BAYLOR GENETICS

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

PHONE
1.800.411.4363
FAX
1.800.434.9850

CONNECT

POSTNATAL CMA / CYTOGENETICS REQUISITION

PATIENT INFORMATION (COMPLETE ONE FORM FOR EACH PERSON TESTED)

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**

☐ Do Not Perform Test Until Patient is Aware of Out-Of-Pocket Costs (excludes prenatal testing)

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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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): _____

INDICATION FOR TESTING (REQUIRED)

CMA OPTIONS

- ☐ Autism Spectrum
- ☐ Developmental Delay
- ☐ Dysmorphic Features
- ☐ Other (Specify): _____
- ☐ Failure to Thrive
- ☐ Multiple Congenital Anomalies
- ☐ Seizure Disorder

CHROMOSOME/FISH OPTIONS

- ☐ Autosomal Trisomies
- ☐ Ambiguous Genitalia
- ☐ Fetal Demise
- ☐ Other (Specify): _____
- ☐ Infertility
- ☐ Klinefelter/Turner
- ☐ Multiple Miscarriages

ICD10 Diagnosis Code(s): _____

SAMPLE INFORMATION

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

SAMPLE TYPE

- ◯ Blood in EDTA Tube (Purple-Top)
- ◯ Blood in Sodium Heparin (Green-Top)
- ◯ Buccal Swab
- ◯ Cord Blood
- ◯ Saliva

CHROMOSOMAL MICROARRAY ANALYSIS (CMA) TESTS

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

TEST CODE	TEST NAME	SAMPLE TYPE*	SPECIFY GENE OF INTEREST	SPECIFY REGION OF INTEREST
☐ 8665	Chromosomal Microarray Analysis (CMA) - HR + SNP Screen (Comprehensive)	BE + BH or BUC **only**		
☐ 8655	Chromosomal Microarray Analysis (CMA) - HR (Basic)	BE + BH		
☐ 8650	Chromosomal Microarray Analysis (CMA) - CytoScan HD SNP Array	BE + BH		

PARENTAL STUDIES RECOMMENDED IN CHILD'S CMA REPORT (ATTACH COPY)

☐ Mother _____ (First, MI, Last) ____ / ____ / ____ (Date of Birth (MM/DD/YYYY)) ◯ ASYMPTOMATIC ◯ SYMPTOMATIC (attach summary of findings)

☐ Father _____ (First, MI, Last) ____ / ____ / ____ (Date of Birth (MM/DD/YYYY)) ◯ ASYMPTOMATIC ◯ SYMPTOMATIC (attach summary of findings)

SAMPLE SPECIFICATIONS TABLE

ABBREVIATION	SAMPLE NAME	RECOMMENDED AMOUNT (2 YRS - ADULT)	RECOMMENDED AMOUNT (NEWBORN - 2 YRS)	SHIPPING INSTRUCTIONS	SPECIAL NOTES
BE	Blood in EDTA tube (purple-top)	3 - 5 cc	2 - 3 cc	Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	
BH	Blood in Sodium Heparin tube (green top)	3 - 5 cc	1 - 2 cc	Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	
BUC	Buccal Swab	See "Special Notes"	See "Special Notes"	Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	Collect with ORAcollect•Dx (OCD-100) self-collection kit (provided by Baylor Genetics with instructions). We highly recommend the sample be collected by a healthcare professional. Buccal swab is an accepted sample type for Chromosomal Microarray Analysis - HR + SNP Screen (Comprehensive) (test code 8665) and FMR1 CGG Repeat Expansion Analysis (test code 6573) ONLY.
CB	Cord Blood	N/A	1 - 2 cc	Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	Ensure properly labeled. Also send 3 cc of maternal blood in properly labeled EDTA tube for MCC studies at no charge as needed.
SA	Saliva	See "Special Notes"	See "Special Notes"	Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	Collected with Oragene DNA Self-Collection Kit (provided by Baylor Genetics with instructions).

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POSTNATAL CMA / CYTOGENETICS REQUISITION

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

CYTOGENETIC TESTS

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

TEST CODE	TEST NAME	SAMPLE TYPE*
☐ 8600	Chromosome Analysis	BH
☐ 8480	FISH for SRY - Related Phenotypes (Metaphase & Interphase Cells) **	BH

** Testing on metaphase cells requires cell culturing.

NOTE: The following tests (8425 and 8426) REQUIRE selecting an accompanying test (8665, 8655, or 8600)

TEST CODE	TEST NAME	SAMPLE TYPE*
☐ 8425	Rapid FISH - AneuVysion (+13/+18/+21/X/Y) (Interphase cells ONLY)	BH
☐ 8426	Rapid FISH - Sex Chromosomes (X/SRY) (Interphase cells ONLY)	BH

+

TEST CODE	TEST NAME	SAMPLE TYPE*
☐ 8665	Chromosomal Microarray Analysis (CMA) - HR + SNP Screen (Comprehensive)	BE + BH or BUC **only**
☐ 8655	Chromosomal Microarray Analysis (CMA) - HR (Basic)	BE and BH
☐ 8600	Chromosome Analysis	BH

CMA + FMR1 TESTING

NOTE: Only one buccal swab sample is needed if test codes 8665 and 6573 are ordered together.

TEST CODE	TEST NAME	SAMPLE TYPE*
☐ 8665	Chromosomal Microarray Analysis (CMA) - HR + SNP Screen (Comprehensive)	BE+BH or BUC only
☐ 6573	FMR1 CGG Repeat Expansion Analysis	BE, BUC, SA

If negative, reflex to:

TEST CODE	TEST NAME
☐ 1500	Proband Whole Exome Sequencing
☐ 1600	Trio Whole Exome Sequencing
☐ 1602	Additional Affected Sibling for Trio*

* The Sibling Trio should be ordered along with, or after a completed Trio (#1600) for the same biological family.

FISH STUDIES

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

TEST CODE	TEST NAME	SAMPLE TYPE*	TEST CODE	TEST NAME	SAMPLE TYPE*
☐ 8462	Charcot-Marie-Tooth Neuropathy Type 1A	BH	☐ 8474	Neurofibromatosis Type I	BH
☐ 8440	DiGeorge/Velocardiofacial Syndrome (22q and 10p) Panel	BH	☐ 8480	SRY-Related Phenotypes	BH
☐ 8486	DiGeorge/Velocardiofacial Syndrome Type I (22q)	BH	☐ 8485	X-Linked Ichthyosis	BH
☐ 8465	DiGeorge/Velocardiofacial Syndrome Type II (10p)	BH	☐ 8490	Chromosome X and Y Centromere Analysis	BH
☐ 8467	Hereditary Neuropathy w/ Liability to Pressure Palsies	BH			

* Refer to Sample Specifications Table (page 2)

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INFORMED CONSENT FOR POSTNATAL CMA / CYTOGENETICS TESTING

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

INFORMED CONSENT FOR GENETIC 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 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