

PROFICIENCY TESTING MATERIALS HANDLING AND REPORTING



Objectives

- ▶ The Center of Medicaid and State Operations (CMS) has identified the improper Proficiency Testing (PT) Referral as a “Risk of Severe Sanctions” to the Laboratory and the Laboratory Directors. The SCPMG Laboratory System understands the strict requirements under the regulations and is providing this course to provide PT performance and handling guidance to all Laboratory Personnel.
 - Provide guidance to meet the regulatory and performance standards for Proficiency Testing Events.
 - Understand the criteria for acceptable PT performance
 - Provide a mechanism on reporting for further investigation those PT performance activities that you suspect might not meet the standards of the SCPMG Laboratory System and CLIA.

Why is Proficiency Testing (PT) Important?

- Proficiency testing is a tool used by the laboratory to demonstrate that testing results are accurate and reliable
- Routine review of PT reports will alert laboratory staff and director that areas of testing are not performing as expected.
- There is a direct link between the performance of PT samples and patient testing outcomes.

“Same Manner”

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 specimens.** CLIA 493.801(b)

“Routine Workload”

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**. CLIA 493.801(b)(1)

Communication

- Laboratories that perform PT samples whether single sites, multiple sites or locations must not engage in any inter-laboratory or across sites/locations 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. CLIA 493.801(b)(1)
- It is the policy of the SCPMG Laboratory System that even after the PT scores or evaluation results are received from the PT provider that no communication take place except for formal Quality Assurance Activities and/or Department staff review.

Sharing

- The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which is certified to perform in its 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. CLIA 493.801 (b)(4)
- Any laboratory that receives PT samples from another laboratory for testing must notify CMS of the receipt of those samples.

Ungraded Practice Question

On Monday, Big Louie, a seasoned LCS received the CAP PT samples for chemistry assays (set C-A). Historically Louie's routine include opening the package, dilutions, notes the date of receipt and places package in refrigerator. Louie's practice has been to perform the PT on either Wednesday or Thursday afternoon when it's typically quiet with few interruptions. Since the CAP due date is 10 days he performs over a number of days.

There is nothing in the case description above that would potentially be contrary to the to the guiding principles of PT.

True or False

Ungraded Practice Question

After review of the material given to him by his supervisor for the PT event, Big Louie felt that to be extra safe that he would run the tests at least twice on subsequent days. He felt that since the primary instrument was close to its scheduled maintenance and results appear to be trending higher lately he would calibrate and perform the maintenance prior to running the PT material. To be extra safe, he would run on the backup instrument to see what values he would obtain.

After performing in the primary and backup instrument and reviewing the QC results of the primary and backup instruments, Big Louie felt averaging the two sets of instrument results would give a better answer as he was taught the object of PT is to get the right answer.

To be extra, extra sure, he asked Fred the evening shift CLS to review and confirm his answers. Fred was concerned about the 3rd sample and ran again to confirm the results and used the printout to put his coffee cup on prior to disposing of the paperwork into the recycle bin.

Big Louie and Fred performed the PT event within the guideline of CMS and SCPMG PT policy.

True or False

Ungraded Practice Question

The next week another CLS from an outlying Kaiser Clinic called Big Louie and happened to mention how difficult sample four was of the C-A PT kit. Big Louie agreed and told him what result he obtained. He also mentioned that someone from Big Sur Hospital called on the advice of the Beckman Rep and also shared their results with him. He told them his results were similar. After ending the call, Bog Louie could not contain himself and proclaimed to the CLS student intern assigned to chemistry that he was in fact correct on his answers. During lunch the CLS student mentioned to those at accurate as other places like Big Sur and the other clinics.

Conversations being overheard in the lunch room the Hematology Lead CLS reported the conversation to SCPMG Regional Compliance for investigation. **The Hematology CLS was correct in reporting.**

True or False

Communication FAQ

- If someone calls on the advice of an instrument vendor about a proficiency testing results to assist in the troubleshooting of their instrument can you give them the result. **No – report incident to your supervisor or laboratory compliance for follow-up.**
- You have a slide from the CB PT event in which you need a consult from the Hematologist in the building next door, can you send for the consult. **No – PT material are never shared with others outside of your department even if consults by others are described in your local PT policies.**
- Who can I call if I have questions about the PT material? **Consult only your PT provider.**
- Can I have another shift or CLS complete a portion of the PT event? **Only if part of the event has been assigned to them.**
- WE commonly (based on local PT policy) have at least two CLS review and the L/S Thin Layer Plates prior to resulting in the Laboratory Information System. Would this violate the PT policies. **No – if you treat patient testing in the “same manner” and this work workflow is documented in your procedures. Remember to identify in the PT event documentation and attestation all testing personnel.**

Testing FAQ

- Can I run the PT samples in duplicate? **No – unless this is how you perform all patient testing and this work flow is described in your procedures.**
- I have no routine patient testing scheduled but I do have a “Stat” to run, can I run the PT samples with the “Stat”? **yes – this would be defined as performing in the same manner as patient testing.**
- Can I use the PT sample for competency or correlations at any time after the PT event. **Even though this practice is allowed under unique circumstances and criteria, the recommendation of the SCPMG Laboratory System is that the material not be used for any other reasons.**
- Is it required to rotate Proficiency Testing samples among staff. **Yes as best as you can under the restrictions of resources, competency, and staffing.**
- It's easier for the supervisor and lead to perform all the PT testing, can I justify this because of resource issues. **No unless the supervisor and lead are your primary testing personnel.**

Do

- Do notify your PT provider if discontinuing testing or changing enrollment of a regulated analyte.
- Do notify your Accrediting Agency of regulated and non-regulated testing changes.
- Do enroll PT per CLIA certificate, not per site or location. Example: multi site hospitals with multiple CIA numbers and locations need multiple PT events.
- Do rotate PT materials among all shifts and personnel where possible.
- Do select a primary instrument to test PT samples.
- DO keep all documentation of the PT event including identification of testing personnel and copies of the attestation.

Do Not

- Do Not use PT samples for other purposes.
- Do Not discuss PT results with another laboratory including another co-workers who may be working in another laboratory.
- Do Not perform the same PT event if performed and working in another laboratory.
- Do Not change PT enrollment until one year of successful participation.
- Do not change PT enrollment in the middle of the calendar year.

Reporting concerns or questions about Proficiency Testing

Local Contacts:

Leads, Supervisors, Manager, Director

Regional Contacts:

Louie Farnacio, SCPMG Quality System Leader: louie.m.farnacio@kp.org, 1-818-503-7029 (teline 397)

Fred Ung, SCPMG Director of Laboratory Compliance & Quality: fred.x.ung@kp.org, 1-818-503+-7025 (teline 397)

Kaiser Compliance Hotline: 1-888-774-9100