Wake Forest™
Baptist Medical Center

Proficiency Testing (PT)

Prepared for WFBH Point of Care Test Groups

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Objectives

- Define Proficiency Testing (PT) and PT requirements—Waived versus Non-Waived
- Understand the importance of proficiency testing
- Understand PT regulations
  - Must successfully participate in CMS-approved PT program
  - Must test PT samples in the same manner as patient specimens by the same personnel that performs patient testing.
  - Understand severity of consequences if there is communication with other test sites, regarding PT results, prior to deadline of submission to PT provider.
  - Understand severity of consequences for referring PT samples to another test site.
- Complete the on-line exam and score 100%.

Proficiency Testing

- Proficiency Testing (PT) is highly regulated by the Federal Government.
  - This information is **not all-inclusive**.

- Our organization must comply with regulations set forth in the Code of Federal Regulations 493.801 Subpart H
    - CDC web site http://wwwn.cdc.gov/clia/regs/subpart_h.aspx

What is Proficiency Testing?

- Proficiency testing is required for any site that performs non-waived testing.
- Proficiency testing or PT is the testing of unknown samples sent to a laboratory by a Centers for Medicare and Medicaid Services (CMS) approved PT program.
- Most sets of PT samples are sent to participating laboratories three times per year.
- After testing the PT samples in the same manner as its patient specimens, the laboratory reports its sample results back to their PT program.
- The program grades the results using the CLIA grading criteria and sends the laboratory scores reflecting how accurately it performed the testing.
- CMS and accreditation organizations routinely monitor their laboratories' performance.

Definitions

- When ‘laboratory’ is referenced in this educational module, the indicated verbiage applies to any site performing ***non-waived*** blood or body fluid testing under the Clinical Lab CLIA certificate.

- This educational module applies to the following **non-waived** point-of-care test methods:
  - i-STAT
  - Hemochron ACT
  - AVOX
  - Medtronic
  - Any other non-waived test methods

Non-Waived POCT Test Sites Managed by the Clinical Laboratory

- CCU
- 7Ardmore
- ECMO
- EP Lab
- Cath Lab
- Respiratory Care
- MRI
- DHP Phlebotomy
- Perfusion
- Interventional Radiology

The list may not be all-inclusive as other non-waived test sites are added.

Proficiency Testing: Waived Tests

- CMS does not require proficiency testing for any test that is waived.
- Currently, there are no point of care test sites that perform waived testing and are also covered by the Clinical Laboratory CLIA certificate.
- There are multiple waived testing CLIA certificates within WFBH.

Why is PT important?

- PT is a tool the laboratory can use to verify the accuracy and reliability of its testing.

- Routine review of PT reports by the laboratory staff and director will:
  - Alert them to areas of testing that are not performing as expected
  - Indicate subtle shifts and trends that, over time, would affect their patient results.

Do I test my PT samples any differently than I test patient specimens?

- 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.
- PT samples should be rotated among the testing personnel in your Point-of-Care test site.
- Please note that some PT sample preparation may be necessary before testing. In other words, after preparation, PT samples must be treated in the same manner as patient specimens.
- **NEVER send PT samples out of your test site for any reason, even if you routinely send out patient specimens for additional or confirmatory testing.**

May I discuss my PT results with another test site?

- NEVER discuss your PT results with another test site and NEVER enter into discussion with another test site about their PT results before the PT event cut-off date.

- Any laboratory or point-of-care test site 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.

What do I do if I am asked to forward my site's proficiency samples to another test site?

- **DO NOT FORWARD the samples.**
- **There are no exceptions!**
- Contact the Director listed on your CLIA certificate and the WFBH Audit and Compliance Office.

  - Dr. A. Julian Garvin is the current WFBH CLIA director for non-waived point of care tests covered by the Clinical Lab CLIA certificate.
    - (i-STAT, ACT, AVOX, Medtronic)

What do I do if I receive PT samples from another test site?

- **DO NOT TEST the samples.**

- Contact the Director listed on the CLIA certificate.

  - Dr. A. Julian Garvin is the current WFBH CLIA director for non-waived point of care tests covered by the Clinical Lab CLIA certificate.

    - (i-STAT, ACT, AVOX, Medtronic)

May I send my PT samples to another test site to see if they get the same results as I do?

- NEVER send your PT samples to another test site, even if you send your patient specimens to another site for confirmation.
- Discussing results and/or sending PT samples to another test site for testing is considered PT referral and will cause serious actions to be taken against:
    - your test site
    - your laboratory
    - your laboratory director
    - the laboratory owner.
- 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.

What must I do if I do not get a passing score when the PT program grades my results?

- **Review the results that were submitted to the PT program**
    - Are there any obvious errors?
    - Clerical or transcription errors are considered incorrect results.
- **You must take remedial actions**
    - Determine the cause of the error or errors
    - Correct the cause of the error
    - Document your actions.
- **Continually monitor the test system performance**
    - Review the results of the quality control materials
    - Discuss with the Clinical Lab Medical Director to be certain the test system is operating properly and producing accurate results.
    - The Clinical Lab Medical Director may want to review the results of the patients tested during the unsatisfactory or unacceptable testing event.
    - Depending upon the test system's performance and the lab director's decision, you may need to contact the manufacturer of the test system for assistance

If I do not successfully participate in PT, what happens?

- 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 that same analyte, subspecialty or specialty may result in your laboratory no longer being allowed to perform the failed testing.

CLIA Federal Regulations

The following slides contain information from the Code of Federal Regulations 493.801 Subpart H

Sec. 493.801 Condition: Enrollment and testing of samples.

- Each laboratory must enroll in a proficiency testing (PT) program that is approved by HHS:

- The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification.

- The laboratory must test the samples in the same manner as patients' specimens.

- The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.

Sec. 493.801 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.

Sec. 493.801 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.

Sec. 493.801 Condition: Enrollment and testing of samples.

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

Sec. 493.801 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.

Sec. 493.801 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 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
    - including 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*) for a minimum of two years from the date of the proficiency testing event.

Sec. 493.803 Condition: Successful participation.

- Each laboratory performing non-waived testing 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.

References

- “Clinical Laboratory Improvement Amendments (CLIA) Proficiency Testing Do’s and Don’ts”

http://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

http://wwwn.cdc.gov/clia/regs/subpart_h.aspx