

Discontinuation Date:

I. PURPOSE:

I-Stat system is designed to perform timely results Blood Gas levels (pH, PCO₂, & PO₂) TCO₂, electrolytes (Sodium, Potassium, Chloride, Ionized Calcium) Bun, Creatinine, Glucose and coagulation assays (ACT, PT/INR) analysis at the patient's bedside.

II. PRINCIPLE:

I-Stat methodology is based on an electrochemical reaction. A micro fabricated sensor is housed in each individual cartridge. The reaction occurs when patients' specimen is placed in the cartridge, and then placed into the hand-held I-stat analyzer and read.

Sodium, Potassium, Chloride, Ionized Calcium, pH, and PCO₂

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 amidohydrolase. 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.

PO₂

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.

ACT

is determined amperometrically. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with a particulate clotting activator – either Celite® brand diatomaceous earth or kaolin. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and the result is reported as a whole blood time (WBT).

PT/INR

is determined amperometrically. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with tissue thromboplastin. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and reported as INR and/or seconds.

III. PERSONNEL:

Nursing
Respiratory Tech

Physician Assistant
Laboratory Personnel
Perfusionist

IV. SPECIMEN

Sample Collection and Handling – Quality Testing begins with reliable specimen. Sample Integrity is Critical in all blood analysis. For sample collection assemble all materials and equipment before obtaining sample.

Identify the patient – use 2 identifiers.

- a. Ask for the name of patient.
- b. Check wristband.

Venipuncture:

- 1) Observe and examine patient's arm/hand select the vein of choice.
- 2) Put on personal protective equipment (PPE) gloves. Use universal precautions.
- 3) Position patient's arm/hand and ask the patient to close his/her hand. Vigorous hand exercise "pumping" should be avoided.
- 4) Wipe site with sterile alcohol. Do not touch or blow.
- 5) Apply Tourniquet (for no longer than 1 minute) on patients arm.
- 6) Inspect needle: Bevel always up.
- 7) Perform Venipuncture: Pay attention to procedure and observe the patient.
- 8) Ask patient to open his/her hand up.
- 9) Release Tourniquet: Discard tourniquet after each procedure.
- 10) Place gauze over needle at Venipuncture site before withdrawing needle.
- 11) Remove needle: Immediately, activate safety device (safety Eclipse needle or butterfly).
- 12) Apply bandage on Venipuncture site: Be sure bleeding stops before bandage is applied.
- 13) Discard used items accordingly.

Precautions:

- 1) IV Line –Do not draw from the arm with IV Line. IV Line solution will dilute the sample.
- 2) Tourniquet – Avoid Localized stasis, which can increase K, pH, and Lactate results and decrease Ionized calcium result.
- 3) Avoid extra muscle activity such as clenching and unclenching.
- 4) Avoid Hemolysis – allow residual alcohol to dry over the puncture site.

Arterial:

Arterial punctures are performed to access gas exchange status. PCO₂, PO₂, pH values change with changes in ventilatory support at a rate dependent on underlying condition. Sample should be drawn under stable condition. **Before any radial arterial puncture is attempted, a collateral circulation testing of the arm (Allen's test) must be performed. See procedure for Allen's Test.**

Sample Handling:

- 1) Use Pre heparinized syringes. If you use a plain syringe the sample should be immediately tested.
- 2) Gently mix blood immediately to avoid clotting. Invert the syringe a few times and roll syringe between palms for at least five seconds.

- 3) Avoid exposing the sample to air. If not processed immediately cap syringe. Expel any air bubbles immediately. If the sample drawn has air bubbles next to the plunger do not allow the air bubble to move through the sample.
- 4) If testing is not immediate remix the syringe, by rolling between the palms for 5 seconds, and then discard the first drop of blood. The first drop of the sample has been exposed to ambient air and you want to use the homogenous blood sample. Also by discarding the first few drops you also check that there are no clots or fibrin strands.
- 5) A clot or fibrin strands is a criteria for rejection and a new sample must be obtained.
- 6) If the blood gas cannot be measured immediately store the sample in ice water (slush) to slow down metabolism. Do not use ice cubes alone as it will freeze and hemolyze the blood cells.

Skin Puncture Samples:

- 1) Select the site, Puncture should be made on the most medial or lateral portions of the plantar or flat surface or the heel. **Do not puncture through previous site or cold /cyanotic areas.**
- 2) It is also important to select the appropriate device based on Patient's weight.
- 3) Warm the site. The site should be wrapped in a heel warmer or warm cloth for approximately five minutes.
- 4) Wear gloves and use universal precaution.
- 5) Cleanse the site. A sterile alcohol pad should be used to cleanse the site. The alcohol should be allowed to air dry before puncture.
- 6) Position safety lancet over site and activate. Once activated the safety lancet cannot be reused.
- 7) Wipe off the first drop of blood because it is most likely to contain an excess of intracellular and interstitial fluid.
- 8) Hold finger/ foot with a moderately firm grip. **Never** milk or massage the finger/foot because this causes hemolysis or mixture of interstitial fluid with the blood.
- 9) Eliminate the first drop of blood except for PT/INR.

Source of Collection Error and Criteria for Rejection

- a. Evidence of clotting.
- b. Sample clotting due to improper mixing.
- c. Ambient air contamination in blood gas samples.
- d. Saline/fluids specimen obtained via an indwelling catheter.
- e. Inadvertent sampling of systemic venous blood instead of arterial.
- f. Time delay in sample analysis-sample allowed remaining at room temperature. Immediate chilling and analysis is necessary for blood gas.
- g. Specimen collected in vacuum tubes with anticoagulant other than lithium or sodium heparin.
- h. Specimens for ACT or PT/INR collected in glass syringes or tubes or with anticoagulant of any kind.
- i. Time delays before filling cartridge, especially ACT, and PT/INR.

V. Equipment and Materials:

1. Equipment
 - ❖ I-Stat Hand-held analyzer.
 - ❖ Quality Control External Simulator.
 - ❖ Downloader.
2. Materials
 - ❖ I-Stat EG7+, Chem8+, CG8+, G3+, Aqueous Quality Control - Three Levels.
 - ❖ I-Stat PT/INR, ACT+celite – Two Levels Aqueous Quality Control.

3. Preparation
 - ❖ A box of cartridges should be at room temperature for one hour prior to use.
 - ❖ A single cartridge must be at room temperature for five minutes prior to use.
4. Storage
 - ❖ Main supply of cartridges is stored at 2-8°C in the Chemistry Laboratory, Room A2-452.
 - ❖ A single box can remain at room temperature for 14 days/2 months but never returned to the refrigerator once it has been at room temperature for more than 30 minutes.
 - ❖ Cartridges should never be exposed to temperatures above 86°C.
 - ❖ Mark expiration date should not exceed **14 days** at room temperature.
Cartridges Chem8+, PT/INR
 - ❖ Mark expiration date should not exceed **2 months** at room temperature.
Cartridges G3+, EG7+, CG8+
ACT+ Celite should not exceed **12 Hours** at room temperature.

5. Cartridge Configurations and Sample Volume:

EG7+ (95µL)

Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Hematocrit (Hct)
pH
PCO2
PO2
TCO2*
HCO3*
BE*
sO2*
Hemoglobin* (Hb)

CeliteACT (40µL)

Celite® ACT

PT/INR(20µL)

Prothrombin Time

G3+(95µL)

pH
PCO2
PO2
HCO3*
TCO2*
BE*
sO2+*

CHEM8+ (95µL)

Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Creatinine (Crea)
Ionized Calcium (iCa)
TCO2
Hematocrit (Hct)
Anion Gap* (Angap)
Hemoglobin* (Hb)

CG8+ (95µL)

Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Glucose (Glu)
Hematocrit (Hct)
pH
PCO2
PO2
TCO2*
HCO3*
BE*
sO2*
Hemoglobin* (Hb)

***Calculated Values**

VI. Quality Control:

1. Internal QC.
Performed simulator QC is automatically ever eight hours, or at the time of testing.
2. Electronic QC.
Simulator QC performed by Point of Care staff twice a year. External Simulator QC will be used when Internal Simulator QC fails.
3. External Liquid QC.

Verification of New Lot of Cartridges: Each new shipment of cartridges is verified with 3 levels of liquid controls run by the OPERATORS or monthly. Values outside the acceptable range warrant repeating of the control material. If results are still out of acceptable range, Technical Service for I-STAT will be contacted and the cartridges will not be used.

4. Remedial Action

If both internal and external QC fails, the analyzer will not be used.

Send a freshly drawn specimen to Clinical Laboratory.

Notify the Point of Care Staff extension 1679 for documentation of replacement.

5. Update of Software Mandatory update from Abbott I-Stat. Clew Update

Update standardization values are to maintain long-term consistency of performance.

Clew update performed 2X annually. If update is successful electronic simulator must be performed. If simulator passes, check Thermal probe. (Limit = $\pm 0.15^\circ\text{C}$). Run Linearity or controls.

VII. PROCEDURES STEPS:

A. Collection Options:

1. Cartridges for Blood Gas/Electrolytes/Chemistries/Hematocrit

- ❖ Skin puncture Lancet and capillary collection tube (plain, lithium heparin for electrolytes and blood gases)
- ❖ Venipuncture: Lithium Heparin collection tubes and disposable transfer device (e.g. Ice syringe and a 16 to 20 gauge needle).
- ❖ Arterial puncture: Plain syringe or blood gas syringe with heparin and labeled for the assays performed or with the least amount of heparin to prevent clotting (10 U heparin/ml of blood).

2. Cartridges for ACT

- ❖ Skin puncture: not recommended
- ❖ Venipuncture and arterial puncture: plain plastic syringe without anticoagulant
- ❖ Venipuncture and arterial puncture: Collection tube or syringe with lithium heparin sodium heparin, or EDTA.

3. Cartridges for PT/INR

- ❖ Skin puncture lancet only needed Cartridge can be filled directly from the finger.
- ❖ Venipuncture and arterial puncture: plain plastic syringe without anticoagulant.

4. Indwelling lines

- ❖ Aspirate a waste volume 6 times the volume of the catheter and connectors before collecting a sample to ensure it will be contaminated with flush solution.

5. Test within 3 minutes for capillary tubes, evacuated tubes or syringes without anticoagulant.

- ❖ 10 minutes for evacuated tubes or syringes with anticoagulant (maintain anaerobic conditions. Tubes and syringes must be well mixed before testing).

6. Analysis Time (2 minutes).

7. Complete all required documentation: Physician's Order, Flow Sheet, and progress note.

B. Procedural Steps Cartridge

1. Remove cartridge from pouch.
 - ❖ Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
2. Direct the dispensing tip or capillary tube containing the blood into the sample well.
3. Dispense the sample until it reaches the fill mark on the cartridge. Avoid any ambient air contact.

Close the cover over the sample well until it snaps into place.

 - ❖ Do not press over the sample well.
4. Insert cartridge into the cartridge door until it clicks into place.
5. Enter operator assigned ID number (four digits).
6. Enter patient ID number. The financial account number (7 digit #). Input the number the 2nd time for verification.
7. Press page soft-key to enter additional parameters (if required):
 - ❖ Choose the number corresponding to the type of sample used when prompted at the Sample Type field.
 - ❖ Press the ENTER soft-key to record the blood gas parameters entered.
8. View results shown on the analyzer's display screen.
9. **Procedure: DownLoading**

Place the analyzer in the IR-link Cradle and Press Menu until "Status and Stored Results" is displayed.

A Cerner accession number will automatically be generated for each test performed and the test results will be entered into the respective patient's permanent record.
10. Test results (up to 500) can be stored in the analyzer for batch transmission.

All results are to be downloaded. **DOWNLOADING MUST BE PERFORMED AT THE END OF EACH SHIFT.**

Place analyzer in the IR Cradle.

 - ❖ Check that status light is green
11. Do not move the analyzer while the message "TRANSMITTING" is displayed on the screen. During transmission, the IR status light will blink red and green.

If transmission is successful, the IR receiver will emit a single high pitched beep.

If transmission is not successful, the IR receiver will emit three low-pitched beeps.

If transmission is not successful, contact the Point of Care Coordinator.
12. Upon completion of transmission to the Central Data Station, an I-Stat Test order, and a barcode number, will automatically be generated by Cerner Lab Information System. The test results are then entered and verified automatically by Cerner and will become part of the patient's permanent record.
13. If any corrections must be made after results have been transmitted or if a problem occurs during downloading, contact the P.O.C. office at extension 1679 immediately.

Limitations of the Procedure:

1. The ">" (greater than sign) indicates that a result falls above the high end of the reportable range.
2. The "<" (less than sign) indicates that a result falls below the low end of the reportable range.
3. The "<>" flag indicates that the calculations for the test are dependent upon another test which has been flagged.

4. The *** flag mean the cartridge is defective or the individual sensor for that test has been compromised or the analyzer need to be checked with an Electronic Simulator.

VIII. REPORTING RESULTS

Reference:

ANALYTE	UNIT	REFERENCE RANGE		CRITICAL VALUE		REPORTABLE RANGE
		(arterial)	(venous)	LOW	HIGH	
Sodium	mmol/L	138-146	138 -146	<120	>155	90.9 - 195.8
Potassium	mmol/L	3.5 - 4.9	3.5 -4.9	<3.0	>6.0	1.8 - 8.69
Chloride	mmol/L	98 -109	98 - 109	<70	>120	67.5 - 134.2
Ionized Calcium	mmol/L	1.12 -1.32	1.12 - 1.32	<0.8	>1.8	0.67 - 2.46
Glucose	mg/dl	70 - 105	70 - 105	<50	>450	25 - 671
Bun	mg/dl	8 -26	8 - 26		>100	1.8 - 179.3
Creatinine	mg/dl	0.6 - 1.3	0.6 - 1.3		>10	0.36 - 15.0
pH	NO UNITS	7.35 - 7.45	7.31 - 7.41	<7.20	>7.60	6.1 - 8.9
pCO2	mm/Hg	35 - 45	41 - 51	<20	>60	17.6 - 85
pO2	mm/Hg	80 - 105		<50		76 - 370
TCO2 (Chem 8 Cartridge only)	mmol/L	23 - 27	24 - 29	<11	>40	9.0 - 59.4
Hematocrit	%	38 - 51		<15	>60	9.9 - 75.9
PT/INR	sec	12.2-13.8		>6.0 INR		0.9 - 8.0
ACT Celite	sec(non warm)	84-139 (non warm)		>400 BYPASS < 480		50 - 874
HC03*	mmol/L	22 - 26	23 - 28			1.0 - 85.0
TCO2*(on all cartridges except Chem8+)	mmol/L	23-27	24 - 29			5 - 50
BE*	mmol/L	(-2) –(+3)	(-2) – (+3)			(-30) – (+30)
Anion Gap*	mmol/L	10 – 20	10 - 20			(-10) – (+99)
sO2*	%	95-98				0 - 100
Hb*	g/dl	12-17	12 - 17			3.4 – 25.5

* Calculated values

When patient results fall outside the reference range, the patient's caregiver must be notified. A comment code must be entered into patient record. The comment codes for the I-Stat meter are:

- 00 No Action Required
- 11 Test Repeated
- 22 Care Giver Notified
- 10 Clean Exterior of Meter

Critical values are verified by repeat analysis. If a critical value is verified by repeat analysis, a specimen must be sent to the chemistry department for retesting

Detection of Data Errors Procedure

1. The coordinator will review monthly 10 – 15 patients test results generated from the I-Stat meter.
2. This selection will be made randomly.
3. Results will be checked for accuracy between QCM3 program and the Cerner input. Any discrepancies will be documented in an incident report and sent to the Pathology Performance Improvement Committee.
4. The coordinator will verify the review of these documents by initialing the package of results.

IX. Maintenance

1. Clean the display screen with a soft dry tissue. Clean the case using a gauze pad moistened with a mild soap and water, rinse using another gauze pad moistened with water and dry.
2. Decontaminate the analyzer whenever a specimen is spilled onto the analyzer.
 - ❖ Use 1:10 solution of household bleach on a gauze pad.
 - ❖ Squeeze the pad to remove excess solution.
 - ❖ Rinse with gauze pad moistened with tap water.
3. Replace 9 volt batteries as necessary (A minimum of 250 uses can be expected).
 - ❖ The analyzer will indicate when replacement is needed with a message on the display screen.
 - ❖ The battery compartment is accessed through a door on the underside of the analyzer.

X. PROFICIENCY TESTING

Proficiency testing (currently available thru CAP) will be performed three times per year. The results will be returned to the outside testing institute by specific date. If the results are not at least 80 % acceptable, the unacceptable grade will be reported to the Medical Director.

1. P.O.C staff will distribute Quarterly proficiency testing samples to the operators of the I-Stat in designated located.
2. Operators for the I-Stat will run the proficiency specimen in proficiency testing mode.
Proficiency specimens will be processed as patient specimens.
3. P.O.C staff will send the Proficiency Test results to the Accrediting Agency (CAP).
4. The evaluation report is reviewed by the Medical Director.
5. Corrective Action plan (if necessary) will be documented and implemented as necessary by the Department for Nursing

XI. EMPLOYEE CERTIFICATION

Personnel Competency Evaluation

Personnel certification is completed upon in-serving, and is required to be renewed six months after first training and annually thereafter. Documentation of certification is maintained in the employee's personnel folder.

Training and certification of nursing personnel will be conducted by the Institute of Continuous Learning annually.

Participants must demonstrate competency in the use of I-Stat. This according to the established validation criteria:

- a). Visual Observation of the operator performing the test and ensuring that written policy and procedures are consistently followed.
- b). Evaluation of a problem solving skills.
- c). Assessment of testing performance through an external proficiency testing (CAP)
- d). Direct observation of instrument maintenance and function checks.
- e). Monitoring the recording and reporting of test results.
- f). Review of intermediate test results (QC, PT results, and preventive maintenance).

XII. PERFORMANCE IMPROVEMENT

The summary of the QA report will be prepared monthly by the Point of Care staff and reviewed by the pathology Performance Improvement Chairperson and then sent to the designated Nursing Quality representative, Director of Nursing, Assistant Director of nursing who will share the information with there respective Head Nurses and there Clinical Staff members.

Appropriate corrective responses will be generated and forwarded to the Point of Care Staff who will then forward to the Pathology Performance Improvement Chairperson. A Copy of this report will be forwarded to the Institute of Continuous Learning to be distributed to there educators.

XIII. VALIDATION

- A. Implementation and Validation of I-Stat Instruments.
To ensure system performance accuracy, assess potential for error; identify method to method differences and to meet regulatory guidelines, all instruments must be calibrated and checked for linearity, accuracy, precision and correlations done with reference method before placing for patient testing.
- B. Criteria for accepting I-Stat in place for patient testing.
 1. **Precision** must be checked and 3 levels of controls will be used (Low, Normal, High). Three (3) replicates measurements must be performed. Precision data will be noted as acceptable if the % coefficient of variation $CV \leq 6\%$ on all levels.
 2. **Linearity** must be verified. The five (5) levels of presets values will be run 3X on each instrument. This procedure will be performed every 6 months on each instrument in use. Linearity verification must meet the acceptable ranges provided by the manufactures linearity material.
 3. **Correlation studies** must be conducted, comparing results between the current reference instrumentation method used in the Chemistry Blood Gas Analyzer and the I-Stat that needs to be implemented. This is done twice (2) per year. Correlation must be performed between the I-Stat analyzers when implementation of new instrumentation is considered. Three (3) samples must be used. Correlation studies will be acceptable if the measured result between instruments. An Acceptable Correlation factor is between 0.95-1.05.
 4. Acceptance of I-Stat Cartridges with a New Lot number. This will be performed to verify that the I-Stat Cartridges with a new lot number are in compliance with the manufacture.
 5. The laboratory will perform and document studies to validate the adequacy of limiting daily QC to the electronic QC by initially validating external QC and internal QC daily for 20 days.

XIV REFERENCE

1. I-Stat System Manual-Distributed By Abbott

PROCEDURE FOR COLLATERAL CIRCULATION TESTING OF THE ARM

PURPOSE: This procedure is designed to test patient's wrist collateral blood flow prior to performing an arterial puncture for blood gases analysis.

DEFINITION: The hand is normally supplied by blood from the ulnar and radial arteries as seen in the figure below. The arteries undergo anastomosis in the hand. Thus, if the blood supply from one of the arteries is compromised, the other artery can supply adequate blood to the hand. A minority of people lack this dual blood supply (an anatomical variant). If blood is drawn from the artery in people with this problem or have thrombosis of the ulnar artery (Hypothenar Hammer Syndrome), the hand may be placed at risk of ischemia if embolization or a thrombus occludes the radial artery. This procedure is sometimes called the Allen test.

PROCEDURE:

1. Patient elevates their hand and makes a fist for 20 seconds
2. Firm pressure is held against both the radial and ulnar arteries with thumb and fingers
3. Patient opens their hand and it should blanch white
4. Examiner releases ulnar compression only

Normal result:

Hand color flushes returning to its pink color within 6 seconds if circulation through that artery is adequate.

Abnormal result

Hand remains white until radial pressure released. This indicates inadequate collateral circulation and risk of serious hand ischemia if vessel spasm occurs.

If result is abnormal (negative Allen test), consult with clinician /do not perform phlebotomy from radial artery.

Reference

Allen test and systolic arterial pressure in the thumb.

Husum B, Berthelsen P.

[Br J Anaesth 1981; 53\(6\): 635-7](#)

