STANDARD OPERATING PROCEDURES

DIVISION OF COMPARATIVE MEDICINE
UNIVERSITY OF SOUTH FLORIDA

TITLE:	**i-STAT®1 Handheld Blood Analyzer**
SCOPE:	Research and Animal Care Personnel
RESPONSIBILITY:	Facility Manager, and Professional & Administrative Staff
PURPOSE:	To Outline the Proper Procedures for Use and Maintenance of the i-STAT®1 Handheld Analyzer System

I. PURPOSE

1. To describe the use of the i-STAT® system portable handheld blood analyzer used to analyze whole blood for blood gas, chemistry, and coagulation at the point of care.

II. RESPONSIBILITY

1. It is the responsibility of the Facility Manager 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 the veterinary professional, administrative, and managerial staff 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. GENERAL EQUIPMENT USE

1. Only fresh blood samples are recommended for use with the i-STAT® System.

2. Specimens should be collected carefully and handled properly to ensure accurate results.
    a. Sample hemolysis may cause inaccurate blood chemistry values (e.g., increased potassium, and decreased calcium).
    b. Specific anticoagulant agents may be required for specific tests.
    c. Anticoagulants must be in the correct ratio to sample volume.
    d. Exposure to air should be avoided when testing venous blood for ionized calcium, pH, ***P***CO_2, and TCO_2.
    e. Test samples immediately for the most accurate results.
        1. Samples for lactate-test immediately
        2. Samples for pH, ***P***CO_2, TCO_2, and ionized calcium should be tested within 10 minutes.
        3. Other analytes should be tested within 30 minutes.
    f. If testing is not immediate remix blood sample. See instruction manual for remix procedures.

3. Cartridges are sealed in individual pouches or portion packs and stored between 35 to 46^0F. Do not allow cartridges to freeze. Cartridges may be stored at room temperature for 14 days, and should not be exposed to temperatures above 86^0F:
    a. Select appropriate cartridge for the test(s) required.
    b. For best results do not remove cartridge from its protective pouch until it has reached room temperature.
    c. Use a cartridge immediately after removing it from its pouch. Prolonged exposure may cause the cartridge to fail a quality check.
    d. Do not use cartridges if pouch has been punctured.
    e. Once cartridges have been brought to room temperature they should not be returned to the refrigerator.
    f. Do not handle the contact pad with fingers or talc from glove.
    g. Do not apply pressure to central area of the label.
    h. To avoid contamination of the analyzer do not use a cartridge on which blood or other fluid has spilled.
    i. Do not use after the label expiration date.

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

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

V. ASSAY INSTRUCTIONS

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

1. Suitable Specimens
    a. Arterial specimens are preferred for blood gas analysis.
    b. Fresh whole blood collected in a plain capillary collection tube or capillary collection tube with heparin.
    c. The heparin-to-blood ration should not exceed 10 U heparin per milliliter of blood.
    d. Avoid hemolysis.
    e. Avoid exposing sample to air/air bubbles.
    f. For the most accurate results test samples immediately after drawing, Samples collected with anticoagulant should be tested within 10 minutes of collection.
    g. If testing is not immediate remix samples by gentle inversion for 5 seconds and rolling between the palms for at least 5 seconds in each of 2 different directions then discard the first 2 drops prior to filling cartridge. (Note: it may be difficult to properly remix a sample in a 1.0cc syringe.
    h. Do not ice samples before testing.

2. 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 120ul 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.
    j. Remove the cartridge after the LCK or “Cartridge Locked” messages disappears is ready for a new cartridge immediately.

VI. REFERENCES

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

Approved: **Date:**