Clinical Laboratory Evaluation Program

Proficiency Testing Guide

Revised November 2019

NEW YORK STATE | Department of Health | Wadsworth Center

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 is required for the tests/analytes offered by the laboratory that are listed in CMS 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). PT participation must be with a federal Centers for Medicaid and Medicare Services (CMS) – approved provider acceptable to NYS.

For analytes with NYS mandated PT, an acceptable PT survey must include 5 samples per analyte and offer 3 test events per year (2 for Mycobacteriology). Surveys 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.

- **Laboratories must authorize their PT provider(s) to send results to NYS (CLEP).**

- **NYS requires PT for analytes listed as NYS mandated PT even if the laboratory is using a kit listed as CLIA-waived by the federal Food and Drug Administration.**

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 proficiency testing programs or through the implementation of an internal proficiency testing program. When external proficiency testing is used as the laboratory's alternate assessment tool for analytes not requiring PT, all NYS Clinical Laboratory Standards of Practice for proficiency testing apply.

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

Rules of 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 participating laboratories under state and federal regulations. Laboratories are expected to follow all NYS Clinical Laboratory Standards related to PT.

- 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 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. This includes final review of results prior to submission to the PT vendor.

- PT samples must not be automatically referred to another laboratory for confirmatory testing, under a reflex testing algorithm or distributive testing algorithm, or any other purpose.

- PT samples must be tested using the laboratory’s primary method. The laboratory cannot test duplicate sets of PT 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 PT samples using multiple methods/systems.

- Laboratories that have multiple locations and share a mailroom must have a method in place to ensure the PT samples are received by the correct laboratory location.

- Any laboratory that receives PT 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.

Approved PT Providers

Laboratories seeking or holding a NYS clinical laboratory permit must successfully participate in proficiency testing for all analytes described as NYS mandated PT. CLEP has screened PT surveys offered by the CMS-approved PT providers to identify those that meet New York State PT requirements for the NYS mandated PT analytes. Other surveys offered by these providers do not meet these requirements but may be used to fulfill requirements for assessment of accuracy and validity for non-subpart I analytes.

The PT providers listed below have been approved by the CMS as meeting the Clinical Laboratory Improvement Amendments (CLIA) related to PT (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html). They offer PT surveys that also meet New York State requirements:

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

NYS approved PT surveys for NYS mandated PT analytes can be found on the Wadsworth Center's website at: https://www.wadsworth.org/regulatory/clep/pt/provider-search.

Choosing a PT Survey

When selecting a PT survey, laboratories should review the statistical analysis of past events to identify surveys where:

1) participants utilize similar methods/instruments and
2) the surveys 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. Ungradeable results may delay the issuance of a permit or amended permit to a newly applying laboratory.

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 survey(s) they will be using for all NYS mandated PT analytes. This is done annually during the PT designation period held in the fall via eCLEP on the Health Commerce System (HCS). For NYS mandated PT analytes only, laboratories are required to update their test menu/PT module choices annually and notify CLEP of any changes throughout the year.

To view acceptable PT Provider/products visit:
https://www.wadsworth.org/regulatory/clep/pt/provider-search.

Instructions for designating PT modules on eCLEP

- In eCLEP, click on “PT Designations”.
- 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 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 the PT provider and product you will enroll in for each test/analyte offered. Do this for all categories that you hold or have requested that include NYS mandated PT analytes.
- Click on “Step 3. View Designations” to review the PT provider and product for tests offered, and any other changes that were made.
- Lastly, click “Step 4. Submit designations”, read the attestation, check the box stating you have read and agree to the attestation and then submit.

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.

For changes to your test menu/PT products for NYS mandated PT analytes during the year please notify CLEP by email (PTAdmin@health.ny.gov). It is not sufficient to notify the PT provider. You must also notify CLEP.

Enrollment

In early January of each year the PT providers send CLEP a file that contains the PT surveys 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 surveys they designated the previous fall*.

If a laboratory has not enrolled in a PT survey they designated the previous fall they will receive a request from CLEP asking for verification that they have enrolled in an acceptable survey for the 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 survey. *An order form is not proof of enrollment*.

If the 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.

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

Participation

Throughout the year PT providers electronically send CLEP the results of their PT surveys (e.g. scores). As results are received CLEP verifies that laboratories have participated in all the PT surveys that were chosen during the PT designation process.

If results for a designated PT survey are not received, the laboratory will receive a request for verification that they participated in the survey 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.

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. In addition, failure to reply to a request for participation verification may result in a citation for non-compliance with PT requirements.

Performance

PT results (e.g. scores) for all analytes, both NYS mandated PT and non-NYS mandated PT, 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 ABO grouping, Rh grouping and compatibility testing where the satisfactory score is 100%.

PT performance investigation

Laboratories must investigate all scores less than 100%. 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%.

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

- ROOT CAUSE – Provide 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 – Please describe 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?

PT performance can be categorized by both analyte type (NYS mandated PT or non- NYS mandated PT) and frequency of occurrence of scores less than 100%. The different types of PT performances are outlined below. Although the laboratory investigation into all scores less than 100% will follow the same steps, any follow-up response to NYS may vary.

Documenting the Proficiency Testing Process

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

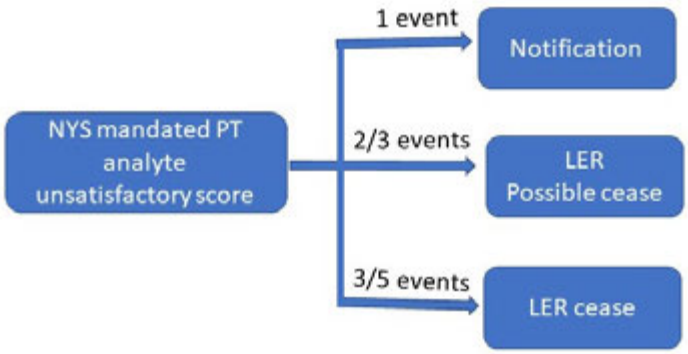
1. Each step taken in preparing, processing, examining, testing and reporting all results in the proficiency test event.
2. The proficiency testing provider's attestation form completed in accordance with the provider's instructions and requirements.
3. Copies of all testing records, including copies of the proficiency test 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, 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 NYS 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 proficiency test event and have an on-site survey, if applicable.

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 and compatibility testing; 80% for all others) for the category or test/analyte (NYS mandated PT analytes) for a testing event, including events that are failed for non-technical reasons such as late submission or failure to participate.

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 laboratory will receive an email which will indicate that a PT document is ready for review and include directions to access the document using *eCLEP*. The laboratory's investigation into the unsatisfactory performance must be available for review upon request.

Unsuccessful Proficiency Testing Performance

Unsuccessful proficiency testing performance is defined as unsatisfactory PT performance for the category or test/analyte (NYS mandated PT analytes) in 2 out of 3 consecutive testing events.

CLEP notifies laboratories following unsuccessful performance via a Laboratory Evaluation Report (LER) similar to the report issued after the onsite survey process. 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.

Formal notification of unsuccessful performance will be made via email from the PT Administration Group. The laboratory will receive an email which will indicate that a PT document is ready for review and include directions to access the document using *eCLEP*. Documentation of the laboratory's investigation and the laboratory's plan of corrective action must be submitted electronically via eCLEP within two weeks of notification of unsuccessful PT performance. CLEP may request additional information. Failure to submit an acceptable plan of correction or failure to implement the plan of correction can result in administrative action or may lead to delays in issuing the laboratory permit.

Please note, removal of the category or test/analyte from the laboratory's test menu, in and of itself, 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 the proficiency testing technical section, 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 the category or test/analyte (NYS mandated PT analytes) in 3 out of 5 consecutive testing events.

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

Formal notification of subsequent unsuccessful performance will be made via email from the PT Administration Group. The laboratory will receive an email which will indicate that a PT document is ready for review and include directions to access the document using *eCLEP*. Documentation of the laboratory's investigation and the laboratory's plan of corrective action must be submitted

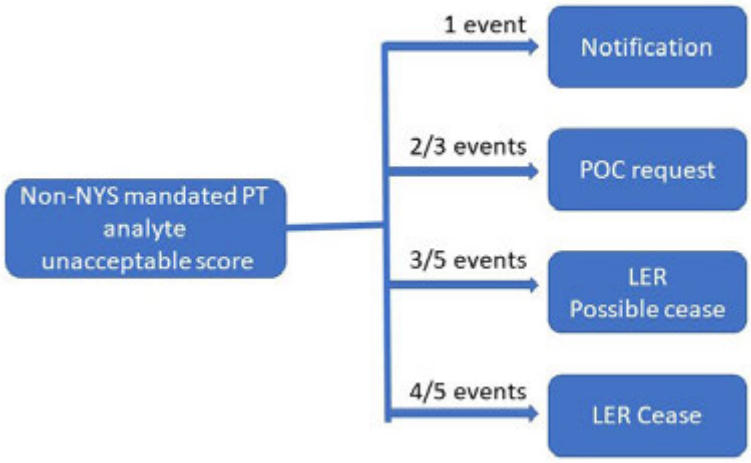
electronically via eCLEP within two weeks of notification of unsuccessful PT performance. CLEP may request additional information. Failure to submit an acceptable plan of correction or failure to implement the plan of correction can result in administrative action or may lead to delays in issuing the laboratory permit.

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 Clinical Standard of Practice, 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.

Non- NYS mandated PT analytes



Note: Laboratories requiring increased departmental scrutiny due to various issues including, but not limited to, onsite survey fundamentals not met or repeated PT failures, may have failures of non-NYS mandated PT analytes escalated similar to that for failure of NYS mandated PT analytes.

Unacceptable Proficiency Testing Performance

Unacceptable performance is the failure to attain the minimum satisfactory score (80%) for the category or test/analyte (non-NYS mandated PT analytes) for a testing event, including events that are failed for non-technical reasons such as late submission or failure to participate. Laboratories receiving an unacceptable score are required to investigate the problem(s) that contributed to the unacceptable performance and implement corrective action. Laboratories may request additional test samples from their PT provider to use as part of the remediation.

Formal notification of unacceptable performance will be made via email from the PT Administration Group. The laboratory will receive an email which will indicate that a PT document is ready for review and include directions to access the document using *eCLEP*. The laboratory's investigation into the unacceptable performance must be available for review upon request.

Repeat Unacceptable Proficiency Testing Performance

Repeat unacceptable performance is the failure to attain the minimum satisfactory score (80%) for the category or test/analyte (non-NYS mandated PT) for 2 out of 3 consecutive testing events, including events that are failed for non-technical reasons such as late submission or failure to participate. Laboratories receiving a repeat unacceptable score are required to investigate the problem(s) that contributed to the unacceptable 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 repeat unacceptable performance will be made via email from the PT Administration Group. The laboratory will receive an email which will indicate that a PT document is ready for review and include directions to access the document using eCLEP. Documentation of the

laboratory's investigation and the laboratory's plan of corrective action must be submitted electronically via eCLEP within two weeks of notification of repeat unacceptable PT performance. CLEP may request additional information. Failure to submit an acceptable plan of correction or failure to implement the plan of correction can result in administrative action or may lead to delays in issuing the laboratory permit.

Unsuccessful Proficiency Testing Performance

Unsuccessful proficiency testing performance is defined as unacceptable PT performance for the category or test/analyte (non-NYS mandated PT analytes) in 3 out of 5 consecutive testing events.

CLEP notifies laboratories following unsuccessful performance via a Laboratory Evaluation Report (LER) similar to the report issued after the onsite survey process. 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, root cause of the unsuccessful performance.

Formal notification of unsuccessful performance will be made via email from the PT Administration Group. The laboratory will receive an email which will indicate that a PT document is ready for review and include directions to access the document using eCLEP. Documentation of the laboratory's investigation and the laboratory's plan of corrective action must be submitted electronically via eCLEP within two weeks of notification of unsuccessful PT performance. CLEP may request additional information. Failure to submit an acceptable plan of correction or failure to implement the plan of correction can result in administrative action or may lead to delays in issuing the laboratory permit.

Please note, removal of the category or test/analyte from the laboratory's test menu, in and of itself, is not acceptable remedial action. Remediation programs should be designed based on the nature of the unacceptable 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 the proficiency testing technical section, 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 PT performance is defined as unacceptable PT performance for the category or test/analyte (non-NYS mandated PT analytes) in 4 out of 5 consecutive testing events.

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

Formal notification of repeat unsuccessful performance will be made via email from the PT Administration Group. The laboratory will receive an email which will indicate that a PT document is ready for review and include directions to access the document using eCLEP. Documentation of the laboratory’s investigation and the laboratory’s plan of corrective action must be submitted electronically via eCLEP within two weeks of notification of subsequent unsuccessful PT performance. CLEP may request additional information. Failure to submit an acceptable plan of correction or failure to implement the plan of correction can result in administrative action or may lead to delays in issuing the laboratory permit.

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 Clinical Standard of Practice, 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

Laboratories will receive notification by email from the PT Administration Group when they have new PT documents to review on eCLEP. 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 PT module.

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 types of documents viewable for PT are listed in the table below:

Document	Analyte	PT<100%
Enrollment verification	NYS mandated PT analyte(s)	
Participation verification	NYS mandated PT analyte(s)	
Unsatisfactory PT performance notification	NYS mandated PT analyte	First occurrence
Unacceptable PT performance notification	Non-NYS mandated PT analyte	First occurrence
Investigation of repeat unacceptable PT performance	Non-NYS mandated PT analyte	Second occurrence
Laboratory evaluation report	NYS mandated PT analyte	2/3 occurrence
Laboratory evaluation report	Non-NYS mandated PT analyte	3/5 occurrence

Responses to PT documents

Enrollment verification
Laboratories need to 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 survey. An order form is not sufficient proof of enrollment. If the analyte(s) is no longer being offered or the laboratory has chosen a different product for PT they must inform us by email. Failure to reply to a request for enrollment verification may result in a citation for non-compliance with PT requirements.

Participation verification
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 analyte(s) in question which puts the laboratory at risk of unsuccessful performance. In addition, failure to reply to a request for participation verification may result in a citation for non-compliance with PT requirements.

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

Investigation of unacceptable PT performance and LER
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.

New Laboratories

Laboratories requesting a NYS clinical laboratory permit must meet all requirements for permit issuance including satisfactory (>80%) participation in PT for each NYS mandated PT analyte (100% for ABO grouping, Rh grouping and compatibility testing), for which a permit is being sought. Satisfactory PT performance is also required for any non-NYS mandated PT analytes requested if the laboratory is performing PT in lieu of alternative assessments.

PT participation must occur after the initial application for a permit has been received by CLEP. Off-cycle PT is acceptable if taken with the PT provider the laboratory is enrolled with for the year.

New laboratories which are part of a larger group must order their PT using the CLIA number and PFI of the NEW laboratory. **We cannot accept PT reports with an incorrect CLIA number**.

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 HCS.

Satisfactory PT (less than 80% for all analytes except ABO grouping, Rh grouping and compatibility testing which require 100%) is required for all NYS mandated PT analytes requested and any non-NYS mandated PT analytes requested if the laboratory is performing PT in lieu of alternative assessments.

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.

Appendix

NYS mandated analytes (includes CLIA subpart I analytes)

Bacteriology
Chlamydia/Neisseria gonorrhoeae by direct detection*
Clostridium difficile direct detection*
Gram stains
Group A Streptococcus direct detection*
Identification of bacteria by culture
Identification of bacterial meningitis pathogens by molecular methods
Identification of blood pathogens (bacterial) by molecular methods
Identification of gastrointestinal bacterial pathogens by molecular methods
Identification of genital pathogens (bacterial) by molecular methods
Identification of respiratory bacterial pathogens by molecular methods
Susceptibility (bacterial) testing (AST)

Blood pH and Gases
pCO2
pH
pO2

Clinical Chemistry
alanine aminotransferase (ALT)
albumin
alkaline phosphatase
amylase
aspartate aminotransferase (AST)
bilirubin, total
calcium, total
chloride
cholesterol, HDL
cholesterol, total
creatine Kinase
creatine Kinase-MB
creatinine
glucose
iron
lactate dehyrogenase (LDH)
lactate dehyrogenase isoenzyme 1
magnesium
potassium
sodium
total protein
triglycerides
urea nitrogen (BUN)
uric acid

Diagnostic Immunology
alpha 1- antitrypsin (AAT)
antinuclear antibody (ANA)
antistreptolysin O (ASO)
complement component C3
complement component C4
hepatitis B core antibody (HBc)
hepatitis B surface antigen (HBsAg)
hepatitis Be antigen (HBeAg)
Heterophile (infectious mono)
human immunodeficiency virus (HIV)
IgA
IgE
IgG
IgM
rheumatoid factor
rubella
syphilis

Endocrinology
cortisol
human chorionic gonadotropin (hCG), serum
T3 Uptake/Related Tests
T4, free
thyrotropin (TSH)
thyroxin (T4)
triiodothyronine (T3)

Hematology
activated partial thromboplastin time (APTT)
fibrinogen
hematocrit
hemoglobin
platelet count
prothrombin time (PT)
red blood cell count (RBC)
white blood cell count (WBC)
white cell differential (automated)
white cell differential (manual)

Immunohematology
ABO grouping
antibody identification
compatibility testing
Rh group
unexpected antibody detection

Mycobacteriology
Acid fast smears
Identification of Mycobacteria by culture
Identification of Mycobacteria by molecular methods
Susceptibility (mycobacteria) testing

Mycology
Cryptococcal antigen detection
Identification of fungi by culture
Identification of fungi by molecular methods

Oncology – Soluble Tumor Markers
alpha-fetoprotein tumor markers (AFPTM)

Parasitology
Giardia/Cryptosporidum antigen detection
Identification of parasites
Identification of parasites by molecular methods

Toxicology – Blood Lead - Comprehensive
blood lead

Toxicology – Blood Lead – ASV Using Screen Printed Sensors
blood lead (LeadCare)

Therapeutic Substance Monitoring / Quantitative Toxicology
carbamazepine
digoxin
ethanol
ethosuximide
gentamicin
lithium
n-Acetyl-Procainamide
phenobarbital
phenytoin
primidone
procainamide
quinidine
theophylline
tobramycin
valproic acid

Virology
Identification of herpes simplex virus (HSV) and related viruses
human papillomavirus (HPV)
Identification of gastrointestinal viruses by molecular methods
Identification of respiratory viruses by molecular methods
Identification of viral meningitis by molecular methods
Identification of virus by culture
Respiratory virus (Influenza and RSV) direct detection*
Rotavirus direct detection*

*Direct detection encompasses both antigen detection and/or molecular detection.