Wake Forest™
Baptist Medical Center

Point of Care Testing
i-STAT ACT KAOLIN
Perfusion/CV-OR Education Module

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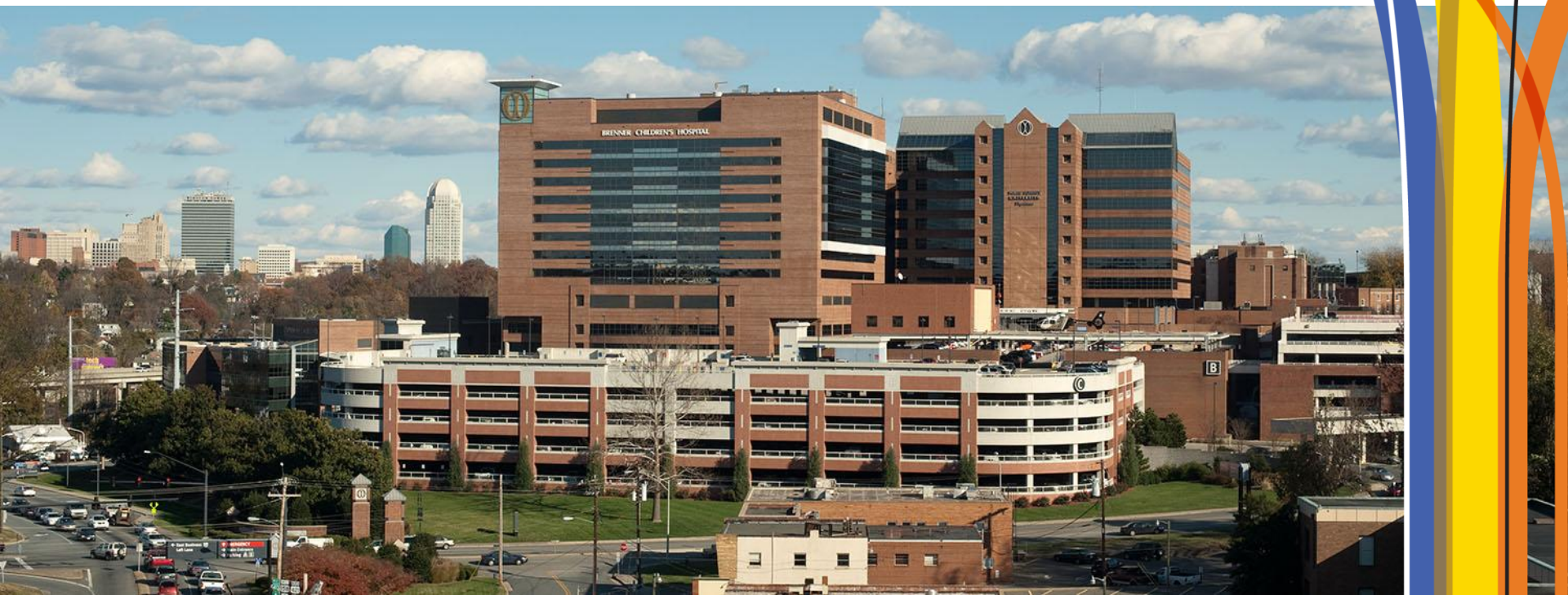
Updated: 01/28/13



i-STAT Support

- Angie Thayer 713-4136
- 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
- i-STAT Tech Support 1-800-366-8020
- 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 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 the 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, carrying the analyzer, and performing QC
  - Disinfect when contaminated with blood and between each OR case
  - Routine external cleaning is recommended for infection control purposes—Disinfect analyzer after each patient case
- DO NOT get close to the cartridge while filling
- A safety shield is recommended
- Place gauze or tissue over snap when closing
- All paperwork should be kept clean and sent in non-biohazard pneumatic tubes, if sent via pneumatic tube
- Transport baskets should be disinfected between patient cases. Use WFBMC approved disinfectant.
- Review the i-STAT procedure for additional information

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
- i-STAT specific rechargeable batteries are utilized
- Analyzer should stay on charger while in OR Lab
- Rotate analyzers on charger each day

Analyzer Environment Considerations

- Room temperature should be a consideration.
- The operating temperature of the analyzer is 61˚-86˚F.
- If the internal analyzer temperature drops too low, the analyzer will give a temperature error code.
- If this occurs, analyzer storage in an insulated container--between sample tests may be required.

Analyzer Display

- CARTRIDGE/SIMULATOR LOCKED
  - Cartridge or simulator locked in analyzer. DO NOT remove when this message is displayed
- BATTERY LOW (flashing battery icon)
  - Battery voltage is low and batteries need to be changed/recharged
- Refer to i-STAT 1 System Manual for additional information and MENU options

i-STAT Analyzer

- Turn on by pressing the on/off keypad—circle with line
- Will automatically turn off after 2 minutes of inactivity
- However, when patient and operator ID information is 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

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

Analyzer Download—OFF Hours

- If the i-STAT is used for patient testing, outside of 7am-7pm M-F, the testing personnel should place the analyzer on the downloader in the OR Lab.

- This will allow results to download into the patient electronic record and recharge of the analyzer batteries.

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 contain bio-sensors to “measure” analytes
- There are different cartridge configurations available from i-STAT
- ACT-Kaolin used by cardio-vascular OR
- Analyzers programmed for Pre-Warm to match Medtronic ACT results

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.

Cartridge Handling

- Store 2-8˚C until manufacturers expiration date
- Can be stored at room temperature (18-30˚C) per manufacturer instructions.
- DO NOT use past the room temperature expiration date!
- Individual cartridges can be used after 5 minutes at room temperature
- A whole box of 25 cartridges needs to sit at room temperature for 1 hour prior to use
- Open by tear symbol
- 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 re-use cartridges
- Do NOT leave exposed to air and moisture
- Do NOT use expired cartridges for patient testing

Analyzer and Cartridge Release

- The OR Blood Gas Lab will maintain i-STAT analyzers and cartridges.
- OR personnel will be required to pick up supplies from this lab prior to each case.
- The supplies will be kept in a carry basket and must be returned to the OR Lab at the end of each case for analyzer download, battery recharge, and restock of test cartridges.
- IT IS THE RESPONSIBILITY OF THE TESTING PERSONNEL TO ENSURE THE I-STAT ANALYZER AND UN-USED CARTRIDGES ARE RETURNED TO THE LAB!
- Confirm adequate battery charge PRIOR to ACT testing. It is recommended that the battery have at least 8.5 V battery charge prior to starting a new case.

Sample Information

In-Dwelling Line

- 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.
- **Coagulation 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 back flush.*

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

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.

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 increased ACT values
- Please NOTE: Different ACT methodologies give different ACT results!
- i-STAT ACT-k uses kaolin as the clot activator and analyzers are programmed in Pre-Warm mode in an effort to more closely match Medtronic ACT values.
- Initial sample comparison testing indicated ACT target values will not change between Medtronic ACT II (HRACT) and the i-STAT kaolin ACT.

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.
- *Patient results will not be given if the simulator fails.*
- If the simulator passes, patient results will be displayed.

Simulators-External

- An 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 2 levels for ACT cartridges
- 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 Medical Center policies for verification of patient identity—Use 2 patient identifiers at the patient bedside
- Ensure sample identity throughout entire testing and reporting process
- The patient armband on the patient should be checked against the label that will be used for i-STAT sample identity, prior to collecting the sample
- Verify patient ID again on result printout or analyzer display

Patient Identity

- The patient ID is entered in the i-STAT analyzer **prior** to sample testing.
- Take extreme care to enter ID correctly
- The patient armband should be scanned.
- If the armband will not scan successfully, the ID can be manually entered. It will require duplicate entry to ensure accurate entry of ID.
- Patient and operator ID is required prior to filling and inserting a test cartridge. The ID will stay active in the analyzer for 15 minutes.

Patient Identity

- To scan, hold the barcode in front of the infrared reader and press and hold SCAN.

- ALWAYS confirm the patient ID entered into the analyzer, whether scanned or manually entered.

Patient Identity-Misidentifications

- Any mis-identified samples/results should be reported to the Clinical Laboratory immediately
- An i-STAT Resolution Requisition should be completed *by the person creating the error* and sent to the OR Blood Gas Lab or ICU Blood Gas Lab--tube station 54.
- 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 that creates the error* to notify appropriate patient care staff (MD and RN) of the patient's that were involved in the mis-identification.
- When results are downloaded, they will report to the patient electronic record. It is critical to enter correct patient ID at the time of testing.

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.

Analyzer Error Codes

- Refer to i-STAT Technical Bulletin for cause of error
- If the same error code occurs multiple times with no apparent code, notify the Clinical Laboratory POCT Coordinator
- Consider using a different analyzer and a different batch of test cartridges
- Return questionable analyzer and cartridges to the OR Blood Gas Lab

Emergency Release of Cartridges

- Each site has a form that 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”
- Leave form on OR Lab counter for lab staff

CAP Notification

- If there are concerns regarding quality of patient results and these concerns are not adequately addressed by WFBMC Management, the College of American Pathologists may be contacted at 1-866-236-7212.

Congratulations

- You have completed the i-STAT power point presentation.
- 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 i-STAT written 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