PATIENT INFORMED CONSENT AND INSURANCE ACKNOWLEDGEMENT

Important – Please Read Carefully: This Patient Informed Consent and Insurance Acknowledgement describes the purpose, procedure, benefits, limitations and possible risks of pharmacogenomics genetic testing to determine the patient's responsiveness to a variety of medications. Pharmacogenomics is the study of how the patient's genetic makeup affects their response to drugs. This is a voluntary test.

Purpose: The primary purpose of this test is to identify variants in the DNA that may predict how a patient responds to a variety of medications and the effectiveness of a particular drug to treat the patient's condition. A variant is a genetic difference expressed in a patient's DNA.

Test Procedure: The physician or their designee will use venipuncture to take a specimen of venous blood of not more than 15 ml or a CytoSoft™ brush to swab the inside of both cheeks. This will be forwarded to our laboratory for testing.

Important - Test Results and Interpretation: Your physician will evaluate and discuss with you the results of your pharmacogenomics genetic test in order to determine the best course of medical treatment. The possible results of the pharmacogenomics genetic testing are:

An Alternative Drug will be Prescribed:	As a result of your pharmacogenomics test, your physician may give a drug different from the one originally prescribed.
An Alternative Dose will be Prescribed:	As a result of your pharmacogenomics test, your physician may prescribe a higher or lower dose of the drug than originally prescribed.
No Changes in your Treatment Plan will be Required:	As a result of your pharmacogenomics test, your physician will continue with the original treatment plan, in terms of the choice of drugs and their dose.

The results of this test become a part of your medical record, and may be made available to individuals/organizations with legal authorization to access your medical record including, but not limited to, the physicians and nursing staff directly involved in your care and your current or future insurance carrier. MDL maintains the confidentiality of your tests results in full compliance with the Health Insurance Portability and Accountability Act (HIPAA) and applicable state laws.

The Federal Genetic Information Nondiscrimination Act of 2008 (GINA) protects individuals from any type of discrimination based on the results of genetic testing. For additional information about GINA and the state laws that also protect against discrimination based on the results of genetic testing, visit: www.ginahelp.org.

Test Benefits: The results of this pharmacogenomic genetic testing will assist you and your physician in making more informed choices concerning the most effective drugs and dosage to treat your condition.

Test Risks: There is a minor risk from the venipuncture required for this test. The patient may experience pain, soreness and bruising at the site of the venipuncture. Unlike other genetic testing, pharmacogenomics genetic tests do not generate results that will predict any disease or condition in your children or family members.

Test Limitations: This test provides information that can guide drug prescribing decisions by your physician. It does not diagnose or treat any disease or condition, nor does it predict responses to drugs other than those specifically indicated on our Test Requisition form and on our Website.

Additional information about this pharmacogenomics genetic testing can be found on the Medical Diagnostic Laboratories (MDL) patient website at: www.mdlab.com

Patient Statement of Informed Consent

By signing below, I have read and fully understand this form, and acknowledge the following:

- I have been informed by my physician of the purpose, procedure, benefits, limitations and possible risks of this pharmacogenomic genetic test. I have been given the opportunity to ask and have all my questions answered about this pharmacogenomic genetic test.
- I have discussed with my physician ordering this test, the reliability of the positive or negative test results and the level of certainty that a positive test result for the gene variant(s) tested serves as a predictor of drug effectiveness.
- I have read this entire document and have been informed that I may retain a copy for my records.
- I consent to this pharmacogenomics genetic test and I will discuss the results and the most effective drug treatment with my physician.
- I understand that my medical history and these test results will not be discussed or disclosed to a third-party, unless related to my treatment or payment for my treatment, without my express written authorization.

have read and fully understand the above, and give my consent to the **performance of this pharmacogenomic genetic test** and accept the consequences of this decision.

Patient Name: _____ Patient/Legal Guardian Signature: _____

Date: _____

Patient Consent to Use Sample for Research

Information obtained from your DNA samples may be used in scientific publications or presentations; all samples will be processed in a de-identified manner. The identity of all individuals who consented to the use of samples for research will not be revealed in any publication or presentation. Your refusal to consent to medical research will not affect your results. All DNA samples are discarded after 60 days unless used for research purposes in which case they are retained indefinitely.

Initial your selection below:

_____ **YES**, I consent to the use of my DNA sample for research purposes.

_____ **NO,** I do not consent to the use of my DNA sample for research purposes.

Patient Insurance Acknowledgement

Pharmacogenomic genetic testing determined to be medically necessary by your physician may or may not be reimbursed by health insurance.

I further understand that I am financially responsible for any amounts not covered by my insurer for this pharmacogenomic genetic test. MDL will perform the pharmacogenomic genetic test and bill me without further contact if my total financial responsibility will not exceed $150.00 for any reason, including co-insurance, co-payments, deductibles or non-covered services. If the out-of-pocket expense will exceed $150.00, I will be contacted to discuss my financial responsibility.

I understand that MDL will honor test cancellations received prior to the initiation of the testing. Once the pharmacogenomic genetic testing process has been initiated, no cancellation request will be honored and a claim for the services performed will be submitted to the patient's insurance company and the test result will be provided to the ordering physician.

I acknowledge that the information provided by me is true to the best of my knowledge. For direct insurance/third-party billing, I hereby authorize my insurance benefits to be paid directly to MDL and authorize MDL to release medical information concerning my testing to my insurer. If applicable, I authorize MDL to be my Designated Representative for purposes of appealing any denial of benefits.

I understand that if I am a patient with Medicare insurance, I may be required to complete an Advance Beneficiary Notice.

I also fully understand that I am legally responsible for sending MDL any money received from my health insurance company for the performance of this genetic test.

I also fully understand and agree to my financial responsibilities concerning the performance of this genetic test.

Patient Name: _____ Patient/Legal Guardian Signature: _____

Date: _____