DECIPHER
PROSTATE **BIOPSY**

Decipher Biosciences
6925 Lusk Boulevard, Suite 200
San Diego, CA 92121
Phone 1.888.792.1601 | Fax 1.858.408.7420
cs@decipherbio.com | www.decipherbio.com

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-------**

ORDERING PHYSICIAN

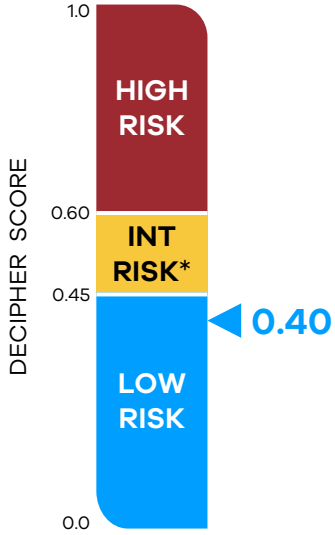
Name: **Sample Physician**
Clinic: **Main St. Urology Associates**
Address: **123 Laurel Canyon Boulevard, Anytown, OH 54321**

CLINICAL AND PATHOLOGY DETAILS

For reference only, not used in calculation of genomic risk

Specimen: **Needle Biopsy**
Clinical Stage: **T1c**
Most Recent PSA: **4.9 ng/mL**
Gleason Score: **3+4**
NCCN Risk Category: **Intermediate**

DECIPHER GENOMIC RISK RESULTS



GENOMIC RISK IS: LOW

0.7%	1.7%	3.1%	19.3%
5-year	10-year	15-year	At RP
Risk of Metastasis		**Risk of Prostate Cancer Mortality**	**Risk of Adverse Pathology**

Clinical studies have shown that Decipher low-risk patients have a favorable prognosis.

- These patients may be ideal candidates for active surveillance.[1-3,6]
- Patients considering definitive treatment may have excellent oncologic outcomes when treated with local therapy alone.[2-5,9]

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

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

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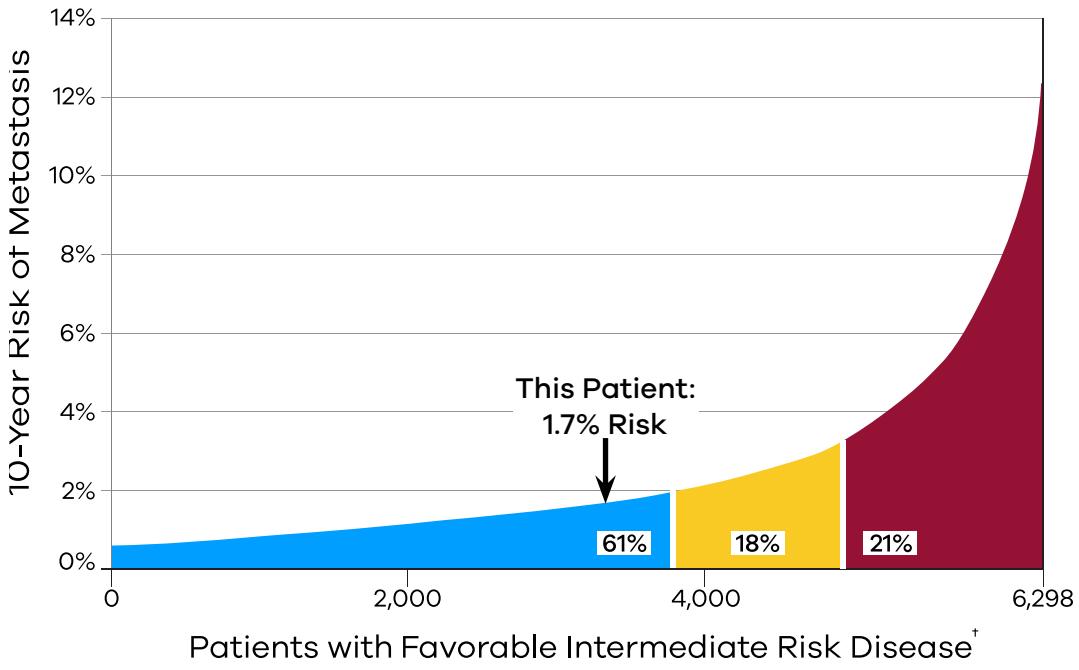
Name: **Sample Patient** Date of Birth: **--/--/----** Decipher Accession ID: **MC-------**

RISK COMPARED TO PATIENTS WITH SIMILAR CLINICAL AND PATHOLOGIC FEATURES



INTERPRETATION

This chart shows the 10-year risk of metastasis for 6,298 patients with similar clinical features at the time of biopsy, ordered from lowest to highest risk. Among these patients 61%, 18%, and 21% were classified as Decipher low-, intermediate-, and high-risk, respectively.

This patient has a predicted 1.7% 10-year risk of metastasis with radical therapy (e.g., radical prostatectomy or radiation therapy) and is in the 53rd percentile of risk, meaning that 52 percent of men with similar clinical features have a lower Decipher score, and 47 percent have a higher Decipher score.

†*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

For more information go to: info.decipherbio.com/studies-fi or scan the QR code above

In clinical studies of NCCN low to favorable intermediate risk patients:

- Active surveillance was the primary management strategy for 76% of patients with lower genomic risk scores.[6]
- Decipher low-risk men had a high probability of organ-confined disease at RP (negative predictive value of 91-96% for adverse pathology).[1]

In a study of patients with newly-diagnosed localized disease, Decipher low-risk men were 100% free from distant metastasis at 10 years when treated with radical prostatectomy or radiation therapy.[3]

In a study of NCCN intermediate risk patients treated with definitive radiation without hormone therapy, 100% of Decipher low-risk men were free from distant metastasis at 5 years.[9]

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ORDERING PHYSICIAN

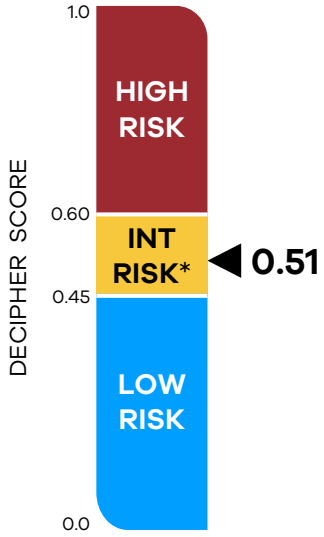
Name: **Sample Physician**
Clinic: **Main St. Urology Associates**
Address: **123 Laurel Canyon Boulevard, Anytown, OH 54321**

CLINICAL AND PATHOLOGY DETAILS

For reference only, not used in calculation of genomic risk

Specimen: **Needle Biopsy**
Clinical Stage: **T1c**
Most Recent PSA: **6.4 ng/mL**
Grade Group: **2**
NCCN Risk Category: **Intermediate**

DECIPHER GENOMIC RISK RESULTS



GENOMIC RISK IS: INTERMEDIATE

1.0%	2.4%	4.1%	25.8%
5-year	10-year	15-year	At RP
Risk of Metastasis		**Risk of Prostate Cancer Mortality**	**Risk of Adverse Pathology**

Clinical studies have shown that Decipher intermediate-risk patients have an average clinical risk and prognosis. Depending on life expectancy and overall health status:

- These patients may not be ideal candidates for active surveillance.[1-3,6]
- These patients may benefit from definitive therapy.[2-5,9]

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
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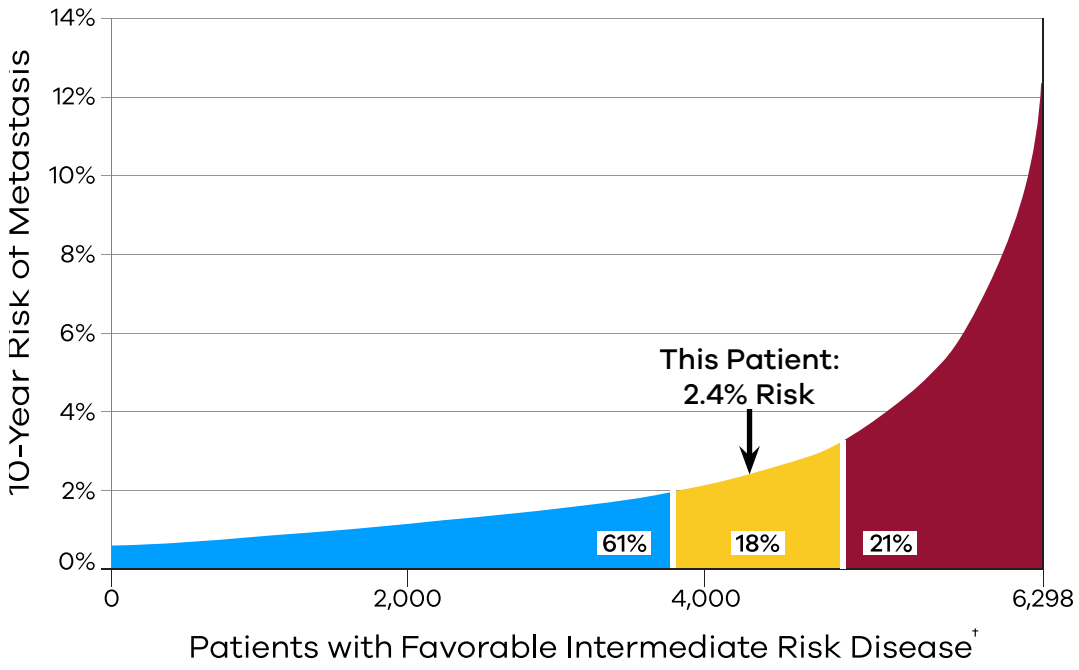
RISK COMPARED TO PATIENTS WITH SIMILAR CLINICAL AND PATHOLOGIC FEATURES



INTERPRETATION

This chart shows the 10-year risk of metastasis for 6,298 patients with similar clinical features at the time of biopsy, ordered from lowest to highest risk. Among these patients 61%, 18%, and 21% were classified as Decipher low-, intermediate-, and high-risk, respectively.

This patient has a predicted 2.4% 10-year risk of metastasis with radical therapy (e.g., radical prostatectomy or radiation therapy) and is in the 68th percentile of risk, meaning that 67 percent of men with similar clinical features have a lower Decipher score, and 32 percent have a higher Decipher score.

†*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

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In clinical studies of NCCN low to favorable intermediate risk patients:

- Active surveillance was the primary management strategy for 46% of patients with higher genomic risk scores.[6]
- 13% of Decipher intermediate-risk men harbored adverse pathology at RP.[2]

In a study of NCCN intermediate risk patients treated with definitive radiation without hormone therapy, 83% of Decipher intermediate-risk men were free from distant metastasis at 5 years.[9]

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Clinical Stage: **T1c**
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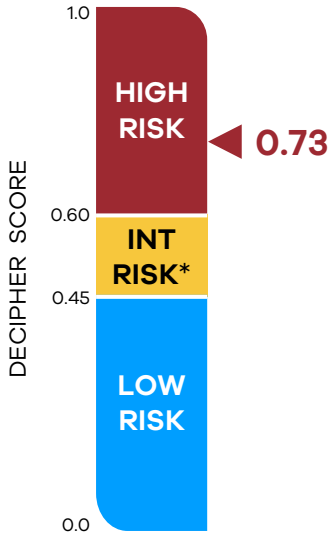
NCCN Risk Category: **Intermediate**

DECIPHER GENOMIC RISK RESULTS



GENOMIC RISK IS: HIGH

2.1%	5.1%	7.4%	42.2%
5-year	10-year	15-year	At RP
Risk of Metastasis		**Risk of Prostate Cancer Mortality**	**Risk of Adverse Pathology**

Clinical studies have shown that Decipher high-risk patients have an unfavorable prognosis.

- These patients may benefit from treatment intensification with multimodal therapy.[2-5,9,10]
- These patients may not be ideal candidates for active surveillance.[1-3,8]

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

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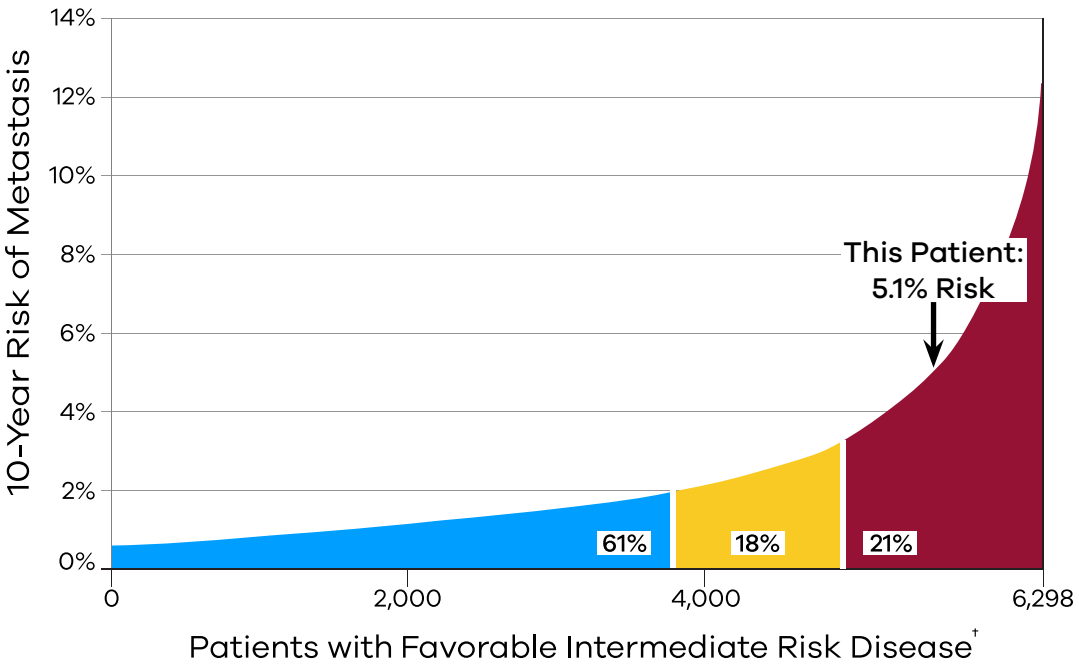
RISK COMPARED TO PATIENTS WITH SIMILAR CLINICAL AND PATHOLOGIC FEATURES



INTERPRETATION

This chart shows the 10-year risk of metastasis for 6,298 patients with similar clinical features at the time of biopsy, ordered from lowest to highest risk. Among these patients 61%, 18%, and 21% were classified as Decipher low-, intermediate-, and high-risk, respectively.

This patient has a predicted 5.1% 10-year risk of metastasis with radical therapy (e.g., radical prostatectomy or radiation therapy) and is in the 88th percentile of risk, meaning that 87 percent of men with similar clinical features have a lower Decipher score, and 12 percent have a higher Decipher score.

†*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

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In clinical studies of NCCN low to favorable intermediate risk patients:

- 41% of Decipher high-risk men had adverse pathology at radical prostatectomy.[2]
- The risk of Gleason score upgrading at first surveillance biopsy was nearly 3 times higher for men with higher genomic risk scores in a study of 1,031 men managed with active surveillance.[8]

In a study of NCCN intermediate risk patients treated with definitive radiation without hormone therapy, 50% of Decipher high-risk men had biochemical failure and 15% had metastasis at 5 years.[9]

Ninety percent (90%) of radiation oncologists recommend the addition of ADT to radiotherapy when the 10-year risk of metastasis is greater than or equal to 5%.[10]

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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:

- Risk of adverse pathology at RP (ie., 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 the Decipher score determined from the initial diagnostic biopsy who were then treated with RP.[2] The percent likelihood for this endpoint ranges from 5.8-64.6%. Risk of adverse pathology is reported only for patients with low or favorable intermediate risk disease.
- 5-year, 10-year risk of clinical metastasis and 15-year risk of prostate cancer specific mortality (PCSM) after curative intent therapy. Probabilities were generated through bootstrapped numerical integration of a) 22,743 patients diagnosed with non-metastatic prostate cancer who had available Decipher scores, b) the 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 after RP or RT (external beam or brachy +/- ADT)[13] and c) the estimated effect sizes of Decipher from meta-analyses of 6 previously published study cohorts with a total of 1,210 patients.[4,14] The percent likelihoods for 5-year metastasis range from 0.1-18.6%, the 10-year metastasis range from 0.3-33.6%, and the 15-year PCSM range from 0.4-42.1%.

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.[15-18]

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 XX.X% to YY.Y%
- 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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