Decipher® prostate cancer classifier

Sample Patient Test Result

Decipher® prostate cancer classifier

GenomeDx Biosciences Laboratory
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Patient Details

Patient Name: John Doe
Medical Record Number: 123456789
Date of Birth: 01/01/1945
Date of Prostatectomy: 02/12/2014

Order Information

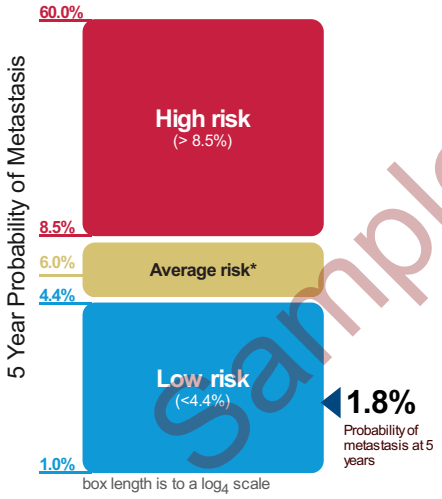
Order Date: 03/14/2014
Specimen Received Date: 03/21/2014
GenomeDx Accession ID: DEC123
Specimen ID: PS12-34567 A10
Ordering Physician: Dr. Physician
Clinic/Hospital: Urology Clinic
1234 Anytown, USA

Clinical Details

Pathology Report Date: 02/14/2014
Referring Pathologist/Laboratory: Dr. Pathologist

Pre-operative PSA (ng/mL): 6.2
Gleason Score (Surgical Pathology): 4+3
☑ EPE ☐ SVI ☑ SM+ ☐ LNI ☐ BCR

Patient's Decipher Risk



Summary of Results

Interpretation: Lower than average risk

Patient's Decipher Risk	**1.8%**
Cohort Average Risk*	6.0%
Relative Risk (Decipher/Average)	0.3X

Decipher Test Result: Decipher probability of developing clinical metastasis within five years of radical prostatectomy: **1.8%** (0.3 times the average risk observed in a clinical study of high risk patients).

Comments: Decipher indicates a patient's probability of developing clinical metastasis within five years of a radical prostatectomy. The average risk for clinical metastasis by five years after radical prostatectomy for clinically high-risk men is 6.0%. The Decipher risk reported here has a 95% confidence interval of 0.8% to 2.8%, which is lower than the average risk and therefore patient is considered to have a lower than average risk of clinical recurrence within that time frame.

***The average risk** 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). A 6.0% rate of metastasis (average risk) was observed at 5 years post radical prostatectomy.

5-Year Predicted Probability of Clinical Metastasis: A genomic risk score is derived by measuring the RNA expression for 22 biomarkers in a primary prostate adenocarci-noma 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 (Karnes et al. 2013)median years of follow-up. Decipher probabilities range between 0% and 100% and relative risk is calculated as a ratio of the patient's Decipher probability to the average risk of Clinical Metastasis observed in a population of Clinically High-Risk men.

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 5 year probability of clinical metastasis after radical prostatectomy. The Decipher probabilities range from 0% to 100%.

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.

Definitions

Clinically High-Risk These men are at high risk of clinical metastasis as defined in the cohort inclusion criterion, which was any of: pre-operative prostate specific antigen (PSA) >20 ng/ml; pathologic Gleason score ?8; Seminal Vesicle Invasion; GPSM nomogram ? 10 (Thompson, 2007)

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.

Relative risk The ratio of the patient's predicted probability of developing clinical metastasis to the average risk (average patient risk in the cohort of 1,010 patients).

References

1. N. Erho, A. Crisan, I. A. Vergara, A. P. Mitra, M. Ghadessi, C. Buerki, E. J. Bergstralh, T. Kollmeyer, S. Fink, Z. Haddad, B. Zimmermann, T. Sierocinski, K. V Ballman, T. J. Triche, P. C. Black, R. J. Karnes, G. Klee, E. Davicioni, and R. B. Jenkins, **Discovery and Validation of a Prostate Cancer Genomic Classifier that Predicts Early Metastasis Following Radical Prostatectomy,** *PLoS One, vol. 8, no. 6, p. e66855*, 2013.

2. R. J. Karnes, E. J. Bergstralh, E. Davicioni, M. Ghadessi, C. Buerki, A. P. Mitra, A. Crisan, N. Erho, I. A. Vergara, L. L. Lam, R. Carlson, D. J. S. Thompson, Z. Haddad, B. Zimmermann, T. Sierocinski, T. J. Triche, T. Kollmeyer, K. V Ballman, P. C. Black, G. G. Klee, and R. B. Jenkins, **Validation of a Genomic Classifier that Predicts Metastasis Following Radical Prostatectomy in an At Risk Patient Population.,** *J. Urol., Vol. 190, no. 6,* pp. 2047-53, Dec. 2013.

3. Thompson, R. H., Blute, M. L., Slezak, J. M., Bergstralh, E. J., & Leibovich, B. C. **Is the GPSM scoring algorithm for patients with prostate cancer valid in the contemporary era?** *The Journal of Urology*. 2007. 178(2), 459-63.

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GenomeDx accession ID: DEC567

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