- *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

1) Zarbo RJ, Nakhleh RE, Walsh M; Quality Practices Committee, College of American Pathologists. Customer satisfaction in anatomic pathology. A College of American Pathologists Q-Probes study of 3065 physician surveys from 94 laboratories. *Arch Pathol Lab Med.* 2003 Jan;127(1):23-9
2) Silverman JF, Pereira TC. Critical values in anatomic pathology. Arch Pathol Lab Med. 2006;130:638-640
3) LiVolsi VA. Critical values in anatomic pathology; how do we communicate? Am J Clin Pathol 204;122:171-172
4) Allen TC. Critical Values in anatomic pathology? Arch Pathol Lab Med 2007;131:684-68
5) Pereira TC, Liu Y, Silverman JF. Critical Values in surgical pathology. Am J Clin Pathol 2004;122:201-205
6) Association of Directors of Anatomic and Surgical Pathology. Critical diagnosis (critical values) in anatomic pathology. Am J Surg Pathol 2006;30:897-899
7) Nakhleh RE, Souers R, Brown RW. Significant and Unexpected Diagnoses in Surgical Pathology: A College of American Pathologists Survey of 1130 Laboratories. *Arch Pathol Lab Med.* 2009; 133;1375-1378.
8) Sarewitz SJ, Williams RB. Significant and Unexpected versus Critical Results in Surgical Pathology. Editorial. *Arch Pathol Lab Med.* 2009; 133:1366.

ANP.12185 Amended Reports — Phase II

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

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

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

Evidence of Compliance:

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

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):3713 [42CFR493.1291(k)].

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

ANP.12350 Cancer Protocols — Phase II

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

NOTE:

1. *This checklist requirement is not applicable to:*
   - *Cancer for which no CAP Cancer Protocol is available*

- *Additional surgical procedures performed after definitive surgical resection such as excision for positive margins or lymph node sampling*
- *Definitive resection specimens that do not contain cancer (eg, following neoadjuvant chemotherapy)*
- *Diagnostic biopsy (except for pediatric tumor types listed in the CAP Cancer Protocols), cytology specimens, or other diagnostic procedures done prior to definitive surgical therapy.*
- *Metastatic tumors or resections for recurrent tumors*
- *Special studies, including biomarker testing performed in another laboratory.*

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

Evidence of Compliance:

- ✓ Surgical pathology reports for definitive cancer resection with required data elements and in synoptic format **AND**
- ✓ Records from processes used to ensure reporting compliance **AND**

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

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.
4) Sluiter CE, van Workum F, Wiggers T, et al. Improvement of care in patients with colorectal cancer: Influence of the introduction of standardized structured reporting for pathology. *JCO Clin Cancer Inform.* 2019;3:1-12.
5) Lankshear S, et al. Standardized synoptic cancer pathology reports - so what and who cares? *Arch of Pathol Lab Med*. 2013;137:1599-1602.
6) Srigley J, et al. Closing the quality loop: facilitating improvement in oncology practice through timely access to clinical performance indicators. *J Oncol Pract.* 2013;9:e255-e261.
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

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

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

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

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

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