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Informed Consent for MyOme Personal Genome,
Proactive Health Report, 81 Genes and Pharmacogenomics Report

INTRODUCTION (all tests)

You have requested that MyOme perform genetic testing (the "Test"), ordered by your healthcare professional. You acknowledge that your submission of a specimen to be tested is voluntary. Please review the information in this Informed Consent carefully before signing. You may wish to speak with a genetic counselor prior to proceeding with a Test. If you decide to proceed with a Test or Tests, please [sign/check] where indicated below. The Test cannot be completed unless you confirm by [signing/checking] below and acknowledging that you have read, understood, and agreed to this Informed Consent.

ABOUT THE TEST(S) (all tests)

The purpose of MyOme Test is to look for mutations or genetic characteristics known to be associated with certain genetic diseases, conditions, and/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, benefits, and limitations.

AVAILABILITY OF GENETIC COUNSELING (all tests)

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.

LIMITATIONS OF THE TEST (all tests)

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. As with any laboratory test, there is a possibility of error. For example, 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 (all tests)

You acknowledge that you should not make medical decisions based on the results of the Test without speaking to your healthcare provider. The genetic test results will include information your healthcare provider may use in combination with their professional knowledge and clinical

information to determine 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 or may be used to inform your healthcare provider's treatment decisions (including prescription regiments). A positive result may have potential health implications for other members of your family. A negative test result indicates that a clinically significant variant was not detected, but false negatives are nonetheless possible. 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. Information regarding the certainty associated with Test results, if established, has been made available to you. Any changes to your healthcare should be performed in consultation with your medical providers, and prescription regimens should never be altered without consulting your prescribing healthcare provider.

INFORMATION COLLECTED (all tests)

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

PROTECTING THE PRIVACY OF YOUR INFORMATION (all tests)

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.

USE OF YOUR SPECIMEN AND INFORMATION (all tests)

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. 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 retention 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.

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 also acknowledge that genetic test results may have implications for your biological family members, and unexpected family relationships may be identified through genomic testing.

SPECIMEN STORAGE (all tests)

MyOme will retain your specimen at its discretion, but for no longer than 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.

Pharmacogenomic Supplementary Information

MyOme pharmacogenomic testing can help the ordering healthcare provider identify the safest, most effective medication and dosage for you and any medications to avoid. For each of the genes tested, you will learn which version (genotype) you have along with an interpretation of how the identified genotype may be expressed by your body and impact medication response (your “phenotype”). For example, based on a certain positive genotype, you might be a “Rapid Metabolizer” phenotype of a certain class of medications, meaning your body breaks them down more quickly than other people. An example of a negative phenotype is a “Normal Metabolizer.” If a list of current medications that you are taking is submitted with your order, you may also learn whether there are any drug–gene interactions or drug–drug interactions that should be taken into account by the ordering healthcare provider when determining your medication regimen. Your authorized healthcare provider(s) will also be given access to clinical decision support tools that provide guidance on drug or dose changes that may be advisable based on your genetics and current medications.

A "normal metabolizer" or “variant absent” result does not guarantee that the gene functions normally, but only that no tested non-normal alleles were detected. You acknowledge that even with a "normal metabolizer" or “variant absent” result, there is still a possibility of false negatives and that non-normal alleles may be present that are not detected by this test. 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.

The FDA, the Clinical Pharmacogenetics Implementation Consortium (CPIC), and PharmGKB provide information about how to interpret pharmacogenomic test results in the context of specific medications.

More information can be found below:

- FDA: https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations
- CPIC: https://cpicpgx.org/
- PharmGKB: https://www.pharmgkb.org/guidelineAnnotations

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The genetic test results will include information your healthcare provider may use in combination with their professional knowledge and clinical information to determine the best medical course of action, if any. MyOme generates a report for the gene(s) that were ordered by your healthcare provider. MyOme will not report variants of uncertain significance in the MyOme Personal Genome 81 Genes Report. 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.

ACKNOWLEDGEMENT (all tests)

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 answered to your satisfaction.

_____ _____

Signature of Patient or Patient's Authorized Representative Date

_____ _____

Signature of Ordering Provider (if applicable) Date