DECIPHER
BY GENOME DX

PROVIDING TREATMENT INFORMATION FOR PROSTATE CANCER PATIENTS

DECIPHER PROSTATE BIOPSY

For patients with localized disease on biopsy*

DECIPHER PROSTATE RP

For patients with adverse pathology after prostatectomy

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

DECIPHER
PROSTATE BIOPSY

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

DECIPHER PROSTATE BIOPSY TEST ACCEPTS:

NCCN Risk Categories

- Very Low/Low
- Favorable Intermediate

Active surveillance?

Local therapy alone?

- Radical Prostatectomy
- Radiation

Multi-modal therapy?

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 such as surgery or radiotherapy[1,2]
Decipher Biopsy High Risk	**Unfavorable prognosis** - may not be suitable candidate for active surveillance and may benefit from intensification with multi-modal therapy[1,2]

DECIPHER BIOPSY ACCURATELY RECLASSIFIES 46% OF PATIENTS FROM NCCN RISK CATEGORY[1]

References

1. Klein, E.A., et al., Decipher Genomic Classifier Measured on Prostate Biopsy Predicts Metastasis Risk. Urology. 2016 Apr; 90:148-52. doi: 10.1016/j.urology.2016.01.012 (unpublished select data available upon request).
2. Nguyen P.L., 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. Jan; doi: 10.1038/pcan.2016.58. In press.
3. Cullen, J., 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.

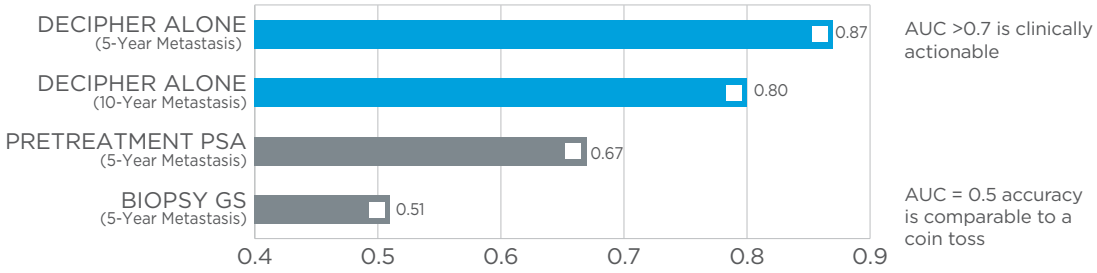
*Decipher Prostate Biopsy is indicated for patients categorized as NCCN Very Low, Low, Favorable Intermediate or Unfavorable Intermediate.

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

COMPARISON OF ACCURACY DURING VARIOUS STAGES

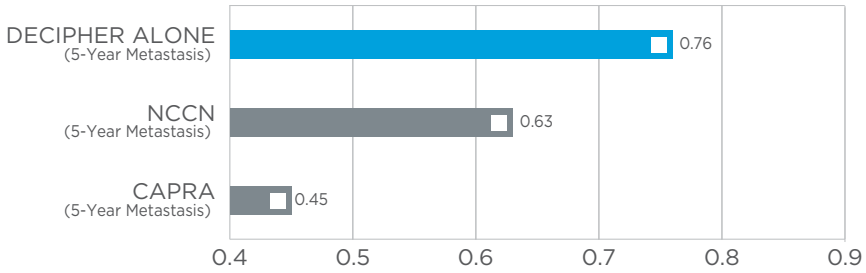
Predicting Metastasis after RP[1]

Predictive Power Measured by Area Under the Curve (AUC)



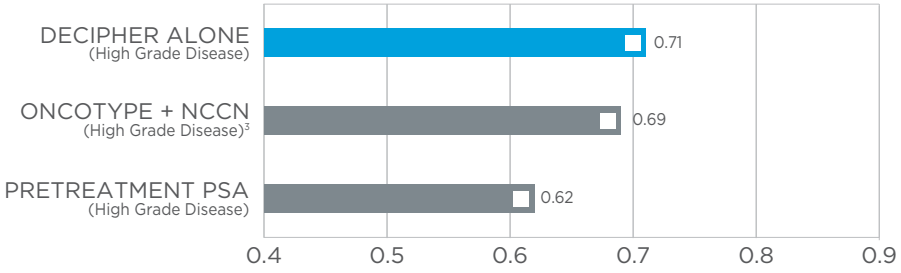
Predicting 5 Year Metastasis after First Line Radiation[2]

Predictive Power Measured by Area Under the Curve (AUC)



Predicting High Grade Disease At RP[1]

Predictive Power Measured by Area Under the Curve (AUC)



DECIPHER
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DECIPHER BIOPSY REPORT

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San Diego, CA 92121
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customersupport@genomedx.com | www.genomedx.com

PATIENT DETAILS

Patient Name:
Medical Record Number:
Date of Birth:
Date of Biopsy:

Pathology Laboratory:
Pathologist:
Address:

ORDER INFORMATION

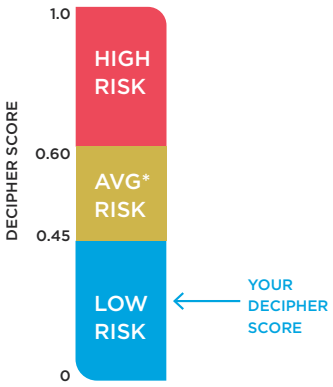
Order Date:
Specimen Received Date:
GenomeDx Accession ID:
Specimen ID:
Ordering Physician:
Clinic/Hospital Name:
Clinic/Hospital Address:
Additional Physician:

CLINICAL DETAILS

PSA, most recent (ng/mL): **5.5**
Specimen Type: **Needle Core**

NCCN risk category: **Intermediate Risk**
# of Positive Cores: **3 (3 of 6 Cores)**

Biopsy Gleason Score: **3+4**
Clinical Stage: **T1c**



YOUR DECIPHER RESULT – GENOMIC LOW RISK

DECIPHER SCORE 0.23

Risk at RP - Percent Likelihood	
High Grade Disease (primary Gleason grade 4 or 5)	**12.3%**
5-Year Metastasis	**1.0%**
10-Year Prostate Cancer Specific Mortality	**1.9%**

INTERPRETATION References on reverse

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.[1-3]

*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.[4]

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.[5] Klein et al. 2016 study found Decipher Biopsy predicted high grade disease at radical prostatectomy with an AUC of 0.71.[5] 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[4]. In a separate cohort, Klein et al. 2016 reported that Decipher biopsy predicted 5-year metastasis with an AUC of 0.874. Subsequently, in another independent cohort, Decipher biopsy predicted 5-year metastasis with an AUC of 0.76 and similarly found that Decipher biopsy was the only significant variable that predicted metastatic onset in multivariable analysis with clinical risk factors[6]. The percent likelihood for this endpoint ranges from 0.3-67%. The average concordance between Decipher biopsy and radical prostatectomy specimens is 81%.

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.[9] All non-PCSM patients in the study had at least 10 years of follow-up. In a validation study with a biopsy cohort of 175 patients, Decipher was a significant predictor of PCSM at diagnosis with a hazard ratio (HR) of 1.57 (95% CI 1.07–2.40) per 10% increase for Decipher score (p=0.02).[9] The percent likelihood for this endpoint ranges from 0.7-30.5%.

GenomeDx Medical Director (Name & Signature)
Medical Directors: Timothy J. Triche, MD, PhD | Doug Dolginow, MD

Date

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PATIENT DETAILS

Patient Name:
Medical Record Number:
Date of Birth:
Date of Biopsy:

Pathology Laboratory:
Pathologist: **D**
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): **1.9**
Specimen Type: **Needle Core**

NCCN risk category: **Intermediate Risk**
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Biopsy Gleason Score: **3+4**
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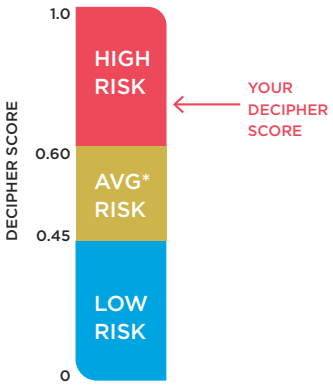

YOUR DECIPHER RESULT – GENOMIC HIGH RISK

DECIPHER SCORE 0.72

Risk at RP - Percent Likelihood	
High Grade Disease (primary Gleason grade 4 or 5)	**39.7%**
5-Year Metastasis	**18.5%**
10-Year Prostate Cancer Specific Mortality	**12.4%**

INTERPRETATION References on reverse

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.[1-3]

*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.[4]

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DECIPHER
PROSTATE RP

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

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

Decipher classification	Treatment recommended post-surgery[6,7,8]	Treatment recommended post-surgery after PSA rise or biochemical recurrence
Genomic Low Risk	Observation with PSA monitoring until detectable PSA rise, if any/ever[1,2] 98.5% 5 year metastasis-free survival[5] 95% 10 year prostate cancer-specific survival[4]	Radiation alone is sufficient. Concurrent hormone therapy may be avoided[3]
Genomic High Risk	80% reduction in metastasis risk in Decipher high-risk patients who receive adjuvant or early radiation[1,2]	Radiation alone is insufficient. Intensification of treatment may be needed[3]

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; pii: S0302-2838(16)00059-2. doi: 10.1016/j.eururo.2016.01.008.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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.
9. 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.

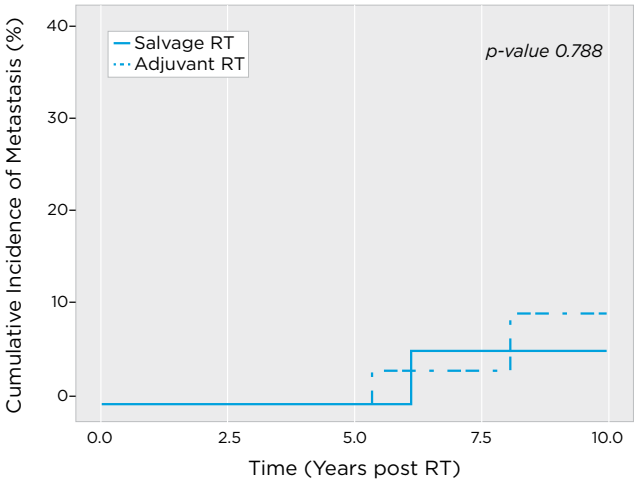
** Covered for Medicare patients whose physicians are registered in the Decipher CTR (Certification and Training Registry)

DECIPHER.
KNOW WHAT TREATMENT. AND WHEN TO TREAT.

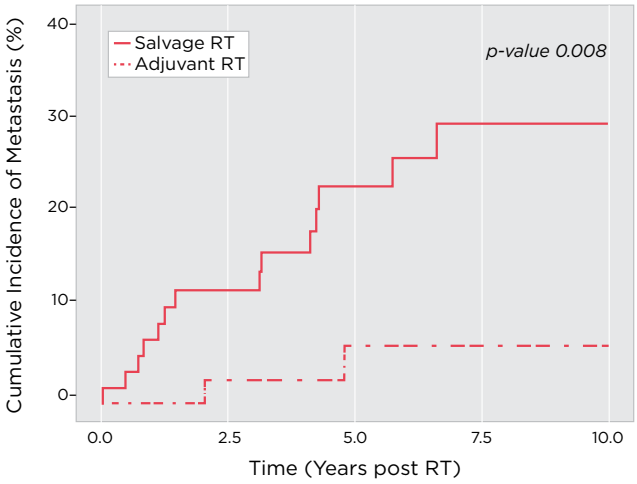
NCCN GUIDELINES HIGHLIGHT DECIPHER AS A CLINICALLY AVAILABLE TISSUE-BASED TEST FOR PROSTATE CANCER[9]

DECIPHER FOR PATIENTS AFTER PROSTATE SURGERY[1]

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

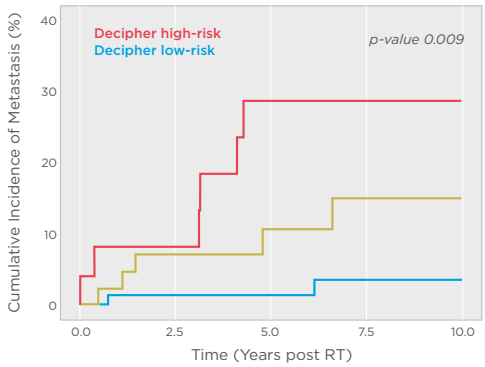


DECIPHER FOR PATIENTS AFTER PROSTATE SURGERY WITH PSA RISE OR BIOCHEMICAL RECURRENCE

Decipher low-risk patients have excellent prognosis with salvage radiation and may avoid concurrent hormonal therapy, as incidence of metastasis remains low.[3]

Decipher high-risk patients may require intensification of therapy beyond radiation as incidence of metastasis remains high.[3]

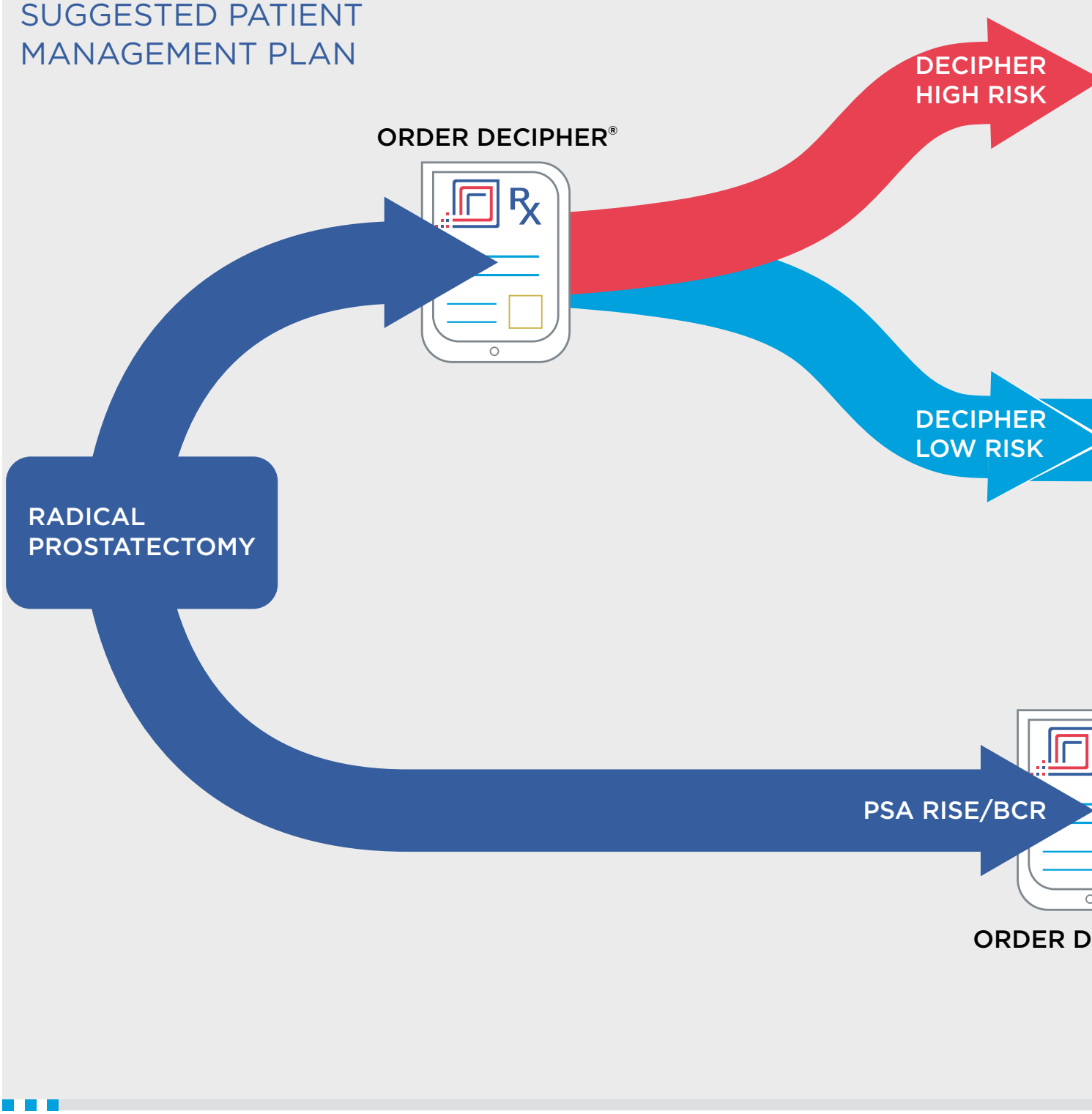
Patients treated with salvage radiotherapy*



*No concurrent hormone therapy given

DECIPHER
PROSTATE RP

SUGGESTED PATIENT MANAGEMENT PLAN



References

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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.
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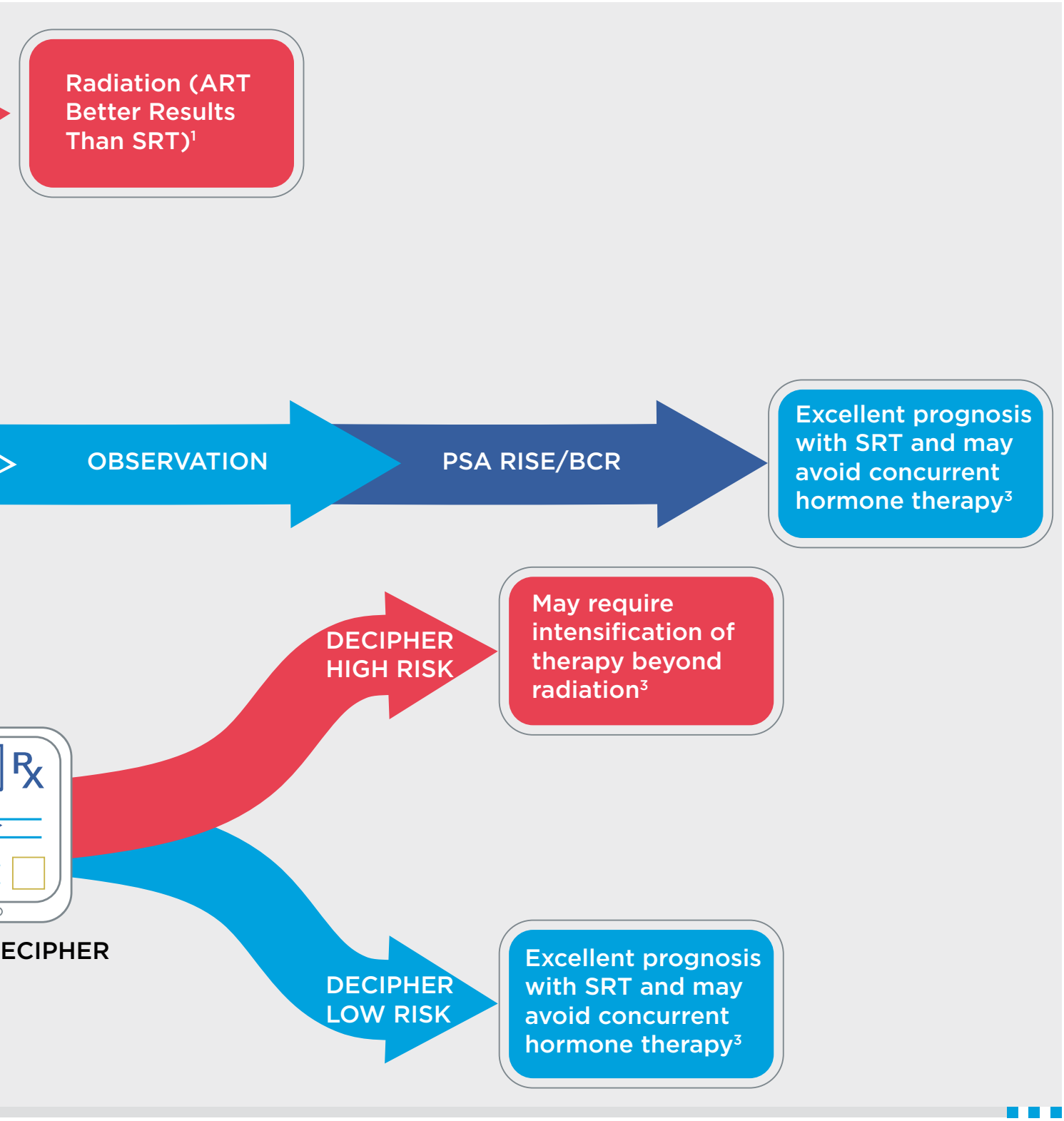
Radiation (ART Better Results Than SRT)[1]
OBSERVATION
PSA RISE/BCR
Excellent prognosis with SRT and may avoid concurrent hormone therapy[3]
DECIPHER HIGH RISK
May require intensification of therapy beyond radiation[3]
Rx
ECIPHER
DECIPHER LOW RISK
Excellent prognosis with SRT and may avoid concurrent hormone therapy[3]

DECIPHER
PROSTATE RP

DECIPHER POST-OPERATIVE REPORT

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PATIENT DETAILS

Patient Name:
Medical Record Number:
Date of Birth:
Date of Prostatectomy:

Pathology Laboratory:
Pathologist:
Address:

ORDER INFORMATION

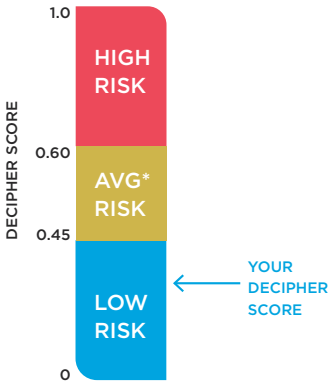
Order Date:
Specimen Received Date:
GenomeDx Accession ID:
Specimen ID:
Ordering Physician:
Clinic/Hospital Name:
Clinic/Hospital Address:
Additional Physician:

CLINICAL DETAILS

PSA, most recent (ng/mL): **4.9** Gleason Score: **4+3** Specimen Type:

☐ SM+ ☒ EPE ☐ SVI ☐ LNI ☐ BCR ☐ Tertiary Gleason 5

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

References on reverse

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.[1-3,12] Upon PSA rise, these patients may be treated with delayed radiotherapy without concurrent hormone therapy.[4,11]

Relevant findings from published clinical studies: Patients with Decipher low risk had >97% 5-year metastasis free survival and >94.7% 10-year cause specific survival.[1,2,3] For these patients there were no significant differences in metastasis free survival with adjuvant, early or late salvage postoperative radiotherapy treatment.[5,6,11]

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.[4]

*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.[1]

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.[1] Decipher had an AUC of 0.76-0.85 in multiple clinical validation studies for prediction of metastasis.[1-8] 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.[9] 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.[2,7,13] Percent likelihood for this endpoint ranges from 0.7-30.5%.

GenomeDx Medical Director (Name & Signature)
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Date

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DECIPHER POST-OPERATIVE REPORT

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PATIENT DETAILS

Patient Name:
Medical Record Number:
Date of Birth:
Date of Prostatectomy:

Pathology Laboratory:
Pathologist:
Address:

ORDER INFORMATION

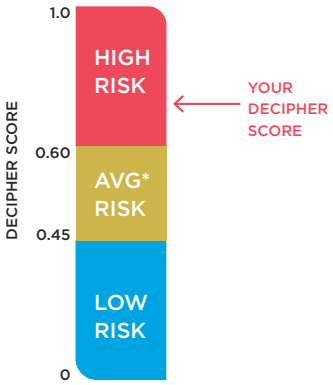
Order Date:
Specimen Received Date:
GenomeDx Accession ID:
Specimen ID:
Ordering Physician:
Clinic/Hospital Name:
Clinic/Hospital Address:
Additional Physician:

CLINICAL DETAILS

PSA, most recent (ng/mL): **4.2** Gleason Score: **4+3** Specimen Type:

☒ SM+ ☐ EPE ☐ SVI ☐ LNI ☐ BCR ☐ Tertiary Gleason 5

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

References on reverse

Clinical studies concluded that Decipher high risk men with adverse pathology have a poor prognosis overall.[1-3,12] These men may benefit from adjuvant or early salvage radiotherapy and consideration for clinical trials.[4-6]

Relevant findings from published clinical studies: Patients with Decipher high risk had 77.5% 5-year metastasis free survival and 76.6% 10-year cause specific survival.[1,2,3] For these patients there was improved metastasis-free survival favoring adjuvant and early salvage postoperative radiotherapy compared to postoperative observation.[5,6,11]

In patients with PSA rise or biochemical recurrence after surgery that received salvage radiotherapy, only 66.9% remained metastasis free after 5 years.[4]

*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.[1]

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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.[9] 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.[2,7,13] Percent likelihood for this endpoint ranges from 0.7-30.5%.

GenomeDx Medical Director (Name & Signature)
Medical Directors: Timothy J. Triche, MD, PhD | Doug Dolginow, MD

Date

Disclaimer The Decipher test was developed and its performance characteristics were determined by GenomeDx Biosciences Laboratory. The GenomeDx Biosciences Laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) to perform high complexity testing. This test has not been cleared or approved by the U.S. Food and Drug Administration. Summary of surgical pathology report provided for convenience of Ordering Physician. Please refer to Referring Pathologist's original pathology report to guide treatment decisions.

DECIPHER
BY GENOME DX

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 L36345): Decipher post-op test covered for Medicare beneficiaries

Private Insurance Coverage

Proven and comprehensive financial assistance for patients

DECIPHER
GRID BY GENOME DX

A tissue sample is precious and finite. Use a molecular test that provides the most comprehensive assessment of your patient's tumor. The Decipher testing platform collects over 1.4 million data points to help better understand the tumor biology. The GRID research program provides exclusive access to this valuable information by sharing an in-depth, personalized Tumor RNA Expression Profile for your Decipher patient. This research use only (RUO) information can provide insights. In addition, the GRID research program aims to foster collaborations among researchers by collectively sharing this wealth of data to facilitate new genomic discoveries. To learn more, visit DecipherGRID.com.

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

BIOLOGICAL PATHWAY	PROSTATE-SPECIFIC BIOMARKERS
Androgen-Signaling	ANO7, PCAT-32, UBE2C
Cell Cycle Progression	NFIB, NUSAP1, ZWILCH
Cell Proliferation, Differentiation	CAMK2N1, MYBPC1, PBX1, THBS2, UBE2C
Cell Structure, Adhesion, Motility	ANO7, 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

Contact the GenomeDx Customer Support Team 1.888.792.1601 (toll-free)
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