

Instructions for Healthcare Providers:

- **For Medicare patients:** A copy of this signed document **MUST** be submitted with the test kit to Myriad Genetic Laboratories, Inc. before testing will begin.
- **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.**

Informed Consent for Hereditary Cancer Genetic Testing

Introduction. This form describes the benefits, risks, and limitations of genetic testing for inherited susceptibility to cancer. This is a voluntary test and you may wish to seek genetic counseling prior to signing this form. Read this form carefully before making your decision about testing.

Purpose. This test analyzes a specific gene or gene(s) for genetic changes called mutations. The gene(s) analyzed are associated with a specific hereditary cancer syndrome. This test will help determine if a person has a significantly increased risk of developing certain tumors due to a mutation(s) in a cancer-predisposing gene. Genetic testing allows a more precise estimate of an individual's risk for hereditary cancer than personal and family history alone.

Test Procedure. Usually, a tube(s) of your blood will be drawn and sent to Myriad Genetic Laboratories, Inc. ("Myriad"). In some instances however, other types of cells will be submitted. Myriad will analyze the DNA of a specific gene(s) to look for mutations associated with a particular hereditary cancer syndrome. Additional technical details about the test can be found in the "Technical Specifications" that are available from Myriad, or on Myriad's website at <http://www.myriadtests.com/provider/testresults.htm>

Test Results and Interpretation. Your results should be evaluated in the context of personal and family health history, the results of physical examination, laboratory and hospital tests, and the clinical impression of your healthcare provider. Possible result outcomes include positive, negative and uncertain.

- **Positive** – A mutation that is associated with an increased risk for hereditary cancer was identified. Knowing this information may help you and your doctor make more informed choices about your health care, such as screening, risk-reducing surgeries and preventive medication strategies.
- **Negative** – A mutation was not identified.
 - If you are the first person tested in your family, you still have at least the same risk of cancer as does a person in the general population. You may still be at greater than average risk for hereditary cancer due to a genetic predisposition that cannot be detected by this test, either in the gene(s) you were tested for or in another gene linked to hereditary cancer.
 - If you test negative for a mutation known to be in your family, you are considered to have the same risks as others in the general population.
- **Uncertain** – A genetic change was detected but it is not known if this change is linked to cancer risk. You still have at least the same risk of cancer as the general population. In addition, you may still be at greater than average risk due to this change or a genetic predisposition that cannot be detected by this test, either in the gene(s) you were tested for or in another gene linked to hereditary cancer.

Genetic tests results have implications for blood relatives. In consultation with an appropriate healthcare provider, you may wish to discuss sharing your test results with certain blood relatives who may be at risk. If you decide to do this, you should also consider the best way to make this disclosure.

Myriad keeps test results confidential and is fully in compliance with all Health Insurance Portability and Accountability Act (HIPAA) regulations. Myriad will only release your test results to your healthcare provider, his or her designee, or to another healthcare provider as directed by you (or a person legally authorized to act on your behalf) in writing, or otherwise as required by federal and state laws.

Benefits. Your genetic test results may help you and your doctor make more informed choices about your health care, such as screening, risk-reducing surgeries and preventive medication strategies.

The identification of gene mutation(s) in a family enables other blood relatives to determine whether or not they share the same hereditary cancer risks. If you are positive, you should discuss with your healthcare provider

how hereditary cancer is inherited and learn about the chance your children and blood relatives may have inherited the same mutation(s) in the gene(s) tested.

If you test negative for a known mutation in your family, you cannot pass on that mutation to your children and you are generally considered to have the same risks for cancer as others in the general population.

Risks. Genetic testing requires DNA most often provided from a sample of blood. Side effects of having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising, and rarely infection.

To address concerns regarding possible health insurance discrimination, most states and the federal government have enacted laws to prohibit genetic discrimination. In addition, some states have enacted laws that limit use of this information by life insurers and by employers. Furthermore, broad federal legislation prohibits unauthorized disclosure of confidential personal health information.

Limitations. This test analyzes only certain important gene(s) associated with a specific hereditary cancer syndrome(s). Genetic testing clarifies cancer risks for only those cancers related to the genes analyzed.

If you are found to be a carrier of a gene that predisposes you to cancer, there may be differing opinions among physicians about the best steps to take. Your medical care is best determined by you in consultation with your healthcare provider.

Analysis for a specific genetic variant of uncertain significance may be considered investigational and may not provide additional cancer risk information to blood relatives.

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.

Financial Responsibility. Genetic testing of appropriate individuals is typically reimbursed by health insurance or covered by HMOs. You are responsible for any cost of the genetic test not reimbursed by insurance.

Future Correspondence. Due to the dynamics of this field, there continues to be new information and data. It is recommended that you keep in contact with your healthcare provider, annually, to learn of any new developments in cancer genetics and to provide any updates to your personal or family history which may affect your cancer risks.

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 limitations of the genetic test(s) to be performed as indicated on the associated test request form or follow-on tests ordered by my healthcare provider.
- I have discussed with the medical practitioner ordering this test the reliability of positive or negative test results and the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease.
- I have been informed about the availability and importance of genetic counseling and provided with written information identifying an appropriate healthcare provider from whom I might obtain such counseling.
- I have read this document in its entirety and realize I may retain a copy for my records.
- I consent to being tested for predisposition to hereditary cancer and I will discuss the results and appropriate medical management with my healthcare provider/genetic counselor.

Name of patient having testing (please print)

Date of Birth

Signature of patient (or legal guardian*)

Date

*Genetic testing on children under the age of 18 requires that the ordering healthcare provider obtain an informed consent from a parent or legal guardian. If legal guardian, specify relationship to the patient:_____