

**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**

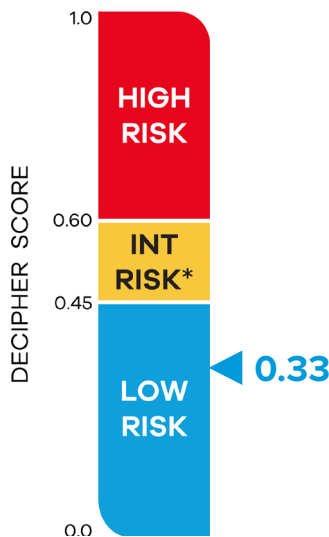
**ORDERING PHYSICIAN**

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: <b>0.07 ng/mL</b>	Specimen: <b>Radical Prostatectomy</b>	Gleason Score: <b>3+4</b>
<input checked="" type="checkbox"/> Positive Surgical Margins (SM+)	<input checked="" type="checkbox"/> Seminal Vesicle Invasion (SVI)	<input type="checkbox"/> Rising or Persistently Elevated PSA
<input checked="" type="checkbox"/> Extraprostatic Extension (EPE)	<input type="checkbox"/> Lymph Node Invasion (LNI)	

**DECIPHER GENOMIC RISK RESULTS**



GENOMIC RISK IS: <b>LOW</b>		
<b>1.2%</b>	<b>2.5%</b>	<b>2.1%</b>
<i>5-year</i>	<i>10-year</i>	<i>15-year</i>
Risk of Metastasis		Risk of Prostate Cancer Mortality

INTERPRETATION
<p>Clinical studies demonstrate that Decipher low-risk patients treated with radical prostatectomy have a favorable prognosis overall.<sup>1-11</sup></p> <ul style="list-style-type: none"> <li>• These patients may be optimally managed with observation/PSA monitoring after surgery.<sup>1-4,8-11</sup></li> <li>• Patients with rising or persistently elevated PSA may be treated with radiotherapy alone, without concurrent hormone therapy.<sup>5-7</sup></li> </ul>

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

Laboratory Director (Signature)  
Bashar Dabbas, MD

Report Date

CLIA ID# 05D2055897  
CAP # 8859006  
Lab Director: Bashar Dabbas, MD

\* INT RISK in Decipher score graphic is an abbreviation of "intermediate-risk"  
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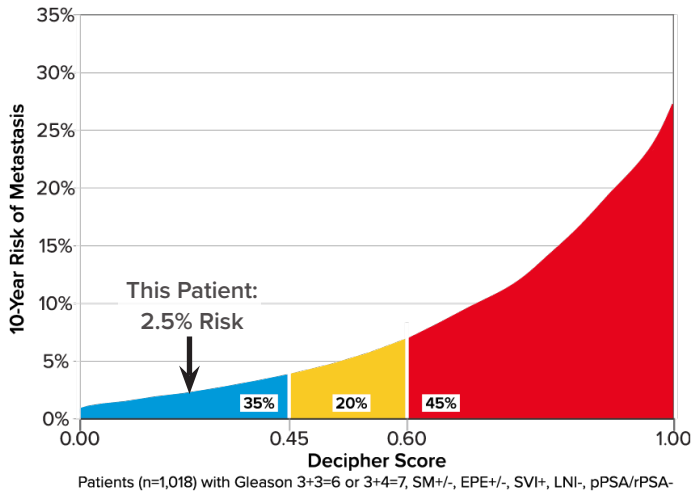
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6925 Lusk Boulevard, Suite 200  
San Diego, CA 92121

T 1.888.792.1601  
F 1.858.766.6575

E cs@decipherbio.com  
W www.decipherbio.com

**RISK COMPARED TO PATIENTS WITH SIMILAR CLINICAL AND PATHOLOGIC FEATURES**



This chart shows the 10-year risk of metastasis for 1,018 men treated with prostatectomy, with similar clinical features to this patient, ordered from lowest to highest risk. Among these patients 35%, 20%, and 45% were classified as Decipher low-, intermediate-, and high-risk, respectively.

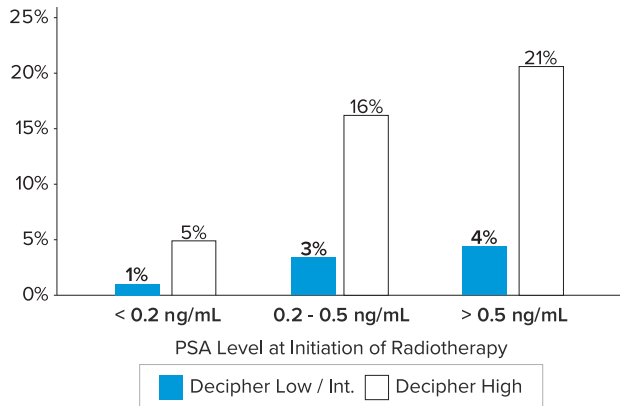
This patient has a predicted 2.5% 10-year risk of metastasis and is in the **18th percentile of risk**, meaning that 17 percent of men with similar clinical features have a lower Decipher score, and 82 percent have a higher Decipher score.

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

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

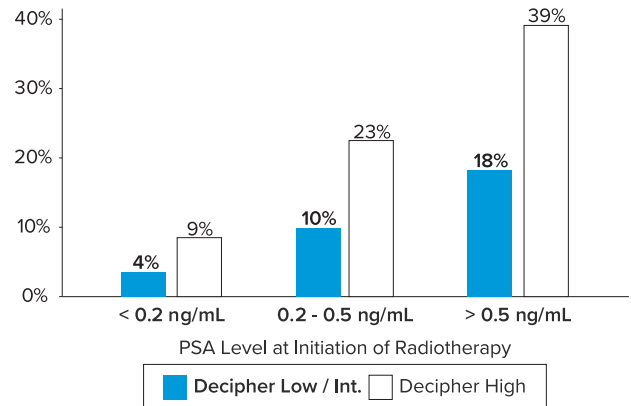
**RADIOTHERAPY TIMING**

**5-year Risk of Metastasis\* After Post-Prostatectomy Radiotherapy**



**TREATMENT INTENSITY: RADIOTHERAPY +/- ADT?**

**5-year Risk of Progression to ADT after Radiotherapy Alone†**



Decipher low-risk patients had similar outcomes with earlier or delayed radiotherapy.<sup>3</sup> Men with rising PSA had low rates of progression to hormonal treatment after radiotherapy alone<sup>15</sup> and received minimal improvement in oncologic outcomes (metastasis, PCSM) from radiotherapy with concurrent hormone therapy.<sup>6</sup>

\* Risk of metastasis figure adapted from Ross, AE et al. Eur Urol 69, 157-165 (2016).  
† Risk of progression figure adapted from Dal Pra, A. et al. J Clin Oncol 39 no. 15\_suppl, (2021).

**FINDINGS FROM CLINICAL STUDIES RELEVANT TO THIS PATIENT**

In clinical studies of men treated with radical prostatectomy (RP):

- Decipher low-risk patients with undetectable PSA had a favorable prognosis, with 98% 5-year freedom from distant metastasis.<sup>14</sup>
- Treatment with radiotherapy prior to a rise in PSA above 0.2 ng/mL did not lead to improvement in outcomes.<sup>2,16,17</sup>

In a prospective, multicenter clinical trial, 76% of Decipher low-risk patients with undetectable PSA were observed with PSA monitoring, 19% received post-operative radiotherapy alone, and 5% were treated with concurrent hormone therapy.<sup>18</sup>

In the Phase 3 randomized clinical trial RTOG 9601, which compared outcomes for post-operative patients with a rising PSA who received radiotherapy with or without hormone therapy, Decipher low-risk patients experienced only minimal improvement (0.4%) in 12-year distant metastasis-free survival from the addition of hormone therapy when their PSA level was <0.7 ng/mL.<sup>6</sup>

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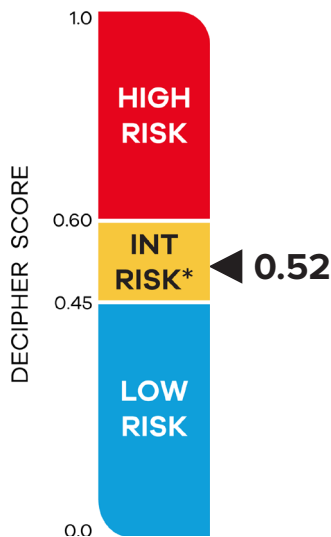
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Clinic: **Sample Clinic**  
Address: **123 Birch Avenue, Suite A, Anytown, CA 54321**  
Additional Physician: **Additional Sample Physician, MD**

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

Most Recent PSA: **0.07 ng/mL**  
 Positive Surgical Margins (SM+)       Seminal Vesicle Invasion (SVI)  
 Extraprostatic Extension (EPE)       Lymph Node Invasion (LNI)  
 Gleason Score: **3+4**  
 Rising or Persistently Elevated PSA

**DECIPHER GENOMIC RISK RESULTS**



GENOMIC RISK IS: <b>INTERMEDIATE</b>		
<b>2.5%</b>	<b>5.1%</b>	<b>4.2%</b>
<i>5-year</i>	<i>10-year</i>	<i>15-year</i>
Risk of Metastasis		Risk of Prostate Cancer Mortality

INTERPRETATION
<p>Clinical studies demonstrate that Decipher intermediate-risk patients treated with radical prostatectomy have an average prognosis overall.<sup>1-3,9,12</sup></p> <ul style="list-style-type: none"> <li>Following prostatectomy, these patients receive modest benefit from earlier radiation.<sup>1-4,11</sup></li> <li>Patients with rising or persistently elevated PSA may receive modest improvement in oncologic outcomes (metastasis and prostate cancer mortality) from radiotherapy with concurrent hormone therapy.<sup>3,5-7</sup></li> </ul>

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

Laboratory Director (Signature)  
Bashar Dabbas, MD

Report Date

CLIA ID# 05D2055897  
CAP # 8859006  
Lab Director: Bashar Dabbas, MD

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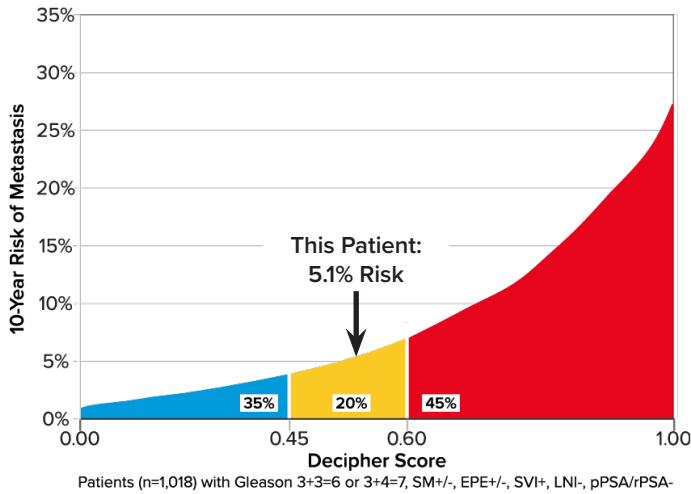
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**RISK COMPARED TO PATIENTS WITH SIMILAR CLINICAL AND PATHOLOGIC FEATURES**



This chart shows the 10-year risk of metastasis for 1,018 men treated with prostatectomy, with similar clinical features to this patient, ordered from lowest to highest risk. Among these patients 35%, 20%, and 45% were classified as Decipher low-, intermediate-, and high-risk, respectively.

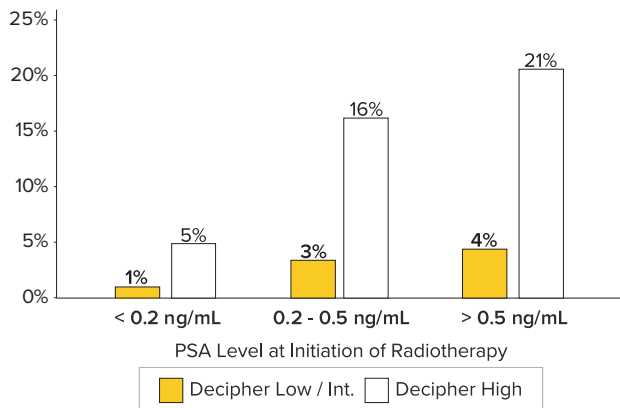
This patient has a predicted 5.1% 10-year risk of metastasis and is in the **46th percentile of risk**, meaning that 45 percent of men with similar clinical features have a lower Decipher score, and 54 percent have a higher Decipher score.

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

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

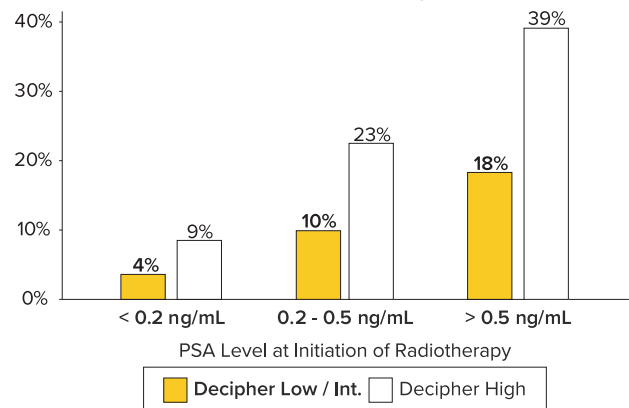
**RADIOTHERAPY TIMING**

**5-year Risk of Metastasis\* After Post-Prostatectomy Radiotherapy**



**TREATMENT INTENSITY: RADIOTHERAPY +/- ADT\***

**5-year Risk of Progression to ADT after Radiotherapy Alone†**



Decipher intermediate-risk patients received modest benefit with earlier radiotherapy.<sup>3</sup> Men with rising PSA had lower rates of progression to hormonal treatment after radiotherapy alone<sup>15</sup>. Those who received radiotherapy with concurrent hormone therapy had modest improvement in oncologic outcomes (metastasis, PCSM).<sup>6</sup>

\* Risk of metastasis figure adapted from Ross, AE et al. Eur Urol 69, 157-165 (2016).  
† Risk of progression figure adapted from Dal Pra, A. et al. J Clin Oncol 39 no. 15\_suppl, (2021).

**FINDINGS FROM CLINICAL STUDIES RELEVANT TO THIS PATIENT**

In clinical studies of men treated with radical prostatectomy (RP):

- Decipher intermediate-risk patients with undetectable PSA had an average prognosis, with 94% 5-year freedom from distant metastasis.<sup>14</sup>
- Decipher intermediate-risk patients who were treated with radiotherapy had superior outcomes when it was administered earlier and at lower PSA levels (<0.2 ng/mL).<sup>1-3</sup>

In a prospective, multicenter clinical trial, 70% of Decipher intermediate-risk patients with undetectable PSA were observed with PSA monitoring, 27% received post-operative radiotherapy alone, and 3% were treated with concurrent hormone therapy.<sup>18</sup>

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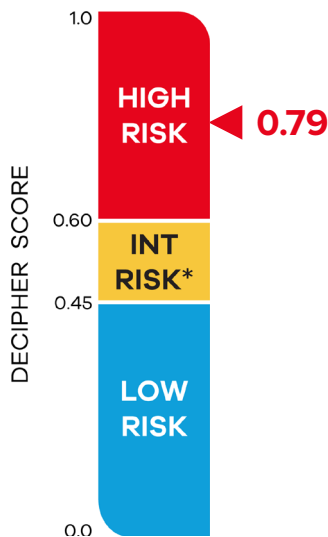
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Address: **123 Birch Avenue, Suite A, Anytown, CA 54321**  
Additional Physician: **Additional Sample Physician, MD**

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

Most Recent PSA: **0.07 ng/mL**      Specimen: **Radical Prostatectomy**      Gleason Score: **3+4**  
 Positive Surgical Margins (SM+)       Seminal Vesicle Invasion (SVI)       Rising or Persistently Elevated PSA  
 Extraprostatic Extension (EPE)       Lymph Node Invasion (LNI)

**DECIPHER GENOMIC RISK RESULTS**



GENOMIC RISK IS: <b>HIGH</b>		
<b>6.6%</b>	<b>13.5%</b>	<b>11.1%</b>
<i>5-year</i>	<i>10-year</i>	<i>15-year</i>
Risk of Metastasis		Risk of Prostate Cancer Mortality

INTERPRETATION
<p>Clinical studies demonstrate that Decipher high-risk patients treated with radical prostatectomy have an unfavorable prognosis overall.<sup>1-14</sup></p> <ul style="list-style-type: none"> <li>• These patients may benefit from earlier, more intense, or multimodality therapy.<sup>14</sup></li> <li>• Patients with rising or persistently elevated PSA are likely to benefit from radiotherapy with concurrent hormone therapy.<sup>3,5-7</sup></li> </ul>

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

Laboratory Director (Signature)  
Bashar Dabbas, MD

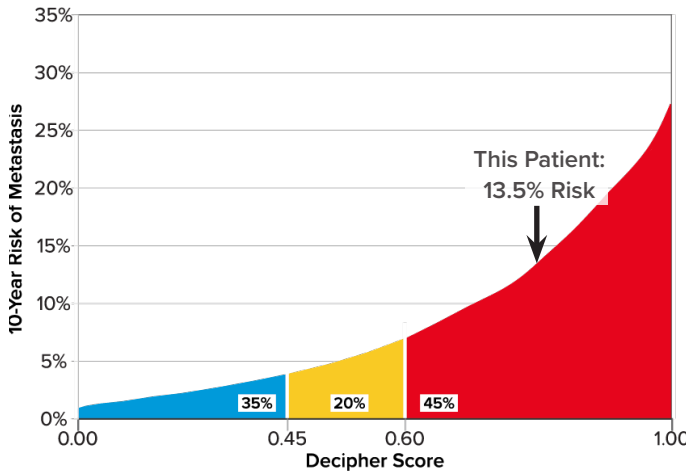
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**RISK COMPARED TO PATIENTS WITH SIMILAR CLINICAL AND PATHOLOGIC FEATURES**



This chart shows the 10-year risk of metastasis for 1,018 men treated with prostatectomy, with similar clinical features to this patient, ordered from lowest to highest risk. Among these patients 35%, 20%, and 45% were classified as Decipher low-, intermediate-, and high-risk, respectively.

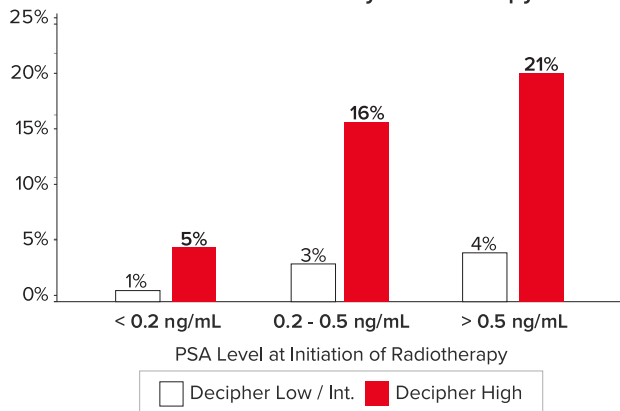
This patient has a predicted 13.5% 10-year risk of metastasis and is in the **77th percentile of risk**, meaning that 76 percent of men with similar clinical features have a lower Decipher score, and 23 percent have a higher Decipher score.

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

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

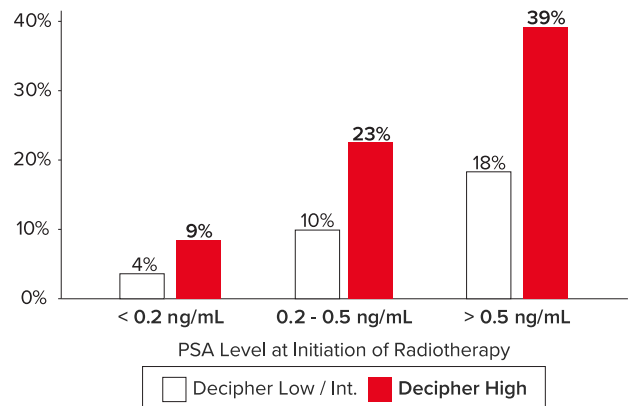
**RADIOTHERAPY TIMING**

5-year Risk of Metastasis\* After Post-Prostatectomy Radiotherapy



**TREATMENT INTENSITY: RADIOTHERAPY +/- ADT?**

5-year Risk of Progression to ADT after Radiotherapy Alone†



Decipher high-risk patients received the most benefit from radiotherapy when their PSA level was less than 0.2 ng/mL.<sup>3</sup> Men with rising PSA had high rates of progression to hormonal treatment after radiotherapy alone<sup>15</sup> and received substantial improvement in oncologic outcomes (metastasis, PCSM) and overall survival from radiotherapy with concurrent hormone therapy.<sup>6</sup>

\* Risk of metastasis figure adapted from Ross, AE et al. Eur Urol 69, 157-165 (2016).

† Risk of progression figure adapted from Dal Pra, A. et al. J Clin Oncol 39 no. 15\_suppl. (2021).

**FINDINGS FROM CLINICAL STUDIES RELEVANT TO THIS PATIENT**

In clinical studies of men treated with radical prostatectomy (RP):

- Decipher high risk patients who were treated with radiotherapy had superior outcomes when it was administered earlier and at lower PSA levels (<0.2 ng/mL).<sup>2,3,16,17</sup>

In a prospective, multicenter clinical trial, 61% of Decipher high-risk patients with undetectable PSA were observed with PSA monitoring, 23% received post-operative radiotherapy alone, and 16% were treated with concurrent hormone therapy.<sup>18</sup>

In the Phase 3 randomized clinical trial SAKK 09/10, post-operative men with a rising PSA were treated with radiotherapy without concurrent hormone therapy. Decipher high-risk patients were more than twice as likely to experience treatment failure and progress to hormone therapy.<sup>15</sup>

In the Phase 3 randomized clinical trial RTOG 9601, which compared outcomes for post-operative patients with a rising PSA who received radiotherapy with or without hormone therapy, Decipher high-risk patients had superior outcomes with the addition of hormone therapy, with absolute improvements in distant metastasis, prostate cancer-specific mortality, and overall survival.<sup>6</sup>

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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 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.<sup>14</sup> 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,<sup>19</sup> and c) the effect size of Decipher were obtained from meta-analyses of 6 previously published study cohorts with a total of 1,210 patients.<sup>14,20</sup> 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) with rising PSA or persistently elevated PSA ( $\geq 0.2\text{ng/mL}$ ). Probabilities were generated through bootstrapped numerical integration of a) 3,209 patients treated with RP who had rising or persistently elevated PSA and available Decipher scores, b) the risk estimates obtained from a Phase III randomized trial of salvage radiation,<sup>6</sup> and c) the estimated effect sizes of Decipher from meta-analyses of 6 previously published study cohorts with a total of 1,210 patients.<sup>14,20</sup> 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  $\geq 0.45$  and  $\leq 0.60$  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>4,13,21</sup>

## INTENDED USE

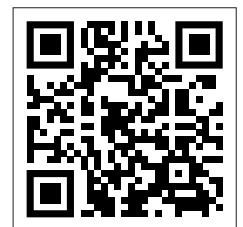
Decipher Prostate RP is intended for use in patients with localized prostate cancer after radical prostatectomy (RP) with undetectable, persistent, or rising prostate-specific antigen (PSA) who are being considered for treatment and have not received pelvic radiation or hormone therapy prior to RP. Decipher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

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2. Den, R. B. et al. J Clin Oncol 33, 944-951, (2015).
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[info.decipherbio.com/studies-rp](http://info.decipherbio.com/studies-rp)  
or scan the QR code above

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