Cytopathology Checklist
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Using the Changes Only Checklist

This document contains new checklist requirements, major and minor requirement revisions, and changes to explanatory text. Changes appear in a track changes format that compares the previous checklist edition to the August 21, 2017 edition. Requirements with major revisions will display a "Revised" flag. These changes may affect your laboratory operations. Requirements with minor revisions will not display a "Revised" flag. They are editorial changes that are not likely to affect your laboratory operations.

Information regarding requirements that have been combined, moved, resequenced or deleted, as applicable, appears in table format below.

2017 CHECKLIST EDITION CHANGES
DELETED, MERGED, AND MOVED REQUIREMENTS *

<table>
<thead>
<tr>
<th>2016 Requirement</th>
<th>Action Taken</th>
<th>2017 Requirement</th>
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*Merged – Combined the requirement with a similar requirement in the same or different checklist

*Moved – Relocated the requirement to another checklist or resequenced it within the same checklist

GENERAL CYTOPATHOLOGY

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

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

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

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

**CYTOLOGY STAINS AND SLIDE PREPARATIONS**

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

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

*NOTE:* Cytology stains undergoing a daily technical quality review are exempt from an annual assessment.

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

**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.

**NEW** 08/21/2017
CYP.04310 Specimen Modification Phase II

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

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

**NEW** 08/21/2017
CYP.04320 Buffer pH Phase II

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

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

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

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

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

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

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

Appropriate negative controls are used.

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

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

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

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

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

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

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

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

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

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

Multitissue blocks may be considered best practice and can have a major role in maintaining quality. When used as a combined positive and negative tissue control as mentioned above, they can serve as a permanent record of the sensitivity and specificity of every stain, particularly when mounted on the same slide as the patient tissue. When the components are chosen appropriately, multitissue blocks may be used for many different primary antibodies, decreasing the number of different control blocks needed by the laboratory. Multitissue blocks are also ideal for determining optimal titers of primary antibodies since they allow simultaneous evaluation of many different pieces of tissue. Finally, they are a useful and efficient means to screen new antibodies for sensitivity and specificity or new lots of antibody for consistency, which should be done before putting any antibody into diagnostic use.
**NEW**       08/21/2017
CYP.04350  Endogenous Biotin  Phase I

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

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

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

**NEW**       08/21/2017
CYP.04360  Control Slide Review  Phase II

When batch controls are run, the laboratory director or designee reviews all control slides each day of patient testing.

NOTE: Records of this daily review must be maintained and should clearly show that positive and negative controls for all antibodies stain appropriately. Batch control records must be retained for two years.

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

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.

**NEW**       08/21/2017
CYP.04370  Antibody Validation  Phase II

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

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

Means of validation may include, but are not limited to: 1) correlating the results using the new antibody with the morphology and expected results; 2) comparing the results using the new antibody with the results of prior testing of the same tissues with a validated assay in the same laboratory; 3) comparing the results using the new antibody with the results of testing the same tissue in another laboratory with a validated assay; or 4) comparing the results using the new antibody with previously validated non-immunohistology tests or testing previously graded tissue challenges from a formal proficiency testing program.
For an initial validation, laboratories should achieve at least 90% overall concordance between the new test and the comparator test or expected results.

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

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

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

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

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

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

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

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

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

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

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

For specific validation requirements for HER and ER/PgR testing in breast carcinoma, refer to the
**NEW** 08/21/2017
CYP.04410 Slide Quality

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.

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**NEW** 08/21/2017
CYP.05295 Pipette Accuracy - Non Class A

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

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

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**REVISED** 07/28/2015
CYP.05300 Result Reporting Cytopathology Report Elements

The cytopathology report includes all of the following required elements:

1. Name of patient and unique identifying number, if available
2. Age and/or birth date of patient
3. Date of collection
4. Accession number
5. Name of 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.

**REVISED** 08/21/2017
CYP.05350 Cytopathology Report Elements  Phase I

The cytopathology report includes all of the following desirable elements:

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

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

PERSONNEL

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

**REVISED** 08/21/2017
CYP.07800 Non-Supervisory Personnel  Phase II

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

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

NOTE: If more stringent state or local regulations are in place for cytotechnologist qualifications, including requirements for state licensure, they must be followed.
For non-US laboratories, education, experience, and/or certification qualifications must meet those of the country in which the laboratory is located, or be equivalent to US qualifications.

**REVISED** 08/21/2017

CYP.08100 Supervisor/General Supervisor Phase II

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

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

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

CYP.08200 Supervisor/General Supervisor Responsibilities Phase II

The cytopathology supervisor/general supervisor fulfills defined responsibilities.

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

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

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

CYTOLOGY WORKLOAD

**REVISED** 08/21/2017

CYP.08400 Screening Workload - US Laboratories Phase II

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

NOTE: While the 100 federal and state regulations on slide/24-hour limit workload limits must never be exceeded, the CAP does not rely solely upon these 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.

**REVISED** 08/21/2017
There is a written workload policy for the manual screening of cytology slides, with evidence of data recording.

NOTE: This checklist requirement applies only to laboratories subject to US regulations. The final rule implementing CLIA requires that each individual evaluating cytology preparations by manual microscopic technique must examine no more than 100 slides (gynecologic and non-gynecologic or both) in 24-hours. In addition, if there are different state regulations for cytology workload, the most stringent regulation must be followed (e.g. workload for cytotechnologists manually screening gynecologic smears under a California state laboratory license is limited to 80 gynecologic slides in a 24-hour period, and reduced proportionately based on other duties performed.

Gynecologic slides include new routine slides, 10% rescreen slides, and five-year look-back negative slides. Records must be maintained showing the total number of slides examined by each individual during each 24-hours.

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

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

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

Additional responsibilities must be considered when evaluating workload.

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

The following are not subject to the workload limit for pathologists:

1. Previously screened reactive/repair, atypical, premalignant and malignant gynecologic slides
2. Rescreened five-year look-back slides
3. 10% rescreen of negative gynecologic slides
4. Previously screened non-gynecologic and FNA slides
5. FNA slides evaluated solely for the purpose of adequacy

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

NOTE: This checklist requirement applies only to laboratories subject to US regulations. Workload calculations may vary with the use of automated screening instruments. Laboratories must assure that CLIA requirements are fulfilled, in addition to following workload calculations as defined in the 07/27/10 FDA alert - How Laboratorians Can Safely Calculate Workload for FDA-Approved Semi-Automated Gynecologic Cytology Screening Devices. This FDA alert provides the following calculation method, which applies to both semi-automated cytology screening systems currently on the market (Hologic’s ThinPrep® Imaging System and Becton Dickenson’s Focal Point™ Guided Screening System):
- All slides with full manual review (FMR) count as one slide equivalent (as mandated by CLIA for manual screening)
- All slides with field of view (FOV) only review count as 0.5 or 1/2 slide equivalents
- Slides with both FOV and FMR count as 1.5 or 1-1/2 slide equivalents
- These values should be used to count workload, not exceeding the CLIA maximum limit of 100 slides in no less than an eight-hour day

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

**REVISED** 08/21/2017
CYP.08575 Individual Maximum Workload - US Laboratories

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

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

CYP.08900 Screening Facility

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

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

LABORATORY SAFETY

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

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

NOTE: Microwave devices should be used in accordance with manufacturer's instructions, unless CAP requirements are more stringent.
**NEW** 08/21/2017  
**CYP.09920** Microwave Monitoring  
**Phase I**

**Microwave Monitoring**

Microwave devices are at least annually monitored for reproducibility.

**NOTE:** Reproducibility is defined as consistency in diagnostic quality obtained from microwave equipment and procedures. For some devices, reproducibility may be evaluated by monitoring the temperatures of identical samples after microwave processing. For those microwave devices (particularly those incorporated into histology processing equipment) that use temperature-independent methods to evaluate reproducibility, the laboratory should have a written procedure for monitoring reproducibility that follows instrument manufacturer's instructions. Information on such procedures is given in the reference to this checklist requirement (see below).

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

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

**Microwave Container Venting**

All containers used in microwave devices are vented.

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

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

**Microwave Venting**

Microwave devices are properly vented.

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

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

The effectiveness of ventilation should be monitored at least annually.

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