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
- ☐ Sex Chromosome Abnormalities
- ☐ Multiple Miscarriages

ICD10 Diagnosis Code(s): _____

SAMPLE INFORMATION

Date of Collection (MM / DD / YYYY)

SAMPLE TYPE

- ◯ Blood in EDTA
- ◯ Skin Biopsy
- ◯ Buccal Swab
- ◯ Extracted DNA from _____
- ◯ Skin Fibroblast

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, SF, SB, BUC only or DNA		
☐ 8655	Chromosomal Microarray Analysis (CMA) - HR (Basic)	BE + BH, SF, SB, BUC only or DNA		

For Chromosomal Microarray Analysis tests, the sample types BE+BH are preferred. BUC and DNA are also acceptable sample types.

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

☐ Mother _____ (First, MI, Last) _____ (Date of Birth (MM/DD/YYYY)) ◯ ASYMPTOMATIC ◯ SYMPTOMATIC (Specify:) _____

☐ Father _____ (First, MI, Last) _____ (Date of Birth (MM/DD/YYYY)) ◯ ASYMPTOMATIC ◯ SYMPTOMATIC (Specify:) _____

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 (test codes 8665 or 8655) and FMR1 CGG Repeat Expansion Analysis (test code 6573).
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.
DNA	DNA, Extracted	10 - 15 ug	10 - 15 ug	Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	Minimal concentration of 50ng/uL; A260/A280 1.75-2.0
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 solid 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, SF, SB, BUC only or DNA
☐ 8655	Chromosomal Microarray Analysis (CMA) - HR (Basic)	BE + BH BUC or DNA
☐ 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, SF, SB, BUC only or DNA
☐ 6573	FMR1 CGG Repeat Expansion Analysis	BE, BUC, SAL, or DNA

If negative, reflex to:

TEST CODE	TEST NAME
☐ 1500	Proband Whole Exome Sequencing
☐ 1600	Trio Whole Exome Sequencing
☐ 1602	Additional Affected Sibling for Trio*
☐ 2055	Comprehensive mtDNA Analysis by Massively Parallel Sequencing (MitoNGS℠)

* The Sibling Trio should be ordered along with, or after a completed Trio (#1600) for the same biological family.
Note: Please include the WES Advantage requisition and consents.

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	☐ *8405	Custom Familial FISH Studies	BH

*Note: Please include the previous report and note the region of interest. Contact the lab to confirm appropriate probe coverage is available.

* 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 yourself or your child. 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). CMA may reveal carrier status for autosomal recessive conditions. 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) Variant of uncertain significance. This is relatively rarely seen, and requires detailed discussion with a physician or genetic counselor.

Secondary Findings: CMA testing can sometimes detect a change in a person's DNA unrelated to the reason for testing. If this change has medical or reproductive significance, it is called a secondary finding. The American College of Medical Genetics (ACMG) has published guidelines for the reporting of these types of secondary findings (PMID: 34012068, 25356965). The guidelines include a list of genes, which are updated periodically, that are considered medically actionable and thus, laboratories should seek and report pathogenic (disease causing) or likely pathogenic findings in these genes. You have the choice to opt-out of receiving this information.

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 you or your child could have one of the medical conditions included in the CMA test that is not detected or that you or your child 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, or your family that is not directly related to the reason for genetic testing via CMA. This information might relate to diseases with symptoms that may develop in the future in you or your child or other family members. Gains and Losses associated with adult-onset dementia disorders will NOT be reported.

(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 you or your child's health.

(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 you or your child were conceived 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.

Small copy number changes (<300 Kb), including single exon changes, may not be detectable by CMA. CNV analysis using alternate methodologies should be considered as clinically indicated.

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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.

PATIENT REPORTING OPTIONS FOR SECONDARY FINDINGS

Pathogenic or likely pathogenic variants in genes included in the ACMG policy statement regarding recommendations for reporting of secondary findings will be reported. There is an option to OPT-OUT receiving pathogenic or likely pathogenic variant information if identified in one of the listed genes. Please note that if the gene is part of a larger copy number event involving other genes and meeting criteria for reporting, then the below option will NOT apply and the data will be reported.

Note: If left blank, pathogenic or likely pathogenic variants in genes included in the ACMG policy statement will be reported.

INITIAL

_____ ◯ Please do NOT report pathogenic or likely pathogenic variants in genes included in the ACMG policy statement.

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