CLARITAS GENOMICS

CLIA ID#: 22D0950490
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www.claritasgenomics.com

EXOME-BASED TESTING REQUISITION FORM

PATIENT INFORMATION

Last Name _____ First Name _____ MI___ Gender ☐ Male ☐ Female ☐ Unknown

DOB (MM/DD/YY) _____ MRN _____ Phone number _____ Email _____

Address _____ City _____ State _____ Zip Code _____

ORDERING PHYSICIAN ☐ Mark If Preferred Contact

Name _____

NPI# _____ Specialty _____

Phone _____ Fax _____

Email _____

Institution _____

Address _____

_____

City _____ State _____ Zip Code _____

GENETIC COUNSELOR ☐ Mark If Preferred Contact

Name _____ Phone _____ Email/Fax _____

ADDITIONAL RESULTS RECIPIENTS

Name _____ Phone _____ Email/Fax _____

Name _____ Phone _____ Email/Fax _____

TEST SUBMISSION CHECKLIST

- ☐ Patient and Sample Information
- ☐ Test Requested
- ☐ Billing Information
- ☐ Clinical Information Form
- ☐ Signed Informed Consent
- ☐ ICD-10 Codes
- ☐ Sample(s) with Two (2) Identifiers
- ☐ Medical Records - Attach
- ☐ Client Registration Form (new clients only)

SAMPLE INFORMATION

Patient *Not all sample types are acceptable for all tests. See the Specimen Requirements page on our website for more detailed information.*

Specimen Type ☐ Whole Blood ☐ DNA ☐ Saliva: NGS tests only

Collection: Date _____ Time ___:____ AM/PM (circle one)

☐ Check this box if the patient has ever had a bone marrow transplant.

STATEMENT OF MEDICAL NECESSITY

*For Providers from **NEW YORK STATE**, a signature below is required.*

By sending this sample, I acknowledge that:

- I am a healthcare provider authorized to order genetic testing in the location that I practice;
- This test is medically necessary for the diagnosis or detection of a disease, illness, impairment, symptom, syndrome, or disorder and that these results will be used in the medical management and treatment decisions for this patient;
- I am responsible for returning the results of genetic testing to my patient and/or legal guardian and for ensuring that my patient receives appropriate genetic counseling to understand the implications of his/her test;
- The patient/legal guardian has been provided information regarding the risks/benefits and limitations of the test(s) ordered and the patient/legal guardian has given consent for the ordered test(s) to be performed;
- I have obtained all signatures as necessary under the laws of my state;
- Upon request I am able to produce the consent form signed by the patient/guardian.

_____ _____

PROVIDER SIGNATURE **DATE** (MM/DD/YY)

Biological parental samples are requested to aid in the interpretation of the patient's results for exome and region of interest tests. If parental sample(s) are marked "To Be Sent Later," testing will proceed as a Proband Only order. If parental samples are to be sent separately from the patient's samples, parental samples should arrive within five days of receipt of the patient's samples. If they will arrive after the five-day window, please contact Client Services directly to discuss testing options.

Mother

☐ Included
☐ Not Available
☐ To Be Sent Later, ETA _____ MM/DD/YY

Name _____

DOB (MM/DD/YY) _____

Specimen Type ☐ Blood ☐ DNA ☐ Saliva

Collection: Date _____

Time ___:____

Clinical Presentation
☐ Unaffected
☐ Not Evaluated
☐ Affected - Attach Details

Father

☐ Included
☐ Not Available
☐ To Be Sent Later, ETA _____ MM/DD/YY

Name _____

DOB (MM/DD/YY) _____

Specimen Type ☐ Blood ☐ DNA ☐ Saliva

Collection: Date _____

Time ___:____

Clinical Presentation
☐ Unaffected
☐ Not Evaluated
☐ Affected - Attach Details

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Test Requested

Whole Exome Sequencing

Claritas Clinical Exome	Test Code
Select requested test(s) below	
☐ Proband Only	N0839
☐ Trio	N0560
☐ Add Companion High-Resolution Deletion/Duplication Analysis	C0164
☐ Add Mitochondrial DNA Analysis*	—
☐ Add Parent(s)—use this only if sending parent(s) separately from proband	N0070

*For Mitochondrial DNA Analysis test codes visit www.claritasgenomics.com/mitochondrial-dna-analysis

How To Order

- Select desired gene list(s), if applicable.
- Next, select Proband Only or Trio
- Select additional options, as available:
  - Companion High-Resolution Deletion/Duplication Analysis
  - Mitochondrial DNA Analysis
- Use the "Other Options" section to add additional components:
  - The "Expansion Options" are available for Region of Interest tests. If one or both of these options are selected, testing will be initiated automatically if the ROI result reveals no diagnostic findings. No additional sample will be necessary.
  - If data delivery is desired, select one or both options.

Additional Information

- The Data Return Program is a free service unless the provider requests that data is returned via a hard drive. More information on this program is available at: claritasgenomics.com/data-return-program
- To send parental samples with the proband's sample, check "Trio" and complete the requested information for the parental samples on page 1 of the requisition form. Only use the "Add Parent" checkbox if the parental samples are being sent separately from the proband's. Testing will not proceed until all samples are received.

Region of Interest Tests

Pediatric Neurology Region of Interest	Test Code
1. Select gene lists. Typically 1-3 lists are selected.	
☐ Neuromuscular Disorders	
☐ Movement Disorders	
☐ Epilepsy/Seizures	
☐ Brain Malformations	
☐ Intellectual Disability/Developmental Delay	
☐ Hereditary Peripheral Neuropathy	
☐ Leukodystrophy/Encephalopathy	
☐ Autism	
2. Select requested test(s) below	
☐ Proband Only	N0883
☐ Trio	N0481
☐ Add Companion High-Resolution Deletion/Duplication Analysis	C0598
☐ Add Parent(s)—use this only if sending parent(s) separately from proband	N0047

Bone Marrow Failure Region of Interest	Test Code
1. Select desired gene list. Select only 1.	
☐ Standard BMF gene list	
☐ BMF gene list without BRCA1 and BRCA2	
2. Select requested test(s) below	
☐ Proband Only	N0030
☐ Trio	N0870
☐ Add Companion High-Resolution Deletion/Duplication Analysis	C0974
☐ Add Parent(s)—use this only if sending parent(s) separately from proband	N0946

Nephrotic Syndrome Region of Interest	Test Code
Select requested test(s) below	
☐ Proband Only	N0698
☐ Trio	N0002
☐ Add Companion High-Resolution Deletion/Duplication Analysis	C0573
☐ Add Parent(s)—use this only if sending parent(s) separately from proband	N0549

Comprehensive Immunology Region of Interest	Test Code
Select requested test(s) below	
☐ Proband Only	N0707
☐ Trio	N0429
☐ Add Companion High-Resolution Deletion/Duplication Analysis	C0892
☐ Add Parent(s)—use this only if sending parent(s) separately from proband	N0290

HLH Region of Interest	Test Code
Select requested test(s) below	
☐ Proband Only	N0636
☐ Trio	N0761
☐ Add Companion High-Resolution Deletion/Duplication Analysis	N0659
☐ Add Parent(s)—use this only if sending parent(s) separately from proband	N0915

Other Options

Data Delivery Options	Test Code
If raw data is desired, select a mode of delivery. Can select more than 1.	
☐ Access to whole exome data in NextCODE system for 3 months	D0539
☐ Download whole exome VCF and BAM files	D0642

Expansion Options	Test Code
For Region of Interest tests for which a diagnostic finding is not generated, whole exome interpretation is available.	
☐ Expand Sequence Analysis To Claritas Clinical Exome	N0527
☐ Expand Deletion/Duplication Analysis to Claritas Clinical Exome Deletion/Duplication Analysis	C0769

Use our General Genetics Testing Requisition form to order testing such as single gene Sanger sequencing, single gene deletion/duplication analysis, and targeted variant analysis.

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Clinical Information

PATIENT NAME: _____ **DOB:** _____

REQUIRED: ICD-10 CODE(S): _____

Provide Main Clinical Indication and Differential Diagnosis/Diagnoses: _____

COGNITIVE/DEVELOPMENTAL/BEHAVIORAL

☐ Global developmental delay
☐ Motor delay: ☐ Gross ☐ Fine
☐ Speech delay
☐ Intellectual disability
☐ Learning disability
☐ Developmental regression
☐ Autism spectrum disorders
☐ Psychiatric symptoms _____
OTHER _____

GROWTH

☐ Stature: ☐ Short ☐ Tall
☐ Obesity ☐ Overgrowth
☐ Failure to thrive
☐ Hemihypertrophy _____
OTHER _____

HEAD/BRAIN/FACE

☐ Micro- ☐ Macro-cephaly
☐ Abnormal head shape: _____ cephaly
☐ Craniosynostosis _____ suture(s)
☐ Brain abnormality: _____
☐ Micro- ☐ Pro- ☐ Retro-gnathia
☐ Cleft: ☐ Lip ☐ Palate
☐ Abnormality of Mouth _____
☐ Abnormality of Nose _____
☐ Abnormality of ☐ Eyes _____ ☐ Vision _____
☐ Hypo- ☐ Hyper-telorism
☐ Abnormality of Eyebrows _____ ☐ Synophrys
☐ Abnormality of Ears _____
☐ Hearing loss: ☐ Sensorineural ☐ Conductive
☐ Abnormality of Teeth _____
☐ Abnormality of Neck _____
☐ Facial asymmetry
☐ Facial: ☐ Palsy ☐ Paralysis ☐ Weakness
OTHER _____

SKIN/HAIR

☐ Hyper- ☐ Hypo-pigmentation
☐ Café-au-lait spots
☐ Skin: ☐ Tags ☐ Tumors
☐ Ichthyosis
☐ Abnormal Nails _____
☐ Alopecia
☐ Abnormal Hair: ☐ Quantity ☐ Texture _____
☐ Abnormal Connective Tissue _____
OTHER _____

PERINATAL HISTORY

☐ Prematurity _____ weeks
☐ IUGR
☐ Oligo- ☐ Poly-hydramnios
☐ Cystic hygroma/increased NT
☐ H/o recurrent pregnancy losses

CARDIOVASCULAR

☐ Conotruncal anomaly _____
☐ Atrial ☐ Ventricular septal defect
☐ Cardiomyopathy: ☐ DCM ☐ HCM ☐ LVNC
☐ Coarctation of aorta
☐ Hypoplastic left heart
☐ Arrhythmia/conduction defect
OTHER _____

GASTROINTESTINAL

☐ Tracheoesophageal fistula
☐ Gastroschisis
☐ Omphalocele
☐ Hirschsprung disease
☐ Chronic diarrhea
☐ Constipation
☐ Recurrent vomiting
☐ Pyloric stenosis
☐ Gastroesophageal reflux
☐ Anal atresia
☐ Hepato- ☐ Spleno-megaly
OTHER _____

GENITOURINARY

☐ Kidneys
  ☐ Hydronephrosis
  ☐ Malformation _____
  ☐ Nephrotic syndrome
  ☐ Tubulopathy
  ☐ Agenesis
☐ Bladder _____
☐ Ambiguous genitalia
☐ Hypospadias
☐ Cryptorchidism
OTHER _____

MUSCULAR/NEUROLOGICAL

☐ Seizures Type _____
☐ Tone: ☐ Hypotonia ☐ Hypertonia
☐ Spasticity
☐ Movement disorder
  ☐ Ataxia
  ☐ Chorea
  ☐ Dystonia
☐ Muscle weakness: ☐ Proximal ☐ Distal
☐ Neurodegeneration
☐ Stroke
☐ Cranial nerve _____
☐ Sleep disturbance
☐ Headache/migraine
☐ Neural tube defect _____
☐ Diaphragmatic hernia
☐ Umbilical hernia
OTHER _____

SKELETAL/LIMB

☐ Limb shortening ☐ Upper ☐ Lower ☐ Right ☐ Left
☐ Limb anomaly _____
☐ Thumb anomaly _____
☐ Polydactyly ☐ Pre- ☐ Post-
☐ Syn- ☐ Ectro- ☐ Arachno-dactyly
☐ Small ☐ Large ☐ Hands ☐ Feet
☐ Club foot ☐ Unilateral ☐ Bi-lateral
☐ Scoliosis ☐ Kyphosis ☐ Lordosis
☐ _____ Fracture(s)
☐ Wormian bones
☐ Vertebral anomaly _____
☐ Contractures
OTHER _____

METABOLIC

☐ CPK abnormality
☐ Ketosis
☐ Amino ☐ Organic ☐ -acidemia ☐ -aciduria
Specify _____
OTHER _____

ENDOCRINE

☐ Diabetes: ☐ Type I ☐ Type II
☐ Hypo- ☐ Hyper-thyroidism
☐ Hypoparathyroidism
☐ Pheochromocytoma/paraganglioma
OTHER _____

IMMUNOLOGIC

☐ Immunodeficiency _____
OTHER _____

HEMATOLOGIC

☐ Anemia
☐ Neutro- ☐ Pancyto- ☐ Thrombocyto-penia
☐ Increased bleeding
☐ Thrombosis
☐ Transient abnormal myelopoiesis
☐ Juvenile myelomonocytic leukemia
OTHER _____

MALIGNANCY

Tumor type/Location _____
Age of onset _____

PREVIOUS TESTING/RESULT

Chromosomes: _____
FISH: _____
Array CGH: DEL _____ DUP _____
Biochemical: _____
Biopsy: _____
Imaging: _____
OTHER: _____

Attach previous results

FAMILY HISTORY *(For complex family histories, attach additional pages)*: _____

ETHNICITY : _____ **CONSANGUINITY:** ☐ **NO** ☐ **YES. IF YES, SPECIFY RELATIONSHIP:** _____

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PATIENT NAME: _____ **DOB:** _____

TEST(S) ORDERED: _____

INFORMED CONSENT

More information on all policies may be found in the Informed Consent Guide.

By signing below, I, the patient/guardian, confirm the following:

a) The risks, benefits, and limitations of the test have been described to me;
b) I have had a chance to have my questions answered;
c) I choose to have this test;
d) No tests other than those authorized shall be performed on the sample.
e) I agree to Claritas's policies on Specimen Retention and De-identified Scientific and Medical Research.

☐ Check here if you do not wish to participate in any research studies.

f) I agree that Claritas may contact me in the future for research opportunities, including treatment.

☐ Check here if you do not want to be contacted in the future for research opportunities, including treatment.

g) Authorization for samples sent by a provider from New York State:

☐ My sample is being sent from a provider from New York State and I, the patient, give permission for Claritas Genomics to retain any remaining sample longer than 60 days after completion of testing and use my de-identified data for scientific and medical research purposes. Such authorization is optional and is not required for testing.

Patient signature, or guardian if patient is under 18 Date

When parental samples are sent for clinical genetic tests that are not "for the purpose of diagnosing or detecting an existing disease, illness, impairment, or disorder," [as per Massachusetts Ann. Laws ch. 111 section 70G (2000)] consent must be documented.

By signing below, the parent confirms the following:

a) I understand the intent of testing a parent is to identify the presence or absence of genetic changes similar to that found in my child;
b) I understand that the interpretation of my child's genetic testing result may change depending on whether or not the genetic change(s) is/are present in me. I understand that for this reason, Claritas Genomics will include my genetic test result in my child's report for the purpose of assisting with the interpretation of that test result;
c) I have had a chance to have my questions answered;
d) I choose to send my sample to Claritas Genomics where it may or may not be used depending on whether genetic changes were identified in my child;
e) No tests other than those authorized shall be performed on my sample.
f) I agree to Claritas's policies on Specimen Retention and De-identified Scientific and Medical Research.

☐ Parent 1 (as signed below): Check here if you do not wish to participate in any research studies.
☐ Parent 2 (as signed below): Check here if you do not wish to participate in any research studies.

g) I agree that Claritas may contact me in the future for research opportunities, including treatment.

☐ Parent 1 (as signed below): Check here if you do not want to be contacted in the future for research opportunities, including treatment.
☐ Parent 2 (as signed below): Check here if you do not want to be contacted in the future for research opportunities, including treatment.

h) Authorization for samples sent by a provider from New York State:

My sample is being sent from a provider from New York State and I, the patient, give permission for Claritas Genomics to retain any remaining sample longer than 60 days after completion of testing and use my de-identified data for scientific and medical research purposes. Such authorization is optional and is not required for testing.

☐ Parent 1 (as signed below): Check here to authorize this statement.
☐ Parent 2 (as signed below): Check here to authorize this statement.

Parent 1 signature Print Name Relationship to Patient (i.e., Mother or Father) Date

Parent 2 signature Print Name Relationship to Patient (i.e., Mother or Father) Date

PATIENT NAME: _____ DOB: _____

SECONDARY FINDINGS: SIGN TO OPT-OUT

The standard analysis of the Claritas Clinical Exome includes a specific list of genes that may be of medical value or utility to the ordering physician and the patient, as recommended by the American College of Genetics and Genomics (ACMG) and is subject to change based on new or updated guidelines. If you sign below, you are choosing not to have these genes analyzed. If you do not sign below, these genes will be analyzed. More information about these genes is available in the Claritas Clinical Exome Informed Consent Guide.

After reviewing the genes recommended by the ACMG with my Provider, I, the patient, ***do not want*** Claritas Clinical Exome to report them.

_____

Patient signature, or guardian if patient is under 18 Date

Parents also have the choice whether Claritas reports on the genes recommended by the ACMG.
Note the following:

- If the patient opts out of receiving information on the genes recommended by the ACMG, any parental samples received by Claritas Genomics will automatically be opted out also.
- If the patient chooses to receive information on the genes recommended by the ACMG, the parents may choose to not receive the information ("opt-out").
- If one parent signs and the other does not, we will default to the choice that is signed. In other words, Claritas Genomics will NOT report secondary findings in either parent. Similarly, if one parent desires this information, but the other parent does not, Claritas Genomics will NOT report secondary findings in either parent.
- Only those variants found in the patient's sample will be investigated in the parental sample(s). Therefore, if no variants in these genes as recommended by the ACMG are reported in the patient, these genes will not be investigated in the parental sample(s).

I/we the parent(s) ***do not want*** Claritas Genomics to report on the genes as recommended by ACMG.

_____

Parent signature Print Name Relationship to Patient (i.e., Mother or Father) Date

_____

Parent signature Print Name Relationship to Patient (i.e., Mother or Father) Date

Billing Information

PATIENT NAME: _____ **DOB:** _____

☐ 1. INSTITUTIONAL BILLING

Client Code _____ Enter the Client Code provided by Claritas Genomics' Client Service team. If you do not have a client code, complete the Client Registration Form, available at www.claritasgenomics.com or by contacting Client Services: clientservices@claritasgenomics.com or toll-free 855-373-9003. **Claritas will not begin testing until all information is complete.**

☐ 2. INSURANCE BILL

Client Code _____ Enter the Client Code provided by Claritas Genomics' Client Service team. If you do not have a client code, complete the Client Registration Form, available at on our website or by contacting Client Services.

Claritas Genomics will directly bill third party insurances. Required Information:

- **A legible photocopy, front and back, of the insurance card**
- **A copy of the insurance authorization, if obtained**
- **Completed Insurance Billing information requested below**

Claritas Genomics will perform an insurance benefits investigation and/or prior authorization, when requested. Please see the insurance billing section on our website for additional information and requirements.

Claritas will not begin testing until all information is complete and obtained.

PRIMARY INSURANCE		SECONDARY INSURANCE	
Policyholder's Name		Policyholder's Name	
Policyholder's Date of Birth (MM/DD/YY)	Relationship to Patient	Policyholder's Date of Birth (MM/DD/YY)	Relationship to Patient
Insurance Carrier	Insurance Carrier Phone Number	Insurance Carrier	Insurance Carrier Phone Number
Policy Number		Policy Number	
Group Number	Auth Number	Group Number	Auth Number
Insurance Address	City/State/Zip	Insurance Address	City/State/Zip
Policyholder's Signature	Date	Policyholder's Signature	Date

Patient/Family Acknowledgment

I (The Insured) acknowledge that the information provided by me is true to the best of my knowledge. For billing my insurance company: I hereby authorize my insurance benefits to be paid directly to Claritas Genomics and authorize them to release medical information concerning my testing to my insurer to achieve payment. If applicable, I authorize Claritas Genomics to be my Designated Representative for purposes of appealing any denial of benefits to achieve payment. I understand that I am financially responsible for any amounts not covered by my insurer for this test. Claritas Genomics will bill patients/families for non-covered services, co-payments, deductibles, co-insurance, or balances as required by their insurer unless the patient meets certain financial criteria as defined in the Claritas Genomics Financial Assistance Program. I also understand that I am legally responsible for sending Claritas Genomics any money received directly from my health insurance company for performance of this test.

Insured's printed name | Signature | Date

Patient's/guardian's phone number, to be used to communicate benefits information

☐ 3. SELF-PAY

Complete the Credit Card Payment Form, available on our website or by calling our Client Services team toll-free at 855-373-9003.

☐ 4. FINANCIAL ASSISTANCE PROGRAM

☐ Check to indicate that patient or family is experiencing economic hardships ☐ Check to indicate Provider is giving free medical care

Include a completed Claritas Patient Financial Assistance Application, which is available on our website or by contacting Client Services.