Mitomic™ Prostate Core Test

Look beyond the core

The Mitomic™ Prostate Core Test from MDNA Life Sciences

MDNA Life Sciences™

Enhance your prostate biopsy results for better patient management

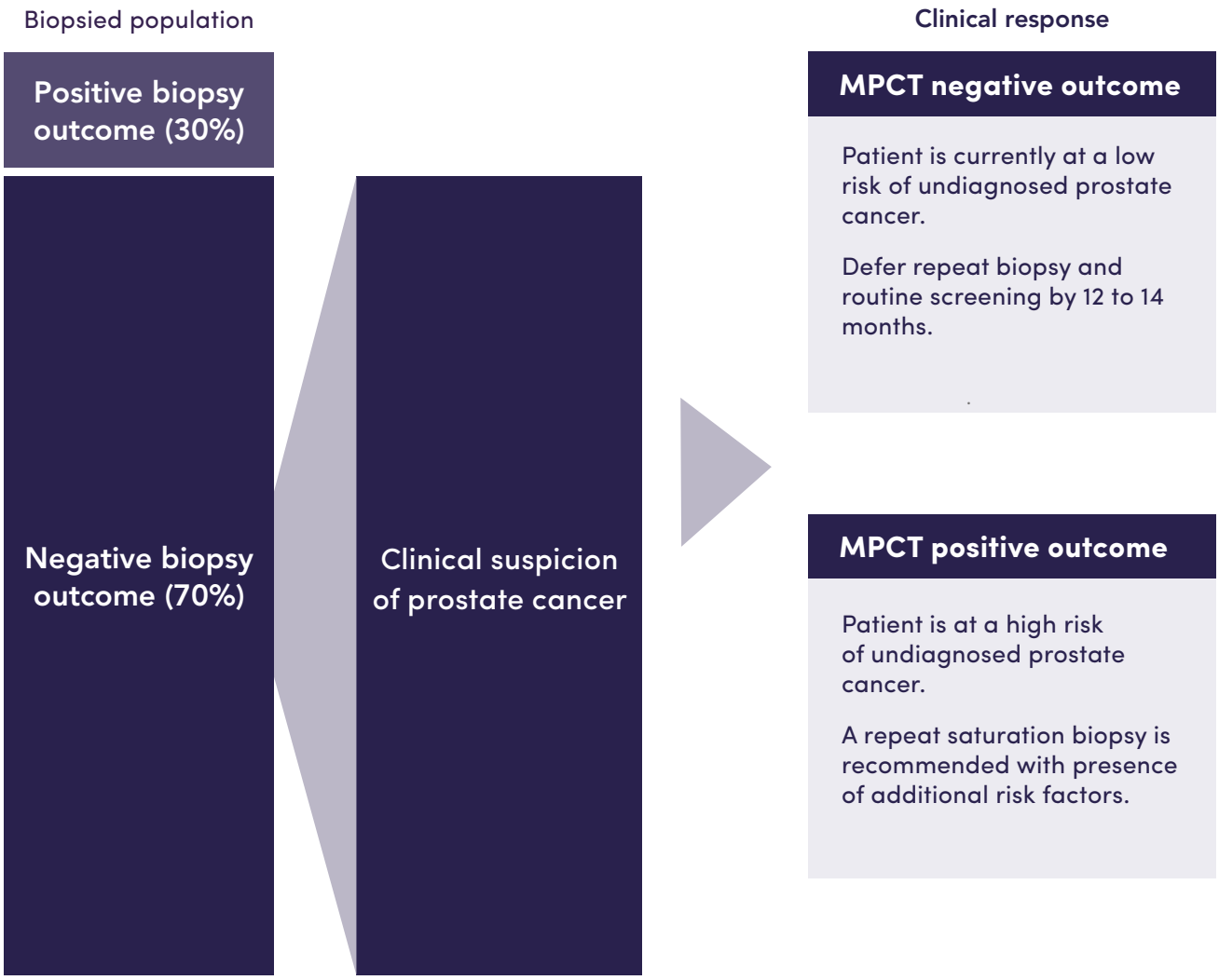
False negative results are common during initial and follow-up biopsy procedures. You're forced to manage false-negative patients in the same manner as those who are negative. But what if you could determine the difference between these patients?

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

What is MPCT?

MPCT 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, MPCT precludes the need for additional office visits or surgeries. You can order MPCT as a reflex test when you submit a biopsy for evaluation or after the biopsy results are available.

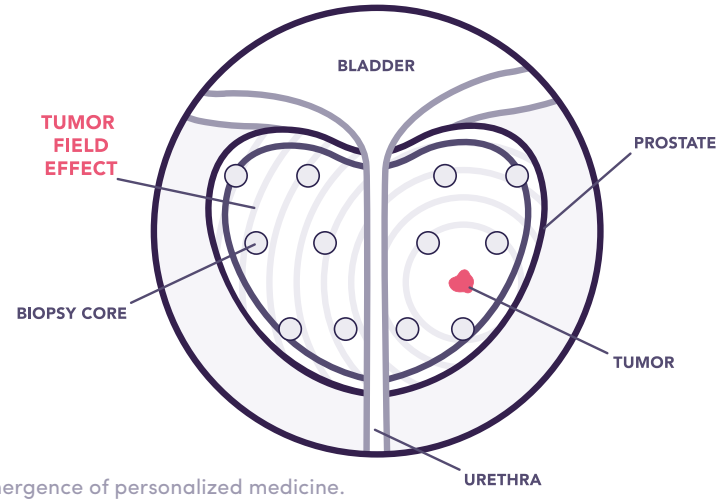
How do you use MPCT?



How does MPCT work?

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

The cancerization field associated with mitochondrial deletions provides a distinct molecular signature that Mitomic Technology 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 Mitomic Technology 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.

MPCT outperforms competitors

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

	MPCT
Sensitivity	85%
Negative predictive value	92%
Field effect extent	Entire prostate
Sample requirement	All negative biopsies require only 20 microns of tissue

Gain an advantage in the fight against prostate cancer

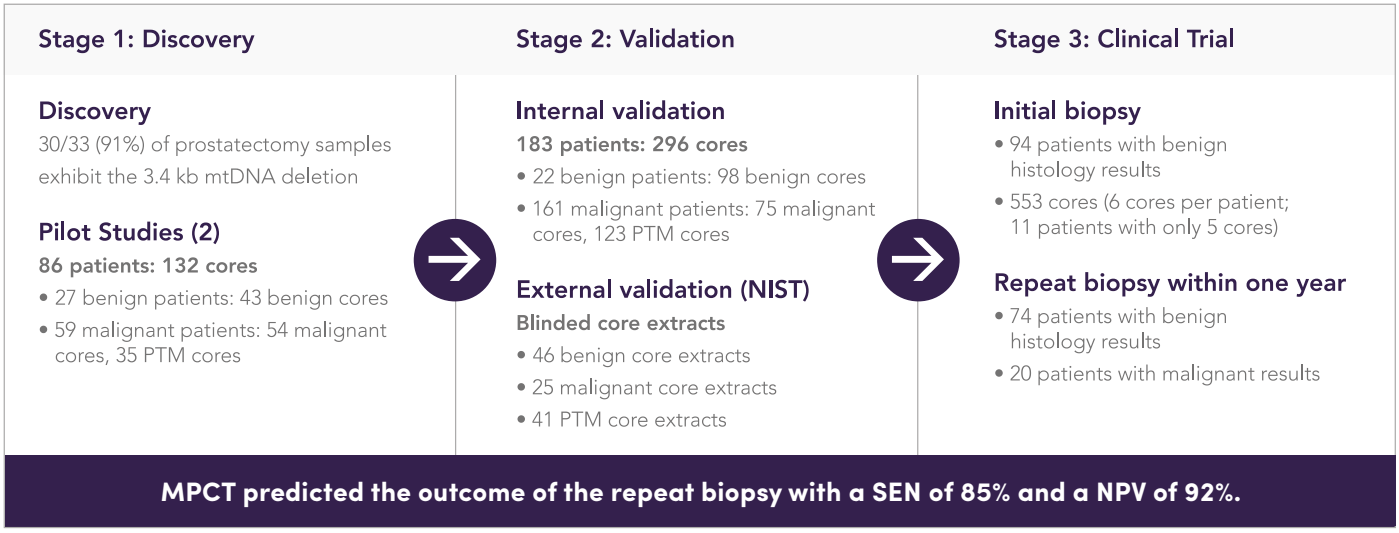
- Be more confident in negative results – and provide peace of mind to patients
- Stratify patients who are free of the disease from those with undiagnosed prostate cancer
- Detect undiagnosed prostate cancer early
- Tailor patient management for improved care
- Avoid causing patients added pain, anxiety,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

Health economic benefits of MPCT

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**

MPCT mtDNA deletion: Stages of discovery and validation

The entire process of discovery and validation involved 302 patients and close to 500 prostate samples. 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:



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 Mitomic Prostate Core Test with your next prostate biopsy pathology.

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

Scientific publications on MPCT

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.

Ryan Parr, Jennifer Creed, Brian Reguly, Cortney Powell, Roy Wittock, Daniel Klein, Andrea Maggrah, Kerry Robinson.* Large-scale mitochondrial genome deletion as an aid for negative prostate biopsy uncertainty. Poster presented as part of the Society of Urologic Oncology Annual Meeting, Bethesda, MD, Dec. 8-10, 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.

Robinson K, Creed J, Reguly B, Powell C, Wittock R, Klein D, et al. Accurate prediction of repeat prostate biopsy outcomes by a mitochondrial DNA deletion assay. Prostate cancer and prostatic diseases. 2010;13(2):126-31. Epub 2010/01/20.

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.

Maki J, Robinson K, Reguly B, Alexander J, Wittock R, Aguirre A, et al. Mitochondrial genome deletion aids in the identification of false- and true-negative prostate needle core biopsy specimens. American Journal of Clinical Pathology. 2008;129(1):57-66. Epub 2007/12/20.

Dakubo GD, Jakupciak JP, Birch-Machin MA, Parr RL. Clinical Implications and Utility of Field Cancerization. Cancer Cell International. 2007;7(2).

Parr RL, Dakubo GD, Crandall KA, Maki J, Reguly B, Aguirre A, et al. Somatic mitochondrial DNA mutations in prostate cancer and normal appearing adjacent glands in comparison to age-matched prostate samples without malignant histology. The Journal of Molecular Diagnostics : JMD. 2006;8(3):312-9. Epub 2006/07/11.

Parr RLM, J.; Reguly, B.; Dakubo, G.D.; Aguirre, A.; Wittock, R.; Robinson, K.; Jakupciak, J.P.;Thayer, R.E.The pseudo-mitochondrial genome influences mistakes in heteroplasmy interpretation. BMC Genomics. 2006;21(7).

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 Mitomic Prostate Core Test

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MDNA Life Sciences
2054 Vista Parkway, Suite 400, West Palm Beach Florida, 33411 USA
T: (+1) 844-321-6362 www.mdnalifesciences.com

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Correct at 12.11.18 - Version 002