BAYLOR GENETICS

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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 any missing or extra copies (copy number) of parts of the chromosomes. 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 Name (Last, First, MI) _____ Date of Birth (MM/DD/YYYY) _____ Biological Sex: ◯ M ◯ F ◯ Unknown

Gender identity (if different from above): _____

☐ *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

1. The test is called Chromosomal Microarray Analysis (CMA). Having the proper amount of genetic material (DNA) in each cell of the body is important for normal growth and development. The DNA is located along the 23 pairs of chromosomes (46 total) in each cell. A basic karyotype analysis can only detect the number of chromosomes in each cell and large structural changes in these chromosomes. CMA is an advanced method of looking at the structure and number of the chromosomes in our body because CMA is able to detect the large changes identified by karyotype, as well as detecting smaller regions of any missing or extra copies (copy number variant, or CNV). These smaller CNVs can also cause abnormal development. In addition, the CMA test can detect an abnormal inheritance pattern of the chromosomes called uniparental disomy (UPD). The CMA test can also detect regions of genetic similarity, called absence of heterozygosity (AOH).
2. While the CMA test is very sensitive, not every genetic condition can be diagnosed by a single test. For some conditions, copy number gains or losses at a particular place in the genome may represent only a certain percentage of the genetic causes of that condition. Therefore, additional testing methodologies should be appropriately considered.
3. 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 changes 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.
4. 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.
5. 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.
6. 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 Genetics at 1-800-411-4363.**

** 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. The CMA test will be performed using materials and protocols developed at the BGL and validated by the laboratory. This laboratory is certified by standards set by the Clinical Laboratory Improvement Acts (CLIA) and the College of American Pathologists.

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.

Signature _____ Printed Name _____ Date (MM/DD/YYYY) _____

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 Signature _____ Physician Name _____ Phone _____ Date (MM/DD/YYYY) _____