



Dynamic DNA Laboratories, LLC
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Informed Consent for Polygenic Risk Score (PRS) Testing

This document should be read with the understanding that mentions of “my healthcare provider,” “my sample,” “my results,” and so on refer to the patient being tested.

My healthcare provider has ordered one or more genetic screens or tests offered by Dynamic DNA Laboratories, LLC (“Dynamic DNA”) and developed by Allelica Inc. (“Allelica”). More information about the screen(s) or test(s) ordered is available from my healthcare provider and can also be found on the Allelica website (allelica.com).

How is testing performed?

Testing is performed on a small sample DNA isolated from a buccal swab. Once collected, the sample will be sent to Dynamic DNA for testing. During testing, Dynamic DNA will be looking for changes at many different places in the DNA sequence, which are known as “variants”. Each of these variants has an effect on your overall genetic risk of disease. These effects are summed together to produce a Polygenic Risk Score (PRS) which is a single value that represents the genetic component of your disease risk. Your PRS is compared to a distribution of scores from people like you to translate it into an estimate of disease risk.

What might I learn from this test?

The results of this genetic test are an assessment of your relative or absolute risk of disease, and could indicate that you are at:

- a. Average genetic risk for a particular disease, and may
 - i. reveal an overall lifetime risk of disease that is not significantly greater than the average population
 - ii. provide recommendations for maintaining average risk as you age
 - iii. be the result of a combined assessment of genetic and clinical risk factors
 - iv. not eliminate future elevation to High risk and/or diagnosis of disease
 - v. change over time as new data and models are developed
- b. High genetic risk for a particular disease, and may
 - i. reveal a predisposition or increased risk for disease compared to the average population
 - ii. provide recommendations for reducing your high risk through modifiable risk factors
 - iii. be the result of a combined assessment of genetic and clinical risk factors
 - iv. not lead to a definitive diagnosis of disease at any point in life
 - v. change over time as new data and models are developed

You may learn information about your ancestry that you do not expect or that makes you uncomfortable. This could include learning your family is originally from areas of the world you were not anticipating and, in rare cases, could even reveal unexpected information about your biological relationship with your family. Understanding your genetic ancestry is necessary because disease risk thresholds vary across different ancestries. For this genetic test, Dynamic DNA assesses ancestry using principal components analysis (PCA) and iAdmix. Your genome will be compared to a set of 26 global populations to provide a summary of your genetic ancestry from five major continental ancestry groups. This result is used to align your PRS to an ancestry-specific



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risk distribution. The result of the continental ancestry group classification is included as a separate section of Allelica's risk report. Due to the varying nature of the methods and reference populations used, Allelica's ancestry report may differ from genetic ancestry inferred through other commercial genetic ancestry tests.

If you do not want to see your genetic ancestry report, you may opt out of receiving this section of the main report by selecting the box below.

I do not wish to receive the results of my genetic ancestry report.

What are the risks and limitations of this test?

This test may or may not help my healthcare provider better understand my health and treatment options. Some types of DNA variant that could cause a specific genetic disorder may not be detected by this test. As with all molecular genetic tests, this test has technical limitations that may prevent detection of some common genetic variants, or may give an inaccurate result, due to: poor DNA quality, rare technical errors in the laboratory, or other types of limitations. Dynamic DNA generates a report for the diseases and traits that were ordered by the healthcare provider. In the course of performing the ordered tests, Dynamic DNA may rarely find variants that are unrelated to the clinical concern that prompted my having the test but are associated with a significant risk for another condition that could negatively impact my health. These are known as "incidental findings." In accordance with well-established medical guidelines, Dynamic DNA will consult with my healthcare provider when there are accepted medical interventions available, and my healthcare provider can discuss these with me. It is my responsibility to consider the possible impact of my test results as they relate to insurance rates, obtaining disability or life insurance and employment. Within the United States, the Genetic Information Nondiscrimination Act (GINA), a federal law, provides some protections against genetic discrimination. For information on GINA, visit <http://www.genome.gov/10002328>.

It is important to note that the results of the PRS analyses presented here are **not diagnostic**. The aim of these genetic and bioinformatic analyses is to provide additional information to clinicians about **my risk of disease that is conferred by my genes**. Depending on the PRS, the analyses take into account a range of between tens to millions of common genetic variants that have been robustly associated with the disease of interest. However, there may still be additional, as yet unidentified, genetic variants involved in my genetic risk. In addition, this test may or may not take into account pathogenic variants in known disease susceptibility genes, which may also contribute to my disease risk. Furthermore, there is a chance that other rare pathogenic variants may also be present but unidentified which may additionally contribute to my genetic risk of developing a disease.

How will I learn my results?

Dynamic DNA's clinical reports are released to the certified healthcare provider(s) listed on the test requisition form. Clinical reports are confidential and will only be shared in accordance with applicable laws.

Who can I speak to about my test and results?

Dynamic DNA recommends that I consult with a genetic counselor or my healthcare provider before consenting to this test. Dynamic DNA also recommends that I speak to a genetic counselor or my healthcare provider about my results.



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Will my test results ever change?

Knowledge of genetic information will improve over time, so new information may become available in the future that could impact the interpretation of my results. Dynamic DNA may notify me of clinical updates related to my genetic test, in consultation with my ordering healthcare provider.

This section describes how Dynamic DNA uses and protects my data and samples and the choices available to me determine how they are used. The principles underlying Dynamic DNA's approach to data are that patients should own and control their own genetic information and that genetic information is more valuable when shared.

Where is my data analyzed?

Genetic data extracted from the buccal sample are analyzed in the CLIA-certified and CAP-accredited laboratory Dynamic DNA Laboratories, LLC, located at 2144 E Republic Road, Suite 204, Springfield, Missouri, 65804.

What types of data does Dynamic DNA use?

Dynamic DNA analyzes the genetic data obtained from the sample and delivers a genetic test report to my healthcare provider. My sample and the health and genetic information Dynamic DNA receives and generates about me (collectively, "my data") is considered as sensitive personal data by regulators. My data is subject to strict legal requirements regarding how it can and can't be used and how it must be protected.

How does Dynamic DNA protect my data?

Dynamic DNA takes robust measures to help keep my data safe and secure and limit use of my data only for permitted purposes. Dynamic DNA uses technical, administrative and physical safeguards to secure my data and protect it against misuse, loss or alteration. Dynamic DNA also takes steps to de-identify or anonymize my data in accordance with applicable laws. De-identified data (also called pseudonymized data) is data that has been stripped of identifying information (such as my name or email address), although the data may contain a key that Dynamic DNA can use to link back to the individual where required. Anonymized data is similar to de-identified data except that there is no ability to link back to an individual.

How may my data be used or shared?

The following activities are a core part of Dynamic DNA's genetic testing services such that when I consent to a genetic test, I am also consenting to the retention, use and disclosure of my data and sample for these activities:

- a. Providing genetic testing services, including preparation and delivery of a genetic test report to my healthcare provider.
- b. Performing operational activities in support of providing and obtaining payment for genetic testing services, such as billing for services Dynamic DNA provides and complying with laboratory regulations.
- c. Conducting quality improvement activities that support genetic testing services. Examples of these activities include making sure test results are accurate and high-quality, ensuring the laboratory and technology systems supporting Dynamic DNA's genetic testing services are kept current and up-to-date, and refining and updating Dynamic DNA's risk prediction algorithms and reports.



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What happens to my data if I am outside the United States?

Dynamic DNA Laboratories and Allelica are located in the United States. My sample and data will be processed in the United States.

How long may my data or sample be retained?

Dynamic DNA may retain my data and sample for as long as reasonably necessary for the purposes described above. *However, if I am a resident of Alaska, my sample will be destroyed no more than 60 days after the sample was taken or at the end of the testing process, whichever is later.*

How can I find more information about how my data is used and shared?

For additional information on how Dynamic DNA uses and shares data or to receive copies of privacy policies, please contact Dynamic DNA laboratories at info@dynamicdnalabs.com.

By signing below, I confirm that:

- (1) I have read (or had read to me) and I understand the information provided in this consent;
- (2) I understand that genetic testing is voluntary, and I may choose not to have my sample tested;
- (3) I have received a copy of this consent form;
- (4) All my questions have been satisfactorily answered; and
- (5) I hereby consent to genetic testing and to the retention, use, and sharing of my data and sample as described in this form.

Signature of Patient or Legal Guardian		Date (MM/DD/YY)	
I am the (<i>check one</i>): <input type="checkbox"/> Patient <input type="checkbox"/> Parent/Guardian			
Patient's Printed Name		Patient's Date of Birth	Patient's Gender
Email Address			
Healthcare Provider Name and Practice Name			
Sample Number (<i>found on DNA collection envelope</i>)			