Cell Search®

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.

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.

**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.](image)
   ![Collect the residual liquid in the bottle and cap.](image)

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 800 8000 8374339 (EU)
<table>
<thead>
<tr>
<th>Date of Revision</th>
<th>Component Code</th>
<th>Description of Technical Changes</th>
</tr>
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| 2017-07-06      | e631600015_EN  | • Added LBL-0022 under part number  
• Rolled tailcode to e631600015_EN  
• Updated ‘JANSSEN DIAGNOSTICS a division of JANSSEN PHARMACEUTICA NV’ company name to ‘Menarini Silicon Biosystems Inc.’  
• Updated to Menarini Silicon Biosystems business attributes, including:  
  – Menarini Silicon Biosystems logo  
  – EC/REP address  
  – Manufacture address  
• Updated Revision Date |
| 2017-01-04      | e631600014_EN  | • Rolled tailcode  
• Updated patent information  
• Updated Revision Date |
| 2016-04-20      | e631600013_EN  | • Rolled tailcode  
• Removed all instances of MAGNEST trademark registration  
• In ‘Limitations’ section:  
  – Added U.S. Federal law sales restrictions Caution statement  
• Updated BVBA company name to ‘JANSSEN DIAGNOSTICS a division of JANSSEN PHARMACEUTICA NV’  
• Updated Revision Date |
| 2015-05-22      | e631600012_EN  | • Rolled tailcode  
• Added DS number under part number  
• In ‘Warnings and Precautions’ section:  
  – Updated sodium azide paragraph from ‘Warning’ to a ‘Caution’  
  – Removed Risk and Safety Phrase R22 and S28 statement  
• Updated Address and Revision Date |
| 2013-08-29      | e631600011_EN  | Technically equivalent to 631500031 with the following changes:  
• Assigned a new part number  
• Updated to Janssen business attributes, including:  
  – Janssen logo  
  – Manufacture address  
  – EC/REP address  
  – Phone numbers  
  – Website  
• In MATERIALS REQUIRED, NOT PROVIDED Section:  
  – Added Catalog numbers  
• In Technical Support Section:  
  – Updated all instances of Veridex, LLC to Janssen Diagnostics, LLC  
  – US Patent Statement updated  
• In KEY TO SYMBOLS Section:  
  – Added Date of Manufacture symbol and text ‘Date of Manufacture’  
• Updated Revision Date |

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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.
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
- LOT Batch code
- SN Serial number
- ⚠️ Caution, consult accompanying documents
- ☒️ Date of Manufacture
- 🏛️ Manufacturer
- Σ Contains sufficient for < n > tests
- REF Catalog number
- EC REP Authorized representative in the European Community
- 🥃 Temperature limitation
- 🦠 Biological risks
- 📒 Consult instructions for use
- IVD In vitro diagnostic medical device
- CONTROL CELLSEARCH® Control Cells