Cytopathology Checklist
CAP Accreditation Program
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# Cytopathology Checklist

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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
08/21/2017 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

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## REVISED Checklist Requirements

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## 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 (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.

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.
Inspector Instructions:

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

**ASK**

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

**DISCOVER**

- 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) Nielsel 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  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 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) Nielsel 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 cytotologic services.

(No policy is needed for fluids such as urines and CSF that do not routinely undergo cytotologic examination.)
CYP.01900 Disparity Resolution

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

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:

READ
• Sampling of specimen collection and handling policies and procedures

ASK
• What is your course of action when you receive unacceptable cytopathology specimens?
• When are FNA slides labeled? What identifiers are placed on the slides and containers?
• What procedures do you have in place to prevent errors in ID, site and testing?

**REVISED** 08/17/2016

CYP.03366 FNA Error Prevention

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

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 Cytopathology Checklist

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 maintained.

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

CYTOLOGY STAINS AND SLIDE PREPARATIONS

Inspector Instructions:

- 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

- Sampling of stains (labeling)
- Sampling of slides (labeling)

- 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?

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

**REVISED** 08/21/2017
CYP.03925 Stain Assessment

Cytology stains are assessed at least annually to ensure their proper storage and acceptable quality.

NOTE: Cytology stains undergoing a daily technical quality review are exempt from an annual assessment.
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 must be confirmed at least annually by technical assessment on actual case material, and as part of the evaluation of cytopathology cases. 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

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

**REFERENCES**

CYP.04150 Cross-Contamination

**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**

CYP.04300 Daily QC

**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 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.

**REFERENCES**
IMMUNOCHEMISTRY (IMMUNOCYTOCHEMISTRY/IMMUNOHISTOCHEMISTRY)

This section is intended for cytology only laboratories performing immunochemistry within the cytology laboratory. This section does not apply to cytology laboratories for which all immunochemistry is performed in a general anatomic pathology immunohistochemistry laboratory that is inspected using the Anatomic Pathology Checklist. Cytology laboratories that are doing histology processing of cell blocks and tissues must be inspected with the Anatomic Pathology Checklist.

Inspector Instructions:

READ

- Sampling of immunochemistry policies and procedures
- Sampling of new antibody validation records
- Sampling of new reagents/shipment confirmation of acceptability records
- Sampling of antibody QC records
- Sampling of buffer pH records
- Sampling of batch control records

OBSERVE

- Sampling of slides (quality)

ASK

- How does your laboratory validate new antibodies?
- How does your laboratory confirm the acceptability of new reagent lots?
- How does your laboratory distinguish non-specific false-positive staining from endogenous biotin?

**NEW** 08/21/2017

CYP.04310 Specimen Modification

If the laboratory performs immunochemical staining on specimens other than formalin-fixed, paraffin-embedded material, the written procedure describes appropriate modifications, if any, for other specimen types.

NOTE: Such specimens include frozen sections, air-dried imprints, cytocentrifuge or other liquid-based preparations, decalcified tissue, and materials fixed in alcohol blends or other fixatives.

REFERENCES


**NEW** 08/21/2017

CYP.04320 Buffer pH

The pH of the buffers used in immunohistochemistry is routinely monitored.

NOTE: pH must be tested when a new batch is prepared or received.
Positive tissue controls are used for each antibody.

NOTE: Positive controls assess the performance of the primary antibody. They are performed on sections of tissue known to contain the target antigen, using the same epitope retrieval and immunostaining protocols as the patient tissue. Results of controls must be recorded, either in internal laboratory records, or in the patient report. A statement in the report such as, “All controls show appropriate reactivity” is sufficient.

Ideally, the positive control tissue would be the same specimen type as the patient test specimen (e.g. small biopsy, large tissue section, cell block), and would be processed and fixed in the same manner (e.g. formalin-fixed, alcohol-fixed, decalcified) as the patient specimen. However, for most laboratories, it is not practical to maintain separate positive control samples to cover every possible combination of fixation, processing and specimen type. Thus, it is reasonable for a laboratory to maintain a bank of formalin-fixed tissue samples as its positive controls; these controls can be used for patient specimens that are of different type, or fixed/processed differently, providing that the laboratory can show that these patient specimens exhibit equivalent immunoreactivity. This can be accomplished by parallel testing a small panel of common markers to show that specimens of different type, or processed in a different way (e.g. alcohol-fixed cytology specimens, decalcified tissue) have equivalent immunoreactivity to routinely processed, formalin-fixed tissue.

A separate tissue section may be used as a positive control, but test sections often contain normal elements that express the antigen of interest (internal controls). Internal positive controls are acceptable for these antigens, but the laboratory manual must clearly state the manner in which internal positive controls are used.

A positive control section included on the same slide as the patient tissue is optimal practice because it helps identify failure to apply primary antibody or other critical reagent to the patient test slide; however, one separate positive control per staining run for each antibody in the run (batch control) may be sufficient provided that the control slide is closely scrutinized by a qualified reviewer.

Ideally, positive control tissues possess low levels of antigen expression, as is often seen in neoplasms. Exclusive use of normal tissues that have high levels of antigen expression may result in antibody titers of insufficient sensitivity, leading to false-negative results.

Evidence of Compliance:
✓ Written procedure for the selection and use of positive tissue controls for each antibody AND
✓ Patient reports or worksheet with control results

REFERENCES
1) O’Leary TJ. Standardization in immunohistochemistry. Appl Immunohistochem Molecul Morphol 2001;9:3-8
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); [42CFR493.1273(a)]

Appropriate negative controls are used.

NOTE: Negative controls must assess the presence of nonspecific staining in patient tissue as well as the specificity of each antibody with the exception listed below. Results of controls must
be recorded, either in internal laboratory records, or in the patient report. A statement in the report such as, “All controls show appropriate reactivity” is sufficient.

For laboratories using older biotin-based detection systems, it is important to use a negative reagent control to assess nonspecific or aberrant staining in patient tissue related to the antigen retrieval conditions and/or detection system used. A separate section of patient tissue is processed using the same reagent and epitope retrieval protocol as the patient test slide, except that the primary antibody is omitted, and replaced by any one of the following:

- An unrelated antibody of the same isotype as the primary antibody (for monoclonal primary antibodies)
- An unrelated antibody from the same animal species as the primary antibody (for polyclonal primary antibodies)
- The negative control reagent included in the staining kit
- The diluent/buffer solution in which the primary antibody is diluted

In general, a separate negative reagent control should be run for each block of patient tissue being immunostained; however, for cases in which there is simultaneous staining of multiple blocks from the same specimen with the same antibody (e.g. cytokeratin staining of multiple axillary sentinel lymph nodes), performing a single negative control on one of the blocks may be sufficient provided that all such blocks are fixed and processed identically. This exception does not apply to stains on different types of tissues or those using different antigen retrieval protocols or antibody detection systems. The laboratory director must determine which cases will have only one negative reagent control, and this must be specified in the department's procedure manual.

The negative reagent control would ideally control for each reagent protocol and antibody retrieval condition; however, large antibody panels often employ multiple antigen retrieval procedures. In such cases, a reasonable minimum control would be to perform the negative reagent control using the most aggressive retrieval procedure in the particular antibody panel. Aggressiveness of antigen retrieval (in decreasing order) is as follows: pressure cooker; enzyme digestion; boiling; microwave; steamer; water bath. High pH retrieval should be considered more aggressive than comparable retrieval in citrate buffer at pH 6.0.

Immunohistochemical tests using polymer-based detection systems (biotin-free) are sufficiently free of background reactivity to obviate the need for a negative reagent control and such controls may be omitted at the discretion of the laboratory director following appropriate validation.

It is also important to assess the specificity of each antibody by a negative tissue control, which must show no staining of tissues known to lack the antigen. The negative tissue control is processed using the same fixation, epitope retrieval and immunostaining protocols as the patient tissue. Unexpected positive staining of such tissues indicates that the test has lost specificity, perhaps because of improper antibody concentration or excessive antigen retrieval. Intrinsic properties of the test tissue may also be the cause of "non-specific" staining. For example, tissues with high endogenous biotin activity such as liver or renal tubules may simulate positive staining when using a detection method based on biotin labeling.

A negative tissue control must be processed for each antibody in a given run. Any of the following can serve as a negative tissue control:

1. Multitissue blocks. These can provide simultaneous positive and negative tissue controls, and are considered "best practice" (see below).
2. The positive control slide or patient test slides, if these slides contain tissue elements that should not react with the antibody.
3. A separate negative tissue control slide.

The type of negative tissue control used (i.e. separate sections, internal controls or multitissue blocks) must be specified in the laboratory manual.

Multitissue blocks may be considered best practice and can have a major role in maintaining quality. When used as a combined positive and negative tissue control as mentioned above,
they can serve as a permanent record of the sensitivity and specificity of every stain, particularly when mounted on the same slide as the patient tissue. When the components are chosen appropriately, multitissue blocks may be used for many different primary antibodies, decreasing the number of different control blocks needed by the laboratory. Multitissue blocks are also ideal for determining optimal titers of primary antibodies since they allow simultaneous evaluation of many different pieces of tissue. Finally, they are a useful and efficient means to screen new antibodies for sensitivity and specificity or new lots of antibody for consistency, which should be done before putting any antibody into diagnostic use.

**Evidence of Compliance:**
- Written procedure for the selection and use of negative reagent (as appropriate) and tissue controls for immunochemistry **AND**
- Patient reports or worksheet with control results

**REFERENCES**
7) 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); [42CFR493.1273(a)]

**NEW** 08/21/2017

**CYP.04350 Endogenous Biotin**  
**Phase I**

If the laboratory uses an avidin-biotin complex (ABC) detection system (or a related system such as streptavidin-biotin or neutravidin-biotin), there is a procedure that addresses nonspecific false-positive staining from endogenous biotin.

**NOTE:** Biotin is a coenzyme present in mitochondria, and cells that have abundant mitochondria such as hepatocytes, kidney tubules and many tumors (particularly carcinomas) are rich in endogenous biotin. Biotin-rich intranuclear inclusions are also seen in gestational endometrium and in some tumors that form morules. If steps are not included in the immunostaining method to block endogenous biotin before applying the ABC detection complex, nonspecific false-positive staining may occur, particularly when using heat-induced epitope retrieval (which markedly increases the detectability of endogenous biotin). This artifact is often localized to tumor cells and may be easily misinterpreted as true immunoreactivity.

**Blocking endogenous biotin involves incubating the slides with a solution of free avidin (which binds to endogenous biotin), followed by incubation with a biotin solution (which saturates any empty biotin-binding sites remaining on the avidin). Biotin-blocking steps should be performed immediately after epitope retrieval and before incubation with primary antibody.**

**REFERENCES**

**NEW** 08/21/2017

**CYP.04360 Control Slide Review**  
**Phase II**

When batch controls are run, the laboratory director or designee reviews all control slides each day of patient testing.
NOTE: Records of this daily review must be maintained and should clearly show that positive and negative controls for all antibodies stain appropriately. Batch control records must be retained for two years.

Immunochemical tests using polymer-based detection systems (biotin-free) are sufficiently free of background reactivity to obviate the need for a negative reagent control and such controls may be omitted at the discretion of the laboratory director following appropriate validation.

The batch control slides must be readily available to pathologists who are signing out cases. The location of the slides should be stated in the procedure manual.

REFERENCES

**NEW** 08/21/2017

CYP.04370 Antibody Validation Phase II

The laboratory has records of validation of new antibodies, including introduction of a new clone, prior to use for patient diagnosis or treatment.

NOTE: The performance characteristics of each assay must be appropriately validated before being placed into clinical use. The initial goal is to establish the optimal antibody titration, detection system, and antigen retrieval protocol. Once optimized, a panel of tissues must be tested to determine the assay’s sensitivity and specificity. The scope of the validation is at the discretion of the laboratory director and will vary with the antibody.

Means of validation may include, but are not limited to: 1) correlating the results using the new antibody with the morphology and expected results; 2) comparing the results using the new antibody with the results of prior testing of the same tissues with a validated assay in the same laboratory; 3) comparing the results using the new antibody with the results of testing the same tissue in another laboratory with a validated assay; or 4) comparing the results using the new antibody with previously validated non-immunochemistry tests or testing previously graded tissue challenges from a formal proficiency testing program.

For an initial validation, laboratories should achieve at least 90% overall concordance between the new test and the comparator test or expected results.

For validation of a nonpredictive assay, the validation should test a minimum of 10 positive and 10 negative tissues. For validation of predictive markers (with the exception of HER2, ER and PgR), the laboratory should test a minimum of 20 positive and 20 negative tissues. In either situation, when the laboratory director determines that fewer validation cases are sufficient for a specific marker (e.g. a rare antigen or tissue), the rationale for that decision needs to be recorded. Positive cases in the validation set should span the expected range of clinical results (expression level), especially for those markers that are reported quantitatively.

When possible, laboratories should use validation tissues that have been processed using the same fixative and processing methods as cases that will be tested clinically. If immunochemistry is regularly done on specimens that are not fixed or processed in the same manner as the tissues used for validation (e.g. alcohol fixed cell blocks, cytologic smears, formalin postfixed tissue, or decalcified tissue), the laboratory should test a sufficient number of such tissues to ensure that assays consistently achieve expected results. The laboratory director is responsible for determining the number of positive and negative cases and the number of predictive and nonpredictive markers to test.

Refer to the subsection “Predictive Markers” in the Anatomic Pathology Checklist for specific validation requirements for HER2 and ER/PgR testing in breast carcinoma.

Evidence of Compliance:
✓ Written procedure for the evaluation/validation of new antibodies
✓ Records of validation, if applicable
REFERENCES

**NEW** 08/21/2017
CYP.04380 New Reagent Lot Confirmation of Acceptability Phase II

The performance of new lots of antibody and detection system reagents is compared with old lots before or concurrently with being placed into service.

NOTE: Parallel staining is required to control for variables such as disparity in the lots of detection reagents or instrument function. New lots of primary antibody and detection system reagents must be compared to the previous lot using at least one known positive control and one known negative control tissue. This comparison should be made on slides cut from the same control block.

Evidence of Compliance:
✓ Written procedure for the confirmation of acceptability of new reagent lots prior to use AND
✓ Records of confirmation of new reagent lots

**NEW** 08/21/2017
CYP.04390 Immunochemistry Assay Performance Phase I

Laboratories confirm assay performance when conditions change that may affect performance.

NOTE: Laboratories should confirm assay performance with at least two known positive and two known negative cases when an existing validated assay has changed in any of the following ways: antibody dilution, antibody vendor (same clone), or the incubation or retrieval times (same method).

Laboratories must confirm assay performance by testing a sufficient number, determined by the laboratory director, of cases to ensure that assays consistently achieve expected results when any of the following have changed: fixative type, antigen retrieval protocol (e.g. change in pH, different buffer, different heat platform), antigen detection system, tissue processing or testing equipment, environmental conditions of testing (e.g. laboratory relocation), or laboratory water supply.

If significant changes are made in testing methods (e.g. antibody clone, antigen retrieval protocol or detection system, probe or pretreatment protocol), revalidation is required.

For specific validation requirements for HER and ER/PgR testing in breast carcinoma, refer to the subsection “Predictive Markers” in the Anatomic Pathology Checklist.

**NEW** 08/21/2017
CYP.04410 Slide Quality Phase II

The immunochemistry stains produced are of acceptable technical quality.

NOTE: The inspector must examine examples of the immunochemical preparations offered by the laboratory. A reasonable sample might include 5-10 diagnostic antibody panels.

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.
Cellular and nuclear detail are sufficient for proper interpretation.

CYP.05000 On-Site Slide Review

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:

- Pipette calibration procedure
- Sampling of pipette checks

- 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

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

**NEW** 08/21/2017

CYP.05295 Pipette Accuracy - Non Class A

Pipettes that are used for quantitative dispensing of material are checked for accuracy and reproducibility at defined intervals (at least annually), and results recorded.

NOTE: Pipette checks must be performed following manufacturer's instructions, at minimum, and as defined in laboratory procedure. Such checks are most simply done gravimetrically. This consists of transferring a number of measured samples of water from the pipette to a balance. Each weight is recorded, the weights are converted to volumes, and then arithmetic means (for accuracy), and SD/CV (for imprecision) are calculated. Alternative approaches include
spectrophotometry or (less frequently) the use of radioactive isotopes, and commercial kits are available from a number of vendors. Computer software is useful where there are many pipettes, and provides convenient records. This checklist requirement does not apply to Class A volumetric pipettes that meet the American Society for Testing and Materials calibration (accuracy) specifications.

REFERENCES


RECORDS AND REPORTS

Inspector Instructions:

- Sampling of reporting policies and procedures
- Sampling of patient reports

- How are reports signed if the reviewing pathologist is not available?
- How do you record intra-departmental and extra-departmental consultations?
- If cases are resulted at different locations, how do you ensure that the testing laboratory name and address are correct on the final report?

CYP.05300 Cytopathology Report Elements

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.

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

REFERENCES
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


**REVISED** 08/21/2017

CYP.05350 Cytopathology Report Elements

The cytopathology report includes all of the following elements:

1. Date specimen received/accessioned by the laboratory
2. Description of specimen on receipt (e.g. bloody fluid)
3. Description of fixative and pre-analytic variables that may affect ancillary testing (e.g. 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 (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; and brush in 10 cc clear yellow fluid.
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

Significant/Unexpected Findings

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

Amended Reports

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

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

A cross-index with histological material is maintained.

CYP.06850 Correlation of Results - Non-Gynecologic

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?

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 - ten 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

■ Slide Storage

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 performance 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.

CYP.07439  Papanicolaou Stain  Phase II

The Papanicolaou stain is used for gynecologic specimens.

REFERENCES


CYP.07452  Unsatisfactory Specimens  Phase II

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

CYP.07465 Pathologist Interpretation Phase II

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

CYP.07478 10% Rescreen Phase II

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

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

REFERENCES
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
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

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

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

<table>
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<tr>
<th>CATEGORY</th>
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<th>75th</th>
<th>90th</th>
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</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>
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<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>
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<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>
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<td>ASC-H (%)</td>
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<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>
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<td>0.3</td>
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<tr>
<td>ASC/SIL</td>
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<td>1.8</td>
<td>2.5</td>
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### SurePath*** Laboratory Percentile-Reporting Rate

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<tr>
<td>Unsatisfactory (%)</td>
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<td>0.5</td>
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<tr>
<td>LSIL (%)</td>
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<td>0.6</td>
<td>0.9</td>
<td>1.2</td>
</tr>
<tr>
<td>ASC-US (%)</td>
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<td>0.4</td>
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<tr>
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<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**

2) Jones BA, Davey DD. Quality management in gynecologic cytology using interlaboratory comparison. *Arch Pathol Lab Med.* 2000;124:672-681

**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  Phase II

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

REFERENCES

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

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  Phase II

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

REFERENCES
PERSONNEL

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

Inspector Instructions:

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


**REVISED** 08/21/2017

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

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

**REVISED** 08/21/2017

CYP.08100 General Supervisor 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 local, regional or national 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 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 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 non-US laboratories, appropriate local, regional or national regulations also apply.

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

REFERENCES

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 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:**

- 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

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

- 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?

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.

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**NOTE:** While federal and state regulations on slide workload limits must never be exceeded, the CAP does not rely solely upon those specific workload limits 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.

**REVISED** 08/21/2017

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. In addition, if there are different state regulations for cytology workload, the most stringent regulation must be followed (e.g. workload for cytotechnologists manually screening gynecologic smears under a California state laboratory license is limited to 80 gynecologic slides in a 24-hour period, and reduced proportionately based on other duties performed.

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 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

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

**REVISED** 08/21/2017
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

In addition, if there are different state regulations for cytology workload, the most stringent regulation must be followed (e.g. workload for cytotechnologists performing automated and semi-automated gynecologic smears under a California state laboratory license is limited to 200 gynecologic slides in a 24-hour period).

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

**REVISED** 08/21/2017
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); this maximum workload limit must conform to applicable federal and state regulations. 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 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.

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:

**READ**
- Hazardous waste disposal policy
- Formaldehyde and xylene monitoring procedure and records of monitoring
- Sampling of microwave reproducibility and ventilation checks

**ASK**
- 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?

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**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**


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**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>
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<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>
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<tr>
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<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**

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**NEW** 08/21/2017
CYP.09910 Microwave Usage

_Microwave devices are used in accordance with manufacturer's instructions._

_NOTE:_ Microwave devices should be used in accordance with manufacturer's instructions, unless CAP requirements are more stringent.

_Evidence of Compliance:_
- ✓ Written procedure for microwave usage

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**NEW** 08/21/2017
CYP.09920 Microwave Monitoring

_Microwave devices are at least annually monitored for reproducibility._

_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 laboratory should have a written procedure for monitoring reproducibility that follows instrument manufacturer's instructions. Information on such procedures is given in the reference to this checklist requirement (see below).

The microwave device should be tested for radiation leakage if there is visible damage to the device.

_Evidence of Compliance:_
- ✓ Written procedure for monitoring the diagnostic quality of specimens processed using microwaves

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**NEW** 08/21/2017
CYP.09930 Microwave Container Venting

_All containers used in microwave devices are vented._

_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.
**NEW** 08/21/2017
CYP.09940  Microwave Venting  Phase I

**Microwave Venting Phase I**

*Microwave devices are properly vented.*

**NOTE:** This checklist item does not apply to microwave devices that are designed by the manufacturer to operate without venting.

*Microwave devices should be placed in an appropriate ventilation hood to contain airborne chemical contaminants and potentially infectious agents. Before operation of the microwave device, flammable and corrosive reagents should 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 should have an integral fume extractor certified by the manufacturer for use in a clinical laboratory.

The effectiveness of ventilation should be monitored at least annually.

*This checklist requirement does not apply if only non-hazardous reagents (and non-infectious specimens) are used in the device (e.g. water, certain biological stains, paraffin sections). The laboratory should consult the safety data sheets (formerly MSDS) received with reagents and stains to assist in determining proper handling requirements and safe use.*

**Evidence of Compliance:**

✓ Records of annual evaluation of ventilation effectiveness