I-Stat Point of Care Procedure **(Specific to: Health Specialties Center Lab, HealthPartners St. Paul Lab, Specialty Center 401 Lung and Sleep Health, Health Specialty Center Radiology and HealthPartners Neuroscience Center Radiology)**	**Attachments** ☐ Yes ☒ No
Key words Point of care testing, Blood Gases, Creatinine, GFR, Potassium, K, I-STAT, ABG, Arterial Blood Gases, CHEM8, EG6	**Number** **GHI-PC-CLINIC LAB-PROCEDURES- I-Stat POCT v. 07-2020**
Category Provision of Care	**Effective Date** **See Electronic File**
Manual Clinic Laboratory Procedure Manual	**Last Review Date** **See Electronic File**
Issued By Laboratory Administration	**Next Review Date** **See Electronic File**
Applicable Health Specialty Center Clinic Laboratory Staff and HealthPartners St. Paul Laboratory Staff Health Specialty Center 401 Lung and Sleep Health Testing Staff Health Specialty Center Radiology Staff HealthPartners Neuroscience Center Radiology	**Origination Date** **October 2005** **Retired Date**
Level of Complexity Blood Gases: Cartridge EG6+: Non-Waived Potassium & Creat: Cartridge CHEM8+: Non-Waived Creatinine: Cartridge CREA	**Approved Date** **See Electronic File**
Review Responsibility Laboratory Administration	**Contact** Regional Clinic Lab Supervisors
APPROVAL(S) Laboratory Medical Director	

Health Specialty Center Specific
Clinic Lab Procedure (Pages 1-6)
Troubleshooting Guide (Page 7)

I. PURPOSE/PRINCIPLE

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The I-STAT is a portable clinical analyzer designed for use at the Point of Care by health care professionals. I-STAT cartridges are available in a variety of panel configurations. Each cartridge contains sensors. The sensors are electrodes micro-fabricated on silicon chips. The electrodes are coated with chemically sensitive films such as ion-selective membranes and enzyme layers. The sensors respond to the calibrant solution and the sample by producing measurable signals related to analyte concentration.

II. POLICY

The iSTAT is a Point of Care instrument, which is used to check Blood gases, Potassium and Creatinine. This policy will apply to all testing personnel who perform this testing which falls under the HealthPartners St. Paul Laboratory, HealthPartners Neuroscience Center or Health Specialty Center Laboratory CLIA number.
At Health Specialty Center the iSTAT is used in the following locations:

- Laboratory: Potassium and Creatinine testing is performed by Laboratory staff
- Lung and Sleep Health PFT Lab: Blood Gases testing is performed by the Respiratory staff
- Radiology: Creatinine testing is performed by Radiology staff.

At HealthPartners St. Paul laboratory, the iSTAT is used by laboratory staff for Potassium and Creatinine testing.

At HealthPartners Neuroscience Center, the I-STAT is used by Radiology staff in the Radiology Department.

HealthPartners family of care uses single-use needle and devices for all phlebotomy and blood collection procedures. Should it be necessary to re-stick a patient, a new, single-use needle or device will be used

HealthPartners family of care will clean the outside of a POCT meter with an approved disinfectant wipe (i.e., Sanicloth AF) after each patient test for meters that come into direct contact with patients in accordance to HPMG policy and CDC requirements. The meter will be cleaned regardless of whether there is visible blood present or not.

III. REAGENTS AND EQUIPMENT

Equipment necessary for testing include the I-STAT portable analyzer, cartridge appropriate for test being performed, and printer.

The following cartridges are used:

- EG6+: cartridges contain pH, pCO2 and pO2
    - (Used in Lung and Sleep Health)
- CHEM8+: cartridge contains Potassium and Creatinine
    - (Used at Health Specialty 401 Lab and HealthPartners St. Paul Clinic Lab)
- Creat: cartridges contain Creatinine
    - (Used at Health Specialty 401 Radiology, HealthPartners Neuroscience Center Radiology and at HealthPartners St. Paul Clinic Lab)

Cartridges are stored at 2-8^{o}C and are stable until expiration. DO NOT FREEZE.
All cartridges should be used immediately after opening pouch. If pouch has been punctured, the cartridge should not be used.

BEFORE USE:
The expiration date changes when the cartridge is removed from the refrigerator. See the back of the cartridge packet for the expiration. Date cartridges when they are removed from the refrigeration and also record the new expiration date. Cartridges must be brought to room temperature (5 minutes at room temperature for individual cartridges or one hour per box) before removing from pouch, and being used. Once at room temperature, EG6+ cartridges are stable for 2 months. Creat cartridges are good for 2 weeks. DO NOT put cartridge back in refrigerator once at room temperature.

NEW SHIPMENT:
Check temperature strip enclosed with each shipment of cartridges. If the windows are clear or if the A window is blue, or the 1 window is red, the cartridges should be accepted. If the B, C or D windows are blue, or the 2, 3, or 4 windows are red, contact Tech Support (1-800-366-8020).

IV. SPECIMEN

EG6+ Cartridge:

- Arterial sample for pH, pCO2, pO2: Fresh arterial whole blood collected in a plain syringe, heparinized syringe filled to capacity or syringe with a minimum volume of lithium heparin to prevent clotting. Lung and Sleep Health uses a prepackaged Arterial Blood Sampling Kit. These samples need to be run within 10 minutes after collection. Maintain anaerobic conditions. Remix before filling cartridge. EG6+ cartridges require a sample volume of 95 microliters.

Creat Cartridge:
Specimen requirement change as of December 1, 2018. Testing blood drawn directly from the line into a syringe is not acceptable. Blood must be placed in a lithium heparinized tube and tested from the tube.

- Samples must be collected in a FULL Lithium Heparin anticoagulant (Light Green Top) tube
- Samples collected with lithium heparin anticoagulant for the measure of Potassium and Creatinine should be used within 30 minutes of collection.

V. SPECIAL SAFETY PRECAUTIONS

Use Universal Blood and Body Fluid Precautions.

VI. QUALITY CONTROL

The Quality Control Regimen for the iStat consists of the automatic checks the I-Stat performs each time a cartridge is run, the internal and external Electronic Simulator, and liquid quality control material.

The laboratory uses values from the manufacturer's package insert for liquid QC ranges as the testing is performed too infrequently to establish POCT lab ranges.

The external electronic simulator is a stable electronic device, which produces signals that simulate the characteristics of the sensors in the cartridges. It simulates two levels of electrical signals, and indicates whether the Analyzers measurements are within specifications. A PASS or FAIL message will appear on the screen. External electronic simulator needs to be run each day of patient testing by trained staff performing testing. It should be performed prior to patient testing. The external electronic simulator should also be run after each CLEW software update which happens twice per year.

Internal Electronic Simulator is a circuit in the analyzer which performs the same functions as the external Electronic Simulator. An internal Electronic Simulator will automatically be performed every eight hours if the I-Stat has not had an external simulator run within the last 8 hours.

A. Procedure for running the external Electronic Simulator

- Press the **On/Off** key to turn the analyzer on.
- Press the **Menu** key.
- Press **3** to select Quality tests.
- Press **4** to select simulator.
- Enter your operator ID and press enter.
- Scan the simulator ID found on box or on the back of the simulator when the I-Stat requests the simulator number.
- Remove the cover protecting the contact pads and insert the simulator straight into the analyzer. Avoid touching the contact pads.
- Do not attempt to remove the simulator until the results are displayed and the "Simulator Locked" message is removed.
- If **PASS** is displayed, the I-Stat is ready for use. Remove the simulator and return it to its protective case.
- If **FAIL**, is displayed, repeat the simulator test. If it fails again, contact the Lab at HSC or call x43544 and the POCT Lab will give you a loaner.
- Once the simulator is run, remove from the I-STAT and replace its protective cover. Store simulator in the simulator box.

B. Liquid Quality Control

The frequency that liquid QC is performed depends on the complexity of the test. At HealthPartners we run EG6+ (Blood Gases), CREA (Creatinine) and CHEM8 (Potassium) cartridges.

EG6+ Cartridge: Test is non-waived. 2 levels of liquid QC is run once per month and with each lot number change based on IQCP.

CREA Cartridge: Test is waived. 2 levels of QC are run one per month and with each lot number change.
CHEM8+ Cartridge: Test is non-waived. 2 levels of QC are run once per month and with each lot number change based on the IQCP

- Control solutions are stored at 2-8°C (35-46°F) until the expiration date on the vial.
- Control solutions may be stored up to 10 days at room temperature (18-30°C)
- Control solutions need to be at room temperature for a minimum of 1 hour before use

To test Liquid QC, the tech performing Quality Control must compare each level of QC results with the corresponding QC ranges to verify they are in range.

- The QC ranges are found on the manufacturer's QC package insert. Verify that the correct CLEW matches the range in use.
- The correct control lot number information, I-STAT cartridge lot number information, ranges, dates, and tech initials must be recorded on the log sheet.
- If the results are out of range, repeat the control one time to see if it comes in range. If not, discontinue testing and notify the lab for further direction.
- Before use, controls must adapt to a temperature of 20 - 25 °C.
- After opening, the vial is stable for 30 seconds.

C. Procedure for running Liquid Quality Controls

To run liquid controls:

- Press the On-Off button (Φ) to turn instrument on.
- Select "Menu" key to access the Administration Menu
- Select the "3" key for Quality Tests
- Press the "1" key for Control.
- Operator ID: Enter your tech I.D.
- Enter the Control lot number by scanning the barcode on the control box with the IR window at the top of the instrument.
- Enter the Cartridge lot number by scanning the barcode on the control box with the IR window at the top of the instrument.
- Fill a cartridge with the control and close the cover.
- Insert the cartridge into the cartridge port.
- View results on analyzer's display
- Remove and discard cartridge when cartridge locked message disappears.
- Press the "1" key for Test Options on the results page and press 1 for Next Level if testing another level of control

Reminder: According to the Internal Quality Control Policy, if expected QC values are not attained, patient results will not be reported until troubleshooting is complete.

VII. CALIBRATION

A one-point calibration is performed each time a cartridge requiring calibration is used. Every cartridge includes a sealed foil pack, which contains a calibrant solution with a known concentration of each analyte. During the first part of the testing cycle the calibrant solution is automatically forced out of the foil pack and over the sensors. The signals produced by the sensors in response to the calibrant solution are stored. Once this sequence is completed, the analyzer automatically moves the sample over the sensors. By comparing the sensors' response to the sample with that of the calibrant, the concentration of each analyte in the sample is calculated.

VIII CALIBRATION VERIFICATION

Per COLA, this step is no longer required.

IX. PROCEDURE

A. Cartridge Test Procedure (for patient samples):

1. Press the On-Off button (Φ) to turn instrument on.
2. Select #2, I-Stat Cartridge from the test menu.
3. Operator ID: Enter your tech I.D.
4. Scan or Enter patient ID.
5. Remove the cartridge from its pouch. Handle a cartridge by its edges. Avoid touching the contact pads or exerting pressure over the center of the cartridge.
6. Dispense the blood into the sample well and fill until the sample reaches the fill mark on the cartridge and the well is about half full.
7. Close the cover over the sample well until it snaps into place. Press on round tab, not over sample well.
8. Insert the cartridge into the cartridge port until it clicks into place. Do not attempt to remove cartridge while Cartridge Locked message is displayed.
9. Patient access number and results can be viewed on the analyzer's display screen.
10. Print results using the Martel printer if needed.
11. Remove cartridge after Cartridge Locked message disappears. The analyzer is ready for the next test.
12. Push #1 test options, and the following choices will appear:
    1. Next patient
    2. Same patient
    3. History.
13. Press #1 to run your next patient.

Sampling Tips:

- Tilt cartridge if sample does not flow to fill mark. You may also tap the cartridge on the counter to make sure the sample is at the fill mark.
- Cartridge may not seal properly if sample well is overfilled. Do not wipe or absorb excess sample with gauze; draw back excess with syringe.
- Do not use cartridge on which blood or any other liquid has spilled as the internal contact pads in analyzer may become contaminated.

Result Flags:

1. Results outside the system's reportable ranges are flagged with a "<" or ">" indicating that the result is below the lower limit or above the upper limit of the reportable range, respectively. The symbol will be followed with a numerical value which is the linearity limit.
2. Results that are unreportable 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 to the laboratory for analysis.
3. Test cycle not completed due to problem with the sample, calibrant solution, sensors, and mechanical or electrical functions of the analyzer.
   Action: Take the action displayed with the message that identifies the problem. See Quality Control checks on Page 7

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

Printing more than one result:
1. Turn the analyzer on.
2. Press the Menu key.
3. Press "2" for Data Review.
4. Press "7" for List
5. Scroll through the test records using the ← and → keys.
6. Press the numbered key for the test records. (Press the numbered key again to deselect a record).
7. Align analyzer and printer IR window to printer. Press the Print key.

X. INTERPRETATION/RESULTS

EXPECTED VALUES/REFERENCE RANGE

Arterial

Test/Age	Reference Range	Reportable Range	Critical Range*
pH 1 month – Adult	7.35 - 7.45	6.5-8.2	≤7.20 or ≥7.60
PCO_2 All Ages	35-45 mm Hg	16-100	<15 or > 70
PO_2 All Ages	80-100 mmol/L	15-650	<50

Test	Reference Range	Reportable Range	Critical Range*
Creatinine	0.6-1.3 mg/dl	0.2-20.0	>7.0
Potassium (K)	3.5-5.3 mmol/L	2.0-7.7	<2.5 or >6.0

*When you get a critical result from a test performed on the I-STAT, the Pulmonary staff, Lab Staff or Radiology staff will notify the physician. A redraw and Lab test are recommended based on the physician's assessment of the patient. The Lab staff follow the HealthPartners Reporting of Critical Value Policy, GHI-PC-LAB-AD Critical Value Policy

*If the test result is out of the reportable range, it must be considered as either greater than or less than the reportable range.

A. Reporting Results:
Pulmonary: When sent to Lab for resulting.

1. Either hand-write or use a computer generated label to supply the following information to the lab with each test request:
   - Patient Name
   - Birth date
   - Medical Record
   - Encounter Number
   - Date & Time of Testing
   - Diagnosis Code
   - Ordering Provider
   - Tech Number
   - Test Name and Test Result

2. Record Results on Manual Worksheet (Check the column with the matching results)
3. If critical result, notify the physician.
4. Fax Health Specialty ABG/COOX worksheet to the Health Specialty 401 Laboratory 651-254-8191. Neuroscience
5. Radiology creatinine results at Neuroscience Center and HealthSpecialty 401 are interfaced and result in Beaker.

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REPORTING RESULTS

Clinic Labs:

Blood Gas	
pH, whole blood	Report to the nearest tenth decimal place
pCO2	Report to the nearest whole number
pO2	Report to the nearest whole number
HCO3	
O2 Saturation	
Inspired O2 Saturation	
Base Excess	
User ID	
Potassium	
Creatinine	

Refer to the EPIC Beaker result entry procedure

XI. TROUBLESHOOTING:

a. The I-Stat will not display results if the test cycle was not completed due to problem with the sample, calibrant solution, sensors, mechanical or electrical functions of the analyzer. If this happens, take the action displayed with the message that identifies the problem. Refer to the I-STAT System Manual's troubleshooting section if necessary

b. When results do not reflect the patient's condition, repeat the test using a fresh cartridge and sample. If results are still suspect, test the lot of cartridges in use with liquid control solutions. If the controls are in range, there may be an interfering substance in the sample. Check the Cartridge and Test Information sheets for the test in question. Refer to Tech Support (1-800-366-8020). If the controls are out of range, there may be a problem with the cartridge lot number. Use another lot number if possible. Notify a lab technical consultant.

c. If Quality Control results are out of range, repeat one time to see if they are in range. If not, notify the

lab and discontinue until further troubleshooting takes place and directions are given.

Quality Check Codes:

127 Wet sensor detected before initial sample movement
128 Invalid sample type
129 Analysis fluid mixed with the sample
130 Air bubble detected in the sample segment
131 Under-filled cartridge
132 Air buddle detected in the sample or increased sample size
133 Expired cartridge lot.
134 User failed to scan the cartridge barcode within the allowed period of time
135 Overfilled cartridge

PROCEDURE NOTES NA

REFERENCES

I-STAT System Manual, 2004
Regions Hospital Laboratory I-STAT Procedure 120707, number RH-PC-POCT-4.3

RELATED DOCUMENTS NA

APPENDIXES NA

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XII. DEFINITIONS

XIII.COMPLIANCE

XIV.ENDORSEMENT

Laboratory Administration