



REF 9572V
24 Test Kit

Control Kit for Circulating Endothelial and Melanoma Cells

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 CELLTRACKS® Control Kit for Circulating Endothelial and Melanoma Cells (CEC/CMC Control) is used as a control for the CELLSEARCH® Endothelial Cell (CEC) Kit or the CELLTRACKS® Circulating Melanoma (CMC) Kit.

Each single-use bottle in the CELLTRACKS® Control Kit contains two populations of SK-Mel-28 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 CEC and CMC reagent Kits contains reagents and supplies for immunomagnetic selection of rare circulating CECs or CMCs from whole blood. 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 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. The control cells are fully compatible with CELLSEARCH® Endothelial Cell and CELLTRACKS® Circulating Melanoma Cell Kit reagents and are automatically identified by the CELLTRACKS ANALYZER II®.

WARNINGS AND PRECAUTIONS

Please read the full package inserts before testing samples. 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.

CAUTION: 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.

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.

LIMITATIONS OF THE PROCEDURE

- For Research Use Only. Not for use in diagnostic procedures. Results should not be used for patient management.

INSTRUMENTATION

The CELLTRACKS® CEC/CMC Control Kit is designed for use with the CELLTRACKS® AUTOPREP® System, the CELLTRACKS ANALYZER II®, and the CELLSEARCH® Endothelial Cell or CELLTRACKS® Circulating Melanoma Cell Kits. The control cells have been optimally formulated for use on this system.

REAGENT STORAGE AND HANDLING

- Reagent is provided ready for use.
- Store at 2–8 °C (36–46 °F).
- Protect reagents from exposure to direct sunlight.

- Remove the control bottle from the refrigerator 30 minutes prior to use and bring to room temperature (15–30 °C or 59–86 °F).
- When properly stored, reagents are stable until the expiration date printed on the reagent container or kit box. Do not use expired reagents.
- 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 3.5 mL bottles of CELLTRACKS® Controls: Fixed SK-MEL-28 cells (a human melanoma derived cell line) in Histopaque®, 5% bovine serum albumin, and 0.09% sodium azide. Cells are stained with a proprietary fluorescent dye.

MATERIALS REQUIRED, NOT PROVIDED

- CELLSEARCH® Endothelial Cell Kit (Catalog #7900009)
- CELLTRACKS® Melanoma Cell Kit (Catalog #9594V)
- 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

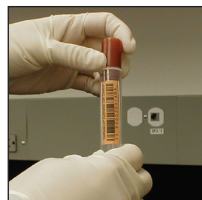
TESTING PROCEDURE

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

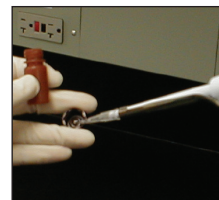
Processing with the CELLTRACKS® AUTOPREP® System

- A CELLTRACKS® CEC/CMC Control should be run each day of sample testing or when using a new lot of CELLSEARCH® Endothelial Cell or CELLTRACKS® Circulating Melanoma Cell Kit. Control cell recovery is indicative of the validity of the overall system performance including instrument and reagents.
 - Remove the CELLTRACKS® CEC/CMC Control bottle from the refrigerator at least 30 minutes before use. Allow the control material and the CELLSEARCH® Endothelial Cell or CELLTRACKS® Circulating Melanoma Cell Kit reagents to warm to room temperature prior to use.
 - Affix an orange CELLTRACKS® Control bar code label vertically to a 15 mL CELLSEARCH® Conical Centrifuge Tube contained in the CELLSEARCH® Endothelial Cell or CELLTRACKS® Circulating Melanoma Cell 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 mean and expected ranges for the high and low controls.
- Vortex the CELLTRACKS® CEC/CMC Control Kit bottle for five seconds. Mix by inverting five times.
 - Pour the contents out of the control bottle into the pre-labeled 15 mL CELLSEARCH® Conical Centrifuge Tube. Use a pipette to transfer any residual liquid in the bottle and bottle cap to the conical centrifuge tube.

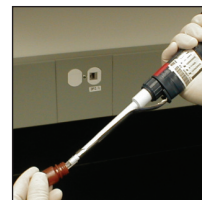
NOTE: Only transfer residual liquid. DO NOT add buffer or any other material to the bottle.



Pour the Control bottle contents into the tube.



Collect the residual liquid in the bottle and cap.



- Place the tube on the CELLTRACKS® AUTOPREP® System when prompted by the software.
- 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 | |
|  Manufacturer | |

REVISION HISTORY

| Date of Revision | Component Code | Description of Technical Changes |
|------------------|----------------|--|
| 2017-01-19 | JDX01001 | <p>Technically equivalent to 631500211 with the following changes:</p> <ul style="list-style-type: none">• Assigned new part number• Updated Veridex name, address, website and phone number to reflect Janssen Diagnostics, LLC.• Updated Veridex trademark and patent information to reflect Janssen Diagnostics, LLC.• Updates to 'WARNINGS AND PRECAUTIONS' section:<ul style="list-style-type: none">- Updated sodium azide paragraph from 'WARNING' to a "CAUTION" and moved with 'CAUTION'- Removed ProClin® 300 'WARNING' paragraph• In GLOSSARY OF SYMBOLS Section:<ul style="list-style-type: none">- Deleted both "Harmful" and "Irritant" DSD Danger Symbols• Updated address to align with ISO certificate• Patent information has been updated. |

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

Histopaque® is a trademark of Sigma Aldrich Company.

ProClin® is a registered trademark of Supelco.

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This technology, including products and/or associated components thereof, and procedures and instrument systems described herein, are protected by United States patents and corresponding international patents and pending patent applications, including one or more of the following: US Patent Numbers 6,136,182; 6,551,843; 6,623,982; 6,790,366; 7,011,794 and 7,332,288.

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