I. PURPOSE AND PRINCIPLE
The i-STAT 1 analyzer is intended for use with i-STAT cartridges for the in vitro quantification of various analytes in whole blood on a few drops of blood in any environment outside of a hospital laboratory.
The i-STAT1 system is a battery powered portable analyzer that utilizes single-use disposable cartridges to analyze blood. When a cartridge is inserted into the analyzer, i-STAT1 controls all functions of testing including fluid movement, calibration, testing of patient sample and continuous quality monitoring.
The i-STAT1 contains a microprocessor that is programmable and able to store user passwords, 6000 patient and control test records.
Each cartridge contains micro fabricated sensors, calibrant solution, fluidics system, and a waste chamber. i-STAT runs a calibration on each cartridge before testing patient sample. 
No patient results are reported if calibration fails.

II. SCOPE
This procedure is intended for those patient areas that have been approved for the use of the i-STAT 1 by the POC Medical Director.

III. PERSONNEL
This procedure is intended for use by RNs, MDs, CLS and Respiratory Therapists who have been trained and demonstrated competency in the use of the i-STAT and the corresponding approved cartridge.

IV. EQUIPMENT & REAGENTS
A. i-STAT1 Analyzer
   1. Display Screen: Displays test and administrative menu, user entry prompts, and test results; use arrow keys to scroll between prompts and pages
   2. Keypad
      i. Scan key: press when scanning user I.D.
      ii. ABC Key
      iii. ← → Arrow keys: use to scroll through alphabet, to clear data entry errors or to scroll up or down display
      iv. Numeric keypad
      v. 0 key: press to backlight the display
      vi. Period key
vii. Enter key: Press to accept data entry.

viii. Menu key: Access to Test Menu and Administration Menu

ix. ON/OFF Key: i-STAT1 is also activated whenever a cartridge is inserted

x. Print Key

3. Infrared communication window is located at the top end of the analyzer.

4. Barcode scanner is located at the top end of the analyzer.

5. Battery compartment is located on the back of i-STAT1. i-STAT is powered by two 9-volt Lithium batteries. Battery status is displayed by pressing Menu, Administrative Menu, and 1-Analyzer Status. i-STAT conserves battery power by automatically shutting down after 2 minutes of inactivity.

6. Cartridge port is located in the bottom end of the i-STAT analyzer.

7. The i-STAT is programmed to verify analyzer performance with an internal Electronic Simulator every 8 hours. The daily internal QC is triggered when i-STAT1 is activated. I-STAT1 will not lock the testing cartridge until it has passed the internal Electronic Simulator. Running the internal electronic simulator adds an additional 20 seconds to the testing process.

8. I-STAT1 operates in an ambient temperature of 18 to 30°C. The analyzer shuts downs and does not allow testing if the ambient temperature exceeds this range. Analyzer Status and data review functions are accessible at this time. Press Menu key, and “1-Analyzer Status” to display ambient temperature. Take corrective action by moving i-STAT1 to an ambient temperature of 18 to 30°C.

9. Two times a year or when necessary, Abbott sends software upgrades with changes to the CLEW standard and MAS RALS System. Software on each analyzer must be upgraded before the current software expires. i-STAT shuts down and will not allow testing after the software expiration date.

B. Cartridges

1. When a sample-filled i-STAT cartridge is inserted into an i-STAT for analysis, the analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration and continuous quality monitoring.

2. Cartridges are sealed in individual pouches and packaged 25 to a box. Cartridges must remain in the individual pouch until needed. Use the cartridge within 5 minutes of removal from its pouch.

3. Store the main supply of cartridges in the refrigerator at temperatures between 2-8°C until its expiration date. DO NOT ALLOW CARTRIDGES TO FREEZE.

4. Cartridges may be stored at room temperatures up to 30°C or 86°F for a limited number of days, depending on the cartridge type (refer to the appendix section of this procedure for each cartridge type). Cartridges should not be returned to the refrigerator once they have been at room temperature.

5. Mark the margins of individual pouches with the revised expiration date after removing the cartridge from the refrigerator. Do not use if room temperature exceeds 30°C or beyond the expiration date.
6. New cartridges are shipped overnight at 2-8°C with a temperature monitor card. The monitor card contains 4 windows labeled 1, 2, 3 and 4 representing temperatures from 2 to 34°C. Accept shipment only if the 1 and/or 2 windows are colored. Reject shipment if windows 3 and or 4 are colored.

7. Notify i-STAT immediately if shipment is unacceptable.

8. Each shipment of cartridges must be tested with the appropriate levels of aqueous liquid controls before they can be used for patient testing. Consult the value assignment sheets on the Abbott Point of Care website (www.abbottpointofcare.com) for acceptable ranges.

9. Refrigerate each new shipment immediately.

C. Portable Martel printer
   1. A re-chargeable lithium battery supplies power to the printer. Turn off printer before recharging. Power is conserved after 2 minutes of inactivity.
   2. Printer communicates with i-STAT1 via infrared light located next to the power switch. Align the i-STAT infrared window with both infrared lights before printing. Printer uses thermal paper that fades with light exposure and is therefore not acceptable as a permanent chartable record.
   3. The i-STAT1 program must be customized to communicate with printer.

V. DATA MANAGEMENT SYSTEM
   A. iSTAT downloader/recharger
      A docking station allows the iSTAT to communicate with the RALS data management program and HIS.
   B. RALS Plus (Medical Automation System)
      A dedicated desktop computer with the RALS Plus system installed provides the primary information management capabilities for the i-STAT System. IR Links for portable clinical analyzers, downloaders and downloader/rechargers for the i-STAT 1 analyzers and a server for blood analysis modules allow for transmission of patient records from a widely distributed network of analyzers to the RALS Plus system can be stored, organized, edited, and transferred to a laboratory information system or other computer system. Cartridge usage and efficiency reports can be generated for management of the System.

VI. QUALITY ASSURANCE MATERIALS
   A. Electronic Simulator (internal and external)
   B. Liquid Controls (refer to cartridge appendix for specifics)
   C. Calibration verification set (refer to cartridge appendix for specifics)
   D. Proficiency survey materials

VII. SPECIMEN REQUIREMENTS
   A. Specimen Labeling
      1. Unless the specimen is analyzed immediately after collection and then discarded, the specimen container must be labeled with the patient’s full name, and medical record number, birth date, sex, time and date of specimen collection, and the requesters name and provider number.
      2. Refer to the appendix for cartridge specific specimen requirements.
VIII. CALIBRATION/CALIBRATION VERIFICATION
 Calibration and linearity checks are performed twice a year. Results are evaluated, and signed off by the POC medical director. Refer to the iSTAT Calibration Verification Procedure.

IX. QUALITY CONTROL
A. Internal Electronic Simulator
   1. The i-STAT automatically verifies the performance of each analyzer every 8 hours with an internal Electronic Simulator. It automatically runs whenever i-STAT is activated. Results are stored as PASS or FAIL and may be viewed by selecting Database from the Menu.
   2. Corrective action for FAIL
      i. Repeat with external Electronic Simulator.
      ii. If external Electronic Simulator fails, call i-STAT Technical Services.
      iii. Document in Daily Maintenance Log and notify manager.
      iv. Take i-STAT1 out of service.

B. External Electronic Simulator
   1. The external Electronic Simulator verifies analyzer performance. It simulates two levels of electrical signals that stress the analyzer’s signal detection function both below and across the measurement ranges.
   2. Use the External Electronic Simulator whenever the internal simulator fails, if the analyzer has been dropped or damaged, if ambient temperature exceeded 30°C, if remedial action is warranted, and for biannual verification of analyzer thermal probe.
   3. Store the Electronic Simulator at room temperature. Protect the contact pads from contamination by replacing the plastic cap each time and store in its protective case.
   4. Use the external Electronic Simulator to test i-Stat’s thermal probes twice a year.

C. Aqueous Controls
   1. See appendix for cartridge specific control material.
   2. Once a week, test cartridges with the appropriate controls on one i-STAT 1, rotating the i-STAT used on a regular basis.
   3. Values that are outside the manufacturer’s acceptance range must be repeated and corrective action documented. Patient samples cannot be run unless all controls are within range.
   4. Test each shipment of i-STAT cartridges with all levels of controls designated for the specific cartridge you are using. Accept cartridge shipment if results are within the manufacturer’s acceptance range. Date and initial all boxes with the QC status on each box.
   5. This device is eligible for option 1 equivalent QC, as dictated by CMS and CLIA “88 regulations. Therefore, it is acceptable to run the liquid controls only once a week provided the automatic internal electronic QC is successfully performed every 8 hours of patient testing. These regulations require that during the initial validation of the analyzer, liquid QC results were acceptable for 10 consecutive testing days.
X. PROCEDURE

A. Daily Maintenance

1. Check Analyzer Status Daily
   i. Press ON.
   ii. Press Menu
   iii. Select Analyzer Status
   iv. The i-STAT displays the following:
      a. Temperature
      b. Barometer Pressure
      c. Battery
      d. CLEW Std
      e. Software version

2. Daily Battery check:
   i. Press On/Off key.
   ii. Press Menu key
   iii. Select 1 for Analyzer Status
   iv. Read and record Battery status on daily log.
   v. If the battery status is < 7, replace both batteries. Do not mix old and new batteries.
   vi. Press Menu to exit screen.

3. Examine infrared window. Clean i-STAT1 with damp gauze; moisten with 10% bleach if necessary. Do not use alcohol on display screen.

4. External Electronic Simulator (if indicated):
   i. i-STAT will power on when external Electronic Simulator is inserted.
   ii. i-STAT may also be powered on by pressing the ON/OFF key.
   iii. Press Menu.
      a. Select 3-Quality Control
      b. Select 4-Electronic Simulator
      c. Follow prompts
      d. Scan or enter user I.D.
      e. Remove blue protective cap on Electronic Simulator.
      f. Insert Simulator when prompted.
      g. “Simulator Locked” is displayed. DO NOT REMOVE until “Locked” disappears.
      h. The i-STAT displays either PASS or FAIL.
      i. Remove when prompted by analyzer.
   iii. Corrective action for FAIL external Electronic Simulator
      a. Repeat external Electronic Simulator on same analyzer
      b. Repeat on second i-STAT analyzer.
      c. If the first analyzer again fails, take it out of service.
      d. If both analyzers fail, Electronic Simulator pins may have been damaged.
      e. Document in Daily Maintenance Log
      f. Notify manager.
      g. Call i-STAT Technical Services at 1-800-366-8020 immediately.

B. Aqueous Controls

1. See appendix for controls in use for each specific cartridge type

2. i-STAT Menu
i. Press ON/OFF key to power i-STAT on.
ii. Press Menu
iii. Select Quality Control
iv. Enter user I.D.
v. Follow prompts for entering control lot number and control level.

3. Testing Controls
i. See cartridge specific appendix.
ii. Remove cartridge from its pouch. Do not touch contact pads.
iii. Hold control between index finger and thumb and shake control vigorously from end to end for 10-15 seconds to equilibrate the solution and gas mixture. Avoid warming the ampule. Do not hold in your palm.
iv. Gently tap to restore solution to the bottom of the ampule allowing bubbles to rise to the top.
v. Cover ampule with a piece of gauze and snap open.
vi. Immediately insert a syringe fitted with a 19-gauge needle into the bottom of the ampule.
vii. Slowly aspirate 0.5 mL of solution. Do not aspirate any air bubbles.
viii. Do not attempt to remove dead space from top of the column of solution.
ix. Remove needle.
x. Place syringe tip over sample well.
xi. Dispense sample to the fill mark.

iii. Close cover over the sample well until it snaps into place. Do not exert pressure over the sample well.

xiii. Insert cartridge into the i-STAT cartridge port when prompted.
xiv. Review displayed results.

xv. Compare results to acceptance range. Document in QC Log.
xvi. Document controls on new cartridge shipment in New Cartridge Receipt Log

xvii. Repeat procedure with remaining required controls.

4. Corrective Action
i. Before repeating with a new ampule of control, review the following:
   a. Ensure that the acceptance range on QC Log is for the appropriate cartridge lot.
   b. Ensure that the CLEW software on the package insert is the same as the CLEW version on the analyzer.
   c. Press Menu and select Analyzer Status to view i-STAT software version and CLEW Std.
   d. Identify Cartridge lot number against control values posted on the appropriate website.

ii. Repeat control with a new ampule after equilibrating it at room temperature for 4 hours

iii. Review control technique with i-STAT trainer and/or POCT coordinator. pO2 failure is usually due to poor technique.

iv. If new shipment of cartridges fails to pass any level of aqueous control after repeat testing, sequester lot with a “Do Not Use” note. Document in Maintenance Log and notify i-STAT and manager immediately.
C. New Shipment of Cartridges

1. Acceptance Criteria
   i. Temperature of cartridge shipping containing does not exceed 8ºC. Only window 1 and 2 can be colored.
   ii. Results of testing with all levels of i-STAT aqueous controls are within the manufacturer’s acceptance range. Document results on New Cartridge Shipment Log.

2. Criteria for Rejection
   i. Windows 3 and or 4 of Temperature Monitor is colored. This is an indication that shipping container temperature has been compromised.
   ii. Results of any level of i-STAT aqueous controls are outside of the manufacturer’s acceptance range.
   iii. Document results on New Cartridge Shipment Log and corrective actions taken.
   iv. Quarantine lot of cartridges. Write “Do Not Use” on box.
   v. Notify unit manager and POCT coordinator.
   vi. Notify i-STAT customer service as soon as possible.

D. Patient Testing Procedure

1. Handling the cartridge:
   i. Cartridge must be at room temperature for a minimum of 5 minutes.
   ii. Remove cartridge from its pouch without touching the contact pads or exerting pressure over the center of cartridge.
   iii. Blood samples must be thoroughly mixed by rolling between the palms in 4 planes for 15 seconds.
   iv. Direct syringe tip or capillary tube containing the sample over the sample well.
   v. Dispense sample until it reaches the fill mark. Sample must be dispensed without a break in one application.
   vi. Inspect and discard if air bubbles are present.
   vii. Close cover over the sample well until it snaps into place. Do not exert pressure over the sample well.

2. Procedure Using the Cartridge Insertion Mode
   i. Insert cartridge into the i-STAT cartridge port.
   ii. Follow displayed prompts.
   iii. Enter operator I.D. by pressing on scan key and scanning user barcode.
   iv. You may also use the ABC key and numeric keyboard to enter user I.D.
   v. Press ENTER to accept.
   vi. Enter patient ID
   vii. i-STAT1 does not allow correction of an accepted entry. To modify a mistake, enter correction into data Field 3.
   viii. Do not remove cartridge when “Locked” is displayed.
   ix. Enter additional information:
       a. Field 1: enter sample type:
          1 1 for arterial
          2 2 for venous
          3 3 for mixed
          4 capillary
5 Cord
6 Other
b. Field 2 and 3: additional information
c. If known, enter patient temperature and FIO2 at prompt.
x. Test results are displayed on several screens. Use arrow key to scroll between screen pages.
xi. After results are displayed on the screen, enter Code 3 into the space at the top of the screen if any result(s) is a critical value. This is a required step for results to transmit to HIS.

E. Procedure Using Information Pre-Entry Mode:
1. Press ON/OFF key to turn i-STAT on.
2. Select 2-i-STAT Cartridge.
3. Enter operator I.D. by pressing the Scan key and scanning user barcode.
4. You may also use the ABC key and numeric keyboard to enter user I.D.
5. Enter patient I.D.
6. Press ENTER to accept. i-STAT1 does not allow correction of an accepted patient I.D. To modify a mistake, enter correction into patient data Field 3.
7. Insert filled cartridge. Do not remove cartridge when “Locked” is displayed.
8. Enter additional information:
   i. Field 1: enter sample type:
      a. 1 for arterial
      b. 2 for venous
      c. 3 for mixed
      d. capillary
      e. Cord
      f. Other
   ii. Field 2 and 3: additional information
   iii. If known, enter patient temperature and FIO2 at prompt.
9. Test results are displayed on several screens. Use arrow key to scroll between screen pages.
10. After results are displayed on the screen, enter Code 3 into the space at the top of the screen if any result(s) is a critical value. This is a required step for results to transmit to HIS.
11. The codes available to enter are:
   i. Code 1: Repeated Test
   ii. Code 2: Order Protocol Used
   iii. Code 3. Notified MD/NP
   iv. Code 4: Lab Draw
12. Do not remove the cartridge when “Locked” is displayed. Remove after ‘locked” message disappears.

F. Printing Results
1. Turn on printer.
2. Align printer’s infrared window with that of i-STAT1.
3. Press print key on analyzer.
4. Do not move analyzer or printer until the printout is completed.
5. Document results in patient record.

G. Recalling Results
1. The i-STAT displays last results when it is powered on.
2. Select 1-for last results from Main Menu.
3. Press Menu key to view previous patient or control results.

H. Suppressed Results
1. These are conditions in which i-STAT will not display results:
   i. Results flagged with < or > are outside of the reportable range.
   ii. Results with <> flag indicates the results for this test is dependent on test flagged with either <or>.
   iii. *** Results are not reportable due to failed internal QC. Repeat test with a fresh sample and new cartridge.
   iv. Quality Check message is displayed if analyzer detects problems with sample, cartridge and/or analyzer.

XI. REPORTING RESULTS
A. Results are displayed numerically with reporting units and adult reference ranges. Refer to appendix for cartridge specific reference ranges and panic values.
B. Result Comment Fields:
   1. After patient testing, add the appropriate comment codes, if needed, to the results as follows:
      i. 1= Repeated Test
      ii. 2= Order Protocol Used
      iii. 3= Notified MD/NP *
      iv. 4= Lab Draw
   2. Note: Critical Value patient results will not print until the comment #3 (MD/NP notified) is appended to the result.
   3. Any number or combination of 2 or 3 numbers can be appended (e.g. 1, 13,124)
   4. The maximum is 3 numbers per entry
   5. Enter code on top of screen
   6. These comment codes are the same as those used for glucose meter reporting.
C. Record patient results in the patient record, per protocol in your department.
D. Whenever a user identifies that an incorrect result has been reported, they are responsible for correcting/commenting the incorrect result (if possible), contacting the ordering provider, notifying them of the error, and documenting this notification, including the time and date, in the patient record.

XII. MAINTENANCE
A. The i-STAT requires two 9V disposable Lithium batteries. Do not mix old and new batteries. You must replace both. In an emergency, you may instead use two-9V alkaline batteries, which drains quickly.
B. Battery status is displayed when you press Menu and Analyzer Status. Replace batteries when battery status is </= 7 volts. In this case, the i-STAT displays a low battery message if it is activated by pressing the ON key.
C. When i-STAT is activated with an inserted cartridge, it will ask you to remove the inserted cartridge before displaying the low battery message.
D. If the low battery message is display after insertion of new batteries, remove batteries from the holder and check alignment of contact points.

E. Replacing the i-STAT battery
   1. Battery door is located next to Infrared window.
   2. Ensure that the i-STAT is on OFF.
   3. Open the door by sliding it away from the analyzer.
   4. Remove the battery holder keeping the contact points clean.
   5. Remove each battery by pulling it down away from the holder.
   6. Write the replacement date on the new i-STAT batteries.
   7. Insert new batteries with the battery contacts in the down position.
   8. Re-insert battery holder into the i-STAT ensuring that the holder contact pads are aligned with those in the analyzer.
   9. Press down on the battery holder and slide the door back in.
  10. i-STAT will not work without the door.

F. Charging the Rechargeable battery
   1. Placing an analyzer in a Downloader/Recharger will automatically initiate recharging of the rechargeable battery. The indicator light on top of the Downloader/Recharger will be green (trickle charge), red (fast charge), or blinking red (fast charge pending) when an analyzer with a rechargeable battery is placed in the Downloader/Recharger.
   2. No damage will be caused if an analyzer with disposable batteries installed is placed in the Downloader/Recharger.
   3. Full recharge from a discharged state takes approximately 40 hours.

G. Bi-annual Thermal Probe Check
   1. The i-STAT analyzer contains a thermal control subsystem consisting of two thermal probes with thermisters 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 +/- 0.15°C.
   2. Procedures for performing Thermal Probe Check
      i. Press Menu, select Quality Control, and Electronic Simulator.
      ii. Insert Simulator when prompted.
      iii. When PASS result is displayed, press the period key.
      iv. i-STAT displays the difference between thermal probes.
      v. Acceptance Criteria: Thermal Difference between probes is within ± 0.1°C.
      vi. Unacceptable results:
         a. Difference between probes is greater than + 0.1°C.
         b. FAIL appended with either a “T”, difference exceeds 0.25°C or “t” average difference exceeds + 0.1°C
         c. Value of “_._” indicates unstable temperature reading. Wait 15 minutes for i-STAT and External Simulator to warm to ambient temperature before repeating.
         d. Verification of Thermal Probe may also be viewed on RALS report after downloading the analyzer by POC Coordinator.
         e. Results other than “_._” are considered in compliance.
3. **Analyzer Software Upgrades**  
   i. Abbott Point-of-Care makes continuous manufacturing process improvements that necessitate re-establishing standardization values to maintain long-term consistency by recalibrating the analyzer. This is accomplished by software upgrades that adjust the calibration on the analyzer. The manufacturer sends out software upgrades twice a year. Included in the packet are instructions and Technical Bulletins related to changes. Software on all i-STAT1 analyzers should be upgraded at the same time and before the current software expires.  
   ii. Upgrading Software Using RALS Plus System i-STAT/DE Customization Workspace to update the i-STAT handheld via the network (to be performed by POC Coordinator).  
   iii. Once the new CLEW software has been installed in RALS, the Nursing Unit will be notified to update the i-STAT handheld.  
      a. Press the On/Off button on the handheld.  
      b. Press the Menu key to bring up the Administration Menu.  
      c. Press 7 – Utility. When prompted for a password, press ENT or try 1234 and press ENT.  
      d. From the Utility menu, press 3 – Receive Software. A “Waiting to Send” message will appear or the handheld display.  
      e. Place the handheld in the downloader / recharger. Do NOT move the handheld. A Communication in Progress message will appear on the screen. After this disappears, the handheld display will stay blank for approximately 5 – 10 seconds.  
      f. The handheld will then display 1’s and 0’s streaming across the screen signifying that it is receiving the software. Once the 1’s and 0’s disappear, the handheld display will go blank for approximately 5 – 10 seconds.  
      g. A Waiting to Send message following by a Communication in Progress message will then appear on the handheld display. After these messages disappear, the handheld display will go blank, and the update process is complete.  
      h. Run the Electronic Simulator in the handheld. When the simulator finishes, PASS should be displayed.  
      i. Repeat the above steps a to h for additional handheld.  
      j. Run all required liquid controls and make sure that the results are within the acceptable range on QC log specific for the CLEW software version. Download and print CLEW Value Assignment Sheets for current control lot. The website is www.abbottpointofcare.com

**XIII. PROCEDURE NOTES**  
A. **Alphanumeric Keys for Data Entry:**  
   1. The i-STAT defaults to the numeric keypad. Access the Alphabet by pressing on the ABC key. Search for desired alphabet by using either the left arrow or right arrow keys.  
   2. Using Alpha Keys:
i. Press ABC key.
ii. Press Left arrow key to start with the letter Z or the right arrow key to start with the letter A.
iii. Press the arrow key until you see the desired letter.
iv. Press ABC key to accept selected letter.
v. Press ABC key again to enter the next letter.
vi. Use the left arrow key to correct an entry error.
vii. Press ABC to return to numeric keyboard.
viii. Press the ENTER key to accept entered ID.
ix. Do not press ENTER key until you have completed I.D entry. You cannot correct patient I.D once it is accepted.
x. If you make a mistake, enter correction into the patient data Field 3.

B. Martel Printer
1. The i-STAT1 is programmed to recognize the printer via customization by POCT staff.
2. Printer operates on re-chargeable Lithium Battery.
3. Power switch is located on the side.
4. Power light becomes green when it is turned on. Printer power is conserved after 2 minutes of inactivity and green light goes off. If the printer is in the conserved power mode, it can be activated by the print function on the i-STAT.
5. Status light indicates when the printer is out of power and the print process slows down. When the status light becomes orange, recharge on the charger. Charger connector is located to the left of the power switch.
6. Turn off power on the printer before recharging. Printer will not recharge if the power is on.
7. Infrared window is located on the side of the printer next to the power switch. Align it with the infrared window on the i-STAT 1 before pressing the i-STAT print key.
8. Printer uses thermal paper (PMM order # 36845) The print fades with age, so is inappropriate to use the iSTAT print-out in permanent patient records

C. Recalling and Printing Results
1. The i-STAT 1 stores 6000 patient and quality control test records.
2. Main Menu
   Press the ON key to view last result. Last result may also be viewed on the Main Menu by selecting 1-Last Result.

D. Administrative Menu
1. Press Menu Key to view Administrative Menu
2. Select 2-Data Review
3. Select 1-Patient: review patient history by I.D.
4. Select 2-Controls: liquid control data
5. Select 3- Proficiency
6. Select 4-. Cal Ver
7. Select 5-Simulator
8. Select 6-All: displays results of all samples, record number displayed/total number of records, press 2 to view previous record
9. Select 7-List: List all test by time, date, and patient I.D. Select a record number to review or print an individual blood gas.
XIV. PRECAUTIONS
See Appendix for cartridge specific precautions.

XV. LIMITATIONS
See Appendix for cartridge specific interfering substances for each test.

XVI. REFERENCES
B. i-STAT Software Upgrade Technical Bulletins
C. i-STAT User Guide 2010
D. UCSF Clinical Labs Laboratory Manual
Appendix 1

i-STAT Cartridge Type: EG7+ Cartridge (25 cartridges per box)

I. REAGENTS
A. For analysis of: (pH, pCO2, pO2, Na, K, iCA)
B. Abbott order number 03P76-25, UCSF PMM # 46001
C. Cartridges are good for 2 months at room temperature or, if kept refrigerated, the expiration date listed on the box. In no case can a cartridge be used past the expiration date indicated on the cartridge container. Be sure to write the new expiration date on cartridges taken out of the refrigerator.

II. SPECIMEN REQUIREMENTS:
A. The EG7+ cartridges require 0.1mL of blood. Draw 0.2 mL if using a 1 mL blood gas syringe.
B. Total volume of blood gas capillary tube is 0.14 mL. Fill 80% of the capillary tube with blood sample.

III. ACCEPTABLE SPECIMENS
A. Arterial samples collected in blood gas syringe with lithium or balance Heparin as anti-coagulant.
B. Arterial samples collected by venipuncture.
C. Arterial samples collected from an indwelling line requires withdrawing a discard syringe equivalent to three to six times the volume of the line, catheter and needle before drawing a sample that is representative of the patient. Arterial samples collected in blood gas syringe without anti-coagulant must be analyzed immediately.
D. Capillary Samples collected in blood gas capillary tubes with lithium or balanced Heparin as anti-coagulant. Follow Nursing Procedure, “Skin Puncture for Blood Sampling and for Blood Gas Analysis” for blood collection instructions.
E. Sample may not contain air bubbles.
F. Avoid repetitive squeezing of the collection site.
G. Test sample immediately.

IV. CRITERIA FOR SAMPLE REJECTION
A. Sample collected in a vacutainer tube
B. Sample collected in anticoagulant other than lithium or balance Heparin
C. Sample contains air bubbles or clots.
D. Sample volume less than 0.1 mL.
E. Sample collected in a blood gas syringe but left uncapped and not tested immediately
F. Sample collected in capillary tube and not tested immediately.

V. CALIBRATION/CALIBRATION VERIFICATION
A. Abbott iSTAT Calibration Verification Set, Levels 1-5 PMM # 36846
B. Calibration and linearity checks are performed twice a year. Results are evaluated, and signed off by the POC director. Refer to the Calibration Verification of Non-Waived tests using the iSTAT1 Procedure.
VI. QUALITY CONTROL

A. Abbott I-STAT Aqueous Controls, level 1, 2 and 3. Each box contains one level of 10 ampules.
   1. Control Level 1 Abbott Order # 06F12-01 UCSF PMM 13819
   2. Control Level 2 Abbott Order # 06F13-01 UCSF PMM 18281
   3. Control Level 3 Abbott Order # 06F14-01 UCSF PMM 13820

B. Handling Aqueous Controls
   1. Aqueous controls are stored in the refrigerator at 2 to 8°C.
   2. Equilibrate controls at room temperature for a minimum of 4 hours before use.
   3. Use a 1cc syringe and 16-20 gauge needles to aspirate controls.
   4. Aspirate control within 30 seconds after opening ampule.

C. Storage
   1. Store at 2 to 8°C (35° to 46°F).
   2. Controls may be stored at room temperature (18 to 30°C or 64 to 86°F) for five days. Do not use after the expiration date indicated on the box.

D. Acceptable control ranges for specific i-STAT Software Version, CLEW Standard, cartridge type and cartridge lots are posted on the Abbott Point of Care website (www.abbottpointofcare.com).

E. Quality Controls Procedures
   1. Remove cartridge from its pouch. Do not touch contact pads.
   2. Hold control between index finger and thumb and shake control vigorously from end to end for 10-15 seconds to equilibrate the solution and gas mixture. Avoid warming the ampule. Do not hold in your palm.
   3. Gently tap to restore solution to the bottom of the ampule allowing bubbles to rise to the top.
   4. Cover ampule with a piece of gauze and snap open.
   5. Immediately insert a syringe fitted with a 19-gauge needle into the bottom of the ampule.
   6. Slowly aspirate 0.5 mL of solution. Do not aspirate any air bubbles.
   7. Do not attempt to remove dead space from top of the column of solution.
   8. Remove needle.
   9. Place syringe tip over sample well.
   10. Dispense sample to the fill mark.
   11. Close cover over the sample well until it snaps into place. Do not exert pressure over the sample well.
   12. Insert cartridge into the i-STAT cartridge port when prompted.
   13. Review displayed results.
   15. Document controls on new cartridge shipment in New Cartridge Receipt Log
   16. Repeat procedure with remaining required controls.
### VII. REFERENCE RANGES: Measured @ 37º C

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Age</th>
<th>Arterial</th>
<th>Venous</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>All</td>
<td>7.35 to 7.45</td>
<td>7.31 to 7.41</td>
</tr>
<tr>
<td>pCO2</td>
<td>&lt;1 year</td>
<td>27 to 41 mmHg</td>
<td>41 to 51 mmHg</td>
</tr>
<tr>
<td></td>
<td>≥1 year</td>
<td>32 to 48 mmHg</td>
<td>41 to 51 mmHg</td>
</tr>
<tr>
<td>pO2</td>
<td>&lt;30</td>
<td>80 to 100 mmHg</td>
<td>35 to 40 mmHg</td>
</tr>
<tr>
<td></td>
<td>≥ 30</td>
<td>83 to 108 mmHg</td>
<td>35 to 40 mmHg</td>
</tr>
<tr>
<td>Na+</td>
<td>All</td>
<td>136 to 146 mmol/L</td>
<td>136 to 146 mmol/L</td>
</tr>
<tr>
<td>K+</td>
<td>≤1 year</td>
<td>3.0 to 5.4 mmol/L</td>
<td>3.0 to 5.4 mmol/L</td>
</tr>
<tr>
<td></td>
<td>&gt; 1 year</td>
<td>3.4 to 4.5 mmol/L</td>
<td>3.4 to 4.5 mmol/L</td>
</tr>
<tr>
<td>iCA++</td>
<td>&lt; 6 mo.</td>
<td>0.95 to 1.50 mmol/L</td>
<td>0.95 to 1.50 mmol/L</td>
</tr>
<tr>
<td></td>
<td>≥ 6 mo.</td>
<td>1.15 to 1.29 mmol/L</td>
<td>1.15 to 1.29 mmol/L</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Calculated Parameters</strong></td>
<td></td>
</tr>
<tr>
<td>HCO3-</td>
<td>All</td>
<td>22-27 mmol/L</td>
<td></td>
</tr>
<tr>
<td>Base Excess</td>
<td>All</td>
<td>-2 to +2</td>
<td></td>
</tr>
<tr>
<td>O2 Sat</td>
<td>All</td>
<td>95-99 %</td>
<td></td>
</tr>
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</table>

### VIII. CRITICAL VALUES and REPORTABLE RANGES:

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Critical Values</th>
<th>Reportable Range</th>
<th>i-STAT Display Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH, Arterial</td>
<td>&lt;7.20 or &gt;7.55</td>
<td>6.5 to 8.2</td>
<td>6.5 to 8.2</td>
</tr>
<tr>
<td>pH, Venous</td>
<td>&lt;7.20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pCO2, Arterial</td>
<td>&lt;25 or &gt;65 mmHg</td>
<td>5 to 130 mmHg</td>
<td>5 to 130 mmHg</td>
</tr>
<tr>
<td>pCO2, Venous</td>
<td>&gt;75 mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analyte</td>
<td>Critical Values</td>
<td>Reportable Range</td>
<td>i-STAT Display Range</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-----------------</td>
<td>------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>pO2 Neonatal Arterial</td>
<td>&lt;40 or &gt;100 mmHg</td>
<td>5 to 800 mmHg</td>
<td>5 to 800 mmHg</td>
</tr>
<tr>
<td>pO2 Arterial Pediatric &amp; Adult</td>
<td>&lt;40 mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Na+</td>
<td>&lt;125 or &gt;155 mmol/L</td>
<td>100 to 180 mmol/L</td>
<td>100 to 180 mmol/L</td>
</tr>
<tr>
<td>K+</td>
<td>&lt;3.0 to &gt;6.0 mmol/L</td>
<td>2.0 to 9.0 mmol/L</td>
<td>2.0 to 9.0 mmol/L</td>
</tr>
<tr>
<td>iCA++</td>
<td>&lt;0.80 or &gt;1.55 mmol/L</td>
<td>0.25 to 2.50 mmol/L</td>
<td>0.25 to 2.50 mmol/L</td>
</tr>
</tbody>
</table>

IX. PRECAUTIONS

A. Cartridges are affected by freezing and should be stored at 2 to 8° C. Freezing causes ionized calcium in the calibrant to precipitate resulting in falsely elevated values.

B. Sources of error can arise from improper collection and handling of blood sample. If sample is drawn from an arterial line, an adequate volume must be discarded before drawing a sample that is representative of the patient. If sample is not tested immediately, it must be well mixed just prior to testing.

C. Room air contamination may compromise samples, especially in samples with very low or high pO2 content. Air contamination may be avoided by expelling any air bubbles in the syringe immediately after drawing the sample. Samples collected in blood gas capillary tube with air bubbles will interfere with pO2 measurement and must be discarded.

D. Hemodilution associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies may cause clinically significant error on pH and electrolyte results. These errors are associated with solutions that do not match the ionic characteristics of plasma.
X. LIMITATIONS

A. Interferences

An interferent is a substance which, if present at significant levels in the blood specimen being analyzed, will produce an error in the result of the analyte being measured.

<table>
<thead>
<tr>
<th>ANALYTE</th>
<th>INTERFERENT</th>
<th>INTERFERENT CONCENTRATION</th>
<th>EFFECT ON ANALYTE RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Bromide</td>
<td>37.5 mmol/L</td>
<td>Increase (↑) Na</td>
</tr>
<tr>
<td>Ionized Calcium</td>
<td>Acetaminophen</td>
<td>1.32 mmol/L</td>
<td>Decrease (↓) iCa</td>
</tr>
<tr>
<td></td>
<td>Magnesium</td>
<td>1.0 mmol/L</td>
<td>Increase (↑) iCa by 0.04 mmol/L</td>
</tr>
<tr>
<td></td>
<td>Acetylcysteine</td>
<td>10.2 mmol/L</td>
<td>Decrease (↓) iCa</td>
</tr>
<tr>
<td></td>
<td>Bromide</td>
<td>37.5 mmol/L</td>
<td>Increase (↑) iCa</td>
</tr>
<tr>
<td></td>
<td>Lactate</td>
<td>6.6 mmol/L</td>
<td>Decrease (↓) iCa by 0.07 mmol/L</td>
</tr>
<tr>
<td></td>
<td>Salicylate (therapeutic)</td>
<td>0.5 mmol/L</td>
<td>Decrease (↓) iCa by approx. 0.03 mmol/L</td>
</tr>
<tr>
<td></td>
<td>Salicylate</td>
<td>4.34 mmol/L</td>
<td>Decrease (↓) iCa</td>
</tr>
<tr>
<td>PCO₂</td>
<td>Propofol (Diprovan®)</td>
<td></td>
<td>For patients administered propofol or thiopental sodium, i-STAT recommends the use of G3+, CG4+, CG8+, EG6+, and EG7+ cartridges, which are free from clinically significant interference at all relevant therapeutic doses. i-STAT does not recommend the use of EC8+ cartridges for patients receiving propofol or thiopental sodium.</td>
</tr>
<tr>
<td></td>
<td>Thiopental Sodium</td>
<td></td>
<td></td>
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PROCEDURE REVIEW HISTORY

**Procedure Title:** i-STAT 1 PORTABLE CLINICAL ANALYZER PROCEDURE for NON-WAIVED CARTRIDGES

**Author:** Sandra Tye | **Date:** 09/18/2003

**Director:** Tim Hamill, MD | **Date:** 09/22/2003

**In Use Date:** 09/22/2003 | **Discontinued Date:**

**ACTION:** Reviewed or Revised/Approved

<table>
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<tr>
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<tr>
<td>Reviewed</td>
<td>Signature</td>
<td>Jean Millard</td>
<td>09/22/03</td>
</tr>
<tr>
<td>Reviewed</td>
<td>Signature</td>
<td>Tim Hamill, MD</td>
<td>03/02/05</td>
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<tr>
<td>Reviewed</td>
<td>Signature</td>
<td>Tim Hamill, MD</td>
<td>06/27/06</td>
</tr>
<tr>
<td>Revised</td>
<td>Signature</td>
<td>Carrie Oto</td>
<td>07/10/07</td>
</tr>
<tr>
<td>Approved</td>
<td>Signature</td>
<td>Tim Hamill, MD</td>
<td>07/11/07</td>
</tr>
<tr>
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<td>Signature</td>
<td>Tim Hamill, MD</td>
<td>05/01/08</td>
</tr>
<tr>
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<td>Signature</td>
<td>Kristin Jensen, CLS</td>
<td>08/26/09</td>
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<tr>
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<td>Tim Hamill, MD</td>
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<td>06/24/10</td>
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<td>06/13/11</td>
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<tr>
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<td>Signature</td>
<td>Kim Lee, CLS</td>
<td>12/7/2012</td>
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<tr>
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<td>Signature</td>
<td>Tim Hamill, MD</td>
<td>12/09/2012</td>
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SEE SIGNATURE MANIFEST
# Signature Manifest

**Document Number:** SOP-0114  
**Revision:** 2  
**Title:** i-STAT 1 procedure for non waived cartridges (Blood Gas, Electrolytes and other analytes)

All dates and times are in Pacific Standard Time.

## iSTAT Non-waived SOP review

### SR Sup Review

<table>
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<tr>
<td>Cynthia Ishizaki (024044224)</td>
<td>POC SR SUP</td>
<td>24 Jun 2013, 01:41:38 PM</td>
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### Med Dir Apprvl

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<td>Tim Hamill (023335003)</td>
<td>PA CB MED DIRECTOR</td>
<td>26 Jun 2013, 01:35:54 PM</td>
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