TruGenome Predisposition Screen

Screen today, plan for tomorrow.

New discoveries and technologies are giving us new insights into our DNA, helping us make sense of the information it contains and what it means for us and our children. The TruGenome Predisposition Screen provides a comprehensive evaluation of your patient's carrier status, genetic predisposition towards adult-onset conditions, and responsiveness to certain medications, enabling you and your patient to make more informed decisions for improved health care management.

What is the TruGenome Predisposition Screen?
The TruGenome Predisposition Screen is a medical test that uses NGS technology to look at your patient's entire genome. Analysis and interpretation are performed on 1691 genes with well-established associations to 1232 conditions (as found in the NIH Genetic Testing Registry and Online Mendelian Inheritance in Man [www.omim.org]), and 11 genes associated with response to 16 different medications (as specified by the FDA or the Clinical Pharmacogenomics Implementation Consortia [CPIC]). This test does not screen for variants associated with complex diseases known to have multiple gene and environmental contributors. A complete list of genes and associated conditions and a list of alleles associated with specific drug response is available.

What information do I learn from this test?
Whole-genome sequencing performed as part of the TruGenome Predisposition Screen might help you evaluate your patient's:

- Risk for developing a genetic-based disease
- Likelihood of passing a genetic disease on to his/her children
- Responsiveness to certain medications

This knowledge may help guide decisions you and your patient make about health care including additional testing or screening, family planning, or evaluating possible treatment options. Using genetic information, you can work with your patient proactively to help them make choices that can lead to healthier lives. A complete description of the TruGenome Predisposition Screen and its intended use is available at www.illumina.com/test_descriptions.

What is involved in getting a Predisposition Screen for my patient?
The Predisposition Screen is a medical test and must be ordered by a licensed physician. If your patient is interested in the Predisposition Screen, or you believe that your patient can benefit from a Predisposition Screen, start with a discussion of the potential value of whole-genome sequencing. Next, request a Sample Collection Kit from Illumina. Use the provided forms to obtain patient consent and the collection tubes to procure a blood sample from your patient. Send the completed paperwork and blood sample to the Illumina Clinical Services Laboratory for processing. An in-house panel of Ph.D. geneticists and bioinformaticians, genetic counselors, and certified medical geneticists will analyze and interpret the data for the conditions and medications covered by the test.

Test results, in the form of an interpreted report, will be sent directly to you, the ordering physician. Additionally, you will be provided with an activation key for the Illumina MyGenome web page (www.understandyourgenome.com) that your patient can use to view his/her genome. Schedule time with your patient to review the test results and discuss any next steps in his/her health care.

How to get a TruGenome Predisposition Screen*

Talk to your patient about whole-genome sequencing.

Order a sample kit from ICSL. Genetic Counselors are available to answer any questions.

Collect blood sample from your patient and ship with a completed Test Requisition Form to ICSL.

Whole-genome sequencing is run at ICSL and clinical interpretation completed.

ICSL sends the clinical report for your patient to you.

Discuss the results with your patient.

* This graphic provides a high-level overview of the process for ordering and receiving a TruGenome Predisposition Screen from Illumina. For complete details, visit www.illumina.com/clinicallab.

About the Illumina Clinical Services Laboratory

The CLIA-certified, CAP-accredited Illumina Clinical Services Laboratory (ICSL) was established in 2009 for the purposes of offering human whole-genome sequencing services to physicians and genetic counselors. It is staffed with certified Clinical Laboratory Scientists who have extensive training and expertise with Illumina NGS technology. Our team of Ph.D. geneticists, genetic counselors, and certified medical geneticists have over 50 years of combined experience analyzing human genetic data.

About Illumina NGS technology

Illumina sequencing by synthesis (SBS) technology is the most published NGS technology. Using a proprietary method, DNA sequence is detected in a base-by-base manner for highly accurate, reproducible sequencing results. Learn more about sequencing at www.illumina.com/sequencing.

Learn more

To learn more about the Illumina Clinical Services Laboratory and the Predisposition Screen, visit www.illumina.com/clinicallab.

Ordering information

Service	Turnaround Time (TAT)	Catalog No.
TruGenome Predisposition Screen	Standard (90 days)	FT-800-1004
	Rapid (contact lab)	FT-800-1014

Disclaimer:
This laboratory test was developed and its performance characteristics were determined by the Illumina Clinical Services Laboratory (CLIA-certified, CAP-accredited). Consistent with laboratory-developed tests, it has not been cleared or approved by the U.S. Food and Drug Administration. Patients who have any questions or concerns about what they might learn through their genome sequence information should be directed to contact their physician or a genetic counselor. Illumina does not accept orders for TruGenome Clinical Sequencing Services from New York.