



Patient
Information

The 4Kscore[®] Test

A BLOOD TEST FOR ASSESSING THE PROBABILITY OF
AGGRESSIVE PROSTATE CANCER



**BETTER INFORMATION LEADS
TO CONFIDENT DECISIONS**

1 in 8 men will be diagnosed with prostate cancer in their lifetime.¹

You have received an abnormal total PSA or DRE result...what's next?

There is a blood test to assess the probability of the presence of high grade prostate cancer...

The 4Kscore[®] Test

Prostate Cancer: Indolent vs. Aggressive

Prostate cancer is one of the most common cancers and a leading cause of cancer death in men. Many prostate cancer cells stay within the prostate gland and never spread. These are called indolent or slow growing prostate cancers. However, there are aggressive, fast growing cancer cells that spread to other parts of the body. This is why early detection and accurate diagnosis of prostate cancer is critical for optimal management of the disease.

Screening and Diagnosis of Prostate Cancer

Prostate cancer screening is recommended for men age 45 and older. Your doctor will perform a Prostate Specific Antigen (PSA) blood test and/or a digital rectal exam (DRE) to screen for signs of prostate cancer.

However, PSA and DRE tests are not sensitive to detect the presence of prostate cancer. After an abnormal PSA or DRE test, the NCCN Guidelines recommend biomarker tests like The 4Kscore[®] Test, which could improve the sensitivity for detecting high grade prostate cancer if a biopsy was to be performed.

A large, multi-center US trial recently found that the majority of prostate biopsy results are either negative for cancer or show the presence of the slow growing type of prostate cancer.²

Intended Use Population

The 4Kscore Test is indicated for men who have no previous prostate biopsy or have history of prior negative biopsy and are considering prostate biopsy because of an abnormal age-specific total PSA and/or DRE result. The intended use population is:

- Men 45-54 years old and total PSA ≥ 2 ng/mL and/or abnormal DRE
- Men 55-75 years old and total PSA ≥ 3 ng/mL and/or abnormal DRE
- Men ≥ 76 year old and total PSA ≥ 4 ng/mL and/or abnormal DRE

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Indication of Use

The 4Kscore Test is indicated for use with other patient information as an aid in the decision for prostate biopsy in men 45 years of age and older who have an abnormal age-specific total PSA and/or abnormal DRE.

- A 4Kscore < 5.0 is associated with decreased likelihood of a Gleason score ≥ 7 on biopsy.
- The 4Kscore Test is intended to provide the probability of finding aggressive prostate cancer (Gleason score ≥ 7 /Gleason Grade Group ≥ 2) in a patient for whom a biopsy would be recommended by a urologist, based on current standards of care.
- The test is not recommended more than once every 6 months.
- The test is intended for professional use only.
- Only a prostate biopsy can diagnosis cancer.



Please consult with your physician to find out if The 4Kscore® Test could help your decision to have a prostate biopsy.

Your physician should ensure that The 4Kscore Test is reasonable and medically necessary for you.

Use of The 4Kscore Test is not advised if you:

- Have been previously diagnosed with prostate cancer
- Have a digital rectal exam (DRE) performed in the 96 hours before a scheduled blood draw
- Have taken 5-alpha reductase inhibitor medication within previous 6 months
- Have had an intervention procedure of the prostate within the last 6 months

NOTE: Biotin (>5 mg/day) may cause interference with assays that are components of The 4Kscore Test and may lead to a false result. Please abstain from taking supplements containing biotin for three days prior to having The 4Kscore Test.

How Much Does a 4Kscore Test Cost?

Coverage for all laboratory tests depends on your particular insurance company. For those who do not have insurance, or who choose to pay out-of-pocket, The 4Kscore® Test is offered at an affordable price.

For more information, please contact the 4Kscore Test Customer Service Hotline.

The 4Kscore Test CUSTOMER SERVICE HOTLINES

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REFERENCES

1. American Cancer Society. <https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html>
2. Parekh et al. A multi-institutional prospective trial in the USA confirmed that the 4Kscore accurately identifies men with high-grade prostate cancer. Eur Urol. 2015;68(3):464-470

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