Wake Forest Baptist Medical Center	Proficiency Testing - Critical Care Labs CCL-005	Dept: 324318	Critical Care Labs
		Effective Date:	Jan 2013
		Revised Date:	Feb 2019
		Contact:	Ann Shoffner
Name & Title: Gregory Pomper, MD CLIA Laboratory Director		Date:	2/25/19
Signature: GPom			

1) **General Procedure Statement:**

a. **Principle:** Proficiency testing (PT) is the testing of unknown samples sent to a laboratory by an approved PT program designated by The Centers for Medicare and Medicaid Services (CMS). The Critical Care Laboratory Section (OR/ICU Lab) uses the PT program offered by our accrediting agency, the College of American Pathology (CAP). Our laboratory adheres to all PT standards or regulations of CLIA as defined CAP. CAP-accredited laboratories must participate in PT for all patient tests designated by CAP.

b. **Purpose:** The Critical Care Laboratory Section follows the Department of Pathology Proficiency Testing Procedure (Lab Admin 12 – Formerly Lab Admin 3). This section specific procedure serves to define specific activities and processes for Critical Care lab staff to successfully perform Proficiency Testing in the Critical Care Lab Section.

c. **Responsible Department/Party/Parties:**

i. Procedure owner: Ann Shoffner
ii. Procedure: Critical Care Lab (CCL) Staff
iii. Supervision: Ann Shoffner
iv. Implementation: Ann Shoffner and Critical Care Lab (CCL) Staff

2) **Procedure:**

A. Current CCL Test Menu:

Blood Gas	Ionized Calcium	Intraoperative PTH
Whole Blood Na	Cooximetry	
Whole Blood K	Whole Blood Glu	
Activated Clotting Time	Whole Blood Lactate	
Creatinine	Serum hCG	

B. Selection of Material: Participation in proficiency testing may be through CAP PT Programs or another testing provider accepted by CAP. Semi-annual alternative performance assessment must be performed on tests for which external PT is not available. Appropriate alternative performance assessment procedures include split sample analysis with a reference/other laboratory or with an established in house method. It is the responsibility of the laboratory director to define such alternative assessment procedures and the criteria for successful performance in accordance with good clinical and scientific laboratory practice. A list of required PT can be found on the CAP website.

1. Proficiency Testing surveys provided by CAP include:

(AQ)	BGAS, Na, K, Glu, ICAS, Lact testing
(CT)	ACT testing
(SO)	Cooximetry testing
(S)	Serum hCG

2. Required alternative performance assessment:
   O2Sat - Biannual sample comparison with iSTAT. Results should agree +/- 3. Results are reviewed and signed off by the Medical Director via POCT coordinator or CCL manager. Results falling outside the acceptable range should be repeated.
3. Additional biannual sample comparisons performed:
   Hb/HCT, Electrolytes/metabolites, (OR Lab/iSTAT/Core Lab) performed in Jan and July
   BGAS, ICAS (OR Lab, iSTAT) performed in Jan and July
   ACT instruments (Hemochron/ISTAT Celite/ISTAT Kaolin) performed in Feb and Aug
   Serum Pregnancy (OR Lab/Core Lab) performed in June and December
4. PTHQ – Quality Cross Check for Intraoperative PTH Testing (Roche Cobas e411)

C. Receipt and Storage:

1. Shipping dates for all PT kits are available on the CAP website. Lab management is notified by CAP Tracker when a kit has been shipped from CAP.
2. PT kits are delivered to the Laboratory Administration mailroom.
3. The lab manager is notified when the kit arrives. If the manager is unable to retrieve the kit, the kit should be placed in the Hematology walk-in refrigerator and its disposition communicated to the lab manager. The receive date should be written on the kit when it arrives.

D. Distribution of Testing:

Every attempt will be made to have all testing employees participate in the proficiency testing process. Lab management will schedule proficiency testing to ensure that testing is rotated among all testing personnel. The schedule should document the PT kit, the sample ID numbers contained in each kit, the tech that performed testing on each sample and the PT test scores for the event/samples.

E. Analysis:

1. PT samples are integrated within the routine daily workload and performed by those people who routinely perform patient testing.
2. PT samples are tested using the same primary method systems used in patient testing.
3. Samples are prepared per the package instructions.
4. If multiple instruments are available, the tech chooses one instrument (tech's choice) and performs the entire survey on that ONE instrument.
5. Do not repeat samples unless an instrument failure or sample error occurs.
6. Inter-laboratory communication regarding PT samples is strictly prohibited.
7. Referral or sharing of PT samples with another laboratory is prohibited until after the deadline for submission of data to the PT provider. This is true even if patient testing is routinely sent out for additional or confirmatory testing. It is the responsibility of every laboratory employee to understand that the referral (receiving or sending) of any PT samples while the testing event is still in progress (before the due date) is prohibited. In the event an 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 WFBMC Internal Audit and Compliance Office before they act.
8. Do not discuss PT results with another test site, prior to the cut-off date for submission of PT results to the PT provider.
9. Below are instructions for each type of PT Survey. These instructions are also found under the CCL-QRG-001 Performing Proficiency Testing - Quick Reference Guide

E. Analysis continued:

- **BGAS (AQ) and Co-Ox (SO) Surveys on the 1265's:**
  1. **Important:** Turn OFF the analytical ranges. From the main 1265 screen, select the following:
     a. *Setup*
     b. *Secured Options*
     c. *Analysis Options*
     d. PASSWORD = 12345
     e. Uncheck the *Analytical Ranges* box
     f. SAVE
  2. Identify the samples in the instrument using the following example (Patient ID = 1. Last Name = AQ1, First Name = 1)
  3. Do not perform tHB or Co-OX testing on the BGAS survey.
  4. OR Lab - If the instrument's printer is not turned on, turn on the printer. We need the instrument tapes.
  5. **Important:** Turn the analytical ranges back ON when you have finished with the survey.
  6. Initial the instrument tapes.
  7. Sign and date the survey's attestation form.
- **iSTAT Creatinine Surveys (AQI) :**
  1. **Important:** Run in PROFICIENCY TESTING mode
  2. The assigned ID must be 11 characters. Use zeros followed by the survey letter and sample number - For example: 00000000A01, 00000000C15
  3. Write your results on the survey form.
  4. Sign and date the survey's attestation form.
- **ACT Hemochron Surveys (CT):**
  1. Initial the instrument tape.
  2. OR Lab – write results on the patient testing log.
  3. Write your results on the survey form.
  4. Sign and date the survey's attestation form.
- **Serum Pregnancy Surveys (S):**
  1. Write results on the patient testing log.
  2. Write your results on the survey form.
  3. Sign and date the survey's attestation form.
- **Intraoperative PTH CrossCheck (PTHQ)**
  1. Initial the instrument print out.
  2. Write your results on the survey form.
  3. Sign and date the survey's attestation form.

F. Retention of PT Kits:

1. PT kits are retained until test results are received and any follow-up activities related to the PT event are completed.
2. PT kit material may be retained in the laboratory to use after the proficiency testing due date for QA and troubleshooting activities.
3. PT Kits may be discarded upon approval from lab management.

G. Reporting Results to CAP:

1. Document PT test results by printing instrument result tapes if available.
2. Record results on the respective manual log if applicable. Give each sample its own line on the log. Make a copy of the log sheet.
3 Record results as directed on the PT testing forms provided.
4. All individuals involved in the testing process should sign the Attestation form.
5. Send the all survey result forms/paperwork along with instrument result tapes and copy of the log sheet with the PT kit to the lab manager.
6. The lab manager should check all documents for accuracy prior to submission to CAP.
7. Results will be submitted electronically to CAP by the lab manager or designee. Electronic result entry should be checked for accuracy prior to final approval.
8. After final approval, the result status will show as "received". Print the approved results along with a print screen of the page showing the results as received. Retain these copies along with the other PT documentation.
9. If electronic results cannot be submitted, results should be faxed. A confirmation email should be received documenting receipt of faxed results. Retain this with other PT records.
10. Completed report forms and paperwork are filed and kept for 2 years in each survey's respective section of the CAP notebook.

H. CAP Survey Result Review:

1. Routine review of PT reports helps to verify accuracy and reliability of testing and can alert management of shifts or trends that, over time, could affect patient results.
2. PT result reports and the Participant Summary are reviewed as soon as possible after they become available. The reports are evaluated and signed by the Medical Director and the lab manager. They are filed along with the survey results in their respective section of the CAP notebook.
3. PT results should be shared with Laboratory Staff.
4. Acceptable participation is a passing score of 80% or more on the testing event.

I. Unacceptable Results:

1. PT challenges that are graded as "unacceptable" should be circled on the report.
2. The results should be reviewed with the tech that performed the testing.
3. Lab management should work with the tech to evaluate possible reasons for failure. This can include a review of PT result documentation, submitted results, QC, calibration and maintenance records.
4. A survey failure response form (*CCL-F093 Proficiency Testing Failure Response Form)* should be completed and signed by the testing tech, lab manager and the lab Medical Director.
5. A summary of findings and conclusion should be documented, compiled and reviewed with testing personnel.
6. Corrective action, if applicable, should be documented.
7. Consult the PT provider instructions and follow their guidance as necessary for additional documentation.
8. If the lab is instructed by CAP to cease patient testing for an analyte due to repeat unsuccessful proficiency testing, laboratory records must demonstrate that no patient results are released until after the laboratory receives approval from the CAP to resume patient testing.

J. Ungraded PT Challenges:

A PT challenge might be ungraded for reasons such as:

- the laboratory submitted its results after the cut-off-date
- the laboratory did not submit the results
- the lab did not complete the result form correctly (for example, submitting the wrong method code or recording a result in the wrong place).
- lack of consensus

In the event that a PT challenge was intended to be graded but was not, the lab must conduct its own evaluation of the challenge using the Participant Summary. For guidance, refer to appendix I in the CAP Laboratory Accreditation Manual for listing of PT exception codes and actions.

K. Training and Competency Assessment:

All staff receives initial proficiency testing training and competency assessment, at 6 months within the first year and annually thereafter.

3) **Related Procedures:**
CCL-001 Critical Care Labs Quality Improvement Plan and Activities
CCL-QRG-001 Performing Proficiency Testing - Quick Reference Guide
Lab Admin – Compliance with CAP Accreditation Policy

4) **Related Information:**
Lab Admin - Proficiency Testing Education 2019 Power point
Lab Admin - PT Education Test employee
CAP – Current year Laboratory Activity Menu

5) **Related Forms:**
CCL-F093 Proficiency Testing Failure Response Form. (Location: G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\CAP\CCL - F093 PT Failure Response Form.docx)

6) **Attachments:** none

7) **References:**
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
American Proficiency Institute Checklist for Corrective Action

8) **Related CAP Standards:** COM.01000, COM.01100, COM.01200, COM.01300, COM.01400, COM.01500, COM.01600, COM.01700, COM.01800, COM.01900, COM.01950

9) **Review/Revision/Implementation:**
- Review Cycle: All procedures must be reviewed at least every 2 years.
- Office of Record: Department of Pathology, Critical Care Laboratory

10) **Previous Revision Date(s):** 8/13, 2/17, 3/18, 5/18

11) **Revised/Reviewed Dates and Signatures:**

Reviewed/Revision Date: 2/12/19 Signature: Ann Shoffner

Reviewed/Revision Date: _____ Signature: _____

Reviewed/Revision Date: _____ Signature: _____