

PATIENT EDUCATION FOR HEREDITARY CANCER GENETIC TESTING

Introduction: This form describes the benefits, risks, and limitations of genetic testing for inherited susceptibility to cancer. Please read this patient information carefully and talk to your healthcare professional if you have any questions.

Purpose: Based on your personal or family history of cancer, your doctor has recommended genetic testing for:

Specify disease and / or genes

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

Test Procedure: Genetic testing requires DNA, most often provided from a sample of blood or from an oral rinse buccal sample. Myriad GmbH will analyze the DNA of specific gene(s) to look for mutations associated with a particular hereditary cancer syndrome.

Test Results and Interpretation. Your results should be evaluated in the context of personal and family health history, the results of physical examination, other laboratory and hospital tests, and the clinical impression of your healthcare professional. Your test result will indicate either positive for a deleterious mutation or negative for a deleterious mutation.

- **Positive for a Deleterious Mutation:** 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 for a Deleterious Mutation:** A deleterious mutation was not identified.
 - If you are the first person tested in your family, your risk of cancer is at least the same as a person from 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) for which you were tested, or in another gene linked to hereditary cancer.
 - If you test negative for a deleterious mutation known to be in your family, you are considered to have the same risks as others in the general population.
 - Variant of Uncertain Significance: On occasion, the test identifies a genetic variant of uncertain significance. The test detected a genetic change, but it is not yet known whether this change is linked to a higher 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) for which you were tested, or in another gene linked to hereditary cancer.

Your genetic test results have implications for blood relatives. In consultation with an appropriate healthcare professional, 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.

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 mutations in a family enables other blood relatives to determine whether or not they share the same hereditary cancer risks. If you are positive for a deleterious mutation, you should discuss with your healthcare professional 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.

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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: Side effects of having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising, infection or, very rarely, nerve damage. Side effects of an oral rinse buccal sample are also uncommon, but may include mouth stinging or dryness.

On occasion, genetic testing may reveal information that is not directly related to the disease(s) under investigation, but may still be of medical importance for you or your children (so-called incidental findings). While the purpose of genetic testing for hereditary cancer is not to determine family relationships, rarely, the results of a genetic analysis may create uncertainty about specified family relationships. If several family members undergo genetic testing, the correct interpretation of the results depends on the accuracy of the specified relationships. There is an extremely small chance of a mix-up in patient samples. Myriad has rigorous procedures in place to avoid these and other pre-analytical and analytical errors.

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. A comprehensive genetic analysis of all genetic-related illnesses is not possible. Genetic testing does not exclude the risk of other illnesses for yourself or your family.

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 professional. Analysis for a specific genetic Variant of Uncertain Significance may be considered investigational and may not provide additional cancer risk information to blood relatives.

Future Correspondence: Due to ongoing scientific advances in this field, there continues to be new information about genetic mutations and associated diseases. It is recommended that you contact your healthcare professional at least once per year to learn of any new developments in cancer genetics and to provide any updates about your personal or family history which may affect your cancer risks.

Conditions: You may withdraw your consent for the genetic testing at any time. You have the right to request that the genetic testing be stopped and demand the destruction of all sample material and all data collected. You have the right to not be informed of all or part of the results of genetic testing (right not to know).

Myriad keeps test results confidential and is fully compliant with all appropriate regulatory requirements regarding data protection and privacy. Myriad will only release your test results to the ordering or referring physician (e.g. in a laboratory). Requests to send results to another healthcare professional must be submitted in writing by you or a person legally authorized to act on your behalf.



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