Laboratory PH PC iSTAT PGR

Effective: 5/10/2016

Review: No Review Date

Name of Associated Policy: General Laboratory Policy

Name of Associated PGR(s): Laboratory PH PC Point of Care Testing PGR

Name of Associated Forms
- iSTAT Inventory Sign out Log Form
- iSTAT Menu PDF Form

DEFINITIONS:

1. POC / POCT – Point of Care Testing
2. UniPOC – POC software and data management system
3. ACT – Activated Clotting Time
4. LQC – Liquid Quality Control

PURPOSE: CLINICAL SIGNIFICANCE AND/OR PRINCIPLE DEFINITIONS:

1. The I-STAT analyzer is intended for use with i-STAT cartridges for in vitro quantification of various analytes in whole blood by trained and certified health care professionals in accordance with the manufacturer and PHR procedures. The i-STAT® System incorporates comprehensive components needed to perform blood analysis at the point of care. The System consists of the following primary components:

   1.1 **Analyzer:** Analyzer is the handheld i-STAT Analyzer. When a sample-filled i-STAT cartridge is inserted into an analyzer for analysis, the analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration and continuous quality monitoring. Results are reported in approximately 120-200 seconds for cartridges with sensors for electrolytes, chemistries, and hematocrit. Results are reported in approximately 10 minutes for immunochemical cartridges such as Troponin I. Results are reported in actual seconds dependent on results for ACTk cartridges up to 1000 seconds.

   1.2 **Cartridges:** A single-use disposable cartridge contains microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber. Sensors for analysis of sodium, potassium, chloride, ionized calcium, glucose, creatinine, urea nitrogen (BUN), and hematocrit are available in a variety of panel configurations. (Table 2). A whole blood sample of approximately 1 to 3 drops is dispensed into the cartridge sample well and the sample well is sealed.
1.3 **Point-of-Care UniPOC/DE Data System:** The i-STAT UniPOC/DE server provides the primary information management capabilities for the i-STAT System. Downloaders for the i-STAT Analyzers allow for transmission of patient records from a widely distributed network of analyzers to the patient’s medical record. Some i-STAT models can transmit data wirelessly. Data is stored, organized, edited, and transferred to the laboratory and hospital information system. Cartridge usage and efficiency reports can be generated for QCM3 management of the system.

**SAFETY PRECAUTIONS:**

1. Always wear gloves, proper PPE, and follow safety and biohazard policies when performing testing with blood.
2. i-STAT analyzer and cartridges must be at room temperature for testing
   2.1 If analyzer is moved from one temperature extreme to another, please allow time reach new temperature before using
   2.2 Operate the i-STAT within the temperature and humidity ranges
3. Store and use cartridges properly
   3.1 Cartridges should be refrigerated and should be used before the box expiration date.
   3.2 Most cartridges are good for **14 days** after removal from the refrigerator. CG8+ cartridges are good for **2 months** after removal from the refrigerator.
   3.3 If cartridges have been at room temperature for **5 minutes** they cannot be returned to the refrigerator. Never put cartridges back in the refrigerator after they are at room temperature.
   3.4 Do not allow cartridges to freeze
   3.5 Do not expose cartridges to temperatures above 86F (30C)
4. i-STAT analyzers should remain still and on flat surface while testing is in progress
5. Only i-STAT cartridges are approved for testing with the i-STAT instrument
6. Handle i-STAT cartridges appropriately at all times
   6.1 Do not touch the cartridge sensors while handling the cartridge
   6.2 Do not hold the cartridge with finger pressure
   6.3 Take care not to crush silver circle while handling the cartridges
   6.4 **NEVER** attempt to remove a cartridge while the monitor screen show “**Cartridge Locked**”
   6.5 Do not overfill the cartridge.
   6.6 Cartridges are good for only one use
7. Only fresh whole blood samples obtained in the approved containers may be used to perform i-STAT testing
8. Verify patient identification before testing using the two identifiers required by collection, PH and lab procedure
   8.1 Verify 10 digit account number on armband before testing
   8.2 All specimens must be properly labeled with the patient full name, MR#, Account# (chart label), the date and time of collection, and the initials of the collector
9. Follow Standard Blood and Body Fluid Precautions and all safety requirements
   9.1 Clean i-STATs with approved cleaners after each use, each patient
9.2 Clean when soiled
9.3 Clean between each patient
9.4 Clean with alcohol or ammonia based cleaners (Cavicide)

10. Questionable results should be repeated with a new sample and or confirmed by laboratory tests

11. Use scanner properly with laser precautions
   11.1 Hold barcode 3-12 inches from scanner, and at a 30-135 degree angle to scan.
   11.2 Never look into the scanner laser or point it toward anyone’s eyes.

12. Check i-STAT for damage before each use
   12.1 Call lab POC staff if problems are noted with the i-STAT analyzer

14. Dispose of lancets or needles in approved sharps containers.
   14.1 Dispose of wastes and cartridges in Biohazardous containers.

RESPONSIBLE POSITIONS (TITLE):
1. Laboratory Workforce, POC
2. PH Trained Nursing Workforce
3. PH Trained Workforce

EQUIPMENT NEEDED:
1. i-STAT analyzer
   1.1 3.04 in x 9.25 in x 2.85 in (7.68 cm x 23.48 cm x 7.24 cm)
   1.2 22.9 ounces / 650 grams
   1.3 Rechargeable batteries or 2 9 volt lithium
   1.4 Memory/clock backup power – Lithium battery
   1.5 Analyzer Storage Temperature 14-115 F (-10-46 C)
   1.6 Operating Temperature 61-86 F (16-30 C)
   1.7 Relative humidity 90% maximum
   1.8 Display – dot matrix supertwist liquid crystal
   1.9 Calibration – Factory: electronic, mechanical, thermal, pressure
   1.10 Communication Link – Infared light-emitting diode (LED)

2. i-STAT Cartridges
3. i-STAT Downloaders
4. Collection devices and equipment

REQUIRED REAGENTS AND INSTRUCTIONS FOR STORAGE AND PREPARATION:
1. **Cartridges** are sealed in individual pouches.
   1.1 Store the main supply of cartridges at a temperature between 2 to 8°C (35 to 46°F).
   1.2 **Do not allow cartridges to freeze.** (Freezing will cause higher than expected ionized calcium results).
   1.3 Cartridges may be stored at room temperature (18 to 30°C or 64 to 86°F) for 14 days, CG8+ may be stored at room temperature for 2 months
   1.4 Cartridges **should not be returned** to the refrigerator once they have been at room temperature for 5 minutes, and should not be exposed to temperatures above 30°C (86°F).
1.5 When you remove a cartridge from the box, stamp or write **Expires** and the date 14 days from the day/ or 2 months for the CG8+ it is removed.

1.5.1 Do not use after the manufacturer or new RT expiration date. All cartridges at room temp should have new expiration date recorded.

1.5.2 Staff obtaining cartridges from the laboratory are responsible for dating supplies.

1.6 Cartridges should remain in pouches until time of use.

1.7 An individual cartridge may be used after 5 minutes out of the refrigerator. An entire box should stand at room temperature for one hour before cartridges are used.

2. **Electronic Simulator**

2.1 Used for instrument failure or maintenance, the electronic simulator is stored in the laboratory

2.2 Store at room temperature and protect contact pads from contamination by replacing the plastic cap and placing the Electronic Simulator in its protective case after use.

3. **Controls**

3.1 **i-STAT TRI Controls for blood gases, electrolytes, and chemistries**

3.1.1 Store at 2 to 8°C (35° to 46°F) good until manufacturers expiration date

3.1.2 Warm to room temperature (follow directions) prior to using.

3.1.3 Controls may be stored at room temperature (18 to 30°C or 64 to 86°F) for five days.

3.1.4 Date when taken out of refrigerator with new expiration

3.1.5 Do not use after expiration date on the box and ampules.

3.2 **i-STAT Controls for ACT**

3.2.1 Store at 2 to 8°C (35° to 46°F)

3.2.2 Do not use after expiration date on the box and vials.

3.2.3 Controls should be warmed to room temperature (for up to 4 hrs) before reconstitution, test immediately after reconstitution.

3.3 **i-STAT Controls for cTnl and BNP**

3.3.1 Store unopened @ 2 to 8°C (35° to 46°F) until the manufacturer expiration date on vial label.

3.3.2 Once opened, vials are stable for 30 days when stored tightly capped @ 2 to 8°C (35° to 46°F). Date with new room temperature expiration date.

3.4 **Eurotrol GAS-ISE-HCT QC / CueSee VeriSTAT**

3.4.1 One vial measures pH, gases, electrolytes, metabolites, and hematocrit in a single ampule

3.4.2 Shelf life refrigerated (2 to 8°C) for 25 months

4.10.4.3 Ampules are stable at room temperature for 10 days unopened. Date with new expiration date for room temperature

4.10.4.4 Warm to room temperature for a minimum of 1 hour prior to opening. Do not put ampules back into the refrigerator once exposed to room temperature.

4.10.4.5 After opening the vials, the product is stable for 30 sec for ABG’s
PERFORMANCE SPECIFICATIONS AND METHOD LIMITATIONS:
1. Reportable Range, UOM, Technical Limits, Panic / Critical  See Table 3
2. Precision, Accuracy, Sensitivity  Refer to Abbott CTI sheets per analyte
3. Limitations  See Table 1
4. Cartridges and analyzers must be at room temperature.
5. Test specimen collection and sample application timing
   5.1 Samples for ACTk must be tested immediately after collection and collected in plastic syringes without anticoagulants
   5.2 Samples for blood gases or iCa must be tested within 10 minutes of collection and collected in completely filled lithium heparin tubes anticoagulated tubes or syringes with balanced heparin anticoagulant filled to labeled capacity. Remix blood in tubes thoroughly before testing.
   5.3 Samples for electrolytes, glucose, or creatinine must be tested within 30 minutes of collection and collected in completely filled lithium heparin tubes or immediately without anticoagulated tubes. Remix blood in tubes thoroughly before testing.
   5.4 Samples for Troponin I must be tested within 30 minutes of collection and collected in completely filled lithium heparin tubes (green top). Remix blood in tubes thoroughly before testing.

| Table 1 | Potential Interfering Substances |

<table>
<thead>
<tr>
<th>ANALYTE</th>
<th>INTERFERENT</th>
<th>INTERFERENT CONCENTRATION</th>
<th>EFFECT ON ANALYTE RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Bromide</td>
<td>37.5 mmol/L</td>
<td>Increase (↑) Na by 5 mmol/L</td>
</tr>
<tr>
<td>Ionized Calcium</td>
<td>Acetaminophen</td>
<td>1.32 mmol/L</td>
<td>Decrease (↓) iCa</td>
</tr>
<tr>
<td></td>
<td>Magnesium</td>
<td>1.0 mmol/L</td>
<td>Increase (↑) iCa by 0.04 mmol/L</td>
</tr>
<tr>
<td></td>
<td>Acetylcysteine</td>
<td>10.2 mmol/L</td>
<td>Decrease (↓) iCa</td>
</tr>
<tr>
<td></td>
<td>Bromide</td>
<td>37.5 mmol/L</td>
<td>Increase (↑) iCa</td>
</tr>
<tr>
<td></td>
<td>Lactate</td>
<td>6.6 mmol/L</td>
<td>Decrease (↓) iCa by 0.07 mmol/L</td>
</tr>
<tr>
<td></td>
<td>Salicylate therapeutic</td>
<td>0.5 mmol/L</td>
<td>Decrease (↓) iCa by 0.03 mmol/L</td>
</tr>
<tr>
<td></td>
<td>Salicylate</td>
<td>4.34 mmol/L</td>
<td>Decrease (↓) iCa</td>
</tr>
<tr>
<td>ANALYTE</td>
<td>INTERFERENT</td>
<td>INTERFERENT CONCENTRATION</td>
<td>EFFECT ON ANALYTE RESULT</td>
</tr>
<tr>
<td>-----------------</td>
<td>---------------------</td>
<td>---------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Glucose (Cartridge)</td>
<td>Acetaminophen</td>
<td>10.2 mmol/L</td>
<td>Decrease (↓) glucose</td>
</tr>
<tr>
<td></td>
<td>Bromide</td>
<td>37.5 mmol/L</td>
<td>Decrease (↓) glucose</td>
</tr>
<tr>
<td></td>
<td>Bromide therupetic</td>
<td>2.5 mmol/L</td>
<td>Decrease (↓) glucose by 5 mg/dL</td>
</tr>
<tr>
<td>pH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxygen</td>
<td></td>
<td>pH: per 0.1 pH units below 7.4 @ 37°C</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>pH: per 0.1 pH units above 7.4 @ 37°C</td>
<td></td>
</tr>
<tr>
<td>Hydroxyurea</td>
<td></td>
<td>0.92 mmol/L</td>
<td></td>
</tr>
<tr>
<td>Thiocyanate</td>
<td></td>
<td>6.9 mmol/L</td>
<td></td>
</tr>
<tr>
<td>Glucose</td>
<td></td>
<td></td>
<td>Decrease (↓) glucose by 0.9 mg/dL (0.05 mmol/L)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Increase (↑) glucose by 0.8 mg/dL (0.04 mmol/L)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>May decrease (↓) glucose</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Increase (↑) glucose</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Decrease (↓) glucose by approx. 7 mg/dL</td>
</tr>
<tr>
<td>Creatinine</td>
<td>Acetaminophen</td>
<td>1.32 mmol/L</td>
<td>Increase (↑) creatinine</td>
</tr>
<tr>
<td></td>
<td>Ascorbate</td>
<td>0.34 mmol/L</td>
<td>Increase (↑) creatinine by 0.3 mg/dL</td>
</tr>
<tr>
<td></td>
<td>Bromide</td>
<td>37.5 mmol/L</td>
<td>Increase (↑) creatinine</td>
</tr>
<tr>
<td>PCO₂</td>
<td></td>
<td>Above 40 mmHg</td>
<td>Increase (↑) creatinine by 6.9% per 10 mmHg PCO₂</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Below 40 mmHg</td>
<td>Decrease (↓) creatinine by 6.9% per 10 mmHg PCO₂</td>
</tr>
<tr>
<td>PCO₂</td>
<td></td>
<td>Above 40 mmHg</td>
<td>Decrease (↓) creatinine by 3.7% per 10 mmHg PCO₂</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Below 40 mmHg</td>
<td>Increase (↑) creatinine by 3.7% per 10 mmHg PCO₂</td>
</tr>
<tr>
<td>Hydroxyurea</td>
<td></td>
<td>0.92 mmol/L</td>
<td>Increase (↑) creatinine, use another method</td>
</tr>
<tr>
<td>Acetylcysteine</td>
<td></td>
<td>10.2 mmol/L</td>
<td>Increase (↑) creatinine</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>White Blood Count (WBC)</td>
<td>Greater than 50,000 WBC/μL</td>
<td>May Increase (↑) hematocrit</td>
</tr>
<tr>
<td></td>
<td>Total Protein</td>
<td>For measured Hct&lt;40%</td>
<td>Decrease (↓) Hct by 1% PCV</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For each g/dL below 6.5</td>
<td>Increase (↑) Hct by 1% PCV</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For each g/dL above 8.0</td>
<td>Increase (↑) Hct by 0.75% PCV</td>
</tr>
<tr>
<td>Lipids</td>
<td></td>
<td>Abnormally high</td>
<td>Increase (↑) Hct</td>
</tr>
</tbody>
</table>
Diprivan is a registered trademark of the AstraZeneca group of companies.

### SPECIMEN REQUIREMENTS:

1. **Always wear gloves and proper PPE when collecting and testing blood samples.**
2. **Always properly identify patients before collections**
   2.1 All specimens must be properly labeled with the patient full name, MR#, Account#, the date and time of collection, and the initials of the collector (units may use chart labels with collection information noted)
3. **In-Dwelling Line**
   3.1 Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: five to six times the volume of the catheter, connectors, and needle.
   3.2 If collecting sample for ACT, clear the line first with 5mL saline and discard the first 5mL of blood.
4. **Arterial Specimens**
   4.1 For cartridge testing of blood gases, electrolytes, chemistries, and hematocrit, fill a plain syringe or fill a blood gas syringe, labeled for the assays to be performed, to the recommended capacity, or use the least amount of liquid heparin anticoagulant that will prevent clotting.
   4.2 Under-filling syringes containing liquid heparin will decrease results due to dilution and will decrease ionized calcium results due to binding.
   4.3 For ionized calcium, balanced or low volume heparin blood gas syringes should be used.
   4.4 Do not expose sample to air or PCO₂ may decrease, pH may increase and PO₂ may decrease if the value is above or increase if the value is below the PO₂ of room air (approximately 150 mmHg).
   4.5 For cartridge testing of ACT, use only a plain, plastic syringe without anticoagulant.
   4.6 Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds. Discard the first two drops of blood.

### Table: Analyte Interference

<table>
<thead>
<tr>
<th></th>
<th>Interferent</th>
<th>Interferent Concentration</th>
<th>Effect on Analyte Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celite ACT</td>
<td>Aprotinin</td>
<td></td>
<td>Falsely extends Celite ACT times</td>
</tr>
<tr>
<td>PCO₂</td>
<td>Propofol (Diprovàn[^])</td>
<td></td>
<td>For patients administered propofol or thiopental sodium, i-STAT recommends the use of G3+, CG4+, CG8+, EG6+, and EG7+ cartridges, which are free from clinically significant interference at all relevant therapeutic doses. i-STAT does not recommend the use of EC8+ cartridges for patients receiving propofol or thiopental sodium.</td>
</tr>
</tbody>
</table>
4.7 For blood gas testing, avoid or remove immediately any air drawn into syringe to maintain anaerobic conditions.

4.8 Test samples collected without anticoagulant immediately.

4.9 Test samples for ACT, PT/INR and lactate immediately.

4.10 For pH, blood gases, TCO₂ and ionized calcium, test within 10 minutes of collection. If not tested immediately, remix the sample and discard the first two drops of blood from a syringe before testing. Note that it may be difficult to properly remix a sample in a 1.0 cc syringe.

4.11 For other cartridge tests, test sample within 30 minutes of collection.

5. **Venous Specimens**

5.1 For cartridge testing of electrolytes, chemistries, and hematocrit, collect sample into an evacuated blood collection tube or a syringe containing lithium, or balanced heparin anticoagulant.

5.2 For ionized calcium measurements, balanced heparin or 10 U of lithium heparin/mL of blood is recommended. Fill tubes to capacity; fill syringes for correct heparin-to-blood ratio. Incomplete filling causes higher heparin-to-blood ratio, which will decrease ionized calcium results and may affect other results. The use of partial – draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended for blood gas or CHEM8+ cartridges because of the potential for decreased PCO₂, HCO₃ and TCO₂ values.

5.3 For cartridge testing of ACT, use only a plain, plastic syringe or collection tube containing no anticoagulant. Use a plastic capillary tube, pipette, or syringe to transfer sample from a tube to a cartridge.

5.4 Mix blood and anticoagulant by inverting a tube gently at least ten times. Roll a syringe vigorously between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Note that it may be difficult to properly mix a sample in a 1 cc syringe.

5.5 Test Sample collected without anticoagulant immediately.

5.6 Test samples for ACT, and lactate PT/INR immediately.

5.7 Test samples for pH, PCO₂, TCO₂ and ionized calcium within 10 minutes of sample draw. If not tested immediately, remix the sample before testing and discard the first two drops of blood from a syringe before testing.

5.8 For other cartridge tests, test sample within 30 minutes of collection.

6. **Capillary Collections**

6.1 Direct application from capillary collections is not acceptable

6.2 Use either plastic heparinized capillary collection tubes or collect in a green heparinized microtainer for transfer to i-STAT cartridge

6.3 Test capillary samples immediately after collection

7. **Specimen Rejection Criteria DO NOT USE:**

7.1 Evidence of clotting – DO NOT USE

7.2 Specimens collected in vacuum tubes with anticoagulant other than lithium or sodium heparin

7.3 Specimens for ACT collected in glass syringes or tubes or with anticoagulant of any kind
7.4 Syringe for pH, $PCO_2$, $PO_2$ and $TCO_2$ with air bubbles in sample

7.5 Incompletely filled vacuum tube for the measurement of ionized calcium, $PCO_2$, $HCO_3$ or $TCO_2$

7.6 Other sample types such as urine, CSF, and pleural fluid

7.7 Avoid collections with the following:

7.7.1 Drawing a specimen from an arm with an I.V.

7.7.2 Stasis (tourniquet left on longer than one minute before venipuncture)

7.7.3 Extra muscle activity (fist pumping)

7.7.4 Hemolysis (alcohol left over puncture site, or a traumatic draw)

7.7.5 Icing before filling cartridge

7.7.6 Time delays before filling cartridge, especially lactate, ACT, and PT/INR

7.7.7 Exposing the sample to air when measuring pH, $PCO_2$, $PO_2$ and $TCO_2$

8. Type of Container Additives

8.1 Cartridges for Blood Gas/Electrolytes/Chemistries/Hematocrit

8.1.1 Skin puncture: lancet and capillary collection tube (plain, lithium heparin, or balanced for electrolytes and blood gases)

8.1.2 Venipuncture: lithium heparin collection tubes and disposable transfer device (e.g., 1cc syringe and a 16 to 20 gauge needle).

8.1.3 Arterial puncture: Plain syringe or blood gas syringe with heparin and labeled for the assays performed or with the least amount of heparin to prevent clotting (10 U heparin/mL of blood)

8.1.4 Fresh whole blood collected in a plain capillary collection tube or capillary collection tube with balanced heparin.

8.1.5 Fresh whole blood collected in a collection tube with lithium heparin anticoagulant. Fill collection tubes to capacity.

8.1.6 Fresh whole blood collected in a plain plastic syringe or in a blood gas syringe labeled for the assays to be performed. Fill syringes for correct blood-to-heparin ratio.

8.2 Cartridges for ACT

8.2.1 Skin puncture/ capillary samples are not acceptable

8.2.2 Venipuncture and arterial puncture: plain plastic syringe without anticoagulant

8.2.3 Fresh whole blood without anticoagulant collected in a plastic syringe. If from an indwelling line, flush the line with 5mL saline and discard the first 5mL of blood or three to six dead space volumes of the catheter.

8.2.4 Fresh whole blood collected in a plastic tube without anticoagulant, clot activators, or serum separators. Device used to transfer sample to cartridge must be plastic.

8.3 Cartridges for Troponin I/ cTnI and CK-MB

8.3.1 Skin puncture/ capillary samples are not acceptable

8.3.2 Venipuncture: lithium heparin collection tubes and disposable transfer device (e.g. 1 cc syringe and a 16 to 20 gauge needle).

8.3.3 Fresh heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium heparin. Collection tubes must be filled at least half full.
MAINTENANCE:
1. Instruments must be kept clean and free of body fluids. Check i-STAT for damage or blood before each use. Contact POC lab if instrument is damaged
2. Clean when soiled, always over a counter or surface, and
   2.1 Clean between each patient
   2.2 Clean with alcohol (preferably not on rubber) or Cavicide cleaner
   2.3 Turn off instrument before cleaning
   2.4 Do not use straight bleach or hydrogen peroxide based cleaners.
   2.5 Do not get moisture into the instrument
   2.6 Exercise standard safety precautions at all times when handling the analyzer, cartridges, and peripherals to prevent exposure to blood-borne pathogens.
   2.7 The analyzer is NOT designed to be sterilized or autoclaved by any method, including those using gas, (e.g. steam, ethylene oxide, etc.) high heat, bead, radiation, or other chemical processes. The analyzer is splash resistant, but should not be immersed in any liquids.
   2.8 If the analyzer is placed on a wet surface or if any liquid is spilled onto it, dry the analyzer immediately. If liquid enters the compartments, the analyzer may be damaged
3. Daily Maintenance
   3.1 Internal Electronic Simulator will be run at least every 8 hrs of instrument use
   3.2 Instruments should be downloaded at a minimum
      3.2.1 Daily, or
      3.2.2 After every patient test, or
      3.2.3 After every patient surgery case
4. Monthly Maintenance
   4.1 All instruments will all have appropriate liquid QC run
5. 6 Months Maintenance
   5.1 CLEW updates as dictated by Abbott and laboratory
   5.2 External Electronic Simulator, Thermal Probe
   5.3 Liquid QC will be run after updating
   5.4 Calibration Verification (3 levels) will be run after updating
   5.5 Semiannual comparisons
6. As needed Maintenance
   6.1 Placing the i-STAT in a downloader/recharger will automatically initiate recharging of the rechargeable battery. Use only i-STAT rechargeable batteries
      6.1.1 The indicator light on top of the downloader/recharger will be green (trickle charge), red (fast charge) or blinking red (fast charge pending)
      6.1.2 Exchange rechargeable batteries from the downloader to the instrument, replacing the spent battery in the downloader
      6.1.3 Placing a rechargeable battery in the recharging compartment on the downloader will initiate a trickle recharge as indicated by green indicator light
6.3 Use of wireless i-STAT will result in a 30% reduction in the life of the battery (in terms of cartridge usage) due to wireless downloads
6.4 External Electronic Simulator for troubleshooting
6.5 Other troubleshooting procedures as recommended by Abbott

7. Proficiency Testing
7.1 According to lab Guideline Proficiency Testing PGR, per analyte

8. Installing the battery pack, note the orientation labels
8.1 Install rechargeable battery pack with the large centrally located red dot facing the front of the i-STAT
8.2 Install rechargeable battery pack with the small off center red dot located to the bottom left of the downloader (make sure that the pack is locked into position)

CALIBRATION PROCEDURES:
1. For cartridges, calibration is automatically performed as part of the test cycle on each cartridge type, except coagulation and immunoassay cartridges. Operator intervention is not necessary.
2. Laboratory will perform validation for all new i-STAT instruments before being placed into use according to Abbott validation procedures. (see i-STAT Management PGR)
3. Laboratory will perform semi-annual correlation studies for all i-STAT instruments in use where applicable
4. External Electronic Simulator will be used by the laboratory for troubleshooting problems
5. CLEW updates as dictated by Abbott
6. Calibration Verifications (3 levels) semi annual

QUALITY CONTROL PROCEDURES:
1. Daily Procedures - Analyzer Verification
   1.1 Verify the performance of each handheld analyzer or Blood Analysis Module in the i-STAT System using the internal electronic simulator at a minimum every 24 or 8 hours of use, or as needed for regulatory compliance
   1.2 Verification using the internal electronic simulator is required every 8 hours for blood gases, hematocrit, ACT, cTnI.
   1.3 Note: If the internal Electronic Simulator is used, the “PASS” message will not be displayed on the analyzer screen.
   1.4 The “PASS” record will appear in the analyzer’s stored results for transmission to the system.
2. Daily refrigerator check:
   2.1 All locations storing iSTAT Cartridges in the refrigerator will verify the refrigerator storage temperature daily and follow Laboratory Guideline POC Testing and Laboratory Guideline for Temperature Dependent Equipment for temperature requirements
   2.2 Refrigerator temperatures must be maintained at 2 to 8 degrees C (35 to 46 degrees F)
   2.3 If the temperature is outside the range of 2 to 8°C (35 to 46°F), quarantine the cartridges in the storage refrigerator.
      2.3.1 Notify the i-STAT POC tech immediately.
      2.3.2 DO NOT USE the cartridges from refrigerator.
2.3.3 Record the temperature failure on Log along with the action taken.

3. **New shipment of cartridges:**
   3.1 Verify that the transit temperature was satisfactory using the four window temperature indicator strip.
      3.1.1 Write ok in the appropriate block matching temperature window to column.
      3.1.2 Enter the date and time received. Initial
      3.1.3 Temperature records will be kept on site for 2 years.
      3.1.4 Cartridges from each lot number received should be tested using
      3.1.4.1 Minimum of 2 levels of liquid QC, or as appropriate

3.2 Units will be required to sign out reagents obtained from the lab to track inventory

4. **Monthly quality control (liquid QC):**
   4.1 All i-STAT testing locations will participate in performing quality control using liquid controls monthly by the users for each i-STAT.
   4.2 Liquid QC will be rotated among users in each area
   4.3 All cartridge types will be included in the monthly quality control check.

5. **Performing i-STAT quality control using liquid quality control** (Performed by testing personnel)
   5.1 Handle all control products using the same safety precautions used when handling any infectious material.
   5.2 Controls should be removed from the refrigerator along with iSTAT cartridges to be tested and brought to room temperature.
   5.3 For CG8+ (containing ICa) the contents of one ampule must be used immediately to fill cartridges, i.e. multiple instruments, or a separate ampule will be required.
   5.4 Ampules for testing ABG’s and Chem must stand at room temperature for at least 1 hour before use (or according to manufacturer instructions)
   5.5 For CG8+ immediately before use, shake the ampule vigorously for 5-10 seconds to equilibrate the liquid and gas phases, holding the ampule at the tip and bottom with forfinger and thumb to minimize increasing the temperature of the solution.
   5.6 For ACT LQC warm to room temperature for at least 45 minutes. Pour entire contents of calcium chloride vial into the lyophilized plasma vial and replace stopper. Allow reconstituted vial to sit for 1 minute, mix by swirling gently for 1 minute, and then invert slowly for 30 seconds. Test within 30 seconds of completed processing.
   5.7 For cTnI LQC, remove vials from refrigerator and bring to room temperature for 15 minutes. Mix completely by swirling contents and avoiding foaming.
   5.8 For Eurotrol LQC allow the ampule to equilibrate at room temperature for at least 1 hour prior to use. (ampules are stable for 10 days at room temp unopened). Shake vigorously for at least 15 seconds to re-equilibrate the gases (thumb and forefinger hold). Pop top carefully and load cartridge within 30 seconds (for gases).
   5.9 Point of Care will distribute the quality control material LQC to be tested to the units.
      5.9.1 Turn iSTAT on.
      5.9.2 Press menu.
      5.9.3 Press 3, Quality Test.
5.9.4 Press 1, Control.
5.9.5 Scan or enter operator ID.
5.9.6 Enter control Lot #, press enter.
5.9.7 Enter cartridge Lot #, by scanning barcode on package.
5.9.8 Immediately before use, shake the control ampule vigorously for 5 to 10 seconds for ABG, Chem testing
  5.9.8.1 To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution.
5.9.9 Protect fingers w/ gauze, tissue, protective sleeve and gloves to snap off ampule neck
5.9.10 Use a syringe or pipette to immediately transfer solution to cartridge
5.9.11 Immediately seal the cartridge and insert it into the analyzer.
5.9.12 Do not remove cartridge when locked message is displayed
5.9.13 When results display, compare the result to the allowable ranges VAS (provided by laboratory Point of Care staff)
5.9.14 Results that exceed the target values must be repeated.
  5.9.14.1 Obtain a new vial of QC material and repeat QC steps
  5.9.14.2 If QC fails again, notify Point of Care immediately.
  5.9.14.3 No testing can be performed on the iSTAT until troubleshooting is done.

5.10 Troubleshooting out-of-range results, Verify that the following conditions are met, and then repeat the test.
5.10.1 The correct expected values insert is being used, and the correct cartridge type and lot number listing is being used.
5.10.2 Expiration date printed on the cartridge pouch and control ampule or vial have not been exceeded.
5.10.3 Room temperature date for cartridge and control has not been exceeded.
5.10.4 Cartridge and control have been stored correctly.
5.10.5 The control material has been handled correctly.
5.10.6 The analyzer being used passes the electronic simulator test.
5.10.7 If the results are still out of range, repeat the test using a new box of control solutions and cartridges.
5.10.8 If the results are still out, call Point of Care; and someone will call Abbott Support Services.

PROCEDURE STEPS:
1. **Patient Testing** (other than Troponin I/cTnI)
  1.1 An individual cartridge may be used after standing 5 minutes, in its pouch, at room temperature. An entire box should stand at room temperature for one hour before cartridges are used.
  1.2 Turn the analyzer on and press 2 for i-STAT Cartridge.
  1.3 Scan or enter the operator ID
  1.4 Scan or enter the patient ID. Repeat if prompted.
  1.5 Scan Cartridge Lot number from the cartridge portion pack.
1.6 Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge. **Hold the cartridge only by the long sides!**

1.7 Following thorough mixing of the properly labeled sample, direct the dispensing tip or device containing the blood into the sample well.

1.7.1 Dispense the sample until it reaches the fill mark on the cartridge and the well is about half full.

1.7.2 Avoid exposing sample to air when testing venous blood for ICA and pH.

1.7.3 A full vacutainer must be drawn for the ionized calcium and pH. Partial draws are not acceptable specimens for testing ICA and pH.

1.8 Close the cover over the sample well until it snaps into place. (Do **not** press over the sample well.)

1.9 Insert the cartridge into the cartridge port on the analyzer until it clicks into place.

1.9.1 Message will appear that states “Identifying Cartridge”

1.9.2 When using an ACT cartridge, the analyzer must remain horizontal during the testing cycle.

1.10 Choose the number corresponding to the type of sample used when prompted at the Sample Type field, this must be entered to obtain results

1.10.1 1-Arterial

1.10.2 2-Venous

1.10.3 3-Capillary

1.11 Never attempt to remove a cartridge while the LCK or “Cartridge Locked” message is displayed. This will damage the i-STAT

1.12 Instrument automatically corrects for CBP.

1.13 Press the → key to return to the results page.

1.14 View results shown on the analyzer’s display screen.

1.15 Enter Comment Code if prompted.

1.16 Remove the cartridge after “Cartridge Locked” message disappears. The analyzer is ready for the next test immediately.

2. **Patient Testing** (Troponin)

2.1 Only acceptable sample is a properly labeled green top (Li Heparin) tube that is properly filled, not clotted, and well mixed

2.1.1 Retain green top tubes in the ER area until the second i-STAT Troponin has been performed

2.2 The i-STAT cTnI cartridges can only be used with the i-STAT1 Analyzer bearing the symbol. This symbol is located on the grey casing next to the lower right corner of the analyzer display screen. Before testing cTnI cartridges on the i-STAT 1 Analyzer, the analyzer must be customized through the software systems by the

2.2.1 Cartridge Information Required & Cartridge Lot Number Required, or

2.2.2 Cartridge Barcode Required.

2.3 Press the On/Off key to turn analyzer on.

2.4 Press 2 for i-STAT Cartridge from the Test Menu.

2.5 Scan or Enter Operator ID.

2.6 Scan or Enter Patient ID. Repeat if prompted.

2.7 Scan Cartridge Lot number from the cartridge portion pack.
2.8 Remove cartridge from portion pack.
2.8.1 Handle the cartridge by its edges.
2.8.2 Avoid touching the contact pads or exerting pressure over the center of the cartridge.
2.9 Following thorough mixing of the properly labeled sample, discard 1-2 drops whole blood from the delivery device to clear unseen bubbles. Hang drop(s) slightly larger than the round “target well”. Touch the drop to the well allowing cartridge to draw sample in. **Do NOT** load cartridge with a needle.

2.10 Close the cTnI cartridge:
2.10.1 First anchor the cartridge in place by using the thumb and index finger of one hand to grasp the cartridge from its side edges away from the sample inlet.
2.10.2 Use the thumb of the other hand to slide the plastic closure clip to the right until it locks into place over the sample well.
2.10.3 Note: When sliding the closure clip, the index finger of that same hand **should not be placed directly across from the thumb**, as this could result in the sample being pushed onto the user’s glove. This index finger should be placed just above the position of the sliding clip during closure or not at all.

2.11 Insert cartridge into cartridge port. Grasp the cartridge “slide cover” between your first finger and thumb, using the thumb recess. Hold the analyzer in place with one hand. With the other gently guide the cartridge into the analyzer, releasing the cartridge **only after it is fully inserted**.

2.11.1 The analyzer must remain on a level surface with the display facing up during testing. **Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.**
2.11.2 Do not move the i-STAT while testing is engaged
2.11.3 You may place i-STAT in the docking station while testing is running (after initiation) and results will auto download when completed

2.12 Choose the number corresponding to the type of sample used when prompted at the Sample Type field
2.12.1 1-Arterial
2.12.2 2-Venous
2.12.3 3-Capillary

2.13 The Time to Results countdown bar will then be displayed. Once time has elapsed, view results on analyzer’s display.
2.14 Remove cartridge after Cartridge Locked message disappears. The analyzer is ready for the next test immediately.

**Cartridge redesign features**

**Old Design**

- Cart and fill well
- Fill line indicator
- Sample latch design
- Thumbwell hold for easier handling and removal

**New Design**

- Cart and fill well
- Fill line indicator
- Sample latch design
- Thumbwell hold for easier handling and removal
RESULTS REPORTING:

1. **Calculations:** The i-STAT handheld contains a microprocessor that performs all calculations required for reporting results.

2. **Displayed Results:** Results are displayed numerically with their units.
   2.1 Electrolyte, chemistry and hematocrit results are also depicted as bar graphs with reference ranges marked under the graphs.

3. **Suppressed Results:** There are three conditions under which the i-STAT System will not display results:
   3.1 Results outside the System’s reportable ranges are flagged with a < or > or <> indicating that the result is below the lower limit or above the upper limit of the reportable range respectively. (See the table of Reportable Ranges.) The <> flag indicates that the results for this test were dependent on the result of a test flagged as either > or <.
   3.1.1 Action: Send specimen(s) to the laboratory for analysis, if necessary
   3.2 Cartridge results which are not reportable based on internal QC rejection criteria are flagged with *** (sensor errors or interfering substances)
   3.2.1 Action: Analyze the specimen again using a fresh sample and another cartridge. If the result is suppressed again, send specimen(s) to the laboratory for analysis in accordance with the Laboratory Procedure Manual.
   3.3 A Quality Check message will be reported instead of results if the handheld detects a problem with the sample, calibrator solution, sensors, or mechanical or electrical functions of the handheld during the test cycle.
   3.3.1 Action: Take the action displayed with the message that identifies the problem. Refer to the i-STAT or i-STAT 1 System Manual’s Troubleshooting if needed
   3.4 Results that are above or below the action ranges are flagged with up or down arrows.
   3.4.1 Validate test results by either repeating or confirming clinically
   3.4.2 Enter appropriate comment code (required) 12 Physician Notified
   3.4.3 Send testing to the lab when appropriate, always match results to patient clinical conditions. Perform lab testing on any questionable results

REFERENCE INTERVALS:

**See Table 3**

CRITICAL AND ALERT VALUES:

**See Table 3**

1. Critical results are test results that fall outside high and low critical limits that define the boundaries of life-threatening values for a test. Critical results represent an emergency condition and must be reported immediately to the patient’s attending physician or nurse.
   1.1 Critical Panic results notifications must be documented in EMR with appropriate information including patient ID, operator ID, date time, provider, test, result, and read back if notification is phoned to provider

2. Test results considered as Panics, will display an up arrow for increased results and down arrow for decreased test results.
2.1 It is always good laboratory practice to verify Panic values by repeat testing before treatment is administered or clinical correlation.

3. If the results obtained on the iSTAT are questioned for any reason a second sample should be drawn (draw enough to fill tubes to send to the Laboratory if necessary) and a repeat test done on the iSTAT.

3.1 Send sample to the lab if i-STAT results are still questionable

3.2 Should the results still be questioned order the appropriate Laboratory test in Cerner.

4. ENTER COMMENT CODE 1 REPEAT TEST. Unit must notify the POC Coordinator if tests should be credited and reasons noted

5. Star outs **** indicate the electronic sensors were compromised. Obtain a new sample and perform the test again.

6. Tests that show the < or > are outside the cartridge reportable range. These tests may need to be verified by having the test performed in the Laboratory.

7. A comment code corresponding to the action taken when panic results are obtained will be requested by the i-STAT. You will not be able to perform another test on the i-STAT until the comment code is entered. Enter the number corresponding to the action taken:

7.1 0 - No Action Required

7.2 1 - Repeat Test

7.3 2 - Procedure Error

7.4 12 - Dr. Notified (required entry for Panic results)

7.5 10 - Lab Verification Requested

8. Warning Message, if testing is disabled due to a warning message, the condition must be corrected and the analyzer must be turned off and back on again before testing is enabled.

8.1 Remove the cartridge after Cartridge-Locked message disappears

8.2 The i-STAT is ready to perform next test

Table 3  Analytes Reference Ranges, Panic Values, Technical Limits

<table>
<thead>
<tr>
<th>ANALYTE</th>
<th>UNIT</th>
<th>AGE RANGE</th>
<th>REFERENCE RANGE</th>
<th>PANIC RESULTS</th>
<th>REPORTABLE RANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>mmol/L</td>
<td>0-6 mos</td>
<td>131 - 142</td>
<td>≤ 125 - &gt;150</td>
<td>100 - 180</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;6 mos to adult</td>
<td>136 - 145</td>
<td>≤ 120 - &gt;160</td>
<td></td>
</tr>
<tr>
<td>Potassium</td>
<td>mmol/L</td>
<td>0-6 mos</td>
<td>3.2 – 6.2</td>
<td>≤ 2.5 - &gt;7.0</td>
<td>2.0 – 9.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;6 mos to adult</td>
<td>3.5 – 5.1</td>
<td>≤ 2.5 - &gt;6.5</td>
<td></td>
</tr>
<tr>
<td>Chloride</td>
<td>mmol/L</td>
<td></td>
<td>97 – 108</td>
<td></td>
<td>65 - 140</td>
</tr>
<tr>
<td>CO2</td>
<td>mmol/L</td>
<td>0-6 mos</td>
<td>13 – 21</td>
<td>≤ 10</td>
<td>5 - 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;6 mos to adult</td>
<td>14 - 32</td>
<td>≤ 10 - &gt;40</td>
<td></td>
</tr>
<tr>
<td>BUN</td>
<td></td>
<td>0-6 mos</td>
<td>1 – 16</td>
<td></td>
<td>0 - 140</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;6 mos to adult</td>
<td>4 - 21</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unit</td>
<td>0-6 mos</td>
<td>&gt;6 mos to adult</td>
<td>≥4.0</td>
<td>≥15.0</td>
</tr>
<tr>
<td>---------------</td>
<td>------------</td>
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<td>-----------------</td>
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<td>-------</td>
</tr>
<tr>
<td>Creatinine</td>
<td>mg/dL</td>
<td>0.1 – 0.8</td>
<td>0.6 – 1.3</td>
<td>≥4.0</td>
<td>≥15.0</td>
</tr>
<tr>
<td>GFR</td>
<td></td>
<td>&gt;60.0</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Glucose</td>
<td>mg/dL</td>
<td>70 – 99 fasting</td>
<td>≤40 - ≥201</td>
<td>≤40 - ≥500</td>
<td>20 - 700</td>
</tr>
<tr>
<td>Ionized Calcium</td>
<td>mmol/L</td>
<td>0.1 – 0.8</td>
<td>0.6 – 1.3</td>
<td>≥0.78 - ≥1.58</td>
<td>0.25 – 2.50</td>
</tr>
<tr>
<td>Troponin I</td>
<td>ng/mL</td>
<td>≤0.08</td>
<td>≥0.60</td>
<td>0.00 – 50.00</td>
<td></td>
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<tr>
<td>Hematocrit</td>
<td>%PCV</td>
<td>30.5 – 54.0</td>
<td>≤25 - ≥65</td>
<td>15 - 75</td>
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<tr>
<td>Hemoglobin</td>
<td>g/dL</td>
<td>10.0 – 19.1</td>
<td>0-1 mos &lt; 9.6</td>
<td>5.1 – 25.5</td>
<td></td>
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<tr>
<td>Kaolin ACT</td>
<td>seconds</td>
<td>82 – 152 (NONWRM)</td>
<td>50 - 1000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td></td>
<td>7.27 – 7.46</td>
<td>≤7.20 - ≥7.50</td>
<td>6.50 – 8.20</td>
<td></td>
</tr>
<tr>
<td>PCO₂</td>
<td>mmHg</td>
<td>32 - 48</td>
<td>≤25 - ≥70</td>
<td>5 - 130</td>
<td></td>
</tr>
<tr>
<td>PO₂</td>
<td>mmHg</td>
<td>45 - 100</td>
<td>≤40 - ≥140</td>
<td>5 - 800</td>
<td></td>
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<tr>
<td>TCO₂</td>
<td>mmol/L</td>
<td>22 - 26</td>
<td>≤11 - ≥40</td>
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<td></td>
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<tr>
<td>HCO₃</td>
<td>mmol/L</td>
<td>-2 to +2</td>
<td>95 - 101</td>
<td>≤85</td>
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</table>

LABORATORY INTERPRETATION: see Table 4
<table>
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<th>Analyte</th>
<th>Some Causes of Increased Values</th>
<th>Some Causes of Decreased Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>Dehydration</td>
<td>Dilutional hyponatremia (cirrhosis)</td>
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<tr>
<td></td>
<td>Diabetes insipidus</td>
<td>Depletional hyponatremia</td>
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<td></td>
<td>Salt poisoning</td>
<td>Syndrome of inappropriate ADH</td>
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<tr>
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<td>Skin losses</td>
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<tr>
<td></td>
<td>Hyperaldosteronism</td>
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<tr>
<td></td>
<td>CNS disorders</td>
<td></td>
</tr>
<tr>
<td>Potassium</td>
<td>Renal glomerular disease</td>
<td>Renal tubular disease</td>
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<tr>
<td></td>
<td>Adrenocortical insufficiency</td>
<td>Hyperaldosteronism</td>
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<tr>
<td></td>
<td>Diabetic Ketoacidosis (DKA)</td>
<td>Treatment of DKA</td>
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<td></td>
<td>Sepsis</td>
<td>Hyperinsulinism</td>
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<td><em>In vitro</em> hemolysis</td>
<td>Metabolic alkalosis</td>
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<td>Diuretic therapy</td>
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<td>Ionized Calcium</td>
<td>Dehydration</td>
<td>Hypoparathyroidism</td>
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<td>Hyperparathyroidism</td>
<td>Early neonatal hypocalcemia</td>
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<td>Malignancies</td>
<td>Chronic renal disease</td>
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<td>Immobilization</td>
<td>Pancreatitis</td>
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<td>Thiazide diuretics</td>
<td>Massive blood transfusions</td>
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<td>Vitamin D intoxication</td>
<td>Severe malnutrition</td>
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<td>Glucose</td>
<td>Diabetes mellitus</td>
<td>Insulinoma</td>
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<tr>
<td></td>
<td>Pancreatitis</td>
<td>Adrenocortical insufficiency</td>
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<td>Endocrine disorders (e.g. Cushing’s syndrome)</td>
<td>Hypopituitarism/Massive liver disease</td>
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<td>Drugs (e.g. steroids, thyrotoxicosis)</td>
<td>Ethanol ingestion/Reactive hypoglycemia</td>
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<td>Chronic renal failure</td>
<td>Glycogen storage disease</td>
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<td>Stress</td>
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<td>IV glucose infusion</td>
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<td>Creatinine</td>
<td>Impaired renal function</td>
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<td>pH</td>
<td>Respiratory alkalosis</td>
<td>Respiratory acidosis</td>
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<td></td>
<td>Metabolic alkalosis</td>
<td>Metabolic acidosis</td>
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<tr>
<td>PCO₂</td>
<td>Acute Respiratory Acidosis:</td>
<td>Respiratory alkalosis:</td>
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<tr>
<td></td>
<td>* Depression of respiratory center</td>
<td>* Increased stimulation of respiratory center</td>
</tr>
<tr>
<td></td>
<td>* Suppressed neuromuscular system</td>
<td>* Hypermetabolic states</td>
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<td>* Pulmonary disorders</td>
<td>* Mechanical hyperventilation</td>
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<td>Chronic respiratory acidosis</td>
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<td></td>
<td>* Decreased alveolar ventilation</td>
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<td></td>
<td>* Hypoventilation</td>
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<tr>
<td>Analyte</td>
<td>Some Causes of Increased Values</td>
<td>Some Causes of Decreased Values</td>
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<tr>
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<td>Compensation in metabolic alkalosis</td>
<td>Carbon-monoxide exposure</td>
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<td>$PO_2$</td>
<td>Breathing oxygen-enriched air</td>
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<td></td>
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<td>Myocardial infarction</td>
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<tr>
<td></td>
<td></td>
<td>Congestive heart failure</td>
</tr>
<tr>
<td>$HCO_3$ and $TCO_2$</td>
<td>Primary metabolic alkalosis</td>
<td>Primary metabolic acidosis</td>
</tr>
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<td></td>
<td>Primary respiratory acidosis</td>
<td>Primary respiratory acidosis</td>
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<td>Hematocrit</td>
<td>Dehydration</td>
<td>Hemolytic anemias</td>
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<tr>
<td></td>
<td>Burns</td>
<td>Iron deficiency</td>
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<tr>
<td></td>
<td>Impaired ventilation</td>
<td>Marrow depression</td>
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<tr>
<td></td>
<td>Renal disorders</td>
<td>Blood loss</td>
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<tr>
<td>ACT Kaolin</td>
<td>Administration of heparin for medical or surgical procedures.</td>
<td></td>
</tr>
<tr>
<td>cTnl</td>
<td>Myocardial Infarction</td>
<td>Rare antibodies to troponin or its circulating complexes</td>
</tr>
<tr>
<td></td>
<td>Coronary vasospasm</td>
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<tr>
<td></td>
<td>Cardiac contusion/trauma</td>
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<tr>
<td></td>
<td>Rhythm disturbance (SVT, AF)</td>
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<tr>
<td></td>
<td>Chemotherapy (ex. Adriamycin)</td>
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<tr>
<td></td>
<td>Myocarditis/pericarditis</td>
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<tr>
<td></td>
<td>Infiltrative diseases (ex. Amyloidosis, sarcoidosis, hemochromatosis, connective tissue disease)</td>
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<tr>
<td></td>
<td>Congestive heart failure</td>
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<tr>
<td></td>
<td>Heart transplantation</td>
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<tr>
<td></td>
<td>Cardiac procedures (PTCA, DC cardioversion)</td>
<td></td>
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<tr>
<td></td>
<td>Intracranial hemorrhage/stroke</td>
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<tr>
<td></td>
<td>Pulmonary embolism</td>
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<td></td>
<td>Pulmonary hypertension</td>
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<td></td>
<td>Chronic renal insufficiency</td>
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<td></td>
<td>Sepsis</td>
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<td></td>
<td>Strenuous exercise</td>
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<tr>
<td></td>
<td>Certain drug ingestions</td>
<td></td>
</tr>
</tbody>
</table>

**ANALYZER TRANSMISSION/DOWNLOADING PROTOCOL:**

1. **Downloading i-STAT instruments** - Transmitting Results from the i-STAT 1 Analyzer to the Data Manager
   1.1 Place handheld in a Downloader or Downloader/Recharger.
   1.2 Do not move handheld while the message “Communication in Progress” is displayed.
   1.3 i-STAT instruments should remain in the downloaders when not in use.
1.4 Tests such as Troponins can be run while the i-STAT instrument is in the downloader, provided the instrument is placed in the downloader prior to the cartridge insertion.

1.5 Wireless i-STAT (blue face) have the ability to transmit results wirelessly, by operator prompt, or if wireless connections fail they can transmit through the downloaders.

1.5.1 Handheld must remain at least 20 cm (apprx 8 inches) from the body when the radio is ON. Radio is ON when:
1.5.1.1 the handheld is transmitting
1.5.1.2 the operator is using the Wireless Utility Menu
1.5.1.3 during the first 2 minutes following a testing cycle
1.5.1.4 When placed in a downloader/recharger the wireless i-STATs will attempt to download wirelessly first, and if unsuccessful the i-STAT will send results through the downloader automatically.

1.5.2 Operators may transmit results wirelessly to the data management system.
1.5.2.1 Directly following an individual test cycle using the Test Options Menu
1.5.2.2 When new test results appear on the display press “1” (Tests Options)
1.5.2.3 Press “4” (Transmit Data). A Waiting to Send message will appear on the screen
1.5.2.4 The “State” line will display a series of messages “Off” /“Booting” /“Joining” /“Associated” /“Connected”
1.5.2.5 Once the “Connected” state is reached, a “Communication in progress” display appears. When this message disappears and the display returns to the Test Menu, the transmission is successful.
1.5.2.6 On-demand using the Transmit Data menu
1.5.2.6.1 Press the “1” key
1.5.2.6.2 Press the menu key
1.5.2.6.3 Press the “6” key Transmit Data
1.5.2.6.4 Press a number key of the data you want to transmit
1.5.2.6.5 The same sequence of messages as above will display

1.5.3 If there are unsent results remaining in the wireless handheld at the completion of a transmission attempt, a “Communication Ended” message will appear on the display, and the number of unsent result

1.5.4 Users can expect a approximate 30% reduction in the life of the battery based on cartridge use due to the wireless downloads.

TROUBLESHOOTING: see Table 6
1. Do not open the instrument, or any other i-STAT product, or perform unauthorized procedure to resolve a problem.
2. The i-STAT performs a self-check when it is turned on. If a condition that should be corrected in the near future, but will not affect results, is detected, a warning is displayed. The operator should turn the i-STAT off and back on to attempt to resolve.
3. Contact the lab when if an i-STAT is dropped or damaged in any way.
3.1 Lab will check error codes for the instrument
3.2 Lab will perform CCC or other troubleshooting action as recommended
3.3 Lab will contact Abbott for troubleshooting recommendations
4. Error code listings can be found in the Technical Bulletin section of the Abbott i-STAT procedure manual

LIS ENTRY OF RESULTS:
1. i-STAT results transmit through the POC interface and report in Cerner with appropriate Reference Ranges
2. POC Laboratory can order and result tests manually in PathNet if necessary

<table>
<thead>
<tr>
<th>MESSAGE DISPLAY</th>
<th>EXPLANATION</th>
<th>ACTION / RESPONSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic Simulator Test required</td>
<td>Scheduled simulator test is due</td>
<td>Run External Electronic Simulator</td>
</tr>
<tr>
<td>Stored Memory Low</td>
<td>Memory space for 50 unsent test records available before “Stored Memory Full” message is displayed</td>
<td>Download i-STAT</td>
</tr>
<tr>
<td>Sored Memory Full</td>
<td>Memory for unsent records is full, potential for unsent records to be deleted</td>
<td>Download i-STAT</td>
</tr>
<tr>
<td>Upload required</td>
<td>Scheduled for uploading/downloading</td>
<td>Download i-STAT</td>
</tr>
<tr>
<td>Battery Low</td>
<td>Voltage dropped to 7.4 volts, enough for only a few more tests</td>
<td>Change or charge the rechargeable batteries</td>
</tr>
<tr>
<td>CLEW expiring</td>
<td>Message appears 15 days before software expires</td>
<td>Lab initiate CLEW update</td>
</tr>
<tr>
<td>Date invalid, check clock</td>
<td>Will not allow date that precedes or exceeds the 6 mos lifetime of the CLEW update</td>
<td>Download i-STAT, contact lab</td>
</tr>
<tr>
<td>Temperature out of range</td>
<td>Temperature internally in instrument is not acceptable</td>
<td>Check temperature of the i-STAT on the Administrative Menu. Warm or cool the instrument. Allow time for the instrument to equilibrate to the new temperature</td>
</tr>
<tr>
<td>Analyzer Interrupted, use another cartridges</td>
<td>Last cartridge run was not completed</td>
<td>Check battery pack for proper insertion, turn instrument on and off, check battery voltage</td>
</tr>
<tr>
<td>Cartridge Error</td>
<td>Multiple reasons including sample related, user, cartridge related, contacts, etc</td>
<td>Use another cartridge</td>
</tr>
<tr>
<td>Cartridge Preburst</td>
<td>Fluid reached sensors before they should have – potentially caused by</td>
<td>Use another cartridge</td>
</tr>
<tr>
<td>MESSAGE DISPLAY</td>
<td>EXPLANATION</td>
<td>ACTION / RESPONSE</td>
</tr>
<tr>
<td>------------------------------</td>
<td>--------------------------------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Sample positioned short of fill mark</td>
<td>Under filled cartridge</td>
<td>Use another cartridge</td>
</tr>
<tr>
<td>Sample positioned beyond fill mark</td>
<td>Overfilled cartridge</td>
<td></td>
</tr>
<tr>
<td>Insufficient sample</td>
<td>Insufficient sample or bubbles</td>
<td></td>
</tr>
<tr>
<td>Cartridge not inserted properly</td>
<td>Cartridge not pushed in all the way</td>
<td>Use another cartridge</td>
</tr>
<tr>
<td>Test cancelled by operator</td>
<td>No response made to mandatory prompt, instrument timed out</td>
<td>Retest, potentially retrain operator</td>
</tr>
<tr>
<td>Analyzer Error, use External Electronic Simulator</td>
<td>Usually recovers. Can be caused by angled insertion of cartridges or simulator</td>
<td>Run external Electronic Simulator properly</td>
</tr>
<tr>
<td>Analyzer Error</td>
<td>Mechanical or electrical failures</td>
<td>Use external Electronic Simulator twice, and run QC. If issue continues call support services @ Abbott</td>
</tr>
<tr>
<td>Cartridge type not recognized</td>
<td>Cartridge not compatible</td>
<td></td>
</tr>
<tr>
<td>No display, blank</td>
<td>Batteries dead, keypad not responding, internal start switch broken</td>
<td>Change or recharge batteries. If not resolved return to lab for repair or replacement</td>
</tr>
<tr>
<td>Cartridge locked, not removed</td>
<td>Mechanical issue or dead batteries</td>
<td>Change battery pack. Turn instrument off and back on. If cartridge is still not released, contact lab</td>
</tr>
</tbody>
</table>

REFERENCES:
4. Abbott Point of Care, [www.abbottpointofcare.com](http://www.abbottpointofcare.com)  CTI sheets per analyte

AUTHOR:
2. Revised Karen W. Sullivan, MT (ASCP) 9/24/2012
4. Revised Karen W. Sullivan, MT (ASCP) 8/14/2014
7. Revised Karen W. Sullivan, MT (ASCP) 1/23/2017