The HudsonAlpha CLINICAL SERVICES LAB®

HudsonAlpha Clinical Services Lab, LLC
601 Genome Way, Rm 3001
Huntsville, AL 35806
256-327-9670 ● info@clinicallab.org

GENOME SEQUENCING TEST REQUISITION AND CONSENT FORM

1. PHYSICIAN COMPLETE

1A. Patient Information

Patient Name: _____ _____
Last First

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

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

Race: ❑ Native American or Alaskan ❑ Native Hawaiian or Pacific Islander ❑ Black/African American ❑ East Asian ❑ South Asian ❑ Middle Eastern ❑ White/Caucasian ❑ Other: _____

Ethnicity: ❑ Hispanic or Latino ❑ Not Hispanic or Latino

Ashkenazi Jewish: ❑ Yes ❑ No

1B. Sample Information

Sample Type: ❑ Blood (EDTA) ❑ Saliva (Oragene) ❑ DNA (extracted) **Date Collected:**_____

Has the patient had prior testing at the HudsonAlpha Clinical Services Lab? ❑ No ❑ Yes, Lab ID: _____

Has a relative of the patient had prior testing at the HudsonAlpha Clinical Services Lab? ❑ No ❑ Yes

Relative's Name: _____ Date of Birth: _____

Relationship to Patient: _____ Lab ID: _____

1C. Test(s) Ordered

❒ **Diagnostic Whole Genome Sequencing (WGS-DX)**

Includes: DNA extraction, as applicable; 30X whole genome sequencing; variant analysis and interpretation; and clinical report of relevant diagnostic findings and requested secondaries (see page 4). Final report issued in ≤60 days.

Required: Medical and family history. Photographs are optional.

❒ **STAT Whole Genome Sequencing (WGS-STAT)**

Includes: DNA extraction, as applicable; 30X whole genome sequencing; variant analysis and interpretation; and clinical report of relevant diagnostic findings and requested secondaries (see page 4). Preliminary report issued in 5-12 days; final report issued in ≤45 days. Saliva not accepted for STAT Genome.

Required: Medical and family history. Photographs are optional.

❒ **Elective Whole Genome Sequencing (WGS-ELEC)**

Includes: DNA extraction, as applicable; 30X whole genome sequencing; variant analysis and interpretation; and clinical report of relevant findings and requested secondaries (see page 4). Final report issued in ≤60 days.

Required: Medical and family history.

❒ **Reanalysis/Reinterpretation (RR-PA)**

Includes: Data reprocessing; variant analysis and interpretation; and clinical report of relevant findings and requested secondaries (see page 4). Final report issued in ≤45 days. For targeted reanalysis, please provide a gene list.

Required: Medical and family history. Photographs are optional.

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Patient Name: **DOB**:

1D. Additional Samples

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

❑ **Comparator Whole Genome Sequencing (WGS-CGS).** Each additional sample will receive clinical genome sequencing (30X coverage) and quality assessment for comparison to the proband in segregation analyses. CPT code: 81426.

❑ **Comparator Segregation Testing (WGS-SEG).** Segregation analysis of proband's primary findings from WGS via Sanger sequencing or copy number testing.

❑ **Comparator Reanalysis/Reinterpretation (RR-CA).** Orthogonal confirmation of findings is not included.

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. Report to be issued for proband only.

Comparator 1: Sample Type: ❑ Blood ❑ Saliva ❑ DNA (extracted) Date Collected: _____

_____ _____ _____
Name Date of Birth Relationship to patient

❑ Unaffected ❑ Affected with: _____ ❑ Unknown

Comparator 2: Sample Type: ❑ Blood ❑ Saliva ❑ DNA (extracted) Date Collected: _____

_____ _____ _____
Name Date of Birth Relationship to patient

❑ Unaffected ❑ Affected with: _____ ❑ Unknown

Comparator 3: Sample Type: ❑ Blood ❑ Saliva ❑ DNA (extracted) Date Collected: _____

_____ _____ _____
Name Date of Birth Relationship to patient

❑ Unaffected ❑ Affected with: _____ ❑ Unknown

Comparator 4: Sample Type: ❑ Blood ❑ Saliva ❑ DNA (extracted) Date Collected: _____

_____ _____ _____
Name Date of Birth Relationship to patient

❑ Unaffected ❑ Affected with: _____ ❑ Unknown

1E. Ordering Clinician Information

Name: _____ **NPI:** _____

Department/Institution: _____

Address: _____ **City:** _____

State: _____ **Zip Code:** _____ **Email:** _____

Phone: _____ **Fax:** _____

Ordering Clinician Signature (required)

_____ _____
Signature Date (MM/DD/YYYY)

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Patient Name:	**DOB**:

1F. 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

- ✓2-4ml of whole blood collected 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.

Rejection Criteria

- ✓Specimen is coagulated.
- ✓Quantity is less than 1mL.
- ✓Collected in the wrong tube type.

Saliva Specimens

Requirements

- ✓Saliva collected in an FDA-approved Oragene OGD-600 or OGD-675 kit following the manufacturer's instructions provided with the kit.
- ✓Specimen must be submitted in original collection tube.

Rejection Criteria

- ✓Specimen collected in a kit other than an FDA-approved Oragene OGD-600 or OGD-675 kit.
- ✓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 and resuspension in elution buffer recommended.
- ✓Purified DNA should be submitted in screw cap tube with minimum 3 µg at ≥20 ng/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 blood and saliva specimens overnight at room temperature. Blood specimens should be in an insulated container and leak-proof packaging.
- ✓Ship extracted DNA overnight on dry ice in an insulated container.
- ✓Include Test Requisition Form/manifest 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
601 Genome Way, Rm 3001
Huntsville, AL 35806

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Patient Name:	**DOB**:

2. PATIENT COMPLETE

2A. Request for Secondary Findings

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/the patient'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/the patient.
2. I may learn that no specific DNA variants were detected that may explain my/the patient's disorder(s). This outcome does not mean that I/the patient 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/the patient'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/the patient'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/the patient'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/the patient'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 73 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.

2B. Additional Studies & Research

You have the option to share your contact information with researchers who have an Institutional Review Board (IRB) approved research study for which you 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 have the option for HudsonAlpha Clinical Services Lab to contact the physician who ordered this test to discuss research studies that you may be eligible for. There is no obligation to participate if contacted.

- ❑ YES, HudsonAlpha Clinical Services Lab may contact my doctor who ordered this test to discuss research studies that I may be eligible for.

- ❑ NO, I DO NOT want my doctor contacted regarding research studies.

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2C. 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 ❑

2D. 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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Patient Name:	**DOB**:

2E. 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 or Patient Representative

❑ I am the patient.

❑ I am authorized to execute the consent on behalf of the patient as the patient's parent, legally-authorized representative, or custodian.

Print Name _____ Relationship to Patient _____

Signature _____ Date (MM/DD/YYYY) _____

Comparator 1 (if applicable)

❑ I am the individual listed as Comparator 1.

❑ I am authorized to execute the consent on behalf of the individual listed as Comparator 1 as the individual's parent parent, legally-authorized representative, or custodian.

Print Name _____ Relationship to Comparator 1 _____

Signature _____ Date (MM/DD/YYYY) _____

Comparator 2 (if applicable)

❑ I am the individual listed as Comparator 2.

❑ I am authorized to execute the consent on behalf of the individual listed as Comparator 2 as the individual's parent parent, legally-authorized representative, or custodian.

Print Name _____ Relationship to Comparator 2 _____

Signature _____ Date (MM/DD/YYYY) _____

Comparator 3 (if applicable)

❑ I am the individual listed as Comparator 3.

❑ I am authorized to execute the consent on behalf of the individual listed as Comparator 3 as the individual's parent, legally-authorized representative, or custodian.

Print Name _____ Relationship to Comparator 3 _____

Signature _____ Date (MM/DD/YYYY) _____

Comparator 4 (if applicable)

❑ I am the individual listed as Comparator 4.

❑ I am authorized to execute the consent on behalf of the individual listed as Comparator 4 as the individual's parent, legally-authorized representative, or custodian.

Print Name _____ Relationship to Comparator 4 _____

Signature _____ Date (MM/DD/YYYY) _____

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Patient Name:	**DOB**:

3. 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/Legally Authorized Representative/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