D3043

§493.1105 Standard: Retention requirements

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

    (a)(7)(i) Slides.

        (a)(7)(i)(A) Retain cytology slide preparations for at least 5 years from

the date of examination (see §493.1274(f) for proficiency testing exception).

Interpretive Guidelines §493.1105(a)(7)(i)(A)

For storage and maintenance requirments use D3013.

NOTE: Cytology specimens include fine needle aspirates.

Retention of cytology slides:
Example:

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?

> **(a)(7)(i)(B) Retain histopathology slides for at least 10 years from the date of examination.**

> **(a)(7)(ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination.**

> **(a)(7)(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.**