Ambry Genetics
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Patient Consent for Cardiovascular Genetic Testing - Page 1 of 2

PLEASE CIRCLE ONE OF THE TEST OPTIONS BELOW OR WRITE-IN THE TEST NAME IF NOT LISTED.

LongQTNext RhythmNext HCMNext DCMNext CMNext ARVCNext FCSNext

NoonanNext CPVTNext CardioNext TAADNext FHNext CustomNext-*Cardio*

Other Test: _____

PLEASE INITIAL NEXT TO EACH STATEMENT AS ACKNOWLEDGMENT THAT YOU 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 ascertain if you carry any mutation(s) causing or leading to increased susceptibility to a hereditary form of cardiovascular disease(s) (syndromic or non-syndromic forms). This test will include analysis of all genes included on the selected test(s), as indicated above. Your healthcare provider can provide you with more information about the specific cardiovascular disease(s) associated with the genes included on the selected test.

The blood, body fluid, or tissue specimen submitted is required for isolation and purification of DNA for molecular genetic testing.

____ 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 other ordering healthcare provider and you should contact your provider to obtain the results of the test. 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:

Mutations in genes included on this test may be associated with several different hereditary cardiovascular diseases and may also be associated with different levels of disease risk. Cardiovascular disease screening and medical management recommendations will depend on the gene(s) in which a mutation is found. Disease risks and medical management recommendations may not be well-defined for some of the genes on this panel. There can be significant variability in the age of onset and severity of disease, which cannot necessarily be predicted based on these test results. In addition, identification of a mutation does not imply that disease screening and medical management options are available or 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 how these mutations, combined, affect your risk for cardiovascular disease.

Results of this test could be associated with increased risk(s) for non-cardiovascular health conditions. These risks will vary depending on the panel ordered, the genes tested and the results of testing. This should also be discussed with your healthcare provider.

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 results that can be generated as a result of genetic testing, including:

Positive - A mutation(s) was identified in a gene(s) associated with increased cardiovascular disease susceptibility. This either confirms a diagnosis of a specific cardiovascular disease(s) if you are symptomatic or means that you are at increased risk of developing the disease(s). The specific type(s) of cardiovascular disease that you could be at increased risk for depends on the particular gene(s) tested. Your healthcare provider will make disease screening and medical management recommendations based on what is known about the gene(s) in which a mutation was found. There could be increased risk for non-cardiovascular health conditions, which will vary depending on the specific gene and/or mutation(s) identified.

Negative - No mutations were identified in any of the genes tested. This result reduces the likelihood that you have a mutation in the genes tested (see limitations of testing). Your healthcare provider will make disease screening and medical management recommendations based on your personal and/or family history.

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 cardiovascular disease. 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 disease screening and medical management recommendations based on your personal and/or family history.

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.

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____ I understand the following information regarding genetic discrimination:

There are federal laws in place prohibiting 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 laws prohibiting life insurance, long term care, or disability insurance companies from discriminating based on genetic information. The results of genetic testing are considered "Protected Health Information" (PHI) as described in the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Public Law 104-191). Release of test results is limited to authorized personnel, such as the ordering healthcare provider, 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 there are mutations that this testing technology is unable to detect. In addition, there may be other genes associated with cardiovascular disease 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 your clinical condition or that of your family members, or technical problems.

____ 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.)

____ NY STATE RESIDENTS ONLY:

☐ I am a New York resident and I give Ambry Genetics permission to store my sample for longer than 60 days. **NOTE:** If left blank, consent is interpreted as "NO".

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)*

15 Argonaut, Aliso Viejo, CA 92656 USA Toll Free +1 866 262 7943 Fax +1 949 900 5501 ambrygen.com