Confirm mdx
for Prostate Cancer

Confirm mdx positive: GS 4+3=7

Age: 68 | PSA: 5.65 ng/mL | DRE: Enlarged | No family history

| Previous negative prostate biopsy | > | Confirm mdx positive | > | GS 4+3=7 prostate cancer diagnosed |

History

02/22/2016

Negative initial biopsy findings:

PSA Level: 6.02 ng/mL
Number of Cores Collected: 14
Histology Findings: Benign Prostatic Tissue
Complications from Bx: None
DRE Results: Enlarged

Results

9/12/2017

Confirm mdx test results:

+

DNA Methylation Positive

At time of Confirm mdx testing
PSA Level: 5.65 ng/mL
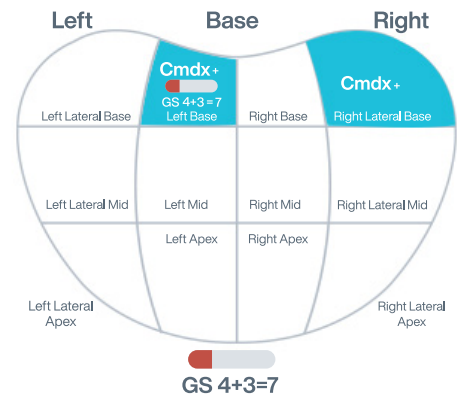DRE Results: Enlarged

Outcome

03/14/2018

Prior to repeat biopsy

PSA Level: 6.48 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

06/11/2018

Repeat biopsy results

Pathology Result: Positive
Clinical Disease Stage: T1
Cancer Grade: G3

Left   Base   Right

Cmdx+
GS 4+3 = 7
Left Base   Right Base

Cmdx+
Right Lateral Base

Left Lateral Base

Left Lateral Mid   Left Mid   Right Mid   Right Lateral Mid

Left Apex   Right Apex

Left Lateral Apex   Right Lateral Apex

GS 4+3=7

Patient Report

Confirm MD**x**®
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:	5.65 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% ———————————————— 100%

36%

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

Posterior View
Base
Left **Right**
Apex
Left Transition Zone
Right Transition Zone