

Creatv's LifeTracDx™ Blood Test for Early Detection of Aggressive Prostate Cancer



Press Release

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Creatv MicroTech (Creatv), a cancer screening and diagnostic company with headquarters in Rockville, Maryland, is announcing a collaboration with the University of Miami School of Medicine on a study supported by the National Institutes of Health / National Cancer Institute entitled “MRI Imaging and Biomarkers for Early Detection of Aggressive Prostate Cancer”. Allan Pollack, Sanoj Punnen and Radka Stoyanova are the study’s Principal Investigators.

The study objective is to evaluate and validate the integration of quantitative imaging features with pathologic, molecular and blood markers to better manage prostate cancer diagnosis and treatment selection. Creatv’s biomarker, cancer associated macrophage-like cells (CAMLs) originated within the cancer stroma and can be found along with circulating tumor cells (CTCs).

The study will evaluate 250 men under active surveillance over a five year period. This will address a fundamental issue with prostate cancer, in that approximately 50% of men will undergo unnecessary biopsies of the prostate, because the patients (1) didn’t have prostate cancer, i.e. false positive or (2) the prostate cancer was a low grade indolent disease not impacting the quality of life. In the latter case, nearly 90% of men diagnosed with prostate cancer historically have undergone treatment, indicating a significant rate of over-treatment.

While active surveillance has reduced overtreatment, the cost of follow-up for active surveillance is high because of the need for periodic biopsies to establish that a significant cancer was not missed or there has been no progression. Methods of assessment developed around this health care issue would improve the negative predictive value (NPV) for significant cancers, which is a specific aim of this study. A high NPV would minimize the risk of missing the > 30% of prostate cancer patients presenting with significant prostate cancer.

Researchers at the University of Miami have developed a new quantitative multi-pixel (mp) MRI habitat risk score (HRS) focusing on patients undergoing active surveillance. To further improve the rate of detecting underlying significant cancers of the prostate, three blood-based biomarkers (CAMLs, CTC’s and 4Kscore) are being added that would serve to trigger the need for template biopsies in the absence of suspicious mpMRI abnormalities. By applying a quantitative approach to mpMRI habitat

classification and the inclusion of body fluid biomarkers, the NPV will increase substantively, potentially obviating the need for prostate biopsy in >25% of referred men.

Creatv will be testing the blood of study participants for the presence of its CAMLs, which are cancer specific blood cells found universally in patients with aggressive solid tumors, but absent in healthy persons.

“CAMLs are found in all stages of cancer, even in Stage I, making it an ideal early cancer detection marker, especially in prostate cancer where the large size of the CAML’s can predict aggressiveness of the tumor,” noted Dr. Cha-Mei Tang, Founder and CEO of Creatv. “In terms of screening, we have been funded for two studies – one by the NIH for a 1,000 patient breast cancer screening and the second by the DoD for a 1,000 patient lung cancer screening,” she added.

Award Disclaimer

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About Creatv MicroTech

Creatv is a privately-held cancer screening and diagnostic company founded in 2000, featuring expertise in both biodetection and microfabrication. Creatv combined the two disciplines to develop the **CellSieve™** microfiltration technology platform which enables the separation and identification of all cancer associated cells in the blood. The company discovered, and analyzed CAMLs from >20 solid tumor types. Creatv has developed liquid biopsy assays (**LifeTracDx™**) for whole blood analysis of CAMLs and CTCs. **LifeTracDx™** blood tests are applicable for cancer screening, companion diagnostics, prediction of treatment response including immunotherapy, providing prognosis, delivering whole tumor DNA for sequencing, detecting minimal residual disease and early detection of cancer recurrence. Currently, the **CellSieve™** microfabrication platform and **LifeTracDx™** Assays are commercially available for research use only and clinical trials. Creatv plans to offer the test to oncologists and physicians treating cancer patients following CLIA approval of their laboratory.

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