ARUP LABORATORIES

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INFORMED CONSENT FOR CYTOGENETIC TESTING

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

Test Indication _____

Sample Type

☐ **Blood**	☐ **Bone Marrow**	☐ **Tissue**
☐ **Cord Blood**	☐ **Amniocytes**	☐ **Chorionic Villi**

Tests Name(s) to be performed _____

I request and authorize ARUP Laboratories to perform the above designated test(s) on the sample from me (or my child or fetus). 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. Cytogenetic testing may:
    a) diagnose whether or not I have (or my child or fetus has) a particular condition or am at risk for developing this condition
    b) identify a chromosomal condition that I did not know I (or my child or fetus) was at risk for
    c) indicate whether or not I (or my child or fetus) am a carrier for this condition
    d) predict another family member has or is at risk for this condition
    e) predict another family member is a carrier of this condition
    f) be indeterminate or negative due to my (or my child's or fetus') clinical status (post-transfusion, etc) at the time the sample was drawn
    g) be indeterminate due to technical limitations
    h) reveal non-paternity, especially in the context of familial testing
    i) reveal a biological relationship between the mother and father of the individual being tested
2. Cytogenetic testing may provide information aiding my (or my child's or fetus') diagnosis.
3. Clinical information and family history may be 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 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. Cytogenetic 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 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. 3301. 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 _____