



INFORMED CONSENT FOR PHARMACOGENETIC TESTING

Pharmacogenetic testing is used to help understand why some people respond better than others to certain medications and why some people develop side effects while others do not. FLEXHEALTH is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity pharmacogenetic testing. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. This pharmacogenetic test involves using your DNA, which can be found in your cells of blood or saliva, to examine your genetic make-up. In order to have your pharmacogenetic testing completed, the following is important information for you to know and understand:

- You are having an oral specimen sample given to examine pharmacogenetic information which may help your provider understand how you may respond to different medications.
- The Genetic Information Nondiscrimination Act (GINA) generally protects you against discrimination based on your genetic information when it comes to health insurance and employment.
- Pharmacogenetic testing is available as a fee-for-service test. By signing this, you understand that you are responsible for what your insurance carrier does not pay. You will be responsible for payment after the testing has begun, even if you decide not to receive results.
- Test results will include:
 - your genotype, which is your personal genetic make-up;
 - your phenotype, which is the functional meaning of your genetic make-up (e.g. “altered gene function”, “fast-”, “normal-”, or “poor metabolizer”).

LIMITATIONS

Pharmacogenetic testing may yield uninterpretable results for the following reasons: 1) Sample contamination, 2) insufficient sample collection, 3) incomplete knowledge of the available genetic markers, 4) technical reasons. This test does not account for all individual variations in the individual being tested. Absence of a detectable gene mutation does not rule out the possibility that a patient has different phenotypes due to the presence of an undetected polymorphism or due to other factors such as drug-drug interactions, comorbidities, and lifestyle habits

GENETIC COUNSELING

It is recommended that you obtain pre-testing and post-testing counseling from someone professionally trained in genetics to consider the purpose, meaning, risks, benefits, and limitations of, as well as any alternatives to, genetic testing in your particular situation, including your personal and family medical history. Counseling may be provided by a genetic counselor (such as those found on the National Society of Genetic Counseling website), doctor and other qualified healthcare professional. Further testing or additional physician consults may be warranted.

PATIENT CONFIDENTIALITY AND TEST RESULTS DISCLOSURE

Your personal information and test results are confidential. While there can be no guarantee of privacy, FLEXHEALTH has established reasonable safeguards to protect it. Test results will only be released to the ordering healthcare professional, to those allowed access to test results by law, and to those whom you authorize in writing. By requesting payment by your insurance company, Medicare or other third-party payor, you specifically authorize the release of your Protected Health Information (“PHI”), including your lab test results, to such third-party payor or its authorized agents or representatives, as necessary for the purpose of determining coverage and facilitating payment.