CLINICALLY HIGH-RISK PATIENTS

oncotype DX®
Genomic Prostate Score

INTRODUCING the Oncotype DX Genomic Prostate Score® (GPS™) assay for clinically high-risk prostate cancer

THE NEW REPORT IS SPECIFICALLY DESIGNED TO HELP GUIDE TREATMENT DECISIONS IN UNFAVORABLE INTERMEDIATE- AND HIGH-RISK PATIENTS

Risk categories associated with clinically high-risk prostate cancer

UNFAVORABLE INTERMEDIATE RISK	HIGH RISK	VERY HIGH RISK*

Common clinical and pathologic features of patients with unfavorable intermediate- or high-risk prostate cancer[1]

- Grade Group 2 with ≥50% biopsy cores positive
- Grade Group 2 and PSA 10-20 ng/mL
- Grade Group 3 or higher
- PSA >20 ng/mL

The challenge in the clinically high-risk setting is deciding on the appropriate level of treatment[2,3]

Treatment modalities vary based on disease severity

TYPICAL TREATMENT CONSIDERATIONS IN THE CLINICALLY HIGH-RISK SETTING[1]

- Single mode of treatment
- Multiple modes of treatment
- Androgen deprivation therapy duration

The GPS™ assay can help you determine the right level of treatment

THE ONCOTYPE DX GENOMIC PROSTATE SCORE® (GPS™) ASSAY

Clinically validated to help answer key questions in the clinically high-risk setting

The GPS assay is a strong independent predictor of adverse outcomes that guide treatment decision making[2,3]

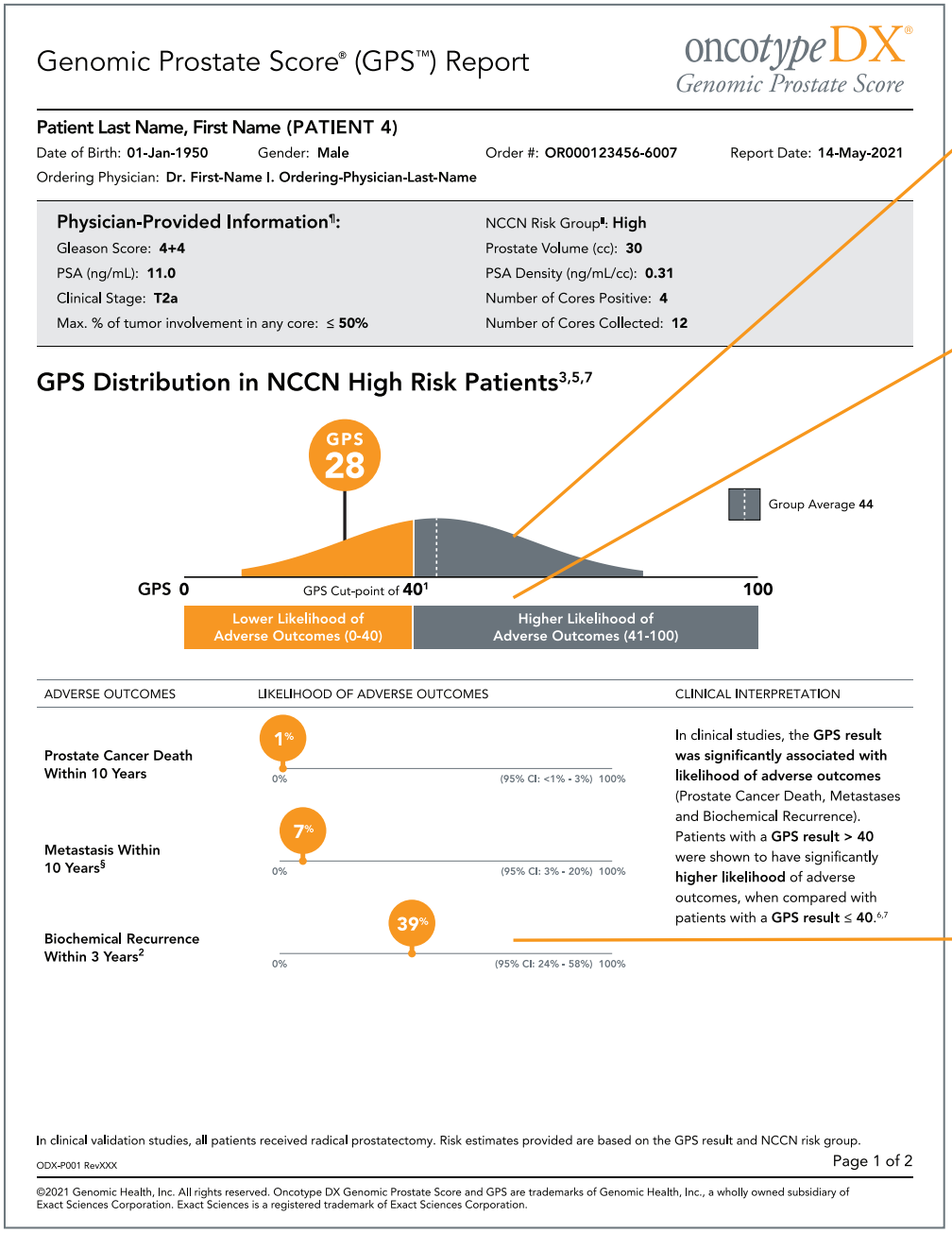
BIOCHEMICAL RECURRENCE (BCR) WITHIN 3 YEARS	PROSTATE CANCER DEATH (PCD) AND METASTASIS WITHIN 10 YEARS
PROVIDES the likelihood of increasing prostate-specific antigen (PSA) levels post-radical prostatectomy (RP) within 3 years of treatment • Defined as either two successive post-RP PSA levels of ≥ 0.2 ng/mL, or initiation of salvage radiotherapy or hormonal therapy after a rising PSA	**PROVIDES** prognostic information about a patient's individual risk of death and metastasis within 10 years of radical prostatectomy

Knowing the likelihood of adverse outcomes helps provide the information you and your patients need to choose a treatment plan with added confidence.

One size does not fit all in prostate cancer

The new report helps you quickly evaluate where your clinically high-risk patient fits in the spectrum of risk

Patients with lower risk levels may require a single modality of treatment, while patients with higher risk levels may require a more aggressive combination therapy approach[2]



Genomic Prostate Score® (GPS™) Report

oncotype DX® Genomic Prostate Score

Patient Last Name, First Name (PATIENT 4)

Date of Birth: **01-Jan-1950** Gender: **Male** Order #: **OR000123456-6007** Report Date: **14-May-2021**

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

Physician-Provided Information¶:

Gleason Score: **4+4**
PSA (ng/mL): **11.0**
Clinical Stage: **T2a**
Max. % of tumor involvement in any core: ≤ **50%**
NCCN Risk Group¶: **High**
Prostate Volume (cc): **30**
PSA Density (ng/mL/cc): **0.31**
Number of Cores Positive: **4**
Number of Cores Collected: **12**

GPS Distribution in NCCN High Risk Patients[3,5,7]

ADVERSE OUTCOMES	LIKELIHOOD OF ADVERSE OUTCOMES	CLINICAL INTERPRETATION
Prostate Cancer Death Within 10 Years	1% (0% – (95% CI: <1% - 3%) – 100%)	In clinical studies, the **GPS result was significantly associated with likelihood of adverse outcomes** (Prostate Cancer Death, Metastases and Biochemical Recurrence). Patients with a **GPS result > 40** were shown to have significantly **higher likelihood** of adverse outcomes, when compared with patients with a **GPS result ≤ 40**.[6,7]
Metastasis Within 10 Years§	7% (0% – (95% CI: 3% - 20%) – 100%)	
Biochemical Recurrence Within 3 Years[2]	39% (0% – (95% CI: 24% - 58%) – 100%)	

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

ODX-P001 RevXXX Page 1 of 2

The bell curve provides a comparison to other patients within the risk category—you can use it to show your patients where they fit

The GPS cut point of 40 helps simplify patient discussions for shared decision making

Actionable endpoints that match the questions in the clinically high-risk setting

Guide your treatment decisions in clinically high-risk patients with the new report.

treatment

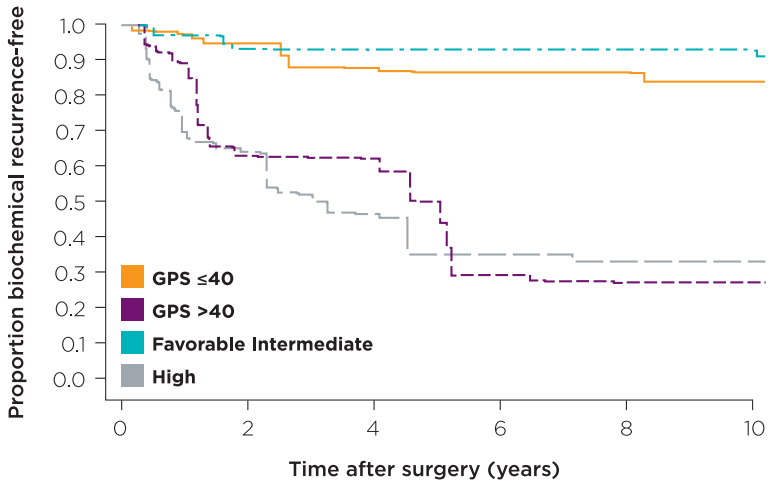
Validated for use in clinically high-risk patients[2,3]

The GPS cut point of 40 was shown to be a strong predictor of adverse outcomes[2,3]

Patients with a GPS result of ≤40 had outcomes similar to those with favorable intermediate disease; patients with a result of >40 had outcomes resembling those with high-risk disease.[2]

- The majority of patients with a GPS result of >40 experienced BCR

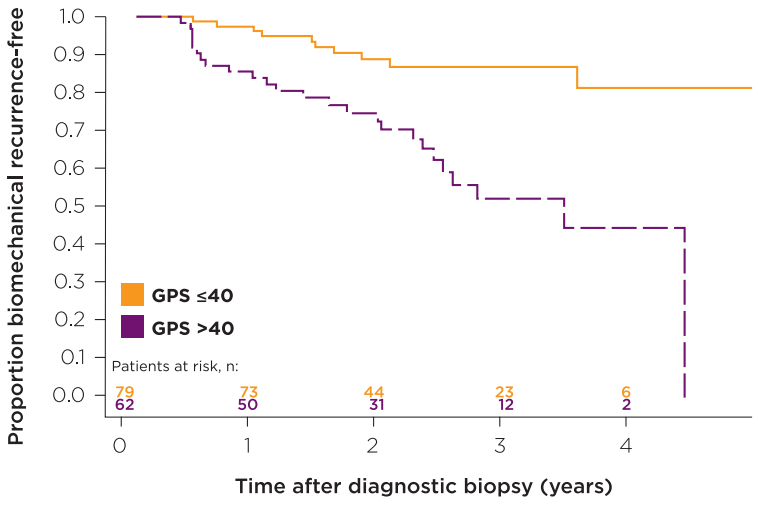
BCR in unfavorable intermediate-risk patients stratified by GPS result ≤40 and >40 (n = 175)



The GPS cut point was prognostic in patients with a risk level of intermediate or higher.[3]

- At any given point during the study, patients with a GPS result >40 had a risk of BCR that was 3.8 times higher than those ≤40

BCR in patients with a risk level of intermediate or higher stratified by GPS result ≤40 and >40 (n = 141)



Use the GPS cut point to inform treatment planning.

BCR = biochemical recurrence.

THE ONCOTYPE DX GENOMIC PROSTATE SCORE® (GPS™) ASSAY

Use the GPS assay to confirm the treatment plan for your clinically high-risk patients[2,3]

The GPS assay is a strong predictor of adverse outcomes in the clinically high-risk setting[2,3]

The new report helps you quickly evaluate where your patient fits in the spectrum of risk

oncotype DX® Genomic Prostate Score

ORDER NOW
Contact your local Exact Sciences representative or Customer Service at **866 ONCOTYPE** (866-662-6897).

*Very high-risk prostate cancer patients are not eligible for the GPS assay.

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer. V.2.2021. ©National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed May 25, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. **2.** Cullen et al. *Urology*. 2020. **3.** Data on file, Exact Sciences.