COLLEGE of AMERICAN PATHOLOGISTS

# Laboratory Quality Improvement Ideas From CAP Inspections

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# Harris S. Goodman, MD, FCAP

- Alameda Health System, Oakland, CA
  - Chief, Department of Pathology
  - Medical Director, Clinical Laboratory
- Paragon Pathology Medical Associates
  - Chief Pathologist, President and CEO
- College of American Pathologists
  - Inspection Team Leader
  - Advisor, Checklists Committee (previously Chair)
- Compulsive runner with a love of Pathology

# Objectives

- Review the most cited deficiencies
- Learn how to improve laboratory processes to prevent deficiencies
- Discuss the latest CAP tools/resources

# Top 10 Deficiencies

| Checklist Requirement | | CAP-wide Ranking |
|---|---|---|
| **GEN.55500** | Competency Assessment | 1 |
| **COM.04250** | Comparability of Instruments and Methods – Nonwaived Testing | 2 |
| **COM.01200** | Activity Menu | 3 |
| **COM.10000** | Policy and Procedure Manual | 4 |
| **COM.01700** | PT and Alternative Assessment Result Evaluation | 5 |
| **COM.30600** | Maintenance/Function Checks | 6 |
| **COM.04200** | Instrument/Equipment Record Review | 7 |
| **COM.01400** | PT Attestation Statement | 8 |
| **COM.30750** | Temperature Checks | 9 |
| **GEN.20450** | Correction of Laboratory Records | 10 |

# GEN.55500 Competency Assessment

- The competency of personnel performing **nonwaived** testing is assessed at the required frequency at the laboratory (CAP/US-based CLIA number) where testing is performed.
  - All variations must be included.
  - May be maintained centrally within a healthcare system but must be available upon request.

# Competency Assessment (cont'd)

- 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 and competency assessments are separate processes.
  - Applicable to new testing personnel only.

# Competency Assessment (cont'd)

- Assessment includes the 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 (eg, automated, manual) needs separate competency assessments.
    - Multiple analytes under single test system do not need separate competency assessments (eg, chemistry panel).
    - Each test system includes assessment of Pre-analytic, Analytic, Post-analytic steps in the testing process.

# Competency Assessment (cont'd)

- The **six** elements of competency include:
  1. Direct observations of routine patient test performance
  2. Monitoring the recording and reporting of test 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 or proficiency testing specimens
  6. Evaluation of problem-solving skills

# Common Deficiencies and How to Avoid Them

Competency Assessments

- Missing all 6 elements of competency
- Missing semiannual competency for new staff
  - Including Point of Care non-waived testing

# Competency Assessment Example

| Ele-ments | Specify Instrument / Assay | Chemistry Analyzer | LC-TOF | GC-FI | GC-MS |
|---|---|---|---|---|---|
| 1 | Patient ID/Prep | n/a | n/a | n/a | n/a |
| 1 | Specimen Collection | n/a | n/a | n/a | n/a |
| 1 | Handling/Processing | 01/08/18 SLM | 01/08/18 SLM | 01/08/18 SLM | 01/08/18 SLM |
| 1 | Testing | 01/08/18 SLM Accession # M123456 | 01/08/18 SLM Accession # M123456 | 01/08/18 SLM Accession # M123456 | 01/08/18 SLM Accession # M123456 |
| 2 | Reporting Criticals | 01/08/18 SLM Accession # M123456 | 01/08/18 SLM Accession # M123456 | 01/08/18 SLM Accession # M123456 | 01/08/18 SLM Accession # M123456 |
| 2 | Reporting Normals | 01/08/18 SLM Accession # M123456 | 01/08/18 SLM Accession # M123456 | 01/08/18 SLM Accession # M123456 | 01/08/18 SLM Accession # M123456 |
| 3 | Review worksheets | 01/08/18 SLM | 01/08/18 SLM | 01/08/18 SLM | 01/08/18 SLM |
| 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 UDS-15 | 03/15/18 SLM Sample UDS-16 | 03/15/18 SLM Sample UDC-16 | 03/15/18 SLM Sample UNK-17 |
| 3 | Review PM records | 01/08/18 SLM | 01/08/18 SLM | 01/08/18 SLM | 01/08/18 SLM |
| 4 | Maintenance | 01/08/15 SLM | 01/08/18 SLM | 01/08/18 SLM | 01/08/18 SLM |
| 5 | Proficiency Testing | 02/17/18 SLM Sample UDS-15 | 02/15/18 SLM Sample UDS-16 | 02/15/18 SLM Sample UDC-16 | 02/15/18 SLM Sample UNK-17 |
| 5 | Blind Samples | 01/08/18 SLM Accession # M234567 | 01/08/18 SLM Accession # M234567 | 01/08/18 SLM Accession # M234567 | 01/08/18 SLM Accession # M234567 |
| 6 | Problem Solving | Written Quiz = 100% 01/08/18 SLM | Trouble Shooting Log 01/09/18 SLM | Abnormal diff quiz = 100% | Verbal quiz = 100% 01/08/18 SLM |

# COM.04250 Comparability of Instruments and Methods – Nonwaived testing

- More than one nonwaived instrument/ method to test for a given analyte.
- Instruments and methods are checked at least twice a year.

# Comparability of Instruments and Methods (cont'd)

- Non-waived methods only
- Methods within a single CAP/CLIA number
- At least twice per year
- Applies to instruments/methods producing the same reportable results
- Written procedures including acceptance criteria

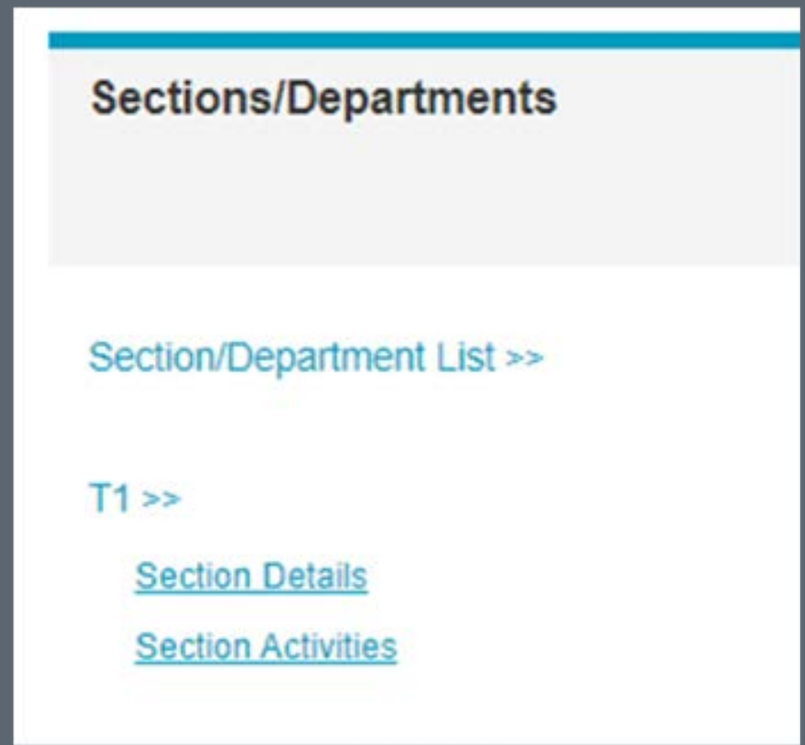
# Common Deficiencies and How to Avoid Them

Comparability of Instruments and Methods

- Missing documentation of two times per year
- Missing acceptability criteria
- Does not include all non-waived testing

# COM.01200 Activity Menu

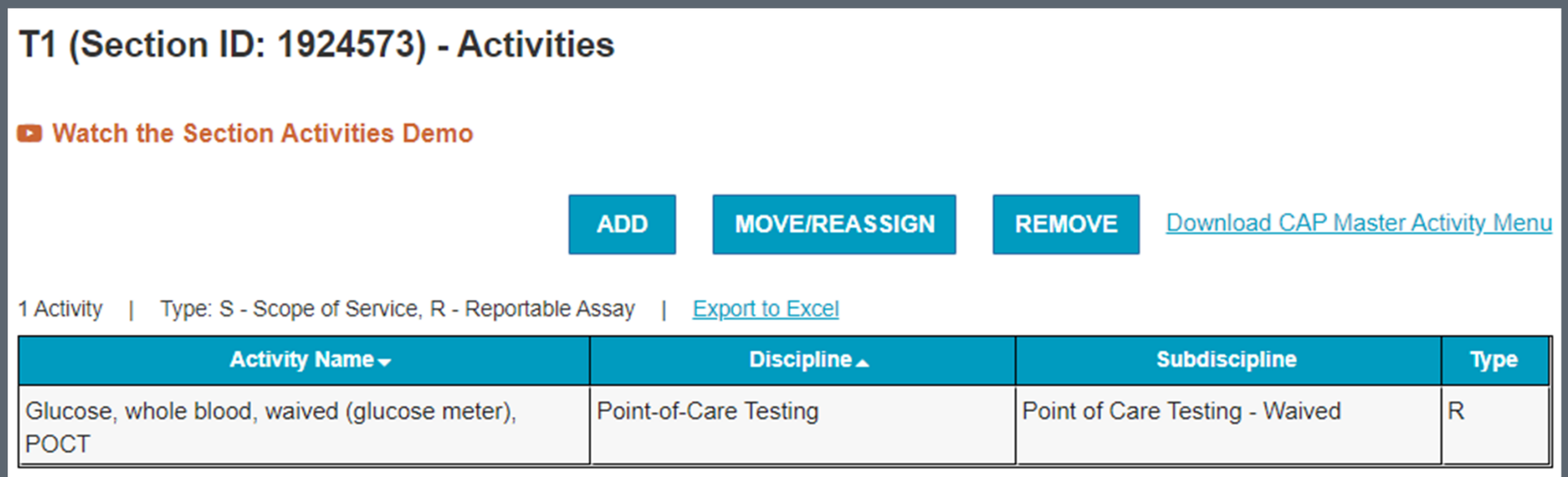
- Laboratory's current CAP Activity Menu accurately reflects the testing performed.
  - Add to new test implementation process.
  - Audit Activity Menu periodically.
  - Remove retired tests.
  - Custom checklist generated by Activity Menu selections.



# Common Deficiencies and How to Avoid Them

## Activity Menu

- New testing performed but not added
- Discontinued testing still on menu



**T1 (Section ID: 1924573) - Activities**

Watch the Section Activities Demo

ADD | MOVE/REASSIGN | REMOVE | Download CAP Master Activity Menu

1 Activity | Type: S - Scope of Service, R - Reportable Assay | Export to Excel

| Activity Name | Discipline | Subdiscipline | Type |
|---|---|---|---|
| Glucose, whole blood, waived (glucose meter), POCT | Point-of-Care Testing | Point of Care Testing - Waived | R |

# COM.10000 Policy and Procedure Manual

- Complete procedure manual is available:
  - Paper-based
  - Electronic
  - Web-based format
- Procedures must match the laboratory's practice.

# Common Deficiencies and How to Avoid Them

Procedure Manual

- Practice does not match procedure.
- Procedures are not available at the bench level.
- Staff are unaware of how to locate electronic procedures.

# COM.01700 PT and Alternative Assessment  Evaluation

- Ongoing evaluation of PT/EQA and alternative assessment results
- Corrective action taken for each unacceptable result
  - Any result or sample not meeting defined acceptability criteria) must be evaluated
    - Investigate for impact on patient sample result
    - Correction of problems appropriate to the failure are performed in a timely manner.

# PT and Alternative Assessment Evaluation

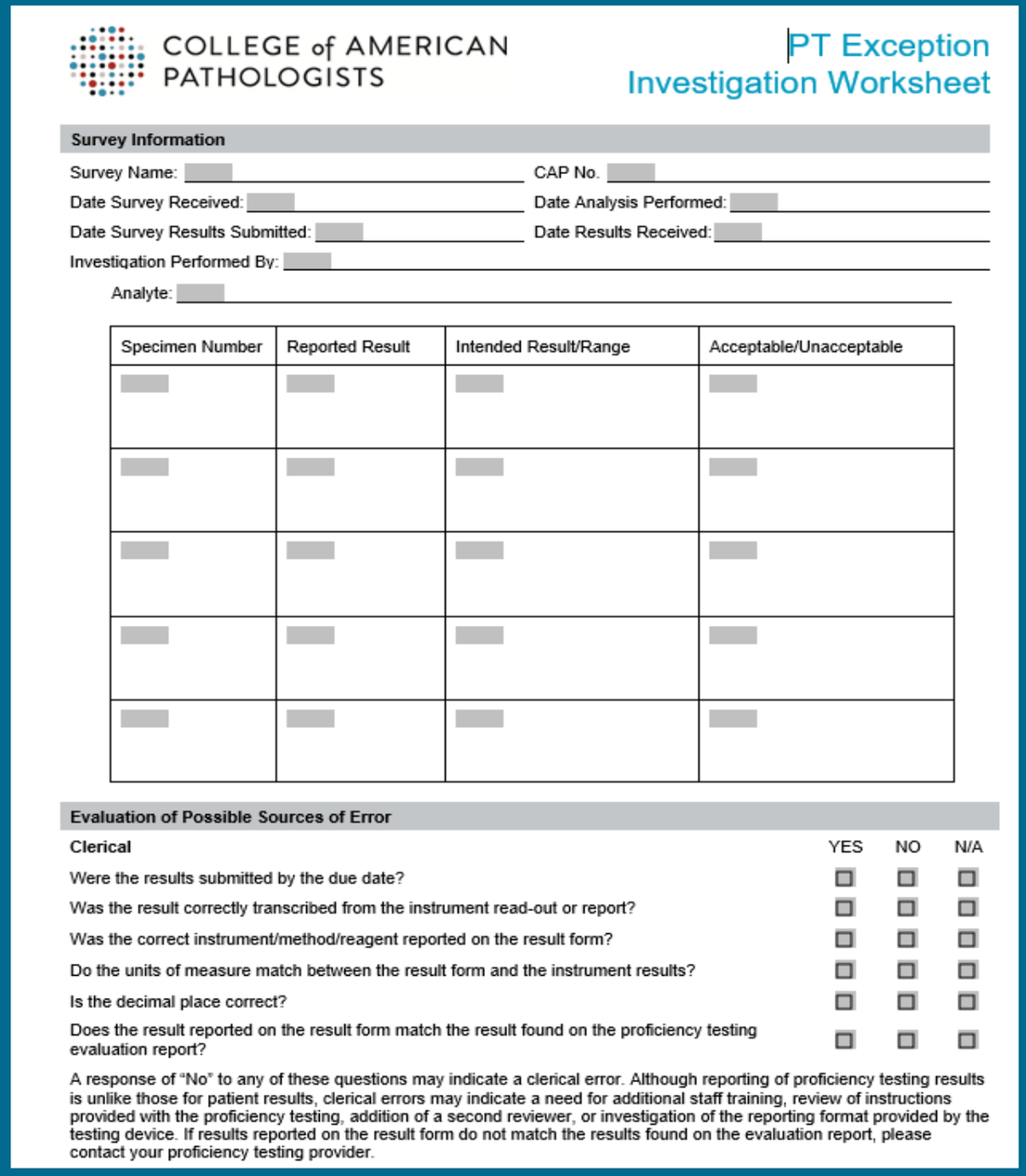
- Reviewing PT/APA results over time can identify:
  - Persistent bias, trends, and shifts
  - Change in system and/or process
  - Systematic error
  - Evidence of corrective action
  - Training opportunities
  - Staff competencies

# Common Deficiencies and How to Avoid Them

PT/APA Evaluation

- Missing corrective actions on failures
- Missing documentation of review of results with codes
- Missing documentation or evaluation of alternative assessments

# PT/EQA Exception Investigation Worksheet



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PT Exception Investigation Worksheet

**Survey Information**

Survey Name: _____ CAP No. _____

Date Survey Received: _____ Date Analysis Performed: _____

Date Survey Results Submitted: _____ Date Results Received: _____

Investigation Performed By: _____

Analyte: _____

| Specimen Number | Reported Result | Intended Result/Range | Acceptable/Unacceptable |
|---|---|---|---|
| | | | |
| | | | |
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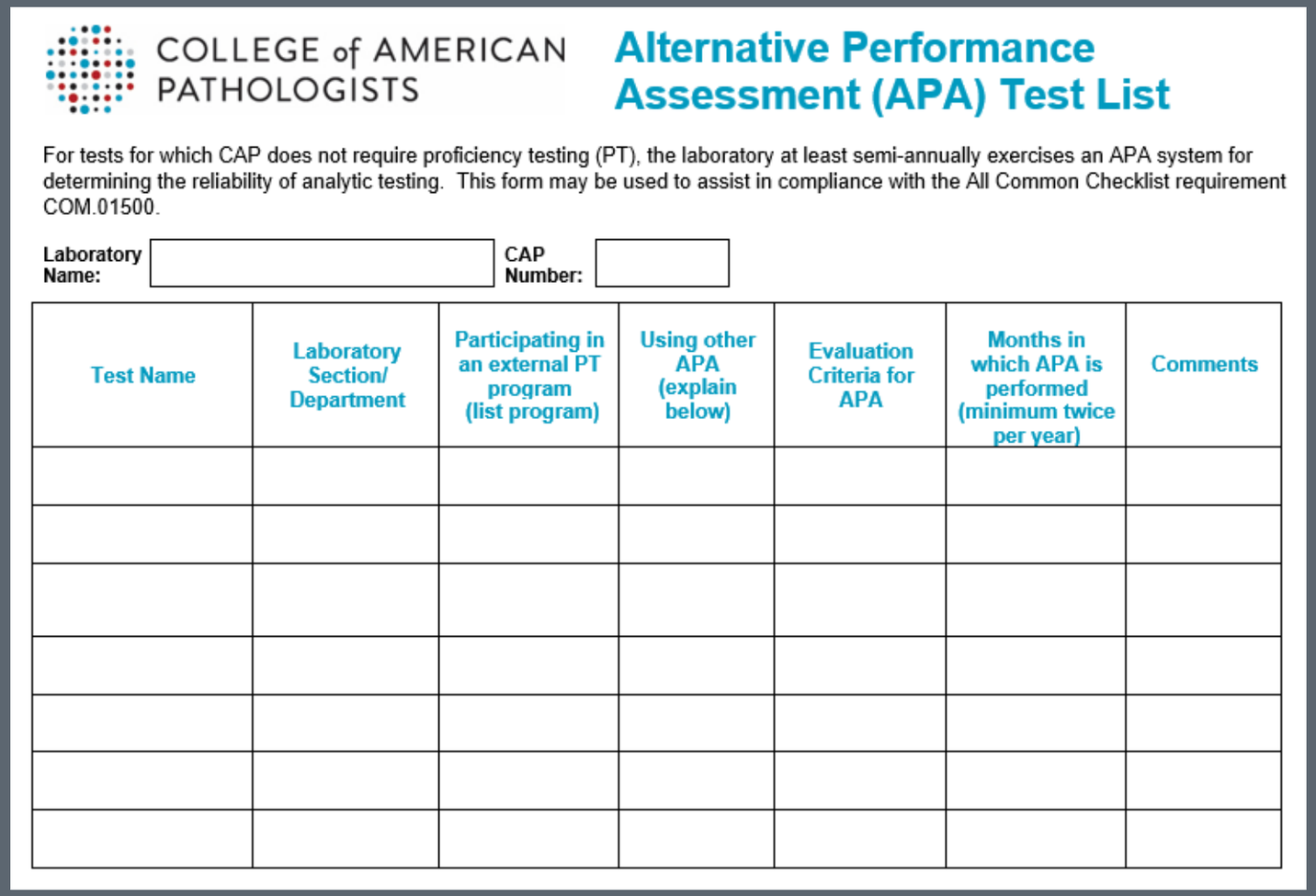
| | | | |
| | | | |

**Evaluation of Possible Sources of Error**

| Clerical | YES | NO | N/A |
|---|---|---|---|
| Were the results submitted by the due date? | ☐ | ☐ | ☐ |
| Was the result correctly transcribed from the instrument read-out or report? | ☐ | ☐ | ☐ |
| Was the correct instrument/method/reagent reported on the result form? | ☐ | ☐ | ☐ |
| Do the units of measure match between the result form and the instrument results? | ☐ | ☐ | ☐ |
| Is the decimal place correct? | ☐ | ☐ | ☐ |
| Does the result reported on the result form match the result found on the proficiency testing evaluation report? | ☐ | ☐ | ☐ |

A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition of a second reviewer, or investigation of the reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.

# Alternative Performance Assessment (APA) Test List



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## Alternative Performance Assessment (APA) Test List

For tests for which CAP does not require proficiency testing (PT), the laboratory at least semi-annually exercises an APA system for determining the reliability of analytic testing. This form may be used to assist in compliance with the All Common Checklist requirement COM.01500.

**Laboratory Name:** _____ **CAP Number:** _____

| Test Name | Laboratory Section/ Department | Participating in an external PT program (list program) | Using other APA (explain below) | Evaluation Criteria for APA | Months in which APA is performed (minimum twice per year) | Comments |
|---|---|---|---|---|---|---|
| | | | | | | |
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# COM.30600 Maintenance/ Function Checks

- Appropriate maintenance and function checks are performed
- Records retained following a defined schedule
  - All instruments and equipment
  - Written procedure
  - Schedule specified by manufacturer
  - Documentation of performance and monthly review

# Common Deficiencies and How to Avoid Them

Maintenance/Function Checks

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

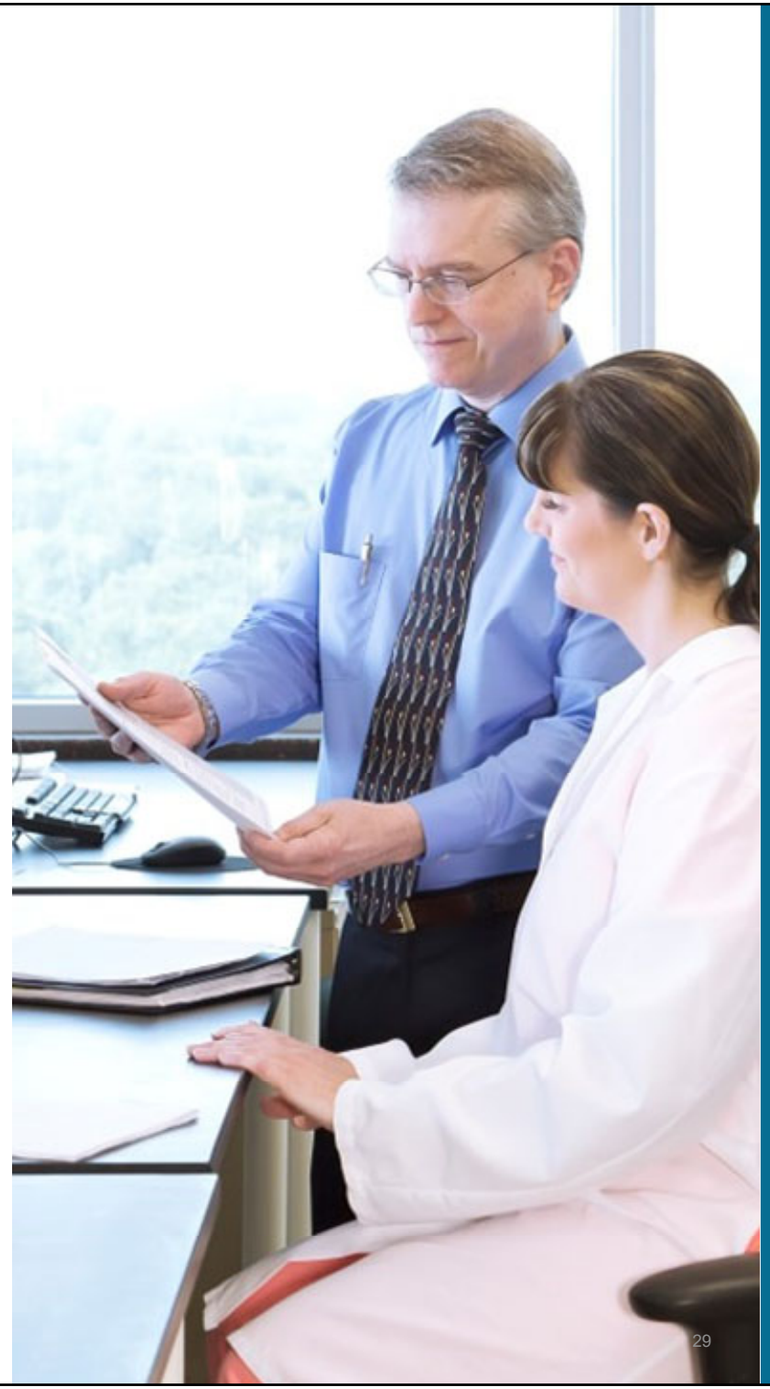
# COM.04200 Instrument/ Equipment Record Review

- Documentation must be reviewed and assessed at least monthly
  - Laboratory Director review
  - Designee review

# Common Deficiencies and How to Avoid Them

Instrument/Equipment Record Review

- Missing documentation
- Missing acceptability criteria
- Does not include all non-waived testing

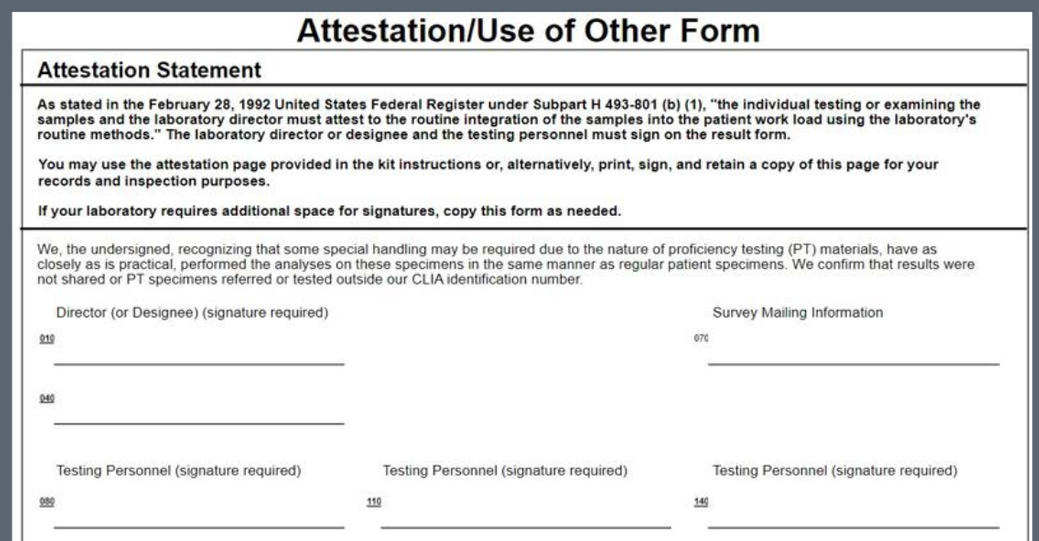


# Instrument/Equipment Review Example

| | | 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 | 02/06/22 | | | | | | | | | | | |
| | Refrigerator Temperature Logs | 02/06/22 | | | | | | | | | | | |
| | Freezer Temperature Logs | 02/06/22 | | | | | | | | | | | |
| | Eye wash Logs / Shower Logs | 02/06/22 | | | | | | | | | | | |
| Chemistry | Instrument A maintenance logs | 02/15/22 | | | | | | | | | | | |
| | Instrument A QC logs | 02/15/22 | | | | | | | | | | | |
| | Instrument A calibration logs | | | | | | | | | | | | |
| | Instrument B maintenance logs | 02/15/22 | | | | | | | | | | | |
| | Instrument B QC logs | 02/15/22 | | | | | | | | | | | |
| | Instrument B calibration logs | | | | | | | | | | | | |
| | Instrument A & B Comparisons | | | | | | | | | | | | |
| | Blood Gas maintenance logs | 02/15/22 | | | | | | | | | | | |
| | Blood Gas QC logs | 02/15/22 | | | | | | | | | | | |
| | Blood Gas calibration logs | 02/15/22 | | | | | | | | | | | |
| | PT Records | 02/27/22 | | | | | | | | | | | |

# COM.01400 PT Attestation Statement

- PT/EQA attestation statement is signed by:
  - Laboratory director or designee
  - All individuals involved in the testing process
  - Physical or secured electronic signatures must be present



**Attestation/Use of Other Form**

**Attestation Statement**

**As stated in the February 28, 1992 United States Federal Register under Subpart H 493-801 (b) (1), "the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using the laboratory's routine methods." The laboratory director or designee and the testing personnel must sign on the result form.**

**You may use the attestation page provided in the kit instructions or, alternatively, print, sign, and retain a copy of this page for your records and inspection purposes.**

**If your laboratory requires additional space for signatures, copy this form as needed.**

We, the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing (PT) materials, have as closely as is practical, performed the analyses on these specimens in the same manner as regular patient specimens. We confirm that results were not shared or PT specimens referred or tested outside our CLIA identification number.

Director (or Designee) (signature required) 010 _____ 040 _____

Survey Mailing Information 070 _____

Testing Personnel (signature required) 080 _____

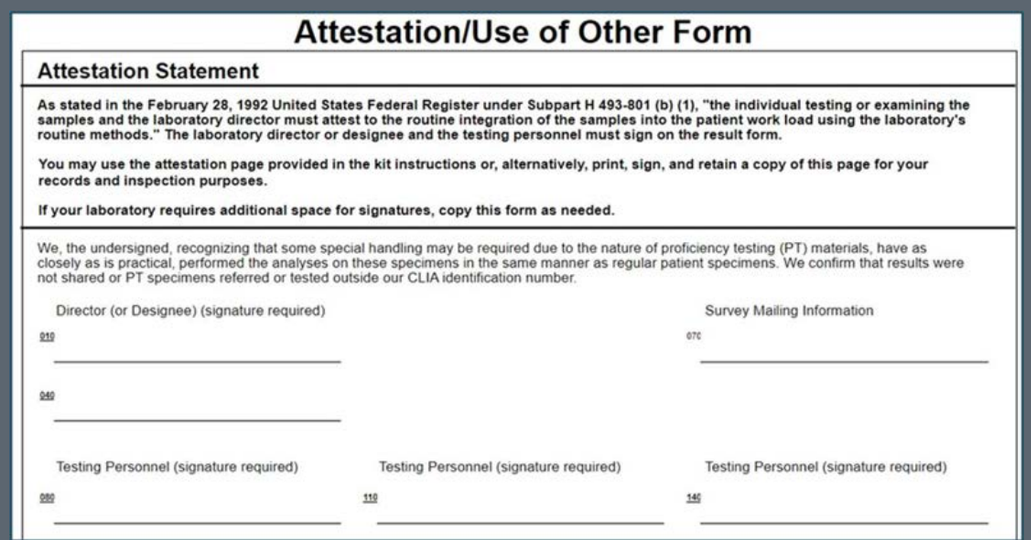
Testing Personnel (signature required) 110 _____

Testing Personnel (signature required) 140 _____

# Common Deficiencies and How to Avoid Them

PT/EQA Attestation Statement

- Missing signature
- Transfusion Medicine or other blood bank-related PT/EQA signed by unqualified personnel



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Director (or Designee) (signature required) 010

Survey Mailing Information 070

040

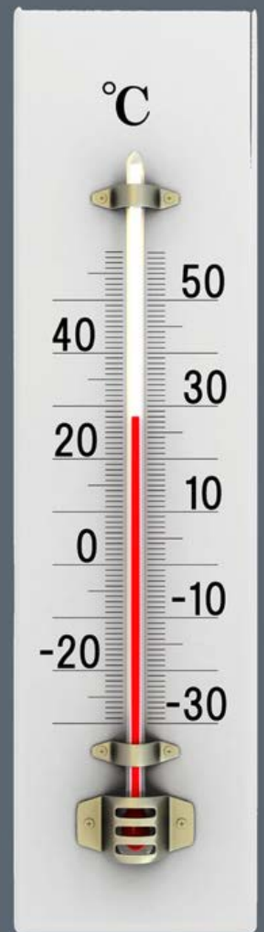
Testing Personnel (signature required) 080

Testing Personnel (signature required) 110

Testing Personnel (signature required) 140

# COM.30750 Temperature Checks

- Temperatures are checked and recorded for all temperature-dependent equipment and environments
  - Can use min/max thermometers
  - Corrective actions when temperatures are out of range



# Common Deficiencies and How to Avoid Them

Temperature Monitoring

- Missing documentation of corrective actions when temperatures are out
- Temperature ranges are not set for all items/materials with the area
- Missing documentation of weekend monitoring if closed

# Example Temperature Log

EXAMPLE: Refrigerator Temperature Log

| Refrigerator name: | Month/Year: |
|---|---|
| Responsible supervisor: | **ACCEPTABLE RANGE: 2-8C** |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| >10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Date** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** | **25** | **26** | **27** | **28** | **29** | **30** | **31** |
| Tech initials | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

**Instructions:**

1. Record current temperature by placing an X in the appropriate box.
2. Record your initials in the appropriate box.

**Corrective Action: Document Below**

1. Investigate the reason for the out of range temperature.
2. If deviation from the acceptable range persists, adjust the temperature dial, and check the temperature again in one hour.
3. **Take action if recorded *temperature* is *outside* the acceptable range. Contact supervisor and move items to another refrigerator.**

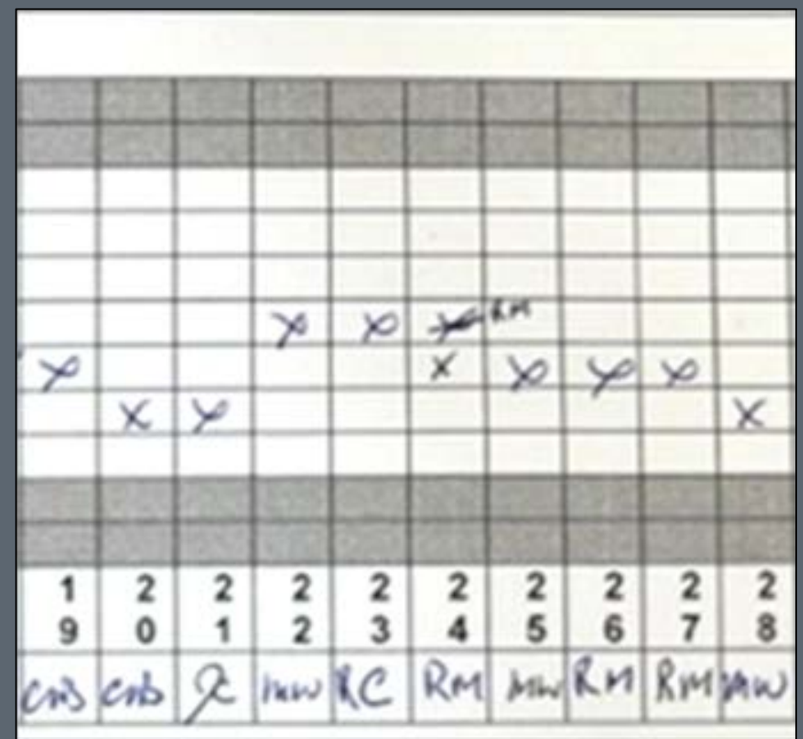
| Date/Time | Temp. | Corrective Actions Taken | Repeat Temp. | Initials |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

Document further occurrences on the back.

Reviewed by and date_____

# GEN.20450 Correction of Laboratory Records

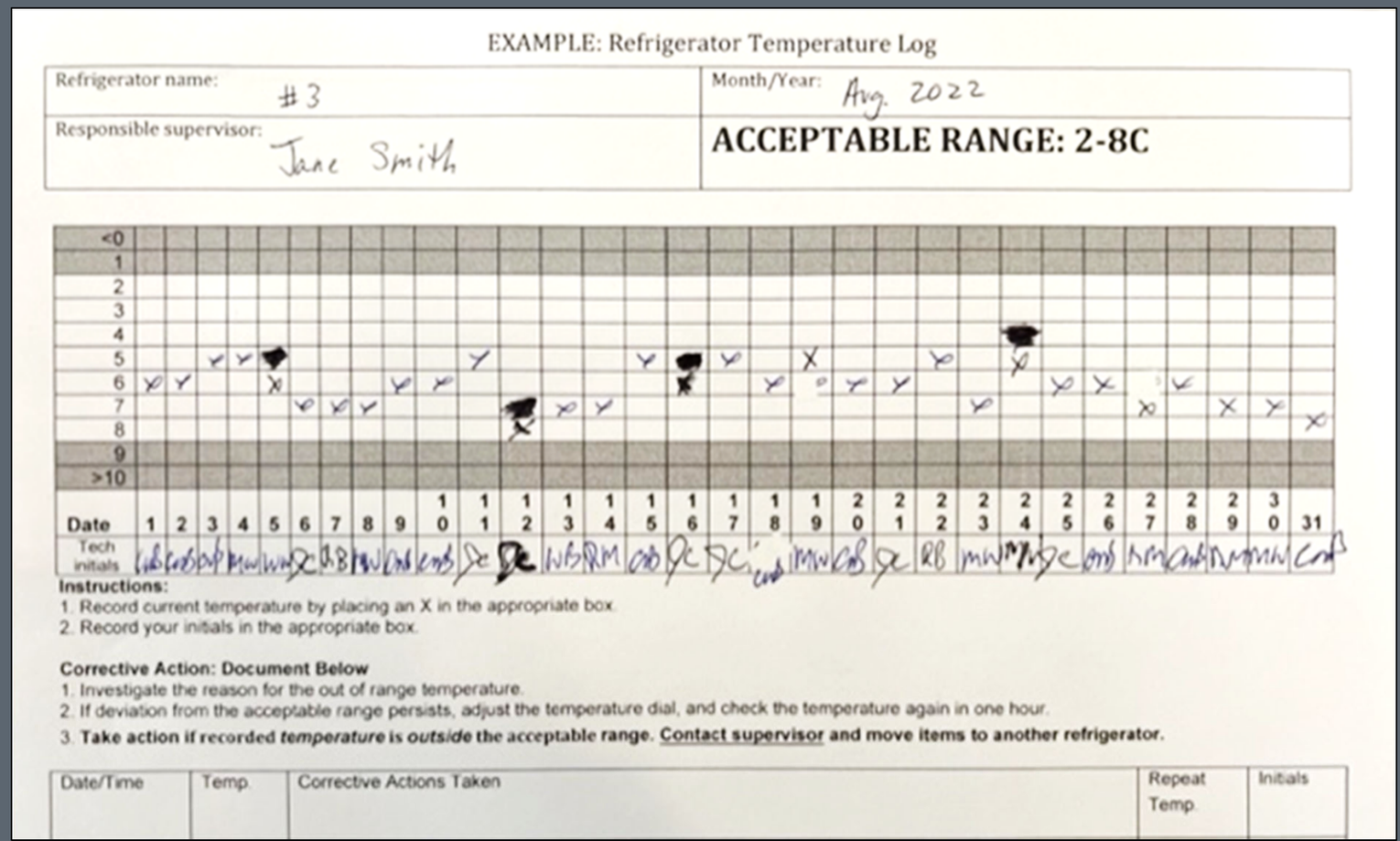
- Policy/procedure must be in place to define how corrections are made
  - Original entry must be visible or accessible
  - Corrected data, including the identity of the individual changing the record, must be accessible
  - Correction fluid and tape are **not** acceptable



# Common Deficiencies and How to Avoid Them

Correction of Laboratory Records

- White out or correction tape use
- Write overs or cross offs
- Not initialing when editing/changing documents



EXAMPLE: Refrigerator Temperature Log

| Refrigerator name: #3 | Month/Year: Aug. 2022 |
|---|---|
| Responsible supervisor: Jane Smith | **ACCEPTABLE RANGE: 2-8C** |

| | Date | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
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| >10 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Date/Time | Temp. | Corrective Actions Taken | Repeat Temp. | Initials |
|---|---|---|---|---|
| | | | | |

# CAP Resources to Keep Up-to-Date

- CAP Today
- e-Alerts
- Online Inspector Training – Team Member/Team Leader
- CAP Accreditation Resources Repository
- Educational webinars – Focus on Compliance Series

# Expanded Accreditation Resources

- Revised and expanded online resources make it easier to find the answers you seek.
- New content includes:
  - A series of Checklist Q&A's written by technical specialists
  - An informative multi-module course, *Laboratory Inspection Preparation: Getting Ready for Your First Inspection*
- Everything is fully searchable to find what you need quickly.

**CAP's e-LAB Solutions Suite is available at any time for accreditation questions.**

# 2023 Focus on Compliance Webinars

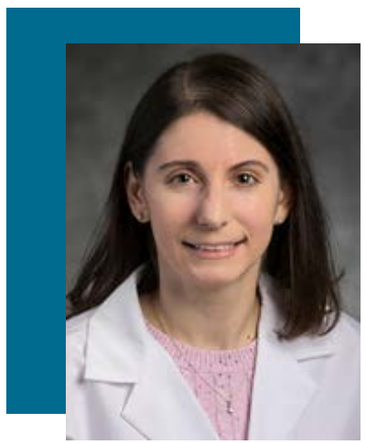
| Date/Time | Program | Presenter |
|---|---|---|
| February 15, 2023 12:00-1:00 PM CST | Labor Shortages: Strategies to Create Change | Christina S. Kong, MD, Jennifer Fralick |
| April 19, 2023 12:00-1:00 PM CST | Competency Assessment: A Building Block to High-Quality Test Results and Patient Care | Earle S. Collum, MD, FCAP, Tab Toochinda, MD, MA, FCAP |
| June 21, 2023 12:00-1:00 PM CST | Laboratory Statistical Analysis and Calculations: Helping Your Lab to Succeed | Andrew Jackson Goodwin IV, MD, FCAP |
| August 16, 2023 12:00-1:00 PM CST | Anatomic Pathology: Predictive Marker Compliance and Quality | Amer Mahmoud, MD, FCAP |
| October 18, 2023 12:00-1:00 PM CST | 2023 CAP Accreditation Checklist Updates: Changes that Matter | Stephen Sarewitz, MD, FCAP, Harris Goodman, MD, FCAP |

- Recorded and shared with registrants
- Get the details and register at learn.cap.org/lms/compliance

# Summary

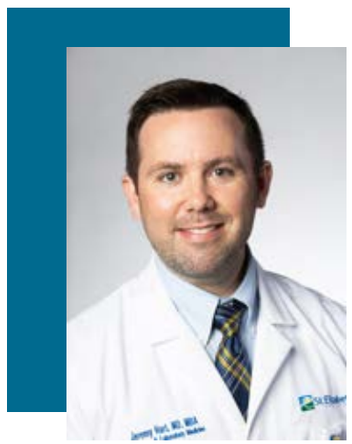
- Deficiencies can be opportunities for education and improvement.
- If it is not documented, it didn’t happen.
- Keep materials updated.
- Ensure the staff have access to education and information.

# Save The Date: 2023 International Webinars



Lisa Stempak, MD
August 8, 2023
9AM & 9PM CT

## Best Practices in Parasitology: Avoiding Common Pitfalls



Gaurav Sharma, MD & Jeremy Hart, MD, MBA
November 28, 2023
8AM & 8PM CT

## Risk Management and Safety

COLLEGE of AMERICAN PATHOLOGISTS

# Contact us!

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