Wake Forest Baptist Medical Center	Quality Control (QC) Plan CCL-002	Dept: 324318	Critical Care Labs
		Effective Date:	June 1995
		Revised Date:	Feb 2019
		Contact:	Ann Shoffner
Name & Title: Gregory Pomper, MD CLIA Laboratory Director		Date:	2/25/19
Signature: G Pomper			

1) General Procedure Statement: The Critical Care Labs use commercially prepared quality control material as part of the internal quality control procedures to monitor analytical performance relative to medical goals and also to alert laboratory personnel to unsatisfactory analytical performance. The performance of all instruments and equipment is verified prior to initial use, after major maintenance or service, and after relocation to ensure that they run according to expectations.

a. **Purpose:** To provide Critical Care Lab staff guidelines for performing quality control testing and evaluation of results to ensure the quality of results reported.

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. **QC Handling:** Control specimens are tested in the same manner and by the same personnel who perform patient testing. Refer to the individual test procedures for complete information regarding test specific QC material, frequency of QC testing and QC documentation.

b. **Electronic/procedural/built in control validation:** For those tests where electronic/procedural/built in controls are used as daily QC (ACT and Serum Pregnancy kit testing), the laboratory has performed comparison studies between external liquid QC and internal/electronic QC in order to validate the adequacy of limiting daily QC to electronic/procedural/built in controls. IQCP Plans have been developed and approved. IQCP plans are reviewed and evaluated annually by the Lab Manager and the Medical Director.

c. **Cobas e411 QC:** 3 levels of Bio-Rad Liquicheck QC are performed on 1st shift Monday – Friday excluding holidays. QC is performed regardless of a scheduled case. QC results are entered into the LIS. QC printouts are filed and retained for 2 years. Refer to *CCL-031 Intraoperative PTH testing on the Roche Cobas e411* for more detailed information.

d. **Documenting QC Results in the LIS:** Refer to each individual test procedure and the *Beaker Quick Reference Guide* for more complete information regarding QC documentation. ACT and Serum Pregnancy QC results are handwritten on their respective QC logs and also entered in the LIS.

e. **RapidLab 1265 QC:** QC results from the Siemens RapidLab 1265 blood gas analyzers are documented and stored in the RapidComm Data Management System. For detailed instructions on processing QC results in RapidComm, see section *6 Validating QC and High G/L Samples* in the *RapidComm Quick Reference Guide.*

RapidLab 1265 QC continued....

1. The RapidLab 1265 Required QC option is turned on in both the OR and ICU Labs.
2. Routinely analyze at least two levels of Rapid QC Complete QC at the beginning of each shift.

   OR Blood Gas Lab –

   1st shift performs levels 1 and 3
   2nd shift performs levels 1 and 2

   ICU Blood Gas Lab – Levels of QC are performed as follows:

   1st shift performs levels 1 and 2
   2nd shift performs levels 1 and 3
   3rd shift performs levels 1 and 2
3. Run 3 levels of Rapid QC Complete post electrode maintenance (refilling, deproteinizing, conditioning), post unscheduled maintenance, after a new reagent cartridge or new Coox sample chamber is installed, after a new electrode is installed, after tubing is changed or any time analyzer performance is in doubt. Exception to the new electrode installation: for Glu and Lactate run the High G/L, level 3 and either level 1 or 2.
4. **Important:** When running QC, start with the analyzer on your left then move to the right.
5. 3rd shift staff should review the levels of QC performed for the day to verify that Levels 1 and 3 QC were performed and those results were acceptable.

f. **QC Confirmation of Acceptability and Protocols for assessment of control results:** Control results are reviewed and deemed acceptable before patient results are reported. Controls are run prior to reporting patient results after reagent change, major maintenance or change of critical instrument components.

   1. **QC Decision Rules:** The Critical Care Labs have adopted the policy of repeating all out of range QC values. **One may not report patient data until all QC failures are resolved and the test method is demonstrated to be "in control".**
   2. **QC Acceptable Range Verification:** For each new lot of control material, the manufacturer's supplied range is verified and a valid range for our lab established before placing the new lot into use. Our established range is often much tighter than the manufacturer's supplied range.
      a. RapidLab 1265 QC: New lots of Rapid QC Complete are run in parallel with existing QC lots in order to establish the QC range and to verify that it is within the manufacturer's QC limits. These parallel runs incorporate all shifts and multiple users throughout multiple days of testing.
      b. ACT Tubes: New lots of ACT tubes are QC'd and the values from testing the new lot of tubes is compared with CCL's historical 24 month QC average.
      c. ACT Liquid QC: For each new Lot of ACT QC, the Lot to Lot average of the current lot is compared to the Lot to Lot average of the new lot. These values should agree within 15%. This information is logged on the *ACT QC Cur vs New lot* tab in the *ICC Monthly Biannual* spreadsheet located under *G:\Lab_Shared\Houska_Shoffner\QA\ICC's Monthly_Biannual.*
      d. Cobas e411 IOPTH QC: New lots of BioRad Liquichek are run in parallel with the existing QC lot (for approx. 20 days) in order to establish the QC range and to verify that it is within the manufacturer's QC limits.

3. **Daily QC review:**
   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. **Weekly QC review:** LIS (Beaker) QC reports for Electronic ACT QC, Liquid ACT QC, Serum HCG QC and IOPTH QC are generated and reviewed weekly by the laboratory manager.
5. **Monthly QC review:** At the beginning of each month, the Levy-Jennings QC reports are generated from RapidComm and the LIS for the previous month and reviewed by the section manager and the Medical Director. Monthly QC reports are 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. RapidComm reports are filed and kept for two years. LIS QC records are stored in Beaker indefinitely. Calibration verification is monitored on a daily and monthly basis using Blood Gas lab quality control data. QC and patient manual logs are reviewed monthly by the section manager. 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 mean value from each level of liquid ACT QC is compared between the ICU lab and OR labs. This value should fall within predefined guidelines established by the laboratory Medical Director. These values are recorded on the *ACT Monthly Comp* tab on the ICC's Monthly_Biannual spread sheet located under *G:\Lab_Shared\Houska_Shoffner\QA\ICC's Monthly_Biannual.*

   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.

   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. **Monthly Imprecision Statistic evaluation:** At the beginning of each month, the Levy-Jennings QC reports are generated from RapidComm and the LIS for the previous month. The monthly SD and CVs are compared with the lot-to-date data and evaluated for variance. CV's that vary more than 2% are noted and evaluated for problems with the test system.
7. **IQCP Ongoing Quality Assessment:** Ongoing quality assessment monitoring is performed by the laboratory to ensure that the quality control plan is effective in mitigating the identified risks for the IQCP and includes records of the following per CAP COM.50600:
   - Review of quality control and instrument/equipment maintenance and function check data at least monthly
   - Evaluation of errors relating to pre-analytic, analytic and post analytic phases of the testing process
   - Review of complaints from clinicians and other healthcare providers regarding the quality of testing to confirm the clinical efficacy of testing

- Evaluation of corrective actions taken if problems are identified
- Re-evaluation of the quality control plan if changes to the reagents, environment, specimen, testing personnel, or test system elements of the risk assessment occur
- Re-approval of the quality control plan by the laboratory director or designee at least annually

NOTE: If ongoing assessments identify failures in one or more components of the quality control plan, the laboratory must investigate the cause and consider if modifications are needed to the quality control plan to mitigate potential risk.

8. **Westgard Rules** help to identify random and systematic error in the test systems in use. Random and systematic errors contribute to total error in an analytical system. The Westgard Multi-Rule system applies appropriate QC rules to detect significant error.
   - **1-2S Rule:** Indicates that one of two or more results is more that 2 SD above the mean. This is usually indicative of random error but can be an early warning of systematic error.
   - **1-3s Rule:** One result is more than 3 SD above the mean. This indicates either increased random error or significant systematic error.
   - **2-2S Rule:** Two consecutive results (within or across controls) falls outside the same 2 SD limit. **(R2S3A, R2S3W)**Tests which are challenged with 3 levels of QC are covered with a variation of this rule which indicates that 2 out of 3 QC failures across or within controls. The corresponding LIS code ending of A or W indicates across or within controls.
   - **R-4S (RR4SA, RR4SW)** Indicates that the range between 2 control results in the same run is more than 4 SD. This indicates increased random error.

f. REMEDIAL ACTION TAKEN WHEN QC PROBLEMS OR ERRORS ARE IDENTIFIED:

Out of range QC values should prompt one to evaluate the test system and determine the cause of the QC flag.

1. Review the results of <u>all</u> QC samples. Consider whether or not the error is random or systematic. Also consider if patient values may be erroneously high, low or imprecise and need to be addressed.
2. Troubleshooting steps should be followed before repeating QC.
3. Review QC results and Levy Jennings charts in RapidComm /LIS.
4. Consider the following while reviewing the QC results:
   - If a trend is noticed, when did the trend begin?
   - Does the change in the QC value coincide with changes in reagents, calibration, controls, instrument maintenance or other variables?
5. For BGAS QC issues, refer to the *BGAS QC Flowchart* in the BGAS Testing section of this manual.
6. Any remarkable observations or action taken should be documented with the results in RapidComm or the LIS.

g. Changing a QC lot from *Trial* to *Active* in the Siemens 1265:

1. Press the "machine" icon in upper right corner
2. Press the "Setup" button in low right corner
3. The QC button is already checked, press "Required QC Ranges" button on right side
4. Pick the level your wish to make active from the trial lot line
   Important: Once a trial lot is made active, the previous active lot ranges are deleted
5. Press the "Set Active" button in lower left corner and hit green "Save" button

h. **Changing a QC lot from *Trial* to *Active* in Rapidcomm:**
   1. In Rapidcomm, select "Devices" from the top of the screen
   2. Select "Material Setup" under Devices
   3. Select "Assign Lots" under Material Setup
   4. Double click the trial lot you wish to make active
   5. Using the drop down box under "State" in upper right corner, change from trial to active
   6. Click the "OK" button in lower right corner, the lot is now active
      Important: Rapidcomm does allow more than one active lot
   7. To make old lot inactive, highlight it and click delete at bottom of screen (This will not delete data)

3) **Related Procedures:**
CCL-001 QA Quality Improvement Plan and Activities
Individual Test Procedures
Department of Pathology - IQCP Plan
Department of Pathology – Quality Control Management Statement

4) **Related Forms:**
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-F079 ACT liquid QC Lot to Date Comparisons (OR Lab/ICU 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)

5) **Attachments:** none

6) **Related CAP Standards:** COM.50600, LSV.37078, LSV.37082, LSV.37086, LSV.37088, LSV.37090, LSV.37092, LSV.37094

7) **References:**
BGAS QC Flowchart in the BGAS Testing section
Validating QC and High G/L Samples in the RapidComm Training Manual.

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):** 3/13, 5/15, 2/17

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

Reviewed/Revision Date: 2/12/2019	Signature: Ann Shoffner
Reviewed/Revision Date:	Signature:
Reviewed/Revision Date:	Signature: