ConfirmMDx Positive: GS 4+4=8
Age: 77 I PSA: 9 ng/mL I DRE: Not Suspicious

Previous negative prostate biopsy > ConfirmMDx Positive > GS 4+4=8 prostate cancer diagnosed
ConfirmMDx Result: POSITIVE DNA METHYLATION
77 year old | PSA 9 ng/mL | DRE: Not Suspicious | No Family History

HISTORY
November 2016  Initial Biopsy Findings:
PSA Level: 9 ng/mL
Number of Cores Collected: 12
Histology Findings: Benign Prostatic Tissue
Complications from Bx: None
DRE Results: Not Suspicious

RESULTS
October 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: 9 ng/mL
DRE Results: Not Suspicious

OUTCOME
January 2018  Prior to Repeat Bx:
PSA Level Prior to Repeat Bx: 19 ng/mL
DRE results: Enlarged
Prostate Volume: 40
Comorbidities: A-Fib, Hypertension, DM
Chronic Medications: Eliquis, Glimepiride
MRI Results: PI-RADS 5
Date of MRI: Jan. 2018

February 2018  Repeat Biopsy Results:
Pathology Results of Repeat Bx: Positive
Clinical Disease Stage: T1c
Cancer Grade: G4
Patient Result: DNA Methylation Positive

The DNA methylation positive test result for this patient indicates an 41% likelihood of detecting prostate cancer, with a 22% probability for low-grade disease (GS ≤ 6) versus a 19% probability of high-grade disease (GS ≥ 7), on repeat biopsy.

Likelihood of prostate cancer upon repeat biopsy

- 41% likelihood of detecting Gleason score ≤ 6 cancer
- 22% likelihood of detecting Gleason score ≥ 7 cancer
- 19% 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.¹⁻⁵⁵