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48667.284 Abbott iSTAT-1: Creatinine (Whole Blood)

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4.0	Approved and Current	Major revision	3/13/2020	4/24/2020	Indefinite

Linked Documents

- 48667.285 Abbott iSTAT 1 Creatinine Test Initial Orientation & Training Form
- 48667.286 iSTAT Daily QC Log
- 48667.287 iSTAT Creatinine Competency Test
- 48667.300 iSTAT 1 Liquid QC Creatinine Log

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Approved by Barbara Haller on 4/24/2020.
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Abbott iSTAT-1: Creatinine (Whole Blood)

PURPOSE

This procedure is to detect patients with renal failure who might be harmed by intravenous contrast media used for imaging procedures. The iSTAT 1 analyzer is intended for use in approved Point of Care locations. With the iSTAT 1 System, the FDA has categorized the Creatinine Cartridge as a Waived Complex **Test** when testing is performed using venous whole blood samples collected in sodium or lithium heparin evacuated tubes only.

PRINCIPLE

Creatinine is hydrolyzed to creatinine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current, which is proportional to the sample creatinine concentration.

TESTING PERSONNEL

A. Qualified and licensed Registered Nurses and Radiology Technologists. NOTE: Radiology Technologists (Diagnostic Imaging Technologist II) may perform the test only in outpatient settings.
B. Testing personnel are required to take the Initial Orientation and Training, a written exam, and a second written exam within the first year of certification for this POC Test.
C. Written competency exams are then required annually thereafter.
D. Upon successful completion of the Initial Orientation and Training and written exam, staff will be issued a barcode ID to be able to use the iSTAT analyzer.
E. This barcode in embedded with unique identifiers specific to each staff member. **IMPORTANT**: ***NEVER*** *share your Barcode ID!*
F. It is the responsibility of the unit Nurse Manager to prevent use by unauthorized staff.

EQUIPMENT AND MATERIALS

- iSTAT 1 Analyzer
- iSTAT Creatinine Cartridge (cat# 03P8425, i-STAT Corporation)
- Disposable transfer device (e.g., syringes, pipets)
- iSTAT dispensing tips
- Portable Printer
- Quality Assurance Materials
  - Electronic Simulator
  - iSTAT Level 1 and Level 3 Control Solutions
- Data Management System
  - iSTAT 1 Downloader/Recharger
- Approved cleaning solutions and materials (e.g., mild non-abrasive cleaner, detergent, soap and water, alcohol, Clorox Healthcare Hydrogen Peroxide cleaner disinfectant wipes, PDI Bleach wipes)
- 9 volt lithium batteries
- Kimwipe tissues
- iSTAT 1 System Manual

GENERAL SAFETY INSTRUCTIONS

A. Only trained health care professionals may operate iSTAT 1 Analyzer. Operators must have received comprehensive instruction in the operation, quality control, and care of the iSTAT 1 Analyzer.

OVERVIEW OF THE iSTAT 1 ANALYZER:

A. **Keypad**

Key	Function
SCAN	Activates the barcode scanner. Information that can be entered into the analyzer via the scanner includes: Operator ID, Patient ID, Control and Cartridge lot number.
← →	Used to move up and down the alphabet when the ABC key is pressed. The → (right arrow) key is used as a page key to move from one screen to the next. The ← (left arrow) key is used to backspace and clear keypad entries, and to move backward through the screens within a menu.
ABC	Used to enter alpha characters on data entry screens.
0 – 9	Used to enter digits on data entry screens and to select menu options and stored records.
	Used to turn the screen backlight on and off.
Enter 	Used to respond to a prompt to complete an action, such as entering an operator or patient ID via the keypad.
MENU	Used to return to the previous menu and switch between the Test and Administration Menus.
Print 	Used to print directly to the portable printer.
On/Off 	Turns the analyzer on or off. When the analyzer is on, the On/Off key must be pressed for a second to turn the analyzer off. This key is inactive when a test is in progress and when the analyzer is prompting for mandatory data.

B. iSTAT 1 Menu Tree – there are two main menus: The Test Menu and the Administration Menu.

1. **Test Menu** – is displayed when the analyzer is turned on using the On/Off key. The options are:
   a. 1 – Last Result
   b. 2 – iSTAT Cartridge

2. **Administration Menu** – is accessed by pressing the Menu key from the Test Menu screen. The options are:
   a. 1 – Analyzer Status – screen contains information about the condition or “status” of the analyzer such as:
      i. Temperature – room temperature.
      ii. Pressure – barometric pressure.
      iii. Battery – battery voltage.
      iv. Uses – total number of cartridge and simulator test cycles, whether or not results

reported.

v. Serial – serial number of the analyzer.
vi. CLEW – version of standardization data installed in the analyzer.
vii. Version – version of application software installed in the analyzer.
viii. Custom – customization profile name. For POC Services use only.
ix. Store records – Total: the number of test records in the analyzer's memory. Unsent: the number of test records that have not been transmitted to the Central Data Station.

b. 2 – Data Review – allows the operator to review stored results by the categories listed below.
   i. 1 – Patient
   ii. 2 – Control
   iii. 3 – Proficiency – not applicable
   iv. 4 – Cal Ver – not applicable
   v. 5 – Simulator: All external and internal Electronic Simulator records.
   vi. 6 – All: All test records in the analyzer's memory.
   vii. 7 – List: Records are listed with Cartridge type, date and time of test, patient ID, or control lot. Any number of test records can be selected for viewing or printing using the number keys.

c. 3 – Quality Tests – non patient tests can be initiated from the Quality Tests menu. The options are:
   i. 1 – Control
   ii. 2 – Proficiency – not applicable
   iii. 3 – Cal Ver – Calibration Verification for cartridges. For POC use only.
   iv. 4 – Simulator – cartridge-reading function only.

d. 4 – Customization – for POC Services use only.

e. 5 – Set Clock – for POC Services use only.

f. 6 – Transmit data – Unsent test records are automatically transmitted to the Central Data Station when an iSTAT 1 analyzer is placed in a Downloader/Recharger. In some cases, it may be desirable to have the capability to retransmit data. The Transmit Data function allows transmission of data in the following manner:
   i. 1 – Most Recent
   ii. 2 – This Month
   iii. 3 – Last Month
   iv. 4 – All
   v. 5 – Unsent

g. 7 – Utility – for POC Services use only.

C. The **Infrared Communication Window** is located at the top left of the analyzer. It provides the analyzer with two-way communication to the Central Data Solution via a Downloader. Allows the analyzer-to-analyzer software updates, and allows analyzer-to-printer communication for printing.

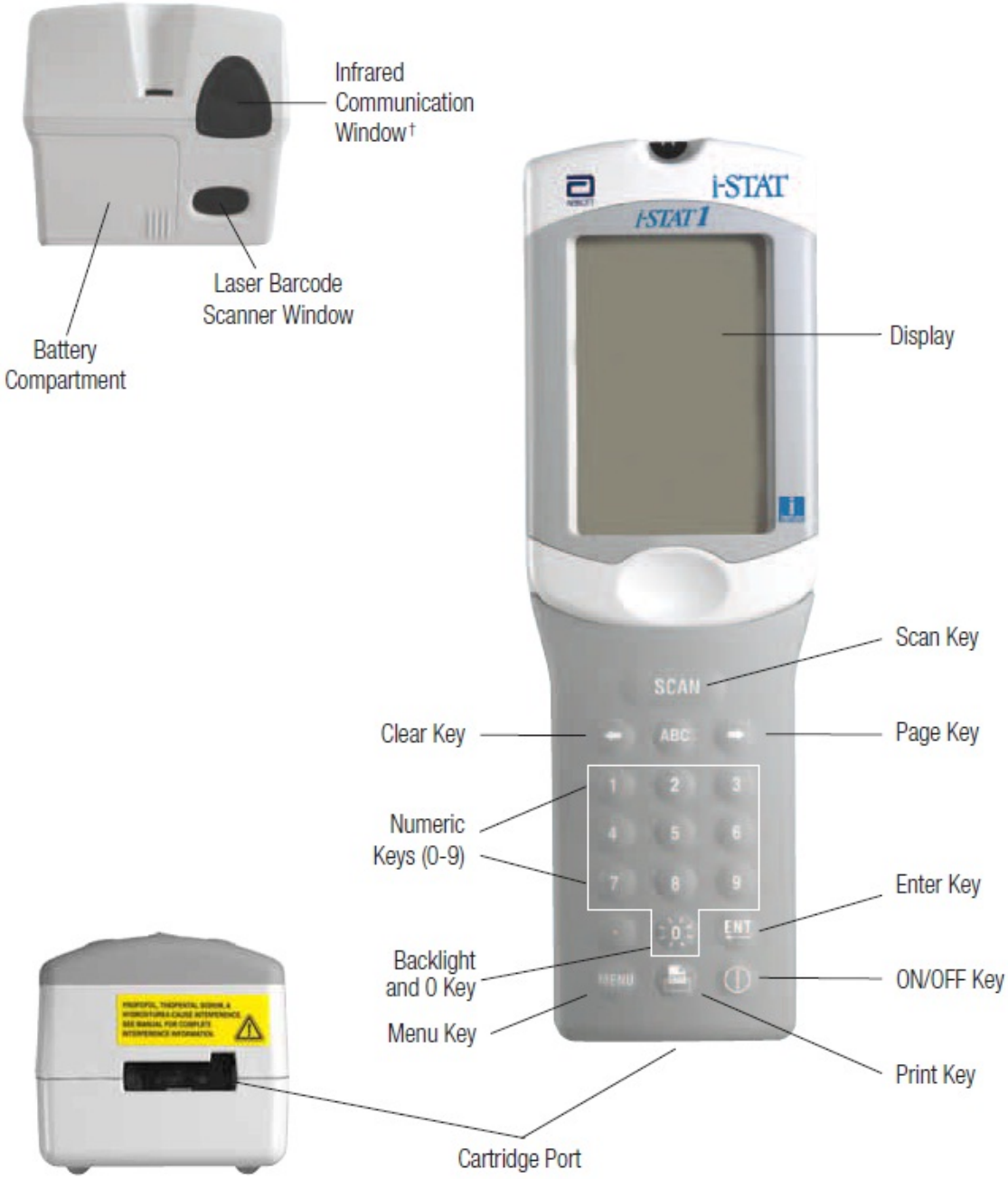
D. **Thermal Control** – The analyzer contains a thermal control subsystem of thermistors and heating contact wires that controls the temperature of the sensors and fluids that come into contact with

the sensors to 37°C. This subsystem is activated automatically when a cartridge containing tests, which require thermal control at 37°C, is inserted into the analyzer.

E. The battery compartment is located at the display end of the analyzer next to the laser barcode scanner window. Only iSTAT lithium rechargeable batteries may be used. iSTAT conserves battery power by automatically shutting down after 2 minutes of inactivity.

F. **Cartridge Port** – Creatinine cartridge and Electronic Simulator are inserted into the analyzer through the cartridge port on the keypad end of the analyzer.

G. **Laser Barcode Scanner** – is located at the top end of the analyzer. Is used to scan barcode information into the analyzer. Parameters that can be entered into the analyzer via the scanner include operator and patient IDs, control and cartridge lot numbers.



CREATININE CARTRIDGES STORAGE AND HANDLING

A. **iSTAT Creatinine Cartridge**

1. A single-use disposable cartridge contains microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber.
2. Each cartridge contains a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. The reactive ingredients of creatinine cartridge are Creatinine, Creatinine Amidinohydrolase, Creatinine Amidinohydrolase, and Sarcosine Oxidase.
3. Each cartridge is sealed in a foil pouch or clear plastic portion pack for protection during storage. Labeling on the carton, cox and pouch pack identify the panel name (Crea cartridge), the tests included in the panel (Creatinine), the lot number, and the expiration date of the cartridge. If the pouch has been punctured, the cartridge should not be used.
4. iSTAT Creatinine Cartridge require thermal control at 37 °C, and include heating elements on the underside of the sensor chips, which are contacted and heated by the handheld's thermal probes.

5. **Receipt and Storage of Creatinine Cartridges:**

   a. **Check Temperature Monitor**

      i. New cartridges are shipped with a temperature monitor card.
      ii. Creatinine cartridges are shipped refrigerated with a four window indicator to monitor temperature during transit.
      iii. If **all windows are WHITE** or if only the **A or B windows are BLUE** or the **1 or 2 windows are RED**, then transit temperatures were **Satisfactory** and the cartridges can be used.
      iv. If a temperature strip reading is **Acceptable**, **run QC Level 1 and 3** and record the results on the i-STAT 1 Liquid QC Creatinine Log, **indicating the new shipment information**. Also, document if the temperature monitor card was acceptable.
      v. Forward materials to refrigerator if there are no issues with the temperature.
      vi. If the **C or D windows are BLUE** or the **3 or 4 windows are RED**:
         - Quarantine the suspect materials
         - Do not use cartridges
         - Record the lot number
         - Contact POCT Services and **do NOT use that shipment/lot of cartridges for patient testing**
      i. If **new shipment/lot of cartridges fails 3 times** either Internal/External Electronic Simulator or Liquid Quality Control, contact POCT Services. **Do NOT use that shipment/lot of cartridges for patient testing**. Document all actions taken on the i-STAT 1 Liquid QC Creatinine log.

   b. **Creatinine Cartridge Storage**

      i. **Refrigerated storage**:
         - Store cartridges at **2°C -8°C (35°F -46°F)**. **Do not FREEZE**.
         - Refrigerated cartridges may be used until date shown on cartridge box and pack.
         - Prior to using a cartridge, cartridges must be removed form refrigerated storage and kept at room temperature for:
            - **Individual Cartridge**: Must be at room temperature for **at least 5 minutes** before using it.
            - **Box of Cartridges**: Must be at room temperature for **at least 1**

hour before using the cartridges.

- It is required that refrigerated storage be equipped with a 24-hour temperature monitor, and that the temperature record be reviewed each day.
- Verify that the cartridges and control materials are stored in the refrigerator are within the expiration date printed on the boxes. If the temperature at which the cartridges are stored is in doubt, do not use them for patient testing and notify POCT.

***NOTE**: This is especially important if freezing conditions are suspected at the back of the refrigerator.*

ii. **Room Temperature Storage**:

- When removing a cartridge box from refrigerated storage, creatinine cartridges may be stored at Room Temperature **(18°C-30°C or 64°F -86°F) for 14 days or until the expiration date on the label if it occurs first**. Mark the margins of individual pouches with the 14-day expiration date on the designated line or use the expiration date on the label if it occurs first. Do NOT write on the center of the pouch as this may result in breakage of the calibrator solution bubble in the center of the cartridge.
- Discard any cartridges after the expiration date.
- Cartridges should not be returned to the refrigerator once they have been at room temperature.
- Cartridges should not be exposed to temperature above 30°C (86°F) or used beyond the expiration date.

i. Verify that cartridges stored at Room temperature are within the expiration date and that the cartridges have been out of the refrigerator less than the time frame indicated on the cartridge box. If the temperature at which the cartridges are stored is in doubt, do not use them for patient testing and notify POCT.

6. Check and record Room and Refrigerator temperatures **DAILY** on the iSTAT Daily QC Log. NOTE: Temp Trak and Apogee may be used for temperature monitoring in lieu of manual logs when in place. Blank copies of the log may be printed from the SFGH-POCT website.

7. **Handling Instructions**:
   a. Creatinine cartridges are sealed in individual pouches and packaged 25 to a box.
   b. Creatinine cartridges should remain in pouches until time of use. **Once pouch is opened, cartridge is only good for 5 minutes.**
   c. If the pouch has been punctured, the cartridge should not be used.
   d. Do not contaminate the contact pads as the analyzer may not be able to make proper contact with the cartridge.
   e. Do not squeeze the foil pack. Handle it only by the edges to prevent accidental release of calibrant from its sealed pouch.
   f. Do not block the air vent as the sample will not flow to the fill mark and the calibrant solution will not flow to the sensors.
   g. Cartridges should be disposed of as biohazardous waste.

***NOTE**: To avoid contaminating the analyzer do not use a cartridge on which blood or any other fluid has spilled. Avoid filling cartridges on surfaces that may cause the cartridge to pick up fibers, fluid or debris that may lodge in the analyzer.*

CALIBRATION

The iSTAT analyzer automatically calibrates each cartridge before the sample is assayed.

CALIBRATION VERIFICATION AND SOFTWARE UPDATES

Calibration Verification is performed by POCT personnel on a semi-annual basis.

METHOD COMPARISON

Patient samples are compared against the reference instrument (Advia 1800 in Chemistry) in the Clinical Laboratory on a regular interval (e.g., every 6 months). POCT will perform the method comparison study. Method comparisons may also be useful for troubleshooting when patient's results are questionable.

QUALITY CONTROL

The quality control procedure for the i-STAT System includes:

A. **Automatic Quality Check**
   1. A series of automatic checks are performed during each test cycle.
   2. If the analyzer detects a problem during power on, a Quality Check message will be displayed indicating the cause and corrective action that must be taken before testing can begin.
   3. A Quality Check message will also be displayed and testing halted if the analyzer detects a problem during the test cycle.
   4. The quality checks detect improper environmental conditions, handheld function, cartridge filling, cartridge function, and sensor function.
   5. If a Quality check failure persists after taking the recommended action, contact POCT services.
   6. See the iSTAT 1 System Manual for the General Quality Check Codes for troubleshooting.

B. **Electronic Simulator Check**
   1. An independent check of the handheld's ability to take accurate and a precise reading from the sensors is performed automatically every 24 hours when cartridges are being tested.
   2. The Electronic Simulator, External and Internal, is a quality control device for the analyzer's cartridge signal-reading function.
   3. Both the **Internal and External Electronic Simulator** sends signals that simulate those of a cartridge to the handheld are signal detection system. The signals are below and above the measurement ranges of the tests and the acceptance limits are tighter than those for liquid control samples. Therefore, the simulator test is more sensitive to an out-of-specification condition than liquid control samples.
   4. Both the internal and external simulator results are stored in the handheld's memory and can be transmitted to the Central Data Station.

   5. **<u>Internal Electronic Simulator</u>**
      a. The internal simulator check is triggered by the insertion of a cartridge once every 24 hours when the analyzer is used continuously.
      b. The internal test will automatically be performed when a cartridge is inserted before the sample is tested, adding about 20 seconds to the testing cycle.
      c. If the check passes, the cartridge test cycle continues. If it fails, the analyzer displays, "ELECTRONIC SIMULATOR FAIL," testing is blocked and the External Electronic Simulator must be performed. Document any corrective actions on the iSTAT Daily QC Log.

6. **External Electronic Simulator**
   a. The external Electronic Simulator is a stable electronic device, which is inserted into the cartridge port. The test cycle for the external Electronic Simulator is about 60 seconds.
   b. An external Electronic Simulator is used:
      i. To verify an internal Electronic Simulator failure
      ii. To verify performance if the analyzer is dropped or damaged
      iii. To check the i-STAT's **Thermal Probe** every 6 months.
      iv. Troubleshooting or as needed.
   c. **Storage:** Store the external Electronic Simulator at Room Temperature (18 - 30^{o}C). Protect the contact pads from contamination by replacing the plastic cap each time and store in its protective case.

      NOTE: *The "Cartridge Locked" or "Simulator Locked" prompt is always displayed when a cartridge or Electronic Simulator is inserted into the analyzer. Any attempt to remove a cartridge or Electronic Simulator before this prompt is removed from the screen may cause damage to the analyzer.*

   d. **Stability:** The i-STAT External Electronic Simulator has no expiration date and can be used unless dropped or damaged.
   e. **Frequency:** The External Electronic Simulator Test must be performed when the Internal Electronic Simulator fails (the analyzer will display "ELECTRONIC SIMULATOR FAIL") and after the analyzer is dropped or damaged.
   f. **Cleaning the Simulator**: cover the connector area with the blue rubber boot. This will minimize the possibility of any cleaning fluid getting into the simulator housing, thus contaminating the internal circuitry. Clean the simulator with a gauze pad moistened with any of the cleaning agents approved for the analyzer (e.g., alcohol wipe). Rinse the simulator using another gauze pad moistened with water and dry.

      NOTE: *Do not immerse the simulator in any fluid, at any time. If the connector itself is contaminated, contact POCT Services.*

7. **Performing the External Electronic Simulator Check:**
   a. Press On / Off key
   b. Press the Menu key
   c. Select 3 – Quality Tests
   d. Select 4 – Simulator
   e. Scan or enter Operator ID
   f. Scan or enter Simulator ID
   g. Insert Simulator; avoid touching the contact pads
   h. Wait until PASS or FAIL is displayed, then Press Menu and wait for message
   i. "Remove Cartridge".
   j. One of two messages will display:
      - PASS – continue to use analyzer
      - FAIL – troubleshoot and document corrective actions taken on the iSTAT Daily QC Log

      NOTE: Removing the simulator or any cartridge before the "Remove Cartridge" message displays will result in damaging the analyzer.

1. **Corrective action if Internal Electronic Simulator Fails or Out of Range**:
   a. If "**FAIL**" is displayed on the analyzer screen, **reinsert** the cartridge.
   b. If "**FAIL**" is displayed a second time, use **External Electronic Simulator** to verify if the failures are being caused by the iSTAT analyzer and not by a faulty cartridge. **DO NOT PERFORM PATIENT TESTING.**

c. If "**PASS**" is displayed with the External Electronic Simulator, use the analyzer.
d. If "FAIL" is displayed a second time with the External Electronic Simulator, contact POCT Services. **DO NOT PERFORM PATIENT TESTING.**
e. Record the failure in the iSTAT QC Log along with the corrective action taken.

***NOTE**: If the check fails, "**FAIL**" and a failure code are displayed. A cartridge test cannot be performed until the handheld passes the simulator check. If there is a delay between the time the cartridge is inserted and the time the display is read, use a fresh cartridge and sample or the external simulator rather than re-inserting the original cartridge.*

C. **i-STAT Liquid Quality Control – Level 1 and Level 3**
1. Aqueous assayed control fluids to verify the integrity of newly received cartridges.
2. Each level of control is packaged in a box of 10 ampules. Control solutions are contained in 1.7 mL glass ampules.
3. The control solutions do not contain human serum or serum products, but do contain buffers and preservatives.
4. **New shipments and new lots of liquid controls**:
   a. New control materials are shipped with a temperature monitor card.
   b. **Check Temperature Monitor**:
      i. iSTAT control materials are shipped refrigerated with a four-window indicator to monitor temperature during transit.
      ii. If **all windows are WHITE** or if only the **A or B windows are BLUE** or the **1 or 2 windows are RED**, then transit temperatures were **Satisfactory** and the controls can be used.
      iii. Fill out the record of receipt and attach temperature reading on the designated log.
      iv. If a temperature strip reading is **Acceptable**, **run QC Level 1 and 3 with Creatinine cartridge from each shipment/lot upon receipt**.
      v. Forward materials to refrigerator if there are no issues with the temperature.
      vi. If the **C or D windows are BLUE** or the **3 or 4 windows are RED**:
         - Quarantine the suspect materials
         - Do not use control materials
         - Record the lot number
         - Contact POCT Services
      vii. If **new shipment/lot of QC fails 3 times** with creatinine cartridges, contact POCT Services.

5. **Storage**: Store controls at 2 to 8 °C until the printed expiration date on the box and ampule labels. Once vials are opened, they must be used immediately. Do NOT return controls to the refrigerator once they have been brought to room temperature. Do NOT use controls if they are cloudy or discolored.
6. **Control Testing Frequency**: Level 1 and Level 3 must be performed
   a. **Monthly**– to ensure proper cartridge storage.
   b. Whenever **new shipments and new lots** of control materials or creatinine cartridges are received.
   c. Whenever temperature at which the cartridges are stored is in doubt, do not use them and notify POCT.
7. Acceptable ranges for liquid quality controls are specific to i-STAT software version, CLEW standard, cartridge type, and cartridge lot numbers are available online at Abbott Website **https://www.abbottpointofcare.com/support/value-assignment-sheets.**

D. **Thermal Probe Check**

1. Two thermal probes in the handheld maintain the cartridges at the correct temperature during the testing cycle. The thermal probe check should be performed **EVERY SIX MONTHS**.
2. Press the period (.) key.
3. Verify that the thermal probe check value ("Thermal Diff") is within the acceptable range (± 0.1ºC).
4. If the reading is unacceptable (a FAIL message with a "t" Quality Check Code or a value greater than 0.1), do not use the instrument and notify POCT. If "--.—" displays, notify POCT.

LIQUID QUALITY CONTROL PROCEDURE

A. **Prepare the Cartridge**
1. Prior to using a cartridge, it must be removed from refrigerated storage and kept at room temperature in its protective pouch for **at least 5 minutes**.
2. Removing a cartridge from the Protective Pouch:
   a. Tear open cartridge pouch at notch.
   b. Remove cartridge from pouch. Always hold by sides.
   c. Place on level surface.

   ***NOTE**: DO NOT remove cartridge until you reach the appropriate step in the patient or control testing process.*

B. **Quality Checks**
1. Quality checks are automatically performed during each test. If a quality check fails, the handheld stops the test and shows a cause and action to be followed.
2. If a Quality check failure persists after taking the recommended action, contact POCT services.

C. **Perform a Control Test** – upon receipt of each shipment or new lot, monthly, as needed
1. **Materials**:
   a. iSTAT analyzer
   b. Creatinine cartridge
   c. iSTAT Level 1 and Level 3 Controls
   d. Disposable transfer device
   e. Value Assignment Sheet – available at www.abbottpointofcare.com
   f. iSTAT 1 Liquid QC Creatinine form
   g. Gauze or Ampule breaker
   h. Container for broken glass disposal

2. **Prior to testing**
   a. Allow iSTAT Liquid Controls and Creatinine cartridge to reach temperature before beginning the test.
   b. **Liquid QC** – remove from refrigerated storage **at least 30 minutes**.
   c. **Creatinine cartridge** - remove from refrigerated storage **at least 5 minutes**.

3. **Test Liquid Quality Control**
   a. **Prepare the iSTAT Analyzer**
      i. Press "ON/OFF" button to turn ON iSTAT analyzer.
      ii. Press "Menu" to change screen to Administration Menu.
      iii. Press "3" for the Quality Tests Menu.
      iv. Press "1" for Control.
      v. Scan or Enter the "Operator ID". **DO NOT SHARE** your barcode ID with anyone.

Sharing barcode ID is prohibited.

vi. Then scan "Control Lot Number".

vii. Scan the "barcoded cartridge lot number".

b. **Prepare to Test**

i. Find a stable surface to perform the test.

ii. Remove cartridge from pouch. Only touch the cartridge by its side to avoid damage or contamination.

iii. Put on disposable gloves.

c. **Prepare the Control Sample**

i. Shake the ampule. Hold the ampule between index finger and thumb. Shake vigorously for 10 seconds.

ii. Tap the top of the ampule to ensure all fluid flows to the bottom of the ampule.

iii. Break the ampule. Hold top of ampule with gauze or ampule breaker. Snap top off.

iv. Fill an empty syringe (no preservatives) halfway with liquid control.

- Tilt opened ampule so fluid flows close to opening.
- Position syringe tip into the fluid.
- Slowly pull back on syringe plunger to draw control into syringe until it is about half full.

iv. Expel air from the syringe.

- Place a gauze pad on the counter.
- Press the syringe plunger until you see 3 drops of control empty from the syringe.

v. Look for any air bubbles in the control fluid.

- If you see any air bubbles in the control, then discard this syringe and control and repeat the test using a new control ampule, new cartridge and new syringe.

d. **Fill the cartridge**

i. Fill the cartridge with control to the fill mark.

- Place tip of the syringe over cartridge sample well.
- Press plunger so that control enters the cartridge until it reaches the fill mark.
- Confirm that there is control fluid in sample well. If you do not see control in sample well, continue to press plunger to deliver more control fluid. Do not wipe off excess sample from the cartridge.

***NOTE**: Grossly over or under filling cartridge may cause an error code requiring you to repeat the test.*

e. **Seal the Cartridge**

i. Touching only the plastic tab and sides of cartridge, fold snap closure over the sample well. **Do not press directly over the sample well**.

ii. Press the tab until it clicks into place. Slightly lift finger or thumb and ensure that the cartridge is closed before completely.

f. **Insert Cartridge**

i. Push the sealed cartridge into the cartridge port until it clicks into place

- To avoid permanent damage to the iSTAT analyzer, **do not remove cartridge until the testing process is complete**.
- Wait about 2 to 3 minutes for the test to complete.

g. **Complete Testing Process**

i. Pull out cartridge from iSTAT analyzer.

ii. Turn off analyzer by pressing the ON/OFF button for one second.
iii. Discard broken ampule in a container that is safe for broken glass.
iv. Discard remaining test materials in biohazard container.

h. **Repeat the steps with each liquid QC level (1 and 3).**

D. **Review Quality Control Results**

1. Target values and ranges are printed on a Value Assignment Sheet (VAS) posted on the APOC website at **www.abbottpointofcare.com**. Control test results are shown in numerical values.
2. If **ALL** results are within the ranges on the Value Assignment Sheet, you can use the cartridges for patient testing. If fails, follow corrective actions.
3. Record results on the iSTAT 1 Liquid QC log sheet.
4. **Corrective Actions if Liquid QC is Out of Range**:
   a. Before repeating with a new ampule of control, review the following.
      i. Ensure that the correct QC level was run.
      ii. Ensure that the acceptance range is for the appropriate cartridge lot number.
      iii. Ensure that the CLEW software is the same as the CLEW version on the iSTAT analyzer. Press “Menu” and select “Analyzer Status” to view iSTAT software version and CLEW standard.
      iv. Contact POCT Services for acceptance range if the analyzer CLEW standard and/or Cartridge lot number is not listed.
   b. Repeat the control with a new ampule. Bring the ampule at room temperature for 30 minutes prior to testing. If the repeat Liquid Quality Control is Out of Range 3 times, contact POCT services.
   c. Do not use iSTAT analyzer for patient testing when QC fails. Consider sending samples to the lab for Creatinine test results.
   d. Document all corrective actions on the iSTAT 1 Liquid QC log.
   e. The POCT designee will contact ABBOTT POC for troubleshooting.
   f. If iSTAT analyzer is broken or out of service, the back up instrument may be retrieved from the Clinical Lab.
   g. POCT will work with Biomed to arrange for the analyzer to be fixed. POCT will then verify the performance of the fixed analyzers that are returned and must have the Clinical Laboratory Director’s approval for reimplementation for patient testing of such analyzers.
   h. When the repaired iSTAT analyzer has been shipped back to POCT department, the POCT designee will evaluate (QC check, PCOMs check, etc.) the repaired iSTAT analyzer. The Clinical Laboratory Director or designee will review the results and sign-off if the loaner is approved for patient testing.

SPECIMEN / SAMPLE COLLECTION AND HANDLING

A. Universal Precautions should be observed through all phases of the testing procedure.
B. The specimen used to fill a cartridge must be collected and handled properly to ensure that the results represent the patient’s current status. Whole blood specimens should be kept in anaerobic conditions (i.e., capped) and analyzed within 30 minutes of collection.
C. **Sodium heparin** or **lithium heparin** is the anticoagulant of choice for analyzing whole blood specimens on the i-STAT analyzer. The heparin-to-blood ratio should not exceed 10 U heparin per milliliter of blood.
D. **Venous whole blood ONLY** collected in lithium or sodium heparin is the only **ACCEPTABLE** sample type.
E. **Minimum specimen volume:** 100 µL
F. **Criteria for Specimen Rejection – Redraw the patient if**:

1. Any evidence of clotting
2. Incorrect anticoagulant
3. Specimens with insufficient quantity
4. Incorrectly drawn specimens
5. Incorrectly handled specimens prior to sampling

G. **Precautions: Potential Sources of Error in Patient Results**
   1. Cartridge stored incorrectly.
   2. Improper sample collection and/or sample handling
   3. Any deviations will cause inaccurate results.
   4. Use of expired cartridges.
   5. See the **LIMITATIONS AND INTERFERENCES** section for additional information regarding factors that can affect results.

PATIENT TESTING PROCEDURE

A. Only Venous whole blood samples collected in evacuated tubes with lithium or sodium heparin for Creatinine testing.
B. Unless immediately analyzing and the patient is the only one in the operating room and the testing is being performed in that same room, label all collected samples with **AT LEAST 2 PATIENT IDENTIFIERS** (Full Name and Medical Record Number or Date of Birth) in the presence of the patient.

   NOTE*: Correct sample collection and handling are important for accurate results.*

C. **Prepare the Cartridge**
   1. Press “ON/OFF” button to turn ON iSTAT analyzer.
   2. Press “2” for iSTAT Cartridge.
   3. Scan or Enter your “Operator ID”. **DO NOT SHARE** your barcode ID with anyone. Sharing barcode ID is prohibited.
   4. Scan or Enter the “Patient Medical Record ID”.
   5. Scan the lot number on the cartridge pouch.
D. **Prepare to Test**
   1. Find a level, stable surface to perform the test. A level surface includes running the iSTAT analyzer in the downloader/recharger.
   2. Remove the cartridge from its pouch and place on a flat surface. Only touch the cartridge by its side to avoid damage or contamination.
   3. Put on disposable gloves.
E. **Prepare the Blood**
   1. Mix the blood sample. Gently invert the green top tube 2 to 3 times.
   2. Fill syringe about halfway with the blood sample.
      a. Invert the tube and push syringe tip through the green stopper into the blood sample.
      b. Slowly pull back on the syringe plunger to draw blood into the syringe until it is about half full.
   3. Expel air from the syringe tip.
      a. Place enough gauze pads on the counter to absorb a few drops of blood.
      b. Hold syringe over gauze without touching it.
      c. Press syringe plunger until you see 3 drops of blood empty from the syringe onto the gauze.
      d. Look for any air bubbles in the blood sample. Remove any air bubbles.
F. **Fill the Cartridge**

NOTE: in lieu of a syringe, the manufacturer's dispensing pipet tip may be used instead (see F2).

1. Dispense blood, slowly and steadily filling the cartridge with sample to the fill mark.
   a. Place the tip of the syringe over the cartridge sample well.
   b. Press plunger so that sample enters cartridge until it reaches the fill mark.
   c. Confirm that there is sample in the sample well. If you do not see sample in the sample well, continue to press the plunger to deliver more sample. Do not wipe off excess from the cartridge.

   ***NOTE**: Grossly over or under filling cartridge may cause an error code requiring you to repeat the test.*
2. Filling the Cartridge with Dispensing Tips:
   a. Remove the plug from the barrel of the dispensing tip.
   b. Immediately insert the tube into the barrel. With the cap pointing away, press the tube into the barrel until needle pierces the stopper.
   c. With the cap pointing up and away, remove the cap.
   d. Align dispensing tip with the sample well on the i-STAT cartridge and apply firm pressure to the end of the blood collection tube to dispense blood.
   e. If the blood collection tube will not be discarded, hold the tube upright and away, gently removing the dispensing tip. Dispose dispensing tip immediately into a biohazardous Sharps container.

   NOTES:
   If the red cap or red plug is missing, dispensing tip may be contaminated and must be discarded immediately into a biohazardous Sharps container.
   Use standard precautions. The needle inside of the barrel is sharp and can puncture the skin.
   More than one cartridge can be filled from the same tube and dispensing tip.
   Do not use the same dispensing tip on a different evacuated tube of blood. Do not put the red plug or red cap back on.

G. **Seal the Cartridge**
   1. Touching only the plastic tab and the sides of the cartridge, fold the snap closure over the sample well. **Do not press directly over the sample well**.
   2. Press the tab until it clicks into place. Slightly lift finger or thumb and ensure cartridge is closed before completely removing the finger or thumb from the closure.

H. **Insert the Cartridge**
   1. Push the sealed cartridge into the iSTAT analyzer port until it clicks into place.
      a. To avoid permanent damage to the iSTAT analyzer, **DO NOT remove cartridge until testing process is complete**.
      b. Wait about 2 to 3 minutes for the test to complete.

I. **Review Patient Results**
   1. The iSTAT analyzer shows the test results by test name, test units, and the numerical values and units with the results. It also shows bar graphs with tic marks for reference ranges.

      ***NOTE**: If iSTAT analyzer turns OFF before review of results is complete, press ON/OFF button to turn it ON, and then press "**1**" for Last Result.*

   2. After reviewing results, remove the cartridge. Discard gloves, tube, transfer device and cartridge in biohazard waste container.

J. **Flagged Results**

1. A Quality Check message will be reported instead of results if the handheld detects a problem with the sample, calibrant solution, sensors, or mechanical or electrical functions of the handheld during the test cycle.

   Remedial Action: Take the action displayed with the message that identifies the problem. Refer to the Analyzer Coded Messages Technical Bulletin in the iSTAT 1 System Manual. If a Quality check failure persists after taking the recommended action, contact POCT services.

2. If stars (***) are displayed instead of a result, it means that a test **failed** internal quality checks.

   Remedial Action: All reported results are accurate as long as the sample integrity is not in question. Remix tube of blood and repeat test using a fresh cartridge. **If result is not displayed again**, **draw a fresh blood sample and repeat test**. If result is still not displayed, contact POCT Services.

3. Results outside the System's Reportable Range are flagged with a "<" is shown in front of the lowest reportable value when the result is lower than this value. ">"is shown in front of the highest reportable value when the result is higher than this value.

   Remedial Action: The radiology practitioner will order samples to be sent to the clinical laboratory for confirmatory testing.

Test Ranges

1. **Reportable Range**
   a. It is the lowest to highest values that the Creatinine test will report.

Test	Reportable Range
Creatinine	0.2 – 20.0 mg/dL
Results below 0.2 are reported as "<0.2" mg/dL. Results above 20.0 are reported as ">20.0" mg/dL.	

2. **Reference Range** is the normal values for adult populations. Reference ranges varies according to age, gender and heritage.

Test	Reference Range
Creatinine, Whole Blood (Adult)	0.50 – 1.10 mg/dL

Record and Report Results

1. Results can be reported only if QC requirements are met and no operational flags or instrument malfunctions have occurred.
2. Results are displayed numerically with their units.
3. To obtain a printout of results:
   - Align the IR window of the analyzer and the printer. Turn the printer ON by pressing the Mode button (printer light green) or press the printer Advance switch to reactivate. To print the displayed test record, press the PRT key on the analyzer. Do NOT move printer or analyzer until the printout is completed.
4. To print the last stored test result:
   - Select option 1 on Main screen for last results.

5. To print more than 1 set of results
   - Press Menu key to view Administrative Menu for previous patient or control results. Select 2- Date Review. Select 7- List…Select records to be printed by pressing the Key(s) corresponding to the numbers beside the record(s). Press the numbered key again to deselect a record. Then press the PRT key.
6. Results are displayed numerically with reporting units and adult reference ranges.
7. Patient results are documented on the Creatinine Results and Test Order form, which will be part of the patient's medical record for perpetuity.

For Electronic Transmission of Results

1. Place iSTAT analyzer in a Downloader/Recharger.
2. Do not move iSTAT analyzer while the message "**Communication in Progress**" is displayed.

RECORD KEEPING

1. All records for QC Testing, Patient Testing, Orientation & Training, Competency Testing, Meter Validation, Patient Comparisons, Maintenance, and Testing Issues will be kept on file in the Clinical Laboratory for at least three years.
2. Patient results are documented on the Results and Test Order form will be part of the patient's medical record for perpetuity.

LIMITATIONS AND INTERFERENCES

1. Interfering substances or other events may be encountered which can affect results.

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Creatinine	Acetaminophen	1.32 mmol/L	Increase (↑) creatinine
	Ascorbate	0.34 mmol/L	Increase (↑) creatinine by up to 0.3 mg/dL
	Bromide (therapeutic)	2.5 mmol/L	Increase (↑) creatinine
<2 mg/dL	*P*CO_2	Above 40 mmHg	Decrease (↓) creatinine by 3.7% per 10 mmHg *P*CO_2
		Below 40 mmHg	Increase (↑) creatinine by 3.7% per 10 mmHg *P*CO_2
>2 mg/dL	*P*CO_2	Above 40 mmHg	Decrease (↓) creatinine by 3.7% per 10 mmHg ***P***CO_2
		Below 40 mmHg	Increase (↑) creatinine by 3.7% per 10 mmHg ***P***CO_2
	Hydroxyurea	0.92 mmol/L	Increase (↑) Creatinine Use Another Method.
	Acetylcysteine	10.2 mmol/L	Increase (↑) creatinine
	Creatine	0.382 mmol/L	Increase (↑) creatinine by up to 0.3 mg/dL
	Glycolic Acid	10.0 mmol/L	Decrease (↓) creatinine Use Another Method.
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Increase (↑) creatinine

MAINTENANCE AND CARE

CAUTION: Exercise universal safety precautions at all times when handling the analyzer, cartridges, and peripherals to prevent exposure to blood-borne pathogens.

1. Daily Maintenance
   - Clean surfaces with gauze moistened with deionized water or mild non-abrasive cleaner (Clorox Healthcare Hydrogen Peroxide cleaner disinfectant wipes are acceptable). Wipe the infrared window with a Kimwipe tissue. NOTE: When dealing with patients in isolation for possible *Clostridium difficile* or Norovirus infections, use PDI Bleach Wipes.
   - Always follow the hospital policy for wet contact time.
   - Check Analyzer Status (Menu\Analyzer Status). Are there any error messages, alerts or quality check codes to investigate? If so, please refer to the i-STAT 1 System Manual.
   - Record Battery Status. If ≤7, replace both batteries and document replacement on the iSTAT Daily QC log. Note: Wait until any test in progress is completed, and turn off the analyzer before replacing the battery or the most recent set of results may be lost. Stored results will not be lost when replacing the batteries.
   - Room and refrigerator temperatures (use thermometer nearest the analyzer) and verify within range (18 – 30 ^{o}C). NOTE: TempTrak may be used in lieu of a temperature log.
   - Verify storage refrigerator temperature is within range (2 – 8 ^{o}C) NOTE: TempTrak may be used in lieu of a temperature log.
   - Perform External Electronic Simulator Test. Record the result (pass or fail) on iSTAT 1 Daily QC Log.
2. Every 6 months
   - POCT will perform the Software Update
     NOTE: The iSTAT 1 will start displaying warnings 20 days prior to when the software updated is due.
   - POCT will verify that the thermal probe check.
3. As needed
   - If the analyzer is placed on a wet surface or if any liquid is spilled onto it, dry the analyzer immediately. If liquid enters the following compartments, the analyzer may be damaged: the electronics compartment, the battery compartment, or the cartridge port.
   - To replace the battery:
     a) Slide the battery compartment door off.
     b) Tilt the analyzer slightly to slide out the battery carrier which contains the two 9-volt batteries.
     c) Remove the old batteries from the carrier. Pull each battery out to the side and then lift back and out.
     d) Note the battery orientation symbol molded into the carrier on each side of the center wall. Starting with one side, orient the new battery so that it matches the symbol. Slide the battery into the carrier, pushing the terminal end in first, under the plastic bar, and slide it up as far as it will go. Then push the bottom of the battery inward. The terminals of the battery should be underneath the protective bar on the carrier.
     e) Repeat for the second battery on the other side of the carrier.
     f) Note the orientation of the battery carrier illustrated on the label on the carrier. The label faces up, and the electrical contact end of the carrier goes into the instrument first. Insert the carrier into the instrument as shown on the label. If the carrier is inserted incorrectly, the battery door will not close.

g) Slide the battery compartment door back into place.

TROUBLESHOOTING

When the analyzer detects a potential or real problem before the test cycle is initiated or at any time during the test cycle, a Quality Check Code number, the type of problem and the next step to be taken will be displayed. Please refer to the Troubleshooting the Analyzer section in the iSTAT 1 System Manual. If a problem persists, notify POCT Services. Technical Support (1-800-366-8020) may be contacted outside of POCT Services' business hours.

STAFF EDUCATION, ORIENTATION & TRAINING, COMPETENCY, & BARCODE IDs

1. Each operator using the i-STAT 1 meter at ZSFG becomes approved to perform this POCT through completion of **Orientation & Training and Competency Testing**, which includes successful demonstration of skills and knowledge. This Competency Testing is required upon initial training, twice during the first year, and annually thereafter.
2. Once approved to test, the new operator will be issued a barcode ID with their unique identifiers imbedded within the barcode. Those renewing their annual Competency will not require a new barcode ID; rather, their current barcode ID will be updated via the POCT Service.
3. If an operator's barcode ID is active (is working), it signifies the operator has completed all prerequisites for patient testing and is currently approved to perform this POCT.
4. If an operator's barcode ID is not active (not working), it signifies the lack of approval for performing this POCT and the need to renew their Competency test.
5. If an employee loses or damages their barcode ID, they may request a new barcode ID from the POCT Services.
6. Barcode IDs are to be secured to the employee's hospital or university ID badge.
7. Barcode IDs are to be treated like secure passwords and thus the sharing of barcode IDs is not allowed.
8. All activity occurring under an employee's barcode ID is the responsibility of that employee.
9. Students are not trained, nor approved, to perform this POCT at SFGH. Their educational experience may be gained only when an employee with an active barcode ID is with them at the patient's bedside supervising and taking full responsibility for the experience, results, documentation, and follow-up actions.

REFERENCES

1. i-STAT 1 System Manual, 3/7/2013
2. i-STAT Software Upgrade Technical Bulletins

DISTRIBUTION

1. Point of Care Testing Master Manual
2. Computed Tomography/Radiology