Genesis Laboratory

PHONE
(408) 909-5826
FAX
(833) 605-0695

WHOLE GENOME SEQUENCING (WGS) REQUISITION

Patient Last Name | Patient First Name | Middle | Date of Birth (MM / DD / YYYY) | Gender at Birth

Address | City | State | Zip | Phone

Medical Record # | Hospital/Doctor's office patient is receiving care in

Ordering Physician | Institution Acct #

Institution Name

Email

Phone | Fax

Additional Reports Sent to:

Name | Email | Phone | Fax

Name | Email | Phone | Fax

◯ SELF PAYMENT

PATIENT BILLING INFORMATION

Amount _____

If I have insurance coverage for this testing, I am electing to be treated as a self-pay patient. As such, I agree that neither Genesis Laboratory nor I will submit a claim to my insurance for this testing. Please Bill my credit card for the full amount stated above. (we accept) ☐ Visa ☐ MasterCard

Name as it appears on card

Credit Card Account Number | **Expiration Date** | **CVC** | **Patient Signature** | **Date**

◯ INSTITUTIONAL BILLING

Institution Name | Account # | Institution Contact Name | Institution Phone | Institution Contact Email

◯ INSURANCE Referral/Prior Authorization #_____ Please attach a copy of Referral/Authorization

☐ Do Not Perform Test Until Patient is Aware of Out-of-Pocket Costs

REQUIRED ITEMS: 1. Copy of the Front/Back of Insurance Card(s) 2. Name of Ordering Physician 3. ICD10 Diagnosis Code(s) 4. Insured Signature of Authorization

ICD10 Diagnosis Code(s) (Required)

Primary Insurance Co. Name | Primary Insurance Co. Phone | Secondary Insurance Co. Name | Secondary Insurance Co. Phone

Primary Member Policy # | Primary Member Group # | Secondary Member Policy # | Secondary Member Group #

Name of Insured | Insured Date of Birth (MM / DD / YYYY) | Name of Insured | Insured Date of Birth (MM / DD / YYYY)

Patient's Relationship to Insured | Phone of Insured | Patient's Relationship to Insured | Phone of Insured

Address of Insured | Address of Insured

City | State | Zip | Patient's Relationship to Insured | State | Zip

I represent that I am covered by insurance and authorize Genesis Laboratory or its affiliates to give my designated insurance carrier, health plan, or third party administrator the information on this form and other information provided by my healthcare provider necessary for reimbursement. I authorize plan benefits to be payable to Genesis Laboratory or our affiliate of choice. I understand that Genesis Laboratory will attempt to contact me for any out-of-pocket costs not covered by insurance (for any reason including co-insurance and deductible, or non-covered services). If Genesis Laboratory is unsuccessful in its attempts to contact me, I understand that it will be my responsibility to contact Genesis Laboratory to determine my out-of-pocket cost and to pay my out-of-pocket responsibility. I will cooperate fully with Genesis Laboratory and its affiliates by providing all necessary documents needed for billing and appeals. I understand that I am responsible for sending Genesis Laboratory or its affiliate any and all of the money that I receive directly from my plan in payment for this test. Reasonable collection and/or attorney's fees, including service fees, shall be assessed if the acount is sent to collections.

Patient / Guardian Printed Name | Patient / Guardian Signature | Date (MM / DD / YYYY)

This requisition hereby incorporates the Terms and Conditions of the Laboratory Services provided to the physician and is available on our website. 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. I permit a copy of this authorization to be used in place of the original.

Physician's Printed Name | Physician's Signature | Date (MM / DD / YYYY)

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INSTRUCTIONS FOR ORDERING

PROBAND WGS TEST OPTIONS

	CPT Code	Test #	Test Description
☐	81425	100	Proband Whole Genome Sequencing
☐	81425	101	Rapid Proband Whole Genome Sequencing

CORRESPONDING COMPARATOR TESTS

	CPT Code	Test #	Test Description
☐	81426	102	Comparator Control ☐ Maternal ☐ Paternal

DUO WGS TEST OPTIONS

	CPT Code	Test #	Test Description
☐	81425	103	Duo Whole Genome Sequencing
☐	81425	104	Rapid Duo Whole Genome Sequencing

CORRESPONDING COMPARATOR TESTS
(One Biological Parent is Required)

	CPT Code	Test #	Test Description
☐	81426	105	Comparator WGS ☐ Maternal ☐ Paternal

TRIO WGS TEST OPTIONS

	CPT Code	Test #	Test Description
☐	81425	106	Trio Whole Genome Sequencing
☐	81425	107	Rapid Trio Whole Genome Sequencing

CORRESPONDING COMPARATOR TESTS
(Both Biological Parents are Required)

	CPT Code	Test #	Test Description
☐	81426	108	Comparator WGS ☐ Maternal ☐ Paternal

QUAD WGS TEST OPTIONS

	CPT Code	Test #	Test Description
☐	81425	109	Quad Whole Genome Sequencing
☐	81425	110	Rapid Quad Whole Genome Sequencing

CORRESPONDING COMPARATOR TESTS
(Both Biological Parents + One Additional Family Member Are Required)

	CPT Code	Test #	Test Description
☐	81426	111	Comparator WGS ☐ Maternal ☐ Paternal
☐	81426	112	Comparator WGS ☐ Sibling ☐ Child Maternal: ☐ Half-Sibling ☐ Aunt/Uncle ☐ Grandparent ☐ First Cousin Paternal: ☐ Half-Sibling ☐ Aunt/Uncle ☐ Grandparent ☐ First Cousin

RE-ANALYSIS

	CPT Code	Test #	Test Description
☐	81427	113	Re-analysis of Previously Performed Whole Genome Sequencing Data

ADDITIONAL REPORTING OPTIONS

Secondary and Incidental Findings

Secondary and Incidental Findings are genetic variants identified in genes unrelated to the primary reason for testing. These may include medically actionable results recommended by the American College of Medical Genetics and Genomics (ACMG) for reporting (e.g., risks for certain cancers, heart conditions, or other treatable disorders). Incidental findings refer to other unexpected variants that may have health implications. Analysis and reporting of ACMG secondary findings and incidental findings is optional and will incur an additional charge per report/individual. This is separate from the primary test analysis.

☐ I elect to receive analysis and reporting of secondary and incidental findings (additional charges apply).

☐ I decline analysis and reporting of secondary and incidental findings.

I confirm that I have been informed about secondary and incidental findings, understand that they are optional, and acknowledge that selecting this option will result in additional charges. I accept financial responsibility for this fee, which may not be covered by insurance.

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PROBAND SAMPLES

Please refer to the cheek swab collection instructions for sample requirements.

- ☐ Cheek Swab (Buccal)(Preferred)
- ☐ Skin Biopsy
- ☐ Blood in EDTA
- ☐ Extracted DNA from _____
- ☐ Cryopreserved Whole Blood

NOTE: Extracted DNA will only be accepted if the isolation of nucleic acids for clinical testing occurs in a CLIA-Certified Laboratory or a laboratory meeting equivalent requirements as determined by the CAP and/or the CMS.

COMPARATOR INFORMATION

Comparator	Last Name	First Name	Gender	Date of Birth (MM / DD / YYYY)	Date of Collection (MM / DD / YYYY)	Sample Type	Symptomatic (Attach summary of findings if yes)
Maternal						☐ Cheek Swab (Buccal)(Preferred) ☐ Blood in EDTA ☐ Cryopreserved Whole Blood	☐ Yes ☐ No
Paternal						☐ Cheek Swab (Buccal)(Preferred) ☐ Blood in EDTA ☐ Cryopreserved Whole Blood	☐ Yes ☐ No
Other Family Member: ☐ Sibling ☐ Child **Maternal** ☐ Half-Sibling ☐ Grandparent ☐ Aunt/Uncle ☐ First Cousin **Paternal** ☐ Half-Sibling ☐ Grandparent ☐ Aunt/Uncle ☐ First Cousin			☐ Male ☐ Female			☐ Cheek Swab (Buccal)(Preferred) ☐ Blood in EDTA ☐ Cryopreserved Whole Blood	☐ Yes ☐ No

ITEM CHECKLIST FOR TESTING

- ☐ Proband Sample (Required)
- ☐ Clinical Note/Summary
- ☐ Indication for Study
- ☐ Comparator Sample (Optional)
- ☐ ICD10 Diagnosis Code(s) (Required)
- ☐ Pedigree (Optional)
- ☐ Signed WGS Consent Forms
- ☐ Requisition

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INDICATION FOR TESTING (REQUIRED)

Please provide the following clinical information regarding the patient to be tested. Please also submit a clinic note and pedigree, if available. Phenotypes listed are in HPO terms with the corresponding HPO number (http://human-phenotype-ontology.github.io/). This information is needed to facilitate interpretation of whole genome sequencing results. If the laboratory requires additional information, please indicate the health care provider to be contacted.

BRAIN - NEUROLOGICAL

- ☐ HP: 0001284 Areflexia
- ☐ HP: 0200134 Epileptic Encephalopathy
- ☐ HP: 0001250 Seizures
  - ☐ HP: 0002373 Febrile Seizures
  - ☐ HP: 0012469 Infantile Spasms
  - ☐ HP: 0002123 Generalized Myoclonic Seizures
  - ☐ HP: 0002069 Generalized Tonic-clonic Seizures
  - ☐ HP: 0010818 Generalized Tonic Seizures
  - ☐ HP: 0010819 Atonic Seizures
  - ☐ HP: 0002121 Absence Seizures
  - ☐ HP: 0011169 Generalized Clonic Seizures
  - ☐ HP: 0001332 Dystonia
  - ☐ HP: 0002072 Chorea
  - ☐ HP: 0001257 Spasticity
  - ☐ HP: 0009830 Neuropathy
- ☐ HP: 0012470 Schizophrenia
- ☐ HP: 0002267 Hyperekplexia (Exaggerated Startle Response)
- ☐ HP: 0001251 Ataxia
  - ☐ HP: 0002073 Progressive Cerebellar Ataxia
  - ☐ HP: 0010871 Sensory Ataxia
  - ☐ HP: 0002497 Spastic Ataxia
  - ☐ HP: 0002078 Truncal Ataxia
  - ☐ HP: 0002066 Gait Ataxia
  - ☐ HP: 0001272 Cerebellar Atrophy
- ☐ _____
- ☐ _____
- ☐ _____

BRAIN STRUCTURAL ABNORMALITIES

- ☐ HP: 0001360 Holoprosencephaly
- ☐ HP: 0001339 Lissencephaly
- ☐ HP: 0002084 Encephalocele
- ☐ HP: 0000238 Hydrocephalus
- ☐ HP: 0002119 Ventriculomegaly
- ☐ HP: 0001273 Abnormality of Corpus Callosum
- ☐ HP: 0002539 Cortical Dysplasia
- ☐ HP: 0012444 Brain Atrophy
- ☐ HP: 0002352 Leukoencephalopathy
- ☐ HP: 0002269 Abnormality of Neuronal Migration
- ☐ HP: 0002126 Polymicrogyria
- ☐ HP: 0001302 Pachgyria
- ☐ HP: 0002500 Abnormality of Cerebral White Matter
- ☐ HP: 0007266 Cerebral Dysmyelination
- ☐ HP: 0006808 Cerebral Hypomyelination
- ☐ HP: 0002134 Abnormality of the Basal Ganglia
- ☐ HP: 0002363 Abnormality of the Brainstem
- ☐ HP: 0007360 Aplasia/Hypoplasia of the Cerebellum
- ☐ HP: 0006817 Aplasia/Hypoplasia of the Cerebellar Vermis
- ☐ _____
- ☐ _____
- ☐ _____

EAR DEFECTS & HEARING

- ☐ HP: 0000407 Sensorineural Hearing Impairment
  - ☐ HP: 0008619 Bilateral
- ☐ HP: 0000405 Conductive Hearing Impairment
- ☐ HP: 0000410 Mixed Hearing Impairment
- ☐ HP: 0004467 Preauricular Pit
- ☐ HP: 0000384 Preauricular Skin Tag
- ☐ HP: 0000369 Low-set Ears
- ☐ HP: 0000377 Abnormality of the Pinna
- ☐ _____
- ☐ _____
- ☐ _____

CARDIAC

- ☐ HP: 0001631 Atrial Septal Defect
- ☐ HP: 0001629 Ventricular Septal Defect
- ☐ HP: 0001655 Patent Foramen Ovale
- ☐ HP: 0001713 Abnormality of Cardiac Ventricle
- ☐ HP: 0001680 Coarctation of Aorta
- ☐ HP: 0001647 Bicuspid Aortic Valve
- ☐ HP: 0002616 Aortic Root Dilatation
- ☐ HP: 0001638 Cardiomyopathy
- ☐ HP: 0011675 Arrhythmia
- ☐ _____
- ☐ _____
- ☐ _____

CRANIOFACIAL

- ☐ HP: 0000256 Macrocephaly
- ☐ HP: 0000252 Microcephaly
- ☐ HP: 0001363 Craniosynostosis
- ☐ HP: 0000204 Cleft Upper Lip
- ☐ HP: 0000175 Cleft Palate
- ☐ HP: 0008050 Abnormality of the Palpebral Fissures
- ☐ HP: 0000288 Abnormality of the Philtrum
- ☐ HP: 0010938 Abnormality of the External Nose
- ☐ _____
- ☐ _____
- ☐ _____

ENDOCRINE

- ☐ HP: 0000819 Diabetes Mellitus
- ☐ HP: 0000873 Diabetes Insipidus
- ☐ HP: 0000821 Hypothyroidism
- ☐ HP: 0000829 Hypoparathyroidism
- ☐ HP: 0000834 Abnormality of the Adrenal Glands
- ☐ HP: 0001738 Exocrine Pancreatic Insufficiency
- ☐ HP: 0002721 Immunodeficiency
- ☐ _____
- ☐ _____
- ☐ _____

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INDICATION FOR TESTING (REQUIRED) - CONTINUED

EYE DEFECTS & VISION

- ☐ HP: 0000505 Visual Impairment
- ☐ HP: 0000618 Blindness
- ☐ HP: 0000568 Microphthalmia
- ☐ HP: 0000486 Strabismus
- ☐ HP: 0000519 Cataract Congenital Bilateral
- ☐ _____
- ☐ _____
- ☐ _____

HAIR & SKIN

- ☐ HP: 0000957 Cafe-Au-Lait Spots
- ☐ HP: 0001034 Hypermelanotic Macule
- ☐ HP: 0001010 Hypopigmentation of the Skin
- ☐ HP: 0008066 Abnormal Blistering of the Skin
- ☐ HP: 0008064 Ichthyosis
- ☐ HP: 0000988 Skin Rash
- ☐ HP: 0001581 Recurrent Skin Infections
- ☐ HP: 0005306 Capillary Hemangiomas
- ☐ HP: 0001597 Abnormality of the Nail
- ☐ HP: 0004554 Generalized Hypertrichosis
- ☐ HP: 0001596 Alopecia
- ☐ HP: 0002208 Coarse Hair
- ☐ HP: 0002299 Brittle Hair
- ☐ _____
- ☐ _____
- ☐ _____

MOTOR/COGNITIVE DEVELOPMENT

- ☐ HP: 0000750 Delayed Speech & Language Development
- ☐ HP: 0001270 Delayed Motor Milestone
- ☐ HP: 0002376 Developmental Regression
- ☐ Intellectual Disability
  - ☐ HP: 0001256 Mild
  - ☐ HP: 0002342 Moderate
  - ☐ HP: 0010864 Severe
- ☐ HP: 0000729 Autistic Spectrum Disorder
- ☐ HP: 0000717 Autism
- ☐ _____
- ☐ _____
- ☐ _____

GASTROINTESTINAL/DIGESTIVE DISORDER

- ☐ HP: 0002021 Pyloric Stenosis
- ☐ HP: 0002020 Gastoesophageal Reflux
- ☐ HP: 0002014 Diarrhea
- ☐ HP: 0002019 Constipation
- ☐ HP: 0002037 Inflammatory Bowel Disease
- ☐ HP: 0004389 Intestinal Pseudo-Obstruction
- ☐ HP: 0001399 Hepatic Failure
- ☐ HP: 0002572 Episodic Vommiting
- ☐ HP: 0001744 Splenomegaly
- ☐ HP: 0002240 Heptomegaly
- ☐ HP: 0001508 Postnatal Failure to Thrive
- ☐ HP: 0002578 Gastroparesis
- ☐ HP: 0002027 Abdominal Pain
- ☐ _____
- ☐ _____
- ☐ _____

HEMATOLOGY

- ☐ HP: 0001875 Neutropenia
  - ☐ HP: 0005549 Congenital
  - ☐ HP: 0410252 Chronic Neutropenia
  - ☐ HP: 0040289 Cyclic Neutropenia
- ☐ HP: 0001873 Thrombocytopenia
- ☐ HP: 0040185 Macrothrombocytopenia
- ☐ HP: 0005518 Erythrocyte Macrocytosis
- ☐ HP: 0004444 Spherocytosis
- ☐ HP: 0012410 Pure Red Cell Aplasia
- ☐ HP: 0001903 Anemia
- ☐ _____
- ☐ _____
- ☐ _____

GENITOURINARY

- ☐ HP: 0000113 Polycystic Kidney Dysplasia
- ☐ HP: 0000107 Renal Cyst
- ☐ HP: 0008738 Partially Duplicated Kidney
- ☐ HP: 0000104 Renal Argenesis
- ☐ HP: 0000085 Horseshoe Kidney
- ☐ HP: 0000069 Abnormality of the Ureter
- ☐ HP: 0000795 Abnormality of the Urethra
- ☐ HP: 0000047 Hypospadias
- ☐ HP: 0000028 Cryptorchidism
- ☐ HP: 0000035 Abnormality of the Testis
- ☐ HP: 0000062 Ambiguous Genitalia
- ☐ _____
- ☐ _____
- ☐ _____

METABOLIC

- ☐ HP: 0001946 Ketosis
- ☐ HP: 0003074 Hyperglycemia
- ☐ HP: 0001943 Hypoglycemia
- ☐ HP: 0001941 Acidosis
- ☐ HP: 0003128 Lactic Acidosis
- ☐ HP: 0003215 Dicarboxylic Aciduria
- ☐ HP: 0002490 Increased CSF lactate
- ☐ HP: 0001992 Organic Aciduria
- ☐ HP: 0030085 Abnormal CSF Lactate Level
- ☐ HP: 0003542 Increased Serum Pyruvate
- ☐ HP: 0003535 3-Methyglutaconic Aciduria
- ☐ HP: 0001942 Metabolic Acidosis
- ☐ HP: 0100493 Hypoammonemia
- ☐ HP: 0001987 Hyperammonimia
- ☐ HP: 0004923 Hyperphenylalaninemia
- ☐ HP: 0003234 Decreased Plasma Carnitine
- ☐ HP: 0003236 Elevated Serum Creatine Phosphokinase
- ☐ Abnormal Newborn Screen
- ☐ Unusual Color/Odor
- ☐ _____
- ☐ _____
- ☐ _____

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INDICATION FOR TESTING (REQUIRED) - CONTINUED

MUSCULOSKELETAL

- ☐ HP: 0011398 Hypotonia
- ☐ HP: 0001276 Hypertonia
- ☐ HP: 0000098 Tall Structure
- ☐ HP: 0004322 Short Structure
- ☐ HP: 0001382 Joint Hypermobility
- ☐ HP: 0001371 Flexion Contracture
- ☐ HP: 0002804 Arthrogryposis Multiplex Congenita
- ☐ HP: 0001161 Hand Polydactyly
- ☐ HP: 0001829 Foot Polydactyly
- ☐ HP: 0006101 Finger Syndactyly
- ☐ HP: 0001770 Toe Syndactyly
- ☐ HP: 0100490 Camptodactyly of Finger
- ☐ HP: 0012165 Oligodactyly
- ☐ HP: 0001762 Talipes Equinovarus
- ☐ HP: 0002757 Recurrent Fractures
- ☐ HP: 0002650 Scoliosis
- ☐ HP: 0002808 Kyphosis
- ☐ HP: 0003307 Hyperlordosis
- ☐ HP: 0001528 Hemihypertrophy
- ☐ HP: 0001513 Obesity
- ☐ HP: 0001548 Overgrowth
- ☐ HP: 0002652 Skeletal Dysplasia
- ☐ HP: 0004442 Sagittal Craniosynostosis
- ☐ HP: 0011330 Metopic Synostosis
- ☐ _____
- ☐ _____
- ☐ _____

PRE/PERINATAL HISTORY

- ☐ HP: 0001622 Prematurity - GA at birth_____
- ☐ HP: 0001511 Intrauterine Growth Restrictions
- ☐ HP: 0001562 Oligohydramnios
- ☐ HP: 0001561 Polyhydramnios
- ☐ HP: 0000476 Cystic Hygroma
- ☐ HP: 0000776 Congenital Diaphragmatic Hernia
- ☐ HP: 0001508 Failure to Thrive
- ☐ HP: 0001539 Omphalocele
- ☐ HP: 0002084 Encephalocele
- ☐ HP: 0010880 Increased Nuchal Translucency
- ☐ _____
- ☐ _____
- ☐ _____

CANCER

- ☐ Type of Cancer_____
- ☐ Age of Diagnosis_____
- ☐ Family History of Cancer and Affected Relatives

_____

_____

GENES OF INTEREST

_____

_____

_____

_____

RESPIRATORY

- ☐ HP: 0002093 Respiratory Insufficiency
- ☐ HP: 0002878 Respiratory Failure
- ☐ HP: 0002104 Apnea
- ☐ HP: 0002791 Hypoventilation
- ☐ HP: 0002883 Hyperventilation
- ☐ HP: 0002788 Recurrent Upper Respiratory Tract Infections
- ☐ _____
- ☐ _____
- ☐ _____

OTHER

- ☐ HP: 0004311 Abnormality of Macrophages
- ☐ HP: 0001954 Episodic Fever
- ☐ HP: 0004313 Hypogammaglobulinemia
- ☐ HP: 0010701 Abnormal Immunoglobulins
- ☐ HP: 0002721 Immunodeficiency
- ☐ HP: 0012088 Abnormal Urinary Odor
- ☐ HP: 0012537 Food Intolerance
- ☐ HP: 0008067 Abnormally lax or Hyperextensible Skin
- ☐ HP: 0100660 Abnormal Involuntary Movements
- ☐ HP: 0001254 Lethargy
- ☐ HP: 0002415 Leukodystrophy
- ☐ HP: 0000007 Autosomal Recessive Inheritance Pattern
- ☐ _____
- ☐ _____
- ☐ _____

ADDITIONAL CLINICAL INFORMATION:
(Age of onset clinical symptoms, etc.)

DIFFERENTIAL DIAGNOSIS:

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WHOLE GENOME SEQUENCING (WGS) AND WHOLE EXOME SEQUENCING (WES) CONSENT

This consent form can only be used for whole genome sequencing and whole exome sequencing.

For the purposes of this consent, "I", "my", "you", and "your" can refer to you, your child, or other individual you are the legal representative of.

TEST INFORMATION

Your healthcare provider (doctor, genetic counselor, or other person with medical training) wants to order a genetic test called Whole Genome Sequencing (WGS) or Whole Exome Sequencing (WES). These tests look for changes, called variants, in a person's DNA that can cause health issues. DNA is our genetic material. These variants can be in certain genes, specific parts of our DNA that are needed for our health. They can also be found in other places in the genome (all DNA that a person has). Based on your known health issues, variants in your DNA that may cause these issues will be reported. This test may explain your health issues. It may not explain your health issues. This test is not a guarantee that you will receive the desired information or outcome. It may also explain health issues that your family may have. Even if this test finds the cause of your health issues, this may not help treat or manage those issues.

Testing where your DNA is compared to one or more family members may be performed. This may help better understand your results or show if your family members have the same variant as you.

Before you sign this consent form, you should speak with your healthcare provider. They can help you understand this testing and what is means for your health.

TEST RESULTS

There are several types of test results that may be reported including but not limited to:

Positive Result: One or more variants were identified in your DNA that are classified as pathogenic (known to cause disease) or likely pathogenic (very likely to cause disease based on current evidence). These variants may be related to your current health concerns and/or may increase your risk of developing certain health conditions in the future.

A positive result can:

- Help explain the cause of your symptoms or condition.
- Provide information about the expected course of the condition.
- Inform risks to family members (including recurrence risks for future children) and potential testing for relatives.

The interpretation is based on the best available scientific and medical knowledge at the time of testing. Classifications may be updated in the future as new evidence emerges. Your healthcare provider or a genetic counselor will discuss the specific variant(s), their implications for your health and family, and any recommended follow-up actions or additional testing.

Negative Result: No variants were identified in your DNA that are known to explain your current health concerns or that are associated with an increased risk of developing certain health conditions in the future.

A negative result does **not** guarantee that your health issue(s) are not caused by a genetic factor. There are several reasons this is possible, including:

- Some disease-causing variants may not yet be discovered or well-understood in current scientific databases and medical literature.
- The test may not detect all types of genetic changes (such as certain complex rearrangements, variants in poorly covered regions, or non-coding variants).
- New genetic associations may be identified in the future as knowledge advances.

Your healthcare provider or a genetic counselor can discuss whether additional testing, periodic reanalysis of your data, or other evaluations might be appropriate.

Variant of Uncertain Clinical Significance (VUS): One or more variants were identified in your DNA, but there is currently insufficient evidence to determine whether they are related to your health concerns, increase future health risks, or have no significant effect (they may be benign). These are called variants of uncertain significance (VUS).

A VUS result is **inconclusive**—it is **not** considered a positive (disease-causing) or negative result. Management decisions (treatment, screening, etc.) should be based on your personal and family medical history, not on the VUS alone. In these cases, the laboratory is uncertain at the time of testing, if this variant is associated with the medical condition.

Over time, as scientific knowledge advances, a VUS may be reclassified (e.g., as pathogenic/likely pathogenic or benign/likely benign). Your healthcare provider or a genetic counselor can discuss:

- Whether additional testing (such as testing family members) might help clarify the variant's meaning.
- Options for periodic re-analysis of your data if new information becomes available.

☐ By signing below I acknowledge and agree to the above terms and information.

Patient Name	Patient Signature	Date Signed (MM / DD / YYYY)

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WHOLE GENOME SEQUENCING (WGS) AND WHOLE EXOME SEQUENCING (WES) CONSENT

TEST RESULTS - CONTINUED

Secondary and Incidental Findings (Optional): Whole genome sequencing may reveal variants unrelated to the reason for your testing (your current health concerns) but that could affect your future health or medical management. These are known as secondary findings (or incidental findings).

The American College of Medical Genetics and Genomics (ACMG) recommends that labs analyze and report pathogenic or likely pathogenic variants in a specific list of genes (currently ACMG SF v3.3, with 84 genes) linked to actionable conditions—such as certain hereditary cancers, heart diseases, and treatable metabolic disorders—where screening, prevention, or treatment can reduce risks.

- By default, your test will not automatically report these secondary findings unless you or your provider opt in. This may result in an additional cost.
- Variants in genes associated with adult-onset neurodegenerative conditions (progressive brain disorders that often start later in life and worsen over time, frequently with no cure or effective treatment) will not be reported unless directly related to your current health issues. This follows ACMG guidance prioritizing actionable benefits over potential harm from disclosing untreatable risks. If you wish to learn about specific genes in this category, your provider can request them by listing the exact gene(s) on the test order.

Opt-in option for secondary findings: If you want to receive information from the ACMG-recommended genes (or others), indicate this on the consent form, discuss with your provider, or have them add it to the test order. If a result includes a note such as "There is additional information in your DNA that you may want to be aware of," this indicates potential secondary findings were identified but not detailed in the initial report as per our lab policy. Discuss this with your healthcare provider or a genetic counselor. They can order targeted follow-up testing, re-analysis of your data, or other evaluations as appropriate.

As knowledge advances, your genomic data may qualify for future reanalysis (e.g., to incorporate updates to the ACMG SF list or new variant interpretations). Contact your provider for details on our re-analysis policy, including any fees or intervals.

Genes of No Known Disease Association (Optional): Testing may find a variant in a gene that is not known to cause disease. This may be helpful to learn more about these genes in the future. These results do not currently impact medical management or indicate a diagnosis.

CONSIDERATIONS AND LIMITATIONS

- You should speak with your provider to understand the risks, benefits, and testing, pertaining to all genetic results. The Laboratory cannot comment on treatment or diagnosis of health issues.

- Testing may show you have, or are at increased chance of having, a health issue. It may show that you have an increased chance of having a child with a health issue.
- Even if the variant(s) causing your health issues are found, how these issues might progress or improve with treatment might not be known. Affected family members with the same variant might not be affected like you are.
- Depending on the results of testing, more testing may be needed to understand these results. This testing might be needed for you and/or additional family members.
- A negative result does not rule out the chance for health issues, caused by a genetic varient. Our knowledge of variants and how they cause disease may change over time as we learn more about genetics. Testing has limitations to what it can find as well.
- Certain factors may lead to incorrect results. These include mislabeled samples, incorrect information in the test order, and rare technical errors. You agree to hold harmless and release liability for unintended errors in results.
- More sample may be needed from you if the first sample is not sufficient to complete testing.
- Genesis Laboratory reserves the right to retain my biological sample and data associated with my sample in accordance to the laboratory policy.

FOR SAMPLES FROM NEW YORK STATE RESIDENTS

Samples from New York State residents shall not be included in research without written consent. Samples from New York State will not be retained for more than sixty (60) days after receipt by Genesis Laboratory, unless authorized by marking below. No tests other than those authorized shall be performed on the samples.

☐ I authorize Genesis Laboratory to retain Biological and Data Sample(s) longer based on the retention policy for test development, quality assurance, training purposes, and future requests.

PATIENT CONFIDENTIALITY AND SAMPLE RETENTION

- If several family members are tested, knowing the correct biological relationships among them is important. In rare cases, testing can show that family members are not related as expected. If this is found, we may contact the provider who ordered your testing.
- If this testing is requested to be cancelled after the order and sample are sent to the laboratory, the cost and charge for the test will still be the responsibility of the patient.

☐ By signing below I acknowledge and agree to the above terms and information

Patient Name	Patient Signature	Date Signed (MM / DD / YYYY)

WHOLE GENOME SEQUENCING (WGS) REQUISITION

Patient Last Name	Patient First Name	Middle	Date of Birth (MM / DD / YYYY)	Gender

WHOLE EXOME SEQUENCING (WES) AND WHOLE GENOME SEQUENCING (WGS) CONSENT

PATIENT CONFIDENTIALITY AND SAMPLE RETENTION - CONTINUED

- Genesis Laboratory and its contracted partners will have access to your sample for the ordered testing. Results from testing will only be released to: (i) a licensed healthcare provider, (ii) those authorized in writing, (iii) the patient or their personal representative, and (iv) those allowed access to test results by law. You have the right to access your test results from Genesis Laboratory by providing a written request. You also have the right to request raw data obtained from your sample by providing a written request and HIPAA Authorization Form.
- In rare cases, people with genetic diseases may have problems with health insurance and employment. The U.S Federal Government has several laws that prohibit discrimination based on test results by health insurance companies and employers. These laws also prohibit unauthorized disclosure of this information. For information, please visit www.genome.gov/10002077.
- Samples will be kept in the laboratory based on our retention policy. Once testing is completed, your sample may be de-identified. The de-identified sample may be used for test development, quality assurance, and training purposes. Samples are not returned to patients or providers unless requested prior to testing. You and your heirs will not receive payments, benefits, or rights to any resulting products or discoveries.
- The information from your testing may be used in scientific research, publications or presentations, but your specific identity will not be revealed. We may contact your provider to obtain more clinical information about you. Genesis Laboratory also collaborates with entities who perform other types of scientific research and may contact you to see if you would like to be involved.
- Variants found may be submitted to databases. The medical community uses these databases to collect information about how variants might cause disease to improve testing and treatment for patients. An example is ClinVar, a free, public archive of reports on human genetics. Limited clinical information may need to be shared with these databases. In rare cases, this information may be enough to allow you or your family members to be identified.
- Genesis Laboratory is committed to protecting your privacy and confidentiality

FINANCIAL AGREEMENT

By signing below, I hereby authorize Genesis Laboratory 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. I designate Genesis Laboratory and whomever they are partnered with, as my designated representative for purposes of appealing any denial of benefits by my insurance carrier. I irrevocably assign associated payment to Genesis Laboratory and whomever they are partnered with, and direct that payment be made directly to the appropriate entity. Please note, some payers may not cover certain screening tests. In these cases payment of unmet charges will be made to Genesis Laboratory or whomever they are partnered with.

If my health insurer does not cover the test or I do not have health insurance, I have received an estimate of the cost for the genetic testing ordered by my provider and agree to pay for the cost of the genetic testing billed to me by Genesis Laboratory or whomever they are partnered with based on that estimate. In these cases, payment of unmet charges will be made to Genesis Laboratory or whomever they are partnered with.

A Medicare Advance Beneficiary Notice (ABN) is required for services Medicare identifies as not medically necessary, for patients using medicare insurance.

PATIENT AUTHORIZATION

By signing this statement of consent, I acknowledge that I have read, understand, and hereby grant my informed consent for genetic testing. I have received appropriate explanations from my healthcare provider about the planned genetic test(s) and possible results. I have been informed by my healthcare provider about the availability and importance of genetic counseling and have been provided with written information identifying a genetic counselor or medical geneticist who can provide such counseling services. All my questions have been answered, and I have had the necessary time to make an informed decision about the genetic test(s).

I hereby give permission to Genesis Laboratory to conduct genetic testing.

Patient Name	Patient Signature	Date Signed (MM / DD / YYYY)

Relationship to Patient	Name	Signature	Date
Relative 1			
Relative 2			
Relative 3			

If one or more family members have a Representative signing on their behalf:

Name	Signature	Date Signed (MM / DD / YYYY)	Representative For	Relationship to Represented Person(s)

*If you are signing on behalf of the patient as the parent(s) and/or person with legal authority to act on behalf of the patient or parent, you may be required to provide evidence of your authority.