# Purpose

The purpose of this policy is to provide fast, accurate quantitative whole blood measurements for blood gases, electrolytes, BUN, and ionized calcium on the i-STAT system. The sodium, potassium, chloride, ionized calcium, and POC2 are measured by electrode potentiometry. The PO2 is measured amperometrically. The HCT is determined conductometrically. As a point of care instrument, the i-STAT reduces turn-around time, producing accurate results without extensive preparation and maintenance.

# Scope

This document applies to Anesthesia and Perfusion teammates of the Operating Room within Advocate Health Inc. entities in the Southeast Region Wake Market, to include High Point Medical Center (HPMC).

# Definitions

Not Applicable

# Policy Guidelines

1. Equipment and Supplies

Cartridges

* 1. Store the main supply of cartridges at 2º to 8ºC (35 to 46ºF). DO NOT allow cartridges to freeze. Cartridges may be stored at room temperature (18º to 30ºC or 64º to 86ºF) for two months. Cartridges should never be returned to the refrigerator once they have been at room temperature above 30ºC (86ºF). Mark the calendar on the box to indicate the two-month room temperature expiration date. Cartridges should remain in pouches until time of use. DO NOT use after the labeled expiration date.

Quality Control Reagents

* 1. I-STAT Controls
		1. Store at 2º to 8º C (35º to 46ºF). Do not use after expiration date on the box and ampules. With each new shipment, random samplings of cartridges are selected. QC must be performed with each new shipment and/or lot number change, as well as every 30 days of storage.
	2. Electronic Simulator
		1. Store at room temperature and protect contact pads from contamination by placing the Electronic Simulator in its protective case. The electronic simulator should be performed if the instrument is dropped or when the indicated by the i-STAT instrument that the internal simulator fails.
	3. Internal Electronic Simulator
		1. Is ran every 8 hours of use for each different cartridge type. The internal electronic simulator is activated when a filled test cartridge is inserted into the analyzer. This automatic simulator is a circuit in the analyzer, it verifies the electrical measurements of the analyzer and performs the same function as the external simulator. If 8 hours have elapsed, the analyzer will automatically perform the internal test before the sample is analyzed, this usually adds 15-20 seconds to the test cycle.
		2. If the internal electronic simulator fails, the instrument will send notification. If the internal electronic simulator fails, run the external electronic simulator. If the external simulator fails, take the instrument out of service and notify the Point of Care Specialist.

Specimen Requirements and Storage

* 1. Fresh whole blood collected in a plastic syringe without anticoagulant. Test within 3 minutes of collection.
	2. Fresh whole blood collected and or in a collection tube or syringe with lithium or sodium heparin anticoagulant. (Fill tubes to capacity; fill syringes for correct blood to heparin ratio). Test within 10 minutes of collection.
1. Procedure
2. Preparation for Use
	1. All cartridges that require thermal control at 37ºC should stand at room temperature for four hours before use (individually or an entire box). Individual cartridges not requiring thermal control may be used after standing just 5 minutes at room temperature. An entire box should stand at room temperature for one hour.
3. Procedure
	1. Scan or manually enter an operator ID number.
	2. Scan or manually enter the patient CSN number.
	3. Scan the cartridge barcode information.
	4. Collect the blood sample.
	5. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
	6. Direct the syringe top or need tip containing the blood into the sample well.
	7. Dispense the sample until it reaches the fill mark on the cartridge. Leave some sample in well.
	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 when required (arterial, venous, CBG)
	11. View results shown on the analyzer’s display screen.
4. Alternative Procedure
	1. Should the i-STAT System become inoperable for any reason, specimens should be collected and submitted to main lab or respiratory.
	2. If the computer system is down a downtime form should be used to record patients results.
	3. Calculations
		1. The i-STAT analyzer contains a microprocessor that performs all calculations required for reporting results.
	4. Suppressed Results
		1. There are three conditions under which the i-STAT System will not display results
5. Results outside the system’s reportable ranges are flagged with a “<” or “>,” indicating that the results is below the lower limit or above the upper limit of the reportable range respectively. See the table of reportable ranges. Action: Send specimen(s) to the laboratory for analysis.
6. Results which are unreportable based on internal QC rejection criteria are flagged with “\*\*\*\*.” Action: Analyze the specimen again using 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 or respiratory for analysis in accordance with the Laboratory Procedure Manual.
7. Results will not be reported if a test cycle has a problem with the sample, calibrant solution, sensors, and mechanical or electrical functions of the analyzer. Action: Take the action displayed with the message that identifies the problem. Refer to the i-STAT System Manual’s Troubleshooting section if necessary and send the analyzer to the POCT Manager for assistance.
8. Reporting Results
	1. Normal Results
		1. The results are verbally given to the anesthesiologist or surgeon.
	2. Unexpected or Unexplained Values
		1. If unexpected abnormal readings are noted on the analyzer, the anesthesiologist and perfusionists are notified. (Perfusionists are notified if on by—pass).
		2. If unexpected abnormal results are encountered, the specimen is to be recollected.
		3. If unexpected abnormal results continue, a new patient samples is sent to the laboratory and/or respiratory therapy for testing.
		4. If i-STAT continue to produce “questionable” results, refer to the POCT Manager for assistance.
9. Transmitting Results
	1. Place the analyzer in the cradle of an IR Interface or Link. The IR status light must be green.
	2. Do not move the analyzer while “transmitting” is displayed. During transmission, the IT status light will blink alternately red and green. If transmission is successful, the IR Link will emit a single high pitched beep and the light will return to green. An unsuccessful transmission is indicated by three low tone beeps. In this case, repeat the transmission process. The analyzer must be docked twice per day.
10. Liquid Quality Controls

Liquid quality controls performed by testing personnel. Refer to the appropriate package insert and i-STAT System Manual for additional handling information and details.

1. i-STAT Liquid Tri-Controls—Used to verify the blood gas, hematocrit, chemistry, and electrolyte sensor performance.
2. Store at 2º to 8ºC (35º to 46ºF) through package expiration date.
3. Controls may be stored at room temperature (18º to 30ºC or 64º to 86ºF) for five days.
4. Do not use after expiration date on the box and ampules.
5. Protect fingers with gauze or tissue when opening vial.
6. If oxygen is being tested, QC material should be equilibrate to room temperature for 4 hours prior to use. Test sample immediately after opening.
7. ACT Liquid Controls—Used to validate performance of i-STAT ACT test cartridges.
8. CAUTION: Handle using standard precautions. This product contains human plasma.
9. Store at 2º to 8ºC through package expiration date.
10. Equilibrate at room temperature for 45 minutes prior to use.
11. Refer to package insert or i-STAT System Manual for additional reconstitution information. Carefully follow timing instructions.
12. Supply Temperature Indicator upon delivery
13. Liquid Quality Control (LQC) is used to verify the integrity of the test cartridges. Appropriate liquid controls should be used to test all analytes. Refer to the i-STAT System Manual for the most current list of available liquid controls.
14. New Cartridge Shipments: LQC checks verify the acceptable integrity of the i-STAT cartridges when they are received from the manufacturer. LQC should be tested on each lot number of each cartridge type received.
15. i-STAT cartridges are shipped refrigerated with a temperature indicator to monitor temperature during transit. The record of receipt is checked and documented.
16. If all windows are white, or if only the ‘A/1’ or ‘B/1’ windows have changed color, then transit temperatures were satisfactory.
17. If any or all of the ‘C/3’ or D/4’ windows have changed color:
18. Quarantine the suspect cartons.
19. Save the temperature card and contact Abbott Tech Support at 1-800-366- 8020 for assistance.
20. Do not use the cartridges from the suspect cartons.
21. Questionable Cartridge or Analyzer Performance: If the cartridge or analyzer performance is in doubt, then LQC checks may also be performed.
22. The supply Inventory form must be completed after evaluating cartridge shipping, liquid quality control, at each shipment.
23. All supply that is shipped with correct temperature indicator, green sticker “Ready for Use” each box with initial and date and refrigerate.

**Reference Ranges and Reportable Ranges:**

**Reference (normal) range** means the range of test values expected from 95% of fasting individuals presumed to be healthy. Our reference ranges come from the normal ranges established by the Clinical Laboratory at Atrium Health Wake Forest Baptist Medical Center and from the i-STAT System Manual (manufacturer IFU). Literature based references used by the Clinical Laboratory include Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics, Henry’s Clinical Diagnosis Management by Laboratory Methods, 23rd Edition (Adults), and Nathan and Oski’s Hematology of Infancy and Childhood, Sixth Edition (Pediatrics).

**Reportable range** means the range of test values over which i-STAT results have been shown to be valid.

The following table contains the Reference Ranges and Reportable Ranges applicable to the i-STAT. Reference the i-STAT System Manual for information not listed in this document.

|  |  |  |  |
| --- | --- | --- | --- |
| **Analyte** | **Unit** | **Reference Range** | **Reportable Range** |
| **Sodium** | mEq/L or mmol/L | 18y: 135-146 | 100-180 |
| 2y: 136-143 |
| 0: 133-142 |
| **Potassium** | mEq/L or mmol/L | 18y: 3.5-5.3 | 2.0-9.0 |
| 9y: 3.5-5.5 |
| 5y: 3.5-5.0 |
| 1y: 3.5-5.5 |
| 3m: 4.0-6.5 |
| **Ionized Calcium** | mmol/L | 1.00-1.30 | 0.25-2.250 |
| **pH** |  | Arterial: 7.350-7.450Venous: 7.310-7.410Capillary: None Defined | 6.50-7.70 |
| **pCO2** | mm/Hg | Arterial: 32-45Venous: 41-51Capillary: None Defined | 15-115 |
| **pO2** | mm/Hg | Arterial: 80-100Venous: None Defined Capillary: None Defined | 15-400 |
| **Hematocrit**(Male) | %PCV | 18y: 42-52 | 15-72 |
| 12y: 37-49 |
| 6y: 35-45 |
| 2y: 34-40 |
| 6m: 33-39 |
| 3m: 29-41 |
| 2m: 28-42 |
| 1m: 31-55 |
| 14d: 39-63 |
| 7d: 42-66 |
| 1d: 45-67 |
| 0d: 42-60 |
| **Hematocrit**(Female) | %PCV | 18y: 37-47 | 15-72 |
| 12y: 36-46 |
| 6y: 35-45 |
| 2y: 34-40 |
| 6m: 33-39 |
| 3m: 29-41 |
| 2m: 28-42 |
| 1m: 31-55 |
| 14d: 39-63 |
| 7d: 42-66 |
| 1d: 45-67 |
| 0d: 42-60 |
| **Hemoglobin**(Male) | g/dL | 18y: 14-17.5 | 5.1-25.5 |
| 12y: 13-16 |
| 6y: 11.5-16.5 |
| 2y: 11.5-13.5 |
| 6m: 10.5-13.5 |
| 3m: 9.5-13.5 |
| 2m: 9-14 |
| 1m: 10-18 |
| 14d: 12.5-20.5 |
| 7d: 13.5-21.5 |
| 1d: 14.5-22.5 |
| 0d: 13.5-19.5 |
| **Hemoglobin**(Female) | g/dL | 18y: 12.5-15.3 | 5.1-25.5 |
| 12y: 12-16 |
| 6y: 11.5-16.5 |
| 2y: 11.5-13.5 |
| 6m: 10.5-13.5 |
| 3m: 9.5-13.5 |
| 2m: 9-14 |
| 1m: 10-18 |
| 14d: 12.5-20.5 |
| 7d: 13.5-21.5 |
| 1d: 14.5-22.5 |
| 0d: 13.5-19.5 |
| **ACT (Activated Clotting Time)****Celite Activated** | Seconds | Celite-Non warmNon-Heparinized84-139 | 50-1000 |

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1. Critical Ranges

 **Point-of-Care Testing (POCT) Critical Value Limits**

**Defined for Point of Care Testing by the Clinical Laboratory**

**in Conjunction with the Medical Directors for POCT User Sites**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Analyte** | **Method** | **Adult****(>18 yrs)** | **Pediatric****(>1 month-18 yrs)** | **Neonate** **(0-28 days)** | **Comments** |
| Glucose mg/dL | NOVA | <50 or >400 | <50 or >200 | <50 or >125 |  |
| Hematocrit % PCV | i-STAT | <=18 or >=60 | <=18 or >=60 | 0d <=18 or >=60.11d <=18 or >=67.13d <=18 or >=66.11w <=18 or >=63.1>=2w <=18 or >=60 | For hematocrit results to be considered critical, they should also fail the normal range defined for the patient's age. |
| Hemoglobin g/dL | i-STAT | <=6 or >=20 | <=6 or >=20 | 0d <=6 or >=201d <=6 or >=22.63d <=6 or >=21.61w <=6 or >=20.6>=2w <=6 or >=20 | For hemoglobin results to be considered critical, they should also fail the normal range defined for the patient's age. |
| INR Value (PT/INR) | i-STAT | >=5 or value not calculated | >=5 or value not calculated | >=5 or value not calculated | INR values equal to or greater than 4.0, as reported by i-STAT will have a reflex venous PT/INR ordered and sent to the Clinical Laboratory for confirmatory testing.  |
| Ionized Calcium mmol/L | i-STAT | <0.75 or >1.40 | <0.75 or >1.40 | <0.80 or >1.40 |  |
|  pCO2 mmHg | i-STAT | <25 or >60 | <30 or >80 | <35 or >80 |  |
| pH | i-STAT | <7.2 or >7.6 | <7.15 or >7.6 | <7.20 or >7.45 |  |
| pO2 mmHg | i-STAT | <50 or >200 | <30 or >200 | <30 or >200 | <30/<50 Arterial Only >200 All Sample Types (does not apply to OR/ECMO circuit arterial samples) |
| Potassium mmol/L | i-STAT | <3.0 or >6.0 | 3m <3.0 or >6.5>=1y <3.0 or >6.0 | 0d <3.0 or >6.27d <3.0 or >7.01m <3.0 or >7.5 | Unexpected results >6 should be verified by the laboratory.Hemolysis falsely elevates results. For potassium results to be considered critical, they should also fail the normal range defined for the patient's age. |
| Sodium mmol/L | i-STAT | <120 or >160 | <120 or >160 | <120 or >150 |  |
| Total CO2 mmol/L | i-STAT | <10 or >40 | <10 or >40 | <10 or >40 |  |

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1. Daily Procedures
2. Verify the performance of each analyzer in the i-STAT System by internal simulator. Any device that fails an electronic simulator (internal or external) should be removed from service and turned in for maintenance.
3. Action
4. If PASS is displayed on the analyzer screen:
5. Remove the Electronic Simulator after the LCK message disappears from the display screen.
6. Transmit the result to the Central Data Station.
7. Use the analyzer as required.
8. Remedial Action
9. If FAIL is displayed on the analyzer screen:
	* 1. Repeat the procedure with the same Electronic Simulator. If PASS is displayed, use the analyzer as required.
		2. If FAIL is displayed repeat the procedure with a different Electronic Simulator.
	1. If PASS is displayed with the second Electronic Simulator:
		1. Use the analyzer as required.
		2. Deliver the questionable Electronic Simulator to the POCT Manager.
	2. If FAIL is displayed with the Second Electronic Simulator:
		1. DO NOT analyze the patient samples with the analyzer.
		2. Deliver the faulty analyzer to the POCT Manager.
10. Verification of Cartridge Storage Conditions
11. Refrigerated Cartridges
12. Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes. Deliver any expired cartridges to the POCT Manager.
13. Verify that the refrigerator did not exceed the limits of 2º to 8ºC (35º to 46ºF).
14. **Action**: If the temperature of the cartridge storage refrigerator is within the range of 2º to 8ºC (35º to 46ºF) use cartridges as required.
15. **Remedial Action**: If the temperature is outside the range of 2º to 8ºC (35º to 46ºF), quarantine the cartridges in the storage refrigerator. Notify the POCT Manager immediately. DO NOT USE the cartridges from the out-of-control refrigerator. Record the QC failure in the i-STAT QC Log along with the action taken.
16. Room Temperature Cartridges
	1. Verify that all boxes of cartridges at room temperature have been out of the refrigerator less than two months.
	2. **Action**: If the measured temperature of the room has been continuously above 30ºC (86ºF) for any period of time:
17. Quarantine the cartridges.
18. Notify the POCT Manager immediately.
19. DO NOT USE the cartridges.
20. Record the out-of-control event in the i-STAT Electronic QC Log and the action taken.
21. Calibration
22. Calibration is automatically performed as part of the test cycle on each cartridge. Operator intervention is not necessary.
23. Maintenance
24. Disinfect when visibly soiled and between each patient using an approved disinfectant wipe, making sure to adhere to the contact time indicated
25. Do not allow moisture to enter the unit enclosure.

# References

None

# Attachments

Downtime ABG Report

Cartridge Supply Inventory

# Revision Dates

5/21, 10/22, 10/23, 9/24

|  |
| --- |
| **Downtime ABG Report** |
| **High Point Regional Health** |
| Patient's Name:  | Location:  |
| Acct. #:  | Physician:  |
| MR #:  | Date and Time Drawn:  |
| Drawn By:  |
| **Patient Information:** |  | **Results:** | **Results:** |
| Site:  | pH:  | Ca+:  |
| Allen's Test:  | PCO2:  | Na:  |
| O2 Equip:  | PO2:  | Hct:  |
| O2 (lpm):  | HCO3:  |  |
| FiO2:  | Base:  |  |
| VT:  | tHb:  |  |
| Rate:  | sO2:  |  |
| CPAP/PEEP:  | O2Hb:  |  |
| PS:  | COHb:  |  |
| Pt Temp:  | tCO2:  |  |
| K+:  |
| Lac:  |
| Ran By:  | Time:  | Date:  |
| RBV To:  | Time:  | Date:  |
| By:  |
| Please refer to Respiratory Care for Reference Ranges Form Updated: 11/22 |

 **Point of Care Testing**

 **i-STAT Supply Inventory**

Anesthesia:

Please complete this inventory record for all i-STAT cartridges currently stored in your location. Check all expiration dates on cartridges.

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

* **Inventory Completed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
* **Document the color of temperature indicator upon delivery of cartridges: \_\_\_\_\_\_\_\_\_\_**
	+ If the indicator show any signs of pink/red or blue color in the first two windows, the cartridges are acceptable.
	+ If any color other than white is in the last two windows the cartridges should be taken out of service, place in the refrigerator and labeled DO NOT USE.
	+ **Call** Abbott tech support 1-800-366-8020 –They will ask for information from the packing slip.
	+ Notify the Clinical Laboratory Point-of-Care Testing office.

Office phone: 336-781-2421; email: vjordan@wakehealth.edu

**If there are expired cartridges, Do NOT use for patient testing.**

**Immediately remove expired cartridges from use and mark as, “DO NOT USE”.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Cartridge Type or****QC** | **Quantity in Supply** | **Storage Conditions****Refrigerated or Room Temperature** | **Expiration Date** | **Are there any expired cartridges or liquid QC?****If so, indicate quantity and remove from use** |
| EG7 cartridge |  |  |  |  |
| Liquid Quality Controls- Level 1 |  |  |  |  |
| Liquid Quality Controls- Level 2 |  |  |  |  |
| Liquid Quality Controls- Level 3 |  |  |  |  |
| ACT-Celite cartridges |  |  |  |  |
| ACT-Celite -Liquid Quality Control Level 1 |  |  |  |  |
| ACT-Celite-Liquid Quality Control Level 2 |  |  |  |  |
| Calibration Verification |  |  |  |  |

Reviewed By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_