Automated, Sensitive Microfluidic Device for CTC Capturing and Characterization

PREP and ANALYZER Platforms
Company

- Celsee Diagnostics
- Founded in 2010
- Fully-integrated, automated CTC capturing and analysis
- Issued patents on proprietary microfluidic technology
- Launched RUO system in 2015
Transforming cancer diagnostics with a non-invasive blood specimen metastasis detection and characterization platform.
Tissue Biopsy Limitations

- The current gold standard practice of metastasis diagnosis
  - Painful
  - Invasive
  - Expensive
  - Slow
  - Infrequent
The Celsee Diagnostics Solution

- Liquid Biopsy based on Circulating Tumor Cells (CTC)
  - CTCs escape from the primary tumor and enter the blood or lymph stream and seed secondary tumors in other organs of the body.
  - Availability of a robust, sensitive system for CTC enrichment that also allows seamless downstream cellular and genomic characterization has been a bottleneck. Celsee provides that solution.
  - Only available FDA system, CellSearch, has low sensitivity and cannot do molecular analysis.

- Low cost, accurate, painless, quick, frequent
Celsee Microfluidic Technology

Microfluidic Technology

On-Chip Single-Cell Analysis

CTC Elution, Purification, and Off-Chip Analysis

Microfluidic Slide: 56,400 cell capture chambers

U.S. Patent No. 9103754
The CTC Platform

Precise, Automated, Accurate

1 CTC Enrichment
2 On-Chip Single Cell Analysis
3 Imaging, Analysis & Reporting
Celsee PREP100

- Simple, entry-level system
- Cell enrichment & retrieval, immunostaining, DNA and mRNA FISH, cell culture
- Compact, low cost & flexible
- Also enable CTC collection and preservation at point of collection
Celsee PREP100

- Set up system with consumables supplied with kit
- Prime slide using Priming Genie included with the PREP100
- Introduce blood and characterization reagents
- Analyze slide on a confocal or fluorescent microscope
Celsee PREP400

- Fully-automated for cell enrichment and downstream chemistries
- Modular design for assay development; unitized reagent cartridge for immunostaining, mRNA FISH & DNA FISH
- Built-in heaters for thermal incubations
- Multiple sample types: blood, urine, bone marrow aspirates
- Custom fluidic manifold to run tissue slides and adhesion slides
- Scalable design for higher throughput
Celsee PREP400

- Use software to start a new run and scan in barcodes
- Set up system with consumables supplied with kit
- Prime slide using Priming Genie included with the PREP400
- Prepare and load reagent cartridge
- Prepare blood sample, enter information into software, load sample and press run
- Analyze slides with the Celsee ANALYZER
Celsee ANALYZER

- Whole slide scanner in bright field & fluorescence
- Compact: 50% smaller footprint compared to available scanners
- Multiplex up to 5 fluorescence colors
- High quality at a reasonable price
- For Celsee assays, on-board cell analysis and report generation
Celsee Kits

- Celsee PREP100/400 CTC Immunochemistry Kit
  - 8 or 20 samples
  - Includes all disposables, re-usable supplies, buffers and antibodies (Pan-CK, CD45, DAPI)
- Celsee PREP100/400 CTC Kit
  - 20 samples
  - Includes all disposables, re-usable supplies and buffers. User adds their own characterization reagents
- Celsee PREP100/400 CTC Enrichment and Purification Kit
  - 8 or 20 samples
  - Includes all disposables, re-usable supplies and reagents to generate an enriched CTC population for PCR or NGS

Priming Genie included with instruments.
Ventana Breast Cancer Validations
Efficient and Reproducible

- Published 2014 in the International Journal of Oncology
- Celsee chip captures cancer cells, both epithelial and mesenchymal directly from blood
- 85% capture efficiency, $C_v < 6.7\%$
Detection of CTCs in Metastatic Cancers

- 128 patients (MPC, MBC, MCRC), 200 normal donors
- Published 2016 in *PLoS ONE*
Comparison of Celsee and CellSearch by Johns Hopkins University

- Sample: 18 patients with metastatic prostate cancer
- Sensitivity: Celsee (94%), CellSearch (61%)
- Celsee detected CTCs (Pan Ck+, CD45-, DAPI+) in 90% of metastatic prostate cancer patients compared to 60% with CellSearch
- Celsee detected CK+ CTC in 30% of localized patients compared to 0% with CellSearch
- Detection of single CTCs as well as CTC-clusters
- Published: 2016 in *PLoS ONE*
On-Chip Single Cell DNA and mRNA in situ Hybridization

DNA FISH
Breast Cancer Cell
Vysis probes

mRNA FISH
Prostate Cancer Cell
ACD probes
Cell Retrieval for NGS and PCR

- High efficiency of cell recovery
- Low leukocyte count, <200 cells
- NGS for DNA mutation (off-chip)
- RTPCR for mRNA expression (off-chip)
Clinical Partners and Collaborators

- The James Buchanan Brady Urological Institute, Johns Hopkins University
- Karmanos Cancer Institute, Wayne State University
- Kimmel Cancer Center, Thomas Jefferson University
- University of Michigan Comprehensive Cancer Center
- South Texas Accelerated Research Therapeutics (START)
- bioTheranostics
Publications

- Development of an automated and sensitive microfluidic device for capturing and characterizing circulating tumor cells (CTCs) from clinical blood samples – PLoS One 2016
- A novel microchannel-based device to capture and analyze circulating tumor cells (CTCs) of breast cancer – International Journal of Oncology, March 2014

Posters

- Mutation and gene expression analysis of circulating tumor cells (CTCs) enriched by a sensitive easy-to-use microfluidic device – AACR 2016
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