Case study #4

Confirm mdx
for Prostate Cancer

Confirm mdx positive: GS 4+4=8

Age: 69 | PSA: 3.9 ng/mL | DRE: Not Suspicious | No family history

Previous negative prostate biopsy › Confirm mdx positive › Rising PSA + MRI › GS 4+4=8 prostate cancer diagnosed

History

11/21/2017

Initial biopsy findings:

Age: **64**
PSA Level: **3.9 ng/mL**
Number of Cores Collected: **12**
Histology Findings: **Benign prostatic tissue in 6 cores; HGPIN in 6 cores**
DRE Results: **Not suspicious**

Results

03/08/2018

Confirm mdx test results:

DNA Methylation Positive

- 46% likelihood of prostate cancer upon repeat biopsy
- 23% likelihood of detecting GS≥7 upon repeat biopsy

At time of Confirm mdx testing:
Age: **64**
PSA Level: **3.9 ng/mL**
DRE Results: **Not Suspicious**

Patient non-compliant with follow-up post-negative biopsy.

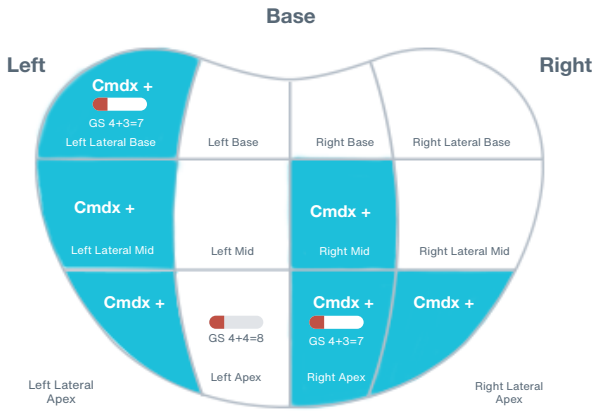
Outcome

Patient returned for monitoring to a different provider. Rising PSA and MRI results led to a repeat biopsy.

02/17/2023

At time of biopsy:

Age: **69**
PSA Level: **7.7 ng/mL**
Pathology Result: **3 of 14 cores positive**
Disease Stage: **T1c**
Cancer Grade: **GG4**
NCCN Risk: **High Risk**



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ConfirmMDx for Prostate Cancer

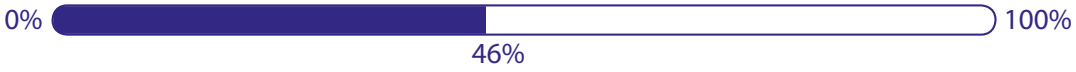
Patient Report

PATIENT		SPECIMEN		ACCOUNT	
Patient Name:		Specimen#:		Physician:	
Date of Birth:		Collection Date:	11/21/2017	Account:	
MRN/Patient#:	Not Provided	Received Date:	3/8/2018		
PATH:	HG-PIN	Report Date:	3/14/2018	Address:	
PSA:	3.9 ng/mL	Specimen Type:	Prostate Tissue Slides		
DRE:	Normal	MDxH Accession#:		City/State/Zip:	

Patient Result: DNA Methylation Positive

The DNA methylation positive test result for this patient indicates a 46% likelihood of detecting prostate cancer, with a 23% probability for low-grade disease (GS ≤6) versus a 23% probability of high-grade disease (GS ≥7), on repeat biopsy.

Likelihood of prostate cancer on repeat biopsy



Likelihood of detecting Gleason score ≤6 cancer

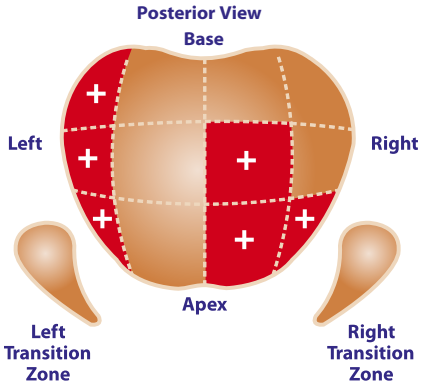
Likelihood of detecting Gleason score ≥7 cancer

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 logistic regression 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.[1-54]

DNA Methylation Status Table

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

Distribution of DNA Methylation Diagram



Comments:

Quality Not Sufficient (QNS): One or more core sample(s) did not yield a valid test result and has been reported as 'QNS' in the DNA Methylation Status Table. The remaining viable core samples met the minimum requirements to generate a valid overall Patient Result.

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