Wake Forest Baptist Medical Center	Proficiency Testing Procedure Lab Admin 3	Dept:	Pathology
		Effective Date:	June 2004
		Revised Date:	June 2013
		Contact:	Linda Kuzio
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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 accreditating 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 Pathology
   ii. Procedure:
   Clinical and Anatomic Pathology sections and Satellite laboratories.
   iii. Supervision:
   Clinical and Anatomic Pathology section managers and Satellite area managers.
   iv. Implementation:
   Department of 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, Regulations/QA 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.
- Documentation of the unregulated test, method of alternative PT being utilized must also be sent to the Manager, Regulations/QA by December 1.

b. Handling and Analyzing

- Samples are integrated into the daily workload and processed in the same manner as patient samples. Samples may be repeated, diluted, etc. in the same manner as a patient sample.
- Samples are prepared per the package instructions.
- Interlaboratory communication regarding PT samples is strictly prohibited.
- 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

- All results represented within the testing event are reviewed, evaluated and signed by the section director, section manager or designee and the reports filed per section specific procedure. Acceptable participation 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: