

# OncoAssure™ Prostate

A Next Generation Risk Stratification Test for Assessment of Prostate Cancer Aggressiveness

## The OncoAssure Prostate Test



Is used to **estimate the risk of having aggressive disease** (post-biopsy) or the **risk of biochemical recurrence** (post-surgery).



Employs a novel approach by utilizing **master driver genes**, which cover a wide range of biological pathways, to develop the prognostic signature; 4 prognostic (FOXM1, MCM3, MTUS1, TTC21B) and 2 reference (ALAS1, PPP2CA) genes.



**Incorporates a well-known and well-validated clinical component;** Cancer of the Prostate Risk Assessment (CAPRA), into the risk score.

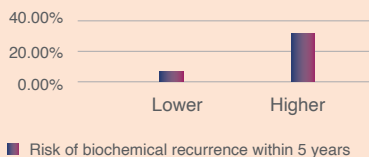


**Is prognostic for contemporary clinical features** associated with tumor aggressiveness and poorer clinical outcomes, including the presence of cribriform morphology and Tertiary Grade 5.

## Benefits of using OncoAssure Prostate

Higher Risk Score  
**9.7 x**  
Risk of adverse pathology

Patients with a higher OncoAssure Prostate result score were **9.7 times more likely to experience adverse pathology** to those with a lower OncoAssure Prostate result.



The **risk of biochemical recurrence** within 5 years was **28.2% for patients with a higher OncoAssure Prostate result**, compared to just 6.4% for patients with a lower OncoAssure Prostate result.

**Reduce unnecessary interventions**

**>20%**

Using the OncoAssure Prostate test to guide treatment decisions instead of treating all patients, would lead to a 20% - 29% reduction in unnecessary interventions.

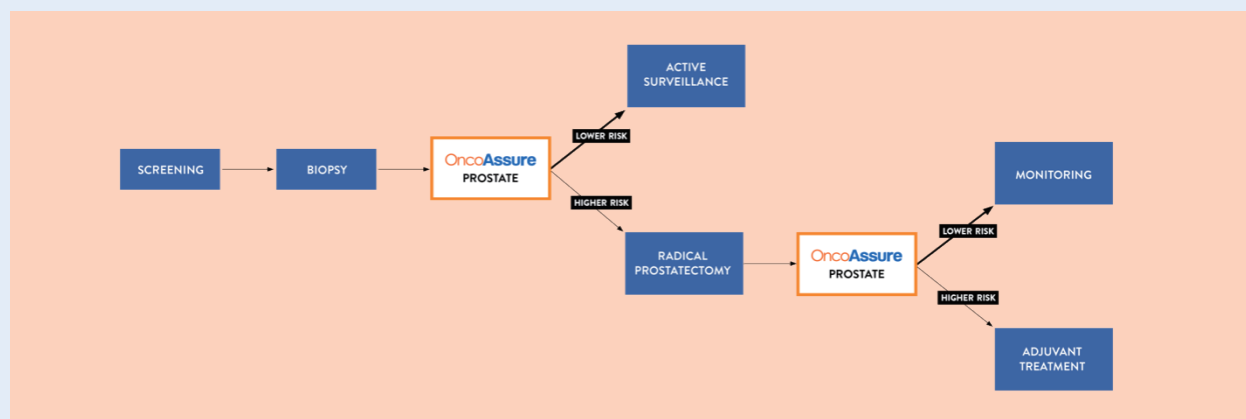
# Introduction to OncoAssure Prostate Test

**OncoAssure Prostate is a newly developed laboratory test (LDT) designed to help stratify risk in patients newly diagnosed with prostate cancer. It has demonstrated performance that is comparable to or better than existing market alternatives.**

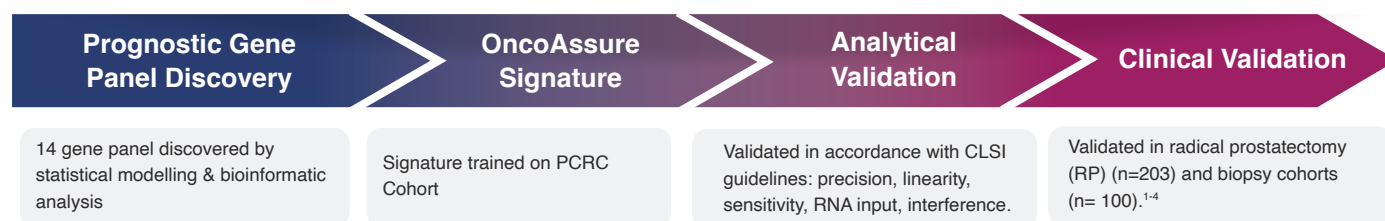
The OncoAssure Prostate test is a multigene prognostic signature incorporating clinicopathological information which assesses the probability of aggressive disease in men recently diagnosed with early-stage prostate cancer or men with localised disease who have undergone radical prostatectomy (RP).

Men whose OncoAssure Prostate risk score indicates they have a lower risk of aggressive disease may be suitable candidates for active surveillance. After RP, patients with a lower risk of biochemical recurrence can be reassured that surgery is sufficient to control their prostate cancer, whereas patients with a higher-risk of recurrence may need adjuvant treatments.

The diagram shows the two intended uses of the tests in the context of prostate cancer diagnosis and management.



## OncoAssure Prostate Test Development



1: ESMO 2022 Paris, September 2022, Krzyzanowska et al. Annals of Oncol 2022, 33(S7):S1190


2: ASCO GU 2023 San Francisco, February 2023, Krzyzanowska et al. J Clin Oncol 2023, 41 (S6; Abstr 374)

3: Krzyzanowska A et al., Development, Validation, and Clinical Utility of a Six-gene Signature to Predict Aggressive Prostate Cancer. Eur Urol Focus. 2023. 9(6): p. 983-991

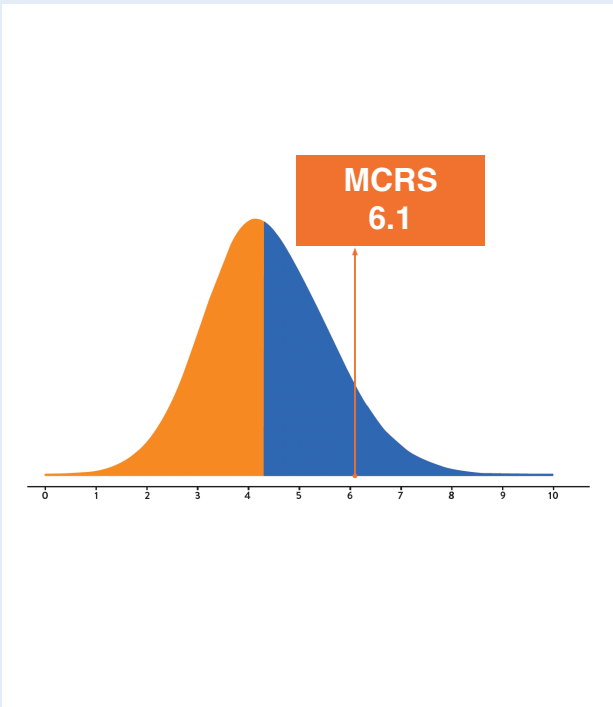
4: Krzyzanowska A, et al. Clinical validation of a biopsy-based six-gene signature prognostic for aggressive prostate cancer. BJUI Compass. 2025; 6(1):e474.

# How to Use the OncoAssure Prostate Test

Based on the MCRS result on the report (see the interpretation example below), physicians can make recommendations on the treatment strategies (see the table below).

		NCCN Risk Category		
		Low/Very Low	Favorable Intermediate	Unfavorable Intermediate /High/Very High
	Lower Risk Score	Consider active surveillance	Consider active surveillance	Consider treatment
	Higher Risk Score	Consider closer surveillance	Consider closer surveillance or treatment	Consider multimodal treatment

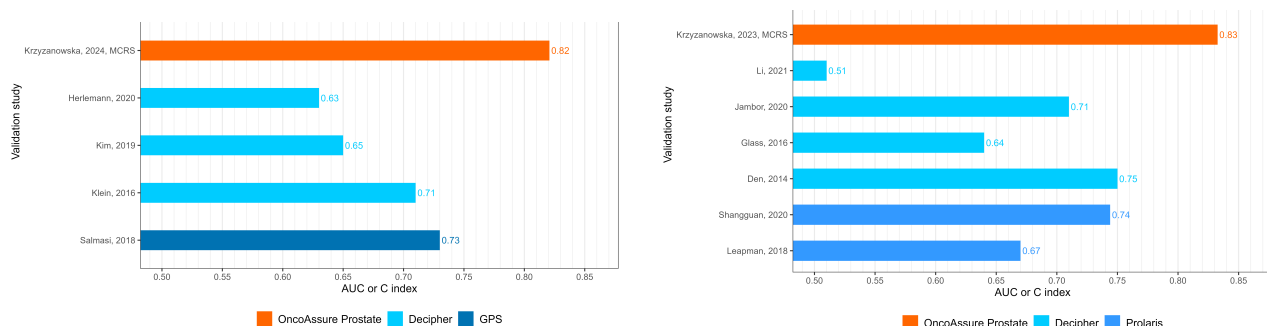
## Example Result for a Higher Risk Score Sample



Risk score (0 to 10)	6.1	The Molecular Clinical Risk Score (MCRS) is calculated from the expression values of six genes in the patient sample and the patient's clinical and pathological details recorded above. MCRS ranges from 0 to 10 and higher MCRS values indicate higher risk of aggressive prostate cancer.
Risk score percentile	93 <sup>rd</sup>	This MCRS is in the 93 <sup>rd</sup> percentile of molecular and clinical risk. This means that 92% of men have a lower MCRS (lower risk of aggressive prostate cancer), and 7% of men have a higher MCRS (higher risk of aggressive prostate cancer).
Risk score category	Higher risk	This MCRS is above the median or middle MCRS value of samples. Therefore, the patient is considered higher risk of aggressive prostate cancer.

# How Does OncoAssure Prostate Compare with 1<sup>st</sup> Generation Tests

## Comparison of OncoAssure Prostate with other competitors



A comparison of data published using other prognostic tests available suggests that the OncoAssure Prostate provides superior prognostic assessments for adverse pathology and biochemical recurrence.

## Order OncoAssure Prostate



Contact us at [support@diacarta.com](mailto:support@diacarta.com) to order the test



Send us the FFPE samples based on our instructions



Review results on the online portal we set up for you after 2 weeks after sample arrival

**Insurance coverage: We build patient insurance or accept cash offers to cover the basic cost.**

Test code: DC-19-1001

CPT code: 0497U

### Disclaimer:

*This laboratory developed test (LDT), OncoAssure™ Prostate, is performed at our CLIA-certified and CAP-accredited laboratory in Pleasanton, California. This test adds clinical value post-biopsy and post-surgery by providing prognostic information for adverse pathology and biochemical recurrence—key indicators of metastasis risk and long-term outcomes. This test has been analytically validated by the laboratory, but has not been cleared or approved by the U.S. Food and Drug Administration (FDA). For more information or to speak with a support specialist, please contact DiaCarta Clinical Laboratory at [support@diacarta.com](mailto:support@diacarta.com)*



DiaCarta Clinical Laboratory



4385 Hopyard Rd, Suite 100, Pleasanton, CA 94588, USA



1-800-246-8878 or email [support@diacarta.com](mailto:support@diacarta.com)