CLARITAS GENOMICS

REQUISITION FORM

CLIA ID#: 22D0950490
Lab Director: Mark D. Kellogg, PhD, DABCC
www.claritasgenomics.com

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
- ☐ ICD9/10 Codes
- ☐ Sample(s) with Two (2) Identifiers
- ☐ Medical Records - Attach
- ☐ Client Registration Form (new clients only)

SAMPLE INFORMATION

Patient

See specimen requirements on website.

Specimen Type ☐ Whole Blood ☐ DNA ☐ Bone Marrow: GATA1 only
☐ Saliva: NGS tests only (Exome and ROIs)
☐ Blood Spot Card: Lysosomal Storage Disorder tests only

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

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 _____

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 _____

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

Claritas Clinical Exome	Test Code
1. Select Requested Test(s) Below	
☐ Proband Only	N0839
☐ Trio	N0560
☐ Add-on Deletion/Duplication Analysis	C0164
2. If 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 BAM file	D0690
☐ Download whole exome VCF	D0642

Pediatric Neurology Region of Interest	Test Code
1. Select Up To Six (6) Gene Lists	
☐ Neuromuscular Disease ☐ Epilepsy/Seizures ☐ Hereditary Peripheral Neuropathy ☐ Movement Disorders ☐ Leukodystrophy/Encephalopathy ☐ Brain Malformations	
2. Select Requested Test(s) Below	
☐ Proband Only	N0883
☐ Trio	N0481
☐ Add-on Companion Deletion/Duplication Analysis	C0598
3. If 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 BAM file	D0690
☐ Download whole exome VCF	D0642

Expansion Options	Test Code
For Region Of Interest Orders, 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

Next-Gen Sequencing Panels	Test Code
☐ Nephrotic Syndrome Panel	N0336

Microarrays	Test Code
☐ ClariView Array	C0744

Sanger Sequencing-Complete Gene	Test Code
☐ ALX3	S0801
☐ ARX	S0962
☐ CDKL5	S0231
☐ CHD7	S0368
☐ CHN1	S0821
☐ COL1A1	S0311
☐ COL1A2	S0640
☐ CYP24A1	S0011
☐ DCX	S0846
☐ DHCR7	S0752
☐ ELANE	S0524
☐ ERCC6	S0161
☐ ERCC8	S0948
☐ F13A1	S0218
☐ F13B	S0961
☐ FANCA	S0715
☐ FANCC	S0348
☐ FANCG	S0075
☐ FGFR2	S0845
☐ FLNA	S0013
☐ FOXG1	S0823
☐ GAA	S0249
☐ GABRG2	S0531
☐ GALT	S0903
☐ GATA1	S0740
☐ GBA	S0613
☐ GJB2 [Connexin 26]	S0908
☐ GLA	S0128
☐ GPR56	S0918
☐ HAX1	S0864
☐ HOXA1	S0390
☐ IDUA	S0495
☐ IRF6	S0074
☐ JAG1	S0581
☐ KRAS	S0713
☐ MECP2	S0440
☐ MSX1	S0900
☐ NLGN3	S0483
☐ NLGN4	S0050
☐ NPHP1	S0339
☐ NSD1	S0544
☐ OCA2	S0212
☐ PHOX2A	S0773
☐ PTEN	S0508
☐ PTPN11	S0204
☐ RAF1	S0690
☐ ROBO3	S0202
☐ RPL11	S0055
☐ RPL5	S0510
☐ RPS19	S0804
☐ RPS24	S0095
☐ SALL4	S0101
☐ SBDS	S0182
☐ SCN1B	S0093
☐ SLC26A3	S0372
☐ SLC26A4	S0587
☐ SLC9A6	S0968

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☐ SMPD1	S0401
☐ SOS1	S0584
☐ SPRED1	S0749
☐ SYNGAP1	S0171
☐ TBX22	S0418
☐ TCF4	S0902
☐ TMPRSS6	S0574
☐ TUBB3	S0983
☐ TWIST1	S0313
☐ TYR	S0896
☐ UBE3A	S0104
☐ XPA	S0004
☐ XPC	S0270

Deletion/Duplication Analysis	Test Code
☐ Claritas Clinical Exome Deletion/Duplication Analysis	C0165
☐ 1p36 Deletion/Duplication	C0822
☐ 1q21 Deletion/Duplication	C0121
☐ 15q13.2q13.3 Deletion/Duplication	C0387
☐ 16p11.2 Deletion/Duplication	C0116
☐ 17q12 Deletion/Duplication	C0109
☐ 17q21 Deletion/Duplication	C0552
☐ Angelman/ Prader-Willi Syndrome Methylation and Deletion/Duplication [15q11q13]	C0703
☐ Cri du Chat Syndrome Deletion [5p-]	C0247
☐ DCX Deletion/Duplication	C0593
☐ DMD Deletion/Duplication	C0507
☐ ERCC6 Deletion/Duplication	C0404
☐ ERCC8 Deletion/Duplication	C0689
☐ FLNA Deletion/Duplication	C0569
☐ GALT Deletion/Duplication	C0046
☐ GJB6 Deletion [Connexin 30]	T0852
☐ JAG1 Deletion/Duplication	C0711
☐ Langer-Giedion Syndrome Deletion [TRPS1, EXT1]	C0049
☐ MECP2 Deletion/Duplication	C0105
☐ Miller-Dieker Syndrome Deletion [17p13.3]	C0975
☐ NF1 Deletion/Duplication	C0582
☐ NF2 Deletion/Duplication	C0699
☐ NSD1 Deletion/Duplication	C0736
☐ PMP22 Deletion/Duplication	C0998
☐ PTEN Deletion/Duplication	C0466
☐ Rubinstein-Taybi Syndrome Deletion [16p13.3]	C0291
☐ Smith-Magenis Syndrome Deletion [17p11.2]	C0304
☐ SMN1 Exon 7 Deletion/Duplication	T0996
☐ SPRED1 Deletion/Duplication	C0905
☐ TCF4 Deletion/Duplication	C0265
☐ TWIST1 Deletion/Duplication	C0537
☐ Velocardiofacial/ DiGeorge Syndrome Deletion/Duplication [10p13-p14, 22q11.2]	C0207
☐ WAGR Syndrome Deletion [11p13]	C0108
☐ Williams Syndrome Deletion [7q11.2]	C0253
☐ Wolf-Hirschhorn Syndrome Deletion [4p-]	C0272

Targeted Variant Analysis	Test Code
CLIA Confirmation of Research Findings ☐ Using Existing Primers ☐ Using Custom-Designed Primers Gene name:_____ Variant(s) in HGVS nomenclature:_____ NM# used for variant analysis:_____ Protocol used (examples: Sanger, forward primer sequence, reverse primer sequence, PCR material and condition):_____	Call to discuss
☐ Familial Targeted Variant Analysis Gene name: _____ Variant(s): _____ Name of proband:_____ Proband MRN: _____ Relationship to proband: _____	Call to discuss
☐ Achondroplasia/Hypochondroplasia Variant Analysis	S0884
☐ Apert Variant Analysis	T0106
☐ Crouzon Syndrome with Acanthosis Nigricans Variant Analysis	T0441
☐ Factor V Leiden Variant Analysis	T0423
☐ KIF21A Select Exon Sequencing	T0868
☐ Melnick-Needles Syndrome Select Exon Analysis	T0635
☐ Mitochondrial 12S rRNA (MT-RNR1) Variants	S0920
☐ Mitochondrial tRNA-Leu (MT-TL1) Variants	T0167
☐ Mitochondrial tRNA-Lys (MT-TK) Variants	T0014
☐ Mitochondrial tRNA-Ser (MT-TS1) Variants	T0419
☐ MTHFR Thermolabile Variant Analysis	T0027
☐ Muenke Syndrome Variant Analysis	T0285
☐ OCA2 2.7 kb Deletion	T0363
☐ Otopalatodigital Syndrome Select Exon Sequencing	T0196
☐ Pfeiffer syndrome FGFR1 Variant Analysis	T0810
☐ Prothrombin Variant Analysis	T0577
☐ Y Chromosome Sequence Detection [SRY, TTTY11, DDX3Y]	T0043

Other	Test Code
☐ FMR1 CGG Repeat Analysis (Fragile X Testing)	T0220
☐ TPMT Haplotype Analysis	T0876
☐ UGT1A TA Repeat Analysis	T0958
☐ DNA Extract and Hold	A0732

Clinical Information Form

It is essential to define the patient's ICD-9/ICD-10 codes below. Detailed information about your patient's clinical findings and history greatly assists the laboratory team in providing accurate and useful results. Please check the box indicating the relevant features below and provide additional information in the marked spaces.

PATIENT NAME: _____ **DOB:** _____

REQUIRED: ICD-9/ICD-10 CODE(S): _____

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: _____

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

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

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Informed Consent Signatures

PATIENT NAME: _____ **DOB:** _____

TEST(S) ORDERED: _____

How to Use This Section

Providers and patients should review information about the test(s) being ordered. Information is available on our website: www.claritasgenomics.com.

The Claritas Clinical Exome is a complex test, and so we have developed an informed consent guide to supplement the conversation between the Provider and the patient. This Guide reviews the risks, benefits, and limitations of the Claritas Clinical Exome. Patients having the Claritas Clinical Exome and patients whose Region of Interest test is expanding to the Claritas Clinical Exome should review the Guide with their Provider.

All patients/ guardians should sign the "Informed Consent" section below to indicate that consent has been given for this testing. If parents are sending samples, they should sign too.

Only patients having the Claritas Clinical Exome or a test that expands to the Claritas Clinical Exome should mark and sign the "Secondary Findings" section. If parents are sending samples (i.e., for a Trio), they should sign this section, too.

INFORMED CONSENT

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) Any sample sent from a Provider from New York State will be destroyed at the end of the testing process or not more than 60 days after the sample was taken.

_____

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 understand that if my sample is sent by a Provider from New York State, it will be destroyed at the end of the testing process or not more than 60 days after the sample was taken.

_____

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

_____

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

PATIENT NAME: _____ DOB: _____

SECONDARY FINDINGS

The following section is to be completed only by patients who are having the Claritas Clinical Exome. This includes patients whose Provider has ordered a test that expands to the Claritas Clinical Exome. Parents of these individuals should also complete this section if parental samples are being sent.

Claritas includes analysis of the 56 genes recommended by the ACMG in the Claritas Clinical Exome Complete Report. More information about the ACMG56 is available in the Claritas Clinical Exome Informed Consent Guide.

☐ After reviewing the ACMG56 with my Provider, I, the patient, ***do not want*** Claritas Genomics to report on the ACMG56.

Your signature below indicates that you have selected the choice marked above.

_____

Patient signature, or guardian if patient is under 18 Date

PARENTS also have the choice whether Claritas reports on the ACMG56.

Note the following:

- If the patient opts out of receiving information on the ACMG56, any parental samples received by Claritas Genomics will automatically be opted out also.
- If the patient chooses to receive information on the ACMG56, the parents may choose to opt out. If no choice is made by the parent(s), Claritas will report on the ACMG56.
- If both parental samples are sent, both parents must make the same choice to opt in or out of the ACMG56.
- Only those variants found in the patient's sample will be investigated in the parental sample(s). Therefore, if no variants in the ACGM56 are reported in the patient, no variants will be investigated in the parental sample(s).

☐ I/we the parent(s) ***do not want*** Claritas Genomics to report on the ACMG56.

_____

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

_____

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

Billing Information

PATIENT NAME: _____ **DOB:** _____

☐ 1. INSTITUTIONAL BILLING

Client Code _____

If you do not have a client code, complete the Client Registration Form, which is available at www.claritasgenomics.com or by contacting Client Services: clientservices@claritasgenomics or toll-free 855-373-9003.
Claritas will not begin testing until this information is complete.

☐ 2. INSURANCE BILL

Claritas will directly process the claim and manage billing to the patient/family's private health insurance company.
Directions: **Claritas will not begin testing until all information is complete.**

- Include a legible photocopy or scan of insurance card, front and back.
- If you have obtained it, include copy of the insurance authorization letter.
- Complete all Insurance Billing information requested below.

Claritas Genomics will attempt to perform a benefits investigation to determine insurance coverage, and will contact the patient if the out-of-pocket amount for testing is estimated to exceed $100.

PRIMARY INSURANCE		SECONDARY INSURANCE	
Policyholder's Name		Policyholder's Name	
Policyholder's DOB	Relationship to Patient	Policyholder's DOB	Relationship to Patient
Insurance Carrier	Policy Number	Insurance Carrier	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 any non-covered services, co-payments, deductibles, or co-insurance balances as indicated 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 at www.claritasgenomics.com or by contacting Client Services: clientservices@claritasgenomics or toll-free 855-373-9003.