

ABOUT CONFIRMMDX

ConfirmMDx is a tissue based prostate cancer marker (PCM) that helps patients with a cancer-negative (HGPIN, ASAP or atypia) prostate biopsy result determine their risk for harboring an undetected clinically-significant prostate cancer.

ConfirmMDX is an epigenetic assay that incorporates the DNA methylation intensity with clinical risk factors (PSA, DRE, age, and histopathology) to determine a patient's risk of having cancer despite a cancer-negative biopsy result.



PCMS
Prostate Cancer Markers

ConfirmMDx

HOW IT'S USED

- Immediately after a cancer-negative biopsy result to determine a patient's risk for clinically significant prostate cancer, and to help guide the patient follow-up management plan or need for re-biopsy/MRI.

INDICATIONS FOR USE

- Men with a cancer negative (HGPIN, ASAP, atypia) prostate biopsy result

SCIENCE

- Detects the methylation status of three cancer specific genes- APC, RASSF1, and GSTP1
- A positive test indicates the patient is at increased risk for clinically significant prostate cancer, their clinical risk factors need to be monitored more closely, or to consider a re-biopsy of the patient.

PRESENTATION OF RESULTS

Test results for ConfirmMDx are presented in a binary fashion.

- **Negative for hypermethylation:** The patient has \leq 4% risk of having clinically significant prostate cancer.
- **Positive for hypermethylation:** This patient is at increased risk and should be monitored more closely or a re-biopsy/MRI should be considered.
- This result demonstrates three risk categories:
 - **Overall risk** of finding prostate cancer upon repeat biopsy.
 - **Percent risk** of a patient having low-grade cancer upon repeat prostate biopsy.
 - **Percent risk** of having clinically significant prostate cancer (greater than or equal to Gleason 7) upon repeat prostate biopsy.

COMPANY CONTACT

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