Procedure Manual

for the i-Stat® System

*This Procedure Manual is required by CLIA and laboratory accreditation bodies.
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I. Purpose and Principles: The i-Stat System incorporates components needed to perform blood analysis at the patient’s side. A portable handheld, a cartridge with the required tests, and 1 to 3 drops of blood will allow the caregiver to view quantitative results for tests commonly needed.

To perform a test, the operator fills a cartridge with sample, seals the cartridge with its closure, and inserts the cartridge into the handheld. The unit-use cartridge contains all components needed to perform the tests. The handheld automatically controls all steps in the testing cycle including: fluid movement, reagent mixing, calibration and temperature control. Quality checks are performed continuously throughout the testing cycle. When the test cycle is complete, results are displayed and the test record is stored. This degree of automation, along with the ability to test fresh whole blood, eliminates many sources of error as well as time-consuming and costly steps inherent in other methods.

II. Scope: This procedure is intended for those patient areas that have been tested, correlated, and approved for the use with the i-Stat system by the Aculabs medical director.

III. Personnel: This procedure is intended for use by personnel that have been trained, demonstrated competency, and have completed phlebotomy and i-Stat training; with the approved cartridges.

SYSTEM OVERVIEW

The System consists of the following primary components:

i-Stat 1

Analyzer
When a sample-filled i-Stat cartridge is inserted into the i-Stat 1 handheld for analysis, the handheld automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration and continuous quality monitoring.

Analysis Time
- Chem 8+ cartridges typically
- 120 to 200 seconds

Note Regarding System Reliability:
The i-Stat System automatically runs a comprehensive set of quality checks of handheld and cartridge performance each time a sample is tested. This internal quality system will suppress results if the handheld or cartridge does not meet certain internal specifications. To minimize the probability of delivering a result with medically significant error, the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the handheld or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions.
Cartridges
A single-use disposable cartridge contains microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber. Sensors for analysis of TCO₂, sodium, potassium, chloride, ionized calcium, glucose, creatinine, urea nitrogen (BUN) and hematocrit are available in a variety of panel configurations. A whole blood sample of approximately 1 to 3 drops is dispensed into the cartridge sample well, and the sample well is sealed before inserting it into the analyzer.

Aculabs Client Portal
Cartridge usage and efficiency reports will be generated for Aculabs management of the system.

The Aculabs Portal will be used for ordering patient tests and viewing results. Results viewed on the i-Stat analyzer should be treated as preliminary results. Aculabs in-house patient record correlation will be done with every cartridge patient test. These finalized results will then be viewable on the Aculabs.com portal. This process has been outlined in the Aculabs online order entry procedure manual.
SUPPLIES and STORAGE REQUIREMENTS

Cartridges
Aculabs will receive and maintain initial bulk lot shipments and the required QC involved in temperature management and shipment verifications.

Required Procedure for Handling New Cartridge:
1. Record temperature on “Receipt of New Cartridges” log found in this manual.
2. Aculabs will test cartridges with liquid control for every lot number in the shipment.

Required Procedure for Cartridge Storage
Cartridges are sealed in individual pouches or portion packs.

Refrigerated Storage
Store the main supply of cartridges at a temperature between 2 to 8°C (35 to 46°F). Do not allow cartridges to freeze. Refrigerated Cartridges may be used until the date shown on the 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. Check cartridges stored in the refrigerator monthly and record the results on the “Monthly Cartridge Check” log found in this manual.

Room Temperature Storage
Cartridges may be stored at room temperature (18 to 30°C or 64 to 86°F) for the time frame indicated on the cartridge box.

Cartridges should NOT
• Be returned to the refrigerator once they have been at room temperature
• Be exposed to temperatures above 30°C (86°F).
• Be used if the pouch has been punctured.
• Be used after the labeled expiration date.

Write the date, with a soft felt tip pen, on the cartridge box or individual cartridge pouches to indicate the room temperature expiration date. Cartridges should remain in pouches until time of use.

Controls

Liquid Controls
Aculabs will maintain storage logs and result records for liquid controls. These controls will be stored and logged within Abbott and CLIA required protocol. All new control documentation is to be kept in the i-Stat QC binder.

Electronic Simulator
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. Monthly reports are to be placed in the i-Stat QC binder.
BLOOD SPECIMENS

Blood Collection Equipment

Cartridges Chemistries/Hematocrit
- Venipuncture: lithium or sodium heparin collection tubes and disposable transfer device.

Blood Volume

See Table 1 below for cartridge volumes.

Table 1: Cartridge Panel Configurations and Blood Volume

<table>
<thead>
<tr>
<th>Cartridge</th>
<th>Vol.</th>
<th>Na</th>
<th>K</th>
<th>Cl</th>
<th>Ca</th>
<th>Glu</th>
<th>BUN</th>
<th>Creat</th>
<th>Hct</th>
<th>TCO₂</th>
<th>Anion Gap</th>
<th>Hb</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHEM8+</td>
<td>95</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>6+</td>
<td>65</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>EC4+</td>
<td>65</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
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<tr>
<td>G</td>
<td>65</td>
<td>*</td>
<td>*</td>
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<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Crea</td>
<td>65</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
</tbody>
</table>

Suitable Specimens (Chemistries and Hematocrit)
- Fresh whole blood collected in a collection tube with lithium or sodium heparin anticoagulant. Fill collection tubes to capacity.

Specimen Labeling

The specimen container must be labeled with the following information:
- Patient name, sex, age
- Patient ID number
- Time and date of collection
- Phlebotomist ID
- Doctor’s name

All of this information can be achieved through online order entry (OOE) of patient test. Print the generated requisition labels and label patients specimens; at the patient’s bedside, post collection.

Specimen Collection and Handling

Correct sample collection and handling are important for accurate results!
- Ensure that the individual collecting the sample is trained on proper blood collection techniques.
- If the sample is not tested immediately, ensure the tube is labeled properly with patient identifiers.

Venous Specimens

Collect sample into an evacuated blood collection tube with balanced heparin anticoagulant. Fill tubes to capacity; 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 CHEM8+ cartridges because of the potential for decreased TCO₂ values. Mix blood and anticoagulant by inverting a tube gently at least ten times.
Criteria For Specimen Rejection

- Evidence of clotting
- Specimens collected in vacuum tubes with anticoagulant other than lithium or sodium heparin
- Syringe for TCO₂ with air bubbles in sample
- Incompletely filled vacuum tube for the measurement of ionized calcium and TCO₂
- Other sample types such as urine, CSF, and pleural fluid

Precautions: Avoid the Following Circumstances

- Drawing a specimen from an arm with an I.V.
- Stasis (tourniquet left on longer than one minute before venipuncture)
- Extra muscle activity (fist pumping)
- Hemolysis (alcohol left over puncture site, or a traumatic draw)
- Icing before filling cartridge
- Time delays before filling cartridge
- Exposing the sample to air

*See the “Interferences” section of this manual to review a complete list of known factors and medications that may interfere with i-Stat Chem8+ assay.
PROCEDURE MANUAL FOR THE i-Stat SYSTEM
SOP-111.800.005 REV-05/21/2018

PROCEDURE FOR ANALYSIS

These testing procedures are for use with the following CLIA-waived i-Stat cartridges: CHEM8+, 6+, EC4+, E3+, Crea, and G. These cartridges include various subsets of the following tests: sodium, potassium, chloride, total carbon dioxide, ionized calcium, glucose, urea nitrogen, creatinine and hematocrit. Testing can be performed at the patient’s bedside.

EC4+, E3+, and 6+ cartridges aid the clinician in assessing a patient’s metabolic state within a few minutes. The glucose cartridge (G) quickly delivers a patient’s diagnostic blood glucose level. The creatinine cartridge (Crea) is used to assess a patient’s renal function. CHEM8+ contains all of these tests in a single cartridge.

Preparation for Use
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.

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

Procedure for Cartridge
Do not open cartridge until instructed to do so in the procedures!

Acceptable Sample Types
Venous whole blood samples collected in evacuated tubes with lithium or sodium heparin anticoagulant (green top). Tubes with gel for separation of cell and plasma are acceptable.

Correct sample collection and handling are important for accurate results

Sample Collection and Handling
A properly trained individual will fill and insert the CHEM8+ cartridge within 10 minutes of sample collection. For other chemistry cartridges, test samples within 30 minutes of collection.

Prior to Testing
Have necessary operator ID and labeled patient sample ready before beginning the test.
Be prepared to complete the entire test without interruption to avoid inaccurate results or error codes.

Prepare the Handheld
The handheld will be customized in accordance to Abbott’s start up procedures prior to first use.

Perform Venipuncture
Be sure to label the specimen(s) at the patient’s bedside with the online order entry accession number securely attached to the blood specimen.

Procedure for Analysis

Preparing the handheld for a cartridge

1. **Press** [1] to turn on handheld


3. Follow the handhelds prompts:
   - Note: You may be prompted to repeat ID entries, so pay careful attention to the prompt.
   - If you make a mistake, *press left arrow key to clear entry.*
   1. **Scan** (or enter) your operator ID as prompted*
      

   2. **Scan** patient specimen **accession number** (or enter) as prompted.
      

   3. **Scan the lot number** on the cartridge pouch.
      - Position barcode 3-9 inches from scanner window on handheld.
      - Press and hold [SCAN] to activate the scanner. Align the red laser light so it covers the entire barcode. The handheld will beep when it reads the barcode successfully.

   | Scan or Enter Operator ID | Scan or Enter Patient ID | Scan or Enter Cartridge Lot Number |

Prepare to Test

1. Find a level, stable surface to perform the test.
2. Remove the cartridge from its pouch and place on a flat surface.
   - **Only touch the cartridge by its sides to avoid damage or contamination.**
3. Put on disposable gloves.

Prepare the Blood Sample

1. Mix the Blood sample. **Gently invert** the green top tube **2 to 3** times.

2. If using pipette- **Fill** with blood sample. Slowly pipette blood about halfway up and expel excess air from the tip.
   - If using transfer device- **Invert** the tube and **push transfer device through the green stopper**
     - If using syringe- **Invert** the tube and push syringe tip through green stopper. Slowly pull back on the syringe plunger to draw blood into the syringe until it is about half full. Expel air from the syringe tip.

*Note: Health care workers are not permitted to share operator ID’s. If an operator ID has been compromised, have the DON contact the point of care coordinator to change it. Operators whom knowingly share operator ID’s, will no longer be permitted to participate in the Aculabs i-Stat program.*
To expel air from blood transfer devices:

- Place enough gauze pads on the counter to absorb a few drops of blood.
- Hold syringe over gauze without touching it.
- Press syringe plunger or squeeze pipette until you see 3 drops of blood empty onto the gauze.

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

**Fill the Cartridge**

1. Fill the cartridge with sample to the fill mark.
   a. **Place the tip** of the syringe, pipette, or other transfer device over the **cartridge sample well**.
   b. Press plunger/squeeze pipette so that sample enters cartridge until it reaches the fill mark.
   c. Confirm that there is sample in the sample well. If you don’t see sample in the sample well, continue to deliver more sample. Do not wipe off excess sample from the cartridge. **Grossly over or under filling cartridge may cause an error code requiring you to repeat the test.**

**Seal the Cartridge**

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

**Insert the Cartridge**

1. Push the sealed cartridge into the handheld port until it clicks.
   a. To avoid permanent damage to the handheld, **do not remove the cartridge until test procedure is complete.** The handheld should remain level until result is obtained.
   b. Wait about 2 to 3 minutes for the test to complete.

**Alternative Procedure**

Should the i-Stat System become inoperable for any reason, specimens should be collected and submitted to the laboratory in accordance with the Laboratory Procedure Manual. DO NOT rely on the results from any handheld that has not passed its required 24-hour EQC. Faulty handhelds should be submitted to Aculabs for replacement.

**Loss of Internet**

If for any reason there has been a loss of internet connectivity when attempting to order a new test or review patient results, call Aculabs. The client service department (phone extension information can be found within your client in-service manual), can assist with entering in new test orders and providing operators with an accession number that can be manually entered into the handheld at “Patient ID” prompt. Test results should be transmitted immediately upon re-connectivity to the facilities internet.

**Faulty Device**

If a handheld is portraying an error code that the “Troubleshooting” section of this manual does not outline, contact you Aculabs point of care coordinator or client service representative for a replacement handheld.

**Failed Quality Control (QC)**

If the handheld does not pass the electronic simulator, refer to the “QC procedures” section of this manual.
RESULTS

The handheld shows the test results by test name, test unit, and the numerical values and units with the results. It also shows bar graphs with tic marks for reference ranges. See the “Test Ranges” section for a list or reportable and reference ranges.

Calculations
The i-Stat handheld contains a microprocessor that performs all calculations required for reporting results.

Displayed Results
Results are displayed numerically with their units. Displayed results are also depicted as bar graphs with reference ranges marked under the graphs.

Suppressed Results
There are three conditions under which the i-Stat System will not display results:

1. 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 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 <.
   “<” is shown in front of the lowest reportable value when the results is lower than this value.
   “>” is shown in front of the highest reportable value when the result is higher than this value.
   “< >” is shown in place of a result is the result is dependent on another result that is flagged with either < or > symbol.

   Action:
   Send specimen(s) to the laboratory for analysis, if necessary.

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

   Action:
   Analyze the specimen again by inverting blood sample 2-3 times or using a fresh sample and another cartridge. If the specimen integrity is not in question, the results that are not suppressed should be reported in the usual manner. If the result is suppressed again, send specimen(s) to the laboratory for analysis in accordance with the Laboratory Procedure Manual.

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

   Action:
   Take the action displayed with the message that identifies the problem. Refer to Troubleshooting section or the “Analyzer Coded Messages” Bulletin if necessary. If problem persists - contact your point of care coordinator.

Potential Sources of Error in Patient Results

- Cartridge stores incorrectly.
- Improper sample collection and/or sample handling:
  - Testing samples other than fresh whole blood samples collected in lithium or sodium heparin anticoagulant.
  - Using tubes not filled to capacity or using “short fill” tubes (for TCO2 testing).
  - Not testing samples within procedural time ranges (within 10-30 minutes of collection).
- Any deviations in procedure will cause inaccurate results.
- Use of expired cartridges.
- See “Interferences” section of this manual for additional information.
Printing and Transmitting Results

Printing Results from the i-Stat 1 Analyzer to the i-Stat Printer

**Without Downloader or Downloader/Recharger**

1. Turn printer on if green power light is not on.
2. Align IR windows of handheld and printer.
3. Display results.
4. Press and hold the Print key.
5. Do not move handheld or printer until printing is complete.
6. If printer is not powered from a wall outlet, turn printer off.

Record and Report Results

The i-Stats displayed result is not intended to be used as the verified patient result. Use the Aculabs.com portal to view patient results that have been verified or flagged based on patient history.

Transmitting results from the i-Stat 1 Analyzer to Aculabs with a downloader/recharger

1. Place handheld in a Downloader or Downloader/Recharger.
2. Do not move handheld while the message “Communication in Progress” is displayed.

Transmitting results from the i-Stat 1 Wireless Analyzer to Aculabs

Transmitting results can either be done from the patient results screen post-patient test or from the “Menu” by pressing the “Menu Key” to reach the “Administrator Manu” and choosing option “6 - Transmit Data”. All option “5 - Unsent” data can be transmitting by choosing this option. Results will be transmitted and a delta check will be done by Aculabs to verify patient trends and test accuracy. If an interfering substance is suspected, send a sample to the laboratory. If not, remix and retest the sample if it was drawn within the acceptable time limit. Otherwise obtain a new sample and repeat the test. If the result is still in question send the blood specimen to the laboratory.

Reviewing Patient Results on the Aculabs Portal

In your web browser, go to www.Aculabs.com, proceed to log in with your facilities individualized user name and password. Under the “Results” section of the website enter in the patient last and first name as required and use the “Start Search” function. Find the correct patient name and proceed to click on it. When the patients report is complete, the results will be viewable along with a “Cumulative report” to verify patient history.
Reviewing Stored Results

A minimum of 1000 test result records are stored by the handheld, and can be reviewed by accessing the data review function.

Press 1 to turn on the handheld ➔ Press MENU to change screen to Administration Menu ➔ Press 2 for Data Review ➔ At the Data Review screen choose the category of results for review. Use 2 to move from the most recent record to the additional records.

Data Review Definitions:

- **Patient**: Records for patients are recalled by scanning or manually entering a patient ID number. If no patient ID is entered, all patient test records are recalled when “Enter” is pressed. Not all tests may be displayed on the first screen. Press the handhelds arrow keys to page through screens.
- **Control**: All quality control test records.
- **Proficiency**: Proficiency testing is a type of Quality Test. Not required for testing under a Certificate of Waiver.
- **Cal. Ver**: Calibration Verification is a type of Quality Test. Not required for testing under a Certificate of Waiver.
- **Simulator**: All external and internal Electronic Simulator records.
- **All**: All test records in the handhelds memory.
- **List**: Records are listed with cartridge type, date and time of test, and patient or control ID (lot number). Records can be selected for viewing or printing using the numbered key. Pressing the number key corresponding to a record selects the record; pressing the number key a second time deselects the record. To view one or more records, select the records and press the enter key.
Ranges, Reportable Ranges, and Test Unit Conversions

Reference range means the range of test values expected from 95% of fasting individuals presumed to be healthy. Reportable range means the range of test values throughout which the measurement system’s results have been shown to be valid.

Critical Results
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.

### ANLYTE
<table>
<thead>
<tr>
<th>UNIT</th>
<th>REFERENCE RANGE (venous)</th>
<th>REPORTABLE RANGE</th>
<th>CRITICAL RANGE</th>
<th>UNIT CONVERSION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>mmol/L (mEq/L)</td>
<td>135 - 145</td>
<td>100 – 180</td>
<td>125 150</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>mmol/L x 1 = mEq/L</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Example: 140 mmol/L = 140 mEq/L</td>
</tr>
<tr>
<td>Potassium</td>
<td>mmol/L (mEq/L)</td>
<td>3.5 - 5.3</td>
<td>2.0 – 9.0</td>
<td>2.8 5.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>mmol/L x 1 = mEq/L</td>
</tr>
<tr>
<td>Chloride</td>
<td>mmol/L (mEq/L)</td>
<td>98 – 107</td>
<td>65 – 140</td>
<td>90 115</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>mmol/L x 1 = mEq/L</td>
</tr>
<tr>
<td>BUN</td>
<td>mg/dL</td>
<td>8 – 23</td>
<td>3 - 140</td>
<td>59.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>mg/dL BUN x 0.357 = mmol urea/L</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Example: 20 mg/dL BUN = 7.1 mmol urea/L</td>
</tr>
<tr>
<td>Glucose</td>
<td>mg/dL</td>
<td>65.99</td>
<td>20 – 700</td>
<td>50 350</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>mg/dL x 0.055 = mmol/L</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Example: 100 mg/dL = 5.55 mmol/L</td>
</tr>
<tr>
<td>Creatinine</td>
<td>mg/dL</td>
<td>0.6 - 1.5</td>
<td>0.2 - 20.0</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>mg/dL x 88.4 = µmol/L</td>
</tr>
<tr>
<td>Ionized Calcium</td>
<td>mg/dL</td>
<td>4.5-5.3</td>
<td>1.0 – 10.0</td>
<td>3.1 6.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>mmol/L x 4 = mg/dL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Example: 1.13 mmol/L x 4 = 4.52 mg/dL</td>
</tr>
<tr>
<td>TCO₂</td>
<td>mmol/L (mEq/L)</td>
<td>22-32</td>
<td>5-50</td>
<td>15 40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>mmol/L x 1 = mEq/L</td>
</tr>
</tbody>
</table>

### ANALYTE
<table>
<thead>
<tr>
<th>UNIT</th>
<th>REFERENCE RANGE (venous)</th>
<th>REPORTABLE RANGE</th>
<th>CRITICAL RANGE</th>
<th>UNIT CONVERSION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematocrit</td>
<td>%PCV</td>
<td>Male: 36-51</td>
<td>15 – 75</td>
<td>25 55</td>
</tr>
<tr>
<td></td>
<td>Female: 32-46</td>
<td></td>
<td></td>
<td>% PCV x 0.01 = Volume fraction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Example: 40% PCV = 0.40 PCV</td>
</tr>
<tr>
<td>Hb*</td>
<td>g/dL</td>
<td>Male: 12.1-17.1</td>
<td>5.1 – 25.5</td>
<td>8 18</td>
</tr>
<tr>
<td></td>
<td>Female: 10.7-15.1</td>
<td></td>
<td></td>
<td>g/dL x 10 = g/L</td>
</tr>
</tbody>
</table>
Interferences
An interferent is a substance which, if present at significant levels in the blood specimen being analyzed, will produce an error in the result of the analyte being measured.

<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>Use Another Method</td>
</tr>
<tr>
<td></td>
<td>Nithiodote (sodium thiosulfate)</td>
<td>16.7 mmol/L</td>
<td>Increase (↑) Na</td>
</tr>
<tr>
<td>Potassium</td>
<td>Bromide</td>
<td>37.5 mmol/L</td>
<td>Use Another Method</td>
</tr>
<tr>
<td></td>
<td>Nithiodote (sodium thiosulfate)</td>
<td>16.7 mmol/L</td>
<td>Decrease (↓) K</td>
</tr>
<tr>
<td>Chloride</td>
<td>Acetylcysteine</td>
<td>10.2 mmol/L</td>
<td>Increase (↑) Cl</td>
</tr>
<tr>
<td></td>
<td>Bromide</td>
<td>37.5 mmol/L</td>
<td>Use Another Method</td>
</tr>
<tr>
<td></td>
<td>Bromide (therapeutic)</td>
<td>2.5 mmol/L</td>
<td>Increase (↑) Cl</td>
</tr>
<tr>
<td></td>
<td>Salicylate</td>
<td>4.34 mmol/L</td>
<td>Increase (↑) Cl</td>
</tr>
<tr>
<td></td>
<td>Thiocyanate</td>
<td>6.9 mmol/L</td>
<td>Increase (↑) Cl</td>
</tr>
<tr>
<td></td>
<td>Nithiodote (sodium thiosulfate)</td>
<td>16.7 mmol/L</td>
<td>Increase (↑) Cl</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 up to 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>Use Another Method</td>
</tr>
<tr>
<td></td>
<td>Lactate</td>
<td>6.6 mmol/L</td>
<td>Decrease (↓) iCa by up to 0.07 mmol/L</td>
</tr>
<tr>
<td></td>
<td>Salicylate (therapeutic)</td>
<td>0.5 mmol/L</td>
<td>Decrease (↓) iCa by up to 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></td>
<td>Nithiodote (sodium thiosulfate)</td>
<td>16.7 mmol/L</td>
<td>Decrease (↓) iCa</td>
</tr>
<tr>
<td></td>
<td>Thiocyanate</td>
<td>6.9 mmol/L</td>
<td>Decrease (↓) iCa by up to 0.07 mmol/L</td>
</tr>
<tr>
<td>Glucose</td>
<td>Acetaminophen</td>
<td>1.32 mmol/L</td>
<td>Increase (↑) glucose</td>
</tr>
<tr>
<td></td>
<td>Hydroxyurea</td>
<td>0.92 mmol/L</td>
<td>Increase (↑) glucose by 0.8 mg/dL</td>
</tr>
<tr>
<td></td>
<td>pH</td>
<td>pH: per 0.1 pH units above 7.4 @ 37°C</td>
<td>Decrease (↓) glucose by 0.9 mg/dL (0.05 mmol/L)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>pH: per 0.1 pH units below 7.4 @ 37°C</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Acetylcysteine</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>Use Another Method</td>
</tr>
<tr>
<td></td>
<td>Bromide (therapeutic)</td>
<td>2.5 mmol/L</td>
<td>Decrease (↓) glucose</td>
</tr>
</tbody>
</table>
## PROCEDURE MANUAL FOR THE i-Stat SYSTEM

**SOP-111.800.005 REV-05/21/2018**

<table>
<thead>
<tr>
<th>ANALYTE</th>
<th>INTERFERENT</th>
<th>INTERFERENT CONCENTRATION</th>
<th>EFFECT ON ANALYTE RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen</td>
<td>PO$_2$ less than 20 mmHg @ 37°C</td>
<td></td>
<td>May decrease (↓) glucose</td>
</tr>
<tr>
<td>Nithiodote</td>
<td>16.7 mmol/L</td>
<td></td>
<td>Decrease (↓) glucose</td>
</tr>
<tr>
<td>(sodium thiosulfate)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thiocyanate</td>
<td>6.9 mmol/L</td>
<td></td>
<td>Decrease (↓) glucose</td>
</tr>
<tr>
<td><strong>BUN/Urea</strong></td>
<td>Bromide</td>
<td>37.5 mmol/L</td>
<td>Use Another Method.</td>
</tr>
<tr>
<td></td>
<td>Hydroxyurea</td>
<td>0.92 mmol/L</td>
<td>Increase (↑) BUN/Urea results</td>
</tr>
<tr>
<td></td>
<td>Nithiodote (sodium thiosulfate)</td>
<td>16.7 mmol/L</td>
<td>Decrease (↓) BUN/Urea results</td>
</tr>
<tr>
<td><strong>Creatinine</strong></td>
<td>Acetaminophen</td>
<td>1.32 mmol/L</td>
<td>Increase (↑) Crea</td>
</tr>
<tr>
<td></td>
<td>Ascorbate</td>
<td>0.34 mmol/L</td>
<td>Increase (↑) Crea</td>
</tr>
<tr>
<td></td>
<td>Bromide (therapeutic)</td>
<td>2.5 mmol/L</td>
<td>Increase (↑) Crea</td>
</tr>
<tr>
<td></td>
<td>Hydroxyurea</td>
<td>0.92 mmol/L</td>
<td>Increase (↑) Crea Use Another Method.</td>
</tr>
<tr>
<td></td>
<td>Acetylcysteine</td>
<td>10.2 mmol/L</td>
<td>Increase (↑) Crea</td>
</tr>
<tr>
<td></td>
<td>Creatine</td>
<td>0.382 mmol/L</td>
<td>Increase (↑) Crea</td>
</tr>
<tr>
<td></td>
<td>Nithiodote (sodium thiosulfate)</td>
<td>16.7 mmol/L</td>
<td>Decrease (↓) Crea Use Another Method.</td>
</tr>
<tr>
<td></td>
<td>Glycolic Acid</td>
<td>10.0 mmol/L</td>
<td></td>
</tr>
<tr>
<td><strong>&gt;2 mg/dL</strong></td>
<td>$\text{PCO}_2$</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Crea$_{corr}$ = Crea*(1+0.0025*(PCO$_2$-40))</td>
<td></td>
</tr>
<tr>
<td><strong>Hematocrit</strong></td>
<td>Bromide</td>
<td>37.5 mmol/L</td>
<td>Increased rate of star (***), outs</td>
</tr>
<tr>
<td></td>
<td>White Blood Count (WBC)</td>
<td>Greater than 50,000 WBC/µL</td>
<td>May Increase (↑) Hct</td>
</tr>
<tr>
<td></td>
<td>Lipids</td>
<td>Abnormally high</td>
<td>Increase (↑) Hct</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>Decrease (↓) Hct by 0.75% PCV</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For measured Hct ≥ 40%</td>
<td>Increase (↑) Hct by 0.75% PCV</td>
</tr>
</tbody>
</table>
QUALITY CONTROL

Daily Procedures

Quality control procedures are used to ensure the continued accuracy of a test system. The quality control program for the i-Stat System includes:

**Automatic quality checks**: A series of automatic quality checks are performed during each test cycle. When there is a quality check failure, a message is displayed with the cause and corrective action. A complete list of quality check messages can be found in the troubleshooting section of this manual. The quality checks detect improper environmental conditions, handheld function, cartridge filling, cartridge function and sensor function.

**Electronic simulator check**: An independent check of the handheld’s ability to take accurate and precise readings from the sensors are performed automatically every 24 hours when cartridges are being tested. An external electronic simulator is used to verify an internal electronic simulator failure and perform the twice yearly thermal probe check. Both the internal and external simulator results are stored in the handheld’s memory.

Both the internal and external electronic simulator send signals that simulate those of a cartridge to the handheld’s signal detection system. The signals are below and above the measurement ranges of the tests and the acceptance limits are tighter than those for liquid control samples. Therefore, the simulator test is more sensitive to an out-of-specification condition than liquid control samples.

*The internal simulator check* is triggered by the insertion of a cartridge once every 24 hours. If the check passes, the cartridge test cycle continues. If the check fails, “FAIL” and a failure code are displayed. A cartridge test cannot be performed until the handheld passes the simulator check. If the FAIL message is observed when it occurs, the cartridge can be re-inserted. If FAIL is displayed a second time, the external simulator can be used to verify that the failure is being caused by the handheld and not by a faulty cartridge. Note that if there is a delay between the time the cartridge is inserted and the time the display is read, use a fresh cartridge and sample or the external simulator rather than re-inserting the original cartridge.

**Liquid control samples**: Used to perform independent checks of system performance. Their use is an accepted way of verifying performance with traditional quantitative tests. Although this is a unit use test system, the waived status categorization for this product requires laboratories (Aculabs) to test controls. Control testing frequency: test one cartridge from each lot in each shipment upon receipt and test a single cartridge from the refrigerator monthly.

**Cartridge storage**: Proper cartridge storage conditions, as described in the cartridge Testing Procedures section, are required for reliable results.

**Handheld Verification**

The i-Stat analyzer should be cleaned in accordance to procedures after each use.

Verify the performance of each handheld in the i-Stat System using the internal or external electronic simulator every 24 hours of use. In the USA verification is required every 8 hours for hematocrit.

**Checking Handheld with the Electronic Simulator**

The external Electronic Simulator is stored at room temperature in its box.

When 24 hours has elapsed since the last electronic simulator test (internal or external), the internal test will automatically be performed when a cartridge is inserted. If the test passes, the handheld proceeds with the measurement of the patient sample. If the test fails, the handheld displays a FAIL message. The handheld cannot be used until the simulator test passes. The external electronic simulator can be used to verify the failure.
To Run the Electronic Simulator

Place the handheld on a flat surface ➔ Press the 1 key to turn on handheld ➔ Press Menu to change to the Administrator Menu ➔ Press 3 for Quality Tests menu ➔ Press 4 for simulator ➔ Enter the Operator ID

Using the number keys ➔ Enter the Operator ID again (if prompted) ➔ Remove the simulator from its box.

Remove protective cap (take care not to touch the gold contact pads) ➔ Enter serial number found on the label of the Electronic simulator ➔ Insert Electronic Simulator into handheld with gold contact pads facing up and forward.

When inserted properly, handheld will display “Contacting Simulator”. DO NOT remove simulator until “Simulator Locked” message is removed and results is displayed.

Action:
If PASS is displayed on the handheld screen (after using the external electronic simulator):
- Remove the external electronic simulator after the LCK or Simulator Locked message disappears from the display screen.
- Transmit the result.
- Use the handheld as required.

Note: If the internal electronic simulator is used, the “PASS” message will not be displayed on the handheld screen. The “PASS” record will appear in the handheld’s stored results

Remedial Action:
If FAIL is displayed on the analyzer screen:
- Repeat the procedure with the same external electronic simulator or rerun the cartridge if the internal electronic simulator is being used. If PASS is displayed use the handheld as required.
- If FAIL is displayed repeat the procedure with a different external electronic simulator.

If PASS is displayed with the second external electronic simulator:
- Use the handheld as required.
- Deliver the questionable external electronic simulator to the Aculabs point of care coordinator.

If FAIL is displayed with the second external electronic simulator:
- DO NOT analyze patient samples with the handheld.
- Transmit the results to Aculabs.
- Deliver the faulty handheld to the Aculabs point of care coordinator.
- Record the failure in the i-Stat QC Log along with the action taken.

Verification of Cartridge Storage Conditions

Room Temperature Cartridges

- Verify that all boxes of cartridges at room temperature have been out of the refrigerator less than the time frame indicated on the cartridge box. Aculabs will pick up all expired cartridges.
- Verify that room temperature has not exceeded 30°C.
- Document in the i-Stat QC log.

Action:
If the measured temperature of the room has been continuously below 30°C (86°F) use cartridges as required.

Remedial Action:
If the measured room temperature has exceeded 30°C (86°F) for any period of time:
- Quarantine the cartridges and notify Aculabs immediately.
- DO NOT USE the cartridges.
- Record the out-of-control event in the i-Stat QC Log and the action taken.
Monthly Procedures

Electronic Simulator Results
Aculabs point of care coordinator will relay a copy of the monthly QC report to DON. Include the report in the i-Stat QC Log.

Control Fluid Analysis Results
Aculabs point of care coordinator will relay a liquid QC report in every shipment of a new cartridge lot number.

Verification of Cartridge Storage Conditions

Refrigerated Cartridges

- Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes.
- Aculabs will collect the expired cartridges.
- Verify that the refrigerator did not exceed the limits of 2 to 8°C (35 to 46°F).
- Document in the i-Stat QC Log.

Action:
If the temperature of the cartridge storage refrigerator is within the range of 2 to 8°C (35 to 46°F) - use cartridges as required.

Remedial Action:
If the temperature is outside the range of 2 to 8 °C (35 to 46 °F), notify the Aculabs coordinator immediately.
Record the QC failure in the i-Stat QC Log along with the actions.

Cleaning and Decontaminating the Handheld

Drying a Wet Handheld
If the handheld is placed on a wet surface or if any liquid is spilled on it, dry immediately. The handheld may be damaged if liquid enters the battery compartment, cartridge port or case.

Cleaning the Handheld
Clean the display screen and case using a gauze pad moistened by any of the following:

- A mild non-abrasive cleaner
- Detergent
- Soap and water
- Alcohol
- 10% bleach solution

Avoid getting excess fluids in the seam between the display screen and the case. Rinse using another gauze pad moistened with water and dry.

Decontaminating the Handheld and Workspace
The handheld must not be sterilized or autoclaved by any method. If blood gets into the handheld, decontaminate it using 10% bleach solution. Wear gloves to protect yourself from blood-borne pathogens while performing this procedure.

1. Prepare a 1:10 solution of household bleach by mixing one part of bleach with 9 parts of tap water. This solution retains its strength for one week.
2. Thoroughly wet two paper towels in the bleach solution.
3. Squeeze the excess fluid out of the towels.
4. Clean handheld’s surface twice using the two towels. Make sure the towels are not dripping wet or the bleach solution may enter the seams of the handhelds case.
   - If the blood has already dried, do not scrape it off the surface, but gently remove it with a paper towel moistened with the bleach solution.
5. Moisten a paper towel with tap water and rinse bleach solution from the surface.
6. Dry the surface with a dry paper towel.

To decontaminate the workspace, cover the area with the bleach solution and allow to stand for 10 minutes. Then wipe dry and rinse the area with tap water. Analyzer decontamination logs should be filled out monthly to ensure proper maintenance.
Periodic Procedures

Check Temperature Monitor

i-Stat cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit.

**Action:**
- Fill out the record of receipt and forward materials to refrigerator.
- If all windows are white or if only the A or B windows are blue or the 1 or 2 windows are red, then transit temperatures were satisfactory and the cartridges can be used.

**Remedial Action:**
- If the C or D windows are blue, or the 3 or 4 windows are red:
  - Quarantine the suspect cartons.
  - Notify the Aculabs System Coordinator immediately.
  - DO NOT USE cartridges from the suspect cartons.
  - Record the out-of-control event in the i-Stat QC Log.

Integrity Testing *

Aculabs will verify the integrity of cartridges included in every shipment, upon receipt, by analyzing two levels of appropriate controls (see table below) along with a representative sample of each new lot and by comparing the results to the expected values published in the Value Assignment Sheets. Any analyzer that has passed the Electronic Simulator test may be used in the verification.

Chem 8+ Cartridges will be tested with TriControls or CHEM8+ control and RNA Medical hematocrit control

*Note: the above information is not a manufacturer’s system instruction; it is a suggestion to comply with regulatory requirements.

Calibration

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.

Quarterly Procedures

Each facilities designated Client Service Representative or Point of Care Coordinator will relay the Aculabs headquarters updated QC logs. These will include: Receipt of new cartridges, Liquid control reports, Storage logs, and facility QC reports. Biannual document verification will be done by Aculabs in accordance to protocol. These reports are to be placed in the i-Stat binder to ensure CLIA requirements are being maintained. Any facility that does not follow ALL required protocol will be found ineligible for participation in the Aculabs Point of Care program.

Updating the Handheld Software

The handhelds software must be updated twice a year. The software expires in June and December. About six weeks before the current software expires, your facility will get a software update completed by Aculabs point of care coordinator. 15 days before the software expires, the handheld will display “CLEW expiring, Update required”. If you receive this message and a scheduled date for the update has not been scheduled, contact your point of care coordinator or customer service representative. Included in this are yearly recertification of operators and a removal of ineligible operators.

Thermal Probe Check

The handheld’s thermal probes should be checked every six months. This procedure will be maintained by Aculabs. This thermal probe check will be done at the same time as the software update. If a date has not been set 15 days prior to the required update; contact your point of care coordinator or customer service representative. The thermal probe check log should be kept in the i-Stat Binder.
### CLINICAL SIGNIFICANCE

<table>
<thead>
<tr>
<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, Diabetes insipidus, Salt poisoning, Skin losses, Hyperaldosteronism, CNS disorders</td>
<td>Dilutional hyponatremia (cirrhosis), Depletional hyponatremia, Syndrome of inappropriate ADH</td>
</tr>
<tr>
<td>Potassium</td>
<td>Renal glomerular disease, Adrenocortical insufficiency, Diabetic Ketoacidosis (DKA), Sepsis, <em>In vitro</em> hemolysis</td>
<td>Renal tubular disease, Hyperaldosteronism, Treatment of DKA, Hyperinsulinism, Metabolic alkalosis, Diuretic therapy</td>
</tr>
<tr>
<td>Chloride</td>
<td>Prolonged diarrhea, Renal tubular disease, Hyperparathyroidism, Dehydration</td>
<td>Prolonged vomiting, Burns, Salt-losing renal disease, Overhydration, Thiazide therapy</td>
</tr>
<tr>
<td>Ionized Calcium</td>
<td>Dehydration, Hyperparathyroidism, Malignancies, Immobilization, Thiazide diuretics, Vitamin D intoxication</td>
<td>Hypoparathyroidism, Early neonatal hypocalcemia, Chronic renal disease, Pancreatitis, Massive blood transfusions, Severe malnutrition</td>
</tr>
<tr>
<td>BUN</td>
<td>Impaired renal function, Prerenal azotemia (e.g. shock), Postrenal azotemia, GI bleeding, High protein diet</td>
<td>Pregnancy, Severe liver insufficiency, Overhydration, Malnutrition</td>
</tr>
<tr>
<td>Glucose</td>
<td>Diabetes mellitus, Pancreatitis, Endocrine disorders (e.g. Cushing’s syndrome), Drugs (e.g. steroids, thyrotoxicosis), Chronic renal failure, Stress, IV glucose infusion</td>
<td>Insulina, Adrenocortical insufficiency, Hypopituitarism/Massive liver disease, Ethanol ingestion/Reactive hypoglycemia, Glycogen storage disease</td>
</tr>
<tr>
<td>Creatinine</td>
<td>Impaired renal function</td>
<td></td>
</tr>
<tr>
<td>TCO₂</td>
<td>Primary respiratory acidosis</td>
<td>Primary respiratory alkalosis</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>Dehydration, Burns, Impaired ventilation, Renal disorders</td>
<td>Hemolytic anemias, Iron deficiency, Marrow depression, Blood loss</td>
</tr>
</tbody>
</table>
Troubleshooting Quality Checks
From the time it powers up until the time it powers down, the handheld performs numerous quality checks. The failure of any quality check causes the handheld to halt the test cycle and display a “cause” and “action” message, and a code.

**The Cause Message:** This message describes the likely cause of the failed quality check. 

**The Action Message:** This message indicates the appropriate action. For example, if the problem is related to an operator or a cartridge, the instruction “Use Another Cartridge” will be displayed.

**The Cause Code:** This is a numeric code associated with the failed quality check. The codes are stored in the handheld’s memory and can be viewed by selecting “All” from the “Data Review” function under the “Administration Menu.” Codes below 16 usually indicate a condition related to the environment or state of the handheld. These conditions usually go away after the next cartridge is inserted or the condition is corrected.

<table>
<thead>
<tr>
<th>Cause Message</th>
<th>Action Message</th>
<th>Code</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dead Batteries</td>
<td>Replace Batteries</td>
<td>1</td>
<td>Replace disposable lithium batteries in the analyzer.</td>
</tr>
<tr>
<td>Temperature Out Of Range</td>
<td>Check Status Page</td>
<td>2</td>
<td>Move handheld to an area within an operating temperature range of 16-30 degrees C (61-81 degrees F).</td>
</tr>
<tr>
<td>Date Invalid</td>
<td>Check the Clock on Status Page</td>
<td>11</td>
<td>Date in the handheld precedes software date. Correct the date in the status page.</td>
</tr>
<tr>
<td>Analyzer Interrupted</td>
<td>Use Another Cartridge</td>
<td>4,8</td>
<td>The analyzer has detected that the last test cycle was not completed. Check the battery voltage on the analyzer status page.</td>
</tr>
<tr>
<td>Invalid Or Expiring CLEW</td>
<td>Update Required</td>
<td>12,13</td>
<td>CLEW software expiring/expired. Contact Aculabs if update has not been scheduled. If update is not due, the software might be corrupt and need to be re-installed.</td>
</tr>
<tr>
<td>Cartridge Not Inserted Properly</td>
<td>Re-insert Cartridge</td>
<td>47,48</td>
<td>Re-insert cartridge until it has reached the back of the door.</td>
</tr>
<tr>
<td>Cartridge Type Not Recognized</td>
<td>Use Another Cartridge</td>
<td>69</td>
<td>Ensure you are using the correct cartridge type, within acceptable non-expired date ranges. Otherwise, verify cartridge lot information, simulator information, and operator ID information has been correctly entered.</td>
</tr>
<tr>
<td>Cartridge Error</td>
<td>Use Another Cartridge</td>
<td>79-81</td>
<td>Indicates cartridge or thermal probe issue. Attempting to remove a cartridge while the “Cartridge Locked” message is displayed, can damage the handheld.</td>
</tr>
<tr>
<td>Test Cancelled by Operator</td>
<td>-</td>
<td>95</td>
<td>This message will appear in the stored test results on the i-Stat analyzer if the analyzer powers down before all mandatory information was entered into the handheld.</td>
</tr>
<tr>
<td>Cartridge Error</td>
<td>Use Another Cartridge</td>
<td>20, 23, 27-29,32,33,40,41,45,49,87,24</td>
<td>If failure persists after running 3 additional control or patient samples, contact Aculabs. The rate of quality check code 45 can be elevated when cartridges are run without allowing sufficient time for cartridges to equilibrate to room temperature.</td>
</tr>
<tr>
<td>Cartridge Error</td>
<td>Use Another Cartridge</td>
<td>42,43</td>
<td>Sensor out of specification. This could be caused by dirty cartridge, contact pads, or connector in the analyzer.</td>
</tr>
<tr>
<td>Cartridge Error</td>
<td>Use Another Cartridge</td>
<td>21</td>
<td>Do not touch the cartridge sensors. Use a new cartridge and be careful where to touch.</td>
</tr>
<tr>
<td>Cartridge Error/Insufficient Sample</td>
<td>Use Another Cartridge</td>
<td>35,36,38,39</td>
<td>Cartridge under filled, did not reach fill mark, or air bubbles trapped in the sample. Use a new cartridge.</td>
</tr>
<tr>
<td>Cartridge Error</td>
<td>Use Another Cartridge</td>
<td>30,37</td>
<td>Cartridge is overfilled. Use a new cartridge and do not fill past the fill mark.</td>
</tr>
<tr>
<td>Unable To Position Sample/Cartridge Error</td>
<td>Use Another Cartridge</td>
<td>31,34,44,46</td>
<td>Snap closure has been left open, sample is clotted, or sample is overfilled</td>
</tr>
<tr>
<td>Cause Message</td>
<td>Action Message</td>
<td>Code</td>
<td>Comments</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------</td>
<td>------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Lot Expired</td>
<td></td>
<td>140</td>
<td>Expired cartridge lot. Check the expiration date on cartridge.</td>
</tr>
<tr>
<td>Electronic Simulator Fail</td>
<td>L, G, R, r, t, B</td>
<td></td>
<td>Allow handheld to adjust to any environmental changes for 30 minutes. If EQC still fails - Contact Aculabs.</td>
</tr>
<tr>
<td>Analyzer Error</td>
<td>See Manual / Use Electronic Simulator</td>
<td></td>
<td>Various codes may be displayed. Attempt EQC two times. If the handheld does not pass, contact Aculabs. Codes 83 and 92 typically indicate a problem with the pressure transducers in the analyzer. Code 83 and 84 indicate an underlying hardware failure in the i-Stat analyzer. Code 55 and 56 occurs when the analyzer detects noise in the thermal circuit. Interference may be from nearby electronic noise. Re-locate the handheld. Code 86 can occur when the analyzer is stored without adequate ventilation. This problem can usually be resolved by relocating the analyzer. For other codes, run the Electronic Simulator twice, then run a cartridge with a sample. If the analyzer passes the simulator check and the quality check does not occur with the sample run, continue to use the analyzer. If handheld does not pass, contact Aculabs for a possible replacement handheld. If you experience code 50,126, and 128 in a short period of time call Aculabs for replacement.</td>
</tr>
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PRECAUTIONS

Potential Sources of Harm to the Operator

To protect yourself and others from infection:

• Do not perform blood or control fluid testing in areas where food and drink are stored or consumed.

• Use gloves and wash hands after handling blood or blood soiled items.

• Do not use a cartridge if blood is spilled on it. Discard contaminated (blood soiled) items in a biohazard waste container.

• Decontaminate handheld if blood is spilled on it. See Start-up section of manual for instructions.

• Since blood spots may not be noticeable on the handheld and since a cartridge could contaminate the inside of the handheld, treat the handheld as capable of transmitting infection.

• Use universal precautions as defined by your organization or by the Occupational Safety and Health Administration (OSHA).

To protect yourself and others against:

• A falling or dropped handheld: Place handheld and peripherals on a stable surface.

• Barcode scanner: Do not look into laser beam coming from scanner, or point into eyes of someone else.

• Needles: Take care to prevent needle sticks. Use a blunt tipped device when transferring sample from blood collection tube to cartridge.

Handheld and Peripherals are NOT suitable for use in an oxygen enriched atmosphere.

Potential Sources of Damage to the Handheld

• Trying to pull a cartridge out of the handheld while “Cartridge Locked” message is displayed.

• Dropping the handheld.

• Getting the handheld wet. Do not place the handheld on a wet surface, or immerse it in water or other liquid.

Do not open the handheld. The handheld may only be opened by factory authorized service personnel. Class 2 laser radiation when open; DO NOT stare into the laser aperture or the laser beam, or point the laser beam at other persons.

Use of controls, adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

Class 2 laser scanners use a low power, visible light diode. As with any bright light source, such as the sun, the user should avoid staring directly into the laser beam. Momentary exposure to a Class 2 laser is not known to be harmful.

The warning label is shown below. The warning label is located on the back or underside of the handheld. The location of the laser window from where the handheld emits the laser beam is also shown below.
ABBOTT PRINCIPLES OF MEASUREMENT

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

**Urea**
is first hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease. The ammonium ions are measured by an ion-selective electrode and the concentration is calculated from the measured potential through the Nernst equation.

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

**Creatinine**
is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the creatinine concentration.

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

**TCO₂**
The measured TCO₂ test method is calibrated to the International Federation of Clinical Chemistry (IFCC) TCO₂ reference method with an algorithm, based on the Henderson-Hasselbach equation, which uses pH, PCO₂, and ionic strength (Na) measurements.

**FOOTNOTES**

Adopted By ________________________________ Date: ____________________________

SOP Change Record

<table>
<thead>
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