



# Technical Bulletin

## PSA Standardization

October 2019

The FastPack® System provides the option to report Total PSA results using either Hybritech or WHO Standardization. From the onset, the default factory setting of the FastPack System was configured to report PSA results using Hybritech Standardized PSA values because the commonly accepted clinical reference ranges were established using methodologies based on the Hybritech standardization.

However, moving forward the factory setting for PSA will now be the WHO Standardization because it has become more prevalent and conventionally accepted among the leading PSA tests used in reference labs.

This change is important for those labs who have been using Hybritech Standardized PSA; if you receive a replacement FastPack System, it will now arrive configured to report WHO Standardized PSA, and you will need to change the setting in the replacement FastPack System in order to continue reporting PSA results in the Hybritech Standardization.

WHO Standard PSA results have a “W” printed to the left of the PSA result, and a “W” appears in the second character row of the analyzer display upon completion of a PSA test.

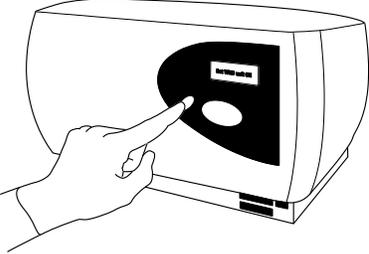
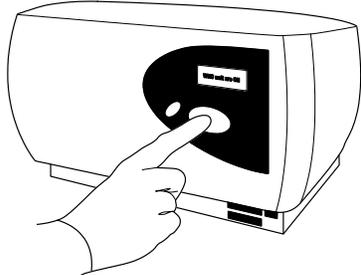
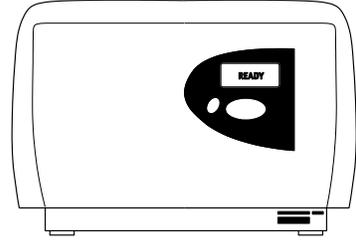
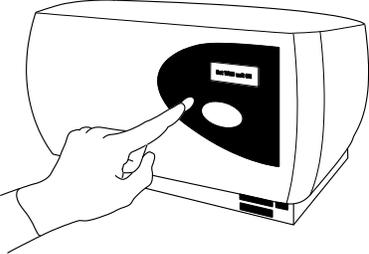
If you currently use the Hybritech Standard based Total PSA setting, and you decide to use WHO Standardized PSA setting instead, Qualigen recommends that your lab:

1. Establish a new baseline for Total PSA patient results because WHO Standardized PSA results are on average 20% lower compared to Hybritech Standardized PSA results.
2. Use the WHO Quality Control ranges printed on the FastPack System Control Range Card when assessing acceptability of quality control results. You will see that the ranges will differ based on which PSA Standardization setting you use.
3. Enroll in the appropriate peer group for your proficiency surveys. For example, API (American Proficiency Institute) has a distinct peer group for Qualigen FastPack WHO PSA.

See Page 2 for instructions on how to set the FastPack System to output WHO Standardized PSA or Hybritech Standardized PSA results.

Please contact Qualigen System Support at [systemsupport@qualigeninc.com](mailto:systemsupport@qualigeninc.com), or 760-579-6900 if you have any questions.

# PSA Standardization Settings

Action	Instrument	Information	Illustration
<p>Press the RED button several times until the display reads</p> <p><b>“PSA=WHO Units Tap blue to chng”</b></p>	<p><b>“PSA=WHO Units Tap blue to chng”</b></p>	<p>This indicates that the analyzer is currently set to output WHO Standardized PSA results.</p>	
<p>Press the BLUE button.</p>	<p><b>“PSA=Hybritech”</b></p>	<p>This action changes the analyzer from WHO Standardized PSA to Hybritech Standardized PSA.</p>	
	<p><b>“Ready”</b></p>	<p>The analyzer display will return to the “Ready” screen.</p>	
<p>Press the RED button several times until the display reads</p> <p><b>“PSA=Hybritech Tap blue to chng”</b></p>	<p><b>“PSA=Hybritech Tap blue to chng”</b></p>	<p>This indicates that the analyzer is currently set to output Hybritech Standardized PSA results.</p>	
<p>Press the BLUE button.</p>	<p><b>“PSA=WHO Units”</b></p>	<p>This action reverts the analyzer back to outputting PSA in WHO Standardized results.</p>	
	<p><b>“Ready”</b></p>	<p>The analyzer display will return to the “Ready” screen.</p>	