Patient Informed Consent

TruGenome™ Predisposition Screen: Patient Informed Consent

Some states/countries may have additional requirements for informed consent. Please ensure that you comply with those requirements and provide a copy of any additional written informed consents, if applicable.

Introduction. This form describes the benefits, risks, and limitations of having your genome tested by sequencing. This is a voluntary test. Read this form carefully before making your decision about testing.

Purpose. The purpose of this test is to detect changes present in your DNA and to understand the potential consequences of these changes for you. This information may help your physician make more informed management decisions for your health. For more information on genetics, genetic disease, inheritance, or genetic testing, consult your physician or genetic counselor.

Test Procedure. A tube of your blood will be drawn and sent to Illumina, Inc. ("Illumina"). Illumina will analyze your material, generate the DNA sequence for your genome, and identify the variants. The variants identified in your genome will be interpreted based on current available scientific information and according to current medical recommendations.

Delivery of Test Results. Your test results will be sent to the physician that ordered the test. Speak with your physician if you would like a copy of the test results. You may request a copy of your test results from the laboratory directly.

Electronic Delivery of Test Results. After your physician has reviewed your results, you may be able to receive the test results using the Illumina MyGenome application. You will need to obtain a unique code from your doctor to download your test results. MyGenome allows you to explore genetics, traits, and your test results. Always consult your health care provider before changing your diet, drugs, vitamins, supplements, exercise, family planning, or any other aspect of your lifestyle based on your test results.

Implications and Limitations of Genetic Testing. Genetics is not the entire story. Your test results may aid in determining the cause of your symptoms. It is also possible that these results may not provide any benefit. Much about genetics is not yet fully understood and your results will include variants that are of unknown clinical significance based on today's science.

Incidental Findings. Additional results that might be important for your health, but are not part of the primary reason for testing, are called incidental findings. You should discuss the possibility of these types of results with your doctor.

Your Family. The test results, like the results of other genetic tests, may have implications for your relatives. Speak with your physician or a genetic counselor about whether you should share your test results with others. If you decide to do this, consider the best way to communicate this information to them.

Benefits. Your test results may help you and your physician make more informed choices about your health care. It is also possible that your test results will not provide any benefit. Much about genetics and its role in health is still not known.

Physical Risks. This test requires DNA most often provided from a sample of blood. Side effects of having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising, and, rarely, infection.

Discrimination Risks. Genetic information could potentially be used as a basis of discrimination. To address concerns regarding possible health insurance and employment discrimination, many US states and the US government have enacted laws to prohibit genetic discrimination in these circumstances. The laws may not protect against genetic discrimination in other circumstances such as when applying for life insurance or long-term disability insurance. Talk to your physician or genetic counselor if you have concerns about genetic discrimination before testing.

Other Risks. Your test results may reveal information about yourself, or your relatives, that you would rather not know. For example, you may learn information about genetic risks/predispositions to disease, including ones that might not be curable, biological parentage, ancestry, etc. It may not be possible to prevent learning such information through this test. Talk to your physician or genetic counselor about the type of information that you do and do not want to know.

Electronic Delivery Risks. The Internet and wireless services may not be 100% secure. There is always a risk that you may lose the device or the security on the device may be breached and someone else may then gain access to your test results.

Limitations of the Test. This test can only detect specific kinds of changes in DNA; other kinds of changes could also cause disease or lead to symptoms. This test cannot sequence all parts of a person's genome. In addition, the testing technology for whole-genome sequencing has limits, including a known error rate (although it is low). This means that other changes may exist in your genome, but they might not be detected by this test. Further testing of you and/or your family may be needed to confirm your test results, which could result in additional expense to you. The meaning of some variants cannot be determined based on today's medical and scientific knowledge.

Privacy. Illumina keeps test results confidential. Illumina will only release your test results to your healthcare provider, his or her designee, other healthcare providers involved in your medical care, or to another healthcare provider as directed by you (or a person legally authorized to act on your behalf) in writing, or otherwise as required or authorized by applicable law.

Use of Information. Pursuant to best practices and clinical laboratory standards, leftover specimen and results may be used by Illumina for purposes of quality control, laboratory operations, and laboratory improvement. All such uses will be deidentified and in compliance with applicable law.

Future Correspondence. Understanding of genetic variation is rapidly advancing, meaning that some of the changes we find in your genome might be better understood in the future. Illumina recommends that you keep in contact with your health care provider on an annual basis to learn of any new developments in genetics and to provide any updates to your personal or family history.

Financial Responsibility. Illumina does not bill insurance providers and this test may not be reimbursed by health insurance or covered by health maintenance organizations (HMOs). This means that you are personally responsible for 100% of the costs of this testing.

Cross-Border Data Transfer. If you are from outside the United States your specimen and associated health information will be sent to the United States in order for the testing to be completed. As part of the testing, additional health information about you will be created and maintained. Your country may consider the legal privacy protections in the United States to be inadequate.

Learn More. Visit www.illumina.com/clinical/illumina_clinical_laboratory/trugenome-clinical-sequencing-services.html to learn more about the Illumina TruGenome Predisposition Screen.

Name of Patient Being Screened (Please Print)	Date of Birth (MM/DD/YYYY)
Signature of Patient	Date (MM/DD/YYYY)