

Decipher® Prostate

RP Genomic Classifier

Sample Report: Not a Real Patient

PATIENT REPORT

REPORT STATUS: FINAL
PAGE: 1 of 3

PATIENT

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

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

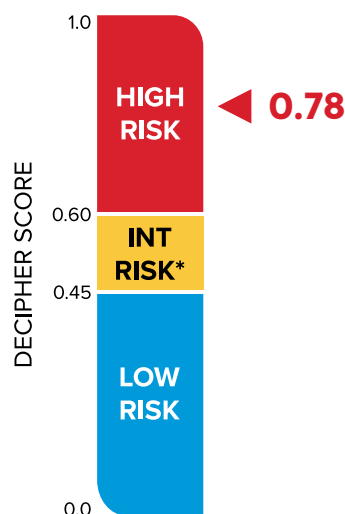
For reference only, not used in calculation of genomic risk

Most Recent PSA: **0.18 ng/mL**
Date of Most Recent PSA: --/--/----
☒ Rising or Persistently Elevated PSA

Specimen: **Radical Prostatectomy**
Gleason Score: **4+3**

- ☐ Seminal Vesicle Invasion (SVI)
- ☐ Lymph Node Invasion (LNI)
- ☐ Positive Surgical Margins (SM+)
- ☐ Extraprostatic Extension (EPE)

DECIPHER GENOMIC SCORE



DECIPHER GENOMIC RISK GROUP IS: **HIGH**

INTERPRETATION

Clinical studies demonstrate that Decipher high-risk patients with rising or persistently elevated PSA after radical prostatectomy have aggressive tumor biology.

- These patients had better outcomes when postoperative radiation was administered with concurrent hormone therapy.^{9,11,12}
- They were more likely to require salvage hormone therapy after treatment with radiation alone.¹⁰
- These patients may benefit from earlier, more intense therapy, and may consider clinical trials of novel therapies.^{1-11,14}

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

RISK ESTIMATES FOR THIS PATIENT

4.2%	14.7%	20.3%
5-year	10-year	15-year
Risk of Metastasis		Risk of Prostate Cancer Mortality

Prostate cancer risk estimates were determined by numerical integration of >9,000 prostate cancer patients with available Decipher scores calibrated to >3,000 patients with long-term follow-up from published meta-analyses. 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

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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 after surgery with undetectable, persistently-elevated, or rising PSA
 - » Metastasis at 5 & 10 years
 - » Prostate Cancer Mortality at 15 years

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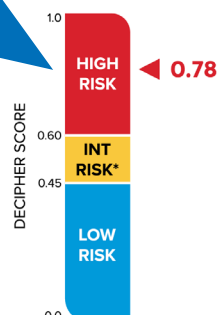
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10-year			
15-year			
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Risk of Prostate Cancer Mortality			

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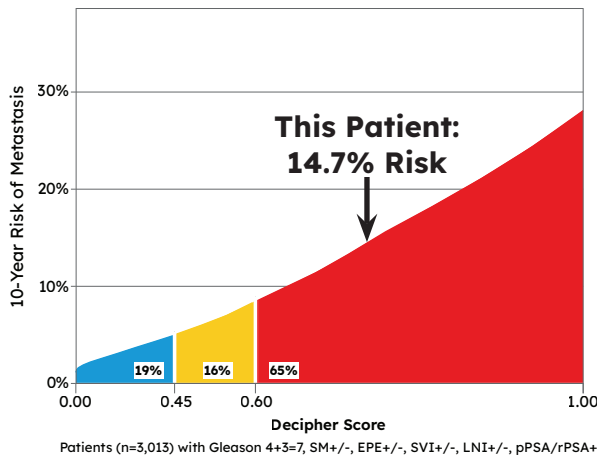
Dynamic Report

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

Interpretation

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

RISK COMPARED TO PATIENTS WITH SIMILAR CLINICAL AND PATHOLOGIC FEATURES



RISK GRAPHIC INTERPRETATION

This chart shows the 10-year risk of metastasis for 3,013 patients treated with prostatectomy, with similar clinical features to this patient, ordered from lowest to highest risk. Among these patients 19%, 16%, and 65% were classified as Decipher low-, intermediate-, and high-risk, respectively.

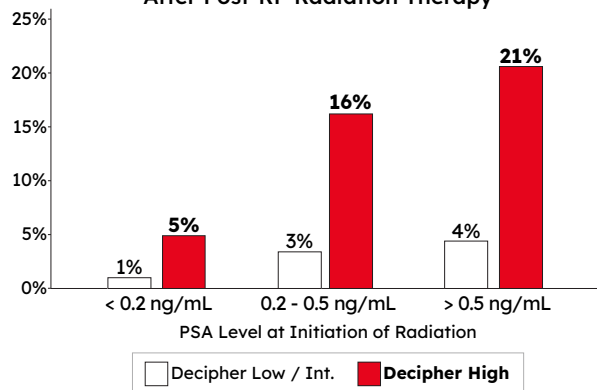
This patient has a predicted 14.7% 10-year risk of metastasis and is in the **58th percentile of risk**, meaning that 57 percent of men with similar clinical features have a lower Decipher score, and 42 percent have a higher Decipher score.

SM: Surgical Margins
SVI: Seminal Vesicle Invasion
rPSA: Rising PSA

EPE: Extraprostatic Extension
LNI: Lymph Node Involvement
pPSA: Persistently Elevated PSA

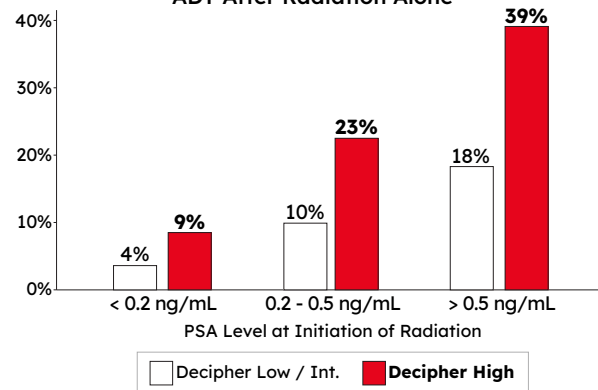
RADIATION TIMING

**5-year Risk of Metastasis*
After Post-RP Radiation Therapy**



TREATMENT INTENSITY: RADIATION +/- ADT?

**5-year Risk of Receiving Salvage
ADT After Radiation Alone†**



Decipher high-risk patients had better outcomes with earlier (PSA <0.2 ng/mL) as compared to delayed (PSA ≥0.2 ng/mL) radiation therapy.³

When earlier postoperative radiation was administered without concurrent hormone therapy, Decipher high-risk patients were more likely to require salvage hormone therapy.¹⁰

*Adapted from Ross, AE et al. Eur Urol 69, 157-165 (2016).

†Adapted from Dal Pra, A. et al. Ann Oncol 33 (9), 950-958 (2022).

FINDINGS FROM CLINICAL STUDIES RELEVANT TO THIS PATIENT

- Decipher high-risk patients who were treated with radiation had better outcomes when it was administered earlier and at lower PSA levels.^{2,3,16,17}
- Decipher high-risk patients with persistently elevated PSA who were treated with radiation without concurrent hormone therapy after surgery had suboptimal outcomes.¹²
- In a prospective, multicenter clinical trial, 27% of Decipher high-risk patients with rising PSA after surgery were managed with PSA monitoring, 30% were treated with radiation alone, 39% were treated with radiation and concurrent hormone therapy, and 5% received hormone therapy alone.¹⁸
- In the randomized phase 3 SAKK 09/10 clinical trial, which compared outcomes for postoperative patients with biochemical recurrence who received standard dose or dose-escalated radiation without concurrent hormone therapy, 26% of Decipher high-risk patients required salvage ADT at 5 years.¹⁰
- In the randomized phase 3 NRG/RTOG 9601 clinical trial, which compared outcomes of patients with rising or persistently elevated PSA who received radiation alone or with concurrent hormone therapy, Decipher high-risk patients with a PSA < 0.7ng/mL had substantial oncologic benefit (11.2% improvement in 12-year distant metastasis-free survival) from the addition of concurrent hormone therapy.⁹

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Risk Comparison

- This patient's 10-year risk of metastasis with respect to 3,013 other patients with Gleason 4+3=7 disease & rising PSA
- The distribution of Decipher risk within the 3,013 patients is:
 - » **19% Decipher Low**
 - » **16% Decipher Int.**
 - » **65% Decipher High**

Clinical Findings

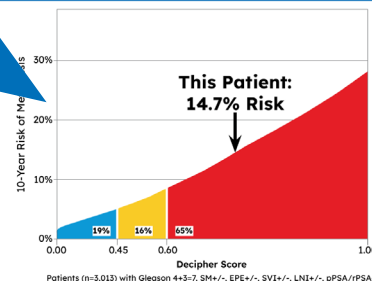
- Clinical study results relevant to this patient

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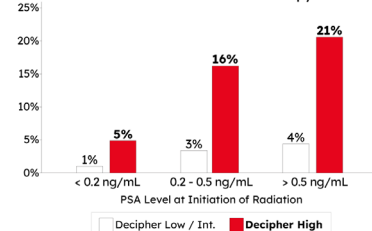
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RADIATION TIMING

5-year Risk of Metastasis*
After Post-RP Radiation Therapy

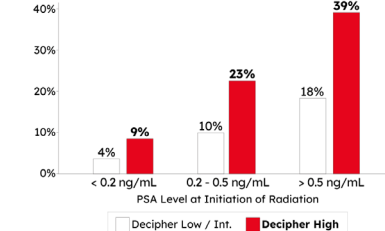


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Interpretation

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

Treatment

Treatment Timing (Left)

- Risk of metastasis after post-RP radiation stratified by Decipher risk & PSA level at time of treatment

Treatment Intensity (Right)

- Risk of receiving salvage ADT after radiation alone stratified by Decipher risk & PSA level at time of treatment

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:

- **5-year, 10-year risk of clinical metastasis after radical prostatectomy (RP).** Probabilities were generated through bootstrapped numerical integration of 52,152 patients treated with RP who had available Decipher scores. Risk estimates and effect sizes of Decipher were obtained from meta-analyses of 3,049 patients from 8 previously published studies.^{9-10,14,22-26} The percent likelihoods for 5-year metastasis range from 0-11% and 10-year metastasis range from 1-22%.
- **15-year risk of prostate cancer specific mortality (PCSM) after RP.** Probabilities were generated through bootstrapped numerical integration of a) 52,152 patients treated with RP who had available Decipher scores, b) risk estimates from a multi-institutional cohort of 23,910 patients treated with RP,¹³ and c) effect sizes for Decipher estimated from meta-analyses of 5 previously published studies with a total of 1,772 patients.^{9,22,24,26-27} The percent likelihoods for 15-year PCSM range from 0-22%.
- **5-year, 10-year risk of clinical metastasis and 15-year risk of prostate cancer specific mortality (PCSM) with rising PSA or persistently elevated PSA ($\geq 0.2\text{ng/mL}$).** Probabilities were generated through bootstrapped numerical integration of a) 9,028 patients treated with RP who had rising or persistently elevated PSA and available Decipher scores, b) risk estimates obtained from a phase 3 randomized trial of salvage radiation,⁹ and c) effect sizes for Decipher estimated from meta-analyses of 9 previously published studies with a total of 3,441 patients.^{9-10,14,22-27} The percent likelihoods for 5-year metastasis range from 0-9%, 10-year metastasis range from 1-28%, and 15-year PCSM range from 1-44%.

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.^{4,19-21}

INTENDED USE

Decipher Prostate RP is intended for use in patients with localized prostate cancer after radical prostatectomy (RP) with undetectable, persistent, or rising prostate-specific antigen (PSA) who are being considered for treatment and have not received pelvic radiation or hormone therapy prior to RP. 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

- 5-year metastasis Decipher risk reported here has a 95% confidence interval of 1.6% to 6.9%
- 10-year metastasis Decipher risk reported here has a 95% confidence interval of 9.6% to 19.8%
- 15-year prostate cancer specific mortality Decipher risk reported here has a 95% confidence interval of 9.7% to 31.3%

REFERENCES

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Test Description

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

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Intended Use

- Decipher Prostate RP is intended for use in post-RP specimens from localized prostate cancer patients with undetectable, persistent, or rising PSA

References

- For each of the clinical studies cited in the report

Confidence Intervals

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

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