Case #2

ConfirmMDx Positive: GS 4+3=7

Age: 68 I PSA: 6 ng/mL I DRE: Enlarged

ConfirmMDx for Prostate Cancer

Previous negative prostate biopsy > ConfirmMDx Positive > GS 4+3=7 prostate cancer diagnosed

ConfirmMDx Result: **POSITIVE DNA METHYLATION**

68 year old | PSA 6 ng/mL | DRE: Enlarged | No Family History

HISTORY

February 2016

Negative Initial Biopsy Findings:
PSA Level: **6 ng/mL**
Number of Cores Collected: **14**
Histology Findings: **Benign Prostatic Tissue**
Complications from Bx: **None**
DRE Results: **Enlarged**

RESULTS

September 2017

ConfirmMDx Results:
Following the initial negative biopsy results, the treating physician ordered a ConfirmMDx test.

POSITIVE

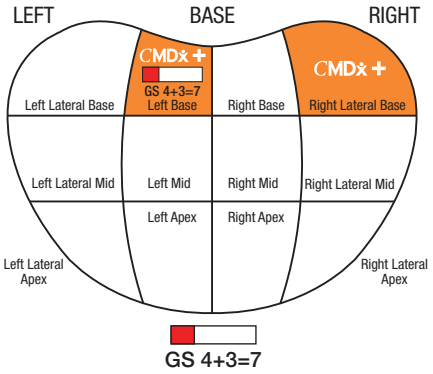
ConfirmMDx DNA Methylation Positive
At time of ConfirmMDx testing
PSA Level: **6 ng/mL**
DRE Results: **Enlarged**

OUTCOME

March 2018

Prior to Repeat Bx:
PSA Level Prior to Repeat Bx: **6 ng/mL**
DRE results: **Enlarged**
Prostate Volume: **58**
Comorbidities: **HBP, Hyperlipidemia**
Chronic Medications: **Tamsulosin, Lisinopril**

MRI Results: **PI-RADS 5-Lesion left anterior apical peripheral zone**



June 2018

Repeat Biopsy Results:
Pathology Results of Repeat Bx: **Positive**
Clinical Disease Stage: **T1**
Cancer Grade: **G3**

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IR-BROC-0083-R01

Patient Report

ConfirmMDx® for Prostate Cancer

PATIENT		SPECIMEN		ACCOUNT	
Patient Name:		**Specimen#:**		**Physician:**	
Date of Birth:		**Collection Date:**		**Account:**	
MRN/Patient#:		**Received Date:**		**Address:**	
PATH:	Benign	**Report Date:**			
PSA:	6 ng/mL	**Specimen Type:**	Prostate Tissue Block	**City/State/Zip:**	
DRE:	Normal	**MDxH Accession#:**			

Patient Result: DNA Methylation Positive

The DNA methylation positive test result for this patient indicates an 36% likelihood of detecting prostate cancer, with a 21% probability for low-grade disease (GS ≤ 6) versus a 15% probability of high-grade disease (GS ≥ 7), on repeat biopsy.

Likelihood of prostate cancer upon repeat biopsy

0% — 36% — 100%

21% Likelihood of detecting Gleason score ≤ 6 cancer

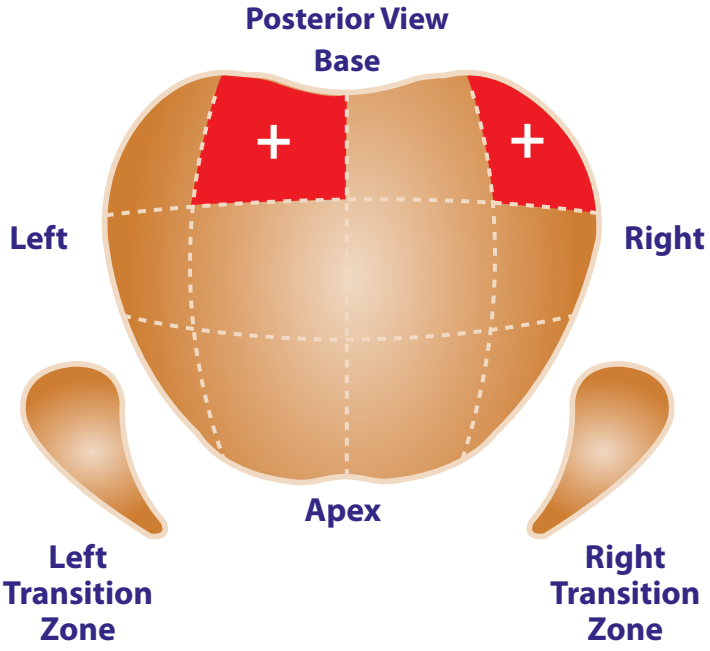
15% Likelihood of detecting Gleason score ≥ 7 cancer

The ConfirmMDx test result indicating the likelihood of GS ≤ 6 and GS ≥ 7 prostate cancer being detected on repeat biopsy is calculated by incorporating DNA methylation intensity with clinical risk factors, including PSA, DRE, age, and histopathology of the previous biopsy, based on a clinical model that yields an area under the curve (AUC) of 0.762 (95% CI: 0.679-0.844). Performance is based on the presence of all relevant data elements; if all data are not available, or 5α-reductase inhibitors (5ARI) have been administered to decrease serum PSA values, results should be interpreted with caution since the AUC of the test may vary. Cancer association with DNA methylation of the ConfirmMDx gene markers has been reported on ~4,500 patients.[1-55]

DNA Methylation Status Table

Biopsy Site	*GSTP1* Methylation	*APC* Methylation	*RASSF1* Methylation
Left Lateral Base:	Negative	Negative	Negative
Left Lateral Mid:	Negative	Negative	Negative
Left Lateral Apex:	Negative	Negative	Negative
Left Base:	**Positive**	Negative	Negative
Left Mid:	Negative	Negative	Negative
Left Apex:	Negative	Negative	Negative
Left Transition Zone:			
Right Base:	Negative	Negative	Negative
Right Mid:	Negative	Negative	Negative
Right Apex:	Negative	Negative	Negative
Right Lateral Base:	**Positive**	Negative	Negative
Right Lateral Mid:	Negative	Negative	Negative
Right Lateral Apex:	Negative	Negative	Negative
Right Transition Zone:	Negative	Negative	Negative

Distribution of DNA Methylation Diagram



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