Documents Status: **Approved**

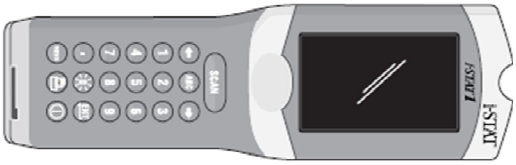
IDENT	labpoct100.013
Type of Document	Policy
Applicability Type	Cross-Organizational
Title of Owner	Network Dir Ops Lab&Path Svcs
Title of Approving Official	Medical Director of Clinical Laboratories
Date Effective	12/17/2018
Date of Next Review	10/31/2020

THE University of Vermont MEDICAL CENTER

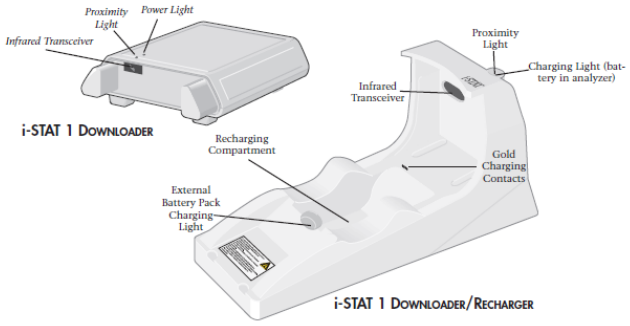
TITLE: **iSTAT TEST SYSTEM**

I. OVERVIEW AND INTENDED USE: The i-STAT analyzer is intended for use with i-STAT cartridges for *in vitro* quantification of various analytes and coagulation times in whole blood. The i-STAT System incorporates a comprehensive group of components needed to perform blood analysis at the point of care. A portable handheld analyzer, a cartridge with the required test, and 2 to 3 drops of blood will allow the caregiver to view quantitative test results for blood gas, chemistry and coagulation tests in approximately 2 minutes. The System consists of the following primary components:

Analyzer: A hand-held analyzer into which the blood-filled cartridge is placed for analysis automatically controls functions of the systems including fluid movement within the cartridge, calibration, and continuous quality monitoring.



iSTAT Downloader/Downloader/Recharger: The Downloader converts test records and transmits results to Epic. The Downloader/Recharger is also capable of recharging rechargeable batteries. The Downloader comes in two models:



Portable Printer: The printer can receive data directly from the analyzer via IR transmission. The printer can be recharged from a power adapter connected to an outlet. Only UVMMC Transport and Anesthesia/Perfusion use these printers.

UniPOC: UniPOC provides the primary information management capabilities for the i-STAT system. IR links and downloaders allow for transmission of patient records from a widely distributed network of analyzers to the POCCS server which communicates to UniPOC. Data can be stored, organized, edited and transferred to the laboratory information system (Sunquest) and then on to the UVMMC EHR, Epic. From UniPOC, cartridge usage and efficiency reports can be generated for management of the Test System.

Cartridges: A single-use disposable cartridge contains a microfabricated sensor array, a calibrant solution, fluidics system, and waste chamber. Sensors for analysis of sodium, potassium, chloride, BUN, creatinine, glucose, pH, pCO2, pO2, lactate and hematocrit are available in a variety of configurations (See Table 1).

II. SUPPLIES and STORAGE REQUIREMENTS:

1. Cartridges:

Store the main supply of cartridges at 2- 8°C (35 to 46°F). Do not allow cartridges to freeze. Cartridges may be stored at room temperature (18 - 30°C or 64 - 86°F) for the time frame indicated on the box and the foil pouches.

Room Temp Storage for 14 days: **Chem8, G, ACT, and CREA** Cartridges

Room Temp Storage for 2 months: **G3, CG4**, & **CG8** Cartridges

Cartridges should **never** 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 box or the cartridge to indicate the two-week or two-month expiration date immediately when removed from the refrigerator. Cartridges should remain in pouches until time of use. Do not use cartridge after the labeled expiration date. Do not use if storage conditions have been exceeded. Do not transport via pneumatic tube.

2. **Analyzer**: The operating and storage temperature for the i-STAT analyzer is 16-30^{0}C (61-86^{0}F). The analyzer monitors its own temperature and will not operate outside the acceptable temperature range. In addition, humidity should not exceed 90% non-condensing and barometric pressure should be between 300-850 mmHg. The analyzer has internal sensors to assure these are within range.

3. Quality Control:

- **i-STAT TriControls:** 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.
- **i-STAT Controls for ACT:** Store at 2 to 8°C (35° to 46°F). Do not use after expiration date on the box and vials. Controls should be used immediately after reconstitution.
- **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.
- **i-STAT Calibration Verification Set Linearity 1-5:** Store at 2 - 8°C (35-36°F). Do not use materials after expiration date. Observe manufacturer's handling instructions.
- **Eurotrol Hypoxic and Hyperbaric Controls**: Store Hyperbaric QC at room temp (15-30°C). Stable until manufacturer's expiration date. After opening, only stable for 30 seconds. Hypoxic should be stored at 2-8°C in the dark. Stable until manufacturer's expiration date. After opening, only stable for 10 minutes.

Documents Status: **Approved**

Quality Control Quick-Guide:

New device (Performed by Point of Care)
1. i-STAT TriConrols Calibration Verification material levels 1 – 5 in singlet
2. ACT QC Levels 1 and 2
3. Eurotrol Hypoxic and Hyperbaric QC material

Replacement devices (Performed by Point of Care)
1. i-STAT TriConrols Calibration Verification material levels 1 – 5 in singlet
2. ACT QC Levels 1 and 2
3. Eurotrol Hypoxic and Hyperbaric QC material

New Shipments of cartridges &/or Monthly QC (Performed by testing departments)
1. Chem8, G3, CG4, CREA, G and CG8+: i-STAT TriControl levels 1, 2, and 3
2. ACT: QC using ACT Level 1 and Level 2 materials
3. Old Lot vs New Lot Comparisons done by POC Team using 2 patient samples for all new lot/shipment of cartridges.

Post Software Upgrade (Performed by Point of Care)
1. i-STAT TriControl Calibration Verification Levels 1 - 5 (Chem8, CG4)
2. ACT QC levels 1 and 2
3. Eurotrol Hypoxic and Hyperbaric QC material
4. Thermal probe check

For more detailed information on the ongoing iSTAT Test System Quality Assurance Plan, see Point of Care Quality Assurance Policy (LabPOCT100.027)

iSTAT Cartridges by UVMMC Location:

DEPARTMENT	ACT-k	G3	CREA	CG4	Chem8	CG8	G
Respiratory Therapy		X		X		X	
Pulmonology		X					
NICU Staff					X		X
Anesthesia/OR	X					X	
Cath Lab	X						
Perfusion	X					X	
Radiology	X						
CT/MRI			X				
UVMHealthNet Transport				X		X	

III. SAMPLE REQUIREMENTS

A. Suitable Specimens for ALL cartridges other than ACT Kaolin:

- Fresh whole blood collected in a capillary collection tube with balanced heparin.
- Fresh whole blood collected in a collection tube with lithium heparin anticoagulant. Fill collection tubes to capacity.
- Fresh whole blood collected in a plain plastic syringe or in a blood gas syringe labeled for the assays to be performed. Fill syringes for correct blood-to-heparin ratio.

B. Suitable Specimens for ACT-Kaolin Cartridges

- Fresh whole blood ***without anticoagulant*** collected in a plastic syringe. If from an indwelling line, flush the line with 5ml saline and discard the first 5ml of blood or six dead space volumes of the catheter.
- Fresh whole blood collected in a plastic tube without anticoagulant, clot activators, or serum separators. Device used to transfer sample to cartridge ***must be plastic***. Sample must be tested immediately after collection.

Table 1: Cartridge Panel Configurations & Blood Volume Requirements:

	G only	G3+	EG6+	CG8+	CG4+	Chem8	ACT Kaolin	Creat
Sample volume	65 uL	95 uL	95 uL	95 uL	95 uL	95 uL	40 uL	65ul
Sodium (Na)			**X**	**X**		**X**		
Potassium (K)			**X**	**X**		**X**		
Chloride (Cl)						**X**		
BUN						**X**		
Glucose(GL)	**X**			**X**		**X**		
Ionized Ca (iCA)				**X**		**X**		
pH		**X**	**X**	**X**	**X**			
PCO_2		**X**	**X**	**X**	**X**			
PO_2		**X**	**X**	**X**	**X**			
Hct			**X**	**X**		**X**		
HCO_3		**X**	**X**	**X**	**X**			
tCO_2		**X**	**X**	**X**	**X**			
sO_2		**X**	**X**	**X**	**X**			
BE		**X**	**X**	**X**	**X**			
Gap								
Lactate (LAC)					**X**			
Creatinine (Creat)						**X**		**X**
ACT							**X**	

IV. SPECIMEN COLLECTION:

Patient must be identified prior to sample collection using guidelines from the Lab Patient Identification Policy, Lab200.037. Standard precautions must be followed, including using the appropriate PPE. Gloves must be worn during patient testing, hand hygiene performed, and gloves changed between patients. Follow site protocol for collection practices, but below are points to consider specific to sample quality for the iSTAT System:

1. In-Dwelling Line:

Back flush line with sufficient amount of blood to remove intravenous solution, heparin or medications that may contaminate the sample. Recommendation: five to six times the volume of the catheter, connectors and needle. Following guidelines for suitable specimen when choosing collection device (see above section).

2. Arterial Specimens:

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. Do not expose sample to air or ***P***CO**2** may decrease, pH may increase and ***P***O**2** may decrease if the value is above or increase if the value is below the ***P***O**2** of room air (approximately 150 mmHg).

For cartridge testing of ACT, use only a plain, plastic syringe without anticoagulant.

Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds. Discard the first two drops of blood. For blood gas testing, avoid or remove immediately any air drawn into syringe to maintain anaerobic conditions.

Test samples collected without anticoagulant immediately. Test samples for ACT and lactate immediately. For pH, blood gases, TCO2 and ionized calcium, test within 10 minutes of collection. If not tested immediately, remix the sample and discard the first two drops of blood from a syringe before testing. Note that it may be difficult to property remix a sample in a 1.0 cc syringe. For other cartridge tests, test sample within 30 minutes of collection.

3. Venous Specimens:

Collect sample into an evacuated blood collection tube or a syringe containing lithium heparin, or balanced heparin anticoagulant. For ionized calcium measurements, balanced heparin or 10 U of sodium or lithium heparin/mL of blood is recommended. Fill tubes to capacity; fill syringes for correct heparin-to blood ratio. Incomplete filling causes higher heparin-to-blood ratio, which will decrease ionized calcium results and may affect other results. The use of partial – draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended for blood gases because of the potential for decreased ***P***CO2, HCO3 and TCO2 values.
Be sure to allow any alcohol on the skin to completely dry before venipuncture, as alcohol contamination can cause hemolysis and inaccurate results.
For cartridge testing of ACT, use only a plain, plastic syringe or collection tube containing no anticoagulant. Use a plastic capillary tube, pipette, or syringe to transfer sample from a tube to a cartridge.

Mix blood and anticoagulant by inverting a tube gently at least ten times. Roll a syringe vigorously between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Note that it may be difficult to properly mix a sample in a 1 cc syringe.

Test Sample collected without anticoagulant immediately. Test samples for ACT and lactate immediately. Test samples for pH, ***P***CO2, TCO2 and ionized calcium within 10 minutes of sample draw. If not tested immediately, remix the sample before testing and discard the first two drops of blood from a syringe before testing. For other cartridge tests, test sample within 30 minutes of collection.

4. Finger and Heelstick Specimens:

Only auto-disabling, single use fingerstick devices can be used for fingerstick and heelstick specimens. 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. Heparinized capillary tubes are not suitable for ionized calcium due to the high concentration of heparin. Use balanced heparin capillary tubes for collection. UVMMC uses Safe-Wrap Combo Blood Collection Tubes for heelstick collection and transfer. Tubes are calibrated to deliver either 65 ul or 95 ul of blood volume. The tubes are Mylar-wrapped and have been treated with calcium-balanced lithium heparin. Test samples immediately to avoid clotting (especially in neonates).

Capillary samples are NOT recommended for ACT testing.

There are conflicting reports in the literature regarding the validity of PO2 analysis performed on arterialized skin puncture specimens compared to arterial PO2. The process of capillary collection may change PO2, PCO_2 and the calculated SO2. Arterial specimens are preferred for blood gas analysis.

Criteria for Specimen Rejection

1. Evidence of clotting
2. Specimens collected in vacuum tubes with anticoagulant other than lithium heparin
3. Syringe for pH, **P**CO_2 and **P**O_2 with air bubbles in sample
4. Other sample types such as urine, CSF and pleural fluid
5. Incompletely filled vacuum tube for the measurement of ionized calcium, ***P***CO**2**, HCO3 or TCO2
6. Samples collected in glass collection device or collection device containing anticoagulants for ACT testing.
7. Samples drawn from insufficiently flushed catheters.

Avoid the Following Circumstances

1. Drawing a specimen from an arm with an I.V.
2. Stasis (tourniquet left on longer than one minute before venipuncture)
3. Extra muscle activity (fist pumping)
4. Alcohol contamination from puncture site during venipuncture (not allowing to dry completely)
5. Traumatic draw
6. Icing before filling cartridge
7. Time delays before filling cartridge
8. Exposing the sample to air when measuring pH, **P**CO_2 and **P**O_2
9. Analyzer not on level surface during testing

****NOTE** Whenever the sample integrity is questioned and/or results do not fit clinical picture, please contact the Point of Care Office at 847-1116 or email Lab-Pointofcare@uvmhealth.org for assistance.**

V. PROCEDURE FOR PATIENT TESTING:

Preparation for Use: An individual cartridge may be used after standing 5 minutes, in its pouch, at room temperature. An entire box should stand at room temperature for one hour before cartridges are used.

Procedural Note: ALWAYS wear gloves and follow UVMMC biohazard safety policies and guidelines when performing tests involving patient blood samples.

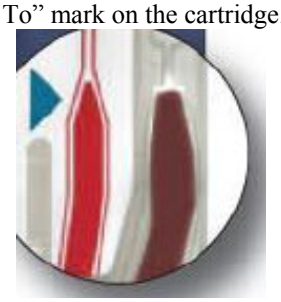
Cartridge Testing:

1. PRESS  to turn on iSTAT. The Test Main Screen will display:
   1- Last Result
   2- i-STAT cartridge
2. On the Test Menu Screen, select 2- i-STAT cartridge and follow the prompts on the screen.
3. Scan your operator ID (your M# on your barcoded UVMMC badge. If badge is unavailable, enter the 6-digit User ID #, omitting the M).

   General iSTAT Scanning Tips:
   - Position barcodes 3-9 inches from scanner window on the iSTAT
   - Press and hold 

 to activate the scanner
   - Align the red laser light so it covers the entire barcode
   - The iSTAT will beep when it reads the barcode successfully
4. Scan the patient ID always using the patient's wrist band whenever available. If necessary, manually entering the patient ID will require the ID to be entered twice.
5. Scan the bar-coded lot# off the individual cartridge package.

6. Remove the cartridge from the pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
7. Direct the dispensing tip or capillary tube containing the blood into the sample well.
8. Dispense the sample until it reaches the "Fill To" mark on the cartridge. Leave some sample in the well.



Fill to blue mark

9. Close the cover over the sample well until it snaps into place. Do not press directly over the sample well, use the tab on the side of the cover.
10. Insert the cartridge into the cartridge door until it clicks into place. Wait for test to complete.

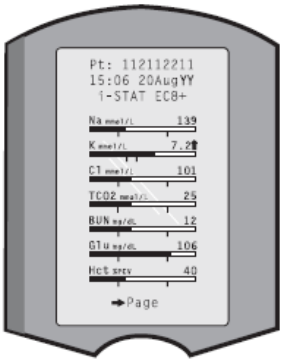
Note: iSTAT analyzer MUST remain on a level, flat surface during testing. ACT results may be affected up to 10% by the analyzer testing on an unlevel surface.

11. Enter additional parameters (if required). Only Respiratory Therapy and UVM HealthNet Transport utilize the free fields.
    - Patient temperature should be entered as degrees Celsius. Use the * key for a decimal point.
    - %FIO2 may be entered as a percentage of oxygen the patient is receiving. Enter the whole number, using % as the unit.
    - Choose the number corresponding to the type of sample used when prompted at the Sample Type field.
    - Press the SAVE softkey to record the blood gas parameters entered.
12. View the results shown on the display screen.
13. Cartridges should be disposed of properly in a biohazardous waste container as per UVMMC Policy.

Backup Procedure: If the i-STAT system is inoperable for any reason, contact the Point of Care Office at 847-1116 during business hours (0800-1630 M-F) for assistance. If an analyzer malfunctions during off-hours, report problem to Point of Care via FrontRange ticket or email Lab-PointofCare@uvmhealth.org . Alternantly, specimens could be collected and submitted to the laboratory in accordance with the UVMMC Laboratory Procedure Manual.

VI. RESULTS

Displayed Results: Results are displayed numerically with their units. Non-blood bas and hematocrit results are depicted as bar graphs with reference ranges marked under the graphs.
Action ranges (or critical values) indicate results that require immediate attention. See the Critical Value Policy section below for site-specific protocols. Critical values are depicted on the iSTAT screen as either too high (↑) or too low (↓). In the example of the screen below, Potassium (K) is depicted as being too high (a critical value):



Note: Since the ↑ and ↓ symbols cannot be printed from the iSTAT printer, action flags will appear with the << >> symbol.

Calculations: The i-STAT contains a microprocessor that performs all calculations required for reporting results. These results include: O2 saturation, base excess, base deficit, TCO2 and temperature correction. The calculations may be found in the i-STAT system manual.

Suppressed Results: There are three conditions under which the i-STAT System will not display results:

1. Results outside the System 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 table of Reportable Ranges.
   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 another cartridge. If the results are not suppressed, report in the usual manner. If the result is suppressed again, send specimen(s) to the laboratory for analysis.
3. A Quality Check message will be reported instead of results if the handheld detects a problem with the sample, calibrant solution, sensors, or mechanical or electrical functions of the handheld during the test cycle.
   Action: Repeat testing using another cartridge. If error code repeats, contact the Point of Care Testing office at 847-1116 , noting the Error Code number and display.

When results are questionable: Whenever results are being questioned as accurate, the following actions are options:

- notify the provider right away of questionable results and document the notification in Epic Notes

- repeat testing using new cartridge or send a specimen to the UVMMC Core Lab for testing.
- For results that have filed into Epic and are known to be errant due to sample integrity, please email the Point of Care Office at Lab-Pointofcare@uvmhealth.org or call 847-1116. Point of Care can append a disclaimer on the result(s) to say: Sample integrity questioned, results may not be reliable or Specimen Contaminated; disregard results.

Other Errors:

Point of Care can also make edits to errors in sample type and FIO2 %s.

Point of Care can correct all reports that have filed errantly into the wrong patient's chart, if notifed. These will also be reported using the SAFE System.

VII. PRINTING and TRANSMITTING RESULTS

Printing from the iSTAT Analyzer (Anesthesia/OR and UVM HealthNet Transport ONLY)

1.Turn printer on if green power light is not on.
2. Align IR windows of handheld and printer.
3. Display results.
4. Press the Print key.
5. Do not move handheld or printer until printing is complete.
6. If printer is not powered from a wall outlet, turn printer off.

Transmitting i-STAT Results Using the Downloader or Wireless Transmission

1. Place analyzer in front of the downloader. When properly aligned, the red proximity light will turn on and the analyzer will automatically upload its data to the Central Data Station.
2. Wireless iSTATs transmit automatically via the wireless network once the testing is complete. Wireless iSTATs may also be placed in the downloader to transmit results if necessary.
3. DO NOT remove the analyzer while data is transmitting. While data is being transmitted the arrows on the screen will "spin".
4. If a corrected report needs to be generated, contact Point of Care Office 847-1116 during business hours (0800-1630, M-F) or Help Desk at 847-1414. During off-hours, a Service Now Ticket will be generated for POCT to review the next business day.

Individual Site Resulting Protocols:

1. **Cardiac Catheterization Lab**: Results are verbally reported by the operator to the physician and to the nurse at the monitor station. Results file into Epic after analyzer is downloaded.
2. **Radiology**: ACT results are recorded on the log sheet and verbally reported to the radiologist. iSTAT is downloaded and results are transmitted to Epic. Reference ranges are in Epic.
3. **CT/MRI**: Results are read on the iSTAT analyzer and transmitted into Epic after analyzer is docked. Reference ranges are on a sticker that is placed on the patient order and scanned into the PACS System.
    a. To calculate GFRs (Glomerular Filtration Rates) from the iSTAT Creatinine results, CT/MRI uses the following website via a dedicated icon on their department's computers:
    http://www.niddk.nih.gov/health-information/health-communication-programs/nkdep/lab-evaluation/gfr-calculators/adults-conventional-unit-ckd-epi/Pages/default.aspx
    b. This calculator is IDMS-traceable and utilizes the MDRD study equation. For children, the same website offers the IDMS-traceable Schwartz calculator using a different tab.
4. **Anesthesia/OR**: Results are printed out and handed to the Anesthesiologist. Critical values and reference ranges are posted in the Anesthesia Workroom and on the iSTAT results form. Patient iSTAT printout is stapled to this form and scanned into Epic. In addition, iSTAT results are filed into Epic by either wireless transmission or when a non-wireless analyzer is docked.
5. **Perfusion**: Results are printed from the iSTAT and recorded on the Cardiopulmonary Bypass Record log. The printout is then handed to the Anesthesiologist and changes in therapy are then made by the Perfusionist and/or the Anesthesiologist. One copy of the two part Cardiopulmonary Bypass Record is kept by the Department of Surgery and the other is scanned into the patient's chart. After iSTAT is downloaded, results file into Epic.

6. **UVMHN Transport**: Results are printed from the i-STAT and recorded in a documentation application utilized by the department, ImageTrend.
7. **Respiratory Therapy and NICU Nurses:** Results are visually read by the RT or NICU Nurse from the iSTAT screen. Results are interpreted and patient treated accordingly in collaboration with the attending provider. Results are transmitted wirelessly and file into Epic.

Reference Ranges, Reportable Ranges, Test Unit Conversions: Reference range means the range of test values expected from 95% of fasting individuals presumed to be healthy. Measurable range is the test reporting limits of the iSTAT analyzer. The following table contains the reference ranges (normal) and measurable ranges applicable to the i-STAT System.

Table 2: REFERENCE RANGES, REPORTABLE RANGES, TEST UNITS

Analyte	Unit	Measurable Range	Normal Reference Range-Arterial	Normal Reference Range-Venous & Capillary
Sodium (Na)	mmol/L	100 – 180	136 - 145	Same as arterial
Potassium (K)	mmol/L	2.0 - 9.0	>17-Adult: 3.5-5.0 1 yr-17 yr: 3.3-4.6 6 mo-1 yr: 3.5-6.1 1 mo-6 mo: 3.5-5.6 1 wk-1 mo: 3.4-6.0 0 d-1wk: 3.2-5.5	Same as arterial
ACT-Kaolin (PreWarm Status)	Seconds	50 - 1000	Baseline (pre-heparin range) : 74-137** 3 min post heparin dose during CPB: 480 *Therapeutic interventional range is dependent upon patient population and procedure type.*	Same as arterial
pH	N/A	6.5 - 8.2	7D-Adult: 7.35- 7.45 ** 1D-7D: 7.29-7.45 0D-1D: 7.26-7.49	7.31- 7.41 **
Creatinine	mg/dL	0.2-20	>18-Adult: 0.6-.1.3** 0-1 year: 0.3-1.0 1-4 year: 0.1-0.6 4-7 year: 0.1-0.7 7- 10 year 0.3-0.7 10-14 year 0.4-1.0 14-18 year 0.6-1.2	Same as arterial
PCO_2	mm/Hg	5 – 130	7D-Adult: 35 – 45** 1D-7D: 27-41 0D-1D: 27-40	41-51 **
PO_2	mm/Hg	5 – 800	7D-Adult: 80-105** 1D-7D: 54-95	N/A **
HCO_3 Calculated	mmol/L	1-85	22-26 **	23-28 **
TCO_2Calculated	mmol/L	5 – 50	23-27 **	24-29 **
BE Calculated	mmol/L	(-30)-(+30)	(-2) - (+3) **	Same as arterial
sO_2 Calculated	%	N/A	95 – 98 **	N/A

Table 2: REFERENCE RANGES, REPORTABLE RANGES, TEST UNITS (cont)				
Chloride	mmol/L	65-140	96-110	Same as arterial
Hematocrit (Hct)	% PCV	15 – 75	>18-Adult Male: 39.5-50.2 >18-Adult Female: 34.9-44.4 12-18 yr Male: 37.0-49.0 12-18 yr Female: 36.0-46.0 6-12 yr Male&Female: 35.0-45.0 2yr-6yr Male&Female 34.0-40.0 6m-2yr Male&Female: 33.0-39.0 3m-6m Male & Female: 29.0-41.0 1m-3m Male & Female: 28.0-42.0 <1m : Not established	Same as arterial
BUN	mg/dL	3-140	>18-Adult: 10-26 14-18 y.o.: 8-21 4-13 y.o.: 7-17 1-3 y.o: 5-17 4m-12m Male: <15 4m-12m Female: <14 1m-3m Male: <13 1m-3m Female: <15 8D-30D Male: <17 8D-30D Female: <16 1D-7D Infants <14	Same as arterial
Glucose (fasting)	mg/dl	20-700	>7D-Adult: 70-100 1D-7D: 50-100 0D-1D: 40-100	Same as arterial
Ionized Calcium	mmol/L	0.25-2.50	6mo-Adult: 1.12-1.32 ** <6 Months: Not established	Same as arterial
Lactate	mmol/L	0.30 – 20.00	>18-Adult: 0.36-1.25** Pediatric ranges: not defined	up to 1.9 mmol/L

****Reference ranges stated are defined by i-STAT. All other reference ranges stated are as defined by the UVMMC Core Lab and verified on the i-STAT.**

Result Reporting Errors: Errors in the testing process that are brought to light will be included in the hospital SAFE reporting system and corrected by the POCT staff, when possible.

VIII. CRITICAL VALUE PROTOCOL: Critical test results fall significantly outside the normal range and may indicate a life-threatening situation. Critical results represent an emergency condition and must be reported immediately to the licensed provider who can change or initiate treatment. Critical value protocol consists of:

- Notifying the licensed provider immediately *–not exceeding 30 minutes*
- Documenting in the patient's chart both the name of provider, and time of notification. Provider should read back the results as per policy LAB200.007

Note: Repeat testing for confirmation is no longer required and will be at the discretion of the provider

In emergent cases such as: **DURING A CODE, IN MEDICAL TRANSPORT, DURING PERFUSION, OR DURING SURGERY**, the critical result will be reported **IMMEDIATELY** to the licensed provider in charge who can initiate or change treatment. Therefore, no documentation of doctor notification is necessary.

Each caregiver is in a position to assess whether or not results are incongruent with patient status. In these instances, the caregiver should exercise clinical judgment as to whether or not the results are consistent with the clinical status of the patient or consistent with previous results.

UVMMC iSTAT Critical Values

Analyte	Age of Patient	↓ Critical	↑Critical
Sodium (Na)	>6 mo-adult	<125 mmol/L	>155 mmol/L
Sodium (Na)	0-6 mos	<125 mmol/L	>150 mmol/L
Potassium (K)	All ages but 6 mo-1yr	<3.0 mmol/L	>6.0 mmol/L
Potassium (K)	6 mo- 1yr	<3.0 mmol/L	>6.1 mmol/L
Potassium (K) All ages, ***Anesthesia ONLY***		<2.8 mmol/L	>6.8 mmol/L
pH	>6 mo-adult	<7.00	>7.60
pH	0-6 mos	<7.20	>7.50
Hematocrit (Hct)	>6 mo-adult	<21%	N/A
Hematocrit (Hct)	0-6 mos	<25%	
Ionized Calcium (iCa)	>6 mo-adult	<0.8 mmol/L	>1.6 mmol/L
Ionized Calcium (iCa)	0-6 mos	<0.8 mmol/L	>1.4 mmol/L
Lactate (Lac)	All ages	N/A	≥2.0 mmol/L
Glucose (Gl)	>6 mo-adult	<50 mg/dl	>500 mg/dl
Glucose (Gl)	0-6 mos	<40 mg/dl	>150 mg/dl
Creatinine (Crea)	All ages	N/A	>15 mg/dl

MONITORING OF CRITICAL VALUES COMPLIANCE: Each morning, critical value iSTAT results are reviewed by POCT staff via the UniPOC Monitoring System and investigated for confirmatory requirements. POCT emails each department with their critical values, and each department is responsible for reviewing and investigating each case for provider notification and documentation requirements.

IX. INTERFERING SUBSTANCES: 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. See the table below and on the next pages for specific known interfering substances:

ANALYTE	INTERFERING SUBSTANCE	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Sodium (Na)	Bromide	37.5 mmol/L	Increase ↑ Na
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Increase ↑ Na
Potassium (K)	Bromide	37.5 mmol/L	Increased rate of star (***) outs
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease ↓K
Chloride (Cl)	Acetylcysteine	10.2 mmol/L	Increase ↑ Cl
	Bromide	37.5 mmol/L	Increase ↑ Cl
	Bromide (therapeutic)	2.5 mmol/L	Increase ↑ Cl
	Salicylate	4.34 mmol/L	Increase ↑ Cl

ANALYTE	INTERFERING SUBSTANCE	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Chloride (Cl)	Iodide	2.99 mmol/L	Increase ↑ Cl
	Thiocyanate	6.9 mmol/L	Increase ↑ Cl
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Increase ↑ Cl
Ionized Calcium (iCa)	Acetominophen	1.32 mmol/L	Decrease ↓iCa
	Leflunomide	0.03 mmol/L	Decrease ↓iCa
	Magnesium	1.0 mmol/L	Increase ↑iCa by up to 0.04 mmol/L
	Acetylcysteine	10.2 mmol/L	Decrease ↓iCa
	Bromide	37.5 mmol/L	Increase ↑iCa
	Lactate	6.6 mmol/L	Decrease ↓iCa by up to 0.07 mmol/L
	Salicylate (therapeutic)	0.5 mmol/L	Decrease ↓iCa by up to 0.03 mmol/L
	Salicylate	4.34 mmol/L	Decrease ↓iCa
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease ↓iCa
	Thiocyanate	6.9 mmol/L	Decrease ↓iCa. ***USE ANOTHER METHOD***
Lactate	Bromide	37.5 mmol/L	Decrease ↓Lactate
	Hyrdroxyurea	0.92 mmol/L	Increase ↑ Lactate ***USE ANOTHER METHOD***
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Increase ↑ Lactate ***USE ANOTHER METHOD***
Glucose (Gl)	Acetominophen	1.32 mmol/L	Increase ↑Gl
	Acetylcysteine	10.2 mmol/L	Decrease ↓Gl
	Bromide	37.5 mmol/L	Decrease ↓Gl
	Bromide (therapeutic)	2.5 mmol/L	Decrease ↓Gl
	pH	per 0.1 pH units below 7.4 @ 37°C	Decrease ↓Gl by 0.9 mg/dl
	pH	per 0.1 pH units above 7.4 @ 37°C	Increase ↑ Gl by 0.8 mg/dl
	Oxygen (O_2)	***P***O_2 <20 mmHg @ 37°C	Decrease ↓Gl
	Thiocyanate	6.9 mmol/L	Decrease ↓Gl
	Hydroxyurea	0.92 mmol/L	Increase ↑ Gl. ***USE ANOTHER METHOD***
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease ↓Gl
BUN/Urea	Bromide	37.5 mmol/L	Increased rate of star (***) outs
	Hydroxyurea	0.92 mmol/L	Increase ↑ BUN
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease ↓BUN

ANALYTE	INTERFERING SUBSTANCE	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
***p*CO₂**	Propofol (Diprovan™) Thiopental Sodium		For patients on propofol or thiopental sodium, iSTAT does NOT recommend EC8 cartridges. G3,CG4,CG8, and EG6 are free from clinically significant interferences at all therapeutic doses.
Hematocrit (HCT)	White Blood Count (WBC)	>50,000 WBC/uL	Increase ↑ HCT
	Lipids	Abnormally High	Increase ↑ HCT
	Bromide	37.5 mmol/L	Increased rate of star (***) outs
HCT <40%	Total Protein	for each g/dL below 6.5	Decrease ↓by 1% PCV
		for each g/dL above 8.0	Increase ↑by 1% PCV
HCT >40%	Total Protein	for each g/dL below 6.5	Decrease ↓by .75% PCV
		for each g/dL above 8.0	Increase ↑by .75% PCV
***p*O₂**	Air Exposure	below 150 mmHg	Increase ↑pO_2
	Air Exposure	above 150 mmHg	Decrease ↓ pO_2
	Iced samples		Increase ↑pO_2
	Cold cartridges		Decrease ↓ pO_2
pH	Venous Stasis (prolonged tourniquet application)		Decrease ↓ pH
	Air Exposure		Increase ↑pH
	Delay in testing (anaerobically in syringe)		Decrease ↓ pH
Creatinine	Acetaminophen	1.32 mmol/L	Increase ↑Creatinine
	Ascorbate	0.34 mmol/L	Increase ↑ Creatinine
	Bromide	2.5 mmol/L	Increase ↑Creatinine
	Hydroxyurea	0.92 mmol/L	Increase ↑Creatinine – ***USE ANOTHER METHOD***
	Acetylcysteine	10.2 mmol/L	Increase ↑Creatinine
	Creatine	0.382 mmol/L	Increase ↑Creatinine
	Glycolic Acid	10.0 mmol/L	Decrease ↓Creatinine—***USE ANOTHER METHOD***
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Increase ↑Creatinine

X. NON-PATIENT TESTING PROCEDURES

1. DAILY TASKS:

Analyzer Verification – All departments using the i-STAT

1. Internal Electronic QC is performed from a patient cartridge every 8 hours.
2. If the internal electronic QC fails twice, run an external simulator (see procedure in Section IX). If the simulator passes, the iSTAT may be used for patient testing.
3. If the external simulator fails. Take the analyzer out of service and return it to the Point of Care office. The Point of Care Office will troubleshoot and/or contact i-STAT Technical Support to determine whether the internal system is functioning properly.
4. Calibration is automatically performed as part of the test cycle on each cartridge. Operator intervention is not necessary.

All departments using the i-STAT Responsibilities

Refrigerated Cartridges

1. Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes or on the cartridge. If cartridges are expired, discard appropriately.
2. Verify that the refrigerator did not exceed the 2-8ºC limit. Current temperature and minimum and maximum temperatures should be taken daily and logged on the temperature log in the department. After temperatures are recorded, the thermometer should be cleared.

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 Lead Respiratory Therapist/Educator/Manage or Point of Care Office immediately. DO NOT USE the cartridges from the out-of-range refrigerator. Note temperature out of range on the temperature log and note action taken under "Action taken if temp is out of range". The lab fridge is a back up to any refrigerator used to store i-STAT supplies.

Room Temperature Cartridges: Verify that all cartridges are stored properly according to the cartridge packaging. Any cartridges stored at room temperature must have the room temperature expiration date written on the cartridge. Room temperatures (current, min and max temps) should be logged daily on the room temperature log.

Action: If the measured temperature of the room has been continuously below 30°C (86°F) use cartridges as required. After temperatures are recorded, the thermometer should be cleared

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

1. Quarantine the cartridges.
2. Notify the Lead Respiratory Therapist/Educator/Manager or Point of Care Office (7-1116) immediately.
3. DO NOT USE the cartridges.
4. Record on room temperature log.

2. MONTHLY QC PROCEDURE FOR ALL ISTAT CARTRIDGES EXCEPT ACT-KAOLIN

Monthly external liquid QC must be performed on all iSTAT cartridges at least every 31 days, or whenever a new shipment/new lot is received. See the procedure below for all cartridges except ACT-Kaolin:

** When running QC material, be sure you are ready to run the test before you open the vial.

1. Turn on the i-STAT analyzer, and select "Menu". Select "3-Quality Test".
2. Select "1-Control".
3. Scan or enter your operator ID. (Scan badge)
4. Select Fluid Vendor. Select 1-APOC
5. Select Fluid Level: Enter 1 for Level 1, 2 for Level 2, 3 for Level 3
6. Scan the control lot number found on the bottle.
7. Scan the Cartridge lot number.

STEP	ACTION
1	Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
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.
3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
5	Immediately seal the cartridge and insert it into a handheld – it is important not to expose the solution to room air since this will alter the results. **Note:** Since aqueous based solutions such as control materials lack the buffering capability of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

8. Results will display, and the analyzer will determine if QC is acceptable by displaying "Pass" or "Fail". If results are out of range, or there is a cartridge error, repeat test with new cartridge. Press "1- Test Options", "1- Next Level". Choose appropriate level.
9. Repeat with next level until all 3 levels are done.
10. Download the i-STAT

For the **CG8+,Chem8, G, G3+, CG4+ and Crea cartridges:** Use i-STAT TriControl levels 1,2, 3. Liquid QC for each cartridge type shall fall within the manufacturer's reference range.

3. MONTHLY QC PROCEDURE FOR ACT CARTRIDGES:

Do not reconstitute both levels of quality control at the same time. To run the quality control: **Reconstitute the control material, and set up meter**. Control solutions may also be stored at room temperature for up to 4 hours (18to 30 °C or 64 to -86 °F). If left out longer than 4 hours at room temperature, they should be discarded.
Prior to testing, vials containing the lyophilized plasma and CaCl2 reconstituting fluid should stand at room temperature (18 - 30 ºC or 64 - 86 ºF) for a minimum of 45 minutes. For best results, vials, cartridges, and analyzers should be at the same temperature.Reconstitute only one level of control plasma at a time. **CONTROL SOLUTIONS MUST BE USED IMMEDIATELY (less than 30 seconds) AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS**

1. After 45 minute room temperature equilibration, remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.
2. Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.
3. Allow the vial to sit at room temperature for 1 minute.
4. Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds.
   Note: To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard the reconstituted fluid and start over with fresh vials.

5. Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the ACT cartridge
6. Immediately seal the cartridge and insert it into an analyzer.

Note: Additional ACT cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample. Results should be within manufacturer's range.

****WHAT IF QC FAILS?**

i-STAT TriControl levels 1,2, & 3 or ACT Levels 1 & 2 will be performed for each cartridge type. QC shall fall within the manufacturer's range. If a parameter is outside limits,verify the following conditions and then repeat the test(s):

- Expiration date printed on cartridge pouch and control ampule have not been exceeded
- Room temperature expiration date for cartridge and control have not been exceeded
- Cartridge and control have been stored correctly
- The analyzer being used passes an Electronic Simulator test.

If the results have exceeded despite meeting the above criteria, **repeat QC using a new box of control solutions and new cartridges.** All QC failures will be reviewed by the POCT Medical Director for further action.

4. PROFICIENCY TESTING FOR THE ISTAT TEST SYSTEM

Participation in CAP proficiency testing occurs two or three times/yr depending on analytes reported. Point of Care Testing will alert department when proficiency testing samples have arrived. All Proficiency Tests should be performed by end-users selected from each department. For more detailed information, please refer to the Point of Care Quality Assurance Policy LABPOCT100.027 and the External Assessment System Policy LAB700.001

To access the Proficiency Test path on the i-STAT 1 Analyzer

1. Press the On/Off key
2. Press the MENU key
3. Press 3 for Quality Tests
4. Press 2 for Proficiency

5. Biannual Procedures Performed by Point of Care

Correlations: Correlations with the main lab will be performed every 6 months. For this, patient specimens will be tested using a sampling of iSTAT devices for each sensor type used. All sensors will be compared with the main lab.
Post Software Update (Calibration Verification): Assay i-STAT TriControl Calibration Verification set in singlet on all cartridge types and a sampling of devices. Eurotrol Hyperbaric and Hypoxic QC are used to validate the AMR for pO2. Liquid QC for each cartridge type shall fall within the manufacturer's reference range. If a parameter is outside limits, it is repeated and reviewed by Medical Director.

6. Periodic Procedures- Performed by Point of Care

New Device- Calibration Verification and QC (See Quick Reference Section): All new analyzers will be validated using the Replacement Device procedure below. The POCT Medical Director must review and approve new analyzer validations.

Analyze i-STAT TriControl Calibration Verification solutions 1-5 in singlet. If a parameter is outside limits, it is repeated in duplicate and the results are averaged to determine acceptability (manufacturer's instructions). If results are still outside the manufacturer's range, consult the Medical Director.

Analyze i-STAT ACT Level 1 and 2 for devices that perform ACT testing. Analyze Eurotrol Hypoxic and Hyperbaric QC material to validate the pO2 AMR. Transmit results to UniPOC and record results. For i-STAT 1's use the linearity graph report in UniPOC. Lot number of calibration verification set must be loaded into UniPOC for each sensor type on each cartridge type.

Replacement Devices- Calibration Verification and monthly QC: The POCT Medical Director must review and approve replacement analyzer validations monthly and QC data for trending or if any issues arise.

Analyze i-STAT TriControl Calibration Verification solutions 1-5 in singlet. If a parameter is outside the manufacturer's limits, it is repeated in duplicate and the results are averaged to determine acceptability (manufacturer's instructions). If results are still outside the manufacturer's range, consult the Medical Director.

Analyze i-STAT ACT Level 1 and 2 for devices that perform ACT testing. Analyze Eurotrol Hypoxic and Hyperbaric QC material to validate the pO2 AMR. Use expected values in inserts to verify results are acceptable.

For i-STAT use the linearity graph report in UniPOC 3.0. Lot number of calibration verification set must be loaded into UniPOC for each sensor type on each cartridge type.

Error codes will be monitored biweekly after implementation.

New Cartridge (Sensor) Types: New cartridge (sensor types) will require validation of accuracy, precision and reportable range, as well as a 10 point validation of 2 levels of i-STAT TriControls versus the electronic QC (EQC validation). The POCT Medical Director must review and approve new sensor validations.

XI. MAINTENANCE

1. Performed by Testing Departments

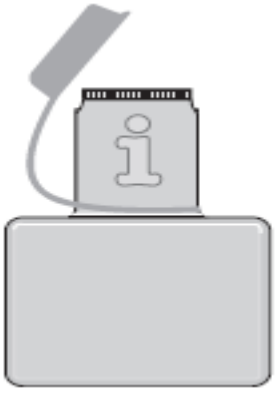
Daily Cleaning: Clean the analyzer after every patient use with alcohol (DisCide wipes) or 10% Bleach solution (DisPatch wipes) . Avoid getting excess fluids in the seam between the display screen and the case, the electronics compartment, battery compartment, cartridge port or test strip port. Clean the Downloader and/or Printer whenever necessary. Use caution when cleaning either devices, as they may be damaged by liquid contamination.

If the analyzer is not to be used for an extended period of time, the batteries should be removed to prevent leakage

Decontamination: Decontaminate the analyzer or downloader whenever a specimen is spilled onto them or before and after any patient in Isolation. Decontaminate with 10% Bleach (DisPatch wipes) , wearing gloves.

External Simulator Testing: The Electronic Simulator, external and internal, is a quality control device for the analyzer's cartridge signal-reading function. It simulates two levels of electrical signals that stress the analyzer's cartridge signal detection function both below and above measurement ranges. UVMMC has all iSTAT analyzers customized to do an Internal simulator check once every 8 hours. If it passes, the analyzer can be used for patient testing. This is automatic and happens without notice. If it does not pass, the analyzer will display "ELECTRONIC SIMULATOR FAIL". iSTAT analyzer will be locked out for patient testing. Please contact Point of Care at 71116 and perform an External Simulator.

Display	Step	Analyzer Response / Comments
	Press the **On/Off** key to turn the analyzer on.	Logo briefly displayed followed by Test Menu.
Test Menu	Press the **Menu** key.	
Administration Menu	Press **3** to select Quality Tests.	
Quality Tests Menu	Press **4** to select Simulator.	
Scan or Enter Operator ID	Press **Scan** to scan the Operator ID or manually enter the Operator ID and press **Enter**.	If enabled, the analyzer will validate ID and/or ask for the ID to be repeated.
Scan or Enter Simulator ID	Press **Scan** to scan the Simulator ID or manually enter the Simulator ID and press **Enter**.	The simulator serial number can be used as an ID. If the simulator does not have a barcode, one can be made on-site and affixed to the simulator (not near contact pads).
INSERT SIMULATOR	Remove the cover protecting the contact pads and insert the simulator straight into the analyzer. Avoid touching the contact pads.	Inserting the simulator at an angle may cause a Quality Check message to be displayed.
Contacting Simulator Please wait… Time to Results bar Simulator Locked	Do not attempt to remove the simulator until the results are displayed and the "Simulator Locked" message is removed.	

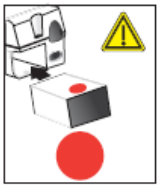


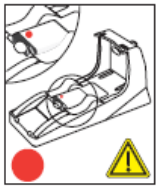
If the External Simulator passes, continue to use the analyzer. Remove the simulator and return to its protective case.
Changing Disposable Batteries: Change or charge rechargeable batteries whenever the analyzer displays "Low Battery". For non-rechargeable batteries, it is recommended that 2 Lithium-ion 9V be used and not 9V Alkaline. Wait until any test in progress is completed, and turn off the analyzer before replacing the batteries or the most recent set of results may be lost. Stored results will not be lost when replacing the batteries.

1. Slide the battery compartment door off.
2. Tilt the analyzer slightly to slide out the battery carrier which contains the two 9-volt batteries.
3. Remove the old batteries from the carrier. Pull each battery out to the side and then lift back and out.
4. Note the battery orientation symbol molded into the carrier on each side of the center wall. Starting with one side, orient the new battery so it matches the symbol. Slide the battery into the carrier, pushing the terminal end in first, under the plastic bar, and slide it up as far as it will go. Then push the bottom of the battery inward. The terminals of the battery should be underneath the protective bar on the carrier. Repeat for the second battery on the other side of the carrier.
5. Note the orientation of the battery carrier illustrated on the label on the carrier. The label faces up, and the electrical contact end of the carrier goes into the instrument first. Insert the carrier into the instrument as shown on the label. If the carrier is inserted incorrectly, the battery door will not close.
6. Slide the battery compartment door back into place.
7. Dispose of old batteries according to UVMMC Policy SEH13, Waste Battery Policy

Changing Rechargeable Batteries: Rechargeable batteries recharge when analyzer is placed in a Downloader/Recharger. In addition, the Downloader has a compartment for recharging the battery outside the analyzer.

1. Slide the battery compartment door off.
2. Tilt the analyzer slightly to slide out the rechargeable battery pack.
3. The battery pack has two labels: one for orientation in the analyzer and one for orientation in the Downloader/Recharger. With the label with the analyzer facing up, and the electrical contact end of the pack facing the analyzer, insert the pack into the analyzer as shown on the label. If the pack is inserted incorrectly, the battery door will not close.
4. Slide the battery compartment door back into place.





If using rechargeable batteries, use only rechargeable batteries and recharging equipment supplied by the POCT Office. Other batteries and rechargers may affect test results and pose other hazards to operators and patients. A falling instrument may cause injury.

MONITORING PLAN: Refrigerator and room temperature logs will be checked monthly by a point of care testing specialist for any reading that is out of range and any corrective action that resulted from the out of range reading.

RELATED POLICIES:

Lab200.007 Critical Values
Lab200.037 The Identification of Patient Specimens
Labpoct100.036 Competency Assessment for Point of Care Non-Waived Tests
LabPOCT100.027 Point of Care Quality Assurance Policy
Lab700.006 Individualized Quality Control Plan
INFC00016 Infection Prevention Practices-Cleanliness of the Envirmonment and Equipment
SEH13 Waste Battery Policy

REFERENCES:

i-STAT Test System Manual, Most recent version

Documents Status: **Approved**

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