Ambry Genetics
A TEMPUS COMPANY

Patient Consent for Molecular Genetic Testing

Genetic Testing Introduction:
Genetic testing can reveal information about your health and potential risks for certain conditions. Your health care provider has or will order one or more tests offered by Ambry Genetics. It's important you understand what the testing involves and how your data and sample will be used. Signing this consent confirms that you understand the process, your rights, and that participation to test is voluntary.

Genetic Test Purpose and Specimen:
The submitted blood, body fluid, or tissue specimen is required for isolation and purification of DNA to be used for molecular genetic testing. The purpose of molecular genetic testing is to determine if you or your child have any pathogenic (disease-causing) or likely pathogenic (likely disease-causing) genetic variants associated with a specific condition or risk for developing one. Molecular genetic testing involves the analysis of the genes relevant to the condition for which your healthcare provider ordered testing. See Ambry's website for more information about the specific test(s) ordered by your healthcare provider: www.ambrygen.com

Genetic Testing Results and Risk Management Information:
Gene(s) included on your report may be associated with multiple genetic conditions. Your healthcare provider's medical management recommendations could differ depending upon the test findings. Identification of a pathogenic or likely pathogenic variant in other genes can also impact medical management decisions, and more data and recommendations are expected to emerge over time. In certain circumstances, results may also be suggestive of a condition different than the original purpose of consenting to this testing. Identification of a pathogenic or likely pathogenic variant in any gene does not imply that screening and risk management options will be covered by health insurance. In rare cases, this molecular genetic test may require an additional blood, body fluid, or tissue sample to obtain accurate results. Dependent on the test results, there may not be enough information available to determine your precise risk. Therefore, the results of the genetic test(s) may or may not have implications for your medical management, and options including preventive screening/intervention or therapeutics based on your genetic testing results may change over time. Further testing may be needed in the future if more information becomes available or if there are changes to your personal or family history.

Types of genetic test results identified by molecular genetic testing:

Positive - A pathogenic or likely pathogenic variant was identified in a gene associated with a specific genetic condition. This may be indicative that you are a carrier of, predisposed to, or have a specific genetic condition. Your healthcare provider will make screening and/or medical management recommendations based on what is known about the clinical impact of the identified variants.

Negative - No pathogenic or likely pathogenic variants were identified in any of the genes evaluated. This may be indicative of a reduced likelihood that you have a pathogenic or likely

pathogenic variant in the genes tested (see limitations of testing). Your physician will make screening and/or medical management recommendations based on your personal and/or family history.

Uncertain - A variant of uncertain significance (VUS) was identified in one or more genes; however, there is not enough information to determine whether this change is associated with an increased risk to be a carrier of, predisposed to, or have a specific genetic condition. Your health care provider will make screening and/or medical management recommendations based on your personal and/or family history. These results may change over time as more data becomes available. You should re-contact your healthcare provider to discuss any changes.

Genetic Discrimination:
Federal laws, such as the Genetic Information Nondiscrimination Act (GINA), protects against genetic discrimination by health insurers and employers, but does not cover life, long-term care, or disability insurance. State laws may offer additional protections.

Technical Testing Limitations:
While this test is designed to identify most detectable pathogenic and likely pathogenic variants in the genes analyzed, it is still possible that there are pathogenic and likely pathogenic variants that the testing technology is unable to detect. In addition, there may be other genes associated with the specific genetic condition you were tested for that are not included in this testing or that are not known at this time.

Standard Laboratory Limitations:
Inaccurate results may occur because of (but not limited to) the following reasons: sample mix-up, inaccurate or misleading information about you, 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 findings will be uninterpretable or of uncertain significance.

Data and Sample Uses:
The test(s) will generate health data about you and Ambry Genetics or the reference lab may receive health data from your medical record in connection with the test(s). Your identifiable data is subject to legal requirements regarding its use and protection. Ambry Genetics may use and disclose the test results and your other health data as described in its notice of privacy practices (NPP) at www.ambrygen.com/legal/notice-of-privacy-practices.

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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- Use deidentified data from your records (including from your genetic testing) for research and other purposes permitted by law.

Patient Acknowledgement:

- You understand that genetic testing is voluntary, and you may choose not to have your sample tested.
- You have read and understand the information provided in this consent, and all your questions have been answered.
- You acknowledge that the information you provided to your healthcare provider is true and correct.
- You 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 your rights prior to signing this informed consent.
- If the law requires you to consent to these terms but you have been unable to sign, provision of your sample to Ambry Genetics indicates your consent.

For NY Residents*: I am aware that genetic counseling is available to me prior to signing this form and after testing is complete.

☐ 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.

***Please ensure the patient's consent to retain the sample is also documented on the paper test requisition form or within AmbryPort.**

Please consult your healthcare provider if you have any questions.

Patient Signature (or Parent/Guardian if patient is a minor)	Date
Name and Relationship (Parent/Guardian if patient is a minor)	Date
Provider Signature	Date

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