

Access[®] Hybritech[®] PSA

Hybritech and WHO Calibration Information

Background

PSA is currently the best clinical biomarker available for detecting and managing prostate cancer, and the only one FDA-approved as an aid in the prognosis and management of patients with prostate cancer, and in conjunction with digital rectal examination (DRE), as an aid in the detection of prostate cancer.^{1,2}

Beckman Coulter's Hybritech PSA assay has a rich history. In 1986, the Hybritech Tandem[™]-R assay became the first PSA assay to be approved by the FDA. In 1994, 4.0 ng/mL was identified as the clinical decision point using the Hybritech PSA assay in a multicenter study on 6,630 men.³ In 2000, the Hybritech Tandem-R assay migrated to the Access Immunoassay System with identical assay performance.

With the addition of the WHO calibration option, you have the freedom of choice to use our PSA assay with a Hybritech or WHO calibration while maintaining the same clinical performance you and your physicians expect.

Beckman Coulter will continue to provide the classic Hybritech PSA calibration that has served as the basis for clinical interpretive criteria in use by physicians for patient management.

Clinical Cutoff

There is a 22% difference between the Hybritech and the WHO cutoffs.

Beckman Coulter evaluated the impact of WHO calibration through analysis of a 6,630 subject prospective clinical study. That study provided the basis for the approval of Hybritech PSA in conjunction with DRE for detection of prostate cancer, and identified 4.0 ng/mL as a value at which to consider a biopsy.

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It was determined that a different clinical cutoff for the WHO calibration is necessary to provide the same clinical sensitivity and specificity as the classic Hybritech calibration. The cutoffs for the respective assays are listed in the table below.

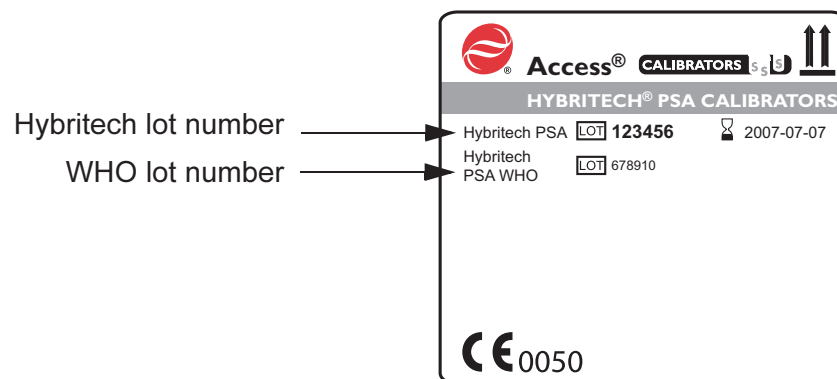
	Hybritech Calibration	WHO Calibration
PSA Cutoff	4.0 ng/mL	3.1 ng/mL

Calibrator

The Hybritech PSA calibrator kit provides two calibration options. The Hybritech and the WHO calibrations use the same calibrators. The kit contains two distinct calibration cards, differentiated by color as follows:

- White card Hybritech calibration
- Yellow card WHO calibration

The WHO calibration card is further differentiated with a unique calibrator lot number. This lot number is also on the Calibration Data Report and on the label of the calibrator kit box, as shown in the example below. The WHO lot number is used only for reporting and tracking purposes.



Quality Control (QC)

The PSA quality control kit contains two value cards. Each card has values specific for the respective calibration option (Hybritech or WHO).

- White card Hybritech QC values
- Yellow card WHO QC values

Test Names and LIS Codes for Hybritech PSA with Dual Calibration

The following table illustrates the different test names and LIS codes for both Hybritech and WHO calibrations.

System Information	Access Hybritech PSA	Access Hybritech PSA WHO
Access / Access 2 / UniCel [®] DxI	PSA-Hyb	PSA-WHO
SYNCHRON LX [®] i / UniCel Dx [®] C 600i	PSA-H	PSA-W
DL2000 Codes	A62	A90

APF & AAF Information

We recommend that you install the most recent version of system software.

System Information	Wash Buffer II (blue label) REF A16792 or A16793
Access	APF 1.1.160.2 or higher
Access 2	APF 1.9.129.2 or higher
UniCel DxI 800	APF 1.10.138.2 or higher
UniCel DxI 600	APF 1.10.145-6.2 or higher
SYNCHRON LXi	APF L1.9.129.2 and AAF 4.10.00 or higher
UniCel Dx [®] C 600i	APF D1.9.129.2 and AAF 5.10.00 or higher
UniCel Dx [®] C 880i	APF 1.10.149.2 and AAF 6.13.00 or higher

More Information?

To find more information on PSA standardization and prostate disease management, go to:

[www.beckmancoulter.com/PSA value](http://www.beckmancoulter.com/PSA_value)

Ordering Information

Access Hybritech PSA — 2 packs of 50 tests/pack	37200
Access Hybritech PSA Calibrators — 6 vials of 2.5 mL/vial	37205
Access Hybritech PSA QC — 3 levels, 1 vial/level, 5 mL/vial	37209
Access Hybritech PSA Sample Diluent — 1 vial of 14 mL	37206

References

- 1 FDA Premarket Approval Application P850048. Use of PSA for prognosis and management of patients with prostate cancer. 1986.
 - 2 FDA Premarket Approval Application Supplement P850048/S009. Use of PSA as an aid in the detection of prostate cancer. 1994.
 - 3 Catalona WJ, et al. Selection of optimal PSA cutoff for early detection of prostate cancer, ROC curves. J Urol 1994; 152: 2037-2042.
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