Cytopathology

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Cytopathology Standard of Practice 1 (CY S1): Staining of Gynecologic Slides The laboratory must use a Papanicolaou or modified Papanicolaou staining method for gynecologic cytology slides.	While the actual staining technique may vary depending on the type of stain used and the modification of the method, any modification must include the four main steps of the standard Papanicolaou method: fixation, nuclear staining, cytoplasmic staining, and clearing.
Cytopathology Standard of Practice 2 (CY S2): Prevention of Cross Contamination Between Specimens During the Staining Process The laboratory must ensure that: a) gynecologic and non-gynecologic cytology slides are stained separately; and b) non-gynecologic cytology slides that have high potential for cross-contamination are stained separately from other non-gynecologic slides, and the stains and solutions are filtered or changed following staining.	10 NYCRR Subparagraph 58-1.13(b)(3)(iii) requires separate staining of gynecologic and non-gynecologic slides. In general, all stains and solutions should be filtered or changed at intervals appropriate to the laboratory's workload to ensure staining quality meets the laboratory's pre-established criteria. Stain quality should be verified every eight (8) hours for laboratories that operate twenty-four (24) hours a day. b) A toluidine blue stain may be used to determine the cellularity of non-gynecologic specimens.
Cytopathology Standard of Practice 3 (CY S3): Targeted Re-examination The laboratory must establish a system for targeted re-examination of at least ten (10) percent of gynecologic slides interpreted as negative for each cytotechnologist. Documentation of re-examination must be available in the	Slides reviewed as part of ten (10) percent re-examination must be included in the workload limit of the cytology supervisor or the cytotechnologist performing the re-examination.

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laboratory for inspection by the Department. Cases must be randomly selected from the total caseload including patients who are at increased risk of developing cervical carcinoma, as determined based on clinical information and results of previous studies, if performed.	
Cytopathology Standard of Practice 4 (CY S4): Reporting Results for Re-examined Slides For gynecologic cytology, the laboratory must not release reports of results for slides selected for re-examination until the re-examination is completed and any discrepancies between initial examination and re-examination are resolved.	For this standard, re-examination includes the targeted re-examination required in Cytopathology Standard of Practice 3.
Cytopathology Standard of Practice 5 (CY S5): Comparison of Results The laboratory must compare: a) clinical information with cytology final reports, if available; and b) 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 to the laboratory (either on site or in storage).	For this standard, re-examination includes the targeted re-examination required in Cytopathology Standard of Practice 3. Cytology-histology correlation studies should be completed in a timely manner. In general, if cytology and biopsy specimens are obtained concurrently, both reports, as well as correlation studies, should be completed within one week. For workload calculations, retrospective cytology-histology correlation studies are for quality assurance purposes and are considered a non-screening activity. Any discrepancies or inconsistent findings must be reconciled.

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Cytopathology Standard of Practice 6 (CY S6): Diagnosis and Retrospective Review of Previous Gynecologic Slides For each patient with a current high grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm: a) the laboratory must review all gynecologic slides received within the previous five (5) years, including those that were interpreted as unsatisfactory, negative, or within normal limits, if available to the laboratory (either on-site or in storage); b) if significant discrepancies are found that could affect current patient care, the laboratory must notify the patient's medical practitioner and issue an amended report according to the laboratory's written procedures for retrospective review, including time frames for completion; and c) results of initial examinations and all re-examinations must be documented.	Retrospective reviews have the potential for an amended report and are considered a screening activity. b) If discrepancies are found that would <u>not</u> affect <u>current</u> patient care, the laboratory need not issue an amended report, but need only document that finding in its records. "Could affect current patient care" minimally includes situations where an archived slide indicates upon re-examination: • a more serious disease state than that reported following initial examination, and/or abnormal cells identified upon re-examination are of a cell type different from those present on a current slide; or • an absence of disease, and abnormal cells were reported following initial examination.
Cytopathology Standard of Practice 7 (CY S7): Laboratory Statistical Evaluations The laboratory must conduct and document an annual evaluation to determine the number of: a) cytology cases examined; b) specimens processed sorted by specimen type;	

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c) cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); d) gynecologic cases with a diagnosis of high grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm for which histology results are available for comparison; e) gynecologic cases where cytology and histology are discordant; and f) gynecologic cases where any re-examination of a normal or negative specimen results in reclassification as low- grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm.	
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	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 non-screening duties and breaks) is used for calculation. Formula #1: (Number of hours examining slides X 80) ÷ 8

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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 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 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.	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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Cytopathology Standard of Practice 9 (CY S9): Workload Calculation Records must be available for the calculation of workloads for each individual who performs primary screening. For purposes of calculating slide examination workload: a) gynecologic cytology slides prepared using liquid-based slide preparatory methods and examined using manual screening must be counted as one (1) slide: i. including slides screened using FDA-approved semi-automated gynecologic cytology screening device's full manual review feature; and b) gynecologic cytology slides screened using an FDA-approved semi-automated gynecologic cytology screening device with field of view only review counted as 0.5 slide; c) gynecologic slides that are screened using both field of view and subsequent full manual review on a semi-automated gynecologic cytology screening device counted as 1.5 slides; d) non-gynecologic cytology slides prepared using a liquid-based slide preparatory method that result in cell dispersion over one-half or less of the total available slide counted as 0.5 slide; and e) gynecologic and non-gynecologic slides prepared by conventional smear techniques counted as one (1)	Liquid-based slide preparatory techniques include cytocentrifugation, filtering, and monolayering techniques, but not liquid-based cover slips. Any instrument used to assist in the adherence of cells to the slide is covered by this standard. "Field of view" is an identified microscopic area, selected based on processed image data from an entire scanned slide, presented to a screener for review by the screening device software.

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slide.	
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 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	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. b) The laboratory director, or assistant director responsible for cytopathology, shall determine the definition of a discrepancy for the laboratory.

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with another pathologist or sending slides out for secondary review.	
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.
Cytopathology Standard of Practice 12 (CY S12): Pathologist Review of Gynecologic Slides The laboratory must have standard operating procedures to document and ensure that a pathologist confirms interpretation of reactive or reparative changes or any of the following epithelial cell abnormalities: a) atypical or suspicious squamous or glandular cells; b) Squamous Intraepithelial Lesion, low or high grade; c) Dysplasia;	The laboratory must specify the descriptive nomenclature used for reporting patient results. The Bethesda System is an example of a recognized system of narrative descriptive nomenclature for gynecologic cytology.

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d) Cervical Intraepithelial Neoplasia; or e) Squamous cell carcinoma, adenocarcinoma or other malignant neoplasm.	
Cytopathology Standard of Practice 13 (CY S13): Pathologist Examination of Non-gynecologic Slides All non-gynecologic slide preparations must be examined by a pathologist.	
Cytopathology Standard of Practice 14 (CY S14): Resolution of Discordant Interpretations The laboratory must establish a procedure to resolve discrepancies whenever a slide is interpreted by more than one cytotechnologist and the interpretations are discordant.	
Cytopathology Standard of Practice 15 (CY S15): Reporting In addition to the requirements in Reporting Standard of Practice 2, laboratory reports must: a) use narrative descriptive nomenclature for all results; b) for gynecologic cytology, indicate the semi-automated gynecologic cytology screening device used for examination, if any, and the slide preparation method used for such a device: i. laboratories that perform only examinations	Descriptive nomenclature must be specified. When cytotechnologists' interpretations are recorded on worksheets in "code", the laboratory should have a mechanism to ensure that the correct nomenclature is used in reporting results. This standard applies to devices approved by the FDA for primary (initial) gynecologic cytology screening. Manual screening means evaluation of material on a slide, performed by a person using a microscope, in a manner that

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using manual screening need not indicate the method on the report; and c) report any unsatisfactory slides or slide preparations that have been identified as unsatisfactory, if applicable.	allows visualization and evaluation of the entire viewable area of a slide. Viewable area for conventional slide preparation (a smear prepared by hand) is the entire slide. Viewable area for slides prepared using liquid-based slide preparatory techniques (e.g., an instrument deposits a monolayer of washed and re-suspended cellular material) is the circular or other area pre-marked on the slide.
Cytopathology Standard of Practice 16 (CY S16): Correlation of Results Cytologic diagnosis of gynecologic and non-gynecologic cases must be correlated with the results of ancillary studies, if any.	Ancillary studies may include immunohistochemistry, flow cytometry and molecular studies.
Cytopathology Standard of Practice 17 (CY S17): Results Retrieval The laboratory must establish and implement a system for timely retrieval of results and other information pertinent to the generation of results.	Information pertinent to the generation of results, which includes, but is not limited to, instrument printouts of quality control data, electronic records and archived review reports, must be retained by the laboratory as required in 10NYCRR Subpart 58-1 and according to Document and Specimen Retention Standard of Practice 9. Requests for reports must be fulfilled within twenty-four (24) hours. Records that duplicate information on reports should be searchable numerically (accession number) and/or alphabetically (patient name).

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Cytopathology Standard of Practice 18 (CY S18): Transfer of Slides The laboratory must document transfer of slides to other entities, including for consultation and slides lent to a proficiency testing program. Documentation must include acknowledgement of receipt by the other party and must be retained for as long as the slides or according to Document and Specimen Retention Standard of Practice 10, whichever is longer. All slides must be retrievable upon request.	

Histopathology

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Histopathology Standard of Practice 1 (HT S1): Examination and Reporting Every tissue specimen submitted for analysis shall be examined and reported by a pathologist.	
Histopathology Standard of Practice 2 (HT S2): Reporting Nomenclature In addition to the requirements in Reporting Standard of Practice 2, the laboratory must use accepted terminology of a recognized system of disease nomenclature in reporting results.	
Histopathology Standard of Practice 3 (HT S3): Immunohistochemical and Gram Stain Controls Immunohistochemical, gram stains and acid-fast bacilli (AFB) must be checked for positive and negative reactivity with each patient slide or group of slides. Quality control run on continuous throughput slide stainers must be done every eight (8) hours for each stain tested. Reactions of the control slide with each special stain must be documented.	A continuous throughput slide stainer is an automated walk-away system that allows continuous loading of slides with reagents that remain on the stainer for at least 8 hours.

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Histopathology Standard of Practice 4 (HT S4): Special Stain Controls For all special stains or other differential stains, a control slide of known, i.e., intended, reactivity, must be stained with each patient slide or group of patient slides. Reaction(s) of the control slide with each special stain must be documented.	