The CHEM8+ cartridge has tests for sodium, potassium, chloride, total carbon dioxide, ionized calcium, glucose, urea nitrogen, creatinine and hematocrit.

**Regulatory Requirements**

To use the CHEM8+ cartridge and i-STAT 1 Handheld Analyzer (Handheld) for patient testing, your facility must have a CLIA Certificate of Waiver, and meet all applicable state and local laboratory testing laws. Further, the instructions provided in this guide must be followed, or your facility may be in non-compliance with the CLIA Certificate of Waiver program.

**Training Requirements**

*Read this whole guide before testing patient samples.*

Follow the instructions exactly. Carefully read the section on Cartridge Storage.

This guide contains information needed to get accurate results with the CHEM8+ cartridge and Handheld. View the video companion CD to the Quick Reference Guide that comes with this guide. It shows how to fill a cartridge and insert it into the Handheld.

Additionally, training can be done over the phone. Contact your local sales person to schedule training as needed.

**Critical Values**

Ask your clinician to record critical values on the Test Range table in this guide.

**Before you begin . . .**

See the Start-up Section of the “i-STAT System Manual for Waived Tests” for how to prepare a new or replacement Handheld for use.

For assistance, contact Technical Support: 800.284.0702 or email: techsvc@i-stat.com
### Precautions

<table>
<thead>
<tr>
<th>Potential Sources of Error in Patient Results</th>
<th>Incorrect cartridge storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect sample collection and/or sample handling:</td>
<td></td>
</tr>
<tr>
<td>• Test only fresh whole blood samples collected in tubes with lithium heparin anticoagulant.</td>
<td></td>
</tr>
<tr>
<td>• Fill tubes to capacity. Do not use “short fill” tubes.</td>
<td></td>
</tr>
<tr>
<td>• Test samples within 10 minutes of collection.</td>
<td></td>
</tr>
<tr>
<td>• Any deviations will cause inaccurate results.</td>
<td></td>
</tr>
</tbody>
</table>

### Use of expired cartridges

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.

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 safety tips when transferring sample from a blood collection tube to a cartridge.

Handheld and peripherals not suitable for use in oxygen enriched atmosphere.

### Potential Sources of Harm to the Operator

<table>
<thead>
<tr>
<th>Potential Sources of Damage to the Handheld</th>
<th>Trying to pull a cartridge out of the Handheld while “Cartridge Locked” message is displayed.</th>
</tr>
</thead>
</table>

Dropping the Handheld.

### Quality Control Requirements

Quality checks are automatically performed during each test. However, a CHEM8+ Level 1 control sample must be tested with each new shipment of cartridges, each new lot of cartridges, and monthly to check cartridges in storage. Follow the procedures in this guide including recommended recordkeeping to ensure your facility is in compliance with the CLIA Certificate of Waiver program.
Cartridge Shipments and Storage

Required procedure for handling new cartridge 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.

2. Fill out information in “Received” section at bottom of card. Mark an “x” in each of the spaces corresponding to a red window. If the “4” window is red, do not use cartridges. Contact Technical Support.

3. Record temperature reading on “Receipt of New Cartridges” log found in the System Resources section of this Manual.

4. If window “4” is not red, take one cartridge from each CHEM8+ lot in the shipment and test with i-STAT CHEM8+ Level 1 control (See “Test a Control Sample” for instructions). If any result is outside its range in the Value Assignment sheet, repeat the test. If any result is still outside its range, do not use the cartridges. Contact Technical Support.

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 pouch.

- 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

Store cartridges at room temperature up to 30˚C (86˚F) for no more than 14 days.

- To avoid waste, take only a few days worth of cartridges out of refrigerator.

- Read date on pouch label. Do not use cartridge if this date has passed.

- If cartridge is not used on day it is removed from refrigerator, use a soft felt pen to mark 14-day expiration date on pouch.

Check Storage Conditions Monthly

1. Remove one CHEM8+ cartridge from refrigerated storage.

2. Test cartridge with i-STAT CHEM8+ Level 1 control as described in “Test a Control Sample”. If any result is outside its range in the Value Assignment sheet, repeat the test. If any result is still outside its range, do not use the cartridges. Contact Technical Support.

3. Record results on the “Monthly Cartridge Check” log found in the System Resources section of this Manual.
Perform a Patient Test

To perform a patient test you will need:

- i-STAT 1 Handheld
- CHEM8+ cartridge
- Blood sample in green top tube
- 1 cc syringe with safety tip
- Disposable gloves
- Gauze
- Biohazard container

Collect the Sample
Correct sample collection & handling are important for accurate results!

- Use a blood collection tube containing lithium heparin (green top tube).
- Use a 20 to 23 gauge needle.
- Do not apply a tourniquet for more than a minute while looking for a vein. Release it and reapply after two to three minutes.
- Do not allow the patient to clench and unclench fist repeatedly.
- If alcohol is used to clean the site, allow it to air dry before performing venipuncture.
- Fill blood collection tube to capacity and gently invert tube about 10 times.
- Perform a new venipuncture if blood does not flow freely into collection tube.
- Perform CHEM8+ test within 10 minutes of sample collection.
- If the sample is not to be tested immediately, label tube with the patient’s name and another identifier, such as date of birth.

Prepare the Cartridge

- After removal from refrigerator, let single cartridge stand in its pouch for 5 minutes at room temperature. An entire box of cartridges should stand for 1 hour before use.

Tear open cartridge pouch at notch.
Remove cartridge from pouch. Always hold by sides.
Place on flat surface.
Fill the Cartridge


2. Invert the tube and push safety tip on syringe through stopper into blood sample. **Slowly** pull back on plunger to draw blood into syringe until it is about half full.

   **Note:** An air bubble near plunger of syringe will not affect results. An air bubble near tip of syringe must be removed - see step 3. If air bubbles are mixed with the blood sample, use another syringe. **DO NOT put blood back into tube.**

3. Hold syringe so tip is pointing upward. Hold a gauze pad at tip to absorb blood. Press syringe plunger slowly until air is removed. If air bubble is stuck, tap syringe gently. If an air bubble was trapped at top of syringe it may start to move toward tip. In this case, wait until bubble reaches tip and remove it.

4. Direct tip of syringe into sample well of cartridge. Gently press syringe plunger to deliver blood into cartridge.

   When blood reaches fill mark on cartridge, stop adding blood. Some blood must be in sample well – add blood to well if necessary.

5. Pressing on tab, fold snap closure over sample well until it clicks into place. **DO NOT press over sample well.**
Insert the Cartridge

1. Push cartridge into Handheld port as shown until cartridge clicks into place. The Handheld will first display “Identifying Cartridge”, then a time-to-result bar. Results will be shown in 2 to 3 minutes.

   DO NOT remove cartridge until the “Cartridge Locked” message is removed and results are displayed on screen.

2. Following prompts on screen, use number keys to enter an Operator and Patient ID. Press ENT when each ID number is complete. If ID numbers are not required, just press ENT to continue.

   Note: Press ← to clear a wrong number.

   Note: ID numbers can also be scanned into the Handheld. (See Start-up section in Manual)

3. When results are shown, the cartridge may be removed and discarded with other test materials:
   - Discard cartridge, syringe, tube of blood and gloves in biohazard container.
   - Wash hands.

Review Results

- The Handheld shows the numerical values and units with the results. It also shows bar graphs with tic marks for reference ranges.

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

- If any result is shown as ***, <, >, or < > see Flagged Results.

- If a message and code are displayed, see Troubleshooting.

Not all results are 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.
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.

<table>
<thead>
<tr>
<th>Test</th>
<th>Test Symbol</th>
<th>Units</th>
<th>Reportable Range</th>
<th>Reference Range</th>
<th>Critical Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Na</td>
<td>mmol/L</td>
<td>100–180</td>
<td>138–146</td>
<td>120 160</td>
</tr>
<tr>
<td>Potassium</td>
<td>K</td>
<td>mmol/L</td>
<td>2.0–9.0</td>
<td>3.5–4.9</td>
<td>2.5 6.5</td>
</tr>
<tr>
<td>Chloride</td>
<td>Cl</td>
<td>mmol/L</td>
<td>65–140</td>
<td>98–109</td>
<td>70 120</td>
</tr>
<tr>
<td>Total Carbon Dioxide</td>
<td>TCO₂</td>
<td>mmol/L</td>
<td>5–50</td>
<td>24–29</td>
<td>15 50</td>
</tr>
<tr>
<td>Ionized Calcium</td>
<td>iCa</td>
<td>mmol/L</td>
<td>0.25–2.50</td>
<td>1.2–1.32</td>
<td>0.70 1.60</td>
</tr>
<tr>
<td>Glucose</td>
<td>Glu</td>
<td>mg/dL</td>
<td>20–700</td>
<td>70–105</td>
<td>45 400</td>
</tr>
<tr>
<td>Urea Nitrogen</td>
<td>BUN</td>
<td>mg/dL</td>
<td>3–140</td>
<td>8–26</td>
<td>50</td>
</tr>
<tr>
<td>Creatinine</td>
<td>Crea</td>
<td>mg/dL</td>
<td>0.2–20.0</td>
<td>0.6–1.3</td>
<td>2.0</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>Hct</td>
<td>% PCV</td>
<td>10–75</td>
<td>38–51</td>
<td>27 70</td>
</tr>
<tr>
<td>Hemoglobin*</td>
<td>Hb</td>
<td>g/dL</td>
<td>3.4–25.5</td>
<td>12–17</td>
<td></td>
</tr>
<tr>
<td>Anion Gap*</td>
<td>AnGap</td>
<td>mmol/L</td>
<td>-10–99</td>
<td>10–20</td>
<td></td>
</tr>
</tbody>
</table>

* Calculated Values

- Your clinician may wish to use different Reference Ranges and Critical Values for tests performed with the CHEM8+ cartridge. Use the table below to replace the values shown above (if applicable).

<table>
<thead>
<tr>
<th>Test</th>
<th>Test Symbol</th>
<th>Units</th>
<th>Reportable Range</th>
<th>Reference Range</th>
<th>Critical Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Na</td>
<td>mmol/L</td>
<td>100–180</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potassium</td>
<td>K</td>
<td>mmol/L</td>
<td>2.0–9.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chloride</td>
<td>Cl</td>
<td>mmol/L</td>
<td>65–140</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Carbon Dioxide</td>
<td>TCO₂</td>
<td>mmol/L</td>
<td>5–50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ionized Calcium</td>
<td>iCa</td>
<td>mmol/L</td>
<td>0.25–2.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose</td>
<td>Glu</td>
<td>mg/dL</td>
<td>20–700</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urea Nitrogen</td>
<td>BUN</td>
<td>mg/dL</td>
<td>3–140</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine</td>
<td>Crea</td>
<td>mg/dL</td>
<td>0.2–20.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematocrit</td>
<td>Hct</td>
<td>% PCV</td>
<td>10–75</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemoglobin*</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Anion Gap*</td>
<td>AnGap</td>
<td>mmol/L</td>
<td>-10–99</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Calculated Values
Record and Report Results

1. Record results on patient record.
   
   Note: If using the portable printer, be aware that the printout will fade after about 5 years. If a more permanent record is required, photocopy the printout.

2. Report results to physician.
   
   If physician questions a result, request a fresh sample and repeat test.
   If a result is still questioned, check “Factors That Affect Results” on the back page of this guide. If an interfering substance is suspected, a sample should be sent to a commercial or hospital laboratory.

Flagged results:

- If stars (***) are displayed instead of a result, it means that a test failed internal quality checks. All reported results are accurate. 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. Some examples and an explanation include:

SAMPLE POSITIONED BEYOND FILL MARK – USE ANOTHER CARTRIDGE
Too much fluid was put into cartridge.

SAMPLE POSITIONED SHORT OF FILL MARK – USE ANOTHER CARTRIDGE
Not enough blood was put into cartridge. Make sure blood reaches the fill mark.

INSUFFICIENT SAMPLE – USE ANOTHER CARTRIDGE
Not enough blood was put into cartridge. Make sure some blood is in the sample well and that there are no air bubbles in the cartridge.

UNABLE TO POSITION SAMPLE – USE ANOTHER CARTRIDGE
Cartridge not closed properly, sample was outside sample well or sample clotted.

“CLEW EXPIRING, UPDATE REQUIRED”
Software will expire 15 days after message is first displayed. Update software.

“CARTRIDGE ERROR, USE ANOTHER CARTRIDGE” (Code 79 or 80)
If code occurs a second time, Handheld has been damaged and needs to be replaced.

A complete list of Quality Checks is in the System Resources section of the “i STAT System Manual for Waived Tests”.
To perform a control test you will need:

- i-STAT 1 Handheld
- CHEM8+ cartridge
- Ampule of CHEM8+ Level One Control
- An ampule breaker, gauze or paper towel
- A 1cc plain syringe
- Value Assignment sheet

Prepare the Control

1. Control fluid is stored in the refrigerator. Allow an ampule of control fluid to stand at room temperature for 30 minutes before use.

   *Do not use a control fluid past the expiration date on the box and ampule label.*

Prepare the Handheld

1. Press \( \text{I} \) to turn on Handheld.

2. Press \( \text{MENU} \) to change screen to Administration Menu.

3. Press \( \text{3} \) for the Quality Tests menu.

4. Press \( \text{1} \) for Control.

5. Following prompt on screen, use number keys to enter an Operator ID, then press \( \text{ENT} \). If ID number is not required, just press \( \text{ENT} \) to continue.

   *Note: Press \( \text{\leftarrow} \) to clear a wrong number.*

6. Enter control ampule lot number and press \( \text{ENT} \).

   *Note: Ignore any letters in the lot number*

7. Enter cartridge lot number and press \( \text{ENT} \).

   *Note: Ignore any letters in lot number*

8. Proceed to next step. The Handheld will wait 15 minutes for a cartridge to be inserted before it turns off.
**Fill the Syringe**

1. Hold the ampule between the index finger and thumb and shake hard for 10 seconds.

2. Tap or flick the top part of the ampule to send all the fluid to the bottom part of the ampule.

3. Place an ampule breaker over the top part of the ampule or protect your fingers with a gauze or paper towel, then break off top with a quick snap.

4. Tilt opened ampule so that fluid flows close to opening.

5. Position syringe tip into the fluid.

6. Slowly pull back on syringe plunger to draw fluid into syringe until it is about half full.

7. Hold syringe tip over gauze pad or waste container. Press syringe plunger just enough to discard three drops of fluid.

**Fill, Close and Insert the Cartridge**

1. Place the syringe tip into the sample well of the cartridge.

2. Gently press syringe plunger until fluid reaches fill mark on cartridge. The fluid is colorless so watch fluid carefully as it moves toward the Fill mark.

3. Pressing on tab, fold snap closure over sample well until it clicks into place. **DO NOT press over sample well.**

4. Push cartridge into Handheld port until cartridge clicks into place. The Handheld will first display “Identifying Cartridge”, then a time-to-result bar. Results will be shown in 2 to 3 minutes.

**DO NOT** remove cartridge until the “Cartridge Locked” message is removed and results are displayed on screen.
5. When results are shown, the cartridge may be removed and discarded with other test materials. Control fluid is water-based and does not contain human blood product, so it is not necessary to discard used materials in a biohazard container. However, it should be disposed of in a container for broken glass.

Review and Log Results

- The Handheld shows the numerical values for each test result. Cartridges may be used if all results are inside the ranges on the Value Assignment sheet. Results should be recorded in a log such as the one in the System Resources section of the i-STAT System Manual for Waived Tests.

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

![Control 02467](image)

Na mmol/L 121
K mmol/L 2.9
Cl mmol/L 78
iCa mmol/L 1.46
TCO2 mmol/L 25

- If any result is outside the range on the Value Assignment sheet, repeat the test following instructions carefully. If one or more results are still outside ranges on the Value Assignment sheet, do not use cartridges. Contact Technical Support for further instructions.

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

Troubleshooting

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

<table>
<thead>
<tr>
<th>Problem</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery Low message and battery icon flashing.</td>
<td>Change batteries.</td>
</tr>
<tr>
<td>Handheld will not turn on when a cartridge is inserted.</td>
<td>Change the batteries.</td>
</tr>
<tr>
<td>FAIL is displayed when a cartridge is inserted.</td>
<td>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.</td>
</tr>
</tbody>
</table>
Factors that Affect Results

Interfering substances or other events may be encountered which can affect results. Refer to summary below, or see information about Cartridge and Test Information sheets in the System Resources section of the “i STAT System Manual for Waived Tests”.

<table>
<thead>
<tr>
<th>Test</th>
<th>Factors that may Increase Results</th>
<th>Factors that may Decrease Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium (Na)</td>
<td>Bromide</td>
<td>1ß-hydroxybutyrate</td>
</tr>
<tr>
<td></td>
<td>Hemodilution¹</td>
<td>Lactate</td>
</tr>
<tr>
<td>Potassium (K)</td>
<td>Hemolysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Delay in testing</td>
<td></td>
</tr>
<tr>
<td>Chloride (Cl)</td>
<td>1ß-hydroxybutyrate</td>
<td>Hemodilution¹</td>
</tr>
<tr>
<td></td>
<td>Bromide</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lactate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Salicylate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Thiocyanate</td>
<td></td>
</tr>
<tr>
<td>Total Carbon Dioxide</td>
<td>Delay in testing</td>
<td>Exposure to air</td>
</tr>
<tr>
<td>(TCO₂)</td>
<td></td>
<td>Incomplete fill of collection tube</td>
</tr>
<tr>
<td>Ionized Calcium (iCa)</td>
<td>Magnesium</td>
<td>1ß-hydroxybutyrate</td>
</tr>
<tr>
<td></td>
<td>Hemodilution¹</td>
<td>Lactate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Salicylate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Incomplete fill of collection tube</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Delay in testing</td>
</tr>
<tr>
<td>Glucose (Glu)</td>
<td>pH above 7.4</td>
<td>Bromide</td>
</tr>
<tr>
<td></td>
<td>Hydroxyurea</td>
<td>pH below 7.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Oxygen less than 20mmHg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thiocyanate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Delay in testing</td>
</tr>
<tr>
<td>Urea Nitrogen (BUN)</td>
<td></td>
<td>Thiocyanate</td>
</tr>
<tr>
<td>Creatinine (Crea)</td>
<td>Acetaminophen</td>
<td>PCO₂</td>
</tr>
<tr>
<td></td>
<td>Ascorbate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bromide</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hydroxyurea</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Creatine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N-acetylcysteine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PCO₂</td>
<td></td>
</tr>
<tr>
<td>Hematocrit (Hct)</td>
<td>White Blood Count</td>
<td>Total Protein &lt;6g/dL</td>
</tr>
<tr>
<td></td>
<td>Total Protein &gt;8g/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lipids</td>
<td></td>
</tr>
</tbody>
</table>

¹ Hemodilution greater than 20% with normal saline or Ringer’s Lactate