OPKO Health

4Kscore®

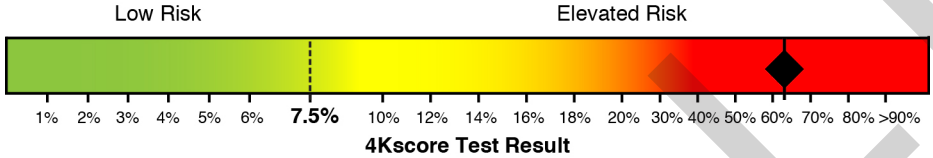
Final Report

PHYSICIAN	PATIENT	SAMPLE
DOCTOR, TEST 1234 MAIN STREET ANYTOWN, USA 12345 Acct #: (XXXXX-X) Tel:(555) 555-5555	PATIENT, TEST DOB:11/01/1950 Age:69 Y Sex:M Address: Tel:	Specimen ID: XXXXXXXXX Date Of Report: 01/18/2020 Time Of Report: Date Collected: 01/16/2020 Time Collected: Date Received: 01/16/2020 Time Received: North America Eastern Time

4Kscore Test Results

ELEVATED RISK **4Kscore:** **63%**

There is a **63%** probability that this patient will have Gleason Score ≥ 7 prostate cancer if a biopsy were to be performed.



Clinical Information

Test	Result	Units	Reference	Reported	Previous	Prev. Date	DRE	Prior Biopsy
PSA Total	4.12*	ng/mL	<4.00	01/18/2020			Nodule	No Prior Biopsy

NOTE: For complete test results, performing laboratory and associated comments refer to the patient's clinical report.

Test Information

The 4Kscore test result is the individual patient's risk for aggressive prostate cancer of Gleason score 7 and higher if a prostate biopsy were to be performed. The 4Kscore is calculated from blood test results of four kallikrein proteins: Total PSA, Free PSA, Intact PSA, and human Kallikrein-related peptidase 2 (hK2), combined with patient age, DRE result (if reported), and history of no prostate biopsy or prior negative prostate biopsy.

The 4Kscore US Validation studies indicated that the 4Kscore risk result shows excellent calibration with prostate biopsy outcome for aggressive prostate cancer.[1],[2]

The US validation studies only included men between 40-80 years old. The clinical utility of the test is unproven for men outside these age groups.

In a large outcomes study of 12,542 men with elevated PSA but a low 4Kscore result of < 7.5%, 10 year follow up data indicated <1% risk of developing distant prostate cancer metastases.[3]

Patient management should be based on the information of risk provided by the 4Kscore test, clinical judgment, and shared decision making.

References:

1. Parekh, DJ, Punnen S, Sjoberg DD, et al. Eur Urol. 2015 Sep;68(3):464-70.
2. Punnen S, Freedland SJ, Polascik TJ, et al. J Urol. 2018 Jun;199(6): 1459-1463.
3. Stattin P,Vickers AJ,Sjoberg DD,et al. Eur Urol. 2015 Aug;68(2):207:13.

Note: The 4Kscore test was evaluated and its performance characteristics determined by BioReference Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. BioReference Laboratories is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical testing. The PSA assay should not be the only test used for diagnostic purposes. Additional evaluation using DRE, ultrasound, TUR or similar procedures maybe used for this purpose. Predictions of disease recurrence should not be based solely upon values obtained from serial PSA values obtained on the patient. Values obtained with different assay methods or kits cannot be used interchangeably. Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

ASSAY INFORMATION FOR TOTAL PSA: Method Electrochemiluminescence Immunoassay