

**REF** 9597  
3.0 mL



## IGF-1R Tumor Phenotyping Reagent

For Research Use Only. Not for use in diagnostic procedures.

### SUMMARY AND EXPLANATION

Cancer metastasis occurs when cells shed from the primary tumor and 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® CXC Kit. The CELLSEARCH® IGF-1R Tumor Phenotyping Reagent may be added to the batch so that CTC with IGF-1R expression may be evaluated using the CELLTRACKS ANALYZER II®.

### PRINCIPLES OF THE PROCEDURE

The CELLSEARCH® IGF-1R Tumor Phenotyping Reagent is a PE conjugate. The Insulin-like Growth Factor 1 (IGF-1) Receptor is a transmembrane receptor that is activated by IGF-1 and by the related growth factor IGF-2. It belongs to the large class of tyrosine kinase receptors and is specific for the extra-cellular alpha subunits of the receptor molecule. The epitope recognized by the 1H7 clone is not cross-reactive to the receptor functional site targeted by blocking molecules. It is a dynamic regulator of cell survival present on normal and malignant cells, and is often expressed in significantly higher amounts in malignant cells.

### PRECAUTIONS

1. Please read the full package insert before testing samples.
2. **Precaution:** Carryover from a CTC count sample with **500 or greater** CTCs per 7.5 mL of blood can affect samples subsequently processed on the CELLTRACKS® AUTOPREP® System, including the subsequent batch. If cells are carried over to subsequent samples, the CTC counts of these samples may be erroneously higher than the patient's actual CTC count. **Please refer to the CELLTRACKS® AUTOPREP® User's Guide for further information.**
3. **CAUTION:** All personnel should follow universal precautions and use laboratory safety equipment (i.e. safety glasses, laboratory coat, gloves).
4. **CAUTION:** Microbial contamination of reagents can cause erroneous results and should be avoided.
5. **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.
6. **WARNING:** This reagent contains sodium azide as a preservative. If swallowed, seek medical advice immediately and provide the containers or labels to the treating provider. 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. Following are the Risk and Safety Requirements:<sup>1</sup>  
R22: Harmful if swallowed.

7. **WARNING:** This reagent contains BSA (bovine serum albumin). Following are the Risk and Safety Requirements:<sup>1</sup>

R43: May cause sensitisation by skin contact.

S28: After contact with skin, wash immediately with plenty of soap.

### LIMITATIONS

1. For Research Use Only. Not for use in diagnostic procedures. Results should not be used for patient management.
2. Draw samples prior to intravenous chemotherapy.

### INSTRUMENTATION

The CELLSEARCH® IGF-1R Tumor Phenotyping Reagent is designed for use with the CELLSEARCH® CXC Kit, the CELLTRACKS® AUTOPREP® System, and the CELLTRACKS ANALYZER II®.

### REAGENT STORAGE AND HANDLING

1. Store at 2 to 8°C.
2. Bring to room temperature (15 to 30°C) before use.
3. Protect reagents from exposure to direct sunlight.
4. When properly stored, reagents are stable until the expiration date printed on the label. Do not use expired reagents.
5. Discard the Tumor Phenotyping Reagent Cup (Reagent Cup) after the sample run is completed.

### MATERIALS PROVIDED

1. Package Insert
2. **3.0 mL anti-IGF-1R-PE:** (Brown cap) Contains 0.0008% mouse monoclonal antibody specific for IGF-1R in PBS containing 0.5% BSA and 0.1% sodium azide.

### MATERIALS REQUIRED, NOT PROVIDED

1. CellSave Preservative Tubes (Catalog # 9528)
2. CELLTRACKS® AUTOPREP® System (Catalog # 9541)
3. CELLTRACKS ANALYZER II® (Catalog # 9555)
4. CELLSEARCH® CXC Kit (Catalog # 7900001)
5. CELLTRACKS® AUTOPREP® Instrument Buffer (Catalog # 7901003)
6. Test Tube Racks
7. Calibrated micro-pipettors and tips

### SPECIMEN COLLECTION AND PREPARATION

Collect whole blood into a CellSave Preservative Tube. Please see the package insert for full instructions for use. Blood samples may be stored or transported in CellSave Preservative Tubes for up to 96 hours at room temperature (15 to 30°C) prior to processing.

#### Processing with the CELLTRACKS® AUTOPREP® System

Refer to the CELLTRACKS® AUTOPREP® System User's Guide for full instructions and follow the screen prompts.

1. Add IGF-1R reagent to the Reagent Cup according to the number of samples that will be processed with the IGF-1R reagent.
2. Place the Reagent Cup in Position 1 on the reagent carrier.
3. Add reagent to the vial according to the number of samples to be processed with the Marker Reagent (refer to the chart below):








# Samples in Batch	Reagent Volume Required (µL)
1	450
2	600
3	750
4	900
5	1050
6	1200
7	1350
8	1500

## Analysis using the CELLTRACKS ANALYZER II®

Refer to the CELLTRACKS ANALYZER II® and Research Use Only User's Guides for complete instructions on sample analysis and data review.

### 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
	Caution, consult accompanying documents
	Manufacturer
	Catalog number
	Temperature limitation
	Consult instructions for use

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### BIBLIOGRAPHY

1. Commission Directive 2001/60/EC of 7 August 2001 adapting to technical progress Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

### REVISION HISTORY

Date of Revision	Component Code	Description of Technical Changes
2013-06-11	631500173	First instruction for use.



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