The HudsonAlpha CLINICAL SERVICES LAB

HudsonAlpha Clinical Services Lab, LLC
601 Genome Way, Rm 3023
Huntsville, AL 35806
256-327-9670 ● info@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: _____
Last First

Date of Birth: _____ Medical Record Number: _____
(MM/DD/YYYY)

Sex: ❑ Male ❑ Female ❑ Unknown ❑ Other: _____

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

2. Clinical Information

Diagnoses: _____ ICD10 Code(s): _____

Date Sample Obtained (MM/DD/YYYY): _____

Sample Type (*check all that apply*): ❑ Blood (EDTA) ❑ DNA (extracted)

REQUIRED FOR ANALYSIS/INTERPRETATION: 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(s) of patient

3. Ordering Clinician Information

Deliver report to:

Name: _____ Phone: _____

Department: _____ Fax: _____

Address: _____ City: _____

State: _____ Zip Code: _____ Email: _____

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

Ordering Clinician: _____ _____
Print Name Signature

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4. Test Ordered

- ❑ **Clinical Genome Sequencing + Interpretation (cGS40-RR).** The sample will have clinical genome sequencing, quality assessment, and data analysis. Clinically relevant findings will be reported. CPT code: 81425.
- ❑ **Clinical Genome Sequencing + Quality Control (cGS30-RD).** The sample will have clinical genome sequencing and quality assessment. Sequencing data and quality metrics report will be provided to the ordering physician. NO data analysis or report of clinically relevant findings will be provided. CPT code: 81425.
- ❑ **Reanalysis/Reinterpretation of Clinical Sequencing Data (CS-RA)**. Please complete the *REQUEST FOR CLINICAL REANALYSIS/REINTERPRETATION* form. CPT code: 81427.
  - ❑ Reanalysis of genome ❑ Reanalysis of up to 25 genes of interest (Complete *Section 6*)
- ❑ **Global Screening Array + Interpretation (GSA-RR).** Select all findings to be reported.
  - ❑ Adult-Onset Actionable Variant Status ❑ Pharmacogenetics ❑ Carrier Status
- ❑ **Global Screening Array + Quality Control (GSA-RD).** Array data and quality metrics report will be provided to the ordering physician. NO data analysis or report of clinically relevant findings will be provided.
- ❑ **Variant Confirmation by Sanger Sequencing (CSS-RR).** Complete *Section 6*. CPT code: 81479 or gene-specific.
  - ❑ With variant interpretation (*please include clinical notes/family history*) ❑ No variant interpretation needed
- ❑ **DNA Extraction and Storage (ENH-BR).** CPT code: 81479.

5. Additional Samples

****A laboratory test report will only be provided for the individual listed in Section 1****

Test to be performed on additional samples:

- ❑ Comparator Clinical Genome Sequencing (cGS40-CR). CPT code: 81426.
- ❑ Clinical Genome Sequencing + Quality Control (cGS30-RD). CPT code: 81426.
- ❑ Comparator for Reanalysis/Reinterpretation of Clinical Sequencing Data (CS-CA).
- ❑ Sanger Sequencing for Family Members/Targeted Variant Confirmation (CSS-SS). CPT code: 81479 or gene-specific.
- ❑ DNA Extraction and Storage (ENH-BR). CPT code: 81479.

Additional samples:

Name: ______________________ Date of Birth: __________ Relationship to patient: ______________

Status: ❑ Unaffected ❑ Affected with: ________________________________ ❑ Unknown

Name: ______________________ Date of Birth: __________ Relationship to patient: ______________

Status: ❑ Unaffected ❑ Affected with: ________________________________ ❑ Unknown

Name: ______________________ Date of Birth: __________ Relationship to patient: ______________

Status: ❑ Unaffected ❑ Affected with: ________________________________ ❑ Unknown

Name: ______________________ Date of Birth: __________ Relationship to patient: ______________

Status: ❑ Unaffected ❑ Affected with: ________________________________ ❑ Unknown

Name: ______________________ Date of Birth: __________ Relationship to patient: ______________

Status: ❑ Unaffected ❑ Affected with: ________________________________ ❑ Unknown

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6. Variant/Gene List *(applicable for CS-RA and CSS-RR only)*

❏ For Variant Confirmation by Sanger Sequencing: List variants by rs ID or genomic coordinates. Specify reference genome used for genomic coordinates (hg19/GRCh37 or hg38/GRCh38).

❏ For Reanalysis/Reinterpretation of Genes of Interest: List genes/regions of interest.

7. Additional Studies & Research

You/your child has the option to share your contact information with researchers who have an Institutional Review Board (IRB) approved research study for which you/your child may be eligible for participation. There is no obligation to participate if contacted. No information, other than the contact information below, will be provided to the researcher.

❏ YES, HudsonAlpha Clinical Services Lab may share my contact information with researchers. I can be contacted at:

Phone: _____ Email: _____

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

You/your child has the option for HudsonAlpha Clinical Services Lab to contact the physician who ordered this test to discuss research studies that you/your child may be eligible for. There is no obligation to participate if contacted.

❏ YES, HudsonAlpha Clinical Services Lab may contact my/my child's doctor who ordered this test to discuss research studies that I/my child may be eligible for.

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

8. Use of Specimens

HudsonAlpha Clinical Services Lab, LLC is committed to improving testing for future patients. Your sample or test results made anonymous (name and other identifiers removed) could be used in the validation of new genetic testing methods and/or other test-related quality improvement and in published scientific education efforts. The identity of individuals studied will not be revealed in such publications or presentations. You will not receive results from any such 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 for the HudsonAlpha Clinical Services Lab, LLC. I understand that my refusal to consent will not affect my results. Initial for consent or denial below. **If nothing is marked, consent is implied.**

I consent to the use of my deidentified sample for lab improvement (*please initial*). _____ YES _____ NO

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9. Data Sharing

HudsonAlpha Clinical Services Lab, LLC is committed to advancing the wealth of knowledge for genomic medicine. As part of this goal, HudsonAlpha Clinical Services Lab, LLC may submit de-identified sequencing results (name and other identifiers removed) to freely available databases such as ClinVar and GeneMatcher.

I understand that I may refuse to have my results shared in this way and may withdraw my consent at any time by contacting the Laboratory Director for the HudsonAlpha Clinical Services Lab, LLC. I understand that my refusal to consent to data sharing will not affect my results.

I consent to the sharing of my deidentified results (*please initial*). _____ YES _____ NO

10. Request for Incidental Findings *(applicable for WGS40-RR and CS-RA only)*

It is highly recommended that the patient/family receive genetic counseling regarding genomic sequencing before and after the test.

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.

Results are classified into three 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 during analysis. 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.
3. Incidental Findings: Additional findings not related to my/my child's disorder that may indicate a risk for other childhood or adult-onset disease, carrier status, and pharmacogenetic variants. These findings are returned upon request only.

Select which optional incidental findings you wish to have reported (*check all that apply*):

- ❑ 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)
- ❑ NO INCIDENTAL FINDINGS REQUESTED. Retain data for future analysis with no obligation to report.

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11. Consent for Testing

By signing this form, I acknowledge that I have reviewed this Test Requisition Form and authorize HudsonAlpha Clinical Services Lab, LLC to perform genetic testing as described.

Patient (If minor, assent if appropriate)

_____
Print Name

_____ _____
Signature Date (MM/DD/YYYY)

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

_____ _____
Print Name Relationship to Patient

_____ _____
Signature Date (MM/DD/YYYY)

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

_____ _____
Print Name Relationship to Patient

_____ _____
Signature Date (MM/DD/YYYY)

Ordering Physician/Genetic Counselor

_____
Print Name

_____ _____
Signature Date (MM/DD/YYYY)

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12. Billing

- The Responsible Party identified below agrees to pay the full price of the test. **HudsonAlpha Clinical Services Lab, LLC 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 256-327-9670.

Select the appropriate billing option and provide the name of the Responsible Party:

❑ Institutional (must be pre-arranged): _____

❑ Patient/Legal Guardian/Other: _____

Responsible Party Information:

Address: _____ City: _____

State: _____ Zip Code: _____ Phone: _____

Email: _____ Fax: _____

Payment Options:

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

❑ Bill my credit card for 100% pre-payment. HudsonAlpha Clinical Services Lab can only accept credit cards from the US. Please select card type:

❑ Visa ❑ Mastercard ❑ AMEX ❑ Discover
❑ HSA ❑ Debit ❑ Flex Spending ❑ Diners Club

Cardholder Name (as it appears on the card): _____

Card Number: _____ Exp. Date: _____ CCV: _____

I authorize 100% of the cost of the test be charged to my credit card above.

_____ _____
Cardholder Signature Date (MM/DD/YYYY)

HudsonAlpha Clinical Services Lab, LLC does not bill to insurance; however, documentation can be provided to patients wanting to file a claim with their insurance provider.

Contact for billing questions:

Institutional billing:
Phone: 256-327-9670
Fax: 256-327-9760
Email: info@clinicallab.org

Patient/legal guardian/other payment:
Phone: 256-327-0434
Fax: 256-327-9699
Email: billing@clinicallab.org

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13. Specimen Requirements and Shipping Instructions

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

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

Oncology Specimen Requirements

✓HudsonAlpha Clinical Services Lab, LLC does not perform extraction of DNA from oncology specimens.
✓Extraction must be performed by a CLIA-certified laboratory (or equivalent outside USA) and sent to HudsonAlpha Clinical Services Lab, LLC.

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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