



GLOBAL LAB SERVICES

LABSERVICES
Powered by CellSearch[®] and DEPArray[™]

Specialized Tools from Drug Discovery through Development



siliconbiosystems.com/en-us/Biopharma



Menarini Silicon Biosystems Lab Services

represent a global, comprehensive and integrated laboratory service involving state-of-the-art technologies and offers to biopharma companies unique, specialized tools to expedite drug discovery and development programs from preclinical through Phase IV trials.

The Lab Services build on Menarini Silicon Biosystems' integrated workflow including the FDA cleared CELLSEARCH® circulating tumor cell (CTC) capture, enrichment and enumeration platform and the DEPArray™ (for research use only), for precise single-cell sorting and retrieval.

Two Lab locations, in the United States and Europe, support multicenter, global clinical trial and accept samples from around the world.

Menarini Clinical Lab in Huntingdon Valley, PA, is CLIA/CAP accredited, NY State accredited, and is ISO 15189-accredited for CELLSEARCH® CTC testing, with over 15 years of clinical lab experience and 20+ successful regulatory audits. The EU Clinical Lab located in Bologna is ISO 15189 accredited for the CELLSEARCH CTC Test. Such accreditation provides evidence of the managerial and technical adequacy of the laboratory with respect to the entire cycle of its activities. The concept of the "Total Testing Process" is therefore applied, verifying: staff competences, adequacy of the process for carrying out the tests and of its pre- and post-analytical phases (collection, transport and samples storage, review and results release), adequacy of the premises and equipment, metrological traceability of the results, quality assurance, ability of the management system to support and demonstrate the regular and consistent fulfillment of the requirements.

MSB Laboratory
Huntingdon Valley, PA
CLIA & ISO Certified

MSB Laboratory
Bologna, Italy



YOUR TRUSTED PARTNER from target drug discovery through commercialization

GOLD STANDARD CTC ENUMERATION

CELLSEARCH CTC Test is the first and only clinically-validated, FDA-cleared test for detecting and counting CTCs in metastatic breast, prostate, and colorectal cancer*

- CLIA-regulated CELLSEARCH tests available in the US Lab.
- Research Use Only assays for CTC enumeration and biomarker detection available in the US and European Labs.
- 96 or 120 hours sample stability from time of collection thanks to our proprietary CellSave and CellRescue tubes.

UNPARALLELED SINGLE-CELL PRECISION

Isolation of individual, intact rare cells to propel your research with the DEPArray PLUS platform.

- Precise isolation of rare cells from enriched blood.
- High resolution images, allowing a higher detection rate for rare events.
- Precise single cell NGS molecular analysis to detect genome-wide chromosomal aberrations and hotspot mutations.

A PROVEN PARTNER FOR ASSAY DEVELOPMENT

Development of reproducible, customized assays for specific biomarkers of interest.

- Global clinical trial service provider to big pharma and emerging biotech companies.
- Extensive knowledge of developing custom assays that fit ISO and CLIA standards.
- Capability of developing customized assay in 3/4 months.

*For more information on the full intended use and limitations please see the Instructions for Use at documents.cellsearchctc.com

SERVICES OFFERED

CLIA - REGULATED TESTS

CLIA-regulated tests are performed in the U.S. lab

- CELLSEARCH® Circulating Tumor Cell (CTC)
- CELLSEARCH® CTC enumeration with HER2 biomarker
- CELLSEARCH® CTC enumeration with PD-L1 biomarker
- CELLSEARCH® CTC enumeration with ER biomarker
- CELLSEARCH® Circulating Melanoma Cell (CMC)
- CELLSEARCH® Circulating Multiple Myeloma Cell (CMMC)
- CELLSEARCH® CTC enumeration with DLL3 biomarker

ENUMERATION ASSAYS

For research use only. Available in the U.S. and European labs

Rare cell enumeration and single marker protein expression

- Circulating Tumor Cells (CTC)
- Circulating Melanoma Cells (CMC)
- Circulating Multiple Myeloma Cells (CMMC)
- CTC enumeration with HER2 biomarker
- CTC enumeration with PD-L1 biomarker
- CTC enumeration with ER biomarker
- Other rare cells
- CTC enumeration with DLL3 biomarker



ENRICHMENT AND STORAGE

For research use only. Available in the U.S. and European labs

- Cell capture and enrichment for downstream molecular analysis.
- DNA extraction.
- Cell storage in glycerol for potential downstream applications.

SINGLE CELL ANALYSIS

For research use only. Available in the U.S. and European labs

- Rare cell enrichment with CELLSEARCH System.
- Single cell sorting with DEPArray PLUS platform.
- Single cell whole genome amplification and molecular analysis with *Ampli1* kits.

ADDITIONAL SERVICES OFFERED

LINEARITY PANEL

A linearity panel is used to establish reportable range and demonstrate precision. It can be used as Verification of Performance Specifications (a CLIA requirement).

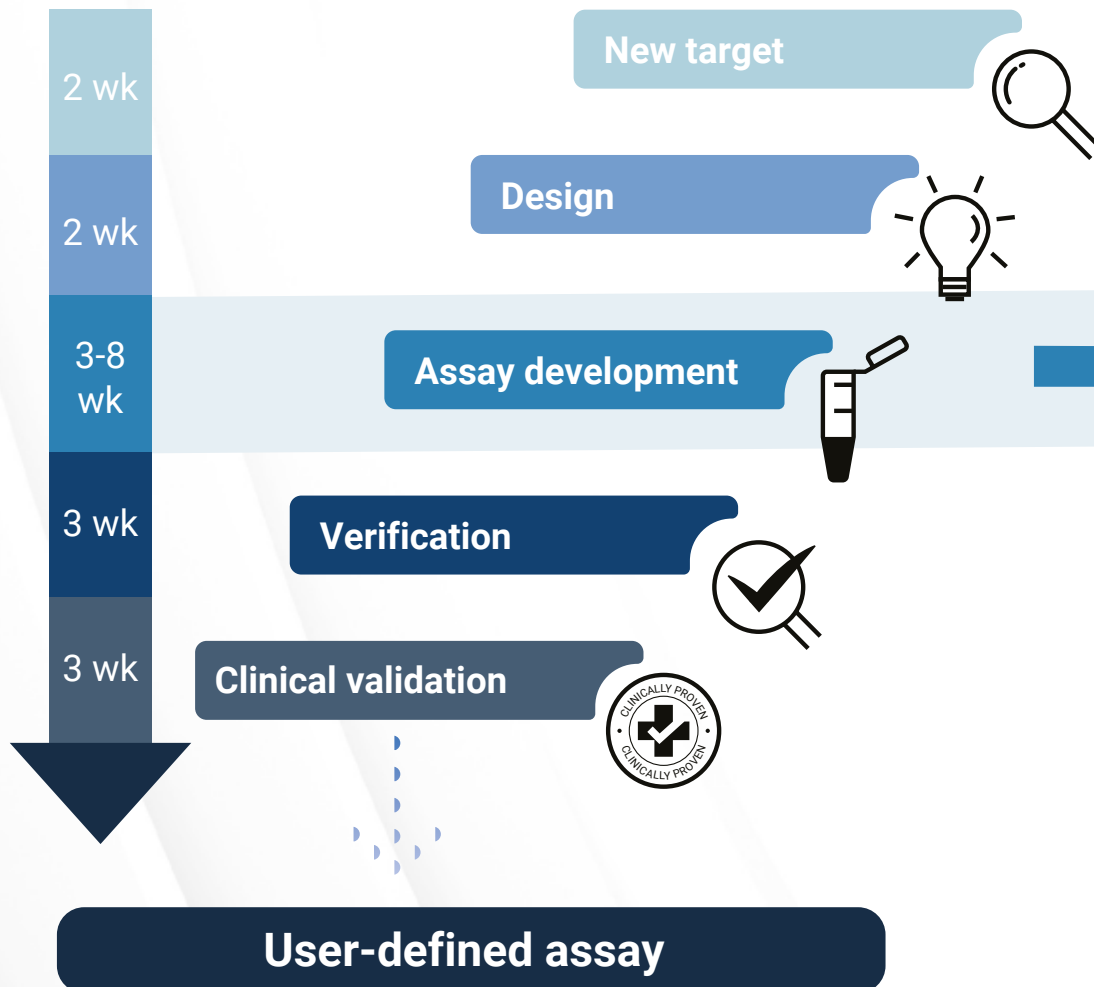
CONCORDANCE STUDY

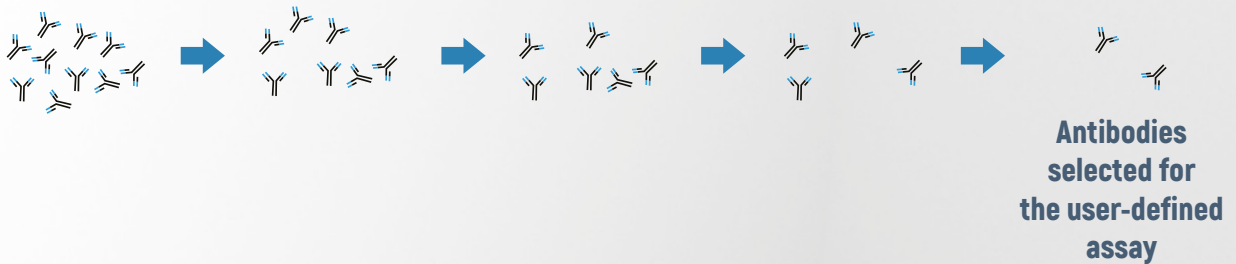
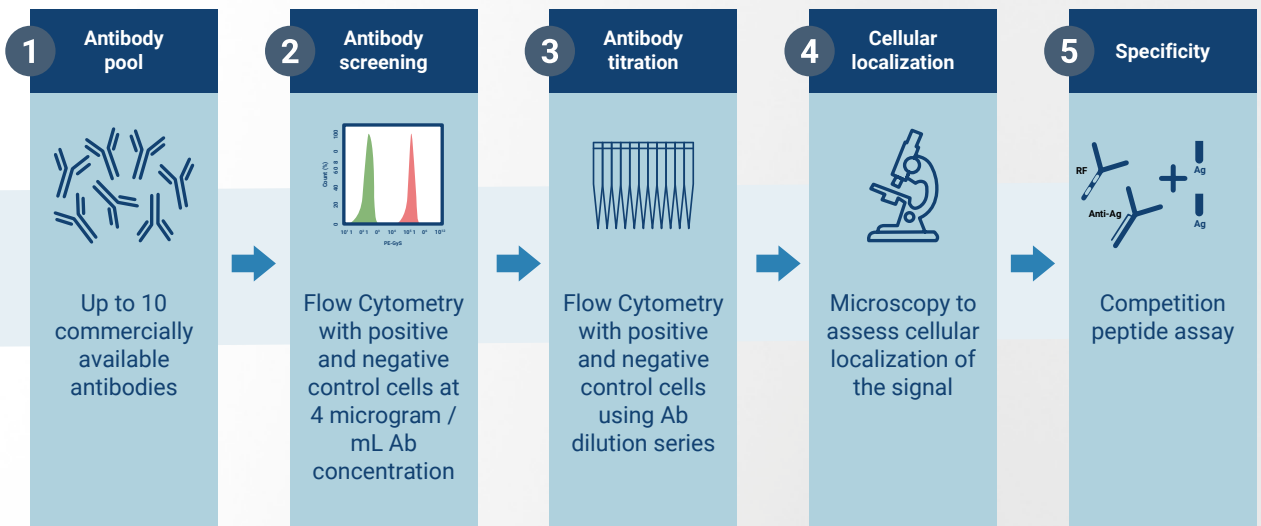
A concordance study establishes if an instrument is equivalent to another instrument and consists of only one spike level. Results can be used to comply with CLIA requirements.

CUSTOMIZED ASSAY DEVELOPMENT

Through our liquid biopsy workflow, we offer pharmaceutical companies in various stages of drug development the ability to design new assays and target biomarkers that can potentially become future indicators of response to drug treatments.

- R&D driven with qualified transfer to clinical operations.
- EpCAM independent custom Ferrofluid development captures specific cells of interest.
- Enables earlier go/no-go decisions on therapies or drugs by targeting specific markers.
- Custom biomarker development in the open channel.





EU Laboratory

Menarini Silicon Biosystems S.p.A.

Via Giuseppe di Vittorio, 21 b/3

I-40013 Castel Maggiore (BO),

Italy t: +39 051 9944100

For questions or complaints please contact

msb-labserviceseu@siliconbiosystems.com

FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES



For the CTC test only in Italy-based lab

USA Laboratory

Menarini Silicon Biosystems Inc.

3401 Masons Mill Rd Suite 100

Huntingdon Valley, PA 19006 USA

t: 1(800)381-4929

e: msb-labservicesus@siliconbiosystems.com

CONTACT AN EXPERT AT www.siliconbiosystems.com/en-us/Biopharma



For the CTC test only in US-based lab



MKT - 000098373

©2023 Menarini Silicon Biosystems S.p.A. All rights reserved



siliconbiosystems.com/en-us/Biopharma



MENARINI
silicon biosystems