

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:

- 2-4 mL of whole blood collected in 1 EDTA (lavender top) tube per patient. For infants, a minimum of 1 mL is required.
- Specimens should be submitted within 48 hours of collection.

Rejection Criteria:

- Specimen is coagulated.
- Quantity is less than 1 mL.
- 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.

FFPE Blocks or Slides

Requirements:

- FFPE blocks (*preferred*): select a block that is representative of the tumor and has a minimum of ~20% tumor cellularity (by nuclei).
- Slides: submit 10 consecutive, unstained slides of 8-10 µm. Also submit an H&E stained slide if available, and if not available, an 11th slide for staining. If the slides are labeled with only one identifier, they must be securely submitted in a container labeled with two identifiers.

Rejection Criteria:

- Blocks or slides with <20% tumor cellularity may be rejected if microdissection cannot sufficiently provide adequate tumor material for analysis.
- Significant tumor necrosis, improper fixation, or treatment with acid decalcification.
- Broken slides.

DNA/RNA 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 as follows:
 - ◆ WGS tests: minimum 3 µg at ≥20 ng/µL
 - ◆ Disease risk, carrier screening, and pharmacogenetics tests: minimum 1 µg at ≥12.5 ng/µL
 - ◆ Targeted variant tests: minimum 500 ng at ≥5 ng/µL
 - ◆ Oncology tests: minimum 250 ng at ≥10 ng/µL
- Purified RNA for oncology tests should be submitted in a screw cap tube with minimum 200 ng at ≥10 ng/µL. AllPrep kit preferred for DNA/RNA extraction from FFPE.

Rejection Criteria:

- Degraded sample.
- Insufficient quantity of DNA/RNA.
- Sample not extracted in a CLIA laboratory.

Accepted Specimen Types by Test					
Test	Blood (EDTA)	Saliva*	Extracted DNA	Extracted RNA	FFPE
Extraction and Storage	X	X			X
Whole Genome Sequencing Tests	X	X	X		
Disease Risk Screening	X	X	X		
Carrier Screening	X	X	X		
Pharmacogenetics Panel	X	X	X		
Targeted Variant Testing (e.g., Sanger)	X	X	X		
Oncology Tests			X	X	X

*Saliva must be collected in an FDA-approved Oragene OGD-600 or ODG-675 kit.

Shipping Instructions	
<p>**Deliveries are accepted Monday-Friday, 8AM-5PM. Submitter is responsible for all shipping costs.**</p> <p>Note: Under special circumstances, weekend deliveries may be accepted. Please contact the CSL prior to shipping.</p> <ul style="list-style-type: none"> ✓ Ship blood and saliva specimens overnight at room temperature. Blood specimens should be in an insulated container and leak-proof packaging. ✓ 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 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@clinicalab.org that a specimen was sent to ensure timely arrival. 	
<p><u>Ship FFPE slides or blocks to:</u></p> <p>HudsonAlpha Clinical Services Lab, LLC; C/O BWPG Lykos Labs 26797 Hanna Rd. Ste 401D Conroe, TX 77381</p>	<p><u>Ship all other specimens to:</u></p> <p>HudsonAlpha Clinical Services Lab, LLC 601 Genome Way, Rm 3001 Huntsville, AL 35806</p>