



COLLEGE of AMERICAN
PATHOLOGISTS

AI Hammadi Hospital AI Nuzha
Laboratory Department

Cytopathology Checklist

CAP Accreditation Program



College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750
www.cap.org

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Cytopathology Checklist



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ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists by logging into cap.org and going to e-LAB Solutions Suite - Accreditation Checklists. They are available in different checklist types and formatting options, including:

- Master — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- Custom — customized based on the laboratory's activity (test) menu; available in PDF, Word/XML or Excel formats
- Changes Only — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

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CAP accredited laboratories have access to additional checklist accreditation tools and resources found on the CAP website (cap.org) by logging into e-LAB Solutions Suite - Accreditation Resources. Content found in Accreditation Resources includes:

- A library of past Focus on Compliance webinars and laboratory inspection preparation videos
- Answers to the most common checklist questions
- Customizable templates and forms (eg, competency assessment, personnel, validation/verification, quality management)
- Proficiency testing (PT) frequently asked questions, forms, and troubleshooting guides
- IQCP eligibility, frequently asked questions, forms, templates, and examples
- Laboratory director education and resources
- Quality management resources
- Inspector training and inspection tip sheets
- Self and post inspection toolbox

SUMMARY OF CHECKLIST EDITION CHANGES

Cytopathology Checklist

12/26/2024 Edition

The information below includes a listing of checklist requirements with significant changes in the current edition and previous edition of this checklist. The list is separated into three categories:

1. New
2. Revised:
 - Modifications that may require a change in policy, procedure, or process for continued compliance; or
 - A change to the Phase
3. Deleted/Moved/Merged:
 - Deleted
 - Moved — Relocation of a requirement into a different checklist (requirements that have been resequenced within the same checklist are not listed)
 - Merged — The combining of similar requirements

NOTE: The requirements listed below are from the Master version of the checklist. The customized checklist version created for inspections and self-evaluations may not list all of these requirements.

Previously Cited Checklist Requirements

- The **inspector's version** of the checklist contains a listing of previously cited checklist requirements. Specific information on those citations, including the inspection date and inspector comments, is included following each related requirement within the checklist.
- Laboratories can access data on previously cited deficiencies by logging into e-LAB Solutions Suite on cap.org and going to Accreditation Reports - Inspection Summation Report.

NEW Checklist Requirements

<u>Requirement</u>	<u>Effective Date</u>
CYP.07620	12/26/2024

REVISED Checklist Requirements

<u>Requirement</u>	<u>Effective Date</u>
CYP.04150	12/26/2024
CYP.05000	12/26/2024
CYP.05300	12/26/2024
CYP.06100	12/26/2024
CYP.06900	12/26/2024
CYP.07100	08/24/2023
CYP.07452	12/26/2024
CYP.07582	12/26/2024
CYP.07600	12/26/2024
CYP.07655	12/26/2024
CYP.07700	12/26/2024
CYP.07800	12/26/2024

DELETED/MOVED/MERGED Checklist Requirements

None

INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a cytopathology laboratory section or department.

Laboratories that do not file slides on-site (eg, "read-only" laboratories) must retain a sample of slides on-site for review by the inspector on all days when the laboratory is subject to its regular on-site inspection. The sample must, at minimum, include all slides accessioned over a continuous two-week period within the previous two years.

If telepathology is used by the pathologist or cytotechnologist to review slides or images for primary diagnosis of cytology or real time evaluation of FNA specimens for adequacy or triaging, refer to the Telepathology section of the Laboratory General Checklist for additional requirements. Telepathology occurs when a pathologist views digitized or analog video or still image(s), and renders an interpretation that is included in a formal diagnostic report or recorded in the patient record. This also includes the review of images by a cytotechnologist when a judgment of adequacy is recorded in the patient record.



Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

Laboratories not subject to US regulations: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).

GENERAL CYTOPATHOLOGY

This Checklist is intended for laboratories that perform on-site preparation and/or interpretation of cytologic specimens. These include GYNECOLOGIC (cervicovaginal), and/or NON-GYNECOLOGIC (exfoliated specimens from other sites, fluids, and aspirates) cytopathology. If the laboratory does NOT perform any on-site examination of cytopathology specimens, but refers all submitted material to an outside laboratory, do NOT use this Checklist. Do NOT use this Checklist if the laboratory's involvement in cytopathology is limited to filing of reports and/or slides.

Cytopathology inspectors must be pathologists or cytotechnologists who have extensive experience in the practice of cytology, are knowledgeable about current CAP Checklist and CLIA requirements, and have completed appropriate inspector training prior to inspecting.

Regardless of the size of the laboratory, the Inspector should spend at least several hours inspecting the cytopathology laboratory. The on-site inspection will require review of case (slide) material, direct observation of technical procedures, and careful review of quality management monitors.

Laboratories that are doing histology processing of cell blocks and tissues must be inspected with the Anatomic Pathology Checklist.

INTERLABORATORY COMPARISONS

NOTE: Peer interlaboratory comparison programs provide valuable educational opportunities based on peer performance comparisons in both technical and interpretive arenas. While not completely emulating cytopathology preparation and interpretation, participation in such programs enables a laboratory to compare its performance to peer laboratories.

CYP.00170 Educational Participation - Gynecologic Cytopathology Phase II



For laboratories not subject to US regulations that perform gynecologic cytopathology, the laboratory participates in the educational component of the CAP PAP Education Program or another interlaboratory peer-comparison educational program in gynecologic cytopathology.

NOTE: Participation in the PAP Education program enables a laboratory to compare its performance to benchmarks derived from a national database of peer laboratories.

Evidence of Compliance:

- ✓ Records of enrollment and participation in the educational component of the CAP PAP PT program **OR**
- ✓ Records of enrollment and participation in another educational gynecologic cytopathology peer-comparison program **OR**
- ✓ Records for participation in a laboratory-developed program by circulating gynecologic case material with other laboratories

CYP.00190 Educational Participation - Non-gynecologic Cytopathology Phase I



For laboratories that perform non-gynecologic cytopathology, the laboratory participates in an interlaboratory peer-comparison educational program in NON-GYNECOLOGIC cytopathology (eg, CAP Interlaboratory Comparison Program in Non-Gynecologic Cytopathology NGC).

Evidence of Compliance:

- ✓ Records of enrollment and participation in the educational component of the CAP NGC program **OR**
- ✓ Records of enrollment and participation in another educational non-gynecologic cytopathology peer-comparison program **OR**
- ✓ Records for participation in a laboratory-developed program by circulating non-gynecologic case material with other laboratories

QUALITY MANAGEMENT

Quality management in cytopathology should address both negative and abnormal/positive cases. The program must include both rescreening and hierarchic case review, as well as correlation of cytological and available histological material. In addition, the laboratory should participate in interlaboratory comparison, self-assessment and performance improvement programs. There must be records of intra- and extra-departmental consultation, as appropriate. Results of QM surveillance should be shared with the responsible pathologist(s) and cytotechnologist(s).

CYP.01650 Cytopathology Exclusion Phase I



The institution defines specimens that may be excluded from routine submission to the cytology department for examination.

NOTE: This policy may be made in conjunction with the hospital administration and appropriate medical staff departments. The laboratory director should have participated in or been consulted by the medical staff in deciding which cytology specimens are to be sent to the laboratory for examination.

(No policy is needed for fluids such as urines and CSF that do not routinely undergo cytologic examination.)

CYP.01900 Disparity Resolution Phase II



If significant disparities exist between histological and cytological findings, these are resolved in a confidential peer-reviewed quality management report, or in an addendum or in the patient report.

NOTE: For requirements specific to gynecologic cytopathology, also refer to the Gynecologic Cytopathology section of this checklist.

CYP.02100 Consultation Report Retention Phase I



Records of intra- and extra-departmental consultations are retained.

NOTE: The retention requirement for reports (10 years) applies to records of consultations.

QUALITY CONTROL

SPECIMEN COLLECTION AND RECEIPT

CYP.03366 FNA Error Prevention Phase II



The pathologist performing FNA procedures verifies patient identification using at least two patient identifiers, the procedure site, and the procedure to be performed.

CYP.03800 Physician Notification Phase II



The laboratory notifies submitting physicians when unacceptable specimens are received.

Evidence of Compliance:

- ✓ Records of physician notification (eg, follow-up correspondence, records of telephone calls or written reports)

CYP.03850 Cytology Assessment Record Phase I

If a statement of adequacy, preliminary diagnosis, or recommendations for additional studies is provided at the time of cytology sample collection, records of that statement are retained.

NOTE: Records might include a note in the patient's medical record or in the final cytopathology report.

CYTOLogy STAINS AND SLIDE PREPARATIONS

CYP.04100 Staining Solutions Phase II



Staining solutions are filtered, covered when not in use, and changed in accordance with a defined schedule.

Evidence of Compliance:

- ✓ Records of solution changes at defined intervals

****REVISED** 12/26/2024**

CYP.04150 Cross-Contamination Phase II



The laboratory prevents cross-contamination of cytologic specimens during processing and staining.

NOTE: Procedures must prevent cross-contamination between the following:

- Gynecologic and non-gynecologic specimens.
- Non-gynecologic cases that have high potential for cross-contamination from other non-gynecologic specimens.

Laboratories must define what is considered a specimen that has a high potential for cross-contamination. Methods to prevent cross-contamination between specimens may include cytocentrifuge, filter, air dried preparations, and monolayer preparations. Direct smears made from the sediment of highly cellular cases should be stained after the other cases, and the staining fluids must be changed or filtered between each of the highly cellular cases. One procedure to detect highly cellular specimens is to use a toluidine blue, or other rapid stain, on a wet preparation.

CYP.04300 Cytologic Preparation Technical Quality Phase II



The pathologist or supervisory-level cytotechnologist performs daily review of the technical quality of cytologic preparations.

NOTE: The technical quality of cytologic preparations must be checked daily (on days processing occurs). This includes checking all stains for predicted staining characteristics each day of use. This check must include all of the types of preparations seen that day such as cytospins, cell blocks, and liquid-based preparations.

If preparation and staining is performed by a different laboratory, there must be a procedure for the laboratory performing the preparation and staining to verify the acceptability of the quality of preparations and the acceptability of controls (if needed) before transfer. Records of this verification must be readily available to the laboratory performing interpretations. There should also be a mechanism for feedback from the interpreting laboratory to the laboratory that prepared the slides of any issues with the preparations.

Evidence of Compliance:

- ✓ Records of daily review of cytologic preparations

ON-SITE MICROSCOPIC REVIEW

On-site review of actual case (slide) material and corresponding reports is an important element of the inspection process. This is NOT a comprehensive rescreening of slides or evaluation of competency, but rather an action to facilitate the Inspector's evaluation of the laboratory's overall procedures.

Laboratories that do not file slides on-site (for example, some "read-only" laboratories) must retain a sample of slides on-site for review by the inspector on all days when the laboratory is subject to its regular on-site inspection. The sample must, at minimum, include all slides accessioned over a continuous two-week period within the previous two years. The laboratory must be able to produce any slide upon the request of an inspector during the required retention period for gynecologic and non-gynecologic slides (including fine needle aspiration slides).

CYP.04900 Cellular/Nuclear Detail

Phase II

Cellular and nuclear detail are sufficient for proper interpretation.

****REVISED** 12/26/2024**

CYP.05000 On-Site Slide Review

Phase II

The findings from the on-site slide review are free of any issues or any significant diagnostic discrepancies as defined in the Inspector Instructions.

NOTE: If p16/Ki67 dual stain is performed, slides should be included in the on-site slide review.

INSTRUMENTS AND EQUIPMENT

The checklist requirements in this section should be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

CYP.05292 Unsuccessful Slide Processing

Phase II



The laboratory has a process to identify and handle slides that are not successfully processed by the automated screening instrument.

NOTE: Laboratories must clearly identify slides that fail screening by an automated instrument and ensure that these slides are completely rescreened by another method. In most instances, manual rescreening will be used.

Evidence of Compliance:

- ✓ Records of slide rescreening

RECORDS AND REPORTS

****REVISED** 12/26/2024**

CYP.05300 Cytopathology Report Elements

Phase II

The cytopathology report includes all of the following elements:

1. Name of patient and unique identifying number, if available
2. Age and/or birth date of patient
3. Date of collection
4. Accession number
5. Name of submitting physician and/or clinic
6. Name of the responsible reviewing pathologist, when applicable
7. Name and address of the laboratory location where the test was performed
8. Date of report
9. Test performed
10. Anatomic source and/or type of specimen
11. Basis for amendment (if applicable)

NOTE: If slide screening is performed at one laboratory location and the interpreting pathologist is at a different location, the names and addresses of both laboratory locations must be on the report. If slide processing and staining are performed at one location and screening and interpretation at a second location, only the name/address of the second location need be on the report.

For institutions utilizing integrated cytology reports (including primary HPV screening, reflex HPV, co-testing, and p16/Ki67 dual stain), the names and addresses of each performing laboratory with a different CLIA number must be on the report.

Refer to CYP.05316 below for additional details regarding the reviewing pathologist.

CYP.05316 Pathologist Identification on Report

Phase II

The cytopathology report clearly indicates the name of the pathologist who has reviewed the slides, when applicable.

NOTE: The records must indicate those who have reviewed the cytology slides.

Cytotechnologists should be identifiable by name, initials, or other identifier in laboratory records. When a pathologist has performed a diagnostic review of the slides, the report must indicate his/her name or signature (in written or electronic form). The reviewing pathologist's name must be distinct from any other pathologist names (eg, the laboratory director) on the report. Electronic signatures must be secure and traceable to the reviewing pathologist. A report may contain the signature/initials of a pathologist or cytotechnologist attesting to an activity other than review of the slides (for example, verification of results of automated screening instruments), but in such cases the report must clearly indicate that the signature/initials attest to the other activity, not review of the slides.

When slides are reviewed by a pathologist for quality control purposes only (eg, the 10% rescreen of gynecologic cytopathology cases), the name of the pathologist must be retained in laboratory records but need not be included on the report.

CYP.05332 Report Review

Phase II

Cytopathology reports are reviewed and signed by the pathologist, when applicable.

NOTE: For gynecologic cases reviewed by a pathologist, and for all non-gynecologic cases, the laboratory must ensure that records indicate that the reviewing pathologist has reviewed and approved the completed report before release. In the occasional situation when the diagnosing pathologist is not available for timely review and approval of the completed report, the laboratory may have a policy and procedure for review and approval of that report by another pathologist. In that circumstance, the names and responsibilities of both the pathologist who made the diagnosis and the pathologist who performs final verification must appear on the report.

This checklist requirement does not apply to cases reviewed by a pathologist for quality control purposes only (eg, the 10% rescreen of gynecologic cytopathology cases).

CYP.05350 Cytopathology Report Elements

Phase I

The cytopathology report includes all of the following elements:

1. Date specimen received/acquisitioned by the laboratory
2. Description of specimen on receipt (eg, bloody fluid)
3. Description of fixative and pre-analytic variables that may affect ancillary testing (eg, type of fixative, time in fixative)
4. Designation of automated screening device, when applicable

NOTE: For description of specimens on receipt, examples include the number of glass slides submitted and how fixed (eg, air-dried or alcohol-fixed); quantity of fluid and fixation (eg, 10 cc bloody fluid in alcohol); Thin Prep vial; SurePath vial; and brush in 10 cc clear yellow fluid.

Evidence of Compliance:

- ✓ Cytopathology reports including the required elements

****REVISED** 12/26/2024**

CYP.06100 Report - Morphologic Findings

Phase II

The cytopathology report includes an interpretation of the morphologic findings, and as appropriate, standard descriptive terminology.

NOTE: Cytopathology reports must clearly communicate whether disease is present, absent, or uncertain. When a definite diagnosis cannot be rendered (ie, terms such as "inconclusive," "indeterminate" or "non-diagnostic" are used), the reason should be given.

Reports must include a concise descriptive diagnosis either in a format similar to a histopathology report, or standard descriptive terminology that includes a general categorization and descriptive diagnosis (as is recommended by the Bethesda System for gynecologic/anal cytology, the Paris System for urinary cytology, or Bethesda System for thyroid cytology). The use of diagnostic numerical categories alone is not recommended.

A simple diagnosis of "Negative" is not an adequate descriptive diagnosis. However, a diagnosis such as, "Negative for malignancy" or "No malignant cells identified" is acceptable for non-gynecologic exfoliative cytology specimens (ie, urine, fluids, washings and brushings). When appropriate (particularly for fine needle aspiration samples of mass lesions), a statement regarding the adequacy of the specimen should be included, with a description of the limitations of the specimen when a specific diagnosis cannot be made.

Evidence of Compliance:

- ✓ Cytopathology reports including morphologic findings

CYP.06450 Significant and Unexpected Findings

Phase II



Significant and unexpected cytopathology findings are communicated to the responsible clinician and records of those communications are retained.

NOTE: Certain cytopathology diagnoses may be considered significant and unexpected, warranting special communication to the responsible clinician(s). The cytopathology department determines diagnoses to be defined as "significant and unexpected," in cooperation with local clinical medical staff. Examples include: invasive carcinoma found in a cervicovaginal specimen, amendments to reports that may significantly affect patient care, and malignancy in an effusion with no patient history of neoplasm.

There must be a reasonable effort to ensure that clinicians receive the communications. The records must include the following:

- Date of communication
- Time of communication (if required by laboratory policy)
- Responsible individual communicating the result

- Person notified using identifiers traceable to that person (a first name alone is inadequate)
- Findings communicated.

An appropriate notification includes a direct dialog with the responsible individual or an electronic communication (secure email or fax) with confirmation of receipt by the responsible individual.

The record of the communication may be included directly on the patient report or in a separate location. It is not necessary to separately summarize the findings communicated if the record of the communication is on the patient report. For communications recorded in a separate location, the findings communicated may be summarized or reference the case number.

This requirement takes the place of critical result notification in the All Common Checklist (COM.30000 and COM.30100) for cytopathology findings.

Evidence of Compliance:

- ✓ Records of communication of significant and unexpected findings

CYP.06475 Amended Reports Phase II



The laboratory issues an amended report and promptly notifies the responsible clinician(s) when there are changes to reports that affect current patient care.

NOTE: The amended report must state the reason for the amendment. The format of amended reports is at the discretion of the laboratory.

Records of notification must include date, responsible laboratory individual, and person notified.

Evidence of Compliance:

- ✓ Patient reports containing reason for the amendment **AND**
- ✓ Records of notification

CYP.06600 Report Retention - Cytopathology Phase II



Cytopathology reports are retained for at least 10 years.

NOTE: Cytopathology reports must be retained in either paper or electronic format. If retained in electronic format alone, reports must include a secure pathologist electronic signature. Images of paper reports, such as microfiche, PDF files, including signature are acceptable.

CYP.06850 Correlation of Results - Non-gynecologic Cytopathology Phase II

The cytologic diagnoses for non-gynecologic cytopathology cases are correlated with the results of specialized studies (eg, molecular studies, immunocytochemistry).

NOTE: It is not in the best interests of the patient to have potentially conflicting diagnoses or interpretations rendered by different sections of the laboratory. The pathologist should issue a report reconciling potentially conflicting data, when appropriate.

RETENTION OF SLIDES

****REVISED** 12/26/2024**

CYP.06900 Slide Retention - Cytopathology Phase II



All glass slides are retained for an appropriate period.

NOTE: Minimum requirements for laboratories rendering cytopathology services, providing these are not less stringent than national, federal, state (or provincial), or local laws and regulations, are:

1. Gynecologic glass slides (including p16/Ki67 dual stain gynecologic cytology slides) -five years
2. Non-gynecologic glass slides (including fine needle aspiration (FNA) slides)-10 years

The retention period for non-gynecologic (non-FNA) glass slides changed from five years to 10 years in the 2019 Checklist edition. Cases diagnosed prior to December 31, 2014 are not subject to the 10-year retention requirement.

Laboratories may utilize archived slides for the benefit of the patient, even if that use destroys the slide. In such cases, the laboratory policy on material and record retention must authorize the destruction of a retained slide for such purposes (eg, molecular testing).

****REVISED** 08/24/2023**

CYP.07100 Slide and Block Storage - Cytology

Phase I

Cytology slides and blocks are properly stored in a temperature controlled, pest-free, organized manner (ie, accessible for retrieval and properly identified).

NOTE: Slides and blocks must be stored in a manner to prevent contamination from blood or other fluids or tissues and be readily accessible for retrieval.

The storage area for blocks must be cool to prevent blocks from melting together. The CAP recommends (but does not require) ambient temperatures in block storage areas to be less than 27°C (as lower storage temperatures slow down DNA, RNA, and protein degradation).

For laboratories using off-site storage facilities, the laboratory director or designee must confirm that storage requirements are met.

Evidence of Compliance:

- ✓ Records of storage temperature monitoring (on-site and off-site locations), including deviations

CYP.07200 Slide Handling

Phase II



The circulation, referral, transfer, and receipt of original slides follows a consistent process that includes records of the location of slides to ensure availability for consultation and legal proceedings.

Evidence of Compliance:

- ✓ Tracking sheet/log that includes identity of slides/blocks, identity of recipient and record of return of slides/blocks

CYP.07300 Acknowledgment of Receipt

Phase II

There are records, including acknowledgment of receipt, when original diagnostic material is loaned to special programs for the purpose of education and/or proficiency testing.

GYNECOLOGIC CYTOPATHOLOGY

Content has been added to some requirements in this section for primary HPV screening. Primary HPV screening is a stand-alone HPV test that is performed as an initial cervical cancer screen, with reflex to additional testing as necessary. This is different than HPV/PAP co-testing where both tests are performed together.

CYP.07439 Papanicolaou Stain

Phase II

The Papanicolaou stain is used for gynecologic specimens.

****REVISED** 12/26/2024**

CYP.07452 Unsatisfactory Specimens - Gynecologic Cytopathology

Phase II



The laboratory has written criteria for identification and reporting of unsatisfactory gynecologic specimens and slide preparations including p16/Ki67 dual stain.

NOTE: Cytopathology reports must clearly specify when a specimen and/or slide preparation is unsatisfactory for evaluation and state the reason in the cytopathology report. The criteria for categorizing a specimen and/or slide preparation as unsatisfactory (eg, scant cellularity, obscuring blood, obscuring inflammation, or quantity insufficient for reflex testing from primary HPV screening) must be defined by the laboratory. Unsatisfactory cases must not be reported as negative or normal. Gynecologic specimens with atypical cells are always "satisfactory," although the report may include comments on the quality of the preparation.

Adequacy criteria are consistent with manufacturer instructions; however, any p16/Ki67 dual stain with positive cell(s) is reported as adequate.

CYP.07517 Retrospective Review

Phase II



All available (either on site or in storage) previously negative slides received within the past five years are reviewed whenever a new high-grade squamous intraepithelial lesion (moderate or severe dysplasia, carcinoma in situ, CIN II or III) or malignant cervical/vaginal cytology is reported.

NOTE: Previously negative slides (read manually or automated) from the index patient must be rescreened or reviewed by an individual qualified as a cytology supervisor (see CYP.08100). Laboratory policy should specify which cases require pathologist review.

CYP.07530 Retrospective Review Requiring Amendment

Phase II



If a significant discrepancy, which would affect current patient care, is found during the retrospective review, an amended report is issued.

Evidence of Compliance:

- ✓ Records of retrospective reviews and amended reports, as necessary

CYP.07543 Correlation of Results

Phase II



Records of attempts to obtain and review follow-up histological reports or material are available within the laboratory when gynecologic cases with high-grade squamous intraepithelial lesion (HSIL) or malignant cytological findings are reported.

NOTE: When the histologic diagnosis is available, correlation to the cytologic findings must be recorded and these records must be readily accessible. The number of cases that have histologic correlation must be recorded.

Evidence of Compliance:

- ✓ Records of the attempts made to obtain and review histological reports or materials

CYP.07556 Additional Reports

Phase II



When a follow-up histological report or material is not available within the laboratory, there are records of attempts to obtain follow-up histological information for correlative

review when gynecologic cases with significantly abnormal (high-grade SIL) or malignant cytological findings are reported.

Evidence of Compliance:

- ✓ Records of attempts to obtain the information (eg, follow-up correspondence, telephone calls, or requests included in the report)

CYP.07569 Correlation of Results - Gynecologic Cytopathology Phase II



Gynecologic cytopathology findings are correlated with clinical information, when available.

NOTE: Methods of clinical correlation must be defined. Examples of clinical correlation methods include: focused rescreening of cases based on clinical history, history of bleeding, or previous abnormality; correlation of glandular cells with hysterectomy status, age of patient, and last menstrual period; review of previous or current biopsy material.

Evidence of Compliance:

- ✓ Records of clinical correlation (eg, policies, problem logs with resolution, or notes in reports)

****REVISED** 12/26/2024**

CYP.07582 Cervical Cancer Screening Test - False Negative Notification Phase I

There is a mechanism to educate providers that cervical cancer screening tests, including primary HPV and Pap tests, are screening tests with inherent false negative results.

NOTE: The preferred mechanism is an educational note on all negative Pap test reports and all primary HPV screening tests. Other mechanisms include sending periodic educational information to providers, conference presentations, specimen collection manual, etc.

****REVISED** 12/26/2024**

CYP.07600 Statistical Records - Gynecologic Cytopathology Phase II



For gynecologic cytopathology cases (not including those reflexed from primary HPV screening), statistical records are maintained and evaluated at least annually, and include the following:

- Total number of gynecologic cytology cases examined
- Number of cases reported by diagnosis for each specimen type (including the number reported as unsatisfactory for diagnostic interpretation)
- Number of cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison
- Number of cases where cytology and histology are discrepant
- Number of cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms
- Number of negative cases rescreened before sign-out
- Number of positive and negative p16/Ki67 dual stains performed.

NOTE: The data must be evaluated by the laboratory director or designee and included in the annual cytopathology statistical report. Inclusion of AGC data is optional. Separate statistics for conventional and each type of liquid-based preparations are required.

If a p16/Ki67 dual stain is used as a follow-up to an HPV positive co-test with a negative Pap test, statistics should be maintained separate from p16/Ki67 dual stain results derived from a positive primary HPV screening test.

The benchmarking data listed in the table below are based on 2021 case volumes. These benchmarking data may not be applicable for laboratories that utilize primary HPV screening

for a significant portion of cervical cancer screening. Results were excluded for laboratories that included primary HPV screening results in the interpretive totals when more than 25% of their cervical/gynecologic cytology slides were from positive primary HPV screening. In evaluating its statistics, the laboratory's patient population should be taken into consideration. Percentile-reporting rates refer to the distribution of individual laboratory responses from reporting rates in various categories. Responses are ranked from lowest to highest, and the 50th percentile-reporting rate refers to the median response. A 25th percentile-reporting rate (which corresponds to 1.7% in the table) for the ThinPrep LSIL category means that a quarter of laboratories have LSIL rates of 1.7% or less. A 90th percentile-reporting rate (which corresponds to 11.7% in the table) for ASC-US in ThinPrep preparations means that 9 of 10 laboratories have an ASC-US rate of 11.7% or less.

The reporting rates for ASC-US, ASC-H, AGC, LSIL, HSIL, and UNSATISFACTORY are given as percentages of total case volume. An ASC-US rate of 2.0% means 2/100 cases in the lab are designated ASC-US. The ASC/SIL figure is a calculated ratio: the percentage or number of a laboratory's ASC-US and ASC-H cases divided by the percentage or number of LSIL, HSIL, and malignant cases. A laboratory with 4% ASC cases and 3% SIL cases has an ASC/SIL ratio of 1.3, as compared to the median ASC/SIL ratio of 1.5 for conventional Paps, 2.0 for ThinPrep® and 1.8 for SurePath.

CONVENTIONAL*							
Laboratory Percentile-Reporting Rate							
CATEGORY	5th	10th	25th	Median	75th	90th	95th
Unsatisfactory (%)	0.0	0.0	0.4	1.3	2.2	5.2	7.1
LSIL (%)	0.0	0.0	0.3	0.8	1.6	2.0	2.8
HSIL (%)	0.0	0.0	0.1	0.3	0.5	0.9	1.1
ASC-US (%)	0.1	0.3	1.0	1.8	3.6	5.3	6.7
ASC-H (%)	0.0	0.0	0.1	0.1	0.4	0.8	1.1
AGC (%)	0.0	0.0	0.0	0.1	0.2	0.6	1.2
ASC/SIL	0.4	0.5	1.0	1.5	2.7	4.2	5.6

ThinPrep**							
Laboratory Percentile-Reporting Rate							
CATEGORY	5th	10th	25th	Median	75th	90th	95th
Unsatisfactory (%)	0.2	0.4	0.9	1.7	2.9	4.8	5.7
LSIL (%)	0.4	0.9	1.7	2.4	3.3	4.8	6.6
HSIL (%)	0.1	0.1	0.2	0.4	0.6	1.0	1.3
ASC-US (%)	1.0	1.9	3.6	5.4	7.9	11.7	15.2
ASC-H (%)	0.0	0.1	0.2	0.4	0.6	1.1	1.5
AGC (%)	0.0	0.0	0.1	0.2	0.4	0.7	1.1
ASC/SIL	0.7	1.1	1.6	2.0	2.7	3.6	4.4

SurePath**							
Laboratory Percentile-Reporting Rate							
CATEGORY	5th	10th	25th	Median	75th	90th	95th

	0.0	0.0	0.2	0.4	0.8	1.2	1.6
LSIL (%)	0.2	0.5	1.0	2.2	3.0	4.3	5.9
HSIL (%)	0.0	0.0	0.2	0.3	0.5	1.0	1.4
ASC-US (%)	0.3	0.7	2.1	4.2	6.6	9.2	10.6
ASC-H (%)	0.0	0.1	0.1	0.3	0.5	0.8	1.3
AGC (%)	0.0	0.0	0.1	0.2	0.5	0.7	1.6
ASC/SIL	0.5	0.9	1.2	1.8	2.9	3.6	4.2

*Includes conventional annual test volume of >60.

**Includes SurePath and ThinPrep annual test volume of >300.

Evidence of Compliance:

- ✓ Records of statistical data for defined categories **AND**
- ✓ Records of data review and evaluation against benchmark data by the laboratory director or designee

****NEW** 12/26/2024**

CYP.07620 Statistical Records - Reflexed Gynecological Cytopathology

Phase I



For gynecologic cytopathology cases reflexed from primary HPV screening, statistical records are maintained and evaluated at least annually, and include the following:

- Number of primary HPV screening tests performed, if available
- Number of Paps reflexed from primary HPV screening
- Number of reflexed Paps reported by diagnosis for each specimen type (including the number reported as unsatisfactory for diagnostic interpretation)
- Number of cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison
- Number of cases where cytology and histology are discrepant
- Number of cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms
- Number of positive and negative p16/Ki67 dual stains performed.

NOTE: The data must be evaluated by the laboratory director or designee and included in the annual cytopathology statistical report.

If a p16/Ki67 dual stain is used as a follow-up to an HPV positive test with a negative Pap test, statistics should be maintained separate from p16/Ki67 dual stain results derived from a positive HPV screening test.

Evidence of Compliance:

- ✓ Records of statistical data for defined categories **AND**
- ✓ Records of data review and evaluation against benchmark data by the laboratory director or designee

CYP.07650 Statistical Records - Outliers

Phase I



If the laboratory's annual ASC/SIL ratio for gynecologic cases falls outside of the 5th or 95th percentiles, the laboratory determines and records the reason(s).

NOTE: The ASC/SIL ratio is useful for interlaboratory comparisons, because the number of ASC and SIL cases varies greatly between laboratories (eg, a private practice with very few HPV infections, a sexually transmitted disease clinic, and a dysplasia clinic). This ratio is one good indicator for the under- or over-interpretation of ASC.

For example, a laboratory with 9% ASC cases might appear to be over diagnosing ASC, since this is higher than the 75% percentile-reporting rate. However, if this same laboratory also has a SIL rate of 6.0%, the ASC/SIL ratio of 1.5 is close to the national median, and it can be concluded that this laboratory serves a high-risk population. A laboratory with 3.0% ASC cases and 0.75% SIL appears to show average ASC rates, but the ASC/SIL ratio of 4.0 is higher than the average laboratory.

The benchmarking data provided in CYP.07600 may not be applicable for laboratories that utilize primary HPV screening for a significant portion of cervical cancer screening.

CYP.07653 HR-HPV Records

Phase I

If available, records are maintained for high-risk human papillomavirus (HR-HPV) tests performed on ASC-US including:

1. Total number of HR-HPV tests performed on ASC-US cases
2. Total number of positive HR-HPV ASC-US cases

NOTE: The percentage of ASC-US cases with a positive HR-HPV result may be a helpful quality metric for both overall laboratory performance and individual performance of pathologists, especially when combined with an individual's ASC-SIL ratio. Data for other HR-HPV testing results (eg, co-testing with a Pap test in women > 30 years of age) may also be helpful quality metrics but should be kept separately.

****REVISED** 12/26/2024**

CYP.07655 Screening Performance

Phase II



The laboratory evaluates and records the ongoing performance of individuals who do cervicovaginal cytology screening against the overall statistics for the laboratory as a whole.

NOTE: Mechanisms can include evaluation of rescreening and interpretive discrepancies and detection rates for abnormalities. This includes screening performance of p16/Ki67 dual stain gynecologic slides.

CYP.07660 Diagnostic Discrepancies/Corrective Action

Phase II

There are records of each individual's diagnostic discrepancies, and corrective action taken.

NON-GYNECOLOGIC CYTOPATHOLOGY

CYP.07666 Unsatisfactory Specimens - Non-gynecologic Cytopathology

Phase II



The laboratory follows defined criteria for identification and reporting of unsatisfactory non-gynecologic specimens, as applicable.

NOTE: The cytopathology report must state the reason for an unsatisfactory specimen.

CYP.07670 Pathologist Slide and Report Review - Non-gynecologic Cytopathology

Phase II

All non-gynecologic slides are reviewed and the reports are signed by a qualified pathologist.

CYP.07675 Correlation of Results - Non-Gynecologic Cytopathology Phase II



Non-gynecologic cytopathology findings are correlated with histological and clinical findings, when appropriate.

NOTE: Correlation of all, or a subset of, non-gynecologic cytology specimens should be performed. Methods of correlation should be recorded in the laboratory procedure manual and selected reports can be reviewed to confirm practice. Possible mechanisms for correlation of histology include correlation of current specimens, focused review of specific specimen/organ types, and/or follow-up of suspicious/positive specimens. Possible clinical correlation mechanisms include additional review or testing based on clinical history or physical findings, review of radiologic findings, microbiology, flow cytometry, or other test results. Clinical correlation may be recorded in quality management records, problem logs, or in patient reports. There is a way to easily reference other material results for correlation and/or diagnosis.

Evidence of Compliance:

- ✓ Records of clinical correlation (eg, quality management records, problem logs, or in patient reports)

CYP.07685 Stains - Non-gynecologic Cytopathology Phase II

The Papanicolaou stain or another appropriate permanent stain is used for non-gynecologic specimens.

CYP.07692 Statistical Records - Non-gynecologic Cytopathology Phase II



For non-gynecologic cytopathology cases, statistical records are maintained and evaluated at least annually, and include the following:

- Total number of non-gynecologic cases examined
- Number of cases by diagnostic category
- Number of unsatisfactory/nondiagnostic cases, as applicable

NOTE: Sub-categorization of non-gynecologic specimen types (eg, urine, pleural fluid, peritoneal fluid, FNA) is at the discretion of the laboratory.

The definition of "unsatisfactory/nondiagnostic" for non-gynecologic cases must be defined by the laboratory. The specific diagnostic categories (eg, benign, atypical, malignant) are at the discretion of the laboratory. The CAP recommends following established guidelines, where available (eg, The Bethesda System for Reporting Thyroid Cytopathology).

Evidence of Compliance:

- ✓ Annual statistical records

PERSONNEL

For laboratories not subject to US regulations, national, state or provincial, and local personnel laws and regulations apply.

****REVISED** 12/26/2024**

CYP.07700 Section Director/Technical Supervisor - Cytopathology Phase II

The cytopathology laboratory has a qualified pathologist as the section director/technical supervisor.

NOTE: The section director/technical supervisor of the cytopathology laboratory must be a doctor of medicine or a doctor of osteopathy licensed to practice medicine in the jurisdiction in which the laboratory is located.

For laboratories subject to US regulations, the section director must also be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

Individuals qualified and serving as a technical supervisor for high complexity testing in a CLIA-certified laboratory as of December 28, 2024, may continue to fill this role if they have done so continuously since December 28, 2024.

If more stringent state or local regulations are in place for supervisory qualifications, including requirements for state licensure, they must be followed.

For laboratories not subject to US regulations, individuals must meet national, state or provincial, or local laws and regulations, and education must be equivalent to US qualifications.

Evidence of Compliance:

- ✓ Records of section director/technical supervisor qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field

****REVISED** 12/26/2024**

CYP.07800 Non-Supervisory Cytotechnologists

Phase II

All non-supervisory cytotechnologists meet at least one of the following qualifications.

1. Graduated from a school of cytotechnology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or
2. Certified in cytotechnology by a certification agency approved by HHS (eg, American Society of Clinical Pathology); or
3. Qualified and served as a cytotechnologist in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024*.

NOTE: If more stringent state or local regulations are in place for cytotechnologist qualifications, including requirements for state licensure, they must be followed.

For laboratories not subject to US regulations, individuals must meet national, state or provincial, or local laws and regulations, and education must be equivalent to US qualifications.

**Cytotechnologist personnel qualifications prior to December 28, 2024, may be found in the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.*

Evidence of Compliance:

- ✓ Records of qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field

CYP.07900 Screening Personnel

Phase II

All screening personnel satisfy one or more of the following three criteria.

1. Pathologist or physician qualified as section director or technical supervisor
2. Supervisory level cytotechnologist
3. Qualified cytotechnologist

Evidence of Compliance:

- ✓ Records of qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field

CYP.08100 General Supervisor Qualifications - Cytopathology

Phase II

The cytopathology laboratory has a general supervisor who meets the qualifications defined by CLIA (for laboratories subject to US regulations) and other applicable national, federal, state (or provincial), or local laws and regulations.

NOTE: The supervisor can be a pathologist boarded in anatomic pathology. Alternatively, the supervisor can be qualified as a cytotechnologist, with at least three years of full-time experience as a cytotechnologist within the preceding 10 years. The section director/technical supervisor may also serve as the general supervisor.

For laboratories not subject to US regulations, appropriate national, state or provincial, or local laws and regulations also apply.

Evidence of Compliance:

- ✓ Records of qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field

CYP.08200 General Supervisor Responsibilities Phase II



The cytopathology general supervisor fulfills defined responsibilities.

NOTE: The general supervisor, as designated by the laboratory/section director, is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This individual must also:

1. Be accessible to provide consultation to resolve technical problems
2. Record the slide interpretation results of each case he or she examined or reviewed
3. For each 24-hour period, record the total number of slides he/she examined (screened/rescreened) or reviewed, as well as ensuring the recording of the total number of slides evaluated by others
4. Record the number of hours he/she spent examining slides in each 24-hour period

For laboratories not subject to US regulations, appropriate national, state or provincial, or local laws and regulations also apply.

Evidence of Compliance:

- ✓ Written job description stating the duties of the general supervisor

CYP.08300 Cytotechnologist Responsibilities Phase II



The cytotechnologist fulfills defined responsibilities.

NOTE: The cytotechnologist is responsible for recording:

1. The slide interpretation results of each case examined or reviewed
2. For each 24-hour period, the total number of slides examined or reviewed in all laboratories
3. The number of hours spent examining slides in each 24-hour period

For laboratories not subject to US regulations, appropriate national, state or provincial, or local laws and regulations also apply.

Evidence of Compliance:

- ✓ Written job description stating the duties of the cytotechnologist

CYTOTOLOGY WORKLOAD

CYP.08450 Screening Workload - Laboratories Not Subject to US Regulations Phase II



Each individual screening cytology slides by manual microscopic technique examines no more than 100 gynecologic slides per 24 hours.

*NOTE: This checklist requirement applies only to laboratories NOT subject to US regulations.
The laboratory must comply with local regulations or laws if more stringent than this requirement.*

This maximum workload may be completed in no less than eight hours.

When automated screening instruments are used, laboratories should follow manufacturer's instructions to establish the maximum daily workload. In any case, the total daily workload may not exceed the equivalent of 100 slides undergoing full manual review (or the daily workload limit in the jurisdiction where the laboratory is located, if such limit is fewer than 100 slides).

For purposes of workload limits, gynecologic liquid-based slides must be counted as one slide.

CYP.08900 Screening Facility Phase II



All cytopathology screening is performed within the laboratory facility or an approved referral laboratory.

NOTE: Cytopathology screening must be performed within the laboratory facility or an approved referral laboratory to provide proper access to technical and professional supervision, pathologist consultation and a controlled working environment. For laboratories subject to US regulations, all cytopathology screening must be performed within a CLIA certified facility or equivalent.

PHYSICAL FACILITIES

CYP.09000 Adequate Space and Utilities Phase I

Space and utilities (water, electrical) are sufficient for processing cytologic material and for microscopic screening of slides.

LABORATORY SAFETY

The inspector should review relevant requirements from the Safety section of the Laboratory General Checklist to assure that the Cytopathology laboratory is in compliance. Please elaborate upon the location and the details of each deficiency in the Inspector's Summation Report.

CYP.09700 Infectious Waste Disposal Phase II



Potentially infectious tissues and other contaminated materials are safely stored and disposed of in compliance with all national, federal, state (or provincial), and local laws and regulations as well as hospital/organizational guidelines.

CYP.09910 Microwave Usage Phase I

Microwave devices are used in accordance with manufacturer's instructions.

CYP.09920 Microwave Monitoring Phase I

Microwave devices are monitored for reproducibility at least annually.

NOTE: Reproducibility is defined as consistency in diagnostic quality obtained from microwave equipment and procedures. For some devices, reproducibility may be evaluated by monitoring

the temperatures of identical samples after microwave processing. For those microwave devices (particularly those incorporated into histology processing equipment) that use temperature-independent methods to evaluate reproducibility, the reproducibility must be assessed following instrument manufacturer's instructions.

The microwave device must be tested for radiation leakage if there is visible damage to the device. A description of the specific damage along with the result of the test must be recorded.

Evidence of Compliance:

- ✓ Records of monitoring the diagnostic quality of specimens processed using microwaves

CYP.09930 Microwave Container Venting Phase I



All containers used in microwave devices are vented or are used in compliance with manufacturer's instructions for the microwave instrumentation used.

NOTE: Venting of containers is necessary so that processing occurs at atmospheric pressure, to prevent explosion. For procedures using pressure above that of the atmosphere, specialized containers must be used with strict adherence to manufacturer's instructions.

CYP.09940 Microwave Venting Phase I

Microwave devices are properly vented and the effectiveness of ventilation is monitored at least annually.

NOTE: Some types of microwave devices need to be operated in an appropriate ventilation hood to contain airborne chemical contaminants and potentially infectious agents. Before operation of the microwave device, flammable and corrosive reagents must be removed from the hood, to prevent fire or chemical damage to the electronic components of the device. Microwave devices used outside a fume hood must have an integral fume extractor certified by the manufacturer for use in a clinical laboratory.

This checklist item does not apply to microwave devices that are designed by the manufacturer to operate without venting. It also does not apply if only non-hazardous reagents (as defined in the safety data sheets) and non-infectious specimens (eg, paraffin specimens) are used in the device.

Evidence of Compliance:

- ✓ Records of annual evaluation of ventilation effectiveness