Genomic Prostate Score® (GPS™) Report

For NCCN Very Low, Low, and Favorable Intermediate Risk Groups

oncotype DX®
Genomic Prostate Score

PATIENT-LAST-NAME, FIRST-NAME I.

Date of Birth: **01-Jan-1950** Gender: **Male** Report Number: **OR000123456-6006** Report Date: **01-Dec-2021**

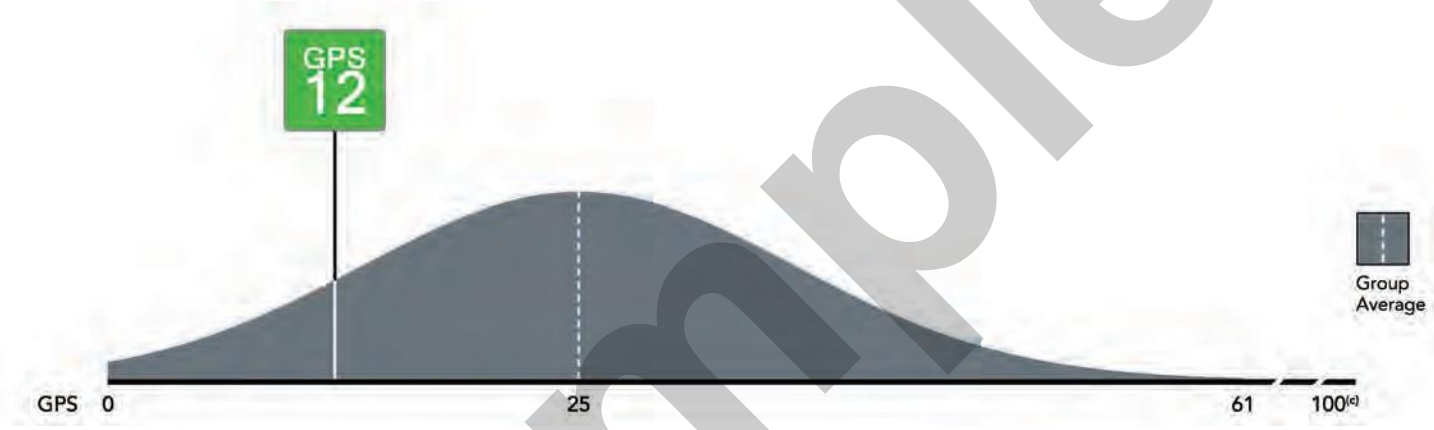
Ordering Physician: **Dr. First-Name I. Ordering-Physician-Last-Name**

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

Physician-Provided Information[(b)] :

Gleason Score: **3+3**	Prostate Volume (cc): **20**
PSA (ng/mL): **5.0**	PSA Density (ng/mL/cc): **0.30**
Clinical Stage: **T2a**	Number of Cores Positive: **1**
Max. % of tumor involvement in any core: **≤ 50%**	Number of Cores Collected: **12**

Patient's GPS Result Is 12



The graph above shows the range of GPS results with estimates of likelihood of adverse pathology for NCCN Low risk.[2,3]

Likelihood of Adverse Pathology at Radical Prostatectomy[(d)]

Clinical Interpretation[(e)]

- This patient's likelihood of adverse pathology (higher Gleason Score and/or extraprostatic disease[(f)]) at radical prostatectomy is **16%** (95% CI: 12% - 21%) based on the combined GPS result and NCCN risk group.
- Data from the clinical validation studies suggest this patient has a **low likelihood** of adverse pathology, compared to other patients in the clinical validation studies.[2,3]
- In our clinical validation studies, 29% of patients with NCCN Low risk prostate cancer had adverse pathology at radical prostatectomy.[2,3]

(a) Calculated or reported from physician-provided clinical information. **(b)** N/A (not available) indicates data has not been provided to Genomic Health. **(c)** Distribution curve for illustrative purposes only. **(d)** Based on GPS result & submitted NCCN risk group. **(e)** All Patients in the clinical validation studies have been treated with radical prostatectomy. **(f)** Gleason Score ≥4+3 and/or pT3+.

Genomic Prostate Score® (GPS™) Report

For NCCN Very Low, Low, and Favorable Intermediate Risk Groups

oncotype DX®
Genomic Prostate Score

PATIENT-LAST-NAME, FIRST-NAME I.

Date of Birth: **01-Jan-1950** Gender: **Male** Report Number: **OR000123456-6006** Report Date: **01-Dec-2021**

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-Nov-2021**

Specimen Received: **18-Nov-2021**

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

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

ADVERSE OUTCOME	LIKELIHOOD OF ADVERSE OUTCOME	CLINICAL INTERPRETATION
High-Grade Disease (Gleason ≥ 4+3)	9% (95% CI: 6% - 13%)	The risk estimates provided are based on the patient's GPS result and submitted NCCN risk group. In our clinical validation studies, all patients received radical prostatectomy.[2,3]
Non-Organ Confined Disease (pT3+)	9% (95% CI: 6% - 12%)	

ADVERSE OUTCOME	LIKELIHOOD OF ADVERSE OUTCOME	CLINICAL INTERPRETATION
Metastasis Within 10 Years After Radical Prostatectomy(g)	1% (95% CI: <1% - 6%)	In our clinical validation studies, **no patient with a GPS result <20 had metastasis or died** from prostate cancer within 10 years post radical prostatectomy.[4]
Prostate Cancer Death Within 10 Years After Radical Prostatectomy	<1% (95% CI: <1% - <1%)	

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.[2,3,4]

(g) In the clinical validation study, metastasis was determined by imaging or biopsy.

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. Klein E, et al. *Eur Urol.* 2014.
3. Cullen J, et al. *Eur Urol.* 2015.
4. Van Den Eeden S, et al. *Eur Urol.* 2017.

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
CLIA Number 05D1018272