Intellectual Property (Non-confidential)



1.0 0.8 Sensitivity 0.6 0.4 TMPRSS2:ERG 0.2 PCA3 PCA3/PSA 0.0 0.6 0.8 0.2 0.4 1.0 0.0 Specificity

Biomarker Array for Prostate Cancer

DESCRIPTION

There are 4 major diagnostic tools for detecting prostate cancer. These tests include: the Prostatespecific antigen test (PSA test), Digital rectal exam (DRE), Transrectal ultrasound, and prostate biopsy. While the PSA test is more sensitive than the digital rectal examination for detecting prostate cancer, some early cases of prostate cancer may be missed by the PSA screening cut-point of 4.0 ng/L. This highlights a need for a method of diagnosing prostate cell proliferative disorders such as prostate cancer with improved sensitivity, specificity and predictive value. This technology addresses the long felt need for the early diagnosis of prostate cell proliferative disorders, in particular for the detection of prostate cancer, prostate carcinoma and prostate neoplasms. This is accomplished via a biomarker array for a novel panel of

genes, RNA sequences, genomic sequences and regulatory regions.

KEY ASPECTS

- This technology does not rely on a single biomarker but instead on a large number of biomarkers and their combined expression pattern
- Some of the biomarkers in included in the array below are: PSA RNA, TMPRSS2:ERG RNA, GSTPI, APC, RARB, RASSFI DNA, TMPRSS2:ERG Type III or V1 fusion RNA, GSTPI, APC, RARB, RASSFI and PCA3
- See published data at: Clark JP, Munson KW, Gu JW, Lamparska-Kupsik K, Chan KG, Yoshida JS, Kawachi MH, Crocitto LE, Wilson TG, Feng Z, Smith SS (2008) Performance of a single assay for both type III and type VI TMPRSS2: ERG fusions in noninvasive prediction of prostate biopsy outcome. *Clin Chem* 54(12): 2007–2017

INTELLECTUAL PROPERTY

Title	US Patent Application	Filed
Assay for Prostate Cancer	12/327,788	12/3/2008

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