Ambry Genetics®

Patient Consent for Multi-Gene Cancer Panels - Page 1 of 3

PANEL ORDERED: *(circle one)*

BrainTumorNext BRCAplus BRCAplus-*Expanded* BreastNext CancerNext CancerNext-*Expanded*

ColoNext CustomNext-*Cancer* GYNplus MelanomaNext OvaNext

PancNext PGLNext ProstateNext RenalNext TumorNext-*Lynch* TumorNext-*HRD*

Testing for genetic conditions is complex. You should discuss with your physician or obtain professional genetic counseling prior to giving consent to fully understand the risks and benefits of having this testing completed. Pre-and post-test genetic counseling provided by a qualified specialist, such as a genetic counselor or medical geneticist, is a recommended option for all individuals undergoing genetic testing.

I hereby consent to participate in genetic testing for :_____.

IT HAS BEEN EXPLAINED TO ME BY MY PHYSICIAN AND/OR GENETIC COUNSELOR AND I UNDERSTAND AND WILL INITIAL NEXT TO EACH STATEMENT AS ACKNOWLEDGMENT THAT I HAVE READ AND UNDERSTAND THE INFORMATION.

____ I understand the following information regarding the test purpose and methodology:

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 include analysis of all genes included on the cancer panel indicated above.

The blood, body fluid, or tissue specimen submitted is required for isolation and purification of DNA for molecular genetic testing. I understand that this specimen will be used for the purpose of attempting to determine if I and/or members of my family are carriers of the disease gene, or are affected with, or at increase risk to someday be affected with this genetic disease.

____ I understand the following information regarding Ambry's results disclosure policy:

Due to the complexity of DNA-based testing and the important implications of the test results, these results will be reported through your designated physician(s) or genetic counselor and you should contact your provider to obtain, discuss the results of the test, and obtain counseling regarding potential specialist interventions for clinically significant test results. Additionally, the test results could be released to all who, by law, may have access to such data.

____ I understand the following information regarding test results:

Genes included on this test may be associated with several different 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 particular gene. For many of the genes, specific screening and medical management recommendations are available for individuals with mutations. These genes include but are not limited to: *APC, BMPR1A, BRCA1, BRCA2, CDH1, EPCAM, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, SMAD4, STK11,* and *TP53.* 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. If mutations are identified in more than one gene on this panel, there may not be sufficient 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.

Genetic test results have implications for your family members. If you are found to carry a mutation/variant in any of the genes analyzed, this may also have implications for your family members. 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 susceptibility. This may be indicative that you are at increased risk of developing cancer. The specific type(s) of cancer depend on the particular 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 healthcare provider will make cancer screening and medical management recommendations based on your personal and/or family history.

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Variant - 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. A thorough review of the variant and the associated literature may suggest that a variant is more likely to be disease-causing or benign. However, in some cases the significance remains unclear. Your healthcare provider will make cancer screening and medical management recommendations based on your personal and/or family history.

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. This means that if you are identified to carry a mutation in one of these genes 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.

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

I understand that this molecular genetic test may require an additional blood, body fluid, or tissue sample to obtain accurate results.

____ I understand the following information regarding 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.

____ I understand the following information regarding technical limitations of this testing:

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.

____ I understand the following information regarding standard laboratory limitations:

I understand that 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 my clinical condition or that of my 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.

____ I understand the following information regarding use of specimens for research:

Ambry Genetics is committed to improving genetic testing for all patients and contributing to scientific research. For more information on research at Ambry Genetics, please visit ambrygen.com/patient-resources. NOTE: If left blank, consent is interpreted as "NO".

☐ I agree to use of my de-identified biospecimen for research to improve genetic testing for all patients and contribute to scientific research.

☐ I am a New York state resident and I give Ambry Genetics permission to store my sample for up to 1 year after testing completion.

☐ In addition to agreeing above, I agree to be contacted by Ambry Genetics regarding research opportunities.

____ I understand that Ambry Genetics reserves the right to:

Suggest additional molecular testing if it would help in resolving your clinical genotyping.

Refuse testing if one of the conditions in this informed consent document is not met.

Report additional testing results (other than requested) if they are clinically relevant to the patients and their families (e.g. The methodologies for evaluating specific gene(s) of interest may rarely identify incidental findings related or unrelated to the reason I/my child have been offered testing. In such instances, these results will be discussed with my healthcare provider and additional testing may be recommended.)

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Patient Acknowledgement: I acknowledge that the information provided by me on the test requisition form (TRF) is true and correct. For direct insurance/3rd party billing: I hereby authorize my insurance benefits to be paid directly to Ambry Genetics Corporation and authorize them to release medical information concerning my testing to my insurer and that I am financially responsible for any amounts not covered by my insurer. I understand that I am legally responsible for sending Ambry Genetics Corporation any money received from my health insurance company. I also authorize Ambry Genetics Corporation to be my designated representative for purposes of appealing any denial of benefits as needed. I acknowledge that Ambry Genetics Corporation has the right to request additional medical records, such as consult notes, pedigrees, and clinical/family history notes directly from my provider(s) for the purposes of insurance verification and billing. For patient payment by credit card: I hereby authorize Ambry Genetics Corporation to bill my credit card.

In order to expedite consideration for eligibility for Ambry's Financial 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.

I have read or have had read to me all of the above statements and understand the information regarding molecular genetics testing and have had the opportunity to ask questions I might have about the testing, the procedure, the risks, and the alternatives prior to my informed consent. 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 and Relationship *(Parent/Guardian if patient is a minor)*

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