Anatomic Pathology Checklist

CAP Accreditation Program
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Anatomic Pathology Checklist

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ON-LINE CHECKLIST AVAILABILITY AND RESOURCES

Participants of the CAP accreditation programs may download the checklists from the CAP website (cap.org) by logging into e-LAB Solutions Suite. 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.

A repository of questions and answers and other resources is also available in e-LAB Solutions Suite under Accreditation Resources, Checklist Requirement Q & A.

SUMMARY OF CHECKLIST EDITION CHANGES
Anatomic Pathology Checklist
06/04/2020 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 on-site inspections and self-evaluations may not list all of these requirements.

NEW Checklist Requirements
None

REVISED Checklist Requirements

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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. Requirements for remote data assessment do not apply to testing performed within the laboratory using the laboratory’s validated software.

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

Inspector Instructions:

- Policy for assessing professional competency
- Sampling of records for assessment of professional competency

**REVISED** 06/04/2020
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:
✓ Policy for assessing professional competency AND
✓ Participation in a peer educational program (e.g., 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 comprehensive quality management and should be included within the defined program. This section determines if there is an active program 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 program 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.

Inspector Instructions:
- Sampling of the following records: previous/current material review, intra-departmental consultations, extra-departmental consultations
- Does your laboratory exclude any specimen types from routine submission to the pathology department?
- What is your laboratory’s course of action when a significant disparity exists between the initial intra-operative consultation and final pathology diagnosis?

ANP.10016 Surgical Pathology Exclusion Phase I

There is a policy that lists specimens that an institution may choose to exclude from routine submission to the pathology department for examination, where applicable.

NOTE: This policy should 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 policy must comply with state or local laws. For example, 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.

REFERENCES
There is a policy regarding what types of surgical specimens (if any) may be exempt from microscopic examination.

NOTE: Irrespective of any exemptions, microscopic examination should 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. If there is such a policy, it should 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.

REFERENCES
7) Zarbo RJ, Nakleh RE. Surgical pathology specimens for gross examination only and exempt from submission. A College of American Pathologists Q-Probes study of current policies in 413 institutions. Arch Pathol Lab Med. 1999;123:133-139
**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 program.

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

**REFERENCES**

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

*Phase II*

**Whenever 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.

**REFERENCES**
1) Bozzo P. Implementing quality assurance. Chicago, IL: American Society of Clinical Pathology, 1991:72-74

**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.**

**REFERENCES**

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

*Phase I*

**The laboratory has a procedure for handling 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.
REFERENCES

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:
✓ Written procedure for handling and reporting of extra-departmental cases

REFERENCES

ANP.10260 Slide/Block Handling Phase I

There is a written procedure for the handling of original slides/blocks 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 written policy 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.
QUALITY CONTROL

SURGICAL SPECIMEN EXAMINATION

Inspectors and laboratories are reminded 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.

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.

Inspector Instructions:

- Sampling of surgical specimen handling and retention policies and procedures
- Sampling of sub-optimal specimen records/log
- Sampling of records of daily review of histologic slide quality
- Sampling of non-pathologist performance evaluations
- Records of non-pathologist personnel education and experience

- Sampling of slides (quality, labeling)

- What is your course of action when you receive sub-optimal specimens?
- How does your laboratory ensure specimen identity throughout processing and examination?
- How does your laboratory ensure quality testing when non-pathologists assist in gross examinations?
- How does your laboratory ensure quality testing when non-pathologists assist in gross examinations?

ANP.11250 Adequate Storage

**Phase I**

Refrigerated storage is available for large or unfixed specimens.

ANP.11275 Radioactive Material Handling

**Phase II**

There are specific policies and procedures for the safe handling of tissues that may contain radioactive material (eg, sentinel lymph nodes, breast biopsies, prostate “seeds,” etc.).

**NOTE:** These procedures should be developed in conjunction with the institutional radiation safety officer, and must comply with any state regulations for the safe handling of tissues containing radionuclides. The policy 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.

REFERENCES

ANP.11525 Tissue Assessment Record Phase I

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

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

ANP.11550 Specimen Retention 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.

Evidence of Compliance:
✓ Written policy for specimen retention

REFERENCES
2) Travers H. Q&A Section. Savage RA, editor. CAP Today, November 1993:86-87
3) Tracey ME. Hospital takes closer look at specimen returns. CAP Today, July 1992:81

**REVISED** 06/04/2020

ANP.11600 Gross Examination - Qualifications Phase II

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

NOTE: For specific tissue types, there are additional qualifications that are accepted for physicians performing tissue examination, including the following:
- For neuromuscular pathology specimens, a neurologist that 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(I) and (m).

Evidence of Compliance:
✓ Written procedure with defined criteria for macroscopic examination
When individuals other than a pathologist or pathology resident assist in gross examinations, the extent of their activities and the nature of supervision (direct vs. indirect) is defined in a written protocol.

NOTE: This protocol must list the specific types of specimens for which non-pathologists are permitted to assist in the gross examination. The nature of the supervision must be established individually, for each non-pathologist. The laboratory director is responsible for this protocol. For Mohs surgery cases, a dermatologist is also qualified to perform the gross examination and to supervise non-pathologists.

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

The following requirements apply to laboratories with California licensure:

- A pathologist assistant certified by the American Association of Pathologists' Assistants or American Society for Clinical Pathology must work under the supervision and control of a qualified pathologist (either physically present in the laboratory or available by telephone or other electronic means).
- Non-certified personnel who perform grossing must work under direct supervision of a qualified pathologist when engaging in the processing of specimens involving dissection (present in the vicinity of the clinical laboratory subspecialty area and be available for consultation and direction).
- Tissue processing that doesn't involve dissection may be performed under the supervision and control of a qualified pathologist.

REFERENCES
2) Cibull ML. Q&A. Northfield, IL: College of American Pathologists CAP Today. 1997;11(7):112
4) California Business and Professions Code §1269.3.

**REVISED** 09/17/2019

ANP.11610 Gross Examination - High Complexity Testing Qualifications Phase II

If individuals other than a pathologist or pathology resident (or an individual who meets the grossing subspecialty qualifications listed under ANP.11600) assist in gross examinations, such individuals qualify as high complexity testing personnel.

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

1. An earned associate degree in a 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 ABHES, NAACLS, or other organization approved by HHS (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.
It is the responsibility of the laboratory director to determine whether an individual's education, training and experience satisfy the requirements of this checklist requirement.

If there are more stringent national, federal, state (or provincial), and local regulations for grossing qualifications, they must be followed.

This checklist requirement applies only to laboratories subject to US regulations.

Evidence of Compliance:
✓ Records of qualifications including degree or transcript and work history in related field

REFERENCES
2) California Business and Professions Code §1269.3.

ANP.11640 Competency Assessment of Non-Pathologists

The competency of non-pathologist(s) who assist in the performance of gross tissue examinations is assessed by a pathologist at least annually.

NOTE: Please refer to GEN.55500, 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 Mohs surgery a dermatologist is also qualified to perform the gross examination and evaluate non-pathologists.

Evidence of Compliance:
✓ Written procedure and schedule for assessing competency of non-pathologists AND
✓ Records of competency assessment performed at a defined frequency

REFERENCES
1) Cibull ML, Q&A. Northfield, IL: College of American Pathologists CAP Today. 1997;11(7):112

**REVISED** 09/17/2019
ANP.11660 Surgical Tissue Diagnosis

All surgical tissue diagnoses are made by a pathologist or other qualified physician as described below.

NOTE: Anatomic pathology services must be provided by a qualified anatomic pathologist, ie, a physician who successfully completed an approved graduate medical education program in anatomic pathology. The following are exceptions for specific types of tissue examination:

- Neuromuscular pathology specimens may be interpreted by a neurologist who 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(l) and (m)

Evidence of Compliance:
✓ Pathology reports signed by diagnosing pathologist or other qualified subspecialty trained physician

REFERENCES
1) Cibull ML, Q&A. Northfield, IL: College of American Pathologists CAP Today. 1997;11(7):112
ANP.11670 Specimen - Gross Examination

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 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.

ANP.11680 Cross Contamination - Grossing

There is a written procedure to prevent cross-contamination of specimens during grossing.

NOTE: The procedure must address steps to prevent cross-contamination during grossing. Problems with cross-contamination must be addressed in the surgical pathology quality management program.

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.

REFERENCES


ANP.11716 Paraffin Microtomy

There is a written procedure that indicates the sectioning thickness of paraffin embedded tissue for various tissue types and procedures.

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.

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<td>Bone Marrow</td>
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<tr>
<td>Nerve histochemical staining</td>
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<tr>
<td>Amyloid demonstration</td>
<td>6 to 12 microns</td>
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ANP.11734 Slide Quality

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 cover slipping. 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.

**Inspector Instructions:**
- Sampling of policies and procedures (gross examinations, frozen sections, touch preps, scrape preps)
- Sampling of verbal report records
- Sampling of final intra-operative consultation reports
- Sampling of cryostat decontamination records
- Sampling of reagents and slides (labeling)
- Sampling of frozen section cases (quality of sectioning and staining)

- What is your laboratory’s course of action regarding residual frozen tissue?

**ANP.11756 Reagents**

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 should be changed or filtered following a defined process, determined by the usage of the reagents.

**Evidence of Compliance:**
- ✓ Written policy defining reagent labeling requirements **AND**
- ✓ Written records of reagent change process **OR** records of reagent change on a QC log

**ANP.11810 Frozen Section Preparation Quality**

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

**ANP.11850 Intra-Operative Results**

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

**REVISED** 06/04/2020

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 verbal reports

ANP.11950 Verbal Report/Patient ID Phase II

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

Evidence of Compliance:
✓ Written policy for reporting intra-operative consultation (eg, frozen section, etc.) results

ANP.12000 Final Report Phase II

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

ANP.12050 Frozen Section Slides 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:
✓ Written procedure for handling and retention of frozen section preparations

REFERENCES


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. 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:
✓ Written procedure for the processing and examination of residual frozen tissue including correlation of the findings

REFERENCES
1) Rickert RR. Quality assurance goals in surgical pathology. Arch Pathol Lab Med. 1990;114:1157-1162

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.

Inspector Instructions:

- Sampling of FNA policies and procedures
- Sampling of slides (approximately five cases for labeling, quality)
- Sampling of primary specimen containers (labeling)
- How do you ensure there is no cross contamination of FNA specimens?

ANP.12094 FNA Error Prevention Phase II

If the pathologist performs FNA procedures, there is a written procedure to verify patient identification using at least two patient identifiers, the procedure site, and the procedure to be performed.

REFERENCES
ANP.12096  FNA Cross Contamination

There is a procedure to prevent cross contamination of FNA specimens during processing and staining.

NOTE: Methods to minimize this problem 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.

Evidence of Compliance:
✓ Written procedure for staining FNA specimens, including methods to prevent cross contamination

REFERENCES

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).

Inspector Instructions:

- Sampling of records of communication of significant/unexpected surgical and cytologic findings
- Written procedures for cancer reporting, including the use of synoptic format (when appropriate)
- Written procedures for auditing cancer protocols
- Records of annual audit of cancer reports
- Sampling of surgical pathology reports for completeness, including gross description and pathologist review

- How does your laboratory correlate the results of specialized studies (eg, flow immunophenotyping, cytogenetics, ISH studies) with the morphologic diagnosis?
- How does your laboratory perform the annual audit of eligible surgical pathology reports for compliance with the data elements required in the CAP Cancer Protocols?

- Review the annual audit of cases requiring the use of the CAP Cancer Protocols. Confirm that there is a mechanism to identify eligible reports and that a sufficient number of reports are being audited. Confirm that the level of compliance with reporting the required elements is acceptable, with records of corrective action if appropriate.
- Select a sampling of surgical pathology reports, including reports from the annual audit, recently changed cancer protocols, or high volume procedures. Evaluate the reports to determine if the reports are in a synoptic format and have the required data elements.
All reports are reviewed and signed by the pathologist or other qualified physician as defined in ANP.11660.

NOTE: 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.

REFERENCES

ANP.12173 Mohs Report

There is a written report generated for each Mohs surgical procedure.

NOTE: A written note, report, or diagram must be included in the patient's medical record or operative report. The report should include required elements such as gross description, accession number, designation of relationship of blocks to the slides, and clear diagnosis on each specimen.

**REVISED** 06/04/2020

ANP.12175 Significant and Unexpected Findings

The laboratory has a written policy regarding the communication of significant and unexpected surgical pathology findings and retains records of those communications.

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 laboratory individual;
- Person notified; and
- 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

**REFERENCES**
2) Silverman JF, Pereira TC. Critical values in anatomic pathology. *Arch Pathol Lab Med.* 2006;130:638-640

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**Amended Reports**

**Phase II**

The laboratory issues an amended report and promptly notifies the responsible clinician(s) when there are changes to reports that significantly affect 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:**
- Written policy for notification of significant amendments to patient reports **AND**
- Patient reports containing the reason for the amendment **AND**
- Records of notifications

**REFERENCES**

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**Gross Description Reporting**

**Phase II**

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

**NOTES:**
1. Descriptions should include information regarding type, number, dimensions and/or weight of specimens, measurements and extent of gross lesions.
2. Processing information should include a summary of block/slide designations.
3. Annotated drawings and photographs are valuable tools for recording gross findings, but are not adequate replacements for a text description.

**Evidence of Compliance:**
- Written procedure for the reporting of the gross examination findings on the surgical pathology report

**REFERENCES**
All required data elements in applicable CAP Cancer Protocols are included with appropriate responses using a synoptic format in at least 90% of the surgical pathology reports from definitive resection specimens for primary invasive malignancies, as well as cases of ductal carcinoma in situ of the breast (DCIS). A self-audit is performed annually to ensure that all required elements are included.

**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, 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 formal 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 self-audit of reports performed by the laboratory must include review of a random sample of at least 10% of the eligible surgical pathology reports, or a total of 150 cases per year (whichever is less stringent). If less than 90% of reports contain all of the required core and applicable conditional elements from the CAP Cancer Protocols, the laboratory must implement and record appropriate corrective action.

8. For reporting errors identified in the self-audit 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**
- Procedure for performing report self-audit **AND**
- QM records of annual self-audit **AND**
- Records of corrective action and result, if deficiencies were identified

**REFERENCES**

**ANP.12400** Correlation of Results

**Phase II**

There is a process to correlate the results of specialized studies (e.g., immunohistochemistry, nucleic acid probes, cytogenetics, flow cytometry, electron microscopy) with the morphologic diagnosis.

**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.

**Evidence of Compliance:**
- Written procedure for correlation of specialized studies with morphologic diagnoses

**REFERENCES**

**REVISED** 09/17/2019
Anatomic Pathology Checklist

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

**NOTE 1:** There must be a written policy for protecting and preserving the integrity and retrieval of surgical pathology materials and records. The retention period should be extended, when appropriate, to provide records for adequate quality control and medical care.

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 below, whichever is most stringent.

<table>
<thead>
<tr>
<th>Type of Record/Material</th>
<th>Retention Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accession log records</td>
<td>2 years</td>
</tr>
<tr>
<td>Wet tissue (stock bottle)</td>
<td>2 weeks after final report</td>
</tr>
<tr>
<td>Paraffin blocks (including cell blocks)</td>
<td>10 years (subject to Notes 2 and 3 below)</td>
</tr>
<tr>
<td>Glass slides (including control slides)</td>
<td>10 years - slides must remain readable for this period</td>
</tr>
<tr>
<td>Surgical pathology reports *</td>
<td>10 years</td>
</tr>
<tr>
<td>Reports of outside consultations on laboratory cases (whether or not requested by the laboratory)</td>
<td>10 years after the date that the original report was issued</td>
</tr>
<tr>
<td>Fluorochrome-stained slides</td>
<td>At the discretion of the laboratory director</td>
</tr>
<tr>
<td>Images or permanent slides of ISH studies</td>
<td>10 years for neoplastic disorders</td>
</tr>
<tr>
<td></td>
<td>20 years for constitutional disorders</td>
</tr>
<tr>
<td></td>
<td>(Subject to Notes 4 and 5 below)</td>
</tr>
<tr>
<td>Images for Circulating Tumor Cells</td>
<td>10 years</td>
</tr>
<tr>
<td>Digital images used for primary diagnosis</td>
<td>10 years if original glass slides are not available; may not replace glass slides</td>
</tr>
<tr>
<td>Datasets from In-Vivo Microscopy (IVM) or Ex Vivo Microscopy (EVM) systems used to aid in interpretation or diagnosis</td>
<td>10 years - data must be retrievable for this period (Subject to Note 6 below)</td>
</tr>
</tbody>
</table>

* 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 integrity. Such 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.
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.

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 glass slide preparations when the source slides remain readable for the required retention period.

NOTE 5: For an ISH assay with a normal result, retain an image of at least one cell illustrating the normal probe signal pattern. For an ISH assay with an abnormal result, retain images of at least two cells illustrating each relevant abnormal probe signal pattern.

NOTE 6: 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.

Evidence of Compliance:
✓ Written record and specimen retention policy(ies)

REFERENCES

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.
Inspector Instructions:

- Sampling of specimen preparation records
- Sampling of histology QC policies and procedures
- Sampling of QC records (immunologic, FISH/ISH methods, histochemical)

- Sampling of tissue blocks
- Sampling of slides (quality)
- Sampling of reagents (expiration date)

- How does your laboratory prevent cross-contamination of specimens in the histology laboratory?

- If problems are identified during the review of histology procedures, further evaluate the laboratory's responses, corrective actions and resolutions
- Select a representative specimen and follow from receipt in the department through accessioning, grossing, processing, time reported and availability in the LIS

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
There is a schedule to change the solutions in automated stainers.

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

Evidence of Compliance:
✓ Written procedure defining frequency of changing staining solutions AND
✓ QC 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. The Centers for Medicare and Medicaid Services (CMS) recognizes the use of polymer-based detection systems (biotin free) may preclude the use of a negative reagent control. However, there have been no changes to the histopathology regulations. The CMS will be looking into an alternate QC method for these types of stains.

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)

References

ANP.21397 Cross-Contamination - Histology Phase II

There is a written procedure to prevent cross-contamination of specimens in the histology laboratory.

NOTE: The procedure 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 program.

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”).

References
IMMUNOFLUORESCENCE MICROSCOPY

Inspector Instructions:

- IF QC policy or procedure
- Sampling of IF QC records

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:

✓ Written procedure for immunofluorescence QC AND
✓ Records of immunofluorescence QC

REFERENCES

IMMUNOHISTOCHEMISTRY

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

- Sampling of IHC policies and procedures
- Sampling of new antibody validation/verification records
- Sampling of new reagents/shipment confirmation of acceptability records
- Sampling of antibody QC records
- Sampling of buffer pH records
- Sampling of batch control records

- Sampling of slides (quality)

- How does your laboratory validate/verify new antibodies?
- How does your laboratory confirm the acceptability of new reagent lots?
- How does your laboratory distinguish non-specific false-positive staining from endogenous biotin?

ANP.22300 Specimen Modification

If the laboratory performs immunohistochemical staining on specimens other than formalin-fixed, paraffin-embedded tissue, the written procedure describes appropriate modifications, if any, for other specimen types.

NOTE: Such specimens include frozen sections, air-dried imprints, cytocentrifuge or other liquid-based preparations, decalcified tissue, and tissues fixed in alcohol blends or other fixatives.

REFERENCES

ANP.22500 Buffer pH

The pH of the buffers used in immunohistochemistry is routinely monitored.

NOTE: pH must be tested when a new batch is prepared or received.

Evidence of Compliance:
✓ Written procedure defining pH range for each buffer in use AND
✓ Records of initial and subsequent QC on each buffer

ANP.22550 QC - Antibodies

Positive tissue controls are used for each antibody.

NOTE: Positive controls assess the performance of the primary antibody. They are performed on sections of tissue known to contain the target antigen, using the same epitope retrieval and immunostaining protocols as the 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.
Ideally, the positive control tissue would be the same specimen type as the patient test specimen (e.g., small biopsy, large tissue section, cell block), and would be processed and fixed in the same manner (e.g., 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 (e.g., 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 section included on the same slide as the patient tissue is optimal practice because it helps identify failure to apply primary antibody or other critical reagent to the patient test slide; however, one separate positive control per staining run for each antibody in the run (batch control) may be sufficient provided that the control slide is closely scrutinized by a qualified reviewer.

Ideally, positive control tissues possess low levels of antigen expression, as is often seen in neoplasms. Exclusive use of normal tissues that have high levels of antigen expression may result in antibody titers of insufficient sensitivity, leading to false-negative results.

**Evidence of Compliance:**

- Written procedure for the selection and use of positive tissue controls for each antibody **AND**
- Patient reports or worksheet with control results **AND**
- Immunohistochemical-stained slides with positive tissue controls

**REFERENCES**

1) O'Leary TJ. Standardization in immunohistochemistry. *Appl Immunohistochem Mol Mol Morphol* 2001;9:3-8
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 2009(Jan 24); [42CFR493.1273(a)]

**ANP.22570 QC - Antibodies**

**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 (e.g., 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.

The Centers for Medicare and Medicaid Services (CMS) recognizes the use of polymer-based detection systems (biotin-free) may preclude the use of a negative reagent control. However, there have been no changes to the histopathology regulations. The CMS will be looking into an alternate QC method for these types of stains.

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 (i.e., 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:**
- ✓ Written procedure for the selection and use of negative reagent (as appropriate) and tissue controls for IHC **AND**
- ✓ Patient reports or worksheet with control results **AND**
- ✓ Immunohistochemical-stained slides with appropriate negative controls

**REFERENCES**

**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), there is a procedure that addresses nonspecific false-positive staining from endogenous biotin.

**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.

**REFERENCES**

**ANP.22660 Control Slide Review Phase II**

When batch controls are run, the laboratory director or designee reviews all control slides each day of patient testing.

**NOTE:** Records of this daily review must be retained and should 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.

REFERENCES

**REVISED** 09/17/2019

ANP.22750 Antibody Validation/Verification - Non-Predictive Marker Phase II

The laboratory has records of validation/verification of new antibodies, including introduction of a new clone, prior to use for patient diagnosis or treatment.

NOTE: The performance characteristics of each assay must be appropriately validated/verified before being placed into clinical use. The initial goal is to establish the optimal antibody titration, detection system, and antigen retrieval protocol. Once optimized, a panel of tissues must be tested to determine the assay’s sensitivity and specificity. The scope of the validation/verification is at the discretion of the laboratory director and will vary with the antibody.

Means of validation/verification may include, but are not limited to: 1) correlating the results using the new antibody with the morphology and expected results; 2) comparing the results using the new antibody with the results of prior testing of the same tissues with a validated/verified assay in the same laboratory; 3) comparing the results using the new antibody with the results of testing the same tissue in another laboratory with a validated/verified assay; or 4) comparing the results using the new antibody with previously validated/verified non-IHC tests or testing previously graded tissue challenges from a formal proficiency testing program.

For an initial validation/verification, laboratories should achieve at least 90% overall concordance between the new test and the comparator test or expected results.

For validation/verification of a nonpredictive assay, the validation/verification should test a minimum of 10 positive and 10 negative tissues. If the laboratory director determines that fewer validation cases are sufficient for a specific marker (eg, a rare antigen or tissue), the rationale for that decision needs to be recorded. Positive cases in the validation/verification set should span the expected range of clinical results (expression level), especially for those markers that are reported quantitatively.

When possible, laboratories should use tissues that have been processed using the same fixative and processing methods as cases that will be tested clinically. If IHC is regularly done on specimens that are not fixed or processed in the same manner as the tissues used for validation/verification (eg, alcohol fixed cell blocks, cytologic smears, formalin post fixed tissue, or decalcified tissue), the laboratory should test a sufficient number of such tissues to ensure that assays consistently achieve expected results. The laboratory director is responsible for determining the number of positive and negative cases and the number of predictive and nonpredictive markers to test.

Refer to the subsection "Predictive Markers" for specific validation/verification requirements for tests that provide independent predictive information (eg, HER2 and ER testing in breast carcinoma).

Evidence of Compliance:
✓ Written procedure for the validation/verification of new antibodies
✓ Records of validation/verification, if applicable

REFERENCES


ANP.22760 New Reagent Lot Confirmation of Acceptability

The performance of new lots of antibody and detection system reagents is compared with old lots before or concurrently with being placed into service.

NOTE: Parallel staining is required to control for variables such as disparity in the lots of detection reagents or instrument function. New lots of primary antibody and detection system reagents must be compared to the previous lot using at least one known positive control and one known negative control tissue. This comparison should be made on slides cut from the same control block.

Evidence of Compliance:
✓ Written procedure for the confirmation of acceptability of new reagent lots prior to use AND
✓ Records of confirmation of new reagent lots

**REVISED** 09/17/2019

ANP.22780 IHC Assay Performance

Laboratories confirm assay performance when conditions change that may affect performance.

NOTE: A change in antibody clone requires full revalidation/verification of the assay (equivalent to initial analytic validation/verification - see ANP.22750).

Laboratories must confirm assay performance with at least two known positive and two known negative cases when an existing validated/verified assay has changed in any of the following ways: antibody dilution, antibody vendor (same clone), or the incubation or retrieval times (same method).

A more extensive study to confirm acceptable assay performance in accordance with published guidelines must be performed when any of the following have changed: fixative type, antigen retrieval protocol (eg, change in pH, different buffer, different heat platform), antigen detection system, tissue processing or testing equipment, environmental conditions of testing (eg, laboratory relocation), or laboratory water supply. This study must include a representative sampling of the assays affected by the change and an appropriate number of positive and negative cases per assay, sufficient to confirm acceptable assay performance. The laboratory director is responsible for determining the extent of the study. The rational for the assays selected and number of positive and negative cases checked per assay must be recorded.

For specific validation/verification requirements for tests that provide independent predictive information (eg, HER and ER testing in breast carcinoma, refer to the subsection “Predictive Markers.”

REFERENCES
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.

REFERENCES

IN SITU HYBRIDIZATION (ISH)

The use of the term in situ hybridization (ISH) in this section applies to all ISH methods, including fluorescence (FISH), chromogenic (CISH), silver (SISH), and brightfield (BRISH) in situ hybridization.

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

Inspector Instructions:

- Sampling of ISH policies and procedures
- Sampling of probe validation records
- Sampling of QC records
- Sampling of patient test reports

- How are ISH cut-off values established?
- How does your laboratory validate assay performance prior to test implementation?
- What is your course of action when a probe does not produce an internal control signal?

**REVISED** 09/17/2019

ANP.22956 ISH Probe Validation/Verification Phase II

There are policies, procedures, and records of validation/verification of all in situ hybridization probes.

NOTE: Refer to ANP.22978 for specific validation/verification requirements for tests that provide independent predictive information (eg, HER2 in breast carcinoma). Additional requirements for test method validation/verification are in the All Common Checklist.

Evidence of Compliance:

✓ Written procedure for validation/verification of ISH probes

REFERENCES

ANP.22957 Interphase ISH - Cut-off Value Phase II
For interphase in situ hybridization (ISH), the laboratory establishes a normal cut-off value for results for each probe used, when applicable.

NOTE: Refer to the All Common Checklist for specific test method validation requirements. Cut-off values are usually required when ISH testing uses locus-specific probes against nuclear DNA.

Evidence of Compliance:
✓ Written procedure for establishing normal cut-off values AND
✓ Records from cut-off value studies

REFERENCES

ANP.22958 New Reagent Lot - ISH Probes

Phase II

Each lot of in situ hybridization (ISH) probe(s) is checked for acceptable performance.

Evidence of Compliance:
✓ Written procedure for the verification of new lot of ISH probes prior to use AND
✓ Records of verification

ANP.22959 ISH Assay Performance

Phase I

There are records of in situ hybridization (ISH) performance for each assay.

NOTE: Assay performance should include monitoring hybridization efficiency, probe signal intensity and overall assay results, including controls, as applicable.

Evidence of Compliance:
✓ Written procedure defining acceptance criteria for ISH assay performance AND
✓ Records of QC monitoring of ISH assay performance at defined frequency

ANP.22960 ISH Probe Intended Target

Phase I

There is a system in place to ensure that the in situ hybridization (ISH) probe used is for the intended target.

NOTE: Examples can include (but may not be limited to): 1) concurrent analysis of any available metaphase cells in an interphase cell analysis; 2) inclusion of an internal or external target that results in a positive signal for each hybridization; 3) written protocols that ensure the respective probe is applied to the intended specimen.

Evidence of Compliance:
✓ Written policy defining the system for ensuring use of the appropriate ISH probe AND
✓ Records confirming intended target

ANP.22963 ISH Scoring

Phase II

When applicable, there are written procedures for scoring in situ hybridization (ISH) results, including the number of cells scored and all analyses are scored according to these procedures.

REFERENCES
1) American College of Medical Genetics Laboratory. Standards and guidelines for clinical genetics laboratories, 2nd ed. Bethesda, MD: ACMG, 1999
ISH Controls

Controls (internal and/or external) are used and recorded for each in situ hybridization (ISH) analysis.

NOTE: What functions as a control depends on the specific assay, signal pattern present, and sample type. For example, assays designed to detect deletions may use internal controls that include both the probe of interest and a control locus probe, both of which map to the same chromosome. In this situation, there are two internal controls, the signal for the probe of interest on the normal homolog and the control locus signals on both the normal and deleted homolog.

For a dual fusion assay, the probe signals on each of the normal homologs function as internal controls. If a probe is used that does not produce an internal control signal (e.g., a Y chromosome probe in a female), another sample that is known to have the probe target must be run in parallel as an external control with the patient sample. In addition, many ISH assays use an external control(s). For FDA-cleared or approved ISH assays, laboratories must follow manufacturer’s instructions for quality control at minimum.

Evidence of Compliance:
✓ Written policy defining use of control loci with each ISH analysis AND
✓ Records of QC results

REFERENCES

Retention - Images and Slides

Photographic or digitized images or permanent slides are retained of all in situ hybridization (ISH) assays for an appropriate period.

NOTE: Images or permanent slides of ISH assays for neoplastic disorders must be retained for 10 years; images or permanent slides of ISH assays for constitutional disorders must be retained for 20 years. For an ISH assay with a normal result, retain an image of at least one cell illustrating the normal probe signal pattern. For an ISH assay with an abnormal result, retain images of at least two cells illustrating each relevant abnormal probe signal pattern.

There is no retention requirement for retaining images of slide preparations when the source slides remain readable for the required retention period.

Evidence of Compliance:
✓ Written retention policy

**REVISED** 06/04/2020

ISH Interpretation

If an in situ hybridization (ISH) study requires consultation with a qualified pathologist and/or a cytogeneticist for an accurate interpretation, the appropriate expert is consulted and their involvement is recorded.

PREDICTIVE MARKERS

This checklist section applies only to immunohistochemical (IHC) and in situ hybridization (ISH) tests used to predict responsiveness to a specific treatment independent of other histopathologic findings. Rather than confirming a specific diagnosis (such as B-cell lymphoma or gastrointestinal stromal tumor), these tests should
differentiate predicted responsiveness to a targeted therapy 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 HER 2 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.

Inspector Instructions:

- Predictive markers policies and procedures
- Sampling of patient reports for completeness, including ASCO/CAP scoring when applicable
- Records of annual benchmark comparison for breast predictive markers
- Sampling of predictive marker assay validation, verification, and revalidation/verification studies

- What is your laboratory's course of action when negative HER2 and/or negative ER by IHC results are obtained and the fixation was not appropriate?
- How did you validate/verify the most recently added predictive marker on your test menu?

**REVISED** 09/17/2019
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: For IHC and ISH studies used to provide predictive information independent of diagnosis or other histopathologic findings (eg, hormone 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).

Evidence of Compliance:
✓ Written procedure for scoring and reporting IHC and ISH results for tests involving predictive markers OR report template containing all required elements AND
✓ Copies of patient reports confirming inclusion of the required elements AND
✓ Established guidelines used by the laboratory

REFERENCES

**REVISED** 06/04/2020
ANP.22970 Annual Result Comparison - Breast Carcinoma Phase II

For HER2 immunohistochemical (IHC) and in situ hybridization (ISH) and ER IHC tests performed on breast carcinoma that provide independent predictive information, the laboratory at least annually compares its patient results with published benchmarks, and evaluates interobserver variability among the pathologists in the laboratory.

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.

Individuals interpreting the assay must also have their concordance compared with each other and this concordance should also be at least 95%.

Evidence of Compliance:
✓ Records of annual result comparison and evaluation of interobserver variability

REFERENCES
Predictive marker testing by immunohistochemistry (IHC) and/or in situ hybridization (eg, FISH, CISH, SISH) is validated/verified and records of validation/verification are retained.

NOTE: Test verification must be performed on a minimum of 40 cases (20 positive and 20 negative samples) for FDA-cleared/approved assays. Laboratories should consider using higher numbers of test cases when validating laboratory-developed tests (LDTs) or modified FDA-approved/cleared tests. If the laboratory director determines that fewer validation cases are sufficient for a specific marker (eg, a rare antigen, tissue, gene, or probe), the rationale for that decision must be recorded.

For HER2 and ER predictive marker testing performed on breast cancer specimens using laboratory-developed tests (LDTs), 40 positive and 40 negative samples must be used, at minimum. Positive cases in the validation set should span the expected range of clinical results (expression levels). Only definitely positive and negative cases should be used for validation.

The validation data should clearly show the degree of concordance between assays or methods. Minimum acceptable concordance levels are 90% for positive and negative results, except for ER IHC methods which are 90% for positive and 95% for negative results.

The characteristics of the cases used for validation/verification should be similar to those seen in the laboratory’s patient population (ie, core biopsy vs. open biopsy, primary vs. metastatic tumor, etc.).

Samples used for validation/verification must be handled in conformance with the guidelines in this checklist. Laboratories should use tissues that have been processed by using the same fixative and processing methods as cases that will be tested clinically.

If significant changes are made to the testing methods (eg, antibody clone, antigen retrieval protocol or detection system, probe or pretreatment protocol), revalidation/verification is required. This requirement is applicable to both new and existing assays. If review of the initial validation/verification does not meet the current standard, it must be supplemented and brought into compliance. It is possible to do this retroactively by review and documentation of past proficiency testing challenges or by sending unstained slides from recent cases to a referral laboratory for correlation. If no records exist from the initial validation/verification, the assay must be fully revalidated/verified.

Evidence of Compliance:
✓ Records of validation/verification data including criteria for concordance

REFERENCES
Anatomic Pathology Checklist

**REVISED** 06/04/2020

Fixation - HER2 and ER Breast Cancer Predictive Marker Testing

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, there is a written procedure to ensure appropriate specimen fixation time.

NOTE: Specimens subject to these tests should be fixed in 10% neutral buffered formalin for at least six hours and up to 72 hours. The volume of formalin should be at least 10 times the volume of the specimen. Decalcification solutions with strong acids should not be used. For cases with negative HER2 results by IHC that were fixed outside these limits, consideration should be given to performing confirmatory analysis by in-situ hybridization.

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 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. The laboratory should consider monitoring compliance and contacting clients when these guidelines are not met.

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

Laboratories testing specimens obtained from another institution should have a policy that addresses time of fixation. Information on time of fixation may be obtained by appropriate questions on the laboratory’s requisition form.

Reports should qualify any negative results for specimens not meeting the above guidelines.

REFERENCES

**REVISED** 09/17/2019

Predictive Marker Testing - Decalcified Specimens

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.”

Using acid decalcified tissues is not recommended.
REFERENCES

DIGITAL IMAGE ANALYSIS

This section applies to laboratories using digital image analysis to evaluate specific features in a tissue section image following enhancement and processing of that image, including but not limited to, IHC (eg, HER2 and ER), morphometric analysis, and ISH. This checklist section does not apply to laboratories that are imaging slides for manual scoring or review by an individual.

If predictive marker testing is performed, additional requirements in the Predictive Markers section also apply.

VALIDATION AND CALIBRATION

Inspector Instructions:

- Sampling of validation and calibration policies and procedures
- Sampling of validation/calibration records

- What is your course of action if calibration is unacceptable?

**REVISED** 09/17/2019
ANP.23004 Preanalytic Testing Phase Validation Phase II

There are records showing that the preanalytic phase of the test system has been validated for each assay, including fixation and processing.

**NOTE:** Applicable requirements under the "Test Method Validation and Verification-Nonwaived Tests" section of the All Common Checklist must be followed.

REFERENCES

**REVISED** 09/17/2019
ANP.23009 Calibration Phase II

Each instrument is calibrated in accordance with the specifications of the instrument.

REFERENCES
**QUALITY CONTROL**

**Inspector Instructions:**

| READ | • Sampling of QC policies and procedures  
       • Sampling of QC records |
| ASK | • How do you determine when QC is unacceptable and corrective actions are needed? |
| DISCOVER | • Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action |

**REVISED** 09/17/2019

**ANP.23018 Quality Control - Digital Image Analysis**  Phase II

Control materials are run concurrently with patient specimens to ensure appropriate functionality of the digital image system.

NOTE: Controls are samples that act as surrogates for patient/client specimens. They are periodically processed like a patient/client sample to monitor the ongoing performance of the analytic process. Controls should check test performance at relevant decision points for the digital image analysis system.

For qualitative tests, a positive and a negative control may be sufficient. For quantitative or semiquantitative tests, controls at more than one level should be used.

**Evidence of Compliance:**

✓ Written QC policy AND
✓ Records of QC results

**REFERENCES**


**ANP.23020 QC Handling**  Phase II

Control specimens are tested in the same manner and by the same personnel as patient/client samples.

NOTE: QC specimens must be analyzed by personnel who routinely perform patient/client testing - this does not imply that each operator must perform QC daily, so long as each instrument and/
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or test system has QC performed at required frequencies, and all analysts participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled.

Evidence of Compliance:
✓ Records reflecting that QC is run by the same personnel performing patient testing

REFERENCES

ANP.23022 QC Confirmation of Acceptability Phase II
The results of controls are reviewed for acceptability before reporting results.

NOTE: Control results must be reviewed before reporting patient/client results.

Evidence of Compliance:
✓ Written policy stating that controls are reviewed and acceptable prior to reporting patient results AND
✓ Records of control result approval

REFERENCES

ANP.23025 Monthly QC Review Phase II
Quality control data are reviewed and assessed at least monthly by the laboratory director or designee.

NOTE: The review of quality control data must be recorded and include follow-up for outliers, trends, or omissions.

The QC data for tests performed less frequently than once per month should be reviewed when the tests are performed.

Evidence of Compliance:
✓ Records of QC review with recorded follow-up for outliers, trends or omissions

SPECIMEN ANALYSIS

Inspector Instructions:

• Sampling of specimen analysis policies and procedures

**REVISED** 06/04/2020
ANP.23027 Area of Analysis Phase II
A qualified pathologist selects or confirms the appropriate areas for analysis, as applicable.
NOTE: Specimens that do not represent “in situ” samples embedded in paraffin may not require pathologist review. Examples include cultured preparations and direct preparations of liquid specimens including blood, urine, pleural fluid, etc.

**REVISED** 09/17/2019
ANP.23028 Analysis Guidelines and Procedures Phase II

There are written guidelines for identification of appropriate areas and cells for analysis.

NOTE: Evaluation of heterogeneous cell populations requires use of specific guidelines and procedures to ensure analysis of the appropriate areas and/or cells, particularly if there is background or nonspecific staining, or if there is cell debris, endogenous pigment, and/or artifacts of aging, sectioning or preparation.

Test results may be affected by fixation parameters, including time of fixation, type of fixative used, hemorrhage, necrosis, and autolysis of tissue.

REPORTS

Inspector Instructions:

- Sampling of patient reports for completeness

ANP.23036 Final Report Interpretation Phase II

The final report includes an interpretation by the responsible pathologist.

NOTE: Interpretation requires correlation with the light microscopic features such as routine histology, immunohistochemistry, cytologic material, cytogenetic and molecular studies, and/or clinical information.

**REVISED** 09/17/2019
ANP.23038 Final Report Elements - Digital Image Analysis Phase II

The final report includes the specimen source, name of the vendor and imaging system used, the antibody clone or probe, and the detection method, as well as any limitations of the test result, if applicable.

PERSONNEL

Inspector Instructions:

- Records of personnel education and experience
ANP.23041 Testing Personnel Qualifications

**Phase II**

Personnel who are responsible for evaluating the imaging system data are qualified as high-complexity testing personnel.

**NOTE:** Refer to the Laboratory General Checklist for high complexity testing personnel (GEN.54750) and general supervisor (GEN.53600) qualifications. Additional information for assessing personnel qualifications is available at the following link: [CAP Personnel Requirements by Testing Complexity](#).

**Evidence of Compliance:**
- Records of qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation, or current license (if required) **AND**
- Work history in related field

**REFERENCES**

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**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.*

**Inspector Instructions:**

- Sampling of tissue processor procedures and records
- Sampling of paraffin bath and dispenser records
- Sampling of microtome records
- Sampling of cryostat decontamination records
- Records of Ex Vivo Microscopy system validation
- Sampling of Ex Vivo Microscopy equipment function checks

- Instruments/equipment (clean and well-maintained)

- How does your laboratory prevent cross-contamination between specimens or cases at the processing, embedding, and microtomy stations?

- If problems are identified during the review of instruments and equipment, or when asking questions, further evaluate the laboratory’s responses, corrective actions and resolutions
- Select a representative assay and follow the entire process from specimen receipt to final result reporting

ANP.23100 Tissue Processor Solutions

**Phase I**

Tissue processor solutions are changed at intervals appropriate for the workload.
Evidence of Compliance:
✓ Written policy defining frequency for changing tissue processor solutions based on workload
AND
✓ Records of solution changes at defined frequency

REFERENCES
1) Baunoch DA, et al. Troubleshooting problems in processing, staining. Advance/Lab. 1999(Oct);8(10):59-64

**ANP.23120** Tissue Processing Programs

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:
✓ Written procedure for validation of new tissue processing programs AND
✓ 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 used to achieve good processing results.

Evidence of Compliance:
✓ Written procedure defining processing programs for various types and sizes of specimen tissues

**REVISED** 06/04/2020

**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.

REFERENCES
ANP.23400  Microtome Maintenance  Phase I

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

**NOTES:**
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

**There is a written procedure for the decontamination of the cryostat at defined intervals, and under defined circumstances, and decontamination records are retained.**

**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. This should 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.

**REFERENCES**

ANP.23420  ISH Slide Processing System Temperature Checks  Phase II

**Individual slide slots (or a representative sample thereof) of *in situ* hybridization (ISH) temperature controlled slide processing systems are checked for temperature accuracy before being placed in service and at least annually thereafter.**

**Evidence of Compliance:**
✓ Written procedure for verification of temperature accuracy **AND**
✓ Records of equipment verification

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**EX VIVO MICROSCOPY**

*Ex Vivo Microscopy (EVM) refers exclusively to the use of imaging systems such as confocal microscopy, optical coherence tomography, multiphoton microscopy, optical spectroscopy/spectroscopic imaging and similar imaging technologies for evaluation of specimens that have been removed from the patient. The In Vivo Microscopy section of this checklist should be used for in vivo applications of these systems.*

ANP.23560  EVM - System Validation  Phase I

**The laboratory performs validation studies before the Ex Vivo Microscopy (EVM) technology is used for the intended purpose(s).**

**NOTE:** The specific components of the validation study are left to the discretion of the laboratory. However, studies should be performed using an adequate number of cases, data should be evaluated, and a summary statement provided prior to implementation. Records of how discordant data or unacceptable variations from the expected were resolved are required.

As general guiding principles, the validation process should:
● Closely emulate the real-world environment and involve tissue types and clinical settings relevant to the intended use(s)
• Be carried out by or under the supervision of a pathologist adequately trained to use the EVM system
• Encompass the entire EVM system, with reevaluation if a significant change is made to a previously validated system.

Evidence of Compliance:
✓ Records of completed validation study with supporting validation data, review and approval

ANP.23570  EVM - Function Checks  Phase II

Regular function checks are performed and records retained on the Ex Vivo Microscopy (EVM) system/instrument.

NOTE: Function checks include confirmation that an instrument or item of equipment operates according to manufacturer's specifications before routine use, at prescribed intervals, or after minor adjustment. Depending on the type of system, function checks may include calibration.

Evidence of Compliance:
✓ Written procedure for function checks and calibration, as required

ANP.23580  EVM - Method Performance Specifications Availability  Phase II

The current Ex Vivo Microscopy (EVM) methods and all significant changes to analytical methodology, including performance specifications and supporting validation data, are retained by the laboratory.

NOTE: Records should include, but are not limited to, components of EVM equipment, software systems, and image viewing systems.

Evidence of Compliance:
✓ Records of changes to analytical methodology

REFERENCES

PHYSICAL FACILITIES

STORAGE AND SUPPLY

ANP.23700  Storage Organization  Phase I

Slides and paraffin blocks are properly stored in an organized manner (ie, accessible for retrieval, and properly identified).

NOTE: Slides and blocks should be stored in a manner to prevent contamination from blood or other fluids or tissues. The storage area for blocks should be cool to prevent blocks from melting together.
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.

Inspector Instructions:

- Sampling of histology safety policies and procedures
- Sampling of microwave reproducibility and ventilation checks
- How does your laboratory ensure the safe handling of suspected CJD tissues?

ANP.24050  Automated Tissue Processor

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-resistant 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

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

ANP.24200  Infectious Waste Disposal

Infectious tissues and other potentially contaminated materials are disposed of with minimum danger to professional, technical, and custodial personnel, and to recipients.

NOTE: Waste disposal must be in accord with all regulations.

Specimens returned to patients (eg, prostheses, gallstones) must be disinfected before release. Specimens released to manufacturers (eg, pacemaker or prosthesis) must be disinfected or be handled in a manner to prevent exposure.

Evidence of Compliance:

✓ Written procedure for waste disposal in accordance with local regulations
**REVISED** 09/17/2019

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

There are written procedures for the special handling of tissues from cases in which transmissible spongiform encephalopathies (TSE), including Creutzfeldt-Jakob disease (CJD) are suspected.

NOTE: In addition to specimen handling, the procedures should include the process for appropriate intralaboratory communication.

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.

REFERENCES
3) Greenblatt, M. Q&A. Northfield, IL: College of American Pathologists, CAP Today 1993(March);7(3):69-70
4) Crain BJ. Safety tips for anatomic studies of possible CJD. Northfield, IL: College of American Pathologists, CAP Today 1996(Jan);10(1):56
5) Rank JP. How can histotechnologists protect themselves from Creutzfeldt-Jakob disease. Lab Med. 1999;30:305

ANP.27150 Glass Slide/Block Disposal  Phase I

There are written procedures for safe disposal 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).

REFERENCES

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.
NOTE: Microwave devices should be used in accordance with manufacturer’s instructions, unless CAP requirements are more stringent.

Evidence of Compliance:
✓ Written procedure for microwave usage

ANP.28290 Microwave Monitoring

Microwave devices are at least annually monitored for reproducibility.

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 laboratory should have a written procedure for monitoring reproducibility that follows instrument manufacturer’s instructions. Information on such procedures is given in the reference to this checklist requirement (see below).

The microwave device should be tested for radiation leakage if there is visible damage to the device.

Evidence of Compliance:
✓ Written procedure for monitoring the diagnostic quality of specimens processed using microwaves

ANP.28860 Microwave Container Venting

All containers used in microwave devices are vented.

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.

Evidence of Compliance:
✓ Written procedure for the use of appropriately vented containers

ANP.29430 Microwave Venting

Microwave devices are properly vented.

NOTE: This checklist item does not apply to microwave devices that are designed by the manufacturer to operate without venting.

Microwave devices should be placed in an appropriate ventilation hood to contain airborne chemical contaminants and potentially infectious agents. Before operation of the microwave device, flammable and corrosive reagents should 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 should have an integral fume extractor certified by the manufacturer for use in a clinical laboratory.

The effectiveness of ventilation should be monitored at least annually.

This checklist requirement does not apply if only non-hazardous reagents (and non-infectious specimens) are used in the device (eg, water, certain biological stains, paraffin sections). The laboratory should consult the safety data sheets (formerly MSDS) received with reagents and stains to assist in determining proper handling requirements and safe use.

Evidence of Compliance:
✓ Records of annual evaluation of ventilation effectiveness
CIRCULATING TUMOR CELL ANALYSIS (CTC)

This section applies to laboratories using a test system to prepare, analyze, and quantify circulating tumor cells in whole blood, including immunomagnetic separation and labeling using antibodies and fluorescent stains.

VALIDATION AND CALIBRATION

Inspector Instructions:

- Sampling of validation and calibration policies and procedures
- Sampling of validation/calibration records
- Sampling of calibration materials (labeling)
- Sampling of calibration slides (labeling)

What is your course of action if calibration is unacceptable?

ANP.29500 Calibration Phase II

An appropriate verification/calibration system is used as appropriate to check performance prior to testing.

NOTE: An appropriate process is used to check the optical and mechanical performance of the system. This may be accomplished using the manufacturer’s provided material. Manufacturer’s instructions must be followed regarding when and how often the verification/calibration is performed.

REFERENCES

ANP.29510 Recalibration Phase II

The test system is recalibrated when calibration verification fails to meet the established criteria provided by the manufacturer.

Evidence of Compliance:
✓ Written policy defining criteria for recalibration AND
✓ Records of recalibration, if calibration or calibration verification has failed

REFERENCES
QUALITY CONTROL

Controls are samples that act as surrogates for patient/client specimens. They are periodically processed like a patient/client sample to monitor the ongoing performance of the analytic process.

Inspector Instructions:

- Sampling of QC policies and procedures
- Sampling of QC records

- How do you determine when QC is unacceptable and corrective action is needed?
- Select several occurrences in which QC is out of range and follow documentation to determine if the steps taken follow the laboratory procedure for corrective action

ANP.29520 Daily QC

Control materials at more than one level are run each day of patient testing.

Evidence of Compliance:
- Written policy defining QC requirements AND
- Records of QC results

REFERENCES

ANP.29530 QC Handling

Control specimens are tested in the same manner and by the same personnel as patient/client samples.

NOTE: QC specimens must be analyzed by personnel who routinely perform patient/client testing; this does not imply that each operator must perform QC daily, as long as each instrument and/or test system has QC performed at required frequencies, and all analysts participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled.

REFERENCES

ANP.29540 QC Confirmation of Acceptability

The results of controls are reviewed for acceptability before reporting results.
NOTE: Control results must be reviewed before reporting patient/client results.

Evidence of Compliance:
✓ Written policy stating that controls are reviewed and acceptable prior to reporting patient results AND
✓ Records of control result approval

REFERENCES

ANP.29550 Monthly QC Review

Quality control data are reviewed and assessed at least monthly by the laboratory director or designee.

NOTE: The review of quality control data must be documented and include follow-up for outliers, trends, or omissions that were not previously addressed.
The QC data for tests performed less frequently than once per month should be reviewed when the tests are performed.

Evidence of Compliance:
✓ Records of QC review with evidence of follow-up for outliers, trends, or omissions

SPECIMEN ANALYSIS

Inspector Instructions:

- Sampling of specimen analysis policies and procedures

ANP.29570 Carryover Detection

There is a procedure for detection and evaluation of potential carryover.

NOTE: The procedure must address criteria for the evaluation of potential carryover from a preceding elevated (high concentration) sample to the following sample in each analytical batch analysis and appropriate actions (eg, wash cycle) to be taken.

Evidence of Compliance:
✓ Records of reassessment of samples with potential carryover

REFERENCES

ANP.29580 Analysis Guidelines

There are written guidelines for differentiating circulating tumor cells from other nucleated circulating cells, such as leukocytes, as well as other cellular debris.

NOTE: Evaluation of circulating tumor cells requires the use of specific guidelines and procedures to distinguish circulating tumor cells from white blood cells and other artifacts.
REPORTS

Inspector Instructions:

- Sampling of patient reports for completeness

ANP.29590  Report Review  Phase II

All reports are reviewed and signed by a pathologist or other qualified physician.

NOTE: The individual who signs the final report must be a pathologist or other physician who qualifies as high complexity laboratory director/technical supervisor and has at least one year of training and experience in the specific area of testing.

The inspector must review a sampling of 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 or other qualified physician may not appear on the report. The laboratory must have a procedure that ensures and provides a record that the responsible physician has reviewed and approved the completed report before its release. In the occasional situation when the diagnosing physician is not available for timely review and approval of the completed report, the laboratory may have a policy and procedure for review and approval of that report by another qualified individual. In that circumstance, the names and responsibilities of both the individual who made the diagnosis and the individual who performs final verification must appear on the report.

ANP.29600  Final Report Elements  Phase II

The final report includes the criteria for favorable and unfavorable results.

NOTE: The range determining favorable and unfavorable results may be determined by the laboratory’s validation of the test system, or through evaluation of manufacturer’s or other published information.

REFERENCES

ANP.29610  Final Report Elements  Phase II

The final report includes the specimen source, name of the vendor and analyzer used, as well as any limitations of the test result, if applicable.
PERSONNEL

Inspector Instructions:

- Records of personnel education and experience

ANP.29620 Morphologic Observation Assessment Phase II

The laboratory at least annually assesses morphologic observations among non-pathologist personnel performing CTC analysis, to ensure consistency.

NOTE: Suggested methods to accomplish this include:
1. Circulation of images with specific qualitative abnormalities for the different cell populations evaluated
2. Use of digital images

Evidence of Compliance:
- Written procedure defining the method and criteria used for evaluation of consistency AND
- Employee records documenting morphologic assessment

ANP.29630 Testing Personnel Qualifications Phase II

Personnel who operate the analyzer are qualified as high-complexity testing personnel.

NOTE: Refer to the Laboratory General Checklist for high complexity testing personnel (GEN.54750) and general supervisor (GEN.53600) qualifications. Additional information for assessing personnel qualifications is available at the following link: CAP Personnel Requirements by Testing Complexity.

Evidence of Compliance:
- Records of qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation, or current license (if required)
- Work history in related field

REFERENCES

FLOW CYTOMETRY DATA INTERPRETATION

This section applies to laboratories that perform the interpretation component of flow cytometry data where the flow cytometry technical component is performed at another laboratory (different CAP or CLIA number).
Inspector Instructions:

- Sampling of flow cytometry immunophenotyping interpretation policies and procedures
- Sampling of peer education records
- Sampling of patient reports and histograms (to include abnormal cell immunophenotypes, interpretive comments, disclaimer when Class I ASRs are used, etc.)
- Record retention policy (gated dot plots/histograms)

- How does your laboratory ensure that the testing is sufficiently comprehensive to facilitate accurate diagnosis, with appropriate gating and retention of records?
- How does your laboratory distinguish neoplastic from non-neoplastic cells?

ANP.29650 Peer Education Program

For laboratories that perform only interpretations of flow immunophenotyping data, the laboratory participates in a peer education program in interpretive flow cytometry.

NOTE: This checklist item applies to laboratories that do not perform staining and acquisition of flow cytometry data, but which receive list mode files and/or representative dot plots from an outside laboratory for interpretation.

Programs dealing with analysis of flow data from hematolymphoid neoplasias and related benign conditions provide valuable educational opportunities for peer-performance comparisons. While not completely emulating the clinical setting involved in flow immunophenotyping, the peer data developed by these programs can provide a useful benchmark against which laboratory performance can be evaluated.

Evidence of Compliance:
✓ Records of enrollment/participation in an educational peer-comparison program for interpretive flow cytometry OR records for participation in a laboratory-developed program circulating cases with other laboratories or within the laboratory's own practice with records of peer review

REFERENCES

**REVISED** 09/17/2019

ANP.29670 Record Retention

Flow cytometry data for evaluation of hematolymphoid neoplasia, PNH, and congenital immunodeficiency evaluations are retained for at least 10 years. Routine lymphocyte subset and CD34+ enumeration data are retained for at least two years.

NOTE: Stored data must include raw listmode data and final interpretation. Storage of gated data is encouraged but not required.

If the laboratory responsible for the interpretation component (interpretation only flow cytometry) does not retain the data locally, it must ensure that the data are being retained for the full retention period, such as with an agreement with the laboratory performing the flow cytometry technical component (see FLO.23706).
Evidence of Compliance:
✓ Written record retention policy AND
✓ Data files with or without gated dot plots and histograms OR
✓ Written agreement with laboratory performing technical component for data storage

ANP.29690 Appropriate Antibodies

The panel of antibodies used is sufficiently comprehensive to address the clinical problem under consideration.

NOTE: Knowledge of the clinical situation and/or the morphologic appearance of the abnormal cells may help to guide antibody selection. Because antibodies vary in their degree of lineage specificity, and because many leukemias lack one or more antigens expected to be present on normal cells of a particular lineage, it is recommended that a certain degree of redundancy be built into a panel used for leukemia phenotyping.

Laboratories interpreting immunophenotyping data from an outside facility (i.e., technical flow laboratory) must ensure that antibody panels used for interpretation are appropriate. There must be a process by which individuals interpreting the results can provide feedback on the appropriateness of the antibody panels used. 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:
✓ Written procedure to select appropriate antibodies, where applicable AND
✓ Gated data plots, histograms, and patient reports

REFERENCES

ANP.29710 Gating Procedure

The laboratory interpreting flow cytometry immunophenotyping data ensures that appropriate gating techniques are used.

NOTE: There must be a process by which individuals interpreting the results can provide feedback on the appropriateness of the gating techniques used. Records of such feedback and corrective action taken when problems are identified may be incorporated into the laboratory's quality management program.

ANP.29730 Final Report

The final report includes information about the immunophenotype of the abnormal cells, if identified, and comments necessary to facilitate the interpretation.

NOTE: Clinical information and available pathologic material should be reviewed to select appropriate antibodies. In cases of suspected hematolymphoid neoplasia direct morphologic correlation of all applicable sample types should be performed when possible and clinically appropriate. In cases involving leukemia and lymphoma phenotyping, correlation should be
made between the immunologic and pathologic results. The flow histograms, rather than just the percentage of positive cells, should be reviewed by the interpreting pathologist in difficult cases. The peak channel and shapes of the curves may be helpful in identifying clonal populations.

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).

REFERENCES

AUTOPSY PATHOLOGY

QUALITY MANAGEMENT

The purpose of this section is to determine if there is an active program of surveillance of the quality of autopsy diagnostic reports and utilization of the information obtained to enhance the quality of patient care.

The requirements in this section are intended to apply to general autopsies, as well as forensic autopsies performed at hospital laboratories by pathologists. Forensic autopsies are defined as those authorized and ordered by the medical examiner or coroner; family consent is not required in these cases.

For forensic autopsy services, the Forensic Autopsy section of this checklist must also be used for inspection.

Inspector Instructions:

- Sampling of the following records: intra- and extra-departmental consultations, autopsy teaching activities
- Annual appraisal of effectiveness of the autopsy QM program
- How does your laboratory communicate important autopsy findings that were undetected clinically?
- How does your laboratory incorporate autopsy findings into the institution’s QM plan?
- Select a representative case and follow the entire process from receipt to final reporting

ANP.30080 Autopsy Quality Management Program Phase II

There is a written quality management program for autopsy services.

NOTE: The quality management program must include processes to review autopsy performance and the quality of associated reports.
Evidence of Compliance:
✓ Records of quality monitoring (eg, random case peer review, autopsy pathologist consensus conference)

REFERENCES

ANP.30100 Postmortem Clinicopathological Correlations Phase II

The findings of the postmortem examination are used for correlative clinicopathological teaching purposes that are designed to enhance the quality of patient care.

NOTE: The autopsy has an important role in medical education and quality improvement. The value of the final autopsy report is enhanced when the findings are used for teaching that emphasizes clinicopathological correlations. This teaching activity should be recorded and may take any of several forms, including a correlative note in the autopsy report, interdepartmental note or summary, or a clinical teaching conference.

Autopsy findings that were clinically unapparent but important should be specifically recorded in the report. Inter-departmental communication of such findings may, in addition, also be accomplished via presentation at an inter-departmental conference.

Evidence of Compliance:
✓ Representative report containing clinical pathological correlation OR
✓ Evidence of presentation at interdepartmental conference

REFERENCES

ANP.30150 Autopsy QM Phase I

The findings from autopsies are incorporated into the institutional quality management program.

NOTE: Some examples of this could include: 1) reporting newly diagnosed infectious diseases to the hospital infection prevention committee, 2) presentation and/or review by institutional quality assurance committees, 3) reporting issues related to quality of care to risk management or sentinel event review committees.

REFERENCES

**REVISED** 06/04/2020
ANP.30160 Significant and Unexpected Findings Phase II

The laboratory has a written policy regarding the communication of significant and unexpected autopsy findings and retains records of those communications.
NOTE: Certain unexpected autopsy findings may be considered significant. Examples include: reportable infectious diseases, heritable genetic abnormalities, procedural complications, and unexpected, potentially fatal malignancy.

There must be a reasonable effort to ensure that the appropriate health care provider and/or medical examiners/coroners, where appropriate, receive the communications by means of telephone, pager, conference presentation to relevant clinicians, or other system of notification. Laboratories should note that significant/unexpected findings may result in a jurisdiction change to the medical examiner/coroner system (eg, trauma, therapeutic misadventure, overdose). The records must include the following:

- Date of communication;
- Time of communication (if required by laboratory policy);
- Responsible laboratory individual;
- Person notified; and
- 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.

This communication must be recorded; it 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 autopsy findings.

Evidence of Compliance:
✓ Records of communications of significant/unexpected findings

REFERENCES
ANP.31100 Medical Examiner Jurisdiction

There are guidelines covering possible medical examiner or coroner jurisdiction over hospital deaths to assess the appropriateness of performing a hospital autopsy.

NOTE: To assess the appropriateness of performing a hospital autopsy, the department must be familiar with applicable statutes and/or regulations that identify hospital deaths subject to medical examiner or coroner jurisdiction. The department should maintain a copy of applicable statute(s) and/or regulation(s) that identify those deaths that are in the jurisdiction of the medical examiner and/or coroner.

Evidence of Compliance:
✓ Written policy defining jurisdiction of medical examiner or coroner

REFERENCES

AUTOPSY ROOM

Inspector Instructions:

READ
• Sampling of temperature checks/logs
• Sampling of scale/balance calibration records

OBSERVE
• Autopsy room and facilities (clean, sufficient lighting and space)
• Photographic facilities
• Access to the morgue

ANP.32180 Limited Access

Access to the morgue or body receiving and handling areas and autopsy suite is limited and controlled.

NOTE: Family viewing areas, if applicable, must be separate to prevent visual and biohazard exposure to autopsy.

REFERENCES

ANP.32200 Adequate Space and Lighting

There is sufficient space and the autopsy room is clean and well-maintained, with adequate lighting.
NOTE: The space should be sufficient for the workload requirements of the service. The autopsy room should be dedicated to the performance of autopsies. Other functions (eg, storage teaching, tissue procurement) should not interfere with the safe performance of the autopsy and the cleaning of the facility.

REFERENCES

ANP.32400 Adequate Storage Phase II

Provisions are available for satisfactory storage of bodies (refrigeration or embalming).

NOTE: For refrigeration, the temperature should be in the range of 34-40°F (1.1-4.4°C).

Evidence of Compliance:
✓ Records of temperature checks

REFERENCES

ANP.32450 Scale/Balance Phase I

A scale and/or balance are provided for reliable weighing of organs.

NOTE: If infants or fetuses are autopsied at the institution, accuracy of balances to 1.0 gm for infants and 0.1 gm for fetuses must be verified by periodic calibration.

Evidence of Compliance:
✓ Record of scale calibration checks and scale in use is appropriate for the types of cases performed

REFERENCES

ANP.32500 Temperature and Ventilation Phase I

Ambient temperature and ventilation control are adequate.

NOTE: Airborne infectious agent control requires appropriate ventilation.

REFERENCES

ANP.32550 Photographic Equipment Phase I

Photographic equipment is available, convenient, and functional.

REFERENCES
AUTOPSY PERFORMANCE AND RECORDS

Inspector Instructions:

**READ**
- Sampling of records of case review/pre-autopsy discussion
- Specimen collection records (as applicable)
- Sampling of final autopsy reports for completeness and pathology review
- Record retention policy

**OBSERVE**
- Autopsy records (organized, readily available)
- Sampling of autopsy slides (quality)
- Labeling and storage of photographs

**ASK**
- How does your laboratory ensure prompt retrieval of cases according to diagnosis?
- How are autopsy services supervised?
- Explain how personal effects found on the body are handled

**DISCOVER**
- If problems are identified during the review of autopsy records, or when asking questions, further evaluate the laboratory's responses, corrective actions and resolutions

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ANP.33000  Clinical Record Review  Phase II

**Pertinent available clinical records are reviewed and/or clinical information obtained from the following individuals before conducting the autopsy:**
- Attending/consulting physician OR
- Clinical house staff/fellows OR
- Person/agency authorizing the autopsy.

**NOTE:** Ideally the case is discussed with relevant clinicians; however, if this is not possible, medical record review satisfies this requirement. Attempts to contact clinicians should be recorded.

**Evidence of Compliance:**
- Records of clinical history in the autopsy report OR
- Records of clinician communication either in the autopsy report or separate record

**REFERENCES**

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ANP.33025  Patient Identity Confirmation  Phase I

**The identity of deceased patients is confirmed, using two identifiers, prior to beginning the autopsy.**
Evidence of Compliance:
✓ Written procedure for verifying patient identity during preparation for the autopsy

REFERENCES

ANP.33050 Autopsy Performance  
Phase II

All autopsies are performed or supervised by a pathologist who is board certified in anatomic pathology, or possesses qualifications equivalent to those required for certification in anatomic pathology.

NOTE: For autopsies performed for non-forensic purposes, "supervised by a pathologist" means that if the pathologist is not directly performing the autopsy he/she must be available to directly observe the entire autopsy or parts of the autopsy as needed.

For forensic autopsies, the pathologist must be physically present and directly observe activities by the pathology assistant or other non-pathologist personnel assisting with the dissections. The autopsy physician is responsible for examining the unclothed body, the diagnosis made, the opinions formed, and any other subsequent opinion testimony.

REFERENCES

ANP.33070 Handling of Personal Effects  
Phase II

There are written procedures for the recording, safekeeping, handling and disposition of money and personal items, prescription drugs, illicit drugs, and evidence, as applicable.

NOTE: When appropriate, legal chain-of-custody procedures must be followed.

REFERENCES

ANP.33100 Preliminary Reports  
Phase I

A written preliminary report of the gross pathologic diagnoses is submitted to the attending physician and the institutional record in 90% of the cases within a reasonable time.

NOTE: For preliminary reports based on gross examination only, two working days is the recommended TAT. For cases with complicated dissections or rush histology, up to 4 working days is recommended. For some cases such as single organ only examination or slide consults, a Provisional Report may not be appropriate or required. Preliminary reports may not be applicable for forensic cases.

Evidence of Compliance:
✓ Review of turnaround time data

REFERENCES
ANP.33120 Final Report TAT

Phase I

The final autopsy report is produced within 60 working days in 90% of the cases.

NOTE: The 90% threshold is used in recognition of the fact that occasional unusual cases may require more than 60 days for completion, particularly when external consultation is required. If cases exceed 60 days, the reason for the delay should be recorded and records of ongoing review of this information by the director of the service retained.

Evidence of Compliance:
✓ Review of turnaround time data

REFERENCES

ANP.33200 Gross and Microscopic Descriptions

Phase II

Gross descriptions are clear and pertinent findings are adequately described. If microscopy is performed, microscopic descriptions are included in the report and a key of block and/or slide designations is included to identify the source of specific microscopic sections.

NOTE: The nature of the final autopsy report is fundamentally different from surgical pathology reports and documentation of microscopic examination is an integral and essential part. The microscopic descriptions need not be lengthy or detailed, but must be included if sections for microscopy were taken and reviewed. At a minimum, the slide/block key must include information on laterality and on specific lesions sampled. Annotated drawings and photographs are valuable tools for recording the autopsy findings, but are not adequate replacements for a text description.

REFERENCES

ANP.33240 Ancillary Testing

Phase I

If specimens are collected for ancillary testing, including toxicology, the anatomical site is recorded.

Evidence of Compliance:
✓ Records of anatomical collection site used for ancillary testing

REFERENCES

ANP.33350 Final Report Content

Phase II

The final autopsy report is reviewed and signed by a pathologist. It contains sufficient information in an appropriate format so that a physician may ascertain the patient’s major disease processes and probable cause of death.

Evidence of Compliance:
✓ Review of representative autopsy report(s)

REFERENCES
ANP.33380  Photograph/Digital Image Labeling and Storage  Phase II

Autopsy photographs and/or digital images are labeled and stored in an appropriate manner and there is a system to prevent loss (eg, electronic storage system to back up data).

NOTE: If an identification photo is taken, the label must be placed in a location that does not obscure the identifying features of the decedent. The record system must allow for the photographs to be easily retrieved.

REFERENCES

ANP.33400  Autopsy Records  Phase I

Autopsy records are organized and readily available for review and are entered into a database to allow for retrieval of cases by diagnosis.

NOTE: At the facility's discretion, the database may be a card file, log book, or an electronic record, depending on the size of the database.

REFERENCES

ANP.33500  Record Retention  Phase II

Autopsy pathology records and materials are retained for an appropriate period.

NOTE 1: There must be a written policy for protecting and preserving the integrity and retrieval of autopsy service materials and records. The retention period shall be sufficient for use of the materials in the institution’s quality improvement activities (eg, morbidity and mortality conferences). 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 below, whichever is most stringent.

<table>
<thead>
<tr>
<th>Type of Record/Material</th>
<th>Retention Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accession log records</td>
<td>2 years</td>
</tr>
<tr>
<td>Wet tissue (stock bottle)</td>
<td>3 months after final report</td>
</tr>
<tr>
<td>Paraffin blocks</td>
<td>10 years</td>
</tr>
<tr>
<td>Glass slides</td>
<td>10 years</td>
</tr>
<tr>
<td>Autopsy reports</td>
<td>10 years</td>
</tr>
<tr>
<td>Autopsy consent</td>
<td>Per institutional medical record retention policy (minimum 10 years)</td>
</tr>
</tbody>
</table>

NOTE 2: For autopsy paraffin blocks, the CAP recommends extending the required retention period to indefinitely or for at least a generation (approximately 20 years); however, it is not a requirement of accreditation. These blocks represent the last opportunity for tissue-based biomarker, genetic, and other testing in the interest of family members and public health.
Strategies, such as retaining even a select number of blocks from each case permanently or partnering with a regional biorepository for permanent storage may be considered.

NOTE 3: Paraffin blocks used for patient diagnostic purposes must be kept for at least 10 years. Such blocks may be released for research purposes if all of the following criteria are met:

1. For a laboratory subject to U.S. law, formal written authorization is obtained in accordance with the requirements of HIPAA if identifiable patient information is released unless, in accordance with 45CFR164.512(i), the laboratory obtains from the researcher a representation that use of the blocks protects the health information of decedents.
2. The laboratory retains sufficient blocks to support the diagnosis 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.
4. In the event of limited material (e.g., 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.

NOTE 4: The wet tissue (stock bottle) refers to small portions of organs that are saved in a small container. There is no CAP requirement or recommendation for retention of whole or large portions of organs.

Evidence of Compliance:
✓ Written record retention policy

REFERENCES

AUTOPSY SAFETY

NOTE TO THE INSPECTOR: This section applies to the on-site autopsy laboratory. The inspector should review relevant requirements from the safety section of the Laboratory General checklist, to assure that the autopsy laboratory is in compliance.

The following requirements pertain specifically to the autopsy laboratory.
Inspector Instructions:

- Sampling of autopsy safety policies and procedures
- Posting of autopsy safety policies
- How does your laboratory ensure inactivation of hepatitis B virus when disinfecting tables, reusable instruments and aprons?

ANP.33650  Autopsy Facilities  Phase II

**Appropriate facilities, equipment and instruments are available to meet safety policies and procedures.**

NOTE: Containers must be available for contaminated waste and hazardous chemicals and policies must be in place for their disposal. Equipment and apparel must be available to provide protection to eyes, hands, and skin surfaces from direct and aerosolized exposures during autopsy performance. Procedures must be in place for the disposition or cleaning of these items for re-use upon completion of the autopsy.

REFERENCES

**REVISED** 06/04/2020

ANP.34000  Safety  Phase II

**There is appropriate signage at entries to the autopsy laboratory warning of the potential presence of hazardous chemicals and biologic materials, and the need for standard precautions. Policies and procedures for contaminated cases/specimens, hazardous chemicals, etc. are written and posted in the autopsy suite.**

NOTE: It is important that persons entering the autopsy laboratory be aware of potential hazards and take appropriate protective measures. Postings may include information such as details of personal protective equipment and emergency contact information.

REFERENCES

ANP.34050  Decontamination  Phase II
The safety policies and procedures provide instructions for cleaning after an autopsy, proper handling of highly infectious cases, and disposal of tissues.

**NOTE:** Tables and reusable instruments and aprons must be adequately disinfected after use. Either autoclaving or chemical disinfection of instruments is acceptable, but the method chosen must be adequate to inactivate the hepatitis B virus.

**REFERENCES**


**REVISED** 06/04/2020

**ANP.34150** Special Handling of Transmissible Spongiform Encephalopathies (TSE) **Phase II**

There are written procedures for the special handling of cases in which Transmissible Spongiform Encephalopathies (TSE), including Creutzfeldt-Jakob disease (CJD), are suspected.

**NOTE:** In addition to practicing standard precautions during the autopsy, procedures must be written for the special precautions to be taken for autopsies on patients in whom the diagnosis of TSE is suspected. Pathologists should consider taking these special precautions as well in cases of (a) rapidly progressive dementia, (b) dementia with seizures, especially myoclonic seizures, and (c) dementia associated with cerebellar or lower motor neuron signs. The recommended method for handling these brains to reduce infectivity is immersion of tissue blocks in 95% formic acid. Aerosol formation must be avoided during removal of the brain.

If there is any suspicion of TSE, the autopsy should be limited to the brain, and the tissue treated as outlined below. There should be very few exceptions to this rule.

Autopsy brain tissues should be handled as follows:

The intact brain is fixed in formalin for 1-2 weeks before cutting. Tissue blocks (representative regions of neocortex, basal ganglia, and cerebellum) are taken, agitated in at least 50-100 mL of 95-100% formic acid for one hour, and then returned to formalin for two days before embedding. Alternatively, one may take the necessary diagnostic sections from the fresh brain, fix them in formalin for 2-7 days, treat with formic acid for one hour, fix again in formalin for two days, and then embed in paraffin. This method significantly reduces infectivity.

At the conclusion of the autopsy, the area of incision and other contaminated skin surfaces are washed with freshly opened undiluted commercial household bleach (sodium hypochlorite). As sodium hypochlorite deteriorates after several months, a newly opened container should be used for each autopsy. After 10 minutes, the skin may be washed with water. All gowns, gloves, plastic sheets, and other disposable supplies are placed in a red or orange biohazard bag and incinerated. Alternatively, they may be autoclaved (132°C steam) and discarded. Hard surfaces are decontaminated with freshly opened undiluted bleach or NaOH. 1N NaOH is adequate unless there will be dilution by surface liquid, in which case 2N NaOH should be used. Bleach and NaOH are equally effective, but NaOH is preferred for steel instruments and surfaces because it is less corrosive than bleach. The disinfectant should remain in contact with the surface for at least 15 and preferably 60 minutes. Autopsy instruments should have any visible blood removed, then decontaminated with undiluted bleach or 1-2N NaOH as above. Alternatively, they may be autoclaved for one hour at 132°C and 20 psi (140 kPa).

For information on handling slides and blocks, refer to the checklist requirement in the Histology Laboratory Safety section of this checklist.

**Evidence of Compliance:**

✓ Written procedures for handling TSE cases
REFERENCES

ANP.34160 Safe Handling of Bariatric Patients

There are written procedures for the special handling of autopsies on bariatric patients where the patient size could represent an occupational hazard to autopsy staff.

NOTE: Individual institutions may set their own specific weight or BMI limits for application of the occupational health policy. Institutions may also choose whether to use special equipment for such patients and what type(s) of equipment to use.

Evidence of Compliance:
✓ Written policy for handling of bariatric patients

REFERENCES

FORENSIC AUTOPSY PATHOLOGY

The Forensic Autopsy section is to be used in conjunction with the Autopsy Pathology section and Chain-of-Custody section in the Laboratory General Checklist for inspections of forensic autopsy services rendered in a hospital setting.

QUALITY MANAGEMENT - FORENSIC AUTOPSY

Inspector Instructions:

- Policies for access to expert forensic consultants
- Policies for the use of laboratory and radiology services
- How do you access the services of a forensic pathologist and expert consultants as needed?
- Where is post-mortem clinical laboratory testing performed?

ANP.35000 Forensic Pathologist and Expert Consultants

The laboratory has access to a forensic pathologist and expert consultants, as appropriate for the following types of services:

- Forensic neuropathology
- Forensic dentistry/odontontology
- Forensic anthropology
- Radiology
NOTE: References for specialties may be found on the following websites:

- American Board of Forensic Anthropology: http://theabfa.org/active-diplomates/
- American Board of Pathology: http://www.abpath.org/index.php/verifying-certification
- American Board of Forensic Odontology: https://abfo.org/resources/member-directory/
- American Academy of Forensic Sciences: https://www.aafs.org/about-aafs/sections/
- National Association of Medical Examiners: http://www.thename.org/

Evidence of Compliance:
✓ Written policy for obtaining consultative services from qualified consultants

ANP.35025 Analysis of Post-Mortem Specimens Phase II
Appropriate forensic toxicology and clinical laboratory services are available for analysis of post-mortem specimens as needed.

NOTE: Testing services must be available on-site or through a referral laboratory for the following tests, where applicable: ethanol, volatiles, carbon monoxide, major drugs of abuse, major acidic drugs, and major basic drugs. Results for carbon monoxide testing must be available in a timely manner. Toxicology testing must be performed in compliance with the guidelines of the Society of Forensic Toxicologists (SOFT) and be accredited by the American Board of Forensic Toxicology (ABFT) or the College of American Pathologists or be a state reference laboratory.

If toxicology testing is requested, information should be provided to the toxicology laboratory for the circumstances surrounding the death and medications taken by the decedent.

Evidence of Compliance:
✓ Written policies for the performance or referral of forensic toxicology and clinical laboratory testing AND
✓ Records of referral laboratory selection

ANP.35050 Radiology and Imaging Services Phase II
Adequate radiology and imaging services are available to allow for radiographs or imaging of the body to be performed and viewed by the pathologists before and during the autopsy as needed.
FORENSIC AUTOPSY PERFORMANCE AND RECORDS

Inspector Instructions:

- Sampling of policies and procedures for forensic autopsies
- Specimen handling policies and procedures for laboratory testing (toxicology, histology, and DNA analysis) and evidence collection
- Chain-of-custody procedures (as applicable)
- Sampling of final autopsy reports and records

- Autopsy records (organized, readily available)
- Copies of national, state, or local guidelines for autopsy performance
- Photographic records (as applicable)

- How does your laboratory ensure prompt retrieval of specimens in cases of delayed death in hospitalized victims?
- How are cases with unidentified bodies handled?

- If problems are identified during the review of autopsy records, or when asking questions, further evaluate the laboratory's responses, corrective actions and resolutions

ANP.36000 Trace Evidence Collection Phase II

In cases that involve the collection of trace evidence (eg, sexual assault, pedestrian struck by motor vehicle, strangulation) appropriate evidence is collected.

NOTE: Appropriate hair samples, swabs, nail clippings/scrapings, and trace evidence are collected for the decedent. Bite marks must be processed according to the procedure consistent with current forensic odontology practice.

REFERENCES

ANP.36025 Specimen Collection Phase II

Specimens are routinely collected and retained for toxicology, potential DNA analysis, and histological examination, as applicable.

NOTE: In cases of delayed death in hospitalized victims, the earliest available appropriate specimens should be obtained from the hospital, as applicable.

ANP.36050 Unidentified Bodies Phase II
There is a written policy defining the actions to be taken prior to the disposition of unidentified bodies (eg, finger printing, photographs/images, radiographs, dentition, DNA sample storage, medical history/devices) to allow for potential future identification.

**REVISED** 09/17/2019
ANP.36075 Photographs Phase II

Photographs are taken, as appropriate, to include:

- Evidence, foreign material, blood patterns, injuries, and other items pertinent to determining the cause and manner of death or necessary for medicolegal interpretation or presentation
- Orientation photographs and close-ups of injuries with measurement scales
- Identification photographs of decedent.

NOTE: The identifying label must be placed in a location that does not obscure the identifying features of the decedent.

ANP.36100 Autopsy Notes and Photographs Phase I

Written notes and photographs are taken to an extent that would allow reconstruction of the autopsy report if dictations are lost or damaged.

ANP.36125 Record Retention - Forensic Autopsy Phase II

Forensic autopsy pathology records and materials are retained for an appropriate period.

NOTE 1: There must be a written policy for protecting and preserving the integrity and retrieval of forensic autopsy service materials and records. The retention period shall be sufficient for use of the materials in the institution's quality improvement activities (eg, morbidity and mortality conferences). Policies for retention of records and materials must comply with federal, state (or provincial), and local laws and regulations, and with the retention periods listed below, whichever is most stringent.

<table>
<thead>
<tr>
<th>Forensic Autopsies</th>
<th>Type of Record/Material</th>
<th>Retention Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body transfer and disposition records</td>
<td>Indefinitely</td>
<td></td>
</tr>
<tr>
<td>Wet tissue (stock bottle)</td>
<td>1 year</td>
<td></td>
</tr>
<tr>
<td>Paraffin blocks</td>
<td>10 years</td>
<td></td>
</tr>
<tr>
<td>Glass slides</td>
<td>50 years or 30 years if a DNA sample is available</td>
<td></td>
</tr>
<tr>
<td>Autopsy reports</td>
<td>Indefinitely</td>
<td></td>
</tr>
<tr>
<td>Gross photographs/images</td>
<td>Indefinitely</td>
<td></td>
</tr>
<tr>
<td>Body fluids and tissues for toxicology</td>
<td>1 year</td>
<td></td>
</tr>
<tr>
<td>Sample suitable for DNA analysis</td>
<td>Indefinitely</td>
<td></td>
</tr>
</tbody>
</table>

NOTE 2: For autopsy paraffin blocks, the CAP recommends extending the required retention period to indefinitely or for at least a generation (approximately 20 years); however, it is not a requirement of accreditation. These blocks represent the last opportunity for tissue-based biomarker, genetic, and other testing in the interest of family members and public health. Strategies, such as retaining even a select number of blocks from each case permanently or partnering with a regional biorepository for permanent storage may be considered.

NOTE 3: The wet tissue (stock bottle) refers to small portions of organs that are saved in a small container. There is no CAP requirement or recommendation for retention of whole or large portions of organs.
Evidence of Compliance:
✓ Written record retention policy

REFERENCES

**ELECTRON MICROSCOPY**

*If the electron microscopy service is a separate and distinct laboratory in the Anatomic Pathology section, the inspector may find it more convenient to use an additional copy of the Anatomic Pathology Checklist for the inspection, answering all applicable requirements.*

**Inspector Instructions:**

- Sampling of EM policies and procedures
- Select a representative EM sample and follow the entire process from specimen receipt to final result reporting

**QUALITY CONTROL**

**ELECTRON MICROSCOPY SAMPLE PREPARATION**

**Inspector Instructions:**

- Sampling of blocks (adequately identified)
- Sampling of slides and electron micrographs (quality, adequately identified)
- How does your laboratory ensure specimen identity throughout testing?
- How does your laboratory ensure appropriate tissue areas are selected for EM examination?

**ANP.52100  Tissue Section Review  Phase II**

*Sections of embedded tissue (face sections) are reviewed by the pathologist to ensure that appropriate areas are selected for electron microscopic examination.*
ANP.52150  Tissue Section Review  Phase I

Where appropriate, one micron sections (prepared after trimming or ultra-thin sectioning) are also reviewed by the pathologist to ensure that appropriate areas have been selected.

NOTE: An example might be a mesenchymal neoplasm where confusion between tumor cells and admixed stromal elements could occur.

ANP.52300  Slide/Electron Micrograph Quality  Phase II

Examine several slides and electron photomicrographs. They are of sufficient quality for proper interpretation of ultrastructural changes.

INSTRUMENTS AND EQUIPMENT

Inspector Instructions:

- Sampling of EM maintenance and repair records
- Sampling of EM calibration records
- Sampling of ultramicrotomes (condition)
- Instrument/equipment records (promptly retrievable)

ANP.53000  Adequate Ultramicrotome  Phase II

Ultramicrotomes are adequate and in good repair.

ANP.53100  EM Maintenance  Phase II

The electron microscope is under a regular, documented maintenance and repair system.

ANP.53150  Magnification Calibration  Phase I

The magnification is calibrated after major maintenance, as appropriate.

Evidence of Compliance:
✓ Written procedure for calibration of magnification AND
✓ Records of calibration
REPORTS

Inspector Instructions:

- Sampling of EM reports (signed, appropriate correlations)

ANP.54000  Report Format  Phase II

The report format provides for correlation with routine light microscope and other (eg, immunohistochemical and immunofluorescent) studies.

ANP.54050  Report Signature  Phase II

All reports are signed by the pathologist.

NOTE: Where diagnostic reports are generated by computer or telecommunications equipment, the actual signature or initials of the pathologist may not appear. It is nevertheless essential that the laboratory have a procedure that ensures and provides a record that the responsible pathologist has reviewed and approved the completed report before its release.

RECORDS, FILES AND PHOTOGRAPHS

Inspector Instructions:

- Specimen retention policies and procedures
- Tissue storage (readily retrievable)

ANP.55100  Record Retention  Phase II

Electron microscopy records and materials are retained for an appropriate period of time.

NOTE: Policies for retention of records and materials must comply with federal, state, and local laws and regulations, and with the retention periods listed below, whichever is most stringent.
<table>
<thead>
<tr>
<th>Type of Record/Material</th>
<th>Retention Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accession log records</td>
<td>2 years</td>
</tr>
<tr>
<td>Wet tissue</td>
<td>2 weeks after the final report</td>
</tr>
<tr>
<td>Resin blocks</td>
<td>10 years</td>
</tr>
<tr>
<td>Pictures and reports</td>
<td>10 years</td>
</tr>
</tbody>
</table>

**Evidence of Compliance:**
- ✓ Written specimen retention policy

## 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 electron microscopy laboratory is in compliance.

The following requirements pertain specifically to the electron microscopy laboratory.

### Inspector Instructions:
- Sampling of EM safety policies and procedures
- Sampling of radiation leakage check records

### ANP.57000  EM Safety  Phase II

**Safety policies and procedures are established for electron microscopy sample preparations and instrument operation.**

### ANP.57070  Hazardous Chemicals  Phase II

**Procedures are adequate for the safe handling and disposal of osmium tetroxide, epoxy resins, and other hazardous chemicals.**

*NOTE: Osmium tetroxide is volatile and toxic. Exposure to its vapor can lead to blindness and serious respiratory complications. There must be a clearly stated and posted procedure addressing accidental spillage. Material for dealing with such a spill should be readily available, eg, corn oil and an absorbent such as saw dust. For US laboratories, disposal of osmium tetroxide must be according to OSHA regulations for toxic compounds. Epoxy resins are highly allergenic, and direct contact should be avoided. The laboratory must have documentation that personnel have been trained in the handling of these materials.*

**REFERENCES**

### ANP.57100  X-Ray Leakage  Phase II

**The electron microscope is checked for x-ray leakage at the time of installation and after major repair.**
**IN VIVO MICROSCOPY (IVM)**

This section applies to In Vivo Microscopy (IVM) technologies for clinical practice, in which a physician views digitized or analog video or still image(s) or other data, and renders an interpretation that is included in a formal diagnostic report or in the patient record. The Ex Vivo Microscopy section of this checklist should be used for in vitro applications of these systems.

This checklist section applies to the application of IVM technologies for:

- Intra-procedural guidance of biopsy or tissue excision
- Surgical (intraoperative) guidance
- Primary evaluation and/or diagnosis
- Screening
- Intra- or extra-institutional consultation
- Post-procedural evaluation and/or diagnosis

Examples of IVM technologies include:

- Confocal microscopy
- Optical coherence tomography (OCT)
- Multiphoton microscopy
- Optical spectroscopy and spectroscopic imaging

This checklist section is NOT applicable to:

- Informal reviews without formal reporting
- Educational or research-only use of these systems

The providers of IVM services (acquisition and interpretation of IVM datasets) may be located entirely within a clinical department, the pathology department (laboratory), or may represent collaboration between a clinical department and the laboratory. The responsibility for checklist requirements rests with the IVM service. The IVM service must ensure that records to demonstrate compliance are available for review by the CAP inspection team, whether the records are located within a clinical department, the laboratory, or both.

**DEFINITION OF TERMS**

**In vivo microscopy (IVM) dataset** — Digitized or analog video or still images or other data (eg, spectroscopic data) generated by an IVM system that is utilized to render a diagnostic interpretation or to guide procedures.

**Confocal microscopy** — A non-invasive, high-resolution optical imaging technique that excludes out-of-focus light, enabling 'optical sectioning' and tomographic imaging of specimens that are thicker than the focal plane. Confocal microscopy can be performed directly on tissue or through an endoscope (confocal laser endomicroscopy or CLE). The latter may be either endoscopy-based (eCLE device built into the endoscope) or probe-based (pCLE device in a probe with fiber-optic cable for image transmission that can be inserted into the accessory port of a standard endoscope). Injection or topical application of a contrast is usually required.
Optical coherence tomography (OCT) — A non-invasive, high-resolution optical imaging technique that provides real-time 2-D and 3-D images of tissue architecture in vivo by mapping reflectivity of light waves focused onto the tissue. Variants of OCT technology include: Optical Frequency Domain Imaging (OFDI) and Full Field OCT (ff-OCT). Contrast agents are usually not required.

Multiphoton microscopy — A high-resolution fluorescence imaging technique that provides 2-D and 3-D tomographic images based on non-linear optical effects. It is also known as 2-photon, 3-photon, or nonlinear microscopy. Contrast agents are usually not required.

Optical spectroscopy — An optical technique that assesses the way in which the spectrum of light is changed by interaction with tissue. Examples include diffuse reflectance spectroscopy, fluorescence spectroscopy, and Raman spectroscopy. Measurements made with any of these techniques can be translated into false color spectroscopic images (optical spectroscopic imaging). Contrast agents are usually not required.

Additional information on IVM may be obtained using the CAP Pathology Resource Guide: In Vivo Microscopy.


Inspector Instructions:

- IVM policies and procedures
- Sampling of reports generated from reviews of datasets obtained by IVM
- Sampling of records for personnel training
- Sampling of records of rejected IVM datasets and notification of clinical personnel
- Sampling of records documenting verbal reports
- Completed validation study(ies) with review and approval
- Quality management plan including IVM

- Review summary statements and supporting validation data to confirm that studies were performed using an adequate number of cases, data was evaluated, and summary statement was approved prior to implementation. If the data showed discordances or unacceptable variations, investigate how they were resolved.

QUALITY MANAGEMENT AND VALIDATION

ANP.57150 IVM Quality Management Program Phase I

IVM services are included in the laboratory's or institution's quality management plan.

NOTE: The specific components of the quality management plan are left to the discretion of the IVM service. Examples include monitoring the quality of clinical information provided to ensure it is adequate for the intended use of the system, and monitoring disparities between initial IVM dataset interpretation and final pathology diagnosis.

Evidence of Compliance:
✓ Written quality management plan including IVM

ANP.57200 IVM Appropriate Use Phase I

There are written policies to ensure that the system(s) used for IVM are appropriate for the intended clinical use.
NOTE: There should be a policy statement in the procedure manual that identifies appropriate use cases.

ANP.57250  IVM System Validation

The IVM service performs validation studies before the technology is used for the intended diagnostic purpose(s).

NOTE: The specific components of the validation study are left to the discretion of the IVM service. However, studies should be performed using an adequate number of cases, data should be evaluated, and a summary statement provided prior to implementation. Records of how discordant data or unacceptable variations from the expected were resolved are required.

As general guiding principles, the validation process should:
- Closely emulate the real-world clinical environment and involve tissue types and clinical settings relevant to the intended use(s)
- Be carried out by or under the supervision of a physician(s) adequately trained to use the IVM system
- Encompass the entire IVM system, with reevaluation if a significant change is made to a previously validated system.

Evidence of Compliance:
✓ Records of completed validation study with supporting validation data, review and approval

ANP.57300  IVM User Training

There are training records for all users of the IVM system.

NOTE: Users of the IVM system include individuals responsible for IVM dataset interpretation. Training may be a coordinated process between a clinical department and the laboratory, depending on the individual needs of the organization. Training records may be part of the credentialing process at a hospital or other health care facility or may be part of the pathology department's records. Because the field is rapidly evolving, consideration should be given to continuous learning opportunities.

Evidence of Compliance:
✓ Records for training of personnel on the use of the IVM system for diagnostic purposes

ANP.57350  IVM System Function Checks

Regular function checks are performed and records retained on the IVM system/instrument by the IVM service.

NOTE: Function checks include confirmation that an instrument or item of equipment operates according to manufacturer's specifications before routine use, at prescribed intervals, or after minor adjustment. Depending on the type of system, function checks may include calibration.

Evidence of Compliance:
✓ Written procedure for function checks and calibration, as required

ANP.57400  Method Performance Specifications Availability

The current IVM methods and all significant changes to analytical methodology, including performance specifications and supporting validation data, are retained by the IVM service.

NOTE: Records should include, but are not limited to, components of IVM equipment, software systems, image viewing systems, and digital image analysis systems. The IVM service must...
also provide data on clinical performance claims to clients upon request, if clinical performance claims are made. The IVM service may at its option require clients to agree to treat such data as confidential and not to share such data with any other party except as required by law.

Evidence of Compliance:
✓ Records of changes to analytical methodology

REFERENCES

IVM ANALYSIS

ANP.57450 Clinical Information Access  Phase I
The individual reviewing cases has access to pertinent clinical information at the time of IVM dataset review.

NOTE: In addition to the usual demographic and clinical information, the individual reviewing cases should have access to information on any special patient preparation and the type of imaging or contrast agent used, if any.

ANP.57500 IVM Confidentiality and Security  Phase II
There are written procedures to ensure that sites engaging in IVM provide reasonable confidentiality and security.

NOTE: Procedures might include message security, system and user authentication, activity logs, encryption, and access restrictions.

For laboratories subject to US regulations, the procedures must be in conformance with HIPAA requirements.

ANP.57550 IVM Dataset Identification  Phase II
There is a written procedure to ensure correct patient and IVM dataset identification.

NOTE: There are multiple ways to accomplish positive patient identification, including verbal communications, images of identifiers, etc.

ANP.57600 IVM Dataset Acceptability Criteria  Phase II
There are written criteria for acceptability of IVM datasets for the intended clinical application.

NOTE: IVM datasets must be of adequate quality for the intended clinical application. This requirement does not imply that all "unsuitable" datasets are discarded or not interpreted. However, there must be a mechanism to notify clinical personnel responsible for patient care when dataset quality is unacceptable for interpretation or if sub-optimal dataset quality impacts the quality of interpretation, with records of notification retained.

IVM REPORTS

ANP.57650 IVM Report Review  Phase II
IVM reports are reviewed and signed by the physician who interprets the IVM datasets.
NOTE: The inspector must review a sampling of reports issued since the previous on-site inspection, representing at least the most common types of IVM datasets interpreted in the IVM service. When diagnostic reports are generated by computer or telecommunications equipment, the actual signature or initials of the physician may not appear on the report. It is nevertheless essential that the IVM service have a procedure that ensures and records that the responsible physician has reviewed and approved the completed report before its release. In the occasional situation when the diagnosing physician is not available for timely review and approval of the completed report, there may be a procedure for review and approval of that report by another physician. In that circumstance, the names and responsibilities of both the physician who made the diagnosis and the physician who performed final verification must appear on the report.

Evidence of Compliance:
✓ Signed IVM reports

ANP.57700 IVM Final Report Elements

The final report includes the dataset source, the imaging technology, as well as any limitations of the result, if applicable.

NOTE: In addition to the requirements above, the IVM system used and name of the vendor may be included in the report to provide users of the report with access to more information about the IVM system. For locally developed IVM systems, this may be in the form of a link to more information about the system on the internet. If a scoring system is used in interpretation, it should be referenced in the report.

The format of the final report is up to the medical director. The IVM report may be part of an encompassing surgical pathology report or stand on its own. Because the discipline is so visually-based, consideration should be given to including IVM images in the final report that reflect the final interpretation or pertinent findings.

Evidence of Compliance:
✓ IVM reports containing appropriate report elements

ANP.57750 IVM Verbal Reports

If verbal reports are given, the physician speaks directly with medical/surgical personnel performing the IVM procedure and retains a record of the verbal report.

ANP.57800 IVM Verbal Report Patient ID

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

Evidence of Compliance:
✓ Written procedure for verbal reporting of IVM dataset interpretation results

ANP.57850 IVM Dataset Retention

There is a written policy for retention of IVM datasets used for interpretation or diagnosis.

NOTE: IVM datasets must be retained for 10 years (data must be retrievable for this period). IVM datasets are stored as digital files. Storage of the entire original data is not required. Stored data should include, at a minimum, the data (original data or derived data) used for interpretation or diagnosis.