Decipher®
prostate cancer classifier

Does my patient need more therapy after prostate cancer surgery?

Contact the GenomeDx Patient Care Team at: **1.888.792.1601 (toll-free)** or e-mail: **client.services@genomedx.com**

Introducing Decipher® Prostate Cancer Classifier

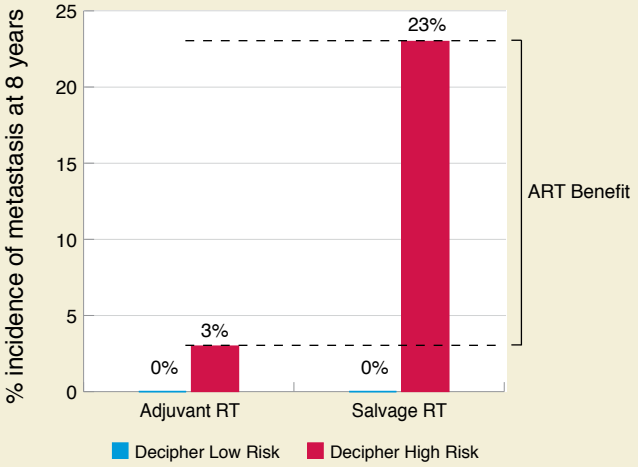
Decipher classifies post-surgery patients* into genomic risk categories for metastasis with 98.5% Negative Predictive Value (NPV).

Know if your patient needs therapy after a radical prostatectomy (RP)

Decipher Classification	Treatment post-surgery
High Risk	Adjuvant therapy
Low Risk	Observation with PSA monitoring

Decipher high risk patients significantly benefitted from adjuvant radiotherapy[6]

Decipher low risk patients show no benefit from adjuvant radiotherapy[6]



Decipher data speaks for itself

- AUA, ASTRO and ASCO guidelines acknowledge radiotherapy candidates are at different risk levels for disease progression, and thus experience varying degrees of benefit from adjuvant radiotherapy.[1,2] NCCN supports use of tumor-based molecular testing when determining risk for disease progression after surgery.[3]
- Decipher has been validated in over 1,500 patients in clinical studies with top U.S. Cancer Centers (including Mayo Clinic, Johns Hopkins University, Thomas Jefferson University, Cleveland Clinic).[4-10]
- Decipher reclassified 60% of men to lower risk categories, in clinical studies of high-risk men after surgery.[9]

References

*Clinically High Risk Patients with pT3, Positive Margins, or Biochemical Recurrence (BCR).

[1]Thompson, I.M., et al., Adjuvant and Salvage Radiotherapy After Prostatectomy: AUA/ASTRO Guideline. J Urol, 2013. 190: p. 441-449.

[2]Freedland, S.J., et al., Adjuvant and Salvage Radiotherapy After Prostatectomy: American Society of Clinical Oncology Clinical Practice Guideline Endorsement. J Clin Oncol, 2014. 32(34): p. 3892-8.

[3]NCCN. NCCN Clinical Guidelines in Oncology (NCCN Guideline). Prostate Cancer. Version 1. 2015. [cited 2014 October 24, 2014]; Available from: http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.p. 3892-8.

[4]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, In press, 2015. doi: 10.1200/JCO.2014.59.0026.

[5]Klein, E. et al. A Genomic Classifier Improves Prediction of Metastatic Disease Within 5 Years After Surgery in Node-Negative High-Risk Prostate Cancer Patients Managed by Radical Prostatectomy Without Adjuvant Therapy. European Urology, Epub ahead of print, Nov 13, 2014, dii: 10.1016/j.eururo.2014.10.036.

[6]Den, R. 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 1; 89(5): 1038-46.

[7]Ross, A.E., et al. A Genomic Classifier Predicting Metastatic Disease Progression in Men with Biochemical Recurrence After Prostatectomy. Prostate Cancer and Prostatic Diseases, 2014, 17, 64-69.

[8]Cooperberg, M.R., et al. Combined Value of Validated Clinical and Genomic Risk Stratification Tools for Predicting Prostate Cancer Mortality in a High-risk Prostatectomy Cohort. European Urology, Epub ahead of print, Jul 2 2014. doi: 10.1016/j.eururo.2014.05.039.

[9]Karnes, R.J., et al. Validation of a Genomic Classifier that Predicts Metastasis Following Radical Prostatectomy in an At Risk Patient Population. J Urol, 2013 Dec, 190(6), 2047-2053.

[10]Erho, N., et al., Discovery and Validation of a Prostate Cancer Genomic Classifier that Predicts Early Metastasis Following Radical Prostatectomy. PLoSOne. 2013 Jun 24;8(6):e66855.

Decipher® prostate cancer classifier

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Patient Details

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

Order Information

Order Date:
Specimen Received Date: 11/17/2014
GenomeDx Accession ID:
Specimen ID:

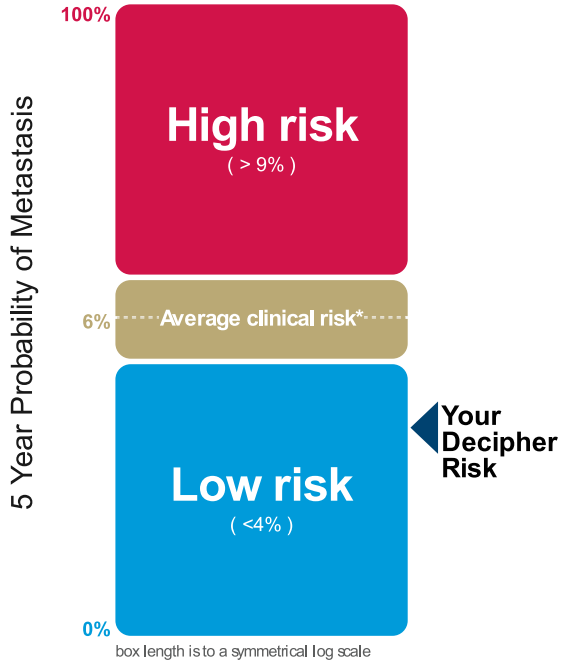
Ordering Physician:
Clinic/Hospital:

Clinical Details

Pathology Report Date: 01/04/2013
Referring Pathologist/Laboratory:

Pre-operative PSA (ng/mL): 6.0
Gleason Score (Surgical Pathology): 4+3
☒ EPE ☐ SVI ☒ SM+ ☐ LNI ☐ BCR

Decipher Result: Genomic low risk



Summary of Decipher genomic risk results

Decipher 5 year risk of metastasis: 2.3%

Genomic risk of developing metastasis within five years of radical prostatectomy is **0.4x** the average clinical risk for a patient with adverse pathology.

Comments: Decipher indicates a patient`s probability of developing metastasis within 5 years of a radical prostatectomy. The average risk* for metastasis by 5 years after surgery for clinically high-risk men is 6.0%. The Decipher risk reported here has a 95% confidence interval of 0.8% to 3.8%, which is significantly lower than average clinical risk and therefore the patient is considered to have a lower than average risk of clinical recurrence within 5 years.

*Average clinical risk refers to the average cohort risk of clinically high-risk men post surgery, established in a cohort of 1,010 clinically high-risk patients that received radical prostatectomy as first line treatment at the Mayo Clinic between 2000 and 2006. The average incidence of metastasis was 6.0% at 5 years post radical prostatectomy.

5-year Predicted Probability of Clinical Metastasis: a genomic risk score is derived by measuring the RNA expression of 22 biomarkers in a primary prostate adenocarcinoma specimen (Erho et al., 2013). Decipher uses the genomic risk score to predict the 5 year probability for developing clinical metastasis; using a cox-proportional hazards survival model based upon a cohort of 1,010 clinically high-risk patients with 6.9 median years of follow-up (Karnes et al., 2013). Decipher probabilities range between 0% and 100%. Decipher risk categories are determined from an optimized statistical model, representing significantly distinct metastatic risk (hazard ratios) between the risk categories. Relative risk is calculated as a ratio of the patient`s Decipher probability as compared to the 6.0% average risk of clinical metastasis observed in this population of clinically high-risk men.

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

11/27/2014
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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Hassle-free Testing for Patients and Physicians

Access for All Patients

- **Medicare Coverage**
  Only post-RP test to receive positive coverage response from CMS
- **Private Insurance Coverage**
  All plans accepted
  In-network status expanding
- **Proven, and comprehensive financial assistance for patients**
  Vast majority of non-insured patients qualify
  Affordable out of pocket
- **Proactive patient outreach by GenomeDx Client Services Team**
  Minimizing calls from patients to physician regarding billing questions and concerns

1 Test Request
The test must be ordered by a practicing physician.

2 Verification
GenomeDx checks test request form and insurance details. Patient eligibility for financial assistance assessed.

3 Tissue Sample Request
GenomeDx will request the tissue sample from the pathology lab for processing.

4 Decipher® Test
The Decipher test is run.

5 Test Results
Test result sent to ordering physician.

6 Consultation & Review
Patient and physician review Decipher results.

To learn more about Decipher® , visit www.DecipherTest.com or contact the GenomeDx Patient Care Team today at 1.888.792.1601 (toll free)

GenomeDx BIOSCIENCES

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