
Topic: Collection and Handling of Thoracic Small Biopsy and Cytology Specimens for Ancillary Studies**Date:** May 13, 2020

Why was this guideline developed?

With the advances in minimally invasive sampling techniques, laboratories can perform multiple ancillary studies on small biopsy and cytology specimens to help in the diagnosis and management of pulmonary pathology. The goal of the College of American Pathologists (CAP) Collection and Handling of Thoracic Small Biopsy and Cytology Specimens for Ancillary Studies Guideline¹ was to provide recommendations to clinicians obtaining samples within the thorax on how to obtain and handle adequate material for diagnostic testing and to pathologists for the prioritization of testing and the appropriate processing of specimens.

Can you provide a definition for “ancillary studies?”

Ancillary studies covered in this guideline include, immunoperoxidase studies (immunohistochemistry and immunocytochemistry), fluorescence in situ hybridization (FISH), mutational analysis, flow cytometry, and microbiologic studies routinely performed in the clinical pathology laboratory.

Why didn't the guideline make recommendations based on tumor volume or size for core needle biopsy samples?

The amount of tissue and tumor can vary in core needle biopsy (CNB) samples depending on the length of the core and the fragmentation of CNB samples leading to a loss of tissue in processing. The literature review did not provide any insight into a specific volume of tissue that would correlate with an adequate amount of tumor for ancillary studies. Therefore, based on the reviewed literature, a total number of passes/cores for bronchoscopic and transthoracic procedures were recommended instead.

Rapid on-site assessment evaluation (ROSE) is costly, and we can't provide these services for every biopsy. What advice do you have to help us follow the guideline as best we can?

The panel recognizes the limitations of offering ROSE as a cytopathology service for every single procedure, as it may not be readily available or practical in all situations at every center. However, based on the limited literature reviewing the utility of ROSE in ensuring adequacy of the material collected and the appropriate triage for downstream ancillary testing, this panel recommends the use of ROSE, specifically in procedures where ancillary studies are anticipated. The primary objective for this guideline is to ensure the collection and appropriate handling of these small specimens to ensure adequate tumor for ancillary studies and minimize the need for repeat biopsies.

The guideline doesn't recommend a specific quantity for pleural fluids being sent to the pathology laboratory. Why not?

The “adequacy” of a pleural fluid can vary widely depending on the cellularity of the fluid and the workup needed to reach a diagnosis and direct further patient management. Therefore, while a low volume cellular pleural fluid sample can be adequate for diagnosis by morphological evaluation, it could potentially be insufficient for further ancillary studies needed for therapeutic decision. Consequently, it is not possible for this panel to recommend a minimum or maximum volume for pleural fluid samples sent to the pathology laboratory. However, the larger the volume submitted to the laboratory, potentially the more adequate the specimen would be for the additional work-up and final diagnosis.



The acceptability of touch preparation seems to be variable. Some institutions find that the quality can be suboptimal or that they deplete material for core biopsies. Does the guideline offer any information or tips for using this technique?

Based on the literature review, adequacy assessment of CNB by touch preparation has been shown to improve diagnostic adequacy, proper specimen triage for ancillary studies, and reduce the number of CNBs needed. However, it is worth noting that vigorous touch preparations should be avoided and appropriate care should be taken not to deplete the cellularity of the CNB, which would render the biopsy insufficient for diagnosis and ancillary studies. The guideline provides further details on best practices for using touch preparations in specific situations.

Why didn't the guideline make specific recommendations for the optimal specimen processing for cytology specimens?

As noted in this guideline, the panel makes a strong recommendation for the use of all cytology specimen preparations, provided they are appropriately validated for the ancillary tests. Most of the studies reviewed in this guideline were performed using laboratory-developed tests and laboratory-specific protocols, making direct comparisons of outcomes for recommending an optimal specimen processing for cytology specimens difficult. The wide variation of collection media, fixatives, and stains found in the systematic review highlights the utilization variability of these methods throughout clinical practice and that satisfactory results may likely be obtained regardless of the cytology specimen and processing technique used. However, the panel recommends that laboratories perform adequate and rigorous validation studies to ensure that the intended use of collection media, fixatives, and stains provides suitable results for the ancillary test of interest and that these assays perform adequately before they are used on patient samples.

How will the guideline be enforced? What happens if a laboratory doesn't follow the guideline?

As with any clinical evidence-based guideline, following the recommendations is not mandatory. Recommendations may be incorporated into future versions of the CAP Laboratory Accreditation Program (LAP) checklists; however, they are not currently required by LAP or any regulatory or accrediting agency. It is only highly encouraged that laboratories adopt these recommendations.

REFERENCES

1. Roy-Chowdhuri S, Dacic S, Ghofrani M, et al. Collection and handling of thoracic small biopsy and cytology specimens for ancillary studies: guideline from the College of American Pathologists in Collaboration with the American College of Chest Physicians, Association for Molecular Pathology, American Society for Cytopathology, American Thoracic Society, Pulmonary Pathology Society, Papanicolaou Society of Cytopathology, Society of Interventional Radiology, and Society for Thoracic Radiology. *Arch Pathol Lab Med*. In Press. DOI: [10.5858/arpa.2020-0119-CP](https://doi.org/10.5858/arpa.2020-0119-CP)

For additional information about the guideline visit [CAP.org](https://www.cap.org).