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.

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 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**

![Likelihood Chart]

- 27% Likelihood of detecting Gleason score ≤ 6 cancer
- 33% 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