Disclaimer and Copyright Notice
On-site inspections are performed with the edition of the Checklists mailed to a facility at the completion of the application or reapplication process, not necessarily those currently posted on the website. The checklists undergo regular revision and a new edition may be published after the inspection materials are sent.

For questions about the use of the Checklists or Checklist interpretation, email accred@cap.org or call 800-323-4040 or 847-832-7000 (international customers, use country code 001).

The Checklists used for inspection by the College of American Pathologists' Accreditation Programs have been created by the CAP and are copyrighted works of the CAP. The CAP has authorized copying and use of the checklists by CAP inspectors in conducting laboratory inspections for the Commission on Laboratory Accreditation and by laboratories that are preparing for such inspections. Except as permitted by section 107 of the Copyright Act, 17 U.S.C. sec. 107, any other use of the Checklists constitutes infringement of the CAP’s copyrights in the Checklists. The CAP will take appropriate legal action to protect these copyrights.

All Checklists are ©2016. College of American Pathologists. All rights reserved.
# Cytopathology Checklist

## TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUMMARY OF CHANGES</td>
<td>4</td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td>6</td>
</tr>
<tr>
<td>GENERAL CYTOPATHOLOGY</td>
<td>6</td>
</tr>
<tr>
<td>INTERLABORATORY COMPARISONS</td>
<td>6</td>
</tr>
<tr>
<td>QUALITY MANAGEMENT</td>
<td>9</td>
</tr>
<tr>
<td>QUALITY CONTROL</td>
<td>10</td>
</tr>
<tr>
<td>SPECIMEN COLLECTION AND RECEIPT</td>
<td>10</td>
</tr>
<tr>
<td>CYTOLOGY STAINS AND SLIDE PREPARATIONS</td>
<td>11</td>
</tr>
<tr>
<td>ON-SITE MICROSCOPIC REVIEW</td>
<td>13</td>
</tr>
<tr>
<td>INSTRUMENTS AND EQUIPMENT</td>
<td>14</td>
</tr>
<tr>
<td>RECORDS AND REPORTS</td>
<td>14</td>
</tr>
<tr>
<td>RETENTION OF SLIDES</td>
<td>18</td>
</tr>
<tr>
<td>STATISTICAL RECORDS</td>
<td>19</td>
</tr>
<tr>
<td>GYNECOLOGIC CYTOPATHOLOGY</td>
<td>20</td>
</tr>
<tr>
<td>NON-GYNECOLOGIC CYTOPATHOLOGY</td>
<td>28</td>
</tr>
<tr>
<td>PERSONNEL</td>
<td>29</td>
</tr>
<tr>
<td>CYTOLOGY WORKLOAD</td>
<td>32</td>
</tr>
<tr>
<td>PHYSICAL FACILITIES</td>
<td>35</td>
</tr>
<tr>
<td>LABORATORY SAFETY</td>
<td>35</td>
</tr>
</tbody>
</table>
ON-LINE CHECKLIST AVAILABILITY

Participants of the CAP accreditation programs may download the checklists from the CAP website (www.cap.org) by logging into e-LAB Solutions. 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.

SUMMARY OF CHECKLIST EDITION CHANGES
Cytopathology Checklist
08/17/2016 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 listing of requirements below is from the Master version of the checklist. The customized checklist version created for on-site inspections and self-evaluations may not list all of these requirements.

NEW Checklist Requirements
None

REVISED Checklist Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>CYP.03366</td>
<td>08/17/2016</td>
</tr>
<tr>
<td>CYP.04300</td>
<td>07/28/2015</td>
</tr>
<tr>
<td>CYP.05300</td>
<td>07/28/2015</td>
</tr>
<tr>
<td>CYP.06475</td>
<td>08/17/2016</td>
</tr>
<tr>
<td>CYP.06600</td>
<td>08/17/2016</td>
</tr>
<tr>
<td>CYP.06900</td>
<td>08/17/2016</td>
</tr>
<tr>
<td>CYP.07100</td>
<td>07/28/2015</td>
</tr>
<tr>
<td>CYP.07530</td>
<td>08/17/2016</td>
</tr>
<tr>
<td>CYP.07600</td>
<td>07/28/2015</td>
</tr>
</tbody>
</table>

DELETED/MOVED/MERGED Checklist Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Effective Date</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>CYP.03333</td>
<td>07/27/2015</td>
</tr>
<tr>
<td>CYP.03700</td>
<td>07/27/2015</td>
</tr>
<tr>
<td>CYP.03900</td>
<td>07/27/2015</td>
</tr>
<tr>
<td>CYP.04700</td>
<td>07/27/2015</td>
</tr>
<tr>
<td>CYP.05257</td>
<td>07/27/2015</td>
</tr>
<tr>
<td>CYP.05285</td>
<td>07/27/2015</td>
</tr>
</tbody>
</table>
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 (e.g. "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.

Note for non-US laboratories: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist.

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 are actively involved with or 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.

If special techniques (such as immunohistochemistry) are performed in the Cytopathology laboratory, the appropriate checklist must be used to inspect those activities (e.g. for immunohistochemistry, the Immunohistochemistry section of 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. Participation in GYNECOLOGIC interlaboratory programs is required (Phase II), while participation in NON-GYNECOLOGIC programs is encouraged (Phase I).

Inspector Instructions:

- Sampling of interlaboratory comparison program policies and procedures
- Sampling of interlaboratory comparison program records including participation, retesting and remedial training, if applicable

- What type of remedial training do you provide when an individual has an unacceptable score on PT?

- Select an example of unacceptable interlaboratory comparison results (if applicable) and follow records from original testing to retesting and remedial training, if necessary. Determine if practice matches policies and procedures.

CYP.00125  PT Participation  Phase II

For laboratories subject to US regulations that perform gynecologic cytopathology, the laboratory and all individuals who examine gynecologic preparations participate in the CAP Gynecologic Cytology PT Program (PAP PT) or another proficiency testing program in gynecologic cytopathology approved by CMS.

NOTE: This checklist requirement applies only to US laboratories and other laboratories subject to CLIA regulations. Laboratories must maintain records of PT performance for at least 2 years. Records must be kept for each individual participating in annual PT, including identification of those who are retested; records of remedial training; records of imposition of limitations on slide examination; and records of re-examination of slides, as required by CLIA.

Evidence of Compliance:
- Written procedure describing handling of PT failures (may include retesting, remedial training, and imposition of limitations on slide examination) AND
- Records that the laboratory is enrolled and all currently employed personnel have successfully completed PT AND
- Records of retesting, remedial training and imposition of limitations, if applicable AND
- Records of notification to the PT provider and CMS for any PAP testing personnel who left employment prior to completion of annual PT

REFERENCES

CYP.00150  Educational Participation  Phase I

For laboratories subject to US regulations that perform gynecologic cytopathology, the laboratory participates in the educational component of the CAP Gynecologic Cytology PT Program (PAP PT) or another educational peer-comparison program in gynecologic cytopathology.

NOTE: Interlaboratory comparison programs in cytopathology provide valuable educational opportunities for peer performance comparisons in both technical and diagnostic arenas.

While not completely emulating cervicovaginal cytopathologic preparation and interpretation,
participation in the PAP program enables a laboratory to compare its performance to benchmarks derived from a database of peer laboratories.

Evidence of Compliance:
✓ Records such as CAP order form, purchase order AND records of completed/submitted results indicating that the laboratory is participating in the educational component of the CAP PAP PT program OR
✓ Records of enrollment/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

REFERENCES
4) Bonfiglio TA, Somark TM. ASCP educational and proficiency testing programs in cytopathology. Lab Med. 1994;25:245-247
6) Nielsen ML. Cytopathology laboratory improvement programs of the College of American Pathologists. Laboratory accreditation program (CAP LAP) and performance improvement program in cervicovaginal cytology (CAP PAP). Arch Pathol Lab Med. 1997;121:256-259

CYP.00170 Educational Participation

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 such as CAP order form, purchase order AND records of completed/submitted results indicating that the laboratory is participating in the educational component of the CAP PAP PT program OR
✓ Records of enrollment/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

REFERENCES
4) Bonfiglio TA, Somark TM. ASCP educational and proficiency testing programs in cytopathology. Lab Med. 1994;25:245-247
6) Nielsen ML. Cytopathology laboratory improvement programs of the College of American Pathologists. Laboratory accreditation program (CAP LAP) and performance improvement program in cervicovaginal cytology (CAP PAP). Arch Pathol Lab Med. 1997;121:256-259

CYP.00190 Educational Participation Phase I

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

Evidence of Compliance:
- Records such as CAP order form, purchase order AND records of completed/submitted results indicating that the laboratory is participating in the educational component of the CAP NGC program OR
- Records of enrollment/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).

Inspector Instructions:
- How are disparities between histological and cytological findings addressed?
- Under what circumstances do you issue a corrected, addendum, or amended report?

CYP.01650 Cytopathology Exclusion Phase I

There is a policy that lists specimens that an institution may choose to exclude from routine submission to the cytology department for examination.

NOTE: This policy should 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.

This checklist item is not applicable if 1) All specimens are submitted to pathology, or 2) The laboratory is not part of an institution that provides cytologic services.
(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.

Evidence of Compliance:
✓ Written procedure defining significant disparities and the process for resolving disparities in histological/cytological findings

CYP.02100 Consultation Report Retention Phase I

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

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

Evidence of Compliance:
✓ Written retention policy

REFERENCES

QUALITY CONTROL

SPECIMEN COLLECTION AND RECEIPT

Inspector Instructions:

**REVISED** 08/17/2016

**CYP.03366 FNA Error Prevention Phase II**

If the pathologist performs FNA procedures, there is a written procedure to verify patient identification using at least two patient identifiers, the procedure site, and the procedure to be performed.

REFERENCES
CYP.03800  Physician Notification  Phase II

There is evidence that submitting physicians are notified when unacceptable specimens are received.

Evidence of Compliance:
✓ Records of physician notification (e.g. follow-up correspondence, records of telephone calls or written reports)

REFERENCES

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 is maintained.

NOTE: Records might include a note in the medical record or in the final report.

CYTOLOGY STAINS AND SLIDE PREPARATIONS

Inspector Instructions:

READ
• Records of annual assessment of stain quality
• Sampling of stain policies and procedures
• Sampling of records of daily review of technical quality of cytologic preparations with corrective action of unacceptable stain quality

OBSERVE
• Sampling of stains (labeling)
• Sampling of slides (labeling)

ASK
• How do you assess the quality of cytopathology stains?
• Who performs the daily review of the quality of cytological preparations?
• What is your course of action when stain quality is unacceptable?
• How frequently do you change stains? Under what circumstances do you filter stains?
• How do you assign expiration dates for laboratory-prepared stains and solutions? If you extend expiration dates, how do you do so?

DISCOVER
• Scan several slides; check stain quality and labeling. Ensure that stain quality is acceptable.

CYP.03925  Stain Assessment  Phase I

Cytology stains are assessed at least annually to ensure their proper storage and acceptable quality.
NOTE: Most stains used in the cytology laboratory are not subject to outdating, so that assignment of expiration dates may have no meaning. The acceptable performance of such stains should be confirmed at least annually by technical assessment on actual case material, and as part of the evaluation of cytopathology cases. Cytology stains undergoing a daily technical quality review are exempt from an annual assessment. Where applicable, expiration dates assigned by a manufacturer must be observed.

Evidence of Compliance:
✓ Written procedure for stain assessment AND
✓ Records of assessment of appropriate quality of each cytology stain in use

CYP.04100 Staining Solutions Phase II

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

REFERENCES

CYP.04150 Cross-Contamination Phase I

There is a written procedure to prevent cross-contamination of specimens during processing and staining.

NOTE: Procedures must prevent cross-contamination between gynecologic and non-gynecologic specimens.

Also, procedures must prevent contamination among non-gynecologic cases when highly cellular specimens are processed. Methods to minimize this potential problem may include cytocentrifuge, filter, 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. One procedure to detect possible contamination is to insert a clean blank slide in each staining run and examine it for contamination.

REFERENCES

**REVISED** 07/28/2015

CYP.04300 Daily QC Phase II

There are records of daily review of the technical quality of cytologic preparations by the pathologist or supervisory-level cytotechnologist.

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 cytopins, 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.

REFERENCES
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 five-year retention period for gynecologic and non-gynecologic slides and 10 years for fine needle aspiration slides.

Inspector Instructions:

- Review a randomly selected representative sample of 10-15 cases using the table below to guide selection:

<table>
<thead>
<tr>
<th>Gynecologic Cases</th>
<th>Non-Gynecologic Cases (including FNA's)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsatisfactory</td>
<td>Negative for malignancy / Reactive</td>
</tr>
<tr>
<td>Negative for intraepithelial lesion or malignancy (NILM) / Repair</td>
<td>Atypical or suspicious with qualifiers / Suspicious for malignancy / Positive for malignancy</td>
</tr>
<tr>
<td>Atypical squamous cells</td>
<td></td>
</tr>
<tr>
<td>LSIL (encompassing HPV)</td>
<td></td>
</tr>
<tr>
<td>HSIL / Carcinoma</td>
<td></td>
</tr>
</tbody>
</table>

Cases should be selected by the laboratory pathologist and/or cytopathology supervisor in a random manner defined by the inspecting Team Leader (e.g. the first 1-3 negative and abnormal cases in each specimen category from a certain date or week). The following are core elements of the on-site review:

- Evaluate slides for quality of technical preparation and specimen adequacy
- Determine if significant cells have been identified
- Compare slides with the diagnostic report for completeness and clarity of diagnostic terminology
- Determine if the information provided with the requisition and included in the diagnostic report is complete and appropriate

If, during the on-site review, there is believed to be a significant diagnostic discrepancy, this should be discussed by the pathologist team leader with the laboratory director. Interpretations may be considered discrepant if there is a significant diagnostic difference in interpretation. An example of this would be an interpretation of Negative for Intraepithelial Lesion/Malignancy, vs. an interpretation of LSIL or greater. Cases considered to be “ASC/AGC” (either by the Inspector or inspectee) should not be included in the analysis to determine significant discrepancies, because of the current lack of interlaboratory reproducibility of these interpretations.
CYP.04900  Cellular/Nuclear Detail  Phase II

Cellular and nuclear detail are sufficient for proper interpretation.

CYP.05000  On-Site Slide Review  Phase II

The findings from the on-site slide review were free of any issues or any significant diagnostic discrepancies as defined in the above note.

**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.*

**Inspector Instructions:**

- How does your laboratory perform ongoing monitoring of screening instrumentation? What corrective action is taken when tolerance limits are exceeded?
- How do you identify slides that have not successfully been processed by the automated screening instrument?
- Follow a slide through automated staining, cover-slipping and automated screening. Determine if practice matches procedure.

CYP.05292  Unsuccessful Slide Processing  Phase II

The laboratory has a written procedure for the handling of slides that are not successfully processed by an 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

**RECkORDS AND REPORTS**

**Inspector Instructions:**

- Sampling of reporting policies and procedures
- Sampling of patient reports
**REVISED** 07/28/2015

CYP.05300 Result Reporting

The cytopathology report includes all of the following required 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 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.

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

REFERENCES
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 2003(Jan 24):3713 [42CFR493.1291(c)(1-6) and (k)(1,2)]

CYP.05316 Pathologist Identification on Report

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 (e.g. 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 (e.g. 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
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 (e.g. the 10% rescreen of gynecologic cytopathology cases).

REFERENCES

CYP.05350 Report Elements

The cytopathology report includes all of the following desirable elements.

1. Date specimen received/accessioned by the laboratory
2. Description of specimen on receipt (e.g. bloody fluid)
3. Designation of automated screening device, when applicable

NOTE: Description of specimens on receipt should indicate the type of specimen received. Examples include the number of glass slides submitted and how fixed (e.g. air-dried or alcohol-fixed); quantity of fluid and fixation (e.g. 10 cc bloody fluid in alcohol); Thin Prep vial; SurePath vial; brush in 10 cc clear yellow fluid, etc.

CYP.06100 Report - Morphologic Findings

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, as the case may be. When a definite diagnosis cannot be rendered (i.e. 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 cytopathology reports). The use of diagnostic “classes” is not recommended, as it does not reflect current understanding of neoplasia, has no comparable equivalent in diagnostic histopathologic terminology, and does not provide for diagnosis of non-neoplastic conditions.

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 (i.e. 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:
✓ Written procedure defining criteria for reporting morphologic findings

REFERENCES
2) Solomon D, Nayar, R, eds. The Bethesda System for Reporting Cervical Cytology; Definitions, Criteria, and Explanatory Notes. 2nd ed., 2004
CYP.06450 Significant/Unexpected Findings Phase II

There is a policy regarding the communication, and recording thereof, of significant and unexpected cytopathology findings.

NOTE: Certain cytopathology diagnoses may be considered particularly significant and unexpected. For example, such diagnoses may include invasive carcinoma found in a cervicovaginal specimen, malignancy in an effusion with no patient history of neoplasm etc. There should be a reasonable effort to ensure that such diagnoses are received by the clinician, by means of telephone, pager, or other system of notification. There must be records of the date of these communications.

Diagnoses to be defined as "significant and unexpected," should be determined by the cytopathology department, in cooperation with local clinical medical staff.

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

Evidence of Compliance:
✓ Records of communication of significant/unexpected findings

**REVISED** 08/17/2016
CYP.06475 Amended Reports Phase II

Amendments to reports that would significantly affect patient care are reported promptly to the responsible clinician(s).

NOTE: Records of notification must include date and person notified, and preferably appear in the amended report. Periodic evaluation of amended reports is commonly included as part of the quality management program.

The format of amended reports is at the discretion of the laboratory.

**REVISED** 08/17/2016
CYP.06600 Report Retention Phase II

Cytopathology reports are retained for at least 10 years.

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

Since a five-year "look-back" period is required when there is a newly identified abnormality in cervical cytopathology, non-computerized laboratories may wish to retain gynecologic cytopathology accession records for five years.

Evidence of Compliance:
✓ Written record retention policy

REFERENCES

CYP.06800 Cross-Index Phase II

A cross-index with histological material is maintained.

CYP.06850 Correlation of Results - Non-Gynecologic Phase II
For non-gynecologic cases, there is a written procedure for the correlation of the results of specialized studies (e.g. molecular studies, immunocytochemistry) with the cytologic diagnosis.

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.

Evidence of Compliance:
✓ Written procedure for correlation of specialized studies with cytologic diagnoses

**RETENTION OF SLIDES**

Inspector Instructions:

- Sampling of slide handling policies and procedures
- Slide storage area (organized, accessible, slides easily retrieved)
- For slides retained for different periods of time, how does your laboratory ensure that the slides are retained for the defined time period?
  - If using off-site storage, how do you ensure that slides are stored appropriately?

**REVISED** 08/17/2016
CYP.06900 Slide Retention Phase II

All glass slides are retained for an appropriate period.

NOTE: Minimum requirements for cytopathology laboratories, providing these are not less stringent than state, regional, or national regulations, are:

1. Gynecologic and non-gynecologic glass slides - five years
2. Fine needle aspiration glass slides - 10 years

Cell blocks must be retained for at least the same period as glass slides. Please refer to the Anatomic Pathology Checklist requirement ANP.12500 for guidelines on the release of cell blocks for research purposes.

Retained slides are both a resource for the patient and a medical record. Laboratories may utilize archived slides for the benefit of the patient, even if that use destroys the slide. It is recommended that the laboratory policy on material and record retention authorize the destruction of a retained slide for diagnostic purposes.

Evidence of Compliance:
✓ Written retention policy

REFERENCES


**REVISED** 07/28/2015

**CYP.07100 Slide Storage** Phase II

**Slides are stored in a manner that ensures preservation and accessibility.**

**NOTES:**
1. There must be a written procedure to protect and preserve stored slides
2. Stored slides must be organized to permit timely retrieval when slides are needed for review or upon request from an inspector
3. Cytopathology slides should be stored at room temperature for optimal preservation

**REFERENCES**

**CYP.07200 Specimen Tracking** Phase II

**There is a written procedure to ensure the proper handling and recording of the use, circulation referral, transfer and receipt of original slides to ensure availability of materials 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

**REFERENCES**

**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.**

**REFERENCES**


**STATISTICAL RECORDS**

**Inspector Instructions:**
- Statistical reporting policy
- Statistical records and annual summary

**CYP.07400 Statistical Records** Phase II

**Statistical records are maintained, and evaluated at least annually, that include the number of cytopathologic specimens and type/sources of specimens.**
NOTE: At a minimum, the laboratory should divide cytology cases into two categories: gynecologic and non-gynecologic cases.

REFERENCES

**GYNECOLOGIC CYTOPATHOLOGY**

**Inspector Instructions:**

- Sampling of gynecologic cytopathology policies and procedures
- Sampling of patient reports for pathologist review and interpretation of specific screening diagnoses
- Sampling of 10% rescreening records
- Sampling of records of retrospective review and evidence of amended reports, if applicable
- Statistical records including evidence of annual review and investigation when the laboratory falls outside the 5th or 95th percentiles
- Records of employee participation monitoring including individual's discrepancies and corrective action

- Use of Papanicolaou stain

- What criteria are used to identify rejected or unsatisfactory specimens?
- What is the laboratory's process for follow-up or investigation of significant results?
- What is your course of action when you are unable to obtain histological reports or material when reporting gynecologic cases with HSIL?
- What is your process for correlating gynecologic cytopathology findings with clinical information?
- How do you educate providers that the Pap test is a screening test with false negative results?
- What is the process for performance monitoring of cytotechnologists?

- Follow a slide through automated staining, cover-slipping and automated screening. Determine if practice matches procedure.
- Review records or specimen log for unsatisfactory specimens. Determine if the quality of the specimens follows defined criteria.
- Review a sampling of rescreening records. Determine if the rescreening was performed by a qualified individual, results are not reported until the rescreen is complete and a minimum of 10% of cases for each screener are rescreened.

**Papanicolaou Stain**

The Papanicolaou stain is used for gynecologic specimens.

REFERENCES
There are written criteria for categorizing a gynecologic specimen as unsatisfactory.

**NOTE:** Gynecologic specimens with atypical cells are always "satisfactory," although the report may include comments on the quality of the preparation.

**REFERENCES**
4) Selvaggi SM. Is it time to revisit the classification system for cervicovaginal cytology? Arch Pathol Lab Med. 1999;123:993-994
8) Selvaggi SM. Is it time to revisit the classification system for cervicovaginal cytology? Arch Pathol Lab Med. 1999;123:993-994

**All gynecologic slides in the following categories are interpreted by the pathologist.**

1. Malignant or suspicious for malignancy
2. Low and high-grade squamous intraepithelial lesions
3. Atypical squamous cells
4. Atypical glandular cells
5. Reactive or repair

**REFERENCES**
3) Selvaggi SM. Is it time to revisit the classification system for cervicovaginal cytology? Arch Pathol Lab Med. 1999;123:993-994

**At least 10% of each cytotechnologist's gynecologic cases that have been interpreted to be negative are rescreened.**

**NOTE:** The 10% rescreening is a CLIA requirement, and only applicable to US laboratories and other laboratories subject to those regulations. An individual who qualifies as a cytotechnologist supervisor and who performs initial screening must also have a minimum of 10% of his or her cases that are initially interpreted as negative subjected to rescreening. This rescreening must include some cases from high-risk patients, based upon criteria established by the laboratory director, as well as random negative cases. Cases screened by MDs or DOs who are certified in Anatomic Pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, or who possess qualifications that are equivalent to those required for the above certifications are not subject to this rescreening requirement. If FDA-approved automated instruments are used for quality control rescreening case selection, the laboratory must ensure that the methods used meet the requirements of CLIA, and that manufacturer and FDA recommendations for quality control are followed.

Slides must be rescreened in their entirety, including slides processed by imaging instruments that select a limited number of microscopic fields for examination by the cytotechnologist.
Evidence of Compliance:
✓ Written rescreening policy defining the qualifications of the individual to perform rescreening and the criteria for case selection AND
✓ Records of rescreened cases with comparison to original screening results

REFERENCES

CYP.07480 Rescreening or Prescreening Negative Cases
Phase II

For laboratories not subject to US regulations, the competency of each screener of gynecologic cytopathology specimens is assessed by either a pre-screening or rescreening process.

NOTE: Laboratories not subject to US regulations may follow the US requirement or may use an alternative procedure. Laboratories subject to US regulations are required to rescreen 10% of each cytotechnologist’s gynecologic cases that have been interpreted to be negative, including some cases from high-risk patients, based upon criteria established by the laboratory director, as well as random negative cases. Alternative procedures for 10% rescreening could include, but are not limited to a rapid rescreening of all cases or rapid prescreening of all cases with targeted rescreening of discrepant cases. Slides must be rescreened or prescreened in their entirety, including slides processed by imaging instruments that select a limited number of microscopic fields for examination.

Evidence of Compliance:
✓ Written rescreening or prescreening policy defining the method to be used for rescreening or prescreening and the criteria for case selection AND
✓ Records of rescreened or prescreened cases with comparison to final comprehensive screening results

CYP.07491 Result Reporting
Phase II

The results of gynecologic cases selected for rescreening are not reported until the rescreen is complete.

Evidence of Compliance:
✓ Written policy prohibiting reporting of patient results prior to rescreen

REFERENCES

CYP.07504 Rescreener Qualifications
Phase II

The rescreening of negative gynecologic cases is performed by an individual qualified as a cytopathology supervisor (see CYP.08100).

Evidence of Compliance:
✓ Records of section director/technical supervisor or supervisor/general supervisor qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field for each individual performing rescreening

REFERENCES

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.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. Fed Register. 2003(Jan 24):5232 [42CFR493.1274(c)(3)]

**REVISED** 08/17/2016

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:
✓ Written policy defining conditions under which an amended report must be issued following retrospective review

REFERENCES
2) Freedman LF. Implications of mandating amended reports following retrospective review of Papanicolaou smears. Arch Pathol Lab Med. 1997;121:299-300

CYP.07543 Result Correlation  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. The number of cases that have histologic correlation should be recorded.

REFERENCES

CYP.07556 Additional Reports/Material Unavailable 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 (e.g. follow-up correspondence, telephone calls, or requests included in the report)

REFERENCES

CYP.07569 Correlation of Results - Gynecology Cytopathology Phase II

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

NOTE: Methods of clinical correlation should be written in the laboratory procedure manual, and selected reports can be reviewed to confirm practice. Possible mechanisms may 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 (e.g. policies, problem logs with resolution, or notes in reports)

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 2003(Jan 24);7169 [42CFR493.1274(c)(2)]

CYP.07582 Pap Test - False Negative Notification Phase I

There is a mechanism to educate providers of cervicovaginal specimens that the Pap test is a screening test for cervical cancer with inherent false negative results.

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

REFERENCES
1) Robb JA. The Pap smear is a cancer screening test: why not put the screening error rate in the report? Diagn Cytopathol. 1993;9:485-486

**REVISED** 07/28/2015
CYP.07600 Statistical Records Phase II
For gynecologic cytopathology cases, statistical records are maintained of the number of cases of the following cytopathology results.

1. Diagnostic category (including unsatisfactory cases), by preparation type
2. Significant cytologic/histologic discrepancies (as defined by laboratory policy)
3. Total number of negative cases rescreened before sign-out
4. Cases for which the rescreen resulted in reclassification as premalignant or malignant
5. Cases for which histopathology results are available to compare with malignant or high-grade squamous intraepithelial lesion (HSIL) cytopathology results

NOTE: The data must be evaluated by the laboratory 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. The benchmarking data listed below were collected in 2013.

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 2.0% in the table) for the ThinPrep LSIL category means that a quarter of laboratories have LSIL rates of 2.0% or less. A 90th percentile-reporting rate (which corresponds to 10.3% in the table) for ASC-US in ThinPrep preparations means that 9 of 10 laboratories have an ASC-US rate of 10.3% 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 2.0 for conventional Paps, 1.8 for ThinPrep® and 1.7 for SurePath.

*Includes conventional annual test volume of >180.

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

<table>
<thead>
<tr>
<th>CONVENTIONAL*</th>
<th>Laboratory Percentile-Reporting Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>CATEGORY</td>
<td>5th</td>
</tr>
<tr>
<td>Unsatisfactory (%)</td>
<td>0.0</td>
</tr>
<tr>
<td>LSIL (%)</td>
<td>0.0</td>
</tr>
<tr>
<td>HSIL (%)</td>
<td>0.0</td>
</tr>
<tr>
<td>ASC-US (%)</td>
<td>0.2</td>
</tr>
<tr>
<td>ASC-H (%)</td>
<td>0.0</td>
</tr>
<tr>
<td>AGC (%)</td>
<td>0.0</td>
</tr>
<tr>
<td>ASC/SIL</td>
<td>0.4</td>
</tr>
</tbody>
</table>
### ThinPrep** Laboratory Percentile-Reporting Rate

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>5th</th>
<th>10th</th>
<th>25th</th>
<th>Median</th>
<th>75th</th>
<th>90th</th>
<th>95th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsatisfactory (%)</td>
<td>0.3</td>
<td>0.4</td>
<td>0.8</td>
<td>1.3</td>
<td>2.1</td>
<td>3.4</td>
<td>4.3</td>
</tr>
<tr>
<td>LSIL (%)</td>
<td>1.1</td>
<td>1.4</td>
<td>2.0</td>
<td>2.7</td>
<td>3.6</td>
<td>4.7</td>
<td>5.5</td>
</tr>
<tr>
<td>HSIL (%)</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
<td>0.4</td>
<td>0.7</td>
<td>1.1</td>
<td>1.4</td>
</tr>
<tr>
<td>ASC-US (%)</td>
<td>2.1</td>
<td>2.7</td>
<td>3.9</td>
<td>5.4</td>
<td>7.5</td>
<td>10.3</td>
<td>12.5</td>
</tr>
<tr>
<td>ASC-H (%)</td>
<td>0.0</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
<td>0.5</td>
<td>0.8</td>
<td>1.0</td>
</tr>
<tr>
<td>AGC (%)</td>
<td>0.0</td>
<td>0.0</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
<td>0.5</td>
<td>0.9</td>
</tr>
<tr>
<td>ASC/SIL (%)</td>
<td>0.8</td>
<td>0.9</td>
<td>1.4</td>
<td>1.8</td>
<td>2.5</td>
<td>3.2</td>
<td>3.8</td>
</tr>
</tbody>
</table>

### SurePath*** Laboratory Percentile-Reporting Rate

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>5th</th>
<th>10th</th>
<th>25th</th>
<th>Median</th>
<th>75th</th>
<th>90th</th>
<th>95th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsatisfactory (%)</td>
<td>0.0</td>
<td>0.1</td>
<td>0.1</td>
<td>0.3</td>
<td>0.5</td>
<td>0.7</td>
<td>1.0</td>
</tr>
<tr>
<td>LSIL (%)</td>
<td>1.1</td>
<td>1.4</td>
<td>2.0</td>
<td>2.8</td>
<td>3.5</td>
<td>4.7</td>
<td>6.2</td>
</tr>
<tr>
<td>HSIL (%)</td>
<td>0.1</td>
<td>0.1</td>
<td>0.2</td>
<td>0.4</td>
<td>0.6</td>
<td>0.9</td>
<td>1.2</td>
</tr>
<tr>
<td>ASC-US (%)</td>
<td>1.9</td>
<td>2.4</td>
<td>3.7</td>
<td>5.0</td>
<td>6.9</td>
<td>9.2</td>
<td>11.5</td>
</tr>
<tr>
<td>ASC-H (%)</td>
<td>0.0</td>
<td>0.1</td>
<td>0.1</td>
<td>0.3</td>
<td>0.4</td>
<td>0.6</td>
<td>0.9</td>
</tr>
<tr>
<td>AGC (%)</td>
<td>0.0</td>
<td>0.1</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
<td>0.6</td>
<td>0.7</td>
</tr>
<tr>
<td>ASC/SIL (%)</td>
<td>0.7</td>
<td>0.9</td>
<td>1.3</td>
<td>1.7</td>
<td>2.2</td>
<td>2.7</td>
<td>3.3</td>
</tr>
</tbody>
</table>

### 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

### REFERENCES


### 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 (e.g. 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.

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 (e.g. co-testing with a Pap test in women > 30 years of age) may also be helpful quality metrics but should be kept separately.

REFERENCES

CYP.07655 Screening Performance

Phase II

The laboratory has a written system to evaluate and record 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.

For laboratories subject to US regulations, this applies to both cytotechnologists and pathologists who do primary cervicovaginal specimen screening.

(Pathologists who do primary cervicovaginal specimen screening are exempted from the 10% rescreen of negative cases.)

REFERENCES

CYP.07660 Diagnostic Discrepancies/Corrective Action

Phase II

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

REFERENCES
NON-GYNECOLOGIC CYTOPATHOLOGY

Inspector Instructions:

- Sampling of non-gynecologic cytopathology policies and procedures
- Sampling of patient reports for pathologist review and signature
- What procedures are in place to prevent cross-contamination during staining?
- What is your process for correlating non-gynecologic cytopathology findings with histological and clinical information?

CYP.07670  Pathologist Responsibility

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

REFERENCES

CYP.07675  Correlation of Results - Non-Gynecologic Cytopathology

An effort is made to correlate non-gynecologic cytopathology findings with histological and clinical findings.

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.

Evidence of Compliance:
✓ Records of clinical correlation (e.g. quality management records, problem logs, or in patient reports)

REFERENCES

CYP.07685  Stains - Non-Gynecologic

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

REFERENCES
PERSONNEL

For laboratories not subject to US regulations, local, regional and national personnel regulations apply.

Inspector Instructions:

- Section director's/technical supervisor's qualifications and job description
- Supervisor's/general supervisor's qualifications and job description
- Cytotechnologist's qualifications and job description

CYP.07700  Section Director/Technical Supervisor  Phase II

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

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

REFERENCES


CYP.07800  Non-Supervisory Personnel  Phase II

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

1. Graduated from an Accrediting Bureau of Health Education Schools (ABHES) accredited school of cytotechnology or other organization approved by Health and Human Services (HHS); or
2. Certified in cytotechnology by a certification agency approved by HHS (e.g. American Society of Clinical Pathology); or
3. Before September 1, 1992, have successfully completed two years in an accredited institution (12 semester hours in science, eight of which are in biology) and have 12 months training in an approved school of cytotechnology; or have received six months formal training in an approved school and six months full-time experience; or
4. Before September 1, 1992, have achieved a satisfactory grade in an HHS proficiency test for cytotechnologists
5. Before September 1, 1994, have two years full-time experience or equivalent within the preceding five years examining slides under the supervision of a physician certified in pathology and before January 1, 1969, be a high school graduate with six months cytotechnology training in a laboratory directed by a physician and completed two years fulltime supervised experience in cytotechnology before 1/1/69; or
6. On or before September 1, 1994, have two years full-time experience or equivalent within preceding five years in the US and on or before September 1, 1995, have either graduated from a CAHEA-approved school or be certified as a cytotechnologist
NOTE: For non-US laboratories, education, experience, and/or certification qualifications must meet those of the country in which the laboratory is located, or be equivalent to US qualifications.

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

REFERENCES

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

REFERENCES

CYP.08100 Supervisor/General Supervisor Phase II

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

NOTE: The section director/technical supervisor may serve as the supervisor/general supervisor. 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. For non-US laboratories, appropriate local, regional or national 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

REFERENCES

CYP.08200 Supervisor/General Supervisor Responsibilities Phase II

The cytopathology supervisor/general supervisor fulfills defined responsibilities.

NOTE: The supervisor/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 non-US laboratories, appropriate local, regional or national regulations also apply.

Evidence of Compliance:
✓ Written job description stating the duties of the supervisor/general supervisor

REFERENCES

CYP.08300  Cytotechnologist Responsibilities  Phase II

Cytotechnologist Responsibilities

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 non-US laboratories, appropriate local, regional or national regulations apply.

Evidence of Compliance:
✓ Written job description stating the duties of the cytotechnologist

REFERENCES
# CYTOLOGY WORKLOAD

## Inspector Instructions:

**READ**

- Workload reporting policies and procedures
- Policy for setting individual workload limits
- Sampling of workload recording records for all individuals (cytotechnologists and pathologists) performing primary screening and for automated screening instruments
- Sampling of personnel assessments for the setting of workload limits

**OBSERVE**

- Workload recording practices in screening area, including computerized and manual recording systems

**ASK**

- What criteria does your laboratory use when evaluating individual cytology workload limits?
- Describe your workload recording process
- How often are workload recording limits exceeded?
- If employees screen slides at other laboratories on days when screening is performed, how is it captured in the laboratory’s workload recording?
- What type of action is taken when there is a workload violation?

**DISCOVER**

Select random examples of workload recording logs for each primary screener (pathologists and cytotechnologists)

- Determine if the records include the number of slides screened and the amount of time spent screening, including slides screened at other laboratories
- Confirm that daily workload is counted and calculated correctly
- Identify if workload is within the established workload limits for each screener (not to exceed 100 slides/day)
- For cytotechnologists, confirm that gynecologic (including 10% rescreen and five year look-back cases) and non-gynecological slides are included

If problems are identified with workload violations, further evaluate the laboratory’s records to determine if actions taken were effective and consistent with laboratory policy.

Select a sampling of automated screening records and follow examples requiring a full manual review to evaluate the workload recording.

---

**CYP.08400 Screening Workload - US Laboratories**

There are sufficient qualified personnel available to handle the volume and variety of cytopathology cases submitted to the laboratory.

*NOTE: While the 100 slide/24-hour limit must never be exceeded, the CAP does not rely solely upon this specific workload limit because: a) the type of case material varies among laboratories; b) the number of cases that may be accurately reviewed by individual screening personnel differs; and c) such personnel may perform other duties. The Inspector should carefully evaluate*
these factors together with applicable quality control and quality management data when judging the adequacy of cytopathology laboratory staffing.

Evidence of Compliance:
✓ Records of workload screening for each individual

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. Fed Register. 2003(Jan 24):5232 [42CFR493.1274(d)]
2) Kline TS. The challenge of quality improvement with the Papanicolaou smear. Arch Pathol Lab Med. 1997;121:253-255

CYP.08450 Screening Workload - Non-US Laboratories 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.08500 Manual Screening - US Laboratories Phase II

There is a written workload policy for the manual screening of cytology slides, with evidence of data recording.

NOTE: This checklist requirement applies only to laboratories subject to US regulations. The final rule implementing CLIA requires that each individual evaluating cytology preparations by manual microscopic technique must examine no more than 100 slides (gynecologic and non-gynecologic or both) in 24-hours. Gynecologic slides include new routine slides, 10% rescreen slides, and five-year look-back negative slides. Records must be maintained showing the total number of slides examined by each individual during each 24-hours.

For primary screening of non-gynecologic liquid-based slide preparations, each slide may be counted as one-half slide for the purpose of workload recording, provided that cells are dispersed over one-half or less of the total available slide area.

For primary screening of all other slide types (including gynecologic liquid-based preparations), each slide must be counted as a single slide for the purpose of workload recording.

The maximum workload of 100 slides can be completed in no less than an eight-hour workday. These total limits apply regardless of the number of laboratories in which an individual works on a given day. For employees working less than eight hours at an individual laboratory, this workload maximum must be prorated according to the formula: number of hours spent screening X 100/8.

Additional responsibilities must be considered when evaluating workload.

Pathologists who screen previously unscreened gynecologic slides and non-gynecologic slides (including FNA direct smears) must adhere to and record the above workload limit.

The following are not subject to the workload limit for pathologists:
1. Previously screened reactive/repair, atypical, premalignant and malignant gynecologic slides
2. Rescreened five-year look-back slides
3. 10% rescreen of negative gynecologic slides
4. Previously screened non-gynecologic and FNA slides
5. FNA slides evaluated solely for the purpose of adequacy

**Evidence of Compliance:**
✓ Records of workload recording for each individual

**REFERENCES**
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. Fed Register. 2003(Jan 24):5232 [42CFR493.1274(d)]
2) Kline TS. The challenge of quality improvement with the Papanicolaou smear. Arch Pathol Lab Med. 1997;121:253-255

**CYP.08550 Automated Screening - US Laboratories**

**Phase II**

If applicable, there is a written workload policy for the automated screening of cytology slides, with evidence of data recording.

**NOTE:** This checklist requirement applies only to laboratories subject to US regulations. Workload calculations may vary with the use of automated screening instruments. Laboratories must assure that CLIA requirements are fulfilled, in addition to following workload calculations as defined in the 07/27/10 FDA alert - How Laboratorians Can Safely Calculate Workload for FDA-Approved Semi-Automated Gynecologic Cytology Screening Devices. This FDA alert provides the following calculation method, which applies to both semi-automated cytology screening systems currently on the market (Hologic’s ThinPrep® Imaging System and Becton Dickenson’s Focal Point™ Guided Screening System):

- All slides with full manual review (FMR) count as one slide equivalent (as mandated by CLIA for manual screening)
- All slides with field of view (FOV) only review count as 0.5 or 1/2 slide equivalents
- Slides with **both** FOV and FMR count as 1.5 or 1-1/2 slide equivalents
- These values should be used to count workload, not exceeding the CLIA maximum limit of 100 slides in no less than an eight-hour day

**REFERENCES**
1) 07/27/10 FDA Alert - How Laboratorians Can Safely Calculate Workload for FDA-Approved Semi-Automated Gynecologic Cytology Screening Devices

**CYP.08575 Individual Maximum Workload - US Laboratories**

**Phase II**

There is a policy for the establishment of an individual maximum workload for the screening of cytology slides.

**NOTE:** This checklist requirement applies only to laboratories subject to US regulations. The section director (technical supervisor) must establish the maximum workload limit (based on capability/recorded performance evaluation) for each individual who screens slides (including pathologists who screen slides). The workload limit must be reassessed at least every six months. Performance must be evaluated using the following: (1) re-evaluation of 10 percent of the cases interpreted to be negative by cytotechnologists; (2) comparing the cytotechnologist’s interpretation in gynecologic specimens with the final cytologic diagnosis; and (3) comparing, in a manner determined by the laboratory, the cytotechnologist’s interpretation in non-gynecologic specimens with the final cytologic diagnosis. These are minimal requirements and the laboratory may use additional methods of evaluating performance such as retrospective reviews, comparison of individual statistic with overall lab statistics, and competency assessment.
REFERENCES

CYP.08900 Screening Facility

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

NOTE: Cytopathology screening must be performed within the laboratory facility or an approved reference 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.

REFERENCES

PHYSICAL FACILITIES

Inspector Instructions:

- Space and utilities are sufficient

CYP.09000 Adequate Space and Utilities

There are sufficient space and utilities (water, electrical) 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.

Inspector Instructions:

- Hazardous waste disposal policy
- Formaldehyde and xylene monitoring procedure and records of monitoring

- How does your laboratory dispose of infectious specimens and contaminated material?
- Have you had any complaints of noxious fumes in the work area?
● Have you had any employee complaints of skin rash or difficulty breathing while working in the laboratory?

CYP.09700 Hazardous Waste Disposal  Phase II

There are procedures for disposal of infectious specimens and contaminated material.

Evidence of Compliance:
✓ Written procedure for the handling and disposal of hazardous waste

REFERENCES

CYP.09900 Formaldehyde and Xylene Safety  Phase II

Formaldehyde and xylene vapor concentrations are maintained below the following maxima, expressed as parts per million.

NOTE: The laboratory must perform an initial formaldehyde monitoring procedure in all areas where this reagent is used. Initial monitoring involves identifying all employees who may be exposed at or above the action level or at or above the STEL and accurately determining the exposure of each employee identified. Further formaldehyde monitoring is mandated at least every six months if results of the initial monitoring equal or exceed 0.5 ppm (eight hr time-weighted exposure, the “action level”) or at least once per year if the results exceed the short term exposure limit (STEL) 2.0 ppm. The laboratory may discontinue periodic formaldehyde monitoring if results from two consecutive sampling periods taken at least seven days apart show that employee exposure is below the action level and the short-term exposure limit, and 1) no change has occurred in production, equipment, process or personnel or control measures that may result in new or additional exposure to formaldehyde, and 2) there have been no reports of conditions that may be associated with formaldehyde exposure.

Formaldehyde monitoring must be repeated any time there is a change in production, equipment, process, personnel, or control measures which may result in new or additional exposure to formaldehyde for any employee involved in the activity. If any personnel report signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, the laboratory must promptly monitor the affected person’s exposure.

Xylene must be monitored initially, but there is no requirement for periodic monitoring of xylene. Repeat monitoring should be considered when there is a change in production, equipment, process, personnel, or control measures likely to increase exposure levels.

<table>
<thead>
<tr>
<th></th>
<th>8 hr Time-Weighted Exposure Limit in ppm</th>
<th>Action Level (8 hr Time-Weighted Exposure) in ppm</th>
<th>15 min Short-Term Exposure Limit (STEL) in ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>0.75</td>
<td>.5</td>
<td>2.0</td>
</tr>
<tr>
<td>Xylene</td>
<td>100</td>
<td></td>
<td>150</td>
</tr>
</tbody>
</table>

Evidence of Compliance:
✓ Written policy for formalin and xylene safety including action limits, criteria for discontinuation of monitoring and criteria for resumption of monitoring AND
✓ Records of initial formalin and xylene monitoring and repeat monitoring when indicated AND
✓ Records of corrective action when exposure limits are exceeded

REFERENCES