

**NOTE:** Cytopathology reports must clearly communicate whether disease is present, absent, or uncertain. When a definite diagnosis cannot be rendered (ie, terms such as "inconclusive," "indeterminate" or "non-diagnostic" are used), the reason should be given.

Reports must include a concise descriptive diagnosis either in a format similar to a histopathology report, or standard descriptive terminology that includes a general categorization and descriptive diagnosis (as is recommended by the Bethesda System for gynecologic/anal cytology, the Paris System for urinary cytology, or Bethesda System for thyroid cytology). The use of diagnostic numerical categories alone is not recommended.

A simple diagnosis of "Negative" is not an adequate descriptive diagnosis. However, a diagnosis such as, "Negative for malignancy" or "No malignant cells identified" is acceptable for non-gynecologic exfoliative cytology specimens (ie, urine, fluids, washings and brushings). When appropriate (particularly for fine needle aspiration samples of mass lesions), a statement regarding the adequacy of the specimen should be included, with a description of the limitations of the specimen when a specific diagnosis cannot be made.

#### **Evidence of Compliance:**

- ✓ Cytopathology reports including morphologic findings

#### **REFERENCES**

- 1) Solomon D, et al. The 2001 Bethesda system. Terminology for reporting results of cervical cytology. *JAMA*. 2002;287:2114-2119
- 2) Solomon D, Nayar, R, eds. The Bethesda System for Reporting Cervical Cytology; Definitions, Criteria, and Explanatory Notes. 2nd ed., 2004
- 3) 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)(5)].

## **CYP.06450 Significant and Unexpected Findings Phase II**



**Significant and unexpected cytopathology findings are communicated to the responsible clinician and records of those communications are retained.**

**NOTE:** Certain cytopathology diagnoses may be considered significant and unexpected, warranting special communication to the responsible clinician(s). The cytopathology department determines diagnoses to be defined as "significant and unexpected," in cooperation with local clinical medical staff. Examples include: invasive carcinoma found in a cervicovaginal specimen, amendments to reports that may significantly affect patient care, and malignancy in an effusion with no patient history of neoplasm.

There must be a reasonable effort to ensure that clinicians receive the communications. The records must include the following:

- Date of communication
- Time of communication (if required by laboratory policy)
- Responsible individual communicating the result
- Person notified using identifiers traceable to that person (a first name alone is inadequate)
- Findings communicated.

An appropriate notification includes a direct dialog with the responsible individual or an electronic communication (secure email or fax) with confirmation of receipt by the responsible individual.

The record of the communication may be included directly on the patient report or in a separate location. It is not necessary to separately summarize the findings communicated if the record of the communication is on the patient report. For communications recorded in a separate location, the findings communicated may be summarized or reference the case number.

This requirement takes the place of critical result notification in the All Common Checklist (COM.30000 and COM.30100) for cytopathology findings.

#### **Evidence of Compliance:**

- ✓ Records of communication of significant and unexpected findings

## **CYP.06475 Amended Reports Phase II**



**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:

<b>READ</b> 	<ul style="list-style-type: none"> <li>• Sampling of slide handling policies and procedures</li> </ul>
<b>OBSERVE</b> 	<ul style="list-style-type: none"> <li>• Slide storage area (organized, accessible, slides easily retrieved)</li> </ul>