COLLEGE of AMERICAN PATHOLOGISTS

Improve Your Quality with CAP Inspector Knowledge and Deficiency Data

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- Involvement with the College of American Pathologists (CAP)
  - Member of Complaints and Investigations Committee
  - International inspector
  - 2021 Laboratory Accreditation Program Service Award (Blumberg) recipient
- US board certified in anatomic and clinical pathology
- Retired from East Carolina University Physicians
  - Brody School of Medicine, Pathology
  - Greenville, North Carolina, US

Objectives

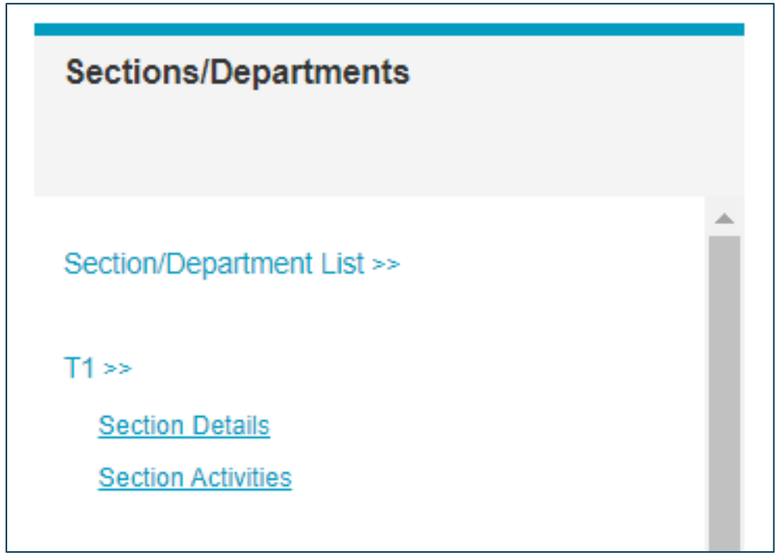
- Review the most cited deficiencies
- Learn how to improve laboratory processes to prevent deficiencies
- Discuss the latest CAP tools/resources

Top 10 Deficiencies

Checklist Requirement		CAP-wide Ranking
COM.01200	Activity Menu	1
GEN.55500	Competency Assessment	2
COM.10000	Procedure Manual	3
COM.04250	Comparability of Instruments and Methods – Nonwaived Testing	4
COM.04200	Instrument/Equipment Record Review	5
COM.30600	Maintenance/Function Checks	6
COM.01700	PT and Alternative Assessment Result Evaluation	7
COM.30750	Temperature Checks	8
COM.01400	PT Attestation Statement	9
COM.30450	New Lot/Shipment Confirmation of Acceptability	10

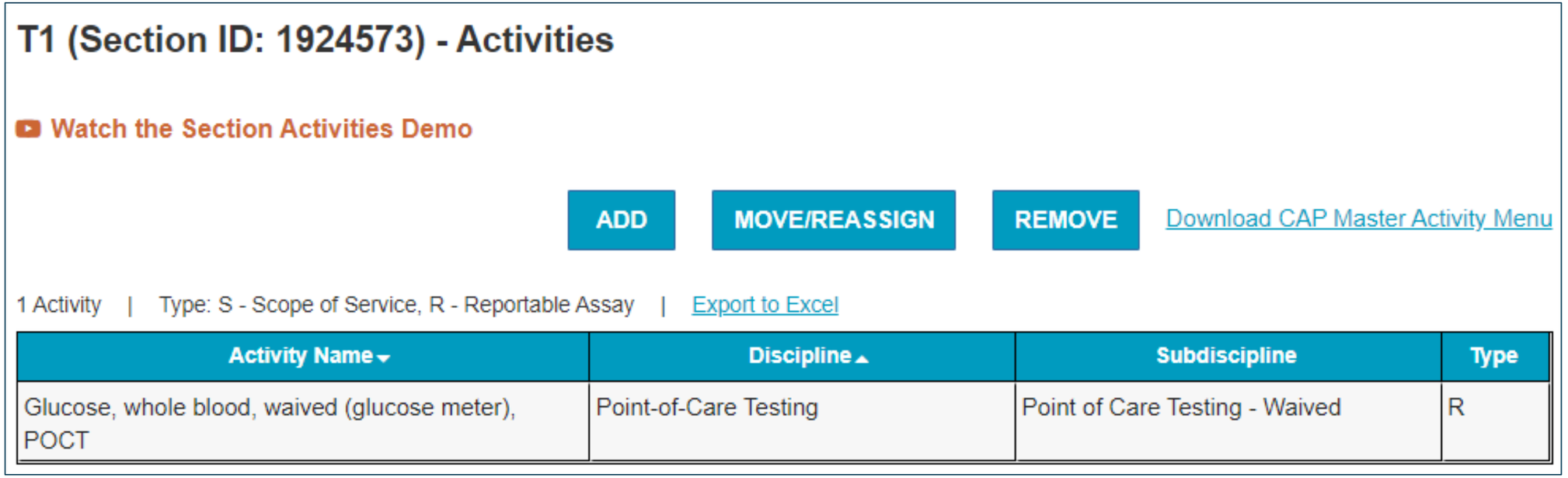
COM.01200 Activity Menu

- 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



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 (part 2)

- 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.

Image Source 1

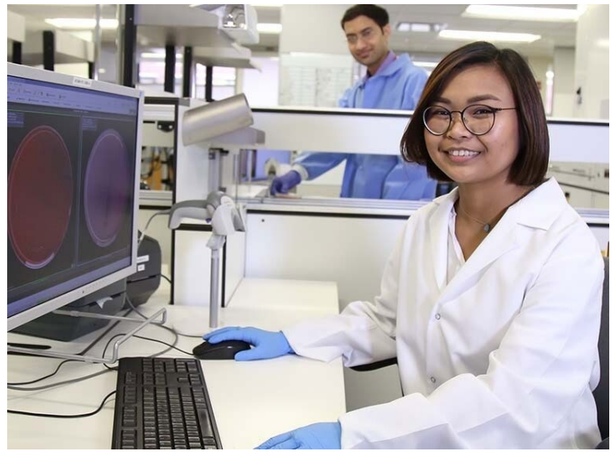
Competency Assessment (part 3)

- 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 (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.

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

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:

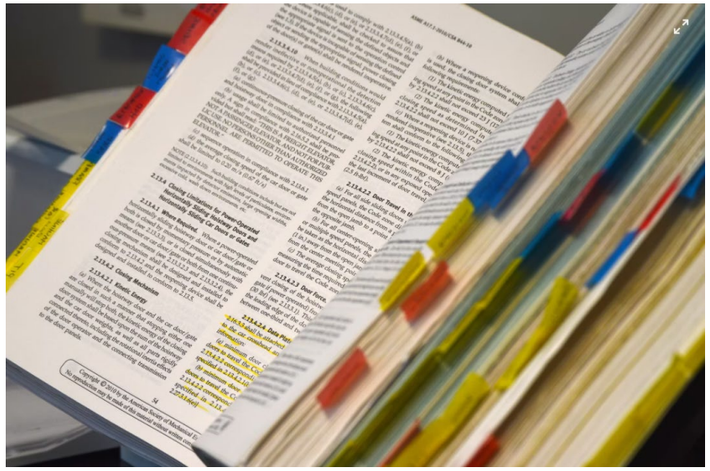
1. Direct observation of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
3. Review 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

COM.10000 Procedure Manual

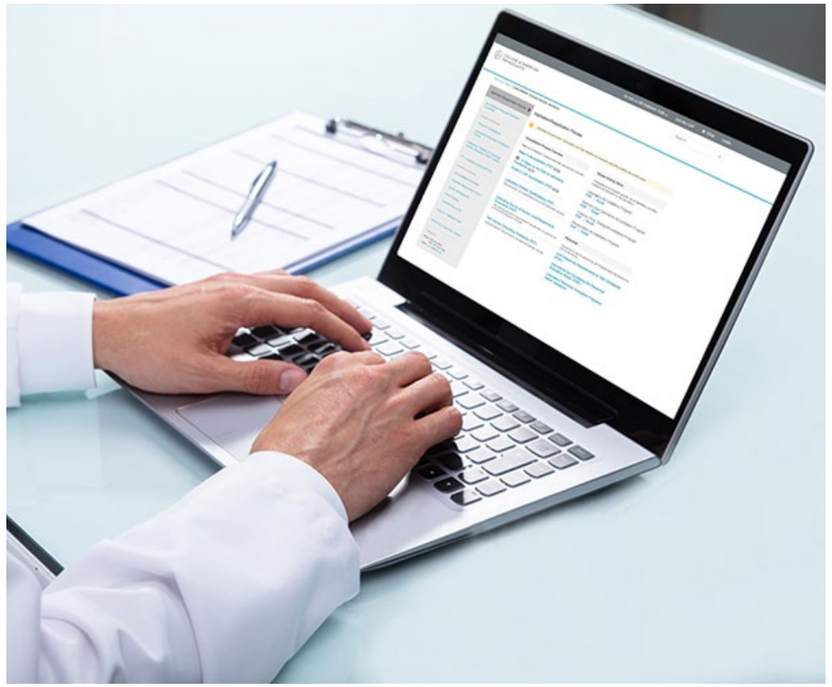
- Complete procedure manual is available:
  - Paper-based
  - Electronic
  - Web-based format

  at the workbench or in the work area.
- 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.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 (continued)

- Non-waived methods only
- Methods within a single CAP/CLIA number
- At least twice a year
- Applies to instruments/methods producing the same reportable results (eg, manual differential vs. automated differential)
- Written procedures including acceptance criteria
- Patient samples, controls

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.04200 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 – requires:
    - Signature/initials
    - Date

Common Deficiencies and How to Avoid Them – Instrument/Equipment Review

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

Instrument/Equipment Review Example

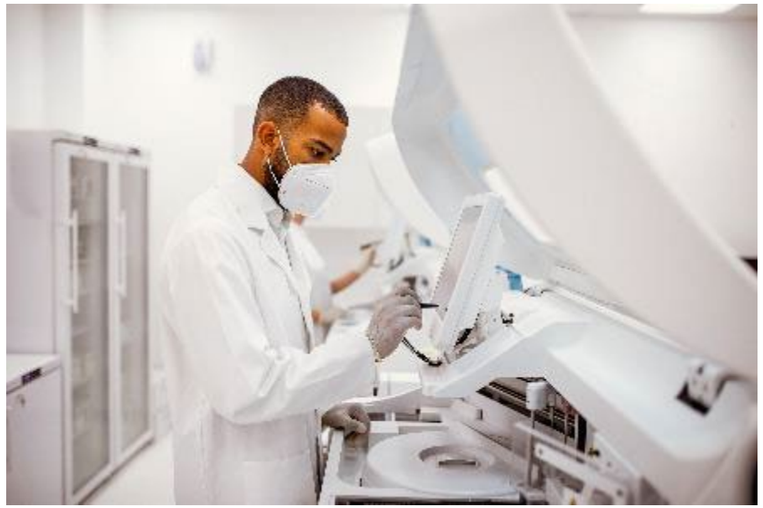
		Fill in the date the document review occurred for that month											
Department	Instrument/Testing	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
All Lab	Room Temperature Logs	02/06/22											
	Refrigerator Temperature Logs	02/06/22											
	Freezer Temperature Logs	02/06/22											
	Eye 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.30600 Maintenance/Function Checks

- Appropriate maintenance and function checks are performed.
- 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 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.01700 Proficiency Testing Evaluation

- Ongoing evaluation of proficiency testing/external quality assessment (PT/EQA) and alternative assessment results with appropriate corrective action taken for each unacceptable result.
  - Each unacceptable PT/EQA 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.

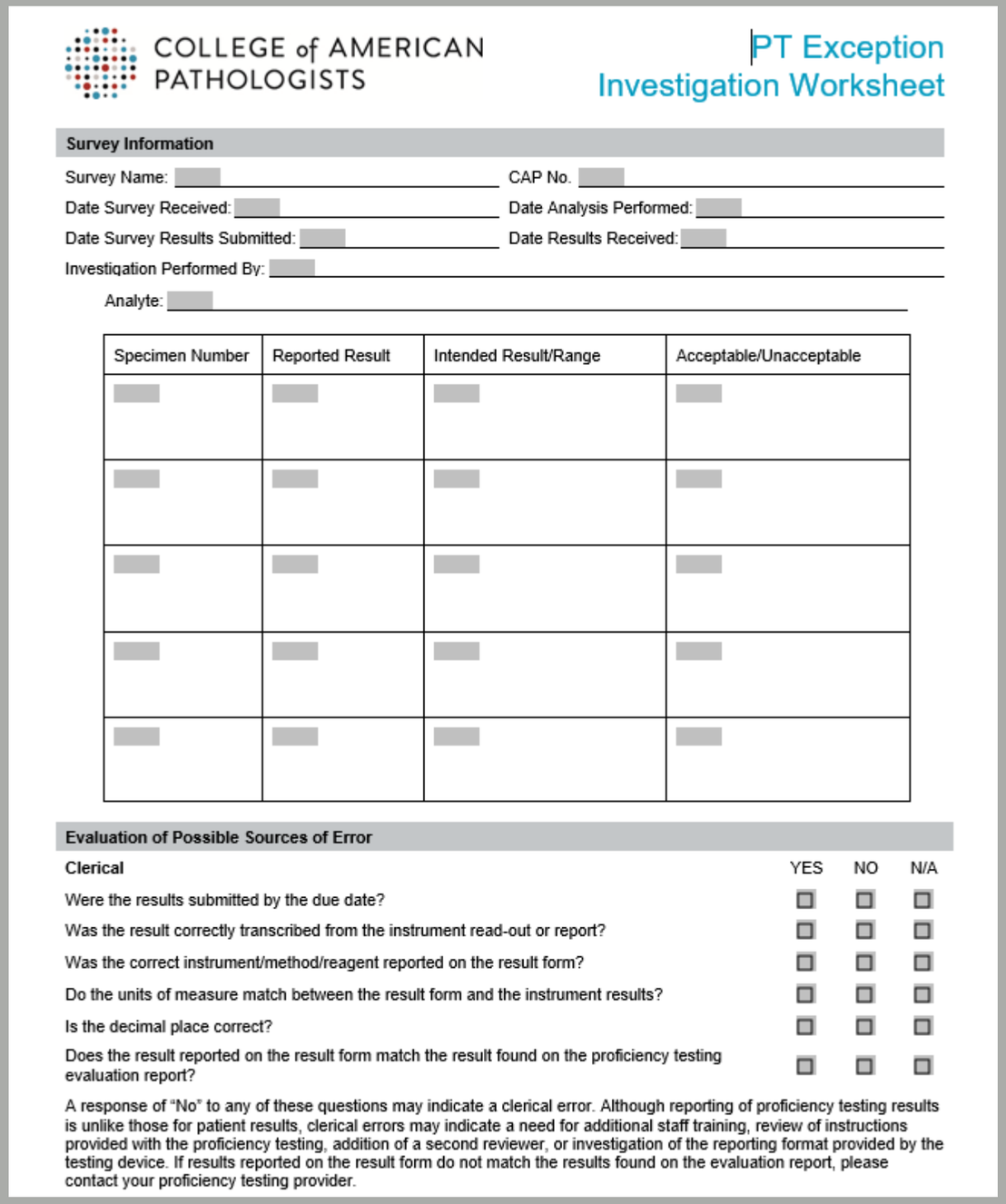
PT/EQA Evaluation

- Reviewing PT/EQA 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/EQA 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/EQA products.

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: _____

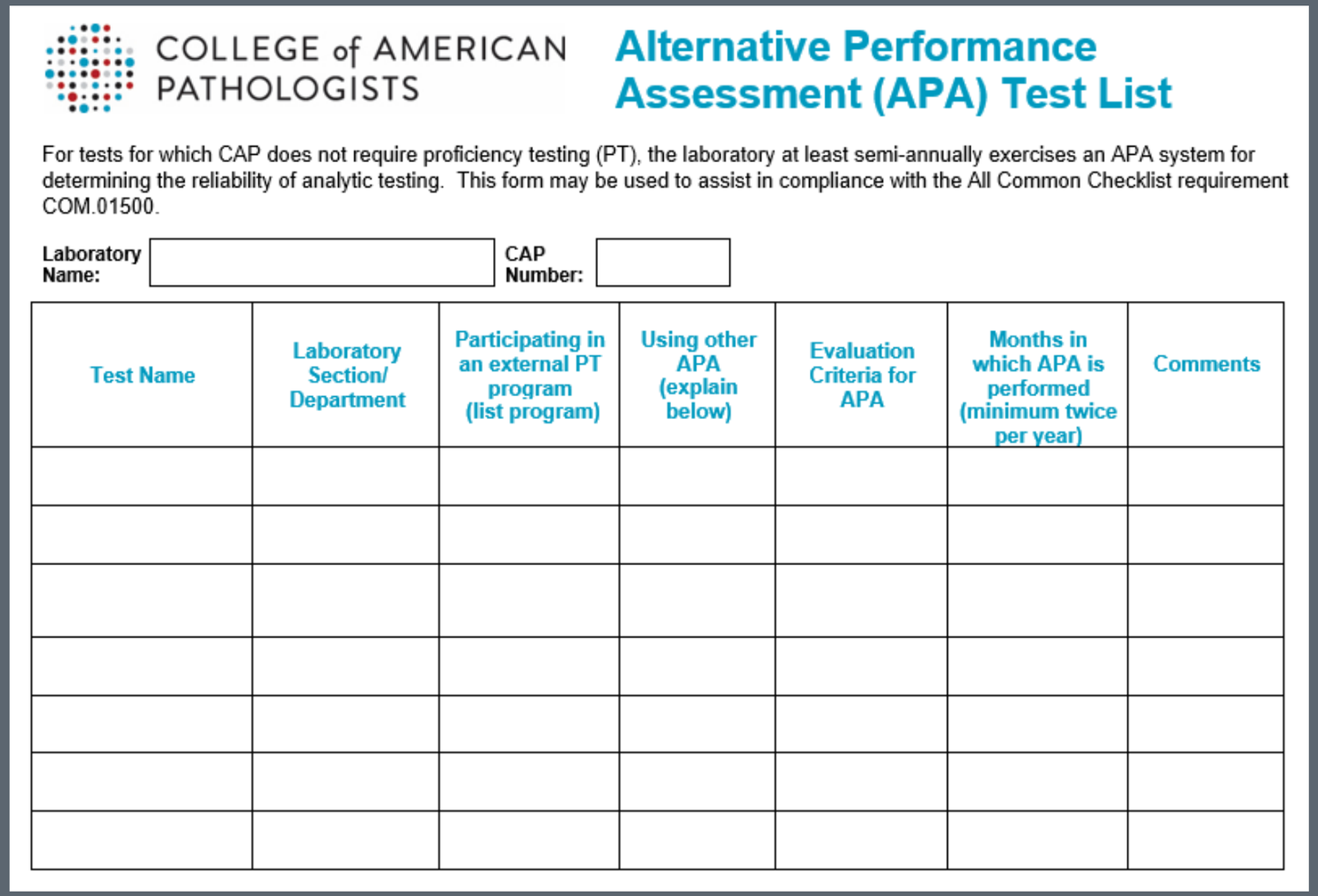
Specimen Number	Reported Result	Intended Result/Range	Acceptable/Unacceptable

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

COM.30750 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 are 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 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 in 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.

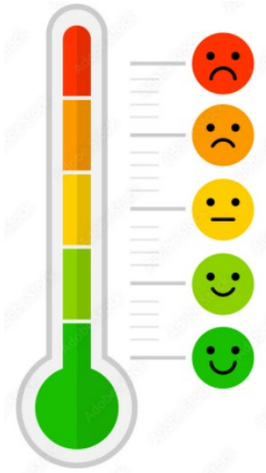


Image Source 2

Example Temperature Log

EXAMPLE: Refrigerator Temperature Log

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

<0																														
1																														
2																														
3																														
4																														
5																														
6																														
7																														
8																														
9																														
>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.

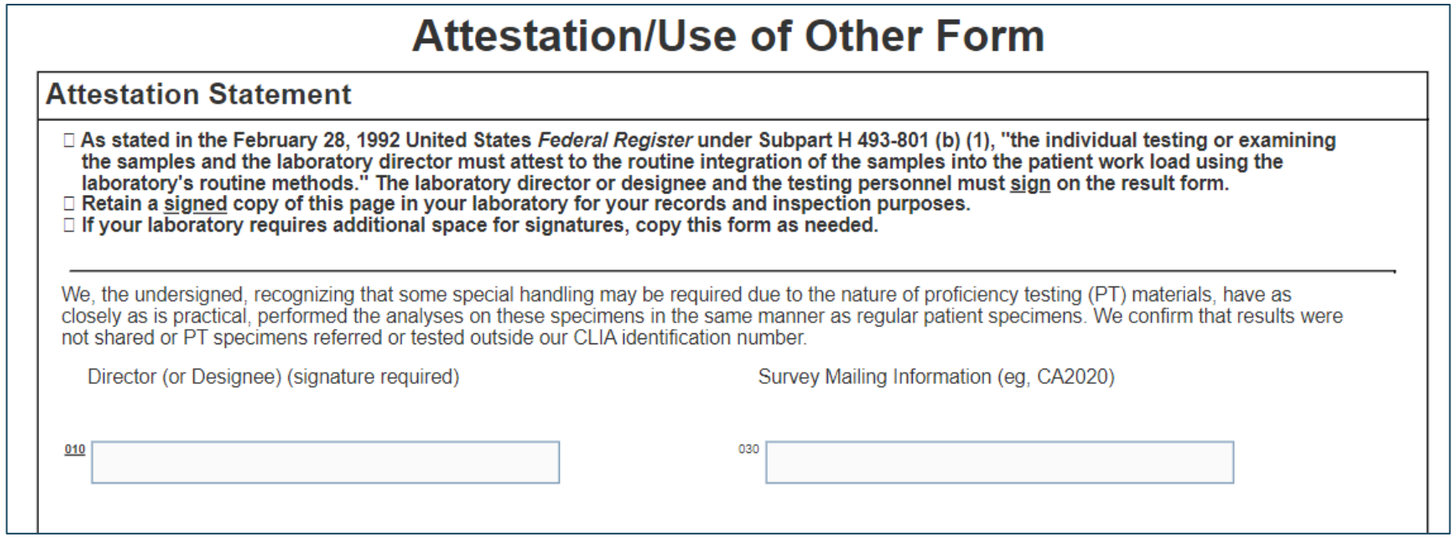
Reviewed by and date: _____

COM.01400 PT Attestation Statement

- The proficiency testing/external quality assessment (PT/EQA) 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.
    - Secure electronic signatures are acceptable if it is a secured electronic signature.

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.**
☐ **Retain a signed copy of this page in your laboratory 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

Survey Mailing Information (eg, CA2020)

030

COM.30450 New Lot/Shipment Confirmation of Acceptability

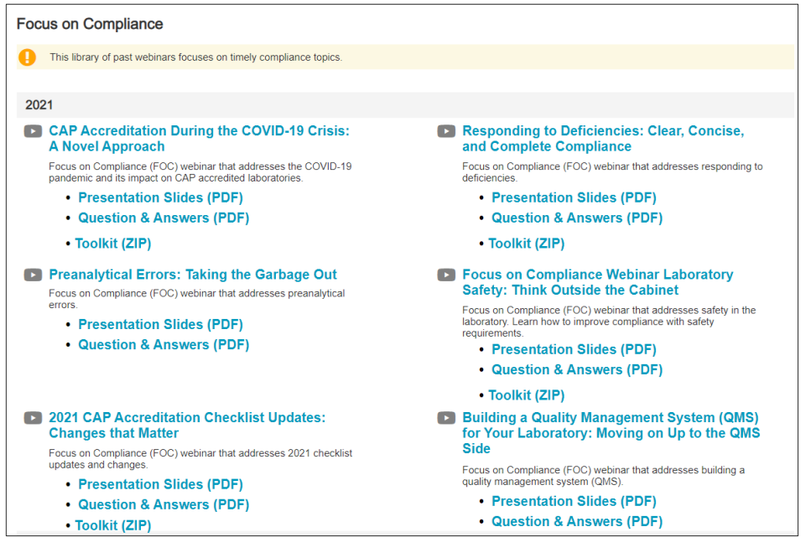
- New reagent lots and shipments are checked against previous reagent lots before being placed in service.
- Examples of suitable reference materials include:
  - Positive and negative patient samples tested on a previous lot
  - Previously tested proficiency testing materials
  - External QC materials tested on the previous lot
  - Control strains of organisms or previously identified organisms for microbiology reagents used to detect or evaluate cultured microorganisms

Common Deficiencies and How to Avoid Them – New Lot/Shipment Confirmation of Acceptability

- No records of new lot and new shipment confirmation
- No acceptability criteria defined

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

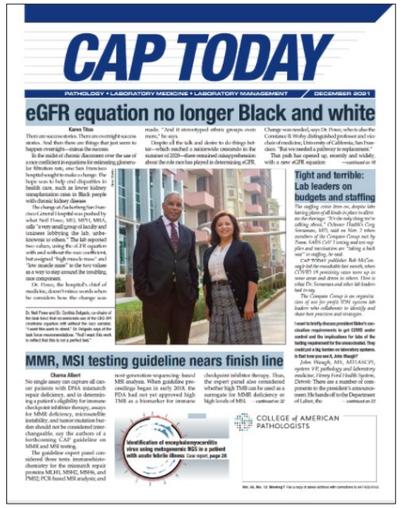
Focus on Compliance (FOC) webinar that addresses safety in the laboratory. Learn how to improve compliance with safety requirements.

- 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)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eGFR equation no longer Black and white

Tight and terrible: Lab leaders on budgets and staffing

MMR, MSI testing guideline nears finish line

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Newly 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.

2022 Focus on Compliance Webinars

Date	Topic	Presenters	Objectives
June 15	Laboratory Collaboration: Communicating with Outside Departments to Get Results	Andrew Jackson Goodwin IV, MD, FCA John McConnell, BA, MA	• Recognize laboratory needs that will involve outside departments (eg, information technology/systems) • Identify unique laboratory operational and regulatory functions that present communication challenges • Describe best practices for collaborating with outside departments to drive results
August 17	Risk Management: A Tool for Quality Improvement and Business Growth	Jeremy Hart, MD, FCAP	• Describe how to identify risks • Explore opportunities to mitigate risk • Use CAP tools to implement a risk management plan • Identify appropriate monitors to evaluate effectiveness of the risk management plan
October 19	2022 CAP Accreditation Checklist Updates: Changes that Matter	Harris Goodman, MD, FCAP Stephen Sarewitz, MD, FCAP	• Describe key changes and the rationale for the changes in the 2022 version of the CAP Accreditation Program requirements • Use CAP resources to identify changes • Implement any necessary changes to ensure compliance with new accreditation requirements
November 16	Update on CAP Accreditation Programs: How it Started, How it's Going	Richard M. Scanlan, MD, FCAP	• Describe CAP Accreditation updates since the pandemic • Explore benefits and challenges to Accreditation program changes • List best practices to maintain compliance in changing times

- 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.

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Thank You!

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Image Sources

1. https://www.villanovau.com/resources/project-management/pmp-exam-preparation-tips/
2. https://stock.adobe.com/search/images?k=thermometer+emoji&asset_id=439915332