Adventist HealthCare

TRAINING UPDATE

Lab Location: GEC
Department: Core lab

Date Distributed: 2/9/26
Due Date: 2/23/26
Implementation: 2/9/26

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
GEC.C35.6 i-STAT 1 System for Arterial and Venous Blood Gas
Description of change(s):
Updated AMR for PO2

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**i-STAT 1 System for Arterial and Venous Blood Gas**
Prepared by	Judy Codling/Cynthia Reidenauer Date: 3/25/2012
Owner	Robert SanLuis Date: 3/25/2012

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Test Code
Blood Gas, Arterial or Venous	i-STAT 1 System	GBG (arterial) GBGV (venous)
Synonyms/Abbreviations		
ABG, VBG		

Department
GEC Lab Only

2. ANALYTICAL PRINCIPLE

The i-STAT 1 Analyzer is intended for use with i-STAT cartridges for in vitro quantification of various analytes in whole blood. The i-STAT System incorporates comprehensive components to perform blood analysis at the point of care. The System consists of a hand-held analyzer and single-use disposable cartridges. The analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration, and continuous quality monitoring. Analyzers with thermal control capability for testing at 37°C and cartridges requiring thermal control are labeled with a 37° symbol.

Blood Gas
PH and PCO2 are measured by direct potentiometry. Concentrations are calculated from the measured potential through the Nernst equation.
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.
sO2 is calculated from measured PO2 and pH and from HCO3 calculated from measured PCO2 and pH.
When the cartridge includes sensors for both pH and PCO2, bicarbonate (HCO3), total carbon dioxide (TCO2) and base excess (BE) are calculated.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Specimens are collected via routine arterial puncture or venipuncture. When filling a blood gas syringe with arterial blood, avoid bubbles; exposure to air may increase PCO2.

Component	Special Notations
Special Collection Procedures	**In-dwelling lines**: it is recommended to withdraw three to six times the volume of the catheter, connectors, and needle to remove intravenous solutions, heparin, and or medications that may contaminate the sample. Avoid drawing specimens from extremity with I.V. Avoid prolonged tourniquet use and clenching and unclenching the fist.
Other	Mix anticoagulated samples by rolling the syringe between palms for at least 5 seconds in two different directions. Invert the syringe repeatedly for at least 5 seconds, and then discard the first 2 drops of blood prior to testing.

3.2 Specimen Type & Handling

Criteria		
Type	**-Preferred**	Arterial or Venous blood
	-Other Acceptable	None
Collection Container		**Arterial:** Plain syringe, heparinized syringe **Venous:** Lithium or sodium heparin collection tube (green top, any size)
Volume	**- Optimum**	**Arterial**: 2 mL in a syringe **Venous**: ¾ to full tube
	- Minimum	2mL
Transport Container and Temperature		Capped syringe or collection tube at room temperature
Stability & Storage Requirements	Room Temperature:	10 minutes
	Refrigerated:	Not established
	Frozen:	Unacceptable
Timing Considerations		Test immediately if collected in a plain syringe or collection tube
Unacceptable Specimens & Actions to Take		Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Additional Criteria for Specimen Rejection: 1. Evidence of clotting 2. The sample is under-filled for ionized calcium analysis. 3. Syringe for pH, PCO2, and PO2 with air bubbles in the sample Request a recollection and credit the test with the appropriate LIS English text code for “test not performed” message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics		Hemodilution and Hemolysis

Criteria	
Other Considerations	N/A

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Blood Gas Cartridge (EG7+)	Abbott 03P76-25

4.2 Reagent Preparation and Storage

Assay Kit	
Reagent	iSTAT cartridge for Blood Gas
Storage	Store at 2-8ºC Working supply is stored at room temperature (18-30°C)
Stability	**Refrigerated**: until expiration date printed on box **Room Temperature**: 2 months, re-date with new expiration date when removed from refrigerator
Preparation	A cartridge should not be removed from its protective pouch until it is at room temperature (18-30°C). Allow a single cartridge to warm at room temperature for 5 minutes and a box for 1 hour. Use a cartridge immediately after removing from the protective pouch, prolonged exposure may cause a cartridge to fail QC

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
TriControl Calibration Verification	Abbott Cat. No. 05P70-01

5.2 Calibrator Preparation and Storage

Calibrator	TriControl Calibration Verification
Preparation	Allow the **blood gas** ampule to equilibrate for 4 hours at room temperature before testing.
Storage/Stability	2-8ºC, until manufacturer's expiration date

5.3 Calibration Verification Procedure

Criteria	Special Notations
Frequency	Every 6 months
Tolerance Limits	Each result must be within the acceptable ranges printed on the value assignment sheet for that analyte.
Procedure	1. Program all calibrators using the quality test menu, select calibrator, and follow prompts. 2. Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phase. 3. Snap off the top of the ampule. Using a plain syringe or pipette transfer the solution into a cartridge. 4. Immediately seal the cartridge and insert it into the analyzer.

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
G7 control level 1	Abbott 06F12-01
G7 control level 3	Abbott 06F14-01

6.2 Control Preparation and Storage

Control	G7 controls
Preparation	Allow the **blood gas** ampule to equilibrate for 4 hours at room temperature before testing.
Storage/Stability	2-8ºC. Controls may be stored at room temperature (18-30°C) for 5 days. Do not use after expiration date on box and ampules.

6.3 Frequency

- The instrument is programmed to run the internal Electronic stimulator every 8 hours when there is a Patient.
- The external Electronic Simulator is run once a day.
- The liquid controls are run once a week and with each new shipment of cartridges.

To enter QC results in Unity Real Time:

1. Log into Unity Real Time
2. Select Lab "224844 GEC Manual tests"
3. Open Blood Gas QC level 1 and enter results
4. Open Blood Gas QC level 3 and enter results
5. SAVE

6.4 Tolerance Limits and Criteria for Acceptable QC

Each result must be within the acceptable ranges printed on the **value assignment sheet for that analyte.**

Step	Action
1	**Run Rejection Criteria** • Anytime the established parameters are exceeded, the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
2	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.

"*" Instead of results**

Stars appear in place of results if the analyzer detects that the sensor's signal is uncharacteristic. Cartridges that have been stored improperly may show "***" instead of results. Check the supply of cartridges in use with a control solution. If the control results are starred, discontinue use of this supply of cartridges. Aged specimens may contain products of metabolism that can interfere with the test(s). A fresh sample should be tested. If the stars reappear there may be an interferent present. When flags occur, the specimen must be tested on a different iSTAT in order to obtain results. **Contact the Tech in Charge at SGMC for a replacement iSTAT.**

6.5 Documentation

- QC tolerance limits are programmed into Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of cartridges and each subsequent shipment of the same lot of cartridges must be tested with external control material and all values must be within the acceptable range before patient testing is done.
- Training must be successfully completed and documented prior to performing this testing.
- The Laboratory participates in CAP proficiency testing.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

iSTAT analyzer

7.2 Equipment

Electronic Simulator
iSTAT Printer
Downloader

7.3 Supplies

N/A

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Set-up Protocol
1.	Press the On/Off key to turn analyzer on.
2.	Press 2 for i-STAT Cartridge from the Test Menu.
3.	Scan or Enter Operator ID. Repeat if prompted.
4.	Scan or Enter Patient ID. Repeat if prompted.
5.	Scan Cartridge Lot number from the cartridge portion pack, or box.

8.2	Specimen Preparation
1.	Mix specimen well before testing: • For a syringe, roll between palms for at least 5 seconds in two different directions. Then invert the syringe repeatedly for at least 5 seconds. Discard the first 2 drops of blood. • For collection tube, remix by gentle inversion at least 10 times.

8.3	Test Run
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.	Discard 1 drop of sample from the delivery device to clear unseen bubbles. Direct the dispensing tip containing the blood into the sample well.
3.	Dispense the sample until it reaches the FILL TO mark on the cartridge. Leave some sample in the well.
4.	Close the cover over the sample well until it snaps into place. (Do not press over the sample well.)
5.	Insert the cartridge into the cartridge door until it clicks into place.
6.	The Time to Results countdown bar will then be displayed. Once time has elapsed, view results on analyzer's display.
7.	Remove cartridge after Cartridge Locked message disappears. The analyzer is ready for the next test immediately.
8.	Dock the analyzer for result printing and enter results manually into LIS.

8.4	Special Handling
1.	Do not attempt to remove the cartridge while the Cartridge Locked message is displayed
2.	The analyzer must remain on a level surface with the display facing up during testing.
3.	Motion of the analyzer during testing can increase the frequency of suppressed results quality check codes

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

The Analyzer contains a microprocessor that performs all calculations required for reporting results.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

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.
   Action: Repeat analysis and if results still have flags indicating the result is above or below the reportable range, report accordingly.

2. Results which are un-reportable based on internal QC rejection criteria are flagged with "****".
   Action: Repeat analysis using another cartridge. The results not suppressed should be reported in the usual manner. If the result is suppressed again, perform testing on a different iSTAT. **Contact the Tech in Charge at SGMC for a replacement iSTAT.**

3. Results will not be reported if a test cycle has a problem with the sample, calibrant solution, and sensors, mechanical or electrical functions of the analyzer.
   Action: Refer to the I-stat System Manual's Troubleshooting section if necessary.

10.1.1 Base Excess vs Base Deficit for Arterial and Venous Blood Gas:

On the iSTAT printout you will see a result for BEecf. If this is a negative number you will result this in the BD test result space as the Base Deficit. If this is a positive number you will result the value in the BE space for Base Excess.
If you answer the Base Deficit, then "hide" the Base Excess.
If you answer the Base Excess, then "hide" the Base Deficit.

10.2 Rounding

N/A

10.3 Units of Measure

Refer to Addendum 1

10.4 Clinically Reportable Range (CRR)

Refer to Addendum 1

10.5 Review Patient Data

Review patient results for unusual patterns, trends or distributions in patient results, such as an unusually high percentage of abnormal results. Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

Repeat testing is only performed if requested by the medical staff.

11. EXPECTED VALUES

11.1 Reference Ranges

Refer to Addendum 1

11.2 Critical Values

Refer to Addendum 1

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
pH	Exposing the sample to air	Prolonged tourniquet application and forearm exercise
PCO2	Airway obstruction, sedatives, anesthetics, respiratory distress syndrome, and chronic obstructive pulmonary disease	Hypoxia due to chronic heart failure, edema and neurologic disorders and mechanical hyperventilation
PO2		Airway obstruction, trauma to the brain, bronchitis, emphysema, pulmonary edema, and congenital defects in the heart

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved
- **Validated Test Modifications:** None

Hemodilution by more than 20% may cause clinically significant error on ionized calcium.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

Refer to Addendum 1

14.2 Precision

N/A

14.3 Interfering Substances

Refer to Addendum 2

14.4 Clinical Sensitivity/Specificity/Predictive Values

N/A

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Safety Data Sheets (SDS)
4. Critical Values (Lab policy)
5. Abbott iSTAT 1 System Manual
6. Current package insert for iSTAT EG7+ cartridge
7. *i-STAT Operation and Testing* 001-18-008, Adventist HealthCare Point of Care Policy Manual
8. i-STAT 1 System Maintenance Log (AG.F213)
9. i-STAT Daily QC Simulator Log (AG.F214)

17. REFERENCES

1. Procedure Manual for the i-STAT System, Abbott Point of Care. ART: 714446-00V, Revised 09/22/2016

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes GEC C052.001		

Version	Date	Section	Reason	Reviser	Approval
000	10/14/14	6.3	Replace QC entry instruction for LIS with Unity Real Time	A Chini	R SanLuis
000	10/14/14	6.6	Replace LIS with Unity Real Time, add QC review process	A Chini	R SanLuis
000	10/14/14	16	Add forms	L Barrett	R SanLuis
000	10/14/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis
1	2/27/17	3.1,8.2	Add mixing instructions	L Barrett	R SanLuis
1	2/27/17	3.2	Add timing specifics	L Barrett	R SanLuis
1	2/27/17	4,5,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
1	2/27/17	4.2	Update stability	R Bridges	R SanLuis
1	2/27/17	6.1	Correct QC level to 1 & 3	L Barrett	R SanLuis
1	2/27/17	6.3	Update Unity instructions	L Barrett	R SanLuis
1	2/27/17	7.2	Update printer	L Barrett	R SanLuis
1	2/27/17	10.5	Move patient review from section 6	L Barrett	R SanLuis
1	2/27/17	15	Update to new standard wording	L Barrett	R SanLuis
1	2/27/17	17	Update reference revision date	L Barrett	R SanLuis
2	2/20/19	Header	Change parent facility	L Barrett	R SanLuis
2	2/20/19	3.1	Add to discard first 2 drops of blood after mixing anticoagulated samples	L Barrett	R SanLuis
2	2/20/19	4.1	Update catalog number	L Barrett	R SanLuis
2	2/20/19	8.3	Revise step 8 to manually enter results	L Barrett	R SanLuis
3	1/30/20	3	Delete finger and heel stick collections	L Barrett	R SanLuis
3	1/30/20	16	Update POC policy title	L Barrett	R SanLuis
3	1/30/20	19	Add addendum 3	L Barrett	R SanLuis
4	9/25/23	2	For pH and PCO2 updated word "ion" potentiometry to "direct" to match PI	D Collier	R SanLuis
4	9/25/23	4.1	Updated cartridge to EG7+	D Collier	R SanLuis
4	9/25/23	5	Updated Calibrator info	D Collier	R SanLuis
4	9/25/23	6.1, 6.2	Updated QC name	D Collier	R SanLuis
4	9/25/23	6.3	Updated entering results into Unity	D Collier	R SanLuis
4	9/25/23	16	Updated package insert to EG7+	D Collier	R SanLuis
4	9/25/23	19	Removed Addendum 3	D Collier	R SanLuis
4	9/25/23	Add1	Updated AMR to package insert	D Collier	R SanLuis
4	9/25/23	Add 3	Removed	D Collier	R SanLuis
5	2/9/26	Add 1	Updated PO2 AMR	R SanLuis	R SanLuis

19. ADDENDA

Addendum	Title
1	Reference / Critical / Reportable Ranges
2	Interferences

Addendum 1

REFERENCE / CRITICAL / REPORTABLE RANGES

ANALYTE	UNIT	REFERENCE RANGE	CRITICAL RANGE	REPORTABLE RANGE (AMR)
pH Arterial		0-30D 7.30-7.42 31D-17y 7.37-7.44 > 18y 7.35-7.45	All ages <7.21, >7.59	6.50 – 8.20
PCO2 Arterial	mmHg	0-30D 35.0-50.0 31D-17y 40.0-52.0 > 18y 41.0-51.0	Pediatric 31D-17yr <21.0, >66.0 Adult <19.0, >67.0	5 - 130
PO2 Arterial	mmHg	0-30D 54-62 31D-17y 80-100 > 18y 80-105	0-30D <37, >92 31D-17y <45,>124 > 18y <43	15-600
%02 Arterial	%	None defined	None defined	48.2-99.6
Base excess/ Base deficit Arterial	mmol/L	0-30D -3 to -7 31D-17y -2 to +2 > 18y -2 to +3	None defined	-30 to +30
HCO3 Arterial	mmol/L	0-30D 17.6-22.8 31D-17y 22.0-26.0 > 18y 22.0-26.0	None defined	1.0-85.0
pH Venous		0-30D 7.320-7.460 31D-17y 7.31-7.41 > 18y 7.31-7.41	None defined	6.852-8.106
PCO2 Venous	mmHg	0-30D 35.0-50.0 31D-17y 40.0-52.0 > 18y 41.0-51.0	None defined	17.5-91.0
PO2 Venous	mmHg	0-30D 30-60 31D-17y 30-50 > 18y 40	None defined	15-600
%02 Venous	%	None defined	None defined	48.2-99.6
Base excess/ Base deficit Venous	mmol/L	31D-17y -2 to +2 > 18y -2 to +3	None defined	-30 to +30
HCO3 Venous	mmol/L	0-30D 20.0-26.0 31D-17y 22.0-28.0 > 18y 23.0-28.0	None defined	1.0-85.0

Addendum 2

INTERFERENCES

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
pH	Standing anaerobically at RT		Decrease (↓)by 0.03 pH units / hr
PCO2	Standing anaerobically at RT		Increase (↑) by 4 mmHg / hr
PO2	Exposure to air Standing anaerobically at RT Cold samples	Values <150mmHg Values > 150mmHg	Increase (↑) Decrease (↓) Decrease (↓)by 2-6 mmHg / hr Falsely elevated