A. Purpose:
Incorporates a comprehensive group of components needed to perform blood analysis at point of care. Just 2-3 drops of fresh whole blood is all that is required, and a portable, battery-powered analyzer displays quantitative test results in approximately 2 minutes. Infrared communication devices allow all patient information obtained at the bedside to be transmitted to centralized information system for record keeping and billing.

1. Principle: A single-use disposable cartridge contains a microfabricated biosensor array, a calibrant, solution, fluidics system and waste chamber. Sensors for analysis of sodium, potassium, chloride, pH, $PO_2$, $PCO_2$, urea nitrogen (BUN), glucose, hematocrit, and ACT (Activated Clotting time, PT/INR and troponin I are available in a variety of panels. A whole blood sample of approximately 2 to 4 drops of blood is dispensed into the cartridge well. A hand-held analyzer into which the blood-filled cartridge is placed for analysis automatically controls all functions of the testing cycle including fluid movement within the cartridge calibration, and continuous quality monitoring. Analyzers with thermal control testing at $37^\circ$C. Information is then transmitted from the analyzer to the RALS middle ware software system where data can be stored, organized, edited and transferred to a laboratory information system or other computer. Sinai currently uses the istat for ACT, INR and troponin testing.

B. Policies:
1. Tests will be performed by certified operators using correct policies and procedures of LifeBridge Health.
2. Tracking of trends in patient results is the responsibility of clinical personnel.
3. Personnel should compare with caution laboratory and bedside test values. The results may not be directly comparable because of the different methods used. In the patient’s medical record, the bedside test and laboratory test results will be maintained separately.

4. INR testing in the Preop must be only performed on patients being monitored for cessation of coumadin therapy. Questionable results need to be confirmed with the lab.

5. When performing PT test, analyzer must be taken to bedside and test performed immediately. PT/INR will be performed using a drop of blood from finger stick only.

6. Patients who have received therapeutic or diagnostic procedures employing immunoglobulins or reagents derived from immunoglobulins may contain antibodies, e.g. HAMA or other heterophile antibodies, which may interfere with immunoassays and produce erroneous results when performing a cTnl (cTroponin I i-STAT Test).

7. Capillary tubes or direct punctures (e.g. fingersticks) should not be used with the cTnl (cTroponin I i-STAT Test).

8. If specimen for cTnl is taken from a tube containing anticoagulants such as EDTA, ovalate, and citrate will cause deactivation of the alkaline phosphates resulting in decreased cTnl readings.

C. Supplies and Storage:
   1. Cartridges:
      a. Stored at 2 to 8º C. Do not allow cartridges to freeze.
      b. May be stored at room temperature for 14 days for non blood gas cartridges at 18 to 30º C or 64 to 86ºF.
      c. Cartridges are never returned to refrigerator once they have been at room temperature, and should not be exposed to temperature above 30º C.
      d. Mark the calendar on the box to indicate the two week room temperature expiration date.
      e. Cartridges should remain in pouches until time of use.
      f. Do not use after expiration date.

D. Specimen:
   1. Specimen type: Whole blood
   2. Patient preparation: N/A
   3. Handling conditions:
      a. Fresh whole blood in a capillary tube or plastic syringe without anticoagulant: Test immediately after collection.
      b. Fresh whole blood collected in a collection tube or syringe with lithium heparin anticoagulant: Fill to capacity: Test within 10 minutes of collection.
d. **PT/INR:** Finger stick only. First drop of blood is dropped directly into the sample well of the cartridge.

4. **Specimen labeling:**
   If the test is not performed at patient’s beside, at the time specimen is drawn, a patient identification label should be attached to sample.

5. **Sample rejection criteria:**
   a. Evidence of clotting.
   b. Specimen collected in vacuum tubes with anticoagulant other than lithium heparin.
   c. Other sample types such as urine, CSF and pleural fluid.
   d. **PT/INR Cartridges:**
      The presence of exogenously added heparin, citrate, oxalate, or EDTA from blood collection devices will interfere with the test results. Glass syringes or tubes may prematurely activate coagulation, resulting in accelerated clotting times and lower the INRs.

E. **Specimen collection:**
   a. **In-Dwelling line:**
      Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: three to six times the volume of the catheter connector, and needle.

   b. **Arterial specimens:**
      Fill blood gas syringe to the recommended capacity or use the least amount of liquid heparin anticoagulant that will prevent clotting. Under-filling syringes containing liquid heparin will decrease results due to dilution. Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds and then inverting the syringe repeatedly for at least 5 seconds. Avoid or remove immediately any air drawn into syringe to maintain anaerobic conditions. A blood sample should be tested within 10 minutes after it has been obtained. (re-mix before testing).

   c. **Venous specimens:**
      If a cartridge cannot be filled immediately, collect sample into a evacuated blood collection tube or a syringe containing lithium heparin anticoagulant. Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds and then inverting the syringe repeatedly for at least 5 seconds. If possible, test samples immediately after drawn; samples should be tested within 10 minutes. (re-mix before testing).

   d. **Finger Stick specimens (PT/INR only):**
Clean and prepare the finger to be sampled. Allow finger to dry thoroughly before sampling. Prick the bottom side of the fingertip with the lancet device. Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first drop of blood. Avoid strong repetitive pressure ("milking") as it may cause hemolysis or tissue fluid contamination of the specimen. Touch the drop of blood against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge. Fold the sample closure over the sample well. Press the rounded end of the closure until it snaps into place. **Note:** Do ensure that the instrument remains on a flat vibration-free surface for testing.

7. **Preparation for specimen collection:**
   All i-STAT cartridges must stand at room temperature for 5 minutes (individually) or 1 hour (entire box of 25 cartridges) before use.

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**F. Equipment and Materials:**

1. **Equipment:** I-STAT analyzer
2. **Materials/supplies:**
   1. Alcohol swab
   2. 2X2 gauge
   3. Lancet: fingerstick/
      Tube/syringe: venous/arterial
   4. I-STAT cartridge
   5. Gloves

**G. Procedure:** (See below procedure when performing Barcoded Cartridge)

1. Take analyzer to bedside.
2. Press the On/Off key to turn analyzer on.
3. Press 2 for I-STAT cartridge from the Test Menu.
4. Scan Operator bar code. ID must be repeat as prompted.
5. Take the i-STAT to the patient's bedside and scan the patient's armband.
6. Remove cartridge from pouch, taking care to hold cartridge by its sides because touching contact pads can damage the cartridge causing “star outs”.
7. Obtain sample in appropriate container.
8. Direct the dispensing tip or capillary tube containing the blood into the sample well. For PT cartridges drop of blood is directly added to cartridge by touching drop of blood against the bottom of the
sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.

9. Dispense the sample until it reaches the FILL TO mark in the cartridge. (Do not press on the sample well).
10. Insert the cartridge into the cartridge door until it clicks into place.
11. At this time you can enter sample type by entering number that corresponds to type of specimen. Specimen types can be seen at the bottom of the page with their appropriate matching number.
12. Press enter.
13. Press page to go back to Result Screen.
14. View results shown on analyzer’s screen.
15. If you obtain a Critical Result, go to ADHoc Charting in Powerchart and fill out the caregiver that was notified with the date and time.
16. Place I-STAT in front of downloader so that intra-light on both the I-STAT and the downloader are facing each other. Results will automatically go from the I-STAT to the RALS system. The results will then flow from the RALS to Cerner and show up in Power Chart on the unit. If the patient ID is not entered correctly, results will only go to RALS. Should the interface be down due to maintenance, etc. results will not go over to Cerner until interface in functioning again.
17. Remove cartridge from instrument and discard cartridge and gloves in biohazard container.

Procedure for cTnl (Cardiac Troponin I i-STAT Test)

Note: Test takes 10 minutes for completion. Only specimen obtained in a Lithium Heparin Tube (dark green top tube, at least half full) or blood gas Lithium Heparin Syringe.
1. Follow procedure G numbers 1 thru 10 only.
2. 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.
3. 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. Note: When sliding the closure clip, the index finger of the same hand should not be placed directly across from the thumb, as this could result in the sample being used into the user's glove. This index finger should be placed just above the position of the sliding clip during the closure or not at all.
4. Insert the cartridge into cartridge port. Grasp the cartridge "slide cover" between the first finger and the 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.

The analyzer must remain on a level surface with the display.
facing up during the testing. Motion of the analyzer during testing can increase frequency of suppressed results or quality control checks.

5. Enter sample type on chart page.
6. View result on analyzer's display.
7. Remove cartridge after Cartridge Lock message disappears.

Quality Check Codes:
There are three additional quality check codes that users may encounter when scanning barcodes. They are summarized in the table below.

<table>
<thead>
<tr>
<th>Cause Message</th>
<th>Action Message</th>
<th>Code</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cartridge Type Not Recognized</td>
<td>Use Another Cartridge</td>
<td>69</td>
<td>The Handheld expects the barcode on the individual cartridge pouch to be scanned. It will not accept keypad entries of the cartridge lot number or a scan of the barcode on the cartridge box.</td>
</tr>
<tr>
<td>Lot Expired</td>
<td></td>
<td>140</td>
<td>The Handheld detected and expired cartridge lot. Check the expiration date and repeat the test using a non-expired cartridge lot.</td>
</tr>
<tr>
<td>Analyzer Error</td>
<td>See Manual</td>
<td>147</td>
<td>The Handheld is not customized appropriately to run cartridges with barcoded pouches. See the instructions in the Technical Bulletin following the Overview section for customizing i-STAT 1 Handhelds to run barcoded cartridges.</td>
</tr>
</tbody>
</table>

H. Results:
1. Flagged Results:
When the analyzer detects an out-of-range result or an uncharacteristic sensor signal, the condition is indicated by a flag. See below for flags and symbols used with results.

a. Results falling outside of the reportable range of the cartridge will be flagged with a <“or”> sign.
Action: Send specimen(s) to laboratory for analysis if you need this result. Clinical action may be appropriate.

b. <> sign appears when a result is dependent on another test that has been flagged.
Action: Send specimen(s) to laboratory for analysis if you need this result.
c. ↑ sign next to the result indicates that the result is above the Critical High action range.
Action:
Notify the physician, record who was notified and see if he/she wants a specimen to be sent to Main Laboratory for verification.

d. ↓ sign next to the result indicates that the result is below the Critical Low action range.
Action:
Notify the physician, record who was notified and see if he/she wants a specimen to be sent to Main Laboratory for verification.

e. *** sign indicates the signals from a particular sensor are uncharacteristic. Uncharacteristic signs can be caused by a compromised sensor or by an interferent in the sample. This flag also appears for any test dependent on another test which is flagged with stars.
Action:
Repeat sample using a new cartridge. If *** are displayed again, draw another sample for testing in the laboratory and report the issue to POC staff.

2. Critical Values:
   a. Any test that exceeds a “critical limit” on the i-STAT should be repeated on the i-STAT. If the result is still critical it will be up to the treating physician whether to send a specimen to the Main Laboratory for verification.
   b. The Physician in charge of the patient should be notified of the critical result, and the notification documented in AdHoc Charting for Critical Values.

Point of Care Reference and Critical ranges
*Values outside the reportable range are not valid on the i-STAT and should be repeated by the laboratory. Reference ranges apply to whole blood samples tested on the i-STAT, and may not match those listed in the computer for in-lab tests. Troponin values do not correlate directly with lab values.
Critical values are adapted from multiple sources and reflect LifeBridge Health historical data.

<table>
<thead>
<tr>
<th>Test</th>
<th>Critical Range(low)</th>
<th>Reference Range</th>
<th>Critical Range(high)</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR</td>
<td>NA</td>
<td>0.9 -1.2</td>
<td>&gt;3.9</td>
</tr>
<tr>
<td>cTnl ng/mL</td>
<td>NA</td>
<td>0.00-0.1</td>
<td>NA*see note</td>
</tr>
</tbody>
</table>

*Note regarding Troponin I: Lifebridge has established a troponin I reference range of 0-0.1 ng/mL for this instrument (Abbott iSTAT). Diagnosis of myocardial infarction requires a documented rise or fall in serial troponin values, with at least one value above the upper reference limit, as well as clinical findings consistent with
cardiac ischemia.

source:i-STAT Procedure manual

I. Quality Control:
   1. Electronic Simulator:
      a. QC is done automatically every eight hours by the internal Quality Control set in the instrument.
      b. These results are transmitted to the RALS where they are stored.
      c. Should the I-STAT fail QC or if the instrument is dropped, the external Electronic Stimulator can be used.
      d. Insert Electronic Stimulator into the analyzer.
      e. If “PASS” is displayed on the analyzer, remove the Electronic Stimulator. In this case transmit this result over the infra red (IR) interface immediately. If “FAIL” is displayed again, replace instrument by going to Specimen Processing and exchange the malfunction instrument with a new one. Inform the Point-of-Care Staff if available.
   2. Liquid Controls:
      Aqueous assayed control fluids are obtained from I-STAT for verifying the integrity of newly received cartridges. These solutions do not contain human serum or serum products. PT Control Level 1 (normal) and PT Control Level 2 (abnormal) are used. Troponin control levels 1 and 3 are used and ACT control levels one and two are used.

Pathology Department, Point-of-Care Testing Specialist / Team Leader will oversee quality control for all cartridges:
   a. Per shipment / lot number to hospital.
      Two levels of controls performed in duplicate on each cartridge lot number per shipment.
      b. Weekly qc will be performed using two levels of controls for each lot number of cartridges in use. Cartridges will be taken to units for operators to perform.
      c. Each i-STAT being use for patient testing will have all analytes performed on it per 3 month rotating schedule. This will be determined by what tests that unit is performing.
      d. Documentation of cartridges, lot numbers and controls will be stored in Pathology.
      e. New Instrument: Refer to this procedure POC.523.03 QC/QA for moderate complex testing-LBH
   f. Controls: (also refer to this procedure POC.013.06 Controls for i-STAT - SHB
      1. Storage
Contained in 1.7mL glass ampules.
Refrigerated at 2 to 8°C (35-36°F).
May be stored at room temperature for up to 14 days at 18°C to 30°C (64-86°F).
Can not be used beyond expiration date.

2. Target Ranges:
   Target values (determined by testing multiple ampules of each level using multiple lots of I-STAT cartridges with I-STAT held analyzers that have passed the Electronic Simulator) are available by going to the web site and printing the control sheets.
   The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly. Should results outside the ranges obtained, refer to Cartridge Troubleshooting section in the I-STAT manual or call I-STAT Technical Help. Always be sure that the lot number printed on the insert matches the lot number on the label of the ampule in use, and that the software revision above the table matches the software revision in the analyzer.

3. Refer to POC.523.03 QC/QA for moderate complex testing-LBH for additional information on quality control testing.

J. Analyzers:

1. Cleaning:
   Wear gloves during the following procedure:
   Remove cartridge from analyzer when test is completed and clean with Hospital Approved bleach wipes. No cartridge is to remain in i-STAT after test is completed.

2. Decontaminate: Use hospital approved bleach wipes between each patient and whenever a specimen is spilled onto the Analyzer or if the analyzer is to be returned to I-STAT for repair and between patients.
   a. Apply gloves
   b. Clean analyzer with Hospital Approved bleach wipes.
   c. Avoid scraping dried blood as contaminated particles may become airborne.
   d. If the analyzer is placed on a wet surface or if any liquid is spilled onto it, dry the analyzer immediately. If the liquid enters the electronic compartment, the battery compartment, or the cartridge port, the analyzer may be damaged.

Changing Batteries:(This is the responsibility of the unit performing the test)
Wait until any test in progress is completed before replacing the batteries or results will be lost. Stored results will not be lost when replacing batteries. To change batteries;
   a. Place the analyzer upright and open the battery compartment door.
b. Remove the old batteries. Orient + and – poles of the new batteries and the + and – labels in the battery compartment and slide the new batteries into place.

c. Discard batteries in appropriate container specified by hospital.
   Note: Lithium batteries can be obtained from Distribution but must specify that you want 9-volt Lithium batteries for the I-STATs.

K. Calibration:
   Calibration is automatically performed as part of the test cycle on each cartridge. Operator intervention is not necessary.

L. 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>Test</th>
<th>Interferent/Limitation</th>
<th>Effect on Analyte Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Troponin I</td>
<td>Gross hemolysis</td>
<td>Decrease of troponin levels</td>
</tr>
<tr>
<td></td>
<td>Hematocrits&gt; 65%</td>
<td>Increase in quality check code errors</td>
</tr>
<tr>
<td></td>
<td>If analyzer does not remain flat during testing</td>
<td>Increases in test imprecision and quality check codes</td>
</tr>
<tr>
<td></td>
<td>Exposure to animals or who have received therapeutic or diagnostic procedures employing immunoglobulins or reagents derived from immunoglobulins may contain antibodies(eg HAMA or other heterophile antibodies.)</td>
<td>Increase in the frequency of suppressed results or quality check codes</td>
</tr>
<tr>
<td></td>
<td>Partially clotted specimen</td>
<td>Could cause erroneous results</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Increase in troponin levels as well as increase in quality check errors</td>
</tr>
<tr>
<td>INR</td>
<td>Exogenously added heparin, citrate, oxalate or EDTA from blood collection devices</td>
<td>Interfere with test results</td>
</tr>
<tr>
<td></td>
<td>Glass syringe or tubes</td>
<td>Falsely decrease INR values(only use plastic tubes or syringes)</td>
</tr>
<tr>
<td></td>
<td>Should not use on a patient that is known or suspected to have lupus anticoagulant antibodies</td>
<td>Could cause erroneous results(use a lab test)</td>
</tr>
<tr>
<td></td>
<td>Cubicin(daptomycin for injection)</td>
<td>Falsely elevated INR levels (use a lab test)</td>
</tr>
<tr>
<td></td>
<td>If analyzer does not remain flat during testing</td>
<td>Increase in the frequency of suppressed results or quality check codes</td>
</tr>
<tr>
<td></td>
<td>Samples contaminated with chlorhexidine gluconate</td>
<td>Falsely elevated INR levels( use lab)</td>
</tr>
<tr>
<td></td>
<td><strong>Hematocrits must be in the range of 24-54% PCV</strong></td>
<td>In this range, results will not be</td>
</tr>
<tr>
<td>ACT kaolin</td>
<td>Exogenously added heparin, citrate, oxalate or EDTA</td>
<td>Interfere with test results</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Glass syringe or tubes</td>
<td>Will cause erroneous results (only use plastic tubes or syringes)</td>
<td></td>
</tr>
<tr>
<td>Hemodilution</td>
<td>May affect test results</td>
<td></td>
</tr>
<tr>
<td>Platelet dysfunction, factor deficiencies, other coagulopathies and other pharmacological compounds</td>
<td>May affect test results</td>
<td></td>
</tr>
<tr>
<td>Fibrinogen concentration of 100-500mg/dL, Sample temperature from 15-37°C</td>
<td>Will not affect test results</td>
<td></td>
</tr>
</tbody>
</table>

M. Troubleshooting:
In the event of broken equipment:
- Vocera Point of Care testing
- Call x24219 or x 22937 to speak to a POC specialist
- Manager for Lifebridge POC testing may be reached at x 25673
- When POCT is not available, call I-STAT (1-800-366-8020) for technical help.

N. Communication of Problems:
1. Monthly report will be sent to Directors identifying any problems found. The Director will be asked to follow-up and return to Pathology actions taken to resolve problems noted.
2. Additional communications will be sent when problems are identified and need immediate attention.

O. Training:
Purpose: To ensure that each operator using the I-STAT has been trained and is competent to use the analyzer.

Responsibility: Only the Point-of-Care Testing Specialist or certified trainers have the authority for training and certification.

Policy:
1. Only an employee who is certified by a LifeBridge Health certified instructor can perform testing on the i-STAT.
2. Certification will include an inservice, completion of written test and a checklist with a certified trainer.
3. All 6 elements of the CAP competency checklist (POC.06910) will be covered.
   - Evaluation of problem solving skills
   - Direct observation of patient testing
   - Monitoring recording and reporting of test results, including, as applicable, reporting critical results.

Written By: Joann O Connor
Date: 08/08/2017
Effective Date: 09/22/2017
- Review of QC records
- Assessment of test performance
- Direct observation of instrument maintenance and function checks, as applicable.

4. See Point of Care Training procedure for more details.

5. Re-certification will be performed after 6 months, the first year, then yearly thereafter. All competencies, original, 6month and yearly will cover the 6 elements in the CAP competency checklists.

P. **Recording and Storage of Data:**
   Results will be downloaded via the intranet and recorded in PowerChart.

Q. **Critical Values:**
   A Critical Value indicates a need to take clinical action, including change in therapy or simply repeating a test or submitting a specimen to the clinical laboratory to verify the original alert value. When a Critical Value is obtained, a Physician or PA must be notified and documented in PowerChart under Critical Value AdHoc Charting.

R. **References:**
   i-STAT package inserts
   i-STAT System Manual
   Clinical Chemistry Theory, Analysis & Correlation, Kaplan/Pesce, 2nd Edition, Pages 850-856, 872-875m 884-888, and 1021-1024.

FOOTNOTES:
Garth, David M.D., emedicine, Webmd, August 23, 2007, Department of Medicine.