PROSTATE CORE MITOMIC TEST™

Clinical Insight

PROSTATE CORE MITOMIC TEST™
Clinical Insight

Biopsies don't tell the whole story.

False negatives are common with initial and follow-up biopsies.

Each core represents

1/2000

of a normal size prostate (30 g).

As many as

30%

of initial negatives prove to be positive on repeat biopsies.

Patients with false negatives are managed in the same manner as those with true negatives.

What if you could determine the difference between a false negative and a true negative?

PROSTATE CORE MITOMIC TEST™
Clinical Insight

Now you can with the Prostate Core Mitomic Test.

PROSTATE CORE MITOMIC TEST™
Clinical Insight

Patient A

Age 62, persistently rising PSA, family history

Biopsy outcome [redacted]

Request PCMT

Negative PCMT Result

[redacted]

Confirm a true negative with

92%

negative predictive value.

PROSTATE CORE MITOMIC TEST™
Clinical Insight

Patient B

Age 62, persistently rising PSA, family history

Biopsy outcome [redacted]

Request PCMT

Positive PCMT Result

Identify patients at high risk for undiagnosed prostate cancer with

85%

sensitivity.

PROSTATE CORE MITOMIC TEST™
Clinical Insight

Confidently stratify your patients.

PROSTATE CORE MITOMIC TEST™
Clinical Insight

Negative PCMT result

- Be more confident in negative results.
- Provide peace of mind to patients.
- Avoid causing patients added pain, anxiety, and risk from unnecessary, extra biopsies.

Positive PCMT result

- Detect undiagnosed prostate cancer early.
- Manage patient based on positive PCMT result and additional risk factors.
- Tailor patient management for improved patient care.

PROSTATE CORE MITOMIC TEST™
Clinical Insight

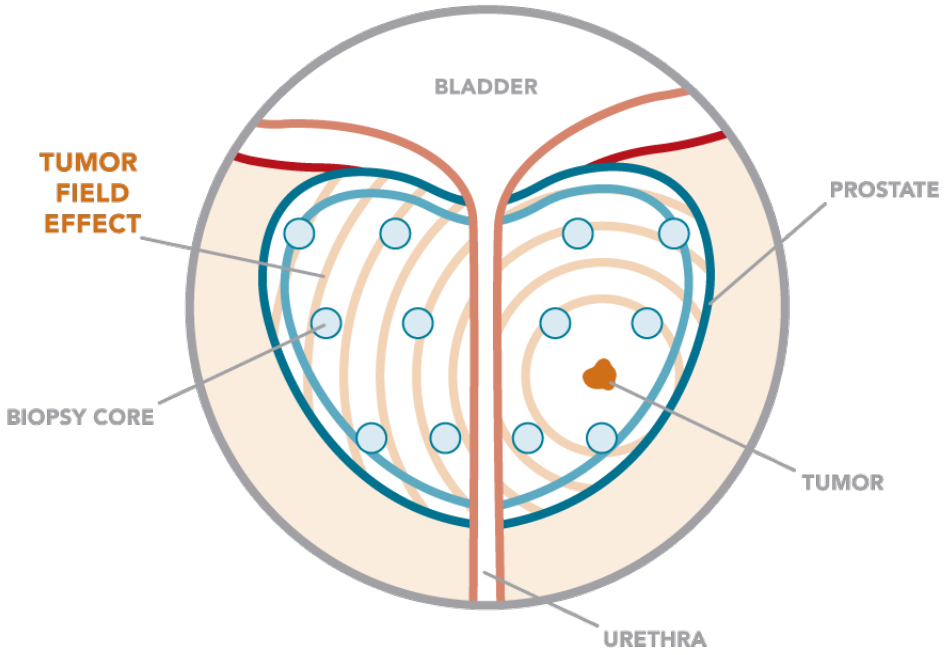
Look beyond the core for better patient management

1. Order the Prostate Core Mitomic Test in conjunction with prostate biopsy pathology.

2. Use existing biopsy tissue – no additional procedures or office visits necessary.

3. Receive the early insight you need.
   - Results are processed in a CLIA laboratory by highly trained and experienced personnel.
   - Results are reported on a per core basis.

Tumor field effect

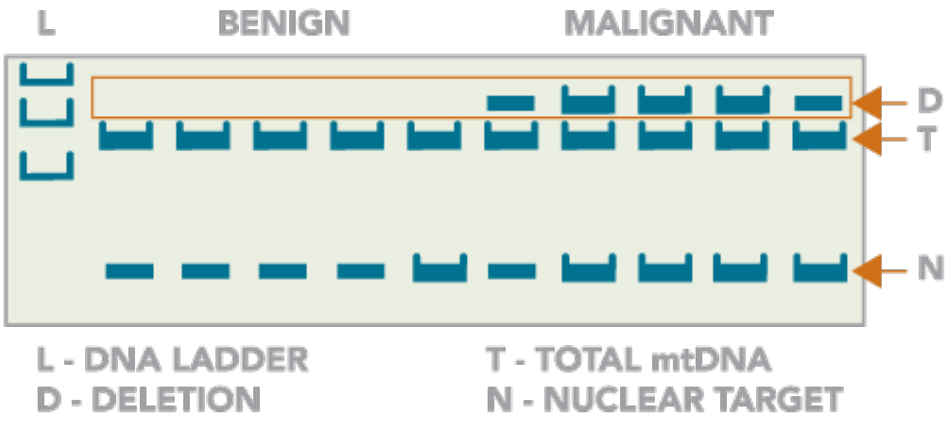


Tumor field effect

- Identifies a large-scale deletion in mitochondrial DNA that indicates cellular change associated with undiagnosed prostate cancer.
- Detects presence of malignant cells in normal appearing tissue across an extended area.

Why mitochondrial DNA?

PROSTATE CORE MITOMIC TEST™
Clinical Insight



The Prostate Core Mitomic Test detects large-scale mtDNA deletion to discriminate between benign and malignant prostate tissue.

Why mitochondrial DNA (mtDNA)?

- Mass copy rate allows for the most extensive field effect possible.
- Mutations associated with prostate cancer appear in tumors and normal tissue.
- High susceptibility to damage enables unprecedented early disease detection.

MITOMICS™

Empowering Clinical Insight™

MITOMICS™

Empowering Clinical Insight™

Exclusive use of mitochondrial DNA-based biomarkers to detect disease

Set an improved standard for performance that creates new categories for screening, diagnosis, and unprecedented early disease detection

Enable physicians to detect disease early and tailor patient management for better patient care

MITOMIC TECHNOLOGY™

Clinical Insight Powered by Mitochondrial Genomics

Available soon:

2012 PROSTATE MITOMIC TEST™ Noninvasive Clinical Insight

2013 ENDOMETRIOSIS MITOMIC TEST™ Noninvasive Clinical Insight

2013 PROSTATE POSITIVE MITOMIC TEST™ Clinical Insight

2014 BREAST MITOMIC TEST™ Noninvasive Clinical Insight

Tests are currently in development for:

- Bladder cancer
- Cervical cancer
- Thyroid cancer
- Melanoma
- Ovarian cancer
- Pancreatic cancer
- Uterine cancer

Appendix

Backed by true evidence

Discovery, characterization, and validation data based on 540 patients and more than 2,700 prostate cores.

External validation performed by the National Institute of Standards and Technology under the Early Detection Research Network of the National Cancer Institute.

Posters and abstracts presented at:

- Society of Urologic Oncology 2010 Annual Meeting
- American Urological Association 2011 Annual Meeting

Published data

- Robinson K, Creed J, Reguly B, Powell C, Wittock R, Klein D, Maggrah A, Klotz L, Parr RL, Dakubo GD. “Accurate prediction of repeat prostate biopsy outcomes by a mitochondrial DNA deletion assay.” *Prostate Cancer and Prostatic Diseases*. 2010.

- Parr RL, Jakupciak JP, Reguly B, and Dakubo GD. 3.4kb “Mitochondrial Genome Deletion Serves as a Surrogate Predictive Biomarker for Prostate Cancer in Histopathologically Benign Biopsy Cores.” *Canadian Urological Association Journal.* 2010.

- Maki J, Robinson K, Reguly B, Alexander J, Wittock R, Aguirre A, Diamandis EP, Escott N, Skehan A, Prowse O, Thayer ER, M. Froberg K, Wilson MJ, Maragh S, Jakupciak JP, Wagner PD, Srivatava S, Dakubo GD, Parr RL. “Mitochondrial genome deletion aids in the identification of both false and true negative prostate needle core biopsies.” *American Journal of Clinical Pathology.* 2008.

- Parr RL, Dakubo GD, Crandall KA, Maki J, Reguly B, Aguirre A, Wittock R, Robinson K, Alexander JS, Birch-Machin MA et al: “Somatic mitochondrial DNA mutations in prostate cancer and normal appearing adjacent glands in comparison to age-matched prostate samples without malignant histology.” *Journal of Molecular Diagnostics.* 2006.

Thank you

MITOMICS™
Empowering Clinical Insight™