(7) Slide, block, and tissue retention—(i) Slides. (A) Retain cytology slide preparations for at least 5 years from the date of examination (see §493.1274(f) for proficiency testing exception). (B) Retain histopathology slides for at least 10 years from the date of examination. (ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination. (iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. (b) If the laboratory ceases operation, the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are retained and available for the time frames specified in this section.


Subpart K—Quality System for Nonwaived Testing

SOURCE: 68 FR 3703, Jan. 24, 2003, unless otherwise noted.

§ 493.1200 Introduction.

(a) Each laboratory that performs nonwaived testing must establish and maintain written policies and procedures that implement and monitor a quality system for all phases of the total testing process (that is, preanalytic, analytic, and postanalytic) as well as general laboratory systems.

(b) The laboratory’s quality systems must include a quality assessment component that ensures continuous improvement of the laboratory’s performance and services through ongoing monitoring that identifies, evaluates and resolves problems.

(c) The various components of the laboratory’s quality system are used to meet the requirements in this part and must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.