The HudsonAlpha CLINICAL SERVICES LAB®

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

POPULATION SCREENING TEST REQUISITION AND CONSENT FORM

1. PHYSICIAN COMPLETE

1A. Patient Information

Patient Name: ____
Last First

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

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

Date Sample Collected: ______________________________

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

1C. Test(s) Ordered

❒ **Pharmacogenetics Panel (ARR-PGX)**

Required: List of current medications (page 3). Testing includes DNA extraction, as applicable; array-based clinical assay; variant analysis and interpretation; and clinical report of relevant pharmacological findings

❒ **Adult-Onset Disease Risk Screening (ARR-AOA)**

Required: Family history (page 4). Testing includes DNA extraction, as applicable; array-based clinical assay; analysis and interpretation of adult-onset actionable disease risk genes (see ACMG SF v3.0 for complete list); and clinical report of relevant actionable findings.

❒ **Carrier Screening (ARR-CS)**

Required: Family history (page 4). Testing includes DNA extraction, as applicable; array-based clinical assay; variant analysis and interpretation; and clinical report of carrier findings.

1D. 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**:

1E. 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 1 μg at ≥12.5 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 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:

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Patient Name: **DOB**:

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.

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.

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2D. Current Medication List (*for Pharmacogenetics Panel orders*)

List all vitamins, supplements, and over-the-counter medications below. A printout attached to this form is preferred.

❑ NO CURRENT MEDICATIONS, VITAMINS, SUPPLEMENTS, OR OTCS

____

____

____

____

2E. Health History (*for Adult-Onset Disease Risk and Carrier Screening orders*)

When available, provide age of diagnosis of disease for first-degree (parents, siblings, and children) and second-degree (half-siblings, grandparents, aunts, and uncles). ❑ Check here if family medical history is unavailable/unknown.

Condition:	Self:	First-Degree Relative:	Second-Degree Relative:
Breast Cancer	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)
Ovarian Cancer	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)
Uterine/Endometrial Cancer	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)
Thyroid Cancer	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)
Colon Cancer	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)
Prostate Cancer	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)
Kidney Cancer	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)
Pancreatic Cancer	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)
Other Cancer	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)
High Cholesterol	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)
Cardiomyopathy	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)
Arrhythmia	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)
Large Blood Vessel Aneurysm/Dissection	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)
Heart Attack/Cardiac Arrest Before Age 50	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)	❑ No ❑ Yes (age: ______)

2F. 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) ______________________

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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