4Kscore®
Solving the PSA Dilemma
PSA DANGER ZONE

Prostate cancer rates are 15-fold higher in patients with PSA ≥1.5 ng/mL

**TRADITIONAL METHODS OF AGGRESSIVE PROSTATE CANCER DETECTION**

**Prostate Specific Antigen (PSA)**

**ADVANTAGES**
- Screening has caused an almost 50% decrease in metastatic prostate cancer over the last 20 years

**DISADVANTAGES**
- Conditions such as benign prostatic hypertrophy (BPH), prostatitis, and trauma can all cause elevated PSA levels
- Conflicting guidelines for prostate cancer screening may cause confusion for providers

**CONSEQUENCES**
- Many patients undergo unnecessary prostate biopsies which can result in overtreatment of indolent cancer
- Reduction in screening due to conflicting guidelines may lead to missing patients with aggressive prostate cancer

**Prostate Biopsies**

**ADVANTAGES**
- Can help identify men with high grade, aggressive prostate cancer

**DISADVANTAGES**
- May lead to overtreatment of patients with indolent cancer
- About 75% of all prostate biopsies will have low grade cancer or no cancer at all

**CONSEQUENCES**
- Approximately 66% of patients who are found with indolent, non-life threatening cancer on biopsy go on to have radical, unnecessary procedures
- Biopsies can result in serious complications such as infection, bleeding, and urinary retention

_A follow-up blood test is needed to help discriminate between aggressive prostate cancer, indolent prostate cancer, and no cancer in men who have an abnormal PSA_

*4Kscore® is the solution*

**PERFORMANCE COMPARISON OF AVAILABLE BLOOD TESTS IN PREDICTING AGGRESSIVE PROSTATE CANCER**

<table>
<thead>
<tr>
<th>Test</th>
<th>Total PSA</th>
<th>PHI1, 8</th>
<th>PCA3</th>
</tr>
</thead>
<tbody>
<tr>
<td>4Kscore Test</td>
<td>0.69</td>
<td>0.72</td>
<td>0.68</td>
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</tbody>
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*Accuracy reflected by Area Under the Curve (AUC)*
4Kscore

Accurately identifies risk for aggressive prostate cancer

**ACCURACY**

Detects men with high-grade prostate cancer who would benefit from referral and treatment

**QUALITY CARE**

Identifies patients who can safely avoid prostate biopsies to reduce overtreatment and patient discomfort

**COST SAVINGS**

Reduces unnecessary biopsies and overtreatment of indolent prostate cancer saving the healthcare system billions of dollars

**EASE OF ORDERING**

Requires only one tube of blood allowing you to reflex the 4Kscore test off of an abnormal PSA to help guide follow-up or referral

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**HOW THE 4Kscore TEST WORKS**

**COMPONENTS**

- 4 Kallikrein Biomarkers
- Total PSA
- Free PSA
- Intact PSA
- bK2
- Plus age, medical history, and optional DRE

**RESULTS**

Percent risk of having aggressive prostate cancer for an individual patient

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**OPTIMIZING THE PROSTATE CANCER CARE PATHWAY**

Suspicion of malignancy based on abnormal PSA or DRE

4Kscore

- Low Risk 4Kscore Result of <7.5%
- Moderate or High Risk 4Kscore Result of ≥7.5%

Continue to follow

Consult or refer to urologist for biopsy

The 4Kscore Test is included in the 2015 NCCN Guidelines as a follow-up to help improve the specificity of PSA
HIGHLIGHTS AND REFERENCES:

Test Code: J254-4 - PSA Reflex to 4Kscore ≥1.5 ng/mL  
J264-3 - PSA Reflex to 4Kscore ≥3 ng/mL  
J148-8 - 4Kscore Test

Methodology: Immunoassay

Preferred Specimen: 1 SST (4mL minimum)

Collection Instructions: Fill tube, invert gently 2-3 times, let stand for 20 minutes, spin for 10-15 minutes and label with patient name

Storage Instructions: Refrigerated

Specimen Stability: 3 Days

TAT: 3 Days

RESULTS INTERPRETATION:

Based on the 4Kscore Test US validation study, prostate biopsy should be considered in most men with a 4Kscore result of 7.5% or higher. Reference ranges are as follows:

- Low Risk: 4Kscore result <7.5%
- Intermediate Risk: 4Kscore result 7.5-19%
- High Risk: 4Kscore result ≥20%

Patient management should be based on clinical judgment. Other clinical information (health status, medical history, family history of prostate cancer, PSA history, etc.) along with the 4Kscore Test result should be considered in the shared physician and patient decision regarding prostate biopsy.

LIMITATIONS AND EXCLUSIONS:

Do not use the 4Kscore Test for a patient:

- With a previous diagnosis of prostate cancer
- That has received a DRE in the previous 96 hours (4 days) before phlebotomy. A DRE performed after the phlebotomy is acceptable
- That has received 5-alpha reductase inhibitor (5-ARI) therapy, such as Avodart® (dutasteride) or Proscar® (finasteride), within the previous six (6) months
- That has undergone any procedure or therapy to treat symptomatic BPH or any invasive, urologic procedure that may be associated with a secondary PSA elevation prior to phlebotomy within the previous six (6) months

REFERENCES


