GENERAL QUALITY CONTROL

ANP.21350 Specimen Preparation Records **Phase II**

The histology laboratory retains records of the number of blocks, slides, and stains prepared.

NOTE: Laboratories must be capable of demonstrating volumes for any given period of time.

ANP.21360 Automated Stainer **Phase II**

The laboratory changes solutions in automated stainers following a defined schedule.

NOTE: Solutions must be changed at intervals appropriate for the laboratory's workload. Changing, filtering, or adding to solutions must be recorded when performed.

Evidence of Compliance:

- ✓ Records for solution changes

ANP.21395 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):7166 [42CFR493.1256(f)]
2) 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):3708 [42CFR493.1256(d)(6)]
3) 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),(f)].
4) 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)].

ANP.21397 Cross-Contamination - Histology **Phase II**

The laboratory prevents cross-contamination of specimens in the histology laboratory.

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