THE ONLY BLOOD TEST THAT ACCURATELY IDENTIFIES RISK FOR AGGRESSIVE PROSTATE CANCER.

Early Detection of Aggressive Prostate Cancer Challenges

- Serum PSA has a high false positive rate
- Over 1 million prostate biopsies performed annually in US
- 75% of biopsies will have low-grade, indolent (Gleason 6) or no prostate cancer
- Serious complications of biopsies include infection and hospitalization
- Overtreatment - 75% of Gleason 6 indolent cancers at prostate biopsy are confirmed at radical prostatectomy
- Recommendation by USPSTF to stop PSA screening misses an opportunity to detect and treat men with high grade (Gleason ≥7), the aggressive form of prostate cancer

What is the 4Kscore Test?

The 4Kscore Test combines four prostate-specific kallikrein assay results with clinical information in an algorithm that calculates the individual patient’s percent risk for aggressive prostate cancer.

Components

- Total PSA
- Free PSA
- Intact PSA
- hK2
- + Age, DRE, and prior biopsy status

OPKO ALGORITHM

Results

% risk of having aggressive prostate cancer for an individual patient
Prospective, Blinded, Multicenter US Study Validates 4Kscore Test

1,012 patients enrolled in 26 centers for validation (Oct. 2013 to Apr. 2014)
Men scheduled for biopsy regardless of PSA, age, DRE status, prior biopsy
TRUS Biopsy of ≥ 10 cores
Excluded for treatments known to influence PSA levels
OPKO Lab developed and performed the 4Kscore Test
Pathology conducted according to the established practice at each center
As presented in the AUA Plenary Session May, 2014; publication pending

Clinical Study Sites

Gleason Score Distribution in Prospective US Study

<table>
<thead>
<tr>
<th>Gleason Grade</th>
<th>N</th>
<th>% All Cancers N=470</th>
<th>% All Patients N=1,012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>542</td>
<td>--</td>
<td>53.6%</td>
</tr>
<tr>
<td>6</td>
<td>239</td>
<td>50.9%</td>
<td>23.6%</td>
</tr>
<tr>
<td>7 (3+4)</td>
<td>108</td>
<td>23.0%</td>
<td>10.7%</td>
</tr>
<tr>
<td>7 (4+3)</td>
<td>59</td>
<td>12.6%</td>
<td>5.8%</td>
</tr>
<tr>
<td>8</td>
<td>35</td>
<td>7.4%</td>
<td>3.5%</td>
</tr>
<tr>
<td>9</td>
<td>26</td>
<td>5.5%</td>
<td>2.6%</td>
</tr>
<tr>
<td>10</td>
<td>3</td>
<td>0.6%</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

Summary

- **77.2%** Negative or Gleason 6 prostate cancer
- **22.8%** Aggressive (Gleason ≥ 7) prostate cancer
The **4Kscore Test** Has the Greatest Accuracy for Predicting Aggressive Prostate Cancer

The higher AUC, the better the accuracy for predicting aggressive prostate cancer.

AUC = area under the curve


The Risk of Aggressive Prostate Cancer Predicted by the 4Kscore Test is Confirmed by Prostate Biopsy

Legend:

- - - - - Aggressive prostate cancer detected by biopsy

n=1012
The 4Kscore Test Summary

- Clinical utility was validated based on a decade of clinical research with the 4Kscore Test biomarkers in over 20,000 men in Europe and the United States
- Identifies the actual risk of aggressive prostate cancer for the individual patient
  - High grade prostate cancer pathology
  - Poor prostate cancer clinical outcomes within 20 years
- Has high sensitivity and high negative predictive value for aggressive prostate cancer
- The only blood test that accurately identifies risk for aggressive prostate cancer

www.4Kscore.com
(877) 922-8364