

INFORMED CONSENT FOR CYTOGENETIC TESTING

Patient Name _____ **Date of Birth** ___/___/___ **Sex** Female Male

Test Indication _____

Test(s) to be performed _____

I request and authorize ARUP Laboratories to perform the above designated test(s) for me (or my child / fetus).

1. Cytogenetic testing may:
 - a) determine whether or not I (or my child / fetus) am affected with, a carrier of, or at risk for developing the above condition
 - b) identify a genetic condition that I did not know I (or my child / fetus) was at risk for
 - c) predict another family member is affected by, is at risk for developing, or is a carrier of this condition
 - d) be indeterminate due to limited information regarding the pathogenicity of identified variant(s), clinical status (post-transfusion, etc.), or technical limitations
 - e) reveal non-paternity or reveal a biological relationship between the parents of the individual being tested
2. Clinical information and family history may be necessary for optimal test interpretation.
3. The significance of a positive and a negative test result based on my family history and clinical indication 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 or contamination, and inaccurate information regarding family relationships.
5. If a chromosome abnormality 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, Inc. 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. These results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.
7. I will be responsible for payment after the genetic testing has begun, even if I decide not to receive results.
8. Genetic counseling is recommended prior to, as well as following, genetic testing. ARUP will provide a referral for genetic counseling at my request.
9. My (or my child's / fetus') sample may be stored indefinitely to be used for test validation or education after personal identifiers are removed. No clinical tests other than the ones authorized will be performed. I may request disposal of my blood /tissue and DNA sample following completion of the test requested above by contacting the laboratory at (800) 242-2787, ext. 3301. For more information about ARUP, please refer to www.aruplab.com.

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 technical information sheet describing the testing 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.

Printed Name of Physician/Genetic Counselor _____ Signature _____

Date _____ Phone Number _____ Practice Type _____