

- Acceptable ranges for patients vary from test to test, based on something called Biological Variation. This will be discussed in MUCH detail in a later module, but can basically be defined here as the natural variation in concentration seen in each analyte tested in the lab. This can be different for each analyte of course, but also will vary depending on the analyte concentration and the individual under study. In other words, it varies a lot!
- If errors or variations in test result are accepted for patient samples, then they must be accepted for QC samples too. Variation is in fact inevitable and healthy; the job of a QC system is to identify unacceptable i.e. too much, variation.
- YOUR job is to decide what to do when variation seems too much. And if for variation, you assume dispersion of results, or Standard Deviations then you have got the picture.
- Finally, it should be clearer that we run CLINICAL labs, not STATS labs.

Learning the language of QC

Definitions are boring and most of us don't read dull and boring lists, so here there will only be what we need to get started – the rest will follow.

QC procedure

This is a specific protocol for analyzing a specific number of control materials and interpreting the outcome. In our type of labs, this usually means collecting test results on stable control materials, then plotting those control observations on a control chart with specific limits.

Control chart

This is a graphical method for displaying control results and helping to evaluate whether a particular test method is in or out of control. Today these charts are generally called L-J Charts, after the two authors of a paper published in 1950 – even though their recommendations are never followed and their suggestions seem very old fashioned today. History has been kind to Levey and Jennings.

Control limits

These are lines drawn on the Control Chart to illustrate the limits of acceptable results on control material. Traditionally, the outer limits of control are set at ± 2 Standard Deviations (SDs) – this will be much discussed and considered in a later module. The concept is that when a control result is inside the control limits, that particular assay run is deemed to be 'in control' and patient results can be reported with a degree of confidence. Conversely, when the control result is outside the control limits, the run is considered to be 'out of control' and thus patient results cannot be reported. This hard and fast situation represents that mythical ideal state yet again, but is adequate to allow us to move on, for the moment.

Westgard Rules

Dr. James Westgard has published widely in the QC field for decades and has rightly come to be regarded as the guru of pathology QC. His rules, the Westgard Rules, were established as an attempt to introduce even more statistical rules into a clinical service.

S A N A S



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