HudsonAlpha Clinical Services Lab, LLC
601 Genome Way, Rm 3023
Huntsville, AL 35806
256-327-9670
test@clinicallab.org

TEST REQUISITION, PATIENT INFORMATION, AND CONSENT
HUDSONALPHA CLINICAL SERVICES LAB

1. Patient Information

HUDSONALPHA CLINICAL SERVICES LAB CANNOT ACCEPT SAMPLES FROM NEW YORK.

Patient Name _____ Medical Record Number _____
Last First

Date of Birth ____ / ____ / ____ Gender ☐ Male ☐ Female ☐ Unknown
Month Day Year

Ethnic Ancestry
☐ African ☐ Hispanic
☐ Ashkenazi Jewish ☐ Caucasian
☐ Middle Eastern ☐ Asian/Pacific Islander
☐ Native American ☐ Other:

2. Pertinent Clinical Information

DIAGNOSES _____ ICD10 Code(s) _____

☐ **REQUIRED:** a copy of physician's note about the patient, including family history
Not needed if samples are submitted for extraction and storage or return of data without analysis.

OPTIONAL: photo of patient

Date Sample Obtained (MM/DD/YYYY) _____

Sample Type (Check all that apply)
☐ Blood (EDTA)
☐ DNA (Extracted)
☐ Saliva

3. Ordering Physician Information

Deliver report to:

Name: _____ Telephone: _____

Department: _____ Fax: _____

Address: _____ Email: _____

_____ Who should the laboratory contact with questions about this case? _____

Ordering Physician: _____ _____
(Print Name) (Signature)

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4. Test Ordered

☐ **Whole genome sequencing and analysis (WGS40-RR).** The sample(s) will have whole genome sequencing and data analysis. Clinically relevant findings will be reported. CPT code: 81425x1 for patient only. CPT code: 81425x1, 81426x2 for trio.

☐ **Whole genome sequencing – return of data without analysis (WGS40-RD).** The sample(s) will have whole genome sequencing ONLY and that data will be provided to the ordering physician. NO data analysis or report of clinically relevant findings will be provided. CPT code: 81425x1 for patient only. CPT code: 81425x1, 81426x2 for trio.

☐ **DNA extraction and storage.** CPT code: 81479

☐ **Variant confirmation by Sanger sequencing.** See Section 6**.**

5. Samples

☐ Whole genome sequencing for patient and _____ other individuals.*

☐ Sanger sequencing for patient and _____ other individuals.

☐ DNA extraction from patient sample and _____ other individuals.

*No separate laboratory report will be provided for other individuals

Other individuals:

Name _____ Date of Birth _____ Relationship to patient _____ (e.g. mother)
☐ Unaffected ☐ Affected with _____

Name _____ Date of Birth _____ Relationship to patient _____ (e.g. mother)
☐ Unaffected ☐ Affected with _____

Name _____ Date of Birth _____ Relationship to patient _____ (e.g. mother)
☐ Unaffected ☐ Affected with _____

Name _____ Date of Birth _____ Relationship to patient _____ (e.g. mother)
☐ Unaffected ☐ Affected with _____

6. Gene List/Variant List

☐ List variants by Rs ID or Hg19/GRCh37 coordinates for each position for Sanger (attach list if necessary).

☐ **OPTIONAL**: List genes/ regions of interest related to patient's phenotype (attach list if necessary).

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7. Request Concerning Secondary Findings Found by Whole Genome Sequencing

Patient Name _____ (Last _____ First) Date of Birth ____ / ____ / ____ (Month Day Year)

It is highly recommended that the patient/family receive genetic counseling regarding whole genome sequencing before and after the test. My signature below indicates that I have been informed of the following facts about the whole genome sequencing test and that I have had the opportunity to have any questions answered.

This test will be performed to find the genetic basis of my/my child's disorder.

1. I may learn that one or more DNA differences, called variants, in one or more genes is likely to explain the cause of the disorder(s) in me/my child.
2. I may learn that no specific DNA variants were detected that may explain my/my child's disorder(s). This outcome does not mean that I/my child do not have a genetic disorder.
3. I may learn that one or more DNA variants were identified that may cause medical conditions that are unrelated to my/my child's disorder(s). These are referred to as Secondary Findings.

This test examines the entire human genome for DNA variants. Results are classified into two possible categories:

1. Primary Results: DNA variants likely to be responsible for the disorder under investigation in my/my child's case. Primary Results will always be included in the laboratory report.
2. Secondary Findings: DNA variants that are not likely to be responsible for the disorder under investigation in my/my child's case but were seen in the process of finding the Primary Result. Secondary Findings that cause a childhood onset disorder where medical intervention can prevent or decrease the effect of a disease will always be included in the laboratory report.

Indicate the types of Incidental Findings you wish to have reported in addition to the required results (check boxes below):

☐ No Other Incidental Findings. Retain data for future analysis with no obligation to report.

OR

☐ Untreatable Childhood Disorders (e.g. Tay-Sachs disease)

☐ Treatable Adulthood Disorders (e.g. Hereditary Colon Cancer)
*This category includes the 59 genes specified by the ACMG (https://www.ncbi.nlm.nih.gov/clinvar/docs/acmg/)

☐ Untreatable Adulthood Disorders (e.g. Alzheimer's Disease)

☐ Carrier of a Disorder (e.g. Phenylketonuria)

☐ Pharmacogenetics (genetic variation that may affect responses to medication)

Signatures (Sign, print, and date here to provide consent.)

Patient (If a minor, assent if appropriate)

Print Name _____ Signature _____ Date (MM/DD/YYYY)

Parent or Guardian (Parent, Guardian, or Legally Authorized Representative may sign if patient is a minor or unable to provide consent)

Print Name _____ Signature _____ Date (MM/DD/YYYY)

Parent or Guardian (Parent, Guardian, or Legally Authorized Representative may sign if patient is a minor or unable to provide consent)

Print Name _____ Signature _____ Date (MM/DD/YYYY)

Name of Ordering Physician or Genetic Counselor

Print Name _____ Signature _____ Date (MM/DD/YYYY)

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8. Billing and Patient Information

- The Responsible Party identified below agrees to pay the full price of the test. ***HudsonAlpha Clinical Services Lab will not begin processing the sample(s) until payment arrangements have been made.***
  Testing may be delayed if satisfactory payment arrangements have not been made. This applies to all tests.
- The Responsible Party shall pay 100% of the test price ***prior*** to initiation of testing.
- For all billing questions, please call 256-327-0438.

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

Institutional Billing (**Must be pre-arranged)**

Facility Name _____

Address, City, State, Zip

_____

_____

Purchase Order # _____

Contact Person _____

Phone _____

Email _____

Patient / Legal Guardian / Other

Name of Responsible Party _____

Billing Address, City, State, Zip

_____

_____

_____

_____

Phone _____

Email _____

Select your payment option:

☐ Payment by wire transfer or personal check (Please contact HudsonAlpha Clinical Services Lab to arrange payment)

☐ Bill my credit card for 100% pre-payment.
(HudsonAlpha Clinical Services Lab can only accept credit cards from the US.)

Card Type: ☐ Visa ☐ Mastercard ☐ AMEX ☐ Discover ☐ Debit
☐ Diners Club ☐ HSA ☐ Flex Spending

Please print Cardholder Name exactly as it appears on the card: _____

Card Number: _____ Expiration Date: _____ CCV: _____

I authorize 100% of the cost of the test be charged to my credit card above. _____
(Cardholder Signature)

PLEASE PRINT Date _____

Patient's Name _____ Referred By _____
Last First MI

Address _____ City _____ State _____ Zip Code _____

Home Phone _____ Work Phone _____ Cell Phone _____

SSN _____ Email Address _____

Patient's Occupation _____ Patient's Employer _____

Employer's Address _____ Employer's Phone _____

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Spouse's Name _____ Spouse's DOB ____ / ____ / ____
Last First MI Month Day Year

Spouse SSN _____

Spouse's Occupation _____ Spouse's Employer _____

Employer's Address _____ Employer Phone (____) _____

Notify in case of emergency _____ Relationship _____

City _____ State _____ Phone (____) _____

Primary Insurance To File

Policy # Group #	Insured's Name
Insured's SSN or ID#	Relationship to Patient
Insured's DOB	Insurance Company Name

Secondary Insurance To File

Policy # Group #	Insured's Name
Insured's SSN or ID#	Relationship to Patient
Insured's DOB	Insurance Company Name

Responsible Party Acknowledgement and Authorization to Assign Benefits, Accept Financial Responsibility, and Disclose Health Records

If I am entitled to benefits under the Medicare program, the Medicaid program, or any insurance policy or other health benefit plan, in consideration for services provided to me by the Laboratory, I assign, transfer, and convey the benefits payable under such program, policy, or plan for such services to the Laboratory. I authorize payment of benefits directly to the Laboratory, with such benefits applied to my bill. I understand and acknowledge that this assignment does not relieve me of financial responsibility for charges incurred by me and I agree to pay charges not paid under this assignment, including any coinsurance amounts and deductibles and any charges for services deemed to be non-covered, not pre-certified, or not preauthorized by my insurance plan. I understand that the Laboratory is permitted to disclose my health information for purposes of payment of bills (if I filled out insurance information above), my continued care or treatment, and healthcare operations. I authorize my physicians or any facility to release my health information to the HudsonAlpha Clinical Services Laboratory for the purposes of payments of bills or claims.

Signature _____ Date _____ Time _____
(Parent, Guardian, or Legally Authorized Representative may sign if patient is a minor or unable to provide consent)

Statement Regarding Test

Whole Genome Sequencing will be performed in the HudsonAlpha Clinical Services Lab under a valid and unexpired Alabama Clinical Laboratory License. The Laboratory is a CLIA (Clinical Laboratory Improvement Amendments) certified and CAP (College of American Pathologists) accredited laboratory. Consistent with Laboratory Developed Tests, it has not been cleared or approved by the U.S. Food and Drug Administration.

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9. Additional Studies - Research

☐ **YES**, HudsonAlpha Clinical Services Lab may share my contact information with researchers who have an Institutional Review Board (IRB) approved research study for which I may be eligible for participation. There is no obligation to participate if contacted. No information, other than the contact information above, will be provided to the researcher.

☐ **NO**, I DO NOT wish to be contacted regarding participation in research studies.

☐ **YES**, HudsonAlpha Clinical Services Lab may contact my/my child's doctor who ordered the Whole Genome test to discuss research studies that I/my child may be eligible for. There is no obligation to participate if contacted.

☐ **NO**, I DO NOT want my/my child's doctor contacted regarding research studies.

Authorization and contact information MUST be completed, or we will not be able to reach you regarding these opportunities.

Signatures (Sign, print, and date here to provide consent.)

Patient (If a minor, assent if appropriate)

Print Name	Signature	Date (MM/DD/YYYY)

Parent or Guardian (Parent, Guardian, or Legally Authorized Representative may sign if patient is a minor or unable to provide consent)

Print Name	Signature	Date (MM/DD/YYYY)

10. Use of Specimens

Use of Specimens: HudsonAlpha Clinical Services Lab is committed to research efforts with the goal of improving testing for future patients. Your sample or test results made anonymous (name and all other identifiers removed) could be used in the validation of new genetic testing methods and/or other test-related research and published scientific education efforts. The identity of individuals studied will not be revealed in such publications or presentations. You will not receive results of any research testing done on your sample.

I understand that I may refuse to submit my specimen for use in this way and may withdraw my consent at any time by contacting the Laboratory Director. I understand that my refusal to consent to medical research will not affect my results. Indicate consent or denial below. **If a box is not marked consent is implied.**

(Initials) I consent to the use of my sample for research. _____YES _____NO

REQUIRED: Patient Signature _____ Date _____
(Parent, Guardian, or Legally Authorized Representative may sign if patient is a minor or unable to provide consent)

11. Specimen Requirements and Shipping Instructions

Deliveries Accepted: Monday – Friday, 8AM-5PM

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Blood Specimen Requirements

- Collect 2-4ml of whole blood in EDTA (lavender top) tube. 2 EDTA tubes containing 2-4ml of whole blood per patient preferred.
- For infants, collect a minimum of 1ml of blood.
- Label the specimen with at least two identifiers; patient name and date of birth are preferred.
- Ship blood in tubes at room temperature in an insulated container.
- Specimen should be submitted within 48 hours of collection. Every attempt will be made to process samples older than 48 hours.
- Possible reason for sample rejection:
  - Coagulated sample
  - Quantity less than 1ml
  - Specimen collected in wrong tube
  - Unlabeled sample

Saliva Requirements

- 2ml collection of saliva (4ml total volume) via OraGene kit according to manufacturer's directions.
- Saliva samples may be shipped at room temperature.

Oncology Specimen Requirements

- The CSL does not perform extraction of DNA from oncology specimens. Extraction must be performed by a CLIA-certified laboratory (or equivalent outside USA) that sends the sample to the CSL.

DNA Requirements - **DNA samples are ONLY accepted from CLIA-certified laboratories (or equivalent outside USA)**

Submitting Lab CLIA License Number: Federal _____ State (if applicable) _____

- DNA Quantitated via Spectrophotometry
  - Submit a screw cap tube of at least 5ug of purified (PureGene preferred) DNA at a concentration of at least 60ng/ul with a 260/280 purity ratio of 1.75 – 2.0.
- DNA Quantitated via Fluorometric Assay (PicoGreen)
  - Submit a screw cap tube of at least 3ug of purified (PureGene preferred) DNA at a concentration of at least 50ng/µl
- DNA may be shipped at room temperature.
- Label the specimen with at least two identifiers; patient name and date of birth are preferred.
- We only accept genomic DNA from CLIA laboratories for testing. We do not accept products of whole genome amplification reactions or other amplification reactions.
- Sanger sequencing specimen requirements
  - Screw cap tube of 500ng of DNA (minimum of 50ng/µl) with a 260/280 purity ratio of 1.75 - 2.0 for each variant.

Ship all specimens and a copy of this completed form to:

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**Submitter is responsible for all shipping costs.*
Deliveries accepted Monday – Friday 8AM-5PM