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i-STAT System

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. To describe how to perform point of care (POC) testing with the i-STAT and to provide quality monitoring and troubleshooting directions for non-laboratory personnel.

1. All i-STAT cartridges used by Beaumont Health, except the creatinine (CREA) cartridge, are classified as non-waived methods that require laboratory-level quality control (QC) and quality assurance. This document describes most of the technical and regulatory requirements that must be met to have approval to use the i-STAT device for POC testing at Beaumont facilities.

B. This document is only applicable to areas that are approved for testing under one of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificates.

II. PRINCIPLE AND CLINICAL SIGNIFICANCE:

The i-STAT System (i-STAT) performs POC whole blood test analysis utilizing a portable hand held analyzer and disposable single-use test cartridges.

A. CREA

1. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.
2. Cartridges contain micro fabricated sensors, a calibrant solution, and a waste chamber. When a sample-filled cartridge is inserted into the device for analysis, the analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration, and continuous quality monitoring.

a. Creatinine is measured amperometrically. Creatinine is hydrolyzed to creatine 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. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current, which is proportional to the creatinine concentration.

B. PT/INR

1. PT/INR is used to monitor oral anticoagulant therapy.
2. PT/INR is determined amperometrically. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with tissue thromboplastin. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen. the product of the thrombin-substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and reported as INR (International Normalized Ratio) and/or seconds.

III. SPECIMEN COLLECTION AND HANDLING:

Always follow established procedures for Standard Precautions/Hand Hygiene when collecting and handling blood specimens. Hands must be washed or disinfected with antiseptic soap or an alcohol-based hand rub as outlined in the Laboratory Infection Control policy before and after gloves are used. Gloves must be worn when performing patient testing and changed between patients.

A. Patient Preparation

1. No patient preparation is required prior to testing.

B. Patient Identification

1. Patients must be identified at the bedside using two identifiers (Joint Commission). Where applicable, scan the barcode on the patient's wristband to obtain the contact serial number (CSN).
2. Areas where patients do not have wristbands or where the wristband is not readily accessible (e.g. Operating Room (OR), Cath. Lab, etc.) the patient CSN will be entered manually using the keypad. Verify that the identification (ID) number appears correctly on the display before proceeding with i-STAT testing.

C. Specimen Labeling

1. i-STAT testing should be performed at the patient's bedside. If the specimen is taken to another location for patient testing, the specimen must be labeled with the patient name and ID number, per Joint Commission.

D. Specimen Types, Handling, and Preservation

1. CREA
    a. Venous, arterial, and capillary whole blood are the only acceptable specimen types.

b. Verify that the specimen collection supplies are not expired.
    i. Arterial: plain syringe, heparinized syringe labeled for analytes to be tested and filled to capacity, or syringe with minimum volume of heparin to prevent clotting (10 U/mL of blood).
        a. If not tested immediately, remix the sample and discard 2 drops of blood before filling the cartridges.
        b. Do not used iced samples.
    ii. Venous: plain syringe, heparinized syringe or whole blood collected in evacuated tubes containing lithium heparin. See the Venipuncture Technique procedure.
        a. Do not leave the tourniquet on for more than 2 minutes.
        b. Do not draw above an I.V.
        c. Blood collection containers must be filled to the capacity of the device to secure accurate test results.
    iii. Capillary:
        a. Stimulate the finger (or heel for babies) by massaging the area to increase capillary flow. Heel warmers may be used to stimulate blood flow for babies.
        b. Use a single-use lancet.
        c. Prepare the puncture site by thoroughly cleaning with an alcohol pad. Allow a few seconds to air dry.
        d. Twist and pull off the lancet tip.
        e. Firmly press the lancet against the fingertip (or heel for babies). The lancet will project and retract immediately.
        f. Dispose of the lancet in a sharps container.
        g. Use gauze to wipe away the first drop of blood.
        h. Squeeze the finger (or heel for babies) gently and slowly (do not milk) and apply steady pressure along the entire length of finger.
        i. With an adequate drop of blood, dose the cartridge immediately.

2. PT/INR
    a. Venous and capillary specimens are the only acceptable specimen types.
    b. Verify that the specimen collection supplies are not expired.
        i. Venous: Use plain plastic syringes or plastic evacuated tubes with no anticoagulant, activators, or serum separators. See the Venipuncture Technique procedure. Glass syringes or tubes may

prematurely activate coagulation, resulting in accelerated clotting time and lower INRs. Venous samples must be collected in plastic tubes or syringes.

a. Do not leave the tourniquet on for more than 2 minutes.
b. Do not draw above an I.V.
c. For venipuncture, some experts recommend drawing and discarding a sample of at least 1 mL prior to drawing samples for coagulation testing.
d. Test sample immediately after collection.
e. If a repeat measurement is needed, draw a fresh sample.

ii. Capillary: The cartridge may be filled directly from the finger.

a. Stimulate the finger by massaging the area to increase capillary flow.
b. Use a single-use lancet.
c. Prepare the puncture site by thoroughly cleaning with an alcohol pad. Allow a few seconds to air dry.
d. Twist and pull off the lancet tip.
e. Firmly press the lancet against the fingertip (or heel for babies). The lancet will project and retract immediately.
f. Dispose of the lancet in a sharps container.
g. Use gauze to wipe away the first drop of blood.
h. Squeeze the finger gently and slowly (do not milk) and apply steady pressure along the entire length of finger.
i. With an adequate drop of blood, dose the cartridge immediately.
j. If a repeat measurement is needed, draw a fresh sample.

E. Specimen Collection, Transportation, Processing, and Disposal

1. Verify that the specimen collection supplies are not expired.
2. All arterial and venous specimens must be free flowing. Do not use excessive force when expelling the blood sample through the needle. This may lead to hemolysis.
3. In-Dwelling Line

a. Back flush the line with a sufficient amount of blood (3 to 6 times the volume of the catheter, connectors and needle) to remove intravenous solutions, heparin, or medications that may contaminate the sample.

4. Arterial and Venous Specimens
    a. Fill an approved syringe (see Specimen Types above) to the recommended capacity. Avoid under or over-filling the syringe.
5. Analyze specimens immediately after collection. If the specimen must be taken from the patient's bedside to the instrument for testing, this should be done immediately and without delay.
6. Mix the sample by inversion prior to testing.
7. Discard the sample in biohazardous waste after testing. Do not save specimens for repeat testing.

F. Criteria for Specimen Acceptability
    1. CREA
        a. Venous, arterial, capillary
        b. Arterial samples must be plain or heparinized. Venous may be plain, heparinized or collected in a lithium heparin tube. Capillary samples must be dosed directly from the finger.
        c. Samples must be tested immediately.
    2. PT/INR
        a. Venous, capillary
        b. Venous samples must be collected in tubes without anticoagulant. Capillary samples must be dosed directly from the finger.
        c. Samples must be tested immediately.

G. Criteria for Specimen Rejection
    1. Evidence of clotting
    2. Incorrect specimen collection device
    3. Incorrect sample types
    4. Unlabeled specimen not tested at the bedside
    5. Delay in testing the sample after collection
    6. Specimens on ice

IV. REAGENTS:

A. Cartridges (CREA, PT/INR)
    1. Availability: Each box contains 25 individually sealed pouches.
        a. Testing areas order and store inventory.
    2. Components: Each single use cartridge contains micro fabricated sensors, a celebrant solution, fluidics system, and waste chamber.
    3. Handling: Store the main supply of cartridges in a refrigerator between 2-8°C. Do not

allow the cartridges to freeze. Equilibrate a single cartridge for 5 minutes or a box of cartridges for 1 hour at room temperature before opening pouches. Each box will be marked with the date placed at room temperature and subsequent room temperature expiration date. Each box is marked with the allowable room temperature storage time. Cartridges should remain in pouches until the time of use. Cartridges should be used immediately after opening the pouch. If the pouch has been damaged or punctured, the cartridge should not be used. Cartridges should not be exposed to temperatures exceeding 30°C. Handle the cartridge from its side edges and avoid touching the contact pads or exerting pressure over the center of the cartridge.

4. Expiration: Cartridges are stable until the manufacturer's expiration date if stored in the refrigerator (2-8°C). If stored at room temperature (15-30°C), the cartridges expire after the room temperature storage time frame indicated on the box. Cartridges should not be returned to the refrigerator once they have been at room temperature. Cartridges should not be used after the manufacturer's expiration date or room temperature expiration date, whichever is first.
5. Warnings/Precautions: For *in vitro* diagnostic use only.

B. i-STAT TriControls (CREA)

1. Availability: Each box contains 10 ready-to-use ampoules.
    a. Testing area orders and stores inventory.
2. Handling: Store the controls in a refrigerator between 2-8°C. Do not allow the controls to freeze. Allow the controls to warm to room temperature for at least 4 hours prior to use. Controls may be stored at room temperature (15-30°C) for up to 5 days.
3. Expiration: Controls are stable until the manufacturer's expiration date if stored in the refrigerator (2-8°C). If stored at room temperature (15-30°C), the controls expire 5 days after removal from the refrigerator. Controls should not be returned to the refrigerator once they have been at room temperature. Controls should not be used after the manufacturer's expiration date or room temperature expiration date, whichever is first.

C. i-STAT PT/INR Controls (PT/INR)

1. Availability: Each box contains 10 ampoules containing lyophilized plasma and 10 vials of calcium chloride reconstituting fluid.
    a. Testing area orders and stores inventory.
2. Handling: Store the controls in a refrigerator between 2-8°C. Do not allow the controls to freeze.
3. Expiration: Controls should be used immediately after reconstitution and before the manufacturer's expiration date.

D. i-STAT Calibration Verification Set

1. Availability: Each set includes 5 levels of solution which span the analytical measurement range for Creatinine.

2. Handling: Store the calibration verification materials in a refrigerator between 2-8°C.Do not allow to freeze.
3. Expiration: Calibration verification materials should be used immediately after reconstitution and before the manufacturer's expiration date.

V. CARTRIDGE CONFIGURATION AND SAMPLE VOLUME:

A. CREA (65 µL)
    1. Creatinine (CREA)

B. PT/INR (20 µL)
    1. Prothrombin Time

VI. EQUIPMENT AND SUPPLIES:

A. i-STAT Analyzer
    1. Batteries: Two Disposable 9-Volt Lithium Batteries or Nickel-Metal-Hydride Rechargeable Battery
    2. Test Port: Cartridges and Electronic Simulator are inserted into the analyzer through the cartridge port on the keypad end of the analyzer.
    3. Infrared Communication Window: The Infrared Communication Window provides the analyzer with a two-way communication to the Central Data Station via a Downloader, allows analyzer-to-analyzer software updates, and allows analyzer-to-printer communication for printing.
    4. 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. This subsystem is activated automatically when a cartridge containing tests which require thermal control at 37°C is inserted into the analyzer.

B. External Electronic Simulator: 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. It is stored in a static-free box in close proximity to the analyzers.
    1. All analyzers that pass the Electronic Simulator test are equivalent, as prescribed by the manufacturer. Therefore, any representative number of analyzers that pass the Electronic Simulator test may be used for compliance with regulatory and accreditation quality assurance procedures. These procedures include initial performance verification studies, calibration verification, comparison studies, and proficiency testing.

C. Downloader/Recharger: The Downloader converts infrared transmissions of test records from the analyzer to electrical form and transmits (uploads) them to the Data Management System. The Downloader also converts electrical signals from the Data Management System to infrared transmissions, which are transmitted (downloaded) to the analyzer. Transmission is

automatic when the analyzer is placed in the Downloader. This unit can also recharge the rechargeable battery in the analyzer. If the analyzer contains a rechargeable battery, the battery begins recharging automatically as soon as the analyzer is placed in the unit. The Downloader/ Recharger also has a compartment for recharging a rechargeable battery outside the analyzer.

1. All i-STAT cartridges may be run in an analyzer that is docked in the Downloader/ Recharger.

D. Printer: The Martel Thermal Portable Printer may be used in the testing area. The printer receives data directly from the analyzer via IR transmission or through a data cable connected to the Downloader/Recharger. The printer can be recharged from a power adapter connected to an electrical outlet.

E. Printer Paper: Use black print thermal paper. Dimensions are 2.25 inches (5.7 cm) wide by 80 feet (25 m) long. Paper grade should be TF50KS-E2C.

VII. CALIBRATION AND CALIBRATION VERIFICATION:

A. Calibration is automatically performed as part of the test cycle on each cartridge. Operator intervention is not necessary. 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 in the device. Once this sequence is completed, the analyzer automatically moves the patient sample over the sensors. By comparing the sensors' responses to the patient sample with that of the calibrant, the concentration of each analyte in the sample is calculated.

1. Calibration Failure Procedure
    a. A message and quality check code will be displayed if calibration fails.
    b. Repeat the test with a new cartridge.
    c. If the error persists, try a new lot of cartridges.
    d. If the error is present with a new lot of cartridges, remove the instrument and cartridges from use and contact the site-specific POC department to notify Abbott Technical Support.

B. Calibration verification is the process of assaying reference standards or calibration materials, in the same manner as patient samples, to confirm the calibration of the analyzer throughout the reportable range. Calibration verification is performed for validation of new devices, and twice per year (approximately every 6 months) for all devices used with non-waived cartridges. Calibration verification is also performed on both waived and non-waived cartridges when indicated by shifts or trends in quality control data and after major maintenance or repair to verify that test results were not affected.

1. The i-STAT system components which could cause shifts and drifts are discarded after each test. The sensors are subjected to a regular check of their accuracy by the Electronic Simulator. Software updates are periodically released by the manufacturer to verify that test results do not change over time. Repaired and new analyzers are

received with factory calibration, and the Electronic Simulator is used to confirm that the analyzer's functions are within factory specifications. Calibration verification performed approximately every 6 months verifies electronic simulator checks for non-waived cartridges.

a. Analyze the calibration verification material in the Cal Ver pathway under the Quality Tests option of the i-STAT 1 Analyzer Administration Menu.

b. Each level of calibration verification material should be run 3 or 4 times.

c. For more detailed information, follow the steps under the Procedure section below.

d. Submit the results to the manager, supervisor, or designee for review and approval.

VIII. MAINTENANCE:

A. Cleaning

1. If the analyzer is placed on a wet surface or if any liquid is spilled on to it, dry the analyzer immediately. Avoid allowing liquid to enter the electronics compartment or the battery compartment of the cartridge port because this could damage the analyzer.
2. Clean the display screen with a soft dry tissue. Clean the case using a gauze pad moistened with a mild non-abrasive cleaner, detergent, soap and water or alcohol. Rinse using another gauze pad moistened with water and dry the analyzer.

B. Thermal Probe Check

1. The i-STAT analyzer contains a thermal control subsystem consisting of two thermal probes with thermistors and heating contact wires. A quality check is performed on thermal probes each time the external Electronic Simulator is used. This check is performed twice per year.
2. To complete this check, the surface temperature of the External Electronic Simulator must not fluctuate. If this condition is not met, the thermal probe check is not completed.
3. See the External Electronic Simulator steps under the QC section below.
    a. Maintain the documentation for the Thermal Probe Check with the site-specific i-STAT QC data.

C. Replacing Paper in i-STAT Printer

1. Open the paper compartment lid by pulling up on the release leaver and remove any remaining paper.
2. Reel off a few centimeters of paper from the new paper roll, with the leading edge of the paper feeding forward from the bottom of the roll.
3. Place the new paper roll in the compartment such that the leading edge is resting outside the compartment on the printer casing.
4. Close the lid until it snaps into place.

D. Replacing Batteries

1. Slide the battery compartment door off.
2. Tilt the instrument slightly to slide out the battery carrier.
3. Remove the old batteries from the carrier and replace with 2 new 9V lithium batteries.
4. Insert the carrier back into the compartment, label facing up and electrical contacts first.
5. Slide the battery compartment door into place.
6. Dispose of the batteries per the site-specific guidelines.

E. Charging Rechargeable Batteries

1. Place the instrument in the Downloader/Recharger. This will automatically initiate recharging.
2. The indicator light on top of the Downloader/Recharger will be green (trickle charge), red (fast charge), or blinking red (fast charge pending) when an instrument with a rechargeable battery is placed in the Downloader/Recharger.
    a. Note: No damage will be caused if an instrument with a disposable battery is placed in the Downloader/Recharger.

F. CLEW Software Update

1. Due to the continuous manufacturing process improvements to the i-STAT system, it is necessary to update standardization values from time to time to maintain long-term consistency of performance. These updates are equivalent to manually adjusting calibration on a traditional laboratory analyzer.
2. New CLEW software, delivered twice per year, re-establishes these standardization values and incorporates refinements to the internal quality monitoring system. New JAMS application software allows the i-STAT instrument to recognize any newly launched cartridge types and to perform any newly launch features.
3. Twice per year the software will expire and will require an update to prevent operator lock-out.
    a. Navigate to https://www.pointofcare.abbott/us/en/log-in?originalRequest=https://www.pointofcare.abbott/us/en/offerings/support/i-stat/istat-system-software-update
    b. Log in to the website.
    c. Click on the "DOWNLOAD SUXXXXXX.EXE".
    d. Save the file to the DE server.
    e. Close the "Download Complete" window.
    f. Now, the i-STAT instruments are ready for the software install.
    g. Press the "On" button on the i-STAT.
    h. Press "Menu" to display the "Administration Menu".

i. Press "7" for "Utility".

j. When prompted for a password, press "ENT".

i. If this fails, enter the site-specific password (37970) then "ENT".

k. From the Utility menu, press "3" for "Receive Software". A "Waiting to Send" message will appear on the instrument's display.

l. Place the instrument on the Downloader. Do not move the instrument until step "n" below. A "Communication in Progress" message will appear on the screen. After this disappears, the instrument display will remain blank for approximately 5-10 seconds.

m. The instrument will then display "1"'s and "0"'s streaming across the screen, signifying it is receiving the software. Once the "1"'s and "0"'s disappear, the instrument display will go blank, again, for approximately 5-10 seconds.

n. A "Waiting to Send" message followed by a "Communication in Progress" message will appear. After these messages disappear, the instrument display will go blank. The update process is complete.

o. Navigate to the "Menu" screen.

p. Press "1" for "Analyzer Status" and confirm the correct software version is displayed in the instrument.

q. Perform the External Electronic Simulator test. See the Quality Control section below.

r. Press the "." button to record the instruments temperature.

s. Run all liquid QC on each cartridge type.

t. Run 3 levels of Calibration Verification samples on each cartridge type.

u. Submit the QC and Calibration Verification data to the Medical Director or designee for review.

G. Emergency Shutdown

1. i-STAT Instrument

a. Remove any inserted cartridge.

b. Press and hold the power button until the instrument powers off.

2. Downloader

a. Unplug the downloader from the wall plug.

IX. NEW LOT VALIDATION:

A. New lots of cartridges must be validated on, at least, one instrument.

B. Result differences between lot numbers must be within the limits posted on the i-STAT New Lot Number Validation form.

C. The completed form is reviewed by the manager, supervisor, or designee.

D. If a new lot of cartridges fail validation, follow-up investigations can include repeat QC analysis, review of external liquid QC results on other instruments, calibration verification, and instrument maintenance. If validation of a new lot fails, the lot should be rejected and not used for patient testing.

X. QUALITY CONTROL (QC):

Routine quality control testing of the i-STAT analyzer includes Electronic Quality Control and liquid QC. Liquid QC should be performed every time a new shipment of test cartridges is received, if the clinical picture does not correlate with patient test results, after major maintenance, and at least every 30 days to meet the Individualized Quality Control Plan (IQCP) requirements. QC is also used to evaluate new analyzers and to investigate i-STAT devices with reported problems.

A. Electronic Quality Control

1. The Electronic Simulator (external or internal) is a quality control device for the analyzer. It simulates two levels of electrical signals that stress the analyzer's signal detection function both below and above measurement ranges. It verifies the ability of the analyzer to take accurate and sensitive measurements of voltage, current, and resistance from the cartridge. An analyzer will pass or fail this test depending on whether or not it measures these signals within specified limits. The Electronic Simulator will fail if high relative humidity interferes with the measurements. The error message "Temperature Out of Range" displays if the analyzer is outside its operating range. The Electronic Simulator is used for troubleshooting or if the analyzer is dropped or damaged.
    a. Internal Electronic Simulator: The Internal Electronic Simulator is a circuit in the analyzer that performs the same functions as the External Electronic Simulator. The i-STAT system has been programmed to perform the Internal Electronic Simulator every 8 hours. If it is due, it automatically initiates when a cartridge is inserted. If 8 hours has lapsed since the last Electronic Simulator test (internal or external), the analyzer will automatically perform the Internal Electric Simulator before the sample is tested. This will add about 20 seconds to the testing cycle.
        i. If the assessment fails, the testing cycle stops and "FAIL" displays on the screen.
            a. Reinsert the patient test cartridge in a different analyzer, if possible. This may prevent the loss of the patient sample and the need to obtain a replacement patient sample.
            b. Do not rerun the cartridge if more than 3 minutes has lapsed from the time of applying the sample.
            c. If the cartridge fails in more than one analyzer, run the External Electronic Simulator. See the steps below.
        ii. If the assessment passes, the cartridge cycle will continue to completion and the operator will receive the patient results.

b. External Electronic Simulator: The External Electronic Simulator is a stable electronic device that is inserted into the cartridge port of the analyzer. The External Electronic Simulator should be stored at room temperature. It is to be run (1) twice per year to coincide with a software update or a new CLEW; (2) after a software change; (3) before pin conditioning using the ceramic cartridge. Running the external Electronic Simulator verifies that the internal simulator cycle will not execute during the pin conditioning process, which could lead to the premature termination of the process; (4) if the analyzer has been dropped.

    i. If the analyzer and simulator have been stored in separate areas where the ambient temperature differs by more than 3°C, allow the simulator and analyzer to stand in the same place, away from air drafts, for 30 minutes before inserting the simulator into the analyzer. Handle the simulator as little as possible to maintain its thermal uniformity and stability.

    ii. Turn the analyzer on.

    iii. Press the "Menu" key to access the "Administration Menu".

    iv. Press "3" for "Quality Tests".

    v. Press "4" for "Simulator".

    vi. Scan or manually enter the operator identification (ID).

    vii. Scan or manually enter the Simulator ID (serial number) on the black case.

    viii. Insert the Simulator into the cartridge port with the "I" facing up.

        a. Do not touch the contact pads.

        b. The "Cartridge Locked" message is displayed indicating that the simulator should not be removed. An attempt to forcibly remove the simulator during this cycle may damage the analyzer.

    ix. View results on the analyzer's screen.

        a. If "PASS" is displayed, continue to use the analyzer.

        b. If "FAIL" is displayed, reinsert the simulator to repeat the check.

            i. If "FAIL" is displayed a second time, do not use the analyzer for patient testing and contact the site-specific POC department to Abbott Technical Support.

    x. The difference between the thermal probes can be viewed on the analyzer's screen while holding down the "DIS" key and pressing "1".

    xi. The interpretation for the Thermal Probe Check results follow:

        a. Acceptable: A value equal to or less than 0.1 (=0.1)

b. Not Acceptable: A "FAIL" message with a "t" and Quality Check Code or value greater than 0.1. Repeat the procedure to confirm the results. Contact Abbott Technical Support of the repeated Thermal Check Value is greater than 0.1.

c. Repeat the Procedure: If "--.--" is displayed, repeat the procedure, taking care to handle the simulator as little as possible. It may help to partially insert the Simulator into the analyzer and let it stand for 15 minutes before inserting it all the way.

xii. Remove the Simulator from the cartridge port and replace the plastic cap and store the Simulator at room temperature in its protective case.

B. Liquid Quality Control

1. Ampoules may be used once the fluid has reached room temperature, approximately 30 minutes for individual ampoules.
2. For best results, ampoules, cartridges, and analyzers should be at the same temperature.
3. PT/INR Control Preparation
    a. Controls must stand at room temperature for 45 minutes before use.
    b. Remove the cap and stopper, pour the entire contents of the calcium chloride vial into the lyophilized plasma vial. Replace the stopper.
    c. Allow the vial to sit for 1 minute. Mix the contents by swirling gently for 1 minute, then inverting slowly for 30 seconds.
4. Liquid QC i-STAT Procedure
    a. Turn on the instrument and press "MENU" to access the "Administration Menu".
    b. Press "3" for "Quality Tests".
    c. Press "1" for "Control".
    d. Press "1" for "i-STAT Cartridge", if prompted.
    e. Scan or enter the operator ID.
    f. Scan or enter the control lot number.
    g. Scan the lot number on the cartridge pouch.
    h. Immediately before use, shake the ampoule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampoule at the ends to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampoule to send the solution back into the bottom section of the ampoule.
    i. Protect fingers with gauze, tissue, or an ampoule breaker to snap the tip

off the ampoule at the neck.

j. When using a syringe (1 mL or 3 mL syringes with 16 to 20 gauge safety needles are recommended), slowly draw approximately 1 mL of solution from the bottom of the ampoule. Remove any air trapped between the leading edge of the solution and the tip of the syringe.

k. Expel 1-2 drops from the syringe before filling the cartridge.

l. Fill the cartridge with the control material and close the cover.

    i. Note: It is important to seal the cartridge promptly after sample addition as to not expose the solution to room air, since this will alter results for some parameters.

m. Insert the cartridge into the cartridge port.

n. Enter chart page information, if applicable.

o. Review the results for acceptability. A message will display at the top of the screen if the results "PASS" or "FAIL".

    i. If the "FAIL" message is displayed, see the Quality Control Failure Procedure below.

p. Remove and discard the cartridge when the "Cartridge Locked" message disappears.

C. Quality Control Failure Procedure

1. If results are outside of the acceptable range, the following items should be verified:
    a. Verify the QC and cartridges are not past their expiration dates.
    b. Confirm proper temperature storage for QC and cartridges.
    c. Confirm the proper procedure was followed.
2. If none of the above parameters are suspect, repeat the testing using new QC and cartridge.
3. If the repeat does not fall within the expected range, follow the site-specific instructions below for assistance:
    a. Dearborn: Call POC at 313-436-2367, 313-593-7970, or 313-982-5661.
    b. Wayne: Call the Wayne Lab Manager at 734-467-4233.

XI. INSTRUMENT COMPARISONS:

A. Instrument comparisons, using both patient samples and QC materials, are performed to verify the agreement between analyzers is acceptable.

1. Note: One set of comparisons is performed using patient samples. The second set may be performed using QC material. A minimum of one sample is required for each comparison study.

B. Twice per year, approximately every 6 months, comparisons will be performed between laboratory instruments and each i-STAT device for each non-waived cassette type in use at

each testing location.

1. Prepare the i-STAT device for running a patient test. See the Procedure section.
2. Scan a training barcode or use a dummy number for the patient ID (111111111).
3. Select remnant patient samples to run on the laboratory instrument and on the iSTAT cartridge method.
    a. Blood gas samples should be assayed, again, on the laboratory instrument to obtain fresh values, then assayed immediately on the iSTAT device.
4. Document the results on the i-STAT Instrument Comparison Form. See the attachment. The site manager, supervisor, or designee will evaluate comparison results according to approved acceptability criteria established by Technical Director or Medical Director.
5. Troubleshoot and resolve any failures and document on the i-STAT Instrument Comparison Form before continuing patient testing with any problem device.

XII. PROCEDURE:

A. Press the On/Off key to turn on the analyzer.

B. Press "2" from the test menu to select "i-STAT Cartridge".

C. Scan or manually enter the operator ID.

D. Scan or manually enter the patient Contact Serial Number (CSN).

E. When prompted to scan the cartridge lot number, scan the barcode on the cartridge packaging.

F. Remove the cartridge from its package. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge. Place the cartridge on a flat surface.

G. Mix the specimen well before sampling. Discard the first two drops of blood from the syringe. Direct the tip of the syringe into the sample well and dispense the sample until it reaches the fill mark on the cartridge and the well is about half full.

H. Close the cover over the sample well until it snaps into place by pressing the rounded edge of the closure. Do not press over the sample well.

I. Hold the cartridge by the thumb recess. Insert the cartridge into the cartridge port until it clicks into place. Keep the analyzer horizontal during the testing cycle.
    1. If blood or any other fluid has been spilled on the portion of the cartridge that will be inserted into the cartridge port, discard the cartridge and start over. Inserting such a cartridge may damage the analyzer.
    2. Do not remove the cartridge while the "Cartridge Locked" message is displayed on the screen.

J. Enter additional parameters on the "Chart" screen, if required.

K. Select the corresponding sample type in the "Sample Type" field.

L. A countdown will appear while the sample is being analyzed.

M. The results will be displayed on the screen.

1. Depending on the analyzer configuration, the results will be transmitted to the electronic health record (EHR) either wirelessly or by placing the i-STAT on the docking station.

N. Remove the cartridge after the "Cartridge Locked" message disappears. Discard the cartridge in a biohazard receptacle.

XIII. RESULT REPORTING:

A. Test Flags

1. ***: Results are not reportable due to sensor errors or interfering substances. Collect a fresh sample and repeat the test. If the results are flagged, again, send a sample to the Laboratory.
2. "<,>" and "<>": Results are below or above the reportable range or dependent on results that are outside the reportable range. Send a sample to the Laboratory.

B. i-STAT instruments that have wireless capabilities will automatically transmit results to the patient's EHR.

C. i-STAT instruments that do not have a wireless configuration must be placed in the Downloader/Recharge to transmit results to the patient's electronic health record.

1. Do not move the instrument until the "Communication in Progress" message disappears.

D. Printing Results Without Downloader/Recharger

1. Turn printer on if the green power light is not on.
2. Align the IR windows of the instrument and printer.
3. Display the results.
4. Press "Print".
5. Do not move the instrument or printer until printing is complete.

E. Printing Results With Downloader/Recharger

1. Turn the instrument on.
2. Press "Menu".
3. Press "2" for "Data Review".
4. Press "7" for "List".
5. Scroll through the test records using the arrow keys.
6. Press the numbered key for the test record.
7. Align the instrument and printer IR window or place in the Downloader/Recharger attached to the printer and press "Print".
8. Do not move the instrument or printer until printing is complete.

XIV. RESULT REVIEW:

Test results are displayed on the screen for 2 minutes after test completion.

A. To review previous results, turn on the instrument.
B. Press the "Menu" button.
C. Press "2" for "Data Review".
D. Press "1" for "Patient".
E. Scan or enter the patient's CSN.
F. Use the "1" and "2" keys to scroll through the test records.
G. Select the test record to be reviewed and press the "Enter" key.

XV. REFERENCE RANGES:

A. Creatinine

Age	Range (mg/dL)
0-14 Days	Male: 0.3-0.9 Female: 0.3-0.9
15 Days - <2 Years	Male: 0.1-0.4 Female: 0.1-0.4
2 - <5 Years	Male: 0.2-0.4 Female: 0.2-0.4
5 - <12 Years	Male: 0.3-0.6 Female: 0.3-0.6
12 - <15 Years	Male: 0.4-0.8 Female: 0.4-0.8
15 - <19 Years	Male: 0.6-1.1 Female: 0.5-0.8
19 Years - Adult	Male: 0.6-1.3 Female: 0.5-1.1

B. INR

Age	Range (INR)
All	0.8-1.2

Therapeutic INR Range for Standard Oral Anticoagulation: 2.0-3.0
Therapeutic INR Range for Mechanical Prosthetic Values: 2.5-3.5

XVI. REPORTABLE RANGE:

A. Creatinine (mg/dL): 0.2-20.0
B. INR (INR): 0.9-8.0

XVII. CRITICAL VALUES:

Critical values are displayed with an up arrow or down arrow.

Follow the institutional policy for critical result reporting and documentation.

A. Creatinine (mg/dL)

1. 0-18 Years: >2.8
2. 19-116 Years >7.0

B. INR (INR)

1. ≥5.0

XVIII. SYSTEM DOWNTIME:

A. If the i-STAT does not download, continue to enter the operator and patient ID and proceed with testing. When the system becomes available, place the instrument on the Downloader to transmit results.

XIX. LIMITATIONS:

A. The analyzer must remain on a level, vibration-free surface with the display facing up during testing. A level surface includes running the instrument in the Downloader/Recharger.

B. Cartridges are single-use only. Do not reuse.

C. Poor technique in sample collection may compromise results.

D. PT/INR: Glass syringes or tubes may prematurely activate coagulation, resulting in accelerated clotting times and lower INRs.

E. Abbott POC has not characterized the i-STAT PT/INR test with patients that have lupus anticoagulant antibodies. If the presence of lupus anticoagulant antibodies is known or suspected, consider using a prothrombin time laboratory assay using a reagent that is know to be insensitive to lupus anticoagulant antibodies or an alternative laboratory method.

XX. INTERFERING SUBSTANCES:

A. Creatinine

1. Creatinine 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.

Substance	Concentration (mmol/L)	Interference	Comment
Acetaldehyde	0.04	No	
Acetaminophen	1.32	Yes	Increased results
Acetaminophen (therapeutic)	0.132	No	
Acetylcysteine	10.2	Yes	Increased results
Acetylcysteine (therapeutic)	0.3	No	
Ascorbate	0.34	Yes	Increased by up to 0.3 mg/dL

Bicarbonate	35.0	No	
Bilirubin	0.342	No	
Bromide (therapeutic)	2.5	Yes	Increased results
Calcium Chloride	5.0	No	
Creatine	0.382	Yes	Increased by up to 0.3 mg/dL
Dopamine	0.006	No	
Formaldehyde	0.133	No	
β-Hydrolybutyrate	6.0	No	
Glycolic Acid	10.0	Yes	Decreased results
Hydroxyurea	0.92	Yes	Increased results
Lactate	6.6	No	
Methyldopa	0.071	No	
Nithiodote (Sodium thiosulfate)	16.7	Yes	Increased results
Pyruvate	0.31	No	
Salicylate	4.34	No	
Uric Acid	1.4	No	

B. PT/INR

1. The presence of exogenously added heparin, citrate, oxalate, or EDTA from blood collection devices will interfere with test results.
2. The PT/INR test is not affected by fibrinogen concentrations between 70 and 541 mg/dL. The test will not reflect the extension of coagulation time associated with the depletion of fibrinogen (e.g., consumptive coagulopathy), disseminated intravascular coagulation (DIC), or defibrination syndrome.
3. The PT/INR test ins not affected by unfractionated heparin concentrations concentrations up to 1.0 U/mL.
4. Hematocrits in the range of 24-54% PCV have been demonstrated not to affect results.
5. Cubicin® (daptomycin for injection) has been found to cause a concentration-dependent false prolongation of PT and elevation of INR when using this test. It is recommended that for patients being treated with this antibiotic to use an alternate method to evaluate PT/INR.
6. This test may report a false prolongation of the PT and elevation of INR on samples contaminated with chlorhexidine gluconate.
7. This test ins not intended for evaluating individual factor deficiencies.

XXI. TROUBLESHOOTING:

A. 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 i-STAT control solutions. If the controls are in range, there may be an interfering substance in the patient sample. Test by another method to verify the result. If the controls are out of range, there may be a problem with the cartridge lot number. Use another lot or repeat the test using another method. Additional troubleshooting information may be obtained from Abbott iSTAT Support Services (1-800-366-8020).

B. The instrument performs self-checks when it is turned on. If a condition that should be corrected in the near future, but that will not affect results, is detected, a warning is displayed. The operator presses the "1" key to access the "Test Menu". The instrument can be customized to lock out the operator until corrective action is taken.

C. If the troubleshooting recommendations below do not resolve the issue, follow the site-specific instructions below. A loaner instrument may be available for use.

    1. Dearborn: Call POC at 313-436-2367, 313-593-7970, or 313-982-5661.
    2. Wayne: Call the Wayne Lab Manager at 734-467-4233.

STARTUP ERROR MESSAGE	CORRECTIVE ACTION
Electronic Simulator Test Required	Insert Electronic Simulator
Stored Memory Low	Place instrument in Downloader
Stored Memory Full	Place instrument in Downloader
Upload Required	Place instrument in Downloader
Battery Low	Replace batteries or recharge battery
CLEW Expiring, Update Required	Update software

Other error messages may be displayed. If unable to resolve using the corrective action suggested, below, contact Support Services.

ERROR MESSAGE	CAUSE	CORRECTIVE ACTION
Date Invalid, Check Clock	Date outside 6 month lifetime of software	Select 5-Clock Set from Administration Menu (Password Protected)
Dead Batteries, Replace Batteries	Insufficient power to complete a test cycle	Replace disposable batteries or recharge the rechargeable battery.
Temperature Out of Range, Check Status Page	Temperature outside operating range of 16-30°C	Check instrument temperature by pressing 1 for Analyzer Status under the Administration Menu. Move instrument to an area within the operating temperature range.
Expired Software, Update Required	Software expired or corrupt	Verify that the instrument's date is correct. Change software, if expired. Update, again, if not expired.

Analyzer Interrupted, Use Another Cartridge	Last cartridge run not completed	Check the battery pack is inserted properly. Check for Low Battery startup warning.
Cartridge Error	Problem with sample or cartridge filling	Use another cartridge. If same code repeats more than twice, use another instrument.
Cartridge Preburst	Calibrant pack burst before cartridge inserted into instrument	Use another cartridge. Do not press on the center of the cartridge. Check that cartridges have not been frozen.
Unable to Position Sample	Cartridge not sealed. Clot in sample. Aberrant cartridge.	Use another cartridge
Sample Positioned Short of Fill Mark	Cartridge underfilled	Use another cartridge. Fill to fill mark.
Sample Positioned Beyond Fill Mark	Cartridge overfilled	Use another cartridge. Do not fill beyond fill mark.
Test Canceled by Operator	User did not respond to mandatory prompt before instrument timed out	No action required.
Cartridge Type Not Recognized	Software does not recognized cartridge	Update software. Check to see if cartridge expired.
Analyzer Error, Use Electronic Simulator	Instrument detects a problem from which it is likely to recover	Insert Electronic Simulator. If "PASS" is displayed, continue to use instrument.
Analyzer Error, See Manual	Instrument detects problem from which it may not recover	Insert Electronic Simulator. If "PASS" is displayed, insert a cartridge with sample or control. If the code does not reappear, continue to use the instrument.
No Display	Disposable batteries dead or rechargeable battery fully discharged. Keypad not responding. Start switch broken.	Change disposable batteries or recharge battery. If still no display, call Support Services.
Cartridge Locked does not disappear after the test cycle is completed	Dead battery(s). Mechanical problem.	Wait until instrument turns off. Turn instrument on. If resets, remove cartridge. If not, change or recharge battery(s) and turn instrument on.

XXII. REFERENCES:

A. The Joint Commission. (2022) Standard NPSG.01.01.01 EP 1 in The Joint Commission. Comprehensive accreditation manual. Hospital edition. Oak Brook, IL: The Joint Commission.

B. Point of Care Testing Approval Process

C. i-STAT1 User Guide, Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL

60064, revision 714254-00AA 04-17-2020 https://www.pointofcare.abbott/us/en/home

D. i-STAT Procedure Manual for the i-STAT 1 System, Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL 60064, revision 714446-00AC 04-15-2020 https://www.pointofcare.abbott/us/en/home

E. i-STAT 1 System Manual, Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL 60064, revision 731335-00E 12-14-2018 https://www.pointofcare.abbott/us/en/home

F. Instructions for Updating i-STAT 1 Handheld Software, Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL 60064, revision 714258-00T 04-17-2020 https://www.pointofcare.abbott/us/en/home

G. Cartridge and Test Information, Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL 60064, revision 714258-00T 04-17-2020 https://www.pointofcare.abbott/us/en/home

H. i-STAT Crea Cartridge, Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL 60064, revision 765791-00 REV. B 03-06-2020 https://www.pointofcare.abbott/us/en/home

I. Prothrombin Time/PT/INR, Abbott Point of Care Inc., 100 and 200 Abbott Park Road, Abbott Park, IL 60064, revision 745236-00S 04-23-2018 https://www.pointofcare.abbott/us/en/home

J. Skin Puncture Techniques

Attachments

i-STAT Instrument Comparison.pdf

i-STAT New Lot Number Validation.pdf

i-STAT Training and Competency Assessment.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Jeremy Powers: Chief, Pathology	11/1/2023
CLIA Medical Directors	Muhammad Arshad: Chief, Pathology	10/31/2023
Policy and Forms Steering Committee Approval (if needed)	Jessica Czinder: Mgr, Division Laboratory	10/31/2023
CP System Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	10/30/2023

	Caitlin Schein: Staff Physician	10/18/2023
Technical Director	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	10/3/2023
POC Best Practices	Jessica Czinder: Mgr, Division Laboratory	10/3/2023
	Jessica Czinder: Mgr, Division Laboratory	10/3/2023

Applicability

Dearborn, Wayne