



Educational Discussion

2022-A Accuracy-Based Glucose, Insulin and C-peptide (ABGIC)

Our original intent was to grade glucose, insulin, and C-peptide starting with the ABGIC Survey 2022-A mailing, but it appears there are still major issues with various IVD manufacturers' calibration for insulin and C-peptide immunoassays. Furthermore, using the wide CLIA criteria for glucose allows everyone to pass. Thus, the committee has elected not to "grade" any of the three analytes in this Survey.

For glucose, laboratories should compare their responses to the GC IDMS reference measurement procedure performed at the CDC reference measurement laboratory. The low number of responses for each specific method make it very difficult to say much about specific measurement procedures' calibration accuracy.

For C-peptide, virtually all IVD manufacturers trace their calibration back to the first or second WHO reference preparation for C-peptide (coded 84/510 or 13/26), which unfortunately are prepared from purified C-peptide, making the reference materials not commutable with modern IVD immunoassays. There are now two Joint Committee on Clinical Laboratory Medicine-certified (JCTLM) (<http://jctlm.org>) LC IDMS reference measurement procedures for C-peptide, including the one shown as the reference measurement procedure target value for C-peptide assigned at the University of Missouri. However, many laboratories using a commercial IVD method appropriately would have unacceptable results if we used the IDMS reference measurement procedure target value. In the future, we hope to grade against this reference measurement procedure result, but first IVD manufacturers need to adjust their calibration traceability.

There is a similar situation for insulin, and virtually all IVD manufacturers trace their calibration back to the first or second WHO reference preparation or international standard for insulin (coded 66/304, 83/500, or 11/212). Again, there is a serious non-commutability issue for these WHO reference materials with modern IVD immunoassays. Grading to the all-method mean target with an acceptability window of ± 3 times the all-method mean would mean virtually all laboratories would "pass." However, this is primarily due to the fact that the all-method SD is so wide as a result of the marked differences in various IVD immunoassay calibrations (e.g., for ABGIC-02 the acceptability window would be $\pm 111\%$ or the all-method mean).

Once manufactures adjust their calibration traceability to internationally accepted reference measurement procedures for insulin and C-peptide, we hope to begin grading this accuracy-based Survey against reference measurement procedure-based target values for these two peptide measurands (analytes) as well as for glucose, but it seems premature to do so at present.

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