

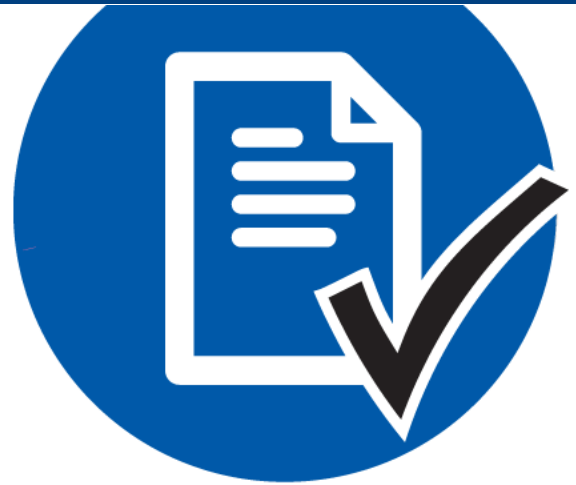


COLLEGE of AMERICAN  
PATHOLOGISTS

**Al Hammadi Hospital Al Nuzha  
Laboratory Department**

# Anatomic Pathology Checklist

CAP Accreditation Program



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## Anatomic Pathology Checklist



### TABLE OF CONTENTS

<b>SUMMARY OF CHANGES.....</b>	<b>4</b>
<b>INTRODUCTION.....</b>	<b>6</b>
<b>GENERAL ANATOMIC PATHOLOGY.....</b>	<b>6</b>
PERSONNEL.....	6
<b>SURGICAL PATHOLOGY.....</b>	<b>7</b>
QUALITY MANAGEMENT.....	7
QUALITY CONTROL.....	10
SURGICAL SPECIMEN EXAMINATION.....	10
INTRA-OPERATIVE CONSULTATION (RAPID DIAGNOSIS).....	14
FINE NEEDLE ASPIRATE (FNA) SPECIMENS.....	16
SURGICAL PATHOLOGY REPORTS.....	16
<b>HISTOLOGY LABORATORY.....</b>	<b>21</b>
GENERAL QUALITY CONTROL.....	21
IMMUNOFLUORESCENCE MICROSCOPY.....	22
IMMUNOHISTOCHEMISTRY.....	23
PREDICTIVE MARKERS.....	26
<b>INSTRUMENTS AND EQUIPMENT.....</b>	<b>30</b>
<b>PHYSICAL FACILITIES.....</b>	<b>31</b>
STORAGE AND SUPPLY.....	31
<b>HISTOLOGY LABORATORY SAFETY.....</b>	<b>32</b>

## ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists by logging into cap.org and going to e-LAB Solutions Suite - Accreditation Checklists. They are available in different checklist types and formatting options, including:

- Master — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- Custom — customized based on the laboratory's activity (test) menu; available in PDF, Word/XML or Excel formats
- Changes Only — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

## CHECKLIST ACCREDITATION RESOURCES

CAP accredited laboratories have access to additional checklist accreditation tools and resources found on the CAP website (cap.org) by logging into e-LAB Solutions Suite - Accreditation Resources. Content found in Accreditation Resources includes:

- A library of past Focus on Compliance webinars and laboratory inspection preparation videos
- Answers to the most common checklist questions
- Customizable templates and forms (eg, competency assessment, personnel, validation/verification, quality management)
- Proficiency testing (PT) frequently asked questions, forms, and troubleshooting guides
- IQCP eligibility, frequently asked questions, forms, templates, and examples
- Laboratory director education and resources
- Quality management resources
- Inspector training and inspection tip sheets
- Self and post inspection toolbox

## SUMMARY OF CHECKLIST EDITION CHANGES

### Anatomic Pathology Checklist

### 12/26/2024 Edition

The information below includes a listing of checklist requirements with significant changes in the current edition and previous edition of this checklist. The list is separated into three categories:

1. New
2. Revised:
  - Modifications that may require a change in policy, procedure, or process for continued compliance; or
  - A change to the Phase
3. Deleted/Moved/Merged:
  - Deleted
  - Moved — Relocation of a requirement into a different checklist (requirements that have been resequenced within the same checklist are not listed)
  - Merged — The combining of similar requirements

*NOTE: The requirements listed below are from the Master version of the checklist. The customized checklist version created for inspections and self-evaluations may not list all of these requirements.*

### Previously Cited Checklist Requirements

- The **inspector's version** of the checklist contains a listing of previously cited checklist requirements. Specific information on those citations, including the inspection date and inspector comments, is included following each related requirement within the checklist.
- Laboratories can access data on previously cited deficiencies by logging into e-LAB Solutions Suite on cap.org and going to Accreditation Reports - Inspection Summation Report.

### NEW Checklist Requirements

<u>Requirement</u>	<u>Effective Date</u>
ANP.10290	12/26/2024
ANP.22560	12/26/2024
ANP.22975	12/26/2024

### REVISED Checklist Requirements

<u>Requirement</u>	<u>Effective Date</u>
ANP.10041	08/24/2023
ANP.11610	12/26/2024
ANP.12350	08/24/2023
ANP.12500	12/26/2024
ANP.22550	12/26/2024
ANP.22969	08/24/2023
ANP.22970	12/26/2024
ANP.24200	08/24/2023

### DELETED/MOVED/MERGED Checklist Requirements

None

## INTRODUCTION

*This checklist is used in conjunction with the All Common (COM) and Laboratory General Checklists to inspect an anatomic pathology laboratory section or department.*

*Do NOT use this Checklist if the laboratory does NOT perform any on-site preparation or examination of anatomic pathology specimens, but refers all submitted material to an outside laboratory, or if the laboratory's involvement in anatomic pathology is limited to filing of reports and/or slides.*

*Laboratories that do not file slides on-site (eg, "read-only" laboratories) must retain a sample of cases and all associated slides on-site for review by the inspector on all days when the laboratory is subject to its regular on-site inspection. The sample must, at a minimum, include all cases and associated slides accessioned over a continuous 2-week period within the previous 2 years.*

*If telepathology is used by the pathologist to review slides or images for primary diagnosis, frozen section diagnosis, formal second-opinion consultations, ancillary techniques in which the pathologist participates in interpretation of images, or real-time evaluation of FNA specimens for triaging and preliminary diagnosis, refer to the Telepathology and Remote Data Assessment section of the Laboratory General Checklist for additional requirements. Telepathology occurs when a pathologist views digitalized or analog video or still image(s), or other data files (eg, flow cytometry files) at an off-site or remote location and an interpretation is rendered that is included in a formal diagnostic report or recorded in the patient record. The Telepathology and Remote Data Assessment section of the Laboratory General Checklist is not applicable if the image(s) and/or data files are generated and interpreted **within the same laboratory** using the laboratory's validated software.*



*Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.*

**Laboratories not subject to US regulations:** Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).

## GENERAL ANATOMIC PATHOLOGY

### PERSONNEL

#### ANP.10010 Professional Competency

#### Phase II



**The laboratory director ensures the professional competency of pathologists who provide interpretive services to the anatomic pathology laboratory.**

*NOTE: The mechanism for competency assessment must be pertinent to the type of interpretive services provided (eg, general anatomic, neuropathology, renal pathology, forensic pathology). There must be a written policy for assessing professional competency at defined intervals, criteria for the assessment, and records of the assessment must demonstrate review by the laboratory director.*

#### Evidence of Compliance:

- ✓ Participation in a peer educational program (eg, CAP Educational Anatomic Pathology Programs) or intra-departmental or inter-institutional peer review program **OR**
- ✓ Metrics developed from diagnostic quality management reports (ANP.10100, ANP.10150, ANP.12075, etc.) **OR**
- ✓ Quality management records (internal audits, error reports, etc.) **OR**
- ✓ Individual assessment according to defined criteria

## SURGICAL PATHOLOGY

### QUALITY MANAGEMENT

Many technical and procedural quality control items are covered elsewhere in this Checklist. They are integral components of a comprehensive quality management system and should be included within the defined system. This section determines if there is an active system of surveillance of the quality of surgical pathology activities, particularly the diagnostic reports. How this is accomplished depends upon the number of departmental staff, as well as the volume and type of diagnostic material. Such a system must include appropriate combinations of activities such as the use of intra- and extra-departmental consultations, circulation of diagnostic material (random or by case type), periodic review of completed surgical pathology reports, and participation in self-assessment and performance improvement programs.

#### ANP.10016 Surgical Pathology Exclusion

Phase I



**The institution defines specimen types that may be excluded from routine submission to the pathology department for examination, where applicable.**

*NOTE: This policy may be made in conjunction with the hospital administration and appropriate medical staff departments and must be in compliance with national, federal, state (or provincial), and local laws and regulations. The laboratory director should have participated in or been consulted by the medical staff in deciding which surgical specimens are to be sent to the pathology department for examination.*

*The California Department of Health Care Services requires all tissues and objects removed during surgery to be submitted for pathology examination, unless a specific request is submitted to the state requesting a variance.*

*This checklist item is not applicable if 1) all specimens are submitted to pathology, or 2) the laboratory is not part of an institution that provides surgical services.*

#### ANP.10032 Surgical Pathology Microscopic Exemptions

Phase I



**The institution defines which types of surgical specimens (if any) may be exempt from microscopic examination.**

*NOTE: Irrespective of any exemptions, microscopic examination may be performed whenever there is a request by the submitting or attending physician, or at the discretion of the pathologist when indicated by the clinical history or gross findings. Policies that exempt certain types of specimens from microscopic examination may be approved by the medical staff or appropriate committee. Typical exempt specimens include foreskins in children, prosthetic cardiac valves without attached tissue, torn meniscus, varicose veins, tonsils in children below a certain age, etc.*

#### ANP.10038 Tissue Sample Quality

Phase II



**Trained histology personnel responsible for tissue processing provide feedback on the quality of the tissue sections received for tissue processing.**

*NOTE: Inadequate fixation, overly thick tissue sections, non-decalcified bone, the presence of staples, etc., can lead to poor quality histologic sections and/or poor quality special stains/special studies.*

*The feedback on quality issues must be provided to a pathologist. When non-pathologist personnel assist in grossing, feedback must be provided to a pathologist with responsibility for supervising non-pathologist personnel. In case of other pathology subspecialties that gross tissue specimens (eg, dermatology), the feedback is provided to the individual responsible for the gross processing of those specimens.*

*This requirement applies to both laboratories that gross tissue and perform all processing onsite, as well as laboratories that gross tissue and send it to another laboratory for processing, embedding, and sectioning (regardless of the outside laboratory's accrediting organization).*

*Records of such feedback and corrective action taken when problems are identified may be incorporated into the laboratory's quality management program.*

**Evidence of Compliance:**

- ✓ Records of feedback and corrective action for problems identified with tissue quality

**\*\*REVISED\*\* 08/24/2023**

**ANP.10041 Quality of Formalin**

**Phase I**



**The laboratory monitors the quality of formalin provided for fixation of specimens to be submitted for pathology and for use as a fixative in the laboratory (eg, spot check or other processes).**

*NOTE: Laboratories that mix their own formalin need to check and record the pH to ensure that it was mixed correctly. The standard for tissue fixation is 10% neutral buffered formalin with a pH of 7.0.*

*Laboratories that purchase formalin ready for use or prefilled containers that are distributed to areas that collect specimens are also responsible for ensuring the quality of the formalin.*

*This requirement does not apply to situations where specimens are received from outside sources using containers not provided by the laboratory.*

**Evidence of Compliance:**

- ✓ Records of pH checks for new batches of formalin prepared by the laboratory **OR**
- ✓ Records of manufacturer's quality control of pH **OR**
- ✓ Records of spot checks performed by the laboratory for purchased formalin ready for use

**ANP.10042 Histologic Preparation Quality**

**Phase I**



**Pathologists or their designees provide feedback to the histology laboratory on the quality of histologic preparations. This process includes the daily recording of the histologic preparation quality for each day of tissue processing and slide preparation.**

*NOTE: Histologic preparations refer to H & E sections, histochemical stains, immunohistochemistry preparations, and in situ hybridization preparations.*

*This requirement applies to laboratories that process and interpret histologic preparations at the same location, as well as laboratories that interpret histologic preparations processed at another laboratory (regardless of that outside laboratory's accrediting organization).*

*When histologic preparations are inadequate or cross-contamination between specimens or cases is identified, feedback and corrective action must be recorded. These records may also be incorporated into the laboratory's quality management system.*

*Specific quality control requirements for special stains, immunohistochemistry, and other special studies are found elsewhere in this checklist.*

**Evidence of Compliance:**

- ✓ Records of feedback and corrective action for problems identified with histologic prep quality

**ANP.10050 Previous/Current Material Review**

**Phase II**



**When appropriate, previous cytologic and/or histologic material from the patient is reviewed with current material being examined.**

*NOTE: Because sequential analysis of cytologic and histologic specimens may be critical in patient management and follow-up, efforts must be made to routinely review previous material. Records of the retrospective review should be included in the current patient report.*

**ANP.10100 Intra-operative/Final Diagnosis Disparity**

**Phase II**



**When significant disparity exists between initial intra-operative consultation (eg, frozen section, intra-operative cytology, gross evaluation) and final pathology diagnosis, it is reconciled and recorded in the surgical pathology report and in the departmental quality management file.**

**ANP.10150 Intra and Extra-Departmental Consultations**

**Phase I**



**The laboratory has a defined process for handling information from intra- and extra-departmental consultations in the patient's final report.**

*NOTE: Intra-departmental consultations may be included in the patient's final report, or filed separately. The pathologist in charge of the surgical pathology case must decide whether the results of intra-departmental consultations provide relevant information for inclusion in some manner in the patient's report.*

*Records of extra-departmental consultations must be readily accessible within the pathology department. The method used to satisfy this requirement is at the discretion of the laboratory director, and can be expected to vary according to the organization of the department. These consultations can be retained with the official surgical pathology reports or kept separately, so long as they can be readily linked.*

**Evidence of Compliance:**

- ✓ Records of consultations included in the final report **OR**
- ✓ Records of consultations readily accessible within the pathology department

**ANP.10250 Extra-Departmental Consultation**

**Phase I**



**When extra-departmental cases are submitted to the laboratory for consultation, they are accessioned according to the standard practices of the laboratory, and a final pathology report is prepared, with a copy sent to the originating laboratory.**

*NOTE: In most cases, original materials including slides and blocks should be promptly returned to the original institution. However, in some situations (for example, when the patient is receiving ongoing care at the referral institution pending tumor resection, etc.) it may be appropriate for the referral laboratory to retain slides/blocks for a period of time. In such situations, a letter should be sent to the originating laboratory along with the consultation report, requesting permission to*

*retain the slides/blocks and accepting transfer of stewardship of the patient materials from the original laboratory to the referral institution.*

**Evidence of Compliance:**

- ✓ Patient reports for extra-departmental cases

**ANP.10260 Slide/Block Handling**

**Phase I**



**The laboratory handles original slides/blocks following a defined process for consultation and legal proceedings.**

*NOTE: This must include appropriate handling and accurate records of the use, circulation, referral, transfer, and receipt of original slides and blocks. The laboratory must have a record of the location of original slides and blocks that have been referred for consultation or legal proceedings.*

**ANP.10270 Off-Site Autopsies**

**Phase I**



**As applicable, there is a defined process for performance of autopsies off-site.**

*NOTE: If feasible, autopsies should be performed within the institution; however, if an institution does not perform autopsies, there must be a written policy that addresses how an autopsy is obtained when one is requested.*

**\*\*NEW\*\* 12/26/2024**

**ANP.10290 Instructions for Body Handling**

**Phase II**



**There are documented instructions covering such items as receipt, storage, and release of bodies.**

*NOTE: In some institutions, such policies and procedures may reside in the nursing or security manuals. In such cases, the laboratory must have copies of the manuals available at the time of inspection.*

*This requirement is not applicable if the laboratory is not responsible for handling bodies.*

## QUALITY CONTROL

### SURGICAL SPECIMEN EXAMINATION

*Note that requirements relating to collection and accessioning of specimens are covered in the Laboratory General Checklist. During the on-site inspection, the handling of surgical specimens must be evaluated.*

*"Grossing" is defined as a tissue specimen examination requiring knowledge of anatomy and judgment about sampling and sectioning. 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.*

*A "pathologist" is defined as a physician who has successfully completed an approved graduate medical education program in pathology. In the US, a physician is defined as a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine who is licensed by the state to practice medicine, osteopathy, or podiatry within the state in which the laboratory is located. In jurisdictions not subject to US regulations, a physician is defined as an individual who has a primary medical school degree (eg, MBBS, MBChB, MD, DO) in keeping with the standards of that particular jurisdiction.*

*Laboratories that do not file slides on-site (for example, some "read-only" laboratories) must retain a sample of cases and all associated slides on-site on all days when the laboratory is subject to its regular on-site inspection. The sample must, at a minimum, include all cases and all associated slides accessioned over a continuous two-week period within the previous two years.*

**ANP.11250 Adequate Storage Phase I**

**Refrigerated storage is available for large or unfixed specimens.**

**ANP.11275 Radioactive Material Handling - Specimens Phase II**



**The laboratory safely handles specimens that may contain radioactive material (eg, sentinel lymph nodes, breast biopsies, prostate "seeds," etc.).**

*NOTE: Policies and procedures may be developed in conjunction with the institutional radiation safety officer, and must comply with state regulations for the safe handling of specimens containing radionuclides. They should distinguish between low radioactivity specimens such as sentinel lymphadenectomy and implant devices with higher radiation levels.*

*The pathology department may wish to monitor these specimens for radioactivity, with safe storage of specimens until sufficient decaying has occurred, before proceeding with processing in the histology laboratory.*

**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.**

**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 subspecialties 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.*

**\*\*REVISED\*\* 12/26/2024**

**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 board or registry deemed comparable by OASD(HD) or their designee Center for Laboratory Medicine Services (CLMS) as an MLT or MT/MLS; OR*
- *Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and currently hold the military enlisted occupational specialty of medical laboratory specialist (laboratory technician).*

**Evidence of Compliance:**

- ✓ Records of qualifications including degree or transcript and work history in related field

**ANP.11640 Competency Assessment of Individuals Assisting with Grossing**

**Phase II**



**The competency of individuals assisting with grossing is assessed at least annually by a qualified pathologist (or by another qualified individual for specific subspecialties as defined in ANP.11600).**

*NOTE: Please refer to GEN.55500 and GEN.55505 on competency assessment in the Laboratory General Checklist for a list of criteria and frequency for competency assessment. Not all six elements may apply in all cases.*

*For dermatopathology cases, including Mohs surgery, an MD or DO dermatologist who is licensed to practice (if required) in the jurisdiction where the laboratory is located and is board certified in dermatology is qualified to perform gross examination and evaluate non-pathologists.*

**Evidence of Compliance:**

- ✓ Records of competency assessment performed at a defined frequency

**ANP.11660 Surgical Tissue Diagnosis**

**Phase II**

**All surgical tissue diagnoses are made by a qualified pathologist. Exceptions for other qualified individuals for specific subspecialties are described in the NOTE.**

*NOTE: The following are exceptions for specific types of tissue diagnosis for non-pathologist individuals:*

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

**Evidence of Compliance:**

- ✓ Pathology reports signed by diagnosing pathologist or other qualified individual based on subspecialty

**ANP.11670 Specimen - Gross Examination**

**Phase I**



**Written instructions or guidelines are readily available in the laboratory for the proper dissection, description, and histologic sampling of various specimen types (eg, mastectomy, colectomy, hysterectomy, renal biopsy, etc.).**

*NOTE: The instructions/guidelines should address large or complicated specimen types and smaller specimens requiring special handling, such as muscle biopsies, renal biopsies, and rectal suction biopsies for Hirschsprung's disease. Guidelines serve an important educational function in departments with postgraduate (residency) programs. However, they also are useful*

*in providing consistency in the handling of similar specimen types in departments without such training programs.*

*The ideal thickness for specimen sections submitted in cassettes is 5 mm or less.*

#### ANP.11680 Cross Contamination - Grossing

Phase II



**The laboratory minimizes cross-contamination of specimens during grossing.**

*NOTE: Problems with cross-contamination must be addressed in the surgical pathology quality management system.*

*At a minimum, cleaning (eg, wiping or rinsing) of forceps and scalpel blades between cases is required. In addition, if a laboratory processes both small specimens (eg, biopsies) and large specimens (eg, surgical resections), cleaning of instruments and cutting surfaces must be performed between cases. Avoid re-using cotton swabs/applicator sticks on multiple specimens or "double-dipping" the cotton swab/applicator in the ink. Some laboratories may choose to use disposable surfaces (eg, formalin absorbent pads, butcher paper, etc.) for large cases. Grossing of similar types of specimens sequentially should be avoided, if feasible.*

#### ANP.11716 Paraffin Microtomy

Phase II



**The appropriate thickness of paraffin embedded tissue sections for various tissue types and procedures is defined.**

*NOTE: Paraffin embedded sections are routinely sectioned at 4-5 microns. Some tissues (eg, renal biopsy) may require thinner sections, while some special stain techniques (eg, Congo red stain) may require thicker sections. Use of the recommendations in the table below is at the discretion of the laboratory director.*

Tissue	Thickness
Routine Paraffin	4 to 5 microns
Renal Sections	1 to 3 microns
Bone Marrow	2 to 3 microns
Nerve histochemical staining	6 to 15 microns
Amyloid demonstration	6 to 12 microns

#### ANP.11734 Slide Quality

Phase II

**Slides are of sufficient quality for diagnosis.**

*NOTE: Histopathology slides must be of adequate technical quality to be diagnostically useful. Criteria to evaluate include adequate tissue fixation, processing, thickness of sections, absence of interfering tissue folds and tears, and good staining technique and coverslipping. For hematoxylin and eosin and other routine stains, the patient slide serves as the internal control to ensure adequate staining technique. The sections must be cut from sufficient depth in the block to include the entire tissue plane.*

## INTRA-OPERATIVE CONSULTATION (RAPID DIAGNOSIS)

*NOTE: This checklist subsection applies to intra-operative consultations including gross examination of specimens, frozen sections, touch preparations, scrape preparations, etc.*

**ANP.11756 Reagents**

**Phase II**



**All solutions and stains are properly labeled and changed on a defined schedule.**

*NOTE: All solutions and stains must be properly labeled with the contents, and, if applicable, date they are changed/filtered and expiration date. All solutions and stains must be changed or filtered following a defined process, determined by the usage of the reagents.*

**Evidence of Compliance:**

- ✓ Written records of reagent change process **OR** records of reagent change on a QC log

**ANP.11810 Intra-operative Slide Preparation Quality**

**Phase II**

**Frozen section, touch and scrape preparations are adequate for intra-operative diagnosis.**

**ANP.11850 Intra-Operative Results**

**Phase II**

**The results of intra-operative surgical consultations are recorded and signed by the individual who rendered the diagnosis.**

*NOTE: The intent of this requirement is for the laboratory to maintain a contemporaneous report of the consultation. This may be a handwritten, signed report or a computer-generated report with electronic signature.*

**ANP.11900 Verbal Reports**

**Phase II**

**If verbal reports are given, the pathologist is able to speak directly with intra-operative medical/surgical personnel.**

**Evidence of Compliance:**

- ✓ Records of intra-operative result report notification

**ANP.11950 Verbal Report/Patient ID**

**Phase II**



**The patient's identification is checked and confirmed before delivery of any verbal report.**

**ANP.12000 Final Report**

**Phase II**

**All intra-operative consultation reports are made a part of the final surgical pathology report.**

**ANP.12050 Intra-operative Slide Handling**

**Phase II**

**All frozen section, touch and scrape preparation slides are permanently stained, mounted, properly labeled, and retained with the rest of the slides from the case.**

**Evidence of Compliance:**

- ✓ Retained frozen section preparation slides

**ANP.12075 Residual Frozen Tissue After Frozen Section Examination**

**Phase I**



**Following frozen section examination, the residual frozen tissue is routinely processed into paraffin, and histologic sections are prepared and examined for comparison with the frozen section interpretation.**

*NOTE: Subject to the exceptions below, the laboratory must prepare a paraffin block and stained slide(s) from each frozen section block.*

*Correlation of frozen section findings with a permanent section prepared from routinely fixed and processed residual frozen tissue is an important quality improvement mechanism. Evaluation of such permanent sections provides important feedback on the accuracy of frozen section diagnoses and improves recognition of specific frozen section morphologic alterations.*

*The only exceptions to this requirement, at the discretion of the laboratory director, responsible pathologist, or Mohs surgeon, are as follows:*

- *Frozen tissue submitted at the time of initial diagnosis for specialized studies or frozen tissue from lesions that have the potential for additional studies using archived frozen tissue at a later time (eg, diffuse gliomas)*
- *Other frozen sections where the margin or lesion has been exhausted during the frozen section evaluation and no pertinent residual tissue remains*
- *Mohs frozen sections. However, occasionally, examination of paraffin sections of tissue from Mohs procedures is warranted (refer to the [American Academy of Dermatology and AAD Position Statement, Appropriate Uses of Paraffin Sections in Association with Mohs Micrographic Surgery](#)).*

**Evidence of Compliance:**

- ✓ Records of frozen and permanent tissue section correlation

## FINE NEEDLE ASPIRATE (FNA) SPECIMENS

*NOTE: This checklist section applies if FNA specimens are evaluated and reported in the Surgical Pathology section.*

*If FNA slides are screened by cytotechnologists, the Cytopathology Checklist must be used.*

### ANP.12094 FNA Error Prevention

Phase II



**The pathologist performing FNA procedures verifies patient identification using at least two patient identifiers, the procedure site, and the procedure to be performed.**

### ANP.12096 Cross-Contamination - FNA

Phase II



**The laboratory prevents cross-contamination of FNA specimens during processing and staining.**

*NOTE: Methods to prevent cross-contamination may include cytocentrifuge, filter and monolayer preparations. Smears made from highly cellular cases should be stained after the other cases, and the staining fluids must be changed or filtered at appropriate intervals. One procedure to detect contamination is to insert a clean blank slide in each staining run and examine it for contaminating cells.*

## SURGICAL PATHOLOGY REPORTS

*Reporting requirements for use of analyte-specific reagents and other reagents used in laboratory-developed tests are included in the All Common Checklist (COM.40850).*

### ANP.12155 Gross Description Report Elements

Phase II

**All surgical pathology reports include gross descriptions, information essential for diagnosis and patient care, and essential processing information.**

**NOTE:**

1. Descriptions must include information regarding type, number, dimensions and/or weight of specimens, measurements and extent of gross lesions, as applicable.
2. Processing information must include a summary of block/slide designations, type of specimen fixation and processing (eg, formalin-fixed paraffin-embedded sections, air-dried imprints), cold ischemia time, and length of time in fixative, as applicable.
3. Annotated drawings and photographs are valuable tools for recording gross findings, but are not adequate replacements for a text description

**Evidence of Compliance:**

- ✓ Surgical pathology reports including the required gross description elements

**ANP.12170 Report Review**

**Phase II**

**All reports are reviewed and signed by the pathologist or other qualified physician as defined in ANP.11660.**

*NOTE: The review of the report by the pathologist must include review of the gross examination, microscopic descriptions (if provided), and pathologic diagnosis.*

*A single signature on the final pathology report indicates that the responsible pathologist has reviewed all sections of that report. Signatures for each section of the report are not necessary.*

*The inspector must review a broad sampling of surgical pathology reports issued since the previous on-site inspection, representing at least the most common types of specimens seen in the laboratory. When diagnostic reports are generated by computer or telecommunications equipment, the actual signature or initials of the pathologist may not appear on the report. It is nevertheless essential that the laboratory have a procedure that ensures and records that the responsible pathologist has reviewed and approved the completed report before its release. In the occasional situation when the diagnosing pathologist is not available for timely review and approval of the completed report, the laboratory may have a procedure for review and approval of that report by another pathologist. In that circumstance, the names and responsibilities of both the pathologist who made the diagnosis and the pathologist who performs final verification must appear on the report.*

**ANP.12175 Significant and Unexpected Findings**

**Phase II**



**Significant and unexpected surgical pathology findings are communicated to the responsible clinician and records of those communications are retained.**

*NOTE: Certain surgical pathology diagnoses may be considered significant and unexpected warranting special communication to the responsible clinician(s). The pathology department determines diagnoses to be defined as "significant and unexpected," in cooperation with local clinical medical staff. Examples include: malignancy in an uncommon location or specimen type (eg, hernia sac, intervertebral disk material, tonsil, etc.), change of a frozen section diagnosis after review of permanent sections, amendments to reports that may significantly affect patient care, neoplasms causing paralysis, or fat in an endometrial curettage.*

*There must be a reasonable effort to ensure that clinicians receive the communications. The records must include the following:*

- Date of communication
- Time of communication (if required by laboratory policy)
- Responsible individual communicating the result
- Person notified using identifiers traceable to that person (a first name alone is inadequate)
- Findings communicated.

*An appropriate notification includes a direct dialog with the responsible individual or an electronic communication (secure email or fax) with confirmation of receipt by the responsible individual.*

*The record of the communication may be included directly on the patient report or in a separate location. It is not necessary to separately summarize the findings communicated if the record of the communication is on the patient report. For communications recorded in a separate location, the findings communicated may be summarized or reference the case number.*

*This requirement takes the place of critical result notification in the All Common Checklist (COM.30000 and COM.30100) for surgical pathology findings.*

**Evidence of Compliance:**

- ✓ Records of communication of significant/unexpected findings

**ANP.12185 Amended Reports**

**Phase II**



**The laboratory issues an amended report and promptly notifies the responsible clinician(s) when there are changes to reports that affect current patient care.**

*NOTE: The amended report must state the reason for the amendment. The format of amended reports is at the discretion of the laboratory. For extensive interpretive or textual data, replicating the entire original and amended pathology reports may be cumbersome and render the report difficult to interpret. In such cases, a comment in the amended report summarizing the previous information and the reason for the amendment may be provided.*

*Records of the notification must include date, responsible laboratory individual, and person notified.*

**Evidence of Compliance:**

- ✓ Patient reports containing the reason for the amendment **AND**
- ✓ Records of notifications

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**ANP.12350 Cancer Protocols**

**Phase II**



**All required data elements in applicable CAP Cancer Protocols are included with appropriate responses using a synoptic format in surgical pathology reports from definitive resection specimens for primary invasive malignancies, as well as cases of ductal carcinoma in situ of the breast (DCIS) and biopsies of pediatric tumor types listed in the CAP Cancer Protocols.**

**NOTE:**

1. *This checklist requirement is not applicable to:*
  - Cancer for which no CAP Cancer Protocol is available
  - Additional surgical procedures performed after definitive surgical resection such as excision for positive margins or lymph node sampling
  - Definitive resection specimens that do not contain cancer (eg, following neoadjuvant chemotherapy)
  - Diagnostic biopsy (except for pediatric tumor types listed in the CAP Cancer Protocols), cytology specimens, or other diagnostic procedures done prior to definitive surgical therapy.
  - Metastatic tumors or resections for recurrent tumors
  - Special studies, including biomarker testing performed in another laboratory.
2. *Reports must include the required core and applicable conditional data elements along with the appropriate responses from the current edition of the CAP Cancer Protocols. Data elements and responses do not have to be identical (ie, verbatim) to that listed in the CAP protocol and may be rephrased (eg, for conciseness) as long as the intended meaning remains clear.*
3. *The synoptic component of the cancer reports meets the following four key criteria:*

- All core elements must be reported whether applicable or not. Elements identified in the Cancer Protocols as conditional only need to be reported if applicable.
  - All data elements and responses must be reported in an element response pair format, ie, defined as data element followed by its response (eg, Histologic type: Invasive lobular carcinoma).
  - Each element response pair must be listed on a separate line or in a tabular format to achieve visual separation. Two or more data elements may NOT be listed together on one line with the following exceptions:
    - Anatomic site or specimen, laterality, and procedure
    - Pathologic Staging Tumor Node Metastasis (pTNM) staging elements
    - Negative margins, as long as all negative margins are specifically enumerated where applicable
  - All required data elements must be listed together in one location in the pathology report and may be listed in any order. Additional items may be added within the synoptic report as needed.
4. Required data elements may appear in a summary format elsewhere in the report IN ADDITION TO, but not as a replacement for the synoptic report (ie, all required elements must be listed together in one location in the synoptic portion of the report in the format defined above).
  5. Additional methods may be used in order to enhance or achieve visual separation such as use of headers, indentations, or bolding and/or font variations.
  6. The synoptic report may be produced either manually or by a commercial electronic reporting tool or specialized software.
  7. The laboratory must either have processes to ensure compliance with this checklist requirement or perform an assessment of compliance. Examples of processes to ensure compliance include LIS-built-in checks, use of templates for reporting, or LIS-generated reports. Alternative processes may be implemented at the discretion of the laboratory director.
  8. For reporting errors that either involve missing required data elements or are deemed to be other omissions or errors that may adversely affect patient care (errors that may be impactful to patient care, errors that affect treatment decisions and staging of cancer, etc.), the laboratory must issue an amended or addendum report. The laboratory is not required to issue an amended or addendum report for omissions or errors that have no significant effect on current patient care.
  9. Laboratories outside of the US may use regionally produced cancer reporting datasets.
  10. The laboratory has up to eight months from the posting date of the CAP Cancer Protocol to implement data element changes.

**Evidence of Compliance:**

- ✓ Surgical pathology reports for definitive cancer resection with required data elements and in synoptic format **AND**
- ✓ Records from processes used to ensure reporting compliance **AND**
- ✓ Records of corrective action if reporting omissions or errors were identified

**ANP.12400 Correlation of Results**

**Phase II**

**Morphologic diagnoses are correlated with the results of specialized studies (eg, immunohistochemistry, nucleic acid probes, cytogenetics, flow cytometry, electron microscopy).**

*NOTE: It is not in the best interests of the patient to have potentially conflicting diagnoses or interpretations rendered by different sections of the laboratory. The pathologist should issue a report reconciling potentially conflicting data, when appropriate.*

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**ANP.12500 Record and Material Retention - Surgical Pathology**

**Phase II**



### Surgical pathology records and materials are retained for an appropriate period.

**NOTE 1:** The retention policy must address protecting and preserving the integrity and retrieval of surgical pathology materials and records.

**Policies for retention of records and materials must comply with national, federal, state (or provincial), and local laws and regulations, and with the retention periods listed in the table below, whichever is most stringent.**

Type of Record/Material	Retention Period
Accession log records	2 years
Wet tissue (stock bottle)	2 weeks after final report
Paraffin blocks (including cell blocks)	10 years Refer to Note 2 below, paragraphs #2 and #3, for deceased patient material
Immunohistochemistry batch control slides	2 years
Surgical pathology glass slides	10 years - slides must remain readable for this period
Surgical pathology reports *	10 years
Reports of outside consultations on laboratory cases (whether or not requested by the laboratory)	10 years after the date that the original report was issued
Fluorochrome-stained slides	At the discretion of the laboratory director
Images or permanent slides of ISH studies	10 years for neoplastic disorders 20 years for constitutional disorders (Subject to Note 4 below)
Images for Circulating Tumor Cells	10 years
Digital images used for primary diagnosis	10 years if original glass slides are not available; may not replace glass slides
Datasets from In-Vivo Microscopy (IVM) or Ex Vivo Microscopy (EVM) systems used to aid in interpretation or diagnosis	10 years - data must be retrievable for this period (Subject to Note 5 below)

\* Pathology reports may be retained in either paper or electronic format. If retained in electronic format alone, the reports must include a secure pathologist electronic signature. Images of paper reports, such as microfiche or PDF files are acceptable.

**NOTE 2:** Paraffin blocks used for patient diagnostic, prognostic and/or predictive purposes must be kept for at least 10 years and be stored in a manner that preserves their identity and integrity. Tissue blocks must be stored in a temperature-controlled, pest-free environment to maintain tissue integrity. The CAP recommends (but does not require) ambient temperatures in block storage areas to be less than 27°C.

Paraffin blocks may be released for research purposes if all of the following criteria are met:

1. For laboratories subject to US regulations, formal written authorization is obtained in accordance with the requirements of HIPAA if identifiable patient information is released.
2. The laboratory retains sufficient blocks to support the diagnosis for the full 10-year period. After a patient has been deceased for two years, only one block containing normal tissue (if it exists) needs to be retained for the full 10-year period.
3. Provision is made for retrieval by the laboratory of any blocks or material that remain after use in research, if the blocks or material are needed for diagnostic, legal, or other legitimate purposes. After a patient has been deceased for two years, only one block containing normal tissue (if it exists) must be retrievable for the full 10-year period.

4. *In the event of limited material (eg, only one diagnostic block), tissue microarray (TMA) cores or portions of the block may be released for research or clinical trials, as long as the original lab retains control or access to the diagnostic material if clinically needed.*
5. *The laboratory meets other relevant requirements including but not limited to the requirements of the institution, the directives of any applicable institutional review board (IRB) or similar entity; and state and local laws and regulations.*

*The restriction on release of blocks does not prohibit release of blocks for purposes of treatment, diagnosis, prognosis, etc., for patients on research protocols as long as release is consistent with patient privacy regulations (eg, HIPAA) and applicable state and local regulations; and there is IRB approval, as applicable.*

*NOTE 3: Given that patient survival rates are increasing and the continued emergence of treatment based on biomarker testing, which at times may be required on the original tissue, it is recommended that, whenever feasible, tissue block retention from patients with diagnosed malignancies be retained beyond the 10 year requirement.*

*NOTE 4: There is no retention requirement for images of slide preparations when the source slides remain readable for the required retention period. If slides are expected to become unreadable before the end of the required retention periods (for example, FISH slides), then images that adequately represent findings on the slides must be retained.*

*If representative images of chromosome ISH slides are retained, those with a normal result must include an image of at least one cell illustrating the normal probe signal pattern, and those with an abnormal result must include images of at least two cells illustrating each relevant abnormal probe signal pattern.*

*NOTE 5: In Vivo Microscopy (IVM) and Ex Vivo Microscopy (EVM) systems include confocal microscopy, optical coherence tomography, multiphoton microscopy, optical spectroscopy/spectroscopic imaging, and similar technologies. These systems may be used by physicians during procedures (IVM) or by the laboratory in the evaluation of specimens that have been removed from the patient (EVM). The dataset refers to digitized or analog video or still images or other data (eg, spectroscopic data) generated by an IVM or EVM system. If such data is used to aid in interpretation or diagnosis, record retention requirements apply. Stored data should include, at a minimum, the data used to aid in interpretation or diagnosis.*

*NOTE 6: Refer to GEN.20425 for record and material retention requirements for laboratories that cease operations.*

## HISTOLOGY LABORATORY

*The current histochemical test menu should be made available to the inspector. The inspector should select a variety of stained slides from the menu and evaluate for quality.*

### GENERAL QUALITY CONTROL

**ANP.21350 Specimen Preparation Records**

**Phase II**

**The histology laboratory retains records of the number of blocks, slides, and stains prepared.**

*NOTE: Laboratories must be capable of demonstrating volumes for any given period of time.*

**ANP.21360 Automated Stainer**

**Phase II**



**The laboratory changes solutions in automated stainers following a defined schedule.**

*NOTE: Solutions must be changed at intervals appropriate for the laboratory's workload. Changing, filtering, or adding to solutions must be recorded when performed.*

**Evidence of Compliance:**

- ✓ Records for solution changes

**ANP.21395 Special Stains/Studies**

**Phase II**



**For special stains, including histochemical stains, and studies using immunologic and ISH methodology, positive and negative controls are verified and recorded as acceptable prior to or concurrent with the reporting of patient results and records retained.**

*NOTE: Controls must be verified and recorded as acceptable by a pathologist or designee (provided the designee meets high complexity testing qualifications).*

*Positive tissue controls must contain the component specific to the special stain that is being applied to the specimen.*

*Immunohistochemical tests using polymer-based detection systems (biotin-free) are sufficiently free of background reactivity to obviate the need for a negative reagent control and such controls may be omitted at the discretion of the laboratory director following appropriate validation.*

*If interpretation of the special stain or study is performed by a different laboratory, there must be a procedure for the laboratory performing the stain or study to verify the acceptability of the controls before transfer, if the controls are not sent with the patient slides (regardless of the outside laboratory's accrediting organization). Records of this verification must be readily available to the laboratory performing the interpretation.*

**Evidence of Compliance:**

- ✓ Records for verification of control acceptability (prior to completion of associated cases)

**ANP.21397 Cross-Contamination - Histology**

**Phase II**



**The laboratory prevents cross-contamination of specimens in the histology laboratory.**

*NOTE: The process must address steps to prevent cross-contamination during the various phases of tissue handling including: processing, embedding, microtomy, and slide preparation. Problems with cross-contamination must be addressed in the surgical pathology quality management system.*

*Instruments must be clean and well-maintained (eg, tissue processors, embedding centers, dispensers, floatation baths, staining and coverslipping equipment).*

*At the embedding station, cleaning or wiping of forceps between cases is required. Only one cassette should be handled at a time.*

*For microtomy, there must be a clear process for handling of blocks and labeling of slides to prevent specimen mix-ups. Floatation baths require periodic water changes or blotting of the water surface so that sections from one patient block are not inadvertently carried over to another case or block (so-called "floaters" or "extraneous tissue").*

## **IMMUNOFLUORESCENCE MICROSCOPY**

**ANP.21850 QC - Immunofluorescence**

**Phase II**

**For immunofluorescence microscopy, appropriate positive and negative controls are performed.**

*NOTE: Internal antigens serve as positive controls (eg, IgA in tubular casts, IgG in protein droplets and C3 in blood vessels). When internal positive controls are absent, daily external positive controls are required. Non-reactive elements in the patient specimen may serve as a negative tissue control. A negative reagent control in which the patient tissue is processed in an identical manner to the test specimen, but with the primary antibody omitted, should be performed for each patient test specimen at the discretion of the laboratory director.*

**Evidence of Compliance:**

- ✓ Records of immunofluorescence QC

## IMMUNOHISTOCHEMISTRY

*This section must be used to inspect immunochemistry staining performed on histology specimens. It should also be used to inspect immunostaining of cytology specimens (eg, air-dried touch imprints, air-dried and/or alcohol fixed smears, cytocentrifuge or other liquid-based preparations, and cellular materials fixed in alcohol blends or other fixatives). However, if the laboratory has a separate section for performing cytologic immunocytochemistry, the Immunocytochemistry section of the Cytopathology Checklist should be used to inspect that laboratory section.*

*The term immunohistochemistry (IHC) used within this section also includes immunocytochemistry.*

*Please refer to the Definition of Terms section in the All Common (COM) Checklist for definitions of analytical validation and analytical verification.*

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**ANP.22550 QC - Antibodies**

**Phase II**



**Positive controls are used for each antibody.**

*NOTE: Positive controls assess the performance of the immunohistochemistry assay (including impact of fixation and antigen retrieval) and can assess the sensitivity of the assay. They should, whenever possible, be subjected to the same processing, antigen retrieval, and immunostaining protocol as patient tissue.*

*Results of controls must be recorded, either in internal laboratory records, or in the patient report. A statement in the report such as, "All controls show appropriate reactivity" is sufficient.*

*For tissue-based positive controls, the ideal control is of the same specimen type as the patient test specimen (eg, small biopsy, large tissue section, cell block), and is processed and fixed in the same manner (eg, formalin-fixed, alcohol-fixed, decalcified) as the patient specimen. However, for most laboratories, it is not practical to maintain separate positive control samples to cover every possible combination of fixation, processing and specimen type. Thus, it is reasonable for a laboratory to maintain a bank of formalin-fixed tissue samples as its positive controls; these controls can be used for patient specimens that are of different type, or fixed/processed differently, providing that the laboratory can show that these patient specimens exhibit equivalent immunoreactivity. This can be accomplished by parallel testing a small panel of common markers to show that specimens of different type, or processed in a different way (eg, alcohol-fixed cytology specimens, decalcified tissue) have equivalent immunoreactivity to routinely processed, formalin-fixed tissue.*

*A separate tissue section may be used as a positive control, but test sections often contain normal elements that express the antigen of interest (internal controls). Internal positive controls*

*are acceptable for these antigens, but the laboratory manual must clearly state the manner in which internal positive controls are used.*

*A positive control included on the same slide as the patient tissue is optimal practice because it helps identify failure to apply primary antibody or other critical reagents to the patient test slide; however, one separate positive control per staining run for each antibody in the run (ie, batch control) may be sufficient provided that the control slide is closely scrutinized by a qualified reviewer.*

*Ideally, positive controls have low levels of antigen expression, as is often seen in neoplasms. Different expression level controls are suggested if related to companion diagnostic clinical decision points (ie, HER2; 0, 1+, 2+, 3+). Exclusive use of normal tissues that have high levels of antigen expression may result in failure to identify assays of insufficient sensitivity, leading to false-negative results.*

*Synthetic materials (eg, microbeads) and cell lines containing IHC analytes of interest may be run as controls in addition to positive tissue controls. Synthetic controls and cell lines should contain the target epitope of the IHC assay. Controls that assess the IHC protocol should be sensitive to the antigen retrieval step.*

*Synthetic and cell line-based controls can be particularly useful to assess assay performance at low expression levels, such as detecting low levels of expression in breast cancer. Synthetic and cell line-based controls are not ideal for optimizing digital pathology algorithms, which are optimally tuned to IHC expression in human tumors.*

#### **Evidence of Compliance:**

- ✓ Patient reports or worksheet with control results **AND**
- ✓ Immunohistochemical-stained slides with positive controls

**\*\*NEW\*\* 12/26/2024**

#### **ANP.22560 Synthetic and Commercial Control Range Establishment or Verification**

**Phase II**



**If synthetic or commercial controls are used for quantitative testing, the laboratory establishes or verifies an acceptable control range for each lot of synthetic or commercial control material.**

*NOTE: The laboratory must verify control ranges supplied by the manufacturer if provided and establish an acceptable range by repetitive analysis if control ranges are not provided by the manufacturer.*

*Control values supplied by the manufacturer may be used without verification for qualitative (eg, positive or negative) testing.*

#### **Evidence of Compliance:**

- ✓ Records for control range establishment or verification of each lot, as applicable

#### **ANP.22570 QC - Antibodies**

**Phase II**



**Appropriate negative controls are used.**

*NOTE: Negative controls must assess the presence of nonspecific staining in patient tissue as well as the specificity of each antibody with the exception listed below. Results of controls must be recorded, either in internal laboratory records, or in the patient report. A statement in the report such as, "All controls show appropriate reactivity" is sufficient.*

*For laboratories using older biotin-based detection systems, it is important to use a negative reagent control to assess nonspecific or aberrant staining in patient tissue related to the antigen retrieval conditions and/or detection system used. A separate section of patient tissue is processed using the same reagent and epitope retrieval protocol as the patient test slide, except that the primary antibody is omitted, and replaced by any one of the following:*

- An unrelated antibody of the same isotype as the primary antibody (for monoclonal primary antibodies)
- An unrelated antibody from the same animal species as the primary antibody (for polyclonal primary antibodies)
- The negative control reagent included in the staining kit
- The diluent/buffer solution in which the primary antibody is diluted

In general, a separate negative reagent control should be run for each block of patient tissue being immunostained; however, for cases in which there is simultaneous staining of multiple blocks from the same specimen with the same antibody (eg, cytokeratin staining of multiple axillary sentinel lymph nodes), performing a single negative control on one of the blocks may be sufficient provided that all such blocks are fixed and processed identically. This exception does not apply to stains on different types of tissues or those using different antigen retrieval protocols or antibody detection systems. The laboratory director must determine which cases will have only one negative reagent control, and this must be specified in the department's procedure manual.

The negative reagent control would ideally control for each reagent protocol and antibody retrieval condition; however, large antibody panels often employ multiple antigen retrieval procedures. In such cases, a reasonable minimum control would be to perform the negative reagent control using the most aggressive retrieval procedure in the particular antibody panel. Aggressiveness of antigen retrieval (in decreasing order) is as follows: pressure cooker; enzyme digestion; boiling; microwave; steamer; water bath. High pH retrieval should be considered more aggressive than comparable retrieval in citrate buffer at pH 6.0.

Immunohistochemical tests using polymer-based detection systems (biotin-free) are sufficiently free of background reactivity to obviate the need for a negative reagent control and such controls may be omitted at the discretion of the laboratory director following appropriate validation.

It is also important to assess the specificity of each antibody by a negative tissue control, which must show no staining of tissues known to lack the antigen. The negative tissue control is processed using the same fixation, epitope retrieval and immunostaining protocols as the patient tissue. Unexpected positive staining of such tissues indicates that the test has lost specificity, perhaps because of improper antibody concentration or excessive antigen retrieval. Intrinsic properties of the test tissue may also be the cause of "non-specific" staining. For example, tissues with high endogenous biotin activity such as liver or renal tubules may simulate positive staining when using a detection method based on biotin labeling.

A negative tissue control must be processed for each antibody in a given run. Any of the following can serve as a negative tissue control:

1. Multitissue blocks. These can provide simultaneous positive and negative tissue controls, and are considered "good practice" (see below).
2. The positive control slide or patient test slides, if these slides contain tissue elements that should not react with the antibody.
3. A separate negative tissue control slide.

The type of negative tissue control used (ie, separate sections, internal controls or multitissue blocks) must be specified in the laboratory manual.

Multitissue blocks or tissue microarrays (TMAs) can have a major role in maintaining quality. When used as a combined positive and negative tissue control as mentioned above, they can serve as a permanent record of the sensitivity and specificity of every stain, particularly when mounted on the same slide as the patient tissue. When the components are chosen appropriately, multitissue blocks may be used for many different primary antibodies, decreasing the number of different control blocks needed by the laboratory. Multitissue blocks are also ideal for determining optimal titers of primary antibodies since they allow simultaneous evaluation of many different pieces of tissue. Finally, they are a useful and efficient means to screen new antibodies for sensitivity and specificity or new lots of antibody for consistency, which should be done before putting any antibody into diagnostic use.

#### **Evidence of Compliance:**

- ✓ Patient reports or worksheet with control results **AND**

- ✓ Immunohistochemical-stained slides with appropriate negative controls

#### ANP.22615 Endogenous Biotin

Phase I



**If the laboratory uses an avidin-biotin complex (ABC) detection system (or a related system such as streptavidin-biotin or neutravidin-biotin), nonspecific false-positive staining from endogenous biotin is addressed.**

*NOTE: Biotin is a coenzyme present in mitochondria, and cells that have abundant mitochondria such as hepatocytes, kidney tubules and many tumors (particularly carcinomas) are rich in endogenous biotin. Biotin-rich intranuclear inclusions are also seen in gestational endometrium and in some tumors that form morules. If steps are not included in the immunostaining method to block endogenous biotin before applying the ABC detection complex, nonspecific false-positive staining may occur, particularly when using heat-induced epitope retrieval (which markedly increases the detectability of endogenous biotin). This artifact is often localized to tumor cells and may be easily misinterpreted as true immunoreactivity.*

*Blocking endogenous biotin involves incubating the slides with a solution of free avidin (which binds to endogenous biotin), followed by incubation with a biotin solution (which saturates any empty biotin-binding sites remaining on the avidin). Biotin-blocking steps should be performed immediately after epitope retrieval and before incubation with primary antibody.*

#### ANP.22660 Control Slide Review

Phase II

**The laboratory director or designee reviews batch control slides for acceptability before reporting results.**

*NOTE: Records of this daily review must be retained and clearly show that positive and negative controls for all antibodies stain appropriately. Batch control records must be retained for two years.*

*Immunohistochemical tests using polymer-based detection systems (biotin-free) are sufficiently free of background reactivity to obviate the need for a negative reagent control and such controls may be omitted at the discretion of the laboratory director following appropriate validation.*

*The batch control slides must be readily available to pathologists who are signing out cases. The location of the slides should be stated in the procedure manual.*

##### **Evidence of Compliance:**

- ✓ Patient reports or worksheet with control results

#### ANP.22900 Slide Quality

Phase II

**The immunohistochemical stains produced are of acceptable technical quality.**

*NOTE: The inspector must examine examples of the immunohistochemical preparations offered by the laboratory. A reasonable sample might include 5-10 diagnostic antibody panels.*

## PREDICTIVE MARKERS

*The term predictive marker as used in this section refers to immunohistochemical (IHC), immunocytochemical, and in situ hybridization (ISH) biomarkers used independent of histologic findings to identify individuals who are more likely to experience a favorable or unfavorable effect from a specific (targeted) therapy, compared to individuals with the same diagnosis lacking the biomarker. Rather than confirming a specific diagnosis (such as B-cell lymphoma or gastrointestinal stromal tumor), these biomarkers predict responsiveness to a specific treatment among cases of the same diagnosis. For example, this section applies to estrogen receptor testing*

used to determine eligibility for hormonal treatment of breast carcinoma, but does not apply to estrogen receptor testing used solely to assist in determining the primary site of origin of a metastatic neoplasm.

The current CAP guidelines (<https://www.cap.org/protocols-and-guidelines/current-cap-guidelines>) relating to predictive marker testing (eg, ASCO/CAP HER2 and ER testing in breast cancer) may be found at <http://www.cap.org> in the Protocols and Guidelines section. The guidelines are periodically updated based on new evidence. Laboratories should review updated predictive marker guidelines and promptly implement changes for items relating to requirements in the checklists (eg, validation, fixation, scoring criteria).

If digital image analysis is used (eg, quantitative image analysis for HER2 by immunohistochemistry), additional requirements in the Digital Image Analysis section also apply.

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**ANP.22969 Report Elements**

**Phase II**

**For immunohistochemical (IHC) and in situ hybridization (ISH) tests that provide independent predictive information, the patient report includes information on specimen processing, the antibody clone/probe, and the scoring method used.**

*NOTE: The laboratory performing the gross examination of the specimen must record the cold ischemia time and the length of time in fixative. If the grossing laboratory refers IHC or ISH studies, this information must be provided to the laboratory(ies) performing these studies.*

*For IHC and ISH studies used to provide predictive information independent of diagnosis or other histopathologic findings (eg, estrogen receptors and HER2 in breast carcinoma, PD-L1 and lung adenocarcinoma predictive immunostains), the laboratory must include the following information in the patient report:*

1. *The type of specimen fixation and processing (eg, formalin-fixed paraffin-embedded sections, air-dried imprints, etc.)*
2. *For IHC studies, the antibody clone and general form of detection system used (eg, LSAB, polymer, proprietary kit, vendor name, etc.; information on the type of equipment used is not necessary)*
3. *For ISH studies, the probe and, if applicable, the detection system used (ie, LSAB, polymer, proprietary kit, vendor name, etc.; information on the type of equipment used is not necessary)*
4. *Criteria used to determine a positive vs. negative result, and/or scoring system (eg, percent of stained cells, staining pattern)*
5. *Laboratory interpretation of predictive marker testing (IHC or ISH) is reported according to the manufacturer's instructions, or when available, following the structure, format, and criteria set forth in the current [CAP guidelines](#) relating to predictive marker testing (eg, ASCO/CAP HER2 and ER testing in breast cancer and CAP/ASCP/ASCO HER2 in gastroesophageal carcinoma)*
6. *Limitations relating to suboptimal preanalytical factors that may impact results, such as prolonged cold ischemia time, unknown ischemia time, or over- or under-fixation.*

**Evidence of Compliance:**

- ✓ Report template containing all required elements **AND**
- ✓ Copies of patient reports confirming inclusion of the required elements **AND**
- ✓ Established guidelines used by the laboratory

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**ANP.22970 Annual Result Comparison - Breast Carcinoma**

**Phase II**



**For HER2 and ER immunohistochemical (IHC) tests performed on breast carcinoma that provide independent predictive information, the laboratory at least annually compares its patient results with published benchmarks.**

*NOTE: For estrogen receptor studies: in general, the overall proportion of ER-negative breast cancers (invasive and DCIS) should not exceed 30%. The proportion is somewhat lower in postmenopausal than premenopausal women (approximately 20% vs. 35%). The proportion of ER-negative cases is considerably lower in well-differentiated carcinomas (<10%) and certain special types of invasive carcinomas (<10% in lobular, tubular, and mucinous types). Investigation is warranted if the proportion of ER-negative cases varies significantly from the published benchmarks.*

*For HER2 studies, the overall proportion of HER2 positive breast cancers is 10-25%. Laboratories must monitor their results. Investigation is warranted if the proportion of HER2 positive cases varies significantly from published data.*

**Evidence of Compliance:**

- ✓ Records of annual result comparison

**\*\*NEW\*\* 12/26/2024**

**ANP.22975 Immunohistochemical (IHC) Predictive Marker Interpretation Phase I**

**Each pathologist interpreting IHC predictive markers participates in an annual analyte-specific quality assessment for each of the following predictive markers, as applicable:**

- **Breast HER2**
- **Breast ER**
- **Gastric HER2**
- **Lung highly sensitive ALK**
- **Lung PD-L1 tumor proportion score (TPS)**

*NOTE: This requirement applies to all pathologists in the laboratory that interpret one or more of these markers, whether in laboratories that perform both staining and interpretation or interpretation only. An individual pathologist need participate only once for each predictive marker used by that pathologist in patient care evaluation, regardless of the number of locations where the pathologist performs interpretations.*

*The quality assessment for each predictive marker must include a comparison of each pathologist's interpretation against the intended results. The laboratory director must define criteria for acceptable results and ensure follow up on each unacceptable result.*

*Examples of how this requirement can be met include the use of:*

- *IHC proficiency testing (PT) stained slides or images used **after** the deadline for submission of results to the PT provider*
- *Educational, peer-based, interpretation-based programs that provide stained slides or images (eg, CAP HER2 and ER Immunohistochemistry Interpretation Only Program [HER1])*
- *Laboratory-developed programs for sharing stained slides or images.*

**Evidence of Compliance:**

- ✓ Records of annual assessment of each pathologist for predictive marker interpretation (performed on site or at another laboratory), where applicable

**ANP.22979 Estrogen Receptor and HER2 Testing in Breast Cancer Samples Phase I**



**At least one tumor sample from all patients with invasive breast cancer (newly diagnosed, recurrent, or metastatic disease) is tested for estrogen receptors and HER2 (by IHC or ISH) if tissue is available.**

**ANP.22983 Fixation - HER2 and ER Breast Cancer Predictive Marker Testing Phase I**



**If the laboratory assesses HER2 protein over-expression by immunohistochemistry, HER2 (ERBB2) gene amplification by in situ hybridization, or estrogen receptor expression**

**by immunohistochemistry for breast cancer predictive marker testing, the laboratory monitors cold ischemia time (one hour or less) and appropriate specimen fixation time.**

*NOTE: The CAP strongly recommends that specimens subject to these tests be fixed in 10% neutral buffered formalin for at least six hours and up to 72 hours at room temperature. Specimens must be fully submerged in the optimal volume of formalin to achieve a formalin to specimen volume of 10:1 or higher, or if not feasible (eg, large specimens) at least 4:1. For cases with negative HER2 results by IHC that were fixed outside these limits, confirmatory analysis by in-situ hybridization is strongly recommended.*

*Laboratories must communicate the following fixation guidelines to clinical services:*

1. *Rapid immersion of specimens in fixative is critical, and must occur within one hour of the biopsy or resection*
2. *If delivery of a resection specimen to the pathology department is delayed (eg, specimens from remote sites), the tumor must be bisected prior to immersion in fixative. In such cases, it is important that the surgeon ensure that the identity of the resection margins is retained in the bisected specimen; alternatively, the margins may be separately submitted.*

*Both the time of removal of the tissue and the time of immersion of the tissue in fixative must be recorded and communicated from the submitting service to the processing laboratory.*

*Communication to clinical services of the need for appropriate information on cold ischemia time, fixative, and fixation time may be through memoranda, website, phone, face-to-face meetings, or other means. Information about fixative, fixation time, and cold ischemia time for each specimen must be recorded as part of the permanent specimen record in the pathology report. The laboratory must monitor for compliance and take corrective action as needed.*

***If specimens are fixed in a solution other than 10% neutral buffered formalin, the laboratory must perform a validation study showing that HER2 and ER results are concordant with results from formalin-fixed tissues.***

*Laboratories testing specimens obtained from another institution must have a policy that addresses cold ischemia time and time of fixation. Information on time of fixation may be obtained by appropriate questions on the laboratory's requisition form. If specimens have undergone any deviation from processing that may interfere with result interpretation, such as the use of specimens that previously were used for frozen section diagnosis, this must be annotated on the final report.*

#### **Evidence of Compliance:**

- ✓ Records of communication of cold ischemia and fixation guidelines to clinical services **AND**
- ✓ Records of action taken when cold ischemia and fixation times are consistently outside of required parameters or are not available to the laboratory

## **ANP.22985 Predictive Marker Testing - Decalcified Specimens**

## **Phase I**

**If the laboratory performs in situ hybridization (ISH) and/or immunohistochemistry for predictive markers on decalcified specimens, the assay was validated for decalcified specimens or the results include a disclaimer noting that these assays have not been validated on decalcified specimens.**

*NOTE: Decalcification may adversely affect patient results. If the assay has not been validated for decalcified specimens, a disclaimer must be included in the patient report, such as, "This assay has not been validated on decalcified tissues. Results should be interpreted with caution given the possibility of false negative results on decalcified specimens."*

*Use of decalcification solutions with strong acids is not recommended.*

## INSTRUMENTS AND EQUIPMENT

The checklist requirements in this section should be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

### ANP.23100 Tissue Processor Solutions Phase I



**Tissue processor solutions are changed at intervals appropriate for the workload.**

*NOTE: When solutions are changed, they must be entirely replaced with new solution and not just "topped off."*

**Evidence of Compliance:**

- ✓ Records of solution changes at the defined frequency

### ANP.23120 Tissue Processing Programs - Validation Phase II

**Tissue processing programs are validated.**

*NOTE: To validate new processing programs, laboratories should run tissue samples of the same size, thickness and fixation in duplicate. Reagents on the processor(s) should be comparable, eg, all fresh reagents. Process, embed, cut, and stain slides at the same time and evaluate the quality of the blocks, eg, firmness, ease of cutting. The slides should be evaluated by the pathologist without knowledge of which processing program was used and graded on quality of section and staining. The new processing program must be of adequate quality before being put into use.*

*This method may also be used to verify a routine processing program before putting a new processor into clinical service.*

*For tissue programs in place prior to July 31, 2012, ongoing records of acceptable tissue processing may be used to demonstrate compliance with this requirement.*

**Evidence of Compliance:**

- ✓ Validation records of processing program changes

### ANP.23130 Tissue Processing Programs Phase I



**Specific tissue processing programs are available for different types and sizes of specimens.**

*NOTE: To achieve acceptable results for diagnostic purposes, processing programs may be needed for different sizes and types of specimens. Biopsy specimens may be processed on a shorter schedule than larger specimens; large, dense or fatty specimens and brain specimens will not process adequately on a shorter schedule. A variety of processing programs should be defined and used to achieve good processing results.*

**Evidence of Compliance:**

- ✓ Defined processing programs for various types and sizes of specimen tissues

### ANP.23350 Paraffin Baths, Flotation Baths, and Embedding Stations Phase II

**Paraffin baths, flotation baths, and embedding stations are clean and well-maintained.**

*NOTE: Instruments must be clean and well-maintained (eg, tissue processors, embedding centers, dispensers, flotation baths, stain lines, coverslipping equipment). The temperature of the paraffin dispenser and paraffin baths must be correct for the type of paraffin used. At a minimum, the equipment must be maintained according to the manufacturer's instructions and paraffin temperatures recorded.*

*The CAP recommends the use of high-quality paraffin with a melting point <60°C. The benefit of low-melt paraffin is that it is removed more efficiently during de-paraffinization and/or antigen retrieval. Efficient paraffin removal is essential for all molecular analyses.*

#### ANP.23400 Microtome Maintenance

Phase I

**Microtomes and microtome knives are clean and well-maintained.**

*NOTE:*

1. *Microtomes must be clean, properly lubricated, and without excessive play in the advance mechanism*
2. *Knives must be sharp and free of nicks*

#### ANP.23410 Cryostat Decontamination

Phase II



**The cryostat is decontaminated at defined intervals and under defined circumstances.**

*NOTE: The cryostat must be defrosted and decontaminated by wiping all exposed surfaces with tuberculocidal disinfectant. The cryostat should be at room temperature during decontamination unless otherwise specified by the manufacturer. Decontamination must be done at an interval appropriate for the institution; this must be weekly for instruments used daily. Trimmings and sections of tissue that accumulate inside the cryostat must be removed during decontamination. Although not a requirement, cut-resistant gloves should be worn when changing knife blades.*

**Evidence of Compliance:**

- ✓ Records of cryostat decontamination

## PHYSICAL FACILITIES

### STORAGE AND SUPPLY

#### ANP.23700 Slide and Block Storage

Phase I

**Slides and paraffin blocks are properly stored in a temperature-controlled, pest-free, organized manner (ie, accessible for retrieval and properly identified).**

*NOTE: Slides and blocks must be stored in a manner to prevent contamination from blood or other fluids or tissues and be readily accessible for retrieval.*

*The storage area for blocks must be cool and dry to prevent blocks from melting together and to maintain tissue integrity. The CAP recommends (but does not require) ambient temperatures in block storage areas to be less than 27°C (as lower storage temperatures slow down DNA, RNA, and protein degradation).*

*For laboratories using off-site storage facilities, the laboratory director or designee must confirm that storage requirements are met.*

**Evidence of Compliance:**

- ✓ Records of storage temperature monitoring (on-site and off-site locations), including deviations

## HISTOLOGY LABORATORY SAFETY

*NOTE TO THE INSPECTOR: The inspector should review relevant requirements from the Safety section of the Laboratory General Checklist, to assure that the histology laboratory is in compliance.*

*The following requirements pertain specifically to the histology laboratory.*

**ANP.24050 Automated Tissue Processor**

**Phase II**

**Each open (ie, generative of flammable vapors into the ambient workspace) automated tissue processor is operated at least five feet (1.5 m) from the storage of combustible materials and from the paraffin dispenser.**

*NOTE: Tissue processors that operate as a closed system confine ignitable vapor hazards within the processor and thus do not pose a hazard requiring five feet of separation.*

*Each open (ie, generative of flammable vapors into the ambient workspace) automated tissue processor must be located at least five feet from the storage of combustible materials unless separated by one-hour fire-resistive construction. Flammable and combustible liquids must not be positioned near sources of heat or ignition. At least five feet must separate each open system tissue processor from the paraffin dispenser.*

**ANP.24100 Microtome Knife Storage**

**Phase II**

**Microtome knives are stored in original containers or by some other means to avoid personnel injury or equipment damage.**

**\*\*REVISED\*\* 08/24/2023**

**ANP.24200 Infectious Waste Disposal**

**Phase II**



**Potentially infectious biologic materials (eg, organs, tissues, body fluids) and other contaminated materials (eg, prostheses, pacemakers) are safely stored and disposed of in compliance with national, federal, state (or provincial), and local laws and regulations as well as hospital/organizational guidelines.**

**ANP.24300 Special Handling of Transmissible Spongiform Encephalopathies (TSE)**

**Phase II**



**The laboratory handles tissues from cases of suspected transmissible spongiform encephalopathies (TSE), including Creutzfeldt-Jakob disease (CJD), using procedures that minimize the risk of transmission.**

*NOTE: Specialized handling instructions and an appropriate process for intra-laboratory communication must be addressed in the written procedure.*

*Neuropathology tissues from suspected cases of Creutzfeldt-Jakob disease should be treated with formic acid. Paraffin blocks and slides prepared from formic-acid-treated tissue may be handled routinely.*

*If tissue has not been treated with formic acid, it must be hand-processed and treated as containing potentially transmissible prions. Double gloves must be worn at all times when*

*handling such tissue. All solutions, including water washes, must be collected and treated with equal volumes of fresh undiluted household bleach for 60 minutes before disposal. Disposables, glassware, tools, etc. must be handled according to the procedures employed in the autopsy room described elsewhere in this checklist. All scraps of paraffin and unused sections should be collected on a disposable sheet. The microtome may be wiped with bleach or NaOH solution. No special precautions are needed in handling intact glass slides once they have been coverslipped. Broken slides should be decontaminated and discarded. Paraffin blocks should be stored in a bag or box and labeled as infectious. Alternatively, the laboratory may reseal the cut surface of the blocks with paraffin. Additional information may be found in the Autopsy section of this checklist.*

**ANP.27150 Glass Slide/Block Disposal**

**Phase I**



**The laboratory safely disposes of used glass slides and paraffin blocks.**

*NOTE: The laboratory must follow CAP retention requirements for slides and blocks (refer to checklist requirement in the Surgical Pathology Reports section of this checklist).*

*NOTE: The following four requirements apply to microwave devices used in the histology laboratory.*

**ANP.27170 Microwave Usage**

**Phase I**

**Microwave devices are used in accordance with manufacturer's instructions.**

**ANP.28290 Microwave Monitoring**

**Phase I**

**Microwave devices are monitored for reproducibility at least annually.**

*NOTE: "Reproducibility" is defined as consistency in diagnostic quality obtained from microwave equipment and procedures. For some devices, reproducibility may be evaluated by monitoring the temperatures of identical samples after microwave processing. For those microwave devices (particularly those incorporated into histology processing equipment) that use temperature-independent methods to evaluate reproducibility, the reproducibility must be assessed following instrument manufacturer's instructions.*

*The microwave device must be tested for radiation leakage if there is visible damage to the device. A description of the specific damage along with the result of the test must be recorded.*

**Evidence of Compliance:**

- ✓ Records of monitoring the diagnostic quality of specimens processed using microwaves

**ANP.28860 Microwave Container Venting**

**Phase I**



**All containers used in microwave devices are vented or are used in compliance with manufacturer's instructions for the microwave instrumentation used.**

*NOTE: Venting of containers is necessary so that processing occurs at atmospheric pressure, to prevent explosion. For procedures using pressure above that of the atmosphere, specialized containers must be used, with strict adherence to manufacturer's instructions.*

**ANP.29430 Microwave Venting**

**Phase I**

**Microwave devices are properly vented and the effectiveness of ventilation is monitored at least annually.**

*NOTE: Some types of microwave devices need to be operated in an appropriate ventilation hood to contain airborne chemical contaminants and potentially infectious agents. Before operation*

*of the microwave device, flammable and corrosive reagents must be removed from the hood to prevent fire or chemical damage to the electronic components of the device. Microwave devices used outside a fume hood must have an integral fume extractor certified by the manufacturer for use in a clinical laboratory.*

*This checklist item does not apply to microwave devices that are designed by the manufacturer to operate without venting. It also does not apply if only non-hazardous reagents (as defined in the safety data sheets) and non-infectious specimens (eg, paraffin specimens) are used in the device.*

**Evidence of Compliance:**

- ✓ Records of annual evaluation of ventilation effectiveness