

Liquid Biopsy Solutions for Circulating Tumor Cell and Rare Cell Analysis



The Value of RareCyte Liquid Biopsy

~90% of cancer mortality is caused by metastasis,¹ whereby cells are shed from tumors and transported in the blood to other organs.

NON-INVASIVE

Liquid Biopsy samples acquired via simple blood draw.

- Liquid biopsy provides a dynamic measure of patient health and disease state
- The non-invasive blood draw enables longitudinal analysis of disease progression and response to treatment

SPECIFIC DETECTION

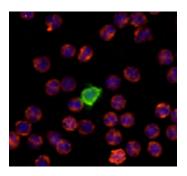
An end-to-end platform for the identification, enumeration, phenotyping and isolation of rare cells from whole blood.

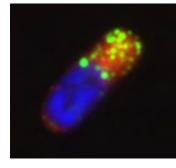
- The AccuCyte[®]-CyteFinder[®] platform has exquisite sensitivity for detecting circulating tumor cells (CTCs) at extremely low levels single cells in a standard 7.5 mL blood draw
- Demonstrated clinical performance^{2,3} compared to CellSearch[®] (FDA cleared) with increased sensitivity by eliminating reliance on EpCAM expression

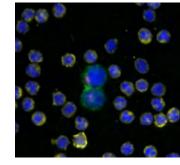
CUSTOMIZABLE BIOMARKERS

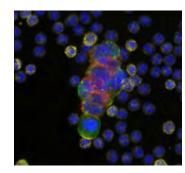
RarePlex® Panel Kits enable highly repeatable phenotyping of CTCs and other rare cells.

- CTC Panel Kits include a nuclear stain, epithelial markers Pan CK and EpCAM, and the white blood cell exclusion marker CD45
- Two additional channels are available to add your own biomarkers of interest with a simple plug-and-play protocol









SAMPLE STABILITY

RareCyte products provide prolonged sample stability to support flexible workflows including long-term sample storage.

- AccuCyte Blood Collection Tubes (BCTs) have been proven to stabilize samples for up to 120 hours prior to processing
- AccuCyte sample preparation provides for samples on slides to be stored for up to 3 years at -20° C with excellent preservation of cellular biomarkers

COMPREHENSIVE ANALYSIS

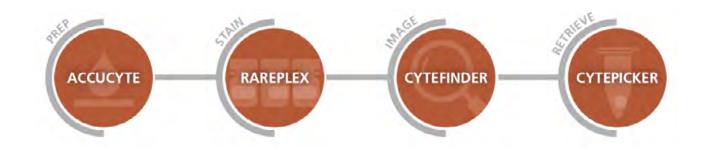
High-resolution imaging and machine learning are united in the CyteFinder imaging system to identify and enumerate candidate CTCs from a single blood sample.

- CyteFinder facilitates detection of target cells regardless of their size or pattern of biomarker expression
- Each cell is automatically scored for identity based on quantitation and subcellular location of target biomarkers⁴
- Individual cells can be isolated for follow up analysis, including genomic profiling, using the unique CytePicker[®] cell retrieval capability^{5,6}

STREAMLINED WORKFLOW

RareCyte's liquid biopsy platform has many parallels to standard histopathology processes that are easily implemented and compatible with existing workflows.

- Samples are spread on standard microscope slides and are amenable to staining and imaging protocols typically used for tissue sections
- RarePlex panel kits are designed to be used with automated staining systems, enabling high throughput and consistent results

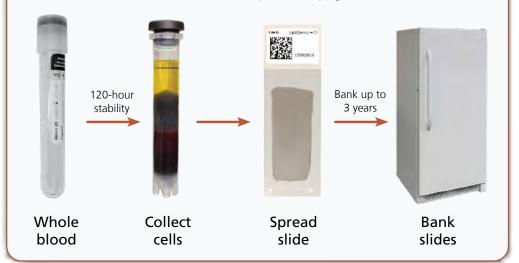


() PREP

AccuCyte[®] Sample Preparation System

- Standard blood draw with extended stability in BCT (120 hours)
- Collect nucleated cells (gentle process for >90%CTC recovery)
- Transfer nucleated cells to slides using repeatable, nowash, no-lysis procedure
- Bank slides for up to 3 years
- Up to 4 mL high-quality plasma may be retained for orthogonal analysis
- Flexible enough for research; robust enough for clinical trials

Flexible, cell-based liquid biopsy workflow



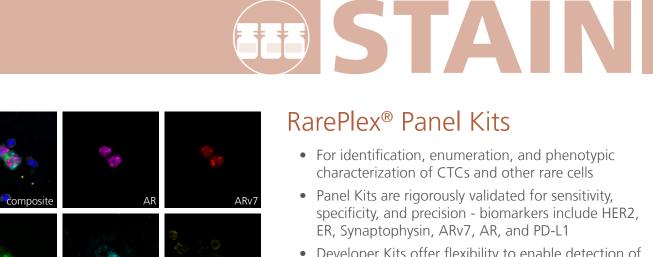
QINAGE

CyteFinder[®] Imaging Instruments

- High speed systems optimized for rare cell detection and analysis
- Integrated machine learning algorithm detects and rank orders candidate cells for user review
- Whole-slide imaging
- Tissue option for digital pathology
- Image up to 7 channels in a single scan



CyteFinder II Instrument with CytePicker Retrieval Module



RarePlex[®] Panel Kits

- For identification, enumeration, and phenotypic characterization of CTCs and other rare cells
- Panel Kits are rigorously validated for sensitivity, specificity, and precision - biomarkers include HER2, ER, Synaptophysin, ARv7, AR, and PD-L1
- Developer Kits offer flexibility to enable detection of any custom protein biomarker - examples include EGFR, Vimentin, Muc1, Ki67, and PSMA
- Compatible with manual staining protocols and with Ventana® and Leica® automated slide staining systems

ORETRIEVE

Optional CytePicker® Retrieval Module

- Needle-based retrieval of single cells or tissue micro-regions from any location on the slide
- Cells can be visualized before and after retrieval
- Preserves sample integrity for downstream molecular analysis
- Retrieval module available on the CyteFinder II Instrument only





CyteFinder II HT Instrument 80-slide capacity for unattended operation



Single cell retrieval



Visually confirm cell deposit

A Comprehensive Liquid Biopsy Solution

RareCyte liquid biopsy technology is compatible with a broad range of sample types. This technology has been utilized across key research and clinical applications, from rare-cell identification to companion diagnostics development.

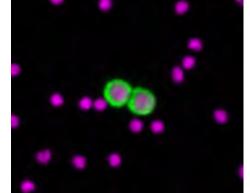
SAMPLE TYPES



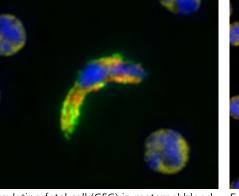


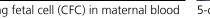


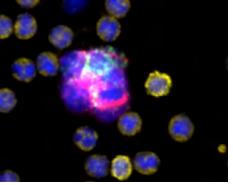




Phenotype and enumerate CTCs



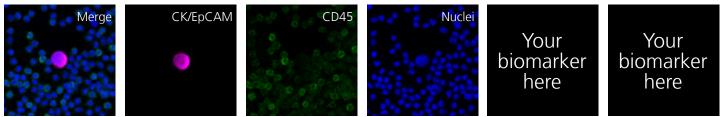




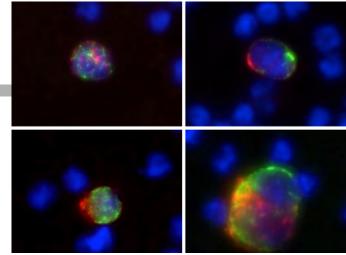
Circulating fetal cell (CFC) in maternal blood 5-cell CTC cluster expressing drug target

RARFPI FX[®] DFVFI OPFR KITS

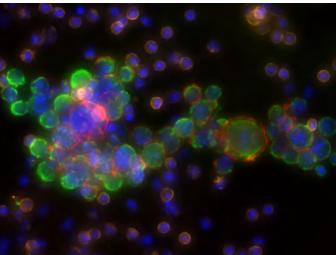
RarePlex Developer Kits enable detection of any custom protein biomarker and offer the flexibility to design the ideal assay to meet your CTC assay requirements. Some examples of biomarkers that have been tested are EGFR, Vimentin, Muc1, Ki67, and PSMA.



Develop custom CTC assays with your biomarkers of interest using Developer Kits



High resolution imaging of CTCs, lung (upper) and breast (lower)



Highly sensitive CTC detection from triple negative breast cancer patient

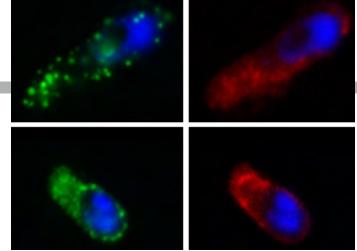
SERVICES

includes:

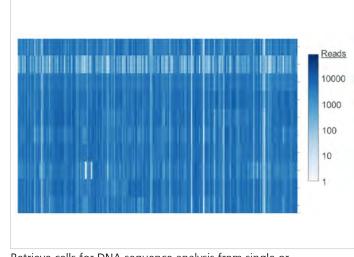
- ISO 13485:2016 certification
- CLIA Lab accreditation

The RareCyte team has expertise in multiple types of service programs:

- Custom assay development
- Research and clinical trial services for rare-cell liquid biopsy assays, biomarker discovery and implementation, pharmaceutical mechanism of action, and drug safety
- Global clients include essential researchers, translational scientists, drug development and diagnostics organizations



Identify circulating fetal cells (CFCs) for NIPT, Cytokeratin marker (left) and trophoblast marker (right)



Retrieve cells for DNA sequence analysis from single or pooled cells

- Clients appreciate our focus on high data quality, quick turn-around-time and responsiveness to meet individual program needs. RareCyte products and services are supported by an infrastructure that



References

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