



Common Regulatory Inspection Deficiencies –

How Do I Avoid Them and What Do I Do if I Receive One

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- Q&As on most common issues in laboratories
- How to avoid deficiencies in these issue areas
- Resources Available







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Proficiency Testing Evaluation

- Ongoing evaluation of proficiency testing (PT) and alternative assessment results with appropriate corrective action taken for each unacceptable result.
 - Each unacceptable PT or alternate assessment result (any result or sample not meeting defined \bigcirc 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 Evaluation - continued

Reviewing PT and alternative assessments results over time can identify •

- Persistent bias, trends, and shifts Ο
- Change in system and/or process Ο
- Systematic error 0
- Evidence of corrective action 0
- Training opportunities Ο
- Staff competencies 0



Common Deficiencies - PT Evaluation

- Missing corrective actions on failures
- Missing documentation of review of results with codes
- Missing documentation or evaluation of alternative assessments
 - Alternative assessments are performed on methods/instruments that do have commercially available PT products





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:								
On a close of the state	Described Description							
Specimen Number	Reported Result	d Result/Range Acceptable/Unacceptable						
			1					
_		_						
	_							
	l							
Evaluation of Possible So	urces of Error							
Cierical					YES	NO		
Were the results submitted	by the due date?							
Was the result correctly tran	nscribed from the inst	rument read	-out or report?					
Vas the correct instrument			•					
Do the units of measure ma								
is the decimal place correct	?							
Does the result reported on evaluation report?	the result form match	h the result f	ound on the proficiency te	sting				
A response of "No" to any o	f these questions may	y indicate a	clerical error. Although re	porting a	f proficiency	testing	res	

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.

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PT Attestation Statement

- The proficiency testing attestation statement is signed by the laboratory director or designee and all individuals involved in the testing process.
 - Physical signatures must be present. Ο
 - 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 secured electronic signature

testation Statement	
the samples and the laboratory director must attest to th	
losely as is practical, performed the analyses on these specim	ens in the same manner as regular patient specimens. We confirm that results were

Common Deficiencies - PT Attestation Statement

- Signature missing
- Transfusion Medicine or other blood bank related PT signed by unqualified personnel

Attestatio	on/Use of Other Form
ttestation Statement	
the samples and the laboratory director must attest to t laboratory's routine methods." The laboratory director of Retain a <u>signed</u> copy of this page in your laboratory for If your laboratory requires additional space for signatur We, the undersigned, recognizing that some special handling closely as is practical, performed the analyses on these special	may be required due to the nature of proficiency testing (PT) materials, have as mens in the same manner as regular patient specimens. We confirm that results were
not shared or PT specimens referred or tested outside our CL Director (or Designee) (signature required)	IA identification number. Survey Mailing Information (eq. CA2020)





Expiration Dates

- All reagents (chemicals, stains, controls, media, antibodies, test strips, testing cartridges, etc.) are used within their indicated expiration date.
 - The laboratory must assign an expiration date if an expiration date is not provided by the \bigcirc manufacturer.

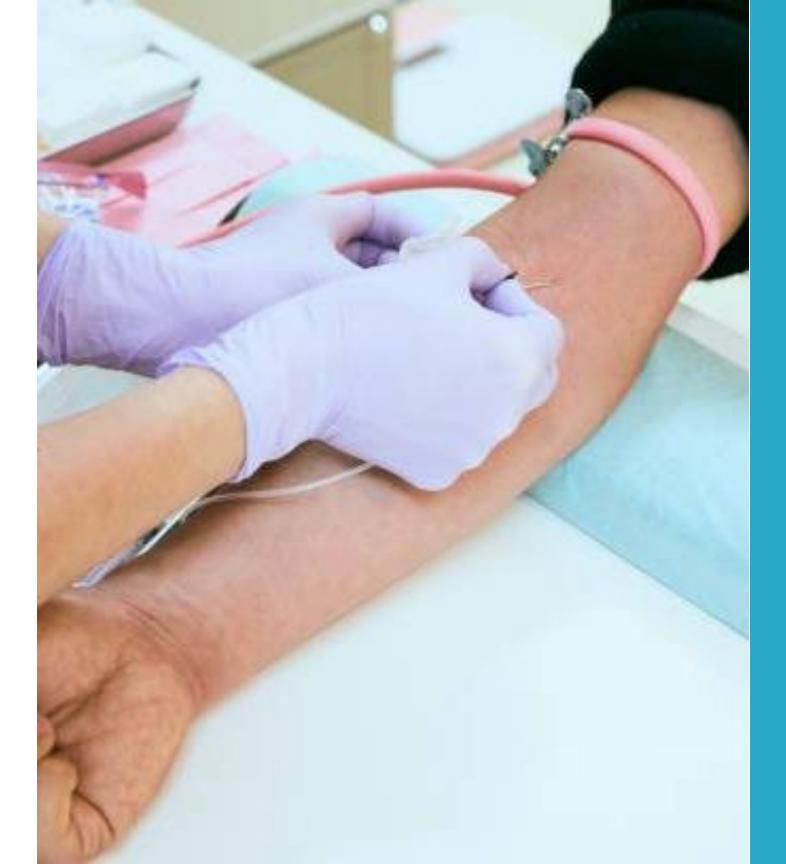


Expiration Dates - continued

- Procedure defining process for assigning expiration dates
 - Use manufacturer instructions to help build process for dates
 - Ensure staff understand this process and procedure
 - Assign to a safety audit to check for expired products







Adverse Events

- Several requirements around adverse events
 - FDA and manufacturer reporting requirements
 - Facility risk management reporting requirements
 - Adverse media attention must be reported to Accreditors



Adverse Events - continued

• Types of adverse events

- Hematoma
- Nausea
- Fainting
- Nerve damage
- Seizure
- Equipment failure
- Arterial puncture complications







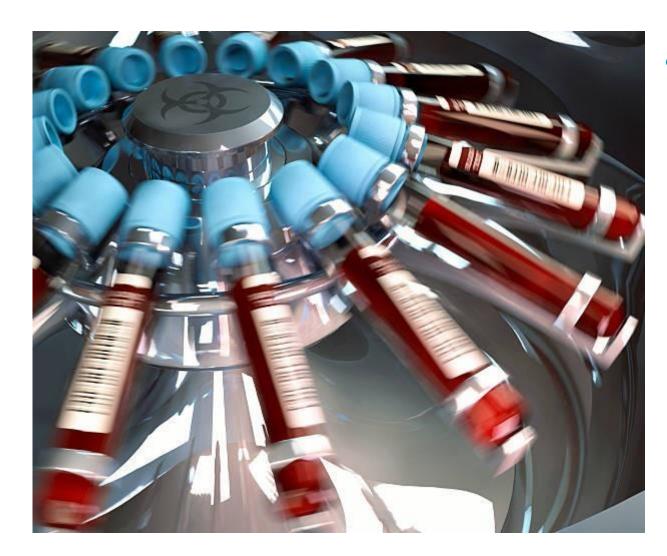
Laboratory Records

Storage of Records

- Alarm checks in blood bank
- Centrifuge maintenance reports
- Eye wash checks
- Pre-employment health screens



Laboratory Records - continued



- Storage of Records
 - Biomedical Engineering
 - Maintenance/Facilities
 - Human Resources
 - Employee Health





GEN.55500 Competency Assessment

- The competency of personnel performing <u>nonwaived</u> testing is assessed at the required frequency at the laboratory (CAP/CLIA number) where testing is performed.
 - Variations must be included \bigcirc
 - May be maintained centrally within a healthcare system but must be available upon request. Ο



Common Deficiencies– Competency Assessments

- Missing all 6 elements of competency at each location
- Personnel performing competencies do not qualify









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Carryover



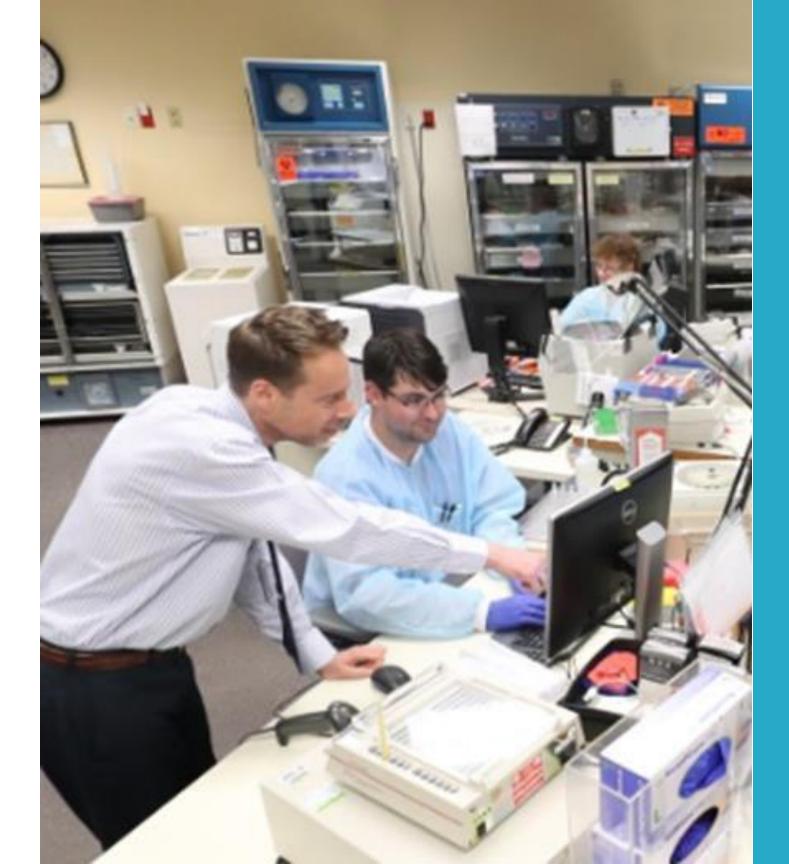
Purpose

Ensure automatic pipetting mechanisms do not introduce material into the next sample 0

How to perform

- Follow manufacturer instructions 0
- Run a High, low/blank, high, low/blank

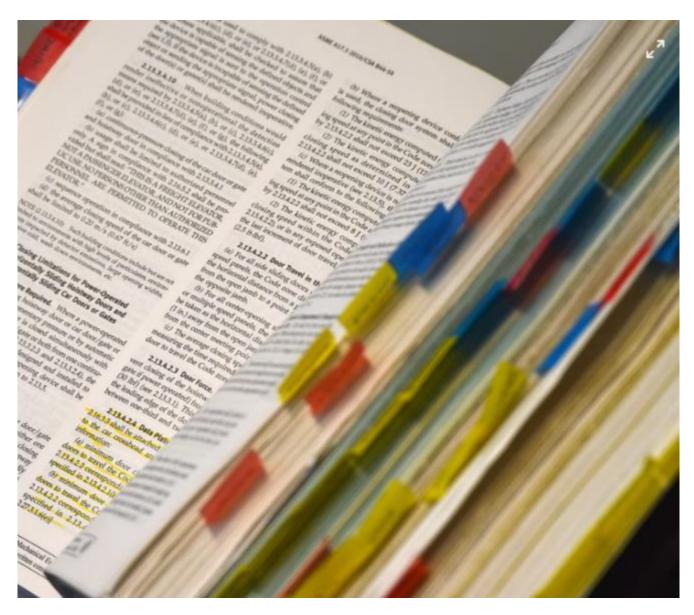




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Strategies to Prevent Deficiencies

- Stay abreast of checklist changes
 - Download new checklists at least annually
- Conduct a thorough interim selfinspection...and correct any deficiencies
 - Utilize laboratory staff to conduct self inspections
 - New eyes have new perspectives



Strategies to Prevent Deficiencies continued

- Focus on areas of the lab that are growing or changing
 - Use the checklists or standards when adding new testing
 - Standardize processes for validation/verification of new tests
- Make it easy for inspectors to establish compliance with checklist items
 - Organization is critical



Suggestions for Demonstrating Compliance

Hyperlink	Hyperlink documents that demonstrate co
Add	Add the pertinent documents' locations w requirements
Tab	Tab procedures and documents with che numbers
Develop	Develop a compliance manual

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compliance

with the checklist

ecklist requirement





Inspection Models



In-Person (Traditional)

In-Person with advance document review

Virtual

Virtual with advance document reveiw





What is a Virtual Inspection?







UTILIZES LIVE STREAMING TECHNOLOGY TO "PERFORM" THE INSPECTION SET UP AN INSPECTION SCHEDULE

ORGANIZE ELECTRONIC MEETINGS FOR DOCUMENT SHARING AND PROCESS REVIEW



IT TAKES WORK!

Either of those "With Advance Document Review"



ACCESS TO DOCUMENTS AND SOPS PRIOR TO INSPECTION INTERACTION

DOCUMENTS REVIEWED AND QUESTIONS "COLLECTED"



ONSITE OR VIRTUAL INSPECTION THROUGH INTERACTIONS WITH LABORATORY STAFF

Advanced Document Review Questionnaire

*Review Option

Laboratory will upload relevant documents to be shared with the inspection team in advance of the inspection.

Questionnaire

*Do you use any individualized quality control (IQCP) plans?

Yes

*In the last 2 years, have you implemented any new tests, instruments or methods in your laboratory?

Yes

*Does the laboratory perform any Laboratory Developed Tests (LDT) or modified FDA cleared/approved tests? No

PROCEED TO ATTACH DOCUMENTS >>



Update

Update

Update

Update

Accreditation Resources

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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

Foc	us on Compliance	
0	This library of past webinars focuses on timely compliance topics.	
202	21	
	CAP Accreditation During the COVID-19 Crisis: A Novel Approach	Responding and Comple
	Focus on Compliance (FOC) webinar that addresses the COVID-19 pandemic and its impact on CAP accredited laboratories.	Focus on Compil deficiencies.
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Application/Reapplication Process

Accreditation Manuals/ Retention Guidelines

Laboratory Webinars

Focus on Compliance

Laboratory Inspection Preparation Course

Proficiency Testing (PT)/External Quality Assurance (EQA) Toolbox

PT Compliance Notice (PTCN)

Checklist Resources

Accreditation Checklists

Checklist Requirement Q & A

Quality Management

IQCP Toolbox

External Resources

Proficiency Testing (PT)/External Quality Assurance (EQA) Toolbox

Everything you need to know about PT/EQA.

1.Escalation Process for PT/EQA Event Failures

Escalation process for PT unsatisfactory, unsuccessful, or repeat unsuccessful events.

Escalation Process for PT Failures of Regulated Analytes (PDF)

PTCN Exception Code List (PDF)

Refer to this document to review exception code definitions that appear on your PT Compliance Notice (PTCN)

2. PT/EQA Result Failure Investigation

Guidance documents to review PT failures.

PT Exception Investigation Worksheet (Word)

Review of Patient Results in Response to a PT Failure (PDF)

Reinstatement Process in Response to a Cease Testing Notification (PDF)

Guidance document for laboratories directed to cease patient testing for an analyte/subspecialty due to repeat unsuccessful proficiency testing (PT) performance, which includes performing a Root Cause Analysis.

4. PT/EQA Do's and Don'ts

Frequently asked guestions related to PT compliance including preventing interlaboratory communication.

PT Compliance FAQs (PDF) Preventing Interlaboratory Communication (PDF)

5. Alternative Performance Assessment

Alternative performance assessment toolbox and test list.

Alternative Performance Assessment Toolbox (PDF) Alternative Performance Test List (Word)

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.



Checklist Q&As

Checklist Resources

Accreditation Checklists

Checklist Requirement Q&A

Templates

Quality Management

IQCP Toolbox

External Resources

CAP Laboratory Director Education, Information & Resources

Chemistry and Toxicology

Cytogenetics

CYG.50000 (PDF)

Section Director/Technical Supervisor Qualifications; The cytogenetics laboratory has a qualified physician or doctoral scientist as section director/technical supervisor.

Cytopathology

Director Assessment

Checklist Q&As - continued



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Checklist Requirement – DRA.11400							
Question -	Answer -						
Does this mean the medical director must physically be present at the site and perform the assessment themselves or are they able to sign off on an assessment done by	The medical director must be phy present to assess the laboratory s environment but would be able to assistance in performing the asse						
another employee?							

ysically safety o have essment.



Fer	nplates
O	
	Competency/Training Templates
	Instruments/Equipment Templates
	Personnel Templates
	Quality Management Templates
	Safety Templates
	Validation/Verification Templates



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
	Room Temperature Logs	02/06/22											
Lab	Refrigerator Temperature Logs	02/06/22											
All	Freezer Temperature Logs	02/06/22											
	Eye wash Logs / Shower Logs	02/06/22											
	Instrument A maintenance logs	02/15/22											
	Instrument A QC logs	02/15/22											
	Instrument A calibration logs	$>\!\!\!\!\!\!\!\!\!\!\!\!\!\!\!\!\!\!\!$	>		\geq	\searrow	\geq	\supset	\geq		\geq	\triangleright	$\geq \leq$
	Instrument B maintenance logs	02/15/22											
stry	Instrument B QC logs	02/15/22											
a i	Instrument B calibration logs	$>\!$	$\geq \leq$		$>\!$	\geq	$\geq <$	\geq	$\geq \leq$		$>\!$	\geq	$\geq \leq$
Š	Instrument A & B Comparisons	$>\!$	>	$>\!$		\geq	\geq	\geq	\geq	\geq		$\geq \leq$	$\geq \leq$
	Blood Gas maintenance logs	02/15/22											
	Blood Gas QC logs	02/15/22											
	Blood Gas calibration logs	02/15/22	$>\!$	$>\!$	\geq	\geq	$>\!$		$>\!$	\geq	$>\!$	\geq	$\geq \leq$
	PT Records	02/27/22											



Example Temperature Log

											E	XAM	IPLE	E: Re	frig	erat	or T	'emj	pera	ture	e Lo	g	
Refrigera	ator	nan	ne:														Mon	th/Y	ear:				
Respons	ible	sup	erv	isor	:												AC	CCE	EP]	[A]	BL	E R	RAN
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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
Tech initials																							
Instructio	ns:																						

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
Document further	occurrences	s on the back.

Reviewed by and date

NGE: 2-8C

23 24 25 26 27 28 29 30 3	
	26 27 28 29 30 31

Repeat Temp.	Initials
Temp.	

"If it's not documented, it didn't happen."

Every Regulatory Agency Inspector

Questions

Please email <u>accred@cap.org</u>

