Wake Forest Baptist Medical Center
Clinical Laboratory Point of Care Testing--i-STAT Monthly ACT QC POC Site

1) At least once each month, test the level 1 and level 2 i-STAT liquid ACT QC. Allow QC material to reach room temperature. Follow instructions in QC package insert.
2) *TREAT QC MATERIALS AS BIOHAZARDOUS SUBSTANCES!!! WEAR GLOVES!!!*
3) Perform testing in the Quality Tests menu
4) **Set-up analyzer for testing PRIOR to reconstituting liquid QC material**
    a. **Menu**
    b. **3-Quality Tests**
    c. **1-Control**
    d. **Enter your operator ID**
    e. **Select 1-APOC**
    f. **Select control level**
    g. **SCAN control lot number—barcode on vial**
5) Enter/scan cartridge lot number from end of cartridge pouch.
6) Follow package insert instructions for reconstitution of the QC material. Adhere EXACTLY to timing instructions.
    a. *Prior to testing, vials containing the lyophilized plasma and CaCl2 reconstituting fluid should stand at room temperature 18-30ºC (64-86ºF) for a minimum of 45 minutes*
    b. *Reconstitute only one level of control plasma at a time.*
    c. *CONTROL SOLUTIONS MUST BE USED IMMEDIATELY (less than 30 seconds) AFTER COMPLETINGTHE RECONSTITUTION AND MIXING STEPS.*
    d. *Remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.*
    e. *Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial.*
    f. *Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.*
    g. ***Allow the vial to sit at room temperature for 1 minute.***
    h. ***Mix the contents of the vial by swirling gently for 1 minute***, *then* ***inverting slowly for 30 seconds***.
    i. *Note: To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard and start over with fresh vials.*
    j. *Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the ACT cartridge.*
    k. *Immediately seal the cartridge and insert it into an analyzer.*
        i. *When the analyzer display indicates field 1,2,3, press the right arrow to bypass this screen. Input of information is not necessary.*
    l. *Note: Additional ACT cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample.*
7) **Confirm all values are within acceptable limits. The analyzer will display PASS or FAIL.**
8) If applicable, document results on site specific log, indicating whether or not quality control passed/failed.
9) If the QC Fails, enter comment code 5 (recheck/retest) and repeat testing using the same analyzer and same lot # of cartridges. **DO NOT USE THE ANALYZER OR CARTRIDGES FOR PATIENT TESTING UNTIL 2 LEVELS of PASSING LIQUID QC HAVE BEEN OBTAINED**
10) If the liquid QC passes, then the cartridges and analyzer can be used for patient testing.
11) If the liquid QC fails after 2 attempts, remove the cartridges and analyzer from use and contact the Clinical Laboratory Quality and Point-of-Care Testing office at 3-4136, 3-4137, or 3-0377. Document all actions on site-specific log, as appropriate.
12) Download the I-STAT analyzer.