

# DECIPHER PROSTATE RP

**Decipher Biosciences**  
6925 Lusk Boulevard, Suite 200  
San Diego, CA 92121  
Phone 1.888.792.1601 | Fax 1.855.324.2768  
cs@decipherbio.com | www.decipherbio.com

## PATIENT

Name: **Jonathan A Doe**  
Date of Birth: **01/01/1945**  
Medical Record #: **123456789**  
Date of Prostatectomy: **01/01/2019**

## SPECIMEN INFORMATION

Order Date: **01/01/2019**  
Specimen ID: **11-22-33-44-55-66**  
Specimen Received Date: **01/01/2019**  
Decipher Accession ID: **MC-222111**

## ORDERING PHYSICIAN

Name: **John Smith, MD**  
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**

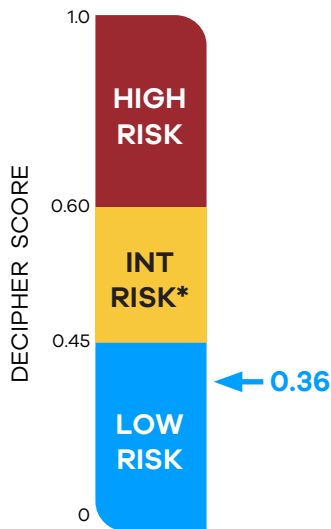
Extraprostatic Extension (EPE)

Biochemical Recurrence (BCR)

Gleason Score: **3+4**

Seminal Vesicle Invasion (SVI)

## DECIPHER GENOMIC RISK RESULTS



### GENOMIC RISK IS: **LOW**

**2.3%**

**Risk of Metastasis  
within 5 years**

**3.1%**

**Risk of Prostate Cancer Mortality  
within 10 years**

### INTERPRETATION

Clinical studies demonstrate that Decipher low-risk patients with adverse pathology have a favorable prognosis overall.<sup>1-11</sup>

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

### 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.<sup>1-3</sup> These patients had >97% 5-year metastasis-free survival and >97% 10-year freedom from prostate cancer-specific mortality.<sup>2,10,12-13</sup>
- 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.<sup>7</sup>
- 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.<sup>5</sup>

Decipher risk 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



CLIA ID# 05D2055897  
CAP # 8859006

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

LAB-FRM-20007 v7.0

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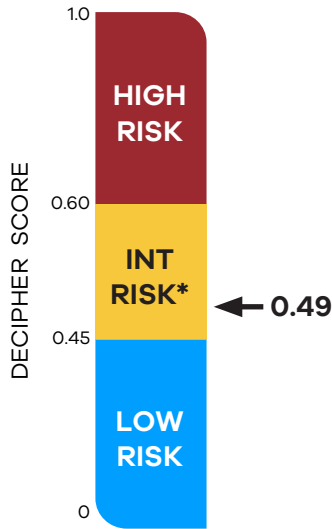
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 Biochemical Recurrence (BCR)

Gleason Score: **3+4**

- Seminal Vesicle Invasion (SVI)

## DECIPHER GENOMIC RISK RESULTS



GENOMIC RISK IS: INTERMEDIATE	
<b>4.9%</b>	<b>5.2%</b>
Risk of Metastasis within 5 years	Risk of Prostate Cancer Mortality within 10 years

INTERPRETATION
<p>Clinical studies demonstrate that Decipher intermediate-risk patients with adverse pathology have an average prognosis overall.<sup>1-3,9,13</sup></p> <ul style="list-style-type: none"> <li>Following prostatectomy, these patients may receive benefit from earlier radiation.<sup>1-4,11</sup></li> <li>When being treated with salvage radiation, these patients may benefit from the addition of hormone therapy.<sup>4-7</sup></li> </ul>

RELEVANT FINDINGS FROM CLINICAL STUDIES
<ul style="list-style-type: none"> <li>Decipher intermediate-risk patients who were treated with early radiation therapy had a 94% 5-year metastasis-free survival rate.<sup>12</sup></li> <li>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.<sup>5</sup></li> </ul>

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

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## DECIPHER GENOMIC RISK RESULTS

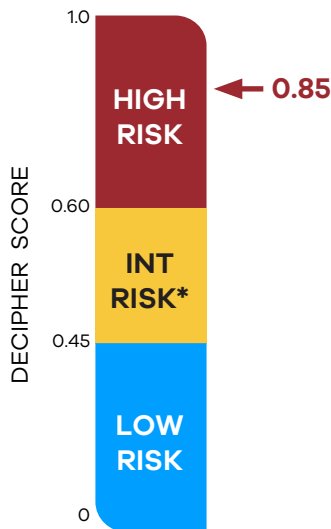
### GENOMIC RISK IS: **HIGH**

**36.0%**

**Risk of Metastasis  
within 5 years**

**19.2%**

**Risk of Prostate Cancer Mortality  
within 10 years**



### INTERPRETATION

Clinical studies demonstrate that Decipher high-risk patients with adverse pathology have an unfavorable prognosis overall.<sup>1-14</sup>

- 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.<sup>1-3,15</sup>
- 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.<sup>7</sup>
- 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.<sup>5</sup>

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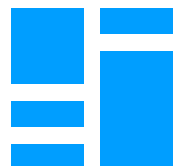
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## TEST DESCRIPTION

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 focus of the tumor is micro-dissected from the corresponding paraffin block and submitted for testing. Decipher uses oligonucleotide microarrays to measure 22 RNA expression biomarkers, extracted from formalin fixed paraffin embedded (FFPE) prostate tissue specimens, to derive a Decipher score (ranging from 0 to 1.0) and corresponding probability of:

- Decipher uses the genomic risk score to predict the 5-year probability of metastasis from the time of RP with an AUC of 0.76 to 0.87. Probabilities were generated using a cox proportional hazards model in a cohort of 1,010 prostate cancer patients, with the average cumulative incidence of metastasis of 6.0% at 5 years post RP.<sup>12</sup> The percent likelihood for this endpoint ranges from 0.3-67%.
- 10-year probability of prostate cancer specific mortality (PCSM). Decipher uses the genomic risk score to predict the 10-year probability of PCSM from the time of RP with a hazard ratio (HR) of 1.57 (95% CI 1.03–2.48) per 10% increase for Decipher score (p=0.037). Probabilities were generated using a logistic regression model in a cohort of 561 prostate cancer patients with 112 prostate cancer deaths.<sup>10</sup> The percent likelihood for this endpoint ranges from 0.7-30.5%.

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.<sup>12,16,17</sup>

## INTENDED USE

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

## CONFIDENCE INTERVALS

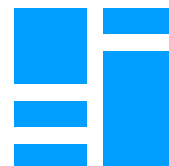
- Decipher risk of 5-year metastasis reported here has a 95% confidence interval of 8.4% to 14.8%
- Decipher risk of 10-year prostate cancer specific mortality reported here has a 95% confidence interval of 5.7% to 12.6%

## REFERENCES

1. Den, RB et al. Genomic prostate cancer classifier predicts biochemical failure and metastases in patients after postoperative radiation therapy. *Int J Radiat Oncol Biol Phys* 89, 1038-1046, (2014).
2. Den, RB et al. Genomic classifier identifies men with adverse pathology after radical prostatectomy who benefit from adjuvant radiation therapy. *J Clin Oncol* 33, 944-951, (2015).
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### Disclaimer:

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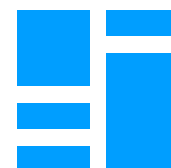
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This is the failure reason

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