Case study

Confirm mdx
for Prostate Cancer

Confirm mdx positive: GS 4+3=7

Age: 77 | PSA: 2.1 ng/mL | DRE: Abnormal | Family history of PCa

Benign TRUS biopsy › Confirm mdx positive › Indeterminant MRI › GS 4+3=7 prostate cancer

History

2021

Initial biopsy findings:

- Number of cores collected: **12**
- Histology Findings: **Benign**

6 weeks

Results

2021

Confirm mdx test results:

DNA Methylation Positive

- 10 of 12 cores positive
- 35% likelihood of GS≥7
- 63% likelihood of any prostate cancer

6 months

2022

MRI results: Indeterminant

- PI-RADS 3
- 0.8 cm lesion left apex posterior

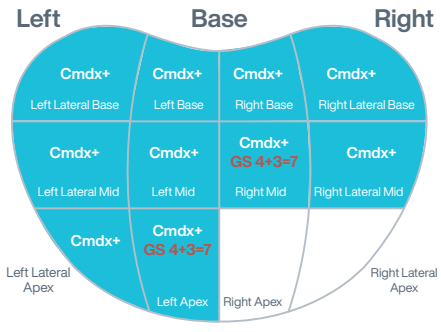
5 weeks

Outcome

2022

Repeat TRUS biopsy findings:

- Number of cores collected: **13**
- Histology Findings: **2 cores positive**
- Cancer Grade: **4+3=7 (GG 3)**



GS 4+3=7

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ConfirmMDx for Prostate Cancer

Patient Report

PATIENT

Patient Name:
Date of Birth:
MRN/Patient#: Not Provided
PATH: Benign
PSA: 2.10 ng/mL
DRE: Abnormal

SPECIMEN

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

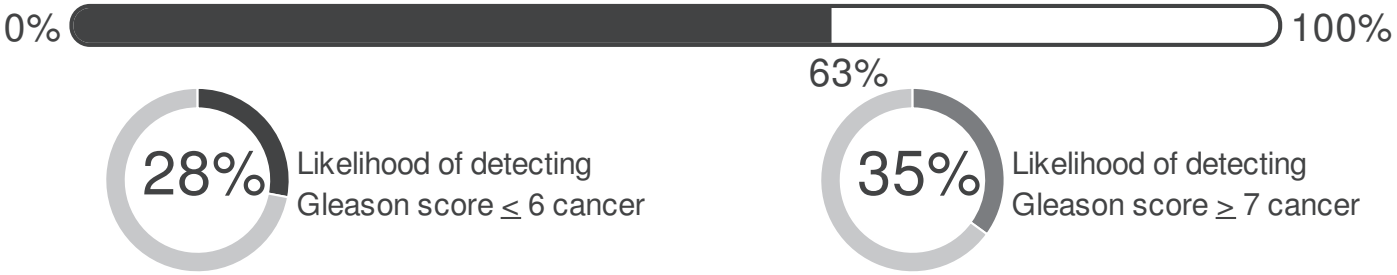
ACCOUNT

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

Patient Result: **DNA Methylation Positive**

The DNA methylation positive test result for this patient indicates a 63% likelihood of detecting prostate cancer, with a 28% probability for low-grade disease (GS ≤ 6) versus a 35% probability of high-grade disease (GS ≥ 7), on repeat biopsy.

Likelihood of prostate cancer on repeat biopsy

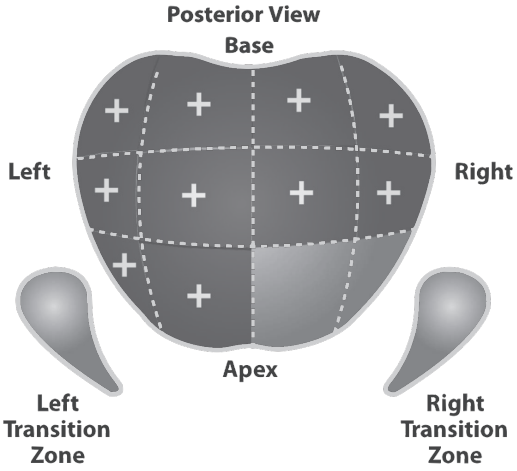


The ConfirmMDx test result indicating the likelihood of GS ≤ 6 and GS ≥ 7 prostate cancer being detected on repeat biopsy is calculated by incorporating DNA methylation intensity with clinical risk factors, including PSA, DRE, age, and histopathology of the previous biopsy, based on a logistic regression 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
Left Apex	Positive	Negative	Negative
Left Base	Positive	Negative	Negative
Left Lateral Apex	Positive	Negative	Negative
Left Lateral Base	Positive	Negative	Negative
Left Lateral Mid	Positive	Negative	Negative
Left Mid	Positive	Negative	Negative
Right Apex	Negative	Negative	Negative
Right Base	Positive	Negative	Negative
Right Lateral Apex	Negative	Negative	Negative
Right Lateral Base	Positive	Negative	Negative
Right Lateral Mid	Positive	Negative	Negative
Right Mid	Positive	Negative	Negative

Distribution of DNA Methylation Diagram



Comments:

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