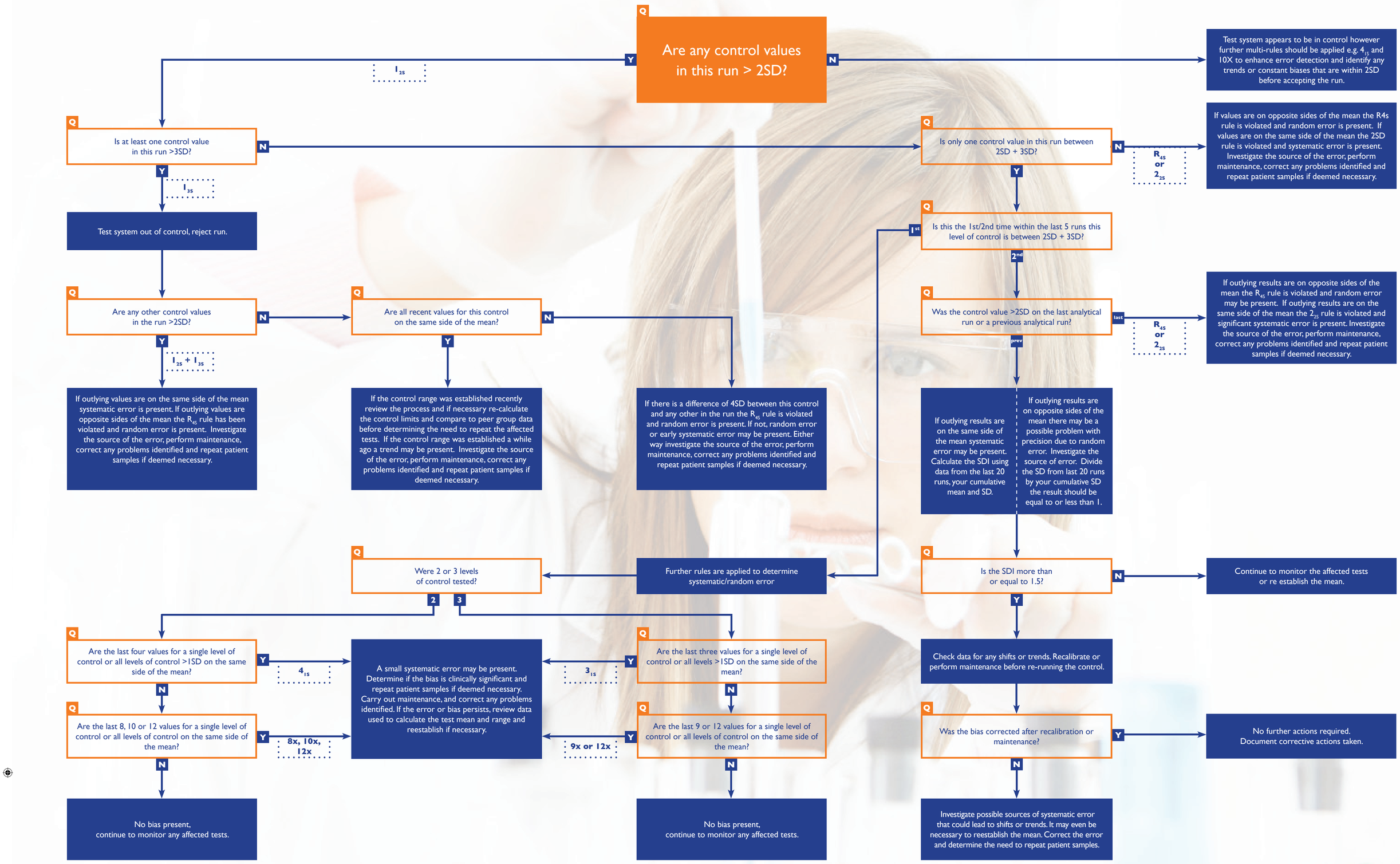
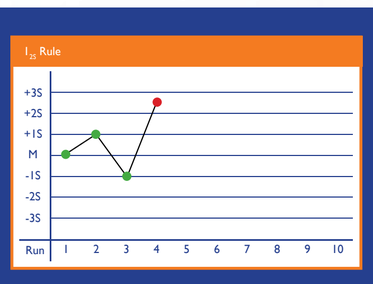
RANDOX
QUALITY CONTROL

Using QC Multi-Rules

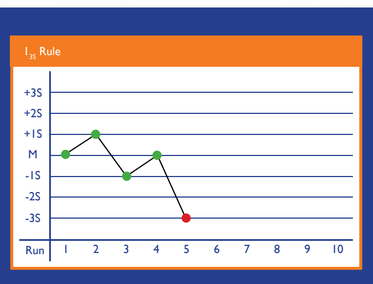
QC Multi-rules are designed and used to minimise false rejections and maintain a high rate of error detection. There are six main rules used to determine if results from a run of patient samples should be accepted or rejected, based on the performance of control materials against the rule criteria. Different combinations can be applied depending on the number of controls in use, total allowable error and the instrument in use. The flow chart below is often used to determine if a run should be accepted or rejected.





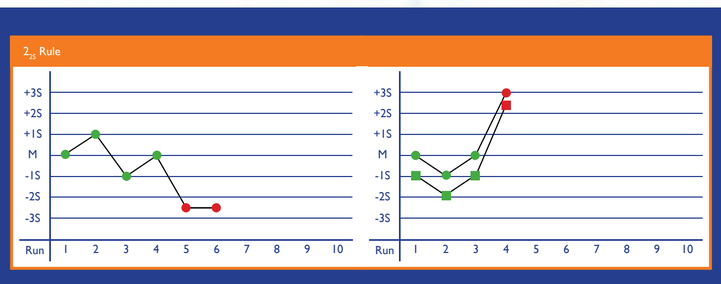
Rule 1_{2S} (1 result exceeds 2SD)

This rule is designed as a warning rule only. If one QC result is more than ±2S 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 leads 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 ±3S 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.

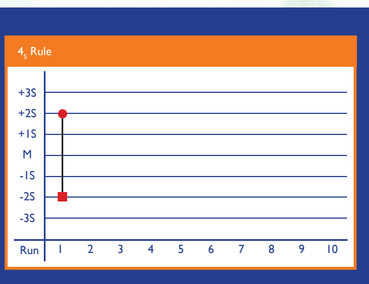


Rule 2_{2S} (2 results exceed 2SD)

This rule states a run must be rejected when two consecutive QC results are greater than ±2S 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.

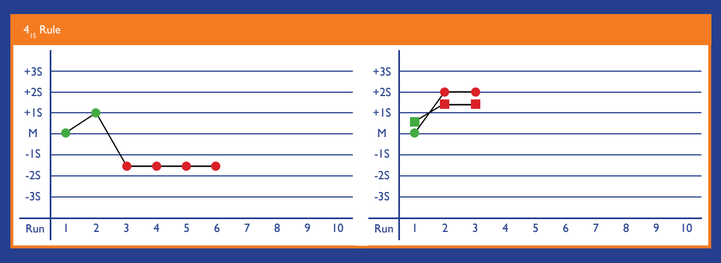
Rule 2 of 3_{2S} (2 of 3 results exceed 2SD)

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



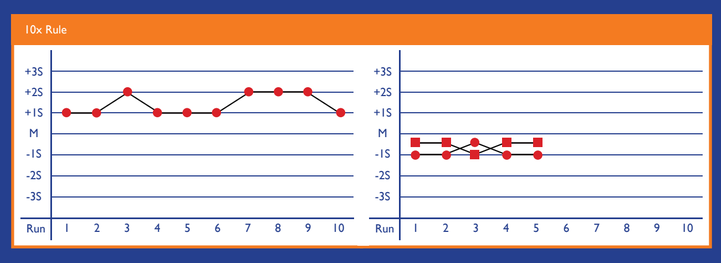
Rule R_{4S} (Range exceeds 4SD)

This rule is violated if there is at least a 4s 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.

Sources of random error

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

Sources of systematic error

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

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For optimum performance and advanced analytical capabilities use Randox third party controls in combination with Acusera 24•7 Live Online. Acusera 24•7 Live Online is an interlaboratory data management and peer group reporting package designed to monitor analytical performance, interpret QC results and improve the overall effectiveness of quality control processes.

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RANDOX QUALITY CONTROL

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