

PATIENT-LAST-NAME, FIRST-NAME I.

Date of Birth: 01-Jan-1950

Gender: Male

Report Number: OR000123456-6006

Report Date: 01-Oct-2020

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

## GPS + NCCN<sup>®1</sup> : Low Risk



### Clinical Interpretation

### Clinical Endpoints

### Individualized Risk (95% Confidence Interval [CI])

The combination of GPS and clinical features predicts that this patient's risk is consistent with **NCCN Low Risk** disease.<sup>‡</sup>

In a clinical validation study including patients with NCCN Very Low, Low, and Intermediate Risk, **no patient with a GPS result <20 had metastasis or died** from prostate cancer within 10 years.<sup>†</sup>

**Prostate Cancer Death Within 10 Years<sup>†</sup>**



**Metastasis Within 10 Years<sup>†§</sup>**



**Adverse Pathology<sup>†</sup>**  
(Gleason  $\geq$  4+3 and/or pT3+)



### NCCN Risk Group<sup>||</sup> : Favorable Intermediate Physician-Provided Information<sup>¶</sup> :

Gleason Score: **3+4**

PSA (ng/mL): **5.0**

Clinical Stage: **T1c**

Max. % of tumor involvement in any core:  **$\leq$  50%**

Prostate Volume (cc): **30**

PSA Density (ng/mL/cc): **0.17**

Number of cores positive: **2**

Number of cores collected: **12**

\* The NCCN Guidelines identify a subset of Favorable Intermediate Risk patients: Gleason Score Group 1 or 2, percentage of positive biopsy cores <50%, and no more than one NCCN Intermediate Risk factor.

<sup>†</sup> In the clinical validation study, all patients received radical prostatectomy. The risk estimates provided are based on the patient's GPS result and NCCN risk group.

<sup>‡</sup> The GPS + NCCN risk group is defined by the likelihood of adverse pathology and/or the risk of metastasis within 10 years and was derived from the clinical validation studies using the clinically relevant endpoint(s) for each risk group. Additional detail on file and available upon request.

<sup>§</sup> In the clinical validation study, metastasis was determined by imaging or biopsy.

<sup>||</sup> Calculated or reported from physician-provided clinical information.

<sup>¶</sup> N/A (not available) indicates data has not been provided to Genomic Health.

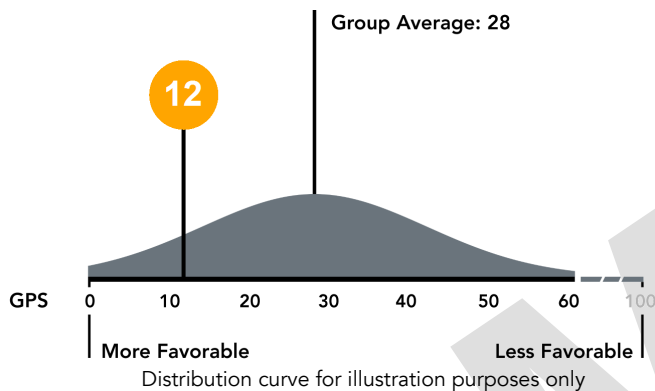
# Genomic Prostate Score<sup>®</sup> (GPS<sup>™</sup>) Report

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Date of Birth: **01-Jan-1950** Gender: **Male** Report Number: **OR000123456-6006** Report Date: **01-Oct-2020**  
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: **16-Sep-2020**  
Specimen Received: **18-Sep-2020**  
Additional Recipient: **Dr. First-Name I. Recipient-Physician-Last-Name**  
Pathologist: **Dr. First-Name I. Pathologist-Last-Name**

## GPS Distribution in NCCN<sup>®</sup> Favorable Intermediate Risk<sup>2,3,5</sup>



## Pathology Endpoints\*\*

Individualized Risk  
(95% Confidence Interval [CI])

**High-Grade Disease**  
(Gleason  $\geq 4+3$ )

**11%**

(95% CI: 7% - 18%)

**Non-Organ-Confined Disease**  
(pT3+)

**11%**

(95% CI: 7% - 17%)

This patient has a GPS result that is **lower than the average** **GPS result** for NCCN Favorable Intermediate Risk.

The Oncotype DX Genomic Prostate Score (GPS) test is a continuous scale (0-100) that quantifies expression of 17 genes in tumor tissue as assessed by RT-PCR. The GPS test has been validated in three prospectively designed studies (N=1056) of biopsy tissue from patients with localized prostate cancer.<sup>2,3,5</sup>

Adverse pathology refers to the finding of an aggressive tumor (high grade) or cancer spread outside of the prostate (non-organ confined). Tumors with a low risk of adverse pathology are less likely to be aggressive and spread.

\*\* In the clinical validation study, all patients received radical prostatectomy. The risk estimates provided are based on the patient's GPS result and NCCN risk group.

**References:** 1. National Comprehensive Cancer Network<sup>®</sup>. NCCN Clinical Practice Guidelines in Oncology<sup>®</sup>: Prostate cancer. Version 2. Accessed July 2020. 2. Klein E, et al. *Eur Urol*. 2014. 3. Cullen J, et al. *Eur Urol*. 2015. 4. Brand T, et al. *Urology*. 2016. 5. Van Den Eeden S, et al. *Eur Urol*. 2017.

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## Laboratory Director(s): William P. Joseph, M.D.

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**

Genomic Health, Inc.  
301 Penobscot Drive, Redwood City, CA 94063 USA  
+1.866.ONCOTYPE (+1.866.662.6897)  
[www.oncotypedx.com/contact](http://www.oncotypedx.com/contact)  
CLIA Number 05D1018272