- For slides retained for different periods of time, how does your laboratory ensure that the slides are retained for the defined time period?
- If using off-site storage, how do you ensure that slides are stored appropriately?

***REVISED** 12/26/2024*

CYP.06900 Slide Retention - Cytopathology **Phase II**

All glass slides are retained for an appropriate period.

NOTE: Minimum requirements for laboratories rendering cytopathology services, providing these are not less stringent than national, federal, state (or provincial), or local laws and regulations, are:

1. *Gynecologic glass slides (including p16/Ki67 dual stain gynecologic cytology slides) -five years*
2. *Non-gynecologic glass slides (including fine needle aspiration (FNA) slides)-10 years*

The retention period for non-gynecologic (non-FNA) glass slides changed from five years to 10 years in the 2019 Checklist edition. Cases diagnosed prior to December 31, 2014 are not subject to the 10-year retention requirement.

Laboratories may utilize archived slides for the benefit of the patient, even if that use destroys the slide. In such cases, the laboratory policy on material and record retention must authorize the destruction of a retained slide for such purposes (eg, molecular testing).

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1105(a)(7)(i)(A)].
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [493.1274(f)(2) through (f)(4)].
3) College of American Pathologists. Retention of laboratory records and materials. Northfield, IL: CAP, current edition

***REVISED** 08/24/2023*

CYP.07100 Slide and Block Storage - Cytology **Phase I**

Cytology slides and blocks are properly stored in a temperature controlled, pest-free, organized manner (ie, accessible for retrieval and properly identified).

NOTE: Slides and blocks must be stored in a manner to prevent contamination from blood or other fluids or tissues and be readily accessible for retrieval.

The storage area for blocks must be cool to prevent blocks from melting together. The CAP recommends (but does not require) ambient temperatures in block storage areas to be less than 27°C (as lower storage temperatures slow down DNA, RNA, and protein degradation).

For laboratories using off-site storage facilities, the laboratory director or designee must confirm that storage requirements are met.

Evidence of Compliance:

✓ Records of storage temperature monitoring (on-site and off-site locations), including deviations

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1105(a)(7)(i)(A)].
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [493.1274(f)(2) through (f)(4)].
3) Compton CC, Robb JA, Anderson MW, et al. Preanalytics and Precision Pathology: Pathology Practices to Ensure Molecular Integrity of Cancer Patient Biospecimens for Precision Medicine. *Arch Pathol Lab Med.* 2019;143(11)1346-63.

CYP.07200 Slide Handling **Phase II**

The circulation, referral, transfer, and receipt of original slides follows a consistent process that includes records of the location of slides to ensure availability for consultation and legal proceedings.

Evidence of Compliance:

✓ Tracking sheet/log that includes identity of slides/blocks, identity of recipient and record of return of slides/blocks

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1105(a)(7)(i)(A)].
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [493.1274(f)(2) through (f)(4)].

CYP.07300 Acknowledgment of Receipt **Phase II**

There are records, including acknowledgment of receipt, when original diagnostic material is loaned to special programs for the purpose of education and/or proficiency testing.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1105(a)(7)(i)(A)].
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [493.1274(f)(2) through (f)(4)].

GYNECOLOGIC CYTOPATHOLOGY

Content has been added to some requirements in this section for primary HPV screening. Primary HPV screening is a stand-alone HPV test that is performed as an initial cervical cancer screen, with reflex to additional testing as necessary. This is different than HPV/PAP co-testing where both tests are performed together.

Inspector Instructions:

READ	• Sampling of gynecologic cytopathology policies and procedures • Written criteria for unsatisfactory specimens • Sampling of patient reports for pathologist review and interpretation of specific screening diagnoses • Sampling of 10% rescreening records • Sampling of records of retrospective review and evidence of amended reports, if applicable • Statistical records including evidence of annual review and investigation when the laboratory falls outside the 5th or 95th percentiles • Records of employee performance monitoring including individual's discrepancies and corrective action
OBSERVE	• Use of Papanicolaou stain • Use of p16/Ki67 dual stain
ASK	• What criteria are used to identify rejected or unsatisfactory specimens? • What is the laboratory's process for follow-up or investigation of significant results? • What is your course of action when you are unable to obtain histological reports or material when reporting gynecologic cases with HSIL?