Genomic Prostate Score® (GPS™) Report

For NCCN Unfavorable Intermediate & High Risk Groups

oncotype DX®
Genomic Prostate Score

LASTNAME, FIRSTNAME MI.

Date of Birth: **01-Jan-1960** Gender: **Male** Report Number: **OR000123456-6007** Report Date: **13-APR-2022**

Ordering Physician: **Dr. First-Name I. Ordering-Physician-Last-Name**

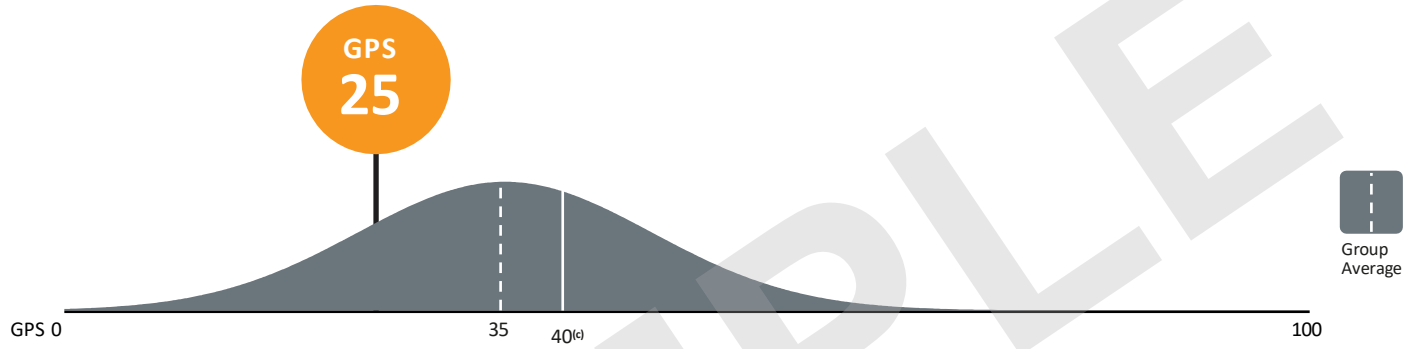
Submitted NCCN Risk Group[(a),1]: Unfavorable Intermediate

Physician-Provided Information[(b)]:

Gleason Score: **3+4**
PSA (ng/mL): **11.0**
Clinical Stage: **T2a**
Max. % of tumor involvement in any core: **≤ 50%**

Prostate Volume (cc): **30**
PSA Density (ng/mL/cc): **0.37**
Number of Cores Positive: **2**
Number of Cores Collected: **12**

Normalized GPS Distribution Curve in NCCN Unfavorable Intermediate Risk Patients[2-4]



Likelihood of Disease Progression

POST THERAPY OUTCOMES*	LIKELIHOOD OF DISEASE PROGRESSION
Metastasis Within 10 Years[(d)]	5% (95% CI: 3% - 9%)
Prostate Cancer Death Within 10 Years	1% (95% CI: 0% - 1%)

Clinical Interpretation

- Based on this patient's GPS result of 25 and their submitted NCCN risk group, their likelihood of distant metastasis within 10 years is 5% and their likelihood of death due to prostate cancer within 10 years is 1%, if treated with radical prostatectomy or radiation therapy.
- In clinical validation studies, the 10-year likelihood of distant metastasis for the mean GPS result in NCCN unfavorable intermediate risk patient is 10% (95%CI: 6%-15%).[3,4]
- In clinical validation studies, patients with a GPS result 40 and below had lower likelihood of disease progression (distant metastasis and death due to prostate cancer) than those with a GPS result above 40, after being treated with either radical prostatectomy or radiation therapy.[3,4]

Footnotes and references are at the bottom of page 2

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Ordering Physician: **Dr. First-Name I. Ordering-Physician-Last-Name**

Medical Record/Patient #: **1234567-01**

Specimen Source/ID: **Prostate/SP-16_0123456**

Date of Collection: **19-Apr-2022**

Specimen Received: **12-Apr-2022**

Additional Recipient: **Dr. First-Recipient-Physician-Last-Name**

Pathologist: **Dr. First-Name I. Pathologist-Last-Name**

10-Year Likelihood of Distant Metastasis in NCCN Unfavorable Intermediate Risk Group

5%

95% CI: 3% - 9%

The 10-year likelihood of distant metastasis is based on the combination of this patient's GPS result and NCCN risk group, after treatment with radical prostatectomy or radiation therapy.

In the clinical validation studies, for the mean GPS result of 35, the 10-year likelihood of distant metastasis is 10% (95% CI: 6% - 15%).[3,4]

IMPORTANT INFORMATION

- The results in this report reflect a meta-analysis of fve clinical validation studies with 597 patients, treated by either radical prostatectomy or radiotherapy and incorporating NCCN risk group and the GPS result to estimate 10-year likelihood of disease progression.[3,4] Patients were treated within 12 months of the biopsy used to generate the GPS result.
- Based on clinical data and clinical guidelines, patients with localized prostate cancer in the unfavorable intermediate and higher risk groups have a high likelihood of disease progression and are candidates for intensifcation of therapy **(see NCCN Guidelines Version 3.2022, PROS-6 and PROS-7)[1].**
- The GPS test is a continuous scale (0-100) that quantifes expression of 17 genes in tumor tissue as assessed by RT-PCR.
- The GPS test has been validated in six prospectively designed studies (N=1,885) of biopsy tissue from patients with localized prostate cancer. [2-4, 6]

Footnotes:

(a) Calculated or reported from physician-provided clinical information. **(b)** N/A (not available) indicates data has not been provided to Genomic Health.[4,5] **(c)** The dichotomous GPS cut-point of 40 was validated in four studies and demonstrated significantly higher likelihood of post-treatment recurrence, metastasis, and prostate cancer death for patients falling above the cut-point.[4,5] **(d)** In the clinical validation studies, metastasis was determined by imaging or biopsy and disease progression is defined by prostate cancer death and metastasis. * In the clinical validation studies, all patients received radical prostatectomy or radiation therapy as their primary intervention. Risk estimates provided are based on the GPS result and submitted NCCN risk group.

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.3.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed April 1, 2022. To view the most recent and complete version of the guideline, go online to NCCN.org. **2.** Cullen J, et al. *Eur Urol*. 2015. **3.** Van Den Eeden S, et al., *Eur Urol*. 2017. **4.** Data on file. **5.** Cullen J, et al., *Urology*. 2020. **6.** Klein E, et al. *Eur Urol*. 2014.

Laboratory Director(s): F. Baehner, MD & P. Joseph, MD

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

EXACT SCIENCES

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