

REF 7900003

24 Tests



**Circulating Tumor Cell
Control Kit**

IVD



INTENDED USE

For *In Vitro* Diagnostic Use

The 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.

SUMMARY AND EXPLANATION

The CELLSEARCH® Circulating Tumor Cell Control Kit (CTC Control Kit) contains single-use bottles of fixed cells from a breast carcinoma cell line (SK-BR-3). The cells are stained with fluorescent markers. They express epithelial cell markers recognized by the antibodies in the CELLSEARCH® Circulating Tumor Cell Kit (CTC Kit) and are used to control for the reproducibility of the assay. Each bottle contains two populations of cells for high and low level control.

The CELLSEARCH® Circulating Tumor Cell Control Kit is used to verify the performance of the CELLSEARCH® CTC Kit reagents, sample processing by the CELLTRACKS® AUTOPREP® System, and cell analysis by the CELLTRACKS ANALYZER II®. The CELLSEARCH® CTC Kit contains reagents and supplies for immunomagnetic selection of rare circulating tumor cells (CTCs) from whole blood. The CELLTRACKS® AUTOPREP® System is designed to automate, standardize and optimize sample preparation with the CELLSEARCH® CTC Kit. Analysis of CTCs is performed using the CELLTRACKS ANALYZER II®, a semi-automated fluorescence microscope used to enumerate fluorescently-labeled CTCs that are immuno-magnetically captured and aligned.

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 CELLTRACKS ANALYZER II®. The control cells are fully compatible with CELLSEARCH® CTC Kit reagents and are automatically identified by the 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 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 CELLTRACKS ANALYZER II®.

MATERIALS PROVIDED

- Instructions for Use
- 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 varies from lot to lot. For lot specific concentration, refer to the Certificate of Analysis in each Kit. (Histopaque® is a trademark of Sigma Aldrich Company.)

MATERIALS REQUIRED, NOT PROVIDED

- CELLSEARCH® Circulating Tumor Cell Kit (Catalog #7900001)
- CELLTRACKS® AUTOPREP® System (Catalog #9541)
- 20 liter container CELLTRACKS® AUTOPREP® Instrument Buffer (Catalog #7901003)
- CELLTRACKS ANALYZER II® (Catalog #9555)
- Vortex
- Micro-pipettor

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.

- **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.
- **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.
- Operator training is required before performing the test procedure.

REAGENT STORAGE AND HANDLING STABILITY

- 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).
- When stored at 2 to 8°C, the CELLSEARCH® CTC Control Kit is stable until the expiration date printed on the bottle.

TEST PROCEDURE

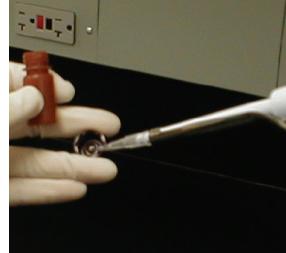
Adherence to the CELLSEARCH® Circulating Tumor Cell Control Kit Procedure (see the CELLTRACKS® AUTOPREP® System User's Guide for additional details on sample preparation) is imperative for achieving optimal results.

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.



Pour the Control bottle contents into the tube.



Collect the residual liquid in the bottle and cap.



6. Place the tube on the CELLTRACKS® AUTOPREP® System when prompted by the software.
7. Scan and Auto Analyze the Control sample according to the CELLTRACKS ANALYZER II® User's Guide.

LIMITATIONS

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

The CELLSEARCH® Circulating Tumor Cell Control Kit is designed for use with the CELLTRACKS® AUTOPREP® System, the CELLTRACKS ANALYZER II®, and the CELLSEARCH® Circulating Tumor Cell Kit. The Control Cells have been optimally formulated for use on this system.

Technical Support

Technical and Customer Support can be reached 8:00 AM to 8:00 PM Eastern Time. Phone: 1-877-837-4339
00 8000 8374339 (EU)

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KEY TO SYMBOLS

The following symbols may have been used in this instruction for use or in the associated labeling.



Use by YYYY-MM-DD or YYYY-MM



Batch code



Serial number



Caution, consult accompanying documents



Date of Manufacture



Manufacturer



Contains sufficient for < n > tests



Catalog number



Authorized representative in the European Community



Temperature limitation



Biological risks



Consult instructions for use



In vitro diagnostic medical device



CELLSEARCH® Control Cells

EC REP

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