

Proficiency Testing

Proficiency Testing	
Former Standard and Guidance	Revised Standard and Guidance
<p>Proficiency Testing Standard of Practice 1 (PT S1): Enrollment, Department Notification and Participation</p> <p>For each category, subcategory and analyte designated as New York State mandated in the Clinical Laboratory Evaluation Program Proficiency Testing Guide, laboratories must:</p> <ul style="list-style-type: none"> a) enroll in a New York State approved and mandated proficiency testing program; b) notify the Department on an annual basis, in a manner prescribed by the Department, of proficiency testing program(s) to be used to fulfill these requirements; c) successfully participate in proficiency testing using their primary method of analysis. <p>Once enrolled with a proficiency testing program to fulfil this requirement, the laboratory must participate with the same program until the end of the calendar year.</p> <p style="text-align: center;">Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)</p> <p>Guidance - Please see 42 CFR §493.801 for federal Proficiency Testing regulations.</p> <p>Information on Department notification and annual Proficiency</p>	<p>Proficiency Testing Standard of Practice 1 (PT S1): Enrollment, Department Notification and Participation</p> <p>For each category, subcategory and analyte designated as New York State mandated in the Clinical Laboratory Evaluation Program Proficiency Testing Guide, laboratories must:</p> <ul style="list-style-type: none"> a) enroll in a New York State approved and mandated proficiency testing program; b) notify the Department on an annual basis, in a manner prescribed by the Department, of proficiency testing program(s) to be used to fulfill these requirements; c) successfully participate in proficiency testing using their primary method of analysis. <p>Once enrolled with a proficiency testing program to fulfil this requirement, the laboratory must participate with the same program until the end of the calendar year.</p> <p style="text-align: center;">Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)</p> <p>Guidance - Please see 42 CFR §493.801 for federal Proficiency Testing regulations.</p> <p>Information on Department notification and annual Proficiency</p>

<p>Testing enrollment is available in the PT Guide and on our website and available at: https://www.wadsworth.org/regulatory/clep/pt.</p> <p>Participation in proficiency testing is recommended for all tests not included in Subpart I, if a formally evaluated program is available.</p> <p>When laboratories use more than one method to determine results for a given analyte, only the primary method should be evaluated using proficiency testing. Secondary methods should be assessed as outlined in Test Performance Specification Standard of Practice 5.</p>	<p>Testing enrollment is available in the PT Guide and on our website and available at: https://www.wadsworth.org/regulatory/clep/pt.</p> <p>Participation in proficiency testing is recommended for all tests not included in Subpart I, if a formally evaluated program is available.</p> <p>When laboratories use more than one method to determine results for a given analyte, only the primary method should be evaluated using proficiency testing. Secondary methods must be assessed against the primary method as outlined in Test Performance Specification Standard of Practice 5.</p>
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<p>Proficiency Testing Standard of Practice 3 (PT S3): Alternative to Proficiency Testing</p> <p>Laboratories must have standard operating procedures to verify the reliability and accuracy of test results for:</p> <ul style="list-style-type: none"> a) New York State mandated analytes for which there is no commercially-available proficiency testing; and b) tests/analytes that are not listed in 42 CFR 493 subpart I for which: <ul style="list-style-type: none"> i. the laboratory does not participate in commercially-available proficiency testing; or ii. proficiency testing is not available. <p>Test reliability and accuracy assessment must be conducted at least semiannually and according to Proficiency Testing</p>	<p>Proficiency Testing Standard of Practice 3 (PT S3): Alternative to Proficiency Testing</p> <p>Laboratories must have standard operating procedures to verify the reliability and accuracy of test results for:</p> <ul style="list-style-type: none"> c) New York State mandated analytes for which there is no commercially-available proficiency testing; and d) tests/analytes that are not listed in 42 CFR 493 subpart I for which: <ul style="list-style-type: none"> iii. the laboratory does not participate in commercially-available proficiency testing; or iv. proficiency testing is not available. <p>Test reliability and accuracy assessment must be conducted at least semiannually and according to Proficiency Testing</p>

<p>Standard of Practice 10.</p> <p>Regulatory authority: 10 NYCRR paragraph 19.3(c)(4) and subdivision 58-1.10(g)</p> <p>Guidance -</p> <p>Information on New York State PT requirements is available at: https://www.wadsworth.org/regulatory/clep/pt.</p> <p>The laboratory may evaluate the accuracy of testing through testing of: split-samples (specimens and/or quality control samples) with another validated method; blind testing of specimens with known results; or other equivalent system.</p>	<p>Standard of Practice 10.</p> <p>Regulatory authority: 10 NYCRR paragraph 19.3(c)(4) and subdivision 58-1.10(g)</p> <p>Guidance -</p> <p>Information on New York State PT requirements is available at: https://www.wadsworth.org/regulatory/clep/pt.</p> <p>The laboratory may evaluate the accuracy of testing through testing of: split- samples (specimens and/or quality control samples) with another validated method; blind testing of specimens with known results; or other equivalent system.</p> <p><u>Participation in proficiency testing is recommended for all tests not included in Subpart I, if a formally evaluated program is available.</u></p> <p><u>When laboratories use more than one method to determine results for a given analyte, only the primary method is required to be assessed twice per year per this standard. Secondary methods must be assessed against the primary method as outlined in Test Performance Specification Standard of Practice 5.</u></p>

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<p>Proficiency Testing Standard of Practice4 (PT S4): Routine Analysis</p> <p>Unless instructed otherwise by the proficiency testing provider, laboratories must use the same test process for proficiency testing samples that is used for patient specimens.</p> <p>Proficiency testing samples must be:</p> <ul style="list-style-type: none"> a) incorporated into the laboratory's routine workflow; and b) rotated among all operators that perform testing. <p>Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)</p> <p>Guidance -</p> <p>Proficiency test samples must be accessioned and handled as much like patient specimens as possible, with the exception of automatic reflex testing to another laboratory.</p>	<p>Proficiency Testing Standard of Practice 4 (PT S4): Routine Analysis</p> <p>Unless instructed otherwise by the proficiency testing provider, laboratories must use the same test process for proficiency testing samples that is used for patient specimens.</p> <p>Proficiency testing samples must be:</p> <ul style="list-style-type: none"> a) incorporated into the laboratory's routine workflow; b) rotated among all operators that perform testing; c) <u>in microbiology, reported to the highest level of organism identification performed by the laboratory.</u> <p>Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)</p> <p>Guidance -</p> <p>Proficiency test samples must be accessioned and handled as much like patient specimens as possible, with the exception of automatic reflex testing to another laboratory.</p> <p><u>The highest level of organism identification means the highest level of identification performed and resulted by the laboratory for patient specimens for the organism identified.</u></p>

**Proficiency Testing Standard of Practice 16 (PT S16):
Proficiency Testing Documentation**

Laboratories must maintain the following documentation of the processing and reporting of proficiency testing samples:

- a) steps taken in preparing, processing, examining, testing and reporting all results in the proficiency test event;
- b) the proficiency testing provider's attestation form completed in accordance with the provider's instructions and requirements; and
- c) copies of all testing records, including copies of the proficiency test report forms that must be retained according to [Document and Specimen Retention Standard of Practice 11](#).

Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)

**Proficiency Testing Standard of Practice 16 (PT S16):
Proficiency Testing Documentation**

Laboratories must maintain the following documentation of the processing and reporting of proficiency testing samples:

- a) steps taken in [handling](#), preparing, processing, examining, testing and reporting all results in the proficiency test event;
- b) the proficiency testing provider's attestation form completed in accordance with the provider's instructions and requirements; and
- c) copies of all testing records, including copies of the proficiency test report forms that must be retained according to [Document and Specimen Retention Standard of Practice 11](#).

Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)

Revised December 2024