CLIA Regulations: Retention Requirements
(42CFR§493.1105)

Sec. 493.1105 Standard: Retention requirements

(a) The laboratory must retain its records and, as applicable, slides, blocks, and tissues as follows:

(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.

(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.

(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and all analytic systems activities specified in Sec. Sec. 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:

(i) Records of test system performance specifications that the laboratory establishes or verifies under Sec. 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.

(ii) Immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii),(b)(3)(v), and (d).

(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

(5) Laboratory quality systems assessment records. Retain all laboratory quality systems assessment records for at least 2 years.

(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following:

(i) Immunohematology reports as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), and (d).

(ii) Pathology test reports for at least 10 years after the date of reporting.

(7) Slide, block, and tissue retention--

(i) Slides.

(A) Retain cytology slide preparations for at least 5 years from the date of examination (see Sec. 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 maintained and available for the time frames specified in this section.

APPENDIX C

Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services

Interpretive Guidelines §493.1105(a)(7)(i)(A)
For storage and maintenance requirements use D3013.
***NOTE**: Cytology specimens include fine needle aspirates.*

Retention of cytology slides:
A laboratory refers all cytology specimens to a reference laboratory for examination. The reference laboratory examines all slide preparations and reports results only on normal, negative, and unsatisfactory cases. At the request of the referring laboratory, the reference laboratory returns those cases that have reactive, reparative atypia (including repair), LSIL, HSIL, all invasive squamous carcinomas, adenocarcinoma, all other malignant neoplasms, and 10% of the normal or negatives cases (including reactive and reparative cases) for quality control review. The referring laboratory must maintain the slides of the cases that it examines and for which it provides diagnosis (i.e., slides exhibiting atypical including repair, LSIL, HSIL, all invasive squamous carcinomas, adenocarcinoma, all other malignant neoplasms, and slides chosen for the 10% rescreen).

The laboratory must maintain documentation to acknowledge the donation of each slide submitted to a proficiency testing program or loaned for other purposes.

Probes §493.1105(a)(7)(i)(A)
What protocol has been established to ensure prompt return of slides, when necessary?