Variantyx

Genomic Unity®
Comprehensive Analyses
Test Requisition Form

Patient Name	
Date of Birth	

Affix barcode label of Patient's sample here

Required Information Checklist:

- ❑ **Patient demographics**
- ❑ **ICD-10 codes**
- ❑ **Healthcare provider signature**
- ❑ **Signed informed consents**
- ❑ **Clinical & genetic counseling notes with pedigree (please include all family history of known chronic and inherited disease and copies of genetic test results, if available)**
- ❑ **Completed TRF and all clinical notes faxed to 617-433-5024**
- ❑ **Letter of medical necessity and/or required insurance forms if applicable**

Missing or insufficient information will cause a delay in pre-authorization and results.

Clinical Information

ICD-10 Code(s)*	Suspected Diagnosis
Are the clinical symptoms onset before the age of 21? Yes / No	Is the patient symptomatic? Yes / No
Are there ongoing pregnancies in the family? Yes / No	Has the patient had previous genetic testing? Yes / No **If yes please include copies of the reports.*

Comprehensive Analyses

◯ Genomic Unity® Whole Genome Analysis **(CP001)** ◯ Singleton ◯ Duo ◯ Trio

- ◯ Option to receive Genomic Unity® Pharmacogenomics Analysis **(PG001)** **No selection will default to opt-out.*
- ◯ Option to receive ACMG Secondary Findings only **No selection will default to opt-out.*
- ◯ Option to receive ACMG Secondary Findings with Incidental Findings **No selection will default to opt-out.*

**This test is applicable for patients with non diagnostic previous exome analysis.*
**Please provide clinical and genetic counseling notes with pedigree and previous genetic testing results.*

◯ Genomic Unity® Exome Plus Analysis **(CP010)** ◯ Singleton ◯ Duo ◯ Trio

- ◯ Option to receive Genomic Unity® Pharmacogenomics Analysis **(PG001)** **No selection will default to opt-out.*
- ◯ Option to receive ACMG Secondary Findings **No selection will default to opt-out.*
- ◯ Option to receive ACMG Secondary Findings with Incidental Findings **No selection will default to opt-out.*
- ◯ If the Genomic Unity® Exome Plus Analysis does not yield a diagnostic result, reflex to Genomic Unity® Whole Genome Analysis (CP001).

**Reflex to CP001 might not be covered by insurance.*

◯ Genomic Unity® Exome Analysis **(CP002)** ◯ Singleton ◯ Duo ◯ Trio

- ◯ Option to receive ACMG Secondary Findings **No selection will default to opt-out.*
- ◯ Option to receive ACMG Secondary Findings with Incidental Findings **No selection will default to opt-out.*
- ◯ If the Genomic Unity® Exome Analysis does not yield a diagnostic result, reflex to:
  - ◯ Genomic Unity® Exome Plus Analysis **(CP010)** ◯ Genomic Unity® Whole Genome Analysis **(CP001)**

  **Reflex to CP001 might not be covered by insurance.*
  - ◯ Receive Genomic Unity® Pharmacogenomics Analysis **No selection will default to opt-out.*

◯ Constitutional Genome-Wide Copy Number Variant Analysis **(CP004)**

- ◯ If the Genomic Unity® Constitutional Genome-Wide Copy Number Variant Analysis does not yield a diagnostic result, reflex to:
  - ◯ Genomic Unity® Exome Analysis (CP002) ◯ Singleton ◯ Duo ◯ Trio
  - ◯ Genomic Unity® Exome Plus Analysis (CP010) ◯ Singleton ◯ Duo ◯ Trio
  - ◯ Genomic Unity® Whole Genome Analysis (CP001) ◯ Singleton ◯ Duo ◯ Trio

  **Reflex to CP001 might not be covered by insurance.*
- ◯ Option to receive Genomic Unity® Pharmacogenomics Analysis **(PG001)** **No selection will default to opt-out.*
- ◯ Option to receive ACMG Secondary Findings **No selection will default to opt-out.*
- ◯ Option to receive ACMG Secondary Findings with Incidental Findings **No selection will default to opt-out.*

Healthcare Provider's Statement

By my signature below, I attest that I am the referring physician, an authorized healthcare provider for the patient or procurator thereof, and this testing is medically necessary for diagnosis and/or treatment of the patient. I attest that the patient or guardian has voluntarily consented to genetic testing for diagnostic purposes, including possible results and outcomes, ACMG secondary findings, and pharmacogenomics analysis, if selected, has been given the opportunity to ask questions about the testing and/or seek genetic counseling, and agrees to allow an independent genetic counselor facilitated through a third party to provide pre-test and/or post-test genetic counseling if required by the insurer and/or referring institution.

Healthcare provider signature _____ Date _____

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Patient Name		Affix barcode label of Patient's sample here
Date of Birth		

Patient Information

First Name	Last Name	MI	DOB	Genetic Sex ◯ Male ◯ Female ◯ Other ____
Address		ID / MR#		Gender identification (optional):
City	State	Zip Code	Phone	Email
Other Name (if different than listed above): ◯ Please use this name in communications.		Pronouns	Preffered language ◯ English ◯ Spanish	

Comparator Information

First Name	Last Name	DOB	Relationship to proband	Genetic Sex ◯ Male ◯ Female ◯ Other ____
If affected by the same disorder as the patient please list the clinical symptoms				Gender identification (optional):
Address		Phone	Email	

Comparator Information

First Name	Last Name	DOB	Relationship to proband	Genetic Sex ◯ Male ◯ Female ◯ Other ____
If affected by the same disorder as the patient please list the clinical symptoms				Gender identification (optional):
Address		Phone	Email	

Ordering Healthcare Provider

First Name	Last Name	Phone	NPI #
Facility Name		Facility Address	City
State	Zip Code	Email	Fax

Additional Report Recipients

Name	Phone	Fax	Email
Name	Phone	Fax	Email

Billing Information

◯ Insurance Billing

Insurance Company		Policy #	Group #
Policy Holder First Name	Policy Holder Last Name	Policy Holder DOB	Who is the Policy Holder? ◯ Patient ◯ Spouse ◯ Parent
Policy Holder Address		Employer's Address	

◯ Institutional Billing — ◯ Patient Payment — *An invoice will be sent to the patient email provided. Insurance will not be billed.*

An invoice will be sent to the institution listed above. Please contact us for alternate billing.

Who should be contacted for billing purposes?
Payer Name:
Payer Phone:
Payer Email:

Patient Sample Information

Sample Type ◯ Saliva* ◯ Saliva swab*† ◯ Assisted saliva* ◯ Blood ◯ Genomic DNA ◯ Other:

* Use Variantyx collection kits only
† Saliva swab is similar to a buccal swab; Saliva swabs may have reduced sensitivity and specificity due to the presence of normal oral flora

Sample Will Be Collected
◯ In-clinic ◯ Patient was given kit ◯ By Variantyx

Please check if your patient has had a: ◯ Blood transfusion within the last two weeks ◯ Bone marrow transplant
We will contact you for additional specimen collection details.

Collection date

*Please note that the newest version of the assay will be selected by default.

Variantyx

Genomic Unity®
Supplement A
Patient Phenotype

Patient Name	
Date of Birth	

Affix barcode label of Patient's sample here

Patient Phenotypes

	1°	2°	Phenotype	Age of onset
Development/Behavior	○	○	Developmental regression	
	○	○	Global developmental delay	
	○	○	Intellectual disability	
	○	○	Delayed fine motor development	
	○	○	Delayed gross motor development	
	○	○	Delayed speech and language development	
	○	○	Speech articulation difficulties	
	○	○	Autism spectrum disorder	
	○	○	Self-injurious behavior	
	○	○	Stereotypy	
Brain Anomalies	○	○	Brain atrophy	
	○	○	Cerebellar hypoplasia	
	○	○	Cortical dysplasia	
	○	○	Encephalocele	
	○	○	Holoprosencephaly	
	○	○	Hydrocephalus	
	○	○	Lissencephaly	
	○	○	Molar tooth sign	
	○	○	Periventricular leukomalacia	
	○	○	Polymicrogyria	
Neurological	○	○	Abnormal nerve conduction velocity	
	○	○	Ataxia	
	○	○	Spasticity	
	○	○	Chorea	
	○	○	Dystonia	
	○	○	Foot dorsiflexor weakness	
	○	○	Headache	
	○	○	Neurodegeneration	
	○	○	Motor axonal neuropathy	
	○	○	Pes cavus	
	○	○	Reduced deep tendon reflexes	
	○	○	Seizures	
	○	○	Sleep apnea	
	○	○	Stroke-like episodes	
	○	○	Tremor	
	○	○	Vocal cord paresis	
Muscular	○	○	Dysphagia	
	○	○	Exercise intolerance	
	○	○	Hypertonia	
	○	○	Hypotonia	
	○	○	Muscle fasciculations	
	○	○	Muscle wasting	
	○	○	Muscle weakness	
	○	○	Muscular dystrophy	
	○	○	Myotonia	
Metabolic	○	○	Aciduria	
	○	○	Abnormal CPK circulation concentration	
	○	○	Decreased plasma carnitine	
	○	○	Elevated serum alanine aminotransferase	
	○	○	Increased serum pyruvate	
	○	○	Ketosis	
	○	○	Lactic acidosis	
Endocrine	○	○	Adrenal hyperplasia	
	○	○	Adrenal insufficiency	
	○	○	Cushing syndrome	
	○	○	Diabetes Mellitus Type I	
	○	○	Diabetes Mellitus Type II	
	○	○	Hypothyroidism	
	○	○	Hypoparathyroidism	
	○	○	Hypogonadism	
	○	○	Paraganglioma	

	1°	2°	Phenotype	Age of onset
Constitutional	○	○	Cleft lip	
	○	○	Cleft palate	
	○	○	Syndactyly	
	○	○	Polydactyly	
	○	○	Failure to thrive	
	○	○	Macrocephaly	
	○	○	Microcephaly	
	○	○	Obesity	
	○	○	Short stature	
	○	○	Tall stature	
Ophthalmology/Auditory	○	○	Blindness	
	○	○	Cataracts	
	○	○	Coloboma	
	○	○	External ophthalmoplegia	
	○	○	Optic atrophy	
	○	○	Ptosis	
	○	○	Rod-cone dystrophy	
	○	○	Visual impairment	
	○	○	Aminoglycoside-induced hearing loss	
	○	○	External ear malformation	
	○	○	Hearing loss	
Cardiac	○	○	Arrhythmia	
	○	○	Cardiomyopathy	
	○	○	Syncope	
	○	○	Tetralogy of Fallot	
Gastrointestinal	○	○	Aganglionic megacolon	
	○	○	Constipation	
	○	○	Diarrhea	
	○	○	Elevated hepatic transaminases	
	○	○	Gastroesophageal reflux	
	○	○	Gastroschisis	
	○	○	Omphalocele	
	○	○	Pyloric stenosis	
	○	○	Tracheoesophageal fistula	
	○	○	Vomiting	
Genitourinary	○	○	Abnormal renal morphology	
	○	○	Ambiguous genitalia	
	○	○	Cryptorchidism	
	○	○	Hydronephrosis	
	○	○	Hypospadias	
	○	○	Renal agenesis	
Skeletal	○	○	Abnormal vertebral morphology	
	○	○	Clubfoot	
	○	○	Craniosynostosis	
	○	○	Multiple joint contractures	
	○	○	Scoliosis	
Skin	○	○	Abnormality of connective tissue	
	○	○	Abnormality of skin pigmentation	
	○	○	Abnormality of temperature regulation	
	○	○	Ichthyosis	
			Other phenotypes	

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