

**What is a pharmacogenomics test?** I understand that a pharmacogenomics (PGx) or pharmacogenetics test is a genetic test that is used to provide insight into how a patient may respond to certain medications. Additional information about this test is available on the National Institutes of Health website: <https://ghr.nlm.nih.gov/primer/genomicresearch/pharmacogenomics>

**What is the name of the test to be performed?** I hereby request the following PGx or pharmacogenetics test: PGxOne™ Plus. I understand that I can seek genetic counseling regarding this testing prior to giving this consent and was provided with written information identifying a genetic counselor or medical geneticist from whom I may obtain such counseling. I have received verbal and/or written information from my physician or from a genetic counselor that described, in words that I understood, the nature of the testing that I, or my child, will undergo. I have been given the opportunity to ask questions about the test and any concerns about the possible test results have been addressed. Prior to giving this consent, I discussed with the medical practitioner ordering the test the reliability of positive or negative test results and the level of certainty that a positive test result for the specific disease or condition tested for serves as a predictor of such disease or condition. I understand that a positive test result may be an indication that I am predisposed to or have the specific disease or condition tested for. The level of certainty that a positive test result for that disease or condition serves as a predictor of such disease will be reported to me, and utilizing that information, I understand that I may consider further independent testing, consult my physician or pursue genetic counseling. I understand that this test analyzes only the specific gene or portion of gene as stated on the requisition. If no mutation is found, I may still be at risk for the specific disease or condition tested for due to a genetic predisposition that cannot be detected by this test, either in the gene I was tested for or in another gene linked to the specific disease or condition tested for.

**What could this genetic test teach me?**

- **Primary Findings:** The test results will include: • Insight for therapeutic decisions • Assistance in developing treatment strategies based on a patient's specific DNA variants • A summary of the evidence behind the gene-drug interactions • The patient's genotype for each sequenced variant.
- **Secondary (Incidental) Findings:** Certain genes included on the PGxOne™ Plus test can be diagnostic or indicative of a genetic condition in addition to providing insight for treatment strategies based on a patient's specific DNA variants. These genes include: *DYPD*, Dihydropyridine dehydrogenase (DPD) deficiency; *G6PD*, Glucose-6-phosphate dehydrogenase deficiency; *UGT1A1*, congenital hyperbilirubinemia; *F2*, prothrombin (Factor II) associated thrombophilia; *F5*, Factor V Leiden associated thrombophilia; *RYR1/CACNA1S*, Myopathy/Malignant Hyperthermia; *CFTR*, Cystic Fibrosis; *POLG*, neurometabolic syndromes; and *MTHFR*, Methylenetetrahydrofolate deficiency.

**What limitations and risks are inherent to this pharmacogenetic test?** Admera Health's PGxOne™ Plus test has an accuracy rating of > 99% specificity and sensitivity. There are no known risks when the test is performed properly. Allergic reactions to the swab have not been reported. The alternative to not testing is to continue to receive standard medical care. Non-genetic factors that influence drug metabolism or inherited disease risk are not covered by this test. This test cannot detect long-term medical risks that I, or my child, might experience. An additional sample may be needed if the initial specimen is not adequate to complete the test.

**Pharmacogenetic/Genetic Counseling:** I understand that I should consult with a physician, pharmacist, genetic counselor, or other health care professional before and after I complete this test. I can find a genetic counselor here: [www.nsgc.org](http://www.nsgc.org). I agree to hold harmless Admera Health, their providers, practitioners, employees, and representatives from and against all responsibility or liability for injuries or damages resulting from 1. any negligent act or omission by Admera Health arising out of or in connection with the test or reporting the test results and 2. my failure to consult with my healthcare practitioner regarding the test results.

**How is the test performed?** At Admera Health, we collect our DNA samples using one of four different collection methods: buccal swab, mouthwash, saliva, and blood. Once the sample is collected, we extract (or remove) the DNA from the solution and purify it to get the DNA ready for sequencing. DNA sequencing is the process of determining the order of DNA building blocks known as nucleotides in a particular region or regions of DNA. There are many types of technology that can be utilized to sequence DNA. At Admera Health, we use Next-Generation Sequencing (NGS). NGS is a type of technology that allows the sequencing of DNA molecule(s) in a high-throughput process. This technology allows users to amplify an individual's DNA and sequences multiple regions in parallel in a quick and efficient manner. NGS also allows the users to read those sequences to detect single variant mutations, or changes in the DNA.

**Patient Release of Medical Documentation:** I authorize the release of my medical records, progress notes, my medication list, and corresponding ICD-10 codes by my provider for the purpose of obtaining the most comprehensive and personalized results for the PGxOne™ Plus test, which is designed to help my healthcare provider to manage my treatment plan.

**Patient Confidentiality:** Admera Health rigorously follows the standards established by the Health Insurance Portability and Accountability Act (HIPAA). Our adherence to HIPAA means that all personally identifiable health information is encrypted and stored safely. I understand that my, or my child's, test results will only be released to the ordering laboratory, the referring health care provider and/or my genetic counselor and will not be released to any other parties without my consent unless required by law. Health insurance companies and employers are prohibited from discriminating based on genetic test results by statutes enacted by the United States Federal Government. The same laws forbid genetic information to be disclosed without authorization. I understand that I can find more information at the following website: <https://www.genome.gov/about-genomics/policy-issues/Genetic-Discrimination>

**International Specimens:** If I, or my child, live outside the United States, I hereby represent that I am not knowingly violating any export ban or other legal restrictions in the country of my, or my child's, residence by providing a sample for testing.

**Specimen Retention:** I understand that the biological sample submitted by me, or my child, will only be used in a test that provides results for the purposes mentioned above, and that no tests other than those authorized above will be performed on such biological sample. I understand that DNA specimens are not returned to referring health care providers nor to individuals unless specific prior arrangements have been made. I understand that samples, including New York residents' samples, are not included in the de-identified research studies described in this authorization and are not retained for more than 60 days after test completion unless authorized explicitly by my selection below. I understand that such permission is optional, and testing and reporting of test results will be unaffected if I do not check the box for the New York authorization language. I understand that the laboratory will not use the biological sample for any other tests other than those authorized herein. However, I understand that my specimen may be de-identified in order to be used by Admera Health for test development and improvement, or for internal validation, quality assurance, or training purposes after the pharmacogenomics test is complete.


**Database Participation:** I have been informed that de-identified medical history and genetic data can help scientists and health care providers learn how genes affect human health and disease. I understand that sharing my, or my child's, information may help health care providers provide better care for their patients and researchers to make discoveries even though I, or my child, may not personally benefit. I understand that if I consent to Admera Health's use of test data, Admera Health may share my de-identified information with scientists, health care providers, and health care databases, and that none of my personal identifying information will be shared. Instead, any of my personal identifying data will be replaced with a unique code. I understand that a risk exists that I, or my child, could be identified based on the genetic and health information that is shared even though only a unique code is shared with the database. Admera Health believes that this is unlikely, although the risk is higher if I have previously shared my, or my child's, genetic or medical history with public resources, such as genealogy websites.

**Research Participation:** Separate from the above, Admera Health may collaborate with researchers, scientists, and drug developers to accelerate genetic disease knowledge and discover or develop novel treatments.

I understand that if I consent to de-identified database and/or research participation, Admera Health may allow my, or my child's, de-identified sample to be utilized and allow my, or my child's, healthcare provider to be contacted for research purposes, such as the development of new testing, drug development, discovery research related to novel variants that could have diagnostic or pharmacogenomic properties, clinical trials in connection with clinical utility validation studies, other treatment modalities, meta-analysis research, scientific research publications and presentations, and/or scientific and marketing written, oral, and/or published materials. I understand that I, or my child, may be contacted directly in certain situations, such as if my health care provider is not available. I understand that medical advances resulting from the research, including new tests, products, or discoveries, may be developed, and owned by the collaborating researchers and Admera Health and may have commercial value. I understand that I, or my child, or my, or my child's, heirs will not be compensated for any commercial value resulting from these studies.

**Acknowledgment and Consent:** I have read this consent form or have had the form read to me. I have a copy of this consent form. I have been given a chance to ask questions before I sign this consent form. I understand and acknowledge that I can ask other questions at any time. I also understand that the results of this testing will become part of my medical record and may only be disclosed to individuals who have legal access to this record or to individuals who I designate to receive this information. If I am signing this form on behalf of a minor for whom I am the legal guardian, I am satisfied that I have received enough information to sign on his or her behalf. By signing this form, I hereby consent to the terms herein and request that this genetic test done be performed.



I understand that genetic testing of appropriate individuals is often reimbursed by health insurance. I hereby agree to be responsible for any cost of the genetic test not reimbursed by insurance, including applicable co-pays or deductibles. I understand that I may contact my insurance company to determine coverage prior to giving this consent.

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| <br>_____<br><b>PHYSICIAN SIGNATURE</b> | _____<br><b>DATE</b> |
| _____<br><b>PRINTED NAME</b>   |                      |

Please indicate how you want your de-identified samples and information to be used:  
 (All specimens, including New York resident's specimens, will be destroyed after 60 days unless checked yes)

I allow my sample DNA and information to be used for research.       Yes     No

I allow my sample and information to be used for commercial products.     Yes     No

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| <br>_____<br><b>PATIENT SIGNATURE</b> | <br>_____<br><b>SIGNATURE OF AUTHORIZED REPRESENTATIVE</b> |
| _____<br><b>PRINT NAME</b>   | _____<br><b>PRINT NAME</b>  |
| _____<br><b>DATE</b>   | _____<br><b>DATE</b>  |
| _____<br><b>RELATIONSHIP</b>   |   |