

4Kscore[®]

A DIAGNOSTIC BLOOD TEST FOR DETECTING THE RISK OF
AGGRESSIVE PROSTATE CANCER

TEST CHARACTERISTICS

4Kscore provides a continuous spectrum of risk for aggressive prostate cancer ranging from <1% to >95%. The average Area Under the Curve (AUC) for 4Kscore, based on 12 clinical trials including over 17,000 men, is 0.82. The AUC of PSA, based on data from the 4Kscore US validation trial, was 0.69.¹

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.¹

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%

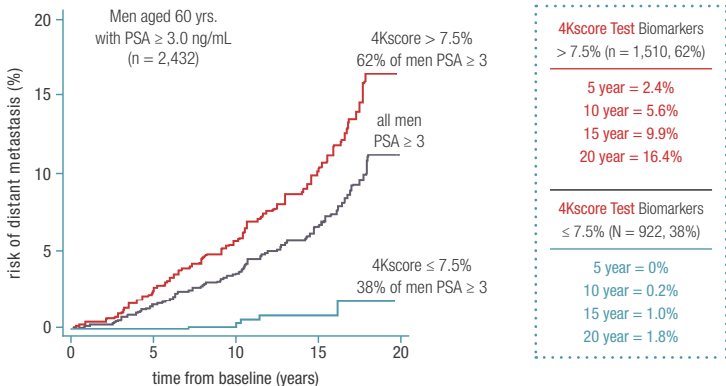
Values derived from data obtained in the US validation study.

- The 4Kscore is intended for men being considered for an initial or repeat prostate biopsy following an abnormal PSA and/or digital rectal examination.
- 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 (age, prior biopsy history, and optionally DRE).

4Kscore has been shown to categorize risk for distant prostate cancer metastases up to 20 years after the test result in otherwise healthy men with an elevated PSA. A population-based cohort in Västerbotten, Sweden followed 12,542 men to determine their risk of distant prostate cancer metastases. In 50 and 60 year old men with an elevated PSA, a low risk 4Kscore predicted low risk for metastasis. Figure 1 shows that 60 year old men with a PSA ≥ 3 ng/mL and a 4Kscore $< 7.5\%$ had a $< 1\%$ chance of developing metastatic prostate cancer by year 15.²

4Kscore Reliability

4Kscore test biomarkers predict the probability of distant metastasis within 20 years²



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.

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