

RANDOX

# THIRD PARTY CONTROLS



ACUSERA

# RANDOX

QUALITY CONTROL

## ACUSERA

TRUE THIRD PARTY CONTROLS  
OFFERING COMPLETE TEST MENU CONSOLIDATION



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

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# BENEFITS

## Radox Quality Control - Global Leader



For over 40 years, Radox has set the standard in diagnostic quality control and external quality assessment globally. The trusted partner of over 100,000 laboratories worldwide, delivering reliable quality control solutions that safeguard patient results and laboratory reputations.



### Superior Consolidation

QC Consolidation that will simplify daily workflows and significantly reduces overall QC costs.



### Clinically Relevant Levels

Analytes at key decision levels, ensuring instrument performance is assessed where it matters most.



### Unrivalled Stability

Extended working stability that reduces waste, lowers the frequency of lot changes and minimises costs.



### Highly Commutable

Controls designed to closely mimic patient samples, enabling a more accurate performance evaluation.



### Trusted Third-Party Controls

Independent, unbiased controls which are compatible for use with any instrument or method.



### Advanced QC Data Management

Automated QC data management and reporting, improving efficiency and regulatory compliance.

How Randox QC Outperformed Competitors in a High - Volume European Lab

PRECISION. STABILITY. CONFIDENCE IN EVERY TEST.

**Objective:** Independent comparative trial to assess the performance of Randox Quality Control materials versus equivalent competitor controls. Evaluating performance under real-world quality control (QC) conditions.

RANDOX QC EVALUATED



- Cardiac Controls
- Chemistry Controls
- Immunoassay Controls
- Immunoassay Speciality I Controls
- Serology Controls
- Specific Proteins Controls

THE TRIAL APPROACH



Direct comparison using lab's existing QC protocols



Performance monitored via Coefficient of Variation (CV)



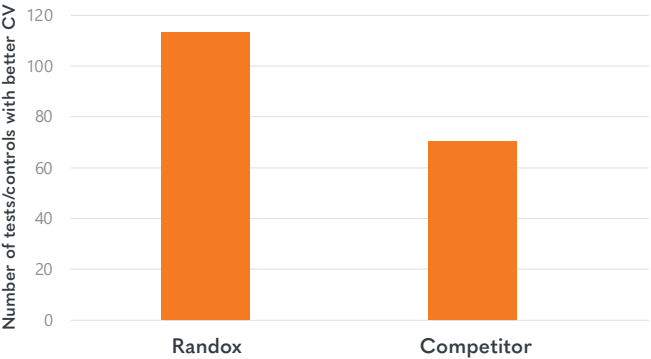
103 analytes including calcium, albumin, TSH, troponin I, vitamin D, and more



Tested up to three QC levels per analyte

INITIAL RESULTS

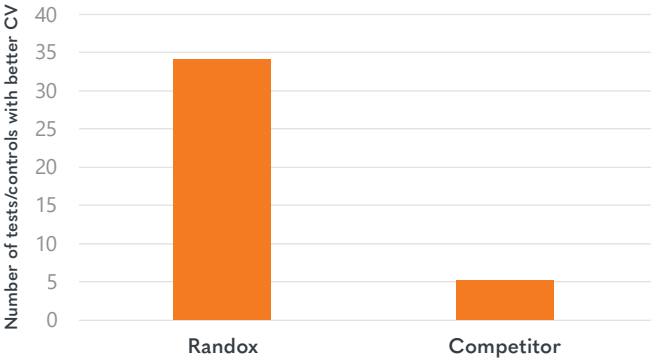
CV Performance



Randox QC demonstrated lower CVs across 110 tests, highlighting greater precision, with testing conducted over 7 days onboard compared to the competitor QC's 1-2 days.

EXTENDED 7-DAY TRIAL

CV Performance



A follow-up trial evaluating clinical chemistry controls for both Randox and competitor QC showed that Randox controls maintained superior long-term stability.

KEY TAKEAWAYS



Stable and precise performance



Lower CVs across a wide analyte panel



Reliable long-term onboard stability

# 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 85,000 laboratory participants in 145 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 37 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. Our unique combination of analytes has facilitated laboratories significantly reducing the number of controls required to cover their test menu and **saving up to £25,000 per annum** when compared to competing products. In addition, the presence of analytes at clinically relevant decision levels has eliminated the need to purchase additional high or low level controls, at extra expense.

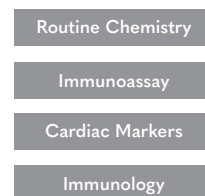
### How can consolidating with Randox Acusera benefit you?

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.

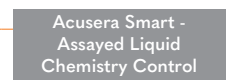
#### Acusera Smart – Assayed Liquid Chemistry Control

Uniquely combining up to 93 analytes including routine chemistry, immunoassays, immunology and cardiac markers in a single vial, you can experience effective consolidation and significant cost savings. The unrivalled stability of key routine analytes in the Acusera Smart - Assayed Liquid Chemistry Control will also contribute to reducing waste, stock management and improve overall cost effectiveness when compared to other Load & Go providers. - turn to page 08 for more information

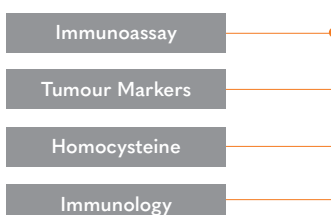
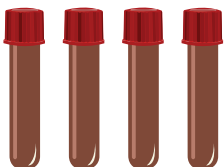
#### Competitor Controls



#### Randox Control



#### Competitor Controls



#### Randox Control



#### Acusera Smart – Liquid Immunoassay Control

Impressively covering 54 analytes including routine tumour markers, therapeutic drugs and routine immunoassay tests, the Acusera Smart - Liquid Immunoassay Control has been uniquely designed to eliminate the need for four or more controls, dramatically reducing costs and QC handling time. The added advantage of ultra-low levels of Ferritin, Vitamin B12 and TSH will help to ensure accurate performance at key decision levels and further reduce the number of controls required. - turn to page 09 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.

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 UKCA marking (an abbreviation of UK Conformity Assessed) is a conformity mark that indicates conformity with the applicable requirements for products sold within Great Britain. The government intended that it should replace the CE marking for products sold in Great Britain. Both markings continue to be accepted in the UK market.



ISO13485:2016

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 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 (IVDR) Medical Device Regulation (EU) 2017/746. This also demonstrates that the product is fit for its intended purpose. Many of our controls have already transitioned to IVDR (EU 2017/746) with many more currently in application, visit [www.randox.com/ivdr](http://www.randox.com/ivdr) to learn more.

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.

# STREAMLINE YOUR QC, THE SMART WAY

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Comprising of both Smartscan and Smartload options, the Acusera Smart controls range is designed to fit directly onto a wide range of test systems without the need to aliquot material, streamlining the QC process by minimising human error and optimising workflow.

### Acusera Smart Product Range

Product Description	Size	Cat No	Page No
Smartload Assayed Liquid Chemistry Control Level 1	12 x 4 ml	LAL10625	09
Smartload Assayed Liquid Chemistry Control Level 2	12 x 4 ml	LAN10626	09
Smartload Assayed Liquid Chemistry Control Level 3	12 x 4 ml	LAE10627	09
Smartscan Assayed Liquid Chemistry Control Level 1	12 x 4 ml	LAL10565	09
Smartscan Assayed Liquid Chemistry Control Level 2	12 x 4 ml	LAN10566	09
Smartscan Assayed Liquid Chemistry Control Level 3	12 x 4 ml	LAE10567	09
Liquid Immunoassay Control Level 1 (Smartload)	12 x 4 ml	LIA5142	10
Liquid Immunoassay Control Level 2 (Smartload)	12 x 4 ml	LIA5143	10
Liquid Immunoassay Control Level 3 (Smartload)	12 x 4 ml	LIA5144	10
Smartscan Liquid Immunoassay Level 1	12 x 4 ml	LIA10568	10
Smartscan Liquid Immunoassay Level 2	12 x 4 ml	LIA10569	10
Smartscan Liquid Immunoassay Level 3	12 x 4 ml	LIA10570	10
Smartload Liquid Cardiac Control 1	5 x 3 ml	CQ10534	11
Smartload Liquid Cardiac Control 2	5 x 3 ml	CQ10535	11
Smartload Liquid Cardiac Control 3	5 x 3 ml	CQ10536	11
Smartscan Liquid Cardiac Control Level 1	5 x 3 ml	CQ10616	11
Smartscan Liquid Cardiac Control Level 2	5 x 3 ml	CQ10617	11
Smartscan Liquid Cardiac Control Level 3	5 x 3 ml	CQ10618	11
PTH Control Level 1 (Smartload)	3 x 3 ml	PTH10608	11
PTH Control Level 2 (Smartload)	3 x 3 ml	PTH10609	11
PTH Control Level 3 (Smartload)	3 x 3 ml	PTH10610	11

Refer to [www.smartdocs.randox.com](http://www.smartdocs.randox.com) or the product insert (IFU) of currently available lots for specific analyte and stability claims.



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# ACUSERA

## SMART



### Reduce Handling Time

By removing the need to locate product inserts, manually enter QC ranges and pipette/aliquot material, the Acusera smart range can **save up to 60 minutes** of valuable laboratory time per control.



### Streamline Workflow

Through consolidation of multiple controls into one, Acusera Smart offers real benefits to the laboratory. Minimising stock management, reducing inventory requirements and leading to significant reduction in overall costs to cover the test menu.



### Minimise Waste

The unrivalled working stability of the Acusera Smart control range improves laboratory efficiency by reducing dead volume wastage, which in turn reduces the overall volume of QC required.



### Reduce Errors

With the removal of transcription errors through Acusera Smart XML and eliminating manual data input with secure transfer, Acusera Smart can significantly reduce transcription errors by laboratory staff.



### Ensure Reliability

Acusera Smart human serum based controls are designed to react to the test system in the same manner as the patient sample. Helping laboratories to meet regulatory requirements and reduce costly shifts in QC results when reagent batch is changed.



### Accelerate Data Review

Designed for use with the Acusera range of controls, the Acusera 24•7 software has been designed to speed up data review and troubleshooting procedures for smarter QC data management. With access to an impressive range of features, including Automatic Uncertainty of Measurement Calculation, Interactive Levey-Jennings Charts and Daily Data Review Reports, Acusera 24•7 has been **saving laboratories up to 938 hours** of valuable staff time annually.

## ACUSERA SMARTLOAD

1. The Smartload QC is directly loaded onto the analyser.
2. Operator follows relevant instructions to upload values.

## ACUSERA SMARTSCAN

1. The Smartscan QC is directly loaded onto the analyser.
2. The analyser scans the barcode.
3. The operator can log on to access the relevant target value file and upload as instructed.

# ACUSERA SMART CONTROLS



## Assayed Liquid Chemistry Control

Analytes			
<p><b>Cardiac</b></p> <ul style="list-style-type: none"> <li>CK (Total)</li> <li>Myoglobin</li> <li>Troponin T</li> </ul> <p><b>Drugs</b></p> <ul style="list-style-type: none"> <li>Amikacin</li> <li>Caffeine</li> <li>Carbamazepine</li> <li>Digoxin</li> <li>Ethanol</li> <li>Gentamicin</li> <li>Lithium</li> <li>Paracetamol</li> <li>Phenobarbitone</li> <li>Phenytoin</li> <li>Salicylate</li> <li>Theophylline</li> <li>Valproic Acid</li> <li>Vancomycin</li> </ul> <p><b>Immunoassay</b></p> <ul style="list-style-type: none"> <li>α-Fetoprotein (AFP)</li> <li>CEA</li> <li>Cortisol</li> <li>DHEA Sulphate</li> <li>Folate</li> </ul>	<ul style="list-style-type: none"> <li>FSH</li> <li>hCG</li> <li>Luteinising Hormone (LH)</li> <li>Progesterone</li> <li>Prolactin</li> <li>PSA (Total)</li> <li>T Uptake</li> <li>T3 (Free)</li> <li>T3 (Total)</li> <li>T4 (Free)</li> <li>T4 (Total)</li> <li>Testosterone</li> <li>TSH</li> <li>Vitamin B12</li> </ul> <p><b>Lipids</b></p> <ul style="list-style-type: none"> <li>Apolipoprotein A-1</li> <li>Apolipoprotein B</li> <li>Cholesterol (HDL)</li> <li>Cholesterol (LDL)</li> <li>Cholesterol (Total)</li> <li>Lipoprotein (a)</li> <li>Triglycerides</li> </ul> <p><b>Proteins</b></p> <ul style="list-style-type: none"> <li>α-1- Acid Glycoprotein</li> <li>α-1-Antitrypsin</li> </ul>	<ul style="list-style-type: none"> <li>β-2-Microglobulin</li> <li>Ceruloplasmin</li> <li>Complement C3</li> <li>Complement C4</li> <li>CRP</li> <li>Ferritin</li> <li>Haptoglobin</li> <li>Immunoglobulin A (IgA)</li> <li>Immunoglobulin E (IgE)</li> <li>Immunoglobulin G (IgG)</li> <li>Immunoglobulin M (IgM)</li> <li>Prealbumin</li> <li>Protein (Total)</li> <li>Transferrin</li> </ul> <p><b>Routine Chemistry</b></p> <ul style="list-style-type: none"> <li>a-HBDH</li> <li>Acid Phosphatase (Total)</li> <li>Albumin</li> <li>Alkaline Phosphatase (ALP)</li> <li>ALT (GPT)</li> <li>Amylase</li> <li>Amylase (Pancreatic)</li> <li>AST (GOT)</li> <li>Bicarbonate</li> <li>Bile Acids</li> <li>Bilirubin (Direct)</li> </ul>	<ul style="list-style-type: none"> <li>Bilirubin (Total)</li> <li>Calcium</li> <li>Chloride</li> <li>Cholinesterase</li> <li>Creatinine</li> <li>D-3-Hydroxybutyrate</li> <li>γGT</li> <li>GLDH</li> <li>Glucose</li> <li>Iron</li> <li>Iron (TIBC)</li> <li>Lactate</li> <li>Lactate Dehydrogenase (LDH)</li> <li>Lipase</li> <li>Magnesium</li> <li>Osmolality</li> <li>Phosphate (Inorganic)</li> <li>Potassium</li> <li>Sodium</li> <li>Urea</li> <li>Uric Acid (Urate)</li> </ul> <p><b>Trace Metals</b></p> <ul style="list-style-type: none"> <li>Copper</li> <li>Zinc</li> </ul>

The Acusera Smart Assayed Liquid Chemistry Control is intended for *in vitro* diagnostic use, in the quality control of diagnostic assays. Three clinically significant levels are available. Covering 93 analytes, the control enables effective consolidation and cost savings.

### Benefits

- Liquid frozen for ease of use
- Human serum based
- Open vial stability of 7 days at 2°C to 8°C for most analytes
- Consolidates 93 analytes
- High levels of CRP and other proteins eliminate the need for multiple controls



Description	Size	Cat. No.
Smartload Assayed Liquid Chemistry Control Level 1	12 x 4 ml	LAL10625
Smartload Assayed Liquid Chemistry Control Level 2	12 x 4 ml	LAN10626
Smartload Assayed Liquid Chemistry Control Level 3	12 x 4 ml	LAE10627



For Siemens Atellica

Description	Size	Cat. No.
Smartscan Assayed Liquid Chemistry Control Level 1	12 x 4 ml	LAL10565
Smartscan Assayed Liquid Chemistry Control Level 2	12 x 4 ml	LAN10566
Smartscan Assayed Liquid Chemistry Control Level 3	12 x 4 ml	LAE10567

# ACUSERA SMART CONTROLS



## Liquid Immunoassay Control



\*Please note assayed target values are not provided for Immunoassay Smartload controls

Analytes			
17-OH-Progesterone	Digoxin	Oestradiol	T4 (Total)
25-OH-Vitamin D	Ferritin	Paracetamol	Testosterone
α-Fetoprotein (AFP)	Folate	Phenobarbital	Theophylline
Aldosterone	FSH	Phenytoin	Thyroglobulin
Androstenedione	Gentamicin	Progesterone	Tobramycin
Anti-Thyroperoxidase (Anti-TPO)	Growth Hormone (GH)	Prolactin	Troponin I
β-2-Microglobulin	hCG	PSA (Free)	Troponin T
CA125	Homocysteine	PSA (Total)	TSH
CA15-3	Immunoglobulin E (IgE)	Sex Hormone Binding Globulin	Valproic Acid
CA19-9	Insulin	(SHBG)	Vancomycin
Carbamazepine	Insulin Like Growth Factor 1	T Uptake	Vitamin B12
CEA	(IGF 1)	T3 (Free)	ACTH*
Cortisol	Luteinising Hormone (LH)	T3 (Total)	C-Peptide*
DHEA-Sulphate	NT-proBNP	T4 (Free)	PTH (Parathyroid Hormone)*

The Acusera Smart Liquid Immunoassay Control is intended for *in vitro* diagnostic use to cover immunoassay testing in a single tube. The three clinically significant levels provided will not only help to accurate performance at key decision levels, but will also eliminate the need for additional controls, enabling greater consolidation and cost savings.

### Benefits

- Liquid frozen for ease of use
- Human serum based
- Stable for 7 days at 2°C to 8°C for most analytes, with the exception of IGF-1 which has a same day stability when stored at 2°C to 8°C.
- Consolidates routinely run tumour markers, cardiac markers, therapeutic drugs and hormones



Description	Size	Cat. No.	Description	Size	Cat. No.
Liquid Immunoassay Control Level 1 (Smartload)	12 x 4 ml	LIA5142	Smartscan Liquid Immunoassay Level 1	12 x 4 ml	LIA10568
Liquid Immunoassay Control Level 2 (Smartload)	12 x 4 ml	LIA5143	Smartscan Liquid Immunoassay Level 2	12 x 4 ml	LIA10569
Liquid Immunoassay Control Level 3 (Smartload)	12 x 4 ml	LIA5144	Smartscan Liquid Immunoassay Level 3	12 x 4 ml	LIA10570

\* May be present in the control, however, no claims are made for the performance or stability of these analytes

# ACUSERA SMART CONTROLS



## Liquid Cardiac Control

Analytes			
CK-MB Digoxin	Homocysteine hsCRP	Myoglobin NT-proBNP	Troponin I

The Acusera Smart Liquid Cardiac Control is designed to cover a range of cardiac markers at clinical decision levels, eliminating the need for additional low-level controls at extra expenses. It is intended for use with *in vitro* diagnostic assays for the quantitative determination of 7 cardiac markers. This control also has an impressive 14 day open vial stability for Troponin I, and 30 days for other analytes. It is designed for use in the routine monitoring of both accuracy and precision.

### Benefits

- Liquid frozen for ease of use
- Human serum based
- Open vial stability of 30 days at 2°C to 8°C for most analytes (excluding Troponin I)
- Consolidates 7 key cardiac markers
- Cut off levels for Troponin I in line with internationally recommended levels



Description	Size	Cat. No.
Smartload Liquid Cardiac Control 1	5 x 3 ml	CQ10534
Smartload Liquid Cardiac Control 2	5 x 3 ml	CQ10535
Smartload Liquid Cardiac Control 3	5 x 3 ml	CQ10536



For Siemens Atellica

Description	Size	Cat. No.
Smartscan Liquid Cardiac Control Level 1	5 x 3 ml	CQ10616
Smartscan Liquid Cardiac Control Level 2	5 x 3 ml	CQ10617
Smartscan Liquid Cardiac Control Level 3	5 x 3 ml	CQ10618



## PTH Control

The Acusera Smart PTH Control is intended for use with *in vitro* diagnostic assays for the quantitative determination of Parathyroid Hormone in human serum and plasma. This notoriously unstable marker is available with an impressive 30 day open vial stability, reducing waste while remaining easy-to-use.

### Benefits

- Liquid frozen for ease of use
- Human serum based
- 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 (Smartload)	3 x 3 ml	PTH10608
PTH Control Level 2 (Smartload)	3 x 3 ml	PTH10609
PTH Control Level 3 (Smartload)	3 x 3 ml	PTH10610

Not suitable for use with Siemens Immulite or Beckman DXI Analysers

# ACUSERA SMART CONTROLS



COMING SOON

## Specific Protein Control

Our Specific Protein Control covers a unique combination of analytes to reduce the number of individual controls required.



COMING SOON

## Urine Chemistry Control

Our Urine Chemistry Control has been designed to consolidate commonly used urine chemistry analytes in a single vial, reducing the number of controls required to cover your complete test menu.

# 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 Product Range

Product Description	Size	Cat No	Page No
Blood Gas Control Level 1	30 x 1.8 ml	BG5001	15
Blood Gas Control Level 2	30 x 1.8 ml	BG5002	15
Blood Gas Control Level 3	30 x 1.8 ml	BG5003	15

Refer to [www.smartdocs.randox.com](http://www.smartdocs.randox.com) or the product insert (IFU) of currently available lots for specific analyte and stability claims.



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# BLOOD GAS

## 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 within 1 minute 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 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 For Beckman	3 x 1 x 1 ml	CQ10520	18
BNP Controls For Siemens	3 x 1 x 1 ml	CQ10522	18
Cardiac Control - Ultra Low (Abbott & Roche)	3 x 3 ml	CQ10453	18
Cardiac Ultra Low Control (Siemens)	6 x 1 ml	CQ10428	18
CK-MB Control	10 x 2 ml	CK1212	19
CK-MB Calibrator	10 x 1 ml	CK2393	19
Tri-Level Cardiac Control	3 x 1 ml	CQ3100	19
Tri-Level Cardiac Control	3 x 2 ml	CQ3259	19
Troponin T Control	6 x 3 ml	CQ10450	19

Refer to [www.smartdocs.randox.com](http://www.smartdocs.randox.com) or the product insert (IFU) of currently available lots for specific analyte and stability claims.



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

## 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 and Siemens systems, these controls are also suitable for other platforms.

- **Liquid ready-to-use**
- **Human serum based**
- **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 For Beckman	3 x 1 x 1 ml	CQ10520
BNP Controls For Siemens	3 x 1 x 1 ml	CQ10522

## Cardiac Control

### Analytes

Troponin I

Delivering an unassayed solution for Troponin I, the Acusera Cardiac Control is designed for use with Abbott, Roche and Siemens systems. This control provides clinically relevant testing levels for 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**
- **Stable to expiry date at -20°C to -80°C**
- **Open vial stability of up to 5 days at 2°C to 8°C**

Description	Size	Cat No
Cardiac Control - Ultra Low (Abbott & Roche)	3 x 3 ml	CQ10453
Cardiac Ultra Low Control (Siemens)	6 x 1 ml	CQ10428

*For Acusera Smart Liquid Cardiac Control see page 11*

# CARDIAC

## 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
- Human serum based
- 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)	Homocysteine Myoglobin	Troponin I Troponin T	CK-MB (Activity)*

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 serum based
- 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

## Troponin T Control

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

- Liquid frozen
- Human serum based
- 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 and liquid/lyophilised formats, options are available to suit all laboratory sizes and budgets.

# CLINICAL CHEMISTRY

Clinical Chemistry Product Range			
Product Description	Size	Cat No	Page No
Aldolase Calibration Serum	3 x 1 ml	AD5000	22
Aldolase Level 2 Control	3 x 1 ml	AD5001	22
Aldolase Level 3 Control	3 x 1 ml	AD5002	22
Ammonia Ethanol Control Level 1	6 x 2 ml	EA1366	22
Ammonia Ethanol Control Level 2	6 x 2 ml	EA1367	22
Ammonia Ethanol Control Level 3	6 x 2 ml	EA1368	22
Human Assayed Multi-Sera Level 2	20 x 5 ml	HN1530	23
Human Assayed Multi-Sera Level 3	20 x 5 ml	HE1532	23
Human Assayed Multi-Sera Level 2 & 3	2 x 5 x 5 ml	HS2611	23
Calibration Serum Level 2	20 x 5 ml	CAL2350	24
Calibration Serum Level 3	20 x 5 ml	CAL2351	24
Ethanol Calibrator and Control Set	4 x 10 ml	DA2703	24
Liquid Assayed Chemistry Premium Plus Level 1	12 x 5 ml	LAL4213	25
Liquid Assayed Chemistry Premium Plus Level 2	12 x 5 ml	LAN4214	25
Liquid Assayed Chemistry Premium Plus Level 3	12 x 5 ml	LAE4215	25
Liquid Chemistry Premium Plus Level 1	12 x 5 ml	LUL5069	26
Liquid Chemistry Premium Plus Level 2	12 x 5 ml	LUN5070	26
Liquid Chemistry Premium Plus Level 3	12 x 5 ml	LUE5071	26
Human Precision Control Level 2	20 x 5 ml	UN1557	27
Human Precision Control Level 3	20 x 5 ml	UE1558	27
Serum Indices	4 x 5 ml	SI10448	27

Refer to [www.smartdocs.randox.com](http://www.smartdocs.randox.com) or the product insert (IFU) of currently available lots for specific analyte and stability claims.



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

## Aldolase Control and Calibration Serum

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 serum based**
- **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 Calibration Serum	3 x 1 ml	AD5000
Aldolase Level 2 Control	3 x 1 ml	AD5001
Aldolase Level 3 Control	3 x 1 ml	AD5002

## Ammonia Ethanol Control

Analytes	
Ammonia	Ethanol

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

# CLINICAL CHEMISTRY

## Human Assayed Multi-Sera

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>	Immunoglobulin M (IgM) 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>Lipids</b> Apolipoprotein A-1 Apolipoprotein B Cholesterol (HDL) Cholesterol (Total) NEFA Triglycerides	<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>Trace Metals</b> Copper Zinc
<b>Electrophoresis</b> α-1-Globulin α-2-Globulin Albumin β-Globulin γ-Globulin	<b>Proteins</b> Immunoglobulin A (IgA) Immunoglobulin G (IgG)		

One of our most popular controls, the Acusera Human Assayed Multi-Sera, combines a comprehensive 67 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 serum based
- 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
Human Assayed Multi-Sera Level 2	20 x 5 ml	HN1530
Human Assayed Multi-Sera Level 3	20 x 5 ml	HE1532
Human Assayed Multi-Sera Level 2 & 3	2 x 5 x 5 ml	HS2611

For Smart Assayed Liquid Chemistry Control see page 09

## Calibration Serum

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

Comprising 39 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 serum based
- 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
Calibration Serum Level 2	20 x 5 ml	CAL2350
Calibration Serum Level 3	20 x 5 ml	CAL2351

## Ethanol Calibrator and 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 and Control Set	4 x 10 ml	DA2703

# CLINICAL CHEMISTRY

## Liquid Assayed Chemistry Premium Plus Control

Analytes			
<p><b>Cardiac</b> CK (Total) Myoglobin Troponin T</p> <p><b>Drugs</b> Amikacin Caffeine Carbamazepine Digoxin Ethanol Gentamicin Lithium Paracetamol Phenobarbitone Phenytoin Salicylate Theophylline Valproic Acid Vancomycin</p> <p><b>Electrophoresis</b> α-1-Globulin α-2-Globulin Albumin β-Globulin γ-Globulin</p>	<p><b>Immunoassay</b> α-Fetoprotein (AFP) CEA Cortisol DHEA Sulphate Folate FSH hCG Luteinising Hormone (LH) Progesterone Prolactin PSA (Total) T Uptake T3 (Free) T3 (Total) T4 (Free) T4 (Total) Testosterone TSH Vitamin B<sub>12</sub></p> <p><b>Lipids</b> Apolipoprotein A-1 Apolipoprotein B Cholesterol (HDL) Cholesterol (LDL) Cholesterol (Total) Lipoprotein (a) Triglycerides</p>	<p><b>Proteins</b> α-1- Acid Glycoprotein α-1-Antitrypsin β-2-Microglobulin Ceruloplasmin Complement C3 Complement C4 CRP Ferritin Haptoglobin Immunoglobulin A (IgA) Immunoglobulin E (IgE) Immunoglobulin G (IgG) Immunoglobulin M (IgM) Prealbumin Protein (Total) Transferrin</p> <p><b>Routine Chemistry</b> α-HBDH Acid Phosphatase (Total) Albumin Alkaline Phosphatase (ALP) ALT (GPT) Amylase Amylase (Pancreatic) AST (GOT) Bicarbonate Bile Acids</p>	<p>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) ACE (Angiotensin Converting Enzyme)*</p> <p><b>Trace Metals</b> Copper Zinc</p>

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 serum based
- 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

\* May be present in the control, however, no claims are made for the performance or stability of these analytes.

For Smart Assayed Liquid Chemistry Control see page 09

## Liquid Chemistry Premium Plus Control

Analytes			
<p><b>Cardiac</b> CK (Total) Myoglobin Troponin T</p> <p><b>Drugs</b> Amikacin Caffeine Carbamazepine Digoxin Ethanol Gentamicin Lithium Paracetamol Phenobarbitone Phenytoin Salicylate Theophylline Valproic Acid Vancomycin</p> <p><b>Electrophoresis</b> α-1-Globulin α-2-Globulin Albumin β-Globulin γ-Globulin</p>	<p><b>Immunoassay</b> α-Fetoprotein (AFP) CEA Cortisol DHEA Sulphate Folate FSH Growth Hormone (GH) hCG Luteinising Hormone (LH) Progesterone Prolactin Testosterone T Uptake T3 (Free) T3 (Total) T4 (Free) T4 (Total) TSH Vitamin B<sub>12</sub></p> <p><b>Lipids</b> Apolipoprotein A-1 Apolipoprotein B Cholesterol (HDL) Cholesterol (LDL) Cholesterol (Total) Lipoprotein (a) Triglycerides</p>	<p><b>Proteins</b> α-1-Acid Glycoprotein α-1-Antitrypsin β-2-Microglobulin Ceruloplasmin Complement C3 Complement C4 CRP Ferritin Haptoglobin Immunoglobulin A (IgA) Immunoglobulin E (IgE) Immunoglobulin G (IgG) Immunoglobulin M (IgM) Prealbumin Protein (Total) Transferrin</p> <p><b>Routine Chemistry</b> α-HBDH Acid Phosphatase (Total) Albumin Alkaline Phosphatase (ALP) ALT (GPT) Amylase Amylase (Pancreatic) AST (GOT) Bicarbonate Bile Acids</p>	<p>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) ACE (Angiotensin Converting Enzyme)* Iron (UIBC)* LAP*</p> <p><b>Trace Metals</b> Copper Zinc</p>

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 serum based
- 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

\* May be present in the control, however, no claims are made for the performance or stability of these analytes.

# CLINICAL CHEMISTRY

## Human Precision Control

Analytes			
<b>Cardiac</b> CK (Total)	<b>Lipids</b> Apolipoprotein A-I Apolipoprotein B Cholesterol (HDL) Cholesterol (Total) NEFA Triglycerides	<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 D-3-Hydroxybutyrate γGT GLDH Glucose Iron Iron (TIBC) Lactate	Lactate Dehydrogenase (LDH) Lipase Magnesium Osmolality Phosphate (Inorganic) Potassium Sodium Urea Uric Acid (Urate) Iron (UIBC)* LAP*
<b>Drugs</b> Digoxin Gentamicin Lithium Paracetamol Salicylate Theophylline Tobramycin	<b>Proteins</b> α-1-Acid Glycoprotein α-1-Antitrypsin Ceruloplasmin Complement C3 Complement C4 CRP Ferritin Haptoglobin Immunoglobulin A (IgA) Immunoglobulin E (IgE) Immunoglobulin G (IgG) Immunoglobulin M (IgM) Prealbumin Protein (Total) Transferrin		<b>Trace Metals</b> Copper Zinc
<b>Immunoassay</b> α-Fetoprotein (AFP) CEA Cortisol Folate Prolactin PSA (Total) T3 (Free) T3 (Total) T4 (Free) T4 (Total) Vitamin B <sub>12</sub>			

Our Human Precision Control conveniently covers 76 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 serum based
- 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
Human Precision Control Level 2	20 x 5 ml	UN1557
Human Precision Control Level 3	20 x 5 ml	UE1558

\* May be present in the control, however, no claims are made for the performance or stability of these analytes.

## Serum Indices

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 serum based
- 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	4 x 5 ml	SI10448

# COAGULATION AND HAEMATOTOLOGY 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 HAEMATOTOLOGY

## Coagulation and Haematology Product Range

Product Description	Size	Cat No	Page No
Coagulation Control Level 1	12 x 1 ml	CG5021	30
Coagulation Control Level 2	12 x 1 ml	CG5022	30
Coagulation Control Level 3	12 x 1 ml	CG5023	30
Haematology Control - Level 1,2,3	3 x 2 x 4.5 ml	HM5162	30

Refer to [www.smartdocs.randox.com](http://www.smartdocs.randox.com) or the product insert (IFU) of currently available lots for specific analyte and stability claims.



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# COAGULATION AND HAEMATOTOLOGY

## 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 - Level 1,2,3

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

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 - Level 1,2,3	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	33
Fructosamine Control Level 3	3 x 1 ml	FR2996	33
Fructosamine Calibrator	3 x 1 ml	FR2993	33
G-6-PDH Deficient Control	6 x 0.5 ml	PD2617	33
G-6-PDH Normal Control	6 x 0.5 ml	PD2618	33
Haemoglobin A1c Control Set	2 x 2 x 0.5 ml	HA5072	33
HbA1c II Calibrator Set	5 x 0.5 ml	HA8124	33
Liquid Glycated Haemoglobin (HbA1c) Control Level 1	6 x 1 ml	HA10224	34
Liquid Glycated Haemoglobin (HbA1c) Control Level 2	6 x 1 ml	HA10225	34

Refer to [www.smartdocs.randox.com](http://www.smartdocs.randox.com) or the product insert (IFU) of currently available lots for specific analyte and stability claims.



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

## 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 Deficient Control	6 x 0.5 ml	PD2617
G-6-PDH Normal Control	6 x 0.5 ml	PD2618

## Haemoglobin A1c Control and Calibrator Set

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 31 days at 2°C to 8°C

### Calibrator

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

Description	Size	Cat No
Haemoglobin A1c Control Set	2 x 2 x 0.5 ml	HA5072
HbA1c II Calibrator Set	5 x 0.5 ml	HA8124

# DIABETES AND WHOLE BLOOD

## Liquid Glycated Haemoglobin (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 Glycated Haemoglobin (HbA1c) Control Level 1	6 x 1 ml	HA10224
Liquid Glycated Haemoglobin (HbA1c) Control Level 2	6 x 1 ml	HA10225

# 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 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 Product Range			
Product Description	Size	Cat No	Page No
AMH Control Level 1	3 x 2 ml	AMH10509	37
AMH Control Level 2	3 x 2 ml	AMH10514	37
AMH Control Level 3	3 x 2 ml	AMH10515	37
AMH Control Level 4	3 x 2 ml	AMH10516	37
Active Vitamin B12 Control Level 1	3 x 2 ml	VB10524	37
Active Vitamin B12 Control Level 2	3 x 2 ml	VB10525	37
Serum Bone Marker Level 1 Control	6 x 2 ml	SBM10574	37
Serum Bone Marker Level 2 Control	6 x 2 ml	SBM10587	37
Serum Bone Marker Level 3 Control	6 x 2 ml	SBM10588	37
Immunoassay Premium Level 1	12 x 5 ml	IA2638	38
Immunoassay Premium Level 2	12 x 5 ml	IA2639	38
Immunoassay Premium Level 3	12 x 5 ml	IA2640	38
Immunoassay Premium Tri-Level	3 x 4 x 5 ml	IA2633	38
Immunoassay Premium Plus Level 1	12 x 5 ml	IA3109	39
Immunoassay Premium Plus Level 2	12 x 5 ml	IA3110	39
Immunoassay Premium Plus Level 3	12 x 5 ml	IA3111	39
Immunoassay Premium Plus Tri-Level	3 x 4 x 5 ml	IA3112	39
Immunoassay Speciality I Level 1	5 x 2 ml	IAS3113	40
Immunoassay Speciality I Level 2	5 x 2 ml	IAS3114	40
Immunoassay Speciality I Level 3	5 x 2 ml	IAS3115	40
Immunoassay Speciality II Level 1	5 x 1 ml	IAS3117	40
Immunoassay Speciality II Level 2	5 x 1 ml	IAS3118	40
Immunoassay Speciality II Level 3	5 x 1 ml	IAS3119	40
Maternal Control Level 1	3 x 1 ml	MSS5024	41
Maternal Control Level 2	3 x 1 ml	MSS5025	41
Maternal Control Level 3	3 x 1 ml	MSS5026	41
Pre-eclampsia Control Level 1	3 x 2 x 2 ml	PE10527	41
Pre-eclampsia Control Level 2	3 x 2 x 2 ml	PE10528	41
Pre-eclampsia Control Level 3	3 x 2 x 2 ml	PE10529	41
Parathyroid Hormone Control Level 1	3 x 3 ml	PTH10110	42
Parathyroid Hormone Control Level 2	3 x 3 ml	PTH10111	42
Parathyroid Hormone Control Level 3	3 x 3 ml	PTH10112	42
Tumour Marker Control Level 2	3 x 2 ml	TU5002	42
Tumour Marker Control Level 3	3 x 2 ml	TU5003	42
Ultra-Low PSA Control	6 x 1 ml	TU10523	42

Refer to [www.smartdocs.randox.com](http://www.smartdocs.randox.com) or the product insert (IFU) of currently available lots for specific analyte and stability claims.



Liquid ready-to-use



Liquid frozen



Lyophilised for enhanced stability



Assayed target values provided



100% human matrix

# IMMUNOASSAY

## 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). Four levels of control are available ensuring accurate performance assessment across the clinical measuring range..

- **Liquid frozen**
- **Human serum based**
- **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

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## Active Vitamin B12 Control

The Acusera Active Vitamin B12 Control is designed to deliver a cost effective, high-quality solution for use in the quantitative determination of Active Vitamin B12 in human serum and plasma.

- **Liquid frozen**
- **Human based material**
- **30 days open vial stability when stored at 2°C to 8°C**
- **Assayed target values and ranges for a wide range of immunoassay systems**

Description	Size	Cat No
Active Vitamin B12 Control Level 1	3 x 2 ml	VB10524
Active Vitamin B12 Control Level 2	3 x 2 ml	VB10525

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## Serum Bone Marker Control

### Analytes

Bone Alkaline Phosphatase (B-ALP)

N-MID Osteocalcin (OC)

Procollagen Type 1 N-Terminal Propeptide (P1NP)

The Randox Acusera Serum Bone Marker Control provides a third party solution for monitoring the performance of bone markers in serum.

- **Lyophilised for enhanced stability**
- **Human serum based**
- **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
Serum Bone Marker Level 1 Control	6 x 2 ml	SBM10574
Serum Bone Marker Level 2 Control	6 x 2 ml	SBM10587
Serum Bone Marker Level 3 Control	6 x 2 ml	SBM10588

Immunoassay Premium Control 

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

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 48 analytes, including fertility, thyroid & steroid hormones, kidney function tests, therapeutic drugs and vitamins, saving you time assigning these in-house. Manufactured using human serum, this control is designed to directly mimic a patient sample, reducing costly shifts when reagent batch is changed.

- Lyophilised for enhanced stability
- Human serum based
- 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

\* May be present in the control, however, no claims are made for the performance or stability of these analytes

# IMMUNOASSAY

## Immunoassay Premium Plus Control

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

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 ensure accurate performance at key decision levels and further reduce the number of controls required. Assayed target values are supplied for 51 analytes in this true third party control. Manufactured using human serum, this control is designed to directly mimic a patient sample, reducing costly shifts when reagent batch is changed.

- Lyophilised for enhanced stability
- Human serum based
- 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

\* May be present in the control, however, no claims are made for the performance or stability of these analytes

For Acusera Smart Liquid Immunoassay Control see page 10

Immunoassay Speciality I Control 

Analytes			
1-25-(OH) <sub>2</sub> -Vitamin D 25-OH-Vitamin D Anti-Thyroglobulin (Anti-TG)	Anti-Thyropoxidase (Anti-TPO) C-Peptide Insulin	Insulin Like Growth Factor-1(IGF-1) PTH (Parathyroid Hormone) Osteocalcin	Procalcitonin

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
- Human serum based
- 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 for all analytes, with the exception of:
  - Anti-TG - 3 days
  - C-Peptide and Procalcitonin - 1 day
  - IGF-1 - 8 hours
  - Osteocalcin and PTH - 4 hours

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

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

# IMMUNOASSAY

## Maternal Control

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

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 Control Level 1	3 x 1 ml	MSS5024
Maternal Control Level 2	3 x 1 ml	MSS5025
Maternal Control Level 3	3 x 1 ml	MSS5026

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## Pre-eclampsia Control

Analytes	
sFlt-1	PlGF

The Pre-eclampsia Control is intended for use with *in vitro* diagnostic assays for the quantitative determination of placental growth factor (PlGF) and soluble fms-like tyrosine kinase-1 (sFlt-1) in human serum and plasma. The Pre-eclampsia Control is assayed with target values and is suitable for use on various immunoassay analysers.

- Liquid frozen
- Human serum based
- 30 days open vial stability when stored at 2°C to 8°C
- Assayed target values and ranges for a wide range of immunoassay systems
- True third-party control delivering unbiased, independent performance assessment

Description	Size	Cat No
Pre-eclampsia Control Level 1	3 x 2 x 2 ml	PE10527
Pre-eclampsia Control Level 2	3 x 2 x 2 ml	PE10528
Pre-eclampsia Control Level 3	3 x 2 x 2 ml	PE10529

Parathyroid Hormone Control 

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

- Liquid frozen
- Human serum based
- 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
Parathyroid Hormone Control Level 1	3 x 3 ml	PTH10110
Parathyroid Hormone Control Level 2	3 x 3 ml	PTH10111
Parathyroid Hormone Control Level 3	3 x 3 ml	PTH10112

For Acusera Smart PTH Control see page 11

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

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 material
- 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. Manufactured from human serum, the controls react to the test system just like patient samples, ensuring an accurate performance evaluation.

Immunology/Protein Product Range			
Product Description	Size	Cat No	Page No
Canine CRP Control Level 2	3 x 1 ml	CP2803	45
Canine CRP Control Level 3	3 x 1 ml	CP2804	45
Liquid CRP Control Level 2	10 x 1 ml	CP2480	45
Liquid CRP Control Level 3	10 x 1 ml	CP2481	45
High Sensitivity CRP Control Level 1	10 x 1 ml	CP2476	45
High Sensitivity CRP Control Level 2	10 x 1 ml	CP2477	45
CRP Calibrator Series	6 x 1 ml	CP2499	45
CSF Control Level 2	10 x 3 ml	CF1500	46
CSF Control Level 3	10 x 3 ml	CF1501	46
Liquid CSF Control Level 1	10 x 3 ml	CF10138	46
Liquid CSF Control Level 2	10 x 3 ml	CF10139	46
Cystatin C Control Level 2	3 x 2 ml	CYS10446	47
Cystatin C Control Level 3	3 x 2 ml	CYS10447	47
Cystatin C Calibrator	5 x 2 ml	CYS10445	47
Cystatin C Control Level 2	3 x 2 ml	CYS5019	47
Cystatin C Control Level 3	3 x 2 ml	CYS5020	47
Cystatin C Calibrator	5 x 2 ml	CYS2699	47
IgE Calibrator Series	6 x 1 ml	IE2492	47
Immunoglobulin Liquid Protein Calibrator	3 x 1 ml	IT3861	47
Liquid Protein Calibrators	5 x 1 ml	IT2691	48
Liquid Protein Calibrators	5 x 1 ml	IT2692	48
Liquid Assayed Specific Protein Control Level 1	3 x 1 ml	PS2682	49
Liquid Assayed Specific Protein Control Level 2	3 x 1 ml	PS2683	49
Liquid Assayed Specific Protein Control Level 3	3 x 1 ml	PS2684	49
Specific Protein Control Level 1	6 x 3 ml	PS10221	49
Specific Protein Control Level 2	6 x 3 ml	PS10222	49
Specific Protein Control Level 3	6 x 3 ml	PS10223	49
Soluble Transferrin Receptor Controls	2 x 3 x 1 ml	TF10162	49
Soluble Transferrin Receptor Calibrator Series	6 x 1 ml	TF10161	49
Xanthochromia Positive Control	6 x 4 ml	XN10505	50
Xanthochromia Negative Control	6 x 4 ml	XN10502	50

Refer to [www.smartdocs.randox.com](http://www.smartdocs.randox.com) or the product insert (IFU) of currently available lots for specific analyte and stability claims.



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# IMMUNOLOGY/PROTEIN

## 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

Analytes	
CRP	hsCRP

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
CRP Calibrator Series	6 x 1 ml	CP2499

## CSF Control

Analytes			
Chloride	Lactate	$\alpha$ -1-Globulin (Electrophoresis)*	$\beta$ -Globulin (Electrophoresis)*
Glucose	Protein (Total)	$\alpha$ -2-Globulin (Electrophoresis)*	$\gamma$ -Globulin (Electrophoresis)*
Immunoglobulin G (IgG)	Sodium	Albumin (Electrophoresis)*	

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

\* Present in the control, however, no claims are made for the expected values or stability.

## Liquid CSF Control

Analytes	
Chloride	$\alpha$ -1-Globulin (Electrophoresis)*
Glucose	$\alpha$ -2-Globulin (Electrophoresis)*
High Sensitivity Immunoglobulin G (hslgG)	Albumin (Electrophoresis)*
Lactate	$\beta$ -Globulin (Electrophoresis)*
Microalbumin	$\gamma$ -Globulin (Electrophoresis)*
Protein (Total)	High Sensitivity Immunoglobulin A (hslgA)*
Sodium	High Sensitivity Immunoglobulin M (hslgM)*

Providing a true third party solution for the measurement of 14 analytes in Cerebrospinal Fluid (CSF), the 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

\* Present in the control, however, no claims are made for the expected values or stability.

# IMMUNOLOGY/PROTEIN

## 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
- Human serum based
- 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

Description	Size	Cat No
Cystatin C Control Level 2	3 x 2 ml	CYS10446
Cystatin C Control Level 3	3 x 2 ml	CYS10447
Cystatin C Calibrator	5 x 2 ml	CYS10445

### For use with Calibrator CYS2699

Description	Size	Cat No
Cystatin C Control Level 2	3 x 2 ml	CYS5019
Cystatin C Control Level 3	3 x 2 ml	CYS5020
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
- Human serum based
- 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 Protein Calibrators

Analytes		
<ul style="list-style-type: none"> <li>α-1-Acid Glycoprotein</li> <li>α-1-Antitrypsin</li> <li>Anti-Streptolysin O (ASO)</li> <li>Complement C3</li> <li>Complement C4</li> </ul>	<ul style="list-style-type: none"> <li>CRP</li> <li>Ferritin</li> <li>Haptoglobin</li> <li>Immunoglobulin A (IgA)</li> <li>Immunoglobulin G (IgG)</li> </ul>	<ul style="list-style-type: none"> <li>Immunoglobulin M (IgM)</li> <li>Prealbumin</li> <li>Rheumatoid Factor (RF)</li> <li>Transferrin</li> </ul>

Multi-analyte calibrator designed for use in the routine calibration of 14 serum proteins including ASO, Ferritin and Rheumatoid Factor (RF). 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**
- **Human serum based**
- **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 Protein Calibrators	5 x 1 ml	IT2691	<b>FOR USE WITH SAMPLES THAT <u>DO NOT</u> REQUIRE PRE-DILUTION</b>

## Liquid Protein Calibrators - 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**
- **Human serum based**
- **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 Protein Calibrators	5 x 1 ml	IT2692	<b>FOR USE WITH SAMPLES THAT REQUIRE PRE-DILUTION</b>

# IMMUNOLOGY/PROTEIN

## Specific Protein Control

Analytes			
<ul style="list-style-type: none"> <li>α-1-Acid Glycoprotein</li> <li>α-1-Antitrypsin</li> <li>α-2-Macroglobulin</li> <li>α-Fetoprotein (AFP)</li> <li>Albumin</li> <li>Anti-Streptolysin O (ASO)</li> <li>Anti-Thrombin III (AT III)</li> </ul>	<ul style="list-style-type: none"> <li>β-2-Microglobulin</li> <li>Ceruloplasmin</li> <li>Complement C3</li> <li>Complement C4</li> <li>CRP</li> <li>Ferritin</li> <li>Haptoglobin</li> </ul>	<ul style="list-style-type: none"> <li>Immunoglobulin A (IgA)</li> <li>Immunoglobulin E (IgE)</li> <li>Immunoglobulin G (IgG)</li> <li>Immunoglobulin M (IgM)</li> <li>Kappa Light Chain</li> <li>Lambda Light Chain</li> <li>Prealbumin</li> </ul>	<ul style="list-style-type: none"> <li>Protein (Total)</li> <li>Retinol Binding Protein (RBP)</li> <li>Rheumatoid Factor (RF)</li> <li>Transferrin</li> </ul>

Covering a unique combination of 25 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 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**
- **Human serum based**
- **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
Liquid Assayed Specific Protein Control Level 1	3 x 1 ml	PS2682
Liquid Assayed Specific Protein Control Level 2	3 x 1 ml	PS2683
Liquid Assayed 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

## Soluble Transferrin Receptor (sTfR) Controls and Calibrator Series

Providing a true third party solution for the measurement of Soluble Transferrin Receptor (sTfR), the Acusera controls 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
Soluble Transferrin Receptor Controls	2 x 3 x 1 ml	TF10162
Soluble Transferrin Receptor Calibrator Series	6 x 1 ml	TF10161

## 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 -80°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
Serology ToRCH EBV Positive Control	1 x 5 ml	SR10350	53
Serology Lyme Disease Negative Control	1 x 5 ml	SR10345	53
Serology Lyme Disease Positive Control	1 x 5 ml	SR10346	53
Serology HBeAg Positive Control	1 x 5 ml	SR10459	54
Serology HIV-1 P24Ag Positive Control	1 x 5 ml	SR10458	54
Serology Negative Control	6 x 5 ml	SR10351	54
Serology I Positive Control	3 x 5 ml	SR10352	54
Serology II Positive Control	3 x 5 ml	SR10353	54
Serology III Positive Control	3 x 5 ml	SR10354	54
Serology ToRCH Negative Control	6 x 5 ml	SR10347	55
Serology ToRCH IgG Positive Control	3 x 5 ml	SR10348	55
Serology ToRCH IgM Positive Control	3 x 5 ml	SR10349	55

Refer to [www.smartdocs.randox.com](http://www.smartdocs.randox.com) or the product insert (IFU) of currently available lots for specific analyte and stability claims.



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# INFECTIOUS DISEASE (SEROLOGY)

## Serology ToRCH EBV Positive Control

### Analytes

Epstein Barr Virus (EBV) EBNA IgG

Epstein Barr Virus (EBV) VCA IgG

Epstein Barr Virus (EBV) VCA IgM

The Acusera Serology ToRCH Epstein Barr Virus (EBV) Positive Control is conveniently supplied as liquid ready-to-use and is suitable for use with most immunoassay analysers.

- Liquid ready-to-use
- Human serum based
- 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
Serology ToRCH EBV Positive Control	1 x 5 ml	SR10350

## Serology Lyme Disease 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
Serology Lyme Disease Negative Control	1 x 5 ml	SR10345
Serology Lyme Disease Positive Control	1 x 5 ml	SR10346

# INFECTIOUS DISEASE (SEROLOGY)

## Serology Controls

Analytes			
<b>Serology HBeAg Positive Control (RUO)</b> HBeAg	Anti-HBe Anti-HBs Anti-HCV Anti-HIV 1 / 2 Anti-HTLV 1 / 2	<b>Serology I Positive</b> Anti-HCV Anti-HIV 1 / 2 Anti-HTLV 1 / 2 HBsAg <i>Treponema pallidum</i> (Syphilis) IgG	<b>Serology II Positive</b> Anti-HAV Anti-HBc Anti-HBe Anti-HBs
<b>Serology HIV-1 P24Ag Positive Control (RUO)</b> HIV-1 P24Ag	HAV IgM HBc IgM HBeAg HBsAg HIV P24Ag		<b>Serology III Positive</b> HAV IgM HBc IgM
<b>Serology Negative</b> Anti-HAV Anti-HBc	<i>Treponema pallidum</i> (Syphilis) IgG		

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
- Human serum based
- 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
Serology HBeAg Positive Control	1 x 5 ml	SR10459
Serology 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)

## Serology ToRCH Controls

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

Our Serology 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 serum based
- 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
Serology ToRCH Negative Control	6 x 5 ml	SR10347
Serology ToRCH IgG Positive Control	3 x 5 ml	SR10348
Serology 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.

# LIPIDS

Lipid Product Range			
Product Description	Size	Cat No	Page No
Apolipoprotein Control Level 1	3 x 1 ml	LE5016	58
Apolipoprotein Control Level 2	3 x 1 ml	LE5017	58
Apolipoprotein Control Level 3	3 x 1 ml	LE5018	58
Apolipoprotein Calibrator	3 x 1 ml	LP3023	58
Apolipoprotein Calibrator 2	3 x 1 ml	LP5047	58
Direct LDL/HDL Cholesterol Calibrator	3 x 1 ml	CH2673	58
Lipid Control Level 1	5 x 1 ml	LE2668	59
Lipid Control Level 2	5 x 1 ml	LE2669	59
Lipid Control Level 3	5 x 1 ml	LE2670	59
Lipid Control Level 1	5 x 3 ml	LE2661	59
Lipid Control Level 2	5 x 3 ml	LE2662	59
Lipid Control Level 3	5 x 3 ml	LE2663	59
Lipoprotein (a) Control	3 x 1 ml	LP3406	59
Lipoprotein (a) Calibrator Series	5 x 1 ml	LP3404	59
sLDL Control Level 1	3 x 1 ml	LE5013	59
sLDL Control Level 2	3 x 1 ml	LE5014	59
sLDL Control Level 3	3 x 1 ml	LE5015	59
sLDL Calibrator	3 x 1 ml	CH5050	59

Refer to [www.smartdocs.randox.com](http://www.smartdocs.randox.com) or the product insert (IFU) of currently available lots for specific analyte and stability claims.



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

## Apolipoprotein Control and Calibrators

### Analytes

#### Apolipoprotein Control

Apolipoprotein A-II  
Apolipoprotein C-II  
Apolipoprotein C-III  
Apolipoprotein E

#### Apolipoprotein Calibrator

Apolipoprotein A-I  
Apolipoprotein B

#### Apolipoprotein Calibrator 2

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	3 x 1 ml	CH2673

# LIPIDS

## 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	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
Anti Microbial III Control	3 x 1 ml	AMC5036	62
Cerebral Array II Tri-Level Control	3 x 3 x 0.5 ml	CBB5009	62
Cytokine Controls	3 x 3 x 1 ml	CY5006	62
Cytokine High Sensitivity Controls	3 x 3 x 2 ml	CY5005	62
Cytokine Control (Series III)	3 x 3 x 1 ml	CY5012	63
Cytokine Control (Series IV)	3 x 3 x 1 ml	CY5011	63
Ransel Control	10 x 1 ml	SC692	63
Ransel Calibrator	10 x 1 ml	SC10154	63
Metabolic Syndrome Array I Controls	3 x 3 x 1 ml	EV3757	64
Metabolic Syndrome Array I Calibrators	9 x 1 ml	EV3756	64
Metabolic Syndrome Array II Controls	3 x 3 x 1 ml	EV3761	64
Metabolic Syndrome Array II Calibrators	9 x 1 ml	EV3760	64
Total Antioxidant Status Control	10 x 5 ml	NX2331	64

Refer to [www.smartdocs.randox.com](http://www.smartdocs.randox.com) or the product insert (IFU) of currently available lots for specific analyte and stability claims.



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

## Anti Microbial III Control

Analytes			
AHD AMOZ	AOZ	Chloramphenicol	Semicarbazine (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
Anti Microbial III Control	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 (sTNFR1)

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

## Cytokine and High Sensitivity Cytokine Controls

Analytes		
Epidermal Growth Factor (EGF) Interferon g (IFNg) Interleukin-1α (IL-1α) Interleukin-1β (IL-1β)	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 α (TNFα) 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 Controls	3 x 3 x 1 ml	CY5006
Cytokine High Sensitivity Controls	3 x 3 x 2 ml	CY5005

# SPECIALITY AND RESEARCH

## Cytokine Control (Series III)

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 Control (Series III)	3 x 3 x 1 ml	CY5012

## Cytokine Control (Series IV)

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 (sTNFR I) Soluble Tumour Necrosis Factor Receptor II (sTNFR II)

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 Control (Series IV)	3 x 3 x 1 ml	CY5011

## 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

## 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 Controls	3 x 3 x 1 ml	EV3757
Metabolic Syndrome Array I Calibrators	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 Controls	3 x 3 x 1 ml	EV3761
Metabolic Syndrome Array II Calibrators	9 x 1 ml	EV3760

## Total Antioxidant Status Control

A human based control designed for use in the routine monitoring of accuracy and precision. The Acusera Total Antioxidant Status (TAS) Control 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 2 days at 2°C to 8°C or 12 hours at 15°C to 25°C

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

# 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 Product Range			
Product Description	Size	Cat No	Page No
Therapeutic Drug Calibrator	6 x 3 ml	TD3417	67
Drug Control Level 1	20 x 5 ml	HD1667	67
Drug Control Level 2	20 x 5 ml	HD1668	67
Drug Control Level 3	20 x 5 ml	HD1669	67

Refer to [www.smartdocs.randox.com](http://www.smartdocs.randox.com) or the product insert (IFU) of currently available lots for specific analyte and stability claims.



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

# THERAPEUTIC DRUG

## 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

## 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
Drug Control Level 1	20 x 5 ml	HD1667
Drug Control Level 2	20 x 5 ml	HD1668
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

## Urine Product Range

Product Description	Size	Cat No	Page No
Assayed Urine Control Level 2	12 x 10 ml	AU2352	70
Assayed Urine Control Level 3	12 x 10 ml	AU2353	70
Liquid Urine Control Level 2	10 x 10 ml	UC5074	70
Liquid Urine Control Level 3	10 x 10 ml	UC5075	70
Microalbumin Calibrator Series	6 x 2 ml	MA1567	71
Urinalysis Control Level 1	12 x 12 ml	UC5033	71
Urinalysis Control Level 2	12 x 12 ml	UC5034	71
Urine Low Osmolality Control	6 x 2 ml	UC10650	71

Refer to [www.smartdocs.randox.com](http://www.smartdocs.randox.com) or the product insert (IFU) of currently available lots for specific analyte and stability claims.



Liquid  
ready-to-use



Liquid  
frozen



Lyophilised for  
enhanced stability



Assayed target  
values provided



100% human  
matrix

## Assayed Urine Control

Analytes			
Amylase	Magnesium	Potassium	Copper*
Calcium	Metanephrine	Protein (Total)	Dopamine*
Chloride	Microalbumin	Sodium	Epinephrine*
Cortisol	Normetanephrine	Urea	Norepinephrine*
Creatinine	Osmolality	Uric Acid (Urate)	Oxalate*
Glucose	Phosphate (Inorganic)	5-HIAA*	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 human urine based 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
- Human urine based
- 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	* May be present in the control, however, no claims are made for the performance or stability of these analytes.
Assayed Urine Control Level 3	12 x 10 ml	AU2353	

## Liquid Urine Control

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

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
- Human urine based
- Stable to expiry date at 2°C to 8°C
- Open vial stability 30 days at 2°C to 8°C

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

# URINE

## Microalbumin Calibrator

Our Acusera Microalbumin Calibrator have been developed for use in the calibration and monitoring of microalbumin immunoturbidimetric assays. Our unique human based material 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**
- **Human based material**
- **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			
Bilirubin Blood Creatinine Glucose	hCG Ketones Leukocytes Microalbumin	Nitrite pH Protein (Total) Specific Gravity	Urobilinogen

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**
- **Human urine based**
- **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

## Urine Low Osmolality Control

Our Acusera Urine Low Osmolality Quality Control is designed to deliver a cost effective, high-quality solution for use with assays for the quantitative determination of low levels of osmolality in human urine.

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

Description	Size	Cat No
Urine Low Osmolality Control	6 x 2 ml	UC10650

# 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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Control Name	Page	Category
BASO-Y		B
Basophils (BASO)		B
% Basophils (% BASO)		B
Bicarbonate		B
Bile Acids		B
Bilirubin (Direct)		B
Bilirubin (Total)		B
Blood		B
Bone Alkaline Phosphatase (B-ALP)		B
<i>Borrelia burgdorferi</i> IgG		B
<i>Borrelia burgdorferi</i> IgM		B
Brain Natriuretic Peptide (BNP)		B
C-Peptide		C
CA 15-3		C
CA 19-9		C
CA 72-4		C
CA 125		C
Caffeine		C
Calcitonin		C
Calcium		C
Carbamazepine		C
CEA		C
Ceruloplasmin		C
Chloramphenicol		C
Chloride		C
Cholesterol (HDL)		C
Cholesterol (LDL)		C
Cholesterol (Total)		C
Cholinesterase		C
CK-MB		C
CK-NAC		C
CK (Total)		C
Complement C3		C
Complement C4		C
Copper		C
Cortisol		C
Creatinine		C
CRP		C
Cyclosporine		C
Cytomegalovirus (CMV) IgG		C
Cytomegalovirus (CMV) IgM		C
CYFRA 21		C
Cystatin C		C
D-3-Hydroxybutyrate		D
D-dimer		D
DHEA-Sulphate		D
DIFF-X		D
DIFF-Y		D
Digoxin		D
Dopamine		D
Eosinophils (EOS)		E
% Eosinophils (% EOS)		E
Epidermal Growth Factor (EGF)		E
Epinephrine		E
Epstein Barr Virus (EBV) EBNA IgG		E

\* May be present in the control, however, no claims are made for the performance or stability of these analytes.















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	CRP Control		Red Blood Cell Distribution Width CV (RDW-CV)	
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	Immunoglobulin Liquid Protein Calibrator		Resistin	
	Liquid Protein Calibrators		Retinol Binding Protein (RBP)	
	Liquid Protein Calibrators (Requires Pre-dilution)		Rheumatoid Factor (RF)	
	Specific Protein Control		Rubella IgG	
	sTFR Control and Calibrator Series		Rubella IgM	
	Xanthochromia Control		Salicylate	S
	ToRCH Epstein Barr Virus (EBV) Positive Control		Semicarbazine (SEM)	
	Lyme Disease ( <i>Borrelia burgdorferi</i> ) Control		Sex Hormone Binding Globulin (SHBG)	
	Serology Controls		sFit-1	
	ToRCH Controls		sLDL	
	Apolipoprotein Control and Calibrators		Sodium	
	Direct LDL/HDL Cholesterol Calibrator		Soluble IL-2 Receptor $\alpha$ (sIL-2R $\alpha$ )	
	Lipid Control		Soluble IL-6 Receptor (sIL-6R)	
	Lipoprotein (a) Control and Calibrator		Soluble Transferrin Receptor (sTFR)	
	sLDL Control and Calibrator		Soluble Tumour Necrosis Factor Receptor 1 (sTNFR I)	
	Anti Microbial III Control		Soluble Tumour Necrosis Factor Receptor 11 (sTNFR II)	
	Cerebral Array II Control		Specific Gravity	
	Cytokine Controls		Streptomycin	
	Ransel Control & Calibrator		T Uptake	T
	Metabolic Syndrome Controls and Calibrators		T3 (Free)	
	Total Antioxidant Status Control		T4 (Free)	
	Drug Control & Therapeutic Drug Calibrator		T3 (Total)	
	Assayed Urine Control		T4 (Total)	
	Liquid Urine Control		Testosterone	
	Microalbumin Calibrator		Testosterone (Free)	
	Urinalysis Control		Tetracyclines (Generic)	
	Urine Low Osmolality Control		Theophylline	
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			Thrombin Time (TT)	
			Thyroglobulin	
			Tobramycin	
			Total Antioxidant Status (TAS)	
			Toxoplasma gondii IgG	
			Toxoplasma gondii IgM	
			Transferrin	
			<i>Treponema pallidum</i> (Syphilis) IgG	
			Triglycerides	
			Trimethoprim	
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			TSH	
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- Immunoassay Controls ■
- Immunology/Protein Controls ■
- Infectious Disease Controls (Serology) ■
- Lipid Controls ■
- Speciality & Research Controls ■
- Therapeutic Drug Controls ■
- Urine Controls ■

\* May be present in the control, however, no claims are made for the performance or stability of these analytes.

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		Assayed Liquid Chemistry Control	Liquid Immunoassay	Liquid Cardiac Control	PTH Control	Blood Gas Control	BNP Controls	Cardiac Control	CK-MB Control and Calibrator	Tri-Level Cardiac Control	Troponin T Control	Aldolase Control and Calibration Serum	Ammonia Ethanol Control	Human Assayed Multi-Sera Calibration Serum	Ethanol Calibrator and Control Set	Liquid Assayed Chemistry Premium Plus Control	Liquid Chemistry Premium Plus Control	Human Precision Control	Serum I/Serum Indices	Coagulation Control	Haematology Control	Fructosamine Control and Calibrator	G-6-PDH Control	Haemoglobin A1c Control and Calibrator Set	Liquid Glycated Haemoglobin (HbA1c) Control	Anti-Müllerian Hormone (AMH) Control	Active Vitamin B12 Control	Serum Bone Marker Control	Immunoassay Premium Control	Immunoassay Premium Plus Control	Immunoassay Speciality I Control	Immunoassay Speciality II Control	Maternal Control	Pre-eclampsia Control	Parathyroid Hormone Control			
U	Unconjugated Oestriol																																					
	Urea	x											x	x		x	x	x																				
	Uric Acid (Urate)	x											x	x		x	x	x																				
	Urine Osmolality																																					
	Urobilinogen																																					
V	Valproic Acid	x	x													x	x																					
	Vancomycin	x	x													x	x																					
	Vanillylmandelic Acid (VMA)																																					
	Varicella Zoster Virus (VZV) IgG																																					
	Vascular Endothelial Growth Factor (VEGF)																																					
	Vitamin B <sub>12</sub>	x	x											x			x	x	x																			
W	White Blood Cells (WBC)																																					
	White Blood Cells Differential (WBC-D)																																					
Z	Zinc	x											x	x		x	x	x																				

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Control Name	Page	Category
Unconjugated Oestriol		U
Urea		U
Uric Acid (Urate)		U
Urine Osmolality		U
Urobilinogen		U
Valproic Acid		V
Vancomycin		V
Vanillylmandelic Acid (VMA)		V
Varicella Zoster Virus (VZV) IgG		V
Vascular Endothelial Growth Factor (VEGF)		V
Vitamin B <sub>12</sub>		V
White Blood Cells (WBC)		W
White Blood Cells Differential (WBC-D)		W
Zinc		Z

- Immunology/Protein Controls
- Infectious Disease Controls (Serology)
- Lipid Controls
- Speciality & Research Controls
- Therapeutic Drug Controls
- Urine Controls

\* May be present in the control, however, no claims are made for the performance or stability of these analytes.

# 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.

## ACUSERA

**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.



### Unique dashboard interface

- Instantly flags any rule violations from the last 7 days, reducing time spent analysing QC data.
- Warns you when QC lots are approaching expiry, avoiding the use of expired QC material.



### True real-time peer group statistics \*

- Peer data is uniquely updated live in real-time ultimately reducing time and money spent troubleshooting, re-running samples and performing instrument maintenance.
- Instantly discover how you compare to other laboratories using the same lot of QC material and identify if issues are unique to your laboratory or a widespread issue.
- No submission deadlines for QC data.

\* T&Cs apply

### Advanced statistical analysis



- Sigma scores, Bias%, Total Error and other performance indicators are automatically calculated, enabling enhanced performance assessment and improved QC strategy design.
- Reject or alert data based on QC multi-rules or user-defined performance limits including RiliBÄK, CLIA and Biological Variation.
- Uncertainty of Measurement (UM) is automatically calculated for each assay and QC lot helping to meet ISO 15189:2022 requirements.



### Fully interactive charts

- Levey-Jennings, Histogram and Performance Summary Charts can be generated on-demand for quick and easy performance monitoring.
- The ability to add events and multiple data sets to a single chart ultimately allows for better identification of trends across multiple instruments.



### Comprehensive reports

- Specifically designed to speed up the review process, our comprehensive range of easy-to-read reports includes: Data Review, Daily Data Review Report, Exception Report and Statistical Reports.
- Reports can be customised to show data for a specific date range and can be filtered to display data for a particular test or instrument.



### Automated data import via Acusera 24•7 Connect

- An optional software solution that allows easy and automated upload of QC data direct to Acusera 24•7 via LIMS or Middleware.
- Eliminates problems associated with manual data entry and increases laboratory efficiency.

# BENEFITS



## Highly flexible to meet individual laboratory needs

- Custom configuration of performance limits, multi-rules, consensus groups and target values for each instrument or QC lot.
- Although intended for use with the Acusera control range, the software's internal functions may be used with any manufacturer's QC material.



## Simple and intuitive interface

- The software is fast, powerful and easy to use, therefore delivering an enhanced user experience.
- Colour coded throughout, providing an instant visual indication of poor performance.
- Simple assay configuration with ability to share a configuration across multiple instruments or affiliated labs.



## Online access anytime, anywhere

- Cloud based software, eliminating the need for local installation and frequent back ups.



## Multiple lab management

- Compare performance to a global peer group or other laboratories in your affiliate network in real-time.
- Stay on top of individual laboratory performance and activity from a central 'co-ordinator' account – accessible anywhere, anytime by users with 'co-ordinator' level access.
- Easily compare performance of individual laboratories within the affiliate group via multi Levey-Jennings, Histogram, Performance Summary Charts and Statistics.



## Technical support

- Expert technical support is available from our team of highly trained specialists.
- Remote access enables immediate troubleshooting without the need for on-site assistance.



## World class controls

- World leading controls offering unrivalled commutability, consolidation, stability and consistency.

# ORDERING DETAILS

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

\* 1 connection

## USER FEEDBACK

### INTERACTIVE LEVEY-JENNINGS CHARTS

*“Every 2 months we would have had to take screenshots from LIMS of every Levey Jennings Chart per analyser. This would have taken 24 hours per analyser. And now with Acusera this takes us 1 hour per analyser.” \**

**Hours lost annually before using Acusera 24•7 amounted to 138 hours**

Levey-Jennings charts are easily generated, providing an instant, visual indication of test system performance over time. The ability to combine multiple instruments, analytes, QC lots and labs on a single chart allows for comparative performance assessment and immediate visualisation of any ongoing or emerging trends.



### AUTOMATIC UNCERTAINTY OF MEASUREMENT (UM) CALCULATION

*“Every month we take a member of staff out of the lab for a full day to calculate measurement uncertainty, sometimes 2 days.” \**

**Hours lost annually before using Acusera 24•7 amounted to 192 hours**

The unique Uncertainty of Measurement report displays the UM of all QC tests currently in use, helping you to meet ISO 15189:2022 requirements. Participants can generate a report for all open QC tests or they can select single or multiple QC tests from the home screen thereby offering greater control over test performance.

### DAILY DATA REVIEW REPORT

*“QC daily review – would have before taken the staff approx. 2 hours to do on LIMS and with Acusera 24•7 it takes about 20 mins and allows you to review multiple lots at one time.” \**

**Hours lost annually before using Acusera 24•7 amounted to 608 hours**

Designed to allow for quick and easy reviewing of all QC results and violations daily within a 7 day window, thus, giving greater control of any potential issues occurring before they become widespread. Filter your QC results to view all results, violated results or specifically the rejected or alerted results whilst also determining whether they have been previously reviewed or not reviewed.



*“Over time, and with Randox’s assistance, 24•7 has become part and parcel of everyday IQC monitoring and management.” \**

**Integrating Acusera 24•7 into a laboratory’s QC workflow could lead to a potential saving of 938 hours annually.**

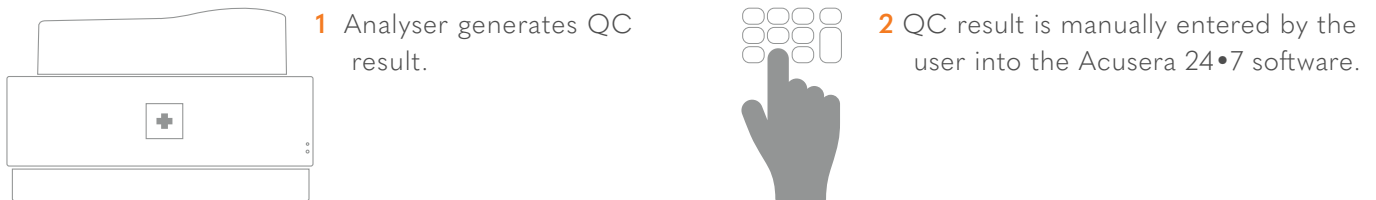
\* Customer Feedback

# 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.



### 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.



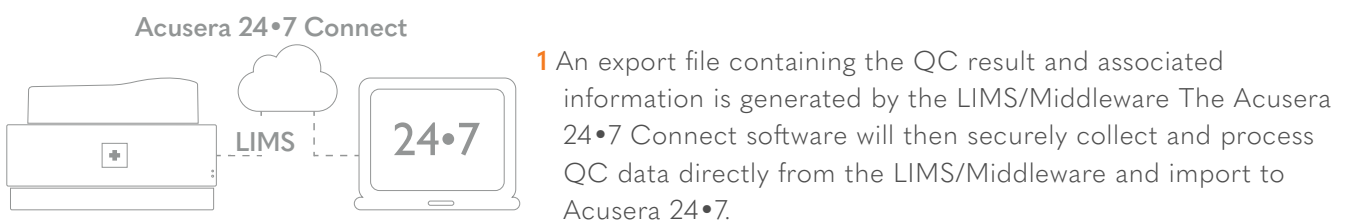
**Note:** First time users must create a new configuration for the EDI file and carry out EDI mapping.

### 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.



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

# 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 world's largest External Quality Assessment scheme with more than 85,000 laboratory participants spanning over 145 countries. 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



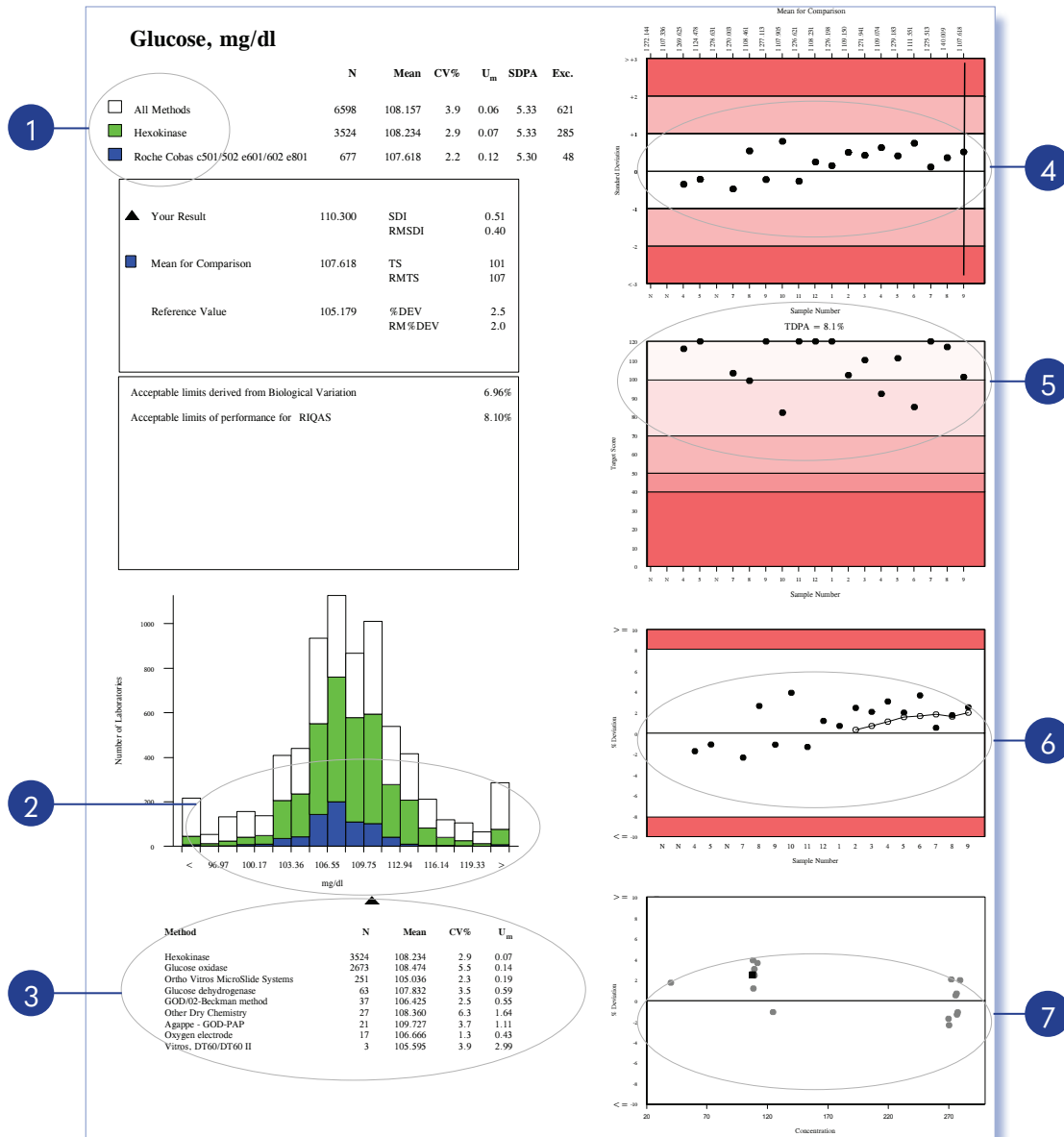
- Samples spanning clinically relevant levels allow identification of concentration related biases, helping to ensure accurate instrument performance.
- Human samples free from interfering preservatives increase confidence that EQA performance mirrors the performance of patient samples.
- Reference method 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



- RIQAS is accredited to ISO/IEC 17043:2023 "Conformity Assessment – General Requirements for Proficiency Testing" which is accepted by national and international accreditation bodies. Please see accreditation schedule for additional information.

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



- 1 **Text Section Chart:** Statistics for all methods, your method and instrument group (programme specific).
- 2 **Histogram Chart:** Method and instrument comparison.
- 3 **Multi-Method Stat Section Chart:** Enables assessment of the performance of each method.
- 4 **Levey-Jennings Chart:** Details features of your laboratory's performance.
- 5 **Target Score Chart:** This unique chart provides a numerical index of performance, allowing at-a-glance assessment.
- 6 **%Deviation by Sample Chart:** Helps to identify trends and shifts in performance.
- 7 **%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 + 1 pilot Samples every month, 1 x 12 month cycle, 12 month subscription	RQ9134/A (1.8 ml) Subsequent instruments 11 Parameters + 1 pilot Samples every month, 1 x 12 month cycle, 12 month subscription
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Bicarbonate Ca++ Cl-	CO <sub>2</sub> (Total) Glucose H+ *	Lactate K+ Na+	pCO <sub>2</sub> pH pO <sub>2</sub>
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## Blood Typing Programme+

RQ9206 (4 ml & 2 ml)  
6 Tests  
2 challenges per quarterly distribution, 1 x 12 month cycle, 12 month subscription

ABO Group Antibody Identification	Antibody Screen Antigen Typing	Compatibility (Cross-Match)	Rh(D)
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## 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	RQ9127/b (1 ml) Full 7 Parameters Samples every month, 1 x 12 monthly cycle, 12 month subscription	RQ9186 (1 ml) Full 7 Parameters Samples every month, 1 x 12 monthly cycle, 12 month subscription
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CK, Total CK-MB (Activity)	CK-MB (Mass) Homocysteine	Myoglobin Troponin I	Troponin T
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## 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
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## 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
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## 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

aPTT  
PT (including INR)  
TT  
Fibrinogen  
Antithrombin III

**RQ9135/b (1 ml)**  
Full 17 Parameters + 1 pilot

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

Factor IX  
Factor X  
Factor XI  
Factor XII  
Plasminogen

Protein C  
Protein S  
Protein S (Free)

## CO-Oximetry Programme+ *With target scoring*

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

Carboxyhaemoglobin (COHb / HbCO)  
Deoxyhaemoglobin (HHb)

Methaemoglobin (MetHb)

Oxyhaemoglobin (O2Hb / HbO2)

Total Haemoglobin (tHb)

## CYFRA 21-1 Programme • *With target scoring*

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

CYFRA 21-1 (Cytokeratin 19 fragment)

## Cytokines Programme • *With target scoring for IL-6*

**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 • *With target scoring*

**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 + 6 pilots

Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription, reference method values

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

**RQ9112/b (5 ml)**  
17 Parameters + 6 pilots

Calcium (Ionised)  
Chloride  
Cholesterol  
Cholinesterase  
CK, Total (CPK)  
Copper  
Creatinine  
D-3-Hydroxybutyrate  
eGFR (estimated glomerular filtration rate)  
FIB-4\*  
Fructosamine  
γGT  
GLDH  
Glucose  
HBDH  
HDL-Cholesterol

**RQ9112/c (5 ml)**  
Full 56 Parameters + 6 pilots

Iron  
Lactate  
LD (LDH)  
LDL-Cholesterol  
Lipase  
Lithium  
Magnesium  
NEFA  
Non-HDL Cholesterol  
Osmolality  
Osmolar Gap\*  
Phosphate (Inorganic)  
Potassium  
Protein (Total)  
PSA  
Sodium

**RQ9128 (5ml)**  
Full 56 Parameters + 6 pilots

Samples every month, 1 x 12 monthly cycle, 12 month subscription

TIBC  
T - Uptake\*  
T<sub>3</sub> (Free)  
T<sub>3</sub> (Total)  
T<sub>4</sub> (Free)  
T<sub>4</sub> (Total)  
Transferrin\*  
Transferrin Saturation\*  
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

# RIQAS PROGRAMMES

## Haematology Programme *With target scoring*

**RQ9118 (2 ml)**  
11 Parameters  
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription

Haematocrit (HCT)  
Haemoglobin (Hb)  
Mean Cell Haemoglobin (MCH)

Mean Cell Haemoglobin Concentration (MCHC)  
Mean Cell Volume (MCV)

**RQ9140 (2ml)**  
11 Parameters  
Samples every month, 1 x 12 monthly cycle, 12 month subscription

Mean Platelet Volume (MPV)  
Platelets (PLT)  
Plateletcrit (PCT)

Red Blood Cell Count (RBC)  
Red Cell Distribution Width (RDW)  
Total White Blood Cell Count (WBC)

## Human Urine Programme *With target scoring*

**RQ9115 (2 x 10 ml)**  
25 Parameters + 2 pilots  
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription

ACR  
Albumin/Microalbumin  
Amylase  
Anion Gap\*  
Calcium  
Chloride  
Copper

Cortisol  
Creatinine  
Dopamine  
Epinephrine  
Glucose  
Metanephrine  
Norepinephrine

**RQ9185 (10ml)**  
25 Parameters + 2 pilots  
Samples every month, 1 x 12 monthly cycle, 12 month subscription

Normetanephrine  
Magnesium  
Osmolality  
Oxalate  
Phosphate (Inorganic)  
Potassium  
Protein (Total)

Protein/Creatinine Ratio\*  
Sodium  
Urea  
Uric Acid  
VMA  
5-HIAA

## Immunoassay Programme *With target scoring*

**RQ9125/a (5 ml)**  
4 Parameters only + 4 pilots

Samples every two weeks, 2 x 6 monthly cycles, 12 month subscription (RQ9125/a, RQ9125/b, RQ9125/c)

ACTH  
AFP  
Aldosterone  
Amikacin  
Androstenedione  
β-2-Microglobulin  
CA125  
CA15-3  
CA19-9  
Carbamazepine  
CEA  
Cortisol  
C-Peptide  
DHEA-Sulphate

**RQ9125/b (5 ml)**  
13 Parameters only + 4 pilots

DHEA Unconjugated  
Digoxin  
Estradiol (Only available in RQ9130)  
Free Androgen Index (FAI)\*  
Ferritin  
Folate  
FSH  
Gentamicin  
GH  
hCG  
IgE  
Insulin  
LH  
Oestradiol

**RQ9125/c (5 ml)**  
Full 50 Parameters + 4 pilots

17-OH-Progesterone  
Paracetamol  
Phenobarbital  
Phenytoin  
Progesterone  
Prolactin  
PSA (Free)  
PSA (Total)  
PTH (Parathyroid Hormone)  
PTH (1-84)  
Salicylate  
SHBG  
T-Uptake\*  
T<sub>3</sub> (Free)

**RQ9130 (5 ml)**  
Full 51 Parameters + 4 pilots  
Samples every month, 1 x 12 month cycle, 12 month subscription (RQ9130)

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*

**RQ9141 (2 ml)**  
10 Parameters + 1 pilot  
Samples every month, 1 x 12 month cycle, 12 month subscription

1-25-(OH)<sub>2</sub>-Vitamin D\*  
25-OH-Vitamin D  
C-Peptide

Anti-TG  
Anti-TPO  
IGF-1

Osteocalcin  
Procalcitonin  
PTH (Parathyroid Hormone)

PTH (1-84)  
Insulin

## Immunoassay Speciality 2 Programme *With target scoring*

**RQ9142 (1 ml)**  
5 Parameters  
Samples every month, 1 x 12 month cycle, 12 month subscription

Calcitonin  
Gastrin

Procalcitonin

Plasma Renin Activity

Renin (Direct Concentration)

## Immunosuppressant Programme • *With target scoring*

**RQ9159 (2 ml)**  
4 Parameters  
Samples every month, 1 x 12 month cycle, 12 month subscription, reference method values

Ciclosporin

Everolimus

Sirolimus

Tacrolimus

## Lipid Programme *With target scoring*

**RQ9126/a (3 ml)**  
3 Parameters only (choose from 7)  
Samples every 2 weeks, 2 x 6 monthly cycles, 12 month subscription

Apolipoprotein A1  
Apolipoprotein B

**RQ9126/b (3 ml)**  
Full 7 Parameters

Cholesterol (Total)  
HDL-Cholesterol

LDL-Cholesterol  
Lipoprotein (a)

Triglycerides

## Maternal Screening Programme *With target scoring*

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

AFP  
free  $\beta$ -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

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

Antimicrobial Susceptibility Testing

Strain Identification

## Neonatal Bilirubin Programme • *With target scoring*

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

Direct Bilirubin

Total Bilirubin

## Pre-eclampsia Programme+

RQ9207 (1 ml)  
4 Parameters  
Samples every month, 1 x 12 month cycle, 12 month subscription

PAPP-A

PIGF

sFlt-1

sFlt-1/PIGF ratio

## Serology Chagas Programme+

RQ9208 (1 ml)  
1 Parameter  
Samples every month, 1 x 12 month cycle, 12 month subscription

*Trypanosoma Cruzi* 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-EBNA IgG

Anti-EBV VCA IgG

Anti-EBV VCA IgM

## Serology (HIV-Hepatitis) Programme+

RQ9151 (1.8 ml)  
17 Parameters  
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

HIV Antibody/Antigen combined  
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)  
15 Parameters  
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



# MOLECULAR INFECTIOUS DISEASE TESTING

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Combine the strengths of Qnostics & QCMD to elevate the accuracy, reliability, and compliance of molecular diagnostics. Together, these industry leaders provide an unparalleled range of molecular IQC and EQA controls, ensuring the highest standards in infectious disease testing.

# IQC BENEFITS

## Qnostics

Qnostics specialises in molecular quality controls designed to support assay verification, routine monitoring, and regulatory compliance.



### True Third Party Controls

Independently manufactured controls ensure unbiased and precise performance monitoring, providing confidence in results across different diagnostic platforms. These controls are particularly valuable for validating assay consistency over time and across multiple locations.



### Whole Pathogen Controls

Contain intact microorganisms that mimic clinical samples, enabling a comprehensive evaluation of the entire diagnostic workflow from extraction to detection. This real-world simulation ensures end-to-end process accuracy.



### Liquid Frozen Format

Pre-prepared and ready-to-use controls minimise errors during preparation, improve workflow efficiency, and reduce time spent on manual handling. This format eliminates the need for reconstitution and ensures consistent results.



### Wide Compatibility

Designed to integrate seamlessly with both commercial and in-house molecular diagnostic platforms, ensuring versatility in application. Whether using automated systems or manual protocols, Qnostics' products deliver consistent performance.



### ISO Compliance

Certified to ISO 17511 for metrological traceability and ISO 13485 for medical device quality, guaranteeing reliability and adherence to global standards.



### Commutable Samples

Qnostics' controls closely match the behavior of real clinical samples, ensuring accurate and reproducible results in diagnostic workflows. This commutability enhances the reliability of results across diverse testing scenarios.



### Clinically Relevant Concentrations

Qnostics' quantitative products are specifically designed with clinically relevant concentrations, enabling accurate diagnostic insights and supporting medical decision-making with confidence.



QCMD offers the world's most extensive catalogue of External Quality Assessment (EQA) schemes, supporting laboratories in monitoring and improving diagnostic performance.



### Extensive Portfolio

With over 300 molecular targets covering viral, bacterial, fungal, and parasitic pathogens, QCMD ensures comprehensive proficiency testing options. This expansive portfolio addresses the needs of laboratories working with routine diagnostics and emerging threats.



### Flexible EQA Formats

Laboratories can select from one, two, or four challenges per year to align with their specific regulatory and operational requirements. This flexibility ensures that EQA participation can adapt to laboratory workflows and compliance mandates.



### Rapid Feedback

Results are provided within two weeks (up to four weeks for specialised schemes), enabling timely corrective actions and performance adjustments. Quick turnaround times support proactive quality improvement.



### High Quality Materials

Utilise clinically relevant samples that simulate real-world diagnostic challenges, ensuring meaningful and practical assessments. These materials are essential for laboratories aiming to maintain high diagnostic accuracy.



### Global Peer Comparisons

With over 16,000 participants in more than 120 countries, QCMD offers the largest peer group network in the world, enhancing statistical validity and benchmarking opportunities. This extensive network provides laboratories with robust data to evaluate their performance against global standards.



### ISO Compliance

Accredited to ISO 17043, ensuring excellence in proficiency testing and adherence to international standards.

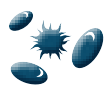


### Commutable Samples

QCMD's EQA samples mimic patient samples, providing laboratories with realistic and reliable proficiency testing. This commutability ensures that EQA results are reflective of true clinical performance.

# IQC & EQA CONTROLS & PROGRAMMES

## Qnostics Controls



Blood Borne Viruses



Central Nervous System



Drug Resistance



Gastrointestinal Infections



Respiratory Diseases



Sexually Transmitted Infections



Transplant Associated Diseases



Other



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## QCMD Programmes



Blood Borne Viruses



Central Nervous System Diseases



Congenital Infections



Drug Resistance



Exotic / Emerging Diseases



Gastrointestinal Diseases



Immunocompromised  
Associated Diseases



Multiple Pathogen /  
Syndromic Infections



Respiratory Diseases



Sexually Transmitted Infections



Transplant Associated Diseases



Typing



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QUALITY CONTROL



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