Variantyx

Genomic Unity®
Patient Informed Consent

Patient Name	
Date of Birth	

Affix barcode label of Patient's sample here

Form instructions:

✓ Review the information on page 1
✓ The patient or legal guardian must sign on page 1

Patient Consent

I have discussed the 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. In the case that independent pre-test and/or post-test genetic counseling is required by my insurance provider and/or physician, I agree, by signing this consent form, to have a third party facilitate the genetic counseling services. By signing this consent form, I authorize Variantyx to release my contact information and any medical information necessary to the third party service, as well as authorize communication and sharing of information between the third party and my referring physician, in order to complete pre-test and/or post-test genetic counseling.

6. 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.

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 test completion, test development/improvement, internal validation, orthogonal variant confirmation at an outside referral laboratory and/or quality assurance and training purposes.

Patient (or authorized individual) first name	**Last name**
Patient (or authorized individual) signature	**Date**

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 | **Document number:** VYX-1014-1123

Variantyx

Genomic Unity®
Comparator Informed Consent
Page 1 of 1

Patient Name	
Date of Birth	

Affix barcode label of Patient's sample here

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 Supplement A of the test requisition form.

Biological Maternal Information

First Name	Last Name	DOB
Sample Collection Date	Sample Type ◯ Saliva* ◯ Blood ◯ Saliva swab† ◯ Genomic DNA	If affected by the same disorder as the patient please list the clinical symptoms:

Biological Paternal Information

First Name	Last Name	DOB
Sample Collection Date	Sample Type ◯ Saliva* ◯ Blood ◯ Saliva swab† ◯ Genomic DNA	If affected by the same disorder as the patient please list the clinical symptoms:

Other Relative's Information

First Name	Last Name	
Sample Collection Date	Sample Type ◯ Saliva* ◯ Blood ◯ Saliva swab† ◯ Genomic DNA	If affected by the same disorder as the patient please list the clinical symptoms:

Relationship to Patient
◯ Brother ◯ Sister ◯ Other

* Use Variantyx collection kits only † Use Variantyx collection kits only; saliva swab is similar to a buccal swab

Family Member Consent

I have discussed the 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/my relative's 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 maternal signature	Date
Biological paternal signature	Date
Other relative's (or authorized individual) signature	Date

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 | **Document number:** VYX-1016-1123