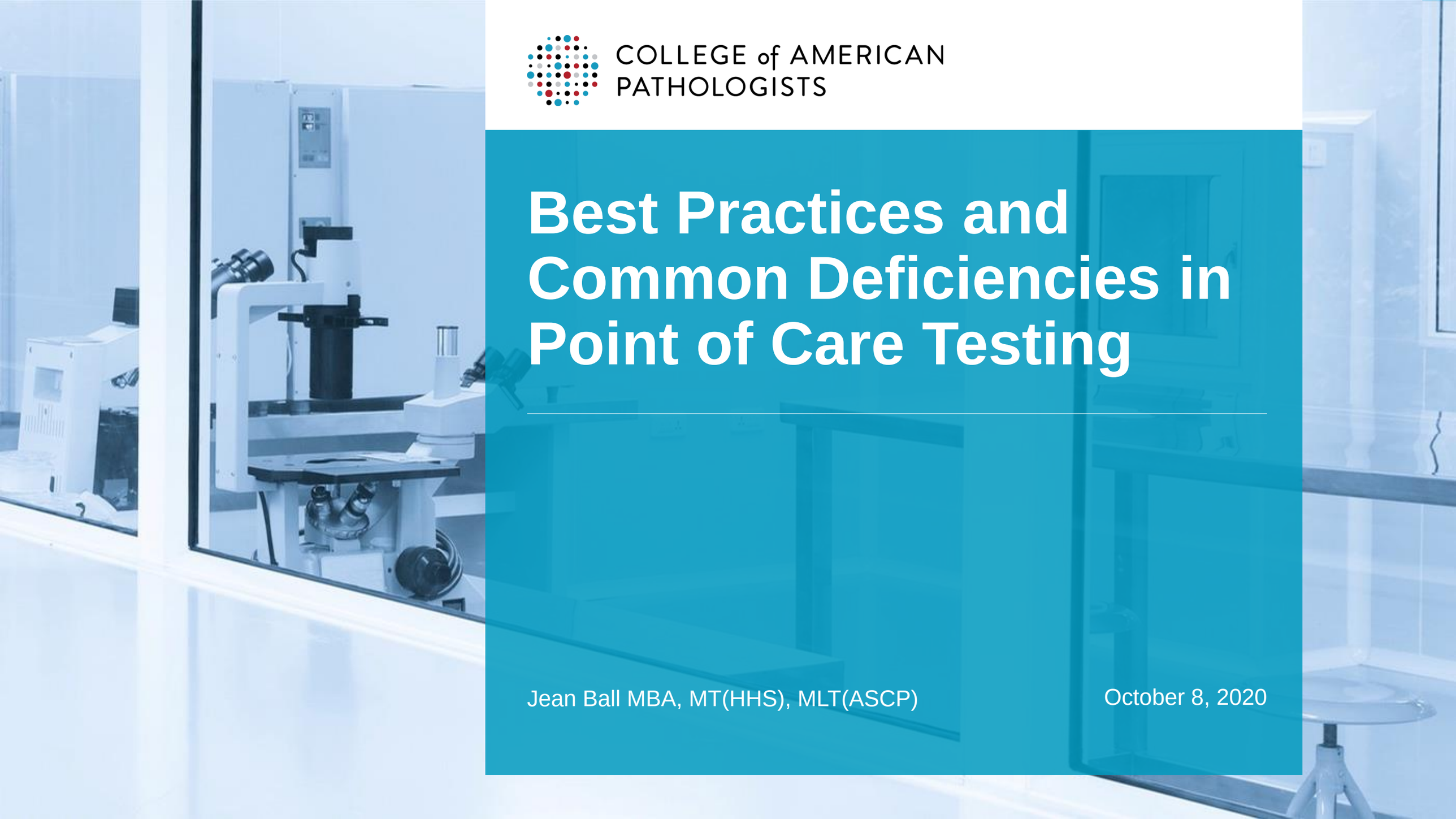

COLLEGE of AMERICAN PATHOLOGISTS

Best Practices and Common Deficiencies in Point of Care Testing

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Learning Objectives

- Brief Overview of CAP
- Best Practices in Point of Care Testing/Laboratories
- Common Deficiencies in Point of Care Testing/Laboratories

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

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**

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.

Competency Assessment - continued

Employee Name:	Sample Employee
Date of Hire:	1/1/2018
Period of Evaluation:	01/01/2018 - 12/31/2018
Evaluator(s):	Sample Manager (SLM)

Elements:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
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
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
6. Evaluation of problem-solving skills

Ele-ments	Specify Instrument / Assay	Point of Care Istat - Nonwaived	Point of Care Glucometer (Waived)	Point of Care ABL	Point of Care GEM
1	Patient ID/Prep	01/08/18 SLM	02/01/18 SLM	n/a	n/a
1	Specimen Collection	01/08/18 SLM	02/01/18 SLM	n/a	n/a
1	Handling/Processing	01/08/18 SLM	n/a	01/08/18 SLM	01/08/18 SLM
1	Testing	01/08/18 SLM Accession # M123456	02/01/18 SLM MR# 111222333	01/08/18 SLM Accession # M123456	01/08/18 SLM Accession # M123456
2	Reporting Criticals	01/08/18 SLM Accession # M123456	n/a	01/08/18 SLM Accession # M123456	01/08/18 SLM Accession # M123456
2	Reporting Normals	01/08/18 SLM Accession # M123456	02/01/18 SLM MR# 111222333	01/08/18 SLM Accession # M123456	01/08/18 SLM Accession # M123456
3	Review worksheets	n/a	n/a	n/a	n/a
3	Review QC	01/08/18 SLM	01/08/18 SLM	01/08/18 SLM	01/08/18 SLM
3	Review PT results	03/15/18 SLM Sample IStat-15	n/a	03/15/18 SLM Sample ABG-16	03/15/18 SLM Sample ABG-17
3	Review PM records	03/15/18 SLM	n/a	n/a	n/a
4	Maintenance	01/08/15 SLM	02/01/18 SLM	01/08/18 SLM	01/08/18 SLM
5	Proficiency Testing	02/17/18 SLM Sample Istat-15	n/a	02/15/18 SLM Sample ABG -16	02/15/18 SLM Sample ABG-17
5	Blind Samples	01/08/18 SLM Accession # M234567	n/a	01/08/18 SLM Accession # M234567	01/08/18 SLM Accession # M234567
6	Problem Solving	Written Quiz = 100% 01/08/18 SLM	Online Quiz = 100% 01/10/18 SLM	Online quiz = 100% 01/08/18 SLM	Verbal quiz = 100% 01/08/18 SLM
	Comments	Competent = yes 03/15/18 SLM	Competent = Yes 02/01/18 SLM	Competent = yes 02/15/18 SLM	Competent = yes 03/15/18 SLM

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

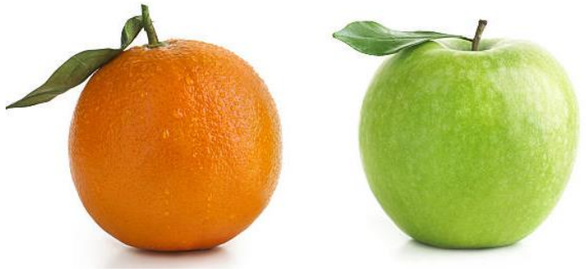
- **Practice must match the procedure**
  - **Ensure that all phases of the testing and laboratory processes match the procedures**
    - **If new instruments are introduced ensure all procedures are updated with accurate information**
  - **Easy to follow procedures allow for ease of competency assessment**

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.***

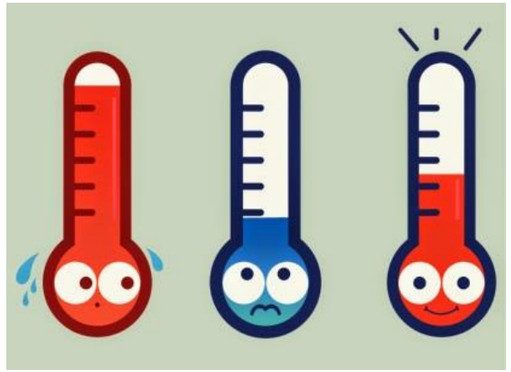
- **Each unacceptable PT or alternate assessment result (any result or sample not meeting defined acceptability criteria) must be evaluated.**
  - Investigate **each** unacceptable PT result for impact on patient sample results.
    - Major categories of investigation include: Clerical; Analytical; Procedural; 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
  - EUAs
  - Locations
  - Methodologies

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!

Questions?

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