variantyx

DCVXUTC03010Q

Genomic Unity®
Test Requisition Form

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

Please fill out the requisition form on pages 1-3 and the informed consent on pages 4-6 for the patient.
When submitting unaffected relative samples for comparison, please fill out page 7.

Patient Information

First Name	Last Name	MI	DOB ___ /___ /_____	Gender ● Male ○ Female
Address			ID / MR#	
City	State	Zip Code	Ethnicity ○ African/African American ○ Latino ○ Ashkenazi Jewish ○ East Asian ○ Other: ○ European ○ South Asian _____	
Phone	Email			

Ordering Healthcare Provider

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

Additional Report Recipients

Name	Phone	Fax	Email
Name	Phone	Fax	Email

Healthcare Provider's Statement

By my signature below, I indicate that I am the referring physician or authorized healthcare provider. This test is medically necessary for the diagnosis or detection of a disease, illness, impairment, symptom, syndrome or disorder. The results will determine my patient's medical management and treatment decisions. I have explained the purpose of the test described in this form. The patient has been given the opportunity to ask questions and/or seek genetic counseling. The patient has voluntarily decided to have the test performed by Variantyx for diagnostic purposes and has provided both oral and written consent.

Healthcare provider signature _____ **Date** _____

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's Employer	
Employer's Address		

○ Institutional Billing	● Patient Payment
An invoice will be sent to the institution listed above. Please contact us for alternate billing.	An invoice will be sent to the patient email provided. Insurance will not be billed.

Patient's Sample Information

Sample Type ○ Blood ○ Saliva ○ Genomic DNA	Sample Will Be Collected ○ In-house ○ By Variantyx	Collection Date* ___ /___ /_____

*Note that the collection date is not the same as the date of service for test billing purposes. For more information, please see CMS guidelines.

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Test Requisition Form

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

All tests are performed on a PCR-free DNA sequencing backbone.
Please specify the analysis to be performed.

○ Expedited analysis is requested

Comprehensive Analyses: Select when you want to include all genes in the analysis	
○ Genomic Unity® Exome Plus Analysis ○ Singleton ○ Trio (Family)	This test provides exome analysis, del/dup analysis, mitochondrial genome analysis with heteroplasmy and full STR analysis. See full test specs: https://www.variantyx.com/exome-plus-analysis
○ Genomic Unity® Whole Genome Analysis ○ Singleton ○ Trio (Family)	This test considers the full genomic sequence. See full test specs: https://www.variantyx.com/whole-genome-analysis. Note that, in general, this test is currently available for patients residing in the following states only: CT, KY, IL, MA, MN, ND, NJ, OH, VA, WA
Targeted Analyses: Select when you want to limit the analysis to a pre-selected list of genes	
○ Genomic Unity® Mitochondrial Analysis	This test provides sequence and del/dup analysis of nuclear mitochondrial genes and mitochondrial genome analysis with heteroplasmy. See full test specs: https://www.variantyx.com/mitochondrial-analysis
○ Genomic Unity® Neurology Analysis	This test provides sequence and del/dup analysis of neurology associated genes and relevant STR analysis. See full test specs: https://www.variantyx.com/neurology-analysis
○ Genomic Unity® Epilepsy Analysis	This test provides sequence and del/dup analysis of seizure associated genes and relevant STR analysis. See full test specs: https://www.variantyx.com/epilepsy-analysis
○ Genomic Unity® Intellectual Disability Analysis	This test provides sequence and del/dup analysis of intellectual disability associated genes and relevant STR analysis. See full test specs: https://www.variantyx.com/intellectual-disability-analysis
○ Genomic Unity® Motor Neuron Disorders Analysis	This test provides sequence and del/dup analysis of motor neuron disorder associated genes and relevant STR analysis. See full test specs: https://www.variantyx.com/motor-neuron-analysis
○ Genomic Unity® Movement Disorders Analysis	This test provides sequence and del/dup analysis of movement disorder associated genes and relevant STR analysis. See full test specs: https://www.variantyx.com/movement-analysis
○ Genomic Unity® Ataxia Analysis	This test provides sequence and del/dup analysis of ataxia associated genes and relevant STR analysis. See full test specs: https://www.variantyx.com/ataxia-analysis
○ Genomic Unity® Ataxia Repeat Expansion Analysis	This test provides STR analysis of ataxia associated genes. See full test specs: https://www.variantyx.com/ataxia-repeat-analysis
○ Genomic Unity® Neuromuscular Disorders Analysis	This test provides sequence and del/dup analysis of neuromuscular disorder associated genes and relevant STR analysis. See full test specs: https://www.variantyx.com/neuromuscular-analysis
○ Genomic Unity® Muscular Dystrophy Analysis	This test provides sequence and del/dup analysis of muscular dystrophy associated genes. See full test specs: https://www.variantyx.com/md-analysis
○ Genomic Unity® DMD Analysis	This test provides sequence and del/dup analysis of the *DMD* gene. See full test specs: https://www.variantyx.com/dmd-analysis
○ Genomic Unity® Neuropathies Analysis	This test provides sequence and del/dup analysis of neuropathy associated genes. See full test specs: https://www.variantyx.com/neuropathies-analysis
○ Genomic Unity® Endocrinology Analysis	This test provides sequence and del/dup analysis of endocrinology associated genes. See full test specs: https://www.variantyx.com/endocrinology-analysis
Custom Analysis: Select when you want to specify the genes analyzed	
○ Genomic Unity® Custom Analysis	This test provides sequence, del/dup and (when relevant) STR analysis of the specified genes. See the list of genes that can be selected from for the 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:	
Optional add ons:	
○ Huntington-related STR analysis: *HTT*, *JPH3*	STR analysis of *HTT*, *JPH3* genes. Needs special consent: https://www.variantyx.com/HTT-JPH3-Consent/
○ Reflex to Genomic Unity® Exome Plus Analysis	In the event that a targeted analysis is negative, automatically reflex.
○ Reflex to Genomic Unity® Whole Genome Analysis	In the event that a targeted analysis is negative, automatically reflex. Note that, in general, this test is currently available for patients residing in the following states only: CT, KY, IL, MA, MN, ND, NJ, OH, VA, WA

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Genomic Unity®
Test Requisition Form

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

Please specify the patient's phenotypes using 1° to indicate the most important primary phenotypes and 2° to indicate less important secondary phenotypes. ICD-10 codes must be specified here and/or in attached clinical notes.

Clinical Information

ICD-10 Code(s)*

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 opthalmoplegia	
	○	○	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	○	○	Abdominal wall defect	
	○	○	Aganglionic megacolon	
	○	○	Constipation	
	○	○	Diarrhea	
	○	○	Elevated hepatic transaminases	
	○	○	Gastroesophageal reflux	
	○	○	Gastroschisis	
	○	○	Omphalocele	
	○	○	Pyloric stenosis	
	○	○	Tracheoesophageal fistula	
	○	○	Vomiting	
Genitourinary	○	○	Abnormal renal morphology	
	○	○	Ambiguous genitalia	
	○	○	Cryptochidism	
	○	○	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	
	○	○	Icthyosis	

Other phenotypes

Address: 1671 Worcester Rd, Suite 300 Framingham, MA 01701 | **Phone:** 617-209-2090 | **Fax:** 617-433-5024 | **Email:** info@variantyx.com | **Website:** www.variantyx.com

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

Informed Consent

Patient Consent

I have read the Test Information section on pages 5 and 6 of this document. I have discussed Genomic Unity® test with my healthcare provider including the purpose and procedure, risks, benefits and alternatives. I have been given an opportunity to ask questions about the test, and any questions I had were answered to my satisfaction. I acknowledge that I have sufficient information and understanding to give this informed consent.

1. I give permission to Variantyx and their affiliates to extract and sequence my DNA and perform genetic testing as described.

2. I give permission for my anonymized DNA to be used by Variantyx and their affiliates for test development or improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

3. I give permission for my anonymized sample and clinical information to be included in variant and allele frequency databases and publications. My name or other personal identifying information will not be used in or linked to any databases or publications.

4. In the case of direct insurance billing: I acknowledge that the information provided by me is true and correct. I authorize my healthcare provider and/or insurer to share medical information with Variantyx related to my condition, diagnosis and treatment as relevant to my genetic testing, as well as information about my healthcare plan benefits. I authorize Variantyx to release my medical information concerning my testing to my insurer. I authorize Variantyx to be my designated representative for purposes of appealing any denial of benefits as needed and to request additional medical records for this purpose. I understand that Variantyx will notify me if my out of pocket costs are determined to exceed $100. I authorize my insurance benefits to be paid directly to Variantyx. I understand that I am responsible for sending Variantyx any and all of the money that I receive directly from my insurer in payment for this test.

5. I ◯ give / ◯ do not give permission for Variantyx to contact me or my healthcare provider about research studies. If no option is selected, no contact will be made.

6. Regarding Secondary Findings and Other Incidental Findings (only available with the Genomic Unity® Exome Plus Analysis and Genomic Unity® Whole Genome Analysis tests, and only for the patient):

I choose ◯ to receive / ◯ not to receive Secondary (ACMG) Findings

I choose ◯ to receive / ◯ not to receive Other Incidental Findings

No selection above will default to an opt-out option and findings in these categories will not be returned to you.

7. For NY state residents : ◯ By checking this box I give permission for Variantyx and their affiliates to retain any remaining sample longer than 60 days for testing completion, test development/improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

Patient (or legal guardian) first name _____ **Last name** _____

Patient (or legal guardian) signature _____ **Date** _____

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

Informed Consent

Test Information

The benefits and risks of the Genomic Unity® test are explained below. It is recommended that you receive genetic counseling from a licensed healthcare provider who can answer your questions about genetic testing and provide information about alternatives. Information about genetic counselors in your area is available at https://www.nsgc.org/.

Background

The purpose of genetic testing is to identify changes in the DNA sequence that are the cause of an affected individual's condition. This test sequences the entire DNA using a PCR-free protocol that produces comprehensive and consistent coverage of all exons and non-coding regions. The resulting data is subjected to in-silico analyses optimized for small sequence changes, structural variants (del/dups), short tandem repeats (STRs) and mitochondrial variants. Genomic Unity® Exome Plus Analysis and Genomic Unity® Whole Genome Analysis tests consider all variants not excluded by technical limitations. All other tests consider variants in or overlapping a subset of genes which are described in brief in the Targeted Analyses section above and in more detail on the individual test information web page indicated. When a Custom Analysis is specified, only variants in or overlapping the listed gene(s) specified is/are considered. When noted for the specified analysis, this test uniquely assesses tandem repeats in genes for disorders involving early-onset intellectual disability (*AFF2*, *AFF3*, *DIP2B*, *FMR1*), disorders involving adult-onset movement issues with or without cognitive involvement (*AR*, *ATN1*, *ATXN1*, *ATXN2*, *ATXN3*, *ATXN7*, *ATXN8OS*, *ATXN10*, *C9ORF72*, *CACNA1A*, *CNBP*, *CSTB*, *DMPK*, *FMR1*, *FXN*, *NOP56*, *NOTCH2NLC*, *PPP2R2B, TBP*) and/or other disorders (*PHOX2B*, *TCF4*). Full and pre-mutation alleles will be reported for these genes when relevant to the patient's clinical symptoms. Based on recommendations by the ACMG, the *JPH3* and *HTT* genes are excluded from this analysis by default, but may be included if a specialized consent form has been signed by the patient/guardian and ordering clinician. Access the form at https://www.variantyx.com/HTT-JPH3-Consent/.

The positive predictive value of this test ranges from 0.99676 to 0.99931 depending upon the specific assay selected. Additional information about Genomic Unity® test is available from your healthcare provider and on the Variantyx website at https://www.variantyx.com/.

Technical Limitations

Genetic testing is accurate, but may not always identify a genetic variant even though one exists. This test attempts to evaluate the entire DNA sequence, but may not be able to detect all DNA changes due to limitations in current technology. Certain regions of the DNA may not be well covered. Certain variant types may not be detectable such as methylation abnormalities, variants in genes with highly homologous pseudogenes and variants in regions that are difficult to assay based on current technology. Unusual circumstances including bone marrow transplantation, blood transfusion, and variants that exist in only a small fraction of cells (mosaicism) may interfere with variant identification. The false negative rate for repeat expansions has not been determined for the following genes: *AFF2*, *AFF3*, *ATXN10*, *CNBP*, *CSTB*, *DIP2B*, *NOTCH2NLC*, *PHOX2B*, *TBP*. Any additional test specific limitations are noted on the individual test information web page indicated. Additionally, interpretation of the results is limited by the current medical understanding of disease and available scientific information. This test requires high-quality DNA. In some cases, an additional sample may be needed if the volume, quality and/or condition of the initial sample is not adequate. Samples submitted as genomic DNA will only be processed if the extraction was performed in a CLIA/CAP accredited laboratory. This test does not consider somatic mutations.

Possible Test Results

Test results will be issued as a single clinical report for the patient. When parental samples are submitted they are used in the evaluation of the patient only. No specific parental results are issued individually or under the family member's name. If the patient chooses to receive secondary or other incidental findings as described below, those findings will be included in a separate section of the clinical report. Incidental findings will not be provided for parental samples. Possible results of this test include:

Positive result - A positive result indicates that one or more genetic variants were identified that either explain or partially explain the cause of the disorder or indicate an increased risk of developing the disorder in the future.

Negative result - A negative result indicates that no genetic variant explaining the disorder was identified by this test. This reduces the likelihood of, but does not exclude the possibility of, the disorder being genetic in nature.

Uncertain result / Variant of uncertain significance (VUS) - A variant of uncertain significance was identified by this test. This means that a genetic variant was identified, but based on available information in the medical literature and research and scientific databases it is not certain whether the variant may cause the disorder. The variant could be a normal genetic difference that does not cause the disorder. Without further information, the effects of the variant cannot be known and an "uncertain/clinically inconclusive" result may be reported. The uncertainty may be resolved over time if additional information becomes available. Periodic reanalysis of the sequence data or further analysis, including testing of additional family members, may be recommended.

Indeterminate result - An indeterminate result indicates that there were relevant genetic variant(s) identified in the analysis, but that there is uncertainty as to whether they are true variants or artifacts. Furthermore, it is considered that a repeat test will not resolve the technical uncertainty and orthogonal confirmation is necessary to resolve the result.

Inconclusive result - A technically inconclusive result indicates that there was an issue with the patient sample that resulted in data that the lab cannot interpret. It is considered that a repeat test will likely resolve the technical uncertainty and therefore a repeat sample is recommended to complete the analysis.

All reportable variants in the clinical report will be categorized as pathogenic, likely pathogenic or a variant of uncertain significance (VUS) utilizing the American College of Medical Genetics and Genomics (ACMG)/Association for Molecular Pathology (AMP) guidelines as published by Richards et al 2015 (for more information see: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4544753/). Variants may have a strong phenotypic correlation with the reported patient phenotype(s) and be considered a strong causal candidate for the disorder or may have some phenotypic overlap with the reason for testing but not be considered the sole genetic cause for the phenotype(s) in the patient. Both types of variants may be reported. Even if this test finds DNA changes that are responsible for the reported symptoms, the testing may not completely predict the severity of the disorder, possible future problems, or response to treatment.

Reporting of Unrelated Findings

With this test related findings are reported, such as genetic findings useful for the current diagnosis of the disease that initially led to the analysis and any clinically relevant genetic findings, which may have immediate benefits for the patient related to present diseases or clinical conditions. However, some unrelated findings may be reported as an option to receive with the report, as listed below, while others such as, pharmacogenomic, high frequency risk alleles and late onset disorders, etc., are outside the scope of testing and would not be typically reported. These different findings and options to receive results are described below.

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

Informed Consent

Test Information

Unrelated Findings
Unrelated Findings are findings obtained from genomic sequencing, usually whole genome or exome sequencing, and can be related to conditions that were not the primary reason for testing or findings that can allow one to deduce information as a result of testing that is not directly related to the test. Unrelated findings can be further defined into different types of incidental and secondary findings.

Unavoidable Incidental Findings (typically reported if present)
Some incidental findings are unavoidable and be deduced from testing, such as discovering non-paternity when testing the parents of a child in trio analysis or discovering that a parent is a carrier for the condition identified in the child. Other incidental findings are variants in genes that may fit the patient's clinical phenotype but are also related to clinical symptoms unrelated or with a later onset. For example, more than 450 different pathogenic variants have been identified in the LMNA gene, which can cause a wide variety of distinct and disparate diseases involving striated muscle (dilated cardiomyopathy, skeletal myopathies), adipose tissue (lipodystrophy syndromes), peripheral nerve (Charcot-Marie-Tooth neuropathy) or multiple systems with accelerated ageing (progerias). These results would likely be reported because they are integral to testing. The possibility of receiving unavoidable incidental findings should be discussed with the patient and family prior to testing, so they are aware that these results, if present, are likely to be returned to them. If the patient does not wish to receive these results, they can decide not to continue with testing.

Patients for whom the Genomic Unity® Exome Plus Analysis or Genomic Unity® Whole Genome Analysis test is ordered have the choice to opt-in to two additional sets of findings:

Secondary (ACMG) Findings (OPTION 1)
The American College of Medical Genetics and Genomics (ACMG) recommends reporting pathogenic, expected pathogenic variants, or both in a list of 59 genes in a gene-specific manner. These variants are not typically reviewed during routine processing of patient samples, but are actively sought and reported to the patient. The ACMG recommends reviewing variants in the genes in their recommended list because the genes are related to conditions that are considered 'actionable', meaning that there are steps that can be taken to mitigate the onset or severity of the clinical outcome. These genes are primarily related to cancer and cardiac conditions. It is important to understand that it is possible to have a pathogenic variant but to have it not detected by the assay. In addition, variants of uncertain significance (VUS) are not reported in these genes. If a variant is a VUS and later is considered pathogenic, that cannot be determined without a reanalysis of the data.

Other Incidental Findings (OPTION 2)
Other incidental findings are discovered in genes unrelated to the patient's present symptoms, but may have some actionability such as monitoring for possible cardiac implications, increased cancer screening, monitoring of iron levels, have a dietary impact or are diseases for which possible treatment is available (e.g. cardiovascular diseases predisposing to sudden cardiac death). These are genes not on the ACMG list but are similar in that they could impact medical management and decision making..

The option to receive Secondary (ACMG) Findings and/or Other Incidental Findings is not available for tests other than Genomic Unity® Exome Plus Analysis and Genomic Unity® Whole Genome Analysis and is not available to relatives (limited to the proband only).

Testing of Family Samples
In the case of trio and/or larger cohort analysis, and for parental confirmation of singleton analysis, sequencing and analysis of family samples may be used to improve the interpretation of genetic variants identified in the patient's DNA. Specifically in the case of Genomic Unity® Exome Plus Analysis, family samples will be subjected to whole exome sequencing (WES) for comparison of small sequence changes and potentially additional sequencing for confirmation of structural variants and tandem repeat expansions as needed. In the case of Genomic Unity® Whole Genome Analysis, family samples are subjected to the same PCR free sequencing protocol as the proband. Accurate interpretation of test results requires accurate assignment of family relationships. Analysis of the sequenced DNA is performed with the assumption that correct family relationships have been provided. It is possible that this test may identify misattributed paternity, for example identifying that the stated father of the patient is not the true biological father, and that it may be necessary to report these findings. Family samples are analyzed only with regard to the patient's condition.

Patient Confidentiality
To maintain confidentiality, test results will only be released to the ordering healthcare provider or ordering laboratory, and upon your request, to additional healthcare provider(s) indicated on this test requisition form. Personnel at Variantyx will not release test results directly to patients and will not discuss the test results with anyone except the medical professional who ordered the test or has been authorized to receive the results. Test results will only be disclosed to others by your written consent and/or if demanded by a court of competent jurisdiction. It is your responsibility to consider the possible impact of test results on insurance rates, the ability to obtain disability, life or long-term care insurance and employment. The Genetic Information Non-discrimination Act (GINA), enacted by the US Federal Government, provides some protection against discrimination by health insurance companies and employers based on genetic test results, but does not cover life, disability or long-term care insurance. Information about GINA is available at https://www.genome.gov/10002328.

Anonymized information obtained from the test may be included in variant and allele frequency databases used to help healthcare providers and scientists understand human disease, as well as in scientific publications. Names and personal identifying information will not be revealed. Separate from the above, if there are opportunities to participate in research relevant to your condition, and you have consented for recontact, Variantyx may contact you or your healthcare provider for research purposes.

Sample Retention
DNA extracted from submitted samples may be stored for at least 3 months following completion of testing and will be discarded thereafter. Extracted DNA is not returned unless requested prior to testing (additional fees apply). After completion of testing, anonymized DNA may be used for test development and improvement, internal validation, quality assurance and training purposes before being discarded.

Patient Name	
Date of Birth	___ / ___ / _____

Please fill out the appropriate relative information section on this page when submitting comparator samples. The relative's signature is required in the consent section below.

If the relative is affected by the same disorder as the patient, please attach clinical notes describing the relative's clinical phenotypes or complete page 3 of a separate requisition form.

Biological Mother's Information

First Name	Last Name	Date of Birth ___ / ___ / _____
Sample Collection Date ___ / ___ / _____	Sample Type ◯ Blood ◯ Saliva ◯ Genomic DNA	Affected by the same disorder as the patient? ◯ Yes ◯ No If yes, attach clinical notes or fill out an additional TRF.

Biological Father's Information

First Name	Last Name	Date of Birth ___ / ___ / _____
Sample Collection Date ___ / ___ / _____	Sample Type ◯ Blood ◯ Saliva ◯ Genomic DNA	Affected by the same disorder as the patient? ◯ Yes ◯ No If yes, attach clinical notes or fill out an additional TRF.

Other Relative's Information

First Name	Last Name	Date of Birth ___ / ___ / _____
Sample Collection Date ___ / ___ / _____	Sample Type ◯ Blood ◯ Saliva ◯ Genomic DNA	Affected by the same disorder as the patient? ◯ Yes ◯ No If yes, attach clinical notes or fill out an additional TRF.

Relationship to Patient ◯ Brother ◯ Sister ◯ Other: _____

Family Member Consent

I have discussed Genomic Unity® test with my healthcare provider including the purpose and procedure, risks, benefits and alternatives. I have been given an opportunity to ask questions about the test, and any questions I had were answered to my satisfaction. I acknowledge that I have sufficient information and understanding to give this informed consent.

1. I give permission to Variantyx and their affiliates to extract and sequence my DNA and perform genetic testing for the purpose of improving the interpretation of genetic variants identified in the patient's DNA.

2. I give permission for my anonymized DNA to be used by Variantyx and their affiliates for test development or improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

3. I give permission for my anonymized sample and clinical information to be included in variant and allele frequency databases and publications. My name or other personal identifying information will not be used in or linked to any databases or publications.

4. For NY state residents : ◯ By checking this box I give permission for Variantyx and their affiliates to retain any remaining sample longer than 60 days for testing completion, test development/improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

Biological mother's first name _____ **Last name** _____

Biological mother's signature _____ **Date** _____

Biological father's first name _____ **Last name** _____

Biological father's signature _____ **Date** _____

Other relative's first name _____ **Last name** _____

Other relative (or legal guardian) signature _____ **Date** _____