



# Providing Treatment Information for Prostate Cancer Patients

## BIOPSY

For all patients with localized  
disease on biopsy

## POST OP

For all patients with adverse  
pathology after prostatectomy

See what *better* looks like



Contact the GenomeDx Customer Support Team  
1.888.792.1601 (toll-free)  
[customersupport@genomedx.com](mailto:customersupport@genomedx.com)

Decipher provides better risk assessment for more individualized treatment for all 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 Classification	Patient Management Recommendations
Decipher Biopsy Low Risk	Favorable prognosis - may be suitable candidate for active surveillance and may have excellent outcomes when treated with local therapy alone <sup>3-5</sup>
Decipher Biopsy High Risk	Unfavorable prognosis - may not be suitable candidate for active surveillance and may benefit from intensification with multi-modal therapy <sup>3-5</sup>

Decipher Biopsy accurately reclassifies 46% of patients from NCCN risk category<sup>3</sup>

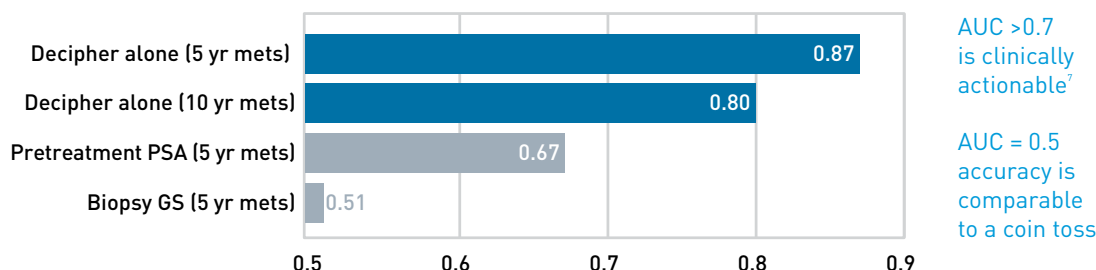
\*Extrapolated from multiple radical prostatectomy Decipher studies.<sup>1,2,3A</sup>

# Decipher<sup>®</sup> Biopsy is the most accurate predictor of disease progression for newly diagnosed patients.

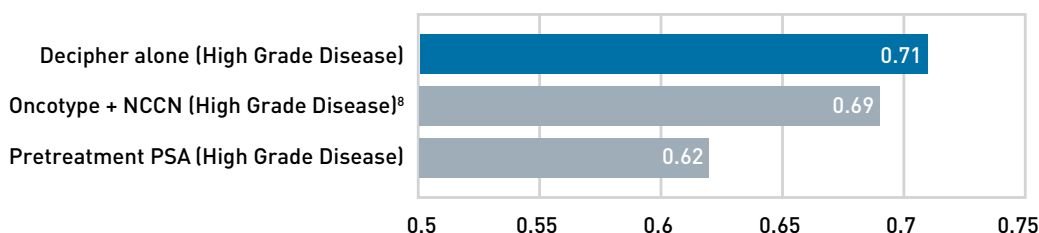
Decipher Biopsy alone predicts metastasis with an AUC of 0.87 and independently outperforms other clinical risk factors.

BIOPSY

## Comparison of Accuracy for Predicting Metastasis Predictive Power Measured by Area Under the Curve (AUC)<sup>3</sup>



## Comparison of Accuracy for Predicting High Grade Disease Predictive Power Measured by Area Under the Curve (AUC)<sup>3</sup>



## References

1. Ross, A.E., et al., Tissue Based Genomics Augment Post-Prostatectomy Risk Stratification in a Natural History Cohort of Intermediate- and High-Risk Men. *European Urology*, 2015 Jan; 69(1): 157-65.
2. Cooperberg, M.R., et al., Combined Value of Validated Clinical and Genomic Risk Stratification Tools for Predicting Prostate Cancer Mortality in a High-risk Prostatectomy Cohort. *European Urology*, 2015 Feb; 67(2): 326-333.
3. Klein, E.A., et al., Decipher Genomic Classifier Measured on Prostate Biopsy Predicts Metastasis Risk. *Urology*, 2016; In Press. DOI: <http://dx.doi.org/10.1016/j.urology.2016.01.012>.
4. Knudsen, B.S., et al., Application of a Clinical Whole-Transcriptome Assay for Staging and Prognosis of Prostate Cancer Diagnosed in Needle Core Biopsy Specimens. *Journal of Molecular Diagnostics*, 2016; In Press.
5. Lee, Hak J., et al., "Evaluation of a Genomic Classifier in Primary Tumor and Lymph Node Metastases in Pre- and Post-Radical Prostatectomy Tissue Specimens from Patients with Lymph Node Positive Prostate Cancer" presented at the 2015 annual meeting of the American Society of Clinical Oncology.
6. Klein, E.A., et al., A Genomic Classifier Improves Prediction of Metastatic Disease within 5 Years After Surgery in Node-Negative High-Risk Prostate Cancer Patients Managed by Radical Prostatectomy without Adjuvant Therapy. *European Urology*, 2015 Apr; 67(4): 778-786.
7. Simon, et al., Development and Validation of Therapeutically Relevant Multi-Gene Biomarker Classifier. *J Natl Cancer Inst*, 2005 Jun; 97(12): 866-7.
8. Cullen, et al., A Biopsy-based 17-gene Genomic Prostate Score Predicts Recurrence After Radical Prostatectomy and Adverse Surgical Pathology in a Racially Diverse Population of Men with Clinically Low- and Intermediate-risk Prostate Cancer. *European Urology*, 2015 Jul; 68(1): 123-31.

## Decipher Biopsy Report

### Patient Details:

Patient Name:  
Medical Record Number:  
Date of Birth: 03/03/1957  
Date of Biopsy:

Pathology Laboratory:  
Pathologist:  
Address:

### Order Information:

Order Date:  
Specimen Received Date:  
GenomeDx Accession ID:  
Specimen ID:  
Ordering Physician:  
Clinic/Hospital Name:  
Clinic/Hospital Address:  
  
Additional Physician:

**Clinical Details:** PSA, most recent (ng/mL): 10 NCCN risk category: **Intermediate Risk** Biopsy Gleason Score: **3+3**  
% Biopsy Cores Positive: 25 Clinical stage: **T1c**

## BIOPSY



## Your Decipher Result – Genomic Low Risk

### Decipher Score 0.26

#### Risk at RP - Percent Likelihood

High Grade Disease (primary Gleason grade 4 or 5)	13.5%
5-Year Metastasis	1.2%
10-Year Prostate Cancer Specific Mortality	2.1%

### Interpretation

Among men with a low risk Decipher prostate cancer classifier score clinical studies have shown that this cancer has a favorable prognosis. Men with a low risk Decipher score may be suitable candidates for active surveillance and may have excellent outcomes even when treated with local therapy alone.<sup>1-3</sup>

References on reverse

\*Average clinical risk refers to the average cohort risk of metastasis at 5 years post radical prostatectomy (RP). The average cumulative incidence of metastasis was 6.0% at 5 years post radical prostatectomy, as reported by Karnes et al., 2013 from analysis of a cohort of 1,010 men with intermediate and high risk clinical features who received radical prostatectomy as first line treatment at the Mayo Clinic between 2000 and 2006.<sup>4</sup>

**Probability of high grade disease (primary Gleason grade 4 or 5) endpoint:** Decipher uses the genomic risk score to predict the probability of primary Gleason grade 4 or 5 disease upon pathologic examination of the radical prostatectomy. Probabilities were generated using a logistic regression model in a prospective cohort of 2,342 prostate cancer patients. The model is adjusted using a prevalence of 27% for a finding of primary Gleason grade 4 or 5 on radical prostatectomy among NCCN low-, intermediate- and high-risk patients.<sup>5</sup> Klein et al. 2016 study found Decipher Biopsy predicted high grade disease at radical prostatectomy with an AUC of 0.71.<sup>5</sup> The percent likelihood for this endpoint ranges from 6.5-61%.

**Five-year probability of metastasis endpoint:** Decipher uses the genomic risk score to predict the 5-year probability of metastasis from the time of radical prostatectomy. Probabilities were generated from a Cox proportional hazards model based upon a cohort of 1,010 men with intermediate and high risk clinical features with a median 6.9 years of follow up.<sup>4</sup> Klein et al. 2016 reported that Decipher Biopsy predicted 5-year metastasis with an AUC of 0.87.<sup>6</sup> The percent likelihood for this endpoint ranges from 0.3-67%.

**Ten-year probability of prostate cancer specific mortality (PCSM) endpoint:** Decipher uses the genomic risk score to predict the 10-year probability of PCSM from the time of radical prostatectomy. Probabilities are generated from a logistic regression analysis based upon a cohort of 557 patients with 112 prostate cancer deaths within 10 years post radical prostatectomy. These probabilities are adjusted for a PCSM cumulative incidence of 5% at 10 years post radical prostatectomy.<sup>7</sup> All non-PCSM patients in the study had at least 10 years of follow-up. Decipher had an AUC of 0.72 in predicting PCSM.<sup>8-10</sup> Percent likelihood for this endpoint ranges from 0.7-30.5%. This risk model has not yet been validated on prostate biopsy specimens but has been validated in multiple radical prostatectomy Decipher studies.<sup>8-10</sup>

GenomeDx Medical Director (Name & Signature)

Medical Directors: Timothy J. Triche, MD, PhD | Doug Dolginow, MD

Date

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## Decipher Biopsy Report

### Patient Details:

Patient Name:  
Medical Record Number:  
Date of Birth: 03/03/1950  
Date of Biopsy:

Pathology Laboratory:  
Pathologist:  
Address:

### Order Information:

Order Date:  
Specimen Received Date:  
GenomeDx Accession ID:  
Specimen ID:  
Ordering Physician:  
Clinic/Hospital Name:  
Clinic/Hospital Address:  
Additional Physician:

**Clinical Details:** PSA, most recent (ng/mL): 3.9 NCCN risk category: Low Risk Biopsy Gleason Score: 3+3  
% Biopsy Cores Positive: 20 Clinical stage: T1c

## BIOPSY



## Your Decipher Result – Genomic High Risk

### Decipher Score 0.70

#### Risk at RP - Percent Likelihood

High Grade Disease (primary Gleason grade 4 or 5)	43.3%
5-Year Metastasis	16.4%
10-Year Prostate Cancer Specific Mortality	11.4%

### Interpretation

Among men with a high risk Decipher prostate cancer classifier score clinical studies have shown that this cancer has an unfavorable prognosis. Men with a high risk Decipher score may not be suitable candidates for active surveillance and may benefit from intensification with multi-modal therapy.<sup>1-3</sup>

References on reverse

\*Average clinical risk refers to the average cohort risk of metastasis at 5 years post radical prostatectomy (RP). The average cumulative incidence of metastasis was 6.0% at 5 years post radical prostatectomy, as reported by Karnes et al., 2013 from analysis of a cohort of 1,010 men with intermediate and high risk clinical features who received radical prostatectomy as first line treatment at the Mayo Clinic between 2000 and 2006.<sup>4</sup>

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**Ten-year probability of prostate cancer specific mortality (PCSM) endpoint:** Decipher uses the genomic risk score to predict the 10-year probability of PCSM from the time of radical prostatectomy. Probabilities are generated from a logistic regression analysis based upon a cohort of 557 patients with 112 prostate cancer deaths within 10 years post radical prostatectomy. These probabilities are adjusted for a PCSM cumulative incidence of 5% at 10 years post radical prostatectomy.<sup>7</sup> All non-PCSM patients in the study had at least 10 years of follow-up. Decipher had an AUC of 0.72 in predicting PCSM.<sup>8,9</sup> Percent likelihood for this endpoint ranges from 0.7-30.5%. This risk model has not yet been validated on prostate biopsy specimens but has been validated in multiple radical prostatectomy Decipher studies.<sup>8-10</sup>

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**Decipher classifies post-surgery patients\* into genomic risk categories for metastasis with 98.5% Negative Predictive Value (NPV).**

## Post radical prostatectomy (RP) indications for Decipher test

### Medicare Indications

- Positive Surgical Margin (SM+)
- Extraprostatic Extension (pT3a disease)
- Seminal Vesicle Invasion (pT3b disease)
- Bladder Neck Invasion (pT4 disease)
- Rising PSA or Biochemical Recurrence

### Additional Indications

- Pre-operative PSA  $\geq$  20ng/mL
- High Gleason Score  $\geq$  7
- Tertiary Gleason 5
- Perineural or Lymphovascular Invasion
- Lymph Node Involvement (LNI)

Decipher Classification	Treatment recommended post-surgery <sup>6,7,8</sup>	Treatment recommended post-surgery after PSA rise or biochemical recurrence
<b>Genomic Low Risk</b>	Observation with PSA monitoring until detectable PSA rise, if any/ever <sup>1,2</sup> <ul style="list-style-type: none"> <li>• 98.5% 5 year metastasis-free survival<sup>5</sup></li> <li>• 95% 10 year prostate cancer-specific survival<sup>4</sup></li> </ul>	Radiation alone is sufficient. Concurrent hormone therapy may be avoided. <sup>3</sup>
<b>Genomic High Risk</b>	80% reduction in metastasis risk in Decipher high-risk patients who receive adjuvant or early radiation <sup>1,2</sup>	Radiation alone is insufficient. Intensification of treatment may be needed. <sup>3</sup>

## References

- Den, R.B., et al., A Genomic Classifier Identifies Men with Adverse Pathology after Radical Prostatectomy who Benefit from Adjuvant Radiation Therapy. *Journal of Clinical Oncology*, 2015 Mar; 33(8): 944-951.
- Den, R.B., et al., A Genomic Prostate Cancer Classifier predicts Biochemical Failure and Metastasis in Patients Following Post Operative Radiation Therapy. *Int J Radiat Oncol Biol Phys.*, 2014 Aug; 89(5): 1038-46.
- Freedland, S.J., et al., Utilization of a Genomic Classifier for Prediction of Metastasis Following Salvage Radiation Therapy after Radical Prostatectomy. *European Urology*, 2016. In Press.
- Ross, A.E., et al., Tissue Based Genomics Augment Post-Prostatectomy Risk Stratification in a Natural History Cohort of Intermediate- and High-Risk Men. *European Urology*, 2016 Jan; 69(1): 157-65.
- Karnes, R.J., et al., Validation of a Genomic Classifier that Predicts Metastasis Following Radical Prostatectomy in an At Risk Patient Population. *J Urology*, 2013 Dec; 190(6): 2047-2053.
- Michaelopolous, S.N., et al., Influence of a Genomic Classifier on Postoperative Treatment Decisions in High-Risk Prostate Cancer Patients: Results from the PRO-ACT Study. *Curr Med Res Opin*, 2014 Aug; 30(8): 1547-56.
- Nguyen, P.L., et al., Impact of a Genomic Classifier of Metastatic Risk on Post-Prostatectomy Treatment Recommendations by Radiation Oncologists and Urologists. *Urology*, 2015 Jul; 86(1): 35-40. Featured on the cover of *Urology* July 2015.
- Badani, 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*, 2013 Apr; 4(4): 600-609.
- Mohler, J.L., et al., Prostate Cancer, Version 1.20: Featured Updates to the NCCN Guidelines. *JNCCN*. 2016 Jan; 14(1): 19-30.

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

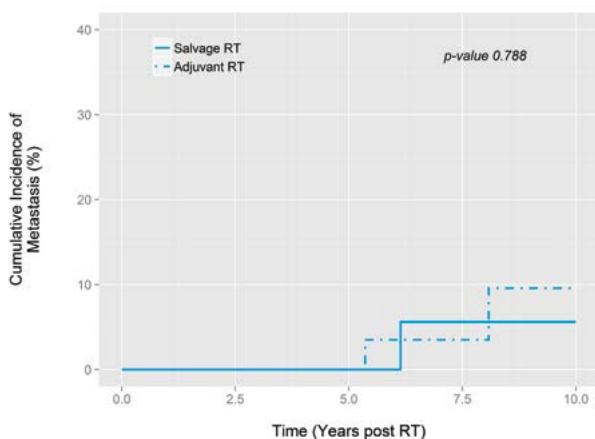
# Decipher.<sup>®</sup>

## Know what treatment. And when to treat.

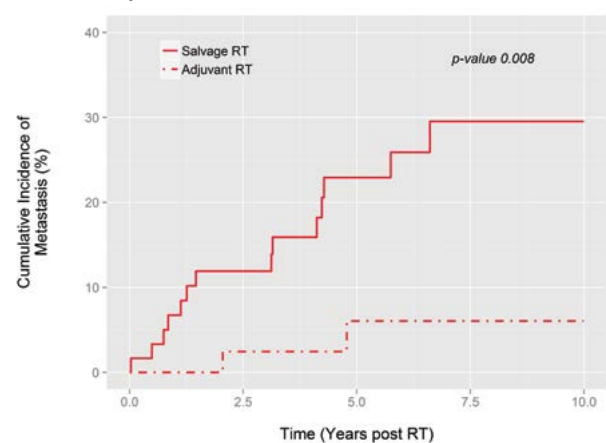
NCCN guidelines highlight Decipher as a clinically available tissue-based test for prostate cancer.<sup>9</sup>

### Decipher for patients after prostate surgery<sup>1</sup>

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



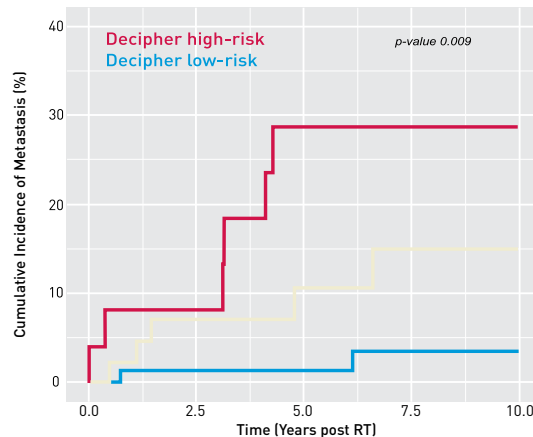
Decipher **high-risk** patients may experience lower rates of metastasis when treated with adjuvant radiation post-RP



### Decipher for patients after prostate surgery with PSA rise or biochemical recurrence

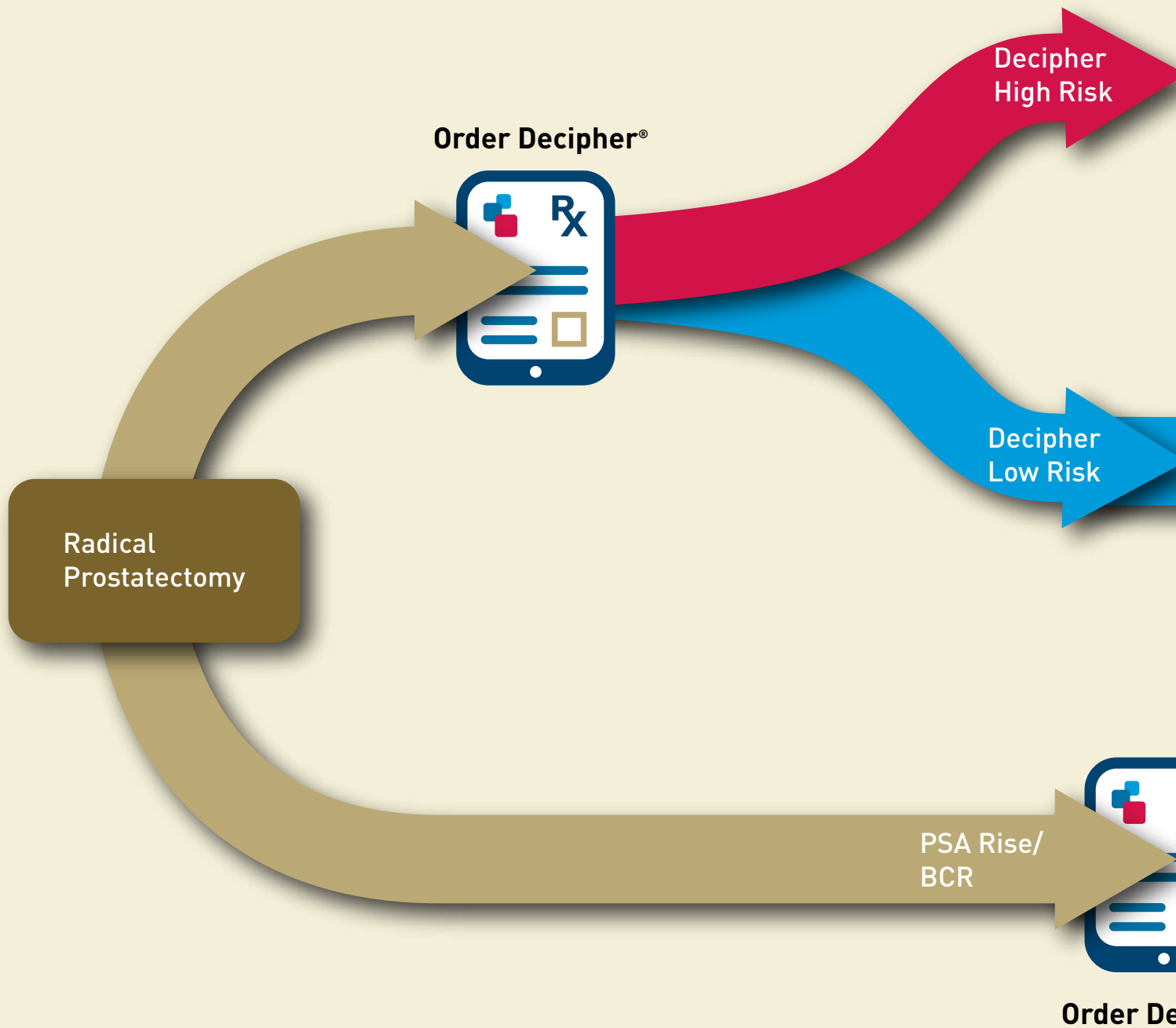
- Decipher **low-risk** patients have excellent prognosis with salvage radiation and may avoid concurrent hormonal therapy, as incidence of metastasis remains low.<sup>3</sup>
- Decipher **high-risk** patients may require intensification of therapy beyond radiation as incidence of metastasis remains high.<sup>3</sup>

#### Patients treated with salvage radiotherapy\*



\*No concurrent hormone therapy given

# Suggested Patient Management Plan



## References

1. Den, R.B., et al., A Genomic Classifier Identifies Men with Adverse Pathology after Radical Prostatectomy who Benefit from Adjuvant Radiation Therapy. *Journal of Clinical Oncology*, 2015 Mar; 33(8): 944-951.
2. Den, R.B., et al., A Genomic Prostate Cancer Classifier predicts Biochemical Failure and Metastasis in Patients Following Post Operative Radiation Therapy. *Int J Radiat Oncol Biol Phys.*, 2014 Aug; 89(5): 1038-46.
3. Freedland, S.J., et al., Utilization of a Genomic Classifier for Prediction of Metastasis Following Salvage Radiation Therapy after Radical Prostatectomy. *European Urology*. 2016. In Press.



Radiation (ART  
Better Results  
Than SRT)<sup>1</sup>

Observation

PSA Rise/BCR

Excellent prognosis  
with SRT and may  
avoid concurrent  
hormone therapy<sup>3</sup>

Decipher  
High Risk

May require  
intensification of  
therapy beyond  
radiation<sup>3</sup>

Decipher  
Low Risk

Excellent prognosis  
with SRT and may  
avoid concurrent  
hormone therapy<sup>3</sup>



Decipher

## Decipher Post-Operative Report

### Patient Details

Patient Name:  
Medical Record Number:  
Date of Birth: **01/01/1945**  
Date of Prostatectomy:

Pathology Laboratory:  
Pathologist:  
Address:

### Order Information

Order Date:  
Specimen Received Date:  
GenomeDx Accession ID:  
Specimen ID:  
Ordering Physician:  
Clinic/Hospital Name:  
Clinic/Hospital Address:

Additional Physician:

### Clinical Details

Preoperative PSA (ng/mL) **4.2**

Gleason Score **4+3**

☒ SM+

☐ EPE

☐ SVI

☐ LNI

☐ BCR

☐ Tertiary Gleason 5

## POST OP

## Your Decipher Result – Genomic High Risk



### Decipher Score 0.7

#### Risk - Percent Likelihood

5-Year Metastasis	16.4%
10-Year Prostate Cancer Specific Mortality	11.4%

### Interpretation

Clinical studies concluded that Decipher high risk men with adverse pathology have a poor prognosis overall.<sup>1-3</sup> These men may benefit from adjuvant or early salvage radiotherapy and consideration for clinical trials.<sup>4-6</sup>

Relevant findings from published clinical studies: Patients with Decipher high risk had 77% 5-year metastasis free survival and 70% 10-year cause specific survival.<sup>1,2</sup> For these patients there was improved metastasis-free survival favoring adjuvant and early salvage postoperative radiotherapy.<sup>4-6</sup>

In patients with PSA rise or biochemical recurrence after surgery that received salvage radiotherapy, only 66.5% remained metastasis free after 5 years.<sup>4</sup>

References on reverse

\*Average clinical risk refers to the average cohort risk of metastasis at 5 years post radical prostatectomy. The average cumulative incidence of metastasis was 6.0% at 5 years post radical prostatectomy, as reported by Karnes et al., 2013 from analysis of a cohort of 1,010 men with intermediate and high risk clinical features who received radical prostatectomy as first line treatment at the Mayo Clinic between 2000 and 2006.<sup>1</sup>

**Five-year probability of metastasis endpoint:** Decipher uses the genomic risk score to predict the 5-year probability of metastasis from the time of radical prostatectomy. Probabilities were generated from a Cox proportional hazards model based upon a cohort of 1,010 men with intermediate and high risk clinical features with a median 6.9 years of follow up.<sup>2</sup> Decipher had an AUC of 0.76-0.85 in multiple clinical validation studies for prediction of metastasis.<sup>1-6</sup> Percent likelihood for this endpoint ranges from 0.3-67%.

**Ten-year probability of prostate cancer specific mortality (PCSM) endpoint:** Decipher uses the genomic risk score to predict the 10-year probability of PCSM from the time of radical prostatectomy. Probabilities are generated from a logistic regression analysis based upon a cohort of 557 patients with 112 prostate cancer deaths within 10 years post radical prostatectomy. These probabilities are adjusted for a PCSM cumulative incidence of 5% at 10 years post radical prostatectomy.<sup>3</sup> All non-PCSM patients in the study had at least 10 years of follow-up. Decipher had an AUC of 0.72 in predicting PCSM.<sup>2,4,6</sup> Percent likelihood for this endpoint ranges from 0.7-30.5%.

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## Decipher Post-Operative Report

### Patient Details

Patient Name:  
Medical Record Number:  
Date of Birth: **01/02/1945**  
Date of Prostatectomy:

Pathology Laboratory:  
Pathologist:  
Address:

### Order Information

Order Date:  
Specimen Received Date:  
GenomeDx Accession ID:  
Specimen ID:  
Ordering Physician:  
Clinic/Hospital Name:  
Clinic/Hospital Address:

Additional Physician:

### Clinical Details

Preoperative PSA (ng/mL) **4.9**

Gleason Score **4+3**

☐ SM+

☒ EPE

☐ SVI

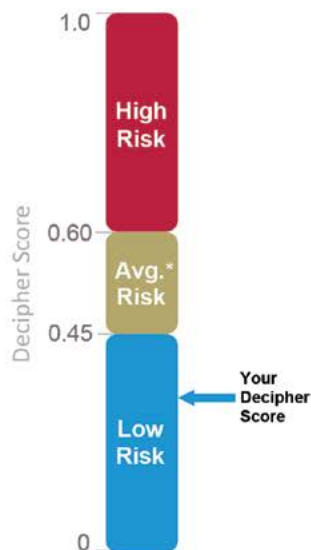
☐ LNI

☐ BCR

☐ Tertiary Gleason 5

## POST OP

## Your Decipher Result – Genomic Low Risk



### Decipher Score 0.3

#### Risk - Percent Likelihood

5-Year Metastasis	1.6%
10-Year Prostate Cancer Specific Mortality	2.5%

### Interpretation

Clinical studies concluded that Decipher low risk results in men with adverse pathology have good prognosis overall and may be optimally managed with observation after surgery.<sup>1-3</sup> Upon PSA rise, these patients may be treated with delayed radiotherapy without concurrent hormone therapy.<sup>4</sup>

Relevant findings from published clinical studies: Patients with Decipher low risk had >98% 5-year metastasis free survival and >95% 10-year cause specific survival.<sup>1,2</sup> For these patients there were no significant differences in metastasis free survival with adjuvant, early or late salvage postoperative radiotherapy treatment.<sup>4-6</sup>

In patients with PSA rise or biochemical recurrence after surgery that received salvage radiotherapy, >97% 5-year metastasis free survival was observed with or without concurrent hormone therapy.<sup>4</sup>

References on reverse

\*Average clinical risk refers to the average cohort risk of metastasis at 5 years post radical prostatectomy. The average cumulative incidence of metastasis was 6.0% at 5 years post radical prostatectomy, as reported by Karnes et al., 2013 from analysis of a cohort of 1,010 men with intermediate and high risk clinical features who received radical prostatectomy as first line treatment at the Mayo Clinic between 2000 and 2006.<sup>1</sup>

**Five-year probability of metastasis endpoint:** Decipher uses the genomic risk score to predict the 5-year probability of metastasis from the time of radical prostatectomy. Probabilities were generated from a Cox proportional hazards model based upon a cohort of 1,010 men with intermediate and high risk clinical features with a median 6.9 years of follow up.<sup>1</sup> Decipher had an AUC of 0.76-0.85 in multiple clinical validation studies for prediction of metastasis.<sup>1-6</sup> Percent likelihood for this endpoint ranges from 0.3-67%.

**Ten-year probability of prostate cancer specific mortality (PCSM) endpoint:** Decipher uses the genomic risk score to predict the 10-year probability of PCSM from the time of radical prostatectomy. Probabilities are generated from a logistic regression analysis based upon a cohort of 557 patients with 112 prostate cancer deaths within 10 years post radical prostatectomy. These probabilities are adjusted for a PCSM cumulative incidence of 5% at 10 years post radical prostatectomy.<sup>3</sup> All non-PCSM patients in the study had at least 10 years of follow-up. Decipher had an AUC of 0.72 in predicting PCSM.<sup>2,7,8</sup> Percent likelihood for this endpoint ranges from 0.7-30.5%.

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Based on the patient's personal tumor-based genomics, Decipher Prostate Cancer Classifier helps determine who:

#### ☐ Decipher Biopsy

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

#### ☐ Decipher Post-Op

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

#### Access for All Patients

- Medicare Coverage (Mol Dx LCD ID L36343): Decipher post-op test covered for Medicare beneficiaries
- Private Insurance Coverage
- Proven and comprehensive financial assistance for patients

To learn more about Decipher, contact the GenomeDx Customer Support Team at 1.888.792.1601 (toll free) or email at [customersupport@genomedx.com](mailto:customersupport@genomedx.com).



A biopsy specimen is precious and finite. Use a molecular test that provides the most information possible to benefit you and your patient. Decipher provides the most comprehensive view of a patient's tumor from a needle biopsy. Unlike other tests, Decipher provides exclusive access to Decipher GRID—a rich resource of genomic data beyond the markers that make-up the present Decipher test. This information may benefit your patient and have future treatment implications. Decipher GRID is for research use only (RUO). To learn more, visit [DecipherGRID.com](http://DecipherGRID.com).

**Decipher Prostate Cancer Classifier represents 22 biomarkers specific to prostate cancer representing multiple biological pathways**

Biological Pathway	Prostate-specific Biomarkers
Androgen-Signaling	NFIB, NUSAP1, ZWILCH
Cell Cycle Progression	AN07, PCAT-32, UBE2C
Cell Proliferation, Differentiation	CAMK2N1, MYBPC1, PBX1, THBS2, UBE2C
Cell Structure, Adhesion, Motility	AN07, EPPK1, IQGAP3, LASP1, MYBPC1, PCDH7, RABGAP1
Immune System Modulation	GLYATL1P4, S1PR4, TNFRSF19, TSBP

#### Robust and Prolific Technology Platform

- Archived FFPE tissue
- Whole genome technology
- Genomic analysis of **1.4 million biomarkers**