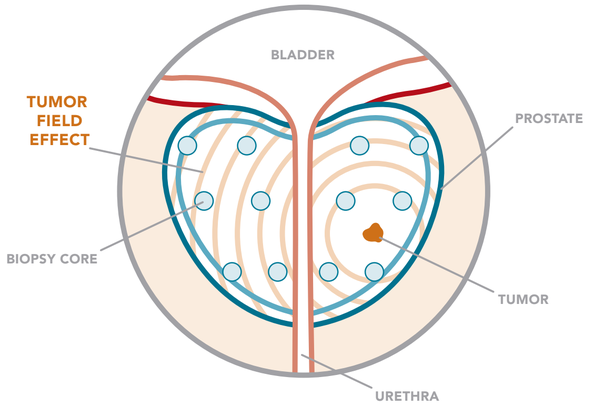
How does PCMT work?

With 85-percent sensitivity, PCMT detects the presence of malignant cells in normal-appearing tissue via a tumor field effect. Studies have indicated the field effect for PCMT is gland-wide. Detect undiagnosed prostate cancer early.



The cancerization field associated with mitochondrial deletions provides a distinct molecular signature that mtGenomic assessment can detect. Though conventional histology of a biopsy sample might not display evidence of malignancy, if the tissue comes from an area that is within the cancerization field, disease onset will be detectable via this signature. Coupling conventional biopsy methodology with mtGenomic assessment to detect this cancerization field provides vital clinical information.

- Parr and Martin: Mitochondrial and nuclear genomics and the emergence of personalized medicine. Human Genomics 2012 6:3.

Scientific publications on PCMT

Parr and Martin: Mitochondrial and nuclear genomics and the emergence of personalized medicine. Human Genomics 2012 6:3.

Kent Froberg*, Laurence Klotz, Kerry Robinson, Jennifer Creed, Brian Reguly, Cortney Powell, Daniel Klein, Andrea Maggrah, Roy Wittock, Ryan Parr. Large-scale mitochondrial genome deletion as an aid for negative prostate biopsy uncertainty. Poster presented as a part of the American Urological Association Annual Meeting, Washington, D.C., May 14-19, 2011. *Abstract published in The Journal of Urology, Vol. 185 No. 4S, e 764, Supplement, May 2011.

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Parr RL, Jakupciak JP, Birch-Machin MA, Dakubo GD. The Mitochondrial Genome: A Biosensor for Early Cancer Detection? Expert Opin Med Diagn. 2007;1(2):169-82.

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John Mills*, Luis Martin, François Guimont, Brian Reguly, Andrew Harbottle, John Pedersen, Jennifer Creed, Ryan Parr. Large-Scale 3.4kb Mitochondrial Genome Deletion is Significantly Associated with a Prostate Cancer Field Effect. *Abstract accepted as part of the American Urological Association Annual Meeting, San Diego, CA, May 4-8, 2013.

Learn more about the Prostate Core Mitomic Test
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NPI# 1528364056

PROSTATE CORE MITOMIC TEST™
Clinical Insight

Look beyond the core.

Enhance prostate biopsy results for better patient management.

False negative results are common during initial and follow-up biopsy procedures. You're forced to manage false-negative patients in the same manner as those who are negative. What if you could determine the difference between these patients?

Now you can. With the Prostate Core Mitomic Test™ (PCMT™), a molecular test ordered with prostate biopsy pathology, you can confidently stratify and better manage patients.

What is PCMT?

PCMT identifies a large-scale deletion in mitochondrial DNA (mtDNA) that indicates cellular change associated with undiagnosed prostate cancer. By using biopsy tissue samples that have already been collected and stored at the lab, PCMT precludes the need for additional office visits or surgeries. You can order PCMT as a reflex test when you submit a biopsy for evaluation or after the biopsy results are available.

How do you use PCMT?

Addressable market

Positive biopsy outcome (30%)

Negative biopsy outcome (70%)

Patient selection

- PSA > 4.0 ng/ml
- PSADT < 3 months
- PSAV > 0.4 ng/ml/year
- Life expectancy > 10 years
- ASAP
- HGPIN
- Family history
- African American

Clinical response

PCMT negative outcome

Patient is currently at a low risk of undiagnosed prostate cancer.

Defer repeat biopsy and routine screening by 12 to 14 months.

PCMT positive outcome

Patient is at a high risk of undiagnosed prostate cancer.

A repeat saturation biopsy is recommended with presence of additional risk factors.

Note: Patient selection and clinical response to a positive or negative PCMT outcome is based on the feedback of an independent panel of leading U.S. urologists and active users of PCMT.

PCMT outperforms competitors

Because mtDNA has an extended field effect compared to nuclear DNA, PCMT can be used for all negative biopsy patients and delivers the highest sensitivity and negative predictive value of all similar tests.

	PCMT
Sensitivity	85%
Negative predictive value	92%
Field effect extent	Entire prostate
Clinical utility	All negative biopsies; requires only 20 microns of tissue

Gain an advantage in the fight against prostate cancer

- Be more confident in negative results – and provide peace of mind to patients.
- Stratify patients who are free of the disease from those with undiagnosed prostate cancer.
- Detect undiagnosed prostate cancer early.
- Tailor patient management for improved patient care.
- Avoid causing patients added pain, anxiety, and risk from extra and potentially unnecessary biopsies.

Health economic benefits of PCMT

Savings category	Range of cost savings (in $US)
Reduce or eliminate unnecessary screening	$3,800 - $15,000
Reduce the number of unnecessary repeat biopsy procedures	$9,600
Eliminate the complications associated with unnecessary repeat biopsy procedures	$2,000
Total	$15,400 - $26,600

PCMT mtDNA deletion: Stages of discovery and validation

The entire process of discovery and validation involved 396 patients and close to 1,700 prostate core samples. Included were 143 patients with benign histology and 253 patients with malignant histology. Stage 2 involved an external validation study performed by the National Institute of Standards and Technology under the Early Detection Research Network of the National Cancer Institute (NCI). Stage 3 was conducted within the framework of a clinical trial. The diagram below outlines the flow of work and the study population used in each stage of assay development:

Stage 1: Discovery

Discovery
30/33 (91%) of prostatectomy samples exhibit the 3.4 kb mtDNA deletion

Pilot Studies (2)
86 patients: 132 cores
- 27 benign patients: 43 benign cores
- 59 malignant patients: 54 malignant cores, 35 PTM cores

Stage 2: Validation

Internal validation
183 patients: 296 cores
- 22 benign patients: 98 benign cores
- 161 malignant patients: 75 malignant cores, 123 PTM cores

External validation (NIST)
Blinded core extracts
- 46 benign core extracts
- 25 malignant core extracts
- 41 PTM core extracts

Stage 3: Clinical Trial

Initial biopsy
- 94 patients with benign histology results
- 553 cores (6 cores per patient; 11 patients with only 5 cores)

Repeat biopsy within one year
- 74 patients with benign histology results
- 20 patients with malignant results

PCMT predicted the outcome of the repeat biopsy with a SEN of 85% and a NPV of 92%.

Genomic deletions within mitochondria begin to happen long before traditional histology can identify disease. Biochemical signatures can identify genomic deletions associated with a disease and predict its onset much earlier than a pathologist can observe a problem, thus creating a greater window of time for treatment possibilities.

- Parr and Martin: Mitochondrial and nuclear genomics and the emergence of personalized medicine. Human Genomics 2012 6:3.

Now you can know more from every biopsy

Receive the early insight you need to tailor patient management. Request the Prostate Core Mitomic Test with your next prostate biopsy pathology.

Learn more about this simple and informative test at mdnalifesciences.com.