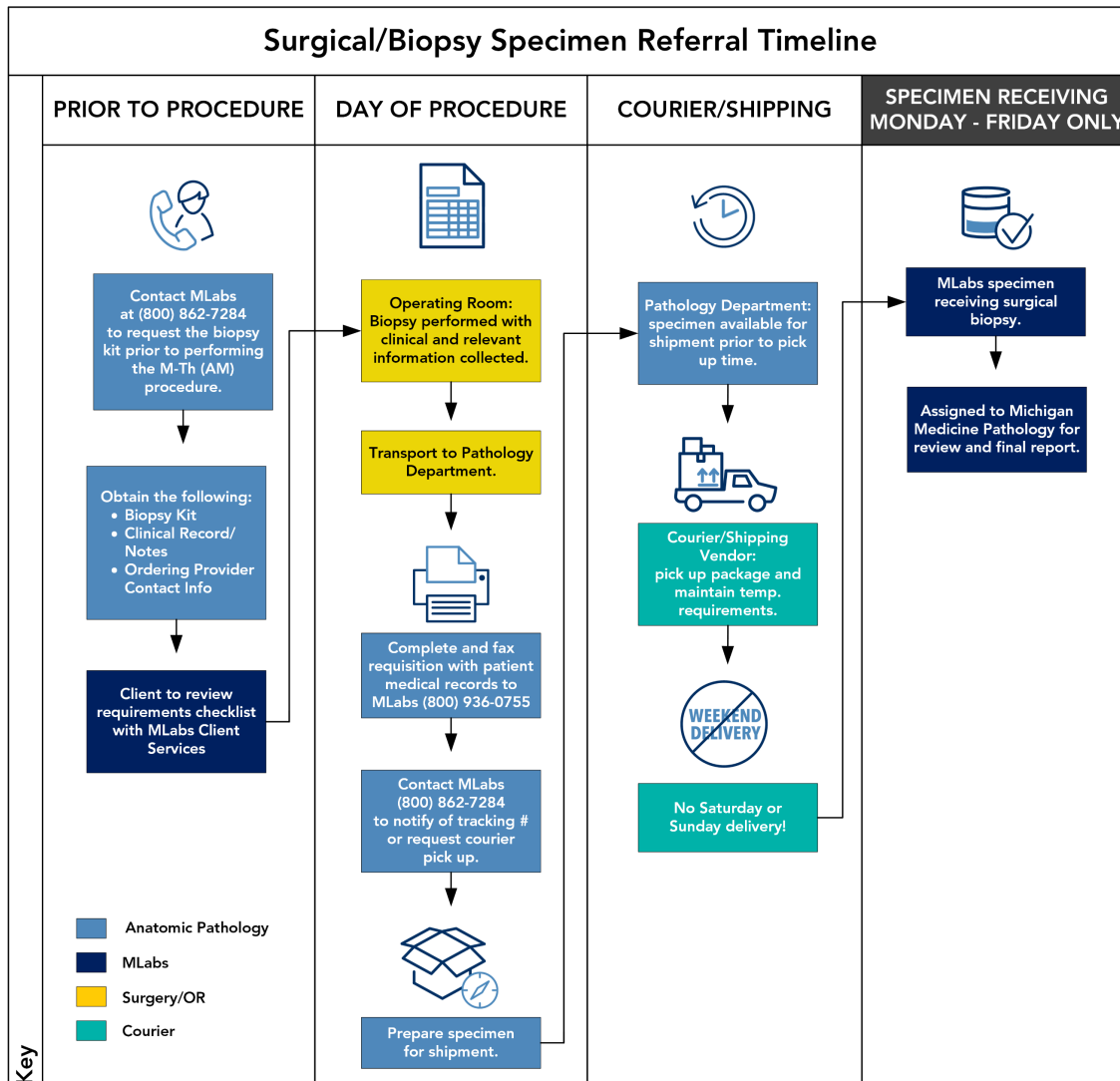


RENAL BIOPSY TISSUE SUBMISSION PROTOCOL

Please notify Michigan Medicine Laboratories (MLabs) Client Services prior to sending a renal biopsy specimen. Renal biopsy collection kits are available from MLabs and will be required in advance of the procedure. The glutaraldehyde fixative included in the kit must be refrigerated until ready for use; the entire kit may be refrigerated. MLabs Client Services can be reached at **800.862.7284** or **734.936.2598** (local). Please fax all associated paperwork to FAX **734.936.0755** prior to or at the time of notification to MLabs of the arriving specimen.

If STAT or RUSH results are required, the clinician requesting the biopsy (e.g., the nephrologist, rheumatologist, or primary care provider) must speak directly with the on-call renal pathologist and provide the patient's clinical history and contact information for results. The Renal Pathology Office can be reached at 734.647.2921.

A renal biopsy is performed to diagnose or monitor treatment for kidney disease. Renal biopsies are processed for light microscopy with special stains, plastic embedding/electron microscopy (EM), and immunofluorescence (IF) microscopy. The evaluation requires both specific surgical technique and unique handling that differs from routine tissue submitted for pathology evaluation. MLabs recommends that renal biopsy procedures be performed Monday through Thursday and in the morning. This ensures that specimen handling can be completed in advance of pick up at your location.



RENAL BIOPSY TISSUE SUBMISSION PROTOCOL



Resources Needed for this Protocol

- MLabs Client Services phone number (**800.862.7284** or **734.936.2598**)
- HIPAA secure fax method
- Shipment or courier method
- MLabs renal biopsy kit
- Items included in renal biopsy kit
 - Test requisition form
 - Patient specimen labels (3)
 - Specimen container with formalin fixative
 - Specimen container with glutaraldehyde fixative (store refrigerated)
 - Specimen container with Zeus/Michel's fixative
 - Refrigerated specimen bag, absorbent pad, bubble wrap
 - UPS Laboratory Pak, FedEx Clinical Pak, or courier transport bag and return service label
- Renal cortex cores from patient biopsy
 - Three (3) separate cores (16-18 gauge) of renal cortex
- Dissecting microscope or inverted microscope ocular
- Telfa gauze pad(s) or Petri dish
- Sterile saline
- Scalpel or razor blade
- Toothpick or blunt probe
- Refrigerator

Preparation Instructions

1. Three (3) separate cores (16-18 gauge) of renal cortex are preferred.
2. Immediately upon obtaining tissue, place the biopsy specimen(s) in saline solution in a Petri dish or wrap specimen in saline saturated gauze.
3. Using a dissecting microscope, inverted microscope ocular, or smartphone with snap-on macro lens, examine the core(s) for the presence of punctate blood-filled glomeruli. Do not crush tissue with instruments.
4. Please complete the [MLabs Renal Biopsy Requisition](#) that is provided in the renal biopsy collection kit. Send a copy of the patient's most recent comprehensive medical record from the requesting clinician, such as an outpatient clinical note, inpatient consultation note, or discharge summary that includes relevant laboratory test results, clinical history, family history, current medications, assessment and plan to MLabs with the specimens. See Required Information page 4 for a detailed listing of the information to include.
5. See also Specimen Handling page 2, Packaging and Transport page 5, and Packaging Diagram page 6.

Specimen Handling

Specimens should be shipped or transported to arrive Monday – Friday by 5:00 PM, excluding holidays. Specimens cannot be accepted during observed Michigan Medicine holidays. Please contact MLabs Client Services for observed holiday dates and hours. Specimens that cannot be shipped for arrival within these timeframes should be refrigerated

RENAL BIOPSY TISSUE SUBMISSION PROTOCOL

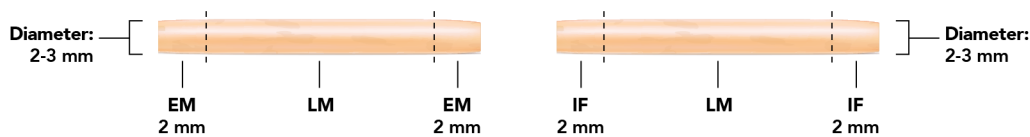


until ready to ship.

FIXED TISSUE

1. Place each of the three (3) cores into the three separate fixatives using a toothpick or blunt probe taking care not to crush the tissue:
 - a. **FORMALIN FIXED TISSUE:** place in 10% neutral buffered formalin (for light microscopy). Store and transport at room temperature or refrigerated.
 - b. **GLUTARALDEHYDE FIXED TISSUE:** place in glutaraldehyde (for electron microscopy). Refrigerate until ready to ship.
 - c. **ZEUS/MICHEL'S FIXED TISSUE:** place in Zeus/Michel's (for immunofluorescence microscopy). Store and transport at room temperature or refrigerated.
2. If the specimen floats in the fixative, it is probably adipose tissue and not renal parenchyma. In this case an additional core or divisions are required.
3. If three (3) cores cannot be obtained, see below for options. Refer to the Modern Pathology article "Practice guidelines for the renal biopsy" for additional guidance <https://www.nature.com/articles/3800239>.
4. If only two (2) cores were obtained, divide with alcohol cleaned razor blades. Cut 2 mm fragments from the ends of each core and transfer them to the glutaraldehyde and Zeus/Michel's fixatives, then place the remainder in formalin.

2 Cores

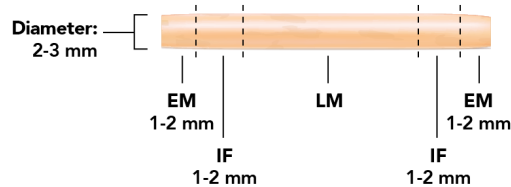


LM: Light Microscopy – Formalin
IF: Immunofluorescent Histology – Zeus/Michel's
EM: Electron Microscopy – Glutaraldehyde

5. If only one (1) core is available, divide using a dissecting scope so that adequate (1-3) glomeruli are present in fragments transferred to glutaraldehyde and Zeus/Michel's with the remainder for formalin. If glomeruli cannot be visualized, cut two 1-2 mm fragments from the ends of the core and transfer them to the glutaraldehyde. Then cut two 1-2 mm fragments from the new ends and transfer them to the Zeus/Michel's fixative. Place the remainder in formalin.

RENAL BIOPSY TISSUE SUBMISSION PROTOCOL

1 Core



LM: Light Microscopy – Formalin
IF: Immunofluorescent Histology – Zeus/Michel's
EM: Electron Microscopy – Glutaraldehyde

Required Information

Please complete all documentation and labeling with indelible ink to preserve documentation during the shipping and handling process. Printed labels are preferred to handwritten labels. Include the following documentation to accompany the specimens:

- Completed [Renal Biopsy Requisition](#) form to include:
 - Client and Ward codes unique to your institution
 - Patient first name, last name, and date of birth
 - Patient medical record number (MRN), if available
 - Billing instruction (client, patient, patient insurance). If patient insurance billing is selected, attach complete patient and insurance demographics.
 - Clinician requesting the biopsy (e.g., nephrologist, rheumatologist, or primary care provider)
 - Surgeon or radiologist who performed the biopsy
 - Collection date
 - Laterality (left, right or allograft)
- The name and telephone number of the clinician who requested the biopsy (e.g., nephrologist, rheumatologist, or primary care provider). The surgeon's contact information alone is not sufficient. Failure to include proper clinical history and clinician contact information may delay or yield incomplete interpretation.
- A copy of the recent comprehensive outpatient clinical note, inpatient consultation note, or discharge summary including relevant laboratory test results, clinical history, family history, current medications, assessment and plan AND/OR a brief clinical summary with differential or clinical question. Laboratory values should include:
 - **Creatinine/GFR** laboratory test result.
 - One or more of the following **urinalysis or urinary protein laboratory test results**: dipstick blood, sediment, protein/creatinine ratio (UPCR), 24 hour urinary protein (24 Hr protein).
 - One or more of the following **immunology** laboratory test results, if applicable: antinuclear antibody (ANA), anti-dsDNA, ANCA, anti-GBM, C3/C4, cryoglobulins, Serum Protein Electrophoresis (SPEP), Serum Free Light Chain ratio (SFLC ratio).
 - Fasting glucose and/or hemoglobin A1c laboratory test results, if applicable.
 - Genetic testing, if applicable.
- Notify MLabs of arriving specimen by calling MLabs Client Services at **800.862.7284** or **734.936.2598** (local) prior to sending the renal biopsy.
- Fax all paperwork to MLabs Client Services at FAX **734.936.0755** prior to sending the renal biopsy.

RENAL BIOPSY TISSUE SUBMISSION PROTOCOL



Packaging and Transport

1. All specimen containers must be labeled with the following required information. Printed labels are preferred to handwritten labels.
 - a. Patient's first and last name.
 - b. A second patient identifier such as date of birth or medical record number.
 - c. Laterality (left, right or allograft).
2. Package specimens for transport to MLabs in the supplied renal biopsy collection kit box for tracking.
3. Once the formalin, glutaraldehyde, and Zeus/Michel's specimens have been placed in their liquid containers and the tops secured, place them inside the refrigerated specimen bag with the absorbent sheet and seal. Secure the specimen bag in bubble wrap. Place wrapped specimen bag in the box along with the completed requisition and clinical history documentation.
4. Please be careful not to contaminate the outside of the transport bags, paperwork, or box when handling. Refrigerate until ready to ship. Specimens may be transported at room temperature or refrigerated.
5. If shipping by **UPS**, place closed box inside UPS Laboratory Pak shipping bag and seal according to instructions. Call 800.742.5877 to schedule pick up. If shipping by **FedEx**, place closed box inside FedEx Clinical Pak shipping bag and seal according to instructions. If transporting by **courier**, place closed box inside courier shipping bag and seal according to instructions. Specimens should be shipped or transported to arrive Monday – Friday by 5:00 PM, excluding Michigan Medicine holidays. Do not send specimens outside of these timeframes unless prior arrangements are made through MLabs Client Services.

PLEASE BE ADVISED: The client is responsible for following all applicable U.S. Department of Transportation (DOT), International Air Transport Association (IATA), and International Civil Aviation Administration (ICAO) shipping guidelines for safety and compliance. Training and certification are available from Michigan Medicine via the links below and is required every two years to remain compliant.

- Create a '[Friend Account](#)' at University of Michigan
- [REGULATIONS FOR SHIPPING BIOLOGICS - INFECTIOUS SUBSTANCES CATEGORY B](#)
- [REQUIREMENTS FOR SHIPPING NON-DANGEROUS GOODS WITH DRY ICE](#)
- Contact MLabs Client Services if you have questions.

RENAL BIOPSY TISSUE SUBMISSION PROTOCOL

Packaging Diagram

RENAL BIOPSY KIT STORE REFRIGERATED / SHIP ROOM TEMPERATURE



Place the specimen containers into the refrigerated specimen bag.



Secure specimen bag in bubble wrap.



Place wrapped specimen bag in box along with completed requisition and clinical history documentation. Transport specimens in this box for tracking.

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Questions

Call MLabs Client Services at **800.862.7284** or visit our website **mlabs.umich.edu**.