

Procedure: Proficiency Testing Guide

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PRINCIPLE:

By law, each laboratory must be enrolled in an approved Proficiency Test (PT) program for each testing analyte performed (regulated / unregulated). This is accomplished by enrollment in a CLIA (Clinical Laboratory Improvement Amendments) approved Proficiency Test program in accordance with accreditation standards. Proficiency Testing performance and assessment are major elements of a laboratory’s Quality Assurance (QA) program. By reviewing the laboratory’s PT results with participant summaries, the laboratory can assess their ability to maintain the accuracy and reliability of its test results. Documentation of Proficiency Testing records must be retained in the laboratory for a minimum of **two years** as required by CLIA.

For those analytes (non-regulated analytes) which are not included in a formal proficiency testing program, the laboratory must provide a method to assess and verify the accuracy and reliability of their analytes (see Alternative Proficiency Assessment Policy).

Proficiency Test handling;

1-The proficiency survey samples must be handled to the same degree possible as a patient sample would be handled. Documentation of any special handling that is different from processing patient samples (i.e. necessary reconstitution, mixing times) is required.

2-Proficiency test samples must be tested with the laboratory’s patient workload by personnel who routinely perform testing, using routine methods assigned to that bench.

3-Proficiency test samples must be tested the same number of times that patient samples are routinely tested. The laboratory must use the same procedures for both patient samples and PT samples. Do not run PT samples multiple times if patient samples for that testing are not routinely run multiple times.

4-The laboratory must **not** engage in inter-laboratory communication regarding Proficiency Testing until **after** the deadline for submitting results to the proficiency test program has passed.

5-PT samples or portions of samples must **not** be referred to other laboratories for analysis or evaluation. A laboratory cannot refer PT samples to another Laboratory for confirmatory testing.

Note: Be sure that the PT submission deadline has passed before using the samples for cross checking or educational challenges. Some laboratories internally cross check PT samples by running them on multiple instruments / methods or they may use the PT samples as a competency by having multiple technologists perform testing on PT samples.

Test Methodology

1-The method used for proficiency testing must be the primary method or system used for patient testing at the time the PT event is received. Different methods can be used in different PT events; however proficiency samples within each survey event must be performed by the same methodology.

2-Care must be taken when completing the PT result form. Results left blank for any enrolled test or incorrect / missing test codes or methodology will result in an unsatisfactory performance.

3- Most PT events with less than 10 lab participants automatically receive a score of 100%. The laboratory **must not** accept this score as having met satisfactory performance. An evaluation of the report must be performed to demonstrate that the laboratory has met established Proficiency Testing criteria. The evaluation must be performed as done for interlaboratory comparisons-(as it would be done for an alternative proficiency program report).

PT Submission

1- All Proficiency test results **must** be submitted on line to the appropriate Proficiency Testing Program when available.

2- Check the individual Proficiency Test Program website for **on-line submission** procedures.

3- Implement an **accuracy review process** prior to final submission of all proficiency testing results.

Note: Failure to submit PT results to the provider within the timeframe specified by the provider will result in score of 0 for the testing event.

Proficiency Test Documentation

1-All proficiency testing records (PT data, instrument output, computer sheets, and corrective actions) must be kept for at least **two years**. These records should be organized in chronological order.

2-The laboratory must document the handling, preparation, processing, examination, and reporting of results for all PT samples. Keep a copy of all records, including a copy of the results submitted to the PT program.

3-The attestation form provided by the PT program **must** be signed by the analyst and the Laboratory Director, attesting to the integration of the PT samples into the patient workload using the laboratory's routine methods.

4- Each PT report generated by a PT program or informal PT program, including the **un-graded / educational** survey reports, must be reviewed, dated, and signed by the **Director or appropriate supervisor**.

When appropriate, reviewer's comments must be documented.

Unacceptable Proficiency Test Results Investigation

A laboratory may have an occasional unacceptable result. This may reveal a problem in specimen handling or in an analytical process that will not be exposed by any other means. Therefore any unacceptable result must be investigated thoroughly to maximize the opportunity to correct a problem. The laboratory is responsible for monitoring all PT discrepancies even those results that are non-scored or deemed "educational" by the PT provider. When investigating an unacceptable result, there are certain points to keep in mind while performing the investigation:

- Gathering and reviewing data

All documentation should be reviewed, and personnel who processed or tested the specimen interviewed. The investigation should include:

- Checking for clerical errors

- Record reviews of Quality control, calibration status and instrument checks (function checks)

- Repeat analysis and calculations (if available).

- Evaluation of the laboratory's historical performance for the analyte in question.

- Evaluation of patient results:

The laboratory must review all patient data generated during the time the unacceptable (PT) was performed. The laboratory is to determine whether patient care was compromised; and if so, what corrective action is required. (I.e. if result discrepancies are noted upon sample run repeat, the patient's physician must be notified)

- Conclusions and Actions:

The Laboratory should make every effort to find the cause(s) of an unacceptable result. If the laboratory can identify an underlying system problem that contributed to the unacceptable result, actions to improve the laboratory system will minimize the risk of reoccurrence and potentially improve the quality of patient results. A performance improvement plan should be implemented to try to prevent the same failure in the future.

- Documentation:

The investigation, conclusions, and corrective actions should be thoroughly documented.

Proficiency Test Evaluation by the CQI Office:

The Pathology CQI Office screens all copies of consultant PT evaluation reports. Notices highlighting QA review information are sent to the laboratory when necessary.

The CQI staff will review each report for:

- any analyte result with trends, with SDI +/-2.0 or greater
- certain evaluation codes given by the PT program
- lab responses for un-graded and educational challenges that do not match the peer group response
- any analyte result with a SDI +/- 3.0 or greater
- any flagged unacceptable response.
- any results that would be flagged by accrediting and licensing organizations who receive copies of the survey evaluation.

The severity of the unacceptable PT survey result will determine the type of communication the laboratory will receive from the CQI office.

FYI (for your information only): Sent electronically to alert the laboratory of possible testing problems. Does not require a formal investigation, but a brief response to the alert.

PTIF (Proficiency Testing Investigation Form):

Forwarded electronically, requires a formal response with proper investigation and documentation.

Accreditation Review of Proficiency Testing:

During the JC (Joint Commission) Laboratory Accreditation inspection, the surveyor will review each laboratory's proficiency testing enrollment, participation and performance for regulated analytes, and non – regulated analytes (if applicable).

The survey will include the following review:

- Verification that the laboratory is properly enrolled in an approved PT program.
- Verification that the laboratory's proficiency test performance is satisfactory and successful for each specialty and sub-specialty, analyte, or test. (see appendix A)

- The retention of the following documents for at least **two** years: Records of test handling, preparation, processing, examination, and results reporting.
- Signed attestation statement provided by the proficiency program.
- Evidence that the laboratory has documented problems or potential problems and remedial action taken when indicated.
- Evidence that the laboratory has documented review of each report by the laboratory director or appropriate supervisor.

To facilitate this review, each laboratory should have its records organized and ready at the time of the survey.

References

CLIA Regulations Sec.493.1236 Standard: Evaluation of proficiency testing performance 2004.

Joint Commission. Comprehensive Accreditation Manual for Laboratory and Point of Care Testing 2007, QC.1.20, -QC1.40, - QC1.60 pg.QC-13-QC-14; 2004 Accreditation Process Guide for laboratories System Tracer: Data Use Pg 47-49

NCCLS. Using Proficiency Testing (PT) to Improve the Clinical Laboratory GP27-A, NCCLS, 940 West Valley Road, Suite, 1400, Wayne PA 19078, 2002

Laboratory's proficiency test performance is satisfactory according to the following:

- _ Attaining a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and D (Rho) typing and compatibility testing.*
- _ Attaining a score of at least 100% for ABO group and D (Rho) typing or compatibility testing.*
- _ Returning proficiency testing results to the proficiency testing provider within the timeframe specified by that provider (**Note:** Failure to return proficiency testing results to the proficiency testing provider within the timeframe specified by that provider results in a score of 0 for the testing event)*
- _ No omission of results on the proficiency testing form (**Note:** Omission of results could lead to a failure of attaining the score necessary for satisfactory performance).*
- _ Participating in a proficiency testing event (**Note:** Failure to participate in a proficiency testing event which results in a score of 0 for the testing event)*