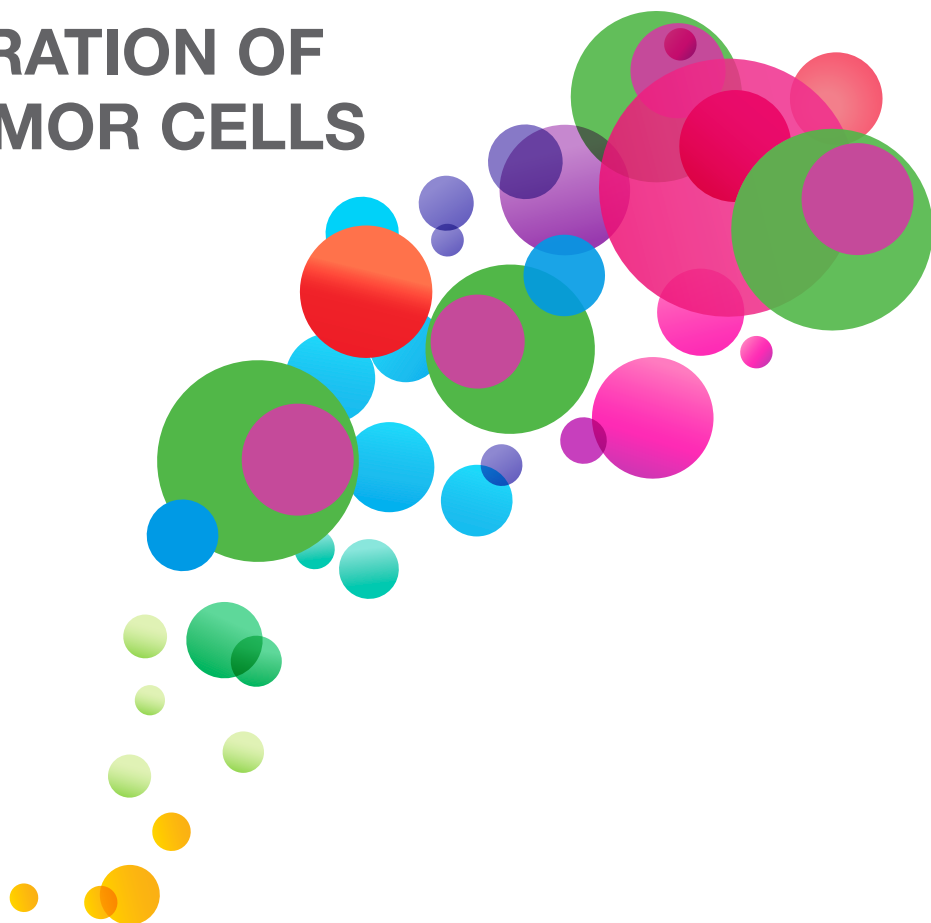


THE CELLSEARCH® SYSTEM

FOR THE ENUMERATION OF
CIRCULATING TUMOR CELLS



Innovation | Automation | Flexibility

janssen 

THE CELLSEARCH® SYSTEM

An Innovative Diagnostic Tool...

The CELLSEARCH® System is an advanced diagnostic platform for circulating tumor cell detection using proprietary immunomagnetic technology. It provides precise, reproducible analysis of cells of epithelial origin. The CELLSEARCH® CTC Test's advanced technology makes it possible to detect circulating tumor cells (CTCs) at an occurrence as low as one CTC in 7.5 mL of whole blood, with a specificity of >99%.

...That Optimizes Laboratory Workflow

The CELLSEARCH® System semiautomates and standardizes CTC analysis into a simple three-step process.



Sample collection

CellSave Preservative Tube

- Sample collection with optimized cell preservative
- Store samples for up to 96 hours at room temperature, allowing batch processing and shipment to remote locations



Sample preparation

CELLTRACKS® AUTOPREP® System

- Automated, reproducible sample preparation for more accurate results



Sample analysis

CELLTRACKS ANALYZER II®

- Semiautomated, rapid sample analysis

CellSave Preservative Tubes

CellSave Preservative Tubes are designed specifically for the collection of fragile CTCs to improve the reproducibility and reliability of analysis. CellSave Preservative Tubes contain a cell preservative that:

- Stabilizes CTCs for up to 96 hours at room temperature, which facilitates sample batching and shipping to remote site



CELLTRACKS® AUTOPREP® System

The CELLTRACKS® AUTOPREP® System enables automated and standardized complex sample processing using immunomagnetic cell capture, enrichment, and fluorescence staining.

- Easy-to-use software assay protocols that allow batch processing of up to eight samples with complete walk-away operation
- Minimal hands-on time and off-line processing
- Sensors that check sample and reagent parameters at multiple points during sample processing to ensure reliable results
- Automatically detects the buffy-coat layer, allowing excess plasma to be aspirated to waste



CELLTRACKS ANALYZER II®

The CELLTRACKS ANALYZER II® is a semiautomated system based on fluorescence optics used to capture and analyze CTCs that have been immunomagnetically selected.

- User-friendly Linux-based interface
 - Simple onscreen commands
 - Intuitive data organization
 - Uniform tables with sorting and exporting functions
- Rapid analysis of each cartridge
- Automated scanning procedure
- Background auto-analyze function
- Quality control data sorting
- Reports true quantitative results because the entire CELLTRACKS® Cartridge is analyzed
- Presentation of candidate fluorescent images in gallery format for final classification by user
- Reporting and long-term archiving of multiple sample image galleries on DVD



AVAILABLE *in vitro* DIAGNOSTIC USE TESTS

CELLSEARCH® CIRCULATING TUMOR CELL TEST

The CELLSEARCH® CTC Test is a simple blood test that captures and assesses CTCs to determine the prognosis of patients with metastatic breast, colorectal, or prostate cancer at any time. The test provides valuable prognostic information for more informed patient care decisions throughout the continuum of care.¹

- Identifies and counts the number of CTCs in whole blood—detecting as few as one CTC in 7.5 mL of blood
- Provides real-time information concerning overall survival and progression-free survival
- Provides prognostic information at baseline and as early as after the first cycle of treatment
- Can be used for serial monitoring of patients throughout the continuum of care

In combination with current standard testing methods, the CELLSEARCH® CTC Test provides a more complete picture of patient prognosis.¹



CELLSEARCH® CIRCULATING TUMOR CELL CONTROL KIT

The CELLSEARCH® CTC Control Kit verifies the performance of reagents, instruments, and operator techniques.

For *in vitro* diagnostic use—for further information on intended use, warnings, and limitations, please refer to the CELLSEARCH® CTC Test Instructions for Use or visit www.cellsearchctc.com.



SPECIFICATIONS



CELLTRACKS® AUTOPREP® SYSTEM

Size and Weight

68" W x 27" D x 27" H
300 pounds

Power Specifications

Rated voltage	~100–240 VAC +10%
Rated frequency	50–60 Hz
Rated power	400 W
Input protection	T5A fuse

Computer Interface Options Specifications

Ethernet port	10/100 Base-T
RS232 port	Serial DB9
Mouse	PS/2 /USB

Standards Compliance

CE Marked
Tested to UL 61010-1, CSA C22.2 No. 61010-1, and EN/IEC 61010-1, 2nd editions.
IEC 61010-2-101, 1st edition.
NRTL Listed for US/Canada
UL Listed
Tested to EN 61326-2-6, EN61326-1, meets Class A,
Tested to FCC CFR 47, Part 15, subpart B, meets Class A

Environmental Specifications (indoor use only)

Operating temperature	Room temperature, 65°–90°F, 18°–32°C
Humidity	20%–80% R.H.
Altitude	Up to 2000 m (6562 ft)
Overvoltage	category Category II, connected to a branch circuit
Pollution	Degree II, normal indoor environment



CELLTRACKS ANALYZER II®

Size and Weight

The bench must be able to support at least 1000 pounds (454 kg)
The work space should be level, vibration-free, and dust-free

Analyzer:

16.0 H x 28.7W x 24.6 D inches (40.6 x 73.0 x 62.6 cm)
Allow 30 inches/76.2 cm height for service access

Computer:

18.5 H x 6.5W x 19.0 D inches (47.0 x 16.5 x 48.3 cm)

Monitor:

17.0 H x 20.0W x 5.0 D inches (43.2 x 50.8 x 12.7 cm)
UPS: 8.8 H x 8.4W x 19 D inches (22.4 x 21.3 x 48.3 cm)

Computer Interface Options Specifications

Ethernet port 10/100/1000 Base-T

Power Specifications

Rated voltage	~100–240 VAC +10%
Rated frequency	50–60 Hz
Rated power	400 W
Input protection	2 T4A fuses (100–240 VAC)

Standards Compliance

CE Marked
Tested to UL 61010-1, CSA C22.2 No. 61010-1, and EN/IEC 61010-1, 2nd editions.
IEC 1010-2-101, 1st edition.
NRTL Listed for US/Canada
Tested to EN61010, ETL Listed
Tested to EN 61326-2-6, EN 61326-1, meets Class A,
Tested to FCC CFR 47, Part 15, subpart B, meets Class A

Optical Specifications

DAPI 365/15BP 405LP FITC 475/25BP 510/20BP
PE 545/15BP 580/25BP APC 620/30BP 680/50BP

Environmental Specifications (indoor use only)

Operating temperature	Room temperature, 65°–90°F, 18°–32°C
Humidity	20%–70% R.H.
Altitude	Up to 2000 m (6562 ft)
Overvoltage	category Category II, connected to a branch circuit
Pollution	Degree II, normal indoor environment

ADVANCED TECHNOLOGY FOR THE ENUMERATION OF CTCs FROM WHOLE BLOOD

The CELLSEARCH® System Empowers you with:

- Rapid, precise, reproducible results
- Easy-to-use technology
- Semiautomation and standardization to fit your lab's workflow needs

For more information on the CELLSEARCH® System, contact your Janssen Diagnostics sales representative, call **1-877-837-4339** or visit **www.cellsearchctc.com**.



Reference: 1. Instructions for Use. Janssen Diagnostics, LLC.

INTENDED USE

For *in vitro* diagnostic use. The CELLSEARCH® Circulating Tumor Cell Kit is intended for the enumeration of circulating tumor cells (CTCs) of epithelial origin (CD45-, EpCAM+, and cytokeratins 8, 18+, and/or 19+) in whole blood. The presence of CTC in the peripheral blood, as detected by the CELLSEARCH® Circulating Tumor Cell Kit, is associated with decreased progression-free survival and decreased overall survival in patients treated for metastatic breast, colorectal, or prostate* cancer. The test is to be used as an aid in the monitoring of patients with metastatic breast, colorectal, or prostate cancer. Serial testing for CTC should be used in conjunction with other clinical methods for monitoring metastatic breast, colorectal, and prostate cancer. Evaluation of CTC at any time during the course of disease allows assessment of patient prognosis and is predictive of progression-free survival and overall survival.

*Metastatic prostate cancer patients in this study were defined as having two consecutive increases in the serum marker PSA above a reference level, despite standard hormonal management. These patients are commonly described as having androgen-independent, hormone-resistant, or castration-resistant prostate cancer.

LIMITATIONS

CELLSEARCH® results should be used in conjunction with all clinical information derived from diagnostic tests (i.e., imaging, laboratory tests), physical examination and complete medical history in accordance with appropriate patient management procedures.

The CELLSEARCH® test does not demonstrate that any current line of therapy is any more or less effective than any other or no therapy.

CELLSEARCH® results and imaging results are not equivalent in assessing the transition of patients between non-progressive disease and progressive disease.

For *in vitro* diagnostic use – for further information on intended use, warnings, and limitations, please refer to the CELLSEARCH® CTC Test Instructions for Use or visit www.cellsearchctc.com.

