



Providing Treatment Information for Prostate Cancer Patients after Biopsy and Surgery



The Decipher Biopsy and Decipher Post-Op tests help you and your doctor decide next steps in your prostate cancer care.



Contact the GenomeDx Customer Support Team
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BIOPSY



Know your prostate cancer risk

The Decipher Biopsy test is the most accurate way to determine the aggressiveness of your prostate cancer and assess your personal risk of metastasis. Using advanced whole genome technology, Decipher Biopsy provides valuable information to you and your doctor so that you can make more informed decisions about your next steps in managing your prostate cancer.



- Is active surveillance through PSA monitoring sufficient for me?
- Is localized treatment sufficient?
- Do I need more than one therapy (multi-modal therapy)?

Decipher Classification

Patient Management Recommendations

Decipher Biopsy Low Risk	Favorable prognosis – may be suitable for active surveillance and may have excellent outcomes with local therapy alone¹⁻³
Decipher Biopsy High Risk	Unfavorable prognosis – may not be suitable for active surveillance and may benefit from intensification with multi-modal therapy¹⁻³

References:

1. Klein, E.A., et al., Decipher Genomic Classifier Measured on Prostate Biopsy Predicts Metastasis Risk. *Urology*, 2016; DOI: <http://dx.doi.org/10.1016/j.urology.2016.01.012>
2. Knudsen, B.S., et al., Application of a Clinical Whole-Transcriptome Assay for Staging and Prognosis of Prostate Cancer Diagnosed in Needle Core Biopsy Specimens. *Journal of Molecular Diagnostics*, 2016; In Press.
3. Lee, Hak J., et al., "Evaluation of a Genomic Classifier in Primary Tumor and Lymph Node Metastases in Pre- and Post-Radical Prostatectomy Tissue Specimens from Patients with Lymph Node Positive Prostate Cancer" presented at the 2015 annual meeting of the American Society of Clinical Oncology.



Answer the following questions to determine if Decipher[®] Biopsy is right for you:

Have you had a prostate biopsy positive for cancer? . . . **Y** **N**

Did your doctor indicate that any of the following apply to you after biopsy?

Very Low Risk

- Prostate Cancer Stage T1c tumor, AND biopsy Gleason score of 6 or less, AND PSA level less than 10ng/mL, AND presence of disease in fewer than 3 biopsy cores, AND less than 50% prostate cancer involvement in any core, AND PSA density less than 0.15 ng/mL/g.

Low Risk

- Prostate Cancer Stage T1a, T1b, T1c, or T2a tumor, AND PSA level less than 10ng/mL, AND biopsy Gleason score of 6 or less.

Intermediate Risk

- T2b or T2c tumor, OR PSA level between 10-20ng/mL, OR biopsy Gleason score of 7

High Risk

- T3a tumor, OR PSA level greater than 20ng/mL, OR biopsy Gleason score between 8 and 10

If you answered **yes** to any of the questions, then the Decipher Biopsy test may play a role in determining what type of therapy you may need.

Contact your doctor to find out how Decipher might play a role in your treatment planning or contact the GenomeDx Customer Support Team at 1.888.792.1601 (toll-free) or e-mail customersupport@genomedx.com.

POST OP



Not all prostate cancers are alike

The Decipher test:

- Tells you how likely your cancer is to spread (or metastasize) beyond your prostate
- Categorizes most patients into Decipher high or low risk, to help determine what to do after your prostate has been removed (radical prostatectomy)

Decipher Test Result	Treatment After Your Prostate Cancer Surgery	Treatment for detectable PSA rise (Biochemical Recurrence)
High Risk	May benefit from early radiation ^{1,2}	May require intensification of therapy beyond radiation ³
Low Risk	May be safely managed with observation until PSA rise (if any) ^{1,2}	Excellent prognosis with SRT and may avoid concurrent hormone therapy ³

References

1. Den, R.B., et al., A genomic classifier identifies men with adverse pathology after radical prostatectomy who benefit from adjuvant radiation therapy. *J of Clin Oncol* 2015; 33:944-951.
2. 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.
3. Freedland, S.J., et al., Utilization of a genomic classifier for prediction of metastasis following salvage radiation therapy after radical prostatectomy. *European Urology*. 2016; DOI: 10.1016/j.eururo.2016.01.008.



Answer the following questions to determine if Decipher[®] is right for you:

Y **N**

Have you had a radical prostatectomy (prostate removed) to treat your prostate cancer?

Did your doctor indicate that any of the following applied to you after surgery?

Medicare Indications

- Positive surgical margins
- Extraprostatic extension.
- Seminal Vesicle Invasion
- Bladder Neck Invasion.
- Has your PSA started to rise after surgery?

Additional Indications

- Was your pre-surgery PSA 20ng/mL or higher?
- High Gleason Score (≥ 7)
- Tertiary Gleason 5
- Perineural or Lymphovascular Invasion
- Lymph node involvement

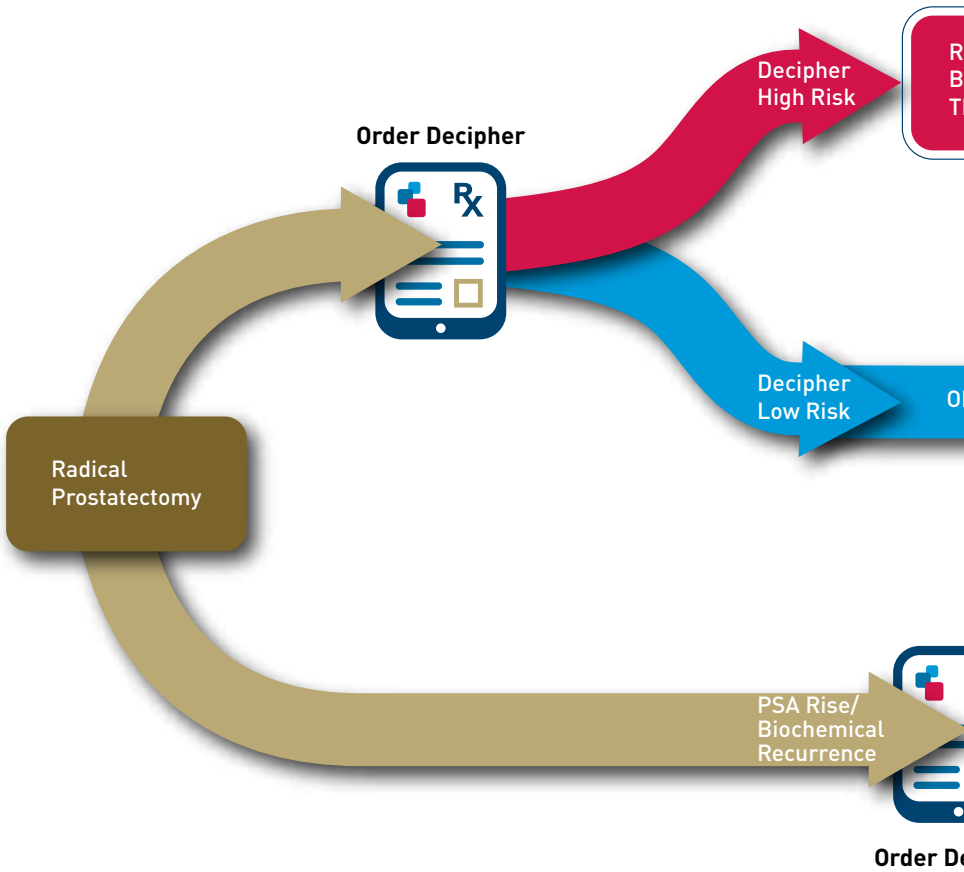
If you answered **yes** to any of the above questions, then Decipher may play a role in determining if and when you need additional therapy after surgery. If you have at least one of the Medicare indications, you will have **no out-of-pocket cost**.



This test is covered by Medicare. We accept all private insurance plans and have a generous financial aid program for qualified patients.

Contact your doctor to find out how Decipher might play a role in your postoperative treatment planning or contact the GenomeDx Customer Support Team at 1.888.792.1601 (toll-free) or e-mail customersupport@genomedx.com.

General Overview



Please discuss further details with your doctor.

*Salvage radiation therapy (SRT)

radiation (ART
letter Results
than SRT)



Observation

PSA Rise/BCR

Excellent prognosis
with SRT* and may
avoid concurrent
hormone therapy

Rx

Decipher

Decipher
High Risk

May require
intensification of
therapy beyond
radiation

Decipher
Low Risk

Excellent prognosis
with SRT* and may
avoid concurrent
hormone therapy



What is the Decipher Test?

Based on the patient's personal tumor-based genomics, Decipher Prostate Cancer Classifier:

Decipher Biopsy

- Performed on your prostate biopsies diagnosed as positive for cancer
- May help determine which men may be suitable candidates for active surveillance, which may need local therapy, and which men may need intensified therapy

Decipher Post-Op

- Performed on your prostate after surgery (after it has been removed)
- May help determine which men after prostate surgery can be safely monitored and which men need additional treatment

Access for All Patients

- Medicare Coverage (MoD Dx LCD ID L35868): Decipher Post-Op test covered for Medicare beneficiaries
- Private Insurance Coverage
- Proven and comprehensive financial assistance for patients

To learn more about Decipher, contact the GenomeDx Customer Support Team at 1.888.792.1601 (toll free) or email at customersupport@genomedx.com.

