Wake Forest™
Baptist Medical Center

Point-of-Care Testing
i-STAT PT/INR Education Module

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

Updated: 01/24/2012

i-STAT Policy and Procedure

- All i-STAT policies and procedures should be reviewed at the time of training and annually thereafter.

- This education module does not include all information that is discussed in the policies and procedures.

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/Procedures/Guidelines

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

Training and Competency

- Competency observations may only be completed by authorized staff members

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
- Only use auto-disabling single-use finger stick devices.
    - Never use finger stick devices for more than one person.

i-STAT Components

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

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

- Where available, 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
- 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 keeping charged >8 volts
- **Data Review** —allows review/print of data stored in analyzer
- **Quality Tests** —quality control checks performed utilizing this menu
- **Other Menu options** —refer to System Manual for additional information

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

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!
- If a small supply of cartridges are kept refrigerated at the POC site, the refrigerator temperature should have 24/7/365 temperature monitoring. The refrigerator temperature must be maintained 2 to 8˚C.
- If the temperature is ever outside of 2 to 8˚C, contact the Clinical Laboratory Point-of-Care Testing Coordinator for assistance..
- **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 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”
- Enter operator and patient ID information Prior to collecting the sample.
- 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

Sample Requirements PT/INR Cartridge

- **ONLY whole blood should be tested on i-STAT**

- **Follow all current manufacturer recommendations**
- Only capillary or venous samples should be used for PTINR testing.
- The first drop of blood from a capillary sample should be used. **I-STAT recommends filling cartridge directly from skin puncture. Capillary tubes are NOT recommended for PT/INR testing.**
- If a collection container is used for a venous sample, the sample must be collected in a **plastic** syringe without anti-coagulant and tested IMMEDIATELY after collection. Transfer devices should not be used to transfer sample to the cartridge. Metal needles should not be used when filling an i-STAT cartridge.
- **If sample testing is delayed, results will be adversely affected.**

Sample Requirements i-STAT PT/INR cartridge

- NEVER use a pre-heparinized or anti-coagulated collection container for i-STAT PT/INR 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

PT/INR Results will be ADVERSELY affected by…

- Using a metal needle to fill cartridge
- Moving/carrying the analyzer during sample testing
- Vibration of the analyzer (Keep the analyzer flat and free of movement.)
- 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.

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

Result considerations

- Unexpected and unexplained results should be repeated by another test method.

- Problems should be reported to Angie Thayer 3-4136

When Results Not Given, etc.

- Cartridge error—Look at Technical Bulletin
- 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

Analyzer Error Codes

- Refer to i-STAT Technical Bulletin for cause of error
- 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

Result Recall

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

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 Identity

- Follow WFBMC policy for verification of patient identity—Use 2 patient identifiers
- Ensure sample identity throughout entire testing and reporting process
- When possible, Scan patient ID into the analyzer
- Verify patient ID again on analyzer display

Patient Identity-Misidentifications

- Any misidentified samples/results should flagged immediately in the electronic medical record.

- The Clinical Laboratory Incident/Credit Report Form must be completed by the person creating the error and sent the Phlebotomy manager.
- The i-STAT analyzer will need to be downloaded for results to be accessible 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 staff (MD) of the patient's who were involved in the misidentification. Documentation should include the name and date/time of the person notified of the error.

Analyzer Download

- Use the Downloader located in each site
- Analyzers should be downloaded within 30 minutes of testing
- 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

- Problems should be reported to the Help Desk

Re-charger

- Can charge battery in compartment and battery in analyzer

Analyzer Download—Downloader Troubleshooting

- Troubleshoot the downloader
  - Check for the 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 to the Help Desk

Clinical Laboratory Incident/Credit Report Form

- Used to communicate with the Clinical Lab management
- Any patient testing that needs to be credited should be requested by using this form.
- 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 MUST have a documented physician order.**
- Any i-STAT result which has a valid medical record #/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 can be obtained from the OR Blood Gas Lab M-F 7am-7pm

- Replacement analyzers can be obtained from Angie Thayer

Emergency Release of Cartridges

- Each site has a form which 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”

Important i-STAT INR Reminders

- **DO NOT DELAY TESTING OF THE SAMPLE!!! Falsely decreased values may occur**
- **Enter operator, patient, and cartridge information PRIOR to 'pricking' the patient finger or collecting the venipuncture sample**
- **The test cartridge MUST be Filled IMMEDIATELY after the skin puncture—NO DELAY—You cannot 'reuse' a finger stick—even if the finger is still bleeding**
- **The first drop of blood from a capillary sample should be used. I-STAT recommends filling cartridge directly from skin puncture. Capillary tubes are NOT recommended for PT/INR testing. If using a finger stick (capillary) sample, the cartridge MUST be filled DIRECTLY from the finger.**
- **The test cartridge MUST be inserted into the analyzer IMMEDIATELY after filling with blood sample—NO DELAY**
- **If testing a venous sample, the cartridge MUST be filled withOUT the needle—If testing a venous sample, fill the i-STAT cartridge PRIOR to filling the sample collection tubes**
- **Do NOT move or bump the analyzer once the cartridge has been inserted into the analyzer**

Important i-STAT INR Reminders

- **If an error code 19 occurs, draw a venous sample and send to the Core Lab.**

- **Any INR > or = 4.0 should have a follow-up (confirmatory) venous sample sent to the Core Lab**

- **i-STAT PT/INR may report a false prolongation of the prothrombin time (PT) and an elevation of the INR on samples contaminated with Chlorhexidine Gluconate. *This chemical can be found in some skin cleansing solutions.***

Important i-STAT INR Reminders

- **Notify all critical values—follow current procedure and document notification in Sunquest**
  - **Sunquest function MEM**
  - **Worksheet ISTAT**
  - **M-*accession number***
  - **Append the critical value notification to the INR value.**
    - **–CTRB-;reported to *type full name of person notified of critical value and their credentials and the date/time of notification***
-

Important i-STAT INR Reminders

- **LIS/Sunquest order code information**
  - **Sunquest function=MEM**
  - **The Worksheet is ISTAT**
  - **The battery order code is ZPTB**
  - **This battery includes the following tests:**
    - **ZSAMP (sample type—CAP (capillary) or VEN (venous)**
    - **ZINR (INR value reported by i-STAT analyzer)**
    - **ZCOM—auto answer comment—POC--Point of Care Testing**
    - **ZDEV (device—helps Sunquest know whether or not to append the DHP address to DHP results) (hidden from clinician) (DHP-Downtown Health Plaza) (S7CSB-seventh floor CSB)**
    - **ZLOC (auto-answer address of testing if performed at DHP—will be hidden if reported by S7CSB device)**
    - **ZTECH—tech code of testing personnel—hidden from clinician**

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 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 on-line i-STAT exam within 1 week of training.

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