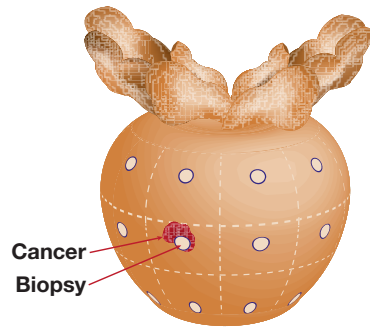


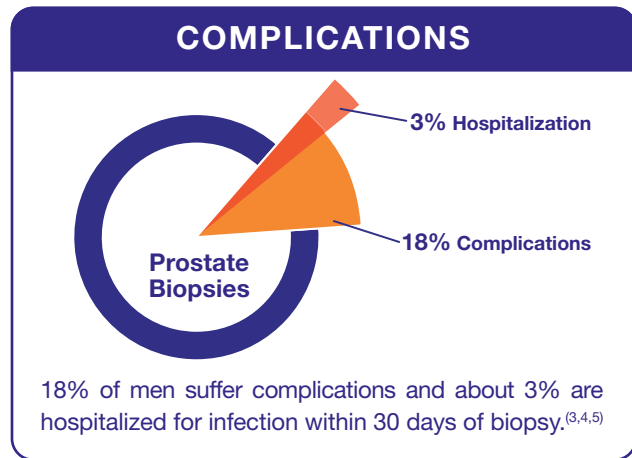
Detecting Prostate Cancer

If you have an elevated PSA test result you may be at risk for prostate cancer. However, an elevated or rising PSA may be caused by benign conditions (non-cancerous) such as prostatitis or benign prostatic hyperplasia (BPH).

Your urologist may recommend a prostate biopsy to determine if you have prostate cancer and if you need treatment.^(1,2) A transrectal ultrasound guided prostate (TRUS) biopsy is the gold standard for the diagnosis of prostate cancer.



Unfortunately, the biopsy procedure is invasive and can result in complications. Common complications from a prostate biopsy may include bleeding, infection, sepsis/bacteremia, urinary symptoms/retention, and sexual dysfunction.



Ask your urologist if the SelectMDx test may help determine your risk for prostate cancer, and if a biopsy is necessary.

SelectMDx[™] for Prostate Cancer

Warnings and Precautions

The SelectMDx for Prostate Cancer test results should be interpreted in conjunction with other laboratory and clinical data available to the clinician and relevant guidelines in the decision for biopsy. The SelectMDx test result may suggest an increased risk for prostate cancer detection in a biopsy. However, it is not a definitive indication of the presence of prostate cancer, a biopsy is necessary in order to determine whether cancer is in fact present. A Very Low Risk SelectMDx 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 Very Low Risk SelectMDx 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.

References:

- 1) American Cancer Society. www.ACS.org 2016
- 2) PSA Test National Cancer Institute <http://www.cancer.gov/types/prostate/psa-fact-sheet>
- 3) Gershman et al.; Eur Uro 2016
- 4) Loeb et al.; Eur Uro 2013.
- 5) Loeb et al.; J Urol. 2011.
- 6) NCI Seer Data 2015. www.seer.cancer.gov/statfacts/html/prost.html

MDxHealth is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. The SelectMDx for Prostate Cancer test was developed and its performance characteristics determined by MDxHealth. It has not been cleared or approved by the US Food and Drug Administration. The 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.

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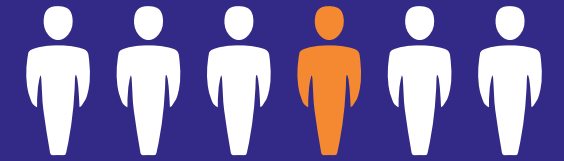
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Do You Have Prostate Cancer?

SelectMDx[™] for Prostate Cancer

A non-invasive test that
only requires a urine sample.

What is your risk for prostate cancer?



1 in 6 men will develop prostate cancer within their lifetime.

1,300,000

men in the US undergo a prostate biopsy every year.

180,000

men will be diagnosed with prostate cancer each year.

Early Detection is Key

98.9%

of men diagnosed with prostate cancer

are alive in 5 years

as compared to only

28%

of men with advanced disease.⁽⁶⁾



Does a high PSA mean I have prostate cancer?

The prostate-specific antigen (PSA) test is the most common method to screen for prostate cancer. A high level of PSA in the bloodstream may be a warning sign for prostate cancer, however it is important to note that there are other non-cancerous causes for an elevated or abnormal PSA level such as benign prostatic hyperplasia (BPH) or prostatitis. Because PSA can be elevated due to a variety of causes, it cannot determine if prostate cancer is present, but may indicate an increased risk for cancer so it is important that you discuss your PSA result with your urologist.

Do I need a prostate biopsy?

If you have an elevated PSA result, your urologist may recommend a prostate biopsy to determine if you have cancer. A prostate biopsy procedure is today's standard of care to assess if cancer is present or not. Although 1 in 6 men will be diagnosed with prostate cancer in their lifetime, the vast majority of men will have a benign (non-cancerous) biopsy result.

Can SelectMDx help determine my risk for aggressive prostate cancer?

The SelectMDx for Prostate Cancer test will provide actionable information to help guide your doctor's decision for a prostate biopsy. If you are at very low risk for aggressive cancer, you may not require a prostate biopsy and may be followed with routine screening. However, if you are at increased risk for aggressive cancer, your urologist may suggest a biopsy, which may improve your chances for early detection and give you more treatment choices.

How does the SelectMDx test work?

SelectMDx is a non-invasive, urine-based (liquid biopsy) test that evaluates the expression of two cancer-related genes. When combined with other clinical risk factors, such as PSA, prostate size, age and family history, the SelectMDx test can help predict the likelihood that prostate cancer will be found by a biopsy and the probability of detecting clinically significant cancer.

Will my insurance cover SelectMDx?

MDxHealth will bill Medicare or your private insurance for the SelectMDx test. You may be responsible for a co-payment, co-insurance, or deductible depending on your health insurance plan and benefits, however the out-of-pocket expense is likely less than the fees associated with a standard prostate biopsy procedure and laboratory review. If you have questions regarding your health insurance coverage, MDxHealth representatives are available from 9:00am to 5:00pm PST, Monday through Friday, toll free at (866) 259-5644 or by email at PatientFirst@MDxHealth.com.

Where can I get the SelectMDx test?

If you have an elevated PSA score or other risk factors for prostate cancer and you are considering a prostate biopsy, ask your urologist about getting the SelectMDx test. Your urologist can collect a urine sample on your next office visit and send it for testing at MDxHealth's state-of-the-art CLIA-accredited, CAP-certified laboratory in Irvine, California.

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

SelectMDx Can Help Determine Your Need for a Biopsy

It is important to understand your risk for aggressive, potentially lethal, prostate cancer. SelectMDx can provide you and your urologist better insight on your personal risk and need for a prostate biopsy. If you are at very low risk for aggressive cancer, you may be followed with routine screening. If you are at high risk, you may benefit from a prostate biopsy and early detection.

SelectMDx[™]
for Prostate Cancer

