Spaulding Hospital Cambridge

Point of Care

i-STAT Operations Procedure

Prefix D

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Abstract:	To ensure quality results when using the i-STAT for point of care testing
Keywords:	i-STAT, CG4+, Troponin I, CHEM 8, blood gas, cardiac
Personnel Involved:	Medical Technologists Respiratory Therapists
Regulatory Reference:	Joint Commission CAMLAB
Related Policies:	CHEM8+ Cartridge Procedure, CG4+ Cartridge Procedure, Troponin I Cartridge Procedure

Purpose

The i-STAT is a portable clinical analyzer used in conjunction with i-STAT cartridges to obtain definitive quantitative measurements of blood gas parameters, lactate, Troponin I and basic chemistries. The disposable cartridge contains all of the system's components reagents, sensors, and waste container).

Policy

There must be a written physician's order for all i-STAT testing. Nursing department is responsible for verification of the order. Respiratory is responsible for Meditech resulting and calling the results to the provider. All tests done via the i-STAT are considered critical so processing specimens as quickly as possible is imperative.

Staff therapists/technicians are allowed to do arterial punctures on the Radial arteries only.

Ordinarily patients receiving anticoagulant therapy should not have an arterial puncture. Notify the ordering physician to clarify whether in fact they still want to draw a blood gas on their patient receiving anticoagulant therapy. If the physician is aware of this and still wants an ABG

drawn, the therapist/technician may draw the blood, and then chart that the physician has been notified. Patients receiving anticoagulant therapy will have pressure held over the artery for a minimum of ten minutes and/or until the bleeding has ceased.

Whenever a therapist attempts an ABG puncture, but is unsuccessful in obtaining the ABG, there must be an entry made in the medical record to document the circumstances and the physician should be notified.

i-STAT Operations Procedure

Calibration verification/Linearity

Calibration verification using the “CAL VER” solutions on all analytes is required. This is done by the laboratory.

CAL VER is performed:

1. On any new, or replacement device before clinically used
2. Every 6 months
3. As part of the troubleshooting process when controls reflect an unusual trend or are consistently out of range.
    - Run each level once
    - i-STAT analyzer must be docked after running the CAL VER solutions
    - POCT program will print out the reports from Precision web.
    - Signed and approved by the Laboratory Manager & Laboratory Director.

To perform CAL VER on i-STAT:

- Press Menu. Press 3 to select Quality Tests.
- Press 3 to select CAL VER.

If the Calibration Verification fails, the analyzer must be removed from use.

Electronic Quality Control

Electronic Simulators:

The Electronic Simulator (both external and internal) is a quality control device for the analyzer. It simulates two levels of electrical signals that stress the analyzer’s signal detection function both below and above measurement ranges. It provides an independent check on the ability of the analyzer to take accurate and sensitive measurements of voltage, current and resistance from the cartridge. An analyzer will pass or fail this test depending on whether or not it measures these signals within specified limits. The Electronic Simulator will fail if high relative humidity interferes with the measurements, making separate recording of humidity unnecessary.

A. Internal Electronic Simulator

The internal electronic simulator runs every 8 hours for blood gases and for all the analytes every 24 hours. Inserting a cartridge triggers the internal simulator. When 8 hours has elapsed since the last Electronic Simulator test (internal or external), it will automatically perform the internal test before the sample is tested, adding about 15-20 seconds to the testing cycle.

1. If it fails, the testing cycle stops and FAIL displays on the screen.
    - Immediately rerun the cartridge in the same analyzer to confirm the FAIL.
    - If the cartridge fails again rerun the cartridge in a different analyzer (if less than three minutes has lapsed from the time of cartridge filling.)
    - If the cartridge fails in more than one analyzer, use a different cartridge.

2. If it passes, the cartridge cycle continues to completion and the user receives the test results.

B. External Electronic Simulator

The external electronic simulator is a stable electronic device, which is inserted into the cartridge port of the analyzer as described above. It should be run when:

1. Daily and recorded in the maintenance log book
2. The analyzer has been dropped
3. After major malfunction
4. Replacement analyzer received from i-STAT

To run the external simulator:

- Press the Menu key to access the Administration menu.
- Press the #3 for Quality test
- Press the #4 for Simulator

1. Insert the simulator into the analyzer facing up. (Do not touch the contact pads). **Cartridge Locked is displayed indicating that the simulator should not be removed. DO NOT ATTEMPT TO REMOVE THE SIMULATOR WHILE THE Cartridge Locked MESSAGE IS DISPLAYED. AN ATTEMPT TO REMOVE FORCIBLY DURING THIS CYCLE MAY DAMAGE THE ANALYZER.**
2. If PASS is displayed on the analyzer screen, remove the simulator **after the CARTRIDGE LOCKED message disappears from the display screen.**
3. If FAIL is displayed on the analyzer screen:
    - Repeat the procedure with the same Electronic Simulator. If PASS is displayed, use the analyzer as required.
    - If FAIL is displayed, repeat the procedure with a different electronic simulator, if available. (Extra simulators are in the laboratory.)
        a) If FAIL is displayed with the second electronic simulator:
        (1) Do not analyze patient samples with the analyzer.
        (2) Transmit the result to Precision Web by docking the meter.

(3) Record the failure in the Instrument Corrective Action Log, along with action taken.

C. Thermal Probe Check

i-STAT analyzers contain a thermal control subsystem consisting of two thermal probes with thermistors and heating contact wires. When measurements are performed at a controlled temperature, the thermal probes in the analyzer contact the metalized area under the chips in the cartridge and maintain the temperature of the sensors and the fluids that come into contact with these sensors at the required temperature of ±0.10°C.

The thermal probe check must be verified twice each year, after the i-STAT software update. Check the thermal probes as follows:

1. If the analyzer and simulator have been stored separately in areas where the ambient temperature differs by more than 3°C, allow the simulator and analyzer to stand in the same place, out of drafts, for 30 minutes before inserting the simulator into the analyzer. Handle the simulator as little as possible to maintain its thermal uniformity and stability.
2. Insert the simulator into the analyzer.
3. When the results are displayed, press the period button and the difference between the thermal probes can be viewed on the analyzer's screen. (Acceptable : a value equal to or less than 0.1) If a FAIL message with "t" Quality Check Code, or a value greater than 0.1 displays repeat the procedure. Repeat the procedure if "--.--"is displayed. Call Technical Support for repeated failures.
4. Documentation of results appears electronically in Precision Web under the test detail of the electronic simulator. This report can also be pulled in Precision Web under the i-STAT Custom Reports tab. This report is pulled every 6 months after the i-STAT CLEW update.

Liquid Quality Control

Liquid Quality Control must be performed:

1. On every analyzer prior to initial placement for patient testing
2. On every new lot number and every new shipment of cartridges
3. When there's a suspected cartridge or storage problem
4. Monthly to check storage conditions of cartridges

For individual quality control procedures, please refer to the cartridge specific procedure.

Barcode Scanning

To scan a barcode

- Hold the analyzer approximately 3-12 inches and at a 10 degree angle from the barcode to be scanned.
- Press and hold down the Scan key to start the barcode scanner.
- When the analyzer accepts the barcode, it will automatically turn off the beam.
- The meter contains a laser. DO NOT stare into the light or point it toward anyone.

Calculations

The i-STAT analyzer contains a microprocessor that performs all calculations required for reporting results.

Reporting Results

The handheld analyzer will display test results once the cartridge has been unlocked and the Cartridge Locked prompt disappears. Results display for 2 minutes. Recall results to the display screen by pressing the MENU key.

Results that are beyond the instrument's linearity will be reported as ">" (greater than) or "<" (less than) indicating that the result is below the lower limit or above the upper limit of the reportable range.

A. Suppressed Results

The i-STAT will not display results under two conditions:

1. A result that is flagged with *** means that:
   a. There is an interfering substance in the sample.
   b. An individual sensor for that test has been compromised.
   c. This particular test is a calculated result that depends on the results of another test that has ***.
   d. The first time *** appears when a sample is tested, retest the sample using a new cartridge.
   e. If *** appears again when the sample is tested a second time on the i-STAT send a specimen to the clinical laboratory or to Cambridge Health Alliance for analysis.
   f. If *** reappears on multiple patient samples, call the laboratory for assistance.

2. Results will not be reported if a test cycle has a problem with the sample, calibrant solution, sensors, mechanical, or electrical functions of the analyzer.
   Action: Take the action displayed with the message that identifies the problem. Refer to the i-STAT system manual's troubleshooting section if necessary. Use another analyzer if necessary.

B. Transmitting Results to the Electronic Medical Record

1. Place the analyzer in the Downloader. The analyzer does NOT need to be turned on. The message “Communication in progress” is displayed. Verify that the display is turned off before removing from Downloader.
2. If unable to resolve data transmission issues by using the SHC Helpdesk via the intranet, please notify the laboratory at extension 3630. For scheduled and unscheduled downtimes, use the downtime form to communicate results to the provider. Results will be held in the analyzer until the LIS is functional. Once the LIS is functional dock the i-STAT and verify the results in Meditech. For further downtime instructions, please refer to that procedure.

Maintenance

A. Daily maintenance checks

These are done on the i-STAT that include checking the temperature, barometric pressure, and battery voltage as well as documenting the room temperature and refrigerator temperature for cartridge stability. All parameters should be within range and if not the laboratory manager should be notified.

To perform daily maintenance:

1. Turn analyzer on.
2. Hit “MENU”.
3. Select “1” for Analyzer Status.
4. Record results in the Maintenance Log.

B. CLEW/JAMS software updates:

Software updates performed twice per year (June and December) re-establishes standardization values and incorporates refinements to the internal quality monitoring system. External Quality Control and the Thermal Probe Check are performed along with the CLEW update. The laboratory will ensure CLEW updates are implemented prior to software expiration.

C. Disnfect exterior of analyzer as needed with hospital-approved disinfectant (Sani-wipe cloths). DO NOT spray any liquid onto or into the analyzer.

Instrument Replacement Policy

The replacement instrument policy applies to the following situations:

1. Any malfunction of the instrument
2. Any new instrument
3. Any major maintenance

The laboratory will perform the following before the replacement instrument is installed:

1. External simulator
2. Thermal probe check
3. CAL VER
4. Liquid quality control
5. Run liquid QC, internal QC and external simulator for 20 days.
6. Perform 20 patient correlations on an existing i-STAT to the new i-STAT.
6. Document all results in the Instrument Validation book.
7. All the reports must be approved and signed by the Medical Director or designee.

Troubleshooting

A. Analyzer

1. **No display:** Either if the display screen remains blank, after a cartridge has been properly inserted or after the On/Off key has been pressed, the batteries should be replaced.
2. **Cartridge Locked:** Cartridge Locked appears on the screen during the testing cycle to indicate that cartridge or simulator is locked in the analyzer and should not be removed. A cartridge or simulator must be removed only after the Cartridge Locked prompt disappears from the screen. Normally the analyzer will reset and release the cartridge after the testing cycle is completed. If the analyzer cannot reset, the Cartridge Locked prompt will remain on the screen. If this occurs, wait until the analyzer deactivates (display screen blank) and press the On/Off key. The analyzer will try to reset. If the Cartridge Locked prompt does not disappear, do not attempt to remove the cartridge. Call the laboratory at ext. 3630.
3. **Low Battery:** Recharge battery in Downloader/Recharger or swap with extra rechargeable battery.
4. **Electronic simulator fail** will appear if the analyzer has not successfully completed the electronic simulator test. Refer to **ELECTRONIC QUALITY CONTROL** section.
5. **CLEW expiring, Upgrade required:** The laboratory would need to perform a software update.
6. **Messages and Quality Check Codes:** If a problem is detected during a testing cycle, the cycle will be stopped and a message box will appear on the screen. The messages will identify the code number. Refer to i-STAT's technical bulletin(s) to determine the meaning of the code number and the suggested action. If the analyzer deactivates before the detected problem is addressed, the message box will reappear the time the On/Off key is pressed. Document all problems on the i-STAT Corrective Action Log in the maintenance book and notify the laboratory. (Note: i-STAT's Technical Bulletin for Quality Check Codes is located at the front of the maintenance log book and can also be accessed at: http://www.abbottpointofcare.com/Customer-Info-Center/User-Documentation.aspx

See section: ***Analyzer Coded Messages (Art# 714260-00N)***

- **Temperature out of range error message:** The analyzer must be moved to an area where the temperature is between 18-30°C. Equilibration can take up to 30 minutes.
- **Other error messages:** Refer to the i-STAT System Manual's Troubleshooting section for more information.

7. **I-STAT Dropped:** Run simulator prior to patient testing.

B. Cartridge: *** Instead of Results:

1. Test the patient specimen with a new cartridge. If *** reappears, send the sample to the clinical laboratory or to Cambridge Health Alliance when laboratory is closed for analysis. The sample may contain a substance that interferes with the test.
2. If *** are obtained for the same test performed on an additional (different) patient, call the laboratory for assistance at ext. 3630. (This problem may have been caused by improper cartridge storage).

Technical Support may be contacted 24 hours x 7 days at 1-800-366-8020

Proficiency Testing

The College of American Pathologists (CAP) sends unknown samples to the laboratory for analysis several times per year. Results are submitted to the CAP within 10 days of survey receipt. If a site fails 2 out of 3 events or two consecutive events according to federal law, it may be required to discontinue testing.

- All survey results are to be handled and reported in the same manner as clinical results following the directions on the CAP Survey package insert. The samples are not to be analyzed in duplicate unless clinical specimens are analyzed in duplicate. Actions or decisions must be documented.
- Participation must be random and not assigned to specific individuals. Successful participation may be used as demonstrating successful competency for that year.
- Upon receiving the survey:
  1. The laboratory will contact the participating departments regarding the survey and timeline of the survey to be performed.
  2. The departments must be available within the period identified by the laboratory.
  3. The Director of Respiratory Therapy must make sure of the following:
     a. Instruments are in good working order
     b. Randomly select staff to participate, but ensure that subsequent surveys are rotated among different staff (e.g. document in a log)
     c. The CAP survey form has been filled out correctly with a signed attestation form.
     d. Submit the survey to the laboratory on time.

- Once results are obtained they should be submitted to the Laboratory Manager who will send them to CAP.
- Laboratory Manager and the Laboratory Director shall review the survey results to assess performance and ensure compliance with the standard and comment.
- Any results that are beyond 2 S.D.I. or any scores less than 100% must be followed up with a corrective action survey exception form.
- Scores of 100% minimally requires documentation of review by the Laboratory Manager or the Laboratory Director.
- Should a site fail proficiency, they will be required to immediately perform a comprehensive investigation and document corrective action. Operator re-training may be required.
- In order to avoid cessation of testing, the site that is failing a challenge will be expected to develop and implement a more aggressive plan for performance improvement.
- Each site is responsible for completing survey challenges when they arrive.

Anticipated Survey Periods:

AQ (Blood Gases) & PCARM (Cardiac Markers)

Product Receipt	Evaluation Receipt
March	April
June	July
October	November

Competency Assessment

Testing personnel must demonstrate competency prior to direct patient testing. All operators initially must read the procedure manual and complete the Operator Training Checklist after initial training and the Competency Written Test in order to become an operator of the i-STAT. After 6 months, competency will be evaluated for all non-waived procedures. At the one year mark and thereafter, competency will be evaluated for both waived and non-waived procedures.

Under no circumstances should any operator share their operator ID or use someone else's. If you do not have one, you must contact your supervisor immediately.

Expired Operators:

Operators that fail to meet competency requirements will be locked out of the system. They will be required to undergo retraining and competency assessment according to above.

In special circumstances, expired operators may be granted a one month extension in order to complete their competency. However this is up to the discretion of the laboratory.

References

i-STAT1 System Manual, i-STAT Corporation, Princeton, N.J., 06/01/01.

EFFECTIVE DATE: _____/_____/ 20

Procedure Authorization:

The Laboratory Director and the Laboratory Manager will initially approve a\each new procedure for a period not to exceed 3 years. In the event the procedure applies to additional departments, the director of that department will also approve the procedure prior to implementation. Each year the Laboratory Director or the director's designee (Laboratory Manager) will review each procedure for appropriateness and the director will be informed of any changes prior to initialing the manual review page. If a procedure is altered or amended the director will initial the three years the procedure will be reviewed, reprinted and approved for another 3 year prior.

Approved by: _____ Date: _____

Stevan E. Martin
Laboratory Manager

Approved by: _____ Date: _____

Rebecca Osgood, M.D.
Director

Reviewed by: _____ Date: _____

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Discontinued: _____Authorization: _____