Case study

Confirm mdx
for Prostate Cancer

Confirm mdx positive: GS 3+4=7

Age: 71 | PSA: 5.1 ng/mL | DRE: Normal | Family history of PCa

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

History

2023

Initial biopsy findings:

- Number of cores collected: **6**
- Histology Findings: **Left-mid ASAP; 6 cores Benign**

14 months

Results

2024

Confirm mdx test results:

DNA Methylation Positive

- 1 of 6 cores positive
- 33% likelihood of GS≥7
- 60% likelihood of any prostate cancer

8 weeks

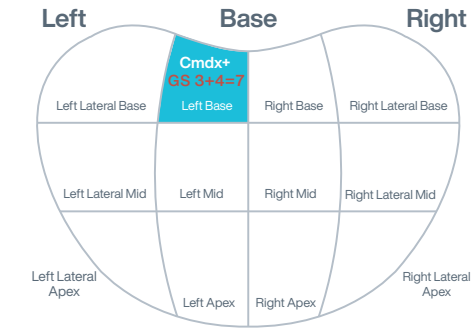
Patient not eligible for MRI due to cochlear implants

Outcome

2024

Repeat biopsy findings:

- Number of cores collected: **6**
- Histology Findings: **1 core positive**
- Cancer Grade: **3+4=7 (GG 2)**



mdxhealth

Superior care made easy. Streamline your workflow while maintaining a high level of care. Mdxhealth delivers comprehensive solutions with dedicated support.

P: 866.259.5644 • F: 949.788.0014 • E: cs@mdxhealth.com • www.mdxhealth.com

ConfirmMDx for Prostate Cancer

Patient Report

PATIENT

Patient Name:
Date of Birth:
MRN/Patient#:
PATH: Atypia
PSA: 5.1 ng/mL
DRE: Not Suspicious

SPECIMEN

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

ACCOUNT

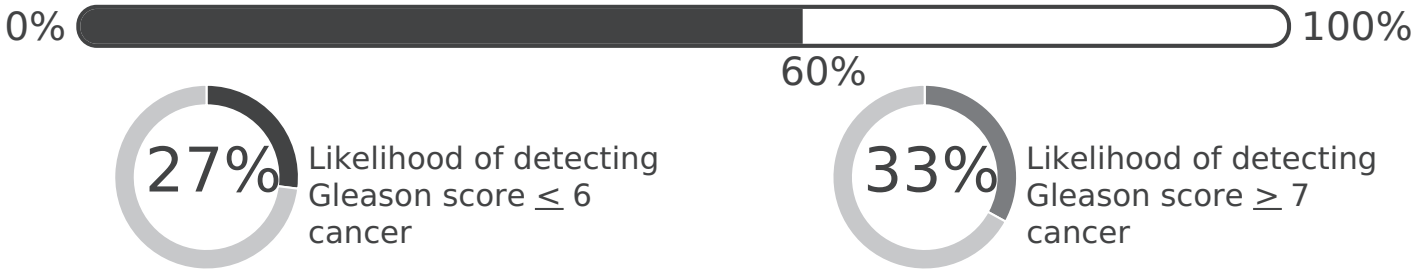
Physician:
Account:

Address:
City/State/Zip:

Patient Result: **DNA Methylation Positive**

The DNA methylation positive test result for this patient indicates a 60% likelihood of detecting prostate cancer, with a 27% probability for low-grade disease (GS ≤ 6) versus a 33% probability of high-grade disease (GS ≥ 7), on repeat biopsy.

Likelihood of prostate cancer on repeat biopsy

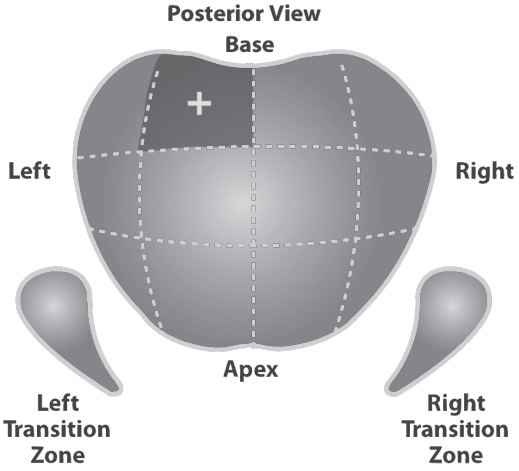


The ConfirmMDx test result indicating the likelihood of GS ≤ 6 and GS ≥ 7 prostate cancer being detected on repeat biopsy is calculated by incorporating DNA methylation intensity with clinical risk factors, including PSA, DRE, age, and histopathology of the previous biopsy, based on a logistic regression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

Distribution of DNA Methylation Diagram



Comments:

MDxHealth
15279 Alton Parkway | Suite 100 | Irvine, CA 92618 | Toll Free: 866.259.5644 | P: 949.812.6979 | F: 949.788.0014 | E: clientservices@mdxhealth.com | www.mdxhealth.com