

**CLIA#22D0883928
New York State# CQP4866**

I request and authorize Dr. Katherine B. Sims and Associates at the Massachusetts General Hospital (MGH) Neurogenetics DNA Diagnostic Laboratory to analyze a sample of DNA isolated from blood or tissue (type) obtained on (date) _____, to assess the probability that myself/ fetus/ child (circle one) has inherited a genetic mutation in the gene(s) for which testing is ordered.

A. The **test procedure** has been explained to me, and I understand that one of number outcomes might result:

1. The test results identify a DNA mutation presumed to be pathologic and indicated, therefore, that is likely that myself/fetus/child will be **AFFECTED** with the disease. The clinical course, however, can not be predicted directly from the mutation identified.
2. The test results identify a DNA change which is presumed a benign polymorphism.
3. The test results identify a DNA change whose significance is unclear.
4. If no mutation is identified (negative test result), in a person with a family history of the DNA genetic disorder, two different conclusions are suggested:
 - a. If a clinically affected family member has had a DNA mutation identified, a negative test (no mutation identified) result on myself/fetus/child (circle one) highly suggest that tested person will **NOT** be **AFFECTED** with the disease.
 - b. If no DNA mutation has yet been identified in affected family members, a negative test result (no mutation identified) can not exclude the possibility that a mutation in the gene exists and has just not been found or that a mutation exists in another gene potentially associated with the clinical phenotype and for which testing was not done.

B. In case of **prenatal testing**, maternal cell/DNA contamination of the fetal sample may occur. If not detected, maternal contamination could result in misdiagnosis.

I understand that the diagnostic testing procedures performed by the MGH Neurogenetics DNA Diagnostic lab will only indicate the likelihood that I/my child/my fetus (circle one) carry a DNA mutation in the tested gene. I understand, if applicable, that the results of prenatal testing do not guarantee the birth of a normal child since the testing only applies to the genetic disorder tested. This testing has a low, but finite, total error rate that is to be less than 1%.

Neurogenetics DNA Diagnostic Lab
Massachusetts General Hospital
Center for Human Genetic Research
CRP Building North, Suite 5300
185 Cambridge Street
Boston, MA 02114

*Consent Form for
DNA-based Analysis*

Director: Katherine B. Sims M.D.
Co-Director: Winnie Xin Ph.D.
Lab Coordinator: Kellie A. Burke
Phone: 617-726-5721/Fax: 617-724-9620
Website: www.dnalab.org
Email: kaburke@partners.org

The MGH Neurogenetics DNA Diagnostic Lab disclaims responsibility, and shall not be liable, for any individual including, but not limited to, the undersigned individual/parents or the fetus, for damages or otherwise for any action taken in response to the test results including termination of the pregnancy where the fetus was found not to be affected, or failure to terminate the pregnancy in instances in the child is affected.

Despite the highly accurate nature of this testing and laboratory quality control measures, errors (false positives and false negatives) may occur at a frequency estimated to be less than 1%.

Results from this clinical genetic testing will be sent by written report to the referring professional. We are available as need to discuss testing methodology, test results, the laboratory interpretation and answer questions directly with the referring professional. Direct discussions with patient and/or family members are not possible.

Results will NOT be entered by us into your medical record. They are stored in our files with code number identifier only. Access to these records is restricted. These records will be maintained in confidentiality in accordance with the applicable laws and the policies of the Massachusetts General Hospital (MGH). You should be aware that genetic information, including molecular DNA test results, may influence insurance and/or employers regarding your health status.

Signature: _____ (patient)

Date: _____

Signature: _____ (parent/legal guardian)

Date: _____

Signature: _____ (professional obtaining consent)

Date: _____