HISTOLOGY

Inspector Instructions:

	• Sampling of histology policies and procedures • Sampling of specimen preparation records • Sampling of histology QC policies and procedures • Sampling of QC records (histochemical) • Sampling of records of daily review of histologic slide quality • Sampling of immunofluorescence QC records • Sampling of IHC policies and procedures • Sampling of new antibody validation/verification records • Sampling of new reagent/shipment confirmation of acceptability records • Sampling of antibody QC records • Sampling of buffer pH records • Sampling of batch control records
	• Sampling of tissue blocks (identification) • Sampling of slides (labeling, quality)
	• How does the histology section ensure specimen identity throughout processing? • How does your biorepository validate/verify new antibodies? • How does your biorepository confirm the acceptability of new reagent lots? • How does your biorepository distinguish non-specific false-positive staining from endogenous biotin?
	• If problems are identified during the review of histology procedures, further evaluate the 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

BAP.05330 Specimen Preparation Records **Phase I**

The histology section retains records of the number of blocks, slides, and stains prepared and appropriately denotes the block from which the slide was prepared.

BAP.05332 Cross-Contamination - Histology **Phase II**

The biorepository prevents cross-contamination of specimens in the histology section.

NOTE: The process must address steps to prevent cross-contamination during the various phases of tissue handling including: processing, embedding, microtomy, and slide preparation. Problems with cross-contamination must be addressed in the biorepository quality management system.

Instruments must be clean and well-maintained (eg, tissue processors, embedding centers, dispensers, floatation baths, staining and coverslipping equipment).

At the embedding station, cleaning or wiping of forceps between cases is required. Only one cassette should be handled at a time.

For microtomy, there must be a clear process for handling of blocks and labeling of slides to prevent specimen mix-ups. Floatation baths require periodic water changes or blotting of the water surface so that sections from one patient block are not inadvertently carried over to another case or block (so-called "floaters" or "extraneous tissue").

REFERENCES
1) Lott R, Tunnicliffe J, Sheppard E, et al. *Practical Guide to Specimen Handling in Surgical Pathology.* Northfield, IL: College of American Pathologists; 2023. 11.0. https://documents.cap.org/documents/practical-guide-specimen-handling.pdf. Published September 2023. Accessed December 21, 2023.
2) Gephardt GN, Zarbo RJ. Extraneous tissue in surgical pathology: A College of American Pathologists study of 275 laboratories. *Arch Pathol Lab Med.* 1996; 120:1009-14.

BAP.05336 Special Stains/Studies Phase II

For special stains, including histochemical stains, and studies using immunologic and ISH methodology, positive and negative controls are verified and recorded as acceptable prior to or concurrent with the reporting of patient results and records retained.

NOTE: Controls must be verified and recorded as acceptable by a pathologist or designee (provided the designee meets high complexity testing qualifications).

Positive tissue controls must contain the component specific to the special stain that is being applied to the specimen.

Immunohistochemical tests using polymer-based detection systems (biotin-free) are sufficiently free of background reactivity to obviate the need for a negative reagent control and such controls may be omitted at the discretion of the laboratory director following appropriate validation.

If interpretation of the special stain or study is performed by a different laboratory, there must be a procedure for the laboratory performing the stain or study to verify the acceptability of the controls before transfer, if the controls are not sent with the patient slides (regardless of the outside laboratory's accrediting organization). Records of this verification must be readily available to the laboratory performing the interpretation.

Evidence of Compliance:

✓ Records for verification of control acceptability (prior to completion of associated cases)

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):[42CFR493.1256(e)(2)].
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(a)]

BAP.05337 Paraffin Microtomy Phase II

The appropriate thickness of paraffin embedded tissue for various tissue types and procedures is defined.

NOTE: Paraffin embedded sections are routinely sectioned at 4-5 microns. Some tissues (eg, renal biopsy) may require thinner sections, while some special stain techniques (eg, Congo red stain) may require thicker sections. Use of the recommendations in the table below is at the discretion of the laboratory director.

Tissue	Thickness
Routine Paraffin	**4 to 5 microns**
Renal Sections	**1 to 3 microns**
Bone Marrow	**2 to 3 microns**
Nerve histochemical staining	**6 to 15 microns**
Amyloid demonstration	**6 to 12 microns**