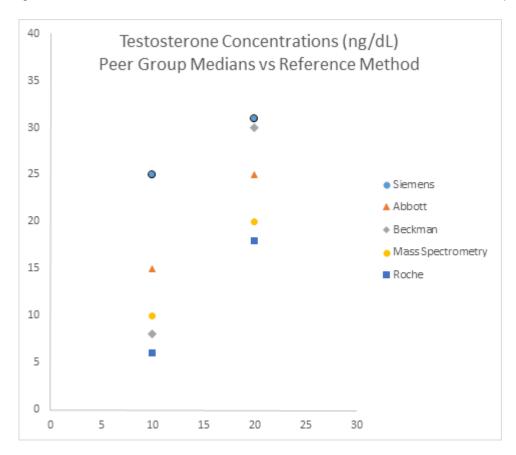


Educational Discussion: Accuracy-Based Testosterone and Estradiol

2017-A Accuracy Based Testosterone and Estradiol Survey (ABS)

CAP accuracy-based proficiency testing and the Centers for Disease Control and Prevention (CDC) Hormone Standardization Program (HoSt)*, together have made tremendous strides in the effort to standardize testosterone and estradiol assays to improve patient care¹⁻². In this program, laboratories can volunteer to enroll with the CDC and become certified after meeting performance criteria (bias and imprecision) over a one year period¹. It should be noted that clinical laboratories with Laboratory Developed Tests (LDT's) as well as research laboratories and industry can enroll in this program¹. As more laboratories continue to enroll and certify in this program, it is likely that standardization for these assays will continue to improve.

The 2017 ABS-A Survey challenges, ABS-03 and ABS-04, reveal much about the performance of liquid chromatography/mass spectrometry (LC/MS) and popular immunoassays at testosterone concentrations found in healthy females. The chart below represents the median results for each peer group plotted against the reference method concentrations. For both challenges, LC/MS methods match the reference method well. In contrast, a few of the immunoassays significantly over-recover and/or do not parallel the doubling of concentration between the two samples. Estradiol methods, too, seem to be progressing to better harmonization, as is evident in the agreement between the reference method and the median of the "All Method Principles."



*LC/MS reference method results for testosterone and estradiol were provided by the Clinical Chemistry Branch of the Centers for Disease Control and Prevention (CDC).

References

- Centers for Disease Control and Prevention. Laboratory Quality Assurance and Standardization Programs. Available at: https://www.cdc.gov/labstandards/hs.html. Accessed October 31, 2017.
- 2. Vesper HW, Botelho JC, Wang Y. Challenges and improvements in testosterone and estradiol testing. *Asian J Androl.* 2014;Mar-Apr;16(2):178-84.

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