



My Signature below acknowledges that a physician has ordered genetic testing. I authorize Express Gene Molecular Diagnostics to perform the genetic testing that was ordered. I understand the potential outcomes, including the benefits, risks and limitations of the screening as described below. I have had the opportunity to ask questions of a physician prior to giving my informed consent, and my questions have been satisfactorily answered. I also acknowledge that it is my responsibility to contact my personal physician, medical provider or genetic counselor and discuss the reported result.

**PURPOSE**

This Genetic Screening test analyzes specific changes in my DNA for the ordered disorders. The purpose of this test is to determine if I have specific genetic changes related to one or more of the ordered genes. Possessing one or more copies of one of these changes may increase my risk of disease associated with these genetic changes or may change the manner in which I metabolize certain medications. My physician may use this test to help determine the efficacy (i.e. will it work?) of a medication or if I am at risk of an adverse drug reaction. This testing may help my physician to identify certain medication to which I may react poorly or to help achieve a better therapeutic outcome. This test does not assess my risk of any other genetic disorder beyond what was ordered. I may use this information to inform my medical treatment decisions. I can find more details about this test, such as description of disorders and genes covered in this test on our website [expressgene.us](http://expressgene.us)

**LIMITATIONS OF THE TEST**

The test cannot determine how individuals respond to all medications in clinical use (see medication quick reference list). Response to medications is complex and may also be influenced by factors which are not tested for (e.g. compliance, concurrent illness, drug-drug interactions.). The test only determines response to indicated medications. Allergic reactions cannot be detected by this genetic test. The test does not detect all known variants in the genes tested. Only common variants present in Caucasian, African and Asian backgrounds are covered. If an individual carries a rare variant not covered by the test, the phenotype may be inaccurately reported. Testing for the common variants is the practice of most screening molecular genetic testing laboratories around the world.

**DNA SAMPLE AND TEST RESULTS DISCLOSURE**

I understand that DNA samples will only be used for testing that is authorized by the ordering physician. Any leftover DNA will be stored for at least 30 days. I understand that some samples may be maintained indefinitely after all testing has been completed for research purposes in an effort to advance scientific knowledge. In such a case, all personal identifiers will be removed in a HIPAA compliant manner, and any new results will not be returned or shared since they are generated from de-identified samples. I understand that I can opt-out of specimen storage by checking the box in the signature section below.

The original test results may be released to any entity that, by statute or law, has the legal authority to request and receive genetic results. Express Gene Molecular Diagnostics may discuss summaries of genetic test results in scientific presentations, publications, or marketing pieces. No names or personal identifiers will be revealed.

**GENETIC COUNSELING**

I understand that genetic screening results can be complex. Genetic counseling, which involves an in-depth discussion of the interpretation of this testing and the impact on me/my family may be useful and can be performed by a physician as well as a medical geneticist and/or a genetic counselor. Additionally, Express Gene Molecular Diagnostics staff is available to answer any questions I may have.

**PATIENT CONFIDENTIALITY**

To maintain confidentiality, the test results will only be released to the referring health care provider, to the ordering laboratory, to me, to other health care providers involved in my care and treatment or to others as entitled by law. The United States Genetic Information Nondiscrimination Act (GINA) of 2008 prohibits discrimination on the basis of genetic information with respect to health insurance and employment. GINA does not include protections from discrimination in life insurance, disability insurance or long-term care insurance.

I have read the Informed Consent document and I give permission to Express Gene Molecular Diagnostics to perform genetic testing as described.

Check here if you wish to opt-out of indefinite storage of your specimen.

\_\_\_\_\_  
Patient signature

\_\_\_\_\_  
Date (DD/MM/YYYY)