

You may say it is a combination of all three of these, but if you had to select only one answer – you **MUST** select the last choice, number 3. It is not an error to have a result outside the 2 SD range – it is a welcome warning sign that you may or may not have a problem, and also is a very clear example of your QC system working! It is supposed to alert you to potential problems – that is the only reason you set it up in the first place – and we need to stop being concerned about “failing” the 2 SD rule.

The fact is – there is no such rule. And results outside 2SDs **MUST** happen one in every twenty QC sample measurements.

Let me give you an example. Many years ago I was responsible for a large continuous flow auto-analyser that shall remain nameless. The daily throughput was approximately 1000 patient samples, with about twenty tests being performed on each patient samples. This was a very busy and very productive instrument. Unfortunately it was not a happy instrument, and to make sure that the final product – the patient result – was good enough, one control sample was placed after every ten patient samples. Now, just add that up. Every day, 100 QC samples passed through that instrument, with twenty tests each time, meaning that every day I had to check 2000 QC results. The fact that I used my own 2 SD range, calculated from the instrument itself – and checked for appropriateness – meant that one result in every twenty (remember 5% of results) were outside the 2 SD range.

Work that out for yourself. That’s right – every day I **EXPECTED** to find 100 QC results outside 2 SDs, and if that did **NOT** happen, I needed to investigate. A QC failure would be anything less than 100 QC results daily outside that supposedly magical +/- 2 SD range!

Now, there were several important elements to this control system. If:

- I found 100 of one test, say calcium, out of control, then I had a serious problem.
- Or if most of the results outside 2SDs were high or low, I had a serious problem.

The “failures” had to be evenly distributed between the twenty analytes, and had to be fairly evenly distributed between high and low “failures”. You could say that this instrument got me used to failure – but this perfectly illustrates the use of sensible QC. It is not an error to have a result outside 2 SDs. It is worth investigating or noting, but it is not a “failure”.

An error is simply a wrong result that is not detected by the lab’s QC system and reaches the patient file – that is what this graph considers and that is what you should be concerned about in your lab.