

Pathology <i>(Including Cytopathology and Histopathology)</i>		
Tag #	Standard	Guidance
	All laboratories shall comply with applicable requirements of Sections 58-1.12 and 58-1.13 of 10 NYCRR. 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.	
	GENERAL	
PH1a PH1b	<p>Pathology Standard 1</p> <p>Reports shall:</p> <p>a) include the signature of the pathologist who examined, reviewed and/or diagnosed the case; and</p> <p>b) indicate limitations of the result due to the laboratory not being provided with requested clinical information.</p>	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).
PH2	<p>Pathology Standard 2</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>

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PH3a PH3b PH3c	<p>Pathology Standard 3</p> <p>To ensure proper specimen identification, the laboratory shall:</p> <p>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;</p> <p>b) label all slides and specimens received with patient name or other unique identifier; and,</p> <p>c) have a procedure for follow-up when the clinical information on the requisition is inconsistent with the findings.</p>	<p>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> <p>In addition to the information required by Section 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>
	CYTOPATHOLOGY	<p>Terms used in the cytopathology standards, including “work standard” and “work day,” have the same meaning as in Section 58-1.12.</p>
CY1	<p>Cytopathology Standard 1</p> <p>If the primary specimen is cellular, or examination at the cellular level is requested, the laboratory must hold a valid permit in the category of cytopathology.</p>	<p>Examination of non-gynecologic cellular material is allowed under a histopathology permit if such material has been collected concurrent with, or has been prepared from, the tissue specimen (e.g., lymph node imprints).</p>

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CY2	<p>Cytopathology Standard 2</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>Laboratories using instrumented examination methods should ensure that cytotechnologists receive adequate training in reading slides stained using proprietary formulas, and their proficiency is verified.</p>
CY3	<p>Cytopathology Standard 3</p> <p>All gynecologic smears interpreted to be showing reactive or reparative changes, and/or atypical squamous or glandular cells of undetermined significance shall be reviewed by a pathologist.</p>	<p>This standard applies in addition to Section 58-1.12 requirements for pathologist review.</p> <p>This standard applies to narrative, non-Bethesda equivalents of the diagnostic categories listed.</p> <p>The laboratory should establish a procedure to resolve discrepancies, to be implemented whenever a slide is interpreted by more than one cytotechnologist (e.g., during hierarchical review) and the interpretations are discrepant.</p>
CY4	<p>Cytopathology Standard 4</p> <p>The laboratory shall ensure that 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>	<p>Section 58.13(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, no less than each day of use, to ensure staining quality meets the laboratory's pre-established criteria.</p>

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<p>CY5a</p> <p>CY5b</p>	<p>Cytopathology Standard 5</p> <p>Laboratory reports shall:</p> <p>a) use narrative descriptive nomenclature for all results; and</p> <p>b) for gynecologic cytology, indicate the instrumented method used for examination, except that a laboratory that conducts only examinations using the conventional method need not indicate the method on the report.</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>b) This standard applies to devices approved by the FDA for primary (initial) screening and/or re-screening for quality assurance purposes. Instrumented methods currently approved include location-guidance and slide profiling systems. Reports need not include the slide preparation method. Reports for slides that undergo initial screening using the FocalPoint slide profiler (TriPath Imaging) and are classified as requiring "no further review" need not identify technical personnel who prepared, processed or loaded slides, and/or reviewed archived review reports.</p> <p>Conventional examination means manual evaluation of material on a slide conducted by a human being, unassisted by other than a microscope, in a manner that allows visualization and evaluation of the entire "viewable area" of a slide. Viewable area for a smear is the area under the cover slip; viewable area for slides prepared by an instrument's depositing a mono-layer of washed and re-suspended cellular material is the circular or other area pre-marked on the slide.</p>
<p>CY6</p>	<p>Cytopathology Standard 6</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 and re-examination resolved.</p>	<p>For this standard, re-examination includes the 10%, targeted, and instrumented re-screening for QA purposes.</p>

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CY7	<p>Cytopathology Standard 7</p> <p>The laboratory shall require and document written acknowledgment for the loan of slides.</p>	<p>The laboratory should have an agreement with the entity borrowing the slides, e.g., a PT program, that loaned slides are retrievable on request.</p> <p>This standard is NOT applicable to slides sent to another laboratory for consultation.</p>
CY8	<p>Cytopathology Standard 8</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 QC data and archived review reports, should be retained by the laboratory as required Part 58.</p> <p>Records that duplicate information on reports should be searchable numerically (accession number) and alphabetically (patient name).</p>
CY9a CY9b	<p>Cytopathology Standard 9</p> <p>For purposes of calculating workload:</p> <p>a) gynecologic cytology slides prepared using liquid-based slide preparatory methods shall be counted as one slide; and</p> <p>b) non-gynecologic cytology slides prepared using liquid-based slide preparatory methods may be counted as one half of one slide.</p>	<p>This standard refers to slide preparatory techniques, not liquid based cover slips. Any instrument used to assist in the adherence of cells to the slide is covered by this standard.</p>

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<p>CY10a</p> <p>CY10b</p>	<p>Cytopathology Standard 10</p> <p>The laboratory director shall ensure that each individual's examination volume limitation is:</p> <p>a) assessed at least every six months, except that cytotechnologists using instrumented examination methods for gynecologic cytology slides shall be assessed at least every three months for the first year they use the device; and</p> <p>b) adjusted as necessary, and reasons for any adjustment are documented.</p>	<p>Documentation of assessments should be maintained for at least two years.</p> <p>The director may delegate responsibility for cytotechnologists' assessment to the person(s) holding a certificate of qualification (CQ) and designated responsible for cytology in the laboratory; input from the CQ holder, supervisors and pathologists should be considered.</p>
<p>CY11a</p> <p>CY11b</p>	<p>Cytopathology Standard 11</p> <p>As part of cytotechnologists' competency assessments, the laboratory director shall ensure:</p> <p>a) the performance of each individual is evaluated against the laboratory's overall statistical values; and</p> <p>b) the reason for any deviation and the corrective action is documented.</p>	<p>Individuals should be given the opportunity to discuss instances of misdiagnosis.</p> <p>a) Performance includes: false-negative and false-positive rates (or number of over- and under-read slides); and rate of referral for pathologist review.</p>

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<p>CY12a</p> <p>CY12b</p> <p>CY12c</p>	<p>Cytopathology Standard 12</p> <p>For each patient with a current high grade squamous intraepithelial lesion (HSIL) or equivalent, or malignancy:</p> <p>a) the laboratory shall review all gynecologic slides interpreted as unsatisfactory, negative or within normal limits received within the previous five years, if available to the laboratory;</p> <p>b) if significant discrepancies are found that would affect current patient care, the laboratory shall notify the patient's medical practitioner and issue an amended report; and</p> <p>c) the laboratory's written procedures for retrospective review and histology-cytology correlation activities shall include reasonable time frames for completion.</p>	<p>Available to the laboratory means either on-site or retrievable within 24 hours.</p> <p>Retrospective review and the histology-cytology correlation are part of quality control procedures and, as such, should be completed in a timely manner.</p> <p>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. "Affect current patient care" minimally includes situations where an archived slide indicates upon re-review a more serious disease state than that reported following initial examination, and/or abnormal cells identified upon re-review are of a cell type different than that involved in the current disease state.</p> <p>For workload calculations, histology-cytology correlation studies are for quality assurance purposes and are considered a non-screening activity. Retrospective reviews have the potential for an amended report and are considered a screening activity.</p>
<p>CY13</p>	<p>Cytopathology Standard 13</p> <p>No laboratory and no cytotechnologist shall exceed the work standard without express written permission of the Department.</p> <p>Each laboratory intending for one or more of the cytotechnologists in its employ to use an instrumented method for initial examination of gynecologic cytology slides in excess of the work standard of 80 slides per work day as set forth in 10 NYCRR Subpart 58-1 shall submit a written request for approval to the Department.</p>	<p>This standard applies to instrumented methods that employ both a human reviewer and an FDA-approved device for primary screening (i.e., initial examination) of gynecologic cytology slides that employs location guidance technology.</p>

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<p>CY14a</p> <p>CY14b</p> <p>CY14c</p>	<p>Cytopathology Standard 14</p> <p>Cytotechnologists using the Thin-Prep Imaging System (Cytoc Corp) as approved by the FDA on June 9, 2003 shall comply with:</p> <p>a) a work standard of 140 gynecologic slides per work day for which examination is restricted to the 22 fields of vision selected by the device and their immediate vicinity as described in the manufacturer’s instructions;</p> <p>b) an hourly examination rate that, on average, does not exceed 17.5 slides per hour, for such examinations; and</p> <p>c) for purposes of calculating workload, any slide for which a cytotechnologist engages the “full review” feature (i.e., <i>Auto-scan</i> mode) shall be considered as a conventional examination subject to the 80 slide work standard (or that individual’s approved conventional examination standard of 96-100 slides)</p>	<p>a) The work standard for location guided methods set forth in Standard 14 may be exceeded by 20 slides, to a maximum of 160 gynecologic slides per work day, provided the examining cytotechnologist has a minimum of three months experience using the device and the cytotechnologist obtains Department approval for the 20 additional slides.</p> <p>Slides that undergo initial screening using the FocalPoint instrument (TriPath Imaging) and are classified as requiring “no further review” need not be counted in the workload of any cytotechnologist involved in the preparation, processing, loading of slides, and/or review of the archived review report. However, such tasks must be considered for pro-rating a his or her individual examination volume limitation pursuant to 10 NYCRR Section 58-1.13(b).</p> <p>The maximum hourly rates of 17.5 slides per hour for location-guided methods and 12.5 slides per hour for conventional examinations should be used to adjust workload.</p>
<p>CY15</p>	<p>Cytopathology Standard 15</p> <p>If, in a given work day, a cytotechnologist examines non-gynecologic or gynecologic cytology slides using the conventional method, the laboratory shall adjust his or her workload for instrumented examinations accordingly.</p>	
<p>CY16</p>	<p>Cytopathology Standard 16</p> <p>When re-examining gynecologic cytology slides initially examined using a location guidance method, the laboratory shall use the conventional examination method or the device’s “full review” feature.</p>	<p>Slides initially examined using the conventional method may be re-examined using either the conventional method or an instrumented method FDA-approved for initial or re-screening.</p> <p>The Thin-Prep Imaging System’s Auto-scan mode is a full review feature.</p>

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	HISTOPATHOLOGY	
HT1	<p>Histopathology Standard 1</p> <p>Every tissue specimen submitted for analysis shall be examined and reported by a pathologist.</p>	
HT2	<p>Histopathology Standard 2</p> <p>The laboratory shall use accepted terminology of a recognized system of disease nomenclature in reporting results.</p>	
HT3	<p>Histopathology Standard 3</p> <p>A laboratory that performs only the tissue-processing component of a histopathology examination must hold a permit in the category of histopathology.</p>	Procedures to identify non-infectious antigens, e.g., immunohistochemical staining of tissue, may be performed under a histopathology permit.
HT4	<p>Histopathology Standard 4</p> <p>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.</p>	Tissue floatation baths do not require temperature monitoring.
HT5	<p>Histopathology Standard 5</p> <p>Immunohistochemical and gram stains shall be checked for positive and negative reactivity with each patient slide or group of slides.</p>	