Wake Forest™
Baptist Medical Center

Point of Care Testing
i-STAT G3, CG4, EG7, Creatinine Education Module

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

Updated: 01/24/13

i-STAT Support

- Angie Thayer 713-4136 or pager 806-6619
- Jane Houska 716-3252
- Central Processing 716-2610
- 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 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 Requirement

- 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
- Only use auto-disabling single-use finger stick devices.
    - Never use finger stick device for more than one person.
- DO NOT get close to the cartridge while filling
    - A safety shield is recommended
- Place gauze or tissue over snap when closing

Safety

- Disinfect analyzer when contaminated with blood AND between EACH patient
- Do NOT send blood-contaminated i-STAT Resolution Requisitions to the Clinical Laboratory
- All paperwork should be sent in non-biohazard pneumatic tubes

i-STAT Components

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

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

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 Information should be scanned directly from the patient armband on the patient.**
- CAUTION: Laser light—do not stare into beam or point at anyone

Information Entered into i-STAT

- A temperature corrected blood gas can be obtained
  - Make sure any entries made at this prompt are true and correct
  - Erroneous temperature entries should be corrected in the electronic medical record—send an i-STAT resolution requisition (purple sheet) indicating correction needed
- The FIO2 should always be entered
  - Can be entered as percent, liters, or decimal entries

Information Entered into i-STAT

- The sample type should always be entered
  - Arterial
  - Venous
  - Capillary
  - Cord
  - Mixed Venous
  - CPB (cardio-pulmonary bypass)—
  - CPB should only be used when patient is hemodiluted due to cardiac bypass. The I-STAT system has a CPB mode to compensate for this phenomenon. The CPB mode should be used on patients during and after Cardio Pulmonary Bypass for as long as the protein is affected.
  - Hematocrit results will be altered if CPB is selected. If CPB is selected in error, do NOT use the hematocrit results—Notify the Clinical Laboratory for appropriate patient credit and result modification in the electronic patient record.

Analyzer Display

- ‘Cartridge 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 above 8 volts
- **Data Review**
    - Allows review/print of data stored in analyzer
- **Quality Tests**
    - Quality control checks are performed utilizing this menu
- **Other Menu options**
    - Refer to i-STAT System Manual for additional information

Analyzer Download

- Use the Downloader located in each site
- The downloader is specifically labeled as the downloader
- Analyzers should be downloaded a minimum of each 8 hours—preferably more often so electronic medical record information is current
- 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 a successful download of data
- An error message will display on the analyzer if results do not successfully transmit
- Problems should be reported to 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
    - For example:
        - G3, CG4, EG7, Creatinine, ACT-K, ACT-C, PT/INR, etc.

i-STAT Cartridges

- E=electrolyte
- G=gas
- C=Chemistry
- #=Number of measured parameters
- Everything above line is measured
- Everything below line is calculated

Cartridge Handling—All Cartridges

- Store 2-8˚C until manufacturers expiration date
- Can be stored at room temperature (18-30˚C) per manufacturer instructions.
  - DO NOT use past room temperature expiration date!
  - 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

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 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

Sample Information

Sample Requirements

- **ONLY whole blood should be tested on the i-STAT**
- Arterial, venous or capillary is acceptable
- Syringe or capillary collection containers may be used
- Non-anti-coagulated whole blood and capillary samples should be tested within 3 minutes of collection
- Lactate, ACT and PTINR samples should be tested **immediately** after collection
- Heparinized whole blood can be used for blood gas and electrolyte testing—test within 10 minutes of collection
- Heparin is the ONLY acceptable anti-coagulant which may be used with the i-STAT
- NOTE: Heparin anti-coagulated collection containers should NEVER be used for ACT and PTINR samples

i-STAT Creatinine Sample Requirements

- **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.
    - When using a vacutainer/evacuated tube, you 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

Sample Considerations

- ALWAYS use a well mixed sample
- Hematocrit is most affected by an improperly mixed sample
- Mix syringe or capillary samples for 15 seconds
- Always squirt out the first drop of blood from syringe or capillary 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!

Sample Considerations

- Any sample collected for pH, pCO2, pO2, ICa, or TCO2 should not be contaminated with air.
- Samples should be capped immediately after collection and kept airtight
- If not kept airtight, results will be adversely affected
- Ionized calcium requires balanced heparin
- Use of non-balanced heparin can falsely decrease ICa results—
- Ionized calcium results will be adversely affected if a balanced heparin collection container is NOT used

Sample Considerations-Capillary

- Capillary samples should always have the first drop of blood wiped away before collecting a sample for i-STAT blood gas, electrolyte, or lactate testing.
- Potassium results may be adversely affected if the first drop of blood is used from a capillary sample
- Capillary samples should be tested within 3 minutes of collection

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.*

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 on the patient
- Verify patient ID again on result printout after testing

Patient Identity

- The patient ID number is entered in the i-STAT analyzer
- Take extreme care to enter ID correctly
- Whenever a patient has Not been registered with a WFBH ID, a pre-approved ‘generic’/temporary ID can be used for i-STAT testing.
- A resolution requisition must be submitted when these ID’s are used for i-STAT testing.

Patient Identity-Misidentifications

- Any misidentified 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 Clinical Laboratory.
- 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.

Results

- Factors affecting results
- Result considerations
- Result evaluation
- Critical Results
- Printing Results
- Patient Credit Requests

Factors Affecting Results

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

- Example:
  - Increased patient lactate, hemodilution, and certain medications can affect results

Result Considerations

- The i-STAT tests whole blood. Hemolysis can Not be determined.
- DO NOT report/treat high potassium results until verified via an alternate method
- Critical values should be repeated and validated. Consider repeat testing via an alternate method.
- Use correct critical value documentation of notification. Follow WFBMC policy.
- Unexpected and unexplained results should be repeated by another test method.
- Problems should be reported to the Clinical Laboratory Point-of-Care Testing Coordinator at 3-4136

Result Considerations

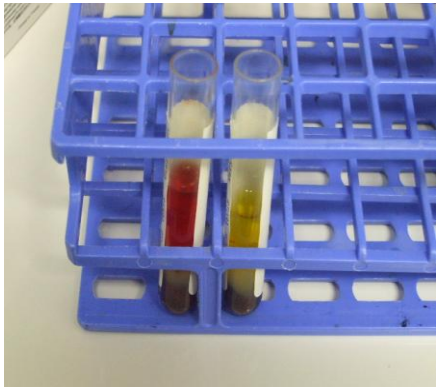
- Samples diluted with IV fluids will give inaccurate results
- Results should be carefully evaluated
- Contamination may be indicated by:
  - Drop in hemoglobin and hematocrit
  - Falsely elevated sodium and decreased potassium if contaminated with saline
  - Blood gas results will be erroneous—low pCO2 may be a possibility

What is Hemolysis?

- The destruction of red blood cells, caused by disruption of the cell membrane and resulting in the release of hemoglobin

How is Hemolysis Detected?

- The sample is spun in a centrifuge
- The supernatant/serum/plasma (**top layer** of fluid) should be evaluated for any pink or red color
- The presence of pink or red color in the serum/plasma indicates the presence of hemolysis



Which Value will be Adversely Affected by Hemolysis?

- Potassium

- When the red blood cell membrane is ruptured, potassium is released from the red cell into the blood sample.

Why Should an Elevated Potassium, Reported by i-STAT, be Verified via an Alternate Method PRIOR to Patient Treatment?

- i-STAT tests whole blood and hemolysis cannot be detected when using i-STAT

Estimated Glomerular Filtration Rate (eGFR)

- Estimated Glomerular Filtration Rate (eGFR) values will be reported when Creatinine 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.

ECMO Specific Information

- If i-STAT is used for ECMO prime or calibration samples, the testing personnel MUST complete an i-STAT resolution requisition form indicating the additional information which should be appended to the results in the electronic medical record.

Critical Values

- Critical values should be evaluated with patient's clinical symptoms and appropriate repeat testing performed.
- Any critical value not consistent with patient symptoms should be repeated by an alternate test method.
- WFBMC policy must be followed for reporting critical values
- Follow "Read Back" procedures
- The i-STAT policy/procedure has defined i-STAT critical values
  - The patient physician must be notified of these critical values
  - Documentation of notification must be included in the patient record--include—result, date and time of notification, name of MD notified, and name of staff member notifying MD

When Results Not Given, etc.

- **Cartridge error**
  - Look at Technical Bulletin ‘Analyzer Coded Messages’ for details
  - If the same error code occurs over and over with no apparent code, notify the Clinical Laboratory POCT Coordinator
  - Consider using a different analyzer and a different batch of test cartridges
- **Star out**
  - Occurs when a specific bio-sensor is 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
- **Suppressed results (<>)**
  - Displays for calculated parameters, if the calculation is dependent on a result that is out of reportable range.

Printing Results

- Printer uses thermal printer
- Results fade over time—can't be used as permanent chartable record
- Printer operates using rechargeable batteries—MUST remain plugged into outlet when not in use so batteries can stay charged
- Verify patient ID on printout against patient sample ID prior to reporting results

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 i-STAT Resolution Requisition.
- Patient results should always be included on the form
- Patient name, medical record, and CSN should be documented on the form

I-STAT Billing/Credits

- All i-STAT testing should 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 credit for any i-STAT testing which should not be resulted or billed.

i-STAT Supplies

- Cartridges and paper 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 room temperature expiration dating period
- Replacement analyzers or printers can be obtained from POCT in the main Clinical Laboratory at anytime

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 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 results
- Discuss Menu Options
- Download of results

• istatONEtrainingpowerpointG3CG4EG7Crea012413