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 surgical pathology 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

IMMUNOFLUORESCENCE MICROSCOPY

Inspector Instructions:

- IF QC policy or procedure
- Sampling of IF QC records

ANP.21850 QC - Immunofluorescence **Phase II**

For immunofluorescence microscopy, appropriate positive and negative controls are performed.

NOTE: Internal antigens serve as positive controls (eg, IgA in tubular casts, IgG in protein droplets and C3 in blood vessels). When internal positive controls are absent, daily external positive controls are required. Non-reactive elements in the patient specimen may serve as a negative tissue control. A negative reagent control in which the patient tissue is processed in an identical manner to the test specimen, but with the primary antibody omitted, should be performed for each patient test specimen at the discretion of the laboratory director.

Evidence of Compliance:

✓ Records of immunofluorescence QC

REFERENCES
1) Walker PD, *et al.* Practice guidelines for the renal biopsy. *Mod. Pathol.* 2004;17:1555-1563
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)].

IMMUNOHISTOCHEMISTRY

This section must be used to inspect immunochemistry staining performed on histology specimens. It should also be used to inspect immunostaining of cytology specimens (eg, air-dried touch imprints, air-dried and/ or alcohol fixed smears, cytocentrifuge or other liquid-based preparations, and cellular materials fixed in alcohol blends or other fixatives). However, if the laboratory has a separate section for performing cytologic

immunocytostaining, the Immunochemistry section of the Cytopathology Checklist should be used to inspect that laboratory section.

The term immunohistochemistry (IHC) used within this section also includes immunocytochemistry.

Please refer to the Definition of Terms section in the All Common (COM) Checklist for definitions of analytical validation and analytical verification.

Inspector Instructions:

	• Sampling of IHC policies and procedures • Sampling of new antibody validation/verification records • Sampling of new reagents/shipment confirmation of acceptability records • Sampling of antibody QC records • Sampling of buffer pH records • Sampling of batch control records
	• Sampling of slides (quality)
	• How does your laboratory validate/verify new antibodies? • How does your laboratory confirm the acceptability of new reagent lots? • How does your laboratory distinguish non-specific false-positive staining from endogenous biotin?

ANP.22300 Specimen Modification **Phase II**

If the laboratory performs immunohistochemical staining on specimens other than formalin-fixed, paraffin-embedded tissue, the written procedure defines appropriate modifications, if any, for other specimen types.

NOTE: Such specimens include frozen sections, air-dried imprints, cytocentrifuge or other liquid-based preparations, decalcified tissue, and tissues fixed in alcohol blends or other fixatives.

REFERENCES
1) Perkins SL, Kjeldsberg CR. Immunophenotyping of lymphomas and leukemias in paraffin-embedded tissues. *Am J Clin Pathol* 1993:99(4):362-373
2) Clinical and Laboratory Standards Institute (CLSI). *Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays; Approved Guideline - Second Edition.* CLSI document I/LA28. Clinical and Laboratory Standards Institute, Wayne, PA; 2011.

ANP.22500 Buffer pH **Phase II**

The pH of the buffers used in immunohistochemistry is routinely monitored.

NOTE: pH must be tested when a new batch is prepared or received.

Evidence of Compliance:

✓ Records of initial and subsequent QC on each buffer

*****REVISED** 12/26/2024***

ANP.22550 QC - Antibodies **Phase II**