

Informed Consent for Prolaris[®] Testing

Instructions for Healthcare Providers:

- **For all non-Medicare patients:** This document is provided for your convenience, and can be used at your discretion.
- **Some states may have additional requirements for informed consent.**

Introduction. This form describes the benefits and limitations of Prolaris testing to determine risk for prostate cancer disease progression.

Purpose. This test utilizes an assay of 46 genes to determine how fast prostate cancer tissue is replicating. The test combines the output of the assay, the Prolaris Score, with the clinical-pathologic features of your (PSA, Gleason score, Stage, etc.) to determine your risk of disease outcome.

Test Procedure. Myriad Genetic Laboratories, Inc. (“Myriad”) 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 Prolaris Score. Additional information about testing can be found on Myriad’s patient website at <http://www.prolaris.com>.

Test Results and Interpretation. Your results should be evaluated in the context of your clinico-pathologic features, personal health history and the clinical impression of your healthcare provider.

- Biopsy Test Result – Result will provide an estimate of 10 year prostate cancer specific mortality risk, if managed with watchful waiting.
- Post Radical Prostatectomy Result – Result will provide an estimate of 10 year biochemical recurrence risk.

Myriad keeps test results confidential and is fully in compliance with all Health Insurance Portability and Accountability Act (HIPAA) regulations.

Benefits. The Prolaris test measures how fast your cancer cells are reproducing, or its aggressiveness. Because all prostate cancers are not the same, getting a Prolaris Score will tell your doctor additional information about your cancer’s aggressiveness. Prolaris provides unique information about your cancer, and may help you and your doctor make a more informed decision about your treatment decision.

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, Myriad may exhaust the tissue sample provided in performing the Prolaris test.

Financial Responsibility. Myriad 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, if any. If your out-of-pocket costs will exceed \$375, you will be contacted by Myriad prior to test start to discuss your options, including cancelling the test.

For the State of New York. The State of New York requires that samples be destroyed at the end of the testing process or not more than sixty days after the sample was taken.

Patient Consent Statement.

By signing below, I, the patient having the test performed, acknowledge that:

- 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 healthcare provider.
- I have read this document in its entirety and realize I may retain a copy for my records.
- I consent to being tested for risk of disease progression and I will discuss the results and appropriate medical management with my healthcare provider.

Name of patient having testing (please print)

Date of Birth

Signature of patient (or legal guardian*)

Date