
Discussion

The majority of troponin values that clinical laboratories report can be grouped into “negative” or “less than” categories. Up to now, the CAP has not included a challenge in this range because of the difficulties associated with their preparation and grading. These include, but are not limited to, issues associated with non-commutability (so-called “matrix effects”) and varying degrees of non-linearity at the lowest measurable concentrations.

In this mailing, we have included our first troponin challenge, CR-12 in this range because it makes clinical sense as it reflects a common test result range. After reviewing the results as well as the manufacturers’ performance specifications, we decided to use a threshold of 0.3 ng/mL or less as the criterion for acceptable performance.

We believe laboratories should take this opportunity to review how they report such values. Modern terminology for lowest reportable concentrations includes such terms as “limit of blank” (LoB), “limit of detection” (LoD), and “limit of quantitation” (LoQ).

Limit of Blank (LoB) LoB is the highest *apparent* analyte concentration expected to be found when replicates of a blank sample containing no analyte are tested.

Limit of Detection (LoD) The lowest analyte concentration likely to be reliably distinguished from the LoB and at which detection is feasible. LoD is determined by utilizing both the measured LoB and test replicates of a sample known to contain a low concentration of analyte.

Limit of Quantitation (LoQ) The lowest concentration at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are met. The LoQ may be equivalent to the LoD or it could be at a much higher concentration.

As most assays are non-linear at the very low end, “0” is not a reasonable choice; eg, results such as <0.02 ng/mL would be more appropriate. We recognize that some labs will have determined their own LoD or LoQ, which may differ from their manufacturer’s, but in all likelihood, the values will not be very different.

Most importantly; communication to the clinicians about the terms used, their meaning and clinical significance is paramount in appropriately utilizing these results. Lastly, these Proficiency Testing (PT) samples follow all of the existing CLIA requirements regarding PT processes ie, treat these PT samples as you would genuine samples – both in terms of analysis and reporting. Especially, if you report values as <0.03 ng/mL for patients, that’s how you should report the PT samples; if you report values as “NEGATIVE”, that is how you should report the PT samples.

Gary L. Horowitz, MD, FCAP
David N. Alter MD, FCAP
CHEMISTRY RESOURCE COMMITTEE

Reference

1. Armbruster DA, Pry T. Limit of blank, limit of detection and limit of quantitation. *Clin Biochem Rev.* 2008 Aug;29 Suppl 1:S49-52.