Informed Consent for Hereditary Cancer Genetic Testing OncoNext Risk

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 specific hereditary cancer risks. 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(s). Genetic testing allows a more precise estimate of an individual's risk for hereditary cancer than personal and family history alone. In some cases the results of this testing may also provide information about risks for non-cancer related medical conditions.

Test Procedure: Usually, a tube(s) of blood will be drawn or a buccal swab sample will be obtained. Genoma will analyze the DNA of a specific gene or genes to look for mutations associated with specific hereditary cancer risks. Additional information about the testing and the genes analyzed for each of the specific tests available can be found on Genoma's patient website at http://www.laboratoriogenoma.eu.

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 in any of the genes included as part of your testing.

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) for which you were tested or in another gene linked to hereditary cancer.

If you test negative for a mutation known to be in your family, you may be considered to have the same genetic 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) for which you were tested 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.

Genoma keeps test results confidential and is fully in compliance with National regulations. Genoma 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 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 risk is inherited and learn about the chance your children and blood relatives may have inherited the same mutation(s) in the gene(s) tested. 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 may be considered to have the same genetic risks for cancer as others in the general population.

Risks: Genetic testing requires DNA most often provided from a sample of blood or from an oral rinse buccal sample. Side effects of having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising and rarely, infection. Side effects of a buccal swab sample are also uncommon, but may include mouth stinging or dryness.

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

Limitations This test analyzes only certain important gene(s) associated with specific hereditary cancer risks. 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.

New Information and Future Correspondence: Due to the dynamics of this field, there continues to be new information and data that may change the interpretation of your test results. It is recommended that you keep in contact with your healthcare provider, at least annually, to learn of any changes to the interpretation of your results or 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.
- I am the owner of my medical history and test results. My healthcare practitioner should not discuss or disclose my test results and associated medical history to a third party, unless related to treatment or payment for treatment, without my express written authorization.

_____ _____

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: _____

_____ _____

Name of the healthcare provider Signature

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