i-STAT POCT CREATININE TESTING

PURPOSE AND PRINCIPLE
The i-STAT1 system is a battery powered portable analyzer that utilizes single-use disposable cartridges to analyze creatinine using 65uL of venous whole blood collected in a green top vacutainer tube.

Creatinine is measured amperometrically. Creatinine is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatin is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide (H2O2). The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample creatinine concentration.

\[
\text{Creatinine} + \text{H}_2\text{O} \xrightarrow{\text{Creatinine Amidohydrolase}} \text{Creatine} \\
\text{Creatine} + \text{H}_2\text{O} \xrightarrow{\text{Creatine Amidohydrolase}} \text{Sarcosine} + \text{Urea} \\
\text{Sarcosine} + \text{O}_2 + \text{H}_2\text{O} \xrightarrow{\text{Sarcosine Oxidase}} \text{Glycine} + \text{Formaldehyde} + \text{H}_2\text{O}_2 \\
\text{H}_2\text{O}_2 \xrightarrow{} \text{O}_2 + 2\text{H}^+ + 2\text{e}^- 
\]

The i-STAT1 creatinine assay agrees with IDMS-traceable Standard Reference Material SRM 967.

SCOPE
This waived test procedure is intended for use in the Radiology clinics, in both the inpatient and the outpatient settings.

PERSONNEL
Intended for use by clinical personnel who have received training and demonstrated competency in this procedure. In the hospital setting, this includes Clinical Laboratory Scientists, Registered Nurses, Nurse Practitioners, Physician Assistants, Physicians, Respiratory Tech. and Perfusionists. In the ambulatory setting, this includes the
aforementioned personnel as well as Medical Assistants, Licensed Vocational Nurses and other licensed Technologists.

It is the responsibility of the unit nurse manager to prevent use by unauthorized staff, and to provide monthly QC logs to the POCT department.

**EQUIPMENT and REAGENTS**

1. iSTAT1 Analyzer
   The i-STAT1 contains a programmable microprocessor that is capable of storing user passwords, and up to 6,000 patient and control test records.

   **Parts of the Analyzer:**
   A. Display Screen: Displays test and administrative menu, user entry prompts, and test results; arrow keys are used to scroll between prompts and pages
   B. Keypad
      i. Scan key: press when scanning user I.D.
      ii. ABC Key
      iii. → Arrow keys: use to scroll through alphabet, to clear data entry errors or to scroll up or down display
      iv. Numeric keypad
      v. 0 key: press to backlight the display
      vi. Period key
      vii. Enter key: Press to accept data entry
      viii. Menu key: Access to Test Menu and Administration Menu
      ix. ON/OFF Key: i-STAT1 is also activated whenever a cartridge is inserted
      x. Print Key
   C. The infrared communication window is located at the top end of the analyzer.
   D. The barcode scanner is located at the top end of the analyzer.
   E. The battery compartment is located on the back of i-STAT1. The i-STAT is powered by two 9-volt lithium batteries. Battery status is displayed by pressing Menu, Administrative Menu, and 1-Analyzer Status. i-STAT conserves battery power by automatically shutting down after 2 minutes of inactivity.
   F. The cartridge port is located in the bottom end.

The i-STAT is programmed to verify analyzer performance with an internal Electronic Simulator every 8 hours. The daily internal QC is triggered when i-STAT1 is activated. The i-STAT1 will not lock the testing cartridge until it has passed the internal Electronic Simulator. Internal Electronic Simulator testing adds an additional 20 seconds to the testing process.

The i-STAT1 operates in an ambient temperature of 18 to 30°C. The analyzer shuts down and does not allow testing if the ambient temperature exceeds this range. Analyzer Status and data review functions are accessible at this time. Press Menu key, and “1-Analyzer Status” to display ambient temperature. Take corrective action by moving i-STAT1 to an ambient temperature of 18 to 30°C.
Three times a year, or when necessary, I-STAT sends software upgrades with changes to
the CLEW standard and Central Data System. Software on each analyzer must be
upgraded before the current software expires. I-STAT shuts down and will not allow
testing after the software expiration date.

2. Cartridges
The creatinine cartridge (i-STAT catalog # 06F10-01) measures creatinine. Each
cartridge contains a buffered aqueous calibrant solution that contains known
concentrations of analytes and preservatives. For creatinine, a list of reactive
ingredients is indicated below:

<table>
<thead>
<tr>
<th>Reactive Ingredient</th>
<th>Biological source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine</td>
<td>N/A</td>
</tr>
<tr>
<td>Creatine Amidinohydrolase</td>
<td>Actinobacillus sp.</td>
</tr>
<tr>
<td>Creatinine Amidinohydrolase</td>
<td>Microbial</td>
</tr>
<tr>
<td>Sarcosine Oxidase</td>
<td>Microbial</td>
</tr>
</tbody>
</table>

A. Storage of Cartridges
Store the main supply of cartridges in the refrigerator at temperatures between 2-
8°C until its expiration date. Do not allow cartridges to freeze.
Cartridges may also be stored at room temperatures at 18 – 30°C (or 64 to 86°F)
for 14 days.
Cartridges should not be returned to the refrigerator once they have been at room
temperature.
Mark the margins of individual pouches with the 14-day expiration date.
Do not use if room temperature exceeds 30°C or beyond the expiration date.
Discard any cartridges after the 14 day expiration date.

New cartridges are shipped overnight at 2-8°C with a temperature monitor card.
The monitor card contains 4 windows labeled 1, 2, 3 and 4 representing
temperatures from 2 to 34°C. Accept shipment only if the 1 and /or 2 windows
are colored. Reject shipment if windows 3 and or 4 are colored. Notify i-STAT
immediately if shipment is unacceptable.

Each shipment of cartridges must pass QC checks. Test one i-STAT with level 1
and level 3 aqueous liquid controls before patient use.

Refrigerate each new shipment immediately.

B. Handling instructions
i. Test cartridges are sealed in individual pouches and packaged 25 to a box.
ii. Cartridges must remain in their individual pouches until needed.
iii. Once a pouch is opened, it is only good for 5 minutes.
iv. Do not squeeze the foil pack. Handle it only by the edges to prevent accidental
release of calibrant from its sealed pouch.
v. Do not touch the cartridge contact pads. Remove the cartridge from the foil
pack by sliding it out onto a clean surface.
vi. When a cartridge is inserted into the analyzer, i-STAT1 controls all functions of testing, including fluid movement, calibration, testing of patient sample and continuous quality monitoring. Results are displayed in 120 seconds.

vii. A whole blood sample of 1 to 3 drops is dispensed into the cartridge sample well, and the sample well is sealed before inserting it into the analyzer.

3. Controls
   A. External Electronic Simulator
      The external Electronic Simulator is inserted into the analyzer to verify analyzer performance. It simulates two levels of electrical signals that stress the analyzer’s signal detection function both below and across the measurement ranges.

      Use the external Electronic Simulator to verify performance if the analyzer is dropped or damaged.

      Store the Electronic Simulator at room temperature. Protect the contact pads from contamination by replacing the plastic cap each time and store in its protective case.

      Use the external Electronic Simulator to test i-STST’s thermal probes twice a year.

   B. Internal Electronic Simulator
      The i-STAT contains an internal electronic simulator. The analyzer is programmed to run the internal electronic simulator every 8 hours. This is part of the daily QC and it is triggered by the insertion of the cartridge. Additionally, the i-STAT will perform the internal test automatically before the sample is tested.

   C. i-Stat Aqueous Controls Levels 1 and 3 (External Controls)
      Store the i-STAT level 1 and level 3 liquid QC material in the refrigerator at 2-8°C. Each box contains one level of 10 ampules and is shipped on ice. Controls may be stored at room temperature up to 30°C for 5 days. Acceptable ranges for aqueous controls specific to i-STAT software version, CLEW standard, and cartridge type and cartridge lot numbers are available on the Abbott web site (www.abbottpointofcare.com/istat). Equilibrate the control ampule to room temperature for at approximately 30 minutes before use.

4. Martel Printer
   Four 1.5 volt alkaline AA batteries power the small portable printer. The power switch is located on the side of the i-STAT. The printer communicates with i-STAT1 via infrared light located next to the power switch.
Align the i-STAT infrared window with both infrared lights before printing. The printer uses thermal paper that fades with light exposure and is therefore not acceptable as a permanent chartable record. The i-STAT1 is programmed to recognize the printer. See Customization Worksheet.

Battery life is approximately 450 test records. The printer will switch to the low power mode after 10 minutes of inactivity.

Reactivate the printer by pressing the advance paper button. Power light becomes green when it is turned on. Printer power is conserved after 2 minutes of inactivity and green light goes off. If the printer is in the conserved power mode, it can be activated by the print function on the i-STAT. Status light indicates when the printer is out of power and the print process slows down. Infrared window is located on the side of the printer next to the power switch. Align it with the infrared window on the i-STAT 1 before pressing the i-STAT print key.

5. IR Link

This is the receiver that converts the infrared signals from the i-STAT to electrical signals for transmission. The IR link can be connected to a portable printer or to the Central Data Station (CDS).

The i-STAT1 is placed on the cradle to ensure proper alignment during transmission. The red/green status light indicates when the CDS is ready to receive a transmission.

SPECIMEN REQUIREMENTS

The Creatinine cartridges require 0.65 uL of fresh venous blood collected by venipuncture into evacuated tubes with sodium or lithium heparin (green top tubes). The FDA has granted waived status to creatinine testing using iSTAT cartridges only when testing venous samples collected in evacuated tubes with sodium or lithium heparin (green top tubes).

Unless the sample is analyzed immediately after collection and then discarded, the specimen container must be labeled with the patient’s name and medical record number, as well as the date and time of collection.

1. Criteria for sample Rejection:
   A. Sample collected in anticoagulant other than lithium or sodium Heparin (anything other than a green top tube or heparinized syringe).
   B. Sample volume less than 0.65 uL
   C. Sample collected in a capillary tube.
   D. Unlabelled samples

CALIBRATION / CALIBRATION VERIFICATION

The i-STAT calibrates each cartridge before the sample is assayed. Creatinine values assigned to the i-Stat’s controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM967 (IDMS-traceable).
QUALITY CONTROL

1. Internal Electronic Simulator:
   The i-STAT is programmed to automatically verify the performance of each analyzer every 8 hours with an internal Electronic Simulator. Additionally, it automatically runs whenever i-STAT is activated. Results are stored as PASS or FAIL and may be viewed by selecting Database from the Menu.

   Corrective action for FAIL:
   A. Repeat with external Electronic Simulator.
   B. If external Electronic Simulator fails, call i-STAT Technical Services.
   C. Document in Daily Maintenance Log and notify manager.
   D. Take i-STAT1 out of service.

2. External electronic Simulator:
   Use the External Electronic Simulator whenever the internal simulator fails, if the analyzer has been dropped or damaged, if ambient temperature exceeded 30° C, if remedial action is warranted, and for biannual verification of analyzer Thermal Probe. The i-STAT will power on when external Electronic Simulator is inserted. Alternatively, the i-STAT may also be powered on by pressing the ON/OFF key.

   A. To use the external Electronic Simulator:
      i. Press Menu.
      ii. Select 3-Quality Control
      iii. Select 4-Electronic Simulator
      iv. Follow prompts
      v. Scan or enter user I.D.
      vi. Remove blue protective cap on Electronic Simulator.
      vii. Insert Simulator when prompted. “Simulator Locked” is displayed.
           *DO NOT REMOVE* until “Locked” disappears.
      viii. i-STAT displays either PASS or FAIL.
      ix. Remove when prompted by analyzer.

   B. Corrective action for FAIL external Electronic Simulator
      i. Repeat external Electronic Simulator on same analyzer
      ii. Repeat on second i-STAT analyzer.
      iii. If the first analyzer again fails, take it out of service.
      iv. If both analyzers fail, Electronic Simulator pins may have been damaged.
      vi. Notify manager.
      vii. Call i-STAT Technical Services at 1-800-366-8020 for assistance, if needed.
3. Aqueous Controls
   Level 1 and level 3 aqueous controls are performed each time a new box of cartridges is opened.

   In addition, once a month, test cartridges with the level 1 and level 3 aqueous controls on each iSTAT to verify storage conditions. Values that are outside the manufacturer’s acceptance range must be repeated and corrective action documented before patient samples can be run.

   Additionally, test each shipment of i-STAT cartridges with the i-STAT Level 1 and Level 3 aqueous controls. Accept cartridge shipment if results are within the manufacturer’s acceptance range.

A. Handling Aqueous Controls:
   i. Aqueous controls are stored in the refrigerator at 2 to 8\(^\circ\) C.
   ii. Controls may also be stored at room temperature up to 30\(^\circ\)C for 5 days.
   iii. QC ampules may be used once the fluid has reached room temperature, approximately 30 minutes for individual ampules.
   iv. Use a 1cc syringe and 16-20 gauge needles to aspirate controls.
   v. Aspirate control within 10 minutes after opening ampule.

   On the i-STAT:
   i. Press ON/OFF key to power i-STAT on.
   ii. Press Menu
   iii. Select Quality Control
   iv. Enter user I.D.
   v. Follow prompts for entering control lot number and control

B. Testing Controls:
   i. Remove cartridge from its pouch. Do not touch contact pads.
   ii. Immediately before use, shake the ampule vigorously for 5-10 seconds.
   iii. Cover ampule with a piece of gauze and snap open.
   iv. Immediately insert a 1 ml syringe fitted with a 16-20 gauge needle into the bottom of the ampule.
   v. Slowly aspirate 0.5 mL of solution. Do not aspirate any air bubbles.
   vi. Remove needle.
   vii. Place syringe tip over sample well and dispense sample to the fill mark.
   viii. Close pressure over the sample well.
   ix. Insert cartridge into the i-STAT cartridge port when prompted.
   x. Review displayed results.
xi. Compare results to acceptance range. Do not report patient results if QC is out of acceptable limits.

xii. Document control results on the QC log sheet.

C. Corrective action if liquid QC is out of range:
   i. Before repeating with a new ampule of control, review the following:
      1. Ensure that the acceptance range on QC Log is for the appropriate cartridge lot.
      2. Ensure that the CLEW software on the control sheet is the same as the CLEW version on the analyzer. Press Menu and select Analyzer Status to view i-STAT software version and CLEW Std.
      3. Call i-STAT Technical Services for acceptance range if the analyzer CLEW Std and/or Cartridge lot number is not listed.

   ii. Repeat the control with a new ampule after equilibrating it at room temperature for 30 minutes. If the repeat LQC is out of range, instrument must be taken out of service.

   iii. Review control technique with i-STAT trainer or POCT coordinator.

   iv. Two levels of liquid controls must be successfully run for 10 days prior to put the instrument back in service.

   v. Evaluate all patients results obtained in the unacceptable test run and since the last run with acceptable QC to determine if the results were adversely affected, before reporting the results and/or issuing corrected reports, if necessary.

** If new shipment of cartridges fails to pass any level of aqueous control after repeat testing, sequester lot with a “Do Not Use” note. Document in Maintenance Log and notify your manager immediately.

4. Internal or External QC out of range follow up:
   Per CLIA equivalent QC regulations, if any control result is outside acceptable limits, retest the unacceptable control one time.

   If FAIL is displayed on the analyzer screen:
   Repeat the procedure with the same external Electronic Simulator or rerun the cartridge if the internal Electronic Simulator is being used.
   • If PASS is displayed use the analyzer as required.
• If FAIL is displayed repeat the procedure with a different external Electronic Simulator.

If PASS is displayed with the second external Electronic Simulator:
• Use the analyzer as required.
• Deliver the questionable external Electronic Simulator to the i-STAT Coordinator.

If FAIL is displayed with the second external Electronic Simulator:
• Take the instrument out of service.
• Record the failure in the QC log along with the action taken.
• Report to i-STAT Coordinator.

5. New Cartridge Shipments
Acceptance Criteria:
A. Temperature of cartridge shipping container does not exceed 8°C. Only window A/1 of Temperature Monitor is colored. Windows B/2, C/3, and D/3 are colorless.
B. Document shipping temperature on Monitor card.
C. Results of testing with i-STAT aqueous controls are within the manufacturer’s acceptance range. Document results on New Cartridge Shipment Log.

Criteria for Rejection:
A. Windows B, C, or D of Temperature Monitor is blue. This is an indication that shipping container temperature has been compromised.
B. Results of any level of i-STAT aqueous controls are outside of the manufacturer’s acceptance range.

PATIENT TESTING PROCEDURE
Verify patient identification using two patient identifiers and explain procedure to patient and/or family.
If sample is not obtained from the patient by the person who will perform the test, and the test is not performed immediately, then the specimen must be labeled with two forms of patient identification, in the presence of the patient.

A. Handling the Cartridge:
   i. Cartridge must be at room temperature for a minimum of 5 minutes.
   ii. Remove cartridge from its pouch without touching the contact pads or exerting pressure over the center of cartridge.
   iii. Blood samples must be thoroughly mixed by rolling between the palms in 4 planes for 15 seconds.
   iv. Direct syringe tip containing the sample over the sample well.
   v. Dispense sample until it reaches the fill mark. Sample must be dispensed without a break in one application.
vi. Inspect and discard if air bubbles are present.

vii. Close cover over the sample well until it snaps into place. Do not exert pressure over the sample well.

**B. Procedure Using the Cartridge Insertion Mode:**

i. Insert cartridge into the i-STAT cartridge port.

ii. Follow displayed prompts.

iii. Enter user I.D. by pressing on scan key and scanning user barcode.

iv. You may also use the ABC key and numeric keyboard to enter user I.D.

v. Press ENTER to accept.

vi. i-STAT1 does not allow correction of an accepted entry. To modify a mistake, enter correction into data Field 3.

vii. Do not remove cartridge when “Locked” is displayed.

viii. Enter additional information if needed.

ix. Remove cartridge when “Locked” is no longer displayed.

**C. Procedure Using Information Pre-entry Mode:**

i. Press ON/OFF key to turn i-STAT on.

ii. Select 2-i-STAT Cartridge.

iii. Enter operator I.D. by pressing the Scan key and scanning user barcode.

iv. You may also use the ABC key and numeric keyboard to enter user I.D.

v. Enter patient I.D. using the ABC key. Enter two patient identifiers, the medical record number and the birthdate.

vi. Press ENTER to accept. The i-STAT1 does not allow correction of an accepted patient I.D.

vii. To modify a mistake, enter correction into patient data Field 1.

viii. Insert filled cartridge. Do not remove cartridge when “Locked” is displayed.

Enter additional parameters if desired.

ix. *Do Not Remove* cartridge when “Locked” is displayed. Remove after Locked disappears.

**D. Printing results:**

i. Turn on printer.

ii. Align printer’s infrared window with that of i-STAT1.

iii. Press print key on analyzer.

iv. Do not move analyzer or printer until the printout is completed.

v. Document results in the patient record.

**E. Recalling Results:**

i. i-STAT displays last results when it is powered on.

ii. Select 1-for last results from Main Menu.

iii. Press Menu key to view previous patient or control results.
REPORTABLE RANGE:

0.2-20.0 mg/dL
Results below 0.2 are reported as “<0.2”. Results above 20.0 are reported as “>20.0”.

REPORTING RESULTS:

Reference Range:

<table>
<thead>
<tr>
<th>Age</th>
<th>Male &amp; Female</th>
<th>Panic Values</th>
<th>Repeat</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; or = 19 years</td>
<td>0.6 - 1.3 mg/dL</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>eGFR</th>
<th>&lt; 18 years</th>
<th>Not calculated (see Additional Information)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; or = 18 years</td>
<td>&gt;60 mL/min/1.73 m2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Results are displayed numerically with reporting units. Document test results in the patient’s chart using the form “RADIOLOGY POINT OF CARE TEST RESULTS”.

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

If results eGFR <60, send the green top tube with a lab requisition to the laboratory for creatinine testing. Notify radiologist for further instructions noted on patient screening form.

Suppressed Results:
Three conditions in which i-STAT will not display results:
A. Results flagged with < or > are outside of the reportable range.
B. Results with <> flag indicates the results for this test is dependent on test flagged with either < or >.
C. *** Results are not reportable due to failed internal QC. Repeat test with a fresh sample and new cartridge.
D. A quality check message is displayed if analyzer detects problems with sample, cartridge and/or analyzer.

Whenever a user identifies that an incorrect result has been reported, they are responsible for correcting/commenting the incorrect result (if possible), contacting the ordering provider, notifying them of the error, and documenting this notification, including the time and date, in the patient record.

DAILY MAINTENANCE
1. Check Analyzer Status each day of patient use:
   A. Press ON.
   B. Press Menu
C. Select Analyzer Status
D. i-STAT displays the following:
   i. Temperature
   ii. Barometer Pressure
   iii. Battery
   iv. Number of uses
   v. Analyzer serial number
   vi. CLEW Standard
   vii. Software Version

2. Check battery status each day of patient use:
   A. Press On/Off key.
   B. Press Menu key.
   C. Select 1 for Analyzer Status
   D. Read and record Battery status on daily log.
   E. If the battery status is \leq 7, replace both batteries. Do not mix old and new batteries.
   F. Press Menu to exit screen.
   G. Document in Daily Maintenance Log.

3. Read and record ambient and refrigerator temperature.

4. Examine infrared window. Clean i-STAT1 with damp gauze; moisten with 10% bleach if necessary. Do not use alcohol on display screen.

PROCEDURE NOTES
1. Alpha Numeric Keys for Data Entry
   I-STAT defaults to the numeric keypad. Access the Alphabet by pressing on the ABC key. Search for desired alphabet by using either the left arrow or right arrow keys.
   A. To Use Alpha Keys:
      i. Press ABC key.
      ii. Press Left arrow key to start with the letter Z or the right arrow key to start with the letter A
      iii. Press the arrow key until you see the desired letter.
      iv. Press ABC key to accept selected letter.
      v. Press ABC key again to enter the next letter.
      vi. Use the left arrow key to correct an entry error.
      vii. Press ABC to return to numeric keyboard.
      viii. Press the ENTER key to accept entered I.D.
      ix. Do not press ENTER key until you have completed I.D. entry. You cannot correct patient I.D. once it is accepted. If you make a mistake, enter correction into the patient data Field 3.

   B. Recalling and Printing Results
      The i-STAT 1 stores 6000 patient and quality control test records.
      To view Results on the i-STAT:
i. Main Menu
ii. Press the ON key to view last result. Last result may also be viewed on the Main Menu by selecting 1-Last Result.
iii. Administrative Menu
iv. Press Menu Key to view Administrative Menu
v. Select 2-Data Review
vi. Select 1-Patient: review patient history by I.D.
vi. Select 2-Controls: liquid control data
viii. Select 3-Proficiency
ix. Select 4-Cal Ver
x. Select 5-Simulator
xi. Select 6-All: displays results of all samples, record number displayed/total number of records, press 2 to view previous record
xii. Select 7-List: List all test by time, date, and patient I.D. Select a record number to review or print an individual result.

C. i-STAT Thermal Probe Procedure
The i-STAT analyzer contains a thermal control system that maintains testing temperature at 37°C. A precise measurement of the temperature cannot be taken during the testing cycle.

Use the Electronic Simulator to check the stability and accuracy of probes over the operational analyzer range biannually.

Analyzer Procedure:
To verify that the ambient temperature of i-STAT1 and Electronic Simulator is within 3°C of each other:
1. Press Menu
2. Select Quality Control
3. Select Electronic Simulator.
4. Insert Simulator when prompted.
5. When PASS result is displayed, press the period key.
6. i-STAT displays the difference between thermal probes.

Acceptance Criteria: Thermal Difference between probes is within ± 0.1°C.

Unacceptable results: Difference between probes is greater than ± 0.1°C. FAIL appended with either a “T”, difference exceeds 0.25°C or “t” average difference exceeds ± 0.1°C.
Value of “_._” indicates unstable temperature reading. Wait 15 minutes for i-STAT and External Simulator to warm to ambient temperature before repeating.

Verification of the thermal probe may also be viewed on Central Data Station report after downloading the analyzer:
1. Click on Data Viewer.
2. Select Record in Menu Task Bar
3. Select Extended Electronic Simulator Report
4. Review Probe Delta, external Simulator.
5. Results other than “_._” are considered in compliance.

D. Analyzer Software Updates

The i-STAT makes continuous manufacturing process improvements that necessitate re-establishing standardization values to maintain long-term consistency by recalibrating the analyzer. This is accomplished by software upgrades that adjust the calibration on the analyzer. The manufacturer sends out software upgrades three times a year. Included in the packet are instructions and Technical Bulletins related to changes. Software on all i-STAT1 analyzers should be upgraded at the same time and before the current software expires. Each testing location is responsible for the updating to the new CLEW and Central Data Station software.

Upgrading Software Using the Central Data System:
2. Follow procedure and install software in PC.
3. Place i-STAT in IR Link.
4. Transmit i-STAT test data to PC.
5. Follow procedure for installing software.
6. Repeat procedure for other analyzers.
7. After software upgrade, test with Electronic Simulator on each analyzer.
9. Update aqueous control ranges for the new Jams Version, CLEW Std, Cartridge Type, and current Cartridge Lot number.
10. If new control acceptance ranges are different, modify acceptance range on QC Log.

Upgrading Software Using an Analyzer with Updated Software
1. Transmit all data from i-STAT1 being upgraded.
2. On sending i-STAT1, press Menu.
3. Select Utility from Administrative Menu.
4. Enter password when prompted.
5. Select 1-Send Software.
6. Select 1-JAMS and CLEW or 2-CLEW Std. “Waiting to send” is displayed.
7. Ensure receiving i-STAT is OFF.
8. Place both i-STATs one foot apart and align their infrared windows.
9. Adjust position until the sending i-STAT displays “Sending” and a scrolling banner appears on the receiving i-STAT1.
10. Do not move until the sending i-STAT1 display returns to the Send Software option with the message “Successful” or “Unsuccessful”.
11. Select Analyzer Status on the receiving i-STAT1 and verify new JAMS and CLEW Std.
12. Test receiving i-STAT1 with external Electronic Simulator.
I-STAT 1 Analyzer menu:

Main Menu
1-Last Result
2-i-STAT Cartridge

Press Menu for Administrative Menu

1-Analyzer Status
Displays: Temperature, Barometric Pressure, Battery Status, Number of stored test records, Analyzer Serial #, CLEW Standard, and Software Version
2-Data Review
3-Quality Test
4-Customization allows operator to customize i-STAT1 program.
5-Set Clock requires key operator password.
6-Transmit Data
7-Utility requires key operator password.

Press Menu Key to return to Administrative Menu

I-STAT 1 Customization Menu
Each analyzer may be individually customized key operator or through the Central Data System. Customization is password protected. However, operators may view settings by selecting 1-View, which does not require Key Operator password.

Press Menu Key.
Select 4-Customization on Administrative Menu.

Customization Menu
1-View
2-Customize
Select 1-View to review customization.
Select program to be reviewed.

Press menu to return to Administrative Menu.

Summary of i-STAT Customization

1-Analyzer
Date Format-mm/dd/yy
Sound enabled
Auto-transmit enabled
Memory Full Allow Test
Inactivity Timeout 120 seconds
Up loader Schedule 744 hours Warn User
Printing Protocol, disabled
Clock Password enabled

2-I.D. Entry
1- Operator I.D.
Minimum Length 5 digits
Maximum Length 8 digits
Repeat I.D. disabled.
Manual entry No check digit
Codes: Enable all
2- Patient I.D.
   Minimum Length 2 digits
   Maximum Length 15 digits
   Repeat I.D. disabled
   I.D. Recall disabled
   Manual entry No check digit
   Codes: Enable all
   (Left arrow to return to Customization Menu)

3- Patient Tests
   Cartridge information and Cartridge lot not required.

4- QC Tests
   Ext Simulator disabled, Int Simulator 8 hours, Int Simulator Schedule Option,
   Lock out

5- Results

PRECAUTIONS
Cartridges are affected by freezing and should be stored at 2 to 8° C. Freezing causes ionized calcium in the calibrant to precipitate resulting in falsely elevated values. Sources of error can arise from improper collection and handling of blood sample. If sample is not tested immediately, it must be labeled with at least 2 patient identifiers and well mixed just prior to testing.

LIMITATIONS
Factors Affecting Results*

<table>
<thead>
<tr>
<th>Interferent</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>Creatinine results will increase by approximately 0.25 mg/dL (22 µmol/L) per every 1 mmol/L of acetaminophen.</td>
</tr>
<tr>
<td>Ascorbate</td>
<td>0.227 mmol/L ascorbate will cause a 0.7 mg/dL (62 mol/L) increase in creatinine.</td>
</tr>
<tr>
<td>Bromide</td>
<td>100 mg/dL (12.5 mmol/L) bromide will increase creatinine by 0.8 mg/dL (71 mol/L) from an initial creatinine concentration of 1.0 mg/dL (88 mol/L).</td>
</tr>
</tbody>
</table>
| CO2 | For Creatinine values below 2 mg/dL:  
For $PCO2$ values above 40 mmHg, the values are increased by 6.9% for every 10 mmHg  
For $PCO2$ values below 40 mmHg, the values are decreased by 6.9% for every 10 mmHg  
$[\text{Cr}]_{\text{corrected}} = [\text{Cr}]_{\text{stat}} \times \{ 1 - ( 0.069 \times [(PCO2 -40)/10]) \}$  
For Creatinine values above 2 mg/dL:  
For $PCO2$ values above 40, the values are decreased by 3.7% for every 10 mmHg  
For $PCO2$ values below 40, the values are increased by 3.7% for...
every 10 mmHg
{\text{Cr}}_{\text{corrected}} = \left( \text{Cr}_{\text{istat}} \times \left(1 - \left(0.037 \times \frac{(40 - \text{PCO}_2)}{10}\right)\right) \right)

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatine</td>
<td>5 mg/dL (382 mol/L) creatine will cause a 0.20 mg/dL (18 mol/L) increase in Creatinine.</td>
</tr>
<tr>
<td>N-acetylcysteine</td>
<td>16.6 mmol/L N-acetylcysteine will cause a 0.4 mg/dL (36 µmol/L) increase in creatinine.</td>
</tr>
<tr>
<td>Hydroxyurea (Droxia, Hydrea)</td>
<td>Hydroxyurea may cause significant errors in the measurement of creatinine with the i-STAT system. Use an alternative method to measure creatinine when patients have been administered hydroxyurea. See note (2) below for typical uses of this drug and note (3) below for details of the interference.</td>
</tr>
</tbody>
</table>

**Notes**

1. The normal range of creatine concentration in plasma is 0.17–0.70 mg/dL (13 – 53 mol/L) in males and 0.35 – 0.93 mg/dL (27 – 71 mol/L) in females. Creatine may be elevated in patients using creatine supplements, experiencing muscle trauma or other primary or secondary myopathies, taking statins for hyperlipidemia control, or in patients with hyperthyroidism or a rare genetic defect of the creatine transporter protein.

2. Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients’ blood may be sustained at approximately 100 to 500 mol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

3. For every 100 mol/L hydroxyurea in the whole blood sample, creatinine will be increased by approximately 1.85 mg/dL (164 mol/L), up to a whole blood hydroxyurea concentration of at least 921 mol/L (maximum concentration tested). The magnitude of the bias is independent of the creatinine level over a range of at least 1.0 mg/dL (88 mol/L) to 12.4 mg/dL (1096 mol/L).

Bicarbonate up to 40 mmol/L, bilirubin up to 20 mg/dL (342 mol/L), calcium up to 5.0 mg/dL (1.25 mmol/L), dopamine up to 13 mg/dL (0.85 mmol/L), methyldopa up to 2.5 mg/dL (118.4 mol/L), salicylate up to 77.5 mg/dL (4.34 mmol/L), sarcosine up to 1.0 mmol/L, and uric acid up to 20 mg/dL (1190 mol/L) were tested and found not to interfere with creatinine results.
*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Additional Information:

To convert mg/dL to µmol/L (SI units) multiply by 88.4. See method details for assay limitations and drug interferences.

The normal range for serum creatinine in adults was verified using donor samples collected from our Donor Center (excludes autologous donors). We adopted the manufacturer's adult reference range of 0.6 to 1.3 mg/dL.

Estimated GFR (eGFR) is reported with serum creatinine results in adults and is determined using the original MDRD study equation. (This equation should be used only with those creatinine methods that have not been recalibrated to be traceable to IDMS)

\[
GFR \ (mL/min/1.73\ m^2) = 186 \times (\text{Scr})^{-1.154} \times (\text{Age})^{-0.203} \times (0.742 \text{ if female}) \times (1.210 \text{ if African-American})
\]

Because the MDRD formula is not considered sufficiently accurate for estimating GFR in patients with normal or mildly reduced renal function, results greater than 60 mL/min/1.73 meters squared body surface area are displayed as > 60 mL/min and are not reported as an exact number. Note that the estimated GFR result is not reliable in certain groups including severely ill patients. The MDRD equation used to estimate GFR has been validated only in Caucasian and African Americans 18 – 70 years of age. The equation has not been validated in other population groups, pregnant women, transplant recipients, medically unstable patients including those with acute renal failure, or in persons with extremes of body size, muscle mass, or nutritional status. Application of the MDRD calculation in these cases may lead to errors in GFR estimation. GFR can also be estimated from serum creatinine in adults by the older formula of Cockcroft DW, Gault MH: (Nephron 1976;16:31):

\[
GFR \ [mL/min] = \frac{(140-\text{age [yrs]}) \times (\text{wt [kg]})}{(72 \times \text{creatinine [mg/dL]})}
\]

For women, multiply the calculated result by 0.85

Note that the Cockcroft-Gault formula is susceptible to many of the same limitations of the MDRD formula and may overestimate GFR by 16% or more when using current methods of creatinine measurement.
According to the National Kidney Disease Education Program, the best equation for estimating glomerular filtration rate (GFR) from serum creatinine in children is the Bedside Isotope Dilution Mass Spectrometry (IDMS)-traceable Schwartz equation


**Bedside IDMS-traceable Schwartz Equation for Children**

GFR (mL/min/1.73 m²) = (0.41 x Height in cm) / Creatinine in mg/dL

**REFERENCES**

i-STAT System Manual, 9/17/2009
i-STAT Waived Testing Regulatory Guide
i-STAT Technical Bulletin “The i-STAT System and Waived Status” 2/19/2009
CLIA Clinical Lab Improvement Amendments, brochure #4: Equivalent Quality Control Procedures. 4/24/2003
## For Approval iSTAT Creatinine

### SR Sup Review

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<td>Cynthia Ishizaki (024044224)</td>
<td>POC SR SUP</td>
<td>18 Jun 2013, 05:30:00 PM</td>
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### Med Dir Apprvl

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<tr>
<td>Tim Hamill (023335003)</td>
<td>PA CB MED DIRECTOR</td>
<td>19 Jun 2013, 09:24:58 AM</td>
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### Quick Approval

### Approve Now

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<td>POC CLS SPEC SUP</td>
<td>20 Jun 2013, 11:55:58 PM</td>
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