The HudsonAlpha CLINICAL SERVICES LAB

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

ONCOLOGY TEST REQUISITION AND CONSENT FORM

1. PHYSICIAN COMPLETE

1A. Patient Information

Patient Name: _____ _____
Last First

Date of Birth: _____ **Medical Record Number/SMART ID**: _____
(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

Diagnosis ICD-10 code: _____ **Patient Stage:** _____

Patient status: ❑ Outpatient ❑ Inpatient **Discharge Date:** _____

1B. Sample Information

Sample Type: ❑ FFPE block ❑ 10 unstained slides + 1 H&E stained slide ❑ Tumor DNA* ❑ Tumor RNA*

**For DNA and RNA, review requirements in section 1E.*

Surgical Pathology Number: _____ **Diagnosis:** _____

Date of Sample Collection: _____

Sample Handling (e.g., acid decalcification): _____

Pathology Department/Institution Contact Information (if sample retrieval is required):

Institution Name/Contact: _____ Phone: _____

Email: _____ Fax: _____

1C. Tests/Services Ordered

❒ TruSight Tumor 170 (TST-RR)

Includes: Pathological evaluation and microdissection of sample(s), nucleic acid extraction (as applicable), TruSight Tumor 170 sequencing panel, quality assessment, and data analysis. Findings are reported with clinical annotations. (CPT 81479 or 81455 depending on payor, 88381).

❒ TruSight Oncology 500 High-Throughput (TSO-RR)

Includes: Pathological evaluation and microdissection of sample(s), nucleic acid extraction (as applicable), TruSight Oncology 500 (High-Throughput) sequencing panel, quality assessment, and data analysis. Findings are reported with clinical annotations. (CPT 81479 or 81455 depending on payor, 88381).

❒ Molecular Pathologist Interpretation of Molecular Findings

Includes: Expert Molecular Genetic Pathologist review of the findings and interpretation of results, providing clinical guidance based on often complex findings. These are highlighted in the Interpretation or Summary sections of the report. (HCPCS G0452).

❒ Clinical Pathology Consultation of the Molecular Test Findings

Includes: Expert Molecular Pathologist review of test result findings and clinical records and/or questions to make specific recommendations based on relevant patient history. These are highlighted in the Interpretation or Summary sections of the report. (CPT 88325).

Required: Recent clinic note, summarizing patient course and treatment, and/or clinical question.

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Patient Name: **DOB**:

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)

1E. Specimen Requirements and Shipping Instructions

Specimen Requirements

*****HUDSONALPHA CLINICAL SERVICES LAB CANNOT ACCEPT SAMPLES FROM NEW YORK*****

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 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.

FFPE Blocks or Slides

Instructions/Requirements

PREFERRED FFPE blocks: Please select a block that is representative of the tumor and has a minimum of ~20% tumor cellularity (by nuclei).
Slides: Please submit 10 consecutive, unstained slides of 8-10 microns. Also submit an H&E stained slide if available, and if not available, an 11th slide for staining.

Rejection criteria

Blocks or slides with <20% tumor cellularity may be rejected if microdissection cannot sufficiently provide adequate tumor material for analysis. Other causes for rejection include significant tumor necrosis, improper fixation, or treatment with acid decalcification.

Tumor DNA/RNA Specimens

Requirements

✓DNA/RNA specimens are only accepted from CLIA-certified laboratories. CLIA License Number (Federal and state, if applicable) is required. Qiagen All Prep kits must be used for isolation.
✓DNA: minimum concentration 10 ng/uL, minimum volume of 25 uL
✓RNA: minimum concentration of 10 ng/uL, minimum volume of 20 uL

Rejection Criteria

Samples will be rejected if not extracted in a CLIA laboratory, or if the sample is degraded or of insufficient quantity.

Shipping Instructions

*****Deliveries are accepted Monday-Friday, 8AM-5PM. Submitter is responsible for all shipping costs.*****
✓Ship FFPE blocks or slides overnight on ice packs. Ensure slides are properly packaged to prevent breaking.
✓Ship extracted DNA/RNA overnight on dry ice in an insulated container.
✓Include corresponding Test Requisition Form with specimens.
✓Submit a complete Hazardous Materials Declaration with the specimens.
✓**Notify the laboratory at submission@clinicallab.org that a specimen was sent to ensure timely arrival.**

Ship DNA/RNA specimens to:	**Ship FFPE slides/blocks specimens to:**
HudsonAlpha Clinical Services Lab, LLC	HudsonAlpha Clinical Services Lab, LLC; C/O BWPG Lykos Labs
601 Genome Way, Rm 3001	26797 Hanna Rd. Ste 401D
Huntsville, AL 35806	Conroe, TX 77381

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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 the doctor who ordered this test to discuss research studies that I may be eligible for.

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

2B. Use of Specimens

HudsonAlpha Clinical Services Lab, LLC is committed to improving testing for future patients. The provided 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 the sample.

I understand that I may refuse to submit specimens for use in this way and may withdraw 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 samples 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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Patient Name: **DOB**:

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. I understand that the testing described above is intended for the detection of somatic variation as it affects my potential treatment options. Germline variation associated with hereditary cancer susceptibility may also be detected by this assay; such variation will be reported if detected. This test is not intended to diagnose disease.

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)

3. BILLING

Select the appropriate billing option: ❑ Self-Pay ❑ Institutional (must be pre-arranged)

Responsible Party Information

Address: _____ City: _____

State: _____ Zip Code: _____ Phone: _____

Email: _____ Fax: _____

Self-Pay

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 US credit cards. 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)

Contact for billing questions:

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

Self-Pay:
Phone: 256-327-0434
Fax: 256-327-9760
Email: billing@clinicallab.org