**PROFICIENCY TESTING
REFERRALS and SANCTIONS
The History of CLIA88 and the TEST Act**

The laboratory consultant community is beginning to see requests from laboratories for education on proficiency sample referral. One most recent request prompted an investigation into Taking Essential Steps for Testing Act of 2012 (TEST Act) Final Rule

The Clinical Laboratory Improvement Amendments (CLIA) were passed by Congress in 1988 establishing standards for all laboratory testing to ensure the quality and accuracy of clinical laboratory testing. The final CLIA regulations were published in the Federal Register in February 1992. The requirements for laboratory compliance are based on the Food and Drug Administration determined complexity of the test being performed and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.

The Centers for Medicaid and Medicare Services (CMS) provides guidance to clinical laboratories in a variety of brochures designed to help explain the Clinical Laboratory Improvement Amendments (CLIA) regulation requirements. In 2008, they published t**he** CLIA Brochure #8 - Proficiency Testing. In this brochure, CMS describes what proficiency testing (PT) is, why it is important and the regulations that govern how it should be performed.

In this document, it is stated that proficiency samples should not be treated any differently than patient samples and it also states the list of actions a lab must never take in regards to proficiency testing.

* **NEVER send PT samples out of the laboratory for any reason, even if normal patient samples are referred for reflex testing or confirmation**
* **NEVER send PT samples to another laboratory even if you send your patient samples to another laboratory if testing platform is unavailable.**
* **NEVER discuss PT result with another laboratory**
* **NEVER enter into a discussion with another laboratory about their PT results**
* **NEVER run PT samples in your laboratory that is referred from another laboratory. DO NOT TEST and notify your accrediting agency of the occurrence immediately.**

**Having said all of this, allow me to speak for most of lab techs that we are rules dominated by nature. Would we cheat on a test, no. Would we fudge a number, no. Would we disregard the proficiency testing “NEVER LIST”, no.**

**BUT CONSIDER THE FOLLOWING SITUATIONS:**

* **In the spirit of mimicking the routine patient testing scenario and in order to blind the testing from the laboratory staff, a laboratory accessions a proficiency test under an assumed patient name and it enters the routine workflow. The laboratory normally reflexes testing for confirmation on this particular test and this patient sample inadvertently gets sent out to the lab’s reference laboratory for confirmation.**
* **A laboratory performing patient testing encounters instrument downtime and in the flurry to send backlogged patient samples to an alternate testing site while they get their instrument up and running, a proficiency testing sample to be run that day gets send to another lab for testing with the routine referred workload.**
* **A laboratory manager randomly gives proficiency testing to a part time employee who responds, “Great, I had to do this PT at my other part-time job and it took 2 tries for us to confirm the faint line as a positive.”**

During the first 14 years in which sanctions were documented 78 laboratories are recorded as having received a principal sanction or denial of accreditation because of PT sample referral or communication. These sanctions were imposed regardless of the situation that led to the PT referral. Additionally, in the period of 1993 to 2006, there were more than 30 appeal hearings and CMS prevailed in all of the appeal decisions.

CMS was given no flexibility by the law in the application of sanctions to allow for cases in which a laboratory might reasonably have been acting in good faith and intended merely to treat the PT sample as it would treat a patient specimen, including referring it to another laboratory for additional testing. The severest of sanctions have been inflicted upon laboratories regardless of whether the referral was intentional or inadvertent. This has included revoking the lab’s CLIA certificate. In these situations, the organization is banned from owning a laboratory for two years and the laboratory director is banned from directing a CLIA-licensed laboratory for two years. Additionally, by regulation, a CLIA certificate can be revoked for a laboratory owned or operated by a person who owned or operated another laboratory that had its CLIA certificate revoked for any reason during the preceding two years.

SANCTIONS: Does the time match the crime?

Studying the specifics of PT Referral or Communication sanctions imposed upon laboratories led to the following conclusions:

* Regulations from CMS lacked specificity about what is allowed and what is not allowed.
* CMS had no latitude to minimize sanctions based upon the circumstances of the referral.
* The consequences of sanctions imposed for laboratories that referred testing inadvertently were severe and appeals were denied.
* Impact of inadvertent disclosure sanctions had negative impact upon patient populations.

As a result of these issues, Congress passed the “Taking Essential Steps for Testing (TEST) Act of 2012,” H.R. 6118 (8). This amendment to the CLIA law, was signed by President Obama at the end of 2012 and was intended to provide the Secretary of Health and Human Services with some discretion in regards to unintentional PT referral. The TEST Act provides clarity that the sending a PT sample to another laboratory is prohibited despite the requirement that PT samples be treated like patient specimens.

The TEST Act gives the Secretary discretion as to whether to revoke a laboratory’s CLIA certificate for one year in the case of a PT referral violation (replacing mandatory revocation). The TEST Act gives the Secretary discretion to substitute intermediate sanctions in lieu of a mandatory two-year ban on a laboratory’s owner/operator when the laboratory’s CLIA certificate is revoked for this reason.

In May 2014, the Taking Essential Steps for Testing Act of 2012 (TEST Act) was fully implemented and three categories of sanctions (most serious, moderate violations and less serious) were established for proficiency testing referral.

The final rule clarifies that a referral would not be considered ‘intentional’ if

* the PT sample referral was sent to another lab for reflex or confirmatory testing
* the referral was not a repeat offense
* the referral “occurred while acting in full conformance with the laboratory’s written, legally accurate, and adequate standard operating procedure”

Most serious violations
Cases of repeat PT referral or cases in which a laboratory intentionally reports another laboratory’s test results as its own constitutes the most serious category of violations. Serious sanctions include revoking the CLIA certificate for at least one year, banning the owner/operator from owning and operating a CLIA-certified laboratory for at least one year and potentially imposing a monetary penalty.

Moderate violations
A referral violation is considered moderate If the following 3 criteria are met:

* a laboratory refers a PT specimen to another facility (different CLIA license) before the PT event close date
* the laboratory reports its own results to the PT program
* The laboratory receives results from the referral laboratory before the event close date.

Moderate referral violation penalties could be suspension or limiting of the CLIA certificate by CMS for less than one year as well as alternative sanctions such as training for the laboratory staff.

Least Serious Violations
Violations are considered in the least serious category when the samples are referred prior to the PT event close date but the laboratory does not receive the results prior to the PT testing event cut-off date. Least serious sanctions would include payment of a civil monetary penalty and compliance with a directed plan of correction, including staff training.

If a conscientious laboratory chooses to mimic the pre-analytical process by reporting testing through the laboratory information system (LIS), what can be done to better insure against accidental referral?

* Some laboratories have developed a mock proficiency testing patient that can be flagged post analytically to prevent send out referral testing.
* Another solution has been to create set of test equivalents for proficiency testing. The PT test equivalent will not automatically reflex and/or cannot be transferred to a send out log.
* Additional LIS solutions are to create a search function that lives on the LIS to review send out logs real time to stop proficiency referrals.
* Receiving laboratories can develop a similar LIS search function to review incoming testing real time to search for common proficiency identifiers, “PT”, “CAP”, “API”, “Event” or the year imbedded in the patient demographics could be flagged and stopped before testing. Receiving laboratory must refer these events to administration because they are required to report the event to their inspection agency.

**It would be wise to take to heart the attestation statement that is signed each time a lab performs a proficiency test,**

**We the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing (PT) materials, have as closely as is practical, performed the analysis on these specimens in the same manner as regular patient specimens. We confirm that results were not shared or PT specimens referred or tested outside our CLIA identification number.**

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