ANP.11525 Tissue Assessment Record **Phase I**

If a statement of adequacy, preliminary diagnosis, or recommendations for additional studies is provided at the time of tissue specimen collection, records of that statement are retained.

NOTE: Records might include a note in the patient's medical record or in the final pathology report.

ANP.11550 Specimen Retention - Grossing **Phase I**

Gross specimens are retained until at least two weeks after the final reports are signed and results are reported to the referring physician.

REFERENCES
1) Travers H. Q&A Section. Northfield, IL: College of American Pathologists CAP Today, March 1992:63
2) Travers H. Q&A Section. Savage RA, editor. CAP Today, November 1993:86-87
3) Tracey ME. Hospital takes closer look at specimen returns. CAP Today, July 1992:81
4) Lester SC. Manual of surgical pathology. New York, NY: Churchill Livingstone, 2001:18-20
5) Zhai Q, Siegal GP. Quality Management in Anatomic Pathology. Northfield, IL: CAP Press, 2017.

ANP.11600 Gross Examination - Qualifications **Phase II**

All macroscopic tissue gross examinations are performed by a qualified pathologist or pathology resident, or another qualified individual (see note), or under the supervision of a qualified pathologist.

NOTE: For specific tissue types only, there are other qualifications that are accepted for individuals performing tissue examination, including the following:

- *For neuromuscular pathology specimens, an MD or DO licensed to practice (if required) in the jurisdiction where the laboratory is located who has completed a training program in neuromuscular pathology approved by HHS (ie, the American Academy of Neurology Committee for Neuromuscular Pathology Training Program) may qualify to perform gross examination.*
- *Other exceptions for dermatopathology, ophthalmic pathology and oral pathology as defined in the CLIA regulation 42CFR493.1449(f) and (g).*

ANP.11605 Gross Examination - Supervision **Phase II**

When individuals other than a pathologist or pathology resident/fellow assist in gross examinations, the extent of their activities and the nature of supervision is defined.

NOTE: A protocol must list the specific types of specimens for which non-pathologists are permitted to assist in the gross examination. The laboratory director is responsible for this protocol. This requirement does not apply to grossing performed by other qualified individuals for specific pathology subspecialities as defined in ANP.11600.

The nature of the supervision (eg, pathologist physically present in the laboratory area versus availability by phone or electronic means for consultation) must be established for each individual. The supervision must be provided by a qualified pathologist (or other qualified individual). For example, an MD or DO dermatologist licensed to practice (if required) in the jurisdiction where the laboratory is located who is board certified in dermatology is qualified to supervise non-pathologists for dermatopathology cases, including Mohs surgery cases.

The protocol must comply with national, federal, state (or provincial), and local laws.

The following requirements apply to laboratories with California licensure:

- *A pathologist assistant certified by the American Association of Pathologists' Assistants or American Society for Clinical Pathology must work under the supervision and control of a*

qualified pathologist (either physically present in the laboratory or available by telephone or other electronic means).

- *Non-certified personnel who perform grossing must work under direct supervision of a qualified pathologist when engaging in the processing of specimens involving dissection (present in the vicinity of the clinical laboratory subspecialty area and be available for consultation and direction).*
- *Tissue processing that doesn't involve dissection may be performed under the supervision and control of a qualified pathologist.*

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28): [42CFR493.1489(b)(7)].
2) Cibull ML. Q&A. Northfield, IL: College of American Pathologists CAP Today. 1997;11(7):112
3) Grzybicki DM, et al. National practice characteristics and utilization of pathologists' assistants. Arch Pathol Lab Med. 2001;125:905-912
4) California Business and Professions Code §1269.3.

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ANP.11610 Gross Examination - Qualifications to Assist with Grossing **Phase II**

For laboratories subject to US regulations, individuals other than a pathologist or pathology resident (or an individual who meets the grossing subspecialty qualifications listed under ANP.11600) who assist in gross examinations meet high complexity testing personnel qualifications. For laboratories not subject to US regulations, such individuals are qualified under national, state or provincial, and local regulations, as applicable.

NOTE: Individuals assisting with grossing may perform physical examination/description of tissue specimens, including color, weight, measurement or other characteristics of the tissue, or other mechanical procedures (eg, dissection) under appropriate supervision. The laboratory director may delegate the grossing of specimens to non-pathologist individuals, but is responsible for determining whether an individual's education, training and experience meet the required qualifications.

For laboratories subject to US regulations, these individuals must be qualified as high complexity testing personnel under the CLIA regulations. The minimum training/experience required of such personnel is:

1. *An earned associate degree in a laboratory science (chemical or biological science) or medical laboratory technology, obtained from an accredited institution, OR*
2. *Education/training equivalent to the above that includes the following:*
   - *60 semester hours or equivalent from an accredited institution. This education must include 24 semester hours of medical laboratory technology courses, OR 24 semester hours of science courses that includes six semester hours of chemistry, six semester hours of biology, and 12 semester hours of chemistry, biology or medical laboratory technology in any combination, AND*
   - *Laboratory training including either completion of a clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), or the Commission on Accreditation of Allied Health Education Programs (CAAHEP) (note that this training may be included in the 60 semester hours listed above), OR at least three months of recorded laboratory training in each specialty in which the individual performs high complexity testing.*

If there are more stringent state or local regulations for grossing qualifications, they must be followed. Additional educational pathways for qualifying as high complexity testing personnel may be found in the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.

For US Department of Defense laboratories, effective May 29, 2014, newly hired high complexity testing personnel must have either:

- *A minimum of an associate degree in a biological or chemical science or medical laboratory technology from an accredited institution **AND** be certified by the ASCP, AMT or other*