

SAMPLE

Patient Report

PATIENT

Patient Name: Lucas Sample
Date of Birth: 10/15/1945
MRN/Patient#: MRN 123
PATH: Negative
PSA: 7.66 ng/mL
DRE: Normal

SPECIMEN

Specimen#: 5641305
Collection Date: 06/20/2016
Received Date: 01/12/2017
Report Date: 01/18/2017
Specimen Type: Prostate FFPE tissue slides
MDxH Accession#: PR-123456

ACCOUNT

Physician: Mike Test, MD
Account: Urology Partners of California
Address: 15279 Alton Parkway
Suite 100
City/State/Zip: Irvine, CA 92618

Patient Result: DNA Methylation Positive

The DNA methylation positive test result for this patient indicates an 84% likelihood of detecting prostate cancer, with a 36% probability for low-grade disease (GS ≤ 6) versus a 48% probability of high-grade disease (GS ≥ 7), on repeat biopsy.

Likelihood of prostate cancer upon repeat biopsy

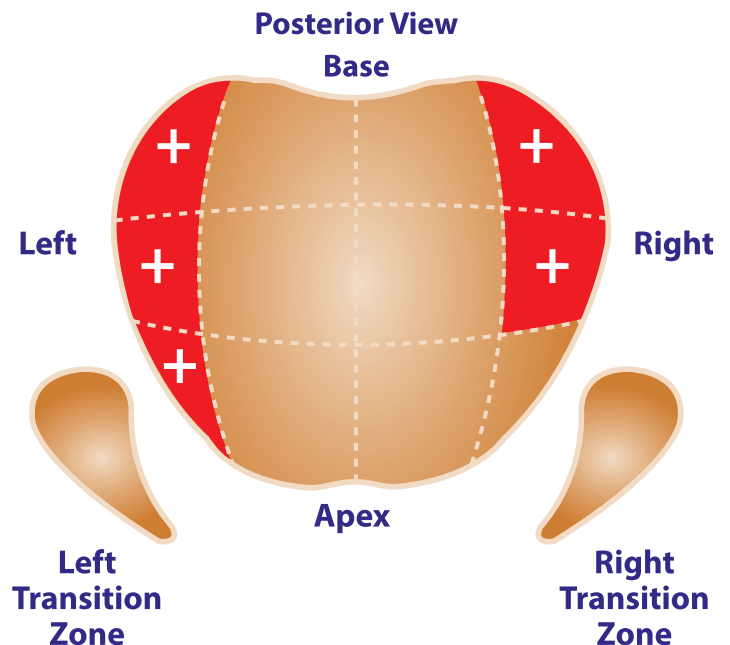


The ConfirmMDx test result indicating the likelihood of GS ≤ 6 and GS ≥ 7 prostate cancer being detected on repeat biopsy is calculated by incorporating DNA methylation intensity with clinical risk factors, including PSA, DRE, age, and histopathology of the previous biopsy, based on a clinical model 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

DNA Methylation Status Table

Biopsy Site	GSTP1 Methylation	APC Methylation	RASSF1 Methylation
Left Lateral Base:	Positive	Positive	Positive
Left Lateral Mid:	Positive	Positive	Positive
Left Lateral Apex:	Positive	Positive	Positive
Left Base:	Negative	Negative	Negative
Left Mid:	Negative	Negative	Negative
Left Apex:	Negative	Negative	Negative
Left Transition Zone:	Negative	Negative	Negative
Right Base:	Negative	Negative	Negative
Right Mid:	Negative	Negative	Negative
Right Apex:	Negative	Negative	Negative
Right Lateral Base:	Positive	Positive	Positive
Right Lateral Mid:	Positive	Positive	Positive
Right Lateral Apex:	Negative	Negative	Negative
Right Transition Zone:	Negative	Negative	Negative

Distribution of DNA Methylation Diagram



SAMPLE

Patient Report

PATIENT

Patient Name: John Sample
Date of Birth: 01/01/1942
MRN/Patient#: MRN 123
PATH: Negative
PSA: 9.4 ng/mL
DRE: Normal

SPECIMEN

Specimen#: 5641305
Collection Date: 12/20/2016
Received Date: 01/11/2017
Report Date: 01/18/2017
Specimen Type: Prostate FFPE tissue slides
MDxH Accession#: PR-123456

ACCOUNT

Physician: Mike Test, MD
Account: Urology Partners of California
Address: 15279 Alton Parkway
Suite 100
City/State/Zip: Irvine, CA 92618

Patient Result: DNA Methylation Positive

The DNA methylation positive test result for this patient indicates a 32% likelihood of detecting prostate cancer, with a 20% probability for low-grade disease (GS ≤ 6) versus a 12% probability of high-grade disease (GS ≥ 7), on repeat biopsy.

Likelihood of prostate cancer upon repeat biopsy

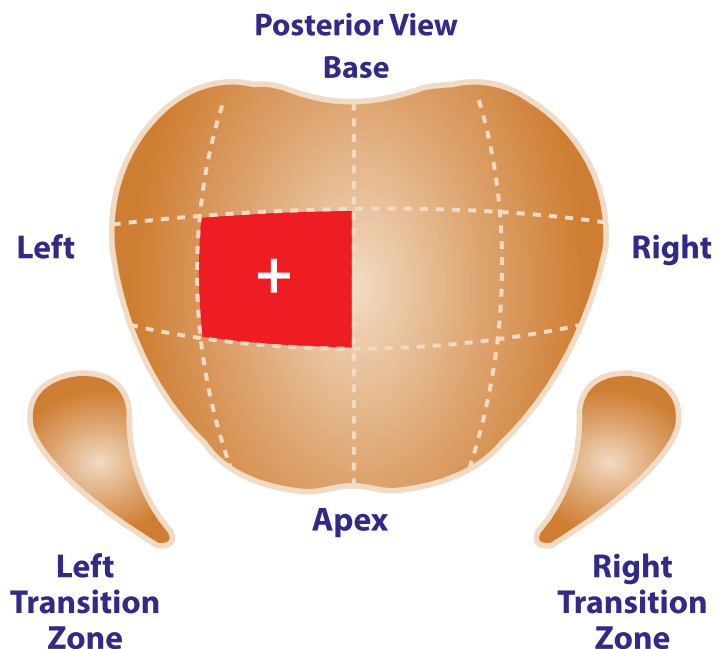


The ConfirmMDx test result indicating the likelihood of GS ≤ 6 and GS ≥ 7 prostate cancer being detected on repeat biopsy is calculated by incorporating DNA methylation intensity with clinical risk factors, including PSA, DRE, age, and histopathology of the previous biopsy, based on a clinical model 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

DNA Methylation Status Table

Biopsy Site	GSTP1 Methylation	APC Methylation	RASSF1 Methylation
Left Lateral Base:	Negative	Negative	Negative
Left Lateral Mid:	Negative	Negative	Negative
Left Lateral Apex:	Negative	Negative	Negative
Left Base:	Negative	Negative	Negative
Left Mid:	Positive	Positive	Positive
Left Apex:	Negative	Negative	Negative
Left Transition Zone:	Negative	Negative	Negative
Right Base:	Negative	Negative	Negative
Right Mid:	Negative	Negative	Negative
Right Apex:	Negative	Negative	Negative
Right Lateral Base:	Negative	Negative	Negative
Right Lateral Mid:	Negative	Negative	Negative
Right Lateral Apex:	Negative	Negative	Negative
Right Transition Zone:	Negative	Negative	Negative

Distribution of DNA Methylation Diagram



SAMPLE
Patient Report

PATIENT

Patient Name: Stephan Sample
Date of Birth: 03/15/1945
MRN/Patient#: MRN 123
PATH: Negative
PSA: 5.2 ng/mL
DRE: Normal

SPECIMEN

Specimen#: 1776
Collection Date: 12/07/2016
Received Date: 01/11/2017
Report Date: 01/19/2017
Specimen Type: Prostate FFPE tissue slides
MDxH Accession#: PR-123456

ACCOUNT

Physician: Mike Test, MD
Account: Urology Partners of California
Address: 15279 Alton Parkway
Suite 100
City/State/Zip: Irvine, CA 92618

Patient Result: DNA Methylation Negative

The negative result for this patient indicates a low likelihood of detecting prostate cancer upon repeat biopsy.

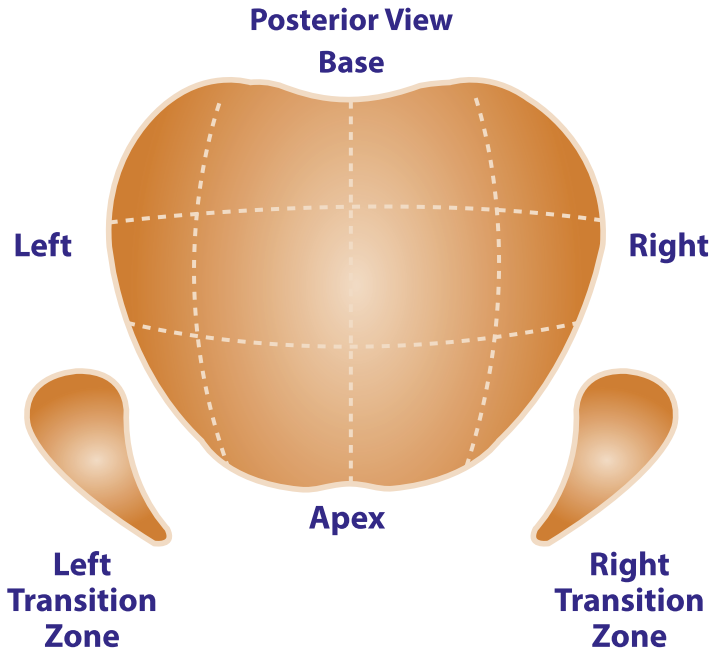
Result Description:

Clinical validation study results indicate a negative predictive value (NPV) of 96% for high-grade disease (Gleason score ≥ 7), and a 90% NPV for all grades of prostate cancer. Cancer association with DNA methylation of ConfirmMDx gene markers has been reported on ~4,500 patients.¹⁻⁵⁵

DNA Methylation Status Table

Biopsy Site	GSTP1 Methylation	APC Methylation	RASSF1 Methylation
Left Lateral Base:	Negative	Negative	Negative
Left Lateral Mid:	Negative	Negative	Negative
Left Lateral Apex:	Negative	Negative	Negative
Left Base:	Negative	Negative	Negative
Left Mid:	Negative	Negative	Negative
Left Apex:	Negative	Negative	Negative
Left Transition Zone:	Negative	Negative	Negative
Right Base:	Negative	Negative	Negative
Right Mid:	Negative	Negative	Negative
Right Apex:	Negative	Negative	Negative
Right Lateral Base:	Negative	Negative	Negative
Right Lateral Mid:	Negative	Negative	Negative
Right Lateral Apex:	Negative	Negative	Negative
Right Transition Zone:	Negative	Negative	Negative

Distribution of DNA Methylation Diagram



SAMPLE Patient Report

Assay Description:

The ConfirmMDx for Prostate Cancer test evaluates the status of *GSTP1*, *APC* and *RASSF1* genes for the assessment of risk for occult disease in men with previous histopathologically cancer-negative biopsy results. 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. ConfirmMDx 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.

References:

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MDxHealth is regulated under the Clinical Laboratory Improvement Amendments (CLIA) and the College of American Pathologists as an accredited laboratory to perform high complexity clinical testing. The ConfirmMDx 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, Atypia or ASAP) within the past twenty-four months. Use outside of this indication has not been validated by MDxHealth. The test results should be interpreted in conjunction with other laboratory and clinical data available to the clinician and relevant guidelines in the decision for repeat biopsy.

MDxHealth is certified by DEKRA for ISO 9001:2008 Quality Management System. This test was performed by MDxHealth, Inc., 15279 Alton Parkway, Suite 100, Irvine, California 92618. CLIA# 05D2033858; CAP# 8015399

Jess Savala, Jr., MD, Laboratory Director



General information about ConfirmMDx for Prostate Cancer can be found at www.mdxhealth.com. If you have any questions regarding this report, please contact MDxHealth Client Services at 866.259.5644 or at client.services@mdxhealth.com.