



# Technical Bulletin

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## PSA Standardization

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There are two standards for PSA calibration: Hybritech and WHO 96/670 (WHO). The first commercially available PSA test was based on the Hybritech standardization. Furthermore, the commonly accepted clinical reference ranges for PSA were established utilizing test values that are based on the Hybritech standardization. For this very important reason, the FastPack® PSA calibration was originally based on the Hybritech standardization, and is set by default to output Hybritech standardized results.

The FastPack System is also capable of outputting WHO standardized PSA results by enabling WHO unit mode. If you decide to enable the WHO unit mode for your Total PSA tests, Qualigen recommends that the lab should:

1. Establish a new baseline for PSA patient results because WHO Standardized PSA results are on average 20% lower compared to Hybritech Standardized PSA results.
2. Use WHO Quality Control ranges when running controls – contact System Support if your current control range card does not have PSA control ranges in the WHO Standardization. The control range card will have a special row labelled “WHO standard” and ranges will be adjusted lower to correspond with the lower WHO Standard values.
3. Enroll in a new peer group for proficiency testing. For example, for API (American Proficiency Institute) participants, the reagent group is *Qualigen FastPack WHO PSA*.

In general, over the broad spectrum of PSA levels, patient results on the WHO standardization may bias lower when compared to patient results on the Hybritech standardization. There can be variations as to the degree of the lower bias, or at what levels this is more apparent.

We encourage you to learn more about PSA standardization. There are many informative resources that discuss PSA standardization at length.<sup>1</sup> Please contact Qualigen System Support at [sytemsupport@qualigeninc.com](mailto:sytemsupport@qualigeninc.com), 877-770-6127 (USA only), or 760-579-6900 if you have any questions.

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<sup>1</sup> [PSA standardization: Making sense of the controversy. Vignati, Giulio. PUB. DATE. March 2009. SOURCE. Urology Times; 3/1/2009, Vol. 37 Issue 3: 24-27](#)