Discussion

The 2019 PCT-A and PCT-B Surveys comprised various challenges encompassing a continuation of the previously established analyte for this Survey. The 2017 PCT-A discussion mentioned the observed performance at lower procalcitonin (PCT) levels is relevant, as the CAP will begin to include a challenge at a low procalcitonin concentration moving forward. Since that time, the CAP has included PCT challenges in 2019 comprised of serum at low procalcitonin concentrations. Sample PCT-02 (2019 PCT-A Survey) and PCT-06 (2019 PCT-B Survey) are comprised of off the clot normal serum pools with no spike of procalcitonin. The introduction of these challenges highlights the clinical relevance of these procalcitonin levels.

Procalcitonin is a hormone secreted mainly by thyroid C-cells to maintain calcium homeostasis. During scenarios of severe systemic inflammation, expression of procalcitonin may be de-regulated and secreted in large quantities by many tissues while the level of calcitonin remains unchanged. Following an infections inflammatory stimulus, procalcitonin is detectable within relatively short time frames and parallels the severity of the inflammation. Clinically, PCT may be indicative of a bacterial infection and/or sepsis and is used in some healthcare settings as an aid in antimicrobial stewardship. Changes at low procalcitonin concentrations become more relevant when assessing these clinical scenarios.

The data from these Surveys indicates relatively well performance across methods at low procalcitonin concentrations (PCT-02 and PCT-06). At higher procalcitonin levels (PCT-01, PCT-03, PCT-04, and PCT-05), however, it is interesting to note (similar to the observation in the 2017 PCT Survey results) there are vast differences in some cases between some method peer groups. These differences may be reflected in the established reference intervals for these methods, or, may represent a phenomenon related to the Survey material or differences in methodology. Because of the fact that these challenges are non-commutable (ie, they do not behave exactly like real patient samples), we do not expect all of the different assays to get the same values. It is also interesting to note that the differences are, in some cases, approximately three times the low and high values for the other peer groups (comparing PCT-05 Roche cobas e411/Elecsys to PCT-05 Beckman AU Series). It is difficult to make conclusions of these differences in the limited data set. Regardless, the mean procalcitonin values (where mean can be calculated) at a lower procalcitonin concentration, as observed with PCT-02 and PCT-06, align more closely, with the exception of the BioMerieux VIDAS, VIDAS 3, miniVidas (PCT-06). It is likely the high value observed for PCT-06 in this peer group represents a clerical error and/or sample mix up with another PCT challenge which is skewing the peer group mean.

Samples PCT-02 and PCT-06 are off the clot normal serum pools with no spike of procalcitonin, which are believed to have low procalcitonin concentrations in them. It is important for laboratories to know, and make their providers aware of, their assay's lowest reporting limit (determined either by the laboratory or the manufacturer). As described in previous Survey discussions (ie, 2015 CAR-A), there are three different ways of defining this lower limit – LOB, LOD, LOQ. Results should never be reported as zero, "0", but rather as less than some value (eg, <0.02). Of interest, it is observed that laboratories, even using the same manufacturer's assay, reported values that had different numbers after the < sign (eg, <0.05, <0.1, <0.2). It is important that every laboratory check their lower reporting limit.

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