Introduction

Proficiency testing (PT) is a process for checking laboratory performance, usually by means of inter-laboratory data comparisons. The phrase “External Quality Assessment Programme” is used in ISO 15189:5.6.3 to refer to PT Programs. Results from proficiency testing are an indication of a laboratory’s competence and are an integral part of the assessment and accreditation process. A2LA’s Clinical Laboratory Accreditation Program, requires successful participation in proficiency testing programs accredited to ISO/IEC 17043 or Centers for Medicare and Medicaid Services (CMS) approved PT programs and compliance with specific requirements associated with ISO 15189.

A2LA encourages laboratories to participate in “educational” proficiency testing activities that may be offered by Proficiency Testing providers. These “educational” PT samples are typically designed by the provider to challenge the participant by purposely providing the analytes of interest at levels close to the limits of detection or with unusual properties or associated with confounding and/or interfering matrices in order to help the laboratory better understand their analytical capabilities. Please note that participation in these programs will not impact (either positively or negatively) the laboratory’s status with respect to meeting A2LA’s Proficiency Testing requirements.

The ILAC requirements document specifying PT participation is entitled ILAC Policy for Participation in Proficiency Testing Activities (ILAC-P9). ILAC P9 requires that “Accreditation bodies (ABs) seeking to sign or seeking to maintain their status as a signatory to the ILAC Multilateral Recognition Arrangement (MRA) shall demonstrate the technical competence of their accredited calibration and testing laboratories. One of the elements by which accredited laboratories can demonstrate technical competence is by satisfactory participation in PT activities where such activities are available and appropriate.”

A2LA assesses compliance with proficiency testing requirements using C915 - General Checklist: Proficiency Testing Requirements for Clinical Testing Laboratories Meeting the ISO 15189 Requirements. This document describes PT required for obtaining and maintaining A2LA Accreditation in the clinical field for laboratories accredited only to ISO 15189.

Those clinical laboratories seeking to achieve accreditation through A2LA shall agree to comply with the following requirements:

- Notify A2LA of the approved program or programs in which it chooses to participate to meet these requirements and designate the program(s) for each specialty, subspecialty and analyte or test to determine compliance with these requirements if the laboratory participates in more than that one PT program approved by CMS or offered by an accredited proficiency testing provider.

- Laboratories will not send PT samples to other laboratories until the PT provider has released the results of the PT challenge.

The Laboratory Director has the responsibility to ensure that the laboratory has subscribed to the necessary PT programs and for monitoring the clinical laboratory’s performance of the PT within those programs.

Specific requirements found in this Policy are in italic type and numbered as in “(PT1)”.

References

ISO 15189:2012 Medical laboratories – Requirements for quality and competence
ISO/IEC 17043:2010 Conformity assessment — General requirements for proficiency testing
ILAC – P9 ILAC Policy for Participation in Proficiency Testing Activities
Definition

Interlaboratory comparison (ILC) is the organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.¹

Laboratory Testing Approach

(PT1) Laboratories shall integrate the PT samples into the normal workload and perform testing on the PT samples in the same manner and number of times that patient samples are tested. If the laboratory’s patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another location, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

(PT2) Laboratories shall also ensure that proficiency testing samples are equally distributed among trained and qualified personnel and satellite locations (where applicable) for the relevant tests. Laboratories shall distribute the PT challenges among those staff that are authorized and competent to perform the testing required for the PT challenge.

Documented Plan & Minimum Coverage

(PT3) At a minimum, PT participation is required in accordance with table 1 below, or if a specialty/sub-specialty is not listed in table 1, the laboratory shall participate in at least 3 proficiency testing activities in that specialty/sub-specialty per year, where relevant and available. The laboratory shall participate in an approved PT program, at the frequency specified by the PT provider, for each specialty/subspecialty and analyte, for which accreditation is being sought and maintained.

¹ ISO 15189:2012 Medical laboratories – Requirements for quality and competence

<table>
<thead>
<tr>
<th>Specialty/Sub-Specialty</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Microbiology</td>
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<tr>
<td>Bacteriology</td>
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<tr>
<td>Mycobacteriology</td>
<td>2 activities per year</td>
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<td>Chemistry</td>
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<td>Routing Chemistry</td>
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<td>Hematology</td>
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<td>Specialty/Sub-Specialty</td>
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<tr>
<td>Pathology</td>
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<tr>
<td>Cytology: Gynecologic Examination</td>
<td>1 10-slide test per year per analyst</td>
</tr>
<tr>
<td>Immunology</td>
<td>3 activities per year</td>
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Each clinical laboratory shall enroll in a proficiency testing (PT) program that is accredited to ISO/IEC 17043 or meets the criteria in Subpart I of 42CFR493 and is approved by CMS. The laboratory shall enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks accreditation. A list of CMS approved PT providers is available at [http://www.cms.hhs.gov/clia/](http://www.cms.hhs.gov/clia/).

A2LA requires that laboratories conduct proficiency testing activities for both primary and secondary test systems. For primary test systems, laboratories shall use available commercial PT programs or, if commercial PT is unavailable, laboratories shall use internal performance verification data.

For secondary testing systems, the laboratory may opt to use internal performance verification data as described in ISO 15189, section 5.6.4 below, in lieu of commercially available PT samples.

Internal performance verification checks include, but are not limited to, the following types of activities:

- a. regular use of certified reference materials and/or internal quality control using secondary reference materials;
- b. replicate tests or calibrations using the same or different methods;
- c. re-testing of retained items.

CAUTION: Performing PT on secondary testing systems using the same PT materials obtained for the primary testing system is not acceptable.

The laboratory shall review and evaluate the results obtained on proficiency testing as specified by the PT provider programs.

Clinical laboratories shall develop a written Proficiency Testing Plan describing how it will meet the minimum proficiency testing participation requirements described in ISO 15189, and the A2LA document, “R903 - General Requirements: Proficiency Testing for Clinical Testing Laboratories Meeting ISO 15189 Requirements.”

ISO 15189, Section 5.6 requires that “The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results.” Therefore, A2LA requires that laboratories have suitably implemented these requirements and (PT4) have a documented plan of how they intend to cover the applicable PT requirements and the specialties, subspecialties analytes and tests listed on their scope of accreditation. (PT5) This plan shall cover any commercially available participation and any intra- and/or inter- laboratory organized studies, as applicable. The plan shall include all methods of testing for all analytes. If an analyte is tested and reported by more than one method, the laboratory shall participate in proficiency testing for all methods that could be utilized to test and report that analyte during that time frame. (PT6) The plan shall also address:

- the handling, preparation, processing, examination of PT samples,
- the steps in the testing and reporting of results of PT testing,
- the laboratory’s process for submission of proficiency testing results to A2LA,
- the corrective action responses arising from PT errors must be submitted to A2LA within 30 days of receipt (see also PT10),
• the description and explanation of what the laboratory is doing in lieu of proficiency testing if proficiency testing is not available for certain test,

• the potential for both announced and unannounced assessments to investigate PT issues, and

• the frequency, scope and personnel to be challenged as part of the proficiency testing participation.

The laboratory shall maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

(PT7) The plan shall be reviewed and updated, as necessary, as part of the laboratory’s management review. This plan will be reviewed by the A2LA assessor during the on-site assessments and submitted to A2LA. Per A2LA R102 – Conditions for Accreditation, laboratories are obliged to inform A2LA of any changes to this plan.

Proficiency Testing Samples

All testing of proficiency testing samples shall be conducted in the laboratory seeking initial or continued accreditation of its testing. The laboratory shall not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory.

Before Accreditation is Granted

(PT8) Applicant clinical laboratories for A2LA accreditation shall demonstrate successful participation in at least one round of approved PT prior to receiving accreditation. This activity shall be successfully completed for each specialty/subspecialty on the laboratory’s requested scope of accreditation.

Applicant laboratories should enroll in suitable PT programs as early as possible to ensure that the completion of the accreditation process is not delayed.

Proficiency Testing Providers

Applicants and accredited clinical laboratories are required to participate in approved PT programs that are accredited to ISO/IEC 17043 or are provided by a CMS approved PT provider. A list of CMS approved PT providers is available at [http://www.cms.hhs.gov/clia/](http://www.cms.hhs.gov/clia/) or on the A2LA website.

If a laboratory is notified that the PT provider for one or more of its analytes has failed to meet the ISO/IEC 17043 accreditation or CMS requirements, the laboratory shall notify A2LA within 30 days and provide a written recovery plan for the affected analytes.

Providing A2LA with PT Results

(PT9) Laboratories must submit the final results or arrange for the direct submittal of the final results by the commercial PT provider to A2LA, followed by subsequent analysis of all relevant proficiency testing participation to A2LA within 30 days upon receipt. The laboratory must provide to A2LA the results of any internal performance verification program as outlined in their documented PT plan. The internal summary data derived from the program must be made available to the assessors during on-site visits.

(PT10) Detailed corrective action responses, including root cause analysis, for any outlying or unacceptable final results related to testing/calibration on their Scope of Accreditation must also be submitted. A2LA may confer with assessors to discuss the results of such studies and assessors will be instructed to review all data associated with these studies during each assessment. Additional charges for assessor review of this data and/or corrective actions may apply.

Laboratories that refuse to provide their PT results to A2LA will not be accredited and those that are already accredited will have their accreditation suspended until such time as the conditions are agreed to.
Failure to participate, patterns of erratic results, successive failures, or other poor performance (as defined further in this document) in required PT programs may result in revocation of accreditation for affected tests/parameters and/or a required on-site surveillance visit by an A2LA assessor. The laboratory’s scope of accreditation found on the A2LA web site will be revised to reflect revocations. Failure to meet minimum participation requirements or to respond to A2LA requests for information may result in an adverse accreditation action (including suspension or revocation of accreditation or revision of the scope of accreditation).

Unsuccessful Participation

Unsuccessful participation in proficiency testing occurs when the laboratory has:

1. Unsatisfactory performance for the same analyte in two consecutive, or two out of three testing events.
2. Repeated unsatisfactory overall testing event scores for two consecutive, or two out of three testing events for the same specialty or subspecialty.
3. An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive, or two out of three testing events.

For initial unsuccessful PT, laboratories shall undertake corrective action to investigate, identify the root cause of and implement corrective steps to prevent the reoccurrence of the cause of the unsuccessful testing. This process may entail process revision, staff retraining, assistance of a consultant or any combination of these or other steps to develop and implement corrective actions.

If a laboratory experiences subsequent unsuccessful PT, the analyte, test, subspecialty, or specialty will remove the testing from the scope of accreditation. The laboratory shall then undergo the reinstatement process (see remedial below).

If, however, as part of an initial or subsequent unsuccessful PT event, any of the following conditions exist:

1. The laboratory fails to provide A2LA with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.
2. The laboratory has a poor compliance history.

A2LA will take appropriate adverse action (restriction of the Scope of Accreditation or suspension or revocation of the Certificate of Accreditation).

Unsuccessful Cytology Proficiency Testing

All A2LA accredited laboratories that perform gynecologic cytology testing shall ensure that each individual (cytotechnologists and pathologists) enrolls in an approved cytology PT program and re-enrolls annually thereafter.

If the laboratory that is accredited to perform cytology fails to:

1. ensure that individuals engaged in the examination of gynecologic preparations are properly tested;
2. ensure that those who fail a testing event are retested; and
3. ensure that required remedial actions is taken

A2LA will take appropriate adverse action (restriction of the Scope of Accreditation or suspension or revocation of the Certificate of Accreditation).

Remedial Action
If unacceptable results are received on a formal proficiency testing program (e.g., CAP), a detailed root cause analysis and corrective action plan shall be provided to A2LA within 30 days of notification of unsuccessful PT performance.

In addition to corrective action responses for unsuccessful PT participation, A2LA requires a corrective action response for each individual failed result of a PT analyte or sub specialty, and every instance of a failure to participate (or late participation) in PT for a given analyte or sub specialty, for every PT round in which these individual failed results are received.

A2LA will request additional documentation if the response is incomplete.

The clinical laboratory shall also provide A2LA with the results obtained from an assayed control material (or other objective evidence) that has been tested after the Corrective Action Plan has been implemented that demonstrates that the laboratory has successfully corrected the problem. Failure to successfully analyze the sample in this “remedial” round will result in immediate revocation of the testing concerned from the laboratory’s Scope of Accreditation.

Following a PT failure and associated corrective action, the laboratory will be required to demonstrate successful performance in the subsequent PT challenge. Failure to demonstrate successful performance on the next PT challenge will result in the outlying analyte being excluded from the scope of testing until such time as the laboratory has provided a successfully executed corrective action plan, and demonstrated satisfactory performance on a proficiency testing challenge.

Repeated PT failures after remedial action may result in the revocation of the testing concerned from the laboratory’s Scope of Accreditation.

Accreditation will be reinstated only upon demonstration of acceptable performance.

**Summary of Requirements**

**(PT1)** Laboratories shall integrate the PT samples into the normal workload and perform testing on the PT samples in the same manner and number of times that patient samples are tested. If the laboratory’s patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another location, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

**(PT2)** Laboratories shall also ensure that proficiency testing samples are equally distributed among trained and qualified personnel and satellite locations (where applicable) for the relevant tests. Laboratories shall distribute the PT challenges among those staff that are authorized and competent to perform the testing required for the PT challenge.

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**(PT4)** Laboratories shall have a documented plan of how they intend to cover the applicable PT requirements and the specialties, subspecialties analytes and tests listed on their scope of accreditation.

**(PT5)** This plan shall cover any commercially available participation and any inter-laboratory organized studies, as applicable.

**(PT6)** The plan shall also address:

- the handling, preparation, processing, examination of PT samples,
• the steps in the testing and reporting of results of PT testing,

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(PT7) The plan shall be reviewed and updated, as necessary, as part of the laboratory’s management review.

(PT8) Applicant clinical laboratories for A2LA accreditation shall demonstrate successful participation in at least one round of approved PT prior to receiving accreditation.

(PT9) Laboratories must submit the final results or arrange for the direct submittal of the final results by the commercial PT provider to A2LA, followed by subsequent analysis of all relevant proficiency testing participation to A2LA within 30 days upon receipt.

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## DOCUMENT REVISION HISTORY

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<td>03/27/20</td>
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| 04/19/20   | • Integrated into Qualtrax  
• Updated Header/Footer to current version  
• Updated format and font for consistency  
• Added Qualtrax hyperlinks                                      |
| 05/18/20   | • Corrected formatting columns error  
• Added missing hyperlinks                                          |