Case study #3

Confirm mdx
for Prostate Cancer

Confirm mdx positive: GS 4+4=8

Age: 77 | PSA: 9 ng/mL | DRE: Not Suspicious | No family history

Previous negative prostate biopsy > Confirm mdx positive > GS 4+4=8 prostate cancer diagnosed

History

09/09/2016

Initial biopsy findings:

PSA Level: **9 ng/mL**
Number of Cores Collected: **12**
Histology Findings: **Benign Prostatic Tissue**
Complications from Bx: **None**
DRE Results: **Not Suspicious**

Results

06/23/2017

Confirm mdx test results:

DNA Methylation Positive

At time of Confirm mdx testing
PSA Level: **9 ng/mL**
DRE Results: **Not Suspicious**

Outcome

01/05/2018

Prior to repeat biopsy

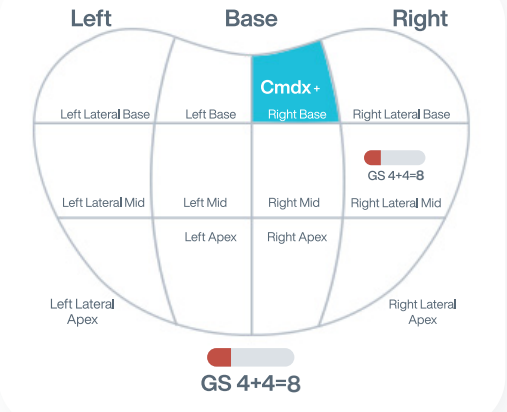
PSA Level: **18.62 ng/mL**
DRE results: **Enlarged**
Prostate Volume: **40.38**
Comorbidities: **A-Fib, Hypertension, DM**
Chronic Medications: **Eliquis, Glimepiride**

MRI Results: **PI-RADS 5**
Date of MRI: **01/28/18**

02/04/2018

Repeat biopsy results

Pathology Result: **Positive**
Clinical Disease Stage: **T1c**
Cancer Grade: **G4**



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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:**		**City/State/Zip:**	
PSA:	9 ng/mL	**Specimen Type:**	Prostate Tissue Block		
DRE:	Not Suspicious	**MDxH Accession#:**			

Patient Result: DNA Methylation Positive

The DNA methylation positive test result for this patient indicates an 41% likelihood of detecting prostate cancer, with a 22% probability for low-grade disease (GS ≤ 6) versus a 19% probability of high-grade disease (GS ≥ 7), on repeat biopsy.

Likelihood of prostate cancer upon repeat biopsy

0% — 41% — 100%

22% Likelihood of detecting Gleason score ≤ 6 cancer

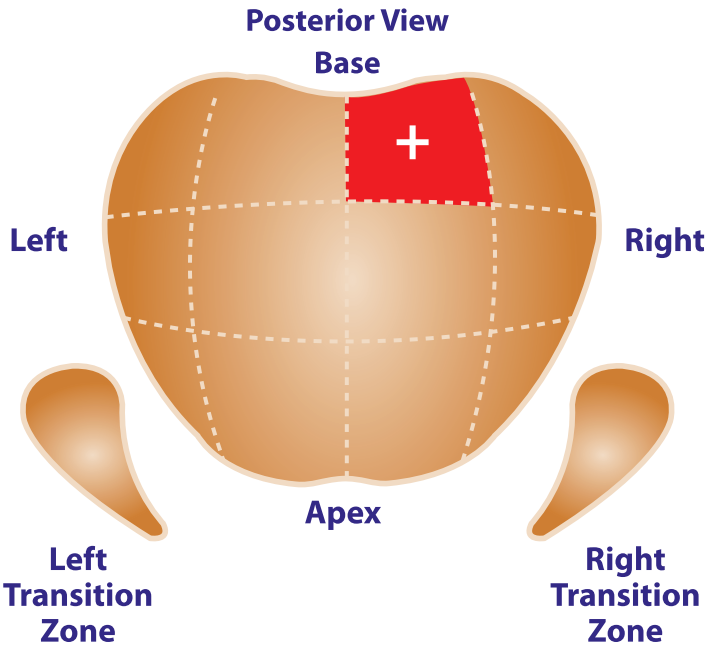
19% Likelihood of detecting Gleason score ≥ 7 cancer

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:	Negative	Negative	Negative
Left Mid:	Negative	Negative	Negative
Left Apex:	Negative	Negative	Negative
Left Transition Zone:			
Right Base:	**Positive**	Negative	Negative
Right Mid:	Negative	Negative	Negative
Right Apex:	Negative	Negative	Negative
Right Lateral Base:	Negative	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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