

CIRCULATING TUMOR CELLS (CTC) SPECIMEN COLLECTION GUIDELINES



The CELLSEARCH® CTC test is a simple, actionable blood test that helps oncologists assess the prognosis of patients with metastatic breast, prostate, or colorectal cancer. The CTC test enumerates circulating tumor cells (CTCs), which are cancer cells that detach from a primary tumor and travel through the bloodstream or lymphatic system to other parts of the body.

The CELLSEARCH® Circulating Tumor Cell Kit is intended for the enumeration of circulating tumor cells (CTC) of epithelial origin (CD45-, EpCAM+, and cytokeratins 8, 18+, and/or 19+) in whole blood. The presence of CTC in the peripheral blood, as detected by the CELLSEARCH® Circulating Tumor Cell Kit, is associated with decreased progression free survival and decreased overall survival in patients treated for metastatic breast, colorectal or prostate* cancer. The test is to be used as an aid in the monitoring of patients with metastatic breast, colorectal or prostate cancer. Serial testing for CTC should be used in conjunction with other clinical methods for monitoring metastatic breast, colorectal and prostate cancer. Evaluation of CTC at any time during the course of disease allows assessment of patient prognosis and is predictive of progression free survival and overall survival.

*Metastatic prostate cancer patients in this study were defined as having two consecutive increases in the serum marker PSA above a reference level, despite standard hormonal management. These patients are commonly described as having androgen-independent, hormone-resistant, or castration-resistant prostate cancer.

Specimen Collection and Handling

Circulating Tumor Cell CellSave collection tubes are available from MLabs. Submit 2 CellSave tubes each containing 7.5 mL of whole blood. Send intact specimen at room temperature. Specimen transport should be arranged so that the specimen is received by MLabs within 72 hours of collection.

Billing

1. MLabs will bill the client or referring institution, or the patient's insurance carrier if appropriate and MLabs is able to do so successfully. Please indicate Client (Referring Institution), Patient Self-Pay, or Patient Insurance in the "Bill To:" section of the test requisition form.
2. Medicare does not cover the CTC test. If the patient has traditional Medicare, an Advance Beneficiary Notice of Non-coverage (ABN) signed by the patient is required.
3. Most commercial insurance plans do not cover the CTC test. If the patient is self-pay or has insurance other than traditional Medicare, please ensure that the patient has been informed of charges that will be billed by Michigan Medicine.

Required Information

Please complete all documentation and labeling with indelible ink to preserve documentation during the shipping and handling process. Printed labels are preferred to handwritten labels. Include the following documentation to accompany the specimens:

- Completed [MCTP Requisition](#) form to include:
 - Client and Ward codes unique to your institution
 - Patient first name, last name, and date of birth
 - Patient medical record number (MRN) if available
 - Billing instructions, patient insurance information, and demographics (attached face sheet)
- Completed [Clinical History Form](#) if applicable.
- Medicare Advance Beneficiary Notice of Non-coverage (ABN) signed by the patient if applicable.

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Shipping

1. All specimen containers must be labeled with the following required information. Printed labels are preferred to handwritten labels.
 - a. Patient's first name and last name.
 - b. A second patient identifier such as date of birth or medical record number.
2. If shipping by **UPS**, place inside Express Pak and seal according to instructions on the Express Pak. Call 800.742.5877 to schedule pick up. Specimens should be shipped or transported to arrive Monday – Friday by 5:00 pm, excluding Michigan Medicine holidays. Do not send specimens outside of these timeframes unless prior arrangements are made through MLabs Client Services.
3. Specimens can be sent via express mail or courier service to:

Michigan Medicine Laboratories (MLabs)
N-LNC Specimen Processing
2800 Plymouth Rd, Bldg 35
Ann Arbor, MI 48109-2800

PLEASE BE ADVISED: The client is responsible for following all applicable U.S. Department of Transportation (DOT), International Air Transport Association (IATA), and International Civil Aviation Administration (ICAO) shipping guidelines for safety and compliance. Training and certification are available from Michigan Medicine via the links below and is required every two years to remain compliant.

- Create a ['Friend Account'](#) at University of Michigan
- [REGULATIONS FOR SHIPPING BIOLOGICS - INFECTIOUS SUBSTANCES CATEGORY B](#)
- [REQUIREMENTS FOR SHIPPING NON-DANGEROUS GOODS WITH DRY ICE](#)
- Contact MLabs Client Services if you have questions.

NOTE: Remaining specimens could be used as quality controls for specimen type validations, or other research purpose for improving diagnostic medicine or other medical advancements.

Questions

Call MLabs Client Services at **800.862.7284** or visit our website mlabs.umich.edu.