



# Cell Search<sup>®</sup>

Circulating Tumor Cell Test

**When starting a new line of therapy for  
your metastatic breast, colorectal,  
and prostate<sup>1</sup> cancer patients...**

- *There is uncertainty whether their 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\**



**MENARINI**  
silicon biosystems

For further information on intended use, warnings, and limitations, please refer to the CELLSEARCH<sup>®</sup> Circulating Tumor Cell Test Instructions for Use. Use of the CELLSEARCH<sup>®</sup> CTC Test does not demonstrate that any current line of therapy is any more or less effective than any other or no therapy. \* Clinical indicators include all information derived from diagnostic tests (eg, imaging, laboratory tests), physical examination, and complete medical history.

With pivotal clinical trial data in 3 key metastatic cancers—Breast, Colorectal, and Prostate<sup>1</sup>



**CELLSEARCH<sup>®</sup> Circulating Tumor Cell (CTC) Test can help you make more informed patient care decisions**

**CELLSEARCH<sup>®</sup> CTC Test is a simple blood test that gives you...**

- *Earlier assessment of prognosis than PSA in patients with metastatic prostate cancer<sup>1</sup>*
- *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*

**CELLSEARCH<sup>®</sup> CTC Test predicts survival independently of other testing methods**

**Tumor-specific cutoffs**

mBC	mCRC	mPC <sup>1</sup>
≥5 CTCs	≥3 CTCs	≥5 CTCs

Favorable	Unfavorable
Below the cutoff	At or above the cutoff

- *Patients with less 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*

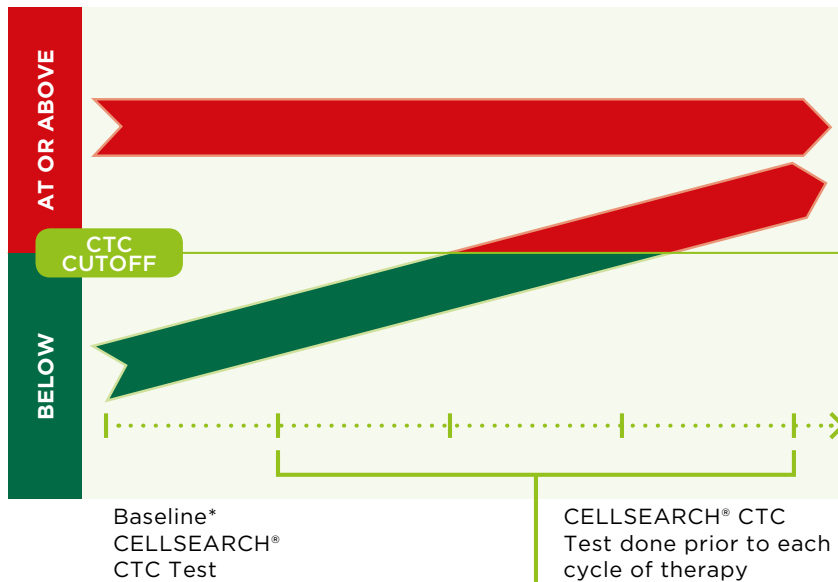
The CELLSEARCH<sup>®</sup> CTC Test results should be used in conjunction with all clinical information derived from diagnostic tests (eg, imaging, laboratory tests), physical examination, and complete medical history, in accordance with appropriate management procedures.

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<sup>®</sup> Circulating Tumor Cell Test, please refer to the Instructions for Use which can be found at [www.documents.cellsearchctc.com](http://www.documents.cellsearchctc.com).



# How serial monitoring with CELLSEARCH<sup>®</sup> Circulating Tumor Cell Test helps physicians make more informed patient care decisions

## Patient care scenarios and implications

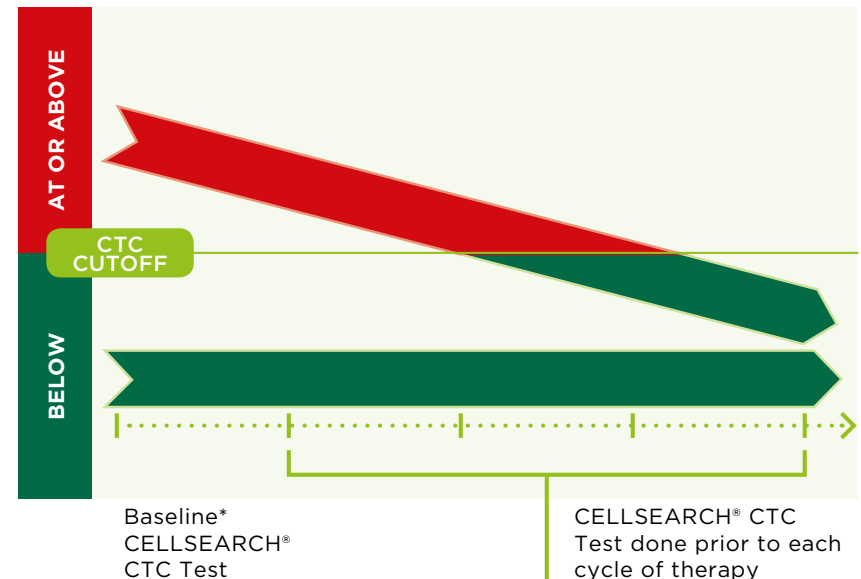


### Implication

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

### Implication

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



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

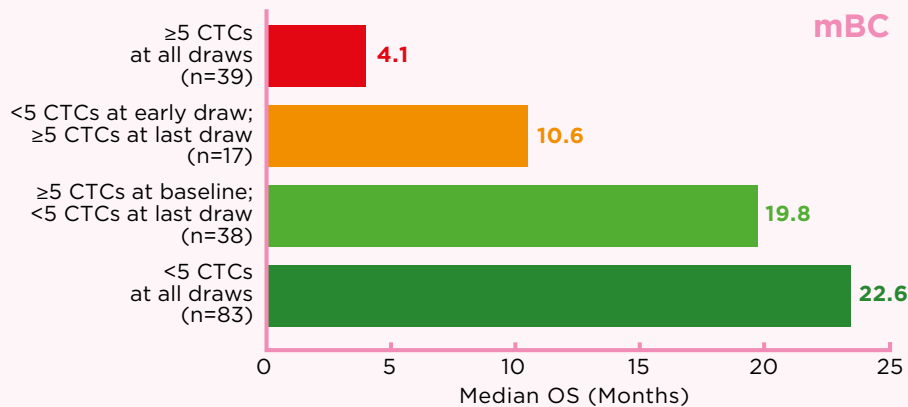


# Helping you make more informed decisions for your Metastatic Breast Cancer (mBC) Patients

mBC

## Serial monitoring with CELLSEARCH® Circulating Tumor Cell TEST predicts prognosis at any time

Changes in CTCs are significant predictors of changes in prognosis



$P \leq 0.0045$  for all comparisons except  $\blacksquare$  vs  $\blacksquare$   $P=0.2023$  and  $\blacksquare$  vs  $\blacksquare$   $P=0.1025$

- Patients with CTC counts  $\geq 5$  at all blood draws had the shortest median OS
- Patients with CTC counts  $< 5$  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  $\geq 5$  CTC counts (21.9 months vs 10.9 months;  $P \leq 0.0001$ )

## 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

$P=0.04$  for all comparisons except 19.9 vs 23.8,  $P=0.12$ ; 19.9 vs 9.2,  $P=0.67$ ; and 6.4 vs 9.2,  $P=0.12$

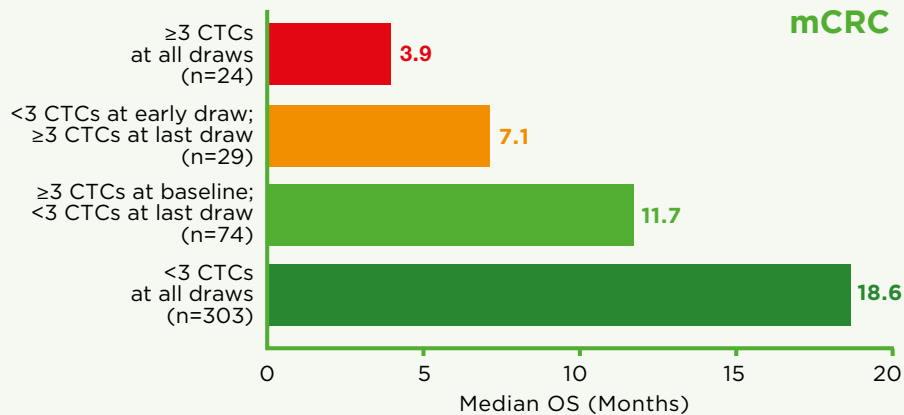


## Helping you make more informed decisions for your Metastatic Colorectal Cancer (mCRC) Patients

mCRC

### Serial monitoring with CELLSEARCH<sup>®</sup> Circulating Tumor Cell TEST predicts prognosis at any time

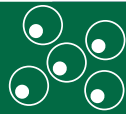
#### Changes in CTCs are significant predictors of changes in prognosis



$P \leq 0.0078$  for all comparisons

- Patients with CTC counts  $\geq 3$  at all blood draws had the shortest median OS
- Patients with CTC counts  $< 3$  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  $\geq 3$  CTC counts (18.5 months vs 9.4 months;  $P \leq 0.0001$ )



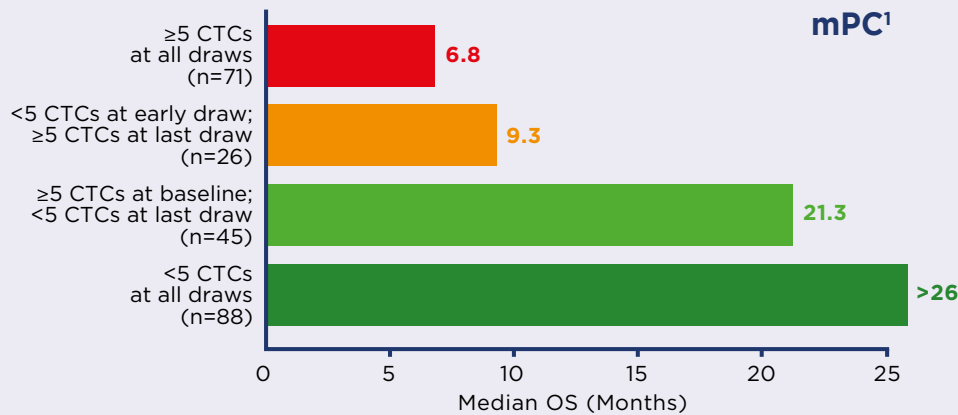


# Helping you make more informed decisions for your Metastatic Prostate Cancer<sup>1</sup> (mPC<sup>1</sup>) Patients

mPC<sup>1</sup>

## Serial monitoring with CELLSEARCH<sup>®</sup> Circulating Tumor Cell TEST predicts prognosis at any time

### Changes in CTCs are significant predictors of changes in prognosis



$P \leq 0.0001$  for all comparisons except ■ vs ■  $P = 0.1528$  and ■ vs ■  $P = 0.5013$

- Patients with CTC counts  $\geq 5$  at all blood draws had the shortest median OS
- Patients with CTC counts  $< 5$  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  $\geq 5$  CTC counts (21.7 months vs 11.5 months;  $P \leq 0.0001$ )

## CELLSEARCH<sup>®</sup> CTC Test provides greater insight than PSA alone in mPC<sup>1</sup> at 2 to 5 weeks

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<sup>®</sup> Circulating Tumor Cell Test, please refer to the Instructions for Use which can be found at [www.documents.cellsearchctc.com](http://www.documents.cellsearchctc.com).

PSA	CTCs	MEDIAN OS
Favorable $\geq 30\%$ reduction	Favorable	17.5 months (n=50)
Favorable $\geq 30\%$ 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<sup>®</sup> CTC Test more accurately predicts prognosis

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



## When starting a new line of therapy for your metastatic breast, colorectal, and prostate<sup>1</sup> 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<sup>®</sup> Circulating Tumor Cell Test can help you make more informed patient care decisions

### CELLSEARCH<sup>®</sup> CTC Test is a simple blood test that gives you...

- *Earlier assessment of prognosis than PSA in patients with metastatic prostate cancer<sup>1</sup>*
- *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*



## When to use the CELLSEARCH<sup>®</sup> 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<sup>®</sup> CTC Test Instructions for Use, or visit [www.cellsearchctc.com](http://www.cellsearchctc.com).*

*\* Clinical indicators include all information derived from diagnostic tests (eg, 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<sup>®</sup> Circulating Tumor Cell Test, please refer to the Instructions for Use which can be found at [www.documents.cellsearchctc.com](http://www.documents.cellsearchctc.com).*



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Circulating Tumor Cell Test

**Corporate**

*Menarini Silicon Biosystems S.p.A.  
Via Giuseppe di Vittorio, 21 b/3  
I-40013 Castel Maggiore (BO),  
Italy t: +39 051 9944100  
f: +39 051 9944199  
e: [info@siliconbiosystems.com](mailto: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  
f: 1(858)202-6936  
e: [us-info@siliconbiosystems.com](mailto:us-info@siliconbiosystems.com)*