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.

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 other actionable findings **No selection will default to opt-out.*
❍ If the test above does not yield a diagnostic result, reflex to Genomic Unity® 2.0 (DS001)

❍ **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 only **No selection will default to opt-out.*
❍ Option to receive ACMG Secondary Findings with other actionable 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).
❍ If the test above does not yield a diagnostic result, reflex to Genomic Unity® 2.0 (DS001).
**This test is applicable for patients with non diagnostic previous exome analysis. *Reflex to CP001 and DS001 might not be covered by insurance.*

❍ **Genomic Unity® Exome Analysis (CP002)** ❍ 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 other actionable 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) ❍ Whole Genome Analysis (CP001)
❍ If the test above does not yield a diagnostic result, reflex to Genomic Unity® 2.0 (DS001).

❍ **Genomic Unity® 2.0 (DS001)** ❍ 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 other actionable findings **No selection will default to opt-out.*
**This test is applicable for patients with non diagnostic previous exome analysis.*

Clinical Information

ICD-10 Code(s)*	Indication for testing
Suspected Diagnosis	Has this patient received counseling from a board certified genetic counselor? Yes /No
Are the clinical symptoms onset before the age of 21? Yes / No	Is the patient symptomatic? Yes / No Age of Onset
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.*
Previous Genetic Testing **To support patient analysis using prior reports, we can include up to five variants (along with parental inheritance information, when available) that were identified by other tests and list them in the report. Please indicate below the variants you would like included.*	
Variant 1:	Variant 2:
Variant 3:	Variant 4:
Variant 5:	

Physician Attestation for Diagnostic Genetic Testing

By signing below, I attest that I am the referring physician or an authorized healthcare provider for the patient (or their legal representative/procurator), and that this genetic testing is medically necessary for the diagnosis and/or treatment of the patient.
I further attest that:
1. The patient or their guardian has voluntarily provided informed consent for genetic testing for diagnostic purposes, including the potential results and outcomes, ACMG secondary findings, other actionable findings, and pharmacogenomic analysis, if applicable and selected.
2. Any designated comparators have voluntarily consented to the use of their sample for testing, specifically for comparison to the patient's genetic data.
3. The patient and any designated comparators have consented to the use of their anonymized sample and clinical information to be used by Variantyx, their affiliates, and their partners to advance genetic testing and interpretation, validate results, confirm variants at an external lab, support quality assurance, contribute to variant and allele frequency databases and publications, and assist in training. The sample may also be used for research aimed at understanding genetic variations and identifying potential treatment targets. The names or any other personal identifying information will not be used in or linked to any databases or publications.
4. The patient, guardian, and comparators (if applicable) have been given the opportunity to ask questions about the testing and/or to seek genetic counseling.
5. The patient or guardian agrees to allow an independent genetic counselor, facilitated through a third party, to provide pre-test and/or post-test counseling if required by the referring institution or insurer.

Consent for Additional Uses

Contact Regarding Research Participation
The patient/guardian gives permission for Variantyx to contact me or my healthcare provider regarding potential **research studies and clinical trial participation**: ☐ Yes ☐ No

Health Information Exchange
The patient/guardian gives permission to share health information through the **Health Information Exchange (HIE) program**: ☐ Yes ☐ No

Healthcare provider signature _____ Date _____

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

Patient Information

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

Patient Sample Information

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

*Use Variantyx collection kits only
† Saliva swab 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.

Comparator Information

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

Comparator Information

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

Ordering Healthcare Provider

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

Additional Report Recipients

Name	Phone	Fax	Email
Name	Phone	Fax	Email

Add GC or other healthcare provider(s)?