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Arboretum Clinical Informed Consent for Coronary Artery Disease Polygenic Risk Score Test

Please read this document carefully. By consenting, you confirm that you understand the information below and voluntarily consent to Coronary Artery Disease Polygenic Risk Score 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.

Coronary Artery Disease Polygenic Risk Score

General Description: Your health care provider has recommended that you (or a minor for which you are the authorized personal representative) receive the **Coronary Artery Disease Polygenic Risk Score**, which measures your genetic risk of developing coronary artery disease based on the combined effect of thousands of common genetic variants across the genome. No test other than those authorized in this consent will be performed.

Purpose of the Test: Unlike single-gene tests that look for rare, high-impact variants, the Polygenic Risk Score ("PRS") captures many common genetic variants in your DNA to estimate your inherited genetic predisposition for coronary artery disease compared to Individuals with similar genetic ancestry. More information about this PRS test is available on our website at arboretumclinical.com/our-tests.

Limitations of the Test: Certain types of DNA variants are not assessed by this test, and the test does not account for rare variants or non-genetic factors (such as environment, lifestyle, medical history, or family history). Additionally, PRS models are based on reference populations and may be less accurate for individuals whose ancestry is underrepresented in current research.

By consenting, you acknowledge that you understand that a biologic specimen (saliva or cheek swab) is required for testing. You understand that this biological specimen will be used by Arboretum or certified partner laboratories for the purpose of estimating your inherited genetic predisposition to developing coronary artery disease. 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.

PRS Results:

The PRS test will result in a percentile rank categorized, as described below:

- **Higher Risk:** This indicates that you have a higher-than-average inherited genetic predisposition to coronary artery disease, which may inform discussion with your healthcare provider about screening, prevention, or risk-reduction strategies. You may wish to consider further independent testing, consult your physician, or pursue genetic counseling. This may also have implications for risk of coronary artery disease in biological relatives.
- **Average Risk:** This indicates that you have an average inherited genetic predisposition to coronary artery disease.
- **Lower Risk:** This indicates that you may have a lower-than-average inherited genetic predisposition to coronary artery disease, but this does not eliminate the possibility for developing coronary artery disease in the future.

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In rare cases, a sample may not yield a reportable result due to quality issues. You or your provider will be notified if this occurs.

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 Clinical, 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 records (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: PRS results have implications for your biological relatives. If you are found to have a high PRS, your biological relatives may also have an increased genetic predisposition, but their risk cannot be determined from your result alone. This result should be discussed with your healthcare provider. Your PRS is calculated from your genetic data and may incorporate additional clinical information to refine your risk estimate. However, family history is not used in the calculation of your score. Your healthcare provider may consider your family history, lifestyle, medical history, and other clinical risk factors alongside your PRS result when making clinical recommendations. Inaccurate family history information could affect clinical recommendations made in light of your PRS result.

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.

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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 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.

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 PRS testing is voluntary and I may choose not to have my sample tested.
- I understand that PRS testing does not diagnose coronary artery disease, rule out the possibility of developing coronary artery disease, or in any way guarantee 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 nature of polygenic risk scores. I understand that my score indicates relative inherited genetic predisposition compared to a reference population and does not diagnose coronary artery disease or determine whether I will or will not develop coronary artery disease . I have had the opportunity to ask questions about the purpose of testing, the test procedure, interpretation of results, the limitations of PRS testing, and my rights with my healthcare provider prior to 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.

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