

PROFICIENCY TESTING PAPERWORK

The paperwork associated with proficiency testing (PT) can be confusing. What forms to complete, which ones to keep, and how long to keep them are questions laboratory staff often ask their proficiency testing provider or regulatory agency. This CLIA Facts offers hints on handling proficiency testing paperwork.

Enrollment Form

The first paperwork associated with PT is the enrollment form. On this form you will indicate to the PT Provider which PT modules you have chosen, and which analytes from these modules will be tested and graded for regulatory purposes. In addition, you can indicate to the PT provider who should receive copies of your scores (i.e., CMS, state agencies, accrediting organizations).

Your CLIA number is required on this form so regulatory and accrediting agencies can receive your PT scores. Keep a copy of this form in your records for two years. Surveyors may want to see this form to confirm your laboratory's enrollment for the next calendar year.

Instruction and Summary Booklets

The laboratory will also need to retain the PT instruction booklet that is sent with the PT specimens. This booklet contains valuable information regarding the correct handling and preparation of the PT samples for testing.

Keep the summary booklet that accompanies your PT scores. It contains information on how your PT scores were evaluated, your method's peer group, and how your laboratory's result compared to that obtained by the peer group. Your peer group is those labs using the same instrument/method of analysis as your laboratory.

Many of the PT providers offer the summary booklets online and only mail them to laboratories that do not have computer access. In most cases, the laboratory must request a hard copy. If you have on-line access, then you will need to know how to access the summary booklets and might want to print a copy for your records.

PT Result Form

Your results for each analyte tested for a PT event are recorded on this form. Some labs like to make photocopies of a blank result form to use as a worksheet when testing.

Transcription problems are a common reason for a laboratory to fail a PT event. Be alert for clerical errors! Be sure to record the result in the correct result box, and include the appropriate instrument/kit and method/reagent codes for each test. Double-check that all entries are recorded correctly.

If required by your PT provider, write in the numeric code number for "test not performed" for those tests included in a module that your laboratory does not perform.

You should keep all worksheets and instrument tapes associated with testing the PT specimens. This will help verify correct result entry and that there are no transcription errors.

If you encounter problems with recording or reporting your PT results, then call your PT provider for assistance. Document all correspondence. If your lab is unable to test or obtain PT results, then send a letter to your PT provider describing the situation before the due date for submitting results. You can request exclusion from the test module or event, as your situation warrants.

Prior to mailing, photocopy the completed PT result form with your results. This copy is valuable in case your result form is lost or damaged in the mail. Keep all copies in your records for two years. Although not required by PT providers, mailing your PT result form by certified/return receipt allows you to trace it and demonstrate proof of when it was mailed.

PT Attestation Statement

This statement is at the bottom of the PT result form and must be signed by the laboratory director and testing personnel. It testifies that the laboratory did not share information concerning their PT event with other laboratories and tested the PT samples in a manner similar to patient samples, including the frequency tested. Laboratories may not test their PT samples at other laboratories, nor share their results before they have submitted their PT results to the provider.

PT Score Report

After receiving your PT result form, the PT provider evaluates each group of results, determines the acceptable range of results, and grades each result accordingly. The PT score report informs the laboratory of its scores and group scores for each analyte tested. Keep this form in your records for two years. This form should be reviewed and signed by the laboratory director and testing personnel to evaluate PT performance.

Investigate or evaluate any score below 80% (below 100% for ABO/Rh or compatibility testing.) Analytes that are ungraded may be due to lack of a statistical peer group (not enough labs performing your method), lack of consensus, or paperwork that was not completed correctly.

CMS Summary Page

This form shows the results received by CMS and state or accrediting organizations for the test methods and analytes you have indicated are to be scored for regulatory purposes. All regulated analytes enrolled in proficiency testing by the primary method of analysis should be listed on the summary page.

If your test results are not on this page, then contact your PT provider because you are not "getting credit" for your PT participation. This form should contain your CLIA ID number and name/identifier of any other agency designated to receive copies of your scores.

Some laboratories, for educational or quality assessment purposes, have more than one method for an analyte evaluated by PT. The laboratory must indicate which method is to be scored for CLIA compliance purposes. Only the results for this method are included on the CMS summary page. Keep the summary page in your laboratory records for at least two years.