FLUXION

IsoFlux™ System

The next generation of CTC Analysis is here

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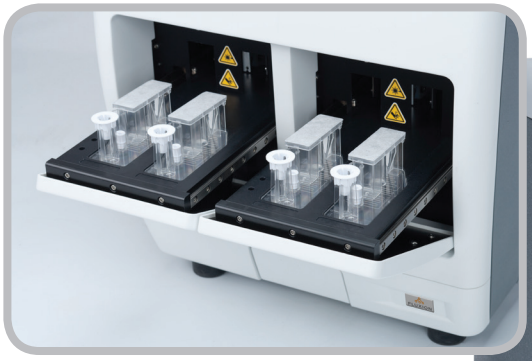
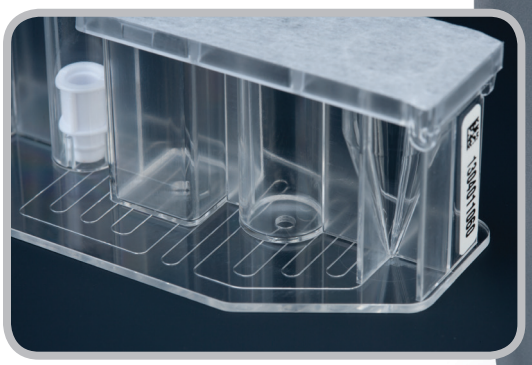
The next generation of circulating tumor cell analysis is here

The IsoFlux System enriches intact rare cells from biological samples and prepares them for further analysis. It gives you immediate access to high-quality, viable cells in a high-density format, ready for use in the application of your choice.





Benefits

Access a Wide Range of Samples – Process multiple starting sample types including whole blood, fractionated blood, dissociated tissue, and cell cultures.

Use Your Own Capture Criteria – Capture cells using single or multiple capture antibodies. Use pre-validated or user-defined kits.

Capture Intact, Pure Cells – Recover target cells with high yield and purity using minimal processing.

Minimize Sample Dilution – Gain immediate access to highly concentrated, low-volume samples ready for molecular and cell-based analysis.

Save Time – Increase your lab's productivity with the IsoFlux System. Requires minimal hands-on time and fits into standard laboratory workflows.

Save Space – Easily fit the IsoFlux system in your laboratory with its small, benchtop footprint.

Utilize Validated CTC Analysis Workflows - Analyze your samples with confidence utilizing Fluxion's validated sample-to-answer workflows. Analysis modalities include enumeration, mutation detection, gene expression, FISH, and more.

Applications

- Next generation sequencing
- Immunofluorescence
- Fluorescence in situ hybridization
- Enumeration
- Mutation detection
- Gene expression

The IsoFlux System is registered as a Class I medical device with the US FDA. The IsoFlux Enrichment Kits are for Research Use Only. All downstream applications discussed here are for Research Use Only. See package inserts for full indications for use.

The CellSpot™ Advantage

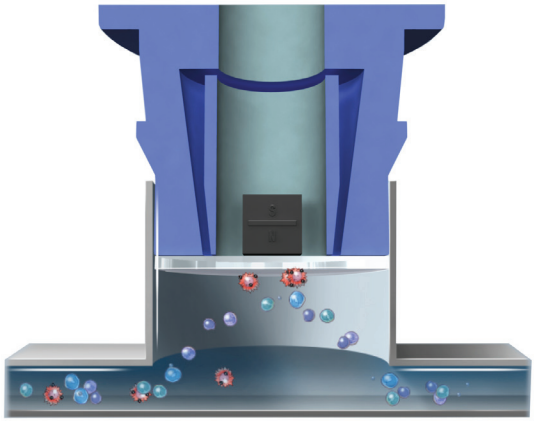
The IsoFlux System uses proprietary CellSpot Technology to deliver enriched cells in a format ideal for next generation molecular applications. CellSpot increases the purity, integrity, and yield of isolated cells, while also making them easy to access for use in downstream applications.

How It Works

1. Sample Loading

A biological sample is prepared with magnetic particles. The sample is loaded into the inlet of the IsoFlux microfluidic cartridge. Up to 4 cartridges can be loaded into the instrument at one time.

The CellSpot Cap is loaded into the cartridge that has a special disk on the bottom that forms the roof of the microfluidic channel.



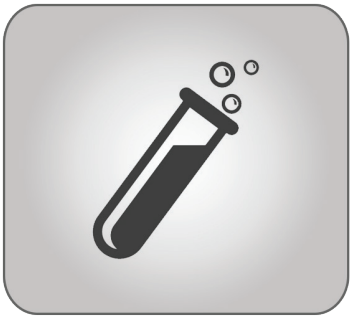
2. Cell Enrichment

Once inside the instrument, the sample flows through the microfluidic channel and reaches an isolation zone. This expanded cavity causes the cells to slow down as they pass through an external magentic field. Labeled cells get pulled upwards against the force of gravity, then washed, resulting in a high-integrity, high purity separation.

3. Cell Retrieval

After the enrichment, the CellSpot Cap is picked up inside the instrument and placed on a microfuge tube. This tube is picked up and inverted to resuspend the cells in the elution buffer. The enriched cells are now ready for further analysis.

Go from sample to analysis faster than you ever thought possible.



Sample Collection

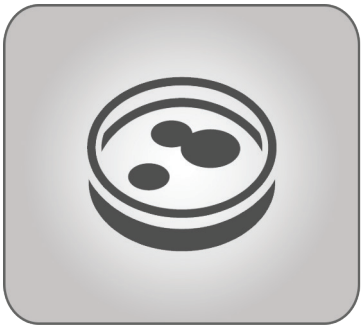
- 7-10mL blood draw
- EDTA
- Overnight shipment

Sample Preperation

- 30 min. hands on time
- 60 min bead coupling

CTC Isolation

- 45 min. inside instrument
- Fully automated



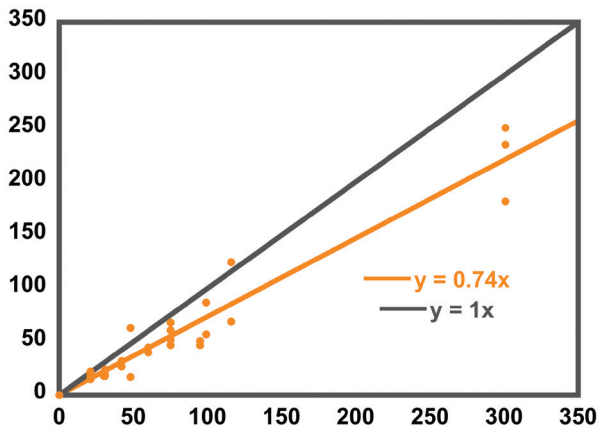
Sample Ready

- Sample ready for analysis

Performance where you need it.

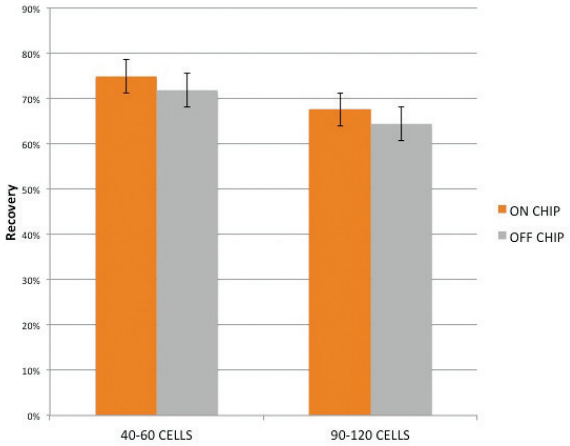
The IsoFlux System delivers high quality CTC enrichment with consistent, reliable performance. Validation testing has demonstrated superior CTC recovery across a wide range of pathologies.

High CTC recovery



High recovery of CTCs is critical to ensuring enough cellular material to perform downstream analysis from a high enough percentage of patients. In this experiment, a prostate cancer cell line (PC3) was spiked into samples of 7mL healthy donor blood (N=36) at varying concentrations, ranging from 0-300 target cells. Average recovery was 74% (R^2=0.94).

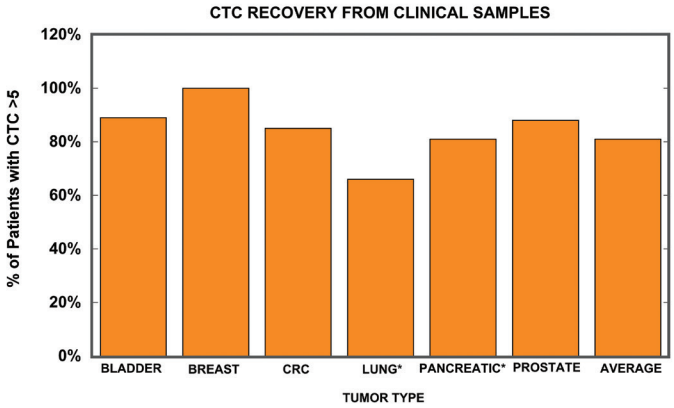
Superior transferability to downstream analysis



The CellSpot cap moves captured cells directly into a microfuge tube with high transfer efficiency. In this experiment, PC3 cells were spiked into 7mL whole blood and enriched with the IsoFlux System (N=8). One group of samples was counted directly on the collection tube and the other was counted after transfer to the collection tube. Transfer efficiency was over 93% across the range.

Superior clinical performance

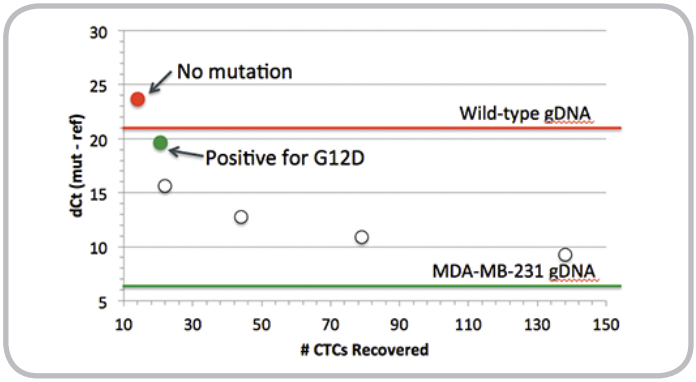
The IsoFlux System has been tested and validated to recover CTCs from a wide range of different pathologies, including breast, prostate, colorectal, lung, and pancreatic cancers. Multiple different starting samples can be used, such as whole blood, fractionated blood products, animal blood, dissociated tissue and cell cultures. Cellspot technology ensures a high quality enrichment and transfer to downstream analysis.



Whole blood samples (N=129) were collected from cancer patients across multiple tumor types and stages. Over 81% of these patients had > 5 CTCs, an amount that is above the limits of detection for many molecular assays.

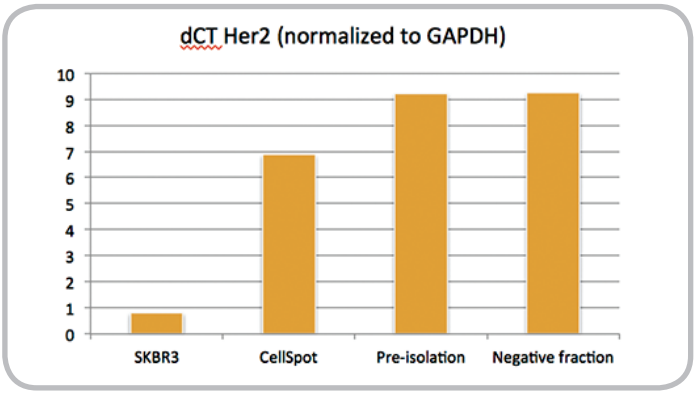
Mutation Analysis

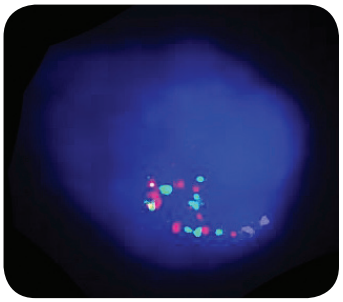
Mutations in genes such as KRAS, EGFR, and BRAF act as molecular switches that can interfere with normal cell regulation. Identification of these mutations can offer insight for how a patient will respond to particular therapies. CTCs recovered from IsoFlux samples can be lysed for DNA recovery and tested for mutations using qPCR, dPCR, or NGS. In this example, a KRAS mutation is detected in a colorectal cancer patient using qPCR.



Gene Expression

Expression profiling is often performed using RT-qPCR when there are many genes of interest in the sample. RNA from IsoFlux samples can be recovered using conventional kits and analyzed on standard and next-generation qPCR instruments. In this example, Her2 over-expression is observed in a breast cancer sample.





Fluorescence *in situ* hybridization

FISH is commonly used to discover cytogenetic abnormalities in cancer samples. A fluorescent probe is hybridized to a targeted DNA sequence and visualized with a fluorescence microscope. In this image, a breast cancer CTC was isolated using the IsoFlux System and analyzed with FISH to show over-amplification of the Her2 gene (green probe).

Discovery Services

Your study. Our technology. Immediate results.

Fluxion provides analytical services for a diverse range of circulating tumor cell applications. This program enables you to get results quickly and efficiently using Fluxion's state of the art technology and laboratory facilities. You design the study, we process and analyze the samples, you get the data...it's that simple.

Key benefits to using Fluxion's Discovery Services

- Flexible isolation markers – combine one or more antibodies including EpCAM, vimentin, MUC-1
- Highest levels of CTC enrichment for downstream analysis
- A diverse range of downstream analysis options - mutational analysis, NGS, gene expression, and more, or have isolated sample (cells, DNA, RNA) sent back to your lab for processing
- A low cost, flexible, scalable model for CTC research

Visit fluxionbio.com/isoflux to request a proposal

IsoFlux System Specifications

Dimensions: 16in wide x 22in tall x 25in deep (40cm x 56cm x 64 cm)
Weight: 120lbs (60kg)
Throughput: 16 samples/day (4 in parallel)
Temperature control: 4°-8° C
Power supply: 110-220V (autoranging)
Touch screen operation
1 year warranty
Catalog No: 950-0100
For *In Vitro* Diagnostic Use

IsoFlux Circulating Tumor Cell Enrichment Kit

Number of samples processed: 8
Cell enrichment method: immunomagnetic beads
Cell enrichment reagent: anti-EpCAM (targeted towards circulating cells of epithelial origin)
Kit contents: 8 microfluidic cartridges, immunomagnetic particles, Fc blocker reagent, binding buffer, protocol.
Catalog No: 910-0091
For Research Use Only

IsoFlux Rare Cell Enrichment Kit, IgG

Number of samples processed: 8
Cell enrichment method: immunomagnetic beads
Cell enrichment reagent: Monoclonal human anti-mouse IgG (suitable for binding user-supplied mouse IgG subclasses via Fc-region)
Kit contents: 8 microfluidic cartridges, immunomagnetic particles, Fc blocker reagent, binding buffer, protocol.
Catalog No: 910-0092
For Research Use Only

IsoFlux Rare Cell Enrichment Kit, Streptavidin

Number of samples processed: 8
Cell enrichment method: immunomagnetic beads
Cell enrichment reagent: Streptavidin coating (suitable for binding user-supplied biotinylated molecules)
Kit contents: 8 microfluidic cartridges, immunomagnetic particles, Fc blocker reagent, binding buffer, protocol.
Catalog No: 910-0103
For Research Use Only

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