DECIPHER PROSTATE RP

Decipher Biosciences
6925 Lusk Boulevard, Suite 200
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Phone 1.888.792.1601 | Fax 1.855.324.2768
cs@decipherbio.com | www.decipherbio.com

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-------**

ORDERING PHYSICIAN

Name: **Sample Physician**
Clinic: **Main St. Urology Associates**
Address: **123 Laurel Canyon Boulevard, Anytown, OH 54321**

CLINICAL AND PATHOLOGY DETAILS

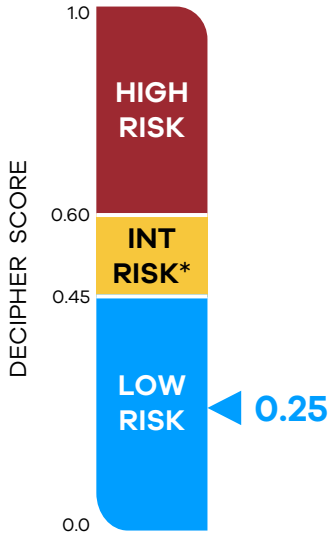
For reference only, not used in calculation of genomic risk

Most Recent PSA: **4.9 ng/mL**
☒ Positive Surgical Margins (SM+)
☐ Bladder Neck Invasion (BNI)

Specimen: **Radical Prostatectomy**
☐ Extraprostatic Extension (EPE)
☐ Biochemical Recurrence (BCR)

Gleason Score: **3+4**
☐ Seminal Vesicle Invasion (SVI)

DECIPHER GENOMIC RISK RESULTS



GENOMIC RISK IS: LOW

0.9%	1.9%	1.5%
5-year	10-year	15-year
Risk of Metastasis		**Risk of Prostate Cancer Mortality**

INTERPRETATION

Clinical studies demonstrate that Decipher low-risk patients with adverse pathology have a favorable prognosis overall.[1-11]

- These patients may be optimally managed with observation/PSA monitoring after surgery.[1-4,8-11]
- Upon PSA rise, these patients may be treated with salvage radiation therapy alone, without concurrent hormone therapy.[5-7]

RELEVANT FINDINGS FROM CLINICAL STUDIES

- Decipher low-risk patients with undetectable PSA after surgery experienced no improvement in metastasis-free survival when treated with earlier radiation therapy.[1-3] These patients had >97% 5-year metastasis-free survival and >97% 10-year freedom from prostate cancer-specific mortality.[2,10,12-13]
- In patients with persistently elevated PSA after prostatectomy, Decipher low-risk patients had >99% 5-year metastasis-free survival when treated with salvage radiation therapy.[7]
- In a retrospective study of RTOG 96-01, a phase III randomized trial of salvage radiation therapy with or without hormone therapy, among the subset treated with early salvage radiation (i.e., PSA <0.7 ng/mL), Decipher low-risk patients had minimal clinical benefit (<0.5% improvement in 12-year distant metastasis rate) from the addition of hormone therapy.[5]

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

Laboratory Director (Signature)
Bashar Dabbas, MD

Report Date

CAP ACCREDITED

CLIA ID# 05D2055897
CAP # 8859006

* INT RISK in Decipher score graphic is an abbreviation of "intermediate-risk"

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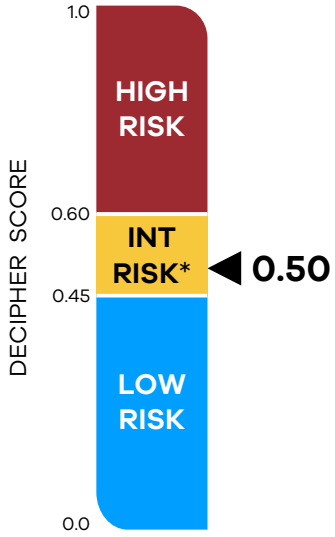

GENOMIC RISK IS: **INTERMEDIATE**		
2.2%	**4.7%**	**3.9%**
5-year	10-year	15-year
Risk of Metastasis		**Risk of Prostate Cancer Mortality**

INTERPRETATION

Clinical studies demonstrate that Decipher intermediate-risk patients with adverse pathology have an average prognosis overall.[1-3,9,13]

- Following prostatectomy, these patients may receive benefit from earlier radiation.[1-4,11]
- When being treated with salvage radiation, these patients may benefit from the addition of hormone therapy.[4-7]

RELEVANT FINDINGS FROM CLINICAL STUDIES

- Decipher intermediate-risk patients who were treated with early radiation therapy had a 94% 5-year metastasis-free survival rate.[12]
- In a retrospective study of RTOG 96-01, a phase III randomized trial of salvage radiation therapy with or without hormone therapy, Decipher intermediate- and high-risk men experienced improvement in metastasis-free, cancer-specific, and overall survival from the addition of hormone therapy.[5]

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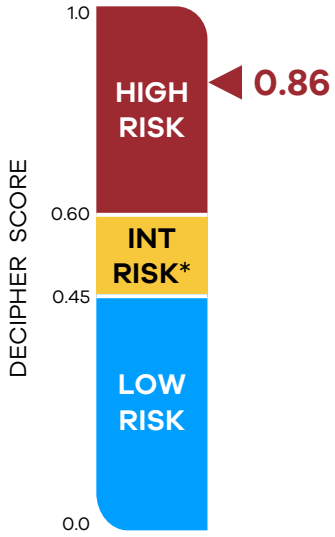

GENOMIC RISK IS: HIGH

8.5%	17.2%	14.1%
5-year	10-year	15-year
Risk of Metastasis		**Risk of Prostate Cancer Mortality**

INTERPRETATION

Clinical studies demonstrate that Decipher high-risk patients with adverse pathology have an unfavorable prognosis overall.[1-14]

- These patients may benefit from earlier, more intense, or multimodality therapy, and may consider clinical trials of novel therapies.

RELEVANT FINDINGS FROM CLINICAL STUDIES

- Decipher high-risk patients with undetectable PSA after surgery who received early radiation showed significant improvement in metastasis-free survival, as well as an 80% reduction in risk compared with patients who received salvage radiation therapy.[1-3,15]
- In a study of patients with persistently elevated PSA after prostatectomy, Decipher high-risk patients had sub-optimal oncologic outcomes when treated with salvage radiation therapy alone.[7]
- In a retrospective study of RTOG 96-01, a phase III randomized trial of salvage radiation therapy with or without hormone therapy, Decipher intermediate- and high-risk men experienced improvement in metastasis-free, cancer-specific, and overall survival from the addition of hormone therapy.[5]

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TEST DESCRIPTION

Hematoxylin and Eosin (H&E) slides are microscopically reviewed by a pathologist to identify the optimal area of tumor that satisfies specimen requirements. The selected region of the tumor is microdissected from surrounding non-neoplastic tissue and submitted for testing. Decipher uses an oligonucleotide microarray to measure 22 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 a) 27,780 patients treated with RP who had available Decipher scores and the risk estimates as well as effect sizes of Decipher were obtained from meta-analyses of 5 previously published study cohorts.[14] The percent likelihoods for 5-year metastasis range from 0-14% and the 10-year metastasis range from 0.1-27%.
- 15-year risk of prostate cancer specific mortality (PCSM) after RP. Probabilities were generated through bootstrapped numerical integration of a) 27,780 patients treated with RP who had available Decipher scores, b) the risk estimates from a multi-institutional cohort of 23,910 patients treated with RP,[16] and effect size of Decipher were obtained from meta-analyses of 6 previously published study cohorts with a total of 1,210 patients.[14,17] The percent likelihood for 15-year PCSM range from 0.1-23%.
- 5-year, 10-year risk of clinical metastasis and 15-year risk of prostate cancer specific mortality (PCSM) after biochemical recurrence (BCR). Probabilities were generated through bootstrapped numerical integration of a) 3,209 patients treated with RP who had biochemical recurrence and available Decipher scores, b) the risk estimates obtained from a Phase III randomized trial of salvage radiation,[5] and c) the estimated effect sizes of Decipher from meta-analyses of 6 previously published study cohorts with a total of 1,210 patients.[14,17] The percent likelihoods for 5-year metastasis range from 0-12%, the 10-year metastasis range from 0.1-40%, and the 15-year PCSM range from 0.2-51%.

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.[12,18,19]

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 XX.X% to YY.Y%
- 10-year metastasis Decipher risk reported here has a 95% confidence interval of XX.X% to YY.Y%
- 15-year prostate cancer specific mortality Decipher risk reported here has a 95% confidence interval of XX.X% to YY.Y%

REFERENCES

1. Den, RB et al. Int J Radiat Oncol Biol Phys 89, 1038-1046 (2014).
2. Den, RB et al. J Clin Oncol 33, 944-951 (2015).
3. Ross, AE et al. Prostate Cancer Prostatic Dis 19, 277-282 (2016).
4. Ross, AE et al. Eur Urol 69, 157-165 (2016).
5. Feng, FY et al. Journal of Clinical Oncology 38, 276-276 (2020).
6. Freedland, SJ et al. Eur Urol 70, 588-596 (2016).
7. Spratt, DE et al. Eur Urol 74, 107-114 (2018).
8. Marascio, J et al. Prostate Cancer Prostatic Dis (2019).
9. Ross, AE et al. Prostate Cancer Prostatic Dis 17, 64-69 (2014).
10. Karnes, RJ et al. Eur Urol 73, 168-175 (2018).
11. Glass, AG et al. J Urol 195, 1748-1753 (2016).
12. Karnes, RJ et al. J Urol 190, 2047-2053 (2013).
13. Spratt, DE et al. J Clin Oncol 36, 581-590 (2018).
14. Spratt, DE et al. J Clin Oncol 35, 1991-1998 (2017).
15. Dalela, D et al. J Clin Oncol 35, 1982-1990 (2017).
16. Eggener, SE et al. J Urol 185, 869-875 (2011).
17. Nguyen, PL et al. Eur Urol 72, 845-852 (2017).
18. Erho, N et al. PLoS One 8, e66855 (2013).
19. Lee, HJ et al. Res Rep Urol 8, 77-84 (2016).