GPS mdx
for Localized Prostate Cancer

Now available

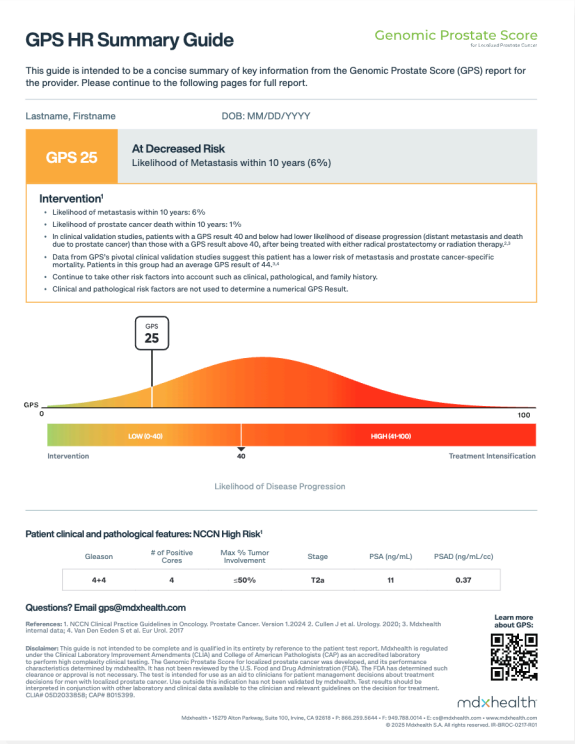
Expedite processing and preserve tissue with our new digital H&E slide workflow using Lumea BxLink™

The average turnaround time for GPS mdx is 5 days*, and now using Lumea BxLink™ we can accept digital H&E slides to reduce the amount of tissue sent and speed up processing time.

Setup Requirements before sending digital H&E slides

- Pathology lab must utilize Lumea BxLink™ system
- Provide access to 5 specimens with digital H&E slides via BxLink to verify:
  - Image legibility and clarity
  - Accurate representation of first and last cut sections
- Complete setup and training with mdxhealth to schedule your go live date.

Once setup and training is complete, upon the go live date, your laboratory can begin the new workflow by following the specimen requirements listed on the other side of this document.



GPS HR Summary Guide

Genomic Prostate Score

This guide is intended to be a concise summary of key information from the Genomic Prostate Score (GPS) report for the provider. Please continue to the following pages for full report.

Lastname, Firstname DOB: MM/DD/YYYY

GPS 25 — At Decreased Risk
Likelihood of Metastasis within 10 years (6%)

Intervention[1]
- Likelihood of metastasis within 10 years: 6%
- Likelihood of prostate cancer death within 10 years: 1%
- In clinical validation studies, patients with a GPS result 40 and below had lower likelihood of disease progression (distant metastasis and death due to prostate cancer) than those with a GPS result above 40, after being treated with either radical prostatectomy or radiation therapy[2,3]
- Data from GPS's pivotal clinical validation studies suggest this patient has a lower risk of metastasis and prostate cancer-specific mortality. Patients in this group had an average GPS result of 44.[3,4]
- Continue to take other risk factors into account such as clinical, pathological, and family history.
- Clinical and pathological risk factors are not used to determine a numerical GPS Result.

GPS 25
GPS 0 100
LOW (0–40) HIGH (41–100)
Intervention 40 Treatment Intensification
Likelihood of Disease Progression

Patient clinical and pathological features: NCCN High Risk[1]

Gleason	# of Positive Cores	Max % Tumor Involvement	Stage	PSA (ng/mL)	PSAD (ng/mL/cc)
4+4	4	≥50%	T2a	11	0.37

Questions? Email gps@mdxhealth.com

References: 1. NCCN Clinical Practice Guidelines in Oncology. Prostate Cancer. Version 1.2024 2. Cullen J et al. Urology. 2020; 3. Mdxhealth internal data; 4. Van Den Eeden S et al. Eur Urol. 2017

Disclaimer: This guide is not intended to be complete and is qualified in its entirety by reference to the patient test report. Mdxhealth is regulated under the Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) as an accredited laboratory to perform high complexity clinical testing. The Genomic Prostate Score for localized prostate cancer was developed, and its performance characteristics determined by mdxhealth. It has not been reviewed by the U.S. Food and Drug Administration (FDA). The FDA has determined such clearance or approval is not necessary. The test is intended for use as an aid to clinicians for patient management decisions about treatment decisions for men with localized prostate cancer. Use outside this indication has not been validated by mdxhealth. Test results should be interpreted in conjunction with other laboratory and clinical data available to the clinician and relevant guidelines on the decision for treatment. CLIA# 05D2033858; CAP# 8015399.

Learn more about GPS:

mdxhealth

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Ask your area representative about sending digital H&E slides today.

*When all specimen requirements are met upon receipt

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How to send digital H&E slides

Important: Pathology laboratory must complete setup and training with mdxhealth prior to sending first digital H&E sample to ensure we can access digital slides and H&E stains meet specifications.

Selecting the Optimal Specimen

Highest available Gleason grade cancer with the **longest tumor length.**

1. Highest Gleason score
2. Tumor length. Calculation: core length multiplied by % of tumor involvement (sample comprising of the largest cross-section of highest-grade carcinoma from the primary site).

Unstained Slide Requirements:

Labeling Instructions:	Label the slides with an additional patient-specific identifier (e.g., specimen accession number, patient name, date of birth, hospital number, or order number). All specimens received require two patient-specific identifiers for processing. Hand-number the serially sectioned unstained slides (1-8, minimum 1-5) to indicate the order in which they were cut.
Specimen Preparation:	1. Prepare 8 (minimum 5) serial unstained sections onto slides. Each section must be 5 µm. 2. H&E stain the first and last slide in the sequence and upload into Lumea BxLink. For each patient, grant the usernames **Mdxconsult** and **Mdxtech** access to this patient's digital H&E slides. 3. Then, prepare the remaining **unstained** slides to be shipped to mdxhealth. Ensure the sections on each slide are oriented similarly. Allow the slides to air dry. Do not place the slides on a hot plate. Do not place cover slips on the unstained slides.
Slide Requirements:	Unstained biopsy core sections on unbaked, positively charged glass slides (standard 1" x 3" or 25mm x 75mm size).
Storage Requirements:	Maintain slides at room temperature
Special Instructions:	Ensure slides are shipped with pathology report and completed test requisition form.

Turnaround Time:

- Within 10 days from receipt of specimen* (Now averaging 5-day turnaround time)

Patient Eligibility:

- Patient with localized prostate cancer who as not yet started treatment and has a life expectancy of ≥10 years is eligible for testing; specimen must have been collected within 36 months.
- The National Comprehensive Cancer Network (NCCN) Prostate Cancer guideline includes Genomic Prostate Score (GPS) (referenced as Oncotype DX Prostate) for patients with low, favorable intermediate, unfavorable intermediate, or high-risk disease.[1]

Causes for Specimen Rejection:

- Insufficient amount of tissue and/or carcinoma/tumor, (i.e. <5 glands of tumor).
- Ductal carcinoma, small cell carcinoma, signet ring cell adenocarcinoma, squamous cell carcinoma, urothelial carcinoma.
- Non-cancerous tissue including high-grade PIN and atypical suspicious acinar proliferation.
- Specimen primary Gleason pattern 5, cT3b-cT4 stage prostate cancer, >4 cores with Grade Group 4 or 5, and/or any other criteria that classify a patient as NCCN Very High Risk (Version 4.2024).[1]
- Broken, unnumbered, and/or stained slides
- Specimens older than 36 months
- Specimens other than FFPE Prostate Biopsy tissue: radical prostatectomy tissue and transurethral resection of the prostate (TURP).

Contact Info:
Client Services
866.259.5644
cs@mdxhealth.com

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

Ruben Gamez, MD
Laboratory Director
CLIA#05D2033858
CAP# 8015399

*When all specimen requirements are met upon receipt.

References:

1. NCCN Clinical Practice Guidelines in Oncology - Prostate Cancer Version 4.2024

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