Clinical Laboratory Evaluation Program

Proficiency Testing Guide

Revised January 2025

NEW YORK STATE | Department of Health | Wadsworth Center

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General Requirements

Mandatory Proficiency Testing Participation

All laboratories applying for or holding a New York State (NYS) clinical laboratory permit must participate in proficiency testing (PT) as defined by NYS. PT participation through a federal Centers for Medicaid and Medicare Services (CMS) – approved provider acceptable to NYS is required for the tests/analytes offered by the laboratory that are listed in 42 CFR 493 Subpart I (CLIA Subpart I) or noted in this document as required by NYS (NYS mandated PT; see Appendix for complete listing).

For analytes with NYS mandated PT, an acceptable PT product must include 5 samples per analyte and offer 3 test events per year (2 for Mycobacteriology). Products are approved by CMS and those acceptable to both CMS and NYS can be found on the Wadsworth Center's website: https://www.wadsworth.org/regulatory/clep/pt/provider-search.

For tests/analytes where PT is not mandated, as determined by NYS, laboratories are required to have an alternate system for verifying the reliability and accuracy of their test results at least twice a year through participation in external PT programs or through the implementation of an internal PT program. When external PT is used as the laboratory's alternate assessment tool for analytes not requiring PT, all NYS Clinical Laboratory Standards of Practice for PT apply.

All laboratories must disclose to the Clinical Laboratory Evaluation Program (CLEP) the CMS – approved PT provider that is being utilized to fulfill federal PT requirements. This is accomplished each fall on the Health Commerce System (HCS) using eCLEP (see PT Designations).

Failure to designate and submit your planned enrollment may result in a citation for non-compliance with PT requirements under NYS Clinical Laboratory Standard of Practice **Proficiency Testing Standard of Practice 1 (PT S1): Enrollment, Department Notification and Participation.**

Rules of PT Participation

Laboratories must adhere to the testing procedures for PT as outlined in this document. Failure to comply with these procedures may result in sanctions being brought against laboratories under state and federal regulations. Laboratories are expected to follow all NYS Clinical Laboratory Standards related to PT.

- Laboratories must authorize their PT provider(s) to send results to NYS (CLEP).
- NYS requires PT for all tests listed as NYS mandated PT analytes even if the laboratory is using a kit listed as CLIA-waived by the federal Food and Drug Administration.
- PT samples must be examined or tested with the laboratory's routine workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods, unless otherwise instructed by the NYS PT program.
- Repeated testing or analysis of proficiency samples is not permitted unless the laboratory performs the same repetitive testing or analysis on patient, donor, insurance applicant or other client samples.
- Laboratories that test proficiency samples must not engage in any inter-laboratory communication or discussion pertaining to the results of test samples until after the date the laboratories are required to report the results to the PT provider.
- Laboratories with multiple testing sites or separate locations cannot participate in any communication or discussion between or among sites/locations concerning test results until after the date the laboratories are required to report the results to the PT provider.
- Laboratories must not send proficiency samples or portions of samples to any other laboratory or location for testing, analysis or review.
- Proficiency samples must not be automatically referred to another laboratory for confirmatory testing under a reflex testing algorithm or distributive testing algorithm, or for any other purpose.
- Proficiency samples must be tested using the laboratory's primary method. The laboratory cannot test duplicate sets of proficiency samples using multiple methods/systems unless they routinely test their patient specimens using multiple methods/systems. After the PT due date has passed laboratories may test their proficiency samples using multiple methods/systems.
- Laboratories that have multiple locations and share a mailroom must have a method in place to ensure the proficiency samples are received by the correct laboratory location.
- Any laboratory that receives proficiency samples from another laboratory for testing must notify CLEP within seventy-two hours of receipt or identification of such samples.
- Any laboratory that has referred its proficiency samples to another laboratory for analysis and/or submitted the other laboratory's results as its own will face administrative sanctions and may have its permit revoked and/or denied for at least one year.

Communication Resources for PT Participation

PT Administration email

ptadmin@health.ny.gov

Clinical Laboratory Evaluation Program (CLEP) website

https://www.wadsworth.org/regulatory/clep

Search publicly available documents:

- Laboratory Standards
- Program Guide
- Permit Modification
- Proficiency Testing

Proficiency Testing Product Search Tool

https://www.wadsworth.org/regulatory/clep/pt/provider-search

HCS Access

The Health Commerce System (HCS) is a restricted website for conducting business with New York State Department of Health: https://commerce.health.state.ny.us

Refer to the CLEP website for information on obtaining HCS accounts and access to eCLEP, the application tool for laboratories to submit changes to the laboratory's operations as well as the laboratory permit reapplication and designation of required PT enrollment.

https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce

The HCS houses the Program application, eCLEP. eCLEP includes a growing number of modules for the collection of information to include:

- **Permit Materials** module for reporting changes to laboratory operations and completing the annual permit reapplication;
- **Proficiency Testing (PT)** module for reporting the laboratory's chosen provider for each calendar year as well receipt of unsatisfactory performance notifications;
- **Gross Annual Receipts (GAR)** module for annual reporting of GAR;
- **LDT Approval** module for viewing the status of validation packages;
- **Survey** module for accessing the laboratory evaluation reports issued after laboratory surveys and unsuccessful PT participation and submission of plans of correction for any deficiencies.
- Other applications located on the HCS include the Electronic Clinical Laboratory Report System (ECLRS) for mandatory reporting of communicable disease testing and the Clinical Laboratory Information Management System (CLIMS) for requesting confirmatory communicable disease testing by the Wadsworth Center Public Health Laboratory.

Approved PT Providers

Laboratories seeking or holding a NYS clinical laboratory permit must successfully participate in proficiency testing for all tests described as NYS mandated PT analytes.

CLEP has screened PT products offered by the CMS-approved PT providers to identify those that meet New York State PT requirements for the NYS mandated PT analytes. Other products offered by these providers do not meet these requirements but may be used to fulfill requirements for assessment of accuracy and validity for analytes that have not been designated as NYS-mandated.

The PT providers listed below have been approved by the CMS as meeting the Clinical Laboratory Improvement Amendments (CLIA) related to PT. They offer PT products that also meet NYS requirements:

- Accutest, Inc. / One World Accuracy
- American Association of Bioanalysts – Medical Laboratory Evaluation (AAB-MLE)
- American Proficiency Institute (API)
- The College of American Pathologists (CAP)
- Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers

A searchable list of NYS approved PT products for NYS mandated PT analytes by permit category is available in the “Proficiency Testing – Product Search Tool” section of the CLEP website at:

https://www.wadsworth.org/regulatory/clep/pt/provider-search

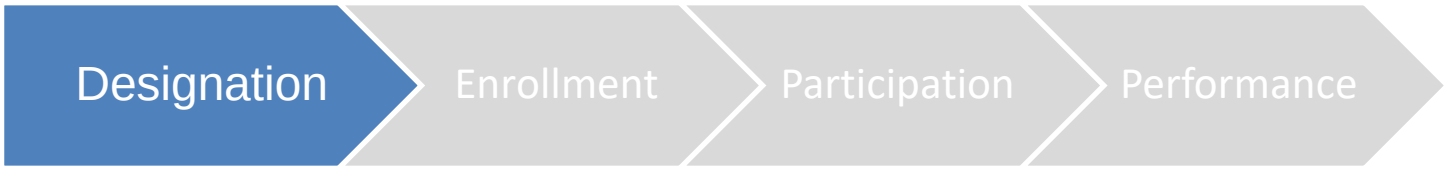
Choosing a PT Product

When selecting for a PT product, laboratories should review the statistical analysis of past events to identify products where:

1) participants utilize similar methods/instruments and
2) the products are graded by the PT provider.

If using an uncommon method/instrument the laboratory should determine how the provider evaluates methods/instruments without a valid peer group.

Laboratories should also be aware of their provider’s ability to send off-cycle test events should the need arise.



PT Designations

Laboratories must notify CLEP of the PT provider(s) and product(s) they will be using for all New York State (NYS) mandated PT analytes via eCLEP on the Health Commerce System (HCS):

- annually during the Fall PT designation period
    - eCLEP Proficiency Testing (PT) Designations module
- when updating their test menu/PT product choices for designated NYS mandated PT analytes at other times throughout the year
    - by email to the PT Administration Group at ptadmin@health.ny.gov
    - the eCLEP Proficiency Testing PT Designations module will be re-opened for updates
    - **It is not sufficient to notify only the CMS-approved PT provider. You must also notify CLEP.**
- when requesting to add a new permit category
    - eCLEP Manual - Permit Materials Module – Add Category request process

Newly applying laboratories - See **New Laboratories section below.*

CLEP has screened PT products offered by these CMS-approved PT providers and identified those that meet NYS PT requirements for NYS mandated PT analytes. A searchable list of NYS approved PT products for NYS mandated PT analytes by permit category is available in the "Proficiency Testing – Product Search Tool" section of the CLEP website at:

https://www.wadsworth.org/regulatory/clep/pt/provider-search

Please note that PT designations for the category of **Cytopathology – Gynecological Testing** is captured during the permit application process each Spring and is not required to be reported during the Fall PT designation period.

Instructions for annual PT designation on eCLEP

- In eCLEP, click on “PT Designations” under Proficiency Testing.
- Click on “PT Designations” on the “Proficiency Testing (PT) – Home” page.
- **Click on “Step 1. Indicate Tests Offered on NYS patients”.**
- Select a permit category from the dropdown menu (only pending or approved permit categories will be displayed) and choose either “Test Offered” or “Test Not Offered” for each NYS mandated PT analyte in the permit category and click “Save”. Do this for all permit categories that you hold or have requested.
- **Click on “Step 2. Designate PT provider and product”.**
- Select the permit category from the dropdown menu (only categories which include NYS mandated PT analytes are displayed) and choose both the PT provider and product you will enroll in for each test/analyte offered. Do this for all permit categories that you hold or have requested.
- **Click on “Step 3. View Designations”.**
- Review the PT provider and product for tests offered, and any other changes that were made.
- **Click “Step 4. Submit designations”.**
- Read the attestation, check the box stating you have read and agree to the attestation and then click on the submit box.

Additional help documents can be found on the left side of the screen in eCLEP.

Laboratories are required to participate in the same PT product for the entire calendar year.

An exception to this requirement is a change in methodology that necessitates a change in PT product.

Failure to participate in the annual PT designation on eCLEP may result in a citation for non-compliance with PT requirements under NYS Clinical Laboratory Standard of Practice **Proficiency Testing Standard of Practice 1 (PT S1): Enrollment, Department Notification and Participation.**

Enrollment

Near the beginning of each year the CMS-approved PT providers send CLEP an electronic file that contains the PT products purchased by all the laboratories holding or requesting a NYS clinical laboratory permit that have enrolled with their program for the coming year. *Information in this file is used to verify that laboratories have enrolled in all the PT products they designated in eCLEP*.

If a laboratory has not enrolled in a PT product that they designated in eCLEP they will receive a request from CLEP asking for verification that they have enrolled in an acceptable product for the designated NYS mandated PT analyte(s) in question.

Laboratories must reply to the request by email to PTAdmin@health.ny.gov within 7 days and attach the receipt or confirmation email from the PT provider showing enrollment in an acceptable product. ***An order form is not sufficient proof of enrollment.***

If the designated NYS mandated PT analyte(s) is no longer being offered or the laboratory has chosen a different product for PT they must inform PTAdmin@health.ny.gov by email. The eCLEP Proficiency Testing (PT) Designation module will be re-opened for necessary updates.

Failure to reply to a request for enrollment verification may result in a citation for non-compliance with PT requirements under NYS Clinical Laboratory Standard of Practice **Proficiency Testing Standard of Practice 1 (PT S1): Enrollment, Department Notification and Participation.**

Participation

Throughout the year the CMS-approved PT providers electronically send CLEP the PT results (e.g. performance scores), from participation in their PT products. As these performance scores are received CLEP verifies that laboratories have participated in all the PT products that were chosen during the PT designation process for NYS mandated PT analytes.

If PT results for a designated PT product are not received, the laboratory will receive a request for verification that they participated in the product or an explanation as to why they did not participate. The laboratory's response must be emailed to PTAdmin@health.ny.gov within 7 days.

If the designated NYS mandated PT analyte(s) is no longer being offered or the laboratory has participated in a different product for PT they must inform PTAdmin@health.ny.gov by email. The eCLEP Proficiency Testing PT Designation module will be re-opened for necessary updates.

Failure to reply may result in a score of 0% for non-participation for the analyte(s) in question which puts the laboratory at risk of unsuccessful performance.

Failure to reply to a request for participation verification may result in a citation for non-compliance with PT requirements under NYS Clinical Laboratory Standard of Practice **Proficiency Testing Standard of Practice 1 (PT S1): Enrollment, Department Notification and Participation.**

Performance

PT results (e.g. performance scores) are made available to CLEP by the CMS-approved PT providers as both electronic files and evaluation reports. After PT results are received at CLEP they are monitored for both participation and performance. The minimum satisfactory score for all analytes is 80%, with the exception of the Immunohematology analytes (ABO grouping, Rh grouping, unexpected antibody detection and compatibility testing), where the satisfactory score is 100%.

A benefit PT performance score for a NYS mandated PT analyte *cannot* be considered in determining eligibility for an initial laboratory permit or new category approval.

Benefit scores may be conferred by the PT provider when PT samples are considered ungradable, most commonly due to a lack of peer group grading. Benefit PT scores may also be conferred by the PT provider when a laboratory is unable to analyze the proficiency samples.

PT performance review

Under NYS Clinical Laboratory Standard of Practice **Proficiency Testing Standard of Practice 10 (PT S10): Performance Review – All Results**, *laboratories must review and document evaluation of all PT results.*

This standard, which applies to all proficiency tests, alternatives to proficiency testing, and educational analytes/events, requires that the review be initiated within two (2) weeks of PT results becoming available from the CMS-approved provider or completing the alternative assessment.

PT performance investigation

Under NYS Clinical Laboratory Standard of Practice **Proficiency Testing Standard of Practice 11 (PT S11): Result Investigation (PT S11),** *laboratories must perform root cause analysis for all proficiency testing results and any results produced as an alternative to proficiency testing.*

Laboratory investigations into the possible cause(s) for all scores less than 100% should include consideration of critical areas as defined in NYS Clinical Laboratory Standards. Laboratories also need to investigate any result reports where the PT provider notes an unacceptable result, even if the overall score is 100%. **This applies to both NYS mandated PT analytes and non-NYS mandated PT analytes.**

Definitions

- NYS mandated PT analyte – All analytes included in CLIA Subpart I and additional analytes determined by NYS; see Appendix for complete listing).
- Designated NYS mandated PT analyte – All analytes included in CLIA Subpart I and additional analytes determined by NYS that the laboratory has designated as "Test Offered" via the eCLEP on the HCS.
- Non-NYS mandated PT analyte – Analytes not included in CLIA Subpart I or otherwise not mandated for PT enrollment by NYS.

An appropriate investigation into PT performance issues should contain the following:

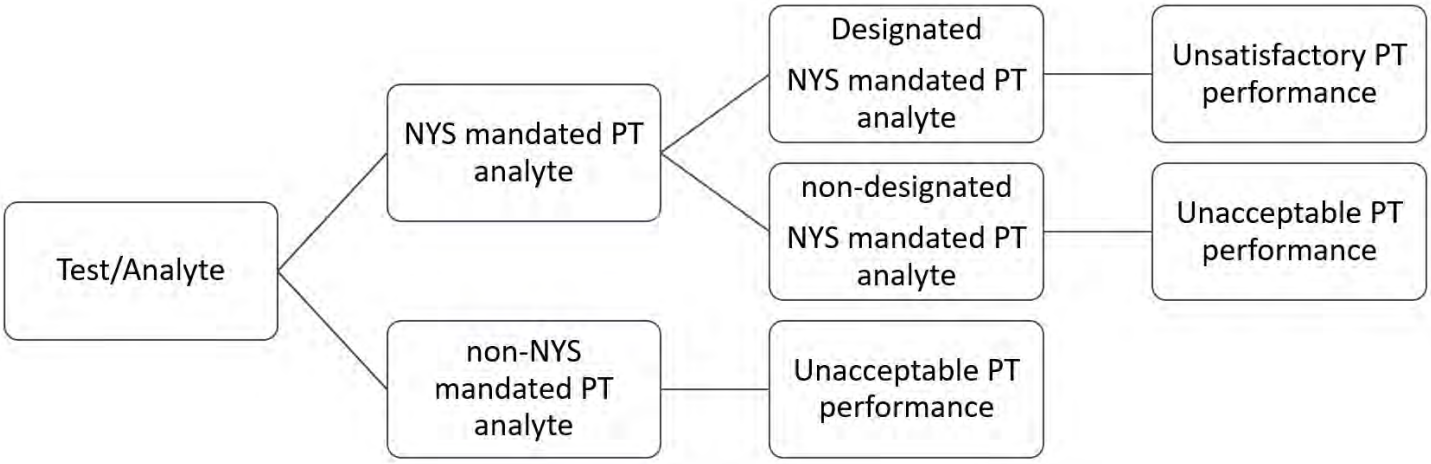
- **ROOT CAUSE** – A summary of the root or contributing cause(s) of the deficiency to include what happened, why and how the nonconformity occurred, when the nonconformity began and who was involved.
- **PATIENT IMPACT** – A summary of the impact of this nonconformity on patient results. If there was impact, describe the impact and what actions were taken to remedy the impact. If there was no impact, explain why.
- **CORRECTIVE ACTION** – What change(s) was put in place to ensure there will not be a repeat of this deficiency?

Remedial action

Under NYS Clinical Laboratory Standard of Practice **Proficiency Testing Standard of Practice 12 (PT S12): Unsatisfactory and Unacceptable Performance – Remedial Action**, laboratories must implement and document corrective action(s), if needed, when an unsatisfactory or unacceptable proficiency testing (PT) or alternative assessment result is identified.

Definitions:

- Unsatisfactory PT performance – Failure to attain the minimum satisfactory score (100% for ABO grouping, Rh grouping, unexpected antibody detection and compatibility testing; 80% for all others) for a designated NYS mandated PT analyte, including events that are failed for non-technical reasons such as late submission, failure to participate or failure to be graded.
- Unacceptable PT performance – Failure to attain the minimum satisfactory score (80%) for either a non-designated NYS mandated PT analyte or a non-NYS mandated PT analyte for a testing event, including events that are failed for non-technical reasons such as late submission or failure to participate.



Documenting the Proficiency Testing Process

Laboratories must maintain the following documentation of the processing of PT materials for review by CLEP staff as required. Review of this documentation may occur during the on-site survey.

Documentation may include:

1. Each step taken in handling, preparing, processing, examining, testing and reporting all results in the proficiency test event.
2. The proficiency testing provider's attestation form completed in accordance with the provider's instructions and requirements.
3. Copies of all testing records, including copies of the PT report forms, for a minimum of two (2) years from the date of the test event for all categories, except Forensic Identity, which requires retention for three (3) years, and Immunohematology, which requires retention for five (5) years.

Temporary Suspension of Testing

Some circumstances require that a laboratory may not be able to offer a particular test or suite of tests due to backlog of reagents, loss of key personnel, instrument breakdown, etc. In these instances, laboratories may elect to temporarily suspend the offering of these test to patients and their participation in proficiency testing.

The laboratory must notify CLEP of their need to temporarily suspend testing.

Notification to the laboratory's PT provider does not replace notification to CLEP.

If the laboratory is unable to participate in two or more consecutive proficiency events for all tests included in a permit category, the category will be deleted from the laboratory permit. To reapply for the category, the laboratory must submit a request to add the category via eCLEP. The laboratory will be required to successfully participate in one PT event for NYS mandated PT analytes. An on-site survey is required for certain high-risk categories prior to permit approval.

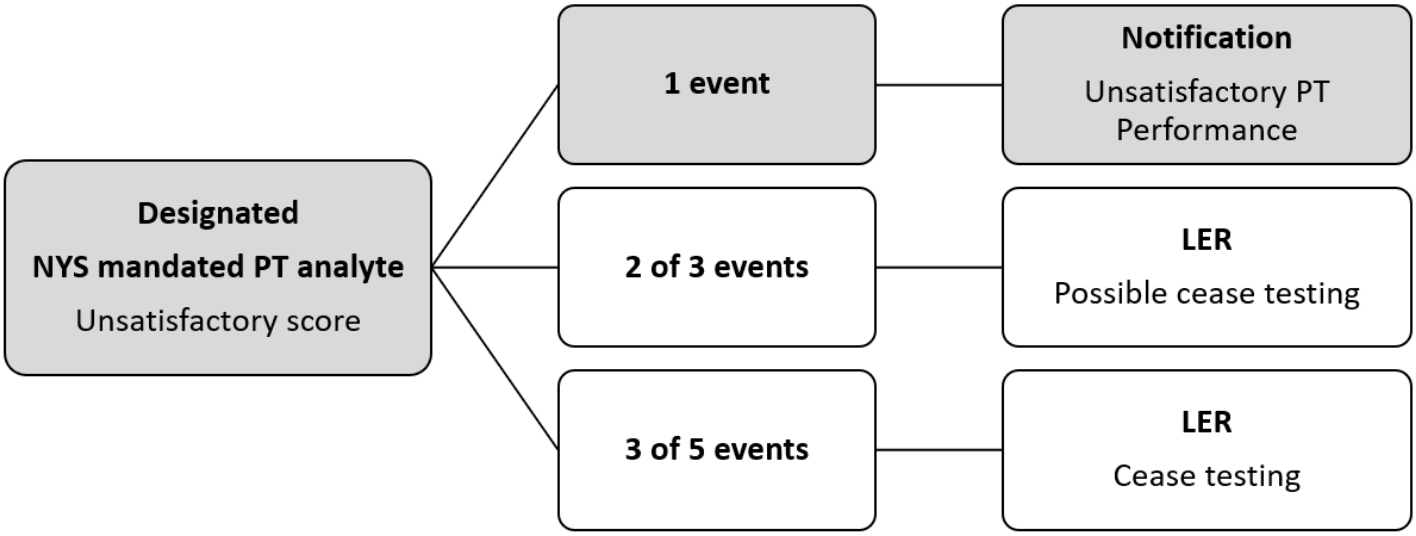
Designated NYS Mandated PT Analytes

Unsatisfactory Proficiency Testing Performance

Unsatisfactory performance is the failure to attain the minimum satisfactory score (100% for ABO grouping, Rh grouping, unexpected antibody detection and compatibility testing in Immunohematology; 80% for all others) for a designated NYS mandated PT analyte for a testing event, including events that are failed for non-technical reasons such as late submission, failure to participate or failure to be graded.

Laboratories receiving an unsatisfactory score are required to investigate the problem(s) that contributed to the unsatisfactory performance and implement corrective action. Laboratories may request additional test samples from their proficiency testing provider to use as part of the remediation.

Formal notification of unsatisfactory performance will be made via email from the PT Administration Group. The email will indicate that a PT document is ready for review and includes directions to access the document using eCLEP. A response to CLEP is not required. Documentation of the investigation should be available for review during the on-site survey.



Unsuccessful Proficiency Testing Performance

Unsuccessful proficiency testing performance is defined as unsatisfactory PT performance for a designated NYS mandated PT analyte in 2 out of 3 consecutive testing events.

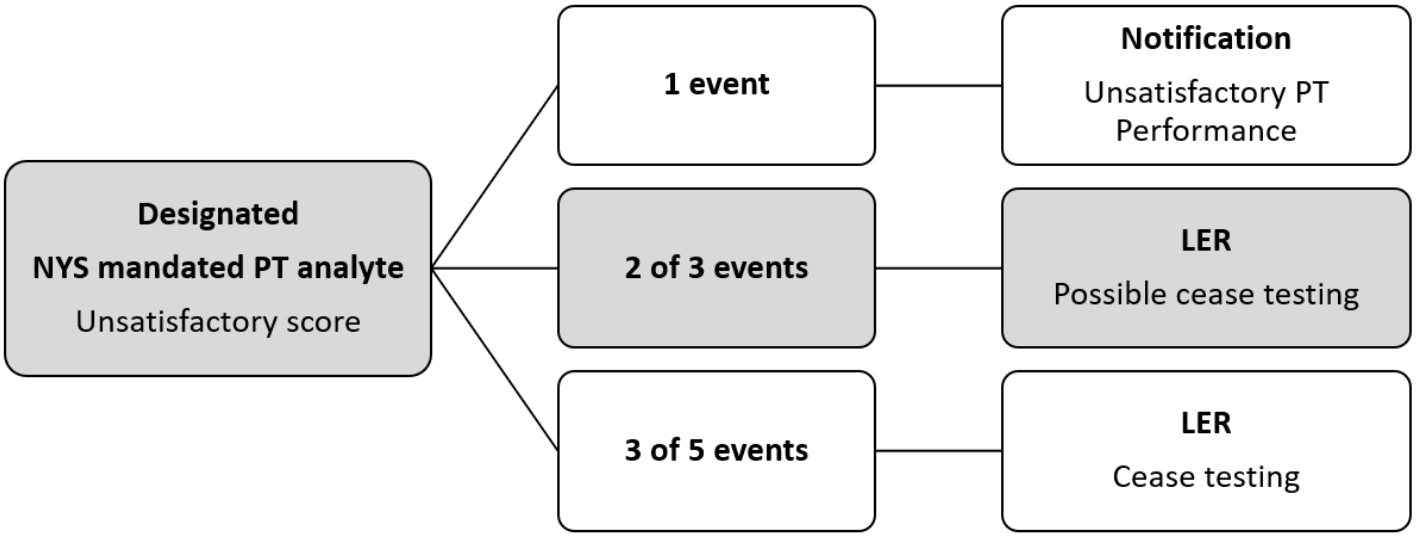
Formal notification of unsatisfactory performance will be made via email from the CLEP Plan of Correction (CLEPPOC) group. The email will direct the laboratory to review the Laboratory Evaluation Report (LER) on eCLEP; similar to the report issued after the on-site survey process; and submit a plan of correction in eCLEP.

There are two types of LERs that can be issued:

- a 2-week notification, or
- a cease testing notification.

The decision as to whether the laboratory receives a 2-week notification or a cease testing notification is based on past performance, immediate jeopardy to patient care, and root cause of the unsuccessful performance.

Please note, removal of the category or test/analyte from the laboratory's test menu, in and of itself, by either the laboratory or CLEP, is not acceptable remedial action. Remediation programs should be designed based on the nature of the unsatisfactory performances and the area of clinical laboratory medicine involved.



2-week notification

The laboratory must:

- investigate and document the problem(s) that contributed to the unsuccessful performance and implement corrective action,
- conduct a retrospective review of patient results to ascertain whether similar error(s) existed in reports of test findings and notify the ordering physician if necessary, and
- reply to the LER within 2 weeks.

The laboratory's remediation must be acceptable to CLEP. If effective corrective action is not implemented and documented to the satisfaction of CLEP, the laboratory will be required to cease testing clinical specimens.

Cease testing notification

The laboratory must:

- **cease testing for the analyte(s) involved in the unsuccessful performance,**
- identify the permitted laboratory where patient specimens will be sent for such testing,
- investigate and document the problem(s) that contributed to the unsuccessful performance and implement corrective action,
- conduct a retrospective review of patient results to ascertain whether similar error(s) existed in reports of test findings and notify the ordering physician if necessary, and
- reply to the LER within 2 weeks.

The laboratory's remediation must be acceptable to CLEP.

Laboratories issued a directive to cease testing clinical specimens due to unsuccessful PT performance will be reinstated after:

- documentation of corrective action has been determined to be acceptable,
- the laboratory demonstrates satisfactory performance in two consecutive test events obtained *from the same proficiency test provider* (one may be an off-cycle event), and
- at least six months has elapsed since the cease testing order.

Subsequent Unsuccessful Proficiency Testing Performance

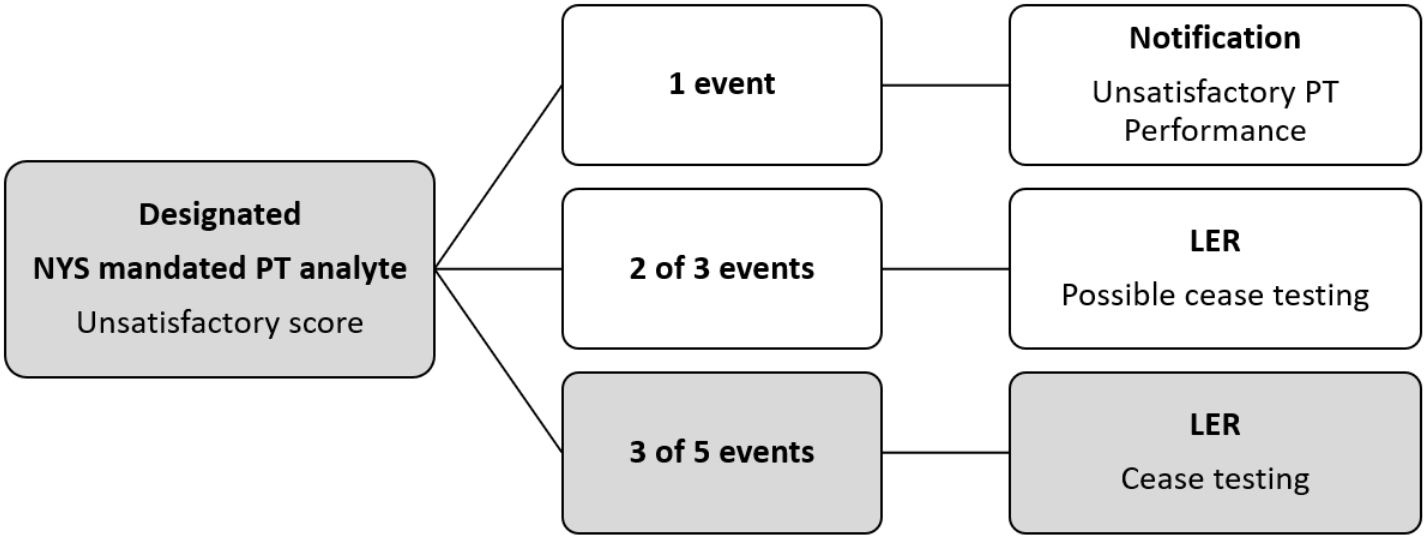
Subsequent unsuccessful proficiency testing performance is defined as unsatisfactory PT performance for a designated NYS mandated PT analyte in 3 out of 5 consecutive testing events.

Laboratories demonstrating a subsequent unsuccessful PT performance will be instructed to cease testing clinical specimens.

Laboratories issued a directive to cease testing clinical specimens due to subsequent unsuccessful PT performance will be reinstated after:

- documentation of corrective action has been determined to be acceptable,
- the laboratory demonstrates satisfactory performance in two consecutive test events obtained *from the same proficiency test provider* (one may be an off-cycle event), and
- at least six months has elapsed since the cease testing order.

Where performance in PT provides evidence of risk for patient harm as determined by the NYS **Proficiency Testing Standard of Practice 15 (PT S15): Unsuccessful Performance – Department Enforcement**, and the laboratory does not cease testing as directed, the Department will take enforcement action as authorized by Sections 576(3) and 577 of New York State Public Health Law, Article 5, Title V.



eCLEP Documents

Documents on Health Commerce System via eCLEP

Proficiency Testing Documents

Laboratories will receive notification by email from the PT Administration Group when they have new PT documents to review on eCLEP/HCS. These will include:

- enrollment,
- participation and
- performance documents.

The document will be viewable by logging into eCLEP through the Health Commerce System and navigating to the **PT Documents** section within the Proficiency Testing (PT) section.

A document may contain the following information:

- NYS Incident Identification Number
- Laboratory name
- CLIA and PFI numbers
- CMS-approved PT provider information, including their name, PT event, test score and PT provider test description.

The three types of PT documents viewable are listed below:

- Verification of Proficiency Testing Enrollment
- Verification of Proficiency Testing Participation
- Unsatisfactory Proficiency Testing Performance

Survey Documents

Laboratories will receive notification by email from CLEP POC when they have new LER documents to review on eCLEP. The document will be viewable by logging into eCLEP through the Health Commerce System and navigating to the **Action Required** section within the **Survey** folder within **Permit Materials**.

Survey describes the type of survey that was performed. The types of PT surveys performed will include:

- Proficiency Testing (PT)
    - Unsuccessful PT performance
- Audit (AS)
    - Failure to participate in the annual designation of both PT providers and products on eCLEP

Responses to PT documents

Enrollment verification notification

Laboratories must reply to the request by email to PTAdmin@health.ny.gov within 7 days and attach the receipt or confirmation email from the PT provider showing enrollment in an acceptable product. An order form is not sufficient proof of enrollment.

If the designated NYS mandated PT analyte(s) is no longer being offered or the laboratory has chosen a different product for PT they must inform PTAdmin@health.ny.gov by email. It is the responsibility of the laboratory to contact the PT Administration Group to arrange the reopening of the eCLEP HCS Proficiency Testing (PT) Designations module for necessary updates.

Failure to reply to a request for enrollment verification may result in a citation for non-compliance with PT requirements under PT S1.

Participation verification notification

The laboratory's response must be emailed to PTAdmin@health.ny.gov within 7 days. Failure to reply may result in a score of 0% for non-participation for the designated NYS mandated PT analyte(s) in question which puts the laboratory at risk of unsuccessful performance.

Failure to reply to a request for participation verification may result in a citation for non-compliance with PT requirements under PT S1.

Performance notification

The laboratory should investigate the root cause, patient impact and implement corrective action. A response to CLEP is not required. Documentation of the investigation should be available for review during the on-site survey.

LER Investigation

The laboratory must investigate the root cause, patient impact and corrective action, and respond to CLEP via the fillable form on eCLEP within 14 days.

When responding to an Audit Survey for not submitting PT designations, it is the responsibility of the laboratory to contact the PT Administration Group at PTAdmin@health.ny.gov to arrange the reopening of the eCLEP HCS PT Designations module for authorized staff to submit the PT designations.

New Laboratories

Laboratories requesting a NYS clinical laboratory permit must meet all requirements for permit issuance.

These include:

- Submission of a complete and accurate Test Menu that describes the testing offered and the chosen PT provider and PT product for each NYS-mandated PT analyte.

- Satisfactory (greater than 80%) participation in PT for each designated NYS mandated PT analyte offered, with the exception of the Immunohematology analytes (ABO grouping, Rh grouping, unexpected antibody detection and compatibility testing), where the satisfactory score is 100%, is required for each NYS-mandated PT analyte designated as being offered by the laboratory on a completed Test Menu or the annual eCLEP PT Designation, if the laboratory was eligible to participate during the PT Designation window.

- **PT participation must occur <u>after</u> the date the initial application for a permit was received by CLEP.**

- Laboratories must authorize their PT provider to release all results to CLEP. If your PT Vendor requests a contact name and fax number, please indicate Beverly Rauch at fax number (518) 408-8666.

- Off-cycle PT is acceptable if taken with the PT provider the laboratory is enrolled with for the calendar year. These off-cycle PT performance scores are NOT provided to CLEP as part of the provider's routine data files. Therefore, laboratories should instruct the PT providers to send the evaluation reports directly to the PT Administration Group at PTAdmin@health.ny.gov.

- All laboratories must order their PT using the CLIA number and PFI of the <u>NEW</u> laboratory.

<u>We cannot accept</u>:

PT reports from the PT provider with an incorrect CLIA number

PT reports directly from the laboratory

Satisfactory PT performance, and continued PT participation with the PT provider on record with NYS, must be maintained to fulfill PT requirements while waiting for all other permit requirements to be met.

Satisfactory PT performance is not met if the PT provider does not provide an accurate peer group assessment of the laboratory's PT results.

This may include:

- Any PT result with a providers' exception code,
- Any ungraded PT result due to lack of an appropriate peer group,
- Any PT result graded as 100% without consensus, or
- Any PT result that does not allow CLEP to verify the accuracy of the laboratory's performance.

Addition of Permit Categories

Laboratories holding a NYS clinical laboratory permit that wish to add permit categories must request the category using eCLEP via the eCLEP Permit Materials module.

We cannot accept:

PT results from events taken prior to the application date (i.e., eCLEP Add Category Request) cannot be accepted

PT reports directly from the laboratory

Laboratories requesting to add a permit category must meet the following requirements.

These include:

- Satisfactory (greater than 80%) participation in PT for each designated NYS mandated PT analyte offered, with the exception of the Immunohematology analytes (ABO grouping, Rh grouping, unexpected antibody detection and compatibility testing), where the satisfactory score is 100%, is required for each permit category requested as part of an initial permit being sought.

- **PT participation must occur after the date the request was submitted by the laboratory to CLEP through eCLEP HCS Add New.**

- Laboratories must authorize their PT provider to release all results to CLEP. If your PT Vendor requests a contact name and fax number, please indicate Beverly Rauch at fax number (518) 408-8666.

- Off-cycle PT is acceptable if taken with the PT provider the laboratory is enrolled with for the calendar year. These off-cycle PT performance scores are NOT provided to CLEP as part of the provider's routine data files. Therefore, laboratories should instruct the PT providers to send the evaluation reports directly to the PT Administration Group at PTAdmin@health.ny.gov.

Satisfactory PT performance is not met if the PT provider does not provide an appropriate peer group assessment of the laboratory's PT results.

This may include:

- Any PT result with a providers' exception code,
- Any ungraded PT result due to lack of an appropriate peer group,
- Any PT result graded as 100% without consensus, or
- Any PT result that does not allow CLEP to verify the accuracy of the laboratory's performance.

Appendix

NYS Mandated PT Analytes (includes CLIA Subpart I analytes)

Bacteriology

Antigen ID of gastrointestinal pathogens (bacterial)
Antigen ID of genital pathogens (bacterial)
Antigen ID of Group A Streptococcus
Antigen ID of meningitis pathogens (bacterial)
Antigen ID of urinary pathogens (bacterial)
Molecular ID of blood pathogens (bacterial)
Molecular ID of gastrointestinal pathogens (bacterial)
Molecular ID of genital pathogens (bacterial)
Molecular ID of meningitis pathogens (bacterial)
Molecular ID of respiratory pathogens (bacterial)
Molecular ID of urinary pathogens (bacterial)
Bacterial toxin
Culture ID of bacteria
Gram stains
Susceptibility (bacterial) testing (AST)

Blood pH and Gases

pCO_2
pH
pO_2
tCO_2

Clinical Chemistry

alanine aminotransferase (ALT)
albumin
alkaline phosphatase
alpha-fetoprotein tumor markers (AFPTM)
amylase
aspartate aminotransferase (AST)
b-natriuretic peptide (BNP)
cancer antigen (CA) 125
carbon dioxide
carcinoembryonic antigen (CEA)
chloride
CK-MB isoenzymes
Creatinine kinase

creatinine
ferritin
gamma glutamyl transferase
glucose
HDL cholesterol
hemoglobin A1c
iron
lactate dehydrogenase (LDH)
LDL cholesterol
magnesium
phosphorous
potassium
proBNP
prostate specific antigen (total)
sodium
total bilirubin
total calcium
total cholesterol
total iron binding capacity (TIBC)
total protein
triglycerides
troponin I
troponin T
urea nitrogen (BUN)
uric acid

Diagnostic Immunology – Diagnostic Services Serology

alpha 1-antitrypsin (AAT)
anti-HBc
anti-HBs
anti-HCV
anti-human immunodeficiency virus (HIV)
antinuclear antibody (ANA)
antistreptolysin O (ASO)
complement component C3
complement component C4
C reactive protein (high sensitivity)
hepatitis B surface antigen (HBsAg)
hepatitis Be antigen (HBeAg)
IgA
IgE
IgG
IgM
Infectious mononucleosis
rheumatoid factor
rubella
syphilis

Diagnostic Immunology – Donor Services Serology

Anti-HBc
Anti-HCV
anti-human immunodeficiency virus (HIV)
hepatitis B surface antigen (HBsAg)
syphilis

Endocrinology

cortisol
estradiol
folate (serum)
follicle stimulating hormone (FSH)
free thyroxine
human chorionic gonadotropin (hCG)
luteinizing hormone (LH)
parathyroid hormone (PTH)
progesterone
prolactin
T3 Uptake/Related Tests
testosterone
thyroid-stimulating hormone (TSH)
thyroxine (T4)
triiodothyronine (T3)
vitamin B12

Hematology

hematocrit
hemoglobin
erythrocyte count
leukocyte count
platelet count
white blood cell differential (automated)
cell identification (manual)
prothrombin time (PT)/INR
activated partial thromboplastin time (APTT)
fibrinogen

Immunohematology

ABO grouping
antibody identification
compatibility testing
D (Rho) typing
unexpected antibody detection

Mycobacteriology

Acid fast smears
Culture ID of mycobacteria
Molecular ID of mycobacteria

Mycology

Antigen ID of fungi
Culture ID of fungi
Molecular ID of fungi

Parasitology

Antigen ID of parasites
Microscopic ID of parasites
Molecular ID of gastrointestinal parasites
Molecular ID of genital parasites

Toxicology – Blood Lead - Comprehensive

blood lead

Toxicology – Blood Lead – ASV Using Screen Printed Sensors

blood lead (LeadCare)

Therapeutic Substance Monitoring / Quantitative Toxicology

ethanol
acetaminophen
carbamazepine
digoxin
gentamicin
lithium
phenobarbital
phenytoin
salicylate
theophylline
tobramycin
valproic acid
vancomycin

Virology

Antigen ID of gastrointestinal pathogens (viral)
Antigen ID of respiratory pathogens (viral)
Culture ID of viruses
Molecular ID of gastrointestinal pathogens (viral)
Molecular ID of genital pathogens (viral)
Molecular ID of herpesvirus-related viruses
Molecular ID of meningitis pathogens (viral)
Molecular ID of respiratory pathogens (viral)