RANDOX
QUALITY CONTROL

Improving Laboratory Performance Through Quality Control

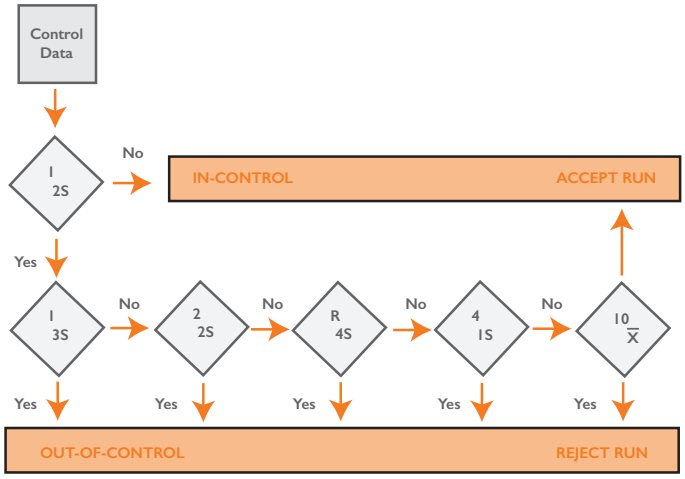
QC Multi-Rules

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

QC Multi-Rules

What are QC Multi-Rules?

Based on statistical process control, QC Multi-rules use a combination of control rules to decide whether an analytical run is in-control or out-of-control.



How to identify an out-of-control event using QC rules

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 alerting lab staff to 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 troubleshooting 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 more than one result exceeds 2SD you may have a problem at hand that is worth investigating further. In short, be careful when using the 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 exceeds 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 and ideally shouldn't be used in isolation.

Recognising out-of-control QC results using multiple rules

Using a combination of multi-rules is the most effective way of recognising out-of-control events. The application of multiple rules will give a high rate of error detection, whilst reducing false rejections. 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-performing tests and high risk tests. With stable, good-performing tests, you can use less multi-rules.

How to use QC Multi-Rules

QC Multi-Rules can be used individually or in combination to evaluate the quality of an analytical run. Combinations are selected by the laboratory depending on the quality required and the performance of each analytical method. The overall objective is to obtain a high probability of error detection and a low frequency of false rejections.

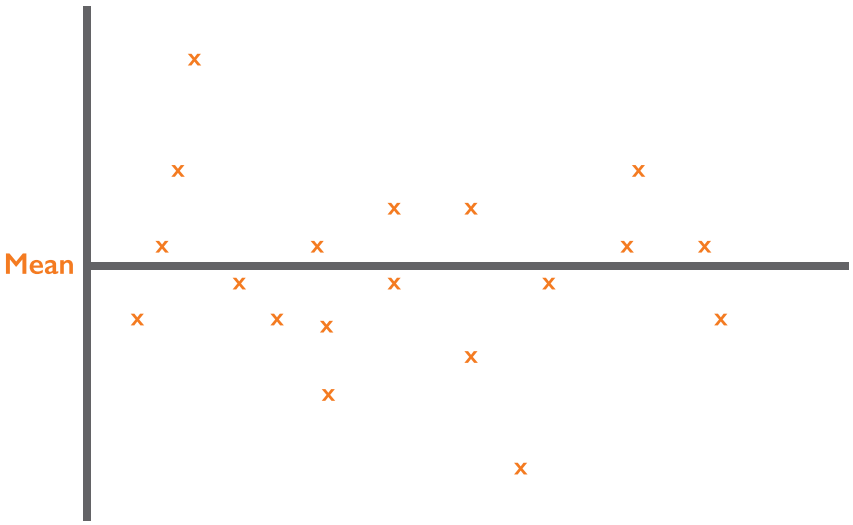
Types of Analytical Errors

QC Multi-Rules can be used to detect systematic or random errors. Recognising if you have either a systematic or random error can help you identify the source of the problem.

Random Errors

The characteristics of Random Errors are as follows:

- Error which varies in an unpredictable manner (in magnitude and sign) whenever a large number of measurements of the same quantity are made under effectively identical conditions.
- Difficult to eliminate but repetition can reduce the influence of random errors.



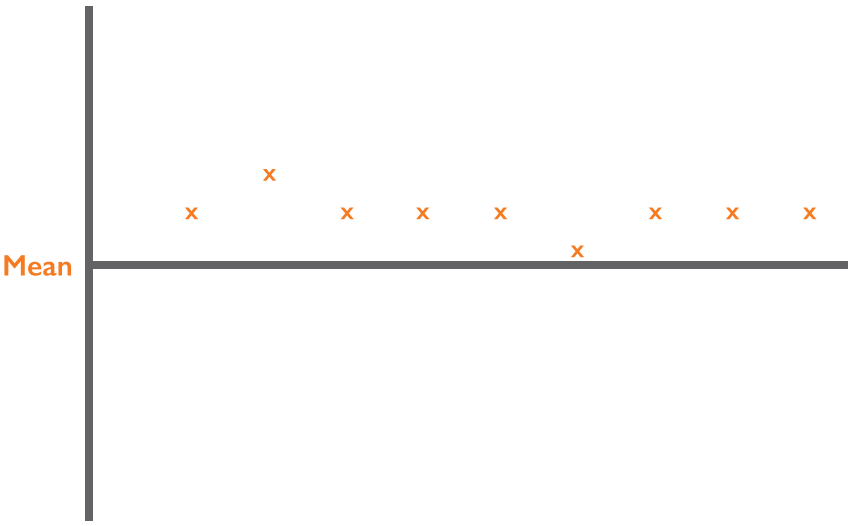
Possible sources of Random Errors include:

- *Power supply*
- *Pipetting technique*
- *Contamination*
- *Bubbles in reagent/sample pipette system*
- *Inappropriate storage*
- *Poor operator technique*

Systematic Errors

The characteristics of Systematic Errors are as follows:

- An error which remains constant when measurements are made under the same conditions or varies according to a definite law when conditions change.
- Create a characteristic bias in the test results and can be accounted for by applying a correction.



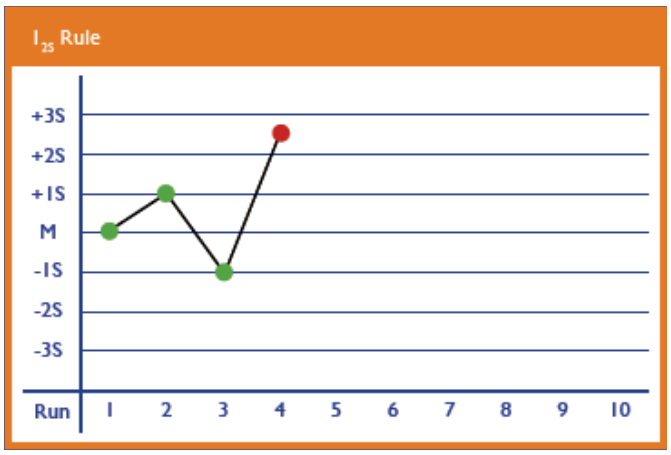
Possible sources of Systematic Errors include:

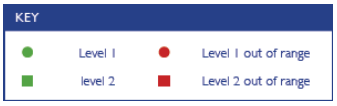
- *Deterioration of reagents, calibrator or controls*
- *Instrument may need recalibrated*
- *Poor calibration*
- *Accumulation of debris on the instrument sample/reagent pipettes*
- *Change of reagent batch or reagent formulation*
- *Instrument error or failure*

Explained QC Multi-Rules

There are 6 basic QC Multi-Rules. Some of these detect random error and some detect systematic error (which may indicate a bias in the system).

Rule 1_{2S} (1 result exceeds 2SD)



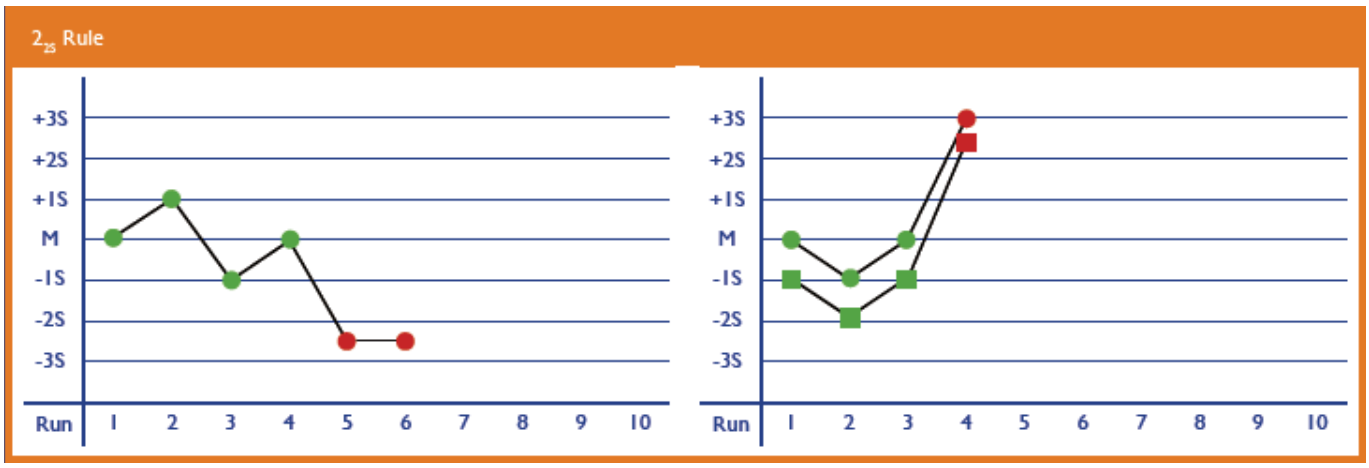


This rule is designed as a warning rule only. If a single QC result is more than ±2 standard deviations from the mean, this run along with previous analytical runs should be evaluated before accepting the run and reporting results. The 1_{2S} rule is designed to warn that random error or systematic error may be present. Using the 1_{2S} rule alone may lead to frequent rejection of valid runs (false rejections).

Rule 1_{3S} (1 result exceeds 3SD)

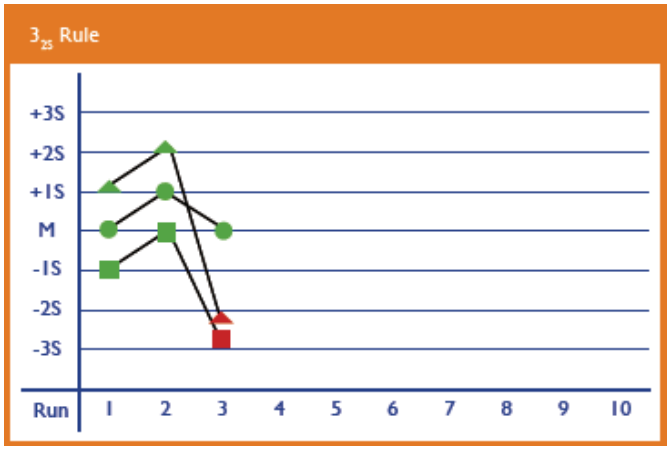
This rule is violated and a run rejected when a single QC result exceeds ±3 standard deviations from the mean. The 1_{3S} rule is applied within run only and is used to identify random error however may also indicate systematic error.

Rule 2_{2S} (2 results exceed 2SD)



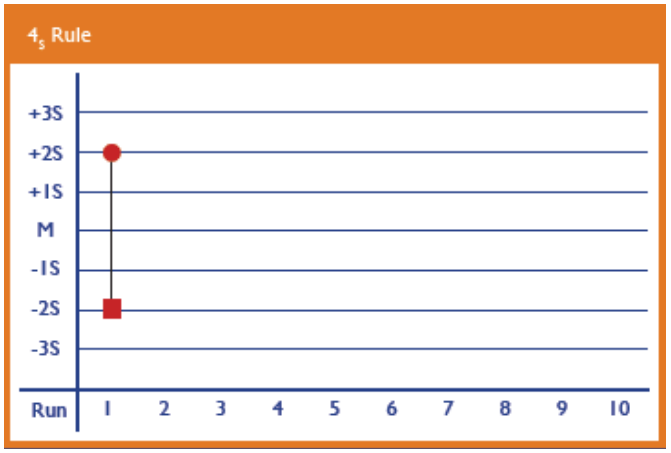
This rule states a run must be rejected when two consecutive QC results are greater than ±2 standard deviations and on the same side of the mean. The 2_{2S} rule is used to detect systematic error and can be applied within and across runs.

Rule 2 of 3_{2S} (2 of 3 results exceed 2SD)



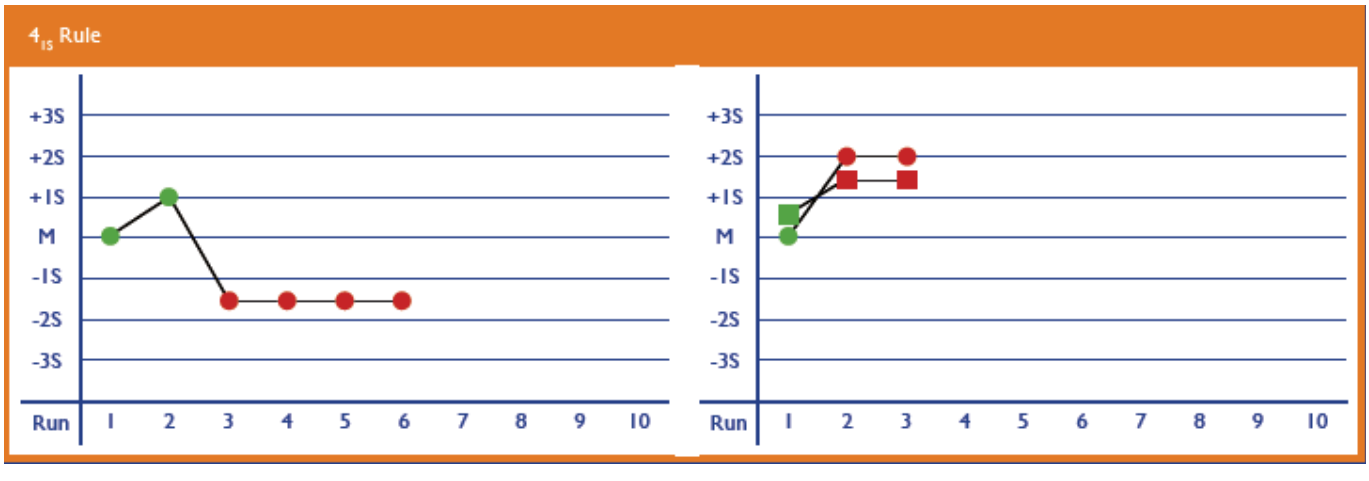
This is a variation of the 2_{2S} rule and is used to detect systematic error. The rule is violated when any two levels of control in a run exceed 2 standard deviations on the same side of the mean.

Rule R_{4S} (Range exceeds 4SD)

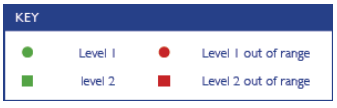


This rule is violated if there is at least 4 standard deviations difference between control values within a single run. In this example the level 1 control is +2S above the mean and the level 2 control is -2S below the mean. The total difference is 4s. This rule identifies random error only.

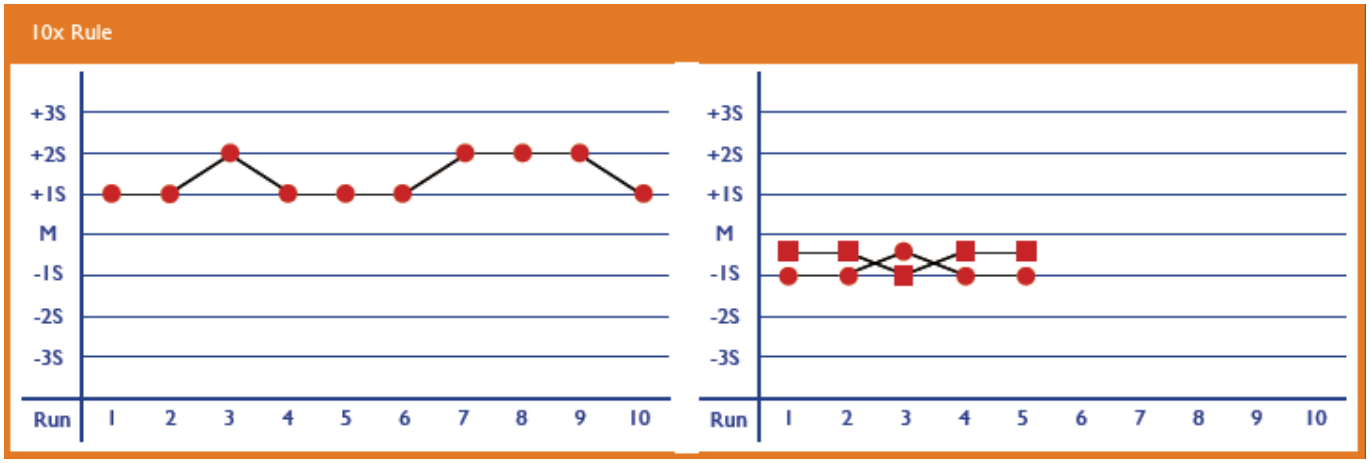
Rule 4_{1S} (4 results exceed 1SD)



This rule is applied both within and across runs. The 4_{1S} rule is violated within run when four consecutive control results for the same control exceed the mean by either +1S or -1S. The rule is violated across run when four consecutive control values for different levels of control exceed the mean by either +1S or -1S. The 4_{1S} rule detects systematic error, rather than rejecting the run, violation of this rule can indicate that instrument maintenance or calibration should be carried out.



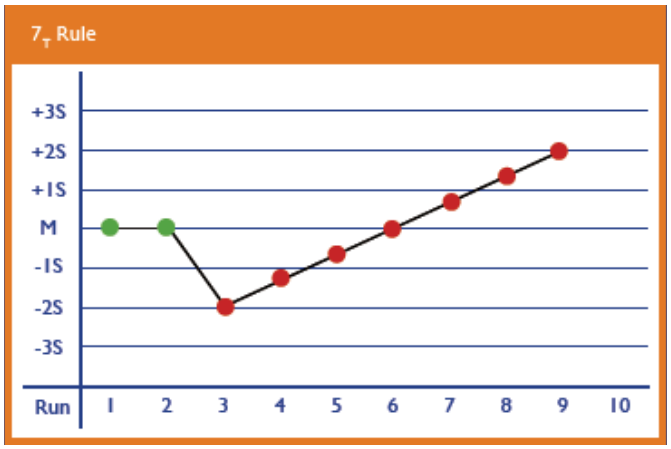
Rule 10x (10 results same side of the mean)



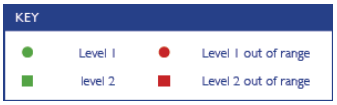
This rule is violated if ten consecutive control results regardless of level fall on the same side of the mean. The rule detects systematic error and can be applied both within and across runs. Violation of this rule may not require rejection of the run but rather indicate that instrument maintenance or calibration is needed.

The 10x rule can be modified to 7,8,9 or 12 consecutive results on the same side of the mean, each giving varying levels of sensitivity to systematic bias.

Rule 7_T (7-Point Trend)



This rule is violated when a group of seven consecutive results for a single level of control show trend in the same direction either increasing or decreasing.



For convenience, short hand notation is used to abbreviate different control rules

- For example, 1_{2S} is used to indicate 1 control measurement exceeding 2s control limits.

- Combinations of these rules can usually be identified with a slash, e.g. 1_{3S} / 2_{2S}.

Tools to assist labs apply QC Multi-Rules

To apply QC Multi-Rules you firstly collect your control measurements in the same way that you would for a Levey-Jennings chart. From this you establish a mean and standard deviation (SD). *All you are changing is the control limits and how the data will be interpreted.*

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.

Acusera 24•7 will apply QC multi-rules automatically!

The ability to apply user-defined QC Multi-Rules will help to reduce false rejections and the number of repeat tests whilst maintaining a high level of error detection. The new Acusera Advisor* tool recommends QC Multi-Rules and a minimum QC frequency based on method performance.

**Not available in USA*

Troubleshooting out of control events

There are many different paths a lab can take when troubleshooting QC errors. The root cause can fall under 5 main categories:

- **Materials** – Problem with sample / reagent
- **Methods** – Were procedures followed?
- **Machine/Equipment** –Instrument fault
- **Human Error** – transcription errors, training etc
- **Environmental** – Storage temperature etc

If you discover any clinically significant errors, all patient samples since your last successful QC evaluation should be repeated.

After you have identified any possible causes the corrective actions to take are as follows:

- Implement any corrective actions
- Make one change at a time
- Monitor the improvement of that change on your QC and especially on your patient results
- Document the solution
- Put procedures in place to prevent the error from occurring again

If you would like further information please contact:

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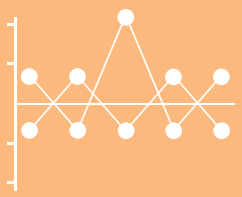
True third party controls offering complete test menu consolidation

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.



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RIQAS

The largest global EQA scheme with over 35,000 lab participants

Comprising over 360 routine and esoteric parameters in 32 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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