Corewell Health™

Consent
HEREDITARY CANCER - GENETIC TESTING

Patient Name
DOB
MRN
Physician
CSN

INTRODUCTION:

Based on my family and/or personal history of cancer, I am requesting genetic testing for inherited susceptibility to cancer. I understand that this is a voluntary test. I have had an opportunity to discuss these tests in detail with my health care provider. Genetic testing on children under the age of 18 requires informed consent from a parent or legal guardian.

Results from this blood test will tell me whether or not I carry a detectable mutation in gene(s) currently known to be associated with cancer.

PURPOSE:

This test analyzes specific gene(s) for genetic changes called mutations. Mutations in these genes are associated with an increased risk to develop certain cancers. A person who inherits a mutation in a cancer predisposing gene has a significantly increased risk of developing certain cancers. Men and women who carry a mutation have a 50% chance of passing it on to each of their children.

PROCEDURE:

Prior to genetic testing, I will have genetic counseling. This process will include reviewing my family and medical histories and a detailed discussion of the risks, benefits, and limitations of genetic testing. After providing informed consent, as documented with my signature on this form, I will have my blood drawn. The sample will be forwarded to an outside laboratory for analysis. When results are available I can elect to receive the results, or delay or decline receiving the results. **Results will be given to me by phone, in person, and/or by mail. I understand that a follow-up appointment for additional genetic counseling may be recommended.**

TEST RESULTS AND INTERPRETATION: My results will be interpreted in the context of my own personal and family history. Possible test results generally include:

Identification of a deleterious mutation:

These results indicate a mutation has been found and that I am at increased risk for certain cancers. My first degree relatives (biological children, sibling(s), parent(s)) are each at 50% risk of carrying the mutation. Other relatives may also carry the mutation.

No deleterious mutation identified:

When my family's gene mutation is already known:

The specific mutation previously identified in my family is not present. This usually means that my cancer risk is no greater than the general population. In rare cases, more than one inherited risk for cancer runs in a family. In these cases, a negative result only rules out the cancer risk associated with the specific mutation that has been ruled out.

When my family's gene mutation is not known:

No mutations were identified in the gene(s) tested. This result does not rule out the possibility of a different gene mutation that cannot be detected using the technologies used for this testing. This could include mutations in the gene(s) being tested, or in other genes. I may remain at increased risk for cancer.

Identification of a variant of uncertain significance (VUS):

These results indicate that there is a change in a gene **but** it is not known whether this change increases the risk of developing certain cancers. Usually, unaffected family members **are not** offered testing for a VUS because it is not known whether the VUS affects a person's risk to develop cancer.

OVER ➔

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BENEFITS:

I understand that these results may allow me to make informed choices regarding my follow up care. If the results show an increased risk for cancer, I may be advised of measures to help lower cancer risks or to detect cancer at an early stage. If I test negative for a known mutation in my family, I may be able to avoid unnecessary procedures. My results may also help my relatives to determine their own cancer risks.

RISKS:

I understand that some individuals undergoing genetic testing may experience feelings of anxiety, depression, guilt, or anger. Most individuals undergoing genetic testing do not have adverse psychological reactions. I understand that in some cases, genetic testing in a family can reveal nonpaternity.

I understand that there is a risk that my ability to obtain life insurance in the future may be adversely affected by genetic testing. Some insurance companies may require information about genetic testing results in order to determine coverage. There are federal laws, including the Health Insurance Portability and Accountability Act (HIPAA) and the Genetic Information Nondiscrimination Act (GINA), that offer some protection against health insurance and employment discrimination based on genetic testing results.

LIMITATIONS:

I understand that this testing will only look for mutations in genes currently known to be associated with a higher risk for certain cancers. If no mutation is found, I still have some risk for cancer which is **at least** the same risk of general population. If a mutation is found, there may be differing opinions about the best steps to take.

CONFIDENTIALITY:

Genetic test results will become part of my electronic medical record. My medical record is confidential. Test results will only be given if I authorize it (in writing) to a specific person or company. My current or future insurance carriers will not have access to this information unless I authorize a release of medical information.

COSTS:

I understand that fees will be charged for my genetic counseling visits and my genetic testing and that my insurance may or may not cover these costs.

I have read this form or it has been explained to me. All my questions about this form have been answered.

_____ ☐ AM ☐ PM _____ ______________________________
Time Date Patient Signature

_____ ☐ AM ☐ PM _____ ______________________________
TIME **DATE** Witness to Signature

If a patient is under 18 years of age or otherwise unable to consent, the following must be completed:

I, ______________________________, hereby certify that I am the ______________ of the patient; that patient is unable to consent because patient is a minor, or because:

____

_____ ☐ AM ☐ PM _____ ______________________________
Time Date Signature of Parent, Legal Guardian, Patient Advocate or Next of Kin

_____ ☐ AM ☐ PM _____ ______________________________
TIME **DATE** Witness to Signature

Confidentiality of this medical record shall be maintained except when use or disclosure is required or permitted by law, regulation, or written authorization by the patient.

INTERPRETING SERVICES:

I certify that I have interpreted, to the best of my ability, into and from the patient's stated primary language, everything said during the informed consent discussion.

TIME _________ ☐ AM ☐ PM **DATE** _________ Interpreter signature ______________________________

Interpreter name (print) ______________________________