Non-Confidential Description - PSU No. 3660
“Selective Capture System for the Enrichment of Viable Circulating Tumor Cells”

Field of Invention/Keywords:
- Circulating Tumor Cells, Cancer metastasis, High-throughput Microfiltration, Cancer Diagnosis and Personalized Medicine, Rare Cell Enrichment, Size-Based Fractionation

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Background
Metastatic cells can fundamentally differ from the primary tumor site in their expression of key biologic characteristics associated with the prognosis and treatment response. Metastatic forms of cancer account for ninety percent (90%) of cancer deaths. Accurate and early diagnosis of metastatic cancer cells may play an important role in successful therapeutic treatment. Circulating tumor cells (CTC) analysis can potentially provide an opportunity to investigate metastasis directly on an individual patient basis. The FDA has approved one circulating tumor cell-based application for prognosis and monitoring of breast, colon, and prostate cancers.

Invention Description
The subject invention is a high-throughput microfiltration system designed to isolate circulating tumor cells (CTCs) from a patient’s bloodstream and effectively capture them without causing significant damage. It also serves as a platform for the culture and enrichment of viable CTCs, thereby potentially contributing to a more accurate and effective diagnostic system. The system relies on physiological parameters that allow for the segregation of CTCs from erythrocytes and most leukocytes. The entrapment of the CTCs occurs without excessive damaging stresses, because of flexible components within the device. These viable CTCs are then isolated, permitted to reproduce to a critical mass that facilitates further detailed analysis as a clinical diagnostic indicator and in the assessment of therapeutic treatment efficacy. The invention’s design also resolves the problem of clogging, which has plagued previous microfilters.

Status of The Invention
The Penn State researchers have validated this microfiltration system using multiple cancer cell lines and cancer patient blood samples. The fabrication process involves known microscale design and fabrication techniques. The invention’s microfiltration capture technology has demonstrated a significant improvement in capture efficiency, cost and processing time over currently competitive techniques. The inventors have data indicating that the processing time shall be less than ten minutes with a capture efficiency on the order of eighty-seven to ninety-two percent (87-92%) for whole blood volume of 7.5mL. The invention does not depend on surface antigen expression, has an enrichment higher than 10⁴ and better than eighty percent (80%) CTC viability.

Commercial Applications
This invention allows the potential for a personalized approach to therapeutic treatment being test ex vivo, instead of the current method of exposing a patient to toxic effects without knowing the potential clinical benefits.