

## **Moderated Poster Details:**

Session Title: Prostate Cancer: Detection & Screening (II)

Session Start: 5/21/2006 3:30:00 PM

Session End:5/21/2006 5:30:00 PM

### **Location:**

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Title

**Specificity of the APTIMA® PCA3 Assay for Prostate Cancer**

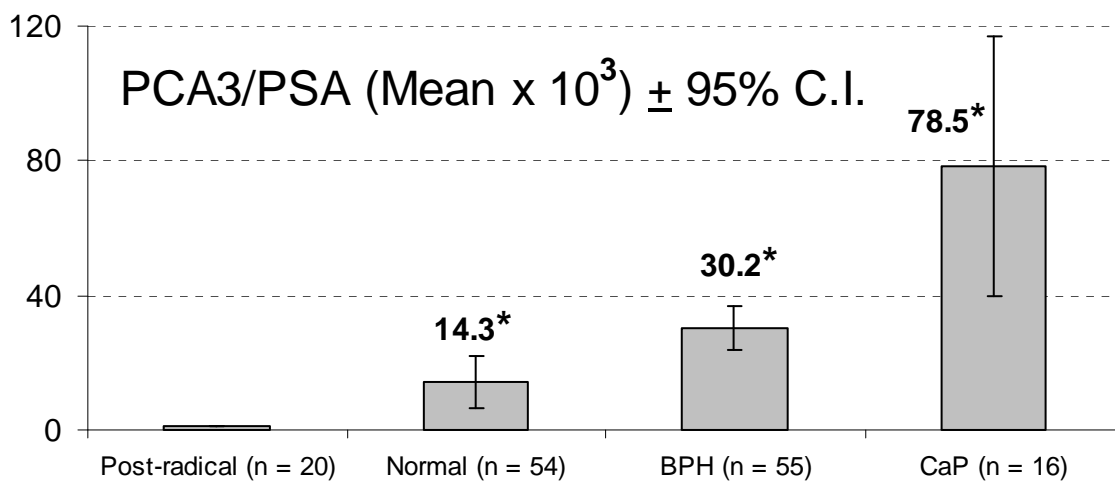
### **Introduction**

PCA3 is a prostate-specific mRNA that is highly up-regulated in prostate cancer (CaP). In earlier studies, a urine test for PCA3 appeared to have greater specificity for CaP than the serum prostate-specific antigen (PSA) assay. We performed a clinical evaluation of an improved prototype PCA3 assay, following 2 years of pre-clinical assay refinement.

### **Methods:**

147 male outpatients (ages 27-92 y.o.) were subjects of the study. Subjects were grouped as follows (see chart): post-radical prostatectomy, normal <45 y.o., benign prostatic hyperplasia (BPH), untreated CaP. Diagnosis of BPH or CaP was made after TRUS-guided biopsy. Subjects underwent history, physical exam, serum PSA testing and, following 'attentive' digital rectal exam (ADRE), whole urine collection. ADRE was 3 firm finger strokes on each side of prostate. Urine was stabilized with detergent solution, then batch-analyzed for PCA3 and PSA mRNA using the prototype PCA3 assay. The ratio of PCA3/PSA mRNA was used as the diagnostic indicator. This PCA3 assay differs from previous methods: it is quantitative for both targets, specimen processing is simple, testing may be completed in hours and the informative specimen rate (i.e., detection of PSA mRNA) is >95%. The assay utilizes a platform and technologies similar to those currently used to screen the U.S. blood supply for HIV & hepatitis (J.Clin. Micro. 40: 2408, 2002).

## Results:



PCA3 testing provided near-complete separation of groups ( $p < 0.01$ )\*. No overlap of 95% C.I. was seen between young healthy men vs. men with BPH vs men with CaP (all Gleason Grade 6-7). No patient cured of cancer by prostatectomy had detectable mRNA levels in urine. Using biopsy as the reference method, receiver operating characteristics (ROC) curve analysis yielded an area under the curve of 0.751; sensitivity was 63% and specificity 82% at a PCA3/PSA mRNA ratio cut-off of  $50 \times 10^{-3}$ . For comparison, the specificity of the serum PSA assay was 42% (cut-off 2.5 ng/mL) for this same subject group.

## Discussion

Using a quantitative, convenient assay and 'attentive' DRE before specimen collection, the PCA3/PSA ratio appears to be highly specific for CaP vs

BPH. The APTIMA PCA3 assay may therefore be useful as an aid in the diagnosis of CaP.

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