Informed Consent for Genetic Testing

In compliance with New York State Civil Law: Section 79-L

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Informed Consent for Genetic Testing

Please provide a copy of completed consent with sample and requisition. Failure to do so may delay testing.

When signed and dated, this written consent is written authorization to participate in genetic testing.

1. Purpose of the Test: My physician has explained the recommended testing: ___________________________ (name of test or MNG test code), which is performed to help diagnose ___________________________.

I am aware that all documentation regarding this testing, including the description of the purpose, methodology, and disorders is freely available at www.mnglabs.com/tests and has either been reviewed with me by my physician or I have read the documentation on my own. Patient (or parent/guardian) initials: ________________

2. Statement Regarding Test Result: A positive test result is an indication that the individual has a genetic cause for the specific disease tested for. A negative result may/may not rule out a genetic disorder depending on clinical history and quality/type of specimen tested. The individual may wish to consider further independent testing, consult a personal physician or pursue genetic counseling.

3. Level of Certainty: Is test-specific and determined by the methods employed, patient’s clinical history and sometimes by the nature of the patient's condition at time of sampling. There is always a small possibility of error or failure in sample analysis; this is true with complex testing in any laboratory. Inclusion of clinical data, such as medical history, family history, images as they relate to the disease or disorder, will decrease the level of uncertainty in an interpretation and are encouraged to be included when submitting samples for analysis. MNG Laboratories will keep personal information private in accordance with HIPAA laws.

I consent to the retention of these documents by MNG Laboratories in their database. Patient (or parent/guardian) initials: ________________

4. Disclosing Test Results: The following categories of persons or organizations that test results may be released to include, but are not limited to: hospitals or laboratories involved in the patient’s care, referring physician(s) and primary care providers, other physician groups (consultants, surgeons), insurance companies (as provided by the patient or referring physician for payment purposes), and other professionals involved in patient care that assist MNG Laboratories in carrying out treatment, payment, and operational activities. Results are kept confidential. Medical Neurogenetics complies with security and privacy statutes of the federal Health Information Portability and Accountability Act (HIPAA). If a patient chooses to specifically declare where results may be released (other than the referring institution and ordering physician), please provide these in writing to the Compliance Officer, MNG Laboratories (quickresponse@mnglabs.com).

5. Consent to Retain Specimen: The laboratory does not return any remaining sample to individuals or physicians unless requested. No clinical tests other than those authorized shall be performed on the sample. A request for additional testing must be made by my referring physician or other authorized healthcare professional and there will be an additional charge. If agreed by the patient, MNG Laboratories will retain the samples for longer periods for use in an anonymous fashion for research/development or for quality assurance processes.

I consent to have my specimens retained after completion of initial testing (this consent may be withdrawn at any time and the laboratory will destroy any remaining sample). Patient (or parent/guardian) initials: ________________

6. Testing for Genetic Conditions can be Complex: If warranted, obtain professional genetic counseling prior to giving consent to fully understand what the risks and benefits are to having the testing completed. I hereby consent to participate in testing described above. I understand that a biologic specimen will be obtained from me and/or members of my family. I understand that this biologic specimen will be used for the purpose of attempting to determine if I, or members of my family, are affected or are carriers of a particular disease or are at increased risk to someday be affected with this genetic disease.

Signature of Patient ___________________________ Date ________________

Authorized Signature (Parent/Guardian) ___________________________ Relationship ________________

Name of Patient (please print clearly) ___________________________ Name of Ordering MD (please print clearly) ___________________________

Referring Facility (please print clearly) ___________________________ Signature of Ordering MD ___________________________

Important: One signature from patient (or parent/guardian), authorized person, or physician is required to complete this form. New York requires signatures from patient (or parent/guardian) AND ordering physician to complete this form.