

# Novel Gene Polymorphisms to Predict Prostate Cancer Recurrence and Guide Therapy Options



*This diagnostic technology is a set of angiogenesis gene polymorphisms that correlate with prostate cancer recurrence after radical prostatectomy. NCCN guidelines recommend either adjuvant radiation therapy (ART) or monitoring for patients after prostatectomy but only approximately 30% of patients are expected to recur within 10 years of surgery, and no criteria exist to reliably estimate the risk of recurrence. As a result, ART could be either recommended unnecessarily, or withheld from patients who would have benefited as suggested by 20% of patients classified as low-risk dying due to watchful waiting. This technology could provide a personalized genomic approach to predict the risk of prostate cancer recurrence.*

## COMMERCIAL OPPORTUNITY

- Over 240,000 men are diagnosed with prostate cancer annually in the US and about half of those men undergo radical prostatectomy (RP). 40% of post-RP patients display adverse clinicopathologic features (such as prostate specific antigen (PSA), positive lymph nodes or a high Gleason score), which designates them as “high-risk”. Adjuvant radiation therapy (ART) is prescribed to the high-risk men to minimize the risk of cancer recurrence.
- However, only a fraction of men deemed “high-risk” will recur as demonstrated by the 24% recurrence rate within 8 years in the patient cohort studied here. Conversely, many men do not have adverse clinical features and yet will recur as evidenced by 20% of patients classified as “low-risk” who die due to recurrence during conservative treatment which is essentially watchful waiting.
- Our diagnostic is a risk stratification tool to more accurately determine which patients are at risk for recurrence and should receive ART. The test might also provide a cost saving by determining which “high-risk” patients could avoid unnecessary ART procedures at ~\$ 6,000 per patient. The test might also determine which “low-risk” patients should actually receive ART and avoid later costly therapeutics for metastatic disease, such as ~\$200,000 worth of drugs per patient receiving full courses of Docetaxel, Sipuleucel-T and Abiraterone acetate, in addition to the cost of doctor visits and managing side effects.
- The unmet need for a test for recurrence after RP is evidenced by two other tests: Decipher by GenomeDx Biosciences and NADiA ProsVue by Iris International. GenomeDx has secured insurance coverage for the 22 gene expression profile Decipher test with three PPO networks representing 63 million covered lives. NADiA ProsVue looks at the rate of change of serum total PSA from six weeks to 20 months post RP, and is only meant to determine which patients have a low risk of recurrence.

## TECHNOLOGY

This technology is a set of 30 Single Nucleotide Polymorphisms (SNPs) in 18 angiogenesis-related genes that were statistically significantly ( $p$ -values  $< 0.005$ ) associated with prostate cancer recurrence in a historical cohort of 1189 prostatectomy patients treated at Moffitt Cancer Center. The patients (297 recurred and 942 non-recurred) were followed for over 8 years, and the association between SNPs and recurrence-free survival was calculated. The most significant association was observed for rs1654680 in *ANGPT* (HR=1.69;  $P<0.0001$ ). Other significant genes include *CDH*, *FGF/FGFR*, *IL* and *MMP*.

## PUBLICATION/PATENT

- PCT patent application filed on 5/9/2013 for Drs. Park, Sellers, Powsang, and Lin

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### LICENSING OPPORTUNITY

