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Arboretum Clinical Informed Consent for Arboretum Hereditary Cardiomyopathy Test

Please read this document carefully. By consenting, you confirm that you understand the information below and voluntarily consent to the Arboretum Hereditary Cardiomyopathy Test testing by Arboretum Clinical, LLC ("Arboretum").

If you have questions about this test before or after receiving your results, please contact your health care provider or a genetic counselor.

Arboretum Hereditary Cardiomyopathy Test

General Description: Your health care provider has recommended that you (or a minor for which you are the legally authorized representative) receive the Arboretum Hereditary Cardiomyopathy Test, a genetic test that examines genes associated with hereditary cardiomyopathy. No test other than those authorized in this consent will be performed.

Purpose of the test: The purpose of this test is to evaluate genetic variants in the gene(s) included in this test that are associated with hereditary cardiomyopathy, which is a group of inherited conditions affecting the heart muscle that can change the size, thickness, or function of the heart and may lead to heart failure, abnormal heart rhythms, or, in some cases, sudden cardiac events. The test examines genes known to be associated with hereditary cardiomyopathy and reports whether a clinically significant variant is present; results may be reported as positive, negative, or as a variant of uncertain significance. Additional test-specific information is available at arboretumclinical.com/our-tests. You acknowledge and agree that you have reviewed information about this specific test and the relevant disease(s), conditions(s), or indication(s) tested for with your health care provider, and understand the risks and benefits of testing.

By consenting, you acknowledge that you understand that a biological specimen (saliva or cheek swab) is required for testing. You understand that this biological specimen will be used for the purpose of attempting to determine whether genetic variants related to hereditary cardiomyopathy are present and whether the results may indicate carrier status, increased risk, predisposition, or a diagnosis, depending on the test ordered.

Limitations of the test: The test analyzes specific genes associated with hereditary cardiomyopathy. It does not rule out the possibility of a variant that the testing technology is unable to detect. There may also be other genes associated with the condition you were tested for that are not included on this panel or are not known at this time. Testing results may be limited based on current testing technologies or incomplete knowledge of genes. Testing results may be uninterpretable or of unknown significance. Depending on the findings, there may not be enough information available to determine a definitive interpretation. This test is designed to evaluate and report findings related to the ordered test. Variants or findings outside the scope of the ordered test, including incidental or secondary findings, may not be analyzed or reported. Further testing may be recommended by your health care provider now or in the future as more information becomes available or if there are changes to your personal or family history. In some cases, testing may not produce a reportable result because of specimen quality, insufficient DNA, technical limitations, or other laboratory factors. A new specimen or additional testing may be requested. There is a chance that you will have hereditary cardiomyopathy but the monogenic test results will be negative. As in any laboratory test, there is a possibility of error.

ARBORETUM CLINICAL

Meaning of a Positive Test Result: A positive test result indicates a clinically significant variant was identified in the gene(s) associated with hereditary cardiomyopathy. It may indicate that you are predisposed to, are a carrier for, or have, the specific condition tested for. You may wish to discuss whether follow-up testing, medical evaluation, or genetic counseling is appropriate with your health care provider. Your health care provider may make recommendations for additional screening or medical management in their professional judgment. You understand the level of certainty associated with a positive test result can vary with the type of test. However, in the case of hereditary cardiomyopathy, a positive result generally indicates an increased likelihood of having or developing the condition, although the degree of risk and its severity can vary from person to person, even within the same family. You further understand that you will be given the opportunity to talk with a genetic counselor about those results.

Meaning of a Negative Test Result: A negative test result indicates a clinically significant gene variant associated with hereditary cardiomyopathy was not detected in the targeted regions. This may indicate a reduced likelihood that you are predisposed to, are a carrier for, or have, the specific condition tested for. Your health care provider may make recommendations for additional screening or medical management in their professional judgment. Negative results may also be due to limitations of testing. You understand that a negative result does not guarantee that you do not have, or will not develop, the condition for which testing was performed.

Variant of Unknown Significance: Your test results may include one or more variants of unknown significance (VUS), which means a gene variant was identified in one or more genes; however, there is not enough information to determine whether the variant is associated with hereditary cardiomyopathy or has clinical significance for you or your family. Results may be amended or reclassified over time as scientific knowledge changes, but this consent does not guarantee automatic reinterpretation or reanalysis of prior results. Your health care provider may make recommendations for additional screening or medical management in their professional judgment.

General Information

Disclosure of Test Results: Test results are disclosed only to the ordering health care provider (or their designated representative), unless required by law or otherwise authorized by you in writing. If you have created an account with Arboretum, your test results will also be made available through your account portal. You may opt out of receiving results through your account by emailing support@arboretumclinical.com. All test results are treated as confidential and are subject to strict legal requirements regarding use and protection. Your health information, including the test results, will become part of your (or your child's or ward's) medical record. This information may be available to individuals who have access to an electronic medical record (EMR) system that contains the information, or other health information exchanges. See our Notice of Privacy Practices for more information.

Family Members and Family History: Genetic testing has implications for your family members. If you are found to have a clinically significant gene variant, your family members may also carry the same gene variant and could benefit from their own evaluation. This should be discussed with your health care provider. Your family history is used during test interpretation to help assess the clinical significance of genetic variants identified. Because of this, the accuracy of your results depends in part on the accuracy of the family and medical history you provide. Incorrect information about biological relationships or a misdiagnosis in a family member could affect how your results are classified.

ARBORETUM CLINICAL

Genetic Discrimination: By signing this consent, you authorize us to release medical information concerning the genetic testing to your health insurance company, if applicable. 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)). However, these laws do not apply to life insurance, long term care, or disability insurance companies, which may be governed by state law.

Genetic Data Privacy: Certain state laws and other state consumer privacy laws give you additional rights regarding your genetic data, including rights to access, correct, delete, or limit the use or disclosure of your data. Arboretum will honor these rights as required by applicable law.

Confidentiality. Testing results will be kept confidential to the extent required by law. Your privacy is important to us. Details about our policies governing your information, including the security measures taken, may be found in our Notice of Privacy Practices. You acknowledge receipt of our Notice of Privacy Practices, which describes how we may use and disclose your health information. A copy can also be obtained on our website, or we will send you a paper copy upon request.

Consent to Electronic Communications. You agree that we may contact you via email or text. You understand that communicating via email or text messages may not be secure, and could be viewed by unintended persons, and you agree to communicate with us via these electronic means. You agree to update your contact information as needed to ensure accuracy in our communications to you. You have the right to opt out of certain of our communications and may do so at any time.

Contacting You with Additional Opportunities: Arboretum may contact you, as permitted by the law, to provide updates to your test report, as well as additional opportunities for genetic testing, education, or research that may help you understand your health or genetic testing results.

Financial Responsibility: You agree to pay for the genetic testing you receive from Arboretum. We may bill your insurance, if applicable, and you authorize your insurance benefits to be paid directly to Arboretum. You understand you are financially responsible for any amounts not covered by your insurer. When you provide us with information about your insurance, that will be considered authorization for us to submit claims to your health insurance plan, and authorization to act as your designated representative for purposes of appealing any denial of benefits as needed and to request additional medical records for this purpose. If paying by credit card, you authorize Arboretum to bill your credit card.

Retention of Specimens and Genetic Information: We will not return any remaining sample to you or your health care provider. Samples will be retained in accordance with specimen retention policies. We also reserve the right to retain your deidentified sample and may utilize the remaining deidentified sample for laboratory quality control or for laboratory test validation or optimization purposes. We may also retain your genetic information data obtained for future health care operations, or as otherwise permitted under applicable laws. See our Notice of Privacy Practices for more information.

If you are a New York Resident: As a New York resident, you understand that under New York law no tests other than those authorized will be performed on your sample and Arboretum must discard your sample after the longer of (a) the end of the testing process or (b) sixty (60) days after the sample was taken. As required under New York law, you are advised that you may wish to obtain professional genetic counseling prior to signing this consent.

ARBORETUM CLINICAL

Other Terms and Conditions: Arboretum's Terms of Service are incorporated by reference and apply to the services provided by us. You acknowledge you have had the opportunity to review the Terms of Service.

Patient Acknowledgement:

- I understand that genetic testing is voluntary and I may choose not to have my sample tested.
- I understand that genetic testing in no way guarantees my health or the health of any family members. I also understand that health care providers may understand more about the meaning of test results in the future. Because of that, I should check with my health care provider for updates from time to time.
- I acknowledge that the information I have provided related to my request for testing is true and correct.
- I have been informed about the reliability of positive or negative results and the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease, and I have had the opportunity to discuss the purpose of testing, the test procedure, the test results, the risks, the limitations to testing, and my rights with my health care provider prior to me signing this informed consent.
- I have read and I understand the information provided in this consent and I agree to the terms and conditions above, as well as those incorporated by reference.

By consenting, you acknowledge that you have read and understand the information above, and you voluntarily consent to receive genetic testing.