Evidence of Compliance:

✓ Records of workload screening for each individual

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(d)].
2) Kline TS. The challenge of quality improvement with the Papanicolaou smear. *Arch Pathol Lab Med.* 1997;121:253-255
3) Mody DR, *et al.* Guest editorial - "workload limits" and CLIA '88 in the 1990's: how much is too much? Or too little? *Diagn Cytopathol.* 1997;16:VII-VIII
4) Cibas, ES, *et al*. Quality assurance in gynecologic cytology: the value of cytotechnologist-cytopathologist discrepancy logs. *Am J Clin Pathol.* 2001;115:512-516
5) Moriarty AT. Cytology workload calculation—Has anything really changed? *Cancer Cytopath.* 2001;119(2):77-79.

CYP.08450 Screening Workload - Laboratories Not Subject to US Regulations Phase II

Each individual screening cytology slides by manual microscopic technique examines no more than 100 gynecologic slides per 24 hours.

NOTE: This checklist requirement applies only to laboratories NOT subject to US regulations. The laboratory must comply with local regulations or laws if more stringent than this requirement.

This maximum workload may be completed in no less than eight hours.

When automated screening instruments are used, laboratories should follow manufacturer's instructions to establish the maximum daily workload. In any case, the total daily workload may not exceed the equivalent of 100 slides undergoing full manual review (or the daily workload limit in the jurisdiction where the laboratory is located, if such limit is fewer than 100 slides).

For purposes of workload limits, gynecologic liquid-based slides must be counted as one slide.

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

CYP.08500 Manual Screening - Laboratories Subject to US Regulations Phase II

Workload data are recorded for cytotechnologists and pathologists who manually screen previously unscreened gynecologic (including p16/Ki67 dual stain gynecologic cytology) and non-gynecologic (including FNA) slides.

NOTE: This checklist requirement applies only to laboratories subject to US regulations. The final rule implementing CLIA requires that each individual evaluating cytology preparations by manual microscopic technique must examine no more than 100 slides (gynecologic and non-gynecologic or both) in 24-hours. In addition, if there are different state regulations for cytology workload, the most stringent regulation must be followed (eg, workload for cytotechnologists manually screening gynecologic smears under a California state laboratory license is limited to 80 gynecologic slides in a 24-hour period, and reduced proportionately based on other duties performed).

Gynecologic slides include new routine slides, 10% rescreen slides, and five-year look-back negative slides. Records must be maintained showing the total number of slides examined by each individual during each 24-hours.

For primary manual screening of non-gynecologic liquid-based slide preparations, each slide may be counted as one-half slide for the purpose of workload recording, provided that cells are dispersed over one-half or less of the total available slide area.

For primary manual screening of all other slide types (including gynecologic liquid-based preparations), each slide must be counted as a single slide for the purpose of workload recording.

The maximum workload can be completed in no less than an eight-hour workday. These total limits apply regardless of the number of laboratories in which an individual works on a given day. For employees screening less than eight hours at an individual laboratory, this workload maximum must be prorated according to the formula: number of hours spent screening X 100/8.