KAISER PERMANENTE®

Proficiency Testing

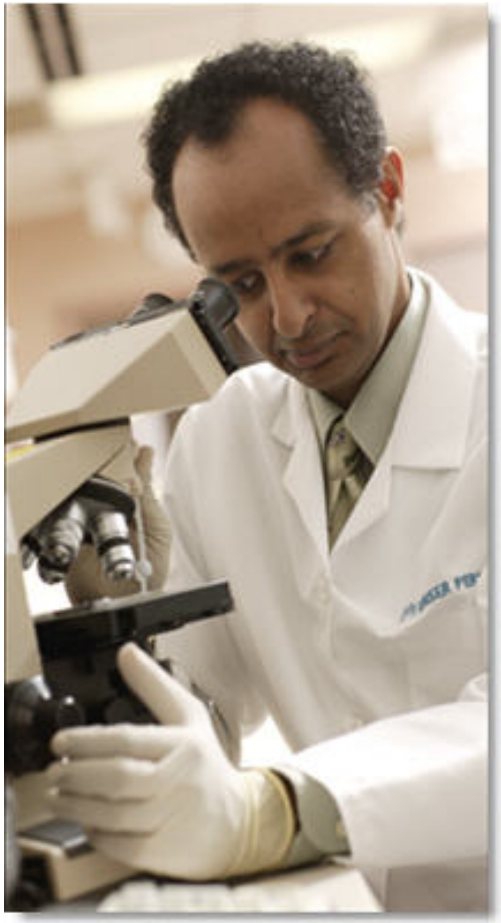
Modified by NCAL-LQC for NCAL Laboratories, 2012, 2016 & 2017

Based on CLS training developed in SCAL KP Laboratories using "CLIA Proficiency Testing DOs and DON'Ts, September 2008"

Target Audience: CLS and MLT

COMPLIANCE. THAT'S RIGHT!

Introduction



Welcome to the NCAL Kaiser Permanente Proficiency Testing training course!

The objective of this course is to understand why proficiency testing compliance is important and to provide you an overview of regulatory requirements and accreditation standards for compliance with Proficiency Testing.

This course was originally developed for SCAL KP labs in 2008 and has been modified by NCAL-Lab Quality & Compliance.

What is Proficiency Testing (PT)?

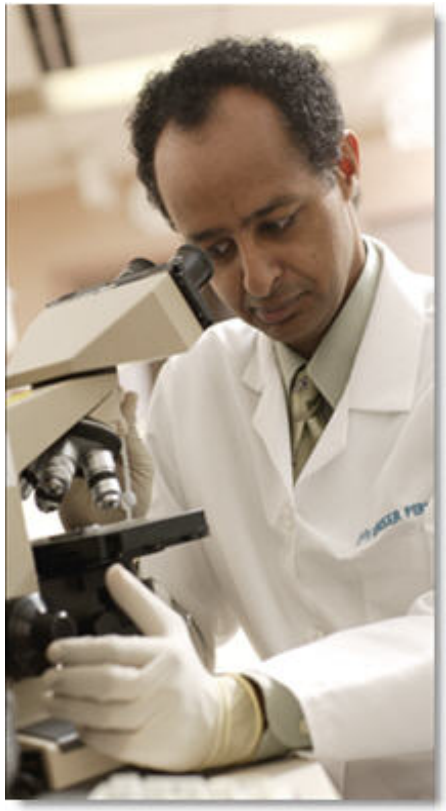
Proficiency Testing or PT is testing of unknown samples sent to a laboratory by a CMS-approved PT program. The majority of PT samples are tested 3 times per year. Testing is done in the same manner as patient specimens to the extent allowed by CLIA and must be managed within the subscribing laboratory. Results are reported back to and are graded by the PT program using CLIA grading criteria. The laboratory scores reflect how accurately it performed the testing. CMS and accreditation organizations routinely monitor laboratory PT performance.

Why is Proficiency Testing (PT) important?

Proficiency Testing is important because it is a tool used to verify the accuracy and reliability of the laboratory's testing. Routine review of PT reports by director and designee(s) will alert them to testing that is not performing as expected or indicate shifts and trends that can affect their patient results."

[based on *CLIA Proficiency Testing DOs and DON'Ts, September 2008*]

Scenario #1

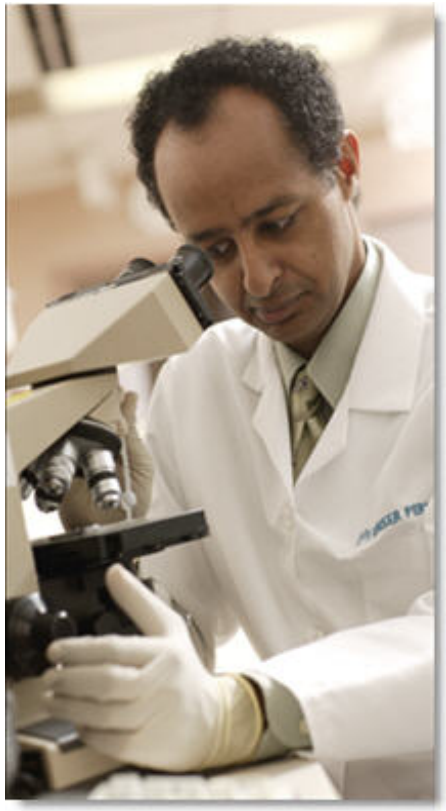


On Thursday, Sam, a seasoned CLS at the Sacramento Laboratory who works in the evening shift, was assigned to perform CAP Proficiency Testing for chemistry (C-A), for analytes glucose, lytes, BUN, creatinine, and calcium. Historically, Sam's routine upon receipt of PT assignment includes: complete the pre-analytical section of the NCAL PT Tracking Form, and keep the PT samples in the refrigerator until testing. Sam's practice has been to perform the PT on Wednesday afternoon when it's less busy in the lab. His reasons of doing it this way are the following:

a. With the goal of achieving a passing score of at least 80%, the practice of putting more time and attention to testing PT samples has been more successful, and

b. Since he has at least 10 days before the PT results due date, it buys him more time to work on the PT samples.

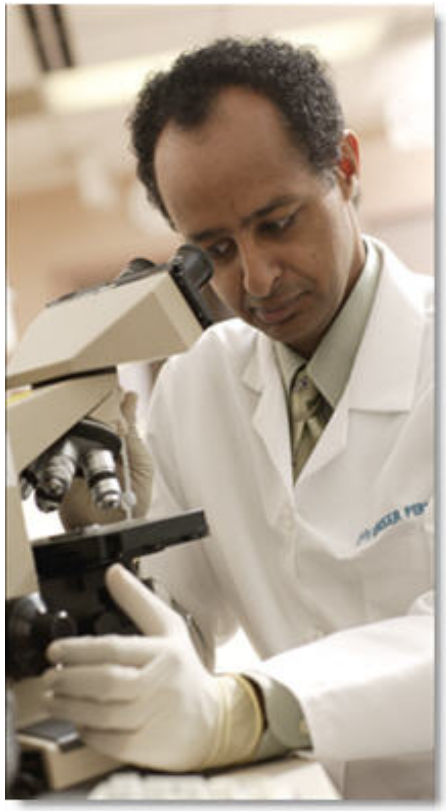
Scenario #1 - Question



After reading scenario #1, how could Sam be violating CLIA regulations and accrediting agency standards for handling the PT samples? Choose all that apply.

1. Keeps PT samples in the refrigerator until he finds time to perform the PT samples.
2. Sam completed the pre-analytical section of the NCAL PT Tracking Form.
3. Sam waited until Wednesday to analyze the PT samples with fewer interruptions.
4. Sam thinks the cut-off date, of 10 days upon receipt, buys him more time before testing the PT samples.

Scenario #1 - Answer



Answer – 1, 3, & 4 are steps violating CLIA regulations and accrediting agency requirements regarding proper handling of PT samples.

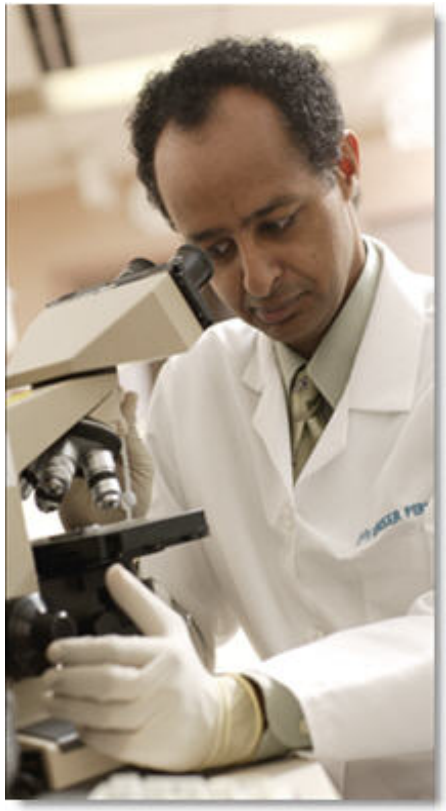
CLIA 493.801(b), states;

The laboratory must examine or test, as applicable, the PT samples it receives from the PT program in the same manner as it tests patient specimen.

CLIA 493.801(b)(1), states;

The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.

Scenario #2

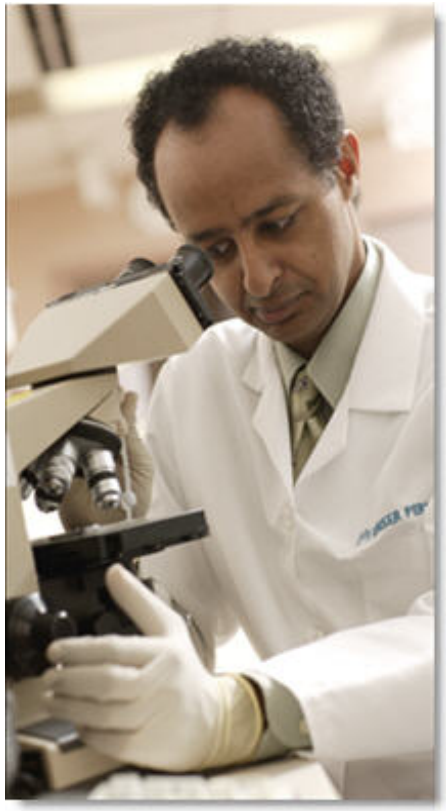


On Wednesday afternoon, Sam planned to work on the CAP PT samples (C-A) for chemistry assays. He aliquoted the PT samples into 5 tubes, manually programmed the PT samples CAP assigned ID on the AU680 Analyzer #1, loaded and ran the PT samples. After a while, the results of the PT samples were printed. Sam pulled the printouts and quickly browsed at the PT results. He then went on to run the same set of PT samples onto the other AU680 analyzer #2.

Sam's PT sample results for vial 1 are as follows:

Analyte	AU680 #1 Result	AU680 #2 Result	Reported to CAP
Glucose	96	102	99
BUN	32	36	34
Creatinine	1.2	1.3	1.2
Calcium	9.6	9.7	9.6
Na	139	139	139
K	1.8	2.4	2.1
Cl	113	115	113
CO2	25	26	25

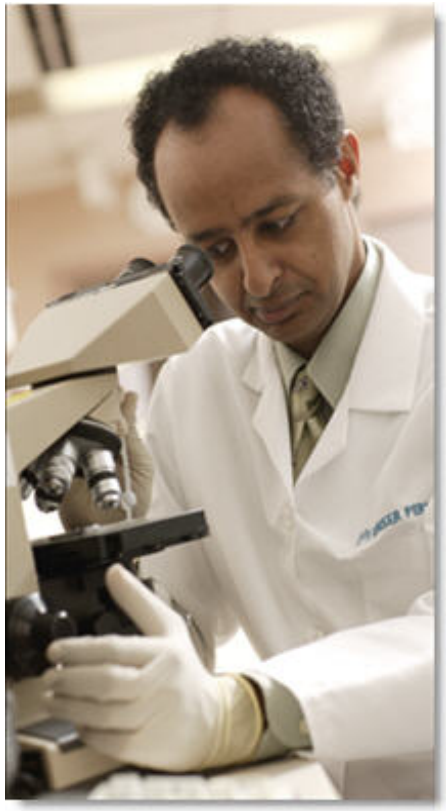
Scenario #2 - Question



After reading scenario #2, what are the steps that Sam could be violating CLIA regulations and accrediting agency standards regarding proper handling of PT samples? Choose all that apply.

1. Run PT samples on both of the AU instruments.
2. Repeated PT samples testing for both normal and abnormal results.
3. He averaged PT results.
4. He did not follow repeat testing policy of the laboratory for patient testing.

Scenario #2 - Answer



Answer – 1, 2, 3, & 4 are steps violating CLIA regulations and accrediting agency requirements regarding proper handling of PT samples.

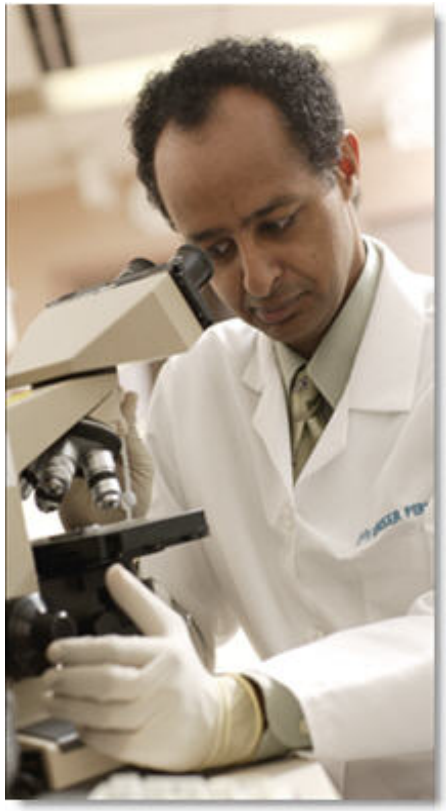
CLIA 493.801(b), states;

The laboratory must examine or test, as applicable, the PT samples it receives from the PT program in the same manner as it tests patient specimen.

CLIA 493.801(b)(2), states;

The laboratory must test samples the same number of times that it routinely tests patient samples.

Scenario #3



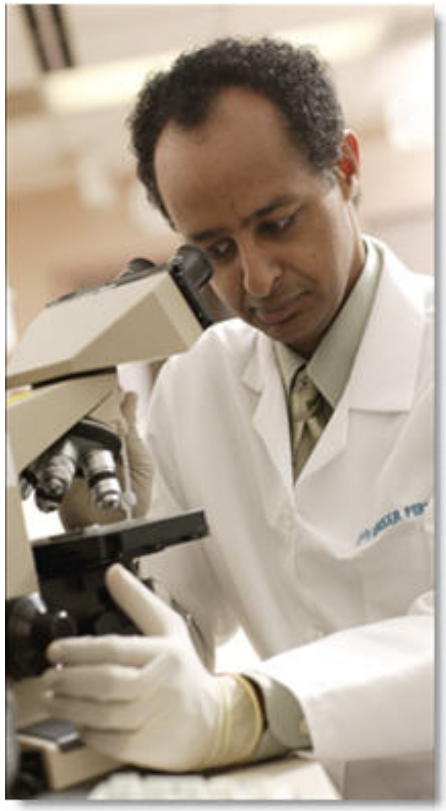
That Wednesday night, Sam also worked at another hospital laboratory in the neighborhood. Knowing the discrepancy on the glucose at the Sacramento lab, he volunteered to perform the same PT samples at the neighborhood lab. Since he is more confident with the results at this lab, he planned to re-do the PT samples, in particular the glucose on vial #2.

The following day, on Thursday Sam informed the Sacramento Supervisor about his dilemma on the glucose discrepancy on vial #2. Sam presented the PT results from the other lab to his Supervisor. Therefore, they decided to just re-calibrate both AUs, run the QCs and re-test vial #2. Further, in order to ensure the accuracy of their PT results, they also decided to send an aliquot of PT sample vial #2 as a blind sample to Regional Laboratory.

Sam's PT sample results for vial 2 are as follows:

Analyte	AU680 #1 Result	AU680 #2 Result	Regional Lab
Glucose (Wed. run)	580	403	
Glucose (Thurs. run)	555 (after re-calibration)	530 (after re-calibration)	545 (as blind sample)
Reported to CAP (after consulting his Supervisor) - 545			

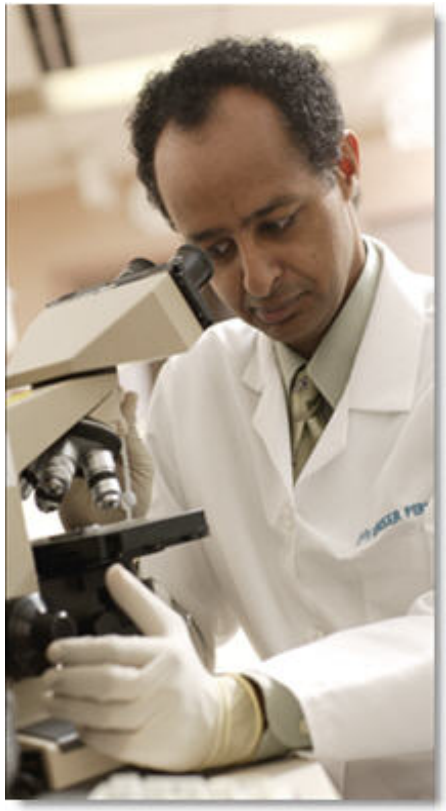
Scenario #3 - Question



After reading scenario #3, what are the steps that Sam is violating CLIA regulations and accrediting agency standards for proper handling of PT samples? Choose all that apply.

1. Run the same PT samples at another laboratory.
2. Comparing PT results from another laboratory.
3. Repeated PT testing after re-calibrating and running QC.
4. Averaging PT results.
5. Referring or sending a PT sample to another laboratory.

Scenario #3 - Answer



Answer – 1, 2, 3, 4, & 5 are steps violating CLIA regulations and accrediting agency standards regarding proper handling of PT samples.

CLIA 493.801(b)(3), states:

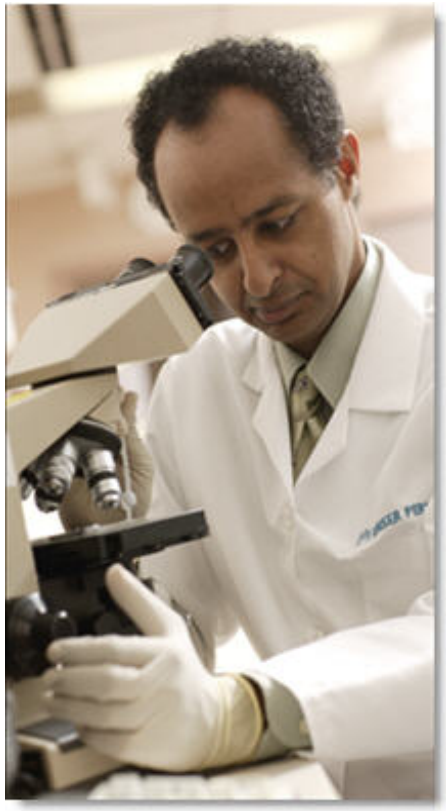
Laboratories that perform tests on PT samples **must not engage in any inter-laboratory communications pertaining to the results of PT samples until after the PT scores or evaluation results are received from the PT provider for the testing event.**

Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning PT sample results until after the PT scores or evaluations results are received from the PT provider for the testing event.

CLIA 493.801(b)(4), states;

The laboratory **must not send PT samples or portions of samples to another laboratory** for any analysis which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred its PT samples to another laboratory for analysis will have its certification revoked for at least 1 year. Any laboratory that receives PT samples from another laboratory for testing must notify CMS of the receipt of those samples.

Scenario #4.

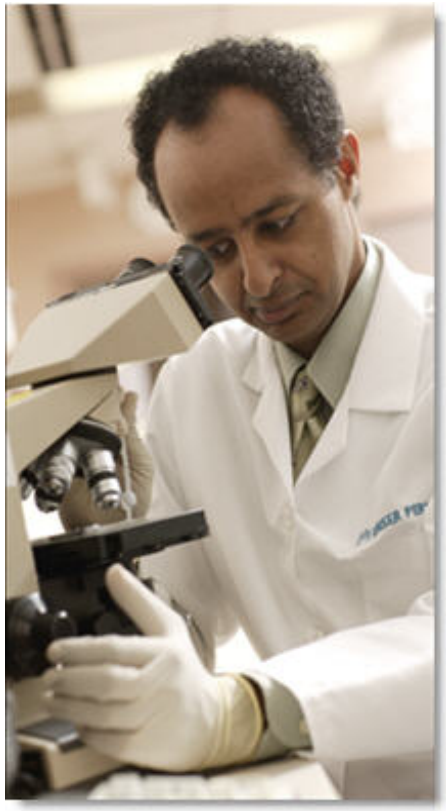


On Friday, after receiving the result from the Regional Laboratory, Sam accessioned the PT samples and entered the PT results in the Laboratory Information System. He signed the PT attestation form before submitting the following documents to his supervisor for review:

- CAP worksheets,
- All instrument printouts, including repeat testing printouts,
- A RILIS report printout.

Mickey, the Laboratory Supervisor, reviewed the results and entered them online. She printed a copy of the online results and attestation form and filed them together with the rest of the documents. She plans to retain the documents for 2 years since the laboratory is CAP accredited.

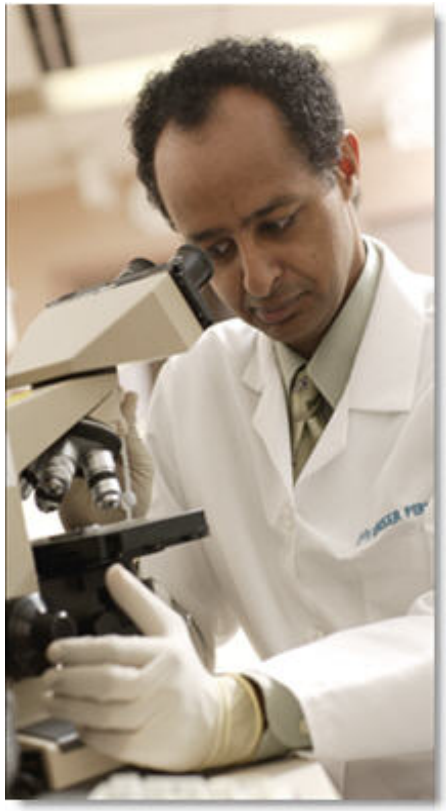
Scenario #4 - Question



After reading scenario #4, what are the steps that Sam could be violating CLIA regulations and accrediting agency requirements regarding proper handling of PT samples? Choose all that apply.

1. He accessioned PT samples after testing.
2. He entered results in RILIS that were not run on the AU680 on that accession.
3. He printed all instrument printouts, including repeat testing printouts.
4. Supervisor plans to retain the documents for 2 years since the laboratory is CAP accredited.

Scenario #4 - Answer



Answer – 1, 2, & 4 – are steps violating CLIA regulations and accrediting agency standards regarding proper handling of PT samples.

CLIA 493.801(b)(5), states;

The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all PT samples. The laboratory must maintain a copy of all records, including a copy of the PT program report forms used by the laboratory to record PT results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that PT samples were tested in the same manner as patient specimens, for a minimum of 2 years from the date of the PT event.

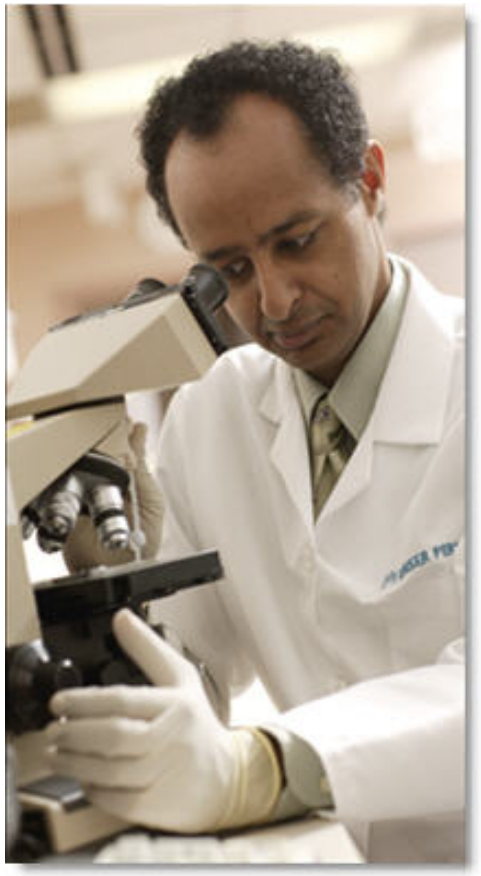
CLIA 493.2, defines;

State – includes all States of the United States, where the State, acting pursuant to State law to act for the State in enforcing requirements equal to or more stringent than CLIA requirements.

State of California BPC 1265(j)(2)(A), states;

Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, **for 3 years** from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.

Scenario #5 -



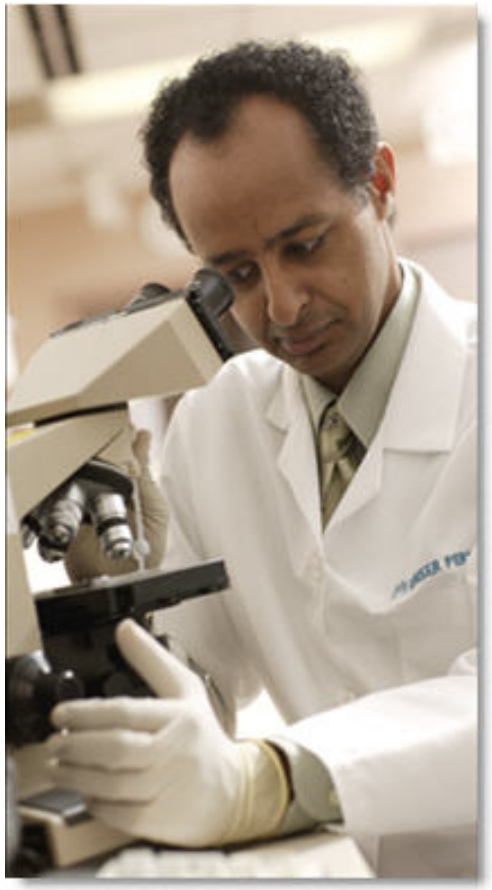
Sam is assessing PT cell identification images. One of the images appears to be a blast cell. All other images are normal cells.

According the LMD approved procedure, blast cells are confirmed by a Pathologist.

In the regular patient specimen workflow, a Pathology Review is ordered in RILIS. The stained smear and RILIS printout with the CLS's preliminary results are sent to Pathology located in a building not at the hospital address. Once assessed by the Pathologist , results are returned to Hematology, the Pathologist's results are entered and verified in RILIS.

Sam orders a Pathology Review in RILIS and places all five PT cell images with the PT results sheet in a transport box to be taken to Pathology for Dr. MD's confirmation.

Scenario #5 - Questions



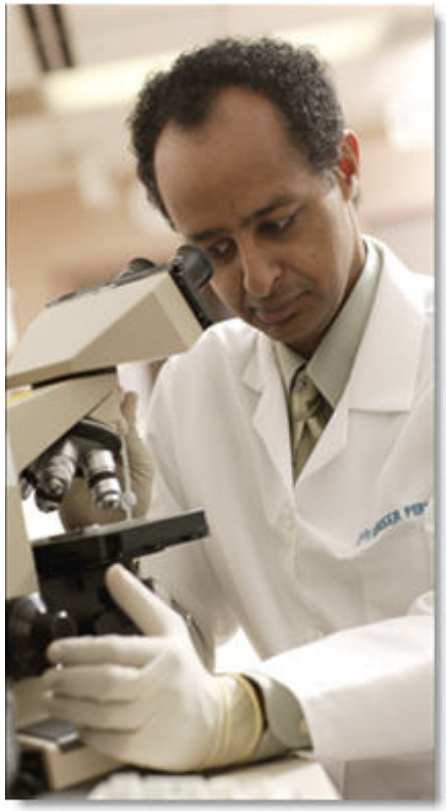
After reading scenario #5, what are the steps that Sam could be violating CLIA regulations and accrediting agency requirements regarding proper handling of PT samples? Choose all that apply.

1. He sent all five images for Pathologist review.
2. He sent the blast cell image, although he was sure it was a blast.
3. He sent PT test materials to Pathology offices, licensed separately from the hospital lab.

Of the three possible violations, which is the most severe? Why?

Proficiency Testing

Scenario #5 - Answers



Answer – 1 is a step violating CLIA regulations and accrediting agency standards regarding proper handling of PT samples. The approved procedure authorizes Sam to request Pathologist review of the blast cell image.

CLIA 493.801(b), states;

The laboratory must examine or test, as applicable, the PT samples it receives from the PT program in the same manner as it tests patient specimen.

Answer – 3 is a step very seriously violating CLIA regulations and accrediting agency standards regarding referral of PT samples to another laboratory. Because Pathology is located outside the hospital it cannot be licensed with the hospital lab. The Pathologist must come to the hospital lab. This is the one exception to managing PT samples in the same manner as patient samples. PT test materials must be managed within one CLIA certified laboratory, with no exceptions. **PT referral is the most severe PT violation and could result in revocation of CLIA certificate.**

CLIA 493.801(b)(4), states;

The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred its PT samples to another laboratory for analysis will have its certification revoked for at least 1 year. Any laboratory that receives PT samples from another laboratory for testing must notify CMS of the receipt of those samples.

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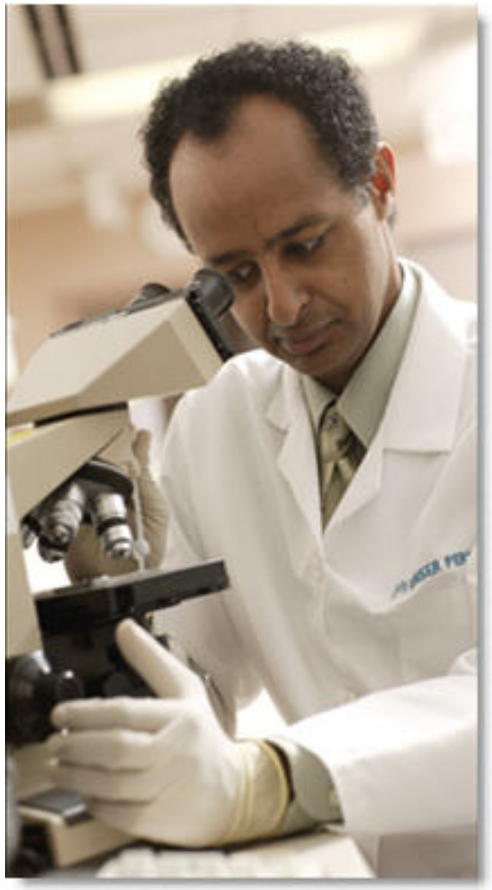
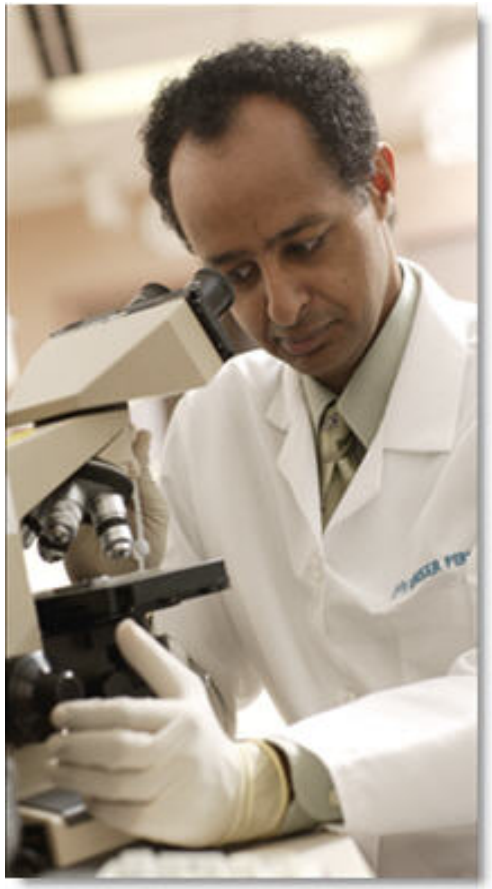


Mickey, the supervisor, received the CAP Summary Report on AQ-A, 2017 and was surprised the lab got 40% on pO2. Upon investigation, she found out that the performing CLS did not let the PT samples sit at room temperature for at least 4 hours. She tested the PT samples immediately after removal from the refrigerator.

The CLS thought that she was just following CLIA regulations to handle PT samples in the exact same manner as patient samples, and did not read the PT kit instructions.

Question: What does “handling PT samples in the same manner as patient samples” mean?

Scenario #6 - Answer



Question: What does “handling PT samples in the same manner as patient samples” mean?

Answer: The laboratory integrates all proficiency testing samples within the routine laboratory workload, and those samples are analyzed by personnel who routinely test patient/client samples, using the same primary method systems as for patient/client/donor samples.

- ✓ No repetitive analysis unless supported by lab policy
- ✓ No group consensus, No extra QCs or PM
- ✓ No <u>additional</u> analytical review beyond what is permitted in the lab policy
- ✓ It does not mean that the specific PT sample handling & testing instructions from the PT provider can be ignored.

Summary - DO's

- ✶Do document date of receipt in the lab.
- ✶Do use the primary instrument used to test patient specimen for testing PT samples.
- ✶Do rotate PT testing events among testing personnel, including those working off shifts.
- ✶Do follow PT provider's PT sample preparation, as applicable
- ✶Do handle PT samples in the same manner as patient specimens.
  - Integrate PT samples with the laboratory's workload as soon as practical
  - Assign unique specimen identifiers (accession in RILIS or manually enter/document the PT sample ID)
  - Follow approved patient testing repeat protocols
  - Repeat PT run according to repeat criteria per approved procedure and attach a copy of repeat run.
  - Document the reason for any repeated PT sample

✶Do define your policy explicitly regarding consultations with another CLS, Supv, Managers, Pathologists. All testing personnel must attest to PT handling. Examples include Smear/Diff, bacti work-up

Summary – DO's

- ✶ Proficiency testing samples must be integrated with the regular patient testing workload.
- ✶ DO enroll PT per CLIA certificate, NOT per site (multiple testing sites – hospital)
- ✶ DO notify CAP or PT provider when discontinuing testing or changing enrollment of a regulated analyte. Example – J to JAT for CMS reporting purposes.
- ✶ DO complete two independent clerical reviews against original test records

1) Ensure the original test records match the completed PT worksheet
2) After online submission, print the report to compare to original test records. Ensure all units of measure and method codes are complete/accurate and that results match the original worksheet, analyzer printout or interpretation documented by Testing Personnel.

Summary - DON'Ts

✶DON'T perform the same PT event again if previously performed when working in another lab.

✶DON'T process and analyze PT samples at your convenience – less busy time, "some other time", within a day or two of the PT reporting due-date.

✶DON'T run PT samples in replicate when not done for patients.

✶ DON'T average PT results when not done for patients.

✶DON'T perform additional analytical review for cell ID or Antibody ID while confirming transcription accuracy.

Summary - DON'Ts

✶DON'T use PT samples for other purposes (competency, correlation, etc.) until AFTER the PT scores or evaluations are returned.

✶ DO NOT EVER refer/reflex PT samples to another lab even if it says on your assay protocol – use "would refer" or "Test Not Performed" on PT result form.

✶NEVER send / take PT samples or records out of your laboratory boundaries for ANY reason.

✶DON'T discuss your PT results verbally or electronically with another laboratory, including a co-worker who may be working in another lab.

✶DON'T change PT enrollment until one year of successful participation.

✶DON'T change PT enrollment in the middle of the calendar year.

Summary

- Training of all staff, make a part of staff meeting – document

- Reinforce and document training of PT policy in staff meetings.

- Supervisors and Managers – Diligently check & review worksheets:
  - PT result forms (hard and online printouts)
  - Signed attestation form and online attestation form
  - Instrument printouts, including repeat instrument printouts **as applicable.**
  - RILIS lab report(s), if printed
  - Manual logsheets, worksheets

- ***Do use the NCAL PT Tracking Form before, during and after PT analysis.***

- ***Do keep PT records for 3 years (State of California)***

- ***Do share, review, and document review of all PT results with staff, satisfactory or unsatisfactory.***

Penalty of “Cheating”

Violation of PT testing rules will be severely punished if discovered.

- **Revocation of CLIA certificate – No testing can be done. The lab is not permitted to perform any lab test.**
- **Civil Money Penalty**
- **Onsite monitoring**
- **Owner/operator and Lab Director are prohibited to own and operate any labs for two years.**

Names of Violators are posted in CMS website
CMS won in every single PT hearing case!

Decision Date and Case Name	Issues	Outcome	Regulatory References
5/29/2015 [CR3919] Adeona Clinical Laboratory, LLC, v. CMS	- Intentional PT Referral	For CMS	42 CFR §493.801 Enrollment and testing of samples
06/15/2010 [CR2156] Victor Valley Community Hospital/Clinical Laboratory and Tomasz Pawlowski, M.D. v. CMS	- Intentional PT referral - Immediate Jeopardy - Laboratory Director - 1 year prohibition (PT referral) - 2 year prohibition (Owner, Operator, Director)	For CMS	42 CFR §493.801(b)(4) Condition: The laboratory must not send PT samples or portions of samples to another laboratory. 42 CFR §493.1441 Condition: Laboratory Director

PT Risk is Transferrable To Other KP Labs:

***CLS may be well-intended to do well on PT*, but lack clear understanding of PT communication actions or the risks**

Due to common ownership, PT risks from one of the NCAL KP laboratories are transferable to other KP labs.

Have you read the NCAL Proficiency Testing Procedures for Testing Persons?

Do you know the "NEVER" events?

PT “NEVER” Events

- **<u>Never</u> send PT samples or images or any portion thereof to any laboratory with a different CLIA certificate during the PT test event period, including any other KP laboratory within a service area**
- **<u>Never</u> test or process PT samples received from any other laboratory, including any other KP laboratory within a service area, with a different CLIA certificate during the PT test event period.**
- **<u>Never</u> physically or electronically transfer PT results or any PT records to any other laboratory with a different CLIA certificate**

PT "NEVER" Events

- **<u>Never</u> engage in discussion about PT results with any laboratory with a different CLIA certificate**
  - **No verbal or email communication**
- **<u>Never</u> access and/or enter PT results for a given laboratory at the location of another laboratory with a different CLIA number.**

Questions

Contact your PT provider if you encounter issues / problems with PT materials. Do not communicate with anyone outside your laboratory.

Notify your LAD or ALAD-LQC if you suspect any one of the “NEVER” events has occurred in your laboratory.

Thank YOU!

References: NCAL Lab PT Risk Mitigation

1. NCAL Laboratory Proficiency Testing Policy
2. NCAL Laboratory Testing Personnel PT Procedure
3. NCAL Laboratory PT Investigation & Corrective Action SOP
4. NCAL Laboratory PT Exception Investigation & Corrective Action Form
5. NCAL PT Tracking Form
6. NCAL CLS / MLT PT Training Slides