

Requisition Completion Guide

1

Patient & Billing Information

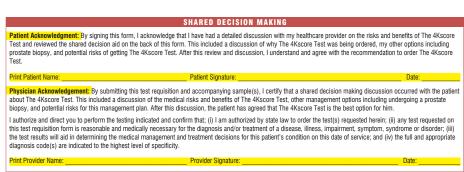
Please **complete** the Patient and Billing Information sections. You **must provide Patient name and date of birth** on the requisition even if you attach Face Sheet or Demographic Sheet.

PATIENT	PATIENT ID		COMMENTS						
	ENTRIES WILL SHOW ON REPORT								
	NAME, LAST (Please Print)			FIRST				M.I.	
	STREET						APT. #		
	CITY			STATE	ZIP	DATE OF BIRTH	AGE	M/F	
	SPECIMEN COLLECTION DATE SPECIMEN COLLECTION TIME							□ AM	
	RACE/ETHNICITY: AFRICAN-AMERICAN ASIAN CAUCASIAN HISPANIC OTHER:								
	PATIENT CELL PHONE NO.	PATIENT HOME PH	ONE NO.	PATIEN	NT EMAIL				
	BILL TO: INSURANCE PATIENT CLIENT ALL INSURANCES RELATION TO SUBSCRIBER:								
6	□ MEDICARE □ MEDICAID □ TRICARE □ CHILD □ SELF □ SPOUSE □ OTHER:								
G INFORMATI	INSURANCE CARRIER		INSURANCE ID # GROUP #						
	SUBSCRIBER'S NAME							DATE OF BIRTH	
	INSURANCE ADDRESS			CITY		STATE	ZIP		
	SECONDARY INSURANCE CARRIER			INSURANCE ID #		GROUP #			
를	DX CODE DX CODE	REFERRING PROV	PROVIDER SOURCE OF REFERRAL						
PATIENT STATUS – ONE MUST BE CHECKED HOSPITAL PATIENT									
	HOSPITAL INPATIENT - HOSPITA	OUTPATIENT	NOT A HOS	PITAL PATIENT	DATE OF DISC	CHARGE/_	/_		

2

Shared Decision Making

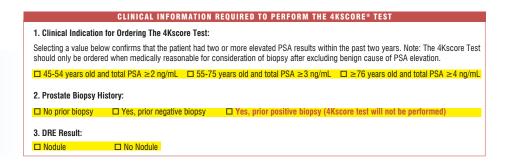
BOTH Provider and Patient signatures, legible names, and dates are required to acknowledge shared decision making discussion.



3

Clinical Information

Each of the three AOEs must have one box checked.





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)



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												
	4Kaaara		N	Likelihood of Gleason Score ≥ 7								
	4Kscore	Total	Gleason Score ≥ 7	Estimate	(95% CI)							
	< 5.0	194	8	4.1%	(2.1%; 7.9%)							
	5.0 - < 10.0	146	14	9.6%	(5.8%; 15.5%)							
Total Study Population	10.0 - < 20.0	198	39	19.7%	(14.8%; 25.8%)							
ropalation	≥ 20.0	399	197	49.4%	(44.5%; 54.3%)							
	Total:	937	258	27.5%								
	< 5.0	42	2	4.8%	(1.3%; 15.8%)							
	5.0 - < 10.0	26	4	15.4%	(6.1%; 33.5%)							
African American	10.0 - < 20.0	53	14	26.4%	(16.4%; 39.6%)							
7.1110110411	≥ 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