

## INFORMED CONSENT FOR MOLECULAR GENETIC TESTING

**Last Name** \_\_\_\_\_ **First Name** \_\_\_\_\_

**Date of Birth** \_\_\_\_\_ **Gender**  Female  Male

**I request DNA analysis for the condition** \_\_\_\_\_

**The intended purpose is**  Screening  Prenatal  Diagnosis  Carrier status  Predictive  
 Other \_\_\_\_\_

**I request the following tests be performed:**  
 \_\_\_\_\_  
 \_\_\_\_\_

I request and authorize ARUP Laboratories to test my (or my child's or my fetus') sample for the above-designated genetic condition. 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) DNA test results may:
  - a) diagnose whether or not I have this condition or am at risk for developing this condition
  - b) indicate whether or not I am a carrier for this condition
  - c) predict another family member has or is at risk for developing this condition
  - d) predict another family member is a carrier of this condition
  - e) be indeterminate due to technical limitations or familial genetic patterns
  - f) reveal nonpaternity
- (2) This DNA test is specific only for the condition named above. It will not detect all mutations possible within this gene, nor detect mutations in other genes.
- (3) The significance of a positive and a negative test result based on my family history has been explained.
- (4) Although mutation and/or linkage analysis usually yield precise information, several sources of error are possible. These include, but are not limited to, clinical misdiagnosis of the condition, sample misidentification, sample contamination, and inaccurate information regarding family relationships.
- (5) DNA testing may cause emotional stress and result in discrimination (insurance or work-related). All test results are treated with standard medical confidentiality. If an insurance provider requires test results for reimbursement purposes, the laboratory is obligated to release them.
- (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 patient management decisions.
- (7) DNA 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 or my fetus') 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 2946. For more information about ARUP, please refer to www.aruplab.com.

**Patient/Guardian Signature** \_\_\_\_\_ **Date** \_\_\_\_\_

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

**Printed Name of Physician/Genetic Counselor** \_\_\_\_\_ **Date** \_\_\_\_\_

**Signature** \_\_\_\_\_ **Phone Number** \_\_\_\_\_