

## i-STAT SYSTEM

	DATE	NAME
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<b>ADOPTED:</b>	1999	SMB
<b>REVIEWED:</b>	1/5/15	MAS
<b>REVIEWED:</b>	2/2/16	KW
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<b>REVISIED:</b>	12/21/16	Dr. Bradley Curtis

Supersedes 6/20/13, MAS, lower limit of pO<sub>2</sub> verified for reporting  
 Revised 12/20/16 to include testing related to Adult and Pediatric Urology

### **PRINCIPLE:**

The i-Stat System performs point of care blood analysis using a single disposable cartridge which contains microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber. The measurements of the different assays are electrochemical, using the microfabricated sensors housed in each cartridge to measure analyte concentrations directly in a single whole blood sample. The analyzer used is the handheld i-Stat Portable Clinical Analyzer. When a cartridge is filled with blood and inserted into the i-Stat Analyzer for analysis, it automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration, and continuous quality monitoring. An Infrared Interface Link (IR Links) for handheld analyzers allows for transmission of patient records from several analyzers to the DE software and in to the QML program. Data can then be stored, organized, edited and is transferred to the St. Cloud Hospital Laboratory Information System.

### **SPECIFIC TEST METHODOLOGY:**

1. **Sodium, Potassium, Chloride, Ionized Calcium, pH, PCO<sub>2</sub>:**  
 These parameters are measured by ion-selective electrode potentiometry. Concentrations are calculated from the measured potential through the Nernst equation.
  
2. **PO<sub>2</sub>:**  
 It is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into a internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.
  
3. **Hematocrit:**  
 It is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.
  
4. **Hemoglobin, HCO<sub>3</sub>, sO<sub>2</sub>:**  
 These parameters are calculated values.
  
5. **ACT:**  
 The endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen and an electrochemical sensor is used to indicate the event of this conversion. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in Fibrinogen. The product of this thrombin-substrate reaction is an electroactive compound that is detected amperometrically, and the time of detection is measured in seconds. The test reports the Activated Clotting Time (ACT) as a whole blood time (WBT) in seconds.
  
6. **PT/INR:**

The time required for complete activation of the extrinsic pathway of the coagulation cascade when initiated (activated) with a thromboplastin. The endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen. An electrochemical sensor is used to detect this conversion.

7. LACTIC ACID:  
Uses the CG4+ i-stat cartridge – CCLS only as a backup method for the Chemistry analyzer. See the Chemistry Manual for details.
8. CREATININE (Crea):  
This parameter is measured amperometrically. Creatinine is hydrolyzed to sarcosine through a two step process. The oxidation of sarcosine produces hydrogen peroxide. This occurs at the electrode and produces a current. The current produced is proportional to the creatinine concentration of the sample.

## **SPECIMEN :**

VOLUME REQUIRED: 95 ul for the EG7+ and G3+ cartridges  
65 ul for Creatinine cartridge  
40 ul for the ACT cartridge  
20 – 45ul for the PT/INR cartridge (single drop from finger or syringe)

### ARTERIAL SPECIMENS:

Allow alcohol to dry over puncture site before collecting blood. Do not collect above an IV. Fill a lithium heparinized blood gas syringe to the recommended capacity as stated by the syringe manufacturer. (*For ionized calcium results, use a balanced or low volume heparin syringes (<10 IU/ml).*) Underfilling syringes containing liquid heparin will decrease results due to dilution and will decrease ionized calcium results due to binding. Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds and then change direction and mix for another 5 seconds. Avoid or remove immediately any air drawn into the syringe to maintain anaerobic conditions. ***For most accurate results, test samples immediately after draw (ACT samples MUST BE tested immediately).*** Blood may be analyzed within 10 minutes of collection, but if there is any time delay between collecting the specimen and insertion of the blood into the i-Stat cartridge, the sample must be remixed as instructed above. Evacuated tubes are not recommended for blood gas analysis.

### VENIPUNCTURE SPECIMENS (NON-WAIVED):

Allow alcohol to dry over puncture site before blood collection. A lithium heparin anticoagulated tube must be collected for testing. The tube must be filled to capacity. Adequate mixing of the sample with the anticoagulant in the tube is necessary to ensure no clotting occurs. Samples suspected of clotting should not be used for testing. For the most accurate results, samples used for Lactic Acid analysis should be tested within 5 minutes of collection. Any delay in testing requires the sample to be put on ice for up to 30 minutes. Samples older than 30 minutes should not be used. Samples for creatinine testing should be performed within 30 minutes of collection.

### VENIPUNCTURE SPECIMENS (WAIVED):

The FDA has granted waived status November 13, 2008 for the Crea cartridge. ***Waived status is applicable only when testing venous samples collected in evacuated tubes with lithium heparin (green top tubes) with the Crea cartridge and the i-Stat I Analyzer.*** If the manufacturer's instructions are not followed for any test categorization, the test defaults to high complexity.

### FINGER AND HEELSTICK SPECIMENS for EG7+ and G3 cartridge:

Allow alcohol to dry over puncture site before collecting blood. Wipe away the first drop of blood, which contains excess tissue fluid, which can increase potassium result and dilute other test values. Do not "milk" finger or heel while collecting blood. Avoid drawing air into the capillary tube. Use balanced heparin capillary tubes (<10 IU/ml) for ionized calcium analysis in the EG7+ cartridge. (Radiometers capillary tubes meet these requirements). Test samples immediately to avoid clotting (especially in neonates).

**IN-DWELLING LINE COLLECTION:**

Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: three to six times the volume of the catheter, connectors, and needle. Follow the procedure for arterial collection.

**SPECIMEN FOR ACT TESTING:**

1. CCNS/CCE/Tele/CPRU nursing personnel may draw the blood sample from the arterial sheath according to the procedure “Arterial Line, Drawing Blood From”, wasting 20 cc and using approximately 2cc for testing. This will be done in the presence of lab personnel to assure appropriate timeliness for sample testing. In the Cath lab, 10 cc of blood is wasted from the arterial sheath and 2 cc of blood is used for testing. Surgery personnel use surgery criteria for drawing and testing blood samples in their setting. Please refer to the Point of Care Activated Clotting Time Testing for CV Surgery for determining the appropriate timing for testing with this methodology in the cardiovascular surgery setting.
2. If blood is obtained by venipuncture, the venipuncture should be clean to avoid contamination of sample with tissue thromboplastin..
3. All samples must be tested immediately.
4. Criteria for unacceptable samples include: insufficient sample, sample drawn from heparinized indwelling catheters or other anticoagulated lines without thoroughly flushing the lines, sample that cannot be tested immediately.

**SPECIMEN FOR PT/INR TESTING:**

**Capillary Punctures:**

1. Remove cartridge from foil pouch and place the cartridge on a flat surface.
2. Prepare lancet device and set aside until needed.
3. Clean and prepare the finger to be samples. Allow finger to dry thoroughly before sampling.
4. Prick the bottom side of the fingertip with the lancet device
5. Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first sample of blood. *Avoid repetitive pressure (“milking”) as it may cause hemolysis or tissue fluid contamination of the specimen*
6. Touch the drop of blood against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.
7. Apply sample until it reaches the fill mark indicated on the cartridge.
8. Fold the sample closure over the sample well.
9. Press the rounded end of the closure until it snaps into place.

**Note:** It is possible to bring the cartridge to the finger for easier application. Make sure to leave the **instrument on a flat vibration-free surface for testing.**

**Venipunctures**

1. Collection technique must be used for good blood flow
2. The sample for testing should be drawn into a **plastic** collection device (either a plastic syringe or plastic evacuated tube).
3. The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
4. The collection device **cannot contain clot activators or serum separators.**
5. The sample should be immediately dispensed into the sample well of a cartridge. A drop of blood should be touched against the bottom of the sample well.
6. If a second measurement is required, a fresh sample should be obtained.

**Note:** It is recommended drawing and discarding a (venous) sample of at least 1.0 ml prior to drawing sample for coagulation testing.

**CRITERIA FOR SPECIMEN REJECTION:**

1. Evidence of clotting
2. Specimens collected in a syringe or tube with anticoagulant other than lithium heparin
3. Syringe for pH, PCO<sub>2</sub>, and PO<sub>2</sub>, with air bubbles in sample
4. Incompletely filled vacuum tube for the measurement of ionized calcium

5. Other fluid types such as urine, CSF, or pleural fluid

AVOID THE FOLLOWING CIRCUMSTANCES:

1. Collecting a specimen from an arm with an I.V.
2. Stasis (tourniquet left on longer than one minute before venipuncture)
3. Extra muscle activity (fist pumping)
4. Hemolysis (alcohol left over puncture site, or a traumatic draw)
5. Icing before filling cartridge.
6. Time delays before filling cartridge
7. Exposing the sample to air when measuring pH, PCO<sub>2</sub>, and PO<sub>2</sub>

(REFER TO THE i-STAT SYSTEM MANUAL FOR FURTHER INFORMATION)

## **SUPPLIES AND REAGENTS:**

St. Cloud Hospital will be using the following cartridge configurations: EG7+, G3+, CG4+, ACT and PT/INR

EG7+: Consists of the following test combinations:  
Sodium, Potassium, Ionized Calcium, Hematocrit, pH, PCO<sub>2</sub>, PO<sub>2</sub>, and calculated parameters of HCO<sub>3</sub>, sO<sub>2</sub>, and Hemoglobin.

G3+: Consists of the following test combinations:  
pH, PCO<sub>2</sub>, PO<sub>2</sub>, and calculated parameters of HCO<sub>3</sub>, BE, and sO<sub>2</sub>.

ACT: Tests for Activated Clotting Time only

PT/INR: Tests for Prothrombin Time only

CG4+: Lactic Acid – back up method for the Chemistry ABL analyzer

Health Plaza Laboratory: CG4+: Lactic Acid testing only

Adult and Pediatric Urology:

Crea: Tests for Creatinine only

## CARTRIDGE STORAGE:

At St. Cloud Hospital, the main supply of cartridges will be stored refrigerated at 2-8C in the Laboratory. Cartridges stored at 2-8C (35-46F) are stable until the printed outdate on the box. **CG4+, EG7+ and G3+** Cartridges may be stored at room temperature 18-30C (64-86F) for **2 months**, while **ACT, PT/INR, and Crea** cartridges may be stored at room temperature 18-30C (64-86F) for **14 days**. *This time frame (date at room temperature and resulting outdate) must be documented on the box by each department doing testing.* Cartridges should never be returned to the refrigerator once they have been at room temperature, and should not be exposed to temperatures above 30C or 86F. Do not freeze cartridges.

## **CALIBRATION:**

Calibration is automatically performed as part of the test cycle on each cartridge. Cartridges are self-calibrating. Operator intervention is not necessary.

Every cartridge includes a sealed foil pack, which contains a calibrant solution with a known concentration of each analyte. During the first part of the testing cycle, the calibrant solution is automatically forced out of the foil pack and over the sensors. The signals produced by the sensors in response to the calibrant solution are stored. Once this sequence is completed, the analyzer automatically moves the sample over the sensors. By comparing the sensors' response to the sample with that of the calibrant, the concentration of each analyte in the sample is calculated. A message and quality check code will be displayed if calibration fails. If a failure occurs, take a new cartridge and try to perform testing again. If the failure reoccurs, refer to the i-Stat System Manual for troubleshooting purposes.

## **QUALITY CONTROL:**

**CONTROLS:** i-Stat Controls are ordered by the Laboratory from Abbott

Level 1 Tri Controls Order # 05P71-01  
Level 2 Tri Controls Order # 05P72-01 (ABG testing ONLY)  
Level 3 Tri Controls Order # 05P73-01

Store i-Stat controls at 2-8C (35-46F). Controls may be stored at room temperature 18-30C (64-86F) for 5 days. Do not use after the expiration date on the box and ampules.

ACT Level 1 control Order # 7G8201

ACT Level 2 control Order # 7G8301

Store ACT controls at 2-8C (35-46F). They may be stored at refrigerated temperature until the printed expiration date on the box and vial labels. Do not use beyond the expiration date on the box and vial labels.

PT/INR Level 1 control Order # 04J50-21

PT/INR Level 2 control Order # 04J50-22

Calibration Verification Order # 05P70-01 (levels 1, 3, 5) are used every 6 month for verifying linearity.

External Electronic Simulator

Store at room temperature and protect contact pads from contamination by placing the Electronic Simulator in its protective case.

**ANALYZER VERIFICIATON:**

The electronic simulator is a quality control device for the analyzer. Every 8 hrs the i-Stat analyzer automatically performs a check using an internal electronic simulator. The i-Stat has a QC lockout mode, meaning patient testing can not be performed if the electronic simulator test has not been done for 8 hours. It will automatically initiate the check before patient testing is to be performed, adding about 15-20 seconds to the testing cycle. While the analyzer performs internal electronic checks and calibration during each testing cycle, the electronic simulator test provides an independent check on the ability of the analyzer to take accurate and sensitive measurements of voltage, current, and resistance from the cartridge. The simulator produces signals at TWO LEVELS to check both the accuracy and sensitivity of the electrical measurement circuitry and the electrical isolation between individual measurement channels. These specific signals which are generated, stress the measurement capabilities of the analyzer well beyond any signals generated during cartridge analysis. When the analyzer is within specification limits, PASS will appear at the conclusion of the testing cycle. If the analyzer is not within specifications, FAIL will display with one or more letters, which are an aid in troubleshooting the problem. (Refer to the I-Stat System Manual for more detailed information).

**INITIAL VALIDATION OF I-STAT METHODOLOGY:**

A cross over study was performed using the I-Stat analyzer and comparing the results to the ABL-700 blood gas analyzer, Vitros 950, the Coulter analyzer, and the Medtronic ACT II instrument and the Sysmex CA-1500. Studies to validate accuracy, precision, reportable range, and linearity were completed.

In addition, external assayed liquid controls were run prior to implementation, and periodically thereafter, along with the electronic checks, to verify confidence in the accuracy and reproducibility of the analyzers.

**DAILY QUALITY CONTROL PROCEDURES:**

**INTERNAL ELECTRONIC SIMULATOR**

Verify that the internal electronic simulator results in a "PASS" message. This "PASS" message will appear in the analyzer's stored results and is transmitted to QML via the DE software enabling the laboratory staff to monitor the performance of each i-Stat analyzer.

1. If the internal electronic simulator ‘FAILS’’, repeat using the external electronic simulator. If a ‘‘PASS’’ message is displayed, it is acceptable to use the analyzer.
2. If a ‘‘FAIL’’ is displayed after using the external electronic simulator, proceed as follows:
  - a. DO NOT analyze patient samples with the analyzer
  - b. Transmit the result to QML via the DE software.
  - c. Deliver the faulty analyzer to the laboratory i-Stat System Coordinator.
  - d. Send any patient samples to the laboratory for analysis, or analyze on a i-Stat analyzer that has successfully passed the electronic simulator test.
3. Record on the i-Stat QC log: ELECTRONIC SIMULATOR ACTION LOG any instances where the internal electronic simulator failed, and the external simulator was used. Document whether the external simulator passed or failed, and what action was taken if it did fail.

**EXTERNAL ELECTRONIC SIMULATOR – performed by the testing personal at the testing sites**

To perform the external electronic simulator please follow the step outlined below.

- Turn on the I-stat
- Press MENU button
- Press #3 for Quality Tests
- Press #4 for Simulator
- Enter or Scan your Operator ID (repeat)
- Enter or Scan the Simulator ID #
- Insert the Simulator

PASS / FAIL will be displayed after 60 seconds

Remove the simulator

**DAILY VERIFICATION OF CARTRIDGE STORAGE CONDITIONS:**

1. Refrigerated Cartridges:
  - a. Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes. Deliver any outdated cartridges to the chemistry area in the laboratory.
  - b. Verify that the refrigerator did not exceed the limits of 2-8C (35-46F). If the temperature is outside the range of 2-8C (35-46F), quarantine the cartridges in the storage refrigerator. Notify the i-Stat system coordinator immediately. DO NOT USE the cartridges from the out-of-range refrigerator.
2. Room Temperature Cartridges:
  - a. Verify that all boxes of cartridges at room temperature have been out of the refrigerator less than 14 days for ACT, PT/INR, and Crea cartridges and less than 2 months for the EG7+ and G3+ cartridges, but need to be out of the refrigerator for more than 5 minutes for testing. Deliver any expired cartridges to the Point of Care Technical Specialist.
  - b. If the measured room temperature has exceeded 30C (86F) for any period of time, quarantine the cartridges. Notify the I-Stat system coordinator immediately. DO NOT USE the cartridges.

**WEEKLY VERIFICATION OF CARTRIDGE CONDITIONS:**

1. G3 cartridge will have 3 levels of TriControls QC
2. EG7 cartridge will have 3 levels of TriControls QC performed. These controls also analyze the NA+, K+, HCT/HGB and the Ionized Calcium.
3. ACT cartridges will have 2 levels of ACT controls
4. PT/INR cartridges will have 2 levels of PT/INR controls

**MONTHLY VERIFICATION OF CARTRIDGE CONDITIONS:**

1. CG4+ cartridge will have 2 levels of Aqueous QC run for Lactic Acid
2. Crea cartridge will have 2 levels of Aqueous QC run

**MONTHLY PROCEDURE: (LABORATORY)**

Print a copy of the electronic simulator results using the reports function from QML.

Print results for any fluid controls analyzed using the reports function from QML.  
(The i-Stat system coordinator will review this information on a monthly basis). Aqueous QC results are monitored via a log by the Plaza Laboratory Coordinator for APU.

Print a utilization report and a utilization error code report.

**SIX MONTH ACCREDITATION REQUIREMENTS:**

**LINEARITY CHECKS: (LABORATORY)**

Every 6 months, linearity checks are performed using the calibration verification set, levels 1,3,5.

**METHOD COMPARISON: (LABORATORY)**

Twice per year the laboratory must evaluate the results obtained with the various instruments and methodologies used within the laboratory compared to the results obtained by the i-Stat analyzer.

- a. 3 lithium heparin tubes will be drawn and assayed for the hematocrit on the Coulter analyzer.
- b. One lithium heparin tube will then be assayed on the Radiometer 90 Flex to obtain the blood gas results.
- c. The 3 samples will then be inserted into the i-Stat cartridge to obtain these results
- d. The one lithium heparin tube will be centrifuged and the plasma will be assayed on the Abbott Architect for sodium, potassium, and troponin results.
- e. A comparison of the results obtained by the i-Stat and those obtained by instrumentation in the main laboratory will be compiled.
- f. Evaluation of results is based on pre-established acceptability criteria (CAP limits).
- g. If the results fall outside the expected range, controls should be tested on the different systems to try to determine which system is not performing according to specifications. After the cause has been determined and corrected, a second sample should be tested to confirm acceptable results. All results and corrective actions are documented and kept by the Point of Care Technical Specialist.

**PERIODIC PROCEDURES FOR TESTING PERSONAL:**

1. The outside of the i-stat instrument must be cleaned in between each patient use for infection control purposes, using a disinfectant wipe approved by the Health System. Care must be taken when using any liquid NOT to get any excess fluid on the meter screen and other openings such as the battery cover and cartridge slot.

**PERIODIC PROCEDURES (LABORATORY):**

Record on the i-STAT QC Log: INCOMING QC

1. New shipment of cartridges received:
  - a. i-Stat cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit. Fill out the record of receipt, and file the card in the i-Stat reagent file folder. To be acceptable, all windows need to be white, or only the "A" window blue, indicating that temperatures were satisfactory during transit.
  - b. If either or both the "C" or "D" windows are blue, quarantine the suspect cartons. Notify the i-Stat system coordinator immediately. Do not use the cartridges from the suspect cartons. Record the information in the i-Stat QC logbook.

2. With each new shipment, the laboratory will verify the cartridge integrity. This is accomplished by assaying three levels of the i-Stat Tricontrols for ABG cartridges, which includes the Na<sup>+</sup>, K<sup>+</sup>, Ionized Calcium and the Hct/Hgb, and Creatinine cartridges. ACT and PT/INR controls are tested with a cartridge of each type that was received. The results obtained must be within the stated expected values published in the package insert. Check that the lot number on the control ampule matches the lot number on the package insert and that the software version listed on the insert matches the software installed in the analyzer. If all results are within expected ranges, use the cartridges as needed. Transmit the results to QML via DE software. Creatinine control values performed at APU will be manually recorded in a log and are monitored by the Plaza Laboratory Services Coordinator.
  - a. Cartridges must be warmed to room temperature for a minimum of 5 minutes before use. (For best results, analyzers, control ampules, and cartridges should be at the same temperature).
  - b. Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the vial.
  - c. When using a capillary tube, fill from the bottom of the vial. Avoid drawing solution from the surface.
  - d. Immediately transfer the solution to the cartridge. It is important not to expose the solution to room air since this will alter the results.
  - e. Results must be within the stated expected values published in the package insert. If the results are not within the expected range, quarantine the cartridges. DO NOT USE FOR PATIENT TESTING. Notify Abbott Point of Care of the problem for replacement cartridges.

#### PROFICIENCY TESTING:

1. The laboratory, including point-of-care sites, at St. Cloud Hospital is enrolled in the College of American Pathologists (CAP) proficiency-testing program.
2. Three times per year, for the AQ survey, CAP sends five unknown specimens for analysis. The point-of-care technical specialist will distribute these samples throughout the areas within the St. Cloud Hospital where the i-Stat analyzer is used. The testing of these samples will be rotated between the different analyzers used, as well as between the various personnel using the i-Stat analyzers. Personnel who routinely perform the testing test (Proficiency samples in the same manner as patient's samples.) The point-of-care charge person will keep documentation of which analyzers are used and which personnel performed the proficiency testing.

#### PERSONNEL COMPETENCY ASSESSEMENT

1. Internal proficiency will be checked on each i-Stat operator initially (during training) and then six months later. Thereafter, competency will be verified on a yearly basis. Each staff member will be required to demonstrate competency by performing >80% on a written i-STAT competency assessment test. Employees of Centracare will be doing an online module under the education system. Please refer to the Point of Care Competency Requirements and Assessment Policy for all additional competency requirements.
2. These results will be documented and retained by the point-of-care charge person for accreditation purposes.
3. Competency of the staff performing testing on the i-Stat is also monitored by the laboratory chemistry staff reviewing the test data that is transmitted to QML via the DE software. Reoccurring errors such as patient identification input errors and cartridge testing errors will be available for review and may require the point-of-care charge person to initiate a retraining session.

## **PROCEDURE:**

### **CARTRIDGE PREPARATION:**

All cartridges are required to be at room temperature for 5 minutes before use.

### **PROCEDURE FOR MONITORING CARTRIDGE STORAGE AND TEMPERATURES IN DECENTRALIZED AREAS :**

Cartridges will be available from the Laboratory. Cartridges are stored in the Laboratory walk-in refrigerator. This area is monitored and the storage data is recorded with the internal temperature monitoring system as well as manually by the Microbiology staff.

Use the i-Stat QC Log: EXPIRATION DATE AND STORAGE CONDITIONS to record daily the following data:

1. Date box with date put into use at room temperature.
2. Mark the outdate on the box based on the date placed at room temperature – 14 days for the ACT, PT/INR, and Crea cartridges and 2 months for the CG4+, EG7+ and G3+ cartridges.
3. Do not use after the labeled expiration date.
4. Monitor and record daily the temperature of the refrigerator used to store cartridge supply.
5. Monitor and record daily the room temperature where the i-STAT cartridges are stored.

### **PROCEDURE FOR PATIENT TESTING:** (While the cartridge is not fragile, it should be handled as follows to avoid difficulty in filling or rejection by the analyzer)

1. Medicare rules require that all laboratory testing be performed only if written authorization is received from the physician or other health care personnel authorized to order laboratory tests. Please ensure that there is a written request for each component of the i-Stat cartridge that is to be performed. Orderable components of the i-Stat cartridge are ABGs, potassium, sodium, hemoglobin, ionized calcium, ACT, PT/INR, creatinine. If no written order request is on the medical record, please stop and obtain the order before proceeding.
2. Press ON/OFF button
3. Press #2 for I-stat cartridge
4. Scan/Enter hospital ID number when the analyzer prompts you to enter “operator” number, and then press the ENT (enter) key. Repeat this process for verification.
5. Scan/Enter patient medical record number when prompted, then press the ENT key. Repeat this number for verification. APU will enter patient’s order accession number.
6. Scan/Enter the Cartridge Lot Number.
7. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge. Do not contaminate the contact pads with finger prints or talc from gloves as the i-Stat analyzer may not be able to make proper contact with the cartridge.
8. Place the cartridge and i-STAT analyzer on a flat surface. For patients in isolation, place the cartridge and i-STAT analyzer on a barrier also, such as a paper towel. Direct the syringe tip or capillary tube containing the blood, which was collected as described previously, into the sample well. Dispense the sample slowly and steadily until it reaches the blue fill mark indicated on the cartridge label. Leave some blood in the well. Do not block the air vent as the sample will not be able to flow to the fill mark and the calibrant solution will not be able to flow to the sensors.
9. If the sample well fills but the rest of the chamber does not, ensure that the air vent is not blocked. Tilt the cartridge slowly so that gravity aids the flow. When the sample starts to flow into the chamber, return the cartridge to a horizontal position. If the sample is considerably short of fill mark, the analyzer will detect the condition and display SAMPLE POSITIONED SHORT OF FILL MARK.

10. If the sample is overfilled, the analyzer will detect this condition and display SAMPLE POSITION BEYOND FILL MARK. If air bubbles are trapped in the sample chamber, discard the cartridge and fill another. This condition would be detected as INSUFFICIENT SAMPLE.
11. Seal the cartridge by folding the snap closure over the sample well. Press the rounded end of the snap closure until it snaps. Avoid exerting excessive pressure on the closure directly over the sample well as doing so may push the sample beyond the fill mark. The analyzer will detect this condition and display SAMPLE POSITIONED BEYOND THE FILL MARK. Closing the cartridge before the sample chamber has filled will stop the flow of the sample. The analyzer will detect this condition and display SAMPLE POSITIONED SHORT OF FILL MARK. Failure to close the cartridge before inserting it into the analyzer will prevent sample movement and can cause the sample to flow backward and out of the sample well. The analyzer will detect this condition and display UNABLE TO POSITION SAMPLE. Be careful not to touch the sensors or contact pads or the center of the cartridge. Handle on side edges only.
12. Orienting the cartridge with the contact pads facing up and toward the cartridge port, push the cartridge slowly and smoothly through the cartridge port until it will go no further. When the cartridge is fully inserted, the sample well area will remain outside the port. The analyzer will acknowledge proper insertion by displaying the CONTACTING CARTRIDGE message. The display will change to TIME TO RESULTS with the time bar counting down. The LCK (lock) prompt is displayed indicating that the cartridge should not be removed. *Never attempt to remove a cartridge while the LCK (lock) message is displayed.* (Damage to the I-Stat analyzer will result if an attempt is made to remove the cartridge when the LCK message is showing). *Do not move the i-STAT when performing an ACT test or PT/INR.*
13. From the screen choose which tests you want to assay from the cartridge. If the entire cartridge panel is to be selected, choose "0" for all. If you want to select specific test parameters and do not need all the tests, choose those you want by entering only the corresponding number of the parameter you wish to assay.
14. After the patient identification number and the test selection are entered, the PAGE key is activated allowing access of an additional data entry screen. (If results are already displayed, press the PAGE key twice to access the data entry screen). The cursor will be flashing at the first input area. Use the numbered keys to input information and press the ENT key to advance to the next input area (or to return to the first area from the last input area). Incorrect entries can be corrected using the CLR key as a backspace.

Patient temperature can be entered as Centigrade or Fahrenheit. Use the \* key for a decimal point. The analyzer will interpret numbers between 50.0 and 110.0 as degrees Fahrenheit and between 10.0 and 45.0 as degrees Centigrade.

FIO2 can be entered as the number of liters or as a percentage of the oxygen a patient is receiving. The analyzer will accept a range of 0 to 100. Use the \* key to enter a decimal point.

**Sample Type, Collection Site, Allen's Test, and Delivery System are all mandatory parameter entry fields.** By pressing the Menu button at each entry field, an option menu will display. Choose the number corresponding with the correct entry for the parameter field.

15. The analyzer will display test results once analysis is complete. The cartridge has been unlocked and the LCK prompt disappears.
16. The i-Stat analyzer electronically attaches its serial number, the test date, and test time to the results.
17. Remove the cartridge after the LCK (lock) message disappears. Grasp the cartridge by the sides of the sample well and pull straight out. Discard the used cartridge in a container designated for biohazardous waste. Once the cartridge is removed, even if results are still display, the analyzer is ready for a new cartridge.

#### TRANSMITTING TEST RESULTS:

1. Place analyzer in Downloader. The analyzer must be turned off for transmission to occur.
2. Do not move analyzer until Communication in Progress message disappears

3. Do not store the analyzer in the Downloader. Remove the analyzer after download process is complete.

## **CALCULATIONS ERROR CODES:**

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

### **SUPPRESSED RESULTS:**

There are three conditions under which the I-Stat system will not display results.

1. Results outside the System's reportable ranges are flagged with a "<" or ">", indicating that the result is below the lower limit or above the upper limit of the reportable range respectively. (See the table of Reportable Ranges listed later in this procedure). Repeat analysis once and if the error reoccurs, send the specimen to the laboratory in accordance with the Laboratory's Procedure Manual for analysis.
2. Results which are unreportable, based on internal QC rejection criteria, are flagged with "\*\*\*\*". Stars will appear in place of concentration if the signals from that particular sensor are uncharacteristic. Uncharacteristic signals can be caused by a compromised sensor or by an interfering substance in the sample. Calculated results that depend on the value from a measured test will show as stars if the measured test shows as stars. When results are flagged with "\*\*\*\*", reanalyze the sample once. If the results are still flagged with stars, contact the lab and send the specimen to the lab in accordance with the laboratory's procedure manual. Also verify that the cartridges have been properly stored. If this error code is reoccurring, contact the i-Stat program coordinator to run control solution with that supply of cartridges. (If the controls are starred, use of this supply of cartridges may need to be discontinued).
3. 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. Repeat with another cartridge. If the problem reoccurs, record the action code displayed with the message that identifies the problem. Refer to the i-Stat Systems Manual for corrective action, and/or to the i-Stat Systems Coordinator.

## **REPORTING RESULTS:**

### **It is very important test results are downloaded to the IR link as soon as possible after testing.**

By downloading through the IR link, QML and the laboratory information system will enable the test to be ordered, billed, and resulted in the same format as other laboratory results. If the operator does not transmit the results, this process will not occur. Telcor is the middleware that transmits the data from the LIS to the HIS.

SEE THE "PROCEDURE" SECTION FOR INFORMATION REGARDING TRANSMITTING RESULTS FROM THE i-STAT TO THE IR LINK.

### **REFERENCE RANGE:**

Sodium:	136 - 146	mmol/L
Potassium:	3.5 - 5.1	mmol/L
pH	7.35 - 7.45	
PCO <sub>2</sub>	35 - 45	mmHg
PO <sub>2</sub>	80 - 105	mmHg
Hematocrit:	Male's 38.7 - 51.4	vol %
	Female's 33.9 - 47.5	vol%
Ionized calcium:	0.95 - 1.31	mmol/L
Base excess/deficit (calculated)	-2 - +3	mmol/L
HCO <sub>3</sub> (calculated)	22 - 26	mmol/L
% Saturation (calculated)	95 - 98	%
Hemoglobin (calculated)	Males 13.1 - 17.1	gm
	Females 11.2 - 15.8	gm
ACT	74 - 125	seconds
PT/INR	0.9 - 1.1	
LACTIC ACID	0.5 - 1.7	mmol/L
CREATININE	0.6 - 1.3	mg/dL

**REPORTABLE RANGE:**

Sodium:	100 - 180	mmol/L
Potassium:	2.0 - 9.0	mmol/L
pH	6.5 - 8.0	
PCO2	5 - 130	mmHg
PO2	40 - 800	mmHg
Hematocrit	15 - 75	vol%
Ionized calcium	0.25 - 2.50	mmol/L
Base excess/deficit (calculated)	-30 - +30	mmol/L
HCO3 (calculated)	1 - 85	mmol/L
% Saturation (calculated)	N/A	
Hemoglobin (calculated)	5.1 - 25.5	gm
ACT	50 - 1000	seconds *
	(* the range from 80-1000 seconds has been verified through method comparison studies)	
PT/INR	0.9 - 8.0	(performance characteristics have not been established of INR >6.0)
LACTIC ACID	0.30 - 20.0	mmol/L
CREATININE	0.2 - 20.0	mg/dL

(For additional information on the performance characteristics of specific assays, refer to the test information section in the i-Stat System Manual).

**ALARM VALUES:**

Any abnormal result may be reassayed at the discretion of the operator. Alarm values must be confirmed by reassaying the specimen, unless the patient's previous results correlate with this critical value. The following parameters are considered ALARM values and must be called to the attention of physician or the nurse in charge.

Sodium	≤ 120 or ≥ 150	mmol/L
Potassium	≤ 3.0 or ≥ 6.0	mmol/L
pH	≤ 7.25 or ≥ 7.60	
PCO2	≤ 20 or ≥ 70	
PO2	≤ 50	mmHg
Bicarbonate	≤ 14 or ≥ 40	mmol/L
Hematocrit	< 25	vol%
Hemoglobin	< 8	gm
PT/INR	>4.0 INR (Any >4.0 INR must be drawn venously and sent to CCLS for testing on The Sysmex CA-1500 analyzer)	
CREATININE	>5.0	mg/dL

(\* NICU alarm values are determined on an individual patient basis by the neonatologists)

(\* Alarm values for patients on by-pass are determined and evaluated by the perfusionists on a per case basis)

**CRITERIA FOR SHEATH PULLS:**

Cardiovascular assistants pull sheaths following these criteria:

<170 seconds	Pull sheath
170 - 200 seconds	Wait 1 hour and recheck ACT
201 - 300 seconds	Wait 2 hours and recheck ACT

**MONITORING REPORTING WITH QML AND DE SOFTWARE (LABORATORY):**

Laboratory will monitor the results downloaded from the i-Stat into QML via the DE software periodically per shift. The technologist will review the individual test results, monitor patient medical records to avoid a duplicate Sunquest order when the test is repeated, and investigate instances where the test results were not transmitted from QML into the laboratory's Sunquest computer.

The technologist will record on a log sheet next to the computer station, the time and date of review, along with an explanation of any corrective action that was taken.

In situations of < or > values, star out errors, or other instances where an unsuccessful result was obtained, the procedure of repeating the testing once and, if the same situation occurs, sending the sample to the laboratory is followed, the technologist will then initiate a credit for the i-Stat results.

In addition to the test results, the Point of Care Specialist will monitor error codes generated by the i-Stat operators, review the data for quality assurance, to monitor for trends based on both the I-Stat serial number and operator code number. This will ensure that the analyzer is operating properly and that the individuals doing the testing are assaying the test cartridges in a competent manner.

#### COMPUTER DOWNTIME:

The i-Stat analyzer will hold 1000's of test results. If the computer is down for a short time, hold the information in the i-Stat analyzer and download it once the computer is operable.

### **LIMITATIONS:**

#### TROUBLESHOOTING:

Refer to the i-Stat System manual for troubleshooting analyzer error codes. The i-Stat system coordinator can be a resource person to help solve the problem. If you are unable to solve the problem, the i-Stat hotline number for troubleshooting is 1-800-366-8020.

#### BATTERY REPLACEMENT:

Two 9-volt **lithium** batteries power the i-Stat analyzer. The low battery indicator (a flashing battery symbol) will appear when the battery voltage drops to 7.4. At this point there is sufficient power to test approximately 50 more cartridges before a DEAD BATTERIES message is displayed (less time if coag testing is being performed).

1. Wait until any testing in progress is completed before replacing the batteries or results will be lost. Stored results will not be lost when replacing the batteries.
2. Place the analyzer upside down and slide the battery compartment door off.
3. Remove the old batteries. Orient the + and - poles of the new batteries with the + and – labels in the battery compartment, and slide the new batteries into place.
4. Reinstall the battery compartment door back into place.

#### SPECIFIC PERFORMANCE CHARACTERISTICS:

Refer to the i-Stat System manual for specific test information regarding clinical significance, performance characteristics, interfering substances, precision, linearity etc., for each assay.

### **REFERENCES:**

i-Stat Corporation, i-Stat System Manual, Publication Code 714446-00M, Revision date 5/2013

i-Stat Corporation, i-Stat Implementation Guide, Publication Code 151570, Revision May 15, 1998

Franklin, Dr. G., Neonatologist, St. Cloud Hospital, May, 1999.