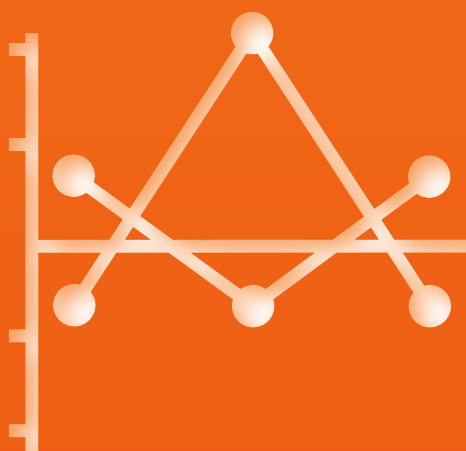# RANDOX

INTERLABORATORY DATA MANAGEMENT
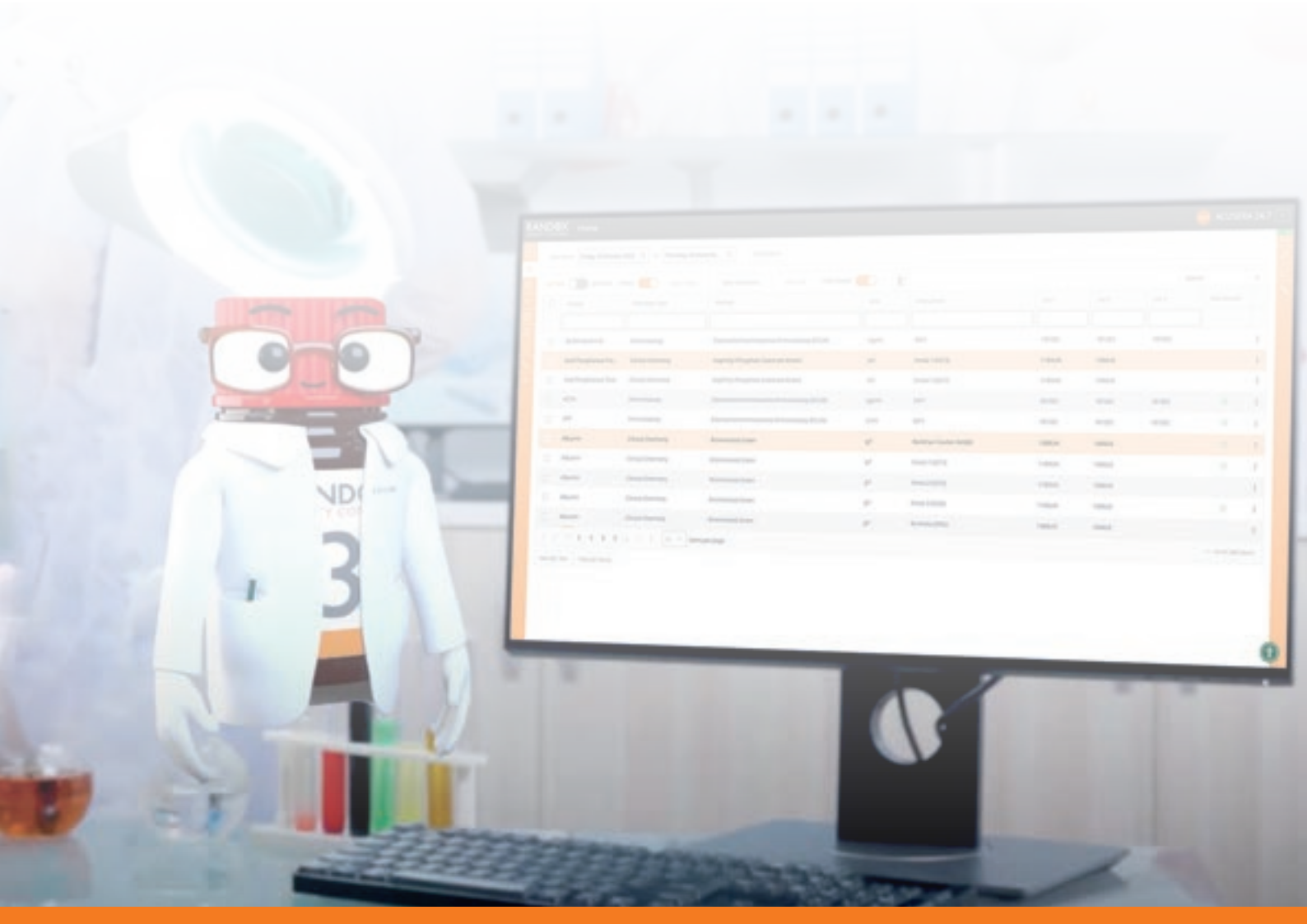
RANDOX
QUALITY CONTROL

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 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.

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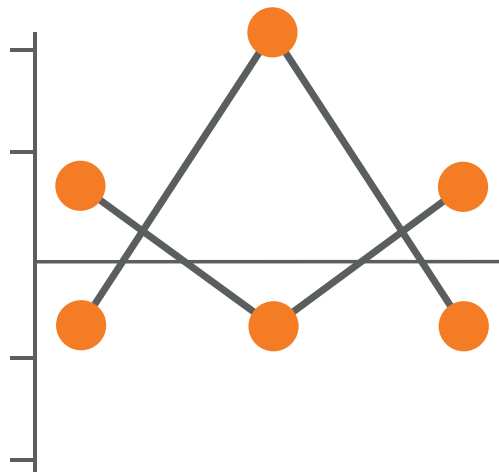
Technical support
- Expert technical support is available from our team of highly trained specialists.
- Remote access enables immediate troubleshooting without the need for on-site assistance.

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

Compatible for use with the Acusera range of third party controls, the Acusera 24•7 software provides a tool to track QC results and manage daily QC activities from all laboratory analysers on one centralised platform. 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 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 & 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 15189:2022 requirements for the review of QC data and calculation of Uncertainty of Measurement (UM).

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 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.

ISO 15189:2022

SOFTWARE OVERVIEW

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

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

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

Peer Data Comparison
- Performance Summary Charts
- Statistical Reports
- Peer Group Statistics

Utilities
- Acusera Advisor
- Audit Report *(by request)*

Internal Performance Review
- Levey-Jennings Chart
- Histogram
- Result History
- Dashboard
- Data Review
- QC Multi-Rules
- Exception Report
- Uncertainty of Measurement 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 interactive charts and reports, Acusera 24•7 is an essential QC tool for laboratories of all sizes.


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

HOMESCREEN & PREVIEW

Recall assay and instrument configurations directly from homescreen
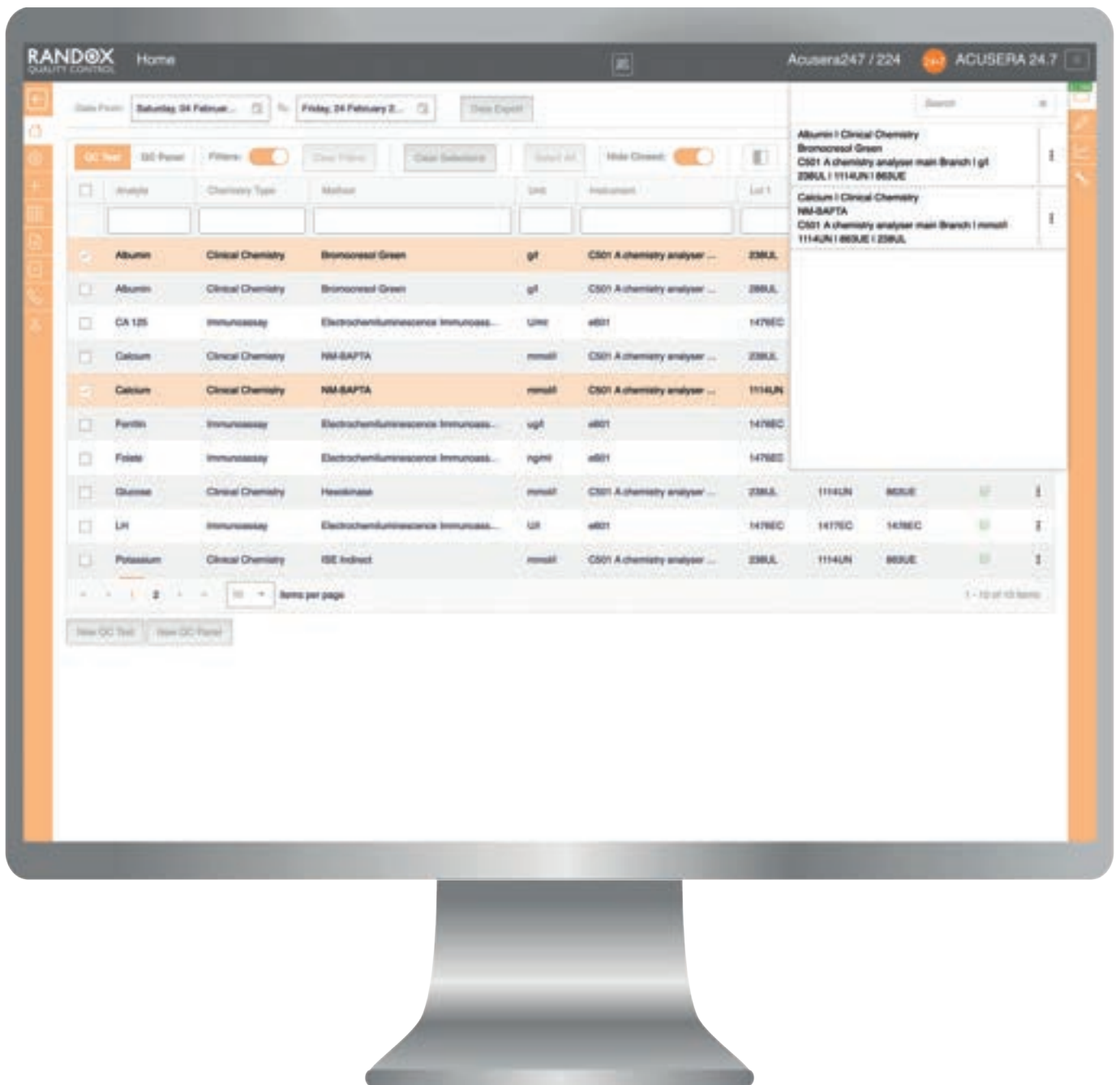
Bringing together the creation of QC tests, QC panels, opening/closing/hiding of QC tests and the ability to export data for a selection of QC tests all within the one base area. No need for navigating to multiple areas within the application to perform these actions.

Available via Homescreen:
Filter Functionality | Configuration | Data Entry
Charts | Utilities | QC Test Selection

Each of the following features can be accessed without having to navigate to each individual screen from the side menus: QC Test Configuration | Instrument Configuration | Assay Configuration | Result History

Using the preview feature, users can easily navigate into the Result Entry | Charts | Data Entry
QC Test Configuration | Instrument Configuration
Assay Configuration for single test from any area in the application.

DAILY DATA REVIEW REPORT

Review all QC results within a 7-day window
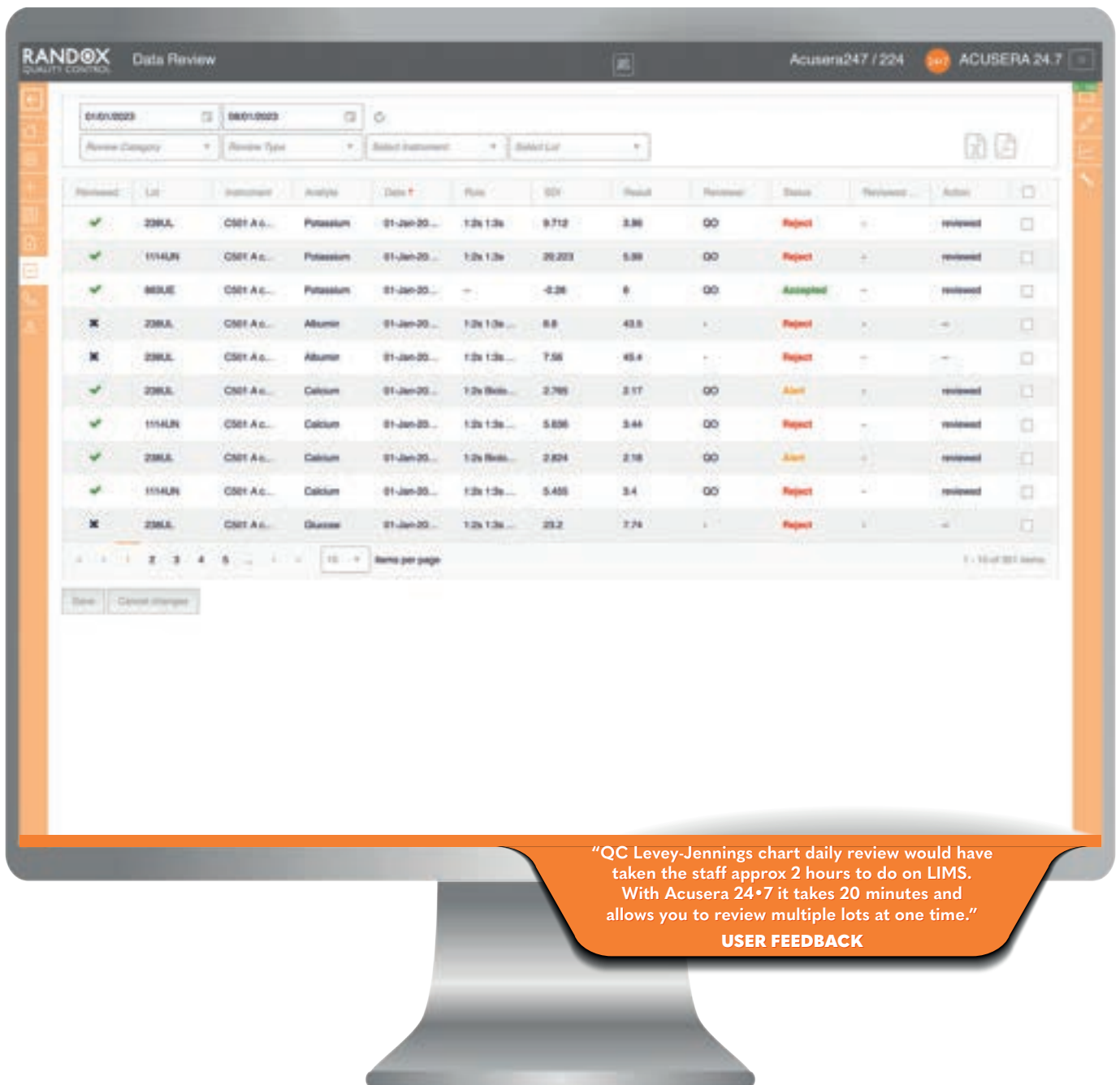
"QC Levey-Jennings chart daily review would have taken the staff approx 2 hours to do on LIMS. With Acusera 24•7 it takes 20 minutes and allows you to review multiple lots at one time."
**USER FEEDBACK**

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. By double clicking on a QC result within the Data Review Report, it is possible to quickly navigate to the Result History and review the QC result further before committing to reviewing the QC result within the Data Review Report.

To speed up the process of reviewing many QC results at once, it is now possible to add an action comment to many QC results in bulk. Remember, that if any QC result has been violated within the last 7 days, it will also display on your Dashboard. However, reviewing your results within the Data Review Report will remove the violation from your Dashboard therefore reducing the number of violations reported on the Dashboard. Once a QC result is reviewed it will record the initials of the user that performed the review.

DASHBOARD

## Rapid identification of QC failures
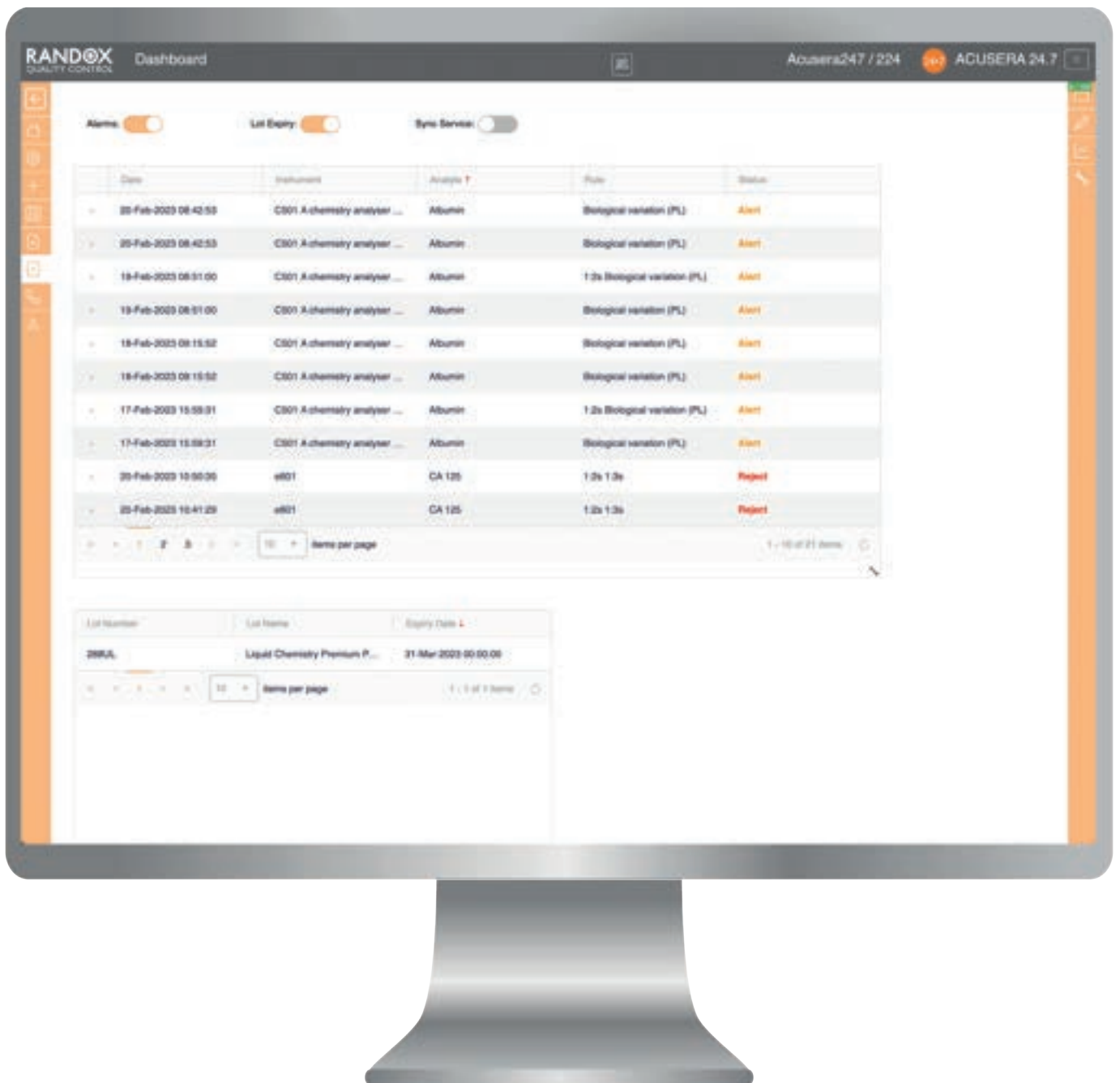
Available to you at no additional cost, the unique Dashboard ensures instant identification of any QC failures and alerted results over the last seven days. Designed to significantly reduce the time spent analysing data, this highly convenient and user-friendly function means corrective actions can be 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 be displayed advising the number of results that have been inserted successfully.

RESULT HISTORY

Provides a visual overview of QC result history
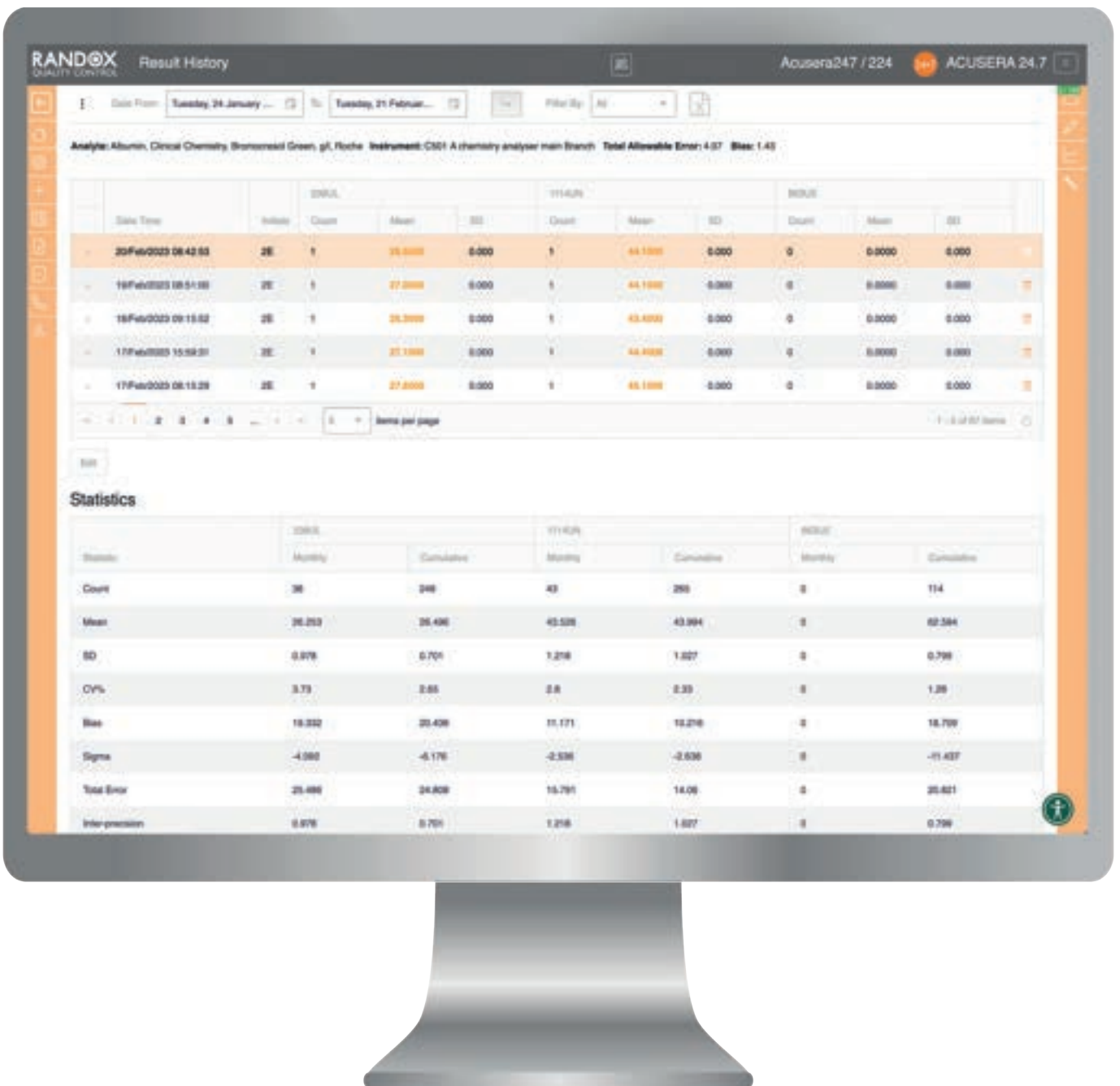
The result history view displays all QC results entered for a particular test. Results are conveniently colour coded red for reject and orange for alert, ensuring quick and easy performance assessment. Monthly and Cumulative statistics including the Mean, SD, %CV, Bias%, Total Error, Sigma score, UM 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.

Group co-ordinators can visualise results from each individual lab within their affiliated group, allowing for in-depth performance analysis from a remote location.

INTERACTIVE LEVEY-JENNINGS CHARTS

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

"Every 2 months we would have had to take screen shots 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."
**USER FEEDBACK**

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, QC lots and labs on a single chart allows for 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 instrument service or maintenance for enhanced review of trends. Group co-ordinators can also easily compare performance between laboratories within their affiliated group for quick identification of performance issues. Using the legend, data can be added or removed for side by side comparison.

INTERACTIVE HISTOGRAM CHARTS

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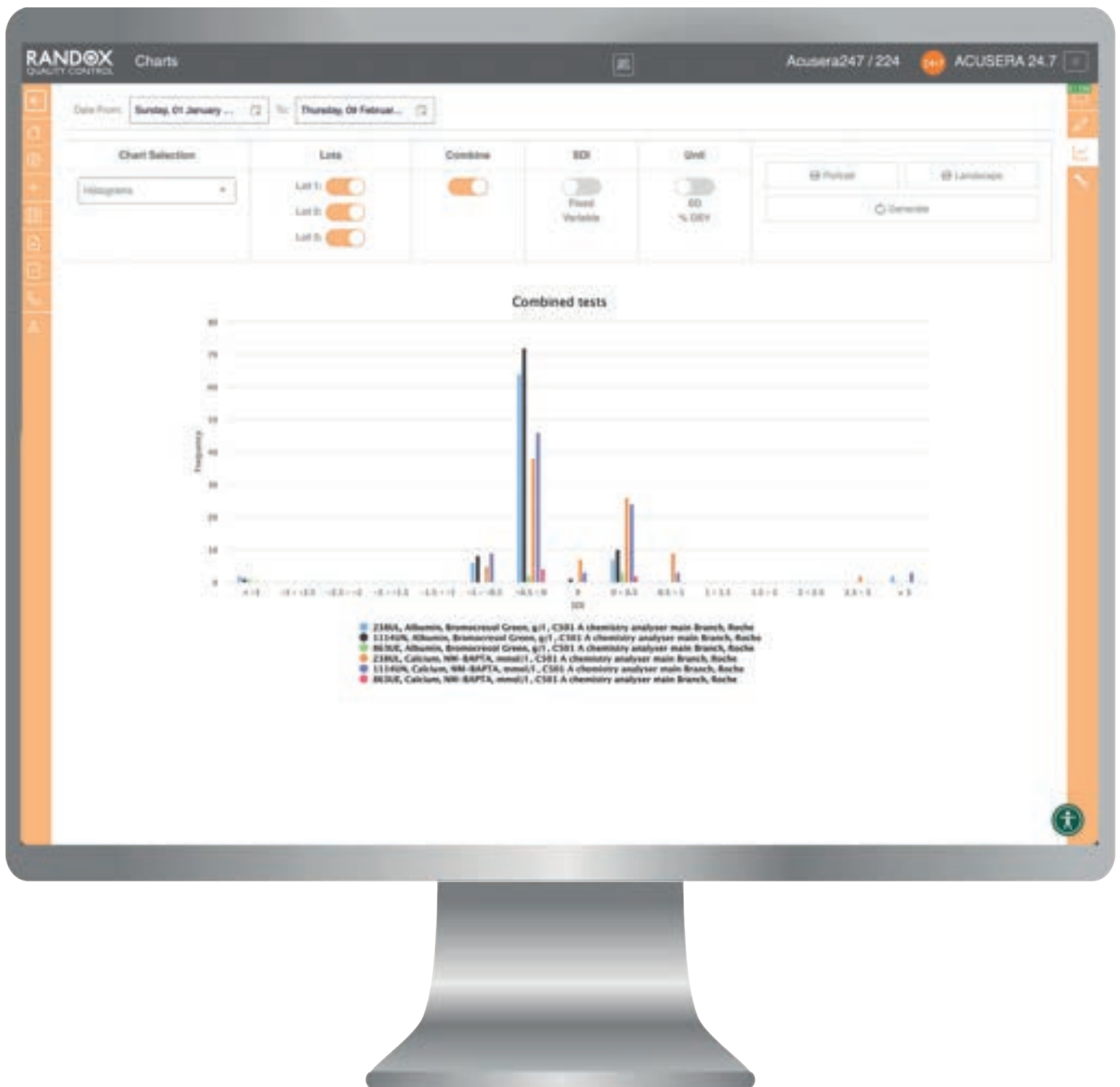
Generated at the touch of a button, the Histogram allows rapid identification of any test system bias for a given time period. Designed to be completely interactive, multiple instruments, analytes, QC lots and labs can be added to a single chart, delivering comparative performance assessment, easy identification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

Using the Histogram, group co-ordinators will be able to quickly identify any labs experiencing performance issues within their affiliated group.

PERFORMANCE SUMMARY CHARTS

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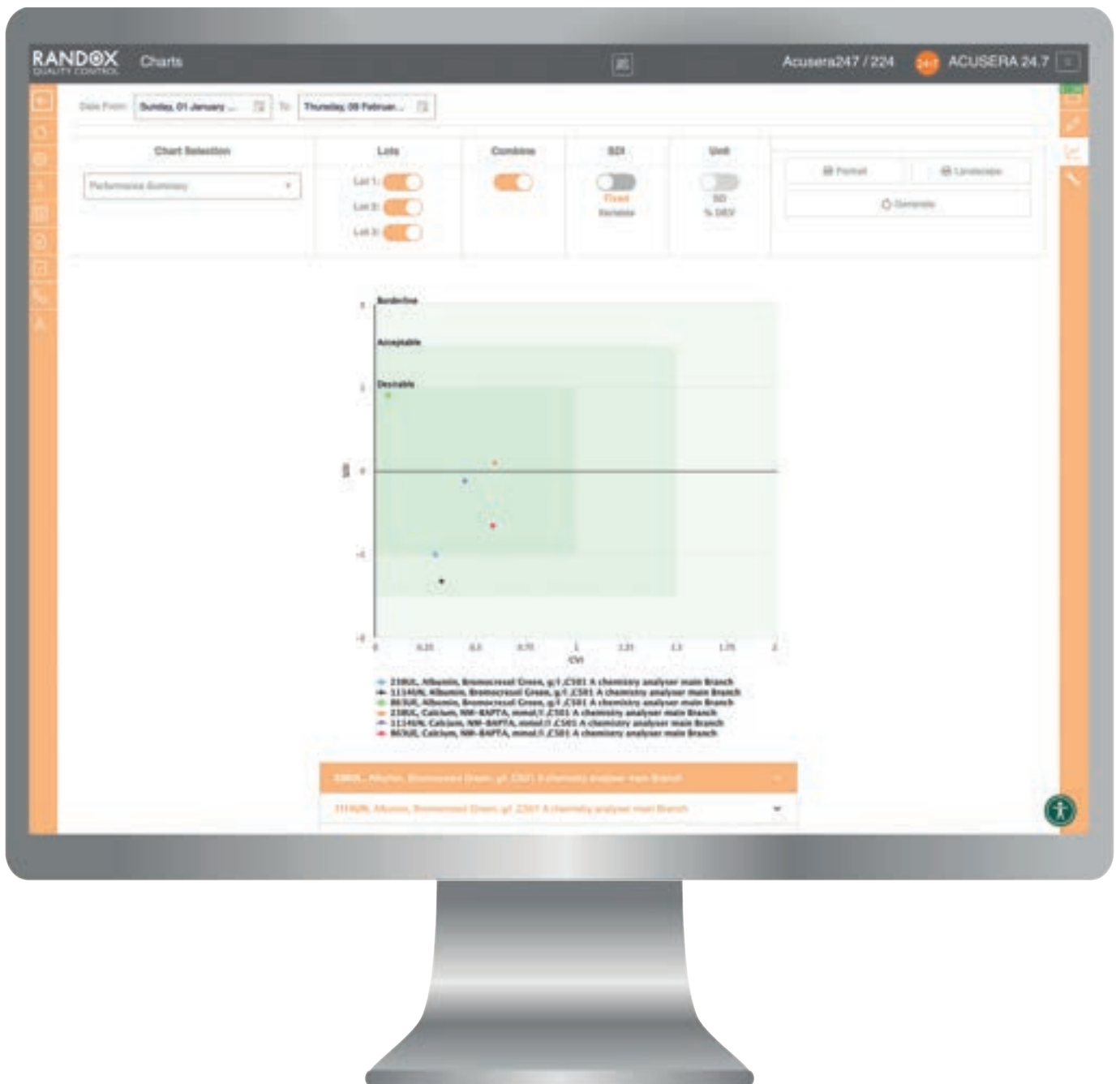

The Performance Summary Chart provides a graphical representation of individual laboratory performance, compared to your chosen peer group. Data is displayed in a colour coded, easy to interpret chart allowing for fast and efficient performance assessment.

Performance Summary Charts can be customised to conveniently display data for multiple analytes and labs within an affiliated group, allowing visual identification of trends.

STATISTICAL REPORTS

Compare monthly and cumulative statistics to worldwide peer group data
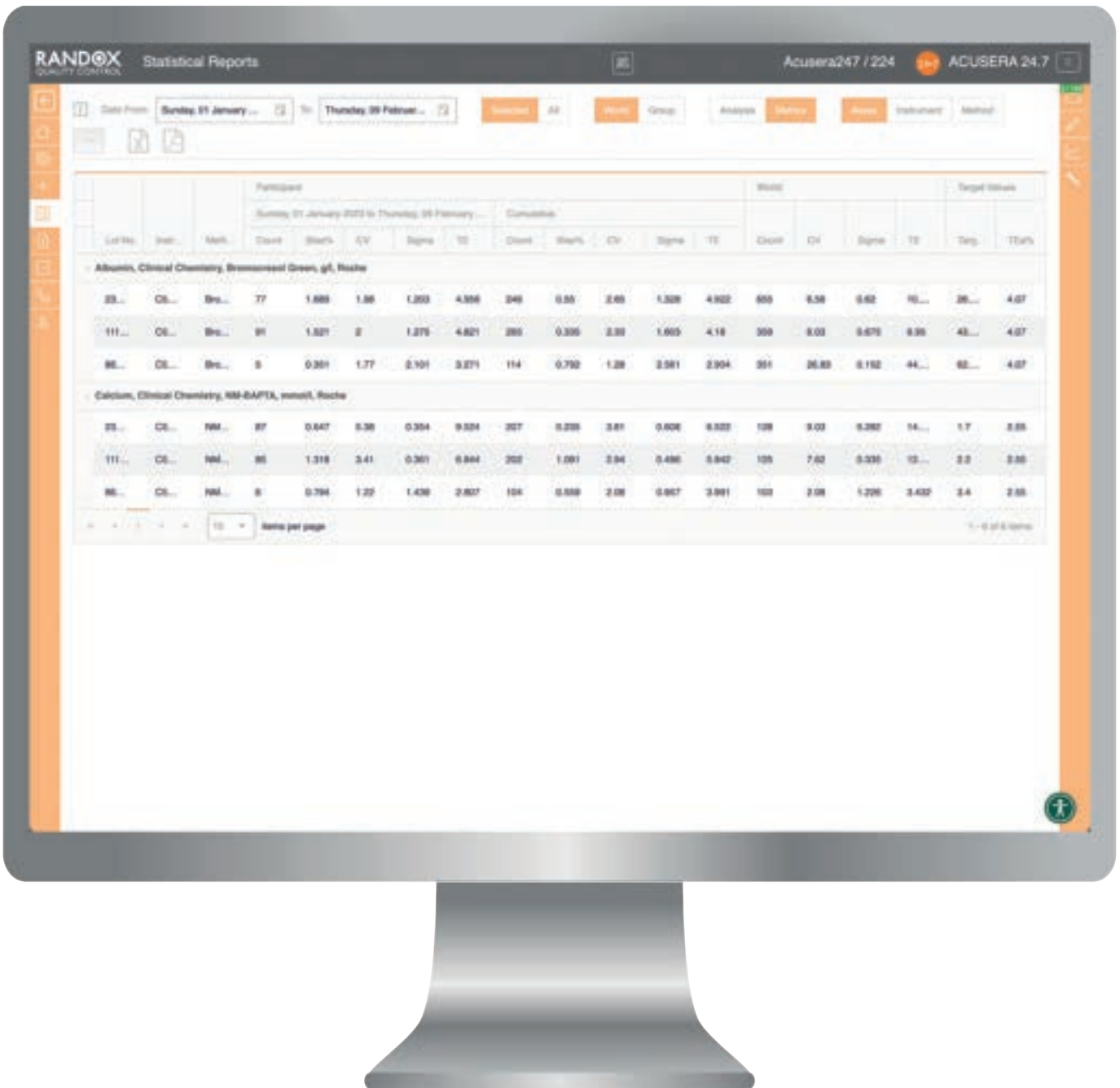
The Statistical Analysis Report provides a complete overview of laboratory performance for a specified date range.

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. Group co-ordinators can also review statistical data for each lab within the affiliated group, allowing for simple data analysis from a central hub.

Participants can generate a report for all open QC tests or they can select single or multiple QC tests from the homescreen thereby offering greater control over test performance.

STATISTICAL REPORTS

Displays several performance metrics on one report
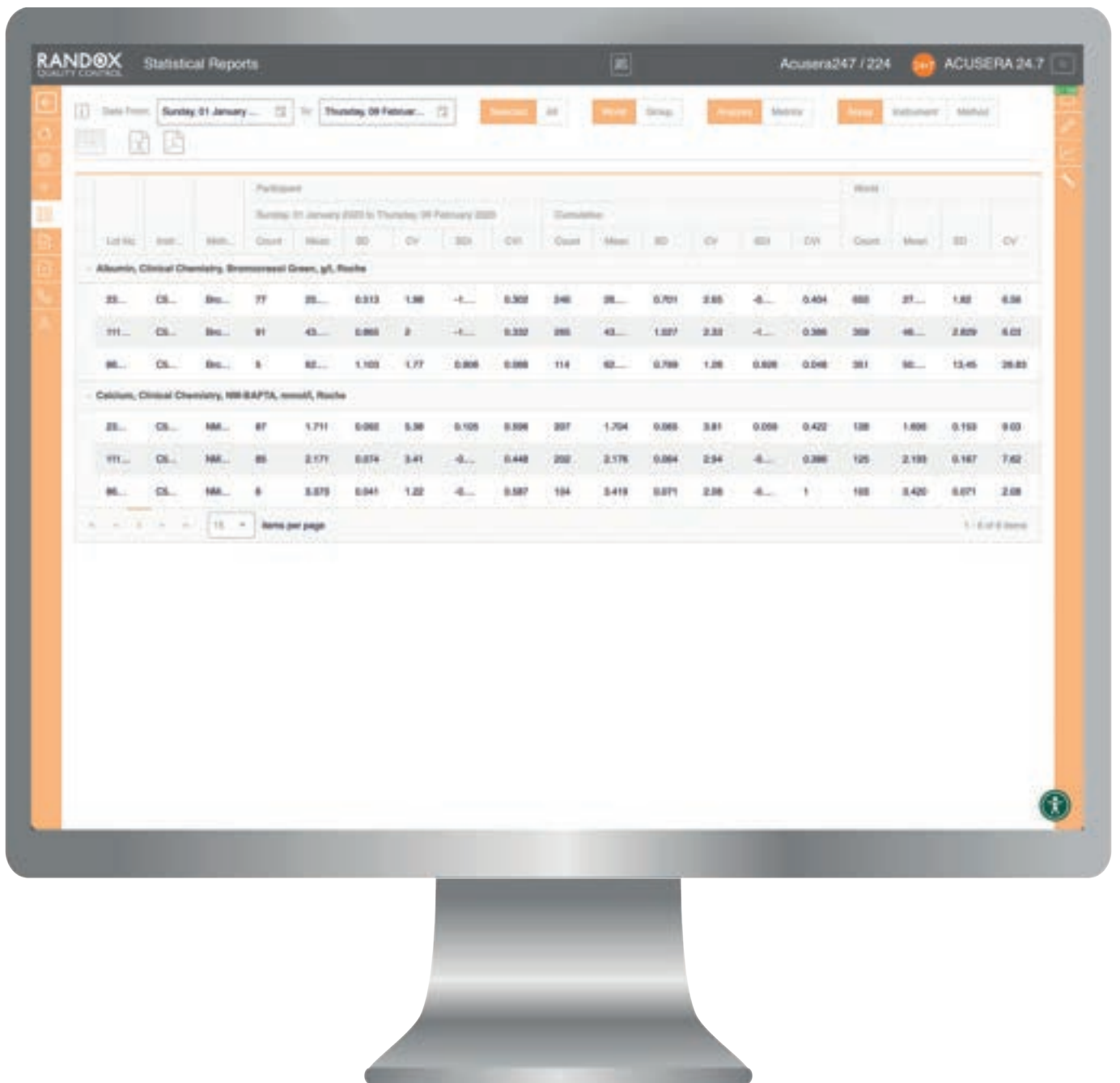
Both statistical reports are viewable from one screen and be interchanged using the buttons at the top of the report.

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. Group co-ordinators can also review statistical data for each lab within the affiliated group, allowing for simple data analysis from a central hub.

UNCERTAINTY OF MEASUREMENT REPORT

Automatic Uncertainty of Measurement (UM) calculation
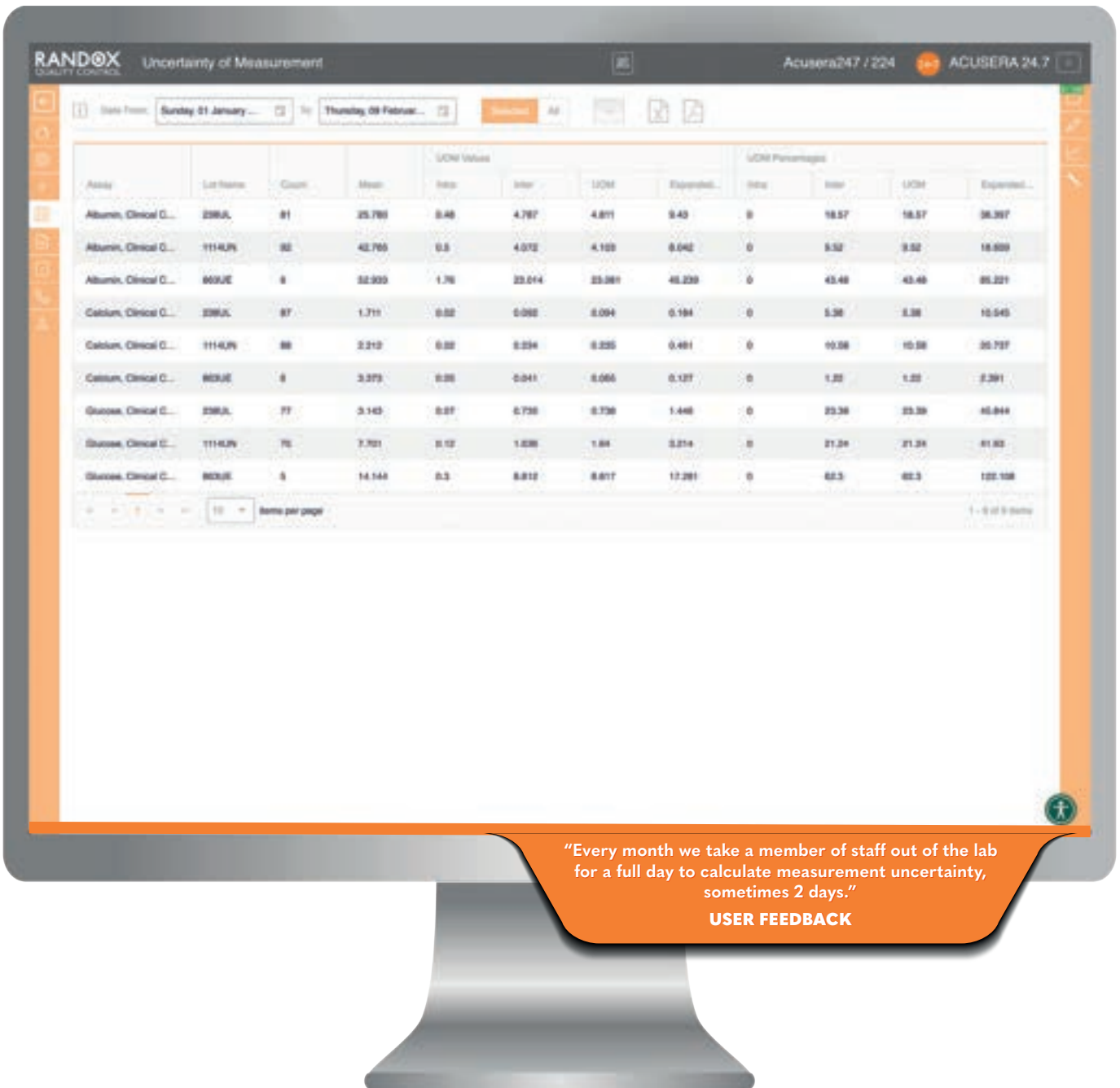
"Every month we take a member of staff out of the lab for a full day to calculate measurement uncertainty, sometimes 2 days."
**USER FEEDBACK**

The unique Uncertainty of Measurement report displays the UM of all QC tests currently in use, helping you to meet ISO 15189:2022 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.

Participants can generate a report for all open QC tests or they can select single or multiple QC tests from the homescreen thereby offering greater control over test performance.

EXCEPTION REPORT

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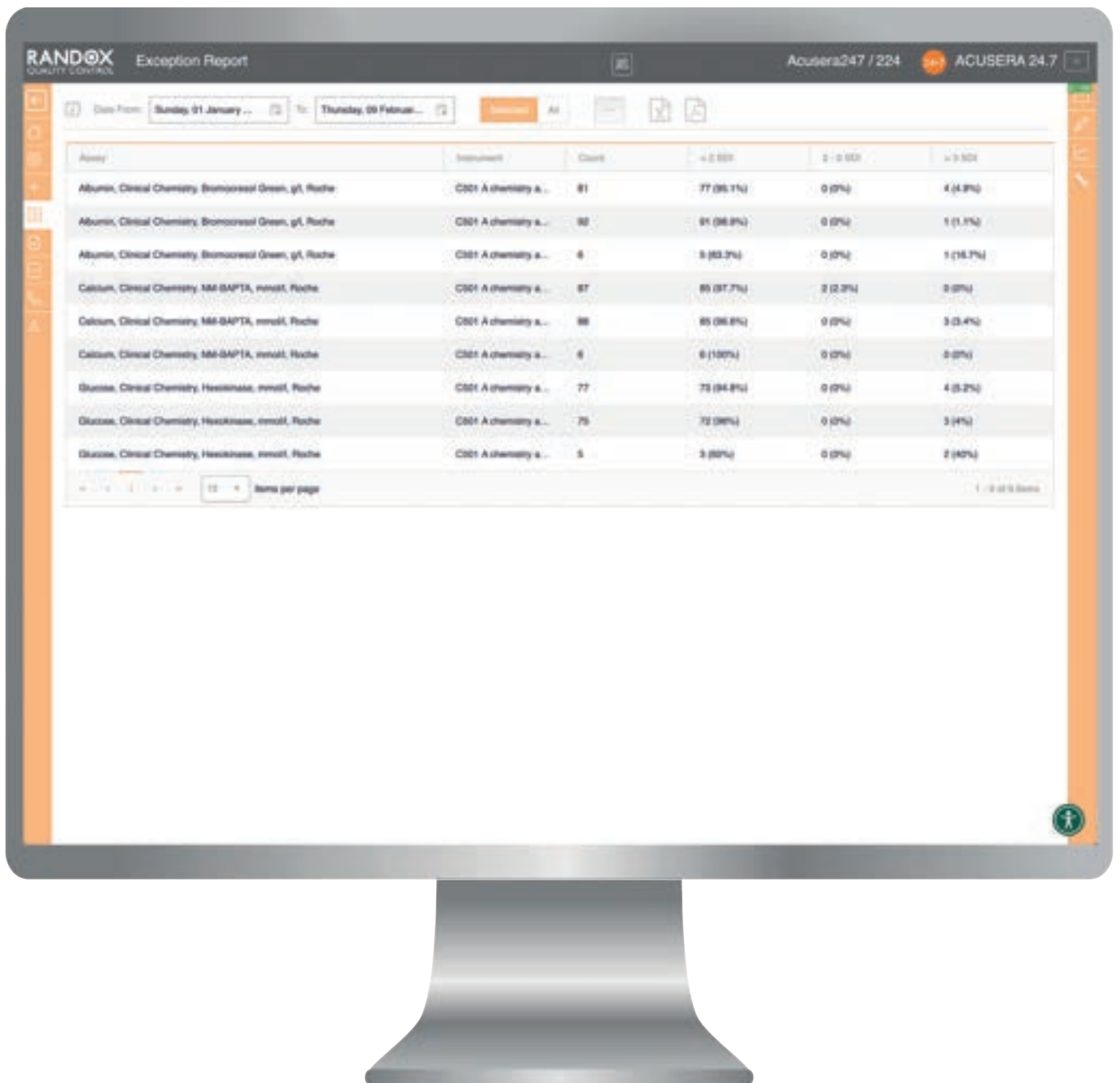
Designed to quickly and easily identify assays with a high percentage of errors, the exception report provides an on screen summary of the number of QC results for each individual assay and control lot that fall within the following categories: <2SD, 2-3SD and >3SD.

Reports are instantly generated for a user-defined date range and may be exported in Excel or PDF format.

Participants can generate a report for all open QC tests or they can select single or multiple QC tests from the homescreen thereby offering greater control over test performance.

PEER GROUP STATISTICS

Access true real-time peer group statistics
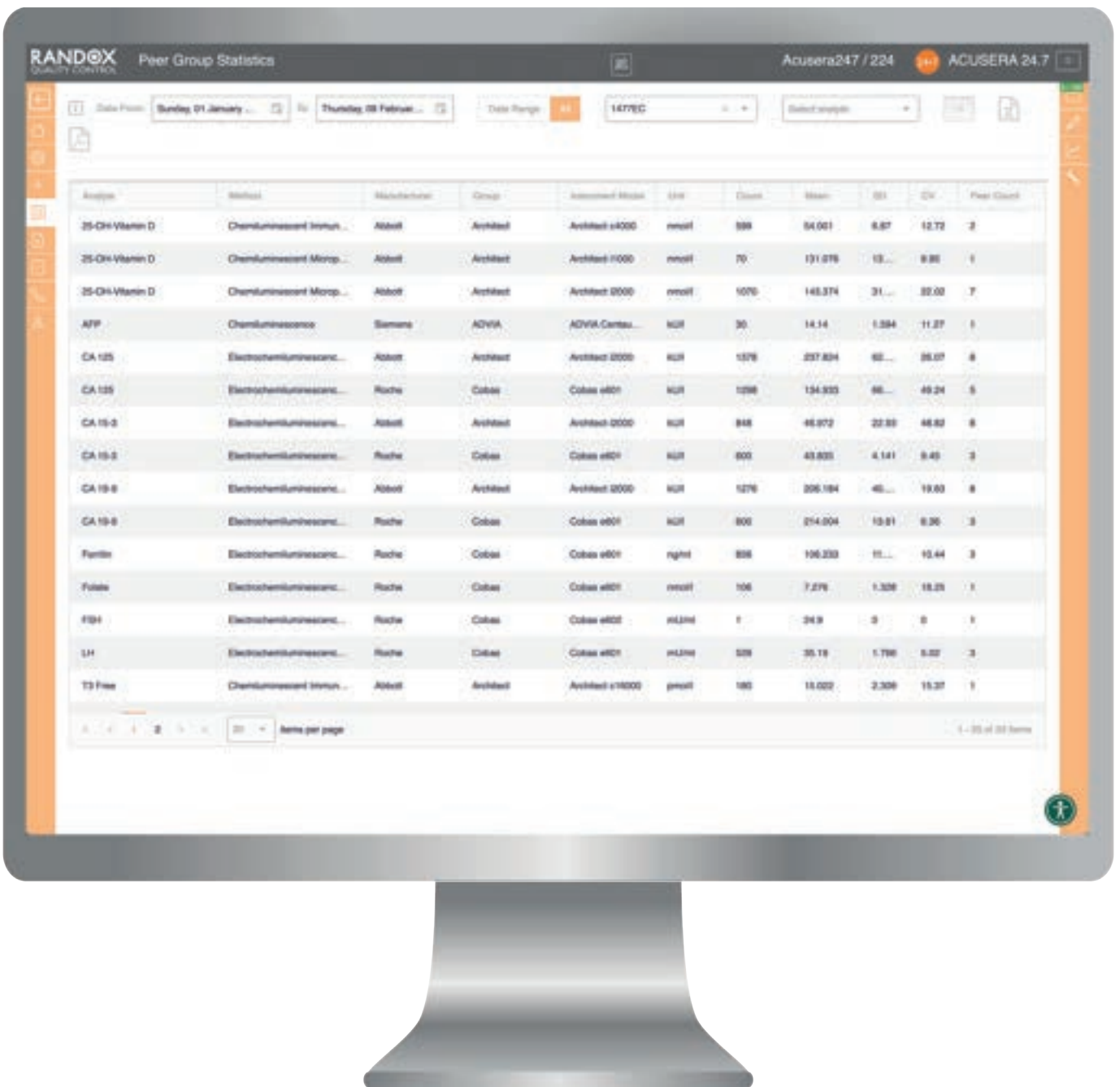
The Peer Group Statistics report provides access to peer data for all lots of Quality Control. Data is instantly updated in real-time*, delivering unique access to the most up-to-date information available. Analysis of peer data in this way will help you to determine if an out of control result is an 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. Data may be based on the global peer group, or to other laboratories in your affiliate group. 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
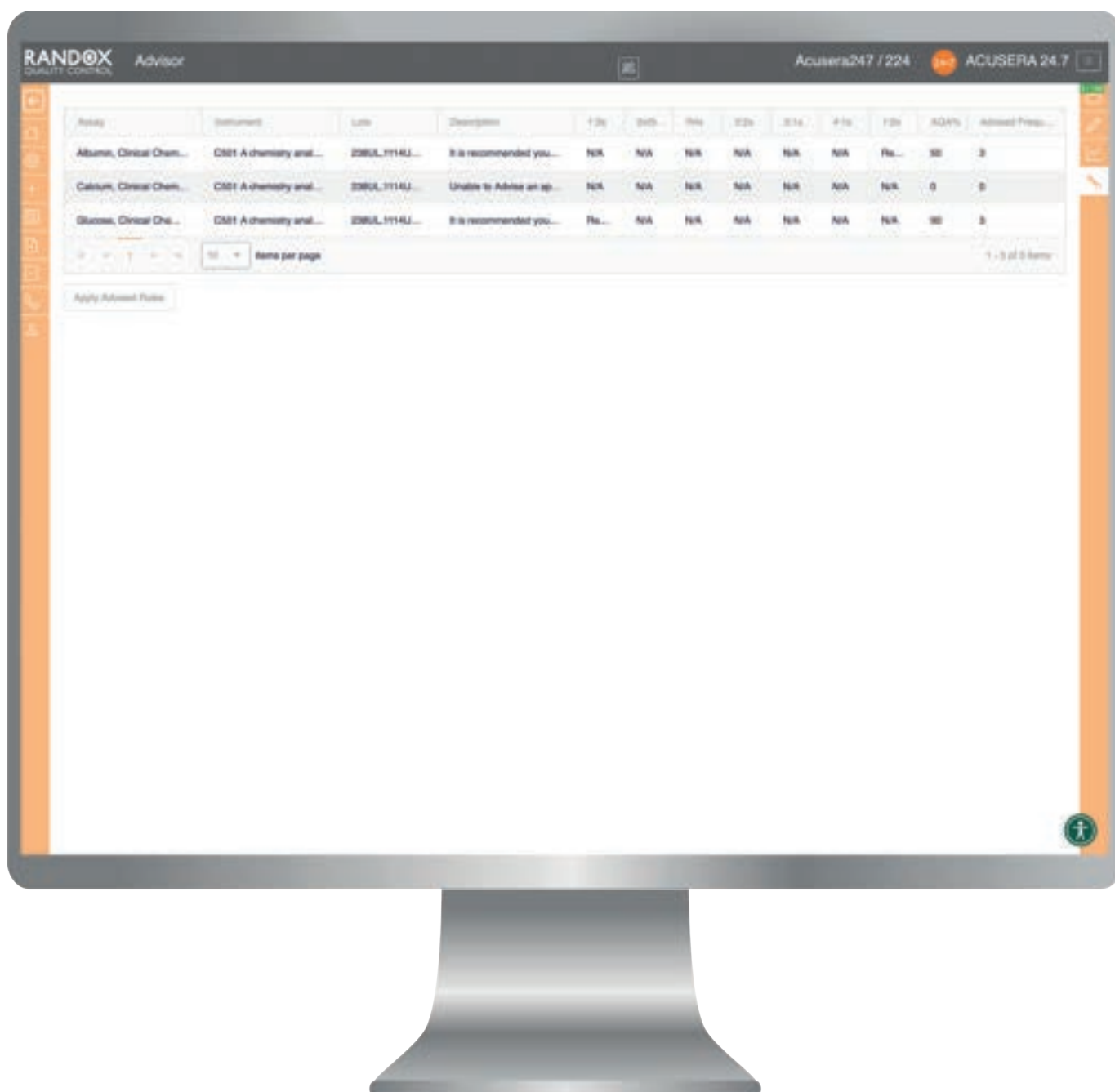
Acusera Advisor is an optional tool designed to help you select the optimum QC strategy for each individual test in use. Not only will the Advisor tool recommend a set of QC multi-rules, it will also suggest a minimum QC frequency based upon the performance of the method in question. The use of QC multi-rules 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 2 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.
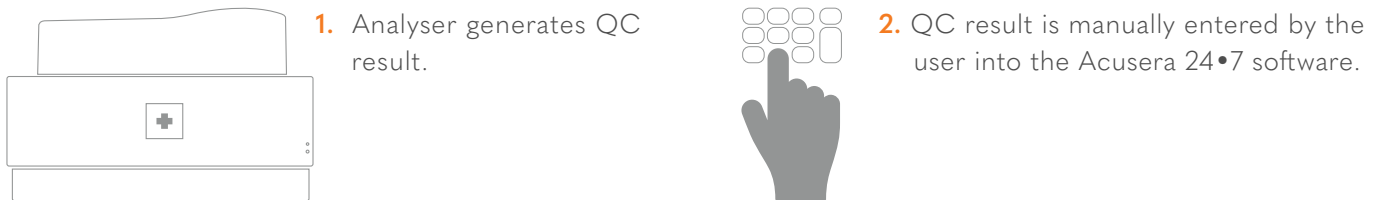
A report can be easily generated displaying a list of all assays along with the Analytical Quality Assurance (AQA) achieved with the currently used multi-rules and a suggested minimum QC frequency.

DATA ENTRY OPTIONS

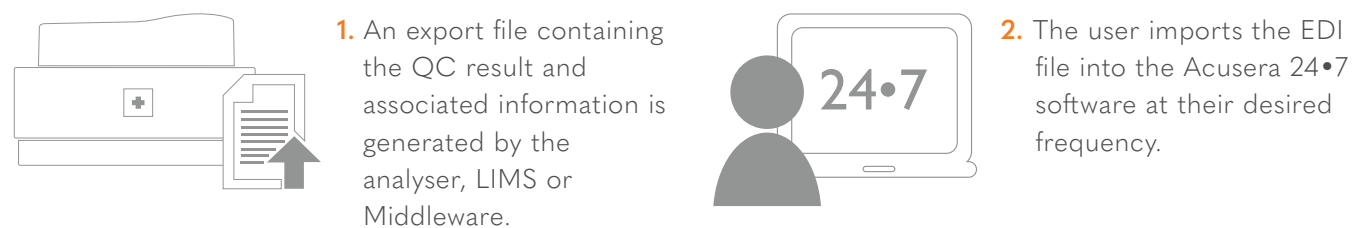## There are three options for QC data entry with Acusera 24•7

Manual result entry

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

1. Analyser generates QC result.

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

Semi-automated result entry via EDI

EDI is the ideal solution for laboratories that don't want the hassle of manual data input but still want to benefit from a reduction in time and elimination of transcription errors.
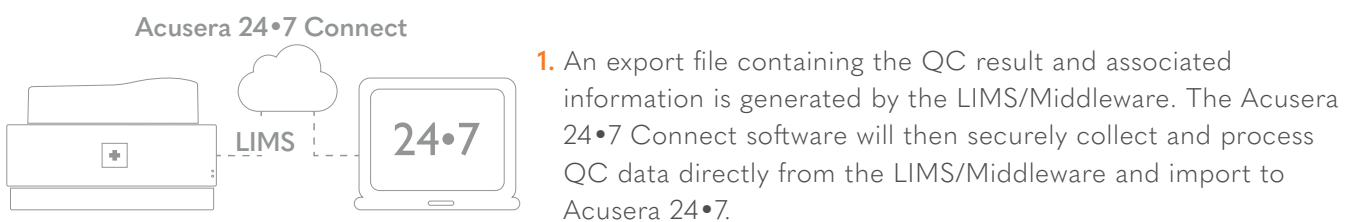
1. An export file containing the QC result and associated information is generated by the analyser, LIMS or Middleware.

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

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

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

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

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

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

Acusera 24•7 Connect

LIMS

24•7

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

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

RANDOX QC PORTFOLIO

Our expertise in Quality Control have led to us creating market leading products that are tried and trusted by laboratory professionals. Our product portfolio offers high quality diagnostic solutions which offer reliable and rapid diagnosis and we believe that by providing laboratories with these tools, we can improve health worldwide.

ACUSERA - True third party controls offering complete test menu consolidation

▶ 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

▶ The largest international EQA scheme, used by more than 76,000 laboratory participants in over 139 countries worldwide. Comprising over 360 routine and esoteric parameters in 35 comprehensive and flexible EQA programmes, RIQAS is designed to cover all areas of clinical testing. Each programme benefits from a wide range of concentrations, frequent reporting and informative yet user-friendly reports.

MOLECULAR - IQC & EQA solutions for infectious disease testing

▶ Our complete quality control solutions for molecular infectious disease testing comprise hundreds of characterised viral, bacterial and fungal targets. Covering a wide range of transplant associated diseases, respiratory infections, blood borne viruses, sexually transmitted infections and more, our Molecular IQC and EQA range covers the full laboratory portfolio. Both our product offering are manufactured using only the highest quality material and the availability of whole pathogen samples ensures the performance of the patient sample is mimicked throughout.

CONTACT US

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

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RANDOX
QUALITY CONTROL

MDSAP Certification Number:
699499

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