

# LAC+USC MEDICAL CENTER POLICY

Subject: <b>TISSUE SPECIMEN EXAMINATION – PATHOLOGY EXEMPT POLICIES</b>	Original Issue Date: 5/8/12	Policy # <b>923</b>
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Policy Owner(s) : Lab Medical Director Executive Sponsor(s) : Chief Medical Officer		
Department(s) and Committee(s) Consulted: Diagnostic Services Labs and Pathology	Reviewed & Approved by: Attending Staff Association Executive Committee Senior Executive Officer	Approved by: (Signature on File) Chief Medical Officer
		(Signature on File) Chief Executive Officer

## PURPOSE

To comply with the California Code of Regulations which requires that, unless specifically exempted by the state of California Department of Public Health (CDPH), all anatomical parts, tissues and foreign objects removed by operation or other procedures must be delivered to a pathologist designated by the hospital and a report of the pathologist's findings must be filed in the patient's medical record.

## POLICY

ALL specimens collected from human subjects for diagnosis, research, or documentation (except those exempted below) must be submitted in a timely manner for examination by a pathologist who is a member in good standing of the LAC+USC Medical Attending Staff. All specimens received by the Department of Pathology for pathological diagnosis and/or documentation will be examined grossly and microscopically unless it is technically impossible to perform the microscopic examination. For example, orthopedic appliances, bullets, teeth, stones, skull bone flaps, and other similar materials that do not lend themselves to microscopic examination will be "gross only," specimens, i.e., the specimen will have a gross description only. Orthopedic appliances, cardiac pacemakers, breast implants and other appliances/devices having a visible unique identifying number, will have this number included in the gross description. Per public law 102-629, the Safe Medical Devices Act (1990), any and all failed mechanical devices must be sent to Pathology for examination.

## THE FOLLOWING EXEMPTIONS APPLY:

1. Skin (that has no lesions) or other normal tissue that is removed during a cosmetic or reconstruction procedure (e.g., blepharoplasty, cleft palate repair abdominoplasty, rhytidectomy), is exempt from pathologist examination provided it is not contiguous with a lesion and the patient does not have a history of malignancy. However, in view of the prevalence of premalignant lesions in the breast, breast tissue from reduction mammoplasties will be examined both grossly and microscopically by a pathologist.
2. Fat removed from liposuction is exempt from pathologist examination.
3. Skin from a recently acquired minor wound or burn debridement is exempt from pathologist examination. A wound, such as a draining sinus tract or burn that has existed for ten or more years requires pathologist examination; as such lesions may harbor squamous cell carcinoma (Marjolin's ulcer).
4. Foreskin from circumcision on newborn is exempt from pathologist examination.

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5. Placenta from normal vaginal delivery is exempt from pathologist examination.
6. Intrauterine and subcutaneous contraceptive devices that are removed without any attached tissue are exempt from pathologist examination.
7. Normal toenails and fingernails that are incidentally removed is exempt from pathologist examination.
8. Tissue for research is NOT exempt from pathologist examination unless the Institutional Review Board (IRB) has authorized certain research tissues/specimens/biopsies, etc. to be collected without examination by Pathology. This exemption requires that a protocol has been approved by both the IRB and by Pathology, and that the biopsy is not expected to lead to a diagnosis and/or impact patient management. If the amount of tissue required for research exceeds what the pathologist requires to render a clinical diagnosis or to provide the necessary staging information, the tissue must go to the pathologist, and not given to research.

### **HOW TO MANAGE EXEMPTED MATERIAL THAT HAS BEEN REMOVED AT SURGERY, BUT NOT SUBMITTED TO PATHOLOGY**

The exempted material (see above list) removed at surgery but not submitted to pathology will be adequately described by the surgeon and documented in the health record. This will include the size, shape color, etc. of the material removed at surgery

### **RESPONSIBILITY**

- Healthcare providers who submit specimens to Surgical Pathology for examination
- Surgical Pathology Staff

### **PROCEDURE DOCUMENTATION**

- Surgical Pathology Manual
- Surgical Pathology Reports
- A true copy of the 'APPROVAL OF PROGRAM FLEXIBILITY' letter (dated 8/15/21) from CDPH will be posted immediately adjacent to the facility's license. [a copy of the letter is attached]

### **REFERENCES**

1. Joint Commission Standard PC.03.01.08

### **REVISIONS**

May, 8, 2012; February 19, 2016; March 22, 2019; November 18, 2019, March 29, 2023