iSTAT1: Appendix A - Quality Assurance Information

Four quality control systems are used with the i-STAT1 System
• Electronic Simulator verifies the electrical performance of the i-STAT1 analyzer. • i-STAT Aqueous Controls are formulated at three clinically relevant levels to verify cartridge and operator performance. • Simultaneous Draw compares a patient sample with the i-STAT1 and the C&W laboratory analyzer or a Central laboratory during a transport or off location. • Proficiency Testing – External Agency – College of American Pathologists.

External Electronic Simulator (EQC)	
	• Internal electronic simulator is pre-programmed once every 24 hours. • External electronic simulator performed once every 8 hours during patient testing. • Test cycle is about 120 seconds. • Will fail in high humidity surroundings. • Results are stored under records in the analyzer data review . • Results are transmitted to the Central Data Station on a date upload. • Each i-STAT1 analyzer has an assigned EQC – referenced by the serial number. • EQC ID is scanned for identification prior to testing.
Function	• Simulates two levels of electrical signals which stresses the analyzer's signal detection function below and above measurement ranges.
Purpose	• Provides an independent check on the ability of the analyzer to take accurate and sensitive measurements. • Voltage – for potentiometric sensors. • Current – for amperometric sensors. • Resistance – for conductometric sensors.
ITT Storage	• 18 to 30º C, Room Temperature • -20 – 50^{o}C, Allowable Temperature extremes • Infant Transport Team Ready Room. Rm. B103 (Shaughnessy Building)
Precaution	• Store in protective case to avoid contamination of contact pads.

2. Aqueous TriControl Level 1, 2 & 3 (AQC) for EG7 + , CG4+, and CHEM 8+ Cartridges	
Function	• Evaluates the analytical performance of operator performance, the analyzer, and cartridge Lot number. • Formulated at three clinically relevant levels.
Constituents measured	• Measures pH, pCO2, pO2, Na, K, Chloride, ionized Ca (uncorrected to pH), Glucose, Creatinine, BUN/Urea, and Lactate. • Calculated values - HCO3, TCO2, Base Excess, O2 Saturation and Hemoglobin. Note: sO2, Hemoglobin, and Hematocrit are not reported @ PHSA.
Composition	• 1.7 mL glass ampoules. (10 ampoules of a level per box). Low Level i-STAT TriControl Level 1 Control Catalog No. 05P71-01 Normal Level i-STAT TriControl Level 2 Control Catalog No. 05P72-01 High Level i-STAT TriControl Level 3 Control Catalog No. 05P73-01 Control solution does not contain human serum or serum products
Main Storage Rm. 2F50	• 2 to 8°C. Expiration date on box. • Walk-in fridge; Rm. 2F50 (located in rear of Outpatient Blood Collections Rm. 2F40)
Infant Transport Oncology Clinic Medical Mobile Unit	• 18 to 30°C. • Room Temperature expiry is 5 days – minimum 4 hours for pO2. • Label vial with Room Temperature expiry date. • Controls are not returned to the refrigerator once at Room Temperature. • Open ampoule is used immediately.
i-STAT Cardiac Markers Level 1, 2, & 3 Controls	
Constituent measured	• Measures cTnI – Troponin I
Composition	1.0 mL glass vials. (Verification kit - 2 ampoules of a level per box – set of 3 Levels). Low Level i-STAT Level 1 Control Catalog No. 6F15-02 Normal Level i-STAT Level 2 Control High Level i-STAT Level 3 Control
Main Storage	• < -18°C. – frozen storage in Chemistry Reagent Freezer. Thaw control material for use: • 2 to 8°C - refrigerated can be used up to within 4 hours. • 18 to 30°C – room temperature can be used up to 15 minutes.
Precaution	• Controls are assayed human sera. • Use appropriate handling cautions as per institutional guidelines • Negative - non-reactive HIV-1, HIV-2, HBsAg, HCV, HTLV-1, HTLV-2. • Contains <0.1% sodium azide as a preservative.

3. Simultaneous Draw:	
This may not be possible during a transport, on deployment location or patient test event at Children's & Women's Health Centre, but is a best practice event.	
On Arrival to Children's & Women's or a Central Laboratory **Simultaneous Draw:**	1. Draw whole blood sample for i-STAT and C&W or Central Laboratory sample when possible. 2. Simultaneously analyze samples on respective instruments. 3. Record i-STAT1 test results and Laboratory whole blood analyzer results onto the patient requisition and transport flowsheet. 4. ITT transfers / photocopies patient whole blood requisition and identifies with Patient Provincial Response #. 5. Copy of both sets of results is sent to Children's and Women's Laboratory – Point of Care Technologist email POCTLab@cw.bc.ca local 7521.
Function	• Compares patient test values on the i-STAT1 analyzer with a Central Laboratory analyzer.
Purpose	• To assure the reliability of patient test results and verify continuity of care. • To test cartridge performance.
4. Proficiency Testing – Performed by Point of Care Technologist	
Three test kits annually	• College of American Pathologists – AQ2 Critical Care Aqueous Blood Gas • 5 levels of unknown solutions are analyzed. • Sample handling is as per Aqueous Quality Control. • Measures pH, pCO2, pO2, Na, K, Chloride, ionized Ca (uncorrected to pH), Glucose, Creatinine, BUN/Urea, and Lactate. • Calculates HCO3, TCO2, Base Excess, O2 Saturation and Hemoglobin. (sO_2, Hemoglobin, and Hematocrit are not reported) • Two sets of results are submitted – all other iSTAT1 analyzer results are compared to the peer group analysis when results are posted.
Function	• Compares known values on the i-STAT1 analyzer with an external agency. • Results are compared to peer groups that subscribe to the external agency. • Mandated by provincial, national, and international accreditation agencies.
Purpose	• To assure the reliability of patient test results and verify continuity of care. • To test cartridge performance.
Testing is performed on all iSTAT-1 analyzers from the different PHSA department when possible. Point of Care Technologist will coordinate testing with the PHSA department.	

REFERENCES

i-STAT1 System Manual. Abbott Point of Care Inc. Abbott Park, IL 60064 USA 20 JAN 2012

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	POCT contact updated	June 23, 2019	Calvin Lee	

Attention: This document is published on the ePOPS website

Revisions made to this document require an update to the corresponding document published on ePOPS website