

apply strict control guidelines to a test that is not done well enough for clinical purposes; and equally it is pointless to fail patient runs when the difference may be clinically irrelevant.

This concept is the crucial basis of sensible QC, to be much discussed in later modules.

Finally

And now, back to patients and clinical decisions. A common question from clinicians runs like this: My patient's result was 8.5 yesterday and now it is 7.9 today. Is that change significant?

There are many ways to tackle this question. Perhaps it should always be referred to a pathologist, in an ideal world, but for the moment we will assume that you have no access to such a person and must answer the question yourself.

Once again, there are factors such as BV to take into account but one approach is to consider it technically, and use your own SDs to work out a suitable response. If we apply the theory of probability to your SDs, you need two consecutive results from a patient to be 2.8 SDs different for you to be sure there has been a change – and that is 2.8 times **your own** SDs worked out on control samples, not those in a commercial package insert.

So, if your SD for this analyte was 0.2, then you would need a change greater than 2.8×0.2 , or 0.56 to be able to say that the change had been significant. In fact the difference above, from 8.5 to 7.9, is 0.6 therefore you could say with confidence that the results were significantly different.

CPD Questions:

7. **It is always best/ simplest to use printed ranges in commercial package inserts to control your Internal QC.**
 - A) True
 - B) False

8. **If the results from a control sample do not conform to Gaussian distribution, what must be done to create a set of control limits, like +/- 2 SDs?**
 - A) It is still OK to calculate the SDs as for Gaussian distributions
 - B) You need to do something else with the results to make them useful, for example log transformations or non-linear statistics