HealthPartners/GHI

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

Health Specialty Center Specific
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I. PURPOSE/PRINCIPLE

This procedure provides direction for doing potassium and creatinine tests on the I-STAT 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 at Health Specialty Center 401 in the laboratory to test Creatinine levels and Potassium levels. This policy applies to all testing personal performing Creatinine and Potassium testing on the I-STAT under the Health Specialty 401 CLIA license. Testing personnel will follow the approved techniques outlined in this procedure.

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.

Specimen:
The following sample types are acceptable:

- Fresh whole blood collected in a capillary tube, a plastic syringe, or a free flowing finger-stick without anticoagulant. For fingerstick samples on tests, wipe away the first drop of blood. Test immediately.
- Fresh whole blood collected in a plastic collection device that does not contain anticoagulants, clot activators or serum separators.
- Fresh whole blood collected in a capillary tube with or without anticoagulant, and samples collected in tubes or syringes without anticoagulant. Test within 3 minutes of collection.
- Fresh whole blood collected in an evacuated collection tube or in a syringe with lithium or sodium heparin anticoagulant. Fill tubes to capacity: fill syringes for correct blood heparin ratio. Test within 10 minutes of collection. Mix well before filling cartridge.
- In-Dwelling Line: Back flush the line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: three to six times the volume of the catheter, connectors, and needle.

Reagents and Equipment:
The I-STAT sensors are placed into a cartridge with micro-fluidic components and in some cartriges, a calibration solution. The following cartridges are used at Health Specialty Center 401 in the laboratory:

CREA contains: Creatinine **E3+** contains: NA, K, Hgb, Hct (Only K is reportable)

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).

CARTRIDGE STORING AND HANDLING:

- Cartridges are stored at 2-8^{o}C. When stored at this temperature, they are good until the expiration date stamped on the cartridge. DO NOT FREEZE.
- Do not use the cartridge if the pouch has been punctured.
- Date cartridges when removed from refrigeration, if they will be stored at room temperature.
- Cartridges must be brought to room temperature (5 minutes for single E3+ and CREA cartridges).
- A full box of cartridges must be at room temperature 1 hour before use.
- Room temperature cartridges are good for 2 weeks.
- Room temperature cartridges must not be returned to the refrigerator.
- Use cartridge immediately after removing it from the pouch.

III. PROCEDURES

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 concentraion of each analyte in the sample is calculated.

Calibration Verification:
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.

There are 5 samples with known values and these 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 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.

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. The external electronic simulator is 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. The 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 either hours if the I-STAT has not had an external simulator run within the last 8 hours.

The trained staff performing testing shall be responsible for performing electronic QC each day of testing. If criteria for Equivalent Quality Control (EQC) has been met, 2 levels of liquid QC are run once per month and with each new lot number of cartridges. If EQC has not been met, run 2 levels of control each day of testing. Document QC on the Quality Control Log and send to the lab at the end of each month.

Liquid controls for potassium and creatinine should sit at room temperature for 30 minutes before using.

- 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 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 logsheet.
- 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 Technical Consultant for further direction.

Equivalent Quality Control:

The I-STAT is a testing system that qualifies for Equivalent Quality Control (EQC) since there is an internal quality control mechanism that monitors all sources of error.

This procedure consists of performing both internal QC and two levels of external QC for 10 consecutive testing days. If all results are acceptable for both internal and external QC, the laboratory may then perform and document internal QC daily and perform and document external QC once per month and with each new lot number.

If any of the following occurs, the lab must stop using the EQC protocol until corrective actions have been completed and documented.

- Either internal or external QC failures that are not resolved by repeating the control one time.
- Proficiency Test failure.
- Any problems identified with this testing as a result of analytic quality assessment activities.

The laboratory must resume performing two levels of external QC every day of patient testing while troubleshooting and problem-solving.

Another EQC study must be performed before resuming the EQC protocol.

To run the simulator:

1. Press the On-Off button (Φ) to turn instrument on.
2. Select “Menu” key to access the Administration Menu
3. Select the “3” key for Quality Tests
4. Press the “4” key for Simulator
5. Simulator Operator ID: Enter your tech I.D.
6. Enter the Simulator ID (serial number) by scanning the barcode on the simulator box with the IR window at the top of the instrument.
7. Remove the blue cap from the simulator.
8. Insert simulator into the cartridge port.
9. The I-STAT will begin performing the test. It takes 2 minutes.
10. View results on the analyzer’s screen
    - If PASS is displayed, continue to use the analyzer.
    - If FAIL is displayed for the external simulator, reinsert the simulator and repeat procedure. If FAIL is again displayed, the I-STAT cannot be used. Return it to the lab.
11. Once the simulator is run, remove from the I-STAT and replace it’s protective cover. Store simulator in the simulator box.

To run liquid controls:

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

NEW CARTRIDGE LOT VERIFICATION:

To verify the accuracy of the test methods (cartridges) through out the reportable ranges, a 5 level calibration verification is run every 6 months.

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. Direct the dispensing tip or capillary tube containing the sample into the sample well.
7. Dispense the sample until it reaches the FILL TO mark on the cartridge. May tap cartridge on counter to make sure sample is at the fill mark .
8. Close the cover over the sample well until it snaps into place. Press on round tab, not over sample well.
9. Insert the cartridge into the cartridge port until it clicks into place. Do not attempt to remove cartridge while Cartridge Locked message is displayed.
10. Patient access number and results can be viewed on the analyzer's display screen.
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
13. History. Press #1 to run your next patient.

Note: If, for whatever reason, the meter is brought to the patient's side for testing, the outside of the meter must be cleaned with an approved disinfectant wipe (i.e. Sanicloth AF) before testing the next patient. Allow the meter to dry before testing. Do not allow moisture into the reagent cartridge slot.

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.

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.

REPORTABLE RANGES

Venous

		Reference Range	Reportable Range	Critical Range:
K	13 months and older:	3.5-5.3	2.0-7.7 mmol/L	≤2.5 or ≥6.0
	2-12 months:	3.5-5.9	2.0-7.7 mmol/L	≤2.5 or ≥6.0
	0-1 Month	3.0-5.9	2.0-7.7 mmol/L	≤2.5 or ≥6.0

	Reference Range	Reportable Range 0.2-20.0 mg/dl	Critical Range
Creat: Adult (20 years and older):			≥ 5.0
Male:	0.66-1.25 mg/dl		
Female:	0.52-1.04 mg/dl		
Male & Female (16 - 19 years):	0.50-1.00 mg/dl		≥ 5.0
Male & Female (15 years):	0.50-1.00 mg/dl		≥ 2.0
9-14 years:	0.39-0.73 mg/dl		≥ 2.0
22 days – 8 years:	0.15-0.53 mg/dl		≥ 2.0
0 – 21 days:	0.33-1.01 mg/dl		≥ 2.0

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

Troubleshooting:

- Results will not display 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. Refer to Tech Support (1-800-366-8020). Check the Cartridge and Test Information sheets for the test in question. Send the specimen to Central Lab for comparison. If the controls are out of range, there may be a problem with the cartridge lot number. Use another lot number if possible. You can perform creatinine-only testing on ISTAT located in Radiology. 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 Technical Consultant and discontinue until further troubleshooting takes place and directions are given.

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

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

Reporting Results:

1. Record Results on Manual Worksheet (Check the column with the matching results)
2. For Computer entry use Function: MEM
3. Worksheet:
   - G3 BG1HS
   - K CHHS
   - GFR CHHS
4. Refer to page 6 for complete result entry instructions.

PROCEDURE NOTES

REFERENCES

I-STAT System Manual, 2004
Regions Hospital Laboratory I-STAT Procedure, 120707, Number RH-PC-POCT-10

RELATED DOCUMENTS

APPENDIXES

AUTHOR/REVIEWER(S)

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IV. DEFINITIONS

V. COMPLIANCE

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

VI. ATTACHMENTS

VII. OTHER RESOURCES

VIII. ENDORSEMENT

Laboratory Administration

ISTAT
Order Code: KWBL
Order Code: CRWBL
Order Code: G3
RESULTING: K

Function MEM, worksheet CHHS

RESPONSE

Test Code	Test Name	Other Comments
KWBL	Potassium	Enter with 1 decimal place, as on instrument printout

RESULTING: GFR

Testing for GFR is performed in the Laboratory and in Radiology at HealthPartners 401 Health Specialty Center. All results are entered in Misys by the HealthPartners 401 Health Specialty Center Lab Staff.

Test Code	Test Name	Other Comments
CRWBL	Creatinine	Enter with 1 decimal place, as on instrument printout
GFRE	Estimated GFR	Automatically calculates when Creatinine is resulted
CFRB	Est. GFR, if black	Automatically calculates when Creatinine is resulted

RESULTING: G3

Testing for G3 is performed in Lung and Sleep Health at HealthPartners 401 Health Specialty Center. Results are entered in Misys by the HealthPartners 401 Health Specialty Center Lab Staff.

Function MEM, worksheet GB1HS

RESPONSE

Test Code	Test Name	Other Comments
TEMP	Last Patient Temp	If this information is unavailable, hit <return>, it will HIDE.
PH	pH, Whole Blood	Round to 2 decimal places.
PCO2	pCO2	Round to closest whole number (no decimal places).
PO2	pO2	Enter as whole number, as on instrument printout.

BE & BD:
Caution: The next 2 tests BE & BD require extra care!
Look at the BEecf result on the instrument printout.
** If result is +, then enter numberical results in BE and add a decimal place (example: 2.0)
If result is - , then enter HIDE for BE.
** If result is - , then enter numerical results in BD. Don't enter a minus sign, just enter the number plus a decimal place (example: 2.0)
If result is + then enter HIDE for BD.
If you get mixed up and do it incorrectly, REJECT and start over.
If you forget to enter a HIDE, either BD or BE will remain pending until you HIDE it.

BE	Base Excess	Displays: "Enter only POS numbers in Base Excess. If NEG number, enter HIDE".
BD	Base Deficit	Displays: "Enter only NEG numbers in Base Deficit. If POS number, enter HIDE".

HCO3	HCO3, Calculated	Enter with 1 decimal place.
TCO2 Prints but is not reported in Misys		Ignore this line on instrument printout.
O2SAT (sO2)	O2 Saturation, Calc	Whole number prints. Add 1 decimal place (example: 98 is resulted as 98.0)
O2IN	Inspired O2 Conc	= amount of oxygen being given to patient (number, to 1 decimal place). If you just <return>, it will result with NOG.
ISID	User ID	Enter tech number of pulmonary function person who performed the testing. This test is suppressed – will not display in Epic or on reports.

Author/Reviewer

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