

Proficiency Testing Interlaboratory Communication—Strategies for Prevention

Know What to Watch for: Four Scenarios

Each scenario below resulted in the laboratory being cited for PT interlaboratory communication. Review the scenarios to identify how your laboratory may be at risk and review potential steps to reduce your risk.

Know the Risks

Large integrated delivery networks or large medical centers can be at risk for an increased likelihood of inappropriate proficiency testing (PT) communication. The laboratories, which may have separate CLIA certifications, think of themselves as part of the main laboratory and appropriately treat their patients in the same manner. But this can result in dire consequences for the group if PT is treated exactly like a patient's specimen, crossing CLIA-defined lines of what constitutes a laboratory. Additionally, if there is a common information system and sharing of personnel, the network or medical center may incur additional risk for inadvertent PT communication.

Know the Requirements

CMS:

§493.801(b) Standard: Testing of proficiency testing samples
(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any interlaboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent.

Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

CAP:

COM.01800 PT Interlaboratory Communication Phase II

There is no interlaboratory communication about proficiency testing samples allowed until after the deadline for submission of data to the proficiency testing provider.

Know the Penalties

PT interlaboratory communication is a violation of federal law. Penalties for a first offense include:

- Compliance with a directed plan of correction, such as training
- Civil monetary penalty—penalty amounts determined by several factors, such as nature, scope, and severity. The ranges for penalties can be \$3,050 to \$10,000 per day of noncompliance or per violation.

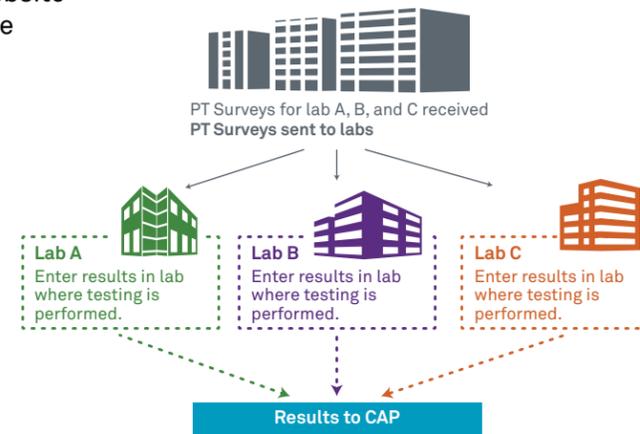
Questions? Email us at accred@cap.org or call 800-323-4040 or 847-832-7000 option 1 (Country code 001).

Scenario 1

A point-of-care (POC) supervisor ordered CAP Surveys (proficiency tests) for three affiliated laboratories under each individual laboratory's account/CLIA number. Surveys were received at the main laboratory and were delivered to the affiliated laboratories for testing. Results were returned to the POC office at the main laboratory where the POC supervisor entered results on the CAP website for each Survey for the three affiliated laboratories.

Prevention:

- Enter results at the affiliate laboratory where testing is performed, even if the POC supervisor enters results for all three affiliates.

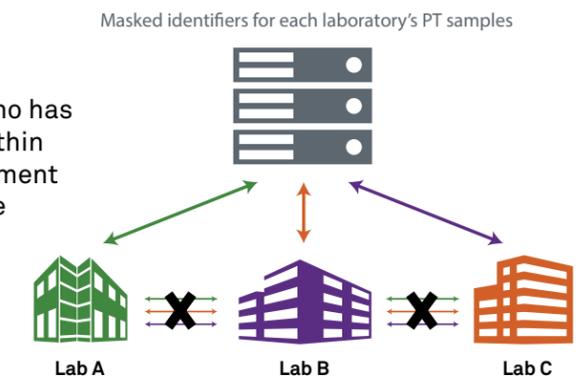


Scenario 2

A medical center with multiple CLIA and CAP numbers uses a common laboratory information system (LIS). The first laboratory to perform PT used the CAP-provided identifier, so other laboratories had easy access to see the PT results before they entered their own results.

Prevention:

- Create safeguards, such as procedures and training, to prevent interlaboratory communication.
- Audit records to identify who has accessed the PT results within the LIS. There is no requirement that laboratories can't have a common LIS.
- Create masked identifiers for each laboratory's PT samples.

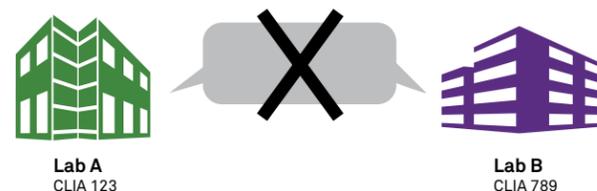


Scenario 3

A tech from Laboratory A was using PT for competency assessment prior to the submission deadline. The tech questioned the result but didn't want to ask the supervisor; instead, the tech contacted Laboratory B to discuss results. Laboratory B recognized that the specimen was a current PT sample and self-reported the inappropriate interlaboratory communication.

Prevention:

- Create policies and train staff that there can be no interlaboratory communication regarding PT samples between two laboratories with different CLIA numbers until after the deadline for submission of data to the PT provider.
- Utilize the CAP's Quality Cross Check programs for competency assessment or assessment of instrument comparability. Quality Cross Check is not a PT program and can be used for various non-PT purposes.



Scenario 4

A laboratory tech was unsure of the cell identification for a CAP Survey. The tech followed the process for patient testing and called the main laboratory to discuss the particular challenge with the supervisor. After this discussion, the tech reported the identification provided by the supervisor from the main laboratory.

Prevention:

- Create policies and train staff that there can be no interlaboratory communication between laboratories with different CLIA numbers about PT samples until after the deadline for submission of data to the PT provider.
- Report only those PT results obtained by personnel within their own laboratory location, not an affiliate laboratory.

