Ambry Genetics®

Genetic Testing Patient Consent for Hereditary Cancer - Page 1 of 2

Genetic Testing Introduction:
Testing for genetic conditions is complex. Pre- and post-test genetic education is recommended for all individuals undergoing genetic testing.

Genetic Test Purpose and Specimen:
The purpose of this molecular genetic test is to determine if you carry any mutation(s) causing increased risk to develop cancer. This test will entail analysis of all genes included on the cancer panel that was ordered by your healthcare provider.

The blood, body fluid, or tissue specimen submitted is required for isolation and purification of DNA for molecular genetic testing. This specimen will be used for the purposes of determining whether there is a gene mutation present which may increase your risk for cancer, now or in the future.

Ambry Genetics' Results Disclosure Policy:
Due to the complexity of germline genetic testing for hereditary cancer and the important implications of the test results, these results will be reported through the ordering provider. Your results report may be available to you after it has been released to you by your healthcare provider, upon your request, or as required to comply with local, state and/or federal regulations and laws. You should contact your provider to obtain and discuss the results of the test and potential medical management recommendations for clinically significant test results. Additionally, the test results could be released to all who, by law, may have access to such data. See Ambry's Privacy Policy for more details: https://www.ambrygen.com/legal/privacy-policy.

Genetic Testing Results and Risk Information:
Genes included on this test may be associated with multiple types of cancer and are also associated with varying levels of cancer risk. Your healthcare provider's recommendations for your medical management could differ depending upon the test findings. All genes on this panel have been implicated in cancer predisposition and are associated with increased lifetime cancer risk(s), although these risks may differ, depending on the gene. For many of the genes, specific screening and medical management recommendations are available for individuals with mutations. Identification of a mutation in other genes can also impact medical management decisions and more data and specific recommendations are expected to emerge over time. Identification of a mutation in any gene does not imply that cancer screening and risk management options will be covered by health insurance. Dependent on the test results, there may not be enough information available to determine your precise cancer risk. Therefore, the results of this genetic test may or may not have implications for your medical management and options including preventive screening/intervention or therapeutics based on your genetic testing result may change over time. Further testing may be needed in the future at the discretion of your healthcare provider as more information and data becomes available or if there are changes to your personal or family history.

Genetic test results have implications for your family members. If you are found to carry a mutation in any of the genes analyzed, your family members may also have a risk to carry the same mutation identified in you. This should be discussed with your healthcare provider.

There are several types of genetic test results, including:
Positive - A mutation was identified in a gene(s) associated with increased cancer risk. This may be indicative that you are at increased risk of developing cancer. The specific type(s) of cancer depend on the gene(s). Your healthcare provider will make cancer screening and medical management recommendations based on what is known about the gene(s) in which a mutation was found.

Negative - No mutations were identified in any of the genes tested. This may be indicative of a reduced likelihood that you have a mutation in the genes tested (see limitations of testing). Your physician will make cancer screening and medical management recommendations based on your personal and/or family history.

Variant of unknown significance (VUS) - An alteration was identified in one or more genes; however, there is not enough information to determine whether this change is associated with an increased risk for cancer. Your health care provider will make cancer screening and medical management recommendations based on your personal and/or family history. These results may change over time as more data becomes available and you should recontact your healthcare provider to discuss any changes.

In addition to increasing cancer risk, some genes on this panel have also been implicated in other genetic conditions which are inherited in a recessive manner. Your results report will indicate if you are a carrier for one of these genetic conditions. This means that if you are identified to carry a mutation in one of these genes (carrier result) and your child's other biological parent also carries a mutation in the same gene there is a 25% chance of a child being affected by one of these recessive conditions. The overall risk of having a child affected with one of these conditions is low. Further testing of you or your reproductive partner may be recommended based on the results of this test.

In rare cases, this molecular genetic test may require an additional blood, body fluid, or tissue sample to obtain accurate results.

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. 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.

Technical Testing Limitations:
While this test is designed to identify most detectable mutations in the genes analyzed, it is still possible that there are mutations that this testing technology is unable to detect. In addition, there may be other genes associated with cancer susceptibility that are not included on this panel or that are not known at this time.

Standard Laboratory Limitations:
Inaccurate results may occur as a result of (but not limited to) the following reasons: sample mix-up, inaccurate or misleading medical information about your clinical condition or that of your 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.

Ambry Genetics reserves the right to:
- Contact you to share additional genetic testing or clinical trial opportunities that may help understand your clinical genotyping.
- Retain your deidentified sample and may utilize the remaining deidentified sample for laboratory quality control or for laboratory test validation optimization purposes.

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Patient Acknowledgement:

- I understand that genetic testing is voluntary and I may choose not to have my sample tested.
- I have read and I understand the information provided in this consent, and all my questions have been answered.
- I acknowledge that the information provided by me on the test requisition form (TRF) is true and correct.
- I have had the opportunity to ask questions about the purpose of testing, about the test procedure, the test results, the risks, the limitations to testing and my rights prior to me signing this informed consent.

Terms and Conditions:

Patient Acknowledgement: I acknowledge that the information provided by me is true and correct. For direct insurance billing: I authorize my insurance benefits to be paid directly to Ambry Genetics Corporation (Ambry), authorize Ambry to release medical information concerning my testing to my insurer, to be my designated representative for purposes of appealing any denial of benefits as needed and to request additional medical records for this purpose. I understand that I am financially responsible for any amounts not covered by my insurer and responsible for sending Ambry money received from my health insurance company.

For patient payment by credit card: I hereby authorize Ambry Genetics Corporation to bill my credit card as indicated above. In order to expedite consideration for eligibility for Ambry's Patient Assistance Program, please provide the total annual gross household income: $_____ and the number of family members in the household supported by the listed income: _____. I authorize Ambry Genetics Corporation to verify the above information for the sole purpose of assessing financial need, including the right to seek supporting documentation.

☐ For NY Residents: By checking this box, I agree that Ambry Genetics will retain my sample for 6 months after the testing above has been completed. By not checking this box, I understand that under New York State law, Ambry Genetics must discard my sample after the longer of (a) testing completion and (b) 60 days after the Date of Collection above.

My signature below acknowledges my voluntary participation in this molecular genetic testing and such genetic analysis in no way guarantees my health, the health of an unborn child, or the health of other family members.

_____ _____

Patient Signature (or Parent/Guardian if patient is a minor) Date

_____ _____

Patient Name (Print) Name/Relationship (if patient is a minor)

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