**ANP.12350** Cancer Protocols

Under [Summit Pathology Landings (2021 On-Site Inspection)](https://www.medialab.com/lms/admin/ad_ic_viewchecklistsforevent.aspx?ichecklisteventid=11603&ichecklisteventhash=8df1d4c6640b76df0e411f142885e918&oid=46469366&o=1112e471cb1e8676b6c7d4f04ef01946) Pre-Inspection Phase » [Histology - Anatomic Pathology](https://www.medialab.com/lms/admin/ad_ic_viewchecklist.aspx?ichecklistid=79894&ichecklisthash=cfb6c93e54656b07bb69aebce4a7f173&ichecklistitemid=7188919&ichecklistitemhash=f7ed9b07b6625bdaf72fa27c54e5931f&oid=46469366&o=1112e471cb1e8676b6c7d4f04ef01946)

[[](https://www.medialab.com/lms/admin/ad_ic_vieweditchecklistitem.aspx?oid=46469366&o=1112e471cb1e8676b6c7d4f04ef01946&ichecklistitemid=7188919&ichecklistitemhash=f7ed9b07b6625bdaf72fa27c54e5931f)Available actions for this item](https://www.medialab.com/lms/admin/ad_ic_vieweditchecklistitem.aspx?oid=46469366&o=1112e471cb1e8676b6c7d4f04ef01946&ichecklistitemid=7188919&ichecklistitemhash=f7ed9b07b6625bdaf72fa27c54e5931f)

|  |  |
| --- | --- |
| **Phase** | 2 |
| **Requirement** | 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. |

|  |  |
| --- | --- |
| **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 |
| **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. |

**ANP.12385** Synoptic Reporting

Under [Summit Pathology Landings (2018 On-Site Inspection)](https://www.medialab.com/lms/admin/ad_ic_viewchecklistsforevent.aspx?ichecklisteventid=4258&ichecklisteventhash=4ab0192b5910af9e4c9300253110f1fb&oid=46469366&o=1112e471cb1e8676b6c7d4f04ef01946) Post-Inspection Phase » [Histology - Anatomic Pathology](https://www.medialab.com/lms/admin/ad_ic_viewchecklist.aspx?ichecklistid=50402&ichecklisthash=2a7889522a476de4fba90255a20b1405&ichecklistitemid=4591009&ichecklistitemhash=35182120f8e24c64f5f82e90326accf0&oid=46469366&o=1112e471cb1e8676b6c7d4f04ef01946)

[[](https://www.medialab.com/lms/admin/ad_ic_vieweditchecklistitem.aspx?oid=46469366&o=1112e471cb1e8676b6c7d4f04ef01946&ichecklistitemid=4591009&ichecklistitemhash=35182120f8e24c64f5f82e90326accf0)Available actions for this item](https://www.medialab.com/lms/admin/ad_ic_vieweditchecklistitem.aspx?oid=46469366&o=1112e471cb1e8676b6c7d4f04ef01946&ichecklistitemid=4591009&ichecklistitemhash=35182120f8e24c64f5f82e90326accf0)

|  |  |
| --- | --- |
| **Phase** | 1 |
| **Requirement** | 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 in synoptic format  \* Synoptic reporting is defined by the data element: followed by its answer (response), eg, "Tumor size: 5.5 cm." Outline format without the paired "data element: response" format is not considered synoptic.  \* The data element does 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.  \* Each diagnostic parameter pair (data element: response) is listed on a separate line or in a tabular format to achieve visual separation. Selected elements may be listed on a single line as long as the individual responses can be distinguished by the reader and as long as the intended meaning remains clear. These selected elements are identified in specific protocols and include the following:  \* 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  \* Required 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 format defined above).  \* Required data elements may be listed in any order \* 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 \* Additional items may be added within the synoptic report as needed  \* The synoptic report may be produced either manually or by a commercial electronic reporting tool or specialized software. |