Childhood Acute Illness & Nutrition Network

KEMRI | Wellcome Trust Clinical Trials

Pancreatic Enzymes and Bile Acids: A Non-Antibiotic approach to Treat Intestinal Dysbiosis in Acutely Ill Severely Malnourished Children

Study Specific Procedure			**SSP No:** LA01 **Version No:** 3.0 **Supersedes:** 2.0 **Effective Date:** 18th July 2022
Title: i-STAT Measurement			
	NAME	**SIGNATURE**	**DATE**
PREPARER	Robert Musyimi		**24th June 2022**
Q.A. AUTHORITY	Aisha Bwika		**15th July 2022**
APPROVING AUTHORITY	Robert Bandsma		**18th July 2022**

1.0 PURPOSE / INTRODUCTION:

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.

1.1 The i-STAT® System can perform blood analysis at the point of care.

1.2 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.

1.3 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.

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

2.0 SCOPE / RESPONSIBILITY:

2.1 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.

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

3.0 DEFINITIONS /ABBREVIATIONS:

3.1 IMS – Industrial methylated spirit

4.0 MATERIALS

4.1 i-STAT analyzer, MN:300G – CAT 04P75-01

4.2 CG4+ i-STAT cartridge

4.3 Safe clinitubes capillary tubes - 125 µl CAT 942-893R1175 or dry-electrolyte balance lithium heparin tube

4.4 23G needle or automatic pricker

5.0 METHODOLOGY:

5.1 **CARTRIDGES** - Required procedure for handling new cartridge or control shipments:

5.1.1 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.

5.1.2 Record temperature reading on “Receipt of New Cartridges” log found in the System

Resources section of this manual.

5.1.3 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).

5.1.4 A single-use disposable cartridge contains micro fabricated sensors, a calibrant solution, fluidics system, and a waste chamber.

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

5.1.6 A whole blood sample of approximately 1 to 3 drops (95µl) is dispensed into the cartridge sample well, and the sample well is sealed before inserting it into the analyzer.

5.2 SUPPLIES AND STORAGE REQUIREMENTS

5.2.1 Cartridges are sealed in individual pouches or portion packs.

5.2.2 Store the main supply of cartridges at a temperature between 2°C to 8°C. Do not allow cartridges to freeze.

5.2.3 Cartridges may be stored at room temperature (18°C to 30°C) for 60 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.

5.2.4 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 labelled expiration date.

5.2.5 **Controls.**

5.2.5.1 i-STAT® Controls for blood gases should be store at 2°C to 8°C.

5.2.5.2 Controls must be dated on date or reception and opening.

5.2.5.3 Controls may be stored at room temperature (18 °C to 30°C) for a maximum five days.

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

5.3 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. Run the simulator before preforming any test on weekly basis. Record the results in i-STAT® lab CRF.

5.4 STARTING THE I-STAT ANALYZER

Turn on the analyzer by pressing the on button. Press 1 to select the device status. Voltage below 8.0 V will give invalid results and the device should be charged before use. Note that the device will not work at temperature above 30.00 C.

5.5 CAPILLARY BLOOD TESTING

Collection of capillary blood

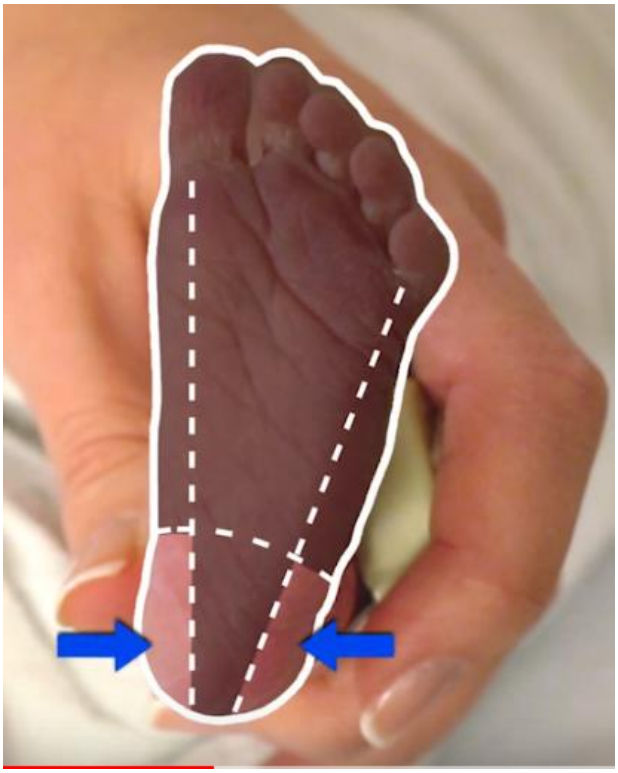
5.5.1 Use PPE while collecting samples.

5.5.2 Confirm patient identity and pre-warm site of puncture to reduce chances of hypothermia. Wrap for example a warm cloth around the hand or foot for 5-10 minutes. This will ensure adequate blood flow at puncture site.

5.5.3 Disinfect puncture area with 70% Industrial Methylated Spirit (IMS).

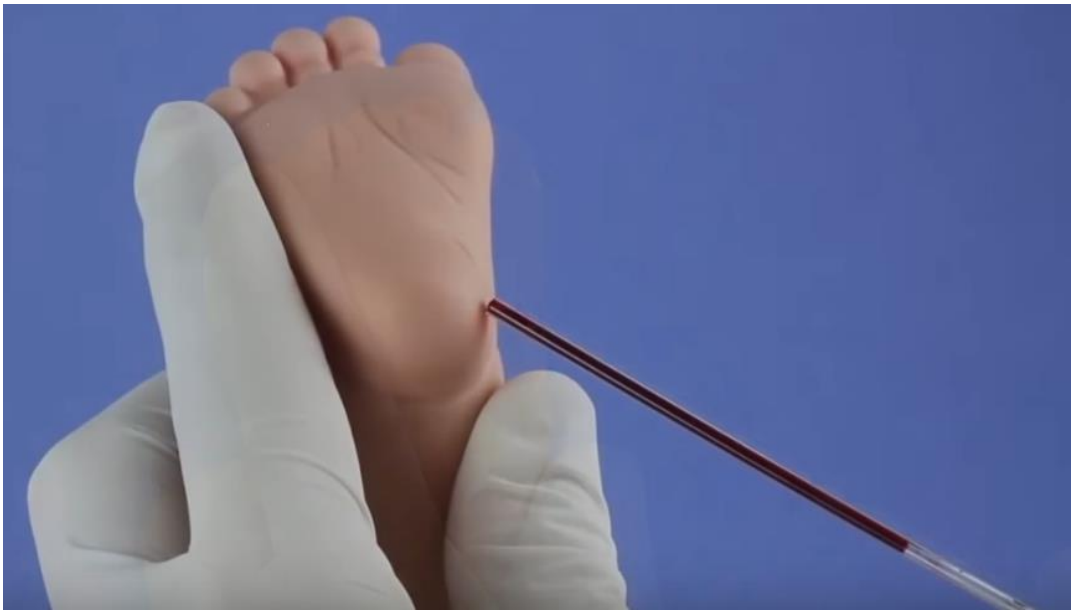
5.5.4 Make a puncture of 3 mm depth with a 23G needle or lancet puncture on the surface of the heel for infants or children. Use the diagram below to identify puncture sites shown by the arrows. Of note, it is common the puncture is not deep enough to produce sufficient blood so ensure you feel comfortable performing this procedure and have been well trained by experienced staff.

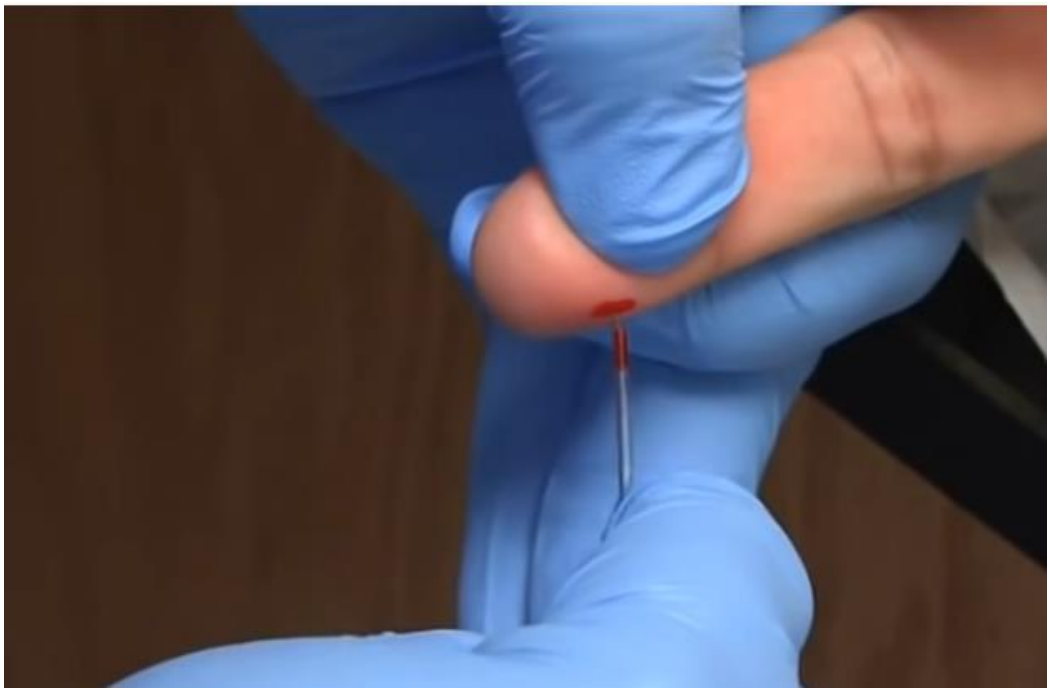
5.5.5 The heel is the most preferred site for children below 6 months. Fingers (especially index finger) of the less used hand is ideal for older children.



5.5.6 Wipe off the first drop of blood.

5.5.7 Hold the capillary tube horizontally to the heel to collect the drop of blood. This will allow blood flow freely through gravity. Avoid creation of bubbles by touching blood drop only, not the patient skin.





5.5.8 If blood is not flowing freely, gently squeeze the heels. Do not milk or squeeze heel or finger as this will result in extraction of tissue fluid that will give invalid results.

5.5.9 Clean excess blood with a dry swab and seal pricking site.

5.5.10 **Procedure for Testing blood on CG4+ cartridge**

5.5.10.1 A maximum 5 tests will be done. Sampling will be twice per day, every 10-14 hours until the 5 samples have been taken. The first will be taken at enrollment. The next sample will be between 6-9 AM on day 1 of the admission. If this falls within 6 hours of the enrollment sample, the next sample will be between 5-8 PM. Again, ensure the time between samples is between 10-14 hours.

5.5.10.2 If a sampling time coincides with a venous blood draw for clinical purposes, this sample can be used for the i-STAT® measurement as long as it is documented on the CRF.

5.5.10.3 Remove the cartridge from pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.

5.5.10.4 Scan cartridge, enter user id and participant ID.

5.5.10.5 Following thorough mixing of the sample, direct the dispensing tip or capillary tube containing the blood into the sample well.

5.5.10.6 Dispense blood by holding the capillary tube at 45^0 to the sample well. Sample volume is adequate when it reaches the fill mark on the cartridge.

5.5.10.7 Close the cover over the sample well until it snaps into place (do not press over the sample well).

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

5.5.10.9 Never attempt to remove a cartridge while the LCK or "Cartridge Locked" message is displayed.

5.5.10.10 Allow i-STAT® device to read test for about 120 seconds. View results shown on the analyzer's display screen.

5.5.10.11 Remove the cartridge after the LCK or "Cartridge Locked" messages disappear is ready for a new cartridge immediately.

Printing and Transmitting Results from the i-STAT® Portable Clinical Analyzer to the HP Portable Printer.

5.5.10.12 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.

5.5.10.13 To print the displayed test record, press the PRT key on the analyzer.

5.5.10.14 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.

5.5.10.15 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.

5.6 WHOLE BLOOD SPECIMENS

Blood Collection Equipment for Blood Gas (CG4+) Cartridges

5.6.1 Skin puncture: lancet and capillary collection tube (No Tube Required).

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

5.6.3 Arterial puncture: Plain syringe or blood gas syringe with heparin and labelled or with the least amount of heparin to prevent clotting (10 U heparin/mL of blood).

Suitable Specimens for Cartridges for Blood Gases

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

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

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

5.6.7 Blood Volume for CG4+ should be 95µl (approximately 4-5 drops).

Specimen Labelling

5.6.8 Label the sample immediately after collection, the specimen container must be labelled with the following information: **Patient initials, sex, DOB, site ID, Participant ID number, Time, and date of collection.**

Specimen Collection and Handling

5.6.9 Test samples immediately for the most accurate results.

- Samples for lactate-test immediately
- Samples for pH, PCO_2, TCO_2, and ionized calcium should be tested within 10 minutes

5.6.10 Whole blood specimen is the preferred sample for blood gases.

5.6.11 Fresh whole blood collected in a plain capillary collection tube or capillary collection tube with heparin or plain syringe. The heparin-to-blood ration should not exceed 10 U heparin per milliliter of blood.

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

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

5.6.14 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).

5.6.15 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.

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

5.6.17 Test sample collected without anticoagulant immediately.

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

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

5.6.20 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 PCO_2 results and calculated HCO_3 and TCO_2 values.

Criteria for Specimen Rejection

5.6.21 Evidence of clotting specimens collected in vacuum tubes with anticoagulant other than lithium or sodium heparin

5.6.22 Syringe for pH, PCO_2, and PO_2 with air bubbles in sample or incompletely filled vacuum tube for the measurement of PCO_2

5.6.23 Precautions for sample handling: Avoid the Following Circumstances

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

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

5.6.23.3 Extra muscle activity (fist pumping)

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

5.6.23.5 Icing before filling cartridge

5.6.23.6 Time delays before filling cartridge, especially lactate

5.6.23.7 Exposing the sample to air, when measuring pH, PCO_2, and PO_2

5.7 ASSAY INSTRUCTIONS

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

5.7.1 We will use CG4+ cartridges for blood gas testing, clearly marked on the cartridge.

5.7.1.1 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.

5.7.1.2 Use a cartridge immediately after removing it from its pouch. Prolonged exposure may cause the cartridge to fail a quality check.

5.7.1.3 Do not use cartridges, if pouch has been punctured.

5.7.1.4 Once cartridges have been brought to room temperature they should not be returned to the refrigerator.

5.7.1.5 Do not handle the contact pad with fingers or talc from gloves.

5.7.1.6 Do not apply pressure to central area of the label.

5.7.1.7 To avoid contamination of the analyzer do not use a cartridge on which blood or other fluid has spilled.

5.7.1.8 Do not use after the label expiration date.

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

5.7.3 Filling and sealing cartridges

5.7.3.1 Place cartridge on a flat surface or hold it in a horizontal position.

5.7.3.2 Direct the tip of the syringe, capillary tube or dispenser into the sample well.

5.7.3.3 Dispense sample slowly until it reaches the fill mark. Leave some sample in sample well. When dispensing with syringe twist the plunger to prevent overfilling.

5.7.3.4 Fold snap closure over the sample well and press until it snaps into place.

5.7.4 Inserting and removing the cartridge into/from analyzer

5.7.4.1 Align the cartridge with the contact pads facing up and toward the cartridge port.

5.7.4.2 Push the cartridge slowly and smoothly until it clicks into place.

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

5.7.4.4 When results are displayed, pull cartridge straight out of the analyzer. Wait for analyzer to prompt you for cartridge removal.

5.7.4.5 Dispose of cartridge in biohazard container.

5.7.5 Performing sample analysis

5.7.5.1 Press SCAN to scan cartridge lot number.

5.7.5.2 Use number keys to select tests to be reported on the Test Selection Page.

5.7.5.3 Enter information on the Chart page.

5.7.5.4 View results on the Results page.

5.7.5.5 Test results are displayed with numerical concentration values in the units

selected and bar graph with reference ranges.

5.7.6 Suppressed results (there are three conditions that i-STAT will not display results:

5.7.6.1 Results outside reportable ranges.

5.7.6.2 Cartridges outside of internal QC rejection criteria.

5.7.6.3 Analyzer detects problem with the sample, calibrant solution, sensors, or mechanical/electrical malfunction.

5.7.7 **Procedure for Testing**

5.7.7.1 Remove the cartridge from pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.

5.7.7.2 Following thorough mixing of the sample, direct the dispensing tip or capillary tube containing the blood into the sample well.

5.7.7.3 Dispense approximately 4-5 drops of blood. Sample volume is adequate when it reaches the fill mark on the cartridge and the well is about half full.

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

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

5.7.7.6 Never attempt to remove a cartridge while the LCK or "Cartridge Locked" message is displayed.

5.7.7.7 Enter the patient ID number.

5.7.7.8 Select tests to be reported, if prompted.

5.7.7.9 View results shown on the analyzer's display screen and transfer results to the CRF.

5.7.7.10 Remove the cartridge after the LCK or "Cartridge Locked" messages disappear is ready for a new cartridge immediately.

5.7.8 Printing and Transmitting Results from the i-STAT Portable Clinical Analyzer to the HP Portable Printer

5.7.9 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.

5.7.10 To print the displayed test record, press the PRT key on the analyzer.

5.7.11 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.

5.7.12 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.

6.0 APPENDICES:

6.1 https://www.news-medical.net/CLINITUBES-Capillary-Tubes-from-Radiometer

6.2 https://www.youtube.com/watch?v=_qOvyph_EyY

7.0 REFERENCES:

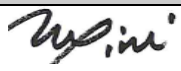
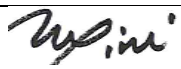
7.1 None

8.0 DOCUMENT CHANGE HISTORY

Version Table:

Version 1.0: Title: **i- STAT Measurement**	Dated: **21st October 2021**	SSP No.: **LA01**	No. Pages: **9**
Version 2.0: Title**: i- STAT Measurement**	Dated: **12th April 2022**	SSP No.: **LA01**	No. Pages: **12**
Version 3.0: Title: **i- STAT Measurement**	Dated: 24th June 2022	SSP No.: **LA01**	No. Pages: **12**
This document is effective from the date of training/last approval signature and will be reviewed in two years.			

SSP Review and Updating Logs

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW AND CHANGES MADE
24th March 2022	Robert Musyimi		- Add section 5.5 on capillary blood collection
24th June 2022	Robert Musyimi		- Add section 5.5.10.1 on capillary blood collection

SSP AWARENESS LOG

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

Number	Name	Signature	Date (dd/mmm/yyyy)
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