ACUSERA 24•7

INTERLABORATORY DATA MANAGEMENT

RANDOX

ACUSERA 24•7

Online QC software with
real-time peer group statistics

BENEFITS

Our vast array of features have been designed to speed up data review and troubleshooting procedures for smarter QC data management.

Unique dashboard interface

- Instantly flags any rejected or alerted results 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 generated 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 score, 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) helps to meet ISO 15189:2012 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, Exception Report, Statistical Analysis Report and Statistical Metrics Report.
- Reports can be customised to show data for a specific date range or can be filtered to display data for a particular test or instrument.

Automated data import via Acusera 24•7 Connect

- Connects to LIMS, eliminating problems associated with manual data entry and increasing productivity.
- Capable of bi-directional communication with LIMS.

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.

BENEFITS

Simple and intuitive interface

- The new-look software is faster, more powerful and easier to use, 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

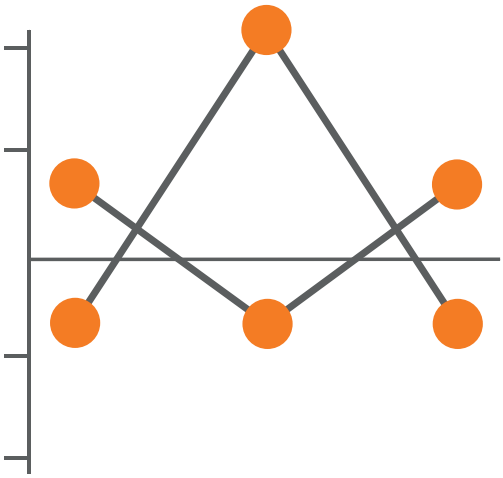
- Real-time comparison of results within your affiliated network or global peer data.
- View data from a specific lab or all labs.

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.



Compatible for use with the Acusera range of third party controls, the Acusera 24•7 software provides a tool for laboratories to analyse and interpret their QC results. With access to an impressive range of features, including interactive charts and real-time peer group data generated from our extensive database of laboratory participants, Acusera 24•7 is the most comprehensive package available on the market.

STRESS FREE QC ANALYSIS

Designed to assist in the management of daily QC activities, Acusera 24•7 Live Online will help to improve analytical performance, meet regulatory requirements and ensure accurate patient results by helping you to;

1. Monitor and interpret IQC data
2. Compare results to live peer group statistics for rapid and effective troubleshooting

Identify trends, system errors and reagent issues

- Access to interactive charts and comprehensive reports allows immediate detection of QC failures.
- Assess whether performance issues are unique to your laboratory with real-time peer group statistics.

Minimise false rejections

- Apply user-defined QC multi-rules to help reduce false rejections, maintain high error detection and make important decisions on whether to accept/reject results.

Facilitate regulatory requirements

- Help meet ISO 15189:2012 requirements for the review of QC data.

Bridge the gap between IQC and EQA

- Daily monitoring of IQC provides added confidence in test system performance between EQA challenges.

Confidence in assigned target values

- Access to peer group data provides immediate confidence in assigned target values.

Get an independent perspective

- Together with Randox true third party controls, Acusera 24•7 reduces the potential for bias and delivers a true assessment of analytical performance.

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

ISO 15189:2012

SOFTWARE OVERVIEW

Manage multiple sites, instruments, tests and QC levels on one centralised platform for greater confidence in analytical testing.

Peer Data Comparison
Performance Summary Charts
Statistical Analysis Report
Statistical Metrics Report
Peer Group Statistics

Configuration
Multi-lingual
Compatible with other manufacturers' QC
Support for multiple devices
Multiple levels of user access

Data Entry
Manual
Semi-automated upload via EDI
Automated upload of QC data
- (via Acusera 24•7 Connect)

Utilities
Audit trail
Acusera Advisor
Bi-directional activity

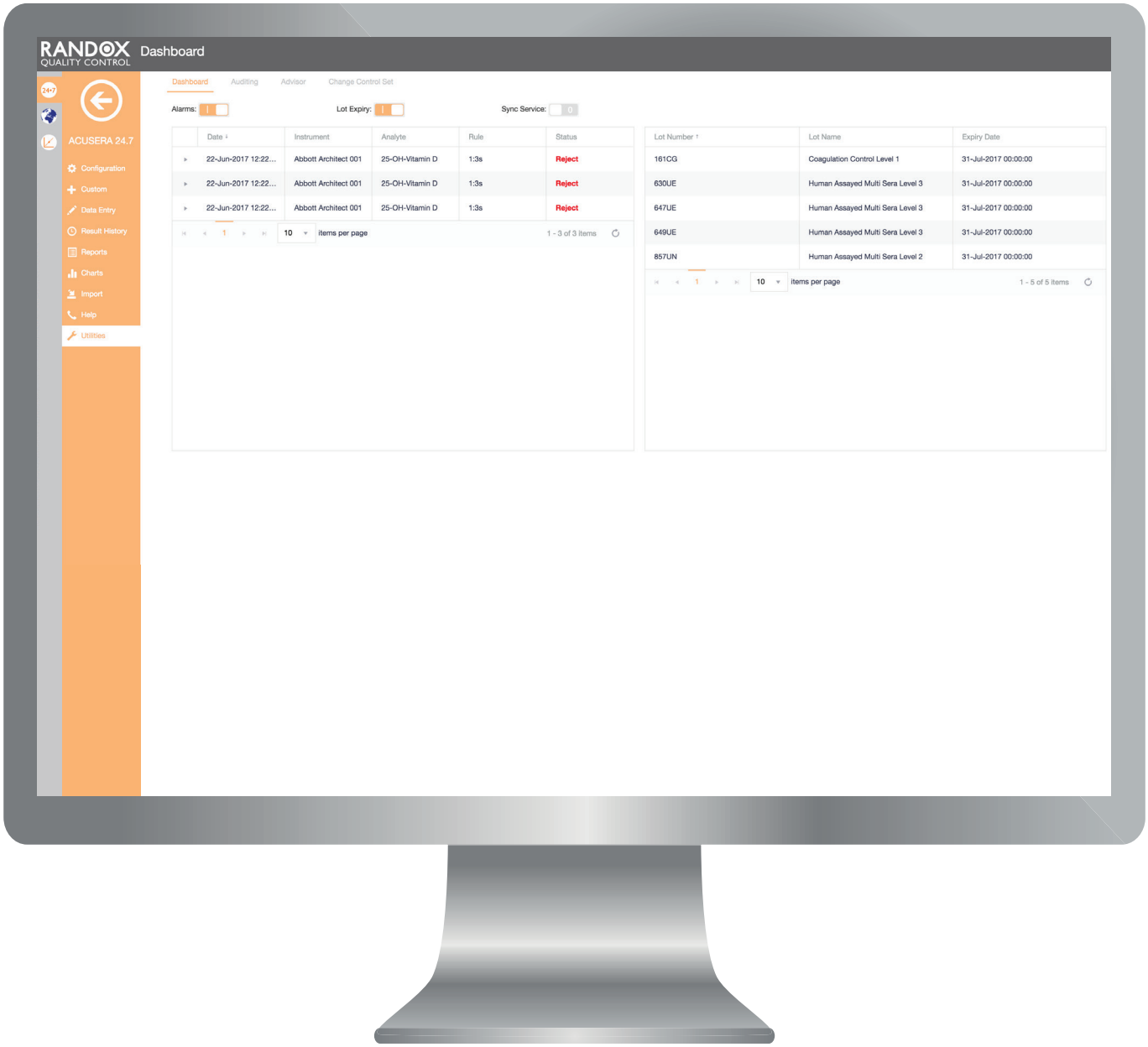
Internal Performance Review
Levey-Jennings Chart
Histogram
Result History
Dashboard
QC Multi-Rules
Exception Report
Performance Limits
(RIQAS, RiliBÄK, CLIA, Biological Variation, User-defined)

Performance Indicators
Bias%
CVI
SDI
Sigma Score
Uncertainty of Measurement
Total Error

With access to peer group data, automatic calculation of QC statistics and easy identification of performance via charts and reports, Acusera 24•7 Live Online is an essential QC tool for laboratories of all sizes.

DASHBOARD

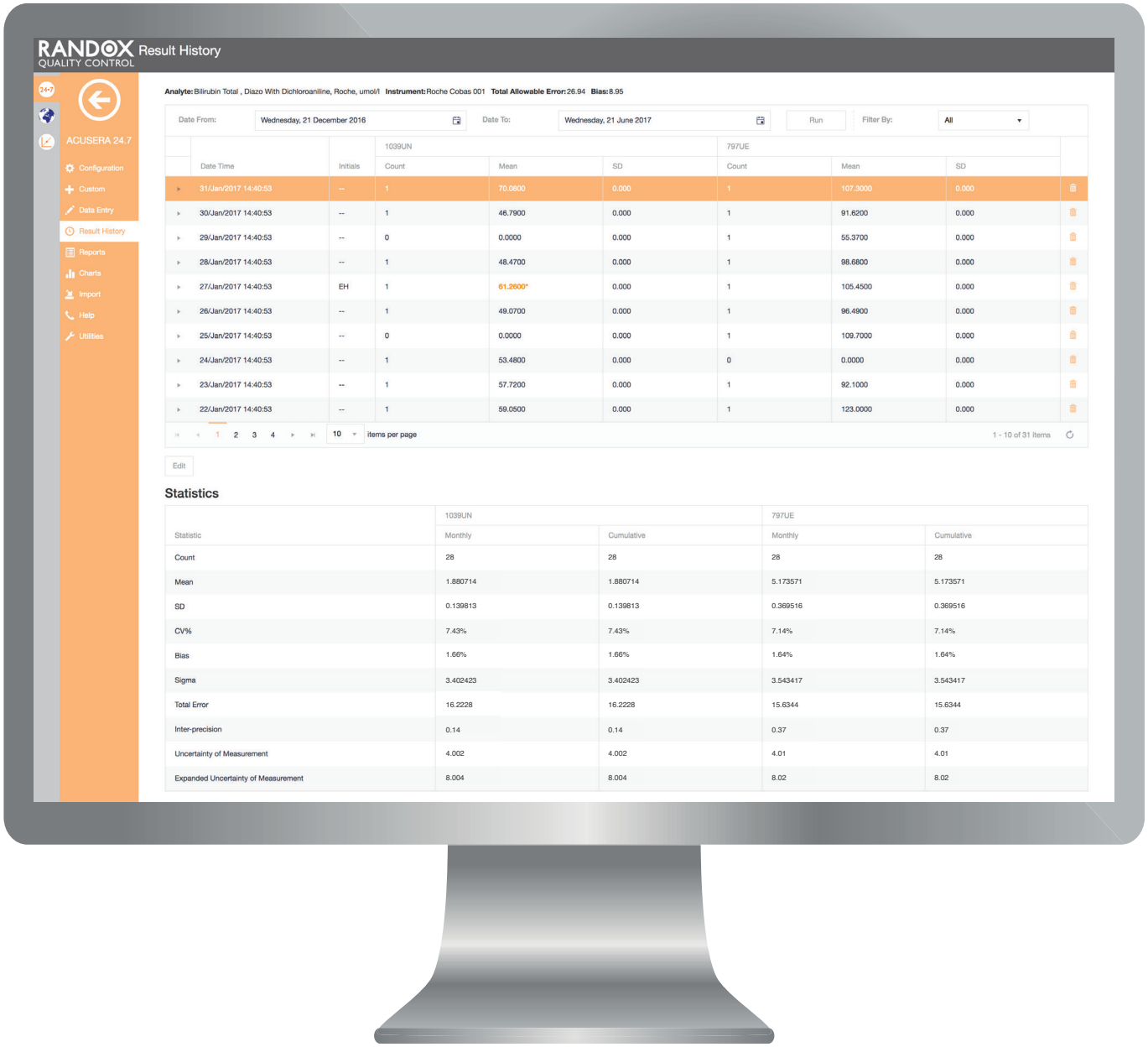
Rapid identification of QC failures



Available to you at no additional cost, the unique Dashboard ensures instant identification of any QC failures and alerted results from the last seven days. Designed to significantly reduce the time spent analysing data, this highly convenient and user-friendly function means corrective actions can be taken immediately with minimum disruption to the laboratory's output. Alerts are also provided when a control lot is reaching expiry, reducing the risk of using expired material. If using EDI or Connect to upload QC results a message will also be displayed advising the number of results that have been inserted successfully.

RESULT HISTORY

Provides a visual overview of QC result history

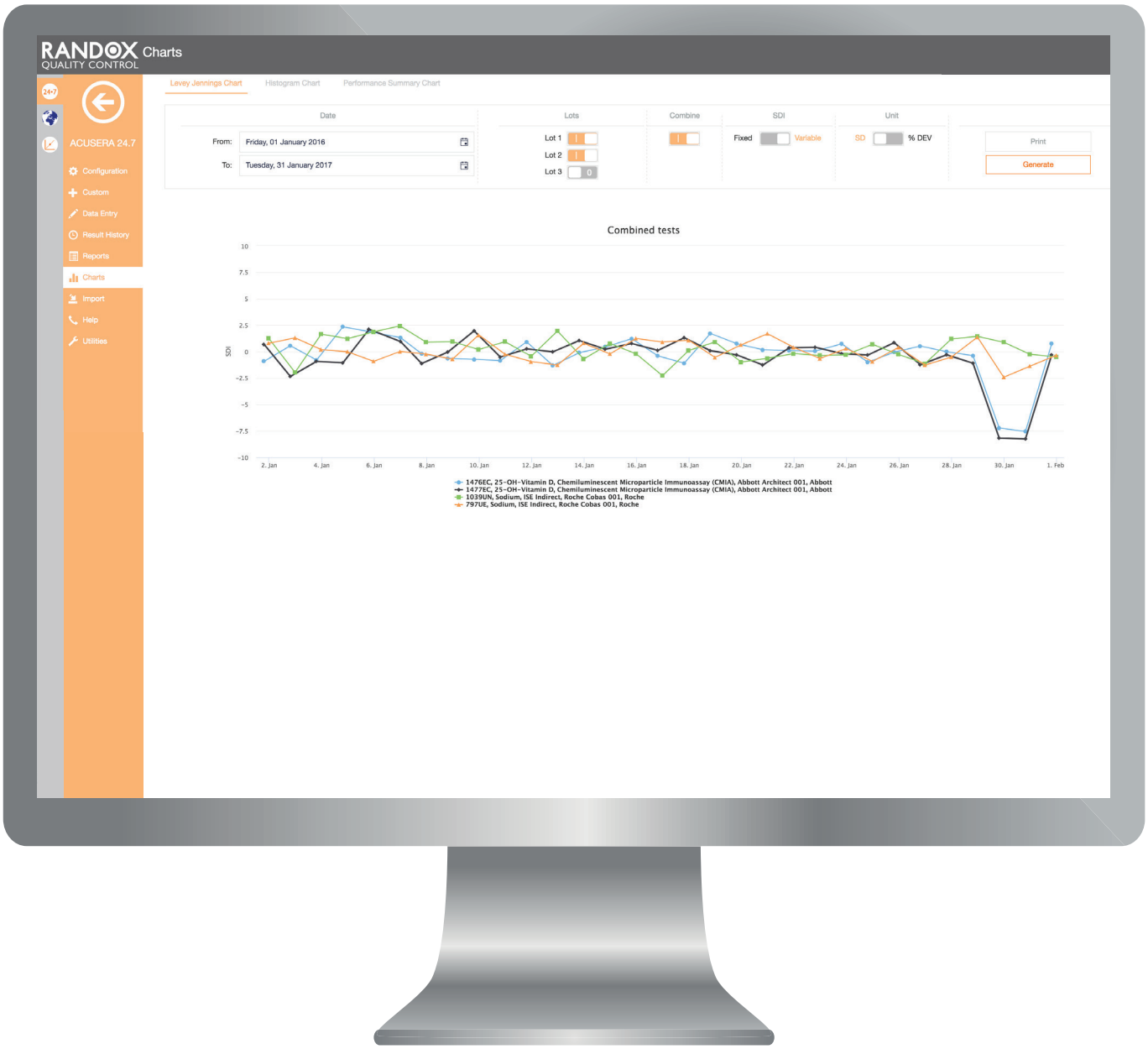


The result history view displays all QC results entered for a particular test. Results are conveniently colour coded red for reject and orange for alert, ensuring quick and easy performance assessment. Monthly and Cumulative statistics including the Mean, SD, %CV, Bias%, Total Error, Sigma score, UM and Expanded UM are automatically calculated and displayed for each lot of control. Results may be filtered to display rule violations or rejected/alerted results for a particular instrument or lot of control.

The ability to add comments and manually accept/reject results directly from the result history view speeds up the review process.

INTERACTIVE LEVEY-JENNINGS CHARTS

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

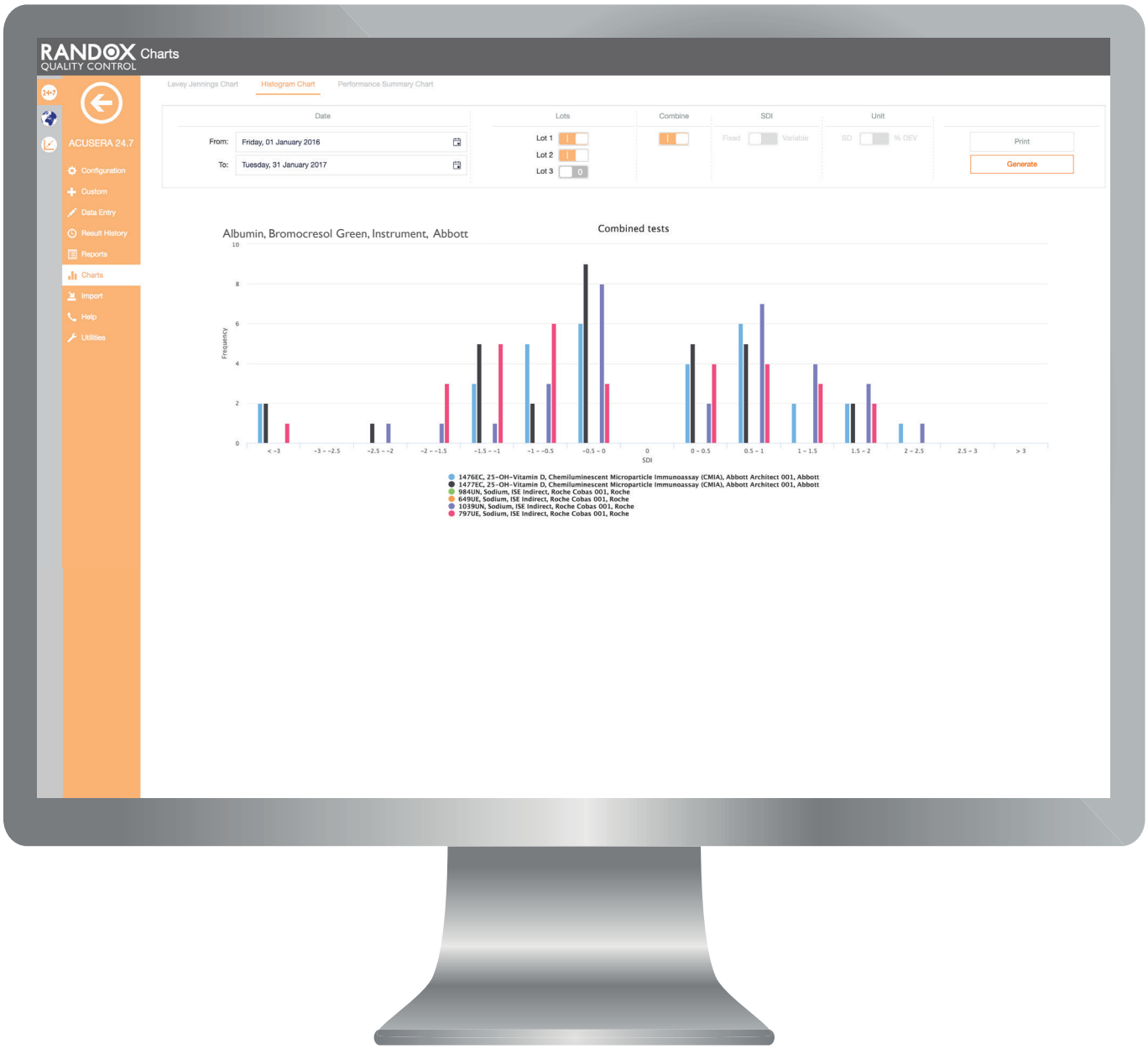


Levey-Jennings charts are easily generated, providing an instant, visual indication of test system performance over time. The ability to conveniently combine multiple instruments, analytes or QC lots on a single chart allows comparative performance assessment and immediate visualisation of any ongoing or emerging trends. Customisation in this way will improve troubleshooting capabilities, enabling you to quickly identify whether an issue is unique to a particular test or instrument.

The user-friendly interface and interactive nature of the chart allows you to view data for a specific date range, zoom in on a specific data point and record events including calibration and reagent lot changes for enhanced review of trends.

INTERACTIVE HISTOGRAM CHARTS

Rapidly identify test system bias

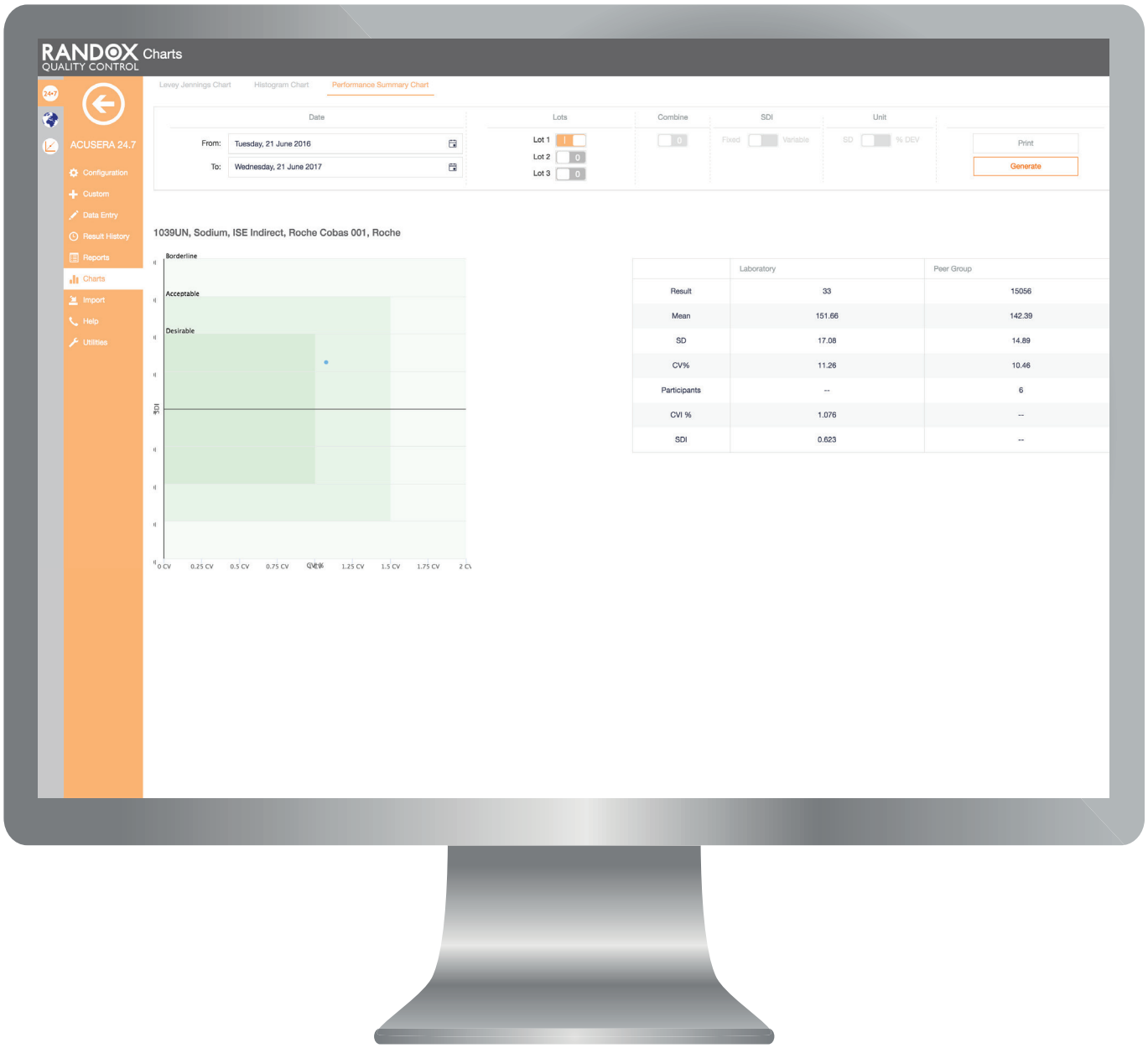


Generated at the touch of a button the Histogram allows rapid identification of any test system bias for a given time period. Designed to be completely interactive, multiple instruments, analytes and QC lots can be added to a single chart delivering comparative performance assessment, easy identification of trends and faster troubleshooting capabilities.

Using the legend, data can be added or removed from the chart as required. There is also an option to print charts directly from the software.

PERFORMANCE SUMMARY CHARTS

Provides a visual assessment of accuracy and precision in relation to chosen peer group

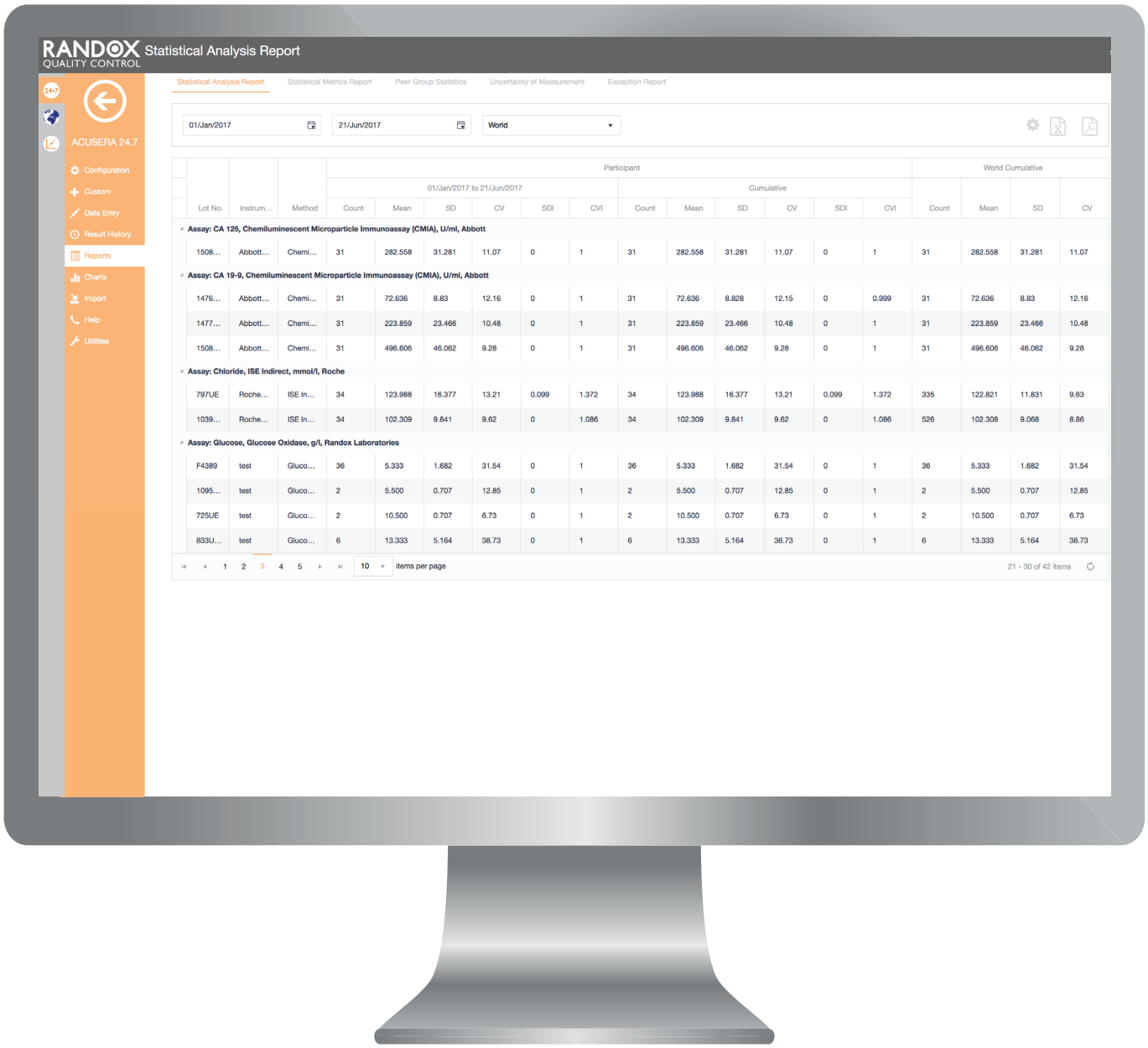


The Performance Summary Chart provides a graphical representation of individual laboratory performance, compared to your chosen peer group. Data is displayed in a colour coded, easy to interpret chart allowing for fast and efficient performance assessment.

Performance Summary Charts can be customised to conveniently display data for multiple analytes, allowing visual identification of trends. Several flexible review options are available; depending on individual preferences, data can be based on monthly/cumulative statistics or world/affiliate group statistics.

STATISTICAL ANALYSIS REPORT

Compare monthly and cumulative statistics to worldwide peer group data

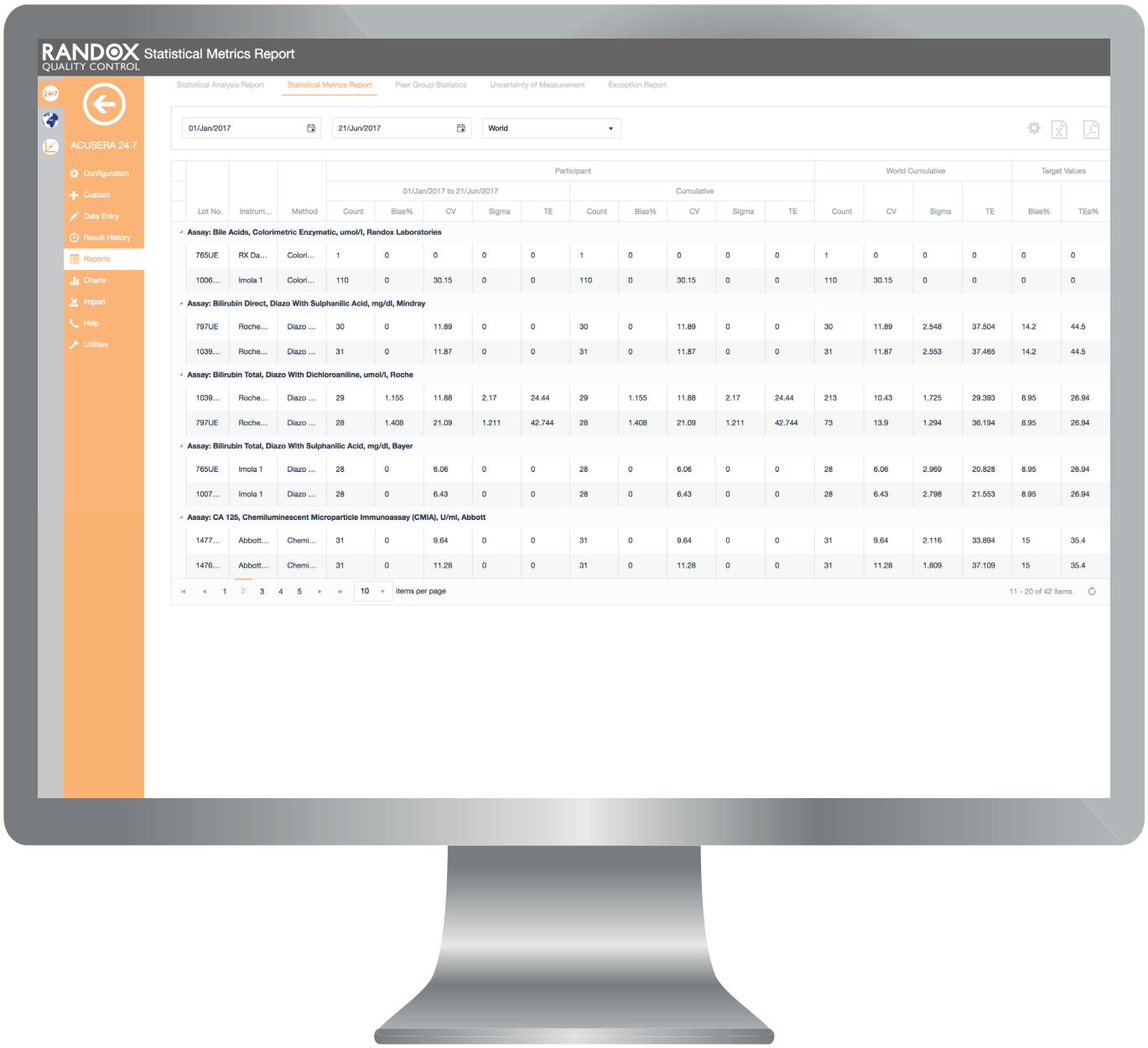


The Statistical Analysis Report provides a complete overview of laboratory performance for a specified date range. Encompassing many vital performance indicators including the Mean, SD, CV, SDI and CVI, it can be used to compare both monthly and cumulative data for each individual test to your chosen peer group.

Reports are instantly generated for a user-defined date range and may be exported as an excel file or PDF.

STATISTICAL METRICS REPORT

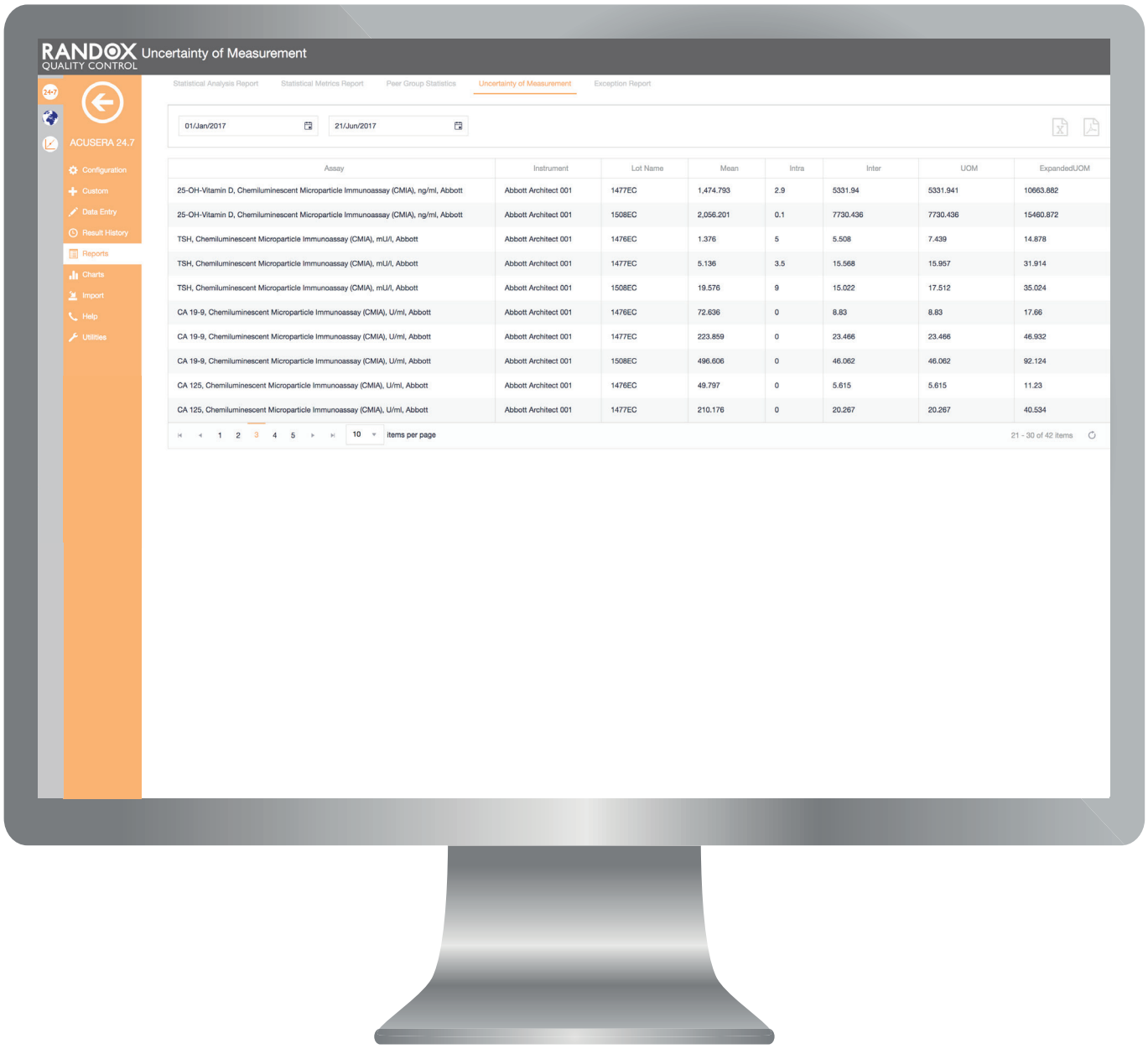
Displays several performance metrics on one report



Displays statistical metrics including Bias%, Sigma and Total Error (TE) for each test alongside those for your chosen peer group. The Bias% provides an indication of your laboratory's performance compared to the peer group mean, while TE gives an indication of the overall error within a test system, taking into account both imprecision and inaccuracy. The availability of a Sigma Score provides a measure of how much your data varies from the TEa% and may be used to design an appropriate QC strategy.

UNCERTAINTY OF MEASUREMENT REPORT

Automatic Uncertainty of Measurement (UM) calculation

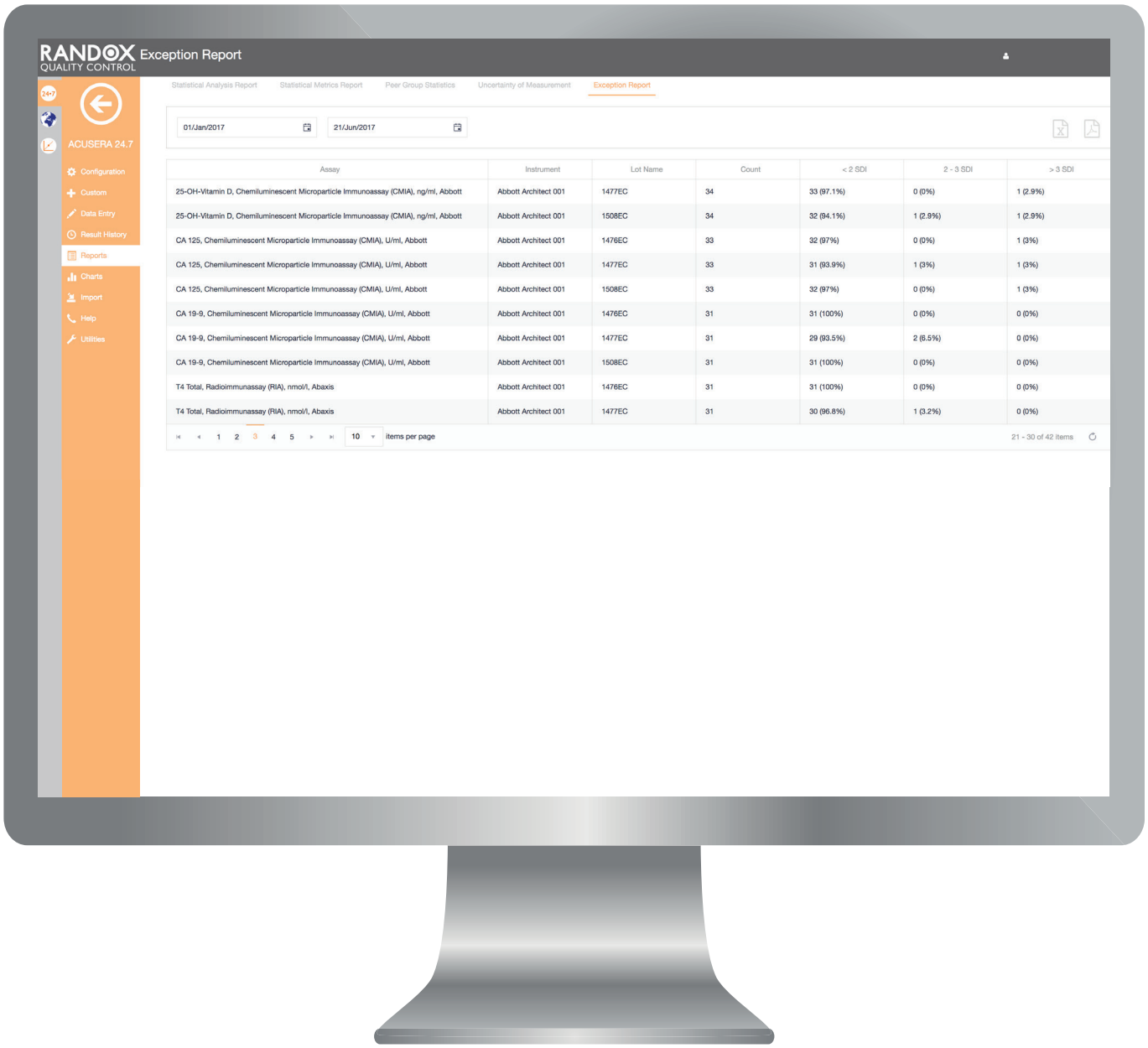


The unique Uncertainty of Measurement report displays the UM of all QC tests currently in use, helping you to meet ISO 15189:2012 requirements. To calculate UM, simply enter the SD or Standard Error of the Mean (SEM) of the intra assay precision for each test and level of control. Based on performance history, the software will then automatically calculate the SD of the inter assay precision.

Reports are instantly generated for a user-defined date range and may be exported as an excel file or PDF.

EXCEPTION REPORT

View assays which show a higher error rate

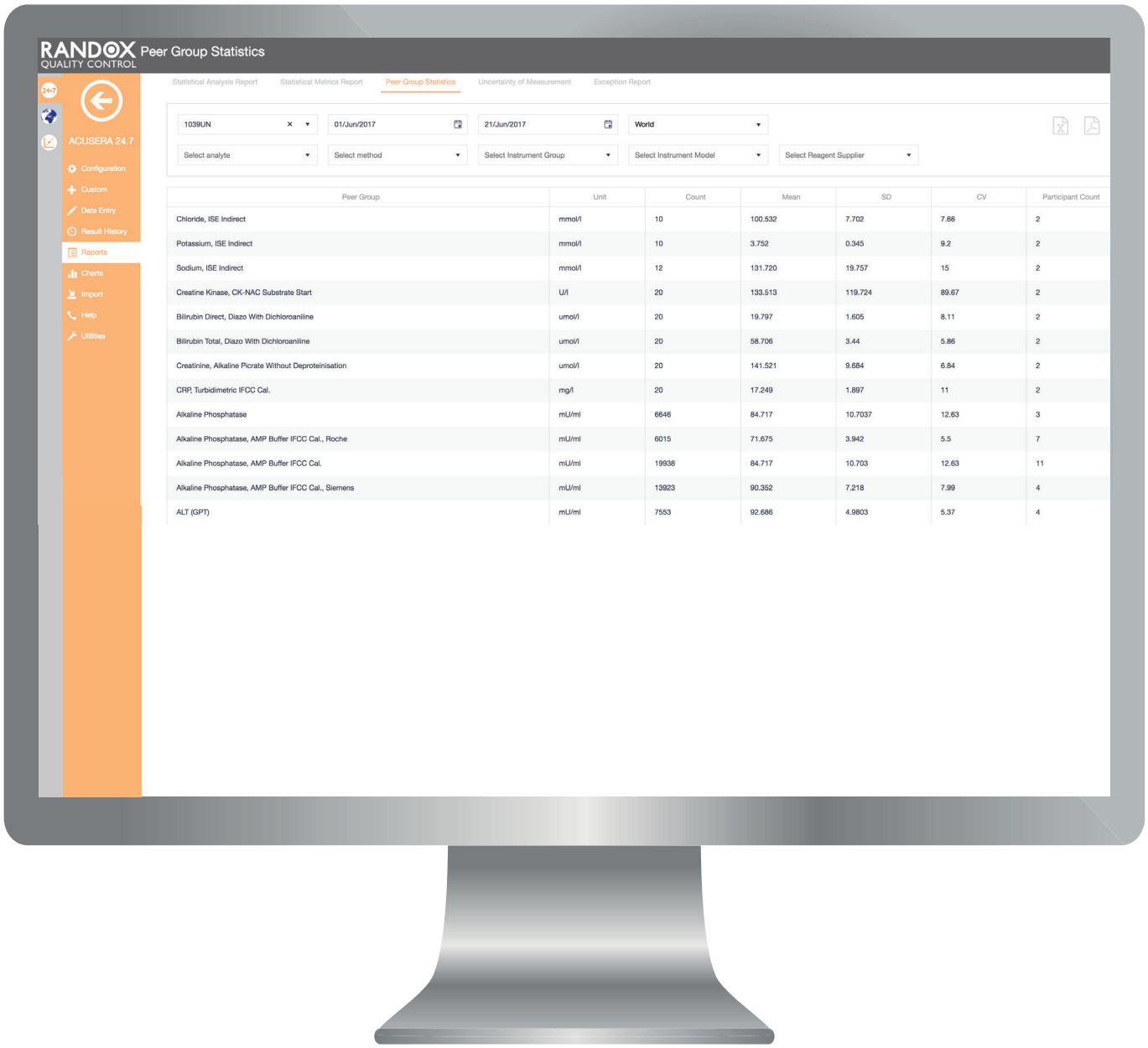


Designed to quickly and easily identify assays with a high percentage of errors, the new exception report provides an on screen summary of the number of QC results for each individual assay and control lot that fall within the following categories <2SD, 2-3SD and >3SD.

Reports are instantly generated for a user-defined date range and may be exported as an excel file or PDF.

PEER GROUP STATISTICS

Access true real-time peer group statistics



The Peer Group Statistics report provides access to peer data for all lots of Quality Control. Data is instantly updated in real-time*, delivering unique access to the most up-to-date information available.

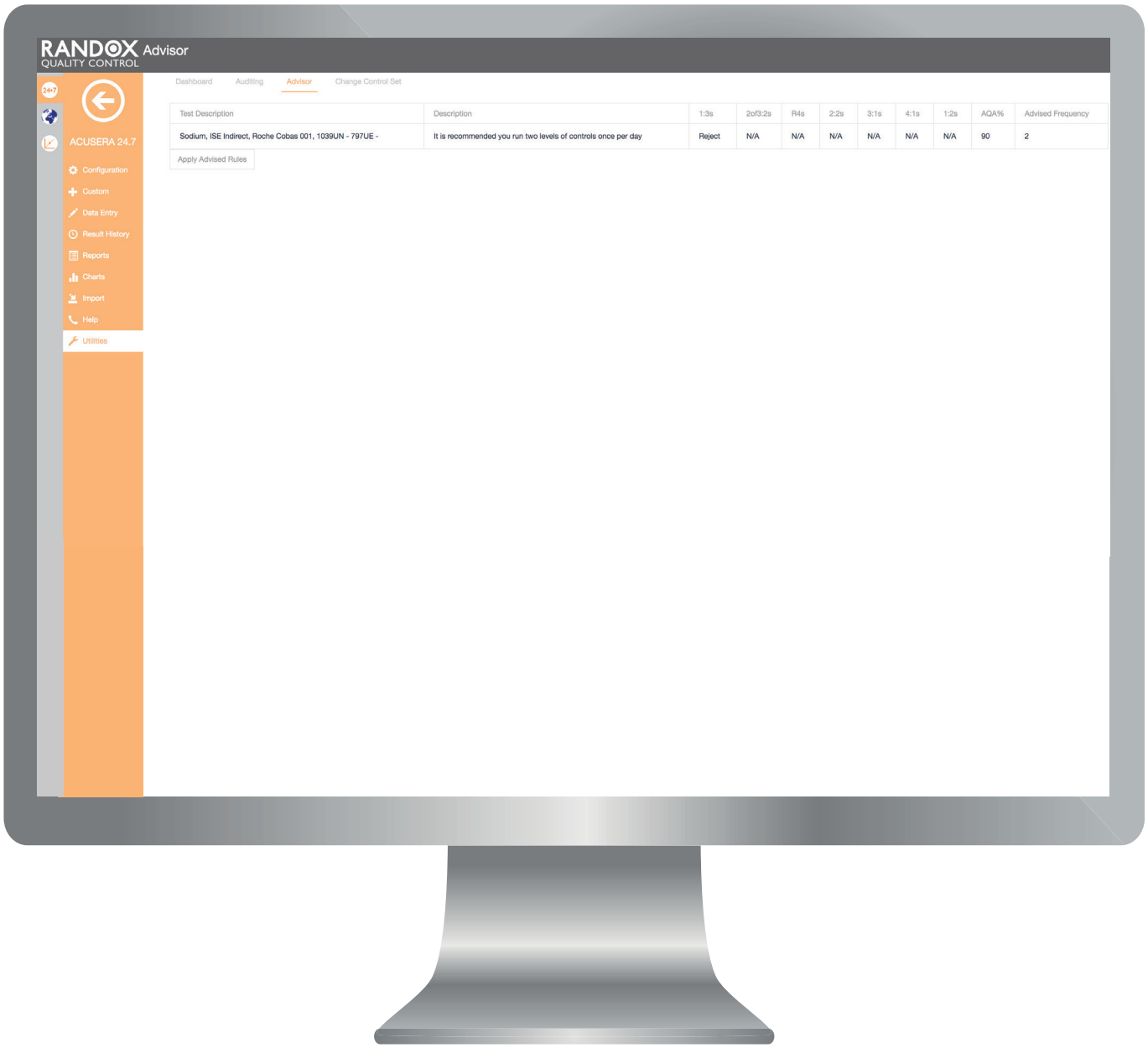
Analysis of peer data in this way will help you to determine if an out of control result is an instrument problem or a widespread issue. You may even be able to identify issues before they arise in your lab.

Data may be filtered by lot number, date range, analyte, method, instrument and reagent supplier. The final report can be exported to excel or PDF displaying the Mean, SD, CV and number of participants.

*** T&Cs apply**

ACUSERA ADVISOR

Automatically recommends QC multi-rules and optimal QC frequency



Acusera Advisor* is an optional tool designed to help you select the 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 upon 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.

Recommendations can be made once you have entered a minimum of 20 results for at least two levels of control and set performance limits.

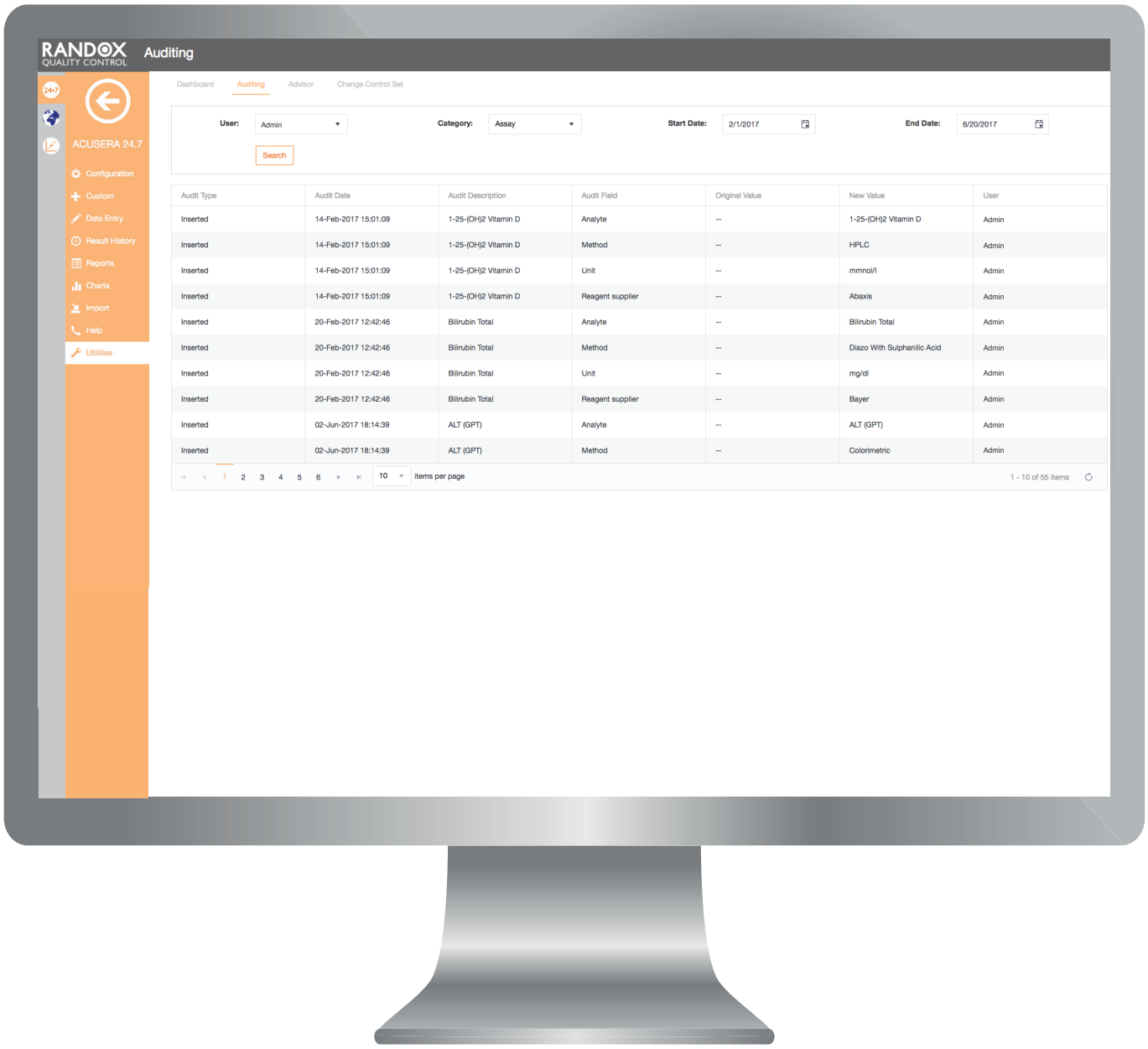
Recommendations are based upon normalised OPSpec charts. Once performance limits have been defined, the software will determine the CV% and Bias%. These are then used to calculate the normalised operating point. A normalised OPSpec chart is then used to select the appropriate QC strategy.

A report can be easily generated displaying 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.

*Not available in USA

AUDIT TRAIL REPORT

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.

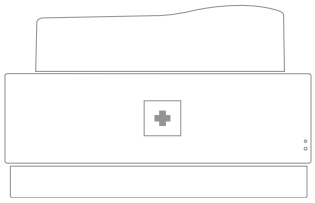
Regulatory bodies frequently require laboratories to document the review of their QC data. Actions, comments and audit trails, when used in combination, provide an effective way of documenting the review process whilst providing a secure method of storing data.

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.

DATA ENTRY OPTIONS

Manual result entry

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

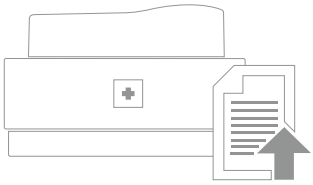


1. Analyser generates QC result.

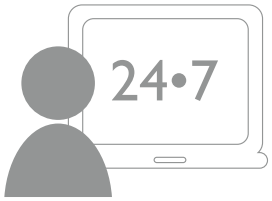
2. QC result is manually entered by the user into the Acusera 24•7 Live Online software.

Semi-automated result entry via EDI

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



1. An export file containing the QC result and associated information is generated by the analyser or LIS/LIMS system.



2. The user imports the EDI file into the Acusera 24•7 Live Online software.

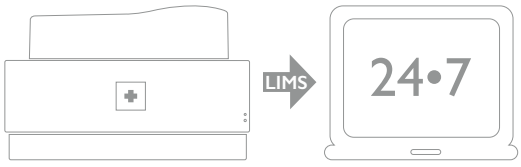
Note: First time users must first create a new configuration for the EDI file and carry out EDI mapping.

Fully automated import of QC data direct from your LIMS

Automatically capture data directly from your LIMS with Acusera 24•7 Connect and import into Acusera 24•7 Live Online without the need to manually import files.

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

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.



1. Acusera 24•7 Connect securely collects and processes QC data directly from the LIS/LIMS for import into Acusera 24•7 Live Online.

Software options

Description	Cat. No.
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**

[+]Pending site survey completion [*]Not available in USA

FAQs

How secure is Acusera 24•7 Live Online?

To authenticate users, a number of security measures are used, including: participant number, username and a password combination (for individual role-based accounts). Password complexity standards are enforced on user account setup. CAPTCHA is enforced after several failed login attempts to prevent or guard against automated attacks. HTTPS and X509 certificate authentication is in place meeting industry security 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.

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 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 laboratory administrator. If an administrator or group co-ordinator forgets their username or password, there is a reset password link available for you to reset your details.

How many user levels are available?

There are five user levels available: administrator, manager, user, group co-ordinator & technical support. Co-ordinators will have access to all group data but will not be able to edit, delete or add any data. User access may be customised per user to ensure access to only the required functionality.

How is Acusera 24•7 Live Online upgraded?

Any new Acusera 24•7 releases will be available online automatically. Additional installation of software is not required.

How do I register for Acusera 24•7 Live Online?

New Acusera 24•7 participants can register their details on the Randox QC Platform, after which login information will be sent to the laboratory administrator. The laboratory administrator will then set up all other users with their access level, username and password.

GLOSSARY

Bias%

Bias%

In Acusera 24•7, Bias is the difference between the Peer Group Mean and the observed value. Bias is generally calculated as a percentage and can either be positive or negative (above or below the target value).

Bias is calculated using the below formula:

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

CVI

Coefficient of Variation Index (CVI)

The CVI compares the precision from your laboratory to the precision of other laboratories in your chosen peer group. The Coefficient of Variance (CV) from your lab is divided by the CV from the Peer Group to give the CVI for your laboratory.

The CVI is calculated using the below formula:

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

SDI

Standard Deviation Index (SDI)

SDI provides an indication of how well your mean compares to the Peer Group Mean for a given assay and control lot. An SDI of 0 means that there is no difference between the laboratory mean and the Peer Group Mean.

SDI is calculated using the below formula:

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

TE

Total Error (TE)

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

TE is calculated using the below formula:

$$\text{TE} = \%\text{Bias} + (1.96 * \%\text{CV})$$

σ

Sigma

Sigma looks at the number of standard deviations (SD) or 'sigmas' that fit within the quality specifications of the process. In the laboratory, the quality specifications relate to the Total Allowable Error (TEa). The higher the number of standard deviations that fit between these limits, the higher the sigma score and the more robust the process or method is. As sources of error or variation are removed from a process the SD becomes smaller and therefore the number of deviations that can fit between the allowable limits is greater, ultimately resulting in a higher sigma score.

A Sigma score can be calculated for each individual assay. Sigma scores of < 3 are undesirable and indicate poor quality QC performance, while a sigma score of 6 or more indicates a world-class quality QC performance.

Sigma is calculated using the below formula:

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

UM

Uncertainty of Measurement (UM)

With every result generated in the laboratory there will always be a degree of error. Uncertainty of Measurement (UM) looks at the doubt that exists for the result of any measurement. In order to calculate the uncertainty, we need to look at the intra-assay precision and inter-assay precision. Intra-assay precision refers to precision within a run (20 replicates or more of the same sample at the same time). Inter-assay precision refers to precision over a number of different runs (20 or more replicates of the same sample over several days e.g. one replicate every day for 20 days). The Standard Deviation (SD) is then calculated for the intra and inter-assay precision.

Uncertainty is calculated using the below formula:

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

$$U = 2 \times u$$

Where;

A = SD of the Intra-assay precision

B = SD of the Inter-assay precision

u = Standard Uncertainty

U = Expanded Uncertainty

RELATED PRODUCTS

ACUSERA True third party quality controls

As a world leading manufacturer of multi-analyte true third party controls, thousands of laboratories rely on Randox to accurately assess test system performance and ultimately empower them with the confidence required to release patient test results. With more than 390 analytes available, the number of individual controls required to cover your test menu is significantly reduced while simultaneously reducing costs, time and storage space. A choice of formats is available, including liquid or lyophilised, which ensures flexibility and suitability for laboratories of all sizes and budgets. Helping you to meet ISO 15189:2012 requirements:

- Designed to react to the test system in the same manner as a patient sample, helping to reduce inconvenient shifts in QC results when reagent batch is changed and ultimately providing a true indication of laboratory performance.
- The presence of analytes at key decision levels ensures accurate instrument performance and eliminates the need for additional low/high controls at extra expense.
- Manufactured independently from any instrument, the Acusera range delivers unbiased performance assessment with any instrument or method, while eliminating the need for multiple instrument specific controls.

Product Portfolio

Antioxidants | Blood Gas | Cardiac Markers | Routine Chemistry | Coagulation | Haematology | Diabetes Immunoassay | Immunology | Lipids | POCT | Therapeutic Drugs | Toxicology | Urine Chemistry

Uniquely combining more than 100 analytes conveniently in a single control, laboratories can significantly reduce costs and consolidate without compromising on quality. As true third party controls, unbiased performance assessment with any instrument or method is guaranteed.

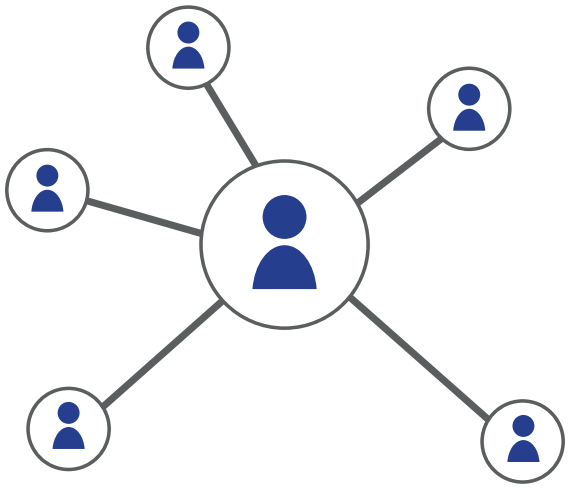
RIQAS Randox International Quality Assessment Scheme

Boasting over 45,000 participants and more than 360 parameters across 32 comprehensive & flexible EQA programmes, RIQAS is the largest international EQA scheme. Designed to cover all areas of clinical testing, each of our multi-analyte programmes is designed to reduce the number of individual programmes required saving precious laboratory time and money. In addition each programme benefits from a wide range of concentrations, frequent reporting, rapid feedback and informative yet user-friendly reports.

- Programmes accredited to ISO/IEC 17043 helping laboratories to meet ISO 15189:2012 requirements.
- Simple one page per parameter report format enables at-a-glance performance assessment saving time spent analysing results.
- Rapid report turnaround within 72 hours from the submission deadline ensures any corrective actions can be taken quickly, minimising the number of sample repeats required.
- Laboratories can register up to 5 instruments per programme at no extra cost and receive a complimentary multi-instrument report for comparative performance assessment.

Programme Offering

Ammonia/Ethanol | Anti-TSH Receptor | Blood Gas | BNP | Cardiac | Cerebrospinal Fluid (CSF) | Clinical Chemistry Coagulation | CYFRA 21-1 | ESR | Glycated Haemoglobin (HbA1c) | Haematology | Human Urine Immunoassay | Immunoassay Speciality 1 | Immunoassay Speciality 2 | Immunosuppressant | Lipid | Liquid Cardiac Maternal Screening | Serology (EBV) | Serology (HIV/Hepatitis) | Serology (Syphilis) | Serology (ToRCH) Specific Proteins | Sweat Testing | TDMs | Trace Elements in Blood | Trace Elements in Serum Trace Elements in Urine | Urinalysis | Urine Toxicology



With over 45,000 lab participants, peer group numbers are maximised ensuring availability of data for a wide range of instruments and methods.

RANDOX - A GLOBAL DIAGNOSTIC SOLUTIONS PROVIDER

RX series of Clinical Analysers

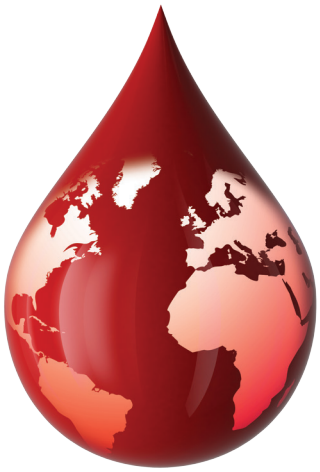
The RX series combines robust hardware and intuitive software with the world leading RX series test menu, including routine chemistries, specific proteins, lipids, therapeutic drugs, drugs of abuse, antioxidants and diabetes testing. Renowned for quality and reliability, the RX series boasts one of the most extensive dedicated clinical chemistry test menus on the market guaranteeing real cost savings through consolidation of routine and specialised tests onto a single platform. This extensive dedicated test menu of high quality reagents guarantees excellence in patient care reducing costly test re-runs or misdiagnosis and offers unrivalled precision and accuracy for results you can trust.

Biochemistry Reagents

Randox offers an extensive range of diagnostic reagents, giving biochemistry laboratories the opportunity to advance their routine and niche testing. The Randox reagents range goes beyond routine chemistries. At Randox we re-invest significantly in research and development to ensure we meet the ever changing needs of the laboratory. As a result, the esoteric reagents range from Randox is extensive and includes sLDL, Lipoprotein(a), H-FABP, Cystatin C, TxBCardio, Adiponectin, Bile Acids, Copper, D-3- Hydroxybutyrate, G-6-PDH, Non-Esterified Fatty Acids, Total Antioxidant Status and Zinc. Randox Reagents provide a number of benefits for the laboratory: Cost savings through excellent stability, automated methods and standards supplied with some kits; confidence in results with high performance methods, minimal interferences and wide measuring ranges; convenience and choice with applications for over 100 biochemistry analysers; liquid ready-to-use reagents, a wide range of kit sizes and complementary controls and calibrators

Biochip Array Technology

Biochip Array Technology (BAT) is an innovative assay technology for multi-analyte screening of biological samples in a rapid, accurate and easy to use format. BAT offers highly specific tests, coupled to highly sensitive chemiluminescent detection, providing quantitative results in easy to interpret reports. Randox BAT assays offer diagnostic, prognostic and predictive solutions across a variety of disease areas including sexually transmitted infection, cardiovascular disease (CVD), familial hypercholesterolemia (FH), colorectal cancer and respiratory infection.



Randox has been supplying laboratories worldwide with revolutionary diagnostic solutions for over 30 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.

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