



Southeast Section – AACCC Checklist Updates for 2011

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Disclosure



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**Dr. Hoeltge has no conflicts of interest to
disclose relevant to this presentation.**

Learning Objectives

- Explain why the Checklists are changing in appearance and organization.
- List selected recent changes to the Laboratory Accreditation Program accreditation requirements (checklists).
- Identify the most common error during laboratory inspections.
- Describe how you can help to improve the CAP Checklists.

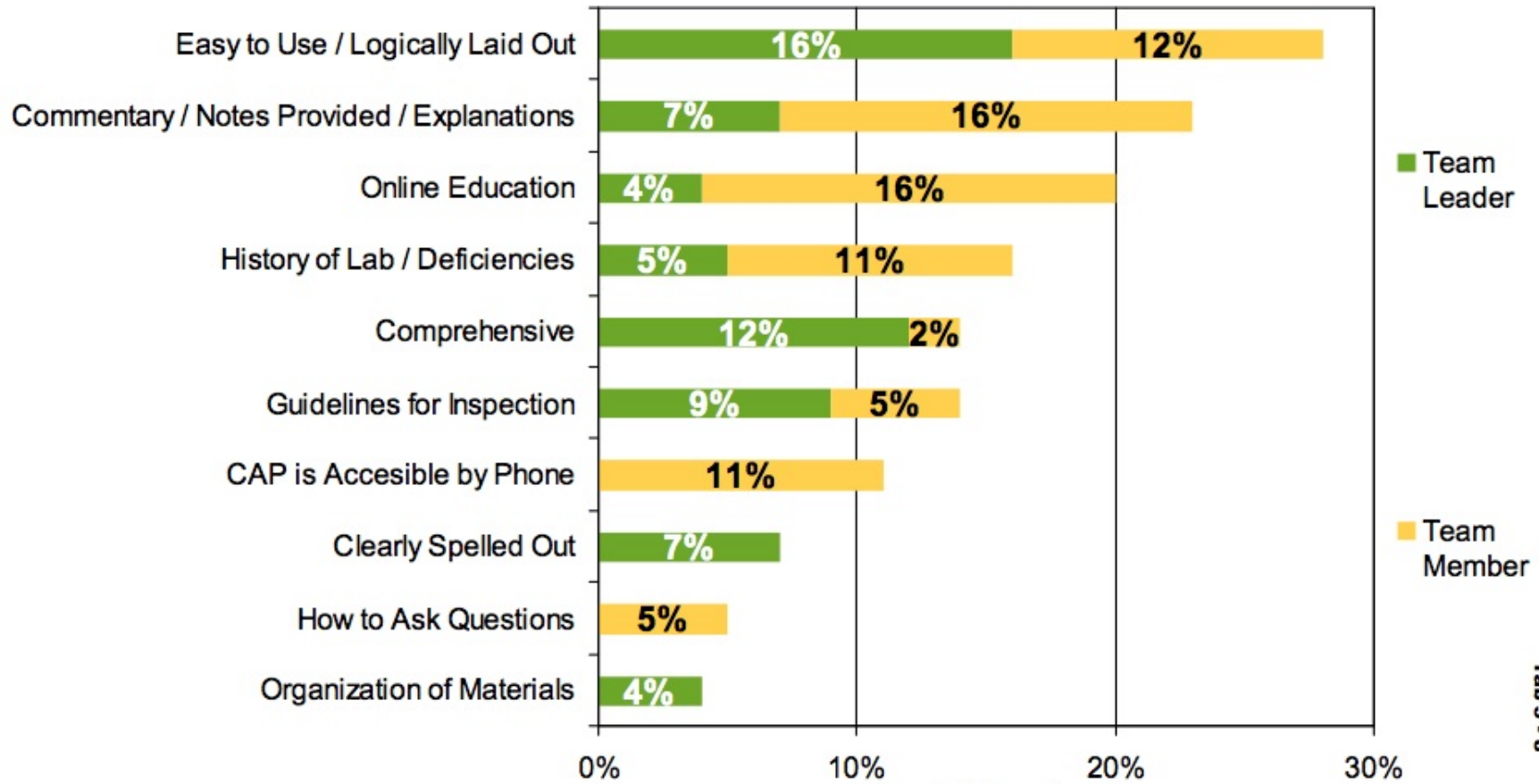
Agenda

1. Improvements in the design and grouping of the Checklists
2. Checklist “Diet”
3. Items of particular interest
 - a) Delegation of responsibilities
 - b) Procedure Manual review
 - c) Laboratory-developed tests
 - d) PT attestation
 - e) QC for IVDs with internal controls





Checklists are an accreditation tool

- *Standards for Laboratory Accreditation*
- Activities Menu
- Proficiency Testing records
- Laboratory Accreditation Manual
- Training modules
- Checklists

What users like about the Checklists



R.O.A.D. instructions

<p>READ</p> 	<p>READ/review a sampling of laboratory documents</p>
<p>OBSERVE</p> 	<p>OBSERVE laboratory practices</p>
<p>ASK</p> 	<p>ASK open-ended, probing questions</p>
<p>DISCOVER</p> 	<p>DISCOVER to "drill down" on areas of concern</p>

New and improved elements of the Checklist

- Improved graphics
- Section instructions
- Descriptive headings
 - Each section
 - Each requirement
- Checklist requirements are declarative statements
- Expanded Notes
- Evidence of Compliance (EOC) field

Section instructions

PROFICIENCY TESTING

Definitions:

Proficiency testing (PT) is defined as determination of laboratory testing performance by means of interlaboratory comparisons, in which a PT program periodically sends multiple specimens to members of a group of laboratories for analysis and/or identification; the program then compares each laboratory's results with those of other laboratories in the group and/or with an assigned value...(adapted from Clinical Laboratory Standards Institute Harmonized Terminology Database; available at <http://www.clsi.org/>).

Alternative assessment is defined as determination of laboratory testing performance by means other than PT--for example, split-sample testing, testing by a different method, etc.

Example

Headings and declarative statements

CHM.10800 Unusual Laboratory Results

Phase II

There is a documented system in operation to detect and correct significant clerical and analytical errors, and unusual laboratory results, in a timely manner.

NOTE: One common method is review of results by a qualified person (technologist, supervisor, pathologist) before release from the laboratory, but there is no requirement for supervisory review of all reported data. The selective use of delta checks also may be useful in detecting clerical errors in consecutive samples from the same patient/client. In computerized laboratories, there should be automatic "traps" for improbable results. The system for detecting clerical errors, significant analytical errors, and unusual laboratory results must provide for timely correction of errors, i.e., before results become available for clinical decision making. For confirmed errors detected after reporting, corrections must be promptly made and reported to the ordering physician or referring laboratory, as applicable. Each procedure must include a listing of common situations that may cause analytically inaccurate results, together with a defined protocol for dealing with such analytic errors or interferences. This may require alternate testing methods; in some situations, it may not be possible to report results for some or all of the tests requested. The intent of this requirement is NOT to require verification of all results outside the reference (normal) range.

Example

Evidence of Compliance

Evidence of Compliance:

Written procedure defining the use of 3.2% buffered sodium citrate for coagulation specimen collection OR procedure with an alternative anticoagulant defined with validation data

Example

Remember: All policies/processes/procedures in the laboratory covered under CAP accreditation must be written (whether explicitly stated in checklist requirement or not)

Why a Checklist “Diet”?

- The Checklists are too big
- Inspections take too long
- Inspection teams have too many people
- Requirements are too hard to understand
- Checklist reorganization is needed for better and long-term program management

Checklist “Diet”

- Step 1: Consolidate requirements where logical to reduce the number of items
- Step 2: Move requirements common to discipline-specific checklists to a separate checklist
- Step 3: Remove unnecessary and unproductive requirements

Checklist Diet: Step 1

- Retain
 - Essential regulatory requirements
 - Are evidence-based
 - Patient or employee safety
- Consolidate items on the same topic wherever possible

(No substantive change in content)

Checklist Diet: Step 1

Checklist	Deleted items	Consolidated	Moved to COM
ANP	18	40	16
CHM	5	34	18
CYG	1	15	5
FDT	3	25	2
FLO	3	24	17
GEN	20	25	0
HEM	3	27	22
HSC	1	21	17
IMM	2	20	17
MIC	2	30	21
MOL	5	10	5
POC	1	3	2
RLM	1	20	18
TLC	3	3	0
TRM	3	14	11
URN	0	18	10
TOTALS	75	353	195

Checklist Diet: Step 2 — the COM checklist

- Requirements that appear in multiple, discipline-specific checklists
 - proficiency testing
 - test method validation
 - procedure manual
 - quality management
 - space and utilities
- 28 requirements will move to the COM checklist in 2011
- Each team member will carry a COM checklist

Checklist Diet - Step 2

- Advantages
 - Team members will have less need to refer to GEN
 - Standardization of language
 - Better identification of systemic issues
- Challenges
 - Inspectors will need specific training
 - Loss of recurrent deficiency detection

Checklist Diet - Step 3

- Remove unneeded items
 - outdated or outmoded technologies
 - unclear or vague in purpose
 - sole purpose of representing a best practice
 - impossible to determine compliance during an on-site inspection
 - rarely cited (non-regulatory)

No loss of determination of whether the laboratory is in compliance with the *Standards*

Safety requirements

- R.O.A.D. items now grouped by topic
 - safety policies and records
 - bloodborne pathogens
 - fire prevention and control
 - chemical safety
 - compressed gases
 - radiation safety
 - environmental safety
 - other hazards
 - waste disposal

Safety requirements

GEN.71650 Fire Detection/Alarm

There is an automatic fire detection and alarm system.

Example

NOTE:

- 1. The system must connect to the facility's overall system where such a system exists. It should sound an immediate alarm in the event of smoke or fire.*
- 2. The fire alarm is audible in all parts of the laboratory, including storage areas, lavatories, and darkrooms.*
- 3. Laboratories employing hearing-impaired persons must have other means to alert these individuals, such as a visual alarm system.*

Safety requirements

GEN.71050 PPE Instruction

Personnel are instructed in the proper use of personal protective clothing/equipment (e.g. gloves, gowns, masks, eye protectors, footwear, etc.)

NOTE:

1. Appropriate personal protective equipment (PPE) are items that do not permit blood or other potentially infectious material to pass through to the skin. Footwear must provide adequate protection.

2. The required elements of training in the use of gloves include [a] Proper fitting of gloves; [b] Replacing gloves immediately when torn or contaminated; [c] Not washing or disinfecting gloves for reuse; [d] Using hypoallergenic gloves when indicated by patient or healthcare provider history; [e] Decontamination of hands after glove removal.

Example

Deleted safety requirement

GEN.71230 CSF Special Handling

Phase II

The laboratory has documented procedures for the special handling of cerebrospinal fluid from cases in which Creutzfeldt-Jacob disease is suspected.

**Deleted in
2011**

REFERENCES

- 1) World Health Organization Communicable Disease Surveillance and Control. WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. March 1999

New safety requirement

GEN.xxxxx

Phase I

The laboratory manages notifications from vendors of defects or issues with supplies or software that may affect patient care.

NOTE: Notifications may take the form of product recalls, market withdrawals, or software patches and upgrades. The laboratory should take action on those that have the potential to affect testing results or laboratory services.

Evidence of Compliance:

Records of manufacturer's recalls received and follow-up documentation.

Revised safety requirement

GEN.72500 Emergency Eyewash

Phase II

The laboratory has adequate plumbed or self-contained emergency eyewash facilities in every area where hazardous chemicals (irritating, corrosive, or toxic by contact or absorption) ~~or significant biohazards~~ are present.

NOTE: The eyewash facility includes the following:

- 1. No greater than 10 seconds travel distance from areas in the laboratory where hazardous chemicals ~~or biohazards~~ are present*
- 2. Capable of delivering 1.5 liters/minute for 15 minutes*
- 3. Flow is provided to both eyes simultaneously*
- 4. Nozzles or covers to protect from airborne contaminants*
- 5. Hands-free flow once activated*
- 6. Signage for location of eyewash*
- 7. Unobstructed path with unlocked doors opening in the direction of the eyewash*
- 8. Plumbed systems are protected from unauthorized shut off*
- 9. Tepid fluid temperature*
- 10. Plumbed systems are activated weekly*
- 11. Self-contained units are visually examined weekly*

Delegation of director responsibilities

TLC.10400 Delegation of functions

Phase II

If the laboratory director has delegated some functions to others, documentation specifies the individuals and the specific activities so authorized.

NOTE:

1. The director is responsible for ensuring that delegated functions are properly carried out. It is the responsibility of the laboratory director to ensure that persons performing delegated functions are qualified to do so.

2. Examples of items that may be delegated include review of QC data, proficiency testing performance, and test methodology.

Delegation of director responsibilities

TLC.10400 Delegation of functions

Phase II

If the laboratory director has delegated some functions to others, documentation specifies the individuals and the specific activities so authorized.

NOTE:

3. Some functions may not be delegated including provision of appropriately trained supervisory and technical staff and the identification of their responsibilities.

4. The laboratory director must demonstrate personal assessment of physical and environmental conditions and the adequacy of staffing.

Procedure manual review

- Already changed in 2011

The director (~~or a designee who meets CAP director qualifications~~) reviews and approves all new policies and procedures, as well as substantial changes to existing documents, before implementation.

- Will change in 2011

There is documentation of **review** ~~at least annual review~~ of all policies and procedures by the current laboratory director or designee **at least every 2 years**.

Direct-to-Consumer (DTC) Testing

The laboratory performs DTC testing and reports results of DTC tests only in jurisdictions where such testing is lawful.

NOTE: No less than every 2 years, the laboratory must verify which jurisdictions permit DTC testing.

The test report includes test results, reference range, interpretation as applicable, and limitations of the test, as applicable, in language readily understandable by a lay person.

Direct-to-Consumer (DTC) Testing

The test report includes information that enables the consumer to contact a licensed healthcare professional about the clinical significance of the test result.

NOTE: This information may consist of the name, phone number and email address of a health care professional. Alternatively, it may be the phone number of an office at the laboratory or medical center that can provide contact information to the consumer.

The laboratory retains the results of DTC tests and reference ranges for at least 10 years after testing.

Direct-to-Consumer (DTC) Testing

- To appear in 2011
 - “does not apply to health fairs”
- Important to remember: DTC analyses are subject to the same validation, QC, QA, etc. requirements as every other kind of laboratory testing.

Laboratory-Developed Test (LDT) — MOL checklist

- The test is performed by the clinical laboratory in which the test was developed*
- The test is neither FDA-cleared nor FDA-approved, or is an FDA-cleared/approved test modified by the laboratory (sample types or the use of collection devices not listed in manufacturer instructions constitute modifications, by this definition)
- The test was first used for clinical testing after April 23, 2003

** i.e., created by the laboratory performing the testing, irrespective of whether fundamental research underlying the test was developed elsewhere or reagents, equipment, or technology integral are from another entity.*

Laboratory-Developed Tests (LDT)

- All method performance specifications pertain to LDTs (accuracy, precision, analytic sensitivity & specificity, reportable range, reference range)
- *Not* part of method performance specifications:
 - **clinical sensitivity** refers to the ability of an assay to detect a disease or clinical condition
 - **clinical specificity** refers to the degree to which an assay is negative when disease is absent

Laboratory-Developed Tests (LDT)

- Major concern is how these tests are used clinically
- Additional definitions:
 - **clinical validity** of a test defines its ability to diagnose or predict the risk of a disorder or other health condition in a defined population
 - **clinical utility** is the net balance of risks and benefits associated with using a test in a specific clinical setting

Laboratory-Developed Tests (LDT)

The clinical performance characteristics of each assay are documented, using either literature citations or a summary of internal study results.

NOTE: The clinical performance characteristics of a test relate to its diagnostic sensitivity and specificity, and its positive and negative predictive values in the (various) target population(s). Issues that affect the clinical interpretation of a test which should be considered include:

(1) the clinical setting in which the test is used,

(2) genotype/phenotype associations when these vary with particular mutations or polymorphisms, and

(3) genetic, environmental or other factors which modify the clinical expression of the genetic alteration detected.

Laboratory-Developed Tests (LDT) - New for 2011

All clinical claims made by the laboratory about a laboratory-developed test are validated.

- Laboratories are *not* required to make clinical claims
- Clinical claims may include statements about
 - diagnostic sensitivity and specificity
 - ability to predict the risk of a disease or condition
 - clinical usefulness
 - cost-effectiveness

Proficiency Testing (PT)

- Participation required for all analytes designated by the Laboratory Accreditation Program as required (refer to your Activities Menu)
- For others, twice a year, do an non-required PT or an alternate performance assessment

Subdiscipline	Test/Activity	Test / Activity ID	PT Required	Alternative Assessment Required
Immunology	Varicella-zoster antibody	751	Y	
Immunology	VDRL	1429	Y	
Immunology	Vitamin D, 1,25 dihydroxy	4060		Y
Immunology	Vitamin D, 25-hydroxy	4061		Y

Example

Proficiency Testing (PT)

- To the extent possible, the laboratory must integrate PT samples into its routine workload
 - Analysis by same personnel who perform patient testing
 - Duplicate testing only if patient samples are tested in duplicate
 - Group consensus on morphologic samples (cell identification; microorganisms; electrophoretic patterns) permitted only if such consensus done for patient samples

Proficiency Testing (PT)

- For FISH tests, laboratory may perform alternative assessment by method and specimen type, rather than for each probe or abnormality (i.e., one assessment program for all FISH studies performed on cell suspensions, etc.)...CYG.10550 and MOL.10160

Proficiency Testing (PT)

- The Attestation Statement provided by the proficiency testing program, certifying appropriate handling of proficiency testing samples must be signed by the analysts performing the tests and the laboratory director or designee.

**New
requirement**

- Evidence of Compliance:

*Written policy prohibiting interlaboratory communication **AND** completed attestation pages from the submitted PT result forms*

Proficiency Testing (PT)

- No interlaboratory communication prior to deadline for data submission
 - GEN.12258, Ph II
- No referral of PT to another lab
 - i.e., another CLIA number
 - GEN.13032, Ph II

Proficiency Testing (PT)

- Ungraded PT that was intended to be graded *must* be evaluated by lab and corrective action taken as needed
 - Examples:
 - results not submitted
 - wrong units or method code
 - use of < or > sign
- Other ungraded PT *should* also be self-evaluated
 - Examples:
 - CAP decision not to grade
 - educational challenge
- For more information...
 - last page in each Participant Summary
 - “*Troubleshooting Guide for Proficiency Testing Data*” on CAP Website

Daily QC

CHM.13900

Daily QC - Nonwaived tests

Phase II

Controls are run daily for quantitative and qualitative tests.

NOTE: Controls should verify assay performance at relevant decision points. The selection of these points may be based on clinical or analytical criteria

Daily QC

CHM.13900

Daily QC - Nonwaived tests

Phase II

Controls are run daily for quantitative and qualitative tests.

NOTE:

- *For quantitative tests, 2 controls at 2 different concentrations*
- *For qualitative tests, a positive and negative control*

Daily QC

CHM.13900

Daily QC - Nonwaived tests

Phase II

Controls are run daily for quantitative and qualitative tests.

NOTE:

Daily controls may be limited to electronic/procedural/built-in (e.g. internal, including built-in liquid) controls for tests meeting the following criteria:

- 1) For quantitative tests, the test system includes 2 levels of electronic/procedural/built-in internal controls that are run daily*

Daily QC

CHM.13900

Daily QC - Nonwaived tests

Phase II

Controls are run daily for quantitative and qualitative tests.

NOTE:

Daily controls may be limited to electronic/procedural/built-in (e.g. internal, including built-in liquid) controls for tests meeting the following criteria:

- 2) For qualitative tests, the test system includes an electronic/procedural/built-in internal control run daily*

Daily QC

CHM.13900

Daily QC - Nonwaived tests

Phase II

Controls are run daily for quantitative and qualitative tests.

NOTE:

Daily controls may be limited to electronic/procedural/built-in (e.g. internal, including built-in liquid) controls for tests meeting the following criteria:

- 3) The system is FDA-cleared or approved, and not modified by the laboratory*

Daily QC

CHM.13900

Daily QC - Nonwaived tests

Phase II

Controls are run daily for quantitative and qualitative tests.

NOTE:

Daily controls may be limited to electronic/procedural/built-in (e.g. internal, including built-in liquid) controls for tests meeting the following criteria:

- 4) *External surrogate sample controls are run*
 - a. *for each new lot number or shipment of test materials*
 - b. *after major system maintenance*
 - c. *and after software upgrade*

Daily QC

CHM.13900

Daily QC - Nonwaived tests

Phase II

Controls are run daily for quantitative and qualitative tests.

NOTE:

Daily controls may be limited to electronic/procedural/built-in (e.g. internal, including built-in liquid) controls for tests meeting the following criteria:

- 5) External surrogate sample controls are run as frequently as recommended by the test manufacturer, or every 30 days, whichever is more frequent*

Daily QC

CHM.13900

Daily QC - Nonwaived tests

Phase II

Controls are run daily for quantitative and qualitative tests.

NOTE:

Daily controls may be limited to electronic/procedural/built-in (e.g. internal, including built-in liquid) controls for tests meeting the following criteria:

- 6) *The laboratory has performed and documented studies to validate the adequacy of limiting daily QC to the electronic/procedural/built-in controls.*
 - a) *at least ~~25 samples~~ 20 consecutive days*
 - b) *applies to validation studies after ~~12/31/2010~~ 1/31/2012*

New: Clinical Biochemical Genetics (CBG)

- Enzyme assays 14 items
- HPLC 3 items
- Mass spectrometry 5 items
- Colorimeters, spectrophotometers
fluorometers 1 item

We are now up to 19 checklists.

TRM checklist

TRM.44955 Bacterial contamination of Platelets

The laboratory (or its blood supplier) utilizes an FDA cleared or equivalent system to detect the presence of bacteria in all platelet components

Evidence of Compliance:

- 1) Individual units or pools tested with an FDA-approved method
- 2) Use of pre-pooled or apheresis Platelets tested by the supplier
- 3) Culture of Platelets destined for pooling
- 4) Other methods validated to have equivalent clinical sensitivity

Changes to LIS requirements

- System maintenance
 - Four requirements combined into

Data and services are protected from loss.

NOTE: Policies and procedures must 1) be adequate to address scheduled and unscheduled interruptions of power or function; 2) be tested periodically for effectiveness 3) include systems to backup programs and data; and 4) include a written plan.

- Deletion of five other requirements

Changes to LIS requirements

- GEN.48500 Phase II
There is a procedure to verify that patient results are accurately transmitted from the point of data entry to patient reports
 - includes results, reference ranges and report formats
 - after new or changed interface
 - reverified every 2 years

Record retention

- Test reports for neoplastic conditions: 10 years
- Test reports for constitutional conditions: 20 years
- Includes
 - photographic images (FISH; karyotypes)
 - stable (brightfield) ISH slides

Affects ANP, CYG, MOL checklists

Continuous improvement in the Checklists

- Your feedback is needed.
 - Format and enhancements
 - Changes to requirements
 - Ambiguities and special cases
 - Gaps and new technologies
- The CLC needs experts to review proposed changes, particularly for the specialty disciplines.

Final “Pearl”

What do you think is the most common discrepancy in validation inspections? **Personnel qualifications**

CMS report to Congress (2009)

- 381 validation inspections
 - ↳ 101 in CAP-accredited labs
 - ↳ 14 condition-level discrepancies
 - ↳ 12 for lack of documentation of personnel qualifications

CAP Personnel Requirements by Testing Complexity

	Director	Clin/Tech Consult.	Techn Supervisor	General Supervisor	Testing Personnel
Waived	CLIA	—	—	—	CAP
Moderate	CLIA	CLIA	—	—	CLIA
High	CLIA/ CAP	—	CLIA	CLIA	CLIA

not shown: cytopathology personnel requirements

Summary

- Changes in the CAP Checklists designed to improve usability and support customization
- New COM checklist
- Significant changes to several checklists for 2011
- Why documentation of personnel qualifications matters

Technical Assistance

<http://www.cap.org>

Email: accred@cap.org

800-323-4040, ext. 6065

	New	Revised	Examples
Anatomic Pathology	1	34	ANP.07650
Clinical Biochemical Genetics	8	36	CBG.14500
Chemistry & Toxicology	4	31	CHM.31800
Common	0	3	---
Cytogenetics	2	12	CYG.43300
Cytopathology	1	5	CYP.06450
Forensic Drug Testing	3	18	FDT.06500
Flow Cytometry	0	6	---
General Laboratory	1	32	GEN.13806
Hematology	0	14	HEM.37800
Histocompatibility Testing	0	10	HSC.10475
Immunology/Serology	0	9	IMM.33910
Microbiology	5	35	MIC.21530
Molecular Pathology	0	20	MOL.36012
Point of Care Testing	0	9	POC.04750
Reproductive Lab Med	3	6	RLM.03990
Team Leader	0	1	---
Transfusion Medicine	0	10	TRM.40875
Urinalysis	0	5	---
Totals	28	296	60

As applicable, there is a policy for performance of autopsies off-site.

NOTE: If feasible, the autopsy room should be located within the institution. Requirements in the Autopsy Pathology section that relate to the physical facility, dissection and handling of organs and tissues apply only to those cases that are performed at the site under CAP accreditation. The pathologist should encourage off-site locations where autopsies are performed (e.g. Funeral homes) to provide facilities that meet the standards expected for accredited autopsy rooms

Reference: Hanzlick RL, et al. Autopsy facility design. In: Collins KA, et al, eds. *Autopsy Performance and Reporting*. 2nd ed. Northfield, IL: College of American Pathologists: 2003; chap 14

Whenever appropriate, pertinent previous cytologic and/or histologic material from the patient is reviewed with current material being examined.

NOTE: Because sequential analysis of cytologic and histologic specimens may be critical in patient management and follow-up, efforts must be made to routinely review pertinent previous material.

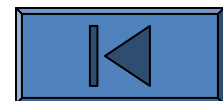
Documentation of the retrospective review should be included in the current patient report.

Reference: Bozzo P. Implementing quality assurance. Chicago, IL: American Society of Clinical Pathology, 1991:72-74

The laboratory has a policy for inclusion of intra- and extra-departmental consultations in the patient's final report.

NOTE: Intra-departmental consultations may be included in the patient's final report, or filed separately. The pathologist in charge of the surgical pathology case must decide whether the results of intra-departmental consultations provide relevant information for inclusion in some manner in the patient's report.

Documentation of extra-departmental consultations must be readily accessible within the pathology department. The method used to satisfy this requirement is at the discretion of the laboratory director, and can be expected to vary according to the organization of the department. These consultations can be maintained with the official surgical pathology reports or kept separately, so long as they can be readily linked.

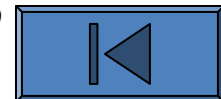


Laboratory reports include an interpretation of the result that reflects the presence or absence of the disease (or carrier state), possible limitations of the test, and, if appropriate, recommendations for additional testing.



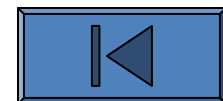
There is documentation that the laboratory has established its own median values or verified that the medians from another source are appropriate for the population being screened.

NOTE: Systematic biases in maternal serum assay values of up to 30% can occur when kits from different manufacturers are used. In addition, between laboratory differences in equipment, reagents, and technique may introduce bias in assay results even when the same kit lot is used. These differences can be minimized by reporting results in multiples of the normal median (assuming that the medians are calculated using values measured on the population to be tested using the kit designated for screening). Ideally, week-specific medians would be established by testing approximately 100 patients per week of gestation. Because analytes are stable, it is possible to use stored frozen specimens collected over a period of years. A second approach is to perform a split specimen study with a reference laboratory and transfer the reference laboratory's medians using the comparison regression equation from the split specimen study. However, in practice the most practical method is to measure values on 300 consecutively collected specimens spread over the appropriate gestational age range, and perform weighted regression analysis using published models. It is not necessary to document that all specimens are collected from unaffected pregnancies. Smoothing data by weighted regression analysis allows median values to be calculated for weeks with limited data. Package insert medians may be outdated or inappropriate and should not be used even for a short time. Incorrect reference data may lead to inappropriate recommendations in the laboratory report.



Photographic or digitized images are retained for documentation of all FISH assays (at least one cell for assays with normal results, and at least two cells for assays with abnormal results).

NOTE: For assays where multiple chromosomal loci (>2) are targets in part of a single test, an image of at least one cell must be retained for documentation of each target. Images of at least two cells are required to document all abnormalities. For FISH studies of neoplastic conditions, retention of the images is required for a minimum of 10 years. For FISH studies of constitutional conditions, retention of the images is required for a minimum of 20 years.

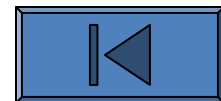


There is a policy regarding the communication, and documentation thereof, of significant and unexpected cytopathology findings.

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

~~*In distinction to the above, the cytopathology department may designate certain diagnoses as "critical results" for which communication to the clinician should be prompt.*~~

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



Only confirmed positives are reported as positive.

NOTE: If the laboratory is required by clients to report non-confirmed positive results for pre-employment samples, then the laboratory must have in place a system that differentiates this non-forensic drug testing service from its forensic drug testing service. If the laboratory refers some or all confirmatory testing, the laboratory's screening results must be withheld pending the receipt of the confirmatory laboratory's results.

Evidence of Compliance:

- Records reflecting confirmatory testing performed on positive results **OR** policy defining situations where unconfirmed positive results may be reported **AND**
- Patient reports with confirmed positive results **OR** patient reports with a statement that clearly differentiates the non-forensic testing result from the forensic drug testing service



The laboratory has a documented quality management (QM) program.

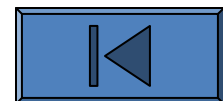
NOTE: : There must be a document that describes the overall QM program. The document need not be detailed, but should spell out the objectives and essential elements of the QM program. The QM plan may be based upon some reference resource such as CLSI HS01-A2, GP22-A2, or GP26-A3; the ISO 9000 series or ISO 15189; AABB's quality program; CAP's quality management publications; or it may be of the laboratory's own design. If the laboratory is part of a larger organization, the laboratory QM program is coordinated with the organization's QM plan.

GEN.16902 QM Implementation

Phase II

For laboratories that have been CAP accredited for more than 12 months, the QM plan is implemented as designed and is reviewed annually for effectiveness.

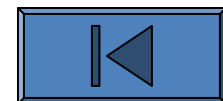
NOTE: Appraisal of program effectiveness may be evidenced by an annual written report, revisions to laboratory policies and procedures, or revisions to the QM plan, as appropriate.



Determinations are performed in duplicate and criteria for agreement are defined.

Evidence of Compliance

- Records or worksheets reflecting duplicate testing of each sample including corrective action when limits of agreement are exceeded.



HSC.10475 Extent of Testing □

Phase II

Proficiency testing specimens are tested to the same extent as clinical specimens.

NOTE: ~~Protocols for additional~~ Proficiency testing samples are ~~used for routine~~ to be tested in the same way as regular patient samples ~~including reflex testing to clarify results should be followed for proficiency testing specimens. However, proficiency samples~~ They should not receive more extensive testing than ~~routine patient samples~~ would be performed under routine testing conditions. For example, high-resolution analysis and sequence-based typing may be used only if they are regularly used in similar clinical circumstances.

⋮

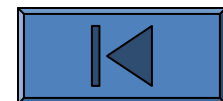
HSC.31178 Crossmatch Cut-off

Phase II

The cut-off for positive crossmatch results are determined by testing an appropriate number of sera from non-alloimmunized donors and established for all pertinent target cells (T-cells, B-cells, etc.).

Evidence of Compliance

- Records for the validation of the positive cut-off

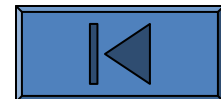


If a result is less than or greater than the AMR, a numeric result is not reported unless the sample is processed by dilution, a mixing procedure or concentration so that the processed result falls within the AMR.

NOTES: 1. A measured value that is outside the AMR may be unreliable and should not be reported in routine practice. Dilution, a mixing procedure* or concentration of a sample may be required to achieve a measured analyte activity or concentration that falls within the AMR. The processed result must be within the AMR before it is mathematically corrected by the concentration or dilution factor to obtain a reportable numeric result.

2. If the concentration or activity of the analyte is determined to be outside the AMR and is reported as "greater than" or "less than" the limits of the AMR, then the checklist requirement is not applicable.

*This procedure is termed the "method of standard additions." In this procedure, a known quantity (such as a control) is mixed with the unknown, and the concentration of the mixture is measured. If equal volumes of the two samples are used, then the result is multiplied by two, the concentration of the known subtracted, and the concentration of the unknown is the difference.



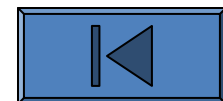
The laboratory has protocols in place to use Gram stain results to provide a preliminary identification of organisms, evaluate specimen quality when appropriate, and to guide work-up of cultures.

NOTE: The laboratory should have guidelines for the interpretation of the Gram stain reaction of the organism, morphology of the organism, and the quantification of organisms and cells. The protocol should address correlation of direct Gram stain results with final culture results.

If group A Streptococcus direct antigen testing is performed, additional confirmatory testing is performed on negative samples.

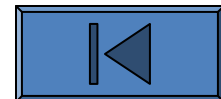
NOTE: 1: Guidelines should be established for the use of cultures or other additional tests on specimens that test negative, as appropriate. These guidelines should take into account the sensitivity of the assay in use, the age and clinical presentation of the patient, and other factors.

2: Direct antigen tests should be performed and reported in a timely fashion, since their principal advantage (compared to more sensitive methods such as culture) is rapid turn-around-time.



The laboratory's database for known ~~alleles is~~ mutations, benign polymorphisms and variants of undetermined significance are documented and updated as needed, when applicable.

NOTE: The database ~~for assignment~~ of ~~alleles~~ mutations must be documented and updated in a timely fashion after new ~~alleles~~ mutations have been reported or verified in the published literature.

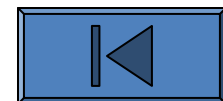


~~The POC program follows~~ All reagents are stored as recommended by the manufacturer ~~instructions for handling.~~

NOTE: If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored and recorded daily. The two acceptable ways of recording temperatures are: 1. recording the numerical temperature, or 2. placing a mark on a graph that corresponds to a numerical temperature (either manually, or using a graphical recording device). The identity of the individual recording the temperature(s) must be documented (recording the initials of the individual is adequate).

If ambient storage temperature is indicated, there must be documentation that the defined ambient temperature range is maintained.

The use of automated (including remote) temperature monitoring systems is acceptable, providing that point-of-care personnel have ongoing immediate access to the temperature data, so that appropriate corrective action can be taken if a temperature is out of the acceptable range. The functionality of the system must be documented daily.



The laboratory has established a standard specimen temperature range for semen analysis assessment, and deviations from this temperature are noted on the report.

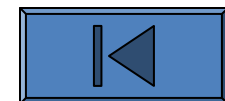
NOTE: Specimen motility is temperature-dependent. Temperature ranges must be defined.

Evidence of Compliance:

- ✓ Written procedure with acceptable temperature range defined **AND**
- ✓ Records showing monitoring of temperatures

REFERENCE

WHO laboratory manual for the examination and processing of human semen, 5th edition. New York, NY: Cambridge University Press, 2010



There is documentation that the transfusion service medical director participates in:

1. The development of policies, processes, and procedures regarding recipient consent for transfusion/transplantation
2. Establishing criteria for transfusion
3. Reviewing cases not meeting transfusion audit criteria
4. Monitoring transfusion practices

NOTE: At a minimum, recipient consent procedures should communicate risks and benefits of transfusion and transplantation, as well as alternatives to transfusion; and the right of the adult patient to refuse transfusion. Procedures should include an opportunity for the transfusion/transplant recipient to ask questions. The transfusion service medical director must be involved in physician education and review of transfusion practices to ensure the appropriateness of use of blood components and the ability of the transfusion service to meet patient needs. The monitoring required to do this effectively can be met by various mechanisms, including reviewing cases not meeting transfusion audit criteria. Suggested monitors include the following: ordering practices, sample collection and usage (including discard of components), and compliance with institutional peer review recommendations. Data from the review and monitoring of transfusion processes should be used to modify blood administration policies, as necessary.



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