MOUNT SINAI GENETIC TESTING LABORATORY

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Biochemical Genetics Laboratory

INFORMED CONSENT FOR BIOCHEMICAL GENETIC TESTING

I, _____, request and authorize Mount Sinai Genetic Testing Laboratory to perform _____ tests on my (or my child's) sample.

I understand that the biological samples (blood, DBS, urine, etc) obtained from me (or my child) for Biochemical Genetic Testing (either metabolite analyses or enzyme analyses) will be used for the diagnosis of genetic metabolic conditions. It may or may not:

1. Diagnose whether or not I have (or my child has) a particular condition or at risk for developing this condition
2. Indicate whether or not I am (or my child is) a carrier for this condition
3. Predict that another family member has or is at risk for developing this condition
4. Predict that another family member is a carrier of this condition
5. Be indeterminate or negative due to my (or my child's) clinical status (fasting, illness, etc.) at the time the sample was drawn or technical limitations
6. Be falsely positive due to my (or my child's) clinical status (illness, medication, etc.) and nutritional status

Clinical information and family history are often necessary for optimal test interpretation. Several sources of error are possible, including, but not limited to: sample mishandling, sample misidentification, and sample contamination. These results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. The result of my (or my child's) test will be explained to me by my physician or by a genetic counselor, who will have opportunity to discuss my results with a clinical geneticist. No test will be performed and reported on my (or my child's) sample other than the one(s) authorized by my physician. My (or my child's) sample may be used for research development or education after personal identifiers are removed. Refusal to permit the use of my sample will not affect my test result. For such use, the sample may be stored indefinitely.

☐ I consent that my (or my child's) remaining samples can be used anonymously for research purpose by this laboratory. Initial: _____.

I have had the opportunity to have all of my questions answered. If I am signing this form on behalf of a minor for whom I am the legal guardian, I am satisfied that I have received enough information to sign on her/his behalf. I understand that this consent is being obtained in order to protect my right to have all of my questions answered before testing. I also understand that the results of this testing will become part of my medical record and may only be disclosed to individuals who have legal access to this record or to individuals who I designate to receive this information.

_____	_____	_____
Signature of Patient (or guardian)	Print name	Date
_____	_____	_____
Signature of Witness	Print name and title	Date