**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**

**Decipher Score 0.3**

### 5-Year Metastasis
- **Risk - Percent Likelihood:** 1.6%

### 10-Year Prostate Cancer Specific Mortality
- **Percent Likelihood:** 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

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*References on reverse*
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

Clinical 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. 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


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.

GenomeDx Accession ID: DEC16981

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