COMMISSION ON LABORATORY ACCREDITATION

Laboratory Accreditation Program

ANATOMIC PATHOLOGY CHECKLIST
QUESTIONS RELATED TO REPORTING OF RESULTS ONLY

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ANATOMIC PATHOLOGY

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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.

ANP.10100    Phase II    N/A    YES  NO

When significant disparities exist between initial intraoperative consultation (e.g., frozen section, cytology, gross evaluation) and final pathology diagnosis, are these reconciled and documented either in the surgical pathology report or in the departmental quality management file?

COMMENTARY:

N/A

ANP.10150  Phase II  N/A  YES  NO

Does the laboratory have a policy for inclusion of INTRA-departmental consultations in the patient's final report?

NOTE: Intradepartmental 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.

COMMENTARY:

N/A


ANP.10200  Phase II  N/A  YES  NO

Are EXTRA-departmental consultations documented, and are records of these consultations maintained in a systematic manner within the pathology department?

NOTE: Documentation 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 maintained with the official surgical pathology reports or kept separately, so long as they can be readily linked.

COMMENTARY:

N/A

When extra-departmental cases are submitted to the laboratory for consultation, are they accessioned according to the standard practices of the laboratory, and is a documented report prepared, with a copy sent to the original pathologist?

**NOTE:** Extra-departmental cases submitted for consultation should be accessioned according to the standard practices of the laboratory, and a report issued. A copy of this report should be sent to the original pathologist. 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 original pathologist 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.

**COMMENTARY:**

N/A


http://www.cap.org/apps/docs/policies/policy_appF.htm

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**SURGICAL SPECIMEN EXAMINATION**

*Inspectors and laboratories are reminded that questions 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.*
ANP.11400 Phase I N/A YES NO

Are dictating facilities available and convenient to use?

COMMENTARY:

N/A

ANP.11450 Phase I N/A YES NO

Are photographic facilities available and convenient?

NOTE: In addition to providing material for a teaching collection, such photographs can serve as valuable documentation for the report.

COMMENTARY:

N/A

ANP.11550 Phase I N/A YES NO

Are all gross specimens retained until at least 2 weeks after the final reports are signed and results reported to the referring physician?

COMMENTARY:

N/A


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INTRAOPERATIVE CONSULTATION (RAPID DIAGNOSIS OR FROZEN SECTION)

-----------------------------------------------------------------
ANP.11850  Phase II  N/A YES NO

Are the results of surgical consultations documented and signed by the pathologist who made the diagnosis?

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

COMMENTARY:

N/A

ANP.11900  Phase II  N/A YES NO

If verbal reports are given, is the pathologist able to speak directly with the surgeon?

COMMENTARY:

N/A

ANP.11950  Phase II  N/A YES NO

Is the patient's identification checked and confirmed before delivery of any verbal report?

COMMENTARY:

N/A

ANP.12000  Phase II  N/A YES NO

Are all intraoperative consultation reports made a part of the final surgical pathology report?

COMMENTARY:

N/A

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SURGICAL PATHOLOGY REPORTS
-----------------------------------------------------------------
**REVISED** 04/28/2005

ANP.12100 Phase II N/A YES NO

Are all reports reviewed and signed by the pathologist?

NOTE: The inspector must review 15-20 recent surgical pathology reports. 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 documents 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 policy and 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.

COMMENTARY:

N/A


ANP.12150 Phase II N/A YES NO

Are reports on routine cases completed within 2 working days?

NOTE: Unusual, complex or special specimens may require prolonged fixation before dissecting and selecting tissue samples, additional time for special stains, etc., and the reporting time may extend beyond 2 working days of receipt by the laboratory conducting the surgical pathology examination. This question is primarily concerned with the majority of routine specimens, and applies to all laboratories.

COMMENTARY:

N/A

**NEW**  03/31/2004

ANP.12175             Phase I N/A YES NO

Is there a policy regarding the timely communication, and documentation thereof, of significant or unexpected surgical pathology findings?

NOTE: Certain surgical pathology diagnoses may be considered particularly significant or unexpected. Such diagnoses may include: malignancy in an uncommon location or specimen type (e.g., hernia sac, intervertebral disk material, tonsil, etc.), absence of chorionic villi when clinically expected (potential ectopic pregnancy), change of a frozen section diagnosis after review of permanent sections, and/or mycobacterial, fungal or other significant infectious organisms identified on special stains. Diagnoses to be defined as “significant” or “unexpected,” if any, should be determined by the pathology department, in cooperation with local clinical medical staff. Consideration should be given to assuring, with reasonable effort, prompt communication of such results, by telephone, pager, or other system. There should be documentation of date and time of such special notification (which may be included in the pathology report or in laboratory files).

COMMENTARY:

N/A


ANP.12200             Phase II N/A YES NO

Do all surgical pathology reports include gross descriptions that contain adequate information regarding type, number, dimensions and/or weight of specimens, measurements and extent of gross lesions, and other information essential to the diagnosis and patient care?

COMMENTARY:

N/A

ANP.12250          Phase II                      N/A    YES   NO

When appropriate, do gross descriptions include a key or summary noting block and slide
designations for special sections (e.g., margins of resection, deepest penetration of tumor, breast
quadrants, lymph node levels, etc.)?

COMMENTARY:

N/A

REFERENCE: Imperato PJ, et al. Radical prostatectomy specimens among Medicare patients in New

ANP.12300          Phase II                      N/A    YES   NO

Do gross descriptions and microscopic findings (if included) support the pathologic diagnosis?

COMMENTARY:

N/A

REFERENCE: Rickert RR. Quality Assurance in Surgical Pathology. Arch Pathol Lab Med
1990;114:1157-1162.

ANP.12350          Phase II                      N/A    YES   NO

In tumor cases, does the final report provide sufficient information as to tumor grade and its
extent within the pathological specimen, for use in standard systems of grading and staging of
neoplasms?

NOTE: The pathology report must provide data that, within the confines of information available to
the pathologist, is sufficient to allow appropriate grading and staging of neoplasms according to
standard classification schemes. This information should be easily identifiable (e.g., bold type,
distinctive font, or visually set apart from the descriptive text of the report). The use of checklists or
synoptic diagnostic reports is recommended, to ensure that all information relevant to staging and
grading is included, and to facilitate interpretation of pathology reports by clinicians.

COMMENTARY:

**REVISIONS** 12/01/2003

**ANP.12400**  
**Phase II**

**N/A YES NO**

Is there a mechanism to correlate the results of specialized studies (e.g., electron microscopy, immunohistochemistry, nucleic acid probes, cytogenetics) 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 correlate all of the special studies, reconcile conflicting data, and render a final interpretation of all correlated studies.

**COMMENTARY:**

N/A


**ANP.12425**  
**Phase II**

**N/A YES NO**

If patient testing is performed using Class I analyte-specific reagents (ASR’s) obtained or purchased from an outside vendor, does the patient report include the disclaimer required by federal regulations?

**NOTE:** ASR’s are antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reaction with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens.

By definition, an ASR is the active ingredient of an in-house-developed (“home brew”) test system. ASR’s may be obtained from outside vendors or synthesized in-house. ASR’s from outside vendors are supplied individually. They are not bundled with other materials in kit form, and the accompanying product literature does not include any claims with respect to use or performance of the reagent.
Class I ASR’s in use in the anatomic pathology laboratory include some antibodies for immunohistochemistry and nucleic acid probes for FISH and ISH.

Class I ASR’s are not subject to preclearance by the U.S. Food and Drug Administration or to special controls by FDA. Thus, if the laboratory performs patient testing using Class I ASR’s obtained or purchased from an outside vendor, federal regulations require that the following disclaimer accompany the test result on the patient report:

"This test was developed and its performance characteristics determined by (laboratory name). It has not been cleared or approved by the U.S. Food and Drug Administration."

The CAP recommends additional language, such as "The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing."

The above disclaimer is not required when using reagents that are sold in kit form with other materials and/or an instrument, and/or with instructions for use, and/or when labeled by the manufacturer as Class I for in vitro diagnostic use (IVD), Class II IVD, or Class III IVD.

Most antibodies used in immunohistochemistry are labeled “for in vitro diagnostic use” and thus do NOT require the disclaimer.

Antibodies, nucleic acid sequences, etc., labeled “Research Use Only” (RUO) purchased from commercial sources may be used in home brew tests only if the laboratory has made a reasonable effort to search for IVD or ASR class reagents. The results of that failed search should be documented by the laboratory director.

The laboratory must establish or verify the performance characteristics of tests using Class I ASR’s and RUO’s in accordance with the Method Performance Specifications section of the Laboratory General checklist.

The laboratory may put an ASR disclaimer on the pathology report for all immunostains, FISH and ISH studies collectively used in a particular case. Separately tracking each reagent used for a case and selectively applying the disclaimer to only the class I ASR’s is unnecessary.

COMMENTARY:

N/A

Can surgical pathology report information be retrieved by patient identifier (e.g., name, medical record number, etc.)?

**NOTE:** For computerized surgical pathology systems, software tools typically permit text-based searches for any element of the report, such as name and diagnosis. Or, these data elements may already be stored in an electronic database. For paper-based manual systems, it is acceptable to store reports by name.

**COMMENTARY:**

N/A

Are surgical pathology records and materials retained for an appropriate period?

**NOTE:** Minimum requirements for surgical pathology, providing these are not less stringent than state and federal regulations, are:

1. Accession log records - 2 years
2. Wet tissue (stock bottle) - 2 weeks after final report
3. Paraffin blocks - 10 years
4. Glass slides and reports - 10 years

The retention period should be extended, when appropriate, to provide documentation for adequate quality control and medical care.

**There must be a documented policy for protecting and preserving the integrity and retrieval of surgical pathology materials and records.**

**COMMENTARY:**

N/A
REFERENCE: College of American Pathologists.
For immunohistochemistry tests that provide independent predictive/prognostic information, does the patient report include information on specimen processing, the antibody clone, and the scoring method used?

NOTE: For immunohistochemical studies used to provide diagnostic predictive/prognostic information independent of other histopathologic findings (e.g., hormone receptors in breast carcinoma, HER-2/neu, EGFR), the laboratory should include the following information in the patient report:

1. The type of specimen fixation and processing (e.g., formalin-fixed paraffin-embedded sections, air-dried imprints, etc.)
2. The antibody clone and general form of detection system used (e.g., LSAB, polymer, proprietary kit, etc.)
3. Criteria used to determine a positive vs. negative result, and/or scoring system (e.g., percent of stained cells, staining pattern, etc.)

The laboratory should periodically compare its patient results with published benchmarks, and also evaluate interobserver variability among the pathologists in the laboratory.

COMMENTARY:

N/A
FLUORESCENCE AND NON-FLUORESCENCE IN SITU HYBRIDIZATION (FISH, ISH)

This section is intended for the application of FISH (e.g., HER-2/neu) and ISH (e.g., HPV, HBV) techniques in histologic sections.

**REVISED** 12/01/2003

ANP.22986    Phase I    N/A YES NO

Is appropriate interpretation of FISH results provided in the report?

COMMENTARY:

N/A
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.

ANP.30050 Phase II N/A YES NO

Are formal intra- and extra-departmental consultations documented and the reports maintained with the patient's autopsy report?

NOTE: When formal intra- and extra-departmental consultations are obtained, they must be documented and the reports kept with the patient autopsy report.

COMMENTARY:

N/A


ANP.30100 Phase II N/A YES NO

Are the findings of the postmortem examination used for correlative clinicopathological teaching purposes 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 documented and may take any of several forms, including a correlative note in the autopsy report, interdepartmental note or summary, or a clinical teaching conference.

COMMENTARY:

ANP.30150 Phase I N/A YES NO

Are the findings from autopsies incorporated into the institutional quality management program?

COMMENTARY:

N/A


**REVISED** 12/01/2003

ANP.30575 Phase II N/A YES NO

Are autopsy findings that were clinically inapparent but important specifically documented and communicated interdepartmentally?
NOTE: The form in which this is accomplished is at the discretion of the laboratory director. For example, presentation at a clinical conference or specifically highlighting these findings in the discussion/case summary of the autopsy report would meet this requirement. The goal is to enhance the quality of patient care by documenting findings that were not detected antemortem.

COMMENTARY:

N/A


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AUTOPSY PERFORMANCE AND DOCUMENTATION

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ANP.33100 Phase II N/A YES NO

Is a documented preliminary report of the gross pathologic diagnoses submitted to the attending physician and the institutional record within a reasonable time (2 working days)?

COMMENTARY:

N/A


ANP.33125 Phase I N/A YES NO

Are the majority of autopsy final reports produced within 30 working days?

NOTE: The clinical and quality management value of the autopsy is enhanced by prompt reporting of results to the referring physician and the institutional record.

COMMENTARY:

N/A


ANP.33150 Phase II N/A YES NO

For all cases, is the final autopsy report produced within 60 working days?

NOTE: Allowance may be needed if portions of a case are referred for external consultation, and completion of the case is dependent upon information from such consultations (e.g., complex neuropathology). If cases exceed 60 days, there should be documentation of the reason for the delay and of ongoing review of this information by the director of the service.

COMMENTARY:

N/A

ANP.33200 Phase II N/A YES NO

Are gross descriptions clear and concise, are all pertinent findings adequately described and do the descriptions support the diagnosis?

COMMENTARY:

N/A


ANP.33250 Phase II N/A YES NO

If microscopic descriptions are included in the report, are they clear and concise, and do they support the diagnosis?

COMMENTARY:

N/A

ANP.33300 Phase II N/A YES NO

When appropriate, does the report include a key or summary noting block and slide designations to allow identification of the source of specific microscopic sections?
NOTE: At a minimum, the key should include information on laterality and on specific lesions sampled.

COMMENTARY:

N/A


ANP.33350 Phase II N/A YES NO

Does the final autopsy report contain sufficient information in an appropriate format so that a physician may ascertain the patient’s major disease processes and probable cause of death?

COMMENTARY:

N/A


ANP.33400 Phase I N/A YES NO

Are autopsy records organized and readily available for review?

COMMENTARY:

N/A

ANP.33450                      Phase I                      N/A YES NO

Are major diagnoses entered into a database that allows prompt retrieval?

NOTE: At the facility’s discretion, this could be accomplished through the use of an electronic database, card file, or log book, depending on the size of the database.

COMMENTARY:

N/A


ANP.33500                      Phase II                      N/A YES NO

Are autopsy pathology records and materials retained for an appropriate period?

NOTE: There must be a documented policy for preserving the integrity of retained autopsy service materials. The laboratory must define the period of time that such materials are retained. The retention period shall provide for adequate quality control and potential medical care of other individuals. In establishing retention requirements, care should be taken to comply with state and federal regulations. Minimum requirements for autopsy pathology, providing these are not less stringent than state and federal regulations, are:

1. Accession log records - 2 years
2. Wet tissue (stock bottle) - 3 months after final report
3. Paraffin blocks - 10 years
4. Glass slides and reports - 10 years

COMMENTARY:

N/A

REPORTS

ANP.54000     Phase II    N/A YES NO

Does the report format provide for correlation with routine light microscope and other (e.g., immunohistochemical and immunofluorescent) studies?

COMMENTARY:

N/A

ANP.54050     Phase II    N/A YES NO

Are all reports 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 documents that the responsible pathologist has reviewed and approved the completed report before its release.

COMMENTARY:

N/A
<table>
<thead>
<tr>
<th>ANP.54100</th>
<th>Phase II</th>
<th>N/A</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

**Are copies of all reports retained by the laboratory?**

**COMMENTARY:**

N/A