

RANDOX

EDUCATIONAL GUIDE

Straightforward QC Data Management



The Foundation of Laboratory Accuracy

In the realm of laboratory operations, the significance of quality control (QC) data management cannot be overstated. This foundational aspect ensures that laboratory results are accurate, reliable, and consistent, thereby upholding the integrity of diagnostic processes. QC data management involves the systematic collection, analysis, and storage of quality control data, which helps laboratories monitor and maintain the precision and accuracy of their analytical instruments and methodologies.

Why is QC Data Management Crucial?

QC data management is vital for several reasons:

Ensuring Accuracy: By regularly assessing the quality of laboratory outputs, QC data management helps identify deviations or errors that could compromise patient results.

Regulatory Compliance: Effective QC data management is essential for meeting the stringent requirements set by accreditation bodies, ensuring that laboratories comply with industry standards and best practices.

Enhancing Efficiency: Streamlined QC processes reduce the need for repeated tests, minimise errors, and save valuable time and resources.

Improving Patient Outcomes: Ultimately, the primary goal of any laboratory is to provide results that can be trusted by healthcare providers. Accurate diagnostics lead to appropriate and timely treatment, directly impacting patient care and outcomes.

Acusera 24/7, a sophisticated QC data management software, stands out in this crucial domain by offering a suite of tools designed to enhance the quality control process in laboratories of all sizes. With its comprehensive features and intuitive design, Acusera 24/7 transforms the traditional challenges of QC data management into a streamlined, user-friendly experience.



Enhanced Reporting with Acusera 24·7

The ability to generate precise and informative reports is critical for laboratories to effectively communicate findings, track performance, and make informed decisions. Acusera 24·7 elevates this process through its advanced reporting features that not only simplify data management but also enhance the overall utility of the reports produced.

Key Features of Acusera 24·7 Reports:

Automation and Customization: Acusera 24·7 allows for both automated and semi-automated data entry, ensuring that the data reflected in reports is accurate and directly corresponds to the results obtained from laboratory instruments. This reduces human error and increases the reliability of the reports. However, you can still input your data manually if you prefer. Additionally, the software offers customizable report templates which enable labs to tailor their reports to meet specific internal and external reporting requirements.

Comprehensive Statistical Analysis: With integrated tools for statistical analysis, including exception reports and peer group statistics, Acusera 24·7 enables laboratories to conduct detailed performance reviews. These tools facilitate the identification of outliers and trends, aiding in the validation and verification of new IQC lots and other quality control standards.

Real-Time Access and Export Capabilities: Reports in Acusera 24·7 are accessible in real-time, providing immediate insights into laboratory performance. The ease of access to current and historical data enhances the ability to make quick, informed decisions. Furthermore, the reports can be exported to PDF or Excel formats, making it easy to share and analyse data outside the software environment.

Reports

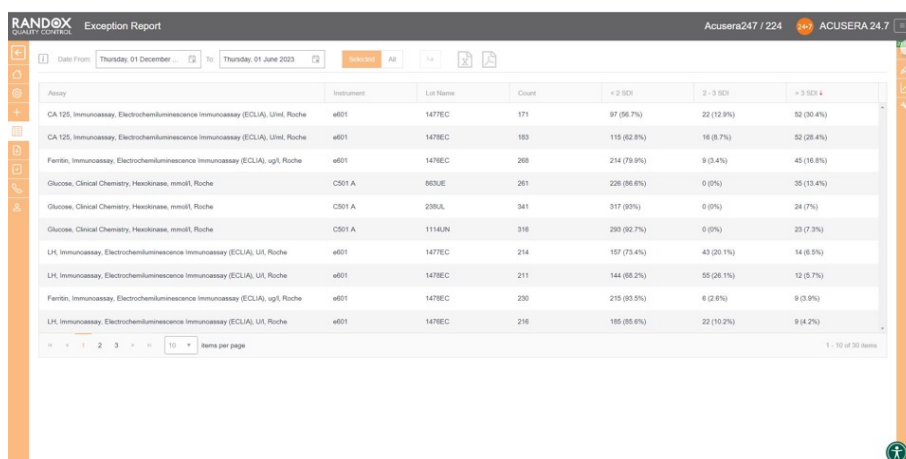
Statistical Analysis Report

This report allows you to view your IQC data from a specified date range, and compare it to your cumulative data, that is, all the IQC data you've collected since you began using that lot, as well as the peer group data for the same lot all within one screen. If you are part of a chain of laboratories, you can compare this data with your laboratory group to see how your lab stacks up by using the World/Group toggle button.

This report provides you with the count, mean, standard deviation (SD), coefficient of variation (CV), standard deviation index (SDI) and coefficient of variation index (CVI) for a lot and can be organised by assay, as shown in the image below, instrument, or method, allowing you full freedom to customise this report to suit your needs. Don't forget, like all our reports and charts, this data is fully exportable to PDF or Excel for filing or data review.

Exception Report

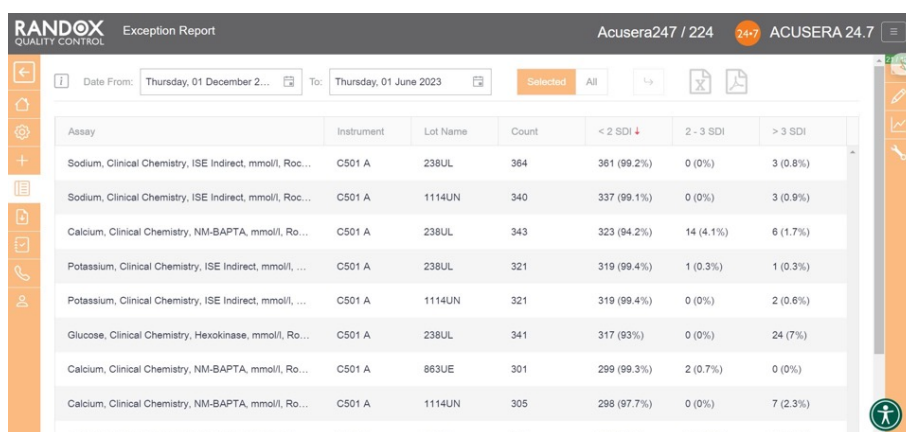
This report is designed to quickly and easily identify assays with a high percentage of errors. The exception report provides an on-screen summary of the number of QC results for each individual assay and control lot that fall within the following categories: $<2SD$, $2-3SD$ and $>3SD$. This comprehensive performance review can be filtered: by clicking on the top of the ' $>3SD$ ' column, this report will display assays in descending order with your worst-performing assays at the top, as shown below.



The screenshot shows the RANDOX Exception Report interface. The top bar includes the RANDOX logo, the title 'Exception Report', and the current filter 'Acusera247 / 224'. Below the top bar is a date range selector from 'Thursday, 01 December 2022' to 'Thursday, 01 June 2023'. The main table lists assays with columns for Assay, Instrument, Lot Name, Count, $<2SD$, $2-3SD$, and $>3SD$. The assays are sorted by the $>3SD$ column in descending order.

Assay	Instrument	Lot Name	Count	$<2SD$	$2-3SD$	$>3SD$
CA 125, Immunoassay, Electrochemiluminescence Immunoassay (ECLIA), U/ml, Roche	e601	1477EC	171	97 (56.7%)	22 (12.8%)	52 (30.4%)
CA 125, Immunoassay, Electrochemiluminescence Immunoassay (ECLIA), U/ml, Roche	e601	1477EC	183	115 (62.8%)	18 (9.7%)	50 (27.4%)
Ferritin, Immunoassay, Electrochemiluminescence Immunoassay (ECLIA), ug/L, Roche	e601	1477EC	268	214 (79.9%)	9 (3.4%)	45 (16.8%)
Glucose, Clinical Chemistry, Hexokinase, mmol/L, Roche	C501 A	863UE	281	226 (80.4%)	0 (0%)	55 (19.6%)
Glucose, Clinical Chemistry, Hexokinase, mmol/L, Roche	C501 A	238UL	541	317 (58.8%)	0 (0%)	224 (41.2%)
Glucose, Clinical Chemistry, Hexokinase, mmol/L, Roche	C501 A	1114UN	318	293 (92.2%)	0 (0%)	25 (7.8%)
LH, Immunoassay, Electrochemiluminescence Immunoassay (ECLIA), U/L, Roche	e601	1477EC	214	157 (73.4%)	43 (20.1%)	14 (6.5%)
LH, Immunoassay, Electrochemiluminescence Immunoassay (ECLIA), U/L, Roche	e601	1477EC	211	144 (68.2%)	55 (26.1%)	12 (5.7%)
Ferritin, Immunoassay, Electrochemiluminescence Immunoassay (ECLIA), ug/L, Roche	e601	1477EC	230	215 (93.5%)	6 (2.6%)	9 (3.9%)
LH, Immunoassay, Electrochemiluminescence Immunoassay (ECLIA), U/L, Roche	e601	1477EC	218	185 (85.0%)	22 (10.2%)	11 (5.0%)

Filtering by ' $<2SD$ ', it will display the same data with your best-performing assays at the top.



The screenshot shows the RANDOX Exception Report interface with the filter changed to 'Acusera247 / 224'. The date range is the same. The table lists assays sorted by the $<2SD$ column in descending order.

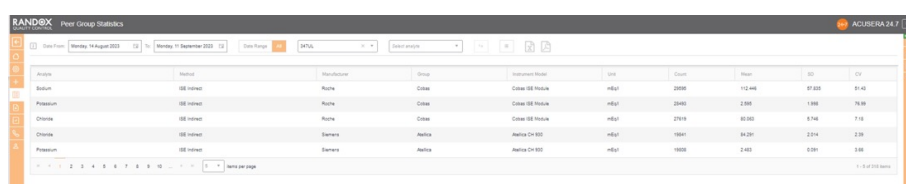
Assay	Instrument	Lot Name	Count	$<2SD$	$2-3SD$	$>3SD$
Sodium, Clinical Chemistry, ISE Indirect, mmol/L, Roche	C501 A	238UL	364	361 (99.2%)	0 (0%)	3 (0.8%)
Sodium, Clinical Chemistry, ISE Indirect, mmol/L, Roche	C501 A	1114UN	340	337 (99.1%)	0 (0%)	3 (0.9%)
Calcium, Clinical Chemistry, NM-BAPTA, mmol/L, Roche	C501 A	238UL	343	323 (94.2%)	14 (4.1%)	6 (1.7%)
Potassium, Clinical Chemistry, ISE Indirect, mmol/L, Roche	C501 A	238UL	321	319 (99.4%)	1 (0.3%)	1 (0.3%)
Potassium, Clinical Chemistry, ISE Indirect, mmol/L, Roche	C501 A	1114UN	321	319 (99.4%)	0 (0%)	2 (0.6%)
Glucose, Clinical Chemistry, Hexokinase, mmol/L, Roche	C501 A	238UL	341	317 (93%)	0 (0%)	24 (7%)
Calcium, Clinical Chemistry, NM-BAPTA, mmol/L, Roche	C501 A	863UE	301	299 (99.3%)	2 (0.7%)	0 (0%)
Calcium, Clinical Chemistry, NM-BAPTA, mmol/L, Roche	C501 A	1114UN	305	298 (97.7%)	0 (0%)	7 (2.3%)
Albumin, Clinical Chemistry, Bromocresol Green, g/L, Roche	C501 A	863UE	305	294 (96.4%)	7 (2.3%)	4 (1.3%)

With this information, you can determine in which of your assay's failures most often occur and encourage staff to look a little more closely at why failures arise and identify changes to improve and minimise errors.

Peer Group Statistics Report

Our Peer Group Statistics Report is updated live and in real-time, with no submission deadlines, allowing you to compare your statistics to those of your peer group, determined by analyte, method, instrument manufacturer and model.

Simply select the IQC lot you wish to analyse and Acusera 24-7 will generate the data for you, displaying the count of QC data, mean, SD and CV, giving you comprehensive insight into your performance vs your peers.



The screenshot shows the RANDOX Peer Group Statistics Report interface. The top bar includes the RANDOX logo, the title 'Peer Group Statistics', and the current filter 'Acusera247 / 224'. Below the top bar is a date range selector from 'Monday, 14 August 2022' to 'Monday, 14 September 2022'. The main table compares performance metrics for different assays and methods.

Analyte	Method	Manufacturer	Group	Instrument Model	Lot	Count	Mean	SD	CV
Bilirubin	ISE indirect	Roche	Colson	Colson 88 Module	863UE	2000	112.448	87.833	81.45
Potassium	ISE indirect	Roche	Colson	Colson 88 Module	863UE	2000	2.995	1.998	70.00
Cholesterol	ISE indirect	Roche	Colson	Colson 88 Module	863UE	2000	80.882	9.748	12.05
Cholesterol	ISE indirect	Roche	Colson	Colson 88 Module	863UE	2000	80.882	9.748	12.05
Potassium	ISE indirect	Roche	Colson	Colson 88 Module	863UE	2000	2.995	1.998	70.00

Advantages of Using Acusera 24·7 for Report Generation:

Efficiency: The streamlined process of generating reports with Acusera 24·7 saves time and labour, allowing laboratory personnel to focus more on analysis rather than administrative tasks.

Accuracy: The reduction of manual data entry errors and the ability to automatically calculate critical statistical parameters ensure that the reports are both accurate and dependable.

Compliance and Accreditation: Acusera 24·7's reporting capabilities are designed to meet the specific standards set by accreditation bodies, making it easier for laboratories to comply with regulatory requirements and pass accreditation assessments with confidence.

The report generation features of Acusera 24·7 not only support the operational needs of the laboratory but also contribute significantly to maintaining high standards of quality and reliability in laboratory testing.

Navigating Data with Precision: Interactive Charts in Acusera 24·7

Acusera 24·7 revolutionises the visualisation of quality control data through its range of interactive charts. These charts not only serve as tools for data representation but also act as analytical instruments, enabling laboratories to achieve a deeper understanding of their QC data trends and variances.

Types of Interactive Charts Available in Acusera 24·7:

Levey-Jennings Charts

A staple in laboratory QC practices, these charts provide a visual timeline of QC results, highlighting variations and trends over a specified period. Acusera 24·7 enhances these charts with interactive features, allowing users to click on individual data points to view detailed information or to annotate them with relevant observations.

The screenshot below shows a Levey-Jennings chart for a single analyte, with the date on the X-axis and SD on the Y-axis. On this chart, you can see data points displayed in different colours. Green data points indicate an acceptable result. Orange points show data that has triggered your predefined alert criteria, while red points are those that have broken your set rejection rules.

The lines marked on the chart below represent events that have been recorded in relation to the data. This allows you to quickly see if a reason has been found for any deviations around that event. For example, in the screenshot below, after the event labelled 'Reagent lot change' you can see a series of alerts and failures. Marking this event on the chart allows for an at-a-glance explanation of this deviation. Data points that appear as a triangle indicate a comment has been added - what text is included in the comment is completely up to you.



You can also generate a Levey-Jennings chart for a panel of tests. Acusera 24-7 panels allow you to group related tests together, helping increase the efficiency of your data review. When viewing these charts live in Acusera 24-7, you can view the data collectively, or home in on individual data sets, simply by hovering over the data you want to see, as shown in the screenshot below.



For a more detailed look at your data, you may wish to include data points which fall outside the 3SD shown in the screenshots above. With the click of a button, you can expand the Y-axis to include all your data points, as shown below.



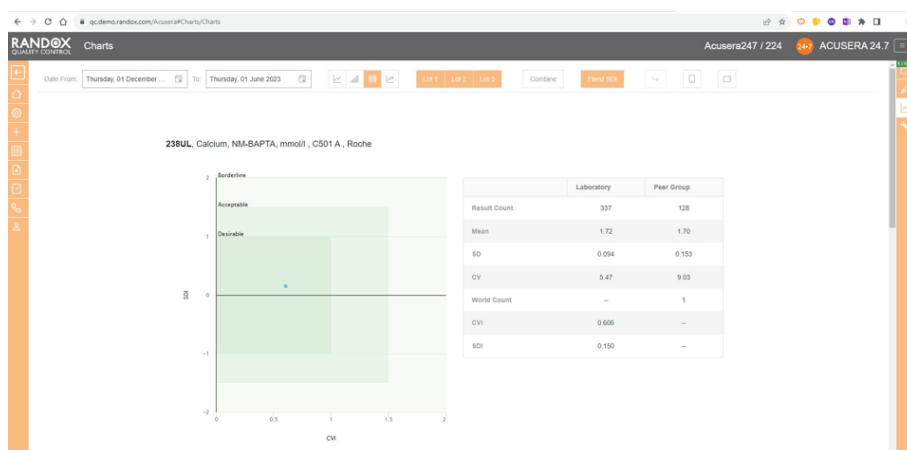
In some cases, you may wish to view this data displayed as '% Deviation'. Again, with the click of a single button, you can convert the Y-axis to show just that, as shown below.



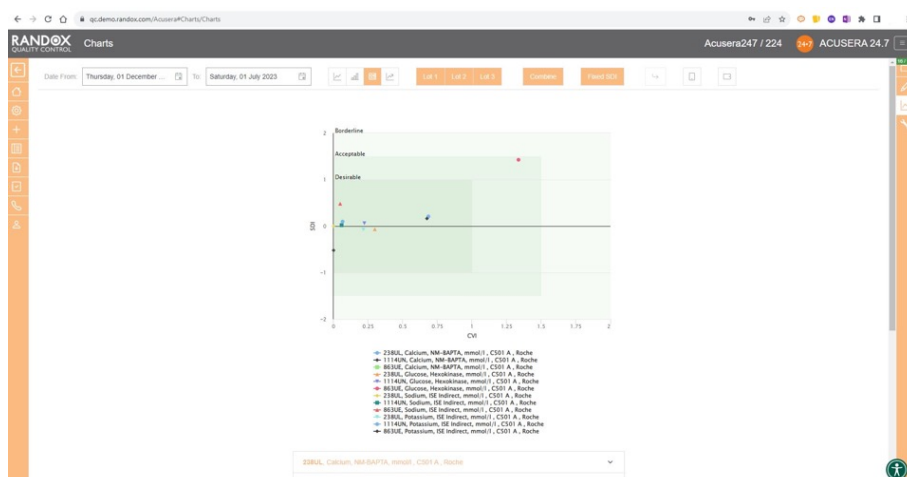
Performance Summary Charts

These charts offer a comparative analysis of your laboratory's performance against peer groups. By displaying data such as mean, CV, and SD, these charts are instrumental in benchmarking and improving laboratory practices.

Peer group comparison of IQC data has a lot of benefits. Comparing your data with other laboratories that use the same QC lot, instrument, method and more, can help you with troubleshooting and continuous process improvement. The Acusera 24-7 Performance Summary Charts do all the work for you. As shown in the screenshot below, these charts display your data and how it compares to your peers including mean, CV, and SD. You can also view this data in a table to get a more detailed picture of your performance.



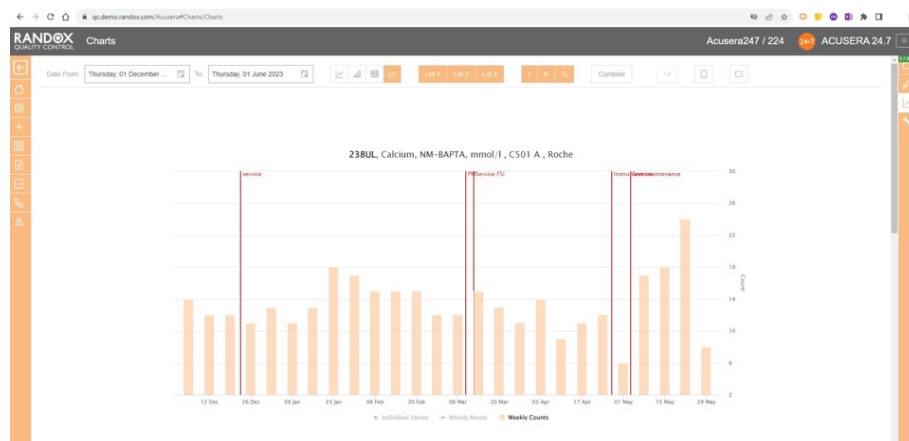
Like the Levey-Jennings charts, you can also combine this information for panels or a selection of multiple lots and analytes, like the example below.



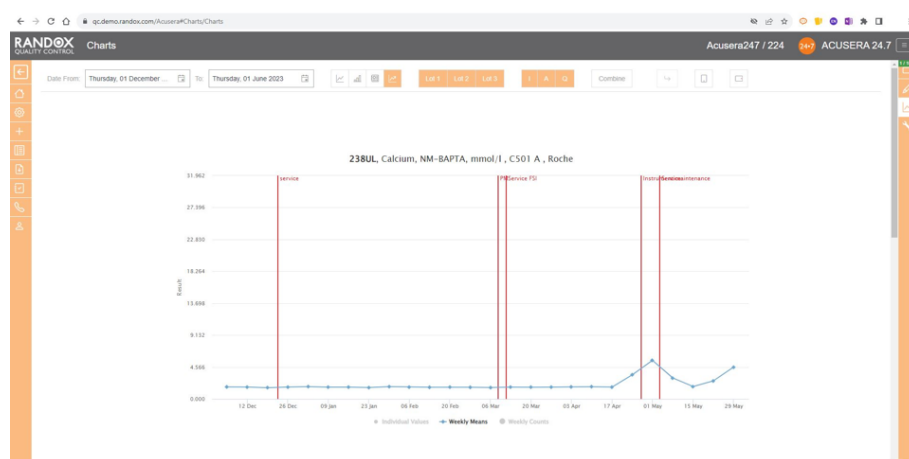
Weekly Mean Charts

This feature enables the tracking of average QC values on a weekly basis, giving a quick overview of performance consistency and identifying any deviations that may need further investigation.

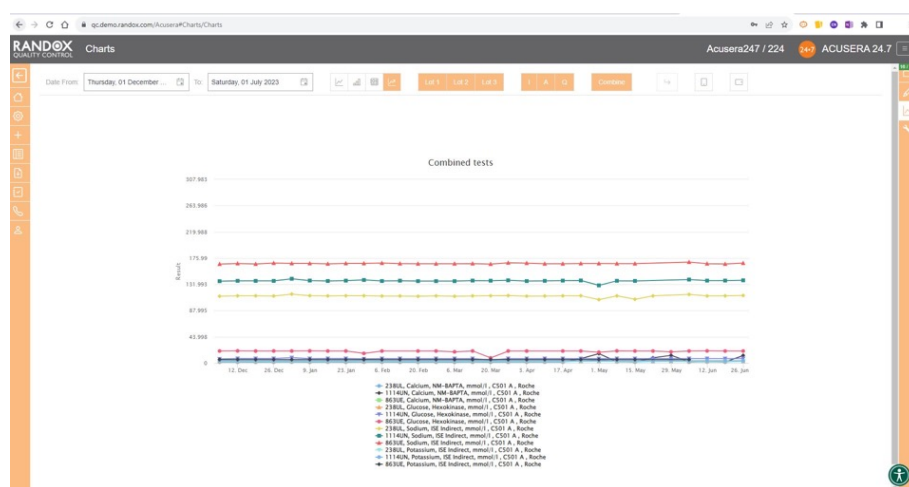
Weekly Mean Charts allow you to view your weekly count of QC results for a specific instrument, assay, or lot. Below is an example in a bar chart format.



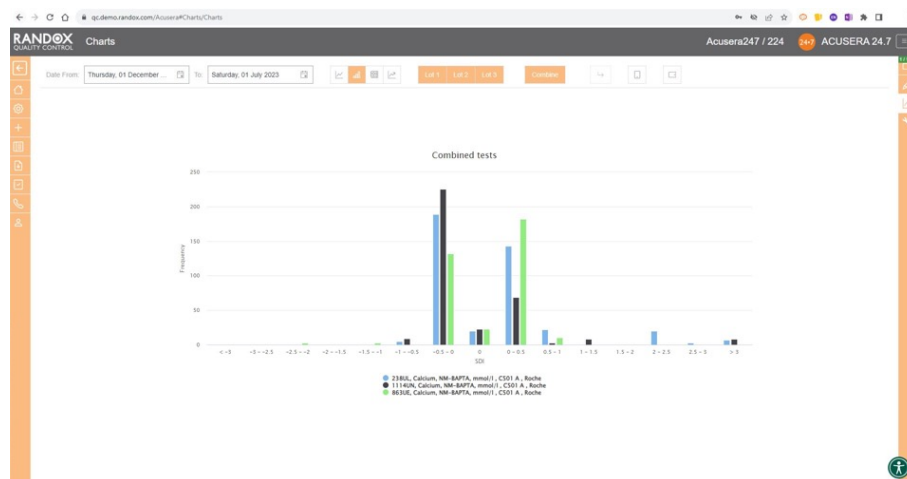
You can also view this data as a line graph, which plots the weekly mean of results from multiple instruments using the same assay and QC lot, allowing a comprehensive overview of your QC data.



Or you can view your weekly means for a range of tests and panels.



Finally, the SD Histograms allow you to view the distribution of your results, for an overview of performance.



Benefits of Using Acusera 24.7's Interactive Charts:

Enhanced Decision-Making: The interactive elements of the charts allow for a dynamic exploration of data, enabling laboratory staff to delve into specifics as needed and make informed decisions based on real-time data analysis.

Improved Troubleshooting: With detailed visualisations, it becomes easier to pinpoint issues such as reagent lot changes or instrument maintenance needs, which might be affecting QC results.

Accreditation Readiness: The ability to demonstrate data trends, compliance, and corrective actions through these charts makes accreditation assessments smoother and more straightforward.

Acusera 24.7's comprehensive suite of interactive charts is not just about displaying data; it's about transforming data into actionable insights that drive quality improvement and operational efficiency in the laboratory.

Advanced Statistical Tools in Acusera 24.7

Acusera 24.7 is not just a tool for managing quality control data; it is a powerful ally in statistical analysis, offering advanced features that simplify complex calculations and provide deeper insights into laboratory operations.

Key Statistical Tools in Acusera 24.7

Uncertainty of Measurement (MU)

Recognising the importance of MU in laboratory quality control, Acusera 24.7 automates its calculation, providing labs with accurate estimations of the variability inherent in their test results. This tool is essential for labs aiming to meet international standards like ISO 15189:2022, which mandates MU evaluation for quality assurance.

If you're not familiar with MU, the calculation of MU gives medical laboratories an estimate of the overall variability in the values they report. Simply put, if we say a piece of rope measures $20\text{cm} \pm 1\text{cm}$, at the 95% confidence level we are really saying that we are 95% sure that the string measures between 19cm and 21cm.



MU is important for 3 main reasons:

1. It helps ensure the measured results are useful and not wildly inaccurate
2. It permits meaningful comparison of medical decision limits and previous results of the same kind in the same individual
3. It's a regulatory requirement – ISO 15189:2022

All measurements involve some degree of inherent variability due to factors such as instrument limitations, environmental conditions, and biological variation. MU aims to quantify the doubt or range of possible values around the measurement result, helping to provide an understanding of the reliability and limitations of measurements. To complete this task comprehensively, the entire measurement process must be examined and should consider components such as systematic errors, random errors and uncertainties related to calibration, equipment, and the environment.

By liberating you from the need to manually calculate MU for all your assays and control levels, Acusera 24·7 streamlines the statistical analysis process, freeing you up to complete your other essential duties. It also helps reduce the chance of errors in the calculation – no matter how talented you are at mathematics, we all make mistakes. The real-time nature of this kind of monitoring means you don't have to recalculate every time you get more data – simply press the refresh button and you'll automatically get a new MU report.

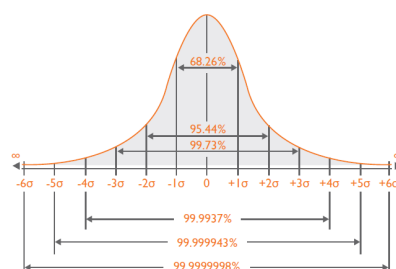
</

Sigma Metrics

Utilising the Sigma metric approach, Acusera 24·7 enables laboratories to assess process performance and identify areas where quality could be compromised. By calculating the number of standard deviations a process deviates from perfection, this tool helps laboratories optimise their QC protocols and improve overall accuracy.

The Sigma model was originally developed for the manufacturing industry as a method of process improvement focusing on minimising errors in process outputs. It has since been adopted by the medical laboratory to improve result reporting.

This model calculates the number of standard deviations or 'Sigmas' that fit within the quality specifications of the process – as the sources of error or variation are removed, the SD becomes smaller, and the sigma score increases – 6 being the target. A 6 Sigma process can be expected to produce 3.4 defects, or false results, per million.



Using your predetermined performance limits, including biological variation (standard), RiliBÄK and CLIA, as the total allowable error (TEa), Acusera 24-7 can calculate a Sigma Score for a particular assay, method, or instrument, saving you the hassle of calculating this manually - freeing you up to investigate the sources of error and make improvements to your process.

This is displayed in our Statistical Metrics report along with Count, Bias%, and CV for your chosen range, your cumulative results and those from other Acusera 24-7 users from around the world to provide straightforward and comprehensive statistical analysis and peer group comparison.

The screenshot displays the RANDOX Statistical Reports interface. The top navigation bar includes the RANDOX logo, 'Statistical Reports', and 'Acusera247 / 224'. Below this, there are filters for 'Date From' (Thursday, 01 December) and 'Date To' (Thursday, 01 June 2023). The main table is titled 'Participant' and shows data for 'Thursday, 01 December 2022 to Thursday, 01 June 2023'. The table is organized into columns for 'Lot No.', 'Instrument', 'Method', 'Count', 'Bias%', 'CV', 'Sigma', 'TE', and 'World'. The data is grouped by assay type: 'Albumin, Clinical Chemistry, Bromocresol Green, g/L, Roche', 'CA 125, Immunoassay, Electrochemoluminescence Immunoassay (ECLIA), U/ml, Roche', 'Ferritin, Immunoassay, Electrochemoluminescence Immunoassay (ECLIA), ug/L, Roche', and 'Folate, Immunoassay, Electrochemoluminescence Immunoassay (ECLIA), ng/mL, Roche'. Each group contains multiple rows of data for different lot numbers and instruments.

Once you've found out your Sigma Score for an assay, you can use this to determine your QC frequency and the multi-rules you should apply to your QC. The higher your Sigma Score, the less multi-rules you need to apply to your analysis and the less often you need to run QC for that assay. The table below shows the multi-rules and QC frequencies associated with each Sigma Score.

Sigma Score	QC Frequency	No. of QC Samples	QC Rules
6 Sigma	Once per day	Both levels of QC	1_{3s}
5 Sigma	Once per day	Both levels of QC	$1_{3s} / 2_{2s} / R_{4s}$
4 Sigma	At least twice per day	Both levels of QC	$1_{3s} / 2_{2s} / R_{4s} / 4_{1s}$
< 4 Sigma	At least four times per day	Both levels of QC	$1_{3s} / 2_{2s} / R_{4s} / 4_{1s} / 8_x$

QC Multi-Rules

Acusera 24-7 includes multi-rule capabilities that can be utilised to monitor your QC data and index it as accepted, rejected, or trigger an alert, depending on the pre-defined multi-rules against which you want to check your data. These features enable the identification of nonconformities and reduce the need for laborious manual statistical analysis while enhancing the accuracy and precision of the laboratory. To read more about the multi-rule features of Acusera 24-7, take a look at our educational guide – *Understanding QC Multi-rules*.

Utility of Advanced Statistics in Acusera 24·7

Enhanced Accuracy: By providing robust statistical tools, Acusera 24·7 aids laboratories in achieving high accuracy levels, crucial for reliable patient diagnosis and appropriate treatment.

Regulatory Compliance: The advanced statistics not only support day-to-day operations but also ensure that laboratories comply with stringent regulatory requirements, helping them pass accreditation assessments with fewer complications.

Operational Efficiency: The automation and integration of statistical analysis into the QC process free up valuable resources, allowing laboratory personnel to focus on more critical aspects of patient care and lab management.

The advanced statistics capabilities of Acusera 24·7 are designed to empower laboratories to perform at their best, ensuring that every result reported is backed by rigorous statistical validation and is within the bounds of scientific and regulatory expectations.

Streamlining Laboratory Operations with Acusera 24·7

In conclusion, Acusera 24·7 QC data management software represents a transformative solution for laboratories seeking to enhance their quality control processes. By integrating advanced statistical tools, comprehensive reporting features, and robust data management capabilities, Acusera 24·7 ensures that laboratories can achieve high standards of accuracy and efficiency, crucial for reliable diagnostics and patient care.

Summarising the Key Benefits:

Enhanced Quality and Accuracy: Through its sophisticated statistical analysis and interactive charts, Acusera 24·7 provides laboratories with the tools necessary to maintain high quality and accuracy in test results, which are vital for effective patient treatment.

Regulatory Compliance: With features designed to meet the stringent requirements of international standards such as ISO 15189:2022, and U.S. standards including CLIA and COLA, Acusera 24·7 facilitates easier compliance with accreditation guidelines, reducing the administrative burden on laboratory staff.

Operational Efficiency: By automating various aspects of the QC process, from data entry to report generation, Acusera 24·7 frees up valuable resources, allowing laboratory personnel to focus more on critical analytical tasks rather than routine data management.

Acusera 24·7 not only supports laboratories in managing day-to-day operations but also empowers them to face audits and accreditation assessments confidently. The software's ability to adapt to the evolving landscape of laboratory requirements makes it an indispensable tool for any laboratory committed to excellence in quality control and patient safety.

For laboratories looking to streamline their QC processes, reduce errors, and enhance operational efficiency, Acusera 24·7 offers a proven, innovative solution that aligns with industry best practices and compliance standards. Whether you are managing a single laboratory or a network of facilities, Acusera 24·7 delivers the reliability, scalability, and support needed to excel in today's fast-paced medical environments.

