TITLE: iSTAT Chem8 Operating Procedure	**Doc #:** 13933
Section: \\Management System\PLM\Point of Care Testing\Multi Test Analyzer\	**Version:** 2.0 Current
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Purpose

This procedure provides instructions to perform blood analysis using the Abbott i-STAT at the point of care.

Abbreviations

Crea	Creatinine	Hct	Hematocrit
Glu	Glucose		

Materials

Description	Package	Storage	Stability
CHEM8+ 03 Abbott-M88-01	(25 cartridges/box)	•2 to 8°C •18 to 25°C	• Labeled expiration date • 14 days

Reagent preparation: None

Note:

- Each time new cartridges are received, mark the date received on each box. (Use the oldest *received* date first). When taken out of the fridge, **write the expiration date** on the outside of the cartridge package (Discard after 14 days).
- **Do not allow cartridges to freeze.**
- 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.
- Cartridges should remain in pouches until time of use.

Supplies	
Collection container • CHEM8+- Lithium heparin container with no additives	
• Roche Cardiac 150ul pipette	• Lancet

Equipment	
Abbott i-STAT 1 Analyzer	Download/Recharge Station
Electronic Simulator	Printer

Note:

- ***Electronic Simulator-*** Store at room temperature and protect contact pads by

replacing the plastic cap and placing the Electronic Simulator in its protective case after each use.
- ***Place the instrument on a flat and stable surface at all times to ensure the instrument does not fall.***

Sample

If samples are required for laboratory analysis refer to: *Laboratory Test Catalogue Collection & Shipping Requirements*

1. Chem8+

Sample type	Amount required	Stability
Whole blood Lithium Heparin	Fully evacuated tube	Sample analyzed immediately after collection, Store samples in specimen rack provided for laboratory retrieval.

Minimum sample requirements: Evacuated tube must be filled to capicity. 95 µL of sample is required for cartridge fill.

Limitations: Incomplete filling causes decrease in TCO2 values, decrease in ionized calcium results and may affect other results.

Specimen Rejection Criteria

• Evidence of clotting	• Air bubbles in sample
• Specimens collected in vacuum tubes with anticoagulant other than lithium heparin	• Other sample types such as urine, CSF, and pleural fluid
• Incompletely filled vacuum tube	

Precautions: Avoid

• Hemolysis	• Specimen from an I.V. arm
• Exposing the sample to air	• Extra muscle activity (fist pumping)
• Tourniquet left on longer than one minute before venipuncture	• Time delays before filling cartridge

Special Safety Precautions

Routine Practices" as directed by Health Canada, must be considered as the level of care provided for all patients. Use Health Canada Guidelines for "Routine Practices" to avoid exposure to blood, body fluids and contaminated surfaces. All patient samples, as well as the materials they contact, are to be considered biohazardous and therefore capable of transmitting infection or cross contamination.

Maintenance

For complete maintenance requirements please see "*ES iSTAT Maintenance Calibration and Quality Control*"
For immediate support please call Abbott Tech Support at **1-800-366-8020**

1. Routine Maintenance

Step	Action
1	• **Clean** the display screen and the case using a gauze pad moistened with a mild non-abrasive cleaner (Soap and water, Alcohol, 10% bleach solution, or Sani-Cloth) • **Rinse** using another gauze pad moistened with water and dry. Avoid getting excess fluids in the seam between the display screen and the case
2	**Decontaminate** -whenever a specimen is spilled on analyzer or downloader • Prepare a 1:10 solution of bleach by mixing one part of bleach with nine parts of tap water (Note Ready to use .05% sodium hypochlorite wipes may be used as an alternate to this bleach preparation) • Moisten gauze pads in the bleach solution. (Squeeze the pads to remove excess solution) • Clean the entire surface of the device • Rinse the surface of the device with gauze pads moistened with tap water and dry **Note:** The analyzer is NOT designed to be sterilized or autoclaved by any method
3	**Dry a Wet Analyzer or Downloader** • If the analyzer is placed on a wet surface or if any liquid is spilled onto it, dry the analyzer **immediately** • Downloader- Unplug from the outlet and dry completely. If liquid enters the analyzer or Downloader, it may be damaged
4	**Recharge battery**-(Battery power > 7.5) • Place the analyzer in re-charger if the iSTAT displays "Low Battery" **Note:** The analyzer is stored on Download/Recharge Station after

	each use to ensure analyzer is always charged.
5	Inform laboratory of any i-STAT quality issues

Note: If a problem is detected during a testing cycle, a message will identify the problem and indicate the next step to be taken. If the problem causes testing to be disabled, the problem must be corrected and the analyzer must be turned off and back on before testing will be enabled. For comprehensive list of messages refer to *i-STAT Job Aid*.

Calibration

For complete calibration requirements please see *ES iSTAT Maintenance Calibration and Quality Control.* Calibration is automatically performed as part of the test cycle on each cartridge type. Operator intervention is not necessary.

Calibrator	Storage	Frequency
Chem 8+ Cal/Ver Kit (Abbott 06F12-17)	2 to 8°C	Automatic with each cartridge
Level 1b sixth level of Cal/Ver kit (Abbott 06F12-14	2 to 8°C	
HCT Cal Verf Control (Abbott 06F12-07)	2 to 8°C	
Electronic Simulator (external)	*18-30 ºC	Monthly
Electronic Simulator (internal)		See note below

Quality Control

Users will be required to participate in scheduled Quality Control testing in accordance with Accreditation Canada requirements, Laboratory will relay schedule by when available.
Routine Quality Control procedures are the responsibility of the laboratory (See *ES iSTAT Maintenance Calibration and Quality Control*).

Control	Level	Storage	Stability	
Chem 8 Control (06F12-13)	1	2 to 8°C	Labeled expiration date	• Monthly <u>and</u> • With each new lot number of cartridge
Chem 8 Control (06F12-15)	2	2 to 8°C		
Chem 8 Control (06F12-15)	3	2 to 8°C		
HCT Control (06F12-04)	1	2 to 8°C		
HCT Control (06F12-	2	2 to 8°C		

05)					
HCT Control (06F12-06)		3	2 to 8°C		

Note: Do not freeze

Procedure

Specimen Labeling

- The specimen container must be labeled with the following information:
- Patient name, Patient MRN and/or HCN number
- Time and date of collection
- Initials of staff drawing blood

Cartridge Notes:

- An individual cartridge may be used after (standing in its pouch) for 5 minutes at room temperature.
- Avoid possible test failure by using the following precautions:
  -If the pouch has been punctured, the cartridge can not be used
  -Do not contaminate the contact pads with fingerprints or talc from gloves
  -Do not apply pressure to the central area of the label (calibrant pack inside could burst prematurely
  -Do not block the air vent (Sample will not flow to the fill mark)

Calculation

Calculations

The i-STAT analyzer contains a microprocessor that performs all calculations required for reporting results. See Cartridge and Test Information (CTI) sheets for specific formulas used.

Result Interpretation

Result flags

Flag	Interpretation
<	Result is below the lower limit the reportable range
>	Result is above the upper limit of the reportable range
< >	Results for this test were dependant on the result of another test flagged as either **>** or **<**.
***	Results which are not reportable based on internal QC rejection criteria are flagged with ***.

Note:

- If questioning the integrity of sample (clots bubbles, etc.), repeat analysis using a

fresh sample and another cartridge.
- If the result is suppressed again, send appropriate sample to the laboratory for analysis
- Results that are not suppressed should be reported in the usual manner

A Quality Check message will be reported instead of results if a problem is detected with the analyzer. See "i-STAT Analyzer Coded Messages" job aid

Expected Values

Analyte	Reference Range	Analytical Range	Critical Range	Units
Sodium	136 -144	100 - 180	<**120** and >**160**	mmol/L
Potassium	3.6 - 5.1	2.0 - 9.0	<**2.8** and >**6.5**	mmol/L
Chloride	101 -111	65-140	<**70** and >**130**	mmol/L
Glucose (AC)	3.6-5.6	1.1-38.9	<**2.2** and >**25.0**	mmol/L
Creatinine	Male 54 -113 Female 37-96	18-1768	>**400**	µmol/L
Ionized Calcium	1.07-1.41	.25-2.50	<**0.60** and>**1.50**	mmol/L
TCO2	22 - 32	5-50	<**10** and >**40**	mmol/L
Hematocrit	Male 0.420 - 0.540 Female 0.370 - 0.470	0.10-0.75	Fraction	Fraction

Limitations

See ***Appendix 3*** for interference substances causing false results.

Hemodilution of plasma by more than 20 % (caused by fluid administration therapies such as normal saline or Ringers lactate) may cause clinically significant errors in sodium, chloride or ionized calcium results. The hemodilution effect is avoided if a philologically balanced multi-electrolyte solution containing low-mobility anions is used.

If **heparinized whole blood is allowed to stand** before testing, potassium values will first decrease slightly, then increase over time. (TCO2 is increased.)

Potassium results from anticoagulated samples may differ from serum laboratory

	results by 0.1 to 0.7 mmol/L. (Potassium is released from platelets as part of the clotting process)
Procedural Notes	**Note:** When a sample-filled i-STAT cartridge is inserted into an analyzer for analysis, the analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration and continuous quality monitoring.
Principle	**PRINCIPLES OF MEASUREMENT** **Sodium, Potassium, Chloride, Ionized Calcium and Urea** measured by ion-selective electrode potentiometry. **Glucose** is measured amperometrically(glucose oxidase) **Creatinine** is hydrolyzed to creatine **Hematocrit** is determined conductometrically. See individual Cartridge and Test Information (CTI) sheets available from laboratory for specific performance characteristics of each parameter
Clinical Utility	The i-STAT 1 Analyzer is intended for use with i-STAT cartridges for *in vitro* quantification of various analytes in whole blood. Analyzers, cartridges, and test strips are used by healthcare professionals trained and certified to use the system and used according to the facility's policies and procedures
Related Procedures and Documents	*ES iSTAT Maintenance Calibration and Quality Control* *Laboratory Test Catalogue Collection & Shipping Requirements* *i-STAT users Guide* *Laboratory Test Catalogue Collection & Shipping Requirements* *Point of Care Results Record*
Reference	• I-STAT System Manual, Abbott Laboratories, Rev. Date: 02-Mar-10 • Tiezt, Norbert, W. "Fundamentals of Clinical Chemistry," WB Saunders Company, Philadelphia, 2001, pp 505-517.

Appendix 1

PROCEDURE FOR EXTERNAL ELECTRONIC SIMULATOR

Display	Step	Analyzer Response / Comments
	Press the **On/Off** key to turn the analyzer on.	Logo briefly displayed followed by Test Menu.
Test Menu	Press the **Menu** key.	
Administration Menu	Press **3** to select Quality Tests.	
Quality Tests Menu	Press **4** to select Simulator.	
Scan or Enter Operator ID	Press **Scan** to scan the Operator ID or manually enter the Operator ID and press **Enter**.	If enabled, the analyzer will validate ID and/or ask for the ID to be repeated.
Scan or Enter Simulator ID	Press **Scan** to scan the Simulator ID or manually enter the Simulator ID and press **Enter**.	The simulator serial number can be used as an ID. If the simulator does not have a barcode, one can be made on-site and affixed to the simulator (not near contact pads).
INSERT SIMULATOR	Remove the cover protecting the contact pads and insert the simulator straight into the analyzer. Avoid touching the contact pads.	Inserting the simulator at an angle may cause a Quality Check message to be displayed.
Contacting Simulator Please wait... Time to Results bar Simulator Locked	Do not attempt to remove the simulator until the results are displayed and the "Simulator Locked" message is removed.	
Result screen: ID of Simulator Date and Time ELECTRONIC SIMULATOR PASS or FAIL 1 - Test Options	Test Options Simulator 1 - Next Simulator 2 - Same Simulator 3 - History	If **PASS** is displayed, continue to use the analyzer. Remove the simulator and return it to its protective case. If **FAIL** is displayed, see the Troubleshooting in this section of the manual.

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Replace the plastic cap and place the Electronic Simulator in its protective case after use

Appendix 2

Common Flags

Flags	Possible Cause	Action
Results flagged with a < or > sign.	Indicates that the result is below or above the limits of the reportable range.	Send a specimen to the laboratory for analysis results are CRITICAL.
Results appearing as *** are unreportable based on internal rejection criteria.	This could be due to interfering substances or improper storage or handling of cartridges.	Use another cartridge. Results not suppressed should be reported. If the results are suppressed again, Send a specimen to the laboratory for analysis when possible
"Cartridge Pre-burst", use another cartridge"	Pressing on the top of the cartridge can cause the pouch to burst.	Use another cartridge.
"Unable to position sample"	Snap closure may not be closed. Sample may be clotted.	Close snap closure. Expel one drop, repeat using another cartridge.
"Sample filled short of the fill mark."	Bubbles Insufficient sample added OR Clot in sample may cause this.	Observe for bubbles and clots, repeat.

Appendix 3

Affected Analyte	Substance	Concentration Producing Interference	Maximum Expected In Vivo Concentration
Cl	Bromide	12.5 mmol/L	↑ chloride 30 mol/L
	Lactate	11 mmol/L	↑ chloride 3.5 mol/L
	Salicylate	4 mmol/l	↑ chloride 5 mol/L
	Thiocyanate	present	↑ or *** (unreportable)
	B-hydrobutyrate	16 mmol/L	↑ chloride 3 mol/L
Crea	Acetaminophen	1 mmol/L	↑ creatinine 22 µmol/L
	Ascorbate	.227 mmol/L	↑ creatinine 62 µmol/L
	Bromide	12.5 mmol/L	↑ creatinine 17 µmol/L
Crea < 180 µmol/L	CO2	PCO2 > 40 mmHg	↑ 6.9% per 10 mmHg PCO2
Crea > 180 µmol/L	CO2	PCO2 > 40 mmHg	↓ 3.7% per 10 mmHg PCO2
Crea < 180 µmol/L	CO2	PCO2 < 40 mmHg	↓ 6.9% per 10 mmHg PCO2
Crea > 180 µmol/L	CO2	PCO2 < 40 mmHg	↑ 3.7% per 10 mmHg PCO2
	Creatine	382 µmol/L	↑ creatinine 18 µmol/L
	N-acetylcysteine	16.6 mmol/L	↑ creatinine 36 µmol/L
Glu	Bromide	37.5 mmol/L	↓ glucose 1.7 mmol/L
	pH	< 7.4 at 37°	↓ 0.05 per 0.1 pH unit
	pH	> 7.4 at 37°	↑ 0.04 per 0.1 pH unit
	pO2	pO2 < 20mmHg at 37°	May ↓ glucose
Hct/Hgb	↑ WBC		↑
	↑ Lipids		↓
Hct < 40%	Total Protein	TP < 65	↓
	Total Protein	TP > 65	↑
Hct < 40%	Total Protein	TP < 65	↓
	Total Protein	TP > 65	↑
iCa	Magnesium	20 mmol/L	↓ ionized calcium 0.05 mmol/L
	Magnesium	1.0 mmol/L	↓ ionized calcium 0.04 mmol/L
	Salicylate	4.34	↓ ionized calcium 0.1 mmol/L
	B-	20 mmol/L	↓ ionized calcium 0.1

	hydrobutyrate		mmol/L
Na	Bromide	37.5 mmol/L	↓ sodium 5 mmol/L
	Lactate	20 mmol/L	↓ sodium 5 mmol/L
	B-hydrobutyrate	16 mmol/L	↓ sodium 5 mmol/L

Hydroxyurea may cause a significant error in the measurement of creatinine on the iSTAT. The magnitude of the bias is independent of the creatinine level. Send sample to laboratory for analysis.

Creatine may be increased in patients using creatine supplements, experiencing muscle trauma or primary or secondary myopathies, taking statins for hyperlipidema control or in patients with hyperthyroidism or in a rare genetic defect of the creatine transporter protein.

The **measured sodium level** in a sample is used to correct the measured conductivity prior to reporting hematocrit results. Factors that affect sodium will therefore also **affect hematocrit**.

Appendix 4

Point of Care Results Record

Place patient identification label here or record information below

Patient Information:

Name:
Med. Rec. #:
Loc/Room/Bed:
Health Card (PMI) #:
Physician:
Sex/Age/DOB:

Collection Information:

Date and time of collection:
Collected by:

(If not indicated on printout)
Analysis Performed by:

Attach instrument printout and fill in Collection Information

Appendix 5

Cartridge Overview