

## **Proficiency Testing**

<b><i>Current Standard</i></b>	<b><i>Current Guidance</i></b>	<b><i>Proposed Standard</i></b>	<b><i>Proposed Guidance</i></b>
<p><b>Proficiency Testing Standard of Practice 1 (PT S1): Enrollment, Department Notification and Participation</b></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"> <li>a) enroll in a New York State approved and mandated proficiency testing program;</li> <li>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;</li> <li>c) successfully participate in proficiency testing using their primary method of analysis.</li> </ul>	<p>Please see 42 CFR §493.801 for federal Proficiency Testing regulations.</p> <p>Information on Department notification and annual Proficiency Testing enrollment is available in the PT Guide and on our website and available at:  <a href="https://www.wadsworth.org/regulatory/clep/pt">https://www.wadsworth.org/regulatory/clep/pt</a>.</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 against the primary method as outlined in <a href="#">Test Performance Specification Standard of Practice 5</a>.</p>	<p>SAME</p>	<p>Please see 42 CFR §493.801 for federal Proficiency Testing regulations.</p> <p>Information on Department notification and annual Proficiency Testing enrollment is available in the PT Guide and on our website and available at:  <a href="https://www.wadsworth.org/regulatory/clep/pt">https://www.wadsworth.org/regulatory/clep/pt</a>.</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 <b>must</b> be assessed against the primary method as outlined in <a href="#">Test Performance Specification Standard of Practice 5</a>.</p>

<b>Current Standard</b>	<b>Current Guidance</b>	<b>Proposed Standard</b>	<b>Proposed Guidance</b>
<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><b>Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)</b></p>			
<p><b>Proficiency Testing Standard of Practice 3 (PT S3): Alternative to Proficiency Testing</b></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"> <li>a) New York State mandated analytes for which there is no commercially-available proficiency testing; and</li> <li>b) tests/analytes that are not listed in 42 CFR 493 subpart I for which:             <ul style="list-style-type: none"> <li>i. the laboratory does not participate in</li> </ul> </li> </ul>	<p>Information on New York State PT requirements is available at: <a href="https://www.wadsworth.org/regulatory/clep/pt">https://www.wadsworth.org/regulatory/clep/pt</a>.</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>SAME</p>	<p>Information on New York State PT requirements is available at: <a href="https://www.wadsworth.org/regulatory/clep/pt">https://www.wadsworth.org/regulatory/clep/pt</a>.</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</u></p>

<b>Current Standard</b>	<b>Current Guidance</b>	<b>Proposed Standard</b>	<b>Proposed Guidance</b>
<p>commercially-available proficiency testing; or</p> <p>ii. proficiency testing is not available.</p> <p>Test reliability and accuracy assessment must be conducted at least semiannually and according to <a href="#">Proficiency Testing Standard of Practice 10</a>.</p> <p><b>Regulatory authority: 10 NYCRR paragraph 19.3(c)(4) and subdivision 58-1.10(g)</b></p>			<p><u>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>
<p><b>Proficiency Testing Standard of Practice 4 (PT S4): Routine Analysis</b></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>	<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><b>Proficiency Testing Standard of Practice 4 (PT S4): Routine Analysis</b></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>	

<b>Current Standard</b>	<b>Current Guidance</b>	<b>Proposed Standard</b>	<b>Proposed Guidance</b>
<p>a) incorporated into the laboratory’s routine workflow; and</p> <p>b) rotated among all operators that perform testing;</p> <p><b>Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)</b></p>		<p>a) incorporated into the laboratory’s routine workflow;</p> <p>b) rotated among all operators that perform testing;</p> <p>c) <u>in microbiology, reported to the highest level of organism identification performed by the laboratory.</u></p> <p><b>Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)</b></p>	
<p><b>Proficiency Testing Standard of Practice 16 (PT S16): Proficiency Testing Documentation</b></p> <p>Laboratories must maintain the following documentation of the processing and reporting of proficiency testing samples:</p> <p>a) steps taken in preparing, processing, examining, testing and reporting all results in the proficiency test event;</p>		<p><b>Proficiency Testing Standard of Practice 16 (PT S16): Proficiency Testing Documentation</b></p> <p>Laboratories must maintain the following documentation of the processing and reporting of proficiency testing samples:</p> <p>a) steps taken in <u>handling</u>, preparing, processing, examining, testing and reporting all results in the proficiency test event;</p>	

<b>Current Standard</b>	<b>Current Guidance</b>	<b>Proposed Standard</b>	<b>Proposed Guidance</b>
<p>b) the proficiency testing provider’s attestation form completed in accordance with the provider’s instructions and requirements; and</p> <p>c) copies of all testing records, including copies of the proficiency test report forms that must be retained according to <a href="#">Document and Specimen Retention Standard of Practice 11</a>.</p> <p><b>Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)</b></p>		<p>b) the proficiency testing provider’s attestation form completed in accordance with the provider’s instructions and requirements; and</p> <p>c) copies of all testing records, including copies of the proficiency test report forms that must be retained according to <a href="#">Document and Specimen Retention Standard of Practice 11</a>.</p> <p><b>Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)</b></p>	