Testing Procedures for i-STAT G and Crea Cartridges

These testing procedures are for use with the following CLIA-waived i-STAT cartridges: **Crea**, and **G**. These cartridges include the following tests: glucose and creatinine. Testing can be performed at the patient's bedside.

The glucose cartridge (**G**) quickly delivers a patient's diagnostic blood glucose level. The creatinine cartridge (**Crea**) is used to assess a patient's renal function.

Contents

Contact Information

To place an order for cartridges, supplies or equipment, contact Abbott Point of Care Inc. at 800-284-0702 – Option 2, or order through your distributor.

Cartridges and controls are shipped Monday through Thursday and delivered within 24 hours.

For Technical Support: Phone: 800.284.0702, Option 1
Fax: 609.452.1905
e-mail: techsvc@apoc.abbott.com

Precautions

Potential Sources of Harm to the Operator	To protect yourself and others from infection: • Do not perform blood or control fluid testing in areas where food and drink are stored or consumed. • Use gloves and wash hands after handling blood or blood soiled items. • Do not use a cartridge if blood is spilled on it. Discard contaminated (blood-soiled) items in a biohazard waste container. • Decontaminate handheld if blood is spilled on it. See Start-up section of manual for instructions. • Since blood spots may not be noticeable on the handheld and since a cartridge could contaminate the inside of the handheld, treat the handheld as capable of transmitting infection. • Use universal 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.
	Needles: take care to prevent needle sticks. Use a blunt tipped device when transferring sample from a blood collection tube to a cartridge.
	Handheld and peripherals are not suitable for use in an oxygen enriched atmosphere.
Potential Sources of Damage to the Handheld	Trying to pull a cartridge out of the handheld while “Do Not Remove Cartridge - Cartridge Locked” message is displayed.
	Dropping the handheld.
	Getting the handheld wet. Do not place the handheld on a wet surface, or immerse it in water or other liquid.

Receipt and Storage of Cartridges & Controls

Required procedure for handling new cartridge or control shipments:

1. Open box marked “Refrigerate Upon Arrival”. Find card with temperature strip attached. Read strip immediately as it will change once it is exposed to room temperature. Follow instructions on card. If the reading is found to be unacceptable, contact Technical Support.
2. Record temperature reading on “Receipt of New Cartridges” log found in the System Resources section of this manual.
3. If temperature strip reading is acceptable, test cartridge(s) with liquid control. Take one cartridge from each lot number in the shipment and test with a control sample (See “Perform a Control Test” for instructions).

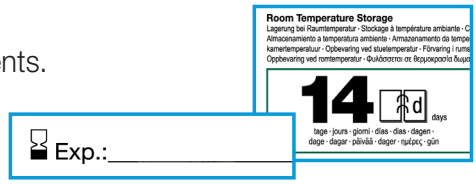
Required procedures for cartridge storage:

Refrigerated Storage

Store cartridges at 2 to 8 ˚C (35 to 46 ˚F).

- Refrigerated cartridges may be used until date shown on cartridge box and pack.
- It is recommended (but not required) that refrigerated storage be equipped with a 24-hour temperature monitor, and that the temperature record be reviewed each day.

Room Temperature Storage



- Refer to the cartridge box for room temperature storage requirements. When removing a cartridge box from refrigerated storage, calculate the appropriate room temperature expiration date and mark it on the box in the area provided.
- **If an individual cartridge is not used on the day it is removed from the refrigerator, use a soft felt pen to mark the room temperature expiration date on the pack, taking care not to puncture the pack.**
- Read date on pack label. Do not use cartridge if this date has passed.
- Do not return cartridges to refrigerator once they have been brought to room temperature.

Check Refrigerated Storage Conditions Monthly

- Check cartridges stored in the refrigerator monthly using the procedure described under “Perform a Control Test”. Record results on the “Monthly Cartridge Check” log found in the System Resources section of this manual.

Required procedures for control storage:

Refrigerated Storage

Store controls at 2 to 8 ˚C (35 to 46 ˚F) until expiration date on box or ampule labels.

Room Temperature Storage

Control ampules may be stored at room temperature (18 to 30 ˚C or 64 to 86 ˚F) for up to 5 days. Do not use after expiration date on box or ampule labels. Do not return controls to refrigerator once they have been brought to room temperature.

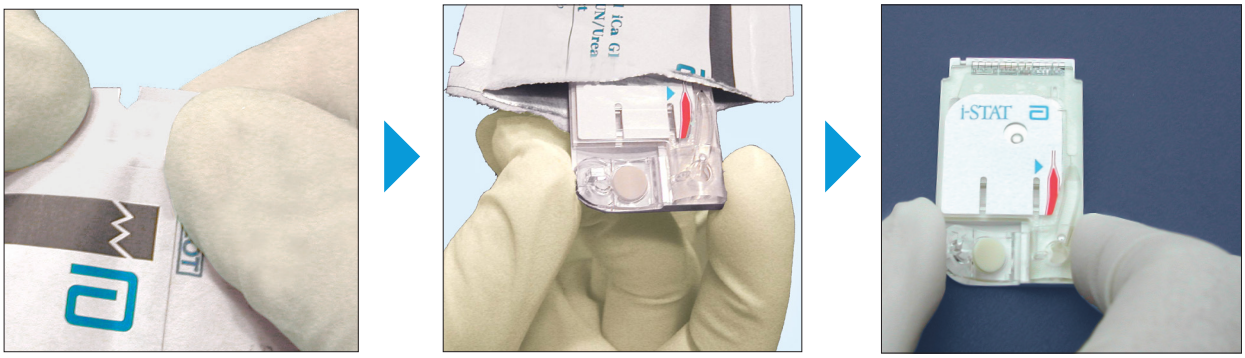
Using a Cartridge for Patient or Control Tests

- Prior to using a cartridge, it must be removed from refrigerated storage and **kept at room temperature in its protective pouch for at least 5 minutes**. An entire box of cartridges must be kept at room temperature for 1 hour before a cartridge is used.

- A cartridge must be used immediately after removing it from its protective pouch. Do not remove it until you reach the appropriate step in the patient or control testing process.

Removing a Cartridge from the Protective Pouch

Note: Do not open cartridge pouch until instructed to do so in the procedures.

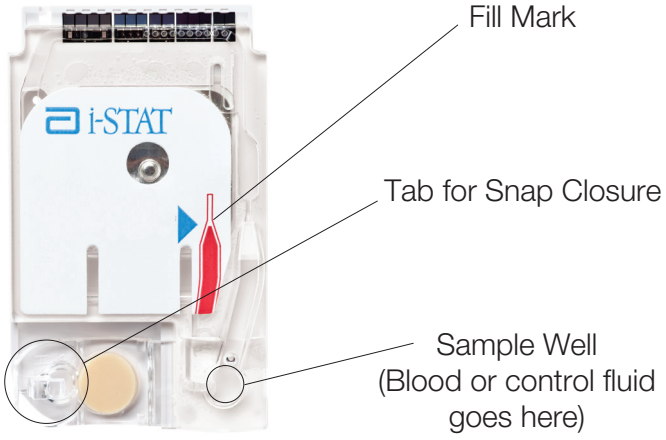


Tear open cartridge pouch at notch.

Remove cartridge from pouch. Always hold by sides.

Place on level surface.

Cartridge Features



Art: 725592-00N, Rev. Date: 19-FEB-2020

Perform a Patient Test

Acceptable Sample Types

- Venous whole blood samples collected in evacuated tubes with lithium heparin anticoagulant (green top tube). Tubes with gel for separation of cells and plasma are acceptable
- Fill tubes to capacity. Do not use tubes designed not to fill completely.

Sample Collection and Handling

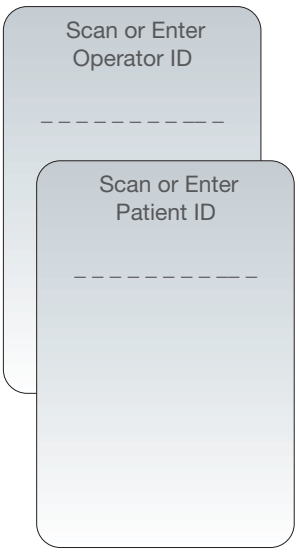
Correct sample collection & handling are important for accurate results!

- Ensure that the individual collecting sample is trained on proper blood collection techniques.
- Test samples within 30 minutes of collection.
- If the sample is not tested immediately, label the tube with the patient's name and another identifier.

Prior to Testing

- If your facility requires that you enter an operator ID and/or a patient ID, have these ready before beginning the test.
  - If your facility does not require this information, you can bypass these entries by pressing ENT.
- Be prepared to complete the entire test without interruption to avoid inaccurate results or error codes.

Prepare the Handheld



1. Press ⏻ to turn on handheld.
2. Press 2 for i-STAT Cartridge.
3. Follow handheld prompts:

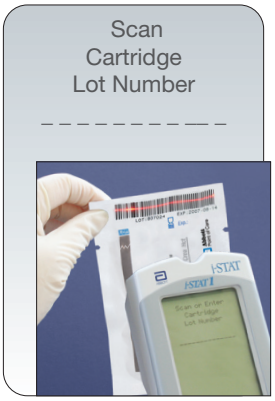
   Note: You may be prompted to repeat ID entries, so pay careful attention to the prompt. If you make a mistake, press left arrow key to clear entry.

   a. Scan or manually enter your operator ID as prompted.

      Press ENT (or press the ENT button to bypass this prompt).

   b. Scan or manually enter the patient ID as prompted.

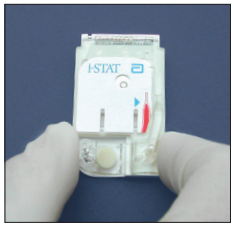
      Press ENT (or press the ENT button to bypass this prompt).



c. Scan the lot number on the cartridge pouch.

Position barcode 3-9 inches from scanner window on the handheld. Press and hold SCAN to activate the scanner. Align the red laser light so it covers the entire barcode as shown in the photo (left). The handheld will beep when it reads the barcode successfully.

Prepare to Test

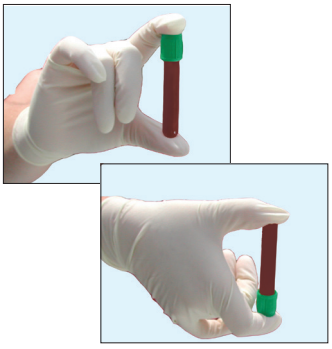


1. Find a level, stable surface to perform the test. A level surface includes running the handheld in the downloader/recharger.
2. Remove the cartridge from its pouch and place on a flat surface.

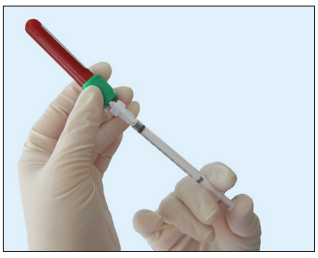
   Only touch the cartridge by its sides to avoid damage or contamination.
3. Put on disposable gloves.

Prepare the Blood Sample

Note: The illustrations and instructions below are for the use of a syringe with a blunt needle to transfer the sample from the tube to the cartridge. Other transfer devices may also be used.



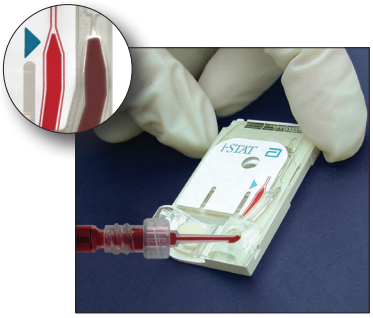
1. Mix the blood sample.
   Gently invert the green top tube 2 to 3 times.
2. Fill syringe about halfway with the blood sample.
   a. Invert the tube and push syringe tip through the green stopper into the blood sample.
   b. Slowly pull back on the syringe plunger to draw blood into the syringe until it is about half full.
3. Expel air from the syringe tip.
   a. Place enough gauze pads on the counter to absorb a few drops of blood.
   b. Hold syringe over gauze without touching it.
   c. Press syringe plunger until you see 3 drops of blood empty from the syringe onto the gauze.



4. Look for any air bubbles in the blood sample.

   If you see any air bubbles in the sample, discard this syringe and sample and repeat the test beginning with warming a new cartridge and withdrawing a new sample from the green top tube. An air bubble stuck on the plunger is OK and will not affect results.

Fill the Cartridge



5. Fill cartridge with sample to the fill mark.

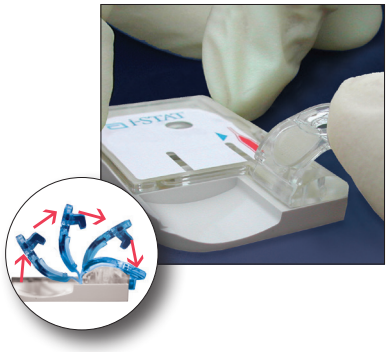
   a. Place the tip of the syringe or other transfer device over the cartridge sample well.

   b. Press plunger so that sample enters cartridge until it reaches the fill mark.

   c. Confirm that there is sample in the sample well. If you do not see sample in the sample well, continue to press the plunger to deliver more sample. Do not wipe off excess sample from the cartridge.

Note: Grossly over or under filling cartridge may cause an error code requiring you to repeat the test.

Seal the Cartridge



6. Seal the cartridge.

   a. Touching only the plastic tab and the sides of the cartridge, fold the snap closure over the sample well. Do not press directly over the sample well.

   b. Press the tab until it clicks into place. Slightly lift finger or thumb and ensure cartridge is closed before completely removing the finger or thumb from the closure.

Insert the Cartridge

7. Push the sealed cartridge into the handheld port until it clicks into place.

   a. To avoid permanent damage to the handheld, do not remove cartridge until testing process is complete.

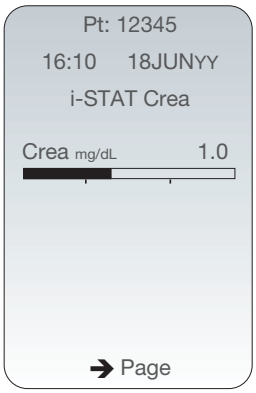
   b. Wait about 2 to 3 minutes for the test to complete.

Review Results

- The handheld shows the test results by test name, test units, and the numerical values and units with the results. It also shows bar graphs with tic marks for reference ranges.

  See “Test Ranges” section for a list of reportable (measurement) ranges and reference (normal) ranges.

  Note: If handheld turns off before review of results is complete, press ⏻ to turn it on, then press 1 for Last Result.



Flagged results:

- If stars (***) are displayed instead of a result, it means that a test failed internal quality checks. All reported results are accurate as long as the sample integrity is not in question. Remix tube of blood and repeat test using a fresh cartridge. If result is not displayed again, draw a fresh blood sample and repeat test. If result is still not displayed, call Technical Support.
- “<” is shown in front of the lowest reportable value when the result is lower than this value. See “Test Ranges” for reportable ranges.
- “>” is shown in front of the highest reportable value when the result is higher than this value.
- “< >” is shown in place of a result if the result is dependent on another result that is flagged with either the < or > symbol.

Quality Checks:

Quality checks are automatically performed during each test. If a quality check fails, the handheld stops the test and shows a cause and action to be followed. A complete list of Quality Checks is in the System Resources section of this manual. Record the quality check failure in the Quality Check Codes log found in the System Resources section of this manual.

⚠ Precautions

Potential Sources of Error in Patient Results	Cartridge stored incorrectly.
	Improper sample collection and/or sample handling: • Testing samples other than fresh whole blood samples collected in tubes with lithium heparin anticoagulant. • Using tubes not filled to capacity. Any deviations will cause inaccurate results.
	Use of expired cartridges.
	See “Factors that Affect Results” for additional information.

Test Ranges:

- Reportable Range is the lowest to highest values the test system will report.
- Reference Range is the normal values for an adult population. Reference ranges may vary according to age, gender and heritage.
- Critical Values indicate that a patient may need treatment right away if results are at or below the low value, or at or above the high value. Ask your clinician to record critical values on the Test Range table below.

Test	Test Symbol	Units	Reportable Range	Reference Range	Critical Values Low	Critical Values High
Glucose	Glu	mg/dL	20–700	70–105	_____	_____
Creatinine	Crea	mg/dL	0.2–20.0	0.6–1.3	_____	_____

Record and Report Results

1. Record results according to your facility's procedure.

   Note: If handheld is customized to print reference ranges along with results, results must be printed before handheld turns off.

2. Report results to physician as required.

   If physician questions a result, check "Factors that Affect Results" at the end of this section. If an interfering substance is suspected, send a sample to a commercial or hospital laboratory. If not, remix and retest the sample if it was drawn within the acceptable time limit. Otherwise, obtain a new sample and repeat the test. If the result is still questionable, contact Technical Support.

3. Press  for one second to turn handheld off. If not done already, cartridge may be removed and discarded with syringe, gauze and gloves in biohazard container. Wash hands.

Perform a Control Test

When to Do This

- Upon receipt of each shipment, test one cartridge from each lot.
- Monthly, test one cartridge from refrigerated storage. Select this cartridge in the following order:
  - Crea
  - G

Materials

- i-STAT 1 handheld
- Selected cartridge
- Correct liquid control in glass ampule

For this cartridge:	Use this control:
Crea	i-STAT or TriControls Level 1 Control
G	i-STAT or TriControls Level 3 Control

- 1 cc syringe
- Value assignment sheet - available at www.pointofcare.abbott.

  Note: If your facility does not have internet access, paper copies may be obtained from Technical Support.
- Control log sheet
- Gauze or ampule breaker
- Container for broken glass disposal

Prior to Testing

Allow these materials to reach room temperature before beginning the test:

- Liquid Control
  - Remove the control glass ampule from refrigerated storage at least 30 minutes before beginning test.
- Select Cartridge
  - Remove one unopened cartridge from refrigerated storage at least 5 minutes before beginning test.

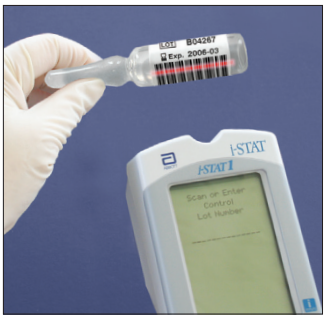
Prepare the Handheld

1. Press ⏻ to turn on handheld.
2. Press MENU .
3. Press 3 for the Quality Tests Menu.
4. Press 1 for Control.
5. Follow handheld prompts:

   Note: If you make a mistake, press left arrow key to clear entry.

   a. Scan or manually enter your operator ID as prompted.

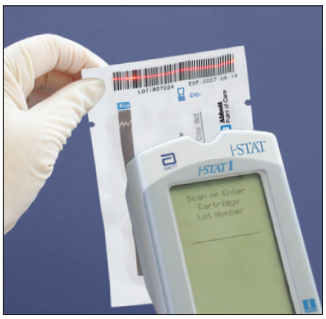
      Press ENT (or press ENT button to bypass this prompt).



   b. Scan the barcode from the control box or ampule.

      Position barcode 3-9 inches from scanner window on the handheld. Press and hold SCAN to activate the scanner. Align the red laser light so it covers the entire barcode as shown in photo (left). The handheld will beep when it reads the barcode successfully.

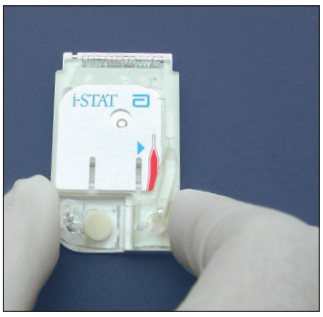
      The control lot number on the ampule can also be entered manually. Use the keypad, ignoring any letters in the lot number, and press ENT .



   c. Scan the lot number on the cartridge pouch.

      Position barcode 3-9 inches from scanner window on the handheld. Press and hold SCAN to activate the scanner. Align the red laser light so it covers the entire barcode as shown in photo (left). The handheld will beep when it reads the barcode successfully.

Prepare to Test



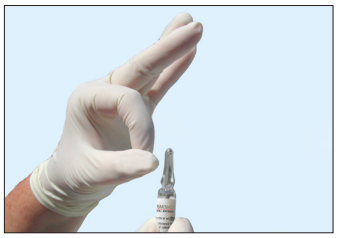
1. Find a stable surface to perform the test.
2. Remove the cartridge from its pouch and place on a level surface. A level surface includes running the handheld in the downloader/recharger.

   Only touch the cartridge by its sides to avoid damage or contamination.
3. Put on disposable gloves.

Prepare the Control Sample

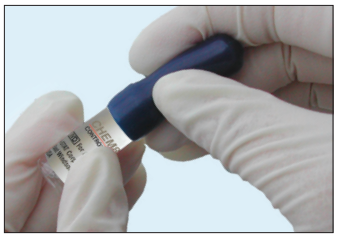
1. Shake the ampule.

   Hold the ampule between index finger and thumb.
   Shake vigorously for 10 seconds.



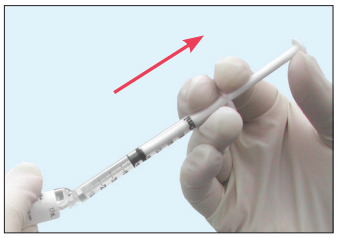
2. Tap the top of the ampule.

   This will cause all fluid to flow to the bottom of the ampule.



3. Break the ampule.

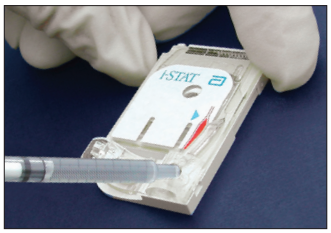
   Hold top of ampule with gauze or ampule breaker.
   Snap top off.



4. Fill the syringe halfway with liquid control.
   a. Tilt opened ampule so fluid flows close to opening.
   b. Position syringe tip into the fluid.
   c. Slowly pull back on syringe plunger to draw control into syringe until it is about half full.
5. Expel air from the syringe.
   a. Place a gauze pad on the counter.
   b. Press the syringe plunger until you see 3 drops of control empty from the syringe.
6. Look for any air bubbles in the control fluid.

   If you see any air bubbles in the control, then discard this syringe and control and repeat the test using a new control ampule, new cartridge and new syringe.

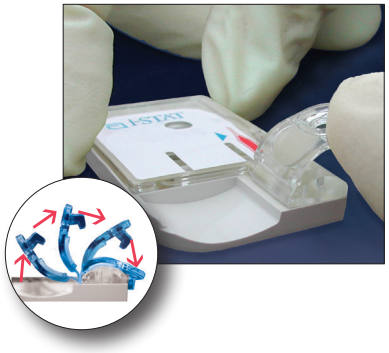
Fill the Cartridge



1. Fill cartridge with control to the fill mark.
   a. Place tip of the syringe over cartridge sample well.
   b. Press plunger so that control enters the cartridge until it reaches the fill mark.
   c. Confirm that there is control fluid in sample well. If you don't see control in sample well, continue to press plunger to deliver more control fluid. Do not wipe off excess sample from the cartridge.

Note: Grossly over or under filling cartridge may cause an error code requiring you to repeat the test.

Seal the Cartridge



1. Seal the cartridge.
   a. Touching only the plastic tab and sides of cartridge, fold snap closure over the sample well. Do not press directly over the sample well.
   b. Press the tab until it clicks into place. Slightly lift finger or thumb and ensure that the cartridge is closed before completely removing the finger or thumb from the closure.

Insert Cartridge

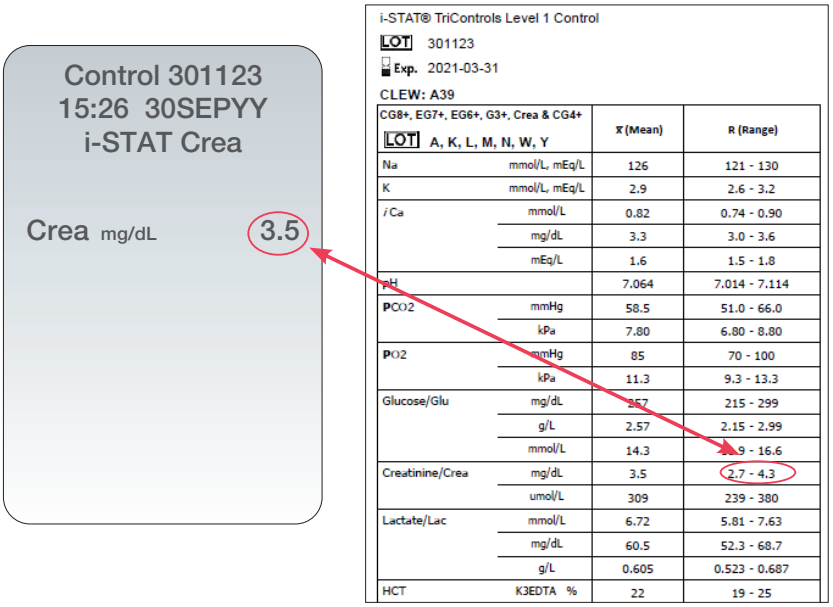
1. Push the sealed cartridge into the cartridge port until it clicks into place.
   a. To avoid permanent damage to the handheld, do not remove cartridge until the testing process is complete.
   b. Wait about 2 to 3 minutes for the test to complete.

Complete Testing Process

1. Pull out cartridge from handheld.
2. Turn off handheld by pressing ⏻ for one second.
3. Discard broken ampule in a container that is safe for broken glass.
4. Discard remaining test materials in biohazard container.

Review Results

Target values and ranges are printed on a Value Assignment Sheet (VAS) posted on the APOC website at www.pointofcare.abbott. If your facility does not have internet access, paper copies of the VAS may be obtained from Technical Support. Control test results are shown in numerical values. For details on how to review control results, see Logs in the System Resources section of this manual.



i-STAT® TriControls Level 1 Control

LOT 301123

Exp. 2021-03-31

CLEW: A39

CG8+, EG7+, EG6+, G3+, Crea & CG4+ LOT A, K, L, M, N, W, Y		x̄ (Mean)	R (Range)
Na	mmol/L, mEq/L	126	121 - 130
K	mmol/L, mEq/L	2.9	2.6 - 3.2
iCa	mmol/L	0.82	0.74 - 0.90
	mg/dL	3.3	3.0 - 3.6
	mEq/L	1.6	1.5 - 1.8
pH		7.064	7.014 - 7.114
PCO2	mmHg	58.5	51.0 - 66.0
	kPa	7.80	6.80 - 8.80
PO2	mmHg	85	70 - 100
	kPa	11.3	9.3 - 13.3
Glucose/Glu	mg/dL	257	215 - 299
	g/L	2.57	2.15 - 2.99
	mmol/L	14.3	[illegible] - 16.6
Creatinine/Crea	mg/dL	3.5	2.7 - 4.3
	umol/L	309	239 - 380
Lactate/Lac	mmol/L	6.72	5.81 - 7.63
	mg/dL	60.5	52.3 - 68.7
	g/L	0.605	0.523 - 0.687
HCT	K3EDTA %	22	19 - 25

If you see this:	Then:
All results are within the ranges on the Value Assignment sheet.	You can use the cartridges. Record results in control log sheet.
Any result is outside the range on the Value Assignment Sheet.	1. Record results. 2. Repeat test using a fresh ampule and syringe. 3. If any result is still outside the range, do not use the cartridges. 4. Call Technical Support at 800-284-0702, Option 1.

Troubleshooting

In addition to the quality checks that are automatically performed during each test, other situations may also occur which require operator action:

Problem	Action
BATTERY LOW message and battery icon flashing.	Change batteries.
Handheld will not turn on when a cartridge is inserted.	Change batteries
FAIL is displayed when a cartridge is inserted.	This is a failure of the internal Electronic Simulator. Use external Electronic Simulator to verify failure. See Start-up Section for procedure. If FAIL occurs again, contact Technical Support.

For assistance, contact Technical Support: 800.284.0702, Option1, or email: techsvc@apoc.abbott.com.

Factors that Affect Results

Interfering substances or other events may be encountered which can affect results. Read the summary below and refer to the Cartridge and Test Information (CTI) sheets at www.pointofcare.abbott for the most recent information.

Test	Factors that may Increase Results	Factors that may Decrease Results
Glucose (Glu)	pH above 7.4 Hydroxyurea **(use alternate method)** Acetaminophen	Acetylcysteine Bromide pH below 7.4 ***P***O_2 level <20mmHg Thiocyanate Delay in testing
Creatinine (Crea)	Acetaminophen Ascorbate Bromide ***P***CO_2: see note Creatine N-acetylcysteine Hydroxyurea **(use alternate method)**	***P***CO_2: see note
	Note: ***P***CO_2 values may affect creatinine results. If a creatinine result is in question and the presence of other interfering substances has been ruled out, refer to "Factors Affecting Results" in the Creatinine CTI sheet for further information.	

Components and Supplies

The following items are available from Abbott Point of Care Inc.

List Number	Description
06F20-20	**i-STAT 1 Analyzer (Handheld and Waived System Manual):** The handheld processes signals from cartridges, displays and stores results. Note: in clinical settings that demand fail-safe testing, a backup handheld or an alternate means of testing is recommended since a handheld can become inoperative due to dropping or damage due to mishandling.
06F20-03	**i-STAT 1 System Manual for Waived Tests:** Contains an overview of the i-STAT System and information required to prepare, use and maintain the handheld.
06F20-06	**i-STAT G and Crea Cartridge Quick Reference Guide:** Contains all the information required to receive and store cartridges and controls, and to perform patient and control tests. Included with order for System Manual.
06F21-26	**Handheld Batteries:** 6 lithium batteries per box. Two 9-volt lithium batteries will provide power for approximately 400 chemistry cartridges.
06F23-55	**Rechargeable Battery for the i-STAT 1 Handheld:** For use with the Downloader/Recharger. This is the only rechargeable battery that may be used with the i-STAT 1 handheld.
06F11-01	**Electronic Simulator:** One per site recommended. Used to verify internal Electronic Simulator failures and perform thermal probe check.
03P83-25	**i-STAT Glucose Cartridge:** 25 cartridges per box, for glucose test.
03P84-25	**i-STAT Creatinine Cartridge:** 25 cartridges per box, for creatinine test.

Components and Supplies (continued)

List Number	Description
06F12-01	**i-STAT Level 1 Control:** 10 single-use ampules per box. Used to check Creatinine cartridges when first received and for the monthly control check. Does not contain human serum or serum products.
05P71-01	**TriControls Level 1:** 10 single-use ampules per box. Used to check Creatinine cartridges when first received and for the monthly control check. Does not contain human serum or serum products.
06F14-01	**i-STAT Level 3 Control:** 10 single-use ampules per box. Used to check Glucose cartridges when first received and for the monthly control check. Does not contain human serum or serum products.
05P73-01	**TriControls Level 3 Control:** 10 single-use ampules per box. Used to check Glucose cartridges when first received and for the monthly control check. Does not contain human serum or serum products.
06F17-11	**Printer Paper:** 6 rolls per box. Approximately 175 printouts of cartridge test records per roll. For use with i-STAT and Martel Printers
06F21-35	Martel Printer rechargeable battery
04P74-04	**i-STAT Printer Kit:** contains the i-STAT printer, power supply with power cord, rechargeable printer battery, and paper.
04P74-03	i-STAT Printer rechargeable battery
04P73-04	**i-STAT 1 Downloader/Recharger:** contains the Downloader/Recharger, power supply, power cord, and cables to be used with the i-STAT 1 Downloader/Recharger. It is needed to perform software updates. Software updates require a PC with Windows 2000 or above. The Downloader/ Recharger allows the use of rechargeable batteries in the handheld.

New Operator Quiz

Name: _____

Check all that apply.

1. What should you do when you receive a new box of cartridges?
   - ☐ a. Read the temperature strip and record
   - ☐ b. Test one cartridge from each new lot with liquid control
   - ☐ c. Call Technical Support if the first window on the temperature strip is colored
   - ☐ d. Store cartridges in the refrigerator

2. How are cartridges stored?
   - ☐ a. In the refrigerator until the expiration date on the box and cartridge package
   - ☐ b. At room temperature until the expiration date on the box and cartridge package
   - ☐ c. At room temperature for the length of time indicated on the cartridge box but not exceeding the expiration date stamped on the box and cartridge package
   - ☐ d. For two weeks beyond the expiration date stamped on the box and cartridge package

3. How do you prepare a new or replacement handheld for use?
   - ☐ a. Install batteries
   - ☐ b. Check handheld time and date
   - ☐ c. Check handheld software and status
   - ☐ d. Customize

4. What should you do if the handheld displays “SIMULATOR FAIL”?
   - ☐ a. Continue to use the handheld
   - ☐ b. Record simulator result on log sheet
   - ☐ c. Insert the external Electronic Simulator into the handheld. If pass is displayed, continue to use the handheld
   - ☐ d. Call Technical Support if FAIL is displayed again

5. How do you know when it is time to change the batteries?
   - ☐ a. The “BATTERY LOW” message will be displayed when handheld is turned on
   - ☐ b. A battery icon will flash on the Test and Administration menus and the result screen
   - ☐ c. The “DEAD BATTERIES” message will be displayed
   - ☐ d. The handheld will not activate when the On/Off key is pressed or a cartridge or simulator is inserted

Check all correct answers.

6. What can damage the handheld?
   - ☐ a. Testing a urine sample
   - ☐ b. Attempting to remove a cartridge before the “Do Not Remove Cartridge - Cartridge Locked” message is removed or results are displayed
   - ☐ c. Using the handheld when the “BATTERY LOW” message is displayed
   - ☐ d. Dropping the handheld

7. It is important not to touch or press . . .
   - ☐ a. The gold contact pads at the top of the cartridge
   - ☐ b. The sides of the cartridge
   - ☐ c. The center of the cartridge
   - ☐ d. Directly over the sample well of the cartridge

8. What should you do if the result does not appear to reflect the patient’s condition?
   - ☐ a. Act on the result immediately
   - ☐ b. Draw a fresh sample and repeat the test

9. When do you need to check and/or change the clock in the handheld?
   - ☐ a. When a new or replacement handheld is received
   - ☐ b. When the batteries are changed
   - ☐ c. Following an Electronic Simulator failure
   - ☐ d. If necessary at the start and end of Daylight Savings Time

10. If you need to test a control sample, how do you know that the results are okay?
    - ☐ a. The handheld will display “PASS”
    - ☐ b. Results reflect those from a normal patient
    - ☐ c. Results are within the ranges in the Value Assignment Sheet
    - ☐ d. Results are exactly the same as you received last time

Check all correct answers.

Glucose and Creatinine Cartridges

1. The proper sample type is?
   - ☐ a. A full purple top tube (EDTA anticoagulant)
   - ☐ b. A green top tube at least half full (lithium heparin anticoagulant)
   - ☐ c. A full green top tube (lithium heparin anticoagulant)
   - ☐ d. A urine sample

2. The sample should be tested within . . .
   - ☐ a. 10 minutes of sample collection
   - ☐ b. 30 minutes of sample collection
   - ☐ c. 60 minutes of sample collection
   - ☐ d. 4 hours after sample collection

Evaluation

For: _____ Date: _____

1. User demonstrated the procedures required to put a new handheld into use.
   - ☐ With ease
   - ☐ With help
   - ☐ With difficulty
   - ☐ Not applicable

2. A patient sample was tested properly.
   - ☐ With ease
   - ☐ With help
   - ☐ With difficulty
   - ☐ Not applicable

3. The user understands what to do when ***, < or > , or a quality check message is displayed.
   - ☐ With ease
   - ☐ With help
   - ☐ With difficulty
   - ☐ Not applicable

4. The external Electronic Simulator was used properly.
   - ☐ With ease
   - ☐ With help
   - ☐ With difficulty
   - ☐ Not applicable

5. A control sample was tested properly.
   - ☐ With ease
   - ☐ With help
   - ☐ With difficulty
   - ☐ Not applicable

☐ It is my assessment that this user is competent to use the i-STAT System.

☐ It is my assessment that this user needs more practice before using the i-STAT System.

Signature: _____ Title: _____

Answers for New Operator Quiz

The following boxes should be checked:

1. a, b, d
2. a, c
3. a, b, c, d
4. b, c, d
5. a, b, c, d
6. b, d
7. a, c, d
8. b
9. a, d
10. c

Glucose and Creatinine Cartridges

1. c
2. b