



Department of Health
Wadsworth Center

Regulatory Update

Beverly Rauch

NYSCLA Annual Meeting | September 10, 2025 | Albany NY

TOPICS COVERED

- PT Requirements Update
- LDT Requirements Update
- Regulatory Revisions Update
- Top Ten Deficiencies CY 2024



PROFICIENCY TESTING 2026

NYS Mandated PT Analyte Clarifications

- Qualitative testing only for:
 - Anti-HBc
 - Anti-HBs
 - Anti-HCV
 - anti-human immunodeficiency virus (HIV)
 - hepatitis B surface antigen (HBsAg)
 - hepatitis Be antigen (HBeAg)



PROFICIENCY TESTING 2026

NYS Mandated PT Analyte Clarifications

- Qualitative testing or semiquantitative testing only for:
 - antinuclear antibody (ANA)
 - antistreptolysin O (ASO)
 - Infectious mononucleosis
 - Rheumatoid Factor
 - Rubella



PROFICIENCY TESTING 2026

NYS Mandated PT Analyte Clarifications

- Troponin I and Troponin T [not high sensitivity]
- LDL cholesterol – direct measured only
- Total Iron Binding Capacity (TIBC) – direct measured only



PROFICIENCY TESTING 2026

Microbiology Guidance

- Laboratories must enroll in as many NYS-acceptable PT products as necessary to cover all of the tests they perform: e.g., Antigen ID, Molecular ID, Culture ID, etc.
- If your laboratory enrolls in a comprehensive PT product, you generally do not need to enroll in additional PT products for individual tests that are already covered by the comprehensive PT product. For example, enrolling in a comprehensive PT product may cover Culture ID of bacteria, Gram stain, AST, Antigen ID of Group A Streptococcus and Bacterial toxin; you would designate this one NYS-acceptable PT product for all four NYS-mandated PT analytes.



PROFICIENCY TESTING 2026

Microbiology Guidance

- For Culture ID of bacteria, choose the most comprehensive product for your laboratory protocol. For example, choose the NYS-acceptable PT product that includes multiple culture sources (e.g., blood, wounds, urines) if your laboratory tests all those specimen types. Alternatively, if your laboratory only performs throat culture, then choose a NYS-acceptable PT product that only includes the culture source of throat.
- For Antigen ID and Molecular ID choose products that best fit the assays (e.g., multiplex panels) offered by your laboratory.
 - For example, the laboratory performs molecular multiplex panels for respiratory and meningitis pathogens; you would designate both a Molecular ID of respiratory pathogens (bacterial) PT product and a Molecular ID of meningitis pathogens (bacterial) PT product.
 - Another example, the laboratory performs CT/NG and Gardnerella testing under Molecular ID of genital pathogens (bacterial) – but there is no PT Product for all three organisms. Choose the PT Product for your highest volume testing under “Molecular ID of genital pathogens (bacterial)”.



PROFICIENCY TESTING 2026

- Annual PT Designation Period will open December 2025.
- You must buy the PT product that you designate.
- PT performance is monitored for those PT products that were designated by the laboratory.
- If patient testing is suspended for any reason, you must notify CLEP! Notification to the PT Provider is not sufficient.



LABORATORY DEVELOPED TESTS (LDTs)

FDA Final Rule Vacated – WHAT DOES THIS MEAN?

- CLEP will continue reviewing LDTs.
- See our [Test Approval page](#) for information.

Test Approval: <https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval>

CLEP Home: <https://www.wadsworth.org/regulatory/clep>



Recent Statutory Revisions

NYS Public Health Law; Article 5, Title 5

- Sections 572 and 573 – Certificates of Qualification
- Amended 12/13/24 and 2/14/25

NYS Public Health Law; Article 30

- Ambulance and ALSFRS to store and distribute blood
- Amended 9/17/24
- ATS authority granted to BEMS



WHAT WE KNOW ABOUT AMBULANCES

- **CLEP/BRP has been working with BEMS on rulemaking**
- **Cannot conduct their own transfusions workups – collaboration with blood bank required**
- **Article 30 covers both pre-hospital and inter-hospital transport**
- **Contact EMS.Licensure@health.ny.gov with questions**



Recent Regulatory Revisions

Subpart 58-2 of 10NYCRR

- Proposed revisions published 5/14/25
- ‘consensus’ changes to conform with federal requirements (visual inspection and records retention)
- Repeal of section 20 related to ATS
- Comment period ended 7/15/25
- (<https://regs.health.ny.gov/sites/default/files/proposed-regulations/Blood%20Banks.pdf>)



Regulatory Revisions In Progress

Part 19 of 10NYCRR

- Under legal review
- Change in CQ application processes



Regulatory Revisions In Progress

Subpart 58-1 of 10NYCRR

- Under legal review
- Will address histotechnologists, patient service centers



TOP TEN DEFICIENCIES - 2024

Deficiency	Instances
Reporting Standard of Practice 2 (REP S2): Test Report Content	70 (15%)
Document Control Standard of Practice 1 (DC S1): Availability	58 (12%)
Laboratory Safety Standard of Practice 7 (LS S7): Biohazard Risk Assessment	49 (10%)
Proficiency Testing Standard of Practice 10 (PT S10): Performance Review – All Results	48 (10%)



TOP TEN DEFICIENCIES - 2024

Deficiency	Instances
Laboratory Equipment and Instrument Standard of Practice 3 (LEI S3): Function Checks and Performance Verification of Instruments, Equipment and Test Systems	47 (10%)
Document Control Standard of Practice 2 (DC S2): Compliance	43 (9%)
Director Standard of Practice 4 (DR S4): Director Responsibilities	43 (9%)
Director Standard of Practice 2 (DR S2): Health Commerce System	42 (9%)



TOP TEN DEFICIENCIES - 2024

Deficiency	Instances
Reagent and Media Standard of Practice 1 (RGM S1): Reagent and Media Records	39 (8%)
Human Resources Standard of Practice 1 (HR S1): Organization Charts and Job Descriptions	36 (7%)

Total surveys 470



Department of Health
Wadsworth Center

Get Informed:

www.wadsworth.org/regulatory/clep

Questions?

clep@health.ny.gov



**Department
of Health**

**Wadsworth
Center**