PROFICIENCY TESTING POLICY	
POLICY #	Prepared by:
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APPROVALS in this section

Approved by: _____ Date: _____
Laboratory Director

RECORD OF REVIEWS

Date	Signature	Title	Procedural Changes/Review

VERSION HISTORY

Revision #	Section #/Changes	Revision Date	Reason for Revision
0			
1			
2			

PROFICIENCY TESTING POLICY	
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PURPOSE

Proficiency testing is required by CLIA for all regulated clinical analytes. In addition, the clinical laboratory and the Environmental Sciences Unit participate in proficiency testing modules provided by Centers for Disease Control (CDC), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA). It is the policy of the [Lab Name] to enroll and participate in external proficiency testing (PT), when it is available, to verify the continuing accuracy of all laboratory tests. When external PT is not available for a clinical test, the CLIA regulations require the laboratory to verify the accuracy of the test twice a year. This policy provides general instructions and regulatory requirements for the ordering, performance, and monitoring of proficiency testing.

The laboratory supervisor is responsible for ensuring that the appropriate PT modules are ordered, and samples processed and reported in a timely manner. The supervisor is also responsible for ensuring that the appropriate corrective action is taken and documented in the event of a PT failure.

ORDERING OF PROFICIENCY TESTING:

1. The QA Manager in coordination with the QA Coordinator and unit managers orders the clinical PT samples in October-November of each year. If the test menu changes during the year, the unit manager is responsible for notifying the QA Manager so changes to the PT program can be made in a timely manner. PT enrollment confirmations are filed in the QA Manager's Office for a minimum of 3 years.

2. The environmental PT samples are ordered by the respective laboratory supervisors. Milk split samples are forwarded directly to the [Lab Name] by US FDA (Food and Drug Administration).

3. The frequency and number of challenges for PT testing is defined by the regulatory agency governing the specific lab area. At the beginning of the calendar year, the QA Manager prepares a spreadsheet for the Mailroom detailing the purchase order numbers for clinical PT orders, the names of PT modules, expected delivery dates, responsible persons, and room numbers.

PROFICIENCY TESTING POLICY	
POLICY #	Effective Date:

RECEIPT AND TESTING OF PT SAMPLES:

1. The PT samples are received, processed and tested as routine samples in the respective unit laboratories. PT samples are received in the Mailroom and delivered to the specified location. The lab receiving the PT samples documents the date of receipt and stores the PT package at the appropriate temperature. The person receiving the PT samples is responsible for notifying the laboratory supervisor or person designated as responsible for PT testing. If the PT samples are damaged in transit or not received within 7-10 days from the scheduled shipping date, the laboratory supervisor must contact the PT vendor to report the missing samples and to request a replacement kit.

2. Laboratories are responsible for submitting PT results to the PT provider by the deadline listed on the instruction form. PT results may be mailed, but should be faxed or entered on-line if this option is available. If PT results are faxed, a fax confirmation sheet must be printed and retained with the lab's PT records. If results are entered on-line to the PT provider, the laboratory must retain a copy of the data submission form or a print-screen of the entered results.

3. For clinical PT modules, the laboratory is responsible for completing and retaining an attestation sheet. Each person who performs testing on the PT samples is required to sign the attestation form. This form must also be signed by the laboratory director or designee, usually the unit manager or technical supervisor. Even if these names are typed into the on-line report module, the laboratory must obtain signatures as well. The purpose of the attestation form is that it is a written statement from each individual involved with the testing that the PT samples were incorporated into the patient workload and tested like routine specimens.

4. If the laboratory is unable to perform testing on PT samples due to an instrument or test method problem **and** patient testing is suspended, the laboratory must report this information to the PT provider so there is no penalty for lack of participation. Also, the laboratory must notify the QA Manager when this problem arises

5. PT samples must be tested in the same manner that patient specimens are tested. This means testing the PT samples the same number of times as patient specimens, at the same time as patient specimens, by the same personnel who routinely test patient specimens, and on the same test system routinely used for testing patient specimens. PT samples should not be tested on a tray by themselves and additional quality control materials or special calibrations should not be performed only for the purpose of testing the PT samples. Participation in PT must be rotated among all staff who perform patient testing, but not all staff are required to participate within one calendar year.

6. If the laboratory area uses LIMS for patient testing, the laboratory must develop and follow a protocol for entering the PT samples as patients so that they are processed in the same manner as patient specimens.

7. It is acceptable if PT sample preparation prior to testing differs from patient specimen preparation. Follow the instructions that come with the PT samples. This may include special handling or mixing that is required prior to testing. Likewise, it is acceptable and recommended to have a second person review the completed results form and/or data submission form, to prevent clerical errors in submission of the results.

8. **NEVER** send PT samples to another laboratory for any reason, even if you routinely send out patient specimens for additional or confirmatory testing. **NEVER** discuss your PT results with another laboratory and **NEVER** enter into discussion with another laboratory about their PT results before the PT event cut-off date. These activities could cause the NCSLPH to lose its CLIA certification.

RECEIPT AND EVALUATION OF PT RESULTS:

1. The QA Manager reviews the evaluated results from the clinical PT programs, and circulates the results to the respective unit manager/technical supervisor, general supervisor and Director/Assistant Director for final reviews. The QA office maintains a log book of all received PT results and corrective actions. A stamp is used to assist in routing and documentation of the PT reports through the various levels of review. Environmental QA PT results are received and reviewed by the Environmental Sciences Manager.

2. Any PT result of less than 100% must be reviewed and an investigation performed to determine the cause of failure. A description of the PT investigation and corrective action with any supporting documentation will be forwarded to the QA Manager for review. If the corrective action is deemed acceptable, it is then forwarded to the Director and/or Assistant Director for a final review and approval. If the PT failure is related to patient testing, i.e. calibration problem or instrument failure, the documented corrective action must include remediation of patient test results. Contact the QA office if assistance is needed with this corrective action plan.

3. If the PT provider does not grade a sample due to lack of consensus or lack of participation, the laboratory is responsible for reviewing the participant summary report and determining if the PT results are acceptable. The laboratory must perform accuracy verification by an additional method if this participant summary information is not available (see below).

4. The laboratory must retain a copy of all PT records for a minimum of 2 years from the date of testing. This includes the raw data from the analyzers, the data submission form, attestation statement, evaluation report with documentation of review, and corrective actions if required. If PT samples are stable, they should be stored at the appropriate temperature until after the PT evaluation report is received. These samples can be useful for troubleshooting PT failures or can be used for future method development.

ENFORCEMENT FOR UNSUCCESSFUL PT:

1. If the laboratory receives scores of less than 80% on a regulated analyte or has a total event score of less than 80% on 2 of 3 consecutive testing events, the laboratory will receive a letter and CMS-2567 (Statement of Deficiencies) from the CLIA state agency requiring an explanation of the PT failures and documentation of corrective actions.

2. If the laboratory has subsequent failures for the same analyte or event within a 3-year period, the PT enforcement action will come from the CLIA Regional Office. In most cases, the laboratory will be required to discontinue this test for a period of 6 months and participate successfully in 2 off-schedule PT events.

3. In both cases, the QA Manager will work with the unit technical and general supervisors to process the paper work completely in a timely manner and to assure that all documentation is complete and meets CLIA expectations.

WHEN NO PT PROGRAM IS AVAILABLE:

If no PT is available for a *clinical* test, the CLIA regulations require the laboratory to verify the accuracy twice annually. These verification activities must be documented and reviewed by the unit technical supervisor. Records are stored in the unit laboratory and must be retained for at least 2 years. Alternate test methods may include:

1. Split patient samples with another laboratory that performs the same test. The unit supervisor must review both the NCSLPH results and results from the external laboratory and establish a system to evaluate and document acceptability.

2. Internal split sample – rerun previously tested patient samples by a different method or if a different method is not available, rerun using different testing personnel.

3. Stored samples – aliquots of patient specimens are stored, retested and the results compared to the original result.

4. Analyze a different lot number of calibrator or control materials, testing them as you would patient specimens to see if you recover the expected values.

5. Perform a review of the test results and how this information relates to the clinical picture or its relationship with other testing. For example: does confirmatory testing over a period of time support the laboratory test result with statistical agreement?

DOCUMENTATION FORMS:

The following forms are available to assist in proficiency testing investigation and documentation:

- Proficiency Test Tracking Form (Appendix A)
- Missed Analyte Investigation Form (Appendix B)

REFERENCES:

1. Clinical and Laboratory Standards Institute (CLSI), Using Proficiency Testing to Improve the Clinical Laboratory, GP 27-A2. Wayne, PA. 2007

2. "Proficiency Testing Dos and Don'ts" CMS CLIA Brochure #8, September 2008.

3. FINAL CLIA Rule, Appendix C: Survey Procedures and Interpretative Guidelines for Laboratories and Laboratory Services. CMS. January 24, 2003.

APPENDICES:

Appendix A: Proficiency Test Tracking Form
Appendix B: Missed Analyte Investigation Form