

ConfirmMDx Positive: GS 4+4=8

Age: 77 | PSA: 9 ng/mL | DRE: Not Suspicious

Previous negative prostate biopsy > ConfirmMDx Positive > GS 4+4=8 prostate cancer diagnosed

ConfirmMDx Result: POSITIVE DNA METHYLATION

77 year old | PSA 9 ng/mL | DRE: Not Suspicious | No Family History

HISTORY

November 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

October 2017 **ConfirmMDx Results:**
 Following the initial negative biopsy results, the treating physician ordered a ConfirmMDx test.



ConfirmMDx DNA Methylation Positive

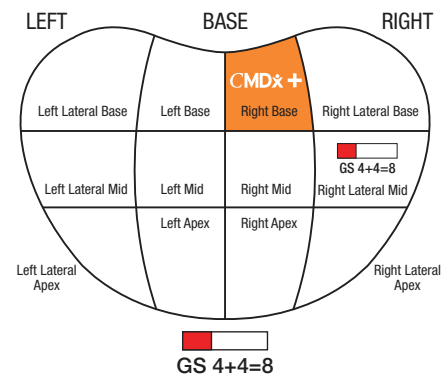
At time of ConfirmMDx testing
 PSA Level: **9 ng/mL**
 DRE Results: **Not Suspicious**

OUTCOME

January 2018 **Prior to Repeat Bx**
 PSA Level Prior to Repeat Bx: **19 ng/mL**
 DRE results: **Enlarged**
 Prostate Volume: **40**
 Comorbidities: **A-Fib, Hypertension, DM**
 Chronic Medications: **Eliquis, Glimepiride**

MRI Results: **PI-RADS 5**
 Date of MRI: **Jan. 2018**

February 2018 **Repeat Biopsy Results:**
 Pathology Results of Repeat Bx: **Positive**
 Clinical Disease Stage: **T1c**
 Cancer Grade: **G4**



Patient Report

PATIENT

Patient Name:
Date of Birth:
MRN/Patient#:
PATH: Benign
PSA: 9 ng/mL
DRE: Not Suspicious

SPECIMEN

Specimen#:
Collection Date:
Received Date:
Report Date:
Specimen Type: Prostate Tissue Block
MDxH Accession#:

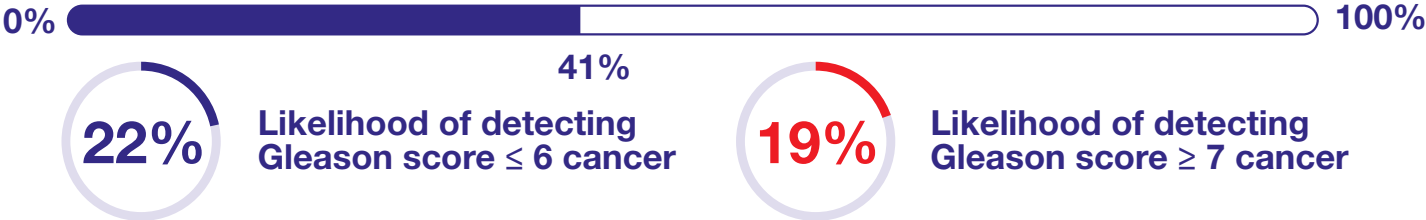
ACCOUNT

Physician:
Account:
Address:
City/State/Zip:

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



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

