DIACARTA INC 4385 Hopyard Road, Suite 100, Pleasanton, CA 94588

**CLIA#:** 05D2110800; **CAP#:** 9374716
**Medical Director:** Chuanyi Mark Lu, MD
**Email:** information@diacarta.com
**Phone:** (800)246-8878

**LABORATORY REPORT**

| PATIENT | | | |
|---|---|---|---|
| Name: | TEST, PATIENT | | |
| Address: | 101 Main Street, #1<br>Pleasanton, CA 94588 | | |
| Phone: | (631) 000-0000 | ID: | ID1989M |
| Date of Birth: 01/01/1974 | | Gender: | Male |
| Race: | White | | |

| SPECIMEN |
|---|
| Type: Needle Biopsy |
| Collection Date: 01/30/24 |
| Received Date: 01/30/24 |
| Reported Date: 02/03/24 |
| **Accession #:** 2401300005 |

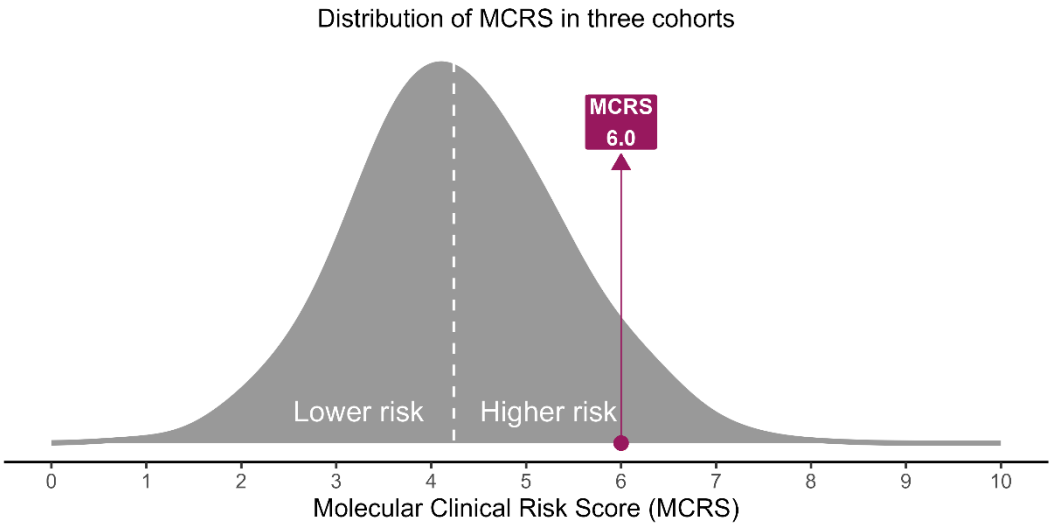
| PHYSICIAN | |
|---|---|
| ID: 1990 | NPI: XXXX |
| Name: 2ND TEST CLIENT | |
| Address: 11 Grace Av, 208<br>Pleasanton, CA 94588 | |
| Phone: (000) 000-0000 | |
| Referring: 1988 DOCTOR Dr. | |

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

# OncoAssure™ Prostate Test Report

## Test Result

Molecular Clinical Risk Score (MCRS): 6.0




## Interpretation

| | | |
|---|---|---|
| **Risk score (0 to 10)** | **6.0** | 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** | **93rd** | This MCRS is in the 93rd percentile of molecular and clinical risk.[1] 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.[1] Therefore, the patient is considered higher 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[1]. Men whose OncoAssure Prostate risk score indicates they have a low risk of underlying aggressive disease may be suitable candidates for active surveillance[2, 3, 4]. 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