ADDENDUM VII

ACCESS HYBRITECH FREE PSA RESULTS

The Access Hybritech free PSA assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of free prostate specific antigen (free PSA) in human serum using the Access Immunoassay Systems. Access Hybritech free PSA is intended to be used in conjunction with Hybritech (total) PSA to calculate the ratio of free PSA to total PSA. This PSA Ratio is indicated for use as an aid in distinguishing prostate cancer from benign prostatic conditions and is used in conjunction with digital rectal examination (DRE).

Free PSA Assay is an in-vitro device for the quantitative measurement of Free Prostate Specific Antigen (Free PSA) in human serum.
The Hybritech Free PSA Assay is intended to be used in conjunction with a PSA (Total) Result to calculate the ratio of Free PSA to Total PSA (The Access HybriTech PSA Ratio). The PSA Ratio is to be used in conjunction with Digital Rectal Exam (DRE).
Among patients with a Total PSA in the 2.5 to 20.0 ng/ml range, recent studies indicate that men with Prostate Cancer tend to have a lower Free PSA/Total PSA ratio than those with Benign Prostatic Hypertrophy.

Prostatic biopsy is required for diagnosis of cancer.

Probability* for cancer by proportion of free to total PSA level, age at disease diagnosis, and total PSA value in patients with a total PSA between 2.5 and 20.0 ng/ml

Total PSA (ng/ml)	Ratio of Free to total PSA (%)			
	<7	7 - 15	16 - 25	>25
Age <60 years				
2.5 - 4.0	84	23	10	2
4.1 - 10.0	87	28	12	3
10.1 - 20.0	93	42	21	5
Age 60 - 70 years				
2.5 - 4.0	94	47	25	6
4.1 - 10.0	95	52	29	7
10.1 - 20.0	97	68	44	13
Age >70 years				
2.5 - 4.0	96	57	33	9
4.1 - 10.0	97	62	38	11
10.1 - 20.0	98	76	54	19

Based on logit log linear models.