

# Confirm mdx positive: GS 3+4=7

Age: 64 | PSA: 4.8 ng/mL | DRE: Normal | Family history of PCa

Benign TRUS biopsy

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Confirm mdx positive

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Positive MRI

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GS 3+4=7 prostate cancer

## History

2024

### Initial biopsy findings:

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

6 weeks

## Results

2024

### Confirm mdx test results:



#### DNA Methylation Positive

- 2 of 12 cores positive
- 17% likelihood of GS $\geq$ 7
- 38% likelihood of any prostate cancer

5 months

2024

### MRI results: Positive

- PI-RADS 4
- 1.8 mm lesion left anterior base

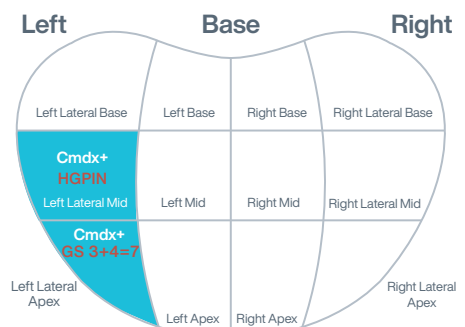
2 months

2024

## Outcome

### Repeat biopsy findings:

- Number of cores collected: **12**
- Histology Findings: **1 core positive; 1 core HGPIN**
- Cancer Grade: **3+4=7 (GG 2)**



## Patient Report

### PATIENT

**Patient Name:**  
**Date of Birth:**  
**MRN/Patient#:**  
**PATH:** Benign  
**PSA:** 4.8 ng/mL  
**DRE:** Normal

### SPECIMEN

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

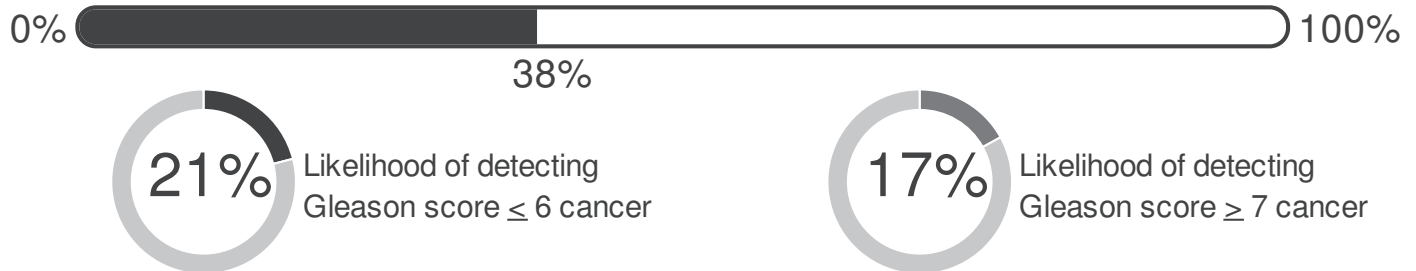
### ACCOUNT

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

**Patient Result:** **DNA Methylation Positive**

The DNA methylation positive test result for this patient indicates a 38% likelihood of detecting prostate cancer, with a 21% probability for low-grade disease ( $GS \leq 6$ ) versus a 17% probability of high-grade disease ( $GS \geq 7$ ), on repeat biopsy.

### Likelihood of prostate cancer on repeat biopsy



The ConfirmMDx test result indicating the likelihood of  $GS \leq 6$  and  $GS \geq 7$  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 5 $\alpha$ -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.<sup>1-54</sup>

### DNA Methylation Status Table

Biopsy Site	<i>GSTP1</i> Methylation	<i>APC</i> Methylation	<i>RASSF1</i> Methylation
Left Apex	Negative	Negative	Negative
Left Base	Negative	Negative	Negative
Left Lateral Apex	Positive	Negative	Negative
Left Lateral Base	Negative	Negative	Negative
Left Lateral Mid	Negative	Negative	Positive
Left Mid	Negative	Negative	Negative
Right Apex	Negative	Negative	Negative
Right Base	Negative	Negative	Negative
Right Lateral Apex	Negative	Negative	Negative
Right Lateral Base	Negative	Negative	Negative
Right Lateral Mid	Negative	Negative	Negative
Right Mid	Negative	Negative	Negative

**Comments:**

### Distribution of DNA Methylation Diagram

