Sutter Health
Sutter Roseville Medical Center

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Owner:	*Kirsten Baker: Coord, Technical*
Policy Area:	*Lab - Point of Care*
References:	
Applicability:	*Sutter Roseville Medical Center*

i-STAT QC Procedure

Purpose

The i-STAT is a hand held analyzer that is operated as a moderately complex point of care device. Single use whole blood cartridges are available in multiple analyte configurations. Refer to "i-STAT Patient Testing" for allowable cartridge types at SRMC. Reliable operation of the i-STAT analyzer is ensured by a robust quality control program.

1. Automated internal cartridge quality measurements that monitor the sensors, fluidics, and instrumentation are done with every test cycle. Refer to "i-STAT Patient Testing" troubleshooting section for information on responding to errors generated from these measurements.
2. Daily verification of analyzer performance by using the internal or external Electronic Simulator.
3. External liquid quality control is used to verify performance of each cartridge new lot and shipment initially, at least monthly, and as needed for troubleshooting.
4. This procedure also outlines the process of managing i-STAT cartridge inventory. Proper cartridge shipment and storage conditions are integral to successful operation of the i-STAT.

Policy

- Laboratory staff performs:
  - Temperature requirement verification for each shipment of cartridges and controls.
  - 2 levels of external liquid controls monthly and with each new lot/shipment of cartridges.
  - Thermal probe check twice a year with each software update.
  - Calibration verification every 6 months.
  - Troubleshooting for analyzers returned from other departments (A loaner will be issued until the problems are resolved).
- Performing departments (Cath lab, Interventional radiology, and Operating room):
  - 2 levels of external liquid controls **weekly** on in use lots of cartridges.
- Verification of the internal electronic simulator occurs every 8 hours of use.
- Cartridge and QC storage temperature is verified daily.

SUPPLIES AND EQUIPMENT

Supplies and Storage Requirements

- **i-STAT ACT, CG4+, CG8+, CREA Cartridges**

- A single-use disposable cartridge containing microfabricated sensors, a calibrant solution, fluidics system, and waste chamber
- Store refrigerated (2-8°C)
- ACT and CREA Cartridges are stable for 14 days at room temperature (18-30oC)
- CG4+ and CG8+ Cartridges are stable for 2 months at room temperature (18-30oC)
- Do not use expired or previously opened cartridges

- **i-STAT ACT QC Level 1 and 2**
  - Store refrigerated (2-8°C)
  - Allow vials to equilibrate to room temperature for a minimum of 45 minutes
  - Reconstitute one level at a time
  - Vials must be used IMMEDIATELY (less than 30 seconds) after completing reconstitution and mixing steps
- **i-STAT TriControls QC Level 1 and 3 - For CG4+, CG8+, and CREA Cartridges**
  - Store Refrigerated (2-8°C)
  - Allow vials to equilibrate to room temperature
    - CG4+ and CG8+ a minimum of **4 hours**
    - CREA a minimum of **30 minutes**
  - Unopened ampules can be stored at room temperature (18-30^{o}C) for up to 5 days
  - New ampules must be used for each CG4+ and CG8+ Cartridge

Equipment
- i-STAT Analyzer
- i-STAT Download station
- Electronic Simulator - External

Internal Simulator

The automated internal Electronic Simulator produces 2 levels of electrical signals that stress the analyzer's signal detection function below and above the measurement range. The internal electronic simulator is automatically performed by the analyzer every 8 hours of testing.

If	Then
PASS	Proceed with testing • The "PASS" result will not display but will transmit when the i-STAT is docked
FAIL	"ELECTRONIC SIMULATOR FAIL" result will be displayed • Repeat testing with another cartridge
FAIL on retest	**Do not use the i-STAT for patient testing** • Proceed to the External Simulator Test procedure - This step will be performed by laboratory staff. • If error occurs on an iSTAT outside of the laboratory, return the meter to the lab and notify the lab supervisor or technical coordinator for troubleshooting.

External Liquid Controls

- In the Laboraotory:

    - Liquid controls are performed monthly and with each new lot/shipment of cartridges.
    - Each new lot/shipment of cartridges is verified before initial patient testing.
- In the performing departments:
    - Liquid controls are performed **weekly** on their in use lots of cartridges.

QC Preparation

Cartridge	ACT	CG4+, CG8+, and CREA*
QC to use	ACT 1 & 2	TriControls 1 & 3
QC preparation	• Allow QC to equilibrate to RT for a minimum of 45 min • Pour entire contents of CaCl vial into lyophilized human plasma control vial • Allow vial to sit at RT for 1 minute • Gently swirl vial for 1 minute then invert slowly for 30 seconds • Immediately transfer the solution into the ACT cartridge (less than 30 seconds)	• Allow ampule to equilibrate to RT for a minimum of 4 hours. • Unopened ampules are stable at RT for up to 5 days. • Mix vial vigorously for 5-10 seconds to equilibrate the liquid and gas phases before use. *Laboratory only: QC for CREA cartridges must equilibrate to RT for a minimum of 30 minutes.

Running Liquid QC

Step	Action
1.	Follow instructions for preparation and handling of QC used to verify the received cartridge type.
2.	Turn the i-STAT analyzer "ON" using the O button on the keypad.
3.	Press Menu on the keypad. • Select 3 - Quality Tests • Select 1 - Control • Scan badge for user ID • Select Fluid Vendor ◦ Select 1 - APOC (i.e. Abbott Point of Care) • Select Fluid ◦ QC Level 1 - Select 1 ◦ QC Level 2 - Select 2 ◦ QC Level 3 - Select 3 • Scan QC lot number • Scan Cartridge lot number
4.	Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
5.	Use a plastic pipette or syringe to transfer the QC solution into the cartridge sample well. Discard the first two drops then transfer QC material to the cartridge slowly until the solution reaches the fill mark and there is solution remaining in the sample well.
6.	Immediately seal the cartridge sample well by folding the snap closure.
7.	Insert the cartridge into the analyzer.

	• ACT cartridges must remain horizontal during the testing cycle.
8.	DO NOT try to remove the cartridge when the analyzer shows "lock".
9.	Results will be displayed in numeric form along with whether the QC run **Passed** or **Failed**. Refer to QC Evaluation section.
10.	When testing is complete, return iSTAT to docking station for data transmission.

QC Evaluation

If QC Results are	Then
Acceptable (PASS)	Cartridges are acceptable for patient testing
Unacceptable(FAIL)	**If** / **Then** First result: 1. Enter comment code 02 (QC Out, Reject/Repeating) 2. Check control and cartridge lot number/exp date 3. Repeat testing using a new vial of controls 4. Do not use i-STAT for patient testing if QC is unacceptable. Repeat result: 1. Enter comment code 03 (QC Rpt Fail, Lab Notified) 2. Try a different vial of QC or box of cartridges if available. 3. Notify the Clinical Laboratory supervisor or Technical Coordinator and quarantine the cartridges. 4. Lab staff will contact service for troubleshooting.

Liquid QC Display Messages

The following messages may appear on the i-STAT 1 handheld when using the Auto QC Pass/Fail. Note: eVAS refers to the electronic Values Assignment Sheet which is uploaded by the Point of Care Technical Coordinator or Supervisor.

Message	Cause/Action
Invalid eVAS	The eVAS file does not exist or is invalid. Notify Technical Coordinator or Supervisor. Use Downtime QC Procedure.
Lot Not in eVAS	The entered cartridge or control lot number could not be found in eVAS file. Notify Technical Coordinator or Supervisor. Use Downtime QC Procedure.
Does Not Match Selected Level	The entered control solution lot number does not match the user selected control level. Repeat QC entry.
Invalid Length	A blank control solution lot number was entered. Repeat QC entry.
Lot Expired	The entered control solution lot number or cartridge lot number is expired. Check QC and Cartridge expiration dates, repeat QC entry.
Invalid Number	The scanned APOC lot number has an invalid format. Repeat QC entry. Notify Technical Coordinator or Supervisor if unsuccessful and use Downtime QC

	Procedure.

Downtime Liquid QC Procedure

Follow the steps below as indicated for messages using the Auto QC Pass/Fail:

Step	Action
1.	Fill in lot number, expiration date, received date, department, and QC indication on the log.
2.	Obtain i-STAT analyzer and determine software version. a. Turn on i-STAT. b. Press Menu button. c. Select 1- Analyzer Status. d. Record CLEW version information on log sheet. e. Press Menu button to return to main menu or Power button to turn off.
3.	Obtain Abbott QC material and corresponding Value Assignment Sheets (VAS.) a. Go to http://www.abbottpointofcare.com/ and select option for Value Assignment Sheets. b. Select current CLEW c. Select control material, level, and lot number. *Note: Verify that the cartridge lot number prefix is listed at the top of the VAS.* d. Repeat Step c for each level.
4.	Transfer ranges from VAS to QC log.
5.	Turn on i-STAT and program the QC testing: a. Press Menu button. b. Select 3 – Quality Tests. c. Select 1 – Control. d. Scan Operator ID. e. Select Fluid Vendor 1. Select 2 – Non-APOC (i.e. other). f. Select Fluid 1. QC Level 1 - Select 1 2. QC Level 2 - Select 2 3. QC Level 3 - Select 3 g. Scan control lot number. h. Scan cartridge lot number i. Load cartridge within 15 minutes
6.	Follow the same control preparation as described in Running Liquid QC.
7.	Record results in the appropriate field on the QC form. Review recorded results and compare to

ranges from VAS.

If QC Results are	Then
Acceptable	1. Select Outcome as 1-PASS on the results screen. 2. Send QC logs and VAS forms to Lab Technical Coordinator or Laboratory Supervisor for review.
Unacceptable (not within range on VAS)	**If** / **Then** First result: 1. Check CLEW version, control lot numbers, units of measurement, acceptable ranges, and results. 2. If clerical error(s) not detected and/or results still not acceptable after correction of clerical errors, ◦ Select Outcome as 2-FAIL on the results screen ◦ Enter required Comment Code 02 (QC Out, Reject/Repeating) and press ENT key. 3. Repeat testing on a new vial of control material. 4. Do not use i-STAT for patient testing if QC is unacceptable. Repeat result: 1. Select outcome as 2-FAIL on the results screen, 2. Enter comment code 03 (QC Rpt Fail, Lab Notified) 3. Try a different vial of QC or box of cartridges if available. 4. Notify Lab Technical Coordinator or Supervisor and quarantine the cartridges. 5. Lab will contact Tech Service

Calibration

The i-STAT test cartridges are self-calibrating:

- Each i-STAT test cartridge contains a pH buffered aqueous solution of the test analytes at known concentrations.
- This fluid is measured by a sensor array.
- If the desired readings for the buffered solution are not obtained, the test cartridge will not function

Laboratory Quality Checks

Inventory Management

Inventory management steps listed below are to be performed by lab staff. Patient care departments will maintain and store room temperature supplies as needed.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1.</td><td>Record reading from disposable temperature monitor on the i-STAT Supply Receipt Log.
<table>
<tr><th>IF</th><th>THEN</th></tr>
<tr><td>1 or 2</td><td>Acceptable</td></tr>
<tr><td>3 or 4</td><td>Unacceptable</td></tr>
</table></td></tr>
<tr><td>2.</td><td>If shipping temperature or visual inspection is unacceptable:
Do not use for patient testing.
Label all boxes in shipment "Do Not Use - Failed Temperature or QC Check."
Notify Clinical Lab Supervisor or Technical Coordinator.
Notify Abbott 1-800-366-8020</td></tr>
<tr><td>3.</td><td>Enter shipment information on the "i-STAT Supply Receipt Log" (from "Date Recd" to "Initial Recd")</td></tr>
<tr><td>4.</td><td>If shipping temperature and visual inspection are acceptable, label boxes with "NEW LOT DO NOT USE UNTIL QC'D."</td></tr>
<tr><td>5.</td><td>Perform external liquid QC.</td></tr>
<tr><td>6.</td><td>Evaluate QC results – refer to External Liquid Quality Control section.
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>Acceptable</td><td>Label boxes with "THIS LOT OK TO USE" and notify Technical Coordinator or Supervisor of new lot.</td></tr>
<tr><td>Not Acceptable</td><td>Label all boxes in shipment "Do Not Use-Failed Temperature or QC Check."</td></tr>
</table></td></tr>
<tr><td>7.</td><td>Technical Coordinator or designee will approve new lot number, expiration date, and cartridge type in RALS (Consumables, Test Material, i-STAT, Cartridges)
Downloaded entry automatically created in RALS with scanned lot number (will include extra digits.) The expiration date will default to the QC test date. Manually edit the expiration date to the cartridge expiration date.
Place a check-mark in next to the "is Reviewed" box to mark approval.</td></tr>
</table>

QC Range Verification

New lots of QC are to be run in the laboratory prior to use to verify QC range acceptability.

External Simulator

The External Electronic Simulator provides an independent check of the analyzer's ability to take accurate and

sensitive measurements of voltage, current, and resistance from the cartridge. External Electronic Simulator testing must be initiated by the operator.

Indications

- Following software updates performed by the Clinical Laboratory.
- At least every 6 months.
- As needed for troubleshooting.

Step	Action
1.	Turn the i-STAT analyzer "ON" using the O button on the keypad.
2.	Press Menu on the keypad. • Select 3 - Quality Tests • Select 4 - Simulator • Scan badge for user ID • Scan or enter Simulator ID
3.	Insert simulator into analyzer (same process as a cartridge). Do not disturb simulator while testing cycle is in progress.
4.	The i-STAT will display a "pass" or "fail" message after the testing cycle is complete.

If	Then
PASS	Proceed with testing
FAIL	Repeat with same external Electronic Simulator
FAIL on repeat	**Do not use for patient testing** • Record error messages and check manual for troubleshooting • Contact Tech Service if unable to resolve • Document all actions taken

5.	Remove simulator, replace the protective rubber cover and return i-STAT to docking station for data transmission.

Thermal Probe Check

The thermal probe check is to be performed at least every six months (after i-STAT software updates) by the laboratory

- i-STAT analyzers contain a thermal control system that maintains testing temperatures at 37C.
- Use of the External Electronic Simulator will check the stability and accuracy of the probes over the operational analyzer ranges.

Step	Action
1.	Refer to the instructions for External Electronic Simulator Testing and run the test.
2.	When the results are displayed, press the period key to display the Thermal Difference. (Results are also displayed in RALS)
3.	Interpretation of the thermal probe check value: • Acceptable: a value equal to or less than 0.1

	• Not acceptable: a FAIL message with a "t" Quality Check Code or a value greater than 0.1. Repeat the procedure to confirm results. Contact Abbott Technical Support if the repeat thermal check value is greater than 0.1. • Repeat the procedure: If "--.--" is displayed. This indicates unstable temperature reading. It may help to partially insert the simulator into the analyzer and let stand for 15 minutes before inserting all the way.

Precautions and Limitations

- Glass syringes and transfer devices cannot be used on the i-STAT coagulation cartridges.
- Cartridge should be allowed to sit at RT at least 5 minutes prior to opening the pouch.
- Use cartridge IMMEDIATELY after removal from pouch.
- Avoid filling the cartridge on a surface that may cause the cartridge to pick up fiber, fluid or debris that may lodge in the analyzer.
- Do not contaminate the contact pads with fingerprints as the analyzer may not be able to make proper contact with the cartridge.
- Do not apply pressure to the central area of the label as the calibrant pack could burst prematurely.

Related Documents

- SRMC Clinical Laboratory Procedure*, i-Stat Patient Testing*

References

i-STAT 1 System Manual, Abbott Point of Care, Abbott Park IL, Rev 8/28/19

All revision dates: 1/20/2022, 2/25/2021, 2/11/2020, 12/20/2019, 11/13/2019

Attachments

Downtime i-STAT QC Log ACTk
Downtime i-STAT QC Log CG4+
Downtime i-STAT QC Log CG8+
Downtime i-STAT QC Log Crea
i-STAT Cartridge Receipt Log

Approval Signatures

Step Description	Approver	Date
Medical Director	Lindsey Westerbeck: Dir, Lab	1/20/2022
Laboratory Director	Lindsey Westerbeck: Dir, Lab	1/20/2022