DECIPHER
PROSTATE **BIOPSY**

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: **Fred Tester**
Date of Birth: **01/01/1945**
Medical Record #: **123456789**
Date of Biopsy: **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-999999**

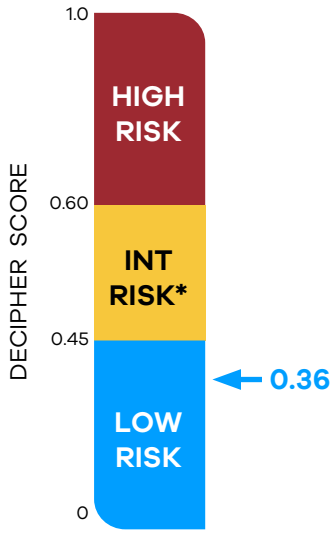
ORDERING PHYSICIAN

Name: **John Smith, MD**
Clinic: **Main St. Urology Associates**
Address: **123 Laurel Canyon Boulevard, Anytown, OH 54321**
Additional Physician: **Jill Smith, MD, PhD**

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: **4+3**
NCCN Risk Category: **Intermediate**

DECIPHER GENOMIC RISK RESULTS



GENOMIC RISK IS: LOW

17.6%	2.3%	3.1%
Risk of High Grade Disease at RP	**Risk of Metastasis** within 5 years	**Risk of Prostate Cancer Mortality** within 10 years

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

- These patients may be ideal candidates for active surveillance.[1-4]
- Patients considering definitive treatment may have excellent oncologic outcomes when treated with local therapy alone.[4-7]

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

CAP ACCREDITED COLLEGE of AMERICAN PATHOLOGISTS
Clinical Laboratory Improvement Amendments
CLIA ID# 05D2055897
CAP # 8859006

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

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PATIENT

Name: **Jackson Tester**
Date of Birth: **01/02/1945**
Medical Record #: **12345678910**
Date of Biopsy: **01/02/2019**

SPECIMEN INFORMATION

Order Date: **01/02/2019**
Specimen ID: **11-22-33-44-55-66-77**
Specimen Received Date: **01/02/2019**
Decipher Accession ID: **MC-999998**

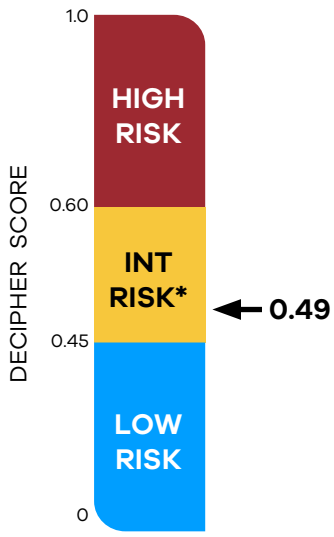
ORDERING PHYSICIAN

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

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**		
24.3%	**4.9%**	**5.2%**
Risk of High Grade Disease at RP	**Risk of Metastasis** within 5 years	**Risk of Prostate Cancer Mortality** within 10 years

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.[1-4]
- These patients may benefit from definitive therapy.[4-7]

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

Laboratory Director (Signature)
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Report Date

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PATIENT

Name: **Zachary Tester**
Date of Birth: **01/03/1945**
Medical Record #: **1234567891011**
Date of Biopsy: **01/03/2019**

SPECIMEN INFORMATION

Order Date: **01/03/2019**
Specimen ID: **11-22-33-44-55-66-77-88**
Specimen Received Date: **01/03/2019**
Decipher Accession ID: **MC-999997**

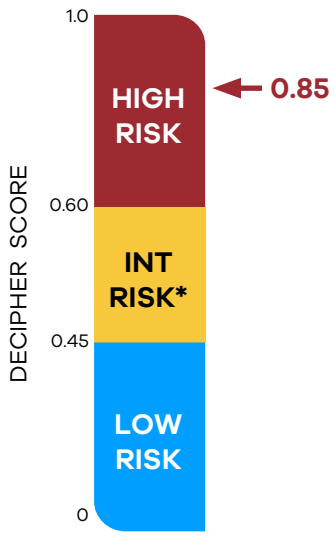
ORDERING PHYSICIAN

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

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: HIGH		
49.5%	**36.0%**	**19.2%**
Risk of High Grade Disease at RP	**Risk of Metastasis** within 5 years	**Risk of Prostate Cancer Mortality** within 10 years

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

- These patients may benefit from treatment intensification with multimodal therapy.[4-7]
- These patients may not be ideal candidates for active surveillance.[1-4]

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

Laboratory Director (Signature)
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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 microdissected 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:

- High grade disease (primary Gleason grade 4 or 5). Decipher uses the genomic risk score to predict high grade disease at radical prostatectomy (RP) with an AUC of 0.71. Probabilities were generated using a logistic regression model in a cohort of 2,342 prostate cancer patients.[8] The percent likelihood for this endpoint ranges from 6.5-61%.
- 5-year probability of clinical metastasis. 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.[9] 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.[10] 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.[9, 11-12]

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. Decipher has been validated in patients with very low-, low-, favorable intermediate-, unfavorable intermediate-, high- and very high- National Comprehensive Cancer Network (NCCN) prostate cancer risk groups, as well as in patients with lymph node involvement at diagnosis who are being considered for treatment.

CONFIDENCE INTERVALS

- High grade probability Decipher risk reported here has a 95% confidence interval of 31.4% to 35.9%
- 5-year metastasis Decipher risk reported here has a 95% confidence interval of 8.4% to 14.8%
- 10-year prostate cancer specific mortality Decipher risk reported here has a 95% confidence interval of 5.7% to 12.6%

REFERENCES

1. Herlemann A, et al. Decipher identifies men with otherwise clinically favorable-intermediate risk disease who may not be good candidates for active surveillance. Prostate Cancer Prostatic Dis 2019.
2. Kim HL, et al. Validation of the Decipher Test for predicting adverse pathology in candidates for prostate cancer active surveillance. Prostate Cancer Prostatic Dis 2019;22(3):399-405.
3. Klein EA, et al. Molecular Analysis of Low Grade Prostate Cancer Using a Genomic Classifier of Metastatic Potential. J Urol 2017;197(1):122-28.
4. Spratt DE, et al. Development and Validation of a Novel Integrated Clinical-Genomic Risk Group Classification for Localized Prostate Cancer. J Clin Oncol 2018;36(6):581-90.
5. Berlin A, et al. Genomic Classifier for Guiding Treatment of Intermediate-Risk Prostate Cancers to Dose-Escalated Image Guided Radiation Therapy Without Hormone Therapy. Int J Radiat Oncol Biol Phys 2019;103(1):84-91.
6. Nguyen PL, et al. Ability of a Genomic Classifier to Predict Metastasis and Prostate Cancer-specific Mortality after Radiation or Surgery based on Needle Biopsy Specimens. Eur Urol 2017;72(5):845-52.
7. Nguyen PL, et al. Utilization of biopsy-based genomic classifier to predict distant metastasis after definitive radiation and short-course ADT for intermediate and high-risk prostate cancer. Prostate Cancer Prostatic Dis 2017;20(2):186-92.
8. Den RB, et al. Decipher correlation patterns post prostatectomy: initial experience from 2,342 prospective patients. Prostate Cancer Prostatic Dis 2016;19(4):374-79.
9. Karnes RJ, et al. Validation of a genomic classifier that predicts metastasis following radical prostatectomy in an at risk patient population. J Urol 2013;190(6):2047-53.
10. Karnes RJ, et al. Validation of a Genomic Risk Classifier to Predict Prostate Cancer-specific Mortality in Men with Adverse Pathologic Features. Eur Urol 2018;73(2):168-75.
11. Erho N, et al. Discovery and validation of a prostate cancer genomic classifier that predicts early metastasis following radical prostatectomy. PLoS One 2013;8(6):e66855.
12. Lee HJ, et al. Evaluation of a genomic classifier in radical prostatectomy patients with lymph node metastasis. Res Rep Urol 2016;8:77-84.

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PATIENT

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Date of Biopsy: **01/01/2019**

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Specimen ID: **11-22-33-44-55-66**
Specimen Received Date: **01/01/2019**
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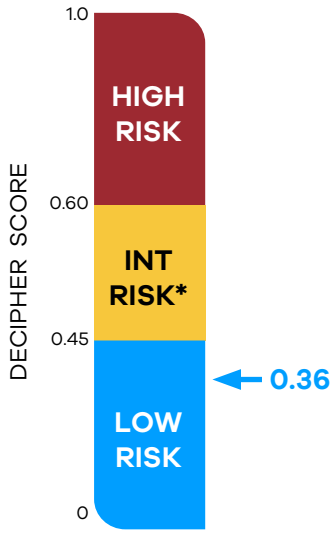
Additional Physician: **Jill Smith, MD, PhD**

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: **4+5**
NCCN Risk Category: **High / Very High**

DECIPHER GENOMIC RISK RESULTS



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- Patients considering definitive treatment may have excellent oncologic outcomes when treated with standard of care therapy.[4-7]

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

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PATIENT

Name: **Jackson Tester**
Date of Birth: **01/02/1945**
Medical Record #: **12345678910**
Date of Biopsy: **01/02/2019**

SPECIMEN INFORMATION

Order Date: **01/02/2019**
Specimen ID: **11-22-33-44-55-66-77**
Specimen Received Date: **01/02/2019**
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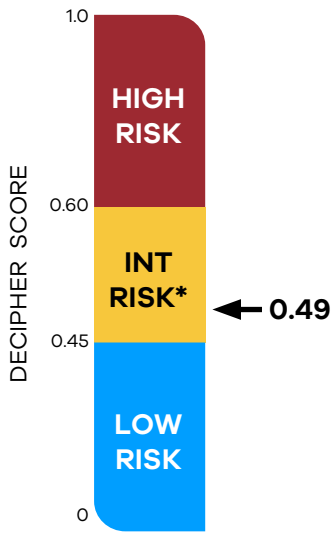
Address: **123 Laurel Canyon Boulevard, Anytown, OH 54321**

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: **4**
NCCN Risk Category: **High / Very High**

DECIPHER GENOMIC RISK RESULTS



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PATIENT

Name: **Zachary Tester**
Date of Birth: **01/03/1945**
Medical Record #: **1234567891011**
Date of Biopsy: **01/03/2019**

SPECIMEN INFORMATION

Order Date: **01/03/2019**
Specimen ID: **11-22-33-44-55-66-77-88**
Specimen Received Date: **01/03/2019**
Decipher Accession ID: **MC-999997**

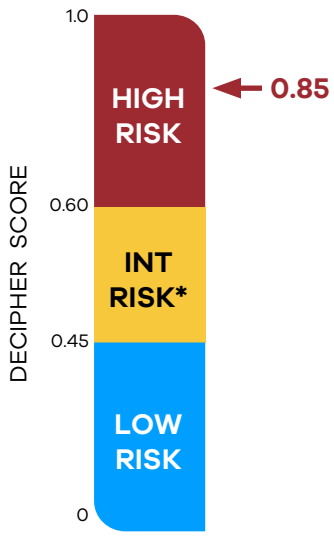
ORDERING PHYSICIAN

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

Specimen: **Needle Biopsy**
Clinical Stage: **T1c**
Most Recent PSA: **4.9 ng/mL**
Gleason Score: **4+5**
NCCN Risk Category: **High / Very High**

DECIPHER GENOMIC RISK RESULTS



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PATIENT	SPECIMEN INFORMATION	ORDERING PHYSICIAN
Name: **William Tester**	Order Date: **01/04/2019**	Name: **John Smith, MD**
Date of Birth: **01/04/1945**	Specimen ID: **22-33-44-55-66-77-88-99**	Clinic: **Main St. Urology Associates**
Medical Record #: **123456789101112**	Specimen Received Date: **01/04/2019**	Address: **123 Laurel Canyon Boulevard, Anytown, OH 54321**
Date of Biopsy: **01/04/2019**	Decipher Accession ID: **MC-999996**	

TEST NOT PERFORMED

This is the failure reason

Laboratory Director: Bashar Dabbas, MD

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