

# The 4Kscore Test<sup>®</sup> Predicts High Grade Prostate Cancer on Biopsy at PSA levels < 4ng/mL

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# Introduction

- Clinical value of PSA to detect prostate cancer has been questioned owing to its poor specificity
- Especially true at lower PSA levels in the Early-Warning or Danger Zone
- 4Kscore Test is a follow up blood test
- Incorporates 4 kallikrein biomarkers plus clinical information in algorithm that calculates an individual's risk for aggressive prostate cancer if a biopsy were performed
- Numerous retrospective and prospective trials: AUC 0.8-0.9
- Objective: Assess ability to predict aggressive cancer in men with PSA <4ng/mL

# Method

- Large prospective study enrolling 1312 men
- Biopsy-naïve and prior negative biopsy
- 26 US sites both academic and community based
- Referred to urologist based on suspicious PSA or clinical findings
- Blood drawn for 4Kscore Test prior to prostate biopsy
- 440 men presented with tPSA <4ng/mL

# Patient demographic, laboratory and clinical values by tPSA

median (IQR) or frequency (%)

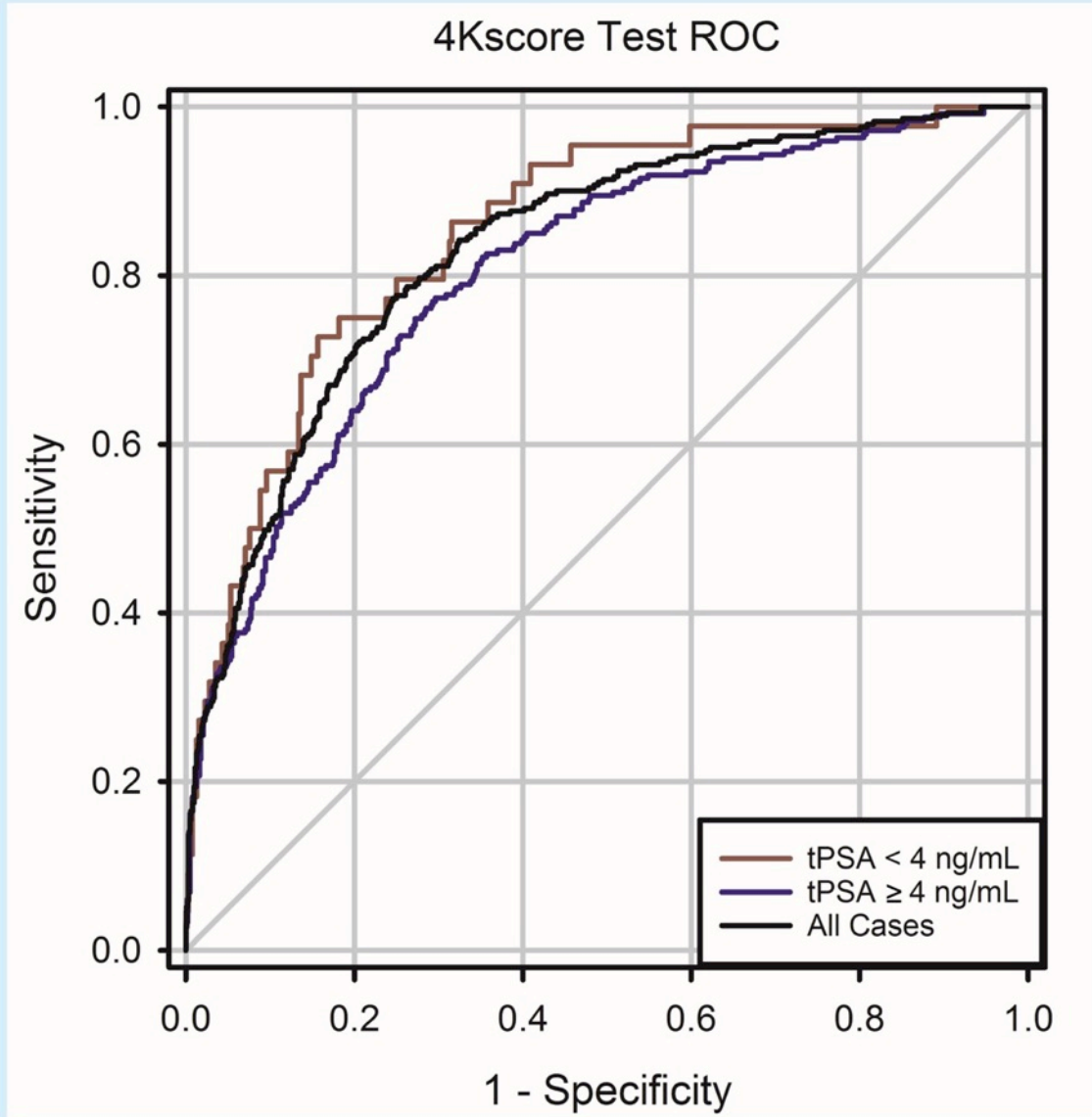
	Patients With tPSA Values < 4ng/ml N=440	Patients with tPSA Values ≥ 4ng/mL N=872
Median age at biopsy	63 (56,68)	65 (60,70)
Total PSA ng/mL	2.82 (1.67, 3.47)	5.84 (4.72, 8.23)
4Kscore	6% (3%, 12%)	17% (7%, 36%)
Biopsy Gleason Score ≥7	44 (10%)	247 (28%)



# Detection of high grade cancer and biopsies avoided tPSA <4ng/mL

4Kscore cut-off	Biopsies performed (n)	Biopsies avoided n (%)	Gleason $\geq 7$ cancers		Gleason Score of Delayed Diagnosis Cases $\geq 7$ n (%)		
			Detected n (%)	Delayed diagnosis n (%)	3+4	4+3	4+4 or above
0%	440	0(0)	44(10)	0(0)	0(0)	0(0)	0(0)
$\geq 6\%$	233	207(47)	42(10)	2(0.5)	2(0.5)	0(0)	0(0)
<b><math>\geq 7.5\%</math></b>	<b>192</b>	<b>248(56)</b>	<b>39(9)</b>	<b>5(1)</b>	<b>2(0.5)</b>	<b>2(0.5)</b>	<b>1(0.2)</b>
$\geq 9\%$	152	288(65)	35(8)	9(2)	3(0.7)	4(0.9)	2(0.5)
$\geq 12\%$	107	333(76)	33(8)	11(3)	5(1)	4(0.9)	2(0.5)
$\geq 15\%$	73	367(83)	25(6)	19(4)	11(3)	5(1)	3(0.7)

# 4Kscore Receiver Operator Curves



**4Kscore (7.5% cutoff)**

**Sensitivity- 89%**

**Specificity- 61%**

# Summary

- 4Kscore Test is an effective predictive instrument in men with tPSA <4 ng/mL
- 4Kscore cut off of 7.5% identifies almost 90% of high grade tumors while avoiding biopsies in 56% of men who would not likely be referred to a urologist
- As a follow up test for a suspicious PSA in the Danger Zone or higher, the 4Kscore Test is a valuable tool to select men who have significant disease and are most likely to benefit from a prostate biopsy