Wake Forest Baptist Medical Center Critical Care Laboratories	**Performing iSTAT Creatinine Testing in the Critical Care Laboratory - Quick Reference Guide** CCL-QRG-003 January 2016

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 in depth and complete instruction on iSTAT testing and Quality Control.

A. Equipment/Supplies:

1. **i-STAT 1 (300 Series) Analyzer:** The i-STAT analyzer is a non-waived testing device used to perform Creatinine analysis in the OR Critical Care Laboratory. When a sample-filled cartridge is inserted into an analyzer for analysis, the analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration, and continuous quality monitoring. All analyzers that pass the Electronic Simulator test are considered equivalent.
2. **Batteries:** i-STAT 1 analyzers can operate using (2) 9-volt lithium batteries or an iSTAT 1 specific rechargeable battery. Alkaline batteries should not be used.
3. **Downloader/recharger:** Results are electronically downloaded and posted to the patient's medical record.
4. **iSTAT Cartridge:** A single use disposable cartridge contains micro fabricated sensors, a calibrant solution, fluidics system, and a waste chamber. Cartridges should be stored at 2° to 8° C (35° to 46°F) and are good through the package expiration date. **Cartridges must equilibrate to room temperature before being used for testing.** Once removed from the refrigerator, a Creatinine cartridge has a 14 day Room Temp expiration date. Cartridges should not be returned to the refrigerator once they have been at room temperature and should not be exposed to temperatures above 30°C (86°F).
5. There are no humidity specifications for the iSTAT analyzer or cartridges. Measurement of humidity is not required. However monitoring of temperature is required.

B. Safety:

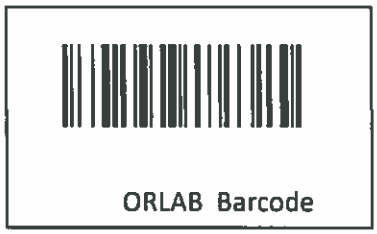
1. PPE Requirements: Lab Coat. Gloves.
2. CAUTION: When using the SCAN function on the i-STAT 1 analyzer, be aware of Laser Radiation—do not stare into the beam. Class 2 product. Laser Diode 650nm Maximum Output 1.0mW.
3. When opening liquid QC vials, protect fingers by wrapping gauze or tissue around vial, prior to breaking open.

C. Sample Requirements:

1. Only **clot free fresh whole blood** may be used for i-STAT testing.
2. Do not perform testing if the sample is clotted.
3. Suitable collection containers for Creatinine are:
   - Fresh clot free whole blood collected in a collection tube with lithium or sodium heparin anticoagulant is our preferred specimen. At WFBMC the tube types are known as FS Grn, GL or GR. Although the amount of blood needed to run the test is minimal (65µL), there is a blood to anticoagulant ratio that must be satisfied. Only **full green** top tubes can be used for testing. Refer all "short filled" tubes to the Core Lab for testing. Samples should be tested within 30 minutes of collection.
   - Fresh clot free whole blood collected in a plain plastic syringe or in a blood gas syringe filled for the correct blood-to-heparin ratio. Non heparinized samples should be tested within 3 minutes of collection.
   - Fresh clot free whole blood collected in a plain capillary collection tube or capillary collection tube with balanced heparin. Capillary samples should be tested within 3 minutes of collection.
   - Do not test CSF, pleural, peritoneal, urine, or any other body fluid that is not whole blood.
   - Do not ice samples prior to test analysis.
4. Samples must be thoroughly mixed prior to testing.

D. Testing:

1. Allow the cartridge to naturally equilibrate to room temperature prior to testing. Individual cartridges may be used after standing at room temperature for 5 minutes. A box of 24/25 cartridges should stand at room temperature for one hour before use.
2. Turn on the iSTAT analyzer. When performing testing, confirm adequate battery voltage prior to testing. (A flashing battery icon or low battery message will indicate low battery voltage.) If battery voltage is low, testing may cease in the middle of a patient test.
3. Remove the cartridge from its pouch without touching the contact pads or exerting pressure on the cartridge.
4. Select ***2 - i-STAT Cartridge***.
   Note: Proficiency samples should be run in Proficiency Mode. Instead of selecting *2 – iSTAT cartridge*, press the Menu button. Select *3 - Quality Tests*, then *2 – Proficiency*.
5. Scan your Operator ID barcode or enter your Operator ID x 2.
6. Scan the patient's CSN barcode. Manually enter the patient's CSN only if the barcode is not available. If manually entering the ID, you will need to enter the ID x 2.
   Note: For ICC samples or test samples that are not to be charged to a patient's record, enter the ID of 10 zeros followed by a letter of the alphabet (ex. 0000000000B).
7. Scan the lot # barcode from the i-STAT cartridge.
8. Dispense the sample into the cartridge until it reaches the fill mark. The sample must be dispensed without a break in one application. Inspect and discard if bubbles are present.
9. Close the cover over the sample well until it snaps into place. Do not exert pressure over the sample well.
10. Wipe off any visible blood from the cartridge. Do not allow blood to seep into the analyzer.
11. Insert the cartridge into the cartridge door until it clicks into place.
12. The cartridge remains locked in the analyzer until testing is completed. Do not try to remove the cartridge when "cartridge locked" is displayed.
13. Select **Test -1** for CRT
14. Press the → to move to the next screen.
15. Enter the sample type from the list at the bottom **(2-venous)**
16. Press **ENTER x 2 to scroll down to *field 2*.**
17. **SCAN the ORLAB barcode into *field 2*.**



18. Press the → to move to the next screen.
19. The results appear.
20. At the top of the screen **"Scan or Enter Code"** appears. Enter a comment code if applicable.
    Press ENTER after you enter the code. See the list of codes, below.
    - **Comment Code 0** – Use for a **Star out** or **procedure error** so no results will post to WakeOne. Results are held in pWeb. If you do not use CC-0, results will post as INSTRUMENT ERROR in WakeOne.
    - **Comment Code 5** – Use if you plan to repeat the test in order to verify the result. Results will post to WakeOne but the patient will not be charged. You could use also this comment if the floor sends you a repeat sample for confirmatory testing.
    - **Comment Code 123** – Use this comment if you are going to **forward the sample to the main campus lab for confirmatory testing**. The results will post to WakeOne but the patient will not be billed for your testing. They will be billed for the confirmatory testing.

D. Testing (continued):

21. Once results are ready, you may remove the cartridge. Discard the cartridge in a biohazard container.
22. Turn off the analyzer.
23. Place the analyzer in the i-STAT Download device.
24. The analyzer displays the message "Communication in Process" when results are being sent via the interface.

E. Result Reporting:

1. For patients 18 years and older, the GFRW and GFRB is calculated in WakeOne. IQ the patient's CRT results in Wake One to make sure all results posted successfully to the patient's medical record.
2. If results did not successfully transmit to Wake One, check pWeb and troubleshoot accordingly.
3. The GFRW and GFRB can be manually calculated by using the POCT Website link to the GFR calculator.
4. To modify results in WakeOne refer to the CCL-QRG-007 *How to Enter Comments and Edit Results in WakeOne - Quick Reference Guide*
5. **i-STAT CRT Reportable Range:** 0.2 – 20.0 mg/dL
   CRT Normal Range: 18 yrs = 0.5 – 1.5 mg/dL
   CRT Critical Value : n/a

F. Instrument Calibration:

Calibration is automatically performed as part of the test cycle on each cartridge. Operator intervention is not necessary.

G. Quality Control: There are 3 types of Quality Control performed on the i-STAT analyzer.

1. **Internal Electronic Simulator (Daily Electronic QC)** – Each i-STAT analyzer automatically performs an *internal electronic simulation* every 8 hours of use for each different cartridge type. This simulation is activated when a filled test cartridge is inserted into the analyzer. If 8 hours have elapsed since the last electronic simulator test, the analyzer will automatically perform the internal test before the sample is analyzed and 15 – 20 seconds will be added to the test cycle.

   If the Internal Electronic Simulator test fails, the FAIL result will be displayed on the analyzer screen and the sample will not be analyzed. If the simulator test FAILS, repeat the electronic simulation test by inserting another test cartridge or run the external electronic simulator QC device. If the electronic simulation passes, results will be reported. If the analyzer does not pass the external electronic simulator testing, contact the Laboratory Manager or the POCT office for assistance.

2. **External Electronic Simulator (As Needed Electronic QC)** – This simulator is used in the following circumstances: If the internal Electronic Simulator test fails, If the analyzer is dropped, if analyzer performance is in question or if a quality check code indicates the simulator should be tested. Do not attempt to remove the simulator while "Simulator Locked" is displayed on the analyzer screen. Damage may occur to the analyzer. It is safe to remove the simulator when the "Simulator Locked" message disappears from the display screen.
   If the External Electronic Simulator test fails, the FAIL result will be displayed on the analyzer screen. Repeat the procedure with a different External Electronic Simulator. If PASS is displayed, the analyzer may be used for patient testing. If FAIL is displayed with the 2nd electronic simulator, do not use the analyzer for patient testing. Contact the Laboratory Manager or the POCT office for assistance.

3. **Liquid Quality Control (LQC)** – Liquid QC is used to verify the integrity of the test cartridges. Liquid QC is performed on new cartridge shipments or when cartridge or analyzer performance is in doubt. For step by step instructions on performing liquid QC, refer to *CCL-QRG-004 Performing Liquid iSTAT Quality Control in the Critical Care Laboratory - Quick Reference Guide.*

QC Documentation: Both the Internal and External Electronic Simulator results along with the Liquid QC results are stored as unique QC records in the analyzer and will be downloaded into the i-STAT data management system when patient data is transmitted. QC data is reviewed by the POCT coordinator or designee. Follow up action is taken as necessary for QC failures.

2) **References:** PRO-POCT-LAB-09 Point of Care Testing (POCT) Using the i-STAT Analyzer System and ART-714446-00P Procedure Manual for the i-STAT System rev. date 23-Apr-2014
CL-QRG-007 *How to Enter Comments and Edit Results in WakeOne - Quick Reference Guide*
CCL-QRG-004 Performing Liquid iSTAT Quality Control in the Critical Care Laboratory - Quick Reference Guide.

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

4) **Guide Created:** 2/13/2015

5) **Previous Revision Date(s):** 2/13/15, 1/8/16

6) **Attachments:** *iSTAT Process with the new pWeb Interface cheat sheet*

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

Reviewed Date:_____ Signature:_____

Reviewed/Revision Date:_____ Signature:_____

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