AAPA Position on Utilization of Non-Pathologist Grossing Personnel in the Anatomic Pathology Laboratory

College of American Pathology (CAP) Qualifications for Gross Examination by Non-Pathologist

If individuals other than a pathologist or pathology resident assist in gross examinations, such individuals qualify as high complexity testing personnel.
(Reference: CAP Anatomic Pathology Checklist item ANP.11610 Gross Examination – High Complexity Testing Qualifications, 06/04/2020)

NOTE: Grossing is defined as a tissue examination requiring judgment and knowledge of anatomy. This includes the dissection of the specimen, selection of tissue, and any level of examination/description of the tissue including color, weight, measurement, or other characteristics of the tissue. The laboratory director may delegate the dissection of specimens to non-pathologist individuals; these individuals must be qualified as high complexity testing personnel under the CLIA regulations. The minimum training/experience required of such personnel is:

- Associate degree in a chemical or biological science, or medical laboratory technology from an accredited institution; **OR**
  - Education/training equivalent to the above that includes the following: 60 semester hours or equivalent from an accredited institution that, at a minimum includes 24 semester hours of medical laboratory technology courses, **OR**
  - 24 semester hours of science courses that include six semester hours of chemistry, 6 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 ABHES, NAACLS, or other organization approved by HHS *(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.
  - Possess a current license issued by the State in which the laboratory is located if such licensing is required**.**

Definition of Terms

- Non-pathologist grossing personnel
  - Pathologists' Assistant
    A Pathologists' Assistant is a highly trained, certified allied healthcare professional who is qualified by academic and practical training to provide services in anatomic pathology under the direction and supervision of a licensed, board certified or board eligible anatomic pathologist.
  - Histologist
    Histotechnician or histotechnologist
  - Histotechnician
    Utilizing specific reagents, chemicals, and dyes, the histotechnician prepares surgical specimens for microscopic screening by the surgical pathologist.

- Histotechnologist
  Utilizing specific reagents, chemicals, and dyes, the histotechnologist prepares surgical specimens for microscopic screening by the surgical pathologist. A histotechnologist has more advanced education and training to give them the qualifications necessary to obtain the certification.
- Cytotechnologist
  Cytotechnologists analyze fluid and tissue specimens for microscopic cellular abnormalities, such as bacterial and viral infections, cancer, meningitis, and other diseases.
- Grossing Technician
  Grossing Technicians may examine low-complexity specimens including small routine biopsies or specimens submitted in toto or entirely for microscopic examination by a pathologist. They must meet the minimum education requirements outlined by the *CAP Anatomic Pathology Checklist item ANP.1161 Gross Examination – High Complexity Testing Qualifications.*

- Tissue submission
  - Selective sampling
    Sampling of a specimen to demonstrate specific pathology which requires in depth knowledge of anatomy, pathology, and principles of sectioning.
  - Representative submission
    Adequate sampling of a specimen to make an accurate diagnosis requiring knowledge of anatomy, pathology, and principles of sectioning.
  - Entire submission
    The specimen is entirely submitted with or without sectioning for microscopic examination by a pathologist.
  - In toto submission
    The specimen is entirely submitted without manipulation or sectioning for microscopic examination by a pathologist.

- Direct vs. indirect supervision
  - Direct supervision
    The supervising physician (or appropriate designee) is present in the vicinity of the clinical laboratory subspecialty area and available for consultation and direction.
  - Indirect supervision
    Direct Supervision Immediately Available - The supervising physician (or appropriate designee) is physically present within the hospital or other site of patient care and is immediately available to provide direct supervision**.**
    OR
    Direct Supervision Available - The supervising physician (or appropriate designee) is not physically present within the hospital or other site of patient care but is immediately available by means of telephonic and/or electronic modalities and is available to provide direct supervision.

AAPA Position on Basic Qualifications for Macroscopic Examination of Specimens Requiring Selective Sampling

For those who perform macroscopic examinations on specimens that require selective sampling, the AAPA maintains the following standard qualifications be met:

- Be a board certified, licensed anatomic pathologist, pathology fellow, or pathology resident, **OR**
- Be an ASCP certified pathologists' assistant, **AND**
- Possess a current license issued by the State in which the laboratory is located, if such licensing is required

Since 2005, successful completion of a NAACLS accredited pathologists' assistant training program is required to sit for the American Society for Clinical Pathology Board of Certification (ASCP BOC) Pathologists' Assistant (PA) certification examination. Prior to 2010, a person with a bachelor's degree in a basic science and specific practical training activities learned on-the-job (via a 3-year supervised internship) could sit for the same examination. To maintain certification, the ASCP BOC requires participation in its Credentialing Maintenance Program (CMP) which for pathologists' assistants includes completion of 60 continuing education (CE) credits per three-year period. The continuing education requirement consists of 15 advanced anatomic pathology credits which address macroscopic examination and staging of cancer resections, 20 anatomic pathology credits, 23 general pathology credits, one laboratory safety credit, and one medical ethics credit.

Due to the variability and complexity of anatomic pathology tissue specimens, the AAPA considers the CLIA '88 regulations for minimal educational requirements to perform high complexity testing to be inadequate and outdated *(42 CFR493.1489 and 1491)*. CLIA '88 regulations for minimum personnel requirements do not reflect the associated liability and potential effect on patient safety related to examining tissue specimens. Furthermore, CLIA '88 personnel requirements do not address specific elements to be mastered during didactic and practical training which are essential in understanding fundamental pathology; developing observational skills, dexterity and manipulation of tissue specimens; and developing appropriate judgement in the anatomic pathology setting.

AAPA Position on Basic Qualifications for Macroscopic Examination of Specimens NOT Requiring Selective Sampling

It is the position of the American Association of Pathologists' Assistants (AAPA) that **all** anatomic pathology specimens be examined by certified pathologists' assistants. However, the appropriate utilization of grossing technicians, histologists, and cytotechnologists in anatomic pathology may be limited to gross examination of specific specimen types under direct supervision only.

- The scope of work should be limited to the macroscopic examination of low-complexity specimens that require entire submission of tissue for microscopic examination without selective sampling.
- Grossing technicians, histologists, and cytotechnologists may be trained to examine limited specimen types and work under the direct supervision of a certified pathologists' assistant or pathologist.
- More complicated specimens requiring knowledge of pertinent pathology and anatomy are excluded *(e.g., gallbladder, breast lumpectomy).*
- There shall be no increase in the level of specimen complexity handled by grossing technicians, histologists, or cytotechnologists. To advance, these personnel must acquire advanced didactic and clinical training obtained by completing a NAACLS accredited pathologists' assistant training program or an ACGME accredited pathology residency program.
- A detailed list of appropriate specimen types for macroscopic examination by non-pathologist grossing personnel is provided in the delineation of privileges by specimen and procedure type template.

To assist in the macroscopic examination of routine biopsy specimens which are entirely submitted for microscopic examination, it is the AAPA's position that personnel must meet the following:

- Be a certified pathologists' assistant **OR**
- Have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological, or clinical laboratory science, medical technology, histotechnology, or cytotechnology from an accredited institution, **AND**
- Have at least three months of recorded laboratory training in anatomic pathology.

Grossing Technicians

The utilization of grossing technicians, biopsy technicians, or other personnel *(e.g., cytotechnologists)* with similar titles and minimal training to assist with the macroscopic examination of routine, low-complexity specimens is relatively common and may be valuable in high volume anatomic pathology laboratories. While larger specimens and complex resections require in depth knowledge of anatomy and pathology and entail extensive dissection and sampling, it is the routine biopsy specimen that is of critical importance to patients in the initial diagnosis of disease including a diagnosis of cancer. Additional testing is frequently performed on biopsy material to further characterize a malignancy, to identify predictive markers, and to guide future therapy. While these specimen types are technically uncomplicated, they come with significant responsibility and liability.

Low-complexity specimens include small routine biopsies or specimens submitted in toto or entirely for microscopic examination by a pathologist. Such specimen types require counting biopsy fragments, providing a measurement of material, or other simple quantification followed by transfer of the entire specimen from specimen container to tissue cassette without sectioning or other manipulation of the tissue. In addition, every specimen type must be carefully handled to ensure correct patient identification is always maintained. Appropriate technique must be employed to avoid cross contamination with other specimens. It cannot be overstated how critical it is to patient safety that such specimens be handled with great attention to detail using proper laboratory technique and organization to avoid errors, loss, or destruction of a specimen.

Simple routine specimen types that require limited sectioning but lend themselves to selective sampling for microscopic examination, such as hernia sacs, appendixes, gallbladders, and various soft tissue lesions, require more than the knowledge of taking basic measurements and appropriate sampling. Even these specimen types require an understanding of specific anatomy, medical terminology and clinical correlation, associated disease entities, and sectioning technique. Most importantly, recognition of uncommon lesions or features that may require additional sampling may be of great significance to patient care.

The lack of guidelines and the absence of structured didactic and practical training of grossing technicians and others who meet minimal education requirements is of great concern when handling specimens that require selective sampling. The extent of on-the-job training, the covered elements, and any measure of competency is variable and unknown. Handling of all types of specimens in the anatomic pathology laboratory merits the use of appropriately qualified and well-trained personnel.

Comment on Cytotechnologist Training
The Commission on Accreditation of Allied Health Education Programs (CAAHEP), Standards and Guidelines for the Accreditation of Educational Programs in Cytotechnology does not list the macroscopic examination of surgical specimens in the Curriculum in Cytotechnology for Entry-level Competencies. The ASCP Board of Certification examination for cytotechnologist does not include a macroscopic examination of surgical specimen assessment.

Grossing Histologists

Due to the increase in volume of biopsies and cost containment concerns, histotechnicians and histotechnologists are being utilized in the anatomic pathology laboratory to a greater extent than before. With adequate training, histologists may be a valuable resource for examining specimen types such as select biopsy specimens (gyn, GI, urinary bladder), needle biopsies (prostate, kidney, bone marrow, breast, lymph node), and muscle and nerve biopsies.

National Accrediting Agency for Clinical Laboratory Science (NAACLS) Unique Standards for the Histotechnician (HT) and Histotechnologist (HTL), Description of Entry Level Competencies of the Histotechnician and Histotechnologist state that both assist with and/or perform macroscopic examinations and frozen section procedures in histopathology as well as prepare cytology specimens. The ASCP BOC examination for HTL does not include a macroscopic examination of surgical specimen assessment. Although some histology students may receive selective training in macroscopic examination with an emphasis on select simple specimen types *(e.g., dermatology specimens)*, any formal didactic and practical macroscopic training they may receive is typically comprised of a general overview of the entire process, from accessioning to maintenance of the gross room.

Since histologists are experienced in embedding and microtomy, they can visualize and predict a small sample's behavior after macroscopic examination to assure that the most diagnostically valuable part of the sample appears on the slide. Histologists may receive practical training in macroscopic examination on-the-job, which is typically limited to non-complex specimen types. Their scope of work should be limited to examining biopsies and small specimens with a defined list determined by an institution's policy.

Summary

A survey of 450 practicing certified pathologists' assistants regarding the appropriate utilization of grossing technicians and histologists in surgical pathology showed that a majority support the use of grossing technicians when there are specific limitations on the specimen types they examine. A significant majority expressed that oversight and supervision of grossing technicians were paramount to patient care and patient safety. Most participants acknowledged that they were allowed more time to focus on complex specimen types when grossing technicians were utilized to examine and process routine biopsy specimens.

The macroscopic examination of surgical specimens that requires dissection and selective sampling should only be performed by professionally trained and qualified individuals, which include board certified anatomic pathologists, pathology fellows, pathology residents, and certified pathologists' assistants. In the interest of patient safety, these are the only personnel who are qualified to examine these types of specimens safely and effectively by way of rigorous formal training with established and detailed requirements.

During training to become a pathologist, the Accreditation Council for Graduate Medical Education (ACGME) outlines elements of pathology residency programs which include a patient care section with detailed milestones for macroscopic examination as residents progress through a four-year residency. The ACGME requires that pathology residents assess at least 2000 surgical specimens, a number upheld by a position paper from the Association of Pathology Chairs to achieve competency. It is an ACGME pathology residency program requirement that PGY-1 residents must be directly supervised while correctly performing the macroscopic examination of three consecutive surgical specimens of each type by organ system before being permitted to examine such specimen types under indirect supervision. Those qualified to supervise residents include pathologists' assistants, senior residents, pathology fellows, or an attending pathologist.

Certified pathologists' assistants similarly progress through a highly structured post graduate didactic and practical curriculum based on NAACLS Standards for Accredited Pathologists' Assistant Training Programs which detail elements of training and entry level requirements in anatomic pathology, including the macroscopic examination of surgical specimens of every organ system. The comprehensive and highly detailed training that pathologists' assistants undergo in macroscopic examination of surgical specimens is obtained during an intensive 24-month curriculum that leads to a master's degree. Graduates of a NAACLS accredited training program are eligible to sit for the ASCP BOC exam and then participation in the ASCP Credentialing Maintenance Program for continuing education is required. Practicing certified pathologists' assistants typically examine 10,000 to 15,000 surgical cases per year, ranging from simple to complex.

Conversely, grossing technicians do not have formal education in pathology, have no standard scope of duties, and have no established training requirements by specimen type for the macroscopic examination of surgical specimens. Grossing technicians have no path to a national credential, such as ASCP certification. They also have no continuing education requirement. While some institutions do have some form of in-house training and delineation of duties, the elements covered, and the quality of training, is variable and unknown. The title of grossing technician is generic with no established standards other than meeting the minimum education requirements outlined by the *CAP Anatomic Pathology Checklist item ANP.1161 Gross Examination – High Complexity Testing Qualifications.*

ASCP certified Histotechnicians (HT) and Histotechnologists (HTL) receive only an overview of macroscopic pathology techniques in their accredited training programs. This overview includes an emphasis on the overall process including accessioning, organizing cases and cassettes prior to macroscopic examination, safety in the gross room, and assisting PAs, residents, and pathologists as they perform the macroscopic examination of specimens. Some histologists receive additional on-the-job training to examine limited specimen types such as biopsy material, dermatology specimens, and other simple specimen types that are entirely submitted for microscopic examination. Cytotechnologists also do not receive training in macroscopic pathology techniques in their training programs. The ASCP certification examinations for HT, HTL, and CT do not include an assessment of the macroscopic examination of surgical specimens.

Pathologists' assistants are often responsible for the training and oversight of pathology residents and other grossing personnel. While evidence of errors in the gross room by grossing technicians and histologists is anecdotal, it is documented that among the most common errors in gross pathology are those committed by first year pathology residents as they learn to examine breast specimens. Such errors observed in this group of new learners demonstrate the expertise required to properly examine a common specimen type which requires clinical correlation, careful examination, and selective sampling. Those with far less education and minimal training, such as grossing technicians, histologists, and cytotechnologists, are clearly not prepared or qualified to examine any specimen that requires dissection and selective sampling.

In many pathology departments the attending pathologist does not view the gross specimen and relies on competent gross room personnel to correctly examine, describe, and sample such specimens. It is an intricate collaboration for the pathologist to trust the eyes and subsequent descriptions of grossing personnel. This trust is tested and expanded upon over time and on a daily basis. It is incumbent on gross room personnel to exercise appropriate judgement in this setting and to recognize when attending pathologist involvement is necessary to ensure that unusual or complicated specimens are correctly examined and sampled. It is the AAPA's view that grossing technicians, histologists, and cytotechnologists are not prepared for this role in providing patient care.

The AAPA, in accordance with our vision and core values, presents our position in the name of patient safety and in support of attending pathologists who are ultimately responsible for rendering an accurate diagnosis. The scope of work for grossing technicians, histologists, and cytotechnologists in surgical pathology must be limited to the macroscopic examination of smaller routine biopsies and low-complexity specimens that require entire submission of tissue for microscopic examination without selective sampling.

References

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APPENDIX I

Suggested Pathologists' Assistant, Grossing Technician/Non-Pathologists' Assistant Delineation of Privileges by Specimen Type/Procedure Type

Specimen/Procedure	Pathologists' Assistant	Grossing Technician Non-Pathologists' Assistant
Abortion	X	
Abscess	X	
Adenoids and/or Tonsils	X	
Adrenal resection	X	
Aneurysm	X	
Appendix	X	
Amputation (extremity)	X	
Atheromatous plaque/biopsy	X	X If submitted in toto
Artery	X	
Bartholin's gland cyst	X	
Bone fragments, exostosis, or pathologic fracture	X	
Bone marrow biopsy	X	
Bone resection, tumor	X	
Bone biopsy or curetting	X	
Brain, biopsy	X	X
Brain tumor resection	X	
Brain, meninges, not tumor	X	
Branchial cleft cyst	X	
Breast mastectomy with/without nodes	X	
Breast biopsy without margins	X	
Breast reduction mammoplasty	X	
Breast, biopsy with margins (no localization)	X	
Breast, biopsy, with margins (localization)	X	
Bronchus, biopsy	X	X
Carpal Tunnel	X	
Cartilage shavings/joint, loose body/knee shavings/meniscus/synovium	X	
Cell Block	X	
Cervix, biopsy	X	X
Cervical cone	X	
Cholesteatoma	X	
Colon biopsy	X	X
Colon, segment or total for tumor	X	
Colon, segment or total for diverticulosis, ischemic bowel, or incarceration	X	
Conjunctiva, biopsy or pterygium or cornea	X	
Debridement, skin or soft tissue	X	

Diverticulum, small intestine or esophagus	X	
Duodenum biopsy	X	X
Dupuytren's contracture (fibromatosis)	X	
Embolus	X	
Endocervix/endometrium, biopsy or curetting	X	X
Esophagus, biopsy	X	X
Esophagus, partial or total resection	X	
Extremity, amputation/disarticulation (tumor)	X	
Eye, enucleation	X	
Fallopian tube, biopsy/sterilization	X	
Fallopian tube, ectopic pregnancy	X	
Femoral head, fracture and without fracture	X	
Fetus, with/without dissection	X	
Fingers/toes, amputation	X	
Fissure/fistula	X	
Foreskin	X	
Gallbladder	X	
Ganglion cyst or sympathetic	X	
Gastrointestinal polyp	X	
Gingival biopsy	X	X
Heart valve	X	
Hematoma	X	
Hemorrhoid	X	
Hernia sac, any location	X	
Hydatid of Morgagni	X	
Hydrocele sac	X	
Inflammatory polyps, nasal	X	
Intervertebral disc	X	X If submitted in toto
Joint resection for benign disease	X	
Kidney, needle biopsy for tumor	X	X
Kidney, needle biopsy (medical)	X	
Kidney, partial or total nephrectomy	X	
Labia biopsy	X	X
Larynx, biopsy	X	X
Laryngectomy, partial and total resection	X	
Leg, amputation, gangrene	X	
Leiomyoma, Uterine myomectomy, with uterus	X	
Lip, biopsy/wedge resection	X	
Lipoma	X	
Liver biopsy, needle or wedge	X	X
Liver, partial resection	X	
Lung, total/lobe/segment resection	X	
Lung, transbronchial biopsy	X	X
Lung, wedge biopsy	X	
Lymph node, biopsy (fresh for lymphoma)	X	
Lymph node, biopsy (other)	X	

Lymph node, regional resection	X	
Mediastinum, mass	X	
Mucocele, salivary	X	
Muscle biopsy	X	
Myocardium	X	
Nasopharynx, oropharynx, sinus, or mucosa biopsy	X	X
Nerve, or nerve biopsy	X	
Neuroma, Morton's or traumatic	X	
Nucleus pulposus	X	X If submitted in toto
Odontogenic tumor	X	
Odontogenic/dental cyst	X	
Omentum, biopsy	X	X
Oral biopsy	X	X
Ovary, with or without tube, neoplastic	X	
Ovary, with or without tube, non-neoplastic	X	
Ovary, biopsy or wedge	X	
Pancreas, biopsy	X	
Pancreas, total, subtotal	X	
Parathyroid gland	X	
Pericardium, biopsy or tissue	X	X If submitted in toto
Peritoneum, biopsy	X	X
Pilonidal cyst/sinus	X	
Pituitary tumor	X	
Placenta	X	
Pleural biopsy or tissue	X	X If submitted in toto
Products of conception	X	
Prostate except radical resection	X	
Prostate, needle biopsy	X	X
Prostate, radical resection	X	
Prostate, TUR	X	
Salivary gland	X	
Salivary gland, biopsy	X	X
Skin, cyst/tag/debridement/nevus, or plastic repair	X	
Skin, punch/shave biopsy	X	
Skin, excision (oriented or unoriented)	X	
Small bowel diverticulum	X	
Small intestine resection for tumor	X	
Small intestine, biopsy	X	X
Small intestine, resection, non-tumor	X	
Soft tissue mass, biopsy or simple excision	X	
Soft tissue tumor, extensive resection	X	
Soft tissue, NOT tumor, lipoma, or debridement	X	
Spermatocele	X	
Spleen	X	
Stoma	X	
Stomach, biopsy	X	X

Stomach, subtotal/total resection for tumor	X	
Stomach, subtotal/total resection, non-tumor	X	
Tendon/tendon sheath	X	
Testis, biopsy or testicular appendage	X	X
Testis, NOT tumor, biopsy or castration	X	
Testis, tumor	X	
Thrombus	X	X If submitted in toto
Thymus tumor	X	
Thyroglossal duct cyst	X	
Thyroid, total or lobe	X	
Tongue resection for tumor	X	
Tongue, biopsy	X	X
Tonsils and adenoids (resection or biopsy)	X	
Tonsil, resection for tumor	X	
Trachea biopsy	X	X
Ureter/urethra biopsy	X	X
Ureter, resection	X	
Urinary bladder biopsy	X	X
Urinary bladder, partial/total resection	X	
Urinary bladder, TUR	X	
Uterus, with or without tubes and ovaries for prolapse (non-tumor)	X	
Uterus, with or without tubes and ovaries for tumor	X	
Vagina, biopsy or mucosa, incidental	X	
Varicocele	X	
Vas deferens, non-sterilization	X	
Vas deferens, sterilization	X	
Vein, varicosity	X	
Vulva, total/subtotal resection	X	
Any specimen submitted with orientation marking, where the orientation cannot be established	X	