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PRENATAL CMA CONSENT FORM

Fetus of: _____ (Patient Last Name) _____ (Patient First Name) _____ (MI) _____ / _____ / _____ (Date of Birth (MM / DD / YYYY))

CONSENT FORM FOR PRENATAL STUDIES USING CHROMOSOMAL MICROARRAY ANALYSIS

BACKGROUND

You are considering the genetic test called Chromosomal Microarray Analysis (abbreviated CMA) for your current pregnancy. The purpose of this document is to provide information about the test so that you can decide whether it is right for you. This information is meant to be used in addition to your discussion with your physician or a genetic counselor. If you decide to have the CMA test, you will be asked to sign at the bottom of this document, indicating that you understand the information provided and wish to have testing. You will be given a copy of this document for your records.

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).

TEST REPORTING

There are several categories of results that may be reported: these include 1) No clinically significant CNV detected (normal result); 2) Clinically significant CNV detected, known to be associated with a genetic condition; 3) CNV detected in the fetus but also detected in a parent. Based on our experience thus far, this has been seen in about 10% of cases. It is generally of low concern, but should be discussed with a genetic counselor; and 4) Variation of uncertain significance detected in the fetus, but not present in either parent. This is relatively rare (seen thus far in about 1-2% of cases) and requires detailed discussion with a physician or genetic counselor.

In addition, regions of genetic similarity (AOH) may be reported if the CMA results indicate the possibility of uniparental disomy (UPD) or consanguinity. If a clinically significant abnormality has been detected, your physician or genetic counselor will discuss the information with you. A clinical geneticist (a specialist in the medical impact of genetic information) may also be consulted.

INFORMATION AND CONSENT FOR TESTING

(1) While the CMA test is very accurate, it is possible that your fetus could have one of the medical conditions included in the CMA test that is not detected or that your fetus could have a medical condition, which cannot be detected by the CMA. This is possible because many genetic syndromes have more than one cause.
(2) Due to the fact that many different regions of the chromosomes and many different conditions are being analyzed, there is a risk that you will learn genetic information about yourself, your fetus, or your family that is not directly related to the reason for monitoring your pregnancy. This information might relate to diseases with symptoms that may develop in the future in your fetus or possibly yourself or other family members.
(3) As with any genetic test, results may be unclear and additional studies may be recommended in order to give you the most accurate information about what the lab finding may mean for the health of your fetus.
(4) It is possible that additional information may come to light during these studies, such as family relationships not being as expected. Because interpretation of CMA results may involve study of the biological parents to determine significance of the findings, the interpretation may not be accurate if specimens from the biological parents are not available for comparative study. If pregnancy was achieved through use of an egg or sperm donor, it is important to inform your physician/genetic counselor so they can work with you and the laboratory to assure the most accurate analysis possible. Your doctor or genetic counselor may be able to coordinate obtaining samples from an egg or sperm donor if necessary.
(5) 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.

The prenatal CMA report will not include findings in genes causing adult onset disorders such as dementia syndromes, for which there is presently no prevention or cure, or findings in genes related to increased cancer risk. There is the option to opt-in to receive this information by checking the YES option below.

If neither box is checked, or if form is not signed, the lab will default to the NO/ do not report option.

INITIAL

_____ ☐ **YES** I would like for the lab to include in my report to my physician information relating to adult onset disorders for which there is presently no prevention or cure, or findings in genes related to increased cancer risk.

_____ ☐ **NO** Please do NOT include in my report to my physician information relating to adult onset disorders for which there is presently no prevention or cure, or findings in genes related to increased cancer risk.

_____
Patient Signature

_____
Printed Name

_____ / _____ / _____
Date (MM/DD/YYYY)