# Genomic Prostate Score® (GPS™) Report

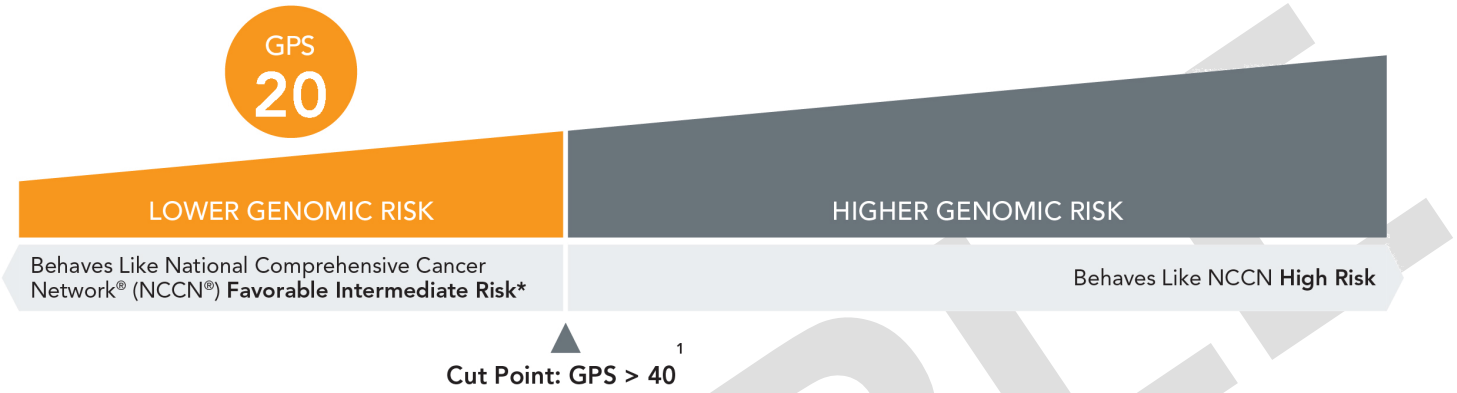
oncotype DX® Genomic Prostate Score

## PATIENT-LAST-NAME, FIRST-NAME I.

Date of Birth: **01-Jan-1950** Gender: **Male** Report Number: **OR000123456-6015** Report Date: **01-Oct-2020**

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

## Genomic Risk:




| Clinical Endpoints | Individualized Risk (95% Confidence Interval [CI]) |
|---|---|
| Prostate Cancer Death Within 10 Years† | <1% (95% CI: <1% - 1%) |
| Metastasis Within 10 Years†§ | 4% (95% CI: 2% - 10%) |
| Adverse Pathology† (Gleason ≥ 4+3 and/or pT3+) | 37% (95% CI: 28% - 47%) |



**NCCN Risk Group‖ : Unfavorable Intermediate**

**Physician-Provided Information¶ :**

| | |
|---|---|
| Gleason Score: **3+4** | Prostate Volume (cc): **30** |
| PSA (ng/mL): **11.0** | PSA Density (ng/mL/cc): **0.37** |
| Clinical Stage: **T2b** | Number of cores positive: **2** |
| Max. % of tumor involvement in any core: **≤ 50%** | 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.

† 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.

§ 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.

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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**

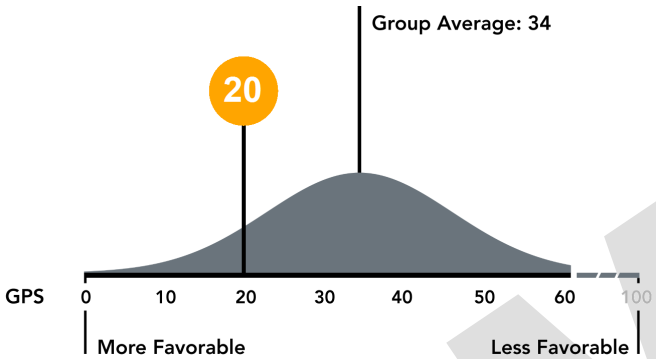
Date of Collection: **16-Sep-2020**

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® Unfavorable Intermediate Risk[2,3,5]




Distribution curve for illustration purposes only

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

| Pathology Endpoints** | Individualized Risk (95% Confidence Interval [CI]) |
|---|---|
| **High-Grade Disease** (Gleason ≥4+3) | 17% (95% CI: 11% - 25%) |
| **Non-Organ-Confined Disease** (pT3+) | 21% (95% CI: 14% - 30%) |

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.[2,3,5]

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.** Cullen J, et al. *Urology*. 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.



## 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