



## PCADM-1: A Novel Urine Marker for Prostate Cancer

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### Abstract

**PCADM-1: A Novel Urine  
Marker for Prostate Cancer**

Development of markers for the early detection of prostate cancer is essential to improved treatment of the disease. Recently, we have developed 'DNA-protein' binding assays for the identification of novel transcriptional regulatory proteins associated with the development of prostate cancer (PCA). One gene identified was a novel 33 Kda chromosomal protein, termed prostate cancer diagnostic marker -1 or PCADM-1. Sequencing revealed that the gene had 6 specific point mutations which appeared to endow the mutant protein with DNA binding activity. RT-PCR assays indicated the mRNA was expressed in human cancer cells and tissue but it was not present in BPH, HGPIN or seminal vesicle tissue. Rabbit and goat polyclonal antibodies were raised against the recombinant protein and employed to evaluate the diagnostic utility of PCADM-1. Western blots, in situ hybridization and immunolabeling studies of human prostate cancer tissue (n=25) clearly showed that PCADM-1 expression was a specifically associated with the glandular epithelial cells in 100% of the glands. The levels of expression increased from +1 to +5 with an increased Gleason score of 4, 6 and 8, respectively. The protein was not expressed by other cancers examined, indicating it was specific for prostate cancer. ELISAs revealed that the protein was a highly sensitive urine marker for prostate cancer. Receiver Operator Curves indicated the limit of detection was 0.1 ng/ml with a cut-off of 0.2 ng/ml for the detection of recombinant PCADM-1 or native PCADM-1 in tissue extracts from prostate cancers. A beta test of the urine of 43 patients with known prostate cancer and 40 with BPH yielded a sensitivity of 75% and a specificity of ~78%. A blinded study was then carried out with 533 patients with either prostate cancer (n=48), BPH (n=88), urinary problems (n=108) or no symptoms (n=289) plus normal people (n=40). The data showed that the PCADM-1 urine assay had a sensitivity of 79% and a specificity of 83% overall (NPV=79%; PPV=78%). A second study of 157 patients diagnosed as having PCA (n=76) and BPH (n=81) yielded a sensitivity of 83% and specificity of 74%. A large scale trial is currently planned to develop an FDA approved test for prostate cancer. Supported by grant #CA076639 from the NIH-NCI to Dr. Stearns.