Individual slide slots (or a representative sample thereof) of in situ hybridization (ISH) temperature controlled slide processing systems are checked for temperature accuracy before being placed in service and at least annually thereafter.

Evidence of Compliance:
- ✓ Records of equipment verification

EX VIVO MICROSCOPY

Ex Vivo Microscopy (EVM) refers exclusively to the use of imaging systems such as confocal microscopy, optical coherence tomography, multiphoton microscopy, optical spectroscopy/spectroscopic imaging and similar imaging technologies for evaluation of specimens that have been removed from the patient. The In Vivo Microscopy section of this checklist should be used for in vivo applications of these systems.

ANP.23560 System Validation - EVM **Phase I**

The laboratory validates Ex Vivo Microscopy (EVM) technology before it is used for the intended purpose(s).

NOTE: The specific components of the validation study are left to the discretion of the laboratory. However, studies should be performed using an adequate number of cases, data should be evaluated, and a summary statement provided prior to implementation. Records of how discordant data or unacceptable variations from the expected were resolved are required.

As general guiding principles, the validation process should:
- *Closely emulate the real-world environment and involve tissue types and clinical settings relevant to the intended use(s)*
- *Be carried out by or under the supervision of a pathologist adequately trained to use the EVM system*
- *Encompass the entire EVM system, with reevaluation if a significant change is made to a previously validated system.*

Evidence of Compliance:
- ✓ Records of completed validation study with supporting validation data, review and approval

ANP.23570 Function Checks - EVM **Phase II**

The laboratory performs and records regular function checks on the Ex Vivo Microscopy (EVM) system/instrument.

NOTE: Function checks include confirmation that an instrument or item of equipment operates according to manufacturer's specifications before routine use, at prescribed intervals, or after minor adjustment. Depending on the type of system, function checks may include calibration.

Evidence of Compliance:
- ✓ Records of function checks and calibration, as applicable

ANP.23580 Method Performance Specifications Availability - EVM **Phase II**

The current Ex Vivo Microscopy (EVM) methods and all significant changes to analytical methodology, including performance specifications and supporting validation data, are retained by the laboratory.

NOTE: Records should include, but are not limited to, components of EVM equipment, software systems, and image viewing systems.

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:

	• Sampling of storage temperature records or records confirming storage conditions at off-site facilities
	• On-site storage areas for slides and paraffin blocks (organized, temperature-controlled, pest-free)
	• 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.