



INTERNATIONAL EXCHANGE SPECIMENS

CLIA Standards – Proficiency Testing (42CFR493)

As stated in the Federal Register under subpart H 493.801(b):

- (1) The samples must be examined or tested with the laboratory’s regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory’s routine methods. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory’s routine methods.
- (2) The laboratory must test samples the same number of times that it routinely tests patient samples.
- (3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report results to the program for the testing event in which the samples were sent.
- (4) Laboratories must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory.
- (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must 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.

Attestation Statement

We the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing (PT) materials, have as closely as practical, performed the analyses on these specimens in the same manner as routine patient samples.

We confirm that results were not referred or discussed outside our laboratory.

Retain this signed document in the laboratory for your records and inspection purposes.

**Survey
Shipment ID**

**Survey
Year**

Director (or Designee)

Date

Testing Personnel

Testing Personnel

Testing Personnel
