The laboratory issues an amended report and promptly notifies the responsible clinician(s) when there are changes to reports that affect current patient care.

NOTE: The amended report must state the reason for the amendment. The format of amended reports is at the discretion of the laboratory.

Records of notification must include date, responsible laboratory individual, and person notified.

Evidence of Compliance:

- ✓ Patient reports containing reason for the amendment **AND**
- ✓ Records of notification

REFERENCES

1) 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): [42CFR493.1274(e)(6)].

CYP.06600 Report Retention - Cytopathology — Phase II

Cytopathology reports are retained for at least 10 years.

NOTE: Cytopathology reports must be retained in either paper or electronic format. If retained in electronic format alone, reports must include a secure pathologist electronic signature. Images of paper reports, such as microfiche, PDF files, including signature are acceptable.

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

CYP.06850 Correlation of Results - Non-gynecologic Cytopathology — Phase II

The cytologic diagnoses for non-gynecologic cytopathology cases are correlated with the results of specialized studies (eg, molecular studies, immunocytochemistry).

NOTE: It is not in the best interests of the patient to have potentially conflicting diagnoses or interpretations rendered by different sections of the laboratory. The pathologist should issue a report reconciling potentially conflicting data, when appropriate.

RETENTION OF SLIDES

Inspector Instructions:

READ	• Sampling of slide handling policies and procedures
OBSERVE	• Slide storage area (organized, accessible, slides easily retrieved)

- 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**