

RANDOX

EDUCATIONAL GUIDE
Troubleshooting QC Errors



QUALITY CONTROL

Troubleshooting QC Errors

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?

Your QC Has Failed, What Do You Do Next?

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
 2. Review your Levey-Jennings charts to understand the type of error that has occurred
 3. Relate the type of error to possible causes
 4. Implement corrective actions, check the effectiveness of the corrective actions and document the solution
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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

There are two types of analytical errors:

Systematic Errors

Random Errors

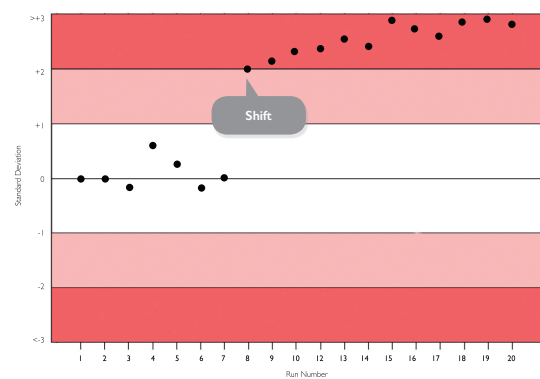
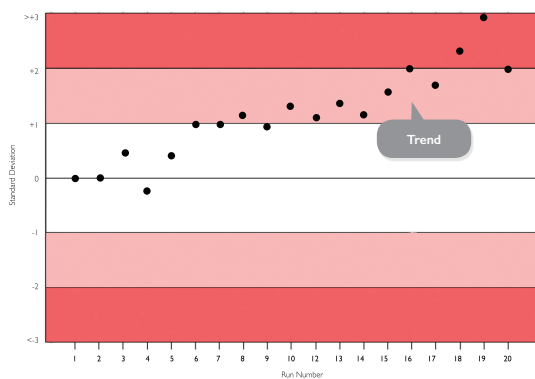
Both of these types of errors can be recognised on a standard Levey-Jennings chart and by using QC multi-rules.

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.

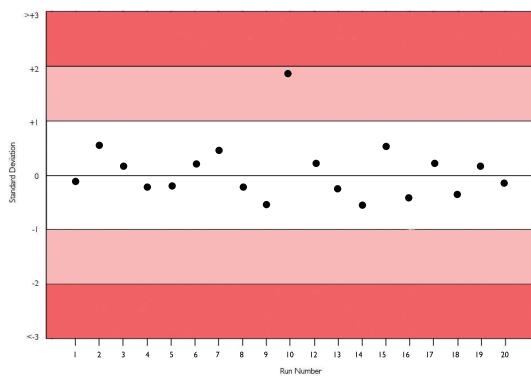


Random Error

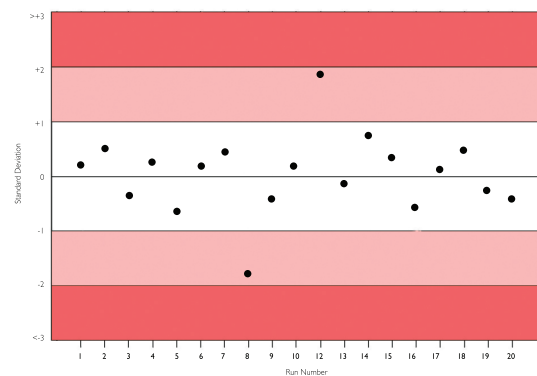
Random errors vary in an unpredictable manner with regard to magnitude and sign. There will always be a degree of random error associated with any set of QC results. There is an acceptable and unacceptable amount of random error.

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, any more than this is an unacceptable amount of random error.

Acceptable amount of random error

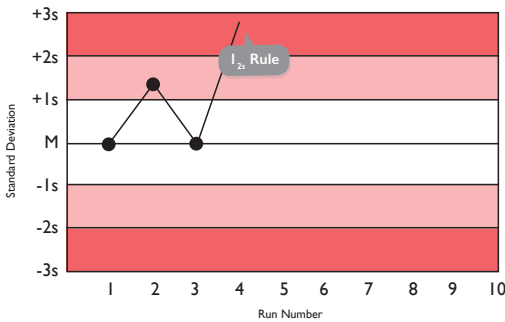


Unacceptable amount of random error



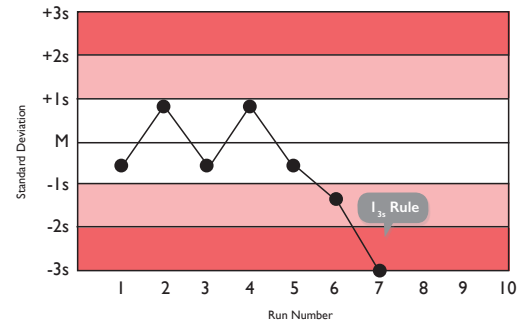
Using QC Multi-Rules To Identify Systematic & Random Error

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



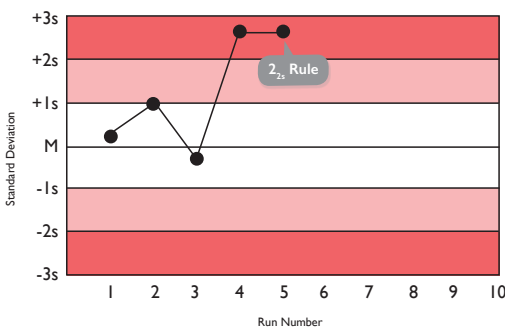
Rule 1_{2s}:

This is a warning rule that is broken when a single control observation is outside the $\pm 2s$ 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.



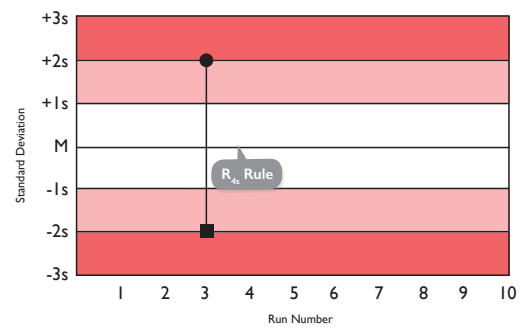
Rule 1_{3s}:

Any QC result outside $\pm 3s$ 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.



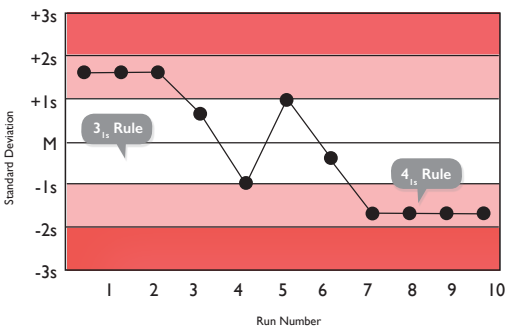
Rule 2_{2s}:

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.

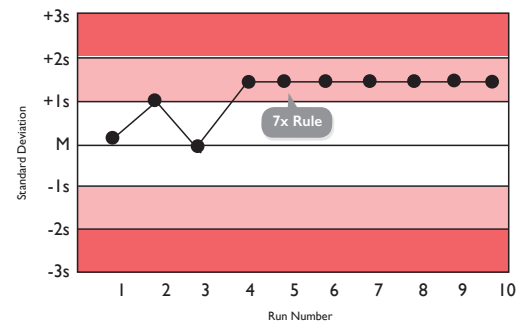


Rule 3_{1s}:

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

Systematic Error: *Trend*

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

Random Error

- | | |
|---|------------------------------|
| 1. Bubbles in reagent/sample syringes | 3. Clog in pipette |
| 2. Improperly mixed/dissolved reagent/control | 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:

- | | |
|---|---|
| 1. Perform instrument maintenance | 4. Check pipettes |
| 2. Recalibrate instrument | 5. Prepare fresh reagents and re-run sample |
| 3. Review reagent / sample storage e.g. | 6. Perform staff training |

Conclusion

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.

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.

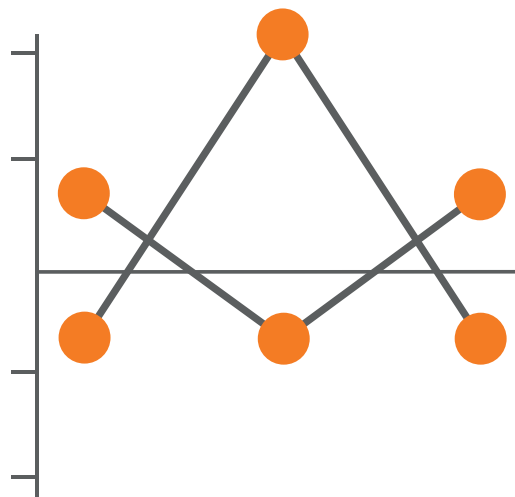
ACUSERA 24•7 Interlaboratory Data Management

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.'

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