

# 4Kscore<sup>®</sup>

*Making informed decisions  
from accurate identification*



**genpath**  
an **OPKO** Health Company

# 4Kscore<sup>®</sup>

Included in the 2015 guidelines  
for Prostate Cancer Early Detection

## DILEMMA

Eighty percent of men who undergo a prostate biopsy are found to have either no cancer or an indolent form of cancer

## SOLUTION

The 4Kscore Test is the most accurate blood test for predicting aggressive prostate cancer, allowing for better informed patient care decisions

### HOW THE

### 4Kscore TEST

### WORKS\*

PROPRIETARY  
TO OPKO

### COMPONENTS

4 Kallikrein Biomarkers

Total PSA

Free PSA

Intact PSA

hK2

Plus age, history of previous  
biopsy, and DRE

4Kscore  
ALGORITHM

### RESULTS

Percent risk of  
having *aggressive*  
prostate cancer  
for an individual  
patient

## OPTIMIZING THE PROSTATE CANCER CARE PATHWAY

Suspicion of  
malignancy based  
on abnormal PSA  
or DRE

4Kscore

Low-Risk 4Kscore  
Result of <7.5%

Intermediate or High-Risk  
4Kscore Result of ≥7.5%

Continue to follow

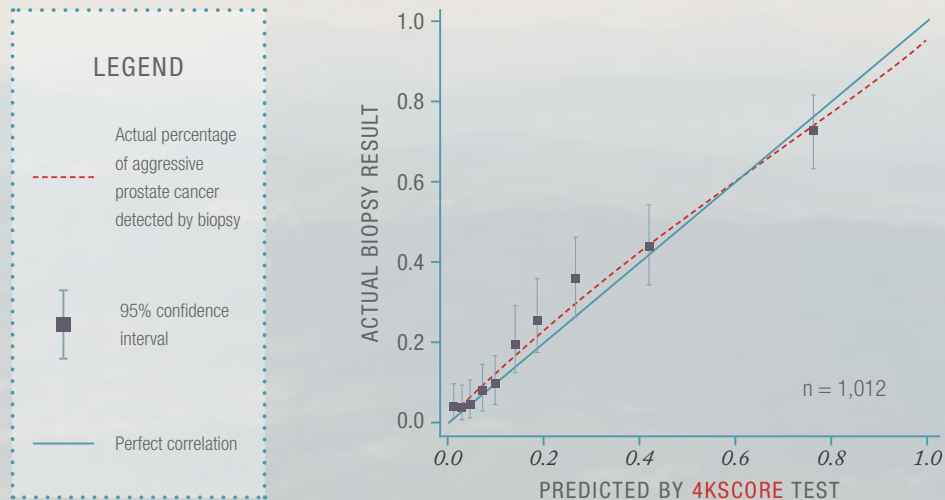
Additional evaluation  
as appropriate

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 biopsy.

# EXCELLENT DIAGNOSTIC PERFORMANCE

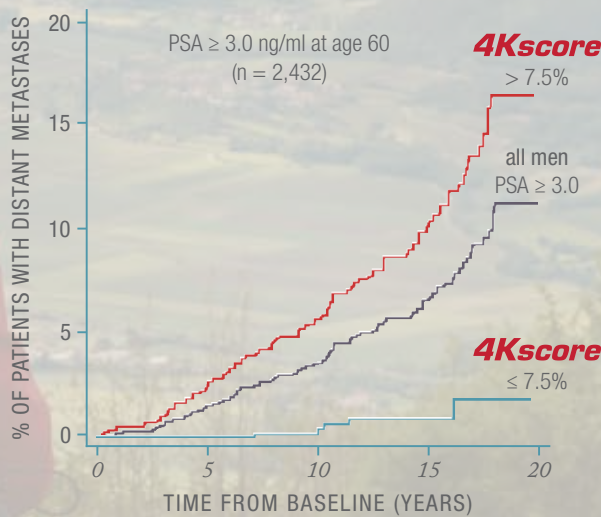
*Allows focused care on high-risk patients  
while avoiding excessive management of low-risk patients*

## THE RISK OF AGGRESSIVE PROSTATE CANCER PREDICTED BY THE 4KSCORE TEST IS CONFIRMED BY PROSTATE BIOPSY<sup>1</sup>



*The 4Kscore Test predicts the risk of aggressive prostate cancer, identifying men most likely to benefit from prostate biopsy*

## THE 4KSCORE TEST PREDICTS THE PROBABILITY OF DISTANT METASTASES WITHIN 20 YEARS<sup>2</sup>



**4Kscore Test Biomarkers**  
 $>$  7.5% (N = 1,510, 62%)

5 year = 2.4%  
10 year = 5.6%  
15 year = 9.9%  
20 year = 16.4%

all men PSA  $\geq$  3

**4Kscore Test Biomarkers**  
 $\leq$  7.5% (N = 922, 38%)

5 year = 0%  
10 year = 0.2%  
15 year = 1.0%  
20 year = 1.8%

*The 4Kscore helps reassure prostate biopsy decisions*



## NOT INDICATED FOR MEN WHO:

1. Have a previous diagnosis of prostate cancer.
2. Have received a DRE in the previous 96 hours (four days) before phlebotomy. A DRE performed after the phlebotomy is acceptable.
3. Are taking or have taken 5-alpha reductase inhibitors within the last 6 months.
4. Have undergone a prostate procedure within the last 6 months.

# OPKO

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## REFERENCES

1. Parekh DJ, et al. A Multi-institutional Prospective Trial in the USA Confirms that the 4Kscore Accurately Identifies Men with High-grade Prostate Cancer. *Eur Uro* 2015;68;464-470.
2. Stattin, et al. Improving the Specificity of Screening for Lethal Prostate Cancer Using Prostate-specific Antigen and a Panel of Kallikrein Markers: A Nested Case -- Control Study. *Eur Urol* 2015; 68 (2): 207-213.
3. Voigt JD, et al. The Kallikrein Panel for prostate cancer screening: its economic impact. *Prostate* 2014;74;250-9.

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