Educational Discussion: Accuracy Based Testosterone and Estradiol

2019-B

Specimens used in Accuracy-Based Surveys are produced following procedures that minimize matrix effects and produce commutable serum pools with characteristics as close as possible to patient specimens. Thus, measurement results can be compared not only within peer-group but also across peer-groups. Measurement results reported by participants using the same assay can be considered replicate measurements. Thus, measurement results from participants can be combined to calculate mean bias and imprecision. The measurement variability and accuracy observed in Accuracy-Based Surveys provides important information about the variability and accuracy occurring in patient care.

The measurement bias, expressed as the percent difference between the measured value and the reference value, may be caused by inconsistent assay calibration and/or sample specific effects, such the presence of interfering compounds or differences in binding protein concentrations. Assay inconsistencies affect all specimens to the same extent, while specimens' specific factors affect specimens differently.

For TSH, the differences among results from all assay manufacturers are consistent across specimens, suggesting inconsistent calibration (Figure 1). Similar patterns are observed for SHBG. In contrast, the bias patterns observed for testosterone appear more complex. While differences between the Abbott and Beckman instruments suggest calibration inconsistencies, specimen interference(s) are also suspected. This is evident by the higher bias of specimen ABS-06 compared to other specimens for the Beckman assays. This specimen has the lowest testosterone concentration of the supplied specimens (26.0 ng/dL vs. 488.0 ng/dL (ABS-04) and 1,518 ng/dL (ABS-05)). The impact of interfering compounds is typically more pronounced at low analyte concentrations. Similar, but less pronounced patterns are observed among specimens for measurements performed with Roche and Siemens assays, but not for mass spectrometry assays (Figure 2).

These examples emphasize the importance of using a range of different specimens covering the analytical measurement range when comparing different platforms to accurately detect potential differences between assays and to better identify the sources causing these differences.

Figure 1: Percent difference of TSH values reported by laboratories compared to the all method mean by assay manufacturer (circles: ABS-04, diamonds: ABS-05, cross: ABS-06)
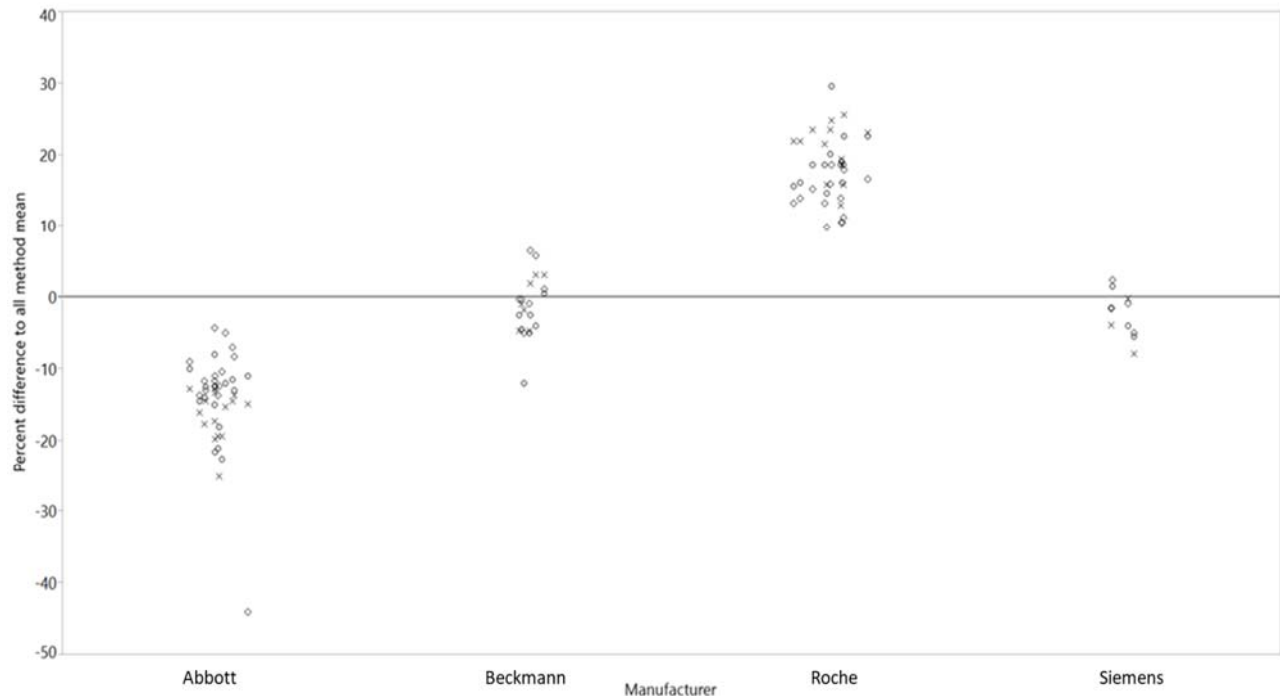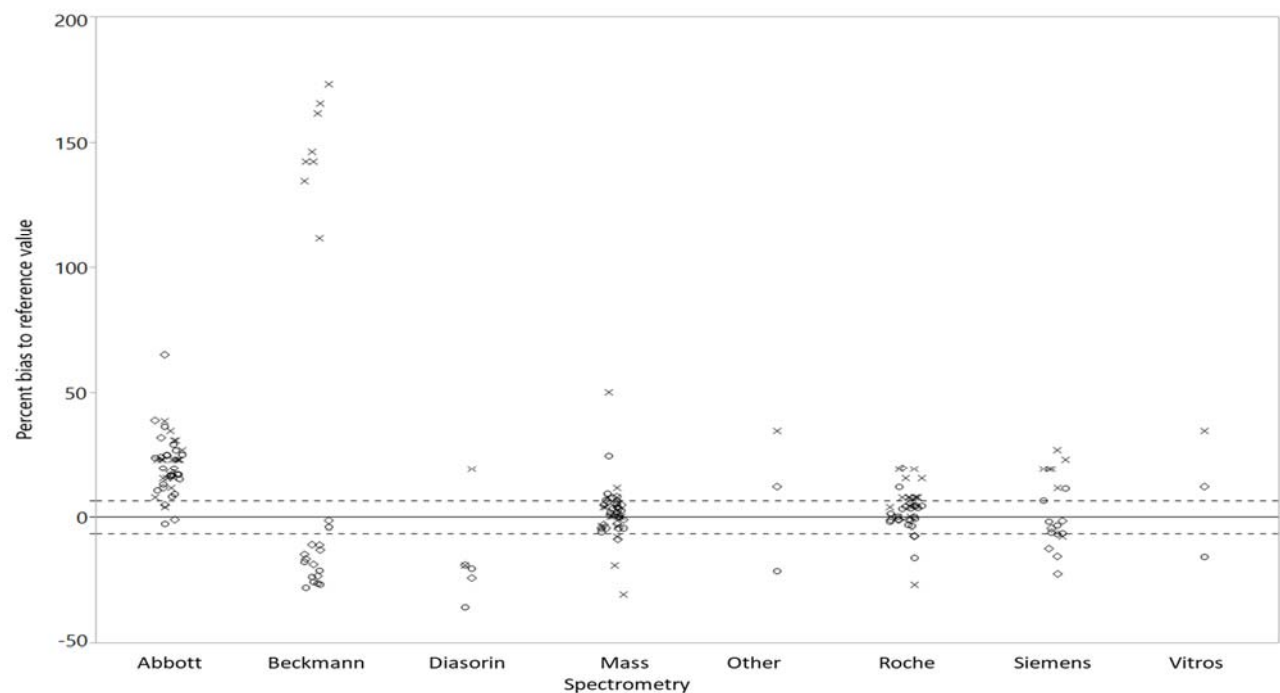

Figure 2: Percent difference of testosterone values reported by laboratories compared to the referenced value by assay manufacturer (circles: ABS-04, diamonds: ABS-05, cross: ABS-06)

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