

MOLECULAR (DNA) TEST REQUISITION

Center for Human Genetics, Inc.

Riverside Technology Center

840 Memorial Drive, Suite 101

Cambridge, MA 02139

Co-directors: Aubrey Milunsky, M.D., D.Sc., Jeff Milunsky, M.D.

Phone: 617-492-7083

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Website: <http://www.chginc.org>

FOR CHG LAB USE ONLY:

Date received: _____

Pedigree #: _____

Family name: _____

Sample type: _____

Lab #: _____

Patient Name: _____

Last

First

Male

Female

Unknown

Hospital/Patient ID#: _____

Date of Birth: _____

Address: _____

Partner/Parent of: _____

Phone: _____

City

State

Zip Code

Referring Provider: NPI #: _____

Referring Laboratory (if different):

Physician signature: _____

Name: _____

Name: _____

Address: _____

Address: _____

City

State

Zip Code

City

State

Zip Code

Phone: _____ Fax: _____

Phone: _____ Fax: _____

Genetic Counselor: _____

Email: _____

Phone: _____ Fax: _____

Email: _____

**** Billing information (Page 4) and copy of insurance card (front and back) MUST accompany sample and requisition form. ****
**** Consent form (Page 5) is REQUIRED for all samples from New York and all predictive testing BEFORE testing can be initiated.****

CLINICAL INFORMATION:

Ethnicity: Ashkenazi Jewish French Canadian Caucasian African American Asian Hispanic
 Sephardic Jewish Armenian Turkish Mediterranean Arabic Other: _____

ICD-10 Diagnosis (REQUIRED): _____

Purpose of Study:

Diagnosis Carrier Screen Prenatal Diagnosis Predictive/Presymptomatic**
 No family history (Call before sending samples)
 Family history* Ultrasound abnormality*

*Please include additional information: _____

Pregnancy information (if applicable): Gestational age _____ By LMP _____ By ultrasound _____
Date Date Date

Name and relationship of family members previously tested at CHG: _____

Name of mutation to be tested (if known in family): _____

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Lab #:

Patient Name:

Last

First

Date of Birth:

****SPECIMEN REQUIREMENTS FOR ALL TESTS LISTED BELOW: 7-10 cc BLOOD IN EDTA OR ACD ANTICOAGULANT****

DNA TEST(S) REQUESTED:

(PLEASE NOTE: **ANALYSIS = SEQUENCING AND MLPA**)

Date Sample Collected: _____

- Aarskog Scott syndrome (*FGD1* analysis)
- ACTG2** sequencing
- Acute Myeloid (Myelogenous) Leukemia
 - FLT3** D835 mutation **NPM1** exon 12 sequencing
- ADGRG2** sequencing
- Alpha-thalassemia/XLID syndrome (*ATRX* analysis)
- Aneurysm osteoarthritis syndrome (*SMAD3* analysis)
- Angelman/Angelman-like syndrome panel
 - Methylation-sensitive MLPA
 - Sequencing of **UBE3A** **SLC9A6**
 - Analysis of **TCF4** **ZEB2**
- Aortic valve disease (*NOTCH1* sequencing)
- ARX** analysis
- Ashkenazi Jewish panel
 - Bloom syndrome LDD/DLD
 - Canavan disease MSUD Type 1B
 - Factor XI deficiency Mucopolidosis type IV
 - Familial Dysautonomia Nemanine Myopathy
 - Familial Hyperinsulinemia Niemann-Pick disease Type A
 - Fanconi anemia Group C Tay Sachs disease
 - Gaucher disease Usher syndrome 1F
 - GSD Type 1A Usher syndrome 3A
 - Joubert disease Walker-Warburg syndrome
- Ataxia panel
 - Spinocerebellar ataxia (check all that apply)
 - Types 1 2 3 6 7 8 10 12 17
 - DRPLA
- Autism/Autism Spectrum Disorder (53 gene panel)
- Autism (with macrocephaly) (*PTEN* analysis and promoter sequencing)
- Banking (circle type) DNA or Lymphoblast
- Beals syndrome (*FBN2* sequencing)
- Borjesen-Forsman-Lehmann syndrome (*PHF6* sequencing)
- Branchio-oculo-facial syndrome (*TFAP2A* analysis)
- Breast/Ovarian Cancer**
 - BRCA1/2** analysis
 - BRCA1/2** (*Ashkenazi Jewish mutations only*)
- C9orf72**-Related Neurodegenerative Disease
- CADASIL (*NOTCH3* sequencing)
- Cardiofaciocutaneous syndrome panel
 - Sequencing of **BRAF** **MAP2K1** **MAP2K2** **KRAS**
- Charcot-Marie-Tooth disease 1A/HNPP (*PMP22* MLPA)
- Charcot-Marie-Tooth disease 1B, 2I, 2J (*MPZ* analysis)
- CHARGE syndrome (*CHD7* analysis)
- Chronic Intestinal Pseudo-obstruction (*ACTG2* sequencing)
- Coffin-Lowry syndrome (*RSK2* analysis)
- Colon Cancer
 - Familial Adenomatous Polyposis (*APC* analysis)
 - Lynch/HNPCC Panel
 - Analysis of **MLH1** **MSH2** **MSH6** **PMS2**
 - EPCAM/TACSTD1** MLPA
 - MYH** Associated Polyposis (*MUTYH* analysis)
- Congenital bilateral absence of vas deferens (CBAVD)
 - 100+ mutations panel **CFTR** analysis **ADGRG2** sequencing
- Congenital Contractural Arachnodactyly (*FBN2* sequencing)
- CONNECT1 (Connective Tissue Disorders analysis)
 - CONNECT1 Sequencing Only (22 genes)
 - CONNECT1 MLPA (circle tests)
 - COL1A1, COL1A2, COL2A1, COL3A1, COL5A1, COL11A1, FBN1, FLNA, MYH11, SMAD3, TGFβ2, TGFβR1, TGFβR2**
- Costello syndrome panel
 - Sequencing of **HRAS** **KRAS** **BRAF**
- Creatine (transporter) deficiency (*SLC6A8* analysis)
- Cystic fibrosis
 - 40+ mutations panel 100+ mutations panel
 - CFTR** analysis
- Deafness
 - Connexin 26 sequencing (nonsyndromic deafness)
 - Connexin 30 deletion (nonsyndromic deafness)
 - Mitochondrial A1555G
- Developmental Language Disorders
 - Sequencing of **FOXP1** **FOXP2**
- Dravet syndrome (*SCN1A* analysis)
- Duchenne or Becker Muscular Dystrophy (*DMD/BMD* MLPA)
- Ehlers-Danlos syndrome
 - Types I/II: **COL5A1** analysis **COL5A2** sequencing
 - Type IV: **COL3A1** analysis
 - Type VII: Analysis of **COL1A1** **COL1A2**
- Ehlers-Danlos variant with periventricular heterotopia (*FLNA* analysis)
- Epilepsy/Intellectual Disability (Female Restricted) (*PCDH19* analysis)
- Familial Mediterranean Fever
 - Common mutations only **MEFV** analysis
- FG syndrome
 - MED12** sequencing **FLNA** analysis
- Fragile X syndrome
- Hemochromatosis
- Huntington disease**
- Infantile Spasms
 - Analysis of **ARX** **CDKL5** **SCN1A**
- Infertility testing
 - Ovarian insufficiency/spermatogenic failure (*NR5A1* analysis)
 - Premature ovarian failure (Fragile X testing)
 - SYCP3** sequencing
 - Y-microdeletion studies
- Intracranial aneurysm
 - Sequencing of **NTM** **TGFβR3**
- Kabuki syndrome
 - Analysis of **MLL2/KMT2D** **KDM6A**
- Kennedy disease (*SBMA*)
- LADD syndrome
 - Analysis of **FGF10** **FGFR2**
 - Sequencing of **FGFR3**
- LEOPARD syndrome panel
 - Sequencing of **PTPN11** **RAF1** **BRAF**
- Loeys-Dietz syndrome
 - Analysis of **TGFβR1** **TGFβR2** **SMAD3** **TGFβ2**
 - Sequencing of **TGFβ3**
- Marfan syndrome (*FBN1* analysis)
- Maternal cell contamination studies
- MED12** related disorders (**MED12** sequencing)
- Melanoma (*CDKN2A* analysis)
- Mitochondrial diseases panel
 - All 37 gene analysis MELAS CPEO/KSS
 - LHON Leigh syndrome/NARP MERRF
- Mowat Wilson syndrome (**ZEB2** analysis)
- Multiple Endocrine Neoplasia, type 1 (**MEN1** analysis)
- Multiple Endocrine Neoplasia, type 2 (**RET** analysis)

** Consent form is REQUIRED prior to the initiation of testing.

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Pedigree #:

Lab #:

Patient Name: _____

Date of Birth: _____

Last

First

****SPECIMEN REQUIREMENTS FOR ALL TESTS LISTED BELOW: 7-10 cc BLOOD IN EDTA OR ACD ANTICOAGULANT****

DNA TEST(S) REQUESTED:

(PLEASE NOTE: **ANALYSIS = SEQUENCING AND MLPA**)

Date Sample Collected: _____

- Myeloproliferative Disease
 - JAK2** (V617F mutation [reflex to exon 12 sequencing])
 - CALR** exon 9 sequencing
 - MPL** sequencing
- Neurexin 1 (**NRXN1** analysis)
- Neurofibromatosis
 - Analysis of **NF1** **NF2**
- Neurofibromatosis type 1-like (Legius) syndrome (**SPRED1** analysis)
- Neuroligin
 - Sequencing of **NLGN3** **NLGN4**
- Noonan syndrome panel
 - Sequencing of **PTPN11** **SOS1** **SOS2** **RAF1**
 - KRAS** **NRAS** **SHOC2** S2G mutation
 - BRAF** **CBL** **RIT1** **LZTR1**
- OpitzG/BBB syndrome (**MID1** analysis)
- Osteogenesis imperfecta Type I, II, III, IV
 - Analysis of **COL1A1** **COL1A2**
- Pancreatitis (hereditary)
 - Pancreatitis panel: **CTRC** sequencing, Analysis of **PRSS1** **SPINK1**
 - CFTR** analysis
- Paraganglioma-Pheochromocytoma syndromes
 - Analysis of **SDHB** **SDHC** **SDHD**
- Paternity testing (Call before sending samples)
- Pelizaeus-Merzbacher disease (**PLP1** analysis)
- Pendred syndrome (**SLC26A4** sequencing)
- Phosphomannomutase 2 (**PMM2** sequencing)
- Phenylketonuria (**PAH** analysis)
- Pitt Hopkins syndrome (**TCF4** analysis)
- Pitt Hopkins-like syndrome
 - CNTNAP2** sequencing Neurexin 1 (**NRXN1** analysis)
- Prader-Willi syndrome (Methylation-sensitive MLPA)
- PTCHD1** analysis
- PTEN** Hamartoma Tumor syndromes (**PTEN** analysis and promoter sequencing)
- Renpenning syndrome (**PQBP1** analysis)
- Rett/Rett-like syndrome panel
 - Analysis of **MECP2** **CDKL5** **FOXG1** **TCF4**
- SCN1A** analysis
- Sickle cell anemia (HbSS, HbSC)
- Small fiber neuropathy (**SCN9A** sequencing)
- Smith-Lemli-Opitz syndrome (**DHCR7** sequencing)
- SNP microarray
- Sotos syndrome (**NSD1** analysis)
- Spinal Muscular Atrophy (**SMN1** exons 7-8 MLPA)
- Stickler syndrome
 - Type I: **COL2A1** analysis
 - Type II: **COL11A1** analysis
 - Type III: **COL11A2** sequencing
- SYNGAP1** sequencing (Intellectual disability, dominant, nonsyndromic)
- Tay-Sachs disease
- Thoracic Aortic Aneurysms/Dissections panel
 - Analysis of **FBN1** **MYH11** **SMAD3**
 - TGFβ2** **TGFβR1** **TGFβR2**
 - Sequencing of **ACTA2** **BGN** **FOXE3** **LOX** **MAT2A**
 - MFAP5** **MYLK** **NTM** **PRKG1** **SKI**
 - SLC2A10** **SMAD2** **SMAD6** **TGFβ3**
- Thrombophilia panel
 - Factor V Leiden (R506Q) MTHFR (665C>T; 1286A>C)
 - Prothrombin (G20210A)
- Tuberous Sclerosis
 - Analysis of **TSC1** **TSC2**
- UPD: (circle test) chromosome 7 14 15
- Visceral Myopathy (**ACTG2** sequencing)
- von-Hippel-Lindau disease (**VHL** analysis)
- Waardenburg syndrome
 - Types 1 and 3: **PAX3** analysis
 - Type 2: Analysis of **MITF** **SOX10**
 - Type 4: Analysis of **SOX10** **EDN3** **EDNRB**
- Wilson disease (**ATP7B** analysis)
- X-inactivation studies
- X-linked lymphoproliferative disease (**SH2D1A** analysis)
- X-linked Intellectual Disability (XLID) (Order whole panel, individual tiers, or single gene)
 - Tier A **NLGN3** sequencing
 - NLGN4** sequencing
 - Rett syndrome (**MECP2** analysis)
 - Rett syndrome - atypical (**CDKL5** analysis)
 - Tier 1 **DLG3** sequencing
 - FTSJ1** sequencing
 - JARID1C** sequencing
 - Borjesen-Forssman-Lehmann syndrome (**PHF6** sequencing)
 - ZNF41** sequencing
 - Tier 2 Asperger syndrome (**GDI1** analysis)
 - FACL4** analysis
 - OPHN1** analysis
 - Renpenning syndrome (**PQBP1** analysis)
 - TMASF2/ITSPAN7** analysis
 - Tier 3 Alpha-thalassemia/XLID syndrome (**ATRX** analysis)
 - Aarskog Scott syndrome (**FGD1** analysis)
 - OpitzG/BBB syndrome (**MID1** analysis)
 - Pelizaeus-Merzbacher disease (**PLP1** analysis)
 - Coffin-Lowry syndrome (**RSK2** analysis)
 - Creatine (transporter) deficiency (**SLC6A8** analysis)
 - Tier 4 **AGTR2** analysis
 - ARHGEF6** analysis
 - MED12** sequencing
 - PAK3** analysis
 - SLC16A2** sequencing
 - Other X-linked intellectual disability genes
 - IL1RAPL1** analysis
 - RAB39B** sequencing
- X-linked Intellectual Disability/Epilepsy Panels
 - Panel 1 Angelman-like syndrome (X-linked Christianson type) (**SLC9A6** sequencing)
 - PCDH19** sequencing (females only)
 - Rett syndrome (**MECP2** analysis)
 - Rett syndrome - atypical (**CDKL5** analysis)
 - Panel 2 **ATP6AP2** sequencing
 - Creatine (transporter) deficiency (**SLC6A8** analysis)
 - OPHN1** analysis
 - SYN1** sequencing
- XY Disorders of sex development (**NR5A1** analysis)
- Y-microdeletion studies/Y-chromosome detection (SRY)
- Zygosity testing

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Phone: (617) 492-7083 Fax: (617) 492-7092

Web: http://www.CHGINC.org

Patient Name: _____

Last

First

MI

Date of Birth: _____

INFORMED CONSENT FOR DNA TESTING

**** A signed consent form is REQUIRED for all samples from New York and all predictive testing BEFORE testing can be initiated.
** A signed consent form is strongly recommended for all genetic testing. If a signed consent is not submitted, the Center for Human Genetics assumes that the ordering physician has appropriately reviewed and obtained the patient's informed consent.**

I/We request and authorize the DNA Diagnostic Laboratory at the Center for Human Genetics, Inc. to analyze a sample of DNA isolated from _____ (sample type) obtained on _____ (date) to assess the probability that I (my/our fetus/child) am (is) affected with or carry the gene for the genetic disease _____ which is _____.

The test procedure has been explained to me/us and I/we understand that:

- I. There are several possible outcomes of this test:
 - 1. The test results may indicate that it is likely or unlikely that I (my/our fetus/child) am (is) affected with, or a carrier for, the above disease.
 - 2. The test results may be indeterminate because of my (my/our fetus'/child's) genetic patterns or the genetic patterns of my family members (if also tested), and/or the limitations of the current technology.
- II. DNA tests are performed with precision and results reflect great accuracy and specific degrees of quoted accuracy (when applicable). Turn-around time is estimated and cannot be guaranteed.
- III. One possible result of DNA testing is that the laboratory could discover evidence of previously undisclosed non-paternity when comparing my (my/our fetus'/child's) sample with samples from other family members.
- IV. Genetic counseling, further testing, or additional physician consults may be warranted after testing in order to complete the testing process.
- V. After the DNA testing of my (my/our fetus'/child's) sample is complete, DNA will be stored at the Center for Human Genetics, Inc. for a minimum of three months. **We do not guarantee the future availability of DNA unless specific arrangements have been made for DNA banking.** After that time, any remaining material will be disposed of at the discretion of the Laboratory Director, and may be used for medical research or education so long as our privacy is maintained.

I can request that remaining DNA not be used for research purposes by initialing here: _____
- VI. The results of this test are to be released only to the ordering physician and referral laboratory (if applicable) per HIPAA regulations.

My/our signature(s) below constitute(s) my/our acknowledgement (1) that the proposed DNA test(s) and its/their limitations for my/our specific situation have been satisfactorily explained to me/us by my/our physician or genetic counselor; and (2) I/we hereby give my/our authorization and consent for this testing.

Patient/Guardian Signature

Witness Signature

Date

*****BILLING INFORMATION AND COPY OF INSURANCE CARD FRONT
AND BACK MUST ACCOMPANY SAMPLE AND REQUISITION FORM*****

SVC PROVIDER: CENTER FOR HUMAN GENETICS INC CLIA #22D0650242 NPI #1821153156

PATIENT INFORMATION:

LAST NAME:	GENDER: (CIRCLE)	DATE OF BIRTH
FIRST NAME:	M F	/ /
MIDDLE:		MM/DD/YYYY
STREET ADDRESS:		APARTMENT# / FLOOR
CITY :	STATE	ZIP
PHONE: HOME()	CELL()	

PAYMENT INFO: (SELECT ONE) (CIRCLE): LAB/HOSP/FAC/INST INSURANCE PATIENT CREDIT CARD

BILLING INFORMATION (MUST BE COMPLETED)

LABORATORY/ HOSPITAL/ FACILITY/ INSTITUTIONAL BILLING ADDRESS:

FACILITY NAME:	AFFIX LABEL HERE:
ADDRESS:	
CITY, STATE, ZIP	
ATTENTION:	
PHONE: ()	
FAX: ()	
PURCHASE ORDER#	
PATIENT MEDICAL RECORD#	

INSURANCE INFORMATION:

INSURANCE COMPANY NAME:	
INSURANCE IDENTIFICATION #	
INSURANCE GROUP #	
SUBSCRIBER NAME:	SUBSCRIBER DATE OF BIRTH:
LAST:	/ /
FIRST:	MM / DD / YYYY
RELATIONSHIP TO PATIENT:	(CIRCLE):
	SELF PARENT SPOUSE
INSURANCE ADDRESS:	INSURANCE TELEPHONE AND EXTENTION:
STREET:	()
	FAX# ()
CITY, STATE, ZIP:	CONTACT NAME/DEPT:
	AUTHORIZATION#
	VALID FROM: / / TO / /
*SECONDARY INS NAME:	SUB NAME:
POLICY #	RELATIONSHIP:
	GENDER: M F
	SUB DOB: / /

PATIENT ACKNOWLEDGEMENT:
I AUTHORIZE ANY HOLDER OF MEDICAL INFORMATION ABOUT ME TO RELEASE TO ANY INSURANCE CARRIER ANY INFORMATION NEEDED FOR THIS CLAIM. I PERMIT A COPY OF THIS AUTHORIZATION TO BE USED IN PLACE OF THE ORIGINAL AND REQUEST THAT THE PAYMENT OF MEDICAL INSURANCE BE PAID TO CHG, INC. I ALSO UNDERSTAND THAT I WILL BE HELD RESPONSIBLE FOR ANY PORTION OF THE CLAIM THAT THE INSURANCE COMPANY DOES NOT PAY.

REQUIRED SIGNATURE:	DATE: / /
MEDICARE ID#:	BENEFICIARY NAME:
BENEFICIARY AGREEMENT:	
I HAVE BEEN NOTIFIED BY THE CENTER FOR HUMAN GENETICS THAT, IN MY CASE, MEDICARE IS LIKELY TO DENY PAYMENT FOR THE SERVICES IDENTIFIED BELOW, FOR THE REASON STATED. IF MEDICARE DENIES PAYMENT, I AGREE TO BE PERSONALLY AND FULLY RESPONSIBLE FOR PAYMENT.	
REQUIRED BENEFICIARY SIGNATURE:	DATE: / /

MEDICARE WILL ONLY PAY FOR SERVICES THAT IT DETERMINES TO BE "REASONABLE AND NECESSARY" UNDER SECTION 1862(a) (1) OF THE MEDICARE LAW. IF MEDICARE DETERMINES THAT A PARTICULAR SERVICE, ALTHOUGH IT WOULD OTHERWISE BE COVERED, IS NOT "REASONABLE AND NECESSARY" UNDER MEDICARE PAYMENT STANDARDS, MEDICARE WILL DENY PAYMENT FOR THAT SERVICE. THE CENTER FOR HUMAN GENETICS BELIEVES THAT MEDICARE IS LIKELY TO DENY PAYMENT FOR MOLECULAR DNA TESTING. PROVIDER #228243

A. Notifier:

B. Patient Name:

C. Identification Number:

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare doesn't pay for **D.** _____ below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the **D.** _____ below.

D.	E. Reason Medicare May Not Pay:	F. Estimated Cost

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the **D.** _____ listed above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

G. OPTIONS: Check only one box. We cannot choose a box for you.

- OPTION 1.** I want the **D.** _____ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.
- OPTION 2.** I want the **D.** _____ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**
- OPTION 3.** I don't want the **D.** _____ listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**

H. Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/TTY: 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

I. Signature:	J. Date:
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According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.