Pathologists who screen previously unscreened gynecologic slides (including p16/Ki67 dual stained gynecologic cytology slides) and previously unscreened non-gynecologic slides (including FNA slides) must adhere to the above workload limit and retain records of compliance.

For all screening personnel, adequacy assessment of fine needle aspiration (FNA) smears or rapid on-site evaluation (ROSE) is not considered primary cytology screening; however, the time spent performing adequacy assessments must be used to prorate the maximum number of slides the individual can screen in a 24-hour period.

The following are not subject to the workload limit for pathologists:

1. *Previously screened reactive/repair, atypical, premalignant and malignant gynecologic, and p16/Ki67 dual stained gynecologic cytology slides*
2. *Rescreened five-year look-back slides*
3. *10% rescreen of negative gynecologic slides*
4. *Previously screened non-gynecologic slides*
5. *Previously screened FNA slides*

Evidence of Compliance:

✓ Records of workload recording 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) Zhai Q, Siegal GP. Quality Management in Anatomic Pathology. Northfield, IL: CAP Press, 2017.
4) Moriarty AT. Cytology workload calculation—Has anything really changed? *Cancer Cytopath.* 2001;119(2):77-79.
5) Centers for Medicare and Medicaid Services. *Clarification Regarding Fine Needle Aspiration (FNA) Specimen Adequacy Assessment, Rapid On-Site Evaluation (ROSE) and Workload Limits.* March 16, 2018. Baltimore, M: Department of Health and Human Services; Ref: QSO18-14-CLIA.

CYP.08550 Automated Screening - Laboratories Subject to US Regulations — Phase II

If applicable, workload data are recorded for the automated screening of cytology slides.

NOTE: This checklist requirement applies only to laboratories subject to US regulations. Workload calculations may vary with the use of automated screening instruments. Laboratories must assure that CLIA requirements are fulfilled. The following includes information on calculating workload using semi-automated gynecologic cytology screening devices:

- *All slides with full manual review (FMR) count as one slide equivalent (as mandated by CLIA for manual screening)*
- *All slides with field of view (FOV) only review count as 0.5 or 1/2 slide equivalents*
- *Slides with **both** FOV and FMR count as 1.5 or 1-1/2 slide equivalents*
- *These values should be used to count workload, not exceeding the CLIA maximum limit of 100 slides in no less than an eight-hour day*

In addition, if there are different state regulations for cytology workload, the most stringent regulation must be followed (eg, workload for cytotechnologists performing automated and semi-automated gynecologic smears under a California state laboratory license is limited to 100 gynecologic slides in a 24-hour period).

REFERENCES

1) 07/27/10 FDA Alert - How Laboratorians Can Safely Calculate Workload for FDA-Approved Semi-Automated Gynecologic Cytology Screening Devices
2) Crothers BA, Darragh TM, Tambouret RH, et al. Trends in Cervical Cytology Screening and Reporting Practices: Results from the College of American Pathologists 2011 PAP Educational Supplemental Questionnaire. *Arch Pathol Lab Med.* 2016; 140(1):13-21.
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(d), (g)].

CYP.08575 Individual Maximum Workload - Laboratories Subject to US Regulations — Phase II

Individual maximum workloads are established for cytology slide screening, including processes for reassessment at least every six months and adjustment when necessary.