BAYLOR GENETICS
READY WITH ANSWERS

SHIPPING Baylor Genetics
2450 Holcombe Blvd., Grand Blvd. Receiving Dock
Houston, TX 77021-2024
Phone: 713.798.6555
Fax: 713.798.2787

PRENATAL CMA & CYTOGENETICS REQUISITION

PATIENT INFORMATION (COMPLETE ONE FORM FOR EACH PERSON TESTED)

Fetus of:

Patient Last Name | Patient First Name | MI | Maternal Date of Birth (MM/DD/YY)

Address | Accession # | Hospital/ Medical Record #

Biological Sex: ◯ M ◯ F ◯ Unknown

City | State | Zip | Phone

Gender identity (if different from above):

REPORTING RECIPIENTS

Ordering Physician | Institution Name

Email (Required for International Clients) | Phone | Fax

◆ **ADDITIONAL RECIPIENTS**

Name | Name

Email | Fax | Email | Fax

PAYMENT (FILL OUT ONE OF THE OPTIONS BELOW)

☐ **SELF PAYMENT**

◯ Bill Patient For Laboratory Testing

☐ **INSTITUTIONAL BILLING**

Institution Name | Institution Code | Institution Contact Name | Institution Phone | Institution Contact Email

☐ **INSURANCE**

REQUIRED ITEMS
1. Copy of the Front/Back of Insurance Card(s)
2. ICD10 Diagnosis Code(s)
3. Name of Ordering Physician
4. Insured Signature of Authorization

Name of Insured | Insured Date of Birth (MM/DD/YY) | Address of Insured

Patient's Relationship to Insured | Phone of Insured | City | State | Zip

Primary Insurance Co. Name | Primary Insurance Co. Phone | Primary Member Policy # | Primary Member Group #

Secondary Insurance Co. Name | Secondary Insurance Co. Phone | Secondary Member Policy # | Secondary Member Group #

By signing below, I hereby authorize Baylor Genetics to provide my designated insurance carrier any information necessary, including test results, for processing my insurance claim. I also authorize benefits to be payable exclusively to Baylor Genetics. I understand that my insurance carrier may not approve or reimburse my medical genetic services in full or any portion thereof, due to a variety of reasons, including, but not limited to: the contract status of my insurance provider with Baylor Genetics, usual and customary rate limits, benefit exclusions, coverage limits, lack of authorization, or medical necessity. I understand that I am responsible for any co-pay, co-insurance, and unmet deductible that the insurance policy dictates. I understand that I am responsible for any amounts not paid by my insurance carrier for reasons including, but not limited to,non-covered and non-authorized services. I understand that I am responsible for sending Baylor Genetics. any and all payments that I receive directly from my insurance company in payment for this test. Please note that Medicare does not cover routine screening tests.

Patient's Name | Patient's Signature | Date

STATEMENT OF MEDICAL NECESSITY (REQUIRED)

This test is medically necessary for the risk assessment, diagnosis, or detection of a disease, illness, impairment, symptom, syndrome, or disorder. The results will determine my patient's medical management and treatment decisions. The person listed as the Ordering Physician is authorized by law to order the test(s) requested herein. I confirm that I have provided genetic testing information to the patient and they have consented to genetic testing.

Physician's Printed Name | Physician's Signature | Date

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Fetus of: _____ (Patient Last Name) _____ (Patient First Name) _____ (MI) ___/___/___ (Maternal Date of Birth (MM/DD/YY)) _____ (Biological Sex)

ETHNICITY

- ◯ African American
- ◯ Ashkenazi Jewish
- ◯ East Asian (China, Japan, Korea)
- ◯ Finnish
- ◯ French Canadian
- ◯ Hispanic American
- ◯ Mennonite
- ◯ Middle Eastern (Saudi Arabia, Qatar, Iraq, Turkey)
- ◯ Native American
- ◯ Northern European Caucasian (Scandinavian, UK, Germany)
- ◯ Pacific Islander (Philippines, Micronesia, Malaysia, Indonesia)
- ◯ South Asian (India, Pakistan)
- ◯ Southeast Asian (Vietnam, Cambodia, Thailand)
- ◯ Southern European Caucasian (Spain, Italy, Greece)
- ◯ Other (Specify) _____

SAMPLE

Date of Collection (MM/DD/YY) ___/___/___

◆ **SAMPLE TYPE**

- ◯ Amniotic Fluid _____ cc
- ◯ CVS _____ mg ☐ TA ☐ TC
- ◯ Fetal Blood _____ cc
- ◯ Cultured Amniocytes
- ◯ Cultured CVS

Products of Conception (POC) and fetal tissue tests should be requested using the "Cytogenetics - Products of Conception Requisition", which can be found at BMGL.com.

◆ **GESTATIONAL INFORMATION ***

U/S Date (MM/DD/YY) ___/___/___

Gestational Age on U/S Date: _____ (Weeks) _____ (Days)

LMP Date (MM/DD/YY) ___/___/___

* Note: Results will differ depending on method checked. U/S dating increases overall screening performance.

INDICATION FOR TESTING (REQUIRED)

- ◯ AMA
- ◯ Abnormal Maternal Screen
  - ◯ NTD ◯ TRI 21 ◯ TRI 18 ◯ Other: _____
- ◯ Abnormal NIPT (attach report)
  - ◯ NTD ◯ TRI 21 ◯ TRI 18 ◯ Other: _____
- ◯ Abnormal U/S (Specify)

  _____
- ◯ Multiple Pregnancy Losses
- ◯ Parental Concern
- ◯ Other Indication (Attach Report and Specify)

  _____

ICD10 Diagnosis Code(s): _____

CHROMSOMAL MICROARRAY ANALYSIS (CMA) COMPREHENSIVE PRENATAL TESTS

- ☐ Targeted CMA + Limited Chromosome Analysis
- ☐ Expanded CMA + Limited Chromosome Analysis

NOTE: Cultured Fetal Samples are not accepted.

◆ **PARENTAL BLOODS (REQUIRED FOR CMA)**

Draw 5-7cc in an EDTA tube and label with name and DOB.

- ◯ Maternal Blood ___/___/___ (Date of Collection (MM/DD/YY))
- ◯ Paternal Blood ___/___/___ (Date of Collection (MM/DD/YY))

_____ (Paternal Last Name) _____ (Paternal First Name)

Date of Birth (MM/DD/YY) ___/___/___

OTHER PRENATAL TESTING OPTIONS

IMPORTANT INSTRUCTIONS FOR CMA: Parental Bloods (Draw 5-7cc in an EDTA tube) are required for CMA. Label with name, DOB, and complete Parental Bloods information above.

- ☐ Targeted CMA
- ☐ Expanded CMA
- ☐ Chromosome Analysis
- ☐ Aneuploidy FISH (24-48hrs for 13, 18, 21, X, Y)
- ☐ AF - AFP
- ☐ AChE

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Fetus of: _____ _____ _____ ____/____/____ _____

Patient Last Name | Patient First Name | MI | Maternal Date of Birth (MM/DD/YY) | Biological Sex

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.

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.

_____ ____/____/____

Patient Signature | Date (MM/DD/YY)

_____

Printed Name