COLLEGE of AMERICAN PATHOLOGISTS

Educational Discussion: Current state of Vitamin D testing

2021-B Accuracy-Based Vitamin D Survey (ABVD)

The 2021 ABVD-B challenges are composed of pooled off-the-clot, fresh frozen serum samples obtained from several donors, some of whom received oral vitamin D2 prior to their blood draw. The target values for 25-hydroxyvitamin D (25-OH vitamin D) were established by the LC-MS/MS reference measurement procedure performed at the Centers for Disease Control and Prevention Reference Laboratory. The minimal processing of the samples prior to distribution was vital in producing samples that are commutable across different assay platforms (including immunoassays, HPLC assays, and LC-MS/MS assays).

Results are provided in this Summary Report for total 25-OH vitamin D, 25-OH vitamin D2, and 25-OH vitamin D3. The reference target values provided by the CDC Reference Laboratory are also shown for each sample.

Grading criteria for this Survey remain unchanged: for total 25-OH Vitamin D, acceptable performance requires a value within 25% of the CDC reference value or within 5 ng/mL, whichever is greater.

Although no formal grading is done for 25-OH Vitamin D2 or for 25-OH Vitamin D3, participants should compare their results to the CDC Reference Laboratory established target values. Importantly, formal grading for 25-OH Vitamin D2 or for 25-OH Vitamin D3 will begin in 2022. Grading criterial will be similar to total 25-OH Vitamin D: acceptable performance will require a value within 25% of the CDC reference value or within 2.5 ng/mL, whichever is greater.

It is important to point out the two different objectives of the Accuracy Based Proficiency Testing materials provided by the CAP: (1) to provide a standardized proficiency testing program in which laboratories can compare the performance of their laboratories with other laboratories running the same method and (2) to provide standardized/harmonized data from actual human samples for all laboratories to illustrate how the different manufacturers' assays (including laboratory developed tests that use chromatographic approaches) compare with one another and the reference method procedure (when there is one available). As a result, each laboratory is able to identify issues that it is having with respect to its peers running the same assay, but each laboratory can also see how its selected platform compares against the reference measurement procedure, which has been recognized as the gold standard methodology for that analyte, or the rest of the assays available commercially or as laboratory developed tests.

There are a few things to notice from the box and whisker plots at the end of the Participant Summary Report: (1) there were a few immunoassay platforms that achieved 100% passing rates for all laboratories for all three challenges, including the Abbott Alinity, Abbott Architect, DiaSorin Liaison, and Roche Cobas e801 platforms, (2) passing rates for LC-MS/MS methods continue to be similar to previous results (~95%) and suggest that some laboratories should focus on their calibration systems and evaluate their ability to separate the epimer of 25-OH vitamin D3, and (3) the results from Beckman, Siemens, and Vitros are similar to those seen over the past several years.

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