- *Educational or research-only use of these systems*

The providers of IVM services (acquisition and interpretation of IVM datasets) may be located entirely within a clinical department, the pathology department (laboratory), or may represent collaboration between a clinical department and the laboratory. The responsibility for checklist requirements rests with the IVM service. The IVM service must ensure that records to demonstrate compliance are available for review by the CAP inspection team, whether the records are located within a clinical department, the laboratory, or both.

DEFINITION OF TERMS

In vivo microscopy (IVM) dataset — Digitized or analog video or still images or other data (eg, spectroscopic data) generated by an IVM system that is utilized to render a diagnostic interpretation or to guide procedures.

Confocal microscopy — A non-invasive, high-resolution optical imaging technique that excludes out-of-focus light, enabling 'optical sectioning' and tomographic imaging of specimens that are thicker than the focal plane. Confocal microscopy can be performed directly on tissue or through an endoscope (confocal laser endomicroscopy or CLE). The latter may be either endoscopy-based (eCLE device built into the endoscope) or probe-based (pCLE device in a probe with fiber-optic cable for image transmission that can be inserted into the accessory port of a standard endoscope). Injection or topical application of a contrast is usually required.

Optical coherence tomography (OCT) — A non-invasive, high-resolution optical imaging technique that provides real-time 2-D and 3-D images of tissue architecture in vivo by mapping reflectivity of light waves focused onto the tissue. Variants of OCT technology include: Optical Frequency Domain Imaging (OFDI) and Full Field OCT (ff-OCT). Contrast agents are usually not required.

Multiphoton microscopy — A high-resolution fluorescence imaging technique that provides 2-D and 3-D tomographic images based on non-linear optical effects. It is also known as 2-photon, 3-photon, or nonlinear microscopy. Contrast agents are usually not required.

Optical spectroscopy — An optical technique that assesses the way in which the spectrum of light is changed by interaction with tissue. Examples include diffuse reflectance spectroscopy, fluorescence spectroscopy, and Raman spectroscopy. Measurements made with any of these techniques can be translated into false color spectroscopic images (optical spectroscopic imaging). Contrast agents are usually not required.

Additional information on IVM may be obtained using the CAP Pathology Resource Guide: In Vivo Microscopy.

Reference: Fitzmaurice M, Crawford JM, Fine JL, et al. *CAP Pathology Resource Guide: In Vivo Microscopy.* Version 8.0(1). Northfield, IL: College of American Pathologists; 2018.

Inspector Instructions:

	• IVM policies and procedures • Sampling of reports generated from reviews of datasets obtained by IVM • Sampling of records for personnel training • Sampling of records of rejected IVM datasets and notification of clinical personnel • Sampling of records documenting verbal reports • Completed validation study(ies) with review and approval • Quality management system including IVM
	• Review summary statements and supporting validation data to confirm that studies were performed using an adequate number of cases, data was evaluated, and summary statement was approved prior to implementation. If the data showed discordances or unacceptable variations, investigate how they were resolved.