TITLE: Testing Procedures for i-STAT® CG4+ blood gas cartridges v1.01

I. PURPOSE

1. To describe the use of the i-STAT® system portable handheld blood analyzer used to analyze for blood gases in whole blood sample as at the point of care.

II. RESPONSIBILITY

1. It is the responsibility of the site coordinator and PI to ensure that equipment is appropriately cleaned, maintained in good working order, and available for research personnel as requested.

2. It is the responsibility of site coordinator to ensure that all research and technical staff are adequately trained to use the i-STAT® system.

III. BACKGROUND

1. The i-STAT® System is capable of performing blood analysis at the point of care.

2. The i-STAT® analyzer contains a microprocessor that performs all calculations for reporting results. Results are displayed numerically with the appropriate units. Electrolyte, chemistry and hematocrit results are also depicted as bar graphs with reference ranges.

3. The i-STAT® Analyzer when used with the Central Data Station program provides system management tools to include real-time monitoring of testing and operator competency.

4. The i-STAT® Analyzer can be interfaced with a printer or data stored for retrieval at a later time.

IV. CARTRIDGES

Required procedure for handling new cartridge or control shipments:

1. Open box marked “Refrigerate Upon Arrival”. Find card with temperature strip attached. Read strip immediately as it will change once it is exposed to room temperature. Follow instructions on card. If the reading is found to be unacceptable, contact Technical Support.

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

3. If temperature strip reading is acceptable, test cartridge(s) with liquid control. Take one cartridge from each lot number in the shipment and test with a control sample (See “Perform a Control Test” for instructions).

4. A single-use disposable cartridge contains microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber.

5. Sensors for analysis of pH, PCO_2, PO_2 and lactate are available in a variety of panel configurations.

6. 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.

V. SUPPLIES and STORAGE REQUIREMENTS

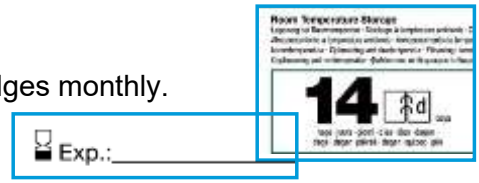
Cartridges

1. Cartridges are sealed in individual pouches or portion packs.
2. Store the main supply of cartridges at a temperature between 2 to 8°C. Do not allow cartridges to freeze.
3. Cartridges may be stored at room temperature (18 to 30°C) for 14 days. Cartridges should not be returned to the refrigerator once they have been at room temperature, and should not be exposed to temperatures above 30°C. If the pouch has been punctured, the cartridge should not be used.
4. Write the date on the cartridge box or individual cartridge pouches to indicate the two-week room temperature expiration date. Cartridges should remain in pouches until time of use. Do not use after the labeled expiration date.

Controls

i-STAT Controls for blood gases

1. Store at 2 to 8°C.
2. Controls may be stored at room temperature (18 to 30°C) for five days.
3. Do not use after expiration date on the box and ampules.
4. Monitor fridge temperatures daily and check stored cartridges monthly.



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.

VI. BLOOD SPECIMENS

Blood Collection Equipment for Blood Gas (CG4+) cartridges

1. Skin puncture: lancet and capillary collection tube (plain, lithium heparin, or balanced heparin for blood gases)
2. Venipuncture: lithium or sodium heparin collection tubes and disposable transfer device (e.g., 1cc syringe and a 16 to 20 gauge needle).
3. Arterial puncture: Plain syringe or blood gas syringe with heparin and labeled or with the least amount of heparin to prevent clotting (10 U heparin/mL of blood)

Suitable Specimens for Cartridges for Blood Gases;

1. Fresh whole blood collected in a plain capillary collection tube or capillary collection tube with balanced heparin.
2. Fresh whole blood collected in a collection tube with lithium or sodium heparin anticoagulant. Fill collection tubes to capacity.

3. 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.

4. Blood Volume for CG4+ should be 95ul.

5. Specimen Labeling

    a. Label the sample immediately after collection, the specimen container must be labeled with the following information:

    b. Patient name, sex, age, site ID, Patient ID number, Time and date of collection

Specimen Collection and Handling

Venous whole blood samples collected in evacuated tubes with lithium or sodium heparin anticoagulant (green top tube). Fresh whole blood collected in a plain capillary collection tube or capillary collection tube with heparin can be used. The heparin-to-blood ration should not exceed 10 U heparin per milliliter of blood.

Test samples immediately for the most accurate results;

- Samples for lactate-test immediately
- Samples for pH, ***P***CO_2, TCO_2, and ionized calcium should be tested within 10 minutes.

Venus whole blood specimen is the preferred sample

1. Fill a plain syringe or fill a blood gas syringe and label it before testing.

2. Under-filling syringes containing liquid heparin will decrease results due to dilution.

3. Do not expose sample to air or PCO_2 may decrease, pH may increase and PO_2 may decrease if the value is above or increase if the value is below the PO_2 of room air (approximately 150 mmHg).

4. 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.

5. Avoid or remove immediately any air drawn into syringe to maintain anaerobic conditions.

6. Test sample collected without anticoagulant immediately.

7. Test samples for lactate within 3 minutes of sample collection. For pH and blood gases, test within 10 minutes of collection.

8. If not tested immediately, remix the sample and discard the first two drops of blood from a syringe before testing.

9. 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 because of the potential for decreased measured PCO2 results and calculated HCO3 and TCO2 values.

Criteria For Specimen Rejection

- Evidence of clotting specimens collected in vacuum tubes with anticoagulant other than lithium or sodium heparin
- Syringe for pH, PCO2, and PO2 with air bubbles in sample or incompletely filled vacuum tube for the measurement of PCO2

Precautions for sample handling: 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, especially lactate
- Exposing the sample to air when measuring pH, PCO2 , and PO2

VII. ASSAY INSTRUCTIONS

Blood Gases (pH, PCO_2, PO_2, Lac, HCO_3, TCO_2, BE, sO_2)

1. We will use CG4+ cartridges for blood gas testing, clearly marked on the cartridge;
    a. Prior to using a cartridge, it must be removed from refrigerated storage and kept at room temperature in its protective pouch for at least 5 minutes for best results until it attains room temperature.
    b. Use a cartridge immediately after removing it from its pouch. Prolonged exposure may cause the cartridge to fail a quality check.
    c. Do not use cartridges if pouch has been punctured.
    d. Once cartridges have been brought to room temperature they should not be returned to the refrigerator.
    e. Do not handle the contact pad with fingers or talc from glove.
    f. Do not apply pressure to central area of the label.
    g. To avoid contamination of the analyzer do not use a cartridge on which blood or other fluid has spilled.
    h. Do not use after the label expiration date.

2. Manual calibration is not necessary. Calibration is automatically performed as part of the test cycle for each cartridge type.

3. Filling and sealing cartridges
    a. Place cartridge on a flat surface or hold it in a horizontal position.
    b. Direct the tip of the syringe, capillary tube or dispenser into the sample well.
    c. Dispense sample slowly until it reaches the fill mark. Leave some sample in sample well.
    d. Fold snap closure over the sample well and press until it snaps into place.

4. Inserting and removing the cartridge into/from analyzer
    a. Align the cartridge with the contact pads facing up and toward the cartridge port
    b. Push the cartridge slowly and smoothly until it clicks into place.

c. Do not attempt to remove the cartridge while the message “Cartridge Locked” remains on the screen.

    d. When results are displayed, pull cartridge straight out of the analyzer.
    e. Dispose of cartridge in biohazard container.

5. Performing sample analysis
    a. Press SCAN to scan cartridge lot number.
    b. Use number keys to select tests to be reported on the Test Selection Page.
    c. Enter information on the Chart page.
    d. View results on the Results page
    e. Test results are displayed with numerical concentration values in the units selected and bar graph with reference ranges.

6. Suppressed results (there are three conditions that i-STAT will not display results:
    a. Results outside reportable ranges
    b. Cartridges outside of internal QC rejection criteria
    c. Analyzer detects problem with the sample, calibrant solution, sensors, or mechanical/electrical malfunction.

7. Procedure for Testing
    a. Remove the cartridge from pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
    b. Following thorough mixing of the sample, direct the dispensing tip or capillary tube containing the blood into the sample well.
    c. Dispense the 95ul of sample. Sample volume is adequate when it reaches the fill mark on the cartridge and the well is about half full.
    d. Close the cover over the sample well until it snaps into place. (Do **not** press over the sample well
    e. Insert the cartridge into the cartridge port on the analyzer until it clicks into place.
    f. Never attempt to remove a cartridge while the LCK or "Cartridge Locked" message is displayed.
    g. Enter the patient ID number.
    h. Select tests to be reported, if prompted.
    i. View results shown on the analyzer's display screen and transfer results to the CRF.
    j. Remove the cartridge after the LCK or "Cartridge Locked" messages disappear is ready for a new cartridge immediately.

8. Printing and Transmitting Results from the i-STAT Portable Clinical Analyzer to the HP Portable Printer
    a. Place the analyzer in the cradle of an IR Link or align the IR windows of the analyzer and printer. Turn the printer on (printer light red) or press the paper advance switch to reactivate.
    b. To print the displayed test record, press the PRT key on the analyzer.
    c. To print a stored test record(s), select "Print Results" from the Stored Results menu. Select records to be printed by pressing the Key(s) corresponding to the numbers beside the record(s). Press the numbered key again to deselect a record. Then press the PRT Key.
    d. Do not move the analyzer while "Printing" is displayed. Take note of the results on the CRF as well and attach the results print out on the CRF.

VIII. REFERENCES

1. Refer to the i-STAT® 1 System Manual for additional information.

Document history

Version 1	Author	Approved by	Dated	SOP No:
iSTAT blood processing SOP	Caroline Tigoi			

Site training record
All sites are required to maintain a master copy of this SOP that documents the site staff that have been trained on this SOP.

Document History				
Version No.	**Trained staff initials**	**Signature of trained staff**	**Date**	**Trainer's Initials**
1.01	KDT	Example row	1st Jan 2016	DM

SOP AWARENESS LOG

I, the undersigned below, hereby confirm that I am aware that the accompanying SOP is in existence from the date stated herein and that I shall keep abreast with the current and subsequent SOP versions in fulfilment of Good Clinical Practice (GCP).

Number	Name	Signature	Date (dd/mmm/yyyy)
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