Informed Consent for the NxGen MDx Hereditary Cancer Panel

This form describes the benefits, risks, and limitations of the NxGen MDx Hereditary Cancer Panel. This test is voluntary, and you may wish to speak to a genetic counselor before signing this form. Please read the form carefully before making your decision about testing.

What is the NxGen MDx Hereditary Cancer Panel?

The NxGen MDx Hereditary Cancer Panel analyzes specific genes for genetic changes, known as variants. The genes analyzed are associated with specific hereditary cancer risks, and this test will help determine a person's risk of developing certain cancers. In some cases, the results of this test will not only provide a precise estimate of hereditary cancer risk but may also provide information about risks for non-cancer related medical conditions as well.

How is the Hereditary Cancer Panel performed?

This test is done on a blood or saliva sample. The sample is sent to NxGen MDx, where the DNA is analyzed to look for variants associated with hereditary cancer risk.

What do my results mean?

Your results should be evaluated with the help of your primary physician and in the context of your personal and family health history, physical examination, and laboratory and hospital tests.

Positive result – A variant that is associated with an increased risk for hereditary cancer was identified. This information may help you and your doctor make more informed choices about your health care, including risk-reducing surgeries and preventative medication strategies.

Negative result – A variant was not found. If you are negative for a known variant in your family, you cannot pass the variant to your children and you may be considered to have the same risk of cancer as a person in the general population. You may still be at a greater risk for hereditary cancer due to a genetic predisposition that cannot be detected by this test.

Uncertain/"Variant of Unknown Significance" – A genetic change was found, but it is not known if the change is linked to an increased risk of cancer. You still have the same risk of cancer as a person in the general population. You may still be at a greater risk for hereditary cancer due to a genetic predisposition that cannot be detected by this test.

Your results may have implications for your blood relatives. You may wish to discuss sharing your results with certain relatives who may also be at risk. If so, you should consider the best way to have this conversation.

NxGen MDx keeps results confidential and complies with all Health Insurance Portability and Accountability Act (HIPAA) regulations. We will only release your results to your health care provider, their designee, or to another health care provider as directed by you or someone legally authorized to act on your behalf.

Benefits

Your results may help you and your doctor make informed choices about your health care, including further screening options, risk-reducing surgeries, and preventive medication.

Identifying a genetic variant enables other relatives to determine whether they share the same hereditary cancer risks. If you are positive, you should discuss with your doctor how hereditary cancer is inherited and learn about the chance your children and relatives may have inherited the same variant(s).

Risks & Limitations

Genetic testing requires DNA, usually from a blood or saliva sample. Side effects of having blood drawn are uncommon but include dizziness, fainting, soreness, bleeding, bruising, and rarely, infection.

Most states and the federal government have laws to prohibit health insurance discrimination and genetic discrimination. There are federal laws in place that prohibit health insurers and employers from discriminating based on genetic information (for example, the Genetic Information Nondiscrimination Act [GINA] of 2008 [Public Law 110-233]). There are currently no federal laws that prohibit life insurance, long term care, or disability insurance companies from discriminating based on genetic information.

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Your state may have more comprehensive laws in this area. The results of genetic testing are considered protected health information and are confidential to the extent allowed by state and federal law. Release of test results is limited to authorized personnel, such as the ordering physician, and to other parties as required by law. Some states also have laws that limit the use of this information by life insurers and employers. Broad federal legislation prohibits unauthorized disclosure of confidential personal health information.

This test analyzes only certain genes associated with hereditary cancer risk. Genetic testing clarifies cancer risks for only those cancers related to the genes analyzed.

If you are found to have a variant in a gene that predisposes you to cancer, your medical care is best determined by you and your health care provider.

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

Inaccurate results may occur as a result of (but not limited to) the following reasons: sample mix-up, samples unavailable from critical family members, inaccurate reporting of family relationships, inaccurate or misleading medical information about a clinical condition or that of family members, or technical problems. Due to limitations in technology and incomplete knowledge of genes, some changes in DNA or protein products that cause disease, may not be detected by the test. There is a possibility that the result findings will be uninterpretable or of unknown significance. In rare circumstances, results may be suggestive of a condition different than that which was originally considered for purpose of consenting to this testing.

The State of New York

The State of New York requires that leftover samples be destroyed within 60 days.

Financial Responsibility

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

New Information and Future Correspondence

New information and data may change the interpretation of your test results. It is recommended that you keep in contact with your health care provider annually to learn of changes to the interpretation of results or new developments in cancer genetics.

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 health care provider the benefits and limitations of the genetic test(s) to be performed as indicated on the associated test request form ordered by my health care provider.
- I have discussed 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 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 health care provider.
- I am the owner of my medical history and test results. My health care 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.

Patient Name (Please Print)

Date of Birth

Patient Signature

Date & Time of Signature