Decipher® Prostate

Biopsy Genomic Classifier

PATIENT

Name: **Sample Patient**
Date of Birth: --/--/----
Medical Record #: --------------
Date of Biopsy: --/--/----

SPECIMEN INFORMATION

Order Date: --/--/----
Specimen ID: --------------
Specimen Received Date: --/--/----
Decipher Accession ID: **MC-123456**

ORDERING PHYSICIAN

Name: **Sample Physician, MD**
Clinic: **Sample Clinic**
Address: **123 Birch Avenue, Suite A, Anytown, CA 54321**
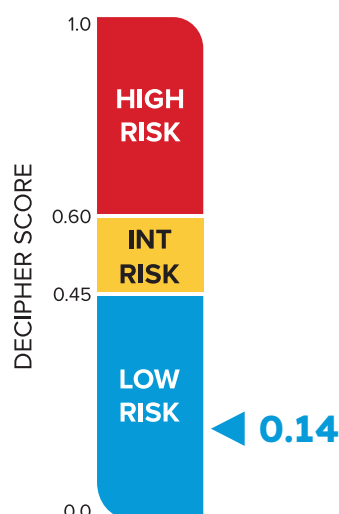Additional Physician: **Additional Sample Physician, MD**

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

Specimen: **Needle Biopsy**
Clinical Stage: **T1c**

Most Recent PSA: **4.9 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%	6.6%
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

veracyte.

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San Diego, CA 92121   F 1.858.766.6575   W veracyte.com/decipher

Decipher Score

- **Reflects genomic risk of metastasis**
- **Determined by tumor biology alone,** independent of clinical & pathological factors (e.g., Gleason, PSA)
- **22 genes, 7 biological pathways**
- **Continuous** genomic risk score classified as low, intermediate or high

Risk Estimates

- Calibrated to outcomes of patients **treated with definitive therapy appropriate for this patient's NCCN risk group**
  - » **Metastasis** at 5 & 10 years
  - » **Prostate Cancer Mortality** at 15 years
  - » **Adverse Pathology** at RP (Grade Group 3-5, pT3b-T4, or lymph node involvement)

Dynamic Report

- The report is tailored to the clinical presentation of this patient

Interpretation

- Summary based on this patient's genomic risk & relevant clinical findings

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**Sample Report:
Not a Real Patient**

PATIENT REPORT

REPORT STATUS: FINAL
PAGE: 1 of 3

PATIENT
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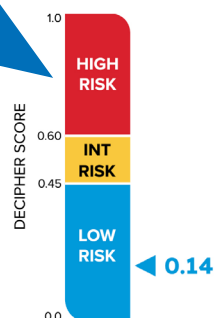Additional Physician: **Additional Sample Physician, MD**

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DECIPHER GENOMIC SCORE

DECIPHER SCORE

1.0
HIGH RISK
0.60
INT RISK
0.45
LOW RISK ◀ 0.14
0.0

DECIPHER GENOMIC RISK GROUP IS: LOW

INTERPRETATION

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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

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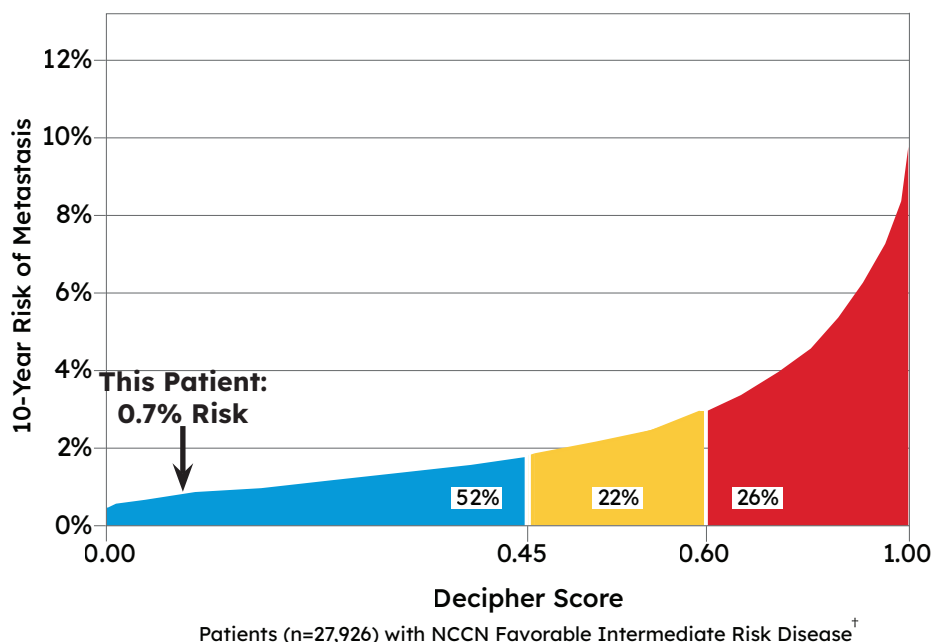F 1.858.766.6575

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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 **4th percentile of risk**, meaning that 3 percent of men with similar clinical features have a lower Decipher score, and 96 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]

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Risk Comparison

- This patient's 10-year risk of metastasis with respect to 27,926 other NCCN Favorable Intermediate Risk patients
- The distribution of Decipher risk within the 27,926 patients is:
  - » **52% Decipher Low**
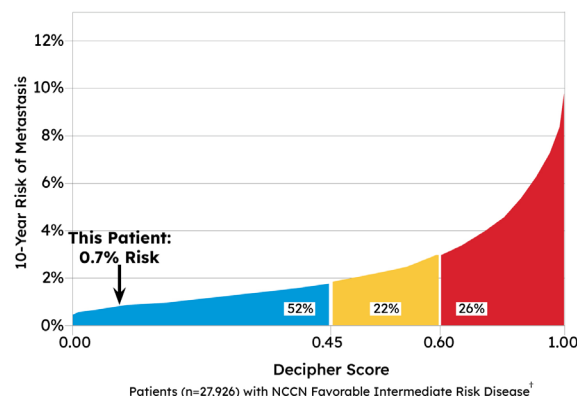 - » **22% Decipher Int.**
  - » **26% Decipher High**

Clinical Findings

- Clinical study results relevant to this patient

Interpretation

- Explains risk comparison graphic
- Provides this patient's **percentile rank** in the tested population

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PAGE: 2 of 3

RISK COMPARED TO PATIENTS WITH SIMILAR CLINICAL AND PATHOLOGIC FEATURES

This Patient: 0.7% Risk

52%   22%   26%

10-Year Risk of Metastasis vs Decipher Score (0.00, 0.45, 0.60, 1.00)

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.

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*SEER = Surveillance, Epidemiology, and End Results Cancer Registries
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REPORT STATUS: FINAL
PAGE: 3 of 3

TEST DESCRIPTION

Sample Preparation: Microdissection is performed which consists of a pathologist identifying the tumor region of interest microscopically, followed by sample capture and testing.

Testing: Decipher uses an oligonucleotide microarray to measure the expression of 22 content genes to derive a Decipher score (ranging from 0 to 1.0) and corresponding calibrated probabilities for the following clinical endpoints:

- **Risk of adverse pathology at RP (i.e., Grade Group 3-5, pT3b-T4, or lymph node involvement).** Probabilities were generated using a logistic regression model in a cohort of 647 low and favorable intermediate risk prostate cancer patients with Decipher scores determined from an initial diagnostic biopsy who were then treated with RP.[1] The percent likelihoods for this endpoint range from 6-65%. Risk of adverse pathology is reported only for patients with low or favorable intermediate risk disease.

- **5-year and 10-year risk of clinical metastasis and 15-year risk of prostate cancer specific mortality (PCSM) after standard therapy.** Probabilities were generated through bootstrapped numerical integration of a) 116,971 patients diagnosed with non-metastatic prostate cancer who had available Decipher scores, b) risk estimates obtained from a cohort of 19,684 men with long-term follow up from 55 sites in the United States, Canada, and Europe[10] and c) effect sizes for Decipher estimated from meta-analyses of 9 previously published studies with a total of 3,441 patients.[11,15,19-20,22,28-31] The percent likelihoods for 5-year metastasis range from 0-16%, 10-year metastasis range from 0-29%, and 15-year PCSM range from 0-45%.

  - **Risk estimates are a function of standard therapy such as radical prostatectomy and radiation (including brachytherapy) with or without hormone therapy, as appropriate for each NCCN risk group.[10]**

Patients with a Decipher score >0.60 are classified as Decipher high-risk, patients with a score <0.45 are classified as Decipher low-risk, and patients with a score ≥0.45 and ≤0.60 are classified as Decipher intermediate-risk. The cut-points between Decipher risk groups were determined by optimizing both the partial likelihood and hazard ratios in a series of Cox linear regression models.[24-27]

INTENDED USE

Decipher Prostate Biopsy is intended for use in patients who are diagnosed with localized or regional prostate cancer who have not received pelvic radiation or hormone therapy prior to the biopsy. Decipher results are intended for use as an adjunct to conventional clinical risk factors for determining the metastatic potential of the tumor and patient prognosis.

CONFIDENCE INTERVALS

- Adverse Pathology Decipher risk reported here has a 95% confidence interval of 4.4% to 8.7%
- 5-year metastasis Decipher risk reported here has a 95% confidence interval of 0.2% to 0.5%
- 10-year metastasis Decipher risk reported here has a 95% confidence interval of 0.4% to 1.2%
- 15-year prostate cancer specific mortality Decipher risk reported here has a 95% confidence interval of 0.3% to 1.7%

REFERENCES

1. Herlemann, A. et al. Prostate Cancer Prostatic Dis 23, 136-143, (2020). 10.1038/s41391-019-0167-9.
2. Kim, H. L. et al. Prostate Cancer Prostatic Dis 22, 399-405, (2019). 10.1038/s41391-018-0101-6.
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Test Description

- Description of:
  - » Decipher testing platform technology
  - » Risk estimates
  - » Cut-points separating Decipher low, intermediate & high

Confidence Intervals

- The 95% confidence intervals for each risk estimate (on page 1)

Intended Use

- Decipher Prostate Biopsy is intended for use in biopsy specimens from patients with localized or pelvic node positive prostate cancer to help inform treatment decisions.

References

- For each of the clinical studies cited in the report

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