DECIPHER PROSTATE

DECIPHER PROSTATE **BIOPSY**

For patients with localized disease at biopsy

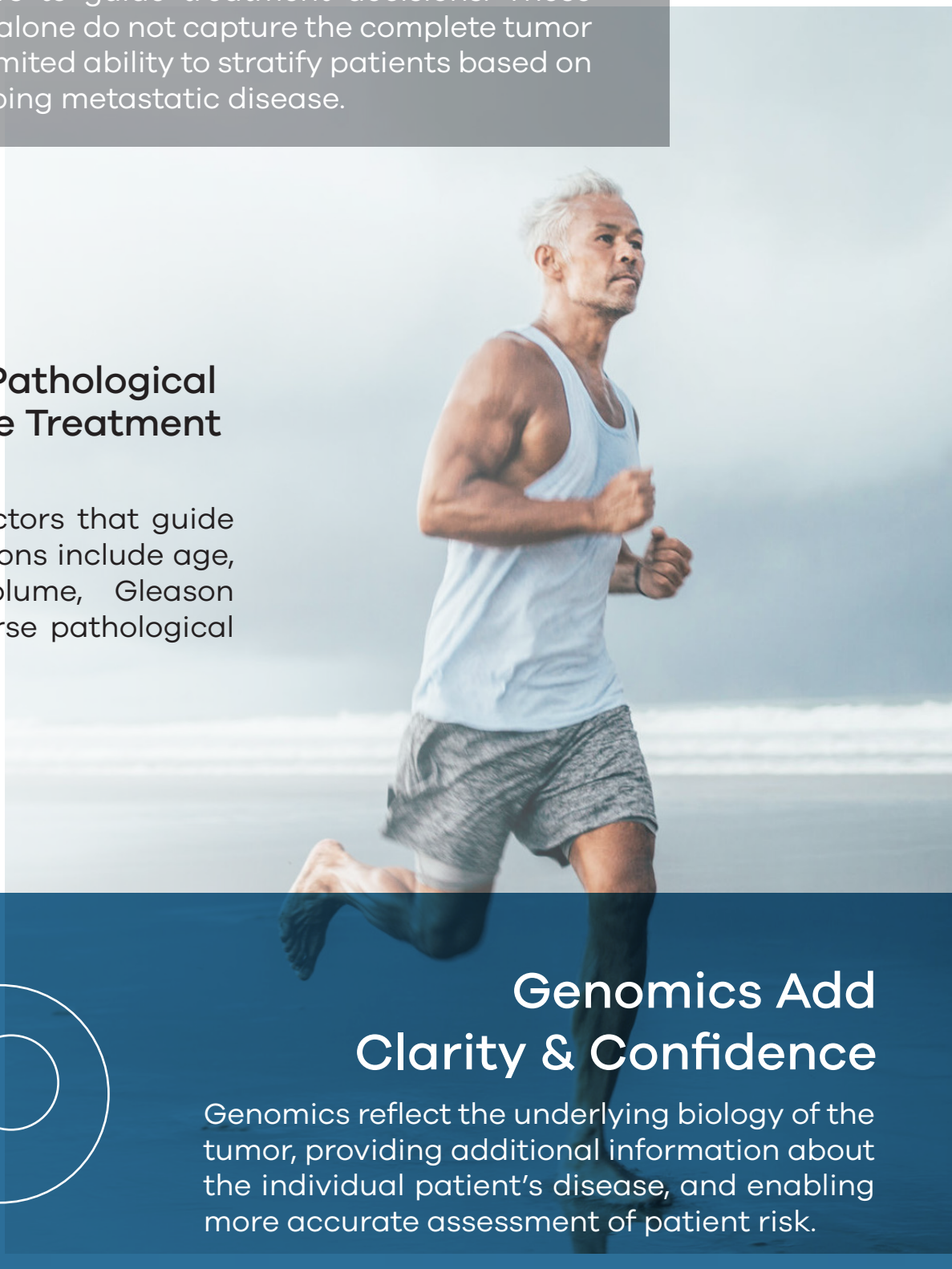
DECIPHER PROSTATE **RP**

For patients after radical prostatectomy

PROVIDING TREATMENT INFORMATION FOR PROSTATE CANCER PATIENTS

Treatment for Newly Diagnosed Prostate Cancer Patients is Guided by Risk

Risk assessment methods have relied on clinical and pathological factors to guide treatment decisions. These prognostic factors alone do not capture the complete tumor biology and have limited ability to stratify patients based on their risk of developing metastatic disease.



Clinical and Pathological Factors Guide Treatment Decisions

Conventional factors that guide treatment decisions include age, PSA, tumor volume, Gleason score, and adverse pathological features.

Genomics Add Clarity & Confidence

Genomics reflect the underlying biology of the tumor, providing additional information about the individual patient's disease, and enabling more accurate assessment of patient risk.

Multiple cancer pathways drive metastatic potential

Decipher® Prostate was developed from a large cohort of metastatic and non-metastatic prostate cancer patients treated at the Mayo Clinic. The whole transcriptome test utilizes 22 coding and non-coding biomarkers to provide a more accurate, independent prediction of risk.

Decipher Prostate Covers 7 Cancer Pathways

- Growth & Differentiation
- Invasion & Metastasis
- Metabolism
- Angiogenesis
- Androgen Signaling
- Immune Activity/Response
- Proliferation & Cell Death

Decipher Risk is Not Weighted by Clinical or Pathological Factors

Based on tumor genomics alone, Decipher Prostate offers superior accuracy in predicting risk of disease progression, enabling the physician and patient to optimize clinical decision-making.

DECIPHER
PROSTATE

DECIPHER
PROSTATE **BIOPSY**

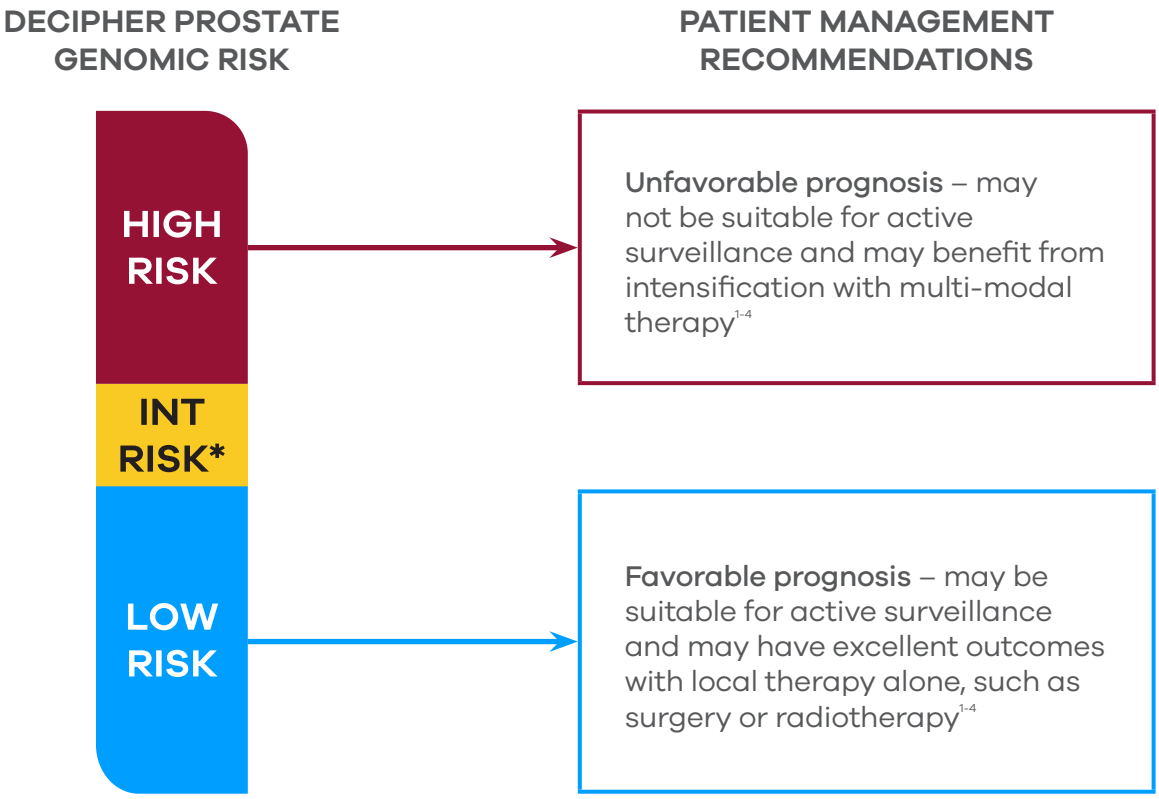
DECIPHER® PROVIDES BETTER RISK ASSESSMENT, ENABLING MORE INDIVIDUALIZED TREATMENT FOR PATIENTS DIAGNOSED WITH LOCALIZED PROSTATE CANCER.

DECIPHER PREDICTS THE LIKELIHOOD OF CLINICALLY USEFUL ENDPOINTS

- High grade disease (Gleason grade 4 or 5)
- 5-year metastasis
- 10-year prostate cancer specific mortality

DECIPHER HELPS DETERMINE THE BEST TREATMENT PLAN

- Active surveillance?
- Local therapy alone?
  - > Radical prostatectomy
  - > Radiation
- Multi-modal therapy?



DECIPHER BIOPSY RECLASSIFIES 51% OF PATIENTS FROM THEIR NCCN RISK CATEGORY TO LOWER OR HIGHER RISK[1]

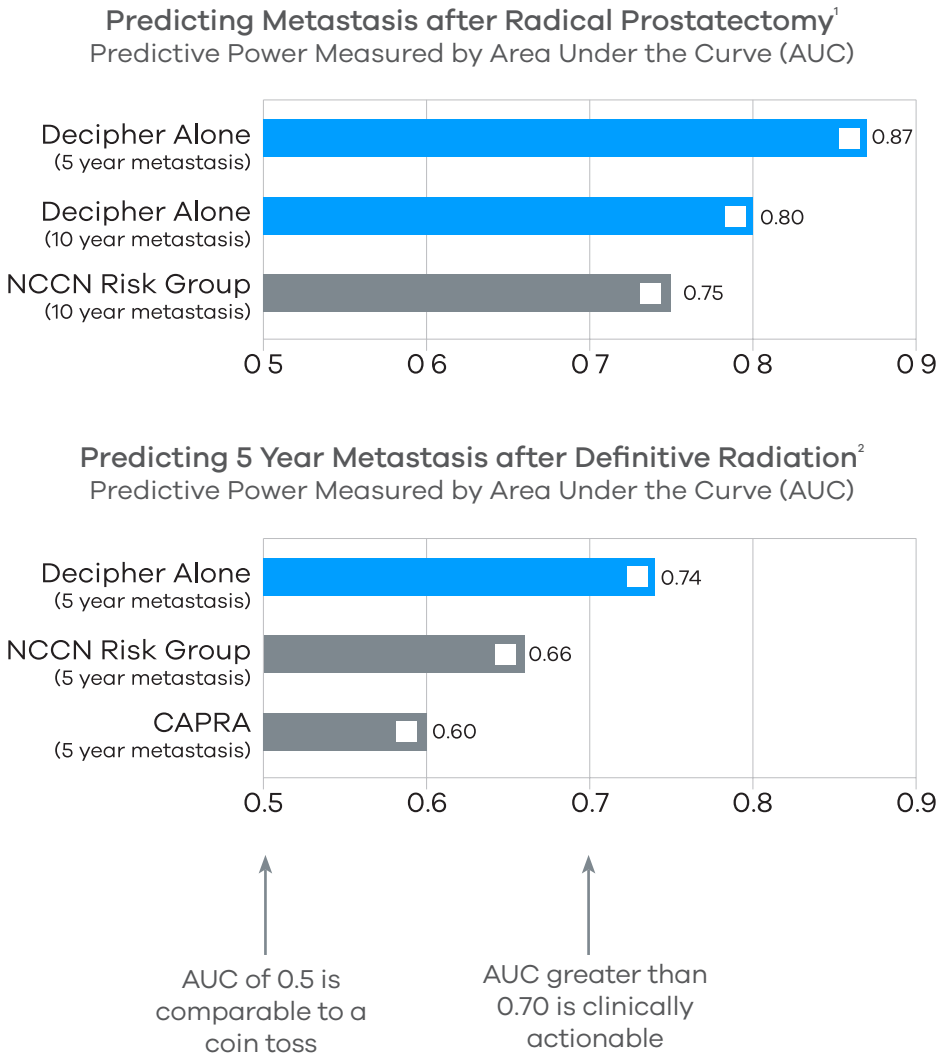
References

1. Klein, E. A. et al. Decipher Genomic Classifier Measured on Prostate Biopsy Predicts Metastasis Risk. Urology (2016). doi:10.1016/j.urology.2016.01.012
2. Berlin, A. et al. Genomic classifier for guiding treatment of intermediate-risk prostate cancers to dose-escalated image-guided radiotherapy without hormone therapy. Int. J. Radiat. Oncol. (2018). doi:10.1016/j.ijrobp.2018.08.030
3. Nguyen, P. L. 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). doi:10.1016/j.eururo.2017.05.009
4. Kim, H. L. et al. Validation of the Decipher Test for predicting adverse pathology in candidates for prostate cancer active surveillance. Prostate Cancer Prostatic Dis. (2018). doi:10.1038/s41391-018-0101-6

WITH DECIPHER,
KNOW **WHO** TO TREAT, **WHEN** TO TREAT, AND **HOW** TO TREAT

DECIPHER BIOPSY IS AN ACCURATE PREDICTOR OF DISEASE PROGRESSION FOR NEWLY DIAGNOSED PATIENTS.

ACCURACY IN PREDICTING METASTASIS AFTER RP AND DEFINITIVE RT



DECIPHER PROSTATE BIOPSY

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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**

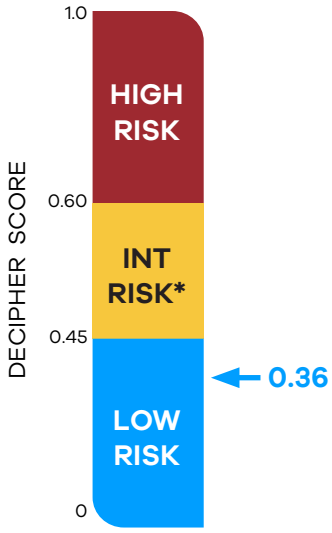
ORDERING PHYSICIAN

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 studiesh aves hown that Decipher low-risk patientsh avea favorable prognosis.

- These patientsm ay be ideal candidates fora ctives urveillance.[1-4]
- Patients considering definitive treatment mayh ave excellent oncologic outcomes when treated with local therapy alone.[4-7]

Comments: Tissue with highest Gleason grade was not available for genomic analysis. The Decipher score reported here may not reflect the most aggressive tumor biology.

Decipher riski sd etermined solelyb y 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: **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**

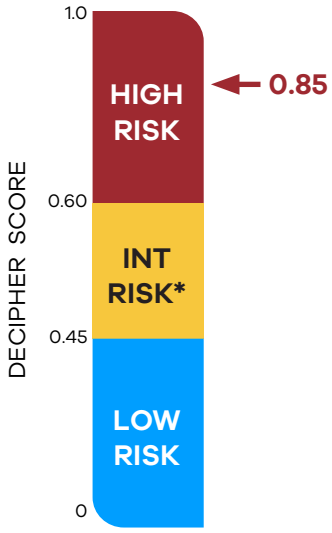
ORDERING PHYSICIAN

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%1	9.2%
Risk of High Grade Disease at RP	**Risk of Metastasis** within 5 years	**Risk of Prostate Cancer Mortality** within 10 years

Clinical studiesh aves hown that Decipher high-risk patientsh ave an unfavorable prognosis.

- These patientsm ay benefit from treatment intensification with multimodal therapy.[4-7]
- These patientsm ay not be idealc andidatesf or active surveillance.[1-4]

Decipher riski sd etermined solelyb y 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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CLIA ID# 05D2055897
CAP # 8859006

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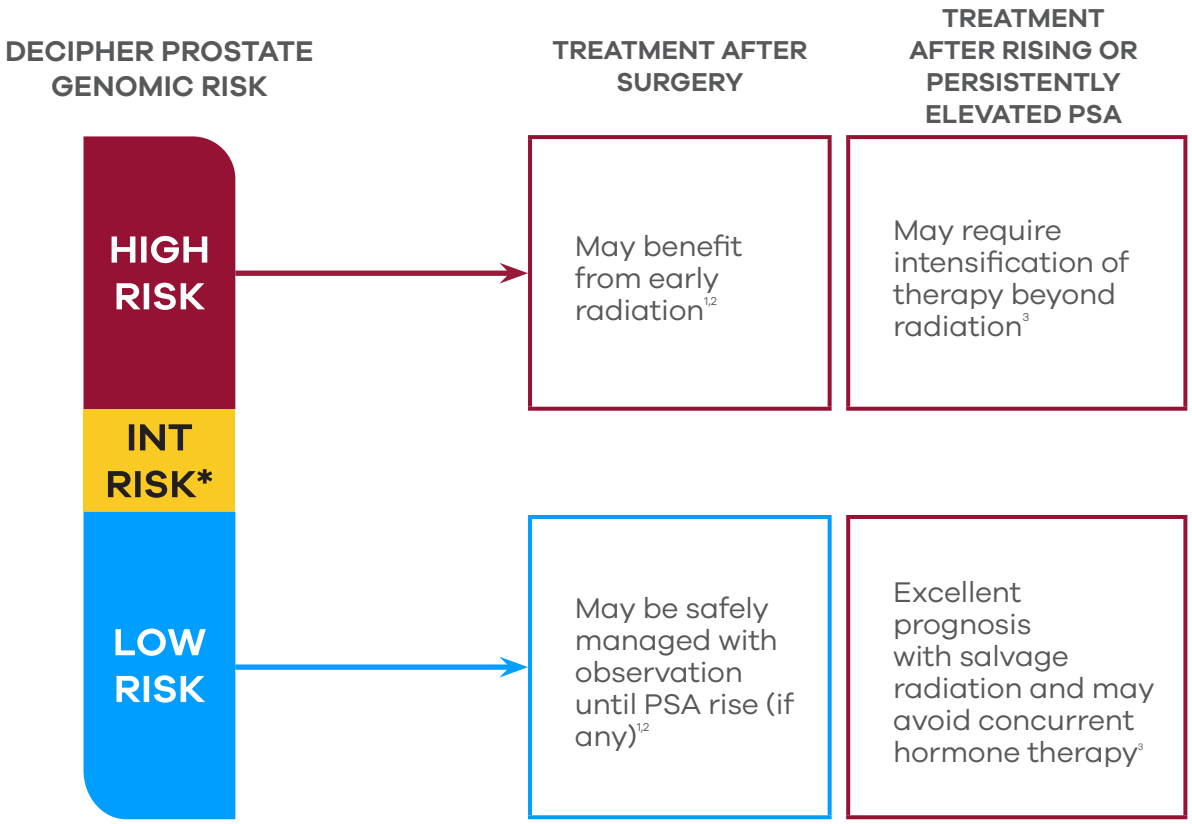
DECIPHER
PROSTATE **RP**

DECIPHER CLASSIFIES POST-SURGERY PATIENTS* INTO CATEGORIES FOR GENOMIC RISK OF METASTASIS WITH 98.5% NEGATIVE PREDICTIVE VALUE (NPV)



References

1. Michalopoulos, S. N. et al. Influence of a genomic classifier on post-operative treatment decisions in high-risk prostate cancer patients: results from the PRO-ACT study. Curr. Med. Res. Opin. 30, 1547–1556 (2014).
2. Nguyen, P. L. et al. Impact of a Genomic Classifier of Metastatic Risk on Postprostatectomy Treatment Recommendations by Radiation Oncologists and Urologists. Urology 86, 35–40 (2015).
3. Badani, K. K. et al. Impact of a genomic classifier of metastatic risk on postoperative treatment recommendations for prostate cancer patients: a report from the DECIDE study group. Oncotarget 4, 600–9 (2013).
4. Den, R. B. 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).
5. Den, R. B. 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).
6. Freedland, S. J. et al. Utilization of a Genomic Classifier for Prediction of Metastasis Following Salvage Radiation Therapy after Radical Prostatectomy. Eur. Urol. 70, 588–596 (2016).
7. Ross, A. E. et al. Tissue-based Genomics Augments Post-prostatectomy Risk Stratification in a Natural History Cohort of Intermediate- and High-Risk Men. Eur. Urol. 69, 157–165 (2016).

* Clinically high risk patients with one or more of the "Post radical prostatectomy (RP) indications for Decipher test" listed above.

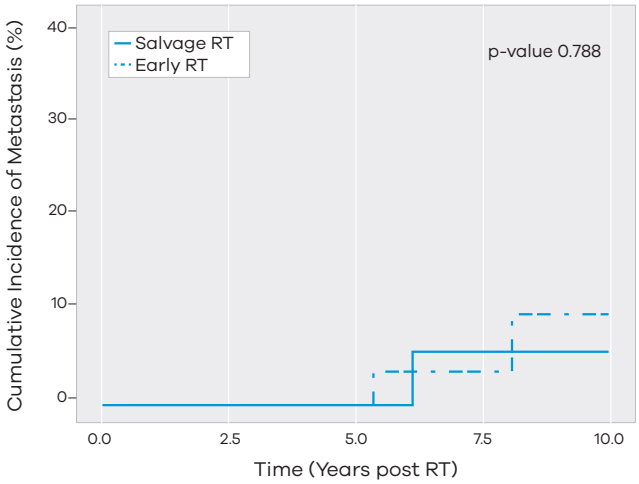
** Covered for Medicare patients whose physicians are registered in the Decipher CTR (Certification and Training Registry).

WITH DECIPHER,
KNOW **WHO** TO TREAT, **WHEN** TO TREAT, AND **HOW** TO TREAT

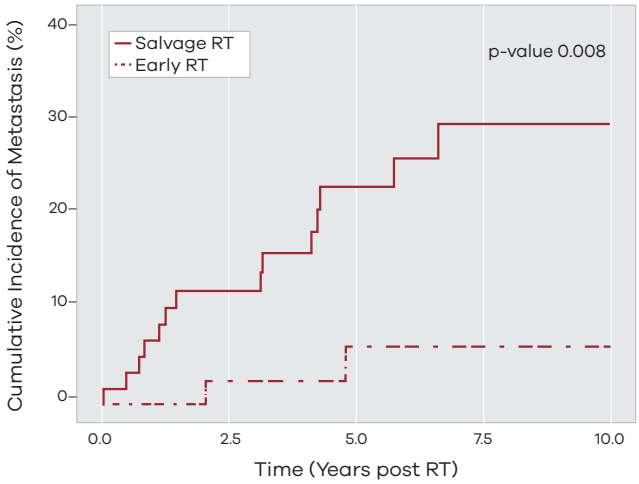
IN THE POST-SURGICAL SETTING, DECIPHER CAN HELP INFORM DECISIONS AROUND TREATMENT TIMING AND INTENSITY

DECIPHER FOR PATIENTS AFTER RADICAL PROSTATECTOMY[5]

Decipher low-risk patients may be managed safely with observation until PSA rise



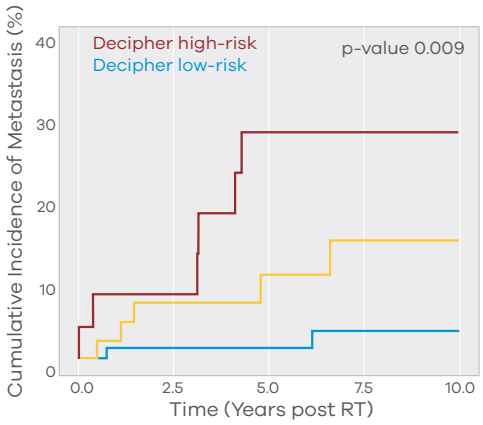
Decipher high-risk patients may experience lower rates of metastasis when treated with early radiation post-RP



DECIPHER FOR PATIENTS AFTER PROSTATE SURGERY WITH PSA RISE OR BIOCHEMICAL RECURRENCE[6]

Decipher low-risk patients have excellent prognosis with salvage radiation and may avoid concurrent hormonal therapy, as incidence of metastasis remains low.

Decipher high-risk patients may require intensification of therapy beyond radiation as incidence of metastasis remains high.



Note: no concurrent hormone therapy given

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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**

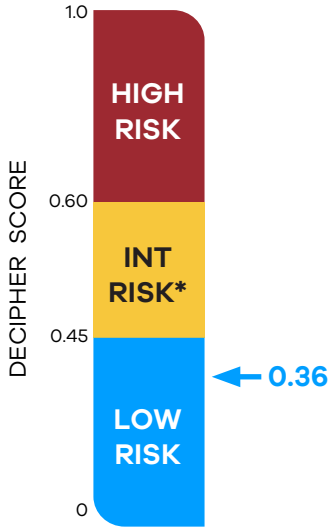
CLINICAL AND PATHOLOGY DETAILS For reference only, not used in calculation of genomic risk

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%	**3.1%**
Risk of Metastasis within 5 years	**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.[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]

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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CLIA ID# 05D2055897
CAP # 8859006

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

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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**
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ORDERING PHYSICIAN

Name: **John Smith, MD**
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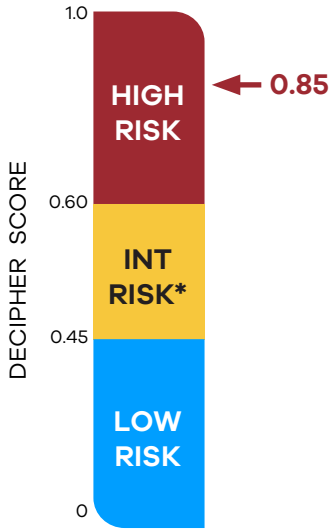
CLINICAL AND PATHOLOGY DETAILS For reference only, not used in calculation of genomic risk

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: HIGH	
36.0%	**19.2%**
Risk of Metastasis within 5 years	**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.[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]

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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BASED ON THE PATIENT'S PERSONAL TUMOR-BASED GENOMICS, DECIPHER PROSTATE CANCER CLASSIFIER HELPS DETERMINE WHO:

- May be suitable candidates for active surveillance
- May be treated with local therapy alone
- May benefit from intensification with multi-modal therapy

DECIPHER PROSTATE BIOPSY

- May be safely observed after radical prostatectomy
- May need early radiation
- May be better managed with salvage radiation
- May avoid hormone therapy with radiation

DECIPHER PROSTATE RP

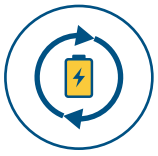
ACCESS FOR ALL PATIENTS

- Covered by Medicare
- Covered by select private insurers
- Generous financial assistance program for patients - Decipher Assist

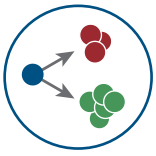
Decipher is a 22-gene signature across 7 cancer pathways


Invasion & Metastasis

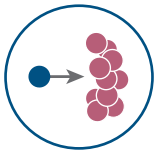

Androgen Signaling


Metabolism


Angiogenesis


Proliferation & Cell Death


Immune Activity & Response


Growth & Differentiation

Contact the Decipher Customer Support Team at
1.888.792.1601 or cs@decipherbio.com

Testing is performed by Decipher Corp., a Decipher Biosciences company