

Evidence of Compliance:

- ✓ Records of changes to analytical methodology

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):7163 [42CFR493.1291(e)].

PHYSICAL FACILITIES

STORAGE AND SUPPLY

Inspector Instructions:

	<ul style="list-style-type: none"> • Sampling of storage temperature records or records confirming storage conditions at off-site facilities
	<ul style="list-style-type: none"> • On-site storage areas for slides and paraffin blocks (organized, temperature-controlled, pest-free)
	<ul style="list-style-type: none"> • Review a sampling of storage temperature records. If corrective actions are not taken to address out of range temperatures, cite COM.30800.

ANP.23700 Slide and Block Storage
Phase I

Slides and paraffin blocks are properly stored in a temperature-controlled, pest-free, organized manner (ie, accessible for retrieval and properly identified).

NOTE: Slides and blocks must be stored in a manner to prevent contamination from blood or other fluids or tissues and be readily accessible for retrieval.

The storage area for blocks must be cool and dry to prevent blocks from melting together and to maintain tissue integrity. The CAP recommends (but does not require) ambient temperatures in block storage areas to be less than 27°C (as lower storage temperatures slow down DNA, RNA, and protein degradation).

For laboratories using off-site storage facilities, the laboratory director or designee must confirm that storage requirements are met.

Evidence of Compliance:

- ✓ Records of storage temperature monitoring (on-site and off-site locations), including deviations

REFERENCES

- 1) Compton CC, Robb JA, Anderson MW, et al. Preanalytics and Precision Pathology: Pathology Practices to Ensure Molecular Integrity of Cancer Patient Biospecimens for Precision Medicine. *Arch Pathol Lab Med*. 2019;143(11):1346-63.
- 2) National Cancer Institute. NCI Best Practices for Biospecimen Resources. B.6.6 Biospecimen Storage. March 2016.