

# Detect with confidence

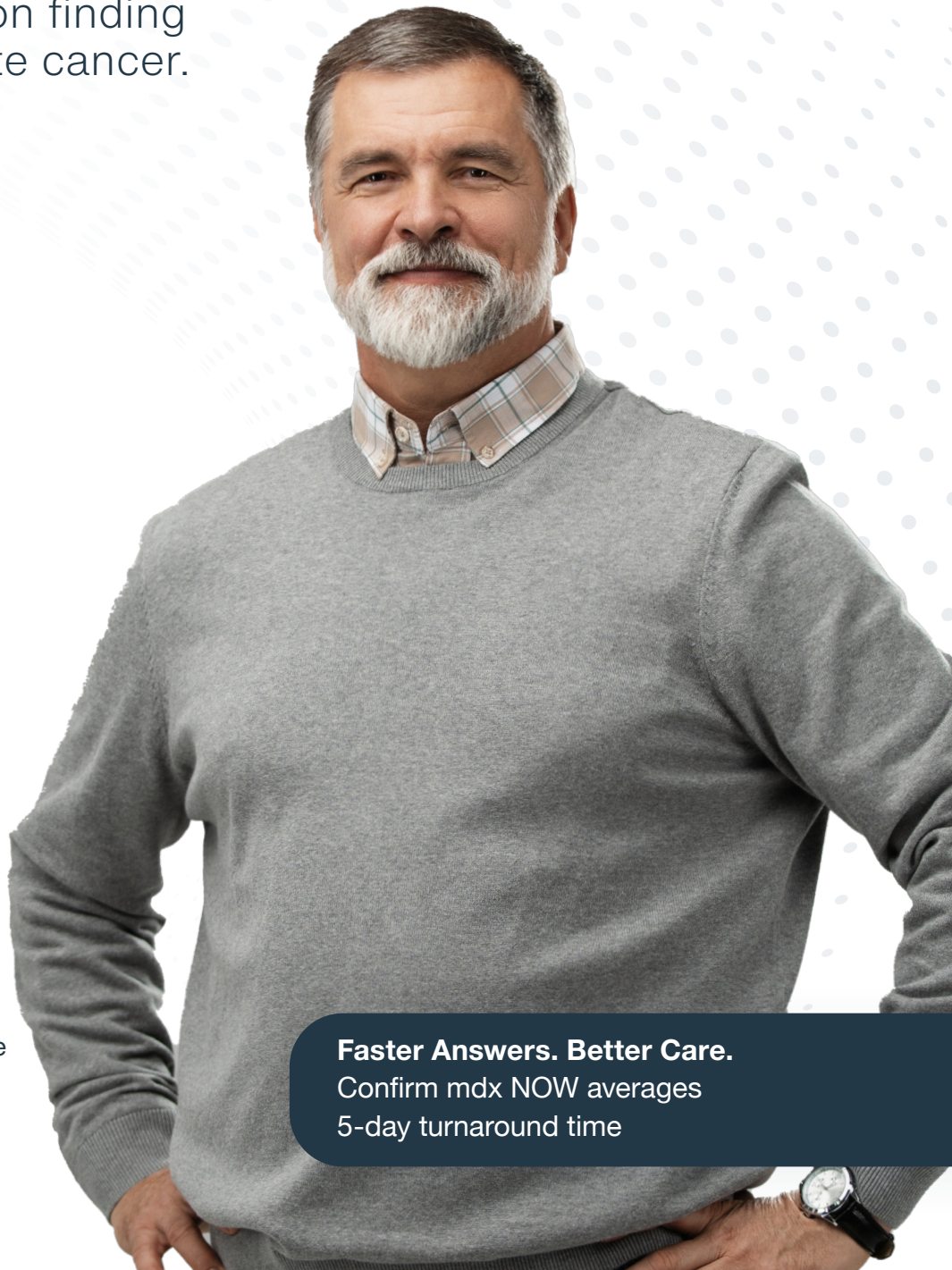
Improves patient stratification so you can focus on finding aggressive prostate cancer.

mdxhealth®

**Superior care made easy.**

Streamline your workflow while maintaining a high level of care. Mdxhealth delivers comprehensive solutions with dedicated support.

**Faster Answers. Better Care.**  
Confirm mdx NOW averages  
5-day turnaround time



# Confirm mdx is a non-invasive epigenetic test that will:



**Rule out** men at decreased risk who could be safely monitored



**Rule in** men at increased risk who may benefit from repeat biopsy or MRI

## Key Benefits



Clinically validated in African American men



Saves the healthcare system \$588 per patient<sup>1</sup>



Specific information for GS $\geq$ 7 (GG $\geq$ 2) prostate cancer

## How it Works

Confirm mdx detects an epigenetic field effect associated with the cancerization process at the DNA level. These changes are indistinguishable under the microscope but can be detected by methylation-specific PCR testing.<sup>2-4</sup>

# 96%

NPV for GS  $\geq$  7 prostate cancer<sup>2-4</sup>

# 90%

NPV for all prostate cancer<sup>2-4</sup>

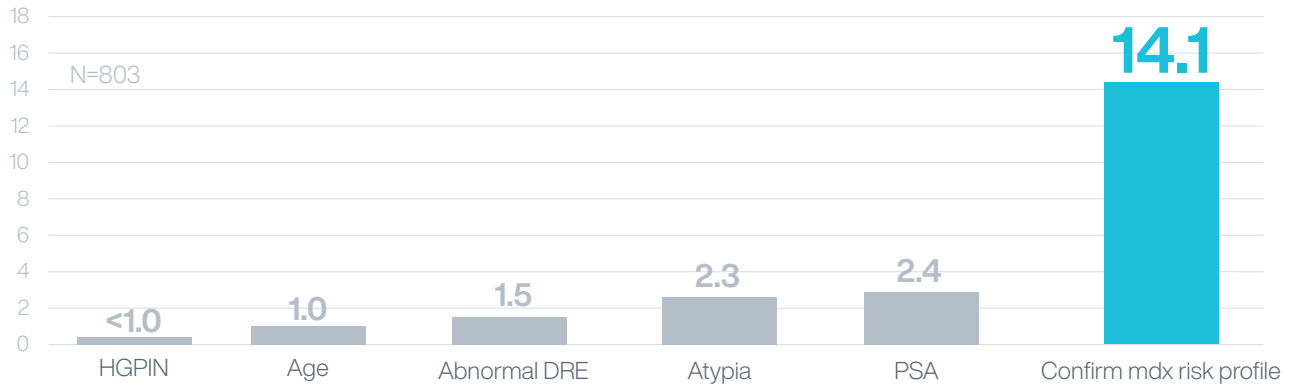
# 55+

studies on genes and technology

# The most significant predictor of prostate cancer detection on repeat biopsy\*

Clinical studies show that after a negative prostate biopsy, Confirm mdx is the single most significant predictor of patient outcome—outperforming clinical risk factors alone.<sup>4</sup>

## Odds Ratio for GS $\geq$ 7<sup>4</sup>



## Actionable binary results

Increase precision in patient stratification after a negative prostate biopsy.<sup>2-5</sup>



## Example Confirm mdx reports

**—** Patient result: DNA methylation negative

DNA methylation status table				Distribution of DNA methylation diagram	
Biopsy site	GSTPI Methylation	APC Methylation	RASSF1 Methylation	Prostate Voxel Diagram	
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		

**+** Patient result: DNA methylation positive

DNA methylation status table				Distribution of DNA methylation diagram	
Biopsy site	GSTPI Methylation	APC Methylation	RASSF1 Methylation	Prostate Voxel Diagram	
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	Negative		
Left Apex	Positive	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	Positive	Positive	Negative		

Xpert One Support is founded on personal attention, responsiveness, and commitment to customer satisfaction. Our Xperts are truly experts on mdxhealth products and processes, from specimen requirements and shipping logistics to clinical insights. Together with your mdxhealth Molecular Diagnostic Specialist, Xpert One Support strives to make your mdxhealth experience the best it can be.

## Comprehensive Solutions, Dedicated Support



### Xpress Response Time

Our goal is to respond to your phone or e-mail inquiry within 24 hours or less.



### Xtraordinary Convenience

Optimize your workflow by customizing your support with specimen shipping, automated supplies replenishment, and more.



### Xpertise On Demand

Answer your questions with clinical resources and industry thought leaders. In addition, our Patient Education Program also provides valuable support to answer questions and educate patients on general prostate health and cancer.



### Xceptional Compassion

Our Patient First Promise ensures MDxHealth tests are accessible and affordable for all patients. If you're facing financial challenges, contact an Xpert One Support patient advocate to find the right assistance options for you.

## Easy to order



mdxhealth obtains archived tissue from pathology



No additional office visit for patient required



Covered by Medicare and most private payors

Get in touch to see how mdxhealth can make your everyday more efficient:



**866-259-5644**



**info@mdxhealth.com**

### References

- 1 Aubrey W, et al. Am Health Drug Benefits. 2013.
- 2 Partin AW, et al. J Uro. 2014.
- 3 Stewart G, et al. J Uro. 2013.
- 4 Van Neste L, et al. Prostate. 2016.
- 5 Waterhouse RL Jr, et al. Urology. 2018.

Mdxhealth is regulated under the Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) as an accredited laboratory to perform high complexity clinical testing. The Confirm mdx for Prostate Cancer test was developed, and its performance characteristics determined by mdxhealth. It has not been reviewed by the U.S. Food and Drug Administration. The FDA has determined such clearance or approval is not necessary. The test is intended for use as an aid to clinicians for patient management decisions about the need for a prostate biopsy on men with clinical risk factors suggesting an increased risk for prostate cancer. Use outside of this indication has not been validated by mdxhealth. Test results should be interpreted in conjunction with other laboratory and clinical data available to the clinician and relevant guidelines on the decision for biopsy.

CLIA# 05D2033858; CAP# 8015399.