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Patient Consent for Molecular Genetic Testing - Page 1 of 2

Test Purpose: 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. The purpose of this molecular genetic test is to ascertain if I am, my child is, or my unborn child is [*please circle appropriate*] carrying mutation(s) predisposing to or causing the specific disease or condition; and I hereby consent to participate in genetic testing for :_____ .

A supplemental disease description sheet is available from Ambry Genetics.

Test Method: The blood, body fluid, or tissue specimen submitted is required for isolation and purification of DNA for molecular genetic testing. The test will cover all disorders requested on the Ambry Genetics requisition form. 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.

It has been explained to me by my physician and/or genetic counselor and I understand the following:

Test Results: I understand that due to the complexity of DNA based testing and the important implications of the test results, these results will be reported only through the patient's designated physician(s) or genetic counselor (where allowed) and that I must contact my provider to obtain the results of the test, to talk with my physician and/or a genetic counselor about these results, and obtain counseling regarding potential specialist interventions for clinically significant test results. The test results, in addition, could be released to all who, by law, may have access to such data. Further testing may be needed.

I understand that if results of the molecular genetics tests are positive, it may be an indication that I may be a carrier of, predisposed to, or have the specific disease or condition tested for and I may want to consider further independent testing, consult with my physician, or pursue genetic counseling. I understand that if results of the molecular genetics tests are negative, it may be an indication that I may not be a carrier of, predisposed to, or have the specific disease or condition tested for and I may want to consider further independent testing, consult with my physician, or pursue genetic counseling. I understand the limitations of these results: the test results could be based upon probabilities, and may not provide a 100% definitive conclusion to either genetic disease predisposition or manifestations. I understand that the molecular genetic test may not generate results and that an additional blood, body fluid or tissue sample may be needed to obtain accurate results. I understand that the molecular genetic test may not generate accurate results. These reasons may include, but are not limited to the following: sample mix-up, samples unavailable from critical family members, maternal contamination of prenatal samples, inaccurate reporting of family relationships, or technical problems. In rare circumstances, a clinically significant finding may be identified in my sample following initial testing as a result of improvements to current technology or discovery of a diagnostic error. Should this occur, your healthcare provider will be re-contacted and provided with the additional results.

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.

Federal laws prohibit health insurers/employers from discriminating based on genetic information. There are currently no federal laws that prohibit life insurance, long term care, or disability insurance companies from discriminating based on genetic information. My 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.

Ambry's Rights: Ambry reserves the right to: 1) suggest additional molecular testing if it would help in resolving the patient's clinical genotyping, 2) 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.), and 3) refuse testing if one of the conditions in the Patient Consent form is not met.

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".

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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 (or authorized individual) Signature | Date

_____ _____

Patient Name (*please print*) | Authorized Individual Name and Relationship (*please print*)

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