

D5623

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1274 Standard: Cytology

(c)(2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies.

***Interpretive* Guidelines §493.1274(c)(2)**

The laboratory must compare clinical information with cytology final reports. For example, an atrophic smear (usually characteristic of a post menopausal woman) from a 21-year-old female with an LMP (last menstrual period) of 2-weeks-ago constitutes inconsistent findings and must be resolved.

The laboratory must define criteria to determine a discrepancy between a final cytological diagnosis of High Grade Squamous Intraepithelial Lesion (HSIL) or squamous carcinoma, adenocarcinoma or other malignant neoplasias and the correlating histology report.

Cases considered HSIL include: moderate and severe dysplasia, carcinoma in-situ (CIS)/Cervical Intraepithelial Neoplasia (CIN) 2 and CIN 3 or with features suspicious for invasion.

Probes §493.1274(c)(2)

How does the laboratory identify and resolve discrepancies for:

- Clinical information vs. cytology report; and
- Gynecologic cytology report vs. histopathology report?