U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Medical Devices

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How Laboratorians Can Safely Calculate Workload for FDA-Approved Semi-Automated Gynecologic Cytology Screening Devices

The purpose of this communication is to clarify for laboratories how workload should be calculated when using currently FDA-approved semi-automated gynecologic cytology screening devices. This communication is intended for cytotechnologists, technical supervisors, and laboratory managers using these systems and addresses how to count fields of view (FOV) and full manual slide reviews (FMR), as well as establishing maximum workload limits. Exceeding the designated maximum workload jeopardizes the ability of device users to detect precancerous and cancerous lesions of the cervix and is a public health risk.

What are the current issues with workload recording and maximum workload limits?

It has been brought to our attention that the current product labeling regarding workload recording for these devices has been difficult to interpret, resulting in variability and lack of standardization in counting methods.

In addition, individual maximum daily workload limits are not being established by the technical supervisor as mandated by CLIA'88. *The maximum daily limit specified in each of the device product labeling is only an upper limit and should never be used as an expectation for daily productivity or as a performance target.*

How can laboratorians safely calculate workload for FDA-approved semi-automated cytology screening device?

To ensure the safety and effectiveness of these devices, given their importance as women's health screening tests, the FDA has determined that laboratorians should use the following method when calculating workload. The calculation method applies to both semi-automated cytology screening systems currently on the market (Hologic's ThinPrep® Imaging System and Becton Dickinson's Focal Point™ Guided Screening System):

- All slides with full manual review (FMR) count as 1 slide (as mandated by CLIA'88 for manual screening)
- All slides with field of view (FOV) only review count as 0.5 or ½ slide
- Then, slides with **both** FOV and FMR count as 1.5 or 1½ slides
- Use these values to count workload, not exceeding the CLIA maximum limit of 100 slides in no less than an 8-hour day.

FMR = 1 slide
FOV = 0.5 slide
FMR + FOV = 1.5 slides
Upper Limit = 100 slides

Note: ALL laboratories should have a clear standard operation procedure for documentation of their method of workload counting and for establishing workload limits.

The following are examples of different counting scenarios that a cytotechnologist may encounter:

Cytology slide count equivalents

Non-gynecologic cytology:

- One smear = 1 slide
- One slide preparation which results in cell dispersion over one-half or less of the total available slide area = 0.5 slide

Gynecologic cytology:

- One conventional Pap smear slide = 1 slide
- One manually screened (non-automated) liquid based cytology preparation = 1 slide
- One FOV (Field of View) slide screened by the automated method = 0.5 slide
- One FMR (Full manual review) slide screened by the automated method = 1 slide
- Then, FOV + FMR screened by the automated method = 1.5 slides

Note: If an FMR slide is rescreened manually as part of 10% QC, it should be counted as 1 slide because it is assumed that this slide will not undergo an FOV review a second time.

Scenario 1:

Cytotechnologist screens non-gynecologic and automated gynecologic slide preparations in the same laboratory

Non-Gyn:

15 smears = 15 slides

10 cytospin slides = 5 slides (10 x 0.5)

Gyn:
50 FOV only (automated screening) = 25 slides (50 x 0.5)
20 FOV + FMR (automated screening) = 30 slides (20 x 1.5)
5 QC (manual screening) = 5 slides
TOTAL NUMBER OF SLIDES SCREENED = 80 slides
Scenario 2:
Cytotechnologist screens gynecologic slide preparations both manually and by automated screening device in the same laboratory
15 conventional Pap smears = 15 slides
20 liquid based cytology slides (manual screening) = 20 slides
60 FOV only slides (automated screening) = 30 slides (60 x 0.5)
20 FOV + FMR slides (automated screening) = 30 slides (20 x 1.5)
TOTAL NUMBER OF SLIDES SCREENED = 95
Scenario 3:
Cytotechnologist screens gynecologic slide preparations both manually and by automated screening device in different laboratories on the same day
Lab #1:
Hours worked = 4
10 Conventional pap smears = 10 slides
30 liquid based cytology slides (manual screening) = 30 slides
Total slides screened in Lab #1 = 40
Lab #2:
Hours worked = 4
50 FOV only slides (automated screening) = 25 slides (50 x 0.5)
15 FOV + FMR slides (automated screening) = 22.5 slides (15 x 1.5)
Total slides screened in Lab #2 = 47.5
TOTAL NUMBER OF SLIDES SCREENED = 87.5

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