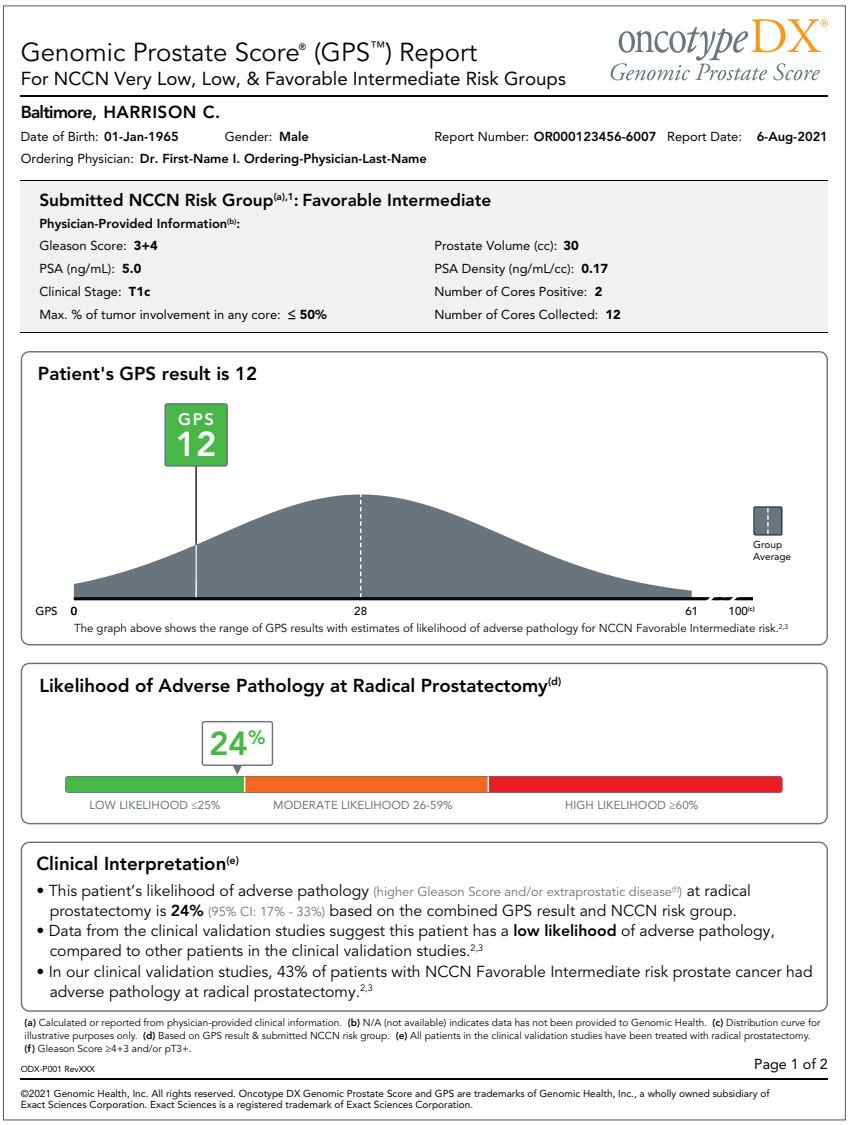
A Tailored Report for Clinically Low Risk Prostate Cancer Patients

Oncotype DX Genomic Prostate Score® (GPS™) assay

The Oncotype DX® GPS™ assay is an important tool for shared decision making with your localized prostate cancer patients. The Oncotype DX GPS report for clinically low risk patients provides actionable data that predicts tumor aggressiveness to help inform the critical treatment decision between active surveillance and immediate treatment.

The redesigned Oncotype DX GPS report:

- Displays the **integration of clinical, pathologic and genomic insights** into actionable information
- Focuses on the right endpoint*, Adverse Pathology, with the most comprehensive definition
- Provides the individualized risk of extraprostatic extension
- Provides risk groups to facilitate impactful patient-physician conversations



Genomic Prostate Score® (GPS™) Report
For NCCN Very Low, Low, & Favorable Intermediate Risk Groups

oncotype DX® Genomic Prostate Score

Baltimore, HARRISON C.

Date of Birth: **01-Jan-1965** Gender: **Male** Report Number: **OR000123456-6007** Report Date: **6-Aug-2021**

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

Submitted NCCN Risk Group[a],1: Favorable Intermediate

Physician-Provided Information[b]:

Gleason Score: **3+4**	Prostate Volume (cc): **30**
PSA (ng/mL): **5.0**	PSA Density (ng/mL/cc): **0.17**
Clinical Stage: **T1c**	Number of Cores Positive: **2**
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 Favorable Intermediate 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 **24%** (95% CI: 17% - 33%) 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, 43% of patients with NCCN Favorable Intermediate 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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Clinical & Pathologic Information

The clinical and pathologic information that is provided by the urologist detailing how the patient initially presented and their submitted risk group.

GPS Distribution Curve

Helps urologists personalize their conversations with patients by illustrating how the GPS result compares to other similar risk patients. In this example, the GPS result for this patient is lower than the average result for other NCCN® Favorable Intermediate risk patients.

Genomics Insights

Adverse Pathology predicts **whether the patient is harboring more or less aggressive disease** represented along a continuum of risk.

Where Insights Connect

The clinical interpretation summarizes what the test predicts and an overall summary. The result is calculated from the combination of the GPS result and NCCN risk group based on the information provided at the time of the order.

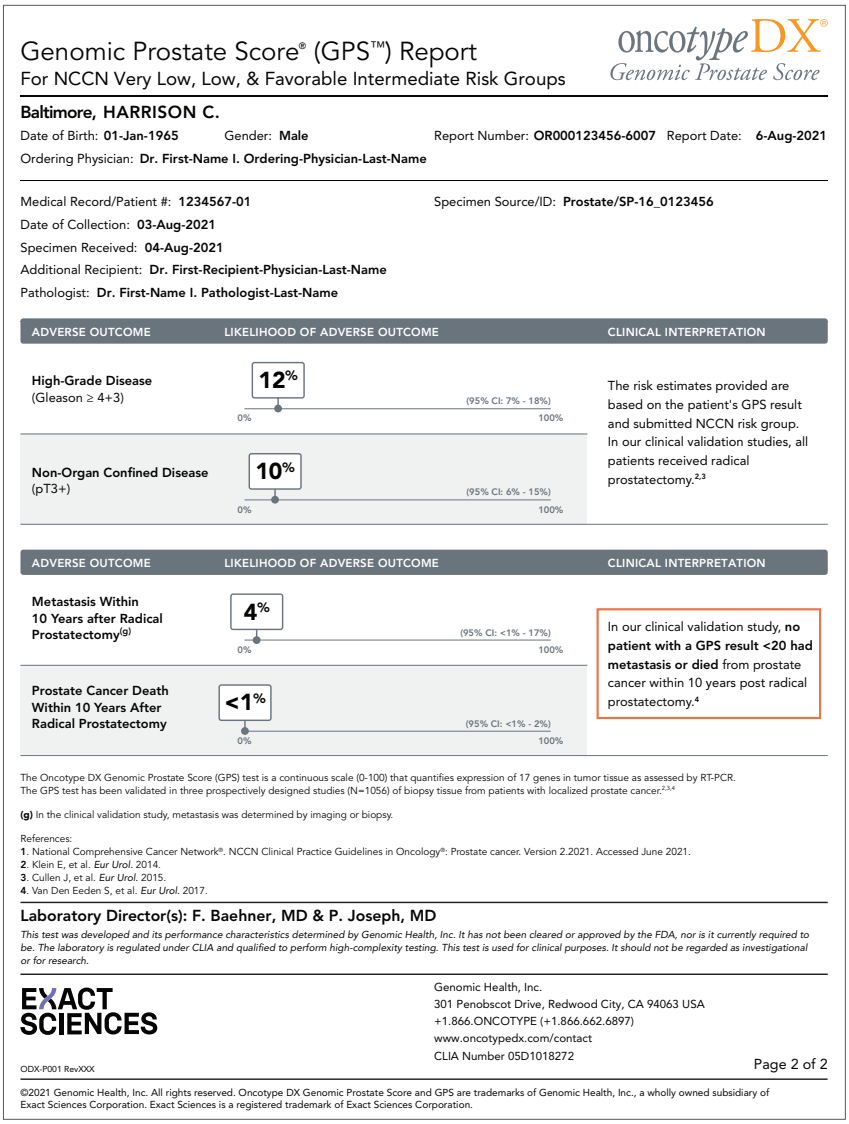
oncotype DX® Genomic Prostate Score

The Oncotype DX® GPS™ test is the only commercially available test to provide all these endpoints.

Adverse Outcomes

Endpoints that the Oncotype DX GPS report includes:

- Risk of high-grade (≥GG3) disease
- Risk of ≥pT3a disease
- Risk of metastasis within 10 years
- Risk of PCa-specific death within 10 years



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oncotype DX® Genomic Prostate Score

Baltimore, HARRISON C.
Date of Birth: **01-Jan-1965** Gender: **Male** Report Number: **OR000123456-6007** Report Date: **6-Aug-2021**
Ordering Physician: **Dr. First-Name I. Ordering-Physician-Last-Name**

Medical Record/Patient #: **1234567-01**
Date of Collection: **03-Aug-2021**
Specimen Received: **04-Aug-2021**
Additional Recipient: **Dr. First-Recipient-Physician-Last-Name**
Pathologist: **Dr. First-Name I. Pathologist-Last-Name**
Specimen Source/ID: **Prostate/SP-16_0123456**

ADVERSE OUTCOME	LIKELIHOOD OF ADVERSE OUTCOME	CLINICAL INTERPRETATION
High-Grade Disease (Gleason ≥ 4+3)	12% (95% CI: 7% - 18%); 0% 100%	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+)	10% (95% CI: 6% - 15%); 0% 100%	

ADVERSE OUTCOME	LIKELIHOOD OF ADVERSE OUTCOME	CLINICAL INTERPRETATION
Metastasis Within 10 Years after Radical Prostatectomy[(g)]	4% (95% CI: <1% - 17%); 0% 100%	In our clinical validation study, **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% - 2%); 0% 100%	

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. National Comprehensive Cancer Network®. NCCN Clinical Practice Guidelines in Oncology®: Prostate cancer. Version 2.2021. Accessed June 2021.
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): 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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Pathology Endpoints

Patient's risk is further broken out into additional pathology endpoints: both the likelihood of High-Grade Disease (Gleason ≥4+3) AND the likelihood of Non-Organ Confined Disease (pT3+), the only commercially available test to provide this information.

Long Term Outcomes

The Oncotype DX GPS test has been validated to independently predict 10-year risk of **prostate cancer death** and **metastasis.**

*Brooks et. al. Urologic Oncology: Seminars and Original Investigations. 2021.

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