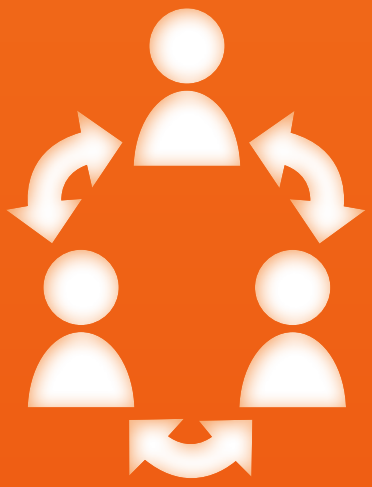
RANDOX

IMPORTANCE OF THIRD PARTY QUALITY CONTROLS



ACUSERA

IMPORTANCE OF THIRD PARTY QUALITY CONTROLS

In the clinical laboratory, Quality Control (QC) refers to the process of detecting analytical errors to ensure both the reliability and accuracy of patient test results. Poor performance can result in misdiagnosis, delayed/inappropriate treatment, increased costs and may even be potentially life threatening for the patient.

There are three types of control material available to laboratories:

1. Dependent / First Party Controls

Dependent controls refer to any control material that has been produced by the instrument or reagent manufacturer for use on a specific test system. Such controls are often manufactured from the same raw materials as the calibrator, making them less sensitive to subtle changes in performance.

As dependent controls are generally optimised for use with the manufacturer's test system, these controls can mask weaknesses, and therefore, are increasingly considered less effective than independent controls.

2. Semi-Dependent Controls

Semi-dependent control material, although produced independently of the instrument or reagent, is often supplied or recommended by the instrument/reagent manufacturer. It is this manufacturing relationship between the two that requires close scrutiny when considering if these controls are fit-for-purpose.

Although the control material is not produced by the instrument manufacturer, it is produced according to their exact specifications and therefore, optimised to work with a specific platform.

3. Independent or Third Party Controls

Independent or third party quality control material has not been designed or optimised for use with any instrument, kit or method. This complete independence enables the quality control material to closely mirror the performance of patient samples, and in doing so, provide an unbiased, independent assessment of analytical performance across multiple platforms.

THIRD PARTY CONTROLS

A table comparing the benefits of third party controls with dependent or semi-dependent controls can be seen below;

Third Party Controls	Dependent / Semi-Dependent Controls
True third party controls are manufactured independently of the reagent and instrument, delivering unbiased performance assessment.	Some manufacturers use the same raw material to manufacture both controls and calibrators, making first party controls less sensitive to performance changes.
The leading third party control manufacturers assign target values using data from thousands of independent laboratories, resulting in genuinely independent, multi-method, and multi-analyser data. The target values are, as a result, more accurate and reliable.	It is not uncommon for instrument/reagent manufacturers to assign their QC values using only a limited number of results generated on their own instruments, using their own reagents and calibrators. This can result in perceived accuracy, unrealistic wide ranges and batch to batch variability.
Some third party controls offer an extended shelf life of up to four years. This enables long term QC monitoring and the detection of shifts upon change of reagent batch. This can help laboratories save time and money due to fewer lot crossovers.	Laboratories using an instrument dedicated control will often receive a new lot of QC with each new batch of reagent, meaning they are constantly changing lot number and do not have the benefit of long term QC monitoring.

REGULATORY REQUIREMENTS

Third party controls are growing in popularity across the globe. More and more laboratories are beginning to use third party controls as part of their daily QC strategy. The benefits of such controls are widely accepted and recommended by both key opinion leaders and regulatory bodies in the field of Quality Control.

> **"Use of independent third party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer"**

ISO 15189:2012 Section 5.6.2.2

ISO 15189:2012 Medical Laboratories – Requirements for Quality and Competence

CASE STUDIES

The benefit of running third party controls in your laboratory cannot be underestimated. The following case studies highlight their many benefits and how they have helped laboratories across the world to provide more accurate and reliable test results.

Case Study One - Identifying Lot-to-Lot Variability with Third Party Controls

A laboratory in the UK contacted Randox Technical Services, reporting higher than expected QC results for Thyroglobulin. When using a third party control (Acusera Immunoassay Premium Plus) the results were four times higher on their main analyser compared to other systems. However, when they ran the instrument manufacturer's control alongside the third party control it did not show the same problem.

After reviewing EQA data, the Technical Services team confirmed there was a significant difference in results compared to other instruments, and set about helping the laboratory troubleshoot. After an exhaustive review of procedures and processes, the customer contacted the instrument manufacturer, who advised of a positive bias with several batches of reagent, including the batch the laboratory was using.

Conclusion: By using a third party control the laboratory was able to detect a shift in results after changing reagent batch that the instrument manufacturer's control did not.

Case Study Two - Overcoming Instrument Errors with Third Party Controls

A laboratory using the Acusera Assayed Chemistry Premium Plus control contacted Randox Technical Services after observing a consistent negative bias for ALT which was not replicated by the instrument control. They had previously contacted their instrument manufacturer who advised that the problem was with the control and not the reagent or instrument.

Randox investigated the problem and demonstrated that patient results were also wrongly reported low. This later led the instrument manufacturer to recommend a wash stage to eliminate any interference.

Conclusion: The use of a third party control in this instance enabled the identification of a procedural error with the instrument that the recommended control did not.

ACUSERA THIRD PARTY CONTROLS BENEFITS

The Acusera range of true third party controls contains more than 390 routine and esoteric parameters. With an extensive product portfolio, our range of third party quality controls help laboratories deliver trustworthy results time and time again.

Commutability

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

Accurate Target Values

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

Shelf Life

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

Consolidation

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

Clinically Relevant Levels

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

Flexible Options

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

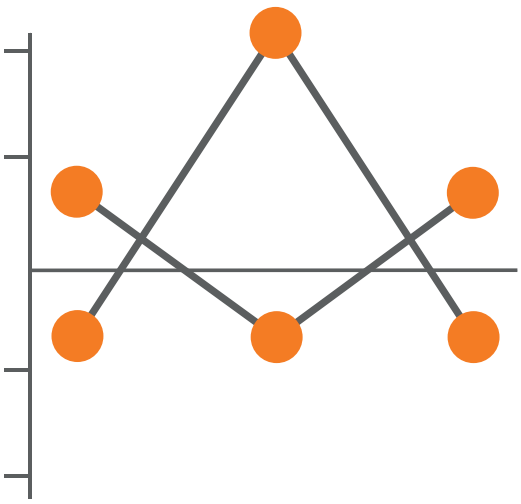
ACUSERA 24•7 Interlaboratory Data Management

Designed for use with the Acusera range of third party controls, the Acusera 24•7 software helps laboratories monitor and interpret their QC data. Access to an impressive range of features, including interactive charts, the automatic calculation of Measurement Uncertainty & Sigma Metrics and live peer group data generated from our extensive database of laboratory participants, ensures Acusera 24•7 is the most comprehensive package available.

- Advanced statistical analysis with automatic calculation of performance metrics including; Sigma, UM, TE & %Bias.
- Instantly discover how you compare to your peers with peer group statistics updated live in real-time, reducing time and money spent troubleshooting.
- Interactive charts allowing you to add events and multiple data sets for quick and easy performance monitoring.
- Automated data import with bi-directional connection to LIMS (eliminating manual data entry).

Software Features

Dashboard | Result History | Interactive Levey-Jennings Charts | Interactive Histogram Charts Performance Summary Charts | Statistical Analysis Report | Statistical Metrics Report Uncertainty of Measurement Report | Exception Report | Peer Group Statistics | Acusera Advisor Audit Trail Report



'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

RELATED PRODUCTS

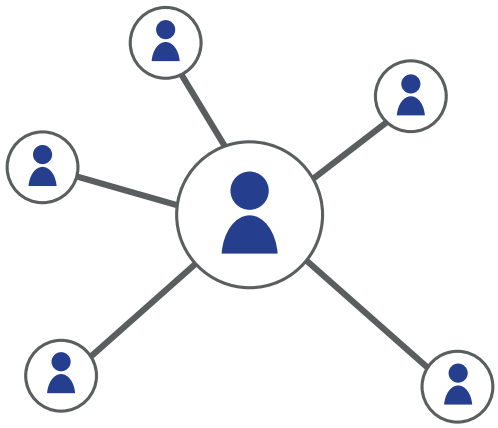
RIQAS Randox International Quality Assessment Scheme

Boasting over 55,000 participants and more than 360 parameters across 37 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 you 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.
- 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 | Cardiac Plus | Cerebrospinal Fluid (CSF) Clinical Chemistry | Coagulation | CO-Oximetry | CYFRA 21-1 | Cytokines | ESR Glycated Haemoglobin (HbA1c) | Haematology | Human Urine | Immunoassay | Immunoassay Speciality 1 Immunoassay Speciality 2 | Immunosuppressant | Lipid | Maternal Screening | Neonatal Bilirubin Serology (EBV) | Serology (HIV/Hepatitis) | Serology (Syphilis) | Serology (ToRCH) | Serum Indices Specific Proteins | Sweat Testing | TDMs | Trace Elements in Blood | Trace Elements in Serum Trace Elements in Urine | Urinalysis | Urine Toxicology



With over 55 ,000 lab participants, peer group numbers are maximised ensuring availability of data for a wide range of instruments and methods.

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

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QUALITY CONTROL

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