# **RANDOX**

# INTERNAL QUALITY CONTROLS





## **ACUSERA**

# TRUE THIRD PARTY CONTROLS OFFERING COMPLETE TEST MENU CONSOLIDATION



- **OI** BENEFITS
- 04 LIQUID CONTROLS
- 07 RANDOX A GLOBAL DIAGNOSTIC SOLUTIONS PROVIDER
- 08 CONTACT US

### **BENEFITS**

For more than 35 years Randox has been shaping the future of clinical diagnostics with our pioneering high quality, cost effective laboratory solutions. With approximately 70% of clinical decisions based on laboratory test results, it is essential that the results provided are accurate and reliable in order to prevent potential misdiagnosis or inappropriate treatment.

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



### Liquid Controls

Available in user-friendly liquid formats, our Acusera range of controls reduce the risk of reconstitution errors and prevent contamination from poor quality water. Liquid ready-to-use controls are also ideal for Point of Care Testing.



#### Commutability

All Acusera controls are designed to react to the test system in the same manner as the patient sample, helping to meet ISO 15189:2012 requirements whilst reducing inconvenient and costly shifts in QC results when reagent batch is changed.



#### **Accurate Target Values**

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



### True Third Party Controls

Manufactured independently, the Acusera range delivers unbiased performance assessment with any instrument or method, helping to meet ISO 15189:2012 requirements whilst simultaneously eliminating the need for multiple instrument dedicated controls.



#### Shelf Life

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



#### Consistency

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



#### **Traceability**

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



#### Consolidation

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



#### Clinically Relevant Levels

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



#### Reduced Waste

The unrivalled working stability of the Acusera control range, combined with excellent 30-day stability, helps to keep laboratory waste and costs to a minimum.



#### Flexible Options

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



#### **Custom Controls**

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

For more information about Randox and for our full range of products, please visit randoxqc.com, or contact your local Randox representative.

# LIQUID CONTROLS

## Liquid Product Range

PRODUCT DESCRIPTION	SIZE	CAT NO.	PAGE NO.
Ammonia/Ethanol Control Level I	6 × 2 ml	EA1366	04
Ammonia/Ethanol Control Level 2	6 × 2 ml	EA1367	04
Ammonia/Ethanol Control Level 3	6 × 2 ml	EA1368	04
Liquid HbA1c Control Level 1	6×1 ml	HA10224	04
Liquid HbA1c Control Level 2	6×l ml	HA10225	04
PTH Control Level I	3 × 3 ml	PTH10110	04
PTH Control Level 2	3 × 3 ml	PTHIOIII	04
PTH Control Level 3	3 × 3 ml	PTH10112	04
Liquid CSF Control Level 1	10 x 3 ml	CF10138	05
Liquid CSF Control Level 2	10 x 3 ml	CF10139	05
Liquid Lipid Control Level I	5 × 3ml	LE10174	05
Liquid Lipid Control Level 2	5 × 3ml	LE10175	05
Liquid Lipid Control Level 3	5 × 3ml	LE10176	05
Liquid Urine Control Level 2	10 × 10 ml	UC5074	06
Liquid Urine Control Level 3	10 × 10 ml	UC5075	06
Urinalysis Control Level 1	12 × 12 ml	UC5033	06
Urinalysis Control Level 2	12 × 12 ml	UC5034	06





## Analytes Ethanol Ammonia

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	$6 \times 2 \text{ ml}$	EA1366
Ammonia Ethanol Control Level 2	$6 \times 2 \text{ ml}$	EA1367
Ammonia Ethanol Control Level 3	$6 \times 2 \text{ ml}$	EA1368



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

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

Description	Size	Cat. No.
Liquid HbA1c Control Level 1	6 x I ml	HA10224
Liquid HbA1c Control Level 2	6 x I ml	HA10225
Liquid HbA1c Control Set	$2 \times 2 \times 0.5 \text{ ml}$	HA10155

# PTH Control 🐉 🔘 🛉





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

- · Liquid frozen
- · 100% human serum
- · Assayed target values and ranges for a wide range of immunoassay systems
- Stable to expiry date at -20°C to -70°C
- Open vial stability of 30 days at 2°C to 8°C

Description	Size	Cat. No.
PTH Control Level I	$3 \times 3 \text{ ml}$	PTH10110
PTH Control Level 2	$3 \times 3 \text{ ml}$	PTHIOIII
PTH Control Level 3	$3 \times 3 \text{ ml}$	PTH10112

### CONTROLS

# Liquid CSF Control 6



 $\alpha$ -I-Globulin (Electrophoresis)  $\alpha$ -2-Globulin (Electrophoresis) Albumin (Electrophoresis) β-Globulin (Electrophoresis)

Chloride γ-Globulin (Electrophoresis) Glucose High Sensitivity Immunoglobulin A (hslgA)\* High Sensitivity Immunoglobulin G (hslgG) High Sensitivity Immunoglobulin M (hslgM)\* Lactate Microalbumin

Protein (Total) Sodium

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

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

Description	Size	Cat. No.
Liquid CSF Control Level 1	$10 \times 3 \text{ ml}$	CF10138
Liquid CSF Control Level 2	$10 \times 3 \text{ ml}$	CF10139

\*No claims are made regarding values or stability.

# Liquid Lipid Control 🐉 🎯 🛉





#### **Analytes** Cholesterol (Total) Lipoprotein (a) CRP Triglycerides

Delivering a true third party solution for a wide range of lipids, the new Acusera Liquid Lipid Control is designed to ensure an unbiased, independent assessment of analytical performance. The added advantage of liquid samples and a 30 day open vial stability keeps waste to a minimum while ensuring the control is easy and convenient to use. Three distinct levels are available covering low risk, borderline and high risk concentrations.

- Liquid frozen
- 100% human serum
- Sodium Azide is not present no interference occurs with clearance methods
- Stable to expiry date at -20°C to -80°C
- Thawed stability of 30 days at 2°C to 8°C

Description	Size	Cat. No.
Liquid Lipid Control Level I	$5 \times 3 \text{ ml}$	LE10174
Liquid Lipid Control Level 2	$5 \times 3 \text{ ml}$	LE10175
Liquid Lipid Control Level 3	$5 \times 3 \text{ ml}$	LE10176

# Liquid Urine Control 6 🌘 🛉





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

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

- · Liquid ready-to-use
- · 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.
Liquid Urine Control Level 2	$10 \times 10 \text{ ml}$	UC5074
Liquid Urine Control Level 3	$10 \times 10 \text{ ml}$	UC5075

# Urinalysis Control 🕻 🎯 🛊





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

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

- · Liquid ready-to-use
- Human based material
- 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	$12 \times 12  \text{ml}$	UC5033
Urinalysis Control Level 2	$12 \times 12 \text{ ml}$	UC5034

## RANDOX - A GLOBAL DIAGNOSTIC SOLUTIONS PROVIDER

Randox has been supplying laboratories worldwide with revolutionary diagnostic solutions for over 35 years. Our experience and expertise allow us to create a leading product portfolio of high quality diagnostic tools which offer reliable and rapid diagnosis. We believe that by providing laboratories with the right tools, we can improve healthcare worldwide.

#### **RX SERIES**



Renowned for quality and reliability, the RX series combines robust hardware and intuitive software with the world leading RX series test menu comprising an extensive range of high quality reagents including routine chemistries, specific proteins, lipids, therapeutic drugs, drugs of abuse, antioxidants and diabetes testing. The RX series offers excellence in patient care delivering unrivalled precision and accuracy for results you can trust, guaranteeing real cost savings through consolidation of routine and specialised tests onto one single platform.

### **REAGENTS**



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

### **EVIDENCE SERIES**



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

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

### **HEADQUARTERS**

Randox Laboratories Ltd, 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom

#### **INTERNATIONAL OFFICES**



#### AUSTRALIA

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



#### CZECH REPUBLIC

Tel: +420 2 1115 1661



#### HONG KONG

Randox Laboratories Hong Kong Limited Tel: +852 3595 0515



Randox Laboratories Polska Sp. z o.o.



#### REPUBLIC OF IRELAND

Tel: +353 7495 22600



#### SOUTH KOREA

Randox Korea Tel: +82 (0) 3 | 478 3 | 2 |



#### UAE

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



#### BRA7II

Randox Brasil Ltda. Tel: +55 | | 5 | 8 | 2024



#### FRANCE

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



Randox Laboratories Ltd. Tel: +39 06 9896 8954



#### PORTUGAL

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



#### SLOVAKIA

Randox S.R.O. Tel: +42 | 2 638 | 3324



#### SPAIN

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



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



#### CHINA

Tel: +86 02 I 6288 6240



#### GERMANY

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



### INDIA

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



#### PUERTO RICO

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



#### SOUTH AFRICA

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



### SWITZERLAND

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



#### VIETNAM

Randox Laboratories Ltd. Vietnam Tel: +84 (0) 8 39 I I 0904

### For technical support contact:

technical.services@randox.com















