FulgentExome General Test Requisition Form

Please attach detailed medical records, insurance card front/back, and clinical information to the requisition form.

PRIMARY PATIENT

LAST NAME	FIRST NAME		
DATE OF BIRTH (MM/DD/YYYY)	GENETIC SEX ◯ Male ◯ Female ◯ Unknown		
MED REC#/PATIENT IDENTIFIER	ETHNICITY		
ADDRESS			
CITY	STATE/PROVINCE	POSTAL CODE	COUNTRY
PHONE	EMAIL		
SAMPLE DRAW DATE (MM/DD/YYYY)	SAMPLE TYPE ◯ Blood ◯ Buccal ◯ Other: ◯ Extracted DNA & DNA Source: (Blood, Buccal, Tissue, Fibroblast)		

I have read the Informed Consent document and I give permission to Fulgent Therapeutics LLC to perform genetic testing as described. I also give permission for my specimen and clinical information to be used in de-identified studies and for publication, if appropriate. My name or other personal identifying information will not be used in or linked to the results of any studies and publications. More information is available at www.fulgentgenetics.com/policies/privacy-policy.

☐ **Check this box if you are a New York state resident and give permission for Fulgent Therapeutics LLC to retain any remaining sample longer than 60 days after sample collection.**

☐ **Opt out of research**

PATIENT SIGNATURE (REQUIRED FOR BILLING PURPOSES)	DATE (MM/DD/YYYY)
X	

ORDER PROVIDER

INSTITUTION/PRACTICE NAME		INSTITUTION PHONE/FAX/EMAIL	
PROVIDER LAST NAME		PROVIDER FIRST NAME	
NPI (USA)	MINC (CANADA)	PROVIDER TITLE (MD, DO, GC)	
PROVIDER ADDRESS			
CITY	STATE/PROVINCE	POSTAL CODE	COUNTRY
PROVIDER PHONE		FAX REPORT TO	
GC/PRIMARY CONTACT		GC/PRIMARY CONTACT PHONE/EMAIL/FAX	

I attest that the patient has received and read the attached Informed Consent document, or has had it read to him or her, and that I have fully informed the patient about the purpose, capabilities, and limitations of the ordered test. The patient has voluntarily given his or her full consent for the ordered test and a signed copy of this consent is available on file. Any Informed Consent that the patient agrees to at a later date will supersede and replace this Informed Consent.

STATEMENT OF MEDICAL NECESSITY

By signing below, I, the ordering Medical Provider, confirm that testing is medically necessary and that test results may impact medical management for the patient.

ORDERING PROVIDER SIGNATURE (REQUIRED)	DATE (MM/DD/YYYY)
X	

TEST REQUESTED

TEST NAME

FULGENTEXOME: FulgentExome is a qualitative, semi-automated, next-generation sequencing (NGS) based system designed for clinical exome analysis to identify germline variants for the purpose of aiding the diagnosis of suspected genetic condition(s) within a patient's clinical and family history. The target population for FulgentExome germline testing are individuals suspected of genetic disorders, suspected of being a carrier, or those with a disease seeking to identify the cause.

PANEL NAME (PANEL ID), GENE(S), OR VARIANT(S) - MANDATORY

Include any relevant test details DUO/TRIO (requires additional info/consent for testing, see Page 2), Known mutation(s), Hold samples, Additional report delivery, etc...

☐ For Clinical or Whole Exome: Check this box if you wish to receive ACMG secondary findings.

TEST OPTIONS

Omitted test options will default to Seq & Del/Dup. Additional charges may apply.

◯ Seq & Del/Dup
◯ Sequencing Only
◯ Del/Dup Only

REFLEX OPTIONS

Reflex options may not be available for all tests. Additional charges will apply.

◯ All-in-One (Extended)
◯ Whole-in-One

ORDER OPTIONS

Additional charges may apply.

☐ Prenatal ☐ Exclude VUS
☐ MCC ☐ Rush/STAT

INDICATIONS FOR TESTING

Check all that apply.

☐ Diagnostic
☐ Presymptomatic
☐ Family History
☐ Family Variant
☐ Other:

CLINICAL/SUSPECTED DIAGNOSIS: Please attach medical records or complete Page 2.

The lab may perform confirmation of parental relationships for quality control or other purposes. See the attached informed consent for more details. ☐ Check here to opt-out.

INSURANCE BILLING

Attach front and back of all insurance cards, ABN, medical criteria form

PLEASE ATTACH INSURANCE CARDS FOR BILLING	ICD-10 VALID CODE	REFERRAL/PRIOR AUTH	FULGENT BENEFITS ID #	By signing above, the patient or insured authorizes Fulgent Therapeutics LLC to release medical information concerning the test to the assigned insurance company.

PRIMARY INSURANCE ID	INSURANCE NAME	STATE	GROUP	INSURANCE PHONE #
INSURANCE PLAN	NAME OF INSURED		RELATION TO PATIENT	DATE OF BIRTH (MM/DD/YYYY)
SECONDARY INSURANCE ID	INSURANCE NAME	STATE	GROUP	INSURANCE PHONE #
INSURANCE PLAN	NAME OF INSURED		RELATION TO PATIENT	DATE OF BIRTH (MM/DD/YYYY)

INSTITUTIONAL BILLING

INSTITUTION/PRACTICE NAME			
ATTENTION TO			
ADDRESS			
CITY	STATE/PROVINCE	POSTAL CODE	COUNTRY
PHONE	FAX/EMAIL		

SELF PAY

◯ Use patient information above for billing
◯ Use information below for billing

By signing above, the patient or payor authorizes Fulgent Therapeutics LLC to contact them directly, and use the provided billing instructions to bill the indicated method.

PAYOR LAST NAME	PAYOR FIRST NAME		
ADDRESS			
CITY	STATE/PROVINCE	POSTAL CODE	COUNTRY
PHONE	FAX/EMAIL		

General Test Requisition Form

Please attach detailed medical records, insurance card front/back, and clinical information to the requisition form.

CLINICAL HISTORY

Clinical Details

Check all that apply:

- ☐ Mosaicism
- ☐ Consanguinity
- ☐ Bone Marrow Transplant
- ☐ Organ Transplant
- ☐ Known Chromosomal Gain/Loss
- ☐ Known Gene Gain/Loss

Please specify any that are checked above:

There are many factors which may affect genetic diagnostic testing: such as gene-gene interactions, high-risk ethnicity groups, and transplants. Please list any that may apply. For additional details, please see the Fulgent website.

Clinical Presentation

Please indicate any clinical presentations and/or findings that may be relevant to genetic testing:

- Behavior
- Conditions
- Pedigree/Family History
- Phenotypes
- Physical
- Symptoms

There are many presentations which may not seem like a direct association for disease. Please list the most suspected presentations and attach detailed medical records and/or pedigree.

Clinical Testing

Please indicate any clinical testing results and/or findings that may be relevant to genetic testing:

- Karyotype
- Previous Genetic Testing
- Vision
- Hearing
- Growth Measurements
- Biochemical Testing
- Imaging
- Pathology Reports

Please also include tests that had a negative result. These tests help our clinical staff process the results of your testing.

FAMILY HISTORY

Attach pedigree and additional pages as needed

FAMILY MEMBER 1 NAME	RELATION TO PATIENT	GENETIC SEX ◯ Male ◯ Female ◯ Unknown	
DIAGNOSIS AND/OR SYMPTOMS		AGE OF ONSET	DOB (MM/DD/YYYY)
FAMILY MEMBER 2 NAME	RELATION TO PATIENT	GENETIC SEX ◯ Male ◯ Female ◯ Unknown	
DIAGNOSIS AND/OR SYMPTOMS		AGE OF ONSET	DOB (MM/DD/YYYY)
FAMILY MEMBER 3 NAME	RELATION TO PATIENT	GENETIC SEX ◯ Male ◯ Female ◯ Unknown	
DIAGNOSIS AND/OR SYMPTOMS		AGE OF ONSET	DOB (MM/DD/YYYY)

FAMILY SAMPLES FOR DUO/TRIO TESTING

Complete this section if family samples have been submitted for testing

LAST NAME	FIRST NAME
DATE OF BIRTH (MM/DD/YYYY)	GENETIC SEX ◯ Male ◯ Female ◯ Unknown
SAMPLE DRAW DATE (MM/DD/YYYY)	SAMPLE TYPE ◯ Blood ◯ Buccal ◯ Other: ◯ Extracted DNA & DNA Source: (Blood, Buccal, Tissue, Fibroblast)
RELATION TO PRIMARY PATIENT	AFFECTED/UNAFFECTED STATUS

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- ☐ **Opt out of research**
- ☐ **Check this box if you are a New York state resident and give permission for Fulgent Therapeutics LLC to retain any remaining sample longer than 60 days after sample acquisition.**

FAMILY MEMBER SIGNATURE	DATE (MM/DD/YYYY)
X	

LAST NAME	FIRST NAME
DATE OF BIRTH (MM/DD/YYYY)	GENETIC SEX ◯ Male ◯ Female ◯ Unknown
SAMPLE DRAW DATE (MM/DD/YYYY)	SAMPLE TYPE ◯ Blood ◯ Buccal ◯ Other: ◯ Extracted DNA & DNA Source: (Blood, Buccal, Tissue, Fibroblast)
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- ☐ **Opt out of research**
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FAMILY MEMBER SIGNATURE	DATE (MM/DD/YYYY)
X	

4399 Santa Anita Ave., El Monte, CA 91731 USA | www.FulgentGenetics.com | info@fulgentgenetics.com | **P** +1 626.350.0537 | **F** +1 626.454.1667
 | **CLIA** 05D2043189 | **D#** TRF-FExome_090925

FulgentExome General Test Requisition Form

Please attach detailed medical records, insurance card front/back, and clinical information to the requisition form.

INSTRUCTIONS

1. Complete the patient and provider information section.
2. Read and sign the informed consent policy statement. The complete patient informed consent form for genetic testing can be found on FulgentGenetics.com. Signature from the provider on Page 1 of the requisition form is required for all testing. Signature from the patient is only required for billing purposes.
3. Write in the test name and indicate any relevant test options. Please call us if you have any questions.
4. Include any clinical presentations, medical records/results, test results, and family history that may be relevant.
5. For Duo/Trio testing, please complete the Family Samples section or submit a separate requisition form for each sample.
6. Please visit FulgentGenetics.com for specimen requirements.

Extracted DNA must extracted from a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CAP and/or CMS.

REQUIRED FOR INSURANCE CHECKLIST

- ☐ Detailed medical record (pedigree if available)
- ☐ ICD-10 codes(s)
- ☐ Physician, patient, and insured signatures
- ☐ Copy of insurance card(s) - front/back
- ☐ Insurer specific forms (i.e. ABN)
- ☐ Insurance authorization, if available
- ☐ For medicare, medicare criteria form is required

For the most updated information and limitations on our products and services, please visit FulgentGenetics.com

REGULATORY INFORMATION (Based on EU IVDR 2017/746)

This test will be conducted using CE-marked devices that comply with Regulation (EU) 2017/746 on in vitro diagnostic medical devices. The devices involved—FulgentExome and FulgentPLM—have defined intended uses and comprehensive documentation, including warnings and precautions, operating instructions, and information regarding biological and hazardous substance content, as outlined in their respective Instructions for Use (IFUs). These IFUs are available internally to trained Fulgent personnel, who are the intended users of the FulgentExome and FulgentPLM assays. Clinicians – and their patients – who request these tests may access the IFUs of these CE-marked devices by contacting the following email address: info@fulgentgenetics.com. Simplified labels are provided below; the complete labels will be included in the associated clinical report.

FulgentExome

REF FulgentExome

IVD

Fulgent Therapeutics LLC
4399 Santa Anita Ave
El Monte, CA 91731
Tel: +1 (626) 350-0537
Fax: +1 (626) 454-1667
Email: info@fulgentgenetics.com
SRN: US-MF-000041408

EU REP

Emergo Europe B.V
Westervoortsedijk 60
6827 AT Arnheim
The Netherlands
Tel: (31) (0) 70 345-8570
Fax: (31) (0) 70 346-7299
Email: EmergoVigilance@ul.com
SRN: DE-AR-000005430

Fulgent Pipeline Manager

REF Fulgent PLM

IVD

Fulgent Therapeutics LLC
4399 Santa Anita Ave
El Monte, CA 91731
Tel: +1 (626) 350-0537
Fax: +1 (626) 454-1667
Email: info@fulgentgenetics.com
SRN: US-MF-000041408

EU REP

Emergo Europe B.V
Westervoortsedijk 60
6827 AT Arnheim
The Netherlands
Tel: (31) (0) 70 345-8570
Fax: (31) (0) 70 346-7299
Email: EmergoVigilance@ul.com
SRN: DE-AR-000005430

 | **CLIA** 05D2043189 | **D#** TRF-FExome_090925

Informed Consent For Genetic Testing

I request and authorize Fulgent Therapeutics LLC to test my (or my child's/fetus') sample for the stated testing.

I understand the following:

RISKS:

1. DNA testing requires a blood sample, buccal swab, or muscle or skin biopsy, all of which have risks associated with obtaining the sample. Additional samples may be needed if the sample is damaged in shipment or inaccurately submitted.

2. **I may learn genetic information about myself/the patient or my/their family members that is not related to the medical concern for which this test is ordered. This information might reveal: •Genetic risks for diseases that may develop later in life •Diseases unrelated to the primary reason for ordering the test •Disorders that do not have current treatment •Unexpected family relationships (e.g. consanguinity, non-paternity). Learning about this information might cause anxiety and psychological stress, which include alteration of self-image, increased anxiety and guilt, altered expectation by self and others, familial stress related to identification of other at-risk family members, difficulty obtaining life and/or disability insurance, and the detection of misattributed parentage.**

3. I authorize Fulgent Therapeutics LLC to release the medical information concerning my testing to my insurance company if the testing is billed through my insurance. The US Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits discrimination on the basis of genetic information with respect to health insurance and employment. However, GINA does not apply to life insurance, disability insurance, or long-term care insurance, which may be governed by state law. If you live outside the US, depending on your country of residence, there may be significant differences in the laws and regulations governing the use or disclosure of genetic information.

4. Results may have clinical or reproductive implications for my/the patient's family members. Participation in genetic testing is completely voluntary. I understand that I may wish to obtain professional genetic counseling prior to signing this consent form. Fulgent will provide a local referral for follow-up genetic counseling at the patient's request.

LIMITATIONS:

1. Genetic testing is complex and Fulgent is taking extensive measures to avoid errors and failed tests. Although the laboratory takes every precaution, technical, biological, and systematic errors may occur. You and/or your healthcare provider will be notified should such an event be discovered.

2. The performance characteristics of this test were validated by Fulgent Therapeutics LLC. The U.S. Food and Drug Administration (FDA) has not approved this test; however, FDA approval is currently not required for clinical use of this test. Fulgent Therapeutics LLC is authorized under Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) to perform high-complexity testing. These results should be interpreted in the context of the clinical findings, biochemical profile, and family history of the patient.

3. Accurate interpretation of test results is dependent upon the patient's clinical diagnosis or family medical history, as well as the fact that any reported family relationships are true biological relationships. An erroneous clinical diagnosis in the patient or family member can lead to an incorrect interpretation of the laboratory result.

4. This analysis is specific only for the test ordered, and only variants deemed to be in relation to the patient's clinical presentation or test order will be reported. This test will not detect all variants in any evaluated gene. There are some types of DNA changes that cannot be detected by this test and there are some disease-related DNA changes which are outside the region of the genome that is queried by this test. My physician may determine that further/other DNA testing is necessary in addition to this test.

REPORTING:

1. A positive result means that a pathogenic or likely pathogenic variant was identified. However, the results should be interpreted in the context of the patient's clinical findings, biochemical profile, and family history. A negative result does not rule out any pathogenic variants in areas not assessed by the test or in regions that were covered at a level too low to reliably assess. Also, it does not rule out variants that are of the sort not queried by this test.

2. Because of the complexity of genetic testing and the implications of the test results, results will only be reported to the ordering healthcare professional. The results are confidential and will only be released to other medical professionals or other parties with my written consent, per the laboratory's privacy policy. All laboratory raw data are confidential and will not be released unless a separate consent is completed (NGS Data Release for Clinical Use) or a valid court order is received.

3. The interpretation of the test results will be based on the laboratory's current information at the time of analysis. As medical knowledge advances and new discoveries are made, the interpretation of results may change. It is possible that re-interpretation of results could lead to new information about potential medical conditions. Such re-interpretation must be requested by a physician and will involve additional costs. However, it may not be possible to re-interpret the test data at a future date, and it may instead require retesting with a new sample. While Fulgent Therapeutics LLC does not guarantee re-analysis of all detected or reported variants, if a significant change is identified the laboratory may issue an updated report or contact the original ordering healthcare provider.

4. **Trio analysis** is also available and focuses on the proband of a familial trio (proband and parents). Familial testing can be expanded to include siblings and/or other relatives. Only one report will be provided specifically focused on the patient's phenotype. Family data will only be compared to the proband's data to refine likely candidate variants based on known and inferred inheritance. **Family members will not receive their own report, and requested incidental findings will only be reported if identified in the proband.** Each family member's sample should be accompanied by their own requisition and consent forms.

5. There may be DNA changes (also called variants) identified that may not be related to the indication for testing. These are known as "secondary findings" or "incidental findings." The symptoms of the conditions associated with these secondary findings may not be evident at this time, and they may or may not develop in the future. Secondary findings can include variants that may pose an increased risk to the development of cancer and/or cardiac disease. Discovery of this information may result in undue stress and financial burden for the family. During the course of reviewing the patient's results, the laboratory may encounter certain secondary findings deemed to be medically actionable in accordance with ACMG Recommendations (*https://www.ncbi.nlm.nih.gov/clinvar/docs/acmg/*). The laboratory will not,

by default, report these results unless they are judged to be immediately relevant to the test indication. This includes carrier variants that are unrelated to the patient's phenotype or indicated for testing.

For exome testing only: However, you may elect to have these results reported even when not directly related to the test indication.

If ordered, I wish to have any additional medically actionable secondary/incidental findings reported in certain genes in accordance with current professional recommendations. Only the primary patient will have secondary/incidental findings reported and, if applicable, the inheritance of the identified variant(s) (maternal or paternal). Secondary/incidental findings in family members of the primary patient beyond those that may be related to the patient's phenotype will not be analyzed or reported. Only DNA changes which are deemed to be pathogenic or likely pathogenic according to current American College of Medical Genetics and Genomics (ACMG) guidelines will be reported; DNA changes that are of unknown significance or which are thought to be benign or likely benign will not be reported. Please contact the laboratory for a list of the relevant genes.

Please note: If a genetic variant(s) is identified, insurance rates, the ability to obtain life and disability insurance, and employment may be impacted. The US Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits discrimination on the basis of genetic information with respect to health insurance and employment. However, GINA does not apply to life insurance, disability insurance, or long-term care insurance, which may be governed by state law. If you live outside the US, depending on your country of residence, there may be significant differences in the laws and regulations governing the use or disclosure of genetic information.

Please note: The National Society of Genetic Counselors (NSGC) and the American College of Medical Genetics and Genomics (ACMG) do not recommend predictive genetic testing of minors under the age of 18 for adult-onset conditions (such as those included in secondary/incidental findings) unless results may impact the child's medical management or otherwise significantly benefit the child.

SAMPLE STORAGE/RETENTION:

The laboratory will not return the remaining sample to individuals or physicians. Samples will be retained in the laboratory in accordance with the laboratory's specimen retention policy:

- Whole Blood/Bone Marrow: Any blood specimen remaining after extraction of DNA will be retained for a period of 90 days after issuance of the final test result. At that time, blood samples may be discarded or stripped of all identifiers except for age and gender and used for quality control purposes.
- Cell-Culture Submissions: Any remaining harvested cells will be stored at -80°C for a minimum of 90 days after issuance of final test results. At that time, the samples may be discarded or stripped of all identifiers except for age and gender and used for quality control purposes.
- Paraffin-embedded blocks/unstained slides: These materials are to be stored for a minimum of 5 years.
- Saliva/Buccal swabs: Used saliva/buccal swab tubes are to be retained for a period of 90 days after issuance of the final test result.
- Fresh tissue or frozen tissue samples: Unextracted tissue samples are to be retained for a minimum of 2 years after the final test result.
- DNA Samples: DNA samples remaining after testing will be retained for a minimum of 2 years after issuance of the final test result. DNA samples may be retained for longer periods of time in case of situations where any future testing is added on and further testing only be performed with the consent of the referring physician. Samples will be anonymized and stripped of all identity with exception of gender if any future research testing shall occur but only with verification of the owner of the sample (the patient or legal guardian, or the designated owner if the patient is deceased) and with subjection to any and all applicable IRB (Institutional Review Board) guidelines. We will not make any claim that the preserved sample (extracted onsite or by the client) will be available or that the sample, if available, will be appropriate or guarantee results for future tests.
- Unacceptable Specimens: All unacceptable specimen types may be disposed of after 14 days of receipt, unless the return of the specimen is requested by the authorizing provider. Biological specimens must be disposed of in the appropriate biohazardous waste containers.

All samples from New York patients will be destroyed within 60 days after Fulgent's receipt of the sample, unless you opt in to storage of your sample.

It may be possible to perform additional studies on the remaining sample. The referring physician or other authorized provider and patient/legal guardian must make the request for additional studies with the potential for additional charges.

RESEARCH/RECONTACT CONSENT:

I may give consent to allow my sample to be used for medical research and/or education, as long as my privacy is maintained. Refusal to permit the use of my sample for research will not affect my test result. Fulgent Therapeutics LLC will not sell your data to a third party. For research use, sample may be stored indefinitely. I can withdraw my consent at any time by contacting the laboratory at info@fulgentgenetics.com.

ACKNOWLEDGMENT OF CONSENT:

By submitting my specimen/order, I acknowledge that I have read and understand the questions and answers set forth above, and that I have had the opportunity to have any additional questions answered by a physician or genetics professional. If applicable I give my consent or consent on behalf of the patient for whom I am legal guardian:

1. To the genetic analysis by Fulgent Therapeutics LLC as ordered by my physician;
2. To the collection and processing by my physician and Fulgent Therapeutics LLC of my personal health information and sample as required to conduct the genetic analysis, including any necessary transfer of my personal health information between my physician and Fulgent Therapeutics LLC across national borders, specifically to the United States;
3. To the analysis of the obtained sample and its storage at Fulgent Therapeutics LLC, in accordance with Fulgent's specimen retention policy, together with my patient file to be able to verify results of the analysis if need be;
4. To the receipt of information by me and/or my physician about the results of the genetic analysis; and
5. To the provision upon request to me or my physician of the raw data of the genetic analysis.

I am aware that I can withdraw my consent in full or in part subject to the terms of the Privacy Policy and that I have the right not to know the results of the genetic analysis as described in this Consent Form.