

Confirm mdx positive: GS 4+3=7

Age: 70 | PSA: 4.7 ng/mL | DRE: Normal | No family history

Indeterminate MRI > Benign TRUS biopsy > Confirm mdx positive > Negative MRI > GS 4+3=7 prostate cancer

History



MRI results: Indeterminant

- PI-RADS 3
- Left anterior lateral apex

Initial biopsy findings:

- Number of cores collected: 13
- Histology Findings: **Benign**

Results

Confirm mdx test results:



DNA Methylation Positive

- 4 of 13 cores positive
- 14% likelihood of GS \geq 7
- 34% likelihood of any prostate cancer

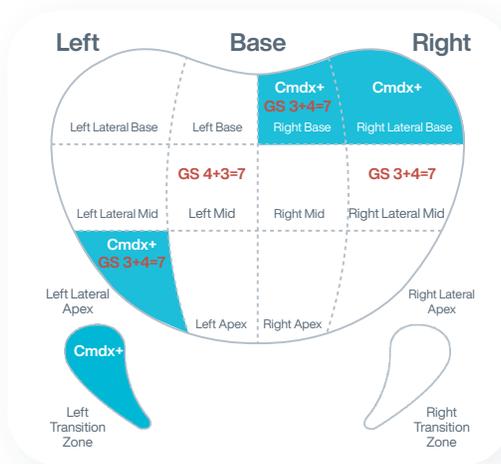
MRI results: Negative

- BPH; Chronic prostatitis
- Left anterior lateral apex lesion no longer seen

Outcome

Repeat biopsy findings:

- Number of cores collected: 16
- Histology Findings: **4 cores positive**
- Cancer Grade: **4+3=7 (GG 3)**



Patient Report

PATIENT

Patient Name:
Date of Birth:
MRN/Patient#:
PATH: Benign
PSA: 4.7 ng/mL
DRE: Normal

SPECIMEN

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

ACCOUNT

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

Patient Result: **DNA Methylation Positive**

The DNA methylation positive test result for this patient indicates a 34% likelihood of detecting prostate cancer, with a 20% probability for low-grade disease (GS ≤ 6) versus a 14% probability of high-grade disease (GS ≥ 7), on repeat biopsy.

Likelihood of prostate cancer on 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 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	Biopsy Site	GSTP1 Methylation	APC Methylation	RASSF1 Methylation
Left Lateral Apex	Positive	Negative	Negative				
Right Base	Positive	Negative	Negative				
Right Lateral Base	Positive	Negative	Negative				
T1 LA (M)	Positive	Negative	Negative				
Left Apex	Negative	Negative	Negative				
Left Base	Negative	Negative	Negative				
Left Lateral Base	Negative	Negative	Negative				
Left Lateral Mid	Negative	Negative	Negative				
Left Mid	Negative	Negative	Negative				
Right Apex	Negative	Negative	Negative				
Right Lateral Apex	Negative	Negative	Negative				
Right Lateral Mid	Negative	Negative	Negative				
Right Mid	Negative	Negative	Negative				

Comments: