Genomic Prostate Score® (GPS™) Report

oncotype DX® Genomic Prostate Score

PATIENT LAST NAME, FIRST NAME

Date of Birth: **01-Jan-1950** Gender: **Male** Report Number: **OR000123456-6007** Report Date: **17-July-2021**

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

NCCN® Risk Group[II,1]: Unfavorable Intermediate

Physician-Provided Information[¶]:

Gleason Score: **3+4**

PSA (ng/mL): **9.2**

Clinical Stage: **T2c**

Max. % of tumor involvement in any core: **≤ 50%**

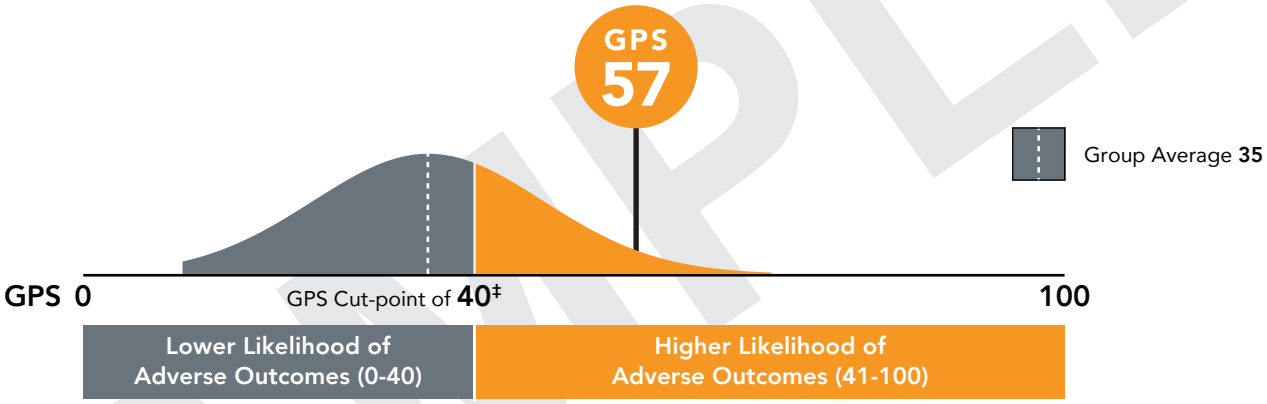
Prostate Volume (cc): **40**

PSA Density (ng/mL/cc): **0.23**

Number of Cores Positive: **6**

Number of Cores Collected: **14**

GPS Distribution in NCCN Unfavorable Intermediate Risk Patients[1,3,5,7]



ADVERSE OUTCOMES	LIKELIHOOD OF ADVERSE OUTCOMES*	CLINICAL INTERPRETATION
Prostate Cancer Death Within 10 Years	5% (0% — (95% CI: 2% - 9%) — 100%)	In clinical studies, the **GPS result was significantly associated with likelihood of adverse outcomes** (Prostate Cancer Death, Metastasis and Biochemical Recurrence). Patients with a **GPS result > 40** were shown to have **higher likelihood** of adverse outcomes, when compared with patients with a **GPS result ≤ 40.**[6,7]
Metastasis Within 10 Years[§]	30% (0% — (95% CI: 15% - 53%) — 100%)	
Biochemical Recurrence Within 3 Years	72% (0% — (95% CI: 60% - 83%) — 100%)	

*In clinical validation studies, all patients received radical prostatectomy. Risk estimates provided are based on the GPS result and NCCN risk group.

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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: **01-May-2021**

Specimen Received: **03-May-2021**

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

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

ADVERSE OUTCOMES	LIKELIHOOD OF ADVERSE OUTCOMES	CLINICAL INTERPRETATION
Adverse Pathology (Gleason ≥ 4+3 and/or pT3+)		The combination of GPS and clinical features predicts that this patient's risk of Adverse Pathology is 77%
High-Grade Disease (Gleason ≥ 4+3)		In the clinical validation studies, all patients received radical prostatectomy. The risk estimates provided are based on the patient's GPS result and NCCN risk group.
Non-Organ Confined Disease (pT3+)		

‡ The dichotomous GPS cut-point of 40 was validated in two studies 6, 7 for likelihood of adverse outcomes and demonstrated significantly higher likelihood of BCR within 3 years, metastasis within 10 years, and prostate cancer death within 10 years for patients falling above the cut-point.

§ In the clinical validation study, metastasis was determined by imaging or biopsy.

‖ Calculated or reported from physician-provided clinical information.

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

References: 1. National Comprehensive Cancer Network®. NCCN Clinical Practice Guidelines in Oncology®: Prostate cancer. Version 2.2021. **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. **6.** Cullen J, et al., Urology. 2020. **7.** Data on File.

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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