I-STAT POCT System

PRINCIPLE:

The i-STAT system uses a single disposable cartridge. The cartridge, which has been filled with fresh blood, is placed into a hand-held analyzer for analysis. The results are printed and also transmitted to a computer where they can be stored and transferred to another system for charting.
PRINCIPLES OF MEASUREMENT:

**Sodium, Potassium, Chloride, Ionized Calcium** are measured by ion-selective potentiometry. Concentrations are calculated from the measured potential through the Nernst Equation.

**Urea** is first hydrolyzed to ammonium ions to be measured by an ion-selective electrode. Concentrations are calculated from the measured potential through the Nernst Equation.

**Glucose** is measured amperometrically. Oxidation of glucose produces hydrogen peroxide, which is oxidized at an electrode to produce an electric current, which is proportional to the glucose concentration.

**Creatinine** is hydrolyzed in several steps to hydrogen peroxide. Hydrogen Peroxide is then oxidized at an electrode to produce a current, which is proportional to the sample Creatinine concentration.

**Hematocrit** is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.
SPECIMEN REQUIREMENTS:

Note: All blood specimens are potentially infectious. Observe standard precautions at all times when handling athlete or race participant specimens.

Chem 8 cartridge: (measures NA, K, CL, CO2, BUN, GLU, Creatinine, Ionized Calcium, Hct calculated Anion Gap and HB)

Fresh whole blood collected in a green top (lithium heparin) collection tube
Test Immediately - Fresh whole-blood collected into a plastic syringe or blood that has not been put into a green top tube.

TEST WITHIN 30 MINUTES OF COLLECTION IN GREEN TOP TUBE
Remix thoroughly before testing
REAGENTS AND SUPPLIES

1. Cartridges stored at 2-8º C (36-46ºF)
   Store main supply refrigerated until expiration date. **DO NOT FREEZE.**
   Cartridge stability at room temperature is noted on back of each cartridge
   **A single cartridge must be at room temperature for 5 minutes prior to use.**
   **A box of cartridges must be at room temp for an hour before use.**
   Date room temperature cartridges with new room temp expiration date.
   Do not return room temperature cartridges to refrigerator.
2. Analyzer
3. Lithium 9V batteries
4. Printer and paper (if used in area, not required)
Blood Collection and Transfer Equipment

1. Gloves
2. Venipuncture collection equipment
3. Green top heparin tubes
4. Transfer device
5. 1cc plain syringe
Liquid Controls

1. I-STAT Chem 6 or Chem 8 Controls depending or cartridges used – may vary from event to event.

2. Liquid controls (supplied by Abbott) should be run on each new shipment of cartridges.
SAFETY PRECAUTIONS

**Always** wear gloves when performing a test and change them if they become contaminated.

Treat all specimens as capable of transmitting disease.

Never access clean supplies with contaminated gloves. Put extra supplies on a paper towel before applying gloves.

When test is complete: remove gloves and perform hand hygiene

Clean the i-STAT with a germicidal if the i-STAT is visibly contaminated with blood.

Do not immerse or spray analyzer
CALIBRATION:

Calibration is automatically performed as part of the test cycle on each cartridge. Operator intervention is not necessary.
QUALITY CONTROL: #1

Upon receipt of a new Shipment of Cartridges (new lot number) testing of a sample cartridge using a liquid test sample (available from Abbott Laboratories) is performed. All control test results must be within Manufacturer’s acceptance range. Document results on New Cartridge Shipment Log.
QUALITY CONTROL: #2  Acceptance Criteria for shipment of cartridges

Temperature of cartridge shipping does not exceed 8°C. Only window A/1 of temperature Monitor on the package is colored. Windows B/2, C/3 and D/3 are colorless. If windows B, C, and D are blue. This is an indication that shipping container temperature has been compromised and the cartridges should not be used.

Results of any of the liquid controls are outside of manufacturer’s acceptance range the cartridges should not be used.

Document results on New Cartridge Shipment Log along with corrective actions taken.

Quarantine lot of cartridges and notify Abbott Customer Service for advice on return or removal.
An electronic stimulator is provided with the i-STAT machine, and is used to test the internal electronics. This is performed each time the i-STAT is taken out for use. In many cases, this procedure will be completed before you receive the i-STAT in the field. We advise that you check with your Medical Director to ensure this testing has been completed.
ISTAT TESTING PROCEDURE:  #1  Athlete or Race Participant  Testing

Press ON/OFF to turn analyzer on.

Select “2- I-STAT Cartridge”.

Dispense the sample until it reaches the fill mark (blue mark) on the cartridge. Fold the SNAP COVER over the sample well until it snaps into place. Press on the round tab, NOT overfill the sample well or a “pre-burst” error will occur and a new cartridge will need to be used.

* Make sure not to touch the platinum mental on the end of the cartridge. This will contaminate the cartridge and render the test inaccurate.
**ISTAT TESTING PROCEDURE:**  #2  Athlete or Race Participant Testing

Carefully insert cartridge into port of I-STAT analyzer. Do not attempt to remove cartridge while “Cartridge Locked” remains on the screen.

Note, for best results keep the i-STAT on a level surface and do not move the i-STAT while it is running.

When screen displays Operator ID, enter your assigned ID # (volunteer number or equivalent) and ENTER. Repeat step.

At Patient ID (athlete bib number or equivalent) enter assigned Patient ID # and ENTER. Repeat step.

Results will appear when tests are complete.

Remove cartridge after Cartridge Locked message disappears. Dispose in a Sharps container. The analyzer is ready for the next test immediately.
**Sampling Tips**

1. Tilt cartridge if sample does not flow to fill mark.

2. Cartridge may not seal properly if sample well is overfilled. Do not draw back excess with syringe. Use a gauze pad over snap closure when covering well. This will absorb the excess but not affect the cell/plasma ratio.

3. Do not use cartridge on which blood or any other liquid has spilled as the internal contact pads in analyzer may become contaminated.

4. Be sure sample is well mixed incorrect results may occur with poorly mixed specimen.

5. Falsely high potassium results can occur from hemolyzed specimens.

6. If results do not match patient condition, repeat the testing with a new cartridge.
Results are available for viewing on i-STAT screen or can be printed using the option i-STAT printer

**LINEARITY / REPORTABLE RANGES OF i-STAT (provided by i-STAT)**

<table>
<thead>
<tr>
<th>Measured:</th>
<th>Reported Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM</td>
<td>100 - 180 mmol/L</td>
</tr>
<tr>
<td>POTASSIUM</td>
<td>2.0 - 9.0 mmol/L</td>
</tr>
<tr>
<td>CHLORIDE</td>
<td>65 - 140 mmol/L</td>
</tr>
<tr>
<td>BUN</td>
<td>3 - 140 mg/dL</td>
</tr>
<tr>
<td>GLUCOSE</td>
<td>20 - 700 mg/dL</td>
</tr>
<tr>
<td>Calcium, Ionized</td>
<td>1.0 – 10.0 mg/dl</td>
</tr>
<tr>
<td>CREATININE</td>
<td>0.2 - 20.0 mg/dL</td>
</tr>
<tr>
<td>TCO2</td>
<td>5 – 50 mmol/L</td>
</tr>
<tr>
<td>HEMATOCRIT</td>
<td>10 – 75 PCV%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Calculated:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>HEMOGLOBIN</td>
<td>3.4 - 25.5 g/dL</td>
</tr>
<tr>
<td>Anion Gap</td>
<td>-10 - +99</td>
</tr>
</tbody>
</table>
Suppressed Results

There are three conditions under which the i-STAT System will not display results:

Results outside the System’s reportable ranges are flagged with a < or >, indicating that the result is below the lower limit or above the upper limit of the reportable range. The <> flag indicates that the results for this test were dependent on the result of a flagged as either > or <.

Action:

Specimen would need to be sent to a laboratory for analysis.
Suppressed Results

Cartridge results were not reportable based on internal QC rejection criteria are flagged with ***.

**Action:**

Analyze the specimen again using a fresh sample from the well mixed blood tube and another cartridge. The results that are not suppressed may be reported in the usual manner. If the result is suppressed a second time, send the sample to a lab for analysis.
**Suppressed Results**

A quality Check message will be reported instead of results if the analyzer detects a problem with the sample, calibrant solution, sensors, or mechanical or electrical functions of the analyzer during the test cycle.

**Action:**

Take the action displayed with the message that identifies the problem.
Printing the i-STAT results

Align the IR windows of the analyzer and the printer. To print displayed results, push the print key.
CALCULATIONS:

The i-STAT analyzer contains a microprocessor that performs all calculations required for reporting results.

LIMITATIONS:

Results outside the systems reportable ranges are flagged with a "< or >" or "<>", send to the lab for analysis.
Results which are unreportable *** based on internal rejection criteria should be retested again with another cartridge.
Results will be suppressed if a test cycle has a problem with sample, calibrant solution, sensors, mechanical or electrical functions of the analyzer. Refer to i-STAT ERROR CODE LIST to troubleshoot problem.
Specimens should be rejected for analysis;
When evidence of clotting is present.
If specimen is collected with an anticoagulant other than heparin.
RECALLING RESULTS:

Press **On/Off** key
Press **1** to continue if prompted
Press **Menu** key to display Administration Menu
Select **2** – Data Review
Select **1** – Patient
Enter patient ID
Bottom of screen will indicate number of pages of results. Scroll back and forth using the **1** and **2** keys.
Press **Menu** key to access another patient or **On/Off** key to end.
MAINTENANCE:

Disinfect analyzer and remove any residual dried blood using a germicidal wipe, or by using a cloth moistened with disinfectant.

1. DO NOT spray disinfectants onto the analyzer.

2. DO NOT use alcohol wipes. That will cause deterioration of the screen and outer covering of analyzer.

3. Avoid wiping plastic screen with disinfectant unless screen is visibly contaminated.
QUALITY CONTROL:

Daily Procedures
Verify the operation of each i-STAT analyzer with an electronic simulator. The Internal Electronic is set to automatically be activated every 8-hours if i-STAT is in use.

INTERNAL ELECTRONIC SIMULATOR
Internal Electronic Simulator will be automatically initiated by the insertion of a cartridge every 8-hours as needed. Results are transmitted to the lab for review.
QUALITY CONTROL:

If result is “PASS” – Pass will not display on screen and analyzer will perform testing on inserted cartridge
If result is “FAIL”- analyzer will display “FAIL” and you will have to remove test cartridge and reinsert to initiate a test cycle.
If “FAIL” is displayed a second time, do not use analyzer and contact the POCT Coordinator.

The integrity of each new shipment of cartridges is verified with assayed controls. Verify that the i-STAT cartridges at room temperature have not been out of the refrigerator more than cartridge packaging specifies and that room temp expiration date is documented on cartridge box or individual cartridge.
CALIBRATION

For cartridges, calibration is automatically performed as part of the test cycle on each cartridge type except for coagulation tests (ACT, PT/INR). Operator intervention is not necessary.
REFERENCE RANGES

Sodium 138 - 146 mmol/L
Potassium 3.5 - 4.9 mmol/L
Chloride 98 - 109 mmol/L
Total CO2 24 - 29 mmol/L
BUN 7 - 25 mg/dl
Glucose 65 - 100 mg/dl
Creatinine 0.8 - 1.3 mg/L
Ionized calcium 4.5 – 5.3 mg/dl
Hematocrit 38 - 51 %
Hemoglobin (calc) 12.0 – 17.0 g/dl
Anion Gap 10 - 20

***Note: Ranges listed above are for adult population