NOTE: The records must indicate those who have reviewed the cytology slides. Cytotechnologists should be identifiable by name, initials, or other identifier in laboratory records. When a pathologist has performed a diagnostic review of the slides, the report must indicate his/her name or signature (in written or electronic form). The reviewing pathologist's name must be distinct from any other pathologist names (eg, the laboratory director) on the report. Electronic signatures must be secure and traceable to the reviewing pathologist. A report may contain the signature/initials of a pathologist or cytotechnologist attesting to an activity other than review of the slides (for example, verification of results of automated screening instruments), but in such cases the report must clearly indicate that the signature/initials attest to the other activity, not review of the slides.

When slides are reviewed by a pathologist for quality control purposes only (eg, the 10% rescreen of gynecologic cytopathology cases), the name of the pathologist must be retained in laboratory records but need not be included on the report.

CYP.05332 Report Review **Phase II**

Cytopathology reports are reviewed and signed by the pathologist, when applicable.

NOTE: For gynecologic cases reviewed by a pathologist, and for all non-gynecologic cases, the laboratory must ensure that records indicate that the reviewing pathologist has reviewed and approved the completed report before release. In the occasional situation when the diagnosing pathologist is not available for timely review and approval of the completed report, the laboratory may have a policy and procedure for review and approval of that report by another pathologist. In that circumstance, the names and responsibilities of both the pathologist who made the diagnosis and the pathologist who performs final verification must appear on the report.

This checklist requirement does not apply to cases reviewed by a pathologist for quality control purposes only (eg, the 10% rescreen of gynecologic cytopathology cases).

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)(2)(3)].

CYP.05350 Cytopathology Report Elements **Phase I**

The cytopathology report includes all of the following elements:

1. **Date specimen received/accessioned by the laboratory**
2. **Description of specimen on receipt (eg, bloody fluid)**
3. **Description of fixative and pre-analytic variables that may affect ancillary testing (eg, type of fixative, time in fixative)**
4. **Designation of automated screening device, when applicable**

NOTE: For description of specimens on receipt, examples include the number of glass slides submitted and how fixed (eg, air-dried or alcohol-fixed); quantity of fluid and fixation (eg, 10 cc bloody fluid in alcohol); Thin Prep vial; SurePath vial; and brush in 10 cc clear yellow fluid.

Evidence of Compliance:

✓ Cytopathology reports including the required elements

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

CYP.06100 Report - Morphologic Findings **Phase II**

The cytopathology report includes an interpretation of the morphologic findings, and as appropriate, standard descriptive terminology.

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