

Reference Lab Requests

Selection of Reference Laboratories

Reference laboratories are chosen based upon quality of performance. Specimens must be referred only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. Documentation of CLIA certification of reference labs should be requested when specimens are sent to them for testing. The chiefs of each section are responsible for selecting reference labs when needed, and for monitoring quality of results and turnaround time. Consults are sent to reference pathologists based upon area of expertise and are selected by LP staff pathologists. LP retains copies of results received from reference labs or consultants.

Request for Material for Reference Laboratory Testing (Sendouts)

On occasion, LP staff are asked to process tissues (FFPE blocks or recut slides) for reference laboratory testing (tests not offered inhouse). Although LP does not have a Sendout Technician, the Archivist will process some sendouts for supplemental tests ordered by LP pathologists to support clinical diagnosis. Please note: under no circumstance is any patient material to be released outside of the Laboratory of Pathology (e.g. to researchers, collaborators, other laboratories, outside clinicians, nurses, etc.) by LP staff other than the Archivist. Release of ANY patient material for sendouts or for temporary release to non-LP staff MUST be processed ONLY by LP's Archivist. The LP Archivist will document and track all released material, and subsequently follow up to ensure the case material is returned to LP's archives.

Clinical Sendout Tests - Requested by an LP Pathologist

- The requesting Pathologist will notify the Archivist of the Sendout request, and identify the Reference Laboratory.
- If the Requesting Pathologist is not the Attending Pathologist who signed out the case, the Signout Pathologist must be consulted prior to sending a case out for external consult. If the Signout Pathologist is not available, the Section Head of Surgical Pathology must be notified.
- The Archivist will review the specimen requirements with the Reference Laboratory and coordinate tissue processing with the Histology Laboratory.
- The Archivist will provide the LP Office of the Chief (OOTC) billing staff (assigned Program Specialist) with a quote/invoice, and the OOTC staff will coordinate purchasing/procurement approval from NCI leadership. The OOTC will complete form [NIH-2541](#) to submit to the CCR Clinical Director. The OOTC Program Specialist must notify the Archivist of approval, denial, or any other issues relating to the order.
- The OOTC Program Specialist will provide the Archivist with the approved NIH-2541, and the Archivist will enter the Purchasing Online Tracking System (POTS) order, attaching the signed NIH-2541 form. Once purchasing has been approved (confirmed POTS order), the Archivist will send the material to the Reference Laboratory.
- When results are returned, the Archivist will provide a copy of the report to the requesting Pathologist and the Attending Pathologist who signed out the original case (if different), and the Signout Pathologist will enter a supplemental report in the Laboratory Information System (LIS), Softpath.
- The OOTC staff will complete the purchasing / payment process after results are received.

Clinical Sendout Tests - Not Requested by an LP Pathologist - Will be sent to a Reference Lab by the PI

- Although the sendout test request is not initiated by an LP Pathologist, a Pathologist must make the determination that the request is clinically-relevant.
- The requesting PI must identify the lab they will be using and the material requirements (e.g. # unstained charged, H&E stain if needed, thickness, curls, etc.). The PI must enter a CRIS order for the material needed (e.g. 5 unstained on charged slides to be sent out by PI to Quest Diagnostics).
- The Hotseat Resident or the Pathologist will enter the recut request in the Softpath LIS based on material needed.
- If the Pathologist is not the Attending Pathologist who signed out the case, the Signout Pathologist must be consulted prior to sending a case out. If the Signout Pathologist is not available, the Section Head of Surgical Pathology must be notified.
- The Resident MUST communicate with Histology that this is a request to be submitted to the non-LP requesting physician to pick up and subsequently send out from their lab. If not, the slides will be filed as typical recuts for unstained.
- The Histology lab will provide the slides/material that day or the following day to the requesting physician so that the material can be sent out from their lab.
- Note: if an outside lab is to pick up the slides, the Resident must tell Histology who each request is for so that the Histology staff can label the trays appropriately.
- If results are returned to the Laboratory of Pathology, whoever receives the report (e.g. the Surgpath Patient Care Coordinator, Archivist or Submitting Pathologist) will provide a copy of the report to the requesting Pathologist. The Attending Pathologist who signed out the original case (if different), in consultation with the Requesting Pathologist, will enter a supplemental report in the Laboratory Information System (LIS), Softpath.
- If LP facilitates this sendout (e.g. using LP's reference lab account number), the Archivist will request a POTS order from the requesting PI or Research Nurse prior to sending the test out. When results and bill/invoice are received: a) a copy of the pathology report goes to the signout attending for supplemental report; and b) PI or Research Nurse enters receiving in POTS for their sendout requisition.

Non-Clinical Sendout Requests

- If the request is for material to send out for testing that a Pathologist does not deem to be clinically-relevant, please refer to the [TRC process](#) to request research material.
- For Medico-Legal requests and Requests to Return Submitted Material, please refer to the Surgical Pathology policy manual for the [MedicoLegal and Returning Submitted Material Policy](#).