COLLEGE of AMERICAN PATHOLOGISTS

CAP Commonly Cited Deficiencies and How to Avoid Them

Objectives

- Review the most cited deficiencies in 2023
- Explain how to improve laboratory processes to prevent deficiencies
- Examine CAP inspection tools and accreditation resources

CAP Top Ten Deficiencies

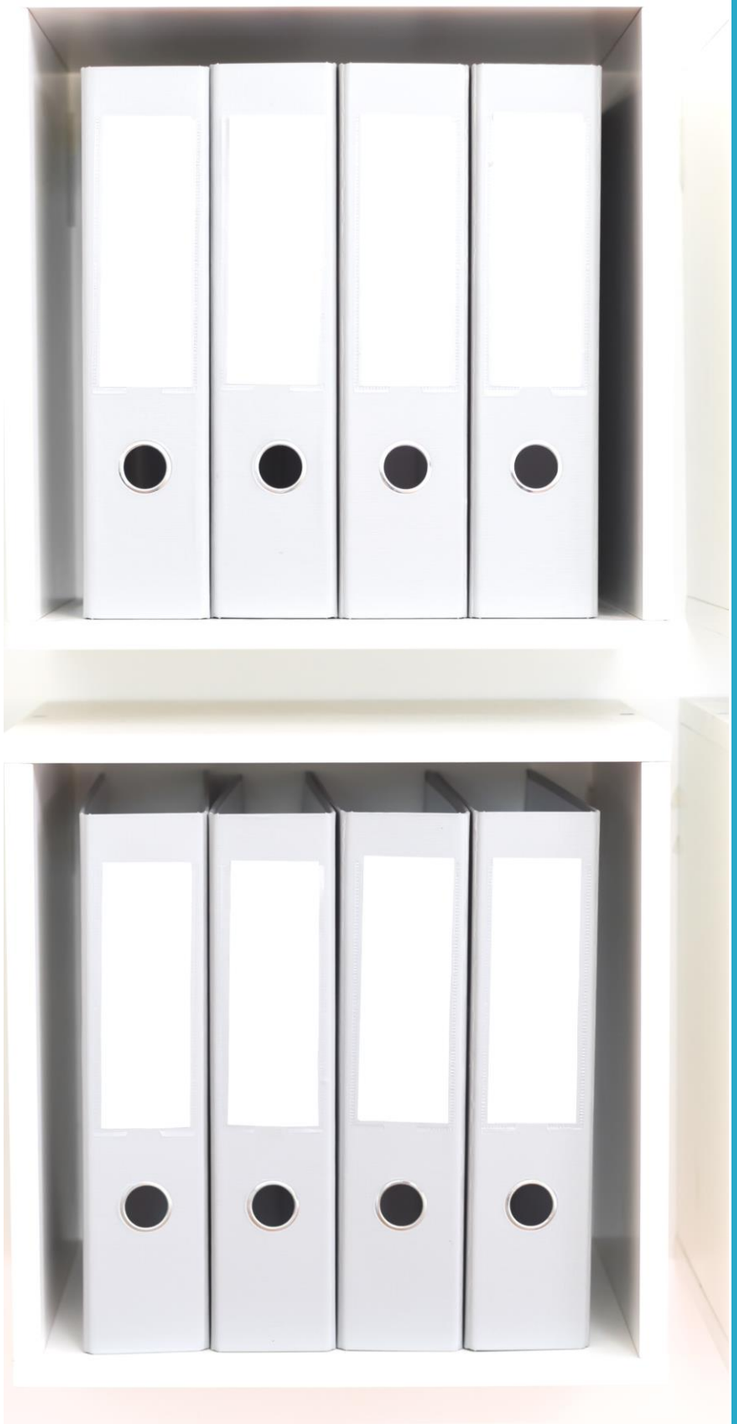
Top 10 Deficiencies in 2023

Checklist Requirement		CAP Ranking # of Time Cited
COM.10000	Policy and Procedure Manual	#1, 741
COM.01200	Activity Menu	#2, 712
COM.04250	Comparability of Instruments and Methods Nonwaived Testing	#3, 694
GEN.55500	Competency Assessment Non-waived Testing	#4, 644
COM.01700	PT and Alternative Assessment Result Evaluation	#5, 610
COM.30600	Maintenance/Function Checks	#6, 598
COM.04200	Instrument/Equipment Record Review	#7, 504
COM.01100	Ungraded PT Challenges	#8, 425
COM.30750	Temperature Checks	#9, 421
COM.01400	PT Attestation Statement	#10, 402

Policy and Procedure Manual
COM.10000

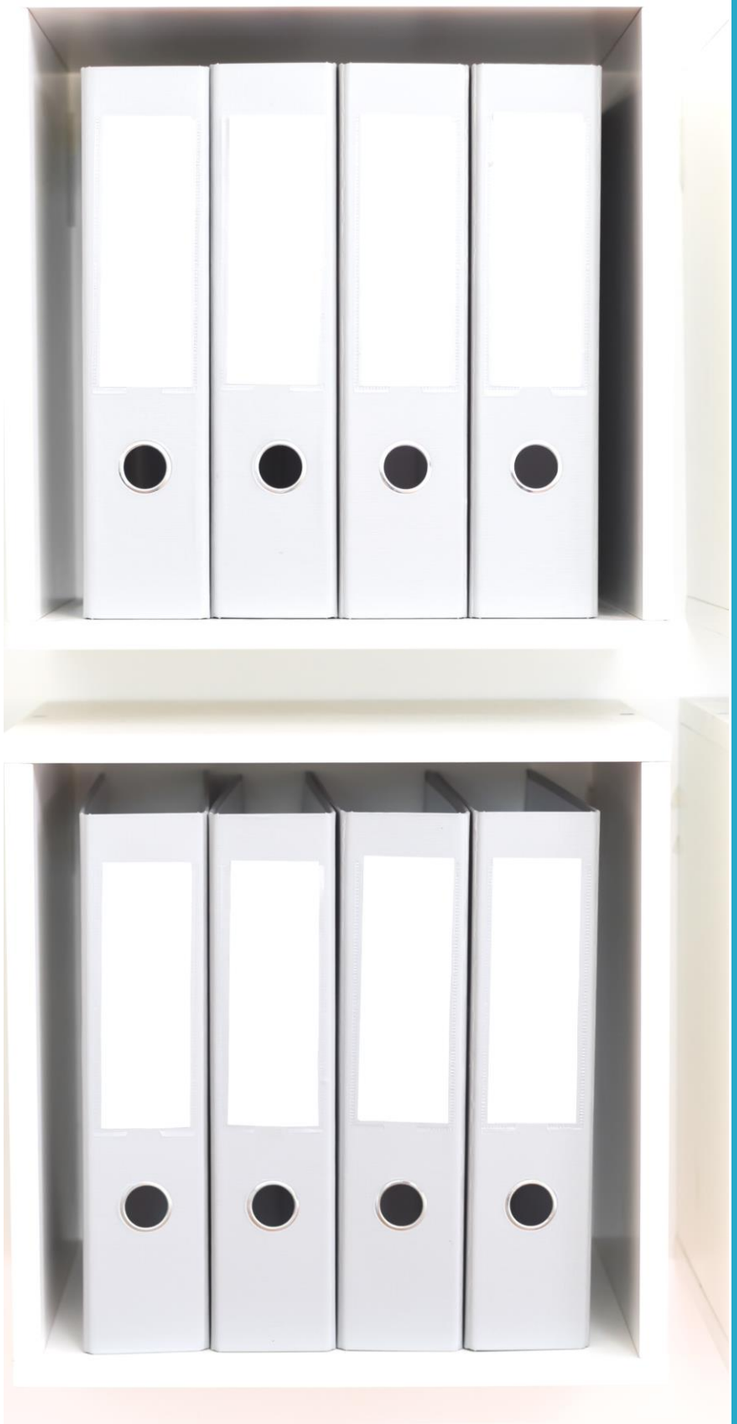
- Complete procedure manual is available:
  - Paper-based
  - Electronic
  - Web-based format

- **Procedures must match practice.**



Poll Question #1

- In your facility, what form of procedure manual do you use?
  - Paper-based
  - Electronic
  - Both



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.

Activity Menu
COM.01200

- **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.

COLLEGE of AMERICAN PATHOLOGISTS

Comparability of Instruments and Methods
COM.04250

- 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 (continued)

- 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

Competency Assessment
GEN.55500

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 (continued)

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 (continued)

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 (continued)

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**
- **Competency events are not traceable**

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

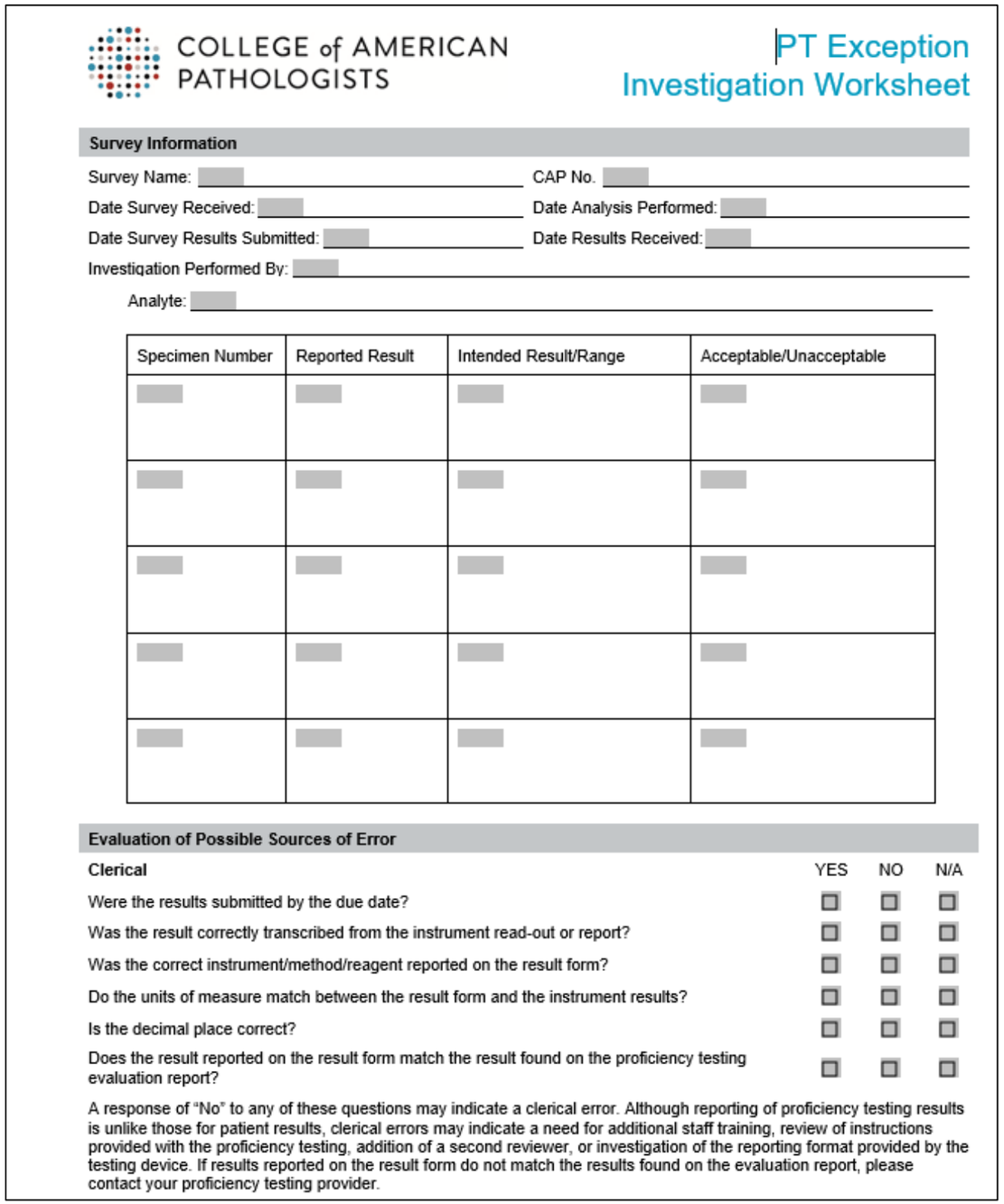
PT and Alternative Assessment Evaluation
COM.01700

- 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.

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



COLLEGE of AMERICAN PATHOLOGISTS

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

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?	☐	☐	☐

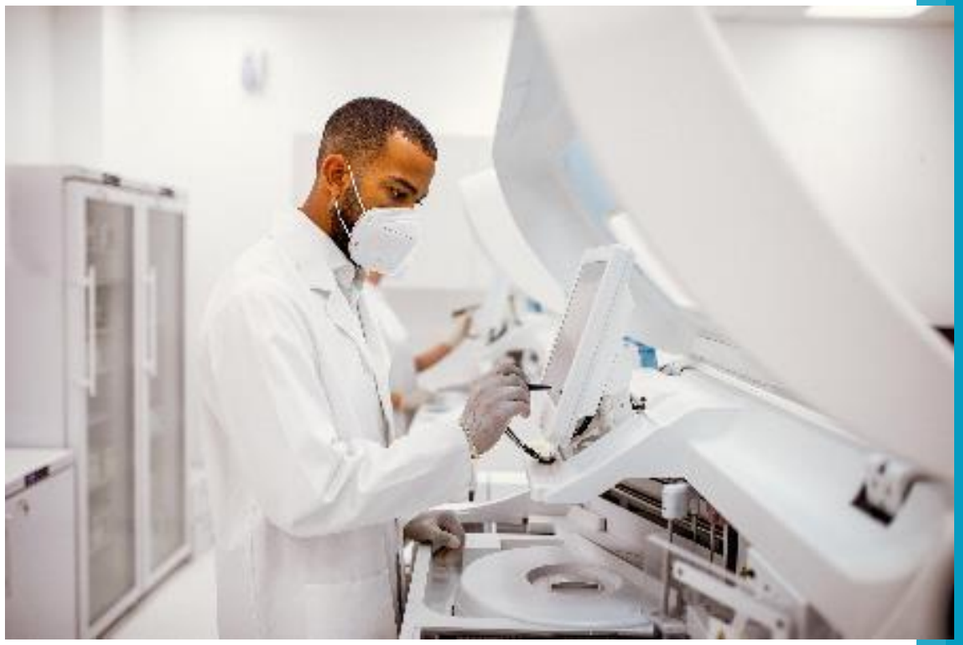
A response of "No" to any of these questions may indicate a clerical error. Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing, addition 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.

Maintenance/Function Checks
COM.30600

- 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



Instrument/Equipment Record Review
COM.04200

- 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											

Ungraded PT Challenges

COM.01100

- Laboratory director or designee assesses performance of PT challenges that are ungraded
  - Records must show ungraded PT results are evaluated for acceptable performance
    - Investigation
    - Corrective action

Common Deficiencies and How to Avoid Them – Ungraded PT Challenges

- Laboratory not defining how it assesses performance on ungraded PT challenges
- Missing signatures or notation of acceptability
- Failing to retain records of review

Temperature Checks
COM.30750

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

Poll Question #2

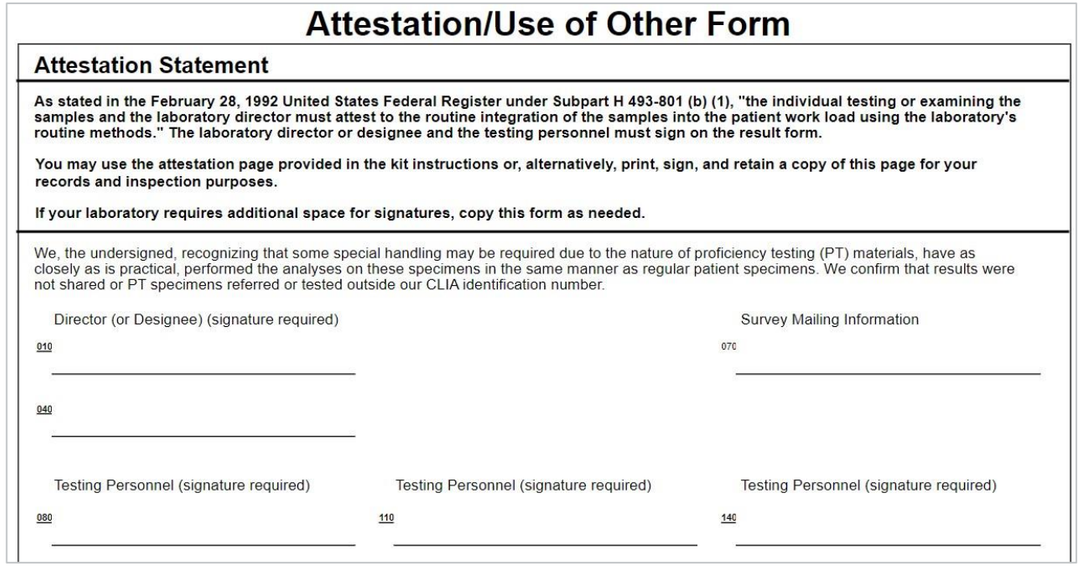
- In your facility, which temperature checks do you use?
  - Manual
  - Electronic
  - Both

Common Deficiencies and How to Avoid Them – Temperature Checks

- 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

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)

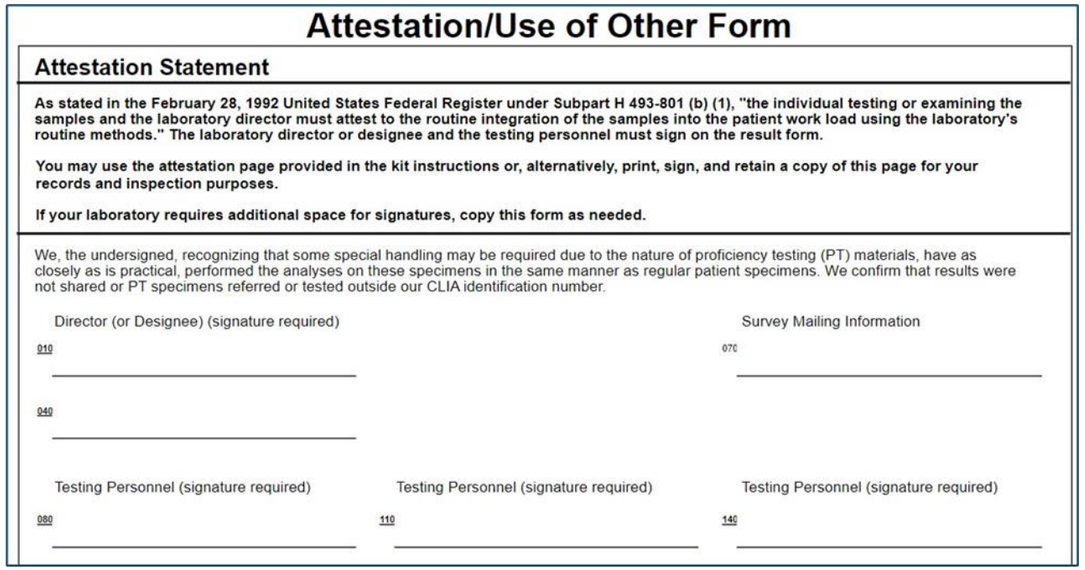
110 _____

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**



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)

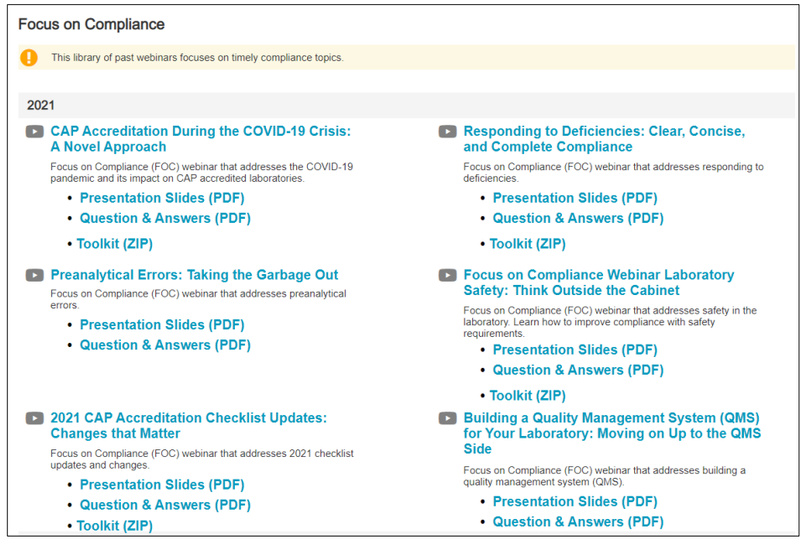
140 _____

Top 10 Deficiencies in 2023

Checklist Requirement		CAP Ranking # of Time Cited
COM.10000	Policy and Procedure Manual	#1, 741
COM.01200	Activity Menu	#2, 712
COM.04250	Comparability of Instruments and Methods Nonwaived Testing	#3, 694
GEN.55500	Competency Assessment Non-waived Testing	#4, 644
COM.01700	PT and Alternative Assessment Result Evaluation	#5, 610
COM.30600	Maintenance/Function Checks	#6, 598
COM.04200	Instrument/Equipment Record Review	#7, 504
COM.01100	Ungraded PT Challenges	#8, 425
COM.30750	Temperature Checks	#9, 421
COM.01400	PT Attestation Statement	#10, 402

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



Focus on Compliance

This library of past webinars focuses on timely compliance topics.

2021

CAP Accreditation During the COVID-19 Crisis: A Novel Approach

Focus on Compliance (FOC) webinar that addresses the COVID-19 pandemic and its impact on CAP accredited laboratories.

- Presentation Slides (PDF)
- Question & Answers (PDF)
- Toolkit (ZIP)

Preanalytical Errors: Taking the Garbage Out

Focus on Compliance (FOC) webinar that addresses preanalytical errors.

- Presentation Slides (PDF)
- Question & Answers (PDF)

2021 CAP Accreditation Checklist Updates: Changes that Matter

Focus on Compliance (FOC) webinar that addresses 2021 checklist updates and changes.

- Presentation Slides (PDF)
- Question & Answers (PDF)
- Toolkit (ZIP)

Responding to Deficiencies: Clear, Concise, and Complete Compliance

Focus on Compliance (FOC) webinar that addresses responding to deficiencies.

- Presentation Slides (PDF)
- Question & Answers (PDF)
- Toolkit (ZIP)

Focus on Compliance Webinar Laboratory Safety: Think Outside the Cabinet

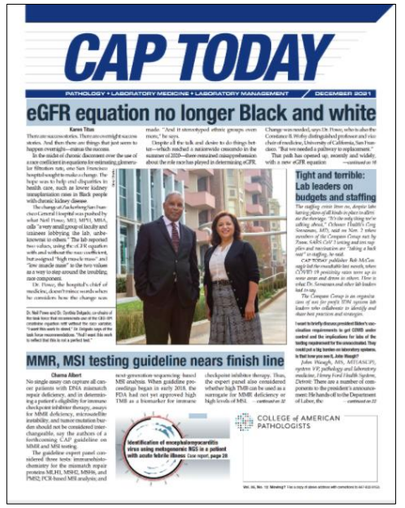
Focus on Compliance (FOC) webinar that addresses safety in the laboratory. Learn how to improve compliance with safety requirements.

- Presentation Slides (PDF)
- Question & Answers (PDF)
- Toolkit (ZIP)

Building a Quality Management System (QMS) for Your Laboratory: Moving on Up to the QMS Side

Focus on Compliance (FOC) webinar that addresses building a quality management system (QMS).

- Presentation Slides (PDF)
- Question & Answers (PDF)



CAP TODAY

PATHOLOGY • LABORATORY MEDICINE • LABORATORY MANAGEMENT DECEMBER 2021

eGFR equation no longer Black and white

Tight and terrible: Lab leaders on budgets and staffing

MMR, MSI testing guideline nears finish line

COLLEGE of AMERICAN PATHOLOGISTS

Newly Expanded Accreditation Resources:
CAP Accredited Laboratories

- **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.

Questions?

COLLEGE of AMERICAN PATHOLOGISTS