Sutter Health
Sutter Roseville Medical Center

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Next Review:	*1/20/2024*
Owner:	*Kirsten Baker: Coord, Technical*
Policy Area:	*Lab - Point of Care*
References:	
Applicability:	*Sutter Roseville Medical Center*

i-Stat Patient Testing

PURPOSE

The i-STAT® System incorporates comprehensive components needed to perform blood analysis on a single whole blood sample with a rapid turnaround time.

POLICY

- Only personnel that have passed the competency assessment may perform testing on the iSTAT meter.
- Only testing ordered by a physician is to be performed.
- Any patient result that exceeds the critical range must be followed-up by the operator per policy.
- No changes are to be made in the procedure or policy except as authorized by the Laboratory Medical Director.
- **Hemoglobin and or hematocrit results are not to be used for transfusion decision making.**
  - Hematocrit and/or hemoglobin results MUST be verified by repeat testing in the Clinical Laboratory for transfusion decisions. iSTAT methods for hematocrit and hemoglobin results are NOT approved by the Laboratory Medical Director for use in transfusion decision making.

PRINCIPLE OF MEASUREMENT

- Sodium, Potassium, Chloride, Ionized Calcium, pH, and PCO_2 are measured by ion-selective electrode potentiometry. Concentrations are calculated from the measured potential through the Nernst equation.
- Glucose is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at an electrode to produce an electrical current which is proportional to the glucose concentration.
- Creatinine is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatine amidohydrolase. Creatine is then hydrolyzed to sacrosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample creatinine concentration.
- Lactate: Is measured amperometrically. The enzyme lactate oxidase, immobilized in the lactate biosensor, selectively converts lactate to pyruvate and hydrogen peroxide. The hydrogen peroxide

is oxidized at a platinum electrode to produce a current which is proportional to the sample lactate concentration.
- PO_2 is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.
- Hematrocrit is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.
- ACT is a measure of the time required for complete activation of the coagulation cascade. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with a particulate clotting activator – kaolin. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and the result is reported as a whole blood time (WBT)

SUPPLIES AND EQUIPMENT

Laboratory department will order and store controls and cartridges. Departments outside of the laboratory that perform testing will obtain and store supplies at room temperature as needed from main lab.

SUPPLIES AND STORAGE:

- **i-STAT ACT, CG4+, CG8+, and CREA cartridges**
- A single-use disposable cartridge containing microfabricated sensors, a calibrant solution, fluidics system, and waste chamber
- Store main supply in the laboratory refrigerator at (2-8°C) until manufacturers printed expiration date.
  - Do not allow cartridges to freeze
- ACT and CREA Cartridges are stable for 14 days at room temperature (18- 30°C)
- CG4+ and CG8+ Cartridges are stable for 2 months at room temperature (18- 30°C)
  - Room temperature expiration date must be noted on the cartridge when it is removed from refrigeration
  - Cartridges cannot be returned to the refrigerator once they have been brought to room temperature.
- Do not use cartridges if room temperature has exceeded 30°C, or beyond the labeled expiration date or the room temperature expiration date
- Individual cartridges should stand at room temperature for 5 minutes before use. An entire box should stand at room temperature for 1 hour before use.

EQUIPMENT:

- **i-STAT 1 Analyzer**
  - When a sample-filled i-STAT cartridge is inserted into an analyzer for analysis, the analyzer automatically controls all functions of the testing cycle including fluid movement within the

cartridge, calibration and continuous quality monitoring.

- **i-STAT 1 Download station**
  - A device that allows the analyzer to communicate with the central data station. All information is bi-directional and will keep the analyzer updated as well as downloading all patient information.
- **RALS**
  - Receives data from the iSTAT and through interface generated orders, results the test in Sunquest.
- **Electronic Simulator - External**
  - Store at room temperature and protect contact pads from contamination by placing the Electronic Simulator in its protective case.

ROUTINE CARE

- Disinfect the handheld with hospital-approved disinfectant between each patient
- Clean the display screen and the case using a moistened wipe/gauze with disinfectant. Avoid getting excess fluids in the seam between the display screen and the case. If needed, rinse the screen/case again using another gauze moistened with water and dry.

PERFORMING DEPARTMENTS

Department	ACT	CREA	CG4+	CG8+
Laboratory		X		
Cath Lab	X		X	
Interventional Radiology	X			X
Operating Room	X			X

Routine testing for ACT, CG4+, and CG8+ is not performed in the laboratory, however lab staff will support performing departments with troubleshooting and QC as needed.

OPERATORS

The following personnel that have completed training competency assessment can perform testing on the iSTAT

- RN in Cath Lab
- RN in Interventional Radiology
- Anesthesia Techs in Operating room
- Clinical Laboratory Scientists (CLS)
- Medical Laboratory Technicians (MLT)

SPECIMEN REQUIREMENTS

- To ensure proper specimen identification in departments outside of the clinical laboratory the drawing of blood samples and the immediate performance of the i-STAT test are to be done at the same patient care location.
- If testing is to be performed in the laboratory, the specimen must be labeled with the following

information, using the patient's armband as the source of information: Patient first and last name, Patient Medical Record Number, Account number, Date and Time of collection, ID of person who collected the specimen.

Requirements by i-STAT cartridge

- ACT:
  - Venous or arterial whole blood drawn into a PLASTIC collection device (syringe) containing **NO** anticoagulant. The sample should be immediately dispensed into the sample well of a cartridge.
  - If from an indwelling line, flush the line with 5mL saline and discard the first 5mL of blood or three to six dead space volumes of the catheter.
  - Do not use on patients receiving anticoagulants other than heparin.
- CG4+ and CG8+:
  - Venous, arterial, or mixed whole blood drawn into a balanced heparin syringe. Do not use plain syringes.
  - Venous samples for lactic acid should be obtained without the use of a tourniquet or immediately after the tourniquet is applied.
  - For the most accurate results, test samples immediately after draw. If not tested immediately, remix the sample and test within 2 minutes.
  - Avoid or remove immediately any air drawn into the syringe. Mix sample by vigorously rolling the syringe between palms for 5 seconds, then invert and repeat. Discard the first few drops of blood.
- CREA:
  - Venous or arterial whole blood in Li heparin tubes

Rejection criteria

- Improper labeling
- Any evidence of clotting
- Gross hemolysis on chemistry samples
- Syringe for blood gas testing with air bubbles in sample
- Samples other than whole blood (fluids, cell saver blood etc)

PATIENT TESTING

- All patient testing must be ordered by a physician.
- PPE, including gloves, must be worn when performing patient testing.

Laboratory testing:

- Specimen will be delivered directly to the chemistry technologist. The Chemistry technologist will
  - Verify that the information is complete
  - Check that the sample is acceptable
  - Note time received
- For CREA cartridges
  - i-STAT Trauma order form must accompany each sample.
  - Once testing is complete, record the results on the i-STAT Trauma form and call result to the extension noted or appropriate ED critical line.
    - Clotted samples are not acceptable

Step	Action

1.	Turn the i-STAT analyzer "ON" using the O button on the keypad
2.	Press 2 for i-STAT Cartridge
3.	Scan the operator ID – badge barcode
4.	Scan patient ID (Primary CSN). Scan barcode just below "MEDS,LABS" on label. Repeat to verify
5.	Scan cartridge barcode to enter lot number.
6.	Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
7.	• CREA cartridge - Lab only ◦ Mix the tube well • ACT, CG4+, or CG8+ cartridge ◦ Thoroughly mix the sample by rolling the syringe 5 seconds in at least 2 different directions, then invert for at least 5 seconds.
8.	With the cartridge sitting on a flat surface, add the sample to the cartridge • CREA Cartridge - Lab only ◦ Using a plastic pipette withdraw the blood from the tube. ◦ Direct the dispensing tip containing the blood into the cartridge sample well ◦ Dispense the sample until it reaches the fill mark on the cartridge and the well is about half full. • ACT, CG4+ or CG8+cartridge ◦ Discard 2 drops of blood ◦ Direct the syringe tip containing the blood into the sample well ◦ Dispense the sample until it reaches the fill mark on the cartridge and the well is about half full.
9.	Fold the snap closure over the sample well until it snaps into place. Do NOT exert pressure over the sample well.
10.	Insert the cartridge into the cartridge port until it clicks into place. • **NOTE:** When using an ACT cartridge, the analyzer must not be moved during the testing cycle.
11.	Enter the sample source code and press ENTER. • 1 - ART (arterial) • 2 - VEN (venous) • 3 - MIX (mixed) CG4+ and CG8+ (optional): • Patient temperature (Pt Temp) if provided. • FIO2 if provided in liters or percentage of oxygen patient is receiving Codes for site descriptions can be entered in field 1. Note - the number entered must **only** be one of the options below.

Field 1	Site	SQ code	ETC translation
11	IVC	IVC	Inferior Vena Cava
22	SVC	SVC	Superior Vena Cava

33	RA	RATRI	Right Atrium
44	RV	RVENT	Right Ventricle
55	PA	PART	Pulmonary Artery
66	AO	AORTIC	Aortic Specimen

12. DO NOT try to remove the cartridge when the analyzer shows "lock".

13.

If	Then
You do not want results transmitted to LIS / EPIC (ID error, wrong sample, hemolyzed, etc.)	• Return to Sample Type by pressing back arrow. • Press Enter to get to Field #1 and enter **01**. • This will prevent results from transmitting
Results are normal	Proceed to recording results
Result is critical	• Critical values will immediately be communicated to the attending physician. The physician will correlate the value with the patient's clinical condition and decide if testing should be repeated on a second sample and or sent to the Clinical laboratory or Blood Gas Lab. • Document notification of Critical Value in the appropriate record. Note: The identity of the testing individual and person notified need not be recorded when the individual performing the test is the same person who treats the patient. However, there must be a record of the critical result, date, and time in the medical record.
Result is < or >	Report as < or > technical limit indicated below
Result is ***	• Repeat testing with a new cartridge • ACT, CG8+ and CG4+ samples must be recollected • Laboratory only: if testing fails again order test in Sunquest and report as "Unable to perform"

14. Dock i-STAT instrument on downloader and allow the data to download. The meter will show "Waiting to Send" and then "Communication in Progress" (swirling arrows). Once the screen has cleared the meter can be removed.

If	Then
Result will not upload to Sunquest	Reconnect jacks at the back of the docking station

The result goes across but is determined to be incorrect	Notify the laboratory. Lab staff to use manual entry to amend the result.

WORKSHEET / TEST CODES

Sunquest Worksheet: RVPIS

Test	Sunquest Test Code
Creatinine	POCCRE
ACT	POCACT
Arterial CG4+	PEG4AR
Venous CG4+	PEG4VE
Mixed CG4+	PEG4M
Arterial CG8+	PC8AR
Venous CG8+	PC8VE

REFERENCE RANGES

Analyte	Critical Values		Reference Range
	Low	High	
pH	ART <7.20, VEN <7.25	ART >7.60, VEN >7.55	ART 7.35-7.45, VEN 7.32-7.43
pCO_2 mmHg	N/A	ART >60.0, VEN >80.0	ART 35.0-45.0, VEN 38.0-50.0
pO_2 mmHg	ART <55, VEN N/A	N/A	ART 80-100, VEN >39
Na mmol/L	≥13Y <120, 0D-12Y <130	>160	136 – 145
K mmol/L	<2.8	>6.2	≥1Y 3.5-5.1, 6M-11M 3.5-6.3, 1M-5M 3.5-5.8, 7D-30D 3.4-6.2, 0D-6D 3.2-5.7
Glu mg/dl	≥7D <50, 0D-6D <40	≥7D >450, 0D-6D >450	≥7D 70-100, 1D-6D 47-100, 0D 30-100
iCa mmol/L	<0.70	N/A	ART 1.13-1.32, VEN 1.15-1.27
Hct %			

Age	Low**	High
≥15Y	<18.0	>61.0
1M-14Y	<20.0	>62.0
0D-30D	<33.0	>71.0

Age	Male	Female
≥11Y	40.0 – 52.0	35.0 – 47.0
5-10Y	33.0 – 45.0	35.0 – 45.0
1M-4Y	33.0 – 43.5	33.0 – 43.5

<table>
<tr><td></td><td></td><td></td><td><table>
<tr><td>6D-30D</td><td>36.0 – 49.0</td><td>36.0 – 49.0</td></tr>
<tr><td>0D-5D</td><td>43.5 – 63.0</td><td>43.5 – 63.0</td></tr>
</table></td></tr>
<tr><td>Lac mmol/L</td><td>N/A</td><td>>18Y >2.0</td><td>≥18Y 0.4-2.0 1Y-17Y 1.0-2.4, 2M-1Y 1.0-3.3, 0D-2M 1.0-3.5</td></tr>
<tr><td>Crea mg/dL</td><td>N/A</td><td>>18Y >5.0</td><td><table>
<tr><td>Age</td><td>Male</td><td>Female</td></tr>
<tr><td>>18Y</td><td>0.50 - 1.30</td><td>0.4 - 1.00</td></tr>
<tr><td>13-17Y</td><td>0.50 - 1.30</td><td>0.40 - 1.00</td></tr>
<tr><td>4Y-12Y</td><td>0.50 - 1.10</td><td>0.5 - 1.10</td></tr>
<tr><td>2Y-3Y</td><td>0.20 - 0.80</td><td>0.2 - 0.80</td></tr>
<tr><td>2M-1Y</td><td>0.20 - 0.50</td><td>0.20 -0.50</td></tr>
<tr><td>8D-1M</td><td>0.30 - 0.80</td><td>0.3 - 0.8</td></tr>
<tr><td>0D-7D</td><td>0.7 - 1.20</td><td>0.7 - 1.20</td></tr>
</table></td></tr>
<tr><td>TCO2* mmol/L</td><td>N/A</td><td>N/A</td><td>Reference Range Not Established For This Analyte</td></tr>
<tr><td>HCO3* mmol/L</td><td>N/A</td><td>N/A</td><td>20-26</td></tr>
<tr><td>sO2* %</td><td>N/A</td><td>N/A</td><td>ART 94-99, VEN 70-75</td></tr>
<tr><td>BE* mmol/L</td><td>N/A</td><td>N/A</td><td>0.0-3.0</td></tr>
<tr><td>Hb* g/dl</td><td colspan="2"><table>
<tr><td>Age</td><td>Low**</td><td>High</td></tr>
<tr><td>≥18Y</td><td><7.1</td><td>>19.9</td></tr>
<tr><td>1M-17Y</td><td><7.1</td><td>>20.9</td></tr>
<tr><td>0D-30D</td><td><9.6</td><td>>24.9</td></tr>
</table></td><td><table>
<tr><td>Age</td><td>Male</td><td>Female</td></tr>
<tr><td>≥18Y</td><td>13.5 – 18.0</td><td>12.0 – 15.5</td></tr>
<tr><td>11-17Y</td><td>13.5 – 18.0</td><td>12.0 – 15.5</td></tr>
<tr><td>5-10Y</td><td>11.5 – 14.5</td><td>11.5 – 14.5</td></tr>
<tr><td>1M-4Y</td><td>11.0 – 14.5</td><td>11.0 – 14.5</td></tr>
<tr><td>6D-30D</td><td>12.0 – 17.0</td><td>12.0 – 17.0</td></tr>
<tr><td>0D-5D</td><td>14.0 – 21.0</td><td>14.0 – 21.0</td></tr>
</table></td></tr>
</table>

*Calculated values

ACT 74-137 seconds for non-anticoaulated patients

- Typically the ACT on an acute MI patient on antithrombin therapy should be 200 – 250 seconds.
- The physician has the final determination as to what range is appropriate for the patient.

****Disclaimer:** Hematocrit and/or hemoglobin results MUST be verified by repeat testing in the Clinical Laboratory for transfusion decisions. iSTAT methods for hematocrit and hemoglobin results are NOT approved by the Laboratory Medical Director for use in transfusion decision making.

TECHNICAL RANGES

Technical Limits - ACT, CG8+, CREA	
Analyte	**Technical Limits**
ACT seconds	50-1000

Na mmol/L	100 - 180
K mmol/L	2.0 - 9.0
Glu mg/dL	20 - 700
pH	6.5 - 8.2
PCO2 mmHg	5 - 130
PO2 mmHg	5 - 800
iCa mmol/L	0.25 - 2.5
Hct** %	15 - 75
HCO3* mmol/L	1.0 - 85.0
TCO2* mmol/L	5 - 50
$_sO_2$* %	0 - 100
BE* mmol/L	-30 - 30
Hgb** g/dL	5.1 - 25.5
CREA mg/dL	0.2 - 20

*Calculated values

Technical Limits - CG4+ only	
Analyte	**Technical Limits**
pH	7.0 - 7.70
pCO_2 mmHg	15 - 130
PO_2 mmHg	15 - 530
Lac mmol/L	0.30 - 20.00
TCO_2* mmol/L	5 - 50
HCO_3* mmol/L	1.0 - 85.0
$_sO_2$* %	0 - 100
BE* mmol/L	-30 - 30

*Calculated values

PRECAUTIONS AND LIMITATIONS

- Glass syringes and transfer devices cannot be used on the i-STAT coagulation cartridges.
- Coagulation samples collected into any device containing anticoagulant cannot be used on the i-STAT coagulation cartridges.
- Cartridge should be allowed to sit at RT at least 5 minutes prior to opening the pouch.
- Use cartridge IMMEDIATELY after removal from pouch.
- Avoid filling the cartridge on a surface that may cause the cartridge to pick up fiber, fluid or debris that may lodge in the analyzer.
- Do not contaminate the contact pads with fingerprints as the analyzer may not be able to make proper contact with the cartridge.

- Do not apply pressure to the central area of the label as the calibrant pack could burst prematurely.
- If results appear inconsistent with the clinical assessment repeat the test with a fresh sample and new cartridge.
- Do NOT use iced specimens.
- **Hemoglobin and or hematocrit results are not to be used for transfusion decision making.**

TROUBLESHOOTING

The following describes troubleshooting for the i-STAT test system. Notify technical coordinator or laboratory supervisor for any i-STAT returned to the lab for further troubleshooting.

- When a Quality Check Code number is displayed, the type of problem and the next step to be taken will also be displayed. Follow the instructions as necessary. Examples: Cartridge Error – Use Another Cartridge or Sample Positioned Short or Beyond Fill Mark – Use Another Cartridge, Dead Batteries – Replace Batteries.
- For other error messages, return the handheld to the Clinical Lab and request a loaner.
- For persistent results that flag "***" or results that consistently do not correlate with the patient's clinical condition, return the handheld to the Clinical Lab and request a loaner.
- If the handheld is dropped, run the external electronic simulator prior to patient testing (may be brought to lab if needed).

INTERFERENCES

Analyte	Interferent	Interferent Concentration	Effect on Analyte Results
Sodium	Bromide	37.5 mmol/L	Increase Na, Use another method
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Increase Na
Potassium	Bromide	37.5 mmol/L	Increased rate of star (***) outs. Increase K, Use another method
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease K
Ionized Calcium	Acetaminophen	1.32 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, Use another method
	Lactate	6.6 mmol/L	Decrease iCa by up to 0.07 mmol/L
	Leflunomide	0.722 mmol/L	Decrease iCa
	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
	Teriflunomide	0.722 mmol/L	Decrease iCa
Glucose	Acetaminophen	1.32 mmol/L	Increase Glu
	Acetylcysteine	10.2 mmol/L	Decrease Glu
	Bromide	37.5 mmol/L	Decrease Glu, Use another method
	Bromide (therapeutic)	2.5 mmol/L	Decrease Glu
	pH	pH: per 0.1 pH units below 7.4 @37C	Decrease Glu by 0.9 ng/dL (0.05 mmol/L)
		pH: per 0.1 pH units above 7.4 @ 37C	Increase Glu by 0.8 mg/dL (0.04 mmol/L)
	Oxygen	PO2 less than 20 mmHg @ 37C	May decrease Glu
	Hydroxyurea	0.92 mmol/L	Increase Glu, Use another method
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease Glu
	Thiocyanate	6.9 mmol/L	Decrease Glu
Hematocrit	White Blood Count (WBC)	Grossly elevated WBC	May increase Hct
	Total Protein	**For measured Hct <40%:**	
		For each g/dL below 6.5	Decrease Hct by 1% PCV
		For each g/dL above 8.0	Increase Hct by 1% PCV
		For measured Hct ≥40%:	
		For each g/dL below 6.5	Decrease Hct by 0.75% PCV
		For each g/dL above 8.0	Increase Hct by 0.75% PCV
	Lipids	Abnormally high	Increase Hct
	Bromide	37.5 mmol/L	Decrease Hct, Increased rate of star (***) outs
Lactate	Bromide	37.5 mmol/L	Decrease Lac results, Use another method
	Glycolic Acid	10.0^{16} mmol/L	Increase Lac
	Hydroxyurea	0.92 mmol/L	Increase Lac
Creatinine >2.0 mg/dL	Acetaminophen	1.32 mmol/L	Increase creatinine
	Ascorbate	0.34 mmol/L	Increase creatinine by up to 0.3 mg/dL
	Bromide (therapeutic)	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 by up to 0.3 mg/dL
	Glycolic Acid	10.0 mmol/L	Decrease creatinine Use Another Method
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Increase creatinine
	PCO_2	$Crea_{corr}$= Crea * (1+0.0025 * (PCO_2-40))	

REFERENCES

- i-STAT 1 System Manual, Abbott Point of Care, Abbott Park IL, Rev 8/28/19.

All revision dates: 1/20/2022, 2/25/2021, 2/11/2020, 11/13/2019

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Director	Lindsey Westerbeck: Dir, Lab	1/20/2022
Laboratory Director	Lindsey Westerbeck: Dir, Lab	1/20/2022