Wake Forest Baptist Medical Center Critical Care Laboratories	**Performing Liquid iSTAT Quality Control in the Critical Care Laboratory - Quick Reference Guide** CCL-QRG-004 Feb 2017

Note: This is a quick reference guide only. Refer to the iSTAT policy, procedure and appendixes in this manual or on the POCT Intranet website for complete instruction on iSTAT testing and Quality Control.
The OR Lab performs Liquid Quality Control (LQC) on each lot number of each cartridge type received prior to the release of cartridges to the user sites. LQC is also performed if cartridge or analyzer performance is in doubt.

PPE Requirements: Lab Coat, Gloves

1) CONTROLS: Until ready for use, all controls are stored at 2° to 8°C (35° to 46°F) through package expiration date.

To program the iSTAT to run QC:

- MENU
- 3-Quality Tests
- 1-Control
- Scan or Enter your Operator ID x 2
- 1-APOC
- Select Field – Select the QC level you wish to run. 1-Level 1, 2-Level 2, 3-Level 3
- Scan Control Lot Number – Scan the ampule barcode
- Scan the cartridge bar code

A. I-STAT Liquid Tri-Controls – Used to verify blood gas, hematocrit, chemistry and electrolyte test cartridges.

1. Controls may be stored at room temperature (18° to 30°C or 64° to 86°F) for five days.
2. QC material not being used for pO2 or HCT cartridges should equilibrate to room temperature for approx 45 minutes prior to use.
3. QC material used for pO2 or HCT cartridges should equilibrate to room temperature for 4 hours prior to use.
4. Program the iSTAT to run the QC (See step 1 above).
5. For blood gas and electrolyte QC, immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. Hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution.
6. Aspirate the liquid QC material into a pipette, capillary or syringe. Aspirate from the bottom of the ampule.
7. Immediately transfer the solution into the cartridge. Avoid air contamination. Dispense the sample until it reaches the fill mark. Sample must be dispensed in one application, without a break.
8. Seal the cartridge and insert it into the analyzer.
9. Enter the cartridge box number in Field 1.

B. ACT Liquid Controls – Used to validate performance of i-STAT ACT Celite and Kaolin test cartridges.

1. Equilibrate at room temperature for 45 minutes prior to use.
2. Carefully follow timing instructions.
3. Obtain one vial of level 1 dried QC + the Calcium Chloride (CaCl) vial for level 1 QC and one vial of level 2 dried QC + the Calcium Chloride (CaCl) vial for level 2 QC.

ACT Liquid Controls continued....

4. Run one level at a time.
5. Program the iSTAT to run the QC(See step 1 above).
6. Pour the entire contents of the CaCl vial into the dried human plasma vial. Do not spill any of the QC or CaCl. Replace the stopper on the vial.
7. Let sit for EXACTLY 1 minute with no agitation.
8. After 1 minute, SWIRL the vial GENTLY for 1 minute.
9. Then INVERT SLOWLY for 30 seconds.
10. Immediately transfer the sample to the cartridge. Dispense the sample until it reaches the fill mark. Sample must be dispensed in one application, without a break.
11. Seal the cartridge and insert it into the analyzer. The sample must be loaded into an ACT cartridge within 30 seconds.
12. Enter the cartridge box number in Field 1.

C. PTINR liquid Controls – Used to validate performance of PTINR test cartridges.

1. Equilibrate at room temperature for 45 minutes prior to use.
2. Carefully follow timing instructions.
3. Obtain one vial of level 1 dried QC + the Calcium Chloride (CaCl) vial for level 1 QC and one vial of level 2 dried QC + the Calcium Chloride (CaCl) vial for level 2 QC.
4. Run one level at a time.
5. Program the iSTAT to run the QC (See step 1 above).
6. Pour the entire contents of the CaCl vial into the dried human plasma vial. Do not spill any of the QC or CaCl. Replace the stopper on the vial.
7. Let sit for EXACTLY 1 minute with no agitation.
8. Then INVERT SLOWLY for 30 seconds.
9. After 1 minute, SWIRL the vial GENTLY for 1 minute.
10. Immediately transfer the sample to the cartridge. Dispense the sample until it reaches the fill mark. Sample must be dispensed in one application, without a break.
11. Seal the cartridge and insert it into the analyzer. The sample must be loaded into an ACT cartridge within 30 seconds.
12. Enter the cartridge box number in Field 1.

2) Evaluating QC results:

1. The analyzer will display PASS or FAIL.
2. If QC passes, the cartridges are ok to use.
3. If QC fails, repeat the QC. If the QC continues to fail, notify the POCT coordinator. DO NOT USE cartridges until the QC passes.

3) References: PRO-POCT-LAB-09 Point of Care Testing (POCT) Using the i-STAT Analyzer System and Appendix C Quality Control/Quality Assurance Procedures.
ART-714446-00P Procedure Manual for the i-STAT System rev. date 23-Apr-2014

4) Review/Revision/Implementation:

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

5) Guide Created: 11/10/2014

6) Previous Revision Date(s):

7) Revised/Reviewed Dates and Signatures:

Reviewed Date:_____ Signature:_____

Reviewed/Revision Date:_____ Signature:_____

Reviewed/Revision Date:_____ Signature:_____

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