

4Kscore™ Test



THE ONLY BLOOD TEST
THAT ACCURATELY IDENTIFIES
RISK FOR **AGGRESSIVE**
PROSTATE CANCER.

Early Detection of Aggressive Prostate Cancer Challenges

- Serum PSA has a high false positive rate
- Over 1 million prostate biopsies performed annually in US
- 75% of biopsies will have low-grade, indolent (Gleason 6) or no prostate cancer
- Serious complications of biopsies include infection and hospitalization
- Overtreatment - 75% of Gleason 6 indolent cancers at prostate biopsy are confirmed at radical prostatectomy
- Recommendation by USPSTF to stop PSA screening misses an opportunity to detect and treat men with high grade (Gleason ≥ 7), the aggressive form of prostate cancer

What is the 4Kscore Test?

The **4Kscore Test** combines four prostate-specific kallikrein assay results with clinical information in an algorithm that calculates the individual patient's percent risk for aggressive prostate cancer.

Components

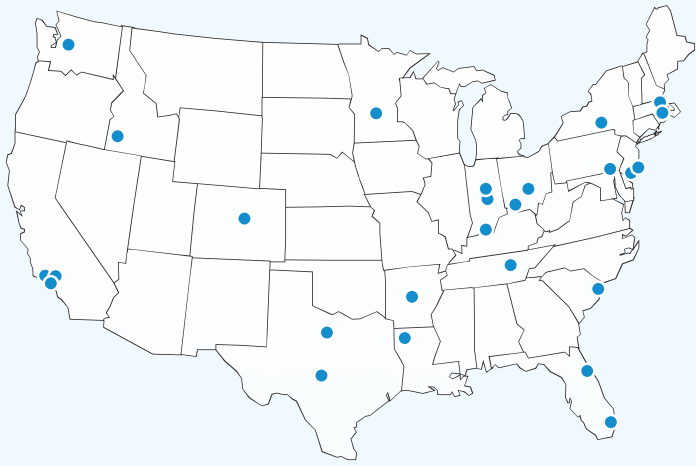
Proprietary to OPKO { Total PSA
Free PSA
Intact PSA
hK2
+ Age, DRE, and
prior biopsy status

OPKO ALGORITHM

Results

% risk of having aggressive prostate cancer for an individual patient

Prospective, Blinded, Multicenter US Study Validates 4Kscore Test



Clinical Study Sites

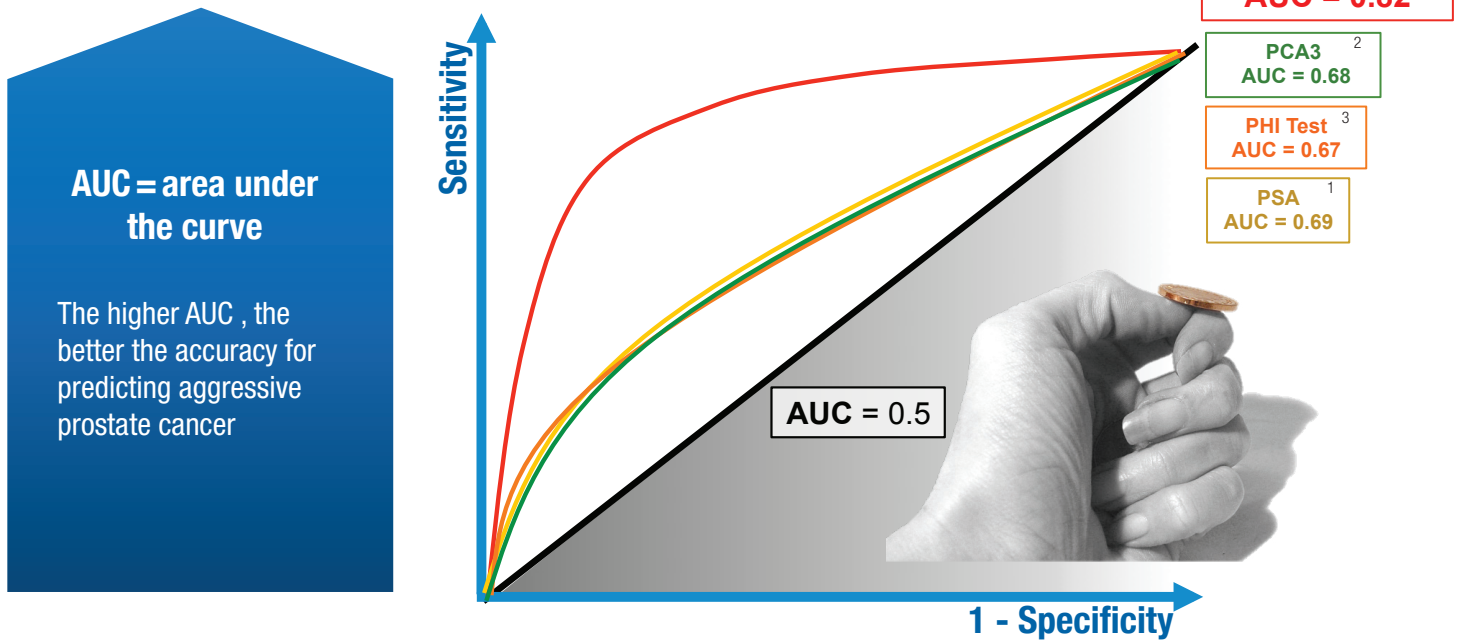
- 1,012 patients enrolled in 26 centers for validation (Oct. 2013 to Apr. 2014)
- Men scheduled for biopsy regardless of PSA, age, DRE status, prior biopsy
- TRUS Biopsy of ≥ 10 cores
- Excluded for treatments known to influence PSA levels
- OPKO Lab developed and performed the **4Kscore Test**
- Pathology conducted according to the established practice at each center
- As presented in the AUA Plenary Session May, 2014; publication pending

Gleason Score Distribution in Prospective US Study

Gleason Grade	N	% All Cancers N=470	% All Patients N=1,012
Negative	542	--	53.6%
6	239	50.9%	23.6%
7 (3+4)	108	23.0%	10.7%
7 (4+3)	59	12.6%	5.8%
8	35	7.4%	3.5%
9	26	5.5%	2.6%
10	3	0.6%	0.3%

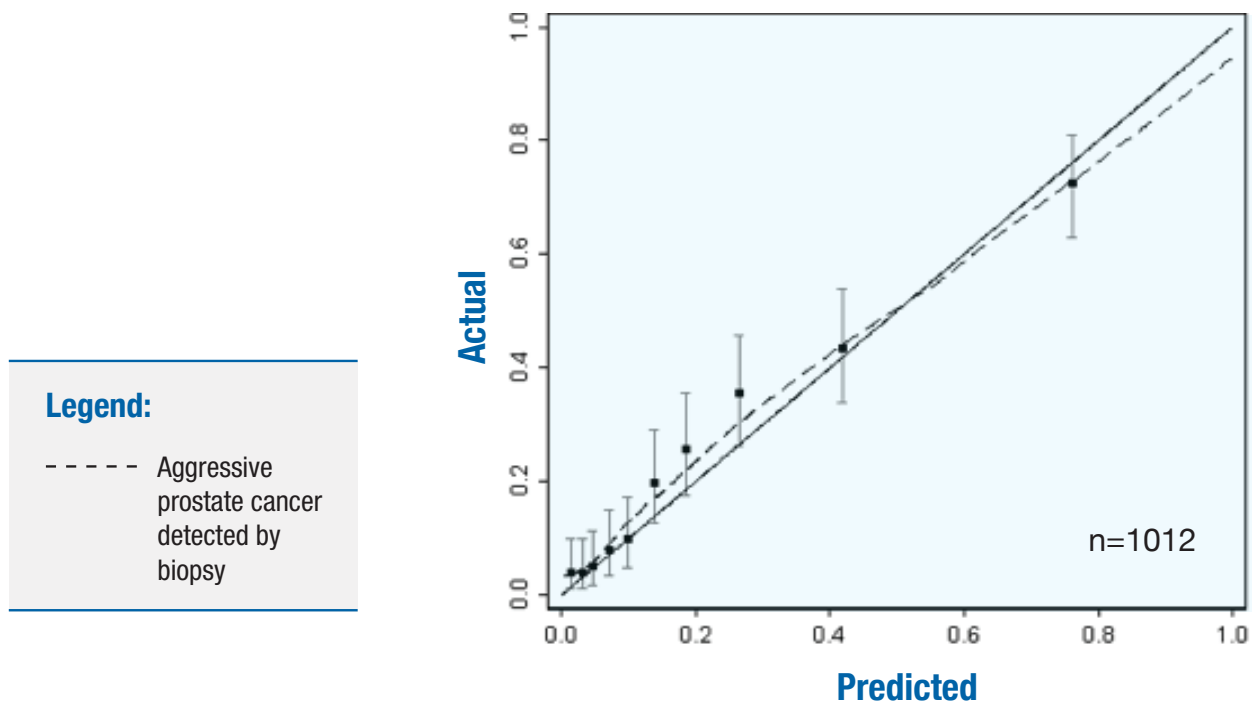
Summary	
77.2%	Negative or Gleason 6 prostate cancer
22.8%	Aggressive (Gleason ≥ 7) prostate cancer

The 4Kscore Test Has the Greatest Accuracy for Predicting Aggressive Prostate Cancer

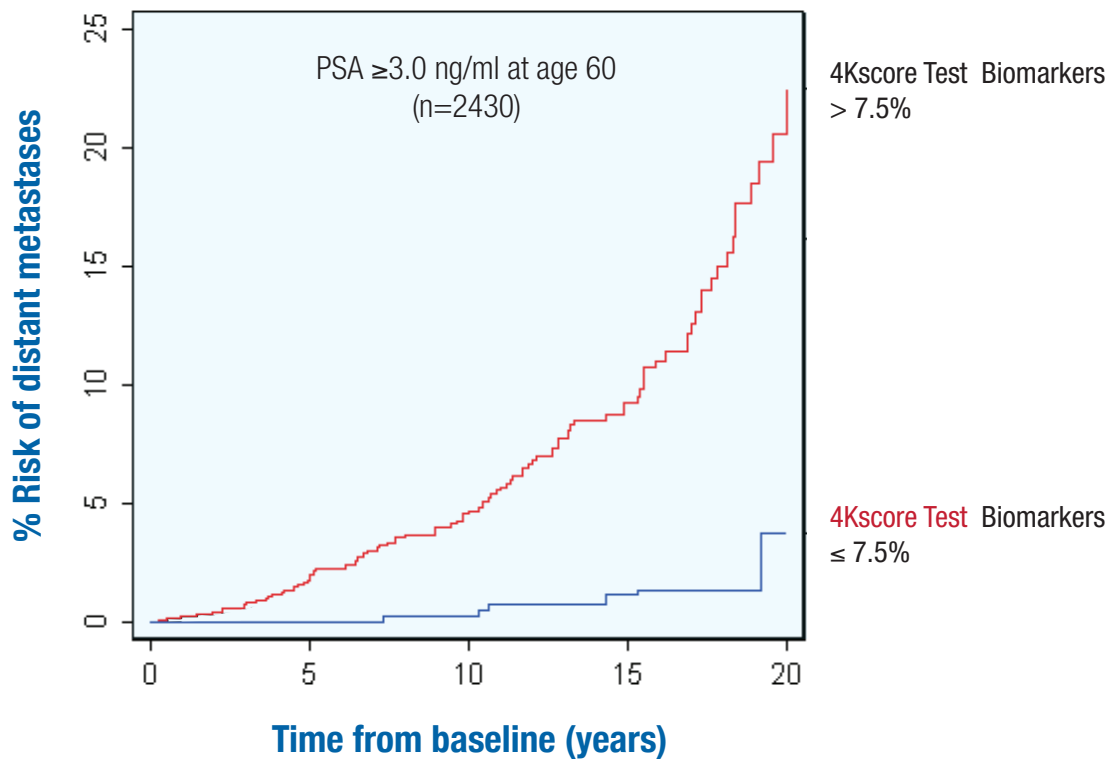


¹Parekh, D et al 2014 submitted; ² Chevli, K et al J Urol 191:1743 2014; ³ Wang, W et al Scientific Reports 4:1-8 2014

The Risk of Aggressive Prostate Cancer Predicted by the 4Kscore Test is Confirmed by Prostate Biopsy



The 4Kscore Test Biomarkers Predict the Probability of Distant Metastases Within 20 Years



Vasterbotten intervention project study
J Clin Oncol 32:5s, 2014 (suppl; abstr 5081)

The 4Kscore Test Summary

- Clinical utility was validated based on a decade of clinical research with the 4Kscore Test biomarkers in over 20,000 men in Europe and the United States
- Identifies the actual risk of aggressive prostate cancer for the individual patient
 - High grade prostate cancer pathology
 - Poor prostate cancer clinical outcomes within 20 years
- Has high sensitivity and high negative predictive value for aggressive prostate cancer
- **The only blood test that accurately identifies risk for aggressive prostate cancer**

www.4Kscore.com
(877) 922-8364

OPKO Lab
a Division of OPKO Health, Inc.