

Creatv MicroTech, Inc.

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Pan-cancer blood test addresses major unmet needs

Privately held Creatv MicroTech has developed LifeTracDx tests to detect cancer at the earliest stages, and for providing diagnoses to guide cancer treatments, thereby saving and improving lives.

Cancer is the second-leading cause of mortality worldwide, accounting for one in six deaths. The American Cancer Society projects that the United States will see 1,806,590 new cases and 630,000 deaths in 2020. Currently, many cancers are detected at a late stage, therefore early detection and treatment are key to improving outcomes and saving lives. To address this unmet need, Creatv MicroTech has developed highly sensitive and specific blood tests called LifeTracDx that detect a biomarker found in all types of solid tumors as early as stage 1, before symptoms develop.

The LifeTracDx tests address cancer's unmet needs with a simple blood test that can provide:

- companion diagnostics to guide treatment, a safer, more reliable and less expensive blood test than tissue biopsy;
- prognosis, letting patients and clinicians know the likely course of disease progression;
- prediction of treatment response soon after treatment starts, including immunotherapy, which is very costly and does not work for all patients; and
- copious amounts of DNA for sequencing, superior to that provided by circulating tumor DNA.

Creatv has published data on pan-cancer screening, showing the potential to detect cancers even at stage 1 or 2, when they are most treatable. Three ongoing research projects for cancer screening are funded by NIH (breast and prostate cancers) and the Department of Defense (lung cancer).

These LifeTracDx assays have many advantages over tissue biopsy, imaging techniques and other blood-based biomarker tests for detecting and treating cancer, including speed, accuracy, lower cost and lower risk to patients.

A unique cancer biomarker

The LifeTracDx tests were made possible by Creatv's discovery of cancer-associated macrophages in cancer patient blood and their clinical applications. These macrophages are scavenger cells that have engulfed tumor cells and debris from the tumor site and re-entered the bloodstream. These macrophages contain tumor material, such as proteins, drug targets and copious amounts of unfragmented high-quality DNA from the tumor. Creatv has named this biomarker cancer-associated macrophage-like cell (CAML). CAMLs, expressing the macrophage markers CD14 and CD11c, are very large and polynucleated (Fig. 1).

Creatv published its discovery of CAMLs in 2014 and holds patents on their use. CAMLs are not circulating tumor cells, which are primarily found only in late-stage breast, prostate and colorectal cancers.

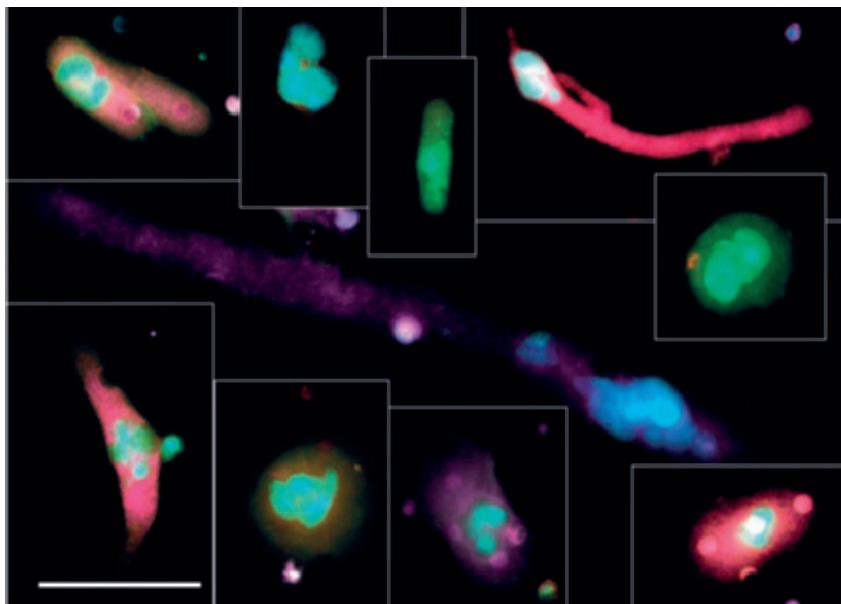


Fig. 1 | Fluorescent microscope images of CAMLs. Images show their morphologies, polyploidy feature and large size. The scale bar is 50 μ m.

To date, CAMLs have been found in all 21 solid tumor types that the company has analyzed, and have been found in statistically significant numbers at all stages of cancer, but not in healthy individuals.

The discovery of CAMLs was made possible by Creatv's high-quality CellSieve microfilters, which enable the capture and characterization of cells in blood larger than 8 μ m. The thin, strong microfilters have a precise pore size, high porosity and low autofluorescence. Creatv collaborated with well-known academic researchers and cancer centers to validate LifeTracDx tests, work that has been published in 17 peer-reviewed journal publications.

Transformative technology

The presence of CAMLs in blood indicates cancer. But it is not just numbers that count: in regards to CAMLs, size is more important than quantity for many clinical applications. The presence of a CAML larger than 50 μ m predicts shorter overall survival and progression-free survival. Large CAMLs are associated with disease progression and poor response to treatment. The tumor material in CAMLs enables companion diagnostic applications and the tumor DNA provides high-quality material for molecular analysis.

A major focus of the company is helping pharmaceutical companies in their cancer drug development

and clinical trials. CAMLs can be used as companion diagnostics to confirm that a patient's tumor contains the drug target. CAMLs can also provide patient stratification and early prediction of response. They can also provide tumor DNA.

"The discovery of CAMLs and the development of an accurate pan-cancer blood test represent a giant step forward in the detection, treatment and monitoring of patients with cancer," said Cha-Mei Tang, President and CEO of Creatv. "We are not aware of any other blood test that can provide all of these clinical applications for solid tumors."

"LifeTracDx tests have broad international patient protection and are currently used in over 20 clinical trials. Creatv is seeking to license the technology, and license or partner with diagnostic and drug companies. In the end, clinical application of these highly sensitive and specific tests holds great potential for significantly improving outcomes and reducing mortality for cancer patients," said Tang.

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