

Pathology	
Standard	Guidance
<p>All laboratories shall comply with applicable requirements of 10NYCRR Subparts 58-1.12 and 58-1.13. Additionally, the following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.</p>	
<p>Pathology Standard 1 (PA S1)</p> <p>Reports shall:</p> <ul style="list-style-type: none"> a) include the signature of the pathologist who examined, reviewed and/or diagnosed the case; and b) indicate limitations of the result due to the laboratory not being provided with requested clinical information. 	<ul style="list-style-type: none"> a) Laboratories using electronic signatures should have a procedure in place that ensures and documents pathologist authorization for each signature occurrence (such as access limited by password).
<p>Pathology Standard 2 (PA S2)</p> <p>SOPM entries for specimen processing procedures shall include complete and distinct instructions for all phases of the process, including fixing, embedding, cutting, staining and cover-slipping.</p>	<p>Instructions for the preparation and use of solutions (including stains) should indicate direction of workflow, using, for example, flow charts or consecutive numbering of steps.</p> <p>Laboratories using instrumented slide preparatory methods (e.g., ThinPrep, SurePath) meet this standard by including in their SOPM the device's operating and maintenance protocols as approved by the FDA and issued by the device manufacturer.</p>

Pathology	
Standard	Guidance
<p>Pathology Standard 3 (PA S3)</p> <p>To ensure proper specimen identification, the laboratory shall:</p> <ul style="list-style-type: none"> a) not report on any slide or specimen unless it is identified by a unique patient identifier and anatomic site from which it was obtained; b) label all slides and specimens received with patient name or other unique identifier; and, c) have a procedure for follow-up when the clinical information on the requisition is inconsistent with the findings. 	<ul style="list-style-type: none"> a) This requires the laboratory to be able to identify the source of material submitted for examination; it does not require the anatomic site to be on the slide or container at the time of acceptance. <p>In addition to the information required by 10NYCRR Subpart 58-1.12 (e) (5), gynecologic cytology requisition forms should solicit information on duration of current pregnancy, menopausal status and whether the patient is at risk for developing cervical cancer or its precursors.</p>

Pathology Cytopathology	
Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
<p>Cytopathology Sustaining Standard of Practice 1 (CY S1): Department Approval</p> <p>Laboratories that examine specimens submitted for cytologic evaluation must hold a valid permit in the category of Cytopathology.</p>	
<p>Cytopathology Sustaining Standard of Practice 2 (CY S2): Staining of Gynecologic Slides</p> <p>The laboratory shall use a Papanicolaou or modified Papanicolaou staining method for gynecologic cytology slides.</p>	<p>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.</p>

<p>Cytopathology Sustaining Standard of Practice 3 (CY S3): Prevention of Cross Contamination Between Specimens During the Staining Process</p> <p>The laboratory shall ensure that:</p> <ul style="list-style-type: none"> 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. 	<p>10 NYCRR Section 58-1.13(b)(3)(iii) requires separate staining of gynecologic and non-gynecologic slides.</p> <p>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.</p> <p>b) A toluidine blue stain may be used to determine the cellularity of non-gynecologic specimens.</p>
<p>Cytopathology Sustaining Standard of Practice 4 (CY S4): Targeted Re-examination</p> <p>The laboratory must establish a system for targeted re-examination of at least 10 percent of gynecologic slides interpreted as negative for each cytotechnologist. Documentation of re-examination must be available in the laboratory for inspection by the Department.</p> <p>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.</p>	<p>Slides reviewed as part of 10 percent re-examination must be included in the workload limit of the cytology supervisor or the cytotechnologist performing the re-examination.</p>
<p>Cytopathology Sustaining Standard of Practice 5 (CY S5): Reporting Results for Re-examined Slides</p> <p>For gynecologic cytology, the laboratory shall 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.</p>	<p>For this standard, re-examination includes the targeted re-examination required in Cytopathology Sustaining Standard of Practice 4.</p>

<p>Cytopathology Sustaining Standard of Practice 6 (CY S6): Comparison of Results</p> <p>The laboratory must compare:</p> <ul style="list-style-type: none"> 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). 	<p>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.</p> <p>For workload calculations, retrospective cytology-histology correlation studies are for quality assurance purposes and are considered a non-screening activity.</p> <p>Any discrepancies or inconsistent findings must be reconciled.</p>
<p>Cytopathology Sustaining Standard of Practice 7 (CY S7): Diagnosis of HSIL Retrospective Review of Previous Gynecologic Slides</p> <p>For each patient with a current high grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm:</p> <ul style="list-style-type: none"> a) the laboratory shall review all gynecologic slides received within the previous five 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 shall notify the patient’s medical practitioner and issue an amended report. The laboratory’s written procedures for retrospective review shall include time frames for completion; and c) results of initial examinations and all re-examinations must be documented. 	<p>Retrospective reviews have the potential for an amended report and are considered a screening activity.</p> <ul style="list-style-type: none"> 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. <p>“Could affect current patient care” minimally includes situations where an archived slide indicates upon re-examination:</p> <ol style="list-style-type: none"> 1. 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 2. an absence of disease, and abnormal cells were reported following initial examination.

**Cytopathology Sustaining Standard of Practice 8 (CY S8):
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;
- 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 Sustaining Standard of Practice 9 (CY S9):
Establishing a Workload Limit**

The laboratory director shall establish a maximum slide examination workload limit for each individual who performs primary screening (i.e., screener) and shall ensure that the examination workload limit is:

- a) not greater than 80 gynecologic slides examined per 24 hour period, in no less than 8-hour workday, calculated using calculation guidance set forth in Cytopathology Sustaining Standard of Practice 10; or
- b) a combined total of 100 gynecologic and non-gynecologic slides examined per 24 hour period, in no less than 8-hour workday, provided that the number of gynecologic slides does not exceed 80; the slide calculation is done using calculation guidance set forth in Cytopathology Sustaining Standard of Practice 10;
 - 1) the 100 slide limit represents an absolute maximum and shall not be exceeded;
- 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;
 - 1) 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 24 hour period must be maintained by the laboratory, irrespective of the site or laboratory where the examinations are performed;
- e) assessed at least every six months, except that screeners using a semi-automated gynecologic cytology screening device shall be assessed at least every three months for the first year they use the device; and
- f) adjusted as necessary, and reasons for any adjustment are documented.

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 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: $(\text{Number of hours examining slides} \times 80) \div 8$

Formula #2: $(\text{Number of hours examining slides} \times 100) \div 8$

Example:

An individual who performs primary screening and spends 4 hours examining slides may examine a maximum of:

- 40 gynecologic slides or
- a combined total of 50 gynecologic and non-gynecologic slides, provided that the number of gynecologic slides does not exceed 40

**Cytopathology Sustaining Standard of Practice 10 (CY S10):
Workload Calculation**

For purposes of calculating slide examination workload:

- a) gynecologic cytology slides prepared using a liquid-based slide preparatory methods and examined using manual screening shall be counted as 1 slide;
 - 1) This includes slides screened using FDA-approved semi-automated gynecologic cytology screening device's full manual review feature;
- b) gynecologic cytology slides screened using an FDA-approved semi-automated gynecologic cytology screening device with field of view only review may be 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 shall be 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 may be counted as 0.5 slide; and
- e) gynecologic and non-gynecologic slides prepared by conventional smear techniques shall be counted as 1 slide.

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.

**Cytopathology Sustaining Standard of Practice 11 (CY S11):
Establishing a Workload Limit: Measures of Performance**

The slide examination workload limit shall be established based on the screener's performance using assessment of the following, with documentation of assessments being retained for two 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. Discrepancies must be documented, including the reason for any deviation and corrective action taken; and
- c) verification of negative cases, to include:
 - 1) for cytotechnologists, a 10 percent re-examination by a pathologist, cytology supervisor, or cytotechnologist with three years of experience, of gynecologic slides interpreted as negative by the cytotechnologist;
 - 2) 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.

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 Sustaining Standard of Practice 13 (CY S13): Pathologist Review of Gynecologic Slides.
- b) The laboratory director, or assistant director responsible for cytopathology, shall determine the definition of a discrepancy for the laboratory.

<p>Cytopathology Sustaining Standard of Practice 12 (CY S12): Exceeding Gynecologic Slide Workload Limit</p> <p>No screener shall exceed the slide examination workload limit without express written approval of the laboratory director.</p> <p>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 Sustaining Standard of Practice 11, and performance on proficiency testing. The upper limit of such approval is 96 gynecologic slides examined per 24 hour period, in no less than 8-hour workday, calculated using Cytopathology Sustaining Standard of Practice 10. This must include work performed at other laboratories.</p>	<p>This standard applies to all slides examined manually and/or using a FDA-approved semi-automated gynecologic cytology screening device.</p> <p>The director must notify the Department by submitting a Documentation of Increased Workload Limit Form for each screener.</p>
<p>Cytopathology Sustaining Standard of Practice 13 (CY S13): Pathologist Review of Gynecologic Slides</p> <p>A pathologist shall confirm interpretation of each gynecologic slide that has been interpreted as:</p> <ul style="list-style-type: none"> a) Reactive or reparative changes; b) Atypical or suspicious squamous or glandular cells; c) Squamous Intraepithelial Lesion, low or high grade; d) Dysplasia; e) Cervical Intraepithelial Neoplasia; or f) Squamous cell carcinoma, adenocarcinoma or other malignant neoplasm. 	<p>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.</p>
<p>Cytopathology Sustaining Standard of Practice 14 (CY S14): Pathologist Examination of Non-gynecologic Slides</p> <p>All non-gynecologic slide preparations shall be examined by a pathologist.</p>	

<p>Cytopathology Sustaining Standard of Practice 15 (CY S15): Resolution of Discordant Interpretations</p> <p>The laboratory shall establish a procedure to resolve discrepancies whenever a slide is interpreted by more than one cytotechnologist and the interpretations are discordant.</p>	
<p>Cytopathology Sustaining Standard of Practice 16 (CY S16): Reporting</p> <p>Laboratory reports shall:</p> <ul style="list-style-type: none"> a) use narrative descriptive nomenclature for all results; and 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; <ul style="list-style-type: none"> 1) Laboratories that perform only examinations using manual screening need not indicate the method on the report. 	<p>Descriptive nomenclature must be specified.</p> <p>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.</p> <p>This standard applies to devices approved by the FDA for primary (initial) gynecologic cytology screening.</p> <p>Manual screening means evaluation of material on a slide, performed by a person using a microscope, in a manner that 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.</p>
<p>Cytopathology Sustaining Standard of Practice 17 (CY S17): Correlation of Results</p> <p>Cytologic diagnosis of gynecologic and non-gynecologic cases must be correlated with the results of ancillary studies, if any.</p>	<p>Ancillary studies may include immunohistochemistry, flow cytometry and molecular studies.</p>

<p>Cytopathology Sustaining Standard of Practice 18 (CY S18): Results Retrieval</p> <p>The laboratory shall establish and implement a system for timely retrieval of results and other information pertinent to the generation of results.</p>	<p>Information pertinent to the generation of results, which includes, but is not limited to, instrument printouts of quality control data and archived review reports, shall be retained by the laboratory as required in 10NYCRR Subpart 58-1.</p> <p>In accordance with Records Retention Sustaining Standard of Practice 2: Reports, requests for reports must be fulfilled within 24 hours.</p> <p>Records that duplicate information on reports should be searchable numerically (accession number) and/or alphabetically (patient name).</p>
<p>Cytopathology Sustaining Standard of Practice 19 (CY S19): Transfer of Slides</p> <p>Documentation of slides referred for consultation must be maintained. Documentation of slides lent to a proficiency testing program or other entity, including an acknowledgment of receipt by the other party, must be maintained. All slides must be retrievable upon request.</p>	

Pathology Histopathology	
Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
Histopathology Standard 1 (HT S1) Every tissue specimen submitted for analysis shall be examined and reported by a pathologist	
Histopathology Standard 2 (HT S2) The laboratory shall use accepted terminology of a recognized system of disease nomenclature in reporting results.	
Histopathology Standard 3 (HT S3) A laboratory that performs only the tissue-processing component of a histopathology examination must hold a permit in the category of histopathology.	Procedures to identify non-infectious antigens, e.g., immunohistochemical staining of tissue, may be performed under a histopathology permit.
Histopathology Standard 4 (HT S4) The laboratory shall monitor paraffin containers on automated processors and/or hot paraffin cabinets for conformance with the defined temperature range for the paraffin in use.	Tissue flotation baths do not require temperature monitoring.

Pathology Histopathology	
Standard	Guidance
Histopathology Standard 5 (HT S5) Immunohistochemical and gram stains shall be checked for positive and negative reactivity with each patient slide or group of slides.	