ARUP LABORATORIES

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Web site: www.aruplab.com

INFORMED CONSENT FOR BIOCHEMICAL GENETIC TESTING

Patient Name _____**Date of Birth** ___/___/___ **Gender** □ **Female** □ **Male**

I request the following tests be performed: _____

The intended purpose is: □ **Diagnosis** □ **Carrier status**

□ **Other** _____

I request and authorize ARUP Laboratories to perform the above designated tests for my (or my child's) sample. My signature below constitutes my acknowledgment that the benefits, risks, and limitations of this testing have been explained to my satisfaction by a qualified health professional.

The following has been explained to me:

1. Biochemical genetic testing may or may not:
   a) diagnose whether or not I have (or my child has) a particular condition or at risk for developing this condition
   b) indicate whether or not I am (or my child is) a carrier for this condition
   c) predict that another family member has or is at risk for developing this condition
   d) predict that another family member is a carrier of this condition
   e) be indeterminate or negative due to my (or my child's) clinical status (fasting, illness, etc.) at the time the sample was drawn
   f) be indeterminate due to technical limitations
2. Biochemical genetic testing may or may not provide information aiding my (or my child's) diagnosis. It will not detect the specific gene mutations responsible for a biochemical genetic disorder.
3. Clinical information and an accurate family history are often necessary for optimal test interpretation.
4. Several sources of error are possible, including, but not limited to: sample mishandling, sample misidentification, and sample contamination.
5. If a genetic disorder is identified, insurance rates, obtaining disability or life insurance, and employability could be affected. Federal law extends some protections regarding genetic discrimination (http://www.genome.gov/10002328). It is my responsibility to consider the possible impact of these results. All test results are released to the ordering health care provider and those parties entitled to them by state and local laws.
6. The performance characteristics of this test were validated by ARUP Laboratories. The U.S. Food and Drug Administration (FDA) has not approved this test; however, FDA approval is currently not required for clinical use of this test. ARUP is authorized under the Clinical Laboratory Improvement Amendments (CLIA) and by all states to perform high-complexity testing. These results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.
7. Biochemical genetic analysis is a fee-for-service test. I will be responsible for payment after the testing has begun, even if I decide not to receive results.
8. ARUP will provide a local referral for follow-up genetic counseling, at my request.
9. My (or my child's) sample may be used for test validation 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 can withdraw my consent at any time by contacting the laboratory at (800) 242-2787, ext. 3301. For more information about ARUP, please refer to www.aruplab.com.

Patient/Guardian Signature _____ Date _____

Physician/Genetic Counselor:
I have explained biochemical genetic testing and its limitations to the patient or legal guardian and answered all questions.

Printed Name of Physician/Genetic Counselor _____ Date _____

Signature _____ Phone Number _____

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THIS IS NOT A TEST REQUEST FORM.
The information below is required to perform biochemical genetic testing.
For electronic orders only, please fill out and submit with the electronic packing list.

PATIENT HISTORY FOR BIOCHEMICAL GENETIC TESTING

Client Number _____

Patient Name _____Date of Birth _____ Gender [ ] Female [ ] Male

Physician/ Genetic Counselor_____ Phone # _____

Comments or Special Instructions _____

_____

Referring Diagnosis _____

_____

PATIENT SYMPTOMS

[ ] Acidosis	[ ] Hypoglycemia	[ ] Hyperammonemia	[ ] Failure to thrive
[ ] Seizures	[ ] Macrocephaly	[ ] Microcephaly	[ ] Developmental delay
[ ] Coarse features	[ ] Organomegaly	[ ] Skeletal anomalies	[ ] Corneal clouding
[ ] Cardiomyopathy		[ ] Other _____	

PATIENT ETHNICITY (check all that apply)

[ ] African American	[ ] Ashkenazi Jewish	[ ] Asian	[ ] Caucasian
[ ] Hispanic	[ ] Middle Eastern	[ ] Native American	[ ] Other_____

LIST THE PATIENT'S MEDICATIONS, INCLUDING ANTIBIOTICS, ANTICONVULSANTS, AND ENZYME REPLACEMENT THERAPY.

_____

LIST THE PATIENT'S SPECIFIC DIET OR FORMULA.

_____

ARE THE PATIENT'S PARENTS RELATED TO ONE ANOTHER?

[ ] No [ ] Yes [ ] Unknown If yes, please describe_____

Please submit with sample or fax this form directly to Dr. Marzia Pasquali, Biochemical Genetics Laboratory (801) 584-5207.

Master Label