Wake Forest Baptist Medical Center	Critical Care Labs Quality Improvement Plan and Activities CCL-001	Dept: 324318	Critical Care Labs
		Effective Date:	Aug 1991
		Revised Date:	Feb 2019
		Contact:	Ann Shoffner
Name & Title: Greg Pomper, MD CLIA Lab Medical Director		Date:	2/25/19
Signature: G Pomper			

1) **General Procedure Statement:** Laboratory processes should be defined to ensure reliable patient data and minimize and identify analytic or clerical errors. This includes assessing:
   - **Variance** of each analytical technique by performing analyses on control material in the same manner as patients' material.
   - **Accuracy** of each analytical technique by participation in statistically evaluated proficiency survey and by formal appraisal of the validity of quality control values through comparison with the values obtained from the same quality control material in other laboratories.
   - **Clinical validity** of patient results through review and evaluation of patient results that exceed technical, critical and delta ranges defined for each test reported for all tests. This would also include physician feedback regarding patient results and a review of corrected results.
     a. **Principle:** To provide lab staff with tools and guidelines to ensure reliable patient data and minimize and identify analytic or clerical errors.
     b. **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. DAILY ACTIVITIES:

1. **QA Report Review:** Ranges are defined in the LIS and the Siemens RapidComm by test to identify critical, technical and normal range failures for tests performed in the Critical Care labs. Technologists are visually and/or audibly warned of these failures when resulting in the LIS and RapidComm and should respond appropriately. All critical values should be called to a responsible clinical staff member and read back to the caller to ensure accurate communications within 15 minutes of the result availability. This communication should be documented in either RapidComm or LIS as defined per procedure. Critical value reporting is monitored daily by the section manager or designee using a RapidComm Quality Assurance Report. The number of critical values called versus not called is documented under G:\Lab_Shared\ICU_ORLab\Daily Reports\QA totals.xlsx. The QA threshold goal is 100% critical values called and documented. Any errors, concerns or corrective action are addressed to the technologist, documented on the report and also on the CCL's QA Log. QA reports are filed and kept for two years.
2. **KOR (Whole Blood Potassium) Hemolysis grading review:** Hemolysis is reported on Potassium levels greater than 5.00mEq/L. At the end of each shift, a *Hemolysis Grading on KOR Report* is called in RapidComm and reviewed by the tech. Refer to *Section 5 (Pulling a KOR Hemolysis Report) in the RapidComm Training Guide* for detailed instructions on how to request this report. A similar report is requested daily for the previous day's shifts and is reviewed by the section manager, assistant manager or designee. Any errors, concerns or corrective action are addressed with the technologist, documented on the report and also on the CCL's QA Log. Hemolysis reports are filed and kept for two years.

3. **QC Review (daily):**
   a. The tech performing QC is responsible for reviewing and verifying that the QC is acceptable prior to reporting patient testing. The tech initials a daily QC verification log (CCL-F088 and CCL-F089 Daily QC Verification Log) as documentation that they reviewed the QC and deem each respective instrument either acceptable or not acceptable for reporting patient testing.
   b. A RapidComm QC report for the previous day is called daily and reviewed by the section manager or designee. Refer to *Section 7 (Pulling a QC Report) in the RapidComm Training Guide* for detailed instructions on how to request this report. Any notations or action taken regarding QC is recorded on this report. Actions taken are also documented on the instrument maintenance log as relevant. All QC reports are filed and kept for two years.
4. **WakeOne Corrected Results:** Reported results that are corrected in the LIS automatically result in a correction statement being appended to the correct result. The correction statement notes that there is a correction along with the date and time it was made. The correcting tech also notes who was notified about the corrected result. The reports lists all results containing the word string "corrected" resulted by the Critical Care Lab staff. All corrections are reviewed and investigated as necessary with documentation of any corrective action taken.
   a. **BKR Corrected Reports Components Report**: A daily LIS corrected result report is generated via Report2Web and is reviewed by the lab manager or designee. Once reviewed, the report is electronically filed under G:\Lab_Shared\Houska_Shoffner\Corrected Result Reports.
   b. **iSTAT Corrected Results Loc Main Campus Report:** A daily iSTAT corrected result report is generated via Report2Web and is reviewed by the lab manager or designee. Once reviewed, the report is electronically filed under G:\Lab_Shared\ICU_ORLab\Daily Reports\Wake1 Corrected Result\year.
5. **iSTAT Instrument Errors Location Main Campus:** This iSTAT instrument error report is generated daily via Report2Web and is reviewed by the lab manager or designee. Once reviewed, the report is electronically filed on the G: drive (G:\Lab_Shared\ICU_ORLab\Daily Reports\Wake1 Instrument Error)
6. **Result Review for Defined Criteria:** Each test procedure includes a defined normal reference range, technical limits and critical values for the particular method as applicable. The reporting tech evaluates results according to the defined criteria and responds as appropriate:
   Technical limits: Each procedure defines action to be taken should a result exceed the technical limit.
   Critical values: All critical values are handled as defined in the Department Policy Calling Critical and or Corrected Values and CCL-016 Corrected Report/Critical Value Reporting Policy - Exceptions to the Department Policy.

B. WEEKLY ACTIVITIES:

1. **Inner-Lab Sample Comparisons:** Each lab (OR & ICU) tests a random sample on all of its blood gas analyzers and compares the blood gas, electrolytes, lactate and tHb results. Results are logged on the Weekly ICC Excel spreadsheet found under G:\Lab_Shared\ICU_ORLab\WEEKLY ICC. The results are compared to ensure consistency between the lab instruments using predefined thresholds. The chosen thresholds meet or exceed the threshold standards established by CAP proficiency testing for the respective analytes evaluated (survey AQ2). Problems will be identified and corrected according to the instructions for the individual systems. These results are reviewed weekly by the manager and monthly by the Laboratory Medical Director.
2. **QC review (weekly):** LIS (Beaker) QC reports for Electronic ACT QC, Liquid ACT QC, Serum HCG QC and IOPTH QC are generated and reviewed/signed weekly by the laboratory manager.
3. **Credited Test Report Review**: A credited test report is called weekly in Beaker. Entries on this report are reviewed for correction statements and proper documentation.

4. **Cancelled Test Report Review:** A cancelled test report is received via email to the manager. Entries are transferred into the corresponding section of the QA Labelling Incident Log for tracking purposes.

C. **MONTHLY ACTIVITIES:**

1. **Inter-Lab (OR/ICU) Sample Comparisons:** A single random sample is run on each blood gas analyzer in the ICU Lab and in the OR Lab. Results are logged on the Weekly ICC Excel spreadsheet found under G:\Lab_Shared\ICU_ORLab\WEEKLY ICC. The blood gas, electrolytes, lactate and Co-Ox results are compared to ensure consistency between the lab instruments using predefined thresholds. The chosen thresholds meet or exceed the threshold standards established by CAP proficiency testing for the respective analytes evaluated (survey AQ2). Problems are identified and corrected according to the instructions for the individual systems. These results are reviewed upon completion by the manager and monthly by the Laboratory Medical Director.
2. **Maintenance Log Sheet Review:** The section manager reviews the maintenance log sheets to verify that all scheduled maintenance is performed and documented appropriately. Any errors, concerns or corrective actions are addressed to the technologist, documented on the report and also on the CCL's QA Log.
3. **QC Review (monthly):** At the beginning of each month, the Levy-Jennings QC reports are generated from RapidComm and the LIS for the previous month and reviewed along with manual QC logs by the section manager. This report is reviewed for QC shifts, trends and other problems that were not picked up during the daily reviews. Any shifts, trends or other problems are noted on the report along with any action taken. These reports are filed and kept for two years. Calibration verification is monitored on a daily and monthly basis using Blood Gas lab quality control data. The monthly means, standard deviations and CVs for each analyte on each instrument in the NCBH labs are compared with lot-to-date data. The monthly SD and CV are compared with the lot-to-date data and evaluated for variance. ACT Liquid QC lot data is kept on a spreadsheet under G:\Lab_Shared\Houska_Shoffner\QA\ICC's monthly_biannual.xlsx. CV's that vary more than 2% are noted and evaluated for problems with the test system. Findings and action taken are documented on the monthly QC report. These reports are also reviewed monthly by the Laboratory Medical Director.
4. **Siemens 1265 Peer Group QC Online Program:** At the beginning of each month, a peer group QC report of Siemens 1265 users is generated and reviewed. RapidComm QC data is transferred via a RapidComm export file to RTQC data conversion software. The conversion software massages the data and changes the format of the report. The report is then sent to Siemens and peer group data is generated.
5. **Cobas e411 IOPTH Peer Group QC Online Program:** We are enrolled in the BioRad unity 2 Peer review QC program. At the beginning of each month, a peer group QC report of Roche Cobas e411 PTH STAT users is generated and reviewed.
6. **Turn-Around-Time Review:** At the beginning of each month, turn-around-time reports are generated from Report to Web for the previous month and reviewed by the manager. No more than 10% of the results reported should exceed the established TAT thresholds. Test groups exceeding the defined thresholds result in the evaluation of testing and operational issues that impact the TAT. Any problems identified are evaluated and addressed in an effort to bring exceptional TAT's within the acceptable threshold. The following represent the major test groups done here and the time limits are all-shift averages. Blood Gases - IN LAB TURN-AROUND-TIME: 15 minutes or less.
7. **Specimen by Hour Report:** At the beginning of each month, a specimen by hour report is generated from Report to Web and delivered to the manager's email for the previous month. The report is reviewed and evaluated for potential changes in the staffing schedule.

8. **Pathology Laboratory Services Quality Assurance and Quality Improvement Committee:** The Critical Care Labs submit a monthly QA report to the Pathology Department QA/QI Committee. The monthly QA report includes
    - % critical values reported
    - % hemolysis documented on K's > 5.0
    - % QC compliance/documentation
    - TAT information
    - Proficiency Testing Survey results
    - Productivity data for the current month
    - Productivity data for YTD
    - New Procedures
    - Employee/Customer complaints
    - Critical equipment incidents
    - RL6 reports
    - Floor patient ID errors
    - Other remarkable occurrences.
    - Procedure Manual Review when applicable
    - ECRI Alerts
    - Supply Chain Failures

    The QA/QI plan is reviewed annually and an assessment form submitted.

D. BI-ANNUAL ACTIVITIES:

1. **Calibration Verification and Analytical Measurement Range** Calibration verification is performed in the Critical Care Labs on the Blood Gas Analyzers and on the Roche Cobas e411 every six months using commercially prepared materials or other materials with known standard reference values. Results obtained must fall within defined performance variability ranges to verify instrument calibration. Results that fall outside the ranges are evaluated the same as quality control results. Refer to the CVM/AMR section of each procedure for process. These results are reviewed upon completion by the manager and the Laboratory Medical Director.
2. **Inter-Lab (OR/ICU/iSTAT/Core Lab) sample comparisons:** Different instruments are used within the Critical Care Labs, Core Lab and point-of-care testing sites. It is possible that the different systems for measuring a particular analyte may meet each lab's QC specifications but give clinically misleading signals when serial results are obtained from different labs. At a minimum, bi-annual inter-lab comparison testing is performed for like tests that are performed using different methods, instruments, lab sections. Testing on the same patient sample is performed in the Critical Care Laboratory, the Core Lab and iSTAT when applicable. The results are compared to ensure consistency between the lab instruments using predefined thresholds. These thresholds have been approved by the Medical Director and meet or exceed the threshold standards established by CAP proficiency testing for the respective analytes evaluated. Other analytes may be added as necessary. Limits of acceptability will be established and approved by the Medical Director at the time of implementation. Problems are identified and corrected according to the instructions for the individual systems. Results are logged on the Monthly_Biannual ICC spreadsheet found under G:\Lab_Shared\Houska_Shoffner\QA\ICC's monthly_biannual. These results are reviewed upon completion by the manager and the Laboratory Medical Director.

ICC Schedule:

Hb/HCT, Electrolytes/metabolytes, (OR Lab/iSTAT/Core Lab) in Jan and July
BGAS, ICAS and O2Sat (OR Lab, iSTAT) in Jan and July
ACT instruments (Hemochron/ISTAT Celite/ISTAT Kaolin) in Feb and Aug
Serum Pregnancy (OR Lab/Core Lab) in June and December.

Thresholds: Agreement thresholds for comparison testing are listed on the respective Weekly ICC, monthly_biannual ICC spreadsheets and also below:

pH	+/- 0.04
pCO2	+/- 5mmHg or 8% whichever is greater
pO2	10% if analyzers are side by side during testing. 20% if testing not "side by side"
Na	+/- 4 meq/L
K	+/- 0.5 meq/L
ICAS	+/- 0.1 meq/L
Glu	+/- 6 mg/dL or 10% whichever is greater
Lact	20%
tHb	+/- 1 g/dl
HCT	+/- 3%
sO2	+/- 3
O2Hb	+/- 3 or 3SD whichever is greater
MetHb	+/- 2
COHb	+/- 3 or 3SD whichever is greater
HHb	+/- 3
Creatinine	+/- 0.3 mg/dl or 15% whichever is greater

3. **Customer Satisfaction Survey:** We distribute a customer satisfaction survey using Survey Monkey every 6 months to at least 10 random customers. The data is compiled and reviewed by staff and management. Input is greatly appreciated. Suggestions for improvement are evaluated.

E. ANNUAL ACTIVITIES:

1. **Competency Assessment:** Competency assessments occur at least annually for all employees. Refer to *CCL-011 Competency Testing Procedure.*
2. **IQCP Annual Review and Medical Director Sign Off:** Each IQCP plan is reviewed and signed by the Medical Director at least annually.
3. **Procedure Review:** Procedures are reviewed and changes made if needed. Additions/changes are communicated to staff via an email and/or Read and Initial item.

F. AS NEEDED:

1. **Specimen issue tracking:** Samples that are clotted, contaminated, mislabeled, unlabeled, broken, lost then found, etc. are ordered (then cancelled) in Beaker. Lost, mislabeled, unlabeled samples along with any incident impacting patient care are entered into RL6. Laboratory "good catches" are also entered into RL6. Specimen issues not captured in Beaker are logged on the QA Labelling Incident Log.
2. **CCL Lab error reporting:** CCL staff should notify lab management either verbally or by email when an error in patient testing occurs. Events are evaluated for root cause – random error vs a process problem. CAPA forms are completed when applicable. Lab QA errors are tracked for both the individual tech and the lab as a whole. Trends are monitored. Corrective action is taken when appropriate.

3. **Instrument Logs:** Instrument maintenance and problem logs are maintained for each instrument or groups of instruments in the lab. These logs should be used to note any technical or functional problems encountered with an instrument. This information should be reviewed periodically by the section manager. Staff should also refer to the book when an instrument problem is encountered to note whether a problem is reoccurring, a trend, new, previously encountered and resolved, etc.
4. **Critical Equipment Incidents:** Critical equipment incidents are reported on the monthly QA report along with a summary of follow-up action taken. This includes any incident involving an instrument that could cause problems or delays in patient care. These could be from the instrument itself or from user error.
5. **Proficiency Testing Results:** Proficiency Testing results are reviewed as they become available from CAP. Any remarkable details are noted with documentation of any follow-up action taken. The CMS Performance Summary Report for Analytes Regulated under CLIA is electronically available to the Medical Director.
5. **Competency Assessment/Employee Orientation/Training:** All employees beginning work in the Critical Care Labs will receive orientation and job training before they begin working independently. Competency assessments will occur at six month intervals within the first year of employment and annually thereafter. Refer to *CCL-011 Competency Testing Procedure.*
6. **Employee/Customer Suggestions:** All suggestions from within or outside the department for additions or improvement in the services offered by the Critical Care Labs are logged and reviewed. Records are kept of disposition (implemented, delayed, etc) and follow-up.
7. **Test listing:** The lab is prepared to provide a listing of test procedures performed in the lab upon request. Test methods and performance specification information can be included with this listing if requested.
8. **Reference Ranges:** The laboratory verifies or establishes a reference interval for each analyte for each specimen source. When a formal reference range study is not feasible, the laboratory evaluates the use of published data for its own use. The reference ranges used in the Critical Care Labs for electrolytes reported on the Siemens RapidLab 1265 are those established by the WFBH Core Lab. Blood gas reference ranges were established by Respiratory Therapy. The reference range for IOPTH testing on the Cobas e411 was obtained by a verification study of the manufacturer's recommended reference range. Criteria for evaluation of reference intervals include: introduction of a new analyte to the test menu, change of analytic methodology or change in patient population.
9. **Review of Trimedx (formerly Aramark) centrifuge and annual function checks:** Service reports are reviewed and signed by the lab manager.
10. **Continuing Education:** Vehicles of Continuing Education include but are not limited to:
    - The MTS system – tracked in MTS
    - Articles of interest from staff – tracked via individual *CCL-F044 Continuing Education Logs*
    - Mandatory medical center annual CE – tracked via ELM and HealthStream
11. **Ongoing Assessment of each IQCP:** Ongoing quality assessment monitoring is performed by the laboratory to ensure that the quality control plan is effective in mitigating the identified risks for each IQCP.

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3) **Related Procedures:**

CCL-002 Quality Control (QC) Plan
CCL- 016 Corrected Report/Critical Value Reporting Policy - Exceptions to the Department Policy
Department of Pathology - Calling Critical and/or Corrected Values
Department of Pathology – Correction of Laboratory Records
Department of Pathology – Customer Satisfaction Surveys Policy
Department of Pathology – QAQI Plan Combined
Department of Pathology - Proficiency Testing Procedure
Department of Pathology – Reporting Quality Issues
Department of Pathology – Procedure for Completing CAPA
Critical Results of Tests and Diagnostic Procedures – Hospital (formerly: PPB-NCBH-10)
Exhibit A – Clinical Lab Values (Pathology Department)
Exhibit B – Point of Care i-STAT Critical Values
CCL-005 Proficiency Testing Procedure – Critical Care Labs
CCL-032 General Specimen Information
CCL-011 Competency Testing Procedure - Critical Care Labs
Individual Test Procedures

4) **Related Forms:**

CCL-F072 Weekly ICC Spreadsheet. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\ICC Forms and Logs)
CCL-F055 thru CCL-F067 Competency Assessment Forms. (G:\Lab_Shared\Houska_Shoffner\PolProcGuidCHkLst\ Checklists_Competency\Critical Care Labs\Training and Observation Competency)
CCL-F076 New lots of ACT tubes compared with the current lots of ACT tubes. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\ICC Forms and Logs\ICC's monthly_biannual.xlsx)
CCL-F077 ACT liquid QC Current Lot vs New Lot Comparisons. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\ICC Forms and Logs\ICC's monthly_biannual.xlsx)
CCL-F078 ACT liquid QC ICU Lab vs OR Lab Monthly Comparisons. (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\ICC Forms and Logs\ICC's monthly_biannual.xlsx)
CCL-F080 Bi-annual ACT Comparisons - Feb/Aug. OR Lab Hemochron Response/iSTAT Celite/iSTAT Kaolin).). (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\ICC Forms and Logs\ICC's monthly_biannual.xlsx)
CCL-F081 Bi-annual Electrolyte Comparisons – Jan/July. (OR Lab/iSTAT/Core Lab).). (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\ICC Forms and Logs\ICC's monthly_biannual.xlsx)
CCL-F082 Bi-annual Hb/Hct Comparisons - Jan/July. (OR Lab/iSTAT/Core Lab).). (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\ICC Forms and Logs\ICC's monthly_biannual.xlsx)
CCL-F084 Bi-annual BGAS/ICAS/O2Sat Comparisons - Jan/July.). (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\ICC Forms and Logs\ICC's monthly_biannual.xlsx)
CCL-F086 Bi-annual Serum Pregnancy Comparisons – June/December (OR Lab/Core Lab).). (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\ICC Forms and Logs\ICC's monthly_biannual.xlsx)
CCL-F088 and CCL-F089 Daily QC Verification Log (G:\Lab_Shared\ICU_ORLab\FORMS and LOGS\Maintenance and QC Forms\CCL-F088 ICU Daily QC Verification Log.xlsx)
CCL-F092 Serum HCG Bi-annual Comparison CCL/Core Lab - Tech Result Form
NCBH Clinical Laboratories QA/QI Annual Assessment. POCT department.
CCL-F017 Shift to Shift Communication Log
CCL-F044 Continuing Education Logs

5) **Attachemets:** none

6) **References:** Code of Federal Regulations, Title 42, Volume 3, Parts 430 to End Revised as of October 1, 1999 From the U.S. Government Printing Office via GPO Access CITE: 42CFR493.1217.

7) **Related CAP Standards:** GEN.13806, GEN.16902, GEN.20316, COM.50600, COM.40605

8) Review/Revision/Implementation:

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

9) Previous Revision Date(s): 2/13, 6/14, 2/17, 11/17, 2/17

10) Revised/Reviewed Dates and Signatures:

Revised and reviewed 2/22/19 *Signature:* Ann Shoffner

Review/Revision Date: _____ *Signature:* _____

Review/Revision Date: _____ *Signature:* _____