



**CellSearch® Circulating Epithelial Cell Control Kit**  
**(Immunomagnetic capture and fluorescent reagents)**  
**Instructions for Use**

**CTC control kit**

**REF**

**7900003**

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**[PRODUCT NAME]**

Generic Name: CellSearch® Circulating Epithelial Cell Control Kit (Immunomagnetic capture and fluorescent reagents)

English name: CellSearch® Circulating Tumor Cell Control Kit

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**[PACKAGING SPECIFICATION]**

CellSearch® Circulating Epithelial Cell Control Kit (Immunomagnetic capture and fluorescent staining) 24 tests/package

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**[INTENDED USE]**

For *in vitro* diagnostic use.

CellSearch® Circulating Tumor Cell Control Kit is intended for use as an assay control to ensure that the sample detection and identification systems are working when performing the CellSearch® Assay.

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**[PRINCIPLES OF THE PROCEDURE]**

Each single use bottle in the CellSearch® CTC Control Kit contains two populations of SK-BR-3 cells at different concentrations (low and high). The two cell populations are distinguished from each other by use of fluorescent dyes that are specific for each population. This permits simultaneous enumeration of low and high control cell populations by the CellSpotter® Analyzer or CellTracks Analyzer II®. The control cells are fully compatible with CellSearch® CTC Kit reagents and are automatically identified by the CellSpotter® Analyzer or CellTracks Analyzer II®. The CellSearch® CTC Kit utilizes ferrofluid-coupled antibodies directed against an epithelial cell surface molecule (EpCAM) to bind and separate epithelial cells from blood cells in a magnetic field.

Epithelial cells are then identified using fluorochrome-coupled antibodies for specific intracellular epithelial cell markers. Non-specifically collected leukocytes and leukocytes binding non-specifically to the epithelial cell marker are identified using a different fluorochrome-coupled leukocyte specific antibody. The CellTracks® AutoPrep® System automates the sample preparation procedure and readies the sample for analysis on the CellSpotter® Analyzer or CellTracks Analyzer II®. After sample preparation is complete, the sample volume containing the magnetically collected and fluorescently labeled cells is transferred to the sample chamber in a MagNest Cartridge Holder presentation device and sealed. The cells with bound ferrofluid are magnetically drawn up to the top of the chamber, where they are held in a magnetic field for enumeration and analysis. Pre-stained and fixed Control Cells are used as a model system to evaluate the functionality of the system.

The cells are identified as control cells by the detection of fluorescence in the high or low control channels of the CellSpotter® Analyzer or CellTracks Analyzer II®.

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**[MAIN COMPOSITION]**

**MATERIALS PROVIDED**

- 24 lot-specific Bar Code labels (orange)
- 24 single-use 3.0 mL bottles of CellSearch® CTC Controls: Two populations of fixed SK-BR-3 cells (a human breast carcinoma derived cell line) in Histopaque®, 5% bovine serum albumin and 0.1% sodium azide. Cells are stained with proprietary fluorescent dyes. The Control Cell population concentrations approximate 1000 cells/test for the High Control Cell and 50 cells/test for the Low Control Cell, but vary from lot to lot. For lot specific concentration, refer to the Certificate of Analysis in each Kit. (Histopaque® is a trademark of Sigma Aldrich)

## CTC control kit

Company.)

### MATERIALS REQUIRED, NOT PROVIDED

- CellSearch® Circulating Tumor Cell Kit
- CellTracks® AutoPrep® System
- 20 liter container CellTracks® AutoPrep® Instrument Buffer
- Cell Spotter® Analyzer or CellTracks Analyzer II®
- Vortex
- Micro-pipettor

### [ REAGENT STORAGE AND HANDLING STABILITY ]

Control	Storage Conditions	Stability
Sealed	Refrigerate at 2-8°C	12 Months

- Reagent is provided ready for use in single use containers.
- Store at 2 to 8°C.
- Protect reagents from exposure to bright sunlight.
- Remove the control bottle from the refrigerator 30 minutes prior to use and bring to room temperature (15 to 30°C).

### [ APPLICABLE INSTRUMENT ]

CellTracks AutoPrep System & CellTracks Analyzer II

### [ TEST PROCEDURE ]

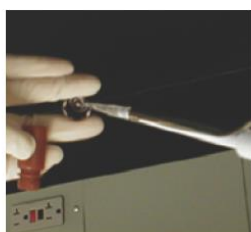
Adherence to the CellSearch® Circulating Tumor Cell Control Kit Procedure (see the CellTracks® AutoPrep® System User's Guide for additional details on sample preparation) is imperative for achieving optimal results.

1. A CellSearch® CTC Control should be run each day of patient testing or when using a new lot of CellSearch® CTC Kit. Control Cell recovery is indicative of the validity of the overall system performance including instrument and reagents.
2. Remove one CellSearch® CTC Control bottle from the refrigerator 30 minutes before use. Allow the control material and the CellSearch® CTC Kit reagents to warm to room temperature prior to use.
3. Affix an orange CellSearch® CTC Control barcode label vertically to a 15 mL CellTracks® AutoPrep® tube contained in the CellSearch® CTC Kit. This label contains the lot information and enables the CellTracks® AutoPrep® System to load the expected values for the lot.

NOTE: If the CellTracks® AutoPrep® System detects a new lot of control material, it will prompt the user to scan the barcode label on the box. The barcode contains the lot number, expiration date, as well as the averages and expected ranges for the high and low controls.

4. Vortex the CellSearch® CTC Control bottle gently for 5 seconds. Mix by inverting 5 times.
5. Pour the contents out of the control bottle into the pre-labeled CellTracks® AutoPrep® Sample Tube. Use a pipette to transfer any residual liquid in the bottle and bottle cap to the sample tube.

NOTE: Only transfer residual liquid. DO NOT add buffer or any other material to the bottle.



## INSTRUCTIONS FOR USE

- Pour the Control bottle contents into the tube. Collect the residual liquid in the bottle and cap.
- Place the tube on the CellTracks® AutoPrep® System when prompted by the software.
  - Scan and Auto Analyze the Control sample according to the CellSpotter® Analyzer or CellTracks Analyzer II® User's Guide.

### [LIMITATIONS]

The CellSearch® Circulating Tumor Cell Control Kit is designed for use with the CellTracks® AutoPrep® System, the CellSpotter® Analyzer or CellTracks Analyzer II®, and the CellSearch® Circulating Tumor Cell Kit. The Control Cells have been optimally formulated for use on this system.

### [WARNINGS AND PRECAUTIONS]

For *in vitro* diagnostic use

Please read the entire instructions for use before testing.

Caution: All personnel should follow universal precautions and use laboratory safety equipment (i.e., safety glasses, laboratory coat, gloves).

Disposal of liquid waste resulting from the use of this kit should be performed in accordance with all local, state and federal laws.

**Warning:**

**All items including cartridges and other materials that come in contact with patient samples should be considered a potential biohazard. Handle as if capable of transmitting infection. Treat and dispose of waste using proper precautions and in accordance with local regulations. Never pipette by mouth.**

**Caution:**

**The CellSearch® CTC Control Kit contains the preservative sodium azide in each bottle. If swallowed, seek medical advice immediately and show the containers or labels. Keep out of reach of children. Keep away from food and drink. Wear suitable protective clothing.**

Contact with acids liberates very toxic gas. Azide compounds should be flushed with large volumes of water during disposal to avoid deposits in lead or copper plumbing where explosive conditions can develop.

Operator training is required before performing the test procedure.

### [BASIC Information]

Legal Manufacturer: Janssen Diagnostics, LLC

Legal Manufacturer Address: 700 US HWY 202 South Raritan, NJ 08869 USA

Manufacture Site Address: 3401 Masons Mill Road Huntingdon Valley, PA 19006 USA;  
545 South Ewing Avenue, St. Louis, Missouri, 63103, USA

Legal Manufacturer Contact Info: 1-877-837-4339

Agent of Customer Service: Johnson & Johnson Medical (Shanghai) Ltd.

Customer Service Agent Contact Info: 400 920 8790

China Agent: Johnson & Johnson Medical (Shanghai) Ltd.

China Agent Address: Location C, 1/2/3 F, #439 Fu Te Xi Yi Road, Pilot Free Trade Zone, Shanghai, P.R. China

China Agent Contact Info. 400 920 8790

Date of Manufacture: Refer to product package

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The following symbols might be used in the label printing of the product.

	Date of Manufacture		<i>In vitro</i> diagnostic medical device		Caution, consult accompanying documents
	Use by YYYY-MM-D D or YYYY-MM		Contains sufficient for < n > tests		Manufacturer
	Batch code		Temperature limitation		Authorized representative in the European Community
	Serial number		Consult instructions for use		Biological risks
	Catalog number		CELLSEARCH® Control Cells		