

## Why do I need *ConfirmMDx*?

If you have an elevated PSA test result and high risk factors you may have prostate cancer. A prostate biopsy procedure is the best method for your urologist to determine if cancer is present. Although 1 in 6 men are diagnosed with prostate cancer during their lifetime, the vast majority of men have a negative prostate biopsy result.<sup>1</sup>

Unfortunately, today's "gold standard" for diagnosis, the prostate biopsy procedure, only provides a limited evaluation by sampling less than 1% of your entire prostate.<sup>4</sup> Prostate cancer may be present in one or more small tumors, and there is a risk the biopsy needle could have missed it.

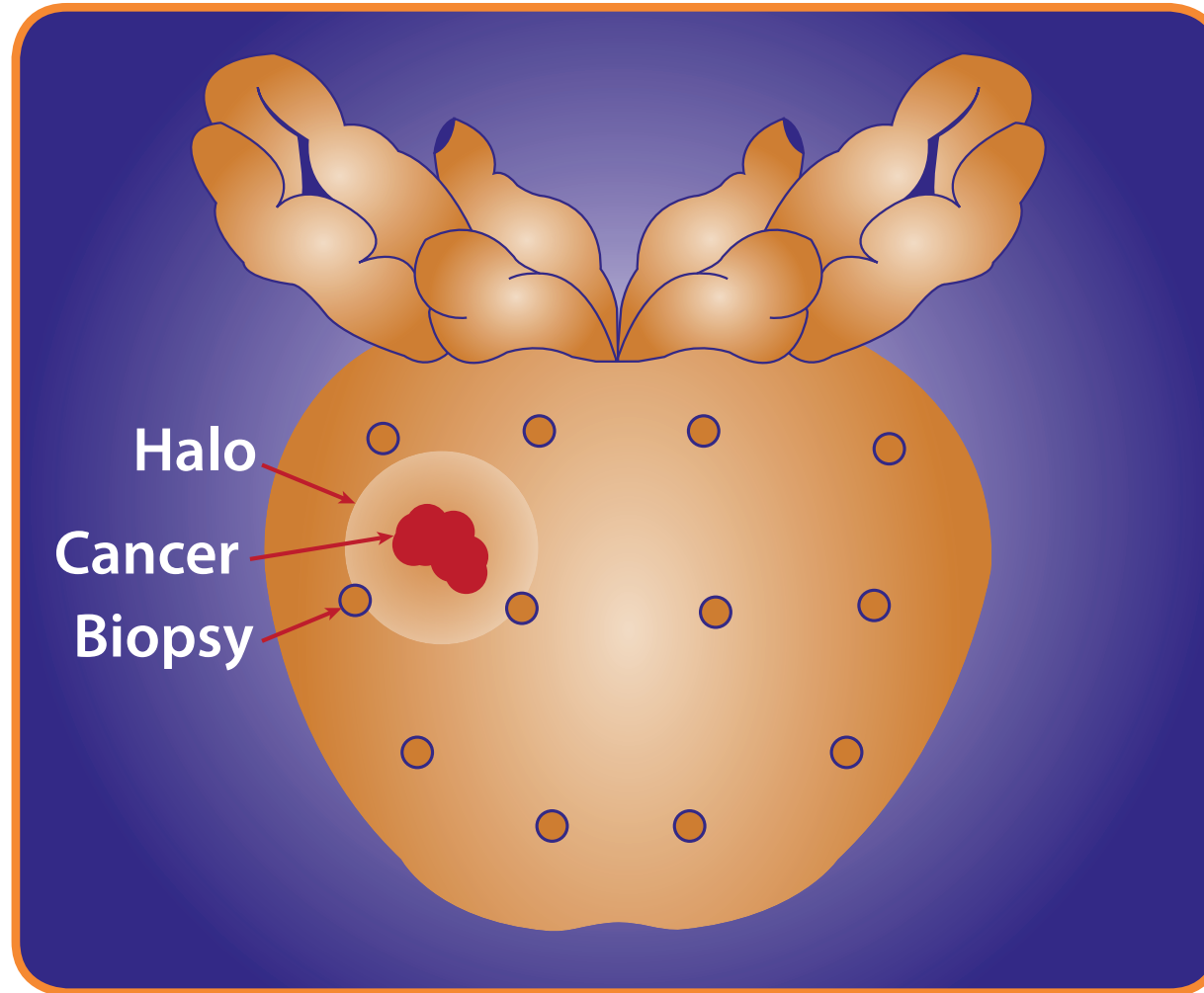
Your urologist may have concerns about your risk for undetected prostate cancer and recommend *ConfirmMDx* to determine your need for a repeat biopsy.

## How does *ConfirmMDx* work?

*ConfirmMDx* works on the DNA level to help identify undetected cancers. The test is able to detect abnormal changes to DNA associated with the presence of prostate cancer.

Since these changes are at the molecular level, they cannot be seen by the standard microscopic evaluation traditionally used for all prostate biopsies.

# *ConfirmMDx*® for Prostate Cancer



*ConfirmMDx* for Prostate Cancer detects a field effect or *halo* associated with the presence of cancer at the DNA level.

This *halo* around a tumor can be detected in prostate cells despite having a normal appearance under the microscope.

## What is my benefit from *ConfirmMDx*?

*ConfirmMDx* can provide your urologist with actionable information that helps:

- Confidently rule out prostate cancer-free men from undergoing unnecessary repeat biopsies.
- Determine if you are at high risk for prostate cancer and may need a repeat biopsy and potential treatment.

## When should I get *ConfirmMDx*?

If you have had a negative prostate biopsy within the past 24 months, ask your urologist if *ConfirmMDx* is right for you. Your doctor can send the remaining tissue samples from your previous prostate biopsy for *ConfirmMDx* testing. *You do not require a repeat biopsy or office visit for this test.*

## Where is *ConfirmMDx* performed?

Your urologist will submit your previously collected, prostate biopsy samples to MDxHealth for testing in its CAP and CLIA accredited laboratory in Irvine, CA. The test will take approximately 2 weeks and then the results will be provided to your urologist.

**For more information and to inquire about having the *ConfirmMDx* for Prostate Cancer test performed, please talk to your doctor.**

**MDxHealth**  
www.mdxhealth.com

References:  
1) Welch H et al: JNCI 2007, 99(18):1395-400 2) Pinsky F et al: BJU International 2007, Apr;99(4):775-9 3) Shen F et al: J Ultrasound Med 2008; 27(6): 895-905  
4) Ross LE et al: Cancer Epidemiol Biomarkers Prev 2008; 17:636-644.



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### Warnings and Precautions

The ConfirmMDx test results should be interpreted in conjunction with other laboratory and clinical data available to the clinician and relevant guidelines in the decision for repeat biopsy. A positive ConfirmMDx test result suggests an increased risk for prostate cancer detection in a repeat biopsy, however it is not a definitive indication of the presence of prostate cancer. Following a positive test result, a repeat prostate biopsy is necessary in order to determine whether cancer is in fact present. A negative ConfirmMDx test result does not guarantee the absence of prostate cancer and does not preclude the possibility of developing cancer in the future. Patients with a negative ConfirmMDx test result should remain under the care and supervision of their urologist with routine screening to mitigate risks associated with delayed cancer detection and treatment.

WHAT IS  
MY RISK FOR  
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BIOPSY?

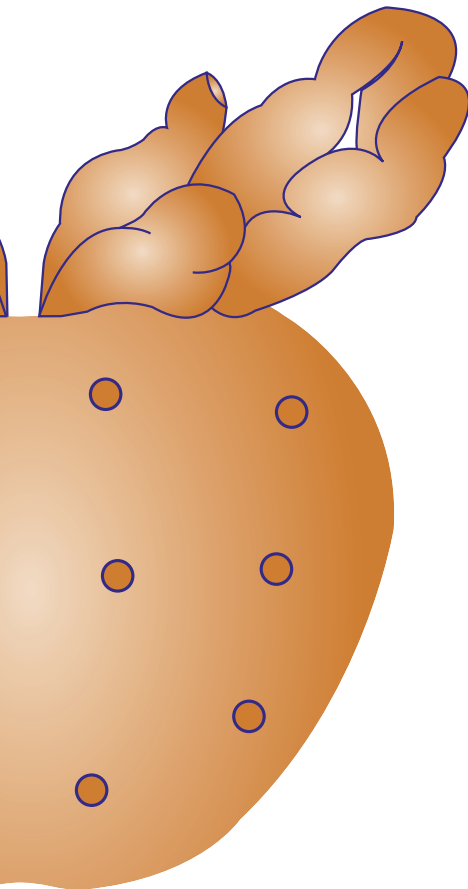
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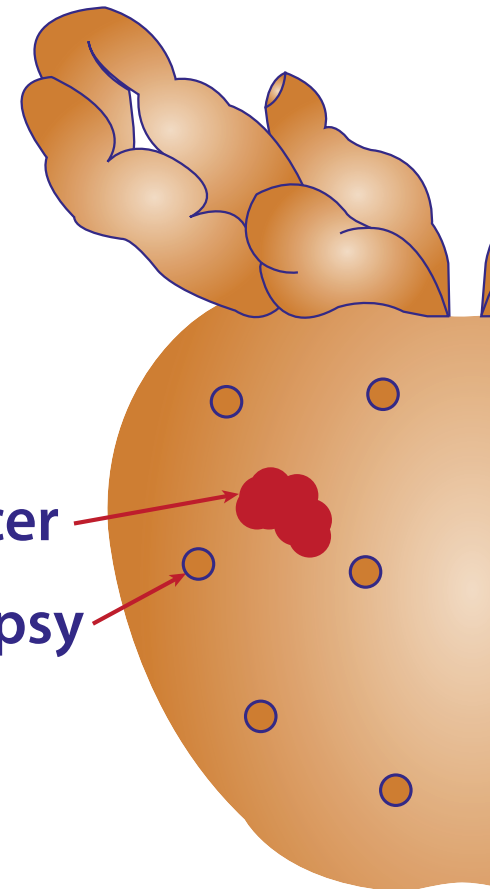


MDxHealth is regulated under the Clinical Laboratory Improvement Amendments (CLIA) and the College of American Pathologists as an accredited laboratory to perform high complexity clinical testing. The ConfirmMDx for Prostate Cancer test was developed and its performance characteristics determined by MDxHealth. This test is intended for use as an aid to clinicians for patient management decisions for the need to perform a repeat biopsy on patients with a previous histopathologically negative biopsy result (benign or HGPIN, but excluding ASAP) within the past twenty-four months and high-risk clinical factors for occult prostate cancer. Use outside of this indication has not been validated by MDxHealth.

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