

# The 4Kscore<sup>®</sup>

## A Precision Test for Risk of Aggressive Prostate Cancer

Reduce Unnecessary Invasive Procedures And  
Healthcare Costs

# PSA Lacks Specificity for Aggressive Prostate Cancer

4Kscore

Abnormal PSA leads to over 1 million prostate biopsies each year

- **Low yield:** 75% of biopsies show no cancer or indolent cancer<sup>1</sup>
- **Unnecessary surgical removal of prostate:** 66% of indolent cancers on biopsy are confirmed indolent when the prostate is removed<sup>2,3</sup>
- **Adverse events:** 4.1% hospitalization rate: bleeding, infections, septicemia<sup>4</sup> and with therapeutic interventions - complications of surgical removal or radiation

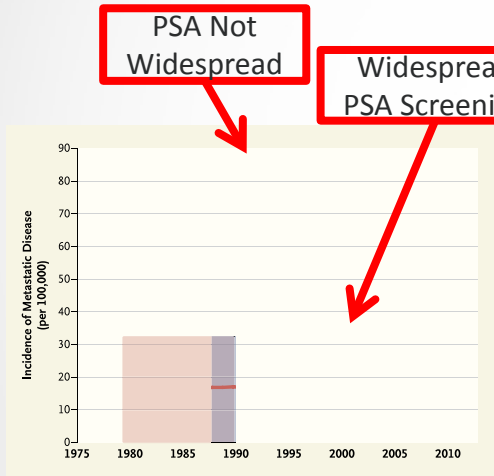
1.Parekh D et al European Urology 2015; 2. Eggener S et al J Urol 2015; 3.Jalloh M et al. European Urology 67:451, 2015;

4.Nam RK et al J Urol 189:S12, 2013

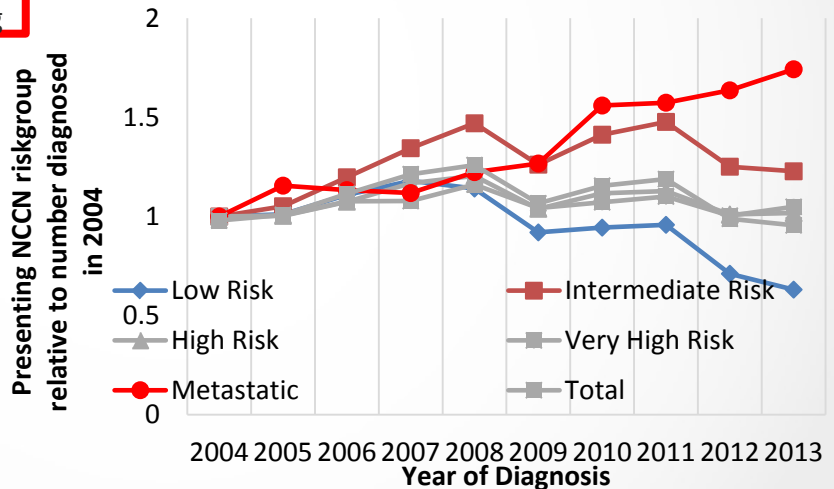
# Impact of USPSTF Recommendations Reducing PSA Utilization



Second leading cause of cancer death in men – 26,000 in 2016



- Results of contemporary reductions in screening: More Metastatic/Lethal disease<sup>2-5</sup>

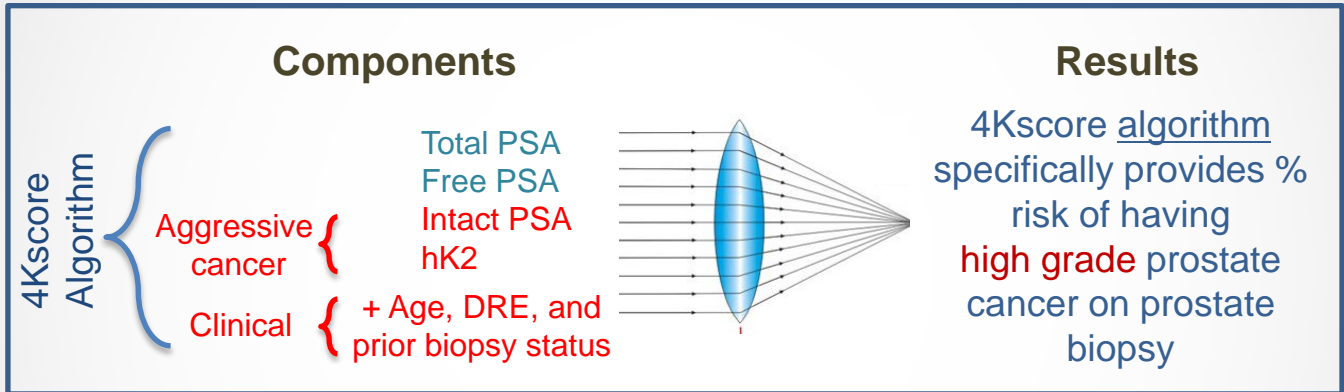


1. Welch HG et al NEJM 2015 2. Weiner AB, et al Prostate Cancer Prostatic Dis 2016 3. Bhandi BM et al J Urol 193:1519, 2015; 4. Barocas D et al J Urol 2015; 5. Hall MD et al J Clin Oncol 33: Abstract 143.

# 4Kscore

A follow up test to identify risk for high grade, aggressive prostate cancer

4Kscore



- Commercial- CLIA certified laboratory developed test
- Designed to identify aggressive prostate cancer- Gleason  $\geq 7$  from Gleason 6 or no cancer
- OPKO - Intact PSA and hK2 associated with poorly differentiated prostate cancer<sup>1-3</sup>

# 4Kscore Cost Savings

The logo for 4Kscore, featuring the text "4Kscore" in white, italicized font on a red, shield-shaped background.

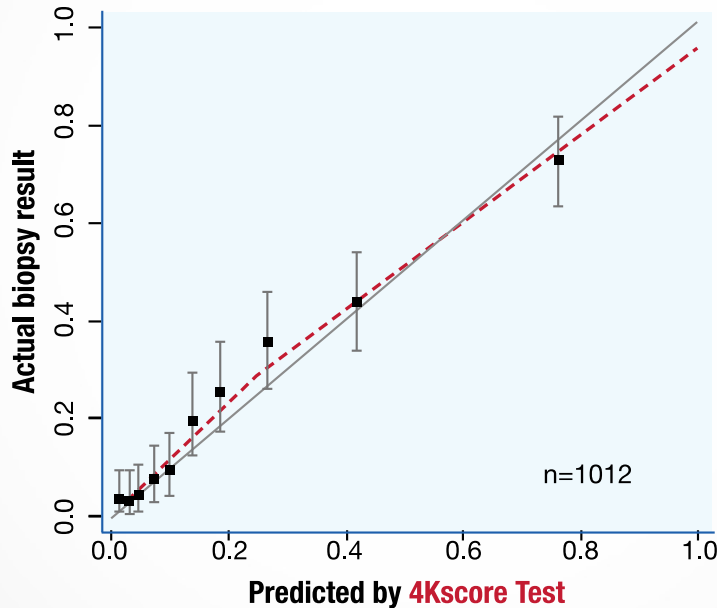
- 4Kscore Medicare Price: \$602.10
- Loaded Cost of Biopsy: Over \$2,100
  - Cost of prostate biopsy
  - Around 4.1% hospitalization rate including septicemia
  - Associated MRI (including mpMRI-Biopsy)
  - Post biopsy consultation/second opinion
  - Molecular confirmatory tests
  - Treatment and complications costs for indolent cancer
- After referral for biopsy - using a low risk 4Kscore (< 7.5%) cutoff for biopsy decisions
  - \$1,500 in savings per patient considered for prostate biopsy

# 4Kscore Predicts Aggressive Prostate Cancer

Validated in a prospective, blinded, multicentre US study of 1012 men using current prostate cancer protocols

**4Kscore**

4Kscore  
predicts biopsy  
results



## Legend:

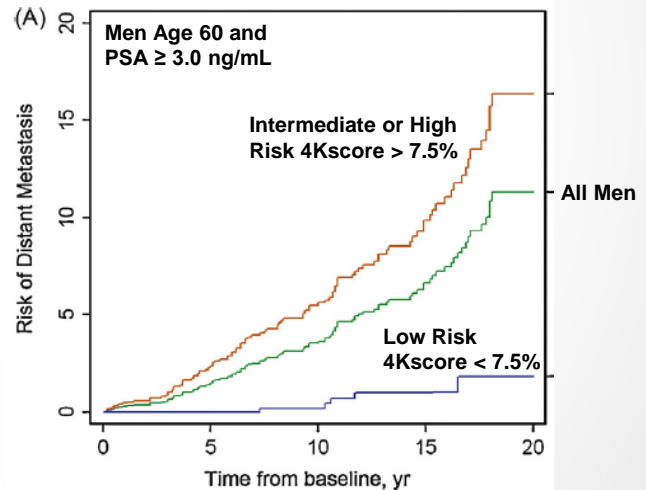
- Actual percentage of aggressive prostate cancer detected by biopsy
- 95% confidence interval
- Perfect correlation

# 4Kscore Categorizes Long Term Risk of Developing Distant Metastasis

**4Kscore**

Men who have a low risk 4Kscore test are at low risk for distant metastasis within 15-20 years

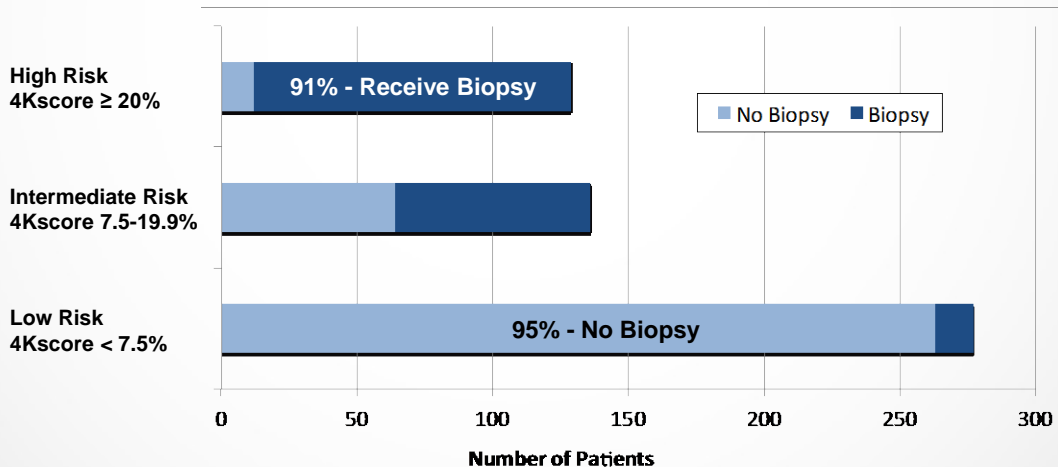
Age 50 PSA $\geq$ 2 ng/mL	10 yr	15 yr	20 yr
4Kscore < 7.5%	0.26%	0.90%	1.25%
4Kscore > 7.5%	2.40%	8.25%	10.68%
Age 60 PSA $\geq$ 3 ng/mL	10 yr	15 yr	20 yr
4Kscore < 7.5%	0.18%	0.99%	1.82%
4Kscore > 7.5%	5.62%	9.85%	16.36%



# 4Kscore Substantially Reduces Biopsy Rate in Low Risk Patients

4Kscore

- 611 subjects with suspicion of prostate cancer seen by 35 urologists
- Overall biopsy reduction rate = 65%
- 542 (89%) of the biopsy decisions were impacted by the 4Kscore. In this group:
  - 95% of 4Kscore low risk group did not receive prostate biopsy
  - 9% of 4Kscore high risk group did not receive a prostate biopsy





## National Clinical Guidelines Include **4Kscore**

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“...for whom the patient and/or the physician wish to further define the probability of high grade cancer”<sup>1</sup>

*r 4Kscore to identify the patient's individual risk of high grade Gleason 7 or higher cancer on prostate biopsy*

# 4Kscore in Clinical Practice

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- Reduces uncertainty by providing an accurate risk percentage for aggressive prostate cancer
- Excellent calibration with prostate biopsy results
- Predicts risk of distant metastasis for up to 20 years
- Included in National Clinical Guidelines
- Influences physician/patient decision making in 88% of cases
- Reduces prostate biopsies by up to 65%
- Reduces complications and pain from unnecessary prostate biopsies and potential unnecessary treatment
- Reduces cost of unnecessary procedures

- Paradigm shift
  - Continue screening of men to find aggressive prostate cancer early
  - Avoid immediate biopsy in all men with a suspicious PSA
    - Reduce complications from unnecessary procedures
    - Reduce healthcare cost
- Provide a continuous risk score with risk categories
  - Reduce uncertainty in physician-patient shared decision making
  - Provide actionable, accurate, and easily interpretable results
- Acceptance amongst payors and providers