Anatomic Pathology Checklist

CAP Accreditation Program
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Using the Changes Only Checklist

This document contains new checklist requirements, major and minor requirement revisions, and changes to explanatory text. Changes appear in a track changes format that compares the previous checklist edition to the August 21, 2017 edition. Requirements with major revisions will display a "Revised" flag. These changes may affect your laboratory operations. Requirements with minor revisions will not display a "Revised" flag. They are editorial changes that are not likely to affect your laboratory operations.

Information regarding requirements that have been combined, moved, resequenced or deleted, as applicable, appears in table format below.

### 2017 CHECKLIST EDITION CHANGES

<table>
<thead>
<tr>
<th>2016 Requirement</th>
<th>Action Taken</th>
<th>2017 Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANP 23042</td>
<td>Merged</td>
<td>GEN 53600</td>
</tr>
<tr>
<td>ANP 29640</td>
<td>Merged</td>
<td>GEN 53600</td>
</tr>
</tbody>
</table>

*Merged – Combined the requirement with a similar requirement in the same or different checklist

*Moved – Relocated the requirement to another checklist or resequenced it within the same checklist

**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.

Laboratories that do not file slides on-site (e.g. "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 (e.g. 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 (e.g. pathologist office using a network or virtual private network (VPN) connection).

Note for non-US laboratories: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist.

**SURGICAL PATHOLOGY**

**QUALITY MANAGEMENT**

**REVISED** 08/21/2017
Anatomic Pathology Checklist

**ANP.10016 Surgical Pathology Exclusion**

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, 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.

**QUALITY CONTROL**

**SURGICAL SPECIMEN EXAMINATION**

**ANP.11525 Tissue Assessment Record**

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

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

**NEW**  08/21/2017

**ANP.11680 Cross Contamination**

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

NOTE: At a minimum, cleaning (e.g. wiping or rinsing) of forceps and scalpel blades between cases is required. In addition, if a laboratory processes both small specimens (e.g. biopsies) and large specimens (e.g. 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 (e.g. formalin absorbent pads, butcher paper, etc.) for large cases. Grossing of similar types of specimens sequentially should be avoided, if feasible.

**SURGICAL PATHOLOGY REPORTS**

**REVISED**  08/17/201621/2017

**ANP.12350 Cancer Protocols**

All data elements required in applicable CAP Cancer Protocols are included with appropriate responses in at least 90% of the surgical pathology reports from definitive resection specimens with an for primary invasive histologic diagnosis malignancies, as
well as cases of ductal carcinoma in situ of the breast, with an audit performed annually to ensure that all required elements are included.

NOTE:

1. This checklist requirement is not applicable to:
   - Diagnostic biopsy specimens, including cervical cone biopsies and bone marrow biopsies and aspirations
   - Cancer for which no CAP Cancer Protocol applies
   - Bone marrow samples (aspirates and biopsies)
   - Transurethral resection specimens of the prostate (TURP) and transurethral resection of the bladder (TURB) specimens TURBT
   - Resection specimens done for positive margins on a previous definitive resection specimen (even if residual cancer is found)
   - Hematopathology lymph node specimens
   - Definitive resection specimens that do not contain cancer (e.g., following neoadjuvant chemotherapy)
   - Metastatic tumors
   - Cytology specimens
   - Special studies, including biomarker testing performed in another laboratory
   - Reports of in situ tumors (except for resected breast specimens with ductal carcinoma in situ)

2. Reports must include the required data elements from the current edition of the CAP Cancer Protocols. The laboratory has up to eight months from the posting date of the CAP Cancer Protocol to implement data element changes.
   - Cancer for which no CAP Cancer Protocol applies
   - Definitive resection specimens that do not contain cancer

2-3. The 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 elements from the CAP Cancer Protocols, the laboratory must implement and record appropriate corrective action.

3. Data elements required by the protocol that do not apply to the specimen must be reported as "not applicable," unless the protocol requires the element only if present in the specimen (e.g., lymph node sampling in the Invasive Breast Protocol)

4. Required data elements not measurable due to specimen characteristics (e.g., proximal and distal margins in an unoriented segmental colon resection specimen) should be noted as such, and if appropriate alternative is indicated (e.g., closest margin), that data element should be reported.

5. Reports must include the required data elements from the current edition of the CAP Cancer Protocols. The laboratory has up to eight months following release of the current edition to implement changes.

6. Laboratories outside of the US may use regionally produced cancer reporting datasets.

Data elements required by applicable CAP Cancer Protocols are reported using a synoptic format in at least 90% of the eligible surgical pathology reports.

NOTE:

1. This checklist requirement is only applicable to surgical pathology reports as defined in ANP.12350

2. All required data elements outlined on the currently applicable surgical case summary from the cancer protocol that are included in the report must be displayed
3. Synoptic reporting is defined by the data element: followed by its answer (response), e.g. “Tumor size: 5.5 cm.”. Outline format without the paired “data element: response” format is not considered synoptic.

- The required data element (RDE), followed by its answer (response), e.g. “Tumor size: 5.5 cm.”
  ➔ Outline format without the paired “RDE: response” format is not considered synoptic.

- The synoptic report may be produced either manually or by a commercial electronic reporting tool or specialized software.

- Each diagnostic parameter pair (RDE data element: response) is listed on a separate line or in a tabular format to achieve visual separation with the following allowable exceptions:
  - Anatomic site or specimen, laterality, and procedure
  - Pathology Staging Tumor Node Metastasis (pTNM) staging elements
  - Negative margins, as long as all negative margins are specifically enumerated where applicable

- The synoptic portion of the report can appear in the diagnosis section of the pathology report, at the end of the report or in a separate section, but all RDE data element and responses must be listed together in one location

- The synoptic report may be produced either manually or by a commercial electronic reporting tool or specialized software.

4. Organizations and pathologists may:

- List the required data elements in any order
- Choose to use additional methods in order to enhance or achieve visual separation such as use of headers, indentations, or bolding and/or font variations
- Add optional additional items within the synoptic report as needed
- Have required elements in a summary format elsewhere in the report IN ADDITION TO but not as replacement for the synoptic report i.e. all required elements must be in the synoptic portion of the report in the format defined above

**REVISED** 08/21/2017

ANP.12425 ASR Disclaimer

If patient testing is performed using Class I analyte-specific reagents (ASRs) obtained or purchased from an outside vendor, the patient report includes the disclaimer statement required by federal regulations.

NOTE: ASRs 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 a laboratory-developed test system.

Class I ASRs in use in the anatomic pathology laboratory include some antibodies for immunohistochemistry and nucleic acid probes for FISH and ISH.

Class I ASRs are not subject to preclearance by the US Food and Drug Administration or to special controls by the FDA. Thus, if

If the laboratory performs patient testing using Class I ASRs 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 US Food and Drug Administration."

The CAP recommends additional language, such as "The FDA does not require this test to go through premarket FDA review. 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 (CLIA) as qualified to perform high complexity clinical laboratory testing."

The above disclaimer is not required when for tests 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.

The laboratory must establish or verify the performance characteristics of tests using Class I ASRs in accordance with the Method Performance Specifications section of the All Common Checklist.

The laboratory may put a single ASR disclaimer on the pathology patient 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 ASRs is unnecessary.

**REVISED**

ANP.12500

Record Retention

Phase II

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 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 (stock bottle)</td>
<td>2 weeks after final report</td>
</tr>
<tr>
<td>Paraffin 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>Fine needle aspiration slides</td>
<td>10 years</td>
</tr>
<tr>
<td>Images or permanent slides of ISH studies</td>
<td>10 years for neoplastic disorders 20 years for constitutional disorders (Subject to Notes 4 and 5 below)</td>
</tr>
<tr>
<td><strong>Images for Circulating Tumor Cells</strong></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</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>
Anatomic Pathology Checklist
08.21.2017

* 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 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 (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.

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 (e.g. HIPAA) and applicable state and local regulations; and there is IRB approval, as applicable.

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

NOTE 4: There is no retention requirement for images of slide preparations when the source slides remain readable for the required retention period.

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 (e.g. 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.

HISTOLOGY LABORATORY

IMMUNOLOGIC AND MOLECULAR METHODS
Anatomic Pathology Checklist

**REVISED** 07/28/2015
ANP.22750 Antibody Validation Phase II

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

NOTE: The performance characteristics of each assay in the immunohistochemistry laboratory must be appropriately validated 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 is at the discretion of the laboratory director and will vary with the antibody.

Means of validation 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 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 assay; or 4) comparing the results using the new antibody with previously validated non-IHC tests or testing previously graded tissue challenges from a formal proficiency testing program.

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

For validation of a nonpredictive assay, the validation should test a minimum of 10 positive and 10 negative tissues. For validation of predictive markers (with the exception of HER2, ER and PgR), the laboratory should test a minimum of 20 positive and 20 negative tissues. In either situation, when the laboratory director determines that fewer validation cases are sufficient for a specific marker (e.g. a rare antigen or tissue), the rationale for that decision needs to be recorded. Positive cases in the validation set should span the expected range of clinical results (expression level), especially for those markers that are reported quantitatively.

When possible, laboratories should use validation 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 (e.g. alcohol fixed cell blocks, cytologic smears, formalin postfixed 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.

Please refer to the subsection "Predictive Markers" for specific validation requirements for HER2 and ER/PgR testing in breast carcinoma below.

**REVISED** 08/21/2017
ANP.22780 IHC Assay Performance Phase I

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

NOTE: Laboratories should confirm assay performance with at least two known positive and two known negative cases when an existing validated assay has changed in any of the following ways: antibody dilution, antibody vendor (same clone), or the incubation or retrieval times (same method).
Laboratories must confirm assay performance by testing a sufficient number, determined by the laboratory director, of cases to ensure that assays consistently achieve expected results when any of the following have changed: fixative type, antigen retrieval method (e.g. change in pH, different buffer, different heat platform), antigen detection system, tissue processing or testing equipment, environmental conditions of testing (e.g. laboratory relocation), or laboratory water supply.

If significant changes are made in testing methods (e.g. antibody clone, antigen retrieval protocol or detection system, probe or pretreatment protocol), revalidation is required.

For specific validation requirements for HER and ER/PgR testing in breast carcinoma, refer to the subsection “Predictive Markers.”

**PREDICTIVE MARKERS**

NOTE: THE REMAINING ITEMS ON PREDICTIVE MARKERS APPLY ONLY TO ASSAYS PERFORMED ON BREAST CARCINOMA.

**REVISED** 08/17/2016 21/2017
ANP.22970 Annual Result Comparison Phase II

For immunohistochemical and in situ hybridization (ISH) 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: Individuals interpreting the assay must also have their concordance compared with each other and this concordance should also be at least 95%.

With specific reference to estrogen and progesterone 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). The proportion of PgR-negative cases is 10-15% higher than for ER-negative in each of these settings. Investigation is warranted if the proportion of ER-negative or PgR-negative cases varies significantly from the published benchmarks.

With specific reference to HER2 studies, the overall proportion of HER2 positive breast cancers is 10-25%. Laboratories must monitor their results. Consideration 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%.

**REVISED** 08/21/2017
ANP.22973 PT for HER2, ER, and PgR Phase II

The laboratory is enrolled in the appropriate CAP Surveys, or other CAP-accepted proficiency testing (PT) program, for HER2, ER, and PgR testing for breast.
carmcinomapredictive markers.

NOTE: HER2 PT is method specific, and laboratories performing HER2 testing by multiple methods must participate in PT for each method. Details are available on the CAP website http://www.cap.org/. Satisfactory performance requires correct responses on at least 90% of graded challenges in each testing event (mailing).

If the laboratory interprets HER2, ER, and/or PgR test results from immunohistochemical stains prepared at another facility, the laboratory must (1) enroll, (2) send, (3) interpret the resulting stains using the same procedures that are used for patient specimens.

If the laboratory interprets *ISH* in situ hybridization stains for HER2 (ERBB2) prepared at another facility, the laboratory must not participate in PT, but must perform an alternative assessment of the test twice annually.

**REVISED** 08/21/2017

ANP.22985 Predictive Marker Testing - Decalcified Tissue

If the laboratory performs *in situ* hybridization (ISH) and/or immunohistochemistry for ER, PgR, and/or HER2 on decalcified tissues, 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: Separate validation Decalcification may adversely affect patient results. If the assay has not been validated for ER, PgR, and/or HER2 testing on decalcified specimens, it is not feasible for most laboratories. As such, a disclaimer must be included in the surgical pathology patient report, which may read, such as, "This assay has not been validated on decalcified tissues. Results should be interpreted with caution given the likelihood of false negativity on decalcified specimens.

Validation and Calibration

VALIDATION AND CALIBRATION

Quality Control

QUALITY CONTROL

ANP.23018 Daily-QCQuality Control - Digital Image Analysis

Control materials at more than one expression (level) are run concurrently with patient specimens.

NOTE: Controls should check test performance at relevant decision points. For many tests, a positive and a negative control are sufficient. Controls need be run only on days when patient specimens are tested. For immunohistochemistry, the laboratory must follow the control requirements in the Immunohistochemistry section of this checklist.
DNA Analysis

Reports

ANP.23037 Final Report Elements

The final report includes the criteria for positive and negative results including reference range intervals.

NOTE: The reference range Reference intervals may be determined by the laboratory’s validation of the test system, or through evaluation of manufacturer’s or other published information.

Personnel

ANP.23041 Testing Personnel Qualifications

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

NOTE: The qualifications Refer to perform the Laboratory General Checklist for high complexity testing can be accessed using 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.

**REVISED** 07/28/2015

ANP.23032 Ex Vivo Microscopy

The person in charge of bench testing/section supervisor for image analysis is qualified to perform high-complexity testing, with experience as defined by a qualified laboratory director.

Evidence of Compliance:
✓ Records of qualifications including degree or transcript, current license (if required) and work history in related field

INSTUMENTS AND EQUIPMENT

Ex Vivo Microscopy

HISTOLOGY LABORATORY SAFETY
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 that is 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 (e.g. 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.

CIRCULATING TUMOR CELL ANALYSIS (CTC)

PERSONNEL

Testing Personnel Qualifications

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

NOTE: The qualifications can be accessed using 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.

Bench Testing Supervision

The person in charge of bench testing/section supervisor for circulating tumor cell analysis is qualified to perform high-complexity testing, with experience as defined by the laboratory director.

Evidence of Compliance:

✓ Records of qualifications including degree or transcript, current license (if required) and work history in related field

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).
**NEW** 08/21/2017
**NEW** 08/21/2017
**NEW** 08/21/2017

**ANP.29650** Peer Education Program  
**ANP.29670** Record Retention  
**ANP.29690** Appropriate Antibodies  
**ANP.29710** Gating Procedure

**Phase II**

**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.

**ANP.29670** Record Retention

Gated dot plots and histograms are retained for at least 10 years. List mode files that include analysis and gates are acceptable.

**NOTE:** The intent of this checklist requirement is retention of gated dot plots and histograms of hematolymphoid neoplasias, CD34 stem cell records, PNH, and congenital immunodeficiency evaluations for 10 years. Paper copies of gated dot plots and histograms are not required if the information is available electronically (e.g., .pdf, .tiff, .jpeg files).

If the laboratory responsible for the interpretation component does not retain the data locally, it must ensure that the data is being retained for the full retention period, such as with an agreement with the laboratory performing the flow cytometry technical component.

**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.

**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.

**NEW** 08/21/2017

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.

AUTOPSY PATHOLOGY

QUALITY MANAGEMENT

**NEW** 08/21/2017

ANP.30160 Significant/Unexpected Findings

There is a written policy regarding the communication and recording of significant and unexpected autopsy findings.

**NOTE:** Certain autopsy findings may be considered significant and unexpected. Such findings may include, but are not limited to the following: reportable infectious diseases, heritable genetic abnormalities, procedural complications, and unexpected fatal malignancy. There should be a reasonable effort to ensure that such diagnoses are communicated to the appropriate health care provider. There must be records of the date of communication of these diagnoses. Records of communication of these diagnoses may be included in the pathology report, or in other laboratory records.

AUTOPSY PERFORMANCE AND DOCUMENTATION

**REVISED** 08/21/2017

ANP.33025 Patient Identity Confirmation

The identity of deceased patients is confirmed using two identifiers, prior to beginning the autopsy.

**REVISED** 08/17/2016 21/2017

ANP.33500 Record Retention

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 (e.g. morbidity and mortality conferences). 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.

### Non-Forensic Autopsies

<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>
</tbody>
</table>

### Forensic Autopsies

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

AUTOPSY SAFETY

**NEW** 08/21/2017
ANP.34160 Safe Handling of Bariatric Patients Phase II

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.