

Effective QC

A definition of what constitutes an effective QC system will inevitably be personal and could generate plenty of discussion, perhaps even an argument. This is healthy, for QC is as much a set of opinions as a set of concrete facts. If anyone reads these pages and disagrees, great! The opinions presented are just that, opinions. So, let's get the definitions going.

- An effective QC system, as well as working for you and your patients, will be able to identify and reject ALL bad results, and recognize and accept ALL good results. Subsequent modules will explain why this is not possible, but for the moment let's accept it as an ideal state.

In real lab life, what that means is that your QC charts, for example the ubiquitous Levey-Jennings (L-J) charts, will NOT look perfect, with all results nicely tucked inside 1 SD. This is important – all subsequent understanding will depend on this being accepted and appreciated. Your L-Js MUST show out of control results, the inevitable 5% of results appearing outside 2SDs. If that figure of 5% confuses you, a later module on constructing L-J charts will help you understand what is a basic and important concept.

Once we accept that we have a real situation as regards controls and their limits, what we now need is a working set of protocols to help with decisions about what to do with those apparent out-of-control results, the inevitable and essential 5% outside YOUR OWN +/- 2 SD range. So, let's expand the definition of an effective QC system.

- An effective QC system, as well as working for you and your patients, will be able to identify ALL bad results, and accept ALL good results. But as this is not possible, it also requires some degree of training (that's why you are doing this course, right?) in interpreting and handling the 5% of results that MUST be outside the 2 SD limit.

To reinforce this, please be very clear on the fact that if your L-J charts show consistently perfect QC, with all values dotted neatly within 1 SD, half above the mean line and half beneath it, then you have a problem! In fact you have a bad QC system.

Let me explain: if a lab takes the package insert values and uses them as the outer 2 SD control limits, the chances are that the ranges are 3 times as wide as they should be. Most package inserts actually tell you this, by saying that the ranges printed are for guidance only and that each lab MUST work out its own control limits. If you use the package insert values you are more or less using about +/- 6 SDs as your control limits. It is not surprising then that you will have "good" QC! The fact is it would take a systematic change of approximately ten times the standard deviation before the QC procedure would tell you have a problem. In other words, you would practically need to run out of reagent before you would notice you had a problem. Not a good idea.

S A N A S



PROFICIENCY TESTING Accredited to ISO Guide 43 and ILAC G13