✓ Records of corrective action if reporting omissions or errors were identified

REFERENCES
1) College of American Pathologists. Resources & Publications: Cancer Protocols www.cap.org/cancerprotocols
2) College of American Pathologists. Resources & Publications: Cancer Protocols-Summary of Required Elements. http://capatholo.gy/cancerprotocols-accreditation
3) Commission on Cancer. Optimal Resources for Cancer Care 2020 Standards. Chicago, IL; American College of Surgeons; 2019.
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5) Lankshear S, et al. Standardized synoptic cancer pathology reports - so what and who cares? *Arch of Pathol Lab Med*. 2013;137:1599-1602.
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7) Karim RZ, et al. The advantage to using a synoptic pathology format for cutaneous melanoma. *Histopathology.* 2008;52:130-8.
8) Pignol JP, Rakovitch E, Zeppieri J, Hanna W. Accuracy and completeness of pathology reporting—Impact on partial breast irradiation eligibility. *Clin Oncol*. 2012;24:177-182.
9) Lam E, et al. Synoptic pathology reporting for thyroid cancer: a review and institutional experience. *Expert Rev Anticancer Ther.* 2013;13.9:1073-9.
10) Haugland HK, et al. Template reporting matters—a nationwide study on histopathology reporting on colorectal carcinoma resections. *Hum Pathol.* 2011;42:36-40.
11) Valenstein PN. Formatting Pathology Reports: Applying Four Design Principles to Improve Communication and Patient Safety. *Arch Pathol Lab Med.* 2008;132:84-94.

ANP.12400 Correlation of Results — Phase II

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

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

REFERENCES
1) Editorial. Incorporation of immunostaining data in anatomic pathology reports. *Am J Clin Pathol.* 1993;99:1
2) Putti T, *et al*. Cost-effectiveness of immunohistochemistry in surgical pathology. *Am J Clin Pathol.* 1998;110:51
3) Raab SS. The cost-effectiveness of immunohistochemistry. *Arch Pathol Lab Med.* 2000;124:1185-1191

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

ANP.12500 Record and Material Retention - Surgical Pathology — Phase II

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

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

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

Type of Record/Material	Retention Period
Accession log records	2 years
Wet tissue (stock bottle)	2 weeks after final report
Paraffin blocks (including cell blocks)	10 years Refer to Note 2 below, paragraphs #2 and #3, for deceased patient material
Immunohistochemistry batch control slides	2 years
Surgical pathology glass slides	10 years - slides must remain readable for this period
Surgical pathology reports *	10 years

Reports of outside consultations on laboratory cases (whether or not requested by the laboratory)	10 years after the date that the original report was issued
Fluorochrome-stained slides	At the discretion of the laboratory director
Images or permanent slides of ISH studies	10 years for neoplastic disorders 20 years for constitutional disorders (Subject to Note 4 below)
Images for Circulating Tumor Cells	10 years
Digital images used for primary diagnosis	10 years if original glass slides are not available; may not replace glass slides
Datasets from In-Vivo Microscopy (IVM) or Ex Vivo Microscopy (EVM) systems used to aid in interpretation or diagnosis	10 years - data must be retrievable for this period (Subject to Note 5 below)

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

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

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

1. *For laboratories subject to US regulations, formal written authorization is obtained in accordance with the requirements of HIPAA if identifiable patient information is released.*
2. *The laboratory retains sufficient blocks to support the diagnosis for the full 10-year period. After a patient has been deceased for two years, only one block containing normal tissue (if it exists) needs to be retained for the full 10-year period.*
3. *Provision is made for retrieval by the laboratory of any blocks or material that remain after use in research, if the blocks or material are needed for diagnostic, legal, or other legitimate purposes. After a patient has been deceased for two years, only one block containing normal tissue (if it exists) must be retrievable for the full 10-year period.*
4. *In the event of limited material (eg, only one diagnostic block), tissue microarray (TMA) cores or portions of the block may be released for research or clinical trials, as long as the original lab retains control or access to the diagnostic material if clinically needed.*
5. *The laboratory meets other relevant requirements including but not limited to the requirements of the institution, the directives of any applicable institutional review board (IRB) or similar entity; and state and local laws and regulations.*

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

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

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

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

an abnormal result must include images of at least two cells illustrating each relevant abnormal probe signal pattern.

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

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

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1105].
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28): [42CFR493.1273(b)].
3) Pantanowitz L, Dickinson K, Evans AJ, et al. ATA guidelines for telepathology. *Telemed JE Health.* 2014;20(11):1049-56.
4) Compton CC, Robb JA, Anderson MW, et al. Preanalytics and Precision Pathology: Pathology Practices to Ensure Molecular Integrity of Cancer Patient Biospecimens for Precision Medicine. *Arch Pathol Lab Med.* 2019;143(11)1346-63.
5) National Cancer Institute. NCI Best Practices for Biospecimen Resources. B.6.6 Biospecimen Storage. March 2016.

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