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Where the Rubber Meets the Road: Getting Ready for your Next CAP Inspection in the Microbiology Laboratory

Christi Wojewoda, MD, FCAP
Director, Clinical Microbiology
University of Vermont Medical Center

Objectives

- Why does CAP perform inspections and how are the checklists written/revised
- Updates to the Microbiology Checklist
- Who, when, and how?
  - Self-Inspections
  - Safety Audits
  - Policy/Procedure Reviews
  - Record Reviews
  - Training and Competency Assessments
- What, where, and when?
  - Activity Menu – Adding or Removing Testing

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What we are not going to be talking about

- FDA Final Rule

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CAP Inspection Process/History

- Founded in 1946
- Achieved deemed status with CMS in 1992
- Collaboration with clinicians and medical societies to develop pathology standards and guidelines to improve patient care and outcomes
- Pathologist members contribute to checklists and the inspection process to keep accreditation programs current

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The Power of Peer Review

Program is built on a unique, reciprocal, peer-based inspection method:

- Pathologist-led inspection teams are practicing laboratory professionals
  - Expertise aligned with test menu
  - Experienced inspector for each discipline
  - No amount of training/continuing education replaces present day real-world experience
- Fresh inspection teams every cycle facilitate continuous improvement

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Reciprocal Inspections

- Outstanding opportunity to gain fresh insights and share best practices with peers
- Identify gaps in your own compliance
- Support from CAP to complete your team
- Thorough training provided
  - CE/CME/SAM credits
- >10,000 laboratory professionals participate annually

Simplify Your Compliance

Our discipline-specific checklists are:

- A living blueprint for running a high-quality laboratory
- Infused with pathologist input on best practices
- Updated annually to stay current with changes
- Written in easy-to-understand language including notes and practical examples
- Easy to allocate to staff

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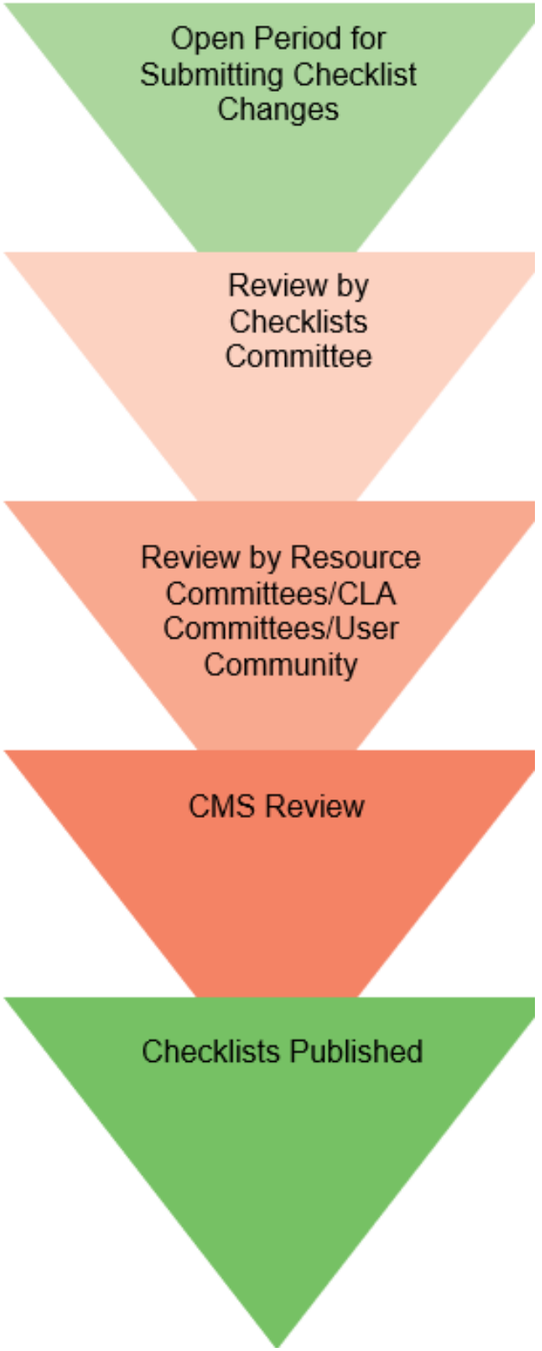
2024 CAP Accreditation Checklists Publication Timeline

- CAP scientific resource committees, Commission on Accreditation committee members, and others submit changes to the CAP Checklists Committee
  - Checklists Committee vets all submitted changes
  - CAP staff updates the checklist database with proposed changes
- Applicable CAP scientific resource committees, Commission on Laboratory Accreditation committee members, and User Community review the draft 2024 checklists and submit feedback
  - Checklists Committee reviews feedback and makes further revisions as appropriate
- CAP staff sends the draft checklists to the Centers for Medicare and Medicaid Services (CMS) for final review and approval
  - CMS sends feedback on the proposed revisions to the CAP and the Checklists Committee submits additional responses to the CMS and adds revisions, as appropriate
- CAP staff completes final publication production steps
  - 4th Quarter 2024 – CAP releases the 2024 edition



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Updates to the CAP Microbiology Checklist

- Multiple edits to combine and streamline

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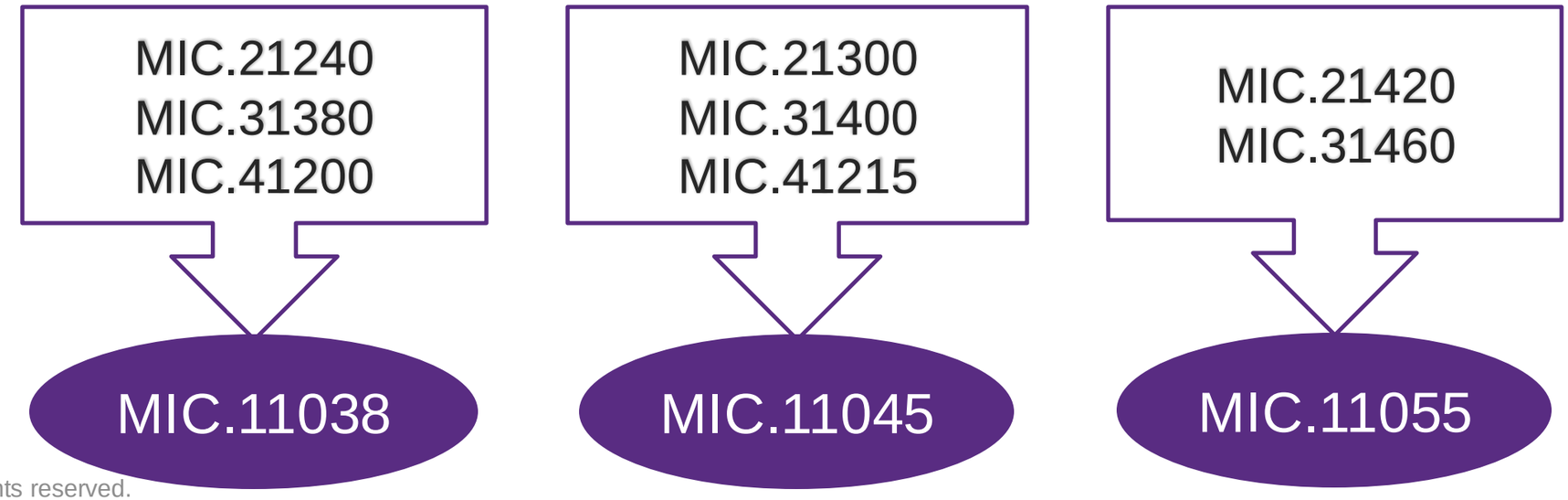
Microbiology Media: Moved and Merged

MIC.11038 **Media QC - Purchased/Acquired** **Phase II**

An appropriate sample from each lot and shipment of each purchased/acquired medium for bacterial, mycobacterial, or mycologic culture is checked before or concurrent with initial use for each of the following:

1. Sterility
2. Ability to support the growth of organisms intended to be isolated on the media by means of stock cultures or by parallel testing with previous lots and shipments
3. Biochemical reactivity, where appropriate

Media requirements in bacteriology, mycobacteriology, and mycology merged and moved to the general microbiology section.



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***REVISED** 08/24/2023*

MIC.11350 Morphologic Observation Evaluation **Phase II**

The laboratory evaluates consistency of morphologic observation among personnel performing microscopic analysis (eg, stains or wet preparations) from direct specimens and cultured organisms at least annually.

NOTE: The laboratory must ensure the description and quantitation (if applicable) of microorganisms and human cells are reported consistently amongst all personnel performing the microscopic analysis.

Suggested methods to accomplish this include:

1. *Circulation of a pre-graded set of organisms with defined staining characteristics.*
2. *Multi-headed microscopy*
3. *Use of photomicrographs with referee and participant identifications (eg, former CAP microbiology Surveys or other photomicrographs from teaching collections)*
4. *Use of digital images*
5. *Enrollment and participation of all personnel in an external assessment program for morphologic observation for Gram stains.*

The laboratory director or designee must determine acceptability criteria for agreement. The laboratory must maintain records of performance and record corrective actions taken for personnel demonstrating significant discrepancies from the group consensus.

Evidence of Compliance:

- ✓ Records of evaluation **AND/OR**
- ✓ Records of enrollment/participation of staff in an external assessment program

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***REVISED** 08/24/2023*

MIC.13325 Rapid Detection of *Mycobacterium tuberculosis* Complex - Laboratories Subject to US Regulations **Phase I**

A nucleic acid amplification test is available, either in the laboratory or by a referral laboratory, for the rapid detection of *Mycobacterium tuberculosis* complex on at least one respiratory specimen submitted to the laboratory (preferably the first diagnostic specimen) for mycobacterial culture.

NOTE: The US Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) algorithms for diagnosis of Mycobacterium tuberculosis complex infections recommend performing a diagnostic nucleic acid amplification test (NAAT) on the initial respiratory specimen from patients suspected of having pulmonary tuberculosis. This can include physician requests for patients with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered, but has not yet been established, and for whom the test result would alter case management or TB control activities (high index of clinical suspicion).

This requirement applies to any laboratory that may receive and/or process requests for mycobacterial culture on respiratory specimens.

Evidence of Compliance:

- ✓ Patient reports/worksheets with NAAT testing results **OR** referral laboratory reports with results, if available

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***NEW** 08/24/2023*

MIC.22050 Culture Media and Incubation Conditions **Phase II**

The laboratory uses defined media and incubation conditions to allow for the recovery of potential pathogens for each culture type, specimen, and/or body site.

NOTE: The media and incubation conditions must permit recovery of the bacteria expected for the specimen type, as clinically indicated or per laboratory protocol. This does not preclude the use of screening or surveillance cultures. At minimum, media and incubation conditions must allow for isolation and identification of potential pathogens for the following:

- *Respiratory specimens: Streptococcus pneumoniae and Haemophilus species*
- *Urine specimens: gram-positive and gram-negative bacteria (use of gram-positive selective media is not required)*
- *CSF and other sterile fluids: fastidious bacteria such as Neisseria meningitidis, Streptococcus pneumoniae, and Haemophilus influenzae*
- *Genital specimens for Neisseria gonorrhoeae: selective media designed for the recovery of N. gonorrhoeae, such as Thayer-Martin media*

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***REVISED** 08/24/2023*

MIC.52100 Ova/Parasite Exam **Phase II**

The microscopic examination of all stools submitted for an ova and parasite (O&P) examination includes a concentration procedure and a permanent stain.

NOTE: When a stool specimen is submitted fresh, the usual approach would be to perform a direct wet preparation (looking for motility), a concentration (helminth eggs/larvae/protozoan cysts), and the permanent stained smear (identification of protozoa missed by concentration and confirmation of suspect organisms). As a minimum (and certainly if the stool is submitted in preservatives), the standard O&P examination would include the concentration procedure and a permanent stained smear. The main point is to ensure that the permanent stained smear is performed on all stool specimens, regardless of what was or was not seen in the concentration wet preparation. Often, intestinal protozoa will be seen in the permanent stained smear, but may be missed in the concentration examination. If the laboratory does not perform both a concentration procedure and a permanent stain, it must refer the testing that is not completed to a referral laboratory so that testing may be completed.

Laboratories in geographic regions that evaluate stool specifically for helminth ova as part of a general health asymptomatic screening program are not required to perform a permanent stain on screening specimens. Laboratories must have a mechanism to identify specimens received for asymptomatic screening, such as through a separate orderable test.

Evidence of Compliance:

- ✓ Patient reports/worksheets with concentration and permanent stain results **OR**
- ✓ Separate ova and parasite exam order for asymptomatic helminth ova screening

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***REVISED** 10/24/2022*

MIC.63252 Quality Monitoring **Phase I**

The laboratory monitors for the presence of false positive results (eg, due to nucleic acid contamination) for all molecular microbiology tests.

NOTE: Examples include review of summary statistics (eg, monitoring percentage of results that are positive for Chlamydia trachomatis and/or Neisseria gonorrhoeae for an increase above historical positive rate within a run or over multiple runs), unexpected increase in positive results for seasonal pathogens outside of the standard epidemiology, performance of wipe testing, and review and investigation of physician complaints on false positive results. Based on monitoring data, the laboratory may implement additional mitigation strategies to minimize risk of contamination, such as process controls.

Evidence of Compliance:

- ✓ Records of data review, wipe testing, statistical data, and evaluation and corrective action if indicated

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When, how, and who?

* Self-Inspections
* Safety Audits
* Policy/Procedure Reviews
* Record Reviews
* Training and Competency Assessments

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What is a Self-Inspection?

Assessment performed by the laboratory during the “off” year of accreditation cycle using custom checklists

Opportunity to correct citations

Maintain records of corrective action

Return self-inspection verification form to the CAP within 60 calendar days

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Why are Self-Inspections Important?

Performing a self-inspection enables:

- Ongoing compliance with CAP checklist requirements with readiness for your next on-site CAP inspection
- Familiarity with changes to CAP checklists
- Uniform practices among departments (and labs)
- Enhanced learning for staff
- Improved laboratory performance
- Quality patient care

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Who Should be Involved…

Staff at all levels should be involved in self-inspection, including:

- **The laboratory director**
- **CLIA technical supervisors/section directors, clinical consultants, general supervisors, and technical consultants**
- **Testing personnel**
- **Administrative, LIS, and other pertinent laboratory and organizational support staff**
- **Residents and fellows**

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How to Prepare a CAP Self-Inspection

- Encourage staff to complete the CAP online inspector training module(s)
  - https://www.cap.org/laboratory-improvement/accreditation/inspection-tools-and-training#tabinspector-training
- Fast Focus on Compliance (FFoC)… | College of American Pathologists (cap.org)

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How to Prepare a CAP Self-Inspection, cont'd

- Review previously cited deficiencies
- Check deficiency responses against current practice
- Ensure compliance with each applicable checklist question, including any new or revised CAP requirements
- Review recent PT performance, focusing on evaluation of misses and ungraded challenges

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How to Perform a CAP Self-Inspection

- Set a timeframe for self-inspection
  - Can be one day or multiple days
- Ideally use inspectors independent of the area being inspected. Options for unbiased inspectors include:
  - Laboratory to laboratory
  - Department to department
  - Residents and fellows who are on or completed rotation on department

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Concluding a CAP Self-Inspection

- Develop and document corrective action plans for any self-cited deficiencies, including a root cause analysis, if necessary.
- Demonstrate implementation of the plan with review of follow-up corrective action taken to ensure compliance.
- Maintain self-inspection records so they are readily accessible for the next inspection.

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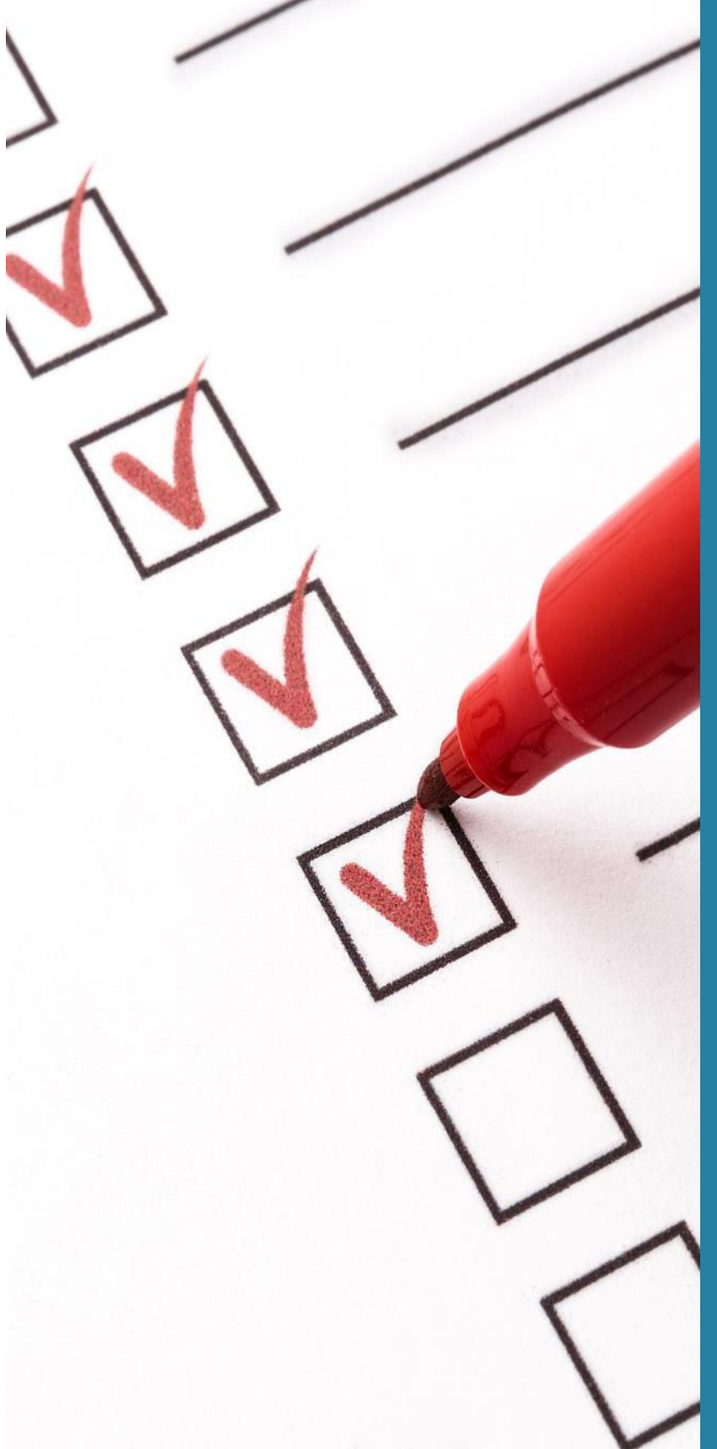
Common Missteps

- Performing a superficial self-inspection
- Feeling bad about citations
  - It is better to self-identify process issues then have them identified during inspection
- Not developing an action plan
- Not implementing and recording corrective actions
- Not following-up on corrective actions to ensure they are effective
  - Not retaining record of corrective action follow-ups



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Safety Audits

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What to include in a Safety Audit?

- Review infection control processes
  - Bloodborne pathogens
  - Highly infectious pathogens
  - Fire prevention and control
  - Electrical safety
  - Chemical safety
  - Radiation safety
  - Security incidents
  - Environmental safety

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How to perform the Safety Audit?

- Risk assessment process
  - Assess reported incidents
  - Identify risks
  - Plan for prevention/mitigating risks
  - Implement risk prevention/mitigation plans
  - Evaluate effectiveness of plans
  - Communicate

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Example Safety Audit Checklist

Department/Area:		Date:		
Surveyor(s) Name:				
	A. EMERGENCY PREPAREDNESS	**Y**	**N**	**Notes**
	Emergency safety locations identified			
	Emergency codes color chart posted			
	Chemicals properly secured. (shelf lips, restraints, cabinets)			
	B. ENVIRONMENTAL SRVCS / MAINTENANCE			
	Area is clean/not cluttered.			
	Handwashing supplies available. (soap, towels)			
	Trash properly stored. (bags tied, non-excessive, posted, covered)			
	Ceiling, walls, floors, windows, furniture, air vents are clean and in good condition			
	Restrooms are clean and free of litter			

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Policy and Procedure Reviews

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Who can approve a new or revised Policy/Procedure (P/P)?

- Laboratory director approval required for technical P/P
  - New testing
  - Significant changes
- Physical Signatures or Electronic Signatures

Laboratory Policy	
Subject: Waived Glucose Testing by Handheld Device	
Prepared By: Laboratory Manger	Page: **1 of 3**
Approved By: *Laboratory Director*, MD, FCAP	**Approved date: June 20, 2021**

Principal and Clinical Significance:

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When should P/P review occur?

- Every two-years (biennial)
  - Review can be delegated
  - Recommend setting up a schedule for reviews
- New laboratory director

Month	Department/Section	Assigned To	Completion Date
January	Coagulation		
February	Hematology		
March	Urines		
April	Main Chemistry		
May	Blood Gases & Kit testing		
June	Microbiology		
July	Molecular		
August	Anatomic Pathology		
September	Phlebotomy		
October	Processing		
November	Point of Care		
December	Transfusion Services		

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How often should staff review P/P?

- All New P/P
- Updated P/P

- Document Staff Reviews

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Record Reviews

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What to include in monthly reviews?

- QC data
- Calibration or Calibration Verification data
- Maintenance Logs
- Temperature Logs
- QM/QA reporting
- Proficiency Testing Including Results
- Incident Logs
- Corrective Action Logs

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When should record reviews occur and by who?

- Monthly
  - Timely review
  - Must include who reviewed and the date reviewed
- Staff with knowledge
  - Managers
  - Leads
  - Section Directors
  - Key Operators

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Fill in the date the document review occurred for that month

Department	Instrument/Testing	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
All Lab	Room Temperature Logs	02/07/24											
	Refrigerator Temperature Logs	02/07/24											
	Freezer Temperature Logs	02/07/24											
	Eye wash Logs / Shower Logs	02/07/24											
Chemistry	Instrument A maintenance logs	02/09/24											
	Instrument A QC logs	02/09/24											
	Instrument A calibration logs												
	Instrument B maintenance logs	02/09/24											
	Instrument B QC logs	02/09/24											
	Instrument B calibration logs												
	Instrument A & B Comparisons												
	Blood Gas maintenance logs	02/09/24											
	Blood Gas QC logs	02/09/24											
	Blood Gas calibration logs	02/09/24											
	PT Records	02/26/24											
Kit Testing/Misc Testing	Viral Test Instrument A maintenance logs	02/18/24											
	Viral Test Instrument A QC logs	02/18/24											
	Viral Test Instrument A calibration logs												
	Viral Test Instrument B maintenance logs	02/18/24											
	Viral Test Instrument B QC logs	02/18/24											
	Viral Test Instrument B calibration logs												
	Viral Test Instrument Comparisons												
	Viral Test IQCP review	02/26/24											
	HCG Kit QC	02/26/24											
	Mono Kit QC	02/26/24											
	Strep Kit QC	02/26/24											
	PT Records	None											

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Training and Competency Assessment

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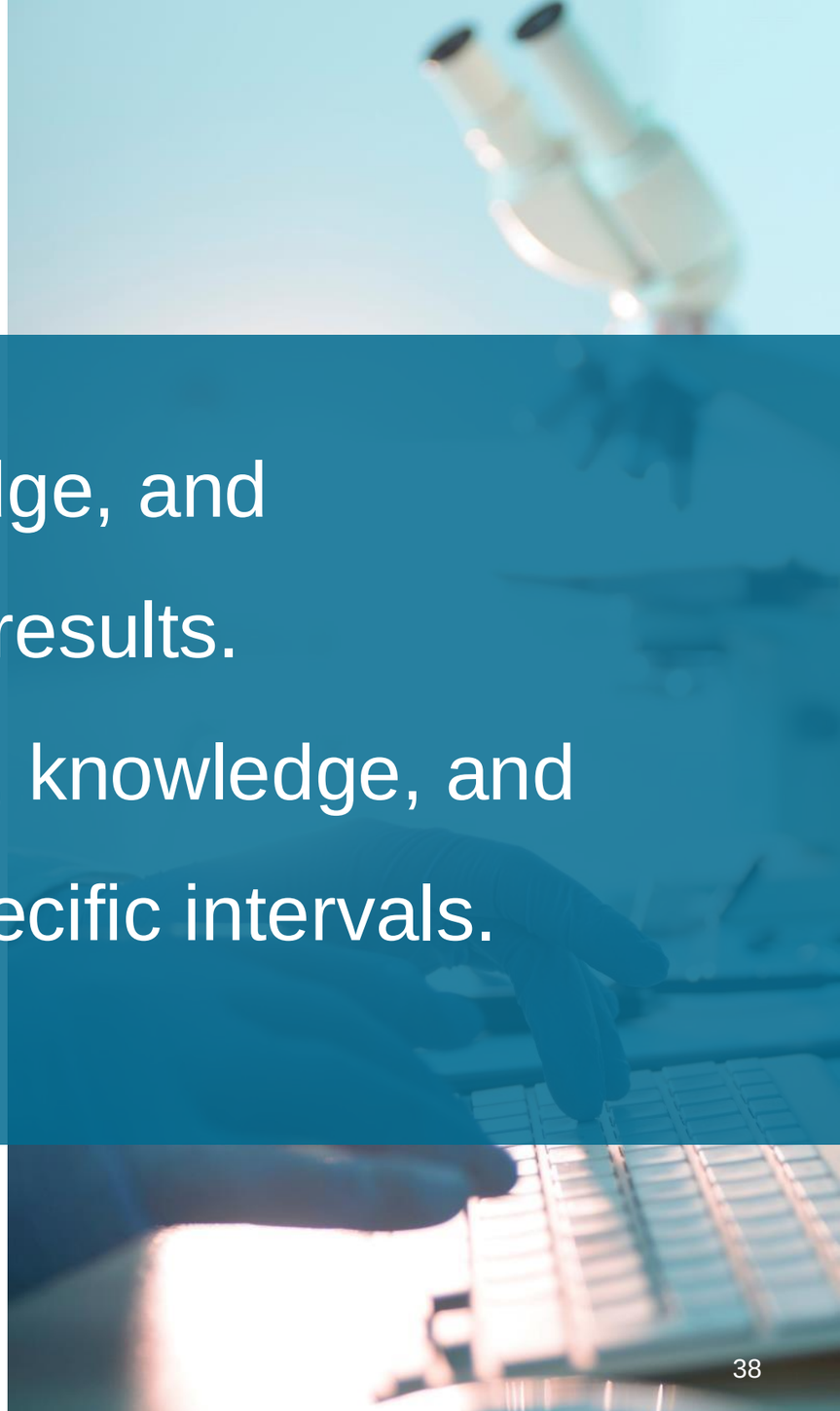
What is the difference between Training and Competency?



- **Training: development** of skills, knowledge, and experience **prior** to reporting patient test results.
- **Competency: application** of these skills, knowledge, and experience **after** training performed at specific intervals.

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How to tell them apart…

Training:

- Occurs ***before*** patient testing begins
- Usually once unless employee fails successful demonstration of skill and retraining is required
- Does ***not*** require the six elements of competency
- Required for new employees and new tests/methods/instruments

Competency:

- Occurs ***after*** independent patient testing begins
- Performed at specific intervals
- ***Does*** require the six elements (as applicable) of competency for nonwaived testing
- Required semiannually in the first year of patient testing and annually thereafter

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What Documents Support Training and Competency?

- Training documents
  - Checklists, self-assessments, vendor training
- Competency assessment
  - Six elements of competency, as applicable
  - Supporting documentation including traceability
- Written procedure

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Template: Training Checklist (example)		
Employee Name	Date of Employment	
Module Name	Department	
Training period		
Start Date	Completion Date	
Section/Procedure:	**Initial Evaluation (Date and initials)**	
	Tech	**Trainer**
Reading Procedure		
Maintenance		
Quality Control		
Troubleshooting		
Interpretation of Results		
Use of LIS		
Reagents		
Specimen Requirements		
Reference Ranges		
Calibration		
Safety		
Written/Oral Exams		
Other such as CD-ROM programs, slides, etc.		
Direct Observation for Competency Assessment and Verification		
For Initial Evaluation		
Employee Signature	Date	
Lead Tech/Supervisor	Date	
Manager/Pathologist	Date	
This training is acceptable and I have no additional questions (Employee initials) Initial:_____		

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	Elements
Employee Name:	1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing.
Date of Hire:	2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
	3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
Period of Evaluation:	4. Direct observation of performance of instrument maintenance and function checks
	5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
Evaluator(s):	6. Evaluation of problem-solving skills

TEST SYSTEM	1	2	3	4	5	6	Retrain/corrective action date/assessor
Bacteriology							
Specimen processing							
Gram stain							
Aerobic culture reading							
Spot tests							
Streptococcal grouping							
Serologic typing (eg Salmonella, Shig)							
Automated ID system							
Automated susc system							
Manual susc							
Anaerobic cultures							
Direct Antigen Kit tests							
Group A Streptococcus							
Legionella Antigen							
Clostridium difficile							
Mycology							
Specimen processing							
KOH							
Calcoflour white							
Fungal cultures							
Mould ID							

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How often do you have to assess competency for non-waived testing?

GEN.55505 Competency Assessment Frequency – Nonwaived Testing

The competency of personnel performing nonwaived testing is assessed at the required frequency at each laboratory (CAP/CLIA) number where testing is performed.

Competency Assessment Frequency – Nonwaived Testing
At least semiannually (**first assessment within seven months from initiation of testing and second assessment no later than 12 months from the start of testing)** during the first year an individual tests patient specimens (new employees)
At least annually after an individual has performed assigned duties for one year
When problems are identified with an individual's performance

The annual competency assessment may be performed throughout the entire year to minimize the impact on workload.

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Who can assess competencies?

Assessor Qualifications Based on Test Complexity	
Waived	**Anyone qualified to perform testing**
Moderate Complexity	**Technical Consultant**
High Complexity	**Technical Supervisor or General Supervisor**

- Must be delegated in writing by name or by title
- Must have knowledge of testing
- Does ***not*** require competency assessment to assess competencies, if the assessor does not perform patient testing

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What, where, and when?

* Activity Menu – Adding or Removing Testing

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What is the 2nd most cited deficiency in CAP?

COM.01200 Activity Menu **Phase I**

The laboratory's current CAP Activity Menu accurately reflects the testing performed.

NOTE: The laboratory's CAP Activity Menu must include all patient/client testing performed by the laboratory.

- *For laboratories with a CLIA certificate, it includes all testing and activities performed under that CLIA certificate.*
- *For laboratories not subject to CLIA, it includes all testing and activities meeting all of the following criteria: 1) performed under the same laboratory director, 2) under the same laboratory name, and 3) at the same physical premises (contiguous campus).*

The testing and activities must be listed on the laboratory's CAP Activity Menu regardless of whether it is also accredited by another organization. Testing performed under a separate CLIA certificate must not be listed on the laboratory's activity menu. ***The laboratory must update its CAP Activity Menu when tests are added or removed by logging into e-LAB Solutions Suite on cap.org and going to Organization Profile - Sections/Departments.*** *In order to ensure proper customization of the checklists, the laboratory must also ensure its activity menu is accurate for non-test activities, such as methods and types of services offered.*

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What is Checklist Customization?

Checklist customization is a process that associates the tests on the laboratory's activity menu with the applicable checklist requirements.

Activities, subdisciplines, scopes of service, and questionnaire responses impact customization.

Unnecessary requirements will be customized out of the laboratory's checklist to the extent possible.

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Resources Available

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Educational Resources Provided by The CAP

- Archives of Pathology & Laboratory Medicine and CAP TODAY
- Educational Webinars
- CAP annual meeting
- Checklists
  - Templates
  - Q&As
  - Master, Customized, Changes Only
- Education offerings https://learn.cap.org/lms/home

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Understand and Prepare for the Impact of the FDA's LDT Final Rule Webinar Series

Sep 18, 2024 12:00 PM - 1:00 PM CT

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Summary

- Covered the who, how, where, what, and when
- Covered from self inspections to harnessing your own data
- Included additional resources available

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Questions?

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