GPS + NCCN® : Very Low Risk

The combination of GPS and clinical features predicts that this patient’s risk is consistent with NCCN Very Low Risk disease.†

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.‡

Prostate Cancer Death Within 10 Years†

Metastasis Within 10 Years†§

Adverse Pathology†

(Gleason ≥ 4+3 and/or pT3+)

NCCN Risk Group II: Low

Physician-Provided Information¶:

Gleason Score: 3+3
PSA (ng/mL): 5.0
Clinical Stage: T2a
Max. % of tumor involvement in any core: ≤ 50%

Prostate Volume (cc): 20
PSA Density (ng/mL/cc): 0.30
Number of cores positive: 1
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.
‡ 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.
§ 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.
Genomic Prostate Score® (GPS™) Report

PATIENT-LAST-NAME, FIRST-NAME I.

Date of Birth: 01-Jan-1950  Gender: Male  Report Number: OR00123456-6003  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® Low Risk

<table>
<thead>
<tr>
<th>Group Average: 25</th>
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<tbody>
<tr>
<td>10</td>
</tr>
</tbody>
</table>

This patient has a GPS result that is lower than the average GPS result for NCCN Low 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.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.

Pathology Endpoints**

<table>
<thead>
<tr>
<th>High-Grade Disease (Gleason ≥4+3)</th>
<th>8%</th>
</tr>
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<tbody>
<tr>
<td>(95% CI: 6% - 12%)</td>
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</table>

<table>
<thead>
<tr>
<th>Non-Organ-Conﬁned Disease (pT3+)</th>
<th>9%</th>
</tr>
</thead>
<tbody>
<tr>
<td>(95% CI: 6% - 14%)</td>
<td></td>
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</tbody>
</table>

**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.


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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.

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