PsiGenex™

Informed Consent for Hereditary Cancer Screening

Introduction

This Informed Consent Form is intended to provide you with information about hereditary cancer screening. It will review benefits, possible results, risks, and limitations of the genetic test that is being ordered by your healthcare provider to assess your risk for developing cancer. If you agree to testing, you will need to sign this consent. You may wish to obtain genetic counseling prior to signing. Genetic counseling can be provided to you upon your request. Please read carefully and discuss any questions you may have with your healthcare provider before signing below.

Purpose of Testing

Hereditary cancer is caused by changes, or mutations, in cancer susceptibility genes. Mutations in these genes can significantly increase a person's risk of developing certain types of cancers. This test analyzes those genes to determine if there are genetic changes present in your test sample that may increase your risk for developing cancer.

Test Procedure

Your healthcare provider typically obtains a blood or saliva sample and sends it to PsiGenex (a Cairo Diagnostics Laboratory). The specific genes related to hereditary cancer are analyzed using Next Generation Sequencing (NGS).

Test Results and Interpretation

Your test results should be explained in support with your personal and family health history, and other laboratory tests. There are three possible results from this test: Positive, Negative, or Variant of Unknown Significance (VOUS).

A Positive Result

A mutation was identified in one or more of the genes analyzed that is associated with an increased risk for developing cancer. A positive result does not mean that you have cancer or that you will definitely develop cancer in your lifetime, it just means that the probability of developing the cancer(s) associated with the gene mutation is higher than it is for the average person. Your exact risk numbers and which type of cancer will depend on both the mutation(s) that was detected and any additional medical or family history that was collected by your healthcare provider.

A Negative Result

No harmful mutations were identified in the genes analyzed with this test, which greatly reduces your risk of developing the hereditary cancers associated with the genes analyzed. This result does not eliminate your risk for developing cancer entirely however, as there are causes such as other genetic predispositions or environmental factors that cannot be detected by this test.

A Variant of Unknown Significance

A mutation was identified in one or more of the genes analyzed but there is not enough data to know with certainty if the mutation is associated with an increased risk for developing cancer. This result does not exclude the risk of developing cancer, it only means that the clinical significance of this mutation is not certain at this time.

Benefits of the Test

The results of your hereditary cancer test will be sent to your ordering physician and may be sent to a third-party genetic counseling company, to provide genetic counseling services, and will become part of your medical record. Your genetic test results may help you and your healthcare provider make more informed decisions about your health such as creating a management plan for better screening and prevention of cancer. In addition, if you are found to carry a mutation in any of the genes analyzed, you may want to consider sharing that information with your family members as they may also be at risk of having the same gene mutation. Family members could benefit from testing as well to determine their risk for developing cancer.

Risks of the Test

Genetic testing is done on DNA obtained from a blood or saliva sample. Side effects from having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising and rarely, infection. Saliva collection is not invasive. Genetic testing may cause you to discover sensitive information about your health or disease risks, including disease risks other than the one you are testing for, or for diseases that currently have no treatment.

The US Genetic Information Discrimination Act-GINA of 2008 prohibits discrimination based on genetic information regarding to health insurance and employment. The results of genetic testing are considered Protected Health Information, PHI, as described in the Health Insurance Portability and Accountability Act, HIPPA of 1996 (Public Law 104.191). Federal legislation prohibits unauthorized disclosure of confidential personal information.

Limitations of the Test

This test only analyzes specific genetic changes that are associated with an increased risk for developing cancer. Genetic testing provides a risk assessment only for those genes(s) being analyzed.

I have read (or have had read to me) all of the above and have had the opportunity to ask questions I might have about the testing, procedure, risks, and alternatives before consenting. My signature below acknowledges my consent to having this testing performed.

Signature of Patient or Authorized Representative

Relationship to Patient (If representative)

Date / /