

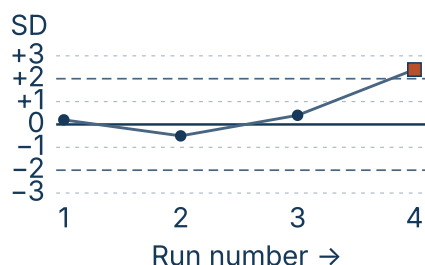
# Common QC rule violations

Six statistical rules and the limits of their interpretation

**Quality control (QC)** compares a control result with its established mean and **standard deviation (SD)**, a measure of usual variation. Random error increases scatter; systematic error shifts results toward one side. The patterns below suggest which type to investigate.

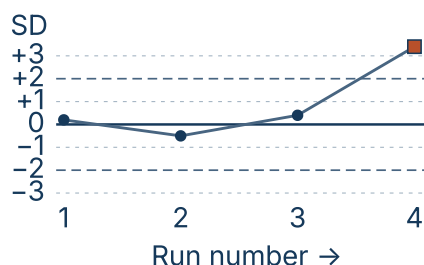
Vertical position = (result – mean) ÷ SD, using each level's own target. Lines: mean (0),  $\pm 1$ ,  $\pm 2$ ,  $\pm 3$  SD. Squares meet the named rule; circles give context.

## **1<sub>2s</sub>** One result beyond $\pm 2$ SD.



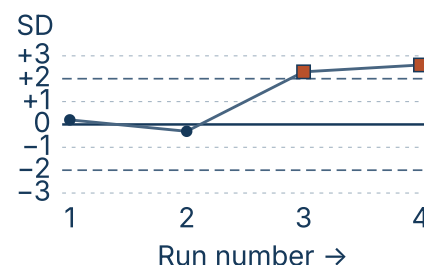
Classic warning. Inspect the selected rejection rules.

## **1<sub>3s</sub>** One result beyond $\pm 3$ SD.



Rejection. May reflect random or systematic error.

## **2<sub>2s</sub>** Two consecutive beyond the same 2 SD limit.



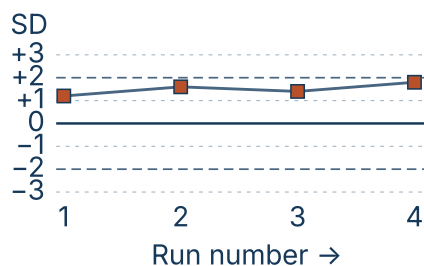
Rejection. Suggests systematic error.

## **R<sub>4s</sub>** One $> +2$ SD, one $< -2$ SD, in one run.



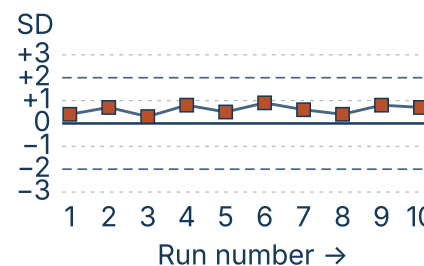
Rejection: possible random error. Spread = 4.8 SD.

## **4<sub>1s</sub>** Four consecutive beyond the same 1 SD limit.



Rejection. Suggests systematic error.

## **10<sub>x</sub>** Ten consecutive on one side of the mean.



Rejection. Suggests systematic error.

Examples use one level across runs, except R<sub>4s</sub> (two levels, one run). The 2<sub>2s</sub> rule also applies across levels within a run; 4<sub>1s</sub> and 10<sub>x</sub> can span levels and runs as the QC plan specifies.

## Warning and rejection

In the classic Westgard scheme, 1<sub>2s</sub> is a warning to check the rejection rules. Plans that evaluate every rule directly can detect the 4<sub>1s</sub> and 10<sub>x</sub> examples here even though no result exceeds 2 SD. The adopted plan defines rules, levels, runs, and look-back periods.

## Respond to a rejection

Hold affected patient results. Use the adopted QC plan to investigate controls, reagents, calibration, and instrument performance. After correction and acceptable QC, assess which patient results need review or repeat testing. A passing repeat alone does not explain the original failure.