

Specialty Requirements by Category

Cytopathology

Cytopathology			
Current Standard	Current Guidance	Proposed Standard	Proposed Guidance
Cytopathology Standard of Practice 8 (CY S8): Establishing a Workload Limit The laboratory director must establish procedures for a maximum slide examination workload limit for each individual who performs primary screening (i.e., screener) and must ensure that the examination workload limit is: a) not greater than eighty (80) gynecologic slides examined per twenty-four (24) hour period, in no less than an eight (8) hour workday, calculated using calculation guidance in Cytopathology Standard of Practice 9; or b) a combined total of one hundred (100) gynecologic and non-	Input from an assistant director responsible for cytopathology, supervisors, and pathologists performing testing onsite at the laboratory should be considered in establishing a workload limit. This slide examination workload limit is applicable to cytotechnologists and pathologists who examine previously unevaluated cytology slides. A period of eight (8) hours is used to prorate the number of slides that may be examined. Only the actual number of hours spent examining slides (excluding the time spent on nonscreening duties and breaks) is used for calculation. Formula #1: (Number of hours examining slides X 80) ÷ 8	Cytopathology Standard of Practice 8 (CY S8): Establishing a Workload Limit The laboratory director must establish procedures for a maximum slide examination workload limit for each individual who performs primary screening (i.e., screener) and must ensure that the examination workload limit is: a) not greater than <u>one hundred (100) eighty-</u>(80) gynecologic; slides examined per twenty-four (24) hour period, with in no less than an eight (8) hours <u>spent examining slides</u> workday, calculated using calculation guidance in Cytopathology Standard of Practice 9; or	Input from an assistant- <u>technical</u> director responsible for cytopathology, supervisors, and pathologists performing testing onsite at the laboratory should be considered in establishing a workload limit. This slide examination workload limit is applicable to cytotechnologists and pathologists who examine previously unevaluated cytology slides. A period of eight (8) hours is used to prorate the <u>maximum</u> number of slides that may be examined <u>per hour within a twenty-four (24) hour period</u>. Only the actual number of hours spent examining slides (excluding the time spent on non-screening duties and breaks) is used for calculation. Formula #1: (Number of

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gynecologic slides examined per twenty-four (24) hour period, in no less than an eight (8) hour workday, provided that the number of gynecologic slides does not exceed 80 using calculation guidance in Cytopathology Standard of Practice 9: i. the one hundred (100) slide limit represents an absolute maximum and shall not be exceeded; and c) prorated based on the actual number of hours spent examining; d) inclusive of the examination of slides at all sites or laboratories where the screener is employed; i. records of the total number of slides examined by each individual who performs primary screening and the number of hours spent	Formula #2: (Number of hours examining slides X 100) ÷ 8 Example: An individual who performs primary screening and spends four (4) hours examining slides may examine a maximum of: • forty (40) gynecologic slides; or • a combined total of fifty (50) gynecologic and non-gynecologic slides, provided that the number of gynecologic slides does not exceed forty (40).	b) a combined total of one hundred (100) gynecologic and non-gynecologic slides examined per twenty-four (24) hour period, in no less than an eight (8) hour workday, provided that the number of gynecologic slides does not exceed 80 using calculation guidance in Cytopathology Standard of Practice 9: i. the one hundred (100) slide limit represents an absolute maximum and shall not be exceeded; and e) b) prorated based on the actual number of hours spent examining; e) c) inclusive of the examination of slides at all sites or laboratories where the screener is employed; i. records of the total number of slides examined by each individual who	hours examining slides X 80) ÷ 8 Formula #2: (Number of hours examining slides X 100) ÷ 8 Example: An individual who performs primary screening and spends four (4) hours examining slides may examine a maximum of: • forty (40) gynecologic slides; or • a combined total of fifty (50) gynecologic and non-gynecologic slides, provided that the number of gynecologic slides does not exceed forty (40).

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examining slides in a twenty-four (24) hour period must be maintained by the laboratory, irrespective of the site or laboratory where the examinations are performed; and e) assessed at least every six (6) months, except that screeners using a semi-automated gynecologic cytology screening device must be assessed at least every three (3) months for the first year they use the device; and f) adjusted as necessary, and reasons for any adjustment are documented.		performs primary screening and the number of hours spent examining slides in a twenty-four (24) hour period must be maintained by the laboratory, <u>as outlined in Subdivision 58-1.12(c)</u>, irrespective of the site or laboratory where the examinations are performed; and e) d) assessed <u>and documented</u> at least every six (6) months, except that screeners using a semi-automated gynecologic cytology screening device must be assessed <u>and documented</u> at least every three (3) months for the first year they use the device; f) e) adjusted as necessary, and reasons for any adjustment are documented; <u>and</u> g) f) <u>not exceeded.</u>	

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Cytopathology Standard of Practice 10 (CY S10): Establishing a Workload Limit – Measures of Performance The laboratory must establish procedures for slide examination workload limit based on the screener's performance using assessment of the following, with documentation of assessments being retained for two (2) years: a) comparison of the screener's interpretation with a pathologist's confirmation of patient slides, including gynecologic slides interpreted to exhibit reactive changes, reparative changes or epithelial cell abnormality, and all non-gynecologic slides; b) evaluation of each screener's interpretations against the laboratory's overall	The laboratory director may delegate responsibility for screeners' assessment to an assistant director responsible for cytopathology. Input from supervisors and pathologists performing testing onsite at the laboratory should be considered. Screeners should be given an opportunity to discuss discrepancies. a) Refer to Cytopathology Standard of Practice 12. The laboratory director, or assistant director responsible for cytopathology, shall determine the definition of a discrepancy for the laboratory.	Same	The laboratory director may delegate responsibility for screeners' assessment to a an assistant technical director responsible for cytopathology. Input from supervisors and pathologists performing testing onsite at the laboratory should be considered. Screeners should be given an opportunity to discuss discrepancies. a) Refer to Cytopathology Standard of Practice 12. The laboratory director, or assistant technical director responsible for cytopathology, shall determine the definition of a discrepancy for the laboratory.

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statistical values with discrepancies documented, including the reason for any deviation and corrective action taken; and c) verification of negative cases, to include; i. for cytotechnologists, a ten (10) percent re-examination by a pathologist, cytology supervisor, or cytotechnologist with three (3) years of experience, of gynecologic slides interpreted as negative by the cytotechnologist; and ii. for pathologists who perform primary screening, a method for verifying negative cases initially screened by them, such as exchanging slides with another pathologist or sending slides out for secondary review.			

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Cytopathology Standard of Practice 11 (CY S11): Exceeding Gynecologic Slide Workload Limit Screeners must not exceed the slide examination workload limit without express written approval of the laboratory director. The director may consider increasing the gynecologic slide examination workload limit, for a particular screener who performs only gynecologic slide examinations, based on the screener's experience, documented accuracy assessed according to Cytopathology Standard of Practice 10, and performance on proficiency testing. The upper limit of such approval is ninety-six (96) gynecologic slides examined per twenty-four (24) hour period, in no less than an eight (8) hour workday, calculated using Cytopathology Standard of Practice 9. This must include work performed at other laboratories.	This standard applies to all slides examined manually and/or using a FDA-approved semi-automated gynecologic cytology screening device. The director must notify the Department by submitting a Documentation of Increased Workload Limit Form for each screener.	Standard deleted. Reserved for future use.	