

**DIAGNOSIS DEFINED**

**CTC**  
**Metastatic Prostate Cancer**  
**Case Study 2**

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# Benefit of CTC Test

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## Key Benefit of Using the CellSearch™ CTC Test

- CTC levels provided an early indication that the patient's prognosis had improved after initiation of chemotherapy, when Prostate Specific Antigen (PSA) was equivocal.

## MPC Definition

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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.

# Patient Information

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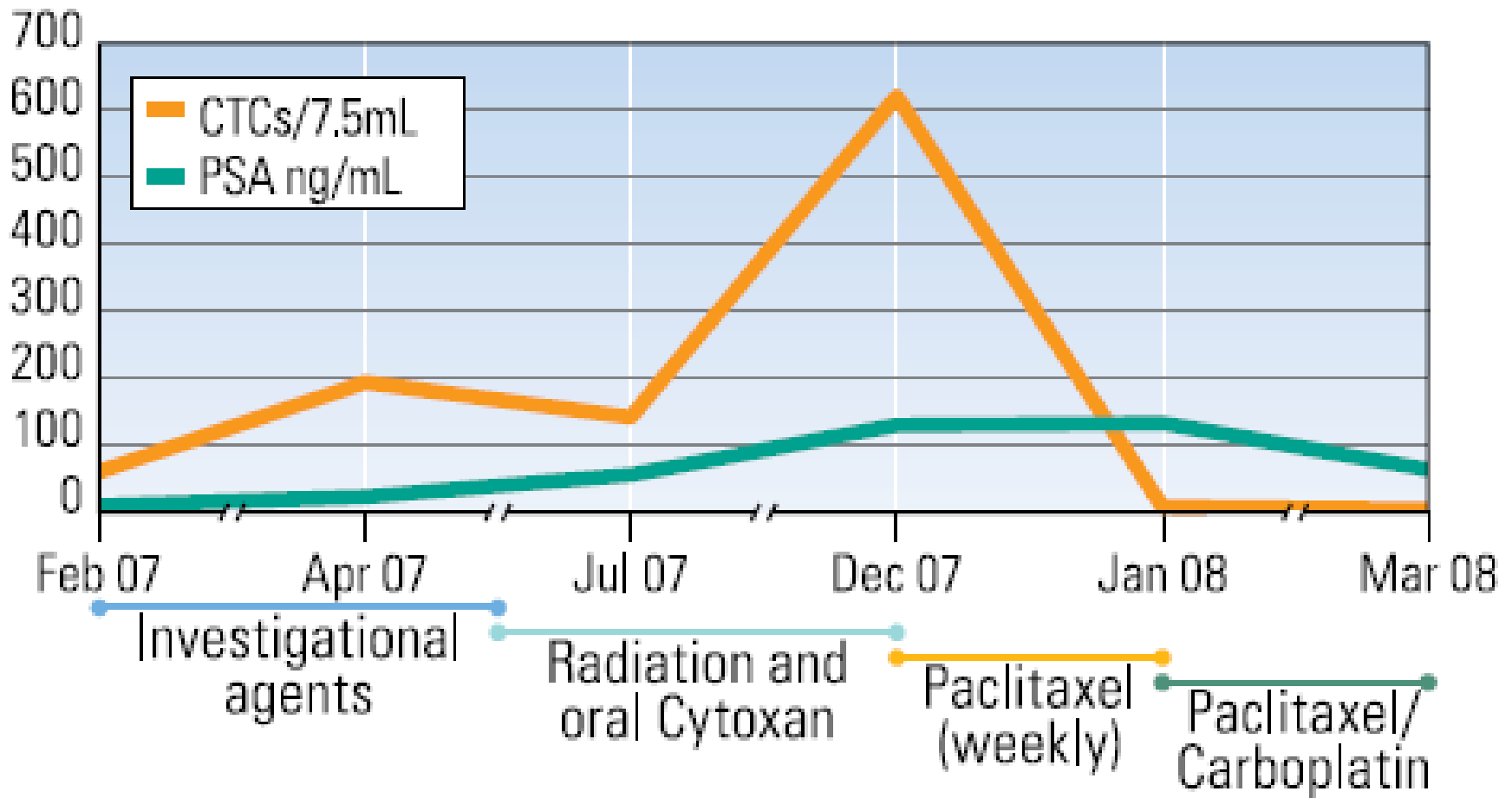
- Age: 68
- Diagnosis: Metastatic Prostate Cancer (MPC)
- Line of Therapy: 5<sup>th</sup>
- Current Therapy: Paclitaxel
- Time with Metastasis: 2 years
- ECOG Score: 2
- Gleason Score: 8
- Sites of Metastasis: Liver, bone, nodes

# Case Study Snapshot

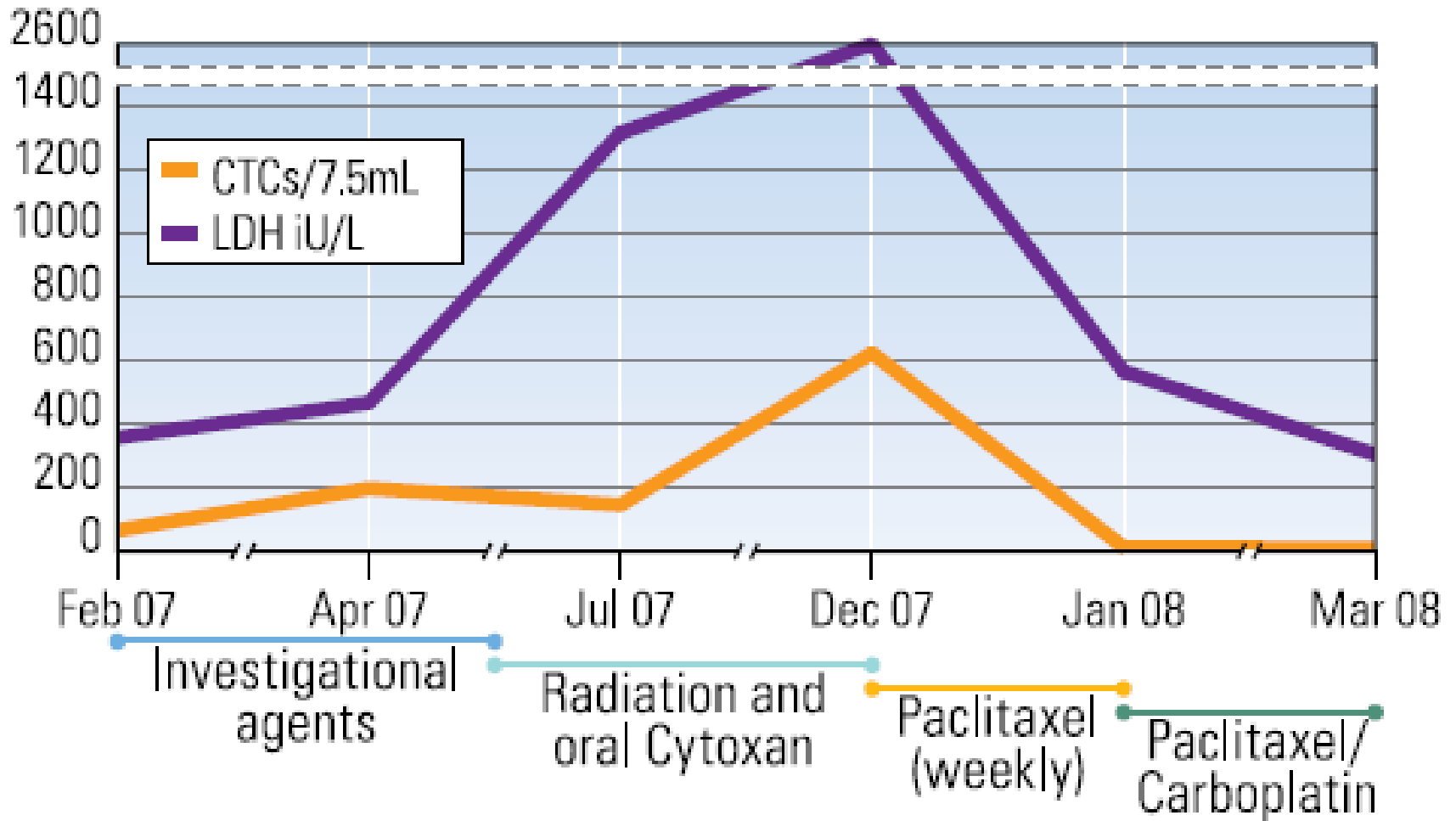
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- Patient showed extremely high CTC, lactate dehydrogenase (LDH) and PSA levels prior to initiation of paclitaxel therapy.
- One month after initiation of paclitaxel, CTC levels declined 77.6 fold and LDH levels declined 4.5 fold while PSA levels remained unchanged.
- CTC and LDH levels continued to decline and PSA levels eventually dropped after the third month of therapy.

# Patient Longitudinal Graph



# Patient Longitudinal Graph



# Patient Longitudinal Graph

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	CTCs/ 7.5mL	PSA ng/mL	LDH iU/L
Feb 07	61	10	365
Apr 07	194	23	571
Jul 07	142	56	1326
Dec 07	621	130	2602
Jan 08	8	133	574
Mar 08	4	64	306

# Background on the Patient

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- Patient is a 68 year-old male who was originally diagnosed with nodal metastasis in 1996.
- He was treated with hormone therapy and vaccines until August 2006 when docetaxel was added for worsening liver, nodal and bone metastasis.
- In February 2007, patient experienced progression in the liver, bone and nodal metastasis and docetaxel neurological toxicity.
- His CTC count per 7.5 mL blood draw was 61, lactate dehydrogenase levels (LDH) were 365 IU/L (upper limits of normal are 250 IU/L) and his prostate specific antigen (PSA) was 10 ng/mL.

# Background on the Patient

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- He was placed on an investigational agent without major effect and by April 2007 his tumor markers had increased sharply; (CTC count of 194, LDH level of 571 IU/L and a PSA level 23 ng/mL) and remained above the clinical cutoff of  $\geq 5$  CTC/7.5 mL blood.
- He was entered onto another early phase trial but by July 2007 the markers were still elevated (CTC 142, LDH 1326 IU/L, and PSA 56 ng/mL).
- He began radiation plus oral cytoxan therapy that controlled the disease until November 2007.

# Background on the Patient

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- In December 2007, Patient was clinically worsening with an enlarged liver and malignant supraclavicular adenopathy.
- A CTC reading, PSA and LDH tests were taken.
- The results were 621 CTC per 7.5 mL of blood, a PSA level of 130 ng/mL, and LDH of 2602 IU/L.
- We began the patient on weekly paclitaxel.

# Background on the Patient

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- On January 31, 2008, we repeated testing and saw a sharp drop in the CTC count to 8 and LDH to 574 IU/L.
- The neck nodes were smaller however, the PSA level remained unchanged at 133 ng/mL.
- Carboplatin was added to patient's therapeutic regime in February 2008.
- Follow-up CTC testing in March 2008 showed a continued decline in CTC to 4, LDH to 306 IU/L and the PSA levels now demonstrated a reduction to 64 ng/mL.

# Value of CTC in the Treatment of this MPC Patient

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- CTC were monitored regularly after this patient's cancer became resistant to docetaxel and complimented clinical findings and therapeutic results over the course of 1 year of treatment.
- In fact, the patient was stable by standard clinical assessment and palpable disease was reduced by only 20-30%.
- However, the dramatic drop in CTC demonstrated an improved prognosis in this patient after initiation of chemotherapy when other signs, including PSA, were equivocal.

# Value of CTC in the Treatment of this MPC Patient

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- Subsequently, I have not ordered radiological studies for the last 6 months because of my positive experience in the ability of the tumor marker panel of CTC assay, LDH and PSA to track the disease.
- The CTC and clinical partial response (regression of neck nodes) to 5th line chemotherapy (weekly paclitaxel) was surprising and we are following it closely.

## For *In Vitro* Diagnostic Use

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- The Circulating Tumor Cell test 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 test, is associated with decreased progression-free survival and decreased overall survival in patients treated for metastatic breast, colorectal or prostate cancer.

## For *In Vitro* Diagnostic Use

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- For further information on intended use, warnings, and limitations, please refer to the CellSearch™ CTC Test Instructions for Use, or visit [www.veridex.com](http://www.veridex.com).
- CTC results should be used in conjunction with all clinical information derived from diagnostic test (e.g., imaging or laboratory tests), physical examination and complete medical history, in accordance with appropriate management procedures.

## For *In Vitro* Diagnostic Use

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- This case study is for educational purposes only and does not constitute professional medical advice.
  - The information provided in this case study should not be relied upon as the basis for making patient management decisions.
  - This case study is not intended to show that any line of therapy is any more or less effective than any other or no therapy.
- \* The content for this presentation was provided by Veridex, LLC a Johnson & Johnson company

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