BAYLOR MIRACA GENETICS LABORATORIES

PHONE: 800-411-GENE | FAX: 713-798-2787 | www.bmgl.com

SHIP TO: Baylor Miraca Genetics Laboratories
2450 Holcombe, Grand Blvd. -Receiving Dock
Houston, TX 77021-2024
Phone: 713-798-6555

CMA POSTNATAL CONSENT FOR NY CLIENTS

I, _____, understand that my physician has recommended genetic testing for myself and/or my child or children for (insert name of test) _____. I hereby voluntarily agree to submit my and/or my child's or children's sample(s) for testing as recommended by my physician. I understand that biological samples will be collected using generally accepted techniques, the risk(s) of which I have been separately informed. I understand that testing of my and/or my child's or my children's sample(s) will be limited to the test ordered by my physician. I understand that the sample(s) will be used for the purpose of attempting to determine if I and/or my family members have a mutation(s) in this disease gene(s). Results may indicate affected status, increased risk to someday be affected with and/or reproductive risk for this disease. The minor child or children for which I hereby give permission to collect biological sample(s) for this test is/are named below*:

_____ _____ Child's Gender: ☐ FEMALE ☐ MALE

Child's Name (Last, First, MI) Child's Date of Birth (MM/DD/YY)

☐ *If additional children are being tested please check this box AND list their name, date of birth, and gender on the back of this consent

I understand that:

1. The test is called array comparative genomic hybridization (CMA). Genomic DNA from the test sample and a control sample are differentially labeled with fluorescent dyes and hybridized to the oligos. Results are analyzed using quantitative imaging methods and analytical software to assist in identifying each targeted-DNA sequence as loss of copy number (deletion), gain of copy number (duplication) or normal copy number.
2. Chromosomal Microarray Analysis may be ordered for all patients with any indication of genomic imbalance which includes: dysmorphic features, unexplained mental retardation/developmental delay, autism spectrum disorder, and/or multiple congenital anomalies. CMA is the more appropriate test for patients who are candidates for subtelomere FISH or multiple individual FISH tests. CMA is well suited for the detection of interstitial duplications that currently can only be detected by interphase FISH. Although CMA can detect some deletions or duplications that cause single gene or contiguous gene phenotypes (e.g. Pelizaeus-Merzbacher), additional testing methodologies should be appropriately considered.
3. CMA is a new and sensitive test. It is possible that the test will detect a genetic abnormality for which there is currently very little medical information available to predict the type of clinical problems that may develop in an individual. While the test is very accurate, not every genomic abnormality (genetic defect) can be detected by a test. For some conditions, genomic gains or losses at a particular locus may represent only a certain percentage of the genetic changes associated with that given disorder. For instance, in some disorders, 99% of the cases may be detected by the test, while for others the detection rate may be 70% or less. There are some changes in chromosomes that CMA can not detect such as balanced rearrangements or changes in regions not covered by the array. Many of these can be detected by karyotype analysis which can be run as a supplemental test.
4. There are several categories of test results that may be reported including:
    a. A clinically significant abnormality IS detected, known to be associated with a genetic disease.
    b. A clinically significant abnormality IS NOT detected, however my clinical diagnosis may still be correct. This event may be due to medical science's current lack of knowledge of all the gene(s) involved with the disease or the inability of the current technology to identify certain types of mutations in the gene (s) which cause the disease.
    c. A result of uncertain clinical significance is detected. Additional testing of the patient and/or other family members may be recommended to help determine the significance of the result.
    d. Unexpected test results may be detected. These results may occur with screening tests that evaluate many different genetic regions. From these tests, information may be learned about you, your child/children or your family that is not directly related to the clinical reason for ordering the test. This information may provide data about the risk for a different genetic disease with symptoms that may or may not be currently evident.
5. An error in the test interpretation may occur if the true biological relationships of the family members being tested are not as I have stated. For example, a deletion or duplication detected in an affected individual but not detected in the parents may be interpreted as a clinically significant change, but this interpretation is wholly dependent on testing of the biological parents. If the stated father of an individual is not the true biological father, this interpretation may be incorrect.
6. This consent form should not be used for prenatal diagnosis. For these cases, we require that the referring professional consult directly with our laboratory regarding all the sample and paperwork requirements. Specific consent forms may also be required.
7. Genetic tests are relatively new and are being improved and expanded continuously. The tests are not considered research, but are considered to be an appropriate means of evaluation at the time of testing. This testing is complex and utilizes specialized materials so that there is always a very small possibility that the test will not work properly or that an error will occur.
8. The laboratory does not return the remaining sample to individuals or physicians; however, in some cases, it may be possible to perform additional studies on the remaining sample. The request for additional studies must be made by my referring physician or other authorized healthcare professional and there will be an additional charge. Samples will be retained in the laboratory in accordance with the laboratory retention policy. I do understand that I have the right to withdraw this consent at any time, and the entity storing the sample shall promptly destroy the sample or portions thereof that have not already been used. **PLEASE INITIAL:** _____
9. Information obtained from the CMA test may be used in scientific publications or presentations, but the identity of all persons studied will not be revealed in such publications/presentations. I understand that my (or my child's) sample may be kept by the laboratory for quality assurance testing. In addition, my (or my child's) sample may be shared with other scientists who are doing research in genetic problems. If my (or my child's) sample is retained in the laboratory or shared with other scientists, my (or my child's) name and any other identifying information will be removed from the sample. For such use, the sample may be store indefinitely. I can withdraw my consent at any time by contacting Baylor Miraca Genetics Laboratories at 1-800-411-GENE.**

** FOR NY PATIENTS: I understand that no genetic test other than those I have authorized shall be performed on my biological sample and the sample will be destroyed at the end of testing or not more than 60 days after the sample was taken.

LAST UPDATED: 2/2015

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10. Because of the complexity of genetic testing and the implications of the test results, results will only be reported to me through the ordering healthcare professional. The results are confidential and will only be released to other medical professionals or other parties with my written consent. All laboratory raw data are confidential and will not be released unless a valid court order is received.
11. Results may have clinical or reproductive implications for my family members. In rare cases, persons with genetic diagnoses have experienced problems with insurance coverage, employment and other entities. Participation in genetic testing is completely voluntary. I understand that I may wish to obtain professional genetic counseling prior to signing this consent form.
12. I understand that a positive test result is an indication that I or the individual(s) being tested may be predisposed to or have the specific disease or condition tested for and may wish to consider further independent testing, consult my or his/her/their physician or pursue genetic counseling.
13. My signature below acknowledges my voluntary participation in this test, but in no way releases the laboratory and staff from their professional and ethical responsibility to me.
14. I will receive a copy of this consent form.

Signature: _____ Printed Name: _____

Date: _____ Relationship to Patient: _____ Witnessed by: _____

PHYSICIAN'S STATEMENT: I have explained the genetic testing specified to this individual. I have addressed the limitations outlined above, and I have answered this person's questions. I have obtained consent from the patient or the legal guardian for this testing.

Physician's Signature: _____ Date: _____

Printed Name: _____ Phone#: _____

LAST UPDATED: 2/2015