Proficiency Testing Policy

PURPOSE

The intent of this document is to provide a clear and thorough description of the Canton City Health Department Laboratory's requirements and procedures for proficiency testing

POLICY

The Laboratory Director ensures that proficiency testing, alternative assessment, and Quality Control (QC) procedures are sufficient for the extent of testing performed in the laboratory. The laboratory is required to perform proficiency testing and will subscribe to the Proficiency Testing (PT) programs in Centers for Medicare & Medicaid Services approved program provider, when available. Each analyte or test will have written procedures for the proper handling, analysis, review and reporting of proficiency testing material specific to that clinical specialty. When CMS approved programs are not commercially available, the laboratory will develop and document their own alternative proficiency testing or self-evaluation programs that are sufficient for the extent and complexity of testing in the laboratory.

BACKGROUND

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003. Together these documents provide a history of a movement toward a process of continuous improvement. Throughout the legislative process an emphasis has been placed on the need for a complete proficiency testing program in all testing laboratories.

GLOSSARY OF TERMS

- Proficiency testing (PT) is the testing of unknown samples sent to a laboratory by a CMS approved PT program.

PROCEDURES & STANDARD OPERATING GUIDELINES

PROFICIENCY TESTING GENERAL POLICY GUIDELINES

- Testing personnel should ensure that proficiency sample testing is performed in the same manner as patient sample testing.
- The laboratory integrates all proficiency testing samples into the routine laboratory workload, and those samples are analyzed by personnel who routinely test

patient/client/donor samples, using the same primary method systems as for patient/client/donor samples.

- If the laboratory uses multiple methods for an analyte, proficiency samples should be analyzed by the primary method.
- The educational purposes of proficiency testing are best served by a rotation that allows all technologists to be involved in the proficiency testing program.
- Proficiency testing records should be retained and can be an important part of the competency and continuing education documentation in the personnel files of the individuals
- Inter-laboratory communication about proficiency testing samples before submission of data to the proficiency-testing provider is strictly prohibited.
- Proficiency survey sample will not be sent to a reference laboratory for additional testing or confirmation of results. This prohibition takes precedence over the requirement that proficiency samples be handled the same as patient specimens if referral lab confirmation is the laboratory's policy.
- Primary records related to PT and alternative assessment testing are retained for two years (unless a longer retention period is required elsewhere in this checklist for specific analytes or disciplines). These include all instrument tapes, work cards, computer printouts, evaluation reports, evidence of review, and documentation of follow-up/corrective action.

The Laboratory Director (or Designee) (LD/D) should document a review of results on each proficiency testing report even if no problems were identified. The laboratory is required to perform proficiency testing and is expected to meet the requirements for acceptability in proficiency testing and maintaining performance at an acceptable level. The LD/D documents solutions or corrective actions. Any significant failure of proficiency testing (including investigation and corrective actions) should be reviewed and approved by the Laboratory Director. Results should be reviewed within five business days of receipt.

- 100% performance score does not require further investigation and can be reviewed and the attestation signed by the LD/D. Proficiency survey results should be shared with testing staff as survey challenges can be an educational or competency assessment tool.

- Survey performance resulting in a score of less than 100% will require further investigation and corrective action utilizing the Incident Investigation Form. Examples may include:

    - Any analyte that fails evaluation against graded criteria should be re-evaluated to identify the reason for the failure and corrective action.
    - Any analyte that is not evaluated or scored by a CMS-approved proficiency-testing program should have a self-assessment performed and appropriately documented.
    - Any analyte that does not reflect test performance (e.g., when PT does not obtain the agreement required for scoring, or the section receives a zero score for nonparticipation, or late return of results).

Proficiency Testing Procedures
The following general procedures should be followed:

- When proficiency testing materials are received, immediately open and inspect them for package and product integrity.
- Following inspection, review instructions for storage and immediately store the product as described by the PT Provider.
- Notify the Lab Manager of the arrival and status of the material.
- The PT Provider should be immediately notified if there are any problems with the material or any other issue that will delay testing or reporting of results.
- The Lab Manager is responsible for assignment of analyte testing by laboratory personnel. Assignment is made based on prior proficiency testing rotation as indicated on the Analyst Rotation Log.
- The Technical Supervisor is responsible for the integration of the testing material into the regular patient workload.
- Following assignment and provision of material, laboratory testing personnel will be expected to handle Proficiency Testing samples in the same manner as patient samples as much as possible; as well as testing in accordance with the associated instructions provided for each PT event.
- Testing personnel must test samples the same number of times that it routinely tests patient samples.
- Proficiency samples should be documented in the same manner as patient samples.
- Additional documentation for proficiency testing purposes include: completion of the proficiency testing worksheet, attestation page and Analyst Rotation Schedule.
- Testing will be completed prior to the due date. This is to ensure meeting grading criteria, and also to ensure specimen integrity.
- Results are to be submitted to the PT Provider prior to the results submission date. Reporting can be done by the testing personnel or the Technical Supervisor.
- Testing Personnel 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 have reported proficiency testing results to the program for the testing event in which the samples were sent and after all off rotation testing personnel have provided their results to the Technical Supervisor.
- Any PT material remaining from testing should be stored for use by off rotation personnel. This material cannot be reevaluated until the submission period has ended.
- Off rotation personnel will be assigned analyte testing by the Lab Manager and follow all PT procedural elements as described above and provide PT results directly to the Supervisor prior to the grading of the PT samples.
- The laboratory should adhere to the PT Providers testing instructions for each survey submitted for analysis. These instructions address proper specimen handling, storage, testing limitations or special instructions, reporting criteria, and instructions for submitting results.
- Upon completion of each cycle of PT, a Laboratory Director Attestation Page form will be completed and along with all of the results, corrective action material and worksheets provided to the laboratory Director for review and attestation.

Unsatisfactory Proficiency Testing (PT) Performance

Unsatisfactory performance for 1 or more analytes on an event requires the laboratory to:

- Investigate the problem utilizing the Incident Investigation Form,
- Determine the cause,
- Implement corrective action, and
- Response to the CLIA Accreditation Program is not required

Unsatisfactory performance on 2 of 3 PT events requires the laboratory to:

- Suspend testing,
- Investigate the problem utilizing the Incident Investigation Form,
- Determine the cause,
- Implement a plan of correction, and
- CLIA Laboratory Accreditation Program must approve the corrective action prior to resuming testing.

Investigation of failed proficiency survey

The investigation of a failed PT event is through the use of the Incident Investigation Form. If applicable, the items below must be documented on the form:

- Review for Clerical Errors

- Review for Technical Issues

    - Reconstitution, pipetting, dilution errors
    - Specimen mix-up
    - Improper specimen handling
    - Incorrect instrument set-up
    - Failure to follow test kit or instrument instructions

- Potential Methodologic Issues

    - Mechanical difficulties (check maintenance and quality control records)
    - Instrument software issues
    - Calibration issues
    - Inadequate reagent performance
    - Instrument failure

Correct the failure and resume testing once issue is identified and resolved. All corrective actions and retesting should be reviewed by the LD/D.

Ungraded Proficiency Challenges

Ungraded PT Surveys require internal assessment of performance, documented evaluation and approval by the LD/D. Reasons for ungraded PT challenges include: the laboratory submitted its results after the cut-off date, the laboratory did not submit results, the laboratory did not complete the result form correctly (for example, submitting the wrong method code or recording the result in the wrong place), lack of consensus among participants.

An ungraded PT challenge will be handled as a failed survey and require internal analysis against survey results utilizing CLIA limits. Results should be reviewed by the LD/D. Documentation can be on the Incident Investigation Form or in a format for the specific event.

Proficiency Testing Organizations
For laboratories subject to US regulations, participation in proficiency testing may only be through CMS-approved PT program.

CLIA-approved Proficiency Testing Programs include:

- **Accutest (DigitalPt) 800-665-2575 www.digitalpt.com**
- **American Association of Bioanalysts 800-234-5315 www.aab-pts.org**
- **American Proficiency Institute 800-333-0958 www.api-pt.com**
- **American Society for Clinical Pathology 800-267-2727 www.ascp.org**
- **California Thoracic Society 714-730-1944 www.thoracic.org/ca.html**
- **College of American Pathologists 800-323-4040 www.cap.org**
- **Medical Laboratory Evaluation 800-338-2746 www.acponline.org/mle**
- **Wisconsin State Laboratory of Hygiene (WSLH) 800-462-5261 www.wslhpt.org**

Alternate Proficiency Survey

For tests for which CLIA does not require PT, the laboratory at least semi-annually 1) participates in external PT, or 2) exercises an alternative performance assessment system for determining the reliability of analytic testing. Additionally, for those analytes that do not have a commercially available proficiency testing provider, the laboratory will perform an alternative performance assessment system for determining the reliability of analytic testing at least semiannually.

- Alternate proficiency should be performed at least semiannually.

- Alternate proficiency methods could include:

    - Split sample analysis with another laboratory
        - Minimum 3 samples. If only 2 of 3 match, increase sample size to 6
        - 5 of 6 should match; 95% confidence should be attained
    - Test against an established alternate method
    - Test against a reference sample (i.e. product calibrator or previous assayed material)

- Test against an established alternate method
- Analysis of patient data (clinical correlation) when external proficiency testing materials are not available. The semi-annual alternative performance assessment process should also be integrated within the routine workload, if practical.

CITATIONS & REFERENCES

Code of Federal Regulations, Title 42-Public Health, Part 493-Laboratory Requirements

CONTIRBUTORS

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APPENDICES & ATTACHEMENTS

400-004-02-01-F_Proficiency Testing Rotation Schedule
400-004-02-02-F_Laboratory Director Attestation Page

REFERENCE FORMS

Proficiency Testing Worksheet (assorted documents)