SUBJECT: **Point of Care: I-STAT**

Policy No.: **ICU 012**
Supersedes: **NEW**
Effective Date: **Septemer 1, 2020**

I. BACKGROUND AND CLINICAL SIGNIFICANCE

The i-STAT System incorporates comprehensive components to perform the in vitro quantification of various analytes from a few drops of whole blood at the point of care location. The components are:

1. The i-STAT 1 analyzer is a battery powered portable device that utilizes single-use disposable cartridges to analyze blood. When a cartridge is inserted into the analyzer, the I-STAT 1 automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration and continuous quality monitoring.

2. The i-STAT Cartridges contain microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber.

3. Downloader/Recharger allows bidirectional transmission of data between the analyzer and the electronic health record. Transmission is automatic when the analyzer is placed in the downloader.

4. The CG8+ cartridge is the only cartridge configuration currently validated for use at Rancho Los Amigos National Rehabilitation Center.

II. TESTING PERSONNEL

Point of care testing is a multidisciplinary team effort among clinical laboratory, nurses, and providers. Whereby the clinical laboratory and staff are responsible for the overall quality assurance of the testing system and certified testing personnel (physicians, nurses, and laboratory scientist) perform patient testing and daily quality assurance requirements.

The i-STAT analyzer is only to be used by competent operators in the Intensive Care Unit (ICU).

The **testing personnel of the Intensive Care Unit** will be responsible for:

- Monitoring the temperature and humidity of the testing and supply storage area
- Performing daily maintenance of the instrument
- Performance of daily quality control samples
- Testing of patient samples

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- Docking the analyzer on the downloader/recharger

The **Department of Pathology – Point of Care** is responsible for the overall quality assurance of the i-STAT system.

- The validation of all analyzer, reagents, and controls before placement into use and at required intervals recommended by the manufacturer or regulatory agency.
- The training and competency assessment of users; including initial, six months, and annual.
- The storage and inventory management of cartridges, controls, and calibrators.
- The monitoring of quality control results and transmission of patient results to the LIS system.
- Every 6 months a series of tests, upgrades, and transmission verification will be conducted as specified in the Pathology and Clinical Laboratory i-STAT Point of care procedure manual.

III. EQUIPMENT AND SUPPLIES

A. i-STAT ANALYZER - MAINTENANCE

Daily (ICU Testing Personnel)

- Check and record room temperature and humidity
- Keep the analyzer clean, using hospital-approved disinfecting wipes (e.g., Sani-cloth, 2 minutes dwell time)
- Handheld or portable testing devices must be disinfected after each patient use.
- If the analyzer is soiled, it must be cleansed before it can be disinfected adhering to specified dwell times. The analyzer must remain visibly wet otherwise it is not disinfected. Use additional wipes as needed to adhere to the dwell time
- If patient has C-diff, employee must use PDI bleach wipes (4 minutes dwell time) to disinfect the meter when dry, follow with an alcohol wipe to remove residual bleach, do not saturate screen, immerse (or spray) meter in water or any cleaning agent. Must be dried thoroughly.
- Analyzer needs to have the battery charged in the docking station when not in use.

B. CARTRIDGES

1. STORAGE AND HANDLING

- Follow the instruction on the temperature card that comes with the shipment
- Store the main supply of cartridges in the laboratory
- Cartridges may be stored at room temperature (Ambient temperature; 18 to 30°C or 64 to 86°F and Humidity temperature; 0-90%) for 2 months. Write the date on the cartridge box or individual cartridge pouches to indicate the 2 month room

temperature expiration date. **Cartridges should not be returned to the refrigerator once they have been at room temperature.**

- Cartridges must not be exposed to temperatures above 30°C (86°F).
- If the pouch has been punctured, the cartridge should not be used. Cartridges should remain in pouches until time of use.
- Do not use after the labeled expiration date.

2. PREPARATION

An individual cartridge may be used after standing 5 minutes, in its pouch, at room temperature. An entire box should stand at room temperature for one hour before cartridges are used.

3. VERIFICATION OF NEW LOT / SHIPMENT

INTENSIVE CARE UNIT:

- Upon delivery, send product immediately to Department of Pathology – Point of Care for validation before use.

DEPARTMENT OF PATHOLOGY – Point of Care

- The product will be stored and validated by laboratory personnel
- Deliver products to ICU, bring to room temperature prior to delivery. Write expiration date on product, Cartridges (2 months at room temp.) and Liquid QC (5 days at room temp).

IV. SPECIMEN REQUIREMENTS

A. Suitable Specimens for CG8 Cartridges

- Fresh whole blood collected in a plastic syringe without anticoagulant.
  Note: Testing must be performed immediately after collection.
- Fresh whole blood collected in a collection tube with **lithium heparin anticoagulant**. Fill collection tubes to capacity.
- Fresh whole blood collected in a heparinized plastic syringe or in a blood gas syringe labeled for the assays to be performed. Fill syringes for correct blood-to-heparin ratio (10 U heparin/mL of blood)

B. Specimen volume: 95 uL

C. Criteria for specimen rejection

- Evidence of **clotting**
- Specimens collected with anticoagulant other than lithium or sodium heparin
- Syringe for pH, PCO_2, PO_2 and TCO_2 with **air bubbles** in sample

- **Incompletely filled syringe** for the measurement of ionized calcium, PCO_2, HCO_3 or TCO_2 (will decrease results due to dilution)
- Other sample types such as urine, CSF, and pleural fluid
- Blood specimens drawn from indwelling line and contaminated with medications and intravenous solutions.

V. TESTING PROCEDURE:

A. QUALITY CONTROL

Enviromental Monitoring

- Check and record room temperature and humidity.
- Check inventory and expiration dates of supplies.

1. Internal Electronic simulator

- Performed automatically when a cartridge is inserted after the customized interval is reached.
- The cartridge test cycle proceeds if the analyzer passes the simulator test
- The analyzer displays " Electronic Simulator Fail" if the analyzer fails the simulator test

2. External – analyzed to verify the integrity of the reagent cartridge.

- Aqueous i-STAT TriControls Control Levels 1 and 3
  - Each level of control is packaged in a box of 10 ampules.
  - Storage temperature - must be monitored and documented.
    - Stable up to the expiration date printed on the box and ampule label if stored at 2 to 8°C (35° to 46°F).
    - Stable up to 5 days if stored at room temperature (Ambient temperature; 18 to 30°C or 64 to 86°F and Humidity temperature; 0-90%). Label the expiration date when stored at room temperature.
    - Frequency of use: External liquid controls are run daily.
      (Designated interval and with every lot or shipment)
      This device is eligible for option 1 equivalent QC, as dictated by CMS and CLIA '88 regulations. Therefore, it is acceptable to run liquid controls at specified interval longer than 8 hours but no longer than the manufacturer's limit provided the automatic internal electronic QC is successfully performed every 8 hours of patient testing. These regulations require validation of the interval before placing into practice.
  - Preparation: If stored at refrigerated temperature, the ampule must be equilibrated to room temperature for 4 hours prior to use.

3. External Liquid QC

Type of cartridge	Equilibration time
CG8+	**Equilibrate the QC for 4 hrs at room temperature** before use. Use only one ampule per cartridge.

Procedure:

1. Turn the device ON
2. Press the Menu key
3. Press #3, Quality Test
4. Press #1, Control

For Scheduled QC Performance

To run Level 1 Quality Control Solution

1. Select #2, Schedule 1
2. Select #1, CG8
3. Select #1, APOC Combo L1
4. Enter Operator ID
5. Scan the Barcode lot number of the liquid QC
6. Scan the Barcode lot number of the Cartridge
7. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
8. Shake the ampule vigorously for 5-10 seconds by holding the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution.
9. Tap the tip of the ampule to restore the solution to the bottom of the ampule.
10. Snap the tip off the ampule at the neck. **Protect finger with gauze or ampule breaker.**
11. Using a syringe (1cc or 3cc syringes with 16 to 20 gauge needles are recommended), slowly draw approximately 1 mL of solution from the bottom of the ampule.
12. Discard the ampule and syringe if air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe; use a fresh ampule and syringe. Expel one or two drops from the syringe before filling the cartridge.
13. Dispense the sample into the sample well of the cartridge, using a steady flow technique, until it reaches the fill mark on the cartridge and the well is about half full.

14. Hold the cartridge on the outside edges, and close the cover over the sample well until it snaps into place. (**Do not** press over the sample well.)
15. Insert the cartridge into the device
16. Results will appear on the screen.

    PASS indicates all the values are within the expected ranges.

    FAIL indicates one or more values are unacceptable. Repeat QC using a new ampule of QC material.

To run Level 3 quality control solution

Scheduled QC Performance

1. Press #1, Test Options
2. Press #1, Next Level
3. Enter Operator ID
4. Select #2, Schedule 1
5. Select #1, CG8
6. Select #2 APOC Combo L3
7. Scan the Barcode lot number of the liquid QC
8. Scan the Barcode lot number of the Cartridge
9. Repeat steps 11-20 (from above).

Note:

- **Two levels of Liquid Controls must be within the acceptable limits prior to performing patient testing.**
- Check that the software version listed on the insert matches the software installed in the analyzer.
- If all results are within expected ranges, use the cartridges as needed.
- Transmit the results to the HIS:
  - At the completion of the test, place handheld into the downloader.
  - I-Stat screen will show “Communication in Progress”
  - Do not interrupt communication
  - Screen goes blank when communication is completed.
  - Leave handheld in rechargeable downloader to “rest and recharge.”

B. PATIENT TESTING

An individual cartridge may be used after standing 5 minutes, in its pouch, at room temperature. An entire box should stand at room temperature for one hour before cartridges are used.

1. Turn the device ON.
2. From the Test Menu, Select Option #2 – i-STAT cartridge
3. Enter an operator ID number. Repeat if required.
4. Scan or Enter the patient ID (FIN) number. Repeat if required.

5. Scan or Enter Cartridge Lot Number
6. The display will read "Insert Cartridge"- (you have approximately 15 minutes to prepare the patient specimen)
7. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
8. Collect the patient sample. The **syringe must be capped immediately** after collection. Whole blood samples for blood gas/electrolyte/glucose analysis should be analyzed as soon as possible (within 5 minutes of collection for glucose testing). **Syringes must be filled to capacity**.
   Note: Gloves must be worn during testing events, Hand hygiene performed, and gloves changed between patients, according to standard precautions. Hands must be cleaned using an effective antimicrobial method.
9. Following thorough mixing of the sample (roll between palms 5 times in 2 directions, then invert 5 times), **discard first 2 or more drops** onto gauze.
10. Direct the dispensing tip or capillary tube containing the blood into the sample well.
11. Dispense the sample until it reaches the fill mark on the cartridge.
12. Close the cover over the sample well until it snaps into place. (Do **not** press over the sample well.)
13. Insert the cartridge into the cartridge port on the analyzer until it clicks into place. The analyzer must remain on a flat surface during the entire testing cycle to avoid vibration which may interrupt testing.
14. **Never attempt to remove a cartridge while the "Cartridge Locked" message is displayed.**
15. Enter additional parameters on the Chart Page if required:
    - Patient temperature can be entered as degrees Centigrade or Fahrenheit. Use the * key on i-STAT Portable Analyzer for a decimal point.
    - FIO_2, can be entered as the number of liters or as a percentage of the oxygen a patient is receiving.
    - Choose the number corresponding to the type of sample used when prompted at the Sample Type field.
16. View results shown on the analyzer's display screen.
17. Remove the cartridge after the "Cartridge Locked" messages disappears is ready for a new cartridge immediately.

VI. RESULTS

A. Three conditions under which the i-STAT System will not display results:
- Results that are outside the validated reportable ranges: flagged with a **<** or **>**.
- Results that are not reportable based on internal QC rejection criteria: flagged with *******.
- Results that are not reportable due to problems detected on the sample by the analyzer: flagged with a Quality Check Code message

B. **Handling of Critical Laboratory Values (if applicable)**

- Prompt notification of the provider by nursing staff
- Document notification:

Note: High and low critical values and any results that do not correlate with the patient's clinical condition may be repeated on the i-STAT or verified in the Core Lab Based upon the provider's assessment and discretion.

C. Downtime results documentation
- Print results from i-STAT
- Turn on instrument
- Press Menu button to get to the Administration Menu
- Select option 2 – data review
- Select option 7 – List
- Identify and press the number containing the patient FIN. Repeat for each result. Press right arrow key if required to retrieve additional results and continue until all have been highlighted.
- Enter Operator ID if required
- Align i-STAT IR windows with i-STAT Portable Printer
- Turn on Printer
- Press the PRT key on i-STAT
- Do not move analyzer and printer until printing is complete
- Affix result printout onto the i-STAT results form
- Make a copy of the form with the result printout affixed on it to go into the patients permanent record along with the original

VII. TRAINING

A. Training may be provided by the:
- Manufacturer
- Point of Care Testing Personnel

B. New employees will:
- Receive the initial training followed by a 6-month competency assessment
- Be authorized to perform the test upon completion of the initial training

C. The POCT certificate or authorization to perform the test:
- Will be valid for a year
- Is renewed annually upon completion of the annual competency assessment
- Must be kept current

D. I-STAT Staff Competency Assessment performance criteria
- Written examination must have 80% or greater to PASS
- Demonstration of performance criteria will be completed following a checklist. **Note:** Staff must have performed one blind test and one Quality control testing.
- Incorrect written response to the examination must be reviewed, discussed to correct staff members understanding.

- Employees who do not meet the competency criteria will be given remedial training and suspended from performing the assay until employee is deemed competent.

REFERENCES

Abbott Point of Care Testing
Procedure Manual for i-STAT System
Rev. Date: 10/04/2018