COMMISSION ON LABORATORY ACCREDITATION

Laboratory Accreditation Program

CYTOPATHOLOGY CHECKLIST

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If a Checklist has been updated since receiving your packet, you will be inspected based upon the Checklists that were mailed. If you have any questions about the use of Checklists in the inspection process, please e-mail the CAP (accred@cap.org), or call (800) 323-4040, ext. 6065.

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# CYTOPATHOLOGY

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SUMMARY OF CHANGES
CYTOPATHOLOGY Checklist

The following questions have been added, revised, or deleted in this edition of the checklist, or in the two editions immediately previous to this one.

If this checklist was created for a reapplication, on-site inspection or self-evaluation it has been customized based on the laboratory's activity menu. The listing below is comprehensive; therefore some of the questions included may not appear in the customized checklist. Such questions are not applicable to the testing performed by the laboratory.

Note: For revised checklist questions, a comparison of the previous and current text may be found on the CAP website. Click on Laboratory Accreditation, Checklists, and then click the column marked Changes for the particular checklist of interest.

NEW Checklist Questions

<table>
<thead>
<tr>
<th>Question</th>
<th>Effective Date</th>
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<tr>
<td>CYP.03333</td>
<td>09/27/2007</td>
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REVISED Checklist Questions

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<td>CYP.05300</td>
<td>09/27/2007</td>
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<td>09/27/2007</td>
</tr>
<tr>
<td>CYP.07517</td>
<td>09/27/2007</td>
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<td>CYP.08500</td>
<td>09/27/2007</td>
</tr>
<tr>
<td>CYP.00125</td>
<td>10/31/2006</td>
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<td>CYP.00150</td>
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<td>10/31/2006</td>
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<tr>
<td>CYP.02100</td>
<td>10/31/2006</td>
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<tr>
<td>CYP.02300</td>
<td>10/31/2006</td>
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<tr>
<td>CYP.03400</td>
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<td>CYP.06100</td>
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<td>10/31/2006</td>
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DELETED Checklist Questions

<table>
<thead>
<tr>
<th>Question</th>
<th>Effective Date</th>
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<tr>
<td>CYP.00750</td>
<td>10/31/2006</td>
</tr>
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CONTINUING EDUCATION INFORMATION

Beginning January 2008, you may earn continuing education credits (CME/CE) by completing an online Inspection Preparation activity that includes review of this checklist.

Prior to reviewing the checklist, log on to the CAP Web site at <www.cap.org <http://www.cap.org>>, click the Education Programs tab, then select Laboratory Accreditation Program (LAP) Education Activities, and Inspection Preparation for complete instructions and enrollment information.

IMPORTANT: The contents of the Laboratory General Checklist are applicable to the Cytopathology section of the laboratory.

******************************************************************************

INSPECTION TECHNIQUES – KEY POINTS

******************************************************************************

I. READ – OBSERVE – ASK – the three methods of eliciting information during the inspection process. These three methods may be used throughout the day in no particular order. Plan the inspection in a way that allows adequate time for all three components.

READ = Review of Records and Documents
Document review verifies that procedures and manuals are complete, current, available to staff, accurate and reviewed, and describe good laboratory practice. Make notes of any questions you may have, or processes you would like to observe as you read the documentation. In reviewing records of quality control, instrument maintenance, documentation of rescreening of gynecological cytology cases, cytology-histology correlation, and other activities, select records from various times during the two-year interval since the previous on-site inspection.

OBSERVE – ASK = Direct Observation and Asking Questions
Observing and asking questions accomplish the following:
1. Verifies that the actual practice matches the written policy or procedure
2. Ensures that the laboratory processes are appropriate for the testing performed
3. Ensures that outcomes for any problem areas, such as issues/problems identified through the quality management process, have been adequately investigated and resolved
4. Ensures that previous deficiencies have been corrected

Use the following techniques:
- **Observe laboratory practices** – look at what the laboratory is actually doing. Compare the written policy/procedure to what you actually observe in the laboratory to ensure the written policy/procedure accurately reflects laboratory practice. Note if practice deviates from the documented policies/procedures. Observe activities in the specimen preparation area, to determine whether specimen identity is maintained throughout all the processing steps that result in the preparation of microscopic slides, and to determine if personnel follow written procedures.

- **Ask open ended, probing questions** – these are starting points that will allow you to obtain large amounts of information, and help you clarify your understanding of the documentation you’ve seen and observations you’ve made. This eliminates the need to ask every single checklist question, as the dialogue between you and the laboratory may address multiple checklist questions.
  - Ask open-ended questions that start with phrases such as “show me how…” or “tell me about …” or “what would you do if…”. By asking questions that are open-ended, or by posing a hypothetical problem, you will avoid “cookbook” answers. For example, ask “Could you show me the specimen labeling policy and how it ensures accurate identification of the specimen throughout processing and reporting?” This will help you to determine how well the technical staff is trained, whether or not they are adhering to the laboratory’s procedures and policies, and give you a feel for the general level of performance of the laboratory.
  - Ask follow-up questions for clarification. Generally, it is best not to ask the checklist questions verbatim. For example, instead of asking the checklist question “Is there documentation of corrective action when an unlabeled specimen is received?” ask, “What would you do if an unlabeled specimen is received?” A follow-up probing question could be, “What would you do if there were repeated instances of unlabeled specimens from the same source?”

**II. PT problem resolution verification:** From the inspector’s packet, review the Variant PT Performance Report that identifies, by analyte, all of the PT scores below 100%. Check to see how problems were resolved. Check to see whether PT performance was used in the biannual evaluation of screening personnel. Be thorough when reviewing these representative records, selecting data from the beginning, middle and end of the period since the last on-site inspection.

**III. Review correction of previous deficiencies:** Review the list of deficiencies from the previous on-site inspection provided in the inspector’s packet. Ensure that they have been appropriately addressed.
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 should be pathologists or cytotechnologists who are actively involved with or have extensive experience in the practice of cytology, and are knowledgeable about current CAP Checklist and CLIA-88 requirements. Inspectors preferably should have attended a recent CAP Inspector Training Workshop, and be familiar with the CAP publication “Quality Management in Anatomic Pathology.”

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 documented review of case (slide) material, direct observation of technical procedures, and careful review of quality management monitors.

INTERLABORATORY COMPARISONS

NOTE: Peer interlaboratory comparison programs provide valuable educational opportunities based on peer performance comparisons in both technical and interpretive arenas. While not completely emulating cytopathology preparation and interpretation, participation in such programs enables a laboratory to compare its performance to peer laboratories. Participation in GYNECOLOGIC interlaboratory programs is required (Phase II), while participation in NON-GYNECOLOGIC programs is encouraged (Phase I).

**REVISED** 10/31/2006

CYP.00125 Phase II N/A YES NO

For laboratories subject to CLIA-88 that perform gynecologic cytopathology, does the laboratory and all individuals who examine gynecologic preparations participate in the CAP Gynecologic Cytology PT Program (PAP PT) or another proficiency testing program in gynecologic cytopathology approved by CMS?
NOTE: This checklist question applies only to laboratories subject to CLIA-88 regulations. Laboratories must maintain documentation of PT performance for at least 2 years. Documentation must be kept for each individual participating in annual PT, including identification of those who are retested; documentation of remedial training; records of imposition of limitations on slide examination; and records of re-examination of slides, as required by CLIA-88.

COMMENTARY:

N/A


**REVISED** 10/31/2006

CYP.00150 Phase I N/A YES NO

For laboratories subject to CLIA-88 that perform gynecologic cytopathology, does the laboratory participate 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.

COMMENTARY:

N/A


**REVISED** 10/31/2006

CYP.00170 Phase II N/A YES NO

For laboratories not subject to CLIA-88 regulations, that perform gynecologic cytopathology, does the laboratory participate 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.

COMMENTARY:

N/A

For laboratories that perform non-gynecologic cytopathology, does the laboratory participate in a peer educational program in NON-GYNECOLOGIC cytopathology (e.g., CAP Interlaboratory Comparison Program in Non-Gynecologic Cytopathology NGC)?

COMMENTARY:

N/A

*************************************************************

QUALITY MANAGEMENT

*************************************************************

The laboratory must have a clearly defined, documented QM program that includes active surveillance of laboratory activities. Evaluation of the results of surveillance must be documented. Surveillance monitors may differ among laboratories. The QM program must ensure quality throughout the pre-analytic, analytic and post-analytic (reporting) phases of testing, including specimen identification, preservation, transportation, and processing; and accurate, timely result reporting. The program must be capable of detecting problems in the laboratory’s systems, and identifying opportunities for system improvement. The laboratory must be able to develop plans of corrective/preventive action based on data from its QM system.

Technical and procedural quality control items are integral components of comprehensive quality management and should be included within the program.

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).
Is there a clearly defined and documented quality management program in cytopathology?

NOTE: Laboratories should consistently review activities and monitor their effectiveness in improving performance. Each laboratory should design a program that meets its needs and conforms to appropriate regulatory and accreditation standards.

COMMENTARY:

N/A

CYP.00900     Phase II     N/A   YES   NO

Are records of the results of quality management surveillance maintained?

COMMENTARY:

N/A

CYP.01900     Phase II     N/A   YES   NO

If significant disparities exist between histological and cytological findings, are these resolved in a confidential peer-reviewed quality management document, or in an addendum report, as appropriate?

COMMENTARY:

N/A

**REVISED** 10/31/2006

CYP.02100     Phase II     N/A   YES   NO

Are documented records of intra- and extradepartmental consultations maintained?

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

COMMENTARY:

N/A


CYP.02200     Phase II     N/A   YES   NO

Is there documented evidence of daily review of the technical quality of cytologic preparations by the pathologist or supervisory-level cytotechnologist?

COMMENTARY:

N/A
QUALITY CONTROL

PROCEDURE MANUAL

The procedure manual should be available to, and used by, personnel at the workbench and should include, as appropriate: test principle, clinical significance, specimen type, required reagents, test calibration, quality control, procedural steps, and interpretation of results. The manual should include pre-analytic, analytic, and post-analytic activities. The specific style and format of procedure manuals are at the discretion of the laboratory director.

The inspection team should review the procedure manual in detail to understand the laboratory's standard operating procedures, ensure that all significant information and instructions are included, and that actual practice matches the contents of the procedure manuals.

**REVISED** 10/31/2006

CYP.02300 Phase II N/A YES NO

Is a complete procedure manual available at the workbench or in the work area?

NOTE 1: The use of inserts provided by manufacturers is not acceptable in place of a procedure manual. However, such inserts may be used as part of a procedure description, if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from this printed or electronic procedure must be detailed in the procedure manual. In all cases, appropriate reviews must occur.

NOTE 2: A manufacturer's procedure manual for an instrument/reagent system may be acceptable as a component of the overall departmental procedures. Any modification to or deviation from the procedure manual must be clearly documented.

NOTE 3: Card files or similar systems that summarize key information are acceptable for use as quick reference at the workbench provided that:

a. A complete manual is available for reference
b. The card file or similar system corresponds to the complete manual and is subject to document control
NOTE 4: Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, so long as the electronic versions are readily available to all personnel. However, procedures must be available to laboratory personnel when the electronic versions are inaccessible (e.g., during laboratory information system or network downtime); thus, the laboratory must maintain either paper copies or electronic copies on CD or other media that can be accessed via designated computers. All procedures, in either electronic or paper form, must be readily available for review by the inspector at the time of the CAP inspection.

Electronic versions of procedures must be subjected to proper document control (i.e., only authorized persons may make changes, changes are dated/signed (manual or electronic), and there is documentation of annual review). Documentation of review of electronic procedures may be accomplished by including statements such as “reviewed by [name of reviewer] on [date of review]” in the electronic record. Alternatively, paper review sheets may be used to document review of electronic procedures. Documentation of review by a secure electronic signature is NOT required.

COMMENTARY:

N/A


CYP.02500 Phase II N/A YES NO

Is there documentation of at least annual review of all policies and procedures in the cytopathology laboratory section by the current laboratory director or designee?

NOTE: The director must ensure that the collection of policies and technical protocols is complete, current, and has been thoroughly reviewed by a knowledgeable person. Technical approaches must be scientifically valid and clinically relevant. To minimize the burden on the laboratory and reviewer(s), it is suggested that a schedule be developed whereby roughly 1/12 of all procedures are reviewed monthly. Paper/electronic signature review must be at the level of each procedure, or as multiple signatures on a listing of named procedures. A single signature on a title page or index of all procedures is not sufficient documentation that each procedure has been carefully reviewed. Signature or initials on each page of a procedure is not required.

COMMENTARY:
Does the director (or a designee who meets CAP director qualifications) review and approve all new policies and procedures, as well as substantial changes to existing documents, before implementation?

*NOTE:* Current practice must match the policy and procedure documents.

COMMENTARY:

N/A


If there is a change in directorship, does the new director ensure (over a reasonable period of time) that laboratory procedures are well-documented and undergo at least annual review?

COMMENTARY:

N/A


When a procedure is discontinued, is a paper or electronic copy maintained for at least 2 years, recording initial date of use, and retirement date?

COMMENTARY:

N/A


<table>
<thead>
<tr>
<th>CYP.02800</th>
<th>Phase II</th>
<th>N/A</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the laboratory have a system documenting that all personnel are knowledgeable about the contents of procedure manuals relevant to the scope of their testing activities?</td>
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**NOTE:** This does not specifically require annual procedure sign-off by testing personnel. The form of this system is at the discretion of the laboratory director.

**COMMENTARY:**

N/A

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**SPECIMEN COLLECTION AND RECEIPT**

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<table>
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<tr>
<th>CYP.02900</th>
<th>Phase II</th>
<th>N/A</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are instructions distributed to physicians and paramedical personnel for proper collection, handling, transportation, and preparation of cytologic specimens?</td>
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</tbody>
</table>

**NOTE:** These requirements apply even if the specimens are not accessioned, stained, interpreted, and/or reported in the institution being inspected. Instructions should be documented for all applicable cytologic specimens, including Pap tests, sputum, washings, brushings, body fluids, fine needle aspirations, etc. These instructions must be included in the procedure or user manuals at all sites where specimens are collected (e.g., nursing stations, clinics, physicians’ offices).

**COMMENTARY:**

N/A

**REFERENCES:**

**CYP.03000** Phase II

Do the instructions include the preferred method for preparation of slides (proper fixation of slides and labeling of slides and containers)?

**COMMENTARY:**

N/A

**CYP.03300** Phase II

Are all specimens properly and adequately identified (*i.e.*, patient's name or other unique and complete identifier on slide or specimen container)?

**NOTE:** The laboratory must not accept inadequately identified specimens.

**COMMENTARY:**

N/A

**NEW** 09/27/2007

**CYP.03333** Phase II

If the pathologist performs FNA procedures or if laboratory personnel participate in FNA procedures, are patient identifiers placed on the prepared slides and any specimen container at the time of the procedure?

**NOTE:** All specimens must be labeled at the time of collection to provide unique identification. Each prepared slide must be labeled separately and any specimen container with collected material (*e.g.*, fluid from aspiration) must also be labeled.

**COMMENTARY:**

N/A
**NEW**  09/27/2007

CYP.03366  Phase I  N/A  YES  NO

If the pathologist performs FNA procedures, is there a documented procedure to prevent errors in the identification of the patient, the site and the procedure?

COMMENTARY:

N/A


**REVISED**  10/31/2006

CYP.03400  Phase II  N/A  YES  NO

Does the cytopathology requisition include space for the following:

1. Name of patient
2. Patient date of birth or age
3. Patient gender
4. Test(s) ordered
5. Date of specimen collection
6. Last menstrual period (for gynecologic specimens)
7. Source of cytologic material
8. Name and address of submitting clinician
9. Pertinent clinical information

NOTE: For gynecologic specimens, specific clinical information such as date of last menstrual period, hormone and other therapies, previous Pap test and biopsy results, etc., are important data.

COMMENTARY:

N/A


CYP.03500  Phase II  N/A  YES  NO

Are specimens recorded in an accession book, computer, or other comparable record and given an accession number upon receipt?
COMMENTARY:

N/A

**CYP.03600**  Phase II  N/A  YES  NO

Does the laboratory have a policy that specimens are accepted only from physicians or other persons authorized under law?

COMMENTARY:

N/A


**CYP.03700**  Phase II  N/A  YES  NO

Are there documented criteria for rejection of specimens (e.g., inadequate requisition information, unauthorized source, broken slides)?

COMMENTARY:

N/A

**CYP.03800**  Phase II  N/A  YES  NO

Is there evidence that submitting physicians are notified when unacceptable specimens are received?

*NOTE*: Notification may consist of follow-up correspondence, documented telephone calls, or written reports.

COMMENTARY:

N/A


----------------------------------------------------------

CYTOLOGY STAINS AND SLIDE PREPARATIONS

----------------------------------------------------------

CYP.03900       Phase II       N/A   YES   NO

Are all working solutions and stains properly labeled?

NOTE: Working solutions and stains must be properly labeled with the contents, and, if applicable, expiration date and/or date changed/filtered.

COMMENTARY:

N/A

CYP.03925       Phase I       N/A   YES   NO

Are cytology stains assessed at least annually to ensure their proper storage and acceptable quality?

NOTE: Most stains used in the cytology laboratory are not subject to outdating, so that assignment of expiration dates may have no meaning. The acceptable performance of such stains should be periodically confirmed by technical assessment on actual case material, and as part of the evaluation of cytopathology cases. Where applicable, expiration dates assigned by a manufacturer must be observed.

COMMENTARY:

N/A

CYP.04050       Phase II       N/A   YES   NO

Are all reagents stored as recommended by the manufacturer?

NOTE: Reagents must be stored as recommended by the manufacturer in order to prevent environmentally-induced alterations that could affect test performance. If ambient storage temperature is indicated, there must be documentation that the defined ambient temperature is maintained and corrective action is taken when tolerance limits are exceeded.
COMMENTARY:

N/A

CYP.04070 Phase II N/A YES NO
Are all reagents used within their indicated expiration date?
COMMENTARY:
N/A

CYP.04100 Phase II N/A YES NO
Are staining solutions filtered or replaced regularly?
COMMENTARY:
N/A

CYP.04200 Phase I N/A YES NO
Are staining solutions covered when not in use, and changed periodically?
COMMENTARY:
N/A

CYP.04300 Phase II N/A YES NO
Are all stains checked for predicted staining characteristics each day of use?
COMMENTARY:
N/A

CYP.04700 Phase II N/A YES NO
Are slides adequately labeled?
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 effort to facilitate the Inspector's evaluation of the laboratory's overall procedures. Time should be allotted to review at least 10-15 cases that are representative of the laboratory’s workload and case mix. Cases should be selected from a variety of diagnostic categories, and include the following case types:

<table>
<thead>
<tr>
<th>Gynecologic Cases</th>
<th>Non-Gynecologic Cases (including FNA’s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsatisfactory</td>
<td>Negative / Reactive</td>
</tr>
<tr>
<td>Negative / Reactive</td>
<td>Suspicious / Positive</td>
</tr>
<tr>
<td>Atypical squamous cells</td>
<td></td>
</tr>
<tr>
<td>HPV / LGSIL</td>
<td></td>
</tr>
<tr>
<td>HGSIL / POS</td>
<td></td>
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</tbody>
</table>

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

1. Slides should be evaluated for quality of technical preparation as well as specimen adequacy.
2. Have significant cells been identified?
3. Slides should be compared with the diagnostic report for completeness and clarity of diagnostic terminology.
4. Is the information provided with the requisition and included in the diagnostic report complete and appropriate?
5. 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.

NOTE: 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** Phase II        N/A  YES  NO

Is cellular and nuclear detail sufficient for proper interpretation?

COMMENTARY:

N/A

**CYP.05000** Phase II        N/A  YES  NO

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

*NOTE: If "NO," describe in the Inspector's Summation Report.*

COMMENTARY:

N/A

-----------------------------------------------------------------

**INSTRUMENTS AND EQUIPMENT**

-----------------------------------------------------------------

A variety of instruments and equipment are used to support the performance of analytical procedures. All instruments and equipment should be properly operated, maintained, serviced, and monitored to ensure that malfunctions of these instruments and equipment do not adversely affect the analytical results. The inspection team should review the procedures for instrument/equipment operations, maintenance, and monitoring records to ensure that these devices are properly used. The procedures and schedules for instrument maintenance must be as thorough and as frequent as specified by the manufacturer.

**CYP.05100** Phase II        N/A  YES  NO

Is all equipment used on a routine maintenance schedule?

COMMENTARY:

N/A
Are instrument maintenance, service and repair records (or copies) promptly available to, and usable by, the technical staff operating the equipment?

NOTE: The effective utilization of instruments by the technical staff depends upon the prompt availability of maintenance, repair, and service documentation (copies are acceptable). Laboratory personnel are responsible for the reliability and proper function of their instruments and must have access to this information. Off-site storage, such as with centralized medical maintenance or computer files, is not precluded if the inspector is satisfied that the records can be promptly retrieved.

COMMENTARY:

N/A

Is there documentation of adherence to the manufacturer’s recommended protocol(s) for implementation and validation of new instruments?

NOTE: Before implementing use of new gynecologic liquid-based methods and instruments, automated preparations, and automated screening instruments, the laboratory must validate and document the functioning of the instrument in its own specific laboratory environment, including the capability of the instrument to replace existing procedure(s), if applicable. If the manufacturer does not provide validation and instrument monitoring recommendations, the laboratory must document the specific validation procedure used.

COMMENTARY:

N/A

Is there documentation of ongoing monitoring of instrument maintenance and function for all devices?

NOTE: There must be documentation of ongoing monitoring of instrument function and maintenance records on all devices. Monitoring of device operation must be in accordance with manufacturers’ instructions. If the manufacturer does not provide monitoring recommendations, the laboratory must document the specific monitoring procedures used. Limits of acceptable variation must be defined in laboratory procedures.

A sample of slides from slide preparation instruments, including those using liquid-based technology and cytocentrifuge or filtration methods, should be routinely reviewed microscopically for technical acceptability.

COMMENTARY:

N/A

Is there documentation of appropriate technical and interpretive training for each of the instruments used?

NOTE: Before the implementation of any automated instrument procedure, staff must receive appropriate training with documented competency. In particular, liquid-based preparation techniques and high-resolution image analysis techniques require both technical and interpretive training by formal external training programs or internal laboratory programs provided by personnel with documented competence.

COMMENTARY:

N/A

If tolerance limits for diagnostic accuracy or determination of specimen adequacy are exceeded, is there documentation of corrective action?

NOTE: Daily review of all automated slide analysis print summaries by the cytology supervisor or designee is suggested as a means of conducting ongoing monitoring. Ongoing monitoring must be frequent enough to minimize adverse reporting. If tolerance limits for correlation of manual review
and automated results are not met, as defined by laboratory policy, corrective action per manufacturer's recommendations must be documented.

COMMENTARY:

N/A

CYP.05285    Phase II    N/A    YES    NO

Is there a documented procedure for handling workload during instrument failure and/or downtime?

NOTE: This procedure must address: (a) final processing and resulting of any cases/specimens that are within the instrument at the time of failure, and (b) alternative procedures to be used during instrument downtime.

COMMENTARY:

N/A


CYP.05292    Phase II    N/A    YES    NO

Has the laboratory defined a system to handle slides that are not successfully processed by the 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.

COMMENTARY:

N/A

RECORDS AND REPORTS

-----------------------------------------------------------------
**REVISED** 09/27/2007

CYP.05300  Phase II  N/A YES NO

Does the cytopathology report include all of the following *required* elements?

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

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

**COMMENTARY:**

N/A


CYP.05316  Phase II  N/A YES NO

Does the cytopathology report clearly indicate 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, initials or signature (in written or electronic form). The reviewing pathologist’s name must be distinct from any other pathologist names (e.g., the laboratory director) on the report. Electronic signatures must be authorized for each case by the pathologist who performed the review. A report may contain the signature INITIALS of a pathologist or cytotechnologist attesting to an activity other than review of the slides (for example, verification of results of automated screening instruments), but in such cases the
report must clearly indicate that the signature/initials attest to the other activity, not review of the slides.

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

COMMENTARY:

N/A

CYP.05332 Phase II N/A YES NO

Are cytopathology reports 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 and document 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 question does not apply to cases reviewed by a pathologist for quality control purposes only (e.g., the 10% rescreen of gynecologic cytopathology cases).

COMMENTARY:

N/A

CYP.05350 Phase I N/A YES NO

Does the cytopathology report include all of the following desirable elements?

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

NOTE: The Inspector must provide specific details of any deficiencies in Part B (Deficiency Summary) of the Inspector’s Summation Report. Description of specimens on receipt should document 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., 10cc bloody fluid in alcohol); Thin Prep vial; SurePath vial; brush in 10 cc clear yellow fluid, etc.
Does the cytopathology report include an interpretation of the morphologic findings, and, as appropriate, standard descriptive terminology?

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

Reports must include a concise descriptive diagnosis either in a format similar to a histopathology report, or standard descriptive terminology that includes a general categorization and descriptive diagnosis (as is recommended by the Bethesda System for gynecologic cytopathology reports). The use of diagnostic "classes" is not recommended, as it does not reflect current understanding of neoplasia, has no comparable equivalent in diagnostic histopathologic terminology, and does not provide for diagnosis of non-neoplastic conditions.

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

**REVISED** 10/31/2006

**CYP.06600**  
Phase II  
N/A  YES  NO

**Are cytopathology records retained for an appropriate period?**

**NOTE:** Records must be retained in accordance with the requirements listed in the Laboratory General checklist. In addition, cytopathology reports must be retained for a minimum of 10 years.

Cytopathology reports may be retained in either paper* or electronic format. If retained in electronic format alone, however, the electronic reports must include a secure pathologist electronic signature when applicable.

Since a 5-year "look-back" period is required when there is a newly identified abnormality in cervical cytopathology, non-computerized laboratories may wish to retain gynecologic cytopathology accession records for 5 years.

*Images of paper reports—such as microfiche or PDF files—are acceptable.

**COMMENTARY:**

N/A


**CYP.06700**  
Phase II  
N/A  YES  NO

**Is a patient index maintained for easy retrieval of information?**

**COMMENTARY:**

N/A

**CYP.06800**  
Phase II  
N/A  YES  NO

**Is a cross-index with histological material maintained?**

**COMMENTARY:**
For nongynecologic cases, is there a mechanism to correlate the results of specialized studies (e.g., molecular studies, immunocytochemistry) with the cytologic diagnosis?

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

COMMENTARY:

N/A

**RETENTION OF SLIDES**

CYP.06900 Phase II N/A YES NO

Are all glass slides retained for an appropriate period?

**NOTE:** Minimum requirements for cytopathology, providing these are not less stringent than state and federal regulations, are:

1. Gynecologic and non-gynecologic glass slides - 5 years
2. Fine needle aspiration glass slides - 10 years

Cell blocks should be retained for the same period as glass slides.

COMMENTARY:

N/A

<table>
<thead>
<tr>
<th>Code</th>
<th>Phase</th>
<th>N/A</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>CYP.07000</td>
<td>Phase I</td>
<td>N/A</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Are slides stored in an orderly manner and readily accessible?</td>
<td>COMMENTARY:</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CYP.07100</td>
<td>Phase II</td>
<td>N/A</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Is there a documented policy for protecting and preserving the integrity and retrieval of original slides in cytopathology?</td>
<td>NOTE: Cytopathology slides must be stored at room temperature for optimal preservation of their integrity. Stored slides must be organized to permit timely retrieval when slides are needed for review.</td>
<td>COMMENTARY:</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>CYP.07200</td>
<td>Phase II</td>
<td>N/A</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Is there a policy to ensure defined handling and documentation of the use, circulation referral, transfer and receipt of original slides to ensure availability of materials for consultation and legal proceedings?</td>
<td>COMMENTARY:</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CYP.07300</td>
<td>Phase II</td>
<td>N/A</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Is there documentation, including acknowledgment of receipt, when material is loaned to special programs such as the CAP Interlaboratory Comparison Program in Cervicovaginal Cytology (PAP)?</td>
<td>COMMENTARY:</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### STATISTICAL ANALYSIS

**CYP.07400 Phase II**

Are statistical records maintained, and summarized annually, that include the number of cytopathologic specimens and type/sources of specimens?

*NOTE:* At a minimum, the laboratory should divide cytology cases into 2 categories: gynecologic and non-gynecologic cases.

**COMMENTARY:**

N/A


### GYNECOLOGIC CYTOPATHOLOGY

**CYP.07439 Phase II**

Is the Papanicolaou stain used for gynecologic specimens?

**COMMENTARY:**

N/A


**CYP.07452 Phase II**

Are there documented criteria for categorizing a gynecologic specimen as unsatisfactory?
NOTE: Gynecologic specimens with atypical cells are always "satisfactory", although the report may include comments on the quality of the preparation.

COMMENTARY:

N/A


Are all gynecologic slides in the following categories interpreted by the pathologist?

1. Suspicious or malignant cells
2. Dysplasia
3. Cervical intraepithelial neoplasia (CIN)
4. Low- and high-grade squamous intraepithelial lesions
5. Atypical cells
6. Reactive or repair

COMMENTARY:

N/A


CYP.07478 Phase II N/A YES NO

Are at least 10% of each cytotechnologist's gynecologic cases that have been interpreted to be negative rescreened?

NOTE: The 10% rescreening is a CLIA-88 requirement, and therefore only applicable to 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-88, and that manufacturer and FDA recommendations for quality control are followed.

Slides must be rescreened in their entirety, including slides processed by imaging instruments that select a limited number of microscopic fields for examination by the cytotechnologist.

The laboratory must document results of all rescreened cases, including comparison to the original screening results.

COMMENTARY:

N/A

CYP.07491  Phase II  N/A  YES  NO

Are the results of gynecologic cases selected for rescreening not reported until the rescreen is complete?

COMMENTARY:

N/A

CYP.07504  Phase II  N/A  YES  NO

Is the rescreening of negative gynecologic cases performed by an individual qualified as a cytopathology supervisor under CLIA-88?

COMMENTARY:

N/A


**REVISED**  09/27/2007

CYP.07517  Phase II  N/A  YES  NO

Are all available (either on-site or in storage) previously negative slides received within the past five years 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 (manually read or from an automated method) from the index patient should be rescreened or reviewed by an individual qualified as a cytology supervisor under CLIA-88. Laboratory policy should specify which cases require pathologist review.

COMMENTARY:

N/A

CYP.07530 Phase II

If a significant discrepancy, which would affect current patient care, is found during the retrospective review, is a corrected report issued?

COMMENTARY:

N/A


CYP.07543 Phase II

Is a documented effort made to obtain and review follow-up histological reports or material 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 documented. The number of cases that have histologic correlation should be documented.

COMMENTARY:

N/A


CYP.07556 Phase II N/A YES NO

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

NOTE: Documentation may consist of follow-up correspondence, telephone calls, or requests included in the report.

COMMENTARY:

N/A


CYP.07569 Phase II N/A YES NO

Is an effort made to correlate gynecologic cytopathology findings with available clinical information?

NOTE: Methods of clinical correlation should be documented 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. Documentation of clinical correlation may include policies, problem logs with resolution, or notes in reports.

COMMENTARY:

N/A


CYP.07582 Phase I N/A YES NO

Is there a policy 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, etc.

**COMMENTARY:**

N/A


CYP.07600 Phase I N/A YES NO

For gynecologic cytopathology cases, are statistical records maintained of the number of cases of the following cytopathology results?

1. Diagnostic category (including unsatisfactory cases)
2. Significant cytologic/histologic discrepancies (as defined by laboratory policy)
3. Where rescreen resulted in reclassification of a result as premalignant or malignant
4. Where histopathology results are available to compare with malignant or high-grade squamous intraepithelial lesion (HSIL) cytopathology results

**NOTE:** These data should be included in the annual cytopathology statistical report. Inclusion of AGC data is optional. The following benchmark data have been collected by the CAP's Cytopathology Resource Committee and may be useful in evaluating the laboratory's statistical data. Separate statistics for conventional and liquid-based preparations are not required, but may be useful/educational in individual laboratory settings. These benchmarking data were collected in 2003:
## CONVENTIONAL

### Laboratory Percentile-Reporting Rate

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>5th</th>
<th>10th</th>
<th>25th</th>
<th>50th</th>
<th>75th</th>
<th>90th</th>
<th>95th</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASC-US (%)</td>
<td>0.3</td>
<td>0.8</td>
<td>1.5</td>
<td>2.4</td>
<td>4.2</td>
<td>6.2</td>
<td>8.2</td>
</tr>
<tr>
<td>ASC-H (%)</td>
<td>0.0</td>
<td>0.0</td>
<td>0.1</td>
<td>0.2</td>
<td>0.4</td>
<td>0.8</td>
<td>1.5</td>
</tr>
<tr>
<td>LSIL (%)</td>
<td>0.3</td>
<td>0.4</td>
<td>0.7</td>
<td>1.3</td>
<td>2.2</td>
<td>3.9</td>
<td>6.7</td>
</tr>
<tr>
<td>HSIL (%)</td>
<td>0.1</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
<td>0.6</td>
<td>1.1</td>
<td>2.0</td>
</tr>
<tr>
<td>ASC/SIL</td>
<td>0.4</td>
<td>0.6</td>
<td>1.1</td>
<td>1.7</td>
<td>2.6</td>
<td>3.8</td>
<td>4.5</td>
</tr>
<tr>
<td>AGC (%)</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.1</td>
<td>0.4</td>
<td>0.7</td>
<td>1.1</td>
</tr>
<tr>
<td>UNSATISFACTORY (%)</td>
<td>0.0</td>
<td>0.1</td>
<td>0.5</td>
<td>1.0</td>
<td>2.4</td>
<td>4.7</td>
<td>5.9</td>
</tr>
</tbody>
</table>

*Includes conventional and conventional with FocalPoint® cases in laboratories with a conventional cytology volume of >500 per year.

## ThinPrep®

### Laboratory Percentile-Reporting Rate

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>5th</th>
<th>10th</th>
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</thead>
<tbody>
<tr>
<td>ASC-US (%)</td>
<td>1.7</td>
<td>2.5</td>
<td>3.3</td>
<td>4.9</td>
<td>6.7</td>
<td>9.6</td>
<td>11.5</td>
</tr>
<tr>
<td>ASC-H (%)</td>
<td>0.0</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
<td>0.6</td>
<td>1.0</td>
<td>2.0</td>
</tr>
<tr>
<td>LSIL (%)</td>
<td>1.1</td>
<td>1.5</td>
<td>2.2</td>
<td>3.0</td>
<td>4.0</td>
<td>6.0</td>
<td>7.3</td>
</tr>
<tr>
<td>HSIL (%)</td>
<td>0.1</td>
<td>0.2</td>
<td>0.4</td>
<td>0.6</td>
<td>0.9</td>
<td>1.3</td>
<td>2.0</td>
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<td>0.8</td>
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<tr>
<td>AGC (%)</td>
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<td>0.0</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
<td>0.9</td>
<td>1.4</td>
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<td>UNSATISFACTORY (%)</td>
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<td>0.6</td>
<td>1.1</td>
<td>1.7</td>
<td>2.9</td>
<td>3.4</td>
</tr>
</tbody>
</table>

*Includes ThinPrep® and ThinPrep® with imaging cases in laboratories with a ThinPrep® cytology volume of >500 per year.
SurePath®

Laboratory Percentile-Reporting Rate

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>5th</th>
<th>10th</th>
<th>25th</th>
<th>50th</th>
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<td>4.1</td>
<td>6.5</td>
<td>10.0</td>
<td>12.8</td>
</tr>
<tr>
<td>ASC-H (%)</td>
<td>0.0</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
<td>0.4</td>
<td>0.6</td>
<td>0.8</td>
</tr>
<tr>
<td>LSIL (%)</td>
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<td>1.9</td>
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<td>3.6</td>
<td>5.9</td>
<td>7.7</td>
</tr>
<tr>
<td>HSIL (%)</td>
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<td>0.2</td>
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<td>0.5</td>
<td>1.0</td>
<td>1.2</td>
</tr>
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<td>0.9</td>
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<td>1.6</td>
<td>2.0</td>
<td>2.7</td>
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<td>0.0</td>
<td>0.1</td>
<td>0.2</td>
<td>0.4</td>
<td>0.5</td>
<td>0.7</td>
</tr>
<tr>
<td>UNSATISFACTORY (%)</td>
<td>0.1</td>
<td>0.1</td>
<td>0.2</td>
<td>0.3</td>
<td>0.6</td>
<td>1.1</td>
<td>1.3</td>
</tr>
</tbody>
</table>

*Includes SurePath® and SurePath® with FocalPoint® cases in laboratories with SurePath® cytology volume >500 per year.

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 0.7% in the table) for the conventional LSIL category means that a quarter of laboratories have LSIL rates of 0.7% or less. A 90th percentile-reporting rate (which corresponds to 9.6% in the table) for ASC-US in ThinPrep® preparations means that 9 of 10 laboratories have an ASC-US rate of 9.6% 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 1.7 for conventional Paps, 1.5 for ThinPrep® and 1.6 for SurePath®.

COMMENTARY:

N/A


**CYP.07650**  **Phase I**  **N/A  YES  NO**

If the laboratory's annual ASC/SIL ratio for gynecologic cases falls outside of the 5th or 95th percentiles, has the laboratory determined and documented the reason(s)?

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

For example, a laboratory with 9% ASC cases might appear to be overdiagnosing 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.

**COMMENTARY:**

N/A

**CYP.07655**  **Phase II**  **N/A  YES  NO**

Does the laboratory have a documented system to evaluate and document the ongoing performance of individuals who do cervicovaginal cytology screening against the overall annual statistics for the laboratory as a whole?

**NOTE:** Under CLIA-88 regulations, this applies to both cytotechnologists and pathologists who do primary cervicovaginal specimen screening. Mechanisms can include evaluation of rescreening and interpretive discrepancies and detection rates for abnormalities. Pathologists who do primary cervicovaginal specimen screening are exempted from the 10% rescreen of negative cases.

**COMMENTARY:**

CYP.07660 Phase II N/A YES NO

Is there documentation of each individual's diagnostic discrepancies, and corrective action taken?

COMMENTARY:

N/A


NON-GYNECOLOGIC CYTOPATHOLOGY

CYP.07670 Phase II N/A YES NO

Are all non-gynecologic slides reviewed and the report signed by a pathologist?

COMMENTARY:

N/A

Is an effort 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 documented 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 documented in quality management records, problem logs, or in patient reports.

COMMENTARY:

N/A


Is there a documented policy for ensuring that non-gynecologic specimens with a high potential for cross-contamination are processed and stained separately from other specimens?

NOTE: Contamination may occur among cases when highly cellular specimens are processed. Methods to minimize this potential problem may include cytocentrifuge, filter, and monolayer preparations. Direct smears made from the sediment of highly cellular cases should be stained after the other cases, and the staining fluids must be changed or filtered between each of the highly cellular cases. One procedure to detect highly cellular specimens is to use a toluidine blue, or other rapid stain, on a wet preparation. One procedure to detect possible contamination is to insert a clean blank slide in each staining run and examine it for contaminating cells.

COMMENTARY:

N/A

CYP.07685 Phase II N/A YES NO

Is the Papanicolaou stain or another appropriate permanent stain used for non-gynecologic specimens?

COMMENTARY:

N/A

CYP.07690 Phase I N/A YES NO

Are 90% of reports on routine non-gynecologic cytology cases completed within 2 working days of receipt by the laboratory performing the evaluation?

NOTE: This question is primarily concerned with the majority of routine specimens, and applies to all laboratories. Longer reporting times may be allowed for specimens requiring special processing or staining (e.g., immunohistochemistry or other molecular analysis), or for screening (as opposed to diagnostic) specimens (for example, urines). If the laboratory has certain classes of specimens, patient types, etc., for which longer turnaround times are clinically acceptable, these must be identified, together with reasonable target reporting times, for Inspector review. Documentation may consist of continuous monitoring of data or periodic auditing of reports by the laboratory. In lieu of this documentation, the Inspector may audit sufficient reports to confirm turn-around time.

COMMENTARY:

N/A


#新人#

PERSONNEL

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The Inspector must review qualifications of the pathologist director (technical supervisor), general supervisor, and cytotechnologist(s).

CYP.07700 Phase II N/A YES NO

Does the cytopathology laboratory have a qualified pathologist as director (technical supervisor)?
For laboratories subject to CLIA-88, do 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)

3. Before September 1, 1992, have successfully completed 2 years in an accredited institution (12 semester hours in science, 8 of which are in biology) and have 12 months training in an approved school of cytotechnology; or have received 6 months formal training in an approved school and 6 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 2 years full-time experience or equivalent within the preceding 5 years examining slides under the supervision of a physician certified in pathology and before January 1, 1969, be a high school graduate with 6 months cytotechnology training in a laboratory directed by a physician and completed 2 years full-time supervised experience in cytotechnology before 1/1/69; or

6. On or before September 1, 1994, have 2 years full-time experience or equivalent within preceding 5 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

CYP.07900    Phase II            N/A YES NO

For laboratories subject to CLIA-88, do all screening personnel satisfy one or more of the following three criteria?

1.  Pathologist (or physician), qualified as director
2.  Supervisory level cytotechnologist
3.  Qualified cytotechnologist

NOTE: If not, please include details in the Inspector's Summation Report.

COMMENTARY:

N/A


CYP.08000    Phase II            N/A YES NO

Does the cytopathology laboratory have a general supervisor, as defined by CLIA-88?

NOTE: The cytopathologist may serve as the general supervisor.

COMMENTARY:

N/A


CYP.08100    Phase II            N/A YES NO

Does the cytopathology general supervisor meet the qualifications defined by CLIA-88?

NOTE: The qualifications for general supervisor can be the same as that of laboratory director (technical supervisor). Alternatively, the general supervisor can be qualified as a cytotechnologist under 42CFR493.1483, with at least 3 years of full-time experience as a cytotechnologist within the preceding 10 years.
Does the cytopathology general supervisor fulfill the responsibilities defined by CLIA-88?

**NOTE:** The general supervisor, as designated by the laboratory 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. Document the slide interpretation results of each case he or she examined or reviewed
3. For each 24-hour period, document the total number of slides he/she examined (screened/rescreened) or reviewed, as well as ensuring documentation of the total number of slides evaluated by others
4. Document the number of hours he/she spent examining slides in each 24-hour period

**CYP.08200 Phase II**

**N/A**  **YES**  **NO**

Does the cytotechnologist fulfill the responsibilities defined by CLIA-88?

**NOTE:** The cytotechnologist is responsible for documenting:

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

**CYP.08300 Phase II**

**N/A**  **YES**  **NO**

**COMMENTARY:**

N/A


**COMMENTARY:**

N/A

N/A


**REVISED** 09/27/2007

CYP.08400 Phase II N/A YES NO

Are there sufficient qualified personnel available to handle the volume and variety of cytopathology cases submitted to the laboratory?

NOTE: While the 100 slide/24-hour limit for laboratories subject to CLIA-88 must never be exceeded, the CAP does not rely solely upon this specific workload limit because: a) the type of case material varies among laboratories; b) the number of cases that may be accurately reviewed by individual screening personnel differs; and c) such personnel may perform other duties. The Inspector should carefully evaluate these factors together with applicable quality control and quality management data when judging the adequacy of cytopathology laboratory staffing.

COMMENTARY:

N/A


CYP.08500 Phase II N/A YES NO

Is there a documented workload policy with evidence of data recording?

NOTE: Applicable only to laboratories subject to CLIA-88. The final rule implementing CLIA-88 requires that each individual evaluating cytology preparations by manual microscopic technique must examine no more than 100 slides (gynecologic and non-gynecologic or both) in 24-hours. Gynecologic slides include new routine slides, 10% rescreen slides, and 5-year look-back negative slides. Records must be maintained showing the total number of slides examined by each individual during each 24-hours.
The laboratory director must establish the maximum workload (based on capability документed performance evaluation) for each individual examining slides and the limit must be reassessed at least every 6 months. Performance must be evaluated using the following: (1) re-evaluation of 10 percent of the cases interpreted to be negative by cytotechnologists; and (2) comparing the cytotechnologist’s interpretation with the final diagnosis on cases of ASC-US, LSIL, HSIL, glandular epithelial cell abnormalities, or other malignant neoplasms. 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.

The maximum workload of 100 slides can be completed in no less than an 8-hour workday. This workload maximum can also be expressed as slides per hour and is 12.5 slides/hour. These total limits apply regardless of the number of laboratories in which an individual works on a given day.

Part-time employees' workload must be prorated based on screening time and an 8-hour day. Additional responsibilities must be considered when evaluating workload.

Pathologists who screen previously unscreened gynecologic slides, and/or rescreen 10% of negative gynecologic slides, or rescreen 5-year lookback slides, must adhere to and document the above workload limit. Pathologist review of the following slides is not included in the workload limit: previously screened reactive/repair, atypical, premalignant and malignant gynecologic slides, previously screened non-gynecologic slides, and slides prepared for determination of specimen adequacy. For primary screening of gynecologic liquid-based preparations, each slide must be counted as a single slide for the purpose of workload recording.

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.

Workload calculations may vary with the use of automated screening instruments. Laboratories should follow manufacturer’s instructions for workload calculations and must assure that CLIA-88 requirements are fulfilled.

COMMENTARY:

N/A

CYP.08900   Phase II

Is all cytopathology screening 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 CLIA-88, all cytopathology screening must be performed within a CLIA-88 certified facility.

COMMENTARY:

N/A

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PHYSICAL FACILITIES

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CYP.09000   Phase I

Is sufficient space provided for processing cytologic material?

COMMENTARY:

N/A

CYP.09100   Phase I

Are utilities (water, sink, electrical) sufficient?

COMMENTARY:

N/A

CYP.09200   Phase I

Are ambient temperature and ventilation control adequate?

COMMENTARY:

N/A
CYP.09300   Phase I   N/A   YES   NO

Is there sufficient space for the microscopes (i.e., an adequate desk or bench area for each cytotechnologist)?

COMMENTARY:

N/A

CYP.09400   Phase I   N/A   YES   NO

Have ergonomic aspects of desks (or benches), chairs, and microscopes been evaluated for good posture and comfort?

COMMENTARY:

N/A


CYP.09500   Phase I   N/A   YES   NO

Is there sufficient space for storage of slides and records?

COMMENTARY:

N/A
Is sufficient space available so that there is no compromise of the quality of work, (including quality control activities) or safety of personnel?

COMMENTARY:

N/A

LABORATORY SAFETY

The inspector should review relevant questions 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.

Are there procedures for disposal of infectious specimens and contaminated material?

COMMENTARY:

N/A

Are formaldehyde and xylene vapor concentrations maintained below the following maxima, expressed as parts per million?

<table>
<thead>
<tr>
<th></th>
<th>8 hr Time-Weighted Exposure Limit</th>
<th>Action Level (8 hr Time-Weighted Exposure)</th>
<th>15 min Short-Term Exposure Limit (STEL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>0.75</td>
<td>0.5</td>
<td>2.0</td>
</tr>
<tr>
<td>Xylene</td>
<td>100</td>
<td></td>
<td>150</td>
</tr>
</tbody>
</table>

NOTE: The laboratory must perform an initial formaldehyde monitoring procedure in all areas where this reagent is used. Further periodic formaldehyde monitoring is mandated if results of the initial monitoring equal or exceed 0.5 ppm (8 hr time-weighted exposure, the "action level") or 2.0 ppm (STEL). The laboratory may discontinue periodic formaldehyde monitoring if results from 2 consecutive sampling periods taken at least 7 days apart show that employee exposure is below the
action level and the short-term exposure limit, and 1) no change has occurred in production, equipment, process or personnel or control measures that may result in new or additional exposure to formaldehyde, and 2) there have been no reports of conditions that may be associated with formaldehyde exposure.

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

Xylene must be monitored initially, but there is no requirement for periodic monitoring of xylene.

COMMENTARY:

N/A