

ConfirmMDx Positive: GS 4+3=7

Age: 71 | PSA: 7 ng/mL | DRE: Enlarged

Previous negative prostate biopsy > ConfirmMDx Positive > GS 4+3=7 prostate cancer diagnosed

ConfirmMDx Result: POSITIVE DNA METHYLATION

71 year old | PSA 7 ng/mL | DRE: Enlarged | No Family History

HISTORY

November 2016 **Negative Initial Biopsy Findings:**
 PSA Level: **7 ng/mL**
 Number of Cores Collected: **12**
 Histology Findings: **Benign Prostatic Tissue**
 Complications from Bx: **None**
 DRE Results: **Normal**

RESULTS

October 2017 **ConfirmMDx Results:**
 Following the initial negative biopsy results, the treating physician ordered a ConfirmMDx test.

POSITIVE

ConfirmMDx DNA Methylation Positive

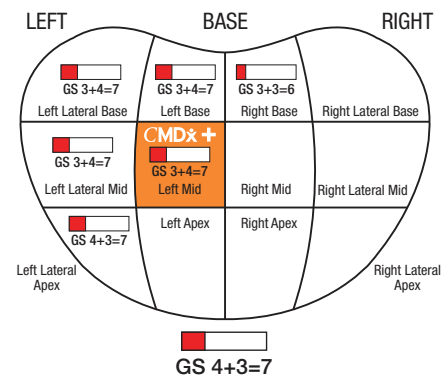
At time of ConfirmMDx testing
 PSA Level: **7 ng/mL**
 DRE Results: **Enlarged**

OUTCOME

November 2017 **Prior to Repeat Bx:**
 PSA Level Prior to Repeat Bx: **2 ng/mL**
 DRE results: **Enlarged**
 Prostate Volume: **35**

MRI Results: **PI-RADS 5**
 Date of MRI: **November 2017**

December 2017 **Repeat Biopsy Results:**
 Pathology Results of Repeat Bx: **Positive**
 Clinical Disease Stage: **T1**
 Cancer Grade: **G3 (GS 4+3)**



Patient Report

PATIENT

Patient Name:
Date of Birth:
MRN/Patient#:
PATH: Benign
PSA: 7 ng/mL
DRE: Not Suspicious

SPECIMEN

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

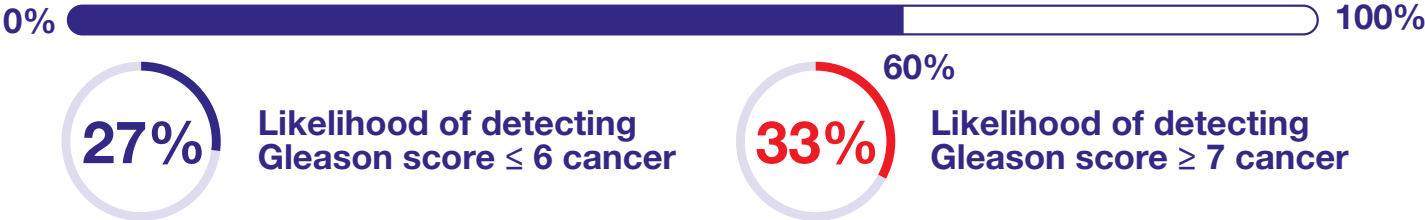
ACCOUNT

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

Patient Result: DNA Methylation Positive

The DNA methylation positive test result for this patient indicates an 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 upon 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 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: | Negative | Negative | Negative |
| Left Mid: | Positive | Positive | 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: | Negative | Negative | Negative |
| Right Lateral Mid: | Negative | Negative | Negative |
| Right Lateral Apex: | Negative | Negative | Negative |
| Right Transition Zone: | | | |

Distribution of DNA Methylation Diagram

