ARUP LABORATORIES

500 Chipeta Way, Salt Lake City, Utah 84108-1221
Phone: (800) 522-2787 Fax: (801) 584-5249
Web site: www.aruplab.com

INFORMED CONSENT FOR MOLECULAR GENETIC TESTING

Patient Name ________________________________ **Date of Birth** ____/____/____ **Sex** ☐ **Female** ☐ **Male**

Condition(s) to be tested: ________________ ____

Testing purpose: ☐ **Diagnosis** ☐ **Carrier status** ☐ **Predictive** ☐ **Prenatal** ☐ **Other** ___________________

I request and authorize ARUP Laboratories to test me (or my child/pregnancy) for the above genetic condition(s).

1. DNA test results may:
   a) determine whether or not I (or my child/pregnancy) am affected with, a carrier of, or at risk for developing the above condition.
   b) predict another family member is affected by, at risk for developing, or is a carrier of this condition.
   c) be indeterminate due to limited information regarding the pathogenicity of identified variant(s), technical limitations, or familial genetic patterns.
   d) reveal non-paternity.

2. DNA testing is specific only for the gene or condition(s) named above and will not detect all disease- causing variants.

3. The significance of a positive and a negative test result based on my family history has been explained.

4. Although DNA testing usually yields precise information, several sources of error are possible. These include, but are not limited to, clinical misdiagnosis of the condition, sample misidentification, and inaccurate information regarding family relationships.

5. If a disease-causing gene variant 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). 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 Clinical Laboratory Improvement Amendments (CLIA) and by all states to perform high-complexity testing. The results are not intended to be used as the sole means for clinical diagnosis or medical management decisions.

7. Genetic counseling is recommended prior to, as well as following, genetic testing. There are psychological risks associated with genetic testing. Positive results may cause feelings of depression, futility or despair. Uncertain results may cause frustration.

8. My (or my child/pregnancy's) de-identified DNA sample may be stored indefinitely for test improvement or education purposes. All samples from New York clients will be disposed of 60 days after testing is complete.

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 and I have been provided a copy of the corresponding additional technical information form describing testing for the condition(s) listed above.

Patient/Guardian Printed Name _____________________ Signature _________________________Date ____________

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

Physician/Genetic Counselor Printed Name ______________________________Signature______________________________

Date _________________Phone Number ______________________________ Practice Type_____________________________