

**TARGETED VARIANT 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  Middle Eastern  Other: \_\_\_\_\_  
 South Asian  White/Caucasian  
**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**

**Targeted Variant Testing (Sanger Sequencing) (TVT-SS)**

**Includes:** DNA extraction, as applicable; Sanger sequencing; variant analysis and interpretation; and clinical report. Final report issued in ≤28 days.

**Required:** Medical and family history. Variant(s) requested: \_\_\_\_\_

**Targeted Variant Testing (Copy Number Testing) (TVT-CNV)**

**Includes:** DNA extraction, as applicable; TaqMan qPCR testing; variant analysis and interpretation; and clinical report. Final report issued in ≤28 days.

**Required:** Medical and family history. Variant(s) requested: \_\_\_\_\_

**1D. Family Members**

No family members being sent for testing.

Additional family members sent for testing (requisition required for each sample):

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_ Relationship: \_\_\_\_\_

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_ Relationship: \_\_\_\_\_

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_ Relationship: \_\_\_\_\_

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_ Relationship: \_\_\_\_\_

<b>Patient Name:</b> _____	<b>DOB:</b> _____
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**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)

**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 500 ng at ≥5 ng/μL.

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

**Patient Name:**

**DOB:**

### 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 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](mailto: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

## 2. PATIENT COMPLETE

### 2A. 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.

### 2B. 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.)

- I wish to OPT OUT of the use of my/the patient's sample for laboratory improvement and/or validation purposes.

<b>Patient Name:</b>	<b>DOB:</b>
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**2C. 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.)

I wish to OPT OUT of the sharing of my/the patient's deidentified data.

**2D. 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)

**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:
- |                               |                                     |  |                                      |
|-------------------------------|-------------------------------------|--|--------------------------------------|
| <input type="checkbox"/> Visa | <input type="checkbox"/> Mastercard | <input type="checkbox"/> AMEX          | <input type="checkbox"/> Discover    |
| <input type="checkbox"/> HSA  | <input type="checkbox"/> Debit      | <input type="checkbox"/> Flex Spending | <input type="checkbox"/> 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