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) ❑ Saliva ❑ 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 only).

OPTIONAL: Photo(s) of patient

3. Ordering Clinician Information

Deliver report to:

Name: _____

Department/Institution: _____

Address: _____ City: _____

State: _____ Zip Code: _____ Email: _____

Phone: _____ Fax: _____

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

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4. Test(s) Ordered

DNA Extraction and Storage

❑ **DNA Extraction & Storage - Blood (ENH-BR).** DNA isolation from blood. Includes quality assessment and sample storage. DNA extracted from blood can be used for all follow-up testing.

❑ **DNA Extraction & Storage - Saliva (ENH-SR).** DNA isolation from saliva. Includes quality assessment and sample storage. DNA extracted from saliva cannot be used for genome sequencing.

Clinical Genome Sequencing

❑ **Clinical Genome Sequencing + Interpretation (cGS30-RR).** The sample will have clinical genome sequencing (30X coverage), quality assessment, and data analysis. Clinically relevant findings will be reported with interpretation. 40X coverage is available upon request (additional fees apply). Contact the CSL for more information. CPT code: 81425.

Reanalysis & Reinterpretation

❑ **Reanalysis/Reinterpretation of Internal Clinical Sequencing Data (iCRA)**. For reanalysis of sequencing previously performed by the HudsonAlpha Clinical Services Lab only. Clinical report with interpretation will be provided. Orthogonal confirmation of primary findings is included if sufficient patient DNA is available.

- ❑ Targeted reanalysis (*complete section 6*)
  - ❑ 1 - 5 genes (iCRA-5) ❑ 6 - 25 genes (iCRA-25) ❑ 26 - 100 genes (iCRA-100)
- ❑ Reanalysis of entire genome (iCRA-GS; CPT code: 81427)

❑ **Reanalysis/Reinterpretation of External Clinical Sequencing Data (eCRA)**. For reanalysis of clinical sequencing performed by an external CLIA-certified laboratory. Clinical report with interpretation will be provided. Orthogonal confirmation of findings is not included. Please complete a *Request for Reanalysis/Reinterpretation* form.

- ❑ Targeted reanalysis (*complete section 6*)
  - ❑ 1 - 5 genes (eCRA-5) ❑ 6 - 25 genes (eCRA-25) ❑ 26 - 100 genes (eCRA-100)
- ❑ Reanalysis of entire exome (eCRA-ES; CPT code: 81417)
- ❑ Reanalysis of entire genome (eCRA-GS; CPT code: 81427)

❑ **Reanalysis/Reinterpretation of External Research Sequencing Data (eRRA).** For reanalysis of sequencing performed in a research laboratory. Research report with interpretation will be provided. Orthogonal confirmation of findings is not included. Please complete a *Request for Reanalysis/Reinterpretation* form.

- ❑ Targeted reanalysis (*complete section 6*)
  - ❑ 1 - 5 genes (eRRA-5) ❑ 6 - 25 genes (eRRA-25) ❑ 26 - 100 genes (eRRA-100)
- ❑ Reanalysis of entire exome (eRRA-ES; CPT code: 81417)
- ❑ Reanalysis of entire genome (eRRA-GS; CPT code: 81427)

Global Screening Array

❑ **Global Screening Array + Interpretation (GSA).** Select all findings to be reported:

- ❑ Pharmacogenetics (GSA-PG)
- ❑ Adult-Onset Actionable Variant Status (i.e., ACMG 59) (GSA-59)
- ❑ Carrier Status (GSA-CS)

Targeting Variant Testing

❑ **Targeted Variant Sequencing (CSS-RR).** Complete *Section 6*. Includes variant interpretation.

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5. Additional Samples

Test(s) to be performed on additional samples (*check all that apply*):

- ❑ **DNA Extraction & Storage - Blood (ENH-BR).** DNA isolation from blood, quality assessment, and sample storage.
- ❑ **DNA Extraction & Storage - Saliva (ENH-SR).** DNA isolation from saliva, quality assessment, and sample storage.
- ❑ **Comparator Clinical Genome Sequencing (cGS30-CR).** Each additional sample will receive clinical genome sequencing (30X coverage) and quality assessment for comparison to the proband in segregation analyses. Report to be issued for proband only. CPT code: 81426.
- ❑ **Comparator Orthogonal Confirmation (CSS-CS).** Orthogonal confirmation of proband's primary findings for segregation analysis. Report to be issued for proband only.
- ❑ **Comparator Reanalysis/Reinterpretation of Internal Sequencing Data (iCRA-CR).** Orthogonal confirmation of findings is not included. Report to be issued for proband only.
- ❑ **Comparator Reanalysis/Reinterpretation of External Sequencing Data (eRA-CR).** Orthogonal confirmation of findings is not included. Report to be issued for proband only.
- ❑ **Targeted Variant Sequencing (CSS-RR).** Complete *Section 6*. Includes variant interpretation. Reports will be issued for each sample provided.

Additional samples: Note that erroneous representation of familial relationships may be detected by this assay and could limit the utility of the samples provided. Attach additional pages as needed.

Comparator 1: ❑ Unaffected ❑ Affected with: _____ ❑ Unknown

Name	Date of Birth	Relationship to patient

Comparator 2: ❑ Unaffected ❑ Affected with: _____ ❑ Unknown

Name	Date of Birth	Relationship to patient

Comparator 3: ❑ Unaffected ❑ Affected with: _____ ❑ Unknown

Name	Date of Birth	Relationship to patient

Comparator 4: ❑ Unaffected ❑ Affected with: _____ ❑ Unknown

Name	Date of Birth	Relationship to patient

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

- ❑ For variant confirmation by Sanger sequencing: List variants by rsID or genomic coordinates. Specify reference genome used for genomic coordinates (hg19/GRCh37 or hg38/GRCh38).
- ❑ For reanalysis of genes of interest: List genes/regions of interest. Attach additional pages as needed.

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7. 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.

8. 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.

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9. 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.

Checking the box below indicates that you **do not** want HudsonAlpha Clinical Services Lab, LLC to use your sample or test results after testing for the purposes described in this section. (If the box is not checked, you are giving HudsonAlpha Clinical Services Lab, LLC permission to use your sample or test results for the purposes stated above.)

Patient (individual listed in Section 1): Opt Out ❑

Comparator 1 (if applicable): Opt Out ❑

Comparator 2 (if applicable): Opt Out ❑

Comparator 3 (if applicable): Opt Out ❑

Comparator 4 (if applicable): Opt Out ❑

10. 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 results without personal health information (PHI, such as name or date of birth) 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; however, any results shared prior to withdrawal may not be removed. I understand that my refusal to consent to data sharing will not affect my results.

Checking the box below indicates that you **do not** want HudsonAlpha Clinical Services Lab, LLC to submit your results (without identifiable information) to public databases. (If the box is not checked, you are giving HudsonAlpha Clinical Services Lab, LLC permission to share your test results as stated above.)

Patient (individual listed in Section 1): Opt Out ❑

Comparator 1 (if applicable): Opt Out ❑

Comparator 2 (if applicable): Opt Out ❑

Comparator 3 (if applicable): Opt Out ❑

Comparator 4 (if applicable): Opt Out ❑

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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)

Ordering Clinician

Print Name

Signature | Date (MM/DD/YYYY)

Comparator 1 (if applicable)

Print Name

Signature | Date (MM/DD/YYYY)

Comparator 2 (if applicable)

Print Name

Signature | Date (MM/DD/YYYY)

Comparator 3 (if applicable)

Print Name

Signature | Date (MM/DD/YYYY)

Comparator 4 (if applicable)

Print Name

Signature | Date (MM/DD/YYYY)

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12. Billing

The Responsible Party identified below shall pay 100% of the test price prior to initiation of testing. **HudsonAlpha Clinical Services Lab, LLC will not process 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.

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% prepayment. 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 to be charged to my credit card above.

_____ _____

Cardholder Signature Date (MM/DD/YYYY)

HudsonAlpha Clinical Services Lab, LLC does not bill 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: 256-327-9760
Email: billing@clinicallab.org

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13. Specimen Requirements and Shipping Instructions

Specimen Requirements

Label specimens with at least two identifiers; patient name and date of birth are preferred but medical record or study identifier is also acceptable. The corresponding identifiers must be included on the corresponding test requisition form. Unlabeled or improperly labeled specimens will be rejected. The HudsonAlpha Clinical Services Lab does not accept products of whole genome amplification reactions or other amplification reactions. Additional requirements vary by specimen type.

Blood Specimens

Requirements

✓Collect 2-4ml of whole blood in 1 EDTA (lavender top) tube per patient. For infants, a minimum of 1ml is required.
✓Specimens should be submitted within 48 hours of collection to allow extraction within 2-7 days of collection.

Rejection Criteria

✓Specimen is coagulated.
✓Quantity is less than 1ml.
✓Specimen was collected in the wrong tube type.

Saliva Specimens

Requirements

✓Collect saliva using an approved kit and following the manufacturer's instructions provided with the kit.
✓Saliva specimens should NOT be submitted for genome sequencing without prior authorization.

Rejection Criteria

✓Specimen collected in a kit other than an approved kit. See the CSL website for details.
✓Insufficient specimen collected.

DNA Specimens

Requirements

✓DNA specimens are only accepted from CLIA-certified laboratories. CLIA License Number (Federal and state, if applicable) is required. Qiagen kits recommended.
✓For DNA quantitated via spectrophotometry: Submit a screw cap tube of at least 5ug of purified DNA at a concentration of at least 60ng/ul with a 260/280 purity ratio of 1.75 – 2.0.
✓For DNA quantitated via fluorometric assay (PicoGreen, Qubit): Submit a screw cap tube of at least 3ug of purified DNA at a concentration of at least 50ng/µl.

Rejection Criteria

✓Degraded sample.
✓Insufficient quantity of DNA.
✓Sample not extracted in a CLIA laboratory.

Shipping Instructions

Deliveries are accepted Monday-Friday, 8AM-5PM. Submitter is responsible for all shipping costs.*
✓Ship specimens overnight at room temperature (blood specimens should be in an insulated container).
✓Include corresponding Test Requisition Form with specimens.
✓Submit a complete Hazardous Materials Declaration with the specimens.
✓If the order has not been submitted to the CSL Portal, notify the laboratory at submission@clinicallab.org that a specimen was sent to ensure timely arrival.

Ship specimens to:

HudsonAlpha Clinical Services Lab, LLC
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