The 4Kscore® Test

Requisition Completion Guide

1 Patient & Billing Information

Please **complete** the Patient and Billing Information sections. You **must provide Patient name and date of birth** on the requisition even if you attach Face Sheet or Demographic Sheet.

PATIENT

PATIENT ID (ENTRIES WILL SHOW ON REPORT) | COMMENTS

NAME, LAST (Please Print) | FIRST | M.I.

STREET | APT. #

CITY | STATE | ZIP | DATE OF BIRTH MM|DD|YYYY | AGE | M/F

SPECIMEN COLLECTION DATE MM|DD|YYYY | SPECIMEN COLLECTION TIME ☐ AM ☐ PM

RACE/ETHNICITY: ☐ AFRICAN-AMERICAN ☐ ASIAN ☐ CAUCASIAN ☐ HISPANIC ☐ OTHER: _____

PATIENT CELL PHONE NO. | PATIENT HOME PHONE NO. | PATIENT EMAIL

BILLING INFORMATION

BILL TO: ☐ INSURANCE ☐ PATIENT ☐ CLIENT ☐ MEDICARE ☐ MEDICAID ☐ TRICARE

ALL INSURANCES RELATION TO SUBSCRIBER: ☐ CHILD ☐ SELF ☐ SPOUSE ☐ OTHER: _____

INSURANCE CARRIER | INSURANCE ID # | GROUP #

SUBSCRIBER'S NAME | DATE OF BIRTH MM|DD|YYYY

INSURANCE ADDRESS | CITY | STATE | ZIP

SECONDARY INSURANCE CARRIER | INSURANCE ID # | GROUP #

DX CODE | DX CODE | REFERRING PROVIDER (SOURCE OF REFERRAL)

PATIENT STATUS – ONE MUST BE CHECKED

☐ HOSPITAL INPATIENT ☐ HOSPITAL OUTPATIENT ☐ NOT A HOSPITAL PATIENT

HOSPITAL PATIENT DATE OF DISCHARGE ____/____/____

2 Shared Decision Making

BOTH Provider and Patient signatures, legible names, and dates are required to acknowledge shared decision making discussion.

SHARED DECISION MAKING

Patient Acknowledgment: By signing this form, I acknowledge that I have had a detailed discussion with my healthcare provider on the risks and benefits of The 4Kscore Test and reviewed the shared decision aid on the back of this form. This included a discussion of why The 4Kscore Test was being ordered, my other options including prostate biopsy, and potential risks of getting The 4Kscore Test. After this review and discussion, I understand and agree with the recommendation to order The 4Kscore Test.

Print Patient Name: _____ Patient Signature: _____ Date: _____

Physician Acknowledgement: By submitting this test requisition and accompanying sample(s), I certify that a shared decision making discussion occurred with the patient about The 4Kscore Test. This included a discussion of the medical risks and benefits of The 4Kscore Test, other management options including undergoing a prostate biopsy, and potential risks for this management plan. After this discussion, the patient has agreed that The 4Kscore Test is the best option for him.

I authorize and direct you to perform the testing indicated and confirm that; (i) I am authorized by state law to order the test(s) requested herein; (ii) any test requested on this test requisition form is reasonable and medically necessary for the diagnosis and/or treatment of a disease, illness, impairment, symptom, syndrome or disorder; (iii) the test results will aid in determining the medical management and treatment decisions for this patient's condition on this date of service; and (iv) the full and appropriate diagnosis code(s) are indicated to the highest level of specificity.

Print Provider Name: _____ Provider Signature: _____ Date: _____

3 Clinical Information

Each of the three AOEs **must have one box checked.**

CLINICAL INFORMATION REQUIRED TO PERFORM THE 4KSCORE® TEST

1. Clinical Indication for Ordering The 4Kscore Test:

Selecting a value below confirms that the patient had two or more elevated PSA results within the past two years. Note: The 4Kscore Test should only be ordered when medically reasonable for consideration of biopsy after excluding benign cause of PSA elevation.

☐ 45-54 years old and total PSA ≥2 ng/mL ☐ 55-75 years old and total PSA ≥3 ng/mL ☐ ≥76 years old and total PSA ≥4 ng/mL

2. Prostate Biopsy History:

☐ No prior biopsy ☐ Yes, prior negative biopsy ☐ **Yes, prior positive biopsy (4Kscore test will not be performed)**

3. DRE Result:

☐ Nodule ☐ No Nodule

4 4Kscore® Test Codes

Only one 4Kscore test code must be selected:

- **J148-8 is the primary test code to order 4Kscore** (Serum Separator Tube).
- J149-6 is for plasma specimen (K2EDTA Tube).
- J246-3 should only be used for patient with only one elevated PSA result within the past two years.

4KSCORE TEST CODES

The 4Kscore® Test

J148-8 ☐ The 4Kscore Test (Serum)

J149-6 ☐ The 4Kscore Test (K2EDTA Plasma)

J264-3 ☐ 4Kscore Reflex on age-stratified elevated PSA value (See age-stratified elevated PSA values listed in Clinical Indication for Ordering The 4Kscore Test)

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4Kscore.com
BioReference Health, LLC is a division of OPKO Health, Inc.

EARLY DETECTION OF AGGRESSIVE PROSTATE CANCER

The background information below for screening and evaluation of prostate cancer is not all inclusive for risk, benefits, or complications for procedures and tests described. Please discuss with your patient to determine the next steps for your patient's care, then both you and your patient sign the consent on the front page of this document.

Screening:

Screening for prostate cancer is an individual decision for patients to discuss with their healthcare provider. There are typically no early warning signs or symptoms for prostate cancer. The first step in evaluating whether a patient is at risk for having prostate cancer is a blood test that measures the level of total Prostate Specific Antigen (PSA) and/or a digital rectal exam (DRE). A patient's PSA level may be elevated in a number of benign, non-cancerous conditions, as well as prostate cancer. PSA is a highly sensitive screening test, but poorly specific for the presence of actionable prostate cancer. Prostate cancers can be roughly divided into low grade, indolent and high grade, aggressive cancer. Distinguishing between aggressive prostate cancer and other causes of an elevated PSA is an important differentiator which will impact potential treatment of, and survivability from, prostate cancer. PSA level and the risk of prostate cancer increases after the age of 45-50, and family history and race may also affect risk. The incidence of prostate cancer is 1.7 times higher, and mortality due to prostate cancer 2.1 times higher, in African-American men than among non-African-American men.

Options after an abnormally elevated screening PSA result include:

Repeat PSA:

As noted, a patient's PSA level may be elevated in many cases unrelated to prostate cancer. Therefore, repeating the PSA test to check on whether it has decreased to a normal range, or if it has remained elevated and/or increased will help distinguish whether further testing or work-up is appropriate. If PSA remains elevated, The 4Kscore® Test is an additional blood test that can risk stratify the patient's probability of finding aggressive prostate cancer upon prostate biopsy. Prostate cancer is only diagnosed by biopsy, in which multiple small pieces of prostate tissue are taken and examined microscopically.

The 4Kscore® Test:

The 4Kscore Test is an FDA approved blood test indicated for use by healthcare providers as an aid in prostate biopsy decision. The 4Kscore Test result is derived by measuring proteins in the blood (biomarkers), combined that with clinical findings and DRE results. It can be used after an abnormal PSA result if a prostate biopsy is being considered, both when the patient has never had a prior prostate biopsy or after a negative prostate biopsy where the provider is still concerned about the patient's probability of aggressive prostate cancer. The 4Kscore Test is a triage tool before a biopsy decision.

The 4Kscore Test Premarket Approval (PMA) by the FDA was supported by two prospective clinical validation studies. The table below summarize the result of these studies for a total of 937 men 45 years of age and older who had an abnormal age-specific total PSA and/or abnormal DRE. Each patient in the study had The 4Kscore Test performed and a biopsy. The FDA concluded that the prevalence of estimate percent likelihood in the three 4Kscore intervals (<5.0, 5.0 – <10.0, and 10.0 – <20.0) were statistically significantly lower than the overall prevalence of 27.5%. The lower part of the table is the probability and prevalence of aggressive prostate cancer found with the 254 (subset of 937) African-American patients in these studies. The clinical validation study data indicates that, even at the same 4Kscore levels, African-American men have a higher likelihood of Gleason Score >= 7 as compared to the total study population.

Likelihood of Gleason Score 7 or higher, by 4Kscore values

	4Kscore	N		Likelihood of Gleason Score ≥ 7	
		Total	Gleason Score ≥ 7	Estimate	(95% CI)
Total Study Population	< 5.0	194	8	4.1%	(2.1%; 7.9%)
	5.0 – < 10.0	146	14	9.6%	(5.8%; 15.5%)
	10.0 – < 20.0	198	39	19.7%	(14.8%; 25.8%)
	≥ 20.0	399	197	49.4%	(44.5%; 54.3%)
	Total:	937	258	27.5%	
African American	<5.0	42	2	4.8%	(1.3%; 15.8%)
	5.0 – < 10.0	26	4	15.4%	(6.1%; 33.5%)
	10.0 – < 20.0	53	14	26.4%	(16.4%; 39.6%)
	≥ 20.0	133	81	60.9%	(52.4%; 68.8%)
	Total:	254	101	39.8%	

Adapted from: PMA P190022: FDA Summary of Safety and Effectiveness Data, The 4Kscore Test, OPKO Health, Inc.

The benefits of The 4Kscore Test include that it is a non-invasive follow-up test and is more specific than PSA and/or DRE for finding the probability of aggressive prostate cancer. Knowing your patient's probability with more certainty may help you and your patient decide on whether a prostate biopsy is appropriate or not.

The 4Kscore Test, like most advanced diagnostic tests, costs more than a PSA test, and is recommended only in men with an abnormal PSA result and/or suspicious DRE, and a prostate biopsy is under consideration, where it can help guide health care decisions. It provides a probability of aggressive prostate cancer and does not diagnose or completely rule out prostate cancer. If other significant high risk factors are present, such as suspicious DRE, rising PSA levels, strong family history of prostate cancer, or high risk hereditary prostate cancer gene mutations, you and your patient should discuss a prostate biopsy instead of further non-invasive testing.

Resources:
1. American Cancer Society; https://www.cancer.org/cancer/prostate-cancer.html
2. NCCN Clinical Practice Guidelines; https://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf
3. NIH SEER Statistics; https://seer.cancer.gov/statfacts/html/prost.html