



Labs Genetic Testing Informed Consent

Testing for genetic conditions can be complex. If warranted, obtain professional genetic counseling prior to giving consent to fully understand what the risks and benefits are to having the testing completed.

I hereby consent to participate in testing for _____ using a genetic test. I understand that a biologic specimen (blood, tissue, amniotic fluid, or chorionic villi) will be obtained from me and/or members of my family. I understand that this biologic specimen will be used for the purpose of attempting to determine if I and possibly members of my family are carriers of the disease gene, or are affected with, or at increased risk to someday be affected with this genetic disease.

It has been explained to me and I understand that:
This test is specific for _____.

* A positive result is an indication that I may be predisposed to or have the specific disease, or condition. Further testing may be needed to confirm the diagnosis. I understand I will be given the opportunity to talk with my physician or a genetic counselor about these results

* There is a chance that I will have this genetic condition but that the genetic test results will be negative. Due to limitations in technology and incomplete knowledge of genes, some changes in DNA or protein products that cause disease, may not be detected by the test.

* There may be a possibility that the laboratory findings will be uninterpretable or of unknown significance. In rare circumstances, findings may be suggestive of a condition different than the diagnosis that was originally considered.

* In many cases, a genetic test directly detects an abnormality. Molecular testing may detect a change in the DNA (mutation). Cytogenetic and Microarray CGH testing may identify whether there is extra, missing or rearranged genetic material. Biochemical methods are sometimes used to look at abnormalities in the protein products that are produced by the genes. Most tests are highly sensitive and specific. However, sensitivity and specificity are test dependent.

* The accuracy of the test depends on correct family history. An error in diagnosis may occur if the true biological relationships of the family members involved in this study are not as I have stated. In addition, testing may inadvertently detect non-paternity. Non-paternity means that the father of an individual is not the person stated to be the father.

* An erroneous clinical diagnosis in a family member can lead to an incorrect diagnosis for other related individuals in question.

* Because of the complexity of genetic testing and the important implications of the test results, results will be reported only through a physician, genetic counselor, or other identified health care provider. The results are confidential to the extent allowed by law. They will only be released to other medical professionals or other parties with my written consent or as otherwise allowed by law. Participation in genetic testing is completely voluntary.

* Additional testing information can be found at: www.urmc.rochester.edu/urmc-labs

I have read the information on the back of this form and discussed it with my health care provider. I have been given an opportunity to ask questions and have them answered about the tests ordered. I do understand that I have the right to withdraw this consent at any time, and the entity storing the sample shall promptly destroy the sample or portions thereof that have not already been used.

I give my consent for genetic testing, and I give my consent for the use of remaining sample for research

Patient/Legal Guardian _____ Date: _____

Physician/Counselor : _____ Date: _____

No tests other than those authorized will be performed on your sample, and your sample will be destroyed after testing or not more than sixty days after the sample is taken.

I, _____, expressly authorize this identified sample to be retained for _____.

_____ (Initial to consent) Not to exceed 10 years.

Besides providing excellent medical care, one of the missions of the University of Rochester and Strong Memorial Hospital is advancing medical science. Our doctors learn about better ways to care for patients and improve the health of people. With your consent, our researchers will be able to use the remaining part of blood samples not needed for the specific tests above for approved development of new or improved laboratory tests. Names and other identifying information are kept strictly confidential. Samples with consent for research are stored indefinitely. We sometimes conduct follow-up studies based on new medical information. If you are eligible, someone will contact you personally. Participation in such studies is voluntary.