CGP210

National Ambulance

Policy and Procedure for Point of Care Testing (POCT)

LINK TO POLICY

LINK TO PROCEDURES & FORMS

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1. POLICY INTRODUCTION

Point of care testing (POCT) is a medical test performed outside the normal laboratory, at or near the site of patient care. The driving principle behind POCT is to bring the test conveniently and immediately to the patient in order to generate a result quickly so that appropriate treatment can be implemented.

There are advantages with POCT compared with conventional laboratory testing. For example, results are available more quickly as time is not lost by transporting samples to the laboratory. This can be vital when managing critically ill patients.

The results from the POCT shall be used only as a guide, and the confirmation of the test should be conducted by a certified and accredited clinical staff.

2. SCOPE

This policy seeks to ensure that all patients subjected to POCT receive the same high standard of care, and to reduce to a minimum the risk to patients from POCT.

3. ROLES AND RESPONSIBILITIES

Chief Administrative & Medical Officer (CAMO)/Delegate is responsible for the development of this Policy and Procedure, review and revision, and any Performance Indicators. The CAMO/delegate is also responsible for developing training to support this Policy and Procedure.

The Chief Operations Officer is responsible for the implementation and monitoring of this Policy and Procedure.

All Operation Managers are responsible for ensuring that staff have induction in alignment with this Policy and Procedure, for monitoring the applicability and ongoing implementation as well as raising any issues with the CAMO and reporting any incidents or near misses through the QHSE system.

National ambulance clinical staff must read, understand and act in accordance with this policy and procedure. They are also responsible for ensuring that they attend or pursue any relevant training recommended by their supervisors. (I.e. eLearning and/or face to face training).

4. POLICY

The policy seeks to ensure that all areas performing POCT:

- Follow best practice in all aspects of the procedures undertaken.
- Adhere to uniform standards across all NA sites.
- Apply the principles of quality management and continuous improvement.
- Comply with all DOH/MOH standards and demonstrate compliance.

National Ambulance clinical staff must be fully aware of the special consent considerations that may be required and ensure they have knowledge of other related Policies and Procedures such as:

- CGP 103 Patient Rights and Responsibilities Policy and Charter
- CGP 105 Patients Consent Policy and Procedure
- CGP 108 Clinical Policy (which lists all Clinical Services policies)
- CGP 110 Patient Assessment/Reassessment & Triage
- CGP 112 Clinical Policy for High Risk Patients
- CGP 116 The Policy and Procedure for the Transport of Special Patient Populations
- CGP 119 Policy & Procedure for Patient Care Record and Patient Care Documentation and Reporting
- CGP 134 Patient Care Protocol
- CGP 141 Care of Paediatric Patients Policy and Procedure
- OPP 116 HEMS Standard Operating Procedures

5. Relevant Legislation

Code, Name of Legislation	Jurisdiction
JCI Accreditation Standards for Medical Transport Organizations, 2nd Edition, (MOI.4) DOH Medical Documentation Checklist	July 2015

6. PROCEDURE

6.1. POCT can be performed by a licensed and trained and competent NA clinician according to their scope of service and privileges and following CGP 134..

6.2. **POCT conducted shall be limited to:**

- Blood Glucose (during patient assessment). Please see attached ANNEX 1 for SOP.
- Blood gas analysis (only by ALS/Physician) at HEMS/MOPA contract.
- Electrolytes (only by ALS/Physician) at HEMS/MOPA contract.
- Full blood count/ Haemoglobin concentration (only by ALS/Physician) at HEMS/MOPA contract.
- Troponin (only by ALS/Physician) at HEMS/MOPA contract.

6.3. All POCT devices must have an SOP, which is subject to regular review and are available to and followed by all operators of the device. The SOP must be written to standards required by DOH/MOH.

6.4. All POCT equipment shall have a preventive maintenance schedule and/ or a service contract, with a logbook documenting operational details, faults, repairs or other corrective action.

6.5. The POCT results shall be documented in the Patient Clinical Record (PCR).

6.6. An IQC system shall be established and demonstrate quality control checks on every test performed and on each piece of testing equipment as recommended by the manufacturer. These checks should be recorded and accessible for review.

6.7. All waste generated, because of POCT shall be handled as biohazard waste and disposed according to CGP 129.

7. RELATED POLICIES AND FORMS

Policy & Procedure /Form
CGP 103 Patient Rights and Responsibilities Policy and Charter
CGP 105 Patients Consent Policy and Procedure
CGP 108 Clinical Policy (which lists all Clinical Services policies)
CGP 110 Patient Assessment/Reassessment & Triage
CGP 112 Clinical Policy for High Risk Patients
CGP 116 The Policy and Procedure for the Transport of Special Patient Populations
CGP 119 Policy & Procedure for Patient Care Record and Patient Care Documentation and Reporting
CGP 134 Patient Care Protocol
CGP 141 Care of Paediatric Patients Policy and Procedure

8. FEEDBACK

Any feedback or suggestions for improvement to this Policy, Processes or Procedures can be submitted to qhse@nationalambulance.ae

9. DOCUMENT CONTROL AND OWNERSHIP

A review and update of this document will take place as necessary, when changes occur that identify the need to revise this Policy such as changes in roles and responsibilities, release of new legislative or technical guidance, or identification of a new policy area.

This document ownership for editing is identified as:

Chief Administrative Medical Officer/Delegate

- **Change Brief**

Version No.	Date	Changes
1	5 November 2018	First Version
2	11 November 2019	Delete Directors and supervisors from the roles and responsibilities section Replace “Blood Sugar” with “Blood Glucose” Change ownership to Medical Director
3	December 2021	Due for Review Change Medical Director to Chief Administrative & Medical Officer Add MOPA to page 5 Delete “OPP116” from the related policies section Delete “Mikrozid wipes” from page 12 and page 32

Review & Approval: _____ Date: _____

Dr. Ayman Ahmad – Chief Administrative & Medical Officer

ANNEX 1

Standard Operating Procedure for Glucose Test

LINK TO POLICY

LINK TO PROCEDURES & FORMS

10. INTRODUCTION

Obtaining accurate blood glucose measurement is an essential part of the patient management. The standardization of monitoring blood glucose may vary slightly in technique widely due to the type of meter used to measure blood glucose. To minimize variability due to known exogenous factors we aim to adhere to the following procedures. The glucometer must not be used as a tool for diagnosing diabetes in patients who exhibit diabetic symptoms.

Glucose dehydrogenase within the test strip, in the presence of the coenzyme (PQQ), converts the glucose in the blood sample to gluconolactone. This reaction creates an electrical charge, which is proportional to the glucose concentration in the sample.

11. SCOPE

Patient blood is obtained using the lancet. A drop of blood is transferred to a test strip that has been inserted into the meter. If the sample area of the test strip has received sufficient sample a countdown will begin. During this countdown period the reaction takes place and concludes with a blood glucose result being displayed on the meter screen.

Blood glucose testing should only be performed by qualified staff. Any member of staff who has not received formal training must not perform this test. Follow this SOP at all times.

12. EQUIPMENT

- Roche ACCU-CHEK Performa Glucose Meter.
- Roche ACCU-CHEK Performa 2-Level Controls.
- Roche ACCU-CHEK Performa Glucose Test Strips.
- Roche Safe-T Pro Plus Lancets.

13. QUALITY ASSURANCE

13.1. All users are to perform internal quality control (calibration) before using the meter for the first time and under the following circumstances:

- Every two weeks for the glucometers used on a regular basis (active devices).
- Every month for the glucometers set as a backup.
- If the result does not agree with the clinical picture.
- After a battery has been changed.

- When a new vial of test strips is opened.
- If the cap is left off or has not been replaced correctly on the vial of test strips.
- If the meter is dropped or damaged.

13.2. In the event that a QC value is outside the manufacturer's stated range for that QC, the following procedure should be adhered to;

- Firstly, repeat the QC and ensure QC vigorously mixed before retest. If the value is still outside of the stated range open a new bottle of QC material. Always mark the side of a new QC bottle with a new expiry date 3 months from the current date. Perform the QC.
- If the QC is still out of range open a new box of test strips and repeat the fresh QC.
- If this does not produce a QC value within the manufacturer's stated range contact place in Quarantine, and complete Asset Fault Report.
- Quality control is to be recorded in the QC logbooks at the point of care site. One logbook is to be used per meter, with that meter's serial number recorded in the logbook. This document is a legal document and must be retained when full and in asset OPIQ.
- These logbooks have been provided by the point of care team and are subject to audit.

14. SAMPLE REQUIREMENTS

Venous, arterial or capillary blood can be used.

15. PROCEDURE

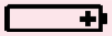
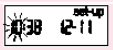
- Check the expiry date of the strips.
- Switch the meter on by holding down the on/off button or insert test strip. Check all figures in the display have no areas missing, especially the 888 figure. Release the On/Off button.
- Check that the code displayed matches the code on the vial of test strips you are using.
- Remove a test strip, replace the lid immediately (the lid contains a desiccant which preserves the integrity of the strips), and insert the test strip into the test strip slot.
- The test strip symbol stops flashing and a blood drop appears on the display.
- Clean the area for blood test. Use a gauze swab to thoroughly dry the area. Do not use cleaning wipes of any kind as they contain lanolin that interferes with the test. Alcohol

wipes should also be avoided as well as paper towels. Maintain barrier controls (gloves, masks, etc..).

- Use a lancet device to obtain a blood sample, promoting blood flow when necessary.
- Touch the droplet of blood obtained to the curved side of the strip and keep it in place until the yellow target area is entirely covered.
- An hourglass symbol will flash on the display until measurement is completed. The result is then displayed.
- Record the result immediately using the appropriate documentation. Remove and dispose of the test strip and any soiled materials.
- Meter will switch off automatically.

Specifications	
Blood volume	0.6 µL
Sample type	Capillary, Venous, Arterial and Neonate
Measuring time	5 seconds
Measurement range	10 – 600 mg/dL 0.6 – 33.3 mmol/l
Test strip storage conditions conditions	2 - 30 °C
System operating conditions conditions	8 – 44 °C
Relative humidity operating range operating range	10 - 90%
Meter storage conditions	Temperature: -25 – 70 °C
Memory capacity	500 blood glucose results and 20 control results with time and date with time and date
Automatic power off	2 minutes
Power supply	One 3-volt lithium battery (coin cell type CR2032)

16. LIST OF DIPLAY AND ERROR MESSAGES

Display	Action
The meter will not turn on or the display is blank.	▪ Battery is dead. Insert new battery. ▪ Display is damaged. Contact Roche. ▪ Meter is defective. Contact Roche. ▪ Extreme temperatures. Move the meter to a more temperate area.
	Battery power is low. Change the battery soon.
	The meter is in set-up mode, waiting for you to change or confirm settings.
	The meter is ready for you to insert a test strip.
	The meter is ready for a drop of blood or control solution.
HI	Blood glucose may be higher than the measurement range of the system. See Chapter 2, Unusual Blood Glucose Results.
LO	Blood glucose may be lower than the measurement range of the system. See Chapter 2, Unusual Blood Glucose Results.
E-1	The test strip may be damaged or not properly inserted. Remove the test strip and replace it with a new test strip.
E-3	Your blood glucose may be extremely high or a meter or a test strip error has occurred. • If your test result matches how you feel, contact your healthcare professional immediately. • If your test result does not match how you feel, repeat the blood glucose test. • If the E-3 code still appears for your blood glucose test, your blood glucose result may be extremely high and above the system's reading range. **Contact your healthcare professional immediately.** • If the second test result does not match how you feel, perform a control test with the control solution and a new test strip. • If the control result is within the acceptable range, review the proper testing procedure and repeat the blood glucose test with a new test strip. • If the control result is not within the acceptable range, see Chapter 4, Understanding Out-of-Range Control Results.
E-4	Not enough blood or control solution was drawn into the test strip for measurement or was applied after the test had started. Discard the test strip and repeat the blood glucose or control test.
E-6	Blood or control solution was applied to the test strip before the flashing drop symbol appeared on the display. Discard the test strip and repeat the blood glucose or control test.
E-7	An electronic error occurred, or in rare cases, a used test strip was removed and reinserted. Turn the meter off and on, or take the battery out for 20 seconds and reinsert it. Perform a blood glucose or control test.
E-8	The temperature is above or below the proper range for the system. Refer to the test strip package insert for system operating conditions. Move to an area with the appropriate conditions, wait 5 minutes, and repeat the blood glucose or control test. Do not artificially heat or cool the meter.
E-9	The battery is almost out of power. Change the battery now. If the message reappears after the battery has been replaced, remove the battery again, press any meter button, then reinsert the battery.
E-10	The time and date settings may be incorrect. Make sure the time and date are correct and adjust, if necessary.

17. CLEANING AND DECONTAMINATION OF EQUIPMENT

- Wipe the outside with non-alcohol wipes.
- Do Not use alcohol or another solvent to clean the glucometer.
- Do Not get any liquids, dirt, dust, blood, or control solution inside the glucometer through the test port or the data port.
- Never spray cleaning solution on the glucometer or immerse it in any liquid.
- Maintenance will not be performed on any equipment returned to the Point of Care Team without decontamination having first taken place as per CGP 129.

18. REPORTING

Quality Control (QC) results are recorded in the QC Logbook provided by Quarantine and the asset fault report and also OPIQ. Patient results are recorded in the PCR.

19. LIMITATIONS/UNCERTAINTY OF MEASUREMENT

- The meter will give results for glucose in the range of 70 – 130 mg/dL.
- The meter should only be operated within the temperature range of 6-44^{o}C.

20. COMPETENCY CHECKLIST

Name (First/Last) Staff ID;		Date	

COMPETENCY	Trainer Initials	Trainee Initials
Identifies meter components • Able to press power button and check status • Understands meter turns on when strip inserted into meter • Checks battery status and knows how to change battery		
Understands storage requirements of QC and test strips		
Demonstrates QC testing • Aware to write opening date on QC vials; • Discard 3 months after opening • Inverts vial to mix, wipes tip & discards first drop • Inserts strip into meter correctly • Waits for meter directions before applying QC solution • Applies solution to the front edge of the test strip • Explains corrective action when QC FAILS		
Demonstrates patient testing • Understands skin puncture process and supplies • knows acceptable sample types • Simulates patient testing/strip in meter before applying blood • Understands to discard first drop of blood and use second drop for testing • Explains critical values and follow up actions as per CGP 134 • Knows to document results immediately on patient chart to prevent errors		
Understands cleaning frequency & drying technique		
Passes CGP 134 Quiz. When to do a blood sugar assessment?		

Employee Signature:	Date:
Instructor Signature:	Date:

Pass: ☐ **Fail:** ☐ **Remediated:** ☐

ANNEX 2

Standard Operating Procedure for i-STAT

LINK TO POLICY

LINK TO PROCEDURES & FORMS

1. INTRODUCTION

Electrolytes are involved in most major metabolic functions in the body. Sodium, potassium and chloride are amongst the most important physiological ions and the most often assayed electrolytes. They are supplied primarily through diet, absorbed in the gastrointestinal tract, and excreted by the kidneys.

These testing procedures are for use with i-STAT cartridges CG8+ and CTnI. These cartridges include various subsets of the following tests: sodium, potassium, total carbon dioxide, ionized calcium, glucose, HCO3, Hb, blood gases, base excess, hematocrit and Troponin I. Testing can be performed at the patient's bedside.

CTnI contains Troponin I and CG8+ contains all other tests in a single cartridge.

2. SCOPE

The aim is to provide clinically useful information through laboratory measurement of samples from patients, taking into account the allocated resources.

This SOP is implemented by the following means;

- Proper sample collection, stabilization, transport, sample preparation and identification.
- Reliable analytical work so that systematic and random errors do not exceed specified limits.
- Turn-around time within specified limits for emergency measurements.
- Data reported in a clear form and supplemented with relevant information, including reference intervals to allow reliable clinical interpretation.
- Appropriate communication to the clinicians so that the results will be interpreted correctly and logically integrated into further (clinical and laboratory) evaluation of the patients, and that the clinicians become aware of unexpected problems and errors.

3. EQUIPMENT

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

For this cartridge:	**Use this control:**
CG8+	i-STAT TriControls Level 1 Control
CTnI	i-STAT CTnI Level 1 Control

- 1cc syringe.

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.

4. RECEIPT AND STORAGE OF CARTRIDGES & CONTROLS

4.1. **Required procedure for handling new cartridge or control shipments:**

- 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.
- Record temperature reading on "Receipt of New Cartridges" log found in the System Resources section of this manual.
- 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).

4.2. **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.

4.3. **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:**

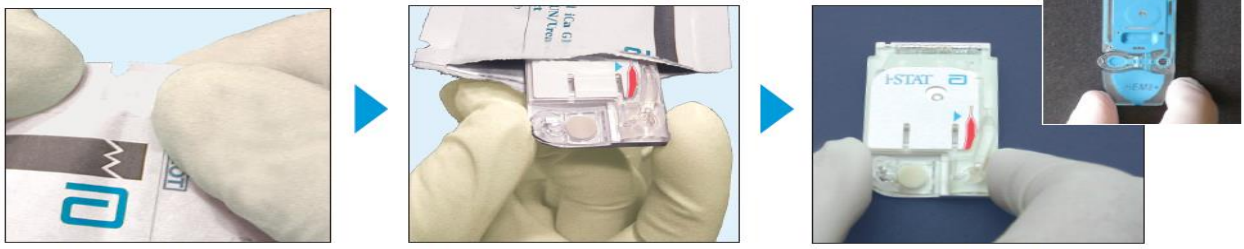
  Control ampules may be stored at room temperature (18 to 30˚C or 64 to 86˚F) for up to 5 days. Do not use after expiration date on box or ampule labels. Do not return controls to refrigerator once they have been brought to room temperature.

5. 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.
- 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.

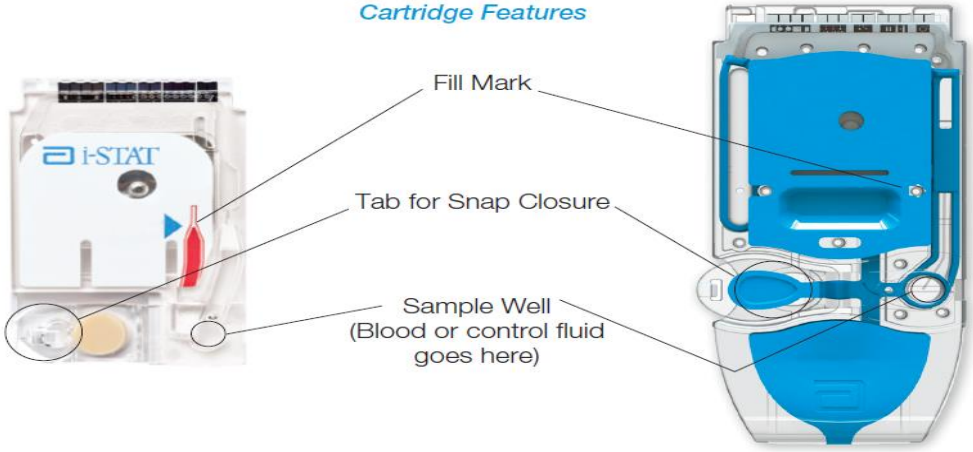


Tear open cartridge pouch at notch.

Remove cartridge from pouch. Always hold by sides.

Place on level surface.

Cartridge Features



6. SAMPLE REQUIREMENTS

- Venous whole blood samples collected in 1 ml syringe.

7. PROCEDURE

7.1 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.
- Fill and insert a CHEM8+ within 10 minutes of sample collection. For other chemistry cartridges, test samples within 30 minutes of collection.
- If the sample is not tested immediately, please discard in the sharp box.

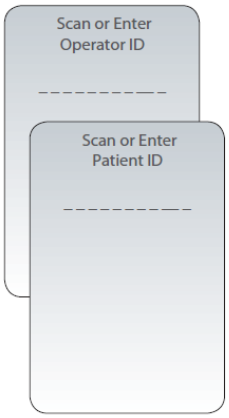
7.2 Prior to Testing:

- Enter your ID and/or a patient ID, have these ready before beginning the test.

- If you did 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.

7.3 Prepare the Handheld:

Note: The handheld must be customized before the first use according to the procedure in the Start-Up section of this manual.



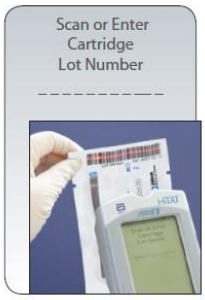
- Press ⏻ to turn on handheld.
- Press 2 for i-STAT Cartridge.
- Follow handheld prompts:

  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.

  ○ Scan or manually enter your operator ID as prompted. Press ENT (or press the ENT button to bypass this prompt).

  ○ Scan or manually enter the patient ID as prompted. Press ENT (or press the ENT button to bypass this prompt).

  ○ 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

7.4 Prepare to Test:

- Find a level, stable surface to perform the test. A level surface includes running the handheld in the downloader/recharger.
- Remove the cartridge from its pouch and place on a flat surface.
- Only touch the cartridge by its sides to avoid damage or contamination.
- Put on disposable gloves.

7.5 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.

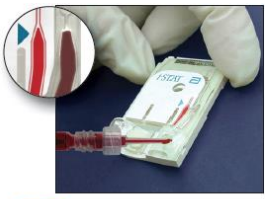
- Slowly pull back on the syringe plunger to draw blood into the syringe until it is about half full.
- Expel air from the syringe tip.
  - Place enough gauze pads on the counter to absorb a few drops of blood.
  - Hold syringe over gauze without touching it.
  - Press syringe plunger until you see 3 drops of blood empty from the syringe onto the gauze.

- 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. An air bubble stuck on the plunger is OK and will not affect results

7.6 Fill the Cartridge:

- Fill cartridge with sample to the fill mark.
  - Place the tip of the syringe or other transfer device over the cartridge sample well.
  - Press plunger so that sample enters cartridge until it reaches the fill mark.
  - Confirm that there is sample in the sample well. If you don't 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.

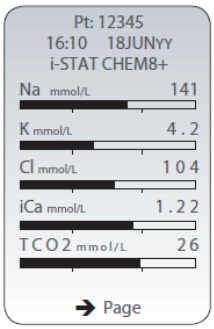
7.7 Seal the Cartridge:

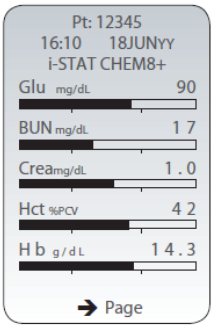
- Touching only the plastic tab and the sides of the cartridge, fold the snap closure over the sample well. *Do not press directly over the sample well.*
- Press the tab until it clicks into place. Slightly lift finger or thumb and ensure cartridge is closed before completely removing the finger or thumb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

7.8 Insert the Cartridge:

- Push the sealed cartridge into the handheld port until it clicks into place.
  - To avoid permanent damage to the handheld, do not remove cartridge until testing process is complete. For hematocrit testing, the handheld should remain level until a result is obtained. A level surface includes running the handheld in the downloader/recharger.
  - Wait about 2 to 3 minutes for the test to complete

7.9 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.
- If all results are not displayed on the first screen, press to page through all screens.

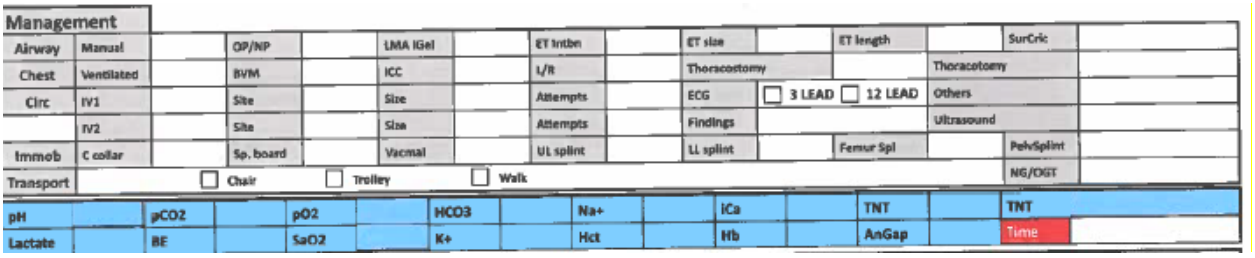
Note: If handheld turns off before review of results is complete, press to turn it on, then press 1 for Last Result.

7.10 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. 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.

7.11 Record and Report Results:

- Use i-STAT specific printer to print and attach the result paper to patient PCR or copy the result to PCR in the blue highlighted section below the management box.



- 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 and disinfect your hands according to CGP 129.

7.12 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.
- Record the quality check failure in the Quality Check Codes log provided by the technical team.

⚠ 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 or sodium heparin anticoagulant. • Using tubes not filled to capacity. • Using "short fill" tubes for TCO_2 testing. • When measuring TCO_2, not testing samples within 10 minutes of collection. Any deviations will cause inaccurate results.
	Use of expired cartridges.

8. PERFORM A CONTROL TEST

9.1 When to Do This:

- Upon receipt of each shipment, test one cartridge from each lot.
- Monthly, test one cartridge from refrigerated storage. Select this cartridges (CG8+ and CTnI)

9.2 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.

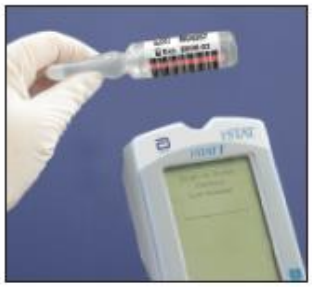
Prepare the Handheld

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.

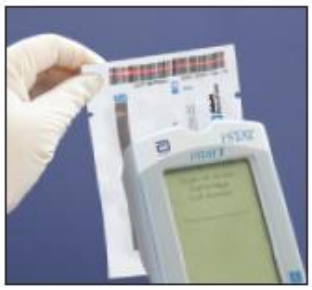
      Press ENT (or press ENT button to bypass this prompt).



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.

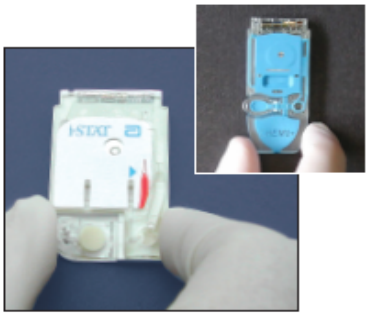
The control lot number on the ampule can also be entered manually. Use the keypad, ignoring any letters in the lot number, and press ENT .



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



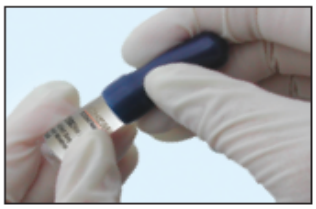
1. Find a stable surface to perform the test.
2. Remove the cartridge from its pouch and place on a level surface. A level surface includes running the handheld in the downloader/recharger.

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

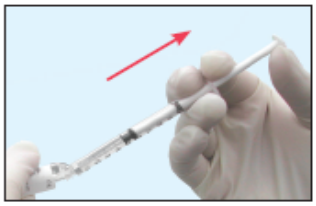
Prepare the Control Sample

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

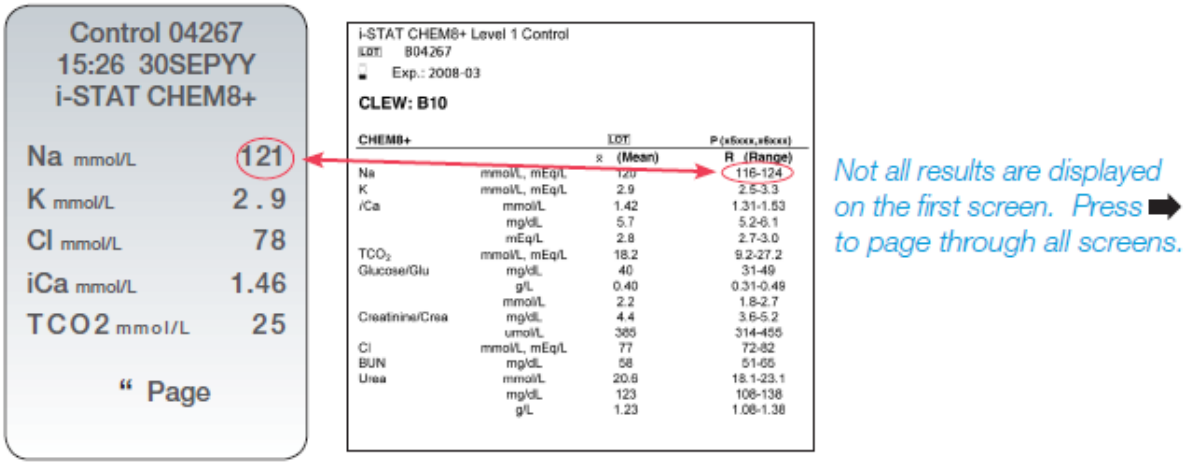
1. Push the sealed cartridge into the cartridge port until it clicks into place.
   a. To avoid permanent damage to the handheld, do not remove cartridge until the testing process is complete.
   b. Wait about 2 to 3 minutes for the test to complete.

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.abbottpointofcare.com. 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.



Not all results are displayed on the first screen. Press ➡ to page through all screens.

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.

9. TROUBLESHOOTING

Alert Prompt	Explanation	Action
No Display *Display screen remains blank*	Dead batteries Keypad not responding Internal start switch broken	Replace Batteries Reinstall current software
"Cartridge Locked" Not Removed	Analyzer will reset & release the cartridge after the testing cycle is complete. If the analyzer cannot reset, LCK prompt will remain on the screen. Dead batteries or mechanical problem.	Wait until analyzer deactivates Turn analyzer OFF. Turn analyzer ON to reset analyzer. If LCK does not disappear contact POCT Technologist. **DO NOT REMOVE CARTRIDGE.**

Start up Messages

Alert Prompt	Explanation	Action
Stored Memory Low	Memory for 50 spaces remaining Memory capacity is 1000	Upload analyzer in downloader
Stored Memory Full	Will not allow further testing	
Upload required	i-STAT1 programmed to alert operator	
Battery Low	When battery voltage <7.4 Sufficient power to test a few more cartridges, dependant on cartridge type	Replace the batteries.
Dead Batteries, Replace Batteries	Insufficient battery power to complete a test cycle	
Batteries Changed *Ready for Use*	Analyzer detects a "jump" in battery voltage.	Ready for Use.
CLEW expiring, Update required	Appears 15 days before the expiration of analyzer's software.	Contact POCT Technologist Upload Software update
Invalid or Expired CLEW	CLEW standardization either expired, missing, or corrupted.	
New Software *Use Electronic Simulator*	Normal response after an upgrade.	Use Electronic Simulator.
Simulator	No Electronic Simulator in the previous 8 hours.	Run Electronic Simulator. Test passes – continue to use.
	An electronic error after a testing cycle is completed.	Test fails – contact POCT Technologist.

Test Cycle Messages and Quality Check Codes

Alert Prompt	Explanation	Action
Date invalid, Check Clock	Analyzer will not allow a date that is earlier or exceeds the lifetime of the CLEW software	Set clock for date and time
Temperature out of range *Check Status Page*	Analyzer is too warm or too cool. Environment too warm or too cool.	Check Status Page. Move to warmer or cooler environment.
Analyzer Interrupted *Use Another Cartridge*	Last cartridge run not completed. When battery voltage low; or making poor contact while still in analyzer.	Check that batteries inserted properly & seated well in analyzer. Battery voltage is >7.4 volts. Run Electronic Simulator. Repeat.

Error in Cartridge or fluid movement		
Alert Prompt	**Explanation**	**Action**
Cartridge Error *Use Another Cartridge*	Sample related problems: Users, cartridges, or analyzer. Single/sporadic problem usually: - sample problem, interferent, bubbles - aberrant cartridge - touching cartridge contacts; pressing on center of cartridge	Repeat with Quality Control check. If test passes – continue to use the analyzer and cartridges. If test fails – repeat Quality Control check on a different analyzer. If test passes on the 2nd i-STAT analyzer call POCT Technologist.
Cartridge Preburst *Use Another Cartridge*	Analyzer has detected fluid on the sensors before it should have. - poor storage conditions of cartridges (frozen or too warm). - Pressure in center of the cartridge	Try another cartridge. Ensure cartridges were not frozen.
Unable to Position Sample *Use Another Cartridge*	Analyzer did not detect movement of sample across the sensors. - inadequate snap closure on cartridge, clots in the sample prevents movement of the sample, an aberrant cartridge.	Try another cartridge.
Sample Positioned Short of Fill Mark *Use Another Cartridge*	Cartridge underfilled. Sample must reach fill mark.	Try another cartridge.
Sample Positioned Beyond Fill Mark *Use Another Cartridge*	Cartridge overfilled. Sample is past the fill mark.	Try another cartridge.
Insufficient Sample *Use Another Cartridge*	Most likely due to insufficient sample or bubbles in the sample well.	Try another cartridge.
Cartridge Not Inserted Properly *Reinsert Cartridge*	Cartridge or Electronic Simulator may not be pushed in all the way. Instrument problem.	Reinsert the cartridge or Electronic Simulator. If instrument problem then contact POCT Technologist.

Electrical or Mechanical Failure		
Alert Prompt	**Explanation**	**Action**
Analyzer Error *Use Electronic Simulator*	Can occur if cartridge or Electronic Simulator "angled" when inserted.	Analyzer usually recovers with an Electronic Simulator. Push cartridge or Simulator straight through the cartridge port. Test passes – continue to use. Test fails – call POCT Technologist.
	If the Electronic Simulator malfunctions, may be due to analyzer mechanical or electrical failure of the analyzer.	Try another Simulator. Test passes – continue to use. Test fails – call POCT Technologist.
Analyzer Error *See Manual*	Mechanical or electronic failures. The analyzer may not be able to recover.	Run Electronic Simulator twice. Run a cartridge with sample or control solution. If okay, continue to use the analyzer. If an error condition persists, contact POCT Technologist.
Cartridge Type Not Recognized *Use Another Cartridge*	Cartridge type not compatible with the version of software in analyzer. If a new cartridge type, update software Analyzer problem is indicated, if the cartridge type was used before.	Software upgrade for new cartridge type. Analyzer may need repair. Contact POCT Technologist.
Internal Simulator Failure	Poor contact made between handheld pins and the contact pads of the cartridge	Immediately rerun the cartridge in another i-STAT1 analyzer – must be within 3 minutes of time it was filled. Validate the failed i-STAT1 analyzer with an electronic simulator and continue testing if successful.

10. FACTORS THAT AFFECT RESULTS

Interfering substances or other events may be encountered which can affect results.

Test	Factors that may Increase Results	Factors that may Decrease Results
Sodium (Na)	Hemodilution[1]	ß-hydroxybutyrate Lactate
Potassium (K)	Hemolysis Delay in testing Placing samples on ice Muscle activity (clenching and unclenching fist)	Hemodilution[1] Tourniquet left on too long
Chloride (Cl)	Bromide Salicylate Thiocyanate Acetylcysteine	Hemodilution[1]
Total Carbon Dioxide (TCO_2)	Delay in testing	Exposure to air Underfilling the collection tube

Test	Factors that may Increase Results	Factors that may Decrease Results
Ionized Calcium (iCa)	Bromide Magnesium Hemodilution[1] Forearm exercise Tourniquet left on too long	Acetaminophen Acetylcysteine Lactate Salicylate Incomplete filling of collection tube Delay in testing Exposure to air Hemodilution[1]
Glucose (Glu)	pH above 7.4 Hydroxyurea **(use alternate method)** Acetaminophen	Acetylcysteine Bromide pH below 7.4 ***P***O2 level <20mmHg Thiocyanate Delay in testing
Creatinine (Crea)	Acetaminophen Ascorbate Bromide ***P***CO2: see note Creatine N-acetylcysteine Hydroxyurea **(use alternate method)**	***P***CO2: see note
	Note: ***P***CO2 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.	
Hematocrit (Hct)	Total Protein >8g/dL	Total Protein <6g/dL
	Abnormally high lipids	Insufficient mixing
	Factors that affect sodium	Factors that affect sodium
	Insufficient mixing White blood cell count >50,000/µL	
	Handheld not on a level surface during testing.	Handheld not on a level surface during testing.

[1] Hemodilution greater than 20% with normal saline or Ringer's Lactate

11. CLEANING AND DECONTAMINATION OF EQUIPMENT

- Wipe the outside with non-alcohol wipes.
- Do Not use alcohol or another solvent to clean the i-STAT.
- Do Not get any liquids, dirt, dust, blood, or control solution inside the i-STAT through the test port or the data port.
- Never spray cleaning solution on the i-STAT or immerse it in any liquid.
- Maintenance will not be performed on any equipment returned to the Point of Care Team without decontamination having first taken place as per CGP 129.

12. REPORTING

Quality Control (QC) results are recorded in the QC Logbook provided by Quarantine and the asset fault report and also OPIQ. Patient results are recorded in the PCR.

13. LIMITATIONS/UNCERTAINTY OF MEASUREMENT

- 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
Sodium	Na	mmol/L	100–180	138–146		
Potassium	K	mmol/L	2.0–9.0	3.5–4.9		
Chloride	Cl	mmol/L	65–140	98–109		
Total Carbon Dioxide	TCO_2	mmol/L	5–50	24–29		
Ionized Calcium	iCa	mmol/L	0.25–2.50	1.12–1.32		
Glucose	Glu	mg/dL	20–700	70–105		
Urea Nitrogen	BUN	mg/dL	3–140	8–26		
Creatinine	Crea	mg/dL	0.2–20.0	0.6–1.3		
Hematocrit	Hct	% PCV	10–75	38–51		
Hemoglobin*	Hb	g/dL	3.4–25.5	12–17		
Anion Gap*	AnGap	mmol/L	-10–99	10–20		

** Calculated Values*

14. COMPETENCY CHECKLIST

Competency Checklist I-Stat

Sample Collection:

1- All materials required for sample collection prepared & checked
2- Patient Consent & at least 2 Patient identifiers recorded
3- Collection site prepared and Patient Counseled
4- Practice hand hygiene & PPE before, during and after sample collection.
5- Obtain adequate sample volume (avoid air bubbles in syringe)

Test Procedure for Cartridges:

1- I-Stat cartridge in use is correct and in date.
2- Cartridges dated upon removal from refrigerator.
3- Handle cartridge by edge and keeps it flat during sample loading.
4- Fill Cartridge to fill point, close flap and insert into analyzer.
5- Cartridge and all contaminated items disposed of as per NA Policy

Result Reporting:

1- Policy and procedure for reporting results followed correctly.
2- Point-of-care decision actions to be taken in accordance to results
3- Demonstrated ability to recall stored results.
4- Demonstrated procedure to transmit results.

Quality Control:

1- Aware of internal Electronic Simulator every 12 hours.
2- Knowledge of Liquid Quality Check (monthly) process & procedure
3- Knowledge of Records required for Temperature & Receipt of i-Stat Sundries
4- Knowledge of routine documentation of room temperature.

Sign-off

NA Staff Member shows proficiency in all aspects of the i-Stat use, care, process and procedure required for Sample Testing and Resultant Management with competence.

NA Staff Full Name: _____ **Staff ID:** _____ **Date**: _____

Assessors Name: _____ **Designation:** _____ **Signature**_____