Preparing Your Lab for What's New, What's Changing Now, and What's to Come in Laboratory Accreditation and Inspections

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Learning Objectives

- **Understand the key areas focused on by accrediting organizations**
- **Learn how to prepare for changes in inspection requirements**
- **Understand anticipated changes in accreditation and inspection requirements**

Current Focus Areas for Accreditation

- **Personnel Qualifications**
- **Quality Management**
- **Competency Assessment**
- **Gynecologic Cytology Workload**
- **PT Referral**

Personnel Qualifications

- **Regulations have NOT changed**
- **GEN.54400 modified for clarity; now states that employers must indicate if personnel require supervision and/or review of work prior to reporting result**
- **CAP has released a form that must be completed as part of a laboratory's application to document that the laboratory is in compliance with the CLIA personnel requirements and has copies of all the required information on employees in its files**

LABORATORY PERSONNEL EVALUATION ROSTER

Laboratory Name: _____ **CLIA #:** _____ **CAP #:** _____
Laboratory Address 1: _____
Laboratory Address 2: _____
City, State and Zip Code: _____
Telephone Number: _____ **License #** (if applicable) _____ **Total # FTE's:** _____

Name (Last, First, MI)	Position Held (a)									SHIFT (b) (1st/2nd/3rd)	COMPLEXITY (c) (Waived/Mod/High)	Hours Per Week (d)	License # & Level (technologist technician, etc.) (e)	Exp Date (f)	Licensed Specialties (g)	Document Verification (h)			To be completed by lab (i): Documents Confirmed by : (date & inititals	CAP Office Use Only - FL: Confirmed by: (date & initials)
	D	CC	TC	TS	GS	TP	CTGS	CT	SP							T	D/C	L		
1																				
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Section (k)
Prepared by (print or type) _____ Signature: _____ Date: _____

I certify that all the individuals listed herein qualify to function in the position indicated, according to the personnel requirements set forth by the College of American Pathologists.
Laboratory Director Name: _____ Signature: _____ Date: _____

FOR FLORIDA INSPECTIONS ONLY: I have reviewed that the above licenses are current and have been posted by the laboratory in accordance with Florida law.
Inspection Team Leader Signature _____ Date _____

What are the Qualification Requirements for Personnel?

- **Personnel Requirements vary depending on the complexity of testing performed**
- **There are 3 categories of testing complexity defined in the CLIA-88 Regulations:**
  1. **Waived Complexity**
  2. **Moderate Complexity**
     a. *Subcategory: PPM*
  3. **High Complexity**
- **Where to find test classification?**

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf

What are the Minimum Requirements for Testing Personnel?

Waived Tests: CLIA does not define any specific personnel requirements. CAP requires waived testing personnel to have an earned high school diploma or equivalent, have documented training and competency assessments.

Moderate Complexity: minimum requirement is high school diploma or equivalent and appropriate training/experience as outlined in 493.1423

High Complexity: minimum requirement is an associate degree for anyone hired after April 24, 1995, except those staff qualified on or before 2/28/1992 (see 493.1491 for these grandfathering provisions). For staff hired prior to this date *and* performing high complexity testing prior to this date that *do not* qualify under 493.1491, refer to 493.1483 and 493.1489 for grandfathering provisions

Competency Assessment

For nonwaived tests, all 6 elements must be evaluated (when applicable) at each assessment (required by CMS and all AOs):

1. **Direct Observation of testing**
2. **Monitoring of test reporting**
3. **Review of testing records**
4. **Direct Observation of Maintenance and Function Checks**
5. **Proficiency and Blind Sample testing**
6. **Problem Solving Skills**

Competency Assessment

- **Ongoing supervisor review is acceptable for certain elements (direct observation of routine test performance)**
- **Checklist completed by supervisor is acceptable**
- **Unlike CLIA, CAP does require competency for waived tests, only selected elements must be evaluated**
- **Assess competency twice within the first year after employee starts patient testing. Thereafter, assess annually**

Quality Management

- **Plan must encompass all areas of laboratory**
  - **If the institution has an overall plan, the lab plan must be integrated within the institution plan**
  - **Lab plan must be implemented as designed**
- **Monitors must be defined and thresholds for performance must be established**
  - **Encompass pre-analytic, analytic and post-analytic phases of testing**
  - **Include CAP Patient Safety Goals (GEN.20365) and Key Indicators (GEN.20316)**
  - **Must show improvement over time**

Quality Management

- **Include review of incident/occurrence reports at defined intervals to identify trends and correct problems that interfere with patient care services**
  - **Must initiate corrective actions as needed**
  - **Root cause analysis for all sentinel events and action plans implemented to prevent recurrence**
- **Must have an annual review for effectiveness**
- **Must be part of the document control system**

Key Indicators of Quality

- Patient/Specimen Identification
- Test Order Accuracy
- STAT Test Turnaround Time
- Critical Value Reporting
- Customer Satisfaction
- Specimen Acceptability
- Corrected Reports – General Lab
- Corrected Reports – Anatomic Pathology
- Surgical Pathology/Cytology Specimen Labeling
- Blood Component Wastage
- Blood Culture Contamination

Gynecologic Cytology Workload

- **FDA recently came out with guidelines for maximum workload for cytotechnologists when using semi-automated screening devices.**
- **Workload maximums are different based on doing full manual review, semi-automated review, or a combination**
- **CAP provided an *e-Alert* to all accredited laboratories alerting them to this change**

Gynecologic Cytology Workload

- **All slides with Full Manual Review (FMR) count as 1 slide (as mandated by CLIA'88 for manual screening)**
- **All slides with Field of View (FOV) only review count as 0.5 or ½ slide**
- **Then, slides with both FOV and FMR count as 1.5 or 1½ slides**
- **Use the following values to count workload, not exceeding the CLIA maximum limit of 100 slides in no less than an 8-hour day.**
  - **FMR = 1 slide**
  - **FOV = 0.5 slide**
  - **FMR + FOV = 1.5 slides**
  - **Upper Limit = 100 slides"**

PT Referral

- **Still no clear discrimination between what is intentional versus unintentional PT Referral**
- **CAP accredited laboratories have access to resources on "Avoiding PT Referral"**
- **CMS provided a "Proficiency Testing – DOs and DON'Ts" brochure to laboratories with references on how to avoid PT referral**

Anticipated Changes in Requirements

- New PT Requirements
- Laboratory Developed Test Requirements
- Direct to Consumer Testing
- More emphasis on personalized health/genetic testing

New PT Requirements

- At most recent CLIAC meeting, CLIAC PT Work Group presented recommendations to expand the list of regulated analytes
- PT Work Group recommended to modify the current PT requirements for microbiology to allow for monitoring of procedures/tests similar to other subspecialties
- Work Group provided recommendations on modification to PT Referral language

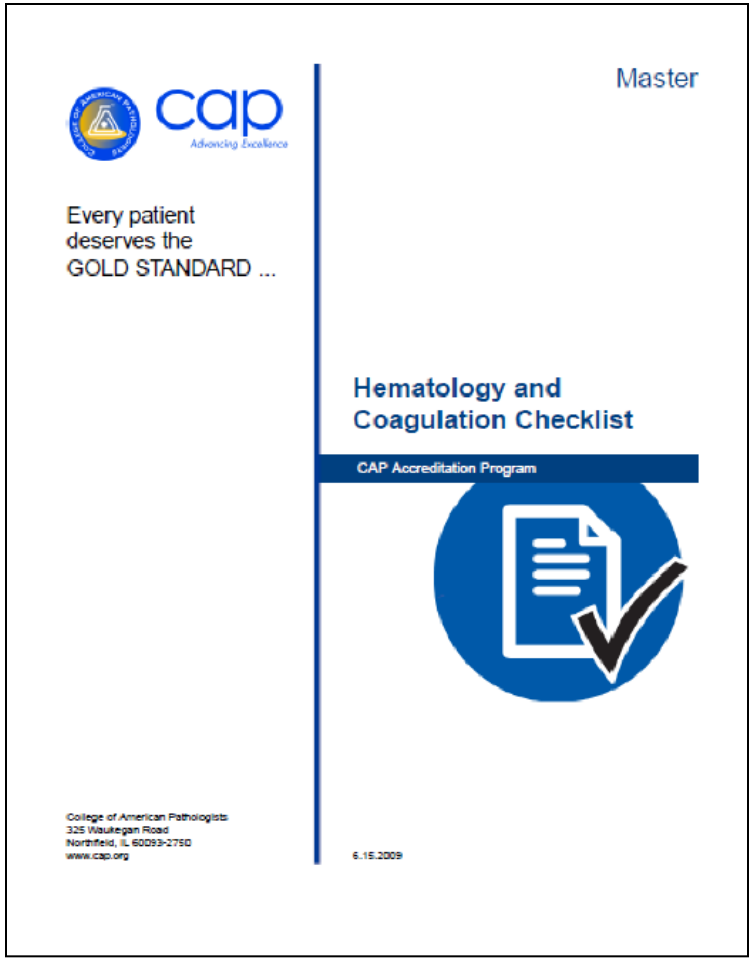
Laboratory Developed Tests

- **The FDA held meetings on July 19 and 20, 2010 on strengthening oversight of laboratory developed tests**
- **Per FDA, "they plan to quickly and clearly define a path to plug regulatory gaps and to create an even playing field while maintaining focus on innovation and patient access to new technology."**
- **Important to remember that a test is no longer FDA approved if the lab makes any change to the manufacturer instructions, including use of a collection device or specimen type not in instructions.**

Direct to Consumer Testing and Genetic Testing

- **CAP currently has requirements for Direct to Consumer Testing but with increases in this testing more requirements could be on the horizon**
- **With emphasis on personalized healthcare more genetic testing is anticipated and will likely result in more regulation**

Checklist Redesign June 2010

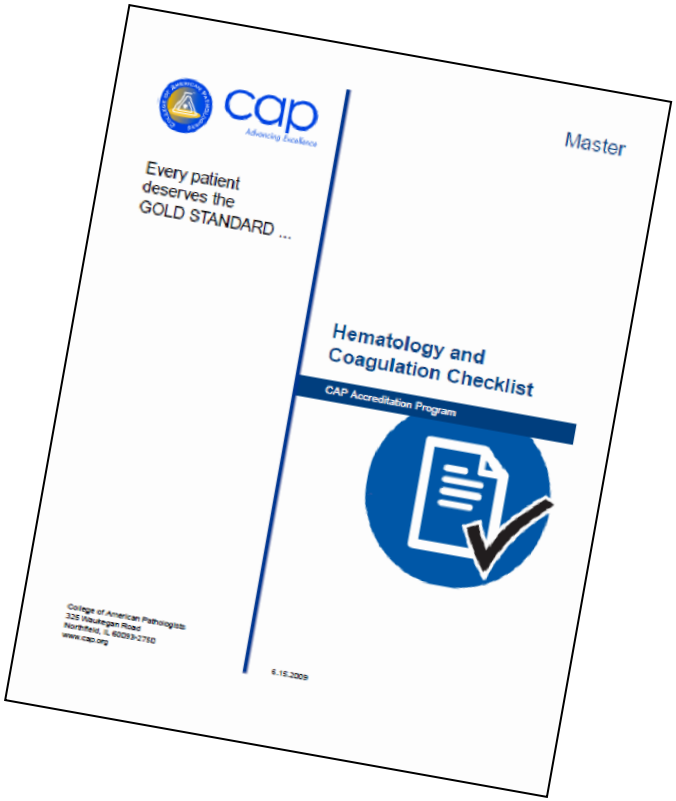


Key Benefits:

- **Help laboratories more efficiently and effectively meet their accreditation requirements**
- **Help inspectors conduct more efficacious inspections by providing a more consistent tool with guidance for interpretation of checklist requirements leading to a more consistent, higher quality inspection**
- **Effective and efficient dialogue and interpretation between inspector and inspectee**
- **Enhanced content and updated design**

Product Features:

- New “Look & Feel”
- Subject Headers
- Declarative Statements
- Evidence of Compliance
- R.O.A.D



Evidence of Compliance

Evidence of Compliance:

- ✓ A complete procedure manual available in all work areas that contains procedures for all tests performed **AND**
- ✓ Procedures written in an acceptable format with required elements

Evidence of Compliance

Information that highlights what is needed to prove that a laboratory is in compliance with the requirement. EOC is intended to:

1) Provide specific examples of acceptable documentation (policies, procedures, records, reports, charts, etc.) *Laboratories may have other types of documentation which provide suitable EOC in addition to those listed by CAP*
2) Assist a laboratory in preparing for an inspection and managing ongoing compliance
3) Drive greater consistency and understanding of requirements between laboratory and inspector

R.O.A.D. - Inspection Process Defined

INSPECTOR INSTRUCTIONS:

	**READ**/review a sampling of laboratory documents. Information obtained from this review will be useful as you observe processes and engage in dialogue with the laboratory staff. *(Example of the complimentary inspector instructions for Procedure Manual section appearing across checklists):* • *Representative sample of procedures for completeness and director review* • *Document control policy*
	**OBSERVE** laboratory practices by looking at what the laboratory personnel are actually doing and note if practice deviates from the documented policies/procedures. *(Example)* • *Availability of procedures to testing personnel*
	**ASK** open-ended, probing questions that start with phrases such as "tell me about..." or "what would you do if..." This approach can be a means to corroborate inspection findings that were examined by other techniques, such as Read & Observe. Ask follow-up questions for clarification. Include a variety of staff levels in your communication process. *(Example)* • *How do you access procedures?* • *How are employees made aware of changes to procedures?*
	**DISCOVER** is a technique that can be used to "drill down" or further evaluate areas of concern uncovered by the inspector. "Follow the specimen" and "teach me" are two examples of Discovery. Utilizing this technique will allow for the discovery of pre-analytic, analytic, and post-analytic processes while reviewing multiple requirements simultaneously. *(Example)* • *Identify a newly-implemented procedure in the prior two years. Follow the steps through authoring, director review and staff training.*

Questions?

- **Technical Assistance Line:**
  - **Phone: 800-323-4040, option 1**
  - **Email: accred@cap.org**

Thank you!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