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.