PROVIDING TREATMENT INFORMATION FOR PROSTATE CANCER PATIENTS

For patients with localized disease on biopsy*

For patients with adverse pathology after prostatectomy

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

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

Decipher Biopsy High Risk | Unfavorable prognosis - may not be suitable candidate for active surveillance and may benefit from intensification with multi-modal therapy

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

References

*Decipher Prostate Biopsy is indicated for patients categorized as NCCN Very Low, Low, Favorable Intermediate or Unfavorable Intermediate.
**Comparing Accuracy during Various Stages**

### Predicting Metastasis after RP
Predictive Power Measured by Area Under the Curve (AUC)

- **DECIPHER ALONE (5-Year Metastasis)**
  - AUC: 0.87
- **DECIPHER ALONE (10-Year Metastasis)**
  - AUC: 0.80
- **PRETREATMENT PSA (5-Year Metastasis)**
  - AUC: 0.67
- **BIOPSY GS (5-Year Metastasis)**
  - AUC: 0.51

**Legend**
- AUC > 0.7 is clinically actionable
- AUC ≤ 0.5 accuracy is comparable to a coin toss

### Predicting 5 Year Metastasis after First Line Radiation
Predictive Power Measured by Area Under the Curve (AUC)

- **DECIPHER ALONE (5-Year Metastasis)**
  - AUC: 0.76
- **NCCN (5-Year Metastasis)**
  - AUC: 0.63
- **CAPRA (5-Year Metastasis)**
  - AUC: 0.45

### Predicting High Grade Disease At RP
Predictive Power Measured by Area Under the Curve (AUC)

- **DECIPHER ALONE (High Grade Disease)**
  - AUC: 0.71
- **ONCOTYPE + NCCN (High Grade Disease)**
  - AUC: 0.69
- **PRETREATMENT PSA (High Grade Disease)**
  - AUC: 0.62
**DECIPHER BIOPSY REPORT**

**PATIENT DETAILS**
- Patient Name: [Redacted]
- Medical Record Number: [Redacted]
- Date of Birth: [Redacted]
- Date of Biopsy: [Redacted]
- Pathology Laboratory: [Redacted]
- Pathologist: [Redacted]
- Address: [Redacted]

**ORDER INFORMATION**
- Order Date: [Redacted]
- Specimen Received Date: [Redacted]
- GenomeDx Accession ID: [Redacted]
- Specimen ID: [Redacted]
- Ordering Physician: [Redacted]
- Clinic/Hospital Name: [Redacted]
- Clinic/Hospital Address: [Redacted]
- Additional Physician: [Redacted]

**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**

<table>
<thead>
<tr>
<th>DECIPHER SCORE 0.23</th>
<th>Risk at RP - Percent Likelihood</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High Grade Disease (primary Gleason grade 4 or 5)</td>
</tr>
<tr>
<td></td>
<td>5-Year Metastasis</td>
</tr>
<tr>
<td></td>
<td>10-Year Prostate Cancer Specific Mortality</td>
</tr>
</tbody>
</table>

**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.1,2

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1. Klein et al. 2016 study found Decipher biopsy predicted high grade disease at radical prostatectomy with an AUC of 0.71. The percent likelihood for this endpoint ranges from 6.5-45%.

2. Klein et al. 2016 study found Decipher biopsy predicted high grade disease at radical prostatectomy with an AUC of 0.71. The percent likelihood for this endpoint ranges from 6.5-45%.

**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.
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
# of Positive Cores: 3 (3 of 9 Cores)
Biopsy Gleason Score: 3+4
Clinical Stage: T1c

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
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

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**POST RADICAL PROSTATECTOMY (RP) INDICATIONS FOR DECIPHER TEST**

<table>
<thead>
<tr>
<th>Decipher classification</th>
<th>Treatment recommended post-surgery</th>
<th>Treatment recommended post-surgery after PSA rise or biochemical recurrence</th>
</tr>
</thead>
</table>
| Genomic Low Risk        | Observation with PSA monitoring until detectable PSA rise, if any/ever*  
98.5% 5 year metastasis-free survival†  
95% 10 year prostate cancer-specific survival‡ | Radiation alone is sufficient. Concurrent hormone therapy may be avoided† |
| Genomic High Risk       | 80% reduction in metastasis risk in Decipher high-risk patients who receive adjuvant or early radiation‡ | Radiation alone is insufficient. Intensification of treatment may be needed† |

**References**


* 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

DECIPHER FOR PATIENTS AFTER PROSTATE SURGERY

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.

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

Patients treated with salvage radiotherapy*

*No concurrent hormone therapy given
SUGGESTED PATIENT MANAGEMENT PLAN

ORDER DECIPHER®

DECIPHER HIGH RISK

DECIPHER LOW RISK

RADICAL PROSTATECTOMY

PSA RISE/BCR

ORDER DECIPHER

References


OBSERVATION

PSA RISE/BCR

EXCELLENT PROGNOSIS WITH SRT AND MAY AVOID CONCURRENT HORMONE THERAPY

RADIATION (ART BETTER RESULTS THAN SRT)

DECIPHER

HIGH RISK

MAY REQUIRE INTENSIFICATION OF THERAPY BEYOND RADIATION

DECIPHER

LOW RISK

EXCELLENT PROGNOSIS WITH SRT AND MAY AVOID CONCURRENT HORMONE THERAPY

RX

EXCELLENT PROGNOSIS WITH SRT AND MAY AVOID CONCURRENT HORMONE THERAPY

ORDER DECIPHER®

EXCELLENT PROGNOSIS WITH SRT AND MAY AVOID CONCURRENT HORMONE THERAPY

EXCELLENT PROGNOSIS WITH SRT AND MAY AVOID CONCURRENT HORMONE THERAPY

EXCELLENT PROGNOSIS WITH SRT AND MAY AVOID CONCURRENT HORMONE THERAPY
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. Upon PSA rise, these patients may be treated with delayed radiotherapy without concurrent hormone therapy.

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. For these patients there were no significant differences in metastasis free survival with adjuvant, early or late salvage postoperative radiotherapy treatment.

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.

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.

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 who received radical prostatectomy as first line treatment at the Mayo Clinic between 2000 and 2006.

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. 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. Percent likelihood for this endpoint ranges from 0.7-30.5%.

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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:

YOUR DECIPHER RESULT – GENOMIC HIGH RISK

DECIPHER SCORE 0.7

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</table>

INTERPRETATION

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

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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 | GLYATLP4, SIPR4, TNFRSF19, TSBP

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

**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

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

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