



Quick Reference Guide for the i-STAT[®] 1 Handheld and i-STAT Chemistry Cartridges

For use with a CLIA Certificate of Waiver

G

6+

EC4+

Crea

CHEM8+

E3+



Quick Reference Guide for the i-STAT® 1 Handheld and i-STAT Chemistry Cartridges

For use with a CLIA Certificate of Waiver

This Quick Reference Guide is for use with the following CLIA-waived i-STAT cartridges: **CHEM8+**, **6+**, **EC4+**, **E3+**, **Crea**, and **G**. These cartridges include various subsets of the following tests: sodium, potassium, chloride, total carbon dioxide, ionized calcium, glucose, urea nitrogen, creatinine and hematocrit.

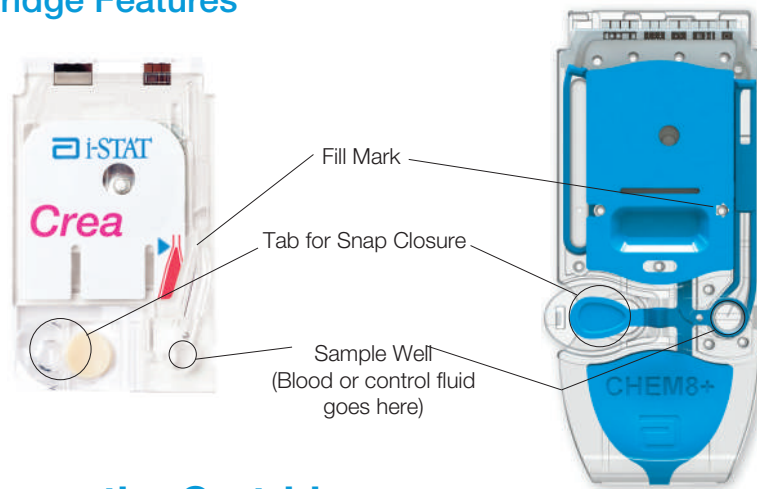
CLIA-waived status applies to testing performed on venous whole blood collected in tubes with lithium heparin anticoagulant only.

Your facility must have a CLIA Certificate of Waiver in order to perform waived tests, must meet all applicable state and local laboratory testing laws, and must follow the manufacturer's instructions.

You should read the complete test procedure before performing the test. See the i-STAT System Manual for Waived Tests for complete information.



Cartridge Features



Prepare the Cartridge

- **Individual Cartridge:** Must be at room temperature for at least **5 minutes** before using it.
- **Box of Cartridges:** Must be at room temperature for at least **1 hour** before using the cartridges.
- Do not remove the cartridge from the pouch until instructed to in the procedures.

To scan the barcoded cartridge lot number, position the barcode 3-9 inches from laser barcode scanner window on the handheld. Press and hold **SCAN** to activate the scanner. Align the red laser light so it covers the entire barcode. The handheld will beep when it reads the barcode successfully.



Scan the barcode.



Tear open pouch at notch.



Remove cartridge.
Always hold by sides.



Place on level surface.

Control Testing Procedure

Control Testing Frequency





- Test one cartridge from each lot in each shipment upon receipt.
- Test a single cartridge from the refrigerator monthly. Select cartridge in the following order:
CHEM8+, 6+, Crea, EC4+, Glucose, E3+

Prepare Control

- **Control Ampule:** Must be at room temperature for at least 30 minutes before using it.
- **CHEM8+ Cartridges:** use the TriControl Level 1 control.
- **6+ & Crea Cartridges:** use the i-STAT or TriControl Level 1 control.
- **EC4+, E3+, Glucose Cartridges:** use the i-STAT or TriControl Level 3 control.

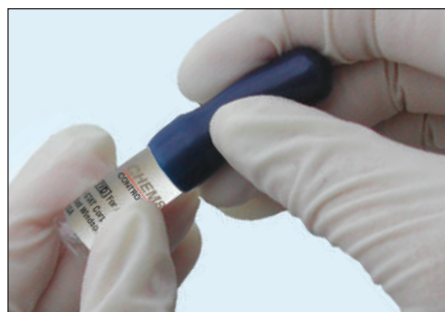


Test Control

1. Press  to turn on handheld.
2. Press  to change screen to Administration Menu.
3. Press  for the Quality Tests menu.
4. Press  for Control.
5. As prompted by the handheld, scan or manually enter the Operator ID and Control Lot number.
6. Scan the barcoded cartridge lot number.
7. Remove cartridge from pouch.
8. Shake the ampule hard for 10 seconds.
9. Break the ampule open. Use an ampule breaker or protect fingers by covering the ampule with gauze.



Shake ampule

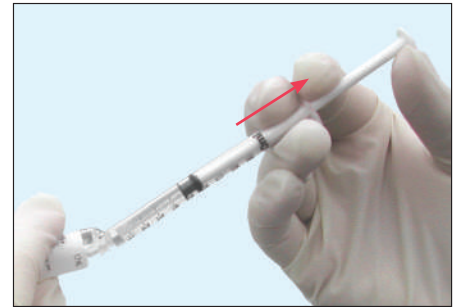


Break ampule

Continued

Control Testing Procedure - continued

- Withdraw the control fluid slowly into a 1 or 3 cc plain syringe until the syringe is half filled. Dispense 3 drops of control fluid onto a gauze pad.



Draw fluid

- Fill the cartridge with the control fluid. Fold the closure over the sample well until it snaps into place.



Fill cartridge



Fold closure



- Push cartridge into the handheld port until it clicks into place, and do not remove until the “DO NOT REMOVE CARTRIDGE – CARTRIDGE LOCKED” message is gone.

Review Results

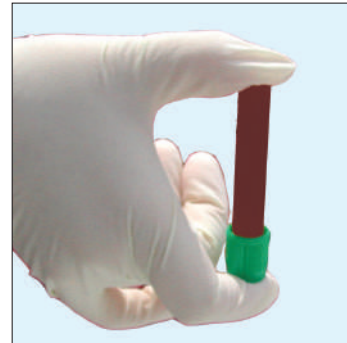
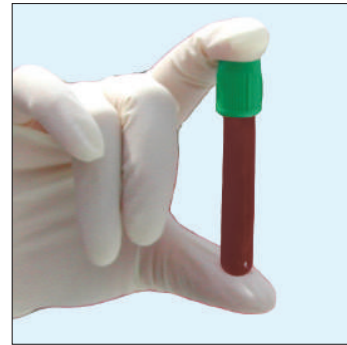
- Compare results on handheld to the Value Assignment Sheet.
- If any result is out of range, repeat the control testing with a fresh ampule and syringe.
- If any result is still out of range, do not use the cartridge lot, and call Technical Support at 800-284-0702, Option 1.

i-STAT® TriControls Level 1 Control			
LOT 301084			
Exp. 2017-12-31			
CLEW: A33			
CHEM8+		\bar{x} (Mean)	R (Range)
LOT H			
Na	mmol/L, mEq/L	122	118 - 126
K	mmol/L, mEq/L	2.9	2.6 - 3.2
Cl	mmol/L, mEq/L	72	67 - 76
iCa	mmol/L	0.84	0.76 - 0.92
	mg/dL	3.4	3.0 - 3.7
	mEq/L	1.7	1.5 - 1.8
TCO2	mmol/L, mEq/L	19	10 - 28
Glucose/Glu	mg/dL	264	222 - 306
	g/L	2.64	2.22 - 3.06
	mmol/L	14.7	12.3 - 17.0
Creatinine/Crea	mg/dL	3.5	2.7 - 4.3
	umol/L	309	239 - 380
BUN	mg/dL	55	48 - 63
Urea	mmol/L	19.6	17.1 - 22.5
	mg/dL	118	103 - 135
	g/L	1.18	1.03 - 1.35
HCT	K3EDTA %	17	14 - 20
	K2EDTA %	18	15 - 21



Patient Testing Procedure

Prepare the Sample

- Mix the sample tube by gently inverting it 2-3 times before filling a cartridge. Do not use a partially filled collection tube.
- **CHEM8+**: Test the sample within **10 minutes** after collecting it.
- **6+**, **EC4+**, **E3+**, **Crea**, and **G**: Test the sample within **30 minutes** after collecting it.

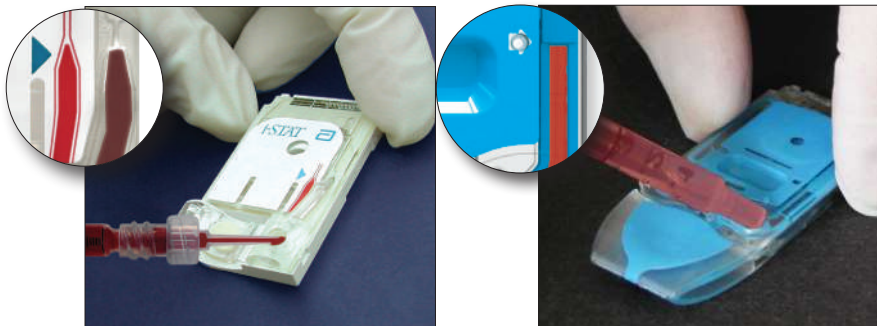


Test Sample

1. Press  to turn on handheld.
2. Press  (i-STAT Cartridge).
3. As prompted by the handheld, use number keys to enter the Operator ID and Patient ID.
4. Scan the barcoded cartridge lot number.
5. Remove cartridge from pouch.
6. Use a sample transfer device to remove some sample from the tube. Dispense 3 drops of sample onto a gauze pad.
7. Hold the sample transfer device over the cartridge sample well.
8. Dispense sample until blood reaches the cartridge fill mark. Some blood must be left in the cartridge well.



Get sample

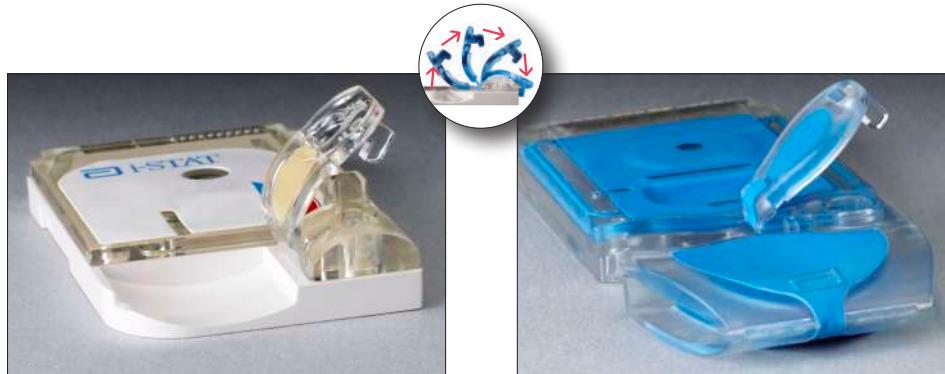


Fill cartridge

Continued

Patient Testing Procedure - continued

- Fold the snap closure over the sample well until it clicks into place. Press on the tab. Do not press directly over the sample well.



Fold closure

- Push the cartridge into the handheld port until it clicks into place. Do not remove the cartridge from the handheld until the “DO NOT REMOVE CARTRIDGE - CARTRIDGE LOCKED” message is gone. For Hct testing, the handheld should remain level until a result is obtained. A level surface includes running the handheld in the downloader/recharger.



Insert cartridge

- After reviewing results, discard gloves, tube, transfer device and cartridge in biohazard waste container.

Review Results

- View results on the handheld. Report results as per your facility policy.
- See *i-STAT 1 System Manual for Waived Tests* if the results are not displayed or if results are questioned.

Pt: 12345	
16:10 25JanYY	
i-STAT CHEM8+	
Na mmol/L	141
K mmol/L	4.2
Cl mmol/L	104
iCa mmol/L	1.22
TCO ₂ mmol/L	26
→ Page	

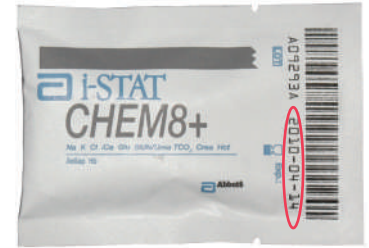
Pt: 12345	
16:10 25JanYY	
i-STAT CHEM8+	
Glu mg/dL	90
BUN mg/dL	17
Crea mg/dL	1.0
Hct %PCV	42
Hb g/dL	14.3
AnGap mmol/L	16
→ Page	

If all results are not displayed on the first screen, press → to page through all screens.

Cartridge and Control Storage

Cartridge Receipt

- Check the temperature strip included with each shipment.
Do not use the cartridges if the 3rd or 4th windows on the strip are colored.
Contact Technical Support at 800.284.0702, option 1.



Cartridge Storage

- Do not use the cartridges after the expiration date on the cartridge pouch and box.
- **Refrigerated Storage:** 2-8 °C (35 to 46 °F)
- **Room Temperature Storage:** Follow instructions on the cartridge pouch and box.

Control Storage

- Do not use controls after the expiration date on the labeling.
- **Refrigerated Storage:** 2-8 °C (35 to 46 °F)
- **Room Temperature Storage:** 18-30 °C (64 to 86 °F) for up to 5 days.



Precautions

Potential Sources of Harm to the Operator	To protect yourself and others from infection, use standard precautions as defined by your organization or by the Occupational Safety and Health Administration (OSHA).
	A falling or dropped handheld: place handheld and peripherals on a stable surface.
	Barcode scanner: do not look into laser beam coming from scanner, or point into eyes of someone else.

i-STAT is a registered trademark of the Abbott Group of Companies in various jurisdictions.
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