HealthPartners®

I-Stat Point of Care Procedure (Health Specialties Center and St. Paul Specific)	**Attachments** ☐ Yes ☒ No
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APPROVAL(S) Laboratory Medical Director	

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

I. PURPOSE/PRINCIPLE

This procedure provides direction for performing blood gas testing using the I-STAT portable analyzer.

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 I-STAT is a Point of Care instrument used in HealthPartners Specialty Center 401 to perform Blood Gas testing. Set-up and performance of ABG analysis will be responsibility of the LRT in the PFT Lab and the lung and Sleep Clinic.

This policy applies to all testing personal performing Blood Gases under the HSC 401 CLIA license. 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 I-STAT sensors are placed into a cartridge with micro-fluidic components and in some cartridges, a calibration solution. The following cartridges are used at Health Specialty Center 401 in Lung and Sleep Health:

- G3: cartridges contain pH, pCO2 and pO2
- E3: cartridges contain Potassium
- Creat: cartridges contain Creatinine

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:
Date cartridges when they are removed from the refrigeration. Cartridges must be brought up 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, G3+ cartridges are stable for 2 months. E3 and 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

G3+ 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. G3+ cartridges require a sample volume of 95 microliters.

Creatinine Cartridge & E3 Cartridge:

- Samples collected in capillary tubes, both with and without lithium heparin anticoagulant **need to be run within 3 minutes after collection.**
- Samples collected in evacuated or non-evacuated tubes and syringes without anticoagulant **need to be run within 3 minutes after collection.**
- Samples collected with lithium heparin anticoagulant for the measurement of pH, pCO_2, pO_2, $TC0_2$, **need to be run within 10 minutes after collection.** Maintain anaerobic conditions. Remix before filling cartridge.

V. SPECIAL SAFETY PRECAUTIONS

Use Universal Blood and Body Fluid Precautions.

VI. QUALITY CONTROL

The Quality Control Regimen for the I-Stat 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.

A. 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 is a stable electronic device which 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.
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.

B. 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.
- Press enter 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.

C. Liquid Quality Control is run at the first of each month and with lot number changes. Document QC on the Quality Control Log and send to the lab at the end of each month.
- 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.
- 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 25 +1 oC.
- After opening, the vial is stable for 30 seconds.

D. 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

Cartridges are self-calibrating. 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

This is performed by the clinic laboratory every 6 months and after instrument service.
To verify the accuracy of the test methods (cartridges) throughout the reportable ranges, a 5 level calibration verification is run every 6 months. Calibration Verification is also performed after instrument service. These samples with known values are tested in the same manner as patients. The results obtained are compared to the known values and must be within established acceptable limits. If the calibration is stable, the recovered result should match the expected value. If not, troubleshooting and corrective action are needed.

For the G3 cartridge, there is also Hyperbaric and Hypoxic QC to verify the low end of the reportable range and the upper end of the reportable range. Run all samples in the Calibration Verification mode of the I-STAT. If the result for a level is outside the reference range, two additional cartridge runs should be performed on this level and the three results averaged and compared to the reference range. If this average value is still outside the acceptable range, troubleshooting and corrective action may be needed

A. I-STAT Calibration Verification Procedure

Cal/Ver solution and the Hypoxic solution are stored at 2-8C and are stable until the expiration date on the box. The Hyperbaric solution is stored at 15-30C and is stable until the expiration date on the box.

1. Allow the ampoule to adapt to a temperature of 25+ 1C before use.
2. Press the On/Off key to turn the analyzer on.
3. Press the Menu Key.
4. Press 3 to select Quality tests.
5. Press 3 to select Cal Ver
6. Enter your 6 digit operator ID and press enter.
7. Enter (scan) Cal Ver kit lot number
8. Replace panel if needed.
9. Select correct level
10. Enter (scan) cartridge lot number
11. Immediately before use, shake the ampoule vigorously 5 to 20 seconds to equilibrate the liquid and gas phase. (15 seconds for hypoxic and hyperbaric)
12. Fill and insert the I-STAT cartridge within 30 seconds of opening the ampule
13. Verify that values are with in the ranges stated on the value assignment sheet found on the Abbott POCT website. Be sure the correct CLEW sheet is being used.

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.

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	Expected Value	Reportable Range	Critical Range*
pH <1 month	7.35-7.45	6.5-8.2	≤7.20 or ≥7.50
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	16-87	≤15 or ≥ 70
PO_2 All Ages	80-100 mm Hg	15-650	≤50

Venous

Test/Age	Expected Value	Reportable Range	Critical Range*
pH <1 month	7.21-7.41	6.5-8.2	≤7.200 - ≥7.500
pH 1 month – Adult	7.31-7.41	6.5-8.2	≤7.200 - ≥7.600
PCO_2 All Ages	40-52 mm Hg	16-87	≤15 or ≥ 70

Test	Expected Value	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 will notify the physician. A redraw and Lab test are recommended based on the physician's assessment of the patient.

*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:

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 worksheet to the Health Specialty 401 Laboratory 651-254-8191. Lab will enter the patient information and their results into Misys so it is available in EPIC.

XI. TROUBLESHOOTING:

- 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

- 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.

- 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
Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

XIV. ATTACHMENTS

XV. OTHER RESOURCES

XVI ENDORSEMENT

Laboratory Administration