

4Kscore[®]

TEST CHARACTERISTICS

4Kscore provides a continuous spectrum of risk for aggressive prostate cancer ranging from <1% to >95%. The test's average Area Under the Curve (AUC), based on several clinical trials, is 0.85 for 4Kscore Test vs. 0.69 for PSA.

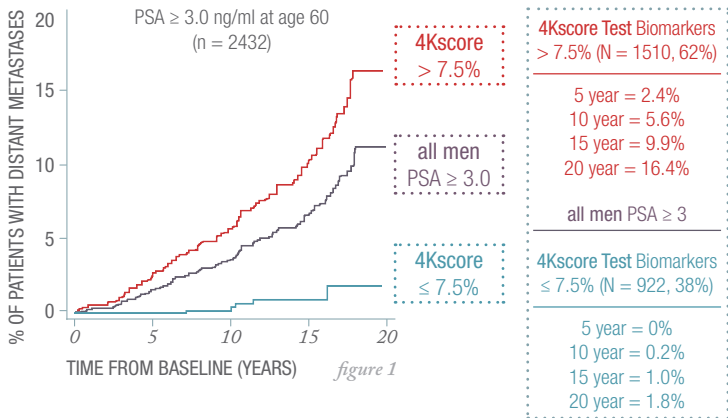
In a prospective, blinded US validation study of 1,012 men, all of whom underwent biopsy, the 4Kscore Test showed significant potential to reduce the number of prostate biopsies while delaying the diagnosis of only a small number of aggressive Gleason ≥ 7 cancers, as indicated by the Table below. Test parameters for different 4Kscore cutoff values have been provided to aid physicians in evaluating the test's performance.

4Kscore Test Cutoff	Negative Predictive Value	Biopsy Reduction	Sensitivity	Specificity	Diagnosis Delayed Gleason		
					3+4	4+3	4+4 or higher
$\geq 7.5\%$	95%	36%	93%	45%	1.3%	0.4%	0.0%
$\geq 20\%$	90%	64%	70%	79%	4.5%	1.2%	1.2%

Values derived from data obtained in the US validation study.

- The 4Kscore is intended for men being considered for a prostate biopsy or after a negative biopsy.
- The 4Kscore provides an individual's calibrated risk for Gleason 7 or higher prostate cancer if a prostate biopsy were to be performed, based on an individual's blood biomarkers and clinical data, including biopsy history.

4Kscore has been shown to predict risk for distant prostate cancer metastases occurring up to 20 years later from a blood sample in otherwise healthy men who have PSA ≥ 2 ng/mL. A population-based cohort in Västerbotten, Sweden followed 12,542 men to determine their risk of distant prostate cancer metastases. Results, as illustrated in Figure 1, show that a group of men who had a 4Kscore of 7.5% or lower were found to have 1% chance of developing metastatic prostate cancer by year 15.



1. Parekh DJ, Punnen Sm, Sjoberg DD, et al. A Multi-institutional Prospective Trial in the USA Confirms that the 4Kscore Accurately Identifies Men with High-grade Prostate Cancer. *Eur Urol* 2014; 68:462-70.
2. Stattin P, Vickers AJ, Sjoberg DD, et al. Improving the Specificity of Screening for Lethal Prostate Cancer Using Prostate-specific Antigen and a Panel of Kallikrein Markers: A Nested Case-Control Study. *Euro Urol* 2015; 68:207-213.