

# 4Kscore<sup>®</sup>

*Solving the PSA Dilemma*



**BioReference**  
LABORATORIES  
an **OPKO** Health Company

# TRADITIONAL METHODS

## *of Prostate Cancer Detection*

### *Prostate Specific Antigen (PSA)*

#### ADVANTAGES

- Screening has caused an almost 50% decrease in metastatic prostate cancer over the last 20 years<sup>1</sup>

#### DISADVANTAGES

- Benign prostatic hyperplasia (BPH), prostatitis, and trauma can all cause elevated PSA levels
- PSA is not highly specific and cannot distinguish between aggressive and indolent forms of prostate cancer

#### CONSEQUENCES

- Many patients undergo unnecessary prostate biopsies resulting in overtreatment of indolent cancer<sup>2</sup>
- Conflicting guidelines for prostate cancer screening may cause confusion for patients and providers

### *Prostate Biopsies*

#### ADVANTAGES

- The current standard of care in prostate cancer diagnosis

#### DISADVANTAGES

- May lead to overtreatment of patients with indolent cancer
- Misses or undergrades prostate cancer 20-30% of the time<sup>3</sup>

#### CONSEQUENCES

- The majority of men found to have indolent disease on biopsy still undergo unnecessary surgery or therapies<sup>4,5</sup>
- Unnecessary biopsies and treatments can result in significant complications and morbidity including sepsis<sup>6</sup>

### PSA DANGER ZONE

*Men with a PSA between 1.5 and 4.0 ng/mL are at a 15-fold higher risk for prostate cancer than those with PSA levels below 1.5 ng/mL<sup>7</sup>*

### PERFORMANCE COMPARISON OF AVAILABLE BLOOD TESTS IN PREDICTING AGGRESSIVE PROSTATE CANCER ON BIOPSY

	4Kscore Test <sup>3</sup>	Total PSA <sup>3</sup>	PHI <sup>7,8</sup>
Accuracy*	0.82	0.69	0.72

\*Accuracy reflected by Area Under the Curve (AUC)

# 4Kscore®

*Accurately identifies risk for aggressive prostate cancer*

## ACCURACY

Distinguishes men with a low risk of having aggressive prostate cancer on biopsy from those with a high risk

## QUALITY CARE

Men with a low risk of aggressive prostate can safely avoid prostate biopsy and be followed by their primary care physician

*Men with a low risk 4Kscore have a 99% chance of not having metastatic prostate cancer within 10 years<sup>10</sup>*

## COST SAVINGS

Reduces unnecessary biopsies and overtreatment of indolent prostate cancer saving the healthcare system billions of dollars<sup>11</sup>

## EASE OF ORDERING

Can be run on the same blood sample as a PSA, eliminating the need for additional blood draws

## HOW THE 4Kscore TEST WORKS

PROPRIETARY TO OPKO

## COMPONENTS

4 Kallikrein Biomarkers  
Total PSA  
Free PSA  
Intact PSA  
hK2

Plus age, previous biopsy results, and optional 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%*

*Continue to follow*

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

*Consult or refer to urologist for biopsy*

*The 4Kscore Test is included in prostate cancer early detection guidelines as a follow-up test to help improve the specificity for PSA, and should be a part of an overall evaluation for prostate cancer risk.<sup>12</sup>*

## HIGHLIGHTS AND REFERENCES:

Test Code: J254-4: PSA Reflex to 4Kscore  $\geq 1.5$  ng/mL

J264-3: PSA Reflex to 4Kscore  $\geq 3$  ng/mL

K136-2: PSA, Total & Free Reflex to 4Kscore  $\geq 1.5$  ng/mL

K135-4: PSA, Total & Free Reflex to 4Kscore  $\geq 3$  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

Turnaround Time: 3 Days

Required Patient Information (AOE): Prior biopsy history

## 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  $\geq 20\%$

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.

## EXCLUSIONS:

Not indicated for men who:

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

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