



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.