

CELLSEARCH® Epithelial Cell Control Kit INSTRUCTIONS FOR USE

For Research Use Only. Not for use in diagnostic procedures. The performance characteristics and safety and effectiveness have not been established and are not cleared or approved by the FDA.

PRODUCT OVERVIEW

The CELLSEARCH® Epithelial Cell Control Kit contains single-use bottles of fixed cells from a breast carcinoma cell line (SKBR-3). Each bottle contains a population of control cells. A CELLSEARCH® Epithelial Cell Control bottle is substituted for a patient sample to verify the performance of the CELLSEARCH® Epithelial Cell Kit reagents, sample processing by the CELLSEARCH® AUTOPREP® System, and cell analysis by the CELLTRACKS ANALYZER II®. The CELLSEARCH® Epithelial Cell 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® Epithelial Cell Kit. Analysis of CTCs is performed using the CELLTRACKS ANALYZER II®, a semi-automated fluorescence microscope that is used to enumerate fluorescent-labeled CTCs that are immunomagnetically captured and aligned.

Each single use bottle in the CELLSEARCH® Epithelial Cell Control Kit contains two populations of SKBR-3 cells. 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® Epithelial Cell Kit reagents and are automatically identified as CTCs by the CELLTRACKS ANALYZER II®. The cells are differentiated as control cells by the detection of fluorescence in the control channels of the CELLTRACKS ANALYZER II®.

WARNINGS AND PRECAUTIONS

Please read the full package insert before testing. Refer to the *CELLSEARCH® Research Use Only User's Guide* for more information.

- CAUTION:** All personnel should follow universal precautions and use laboratory safety equipment (i.e., safety glasses, laboratory coat, gloves).
- CAUTION:** Microbial contamination of reagents can cause erroneous results and should be avoided.
- WARNING:** All biological specimens, cartridges and other materials coming into contact with the specimen(s) are considered biohazardous. Handle as if capable of transmitting infection. Treat and dispose of waste using proper precautions and in accordance with local, state, and federal regulations. Never pipette by mouth.
- WARNING:** Some of the reagents contain sodium azide preservative. If swallowed, seek medical advice immediately and provide 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.
- R22: Harmful if swallowed.
S28: After contact with skin, wash with plenty of soap.
- WARNING:** Some of the reagents contain ProClin® 300 as a preservative. Symptoms of overexposure to ProClin® 300 may include skin and/or eye irritation as well as irritation to mucous membranes and upper respiratory tract.

LIMITATIONS OF THE PROCEDURE

- For Research Use Only. Not for use in diagnostic procedures. Results should not be used for patient management.
- User-defined reagents cannot be run with control cells.

INSTRUMENTATION

The CELLSEARCH® Epithelial Cell Control Kit is designed for use with the CELLTRACKS® AUTOPREP® System and the CELLTRACKS ANALYZER II®.

REAGENT STORAGE AND HANDLING

- Reagent is supplied ready for use in single use containers
- Store at 2–8 °C (36–46 °F). Do not freeze or expose to temperatures in excess of 35 °C (95 °F).
- Protect reagents from exposure to bright light.
- Remove the control bottle from the refrigerator at least 30 minutes prior to use and bring to room temperature (15–30 °C or 59–86 °F).
- When stored at 2–8 °C (36–46 °F), the CELLSEARCH® Epithelial Cell Control Kit is stable until the expiration date printed on the bottle.
- After opening, reagents in the reagent pack should be stored up to 30 days at 2–8 °C (36–46 °F) with caps on.

MATERIALS PROVIDED

- 1 Package Insert**
- 24 lot-specific Bar Code labels (orange)**
- 24 single-use 3.0 mL bottles of CELLSEARCH® Epithelial Control Cells:** Two populations of fixed SKBR-3 cells (a human breast carcinoma derived cell line) in Histopaque® solution, 5% bovine serum albumin and 0.1% sodium azide.

MATERIALS REQUIRED, NOT PROVIDED

- CELLSEARCH® Epithelial Cell Kit (Catalog #7900000)
- CELLTRACKS® AUTOPREP® System (Catalog #9541)
- CELLTRACKS® AUTOPREP® Instrument Buffer (Catalog #7901003)
- CELLTRACKS ANALYZER II® (Catalog #9555)
- Test tube racks
- Calibrated micro-pipettes and tips
- Vortex mixer

TESTING PROCEDURE

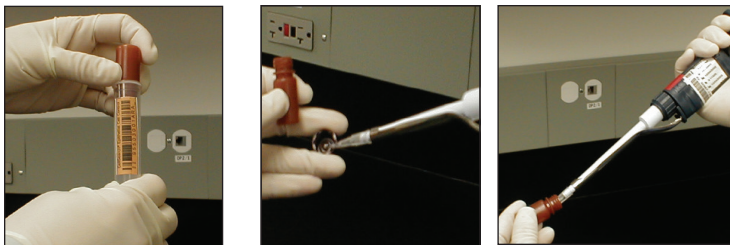
Adherence to the CELLSEARCH® Epithelial Cell Control Kit Procedure (see the *CELLTRACKS® AUTOPREP® System User's Guide* for additional details on sample preparation) is imperative for achieving optimal results.

- A CELLSEARCH® Epithelial Cell Control Kit should be run each day of patient testing or when using a new lot of CELLSEARCH® Epithelial Cell reagent kit. Control Cell recovery is indicative of the validity of the overall system performance including instrument and reagents.
- Remove one CELLSEARCH® Epithelial Cell Control Kit bottle from the refrigerator 30 minutes before use. Allow the control material and the CELLSEARCH® Epithelial Cell Control Kit reagents to warm to room temperature prior to use.
- Affix an orange CELLSEARCH® Epithelial Cell Control Kit barcode label vertically to a 15 mL conical tube contained in the CELLSEARCH® Epithelial Cell reagent 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.

- Vortex the CELLSEARCH® Epithelial Cell Control Kit bottle gently for five seconds. Mix by inverting five times.
- Pour the contents out of the control bottle into the pre-labeled conical tube. Use a pipette to transfer any residual liquid in the bottle and bottle cap to the conical 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 review the Control sample according to the *CELLTRACKS ANALYZER II® User's Guide* and the *CELLSEARCH® Research Use Only User's Guide*.

RESULTS













Results must fall within ranges defined for each lot. Refer to package labeling for more information.

INTERFERING SUBSTANCES

Not applicable.

GLOSSARY OF SYMBOLS

The following symbols may have been used in the labeling of this product.

 Use by or Expiration Date (Year-Month-Day)	 Contains Sufficient for "n" Tests
 Lot Number	 Temperature Limitation
 Serial Number	 Consult Instructions for Use
 Catalog Number or Product Code	 Biological Risk
 Caution	 Irritant
 Manufacturer	 Harmful

REVISION HISTORY

Date of Revision	Component Code	Description of Technical Changes
2013-02-28	631500051	<p>New format, technically equivalent to 7800025.05 with the following minor changes indicated with change bars:</p> <ul style="list-style-type: none"> • WARNINGS AND PRECAUTIONS: Updated wording to Biohazard warning • TESTING PROCEDURE section updated • GLOSSARY OF SYMBOLS: Symbols used and layout updated <p>Changes not indicated with change bars:</p> <ul style="list-style-type: none"> • Assigned new part number, updated Veridex address and updated logo

*The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

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ProClin® is a registered trademark of Supelco.

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