BAYLOR GENETICS

BAYLOR GENETICS
2450 HOLCOMBE BLVD.
GRAND BLVD. RECEIVING DOCK
HOUSTON, TX 77021-2024

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CONNECT

PRENATAL CHROMOSOMAL MICROARRAY ANALYSIS (CMA) & CYTOGENETICS REQUISITION

PATIENT INFORMATION (COMPLETE ONE FORM FOR EACH PERSON TESTED)

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

Address | City | State | Zip | Phone

Accession # | Hospital / Medical Record #

Patient discharged from the hospital/facility: ◯ Yes ◯ No

Biological Sex: ◯ Female ◯ Male ◯ Unknown

Gender identity (if different from above):

REPORTING RECIPIENTS

Ordering Physician | Institution Name

Email (Required for International Clients) | Phone | Fax

ADDITIONAL RECIPIENTS

Name | Email | Fax

Name | Email | Fax

PAYMENT (FILL OUT ONE OF THE OPTIONS BELOW)

◯ **SELF PAYMENT**

☐ Pay With Sample ☐ Bill To Patient

◯ **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 / YYYY)

Patient's Relationship to Insured | Phone of Insured

Address of Insured

City | State | Zip

Primary Insurance Co. Name | Primary Insurance Co. Phone

Primary Member Policy # | Primary Member Group #

Name of Insured | Insured Date of Birth (MM / DD / YYYY)

Patient's Relationship to Insured | Phone of Insured

Address of Insured

City | State | Zip

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 insurance carrier any information necessary, including test results, for processing my insurance claim. I understand that I am responsible for any co-pay, co-insurance, and unmet deductible that the insurance policy dictates, as well as 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 Printed Name | Patient's Signature | Date (MM / DD / YYYY)

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 (MM / DD / YYYY)

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

SAMPLE INFORMATION (REQUIRED)

Date of Collection: ____ / ____ / ____ (MM / DD / YYYY)

SAMPLE TYPE

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

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 / YYYY)

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

LMP Date: ____ / ____ / ____ (MM / DD / YYYY)

*** NOTE:** U/S dating increases Amniotic Fluid Alpha Fetoprotein (AFAFP) and Acetylcholinesterase (AChE) performance.

INDICATION FOR TESTING (REQUIRED)

- ☐ Advanced Maternal Age
- ☐ Abnormal Maternal Screen:
  - ◯ NTD ◯ TRI 21 ◯ TRI 18 ◯ Other: _____
- ☐ Abnormal NIPT (attach report)
  - ◯ TRI 21 ◯ TRI 13 ◯ TRI 18 ◯ Other: _____
- ☐ Abnormal U/S (Specify): _____
- ☐ Multiple Pregnancy Losses
- ☐ Parental Concern
- ☐ Other Indication (Attach Report and Specify):

  _____
- ☐ ICD10 Diagnosis Code(s): _____

PARENTAL BLOODS (REQUIRED FOR CMA)

- ◯ 8600 Parental Blood Chromosome Analysis (Recurrent Pregnancy Loss) Draw in NaHep tube (5-7cc)
- ◯ Control Prenatal CMA (Required) Draw in an EDTA tube (5-7cc)
- ◯ Control Other Draw in an EDTA tube (5-7cc)

MATERNAL SAMPLE

☐ Maternal Blood

Date of Collection: ____ / ____ / ____ (MM / DD / YYYY)

PATERNAL SAMPLE

☐ Paternal Blood

Date of Collection: ____ / ____ / ____ (MM / DD / YYYY)

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

Date of Birth: ____ / ____ / ____ (MM / DD / YYYY)

PRENATAL TEST OPTIONS (SEE PAGE 3 FOR CHROMOSOMAL MICROARRAY ANALYSIS (CMA) CONSENT)

CVS SPECIMENS >30 MGS OR AMNIOTIC FLUID >16 WKS GA AND > 30 CC ARE REQUIRED FOR REFLEX ORDERS. If less is received or if AF specimen is hemolyzed, you will be notified that culturing may be required, thus increasing TAT by up to 2 weeks. Typical TAT for CMA from direct specimen is 7-10 calendar days. CMA plus limited chromosome includes a 5 cell-chromosome analysis to assess for cytogenetic events NOT detected by microarray. Please see website www.BMGL.com for information on targeted and expanded array options.

CONCURRENT STUDIES

(Please see reflex column if studies should be done reflexively)

- ☐ Aneuploidy FISH (For 13, 18, 21, X and Y; chromosomes or CMA must also be ordered)
- ☐ Expanded CMA + Limited Chromosome Analysis (DIRECT SPECIMEN ONLY)
- ☐ Targeted CMA + Limited Chromosome Analysis (DIRECT SPECIMEN ONLY)
- ☐ Chromosome Analysis
- ☐ Expanded CMA
- ☐ Targeted CMA

Studies available only on amniotic fluid & only if chromosomes or CMA is also ordered *

☐ AF-AFP ☐ AChE

* AF-AFP and AChE performed at Integrated Genetics
** Additional charges will apply, TAT commences from date reflex order is added

REFLEX STUDIES

(Please see concurrent testing column for additional orders)

- ☐ Chromosome Analysis - If chromosomes are **normal**, add: **
  - ◯ Expanded CMA ◯ Targeted CMA
- ☐ Aneuploidy FISH and Chromosome Analysis - If FISH is **normal**, add: **
  - ◯ Expanded CMA ◯ Targeted CMA
- ☐ Aneuploidy FISH and Chromosome Analysis - If chromosomes are **normal**, add: **
  - ◯ Expanded CMA ◯ Targeted CMA
- ☐ Aneuploidy FISH and Expanded CMA - If FISH is **abnormal**, add: **
  - ◯ Chromosome Analysis
- ☐ Aneuploidy FISH and Targeted CMA - If FISH is **abnormal**, add: **
  - ◯ Chromosome Analysis

For Prenatal Noonan testing and/or other fetal test options please use the "Prenatal Comprehensive" requisition and call 713-798-6555 to review orders with a genetic counselor. Additional testing information and requisitions are available at www.BMGL.com.

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PRENATAL CHROMOSOMAL MICROARRAY ANALYSIS (CMA) & CYTOGENETICS REQUISITION

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

INFORMATION AND CONSENT FOR TESTING

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. Gains and Losses associated with adult-onset dementia disorders will NOT be reported. See below for options regarding receipt of certain categories of results in the report.

(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.

Due to the nature of the methodology of this testing we are unable to guarantee that all CNVs in each option will be detected by the CMA. The below options apply to the reporting of fetal data.

There are some findings that may be identified by CMA that do not directly impact the health of your pregnancy, but are considered medically actionable because they have clear medical significance to the health of the fetus later in life. Parental studies will NOT automatically be run for this category of reporting since it will not aide in the interpretation of the fetal result. The American College of Medical Genetics (ACMG) has published guidelines for the reporting of these types of medically actionable or incidental findings (PMID: 23788249, 27854360). These guidelines include a list of genes, which may be updated periodically. In accordance with an update to this policy statement (PMID: 25356965), there is the option to receive pathogenic variant information if identified in one of the listed genes. Please note that if one of these is part of a larger copy number event that meets criteria for reporting then the below option will NOT apply and the data will be reported.

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INFORMED CONSENT FOR PRENATAL CHROMOSOMAL MICROARRAY ANALYSIS & CYTOGENETICS TESTING

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

INFORMED CONSENT FOR GENETIC TESTING

PATIENT CONFIDENTIALITY AND SPECIMEN RETENTION

- Results will only be released to a licensed healthcare provider, to those allowed access to test results by law, and to those authorized in writing.
- In rare cases, persons with genetic diagnoses have experienced problems with insurance coverage and employment. The U.S. Federal Government has enacted several laws that prohibit discrimination based on genetic test results by health insurance companies and employers. In addition, these laws prohibit unauthorized disclosure of this information. For more information, you can visit www.genome.gov/10002077.
- Samples will be retained in the laboratory in accordance with the laboratory retention policy.
- After testing is complete, the de-identified submitted specimen may be used for test development and improvement, internal validation, quality assurance, and training purposes. DNA specimens are not returned to individuals or to referring heath care providers unless specific prior arrangements have been made.
- Samples from residents of New York State will not be included in the de-identified research studies described in this authorization and will not be retained for more than 60 days after test completion, unless specifically authorized by your selection. No tests other than those authorized shall be performed on the biological sample.
- Information including results, indications for testing and clinical status obtained from this testing may be shared with healthcare providers, scientists and healthcare databases or used in scientific publications or presentations, but the personal identifying information of all persons studied will not be revealed in such data sharing or publications/presentations.

RESEARCH & RECONTACT CONSENT

For more information on research at Baylor Genetics, please visit baylorgenetics.com. Please read the below statements carefully and check the appropriate box.

Note: If left blank, consent is interpreted as "NO."

☐ I agree to use of my de-identified specimen for research to improve genetic testing for all patients and contribute to scientific research.

☐ I am a New York State Resident, and I give Baylor Genetics permission to store my specimen in accordance to the laboratory retention policy for internal quality assurance and possible research studies.

☐ In addition to agreeing above, I agree to be contacted by Baylor Genetics regarding research opportunities.

For Option below: If neither box is checked, or the form is not signed, or the form is NOT received, the lab will default to the NO/do NOT report option.

INITIAL

_____ ◯ **YES** Please report pathogenic copy number variants in genes determined to be medically actionable by the ACMG policy statement.

_____ ◯ **NO** Please do NOT report pathogenic copy number variants in genes included in the ACMG policy statement.

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 AUTHORIZATION

By signing this statement of consent, I acknowledge that I have read and understand the informed consent for genetic testing. I have received appropriate explanations from my physician regarding the purpose, scope, type and significance of the planned genetic testing and achievable results. All my questions have been answered and I have had the necessary time to make an informed decision about the genetic test.

I give permission to Baylor Genetics to conduct genetic testing as recommended by my physician.

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

_____ (Printed Name)