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Cytopathology Checklist

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ON-LINE CHECKLIST AVAILABILITY AND RESOURCES

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

A repository of questions and answers and other resources is also available in e-LAB Solutions Suite under Accreditation Resources, Checklist Requirement Q & A.

SUMMARY OF CHECKLIST EDITION CHANGES
Cytopathology Checklist
09/22/2021 Edition

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

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

NOTE: The requirements listed below are from the Master version of the checklist. The customized checklist version created for 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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INTRODUCTION

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

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

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

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

GENERAL CYTOPATHOLOGY

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

Cytopathology inspectors must be pathologists or cytotechnologists who 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

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

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

CYP.00125  PT Participation - Gynecologic Cytopathology  
**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 the Centers for Medicare and Medicaid Services (CMS).

**NOTE:** This checklist requirement applies only to US laboratories and other laboratories subject to CLIA regulations. Laboratories must retain 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 - Gynecologic Cytopathology  
**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

CYP.00170 Educational Participation - Gynecologic Cytopathology

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

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

Evidence of Compliance:
- Records such as CAP order form, purchase order AND records of completed/submitted results indicating that the laboratory is participating in the educational component of the CAP PAP PT program OR
- Records of enrollment/participation in another educational gynecologic cytopathology peer-comparison program OR
- Records for participation in a laboratory-developed program by circulating gynecologic case material with other laboratories

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


CYP.00190 Educational Participation - Non-gynecologic Cytopathology

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

Evidence of Compliance:
- Records 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

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

CYP.01900 Disparity Resolution Phase II
If significant disparities exist between histological and cytological findings, these are resolved in a confidential peer-reviewed quality management report, or in an addendum or in the patient report.

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

CYP.02100 Consultation Report Retention Phase I
Records of intra- and extra-departmental consultations are retained.

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:

• Sampling of specimen collection and handling policies and procedures

• 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?

CYP.03366 FNA Error Prevention Phase II
If the pathologist performs FNA procedures, there is a written procedure to verify patient identification using at least two patient identifiers, the procedure site, and the procedure to be performed.

REFERENCES

CYP.03800 Physician Notification Phase II
There is evidence that submitting physicians are notified when unacceptable specimens are received.

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

REFERENCES

CYP.03850 Cytopathology Checklist

Cytology Assessment Record

Phase I

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

NOTE: Records might include a note in the 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.

CYP.04100 Staining Solutions

Phase II

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

REFERENCES
**REVISED** 09/22/2021

CYP.04150  Cross-Contamination  Phase I

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

NOTE: Procedures must prevent cross-contamination between the following:
- Gynecologic and non-gynecologic specimens.
- Non-gynecologic cases that have high potential for cross-contamination from other non-gynecologic specimens.

Methods to minimize cross-contamination between specimens 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  Phase II

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

NOTE: The technical quality of cytologic preparations must be checked daily (on days processing occurs). This includes checking all stains for predicted staining characteristics each day of use. This check must include all of the types of preparations seen that day such as 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.
Please refer to the Definition of Terms section in the All Common (COM) Checklist for definitions of analytical validation and analytical verification.

Inspector Instructions:

- Sampling of immunochemistry policies and procedures
- Sampling of new antibody validation/verification 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

- Sampling of slides (quality)

- How does your laboratory validate/verify 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?

**REVISED** 09/22/2021

CYP.04310 Specimen Modification

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

NOTE: Such specimens include air-dried touch imprints, air-dried and/or alcohol fixed smears, cytocentrifuge or other liquid-based preparations, and cellular materials fixed in alcohol blends or other fixatives.

REFERENCES

CYP.04320 Buffer pH

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

NOTE: pH must be tested when a new batch is prepared or received.

Evidence of Compliance:
- Written procedure defining pH range for each buffer in use AND
- Records of initial and subsequent QC on each buffer

**REVISED** 09/22/2021

CYP.04330 QC - Antibodies

Positive controls are used for each antibody.
NOTE: Positive controls assess the performance of the primary antibody. They are performed on sections of tissue or cells known to contain the target antigen, using the same epitope retrieval and immunostaining protocols as the patient specimen. 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 (but not essential to satisfy this requirement), the positive control would be the same specimen type/fixative as the patient test specimen (e.g., air-dried touch imprints, air-dried and/or alcohol fixed smears, cytocentrifuge or other liquid-based preparations, and cellular materials fixed in alcohol blends or other fixatives). 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) have equivalent immunoreactivity to routinely processed, formalin-fixed tissue.

A separate tissue section may be used as a positive control, but cytology specimens may 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 specimen 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 controls 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 controls for each antibody AND
✓ Patient reports or worksheet with control results AND
✓ Immunochemical-stained slides with positive controls

REFERENCES
1) O’Leary TJ. Standardization in immunohistochemistry. *Appl Immunohistochem Molec Morphol* 2001;9:3-8
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 specimens related to the antigen retrieval conditions and/or detection system used. A separate section of patient specimen 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 specimen being immunostained; however, for cases in which there is simultaneous staining of multiple specimens from the same specimen with the same antibody, performing a single negative control on one of the specimens may be sufficient provided that all such specimens 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.

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 Centers for Medicare and Medicaid Services (CMS) recognizes the use of polymer-based detection systems (biotin free) may preclude the use of a negative reagent control. However, there have been no changes to the histopathology regulations. The CMS will be looking into an alternate QC method for these types of stains.

It is also important to assess the specificity of each antibody by a negative cellular/tissue control, which must show no staining of cells/tissues known to lack the antigen. The negative 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, cells/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 cellular sample or tissue control must be processed for each antibody in a given run. Any of the following can serve as a negative cellular/tissue control:

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

The type of negative cellular/tissue control used (i.e., separate sections, internal controls or multitissue blocks) must be specified in the laboratory manual.
Multitissue blocks or tissue microarrays (TMAs) 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 cellular/tissue controls for immunochemistry AND
✓ Patient reports or worksheet with control results AND
✓ Immunochemical-stained slides with appropriate negative controls

REFERENCES

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
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 retained 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 Centers for Medicare and Medicaid Services (CMS) recognizes the use of polymer-based detection systems (biotin free) may preclude the use of a negative reagent control. However, there have been no changes to the histopathology regulations. The CMS will be looking into an alternate QC method for these types of stains.

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
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(f)]

**REVISED** 09/22/2021
CYP.04370 Antibody Validation/Verification - Non-Predictive Marker Phase II

The laboratory has records of validation/verification 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/verified 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 cellular samples or tissues must be tested to determine the assay’s sensitivity and specificity. The scope of the validation/verification is at the discretion of the laboratory director and will vary with the antibody.

Means of validation/verification 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/verified assay in the same laboratory; 3) comparing the results using the new antibody with the results of testing the same cellular samples or tissue in another laboratory with a validated/verified assay; or 4) comparing the results using the new antibody with previously validated/verified non-immunochemistry tests or testing previously graded tissue challenges from a formal proficiency testing program.

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

For validation/verification of a nonpredictive assay, the validation/verification should test a minimum of 10 positive and 10 negative cellular samples or tissues. If the laboratory director determines that fewer validation/verification cases are sufficient for a specific marker (eg, a rare antigen or cell/tissue), the rationale for that decision needs to be recorded. Positive cases in the validation/verification set should span the expected range of clinical results (expression level), especially for those markers that are reported quantitatively.

When possible, laboratories should use cellular samples or 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/verification (eg, air-dried touch imprints, air-dried and/or alcohol fixed smears, cytocentrifuge or other liquid-based preparations, and cellular materials fixed in alcohol blends or other fixatives), the laboratory should test a sufficient number of such
cellular samples or tissues to ensure that assays consistently achieve expected results with the alternative fixative/processing conditions. 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/verification requirements for tests that provide independent predictive information (eg, HER2 and ER testing in breast carcinoma).

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

REFERENCES

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 cellular samples or 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

CYP.04390 Immunochemistry Assay Performance Phase I

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

NOTE: A change in antibody clone requires full revalidation/verification of the assay (equivalent to initial analytic validation/verification - see CYP.04370).

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

A more extensive study to confirm acceptable assay performance in accordance with published guidelines must be performed when any of the following have changed: fixative type, antigen retrieval protocol (eg, change in pH, different buffer, different heat platform), antigen detection system, cytologic preparation/tissue processing or testing equipment, environmental conditions of testing (eg, laboratory relocation), or laboratory water supply. This study must include a representative sampling of the assays affected by the change and an appropriate number of
positive and negative cases per assay, sufficient to confirm acceptable assay performance. The laboratory director is responsible for determining the extent of the study. The rationale for the assays selected and number of positive and negative cases checked per assay must be recorded.

For specific validation/verification requirements for tests that provide independent predictive information (eg, HER2 and ER testing in breast carcinoma), refer to the subsection “Predictive Markers” in the Anatomic Pathology Checklist.

REFERENCES

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

PREDICTIVE MARKERS

This checklist section applies only to immunochemical tests used to predict responsiveness to a specific treatment independent of other cytopathologic findings. Rather than confirming a specific diagnosis (such as B-cell lymphoma or gastrointestinal stromal tumor), these tests should differentiate predicted responsiveness to a targeted therapy among cases of the same diagnosis. For example, this section applies to estrogen receptor testing used to determine eligibility for hormonal treatment of breast carcinoma but does not apply to estrogen receptor testing used solely to assist in determining the primary site of origin of a metastatic neoplasm.

The current CAP guidelines (https://www.cap.org/protocols-and-guidelines/current-cap-guidelines) relating to predictive marker testing (eg, ASCO/CAP HER2 and ER testing in breast cancer) may be found at cap.org in the Protocols and Guidelines section. The guidelines are periodically updated based on new evidence. Laboratories should review updated predictive marker guidelines and promptly implement changes for items relating to requirements in the checklists (eg, validation, fixation, scoring criteria).

Inspector Instructions:

- Predictive markers policies and procedures
- Sampling of patient reports for completeness, including ASCO/CAP scoring when applicable
- Records of annual benchmark comparison for breast predictive markers
- Sampling of predictive marker assay validation, verification, and revalidation/verification studies

- What is your laboratory’s course of action when negative HER2 and/or negative ER by immunochemical results are obtained and the fixation was not appropriate?
- How did you validate/verify the most recently added predictive marker on your test menu?
For immunochemical tests that provide independent predictive information, the patient report includes information on specimen processing, the antibody clone, and the scoring method used.

NOTE: The laboratory processing the cytology specimen must record the cold ischemia time (if applicable) and the length of time in fixative. If the cytopathology laboratory refers immunochemistry or ISH studies, this information must be provided to the laboratory(ies) performing these studies.

For immunochemical studies used to provide predictive information independent of diagnosis or other cytopathologic findings (eg, hormone receptors and HER2 in breast carcinoma, PD-L1 and lung adenocarcinoma predictive immunostains), the laboratory must include the following information in the patient report:

1. The type of specimen fixation and processing (eg, formalin-fixed paraffin-embedded sections, air-dried imprints, etc.)
2. The antibody clone and general form of detection system used (eg, LSAB, polymer, proprietary kit, vendor name, etc.; information on the type of equipment used is not necessary)
3. Criteria used to determine a positive vs. negative result, and/or scoring system (eg, percent of stained cells, staining pattern)
4. Laboratory interpretation of predictive marker testing is reported according to the manufacturer's instructions, or when available, following the structure, format, and criteria set forth in the current CAP guidelines relating to predictive marker testing (eg, ASCO/CAP HER2 and ER testing in breast cancer and CAP/ASCP/ASCO HER2 in gastroesophageal carcinoma)
5. Limitations relating to suboptimal preanalytical factors that may impact results, such as prolonged cold ischemia time or over- or under-fixation.

Evidence of Compliance:
✓ Written procedure for scoring and reporting immunochemical results for tests involving predictive markers OR report template containing all required elements AND
✓ Copies of patient reports confirming inclusion of the required elements AND
✓ Established guidelines used by the laboratory

REFERENCES
of ER-negative cases is considerably lower in well-differentiated carcinomas (<10%) and certain special types of invasive carcinomas (<10% in lobular, tubular, and mucinous types). Investigation is warranted if the proportion of ER-negative cases varies significantly from the published benchmarks.

For HER2 studies, the overall proportion of HER2 positive breast cancers is 10-25%. Laboratories must monitor their results. Investigation is warranted if the proportion of HER2 positive cases varies significantly from published data.

Individuals interpreting the assay must also have their concordance compared with each other and this concordance should also be at least 95%.

Evidence of Compliance:
✓ Records of annual result comparison and evaluation of interobserver variability

REFERENCES

**NEW** 09/22/2021
CYP.04530 Predictive Marker Testing - Validation/Verification Phase II

Predictive marker testing by immunochemistry is validated/verified and records of validation/verification are retained.

NOTE: Test verification must be performed on a minimum of 40 cases (20 positive and 20 negative samples) for FDA-cleared/approved assays. Laboratories should consider using higher numbers of test cases when validating laboratory-developed tests (LDTs) or modified FDA-approved/cleared tests. If the laboratory director determines that fewer validation cases are sufficient for a specific marker (eg, a rare antigen or tissue), the rationale for that decision must be recorded.

For HER2 and ER predictive marker testing performed on breast cancer specimens using laboratory-developed tests (LDTs), 40 positive and 40 negative samples must be used, at minimum. Positive cases in the validation set should span the expected range of clinical results (expression levels). Only definitely positive and negative cases should be used for validation.

The validation data should clearly show the degree of concordance between assays or methods. Minimum acceptable concordance levels are 90% for positive and negative results, except for ER IHC methods which are 90% for positive and 95% for negative results.

The characteristics of the cases used for validation/verification should be similar to those seen in the laboratory’s patient population (ie, core biopsy vs. open biopsy, primary vs. metastatic tumor, etc.).

Samples used for validation/verification must be handled in conformance with the guidelines in this checklist. Laboratories should use tissues that have been processed by using the same fixative and processing methods as cases that will be tested clinically.

If significant changes are made to the testing methods (eg, antibody clone, antigen retrieval protocol or detection system, or pretreatment protocol), revalidation/verification is required.

This requirement is applicable to both new and existing assays. If review of the initial validation/verification does not meet the current standard, it must be supplemented and brought into compliance. It is possible to do this retroactively by review and documentation of past proficiency
testing challenges or by sending unstained slides from recent cases to a referral laboratory for correlation. If no records exist from the initial validation/verification, the assay must be fully revalidated/verified.

Evidence of Compliance:
✓ Records of validation/verification data including criteria for concordance

REFERENCES

**NEW** 09/22/2021
CYP.04540 Estrogen Receptor and HER2 Testing in Breast Cancer Samples

At least one tumor sample from all patients with invasive breast cancer (newly diagnosed, recurrent, or metastatic disease) is tested for estrogen receptors and HER2 (by IHC or ISH) if tissue is available.

REFERENCES

**NEW** 09/22/2021
CYP.04550 Fixation - HER2 and ER Breast Cancer Predictive Marker Testing

If the laboratory assesses HER2 protein over-expression by immunochemistry, or estrogen receptor expression by immunochemistry for breast cancer predictive marker testing, the laboratory monitors cold ischemia time (one hour or less), if applicable, and appropriate specimen fixation time.

NOTE: The CAP strongly recommends that specimens subject to these tests be fixed in 10% neutral phosphate-buffered formalin for at least six hours and up to 72 hours at room temperature. Specimens must be fully submerged with the optimal formalin to approximate specimen volume of 10:1 or higher, or if not feasible (eg, large specimens) at least 4:1. For cases with negative HER2 results by immunochemistry that were fixed outside these limits, confirmatory analysis by in-situ hybridization is strongly recommended.

Both the time of removal of the tissue and the time of immersion of the tissue in fixative must be recorded and communicated from the submitting service to the processing laboratory. Communication to clinical services of the need for appropriate information on cold ischemia time, fixative, and fixation time may be through memoranda, website, phone, face-to-face meetings, or other means. Information about fixative, fixation time, and cold ischemia time (if applicable) for each specimen must be recorded as part of the permanent specimen record in the pathology report. The laboratory must monitor for compliance and take corrective action as needed.

If specimens are fixed in a solution other than 10% neutral phosphate-buffered formalin, the laboratory must perform a validation study showing that results are concordant with results from formalin-fixed tissues.

Laboratories testing specimens obtained from another institution must have a policy that addresses cold ischemia time (if applicable) and time of fixation. Information on time of fixation may be obtained by appropriate questions on the laboratory’s requisition form. If specimens have undergone any deviation from processing that may interfere with result interpretation, this must be annotated on the final report.
Evidence of Compliance:
✓ Written policy for monitoring cold ischemia (if applicable) and fixation times AND
✓ Records of communication of cold ischemia (if applicable) and fixation guidelines to clinical services AND
✓ Records of action taken when cold ischemia (if applicable) and fixation times are consistently outside of required parameters or are not available to the laboratory

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 retention period for gynecologic and non-gynecologic slides (including 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 (eg, the first 1-3 negative and abnormal cases in each specimen category from a certain date or week). The following are core elements of the on-site review:

- Evaluate slides for quality of technical preparation and specimen adequacy
- Determine if significant cells have been identified
- Compare slides with the diagnostic report for completeness and clarity of diagnostic terminology
- Determine if the information provided with the requisition and included in the diagnostic report is complete and appropriate
If, during the on-site review, there is believed to be a significant diagnostic discrepancy, this should be discussed by the pathologist team leader with the laboratory director. Interpretations may be considered discrepant if there is a significant diagnostic difference in interpretation. An example of this would be an interpretation of Negative for Intraepithelial Lesion/Malignancy, vs. an interpretation of LSIL or greater. Cases considered to be "ASC/AGC" (either by the Inspector or inspectee) should not be included in the analysis to determine significant discrepancies, because of the current lack of interlaboratory reproducibility of these interpretations.

CYP.04900  Cellular/Nuclear Detail

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:

- 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
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  Phase II

The cytopathology report includes all of the following elements:

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

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

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

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

CYP.05316  Pathologist Identification on Report  Phase II

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

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

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

CYP.05332 Report Review Phase II

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

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

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

REFERENCES

CYP.05350 Cytopathology Report Elements Phase I

The cytopathology report includes all of the following elements:

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

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

CYP.06100 Report - Morphologic Findings Phase II

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

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

Reports must include a concise descriptive diagnosis either in a format similar to a histopathology report, or standard descriptive terminology that includes a general categorization and descriptive diagnosis (as is recommended by the Bethesda System for gynecologic 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 (ie, urine, fluids, washings and brushings). When appropriate (particularly for fine needle aspiration samples of mass lesions), a statement regarding the adequacy of the specimen should be included, with a description of the limitations of the specimen when a specific diagnosis cannot be made.

Evidence of Compliance:
✓ 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

**REVISED** 06/04/2020
CYP.06450 Significant and Unexpected Findings Phase II

The laboratory has a written policy regarding the communication of significant and unexpected cytopathology findings and retains records of those communications.

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

There must be a reasonable effort to ensure that clinicians receive the communications. The records must include the following:
- Date of communication;
- Time of communication (if required by laboratory policy);
- Responsible laboratory individual;
- Person notified; and
- Findings communicated.

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

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

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

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

**REVISED** 06/04/2020
CYP.06475 Amended Reports Phase II

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

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

Records of notification must include date, responsible laboratory individual, and person notified.
Evidence of Compliance:
✓ Written policy for notification of significant amendments to patient reports AND
✓ Patient reports containing reason for the amendment AND
✓ Records of notification

REFERENCES

CYP.06600 Report Retention - Cytopathology Phase II

Cytopathology reports are retained for at least 10 years.

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

Evidence of Compliance:
✓ Written record retention policy

REFERENCES

CYP.06800 Cross-Index Phase II

A cross-index with histological material is maintained.

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

For non-gynecologic cytopathology cases, there is a written procedure for the correlation of the results of specialized studies (eg, 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?

CYP.06900  Slide Retention - Cytopathology  Phase II

All glass slides are retained for an appropriate period.

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

1. Gynecologic glass slides - five years
2. Non-gynecologic glass slides (including fine needle aspiration (FNA) slides) - 10 years

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

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

Evidence of Compliance:
✓ Written retention policy

REFERENCES

**REVISED** 09/22/2021
CYP.07100  Cytology Slide and Block Storage  Phase II

Cytology slides and blocks are properly stored in a temperature controlled, pest-free, organized manner (i.e., accessible for retrieval and properly identified).
NOTE: Slides and blocks must be stored in a manner to prevent contamination from blood or other fluids or tissues and be readily accessible for retrieval.

The storage area for blocks must be cool to prevent blocks from melting together. Storage temperature must be maintained between 18°C to 27°C.

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

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

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
GINOCOLOGIC CYTOPATHOLOGY

Inspector Instructions:

- Sampling of gynecologic cytopathology policies and procedures
- Written criteria for unsatisfactory specimens
- 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

The Papanicolaou stain is used for gynecologic specimens.

REFERENCES

**REVISED** 09/22/2021

CYP.07452  Unsatisfactory Specimens - Gynecologic Cytopathology
There are written criteria for identification and reporting of unsatisfactory gynecologic specimens and slide preparations.

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

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

**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**

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 cytotecnologist’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**

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**

The rescreening of negative gynecologic cases is performed by an individual qualified as a cytopathology supervisor (see CYP.08100).
Evidence of Compliance:
✓ Records of section director/technical supervisor or supervisor/general supervisor qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field for each individual performing rescreening

REFERENCES

CYP.07517 Retrospective Review Phase II

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

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

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

CYP.07530 Retrospective Review Requiring Amendment Phase II

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

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

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

CYP.07543 Result Correlation Phase II

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

NOTE: When the histologic diagnosis is available, correlation to the cytologic findings must be recorded. The number of cases that have histologic correlation should be recorded.

REFERENCES


CYP.07556 Additional Reports/Material Unavailable

When a follow-up histological report or material is not available within the laboratory, there are records of attempts to obtain follow-up histological information for correlative review when gynecologic cases with significantly abnormal (high-grade SIL) or malignant cytological findings are reported.

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

REFERENCES

CYP.07569 Correlation of Results - Gynecologic Cytopathology

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 (eg, policies, problem logs with resolution, or notes in reports)

REFERENCES

CYP.07582 Pap Test - False Negative Notification

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

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

**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 are based on 2019 case volumes. In evaluating its statistics, the laboratory’s patient population should be taken into consideration. Percentile-reporting rates refer to the distribution of individual laboratory responses from reporting rates in various categories. Responses are ranked from lowest to highest, and the 50th percentile-reporting rate refers to the median response. A 25th percentile-reporting rate (which corresponds to 1.7% in the table) for the ThinPrep LSIL category means that a quarter of laboratories have LSIL rates of 1.7% or less. A 90th percentile-reporting rate (which corresponds to 15.2% in the table) for ASC-US in ThinPrep preparations means that 9 of 10 laboratories have an ASC-US rate of 15.2% or less.

The reporting rates for ASC-US, ASC-H, AGC, LSIL, HSIL, and UNSATISFACTORY are given as percentages of total case volume. An ASC-US rate of 2.0% means 2/100 cases in the lab are designated ASC-US. The ASC/SIL figure is a calculated ratio: the percentage or number of a laboratory's ASC-US and ASC-H cases divided by the percentage or number of LSIL, HSIL, and malignant cases. A laboratory with 4% ASC cases and 3% SIL cases has an ASC/SIL ratio of 1.3, as compared to the median ASC/SIL ratio of 1.6 for conventional Paps, 1.9 for ThinPrep® and 2.0 for SurePath.

### CONVENTIONAL*

#### Laboratory Percentile-Reporting Rate

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>5th</th>
<th>10th</th>
<th>25th</th>
<th>Median</th>
<th>75th</th>
<th>90th</th>
<th>95th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsatisfactory (%)</td>
<td>0.0</td>
<td>0.1</td>
<td>0.2</td>
<td>1.1</td>
<td>2.9</td>
<td>4.4</td>
<td>5.0</td>
</tr>
<tr>
<td>LSIL (%)</td>
<td>0.0</td>
<td>0.0</td>
<td>0.2</td>
<td>0.8</td>
<td>1.5</td>
<td>2.4</td>
<td>3.7</td>
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<tr>
<td>HSIL (%)</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.2</td>
<td>0.5</td>
<td>1.0</td>
<td>1.2</td>
</tr>
<tr>
<td>ASC-US (%)</td>
<td>0.2</td>
<td>0.4</td>
<td>1.0</td>
<td>1.7</td>
<td>3.7</td>
<td>6.7</td>
<td>8.2</td>
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<tr>
<td>ASC-H (%)</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.1</td>
<td>0.4</td>
<td>1.0</td>
<td>1.5</td>
</tr>
<tr>
<td>AGC (%)</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
<td>0.9</td>
</tr>
<tr>
<td>ASC/SIL</td>
<td>0.5</td>
<td>0.9</td>
<td>1.2</td>
<td>1.6</td>
<td>2.9</td>
<td>3.5</td>
<td>4.8</td>
</tr>
</tbody>
</table>
### Cytopathology Checklist

**ThinPrep** laboratory percentile-reporting rate

<table>
<thead>
<tr>
<th>CATEGORY</th>
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<th>10th</th>
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</tr>
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<td>3.4</td>
<td>4.5</td>
<td>6.0</td>
</tr>
<tr>
<td>HSIL (%)</td>
<td>0.1</td>
<td>0.1</td>
<td>0.2</td>
<td>0.4</td>
<td>0.7</td>
<td>1.1</td>
<td>1.5</td>
</tr>
<tr>
<td>ASC-US (%)</td>
<td>1.0</td>
<td>2.1</td>
<td>3.6</td>
<td>5.4</td>
<td>7.7</td>
<td>10.7</td>
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<tr>
<td>ASC-H (%)</td>
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<td>4.5</td>
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</table>

**SurePath** laboratory percentile-reporting rate

<table>
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<td>1.3</td>
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<td>ASC-H (%)</td>
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<td>2.0</td>
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<td>3.5</td>
<td>4.5</td>
</tr>
</tbody>
</table>

*Includes conventional annual test volume of >60.

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

### Evidence of Compliance:

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

### REFERENCES


### CYP.07650 Statistical Records - Outliers

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

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

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

CYP.07653 HR-HPV Records

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

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

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

REFERENCES


CYP.07655 Screening Performance

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.

REFERENCES


CYP.07660 Diagnostic Discrepancies/Corrective Action

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
- Statistical reporting policy
- Statistical records and annual summary

- 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?

**NEW** 09/22/2021

CYP.07666 Unsatisfactory Specimens - Non-gynecologic Cytopathology Phase II

There are written criteria for identification and reporting of unsatisfactory non-gynecologic specimens, as applicable.

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

REFERENCES

**REVISED** 09/22/2021

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

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

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 (eg, quality management records, problem logs, or in patient reports)

REFERENCES

CYP.07685 Stains - Non-gynecologic Cytopathology

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

REFERENCES

**REVISED** 09/22/2021

CYP.07692 Statistical Records - Non-gynecologic Cytopathology

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

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

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

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

Evidence of Compliance:
✓ Written policy for statistical record keeping AND
✓ Annual statistical records

REFERENCES

PERSONNEL

For laboratories not subject to US regulations, national, state or provincial, and local personnel laws and 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
The section director/technical supervisor of the cytopathology laboratory is a pathologist board certified in anatomic pathology or possesses qualifications equivalent to those required for board certification.

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

REFERENCES

CYP.07800 Non-Supervisory Personnel Phase II

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

1. Graduated from a school of cytotechnology accredited by the Commission on Accreditation of Allied Health Education Programs or other organization approved by Health and Human Services (HHS); or
2. Certified in cytotechnology by a certification agency approved by HHS (eg, 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 full-time 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 laboratories not subject to US regulations, education, experience, and/or certification qualifications must meet or be equivalent to US qualifications or meet national, state or provincial, or local laws and regulations.

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

REFERENCES

CYP.07900 Screening Personnel Phase II

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

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

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

REFERENCES

CYP.08100 General Supervisor

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

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

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

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

REFERENCES

CYP.08200 General Supervisor Responsibilities

The cytopathology general supervisor fulfills defined responsibilities.

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

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

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

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

REFERENCES

CYP.08300 Cytotechnologist Responsibilities

The cytotechnologist fulfills defined responsibilities.

NOTE: The cytotechnologist is responsible for recording:

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

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

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

REFERENCES
# CYTOLOGY WORKLOAD

## Inspector Instructions:

| READ | **Workload reporting policies and procedures**  
|      | *Policy for setting individual workload limits*  
|      | *Sampling of workload recording records for all individuals (cytotechnologists and pathologists) performing primary screening and for automated screening instruments*  
|      | *Sampling of personnel assessments for the setting of workload limits* |
| **OBSERVE** | **Workload recording practices in screening area, including computerized and manual recording systems** |
| **ASK** | **What criteria does your laboratory use when evaluating individual cytology workload limits?**  
|      | *Describe your workload recording process*  
|      | *How often are workload recording limits exceeded?*  
|      | *If employees screen slides at other laboratories on days when screening is performed, how is it captured in the laboratory’s workload recording?*  
|      | *What type of action is taken when there is a workload violation?* |
| **DISCOVER** | Select random examples of workload recording logs for each primary screener (pathologists and cytotechnologists) over the previous two-year period  
|      | *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-gynecologic 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 over the previous two-year period and follow examples requiring a full manual review to evaluate the workload recording.

---

**CYP.08400**  
**Screening Workload - Laboratories Subject to US Regulations**

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

*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 - Laboratories Not Subject to US Regulations**

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** 09/22/2021

**CYP.08500 Manual Screening - Laboratories Subject to US Regulations**

There is a written workload policy for the manual screening of cytology slides, with evidence of data recording for cytotechnologists and pathologists who screen previously unscreened gynecologic and non-gynecologic (including FNA) slides.

**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 (eg, 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 manual 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 manual 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 screening 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.

Pathologists who screen previously unscreened gynecologic slides and previously unscreened non-gynecologic slides (including FNA slides) must adhere to the above workload limit and retain records of compliance.

For all screening personnel, adequacy assessment of fine needle aspiration (FNA) smears or rapid on-site evaluation (ROSE) is not considered primary cytology screening; however, the time spent performing adequacy assessments must be used to prorate the maximum number of slides the individual can screen in a 24-hour period.

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 slides
5. Previously screened 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

CYP.08550 Automated Screening - Laboratories Subject to US Regulations 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. The following includes information on calculating workload using semi-automated gynecologic cytology screening devices:

- 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 (eg, workload for cytotechnologists performing automated and semi-automated gynecologic smear under a California state laboratory license is limited to 100 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
3) 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),(g)].
There is a policy for the establishment of an individual maximum workload for cytology slide screening, including processes for reassessment at least every six months and adjustment when necessary.

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.

Performance must be reassessed using the following:

- Re-evaluation of 10 percent of the cases interpreted to be negative by cytotechnologists
- Comparing the cytotechnologist's interpretation in gynecologic specimens with the final cytologic diagnosis
- 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
LABORATORY SAFETY

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

Inspector Instructions:

- Hazardous waste disposal policy
- Sampling of microwave reproducibility and ventilation checks
- How does your laboratory dispose of infectious specimens and contaminated material?

CYP.09700 Infectious 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 infectious waste

REFERENCES


CYP.09910 Microwave Usage Phase I

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

CYP.09920 Microwave Monitoring Phase I

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

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.

Evidence of Compliance:
✓ Written procedure for the use of appropriately vented containers

CYP.09940 Microwave Venting

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 (eg, 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