

**R306 – GENERAL REQUIREMENTS: PROFICIENCY
TESTING ISO 15189 MEDICAL TESTING
LABORATORIES**

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Introduction

I. Proficiency Testing

Proficiency testing (PT) is a process for checking actual laboratory performance usually by means of interlaboratory data comparisons. A2LA's Medical Laboratory Accreditation Program requires successful participation in CMS approved PT programs and PT is a requirement for accreditation to ISO 15189. Results from proficiency testing are an indication of a laboratory's competence and are an integral part of the assessment and accreditation process.

This document describes the general information pertaining to PT required for obtaining and maintaining A2LA Accreditation and is not intended to cover all Proficiency Testing regulatory requirements that appear in 42CFR493.

II. Testing samples

Proficiency testing samples shall *not* be sent to another laboratory for analysis.

The laboratory must not send a PT sample or a portion of a PT sample to another laboratory for analysis which it is accredited to perform in its own laboratory.

III. Laboratory Testing

Laboratories shall conduct proficiency tests in accordance with their normal patient testing and reporting procedures, unless otherwise specified in the instructions from the proficiency test provider.

Laboratories shall also ensure that proficiency testing samples are equally distributed among personnel trained and qualified and who normally perform the test.

Laboratories shall test the PT sample the same number of times that it routinely tests the patient sample.

The individual testing the sample and the laboratory director must attest that the PT samples were routinely integrated into the patient workload using the laboratory's routine methods.

IV. Applicable to Specialties/Subspecialties on Scope

It is necessary to participate in proficiency testing only for the non-waived test methods, for which accreditation is being sought and maintained.

V. Minimum Coverage

At a minimum, proficiency testing participation is required in accordance with the Subpart H 42CFR493 for each specialty/subspecialty and analytes on the scope of the accreditation listed in subpart I 42CFR493.

For those tests performed by the laboratory that are not included in Subpart I 42CFR493 the laboratory must establish and maintain the accuracy of its testing procedures in accordance with §493.1236(c)(1) Evaluation of Proficiency testing performance

VI. Before Accreditation is Granted

Applicant laboratories for A2LA accreditation must be able to demonstrate successful participation in at least one HHS approved proficiency testing activity on the scope **prior to receiving accreditation**.

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

VII. Proficiency Testing Providers

Applicants and accredited laboratories are required to participate in relevant and available HHS approved proficiency testing provided by organizations administering acceptable proficiency testing programs.

When such programs are not available or relevant to the scope of accreditation, internal performance-based data in accordance with §493.1236(c)(1) Evaluation of Proficiency testing performance are acceptable. Internal performance-based checks include (but are not limited to) the following types of activities: regular use of certified reference materials and/or internal quality control using secondary reference materials; replicate tests or calibrations using the same or different methods; re-testing of retained items. In these instances, you will be required to provide a representative sample of your twice annually 'checks' along with your annual review submittal.

VIII. Providing A2LA with PT Results

Laboratories must ensure that A2LA receives copies of all reports/results and the accompanying summary information at the same time as they are distributed to the participating laboratory.

Detailed corrective action responses for any outlying or unacceptable results related to testing on their Scope of Accreditation must also be submitted. Further, the laboratory must authorize A2LA in to submit the results of the PT to HHS.

To facilitate A2LA review, laboratories must complete *F104 - Proficiency Testing Data Submission Form* along with the data and corrective actions. *This form can be provided to you in either hard copy or electronic format by contacting A2LA or can be downloaded from our web site.* 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.

Failure to participate, patterns of erratic results, successive failures (as defined in subpart H 42CFR493), or other poor performance (in accordance with the PT provider evaluation criteria) in required proficiency testing programs may result in revocation of accreditation for affected 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 any revocations. Failure to meet minimum participation requirements or to respond to A2LA requests for information may result in an adverse accreditation action.

IX. Remedial Actions:

When a laboratory fails a PT challenge there is not one answer for every case. A2LA takes into consideration the laboratories compliance history, its willingness and expedience in taking remedial actions, the effectiveness of the remedial actions and the professional judgment of the qualified assessors and A2LA staff.

APPENDIX A - Document Revision History

Date	Description
June 7, 2007	Issued