ConfirmMDx Positive: GS 4+3=7
Age: 68 | PSA: 6 ng/mL | DRE: Enlarged

Previous negative prostate biopsy > ConfirmMDx Positive > GS 4+3=7 prostate cancer diagnosed
ConfirmMDx Result: POSITIVE DNA METHYLATION
68 year old | PSA 6 ng/mL | DRE: Enlarged | No Family History

HISTORY
February 2016
Negative Initial Biopsy Findings:
- PSA Level: 6 ng/mL
- Number of Cores Collected: 14
- Histology Findings: Benign Prostatic Tissue
- Complications from Bx: None
- DRE Results: Enlarged

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

ConfirmMDx DNA Methylation Positive
At time of ConfirmMDx testing
- PSA Level: 6 ng/mL
- DRE Results: Enlarged

OUTCOME
March 2018
Prior to Repeat Bx:
- PSA Level Prior to Repeat Bx: 6 ng/mL
- DRE results: Enlarged
- Prostate Volume: 58
- Comorbidities: HBP, Hyperlipidemia
- Chronic Medications: Tamsulosin, Lisinopril
- MRI Results: PI-RADS 5-Lesion left anterior apical peripheral zone

June 2018
Repeat Biopsy Results:
- Pathology Results of Repeat Bx: Positive
- Clinical Disease Stage: T1
- Cancer Grade: G3
The DNA methylation positive test result for this patient indicates an 36% likelihood of detecting prostate cancer, with a 21% probability for low-grade disease (GS ≤ 6) versus a 15% probability of high-grade disease (GS ≥ 7), on repeat biopsy.

Likelihood of prostate cancer upon repeat biopsy

0% 100%

36% Likelihood of detecting Gleason score ≤ 6 cancer

21%

15% Likelihood of detecting Gleason score ≥ 7 cancer

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.¹⁻⁵⁻⁵