JAX ADVANCED PRECISION MEDICINE LABORATORY

GERMLINE REQUISITON

All Fields Required

PATIENT INFORMATION

Last Name:		First Name:	
Date of Birth:		Medical Record #:	
Address:			
City:	State:	Zip Code:	Country:
Primary Phone #:			

Gender Identity:
- ☐Male
- ☐Female
- ☐Non-binary
- ☐Unknown
- ☐Gender identity not listed: _____

Sex assigned at birth:
- ☐Male
- ☐Female
- ☐Unknown
- ☐Sex not listed: _____

Race: *(Check all that apply)*
- ☐ Black/African American
- ☐ East Asian
- ☐ Indigenous, Native American or Native Alaskan
- ☐ Native Hawaiian or Pacific Islander
- ☐ North African/Middle Eastern
- ☐ South Asian
- ☐ White
- ☐ Race not listed_____
- ☐ Prefer not to respond

Ashkenazi Jewish:
- ☐ Yes
- ☐ No
- ☐ Prefer not to respond

Ethnicity:
- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Prefer not to respond

SPECIMEN INFORMATION *(Please see specimen requirements for test specific acceptance criteria)*

Specimen ID:	Specimen Type:
Date Collected:	☐ Whole Blood (EDTA; 1-2 mL, or ≥.5 mL for infants, is required)
State of Collection (*samples from NY are not accepted*):	ICD10 (Diagnosis) Code(s):

Clinical Indication for Testing (Please attach the most recent clinical note, photos, pedigree, and additional testing records to the requisition)

TEST MENU *Please choose the appropriate test to be executed on the submitted specimen.*

☐ **JAX Genome** ☐ **JAX Rapid Genome** *(5-12 days)* ☐ **JAX Genome Reanalysis** (*>12 mo. since initial analysis*)

ORDERING PHYSICIAN INFORMATION

Ordering Physician Name:		NPI #:	
Ordering Physician Role/Title:			
Practice/Institution:			
Facility Street Address:			
City:	State:	Zip Code:	Country:
Primary Phone #:	Fax # or Email:		
Contact for Questions:			

AUTHORIZATION

I certify (a) that the laboratory test requested is medically necessary and will assist me in treating my patient, (b) that I have informed the patient and/or their legal representative of the benefits, risks, and limitations of the test, (c) and that I have obtained the patient's informed consent, to the extent legally required, to permit The Jackson Laboratory to (i) perform the testing specified herein, (ii) retain the test results for an indefinite period for internal quality assurance/operations purposes, (iii) de-identify the test results and use or disclose for future unspecified research or other purposes, and (iv) release the test results to the patient's third party payor as needed for reimbursement purposes.

Ordering Physician Signature **Date**

Laboratory Use Only		
Date and Time of Specimen Receipt:	Accessioning Tech Initials:	Order ID #:
Notes/Event #:		Specimen ID #:

ADDITIONAL SAMPLES

For additional family members, complete the information below and select the appropriate test (report not provided for additional samples):

- **Comparator Genome Sequencing** – Sample to receive 30X GS to be used in the analysis of the patient's GS.
- **Targeted Segregation Testing** – Sample to undergo targeted testing of primary findings identified in the patient.
- **Comparator Reanalysis** – Sample data to be used in the analysis of the patient's GS reanalysis.

ADDITIONAL SAMPLE #1		
Last Name:	**First Name**:	**Date of Birth**:
Relationship to Patient:	**Specimen Type**: Whole Blood (EDTA)	**Date Collected**:
Sex Assigned at Birth: ☐Male ☐Female ☐Unknown	**Gender Identity**: ☐Male ☐Female ☐Nonbinary ☐Not listed:	
Test Ordered: ☐Comparator Genome Sequencing	☐Targeted Segregation Testing	☐Comparator Reanalysis
ADDITIONAL SAMPLE #2		
Last Name:	**First Name**:	**Date of Birth**:
Relationship to Patient:	**Specimen Type**: Whole Blood (EDTA)	
Sex Assigned at Birth: ☐Male ☐Female ☐Unknown	**Gender Identity**: ☐Male ☐Female ☐Nonbinary ☐Not listed:	
Test Ordered: ☐Comparator Genome Sequencing	☐Targeted Segregation Testing	☐Comparator Reanalysis
ADDITIONAL SAMPLE #3		
Last Name:	**First Name**:	**Date of Birth**:
Relationship to Patient:	**Specimen Type**: Whole Blood (EDTA)	
Sex Assigned at Birth: ☐Male ☐Female ☐Unknown	**Gender Identity**: ☐Male ☐Female ☐Nonbinary ☐Not listed:	
Test Ordered: ☐Comparator Genome Sequencing	☐Targeted Segregation Testing	☐Comparator Reanalysis
ADDITIONAL SAMPLE #4		
Last Name:	**First Name**:	**Date of Birth**:
Relationship to Patient:	**Specimen Type**: Whole Blood (EDTA)	
Sex Assigned at Birth: ☐Male ☐Female ☐Unknown	**Gender Identity**: ☐Male ☐Female ☐Nonbinary ☐Not listed:	
Test Ordered: ☐Comparator Genome Sequencing	☐Targeted Segregation Testing	☐Comparator Reanalysis

INFORMED CONSENT FOR GENETIC TESTING

Genome sequencing (GS), sometimes referred to as "whole genome sequencing", examines the coding and noncoding regions of the genome. Millions of DNA variants will be detected, some which may cause disease while others are benign variation. Your provider has recommended this test to help identify the variant(s) in your genome potentially causing your symptoms. This test will include DNA extraction from your sample; genome sequencing; variant analysis and interpretation; and a clinical report. The final report will be issued in 6 to 8 weeks.

This test will be performed to identify the genetic basis of your condition (Primary Findings) as well as variant(s) associated with disease risk that are not related to your condition (Secondary Findings). Genetic counseling is recommended for all people receiving genetic testing.

1. The possible results you may receive are:
    a. Positive result(s): One or more variants, in one or more genes is likely to be the cause of the genetic disease(s) in me/the patient. Members of my biological family may also be affected or at risk of carrying the same variant. There may or may not be treatment available for the condition that has been diagnosed.
    b. Negative result(s): No specific variants were detected that may explain my/the patient's disease(s). This outcome does not mean that I/the patient do not have or am not a carrier of a genetic disorder. It means that based on this specific test, the cause of my disease was not detected.
    c. Variant of uncertain significance: While genetic testing is a valuable tool, it may not always give a definitive answer about the genetic status of an individual. Variants of uncertain significance are results that have an unknown significance to my/the patient's specific disease.
        i. Genetic and genomic knowledge is constantly evolving therefore our understanding of previous variants of uncertain significance may change. You or your physician should contact the lab periodically to check if any variants of uncertain significance have been recategorized. The results of this test may indicate that you are predisposed to or have an inherited disease, or that you are a carrier of a genetic disorder. Depending on the results of this test, your physician may recommend further genetic counseling or testing.
2. The Genetic Information Nondiscrimination Act (GINA) of 2008 prohibits health insurance plans and some employers from discrimination based on genetic information, including the results of genetic testing. However, GINA does not protect against discrimination by life insurance, disability insurance, and/or long-term care insurance; therefore, genetic testing may be utilized by these types of insurances to determine coverage.
3. The Jackson Laboratory will only provide test results to my health care team, my health insurance carrier, or as otherwise permitted or required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Results may be sent to additional providers or other individuals with appropriate written consent.
4. Results from genetic testing are usually highly accurate, however, infrequent errors may occur. Some possible sources of error include clinical misdiagnosis, inaccurately reported familial relationships, sample contamination or mislabeling, stem cell replacement therapy, active hematological cancers, technology restrictions, and technical errors. If you have questions about the test results, you are encouraged to consult your genetic counselor or physician.
5. Genetic testing may detect discrepancies in relationships of the individuals tested (e.g., the person stated to be the patient's biological father is not, in fact, the biological father), or may suggest that the parents of the individual tested are blood relatives (i.e., possible consanguinity). If detected, these findings will not be revealed to you or your family.

INFORMED CONSENT CONTINUED ON PAGE 3

INFORMED CONSENT FOR GENETIC TESTING, CONTINUED

Secondary Findings

You have the option to receive Secondary Findings which are **unrelated to the indication for testing**. These findings include the **medically-actionable disorders** as well as **carrier findings** as recommended by the American College of Medical Genetics and Genomics (ACMG). If no selection is made, Secondary Findings will not be reported. Please initial to indicate you wish to be informed of Secondary Findings.

_____ **I wish to be informed** of ACMG-recommended Medically-Actionable Secondary Findings (PMID: 35802134).

_____ **I wish to be informed** of ACMG-recommended Carrier Findings (PMID: 25730230).

Use of Specimens

After testing is completed, your **deidentified** specimen may be used for **laboratory improvement** and **validation** purposes. Results from such use will **not be provided** to clinicians or patients. If you **do wish** for The Jackson Laboratory to retain your deidentified sample for laboratory improvement purposes, please initial below, as applicable.

_____ Patient wishes to **opt in** for use of specimens for laboratory improvement.

_____ Additional sample #1 wishes to **opt in** for use of specimens for laboratory improvement.

_____ Additional sample #2 wishes to **opt in** for use of specimens for laboratory improvement.

_____ Additional sample #3 wishes to **opt in** for use of specimens for laboratory improvement.

_____ Additional sample #4 wishes to **opt in** for use of specimens for laboratory improvement.

Data Sharing & Publication

In the interest of advancing the understanding of genetic conditions, a **deidentified summary of your information**, including results from this test, may be presented at **meetings, in publications, or on the internet**. Deidentified information, including raw data, may be **shared** with **publicly available databases** (e.g., ClinVar) to expand knowledge in the field. **No identifying information will ever be disclosed, unless authorized in writing**. If you **do wish** for The Jackson Laboratory to retain your deidentified data for such purposes, please initial below, as applicable.

_____ Patient wishes to **opt in** for data sharing and publication.

_____ Additional sample #1 wishes to **opt in** for data sharing and publication.

_____ Additional sample #2 wishes to **opt in** for data sharing and publication.

_____ Additional sample #3 wishes to **opt in** for data sharing and publication.

_____ Additional sample #4 wishes to **opt in** for data sharing and publication.

Informed Consent for Genetic Testing

By signing this form, I acknowledge that I understand the potential risks and benefits of the genetic test being ordered and that I have reviewed this Test Requisition Form. I authorize The Jackson Laboratory to perform genetic testing as described and to release my test results only to the ordering clinician. No clinical test(s) other than those authorized herein will be performed on the sample(s) provided without prior authorization.

☐I am the patient.

☐I am authorized to execute consent on behalf of the patient.

Printed Name	Relationship to Patient	Signature	Date

☐I am the individual listed as Additional Sample #1.

☐I am authorized to execute consent on behalf of the individual listed as Additional Sample #1.

Printed Name	Relationship to Sample #1	Signature	Date

☐I am the individual listed as Additional Sample #2.

☐I am authorized to execute consent on behalf of the individual listed as Additional Sample #2.

Printed Name	Relationship to Sample #2	Signature	Date

☐I am the individual listed as Additional Sample #3.

☐I am authorized to execute consent on behalf of the individual listed as Additional Sample #3.

Printed Name	Relationship to Sample #3	Signature	Date

☐I am the individual listed as Additional Sample #4.

☐I am authorized to execute consent on behalf of the individual listed as Additional Sample #4.

Printed Name	Relationship to Sample #4	Signature	Date

BILLING INFORMATION *Please check one*

☐ **Institution or Study**

Institution/Study Name Account/Study #

☐ **Self-pay**

Contact Name Email Phone #

If I have selected the patient insurance billing option, I authorize my health plan or insurance carrier, and other third parties involved in the administration of my plan, to disclose to The Jackson Laboratory information concerning my plan, including benefits, coverage limitations, and payments made for services. Further, I authorize The Jackson Laboratory to bill my insurance carrier and assign and authorize payment directly to The Jackson Laboratory of any benefits for the services provided. I understand that my insurance may not cover these services or may only pay up to usual and customary rates, and that I am ultimately responsible for all costs of this test and costs of collections, except where my liability is limited by contract or applicable state or Federal law.

Patient/Legal Representative Printed Name **Date**

SPECIMEN REQUIREMENTS

Specimen Type	Available Tests	Shipping Temperature	Sample Storage for Transport	Amount & Quality Requirements	Rejection Criteria
Whole Blood (EDTA lavender top tube)	JAX Genome JAX Rapid Genome	Ship overnight at room temperature	Ship in an insulated container and leak-proof packaging. Include Test Requisition Form/manifest with specimens	1-2 mL of whole blood collected in 1 EDTA (lavender top) tube per patient. For infants, a minimum of 0.5 mL is required.	Specimen is coagulated. Quantity is less than 0.5 mL. Specimen is collected in the wrong tube type.

All specimens must be accompanied by clinical notes.

All specimens should be shipped priority overnight in appropriate packaging container per relevant shipping conditions (see table above) and comply with relevant shipping criteria (e.g., DOT and/or IATA). Shipments should be planned to arrive to JAX Monday-Friday 8 AM to 5 PM only. Please label all specimens with at least two identifiers corresponding to the patient or specimen information provided on this form and ensure that this completed form is included in the shipment.

Any specimens not meeting the above criteria will be processed at the discretion of the Clinical Laboratory Director. All samples are subject to additional downstream QC requirements. Please contact the laboratory for questions regarding acceptable specimens.

SHIPPING ADDRESS

JAX Advanced Precision Medicine Laboratory
The Jackson Laboratory for Genomic Medicine
10 Discovery Drive
Farmington, CT 06032

CONTACT JAX

Phone # 860-837-2320
Fax # 855-414-4792
Email CGL_CS@jax.org
Please use this email for service-related questions only. Due to the sensitive nature of PHI, do not submit this requisition via unencrypted email.