Genomic Prostate Score® (GPS™) Report

Genomic Prostate Score

(Formerly Oncotype DX GPS)

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

FIRSTNAME, LASTNAME MI.

mdx #: A123456

Date of Birth: 01-Jan-1950 Gender: Male Report Number: 000000000000000 Report Date: 01-DEC-2021

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

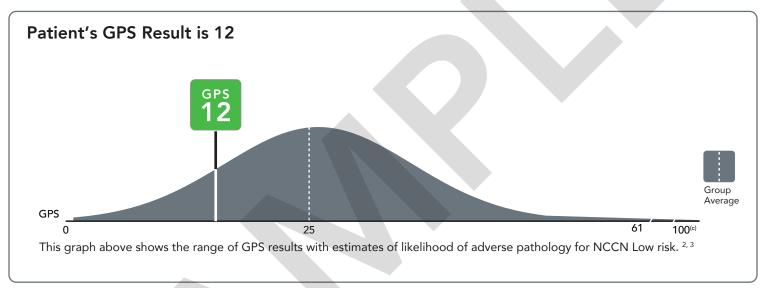
Submitted NCCN Risk Group^{(a),1}: Low

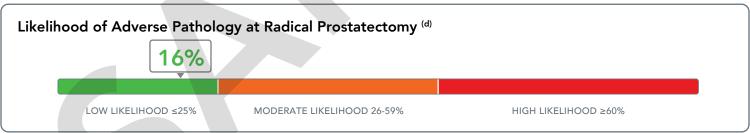
Physician-Provided Information(b):

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





Clinical Interpretation(e)

- This patient's likelihood of adverse pathology (higher Gleason Score and/or extra prostatic 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+.

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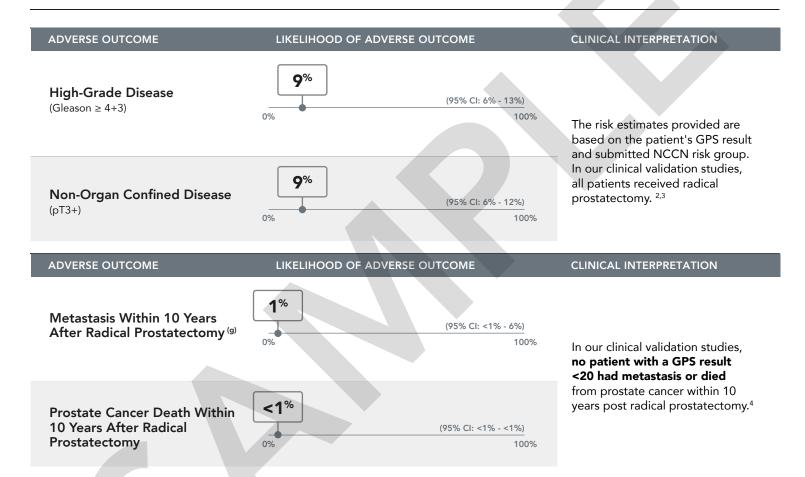
Date of Birth: 01-Jan-1950 Gender: Male Report Number: 000000000000000 Report Date: 01-DEC-2021

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: **10-Apr-2023**Specimen Received: **12-Apr-2023**



The Oncotype DX Genomics 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 patents with localized prostate cancer. ^{2,3,4}

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

References: 1. 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 guidelines, 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, 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.



mdxhealth

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