ClearCell® FX System
The Label-Free Liquid Biopsy Solution
Label-free Enrichment of Circulating Tumour Cells (CTCs)

More than 80% of cancer patients die from metastasis and not the primary tumour. The importance of Circulating Tumour Cells (CTCs) in metastasis is well established. CTCs obtained via a non-invasive liquid biopsy hold significant clinical potential as diagnostic, prognostic and predictive markers in cancer development. They could provide oncologists with a reliable, cost-effective real-time monitoring solution. Now there is an elegant and robust system for CTC enrichment – ClearCell® FX1.

The ClearCell® FX System isolates more wholly intact and viable CTCs to a higher degree of purity than most other enrichment methods. Fully automated and entirely label-free, the ClearCell® FX System is empowering doctors and researchers, bringing clarity to cancer so that patients can receive the timely, tailored treatment that they need.

**Features**

- Label-free CTC enrichment of heterogeneous populations of cancer cells
- Up to 10,000x enrichment of CTCs that are wholly intact, viable and path-lab ready
- Large blood volume enrichment from 7.5 ml of patients’ blood
- Fast processing time of < 1 hr
- Automated workflow
- Sensitive, with a high dynamic range
- Easy and ready integration with a wide variety of downstream molecular diagnostics and pathology assays
- CE IVD and ISO 13485 certified, verifying comprehensive quality management

**Principle of Operation**

The ClearCell® FX System is driven by the CTChip® FR. This microfluidic biochip isolates CTCs based on size, deformability and inertia, relative to other blood components, by using inherent Dean vortex flows present in curvilinear channels, termed Dean Flow Fractionation (DFF).

Through the process of DFF, blood cells separate and distribute themselves within the channels of the CTChip® FR, with the larger cells along the inner wall and the smaller cells away from it. The ClearCell® FX System thus enables effective and rapid separation without compromising the quality of retrieved cells.

**Workflow**

1. **Sample Collection**
   - 7.5ml blood sample is collected in EDTA/Streck blood collection tube

2. **RBC Lysis**
   - Red blood cell lysis is performed

3. **CTC Enrichment**
   - CTC enrichment is performed on the ClearCell® FX System

4. **Enriched CTC sample**
   - Enriched CTC output ready for downstream analysis
Applications

Fluorescence In Situ Hybridisation (FISH)
CTCs isolated using the ClearCell® FX System can be characterised by FISH, a technique that allows cytogeneticists to identify chromosomal abnormalities in cells. Fluorescent probes that bind specific chromosomal locations are applied to the cells, and the presence or absence of specific DNA sequences is detected by noting the location and counts of fluorescent dots after probe hybridisation.

Cell Culture
The ClearCell® FX System isolates CTCs with high viability and integrity, so the cells can be subsequently cultured in vitro. The in vitro culture of cancer cells has numerous applications, ranging from studying the biology of cancer to the development of novel therapeutics. Culturing CTCs could enable the creation of patient-derived tumour xenograft models that could provide invaluable insights into metastasis.

Molecular Analysis
Gene mutations can be key predictors of cancer. The targeted molecular analysis of CTCs could offer a powerful companion diagnostic test for treatment selection and patient monitoring. The ClearCell® FX System yields CTC-enriched samples that can be seamlessly integrated into traditional laboratory protocols for DNA and RNA extraction. Options for analysis include qPCR, dPCR, or NGS for targeted molecular profiling.

Immunofluorescence (IF)/ Immunocytochemistry (ICC)
The visualisation of antibodies specific to cellular antigens provides a simple way to differentiate cancer cells from healthy cells. Cells enriched using the ClearCell® FX System can be stained with various antibodies to identify CTCs, as well as to measure target antigen expression levels. The output CTC suspension can be either cytopsins onto glass slides or embedded in formalin-fixed paraffin matrix (FFPE) for imaging, for integration into pathology lab workflows.

CTC Patient-Derived Xenografts (CTC PDX)
Patients' CTCs isolated using the ClearCell® FX System can be implanted into immune-deficient mice to create patient-specific CTC-derived xenograft models (CTC PDX). These CTC PDX models will be used to develop metastatic tumour models, study drug sensitivity and determine patient specific dosage, a hallmark of personalised medicine. Additionally, these models can be used by pharmaceutical companies for novel drug development and clinical studies.

Protein Analysis
CTCs isolated using the ClearCell® FX System retain high cell integrity and can be used for a wide range of protein analysis. Protein analysis helps identify intracellular pathways in CTCs, providing important information on pathway-specific drug activity and guide dosing selection. This is an important tool for targeted drug development and treatment, such as PD-L1 for immunotherapy.
Product Specifications

Unit Dimensions (Unboxed)
- Height: 51 cm (20 inches)
- Width (Including reagent bottle): 51 cm (20 inches)
- Depth: 40 cm (16 inches)
- Weight: 35 kg (78 pounds)

Power Specifications
- Required Voltage: 100-240 VAC, 1A
- Power Rating: 96 W

Environmental Specifications
- Operating Temperature: 18-32°C (65-90°F)
- Storage Temperature: 5-40°C (41-104°F)
- Operating Environment: For indoor use only
- Humidity: 20-60%

About Clearbridge BioMedics

Clearbridge BioMedics is a clinical stage oncology research and diagnostics company that enables real-time liquid biopsy using a label-free rare-cell CTC enrichment platform. It is a National University of Singapore (NUS) spin-off company that is committed to revolutionising cancer diagnostics and patient care. The ClearCell® FX System, using the CTChip®, is based on novel microfluidics technology that effectively isolates intact and viable CTCs from patients' blood. The system uses Dean flow fractionation for label-free CTC enrichment, capturing heterogeneous and dynamic cancer cells that could be used for cancer screening, diagnosis, staging, personalized medicine and treatment monitoring. Utilizing the next generation non-invasive liquid biopsy to analyze blood samples for CTCs, the device allows for real time analysis of disease before, during, and after treatment, which has become increasingly critical in the new era of precision medicine.

Headquartered in Singapore, Clearbridge BioMedics currently has customers spanning Asia Pacific, Europe and North America. The company has won numerous awards and garnered global recognition for the ClearCell® FX System.

Ordering Information

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