

**LABORATORY REPORT**

PATIENT		SPECIMEN	PHYSICIAN	
Name: TEST, PATIENT		Type: Needle Biopsy	ID: 1990	NPI: XXXX
Address: 101 Main Street, #1 Pleasanton, CA 94588		Collection Date: 01/30/24	Name: 2ND TEST CLIENT	
Phone: (631) 000-0000	ID: ID1989M	Received Date: 01/30/24	Address: 11 Grace Av, 208 Pleasanton, CA 94588	
Date of Birth: 01/01/1974	Gender: Male	Reported Date: 02/03/24	Phone: (000) 000-0000	
Race: White		<b>ACCESSION #:</b> 2401300005	Referring: 1988 DOCTOR Dr.	

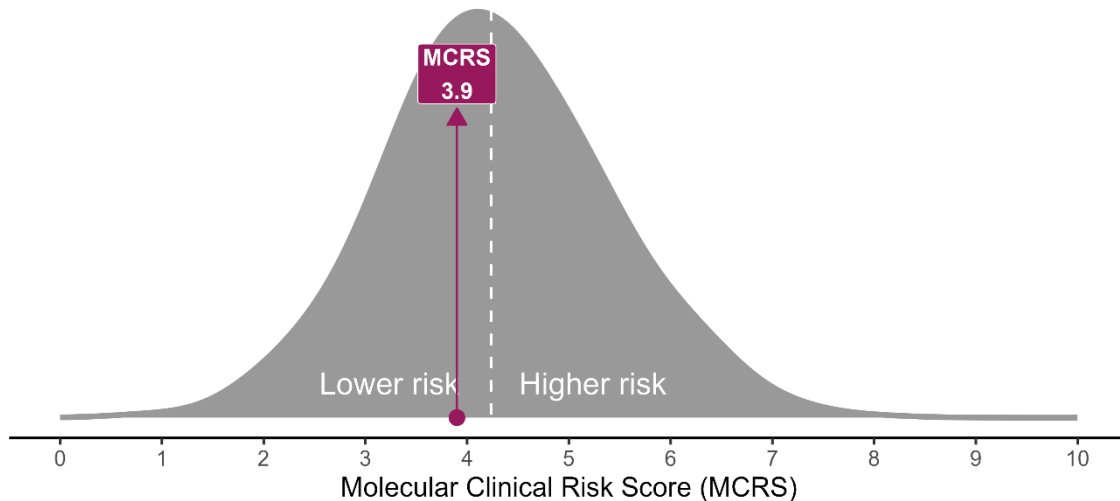
CLINICAL AND PATHOLOGY DETAILS			
Age at Diagnosis: 79	PSA at Diagnosis: 4.9 ng/mL	Biopsy Gleason Score: 3 + 4	Percentage Positive Biopsy Cores: 35%
Clinical Stage: cT1		National Comprehensive Cancer Network® (NCCN®) Risk Category: Favorable Intermediate	

## OncoAssure™ Prostate Test Report

### Test Result

Molecular Clinical Risk Score (MCRS): 3.9

Distribution of MCRS in three cohorts



### Interpretation

<b>Risk score (0 to 10)</b>	<b>3.9</b>	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.
<b>Risk score percentile</b>	<b>38<sup>th</sup></b>	This MCRS is in the 38 <sup>th</sup> percentile of molecular and clinical risk. <sup>1</sup> This means that 37% of men have a lower MCRS (lower risk of aggressive prostate cancer), and 62% of men have a higher MCRS (higher risk of aggressive prostate cancer).
<b>Risk score category</b>	<b>Lower risk</b>	This MCRS is below the median or middle MCRS value of samples. <sup>1</sup> Therefore, the patient is considered lower risk of aggressive prostate cancer.

## TEST DESCRIPTION

The OncoAssure Prostate test is a multigene prognostic signature used to assess the probability of aggressive disease in men recently diagnosed with early-stage prostate cancer. The OncoAssure Prostate test result is indicated for use by physicians as a prognostic indicator only and should be interpreted along with other established methods and clinicopathological risk factors. The OncoAssure Prostate test estimates the risk of aggressive disease based on a continuous risk score calculated from a linear combination of normalized expression levels of the OncoAssure Prostate gene panel combined with patient clinical information<sup>1</sup>. Men whose OncoAssure Prostate risk score indicates they have a low risk of underlying aggressive disease may be suitable candidates for active surveillance<sup>2, 3, 4</sup>. Additionally, the OncoAssure Prostate test can be used to estimate a patient's risk for 5-year biochemical recurrence following the radical prostatectomy (RP) procedure using the gene expression profile of FFPE prostate cancer tissue samples collected at RP.

Gene expression levels are used to calculate the OncoAssure Prostate molecular risk score (MRS), which is then combined with patient clinicopathological information to generate the OncoAssure Prostate molecular clinical risk score (MCRS). The MCRS is used to estimate the risk of having aggressive disease (post-biopsy) or the risk of biochemical recurrence (post-surgery).

## References

1. 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):983-991.
2. Cooperberg M., et al, The diverse genomic landscape of clinically low-risk prostate cancer. *Eur Urol*, 2018, 74(4):444-452.
3. Eggener S., et al, Molecular biomarkers in localized prostate cancer: ASCO Guideline. *JCO*, 2019, 38:1474-1494.
4. Basourakos S.P., et al, Tissue-based biomarkers for the risk stratification of men with clinically localized prostate cancer. *Fron. Oncol.*, 2021, 11:676716

DISCLAIMER: The test is performed at DiaCarta laboratory as a laboratory developed Test (LDT). The test is not cleared or approved by the U.S. Food and Drug Administration (FDA). The interpretation of the test result should be treated cautiously by professionals. DiaCarta is not responsible for the decision made based on this test. The DiaCarta laboratory is regulated under CLIA as qualified to perform high-complexity testing. For questions about this report or to speak with a DiaCarta Support Specialist, please call (800) 246-8878.