

RECORDS AND REPORTS

Inspector Instructions:

 READ	<ul style="list-style-type: none"> • Sampling of reporting policies and procedures • Sampling of patient reports
 ASK	<ul style="list-style-type: none"> • How are reports signed if the reviewing pathologist is not available? • How do you record intra-departmental and extra-departmental consultations? • If cases are resulted at different locations, how do you ensure that the testing laboratory name and address are correct on the final report?

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

CYP.05300 Cytopathology Report Elements

Phase II

The cytopathology report includes all of the following elements:

1. Name of patient and unique identifying number, if available
2. Age and/or birth date of patient
3. Date of collection
4. Accession number
5. Name of submitting physician and/or clinic
6. Name of the responsible reviewing pathologist, when applicable
7. Name and address of the laboratory location where the test was performed
8. Date of report
9. Test performed
10. Anatomic source and/or type of specimen
11. Basis for amendment (if applicable)

NOTE: If slide screening is performed at one laboratory location and the interpreting pathologist is at a different location, the names and addresses of both laboratory locations must be on the report. If slide processing and staining are performed at one location and screening and interpretation at a second location, only the name/address of the second location need be on the report.

For institutions utilizing integrated cytology reports (including primary HPV screening, reflex HPV, co-testing, and p16/Ki67 dual stain), the names and addresses of each performing laboratory with a different CLIA number must be on the report.

Refer to CYP.05316 below for additional details regarding the reviewing pathologist.

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)].
- 2) 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):3713 [42CFR493.1291(c)(1-6) and (k)(1,2)].

CYP.05316 Pathologist Identification on Report

Phase II

The cytopathology report clearly indicates the name of the pathologist who has reviewed the slides, when applicable.

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/initals 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/initals 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

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CYP.06100 Report - Morphologic Findings Phase II

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