RECORDS AND REPORTS

Inspector Instructions:

	• Sampling of reporting policies and procedures • Sampling of patient reports
	• 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.