



Department
of Health

Wadsworth
Center

Hot Topics in NYS Clinical Laboratory Oversight

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Clinical Laboratory Evaluation Program

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CLEP Overview



Clinical Laboratory Evaluation Program (CLEP)

Oversight of clinical laboratories performing testing on specimens originating from New York State.

Elements of oversight:

- On-site survey
- Monitor proficiency testing performance
- Review of laboratory developed tests (LDT)



Today's Topics



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- Regulatory Changes
- Proficiency Testing Monitoring



Regulatory Changes



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Regulation Revision

Part 19 Clinical Laboratory Directors

- NYS Public Health Law requires that all laboratory directors hold a Certificate of Qualification (CQ).
- Part 19 defines the qualifications for a CQ
 - Education
 - Certifying boards
 - Experience



Part 19 Clinical Laboratory Directors

Overview of changes:

- Addition of new certifying boards
 - American Osteopathic Board of Pathology (AOB)
 - High Complexity Laboratory Director board of the American Board of Bioanalysis (ABB)
 - National Registry for Certified Chemists (NRCC)
 - Molecular Genetic Pathology board of the American Board of Pathology (MGB-ABP)



Part 19 Clinical Laboratory Directors

Overview of changes:

- Updated existing definitions
- Introduced new definitions
- Updated list of laboratory director responsibilities

Adopted and became effective on June 12, 2019



Regulatory Revisions

Revisions are also in progress to
Subpart 58-1 Clinical Laboratories



PT Monitoring



Proficiency Testing Requirements

Laboratories must enroll in PT from a CMS-approved PT vendor for all tests described in 42 CFR 493 subpart H and/or subpart I.

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ptlist.pdf>

CMS-Approved Vendors

- CAP
- API
- AAB
- ASCP
- PA
- ACCUTEST
- AAFP-PT
- MLE
- WSLH PT
- Puerto Rico



Proficiency Testing Requirements

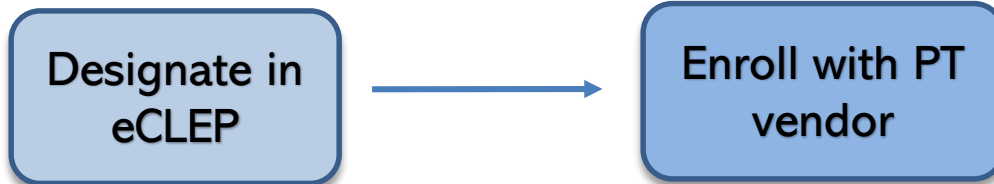
Laboratories must enroll in a PT module approved by CLEP to meet all PT requirements for Subpart I analytes.

In general, the module:

- **Must include 5 samples per event**
- **Must include 3 events per year**



So what do I have to do?



Proficiency Testing Requirements

PT Designation

- Labs must inform CLEP of the intended PT vendor and module/survey for each Subpart I analyte tested
 - Choices in eCLEP include **only** those modules/surveys **approved by CLEP.**
- Designation performed in eCLEP each Fall and upon addition of new permit category AND addition of new Subpart I analyte

Remember – CLEP no longer requires notification of new FDA-approved tests under an approved category **BUT** labs must ‘designate’ a PT vendor when adding a Subpart I test/analyte



Proficiency Testing Requirements

PT Designation

- Labs may decide to purchase PT from a vendor different than the one chosen during PT Designation, HOWEVER:
- The laboratory must use the same vendor for all PT events for a particular analyte for the **entire calendar year**
- The PT vendor and module/survey purchased must be approved by CLEP to meet all PT requirements.



Proficiency Testing Pitfalls

Lab 'designates' through eCLEP from vendor A.

Lab purchases from vendor B.

Possible issue:

- CLEP receives data from vendor A and no results are found
- Potential unsatisfactory performance based on non-participation when vendor B results are received after vendor A results



Proficiency Testing Pitfalls

Lab 'designates' through eCLEP from vendor A for module X, which has been approved by CLEP to satisfy PT requirements (5 samples per event, 3 events per year)

Lab purchases module Y, which is not approved by CLEP. (<5 samples per event and/or only 2 events per year)

Result:

- **Unsatisfactory performance based on non-participation in an approved PT**
- **Lab must enroll with a CLEP-approved module**



Proficiency Testing Requirements

What about analytes not included in Subpart I?

Laboratories must verify the reliability and accuracy of the test results at least twice per year. (Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy)

Options:

- enroll in commercial PT
- re-test blinded specimens
- exchange specimens with another lab
- review clinical outcomes



Proficiency Testing Requirements

Using a commercial PT for non-Subpart I analytes

All NYS PT Standards apply!

<https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-standards>



PT Performance Monitoring

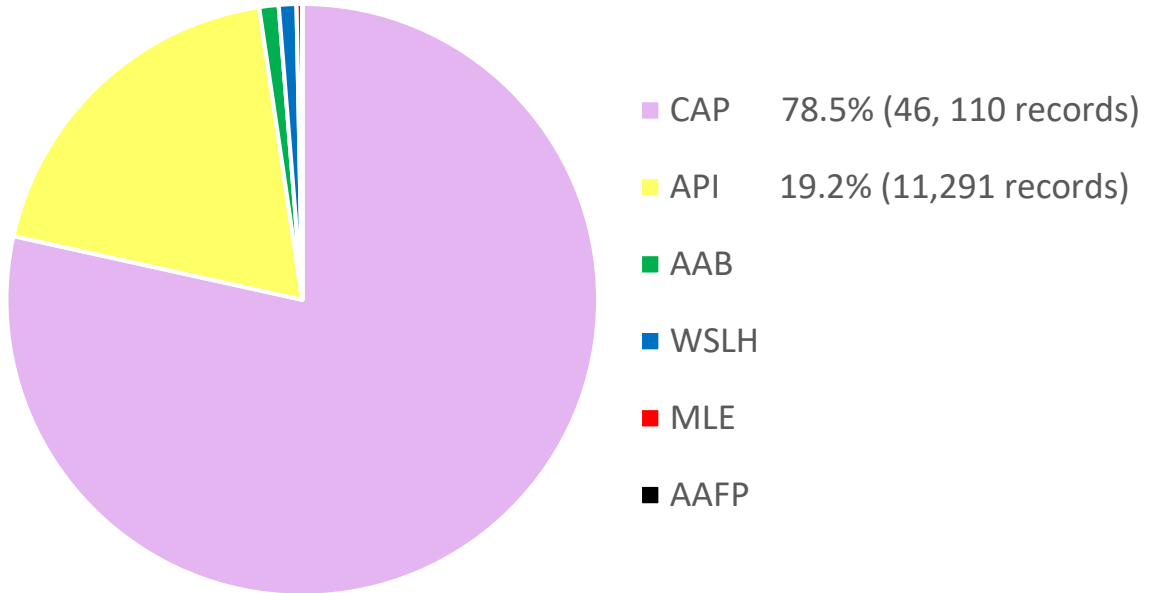
CLEP receives data files routinely from the following CMS-approved PT vendors:

- CAP
- API
- AAB
- Accutest
- AAFP-PT
- MLE
- WSLH PT

PT participation for each Subpart I analyte offered is verified. Labs are notified when results for an analyte are not received from the designated vendor. They are asked to verify their participation in an approved PT for the analyte(s) in question.



2019 Event 1 Proficiency Testing Results by CMS-Approved Provider



PT Performance Monitoring

Scores are received for both Subpart I AND non-Subpart I analytes

Vendors do not mask non-Subpart I PT scores

Data files are reviewed for scores <100 and scores with exception codes



PT Performance Monitoring

Subpart I analytes:

- PT events include a minimum of 5 samples per analyte
- Passing score is 80% (100% in Immunohematology)
- Fail one sample – still a passing score



PT Performance Monitoring

Subpart I analytes:

Fail 2 or more samples – unsatisfactory performance

Unsuccessful performance =

- 2 consecutive unsatisfactory events
- 2 unsatisfactory events out of 3

Consequences:

PT Laboratory Evaluation Report (LER) issued

Lab must respond to the LER

Cease testing order may be imposed!



PT Performance Monitoring

Subpart I analytes:

Subsequent Unsuccessful performance =

- 3 consecutive unsatisfactory events
- 3 unsatisfactory events out of 5

Consequences:

- PT Laboratory Evaluation Report (LER) issued
- **Cease testing order imposed!**
- Lab must respond to the LER
- Lab must perform satisfactorily on 2 consecutive PT events before testing can resume, only 1 event can be an 'off-cycle' PT
- All PT events must be from the same vendor during the calendar year



PT Performance Monitoring

Non-Subpart I analytes:

PT events frequently include 1 to 3 samples per analyte

NYS Passing score is 80%

Fail one sample – unacceptable performance!

1/2 = 50%

2/3 = 66%

1/3 = 33%

Consequence:

Labs may receive a reminder that root cause analysis and corrective action must be performed.



PT Performance Monitoring

Non-Subpart I analytes :

Unsuccessful performance =

- 3 consecutive unacceptable events
- 3 unacceptable events out of 5

Consequences:

PT Laboratory Evaluation Report (LER) issued
Lab must respond to the LER

Cease testing order may be imposed!



PT Performance Monitoring

Non-Subpart I analytes :

Subsequent Unsuccessful performance =

- 4 consecutive unacceptable events
- 4 unacceptable events out of 5

Consequences:

- PT Laboratory Evaluation Report (LER) issued
- **Cease testing order imposed!**
- Lab must respond to the LER
- Lab must perform satisfactorily on 2 consecutive PT events before testing can resume, only 1 event can be an 'off-cycle' PT
- All PT events must be from the same vendor during the calendar year



Proficiency Testing Pitfalls

Lab orders multiple PT sets/kits that include the same analyte

e.g. Module K and Module L overlap several Subpart I analytes

Possible issue:

- Lab may not have had received Module K-A scores before Module L-A PT samples were received, and therefore could not perform corrective action
- Lab fails Module K and Module L for same analyte = unsuccessful



Proficiency Testing Pitfalls

Lab orders PT sets/kits for the same analyte from 2 different vendors

Possible issues:

- Lab fails 1st event from vendor **A**
- Lab fails 1st event from vendor **B** = unsuccessful!
- Lab fails 2nd event from vendor **A** = subsequent unsuccessful!





Get Informed:

www.wadsworth.org/clep

Questions?

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