

■ THE GOLD STANDARD



■ **The first actionable test for detecting CTCs in cancer patients with metastatic breast, colorectal or prostate* cancer**

For further information on intended use, warnings, and limitations, please refer to the CELLSEARCH® Circulating Tumor Cell Test Instructions for Use. Use of the CELLSEARCH® CTC Test does not demonstrate that any current line of therapy is any more or less effective than any other or no therapy. * Metastatic prostate cancer patients were defined as having two consecutive increases in the serum marker prostate-specific antigen above a reference level, despite standard hormonal management. These patients are commonly described as having androgen-independent, hormone-resistant, or castration-resistant prostate cancer.



www.cellsearchctc.com



MENARINI
silicon biosystems

CELLSEARCH® CTC TEST

CAN HELP YOU MAKE MORE INFORMED
PATIENT CARE DECISIONS



With pivotal clinical trial data in 3 key metastatic cancers—Breast, Colorectal, and Prostate¹

CELLSEARCH® CTC TEST IS A SIMPLE BLOOD TEST THAT GIVES YOU...

- The detection of changes in prognosis at any time
- Assurance that you have a complete picture of your patient's status when used with other clinical indicators
- Earlier assessment of prognosis than PSA in patients with metastatic prostate cancer¹

CELLSEARCH® CTC TEST PREDICTS SURVIVAL INDEPENDENTLY OF OTHER TESTING METHODS

TUMOR-SPECIFIC CUTOFFS

mBC	mCRC	mPC ¹
≥5 CTCs	≥3 CTCs	≥5 CTCs

Favorable	Unfavorable
Below the cutoff	At or above the cutoff

- Patients with fewer than the cutoff number of CTCs were found to have longer overall survival (OS) and progression-free survival (PFS)
- Patients with more than or equal to the CTC cutoffs had shorter OS and PFS

The CELLSEARCH® CTC Test results should be used in conjunction with all clinical information derived from diagnostic tests (e.g. imaging, laboratory tests), physical examination, and complete medical history, in accordance with appropriate management procedures.

1. Metastatic prostate cancer patients were defined as having two consecutive increases in the serum marker prostate-specific antigen above a reference level, despite standard hormonal management. These patients are commonly described as having androgen-independent, hormone-resistant, or castration-resistant prostate cancer. For more information on the intended use and limitations for the CELLSEARCH® CTC Test, please refer to the Instructions for Use which can be found at www.documents.cellsearchctc.com.

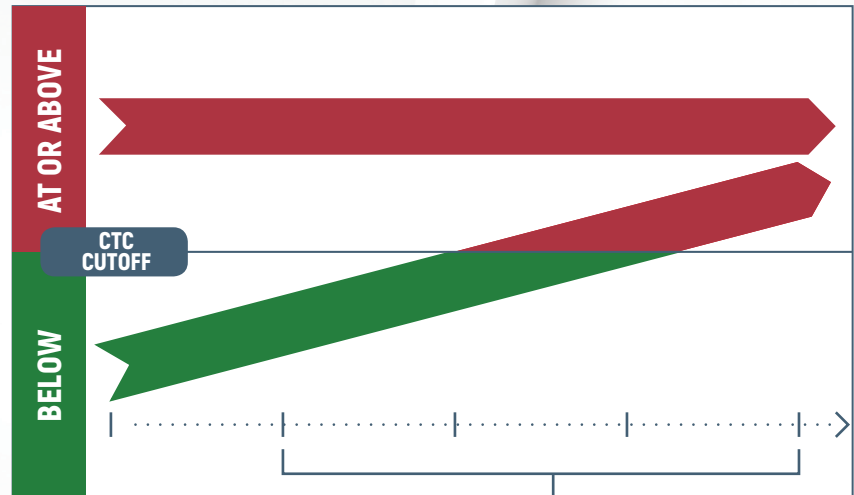
HOW SERIAL MONITORING WITH CELLSEARCH® CTC TEST

HELPS PHYSICIANS MAKE MORE INFORMED PATIENT CARE DECISIONS

PATIENT CARE SCENARIOS AND IMPLICATIONS

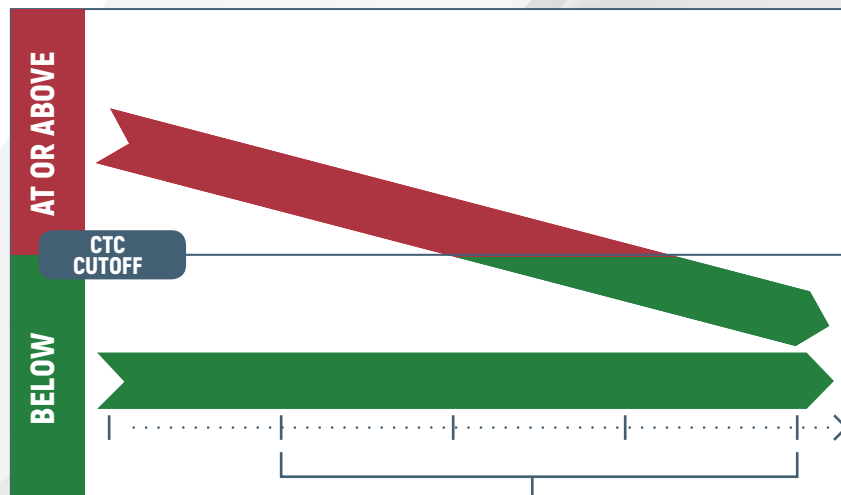
IMPLICATION

Patients whose CTCs remain above the cutoff or rise above the cutoff have an unfavorable prognosis



Baseline*
CELLSEARCH®
CTC Test

CELLSEARCH® CTC
Test done prior to
each cycle of therapy



Baseline*
CELLSEARCH®
CTC Test

CELLSEARCH® CTC
Test done prior to
each cycle of therapy

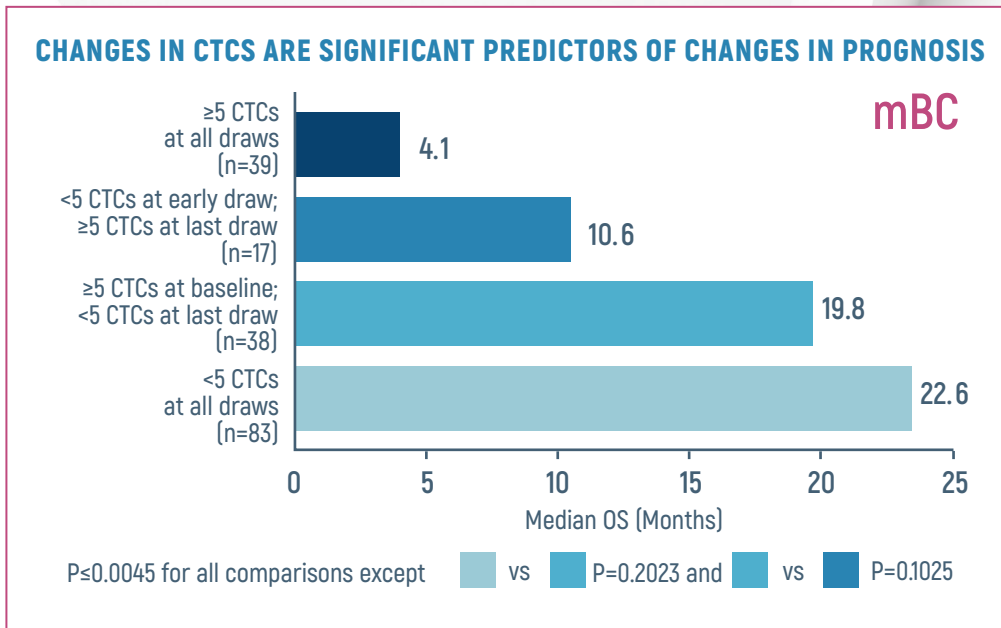
IMPLICATION

Patients whose CTCs remain or drop below the cutoff have a more favorable prognosis

*Baseline in the bottom green line is defined as baseline blood draw or early blood draw.

HELPING YOU MAKE MORE INFORMED DECISIONS FOR YOUR METASTATIC BREAST CANCER (mBC) PATIENTS

SERIAL MONITORING WITH CELLSEARCH® CTC TEST PREDICTS PROGNOSIS AT ANY TIME



- Patients with CTC counts of ≥5 at all blood draws had the shortest median OS
- Patients with CTC counts of <5 at all blood draws had the longest median OS
- Prognosis changed if the patient's CTC count moved above or below cutoff
- Patients with <5 CTC counts were found to have a 2.0-fold improvement in median OS compared with patients with ≥5 CTC counts P≤0.0045 for all comparisons except vs P=0.2023 and vs P=0.1025 (21.9 months vs 10.9 months; P≤0.0001)

CELLSEARCH® CTC TEST PROVIDES GREATER INSIGHT THAN IMAGING ALONE IN MBC AT FIRST FOLLOW-UP

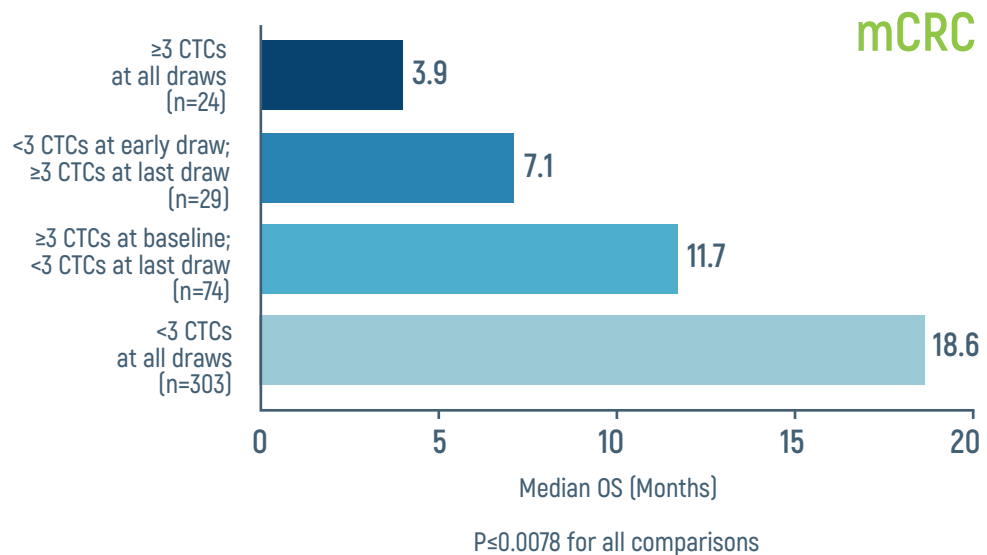
IMAGING	CTCs	MEDIAN OS
Favorable	Favorable	23.8 months (n=84)
Favorable	Unfavorable	9.2 months (n=12)
Unfavorable	Unfavorable	6.4 months (n=22)
Unfavorable	Favorable	19.9 months (n=20)

With discordance, CELLSEARCH® CTC Test more accurately predicts prognosis

HELPING YOU MAKE MORE INFORMED DECISIONS FOR YOUR METASTATIC COLORECTAL CANCER (mCRC) PATIENTS

SERIAL MONITORING WITH CELLSEARCH® CTC TEST PREDICTS PROGNOSIS AT ANY TIME

CHANGES IN CTCs ARE SIGNIFICANT PREDICTORS OF CHANGES IN PROGNOSIS

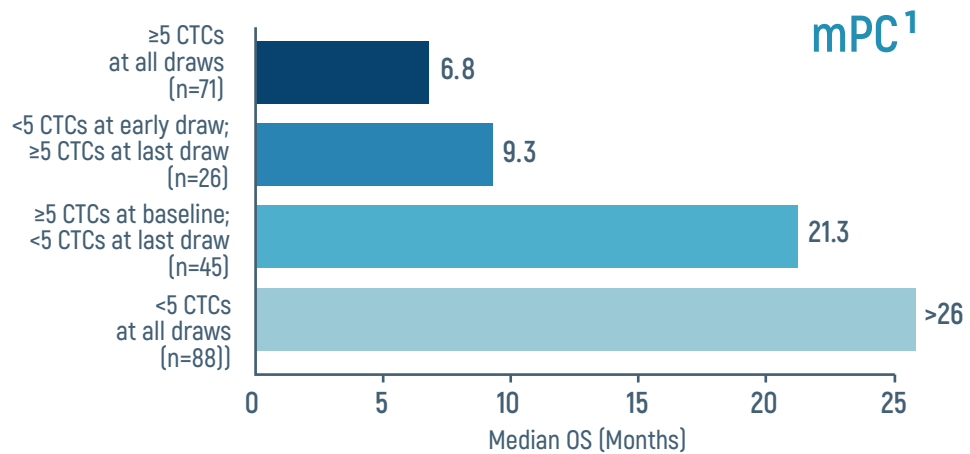


- Patients with CTC counts of ≥3 at all blood draws had the shortest median OS
- Patients with CTC counts of <3 at all blood draws had the longest median OS
- Prognosis changed if the patient's CTC count moved above or below cutoff
- Patients with <3 CTC counts were found to have a 1.97-fold improvement in median OS compared with patients with ≥3 CTC counts (18.5 months vs 9.4 months; P≤0.0001)

HELPING YOU MAKE MORE INFORMED DECISIONS FOR YOUR METASTATIC PROSTATE CANCER¹ (mPC¹) PATIENTS

SERIAL MONITORING WITH CELLSEARCH[®] CTC TEST PREDICTS PROGNOSIS AT ANY TIME

CHANGES IN CTCs ARE SIGNIFICANT PREDICTORS OF CHANGES IN PROGNOSIS



P≤0.0001 for all comparisons except ■ vs ■ P=0.1528 and ■ vs ■ P=0.5013

P≤0.0029 for all comparisons except 17.5 vs >20.6, P=0.0602; and 10.7 vs 8.6, P=0.4631

- Patients with CTC counts of ≥5 at all blood draws had the shortest median OS
- Patients with CTC counts of <5 at all blood draws had the longest median OS
- Prognosis changed if the patient's CTC count moved above or below cutoff
- Patients with <5 CTC counts were found to have a 1.89-fold improvement in median OS compared with patients with ≥5 CTC counts (21.7 months vs 11.5 months; P≤0.0001)

CELLSEARCH[®] CTC TEST PROVIDES GREATER INSIGHT THAN PSA ALONE IN mPC¹ AT 2 TO 5 WEEKS

PSA	CTCs	MEDIAN OS
Favorable ≥ 30% reduction	Favorable	17.5 months (n=50)
Favorable ≥ 30% reduction	Unfavorable	10.7 months (n=11)
Unfavorable < 30% reduction	Unfavorable	8.6 months (n=67)
Unfavorable < 30% reduction	Favorable	>20.6 months (n=69)

With discordance, CELLSEARCH[®] CTC Test more accurately predicts prognosis

1. Metastatic prostate cancer patients were defined as having two consecutive increases in the serum marker prostate-specific antigen above a reference level, despite standard hormonal management. These patients are commonly described as having androgen-independent, hormone-resistant, or castration-resistant prostate cancer. For more information on the intended use and limitations for the CELLSEARCH[®] Circulating Tumor Cell Test, please refer to the Instructions for Use which can be found at www.documents.cellsearchctc.com.

WHEN STARTING A NEW LINE OF THERAPY

FOR YOUR METASTATIC BREAST, COLORECTAL,
AND PROSTATE¹ CANCER PATIENTS...

- there is uncertainty whether the patient's prognosis will improve.
- it can take as long as 3 months to learn whether their cancer has progressed
- standard clinical indicators alone can be—and may remain—unclear*

CELLSEARCH[®] CTC TEST

CAN HELP YOU MAKE MORE INFORMED
PATIENT CARE DECISIONS

CELLSEARCH[®] CTC Test is a simple blood test that gives you...

- detection of changes in prognosis at any time
- assurance that you have a complete picture of the status of your patient when used with other clinical indicators
- earlier assessment of prognosis than PSA in patients with metastatic prostate cancer¹

WHEN TO USE

THE CELLSEARCH[®] CTC TEST

Order the test at any time during the course of the disease to assess prognosis and to inform patient care

For further information on intended use, warnings, and limitations, please refer to the CELLSEARCH[®] CTC Test Instructions for Use, or visit www.cellsearchctc.com.

* Clinical indicators include all information derived from diagnostic tests (e.g. imaging, laboratory tests), physical examination, and complete medical history.

1. Metastatic prostate cancer patients were defined as having two consecutive increases in the serum marker prostate-specific antigen above a reference level, despite standard hormonal management. These patients are commonly described as having androgen-independent, hormone-resistant, or castration-resistant prostate cancer. For more information on the intended use and limitations for the CELLSEARCH[®] Circulating Tumor Cell Test, please refer to the Instructions for Use which can be found at www.documents.cellsearchctc.com.

Corporate

Menarini Silicon Biosystems S.p.A.
Via Giuseppe di Vittorio, 21 b/3
I-40013 Castel Maggiore (BO),
Italy t: +39 051 9944100
e: info@siliconbiosystems.com

U.S.A.

Menarini Silicon Biosystems Inc.
3401 Masons Mill Rd Suite 100
Huntingdon Valley, PA 19006 USA
t: 1(800)381-4929
e: us-info@siliconbiosystems.com

