### Overview

**Useful For**
Aiding in the monitoring of patients with metastatic prostate cancer

**Special Instructions**
- [Pathology/Cytology Information](#)

### Method Name
CellSearch System

### NY State Available
Yes

### Specimen

**Specimen Type**
Whole blood

**Advisory Information**
The CellSearch System is also FDA approved for metastatic breast and metastatic colon cancer.

- For metastatic breast cancer patients, order CTCBC / Circulating Tumor Cells (CTC) for Breast Cancer by CellSearch, Blood.

- For metastatic colon cancer patients, order CTCCC / Circulating Tumor Cells (CTC) for Colorectal Cancer by CellSearch, Blood.

**Shipping Instructions**
Specimen must be shipped immediately to ensure processing can be completed within 96 hours of draw. Send specimen Monday through Friday only and not the day before a holiday. Ship specimen overnight in an Ambient Shipping Box-Critical Specimens Only (T668).

Ship specimen ambient. Do not refrigerate or freeze. Protect from extreme temperatures.

### Necessary Information
**Date and time of draw are required.**

### Specimen Required

**Patient Preparation:** Patients on doxorubicin (Adriamycin) must wait a minimum of 7 days after administration before blood can be drawn for this test.

**Supplies:**

- Circulating Tumor Cell Collection Kit (T630)-Required

- Ambient Shipping Box-Critical Specimens Only (T668)
**Test Definition: CTCPC**

**Circulating Tumor Cells, Prostate**

**Container/Tube:** CellSave tubes only

**Specimen Volume:** Two 10-mL tubes

**Collection Instructions:**

1. Collect whole blood in 2 CellSave preservative 10-mL tubes.

2. Collect a minimum of 7.5 mL of whole blood into each tube; tubes cannot be combined; each tube must contain at least 7.5 mL.

3. Immediately gently invert each tube 8 times.

4. Send specimen on same day of draw.

**Forms**

1. **Pathology/Cytology Information** (T707) in Special Instructions

2. If not ordering electronically, complete, print, and send an **Oncology Test Request** (T729) with the specimen.

**Specimen Minimum Volume**

7.5 mL

**Reject Due To**

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>Specimen drawn in a tube other than CellSave tube or submitted in an expired CellSave tube. Specimens &gt; or =96 hours old. Specimens submitted for reasons other than monitoring metastatic prostatic carcinoma.</td>
</tr>
</tbody>
</table>

**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood</td>
<td>Ambient</td>
<td>4 days</td>
<td><strong>CELLSAVE PRESERVATIVE TUBE</strong></td>
</tr>
</tbody>
</table>

**Clinical and Interpretive**

**Clinical Information**

According to the American Cancer Society, prostate cancer claims approximately 28,000 lives each year, the vast majority of which are a result of metastatic disease. Although there are many options for the treatment of metastatic prostate cancer, oncologists often have to wait several months after initiation of treatment before they can determine if the treatment is beneficial to the patient.

The CellSearch System identifies and enumerates the number of circulating tumor cells (CTCs) in a blood specimen.(1) Studies suggest that the number of CTCs is associated with progression-free and overall survival in patients with metastatic prostate cancer.(2,3)
Reference Values
An interpretive report will be provided.

Interpretation
Results are reported as favorable or unfavorable. In patients with metastatic prostate cancer, the finding of ≥ 5 circulating tumor cells/7.5 mL of blood is predictive of shorter progression-free survival and overall survival.(2)

Cautions
This test is FDA approved only for monitoring prostate cancer patients with metastatic disease and is not suitable for monitoring prostate cancer patients with nonmetastatic disease.

This test does not predict whether patients with unfavorable results will have better clinical outcomes if they are switched to alternative treatment regimens. It does not provide information about the primary site of a tumor.

Blood specimens must be drawn into a CellSave tube and processed in the laboratory within 96 hours of draw.

Interfering substances may cause the ferrofluid reagent to aggregate, which may compromise results. The analysis process may not be able to detect all CTCs in the sample.

Clinical Reference

Performance
Method Description
The CellSearch system consists of a CellTracks AutoPrep System and a CellTracks Analyzer. The AutoPrep system uses a ferrofluid reagent conjugated with monoclonal antibodies to epithelial cell adhesion molecule (EpCAM) to immunomagnetically separate epithelial cells from other blood components. Because the epithelial cell enrichment with EpCAM does not result in a completely pure epithelial cell population, the CellSearch System also utilizes 3 stains (DAPI, anticytokeratin, and anti-CD45) to help distinguish true circulating tumor cells (CTCs) from contaminating leukocytes. DAPI stains the nuclei of cells and helps distinguish true cells from nonspecific debris. CTCs are identified with phycoerythrin (PE)-labeled antibodies to cytokeratin (CK) 8, 18, and 19. Leukocytes are identified with allophycocyanin (APC)-labeled antibodies to CD45. Cells that are DAPI+/CD45-/CK+ are considered tumor cells. Cells that are DAPI+ /CD45+/CK- are considered leukocytes. (Package insert: CellSearch Circulating Tumor Cell [CTC] Kit. Menarini Silicon Biosystems Inc, Huntington Valley, PA.Â September, 2017)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday, Sunday
Analytic Time
4 days

Maximum Laboratory Time
5 days

Specimen Retention Time
Until reported

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer’s instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
86152
86153

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTCPC</td>
<td>Circulating Tumor Cells, Prostate</td>
<td>In Process</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>54670</td>
<td>Result Summary</td>
<td>50397-9</td>
</tr>
<tr>
<td>54671</td>
<td>Result</td>
<td>68123-9</td>
</tr>
<tr>
<td>54672</td>
<td>Interpretation</td>
<td>69965-2</td>
</tr>
<tr>
<td>54915</td>
<td>Reason for Referral</td>
<td>42349-1</td>
</tr>
<tr>
<td>54916</td>
<td>Specimen</td>
<td>31208-2</td>
</tr>
<tr>
<td>54673</td>
<td>Released By</td>
<td>19139-5</td>
</tr>
</tbody>
</table>