PROSTATE SPECIFIC ANTIGEN/SOLVENT INTERACTION ANALYSIS (PSA/SIA): INITIAL REVIEW OF CLINICAL DATA FOR SERUM PSA IN THE RANGE OF 2 < [PSA] < 4 NG/ML.

INTRODUCTION: We conducted preliminary evaluation of PSA/SIA, a novel protein structural assay for CaP diagnosis, at low serum PSA levels. 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 high performance data for urine and serum in samples with serum PSA above 4 ng/ml. Since the assay is ratiometric and only responsive to changes in isoform composition related to cancer, it should perform similarly at different PSA levels. In this study we test the assay at the same cut−off value of the test statistic, K, and compare against previously reported data for PSA > 4 ng/ml.

METHODS: 94 serum samples were obtained from multiple clinical sites, collected prior to prostate biopsy from patients with serum PSA between 2 and 4 ng/ml. These serum samples were evaluated using PSA/SIA with complexed PSA as the test analyte, and with biopsy results as gold standard. The fraction of cancer in the sample cohort was 25%.

RESULTS: PSA/SIA results are reported using a ratiometric composite structural coefficient, K. Using ROC analysis, AUC=0.82, SN=100%, and SP=46%, NPV=100, and PPV=56% at K cut−off value of 0.14, at cohort cancer prevalence of 25%. Previous data for samples with PSA > 4 ng/ml resulted in AUC=0.81, SN=96%, SP=48%, NPV=95%, and PPV=38% at the same cut−off level, and with cancer prevalence of 41%.

CONCLUSIONS: This study provides preliminary validation that PSA/SIA diagnostic performance is independent of the absolute serum PSA level.