COLLEGE of AMERICAN PATHOLOGISTS

Unannounced Inspections & Inspection Day Tips

Ready or Not…..

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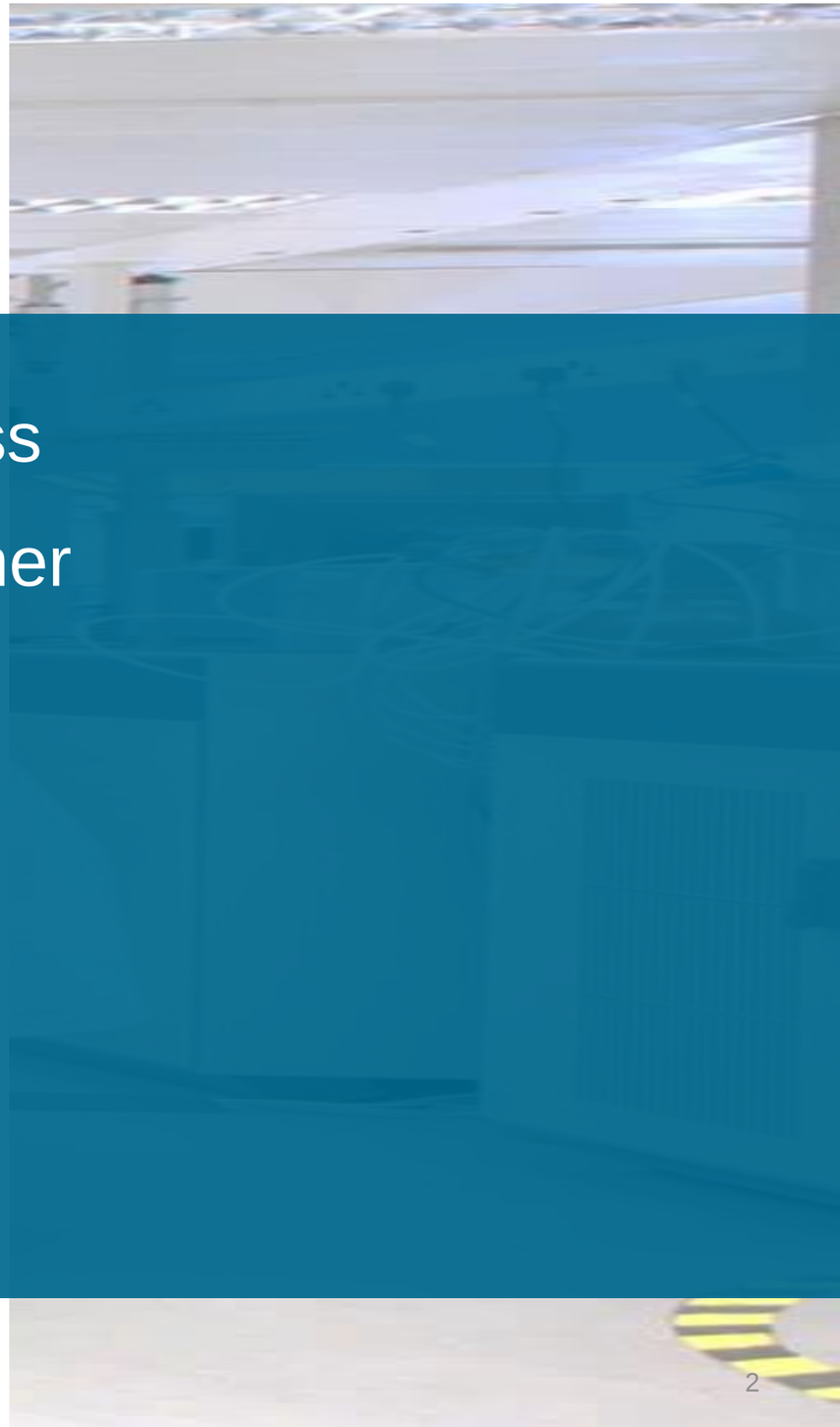
Objectives



- Explain 14 day versus 1 hour notification process
- Prepare for the day of Inspection – Get it Together
- Identify most commonly cited deficiencies
- How to respond to deficiency responses
- Explain accreditation resources

Ready or NOT

Day of Inspection

Get It Together

Departments to notify of the inspection

- Education personnel for point of care and transfusion medicine
- Human Resources/Employee Health
- Respiratory Therapy
- Biomedical
- Laboratory Information Systems

Introductions

- Meeting room/space for inspection team
- Introductory meeting with staff
- Brief laboratory tour

Inspection team needs

- Contact information for key personnel
- Telephone and computer access
- Office supplies (stickies, pens, pads, etc.)
- Badge access/escort

Last Minute Items

- Current activity menu
- Current employee roster
- Backup for supervisors

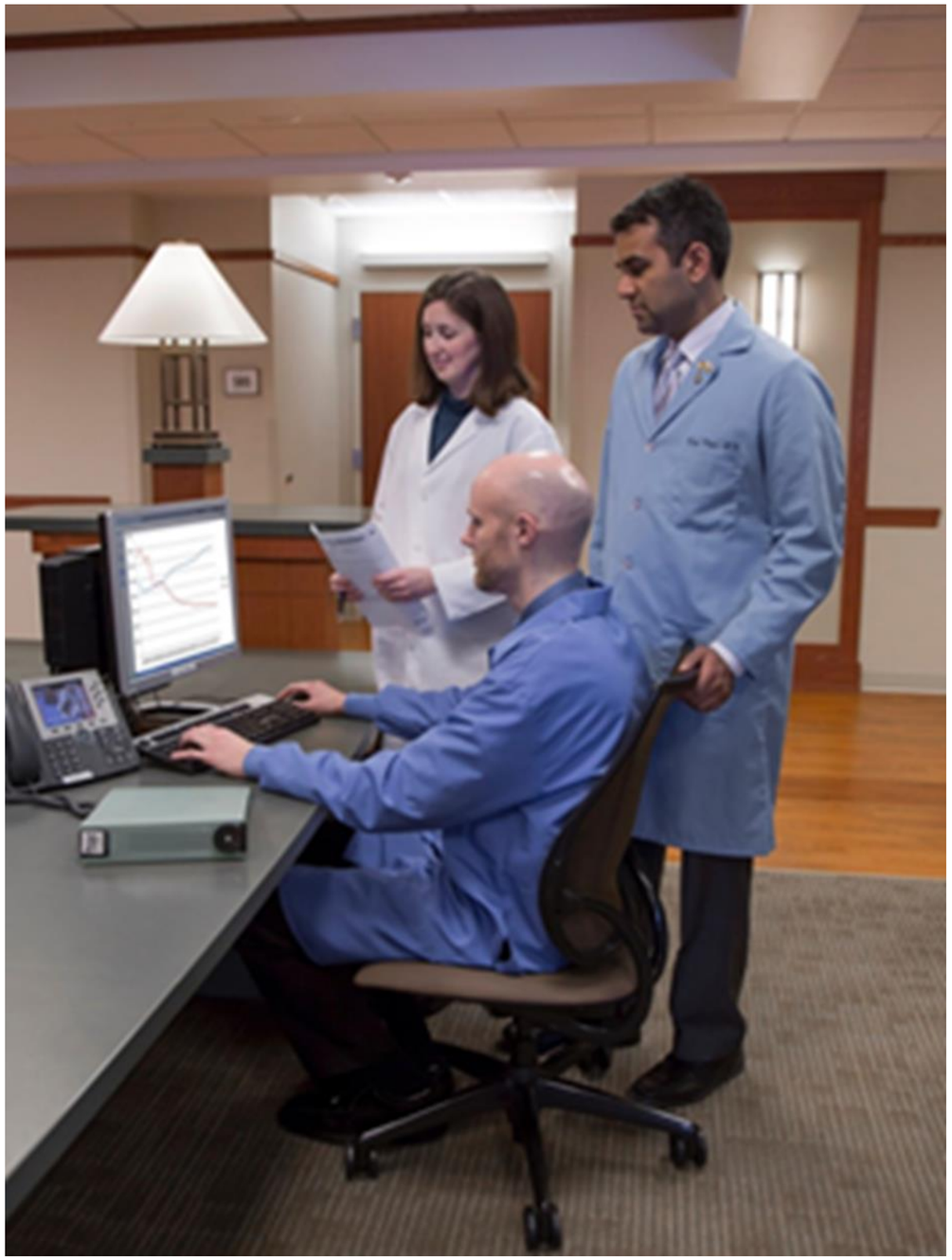
Documents? What Documents??

Documents include:

- Policies & Procedures
  - Every instrument
  - Every method
  - Every process
  - Approval by Medical Director
  - Review by staff
  - Biennial Review
  - Downtime procedures

Quality Management Plan

- List of Quality Indicators
- Quality Dashboard
- Root Cause Analysis
- Annual evaluation
- IQCP’s & biennial evaluations



Safety Plan

- Chemical Hygiene Plan
  - Chemical Inventory
    - Carcinogens / Acute & Reproductive Toxins
    - Spill Kits & posted instructions
    - Formaldehyde / Xylene Monitoring
    - Biological Safety Cabinets
  - Eyewash Activations
  - Safety Inspections (Medical Director Review)
  - Fire Safety Training

Personnel Files

- Current personnel roster
- Personnel files
- Initial training/competency assessments

Personnel Files

- Diploma/Transcript/PSV/Licensure
- Job Descriptions
- Training / Competency Records
- Delegation Documents
- Performance assessments of delegated duties

Proficiency Testing

- Activity Menu
- Attestation Pages
  - Signed by all testing personnel
  - Signed by Medical Director
- Raw Data / Instrument Printout
- Final Report
  - Reviewed by Medical Director or designee
  - Evaluation of Unacceptable Results
  - Evaluation of Ungraded Results
    - **Educational Challenges, Lack of Consensus, etc.**

Instrument / Method Validations

- Analytical Accuracy
- Analytical Precision
- Reportable Range
- All validations since the last inspection
- Summary Statement

  "I have reviewed the verification (or validation) data for the performance specifications listed below for the (insert instrument/test name), and the performance of the method is considered acceptable for patient testing."

Quality Control Records

- Per instrument/method
- Daily / Weekly / Monthly
- Supervisor’s Monthly Review
- Corrective Action for outliers

Maintenance & Function Checks

- Every Instrument
- Centrifuges
- Microscopes
- Pipette Calibrations
- Thermometers
- Temperatures
  - Remote Monitoring
  - Daily and/or Min/Max Thermometers

More documents

- Sample laboratory reports
- Other documents as requested

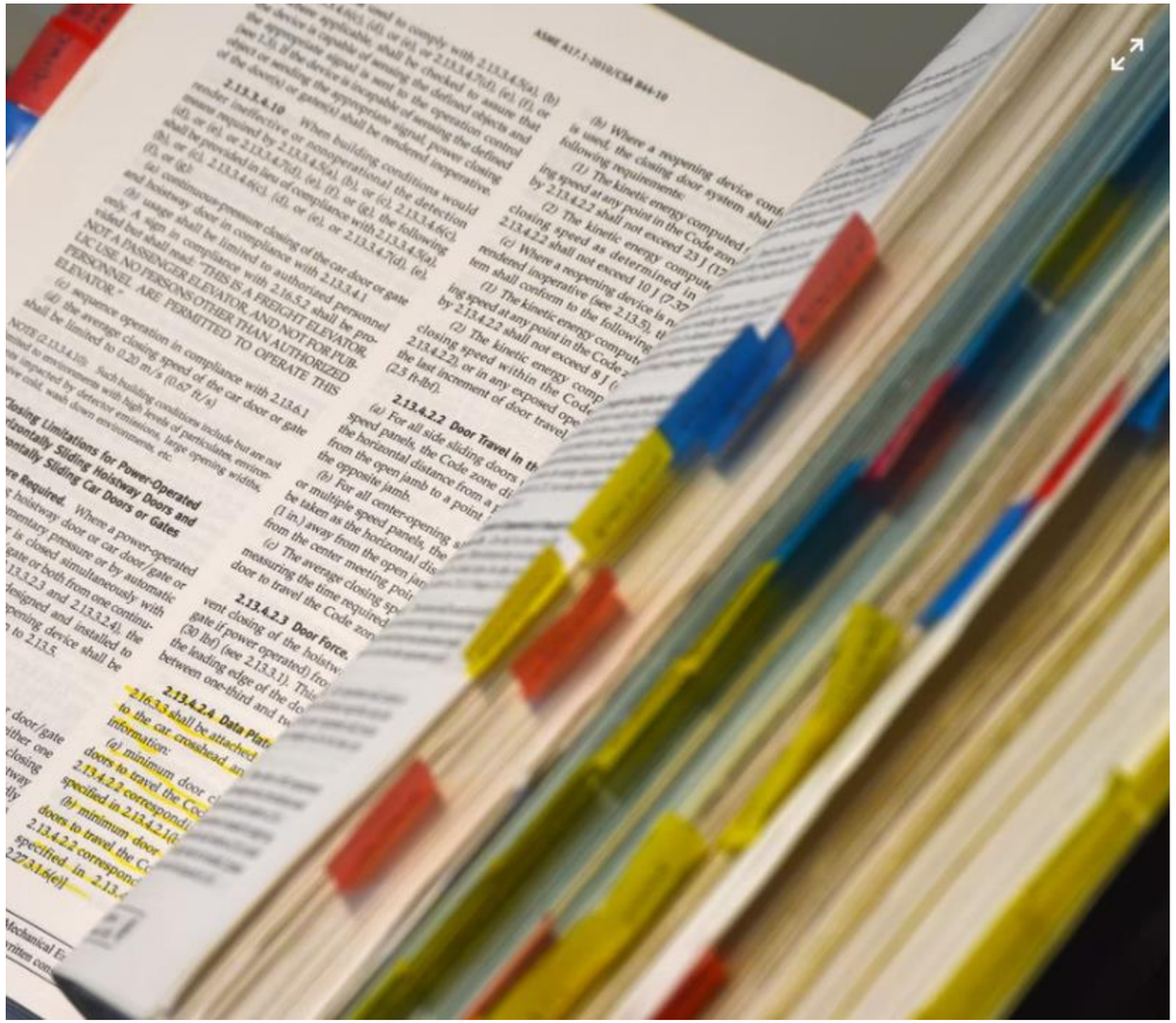
Laboratory Information System

- LIS Records
  - Director’s Biennial Review of Report
  - Downtime Reports
  - Reference Intervals
  - Critical Results with read-back
  - Interface Verifications
    - Prior to implementation of an interface
    - Whenever any change is made to an existing interface that could affect the accuracy of transmission of patient results

“You’re going to cite me for what?????”

Strategies to Prevent Deficiencies

- Stay abreast of checklist changes.
- Conduct a thorough interim self-inspection…and correct any deficiencies.
- Focus on areas of the lab that are growing or changing.
- Make it easy for inspectors to establish compliance with checklist items.



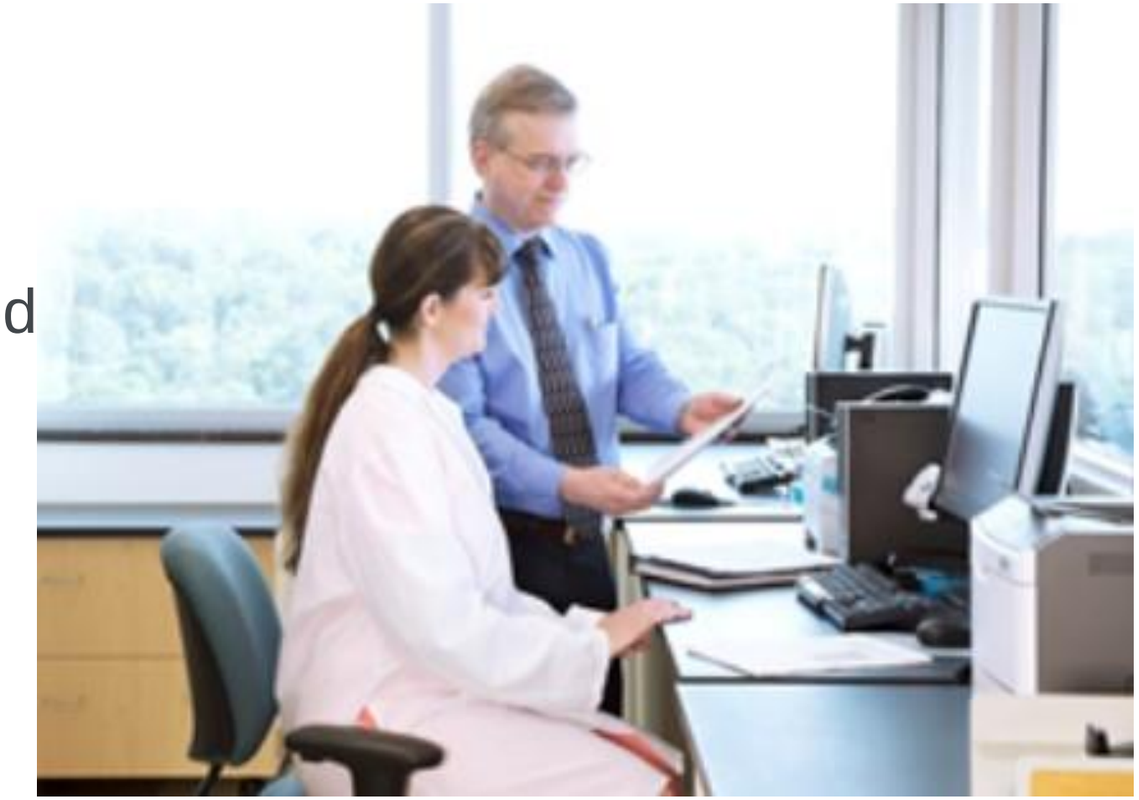
Suggestions for Demonstrating Compliance

Hyperlink	Hyperlink documents that demonstrate compliance
Add	Add the pertinent documents' locations with the checklist requirements
Tab	Tab procedures and documents with checklist requirement numbers
Develop	Develop a compliance manual

Deficiency Investigation Strategies

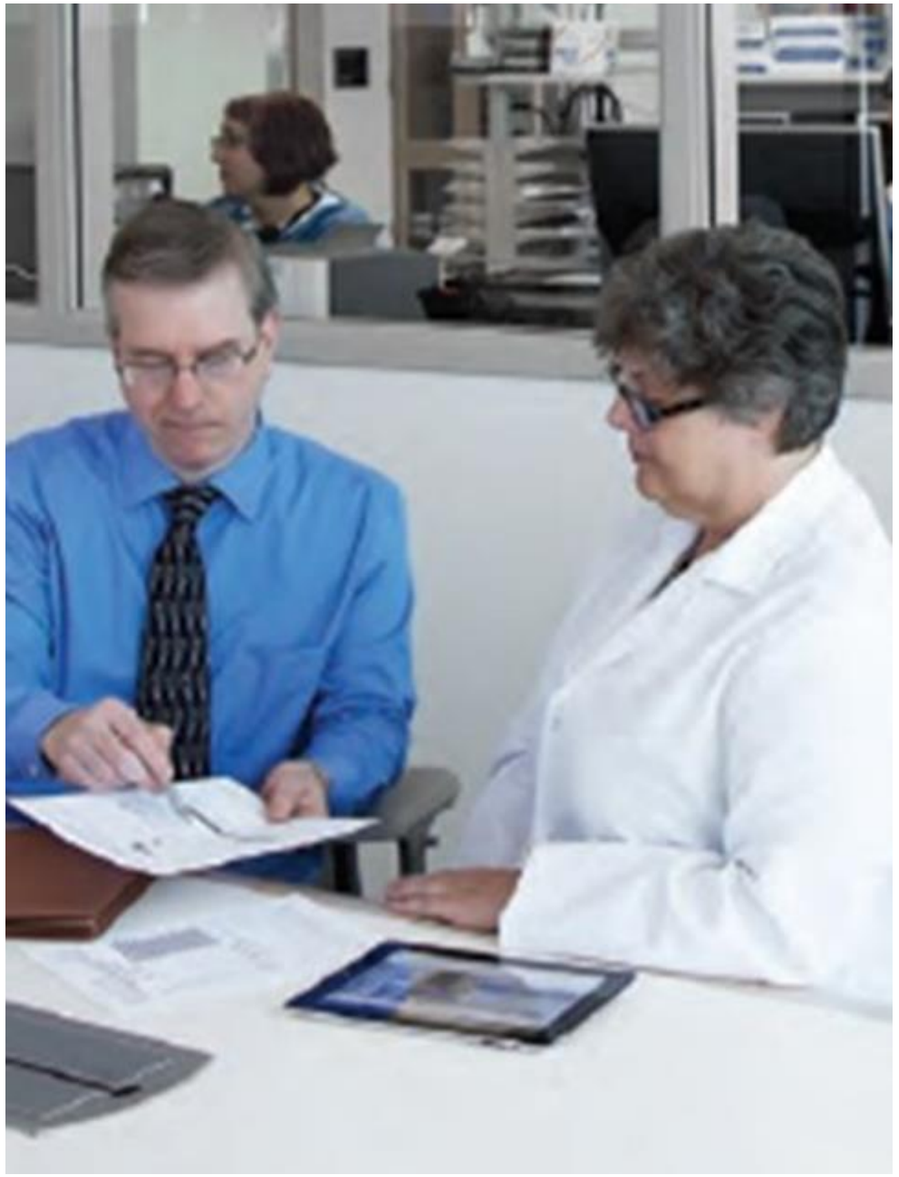
Questions to consider:

- Do lab practices completely meet the intent of the checklist requirement?
- Was the policy/procedure being followed as written?
- Was there a record of review and/or corrective action when applicable?



Deficiency Investigation Strategies, cont’d

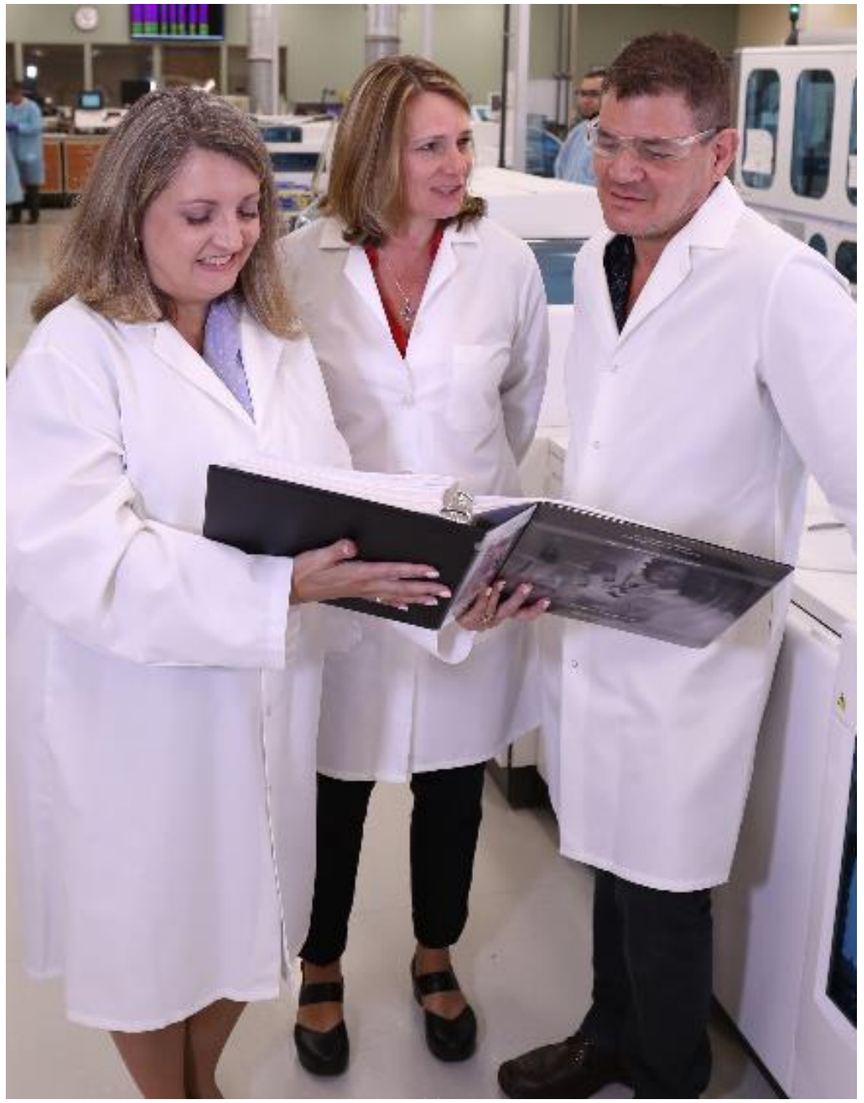
- Did testing personnel receive appropriate comprehensive training and competency assessments applicable to their job responsibilities?
- Was the appropriate documentation in place at the time of inspection but the inspector missed reviewing it?



Investigation Strategies: Path to Corrective Actions

If the laboratory answered “no” to any of the questions on the previous slides, the laboratory should:

- Investigate the cause of the deficiency
- Implement corrective actions



Most Commonly Cited Deficiencies and How to Avoid Them

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 & 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

#1 Non-Waived 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 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 and competency assessments are separate processes.
  - Applicable to new testing personnel only.

Competency Assessment Elements

- Assessment includes all applicable six elements of competency 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 – 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 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

#2 Comparability of Instruments and Methods – Nonwaived testing

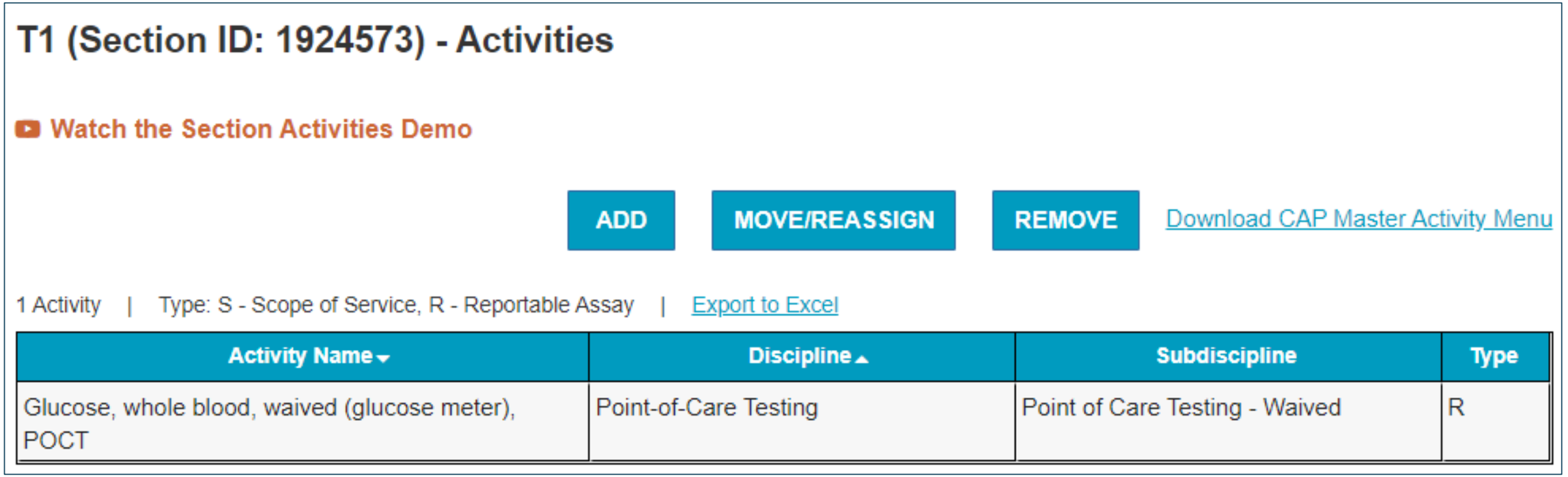
- Non-waived methods only
- Methods within a single CAP/CLIA number
- At least twice a year
- Applies to instruments/methods producing the same reportable results (eg, manual differential vs. automated differential)
- Written procedures including acceptance criteria

#2 Comparability of Instruments and Methods – Nonwaived testing

- Compared twice each year
- Missing acceptability criteria
- Does not include all non-waived testing

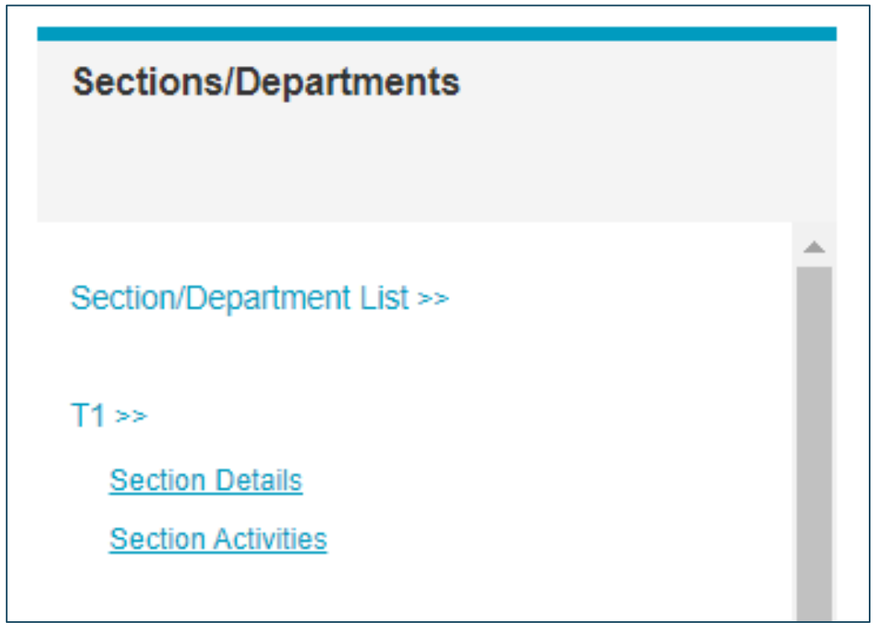
#3 Activity Menu

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



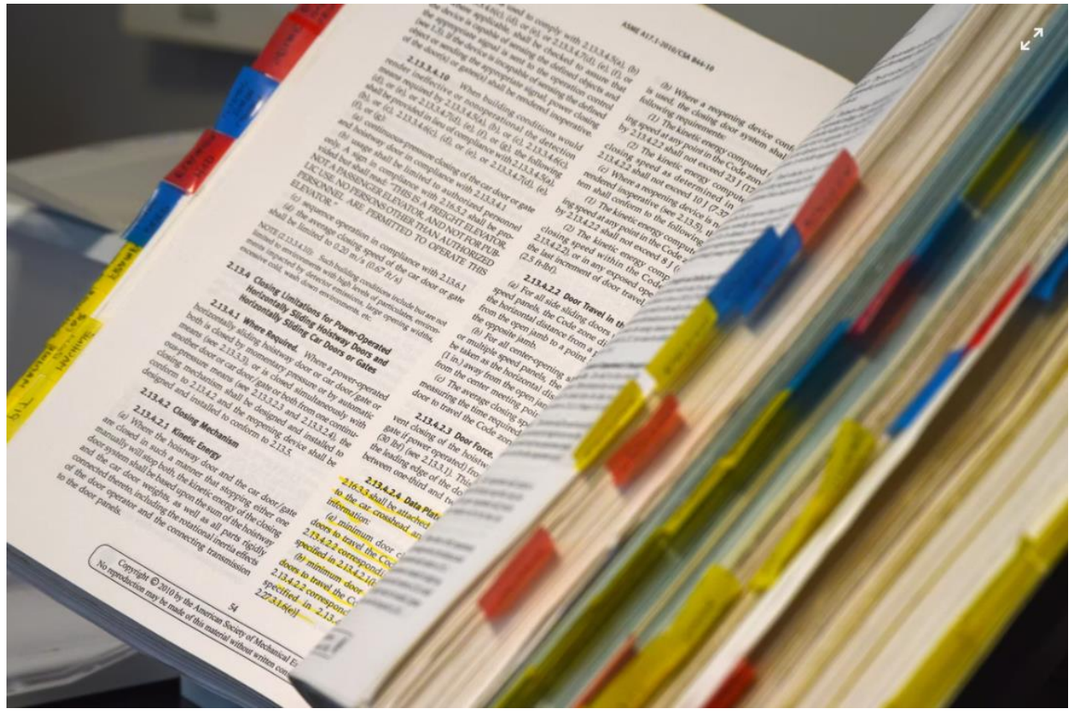
#3 Activity Menu

- 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
  - Proficiency Testing Failures linked to menu



#4 Procedure Manual

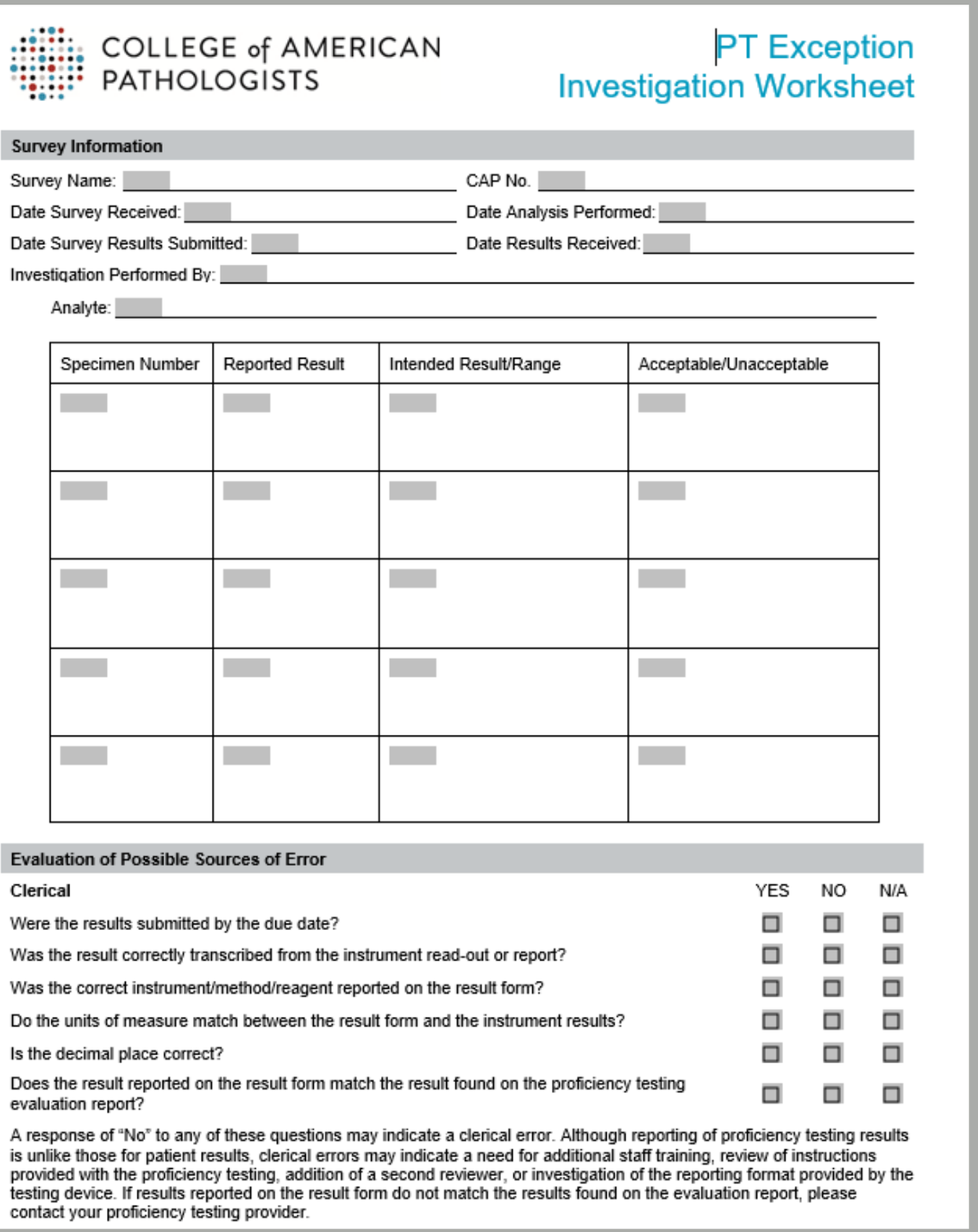
- Complete procedure manual is available:
  - Paper-based
  - Electronic
  - Web-based format
  - at the workbench or in the work area
- Procedures must match practice.



#5 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 or alternate assessment result 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**

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: _____

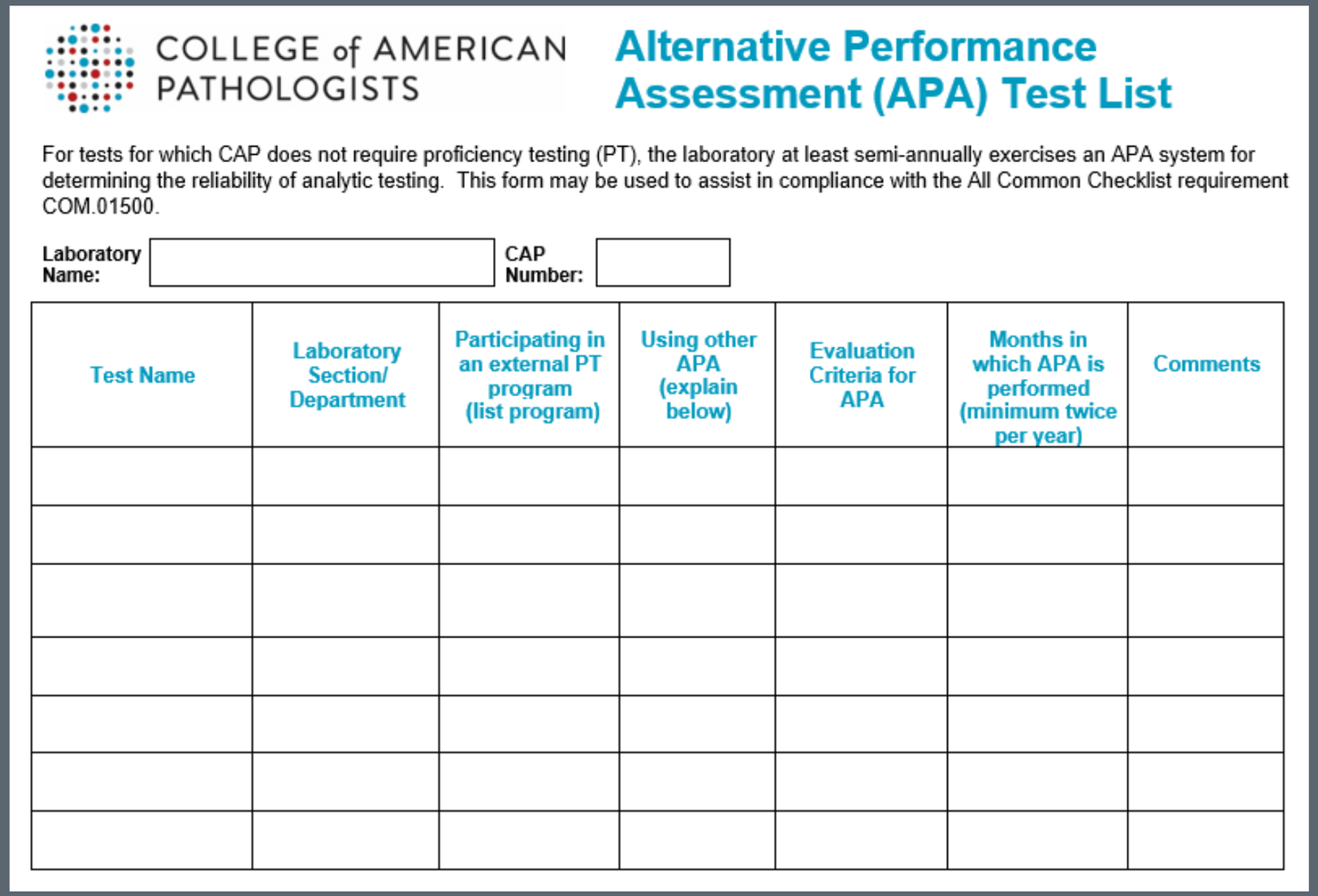
Specimen Number	Reported Result	Intended Result/Range	Acceptable/Unacceptable

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

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.

#6 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

#7 Instrument/Equipment Record 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

#7 Instrument/Equipment Record 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											

#8 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.
  - Secure electronic signature
  - Physical signatures

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)

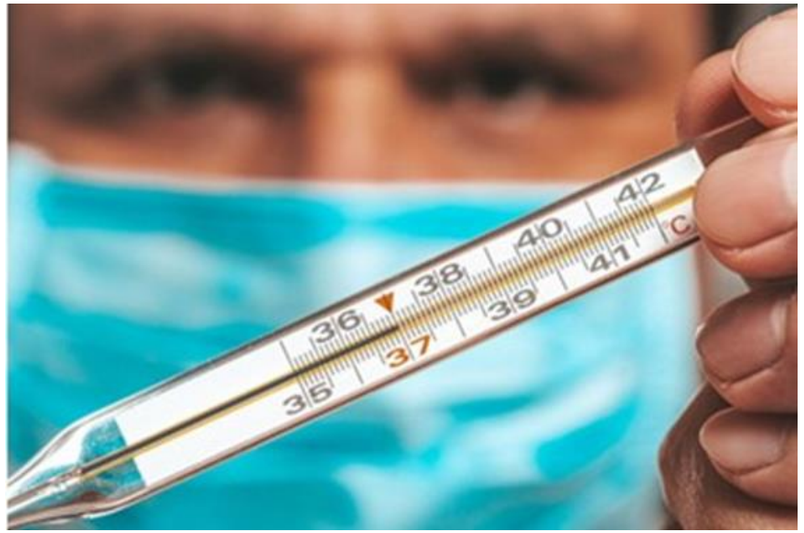
110 _____

Testing Personnel (signature required)

140 _____

#9 Temperature Checks

- Temperatures are checked and recorded 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, there must still be temperature monitoring
    - Continuous Temperature Monitoring
    - Min/max thermometers
  - Any temperatures outside of the defined ranges must have documented corrective action



Example Temperature Log

EXAMPLE: Refrigerator Temperature Log

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

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5																														
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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.**

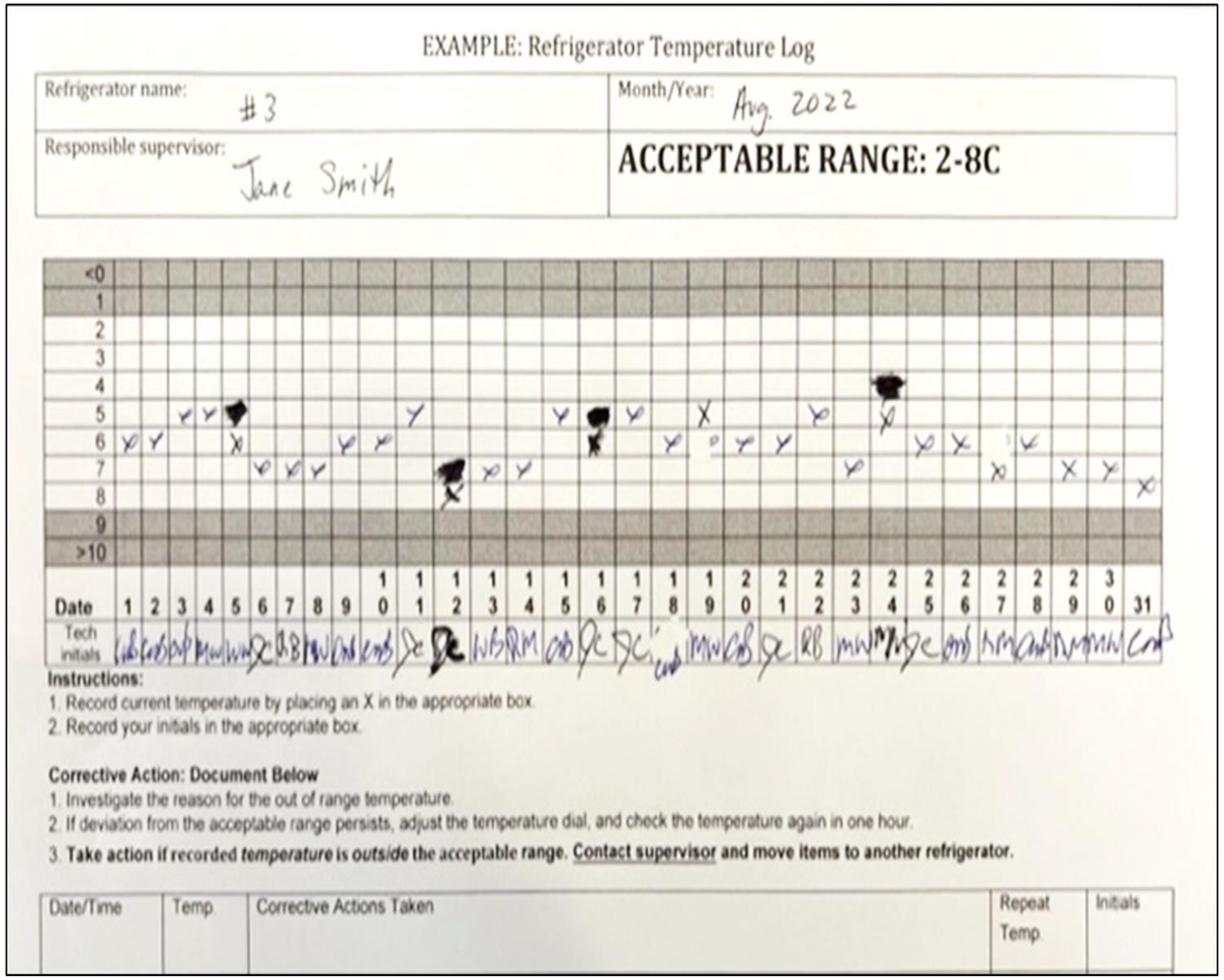
Date/Time	Temp.	Corrective Actions Taken	Repeat Temp.	Initials

Document further occurrences on the back.

Reviewed by and date_____

#10 Correction of Laboratory Records

- The lab makes corrections to laboratory records (eg, quality control data, temperature logs, and intermediate test results or worksheets) using appropriate techniques.
  - Written procedure covers both paper and electronic records
  - Must be legible and indelible



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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Date/Time	Temp	Corrective Actions Taken	Repeat Temp	Initials

Top 10 Point of Care Deficiencies

Checklist Requirement		CAP-wide Ranking
POC.06910	Competency Assessment Elements - Nonwaived	6.0%
POC.06920	Competency Assessment – Assessor Qualifications	3.7%
POC.08600	AMR Verification	3.0%
POC.06915	Competency Assessment Frequency – Nonwaived	2.9%
POC.07037	QC - Waived	2.8%
POC.07550	Monthly QC Review	2.5%
POC.08500	AMR Verification Materials	1.9%
POC.07300	Daily QC - Nonwaived	1.7%
POC.06875	Competency Assessment - Waived	1.3%
POC.06850	Personnel Training	1.2%

Responding to Deficiencies

Deficiency Response: Types of Appropriate Documentation

New or revised policies and procedures with appropriate review and approval

Sections of policies and procedures that have been underlined or highlighted

Quality control, calibration, maintenance, temperature records, etc

Documents? What Documents??

Accreditation Resources

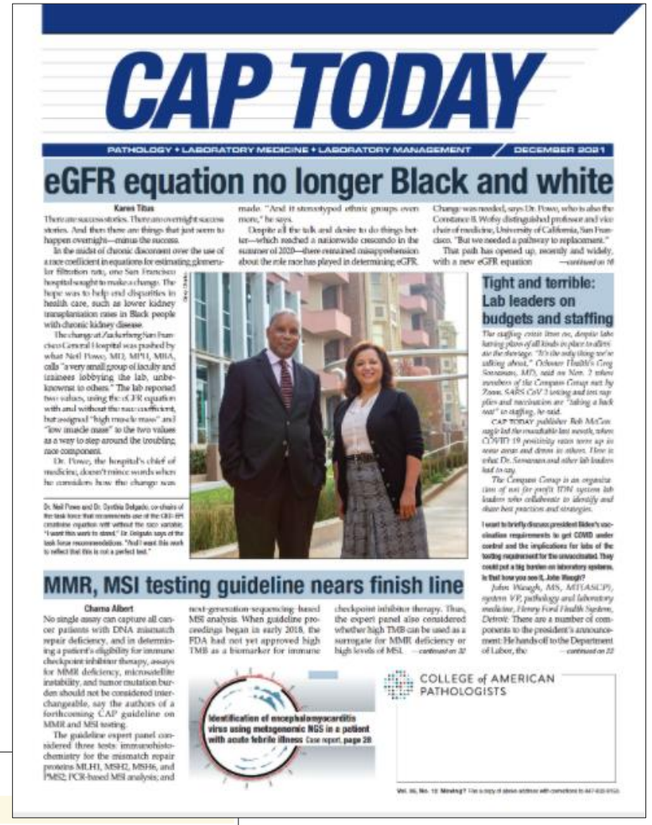
Expanded Accreditation Resources

- Revised and expanded online resources
- 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.

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



CAP TODAY

PATHOLOGY + LABORATORY MEDICINE + LABORATORY MANAGEMENT DECEMBER 2021

eGFR equation no longer Black and white

Karen Titus

There are success stories. There are overnight success stories. And then there are things that just seem to happen overnight—minus the success.

In the midst of chronic discontent over the use of a race coefficient in equations for estimating glomerular filtration rate, one San Francisco hospital sought to make a change. The hope was to help end disparities in health care, such as lower kidney transplantation rates in Black people with chronic kidney disease.

The change at Zuckerberg San Francisco General Hospital was pushed by what Neil Powe, MD, MPH, MBA, calls "a very small group of faculty and trainees lobbying the lab, unbeknownst to others." The lab reported two values, using the eGFR equation with and without the race coefficient, but assigned "high muscle mass" and "low muscle mass" to the two values as a way to step around the troubling race component.

Dr. Powe, the hospital's chief of medicine, doesn't mince words when he considers how the change was made. "And it stereotyped ethnic groups even more," he says.

Despite all the talk and desire to do things better—which reached a nationwide crescendo in the summer of 2020—there remained misapprehension about the role race has played in determining eGFR. Change was needed, says Dr. Powe, who is also the Constance B. Worby distinguished professor and vice chair of medicine, University of California, San Francisco. "But we needed a pathway to replacement."

That path has opened up, recently and widely, with a new eGFR equation —continued on 16

Tight and terrible: Lab leaders on budgets and staffing

The staffing crisis lives on, despite labs having plans of all kinds in place to alleviate the shortage. "It's the only thing we're talking about," Delaware Health's Craig Sorensen, MD, said on Nov. 3 when members of the Compass Group met by Zoom. SARS-CoV-2 testing and test supplies and vaccination are "taking a back seat" to staffing, he said.

CAP TODAY publisher Rob McClan ought led the roundtable last month, when COVID-19 positivity rates were up in some areas and down in others. Here is what Dr. Sorensen and other lab leaders had to say.

The Compass Group is an organization of not for profit, IDN systems lab leaders who collaborate to identify and share best practices and strategies.

I want to briefly discuss president Biden's vaccination requirements to get COVID under control and the implications for labs of the testing requirement for the unvaccinated. They could put a big burden on laboratory systems. Is that how you see it, John Waugh?

John Waugh, MS, MTASCP), system VP, pathology and laboratory medicine, Henry Ford Health System, Detroit: There are a number of components to the president's announcement. He hands off to the Department of Labor, the —continued on 18

MMR, MSI testing guideline nears finish line

Charna Albert

No single assay can capture all cancer patients with DNA mismatch repair deficiency, and in determining a patient's eligibility for immune checkpoint inhibitor therapy, assays for MMR deficiency, microsatellite instability, and tumor mutation burden should not be considered interchangeable, say the authors of a forthcoming CAP guideline on MMR and MSI testing.

The guideline expert panel considered three tests: immunohistochemistry for the mismatch repair proteins MLH1, MSH2, MSH6, and PMS2; PCR-based MSI analysis; and next-generation-sequencing–based MSI analysis. When guideline proceedings began in early 2018, the FDA had not yet approved high TMB as a biomarker for immune checkpoint inhibitor therapy. Thus, the expert panel also considered whether high TMB can be used as a surrogate for MMR deficiency or high levels of MSI. —continued on 32

Identification of encephalomyocarditis virus using metagenomic NGS in a patient with acute febrile illness Case report, page 28

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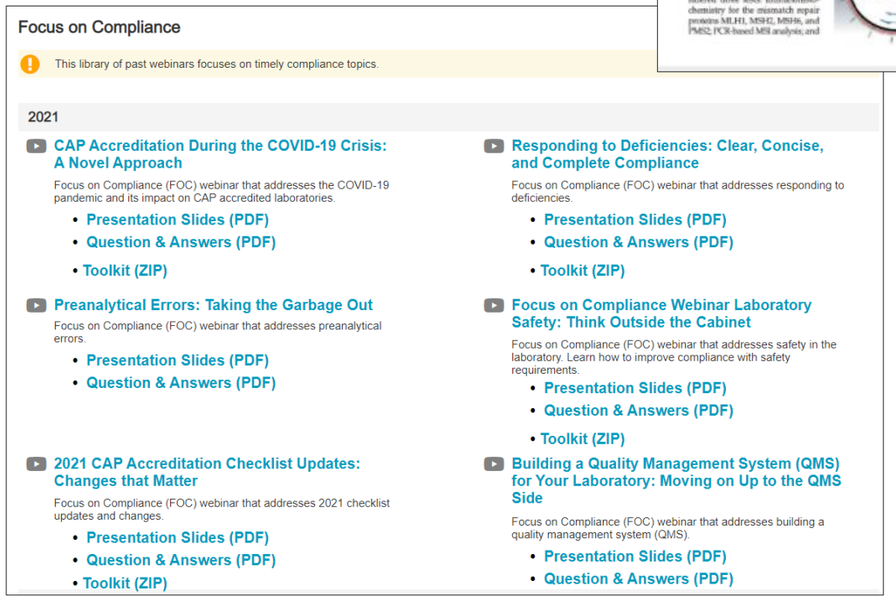

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