



## Profile Kit

**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.**

The CellSearch® Profile Kit is for the isolation of circulating tumor cells (CTC) of epithelial origin in whole blood in conjunction with the CellTracks® AutoPrep® System.

## PRODUCT OVERVIEW

Cancer metastasis occurs when cells shed from the primary tumor enter the circulation and begin to grow in distant locations in the body. Malignant carcinomas are derived from epithelial cells that are not normally found in circulation (Cancer Biology, 3rd edition, Ray Ruddon 1995). The CellTracks® AutoPrep® System was designed to standardize and optimize the sample preparation protocol using the CellSearch® Profile Kit. Analysis of CTC may be performed using a variety of analytical methods, including flow cytometry and molecular techniques.

The CellSearch® Profile Kit contains a ferrofluid-based capture reagent, which consists of nano-particles with a magnetic core surrounded by a polymeric layer coated with antibodies targeting the Epithelial Cell Adhesion Molecule (EpCAM) antigen for capturing CTC. The CellTracks® AutoPrep® System precisely dispenses reagents and performs magnetic incubation steps. The vast majority of leukocytes and other blood components are depleted from the final sample, rendering it ready for further analysis using the laboratory's validated methods.

## PRECAUTIONS

1. Please read the full instructions for use before testing samples.
2. **Precaution:** Sample carryover may be of concern when a specimen with more than 5,000 CTC per 7.5 mL of blood is immediately followed in the CellTracks® AutoPrep® System by a specimen yielding a CTC result in the range of 3 to 15 CTC per 7.5 mL of blood. In this case, we recommend obtaining a new blood sample from the low CTC specimen and performing a confirmatory CTC analysis. To identify following samples, refer to the CellTracks® AutoPrep® User's Guide section on Viewing System Data and obtain the detailed batch data, including sample and patient identification for each tube in the batch.
3. **Caution:** For downstream cellular analysis applications, collect blood into a CellSave Preservative Tube only. Circulating Tumor Cells are fragile and require preservation for accurate analysis. For molecular applications, use EDTA tubes because higher quality nucleic acid is generally recovered from EDTA tubes, using easier processing protocols.
4. **Caution:** All personnel should follow universal precautions and use laboratory safety equipment (i.e., safety glasses, laboratory coat, gloves).
5. **Caution:** Microbial contamination of reagents can cause erroneous results and should be avoided.

6. **Warning:** All biological specimens 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 regulations. Never pipette by mouth.
7. **Warning:** Some of the reagents contain sodium azide as a 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. Risk and Safety phrases R22 (Harmful if swallowed) and S28 (After contact with skin, wash with plenty of soap).
8. **Warning:** One of the reagents contains 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.
9. Operator training is required to perform the test procedure.

## LIMITATIONS

- For research use only. Not for use in diagnostic procedures. Results should not be used for patient management.

## INSTRUMENTATION

The CellSearch® Profile Kit is designed for use with the CellTracks® AutoPrep® System.

## STORAGE AND HANDLING

- Reagents are supplied ready for use. Store at 2° to 8°C.
- After opening, reagents in the reagent pack should be stored up to 30 days at 2° to 8°C with caps on.
- NOTE: After opening, the dilution buffer bottle that is used for sample preparation, must be stored at room temperature for up to 30 days.
- Protect reagents from heat in excess of 35°C. Do not freeze.
- Bring to room temperature (15 to 30°C) before use.
- Protect reagents from exposure to direct sunlight.
- When properly stored, unopened reagents are stable until the expiration date printed on the reagent pack. Do not use expired reagents.
- The kit components are manufactured and tested as a master lot. Do not mix and match reagents from different kits.

## MATERIALS PROVIDED

- Instructions for Use.
- **3.0 mL anti-EpCAM-Ferrofluid:** Contains a suspension of 0.022% magnetic nanoparticles conjugated to a mouse monoclonal antibody that recognizes a cell surface marker present on epithelial cells in a buffer containing 0.03% bovine serum albumin (BSA) and 0.05% ProClin™ 300 preservative. (brown cap)
- **3.0 mL Capture Enhancement Reagent:** Contains PBS, 0.5% BSA, 0.02% proprietary reagent for controlled ferrofluid aggregation and 0.1% sodium azide. (clear cap)
- **3.0 mL Biotin/PBS:** Contains PBS, 0.62% proprietary reagents and 0.1% sodium azide. (red cap)
- **2 x 110 mL Dilution Buffer:** Contains PBS, 0.5% BSA, 0.6% other animal protein, and 0.1% sodium azide.
- **16 x 15 mL Conical Tubes and Conical Tube Caps**

## MATERIALS REQUIRED, NOT PROVIDED

- CellSave Preservative Tubes (cellular analysis) (Catalog #7900005)
- EDTA tubes (molecular analysis)
- CellTracks® AutoPrep® System (Catalog #9541)
- CellTracks® AutoPrep® Instrument Buffer (Catalog #7901003)
- Centrifuge capable of 800xg
- Calibrated micro-pipettors and tips

## SPECIMEN COLLECTION AND PREPARATION

1. Draw samples prior to intravenous therapy.
2. Collect at least 7.5 mL of whole blood aseptically by venipuncture or from a venous port.

### For Cellular Analysis

Use CellSave Preservative Tubes if subsequent analysis of the epithelial cells is for cellular analysis. CTCs are fragile and require preservation for accurate analysis. Please refer to the CellSave Preservative Tube package insert for shipping and handling instructions.

### For Molecular Analysis

Use EDTA tubes if samples will be processed for isolation of RNA or DNA. Follow the manufacturer's instructions. Process samples as soon as possible to maximize nucleic acid integrity and recovery. A 2-3 fold loss of mRNA from epithelial cells may result if processing is delayed up to 36 hours when compared to immediate processing as measured by real-time quantitative RT-PCR. Blood samples may be stored or transported in EDTA tubes for up to 36 hours at room temperature (15 to 30°C) prior to processing. Do not refrigerate or freeze.











**CAUTION:** Examine each sample for clotting before processing on CellTracks® AutoPrep® System. Clotted samples should be discarded, as blood clots interfere with the performance of the assay.

### Processing with the CellTracks® AutoPrep® System

Process on the CellTracks® AutoPrep® System **within 1 hour** of the sample preparation. Refer to the CellTracks® AutoPrep® System User's Guide for full instructions and follow the prompts on the screen.

## KEY TO SYMBOLS

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
	Manufacturer
	Contains sufficient for < n > tests
	Catalog number
	Temperature limitation
	Biological risks
	Consult instructions for use

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