CAP accreditation withdraws ANP.10039 from checklist

Harris S. Goodman, MD
Richard M. Scanlan, MD
Emily E. Volk, MD

December 2021—The CAP has decided to temporarily withdraw the anatomic pathology checklist requirement ANP.10039 (Total Fixation Time) from the 2021 checklist edition, and this requirement will no longer appear in customized checklists provided to laboratories and inspectors using the 2021 edition.

The decision was based on further review of the requirement by the CAP's Checklists Committee and Commission on Laboratory Accreditation in response to concerns that CAP-accredited laboratories and CAP scientific committee members expressed about the scientific data supporting the requirement and the feasibility of compliance.

The original intent in adding ANP.10039 to the 2021 checklist edition was to minimize preanalytic variables related to specimen fixation that detrimentally affect the quality of pathology specimens and ultimately have an impact on the downstream results of tests used for patient care and precision medicine. The total fixation time in formalin has been shown to impact the quality of nucleic acids extracted for molecular testing, protein recovery for mass spectroscopy, and immunoreactivity of proteins. Inadequate fixation may lead to hydrolysis, formalin-induced mutation, and DNA/RNA fragmentation. ANP.10039 required laboratories to have a process to ensure optimal total fixation time in formalin for specimens clinically suspected (as stated on the requisition) or otherwise known to contain malignancy that are likely to be submitted for ancillary testing, such as breast and gastroesophageal carcinomas. The following statements in the requirement note were the area of concern for this requirement: "A total fixation time at room temperature of no less than six hours and no greater than 36 hours is required for most tissues. Tissues with high fat content can be fixed up to 48 hours."

Peer-reviewed literature[1-4] promotes the fixation parameters that were included in the checklist note. However, the CAP's accreditation program must weigh the rigor of available evidence supporting the practice with the feasibility for laboratories to implement the practice. When a requirement is included in a checklist, it becomes a requirement of accreditation, and noncompliance with that requirement could jeopardize a laboratory's accreditation. After an in-depth review of peer-reviewed literature, the CAP determined that it was premature to implement this requirement in the 2021 checklist edition based on the available evidence. The CAP's Checklists Committee will work with the CAP's scientific experts to reevaluate this requirement for the 2022 checklist edition.

The CAP values input from its laboratories and members on the accreditation checklists and uses it to improve the quality of the checklists and other resources. Because of the impact of preanalytic variables on the quality of pathology specimens, the CAP encourages laboratories to evaluate their current processes and take actions to address both internal and external issues that may compromise specimen quality.

1. 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):1346–1363.
2. Carithers LJ, Agarwal R, Guan P, et al. The biospecimen preanalytical variables program: a multiassay comparison of effects of delay to fixation and fixation duration on nucleic acid quality. *Arch Pathol Lab Med.* 2019;143(9):1106–1118.

3. Kashofer K, Viertler C, Pichler M, Zatloukal K. Quality control of RNA preservation and extraction from paraffin-embedded tissue: implications for RT-PCR and microarray analysis. *PLoS One*. 2013;8(7):e70714.
4. Bagchi A, Madaj Z, Engel KB, et al. Impact of preanalytical factors on the measurement of tumor tissue biomarkers using immunohistochemistry. *J Histochem Cytochem.* 2021;69(5):297–320.

Dr. Goodman, chief of anatomic pathology at Alameda Health System Highland Campus, Oakland, Calif., is chair of the CAP Checklists Committee. Dr. Scanlan, professor of pathology at Oregon Health and Science University and laboratory medical director in the OHSU Department of Pathology and Laboratory Medicine, is chair of the CAP Council on Accreditation and a governor on the CAP Board of Governors. Dr. Volk, associate professor of pathology at the University of Louisville and chief medical officer at Baptist Health Floyd in Indiana, is CAP president.