OPKO Health

4Kscore®

Final Patient Summary Report

ONCOLOGY genpath an OPKO Health Company

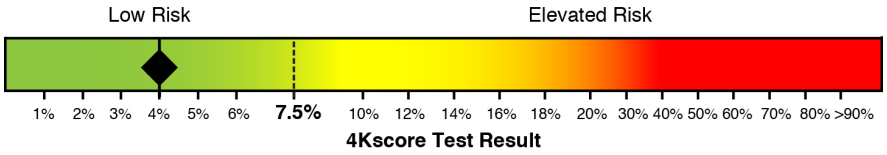
PHYSICIAN	PATIENT	SAMPLE
DOCTOR, TEST	PATIENT, TEST	Specimen ID: 000000000
1243 Main St	DOB:02/15/1970 Age: 48 Y	Date Of Report: 03/07/2018
Anytown, USA 12345	Sex: M	Date Collected: 03/05/2018
Acct #: (J3333-7)	Address:	Time Collected:
Tel:(111) 222-3333	Tel:	Date Received: 03/05/2018
		Time Received: 07:49
		North America Eastern Time

4Kscore Test Results

LOW RISK

4Kscore: 4%

There is a **4%** 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	4.70	ng/mL	<4.00	03/07/2018			No 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]

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. 2017 [Epub ahead of print]. DOI: 10.1016/j.juro.2017.11.113.
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, TURP or similar procedures may be 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 METHOD INFORMATION FOR TOTAL PSA: Electrochemiluminescence Immunoassay.