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Illumina Clinical Services Laboratory
CLIA Certificate No.: 05D1092911

Illumina Clinical Services Laboratory

TruGenome™ Predisposition Screen Requisition Form

The TruGenome Predisposition Screen is intended for use as a screen for genetic predisposition and genetic carrier status for a predefined set of highly penetrant, monogenic conditions. Analysis and interpretation are designed to detect and report on single nucleotide variants (SNVs) and small insertion/deletion events found within ~1700 genes that have well-established associations to ~1200 conditions [as found in the national Genetic Testing Registry (www.ncbi.nlm.nih.gov/gtr) and Online Mendelian Inheritance in Man (www.ncbi.nlm.nih.gov/omim)]. This set of genes/conditions includes genes recommended by the American College of Medical Genetics and Genomics (ACMG) for secondary findings. This screen is intended for adults 18 years of age or older in the United States or the age of majority established in the country from which the test is ordered.

Statement Regarding the TruGenome Predisposition Screen

- The TruGenome Predisposition Screen was developed, and performance characteristics determined, by the Illumina Clinical Services Laboratory. This screen has not been cleared or approved by the US Food and Drug Administration (FDA). The laboratory is regulated under Clinical Laboratory Improvement Amendment (CLIA) as qualified to perform high-complexity testing. This screen is intended for clinical purposes and should not be regarded as investigational or for research.
- The TruGenome Predisposition Screen will be performed in the Illumina Clinical Services Laboratory. The laboratory is CLIA-certified and College of American Pathologists (CAP)-accredited.
- The Illumina Clinical Services Laboratory offers several tests in addition to the TruGenome Predisposition Screen. Review the test descriptions at www.illumina.com/clinical/illumina_clinical_laboratory/trugenome-clinical-sequencing-services.html to make sure that the most appropriate test is ordered.
- Illumina cannot accept samples from New York State.

To submit a sample for sequencing, you will need:

- A completed test requisition form.
  - Section 5 is optional.
  - Section 7 is required unless payment has already been received. **NOTE: If your patient is an Understand Your Genome (UYG) attendee and has paid in full, billing information is not required.**

NOTE: PATIENTS PARTICIPATING IN A UYG EVENT MUST COMPLETE THE SAMPLE RELEASE AUTHORIZATION FORM ON PAGE 5 TO ACCESS THEIR DATA THROUGH THE MYGENOME WEB APPLICATION AT THE UYG EVENT.

- Properly labeled sample in the proper collection tube.
  - Instructions are available at www.illumina.com/clinical/illumina_clinical_laboratory/how-to-order.html.

Send the **completed** items to:

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

Contact the Illumina Clinical Services Laboratory at GenomicServices@illumina.com with any questions.

Place Barcode Here

1. Requested Test/Reason for Referral

For test definition and pricing, visit www.illumina.com/clinical/illumina_clinical_laboratory/trugenome-clinical-sequencing-services.html

- ☐ TruGenome Predisposition Screen — FT-800-1004
- ☐ UYG Symposium* — FT-800-1021
  UYG Event Date and City _____

* Must have preregistered for the UYG event. Visit www.understandyourgenome.com to learn more.

NOTE: PATIENTS PARTICIPATING IN A UYG EVENT MUST COMPLETE THE SAMPLE RELEASE AUTHORIZATION FORM ON PAGE 5 TO ACCESS THEIR DATA THROUGH THE MYGENOME WEB APPLICATION AT THE UYG EVENT.

Reason for referral

2. Physician and Institution Information

Authorized Physician (Print Full Name)	NPI (or License if no NPI) Number
Institution Name	Institution Address (Required for Return of Results)
Physician Office Phone Number	

Physician Email (Required: Notification of return of results and authorization codes to access clinical deliverables will be sent to this email address)

Names and email addresses of other clinicians who may receive delivery notification/copy of results

3. Patient Information

First Name | Middle Initial | Last Name

Date of Birth (MM/DD/YYYY)

Sex ☐ Male ☐ Female ☐ Unknown

☐ African-American ☐ Ashkenazi Jewish ☐ Asian/Pacific Islander ☐ Caucasian ☐ Hispanic ☐ Middle Eastern ☐ Native American ☐ Other _____

Email address

4. Sample Collection Information

Instructions are available at www.illumina.com/clinical/illumina_clinical_laboratory/how-to-order.html

Date Sample Obtained (MM/DD/YYYY)	Sample Type
	☐ Blood (PAXgene or EDTA tube) If other sample type, contact the laboratory at GenomicServices@illumina.com

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5. Optional Request for Blinding

Select any category your patient does **NOT** wish to know about. If selected, variants in genes associated with conditions in the selected category will **NOT** be analyzed and variants in those genes will **NOT** be interpreted. Carrier status for recessive disorders within these lists will also not be identified.

☐ **Patient does NOT wish to receive analysis of the listed genes related to cancer predisposition.**

These genes are associated with genetic diseases that give adults a higher risk for cancer. Most have specific treatment or screening recommendations that you and your doctor can discuss.

ASXL1, ATM, ATR, BAP1, BARD1, BRAF, BRCA1, BRCA2, BRIP1, CHEK2, EZH2, FGFR1, FGFR2, FH, GATA3, HGF, HNF1A, JAK3, KIT, KMT2D, KRAS, LIFR, MC1R, MET, MLH1, MLH3, MPL, MSH2, MSH6, MUTYH, NRAS, NSD1, PALB2, PALLD, PDGFRA, PMS1, PMS2, PRX, PTPN11, RAD51C, RAD51D, RB1, RPL5, SETBP1, SMARCB1, SMC1A, SMC3, SOX9, TBX3, TGFBR2

☐ **Patient does NOT wish to receive analysis of the listed genes related to adult-onset neurologic conditions.**

These genes are associated with genetic diseases that usually occur in adults that can affect how the brain and/or muscles work. These disorders usually do not have treatments for most of the symptoms. This category does not include autism, developmental delay, or intellectual disability (mental retardation).

AARS, AFG3L2, ALS2, AMACR, AMPD1, ANG, ANO10, ANO5, AP5Z1, APP, ATL1, ATP13A2, ATP1A2, ATP1A3, BSCL2, C9orf72, CACNB4, CAV3, CHMP2B, CP, CPOX, CRYAB, CSF1R, DCTN1, DNM2, DNMT1, DRD3, DYNC1H1, EGR2, ELOVL4, FBXO7, FGF14, FIG4, FTL, FUS, GARS, GBE1, GRN, GSN, HARS, HMBS, HSPB1, HSPB3, HSPB8, HSPD1, HTRA2, INF2, ITPR1, KIAA0196, KIF1B, KIF5A, LDB3, LITAF, LMNB1, LRRK2, LRSAM1, MAPT, MED25, MPZ, NAGA, NAGLU, NEFL, NF1, NIPA1, NR4A2, OPTN, PARK2, PARK7, PDE8B, PDYN, PINK1, PMP22, PPOX, PRKCG, PRNP, PRX, PSEN1, PSEN2, RAB7A, SCN9A, SETX, SH3TC2, SLC20A2, SNCA, SNCAIP, SOD1, SPAST, SPG7, SPTBN2, SPTLC1, SPTLC2, SQSTM1, SYNE1, TARDBP, TGM6, TREM2, TTBK2, TTN, TTR, TYROBP, UCHL1, VAPB, VCP, VPS13A, VPS35, YARS, ZFYVE27

6. Physician Signature

Please review the Illumina Patient Informed Consent Form with your patient prior to ordering this test.

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 test performed, (ii) the informed consent obtained from the patient meets the requirements of applicable law and Illumina Patient Informed Consent, and (iii) I am a medical doctor with the proper licensing in my country to order this testing. I agree to provide Illumina, or its designee, any and all information reasonably required for this genetic screening to be performed.

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

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7. Billing Information/Payment

- **NOTE: If you are a UYG attendee and have already paid in full, billing information is not required.**
- 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 will be delayed if 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.

Select the most appropriate billing option (this is the Responsible Party)

☐ Facility/Contract Billing ☐ Facility/Physician billing must be prearranged	☐ 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 Bill my credit card for 100% prepayment 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

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SAMPLE OR RESULTS RELEASE AUTHORIZATION FORM

For completion by the patient being tested through the TruGenome Predisposition Screen.

If you would like to access your data through the MyGenome web application, this form must be completed and returned with your sample authorizing the release of your data to the MyGenome web application team. Complete Section 1 and sign and date Section 4.

1. Patient Information (Person whose protected health information is being disclosed)

**Patient name, date of birth, and address are required.*

Last Name	First Name	Middle

Date of Birth (MM/DD/YYYY)

Address	City	State	Country	Zip

Patient Email	Sample ID/Lab Number (If known)

I request and authorize Illumina, Inc. and its subsidiaries and affiliates to disclose my protected health information, which I understand may include genetic information, as described below.

- ☑ My laboratory test results
- ☐ My residual laboratory specimen
- ☑ My genomic data set
- ☐ Other

To the following person or entity at the following address:

I understand that if the person/organization authorized to receive and use the information is not a health plan or health care provider, the disclosed information may no longer be protected by privacy laws or regulations, such as the Health Insurance Portability and Accountability Act (HIPAA).

2. Information

Organizations authorized to receive my information MyGenome web application team, a part of Illumina, Inc., but separate from the Illumina Clinical Services Laboratory that performed my testing.	**Relationship** N/A
Purpose Transfer of whole-genome sequencing data and all clinical reports and associated files to the MyGenome web application team for uploading to the www.understandyourgenome.com website and MyGenome web application.	
Contact Name or Individual Receiving Customer Solutions	**Telephone Number** 858.255.5134
Address Customer Solutions	**City, State, Zip/Post Code/Country** San Diego, CA, 92122 USA
Email GenomicServices@illumina.com	

3. Expiration and Revocation

Expiration: This authorization will expire (must choose one)

- ☑ One year from the date it is signed
- ☐ Other (insert date or event):_____

Revocation. I understand that I may revoke this authorization at any time by giving written notice to the address listed in 2. Information (above). I understand that revocation of this authorization will not affect any action Illumina, Inc. or its subsidiaries and affiliates took in reliance on this authorization before Illumina, Inc. received notice of revocation.

4. Signature

(this document must be signed by the patient, parent of the patient if the patient is a minor child, or the patient's personal representative). I understand that this authorization is voluntary and that Illumina cannot condition my eligibility for benefits, treatment, testing, enrollment, or payment of claims on the signing of this authorization. I understand that if I am signing on behalf of a minor child, this authorization will expire upon the child reaching the age of 18, unless there is proof of legal guardianship.

_____ _____

Signature Date: month/day/year

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