Confirm mdx
for Prostate Cancer

SAMPLE Patient Report

Patient

Patient Name:	David Sample
Date of Birth:	12/27/1959
MRN/Patient #:	8979821
Path:	Negative
PSA:	9.4 ng/mL
DRE:	Normal

Specimen

Specimen #:	5641305
Collection Date:	08/22/2024
Received Date:	09/12/2024
Report Date:	09/23/2024
Specimen Type:	FFPE tissue slides
Mdx Accession #:	PR-123456

Physician

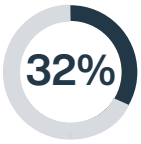
John Sample, MD
Urology Associates
15279 Alton Parkway,
STE 100
Irvine, CA 92618

PATIENT RESULT: DNA METHYLATION POSITIVE

DNA Methylation Positive: This patient's test result indicates a 12% risk for Gleason Score GS≥7 (3+4) cancer, 20% for GS 6 cancer and a 32% risk for any prostate cancer.

Likelihood of detecting GS≥7 (3+4) upon repeat biopsy:

Likelihood of detecting GS 6 cancer upon repeat biopsy



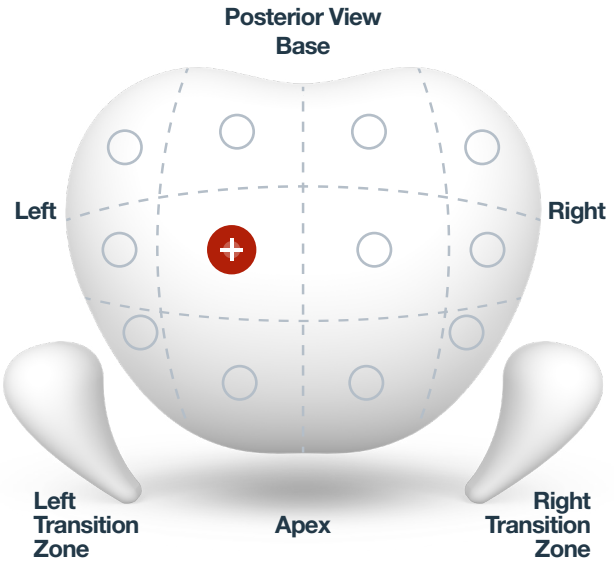
Likelihood of any prostate cancer upon repeat biopsy

DNA Methylation Status Table

Biopsy Site	GSTP1 Methylation	APC Methylation	RASSF1 Methylation
Left Apex	NEG	NEG	NEG
Left Base	NEG	NEG	NEG
Left Lateral Apex	NEG	NEG	NEG
Left Lateral Base	NEG	NEG	NEG
Left Lateral Mid	NEG	NEG	NEG
Left Mid	**POS**	**POS**	NEG
Right Apex	NEG	NEG	NEG
Right Base	NEG	NEG	NEG
Right Lateral Apex	NEG	NEG	NEG
Right Lateral Base	NEG	NEG	NEG
Right Lateral Mid	NEG	NEG	NEG
Right Mid	NEG	NEG	NEG

Report Key
NEG = DNA METHYLATION NEGATIVE
POS = DNA METHYLATION POSITIVE

Distribution of DNA Methylation Prostate Diagram



Comments:

Test Description

Confirm mdx results indicating the likelihood of GS 6 and GS≥7 (3+4) prostate cancer being detected upon 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 -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 Confirm mdx gene markers has been reported on ~4,500 patients.

Confirm mdx for Prostate Cancer assesses the status of GSTP1, APC and RASSF1 genes in histopathologically cancer-negative biopsy specimens from men considered at risk for prostate cancer. If one or more of these genes, in one or more core samples, is interpreted as positive for methylation, the Patient Result is reported as positive; otherwise, the Patient Result is reported as negative. Confirm mdx is a DNA methylation specific PCR (MSP) assay, based upon the ability to discriminate methylated from non-methylated cytosines following bisulfite treatment of the DNA.

Patient samples are derived from paraffin-embedded prostate core biopsy tissues fixed in 10% neutral buffered formalin (NBF) or other validated fixatives. Prior to DNA isolation, a deparaffinization step is performed to dissolve the paraffin into which patient samples are embedded. After DNA isolation, the nucleic acids are bisulfite treated which converts unmethylated cytosines to uracil while the methylated cytosines remain unchanged. Following chemical conversion, methylated DNA can be distinguished from the unmethylated DNA by methylation specific PCR (MSP). The GSTP1, APC and RASSF1 genes are amplified using methylation specific primers and quantified using molecular beacons.[1-3]

References:

1. Partin AW, et al. J Uro. 2014.
2. Stewart G, et al. J Uro. 2013.
3. Van Neste L, et al. Prostate. 2016.

Disclaimer:
Mdxhealth is regulated under the Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) as an accredited laboratory to perform high complexity clinical testing. The Confirm mdx for Prostate Cancer test was developed, and its performance characteristics determined by mdxhealth. This test is intended for use as an aid to clinicians for patient management decisions for the need to perform a repeat biopsy on patients with a previous histopathologically negative biopsy result (benign, HGPIN, or ASAP) within the past 30 months and high-risk clinical factors for occult prostate cancer.
CLIA# 05D2033858; CAP# 8015399.

Ruben Gamez, MD, Laboratory Director

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