

The benefit of using an independent Quality Control

Questions and Answers

Quality
Control

1. Case Study #4: How did you initially decide that it was a calibrator issue and not a reagent problem, since BOTH were new?

When you have new reagent and new calibrator, you are right the problem could be from either one. In this case since the reagent was just a new lot number but the calibrator was totally new, first lot number of first time manufacturing such a 6 point calibrator (before it was a 2 point calibration).

Our investigation also included the QC material (we tried two different QC lot numbers), reagent and calibrator but concentrated more on the calibrator which was found to be the cause.

2. If we compare our QC mean to the peer group mean every month, why would we not want to set our target mean in Unity to the peer group mean rather than using our own mean? Wouldn't setting the target mean to the peer alert us to problems earlier rather than comparing ourselves to ourselves every day?

Very good question and opens a good discussion. In short, when we establish our QC range for our instrument we should keep the peer group mean as a reference and make sure our new established mean is not out of the peer group range. This will alert you immediately at the early stage of collecting data points for your establishing your range. But you should still set your mean and SD based upon your instrument performance (this is also a recommendation found in CLSI C24 A4 Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions). Peer group means and ranges are based on multiple instruments with different reagent lots and calibrator lots, so the mean can be different and the ranges can be wider than what your individual instrument can achieve.

3. When you perform calibration without calibration factor set up, did you not get calibration error?

How was your EQA performance?

If this question is for case #1:

In this case there was no calibration error because there was no calibration factor problem. As far as the Instrument was concerned, at a certain period there was a communication from the vendor stating the recommendation to adjust the calibration factor. So either you adjust the factor or not. The instrument has a calibration factor and will not flag a calibration error, it will just read higher or lower compared the to the peer group who did the recommended adjustment. Our proficiency testing sample (CAP) was showing the same exact picture as the Unity peer group comparison (on the positive bias, close to +2 SDI (standard deviation index) but not outside the acceptable range) and after we changed the factor both the peer group comparison and CAP report showed the same picture, or again close to the mean of the peer group.

The following questions were asked during the presentation. Please see the webinar recording for the responses.

4. For the GGT example you showed us, the test was performing at higher bias for a while. Did the proficiency testing pick up on this?
5. Can I use my calibrator material to test my performance?
6. How often would you recommend to run QC?
7. When the manufacturer says I have to run the in kit control, should I still run an independent control?
8. Is independent QC mandatory?