VERSITI DIAGNOSTIC LABORATORIES
638 N. 18th Street, Milwaukee, WI 53233-2121
Phone (414) 937-6250 Fax (414) 937-6206
(800) 245-3117, ext. 6250

Informed Consent

I request and authorize Versiti, Inc. through its controlled affiliates ("Versiti") to test my sample or my legal dependent's sample for the designated genetic condition(s) and/or with the testing listed below. My signature constitutes my acknowledgement that the indications, benefits, risks and limitations of the testing have been explained to my satisfaction by a qualified health care professional. A general description of the test, purpose, sensitivity, analytical limitations, and the features and genetics of the condition(s) has been discussed. Additional information can also be found at www.versiti.org under test descriptions.

Genetic counseling: Participation in genetic testing is voluntary. I understand that the implications of genetic testing can be complex and involve medical, emotional, psychological, and social issues, and may raise concerns about genetic discrimination, health insurance, life insurance and disability insurance. Questions or concerns about any of these issues should be discussed with my healthcare provider. In addition, I may wish to obtain genetic counseling prior to genetic testing and/or after the genetic testing is completed, in order to understand the complexities and the implications of the testing results for my healthcare and other considerations relevant to me, my legal dependent, and my biologic relatives. If desired, a request for genetic counseling should be made to my provider. My provider can contact Versiti if assistance is needed in identifying available genetic counseling services.

It has been explained, and I understand, that genetic testing results may:

- Diagnose whether I have, or I am at risk for developing, this or another genetic condition
- Indicate whether I am a carrier for a genetic condition
- Predict if another family member has, or is at risk for developing, this or another genetic condition
- Predict if another family member is a carrier of this or another genetic condition
- Suggest a condition or disease that is different from what was originally considered
- Identify a variant of uncertain significance, in which further testing and/or family studies may be useful
- Be negative; however, this may not exclude the possibility that I have this genetic condition or another similar genetic condition
- Reveal unanticipated family relationships, such as non-paternity, or some other previously unrecognized information about family relationships.

Accuracy:

- This genetic test is specific only for the condition(s) listed below. Due to technical limitations and evolving knowledge of genetics at the time of the testing, not all clinically significant variants within this gene(s) may be detected.
- The significance of the test result, including a negative result, may depend on my family and clinical history.
- Over time, due to changes in genetic technology and knowledge, reclassification of variants may occur. My provider can periodically inquire about any changes in variant classification and request re-interpretation of variants; this may be encouraged if there are significant changes in my medical and family history.
- Although Versiti uses reasonable measures to avoid errors in the samples that it handles, I understand that several sources of error are possible in all types of laboratory testing, including, but not limited to, sample misidentification and sample contamination. In addition, clinical misdiagnosis of the condition and inaccurate information regarding family relationships may impact the accuracy of test results.

Confidentiality: Genetic testing results and patient information are confidential and will only be released to the referring healthcare provider, institution, or an authorized agent or healthcare provider as allowed by confidentiality laws or as is required by law. I or my authorized representative may request test results. More information can be found here: https://www.versiti.org/about-us/privacy-practices.

Cost: Genetic testing is a fee-for-service offering. I understand that I will be responsible for payment after testing has begun, even if I decide not to receive results. Versiti will accept direct payment for testing upfront from patients but does not directly bill patients or insurance carriers, except for outpatient Medicare enrollees and recipients of Wisconsin Medicaid. Specific questions regarding billing, insurance or other costs should be directed to my healthcare provider or insurance carrier.

Conditions of Consent: I consent to allow my sample to be stored and used for test validation, education, or medical research, with the understanding that all sample identification will be removed from the sample if it is used for any purpose other than the clinical test requested. The sample may be stored indefinitely for these uses. If I do not wish to have my sample available for the above purposes, I can withdraw my consent at any time by contacting Versiti. Refusal to permit the use of my sample for these purposes will not affect my test result(s).

For all New York State patients:
NY patients may opt in to Conditions of Consent by checking the box and signing below. Otherwise, samples from NY patients will not be used for research or quality assurance and will be disposed of within 60 days of collection.

Consent

Last Name _____ First Name _____

Maiden/ Previous Legal Name _____ Patient MRN# _____
(If applicable)

Date of Birth ____/____/____ Patient sex/gender

I agree to the Conditions of Consent as stated above. ☐ Yes ☐ No (NY patients must mark Yes to opt in; for others, consent is implied if not marked)

I request DNA/Molecular testing for the genetic condition/disease:_____

The following test(s) to be performed include:_____

The intended purpose may be for diagnosis, predictive, carrier status, prenatal diagnosis, or for other reasons.

Name of referring physician/healthcare provider_____ Date_____

Signature of referring physician/healthcare provider_____ Date_____

Signature of patient or guardian _____ Date _____

Signature of witness Date _____

Please contact Versiti Diagnostic Laboratories Client Services
if you would like more information regarding any of our policies or services.
(414) 937-6250 or (800) 245-3117 ext 6250