DECIPHER PROSTATE RP

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DECIPHER RADICAL PROSTATECTOMY REPORT

PATIENT DETAILS

Patient Name: **Hector Tester**
MRN/Patient ID: **23948207**
Date of Birth: **12/04/1973**
Date of Prostatectomy: **06/04/2015**

Pathology Laboratory: **Desert Valley Hospital Pathology**
Pathologist: **Yvonne Noronha, MD**
Address: **16850 Bear Valley Road, Victorville, CA 92392, USA**

ORDER INFORMATION

Order Date: **02/09/2016**
Specimen Received Date: **03/14/2016**
Accession ID: **MC-001359**
Specimen ID: **S15-1133-A14**
Ordering Physician: **Ilbeigi, Pedram**
Clinic/Hospital Name: **Urological Institute of High Desert 18400A**
Clinic/Hospital Address: **18400 Highway 18 N Ste A, Apple Valley, CA 92307, USA**

CLINICAL DETAILS

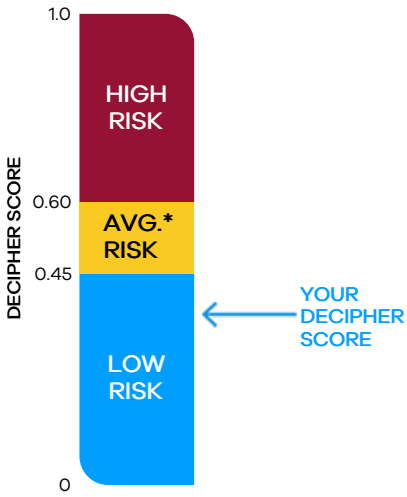
Pre-operative PSA (ng/mL): **7.78**

Specimen Type: **Radical Prostatectomy**

Grade Group: **3**

- ☐ Positive Surgical Margins (SM+)
- ☐ Bladder Neck Invasion (BNI)
- ☐ Extraprostatic Extension (EPE)
- ☐ Biochemical Recurrence (BCR)
- ☑ Seminal Vesicle Invasion (SVI)

YOUR DECIPHER RESULT: GENOMIC LOW RISK



DECIPHER SCORE: 0.36

Risk at RP - Percent Likelihood	
5-Year Metastasis	**2.3%**
10-Year Prostate Cancer Specific Mortality	**3.2%**

INTERPRETATION

References on reverse

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.[1-3,8] Upon PSA rise, these patients may be treated with delayed radiotherapy without concurrent hormone therapy.[4,7,14]

Relevant findings from published clinical studies: Patients with Decipher low risk had > 97% 5-year metastasis free survival and > 94.7% 10-year cause specific survival.[1,2,3] For these patients there were no significant differences in metastasis free survival with adjuvant, early or late salvage post-operative radiotherapy treatment.[5,6,7]

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.[4,14]

Additional Comment: Tumor heterogeneity exists in most cancers, including prostate. To ensure that the most aggressive tumor tissue was evaluated, analysis was repeated on two different areas of the tumor. Both samples resulted in a low risk Decipher score. The higher score was reported here.

*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.[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 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.[1] Decipher had an AUC of 0.76-0.86 in multiple clinical validation studies for prediction of metastasis.[1-6,9,10,14] 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 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.[11] All non-PCSM patients in the study had at least 10 years of follow-up. Decipher had an AUC of 0.73 in predicting PCSM.[2,11,13] Percent likelihood for this endpoint ranges from 0.7-30.5%.

Medical Director (Signature)
Bashar Dabbas, MD

Report Date

Summary of surgical pathology report is provided for the convenience of the Ordering Physician. Please refer to Referring Pathologist's original pathology report to guide treatment decisions.

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DECIPHER RADICAL PROSTATECTOMY REPORT

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 probability of 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.

CONFIDENCE INTERVALS

- Probability of 5-year metastasis reported here has a 95% confidence interval of 0.8% to 3.8%

- Probability of 10-year Prostate Cancer Specific Mortality reported here has a 95% confidence interval of 1.5% to 4.8%

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: pre-operative 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 metastasis at 5 years post 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.[1]

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]

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

1. Karnes RJ, Bergstralh EJ, Davicioni E, et al. Validation of a genomic classifier that predicts metastasis following radical prostatectomy in an at risk Patient population. J Urol. 2013;190(6):2047-2053.
2. Ross AE, Johnson MH, Yousefi K, et al. Tissue-based Genomics Augments Post-prostatectomy Risk Stratification in a Natural History Cohort of Intermediate- and High-Risk Men. Eur Urol. 2016;69(1):157-165.
3. Glass AG, Leo MC, Haddad Z, et al. Validation of a Genomic Classifier for Predicting Post-Prostatectomy Recurrence in a Community Based Health Care Setting. J Urol. 2016;195(6):1748-1753.
4. Freedland SJ, Choeurng V, Howard L, et al. Utilization of a Genomic Classifier for Prediction of Metastasis Following Salvage Radiation Therapy after Radical Prostatectomy. Eur Urol. 2016;70(4):588-596.
5. Den RB, Feng FY, Showalter TN, et al. Genomic prostate cancer classifier predicts biochemical failure and metastases in patients after postoperative radiation therapy. Int J Radiat Oncol Biol Phys. 2014;89(5):1038-1046.
6. Den RB, Yousefi K, Trabulsi EJ, et al. Genomic classifier identifies men with adverse pathology after radical prostatectomy who benefit from adjuvant radiation therapy. J Clin Oncol. 2015;33(8):944-951.
7. Ross AE, Den RB, Yousefi K, et al. Efficacy of post-operative radiation in a prostatectomy cohort adjusted for clinical and genomic risk. Prostate Cancer Prostatic Dis. 2016;19(3):277-282.
8. Spratt DE, Yousefi K, Deheshi S, et al. Individual Patient-Level Meta-Analysis of the Performance of the Decipher Genomic Classifier in High-Risk Men After Prostatectomy to Predict Development of Metastatic Disease. J Clin Oncol. 2017;35(18):1991-1998.
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11. Eggener SE, Scardino PT, Walsh PC, et al. Predicting 15-Year Prostate Cancer Specific Mortality After Radical Prostatectomy. J Urol. 2011;185(3):869-875.
12. Thompson RH, Blute ML, Slezak JM, Bergstralh EJ, Leibovich BC. Is the GPSM Scoring Algorithm for Patients With Prostate Cancer Valid in the Contemporary Era? J Urol. 2007;178(2):459-463.
13. Karnes RJ, Choeurng V, Ross AE, et al. Validation of a Genomic Risk Classifier to Predict Prostate Cancer-specific Mortality in Men with Adverse Pathologic Features. Eur Urol. April 2017. doi:10.1016/j.eururo.2017.03.036.
14. Spratt DE, Dai DLY, Den RB, et al. Performance of a Prostate Cancer Genomic Classifier in Predicting Metastasis in Men with PSA Persistence Post-Prostatectomy. Eur Urol. 2017 Dec 10. pii: S0302-2838(17)31016-3. doi: 10.1016/j.eururo.2017.11.024.

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DECIPHER RADICAL PROSTATECTOMY REPORT

PATIENT DETAILS

Patient Name: **Brian Tester**
MRN/Patient ID: **Not Provided**
Date of Birth: **12/04/1975**
Date of Prostatectomy: **07/18/2012**

Pathology Laboratory: **Saint Francis Hospital**
Pathologist: **Anne Jordan, MD**
Address: **Department of Pathologist 5959 Park Ave, Memphis, TN 38119, USA**

ORDER INFORMATION

Order Date: **03/08/2016**
Specimen Received Date: **03/14/2016**
Accession ID: **MC-001361**
Specimen ID: **SC12-4687-A12**
Ordering Physician: **Rayford, Walter**
Clinic/Hospital Name: **The Urology Group, P.C.**
Clinic/Hospital Address: **6029 Walnut Grove Rd Suite 300, Memphis, TN 38120, USA**

CLINICAL DETAILS

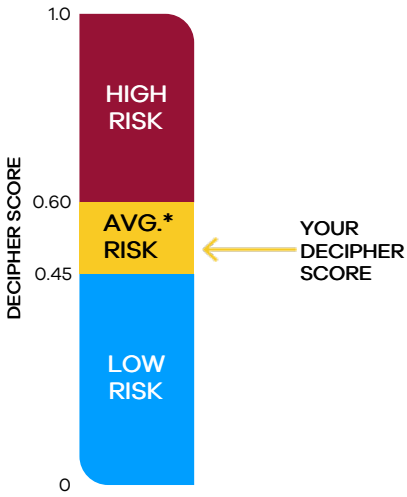
Pre-operative PSA (ng/mL): **21.8**

Specimen Type: **Radical Prostatectomy**

Gleason Score: **4+3**

- ☐ Positive Surgical Margins (SM+)
- ☑ Bladder Neck Invasion (BNI)
- ☐ Extraprostatic Extension (EPE)
- ☑ Biochemical Recurrence (BCR)
- ☐ Seminal Vesicle Invasion (SVI)

YOUR DECIPHER RESULT: GENOMIC AVERAGE RISK



DECIPHER SCORE: 0.50

Risk at RP - Percent Likelihood	
5-Year Metastasis	**5.1%**
10-Year Prostate Cancer Specific Mortality	**5.4%**

INTERPRETATION

References on reverse

Clinical studies concluded that Decipher average risk men with adverse pathology have an average prognosis and may benefit from adjuvant or early salvage radiotherapy.[1-8,14]

Relevant findings from published clinical studies: Patients with Decipher average risk had 94% 5-year metastasis free survival and 92.6% 10-year cause specific survival.[1,2,3]

These patients had outcomes consistent with the average clinical risk of patients with adverse pathology. For these patients there was improved metastasis-free survival favoring adjuvant and early salvage post-operative radiotherapy.[5,6,7]

In patients with PSA rise or biochemical recurrence after surgery that received salvage radiotherapy, 91.6% remained metastasis free after 5 years.[4,14]

*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.[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 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.[1] Decipher had an AUC of 0.76-0.86 in multiple clinical validation studies for prediction of metastasis.[1-6,9,10,14] 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 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.[11] All non-PCSM patients in the study had at least 10 years of follow-up. Decipher had an AUC of 0.73 in predicting PCSM.[2,11,13] Percent likelihood for this endpoint ranges from 0.7-30.5%.

Medical Director (Signature)
Bashar Dabbas, MD

Report Date

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- 5-year probability of 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.

CONFIDENCE INTERVALS

- Probability of 5-year metastasis reported here has a 95% confidence interval of 2.9% to 7.3%

- Probability of 10-year Prostate Cancer Specific Mortality reported here has a 95% confidence interval of 3.3% to 7.4%

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: pre-operative 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 metastasis at 5 years post 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.[1]

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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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DECIPHER RADICAL PROSTATECTOMY REPORT

PATIENT DETAILS

Patient Name: **Robert Tester**
MRN/Patient ID: **Not Provided**
Date of Birth: **12/04/1970**
Date of Prostatectomy: **10/15/2015**

Pathology Laboratory: **Desert Valley Hospital Pathology**
Pathologist: **Yvonne Noronha, MD**
Address: **16850 Bear Valley Road, Victorville, CA 92392, USA**

ORDER INFORMATION

Order Date: **02/09/2016**
Specimen Received Date: **03/14/2016**
Accession ID: **MC-001354**
Specimen ID: **S15-2130-A10**
Ordering Physician: **Ilbeigi, Pedram**
Clinic/Hospital Name: **Urological Institute of High Desert 18400A**
Clinic/Hospital Address: **18400 Highway 18 N Ste A, Apple Valley, CA 92307, USA**
Additional Physician: **Wallace, Jordan**

CLINICAL DETAILS

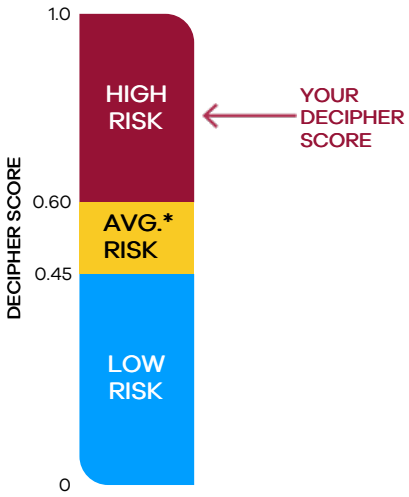
Pre-operative PSA (ng/mL): **21.8**

Specimen Type: **Radical Prostatectomy**

Grade Group: **5**

- [x] Positive Surgical Margins (SM+)
- [ ] Bladder Neck Invasion (BNI)
- [x] Extraprostatic Extension (EPE)
- [ ] Biochemical Recurrence (BCR)
- [ ] Seminal Vesicle Invasion (SVI)

YOUR DECIPHER RESULT: GENOMIC HIGH RISK



DECIPHER SCORE: 0.78

Risk at RP - Percent Likelihood	
5-Year Metastasis	**25.5%**
10-Year Prostate Cancer Specific Mortality	**15.3%**

INTERPRETATION

References on reverse

Clinical studies concluded that Decipher high risk men with adverse pathology have a poor prognosis overall.[1-3,8] These men may benefit from adjuvant or early salvage radiotherapy and consideration for clinical trials.[4-6,14]

Relevant findings from published clinical studies: Patients with Decipher high risk had 77.5% 5-year metastasis free survival and 70.0% 10-year cause specific survival.[1,2,3,9] For these patients there was improved metastasis-free survival favoring adjuvant and early salvage post-operative radiotherapy compared to post-operative observation.[5,6,7]

In patients with PSA rise or biochemical recurrence after surgery that received salvage radiotherapy, only 66.9% remained metastasis free after 5 years.[4,14]

Additional Comment: Tumor heterogeneity exists in most cancers, including prostate cancer. To ensure that the most aggressive tumor tissue was evaluated, analysis was repeated on two different areas of the tumor. The higher Decipher risk score was reported.

*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.[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 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.[1] Decipher had an AUC of 0.76-0.86 in multiple clinical validation studies for prediction of metastasis.[1-6,9,10,14] 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 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.[11] All non-PCSM patients in the study had at least 10 years of follow-up. Decipher had an AUC of 0.73 in predicting PCSM.[2,11,13] Percent likelihood for this endpoint ranges from 0.7-30.5%.

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INTENDED USE

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CONFIDENCE INTERVALS

- Probability of 5-year metastasis reported here has a 95% confidence interval of 16.8% to 33.4%

- Probability of 10-year Prostate Cancer Specific Mortality reported here has a 95% confidence interval of 7.8% to 22.7%

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: pre-operative 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 metastasis at 5 years post 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.[1]

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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.

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