i-STAT TESTING Training Guide

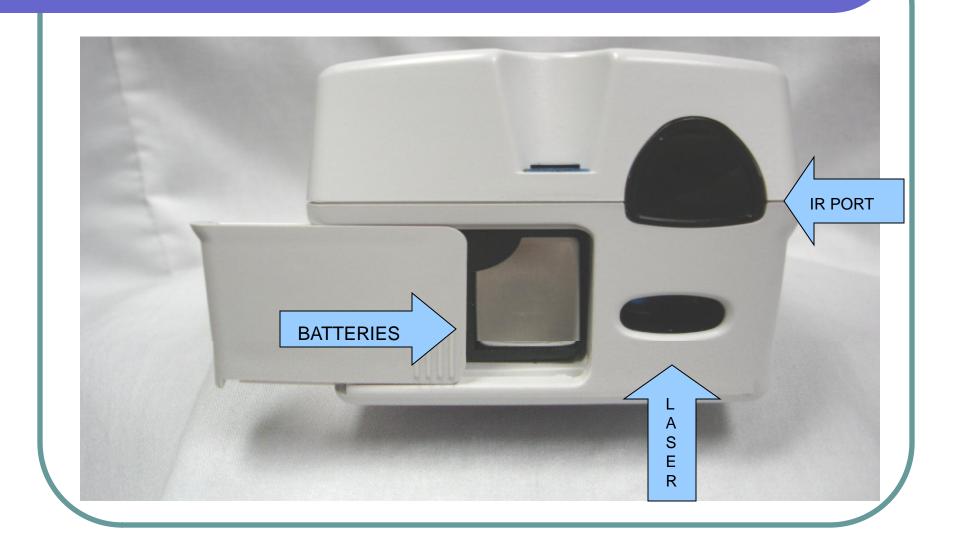


i-STAT 1 System Components

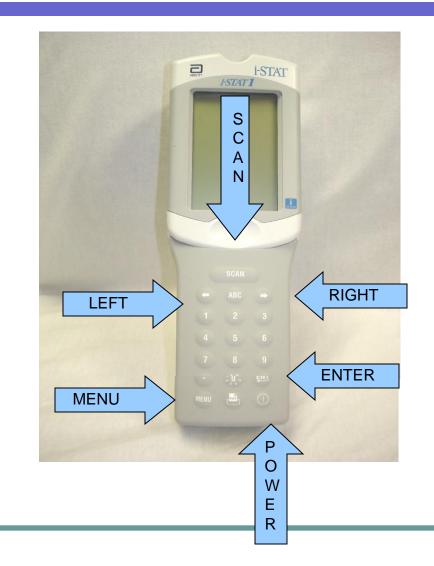
Batteries

- Rechargeable Downloader
- Electronic Simulator
- Analyzer
- Cartridges

Overview of i-STAT



Overview of the i-STAT



Overview of the i-STAT



Rechargeable Downloader

- Download results ASAP
- Charges the battery
- Downloads results to Meditech
- Screen states:
- "Communication in Progress"

i-STAT Cartridge

Cartridge Storage Expiration Dates

If refrigerated: Good until Expiration Date on pouch or box

If at Room Temperature:

- Chem 8:
- 14 Days (Cross out manufacturer's expiration date on box and change expiration date to 14 days from when taken out of refrigerator)
- CG4+:
- 2 months (Cross out manufacturer's expiration date on box and change expiration date to 2 months from when taken out of refrigerator)
- Troponin I:
- 14 Days (Cross out manufacturer's expiration date on box and change expiration date to 14 days from when taken out of refrigerator)

When taking cartridges out of refrigerator let them Warm-Up for

- Whole Box: 1 hour
- One Cartridge: 5 minutes

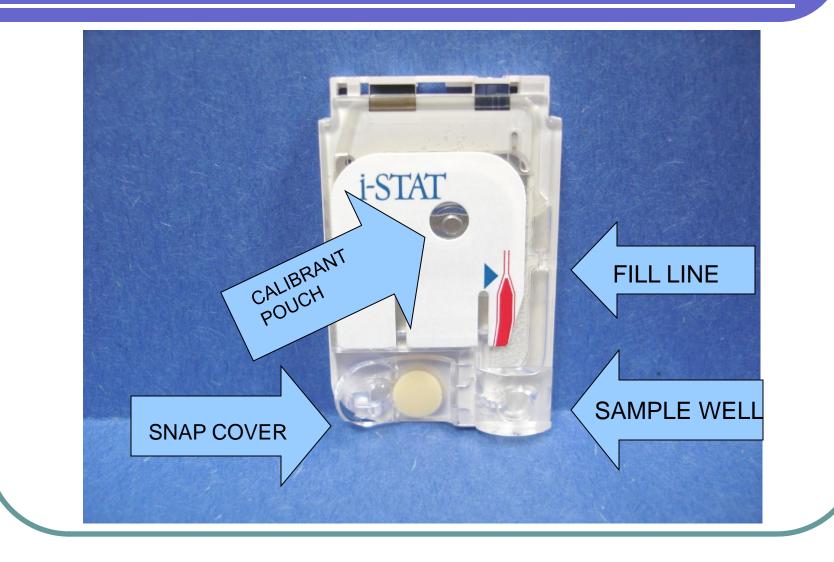
before performing testing

Cartridge Handling

- Remove cartridge from pouch.
- Handle cartridge by its edges.

Avoid touching the contact pads or exerting pressure over the center of the cartridge.

Cartridge



Where to Get Cartridges

- i-STAT cartridges are stored in the refrigerator in the POC room on 3 West. Additional cartridges are kept in the laboratory located in the Microbiology department immediately to the right once you walk through the door.
- Document the number of boxes taken, the lot number, the expiration date, your initials. If the boxes are in the new lot/ new shipment area of the refrigerator, you will need to perform quality control on the cartridges before putting them into use.

i-STAT Quality Control

1. Internal simulator is set to run automatically every 8 hrs.

- 2. External simulator is run daily. It should also be run if the internal simulator fails, if the analyzer has been dropped, or if the analyzer displays: "Analyzer error/Use Electronic Simulator."
- Liquid controls are run on a monthly basis on the 1st Wednesday of the month. In addition to the monthly QC, controls must be run when there is a new lot/new shipment being put to use.

New lots/New Shipments:

Liquid QC must be done and within the acceptable range before putting the new lot/new shipment cartridges into use for patient testing.

If the QC fails, retest with a new cartridge and a new vial of control. DO NOT REPORT PATIENT RESULTS UNTIL QC IS WITHIN THE ACCEPTABLE RANGE. If QC fails the second time, contact the laboratory @ ext. 3630 and/or email the laboratory manager at semartin@partners.org and send the patient test out to Cambridge Health Alliance as STAT.

i-STAT Sample Requirements

Arterial:

- A heparinized syringe should be used at all times.
- Mix the syringe by rolling between the palms for at least 5 seconds in two directions, then invert the syringe repeatedly for at least 5 seconds.
- The CG4 cartridge should be tested within 10 minutes of collection time. Chem 8 cartridge should be tested within 30 minutes of collection time.
- If not tested immediately after mixing, remix and discard 2 drops of blood before filling the CG4 cartridge.
- Avoid drawing air into syringes for blood gas testing.
 - Do not use samples that were collected on ice.

i-STAT Sample Requirements

Venous:

Collection tube with lithium heparin filled to capacity and mixed by gentle inversion at least 10 times. Test within 10 minutes.

Lactates are only to be collected venously and must be tested immediately.

CHEM 8+ Cartridges

Requires the use of:

 Heparinized whole blood collected in balanced heparin syringes

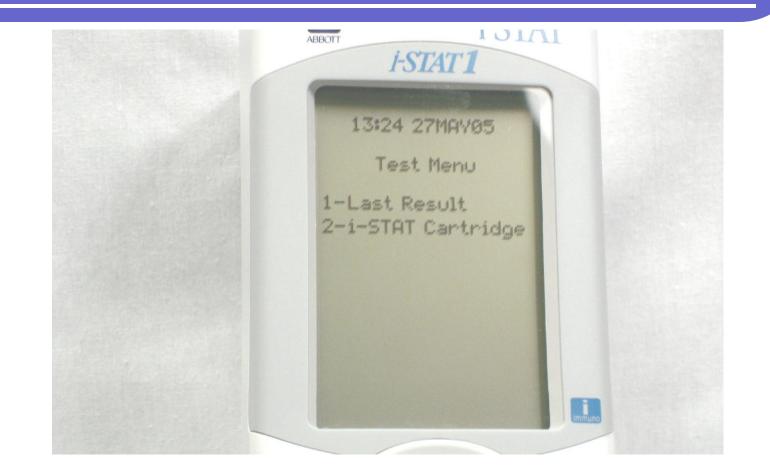
OR

 Heparinized whole blood collected in evacuated tubes containing lithium heparin, as long as the tubes are filled to capacity

Troponin I Sample Requirements

- Fresh whole blood collected in a collection tube with lithium heparin
- Fresh whole blood collected in a heparinized blood gas syringe
- Collection tubes should be filled to capacity

i-STAT Test Menu



i-STAT Testing

- 1. Turn analyzer on by pressing the on/off key
- 2. Test Menu: select 2 for i-STAT Cartridge
- 3. Scan or Enter Operator ID. (4 digits in length)
- 4. Enter Patient ID. (6 digit medical record number). Repeat entry.
- 5. Enter cartridge lot# by scanning barcode on cartridge package. Place analyzer on a flat surface and do not move during testing.
- 6. Remove cartridge from pouch. *Handle a cartridge by its edges. Avoid touching contact pads or exerting pressure over center of cartridge.*
- 7. Thoroughly mix sample and dispense sample until it reaches the fill mark on the cartridge (blue arrow).
- 8. Close cartridge by pressing on outside edge of door until it snaps in place. For Troponin I cartridges, there is a sliding lever that should be pushed gently to the right in order to close the cartridge.
- 9. Insert cartridge into cartridge port.
- 10. Enter sample type when prompted.
- 11. View patient results. You may print the results as well.
- 12. Dock the iSTAT in the downloader so the results can go into Meditech.
- 13. After notifying the MD of the results, put in the results of the Allen's test, patient temperature, etc. as needed and verify the test in Meditech and comment which provider was notified of the results.

TEST AND RESULT FLAGS

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- Results are not reportable due to sensor errors or interfering substances
- Repeat test with new cartridge.
- If results are flagged again, draw a fresh sample and retest.

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• Results that are less than or greater than the reportable range or dependant on results that are outside the reportable range.

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 If results appear with a bold arrow pointing up or down, the results are above or below the critical value range.

Troubleshooting

Error Code/Description

- 128: Invalid sample type
- 130: Air bubble detected in sample
- 131: Under-filled cartridge
- 140: Expired cartridge lot
- 141: Barcode not scanned
- 146: Overfilled cartridge

Message/Action

Battery Low: Replace or charge Batteries

Upload Required: Place analyzer in downloader

Cartridge Preburst: Use another cartridge. Do not press on center of cartridge

Unable to Position Sample: Cartridge notsealed or sample clotted. Use another cartridge

Analyzer Error/Use electronic simulator: Run electronic simulator.

Cartridge Error: Use another cartridge.

Testing Quality Control for CG4

- QC for the CG4 (blood gas + lactate) cartridge has 3 levels of controls. Record your results on the QC form located in your QC binder. All results should be within the acceptable ranges as written on your QC form.
- To perform QC for the CG4 cartridge, take out:
 - 2 vials of level 1 Note: You need 2 since you will be testing both iSTATs
 - 2 vials of level 2
 - 2 vials of level 3
- Let the vials warm up to room temperature for 4 hours.
- When vials have equilibrated to room temperature, turn the iSTAT handheld on and press "MENU"
- Press "3" for Quality Tests.
- Press "1" for Control.
- Press "1" for iSTAT cartridge
- Enter your operator ID.
- Enter/scan the control lot number.
- Scan the lot number on the cartridge pouch.
- Immediately before use, shake the vial vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the vial.
- Protect fingers with gauze, tissue, or glove, or use an vial breaker to snap off the tip of the ampule at the neck.
- Immediately fill the cartridge with the control and close the snap cover.
- Insert the cartridge into the cartridge port.
- View results on handheld's display and record the results on the QC form. Check to make sure the results are acceptable.
- Remove and discard cartridge when Cartridge Locked message disappears.

Press "1" for Test Options on the results page and press "1" for Next Level. Proceed to test levels 2 and 3

Testing QC for CHEM 8+

- QC for the CHEM8+ cartridge has 2 levels of controls. Record your results on the QC form located in your QC binder. All results should be within the acceptable ranges as written on your QC form.
- To perform QC for the CHEM8+ cartridge, take out:
 - 1 vial of level 1
 - 1 vial of level 3
- Let the vials warm up to room temperature for 30 minutes.
- When vials have equilibrated to room temperature, turn the iSTAT handheld on and press "MENU"
- Press "3" for Quality Tests.
- Press "1" for Control.
- Press "1" for iSTAT cartridge
- Enter your operator ID.
- Enter/scan the control lot number.
- Scan the lot number on the cartridge pouch.
- Immediately before use, shake the vial vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the
 ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip
 of the ampule to send solution back into the bottom section of the vial.
- Protect fingers with gauze, tissue, or glove, or use an vial breaker to snap off the tip of the ampule at the neck.
- Immediately fill the cartridge with the control and close the snap cover.
- Insert the cartridge into the cartridge port.
- View results on handheld's display and record the results on the QC form. Check to make sure the results are acceptable.
- Remove and discard cartridge when Cartridge Locked message disappears.
- Press "1" for Test Options on the results page and press "1" for Next Level. Proceed to test the remaining levels.

Testing QC for Troponin I

- QC for the Troponin I cartridge has 3 levels of controls. Record your results on the QC form located in your QC binder. All results should be within the acceptable ranges as written on your QC form.
- To perform QC for the Troponin I cartridge, take out:
 - 1 vial of level 1
 - 1 vial of level 2
 - 1 vial of level 3
- Let the vials warm up to room temperature for at least15 minutes.
- When vials have equilibrated to room temperature, turn the iSTAT handheld on and press "MENU"
- Press "3" for Quality Tests.
- Press "1" for Control.
- Press "1" for iSTAT cartridge
- Enter your operator ID.
- Enter/scan the control lot number.
- Scan the lot number on the cartridge pouch.
- Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.
- Immediately fill the cartridge with the control using the dropper tip and close the snap cover.
- Insert the cartridge into the cartridge port. Tightly recap the control vial and store it at 2-8°C. Once opened the control is good for 30 days when stored properly. Be sure to write the open date and expiration date on each vial.
- View results on handheld's display and record the results on the QC form. Check to make sure the results are acceptable.
- Remove and discard cartridge when Cartridge Locked message disappears.
- Press "1" for Test Options on the results page and press "1" for Next Level. Proceed to test the remaining levels.

Cleaning the Handheld and Downloader

 You may clean the iSTAT handheld and or downloader with the purple top PDI Super Sani-Cloths as needed.

Lab Hints for Chem8+ Testing

- Potassium and glucose are stored inside red blood cells so if the specimen is hemolyzed, the blood cells have been broken up → releasing the potassium and glucose so then these results will be falsely elevated.
- Potassium is also used as part of an anticoagulant in the purple top EDTA tube so if you use the purple top to do a Chem8+ → then the patient's potassium level will be falsely elevated. So if you are getting a critically high potassium level – ask yourself "Was the blood drawn in a purple top tube?" If it was, reject the specimen and recollect the sample in the lithium heparin (green) tube.
- Hemoglobin and Hematocrit follows the Rule of 3's HGB x 3 = HCT (+/-3)

Volume of blood that consists of red blood cells is the Hematocrit A protein molecule in red blood cells that carries oxygen is called Hemoglobin

The iSTAT only measures the Hematocrit and then calculates for the Hemoglobin.

Lactate needs to be tested immediately for accurate results.