Wake Forest Baptist Medical Center	Proficiency Testing Procedure Lab Admin 12 (Formerly Lab Admin 3)	Dept:	Pathology
		Effective Date:	June 2004
		Revised Date:	3/16/2018
		Contact:	Laboratory Compliance and QA
Name & Title: Gregory J. Pomper, MD		Date:	3/16/18
Signature: Gregory J. Pomper			

1) **General Procedure Statement:**

a. **Scope:** Defines the proficiency testing (PT) program to include the following areas: selection of approved PT materials for regulated analytes, appropriate handling of samples, sample analysis, results reporting, event results review and employee training/competency assessments.

It is the policy of the Department of Pathology and any other laboratory area performing lab testing subject to proficiency testing requirements under CLIA (Clinical Laboratory Improvement Amendments), to adhere to all proficiency testing standards or regulations of CLIA and/or other accrediting laboratory agencies such as: College of American Pathology (CAP), American Association of Blood Banks (AABB), American Society of Histocompatibility and Immunogenetics (ASHI), Commission on Office Laboratory Accreditation (COLA) and The Joint Commission (TJC).

b. **Responsible Department/Party/Parties:**
   i. Procedure owner: Department of Laboratory Medicine and Pathology
   ii. Procedure: Department of Laboratory Medicine and Pathology and Satellite laboratories.
   iii. Supervision: Department of Laboratory Medicine and Pathology, Associate Directors and Section Managers
   iv. Implementation:
   Department of Laboratory Medicine and Pathology Chairman, named CLIA Laboratory Medical Director and Department of Pathology Administrative Director

2) **Definitions:**

- **Regulated Analyte** – analytes that according to CLIA federal regulations require a laboratory to enroll in and successfully participate in a CMS approved proficiency testing program.

- **Unregulated Analyte** – analytes performed by a laboratory that are not included in the regulated listing found in the Federal Regulations Subpart I

3) Procedure:

a. Selection of Material

Analytes for which purchased PT materials are available:

- Annually (by December 1) all purchased PT materials for regulated analytes will be reviewed by designated individuals within the Department of Clinical and Anatomic Pathology to assure they are accounted for on their purchase forms for the areas they are held accountable. PT providers may offer purchased materials for some unregulated analytes as well. If any areas choose to purchase unregulated PT materials, they should do so at this time.
- All purchased PT orders will be placed by the Manager, Laboratory Compliance, QA, Safety and POCT based on the information submitted by the responsible individuals.

Unregulated Analytes:

- All tests for which there is no PT materials available for purchase must still be evaluated at least biannually with an acceptable PT alternative.
- Acceptable alternative methods include:

  Duplicate/Split Sample testing – In which a single sample is divided into aliquots where one aliquot is tested on a particular assay system or by a particular analyst, other aliquots are tested other instruments or by other analysts and the results are compared.

  CLIA Certified Lab to Lab Comparison
  Every six months, the laboratory sends five specimens to a CLIA-certified reference laboratory to compare results with its own laboratory.

  Interlaboratory Quality Control comparison
  Interlaboratory quality control results are used to verify the Continuing reliability of the tests not included in the proficiency testing program (for example, peer comparisons).

  Microscopic Testing
  The technical supervisor of the lab retests random samples throughout the year to cover all testing staff.

  Anatomical Pathology
  - Peer review of interpretation of slides
  - Peer review at case level including diagnosis

- Documentation of the unregulated test, method of alternative PT being utilized must be sent to the Manager Laboratory Compliance, QA, Safety and POCT by December 1 of each year.
- Documentation of alternative assessments chosen should also be documented in the procedure manual along with a method of evaluation of results and defined limits of acceptability for the performance. Corrective actions in response to unacceptable performance to alternative assessments must also be documented and maintained in the same manner as purchased PT surveys.
- The CLIA Lab Director in conjunction with the Section Medical Director will be responsible for determining the acceptable differences allowed when evaluating the results obtained using alternative assessment methods.

  Assessment of the results can take place by utilizing various methods but a commonly suggested method paired with split sample testing would include: agreement across the range of results by plotting results on a two dimensional graph. The lab referenced to would represent the X axis and your lab the Y axis. A line of agreement is drawn in the body of the graph (Y=X). Upon visual assessments of the graph any trends or bias should be easily identified. Documentation of the acceptability of the results should be performed by the section and reviewed, signed and dated by the Medical Director and/or the CLIA Lab Director. If the results are not acceptable, corrective actions and documentation will be necessary.

b. Handling and Analyzing

- The laboratory integrates all proficiency testing samples within the routine laboratory workload, and those samples are analyzed by personnel who routinely test patient/client samples, using the same primary method systems as for patient/client/donor samples. Samples may be repeated, diluted, etc. in the same manner as a patient sample.
- The laboratory (which is subject to regulation by the Centers for Medicare and Medicaid Services
- (CMS) do not test the same analytes from the same PT product on more than one instrument or method unless that is how the laboratory tests patient specimens.
- If the laboratory (under one CLIA license) uses multiple methods for an analyte, proficiency samples must be analyzed by the primary method at the time of the PT event, or rotated among primary methods each PT shipment. Laboratories subject to CMS regulation are not allowed to order multiple PT kits for the purpose of testing the same sample/analyte on multiple instruments or methods prior to the due date for submitting results to the provider.

- Samples are prepared per the package instructions.
- Interlaboratory communication regarding PT samples is strictly prohibited until after the deadline for submission of data to the proficiency testing provider.
- Proficiency testing records must not be shared with and should be inaccessible to personnel of other laboratories, including an affiliated laboratory until after the deadline for submission of results. Laboratories that share a common computer system must take appropriate steps to ensure that records are not readily accessible by other laboratories.
- Samples are to be run on a single analyzer, yielding a single result which is reported. (To prevent duplicate testing and comparison of results).
- Referral or sharing of PT samples with another laboratory is prohibited until after the deadline for submission of data to the proficiency testing provider.
- It is the responsibility of every laboratory employee to understand that the referral (receiving or sending) of any proficiency samples while the testing event is still in progress (before the due date) is prohibited. In the event any employee should be asked to engage in such practice, they are required to immediately notify the CLIA Laboratory Director in charge of their lab and the WFBH Internal Audit and Compliance Office.

- Every attempt will be made to have all testing employees participate in purchased PT surveys or an alternative method.
    - Except in limited circumstances where patient testing occurs over more than one work shift and thus multiple employees conduct the testing (e.g., in the microbiology lab where cultures and testing can take longer that one shift), all samples contained in a single test event will be tested by a single person to whom the event will be assigned by laboratory management and will be completed as soon as practicable following assignment. All proficiency tests will use the same procedures used for patient samples requiring the same test. In those instances where multiple employees conduct a proficiency test, each employee conducting the test must sign the attestation statement for the event.
    - Individual test events will be rotated, where applicable, throughout the lab as follows – Event 1 will be tested by 1st shift employees, Event 2 will be tested by 2nd shift employees and Event 3 will be tested by 3rd shift employees.

- If patient samples are written on a daily log, PT samples should be logged.

c. Reporting

- For purchased PT materials, results are recorded as directed per kit instructions, using the PT testing forms provided, within the allotted time frame indicated for that event. Completed report forms are filed with pertinent work sheets, QC documentation, instrument data, etc. and are maintained for at least 2 years.
- The attestation sheet must be signed by the analyst and the laboratory director (or designee), in addition to electronic submission.
- All recorded information is checked for accuracy and completeness by the manager prior to submission.
- Results are submitted to the appropriate agency for evaluation via fax, mail or electronically.
- The laboratory must document the handling, preparation, processing, examination and each step in the testing and reporting of results for all PT samples.
- The laboratory must maintain a copy of all records, including a copy of the PT program report forms used by the laboratory to record PT results including the attestation statement provided by the PT program for two years.

d. Results Review

- As delegated by the CLIA lab director, the section medical director or section manager or laboratory specialist will review all results (graded, ungraded, educational, etc.) represented within the testing event. During the event review process ungraded analytes must be assessed for acceptable performance in addition to graded responses. In the event the ungraded result is found to be unacceptable based on peer data review, corrective action process will be required.

  If a PT challenge was intended to be graded, but was not, for reasons such as:

  1) The laboratory submitted its results after the cut-off date,
  2) The laboratory did not submit results,
  3) The laboratory did not complete the result form correctly (for example, submitting the wrong method code or recording the result in the wrong place). Then the laboratory should perform their own assessment of the PT challenge. The PT assessment for ungraded

challenges must include an assessment/conclusion from the medical director (or designee) as to whether the laboratories response was acceptable or unacceptable.

- Acceptable participation in the event means you received a passing score of 80% or more on the testing event.
- For any results that did not receive a passing score in the event, the manager must evaluate and document possible reasons for failure and any corrective action that may be necessary.
- Depending on the PT provider utilized, additional documentation submission back to the PT provider may be necessary. Consult the PT provider instructions and follow their guidance as necessary in addition to section specific documentation.

e. Training/Competency Assessment

- Employees within the laboratory will receive specific training on the handling and testing of PT samples and events at the following intervals:
  1) Initial new employee laboratory orientation (new employee checklist)
  2) New employee end of probation review (at 90 days)
  3) Annually as part of every employees yearly lab specific competency assessment thereafter.

- Orientation/Competency Assessment procedures may vary between sections. See Section specific procedures for checklists and procedure.

4) Review/Revision/Implementation:

a. Review Cycle: 2 years
b. Office of Record: Department of Pathology

5) Related Policies: N/A

6) References, National Professional Organizations, etc.:
CLIA Regulations Section 493.1236 Standard: Evaluation of proficiency testing performance 2004.

CLIA Regulation and Guidance Brochures, Brochure #8 Proficiency Testing

College of American Pathology Standards for Proficiency Testing

7) Attachments: N/A

8) Revision Dates: January 23, 2017, May 15, 2017, March 16, 2018