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Proficiency Testing (PT)

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Objectives

- Define Proficiency Testing (PT)
- Understand the importance of PT
- Understand receiving, testing, handling, identifying and record retention of PT samples
- Understand severity of consequences if there is interlaboratory communication prior to deadline of submission.
- Understand severity of consequences for referring PT samples to another lab.
- Understand requirements for staff training
- Know the common PT samples used in the laboratory
- Understand Atrium Health Wake Forest Baptist Medical Center Proficiency Testing Policy:
- Understand PT regulations
- Complete the on-line test.

What is Proficiency Testing (PT)

- Proficiency testing or PT is the testing of unknown samples sent to a laboratory by a CMS approved PT program.
- Proficiency testing is required for any lab that performs testing on human specimen.
- Most PT samples are sent to participating laboratories two or three times per year by Centers for Medicare and Medicaid Services (CMS) approved PT program provider.
- CMS and accreditation organizations routinely monitor the laboratories' PT performance.

Why is PT important?

PT is a tool that the laboratory can:

- use to verify the accuracy and reliability of its testing

- use to validate the entire testing process, including competency of the testing personnel

- alert to areas of testing that are not performing as expected

- use to indicate subtle shifts and trends that, overtime, would affect the patient's results

Receiving PT Samples in the Lab

- **Proficiency Kit**: A complete set of materials (either physical or online) required to perform and report results for a PT program. Items may include specimens and kit instructions.
- Open your kit as soon as possible upon receipt. Visually inspect the material for any damage and verify it has arrived at the appropriate temperature (see kit instructions).
- Any problems identified with the PT sample, follow your lab policy and notify your manager.
- Handle and store all PT samples according to PT provider instructions, your lab policy and procedure.

Testing PT Samples

- **Before you start testing, thoroughly read each kit instructions for the up-to-date information.**
- **Do I test my PT samples any differently than I test patient specimens?** ***NO***
  - PT samples must be tested in the same manner you test patient specimens.
    - Test PT samples the same number of times, at the same time, by the same personnel that routinely test the patient specimens.
    - Use the same test system that is routinely used for the patient specimens.
    - Some PT sample may require preparation before testing. But, after preparation, PT samples must be treated in the same manner as patient specimens.
  - PT samples should be rotated among the testing personnel.
  - **NEVER send PT samples out of your laboratory for any reason, even if you routinely send out patient specimens for additional or confirmatory testing.**

Attestation Statement

- An attestation statement is a page included in the result form attesting to the routine integration of the PT samples into the patient workload using the laboratory's routine methods.
- The individual testing or examining the PT samples and the Laboratory Director (or designee) ***must*** sign the attestation page.
- Retain a copy of signed attestation page for your laboratory records and inspection documentation for the appropriate time. This document does not need to be returned to the CAP.

Retention of PT Results, Records and Data

All PT records must be retained according to the laboratory record retention policy.

- Examples of some records to retain (electronic or paper):
  - QC and Calibration records
  - Maintenance records
  - Instrument printout, manual worksheets, logs
  - All images
  - PT results on the test result form
  - Signed attestation statement
  - Review of PT evaluation
  - Records of unacceptable PT investigation and corrective action

Proper and Improper Handling of PT

- Proper handling of PT samples:
  - No interlaboratory communication before the PT event cut-off date.
  - No intentional or unintentional referral of PT sample to another laboratory.
  - Identify PT samples that are sent to your lab from another lab.

- Improper handling of PT samples:
  - Interlaboratory communication before the PT event cut-off date.
  - Referring PT sample for any reason intentionally or unintentionally to another laboratory.
  - Receiving and performing a test on a PT sample from another laboratory.

For more information: Refer to Atrium Health Wake Forest Baptist Proficiency Testing Policy

Interlaboratory Communication

- **May I discuss my PT results with another laboratory? *NO***
  - ***NEVER*** discuss your PT results with another laboratory and ***NEVER*** enter into discussion with another laboratory about their PT results before the PT event cut-off date.
  - Any laboratory that discusses results of PT, prior to the deadline for submission to the PT provider could cause loss of CLIA certificate coverage for at least 1 year.

PT Samples Referral

- **PT referral means any instance in which a PT sample, or a portion of a sample is referred, for any reason, to another laboratory for testing before the PT program event cut-off date.**
- **What do I do if I receive PT samples from another test site?**
  - **DO NOT TEST** the samples.
  - **Immediately notify your manager.**
  - **Immediately notify the Laboratory Director listed on the CLIA certificate and the Quality, Safety and Accreditation Director.**
- A laboratory may not accept a specimen for testing from another laboratory if the specimen appears to be a PT sample.
- Laboratory must notify CMS and CAP if it receives an improperly referred PT specimen.

For more information: Refer to Atrium Health Wake Forest Baptist Proficiency Testing Policy

PT Samples Referral

- **May I send my PT samples to another laboratory? *NO***
  - **NEVER** send your PT samples to another laboratory, even if you send your patients' specimens to another laboratory for confirmation.
  - Discussing results and/or sending PT samples to another laboratory for testing is considered PT referral and will cause serious actions or penalties against your laboratory.
  - Even if a lab accidentally sends a PT sample to another lab for testing, the lab may still be held accountable for referring PT sample.
  - The penalties include:
    - Loss of your laboratory's CLIA certificate for at least one year
    - Your director cannot direct a laboratory for two years
    - Your laboratory owner may not own or operate a laboratory for two years.

Even if it's common practice for patient specimens, do not refer PT samples to another lab for analysis.

Identifying PT Samples

- **How do I identify PT samples received from another laboratory?**
  - **The PT samples are usually named with unusual combination of letters and numbers. In other words, the first name and last name are not usual patients' name.**
    - **Example:**
      - **API, GLU-04**
      - **CAP, UA-02**
      - **CAP, CHM-05**

PT Results Evaluation

- Review your evaluation and participant summary
  - Look for any unacceptable results. Reasons for unacceptable results may include:
    - Incorrect or incomplete method/instrument data
    - Clerical error
    - PT sample handling error
    - Analytical error
  - Remember, whatever the cause, all PT deficiencies must be investigated, and corrective action must be taken to resolve the deficiency.
  - All ungraded PT results (including educational challenge) must be evaluated for accuracy.

Review your PT evaluation report for ungraded, unacceptable and trending PT results.

Unsuccessful PT Performance

- **If your laboratory has never had an unsuccessful performance for any PT analyte, subspecialty, or specialty, the CLIA regulations, under certain circumstances, permit technical assistance and training to take place, rather than a more serious sanction.**

- **However, repeated unsuccessful PT performance for the same analyte, subspecialty or specialty may result in your laboratory no longer being allowed to perform testing for the failed analyte, subspecialty or specialty.**

Staff / Team Members Training

- **Are there requirements for training of staff regarding PT referral?**
  - Yes, checklist item COM.01900 requires laboratories have a policy prohibiting referral of PT to another laboratory or accepting PT from another laboratory.
  - Proficiency testing specimens are not referred to other laboratories and are not accepted from other laboratories for analysis.
  - Staff involved in the PT process should be trained to this policy, and documentation of this training is highly recommended.
  - Regulations regarding the handling, testing, and reporting of PT are complex and can be violated unintentionally if not well understood.

CLIA APPROVED PROFICIENCY TESTING PROGRAMS

- CLIA provides a list of approved PT program providers.
  - The two main PT program providers that are used throughout the Atrium Health Wake Forest Baptist System are:
    - The College of American Pathologists (CAP) and
    - American Proficiency Institute (API)

Note: The only approved PT at any AH WFBMC laboratory is CAP. If a PT sample from API arrives at any AH WFBMC laboratory, the sample should be given to the Lab Manager immediately. If the Lab Manager is not available (afterhours or out of office for other reasons) the API sample should NOT be processed but held until any lab manager is available to take the sample. The Manager, CLIA Laboratory Director and the Quality, Safety & Accreditation Director must immediately be notified.

Example of PT Samples - From College of Americans Pathologists (CAP)

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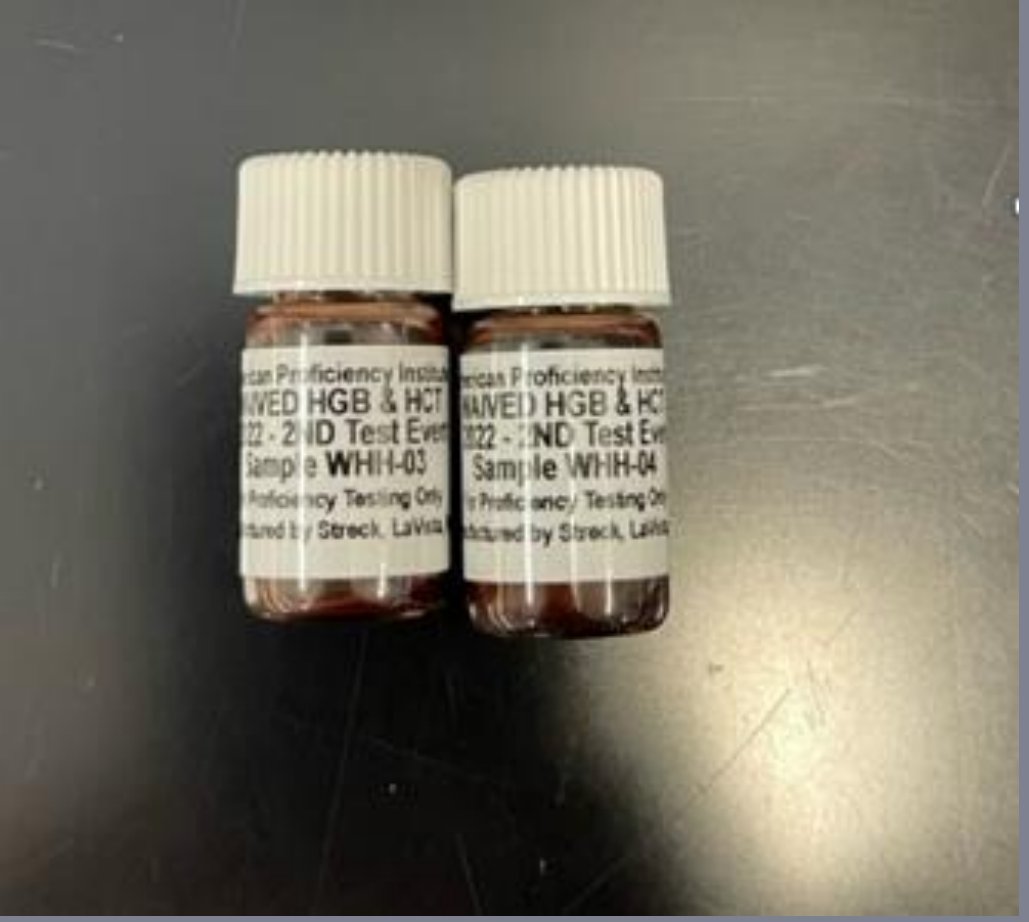

Example of PT Samples - From American Proficiency Institute (API)

Atrium Health Wake Forest Baptist Medical Center Proficiency Testing Policy: QUAL-POL-0012

- *On page 5* of the Proficiency Testing Policy, *Section C, #2: PT Referral* states "**Do not refer PT specimen to another laboratory or accept PT specimen from another laboratory**".
  - This policy strictly prohibits referral or acceptance of proficiency testing specimens for analysis from other laboratories. This prohibition takes precedence over the requirement that proficiency testing specimens be handled in the same manner as patient specimens.

CLIA PT Regulation

CLIA Federal Regulation (section 493.801)

- The Clinical Laboratory Improvement Amendments (CLIA) law and regulations require that all laboratories enroll in approved proficiency testing programs.
- In addition, the laboratory “must test [proficiency testing] samples in the same manner as [the laboratory] tests specimens”.
  - This means that personnel who routinely perform the testing should test PT samples with the laboratory’s regular workload.
    - As an example, if a laboratory tests a patient specimen only once before reporting, then PT specimens also must be run only one time, not in duplicate, before reporting.
    - It also means that the testing of PT samples should be rotated among all staff members who routinely perform the patient testing.

CLIA PT Regulation

Condition: Enrollment and testing of samples

- Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory 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.

CLIA PT Regulation

Condition: Enrollment and testing of samples

- The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

- The laboratory must test samples the same number of times that it routinely tests patient samples.

CLIA PT Regulation

Condition: Enrollment and testing of samples

- The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory

- Any laboratory that CMS determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year.

- Any laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples.

CLIA PT Regulation

Condition: Enrollment and testing of samples

- The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must test samples the same number of times that it routinely tests patient samples.

- The laboratory must maintain a copy of all records, including:
  - a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results.
  - the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens.
  - maintain records (according to the laboratory's record retention policy) from the date of the proficiency testing event.

CLIA PT Regulation

Condition: Successful participation

- Each laboratory performing testing on human sample must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

Penalty Categories for PT Referral

"Whether or not acts are authorized or even known by the laboratory's management, a laboratory is responsible for the acts of its employees," the CMS says in the May 12 rule. "Among other things, laboratories need to have procedures in place and train employees on those procedures to prevent staff from forwarding PT samples to other laboratories even in instances in which they would normally forward a patient specimen for testing."

Penalty categories for PT referral

Category	Detail of violation	Penalty
First	Repeat PT referrals or cases where a laboratory reports another laboratory's test results.	◆ Revoke the CLIA certificate for at least one year ◆ Ban owner and operator for at least one year ◆ Civil monetary penalty*
Second	A laboratory refers PT sample to a laboratory that operates under a different CLIA number before the PT event close date and, while the laboratory reports its own results to the PT program, it receives results from the second laboratory prior to the event close date.	◆ Suspend or limit CLIA certificate ◆ Civil monetary penalty*
Third	The referring laboratory does not receive test results prior to the event cutoff date from another laboratory as a result of the PT referral.	◆ Comply with a directed plan of correction such as training ◆ Civil monetary penalty*

**Penalty amounts are 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 for conditions that pose immediate jeopardy, or $50 to $3,000 per day of noncompliance or per violation for conditions that do not pose immediate jeopardy.*

Source: https://www.captodayonline.com/pt-referral-rules-bring-regulatory-relief-for-labs/

Examples of PT Referral

Scenario One

Referral Test

- A laboratory CLIA director works with two laboratories, one is a small community hospital laboratory (Lab A), and the other laboratory (Lab B) is a sister hospital that serves as a reference lab. Both are under the same ownership and operations between the two labs are standardized. However, the laboratories are at 2 different addresses and have different CAP/CLIA numbers. Components of tests and some reflex testing are performed at the two laboratories. For example, total serum protein is performed at Lab A and protein electrophoresis is performed by Lab B by using the total serum protein result from Lab A.

Examples of PT Referral

Scenario One Continued…

How to Treat a Patient Specimen

- Lab A would report total serum protein and send the patient specimen to Lab B for the protein electrophoresis.

Examples of PT Referral

Scenario one continued…

How to Treat a PT Sample

- Lab A would need to enroll in a proficiency testing product for total protein and report the total protein the laboratory performs.
- Lab B would need to enroll in a proficiency testing product for protein electrophoresis and report the protein electrophoresis the laboratory performs.
- PT samples and data generated from the PT samples cannot be shared between Lab A and Lab B.
- Each site must be enrolled separately based on location and only for testing that is performed at the location of the laboratory.

Examples of PT Referral

Scenario Two

Reflex and Confirmatory Testing

- Example:
  - A positive GC/Chlamydia Amplification (in urine samples from pediatric patients) requires confirmation and will reflex to Molecular testing which is a send out test.
  - A negative Strep screen result on a pediatric patient will reflex to Throat Culture which is referred to Atrium Health Wake Forest Baptist Medical Center Lab.

Examples of PT Referral

Scenario two continued…

How to Treat a Patient Specimen

- If a laboratory does not perform the confirmatory or reflex test that is indicated and/or required as a result of an initial test result, the specimen would typically be sent to a different, referral laboratory for that testing.

Examples of PT Referral

Scenario Two Continued…

How to Treat a PT Sample

- A laboratory should report PT results for the initial testing that is done in that laboratory. If the laboratory does not perform the confirmatory or reflex testing, then the laboratory should refer to the PT Provider kit instructions on how to record a result for a test not performed in the laboratory. The laboratory is prohibited from sending the PT sample to another laboratory.
- All results and signatures must be confined to the site with the same CAP/CLIA number in which the PT sample was received.

Example of PT Referral

Scenario Three:

- 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 who recognized that the specimen was a current PT sample and self-reported the inappropriate interlaboratory communication.

Example of PT Referral

Scenario three continued…

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 deadline for submission of data to the PT provider.

- Do not use PT samples for competency assessment before the due date.

Conclusion

It is very important to know your policies and procedures regarding Proficiency Testing.

It is very important to know your notification and escalation process in the event of PT Referral and Interlaboratory PT Communication.

Reference

- Proficiency Testing (PT) Manual Available at: https://www.cap.org/gated-assets/uploads/private/cap-proficiency-testing-manual.pdf
- Clinical Laboratory Improvement Amendments (CLIA).Centers for Medicare and Medicaid Services (CMS). Available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia.
- Clinical Laboratory Improvement Amendments (CLIA): Proficiency Testing. Centers for Medicare and Medicaid Services (CMS). Available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/cliabrochure8.pdf
- Centers for Disease Control and Prevention—Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing Available at: http://wwwn.cdc.gov/clia/regs/subpart_h.aspx
- Atrium Health Wake Forest Baptist Medical Center Proficiency Testing Policy can be found in Policy Tech at the following link: Proficiency Testing Policy (NCBH)