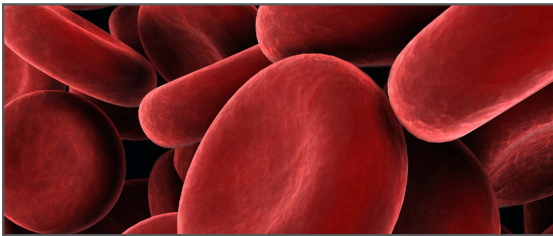


Oncology

CellSearch™

Circulating Tumor Cell (CTC) Test for Metastatic Breast, Colon and Prostate Cancer



The advanced CellSearch™ System identifies and counts circulating tumor cells (CTCs) in a small blood sample to predict progression-free survival (PFS) and overall survival (OS) in patients with metastatic breast, colorectal and prostate cancer.

Test Code

CellSearch

Specimen Requirements

Collect two tubes, 10 mL (min. 7.5 mL) of whole blood in CellSave® preservation tube. Invert tube 8 times.

Do not use EDTA, Heparin or ACD.

Storage and Handling

Ship specimen ambient day drawn.

Do not freeze or refrigerate.

Specimen Stability

15-30° for 96 hours.

CPT Codes

88346 x 4

88361 x 2

Turnaround Time

4 days

For more information, contact us at **800.932.2943**, or visit us online at **www.mplnet.com**.

Count CTCs, Assess Progression of Metastatic Cancer and Monitor Treatment Effectiveness

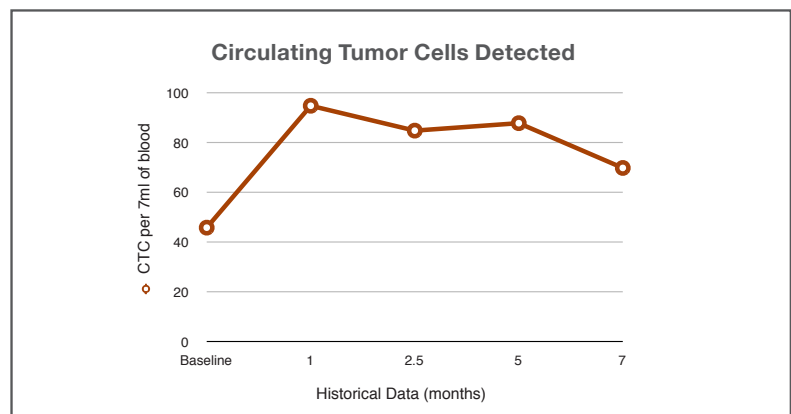
Results of serial CTC testing with the CellSearch test, in conjunction with other clinical methods for disease monitoring, can assist physicians with assessing disease progression and guiding more informed treatment decisions earlier.

- Serial testing with CellSearch allows physicians to monitor disease progression any time during therapy.
- Combining CTC measurement and imaging provides the most accurate assessment of disease status.

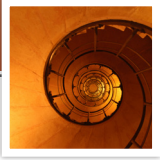
CTC Historical Reporting

Our easy-to-read reports indicate an increase or decrease in CTCs, and show disease progression or regression in response to treatment for patients with metastatic breast, colorectal and prostate cancer.

- Changes in CTC counts can be observed as early as the first cycle of treatment.
- CTC levels at baseline is strong, independent predictor of PFS and OS.
- Detection of CTCs before initiation of first-line therapy is highly predictive of PFS and OS.
- CTC levels >5 / 7.5 mL of blood in metastatic breast or prostate cancer at first follow-up strongly suggest patient is not responding to therapy. ^{3,4,5}
- CTC levels >3 / 7.5 mL of blood in metastatic colon cancer at first follow-up strongly suggest the patient is not responding to therapy. ²



Historical reports parallel disease progression or regression in response to treatment.



Oncology

Order CellSearch

Step 1:

Obtain and Send Sample:

- Collect 10 mL of blood in two CellSave® preservative tubes enclosed. (Do not collect while IV is being administered. Do not collect within 7 days of doxorubicin (Adriamycin) therapy to prevent interference.)
- Gently invert the two tubes 8 times after draw, and transport at room temperature. (Never refrigerate tubes.)
- Specimen must be tested within 96 hours of draw. (Ship in provided transport kit promptly to arrive next morning.)

Step 2:

Contact MPLN:

- If you have an account with MPLN, complete the requisition form(s), ship per usual method and contact us at 800.932.2943 to provide the tracking number.
- If you do not have an account with MPLN, please contact us and we will provide you with details to order the CellSearch Circulating Tumor Cell Test.



CTC Transport Kit

Place CellSave tubes into foam cutouts. Place kit in biohazard bag. (Use for the CellSearch Circulating Tumor Cell Test only.)

StrataFLEX™

Successful healthcare management of patients with metastatic cancer requires a rational, strategic approach to reduce treatment costs, provide effective therapy, and predict and prolong survival.

The CellSearch circulating tumor cell test is an important component of StrataFLEX, our personalized and strategic approach to laboratory medicine.

To move clinicians easily through the testing process – from diagnosis and prognosis to treatment selection and monitoring – we offer StrataFLEX to provide patient-specific reflex testing in a timely, cost effective manner.

References

1. De Bono et al. (2008). Circulating tumor cells predict survival benefit from treatment in metastatic castration-resistant prostate cancer. *Clin Cancer Res* 14:6302-6309.
2. Cohen et al. (2008). Relationship of circulating tumor cells to tumor response, progression-free survival, and overall survival in patients with metastatic colorectal cancer. *J Clin Oncol* 26:3213-3221.
3. Danila et al. (2007). Circulating tumor cell number and prognosis in progressive castration-resistant prostate cancer. *Clin Cancer Res* 13:7053-7058.
4. Budd et al. (2006). Circulating tumor cells versus imaging – predicting overall survival in metastatic breast cancer. *Clin Cancer Res* 12:6403-6409.
5. Cristofanilli M. et al. (2005). Circulating tumor cells: a novel prognostic factor for newly diagnosed metastatic breast cancer. *J Clin Oncol* 23:1420-1430.
6. Cristofanilli M. et al. (2004). Correlation of circulating tumor cells with progression and survival in metastatic breast cancer. *N Engl J Med* 351:781-91.
7. CellSearch Circulating Tumor Cell Kit Instructions for Use. Veridex, LLC. www.veridex.com.

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StataFLEX is a trademark of Molecular Pathology Laboratory Network, Inc.



MPLN

ONE SOURCE FOR LABORATORY TESTING

Make the right move.

Contact one of our client service specialists at **800.932.2943**, and visit our website at **www.MPLNET.com**.