

INFORMED CONSENT FOR GENETIC TESTING



Patient Name: _____ Birth Date: ____/____/____ Sex: [] M [] F

I request the following test(s) ordered: _____

The Department of Health and Human Services defines genetic testing as "...an analysis performed on human DNA, RNA, genes and/or chromosomes to detect heritable or acquired genotypes, phenotypes, or karyotypes that cause or are likely to cause a specific disease or condition. A genetic test is also the analysis of human proteins and certain metabolites, which are predominantly used to detect heritable or acquired genotypes, mutations, or phenotypes."

Before testing, you should be well informed about the possible test results and how it may affect your life. The implications that may arise from the test results may involve both medical and psychosocial issues. The lab reports the test results only to the ordering physician, yourself, or another person of your choosing. Although the Genetic Information Nondiscrimination Act (GINA) of 2008 was signed into law, it is still possible that the result of genetic tests may lead to undesired discriminations (insurance, work-related, other). Genetic testing performed by the laboratory is highly accurate. However, due to technological and scientific limitations, some genetic testing may not always give a definite answer as desired. Usually, genetic test results may: (a) diagnose whether or not you have, or may be at risk for, a genetically inherited condition, (b) indicate whether or not you are a carrier for a condition, (c) predict if another family member has, is at risk for developing, or is a carrier of a genetically inherited condition, (d) be indeterminate due to technical limitations or familial genetic patterns, or (e) reveal non-paternity when both father and child are tested.

This genetic test is specific only for the tests requested (named above). It may not detect all mutations possible within this gene, nor detect mutations in other genes. Your sample, or your children's or fetus' samples, may be used for validation of future tests and/or educational purposes after personal identifiers are removed (irreversibly de-identified). For such use, the sample(s) may be stored for up to 20 years. If any de-identified sample test result shows that the health of the donor (the person from whom sample was obtained) may be at significant risk by a potentially serious disease, an informative letter will be mailed to everyone whose sample may have been included in the batch of de-identified samples. Refusal to permit the use of your sample for such future test validation and/or educational purposes will not affect the results of the tests ordered above. You can withdraw your consent at any time by contacting the laboratory.

Please be sure to provide your physician with accurate reports of family medical history and biological relationships. Test interpretation may depend on accurate family history information. Also, it is the patient's responsibility alone to inform other family members of possible genetic risks they may have. In some cases, genetic testing may reveal previously unrecognized biological relationships, such as non-paternity or a genetic condition in another family member. Genetic analysis is a fee-for-service test. You will be responsible for payment after the testing has begun, even if you decide not to receive the results.

I, the undersigned hereby consent to the laboratory test that are ordered by my healthcare provider. I further authorize and instruct that all insurance payments of benefits under my policy for laboratory services furnished to me, my dependent, or insured under my policy be made directly to FirmaLab, Inc. I further acknowledge that FirmaLab is an out-of-network provider and that my insurance may only cover a portion of the total bill that I may be responsible for. I agree to cooperate with FirmaLab on any collections or appeals process and that I am responsible for paying any payments, co-pays, and deductibles not covered. In addition, I hereby authorize the release of my protected health information to FirmaLab representatives and I authorize and release FirmaLab, their agents, officers, employees and representatives from any and all liability that may arise as a result of disclosure of any protected health information to other third parties for reimbursement. With this release and assignment, I am requesting that FirmaLab instructs my insurance carrier to forward all payments for lab services to FirmaLab directly. I understand that some insurance companies may send payments directly to me, my dependent, or persons that are insured under my policy. I agree to endorse and forward those payments to FirmaLab immediately. If I do not forward these payments to FirmaLab immediately, I may be responsible for all reasonable costs of collection, including attorney's fees. I further acknowledge that keeping insurance proceeds of FirmaLab may potentially have severe civil and criminal consequences. I acknowledge receipt of a copy this Assignment and Release. A photocopy of this authorization shall be considered as effective and valid as the original. This Assignment of Benefits and Release will remain in effect until revoked by me in writing.

I am voluntarily seeking laboratory service and hereby consent to provide a sample as requested. I have the right to refuse testing, but I understand this may impact my treatment. This agreement can be revoked by me at any time with written notification and is valid until revoked. I hereby assign to the laboratory my right to insurance benefits that may be payable to me for services provided arising from any insurance policy, self-insured health plan, Medicare or Medicaid in my name or on my behalf. I further authorize payment of benefits directly to the laboratory. I understand acceptance of insurance does not relieve me from any responsibility concerning payment for laboratory services and that I am financially responsible for all charges whether or not they are covered by my insurance. I understand that any payment I receive for services rendered by the laboratory from my insurance provider should be forwarded to the laboratory immediately.

I request and authorize the use of my sample for genetic testing. My signature below constitutes my acknowledgment that the benefits, risks, and limitations of this testing have been explained to my satisfaction by a qualified clinician. I authorize the release of my test result to the clinician listed below.

Print Name of Legal Guardian (If patient is below 18 years of age) _____ Print Patient's Name

Signature _____ Relationship to Patient _____ Date _____