



## I-STAT PORTABLE CLINICAL ANALYZER (PCA) SYSTEM

### **HBL.ISTAT.1.0 I-STAT PORTABLE CLINICAL ANALYZER (PCA) SYSTEM**

#### **INTENDED USE**

The i-STAT® System will be utilized in a variety of Mid America Clinical Laboratory settings--in some settings it will be a primary instrument, in others it will be used as a backup for the site's primary instrument. The results provided will depend on the test cartridge utilized.

#### **PRINCIPLE**

The i-STAT® System consists of a lightweight, portable, easy to use handheld analyzer and single-use disposable cartridges that utilize advanced biosensor technology to provide a result on a whole blood specimen in approximately two minutes for a broad menu of the most commonly performed diagnostic tests, including electrolytes, chemistries, blood gases, ionized calcium and lactate, hemoglobin and hematocrit.

#### **DOCUMENT OWNER**

Technical Director, Community Westview Hospital laboratory

#### **RELATED DOCUMENT S**

- HBL.ISTAT.1.1 ISTAT Electronic Simulation Log
- HBL.ISTAT.1.2 ISTAT Monthly Maintenance Log
- HBL.ISTAT.1.3 ISTAT ABG QC Log
- HBL.ISTAT.1.4 ISTAT CHEM8 QC Log
- HBL.ISTAT.1.5 ISTAT Patient results log

#### **SPECIMEN**

- A. Patient Preparation: None.
  
- B. Specimen: Fresh whole blood collected with lithium heparin as an anticoagulant.
  - 1. All blood specimens should be handled as if they were capable of transmitting disease; standard precautions must be observed.
  - 2. For the most accurate results, test samples immediately after drawing. Samples for lactate must be tested immediately. Samples for blood gases and ionized calcium should be tested within 10 minutes. Other analytes should be tested within 30 minutes.
  - 3. All specimens should be well-mixed and avoid exposure to air before testing.
  - 4. Care should be taken to avoid hemolysis during specimen collection.
  - 5. Clotted specimens must be rejected and re-collected.
  
- C. Sample dilution: Not applicable.



## I-STAT PORTABLE CLINICAL ANALYZER (PCA) SYSTEM

### REAGENTS

- A. i-STAT® Test Cartridges are the only reagent required for testing.
- B. When stored at 2-8°C, test cartridges are stable until the expiration date given on the cartridge packaging.
- C. All cartridges must warm to room temperature for a minimum of 5 minutes for a single cartridge or 60 minutes for a box of 25 cartridges. Cartridges should remain in their protective pouches until they reach room temperature.
- D. Refer to the cartridge box for room temperature storage information; do not return cartridges to the refrigerator once they have been at room temperature.
- E. Use the cartridge immediately after removing it from its protective pouch.
- F. Cartridges should be handled by the edges only. Avoid touching the contact pads or exerting pressure over the center of the cartridge.

### EQUIPMENT

- A. i STAT analyzer
- B. i STAT External Electronic Simulator
- C. Syringe or pipette

### CALIBRATION VERIFICATION

Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. **The i-STAT® must be verified before the analyzer can be used for patient testing and every 6 months thereafter for blood gas cartridges and other cartridges used as a primary method. CHEM 8 cartridges used as a back –up method do not require calibration verification every six months, but require correlation with the primary testing method every six months.** While the Calibration Verification Set contains 5 levels, verification of the measurement range can be accomplished using the Levels 1, 3 and 5 Calibrators.

- A. Calibrators (as applicable):
  - 1. i-STAT® 5-level Tricontrol Calibration Verification Set - When stored at 2-8°, all calibrators are stable until the expiration date given on the package. Calibration



## I-STAT PORTABLE CLINICAL ANALYZER (PCA) SYSTEM

Verification materials should be equilibrated to room temperature (18-30°C) for at least 4 hours prior to use, but may be stored at room temperature for up to 5 days

2. Eurotrol Hyperbaric QC – When stored at 2-30°C, stable until the expiration date given on the package. After opening, the product is stable for 30 seconds.
3. Eurotrol CueSee® Hypoxic QC – When stored at 2-8°C in the dark, stable until the expiration date given on the package. After opening, the product is stable for 10 minutes.

### QUALITY CONTROL

Two types of quality control, electronic and liquid, are used with the i-STAT® System.

- A. Electronic Quality Control: Electronic quality control provides an independent check on the ability of the analyzer to take accurate and sensitive measurements of voltage and current from the cartridge.
  1. Internal Electronic Simulator Test: The i-STAT® will be set to perform an electronic simulator test with each patient testing; this happens automatically when a cartridge is inserted into the i-STAT®.
  2. External Electronic Simulator Test: Run every six months, after a CLEW update, or if the Internal Electronic Simulator fails.
    - a. Press the On/Off key to turn the analyzer on.
    - b. Press the Menu key.
    - c. Press 3 to select Quality Tests.
    - d. Press 4 to select Simulator.
    - e. Press Scan to scan the Simulator ID or manually enter the Simulator ID and press Enter.
    - f. Remove the cover protecting the contact pads and insert the simulator straight into the Cartridge Port of the analyzer. Avoid touching the contact pads.
    - g. Do not attempt to remove the simulator until the results are displayed and the “Simulator Locked” message is removed.
    - h. If PASS is displayed, continue to use the analyzer. Remove the simulator and return it to its protective case.
    - i. If FAIL is displayed, see the Troubleshooting section of the i-STAT® 1 System Manual.

**NOTE:** Occasionally when an analyzer is moved from a cold environment to a warm, humid environment, moisture may condense on the internal connector. An analyzer in this condition will fail the



## I-STAT PORTABLE CLINICAL ANALYZER (PCA) SYSTEM

electronic simulator test and the code "L" will be displayed. If this occurs, allow the analyzer to sit for 30 minutes to allow the moisture to evaporate and repeat the External Electronic Simulator Test.

### B. Liquid Quality Control:

#### 1. Quality Control Materials:

I-STAT® Controls Levels 1, 2 and 3 or I-STAT Tri-Controls Levels 1, 2 and 3 are aqueous assayed controls used to verify the performance of the analyzer and cartridges. I-STAT® controls do not contain human or biological materials. For control values go to [www.abbotpointofcare.com](http://www.abbotpointofcare.com)

- a. i-STAT® Controls are stable until the expiration date given on the label when stored at 2-8°C; freezing should be avoided. I-STAT® Controls may be stored at room temperature (18-30°C) for up to 5 days.
- b. I-STAT® Controls should be equilibrated to room temperature for a minimum of 30 minutes; allow a minimum of 4 hours if blood gas analysis will be performed.

#### 2. Quality Control Frequency:

- a. Each new cartridge lot number and/or shipment must have all applicable QC (site-specific) run before the cartridges are used for patient testing.
- b. All applicable liquid QC must be run every 30 days.
  - 1) Per CAP standards, 3 levels of QC material **must** be performed on all cartridges used for blood gas testing.
  - 2) Per CAP standards, 2 levels of QC material are sufficient for cartridges not used for blood gas testing.

#### 3. Quality Control Testing Procedure;

- a. Press the On/Off key to turn the analyzer on.
- b. Press the Menu key.
- c. Press 3 to select Quality Tests.
- d. Press 1 to select Control.
- e. Scan in via a barcode or manually enter the lot number of the control to be run.
- f. Scan the lot number on the cartridge pouch or enter it manually.
- g. Immediately before use, shake the ampule of QC material vigorously for 5 –10 seconds to equilibrate the liquid and gas phases. Tap any solution caught in the tip of the ampule back into the bottom. Protect fingers with gauze, kimwipes or an ampule breaker and carefully snap off the top of the ampule. Immediately transfer the control solution from the ampule to the cartridge using a small syringe or pipette.
- h. Dispense the specimen until it reaches the FILL TO mark on the cartridge.



## I-STAT PORTABLE CLINICAL ANALYZER (PCA) SYSTEM

- 1) If the cartridge is overfilled, under-filled or contains an air bubble, an error message will be displayed if an accurate result cannot be obtained. If there is no error message, the results are accurate.
- 2) If the sample well is so full that the sample is seen above the sample well after the sample chamber is filled, do not wipe or absorb the excess with a gauze or tissue, but rather, draw the excess back into the syringe.
  - i. Fold the snap cover over the sample well until it snaps into place. An error message will appear if the cover is closed before the sample chamber has filled completely or if the cover is not closed before the cartridge is inserted into the analyzer.
  - j. Push the sealed cartridge into the Cartridge Port of the analyzer until it clicks. Wait for the test to complete.
  - k. Review the results.
4. If any control result exceeds the acceptable range, the following action must be taken:
  - a. Rerun the control using the ampule already opened.
  - b. If the results are still unacceptable, open a new ampule of control and repeat testing.
  - c. If the results are still unacceptable, refer to the System Manual for troubleshooting assistance and/or call i-STAT® Technical Assistance.
  - d. If any control value exceeds the acceptable range, appropriate corrective action must be documented. Patient specimens cannot be analyzed until all control results are within the acceptable range.
5. If patient results are questionable (significantly different from previous results) or do not correlate with the patient's clinical status, controls should be run to ensure that the i-STAT® is working properly.

### PROCEDURE

- A. Perform any as-needed maintenance such as printer paper replacement, battery replacement or changing the time or date. All of these procedures are discussed in the i-STAT 1 System Manual.
- B. Turn on the i-STAT® analyzer.
- C. Select the "2 – i-STAT® Cartridge" option from the menu.
- D. Scan or manually enter the Operator ID.
- E. Scan or manually enter the Patient ID.
- F. Remove the test cartridge (warmed to room temperature) from its protective pouch, handling it



## I-STAT PORTABLE CLINICAL ANALYZER (PCA) SYSTEM

- by its edges. Avoid touching the contact pads or exerting pressure over the center of the cartridge. Place it on a flat surface or hold it horizontally.
- G. After mixing the specimen well, direct the syringe tip, pipette tip or capillary tube into the sample well. Dispense the specimen until it reaches the FILL TO mark on the cartridge.
    - 1. If the cartridge is overfilled, under-filled or contains an air bubble, an error message will be displayed if an accurate result cannot be obtained. If there is no error message, the results are accurate.
    - 2. If the sample well is so full that the sample is seen above the sample well after the sample chamber is filled, do not wipe or absorb the excess with a gauze or tissue, but rather, draw the excess back into the dispensing device (syringe, pipette, capillary).
  - H. Fold the snap cover over the sample well until it snaps into place. An error message will appear if the cover is closed before the sample chamber has filled completely or if the cover is not closed before the cartridge is inserted into the analyzer.
  - I. Insert the cartridge into the cartridge port on the analyzer and wait for the results. Never attempt to remove a cartridge while the CARTRIDGE LOCKED message is displayed.
  - J. Select the test(s) to be run.
  - K. Print the results by aligning the analyzer's Infrared Communication Window with the Martel printer's IR LED window, keeping them 1-5" apart. Display the results to be printed on the analyzer and press the PRINT button. Do not move the analyzer or the printer until the printout is complete.
 

**NOTE:** Results printed on thermal paper will fade with time and are therefore not acceptable as a permanent chartable record.
  - L. Download the results (if applicable).

### CALCULATIONS

The i-STAT® microprocessor performs all calculations required to obtain reportable results.

### REPORTING RESULTS

- A. AMR, Reference Ranges, Critical Ranges and Units of Measure:

<u>Analyte</u>	<u>AMR</u>	<u>Reference Range</u>	<u>Critical Range</u>	<u>Units of Measure</u>
Sodium	100 – 180	138 – 146	<120 or >160	mmol/L
Potassium	2.0 – 8.0	3.5 – 5.5	<2.8 or >6.0	mmol/L



I-STAT PORTABLE CLINICAL ANALYZER (PCA) SYSTEM

Potassium <29Days	2.0 – 8.0	3.5 – 4.9	<2.6 or >6.0	mmol/L
Chloride	65 – 130	98 – 109	not stated	mmol/L
TCO <sub>2</sub>	10 – 45	24 – 29	not stated	mmol/L
Ionized Calcium	0.30 – 2.30	1.12 – 1.32	<0.68 or >1.58	mmol/L
Glucose	24 – 650	65 – 99	<40 or >500	mg/dL
Glucose <29 Days	24 – 650	65 – 99	<40 or >150	mg/dL
BUN	4 – 120	8 – 26	not stated	mg/dL
Creatinine	0.25 – 15.00	0.6 0– 1.30	not stated	mg/Dl
GFR/GFR <sub>A</sub>		>60		ml/min/1.73 m <sup>2</sup>
Lactate	0.40– 15.00	0.9 – 1.7	>3.4	mmol/L
pH (art)	6.50 – 7.90	7.35 – 7.45	<7.20 or >7.60	
pH (ven)	6.50 – 7.90	7.31 – 7.41	<7.20 or >7.60	
pCO <sub>2</sub> (art)	15 – 100	35 – 45	<20 or >70	mmHg
pCO <sub>2</sub> (ven)	15 – 100	41 – 51		mmHg
pCO <sub>2</sub> (ven) <29Days	15 – 100	41 – 51	<25 or >75	mmHg
pO <sub>2</sub> (art)	15 – 660	80 - 105	<41	mmHg
pO <sub>2</sub> (ven)	15 – 660	25 – 43	none stated	mmHg
HCO <sub>3</sub> (art)	1 – 85	22 – 26	none stated	mmol/L
HCO <sub>3</sub> (ven)	1– 85	23 – 28	none stated	mmol/L
Base Excess (+)	0 – 30	0 – 3	none stated	mmol/L
Base Deficit (-)	0 – 30	0 – 2	none stated	mmol/L
O <sub>2</sub> sat/sO <sub>2</sub> (art)	0 – 100	95 – 98	none stated	%
O <sub>2</sub> sat/sO <sub>2</sub> (ven)	0 – 100	60 – 85	none stated	%
Hemoglobin	3.4– 25.0	12.0 - 17.0	<6.0	g/dL
Hematocrit	15.0– 70.0	38.0 - 51.0	<18.0	%
Hematocrit <15 Days	15.0– 70.0	38.0 - 51.0	<28.0	%

B. Critical values:

1. Results significantly outside the range of expected values require immediate notification of a nurse and/or physician. Per MA CL Policy QA.REPORT.1.0 *Critical Values—Reporting of Significant Results*, all critical values must be called and documented.
2. Critical results should be confirmed by repeat analysis either on the i-STAT® or another laboratory instrument (if available).

C. Computer Entry:

1. When an i-STAT is used as the **primary** (not backup) testing instrument:
  - a. Manual entry in Sunquest:
 

FUNCTION:	MEM
TECH:	Verify tech code [Enter]



## I-STAT PORTABLE CLINICAL ANALYZER (PCA) SYSTEM

- |  |   |
|--|---|
| SHIFT:   | [Enter] or indicate shift 1, 2 or 3   |
| WORKSHEET:   | Site-specific   |
| TEST-1:  | [Enter] to default to all   |
| METHOD:  | BGIST   |
| ACCEPT (A), MODIFY (M),<br>ACC. NO.  | A<br>Enter accession number. Enter all results.   |
| ACCEPT (A), MODIFY (M),<br>DISPLAY PRIOR (D),<br>PRELIM (P) OR REJECT (R)? | <b>Accept</b> if correct. <b>Modify</b> to add text code.<br><b>Display</b> prior to compare to previous.<br><b>Preliminary</b> results will not be printed on<br>patient reports. <b>Reject</b> results. |
- b. Manual entry in QLS:
- |                      |  |
|----------------------|--|
| Selection:           | 3,3,1 [Enter]                              |
| Allow Release? <Y>   | [Enter]                                    |
| WORKLIST:            | Site-specific [Enter]                      |
| ACCESSION:           | Enter accession number. Enter all results. |
| RELEASE RESULTS? <N> | Hit "Y" to release results.                |
2. When an i-STAT is used as a **backup** testing instrument:
- a. Manual entry in Sunquest:
- |  |   |
|--|---|
| FUNCTION:  | MEM   |
| TECH:  | Verify tech code [Enter]  |
| SHIFT:   | [Enter] or indicate shift 1, 2 or 3   |
| WORKSHEET:   | Site-specific   |
| DEVICE LAB LOCATION:   | Site-specific   |
| TEST-1:  | [Enter] to default to all   |
| MODIFY METHOD:   | Modify method from primary to BGIST   |
| ACC. NO.   | Enter accession number. Enter all results.  |
| ACCEPT (A), MODIFY (M),<br>DISPLAY PRIOR (D),<br>PRELIM (P) OR REJECT (R)? | <b>Accept</b> if correct. <b>Modify</b> to add text code.<br><b>Display</b> prior to compare to previous.<br><b>Preliminary</b> results will not be printed on<br>patient reports. <b>Reject</b> results. |
3. On-line entry: Not applicable.
4. If the HIS or LIS systems are not functional, see the Laboratory Computer Downtime Policy.





## I-STAT PORTABLE CLINICAL ANALYZER (PCA) SYSTEM

5. For waived testing performed at a Laboratory Service Center (LSC), the following procedure should be followed:
  - a. After testing is performed, the results should be written on a report sheet and issued to the physician.
  - b. A copy of the report sheet and the analyzer printout should be faxed to the technical lab.
  - c. The technologist at the technical lab will review the data and document review of the data in the LIS.
6. For BMET: Modify the method to BGIST for all analytes except calcium. Enter all i-STAT results and leave the calcium pending until can be run later on main analyzer or send to another site for testing.
7. Hematocrit- i-STAT HCT results will report with the following comment:  
“Due to technical limitations, transfusion decisions should not be made on this test alone.”

### PROCEDURE NOTES

- A. Stars (\*\*\*) will appear in place of a concentration if the signals from that particular sensor are uncharacteristic. Stars will also appear for any tests that depend on another test that is flagged with stars. DO NOT report these values; the specimen should be retested using another cartridge.
- B. Results that are outside of the AMR (reportable range) are flagged with “<” or “>.” DO NOT report these values. The “<>” flag indicated that the calculations for the test are dependent upon another test which has been flagged “<” or “>.”
- C. If the analyzer is placed on a wet surface or if any liquid is spilled onto it, dry the analyzer immediately. The analyzer may be damaged if liquid enters the microprocessor compartment, the battery compartment or the cartridge door.
- D. Expected Turnaround Time (TAT): Nursing units are to be notified if the turnaround time is unable to be met per current MACL network turnaround time standards.
- E. Backup method: When testing cannot be performed, the testing site’s backup policy should be followed.
- F. Additional items to be performed periodically:
  1. Linearity verification (CAL VER) should be performed every 6 months for blood gas cartridges and other cartridges used as a primary testing method.



## I-STAT PORTABLE CLINICAL ANALYZER (PCA) SYSTEM

2. If the i-STAT is being used to backup a primary instrument, a method-to-method comparison is required every 6 months for all analytes reported from the i-STAT. If the i-STAT is being used as a primary instrument, this requirement does not apply.
3. Twice a year, Abbott will send notification of a new CLEW software and directions for performing the update (found at [www.abbottpointofcare.com](http://www.abbottpointofcare.com)). Installation of this software allows the i-STAT Handheld to recognize any newly launched cartridge types and to perform any newly launched features. Installing this update is mandatory.
  - a. At least one i-STAT Handheld must be updated using the Jammlite procedure or as found online.
  - b. Additional i-STAT Handheld units can be update using the Jammlite procedure or the Handheld-to-Handheld Process as follows:
    - 1) Put updated i-STAT on the right side beam facing the other meter beam approximately 1-2 inches apart. Turn on updated meter only. (Do not turn on meter to be updated).
    - 2) Press the Menu key on updated meter.
    - 3) Press 7 for Utility. When prompted for a password, press 2560 ENT or just ENT.
    - 4) From the Utility menu, press 1 to send software.
    - 5) Select the new software version. Do not move either meter. Updated meter “beams” to update old meter and will say “Sending Software”. Old meter will turn on by itself and you will see data streaming on the screen.
    - 6) When it finishes updating, it will say “Last Send Successful”. Newly updated meter will turn off by itself.
    - 7) Turn newly updated meter on and select Menu key/Quality Tests/Simulator to perform External Electronic Simulator. When complete and it says PASSED, hit “.” for the Thermal Probes Difference reading. Acceptable results are less than or equal to 0.1. Record result on log sheet.
    - 8) To check the software status, select Menu/1.
4. Record Thermal Probe Check every six months as follows: Run External Electronic Simulator, after it says PASSED, push the “.”(Period) key for the Thermal Probe Check result. Acceptable value is less than or equal to 0.1.

### TROUBLESHOOTING

Quality Check Code 23 may be reduced by restoring an analyzer with the reusable i-STAT Ceramic Conditioning Cartridge (CCC)

1. Run an external Electronic Simulator.
2. Run the CCC two times as follows: Initiate the CCC cycle as you would initiate an external Electronic Simulator cycle. The instrument will identify the CCC as an external Electronic Simulator and display a



## I-STAT PORTABLE CLINICAL ANALYZER (PCA) SYSTEM

Simulator Failure Code (i.e: rRGL) when the cycle is complete. Disregard the code, as this is expected behavior.

3. Document CCC usage on maintenance or other usage log.
4. Return the analyzer to service.

Error code troubleshooting:

If codes are G or L, run external simulator.

For all other error codes, refer to the iStat System Manual or contact the hotline at 800-366-8020 for assistance.

See the i-STAT 1 System Manual section "Troubleshooting the Analyzer."

Abbott hotline 1-800-366-8020 or [www.abbottpointofcare.com](http://www.abbottpointofcare.com)

### REFERENCES

i-STAT® 1 System Manual. Copyright 2011, Abbott Point of Care, Inc.