

INFORMED CONSENT FOR MOLECULAR CYTOGENETIC TESTING



TEL 509.474.6840 / FAX 509.474.6839
TOLL FREE 1.877.SigChip (744.2447)
www.signaturegenomics.com / info@signaturegenomics.com

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

I request the following tests be performed: _____

I request and authorize Signature Genomic Laboratories, LLC 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. Based on these explanations, I understand the following:

1. The test is called array comparative genomic hybridization (array CGH). It is a test that compares the DNA of a known normal reference control to that of a patient with a suspected DNA copy number change.
2. The purpose of this test is to determine whether my (or my child's or my fetus') sample has changes in the DNA copy number that may explain the clinical presentation.
3. I was informed that I may wish to obtain genetic counseling prior to signing this consent form.
4. If the test is "positive," this would be an indication that I (or my child or my fetus) may be predisposed to or have the specific condition(s) tested for, and I may wish to consider further independent testing, consult my physician, or pursue genetic counseling.
Note: a "positive" result may be disease-causing or may be considered "of unclear clinical significance." Signature Genomics' "positive" detection rate is 21%, including 6-8% of unclear clinical significance.
5. The conditions I am tested for are listed on the loci list provided by Signature Genomics, and can be found on its website at <http://www.signaturegenomics.com/resources.html>.
6. The SignatureChip is a "whole genome" array and therefore may identify genetic conditions not included in the representative list of Disorders Tested. The SignatureChip may identify copy number changes associated with adult-onset conditions and/or cancer predisposition that are potentially unrelated to the patient's current clinical findings, but that may become apparent later in life.
7. I authorize Signature Genomic Laboratories, LLC to release the results of this test to my ordering physician and/or genetic counselor.
8. I have been informed that no tests other than those authorized shall be performed on my (or my child's or my fetus') biological sample and that my (or my child's or my fetus') biological sample shall be destroyed at the end of the testing process or not more than sixty (60) days after the sample was taken, unless a longer period of retention is expressly authorized in the consent.
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 Signature Genomics at 877.SigChip (877.744.2447).
10. I do not wish to allow my (or my child's or my fetus') sample to be used for test validation or education. Therefore, I am checking this box to indicate that the sample should be used only for the test specified above and will be destroyed after 60 days.

Parent/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: _____