



New Prostate-Specific Antigen Assay Improves Accuracy for Bound and Free Forms

Lawrence M. Killingsworth, Ph.D., DABCC, Chief Science & Technical Officer

ON DECEMBER 17, 2001, PAML will begin offering a new "equimolar" assay for Prostate Specific Antigen (PSA). The advantage of the new assay is that the immunochemical reagents react equally with both the bound and free forms of PSA.

Although this reagent change is primarily an analytical improvement, there are some potential clinical advantages. Currently, there are large differences in PSA results between laboratories that use different methods. This can be confusing to physicians managing patients with prostatic carcinoma when results are obtained from different laboratories. Manufacturers of PSA assay reagents are moving to equimolar methods in an effort to minimize differences between assays and laboratories. It is still recommended that physicians stay with one laboratory when monitoring a patient's PSA results, but as all manufacturers adopt equimolar methods and standardization improves, differences between methods and laboratories should become less significant.

PAML has carried out correlation studies between our current PSA method and the equimolar method. The relationship between results from the two methods can be characterized by the following equation:

$$\text{New method result} = (0.935) \times \text{old method result} + 1.1$$

For example, if the patient's result from the old method was 10.0 ng/mL, the result from the new method would be 10.4 ng/mL. Higher results will show proportionately larger differences. If the patient's result from the old method was 50.0 ng/mL, the result from the new method would be 47.8 ng/mL. These calculations demonstrate the statistical differences between the two methods, based on the population of patients in the study.

As the correlation studies show, most patients should not show substantial differences in PSA results from the current method to the new equimolar method. However, individual patients may vary more than would be calculated from the correlation equation. As is our usual practice when changing methods for tumor markers, PAML will re-baseline patients with the new method at no charge for three months, ending on March 17, 2002.

Selected references

1. Fox MP, et al. Effect of the ratio of free to total prostate specific antigen on interassay variability in proficiency test samples. *Clin Chem* 1999;45:1181-9.
2. Cheli CD, et al. Variation in the quantitation of prostate specific antigen in reference material: Differences in commercial immunoassays. *Clin Chem* 1998;44:1551-3.

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For more information, please contact your local representative.

To Request PSA Rebaseling at No Charge

- ▶ On paper laboratory requisitions, write "**Rebaseline PSA**" when ordering PSA or Free PSA batteries.
- ▶ For electronic orders, "**Rebaseline PSA**" must be entered into the tech comments field when ordering PSA or Free PSA batteries.

- ▶ Ultrasensitive method sensitivity is 0.01 ng/mL.

For more information, please contact Client Services.