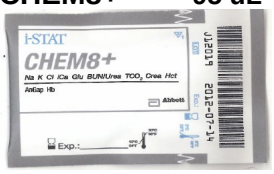
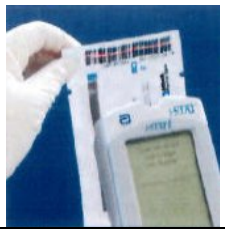
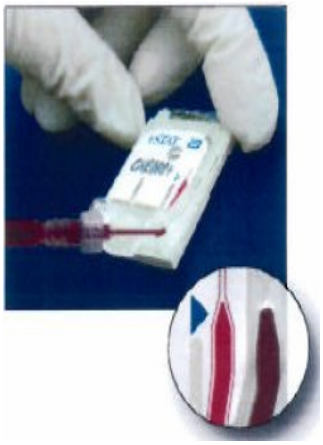
iSTAT1: Patient Test Procedure

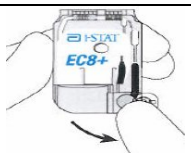
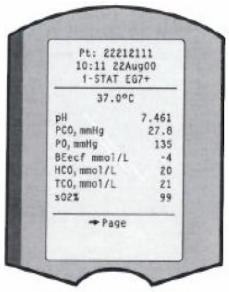
Purpose: i-STAT1 is used at the point of care for whole blood analysis by the Infant Transport Team for analysis of electrolytes and blood gases; Oncology department for pH and ionized Calcium for plasmapheresis patients only, the Medical Mobile Unit for electrolytes, blood gases and Troponin I.

ASSEMBLE SUPPLIES:	**Requirement**
1. Assemble blood collection supplies. See below for collection and lancet devices. Follow institutional guidelines.	Venous samples are obtained from blood collection devices filled to their stated volume, regardless of cartridge type and cartridge volume requirement.
2. Cartridges. Confirm Lot # / Expiry in use. Confirm Room Temperature Expiry. Caution: Cartridge sample entry well gasket and tab contain natural latex rubber.	Individually sealed pouch. Main supply storage at 2 – 8°C. Cartridge is at room temperature for a minimum 5 minutes.
3. i-STAT1 Handheld analyzer. Each i-STAT-1 Analyzer has a designated Electronic Simulator (ES). Use appropriate ES.	External Electronic QC performed prior to analysis, or once every 8 hours during patient testing.

Neonate Capillary, Venous or Arterial Collections.

i-STAT Cartridge **Sample Volume**	**Test Order**	**Collection Devices**
EG7+ **95 uL** 	pH, pCO2, pO2, HCO3, TCO2, BE, Na+,K+,iCa sO_2, Hct & Hb results are not reported at C&W.	**Venous or Arterial Collection** • Lithium Heparin tube • non-additive syringe • additive syringe is balanced Heparin MARQUEST™ GASLYTE® 1cc; 2.8 units balanced heparin. *REF 601RH(C&W), SafePICO Self-filling (vented) Arterial Sampler Lithium Heparin 3cc with 23G x 1" needle (MMU)* • Transfer needle – 18 g blunt **Capillary Collection** • Plastic rod – BAYER MultiCap-S REF 02043295 . Each tube contains 175 uL; 130-200 I.U./mL Na+/Li+/Ca++ heparin titrated with KCl.)
CHEM8+ **95 uL** 	Na, K, iCa, BUN/Urea, TCO2, Crea sO_2, Gluc, Hct & Hb results are not reported at C&W.	
CG4+ **95 uL** 	pH, PCO2, PO2, HCO3, TCO2, BE, Lac sO_2 results are not reported at C&W.	Puncture Device Neonate / Infant Heel • **Pink BD Quikheel Infant Lancet** **0.85 X 1.75 mm** **Neonate (< 30 Days), Infant** **Moderate volume collection**  • **Green BD Quikheel Infant Lancet** **1.0x 2.5 mm** **Infant (> 30 days)** **High Volume Collection** 
cTnI **17 uL** 	Troponin I Note: Capillary collection is not recommended. Collect in vacutainer, or a non-additive syringe (if tested within one minute of collection).	

Patient test Procedure		
1	Assemble supplies	
2	Obtain i-STAT1 Analyzer. Press [ON]. Note: Electronic QC (EQC) performed just prior or within 8 hours of AQC test.	
3	Press [2 – i-STAT Cartridge].	
4	Scan or enter Operator ID. Repeat.	
5	Scan or enter Patient ID. Repeat	
6	Obtain cartridge. • Scan or enter Cartridge Lot #. • *i*-STAT1 analyzer will stay on for 15 minutes with "Insert Cartridge" displayed.	
7	Ready EG7+ cartridge • Remove from its pouch by holding the sides of the cartridge. • Do not exert pressure on the calibrant pack in the center of the cartridge. • Set aside. • Can be out of storage pouch for up to 5 minutes before sample application.	
8	Obtain the blood sample anaerobically without bubbles. Venous, arterial, line or capillary puncture. • Syringe is non-additive or balanced heparin. • Capillary rod is balanced heparin. (wipe away first drop of blood to avoid tissue fluid contamination). • Mix syringe or capillary rod well by rolling between palm of hands for at least 5 seconds in 2 directions. • Invert repeatedly for at least 5 seconds.	 Do not over fill the sample well. If a capillary rod (175 uL) is used, then fill approximately 2/3 of the rod to ensure adequate sampling into the cartridge port.
8	Test sample immediately to prevent clots and invitro homeostasis changes in the sample. • <1 minute if non-additive; • < 5 minutes if anticoagulated.	
9	Fill sample well 95uL whole blood. Direct tip: *Syringe (with transfer needle)* and gently dispense until sample reaches the fill mark on the cartridge. *Capillary rod* – is approximately 2/3 full - allow to fill the cartridge well with capillary action. Remove rod. Remix and discard 2 drops if there is a delay in sample application.	

<table>
<tr><td></td><td>(cap the rod /place on ice).</td><td></td></tr>
<tr><td>10</td><td>Snap cartridge shut with tab on side.
Ensure the cartridge is closed tight.</td><td>  </td></tr>
<tr><td>11</td><td>Insert cartridge into the cartridge port, electrodes first.
Wait for analyzer to show that contact is made.
Do not remove the cartridge during the testing cycle.
Note: always perform testing on a level surface.</td><td>  </td></tr>
<tr><td>12</td><td>View results on the display screen.
Results are available in 120 seconds.
Page through the results using the soft keys to arrow forward or backward.
Infant Transport - pH, pCO_2, HCO_3, TCO_2, PO_2, BE, sO_2, Na, K, iCa.
CH-Oncology Clinic – pH, iCa
MMU - Na, K, iCa, BUN/Urea, TCO2, Crea; pH, PCO2, PO2, HCO3, TCO2, BE, Lac; Troponin I
Note: sO_2, Gluc, Hct & Hb not reported @ PHSA</td><td>  </td></tr>
<tr><td>13</td><td colspan="2">Record on Patient Transport Form, Patient Chart, and (Report Form- applicable to Oncology Clinic only). Include date and time of collection.</td></tr>
<tr><td>14</td><td colspan="2">Review results.
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>Patient results are within therapeutic range or clinically expected.</td><td>Proceed to further testing – AQC or patient.</td></tr>
<tr><td>Patient results not expected or some test parameters are given as “***”.</td><td>Review patient test, cartridge handling for any possible error.
Repeat EQC to confirm that the analyzer is functioning properly.
Repeat the patient test.</td></tr>
</table></td></tr>
<tr><td>15</td><td colspan="2">Remove the AQC test cartridge.
Press [1-Test Options].
“Remove Cartridge” message appears. It is now safe to remove the cartridge.</td></tr>
<tr><td>16</td><td colspan="2">In the event of an error code – refer to Appendix F – Troubleshooting Guide.</td></tr>
<tr><td>17</td><td colspan="2">Discard syringe with blunt needle, ampoule and cartridge into the appropriate institutional biohazard container.</td></tr>
<tr><td>18</td><td colspan="2">Data download to iSTAT Central Data Station:
On arrival to Children’s and Women’s Hospital after a patient transport.
Monthly at a minimum.</td></tr>
</table>

ANALYZER RESULT DISPLAY		
Display	**EXPLANATION**	**ACTION**
Result is (<) or (>)	Result is outside the Reportable Range. See table of Reportable Ranges.	If consistent with clinical status take action as clinically indicated. Defer testing until clinical action completed or Simultaneous Draw at C&W on arrival.
(****)	Results which are unreportable based on instrument internal QC rejection criteria.	Analyze the specimen again using another cartridge. Results not suppressed should be reported in the usual manner. If result is suppressed again, defer testing until Simultaneous Draw at C &W on arrival.
No result	Result is not reported if a test cycle has a problem with the sample, the calibrant solution, the sensors, or if there are mechanical or electrical malfunctions of the analyzer.	Take the action displayed with the message that identifies the problem. Refer to Instrument Trouble Shooting. Note on Patient Transport Form.
Note: If the instrument is inoperable notify POCT Technologist email POCTLab@cw.bc.ca local **7521** or after hours contact local **7850** with instrument troubleshooting and possible replacement.		

ANALYZER TEST RESULTS		
Biological Range	The range of test values expected from 95% of fasting individuals presumed to be healthy.	Table page 5
Reportable Range	The range of test values throughout which the results have been shown to be valid.	Table page 5
Critical Results	Test results that fall outside high and low critical limits which define the boundaries of life-threatening for a test.	Table page 5
Preanalytical Interferences	Biochemical process which is usually due to improper sample handling and causes a significant change to the actual analyte being measured. eg. A traumatic draw will cause hemolysis with a false increase in K+.	Table page 6
Analytical Interferences	A substance when present at significant levels in the blood specimen being analyzed produces an error in the result of the analyte being measured. eg. B-hydroxybutyrate at sample concentration of 16 mmol/L would decrease Na+ by 4 mmol/L	Table page 6.

i-STAT Reference Range with Critical Values							
ANALYTE	**UNIT**	**Reference Range**			**Reportable Range**	**Critical Values**	
		Age	**Range**			**Low**	**High**
Sodium (Na)	mmol/L	0-adult	135-145		100-180	< 121	> 156
Potassium (K)	mmol/L	0-5 years	3.5-5.5		2.0-9.0	< 2.5	> 6.5
		5 years-adult	3.5-5.0				
Chloride	mmol/L	0-adult	95-107		65-140	< 90	> 110
Anion Gap		0-adult	3-16		(-10)-(+99)		
Ionized Calcium (iCa)	mmol/L	0-5 days	0.90-1.30		0.25-2.50	< 0.80	> 1.40
		6 day-adult	1.10-1.30				
Urea Nitrogen	mmol/L	0 – 7D	0.7-4.6		1.0-50.0	< 0.7	> 15
		8D -1 M	0.-7-5.4				
		1M – 3 M	0.7 – 5.0				
		4 M – 6 M	0.4 – 4.6				
		7 M – 1 YR	0.4 – 4.6				
		1 YR – 3 YR	1.8 – 6.1				
		4 YR – 13 YR	2.5 – 6.4				
		14YR - adult	2.9 – 7.5				
Creatinine	umol/L		male	Female	18-1768	< 10	> 160
		0 – 2 yr	< 78	<78			
		3 yr	< 43	< 40			
		4 yr	< 49	<97			
		5 yr	< 52	< 51			
		6 yr	< 55	< 55			
		7 yr	20-58	20-57			
		8 yr	20-61	20-60			
		9 yr	29-64	29-64			
		10 yr	29-67	29-67			
		11 yr	29-70	29-70			
		12 yr	29-72	29-74			
		13 yr	29-88	29-91			
		14 yr	39-93	39-96			
		15 yr	39-98	39-97			
		16 yr	39-103	39 - 103			

i-STAT Reference Range with Critical Values						
ANALYTE	**UNIT**	**Reference Range**		**Reportable Range**	**Critical Values**	
		Age	**Range**		**Low**	**High**
		17 yr - adult	39-106 39-106			
Lactate	mmol/L	0 - adult	0.5 – 2.2	0.30-20.0	< 0.5	> 3.0
PH		2-5 d	7.30-7.49	6.50-8.20	< 7.25	> 7.65
		5 d-adult	7.35-7.45			
***P*CO$_2$**	mm/Hg	0-2 y	26-41	5-130	< 20	> 80
		3 y-adult	35-45			
***P*O2**	mm/Hg	0-1 m	80-100	5-800	< 50	
		2 m-adult			< 60	
TCO$_2$ *	mmol/L		23-27	5-50		
HCO$_3$- *	mmol/L	2-5 d	19-29	1-85		
		5 d-2 year	17-24			
		3-16 years	18-27			
Base Excess	mmol/L			(-30)-(+30)		> 16
cTnI	ug/mL	0-adult	< 0.10 ug/L	0.00 – 50.00		

* Indicates calculated values. Hematocrit/ Hb/ Glucose/ SO2 results are suppressed and not reported.

Test Limitations and Interferences

Note: General criteria for specimen rejection - evidence of clotting, samples collected in vacuum tubes other than lithium heparin, incomplete fill of vacuum tubes for the measurement of ionized Calcium and blood gases, syringe with air bubbles in the sample.

Avoid – drawing a specimen from an arm with an IV; stasis (tourniquet left on for > one minute prior to venipuncture; time delays before filling cartridge, lactate is < one minute after sample collection.

Analyte	Interferent	Concentration	Effect on Analyte Result
Sodium * Na	B-hydroxybutyrate	16 mmol/L	Decrease i-STAT Na by 4 mmol/L
	Bromide	37.5 mmol/L	Increased i-STAT Na. 2.5 mmol/L is therapeutic. Bromide is released in halothane anesthesia.
Potassium * K	Sample not tested immediately or Hemolysis		Increase plasma K due to release from red blood cells. Interference from interstitial fluid from imporoper technique during the collection procedure.
	Specimen ON ICE		
Chloride* Cl	Acetylcysteine	10.2 mmol/L	Decrease i-STAT Cl. 0.30 mmol/L is therapeutic. Treatment to reverse acetaminophen poisoning.
	Bromide	37.5 mmol/L	Increase i-STAT Cl. 2.5 mmol/L is therapeutic. Bromide is released in halothane anesthesia.
	Salicylate,	4.34 mmol/L	Increase i-STAT Cl. 0.5 mmol/L is therapeutic.

Test Limitations and Interferences

Note: General criteria for specimen rejection - evidence of clotting, samples collected in vacuum tubes other than lithium heparin, incomplete fill of vacuum tubes for the measurement of ionized Calcium and blood gases, syringe with air bubbles in the sample.

Avoid – drawing a specimen from an arm with an IV; stasis (tourniquet left on for > one minute prior to venipuncture; time delays before filling cartridge, lactate is < one minute after sample collection.

Analyte	Interferent	Concentration	Effect on Analyte Result
	Thiocyanate	6.9 mmol/L	Increase i-STAT Cl.
Ionized Calcium* iCa	Venous stasis		Increase iCa with prolonged tourniquet application and forearm exercise, due to a decrease in pH caused by localized production of lactic acid.
	Magnesium	1.0 mmol/L	Increase iCa by 0.04 mmol/L
	Air exposure		Decrease iCa due to increase in pH with loss of CO2
	Heparin		Decrease iCa – correct amount of sample fill in tube
	Acetaminophen	1.32 mmol/ l	Decreased i-STAT iCa . 0.132 mmol/L is the upper end of therapeutic)
	Acetylcysteine	10.2 mmol/ l	Decreased i-STAT iCa. 0.30 mmol/L is therapeutic. Treatment to reverse acetaminophen poisoning.
	Bromide	37.5 mmol/ l	Increased i-STAT iCa. 2.5 mmol/L is therapeutic. Bromide is released in halothane anesthesia.
	Magnesium	1.0 mmol/ l	Increased i-STAT iCa
	Lactate	6.6 mmol/ l	Decreased i-STAT iCa
	Salicylate	4.34 mmol/ l	Decreased i-STAT iCa. 0.5 mmol/L is therapeutic and known to decrease i-STAT iCa by 0.03mmol/L.
PH, PCO_2, PO_2 * *(TCO_2, HCO3 – calculated values)*	Exposure to air	If PO_2 <150mmHg	Increases pH, PO_2 Decreases PCO_2 *(false decrease calculated values)*
		If PO_2 >150mmHg	Decreases pH, PO_2 Increases PCO_2 *(false increase of calculated values)*
	Delay in Analysis Venous stasis		Decreases pH(0.03 pH unit/hr) & Increases PCO_2. Decreases PO_2 (2-6 mm.HG/hr), cellular metabolism. Increases calculated values due to metabolic processes
Creatinine * CREA	Acetaminophen	1.32 mmol/ l	Increased i-STAT CREA. 0.132 mmol/L is the upper end of therapeutic
	Acetylcysteine	10.2 mmol/ l	Increased i-STAT CREA. 0.30 mmol/L is therapeutic. Treatment to reverse acetaminophen poisoning.
	Ascorbate	0.34 mmol/L	Increased i-STAT CREA
	Bromide	37.5 mmol/ L 2.5 mmol/L	Increased i-STAT CREA. 2.5 mmol/L is therapeutic Bromide is released in halothane anesthesia.

Test Limitations and Interferences

Note: General criteria for specimen rejection - evidence of clotting, samples collected in vacuum tubes other than lithium heparin, incomplete fill of vacuum tubes for the measurement of ionized Calcium and blood gases, syringe with air bubbles in the sample.

Avoid – drawing a specimen from an arm with an IV; stasis (tourniquet left on for > one minute prior to venipuncture; time delays before filling cartridge, lactate is < one minute after sample collection.

Analyte	Interferent	Concentration	Effect on Analyte Result	
Creatinine * CREA	Creatine	0.38 mmol/L	Increased i-STAT CREA - patients on creatine supplements, muscle trauma, primary or secondary myopathies, statins for hyperlipidemia control, hyperthyroidism.	
	Hydroxyurea	0.92 mmol/L	Increased i-STAT CREA. DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, HIV infection, polycythemia vera, thrombocytopenia, and psoriasis. (approximately 0.100 to 0.500 mmol/L or higher is known to be therapeutic).	
	PCO2		CREA < 177 umol/L	CREA > 177 umol/L
		> 40 mmHg	↑ 6.9% / 10 mmHg PCO_2	↓ 3.7% / 10 mmHg PCO_2
		< 40 mmHg	↓ 6.9% / 10 mmHg PCO_2	↑ 3.7% / 10 mmHg PCO_2
Lactate* LAC	Venous stasis		Increase in Lactate. For a steady state Lactate analysis patient should be at rest for at least 2 hours; no tourniquet applied (or immediately after tourniquet application.	
	Delay in Analysis (sample not on ice)		Increase in Lactate. Lactate increases by as much as 70% at 25^0C due to glycolysis.	
	Bromide	37.5 mmol/ l	Decrease i-STAT LAC. 2.5 mmol/L is therapeutic. Bromide is released in halothane anesthesia.	
	Glycolic Acid	10.0 mmol/L	Increase i-STAT LAC. Patients with ethylene glycol ingestion (can present with levels at 0.97-130.6 mmol/L, unknown high anion gap metabolic acidosis.	
	Hydroxyurea	0.92 mmol/L	Increase i-STAT LAC. Approximately 0.100 to 0.500 mmol/L or higher is known to be therapeutic). DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, HIV infection, polycythemia vera, thrombocytopenia, and psoriasis.	
cTnI * **	Heparin anticoagulant to sample ratio		Increased cTnI due to incorrect sample to anticoagulant ratio. Heparinized whole blood (or plasma sample) collected in syringes or evacuated tubes with lithium or sodium heparin is filled to their maximum stated volume.	

Test Limitations and Interferences

Note: General criteria for specimen rejection - evidence of clotting, samples collected in vacuum tubes other than lithium heparin, incomplete fill of vacuum tubes for the measurement of ionized Calcium and blood gases, syringe with air bubbles in the sample.

Avoid – drawing a specimen from an arm with an IV; stasis (tourniquet left on for > one minute prior to venipuncture; time delays before filling cartridge, lactate is < one minute after sample collection.

Analyte	Interferent	Concentration	Effect on Analyte Result
cTnI * **	immunoglobulin therapy		May interfere with immunoassays and produce erroneous results.
	Interfering antibodies		Interfering antibodies in response to bacterial infections has been reported.
	Hemolysis		Can cause a decrease detection of cTnI
	Hematocrit	>.65 g/L	Increase in test imprecision of cRnI
	** Results from the i-STAT cTnI assay should be considered in the context of the entirety of the available clinical information. Medical decisions should not be based on a single i-STAT measurement. Cardiac troponin may not appear in the circulation for 4-6 hours following the onset of symptoms of Myocardial Infarction(MI). Consequently, a single negative result is insufficient to rule out MI. The use of a serial sampling protocol is recommended practice. Different cTnI assays generally are not comparible due to different cTnI antibody sensitivities. Confirm with laboratory.		

* Sodium, Potassium, Chloride, pH, pO2, pO, creatinine, lactate, cTnI are all analytes that are susceptible to hemodilution. An increase or decrease of a particular analyte may occur depending on the fluid administration therapy. The use of physiologically balanced multi-electrolyte solution with low-mobility anions is recommended.

REFERENCES:

i-STAT1 System Manual. Abbott Point of Care Inc. Abbott Park, IL 60064 USA 20 JAN 2012
BD Quikheel Lancet product information. BD Vacutainer Systems Preanalytical Solutions 1 Becton Drive, Franklin Lakes, NJ 07417 2002 www.bd.com/vacutainer

REVISION & APPROVAL LOG

Version	Revision Type	Description of Change	Revision Date	Technical Approval	Medical Approval
1.0		New document	25 Nov 2013	Elvira Kozak	Dr. Cathy Halstead
1.1	Minor	Document title and number change. Upload to QMS document control	22 Dec 2016		Dr. Benjamin Jung
1.2	Minor	Reformatted, updated POCT Contact	June 21, 2019	Calvin Lee	Dr. H. Vallance

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