RANDOX

EDUCATIONAL GUIDE

Designing an Appropriate QC Procedure

QUALITY CONTROL

Designing an Appropriate QC Procedure

It is easy to get caught up in an abundance of QC statistics and forget the fundamental reason why QC exists in the first instance. QC is about detecting errors and ensuring that the results you produce are accurate and reliable. All QC procedures should focus on reducing the risk of harm to the patient. We are not examining statistics; we are examining real patients, real results and real lives. Around 70% of all medical decisions are based on laboratory results, which is why it is of utmost importance that each and every laboratory, has a well-designed QC procedure in place.

An effective QC strategy is not as complicated as you might think, it does not require you to become an 'advanced mathematician'. If you stick to these five simple steps you can be assured that you are releasing quality QC results.

5 Simple Steps for QC Success

1. Identify the quality specifications for the test
2. Choose good quality control materials
3. Start and end patient testing with a QC evaluation
4. Ensure you know the characteristics of good QC results
5. Ensure you are able to recognise and troubleshoot an out-of-control event

1. Identify The Quality Specifications For The Test

- Not every test performs the same
- Not every test needs to perform the same
- Give poor-performers and high risk tests more QC attention

Not every test in the laboratory performs the same way. Some tests for example are the well-known, well liked, laboratory "goodperformers, always showing excellent recovery rates. However, other tests such as the laboratory "poor-performers", show a lot more inconsistencies in performance, and can often be slightly more problematic and frustrating.

"It's important that you know which tests are your well performing tests and which are your poor performing tests."

You can identify which tests generally perform better, through monitoring your precision over time, via method validation and comparing your performance to peers through either an EQA scheme or through a peer-group reporting software. Using this differentiation, afford your "poor-performer" QC tests, a little more QC attention. Run QC more frequently and monitor the results closely, to ensure that they are both accurate and reliable.

It is also important to remember that not every test needs to perform the same. Some tests, compared to others, have a little more scope for error before they have an impact on patient care. It is therefore important to ensure that you identify the important "high risk tests". Any tests that have one or more of the following characteristics, should be considered high risk:

- A test where there could be a detrimental consequence, should the wrong result be released
- A test that supports the clinicians decision in isolation
- A test that is acted upon immediately
- A test that is performed on a specimen that is difficult/painful to collect

Additionally, make sure you take note of the CLIA analytical quality requirements, to identify the quality specifications of particular tests. For any test that you identify as high risk, make sure you run QC more frequently and play close attention to your QC results.

2. Choose Good Quality Control Materials

The effectiveness of any QC procedure is underpinned by the quality of the control materials that you choose to use. ISO 15189 recommends that the:

> "laboratory shall use quality control materials that react to the examining system in a manner as close as possible to patient samples".

It is important to note that differently manufactured QC material, will not perform in the same way. It is of utmost importance that you choose the best quality material available on the market, as you may otherwise be putting patients at risk.

Look out for the following qualities in your QC material:

• Have accurately assigned values; the narrower the control ranges used, the more efficient you will be at assessing your performance. Unfortunately, many manufacturers assign their QC values based on only a handful of results, meaning that control ranges are far too wide to monitor performance effectively. Choose materials that have assigned values based on thousands of laboratory results.

• QC material that is "as close as possible to a patient samples"; as recommended by ISO 15189; In order to behave and react like a patient sample, the material needs to be in a matrix similar to a patient's as this will allow the best assessment of performance. Look out for materials that are described as 100% or fully human and look out for lyophilised products that are free from any artificial materials and preservatives. Many manufacturers describe their material as "human-based", as these materials contain components of animal origin and will not be "as close to a patient sample" as possible. This is particularly important for anti-body based tests. Make sure you check your QC kit insert to ensure you are using 100% human material and that your lyophilised material is free from preservatives.

• A format suitable for use; QC materials come in lyophilised, liquid-frozen and liquid ready-to-use formats. Lyophilised materials are great for hotter climates. Liquid frozen and liquid ready-to-use samples, eliminate the chance of reconstitution errors, with liquid ready-to-use samples requiring the least effort for preparation, saving you time and making them ideal for point of care testing.

• Are they third party materials; ISO 15189 recommends the "use of independent third party control materials". Third party materials offer many advantages, enabling an unbiased assessment of performance that can be used on all instrument platforms.

• Cover the full clinical range; ISO 15189 recommends that the "laboratory should choose concentrations of control materials, wherever possible, especially at or near clinical decision values, which ensure the validity of the decisions made".

• Match their stability claims; Many manufacturers, in an attempt to make their material 'look better', give inaccurate stability claims and often give different stability claims for different analytes in the material. Don't forget that a QC material is only as stable as its least stable analyte. Make sure your QC manufacturer is being honest about their stability claims and avoid those who make different stability claims for different analytes in the same sample.

3. Start And End Patient Testing With A QC Evaluation

Make sure you are testing patient samples in "batches" and are starting and ending patient sampling with a QC evaluation. If you only run QC every morning and one morning you find that your QC is out of range, you may be unaware as to whether the malfunction occurred the previous day or not. Your staff will have to troubleshoot, without knowing if the previous days results have been affected or not, by re-running samples, perhaps unnecessarily.

Running QC at the end of the day, assures you that that day's results are not affected, saving you a lot of time and money! If your lab runs in 24hr operation, make the time between QC evaluations shorter than the time needed to correct erroneous results, as this is the most cost effective strategy for your lab. Additionally, ensure that you know the number of patient results between QC evaluations, as this will help you ascertain the number of patients at risk, should an out-of control event occur.

4. Ensure You Know The Characteristics Of Good QC Results

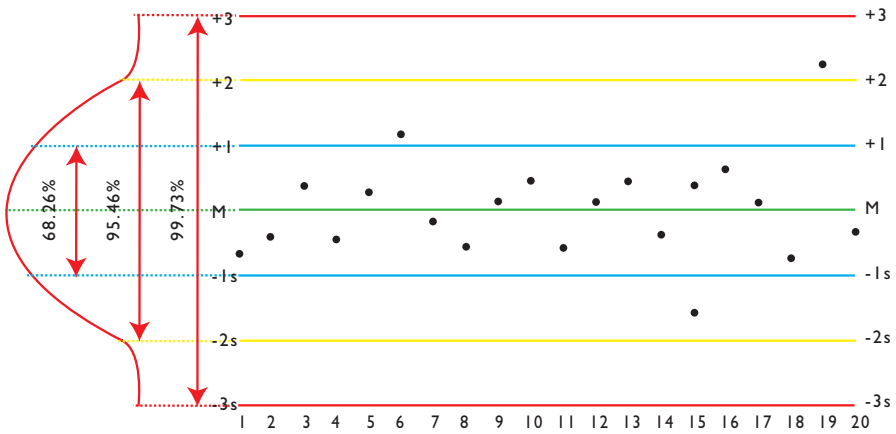
In order to recognise a "bad" result, it is important that you are able to recognise the qualities of a "good" set of QC results. In an ideal world, the characteristics of good/normal QC results on a Levey-Jennings chart should;

- Fluctuate randomly around the mean for comparison. There should be an equal number of results above the mean as below the mean
- Very rarely exceed 3SD; 3 in every 1000 results should be outside 3SD
- On the whole be within 1SD
- On Occasion exceed 2SD; It is normal for 1/20 results to exceed 2SD

It is important to keep these normal characteristics in mind when examining your QC results, to ensure you are not falsely rejecting acceptable results. Ensure you are maintaining a record of your QC results, to evaluate over time, the norm for your laboratory.

There are various QC management software packages available on the market, that make monitoring your QC results easy. Some QC management software packages also have functionality that allows you to compare your results to other laboratories, using the same system as yourself. Knowing that you are comparing well to others, provides you with confidence that your results are in fact good/ normal. Look out for software that allows:

- Multiple instrument registrations
- Results to be entered online, anywhere, any time
- Real time monitoring of peer group data. Ideally peer group data should be updated daily
- Interactive charts such as Levey-Jennings and Histogram charts
- Different user level accounts so that lab managers can keep trace of the entering and acceptance of results
- User defined multi-rules, to be applied to QC results, so that results can automatically be rejected or accepted



5. Ensure You Are Able To Recognise And Troubleshoot An Out-Of-Control Event

- The most effective way to recognise errors is to use QC multi-rules
- Participate in a ISO 17043 accredited EQA scheme to help recognise errors
- Make sure you estimate the magnitude and size of the out of control event, before you correct it

There are various approaches for recognising possible out-of-control events. Some labs use a single rule and other labs opt to use QC multi-rules. It is important for whatever rule(s) you use, that you are able to identify errors quickly and effectively, without falsely rejected results, wasting time and money. It is also important that you choose assayed QC material that has tight ranges or conversely assign the ranges yourself to ensure you have effective error detection.

Recognising out-of-control QC results using a Single rule

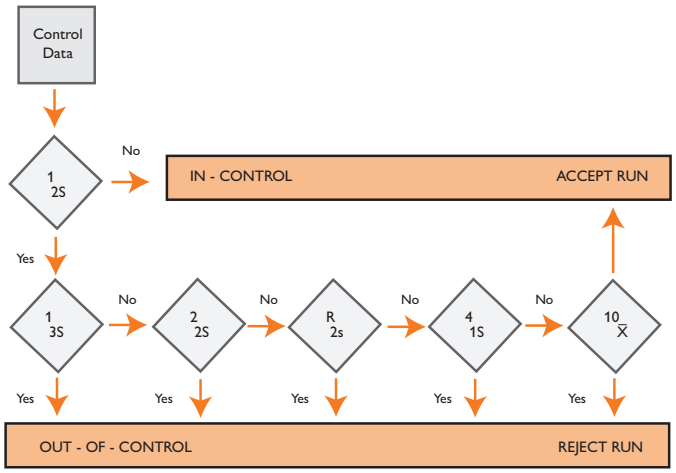
A laboratory favourite is the 1 result outside 2SD rule. This is a great rule for alarming possible out-of-control events, however, you must be careful as it does have a high false rejection rate. Remember, it is normal for 1/20 results to be outside 2SD! It is important that you also consider the strategy you use when you have a result outside 2SD. Avoid the "repeat, repeat, repeat… got lucky!" tactic. This is not an effective error detection method, as if 2/3 results exceed 2SD you may have a problem at hand that is worth investigating further. In short, be careful when using 1 result outside 2SD rule and ensure that if you do repeat, you do so only once!

Another single rule that is sometimes used, is when 1 result is outside 3SD. This rule has a very low false rejection rate. Remember only 3 in 1000 results should be outside 3SD. However, this is not the best rule for sensitive error detection. This rule ideally shouldn't be used in isolation.

Recognising out-of-control QC results using Multi-rules

Using a combination of multi-rules is the most effective way of recognising out-of-control events. Applying multi-rules means that you will have a high rate of error detection, whilst maintaining a low rate of false rejection. This means you will run less unnecessary repeats and waste less time carrying out unnecessary troubleshooting, in turn saving you money.

As a general rule, apply more multi-rules to poor-performer tests and high risk tests. With stable, good-performer, you can use less multi-rules. The diagram below summarises a variety of commonly used multi-rules.



Participate in an Accredited EQA Scheme

QC alone isn't sufficient for detecting errors and so you should participate in an IS0 17043 accredited EQA scheme. ISO 15189 states that the "laboratory should participate in interlaboratory comparison programmes". Not only will EQA help you detect errors, it will provide you, the physicians and patients you supply results to, confidence and evidence that you are releasing accurate patient results.

Troubleshooting Out-of-Control Events

Make sure you estimate the magnitude and size of the out of control event before you correct it. It's a good idea to take note and monitor your average patient mean or test a known patient sample. That way, you can measure the extent of the problem and the effect the out-of-control event has had on patient results. Measuring the direction and magnitude of the shift in results, can help you decide whether any clinical significant errors may have occurred and whether or not you need to repeat the patient results.

When an out-of-control event has occurred, ISO 15189 requires laboratories to "evaluate the results from patient samples that were examined after the last QC event".

Ensure you know how many samples were run from the last QC event and do not release any patient results until the problem has been rectified.

Conclusion

Armed with these 5 simple steps, you can be assured that you are on the way to producing an effective and simple QC strategy, reducing the risk of harm to your patients. Remember that you do not need to become a statistician to design effective QC procedures.

Improvement in your QC procedures simply requires the desire and determination to take incremental steps. With each step you take, the next step becomes easier and you will soon reach your goal of QC success!

ACUSERA True third party quality controls

As a world leading manufacturer of multi-analyte true third party controls, thousands of laboratories rely on Randox to accurately assess test system performance and ultimately empower them with the confidence required to release patient test results. With more than 390 analytes available, the number of individual controls required to cover your test menu is significantly reduced while simultaneously reducing costs, time and storage space. A choice of formats is available, including liquid or lyophilised, which ensures flexibility and suitability for laboratories of all sizes and budgets. Many features of the Acusera range can help you to meet ISO 15189:2012 requirements:

- Designed to react to the test system in the same manner as a patient sample, helping to reduce inconvenient shifts in QC results when reagent batch is changed and ultimately providing a true indication of laboratory performance.
- The presence of analytes at key decision levels ensures accurate instrument performance and eliminates the need for additional low/high controls at extra expense.
- Manufactured independently from any instrument, the Acusera range delivers unbiased performance assessment with any instrument or method, while eliminating the need for multiple instrument specific controls.

Product Portfolio

Antioxidants | Blood Gas | Cardiac Markers | Routine Chemistry | Coagulation | Haematology | Diabetes Immunoassay | Immunology | Lipids | POCT | Therapeutic Drugs | Toxicology | Urine Chemistry

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.

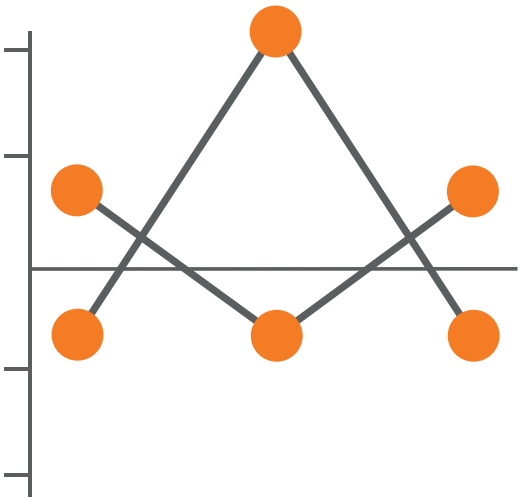
ACUSERA 24•7 Interlaboratory Data Management

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

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