



NCCN Guidelines Level 1 Update
For Internal Use Only January 2025

GPS Evidence Summary and NCCN Guidelines Review

Please refer to this piece, distributed December 11, 2024

To achieve NCCN level 1 evidence the only requirement differentiating GPS and Decipher is a prospective clinical trial

GPS currently has a prospective controlled trial in progress, and >30 studies documenting the clinical validity and utility of the test.

Decipher, GPS, and Prolaris do not have Level 1 Evidence for Very Low and Low Risk

Genomic Prostate Score[®]

Genomic Prostate Score Level of Clinical Validation Evidence

The Genomic Prostate Score (GPS) test represents a breakthrough in prostate cancer risk stratification, with robust clinical validation studies demonstrating its exceptional predictive capabilities. The GPS test has been validated through multiple studies showing its ability to provide more precise risk assessment beyond traditional clinicopathological parameters. Multiple validation studies have demonstrated GPS's guide more personalized treatment decisions, with key findings published in leading urology journals.

GPS has 31 studies total

- 11 Clinical Validation studies
- 7 Clinical Utility studies
- 7 Prospective Studies (2 of which are multi-center)
- 24 Retrospective Studies
- Per NCCN risk group
 - 26 Very Low-/Low-Risk
 - 29 Intermediate-Risk
 - 6 High-Risk

Licensed and approved to accept specimens from all 50 states and accredited by:

- Clinical Laboratory Improvement Amendments (CLIA) for the Centers for Medicare and Medicaid Services
- College of American Pathology (CAP)

Clinical evidence reviewed and approved by:

- New York State Department of Health Wadsworth Center (NYSDOH)
- Medicare (MoIDX[®] Program)

Listed in guidelines:

- American Society of Clinical Oncology Genitourinary Cancers (ASCO GU)
- American Urological Association (AUA)
- European Association of Urology (EAU)
- Major insurance providers, such as United Healthcare (UHC)

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Genomic Prostate Score[®]

NCCN Prostate Cancer Guidelines Update Clinical Evidence Requirement

On December 4th, the NCCN changed its rating system for localized prostate cancer biomarkers. The NCCN Prostate Cancer Guidelines Version 1. 2025 now requires a prospective trial that meets Simon Level 1 criteria for Clinical Validation for molecular biomarkers. Simon Levels 2B, 2C, 3C, 4-5D are no longer considered by the NCCN.

To date, no biomarker test has achieved Simon Level 1 criteria for the NCCN low-risk, localized prostate cancer cohort.

	Decipher	GPS	Prolaris
Very Low Risk	No Level 1 Evidence	No Level 1 Evidence	No Level 1 Evidence
Low Risk	No Level 1 Evidence	No Level 1 Evidence	No Level 1 Evidence

Note: The NCCN level of evidence requirement does not indicate a specific performance requirement; it only requires that a prospective clinical trial be completed and have a positive result. Decipher 22-Gene Genomic Classifier (GC) Assay is only listed for use in NCCN Intermediate-Risk, NCCN High-Risk, and Post-RR BCR.

- The action taken by the NCCN panel has nothing to do with the performance characteristics of GPS. They are only applying an alternate rating system as a qualifying factor.
- No biomarker test currently has Simon Level 1 data or evidence supporting indications for NCCN low-risk, or for active surveillance decision-making.
- This change does not diminish the value of these tests within localized prostate cancer.

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Robust Evidence

- This section includes a summary of the published data
- Who we are licensed with
- Who has reviewed our evidence
- Where we are listed in guidelines

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Who has Level 1 Evidence in Low-Risk patients

	Decipher	GPS	Prolaris
Very Low Risk	No Level 1 Evidence	No Level 1 Evidence	No Level 1 Evidence
Low Risk	No Level 1 Evidence	No Level 1 Evidence	No Level 1 Evidence

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Summary of Piece

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