RANDOX
QUALITY CONTROL

ACUSERA 24•7

Interlaboratory Data Management

Complete **QC** solutions for results you can **trust**

An Effective Tool For Evaluating Laboratory Performance

Acusera 24•7 is an interlaboratory data management package, primarily designed to complement the Acusera range of true third party controls.

An effective IQC and peer group reporting program like Acusera 24•7 will help to improve your laboratory's analytical performance, meet regulatory requirements and most importantly, ensure accurate results.

The software has two complementary functions; the internal function of the software is designed to help laboratories manage and interpret their daily QC data while the peer group function of the software allows comparison to world wide peer group statistics, enabling rapid and effective troubleshooting.

Identify any trends, system errors or reagent issues

Acusera 24•7 will allow users to immediately detect and identify errors in their laboratory test system.

Access to comprehensive charts and peer group data allows users to identify problems that may otherwise have gone unnoticed and assess if shifts in QC recovery are unique to their laboratory. Access to peer group data may even alert lab staff to future issues before they are encountered in their laboratory.

Minimise false rejections using QC multi-rules

The ability to apply user-defined QC multi-rules will help to reduce false rejections and the number of repeat tests whilst maintaining a high level of error detection. The new Acusera Advisor tool will recommend QC multi-rules and a minimum QC frequency based on method performance.

Bridge the gap between IQC and EQA

Acusera 24•7 is designed to complement your current EQA scheme, providing users with added confidence in-between samples.

EQA is performed retrospectively therefore, acceptable EQA performance at the time of analysis does not guarantee the accuracy and reliability of laboratory testing.

Participation in an effective interlaboratory program like Acusera 24•7 is essential in order to ensure the accuracy and reliability of patient test results. It may even help to improve EQA performance.

Have confidence in assigned target values

Together with data from RIQAS, the worlds largest international EQA scheme, Acusera 24•7 provides immediate confidence in assigned target values.

Facilitate regulatory requirements

Participation in an interlaboratory or peer group reporting program is becoming compulsory in countries worldwide.

IS015189:2012 states that:
"The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure. When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results shall be rejected.... Quality Control data shall be reviewed at regular intervals to detect trends in examination performance."

Get an independent perspective

Dedicated controls supplied by the instrument manufacturer can mask weaknesses within a test system, increasing the risk that a shift in patient results will go unnoticed.

The combination of Randox third party quality controls and Acusera 24•7 can reduce the potential for bias and provide a true assessment of analytical performance.

Online access anytime, anywhere

- Eliminates the need for local installation and frequent back ups, making it suitable for laboratory groups and chains.
- Convenient and easy to use.

Optional automated QC data import via Acusera 24•7 Connect

- Capable of connecting directly to your laboratory's LIS or Middleware.
- Increases productivity and eliminates the problems associated with manual data entry.

Simple and intuitive user interface

- The software is colour coded throughout, enabling an instant visual indication of poor performance.
- The built in help file is divided into user-friendly sections that help to guide the user through the software.

Fully interactive charts

- Levey-Jennings, Histogram and Performance Summary Charts are automatically generated, enabling identification of trends or bias.

Real time peer group data

- Peer group statistics uniquely generated every 24 hours from our extensive database of laboratory participants.

Comprehensive reports

- A range of comprehensive reports are available, helping laboratories to monitor performance and meet regulatory requirements.

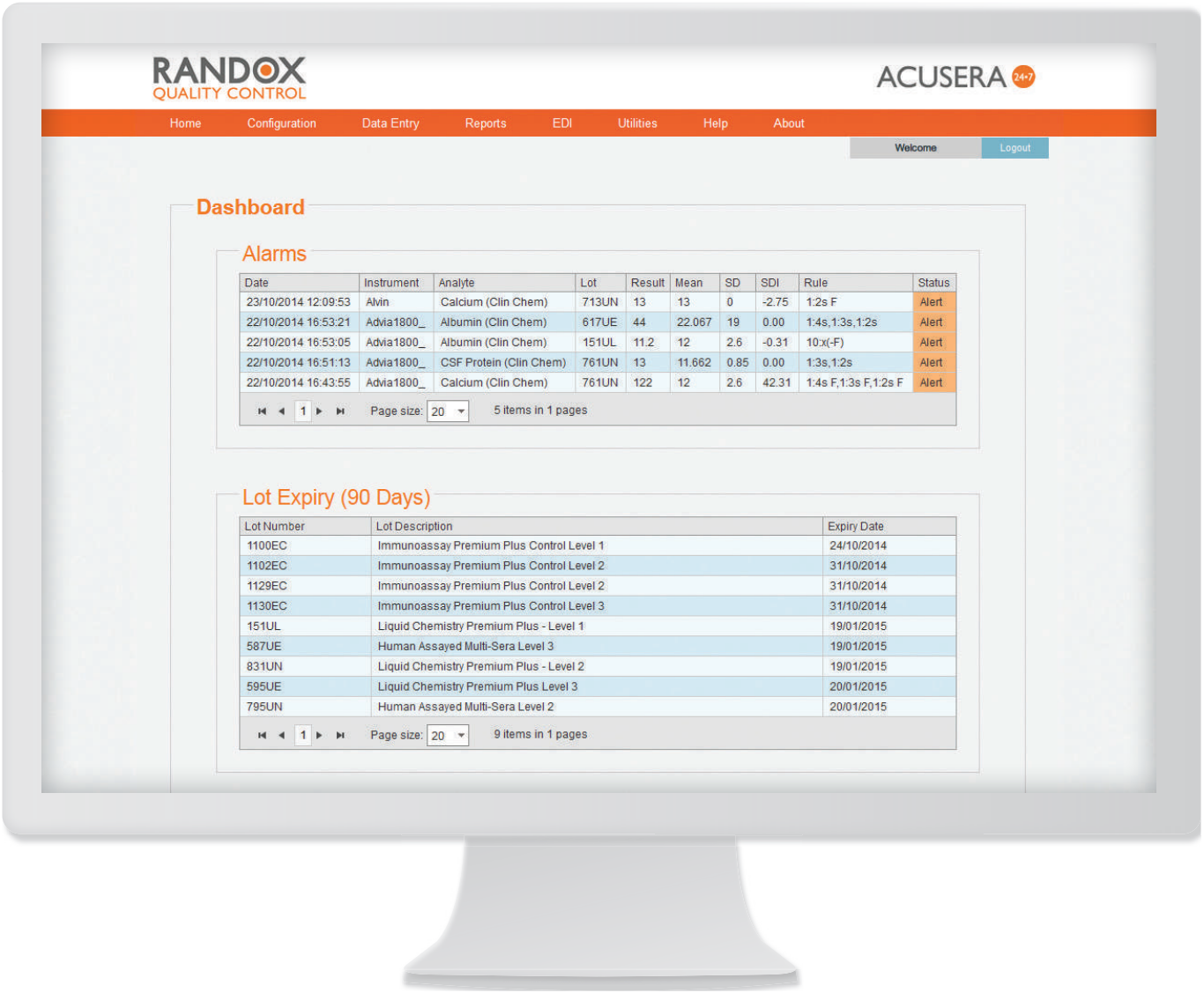
Highly flexible to meet individual laboratory needs

- Multi-lingual software.
- Although intended for use with the Acusera control range, the software's internal functions may be used with any QC material.

Dashboard

- The unique Dashboard instantly flags any rejected or alerted results and warns users when QC lots are approaching expiry.

Dashboard Interface



The unique Dashboard interface provides a rapid indication of poor performance

The unique Dashboard interface is available at no extra cost to laboratories. It is automatically displayed and updated every minute, instantly bringing all unreviewed, alerted or rejected QC results from the last seven days to the user's attention. This highly convenient and user-friendly function allows quick and easy identification of any poor performing tests that require further investigation. It also alerts users when a control lot is reaching its expiry date.

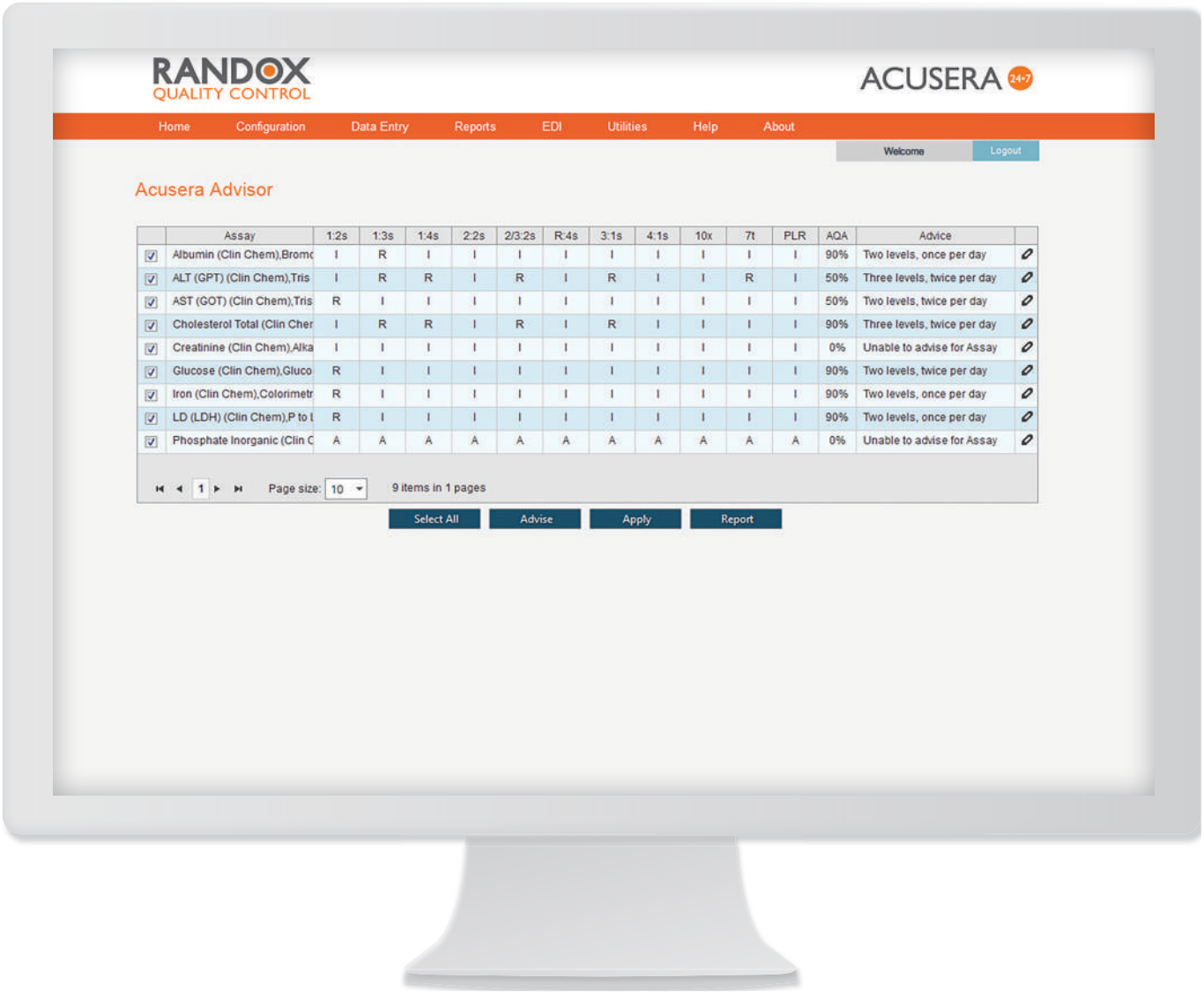
The date, instrument, analyte, lot number, result, $\bar{x}$, SD, SDI and rule violation are displayed. Results are colour coded red for reject and orange for alert. QC results are alerted or rejected based on the user defined or Acusera Advisor recommended QC multi-rules.

Provides users with a visual overview of current analytical performance

The data entry function is used to manually enter QC data, but also provides an on-screen summary of all QC data entered to date. Acusera 24•7 will automatically calculate statistical data, including the Mean and SD. Data is presented in a user-friendly format, allowing any sudden or gradual changes in performance to be identified immediately.

The summary provides a breakdown of monthly and cumulative data for up to three lots of control and enables comparison to a user defined Fixed Mean and SD.

Results are colour coded so that those outside selected acceptable limits of performance are highlighted in orange for 'alert' and red when 'rejected', thus allowing for quick and easy identification. The system also indicates which rule has been violated. Users may add comments or actions, enabling advanced data review.

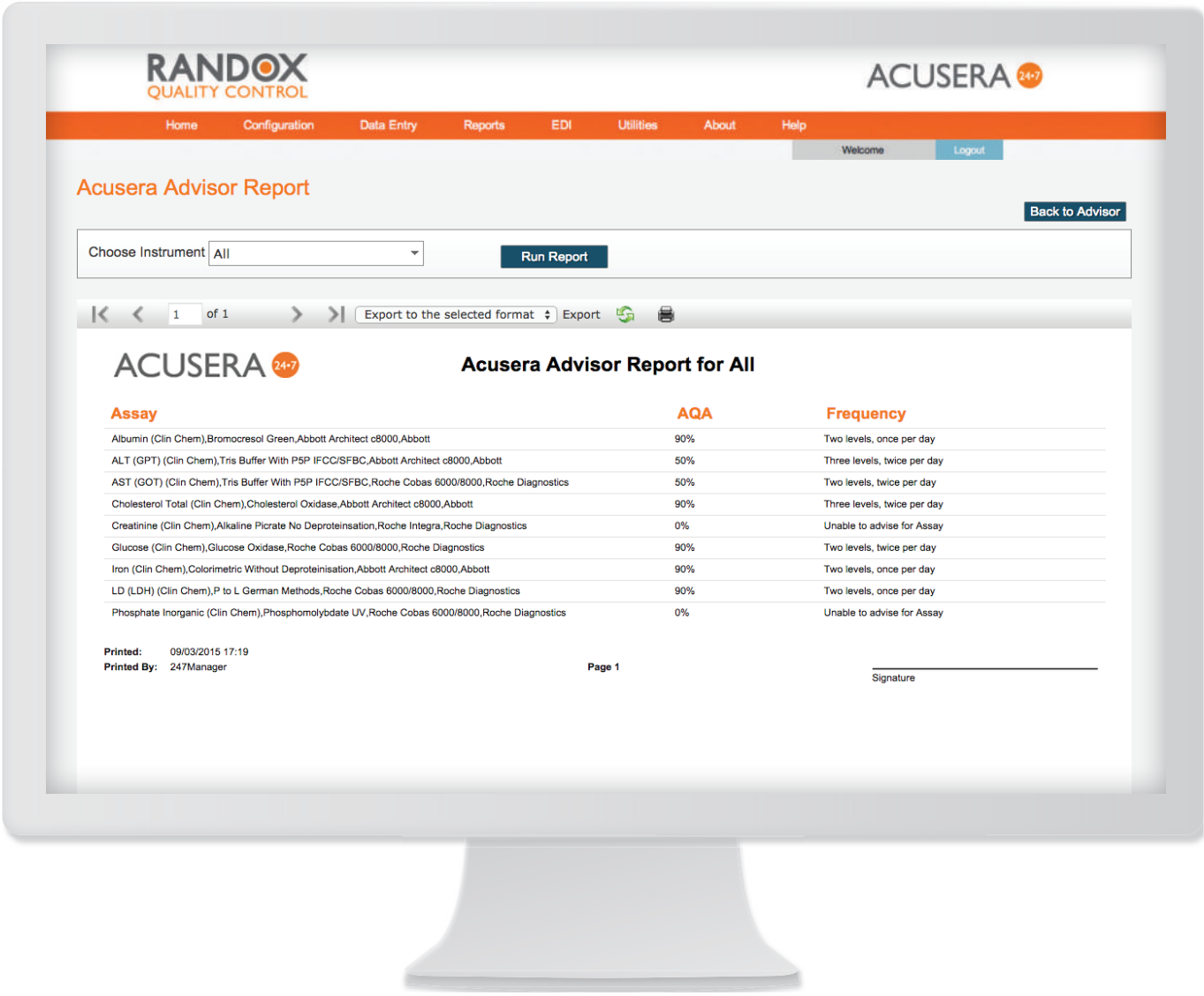


Automatically recommends QC multi-rules and optimal QC frequency

Acusera Advisor is an optional tool designed to help laboratories select an optimum QC strategy for each individual test in use. Not only will the advisor tool recommend a set of QC multi-rules, it will also suggest a minimum QC frequency based on the performance of the method in question. The use of QC multi-rules will reduce false rejections, unnecessary troubleshooting and the need for costly repeat tests without affecting error detection.

Before any recommendations can be made for a particular method, users must enter a minimum of 20 results for at least two levels of control and set user defined performance limits.

Recommendations are based on normalised OPSpec charts. Once performance limits have been defined, the software will determine the %CV and %Bias. These are then used to calculate the normalised operating point. A normalised OPSpec chart is then used to select the appropriate QC strategy.



Displays a suggested QC frequency and Analytical Quality Assurance for each assay

The Acusera Advisor report is easily generated and provides a list of all assays along with the Analytical Quality Assurance (AQA) achieved with the currently used multi-rules and a suggested minimum QC frequency.

The report can be generated for each individual instrument or for all instruments in use.

Interactive Levey-Jennings Charts

Identify trends, bias and precision problems at-a-glance

Levey-Jennings charts are easily generated by the software and can be based on either SD or %DEV. Each chart provides an instant visual indication of whether or not a test is performing well.

Using the unique overview bar, users can scroll through past data to look at previous trends or zoom in on a specific time period to provide a more in-depth look at performance. The interactive nature of the chart also allows users to add actions or comments for advanced data review.

The test, date and SDI is easily displayed by hovering over any of the data points; further information can be accessed simply by clicking on each individual data point.

Combine multiple levels of control, parameters and instruments on the same chart

With Acusera 24•7 Live Online, users have the ability to combine multiple instruments, parameters and serum lots on a single, easy to interpret chart.

The ability to customise charts in this way provides a means of assessing QC performance from multiple instruments and enables users to determine whether or not an issue is unique to a particular test or instrument.

The navigation tree at the side of the chart allows users to select multiple lots, instruments and parameters. Using the legend, users may choose to show/hide data points to make charts more manageable.

Interactive Histogram Charts

Displays your monthly Mean for each parameter, allowing identification of long term trends

Like the Levey-Jennings chart, the Histogram can be based on either SD or %DEV and provides a visual representation of a laboratory's performance.

Like all Acusera 24•7 charts, the interactive nature of the Histogram means users can zoom in on a specific month or time period for a more in-depth look at performance.

Users can choose to display data for multiple levels of control, multiple parameters or multiple instruments on the same Histogram chart.

The ability to display multiple data sets on a single chart enables laboratories to determine if the same shift in control values is seen between different levels of control or with more than one parameter.

Similar to the Levey-Jennings chart, the SDI / %DEV from the Mean can be displayed by simply hovering over the bar relating to the month of interest.

Provides a visual assessment of both your accuracy and precision in relation to the peer group

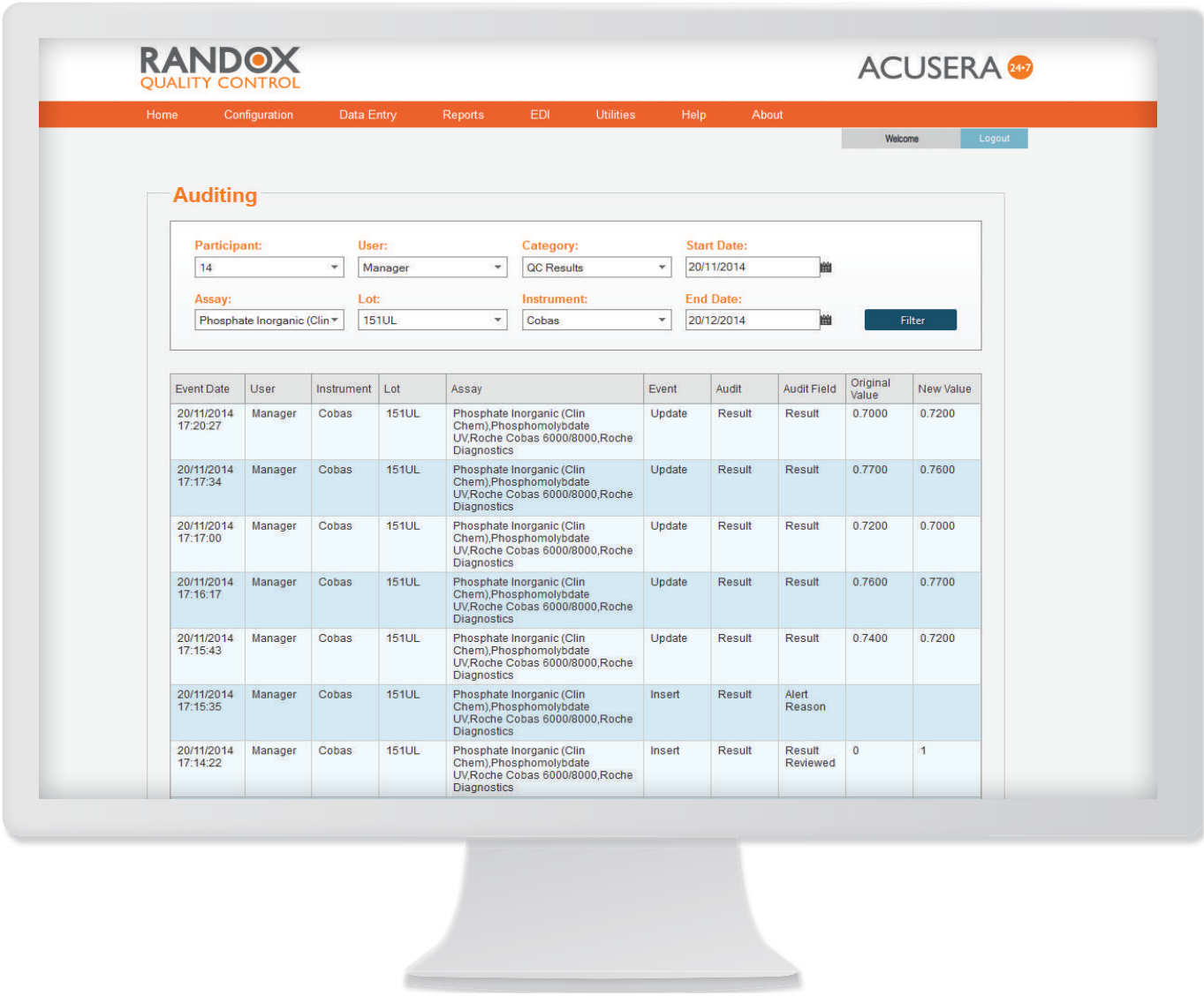
The Performance Summary Chart highlights potential bias and precision issues, displaying your SDI on the y-axis and your CVI on the x-axis. Individual laboratory performance versus your chosen peer group are plotted. A user's cumulative or monthly results may be compared to world or affiliate group statistics, enabling enhanced troubleshooting capabilities.

Analytical performance can be quickly and easily interpreted by identifying where your result falls in the shaded region.

Evaluate and review any poor performing QC tests

The Data Review report displays data for all unreviewed QC tests which have fallen outside the laboratory's user defined performance limits. Data may be filtered by date, instrument, lot number or rule violation. It may also be filtered to display only alerted/rejected results. The report can be exported or printed easily to document the review process.

As always, results are colour coded for user convenience. Once results have been evaluated, managers can record their actions by marking each result as 'reviewed'. A 'reviewed' result will no longer appear on the Dashboard.



Event Date	User	Instrument	Lot	Assay	Event	Audit	Audit Field	Original Value	New Value
20/11/2014 17:20:27	Manager	Cobas	151UL	Phosphate Inorganic (Clin Chem),Phosphomolybdate UV,Roche Cobas 6000/8000,Roche Diagnostics	Update	Result	Result	0.7000	0.7200
20/11/2014 17:17:34	Manager	Cobas	151UL	Phosphate Inorganic (Clin Chem),Phosphomolybdate UV,Roche Cobas 6000/8000,Roche Diagnostics	Update	Result	Result	0.7700	0.7600
20/11/2014 17:17:00	Manager	Cobas	151UL	Phosphate Inorganic (Clin Chem),Phosphomolybdate UV,Roche Cobas 6000/8000,Roche Diagnostics	Update	Result	Result	0.7200	0.7000
20/11/2014 17:16:17	Manager	Cobas	151UL	Phosphate Inorganic (Clin Chem),Phosphomolybdate UV,Roche Cobas 6000/8000,Roche Diagnostics	Update	Result	Result	0.7600	0.7700
20/11/2014 17:15:43	Manager	Cobas	151UL	Phosphate Inorganic (Clin Chem),Phosphomolybdate UV,Roche Cobas 6000/8000,Roche Diagnostics	Update	Result	Result	0.7400	0.7200
20/11/2014 17:15:35	Manager	Cobas	151UL	Phosphate Inorganic (Clin Chem),Phosphomolybdate UV,Roche Cobas 6000/8000,Roche Diagnostics	Insert	Result	Alert Reason		
20/11/2014 17:14:22	Manager	Cobas	151UL	Phosphate Inorganic (Clin Chem),Phosphomolybdate UV,Roche Cobas 6000/8000,Roche Diagnostics	Insert	Result	Result Reviewed	0	1

Provides a complete overview of historical actions that cannot be edited or deleted

The Audit Trail Report is a secure, computer generated, electronic report displaying all events leading to the creation, modification and deletion of an electronic record.

Regulatory bodies frequently require laboratories to document review of their QC data. Actions, comments and audit trails, when used in combination, provide an effective way of documenting the review process whilst providing a secure method of storing data.

The report can be filtered by any of the following criteria: date, instrument ID, lot number, test or action. The report can be easily converted to PDF and printed for reference.

Peer Group Statistics

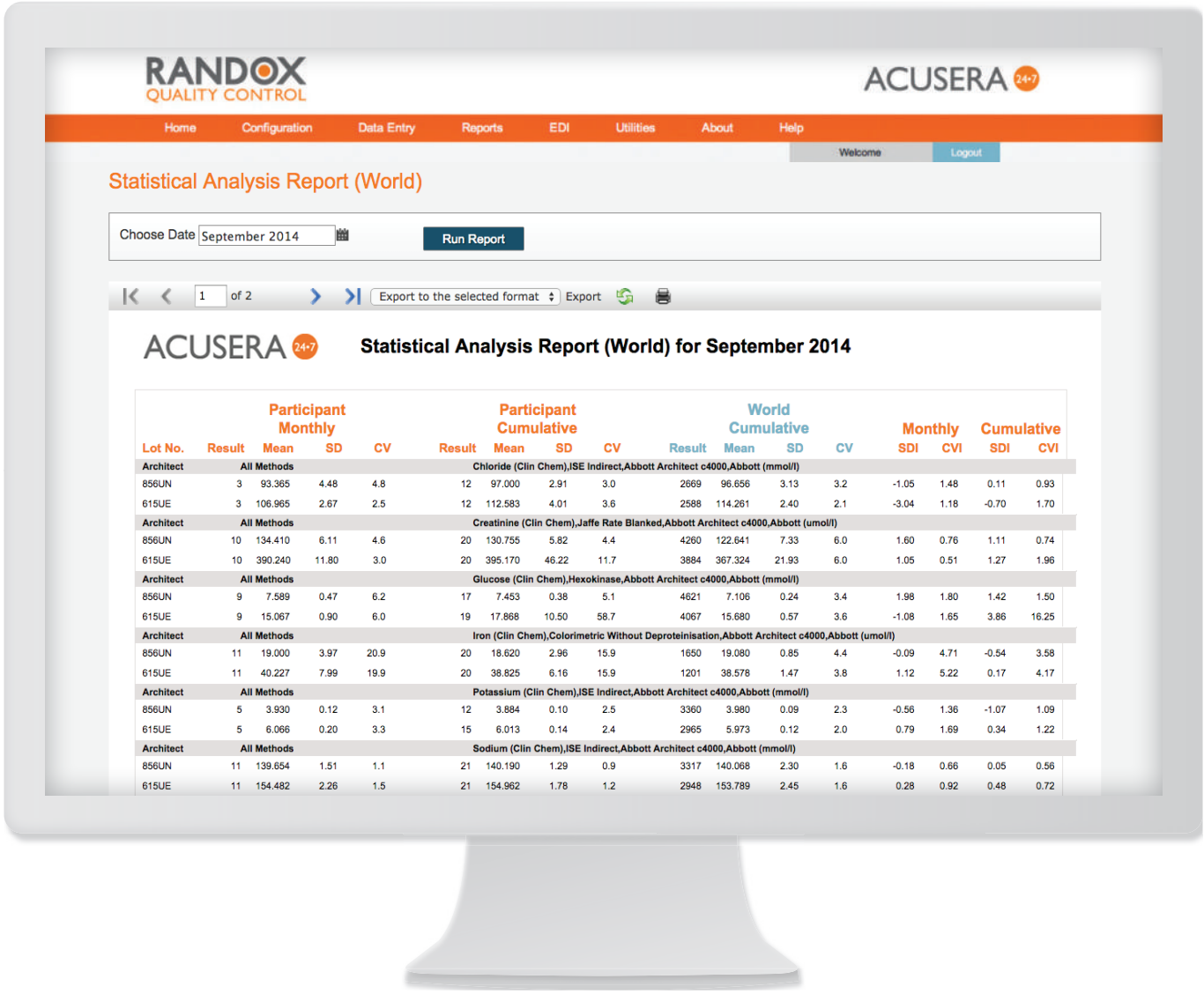
Users can select the peer group statistics to which their results are compared

Several options are available:

- All methods
- Method
- Method / Reagent
- Method / Instrument Model
- Method / Instrument Model / Reagent
- Method / Instrument Group
- Method / Instrument Group / Reagent

Peer group data is generated from our extensive database of laboratory participants and is uniquely updated every **24 hours**, ensuring effective troubleshooting and access to the most up-to-date information available.

Peer group data can be compared to worldwide peer group statistics or affiliate group statistics. Group co-ordinators can view the performance of others in their group of affiliate laboratories.



		Participant Monthly			Participant Cumulative				World Cumulative				Monthly		Cumulative	
Lot No.	Result	Mean	SD	CV	Result	Mean	SD	CV	Result	Mean	SD	CV	SDI	CVI	SDI	CVI
Architect	All Methods				Chloride (Clin Chem),ISE Indirect,Abbott Architect c4000,Abbott (mmol/l)											
856UN	3	93.365	4.48	4.8	12	97.000	2.91	3.0	2669	96.656	3.13	3.2	-1.05	1.48	0.11	0.93
615UE	3	106.965	2.67	2.5	12	112.583	4.01	3.6	2588	114.261	2.40	2.1	-3.04	1.18	-0.70	1.70
Architect	All Methods				Creatinine (Clin Chem),Jaffe Rate Blanked,Abbott Architect c4000,Abbott (umol/l)											
856UN	10	134.410	6.11	4.6	20	130.755	5.82	4.4	4260	122.641	7.33	6.0	1.60	0.76	1.11	0.74
615UE	10	390.240	11.80	3.0	20	395.170	46.22	11.7	3884	367.324	21.93	6.0	1.05	0.51	1.27	1.96
Architect	All Methods				Glucose (Clin Chem),Hexokinase,Abbott Architect c4000,Abbott (mmol/l)											
856UN	9	7.589	0.47	6.2	17	7.453	0.38	5.1	4621	7.106	0.24	3.4	1.98	1.80	1.42	1.50
615UE	9	15.067	0.90	6.0	19	17.868	10.50	58.7	4067	15.680	0.57	3.6	-1.08	1.65	3.86	16.25
Architect	All Methods				Iron (Clin Chem),Colorimetric Without Deproteinisation,Abbott Architect c4000,Abbott (umol/l)											
856UN	11	19.000	3.97	20.9	20	18.620	2.96	15.9	1650	19.080	0.85	4.4	-0.09	4.71	-0.54	3.58
615UE	11	40.227	7.99	19.9	20	38.825	6.16	15.9	1201	38.578	1.47	3.8	1.12	5.22	0.17	4.17
Architect	All Methods				Potassium (Clin Chem),ISE Indirect,Abbott Architect c4000,Abbott (mmol/l)											
856UN	5	3.930	0.12	3.1	12	3.884	0.10	2.5	3360	3.980	0.09	2.3	-0.56	1.36	-1.07	1.09
615UE	5	6.066	0.20	3.3	15	6.013	0.14	2.4	2965	5.973	0.12	2.0	0.79	1.69	0.34	1.22
Architect	All Methods				Sodium (Clin Chem),ISE Indirect,Abbott Architect c4000,Abbott (mmol/l)											
856UN	11	139.654	1.51	1.1	21	140.190	1.29	0.9	3317	140.068	2.30	1.6	-0.18	0.66	0.05	0.56
615UE	11	154.482	2.26	1.5	21	154.962	1.78	1.2	2948	153.789	2.45	1.6	0.28	0.92	0.48	0.72

Compare monthly and cumulative statistics to worldwide peer group data

The Statistical Analysis Report provides a complete overview of laboratory performance for any given month. This report encompasses many vital statistics including the $\bar{x}$, SD, CV, SDI and CVI. It can be used to compare both monthly and cumulative data for each individual test, as well as control lots to worldwide peer group statistics. Participants may also choose to compare their results to other laboratories in their group or chain via the Statistical Analysis (Group) Report.

Peer group statistics are uniquely updated every **24 hours** providing users with access to the most relevant data available.

The Statistical Analysis Report can be exported to PDF or .csv file formats and printed for review purposes.

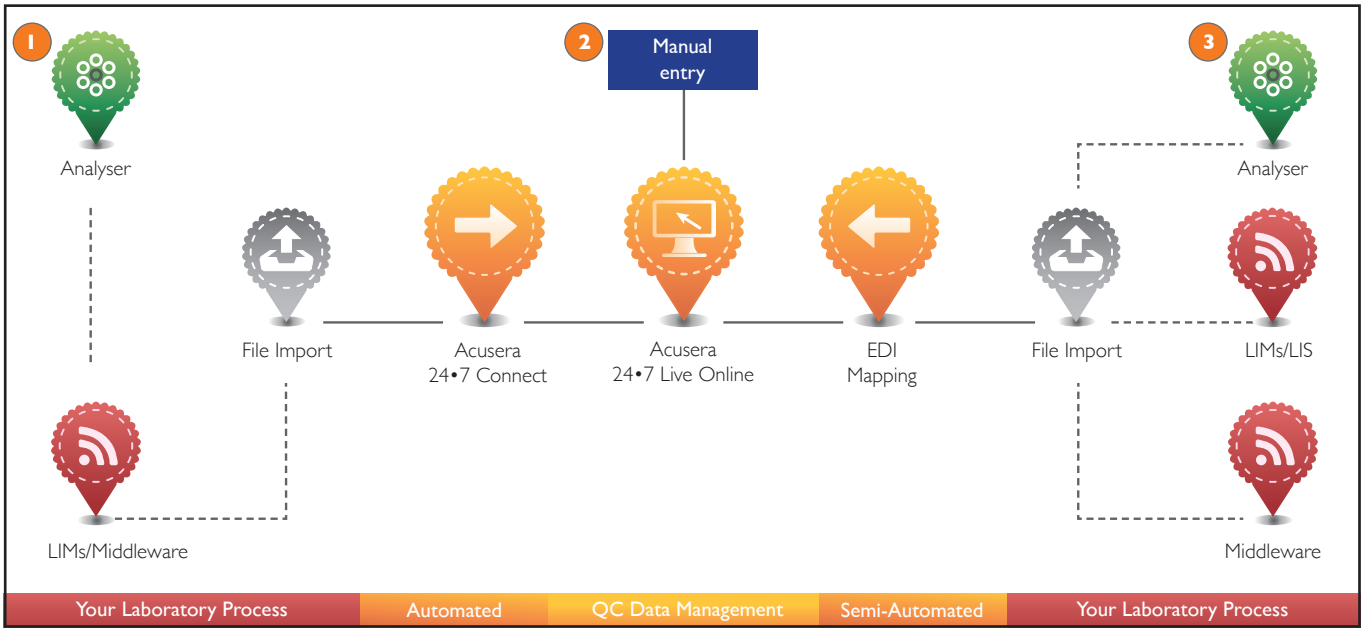
Acusera 24•7 Connect is a complementary hardware and software solution designed to provide a fully automated method of securely importing QC data direct from your laboratory's LIS or middleware to Acusera 24•7 Live Online.

- Highly convenient, eliminating issues associated with manual data entry.
- Increased productivity and efficiency.
- Imports QC data only, any patient test results are automatically ignored.
- Provides a secure real time connection.

QC result capture options

The diagram below demonstrates the three different methods of transferring QC data to Acusera 24•7 Live Online.

1. Fully automated import via Acusera 24•7 Connect.
2. Manual data entry.
3. Semi-automated import using EDI Mapping.



What is the speed?
The speed depends on your laboratory's local network, internet connection and other activities utilising the bandwidth.

How secure is Acusera 24•7?
A number of security measures have been introduced including participant number, username and password combination used to authenticate users, password complexity standards enforced on user account setup, CAPTCHA after several failed login attempts to prevent against automated attacks, individual role based accounts to ensure a principle of least privilege and X509 certificate authentication when sending results via the Connect software to meet security industry standards.

Are there any additional software requirements?
You must have access to a Java applet. This software is available as standard on almost all modern computers, laptops and notebooks.

How much data can be stored?
There are currently no limitations to the amount of data storage. Laboratories do not need to backup separately as Randox stores all data securely.

Is Acusera 24•7 Connect required to import QC data?
Acusera 24•7 Connect is only required if you wish to import QC data automatically. Data can also be entered manually using the data entry screen or in a semi-automated manner using the EDI function.

What if the connection goes down?
If connection is lost from the laboratory's side, all data will be transferred to the web and once reconnected, the previous session will also be remembered. Emergency power generators and fall over servers are in place to ensure 99.8% uptime is guaranteed.

Is there a limitation to the number of concurrent users?
There is no limit to the number of concurrent users.

What if I forget my username or password?
If an individual with user level or manager level access forgets their username and password, they should contact the administrator. If an administrator or group co-ordinator forgets their username or password they should contact Randox who will verify the administrator and send a new link to the registered email account.

How many user levels are available?
There are four user levels available: administrator, manager, user and co-ordinator. Co-ordinators will have access to all group data but will not be able to edit, delete or add any details.

How is Acusera 24•7 Live Online upgraded?
All new Acusera 24•7 releases will be available online automatically. Additional installation of software is not necessary.

Is Acusera 24•7 available in any other languages?
Yes, Acusera 24•7 is currently available in English, Spanish, Italian, French, Portuguese, Chinese, German and Swedish. A unique software selection facility allows users to switch between languages if and when required.

How do I register for Acusera 24•7 Live Online?
Register interest via **www.acusera247.com**. All participants will be registered on the host system; Live Online users will be flagged and emailed a link to provide administrator access. The administrator will then set up all other users with their access level, username and password.

Will the data be recorded with our local time?
Time zone is assigned initially at registration. All data is then recorded against a universal co-ordinated time (UTC).

Ordering Details

Description	Cat. Number
Acusera 24•7 Live Online Peer Group Activation and 12 Month License	QC4218
Acusera 24•7 Live Online Peer Group 12 Month License Renewal	QC4204
Acusera 24•7 Connect*	QC4205
Acusera 24•7 Advisor	QC4223
Acusera 24•7 Live Online Upgrade from Acusera 24•7 Live	QC4220
Acusera 24•7 Live Online Training	QC4221

*pending site survey completion

Software & Connectivity Solutions

Randox offers two different solutions for participation in the Acusera 24•7 interlaboratory data management program. Acusera 24•7 Live Online eliminates the need to install and update software locally, making it ideal for group installations, while Acusera 24•7 Live is suited to laboratories requiring a more basic range of features. The table below is designed to help you determine the best solution for your laboratory.

Features	Acusera 24•7 Live Online	Acusera 24•7 Live
Type of Solution		
Web service (internet based)	✓	▪
Desktop software	▪	✓
Platform		
Hosted by Randox	✓	▪
Installed on PC	▪	✓
Requirements		
Internet Connection	✓	✓ (for peer group only)
QC Data Management		
QC multi-rules	✓	✓
Acusera Advisor	✓	▪
Suitable for use with other manufacturers' controls	✓	✓
Dashboard Interface	✓	▪
Data Review	✓	▪
Charts		
Summary of results	✓	✓
Audit Trail Report	✓	▪
Levey-Jennings Chart	✓	✓
Multi Levey-Jennings Chart	✓	▪
Histogram Chart	✓	✓
Multi Histogram Chart	✓	▪
Performance Summary Chart	✓	✓
Peer Group Statistics	✓	✓
Reports		
Audit Trail Report	✓	▪
Analytical Goals		
Medical Relevance	✓	✓
RIQAS Target Deviation	✓	✓
Peer group Data		
Updated every 24 hours	✓	✓
Connectivity		
Automated upload of QC data	✓	▪
Semi-automated upload via EDI	✓	✓
Manual data entry	✓	✓

ACUSERA

True third party controls offering complete test menu consolidation

Randox is a world leading provider of multi-analyte, third party controls designed to help streamline QC in even the most demanding laboratories. Our unique combination of analytes enables complete test menu consolidation and will ultimately reduce costs without compromising on quality or performance.

Helping to facilitate ISO 15189 accreditation, our complete range of true third party controls will enable unbiased performance assessment with any instrument or method.

Why choose Randox as your third party QC provider?

- The most accurate controls available with target values traceable to reference methods ensuring unrivalled accuracy and reliability
- Partner of choice to national EQA schemes worldwide, testament that our QC materials are of the highest quality and reliability
- The most commutable controls available ensuring performance mimics that of the patient sample
- Availability of liquid frozen and liquid ready-to-use controls

Product Portfolio

- **Blood Gas**
- **Cardiac Markers**
- **Clinical Chemistry**
- **Coagulation**
- **Diabetes**
- **Haematology**
- **Immunoassay**
- **Immunology/Proteins**
- **Lipids**
- **Speciality/Research**
- **Therapeutic Drugs**
- **Toxicology**
- **Urinalysis**
- **Urine Chemistry**

RIQAS

The largest global EQA scheme with over 31,000 participants

When it comes to EQA there is power in numbers. With over 31,000 laboratory participants in more than 115 countries worldwide RIQAS truly is the largest EQA provider in the world.

Our comprehensive product offering currently covers over 360 parameters and 24 flexible EQA programmes. Each programme contains a unique combination of parameters meaning laboratories can significantly reduce the number of individual programmes required while increasing efficiency and reducing costs. Further benefits include accreditation to ISO 17043:2010, frequent reporting and the ability to register up to 5 instruments for each programme at no extra cost.

Product Portfolio

- **Ammonia/Ethanol**
- **Blood Gas**
- **BNP**
- **Cardiac**
- **Clinical Chemistry**
- **Coagulation**
- **ESR**
- **Haematology**
- **HbA1c**
- **Human Urine**
- **Immunoassay**
- **Immunoassay Speciality I**
- **Immunoassay Speciality II**
- **Lipids**
- **Liquid Cardiac**
- **Maternal Screening**
- **Serology Epstein Barr Virus**
- **Serology HIV/Hepatitis**
- **Serology ToRCH**
- **Serology Syphilis**
- **Specific Proteins**
- **Therapeutic Drugs**
- **Urinalysis**
- **Urine Toxicology**

Why choose RIQAS as your EQA provider?

- Internationally accredited to ISO/IEC 17043:2010 ensuring added confidence in all aspects of the scheme organisation
- Flexible reporting options available to suit laboratories of all sizes and budgets
- User friendly yet comprehensive reports allowing performance assessment at a glance
- Reports available within 72 hours of submission deadline allowing any corrective actions to be taken immediately
- End of cycle reports provide a complete summary of statistics and allows comparison to the previous cycle

RANDOX
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