**A Live Cell Microfluidics Device Utilizing Phenotypic Biomarkers for Prostate Cancer.**

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**Introduction: A novel tissue based biomarker panel is introduced to objectively assess disease aggressiveness and invasive potential of Prostate Cancer (CaP). The biomarker diagnostic platform incorporates both molecular and phenotypic data that may allow an improved understanding of local growth and metastatic potential. The tissue based diagnostic incorporates matrix biology, phenotypic biomarkers, microfluidics, and machine vision. This technology presents the opportunity to culture samples, and both determine and automate biomarker measurements from machine vision algorithm analysis. Data are presented towards clinical validation, the ability to risk stratify, and prediction of local aggressiveness and metastasis.**

**Methods: Conditions were optimized for reliably culturing primary cancer cells *in vitro* by simulating *in vivo* conditions on an extracellular matrix formulation. A microfluidics device was used to culture live tumor samples *ex vivo* enabling automated imaging of the label free and label-based biomarkers.**

**Results: The validation study was IRB approved and performed in 200 consecutive CaP radical prostatectomy derived specimens collected between 03/2014 and 09/2015. Data was analyzed with receiver operating characteristics (ROC) generated Area-under-the-Curve (AUC) and specifically included capsular penetration, seminal vesicle invasion, as well as margin-positive disease. AUC Graphs are presented. The study further demonstrated that a normal set of phenotypic biomarkers can produce secondary metrics termed General Adverse Pathology Potential (GAPP), Local Adverse Pathology Potential (LAPP), & Metastatic Adverse Pathology Potential (MAPP) . Concordance analysis supports that LAPP and MAPP are integral for distinguishing between benign histology and malignancy, predicting both stage and adverse pathology such as extra-prostatic extension (EPE) and lympho-vascular invasion (LVI). The study results demonstrate AUCs greater than 0.85 in predicting EPE and LVI.**

**Conclusion: Results support the clinical validation of a novel live- cell phenotypic *in vitro* tumor diagnostic test. This test has the potential to predict adverse pathologies for CaP and may have extended clinical applications to optimize staging and risk stratification.**