

## Improving Laboratory Performance Through Quality Control

Five simple steps for QC success



### Which QC is the Right QC?

Ask the Right Questions to get the Right Answers

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

## Which QC is the Right QC?

Anyone working in a laboratory will understand the importance of quality control (QC). QC is the process used to detect errors in order to ensure the reliability and accuracy of patient test results. Without QC, laboratory errors could go unnoticed potentially resulting in misdiagnosis and inappropriate or delayed treatment, all of which could be life-threatening for the patient.

When running internal QC, laboratories need to be assured of the accuracy of the results produced and, to ensure this, they need to have confidence in the QC materials they are using.

ISO 15189:2012 states that:

***“The laboratory shall use quality control materials that react to the examining system in a manner as close as possible to the patient samples. The laboratory shall choose concentrations of control materials, wherever possible, especially at or near clinical decision values, which ensure the validity of decisions made. 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.”***

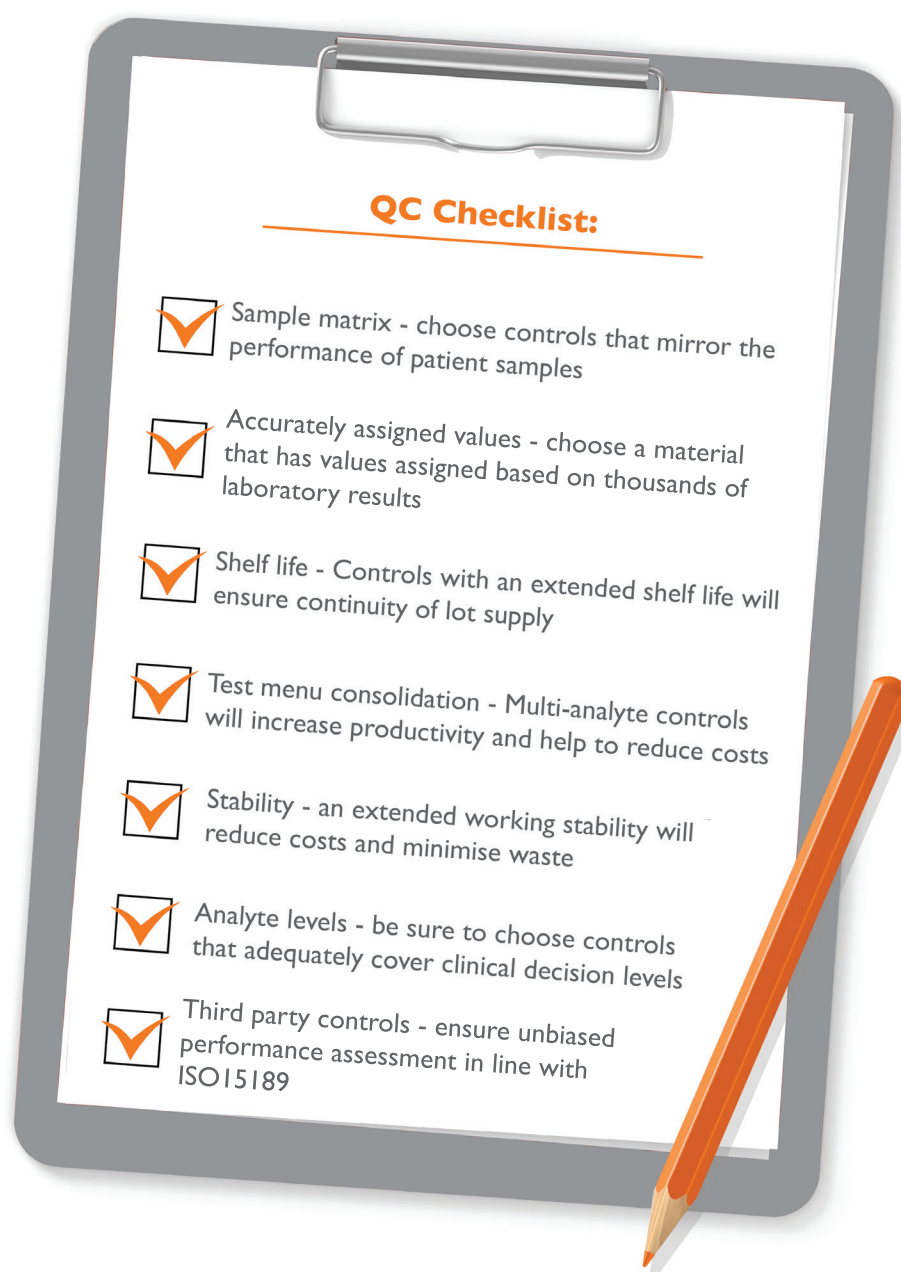


This document explores the different types of quality control products available and draws conclusions about what best meets ISO15189:2012 requirements.

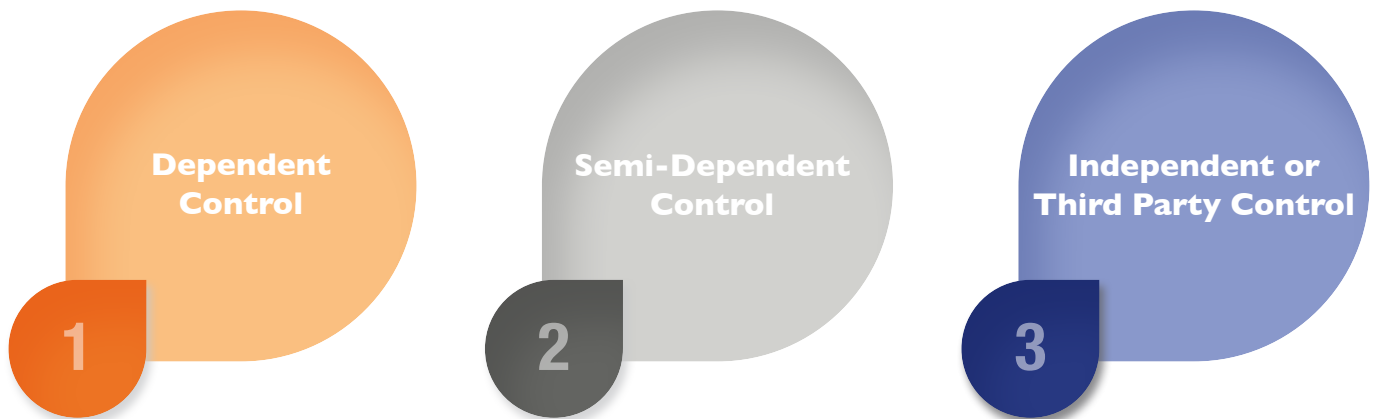
QC material is tested by laboratory staff in the same way a patient sample is. The results are then used to validate whether the test system is operating within the pre-defined specifications. If QC results fall outside the pre-defined limits this infers that there may be a problem with the test system or equipment, that could lead to the release of inaccurate patient results.

QC products are patient-like materials usually made from human serum, urine, or in some cases, spinal fluid. Control products can be liquid or freeze-dried (lyophilised) and are either assayed, where target values and ranges for the test results are pre-defined by the control manufacturer, or unassayed, where the laboratory has to define their own target values.

The validity of QC results largely hinges on the reliability of the QC material in use. When deciding on which type of control product to trust it is important to be aware of the different types of material available on the market.



There are three types of control material available:



***Dependent Control***



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 manufacturer's test system, these controls can mask weaknesses, and therefore, are increasingly considered less effective than completely independent controls.

***Semi-Dependent Control***



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.

In many cases 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. For example, if an instrument has known precision issues at lower concentrations, control material can be manufactured at higher levels, thus masking any issues.

As semi-dependent controls usually carry product labelling that is different from the instrument or reagent some laboratories may unwittingly be using semi-dependent controls. In doing so, weaknesses and errors may go unnoticed.

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## Independent or Third Party Control

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.

This is a fact that is recognised by regulatory bodies and standards around the world, and is corroborated in ISO 15189. The Clinical and Laboratory Standards Institute (CLSI) sums it up in the following statement:

***“Quality control materials should be different from the calibrator materials to ensure that the QC procedure provides an independent assessment of the measurement procedure’s performance in its entirety, including the procedure for calibration of the measurement.”***

Independent Third Party Controls	Versus	Dependent/Semi-Dependent Controls
True third party controls are manufactured independently meaning they give totally unbiased results.		Some manufacturers use the same raw material to manufacture both controls and calibrators, making the 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. The same is true for semi-dependent controls.
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 'in-kit' control will receive a new lot of QC with each new batch of reagents meaning they are constantly changing lot number and do not have the benefit of long term QC monitoring.

## **Case Studies**

The following real-life laboratory case studies highlight the importance of third party controls and how they can be used to help identify instrument, reagent and procedural errors. If errors remain undetected they could result in incorrect patient results, misdiagnosis, unnecessary treatment, increased costs and may even be potentially life threatening for the patient.

For more information on the benefits of third party controls visit [randoxqc.com](https://randoxqc.com).

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### **Identifying Lot-to-Lot Variations 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 Control) 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 the EQA data, the Technical Services team confirmed there was a significant difference in results between the 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.**

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### **Overcoming Instrument Errors with Third Party Controls**

A laboratory using a third party chemistry control contacted Randox Technical Support after observing a consistent negative bias for ALT. The instrument manufacturer advised the laboratory that it was a control problem and recommended they use a control from another manufacturer.

Randox investigated the problem and demonstrated that patient results were also being wrongly reported low. When Randox ran the test using the control recommended by the instrument manufacturer it failed to highlight the problem. The instrument manufacturer later recommended a wash stage to the customer which eliminated the carryover interference which was causing the low ALT results.

#### **Conclusion:**

**The customer overcame this problem by programming in an extra wash cycle. However, had the lab used the QC recommended by the instrument manufacturer they would never have identified the problem in the first instance and would have continued to report inaccurate patient results leading to possible patient misdiagnosis.**

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### **Identifying Procedural Errors using Third Party Controls**

A laboratory, using the Randox Immunoassay Premium Plus Control, reported that their QC results for Sex Hormone Binding Globulin (SHBG) were much higher than the target value provided. When the lab ran the reagent manufacturer's control the results were within the supplied ranges.

After reviewing the reagent kit insert the Randox Technical Services team noticed that the instrument the laboratory was using automatically diluted patient samples but not controls. Lab staff were unaware of this and had not been diluting the controls.

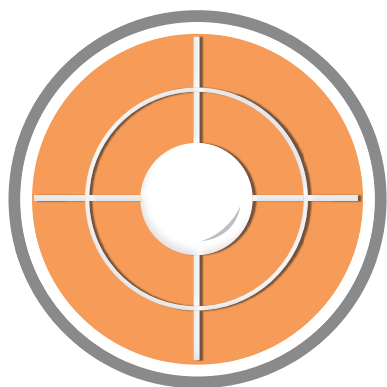
#### **Conclusion:**

**By using third party controls, a procedural error was identified that the reagent manufacturer's control was masking. Good laboratory practice is when a quality control material is run in the same way as a patient sample.**

## Acusera Third Party Controls

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The Acusera range of true third party controls is extensive, covering over 390 routine and esoteric parameters. All controls are designed to deliver unbiased performance assessment with any instrument or method.



### Accurate Target Values

Randox controls have the most accurately assigned target values and ranges on the market. This is made possible through access to a unique database of over 31,000 laboratory participants.



### Consolidation

With Randox multi-analyte QC, you can dramatically reduce the number of controls used in your laboratory and save money by replacing multiple instrument specific controls with a single multi-analyser product.



### Highest Quality Material

Randox controls are the most commutable available providing a matrix that reacts to the examining system in the same manner as a patient sample. Our lyophilised controls contain no added preservatives or stabilisers which can cause interference.



### Unrivalled Stability

Randox lyophilised controls have a shelf life of up to four years enabling long term QC monitoring. The extended working stability of Acusera controls means they meet and often exceed the stability claims quoted.



# RANDOX

## QUALITY CONTROL

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## ACUSERA ©

### True third party controls offering complete test menu consolidation

Uniquely combining more than 100 parameters 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.



## ACUSERA 24•7

### Online QC software with real-time peer group statistics

Compatible for use with the Acusera range of third party controls, the Acusera 24•7 software is designed to help laboratories monitor and interpret their QC data. Access to an impressive range of features including interactive charts and real time peer group data generated from our extensive database of laboratory participants, ensures Acusera 24•7 is the most comprehensive package available.



## RIQAS 🌐

### The largest global EQA scheme with over 31,000 lab participants

Comprising over 360 routine and esoteric parameters in 24 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 comprehensive yet user-friendly reports.



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