Illumina Clinical Services Laboratory

TruGenome™ Technical Sequence Data Test Requisition Form

The Illumina Clinical Services Laboratory provides whole-genome sequencing data in two formats: a gVCF and a BAM. The gVCF represents all calls at all positions that passed the quality thresholds set within the laboratory, and represents an accuracy consistent with other clinically actionable tests. The second format is called a BAM format, and is appropriate solely for downstream CLIA/CAP laboratory use or for use in clinical research under IRB approval. The BAM data files do not constitute an analytically validated result and are not appropriate for downstream clinical use unless processed by another clinical laboratory according to their analytically validated pipeline.

- The test consists of whole-genome sequencing of germline DNA to 30× average depth from blood. This test has a technical deliverable of the sequencing data, with all reads, quality scores, variant calls for further analysis, and a technical report displaying quality and regions of genome coverage. This test does not include interpretation.

Statement Regarding the TruGenome Technical Sequence Data Test

- This test was developed, and its performance characteristics determined, by the Illumina Clinical Services Laboratory. The test has not been cleared or approved by the FDA. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is intended for clinical purposes. It should not be regarded as investigational or for research unless performed under an IRB approved protocol.
- The TruGenome Technical Service will be performed in the Illumina Clinical Services Laboratory. The laboratory is CLIA-certified and CAP-accredited.
- The Illumina Clinical Services Laboratory offers several tests in addition to the TruGenome Technical Sequence Data Test. Review the test descriptions at www.illumina.com/test_descriptions to make sure that the most appropriate test is ordered.
- Illumina cannot accept samples from New York state.
- The laboratory used to test your sample is in the United States. If you are outside of the United States then you are consenting that your sample and your data, including your personal information that may be of sensitive nature, are being sent outside of your country to the United States or created in the United States as part of the testing and analysis performed by Illumina.

To submit a sample for sequencing, you will need:

- A **completed** test requisition form
  - All sections are required
  - Physician signature on page 1
  - Billing information and signature on page 2 (NOTE: If you are a UYG attendee and have paid in full, billing information is not required.)
- Patient Consent Form with signature
- Properly labeled sample in the provided collection tube

Send the **completed** items listed above to:

Illumina, Inc.
ATTN: Illumina Clinical Services Laboratory
5200 Illumina Way
San Diego, CA 92122

Contact the Illumina Clinical Services Laboratory at 858.736.8080 if you have any questions

Place Barcode Here

1. Requested Test (visit http://www.illumina.com/clinical/illumina_clinical_laboratory/trugenome-clinical-sequencing-services.html for test definitions).

Description	Standard TAT
TruGenome Technical Sequence Data—Individual Genome Sequence	☐ FT-800-1001

2. Physician and Institution Information

Authorized Physician (Print Name)	NPI (or License if no NPI) No.
Email **(Required for Return of Results)**	Phone Number
Institution Name	Genetic Counselor
Institution Address **(Required for Return of Results)**	

1) I acknowledge that the Illumina Clinical Services Laboratory provides whole-genome sequencing data (in gVCF format and/or BAM format) solely for use in clinical research under IRB approval or for use by a CLIA certified laboratory. These data are appropriate for analysis in IRB approved research or downstream clinical analysis in a different CLIA/CAP laboratory. I understand these statements and will comply with these requirements.

Authorized Physician Signature *(required)* | Date (MM/DD/YYYY)

2) I certify that (i) the patient (or authorized representative on the patient's behalf) has given his/her informed consent (which includes written informed consent or written authorization when required by law) to have this genetic screen performed, and (ii) the informed consent obtained from the patient meets the requirements of applicable law and Illumina Patient Informed Consent.

Authorized Physician Signature *(required)* | Date (MM/DD/YYYY)

3) I certify that I am a medical doctor with the proper licensing in my country to order this testing.

Authorized Physician Signature *(required)* | Date (MM/DD/YYYY)

3. Patient Information

*First Name	Middle Initial	Last Name

Date of Birth (MM/DD/YYYY)	Sex								
	◯ Male	◯ Female	☐ African-American	☐ Asian/Pacific Islander	☐ Hispanic	☐ Native American	☐ Ashkenazi Jewish	☐ Caucasian	☐ Middle Eastern	☐ Other _____

ICD-10 codes

*Subject identifiers may be used for IRB-approved study samples

IRB Institution	IRB Protocol No.

4. Blood Collection Information

Date Sample Obtained (MM/DD/YYYY)	Sample Type
	☐ Blood in Collection Tube ☐ DNA sample

5. Billing Information

- The Responsible Party identified below agrees to pay the full price of the test. Illumina will not begin processing the sample until payment arrangements have been made. Testing may be delayed if satisfactory payment arrangements have not been made.
- Illumina does not bill health insurers or institutional billing departments. If reimbursement is necessary or desired, the Responsible Party will make his/her own arrangement to receive reimbursement.

Please select the most appropriate billing option (this is the Responsible Party)

☐ Facility / Contract Billing *Facility / Physician billing must be pre-arranged*	☐ Patient / Legal Guardian / Other
Facility Name	Name (Name of Responsible Party)
Address	Billing Address
City / State / Zip	City / State / Zip
Purchase Order No. / Contact Person	Phone / Email
Phone / Email	

I agree that I am financially responsible for the full amount of the test price.

Responsible Party Acknowledgement and Signature

Date (MM/DD/YYYY)

Select your payment option: ☐ Payment by wire transfer (Illumina will contact me to arrange payment). ☐ Bill my credit card for 100% pre-payment **Illumina can only accept credit cards from the US and Canada*	Cardholder Name Card Number
Card Type: ◯ Visa ◯ MasterCard ◯ American Express	Exp Date (MM/YYYY) / CVV

Patient Informed Consent

For the TruGenome Technical Sequence Data service

Some states/countries may have additional requirements for informed consent. Make sure that you comply with those requirements and provide a copy of any additional written informed consents.

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

Purpose. The purpose of this test is to detect changes that are present in your DNA and to understand the potential consequences of these changes. 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 sample, generate the DNA sequence for your genome, and identify the variants.

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.

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 aid in determining a diagnosis for your symptoms and help you and your physician make more informed choices about your healthcare. 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 U.S. states and the U.S. 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.

Limitations of the Test. This test can only detect some kinds of changes in DNA; other kinds of changes could cause disease or lead to symptoms. This test also 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 (though 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.

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 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 healthcare 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 HMOs. This means that you are personally responsible for 100% of the costs of this testing.

Learn More. Visit www.illumina.com/test_description to learn more about the Illumina TruGenome Technical Sequence Data service.

Patient Informed Consent Statement

By signing below, I, the patient having the test performed, acknowledge that:

- I have been offered the opportunity to ask questions and discuss with my healthcare provider the benefits and limitations of the test to be performed as indicated on the associated test request form.
- I have discussed with the medical practitioner ordering this test the reliability of positive or negative test results and the level of certainty that a positive test result for a given disease or condition serves as a predictor of that disease or condition.
- I have been informed about the availability and importance of genetic counseling and have been provided with information identifying an appropriate healthcare provider from whom I might obtain such counseling.
- I have read this document in its entirety and realize I may retain a copy for my records.
- I consent to having this test performed and I will discuss the results and appropriate medical management with my healthcare provider/genetic counselor.

Name of Patient Being Tested (please print)	Date of Birth (MM/DD/YYYY)
Signature of Patient (or Legal Guardian†)	Date (MM/DD/YYYY)
†Genetic testing on children under the age of majority requires that the ordering healthcare provider obtain informed consent from a parent or legal guardian.	
If legal guardian, specify relationship to the patient:	