



Informed Consent for Molecular/Genomic Testing

Purpose. As part of our ongoing commitment to providing state-of-the-art care customized to the needs of each individual patient, our practice has incorporated certain molecular and genetic tests which adds valuable prognostic information for patients beyond the clinical-pathologic features of your disease, if present. **These tests may be ordered in two specific instances by your physician.**

YOU ARE NOT OBLIGATED TO SIGN THIS CONSENT BEFORE YOUR BIOPSY.

1. If your biopsy results reveal prostate cancer which falls into certain categories your physician has advised the pathology lab to submit your tissue for further genetic testing using Decipher[®], performed by Decipher Biosciences, Inc. (“Decipher”). These categories include all biopsies with certain pathological scores within certain defined risk categories based on other factors including your PSA and exam, and are based on extensive review of local and national prostate biopsy results. This test utilizes an assay of 22 genes combined with a proprietary machine-learning algorithm to determine the biological nature of your tumor. The test provides the Decipher[®] Score, which your doctor will use along with other factors to provide you better information with regards to treatment options or whether initial treatment is necessary at all.

If you agree to have this test performed please sign in the first box below at the time of your biopsy.

Test Procedure. Decipher will obtain a sample of your prostate cancer tissue (either biopsy or radical prostatectomy) from the pathology lab that is storing your tissue. The sample will then be analyzed to determine your Decipher Score. Additional information about testing can be found on Decipher’s patient website at www.decipherbio.com.

Benefits. The Decipher test measures how likely it is that your cancer spreads, or its aggressiveness. Because all prostate cancers are not the same, getting a Decipher[®] Score will tell your doctor additional information about your cancer’s aggressiveness. Decipher provides unique information about your cancer, and may help you and your doctor make a more informed decision about your treatment decision.

Test Results and Interpretation. Your results will be evaluated in the context of your clinico-pathologic features, personal health history and the clinical impression of your healthcare provider. Decipher keeps test results confidential and is fully in compliance with all Health Insurance Portability and Accountability Act (HIPAA) regulations.

- Biopsy Test Result – Result will provide an estimate of the risk that your cancer will spread within 5 years, the risk of prostate cancer specific mortality at 10 years or the likelihood of adverse pathology upon removal of your prostate.
- Post Radical Prostatectomy Result- Result will provide an estimate of the risk that your cancer will spread within 5 years and/or the risk of prostate cancer specific mortality at 10 years.

Risks. No test result will be provided if there is insufficient cancer tissue to run the test. Any unused tissue will be returned to the pathology lab that sent the tissue. However, Decipher may exhaust the tissue sample provided in performing the Decipher test.

Financial Responsibility. Decipher will work with your insurance provider to help get the appropriate coverage allowed by your plan. You will be responsible for paying out-of-pocket costs, which may include copays, coinsurance and/or deductibles as assigned by your health plan. **If your out-of-pocket costs will exceed \$395, you will be contacted by Decipher to discuss your eligibility for patient assistance programs including Decipher Assist.**

Patient Consent Statement: By signing below, I, the patient having the test performed according to the guidelines outlined in #1 above, acknowledge:

- I have been offered the opportunity to ask questions and discuss with my healthcare provider the benefits and risks of the test(s) to be performed as indicated on the associated test request form or follow-on tests ordered by my provider.
- I have read the document in its entirety and realize I may retain a copy for my records
- I consent to be tested for the risk of disease progression and I will discuss the results and appropriate medical management with my health care provider.

Name of patient (please print)

Date of birth

Signature of patient (or guardian)

Date

2. There are a number of alternate genomic markers which may offer benefit to you and your urologist when you discuss the results of your biopsy. Some of these tests are done on biopsies that do not show cancer and others are done on biopsies with cancer but do not fall into category (1) as outlined in page 1 of this document. Your doctor may want to order this test on your specimen.

Test procedure. The pathology lab will provide the outside lab doing the testing with your tissue sample which will be analyzed. The tests that are included in this consent are Confirm MDX®, Oncotype DX®, Decipher® and Prolaris®. Specifics regarding each test are in the table below:

Test Name	Service Provider	Clinical Indication
Confirm MDX®	MDxHealth Inc.	may be useful in evaluating the need for repeat biopsies when the initial biopsy shows no cancer
Oncotype DX®	Genomic Health Inc.	predicts likelihood that your prostate cancer has less favorable pathology and can be used to predict whether the cancer is confined to your prostate
Decipher®	Decipher Biosciences, Inc.	predicts the 5 year spread of disease, 10 year prostate cancer specific mortality, and the risk of adverse pathology upon removal of the prostate
Prolaris®	Myriad Genetic Laboratories, Inc	predicts the risk of disease progression as well as your prostate cancer specific risk of dying of the disease

Test Results and Interpretation.

Your provider will use the information from the selected test along with other information including your overall health, other lab data, and the pathology results to help you make a more informed decision about your treatment or further testing.

Risks

There is only a finite amount of tissue available for testing. This tissue may be exhausted by doing one of the tests making it unavailable for further testing in the future.

Financial Responsibility

Test Name	Clinical Indication
Confirm MDX®	Traditional Medicare patients will be covered with \$0 out of pocket Commercial insurance patients may be responsible for any co-insurance, deductible or co-pay whether you are in-network or out-of-network. If you have any billing questions either prior to or after your biopsy, please contact Linda Sheldon at MDxHealth at 866-259-5644 ext. 4213

<p>Oncotype DX®</p>	<p>Medicare has established coverage for the Oncotype DX Prostate Cancer test for qualified Medicare patients with early-stage prostate cancer. For patients with commercial insurance Genomic Help has “Genomic Access Program” which will predetermine your coverage and contact you if your out-of-pocket cost exceeds \$100.</p>
<p>Decipher®</p>	<p>Medicare has established coverage for Decipher for men with localized and recurrent prostate cancer. For patients with commercial insurance, Decipher has Decipher Assist, a program designed to provide options to help eligible patients with out-of-pocket costs. If your out-of-pocket costs exceed \$395, Decipher’s Medical Accounts Team will reach out to discuss your eligibility for patient assistance including Decipher Assist.</p>
<p>Prolaris®</p>	<p>The company will work with your insurance provider to help get the appropriate coverage allowed by your plan. If your out-of-pocket costs will exceed \$375, you will be contacted prior to the test to discuss options including cancellation of the test.</p>

Patient Consent Statement: By signing below, I the patient agree to have one of the tests above performed as advised by my physician.

- I have been offered the opportunity to ask questions and discuss with my healthcare provider the benefits and risks of the test(s) to be performed as indicated on the associated test request form or follow-on tests ordered by my provider.
- I have read the document in its entirety and realize I may retain a copy for my records
- I consent to have a one of the genetic tests listed above to be performed on my biopsy in order to assist my provider in advising me about further testing or treatment depending on the results of the biopsy.

Name of patient (Please print)

Date of birth

Signature of patient (or guardian)

Date