BAYLOR GENETICS
READY WITH ANSWERS

SHIPPING Baylor Genetics
2450 Holcombe Blvd., Grand Blvd. Receiving Dock
Houston, TX 77021-2024
Phone: 713.798.6555
Fax: 713.798.2787

ADULT HEREDITARY CANCER GENE TESTING CONSENT FORM

Your physician has advised you to undergo genetic testing for hereditary cancer and is requesting testing for:

Name of Test

The purpose of this document is to provide information about the test. This information is meant to be used as a supplement to your discussion with a health care professional. If you agree to have genetic testing for hereditary cancer, you will be asked to sign the last page of this document, indicating that you understand the information provided and wish to have testing. You will be given a copy of this document for your records.

◆ DESCRIPTION OF GENETIC TESTING FOR HEREDITARY CANCER

Hereditary cancer is due to mutations (changes) in the DNA sequence of genes responsible for cell development. Mutations can be the result of a sequence change, missing/deleted segment, or extra/duplicated region of a gene. Multiple genes have been discovered and linked to an increased risk for developing various cancers. The purpose of genetic testing for hereditary cancer is to determine if you carry a mutation in a cancer susceptibility gene. Mutations in specific genes can be responsible for different hereditary cancer syndromes. Genetic testing is available to test for individual genes or multiple genes simultaneously as part of panel tests. The type of cancer and lifetime risk of developing cancer varies for each gene.

◆ INDICATIONS FOR TESTING

The decision to undergo genetic testing for hereditary cancer (single gene or gene panel analysis) is made by you and your physician. In general, single gene/panel analysis is first performed for an individual with cancer history suggestive of hereditary predisposition. You will be required to submit a sample (most likely blood) and DNA will be isolated and purified from this sample for genetic analysis. This testing is complex and utilizes specialized materials so that there is always a very small possibility that the test will not work properly or an error will occur requiring additional sample to be collected from you. If you are found to carry a mutation in a hereditary cancer gene, this may have implications for your family members and analysis of the specific gene in the family members may be recommended. This will require accurate information regarding biological relationship with your family members.

Pre-and post-test genetic counseling by a genetic specialist, such as a certified genetic counselor or medical geneticist, is highly recommended for all individuals undergoing genetic testing.

◆ TEST REPORTING

Results are confidential and will only be released to your designated physician or genetic counselor. Your results will not be released to other parties without your written consent. Testing cannot detect all types of mutations causing hereditary cancers or other genetic disorders, and results will only include the gene(s), and specific regions of the genes, ordered by your physician. Cancer screening and medical management options are available if a mutation is detected in a well-described hereditary cancer gene. Additional recommendations may become available as new therapies and discoveries emerge over time for hereditary cancers.

◆ TYPE OF RESULTS

There are various types of results that can be reported from genetic testing, including:

Positive result - A mutation was identified in a gene(s) that explains either the cause of your cancer history or the risk to develop cancer in the future. The specific type(s) of cancer will depend on the gene(s) involved. Your physician or genetic counselor will review cancer screening and medical management options based on current understanding of the gene(s) in which the mutation was found.
Negative result - No mutations were identified in the genes tested. Decisions for future cancer screening and medical management will be based on your personal and/or family history.
Variant result - A change was detected in one or more genes; however, there is limited information to determine if the change is associated with increased cancer risk, therefore, it is referred to as a variant. The laboratory will review the medical literature and provide information about any known clinical significance of the variant. Testing other close family members for the variant may be offered to determine significance. However, in some cases, significance remains unclear until more data is available.

In addition to hereditary cancer risk, some of the genes tested may be known to also cause other genetic conditions inherited in a recessive manner. This means that if you carry a mutation in one of these genes and your child's other biological parent carries a mutation in the same gene there is a 25% chance of having a child affected with one of these recessive conditions. Further testing may be recommended for you and your reproductive partner based on the results from a hereditary cancer test.

◆ SAMPLE RETENTION

Baylor Genetics is not a specimen banking facility and your specimen may not be available for future clinical studies. Your sample will be used only for the genetic testing as authorized by your consent and your specimen will not be used in any identifiable fashion for research purposes without your consent. However, in some cases, it may be possible to perform additional studies on the remaining sample. The request for additional studies must be made by your referring physician or other authorized healthcare professional and there may be an additional charge. Samples may be retained in the laboratory in accordance with the laboratory retention policy. You have the right to withdraw this consent at any time, and the entity storing the sample shall promptly destroy the sample or portions thereof that have not already been used.

INITIAL _____

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◆ GENETIC DISCRIMINATION

There are federal laws in effect that prohibit health insurers and employers from discriminating based on genetic information. The Genetic Information Nondiscrimination Act (GINA) of 2008 (Public Law 110-233) prohibits this type of discrimination. In addition, genetic results are deemed "Protected Health Information" per the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Public Law 104-191). This law prohibits unauthorized disclosure of such information and release of genetic test results is limited to authorized personnel. Some states may have laws limiting the use of genetic information by other types of insurers as well. More detailed information pertaining to federal and state regulations of personal genetic information can be viewed at http://www.genome.gov/10002077.

INITIAL _____

Please sign here to provide consent for genetic testing at the Baylor Genetics:

_____ _____
Patient Signature Date (MM/DD/YY)

_____ _____
Patient's Legal Guardian Signature Date (MM/DD/YY)

_____
Relationship to Patient

Physician's Statement: I have explained the genetic testing specified to this individual. I have addressed the limitations outlined above, and I have answered this person's questions. I have obtained consent from the patient or the legal guardian for this testing.

_____ _____ _____
Physician Signature Physician Name Date (MM/DD/YY)

_____
Phone