

## iSTAT1: Aqueous Quality Control Procedure

### Purpose:

i-STAT1 is tested with appropriate Aqueous Quality Control solution to confirm cartridge, analyzer and operator performance.

### Aqueous Quality Control Regimen

#### To validate new lot # of cartridges – Point of Care Technologist.

One of each of the AQC TriControls (Level 1 and Level 3) on all analyzers.

#### On day of patient testing – Oncology Clinic and Mobile Medical Unit

One of each of the AQC TriControls (Level 1 and Level 3) on the analyzer in use.

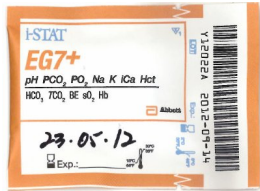
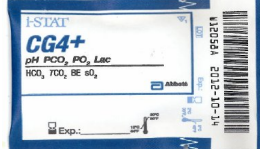

#### Operator validation / Competency – Infant Transport, Oncology Clinic and Mobile Medical Unit

All operators must perform at a minimum:

- Monthly – either a Level 1 or 3 of AQC TriControls or a patient sample.
- Within a 3 Month Period – both Level 1 and Level 3 AQC TriControls.

### Assemble Supplies

1. i-STAT1 analyzer – designated for area of use.
2. Electronic Simulator – designated for the i-STAT1 analyzer.
3. Non-additive syringe – 1 mL. One per AQC ampoule.
4. Transfer blunt needle – 18 gauge. One per AQC ampoule.
5. Cartridges and appropriate AQC.

Department	Cartridge	AQC	AQC Requirement
<b>Infant Transport Team</b>  <b>Oncology Clinic</b> <b>EG7+ 95 uL</b>		TriControls Level 1, 2, and 3 Controls (1.7 mL glass vial – 10 ampoules per box). (Blood Gas/ Electrolytes/Metabolite Cartridges – pH, PCO <sub>2</sub> , PO <sub>2</sub> , TCO <sub>2</sub> , Na, K, Cl, Glu, Urea, iCa, Lactate, Creatinine). <i>sO<sub>2</sub>, Hb, Hct not reported at PHSA</i>	<ul style="list-style-type: none"> <li>• Refrigerated 2-8°C until printed expiration</li> <li>• @ Room Temperature 18-30°C before use.</li> <li>• Minimum of 4 hours Maximum of 5 days</li> </ul>
<b>Mobile Medical Unit</b>  <b>CG4+ 95 uL</b>  <b>CHEM8+ 95 uL</b>	 		

Medical Approval: Dr Benjamin Jung

Version: 1.3


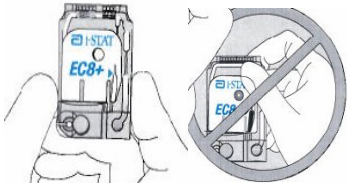
Folder Name: CW\Point of Care\Blood Gas Electrolytes - iSTAT




This is a controlled document for CW use only. Any printed copies are uncontrolled unless specified. Please refer to Lab QMS

Medical Approval Date: 22 Dec 2016

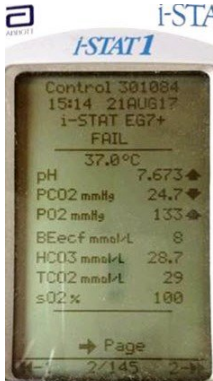
Implementation Date: 10/25/2017 12:26:38 AM

**How to test Aqueous QC TriControls Levels 1, 2 or 3 Control for EG7+, CG4+ and CHEM8+ Cartridges**

1.	Obtain i-STAT1 Analyzer. Press [ON]. Note: Electronic QC (EQC) performed just prior or within 8 hours of AQC test.	
2.	Press [MENU]	
3.	Press [3 – Quality Tests].	
4.	Press [1-Control].	
5.	Scan or enter Operator ID. Repeat ID entry.	
6.	“ <b>Select Fluid Vendor</b> ” displayed, select <b>1-APOC</b>	
7.	Scan or enter Control Lot #. <i>Note: Bar Code or Lot # is on the glass ampoule</i>	
8.	Scan or enter Cartridge Lot #. <ul style="list-style-type: none"> <li>• i-STAT1 ready for AQC for testing</li> <li>• screen times out is in 15 minutes.</li> </ul>	
9.	Obtain appropriate AQC control solution for testing. (TriControl or Cardiac Control). <ul style="list-style-type: none"> <li>• Confirm that the appropriate AQC is being used for the specific cartridge.</li> <li>• Confirm Lot # and expiry date with the current AQC chart.</li> <li>• To test the EG7+, CG4+ or Chem8+ Cartridges, ensure AQC solution is at room temperature (RT), 18-30°C for a minimum of 4 hours (maximum 5 days).</li> </ul>	
10.	Prepare i-STAT1 AQC control solution. For EG7+, CG4+ or Chem8+ Cartridges, equilibrate the liquid and gas phases just before use. <ul style="list-style-type: none"> <li>• Shake the ampoule vigorously for 10 – 15 seconds.</li> <li>• To shake, hold the ampoule at the tip and bottom with forefinger and thumb, to minimize increasing the temperature of the solution.</li> <li>• Tap the ampoule to send solution into the bottom.</li> <li>• Set aside for bubbles to disappear.</li> <li>• Assemble non-additive syringe (1 mL) and blunt needle (18 gauge). Set aside.</li> </ul>	
11.	Cartridge is at room temperature. <ul style="list-style-type: none"> <li>• Remove from its pouch by holding the sides of the cartridge.</li> <li>• Do not touch the contact pads or exert any pressure on the cartridge. Set aside.</li> <li>• Can be out of storage pouch for up to 5 minutes.</li> </ul>	
12.	Open ampoule to fill syringe for transfer into the cartridge. <b>For multiple analyzers, one ampoule can be used to fill more than one cartridge.</b> To test EG7+, CG4+ or Chem8+ Cartridges: <ul style="list-style-type: none"> <li>• Protect fingers with gauze, tissue or glove to snap off the tip of the ampoule.</li> <li>• Slowly draw approximately 1 mL of solution from the bottom of the ampoule.</li> <li>• Do not expose the solution to room air.</li> </ul>	

	<ul style="list-style-type: none"> <li>If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe.</li> <li>If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampoule and syringe. Use a fresh ampoule and syringe and repeat the process.</li> </ul>							
13.	<p>Fill the cartridge with control solution.</p> <p><i>Note: Aqueous based solutions lacks the buffering capabilities of whole blood, therefore the transfer process from ampoule to cartridge must be more expedient than with a patient sample.</i></p> <p>For EG7+, CG4+ or Chem8+ Cartridges:</p> <ul style="list-style-type: none"> <li>Expel one or two drops from the syringe before filling the cartridge.</li> <li>Direct tip and dispense into the sample well.</li> <li>Fill the cartridge to the indicated mark. Do not overfill sample well.</li> </ul>							
14.	<p>Seal the cartridge</p> <ul style="list-style-type: none"> <li>Immediately by snapping shut tab on side.</li> <li>Ensure the cartridge is closed tight.</li> </ul>							
15.	<p>Insert cartridge into the cartridge port, electrodes first.</p> <ul style="list-style-type: none"> <li>Wait for analyzer to show that contact is made.</li> </ul> <p>Results are available:</p> <ul style="list-style-type: none"> <li>120 seconds ( EG7+, CG4+ or Chem8+ Cartridges)</li> </ul>							
16.	<p>Review AQC Results.</p> <ul style="list-style-type: none"> <li>Page through the screens using the soft keys to arrow forward or backward.</li> </ul> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">If</th> <th>Then</th> </tr> </thead> <tbody> <tr> <td>AQC within range</td> <td> <ul style="list-style-type: none"> <li>Proceed to further testing – AQC or patient.</li> </ul> </td> </tr> <tr> <td>AQC not within range (flagged with up or down arrows):</td> <td> <p>Repeat testing after:</p> <ul style="list-style-type: none"> <li>Confirm current software CLEW, Lot # and expiry dates for AQC and EG7+ Cartridges in use.</li> <li>Confirm storage conditions for AQC and cartridges.</li> <li>Review AQC handling steps for possible error.</li> <li>Run EQC to confirm that the analyzer is working properly.</li> <li>Refer to AQC trouble guide and take action accordingly. See table following.</li> </ul> </td> </tr> </tbody> </table>	If	Then	AQC within range	<ul style="list-style-type: none"> <li>Proceed to further testing – AQC or patient.</li> </ul>	AQC not within range (flagged with up or down arrows):	<p>Repeat testing after:</p> <ul style="list-style-type: none"> <li>Confirm current software CLEW, Lot # and expiry dates for AQC and EG7+ Cartridges in use.</li> <li>Confirm storage conditions for AQC and cartridges.</li> <li>Review AQC handling steps for possible error.</li> <li>Run EQC to confirm that the analyzer is working properly.</li> <li>Refer to AQC trouble guide and take action accordingly. See table following.</li> </ul>	
If	Then							
AQC within range	<ul style="list-style-type: none"> <li>Proceed to further testing – AQC or patient.</li> </ul>							
AQC not within range (flagged with up or down arrows):	<p>Repeat testing after:</p> <ul style="list-style-type: none"> <li>Confirm current software CLEW, Lot # and expiry dates for AQC and EG7+ Cartridges in use.</li> <li>Confirm storage conditions for AQC and cartridges.</li> <li>Review AQC handling steps for possible error.</li> <li>Run EQC to confirm that the analyzer is working properly.</li> <li>Refer to AQC trouble guide and take action accordingly. See table following.</li> </ul>							

PHSA Laboratories CW Site - Point of Care  
**Title: CWPC\_BGE\_0125 iSTAT1 Aqueous Quality Control Procedure**

	 <p>Control 301084          15:14 21AUG17          i-STAT EG7+  <b>FAIL</b>          37.0°C          pH 7.673          PCO2 mmHg 24.7          PO2 mmHg 133          BEecf mmol/L 8          HCO3 mmol/L 28.7          TCO2 mmol/L 29          sO2% 100</p>		
	<p><i>Note: i-STAT1 error codes are stored.</i></p>		
17.	<p>Remove the AQC test cartridge.</p> <ul style="list-style-type: none"> <li>Press [1-Test Options].</li> <li>“Remove Cartridge” message appears. It is now safe to remove the cartridge.</li> </ul>		
18.	<p>In the event of an error code – refer to Appendix F – Troubleshooting Guide.</p>		
19.	<p>Discard syringe with blunt needle, ampoule and cartridge into the appropriate institutional biohazard container.</p>		
20.	<p>Data download to i-STAT Central Data Station:</p> <ul style="list-style-type: none"> <li>After performing Quality Checks or a Patient Test when possible.</li> <li>Monthly at a minimum.</li> </ul>		<p>QC Data Transfer and Results Reporting Procedure</p>

**Aqueous Quality Control Troubleshooting**

If in the event the AQC result is not within the specified range (flagged with up or down arrows or as specified by the laboratory QC chart), the supply of cartridges should not be used for patient testing until the cause is identified and corrected.

Repeat same source	<p>Repeat the AQC test using the same source of control and cartridge.          Ensure that AQC ampoules and cartridges are at RT.          AQC result is now within QC limits – corrective action is “repeat test, in-range”.          AQC result is still out of QC limits – continue with next step.</p>
Use new source of cartridge	<p>Same lot number of cartridge at RT storage. If the QC result is now in-range, the corrective action is “fresh cartridges, query storage problem 18-30°C”.          Same lot number cartridge, refrigerated storage. If the QC result is now in-range, the corrective action is “fresh box of cartridges, query storage problem 18-30oC”.</p>

Contact Point of Care Technologist for availability of a new lot # of AQC solution; new box or new shipment of a particular cartridge if applicable.  
 If the AQC result is now in-range, with a lot # change of either the AQC or the cartridge, the corrective action is “new shipment of AQC/cartridges, query previous lot# of AQC/cartridges.”

**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	Corrected MMU name. Added APOC step. Removed cTnl Cartridge reference.	Oct 24, 2017	Calvin Lee	
1.3	Minor	Reformatted	Oct 24, 2017	Calvin Lee	

**Attention: This document is published on the BCCW SharePoint website**

**Revisions made to this document require an update to the corresponding document published on BCCW SharePoint website**