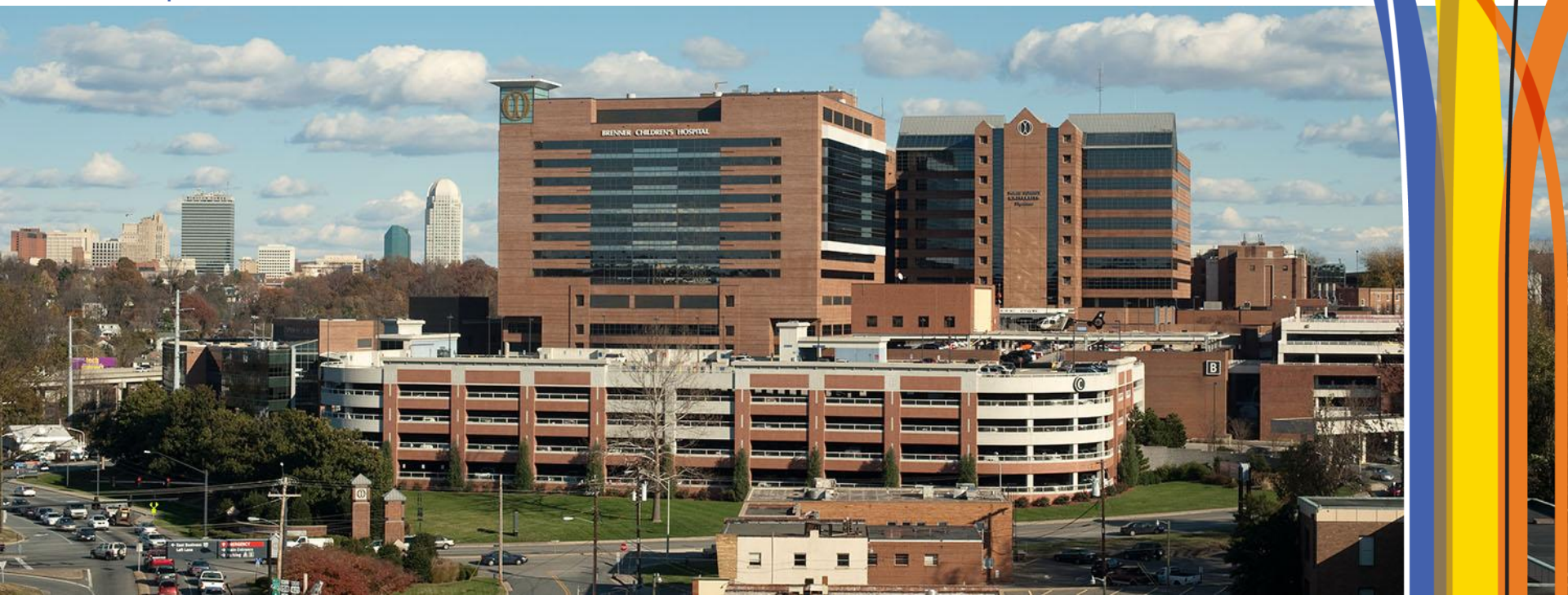
Wake Forest™
Baptist Medical Center

Point of Care Testing
i-STAT ACT Celite and Creatinine
Interventional Radiology Education Module

Prepared by Angie Thayer, BSMT (ASCP), Clinical Lab POCT Coordinator

Updated: 01/25/13



i-STAT Support

- Angie Thayer 713-4136 or pager 806-6619
- Jane Houska 716-3252
- OR Blood Gas Lab 716-2181 (M-F 7am-7pm)
- Refer to the i-STAT System Manual and WFBMC specific i-STAT policies
- WFBMC POCT web site

i-STAT Policies and Procedures

- Posted on the WFBMC Intranet
- Departments—Point of Care Testing—Policies
- The i-STAT System Manual can be found under Resource Links—Abbott POC i-STAT web site

i-STAT Operator ID

- User specific
- Serves as identification of testing personnel
- Do NOT share operator ID’s
- Do NOT enter your operator ID into analyzer and allow use by another individual

Training and Competency Requirements

- Must be documented
- Initial training
- Initial competency evaluation
- 6 month competency evaluation-NEW users
- On-going Annual competency evaluation—at least 2-point –usually written exam and direct observation
- Failure to maintain updated training and competency will result in loss of testing privileges
- Competency observation may only be completed by an authorized staff member

Safety

- Always wear gloves when handling analyzer
  - Including patient testing and performing QC
- Disinfect when contaminated with blood AND between EACH patient
- DO NOT lean over the cartridge while filling with sample
- A safety shield is recommended
- Place gauze or tissue over snap when closing
- Do NOT send blood-contaminated i-STAT Resolution Requisitions to the Clinical Lab

i-STAT Components

- Analyzer
- Cartridge
- Simulator (Electronic Quality Control)
- Liquid Quality Control Materials
- Downloader
- Recharger

Analyzer

i-STAT Analyzer (Handheld)

- Volt Meter
- Testing occurs on the test cartridge bio-sensors
- Rechargeable batteries are utilized—care should be taken to keep batteries charged—do not discard rechargeable batteries
- Rotate analyzers on charger each day

i-STAT Analyzer

- Will turn off after 2 minutes of non-use
- Can be turned on by pressing the on/off keypad—circle with line
- If operator or patient information has been entered, the analyzer will remain on for 15 minutes

Patient ID/Barcode Scanner

- The patient ID should be scanned to ensure correct ID entry
- Press and hold the SCAN key pad
- Confirm correct ID scanned—erroneous scans should be reported to the Clinical Laboratory Point of Care Testing Coordinator
- **Patient ID should be scanned directly from the patient armband**
- CAUTION: Laser light—do not stare into beam or point at anyone

Analyzer display

- ‘Cartridge/Simulator Locked’
    - Cartridge or simulator locked in analyzer.
    - DO NOT remove when this message is displayed
- Flashing battery icon or ‘Low Battery’ indicates battery voltage is low and batteries need to be re-charged

Menu Options

- **Analyzer Status**
  - Allows viewing of battery voltage-recommend maintaining charge >8 volts
- **Data Review**
  - Allows review/print of data stored in analyzer
- **Quality Tests**
  - Quality control checks utilize this menu
- **Other Menu options**
  - Refer to i-STAT System Manual for additional information

Analyzer Download

- Use the Downloader located in each site
- Analyzers should be downloaded after each case
- It is the responsibility of testing personnel to download i-STAT analyzers
- You can’t “over-download”

Analyzer Download

- The downloader will display “Communication in Progress” indicating successful download of data
- An error message will display on the analyzer if results do not successfully transmit. If an error occurs:
    - Troubleshoot the downloader
    - Check for a power light
    - Check all cord/cable connections to the down loader
    - Try unplugging and re-plugging the cables
    - If troubleshooting does not resolve problem, report problem the Help Desk

Re-charger

- Can charge battery in compartment and battery in analyzer

- Rotate analyzers on chargers to ensure they stay adequately charged

Cartridges

i-STAT Cartridges

- Testing occurs in the cartridge
- Cartridges have bio-sensors that “measure” the analytes tested
- There are different cartridge configurations available from i-STAT

i-STAT Cartridges

- ACT-CELITE and Creatinine will be used by Interventional Radiology.
- **ENSURE the correct ACT cartridge is used.**
- There is another i-STAT ACT cartridge in use at WFBMC. It WILL give different results than the ACT-CELITE cartridge

Cartridge Storage

- Cartridges are stored refrigerated 2 to 8˚C until the manufacturer's expiration date.
- Do NOT use past manufacturer's expiration date
- Can be stored at room temperature (18 to 30˚C) per manufacturer instructions.
- DO NOT use past the room temperature expiration date!
- Interventional may keep a small amount of refrigerated cartridges IF the refrigerator temperature is monitored twice per day and kept 2 to 8˚C.
- If the temperature is ever outside of 2 to 8˚C, the cartridges should be removed from the refrigerator and marked with a 2-week room temperature expiration date.
- **Cartridges should not be returned to the refrigerator once they have been stored at room temperature.**

Cartridge Handling—All Cartridges

- Individual cartridges can be used after 5 minutes at room temperature
- A box of 25 cartridges must sit at room temperature for 1 hour prior to use
- Open by tear symbol
- Use cartridge IMMEDIATELY after opening
- Fill to blue triangle—leave “blood dome”
- Insert into analyzer immediately after filling with sample

Cartridge Handling-DO NOT's

- DO NOT use "quick heating"—holding close to body or near a warm surface
- DO NOT store or expose cartridges to extreme cold or heat such as freezing or stored above lights or computers
- Do NOT re-refrigerate cartridges once they have warmed to room temperature
- Do NOT touch bio-sensors
- Do NOT pre-rupture silver calibrant disc
- Do NOT re-use cartridges
- Do NOT leave exposed to air and moisture
- Do NOT use expired cartridges for patient testing

Sample Information

In-Dwelling Line Sample Collection

- Always adequately ‘clear’ line prior to collecting a sample for testing on i-STAT
- Inaccurate results will be given if samples are contaminated.
- Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample.
- **i-STAT Recommendation:** five to six times the volume of the catheter, connectors, and needle should be collected as ‘waste’ for creatinine samples.
- **ACT cartridges:** If blood must be drawn from an indwelling line, possible heparin contamination and specimen dilution should be considered. The line should be flushed with 5mL of saline and the first 5mL of blood **or** six dead space volumes of the catheter should be discarded.
- ***Accurate results depend on an adequate back flush to eliminate the possibility of sample contamination with IV fluids.***
- *Caution should be taken when collecting from lines which have had fluids that could adhere to the sides of the tubing. These lines may be difficult to adequately ‘clear’.*

Sample Requirements Creatinine Cartridge

- **ONLY whole blood should be tested on i-STAT**
- Non-anti-coagulated whole blood for creatinine testing should be tested within 3 minutes of collection
- Heparinized whole blood can be used for creatinine testing.
- MUST use the BD Vacutainer lithium heparin green top 4ml tube—FILL TO CAPACITY or results may be adversely affected.
- Heparinized samples may be tested up to 30 minutes after collection.

- Heparin is the ONLY acceptable anti-coagulant which may be used with the i-STAT creatinine cartridge
- NEVER NEVER use a heparinized sample for ACT testing

CREATININE Sample Considerations

- ALWAYS use a well mixed sample
- Mix samples for 15 seconds
- Always squirt out the first drop of blood from syringe samples
  - To check for clots and to get rid of any micro air bubbles
- NEVER ever run a sample that has or has had a clot. Inaccurate results may be obtained!

Creatinine GFR Results

- Estimated Glomerular Filtration Rate (eGFR) values will be reported when results are downloaded into the electronic medical record
- The values may be accessed via Wake One
- The i-STAT handheld will NOT report eGFR values.

Sample Requirements **ACT** cartridge

- NEVER use a pre-heparinized or anti-coagulated collection container for ACT testing
- Plastic collection containers must be used
- Use fresh whole blood and test IMMEDIATELY after collection
- Do NOT let the sample sit for any period of time prior to testing
- Squirt out the first drop of blood from syringe, prior to filling test cartridge

i-STAT ACT Methodology

- Does not use mechanical detection of clot
- The endpoint is indicated by the conversion of a thrombin substrate.
- An electrochemical sensor is used to detect this conversion.

Results

- Factors affecting results
- Result considerations
- Result evaluation

Cartridges-Factors Affecting Results

- Refer to the i-STAT System Manual—Cartridge Test Information (CTI) sheets for factors which can adversely affect i-STAT results

ACT Results may be ADVERSELY affected by…

- Using a metal needle to fill cartridge
- Moving/carrying the analyzer during sample testing
- Vibration of the analyzer
- Tilting the analyzer during testing. The analyzer MUST remain flat during sample testing.
- Refer to the i-STAT System Manual—Cartridge Test Information (CTI) sheets for other factors that can adversely affect results

Result considerations

- Prior to acting on any ACT result, testing personnel should wait until the ACT value is final.
  - If ACT values are prematurely interpreted, inappropriate patient treatment could occur.
- Unexpected and unexplained results should be repeated by another test method.
- Problems should be reported to the Clinical Laboratory Point of Care Testing Coordinator

Result Considerations

- Samples diluted with IV fluids will give inaccurate results
- Results should be carefully evaluated
- Contamination may be indicated by:
    - Falsely decreased creatinine value
    - Falsely prolonged ACT results

When Results Not Given, etc.

- **Cartridge error**
  - Refer to Technical Bulletin, ‘Analyzer Coded Messages’ Technical Bulletin
  - If the same error code occurs multiple times with no apparent cause, notify the Clinical Laboratory POCT Coordinator
  - Consider using a different analyzer and a different batch of test cartridges
- **Star out**
  - Occurs when specific bio-sensor compromised or there is an interfering substance in the sample
- **Out of instrument range (>x value or <x value)**
  - Result is out of reportable range for the analyzer

Result Recall

- Turn on analyzer
- Select MENU
- Select 2 DATA REVIEW
- Select desired data
- PATIENT DATA requires entry of patient and operator ID information

Quality Controls (QC) and Maintenance

- Simulators
- Liquid QC
- Maintenance

Simulators

- Electronic Quality control that is used to validate the i-STAT analyzer
  - Pass or Fail
- QC results are automatically documented when the i-STAT analyzer is downloaded

Simulators-Internal

- An INTERNAL electronic simulator is performed automatically by the analyzer every 8 hours of use with each cartridge type.
- The internal simulator is performed when a patient cartridge is inserted.
- *Results will not be given if the simulator fails.*
- If the simulator passes, patient results will be displayed.

Simulators-External

- The EXTERNAL electronic simulator is the same as the internal simulator but is an external device and can be tested upon demand.

Simulators-External

- The external simulator should be used:
  - If the analyzer is dropped
  - If the internal simulator fails
  - If an error code occurs that indicates the simulator should be tested.
  - If analyzer performance is in question
  - Prior to and after performing the ceramic cartridge cleaning procedure

Liquid Quality Control

- Used to validate performance of test cartridges
- Consists of multiple levels
  - test cartridge specific
- Should be performed:
  - On each new cartridge shipment per cartridge type per cartridge lot # PRIOR to patient use—by Clinical Lab staff
  - Monthly—by testing site staff
  - If cartridge/analyzer performance is in question

i-STAT Maintenance, etc.

- Recharge batteries
- Disinfect outside of analyzer between patients
- Do not get moisture inside of the analyzer
- Perform ceramic cartridge pin conditioning when indicated by analyzer error codes. (scheduled conditioning is not recommended)
  - Each site has a ceramic cartridge and instructions for performing this procedure

Patient and Sample Identification

Patient identity

- Follow WFBMC policy for verification of patient identity—Use 2 patient identifiers **at the patient bedside**
- Ensure sample identity throughout entire testing and reporting process
- Scan patient ID into the analyzer DIRECTLY from the patient armband
- Verify patient ID again on analyzer display

Patient Identity-Misidentifications

- Any mis-identified samples/results should be reported to the Clinical Lab immediately.
- An i-STAT Resolution Requisition should be completed by the person creating the error and sent to the ICU Blood Gas Lab
- The i-STAT analyzer will need to be downloaded so lab staff can access results to replace with a BADID code in the electronic medical record.
- It is the responsibility of the staff member, who creates the error, to notify appropriate patient care providers of the sample misidentification.

Miscellaneous Information

i-STAT Resolution Requisition—(Purple Sheet) Use

- Used to communicate with the Clinical Lab
- Any patient testing that needs to be credited should be requested by using the purple sheet.
- Patient results should always be included on the purple sheet
- Patient name, medical record #, and CSN should be documented on the purple sheets.

I-STAT Billing/Credits

- **All i-STAT testing MUST have a documented physician order.**
- Any i-STAT result which has a valid medical record # and CSN is automatically ordered, billed and resulted to that patient.
- It is the responsibility of the testing personnel to request credits for any i-STAT testing which should not be resulted or billed.

i-STAT Supplies

- Cartridges can be obtained from the OR Blood Gas Lab M-F 7am-7pm
- Care should be taken to only get the amount of cartridges which will be used within the 2 week room temperature expiration dating
- Replacement analyzers can be obtained from the Clinical Laboratory Point of Care Testing Coordinator

Emergency Release of Cartridges

- An i-STAT Emergency Cartridge Release form must be completed should i-STAT cartridges be needed outside of M-F 7am-7pm.

- The site picking up the cartridges is responsible for room temperature dating of the cartridges

- NEVER take cartridges that are marked with “Do Not Use”

College of American Pathologists (CAP)

- If there are concerns regarding result quality and the concerns are not adequately addressed by Lab or WFBMC management, CAP can be notified at 1-866-236-7212

Congratulations

- This concludes the i-STAT 1 education module.
- Please note that this power point does not replace the i-STAT policies and procedures.
- The presentation only gives highlights of i-STAT information
- Please complete the on-line i-STAT exam.

Hands On Experience

- Change batteries and check battery voltage
- Test External electronic simulator
- Test/Discuss Liquid QC
- Test patient sample
- Recall of results
- Discuss Menu Options
- Download of results