Variantyx

Genomic Unity®
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

Comprehensive Analyses	
◯ Genomic Unity® Whole Genome Analysis (CP001) ◯ Singleton ◯ Duo ◯ Trio	Provides sequence analysis (single nucleotide variants, deletions/insertions, intronic, regulatory and intergenic variants); analysis of copy number variants, duplications/deletions, regions of homozygosity, mobile element insertions, inversions, and aneuploidy; mitochondrial genome sequence analysis with heteroplasmy and large deletions; and short tandem repeat expansion analysis in select genes. See full test information: https://www.variantyx.com/whole-genome-analysis.
◯ Genomic Unity® Exome Plus Analysis (CP010) ◯ Singleton ◯ Duo ◯ Trio	Provides sequence analysis (single nucleotide variants, deletions/insertions, and characterized intronic and regulatory variants); analysis of copy number variants, duplications/deletions, regions of homozygosity, mobile element insertions, inversions, and aneuploidy; mitochondrial genome sequence analysis with heteroplasmy and large deletions; and short tandem repeat expansion analysis in select genes. See full test information: https://www.variantyx.com/solutions/diagnostic-testing/genomic-unity-analyses/exome-plus-analysis/
◯ Genomic Unity® Exome Analysis (CP002) ◯ Singleton ◯ Duo ◯ Trio	Provides whole exome sequence analysis of exonic regions, characterized intronic and regulatory variants, and short tandem repeat expansion analysis of select genes. See full test information: https://www.variantyx.com/exome-analysis.
Secondary Findings (opt in)*	
◯ I choose to receive ACMG Secondary Findings	*No selection will default to opt-out.* **Secondary findings are optional for CP001, CP010 and CP002.* **This option is not available for other comprehensive or phenotype based analyses, unless reflexed to CP001, CP010 and CP002.*
Other Comprehensive Analyses	
◯ Genomic Unity® Mitochondrial Genome Analysis (CP003)	Provides mitochondrial genome sequence analysis with heteroplasmy and large deletions. See full test information: https://www.variantyx.com/mito-genome-analysis.
◯ Genomic Unity® Constitutional Genome-Wide Copy Number Variant Analysis (CP004)	Provides constitutional genome-wide copy number variant analysis, deletions, duplications, inversions, regions of homozygosity, mobile element insertions, and aneuploidy of the nuclear genome. See full test information: https://www.variantyx.com/cnv-analysis.
Phenotype Based Comprehensive Analyses	
◯ Genomic Unity® Comprehensive Mitochondrial Disorders Analysis (MD001)	Provides mitochondrial genome sequence analysis with heteroplasmy and large deletions; and sequence analysis and duplication/deletion analysis of 335 nuclear genes related to mitochondrial disorders. See full test information: https://www.variantyx.com/solutions/diagnostic-testing/genomic-unity-analyses/mitochondrial-analysis/
◯ Genomic Unity® Intellectual Disability Analysis (NR001)	Provides genome-wide copy number variant analysis, duplications/deletions, regions of homozygosity, mobile element insertions, inversions, and aneuploidy; short tandem repeat expansion analysis of *FMR1* and *AFF2*; and full gene sequence analysis and duplication/deletion analysis of 12 genes related to intellectual disability. See full test information: https://www.variantyx.com/intellectual-disability-analysis.
◯ Genomic Unity® Comprehensive Ataxia Analysis (NR002)	Provides sequence analysis and duplication/deletion analysis of 51 genes related to ataxia as well as short tandem repeat expansion analysis of *ATN1, ATXN1, ATXN2, ATXN3, ATXN7, ATXN8OS, ATXN10, CACNA1A, FXN, NOP56, PPP2R2B, TBP.* See full test information: https://www.variantyx.com/ataxia-analysis.
◯ Genomic Unity® Ataxia Repeat Expansion Analysis (NR003)	Provides sequence analysis, duplication/deletion analysis and short tandem repeat expansion analysis of *ATN1, ATXN1, ATXN2, ATXN3, ATXN7, ATXN8OS, ATXN10, CACNA1A, FXN, NOP56, PPP2R2B, TBP.* See full test information: https://www.variantyx.com/ataxia-repeat-analysis.
◯ Genomic Unity® Epilepsy Analysis (NR004)	Provides sequence analysis and duplication/deletion analysis of 378 genes related to seizures as well as short tandem repeat expansion analysis of *AFF2, CSTB, DIP2B, FMR1.* See full test information: https://www.variantyx.com/epilepsy-analysis.
◯ Genomic Unity® Motor Neuron Disorders Analysis (NR005)	Provides sequence analysis and duplication/deletion analysis of 116 genes related to motor neuron disorders as well as short tandem repeat expansion analysis of *AR, C9ORF72.* See full test information: https://www.variantyx.com/motor-neuron-analysis.

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Phenotype Based Comprehensive Analyses (cont.)

◯ Genomic Unity® Movement Disorders Analysis (NR006)	Provides sequence analysis and duplication/deletion analysis of 232 genes related to movement disorders as well as short tandem repeat expansion analysis of *ATN1, ATXN1, ATXN2, ATXN3, ATXN7, ATXN8OS, ATXN10,CACNA1A, FMR1, FXN, HTT, JPH3, NOP56, NOTCH2NLC, PPP2R2B, TBP.* See full test information: https://www.variantyx.com/movement-analysis.
◯ Genomic Unity® Neuromuscular Disorders Analysis (NR007)	Provides sequence analysis and duplication/deletion analysis of 126 genes related to neuromuscular disorders as well as short tandem repeat expansion analysis of the *CNBP* and *DMPK*. See full test information: https://www.variantyx.com/neuromuscular-analysis.
◯ Genomic Unity® Muscular Dystrophy Analysis (NR008)	Provides sequence analysis and duplication/deletion analysis of 52 genes related to muscular dystrophies. See full test information: https://www.variantyx.com/md-analysis.
◯ Genomic Unity® Neuropathies Analysis (NR009)	Provides sequence analysis and duplication/deletion analysis of 98 genes related to neuropathies. See full test information: https://www.variantyx.com/neuropathies-analysis.

Custom Analysis Select when you want to specify the genes analyzed

◯ Genomic Unity® Custom Analysis (CA001)	Provides results that are filtered from Genomic Unity® Whole Genome Analysis. Test results include sequence analysis, duplication/deletion analysis and short tandem repeat analysis (when relevant) for the specific genes requested. See the list of genes available for this analysis: https://www.variantyx.com/custom-analysis.
List the gene(s) to be included in the analysis. If more room is required, please attach a separate page:	

The selected genes included in this custom analysis are filtered from a whole genome backbone whereby variants outside the regions of interest are masked, therefore the performance characteristics are based on Genomic Unity® Whole Genome Analysis. The selected genes may: (1) have not been curated and assessed for clinical relevance and utility; (2) have not been sequenced completely (not fully covered) and therefore pathogenic variants in uncovered regions may not be identified; (3) have variants that are not identified or identified with reduced confidence by the Variantyx platform, included but not limited to non-unique genomic regions and high population frequency variants; and/or (4) have variants that require special interpretation that may not be reported.

Other Analyses Select from additional analyses offered online at Genomic Unity® Analyses

Test code:	Test name:

Optional Reflex

In case the targeted analysis selected does not yield a diagnostic result, select one of the following:

◯ Reflex to Genomic Unity® Exome Analysis (CP002)

◯ Optionally add-on: Genomic Unity® Constitutional Genome-Wide Copy Number Variant Analysis (CP004)

◯ Reflex to Genomic Unity® Exome Plus Analysis (CP010)

If the above reflex option is selected, please choose:

◯ Singleton ◯ Duo ◯ Trio

◯ In case the Genomic Unity® Exome Analysis or Genomic Unity® Exome Plus Analysis does not yield a diagnostic result reflex to Genomic Unity® Whole Genome Analysis.

Clinical Information

ICD-10 Codes (required for insurance billing)	Suspected Diagnosis

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 been appropriately consented about the test including possible results and outcomes, including ACMG secondary findings, if selected, and 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. I attest that the patient (or guardian) has voluntarily consented to testing performed by Variantyx for diagnostic purposes through both oral and written consent.

Healthcare provider signature _____ Date _____

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Patient Name	
Date of Birth	

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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		

Ordering Healthcare Provider

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

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
Policy Holder Address	Who is the Policy Holder? ◯ Patient ◯ Spouse ◯ Parent	
Employer's Address		

◯ Institutional Billing

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

◉ Patient Payment

Who should be contacted for billing purposes?

Payer Name:

Payer Phone: Payer Email:

An invoice will be sent to the patient email provided. Insurance will not be billed.

Patient Sample Information

Sample Type	Sample Will Be Collected	Collection date
◯ Saliva ◯ Assisted saliva ◉ Blood ◯ Genomic DNA ◯ Other:	◯ In-clinic ◯ By Variantyx ◯ Patient given kit	

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.

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Genomic Unity®
Supplement A::
Patient Phenotype

Patient Name	
Date of Birth	

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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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