true third party solution for laboratories of all sizes.

- Lyophilised for enhanced stability
- 100% human serum
- Sodium Azide is not present - no interference occurs with clearance methods
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of up to 7 days at 2°C to 8°C or 28 days at -20°C

Description	Size	Cat No
Lipid Control Level 1	5 x 1 ml	LE2668
Lipid Control Level 2	5 x 1 ml	LE2669
Lipid Control Level 3	5 x 1 ml	LE2670
Lipid Control Level 1	5 x 3 ml	LE2661
Lipid Control Level 2	5 x 3 ml	LE2662
Lipid Control Level 3	5 x 3 ml	LE2663

## Lipoprotein (a) Control and Calibrator

The Acusera Lipoprotein (a) control has been designed for the routine monitoring of the Randox Lipoprotein (a) assay. The Acusera Lipoprotein (a) calibrator has been designed to calibrate Lipoprotein (a) assays on clinical chemistry analysers.

- Lyophilised for enhanced stability
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 14 days at 2°C to 8°C
- Multi-point calibrator

Description	Size	Cat No
Lipoprotein (a) Control Level 3	3 x 1 ml	LP3406
Lipoprotein (a) Calibrator Series	5 x 1 ml	LP3404

## sLDL Control and Calibrator

The Acusera sLDL Control and Calibrator have been designed for the use in the routine monitoring of both accuracy and precision.

- Lyophilised for enhanced stability
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 5 days at 2°C to 8°C
- Single point calibrator

Description	Size	Cat No
sLDL Control Level 1	3 x 1 ml	LE5013
sLDL Control Level 2	3 x 1 ml	LE5014
sLDL Control Level 3	3 x 1 ml	LE5015
sLDL Calibrator	3 x 1 ml	CH5050

# SPECIALITY AND RESEARCH CONTROLS

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Our Speciality and Research Quality Controls cover a wide range of assays employed by universities, pharmaceutical companies, forensic laboratories and so on. Available in various formats and pack sizes, our multi-analyte Speciality and Research controls cover a range of specialised assays.

# SPECIALITY AND RESEARCH

Speciality and Research Product Range			
Product Description	Size	Cat No	Page No
Adhesion Molecules Tri-Level Control	3 x 3 x 1 ml	EV3569	61
Adhesion Molecules Calibrator Series	9 x 1 ml	EV3568	61
Antimicrobial Control III	3 x 1 ml	AMC5036	61
Cerebral Array II Tri-Level Control	3 x 3 x 0.5 ml	CBB5009	61
Cytokine Array I Tri-Level Control	3 x 3 x 1 ml	CY5006	62
High Sensitivity Cytokine Array Tri-Level Control	3 x 3 x 2 ml	CY5005	62
Cytokine Array Calibrator Series	9 x 1 ml	EV3561	62
Cytokine Array III Tri-Level Control	3 x 3 x 1 ml	CY5012	62
Cytokine Array IV Tri-Level Control	3 x 3 x 1 ml	CY5011	62
Metabolic Syndrome Array I Control	3 x 3 x 1 ml	EV3757	63
Metabolic Syndrome Array I Calibrator	9 x 1 ml	EV3756	63
Metabolic Syndrome Array II Control	3 x 3 x 1 ml	EV3761	63
Metabolic Syndrome Array II Calibrator	9 x 1 ml	EV3760	63
Synthetic Steroids Control	3 x 1 ml	EV3709	63



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# SPECIALITY AND RESEARCH

## Adhesion Molecules Control and Calibrator

Analytes	
E-Selectin (E-SEL) Intercellular Adhesion Molecule-1 (ICAM-1) L-Selectin (L-SEL)	P-Selectin (P-SEL) Vascular Cell Adhesion Molecule-1 (VCAM-1)

A multi-analyte control with target values and ranges supplied for 5 different adhesion molecules.

- Lyophilised for enhanced stability
- Assayed values available for Randox Biochip systems
- Recombinant proteins in buffer
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 24 hours at 2°C to 8°C or 7 days at -20°C

Description	Size	Cat No
Adhesion Molecules Tri-Level Control	3 x 3 x 1 ml	EV3569
Adhesion Molecules Calibrator Series	9 x 1 ml	EV3568

## Antimicrobial Control III

Analytes			
AHD AMOZ	AOZ	Chloramphenicol	Semicarbazide (SEM)

Multi-analyte control containing values for 5 different antimicrobial agents.

- Lyophilised for enhanced stability
- Assayed values available for Randox Biochip systems
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 28 days at 2°C to 8°C or 28 days at -20°C

Description	Size	Cat No
Antimicrobial Control III	3 x 1 ml	AMC5036

## Cerebral Array II Control

Analytes	
D-dimer Neuron Specific Enolase (NSE)	Neutrophil Gelatinase-associated Lipocalin (NGAL) Soluble Tumour Necrosis Factor Receptor I (sTNFRI)

A multi-analyte control with target values and ranges provided for 4 analytes.

- Lyophilised for enhanced stability
- Assayed values available for Randox Biochip systems
- Recombinant proteins in buffer
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 4 hours at 2°C to 8°C or 14 days at -80°C

Description	Size	Cat No
Cerebral Array II Tri-Level Control	3 x 3 x 0.5 ml	CBB5009

# SPECIALITY AND RESEARCH

## Cytokine Array I and High Sensitivity Cytokine Array I Controls and Calibrator

Analytes		
Epidermal Growth Factor (EGF) Interferon $\gamma$ (IFN $\gamma$ ) Interleukin-1 $\alpha$ (IL-1 $\alpha$ ) Interleukin-1 $\beta$ (IL-1 $\beta$ )	Interleukin-2 (IL-2) Interleukin-4 (IL-4) Interleukin-6 (IL-6) Interleukin-8 (IL-8)	Interleukin-10 (IL-10) Monocyte Chemoattractant Protein-1 (MCP-1) Tumour Necrosis Factor $\alpha$ (TNF $\alpha$ ) Vascular Endothelial Growth Factor (VEGF)

Multi-analyte controls with target values and ranges provided for 12 different cytokines.

- Lyophilised for enhanced stability
- Assayed values available for Randox Biochip systems
- Recombinant proteins in buffer
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 4 hours at 2°C to 8°C or 14 days at -20°C
- High sensitivity - Reconstituted stability of 4 hours at 2°C to 8°C or 21 days at -20°C

Description	Size	Cat No
Cytokine Array I Tri-Level Control	3 x 3 x 1 ml	CY5006
High Sensitivity Cytokine Array I Tri-Level Control	3 x 3 x 2 ml	CY5005
Cytokine Array Calibrator Series	9 x 1 ml	EV3561

## Cytokine Array III Control

Analytes		
GM-CSF Interleukin-5 (IL-5)		Interleukin-15 (IL-15) Macrophage Inflammatory Protein-1 $\alpha$ (MIP-1 $\alpha$ )

A multi-analyte control with target values and ranges provided for 4 analytes.

- Lyophilised for enhanced stability
- Assayed values available for Randox Biochip systems
- Human based recombinant antigen
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 4 hours at 2°C to 8°C or 28 days at -20°C

Description	Size	Cat No
Cytokine Array III Tri-Level Control	3 x 3 x 1 ml	CY5012

## Cytokine Array IV Control

Analytes		
Matrix Metalloproteinase-9 (MMP-9) Soluble Interleukin-2-Receptor $\alpha$ (sIL-2R $\alpha$ ) Soluble Interleukin-6-Receptor (sIL-6R)		Soluble Tumour Necrosis Factor Receptor I (sTNFRI) Soluble Tumour Necrosis Factor Receptor II (sTNFRII)

A multi-analyte control with target values and ranges provided for 5 analytes.

- Lyophilised for enhanced stability
- Assayed values available for Randox Biochip systems
- Native human antigen in buffer
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 5 days at 2°C to 8°C or 14 days at -20°C

Description	Size	Cat No
Cytokine Array IV Tri-Level Control	3 x 3 x 1 ml	CY5011

# SPECIALITY AND RESEARCH

## Metabolic Syndrome Array I Control and Calibrator

Analytes		
Ferritin Insulin Interleukin-1 $\alpha$ (1L-1 $\alpha$ )	Interleukin-6 (1L-6) Leptin	Plasminogen Activator Inhibitor-1 Resistin Tumour Necrosis Factor $\alpha$ (TNF $\alpha$ )

A multi-analyte control with target values and ranges provided for 8 analytes associated with metabolic syndrome.

- Assayed values available for Randox Biochip systems
- Native antigens in buffer base
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 4 hours at 2°C to 8°C and 28 days at -20°C

Description	Size	Cat No
Metabolic Syndrome Array I Control	3 x 3 x 1 ml	EV3757
Metabolic Syndrome Array I Calibrator	9 x 1 ml	EV3756

## Metabolic Syndrome Array II Control and Calibrator

Analytes		
Adiponectin	CRP	Cystatin C

A multi-analyte control with target values and ranges provided for 3 analytes associated with metabolic syndrome.

- Lyophilised for enhanced stability
- Assayed values available for Randox Biochip systems
- Recombinant antigen in buffer base
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 8 hours at 2°C to 8°C and 28 days at -20°C

Description	Size	Cat No
Metabolic Syndrome Array II Control	3 x 3 x 1 ml	EV3761
Metabolic Syndrome Array II Calibrator	9 x 1 ml	EV3760

## Synthetic Steroids Control

Analytes			
17 $\beta$ -Colestebol Ethinylestradiol	Gestagens (Generic)	Methandriol	Methyltestosterone

Human based control designed for use in the routine monitoring of both accuracy and precision. Assayed target values and ranges are provided for 5 different synthetic steroids.

- Lyophilised for enhanced stability
- Assayed values available for Randox Biochip systems
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 3 days at 2°C to 8°C or 14 days at -20°C

Description	Size	Cat No
Synthetic Steroids Control	3 x 1 ml	EV3709

# Therapeutic Drug Controls

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Patients absorb and metabolise medication at different rates. As a result, it is simply not acceptable to administer a standard volume to each one. Due to the problems that over and under prescribing medication can cause, it is vital that levels are closely monitored and medical personnel can trust that the test results they receive are accurate and reliable. Our Therapeutic Drug Controls are manufactured from 100% human serum and have a reconstituted stability of 4 weeks, ensuring minimal waste, thus saving your laboratory money.

# THERAPEUTIC DRUG

Therapeutic Drug Product Range			
Product Description	Size	Cat No	Page No
Therapeutic Drug Calibrator	6 x 3 ml	TD3417	66
Therapeutic Drug Control Level 1	20 x 5 ml	HD1667	66
Therapeutic Drug Control Level 2	20 x 5 ml	HD1668	66
Therapeutic Drug Control Level 3	20 x 5 ml	HD1669	66



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

## Therapeutic Drug Calibrator

Analytes			
Carbamazepine Digoxin	Phenobarbitone	Phenytoin	Valproic Acid

The Acusera Therapeutic Drug calibrator has been designed for use in the calibration of 5 therapeutic drug assays on clinical chemistry analysers. An extended stability of 28 days will help to reduce waste and costs.

- Lyophilised for enhanced stability
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 28 days at 2°C to 8°C or 8 weeks at -20°C
- Multi-point calibrator

Description	Size	Cat No
Therapeutic Drug Calibrator	6 x 3 ml	TD3417

## Therapeutic Drug Control

Analytes			
Amikacin Caffeine Carbamazepine Cyclosporine Digoxin	Ethosuximide Gentamicin Lithium Methotrexate Paracetamol / Acetaminophen	Phenobarbitone Phenytoin Primidone Salicylate Theophylline	Tobramycin Valproic Acid Vancomycin

Multi-analyte therapeutic drug control covering 18 analytes at three clinically relevant levels. Method specific target values and ranges are supplied for this true third party control. With an extended reconstituted stability of 28 days, waste is kept to a minimum.

- Lyophilised for enhanced stability
- 100% human serum
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 28 days at 2°C to 8°C

Description	Size	Cat No
Therapeutic Drug Control Level 1	20 x 5 ml	HD1667
Therapeutic Drug Control Level 2	20 x 5 ml	HD1668
Therapeutic Drug Control Level 3	20 x 5 ml	HD1669

# URINE CONTROLS

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Our Acusera Urine Chemistry Controls are available in a choice of lyophilised and liquid ready-to-use formats, covering the full range of clinical testing.

With flexible options available, we have a urine control to suit all laboratory sizes and budgets.

Urine Product Range			
Product Description	Size	Cat No	Page No
Assayed Urine Control Level 2	12 x 10 ml	AU2352	69
Assayed Urine Control Level 3	12 x 10 ml	AU2353	69
Liquid Urine Control Level 2	10 x 10 ml	UC5074	69
Liquid Urine Control Level 3	10 x 10 ml	UC5075	69
Microalbumin Calibrator Series	6 x 2 ml	MA1567	70
Urinalysis Control Level 1	12 x 12 ml	UC5033	70
Urinalysis Control Level 2	12 x 12 ml	UC5034	70



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# URINE

## Assayed Urine Control

Analytes			
5-HIAA* Amylase Calcium Chloride Copper* Cortisol	Creatinine Dopamine* Epinephrine* Glucose Magnesium Metanephrine	Microalbumin Norepinephrine* Normetanephrine Osmolality Oxalate* Phosphate (Inorganic)	Potassium Protein (Total) Sodium Urea Uric Acid (Urate) Vanillylmandelic Acid (VMA)*

Comprising 24 urine chemistry analytes in a single multi-analyte control, the Acusera Assayed Urine Control is designed to cover your complete test menu, reducing costs and preparation time. Our unique 100% human urine matrix will mirror the performance of patient samples and ensure target values don't shift after changing reagent batch. Assayed target values and ranges are provided for this true third party control.

- Lyophilised for enhanced stability
- 100% human urine
- Stable to expiry date at 2°C to 8°C
- Reconstituted stability of 5 days at 2°C to 8°C or 14 days at -20°C

Description	Size	Cat No
Assayed Urine Control Level 2	12 x 10 ml	AU2352
Assayed Urine Control Level 3	12 x 10 ml	AU2353

\*No claims are made regarding stability

## Liquid Urine Control

Analytes			
Amylase Calcium Chloride Cortisol Creatinine	Glucose hCG Magnesium Microalbumin Osmolality	pH Phosphate (Inorganic) Potassium Protein (Total) Sodium	Specific Gravity Urea Uric Acid (Urate)

Our Acusera Liquid Urine Control has been designed to consolidate up to 18 commonly used urine chemistry analytes in a single vial, reducing the number of controls required to cover your complete test menu. Supplied in a user-friendly liquid ready-to-use format with an open vial stability of 30 days, waste and time is kept to a minimum. Assayed target values and ranges are provided for this true third party control.

- Liquid ready-to-use
- 100% human urine
- Stable to expiry date at 2°C to 8°C
- Open vial stability 30 days at 2°C to 8°C
- Multi-point calibrator

Description	Size	Cat No
Liquid Urine Control Level 2	10 x 10 ml	UC5074
Liquid Urine Control Level 3	10 x 10 ml	UC5075

## Microalbumin Calibrator

Our Acusera Microalbumin Calibrator have been developed for use in the calibration and monitoring of microalbumin immunoturbidimetric assays. Our unique 100% human urine matrix ensures it behaves like a patient sample and reduces costly shifts when reagent batch is changed. As a true third party calibrator, it is compatible for use on a wide range of clinical analysers.

- Liquid ready-to-use
- 100% human urine
- Stable to expiry date at 2°C to 8°C
- Once opened stable to expiry date at 2°C to 8°C

Description	Size	Cat No
Microalbumin Calibrator Series	6 x 2 ml	MA1567

## Urinalysis Control

Analytes			
Albumin	Glucose	Nitrite	Urobilinogen
Bilirubin	hCG	pH	
Blood	Ketones	Protein (Total)	
Creatinine	Leukocytes	Specific Gravity	

The Acusera Urinalysis Control has been specifically designed for use in the quality control of urine test strips. Our user-friendly liquid ready-to-use format will dramatically reduce preparation time while a stability of 30 days will keep waste to a minimum. Assayed values are provided for 13 analytes covering a range of test strip manufacturers.

- Liquid ready-to-use
- 100% human urine
- Suitable for use in POCT
- Stable to expiry date at 2°C to 8°C
- Open vial stability of 30 days or 20 immersions at 2°C to 25°C

Description	Size	Cat No
Urinalysis Control Level 1	12 x 12 ml	UC5033
Urinalysis Control Level 2	12 x 12 ml	UC5034

# INTER- LABORATORY DATA MANAGEMENT

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Compatible for use with the Acusera range of third party controls, the Acusera 24•7 software is designed to help laboratories monitor and interpret their QC data. Access to an impressive range of features including interactive charts and real-time peer group data generated from our extensive database of laboratory participants, ensures Acusera 24•7 is the most comprehensive package available.

# WHAT IS ACUSERA 24•7?

## ACUSERA 24•7

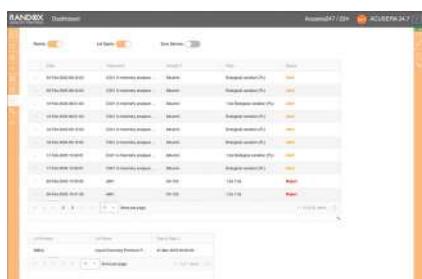
**Acusera 24•7** is an interlaboratory data management and peer group reporting package designed to complement the **Acusera** range of third party controls. Using **Acusera 24•7** will help you to improve error detection, reduce false rejections and ensure accurate patient test results.

### Why run a peer group reporting program?

- Quickly identify trends, system errors and reagent issues, minimising expensive repeat tests
- Bridge the gap between daily quality control and external quality assessment
- Improve EQA performance by eliminating any undetected bias
- Facilitate regulatory compliance
- Reduce false rejections through the use of QC multi-rules
- Increase confidence in assigned QC target values
- Carry out rapid and effective troubleshooting leading to shorter delays in reporting

With **Acusera 24•7**, peer group data is uniquely updated live, in real-time, giving you access to the most up-to-date information available. Access to relevant peer group data enables rapid and effective troubleshooting, it may even help to identify errors earlier.

## FEATURES



### Dashboard

The unique Dashboard interface displays any alerted or rejected QC results that have fallen outside user-defined performance limits and multi-rules in the last seven days.

### Acusera Advisor

Acusera Advisor is an optional tool designed to help you select an optimum QC strategy for each individual test in use. Not only will the advisor tool recommend a set of QC multi-rules, it will also suggest a minimum QC frequency based on the performance of the method in question.



### Interactive Charts

Levey-Jennings, Histogram and Performance Summary Charts are automatically generated by the software. The ability to combine multiple data sets enables you to identify and assess trends in QC data or a bias between instruments. It is also possible to record events such as instrument service/maintenance on Levey-Jennings Charts for faster troubleshooting.

### Peer Group Statistics

Peer groups can be customised depending on your instrument, method or reagent supplier. Peer group reporting allows you to compare the performance of your own instrument and/or assay method against other laboratories using the same lot of control. Statistics are uniquely updated live, in real-time, and are generated from our extensive database of laboratory participants.



### Advanced Statistical Analysis

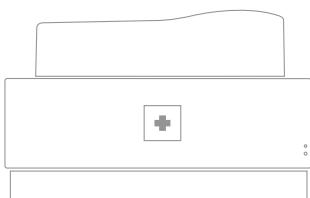
The Statistical Metrics Report incorporates %Bias, Total Error and a Sigma score for optimum QC strategy design while the Uncertainty of Measurement Report helps to meet ISO15189:2022 requirements.

# DATA ENTRY OPTIONS

There are three options for QC data entry with Acusera 24•7

## Manual result entry

Easily create custom panels for faster result entry of multiple tests at once, with the option to enter single or summarised data for each test or panel.



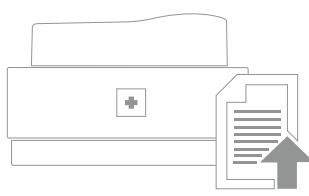
- 1 Analyser generates QC result.



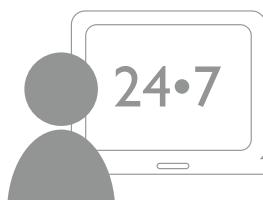
- 2 QC result is manually entered by the user into the Acusera 24•7 software.

## Semi-automated result entry via EDI

EDI is the ideal solution for laboratories that don't want the hassle of manual data input but still want to benefit from a reduction in time and elimination of transcription errors.



- 1 An export file containing the QC result and associated information is generated by the analyser, LIMS or Middleware.



- 2 The user imports the EDI file into the Acusera 24•7 software at their desired frequency.

**Note:** First time users must create a new configuration for the EDI file and carry out EDI mapping.

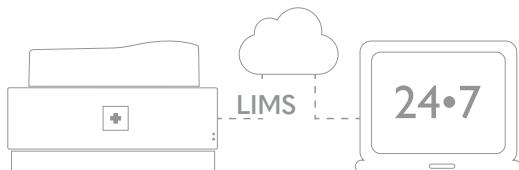
## Fully automated import of QC data direct from your LIMS/Middleware

Automatically capture data directly from your LIMS/Middleware with Acusera 24•7 Connect and import into Acusera 24•7 without the need to import files or manually input data.

- Reduce workload by eliminating manual data entry or file import
- Eliminate transcription errors
- Secure real-time connection without disruption to the laboratory workflow

Several options are available for automated data entry, our Acusera 24•7 Connect team will work directly with you and your IT team to implement the best solution for your lab's requirements.

### Acusera 24•7 Connect



- 1 An export file containing the QC result and associated information is generated by the LIMS/Middleware. The Acusera 24•7 Connect software will then securely collect and process QC data directly from the LIMS/Middleware and import to Acusera 24•7.

**Note:** First time users must create a new configuration for the EDI file and carry out EDI mapping.

# OPTIONS FOR PARTICIPATION

Randox offers several options for participation in the Acusera 24•7 program ranging from basic to advanced user options. The table below is designed to help determine the best solution for your laboratory.

FEATURES	PLATINUM	GOLD	SILVER
<b>Global Peer Data</b>			
Access to real-time peer group data	✓	✓	✓
<b>Users</b>			
Multiple levels of user access	✓	✓	✗
Unlimited number of registered users	✓	✗	✗
<b>Configuration</b>			
Custom Multi-Rules	✓	✗	✗
Ability to use other manufacturer controls or custom controls	✓	✗	✗
<b>Data Entry</b>			
Data import via Acusera 24•7 Connect *	✓	✓	✓
Manual data entry by panel	✓	✓	✗
Semi automated data entry via EDI	✓	✓	✓
Recording of instrument events	✓	✗	✗
<b>Result History</b>			
Automatic calculation of Mean, SD and %CV	✓	✓	✓
Result History	✓	✓	✓
Automatic calculation of %Bias and Total Error	✓	✓	✗
Automatic calculation of Inter-Precision, Sigma Scores, Uncertainty of Measurement and Expanded Uncertainty	✓	✗	✗
<b>Reports</b>			
Statistical Analysis Report	✓	✓	✓
Peer Group Statistics Report	✓	✓	✓
Exception Report	✓	✓	✗
Statistical Metrics Report	✓	✗	✗
Uncertainty of Measurement Report	✓	✗	✗
<b>Charts</b>			
Levey-Jennings Chart	✓	✓	✓
Histogram Chart	✓	✓	✓
Performance Summary Chart	✓	✓	✓
Multi-Levey Jennings/Histogram Charts	✓	✓	✗
<b>Utilities</b>			
Dashboard	✓	✓	✗
Advisor Tool	✓	✗	✗
Data Review	✓	✓	✓

ORDERING DETAILS			
Description	Cat No	Description	Cat No
Acusera 24•7 Platinum (1 - year licence)	QC4218	Acusera 24•7 Connect Box	QC4227
Acusera 24•7 Gold (1 - year licence)	QC10232	Acusera 24•7 Cloud Connect	QC4228
Acusera 24•7 Silver (1 - year licence)	QC10233	Installation of Randox Connect Box (Onsite)	QC4229
Acusera 24•7 Configuration/Mapping	QC4224	Installation of Customer Connect Box (Onsite)	QC4230
Acusera 24•7 Training (on-site)	QC4225	Installation of Customer Connect Box (Remote)	QC4231
Acusera 24•7 Training (remote)	QC4226	Acusera 24•7 End User Cloud Connect*	QC4232

\* 1 connection

# GLOSSARY

## Bias%

In Acusera 24•7, Bias is the difference between the Peer Group Mean and the observed value.

$$\text{Bias\%} = \frac{\text{Laboratory Mean} - \text{Peer Group Mean}}{\text{Peer Group Mean}} \times 100$$

## CVI

### Coefficient of Variation Index (CVI)

The CVI compares the precision from your laboratory to the precision of other laboratories in your chosen peer group.

$$\text{CVI} = \frac{\text{Laboratory CV}}{\text{Peer Group CV}}$$

## SDI

### Standard Deviation Index (SDI)

SDI provides an indication of how well your Mean compares to the Peer Group Mean for a given assay and control lot.

$$\text{SDI} = \frac{\text{Laboratory Mean} - \text{Peer Group Mean}}{\text{Peer Group Standard Deviation}}$$

## TE

### Total Error (TE)

Total Error represents the overall error in a test result that is attributed to imprecision (%CV) and inaccuracy (Bias%).

$$\text{TE} = \text{Bias\%} + (165 \times \% \text{CV})$$

## $\sigma$

### Sigma

Sigma looks at the number of standard deviations (SD) or 'sigmas' that fit within the quality specifications of the process. In the laboratory, the quality specifications relate to the Total Allowable Error (TEa). The higher the number of standard deviations that fit between these limits, the higher the sigma score and the more robust the process or method is.

$$\text{Sigma} = \frac{\text{TEa\%} - \text{Bias\%}}{\% \text{CV}}$$

## UM

### Uncertainty of Measurement (UM)

With every result generated in the laboratory, there will always be a degree of error. Uncertainty of Measurement (UM) looks at the doubt that exists for the result of any measurement.

$$u = \sqrt{A^2 + B^2}$$

$$U = 2 \times u$$

Where:

A = SD or SEM of the Intra-assay precision

B = SD of the Inter-assay precision

u = Standard Uncertainty

U = Expanded Uncertainty

# EXTERNAL QUALITY ASSESSMENT

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EQA is an effective partner to your IQC plans. An EQA scheme, such as RIQAS, utilises 'blind' samples to measure a laboratory's accuracy. These 'blind' samples are analysed by the laboratory as though they are patient samples and the results returned to the scheme organiser for statistical analysis. When the analysis is complete, each participant receives a report enabling them to compare the performance of their laboratory to other participants within their method and instrument groups.

# FEATURES AND BENEFITS

## Randox International Quality Assessment Scheme RIQAS

**RIQAS** is the largest international EQA scheme, used by more than 55,000 laboratory participants in over 134 countries worldwide. This large number of participants ensures an extensive database of results for many analytical methods, directly increasing statistical validity as a result.



### Large Database of Users

- A high level of participation means peer group numbers are maximised whilst ensuring availability of data for a wide range of instruments and methods.



### User-friendly Reports

- Simple, one page per parameter format, enables at-a-glance performance assessment, saving valuable laboratory time.
- Complimentary multi-instrument and interlaboratory reports allow comparative performance assessment of all laboratory systems and multiple connected laboratories.
- End-of-Cycle reports, summarising performance compared to the previous cycle, allows you to identify improvements in quality over time.



### Cost Effective

- Our extensive range of multi-analyte programmes will reduce the number of individual programmes required to cover your test menu, saving both time and money.
- Reduced parameter options for selected programmes offer greater flexibility, ensuring suitability for laboratories of all sizes and budgets.
- Register up to five instruments per programme (volume permitting) at no extra cost for comparative performance assessment.



### Frequency

- Frequent reporting allows early identification of system errors and implementation of any necessary corrective actions with minimum disruption to the lab.
- With a turnaround of less than 72 hours for most reports, corrective action can be implemented earlier, potentially reducing costly errors with patient results.



### High Quality Samples

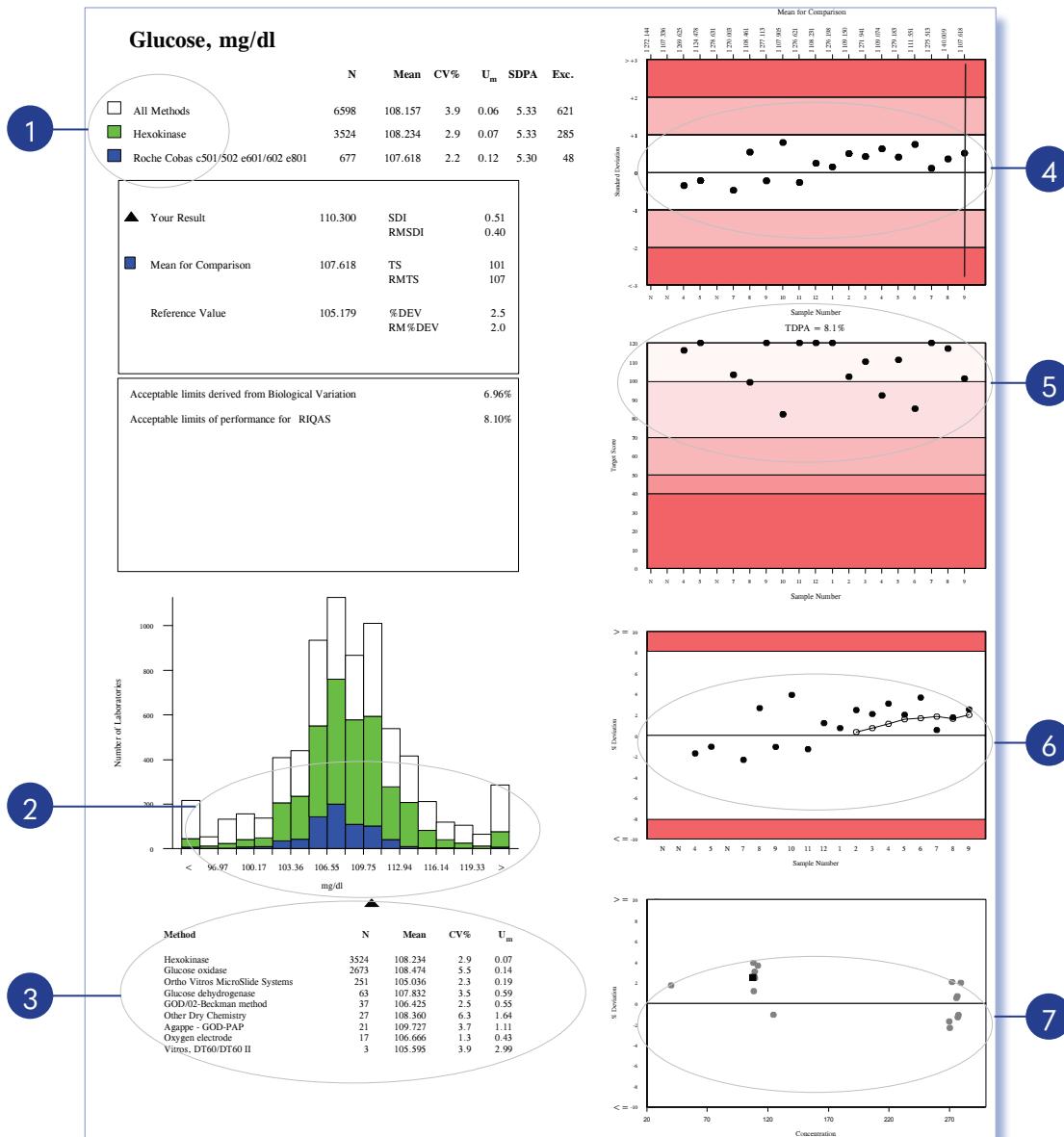
- Samples spanning clinically relevant levels allow identification of concentration related biases, helping to ensure accurate instrument performance.
- Human samples free from interfering preservatives increase confidence that EQA performance mirrors the performance of patient samples.
- Reference method values are provided in the Clinical Chemistry programme for selected parameters and lots, while for the Immunosuppressant programme they are provided for all parameters and lots.



### Highly Accredited

- Programmes accepted by National and International accreditation bodies worldwide.
- Participant certificates provide evidence of participation in a reputable EQA scheme.

Performance data is presented in a one page format with up to seven sub-reports.



- Text Section Chart:** Statistics for all methods, your method and instrument group (programme specific).
- Histogram Chart:** Method and instrument comparison.
- Multi-Method Stat Section Chart:** Enables assessment of the performance of each method.
- Levey-Jennings Chart:** Details features of your laboratory's performance.
- Target Score Chart:** This unique chart provides a numerical index of performance, allowing at-a-glance assessment.
- %Deviation by Sample Chart:** Helps to identify trends and shifts in performance.
- %Deviation by Concentration Chart:** Rapid assessment of concentration related biases.

**Note:** This example is for quantitative programmes Other types of report are also available.

# RIQAS PROGRAMMES

## Ammonia/Ethanol Programme With target scoring



RQ9164 (2 ml)  
2 Parameters  
Samples every month, 1 x 12 month cycle, 12 month subscription

Ammonia

Ethanol

## Anti-Müllerian Hormone (AMH) Programme+



RQ9198 (1 ml)  
1 Parameter  
Samples every month, 1 x 12 month cycle, 12 month subscription

Anti-Müllerian Hormone (AMH)

## Anti-TSH Receptor Programme+ With target scoring



RQ9174 (1 ml)  
1 Parameter  
Samples every month, 1 x 12 month cycle, 12 month subscription

Anti-TSH Receptor (TRAb)

## Blood Gas Programme With target scoring



RQ9134 (1.8 ml)  
First registered instrument  
11 Parameters  
Samples every month, 1 x 12 month cycle, 12 month subscription

Bicarbonate  
Ca++  
Cl-

RQ9134/A (1.8 ml)  
Subsequent instruments  
11 Parameters

K+  
Na+  
pCO<sub>2</sub>

pH  
pO<sub>2</sub>

## BNP Programme+ With target scoring



RQ9165 (1 ml)  
1 Parameter  
Samples every month, 1 x 12 month cycle, 12 month subscription

BNP

## Cardiac Programme With target scoring



RQ9127/a (1 ml)  
2 Parameters only (choose from 7)  
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription

CK, Total  
CK-MB (Activity)

RQ9127/b (1 ml)  
Full 7 Parameters  
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription

CK-MB (Mass)  
Homocysteine

RQ9186 (1 ml)  
Full 7 Parameters  
Samples every month, 1 x 12 monthly cycle, 12 month subscription

Myoglobin  
Troponin I

Troponin T

## Cardiac Plus Programme With target scoring



RQ9190 (3 ml)  
11 Parameters  
Samples every month, 1 x 12 month cycle, 12 month subscription

CK, Total  
CK-MB Activity  
CK-MB Mass

D-dimer  
Digoxin  
Homocysteine

hsCRP  
Myoglobin  
NT proBNP

Troponin I  
Troponin T

## Cerebrospinal Fluid Programme+ With target scoring



RQ9168 (3 ml)  
7 Parameters  
Samples every month, 1 x 12 month cycle, 12 month subscription

Albumin  
Chloride

Glucose  
IgG

Lactate  
Protein (Total)

Sodium

= Liquid ready-to-use samples

= Lyophilised samples

**PURPLE** = The only parameters available on RQ9135/a

+ = Not accredited

\* = Pilot study ongoing

## Coagulation Programme With target scoring



**RQ9135/a (1 ml)**  
5 Selected parameters only + 1 pilot  
(aPTT, PT, TT, Fibrinogen, Antithrombin III)  
Samples every month, 1 x 12 month cycle, 12 month subscription

**RQ9135/b (1 ml)**  
Full 16 Parameters + 1 pilot

aPTT  
PT (including INR)  
TT  
Fibrinogen  
Antithrombin III

D-dimer\*  
Factor II  
Factor V  
Factor VII  
Factor VIII

Factor IX  
Factor X  
Factor XI  
Factor XII  
Plasminogen

Protein C  
Protein S

## CO-Oximetry Programme+



**RQ9177 (1.2 ml)**  
First registered instrument  
7 Parameters  
Samples every month, 1 x 12 month cycle, 12 month subscription

**RQ9177/A (1.2 ml)**  
Subsequent instruments  
7 Parameters

Carboxyhaemoglobin (COHb / HbCO)  
Deoxyhaemoglobin (HHb)

Methaemoglobin (MetHb)  
Oxygen Content (O2CT)

Oxygen Saturation (sO2 / Vol O2)  
Oxyhaemoglobin (O2Hb / HbO2)

Total Haemoglobin (tHb)

## CYFRA 21-1 Programme+



**RQ9175 (1 ml)**  
1 Parameter  
Samples every month, 1 x 12 month cycle, 12 month subscription

CYFRA 21-1 (Cytokeratin 19)

## Cytokines Programme+



**RQ9195 (1 ml)**  
1 Parameter + 11 pilots  
Samples every month, 1 x 12 month cycle, 12 month subscription

Epidermal Growth Factor (EGF)\*  
Interleukin - 1 alpha (IL-1α)\*  
Interleukin - 1 beta (IL-1β)\*  
Interleukin - 2 (IL-2)\*

Interleukin - 4 (IL-4)\*  
Interleukin - 6 (IL-6)  
Interleukin - 8 (IL-8)\*  
Interleukin - 10 (IL-10)\*

Interferon gamma (INF-γ)\*  
Monocyte Chemoattractant Protein -1 (MCP-1)\*  
Tumour Necrosis Factor alpha (TNF-α)\*

Vascular Endothelial Growth Factor (VEGF)\*

## ESR Programme+



**RQ9163 (4.5 ml)**  
1 Parameter  
2 samples per quarterly distribution, 1 x 12 month cycle, 12 month subscription

ESR (Erythrocyte Sedimentation Rate)

## General Clinical Chemistry Programme With target scoring



**RQ9112/a (5 ml)**  
10 Parameters  
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription, reference method values

**RQ9128 (5ml)**  
Full 56 Parameters  
Samples every month, 1 x 12 monthly cycle, 12 month subscription

ACE (Angiotensin Converting Enzyme)  
Acid Phosphatase (Prostatic)  
Acid Phosphatase (Total)  
Albumin  
Alkaline Phosphatase  
ALT (ALAT)  
Amylase (Pancreatic)  
Amylase (Total)  
AST (ASAT)  
Bicarbonate  
Bile Acids  
Bilirubin (Direct)  
Bilirubin (Total)  
Calcium

Calcium, Adjusted  
Calcium (Ionised)  
Chloride  
Cholesterol  
Cholinesterase  
CK, Total (CPK)  
Copper  
Creatinine  
D-3-Hydroxybutyrate  
eGFR (estimated glomerular filtration rate)  
Fructosamine  
γGT  
GLDH  
Glucose

HBDH  
HDL-Cholesterol  
Iron  
Lactate  
LD (LDH)  
LDL-Cholesterol  
Lipase  
Lithium  
Magnesium  
NEFA  
Non-HDL Cholesterol  
Osmolality  
Phosphate (Inorganic)  
Potassium

Protein (Total)  
PSA  
Sodium  
TIBC  
 $T_3$  (Free)  
 $T_3$  (Total)  
 $T_4$  (Free)  
 $T_4$  (Total)  
Triglycerides  
TSH  
UIBC  
Urea  
Uric Acid  
Zinc

## Glycated Haemoglobin Programme (HbA1c) With target scoring



**RQ9129 (0.5ml)**  
2 Parameters  
Samples every month, 1 x 12 month cycle, 12 month subscription

HbA1c

Total Haemoglobin

= Liquid ready-to-use samples

= Lyophilised samples

**PURPLE** = The only parameters available on RQ9135/a

+ = Not accredited

\* = Pilot study ongoing

# RIQAS PROGRAMMES

## Haematology Programme With target scoring

<b>RQ9118 (2 ml)</b> 11 Parameters Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription	<b>RQ9140 (2ml)</b> 11 Parameters Samples every month, 1 x 12 monthly cycle, 12 month subscription
Haematocrit (HCT) Haemoglobin (Hb) Mean Cell Haemoglobin (MCH)	Mean Cell Haemoglobin Concentration (MCHC) Mean Cell Volume (MCV)

## Human Urine Programme With target scoring

<b>RQ9115 (2 x 10 ml)</b> 25 Parameters Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription	<b>RQ9185 (10ml)</b> 25 Parameters Samples every month, 1 x 12 monthly cycle, 12 month subscription
ACR Albumin/Microalbumin Amylase Calcium Chloride Copper Cortisol	Creatinine Dopamine Epinephrine Glucose Metanephrine Norepinephrine

## Immunoassay Programme With target scoring

<b>RQ9125/a (5 ml)</b> 4 Parameters only + 2 pilots Samples every two weeks, 2 x 6 monthly cycles, 12 month subscription (RQ9125/a, RQ9125/b, RQ9125/c)	<b>RQ9125/b (5 ml)</b> 13 Parameters only + 2 pilots	<b>RQ9125/c (5 ml)</b> Full 49 Parameters + 2 pilots	<b>RQ9130 (5 ml)</b> Full 49 Parameters + 2 pilots Samples every month, 1 x 12 month cycle, 12 month subscription RQ9130
ACTH AFP Aldosterone Amikacin Androstenedione β-2-Microglobulin CA125 CA15-3 CA19-9 Carbamazepine CEA Cortisol C-Peptide	DHEA-Sulphate DHEA Unconjugated Digoxin Ferritin Folate FSH Gentamicin GH hCG IgE Insulin LH Oestradiol	17-OH-Progesterone Paracetamol Phenobarbital Phenytoin Progesterone Prolactin PSA (Free) PSA (Total) PTH Salicylate SHBG T <sub>3</sub> (Free) T <sub>3</sub> (Total)	T <sub>4</sub> (Free) T <sub>4</sub> (Total) Testosterone (Free)* Testosterone (Total) Theophylline Thyroglobulin TSH Valproic Acid Vancomycin Vitamin B12 1,25-(OH) <sub>2</sub> -Vitamin D* 25-OH-Vitamin D

## Immunoassay Speciality 1 Programme With target scoring

<b>RQ9141 (2 ml)</b> 9 Parameters + 1 pilot Samples every month, 1 x 12 month cycle, 12 month subscription	Anti-TG Anti-TPO IGF-1	Osteocalcin Procalcitonin PTH	Insulin
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## Immunoassay Speciality 2 Programme With target scoring

<b>RQ9142 (1 ml)</b> 5 Parameters Samples every month, 1 x 12 month cycle, 12 month subscription	Calcitonin Gastrin	Procalcitonin	Plasma Renin Activity	Renin (Direct Concentration)
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## Immunosuppressant Programme+

<b>RQ9159 (2 ml)</b> 4 Parameters Samples every month, 1 x 12 month cycle, 12 month subscription, reference method values	Ciclosporin Everolimus Sirolimus Tacrolimus
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## Lipid Programme With target scoring

<b>RQ9126/a (3 ml)</b> 3 Parameters only (choose from 7) Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription	<b>RQ9126/b (3 ml)</b> Full 7 Parameters Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription	Cholesterol (Total) HDL-Cholesterol	LDL-Cholesterol Lipoprotein (a)	Triglycerides
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 = Liquid ready-to-use samples

 = Lyophilised samples

**PURPLE** = The only parameters available on RQ9135/a

+ = Not accredited

\* = Pilot study ongoing

## Maternal Screening Programme With target scoring



RQ9137 (1 ml)  
6 Parameters  
Samples every month, 1 x 12 month cycle, 12 month subscription

AFP  
free β-hCG

Total hCG  
Inhibin A

PAPP-A

Unconjugated Oestriol

## Microbiology (Bacterial Identification) Programme+



RQ9197  
1 strain (complete with case study)  
Samples every 2 months, 1 x 12 month cycles, 12 month subscription

Antimicrobial Susceptibility Testing

Strain Identification

1 strain complete with case study Identification of the micro-organisms can be made at Gram positive / negative, Genus and Species level Antimicrobial Susceptibility Testing on identified strain

## Neonatal Bilirubin Programme+



RQ9191 (3 ml)  
2 Parameters  
Samples every month, 1 x 12 month cycle, 12 month subscription

Direct Bilirubin

Total Bilirubin

## Serology (Anti-SARS-CoV-2) Programme+



RQ9193 (0.5 ml)  
3 Parameters  
Samples every month, 1 x 12 month cycle, 12 month subscription

IgG

IgM

Total Antibodies

## Serology (EBV) Programme+



RQ9153 (1 ml)  
3 Parameters  
Samples every month, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results

Anti-EBV VCA IgG

Anti-EBNA IgG

Anti-EBV VCA IgM

## Serology (HIV-Hepatitis) Programme+



RQ9151 (1.8 ml)  
10 Parameters + 6 pilots  
Samples every month, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results

Anti-CMV (Total)  
Anti-HAV IgM\*  
Anti-HAV (Total)\*  
Anti-HBc

Anti-HBc IgM\*  
Anti-HBe (Total)\*  
Anti-HBs (Total)\*  
Anti-HCV

Anti-HIV-1  
Anti-HIV-2  
Anti-HIV combined  
Anti-HTLV I

Anti-HTLV II  
Anti-HTLV combined  
HBsAg  
P24\*

## Serology (Syphilis) Programme+



RQ9154 (1 ml)  
1 Parameter  
Samples every month, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results

Syphilis (Methods available include immunoassay RPR, VDRL and TPHA)

## Serology (ToRCH) Programme+



RQ9152 (1 ml)  
12 Parameters + 3 pilots  
Samples every month, 1 x 12 month cycle, 12 month subscription, Quantitative and Qualitative results

Anti-CMV IgG  
Anti-CMV IgM  
Anti-HSV1 IgG  
Anti-HSV1 IgM

Anti-HSV2 IgG  
Anti-HSV2 IgM  
Anti-HSV1/2 IgG  
Anti-HSV1/2 IgM

Anti-Measles IgG\*  
Anti-Mumps IgG\*  
Anti-Rubella IgG  
Anti-Rubella IgM

Anti-Toxoplasma IgG  
Anti-Toxoplasma IgM  
Anti-VZV IgG\*

= Liquid ready-to-use samples

= Lyophilised samples

PURPLE = The only parameters available on RQ9135/a

+ = Not accredited

\* = Pilot study ongoing



# ANALYTE INDEX

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Approximately 70% of clinical decisions are based on laboratory test results. Poor laboratory quality can result in unreliable test results, ultimately leading to misdiagnosis, inappropriate treatment and may even be potentially life threatening to your patient. Availability of comprehensive controls covering the full spectrum of laboratory tests is critical in order to assure quality of testing.

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<b>B</b>	BASO-X																																					
	BASO-Y																																					
	Basophils (BASO)																																					
	Basophils % (% BASO)																																					
	Bicarbonate					x						x	x	x			x	x	x																			
	Bile Acids											x	x	x			x	x	x																			
	Bilirubin (Direct)											x	x	x	x		x	x	x	x																		
	Bilirubin (Total)											x	x	x	x		x	x	x	x																		
	Blood																																					
	Bone Alkaline Phosphatase (B-ALP)																																			x		
	Borrelia burgdorferi IgG																																					
	Borrelia burgdorferi IgM																																					
	Brain Natriuretic Peptide (BNP)					x																																
<b>C</b>	C-Peptide																														x	x	x					
	C-Telopeptide																														x							
	CA 15-3																																					
	CA 19-9																																				x	
	CA 72-4																																				x	
	CA 125																																				x	
	Caffeine																								x	x												
	Calcitonin																																				x	
	Calcium				x							x	x	x			x	x	x																x			
	Carbamazepine																								x	x	x				x	x						
	CEA																							x	x	x				x	x							
	Ceftiofur																																					
	Ceruloplasmin																								x	x	x											
	Chloramphenicol																																					
	Chloride			x								x	x	x			x	x	x																			
	Cholesterol (HDL)											x					x			x	x	x																
	Cholesterol (LDL)																			x	x																	
	Cholesterol (Total)											x	x	x			x	x	x																			
	Cholinesterase											x	x				x	x	x																			
	CK-MB			x	x																																	
	CK (Total)					x						x	x	x			x	x	x																			
	Complement C3																			x	x	x																
	Complement C4																		x	x	x																	
	Copper											x	x	x			x	x	x																x			
	Cortisol											x	x				x	x	x																x	x		
	CRP																		x	x	x																	
	Creatinine											x	x	x			x	x	x																x			
	Cyclosporine																		x	x	x																	
	Cytomegalovirus (CMV) IgG																																					
	Cytomegalovirus (CMV) IgM																																					
	CYFRA 21																																					
	Cystatin C																																					
<b>D</b>	D-3-Hydroxybutyrate															x	x	x		x	x	x																
	D-dimer																		x	x																		
	Deoxypyridinoline																			x	x															x		
	DHEA-Sulphate																			x	x														x	x		
	DIFF-X																																					
	DIFF-Y																																					
	Digoxin											x				x	x	x	x																x	x		
	Dopamine																																				x	
<b>E</b>	E-Selectin (E-SEL)																																					
	Eosinophils (EOS)																															x						

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	Basophils (BASO)	
	Basophils % (BASO)	
	Bicarbonate	
	Bile Acids	
	x Bilirubin (Direct)	
	x Bilirubin (Total)	
	x Blood	
	Bone Alkaline Phosphatase (B-ALP)	
	Borrelia burgdorferi IgG	
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	Brain Natriuretic Peptide (BNP)	
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	CA 15-3	
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	Caffeine	
	Calcitonin	
	Calcium	
	Carbamazepine	
	CEA	
	Ceftiofur	
	Ceruloplasmin	
	Chloramphenicol	
	Chloride	
	Cholesterol (HDL)	
	Cholesterol (LDL)	
	Cholesterol (Total)	
	Cholinesterase	
	CK-MB	
	CK (Total)	
	Complement C3	
	Complement C4	
	Copper	
	Cortisol	
	CRP	
	Creatinine	
	Cyclosporine	
	Cytomegalovirus (CMV) IgG	
	Cytomegalovirus (CMV) IgM	
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	D-3-Hydroxybutyrate	
	D-dimer	
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	DHEA-Sulphate	
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	Digoxin	
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	Factor X	
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	Fibrinogen	
	Folate	
	Fructosamine	
	FSC-X	
	FSH	
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	γ-Globulin (Electrophoresis)	
	γGT	
	Gastrin	
	Gentamicin	
	Gestagens (Generic)	
	GLDH	
	Glucose	x
	Glutamate	
	Glutathione Peroxidase (Ransel)	x
	Glutathione Reductase	x
	Glycerol	
	GM-CSF	
	Growth Hormone (GH)	
<b>H</b>	Haematocrit (HCT)	
	Haemoglobin (HGB)	
	Haemoglobin (Total)	
	Haemolysis (H)	
	Haemopoietic Progenitor Cell (HPC)	
	Haptoglobin	
	HAV IgM	
	HbA1c	
	HBc IgM	
	HBeAg	
	HBsAg	
	hCG	
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	Total β-hCG	
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	Icterus (I)
	IMIDC
	IMIRF
	Immature Granulocytes (IG)
	% Immature Granulocytes (% IG)
	Immature Myeloid Information (IMI)
	Immature Platelet Fraction (IPF)
	Immunoglobulin A (IgA)
	High Sensitivity Immunoglobulin A (hsIgA)
	Immunoglobulin E (IgE)
	Immunoglobulin G (IgG)
	High Sensitivity Immunoglobulin G (hsIgG)
	Immunoglobulin M (IgM)
	High Sensitivity Immunoglobulin M (hsIgM)
	Inhibin A
	Insulin
	Intercellular Adhesion Molecule-I (ICAM-I)
	Interferon-γ (IFN-γ)
	Interleukin-1α (IL-1α)
	Interleukin-1β (IL-1β)
	Interleukin-2 (IL-2)
	Interleukin-4 (IL-4)
	Interleukin-5 (IL-5)
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	Kappa Light Chain
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	Lactate
	Lactate Dehydrogenase (LDH)
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	Lambda Light Chain (Free)
	LAP
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	Lithium
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	pCO <sub>2</sub>	
	pH	
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# CONTACT US

Contact us for more information on any of our products and services:

## HEADQUARTERS

Randox Laboratories Ltd, 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom  
+44 (0) 28 9442 2413    marketing@randox.com    [randox.com](http://randox.com)

## INTERNATIONAL OFFICES



### AUSTRALIA

Randox (Australia) Pty Ltd.  
Tel: +61 (0) 2 9615 4640



### BRAZIL

Randox Brasil Ltda.  
Tel: +55 11 5181 2024



### CHINA

Randox Laboratories Ltd.  
Tel: +86 021 6288 6240



### CZECH REPUBLIC

Randox Laboratories S.R.O.  
Tel: +420 2 1115 1661



### FRANCE

Laboratoires Randox  
Tel: +33 (0) 130 18 96 80



### GERMANY

Randox Laboratories GmbH  
Tel: +49 (0) 215 1937 0611



### HONG KONG

Randox Laboratories Hong Kong Limited  
Tel: +852 3595 0515



### ITALY

Randox Laboratories Ltd.  
Tel: +39 34 0080 9323



### INDIA

Randox Laboratories India Pvt Ltd.  
Tel: +91 80 6751 5000



### POLAND

Randox Laboratories Polska Sp z oo.  
Tel: +48 22 862 1080



### PORTUGAL

Irlandox Laboratorios Quimica Analitica Ltda  
Tel: +351 22 589 8320



### PUERTO RICO

Clinical Diagnostics of Puerto Rico, LLC  
Tel: +1 787 701 7000



### REPUBLIC OF IRELAND

Randox Teoranta  
Tel: +353 7495 22600



### SLOVAKIA

Randox S.R.O.  
Tel: +421 2 6381 3324



### SOUTH AFRICA

Randox Laboratories SA (Pty) Ltd.  
Tel: +27 (0) 11 312 3590



### SOUTH KOREA

Randox Korea  
Tel: +82 (0) 31 478 3121



### SPAIN

Laboratorios Randox S.L.  
Tel: +34 93 475 09 64



### SWITZERLAND

Randox Laboratories Ltd (Switzerland)  
Tel: +41 41 810 48 89



### UAE

Randox Medical Equipment Trading LLC  
Tel: +971 55 474 9075



### USA

Randox Laboratories-US, Ltd.  
Tel: +1 304 728 2890



### VIETNAM

Randox Laboratories Ltd Vietnam  
Tel: +84 (0) 8 3911 0904

## For technical support contact:

[technicalservices@randox.com](mailto:technicalservices@randox.com)



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LT027 MAR23