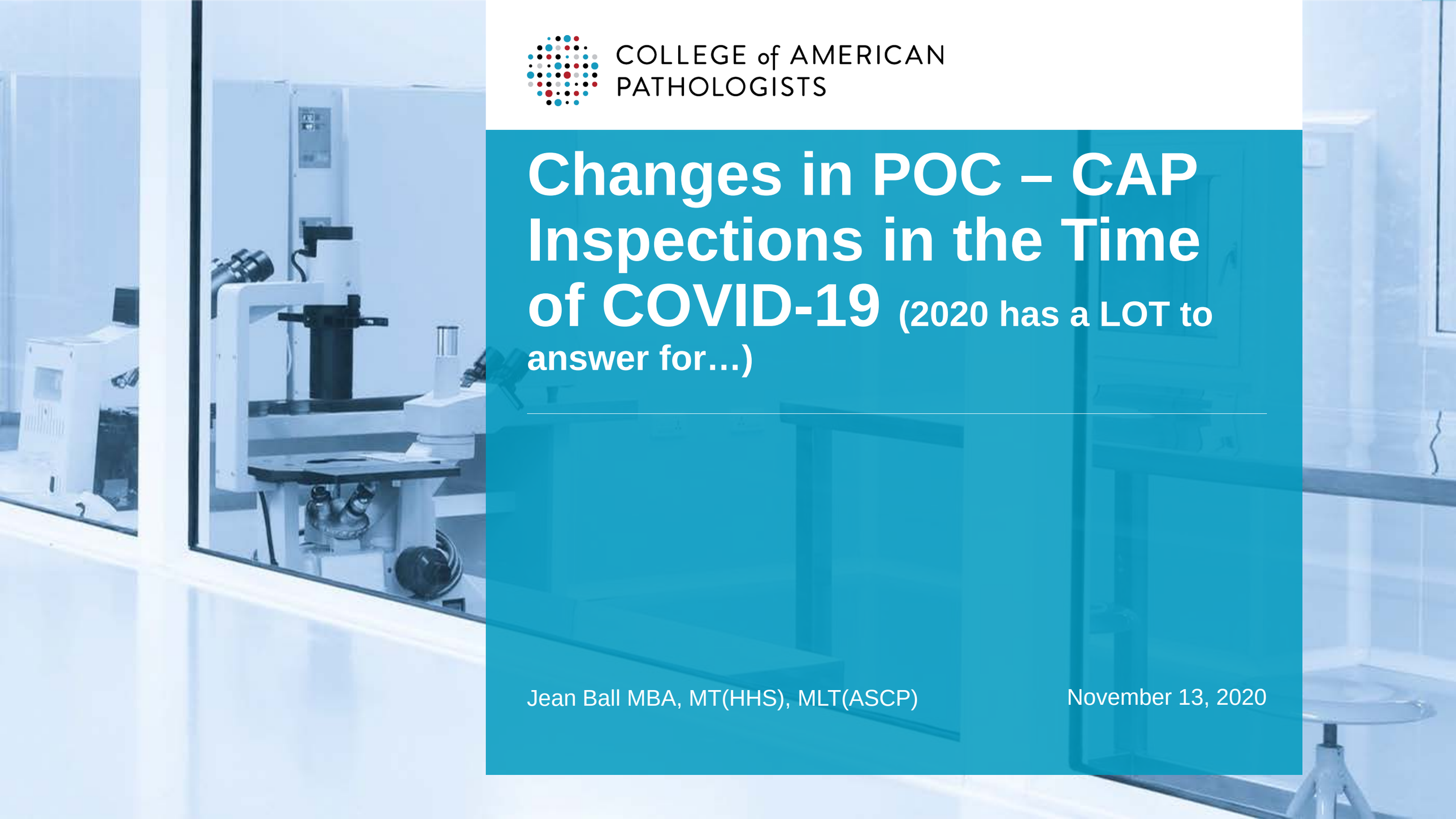

COLLEGE of AMERICAN PATHOLOGISTS

Changes in POC – CAP Inspections in the Time of COVID-19 (2020 has a LOT to answer for…)

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Learning Objectives

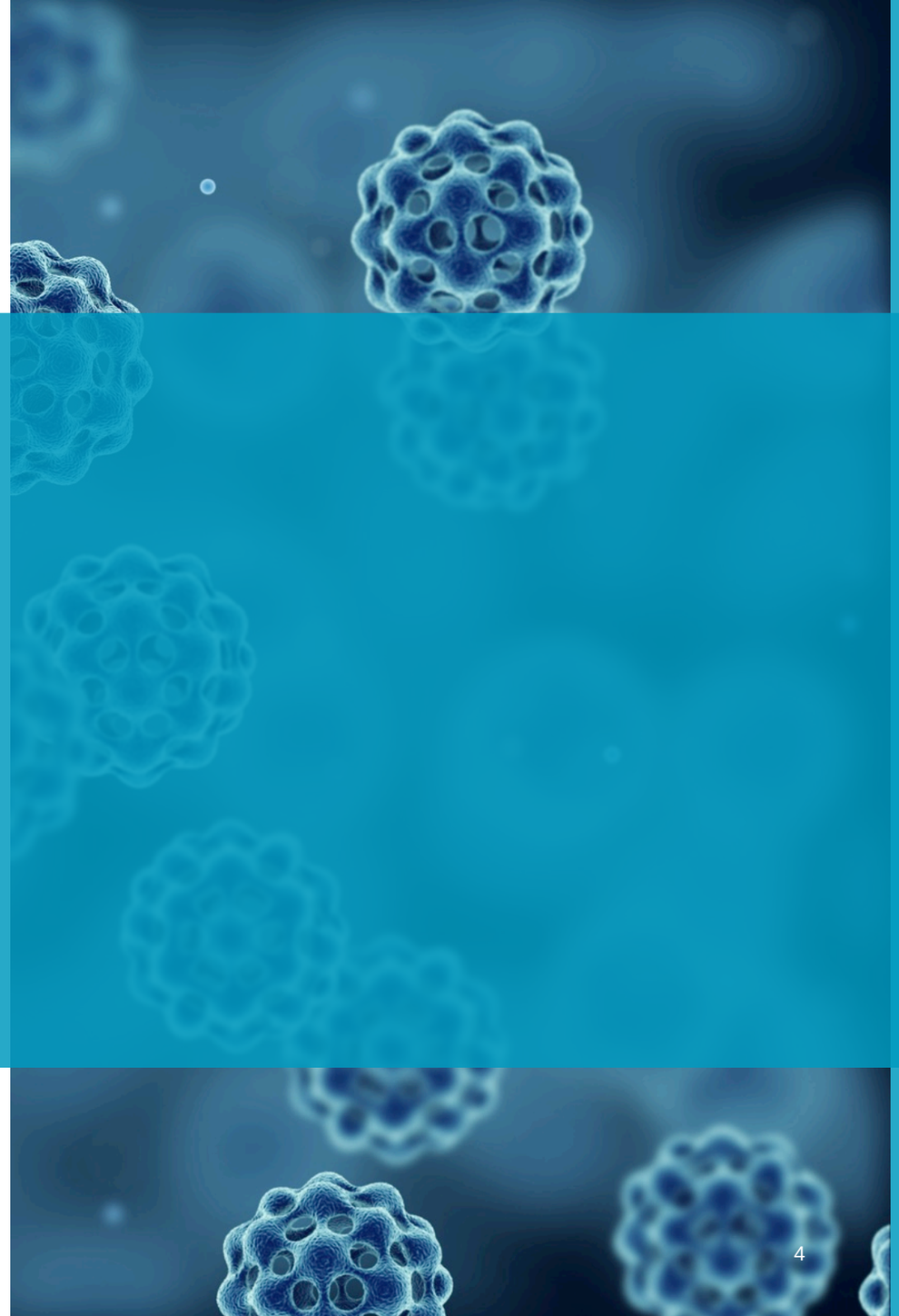
- Brief Overview of CAP Inspections
- Best Practices in Point of Care Testing/Laboratories
- Common Deficiencies in Point of Care Testing/Laboratories
- Current issues in POC

CAP Inspections – COVID-19

- Traditional
- Hybrid/Modified
- Virtual
  - CLIA labs
  - Non-CLIA labs

What’s different?

- Face-to-face OR “face-to-face”
- Number of inspectors
- Timing of the inspection
- Scope of the onsite portion



Best Practices in Point of Care Testing And Common Deficiencies

Best Practices in All Laboratories

- Quality laboratories will give quality results
- Best Practices for establishing a quality laboratory are:
  - Established and well-defined quality management plan
  - Laboratory director involvement
  - Thorough training and competency assessment program
  - Clear policies/procedures for all staff

Quality Management Plan (QM Plan) – Indicators of Quality

- QM plan must have indicators of quality or benchmarks established.
- Must include all phases of testing for all areas of the laboratory:
  - Pre-analytic
  - Analytic
  - Post-analytic
- Evaluate corrective actions when benchmarks are not met.

QM Plan Indicators of Quality - continued

- **Examples of Indicators to monitor:**
  - Patient/Specimen Identification
  - Test Order Accuracy
  - Specimen Acceptability
  - Stat Test Turnaround Time
  - Critical Result Reporting
  - Customer Satisfaction
  - Corrected Reports

- COVID testing results – report and monitor

Common Deficiencies with QM Plan

- **Missing all three phases of testing**
  - **Pre-analytic, analytic, and post-analytic phases**
- **Missing the annual assessment of effectiveness**
  - **Review of previous years QM indicators and make adjustments as needed**
- **Missing documentation of corrective actions**
  - **When benchmarks are not attained, what was done**

- **Surging emphasis on reporting COVID results**

Laboratory Director Involvement

To provide effective leadership in:

- **Medical care and service to the patient**
- **Education of colleagues and staff**
- **Administration of your service unit**

Effective Laboratory Directors -

- Influence other health care professionals
- Direct people and programs
- Use resources in a clinically effective and cost-effective fashion

- Comply with all regulatory requirements
- Maintain a patient-centric focus
- Promote patient safety and optimal clinical outcomes
- Promote medical professionalism

Common Deficiencies with Director Involvement

- **Delegations of competency assessment to unqualified personnel**
  - **For moderately complex testing must meet technical consultant qualifications**
- **QM Plan annual assessments**
  - **Missing documentation of the annual assessment of the QM plan**

Training and Competency Assessment

- **Training is a process to provide and develop the knowledge, skills, and behaviors to meet established requirements. Documentation of training is separate from competency assessment.**
- **Competency is the application of the knowledge, skills and behaviors for performance.**
- **The difference between training and competency is that training happens before someone begins testing and competency assessment confirms that they are doing the testing correctly.**

Competency Assessment

- ***The competency of personnel performing nonwaived testing is assessed at the required frequency at the laboratory (CAP/CLIA number) where testing is performed.***
  - All test performance variations must be included in the competency assessment specific to the site or laboratory.
  - Records of competency assessment may be maintained centrally within a healthcare system but must be available upon request.
  - Separate requirement for waived testing (GEN.55499).

Competency Assessment - continued

- ***….at the required frequency……***

- **During the first year of an individual's duties, competency must be assessed at least semiannually and annually thereafter.**
  - Prior to performing patient testing, training must be completed and evaluated for proper test performance.
  - Training (GEN.55450) and competency assessments are separate processes.
  - Applicable to new testing personnel only and not for existing testing personnel trained on new test methods.

Competency Assessment - continued

- ***Assessment includes all applicable six elements of competency noted under GEN.55500 for each test system.***

  - Use laboratory activity menu to identify test systems.
    - Same analyte with two test systems (e.g. automated, manual) needs separate competency assessments.
    - Multiple analytes under single test system do not need separate competency assessments (e.g. chemistry panel).
    - Each test system includes assessment of pre-analytic, analytic, and post-analytic steps in the testing process.

Common Deficiencies with Competency Assessments

- **Incomplete documentation of all 6 elements**
  - **Each test system/method must have all 6 elements assessed for all non-waived testing**
- **Ineligible competency assessor**
  - **For all moderately complex testing, must meet technical consultant qualifications**
    - **Must have a bachelor's degree in a chemical, physical, biologic or laboratory science**
    - **Must have at least two years of experience in the same complexity of testing**
    - **Must be delegated in writing**

Policy/Procedure Manual

- **A complete procedure manual is available in a paper-based, electronic, or web-based format at the workbench or in the work area.**
  - ***In all cases, procedures must match the laboratory's practice, the laboratory's practice must follow written procedure, and appropriate reviews must occur.***

Common Deficiencies with the Procedure Manual

- **Practice must match the procedure**
  - **Ensure that all phases of the testing and laboratory processes match the procedures**
    - **If new instruments are introduced ensure all procedures are updated with accurate information**
  - **Easy to follow procedures allow for ease of competency assessment**

Basics covered!

Now, you can address some other common deficiencies in POCT!

Comparability of Instruments and Methods – Nonwaived testing

- ***If more than one nonwaived instrument/method is used to test for a given analyte, the instruments and methods are checked against each other at least twice a year for comparability of results.***

Common Deficiencies in Comparability of Instruments

- Incomplete documentation
  - May be accomplished during calibration verification but not documented
- No acceptability criteria established for comparisons
- Unacceptable comparisons with no documentation of corrective actions

Activity Menu

- ***The laboratory's current Activity Menu accurately reflects the testing performed.***
  - **Procedure manual should correspond to Activity Menu**
  - **Add to new test implementation process**
  - **Audit Activity Menu periodically at the section/department level, especially when doing reapplication**
  - **Remove retired tests**

Common Deficiencies with the Activity Menu

- **Missing testing**
  - **When new testing is introduced the activity menu must be updated**
- **Discontinued testing still listed**
  - **If there is testing that is discontinued the activity menu must be updated**

Maintenance/Function Checks

- ***Appropriate maintenance and function checks are performed, and records retained for instruments (eg, analyzers) and equipment (eg, centrifuges) following a defined schedule, at least as frequent as specified…***
  - **All instruments and equipment**
  - **Includes centrifuges, microscopes, temperature logs**
  - **Written procedure**
  - **Schedule specified by manufacturer**
  - **Documentation of performance and monthly review**

Common Deficiencies for Maintenance/Function Checks

- No documentation of required PM
- Missing documentation of maintenance
- No corrective actions for missed maintenance

Instrument/Equipment Review

- ***Instrument/Equipment maintenance and function check records are reviewed and assessed at least monthly by the laboratory director or designee.***

- **Assessed at least monthly – signature/initials and date required**
  - Ensure all maintenance form templates include reviewed by and date
  - Implement a checkoff list of equipment to review; especially manual things that may be forgotten

Common Deficiencies with Instrument/Equipment Review

- Missing documentation of review
- Missing corrective actions with missing documentation
- Timely review of documentation

PT Attestation Statement

- ***The proficiency testing attestation statement is signed by the laboratory director or designee and all individuals involved in the testing process.***
  - Physical signatures must be present.
    - PT results submitted electronically can have printed names but will require the physical signatures on the original attestation page.
    - Electronic signatures are not acceptable.

Common Deficiencies in PT Attestation Statements

- No physical signature from testing staff
- No physical signature from laboratory director or designee

Proficiency Testing Evaluation

- ***There is ongoing evaluation of proficiency testing (PT) and alternative assessment results with appropriate corrective action taken for each unacceptable result.***

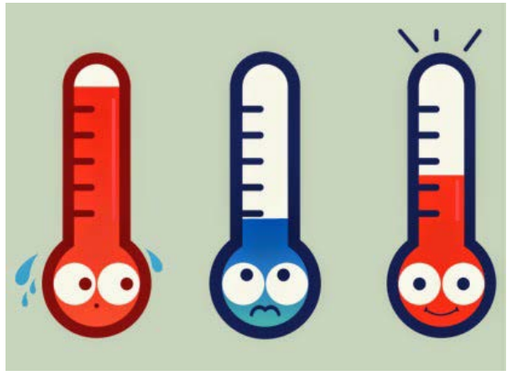
- **Each unacceptable PT or alternate assessment result (any result or sample not meeting defined acceptability criteria) must be evaluated.**
  - Investigate **each** unacceptable PT result for impact on patient sample results.
    - Major categories of investigation include: Clerical; Analytical; Procedural; Specimen handling; PT material
  - Correction of problems appropriate to the failure are performed in a timely manner.

Common Deficiencies in PT Evaluation

- Missing corrective actions on failures
- Missing documentation of review of results with codes
- Missing documentation or evaluation of alternative assessments
  - Alternative assessments are performed on methods/instruments that do have commercially available PT products

Temperature Checks

- ***Temperatures are checked and recorded each day of use for all temperature-dependent equipment and environments using a calibrated thermometer.***
  - **If the laboratory is not "open" on the weekends and there is temperature dependent reagents/equipment stored in the laboratory, there must still be temperature monitoring.**
    - Can use min/max thermometers
  - **Any temperatures outside of the defined ranges must have documented corrective action.**



Common Deficiencies in Temperature Monitoring

- Missing documentation of corrective actions when temperatures are out
- Temperature ranges are not set for all items/materials with the area
  - If the lab stores multiple reagents or kits you must evaluate all temperature requirements
- Missing documentation of weekend monitoring when the laboratory is not open

You’re ready…or are you?

(what changed…*today*?)

New issues in POCT

- **COVID testing – that takes a priority!**
  - **EUAs**
  - **Locations**
  - **Methodologies**
  - **Availability of reagents, kits, supplies**

- **Will I get cited? We had COVID!**
  - **Document…document…document…**

- **“Other” changes….?**

New Resource for you!

- **On the CAP website**
- **Under eLab Solutions Suite**
- **Accreditation Resources**
- **Repository of templates, examples, Q&A, LOTS of things to make your life easier!**
- **Don’t reinvent the wheel! Check Accreditation Resources first!**

Summary: Avoiding the Most Common Deficiencies

- Written procedure for what you are doing.
- Document that shows that you are doing it.
- Anticipate inspector requests.
- Cross reference checklist item with documentation.
- Think like an inspector!
- Don’t worry about your inspection…
  - Just keep doing what you do best – Patient Care!
  - Do the best you can with everything else!

Questions?

Contact the CAP Accreditation Technical Specialists at:
1-800-323-4040 extension 6065
Send email inquiries to accred@cap.org
Visit our Accreditation Resources for CAP Accredited laboratories at CAP.ORG.

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