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POC 1 113 I-STAT

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Comments for version 2.0 (last major revision)

REVISED/ REMOVED QUALITY COMPONENTS INTO ANOTHER SOP

REVISED FORMATTINGFormat only.concurFormatting

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Revised to add statement on aceptable/ failed QC //kab

quality conttrol revisionReviewed by A. Hankerson

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	9/30/2020	2.0	Eugene Pearlman	
Periodic review Captured outside MediaLab	Designated Reviewer	6/27/2019	1.0	Dr. Eugene Pearlman	Recorded on 9/18/2019 by Kimberly Ballard when document added to MediaLab

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Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
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2.1	Retired	Minor revision	12/6/2020	2/22/2021	7/10/2021
2.0	Retired	Major revision	4/9/2020	9/30/2020	2/22/2021
1.0	Retired	First version in Document Control	9/18/2019	6/27/2019	9/30/2020

11/7/2021

ISTAT

POC 1 113

Memphis VA Medical Center
Memphis, TN 38104

Service Line(s):
Pathology and Laboratory Medicine Service- Ancillary Testing Department

Signatory Authority:
Chief, Pathology and Laboratory Medicine Service

Effective Date:
February 4, 2021

Responsible Owner:
Kimberly Ballard, MHA, MLS (ASCP)
Ancillary Testing Coordinator

Recertification Date:
February 28, 2026

1. PURPOSE AND AUTHORITY

a. The purpose of this standard operating procedure (SOP) contains the policies and procedure to be followed when performing tests with the I-STAT point of care instrument. This SOP must be followed by users who utilized the I-STAT instrument.

b. The I-STAT is a point of care instrument with which several different tests can be performed on blood specimens. Some of these are classified by the FDA as "waived" tests and can be performed after minimal training by most clinical staff. Others are FDA "non-waived" tests which can only be performed by personnel who have completed initial training and who are required to demonstrate their competency via lab-managed testing every six months. All these tests and instruments must be monitored regularly for accuracy and precision by the pathology and laboratory medicine service.

c. This SOP sets fourth mandatory procedures and processes to ensure compliance with VA/VHA Directive 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, January 29, 2016, Joint Commission, the Food and Drug Administration (FDA), and College of American Pathology.

2. ASSIGNMENT OF RESPONSIBILITIES

a. **Laboratory Director.** Has the overall responsibility for ensuring that the provisions of this SOP are followed by all personnel involved in the use of i-STAT instruments in the Memphis VA Medical Center.

b. **Ancillary Testing Coordinator.** Responsible for all quality management and technical oversight functions regarding the instrument as described in detail in Memphis VAMC Ancillary Testing policy 113-02.

c. **Ancillary Testing Program Specialist.** Will provide technical assistance to testing personnel as needed, perform all required proficiency testing, provide

feedback to testing personnel on any specimen quality issues as well as any issues regarding unclear test orders, and assist the Ancillary Testing Coordinator in the performance of his/her duties.

d. **Testing Personnel.** Will be responsible for the proper performance and documentation of all procedures as described in the “Procedures” of this Standard Operating Procedure (SOP). Testing personnel includes Licensed Practical Nurses (LPN), Registered Nurses (RN), Respiratory Therapists, and Medical Technologists assigned to locations that perform ancillary testing.

3. DEFINITIONS

a. **Reference Range**. Means the range of test values expected from 95% of fasting individuals presumed to be healthy.

b. **Reportable Range.** Means the range of test values throughout which the measurement system’s results have been shown to be valid.

c. **Critical Results.** Those that fall above or below defined values such that they pose an immediate risk to the patient.

4. SPECIMEN INFORMATION

a. Chem8, Creatinine, and cTnI cartridges: heparin (light green top) tubes are most commonly used. Although the i-STAT only requires a fraction of a cc of specimen, the tubes must be filled properly approximately 80% full in order to generate accurate results. Sodium heparin (dark green top) tubes may also be used.

b. ACT cartridge: Blood drawn into a plain plastic syringe is most commonly used. If drawn through a line, the line must be flushed with 5 ml saline and the first 5 ml of blood drawn through it must be discarded before obtaining the specimen to be tested.

c. Blood gas (CG8+,CG4+) Cartridges: Venous heparinized syringes (optimally 10 U heparin per mL of blood) are used.

d. All cartridges, calibrators, and controls are stored at 2-8°C degrees. Reagents must come to room temperature before testing or use according to manufacturer’s instructions.

e. TABLE 1: Cartridge Panel Configurations and Blood Volume (Shading denotes calculated values) * Note that the expiration is in days at room temperature. Refrigerated (2-8 °C) expiration is until date on box. Always refer to the box for expiration and storage conditions.

Table 1.

Cartridge	Volume µL	Expiration Days @ RT*	pH	PCO_2	PO_2	HCO_3	TCO_2	SO_2	BE	Anion Gap	Na	K	Cl	iCa	Glu	BUN	Crea	Lact	Hct	Hgb	ACT	cTnI
Chem8+	95	14								●	●	●	●	●	●	●	●		●	●		
CG4+	95	60	●	●	●	●	●	●	●									●				
CG8+	95	60	●	●	●	●	●	●	●		●	●		●	●				●	●		
Crea	65	14															●					
ACT	40	14																			●	
cTnI	17	14																				●

5. SPECIAL SAFETY PRECAUTIONS

a. Operators of the I-STAT metering system must don facility required personal protective equipment which includes but is not limited to gloves, face shield, lab coat, etc. when collecting, handling, and testing of patient blood samples.

b. Text orders are to be placed by the provider. Lab orders for I-STAT testing is prohibited except for certain tests. The I-STAT system will create an order and accession each time a sample is performed using the patient's social security number and the assigned location.

c. The I-STAT can be used to perform several different tests. The tests to be performed are dependent on the type of testing cartridge. Some cartridges are designed to quantify a single blood or plasma value (or 'analyte') while others simultaneously assess multiple analytes. Most clinics have available only the cartridges needed for testing of their population.

d. The FDA classifies point of care tests as either low complexity (waived), moderate complexity (non-waived), or high complexity.

e. Depending on the cartridge used, I-STAT tests at this hospital fall into one of the first two categories. The FDA stipulates more stringent requirements for testing personnel, for quality control, and for non-waived vs. waived.

f. The cartridges currently in use at the Memphis VAMC, and the analytes they measure, are shown in Table 1. These include a routine chemistry cartridge (Chem8) that also generates a HCT and calculated HGB; one blood gas cartridge (CG8), a simplified renal function (creatinine) cartridge; one cartridge for assessing blood coagulation (ACT); one for cardiac troponin values (cTnI). Although they are subject to routine quality control procedures, in general these tests are not held to the same standards of accuracy and precision as are corresponding tests performed in the hospital's Core Lab.

6. EQUIPMENT/FORMS

a. ISTAT Meter

b. Downloader/Base (with power cord and ethernet cable)

c. 9 Volt Lithium batteries

d. CPRS/VISTA

e. RALS

f. IQCP (Individualized quality control plan must be formed for non-waived tests).

7. REAGENTS

a. Quality Control, calibrators, or linearity material

b. Disposable plastic pipettes or SAF-Evac dispensers

c. Patient blood sample (dependent on test to be performed)

d. Cartridges

(1) Chemistry and creatinine cartridges (Chem8+ & Crea): These are “waived” tests. Most of the analytes tested with these cartridges are measured by quantifying the voltage across a blood-saturated ion-selective membrane. Glucose, creatinine, and BUN are measured by the electrochemical activity of enzyme-generated breakdown products. In clinical context in which ONLY the creatinine value is needed, a cartridge for measuring only that analyte can be used. The hematocrit is measured via conductance of whole blood; the known effects of the (separately measured) plasma electrolytes are quantitatively factored out to allow an accurate measurement. Hemoglobin ratio present in most normal blood samples. These tests usually take 2 minutes to result using arterial, venous, or capillary whole blood samples.

(2) Activated clotting time (ACT): This is a non-waived test. This assay is available only in point of care instruments, not in the “core lab”. It is sensitive to heparin at the high concentrations used in cardiac surgery, thereby providing a guide for the adequacy of heparin treatment in that context. This test is dependent on the clotting time and utilizes arterial or venous whole blood.

(3) cTnI: This is non-waived test. This assay is performed via a modified ELISA method with an electrochemical readout. Results show a similar reportable range to those provided by the “core lab” instrument, but with less precision (a CV of 7.8% in the range of the presumed AMI cutoff value of 0.12 µg/L, vs 3.7% for the core lab instrument). Test usually results in 10 minutes utilizing heparinized whole blood or plasma sample collected in syringes or evacuated tubes with lithium heparin. One can use non-heparinized whole blood samples tested within 1 minute of drawing into a plastic syringe or plastic evacuated tube containing no additives.

(4) Blood gas (CG8+, CG4+) cartridges: These are non-waived tests. These blood gas cartridges allow measurement of pH, pCO2, and pO2 via potentiometric and other electrochemical methods. They then calculate values of TCO2, HCO3, sO2, and base excess (BE). These calculations are less reliable than, for example, direct measurement of sO2 via pulse oximetry. The CG8 cartridge includes a limited set of routine chemistry tests as shown in table 1. Tests usually results in 2minutes utilizing samples collected from arterial, venous, or capillary whole blood.

8. QUALITY CONTROL

a. Chemistry/Blood Gas Testing

(1) External (liquid) controls for non-waived tests, values obtained with two levels of external controls must be recorded for each instrument, monthly.

(2) Quality controls are indicated by either “PASS” or “FAIL”. Instruments where quality controls have “PASSED” are satisfactory for patient use.

(3) Instruments where quality controls have “FAILED” should be repeated using a new test strip/ cartridge and control solutions. Failed results could be an indicator of sampling air bubbles, expired reagents/ supplies, or underfilling test strips/ cartridges.

(4) Cease patient testing if failed quality controls persist by the third trial. Contact ATC for further troubleshooting instructions, to gain a replacement meter, or other testing supplies.

(5) If ATC is unavailable, cease patient testing, remove meter from service (attach a ‘Do Not Use” label or give to charge nurse on duty to arrange return to ATC) collect appropriate patient sample for analysis by the main lab.

(6) Validation of new lots of cartridges: From each lot of blood gas/chemistry cartridges received, the ATS must use a representative number of cartridges to analyze I-STAT Level 1 and 3 Controls.

(7) For CHEMS+ cartridges, analyze I-STAT Tricontrols Level 1 and Level 3.

(8) When performing quality controls, chose option 3 on the main menu for quality tests, then quality control, then the desired level to be run.

(9) Scan the barcode on the vial of the control to be performed after verifying that is the same lot number on the reagent box.

(10) V igorously shake the vials for 5-10 seconds to equilibrate the liquid and gas phases.

(11) D
o not use solution left in the pipette tube for additional testing of the cartridges that contain sensors for ionized calcium, pH, PCO2, or PO2. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.

(12) A
lways remember to analyze the control material in the Control pathway and the calibration verification material in the Cal Ver pathway under the Quality Tests option of the I-STAT 1 Analyzer Administration Menu.

(13) C
ompare results to the package insert values. Check that the lot number on the control ampule matches the lot number on the package insert and that the software version listed on the insert matches the software installed in the analyzer. If all results are within expected ranges, use the cartridges as needed. Transmit the results to the Central Data Station.

b. ACT Testing

(1) For ACT cartridges, analyze I-STAT Levels 1 and 2 ACT controls.

(2) Prior to use, allow one vial each of the lyophilized plasma and calcium chloride reconstituting fluid to stand at room temperature for a minimum of 45 minutes.

(3) Remove the cap and stopper from the vials and pour the entire contents of the calcium chloride vial into the lyophilized plasma vial. Place the stopper back on the reconstituted vial.

(4) Allow the vial to sit for 1 minute and then mix the contents by swirling gently for 1 minute, then inverting slowly for 30 seconds before testing.

c. cTnI Testing

(1) Remove vials from refrigerator and let come to room temperature (18-30° C) for 15 minutes.

(2) Thoroughly mix by gently swirling the bottle. Avoid foaming of the sample. They are stable until the expiration date on the vial label when stored unopened at 2 to 8°C (35 to 46°F). once opened, the I-STAT cTnI controls are stable for 30 days when stored tightly capped at 2 to 8°C.

(3) See value assignment sheet accompanying the control or calibration verification material. The value assignment sheet displays target values and ranges expected when materials and equipment are performing properly. Should results fall outside the range, refer to the System Manual.

(4) Always ensure that the lot number and software revision on the value assignment sheet matches the lot number of the vial in use and the software revision in the analyzer.

(5) Target values are specific to the I-STAT System. Results may differ if used with other methods (i.e., other IVD instrumentation).

9. EQUIPMENT CALIBRATION AND MAINTENANCE

a. The purpose of these validations studies are to verify that identical specimens yield comparable results when tested on different I-STAT instruments, or when tested by different methods (generally, core lab vs. I-STAT instruments). Literature standards, may referable to CUA, are used to determine whether the degree of agreement between instruments or platforms is acceptable. Requirements for these studies as listed by inspecting agencies fall into two categories: those for non-waived tests and those for waived tests.

b. Correlation studies for both waived and non-waived tests: For instruments at the Memphis VAMC, I_STAT inter-instrument, cross-platform correlations, and AMR must be performed at least twice a year.

c. Verification of cartridges are performed upon each new lot shipment.

d. Routine maintenance is performed monthly which consist of visual inspection, electronic simulator test, and any other troubleshooting as necessary.

e. Meters are to be cleaned and disinfected between each patient and when visibly soiled using Super Sani-Cloth.

10. PROCEDURES

a. **General Procedure.**

(1) Press button to turn the meter on and then press “2” on ISTAT keypad. If testing quality control or calibrator, select quality tests from the main menu then select appropriate test type.

(2) Scan or manually enter the operator ID then patient ID. Repeat if prompted.

(3) Scan the barcoded lot number on the individual cartridge.

(4) Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.

(5) Collect blood sample according to testing type and as prescribed hospital protocol.

(6) Using a disposable plastic transfer pipette to fill the sample well of the cartridge fully with the patient's sample, quality control material, or calibrator while making sure not to overfill, underfill, and not to aspirate any air bubbles.

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

(8) Insert the cartridge into the cartridge port on the meter until it clicks into place.

(9) View results shown on the analyzer's display screen. The instrument will flag critical values (heavy dark arrows; these must be communicated to the patient's health care provider within 30 minutes, and that communication must be documented in the patient's medical record using the appropriate template.

(10) Remove the cartridge after "Cartridge Locked" message disappears. The analyzer is ready for the next test immediately by repeating steps 1 thru 10.

(11) As soon as possible, place the meter in the downloader to allow the results to be transmitted to the patient's medical record. Do not move the meter while message "Communication is in Progress" is displayed.

b. **Prerequisite for Testing.**

(1) I-STAT test can be performed if:

(a) Testing personnel have been appropriately trained and, if necessary, have undergone competency assessments at required intervals.

(b) Quality control procedures appropriate for the test(s) to be performed have been followed and have produced acceptable results.

(c) Appropriate blood specimens have been obtained.

(d) Employees are not allowed to perform testing on themselves or on co-workers without proper authorization. Employees must report to their supervisor or employee health prior to testing.

c. **Interferants.**

Table 2

ANALYTE	INTERFERRENT & CONCENTRATION	EFFECT on ANALYTE RESULT
Sodium	Bromide 37.5 mmol/L Nithiodote (sodium thiosulfate) 16.7mmol/L	Use another method. Increase (↑) Na
Chloride	Acétylcystéine 10.2mmol/L Bromide 37.5mmol/L Bromide (therapeutic) 2.5mmol/L	↑ Cl Use another method. ↑ Cl

	Salicylate 4.34mmol/L Thiocyanate 6.9mmol/L Nithiodote 16.7mmol/L	↑ CI ↑ CI ↑ CI
Ionized Calcium	Acetaminophen 1.32mmol/L Magnesium 1.0mmol/L Acetylcysteine 10.2mmol/L Bromide 37.5mmol/L Lactate 6.6mmol/L Salicylate (Therapeutic) 0.5mmol/L	↓ iCa ↑ iCa by up to 0.04mmol/L. ↓ iCa use another method. ↓ iCa by up to 0.07mmol/L. ↓ iCa by up to 0.03mmol/L. ↓ iCa, use another method
Kaolin ACT	Aprotinin	Falsely extends Celite ACT times
PCO_2	Propofol (Diprovan®) Thiopental Sodium	For patients administered propofol or thiopental sodium, APOC recommends the use of CG4+ & G3+ (& EG6+ & EG7+) cartridges, which are free from clinically significant interference at all relevant therapeutic doses. EC8+ cartridges are not recommended for use by APOC.
Glucose	Acetaminophen 1.32mmol/L Acetylcysteine 10.2mmol/L Bromide 37.5mmol/L Bromide (therapeutic) 2.5 mmol/L pH per 0.1 pH units below 7.4 @ 37℃ Oxygen PO_2 < 20 mmHg @ 37℃ Hydroxyurea 0.92 mmol/L Nithiodote 16.7 mmol/L Thiocyanate 6.9 mmol/L	↑ glucose ↓ glucose Use another method. ↓ glucose ↓ glucose by 0.9mg/dL (0.05mmol/L) ↓ glucose ↑ glucose Use another method. ↓ glucose ↓ glucose
BUN/Urea	Bromide 37.5mmol/L Hydroxyurea 0.92 mmol/L Nithiodote 16.7mmol/L	Use another method. ↑ BUN/Urea ↓ BUN/Urea
Creatinine < 2.0 mg/dL > 2.0 mg/dL	Acetaminophen 1.32mmol/L Ascorbate 0.34 mmol/L Bromide (therapeutic) 2.5 mmol/L PCO_2 >40mmHg <40mmHg Acetylcysteine 10.2 mmol/L Hydroxyurea 0.92mmol/L PCO_2 >40 mmHg < 40mmHg Glycolic Acid 0.382mmol/L Nithiodote Thiosulfate 10.0mmol/L	↑ creatinine ↑ creatinine by up to 0.3mg/dL ↑ creatinine ↑ creatinine by 6.9% per 10mmHg PCO_2 ↓ creatinine by 6.9% per 10mmHg PCO_2 ↑ creatinine ↑ creatinine ↓ creatinine by 3.7% per 10mmHg PCO_2 ↑ creatinine by 3.7% per 10mmHg PCO_2 ↓ creatinine ↑ creatinine
Hematocrit	WBC > 50,000 WBC/µL Total Protein <u>For measured Hct <40%</u>	↑ hematocrit ↓ Hct by 1.0% PCV

	For each g/dL < 6.5 For each g/dL > 8.0 Lipids For measured Hct <40% For each g/dL < 6.5 For each g/dL > 8.0 Bromide Abnormally high/ 37.5 mmol/L	↑ Hct by 1.0% PCV ↓ Hct by 0.75% PCV ↑ Hct by 0.75% PCV ↑ hematocrit

11. ENTRY OF RESULTS

a. I-STAT results are displayed on the meter and are then automatically entered into the patient's medical record when the meter is placed in the downloader.

b. Reference Ranges, Reportable Ranges, & Unit Conversions

(1) The following Table 3 contains the Reference Ranges (for adults) and Reportable Ranges applicable to the I-STAT System.

Table 3

ANALYTE UNIT of MEASURE	REFERENCE RANGE(s)	REPORTABLE RANGE	Critical Value Low	 High
SODIUM mmol/L	138-146	100-180	<120	>155
POTASSIUM mmol/L	3.5-4.9	2.0-9.0	<3.0	> 6.0
CHLORIDE mmol/L	98-109	65-140	>85	>120
BUN mg/dL	8 - 26	3 - 140	------	------
GLUCOSE mg/dL	70 - 105	20-700	<40	> 450
CREATININE mg/dL	0.6 - 1.3	0.2 – 20.0	----	>30
IONIZED CALCIUM mmol/L	1.12 – 1.32	0.25 – 2.50	<0.78	>1.58
Lactate mmol/L	0.36 - 25mmol/l	0.30 – 20.0 mmol/L	-----	>6.0
pH	7.35 - 7.45 arterial 7.31 - 7.41 venous	6.50 – 8.20	Art: 7.22 Mix Ven: 7.1	7.55 7.6
PCO_2 mmHg	35 – 45 arterial 41 – 51 venous	5 - 130	Art: 20 Mix Ven: 20	60 60
PO_2 mmHg	80 - 105	5 - 800	Art: 50 Mix Ven: 30	---- ----
TCO_2* mmol/L	23 – 27 arterial 25 – 29 venous	5 - 50	10	45
sO_2* %	95 - 98	0 - 100		
HEMATOCRIT %PCV	38- 51	15 - 75	<21	> 60
HEMOGLOBIN* g/dL	12–17 7-11	5.1-25.5 3.2-15.8	<7	>20
HCO_3* mmol/L	22 -26 arterial	1.0 - 85		

	23 – 28 venous		
BE* mmol/L	(-2) – (+3)	(-30) – (+30)	
ANION Gap* mmol/L	10 - 20	(-10) – (+99)	
Kaolin ACT secs	74-137 Prewarm 82-152 Nonwarm	50 - 1000	---- 500
cTnI ng/mL	0.00 – 0.08 **	0.00 – 50.00	--- > 1.5

(2) Each facility should establish its own reference range using the cTnI assay.

12. NOTIFICATION

a. The instrument will flag critical values with heavy dark arrows. These results will be automatically flagged as critical on the instrument's display. Per hospital policy, these results must be reported to the patient's health care provider within 30 minutes. The results reported, the time at which they were communicated, and the notified provider must subsequently be documented int the patient's medical record using the critical value template. Current critical value limits are shown in Table 2.

13. REFERENCES

a. VHA Directive 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, January 29, 2016, http://vaww.lab.med.va.gov/References_Directives_and Regulations_P.asp

b. I-STAT Operations Manual, 2013

c. Method Validation Program: Lab SOP# POC 12 113

14. APPENDICES

None

15. REVIEW

This SOP will be reviewed at least every 2 years, when there are changes to the government document that need to be made and any regulatory requirement for frequent review.

16. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of February 2026. In the event of contradiction with national policy, the national policy supersedes and controls.

17. SIGNATORY AUTHORITY

Dr. Eugene Pearlman
Pathology and Laboratory Medicine Service, Chief
NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: This SOP is available in Media Lab at:
https://www.medialab.com/lms/admin/ad_tab_doc_frameset.aspx?oid=46082727&o=0ee34cd948dc1b517d688fd08583bc81