RANDOX
QUALITY CONTROL

Improving Laboratory Performance Through Quality Control

Five simple steps for QC success

Troubleshooting QC Problems:

Your QC has failed, what do you do next?

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

Your QC has failed, what do you do next?

So you ran QC this morning and realised that one of your analytes has been flagged as "out-of-control", what do you do next? Do you ignore the warning and continue patient testing, repeat the control until it's within range or do you halt patient testing and investigate the source of the error?

When it comes to troubleshooting QC errors, unfortunately there is no easy path to take. However, it's important that you have standard operating procedures in place, outlining what to do in the event of an out-of-control error. Errors occur in laboratories all over the world. A lab with effective troubleshooting procedures in place will still have errors but will be able to detect them, quickly reducing their impact and reducing the risk of wasting both time and money.

Although there is perhaps no correct way to go about troubleshooting, here are some helpful tips that your laboratory can use in order to ensure it has effective troubleshooting procedures in place.

1. Put the problem into perspective before you begin troubleshooting

- **Outline what you recognise as an out-of-control event**
- **It's important to estimate the magnitude and size of the out-of-control event before you attempt to correct it.**

Using QC multi-rules is a great way to ensure sensitive error detection, whilst keeping the false rejection rate low. Make sure you outline what you recognise as an out-of-control event that warrants corrective action to take place. In the event that a series of QC multi-rules have been broken, you should halt patient testing immediately until the problem has been rectified. In the event that only a single rule has been broken, you should repeat the control ensuring you do so only once.

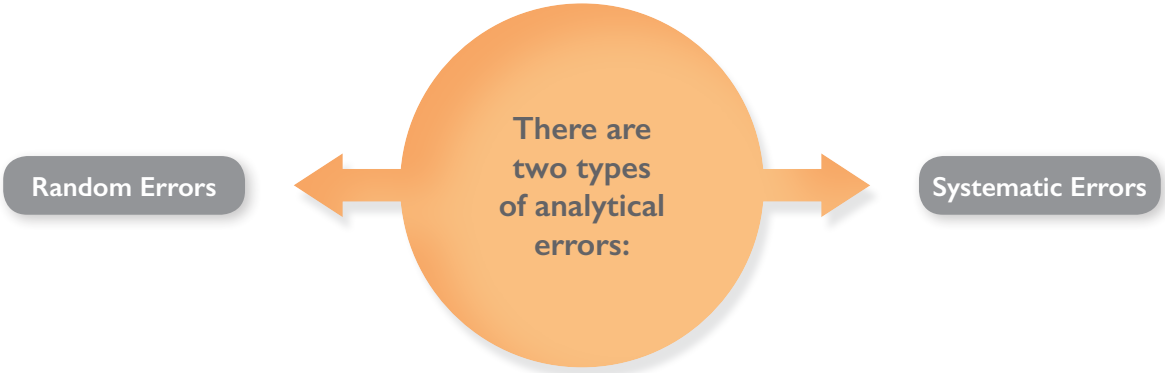
It's important to estimate the magnitude and size of the out-of-control event before you attempt to correct it. It's a good idea to monitor your average patient mean or test a known patient sample. That way, you can measure the extent of the problem and the effect the out-of-control event has had on patient results.

Measuring the direction and magnitude of the shift in results, can help you decide whether any clinically significant errors may have occurred and whether or not you need to repeat 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.

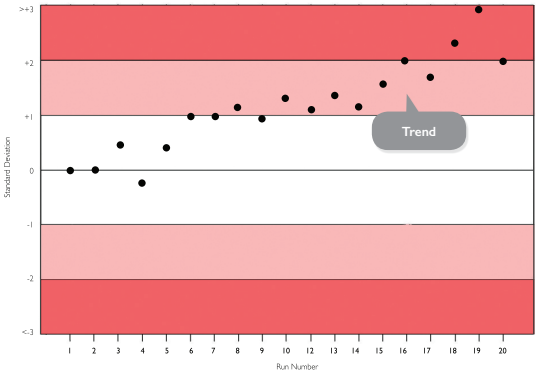
2. Review your Levey-Jennings charts to understand the type of error that has occurred

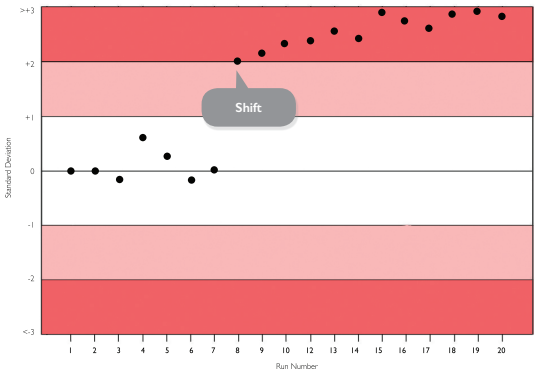


Both of these types of errors can be recognised on a standard Levey-Jennings chart and by using QC multi-rules. Identifying the type of error will help you relate the error to a possible cause.

Systematic Error

Systematic errors create a characteristic bias and can be identified by a change in the mean of control values. The change in the mean may be either a ***gradual trend*** or an ***abrupt shift*** in control results.

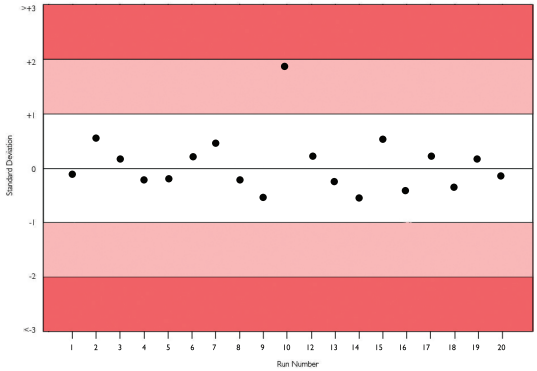




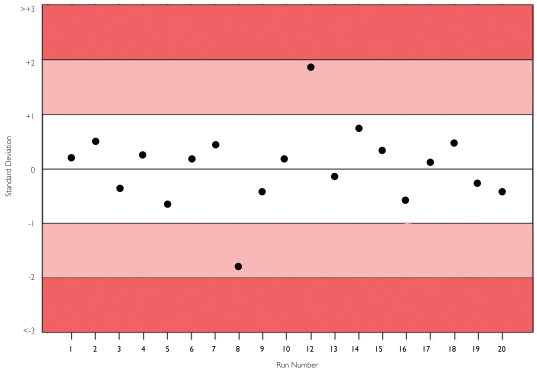
Random Error

Random errors vary in an unpredictable manner with regard to magnitude and sign. There will always be a degree of random error associated with any set of QC results. There is an acceptable and unacceptable amount of random error. Using QC multi-rules can help decide when the amount of random error in your test system has become unacceptable. It is acceptable for 1 in 20 results to be outside 2SD, anymore than this is an unacceptable amount of random error.

Acceptable amount of random error

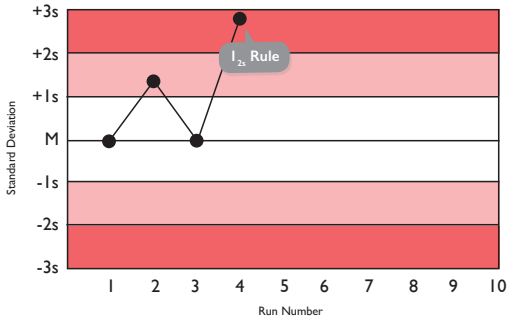


Unacceptable amount of random error



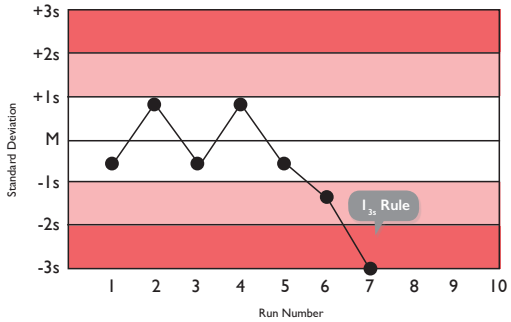
Using QC Multi-rules to Identify Systematic and Random Error

You can use QC multi-rules to differentiate between systematic and random error.



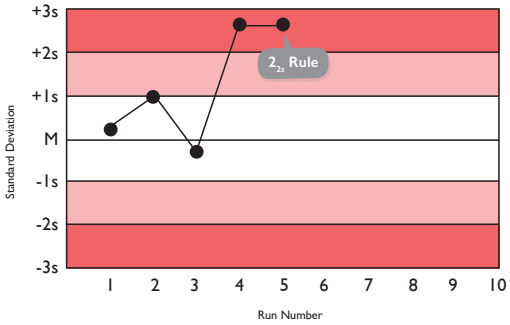
Rule 1_{2s}:

This is a warning rule that is broken when a single control observation is outside the +/-2s limits. This rule warns that either a random or systematic error is present in the test system. If no other unacceptable results are apparent in the test system, it must be assumed that this is simply a random error and no further troubleshooting action is necessary.



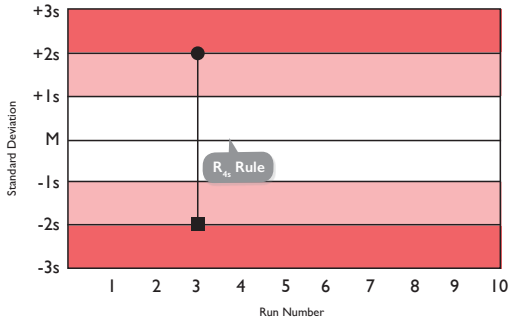
Rule 1_{3s}:

Any QC result outside +/-3s breaks this rule. This rule identifies unacceptable random error or possibly the beginning of a large systematic error. If this rule is broken, troubleshooting should occur to investigate the source of the error.



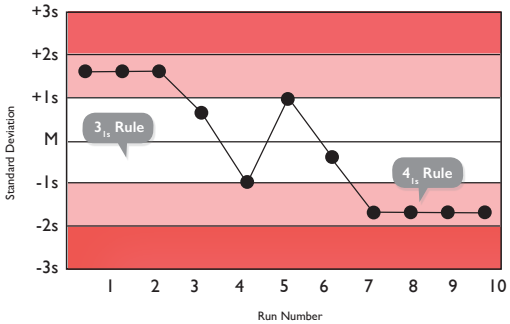
Rule 2_{2s}:

This rule is broken when two results are greater than 2s on the same side of the mean. It is indicative of systematic error. It could indicate the start of a trend or a shift in QC results.



Rule R_{4s}:

If there is at least a 4s difference between control values within a single run, this rule is violated and can represent random error.

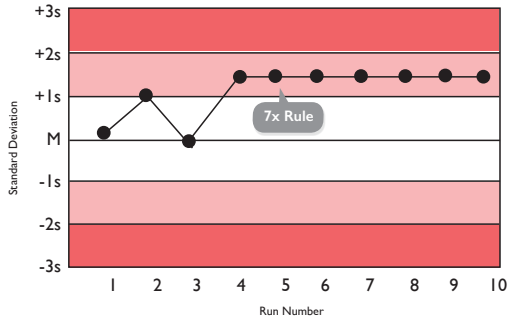


Rule 3_{1s}:

When three respective control results are greater than 1s and on the same side of the mean.

Rule 4_{1s}:

When four results are greater than 1s and on the same side of the mean. Both these rules are indicative of systematic error but don't necessarily require you to reject the analytical run. As long as this error is not clinically significant there is no need to troubleshoot this small amount of error. However, this analytical bias can be eliminated by performing calibration or instrument maintenance.



Rule 7X, 8X, 9X 10X and 12X:

These rules are broken when 7, 8, 9, 10 or 12 QC results are on the same side of the mean. This is indicative of a systematic error. Again, these rules don't necessarily require you to reject the analytical run. As long as the error is not clinically significant, there is no need to carry out any troubleshooting. However, this analytical bias can be eliminated by performing calibration or instrument maintenance.

3. Relate the type of error to possible causes

Ask yourself questions in order of likely relevance and review the most common solutions to the problem. Dependent on whether you have identified a systematic or random error in your system, this can help you determine the possible root cause of the error. See below for some common causes of systematic and random errors.

Systematic Error: *Shift*

1. Change or failure in light source
2. Major instrument maintenance
3. Failure in sampling system
4. Change in temperature
5. Failure in reagent dispense system
6. Change in reagent formulation
7. New reagent lot
8. Recent calibration
9. Change in calibration lot

Systematic Error: *Trend*

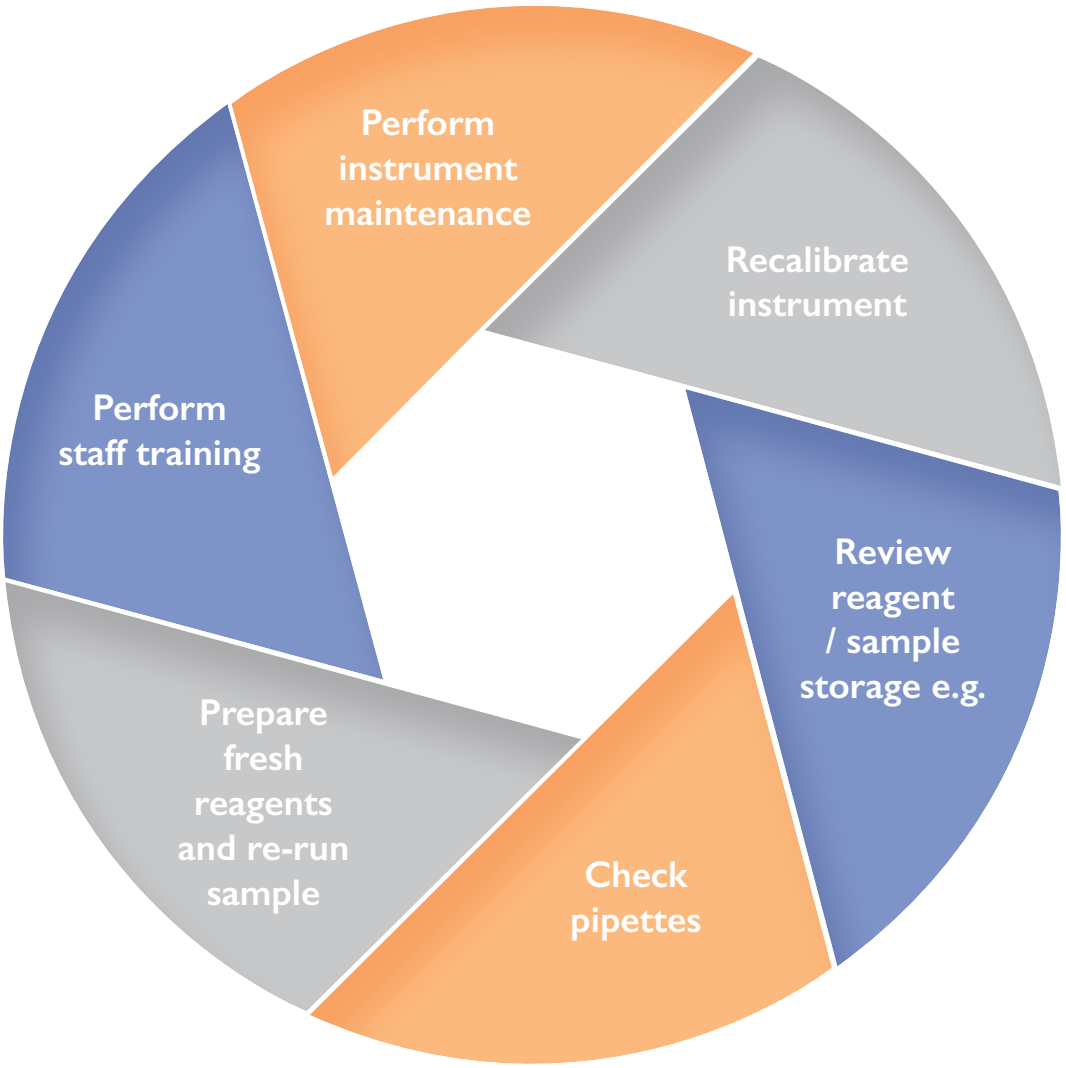
1. Slowly deteriorating reagent or control material
2. Calibration shift
3. Change in instrument temperature
4. Deteriorating lamp or filter

Random Error

1. Bubbles in reagent/sample syringes
2. Improperly mixed/dissolved reagent/control
3. Clog in pipette
4. Power supply fluctuations

4. Implement corrective actions, check the effectiveness of the corrective actions and document the solution

Once you have identified possible causes of the out-of-control event, implement any necessary corrective action. It's important that you implement only one change at a time and monitor the improvement of that change on your QC and patient results. It's important that you document the solution and learn from your previous laboratory failures. Put procedures in place to prevent any errors from reoccurring. Remember that a single unacceptable result is most likely due to random error. In this instance re-run the sample, if the result of repeat analysis is acceptable then corrective actions is not required. If the issue persists, investigate possible sources of systematic error. See below for some suggested actions that may help to resolve systematic errors:



In conclusion, make sure you have effective troubleshooting procedures in place. Keeping these few tips in mind will help assure your laboratory is on the right track when it comes to troubleshooting QC failures.

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Randox Laboratories Ltd, 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
☎ +44 (0) 28 9442 2413 🖷 +44 (0) 28 9445 2912 ✉ marketing@randox.com randoxqc.com

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