

CELLSEARCH® CXC Control Cell 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® CXC Control Cell 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® CXC Control Cell bottle is substituted for a patient sample to verify the performance of the CELLSEARCH® CXC Kit reagents, sample processing by the CELLTRACKS® AUTOPREP® System, and cell analysis by the CELLTRACKS ANALYZER II®. The CELLSEARCH® CXC 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® CXC 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 immuno-magnetically captured and aligned.

Each single use bottle in the CELLSEARCH® CXC Control Cell Kit contains one population of SKBR-3 cells at a concentration of approximately 1000 cells/test. The control cells are fully compatible with CELLSEARCH® CXC 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 channel of the CELLTRACKS ANALYZER II®.

WARNINGS AND PRECAUTIONS

Please read the full package insert 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.
- User-defined reagents cannot be run with control cells.

INSTRUMENTATION

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

REAGENT STORAGE AND HANDLING

- Reagent is provided 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® CXC Control Cell 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® CXC Control Cells:** One population of fixed SKBR-3 cells (a human breast carcinoma derived cell line) in Histopaque® solution, 5% bovine serum albumin and 0.09% sodium azide.

MATERIALS REQUIRED, NOT PROVIDED

- CELLSEARCH® CXC Kit (Catalog #7900017)
- 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

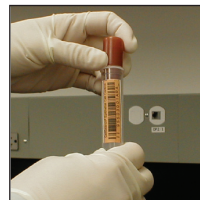
Adherence to the CELLSEARCH® CXC Control Cell Kit Procedure (see the CELLTRACKS® AUTOPREP® System User's Guide for additional details on sample preparation) is imperative for achieving optimal results.

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

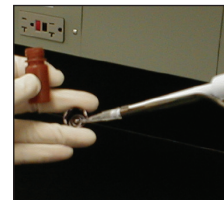
NOTE: If the CELLTRACKS® AUTOPREP® System detects a new lot of control material, it will prompt the user to scan the barcode label on the box. The barcode contains the lot number, expiration date, as well as the mean and expected ranges for the high and low controls.

4. Vortex the CELLSEARCH® CXC Control Cell Kit bottle gently for five seconds. Mix by inverting five times.
5. 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 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 the Control sample according to the CELLTRACKS ANALYZER II® User's Guide and the CELLSEARCH® Research Use Only User's Guide.
8. The CELLSEARCH® CXC Control is a one-level control and does not require a review of images

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
01-19-2017	JDX02701	<p>Technically equivalent to 631500201 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 to 'CAUTION' section - Removed R22 and S28 DSD Risk and Safety Phrases - 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.

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ProClin® is a registered trademark of Supelco.

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