

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