Abbott iSTAT CG8 (LTR39866)

Analyzers

iStat a handheld Portable Clinical Analyzer utilizing microfluidics and electronic technology to measure clinical analytes in whole blood. When a sample-filled i-STAT cartridge is inserted into an analyzer for analysis, the analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration and continuous quality monitoring. Results are reported in approximately 120 seconds for cartridges with sensors for blood gases, electrolytes, chemistries.

Competency Assessment

Testing personnel must demonstrate competency prior to direct patient testing. Refer to the individual cartridge procedures for specific competency requirements. All operators must read the procedure manual and complete the *Operator Training Checklist* after initial training and *Competency Assessment Checklist* after completing the competency assessment.

Expired Operators:

Operators that fail to meet competency requirements within 365 days will be locked out of the system and will be required to undergo retraining and competency assessment according to above.

SUPPLIES and STORAGE REQUIREMENTS

Cartridges

Cartridges are sealed in individual pouches. Store the main supply of cartridges at a temperature between 2 to 8°C (35 to 46°F). **Do not allow cartridges to freeze.** (Freezing will cause higher than expected ionized calcium results). Cartridges may be stored at room temperature (18 to 30°C or 64 to 86°F) for time specified by manufacturer: 14 days, 2 months as indicated. Cartridges should not be returned to the refrigerator once they have been at room temperature, and should not be exposed to temperatures above 30°C (86°F). Mark the calendar on the box or date individual cartridges to indicate the room temperature expiration date. Cartridges should remain in pouches until time of use. Do not use after the labeled expiration date.

Controls

i-STAT Controls for blood gases, electrolytes, and chemistries

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

Electronic Simulator

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

Calibration Verification

Calibration Verification (CAL VER) using the “CAL VER” solutions (low, medium, and high levels) on all non-waived analytes is required.

CAL VER is performed:

1. On any new, or replacement device before clinically used
2. On every new lot number of cartridges
3. Every 6 months

4. As part of the troubleshooting process when controls reflect an unusual trend or are consistently out of range.
    - Run each level once.
    - POC Coordinator will review results to insure Cal Verf has passed
    - POC Coordinator will document results, sign off on the document, and present results to the POC Director or designee.

To perform CAL VER on i-STAT:

1. Press Menu. Press 3 to select Quality Tests.
2. Press 3 to select CAL VER.
3. If the Calibration Verification fails, the analyzer must be removed from use.

BLOOD SPECIMENS

Blood Collection Equipment

Cartridges for Blood gas/Electrolytes/Chemistries/Hematocrit

- ❑ Skin puncture: lancet and capillary collection tube (plain, lithium heparin, or balanced heparin for electrolytes and blood gases)
- ❑ Venipuncture: lithium heparin collection tubes and disposable transfer device (e.g., 1cc syringe and a 16 to 20 gauge needle).
- ❑ Arterial puncture: Plain syringe or blood gas syringe with heparin labeled for the assays performed or with the least amount of heparin to prevent clotting (10 IU heparin/mL of blood)

Blood Volume

See Table below for cartridge volumes. For the glucose test strip, sufficient sample to cover target area, approximately one drop, is required.

Table 1: Cartridge Panel Configurations and Blood Volume

Cartridge	Vol. µL	pH	PCO_2	PO2	Na	K	Cl	iCa	Glu	BUN	Creat	Lact	Hct	ACT	HCO3	TCO2	SO2	BE	Anion Gap	Hb
CG8+	95	•	•	•	•	•		•	•				•		•	•	•	•		•

Shading denotes calculated values

Suitable Specimens for Cartridges for blood gases, electrolytes, chemistries, and hematocrit

- ❑ Fresh whole blood collected in a plain capillary collection tube, capillary collection tube with balanced heparin, or a plastic syringe without anticoagulant. Test immediately.
- ❑ Fresh whole blood collected in a collection tube with lithium or sodium heparin anticoagulant. Fill collection tubes to capacity. Test within 10 minutes of collection. (Not recommended for blood gases.)
- ❑ Fresh whole blood collected in a blood gas syringe labeled for the assays to be performed. Fill syringes for correct blood-to-heparin ratio. Test within 10 minutes of collection.

Specimen Labeling

Specimen must be labeled with a computer generated label which includes: Patient Name, DOB, Gender, Date and MRN Time of Collection, Lab Accession Number. This procedure applies to identified patients.

Unidentified Patient Note: Includes unidentified patient presenting to the Emergency Department and mass casualty disaster; multiple patients presenting to Emergency Department. Use pre-assigned Corporate Person Index (MRN) number as defined in the Emergency Department specific procedure titled, **Disaster Chart/Unidentified Patient Protocol**.

If lab (SoftID) generated label or pre-assigned MRN for unidentified patient is not available: The specimen container must be labeled with the following information:

Patient name, sex, DOB
Patient ID number
Time and date of collection
Phlebotomist ID # or initials

Specimen Collection and Handling

In-Dwelling Line

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.

Arterial Specimens

For cartridge testing of blood gases, electrolytes, chemistries, and hematocrit, fill a plain syringe or fill a blood gas syringe, labeled for the assays to be performed to the recommended capacity, or use the least amount of liquid heparin anticoagulant that will prevent clotting. Under filling syringes containing liquid heparin will decrease results due to dilution and will decrease ionized calcium results due to binding. For ionized calcium, balanced or low volume heparin blood gas syringes should be used.

Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds and then inverting the syringe repeatedly for at least 5 seconds. For blood gas testing, avoid or remove immediately any air drawn into syringe to maintain anaerobic conditions.

Test samples for ACT immediately. Test samples for lactate within 3 minutes of sample collection. For other cartridges, test within 10 minutes of collection. If not tested immediately, remix the sample and discard the first one or two drops of blood from a syringe before testing. For the glucose test strip, test sample within 30 minutes of collection.

Finger and Heelstick Specimens

For cartridge testing, wipe away the first drop of blood, which contains excess tissue fluid, which can increase potassium result and dilute other test results. Avoid drawing air into capillary tube. Use balanced heparin or plain capillary tubes for ionized calcium. Test samples immediately to avoid clotting (especially in neonates).

Specimen Rejection Criteria

- ❑ Evidence of clotting
- ❑ Specimens collected in vacuum tubes with anticoagulant other than lithium or sodium heparin
- ❑ Specimen for ACT collected in glass syringe or tube or with anticoagulant of any kind
- ❑ Syringe for pH, $\boldsymbol{P}CO_2$, and $\boldsymbol{P}O_2$ with air bubbles in sample
- ❑ Incompletely filled vacuum tube for the measurement of ionized calcium or $\boldsymbol{P}CO_2$
- ❑ Other sample types such as urine, CSF, and pleural fluid

Precautions: Avoid the Following Circumstances

- ❑ Drawing a specimen from an arm with an I.V.
- ❑ Stasis (tourniquet left on longer than one minute before venipuncture)
- ❑ Extra muscle activity (fist pumping)
- ❑ Hemolysis (alcohol left over puncture site, or a traumatic draw)
- ❑ Icing before filling cartridge
- ❑ Time delays before filling cartridge, especially lactate and ACT
- ❑ Exposing the sample to air when measuring pH, $\boldsymbol{P}CO_2$, and $\boldsymbol{P}O_2$

PROCEDURE FOR ANALYSIS

Preparation for Use

An individual cartridge may be used after standing 5 minutes, in its pouch, at room temperature. An entire box of cartridges should stand at room temperature for one hour before cartridges are used. (Be sure to write expiration date for room temperature storage on the box).

Procedure for Cartridge Testing

1. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
2. Enter or scan operator ID
3. Scan the patient ID number. Repeat.
4. Scan the cartridge barcode.
5. Mix the sample well with gentle inversion
6. Direct the dispensing tip or capillary tube containing the blood into the sample well.
7. Dispense the sample until it reaches the fill mark on the cartridge and the well is about half full.
8. Close the cover over the sample well until it snaps into place. (Do not press over the sample well.)
9. Insert the cartridge into the cartridge door until it clicks into place.
10. Enter additional parameters if required:
    - Patient temperature can be entered as degrees Centigrade or Fahrenheit. (Use the * key on the i-STAT Portable Analyzer for a decimal point.)
    - FIO_2 can be entered as the number of liters or as a percentage of the oxygen a patient is receiving.
    - Fields 1, 2, and 3 are user-defined fields, typically used for ventilator settings such as PIP or PEEP.
    - Choose the number corresponding to the type of sample used when prompted at the Sample Type field. Select CPB for patient in cardiopulmonary bypass surgery.
11. View results shown on the analyzer's display screen.

Alternative Procedure

Should the i-STAT System become inoperable for any reason, specimens should be collected and submitted to the laboratory in accordance with the Laboratory Procedure Manual.

RESULTS

Calculations

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

Displayed Results

Results are displayed numerically with their units. Electrolyte, chemistry and hematocrit results are also depicted as bar graphs with reference ranges marked under the graphs.

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.) The **<>** flag indicates that the results for this test were dependant on the result of a test flagged as either **>** or **<**.

   Action:
   Send specimen(s) to the laboratory for analysis.
2. Cartridge results which are not reportable based on internal QC rejection criteria are flagged with *******.

   Action:
   Analyze the specimen again using a fresh sample and another cartridge. The results that are not suppressed

should be reported in the usual manner. If the result is suppressed again, send specimen(s) to the laboratory for analysis in accordance with the Laboratory Procedure Manual.

3. A Quality Check message will be reported instead of results if the analyzer detects a problem with the sample, calibrant solution, sensors, or mechanical or electrical functions of the analyzer during the test cycle.

   Action:
   Take the action displayed with the message that identifies the problem. Refer to the i-STAT System Manual's Troubleshooting section if necessary.

Transmitting Results

1. Once testing has been completed the results will be transmitted wirelessly to a middleware product which will send the results directly to EPIC. Testing results should be available in EPIC within 5 minutes of release. Should the wireless system be down for any reason the iStat will hold the results in the device and transmit the results once the wireless network is operational. Each iStat device will hold 1000 patient samples.

2. Test results are available in the device.

   a. Turn on the iStat

   b. Choose item (1) – Last Result. The patient ID will appear on the top of the screen and the test results will appear below.

   c. Prior to Last Result patient results can be located by pressing Menu>2 Data Review>7 List> chose number of desired result and press ENT key

Reference Ranges[1,2], Reportable Ranges

Reference range means the range of test values expected from 95% of fasting individuals presumed to be healthy. Reportable range means the range of test values throughout which the measurement system's results have been shown to be valid. The following table contains the Reference Ranges (for adults) and Reportable Ranges applicable to the i-STAT System.

ANALYTE	UNIT	REFERENCE RANGE (arterial) (venous)		REPORTABLE RANGE
Sodium	mmol/L	138 – 146	138 - 146	100 – 180
Potassium	mmol/L	– 4.9	3.5 - 4.9	2.0 – 9.0
Chloride	mmol/L	98 – 109	98 – 109	65 – 140
BUN	mg/dL	8 – 26	8 – 26	3 – 140
Glucose	mg/dL	70 – 105	70 – 105	20 – 700
Creatinine	mg/dL	0.6 - 1.3	0.6 - 1.3	0.2 - 20.0
Ionized Calcium	mmol/L	1.12 – 1.32	1.12 – 1.32	0.25 – 2.50
pH		7.35 – 7.45	7.31 – 7.41	6.50 – 8.00
***P*CO_2**	mm/Hg	35 – 45	41 – 51	5 – 130
***P*O_2**	mm/Hg	80 – 105		5 – 800
Hematocrit	%PCV	38 – 51	38 - 51	10 – 75

Lactate	mmol/L mg/dL	0.36 –1.25 3.2 – 11.3	0.90-1.70 8.1–15.3	0.30 – 20.0
HCO_3*	mmol/L	22 – 26	23 - 28	1 – 85
TCO_2*	mmol/L	23 – 27	24 - 29	1 – 85
BE*	mmol/L	(-2) – (+3)	(-2) – (+3)	(-30) – (+30)
Anion Gap*	mmol/L	10 – 20	10 – 20	(-10) – (+99)
sO_2*	%	95 – 98		N/A
Hb*	g/dL	12 – 17	12 – 17	3 – 26

*Calculated values.

Critical Results[3]

Critical results are test results that fall outside high and low critical limits that define the boundaries of life-threatening values for a test. Critical results represent an emergency condition and must be reported immediately to the patient's attending physician or nurse

.ANALYTE (units)	ADULT		CHILDREN		NEONATES	
	low	**high**	**low**	**high**	**low**	**high**
Sodium (mmol/L)	120	158	121	156	121	156
Potassium (mmol/L)	2.8	6.2	2.8	6.4	2.8	6.5
Chloride (mmol/L)	75	126	77	121	77	121
TCO_2 (mmol/L)	11	40	11	39	–	–
Ionized Calcium (mmol/L)	0.78	1.58	0.74	1.57	–	–
pH	7.21	7.59	7.21	7.59	–	–
PCO_2 (mmHg)	19	67	21	66	–	–
PO_2 (mmHg)	43	–	45	124	37	92
BUN (mg/dL)	–	104	–	55	–	55
Glucose (mg/dL)	46	484	46	445	32	328
Creatinine	–	7.4	–	3.8	–	–
Hematocrit (%PCV)	18	61	20	62	33	71

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. For example, in the table below, β-hydroxybutyrate at sample concentration level of 16mmol/L would decrease the measured sodium by 4mmol/L.

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Sodium	β-hydroxybutyrate	16mmol/L (166mg/dL)	Decrease (↓) Na by 4mmol/L
Chloride	β-hydroxybutyrate Bromide Lactate Salicylate	16mmol/L (166mg/dL) 12.5mmol/L (100mg/dL) 11mmol/L (100mg/dL) 4mmol/L	Increase (↑) Cl by 6mmol/L Increase (↑) Cl by 30mmol/L Increase (↑) Cl by 3.5mmol/L Increase (↑) Cl by 3mmol/L
Ionized Calcium	Magnesium	1.0mmol/L	Increase (↑) iCa by 0.04mmol/L
Glucose (Cartridge)	Bromide pH Oxygen	12.5mmol/L pH: 7.2@37° pH: 7.6@37° ***P*0$_2$** less than 20mmHg@37°	Decrease (↓) glucose by 55mg/dL Decrease (↓) glucose by 4mg/dL Increase (↑) glucose by 1mg/dL May Decrease (↓) glucose
***P*CO2**	Thiopental sodium	10μL/mL 50μL/mL	May decrease ***P***CO2 by approximately 4 mmHg (0.53 kPa) May decrease ***P***CO2 by approximately 12 mmHg (1.6 kPa)
Creatinine	Bromide Dopamine PCO_2 PCO_2 **Hydroxyurea**	12mmol/L 0.7mmol/L Above 40 mmHg Below 40 mmHg	Increase (↑) creatinine by 0.06mg/dL Increase (↑) creatinine by 0.077mg/dL Increase (↑) creatinine by 3.8% per 10mmHg PCO_2 Decrease (↓) creatinine by 3.8% per 10mmHg PCO_2 **Significant false elevations may be as high as 7mg/dL.**
Hematocrit	White Blood Count (WBC) Total Protein	Greater than 50,000 WBC/μL <u>For measured Hct<40%</u> For each g/dL below 7 For each g/dL above 7 <u>For measured Hct≥40%</u> For each g/dL below 7	May Increase (↑) hematocrit Decrease (↓) Hct by 1% PCV Increase (↑) Hct by 1% PCV Decrease (↓) Hct by 0.75% PCV

		For each g/dL above 7	Increase (↑) Hct by 0.75% PCV

QUALITY CONTROL

Liquid Quality Control must be performed:

1. On every analyzer prior to initial placement for patient testing.
2. On every new lot number and every new shipment of cartridges.
3. When there's a suspected cartridge or storage problem.
4. On any back up analyzer placed in use before patient testing.
5. On all cartridge/reagent types as well as all analytes. If the same analyte occurs on multiple cartridge/reagent types, it must be tested on every cartridge/reagent type.
6. Monthly to check storage conditions of cartridges

Note: Implementing a new or replacement device that uses Non-Waived Cartridges: i-Stat is considered an option #1 device under CLIA. Point of care testing staff must run liquid controls daily for the first 10 days concurrently with EQC, both internal and external. If no QC failures occur then the analyzer is ready to use. Any failure will require further evaluation. Document results on i-STAT Instrument Validation Log.

Electronic Simulators:

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

A. Internal Electronic Simulator:

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

1. If it fails, the testing cycle stops and FAIL displays on the screen, immediately rerun the cartridge in the same analyzer to confirm the FAIL.

☐ If the cartridge fails again rerun the cartridge in a different analyzer (if less than three minutes has lapsed from the time of cartridge filling.)

☐ If the cartridge fails in more than one analyzer, use a different cartridge.

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

External Electronic Simulator:

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

1. The analyzer has been dropped
2. Every six months
3. After major malfunction
4. Replacement analyzer received from i-STAT

To run external Simulator:

☐ Press the Menu key to access the Administration menu.

☐ Press the #3 for Quality test

☐ *Press the #4 for Simulator*

1. Insert the simulator into the analyzer with the "I" facing up. (Do not touch the contact pads). **Cartridge Locked is displayed indicating that the simulator should not be removed. DO NOT ATTEMPT TO REMOVE THE SIMULATOR WHILE THE Cartridge Locked MESSAGE IS DISPLAYED. AN ATTEMPT TO REMOVE FORCIBLY THE SIMULATOR DURING THIS CYCLE MAY DAMAGE THE ANALYZER.**
2. If PASS is displayed on the analyzer screen, remove the simulator **after the Cartridge, Locked message disappears from the display screen.**
3. If FAIL is displayed on the analyzer screen:
4. Repeat the procedure with the same Electronic Simulator. If PASS is displayed, use the analyzer as required.
5. If FAIL is displayed, repeat the procedure with a different Electronic simulator, if available.
    a) If PASS is displayed with the second simulator, use the analyzer as required.
    b) If FAIL is displayed with the second Electronic simulator:
        1. Do not analyze patient samples with the analyzer.
        2. Record the failure in the Instrument Corrective Action Log, along with action taken.

Prior to performing liquid quality control, determine if additional preparation is required.
i-STAT Aqueous Liquid Controls: **(For, CG8+, CG4+)**

1. Aqueous liquid controls require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampoule for 4 hours. If not, equilibrate the ampoule for approximately 30 minutes at room temperature.
2. Hold the ampoule at the top, bottom (with forefinger and thumb), and shake 15-20 times (about 10 seconds) to mix the solution. Tap the ampoule to restore the liquid to the bottom of the ampoule.
3. Open the ampoule by snapping off the tip. Protect fingers with gauze or use an ampoule breaker.
4. Immediately transfer control to syringe as follows: Use a clean 3 mL syringe. Replace attached needle with a 19-gauge blunt tip needle.
5. Aspirate the control from the ampoule into the syringe. Be careful that air is not drawn in with the liquid. Expel one or two drops of liquid before filling the cartridge. If desired, you may detach the blunt tip needle before filling the cartridge.
6. Immediately transfer the solution into a cartridge.
7. Immediately seal the cartridge and insert it into an analyzer.
8. Do not use the solution left in a syringe or ampoule for additional testing of cartridges that contain sensors for ionized calcium, pH, PCO_2, or PO_2. Open a new ampoule.

Running the controls:

1. Put on gloves.
2. Press the On/Off key
3. Press the Menu key
4. Press 3 to select Quality Tests.

NOTE: Always remember to analyze control materials in the Control pathway under the Quality Tests option of the i-STAT 1 Analyzer Administration Menu. Do not analyze controls under the Patient Test pathway. This must be done before inserting the test cartridge into the analyzer. The analyzer allows 15 minutes to insert the cartridge after the last keystroke.

5. Press 1 to select Control.
6. Press "Scan" to scan Operator ID
7. Press "Scan" to scan Control Lot number
8. Press "Scan" to scan the cartridge lot number from the box or manually enter the number using the keypad and press Enter.
9. Fill cartridge with the control (see below). Insert cartridge.
10. Enter 1 for i-STAT Level 1. Enter 2 for i-STAT Level 2.
11. Results will appear. At the bottom of one of the result pages, you will see 1- Test Options Select 1.
12. You will now have the following options:
    - Next level

- Repeat level
- History

***Using these options will allow you to continue your Quality Control testing without having to* start again at the top of the QC menu.**

1. Document results on the Record of Receipt /QC Documentation Log and compare results to the ranges to determine acceptability.
2. The operator performing the quality controls is responsible for evaluating the controls and performing any necessary corrective actions. If the results are out of range, corrective action must be documented on the Record of Receipt /QC Documentation Log.
3. If all results are within expected ranges, use the cartridges as needed. Transmit the results when finished.
4. The result statistics will be reviewed monthly by the Medical director or Designee.

Quality Control Corrective Action:

1. If any liquid control result is unacceptable, patient testing can not be performed until the problem has been resolved. Use another analyzer or send the specimen to the Clinical Laboratory.
2. Repeat any out of range control, verifying that the control procedure above has been followed carefully.
3. Document all the results and corrective actions on the Record of Receipt /QC Documentation Log.
4. If new control solutions fail a second time, analyzer, control solutions and cartridges should be pulled from use and the POCT program notified (847-570-4684; pager 8585). An investigation will be done to determine the cause of failure.

Verification of Cartridge Storage Conditions

Refrigerated Cartridges

- ❑ Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes. Deliver any expired cartridges to the Laboratory.
- ❑ Verify that the refrigerator did not exceed the limits of 2 to 8°C (35 to 46°F).
- ❑ Document in the i-STAT QC Log.

Action:
If the temperature of the cartridge storage refrigerator is within the range of 2 to 8°C (35 to 46°F) use cartridges as required.

Remedial Action:

If the temperature is outside the range of 2 to 8°C (35 to 46°F), quarantine the cartridges in the storage refrigerator. Notify the i-STAT System Coordinator immediately. DO NOT USE the cartridges from this refrigerator. Record the QC failure in the i-STAT QC Log along with the action taken.

Room Temperature Cartridges

- ❑ Verify that all boxes of cartridges at room temperature have been out of the refrigerator less than two weeks. Deliver any expired cartridges to the i-STAT System Coordinator.
- ❑ Verify that room temperature has not exceeded 30 °C.
- ❑ Document in the i-STAT QC log.

Action:
If the measured temperature of the room has been continuously below 30°C (86°F) use cartridges as required.

Remedial Action:
If the measured room temperature has exceeded 30°C (86°F) for any period of time:

- ❑ Quarantine the cartridges.
- ❑ Notify the Laboratory immediately.
- ❑ DO NOT USE the cartridges.
- ❑ Record the out-of-control event in the i-STAT QC Log and the action taken.

Monthly Procedures

Periodic Procedures for Cartridges

For acceptance of newly received cartridge lots, check the Temperature Monitor and perform integrity testing.

Check Temperature Monitor

i-STAT cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit.

Action:

- ❑ Fill out the record of receipt and forward materials to refrigerator.
- ❑ If all windows are white or if only the A windows is blue, then transit temperatures were satisfactory and the cartridges can be used.

Remedial Action:

If the B window is blue, contact the Laboratory before using cartridges.
If the C, or D windows are blue:

- ❑ Quarantine the suspect cartons.
- ❑ Notify the Laboratory immediately.
- ❑ DO NOT USE cartridges from the suspect cartons.
- ❑ Record the out-of-control event in the i-STAT QC Log.

Integrity Testing

From each lot of blood gas/chemistry cartridges received, use a representational number of cartridges to analyze i-STAT or Eurotrol Level 1 and 3 Controls. Use any verified analyzer for control testing. Transmit the results to the Central Data Station. Use the expected values published in the package inserts to verify the integrity of the cartridges.

Procedure for testing cartridges with Level 1 and Level 3 Controls:

1. Prior to testing cartridges that measure PO2, ampules should stand at room temperature a minimum of 4 hours before use. When testing other cartridges (EC8+), ampules may be used once the fluid has reached room temperature, approximately 30 minutes for individual ampules. For best results, ampules, cartridges, and analyzers should be at the same temperature. When using cartridges that contain sensors for measuring ionized calcium, pH, PCO_2, or PO_2 (,CG 8+,), a separate ampoule must be used for each cartridge being tested; if these sensors are not present (i.e., the CHEM8+ cartridge), the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 10 minutes of opening the ampule.
2. 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 solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule. Protect fingers with gauze, tissue, or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
3. Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge. Immediately seal the cartridge and insert it into an analyzer-it is important not to expose the solution to room air since this will alter the results.
   - ❑ When using a capillary tube, fill from the bottom of the ampule. Avoid drawing solution from the surface by covering the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

- When using a syringe (1cc or 3cc sterile syringes with 16 to 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule. If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe. If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe. Expel one or two drops from the syringe before filling the cartridge.
- Do not use solution left in the syringe, ampule, or capillary tube for additional testing of the cartridges that contain sensors for ionized calcium, pH, ***P***CO_2, or ***P***O_2. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.

4. Compare results to the package insert values. 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 the Central Data Station.

Remedial Action:
If any results are outside the published expected ranges:

- DO NOT USE cartridges from the suspect lot.
- Quarantine the suspect lot.
- Notify the i-STAT System Coordinator immediately.
- Record the QC failure in the i-STAT QC Action Log along with the action taken.

CALIBRATION

For cartridges, calibration is automatically performed as part of the test cycle.

PRINCIPLES OF MEASUREMENT

Sodium, Potassium, Chloride, Ionized Calcium, pH, and *P*CO_2

are measured by ion-selective electrode potentiometry. Concentrations are calculated from the measured potential through the Nernst equation.

Urea

is first hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease. The ammonium ions are measured by an ion-selective electrode and the concentration is calculated from the measured potential through the Nernst equation.

Glucose

is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at an electrode to produce an electric current which is proportional to the glucose concentration.

Creatinine

is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the creatinine concentration.

***P*O_2**

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 an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

Hematocrit
is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.

PREVENTATIVE MAINTENANCE

A. Rechargeable battery:
A lithium rechargeable battery powers the analyzer. The battery recharges when the analyzer is placed in a Recharger. The battery pack can also be removed from the analyzer and placed in the separate recharging compartment on the Recharger. Full recharge from a discharged state takes approximately 8 hours. The analyzer will display "Low Battery" when battery recharge is needed.

B. Disinfect exterior of analyzer between each patient with hospital-approved disinfectant. See Policy 10.7 non Dedicated Patient Care Equipment.

C. CLEW/JAMS software updates:
Software updates performed twice per year re-establishes standardization values and incorporates refinements to the internal quality monitoring system. External Quality Control and the Thermal Probe Check are performed along with the CLEW update. The POCT Program will ensure CLEW updates are implemented prior to software expiration.

TROUBLESHOOTING

A. Analyzer:
1. **No display:** Either if the display screen remains blank, after a cartridge has been properly inserted or after the On/Off key has been pressed, the batteries should be replaced.
2. **Cartridge Locked:** Cartridge Locked appears on the screen during the testing cycle to indicate that the cartridge or simulator is locked in the analyzer and should not be removed. **A cartridge or simulator must be removed only after the Cartridge Locked prompt disappears from the screen.** Normally the analyzer will reset and release the cartridge after the testing cycle is completed. If the analyzer cannot reset, the Cartridge Locked prompt will remain on the screen. If this occurs, wait until the analyzer deactivates (display screen blank) and press the On/Off key. The analyzer will try to reset. **If the Cartridge Locked prompt does not disappear, do not attempt to remove the cartridge.** Call the Point of Care Testing program 847-570-4684.
3. **Low Battery:** Recharge battery in Recharge or swap with extra rechargeable battery.
4. **Electronic simulator fail** will appear if the analyzer has not successfully completed the electronic simulator test. Refer to **ELECTRONIC QUALITY CONTROL** section.
5. **CLEW expiring, Upgrade required,** Point of Care Testing would need to perform a software update.
6. **Messages and Quality Check Codes:** If a problem is detected during a testing cycle, the cycle will be stopped and a message box will appear on the screen. The messages will identify the code number. Refer to i-STAT's technical bulletin(s) to determine the meaning of the code number and the suggested action. If the analyzer deactivates before the detected problem is addressed, the message box will reappear the next time the On/Off key is pressed. Document all problems on the Instrument Corrective Action Log and notify Point of Care Testing.
    - **Temperature out of Range error message:** The analyzer must be moved to an area where the temperature is between 18-30° C. Equilibration can take up to 30 minutes.
    - **Other error messages:** Refer to the i-STAT System Manual's Troubleshooting section for more information.
    - **i-STAT Dropped:** Run simulator prior to patient testing**.**
    - **Power Outage or Disaster scenario:** Contact the POCT program for assistance.

B. Cartridge: *** Instead of Results:
1. Test the patient specimen with a new cartridge. If *** reappears, send the sample to the Clinical Laboratory for analysis. The sample may contain a substance that interferes with the test.

2. If *** are obtained for the same test performed on an additional (different) patient, page Point of Care Testing for assistance pager 8485 (Text page with problem and complete phone#)

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

REFERENCES

1. i-STAT System Manual
2. Fundamentals of Clinical Chemistry, N. Tietz, Third Edition, Pages: 426–435, 614–616, and 676–678.
3. Clinical Chemistry Theory, Analysis & Correlation, Kaplan/Pesce, 2nd Edition, Pages 850–856, 872–875, 884–888, and 1021–1024.

Written by: Robert Rosecrans, Ph.D.