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Evaluation of Siemens fPSA assay on Immulite® 2000.

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Aculabs, Inc. East Brunswick, NJ, USA. AAB 2008 Conference and CRB Symposium.

Background

Prostate cancer is the most common tumor in men in the United States, with an estimated 218,890 new cases and 27,050 deaths in 2007 according to the statistic data from the American Cancer Society. Although prostate cancer is the number one cancer in men, it appears that most affected men die of causes other than their cancer; but once it reaches advanced stages it becomes resistant to most treatment options. Prostate specific antigen (PSA) is used for screening and monitoring of prostate cancer, because of the limitation of PSA in the gray zone (4.0-10.0 ng/mL) and because benign prostate hyperplasia (BPH) can increase total PSA, the fPSA/tPSA ratio has been widely used in the clinical practice to differentiate between benign and malignant prostate diseases.

Methodology

Immulite® 2000 fPSA assay is a solid phase sequential chemiluminescent immunometric assay. We evaluated the assay sensitivity, specificity, intra- and inter-assay CV, linearity, cold recovery, cross reactivity, reliability and correlation with other method (Dade DXI). All statistic calculations were done using Analyze-it program.

Results

The intra- and inter-assay CV were <10 %, the assay has no interference with CEA, AFP or ferritin up to the concentration used. The functional sensitivity was 0.5 ng/mL. The assay was linear up to the functional sensitivity of the assay. Cold recovery ranged from 94 % to 95.6 %. Freeze/thaw cycle did not have a major effect on samples within the assay limit of sensitivity. Correlation with the DXI gave a proportional bias of 0.77.

Conclusion

Immulite fPSA assay is a specific assay and linear; freeze/thaw did not affect the samples. The loss of the linearity and the increase in the CV for the samples below 0.5 ng/mL could be due to the reproducibility of the assay at that level (below the sensitivity). The heterogeneity of the PSA molecule, different standards used by different companies, and the use of different antibodies which recognize different epitopes on the molecule explain the difference in results obtained from different methods. A Laboratory should alert ordering physicians when there is change in the assay method to eliminate the misinterpretation of the difference in the results obtained from different instruments.