KAISER PERMANENTE®

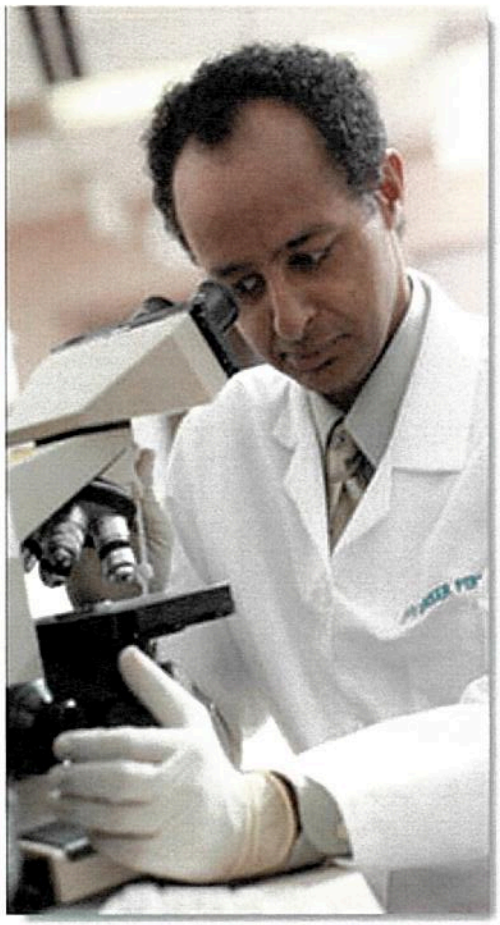
Proficiency Testing

Modified by NCAL-LQC for NCAL Laboratories, 2012.

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

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)?

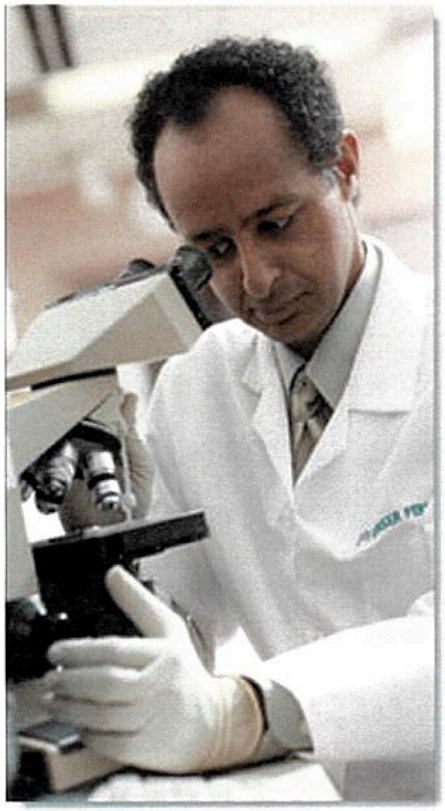
Proficiency Testing or PT is testing of unknown samples sent to a laboratory by a CMS-approved PT program. The majority of PT samples are testing 3 times per year. Testing is done in the same manner as patient specimens and must be managed within the subscribing laboratory. Results are reported back 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

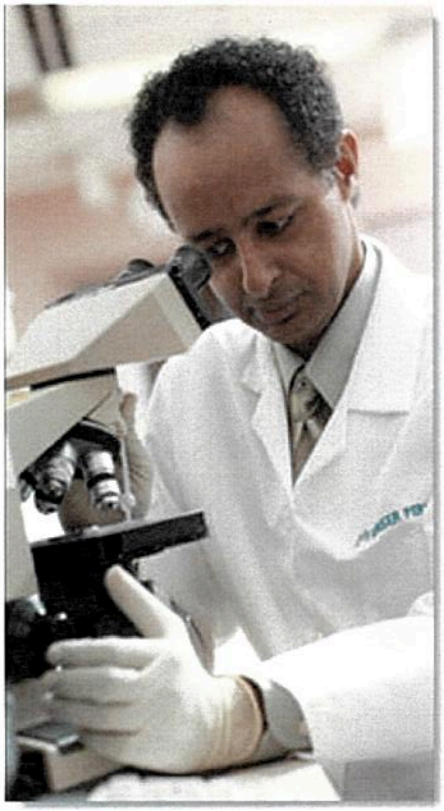


On Monday, Sam, a seasoned CLS at the Sacramento Laboratory, received the CAP PT samples for the chemistry (C-A), for analytes glucose, lytes, BUN, creatinine, and calcium. Historically, Sam's routine upon receipt of PT includes; open the package, pull out the worksheets, note the date of receipt on the worksheet, and keep the PT samples in the refrigerator time to test the PT samples. Sam's practice has been to perform the PT on either Wednesday or Thursday 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.

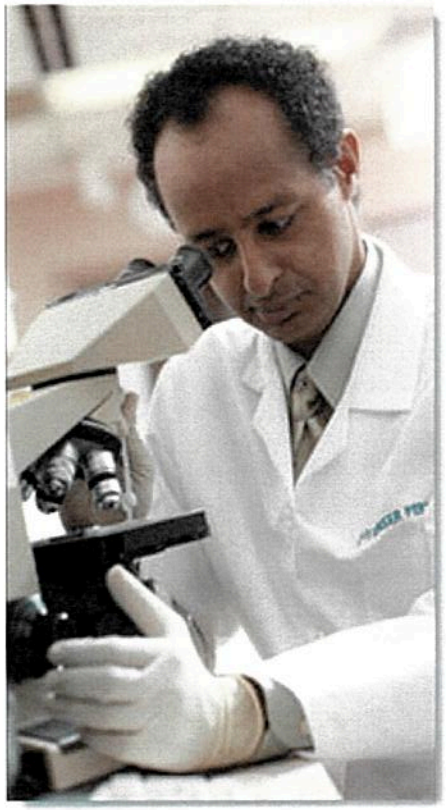
Scenario #1 - Question



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

1. Keeps PT samples in the refrigerator until he finds time to perform the PT samples.
2. Sam noted the date of receipt on the worksheet.
3. Sam waited until Wednesday or Thursday 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.

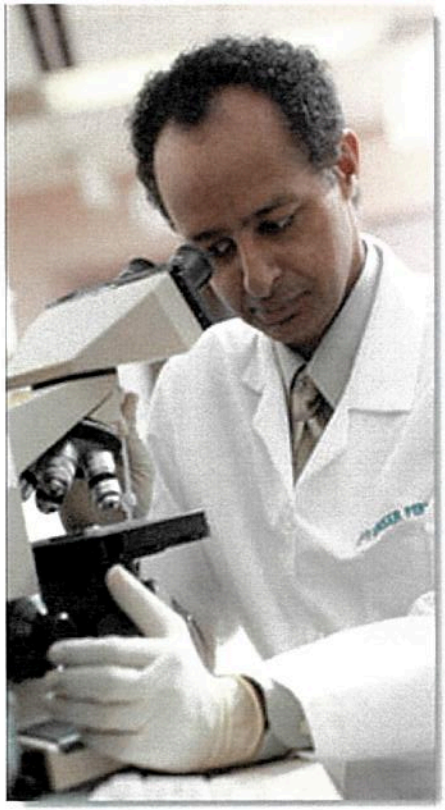
CLIA 493.801(b), states;

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

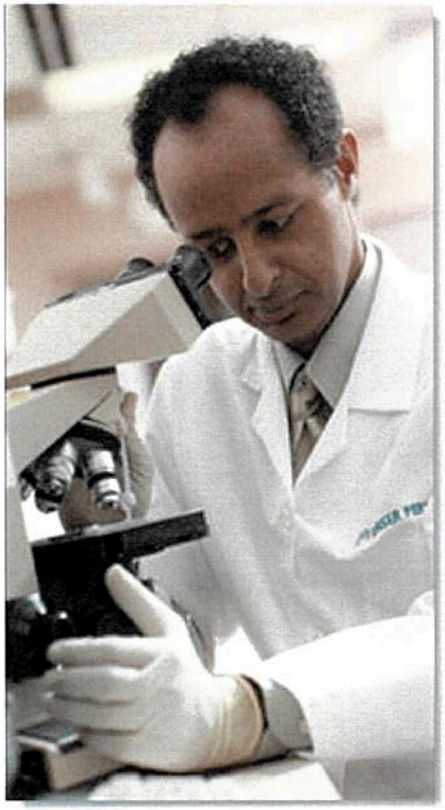


On Wednesday afternoon, Sam planned to work on the CAP PT samples (C-A) for chemistry assays. He aliquoted the PT samples into 5 tubes, manually programmed the PT samples CAP assigned ID on the Fusion Analyzer #1, loaded and ran the PT samples. After a while, the results of the PT samples were printed on the Fusion. 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 Fusion analyzer #2.

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

Analyte	Fusion #1 Result	Fusion #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

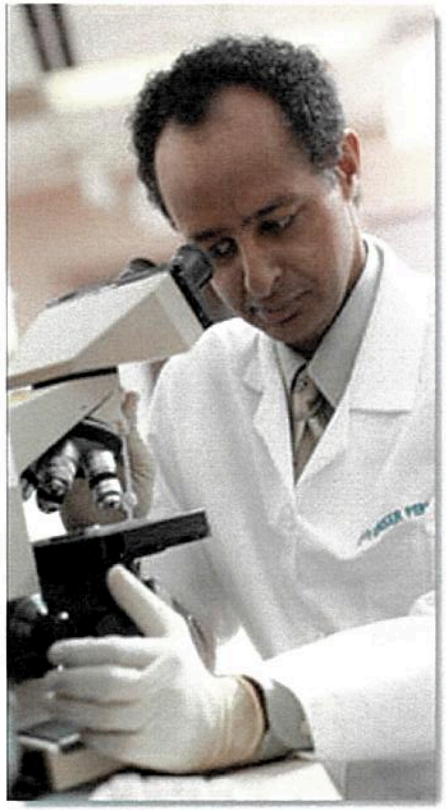
Scenario #2 - Question



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 the apply.

1. Run PT samples on both of the Fusion 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;

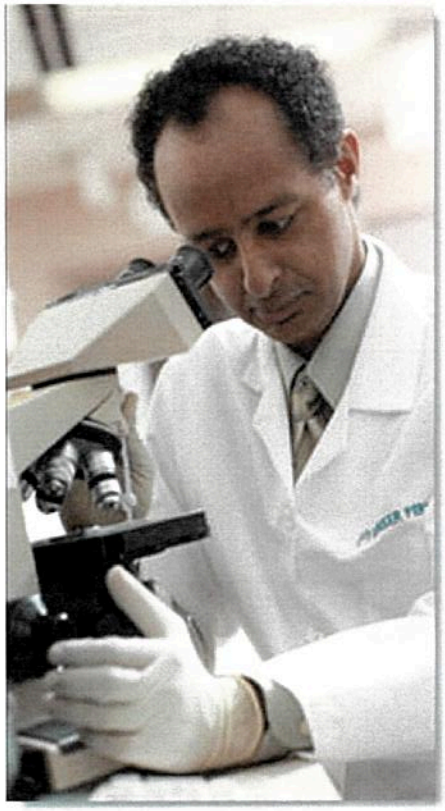
The laboratory must examine or test, as applicable, the PT samples it receives from the PT program in the same manner as it tests patient specimen.

CLIA 493.801(b)(2), states;

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

Proficiency Testing

Scenario #3



That Wednesday evening, Sam also worked at another hospital laboratory in Modesto. Knowing the discrepancy on the glucose at the Sacramento lab, he volunteered to perform the same PT samples at the Modesto laboratory. 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 his 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 Fusions, 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:

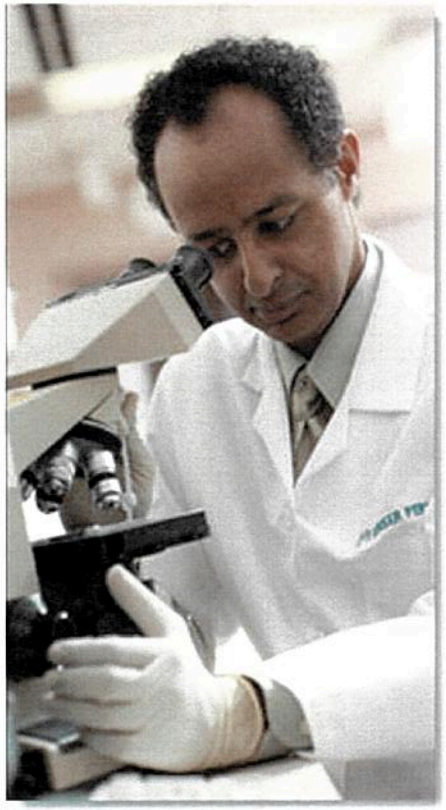
Analyte	Fusion #1 Result	Fusion #2 Result	Regional Lab
Glucose (Wed. run)	580	403	
Glucose (Thurs. run)	555 (after re-calibration)	530 (after re-calibration)	545 (as blind sample)
Reported to CAP (after consulting his Supervisor) - 545			

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 the 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:

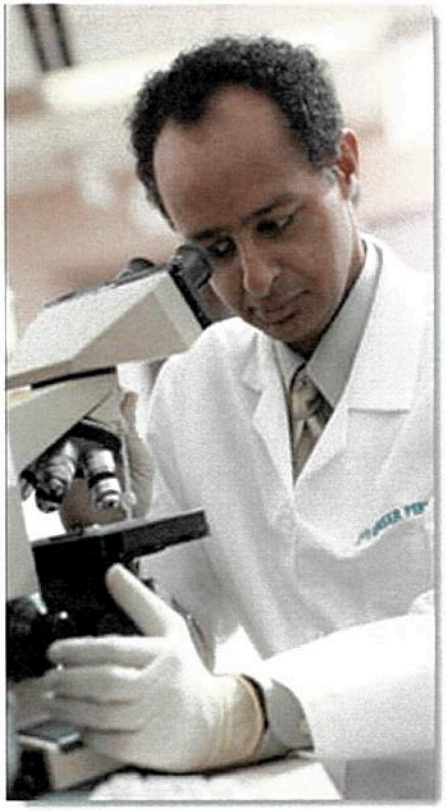
Laboratories that perform tests on PT samples must not engage in any inter-laboratory communications pertaining to the results of PT samples until after the PT scores or evaluation results are received from the PT provider for the testing event.

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.

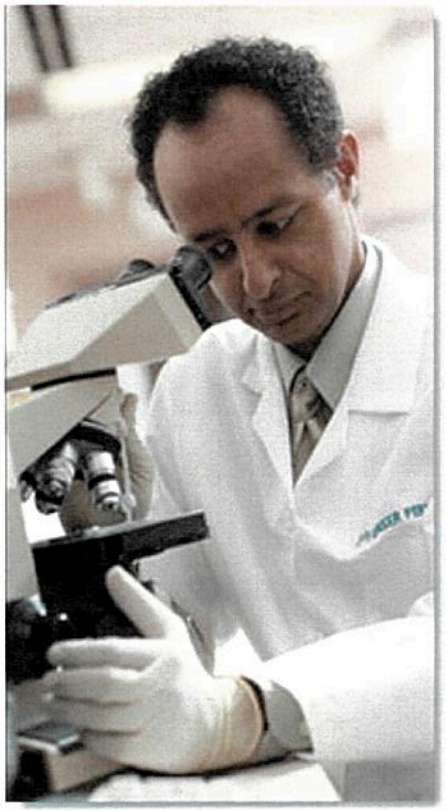


On Friday, after receiving the result from the Regional Laboratory, Sam accessioned the PT samples and entered the PT results in the Laboratory Information System. He signed the PT attestation form before submitting the following documents to his supervisor for review:

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

Susan, 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.

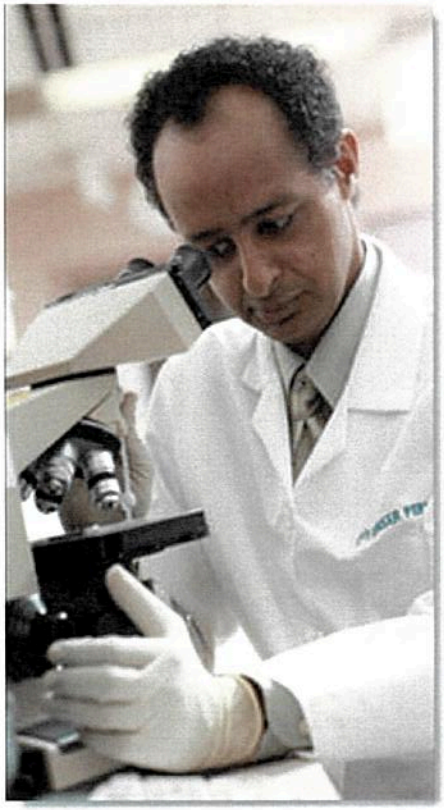
Scenario #4 - Question



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 the apply.

1. He accessioned PT samples after testing.
2. He entered results in RILIS that were not run on the Fusion on that accession.
3. He printed all instrument printouts, including repeat testing printouts.
4. He 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.

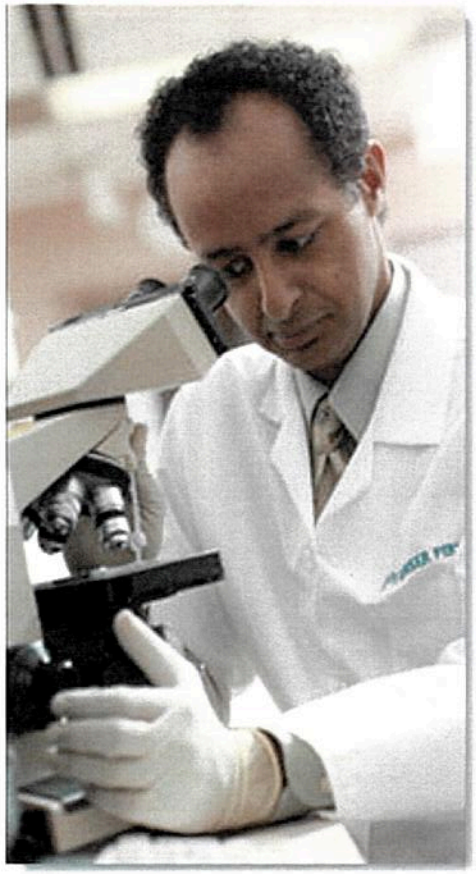
CLIA 493.2, defines;

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(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 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. Smyth's confirmation.

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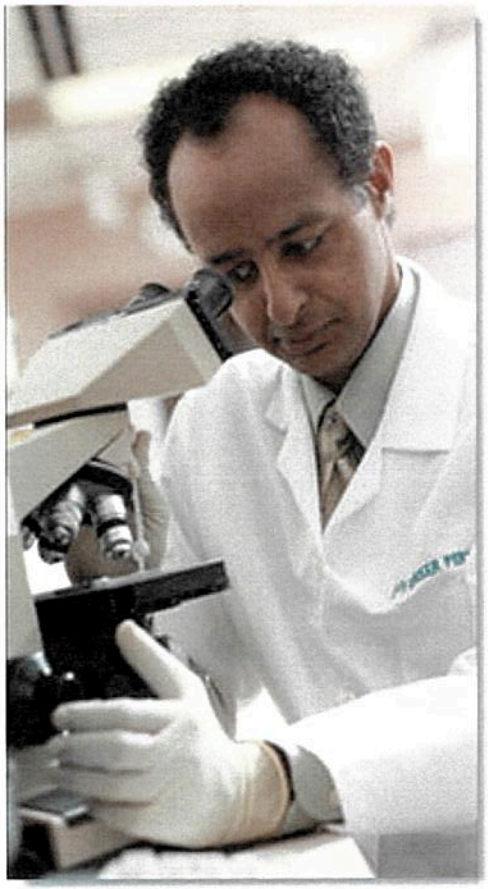
Scenario #5 - Questions



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 the 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?

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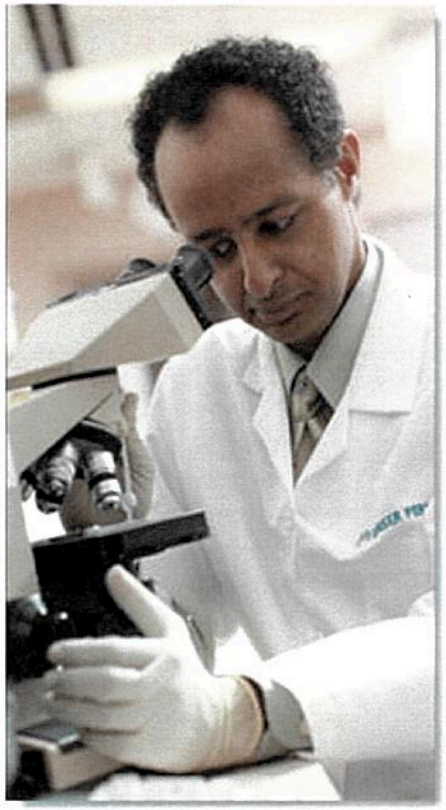
Scenario #5 - Answers



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;

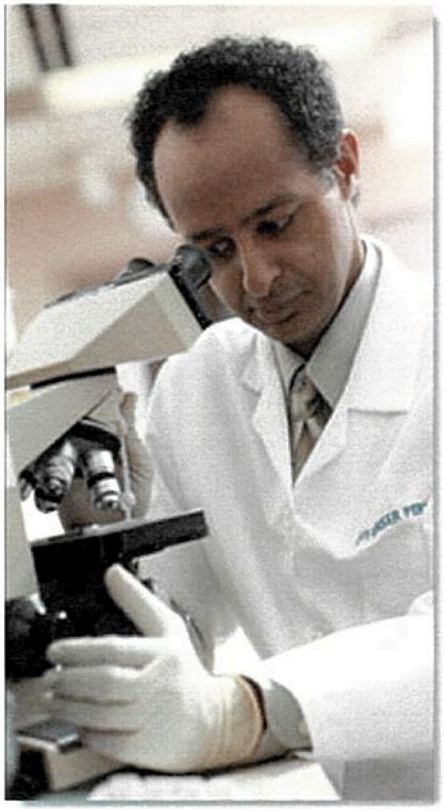
The laboratory must examine or test, as applicable, the PT samples it receives from the PT program in the same manner as it tests patient specimen.

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.**

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.

Electronic Submission



Final Clerical Review:

Save results after entering online. Once submitted, print the report form. Ensure all method codes and units of measure are complete/accurate. Use the worksheet published by the PT provider for the kit shipment, as the PT provider can change coding between kits. Ensure results match the original test records (worksheets, analyzer printouts, interpretation documented by Testing Personnel.)

View/print your saved data:

Clinical Microscopy Miscellaneous With Photographs and CD-ROM Result Form

Reporting Code Selection	
• If your method summary page states, "Please Provide a Valid Code," • If your code is listed incorrectly, or • If you have changed your methodology, Review the master list for an appropriate code and enter it on the result form. If there is no master list, select the code directly on the result form.	*If you cannot find an appropriate code:* Select Other from the kit instructions or result form and describe your method in the Use of Other section of the result form. If you need assistance, please call the Customer Contact Center at 800-323-4040 option 1 (domestic), or 847-832-7000 option 1 (international).
View the e-*LAB* Solutions™ user guide via www.cap.org	© CAP 2012

CMMP Photographs — Alert! If your laboratory does not perform testing on a specific specimen type, fill the bubble for code 100. Do not leave a reporting area blank. Exception Code 010 ○ 11 ○ 33

Fern Test CMMP-36	KOH Preparation CMMP-37 If you perform KOH, please report regardless of source.	Nasal Smear CMMP-38
Indicate whether ferning is present or absent (VAGINAL, UNSTAINED)	Indicate whether yeast/fungi are present or absent (VAGINAL, KOH)	Indicate whether eosinophils are present or absent (NASAL, WRIGHT-GIEMSA)
020 ○ 236 Ferning is present ○ 237 Ferning is absent ● 100 Testing not performed on specific specimen type	030 ● 195 Yeast/fungi are present ○ 196 Yeast/fungi are absent ○ 100 Testing not performed on specific specimen type	040 ○ 191 Eosinophils are present ○ 192 Eosinophils are absent ● 100 Testing not performed on specific specimen type

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Electronic Submission

- "Result Form Details" allows the completed Report From to be viewed or printed.
- Print "Saved Data" for the final clerical review, comparing the printed report to the original worksheet, analyzer printout data documented by Testing Personnel.
- A kit transaction history may also be viewed – and used to verify that are results have been submitted and "Received Online" by the CAP 5 days before the close date.

Result Form Details

Permanente Medical Group Inc
CAP #: 2393101-01

CMB2012 — Clinical Microscopy
Kit #: 24613365
Due Date: September 18, 2012

View Image(s)

Page	Status	Date Received	Via	Data
1	Received	9/7/12 4:22 PM	Online	View/Edit
2	Received	9/7/12 4:22 PM	Online	View/Edit
3	Received	9/7/12 4:22 PM	Online	View/Edit
4	Received	9/7/12 4:22 PM	Online	View/Edit

Related Links
Help
Return to kit list
Download a blank result form
View/print your saved data
View kit transaction history
Kit Instructions

Electronic Submission

- Review the Kit Transaction History to Track all transactions for each page of the PT report. Events of each page are listed in reverse chronological order.
- Enter and "Save Data" online.
- After "Saved Data" is reviewed, approve and submit data. This changes status to "Received Online"'.
- Data can be edited and resubmitted online prior to the close data.
- CAP evaluates the date once status is "Received Online" and the kit's close date is reached.

Kit Transaction History

Permanente Medical Group Inc
CAP #:2393101-01

CMB2012 — Clinical Microscopy
Kit #:24613365

Page	Action	Date/Time	User	Note
1	Received Online	9/7/12 4:22 PM	CAP	
1	Approved	9/7/12 4:22 PM	1070628	
1	Saved Data	9/7/12 3:44 PM	1070628	
1	Saved Data	9/7/12 3:36 PM	1070628	
2	Received Online	9/7/12 4:22 PM	CAP	
2	Approved	9/7/12 4:22 PM	1070628	
2	Saved Data	9/7/12 3:46 PM	1070628	
2	Saved Data	9/7/12 3:37 PM	1070628	

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.
  - Batch Testing: Do analyze PT samples in the next batch testing, as applicable
  - Continuous Flow (FIFO): DO test PT samples as you receive them
  - 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 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 clerical review at two critical steps.

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 if 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.

Summary - DON'Ts

✶DON'T use PT samples for other purposes (competency, correlation, etc.) until AFTER the submission deadline.

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

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