

RANDOX

EDUCATIONAL GUIDE

Commutability



QUALITY CONTROL

Commutability

Approximately 70% of all clinical decisions are based on laboratory test results reinforcing the need for quality throughout the laboratory. Poor laboratory quality can lead to unreliable test results ultimately leading to misdiagnosis, inappropriate treatment and may even impact on the quality of life for the patient. With this in mind we need to ask ourselves “*just how important is quality to a laboratory?*” – The answer to this question should always be very.

Why use Commutable Controls?

One important factor to consider when talking of quality is what samples your laboratory is currently using. When undergoing analysis it is extremely important that quality control material reacts in a similar manner to that of a patient sample. Over recent years there has been a general misconception that variation in QC results when changing reagent batches is common, however this is not always the case with patient samples and thus shouldn't be overlooked for quality control samples. It is essential that the quality control material you choose is fit for purpose. A good QC material has many essential properties but above all, controls must perform consistently and reflect the performance of patient samples - if a control meets these requirements then we can say it is commutable.

Laboratories rely heavily on quality control to detect errors in their test system and to ultimately make critical decisions regarding the accuracy and reliability of patient test results, therefore highlighting the need to use commutable quality controls in your laboratory.

The value of commutable control materials is internationally recognised, ISO 15189:2012 states that laboratories must “use quality control materials that react to the examining system in a manner as close as possible to patient samples.”

Consequences for the Lab

The effect of non-commutable controls is most apparent after changing reagent batch. Most laboratories will have noticed control values shifting in response to a reagent batch change, resulting in a frequent and frustrating need to re-assign their means. This value assignment process is not only time consuming but costs can be significant considering the extra use of reagent, control material and other consumables. The use of commutable quality controls may

reduce the need for additional assignment work therefore reducing costs and time.

An easy way to check if a control material is commutable is to test it alongside a set of patient samples. Any trends or shifts in patient sample results should be reflected by the QC samples.

Our Controls

At Randox we take quality seriously, that's why all QC products are manufactured to the highest possible standard, delivering controls of unrivalled quality. Designed to be

commutable, the Acusera range will ensure accurate and reliable instrument performance while simultaneously helping laboratories to meet ISO 15189:2012 requirements.

Case Study

The following real life case study demonstrates how Randox may reduce unnecessary shifts in QC values when reagent batch is changed.

A laboratory running a competitors 3rd party Microalbumin QC noticed shifts in their QC values whenever they changed reagent batch. They tested two levels of quality control over three different batches of reagent the results can be seen in the table below.

Competitor Control - Microalbumin		
Reagent Batch	QC Level One	QC Level Two
1	19.9	81.0
2	29.7	90.5
3	50.4	122.4

As can be seen from the findings above, Microalbumin results shifted significantly each time they changed reagent batch. This was the case for both the level one and level two control however when the lab tested the same set of patient samples across the three reagent batches results were consistent and did not show the same shifts.

The laboratory decided to contact Randox and ask about our Microalbumin controls. They were concerned about the shifts seen with their current supplier and highlighted the

fact they were no longer confident in the results they were releasing. This led to them trialling the Randox liquid ready-to-use Microalbumin control with the same three reagent batches they tested previously.

Having tested two levels of the Randox control over the same three reagent batches the laboratory reported to us that their results were back on track and they were delighted with the outcome! The results of the Randox control can be seen in the table below.

Randox Control - Microalbumin		
Reagent Batch	QC Level One	QC Level Two
1	33.5	158.8
2	34.9	164.9
3	34.8	168.0

The difference seen with the Randox control across the three reagent batches was much smaller than that of their previous control and was in line with the changes seen with their patient samples.

This case study highlights the commutability of the Randox QC range. By using a control with a matrix that reacts to the test system in the same manner as the patient sample the laboratory was confident in the patient test results produced and were able to meet ISO 15189:2012 requirements.

Conclusion

Many of Randox's controls can be trusted to be 100% human. Our extensive range of Acusera true third party controls contain over 390 routine and esoteric analytes. All our controls are designed to help accurately and reliably

identify performance issues and weaknesses with a testing system as well as allowing laboratories to be confident that their patient sample testing is correct.

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