DECIPHER
PROSTATE BIOPSY

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DECIPHER BIOPSY REPORT

PATIENT DETAILS

Patient Name:
MRN/Patient ID:
Date of Birth:
Date of Biopsy:

Pathology Laboratory:
Pathologist: R
Address: D

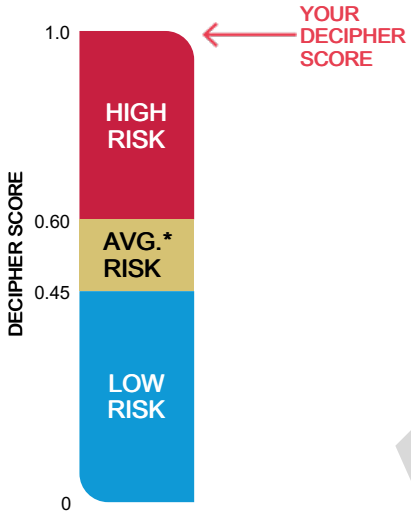
ORDER INFORMATION

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): **4.1**
Specimen Type: **Needle Biopsy**
NCCN Risk Category: **Low Risk**
# of Positive Cores: **8 (8 of 32 Cores)**
Gleason Score: **3+3**
Clinical Stage: **T2a**

YOUR DECIPHER RESULT: GENOMIC HIGH RISK



DECIPHER SCORE: 0.99

Risk at RP - Percent Likelihood	
High Grade Disease (primary Gleason grade 4 or 5)	**33.7%**
5-Year Metastasis	**11.6%**
10-Year Prostate Cancer Specific Mortality	**9.1%**

INTERPRETATION

References on reverse

Clinical studies have shown that men with a Decipher high risk have an unfavorable prognosis. These men 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 RP, 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 RP 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 RP. Probabilities were generated using a logistic regression model in a prospective cohort of 2,342 prostate cancer patients.[5] The model is adjusted using a prevalence of 27% for a finding of primary Gleason grade 4 or 5 on RP among NCCN low-, intermediate- and high-risk patients.[5] Klein et al. 2016 study found Decipher Biopsy predicted high grade disease at RP with an AUC of 0.71.[3] 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 RP. 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 0.87.[3] 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.[2] The percent likelihood for this endpoint ranges from 0.3-67%. The average concordance between Decipher biopsy and RP specimens is 70%. Needle biopsy sampling accuracy impacts concordance.

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 RP. Probabilities are generated from a logistic regression analysis based upon a cohort of 557 patients with 112 prostate cancer deaths within 10 years post RP. These probabilities are adjusted for a PCSM cumulative incidence of 5% at 10 years post RP.[6] All non-PCSM patients in the study had at least 10 years of follow-up. In a validation study with a biopsy cohort of 235 patients, Decipher was a significant predictor of PCSM at diagnosis with a hazard ratio (HR) of 1.57 (95% CI 1.03–2.48) per 10% increase for Decipher score (p=0.037).[1] The percent likelihood for this endpoint ranges from 0.7-30.5%.

GenomeDx Medical Director (Signature)

Report Date

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

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TEST DESCRIPTION

Decipher uses oligonucleotide microarrays to measure 22 RNA expression biomarkers, extracted from formalin fixed paraffin embedded (FFPE) prostate biopsy specimens, to derive a Decipher score and corresponding probability of:

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

All probabilities reflect the likelihood of outcome upon the patient undergoing radical prostatectomy. The Decipher score ranges from 0 to 1.0.

INTENDED USE

Results from Decipher are intended for use by the physician and patient as an adjunct to conventional clinical variables and models currently used for determining prognosis of patients diagnosed with localized prostate cancer by biopsy. Decipher is intended for use in those patients who present with a low-, intermediate- or high-risk biopsy result according to NCCN Guidelines upon pathologic evaluation.

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%

DEFINITIONS

NCCN Low Risk: Includes men with a T1a, T1b, T1c, or T2a tumor AND PSA level less than 10 ng/mL, AND biopsy Gleason score of 6 or less.[8]

NCCN Intermediate Risk: Includes men with a T2b or T2c tumor OR PSA level between 10 and 20 ng/mL, OR biopsy Gleason score of 7.[8]

NCCN High Risk: Includes men with a T3a tumor, OR PSA level greater than 20 ng/mL, OR biopsy Gleason score between 8 and 10. Two or all three conditions of NCCN Intermediate Risk, as listed above, is also considered as NCCN High Risk.[7]

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 RP, 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 RP as first line treatment at the Mayo Clinic between 2000 and 2006.[4]

Decipher Genomic low or high risk: Based on the individualized genomic risk of metastasis identified by Decipher, these men have significantly higher (Decipher score > 0.60) or lower (Decipher score < 0.45) risk than the average clinical risk as defined above. These Decipher risk categories were selected by optimizing both the partial likelihood and hazard ratios in a series of Cox models. The categories were trained using data from the Karnes, et al. study and validated in Ross, et al. study.[4,8]

Clinical Metastasis: Regional (e.g., to regional lymph nodes) or distant (e.g., to bones) spread of cancer from the prostate as confirmed by positive CT and/or bone scan.

High Grade Disease: Primary Gleason grade 4 or 5 on surgical pathology.

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GenomeDx Accession ID: MC-001543

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