Decipher® prostate cancer classifier

Sample Patient Test Result

Decipher® prostate cancer classifier POST OP

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Decipher Post-Operative Report

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:

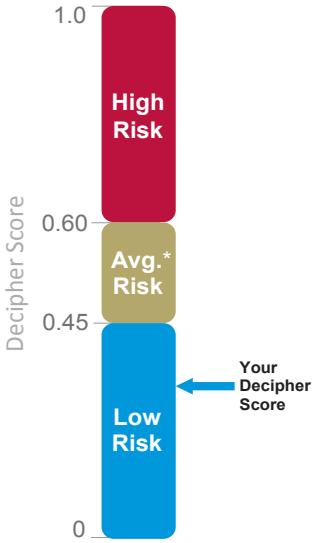
Clinical Details

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

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.[1,2] For these patients there were no significant differences in metastasis free survival with adjuvant, early or late salvage postoperative radiotherapy treatment.[4-6]

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]

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.[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.[1-6] 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.[2,7,8] 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.

CLIA ID # 05D2055897

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Test Description

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

- 5-year clinical metastasis
- 10-year prostate cancer specific mortality

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 and treatment of prostate cancer patients after radical prostatectomy. Decipher is intended for use in those patients who present with specific risk factors for the recurrence of prostate cancer after radical prostatectomy: (1) stage T2 disease with positive surgical margins, or (2) stage T3 disease, or (3) rising prostate-specific antigen (PSA) levels after initial PSA nadir when PSA is undetectable, or (4) preoperative PSA of 20 ng/mL or higher, or (5) lymph node involvement (LNI), or (6) high Gleason Score of 8-10.

Confidence Intervals

- Probability of 5-year metastasis reported here has a 95% confidence interval of 0.4% to 2.8%
- Probability of 10-year prostate cancer specific mortality reported here has a 95% confidence interval of 1.0% to 4.0%*

Definitions

Clinically High Risk: These men are at high risk of clinical metastasis as defined in the Karnes, et al. study cohort inclusion criteria, which was any of: preoperative Prostate-Specific Antigen (PSA) >20 ng/mL; pathologic Gleason score >8; Seminal Vesicle Invasion; GPSM nomogram >10.[10]

Average Clinical Risk: Refers to the average cohort risk of clinically high risk men in the pivotal Decipher validation study.[1] An average clinical risk of 6.0% was established in a cohort of 1,010 clinically high risk patients that received radical prostatectomy (robotic or open) as first line treatment at the Mayo Clinic between 2000 and 2006 (median 6.9 years of follow-up). The average incidence of metastasis was 6.0% at 5 years post radical prostatectomy.

Genomic Low or High Risk: Based on the individualized genomic risk of metastasis identified by Decipher, these men have significantly higher (Decipher result >0.6) or lower (Decipher result <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.[1,2,11]

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.

References

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10. Thompson, R.H.[1], et al., “Is the GPSM scoring algorithm for patients with prostate cancer valid in the contemporary era?” J Urol. 2007 Aug;178(2):459-63; discussion 463. Epub 2007 Jun 11. [1]Department of Urology and Division of Biostatistics, Mayo Clinic College of Medicine, Rochester, Minnesota 55905, USA.

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GenomeDx Accession ID: DEC16981

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