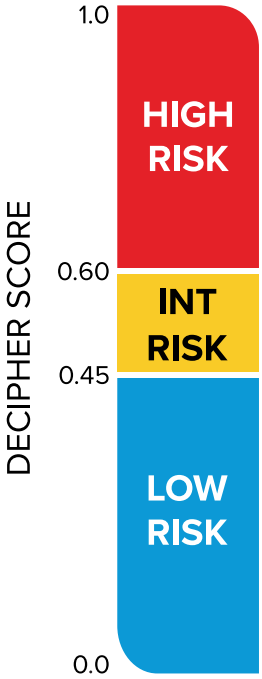


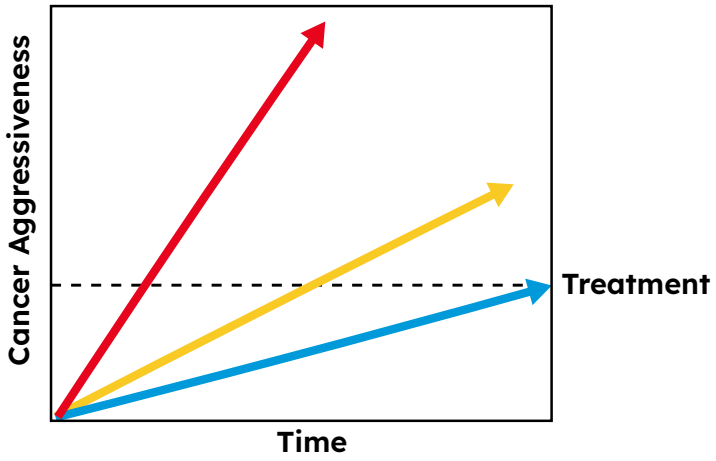
Decipher® Prostate

Genomic Classifier

veracyte®

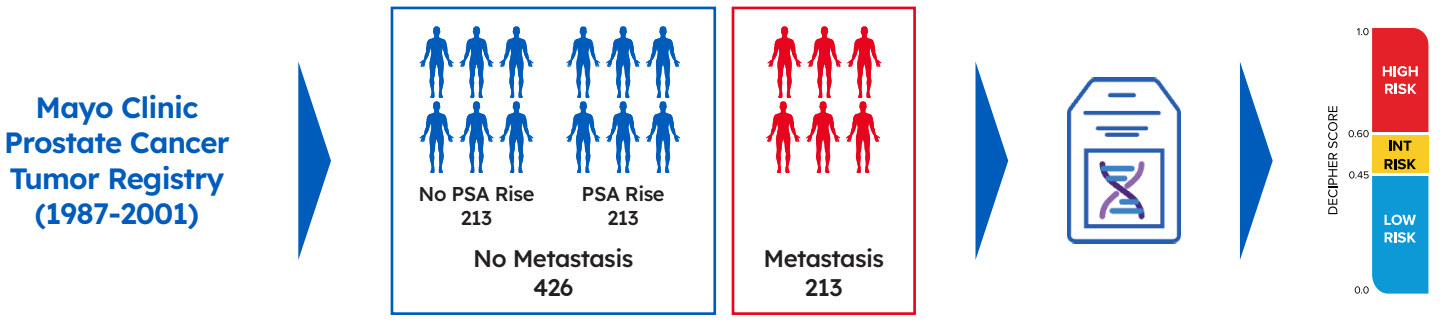
What is the Decipher Prostate Genomic Classifier?

- Tissue-based gene expression test utilizing whole-transcriptome microarray technology to assess the underlying biology of a patient's tumor
- Performed on prostate tumor tissue from biopsy or radical prostatectomy (RP)
- Result is a continuous score between 0 and 1 that reflects the metastatic potential of the tumor (Decipher Score), which is classified as Decipher Low, Decipher Intermediate, or Decipher High
- Used to inform key decisions regarding treatment timing & intensity across the spectrum of prostate cancer
- Decipher Prostate is the most validated & utilized gene expression test in prostate cancer, backed by the strongest foundation of evidence.



Use of clinical & pathological features alone to assess patient risk does not always reflect a patient's true risk of metastasis.

Decipher Prostate was Developed to Predict Metastasis



639 Post-RP Patients

Patients with long-term follow-up: Gleason 8-10 or Pre-Op PSA>20 ng/mL or Stage T3 or greater or SM+

Whole Transcriptome Microarray

Decipher Risk

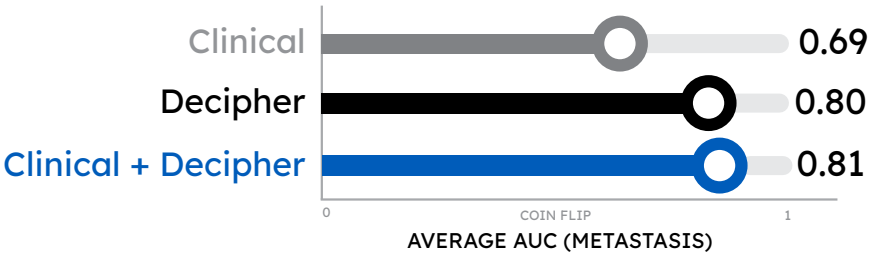
Well-annotated tumor registry with long-term treatment & outcomes data

Clinically high-risk patients with different 5-year outcomes: no PSA rise, PSA rise, & distant metastasis

Compared gene expression from tumor tissue of patients who developed metastasis vs. those who did not

Identified the 22 biomarkers that comprise the test

Decipher Prostate is the Strongest Independent Predictor of Metastasis



- Average from all publications where metastasis was an endpoint and the AUC for metastasis was reported.[1-17]
- n=5,335 patients

Decipher Prostate Informs Treatment Decisions Across the Spectrum of Disease

National Comprehensive Cancer Network (NCCN®)

Clinical Use of Decipher Prostate After Biopsy

NCCN Risk Group	Clinical Decision	Treatment Considerations
Low & Favorable Int.	Active Surveillance Protocol	More Intense Surveillance [15,18-21] Less Intense Surveillance [15,18-21]
Low & Favorable Int.	Active Surveillance OR Definitive Therapy	Definitive Therapy [15,18-21] Active Surveillance [15,18-21]
Favorable Int. & Unfavorable Int.	Radiation OR Radiation + ADT	Radiation + ADT [15,18,21-22] Radiation Alone [15,18,21-22]
Unfavorable Int. & High	Duration of Hormone Therapy with Radiation	Radiation + Long-term ADT [3,23] Radiation + Short-term ADT [3,23]

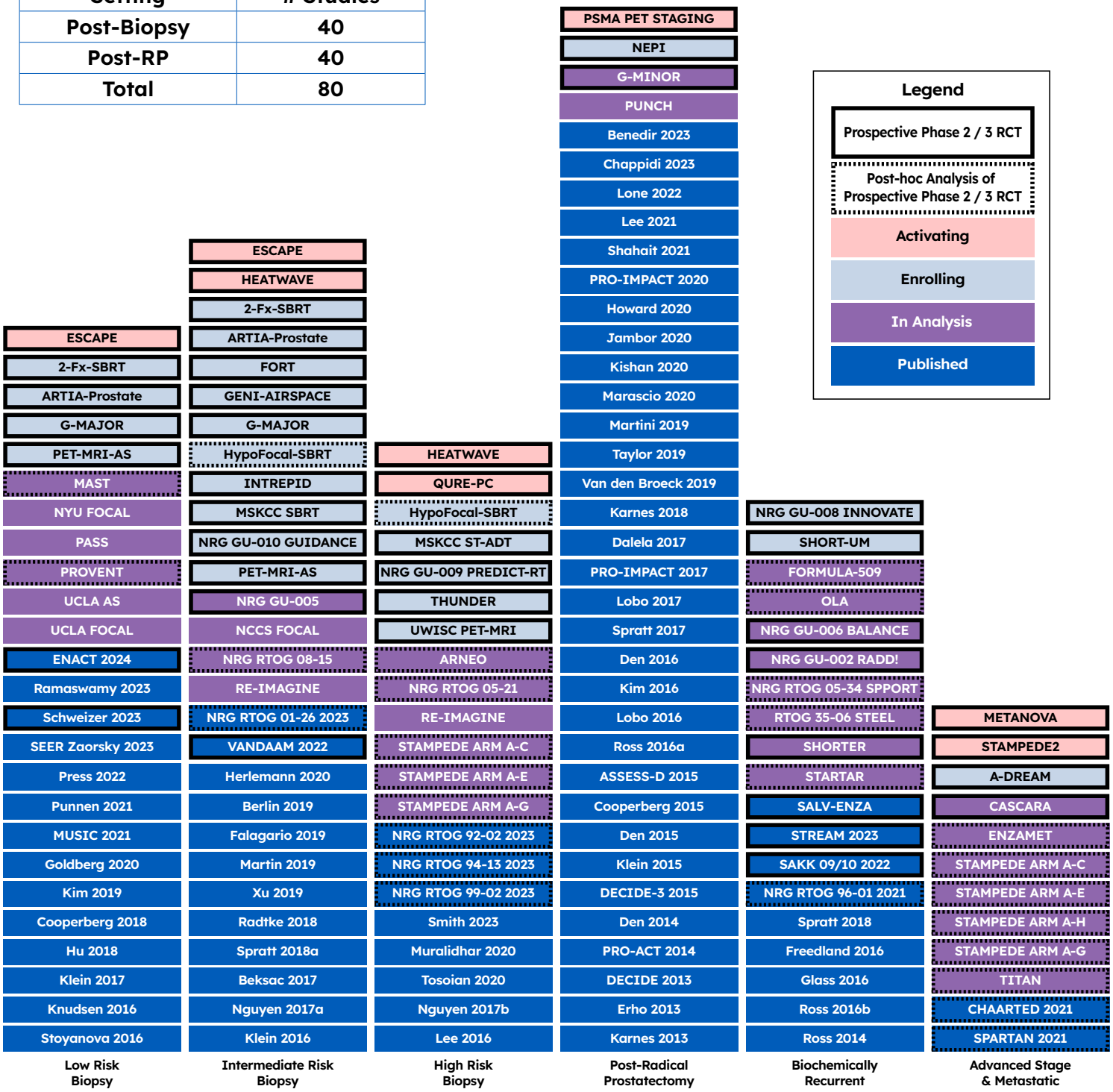
Clinical Use of Decipher Prostate After Radical Prostatectomy

Clinical Decision	Treatment Considerations
PSA Monitoring OR Treatment	Treatment [8,24-25] PSA Monitoring [8,24-25]
Radiation OR Radiation + ADT	Radiation + ADT [16,26-27] Radiation Alone [16,26-27]

Please see page 7 for NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Treatment Implications table for clinical use of Decipher Prostate.

Veracyte's Continued Pursuit of Evidence is Supported by Decipher Prostate Publications & Ongoing Clinical Trials Across the Prostate Cancer Continuum

Decipher Publications: Clinical Validity / Utility	
Setting	**# Studies**
Post-Biopsy	40
Post-RP	40
Total	80



22-gene Genomic Classifier (GC) (Decipher Prostate) is the Only Gene Expression Test with Simon Level 1B Evidence in the 2024 NCCN Guidelines® [29]

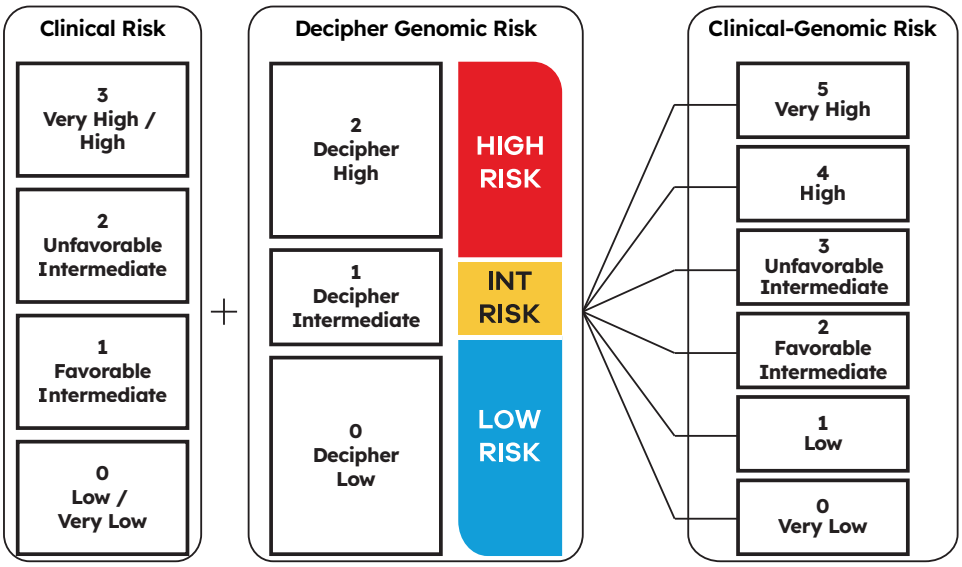
"There are an extensive number of these tools created with substantial variability in quality of reporting and model design, endpoint selection, and quality and caliber of validation. **It is recommended to use models that have high-quality and robust validation, ideally with high-quality, long-term clinical trial data, which usually comes from randomized trials and across multiple clinical trials.**" PROS-H 1 of 8

Risk Stratification: Selected Advanced Tools for Localized Prostate Cancer Post-Biopsy*						
Category	**Tool**	**Predictive**	**Prognostic**	**Prognostic Endpoint Trained For[a]**	**Simon Level of Evidence [28,b]**	**Treatment Implications**
Gene Expression Testing	**22-gene genomic classifier (GC) (Decipher)**	**No**	**Yes**	**Metastasis**	**IB**	**See Table 3**
	31-cell cycle progression (CCP) gene assay (Prolaris)	No	Yes	See footnote[c]	IIIC[d]	
	17-gene Genomic Prostate Score (GPS) assay	No	Yes	Adverse pathology	IIIC	
Risk Stratification: Selected Advanced Tools Post-RP						
Gene Expression Testing	**22-gene GC**	**No**	**Yes**	**Metastasis**	**IB**	**See Table 3**
	31-CCP gene assay	No	Yes	See footnote[c]	IVD	
	17-gene assay	No	Yes	Adverse pathology	IVD	

PROS-H, 3 of 8
Table 2

a. The listed models or variables may have demonstrated they are prognostic for additional endpoints. This column indicates what the original model was trained for.
b. Simon level of evidence criteria are as follows[28]:
   - 1A, Prospective clinical trial(s) designed to address tumor marker
   - **1B, Prospective clinical trial(s) using archived samples with design that accommodates tumor marker utility, ≥1 validation study available with consistent results**
   - IIB Prospective clinical trial(s) using archived samples with design that accommodates tumor marker utility, no validation studies available, or validation studies have inconsistent results
   - IIC, Prospective observational registry, ≥2 validation studies available with consistent results
   - IIIC, Prospective observational registry, no validation studies available, or 1 validation study with consistent or inconsistent results
   - IVD, Small retrospective/observational studies with no prospective aspect
   - IVD, Small retrospective/observational pilot studies with no prospective aspect, designed to determine biomarker marker levels in a population.
c. CCP was not specifically trained for a clinical endpoint.
d. The CCP biomarker is level IVD except for grade group 1 cancer where it is level IIIC, where CCP was independently associated with minor upgrading, but was not significantly associated with major upgrading or biochemical recurrence. Cooperberg MR, et al. Eur Urol 2021;79:141-149.

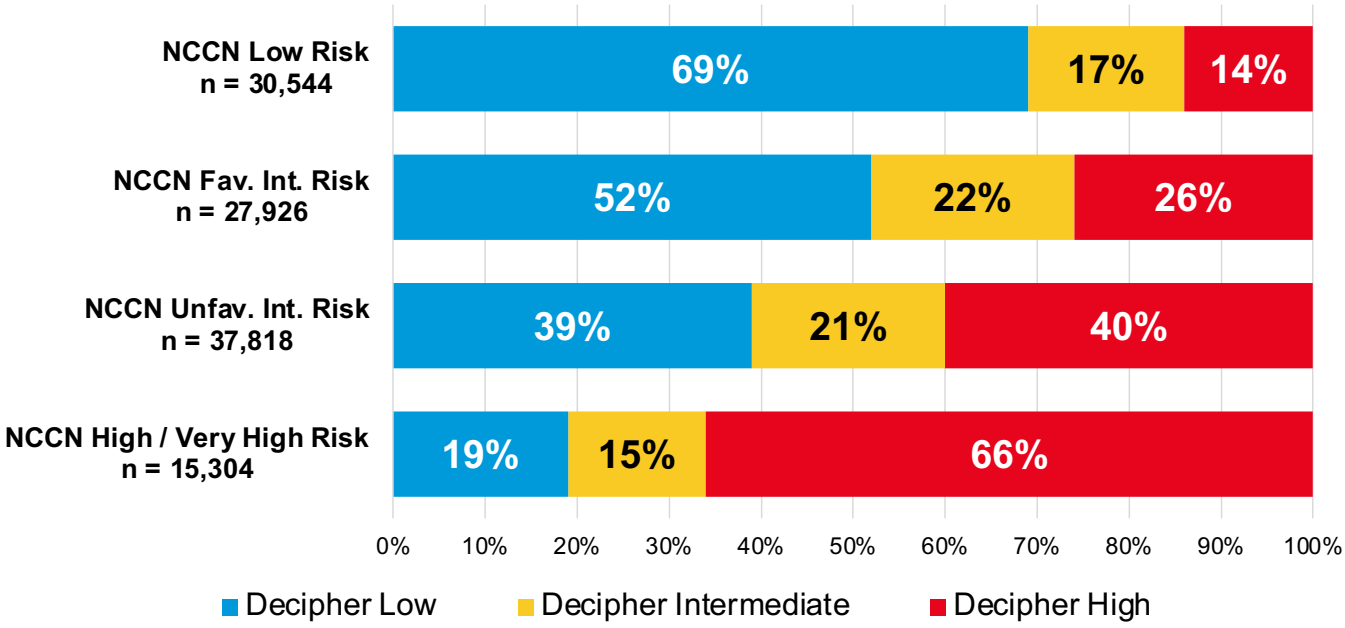
Treatment Recommendations for Adjacent Risk Groups May Be Appropriate Per 2024 NCCN Guidelines for Prostate Cancer



Spratt, DE et al. J Clin Oncol 36, 581-590. 2018.

"Given the moderate prognostic performance of NCCN risk groups to risk stratify localized prostate cancer, there is intrinsic heterogeneity in prognosis within a given NCCN risk group. Thus, treatment recommendations for adjacent risk groups may be appropriate when using more accurate risk stratification methods in addition to NCCN risk group assignments." PROS-H 1 of 8

Decipher Risk Distribution by NCCN Risk Group in the Decipher Database



"The intensity of active surveillance may be tailored based on patient life expectancy and risk of reclassification." **PROS-F 2 of 5**

NCCN Low Risk: "The panel recognizes that there is heterogeneity across this risk group, and that some factors may be associated with an increased probability of near-term grade reclassification including high PSA density, a high number of positive cores (e.g., ≥3), and high genomic risk (from tissue-based molecular tumor analysis). For some of these patients, upfront treatment with RP or prostate RT may be preferred based on shared decision-making." **PROS-F 1 of 5**

NCCN Favorable Intermediate Risk: "Particular consideration for active surveillance may be appropriate for those patients with a low percentage of Gleason pattern 4 cancer, low tumor volume, low PSA density, and/or low genomic risk (from tissue-based molecular tumor analysis)." **PROS-F 1 of 5**

Treatment Implications for Advanced Tools: 22-Gene Genomic Classifier (GC) Assay*

Population	Score	Treatment Decision	Treatment Implications
NCCN Low-Risk	≥0.6	Active Surveillance Intensity vs. Radical Therapy	**Evidence:** In a prospective multicenter statewide registry, GC high risk (≥0.6) was associated with shorter time on active surveillance and shorter time to treatment failure (TTF) for those who underwent radical therapy.[18] **Evidence synthesis:** More intensive active surveillance frequency should be considered for patients with NCCN low-risk disease and a high GC score, given the higher probability of transitioning off active surveillance and subsequent progression.
NCCN Intermediate-Risk	≤0.45 vs. ≥0.60	RT vs. RT + ST-ADT	**Evidence:** NRG/RTOG 0126 phase III randomized trial was profiled post-hoc with a prespecified analysis plan.[22] The study demonstrated the independent prognostic effect of GC on biochemical failure, secondary therapy, DM, PCSM, MFS, and OS. Patients receiving RT alone with low GC scores had 10-year DM rates of 4%, compared with 16% for GC high risk. **Evidence synthesis:** RT alone should be considered for patients with a low GC score and NCCN intermediate-risk disease. The addition of ST-ADT should be considered for patients with a high GC score given their increased risk of DM and significant benefit of ST-ADT on DM, even with dose-escalated RT or brachytherapy boost.
NCCN High-Risk	≤0.45 vs. ≥0.60	RT + LT-ADT vs. RT + ST-ADT	**Evidence:** A meta-analysis of three phase III randomized trials (NRG/RTOG 9202, 9413, and 9902) were profiled post-hoc with a prespecified analysis plan.[23] The study demonstrated the independent prognostic effect of GC on biochemical failure, DM, MFS, PCSM, and OS. Patients with low GC scores had 10-year DM rates of 6%, compared with 26% for GC high risk. The absolute benefit of LT-ADT over ST-ADT was 11% for patients with high GC scores (NNT of 9), and 3% for patients with low GC scores (NNT of 33). **Evidence synthesis:** RT + LT-ADT should be recommended for most patients with NCCN high-risk disease regardless of the GC score outside of a clinical trial, even with dose-escalated RT or brachytherapy boost. However, patients with a GC low risk score should be counseled that the absolute benefit of LT-ADT over ST-ADT is smaller than for patients with GC high risk scores and when accounting for patient age, comorbidities, and patient preferences, it may be reasonable with shared decision-making to use a duration shorter than LT-ADT.
Post-RP BCR	<0.6 vs. ≥0.6[a]	RT vs. RT + ADT	**Evidence:** Two phase III randomized trials post-RP were profiled post-hoc with prespecified analysis plans. NRG/RTOG 9601 demonstrated the independent prognostic effect of GC on DM, PCSM, and OS, and found that for patients with lower entry PSAs (<0.7 ng/mL), the 12-year DM rate benefit from hormone therapy for patients with GC lower risk vs. GC higher risk was 0.4% vs. 11.2%.[26] The SAKK 09/10 phase III trial tested post-RP lower vs. higher dose RT alone. The study demonstrated the independent prognostic effect of GC on biochemical progression, clinical progression, secondary hormone therapy, DM, and MFS.[27] **Evidence synthesis:** For patients with node-negative disease post-RP planned for early secondary RT (PSA ≤0.5 ng/mL) with GC low or intermediate risk, use of RT alone should be considered. For patients planned for early secondary RT with a GC high-risk tumor, use of secondary RT with ADT is recommended. Currently, it is unclear how best to use GC for patients receiving late post-RP secondary RT (PSA >0.5 ng/mL). Optimal ADT duration (ie, 6 vs. 24 months) based on GC score is unknown at this time.

PROS-H, 4 of 8, 5 of 8
Table 3

GC = genomic classifier (Decipher), RP = radical prostatectomy, BCR = biochemical recurrence, RT = radiation therapy, ST = short-term, LT = long-term, ADT = androgen deprivation therapy, DM = distant metastasis, PCSM = prostate cancer-specific mortality, MFS = metastasis-free survival, OS = overall survival, NNT = number needed to treat, PSA = prostate specific antigen

a. SAKK 09/10 combined GC low and intermediate risk due to relatively similar prognosis. NRG/RTOG 9601 dichotomized patients by GC low versus intermediate and high risk. However, due to the age of the tissue from NRG/RTOG 9601 (>20 years old) there is a known shifting of GC scores, and a more contemporary distribution of score distribution would approximate closer to combining GC low and intermediate risk together.

Decipher Prostate Biopsy Example Test Report Page 1

NCCN Favorable Intermediate Risk

Decipher® Prostate
Biopsy Genomic Classifier

PATIENT REPORT

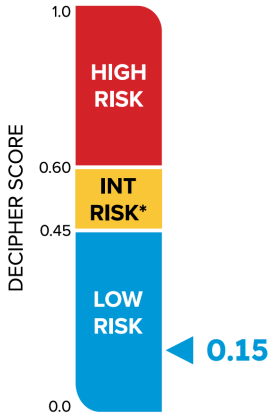
REPORT STATUS: FINAL

PATIENT	SPECIMEN INFORMATION	ORDERING PHYSICIAN
Name: **Sample Patient** Date of Birth: **--/--/----** Medical Record #: **----------** Date of Biopsy: **--/--/----**	Order Date: **--/--/----** Specimen ID: **----------** Specimen Received Date: **--/--/----** Decipher Accession ID: **MC-123456**	Name: **Sample Physician, MD** Clinic: **Sample Clinic** Address: **123 Birch Avenue, Suite A, Anytown, CA 54321** Additional Physician: **Additional Sample Physician, MD**

CLINICAL AND PATHOLOGY DETAILS For reference only, not used in calculation of genomic risk

Specimen: **Needle Biopsy** Clinical Stage: **T1c**	Most Recent PSA: **3.9 ng/mL** Gleason Score: **3+4**	National Comprehensive Cancer Network® (NCCN®) Risk Category: **Intermediate**

DECIPHER GENOMIC SCORE



DECIPHER GENOMIC RISK GROUP IS: LOW

INTERPRETATION

Clinical studies have shown that patients with NCCN favorable intermediate risk prostate cancer and Decipher low risk scores have less aggressive tumor biology and a favorable prognosis.

- These patients may be good candidates for active surveillance.[1-5]
  - They were more likely to remain on active surveillance and less likely to be upgraded on subsequent biopsy, to harbor adverse pathology (or be upgraded and/or upstaged) at radical prostatectomy, or to experience disease recurrence after treatment.[4,6,7]
- These patients may have favorable outcomes when treated with definitive therapy, such as radical prostatectomy or radiation without concurrent hormone therapy.[1,3,8,9,14,15]

The Decipher score is determined solely by genomic characteristics of the tumor, independent of the NCCN risk category. No other clinical or pathologic parameters factor into the score.

RISK ESTIMATES FOR THIS PATIENT WITH STANDARD THERAPY FOR THEIR CLINICAL RISK GROUP

0.3%	0.7%	0.8%	6.8%
5-year	10-year	15-year	At RP
Risk of Metastasis with Standard Therapy		Risk of Prostate Cancer Mortality with Standard Therapy	Risk of Adverse Pathology

Prostate cancer risk estimates were determined by numerical integration of >100,000 prostate cancer patients with available Decipher scores calibrated to >20,000 patients with long-term follow-up from published meta-analyses. "Standard therapy" included **definitive treatment** relevant to **this patient's clinical risk group**. For further details, see page 3.

Approved By:

E-SIGNED BY NAME, CREDENTIAL ON DATE AT TIME

CLIA ID# 05D2055897
CAP # 8859006
Lab Director: [Lab Director Name, MD]

* INT RISK in Decipher score graphic is an abbreviation of "intermediate-risk", ' RP= radical prostatectomy

A copy of this form shall be as valid as the original. This test was developed and its performance characteristics determined by Veracyte Labs SD. The laboratory is regulated under CLIA '88 as qualified to perform high complexity clinical testing. This test has not been cleared or approved by the FDA. This test is used for clinical purposes and clinical correlation of its results are recommended. It should not be regarded as investigational or for research.

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Decipher Prostate Biopsy Example Test Report Page 2

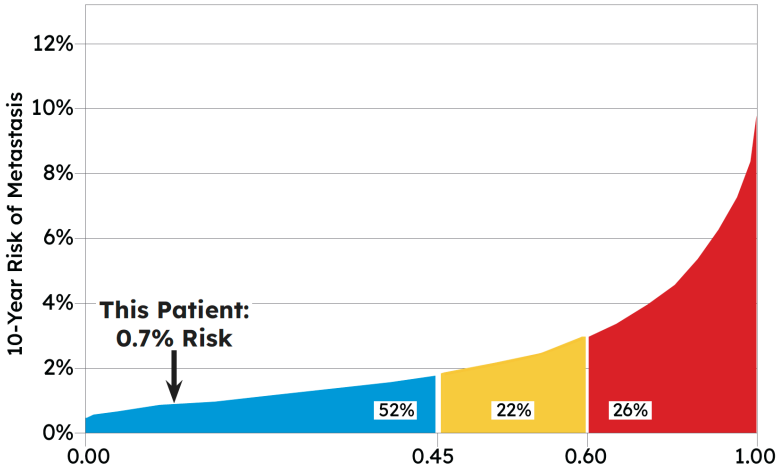
Decipher® Prostate
Biopsy Genomic Classifier

Name: **Sample Patient**
Date of Birth: **--/--/----**
Decipher Accession ID: **MC-123456**

PATIENT REPORT

REPORT STATUS: FINAL

RISK COMPARED TO PATIENTS WITH SIMILAR CLINICAL AND PATHOLOGIC FEATURES



Patients (n=27,926) with NCCN Favorable Intermediate Risk Disease†

RISK GRAPHIC INTERPRETATION

This chart shows the 10-year risk of metastasis for 27,926 patients with similar clinical features at the time of biopsy, ordered from lowest to highest risk. Among these patients 52%, 22%, and 26% were classified as Decipher low-, intermediate-, and high-risk, respectively.

This patient has a predicted 0.7% 10-year risk of metastasis with standard therapy appropriate for their clinical risk group and is in the **5th percentile of risk**, meaning that 4 percent of men with similar clinical features have a lower Decipher score, and 95 percent have a higher Decipher score.

†**NCCN Favorable Intermediate Risk Disease:** *Gleason 3+3=6 or 3+4=7 with <50% cores positive, one intermediate risk factor (i.e., Gleason 3+4=7, T2b-T2c, PSA 10-20 ng/mL), and no high risk factors (i.e., Gleason 8-10, T3-T4, PSA >20ng/mL).*

FINDINGS FROM CLINICAL STUDIES RELEVANT TO THIS PATIENT

- In an analysis of over 8,000 patients from the SEER* national cancer registry tested with Decipher, the subset who were clinically favorable risk and Decipher low risk were more likely to be managed with active surveillance or watchful waiting and less likely to harbor adverse pathology (or be upgraded and/or upstaged) at radical prostatectomy.[5,7]
- In clinically favorable risk patients being managed with active surveillance, Decipher low-risk patients had a lower likelihood of harboring higher grade disease on subsequent biopsy.[6]
- Analyses of the state-wide Michigan Urological Surgery Improvement Collaborative (MUSIC) registry found that:
  - Active surveillance was the primary management strategy for 76% of patients with low genomic risk.[12]
  - Decipher low-risk patients remained on active surveillance more than twice as long (median of 33 months) as Decipher high-risk patients (median of 13.6 months).[4]
- In a study of NCCN favorable and unfavorable intermediate risk patients treated with radiation alone (without concurrent hormone therapy), 100% of Decipher low-risk patients were free from distant metastasis at 5 years.[14]
- In a post-hoc analysis of the randomized phase 3 RTOG 01-26 clinical trial of NCCN favorable and unfavorable intermediate risk patients treated with radiation alone (without concurrent hormone therapy), Decipher low-risk patients had a 4% risk of 10-year distant metastasis.[15]

*SEER = Surveillance, Epidemiology, and End Results Cancer Registries

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Covered by Medicare & Major Insurance Plans

Medicare covers Decipher Prostate for all beneficiaries with localized prostate cancer

Decipher Prostate is included in the **NCCN Guidelines[29] and AUA/ASTRO Guidelines for Prostate Cancer** and is covered by **major insurance plans** throughout the US

Financial assistance is available via the **Veracyte Access Program***

Medicare Coverage Across the Spectrum of Localized Disease

Decipher Prostate Biopsy	**NCCN Very Low**	✔
	NCCN Low	✔
	NCCN Favorable Intermediate	✔
	NCCN Unfavorable Intermediate	✔
	NCCN High	✔
	NCCN Very High	✔
	Lymph Node +	✔
Decipher Prostate RP	**Undetectable PSA**	✔
	Persistent PSA	✔
	Rising PSA	✔

How to Order Veracyte's Decipher Prostate Test

Place orders, track order status, and view results on the **Decipher Portal**

Requisitions can be **emailed** to client.service-urology@veracyte.com

Requisitions can be **faxed** to 1.858.766.6575

What to include with each order:

- Demographic & Insurance Information
- Pathology Report
- Office Notes

For **fax and email orders**, the fillable requisition can be found on our website or by scanning this QR code:

Veracyte's Decipher Portal is an online tool that enables you to place orders, track order status, and view results of all orders. If your practice does not have a Decipher Portal account, please contact us at client.service-urology@veracyte.com and a representative will reach out to you to setup your account.

We are Committed to Ensuring Access for all Eligible Patients

Through Veracyte Access, we offer two programs to ensure testing is affordable for patients:

1. **Financial assistance** for patients with demonstrated financial need
2. **Tailored payment plans** to accommodate certain financial circumstances

Financial Assistance

Designed for qualified patients with commercial insurance

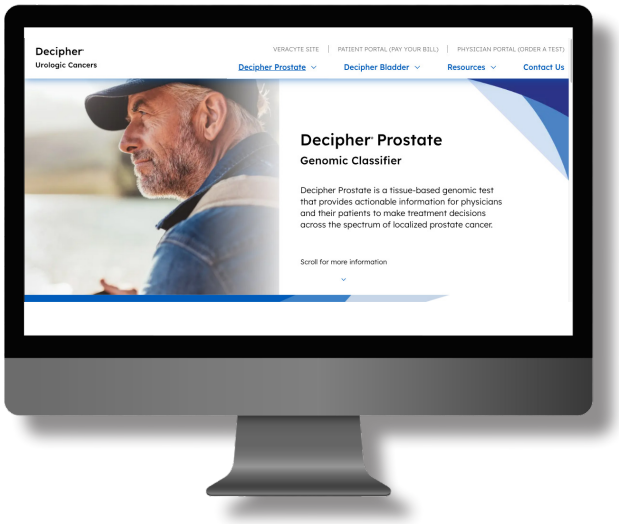
- Patients may be eligible for a reduction to non-covered costs
- Eligibility requirements include:
    - Determination of medical necessity for Decipher testing by a physician
    - Completed Veracyte Access application
    - Financial qualification

Payment Plans

Customized for patients at specific income levels

What Resources are Available to Provide to Patients?

- There are a variety of resources available on our website:
    - Veracyte Access information & forms
    - Decipher Prostate Patient Brochure
    - Decipher Prostate patient videos in both English & Spanish



Visit the patient page of our website by scanning the QR code or by visiting the website url below:

https://decipherbio.com/decipher-prostate/patients/decipher-prostate-overview/

To learn more about Veracyte's Decipher Prostate Genomic Classifier, contact us at **1.888.792.1601** or **client.service-urology@veracyte.com**

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** Based on data available from commercial websites as of March 1, 2024.

†Based on claims submitted for CPT codes 81542 (Decipher), 81541 (Prolaris), 0047U (GPS). Count of claims is equivalent to the Physician/Supplier Procedure Summary (PSPS) Submitted Service Count, or the count of the total number of submitted services for 2020-2022. Data downloaded October 24, 2023. Centers for Medicare & Medicaid Services (CMS). (2023, October 24). Physician/Supplier Procedure Summary. Data.CMS.gov. https://data.cms.gov/summary-statistics-on-use-and-payments/physiciansupplier-procedure-summary/data.