

UPH PROFICIENCY TESTING REFRESHER

CAP Review, Proficiency Testing

PROFICIENCY TESTING FOCUSED REVIEW

- UnityPoint Health Hospital and Clinic Laboratories are under focused review due to a issue that occurred in the Cedar Rapids region.
- A clinic changed it's physical address but forgot to change the mailing address for the PT material. When the clinic reported the PT, the addresses did not match so it appeared that the clinic referred PT testing out to be performed.
- This is a violation of self referral as outlined in CLIA.
- Cedar Rapids was fined by CMS and the clinic is no longer performing lab work at that site.
- As a result of this issue, CMS focuses on the entire UnityPoint Health System (hospitals and clinics) regarding appropriate Proficiency Testing handling.
- The state of Iowa performed a surprise inspection on one of Des Moines Clinics with focus on employee training and appropriate PT testing.
- Part of the corrective action response is to review PT regulations.

PT REGULATIONS - CAP

- COM.01400 PT Attestation Statement Phase II
- **The proficiency testing attestation statement is signed by the laboratory director or designee and all individuals involved in the testing process.**

NOTE: Physical signatures must appear on a paper version of the attestation form. A listing of typed names on the attestation statement does not meet the intent of the requirement.

The signature of the laboratory director or designee need not be obtained prior to reporting results to the proficiency testing provider. Designees must be qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing. For high complexity testing, it may be delegated to an individual meeting the qualifications of a technical supervisor or section director, e.g. must be a pathologist.

For moderate complexity testing, it may be delegated to an individual meeting the qualifications of a technical consultant. This can be an MT (MLT does not qualify).

PT REGULATIONS - CAP

- COM.01600 PT Integration Routine Workload Phase II
- **The laboratory integrates all proficiency testing samples within the routine laboratory workload, and those samples are analyzed by personnel who routinely test patient/client samples, using the same primary method systems as for patient/client/donor samples.**

PT REGULATIONS - CAP

- COM.01800 PT Interlaboratory Communication Phase II
- **There is a policy that prohibits interlaboratory communication about proficiency testing samples** until after the deadline for submission of data to the proficiency testing provider.
 - Includes:
 - **Having other personnel also run specimens to compare**
 - **Sending to another lab (UPH or any other lab)**
 - **Running on more than one instrument / using a different methodology**

PT REGULATIONS - CAP

- COM.01900 PT Referral Phase II
- **There is a policy that prohibits referral of proficiency testing specimens to another laboratory or acceptance from another laboratory.**
 - Note that we are obligated to report to CAP if we suspect a lab referred PT material to us to perform.
 - We are obligated to educate staff to understand about referral of PT.
 - **Penalty may include loss of CLIA license which is a lab death sentence.**

PT REGULATIONS - CAP

Thank you for your time and attention!

