

## **Informed Consent for MyOme Personal Genome Pharmacogenomics Genetic Testing**

**INTRODUCTION:** You have requested the performance of MyOme Personal Genome Pharmacogenomics (the “Test”) ordered by your health care professional. You acknowledge that your submission of a specimen to be tested is voluntary. Please carefully review the information in this Informed Consent before signing. You may wish to speak with a genetic counselor prior to proceeding with the Test. If you decide to proceed with the Test, please sign where indicated below. The Test cannot be completed unless you confirm by signing below and acknowledge that you have read, understood, and agree to this Informed Consent.

**ABOUT THE TEST:** The purpose of the Test is to look for mutations or genetic characteristics known to be associated with certain genetic diseases, conditions, or pharmaceutical therapies. You acknowledge that you have reviewed information specific to the Test and your health care provider has explained the test’s risks and benefits.

Pharmacogenomic testing involves looking at genetic variations that are involved with how the body metabolizes and/or responds to medications.

Results may have implications for current and future medications prescribed for you. In addition, the test report may also include results related to inherited disease risk.

**AVAILABILITY OF GENETIC COUNSELING:** You acknowledge that you have been provided with information about obtaining genetic counseling prior to giving your consent, and you understand that you may seek consultation with a geneticist, genetic counselor, and/or physician after testing.

**INFORMATION COLLECTED:** You will be asked to provide a blood, cheek swab, or saliva specimen in accordance with specified collection procedures. You will also be asked to provide certain health and other personal information, such as name, address, DOB, and certain medical history. In order for the Test to be performed as intended, the information provided must be accurate and complete.

**USE OF YOUR SPECIMEN AND INFORMATION:** Your specimen, along with your other personal information, will be sent for analysis to MyOme. DNA will be extracted from the specimen, and certain markers within regions of your genome relevant to the Test will be sequenced and analyzed. Upon successful completion of the Test, the results will be sent to the authorized person. No other tests will be performed using the specimen except as authorized herein or permitted by applicable law.

You hereby acknowledge that the Test results may become part of your permanent medical record and understand that some test results may impact your ability to obtain certain insurance benefits. You hereby acknowledge that genetic test results may have implications for your biological family members and unexpected family relationships may be identified through genomic testing.

**LIMITATIONS OF THE TEST:** The Test analyzes specific gene regions based on currently available information in the medical literature and scientific databases, as well as laboratory informatics and algorithms that may be subject to change. As such, new information may replace or add to the information that was used to analyze your results that may impact the interpretation of results. Results may not provide definitive conclusions regarding current or future medications. As with any laboratory test, there is a possibility of error. For example, as with all medical tests, there is a chance of a false positive or a false negative result. A false positive result means a relevant marker or variant is incorrectly reported as present. A false negative result means that a variant of interest is not identified when it is in fact present and within the reportable range. Other sources of error, while rare, include specimen mix-up, poor specimen quality or contamination, inherent DNA sequence properties, and technical errors in the

laboratory. In addition, if you have certain rare biological conditions or have had certain bone marrow, kidney, liver or heart transplants, transfusions, or hematologic malignancies, these conditions may limit the accuracy or relevance of the results or prevent the Test from being completed. MyOme expressly disclaims any liability for the inaccuracy of the genetic test results due to such conditions or the failure to provide accurate, correct or complete information, and you hereby waive any claims against MyOme with respect thereto.

**POTENTIAL RESULTS OF TESTING:** You acknowledge that you should not make medical decisions based on the results of the Test without speaking to your healthcare provider. Prescription regimens should never be altered without consulting a prescribing health provider. The genetic test results will include information your healthcare provider may use in combination with their professional knowledge and clinical information to determine what might be causing your symptoms and the best medical course of action, if any. A positive result indicates that you may be predisposed to or have a specific disease or condition and/or may be used to inform your healthcare provider's treatment decisions and which may have potential health implications for other members of your family. You acknowledge that information regarding the certainty associated with test results, if established, has been provided to you. A negative test result indicates that a clinically significant variant was not detected, but you hereby acknowledge that false negatives are nonetheless possible. You hereby acknowledge that a negative result does not guarantee that you or, if applicable, your child will not develop a certain disease or condition. Some genetic changes may also be detected, but their clinical significance may be unknown. Sometimes a result cannot be generated and additional samples might be needed.

**PROTECTING THE PRIVACY OF YOUR INFORMATION:** Your privacy is important to MyOme. Details about MyOme's policies governing patient privacy and health information, including patient rights regarding such information, can be found in our Terms of Use and Privacy Policy.

**OTHER USES OF YOUR SPECIMEN AND INFORMATION:** MyOme will obtain, retain, and use your personal information, specimen, and test information in compliance with applicable law and maintain the confidentiality thereof and protect from unauthorized disclosure or misuse. MyOme may de-identify your discarded specimen and information for regulatory compliance purposes, internal quality control, validation studies, or research and development. Any use or disclosure of the specimen and any data will be done in an anonymized manner by either encrypting or removing personally identifiable information in accordance with applicable law.

The US Genetic Information Nondiscrimination Act of 2008 ("GINA") prohibits discrimination on the basis of genetic information with respect to health insurance and employment; however, there are exceptions and we encourage you to review GINA and implementing regulations. The retentions and use of genetic information may also be governed by applicable state laws. For more information on this, visit: <https://www.genome.gov/about-genomics/policy-issues/Genetic-Discrimination>.

**SPECIMEN STORAGE:** MyOme will retain your specimen for the maximum duration permitted under applicable law or regulation. In certain states you have the option of giving MyOme permission to store any specimen that remains after testing has been completed. If applicable and you select this option, MyOme may store your specimen at its discretion. If, after opting into this storage option, you later ask us to destroy your specimen, MyOme will destroy any remaining portion that has been stored and not yet used, in accordance with applicable federal and state regulations.

Please check below to indicate you are a resident of Delaware, if applicable.

- Delaware: Specimens from Delaware residents will be destroyed promptly after completion of the Test unless you opt into the specimen storage option below.

If you are a resident of Delaware and consent to the storage of your specimen described above, please check the box below:

- Optional: I consent to the retention and storage of my specimen as described above.

The signature below indicates that:

- You are of legal age to request the test services and consent hereto, or you are the parent, legal guardian, or person having legal authority to act on behalf of the individual who will receive the test services.
- You have read, or had read to you, and understand the above information.
- The decision to consent to, or to refuse, the above testing is voluntary and entirely yours.
- You have had the opportunity to discuss the testing, including the purposes, limitations, and possible risks, with your healthcare provider or genetic counselor of your choice.
- You have all the information you want, and all your questions have been satisfactorily answered.

\_\_\_\_\_  
Signature of Patient or Patient’s Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Ordering Provider (if applicable)

\_\_\_\_\_  
Date