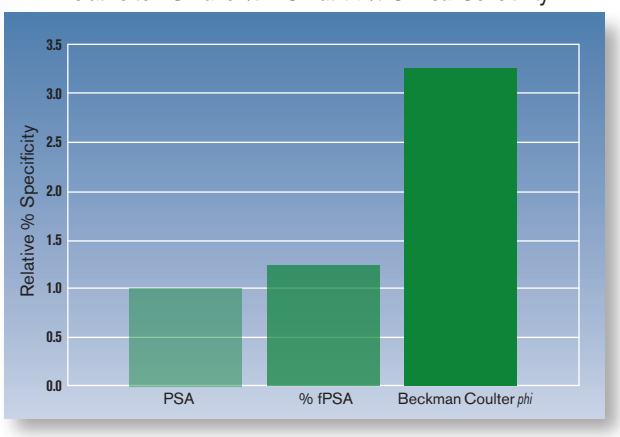
Better guidance for more confident prostate biopsy decisions.

Access Hybritech p2PSA* and Prostate Health Index (*phi*)

Several isoforms of free prostate-specific antigen (fPSA) have been identified as precursor forms of PSA (proPSA). One form, [-2]proPSA, has been determined to be the most specific for prostate cancer.[1] The new Access Hybritech p2PSA test measures the [-2]proPSA concentration in serum.

When p2PSA measurements are combined with Access Hybritech PSA and free PSA, the resulting index demonstrates a significant improvement in clinical specificity for prostate cancer detection, relative to PSA and fPSA alone in the PSA range of 2-10 ng/mL in men 50 years of age or older and with non-suspicious digital rectal exam (DRE) findings. This resulting index, a patient's personalized prostate cancer risk assessment, is known as the Prostate Health Index or *phi*.[2,3,4]

Prostate Cancer Detection: % Specificity of Beckman Coulter *phi* Relative to PSA and % fPSA at 90% Clinical Sensitivity



Beckman Coulter *phi* offers:

- Enhanced clinical specificity – provides significantly improved clinical specificity leading to a potential reduction of unnecessary biopsies
- Personalized results – provides individualized risk assessment for prostate cancer
- Automated results - when Hybritech p2PSA is used in conjunction with Hybritech PSA and free PSA
- Equally effective - when used with either Hybritech or WHO calibrations for PSA and free PSA

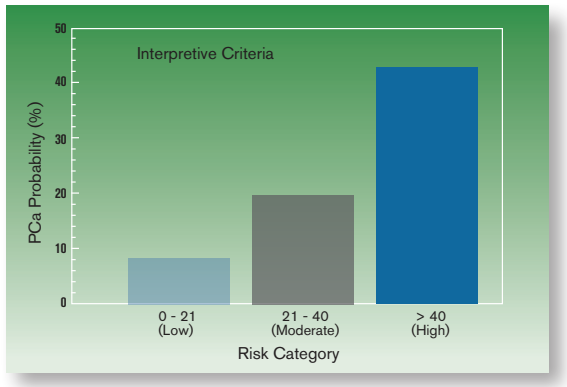
*Not available in the U.S.

Access Hybritech p2PSA and *phi*

The *phi* results provide patients more specific information about the prostate cancer risk their elevated PSA may represent. A low *phi* result indicates a potentially lower risk of prostate cancer, while an elevated *phi* result may suggest that a recommendation for a prostate biopsy is more necessary (see charts below).

Beckman Coulter *phi* can be used to categorize patients into appropriate low, moderate and high probabilities of prostate cancer found on biopsy. The resultant *phi* ranges have been associated with increasing probabilities of cancer as listed below:

Probability of Prostate Cancer in Patients with PSA levels in the 2-10 ng/mL range using *phi* with Hybritech calibrations			
phi Result Range (Hybritech Calibration)	Prostate Cancer Risk Category	Probability of Cancer	95% Confidence Interval
0-20.9	Low	8.4%	1.9% - 16.1%
21.0 - 39.9	Moderate	21.0%	17.3% - 24.6%
40+	High	44.0%	36.0% - 52.9%
Probability of Prostate Cancer in Patients with PSA levels in the 1.6-7.8 ng/mL range using *phi* with WHO calibrations			
phi Result Range (WHO Calibration)	Prostate Cancer Risk Category	Probability of Cancer	95% Confidence Interval
0-22.9	Low	8.7%	2.0% - 17.0%
23.0 - 44.9	Moderate	20.6%	17.1% - 24.1%
45.0+	High	43.8%	35.8% - 52.2%



*In patients with tPSA between 2-10 ng/mL using Hybritech calibration

Characteristics

Sample Type	Serum
Time to First Result	Approx. 20 mins
Limit of Blank (LOB)	0.50 pg/mL
Dynamic Range	Approx. 0.50 to 5000 pg/mL
Open Pack Stability	28 days
Calibration Stability	28 days
Limit of Quantitation (LOQ)	3.23 pg/mL

Ordering Information

Reagent Kit (2 x 50 tests)	A49752
Calibrator Kit (7 x 2.1 mL)	A49753
Control Kit (3 levels; 1 x 5.0 mL)	A56934

References

1. Mikolajczyk SD. Proenzyme forms of prostate-specific antigen in serum improve detection of prostate cancer. Clin Chem 2004 March;50:1017-1025.
2. Jansen FH. Prostate-specific antigen (PSA) isoform p2PSA in combination with total PSA and free PSA improves diagnostic accuracy in prostate cancer detection. Eur Urol 2010;57(6):921-927.
3. Sokoll L. [-2]proenzyme prostate-specific antigen for prostate cancer detection: a National Cancer Institute Early Detection Research Network validation study. J Urol 2008;180(2):539-543.
4. Le BV. [-2]proenzyme prostate-specific antigen is more accurate than total and free prostate-specific antigen in differentiating prostate cancer from benign disease in prospective prostate cancer screening study. J Urol 2010;183:1355-59.

Access Tumor Markers: A Menu that Matters

Hybritech PSA	Hybritech free PSA	Hybritech p2PSA*
BR Monitor	GI Monitor	OV Monitor
CEA	AFP	

*Not available in the U.S.

Access tumor markers are part of a comprehensive assay menu featured on the Access and UniCel Immunoassay systems. To learn more, visit ***www.beckmancoulter.com/tumormarkers.***

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