

PROSTATE SPECIFIC ANTIGEN/SOLVENT INTERACTION ANALYSIS (PSA/SIA): CONTINUED EXAMINATION OF POTENTIAL PSA ISOFORMS FOR A NEW ASSAY FOR PROSTATE CANCER

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INTRODUCTION: We describe exploratory data obtained using a novel protein structural assay for CaP diagnosis. The assay uses the novel technique called PSA/SIA (PSA/Solvent Interaction Analysis) to detect changes in PSA isoform composition that differentiate benign and malignant disease. We previously reported preliminary data using PSA/SIA on urine samples of 222 patients with excellent performance in biopsy cancer detection (ROC AUC 0.90, Sensitivity 100%, Specificity 80.3%), and also using serum samples in a separate study. Here we report continued examination of potential PSA isoforms using the same technology with different SIA assay chemistries.

METHODS: 149 serum samples were obtained from multiple clinical sites, collected prior to prostate biopsy. These serum samples were evaluated using PSA-SIA, with biopsy results as gold standard.

RESULTS: PSA/SIA results are reported using a ratiometric composite structural coefficient, K. Using ROC analysis comparing total serum PSA, %free PSA, and PSA/SIA performed for total PSA and complex PSA (calculated as the difference between total and free PSA concentrations), the corresponding AUC were 0.6, 0.7, 0.77, and 0.83, respectively.

CONCLUSIONS: PSA/SIA uniquely exploits the structural heterogeneity in PSA resulting in enhanced diagnostic performance of CaP. The assay responds solely to structural changes and/or changes in PSA complex formation, and not to its absolute amount. Superior performance so far has been demonstrated by focusing the assay on complex PSA isoforms in the mixture. Further studies, including further assay optimization, a large scale validation study, and elucidation of the detected underlying structural differences will address these and other issues.