

# CLIA Corner

State Hygienic Laboratory at The University of Iowa

Second Quarter 2016



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## In This Issue of the CLIA Corner we address:

- **Proficiency Testing – Testing of Samples**
- **Announcements: Nancy Grobe Sets Retirement for Fall 2016 and Welcomes Iowa's New CLIA Laboratory Surveyor, Melinda Bochmann**

## Proficiency Testing – Testing of Samples

The laboratory must enroll in a CMS-approved proficiency testing (PT) program for all regulated specialties, subspecialties and analytes they perform. The list of regulated specialties, subspecialties and analytes is found in the Code of Federal Regulations, 42 CFR part 493, subpart I. The laboratory may also enroll in a PT program to verify the accuracy of non-regulated tests.

For regulated tests, the PT program offers modules containing at least three (3) testing events annually with a minimum of five (5) samples per event (excluding mycobacteriology, which only needs two (2) testing events annually). For non-regulated tests, the number of events may vary from two or three events per year with a various number of samples provided.

Under the regulation, §493.801 Condition: Enrollment and testing of samples, the laboratory must test the PT samples in the same manner as patients' specimens. Here are the requirements that the laboratory must meet when testing PT samples.

- 1) PT samples must be examined or tested in the same manner as its patient specimens. If the laboratory's patient specimen testing procedures would normally require reflex, distributive or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until

the point it would refer a patient specimen to a second laboratory for any form of further testing. In other words, if a laboratory routinely performs only presumptive testing or screening methods and refers patient samples to another laboratory for definitive or confirmatory testing or comparison of test results, the laboratory **must not refer PT samples to another laboratory for confirmatory testing.**

- 2) PT samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory, using the laboratory's routine methods.
- 3) The individual who tests or examines the PT samples as well as the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine method.
  - For most specialties and subspecialties except for histopathology and immunochemistry (high complexity testing), the laboratory director may delegate this responsibility, in writing, to the technical supervisor for high complexity testing or technical consultant for moderate complexity testing.
  - The signature of the director or technical consultant/supervisor need not be obtained prior to reporting PT results to the PT provider.

- 4) The PT samples must be tested the same number of times that the laboratory routinely tests patient samples. The laboratory can repeat the testing or run in duplicate only if this is the laboratory's procedure for testing its patient specimens.
- 5) The laboratory must not engage in any inter-laboratory communications pertaining to the results of the PT samples until after the date by which the laboratory must report PT results to the program for the testing event in which the samples were sent.
  - This includes laboratories with multiple testing sites or separate locations. They 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.
- 6) **The laboratory must NEVER, NEVER send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory.**
  - Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year.
  - If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with § 493.1804(c), but not intentional.
  - Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason. The regulation refers to referral of PT specimens to another laboratory for analysis.
  - For those tests not listed under Subpart I (not regulated), the laboratory is free to enroll in a PT program to verify the accuracy of their test or procedure. Due to the breadth of the statutory bar on PT sample referrals, however, laboratories should take great measures to avoid sending any such PT samples (or test results) to another laboratory for any reason prior to the PT testing event cutoff date. The PT referral consequences (loss of certificate and bar on owner/operator) apply equally to all PT testing samples and results.
  - **Bottom line – DO NOT send PT samples to a reference or another laboratory site for ANY reason.**
- 7) **DOCUMENT, DOCUMENT, DOCUMENT** – The laboratory must document the handling, preparation, processing, examination and each step in the testing and reporting of the results, including the dates and laboratory personnel identity.
- 8) The laboratory must maintain a copy of all PT records for a minimum of two (2) years, which includes the following:
  - PT program forms used by the laboratory to record and submit the PT results. If the laboratory submits its results electronically to the program, the laboratory either must be able to retrieve a copy or retain a printout of these results.

- Attestation statements signed by the analyst(s) and the laboratory director, or technical consultant/supervisor;
  - PT program reports and summaries; and
  - All testing records (e.g. instrument printouts, worksheets, etc.).
- 9) PT is required for only the test system, assay or examination used as the primary method for patient testing during the PT event.

#### 10) Excused from Participation

If a problem (e.g. instrument failure, personnel on emergency leave, test kit or reagent back ordered, etc.) occurs that will temporarily suspend patient testing at the time of the PT event and delay reporting the results to the PT program until after the due date, **the laboratory must do the following to be excused from participation:**

- Suspend patient testing during the time frame allotted for testing and reporting of the PT samples;
- Notify inspecting agency and PT provider within the time frame for submitting PT results with the reason(s) that the laboratory is unable to test the PT samples; and
- Be a participant in the previous two (2) PT testing events.

#### **TIPS for Successful PT Testing**

- ✓ Check that your laboratory is enrolled for all regulated testing it performs.
- ✓ Review the PT program's shipping schedule, testing timeframe and reporting deadline for each testing event.
- ✓ Follow the PT program's instructions exactly for handling, storage, processing and testing of the PT samples.
- ✓ If there are any problems with the PT samples, contact the program immediately and document the actions taken.
- ✓ Check that testing is being rotated to include all testing personnel on all shifts.
- ✓ Perform instrument maintenance, controls and calibration in the same manner as for patient testing.
- ✓ Save the PT samples for repeat testing.  
If your laboratory uses PT samples for comparison of method studies or to assess competency, for these purposes, the PT samples should be tested only after the date the results were submitted to the PT program. A better way to avoid any problems is to wait until the laboratory receives its scores/report from the PT program.

You can find the CLIA regulations and interpretive guidelines referenced in this article at: [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/App-C\\_Survey-Procedures-IGs-for-Labs-Labs-Svcs-Final.pdf](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/App-C_Survey-Procedures-IGs-for-Labs-Labs-Svcs-Final.pdf).

# Announcements

## *Nancy Grobe's Retirement*

After more than 24 years with the Iowa CLIA Laboratory Program, Nancy plans to retire in late fall. She will continue to work for the program on a part-time basis so you may see her name on the CLIA Corner. Upon Nancy's retirement, Kristi Rotzoll will take over as the program's manager.

## *Introducing Iowa's New CLIA Surveyor*

We are pleased and excited to announce the newest member of our team. Melinda Bochmann, BA, MT(AMT), started on April 11, 2016, as a CLIA Compliance Specialist. She received her bachelor of arts degree in biology from Wartburg College in Waverly, Iowa. Her work experience includes six years as a medical technologist at an independent laboratory followed by three years as a technical consultant for a hospital and its clinics.

