Blanchard Valley Health System
Laboratory Servies

Blanchard Valley Hospital
1900 South Main Street, Findlay, OH 45840

Bluffton Community Hospital
139 Garau Street, Bluffton, OH. 45817

i-STAT Wireless for Point of Care Testing (LTR52286)

Last Approved By: Hashbarger, Bridgette (Regulatory Quality Compliance Manager) (Electronic Signature Timestamp: 08/05/2024)
Griggs, Shawn (Laboratory Manager) (Electronic Signature Timestamp: 08/02/2024)
Wonder, Teresa (Medical Technologist) (Electronic Signature Timestamp: 08/01/2024)
Budke, Heidi (BVH and AFCCC Laboratories Medical Director) (Electronic Signature Timestamp: 11/18/2024)
Praprotnik, Darja (Bluffton Laboratory Medical Director) (Electronic Signature Timestamp: 10/25/2024)
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Attention: Printed copies MAY not be the most current information. Please consult the Lab QMS for the current version.

i-STAT Wireless for Point of Care Testing

Updated 8/1/2024

Test analyte: cartridge dependent
Method: i-STAT-1 Wireless
CLIA complexity: some cartridges waived and some cartridges non-waived, moderately complex

Cartridge: Crea

Test analyte: Creatinine (Creat)

CLIA complexity: waived for whole blood collected in evacuated tubes with lithium heparin

Cartridge: G

Test analyte: Glucose (Glu)

CLIA complexity: nonwaived (moderately complex) on newborn heel sticks but waived for whole blood collected in evacuated tubes with lithium heparin

Cartridge: EG7+

Test analytes:

- Sodium (Na)
- Potassium (K)
- Ionized Calcium (iCa)
- Hematocrit (Hct)
- pH

PCO2
PO2
TCO2*
HCO3*
BE*
sO2*
Hemoglobin* (Hb)
**Calculated*

CLIA complexity: nonwaived (moderately complex)

Cartridge: CG8+

Test analytes:
Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Glucose (Glu)
Hematocrit (Hct)
pH
PCO2
PO2
TCO2*
HCO3*
BE*
sO2*
Hemoglobin* (Hb)
**Calculated*

CLIA complexity: nonwaived (moderately complex)

Cartridge: Chem8+

Test analytes:
Sodium (Na)
Potassium (K)
Chloride (Cl)
Ionized Calcium (iCa)
Glucose (Glu)
BUN
Creatinine (Creat)
Hematocrit (Hct)
TCO2 (measured not calculated)
Anion Gap*
Hemoglobin* (Hb)
**Calculated*

CLIA complexity: nonwaived (moderately complex)

Waived vs Nonwaived Status

The FDA has granted waived status for the following i-STAT test cartridges:

- Crea and G (granted November 13, 2008).

Waived status is applicable only when testing venous samples collected in evacuated tubes with lithium heparin (green top tubes) with any of the above listed cartridges with the i-STAT 1 Analyzer (Handheld). These new test categorizations will be listed on the CLIA database at http://www.fda.gov/cdrh/clia/ and can be found on the list of waived tests available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/testswaived.cfm.
The following are **additional** manufacturer's quality system instructions for i-STAT cartridges granted waived status. A list of **all** of the manufacturer's instructions are included in both the i-STAT 1 System Manual for Waived Tests and the standard i-STAT 1 System Manual.

Additional Manufacturer's Quality System Instructions for Waived Tests

New Shipment of Cartridges	Check one cartridge from each newly received lot with the appropriate i-STAT control: Crea Cartridges: use TriControls Level 1 Control, G Cartridges: use TriControls Level 3 Control.
Ensure Proper Cartridge Storage (Including Monthly Check)	Verify that cartridges stored at room temperature are within expiration date and that cartridges have been out of the refrigerator less than the time frame indicated on the cartridge box. If the temperature at which cartridges are stored is in doubt, use a liquid control to verify that the cartridges are performing properly. Check storage conditions monthly by testing the one cartridge from refrigerated storage with the appropriate i-STAT level control. Select the one cartridge to be tested using the following order: Creatinin, and Glucose. If the cartridge being tested is a: Crea: use Tri Controls Level 1 Control. G: use Tri Controls Level 3 Control. Test the cartridge on any Handheld.

PRINCIPLE:

PRINCIPLES OF MEASUREMENT:

Sodium, Potassium, Chloride, Ionized Calcium, pH, and *P*CO_2

are measured by ion-selective electrode potentiometry. Concentrations are calculated from the measured potential through the Nernst equation.

Urea

is first hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease. The ammonium ions are measured by an ion-selective electrode and the concentration is calculated from the measured potential through the Nernst equation.

Glucose

is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at an electrode to produce an electric current which is proportional to the glucose concentration.

Creatinine

is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the creatinine concentration.

***P*O_2**

is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

Hematocrit

is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.

TCO_2

The measured TCO_2 test method is calibrated to the International Federation of Clinical Chemistry (IFCC) TCO_2 reference method with an algorithm based on the Henderson-Hasselbach equation, which uses pH, ***P***CO_2, and ionic strength (Na) measurements.

SYSTEM OVERVIEW:

The i-STAT 1 System incorporates comprehensive components needed to perform blood analysis at the point of care. The system consists of the following primary components:

i-STAT 1 Analyzer

When a sample-filled i-STAT cartridge is inserted into the i-STAT 1 Handheld for analysis, the handheld automatically controls all functions of the testing cycle, including fluid movement within the cartridge, calibration, and continuous quality monitoring.

Analysis Time

- Most cartridges: typically 130 to 200 sec

Cartridges

A single-use disposable cartridge contains micro-fabricated sensors, a calibrant solution, fluidics system, and a waste chamber. Sensors for analysis of pH, ***P***CO2, ***P***O2, TCO2, sodium, potassium, chloride, ionized calcium,

glucose, creatinine, urea nitrogen (BUN) and hematocrit are available in a variety of panel configurations. A whole-blood sample of approximately 1 to 3 drops is dispensed into the cartridge sample well, and the sample well is sealed before inserting it into the analyzer.

Data Manager

The TELCOR computer system handles the Vendor i-STAT DE customization and provides the primary information management capabilities for the i-STAT 1 System. Wireless capabilities along with Downloaders and Downloader/Rechargers for the i-STAT 1 Analyzer allow for transmission of patient records from a widely distributed network of handhelds to TELCOR. Data can be stored, organized, edited, and transferred to LIS (Laboratory Information System). Cartridge usage and efficiency reports can be generated for management of the system.

CLINICAL SIGNIFICANCE:

Note that the manufacturer's table is all inclusive and may not reflect the actual patient testing done at BVHS.

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Sodium	Dehydration Diabetes insipidus Salt poisoning Skin losses Hyperaldosteronism CNS disorders	Dilutional hyponatremia (cirrhosis) Depletional hyponatremia Syndrome of inappropriate ADH
Potassium	Renal glomerular disease Adrenocortical insufficiency Diabetic Ketoacidosis (DKA) Sepsis *In vitro* hemolysis	Renal tubular disease Hyperaldosteronism Treatment of DKA Hyper-insulinism Metabolic alkalosis Diuretic therapy
Chloride	Prolonged diarrhea Renal tubular disease Hyperparathyroidism Dehydration	Prolonged vomiting Burns Salt-losing renal disease Over-hydration Thiazide therapy
Ionized Calcium	Dehydration Hyperparathyroidism	Hypoparathyroidism Early neonatal hypocalcemia

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
	Malignancies Immobilization Thiazide diuretics Vitamin D intoxication	Chronic renal disease Pancreatitis Massive blood transfusions Severe malnutrition
BUN	Impaired renal function Prerenal azotemia (e.g., shock) Postrenal azotemia GI bleeding High protein diet	Pregnancy Severe liver insufficiency Over-hydration Malnutrition

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Glucose	Diabetes mellitus Pancreatitis Endocrine disorders (e.g., Cushing's syndrome) Drugs (e.g., steroids, thyrotoxicosis) Chronic renal failure Stress I.V. glucose infusion	Insulinoma Adrenocortical insufficiency Hypopituitarism/Massive liver disease Ethanol ingestion/Reactive hypoglycemia Glycogen storage disease
Creatinine	Impaired renal function	
Lactate	Hypoxia (shock, hypovolumia, left ventricular failure) diabetes mellitus neoplasia liver disease drug or toxins (ethanol, methanol, salicylates) glycolic acid as a product of ethylene glycol metabolism	
pH	Respiratory alkalosis Metabolic alkalosis	Respiratory acidosis Metabolic acidosis
***P*CO$_2$**	Acute Respiratory Acidosis: • *Depression of respiratory center* • *Suppressed neuromuscular system* • *Pulmonary disorders* • *Inadequate mechanical ventilation* Chronic respiratory acidosis • *Decreased alveolar ventilation* • *Hypoventilation* Compensation in metabolic alkalosis	Respiratory alkalosis: • *Increased stimulation of respirator center* • *Hypermetabolic states* • *Mechanical hyperventilation* Compensation in metabolic acidosis
***P*O$_2$**	Breathing oxygen-enriched air	Carbon-monoxide exposure Pulmonary disorders Myocardial infarction Congestive heart failure

HCO_3 ***and*** ***T*****CO_2**	Primary metabolic alkalosis Primary respiratory acidosis	Primary metabolic acidosis Primary respiratory alkalosis

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Hematocrit	Dehydration Burns Impaired ventilation Renal disorders	Hemolytic anemias Iron deficiency Marrow depression Blood loss
ACT Celite	Administration of heparin for medical or surgical procedures. Administration of aprotinin.	
PT/INR	Administration of oral anticoagulant therapy.	
ACT Kaolin	Administration of heparin for medical or surgical procedures.	
cTnI	Myocardial Infarction Coronary vasospasm Cardiac contusion/trauma Rhythm disturbance (SVT, AF) Chemotherapy (e.g., Adriamycin) Myocarditis/pericarditis Infiltrative diseases (e.g., Amyloidosis, sarcoidosis, hemochromatosis, connective tissue disease) Congestive heart failure Heart transplantation Cardiac procedures (PTCA, DC cardioversion) Intracranial hemorrhage/stroke Pulmonary embolism Pulmonary hypertension Chronic renal insufficiency Sepsis Strenuous exercise Certain drug ingestions	Rare antibodies to troponin or its circulating complexes

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
CK-MB	Myocardial Infarction Coronary vasospasm Cardiac contusion/trauma Myocarditis/pericarditis Infiltrative diseases (e.g., Amyloidosis, sarcoidosis, hemochromatosis, connective tissue disease) Cardiac procedures (PTCA, DC cardioversion) Intracranial hemorrhage/stroke Pulmonary embolism Pulmonary hypertension Chronic renal insufficiency Sepsis Strenuous exercise Certain drug ingestions (cocaine) Skeletal muscle disease	Lean muscle mass
BNP	Congestive heart failure Chronic obstructive pulmonary disease (COPD) Asthma Pulmonary hypertension Cor pulmonale Pulmonary embolism Acute coronary syndrome Chronic renal failure Age Female sex	Obesity (BMI >30 Kg/m^2) Flash pulmonary edema (elevation may be delayed)
Total β-hCG	Pregnancy Gestational trophoblastic disease Nontrophoblastic neoplasms Menopause	

SPECIMEN:

A. COLLECTION AND PROCESSING

NOTE: blood collection devices, e.g., evacuated tubes, capillary tubes, and syringes, must be filled to the capacity of the device being used in order to ensure accurate test results.

Blood Collection Equipment

Cartridges for Blood Gas/Electrolytes/Chemistries/Hematocrit

- Skin puncture: lancet and capillary collection tube (lithium heparin, or balanced heparin for electrolytes and blood gases)
- Venipuncture: lithium heparin collection tubes and disposable transfer device.
- Arterial puncture: Plain syringe or blood gas syringe with heparin and labeled for the assays performed or with the least amount of heparin that will prevent clotting (10 U heparin/mL of blood)

Blood Volume (See Table 1)

Table 1: Cartridge Panel Configurations and Blood Volume (**Shading denotes calculated values)**
Note that the manufacturer's table is all inclusive and may not reflect the actual patient testing done at BVHS.

Cartridge	Vol. (µL)	pH	PCO_2	PO_2	Na	K	Cl	iCa	Glu	BUN	Creat	Lact	Hct	TCO_2	ACT	PT/INR	CK-MB	cTnI	BNP	Total β-hCG	HCO_3	TCO_2	SO_2	BE	Anion Gap	Hb
CHEM8+	95				•	•	•	•	•	•	•		•	•											•	•
CG8+	95	•	•	•	•	•		•	•				•								•	•	•	•		•
EG7+	95	•	•	•	•	•		•					•								•	•	•	•		•
EG6+	95	•	•	•	•	•							•								•	•	•	•		•
CG4+	95	•	•	•								•									•	•	•	•		
G3+	95	•	•	•																	•	•	•	•		
EC8+	65	•	•		•	•	•		•	•			•								•	•		•	•	•
6+	65				•	•	•		•	•			•													•
EC4+	65				•	•			•				•													•
E3+	65				•	•							•													•
G	65								•																	
Crea	65										•															
ACT	40														•											
PT/INR	20															•										
cTnI	17																	•								
CK-MB	17																•									
BNP	17																		•							
Total β-hCG	17																			•						

Suitable Specimens

Suitable Specimens for Cartridges for Blood Gases, Electrolytes, Chemistries, and Hematocrit

- ❑ Fresh whole blood collected in capillary collection tube with balanced heparin.
- ❑ Fresh whole blood collected in a collection tube with lithium heparin anticoagulant. Fill collection tubes to capacity.
- ❑ Fresh whole blood collected in a plain plastic syringe or in a blood gas syringe labeled for the assays to be performed. Fill syringes for correct blood-to-heparin ratio.

Specimen Labeling

Unless the specimen is analyzed immediately after collection and then discarded, the specimen container must be labeled with the following information:

Patient name and date of birth
Patient FIN number
Time and date of collection
Phlebotomist ID

Specimen Collection and Handling

In-Dwelling Line

Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: five to six times the volume of the catheter, connectors, and needle.

Arterial Specimens

For cartridge testing of blood gases, electrolytes, chemistries, and hematocrit, fill a plain syringe or fill a blood gas syringe, labeled for the assays to be performed, to the recommended capacity, or use the least amount of liquid heparin anticoagulant that will prevent clotting. Under-filling syringes containing liquid heparin will decrease results due to dilution and will decrease ionized calcium results due to binding. For ionized calcium, balanced or low volume heparin blood gas syringes should be used. Do not expose sample to air or ***P***CO**2** may decrease, pH may increase and ***P***O**2** may decrease if the value is above or increase if the value is below the ***P***O**2** of room air (approximately 150 mmHg).

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. For blood gas testing, avoid or remove immediately any air drawn into syringe to maintain anaerobic conditions.

Test samples collected without anticoagulant immediately. For pH, blood gases, TCO_2 and ionized calcium, test within 10 minutes of collection. If not tested immediately, remix the sample and discard the first two drops of blood from a syringe before testing. Note that it may be difficult to property remix a sample in a 1.0 cc syringe. For other cartridge tests, test sample within 30 minutes of collection.

Venous Specimens

For cartridge testing of electrolytes, chemistries, and hematocrit, collect sample into an evacuated blood collection tube or a syringe containing lithium or balanced heparin anticoagulant. For ionized calcium measurements, balanced heparin or 10 U of lithium heparin/mL of blood is recommended. Fill tubes to capacity; fill syringes for correct heparin-to-blood ratio. Incomplete filling causes higher heparin-to-blood ratio, which will decrease ionized calcium results and may affect other results. 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 for blood gas or CHEM8+ cartridges because of the potential for decreased ***P***CO2, HCO_3 and TCO_2 values.

For glucose cartridge testing, EDTA is also an acceptable anticoagulant.

Mix blood and anticoagulant by inverting a tube gently at least ten times. Roll a syringe vigorously between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Note that it may be difficult to properly mix a sample in a 1 cc syringe.

Test blood sample collected without anticoagulant immediately. Test samples for pH, ***P***CO2, TCO_2 and ionized calcium within 10 minutes of sample draw. If not tested immediately, remix the sample before testing and discard the first two drops of blood from a syringe before testing. For other cartridge tests, test sample within 30 minutes of collection.

Finger and Heelstick Specimens

Wipe away the first drop of blood, which contains excess tissue fluid which can increase the potassium result and decrease other test results. Avoid drawing air into the capillary tube. Use balanced heparin for ionized calcium. Test samples immediately to avoid clotting (especially in neonates).

RUNNING CARTRIDGES IN A HANDHELD

All i-STAT cartridges may be run in handhelds on a flat surface.

RUNNING CARTRIDGES IN A HANDHELD DOCKED IN THE DRC-300

All i-STAT cartridges may be run in handhelds that are docked in the Downloader/Recharger DRC-300.

B. REJECTION

Criteria for Specimen Rejection

- ❑ Evidence of clotting
- ❑ Specimens collected in vacuum tubes with anticoagulant other than lithium or sodium heparin (or EDTA for glucose cartridges)
- ❑ Syringe for pH, ***P***CO**2**, ***P***O**2** and TCO_2 with air bubbles in sample
- ❑ Incompletely filled vacuum tube for the measurement of ionized calcium, ***P***CO**2**, HCO_3 or TCO_2
- ❑ Other sample types such as urine, CSF, and pleural fluid

Precautions: avoid the following circumstances

- ❑ Drawing a specimen from an arm with an I.V.
- ❑ Stasis (tourniquet left on longer than one minute before venipuncture)
- ❑ Extra muscle activity (fist pumping)
- ❑ Hemolysis (alcohol left over puncture site, or a traumatic draw)
- ❑ Icing before filling cartridge
- ❑ Time delays before filling cartridge
- ❑ Exposing the sample to air when measuring pH, PCO_2, PO_2 and TCO2

C. STORAGE AND PRESERVATION

After testing, store tubes of blood specimens for up to 48 hours in a refrigerator designated for biohazards, if desired. There are no specimen storage or preservation requirements for i-STAT point of care testing.

INSTRUCTIONS FOR USE

06F24-16

Σ 500

For use in filling i-STAT cartridges from evacuated blood tubes.
If tube does not contain anticoagulant, dose immediately.

1

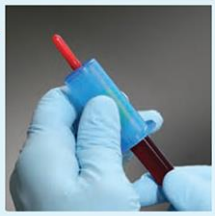
Remove Plug

Remove plug from barrel of Dispensing Tip. If the red cap or red plug is missing, Dispensing Tip may be contaminated -- discard immediately.

The internal needle is sharp -- do not touch.

Use Dispensing Tip immediately after removal of red plug.

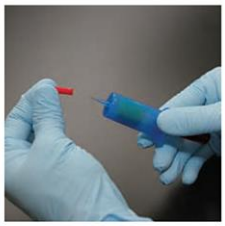
2



Insert Tube

Hold the plastic barrel so the Dispensing Tip points up and away from you. Place the blood collection tube into the barrel so the center of the stopper touches the internal needle. Press the tube onto the internal needle until the stopper is pierced. Follow Universal Precautions.

3

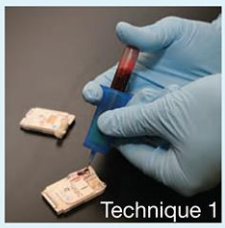


Remove Cap

Keeping the Dispensing Tip up and away from you, remove the red, plastic cap.

Do not handle the metal tip. It may contaminate the sample.

4



Dispense Blood

Align Dispensing Tip with the sample entry port on i-STAT cartridge and apply firm pressure to the end of the blood collection tube to dispense blood.

More than one cartridge can be filled from the same tube and Dispensing Tip. Do not use the same Dispensing Tip on a different evacuated tube of blood.

Do not re-use. Do not put the red plug or red cap back on.

5

Discard in Sharps Box

If the blood collection tube will not be discarded, hold the tube upright but tilted away from you and gently remove the Dispensing Tip.

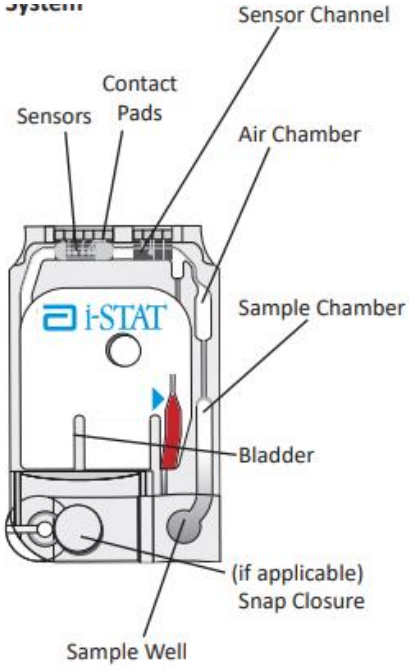
Dispose Dispensing Tip immediately according to your institution's policy and procedures for disposal of medical waste.

It is strongly recommended that good laboratory processes are followed and proper precautions are taken to minimize the risk of exposure to blood-borne pathogens. Handle all biologic samples, blood collection devices, and blood dispensing devices in accordance with the policies and procedures of your institution.

REAGENTS, STANDARDS, AND CONTROLS:

A. PREPARATION:

Cartridges

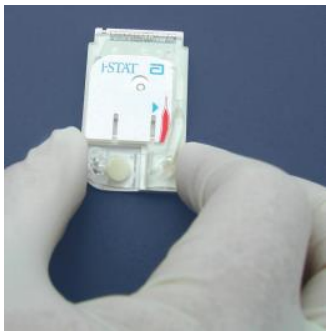


Cartridges are sealed in individual pouches or portion packs. Store the main supply of cartridges at a temperature between 2 and 8 °C (35 to 46 °F). **Do not allow cartridges to freeze.** Cartridges may be stored at room temperature (18 to 30 °C, or 64 to 86 °F) for the time frame indicated on the cartridge box. Cartridges should not be returned to the refrigerator once they have been at room temperature, and they should not be exposed to temperatures above 30 °C (86 °F). If the pouch has been punctured, the cartridge should not be used. Write the date on the cartridge box or individual cartridge pouches to indicate the room temperature expiration date. Cartridges should remain in pouches until the time of use. Do not use after the labeled expiration date.

Note: Temperature must also be checked and documented upon receipt of a new shipment using the four-window temperature indicator included with cartridges for transit. Records should be kept in a binder.

An individual cartridge may be used after standing 5 minutes, in its pouch, at room temperature. An entire box should stand at room temperature for one hour before cartridges are used.

Contact Pads and Sensors	Avoid touching the contact pads, as this may cause contamination and prevent the analyzer from making proper contact with the cartridge. Avoid touching the sensors on the top.



Calibrant Pack	Do not apply pressure to the central area of the label as the calibrant pack inside could burst prematurely.
Air Vent	Do not block the air vent as the sample will not flow to the fill mark and the calibrant solution will not flow to the sensors.
Contamination	To avoid contaminating the analyzer do not use a cartridge on which blood or any other fluid has spilled. Avoid filling cartridges on surfaces that may cause the cartridge to pick up fibers, fluid or debris that may lodge in the analyzer.

Controls

i-STAT TriControls for blood gases, electrolytes, and chemistries

Store at 2 to 8 °C (35 to 46 °F). Controls may be stored at room temperature (18 to 30 °C, or 64 to 86 °F) for five days. Do not use after expiration date on the box and ampules.

An individual control ampule may be used for blood gases after standing 4 hours at room temperature. For glucose and creatinine cartridges, 30 minutes should be sufficient to warm to room temperature.

QC Requirements
Test both levels of liquid controls as required, such as for IQCP.

B. CONTROL PROCEDURE:

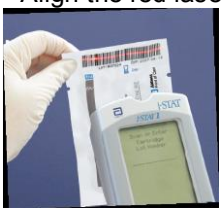
Procedure for testing cartridges with TriControls Level 1 and Level 3 Controls:

Prior to testing cartridges that measure ***P***O2, ampules should stand at room temperature a minimum of 4 hours before use. When testing other cartridges (G, Crea, CHEM8+), ampules may be used once the fluid has reached room temperature, approximately 30 minutes for individual ampules. For best results, ampules, cartridges, and handhelds should be at the same temperature. When using cartridges that contain sensors for measuring ionized calcium, pH, ***P***CO_2, or ***P***O_2 (EG7+, CG8+, or CHEM8+), a separate ampule must be used for each cartridge being tested; if these sensors are not present (i.e., the 6+ cartridge), the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into a handheld within 10 minutes of opening the ampule.

- DO NOT insert cartridge to start test.
- Ensure controls, cartridges and handheld analyzers are at room temperature
- Scan the cartridge barcode before opening cartridge pouch
- Use a cartridge immediately after removing it from its protective pouch.
- Ensure that quality control testing is performed from the Quality Test Menu for the purpose of documentation and review.

1. Press  (Power key) to turn on handheld.
2. Press the *Menu* key.
3. Press the *3* key to select *Quality Test.*
4. Press the 1 key to select *Control*.
5. Scan or enter the Operator ID.
6. Press the 1 key to select *APOC* Fluid Vendor. (APOC – Abbott Point of Care)
7. Scan the Control Lot Number (on the ampule).
8. Scan the Cartridge Lot Number (on the pouch).
   - Position barcode 3–9 inches (8–23 cm) from scanner window on the handheld.
   - Press and hold 

   to activate the scanner.
   - Align the red laser light so it covers the entire barcode.



   - The handheld will beep when it reads the barcode successfully.

Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule. Protect fingers with gauze, tissue, or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.

Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge. Immediately seal the cartridge and insert it into a handheld. It is important not to expose the solution to room air since this will alter the results.

- ❑ When using a capillary tube, fill from the bottom of the ampule. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.
- ❑ When using a syringe (1 cc or 3 cc syringes with 16- to 20-gauge needles are recommended), slowly draw approximately 1 cc of solution from the bottom of the ampule. 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. If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe. Expel one or two drops from the syringe before filling the cartridge.
- ❑ Do not use solution left in the syringe, ampule, or capillary tube for additional testing of the cartridges that contain sensors for ionized calcium, pH, ***P***CO_2, or ***P***O_2. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.

9. Continue normal procedures for mixing the control sample, filling and sealing the cartridge.
10. Insert the cartridge into the handheld cartridge port until it clicks in place. Wait for the test to complete. Note: For Hct, and immunoassay testing, the handheld must remain on a level surface with the display facing up during testing.
11. Review results. The display will say PASS or FAIL according to the electronic Abbott Point of Care Value Assignment correct ranges. Do not continue with patient testing until both levels of control PASS.
12. Press the 1 key to select *Test Options* on the results page.
13. Press the 1 key for *Next Level* if testing another level of control.

REMOVING THE USED CARTRIDGE FROM THE ANALYZER

Do not attempt to remove the cartridge while the message "Cartridge Locked" remains on the screen.

1) Press "1" to access the "Test Options" menu
2) When message appears to remove cartridge, pull the cartridge straight out of the analyzer.
3) Dispose of the cartridge in a puncture resistant container for biohazards.
4) After the cartridge is disposed of, press "4" to select "Transmit Data."

If all results are within expected ranges, use the cartridges as needed. Note: The i-STAT 1 System Coordinator, BVHS Laboratory Point of Care Testing Coordinator, BVH Laboratory Administrative Director, or Bluffton Laboratory Coordinator will ensure that the lot number and software revision on the Value Assignment Sheet matches the lot number of the vial in use and the software revision in the handheld

Value Assignment Sheets

Value Assignment Sheets are used to locate correct ranges for controls. The correct ranges are to be linked through TELCOR QML DE Customization. They can also be looked at online and printed.

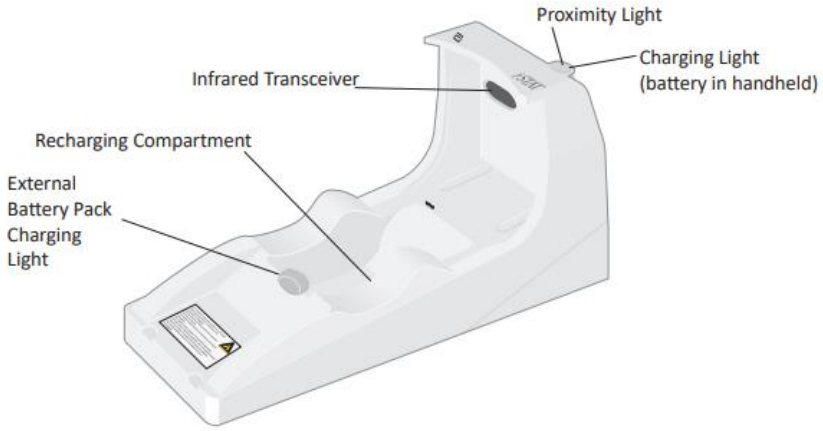
1. Go to www.globalpointofcare.abbott.
2. Under *Customer Quick Links* select *Value Assignment Sheets*.
3. Select the current CLEW version for your handheld (the CLEW version can be found under the Administration Menu, Option 1 for *Analyzer Status*.
4. Locate and Select the *Control Lot and Type* that corresponds with your control lot number.
5. Locate C*artridge Type* and *Lot Prefix Letter* within the value sheet that corresponds with your cartridge.

EQUIPMENT:

A. Instruments

i-STAT 1 Wireless Analyzer

i-STAT 1 Downloader/Recharger



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.

A. MICROSCOPIC EXAMINATIONS (AND REJECTIONS): None.

PROCEDURE:

A. PERFORMANCE

- DO NOT insert cartridge to start test.
- Ensure cartridges and handheld analyzers are at room temperature
- Scan the cartridge barcode before opening cartridge pouch
- Use a cartridge immediately after removing it from its protective pouch. Prolonged exposure may cause a cartridge to fail a Quality Check.

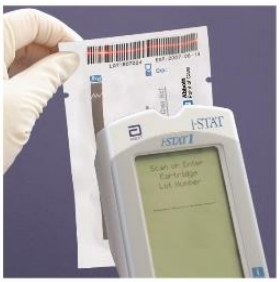
1. Press  to turn on handheld.

2. Press  for i-STAT cartridge.

3. Follow the handheld prompts. Scan or enter the Operator ID (small barcode for associate ID number). Scan patient barcode or enter Patient ID (Patient FIN). Note: For manual entry, enter patient FIN twice, if required.

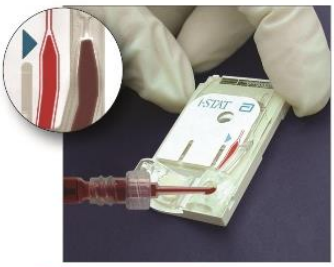
4. Scan the lot number on the cartridge pouch.

   - Position barcode 3-9 inches from scanner window on handheld.
   - Press and hold  to activate the scanner.
   - Align the red laser light so it covers the entire barcode.
   - The handheld will beep when it reads the barcode successfully.



5. Continue normal procedures for preparing the sample, filling, and sealing the cartridge.

6. Push the sealed cartridge into the handheld port until it clicks into place.



Enter a number to identify the specimen type (arterial, venous, etc.), and then press “Enter.”

Wait for the test to complete.

Note: For Hct, and immunoassay testing, the handheld must remain on a level surface with the display facing up during testing. A level surface includes running the handheld in the downloader/recharger.

7. Review results. Use the right arrow button (→) to scroll/view all of the pages of data.

Press the arrow button (→) to review the data.

The trained operator is now ready to transmit the data.

Properly Filled Cartridge
(Chemistry/Electrolyte/Blood Gas)

Properly Closed Cartridge

REMOVING THE USED CARTRIDGE FROM THE ANALYZER

Do not attempt to remove the cartridge while the message "Cartridge Locked" remains on the screen.

5) Press "1" to access the "Test Options" menu
6) When message appears to remove cartridge, pull the cartridge straight out of the analyzer.
7) Dispose of the cartridge in a puncture resistant container for biohazards.
8) After the cartridge is disposed of, press "4" to select "Transmit Data."

B. CALCULATIONS:

The i-STAT 1 Handheld contains a microprocessor that performs all calculations required for reporting results.

C. INTERPRETATION OF RESULTS:

Displayed Results

Results are displayed numerically with their units. Electrolyte, chemistry and hematocrit results can also be depicted as bar graphs with reference ranges marked under the graphs.

Suppressed Results

There are three conditions under which the i-STAT 1 System will not display results:

1. Results outside the reportable ranges are flagged with a **<** or **>**, indicating that the result is below the lower limit or above the upper limit of the reportable range respectively. (See the table of Reportable Ranges.) The **< >** flag indicates that the results for this test were dependent on the result of a test flagged as either **>** or **<**.

   Action:

Send specimen(s) to the Laboratory for analysis, if necessary.

2. Cartridge results which are not reportable based on internal QC rejection criteria are flagged with ***.

   Action:
   Analyze the specimen again using a fresh sample and another cartridge. If the specimen integrity is not in question, the results that are not suppressed should be reported in the usual manner. If the result is suppressed again, send specimen(s) to the Laboratory.

3. A Quality Check message will be reported instead of results if the handheld detects a problem with the sample, calibrant solution, sensors, or mechanical or electrical functions of the handheld during the test cycle.

   Action:
   Take the action displayed with the message that identifies the problem. Refer to the Troubleshooting section of the i-STAT 1 System Manual or the "Analyzer Coded Messages" Technical Bulletin if necessary.

Unexpected Results

When results do not reflect the patient's condition, repeat the test using a fresh cartridge and sample. If results are still suspect, test the lot of cartridges in use with i-STAT TriControl solutions. If the controls are in range, there may be an interfering substance in the sample. Check the Cartridge and Test Information (CTI) Sheets/Instructions for Use (IFU) for the test in question. Test by another method to verify the result by sending a specimen to the Laboratory. If the controls are out of range there may be a problem with the cartridge lot number. Use another lot number or repeat the test using another method, and contact i-STAT 1 System Coordinator, BVHS Laboratory Point of Care Testing Coordinator, BVH Laboratory Administrative Director, or Bluffton Laboratory Coordinator

QC PERFORMANCE POLICY:

A. CALIBRATION AND CALIBRATION VERIFICATION:

CALIBRATION: For cartridges, calibration is automatically performed as part of the test cycle on each cartridge type, except coagulation and immunoassay cartridges. Operator intervention is not necessary.

CALIBRATION VERIFICATION: See below for Periodic Procedures Performed Every 6 Months

IQCPs (Individualized Quality Control Plan) for Nonwaived Tests:

BVH Surgery – CG8+ cartridge:
The *Internal* Electronic Simulator will run every 8 hours the analyzer is in use. The *External* Electronic Simulator is to be performed as needed, after software upgrades, or after any instances that the analyzer is dropped. Both levels of external liquid controls must be tested with each new lot and/or shipment of i-STAT cartridges or at least every 30 days, preferably at the beginning of the month. Controls must also be run prior to resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventative maintenance, change of a critical instrument component, or with software changes, as appropriate.

This quality control plan has been customized according to test method and use, environment, and personnel competency while providing for equivalent quality testing.

BVH Special Care Nursery EG7+ cartridge:
The *Internal* Electronic Simulator will run every 8 hours the analyzer is in use. The *External* Electronic Simulator is to be performed as needed, after software upgrades, or after any instances that the analyzer is dropped. Both levels of external liquid controls must be tested with each new lot and/or shipment of i-STAT cartridges or at least every 30 days, preferably at the beginning of the month. Controls must also be run prior to resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventative maintenance, change of a critical instrument component, or with software changes, as appropriate.

This quality control plan has been customized according to test method and use, environment, and personnel competency while providing for equivalent quality testing.

BVH Special Care Nursery G (Glucose) cartridge:
The *Internal* Electronic Simulator will run every 8 hours the analyzer is in use. The *External* Electronic Simulator is to be performed as needed, after software upgrades, or after any instances that the analyzer is dropped. Both levels of external liquid controls must be tested with each new lot and/or shipment of i-STAT cartridges or at least every 30 days, preferably at the beginning of the month. Controls must also be run prior to resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventative maintenance, change of a critical instrument component, or with software changes, as appropriate.

This quality control plan has been customized according to test method and use, environment, and personnel competency while providing for equivalent quality testing.

B. FAILURE/REMEDIAL ACTION:

TROUBLESHOOTING OUT-OF-RANGE CONTROL RESULTS ON CARTRIDGES

Should results fall outside the range, verify the following conditions have been met:

- The correct expected values insert is being used and the correct cartridge type and lot number listing is being used.
- Expiration date printed on cartridge pouch and control ampule or vial have not been exceeded.
- Room temperature expiration date for cartridge and control have not been exceeded.
- Cartridge and control have been stored correctly.
- The control has been handled correctly–see the directions for use.
- The analyzer being used passes the Electronic Simulator test.

Then repeat the testing. Review results. If the results are still out of range despite meeting the above criteria, repeat the testing using a new box of control solutions and/or cartridges.

Remedial Action:

If any results are outside the published expected ranges:

- ❑ DO NOT USE cartridges from the suspect lot.
- ❑ Quarantine the suspect lot.
- ❑ Notify the i-STAT 1 System Coordinator, BVHS Laboratory Point of Care Testing Coordinator, BVH Laboratory Administrative Director, or Bluffton Laboratory Coordinator immediately.
- ❑ Record the QC failure in the i-STAT QC Action Log along with the action taken.

REPORTING RESULTS:

A. NORMAL VALUES:

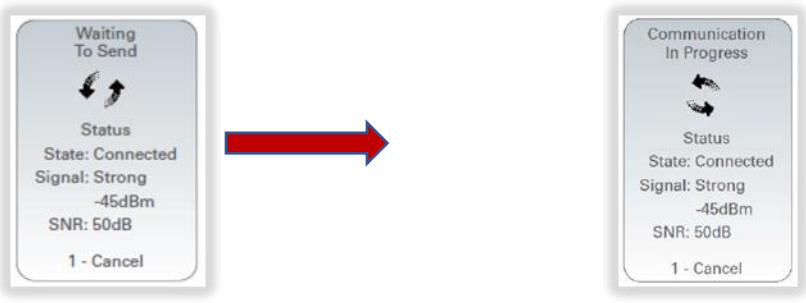
A normal result is defined as a result within the appropriate reference range, possibly based on age and/or gender, as approved by the Laboratory Medical Director. It can be transmitted wirelessly to the patient electronic record.

B. CRITICAL VALUES:

A critical result is defined as a result outside the normal range in such a degree that an immediate health risk to the patient is evident and/or immediate action may be required on behalf of the ordering physician. BVHS critical results are listed above and should be reported in compliance with the Point of Care Testing Policy.

STEPS FOR WIRELESS DATA TRANSMISSION FOLLOWING A PATIENT TEST CYCLE

1) When newly-generated data appears on the handheld display, review the data, and press "1" to access the "Test Options" menu.
2) Remove the cartridge, and then press "4" to select "Transmit Data."
3) A "Waiting to Send" message will appear on the display screen (see screen-shot below).
4) Once the connected state is reached, a "Communication in Progress" message will appear (see screen-shot below).



5) When the "Communication in Progress" above message disappears, and the display returns to the "Test Menu", the transmission is successful.
6) Transmitted data can now be seen in "Results Review" in Cerner.

Printing and Transmitting Results

Printing Results from the i-STAT 1 Analyzer to the Martel Portable Printer or to the i-STAT Printer

Without Downloader or Downloader/Recharger:

1. Turn printer on if green power light is not on.
2. Align infrared windows of handheld and printer.
3. Display results.
4. Press the *Print* key.
5. Do not move handheld or printer until printing is complete.
6. If printer is not powered from a wall outlet, turn printer off.

With Downloader or Downloader/Recharger and a connected printer:

1. Place handheld in Downloader or Downloader/Recharger that is wired to the printer.
2. Display results.
3. Press the *Print* key.
4. Do not move handheld or printer until printing is complete.

Printing more than one result at a time:

1. Press the *Power* key to turn the handheld on.
2. Press the *Menu* key.
3. Press *2* key for *Data Review*.
4. Press 7 key to select *List.*
5. Scroll through the test records using the left and right arrow keys.
6. Press the numbered key(s) for the test record(s). (Press the numbered key again to deselect a record.)
7. Align handheld and printer infrared window or place in Downloader or Downloader/Recharger attached to the printer.
   Press the *Print* key.
8. Do not move handheld or printer until printing is complete.
9. If printer is not powered from a wall unit using the AC adapter, turn printer off.

TRANSMITTING DATA FROM THE DRC-300 TO i-STAT/DE

1. Place handheld in the Downloader/Recharger DRC-300 cradle. If properly aligned, the blue proximity light will turn on and a “Waiting to Send” message will be displayed on the handheld until communication is established with the i-STAT/DE software.

2. Once the handheld establishes communication with the i-STAT/DE software, a “Communication in Progress” message will then appear on the handheld display and the arrows will circle until the transmission is complete.

Note: Do not move handheld until the "Communication in Progress" message disappears.

TRANSMITTED INFORMATION

- The following information is transmitted from the i-STAT 1 handheld with each test record:
- Date and time the test was performed.
- Operator and Patient ID or Quality Test fluid lot number.
- All information entered by the operator, e.g., lot numbers, sample types, and comment codes.
- Result(s).
- Serial number of the handheld.
- Uses count on the handheld.
- Application software version in the handheld.
- CLEW standardization software in the handheld.

STEPS FOR VIEWING PATIENT DATA DURING A DOWNTIME SCENARIO

If you want to view patient data during a downtime scenario, please follow the steps below:

•To view the most-recent sample data during a downtime scenario:

1) Turn on the i-STAT (as needed).
2) The "Test Menu" appears.
3) Press the "1" button ("Last Result").
4) The most-recent sample data will appear.
5) Use the right arrow button (→) to scroll/view all of the pages of data.

•To view all older sample data during a downtime scenario:

1) Turn on the i-STAT (as needed).
2) The "Test Menu" appears.
3) Press the "Menu" button.
4) The "Administration Menu" appears.
5) Press the "2" button ("Data Review").
6) Press "1" to view stored data by patient.
7) Enter the patient's FIN and your User ID.
8) When sample data appears, use the right arrow button (→) to scroll/view all of the pages of data.
9) Press the "1" or "2" button to view data from different samples. Different samples can be identified by date/time.

TROUBLESHOOTING UNSUCCESSFUL I-STAT 1 RESULTS TRANSMISSION

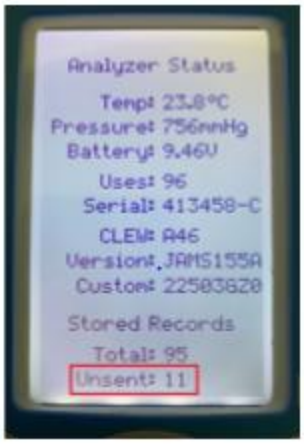
If i-STAT 1 results are not transmitting to your data management system (DMS), below are some troubleshooting steps to assist with identifying the cause and resolving the issue.

Note: i-STAT results transmit from the i-STAT 1 analyzer --> i-STAT/DE server --> DMS.

- If i-STAT 1 results are not transmitting to your DMS:

    o Verify **Unsent** records on the i-STAT 1 analyzer(s) under Stored Records by pressing the **Menu** key to access the **Administration Menu > 1 – Analyzer Status** and note the number of **Unsent records** on the last line as shown in *Picture 1.*

    o *Picture 1*



Scenario 1 – *A subset of i-STAT 1 analyzers (one or two analyzers) are not transmitting results*

o When the analyzer is docked in a networked downloader to attempt communication of results, the communication ends and shows the number of **Unsent** records as shown in *Picture 2.*

o *Picture 2*

1. Verify the downloader is connected to power & to the correct network port on the wall.

2. Disconnect & reconnect the downloader from both the power & network & redock analyzer.

3. Verify the blue proximity light on the top of the i-STAT 1 downloader/recharger is illuminated when the analyzer is seated in the downloader.

4. Recheck for unsent results on the analyzer.

5. If the results do not transmit from the downloader, have your IT/network team verify the downloader settings (IP address, Subnet Mask, Default Gateway; DE Server IP address).

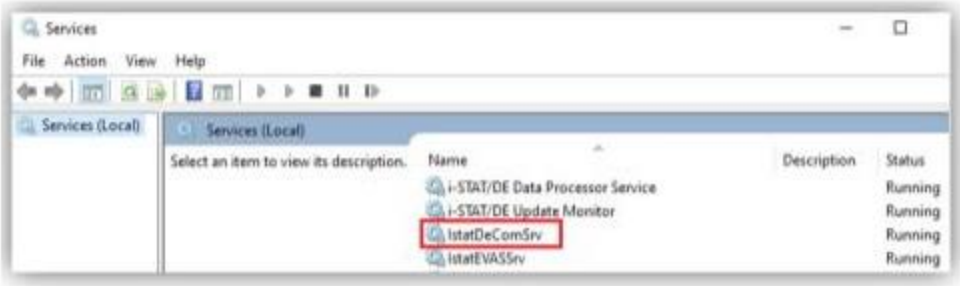
Note: You can also try to dock the analyzer in a different downloader (if available) to try to transmit the results. Recheck for unsent results on the analyzers (as shown in *Picture 1* above).

· **Scenario 2** – *There are Unsent results on all i-STAT 1 analyzers (as shown in Picture 1).*

1.Verify on **i-STAT/DE System** > **Main/Status** page that **Services** have statuses shown as "Running."

2. Verify **i-STAT/DE System** > **View/Set Configuration** page has "Enable Network Communications" checked and "i-STAT Series 300 (i-STAT 1) Analyzer" is checked with Port set to 6004.

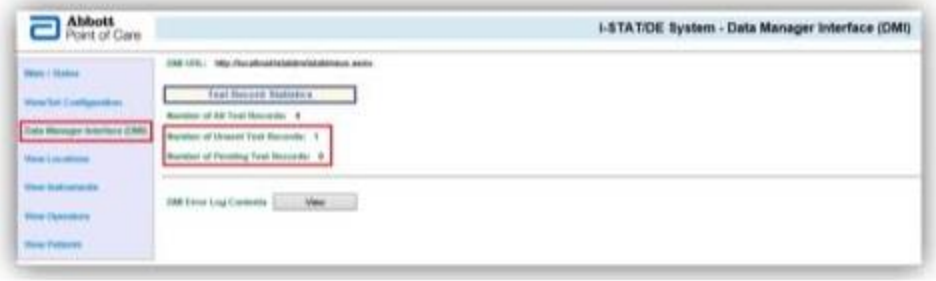
3.On the **i-STAT/Server**, have your IT/network team restart the **IstatDEComSrv** service.



4.Place the analyzer(s) in the downloader and verify that the results transmit from the analyzer(s). Recheck for unsent results on the analyzers.

·**Scenario 3** – *There are no Unsent results on the i-STAT 1 analyzers, but results are not in the DMS*

1.Review **i-STAT/DE System**>**Data Manager Interface** (DMI) for any unsent or pending records.



2.If there are any unsent / pending recors on DMI request your IT/network team to reboot the data manager and DE server.

3.If this does not resolve the issue contact your DMS vendor for QML (Telcor).

You can find additional information about i-STAT/DE and Info HQ at this link in the specific user guides. Technical Bulletins & Product Updates | Abbott Point of Care (globalpointofcare.abbott)

CLEANING THE HANDHELD i-STAT ANALYZER BETWEEN PATIENTS

Clean the display and case with any of the following

- gauze pad moistened with isopropyl alcohol
- gauze pad moistened with 10% bleach solution.
- Super Sani-Cloth

Rinse the case using another gauze pad moistened with water and dry. Avoid getting excess fluids in the seam (A) between the display screen and the case.

Decontaminate the analyzer or Downloader whenever a specimen is spilled onto it or if the item is to be returned to Abbott Point of Care for repair. Wear gloves while performing the following procedure.

STEP	ACTION
1	Prepare a 10% solution of household bleach by mixing one part of bleach with nine parts of tap water.
2	Soak a few gauze pads in the bleach solution. Before use, squeeze the pads to remove excess solution.
3	Soften, then remove any dried blood with one or two of the gauze pads soaked in the bleach solution. Avoid scraping dried blood as contaminated particles may become airborne.
4	Clean the entire surface of the device twice with gauze pads soaked in the bleach solution.
5	Rinse the surface of the device with gauze pads moistened with tap water and dry.
6	If the device is to be shipped, place it in a plastic bag.

A. Periodic Procedures

For acceptance of newly received cartridge lots, check the Temperature Monitor and perform integrity testing.

Note: This is not a manufacturer's system instruction. It is a requirement to comply with regulations.

Check Temperature Monitor

i-STAT cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit.

Note: All control and calibration verification materials, except for those shipped on dry ice, will also include a four-window indicator to monitor temperature during transit.

Action:

- ❑ Fill out the record of receipt and forward materials to refrigerator.

- ❑ If all windows are white or if only the A or B windows are blue or the 1 or 2 windows are red, then transit temperatures were satisfactory and the cartridges can be used. Store the record in a binder.

Remedial Action:

If the C or D windows are blue, or the 3 or 4 windows are red:

- ❑ Quarantine the suspect cartons.
- ❑ Notify the i-STAT 1 System coordinator, BVHS Laboratory Point of Care Testing Coordinator, BVH Laboratory Administrative Director, or Bluffton Laboratory Coordinator immediately.
- ❑ DO NOT USE cartridges from the suspect cartons.
- ❑ Record the out-of-control event in the i-STAT QC Log.

Integrity Testing *

Verify the integrity of cartridges included in every shipment, upon receipt, by analyzing two levels of appropriate controls (see table below) along with a representative sample of each new lot and by comparing the results to the expected values published in the Value Assignment Sheets. Any analyzer that has passed the Electronic Simulator test may be used in the verification.

***Note:** the information in the above paragraph is not a manufacturer's system instruction. It is a suggestion to comply with regulatory requirements that may pertain to your laboratory. Note that the manufacturer's table is all inclusive and may not reflect the actual patient testing done at BVHS.

Verification of Cartridges Using 2 Levels of Specified Controls	
CARTRIDGE TYPE	**CONTROL TYPE**
G, Crea, G3+, CG4+	TriControls [1] ***or*** i-STAT controls [1]
CHEM8+, E3+, EC4+, 6+, EC8+, EG6+, EG7+, CG8+	TriControls [1]
ACTk, ACTc	i-STAT ACT controls [2]
PT/INR	i-STAT PT/INR controls [2]
cTnI	i-STAT cTnI controls [1]
CK-MB	i-STAT CK-MB controls [1]
BNP	i-STAT BNP controls [1]
Total β-hCG	i-STAT Total β-hCG controls [1]

[1] Use Level 1 and 3 Controls.
[2] Use Level 1 and 2 Controls.

PERIODIC BATTERY REPLACEMENT

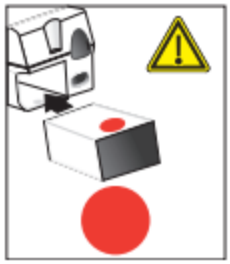
Charge battery before use: Put new rechargeable battery in external charging bay on the i-STAT 1 Downloader/Recharger for 40 hours. Battery will be 100% charged and ready for use. Analyzer with disposable

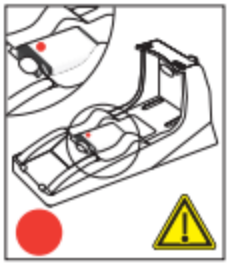
batteries may be placed on Down/loader/Recharger to download data until rechargeable battery is ready. Note: No damage will be caused if a handheld with disposable batteries installed is placed in the DRC-300.

Keep battery charged: Fully charged battery, if not periodically recharged, will self-discharge in approximately three months. Prevent self-discharge by either
(1) keeping the rechargeable battery in an i-STAT analyzer that is periodically on the Downloader/Recharger, or
(2) store the rechargeable battery separately in the external charging bay on the Downloader/Recharger.

Removing and Replacing the Rechargeable Battery: Wait until any test in progress is completed, and turn off the analyzer before replacing the battery or the most recent set of results may be lost. Stored results will not be lost when replacing the batteries

STEP	ACTION
1	Slide the battery compartment door off.
2	Tilt the analyzer slightly to slide out the rechargeable battery pack.
3	The battery pack has two labels: one for orientation in the analyzer and one for orientation in the Downloader/Recharger. With the label with the analyzer facing up, and the electrical contact end of the pack facing the analyzer, insert the pack into the analyzer as shown on the label. If the pack is inserted incorrectly, the battery door will not close.
4	Slide the battery compartment door back into place.





Disposal: Do not attempt to disassemble the NiMH battery pack. If disposing of battery, do not incinerate. Contact local authorities to enquire about disposal or recycling activities.
Note: The battery label BODxxxx-xx defines the year and month of manufacture.

CHARGING A RECHARGEABLE BATTERY WHILE INSTALLED IN THE HANDHELD

Placing a handheld containing the rechargeable battery in the DRC-300 will automatically initiate charging of the rechargeable battery. The indicator light on top of the DRC-300 will be:
- green (trickle charge),
- red (fast charge), or
- blinking red (fast charge pending).

CHARGING A RECHARGEABLE BATTERY IN THE EXTERNAL RECHARGE COMPARTMENT

Placing a rechargeable battery into the external recharging compartment will automatically initiate trickle recharging. The indicator light near the recharging compartment will be green when a rechargeable battery is placed in the compartment.

1. The battery pack has two labels: one for orientation in the handheld and one for orientation in the DRC-300. With the label with the Downloader facing up and the electrical contact end of the pack facing the contacts in the battery compartment, insert the pack into the compartment as shown on the label.

2. To remove the battery after it is charged, back the pack out of the compartment.

PERIODIC PRINTER PAPER REPLACEMENT

1. Open the paper compartment lid by pulling up on the release lever and remove any remaining paper.
2. Reel off a few centimeters of paper from the new paper roll, with the leading edge of the paper feeding forward from the bottom of the roll.
3. Sit the new paper roll in the compartment such that the leading edge is resting outside the compartment on the printer casing.
4. Close the lid until it snaps into place.

B. Daily Procedures

Humidity

RELATIVE HUMIDITY	10-90% non-condensing

- ❑ Verify that the recorded relative humidity of the testing environment did not exceed the limits of 10-90 % non-condensing.

  Action:

  If the measured relative humidity of the room has been continuously within 10-90 % non-condensing, use i-STAT Wireless analyzer as required.

  Remedial Action:

  If the measured relative humidity of the room is outside the range of 10-90 % non-condensing, notify the i-STAT 1 System coordinator, BVHS Laboratory Point of Care Testing Coordinator, BVH Laboratory Administrative Director, or Bluffton Laboratory Coordinator immediately. Record the QC failure in the i-STAT QC Log along with the actions taken.

Verification of Cartridge Storage Conditions

Refrigerated Cartridges

- ❑ Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes.
  Deliver any expired cartridges to the i-STAT 1 System coordinator.
- ❑ Verify that the refrigerator did not exceed the limits of 2 to 8 °C (35 to 46 °F).
- ❑ Document in the i-STAT QC Log.

Action:

If the temperature of the cartridge storage refrigerator is within the range of 2 to 8 °C (35 to 46 °F) use cartridges as required.

Remedial Action:

If the temperature is outside the range of 2 to 8 °C (35 to 46 °F), notify the i-STAT 1 System coordinator, BVHS Laboratory Point of Care Testing Coordinator, BVH Laboratory Administrative Director, or Bluffton Laboratory Coordinator immediately. Record the QC failure in the i-STAT QC Log along with the actions taken.

Room Temperature Cartridges

- ❑ Verify that all boxes of cartridges at room temperature have been out of the refrigerator less than the time frame indicated on the cartridge box. Deliver any expired cartridges to the i-STAT 1 System coordinator.
- ❑ Verify that room temperature has not exceeded 30 °C (86 °F).
- ❑ Document in the i-STAT QC log.

Action:

If the measured temperature of the room has been continuously below 30 °C (86 °F) use cartridges as required.

Remedial Action:

If the measured room temperature has exceeded 30 °C (86 °F) for any period of time:

- ❑ Quarantine the cartridges.
- ❑ Notify the i-STAT 1 System coordinator, BVHS Laboratory Point of Care Testing Coordinator, BVH Laboratory Administrative Director, or Bluffton Laboratory Coordinator immediately.
- ❑ DO NOT USE the cartridges.
- ❑ Record the out-of-control event in the i-STAT QC Log and the action taken.

Handheld Verification

Verify the performance of each handheld in the i-STAT 1 System using the internal or external Electronic Simulator every 24 hours of use. Verification is required every 8 hours for blood gases and hematocrit. The i-STAT 1 System should be programmed to automatically perform daily internal electronic checks at the required intervals based on the testing performed.

Note: If the internal Electronic Simulator is used, the “PASS” message will not be displayed on the handheld screen. The “PASS” record will appear in the handheld’s stored results for transmission to the data manager.

Procedure for Internal Electronic Simulator

The internal Electronic Simulator test cycle is automatically activated when a cartridge is inserted after the customized interval is reached. If the analyzer passes the simulator test, the cartridge test cycle proceeds. If not, the analyzer displays “ELECTRONIC SIMULATOR FAIL.” If the analyzer is customized to block testing when it fails the simulator test, the same cartridge can be re-inserted immediately after the FAIL message is displayed. If the analyzer fails the simulator test again, see the Troubleshooting section below. If less than

three minutes has elapsed, the cartridge can be inserted into another analyzer. If the analyzer is not customized to block testing after a failed simulator test, the internal simulator test will not repeat until the programmed interval has elapsed.

TROUBLESHOOTING FAILED INTERNAL ELECTRONIC SIMULATOR TEST

Introduction

With both the internal and external Electronic Simulator, an analyzer may occasionally fail a simulator test even though it is in proper operating condition due to the extremely sensitive nature of the test.

Failed Internal Simulator

The cartridge or an external Electronic Simulator should be rerun to confirm the failure. The analyzer's connector pins are in contact with the biosensor chips in the cartridge being tested when the internal Electronic Simulator test is being performed. The test can fail if the contact pads have been contaminated in some way.

Lockout Enabled: Rerun the cartridge in the same analyzer to ensure the FAIL was not due to a one-time spike of electrical noise. If the test fails again, rerun the cartridge in another analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. If the cartridge fails in more than one analyzer, use another cartridge. When Lockout is enabled, the analyzer will continue to perform the internal Electronic Simulator test each time a cartridge is inserted until the test (internal or external) passes.

Lockout Not Enabled: Rerun the cartridge in another analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. When Lockout is not enabled, the analyzer will run the next cartridge without performing the internal Electronic Simulator test until the specified time has elapsed. Verify the analyzer using an external Electronic Simulator.

If PASS is displayed on the handheld screen after using the external Electronic Simulator:

- ❑ Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ❑ Transmit the result.
- ❑ Use the handheld as required.

Note: If the internal Electronic Simulator is used, the "PASS" message will not be displayed on the handheld screen. The "PASS" record will appear in the handheld's stored results for transmission to the data manager.

If FAIL is displayed on the handheld screen after using the external Electronic Simulator:

- ❑ Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ❑ Repeat the procedure with the same external Electronic Simulator or rerun the cartridge if the internal Electronic Simulator is being used. If PASS is displayed use the handheld as required.

If FAIL is displayed again,

- ❑ Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ❑ Repeat the procedure with a different external Electronic Simulator.

If FAIL is still displayed with the second internal/external Electronic Simulator:

- ❑ DO NOT analyze patient samples with the handheld.

- ❑ Transmit the result.
- ❑ Deliver the questionable/faulty handheld to the i-STAT 1 System coordinator, BVHS Laboratory Point of Care Testing Coordinator, BVH Laboratory Administrative Director, or Bluffton Laboratory Coordinator immediately.
- ❑ Record the failure in the i-STAT QC Log along with the action taken.

- ❑ Contact Abbott Point of Care Technical Support.

C. Monthly or As Needed Procedures

Battery Rotation

Rotate the batteries in the i-STAT analyzer and downloader/recharger at the beginning of each month. Document completion of this task in the i-STAT QC Log.

Electronic Simulator Results

Run the external Electronic Simulator as needed, such as for IQCP requirements. Document completion of this task in the i-STAT QC Log.

Procedure for External Electronic Simulator

1. Press the *On/Off* key to turn the analyzer on. Logo briefly displayed followed by Test Menu. *Note: Do not insert or remove external electronic simulator unless instructions to appear on instrument display screen. Otherwise, damage will occur and analyzer will not be operational.*

2. Test Menu
   Press the *Menu* key.

3. Administration Menu
   Press 3 to select *Quality Tests*.

4. Quality Tests Menu
   Press 4 to select *Simulator.*

5. Scan or Enter Operator ID
   Press Scan to scan the Operator ID or manually enter the Operator ID and press Enter.

6. Scan or Enter Simulator ID
   Press Scan to scan the Simulator serial number.

7. 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.

8. Contacting Simulator Please wait…
   Time to Results bar
   Simulator Locked

   Caution: Do not attempt to remove the simulator until the results are displayed and the "Simulator Locked" message is removed.

9. View results on handheld's screen.

   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

10. If PASS is displayed, continue to use the analyzer. Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen. Return the external Electronic Simulator to its protective case. Transmit the result. The results of the external electronic simulator check are stored in the data manager.

    If FAIL is displayed, see the Troubleshooting instructions below.

TROUBLESHOOTING FAILED EXTERNAL ELECTRONIC SIMULATOR TEST

Introduction

With both the internal and external Electronic Simulator, an analyzer may occasionally fail a simulator test even though it is in proper operating condition due to the extremely sensitive nature of the test.

External Simulator

Run the test again, as it is possible that the test will pass on a second try. DO NOT INSERT OR REMOVE SIMULATOR FROM HANDHELD ANALYZER UNTIL INSTRUCTED BY INSTRUMENT READING. SIMULATOR COULD BECOME JAMMED IN THE HANDHELD ANALYZER, RENDERING BOTH USELESS. The test can also fail if the external Electronic Simulator is malfunctioning such as after being dropped.

If PASS is displayed on the analyzer screen:

- ❑ Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ❑ Transmit the result.
- ❑ Use the handheld as required.

If FAIL is displayed on the analyzer screen:

- ❑ Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ❑ Repeat the procedure with a different external Electronic Simulator

A different external Electronic Simulator should be rerun to confirm the failure.

If PASS is displayed on the analyzer screen:

- ❑ Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ❑ Transmit the result.
- ❑ Deliver the questionable/faulty external Electronic Simulator to the i-STAT 1 System coordinator, BVHS Laboratory Point of Care Testing Coordinator, BVH Laboratory Administrative Director, or Bluffton Laboratory Coordinator immediately.

If FAIL is displayed on the analyzer screen:

- ❑ Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ❑ Repeat the procedure with an external Electronic Simulator setting 30 minutes near the entry of the analyzer. Occasionally when an analyzer is moved from a cold environment to a warm, humid environment, moisture may condense on the internal connector. An analyzer in this condition will fail the electronic test and the failure code "L" will be displayed. Allow the analyzer to sit for half an hour to allow the moisture to evaporate, then insert the external Electronic Simulator and rerun.

If PASS is displayed on the analyzer screen after setting 30 minutes:

- ❑ Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ❑ Transmit the result.
- ❑ Use the handheld as required.

If FAIL is displayed on the analyzer screen after setting 30 minutes:

- ❑ Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ❑ Repeat the procedure with the same external Electronic Simulator. If PASS is displayed use the handheld as required.
- ❑ If FAIL is displayed repeat the procedure with a different external Electronic Simulator.

A different external Electronic Simulator should be rerun after setting 30 minutes to confirm the failure.

If PASS is displayed with the second external Electronic Simulator after setting 30 minutes:

- ❑ Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ❑ Transmit the result.
- ❑ Use the handheld as required.

- ❑ Deliver the questionable/faulty external Electronic Simulator to the i-STAT 1 System coordinator, BVHS Laboratory Point of Care Testing Coordinator, BVH Laboratory Administrative Director, or Bluffton Laboratory Coordinator immediately.

If FAIL is displayed with the second external Electronic Simulator after setting 30 minutes:

- ❑ DO NOT analyze patient samples with the handheld.
- ❑ Remove the external Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ❑ Transmit the result.
- ❑ Deliver the questionable/faulty handheld to the i-STAT 1 System coordinator, BVHS Laboratory Point of Care Testing Coordinator, BVH Laboratory Administrative Director, or Bluffton Laboratory Coordinator immediately.
- ❑ Record the failure (the letter or Quality Check Code displayed with the FAIL message) in the i-STAT QC Log along with the action taken.
- ❑ Contact Abbott Point of Care Technical Support.

TROUBLESHOOTING i-STAT MESSAGE ON DISPLAY: 79-81 Cartridge Error/Use Another Cartridge

Bad contact between the thermal probes in the analyzer and the metalization on the back of the chips
In the cartridge trigger these codes. Causes are poor metallization of the chips, dirt on the metallization, or bent or broken thermal probes in the analyzer.

12.2 Cleaning the Thermal Probes (as needed to remedy error)
Codes 79-81 can be caused by dirt on the thermal probes, although most often these codes are due to bent or broken probes. To clean the probes:
1. Remind user of instruction in i-STAT Manual -- "Whenever handling the analyzer, cartridges, and peripherals exercise universal precautions to protect yourself from blood-borne pathogens."
2. Obtain a new thermal cartridge.
3. Looking at the underside of the cartridge locate the two depressions (half circle) under the sensors.
4. Drop alcohol into the depressions, then shake off the excess alcohol.
5. Run the cartridge like a test. Ignore error codes, if any.
6. Repeat previous steps using another new cartridge.
7. Run a new thermal cartridge filled with blood or a control fluid. If codes continue, the analyzer must be replaced.

D. Every 6 Months Procedures

Thermal Probe Check

i-STAT analyzers contain a thermal control subsystem consisting of two thermal probes with thermistors and heating contact wires. When measurements are performed at a controlled temperature, the thermal probes in the analyzer contact the metalized area under the chips in the cartridge and maintain the temperature of the sensors and the fluids that come into contact with these sensors at the required temperature ± 0.15°C. A quality check is performed on the thermal probes each time the external Electronic Simulator is used. To

complete this check, the surface temperature of the external Electronic Simulator must not fluctuate. If this condition is not met, the thermal probe check is not completed. Therefore, Abbott Point Of Care recommends that the thermal probe check be verified every six months. The i-STAT 1 System Coordinator, BVHS Laboratory Point of Care Testing Coordinator and/or BVH Laboratory Director and/or Bluffton i-STAT Coordinator will direct and assign thermal probe checks for each analyzer every six months.

Check the thermal probes on the i-STAT 1 Analyzer as follows:

1. If the analyzer and simulator have been stored separately in areas where the ambient temperature differs by more than 3 °C (5 °F), allow the simulator and analyzer to stand in the same place, out of drafts, for 30 minutes before inserting the simulator into the analyzer. Handle the simulator as little as possible to maintain its thermal uniformity and stability.

2.Insert the simulator into the analyzer. Perform external electronic simulator check. After result appears, press the period key. Review result.

3. Interpretation of the thermal probe check value:

• Acceptable: a value from -0.1 to +0.1, inclusive.
• Repeat the procedure if a FAIL message with a “t” Quality Check Code or a value less than -0.1 or greater than 0.1 is displayed.
• Repeat the procedure if “--.--” is displayed. Take care to handle the simulator a little as possible. DO NOT INSERT OR REMOVE SIMULATOR FROM ANALYZER UNTIL INSTRUCTED BY INSTRUMENT READING. SIMULATOR COULD BECOME JAMMED IN ANALYZER, RENDERING BOTH USELESS. When repeating procedure, it may help to partially insert the simulator into the analyzer and let it stand for 15 minutes before inserting all the way.
• Contact your Technical Support representative if the repeat thermal check value is greater than 0.1 or less than -0.1 or if a Quality Check Code is displayed.

Documentation of Results
Document completion of this task in the i-STAT QC Log. The results of the thermal probe check are stored in the data manager.

Calibration Verification (Nonwaived Tests)
Laboratory regulation require that for tests categorized as nonwaived, a calibration verification procedure be performed and documented at least once every six months. Abbott Point of Care Inc’s. position is that the cartridges, or more specifically, the sensors, rather than the analyzers, should be subject to the six-month check on the accuracy of the reportable range. Abbott Point of Care Inc. also claims that all analyzers that pass the Electronic Simulator test are equivalent, which should preclude the testing of three levels, twice a year, on each and every analyzer on site.

Calibration verification is performed and documented:
1. At changes of reagent lots, unless the user can demonstrate that the use of different lots does not affect the accuracy of patient test results and the range used to report patient test data, or the control value.
2. If QC materials reflect an unusual trend or shift or are outside the laboratory’s acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.
3. After major maintenance or service.
4. As recommended by the manufacturer.
5. At least every six months.

6. On every analyzer prior to initial placement for patient testing.

Test systems are recalibrated when calibration verification fails to meet the established criteria of the POCT program and records maintained.

The BVHS Laboratory Point of Care Testing Coordinator and/or Bluffton i-STAT Coordinator will direct calibration verification every six months on nonwaived tests. First, the BVHS Laboratory Point of Care Testing Coordinator and/or Bluffton i-STAT Coordinator orders the following from the vendor, Abbott, every 6 months (spring & fall):

i-STAT TriControls Calibration Verification Set Levels 1-5 05P70-01

These are matrix-appropriate materials of known analyte value appropriate to the AMR of the i-STAT instrument. The set includes low, midpoint, and high values that are near the stated AMR, analytic measurement range.

After the materials arrive, the BVHS Point of Care Testing Coordinator determines which instruments, based on rotation, should be tested and prepares the paperwork. The trained operators are then assigned to perform testing and submit the data for all assays to the BVHS Laboratory Point of Care Testing Coordinator or Bluffton i-STAT Coordinator for both calibration verification and AMR verification. The results are to be evaluated for acceptability based on CLIA limits (CAP Evaluation Criteria) and/or BVHS approved limits, and records maintained. Calibration verification/ AMR verification documents should be kept in a binder.

Note that since the materials used for calibration or for calibration verification include low, midpoint, and high values, that are near the AMR, and when calibration verification data are within the user's acceptance criteria, the AMR has been verified: no additional procedures are required.

Single-use devices such as the i-STAT instruments are a special case in which a large number of devices may be in use at any time within an institution. The AMR must be verified for each device when placed in service, and following maintenance or repair. However it may not be practical to perform the semiannual verification of the AMR using a special set of specimens for all devices, and verification may be performed on a sample of devices, provided that such a sampling procedure does not conflict with manufacturer instructions. (If different types of instruments and different lots of reagent strips/cartridges are in use, a sample of each instrument type and each lot of strips/cartridges must be included in this subset.) For the devices not sampled, verification of the AMR may be inferred by other approaches. Examples include: 1) review of external QC results to ensure acceptability; 2) comparison of POCT results with near-simultaneously collected specimens analyzed in the main laboratory. (This type of comparison is facilitated when the POCT results are downloaded to a central data management computer.) Other approaches may be satisfactory. Manufacturer's instructions for calibration verification/AMR verification must be followed. The sample of devices on which reverification is performed should be rotated so that over time all devices are directly verified.
Note that the AMR must be verified every six months, when there is a change in major test system components and/or there is a change in lots of chemically or physically active reagents. However, there is an exception to the latter. If the laboratory can show that changing lots does not affect the range used to report patient results, the AMR does not need to be verified

CALIBRATION VERIFICATION FOR BLOOD GAS / ELECTROLYTE / METABOLITE CARTRIDGES

Purpose: Calibration verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure is not a manufacturer's system instruction. However, it is required by accreditation bodies such as CAP. While the Calibration Verification Set contains five levels, verification of the measurement range could be accomplished using the lowest, highest and mid levels.
Overview of Procedure APOC (Abbott Point of Care) recommends that each sensor type be included in the calibration verification procedure using a selection of analyzers that have passed the Electronic Simulator check. See the Technical Bulletin "Calibration Verfication and the i-STAT System" for more information.

Calibration Verification Solutions for G, Crea, EG7+, CG8+ and CHEM8+ Cartridges:

i-STAT TriControls Calibration Verification Set Levels 1-5 05P7-01

This five-level Calibration Verification Set is available to verify the calibration of i-STAT cartridges throughout the reportable ranges for:

Sodium	pH	Glucose
Potassium	PCO_2	BUN/Urea
Chloride	PO_2	Creatinine
Ionized Calcium	TCO_2	Hematocrit

There are four 1.7 mL glass ampules of each level in the set.

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels. Calibration Verification fluids may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F).
Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels. If stored refrigerated, the calibration verification material should be equilibrated to room temperature for at least four (4) hours prior to testing.

Ampule Use

When using cartridges that contain sensors for pH, PCO_2, PO_2 and ionized calcium, a separate ampule must be used for each cartridge being tested. If these sensors are not present, the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 10 minutes of opening the ampule.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

i-STAT CALIBRATION VERIFICATION SET

Before Use

i-STAT Calibration Verification solutions require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampule to room (ambient) temperature for 4 hours. If not, equilibrate the ampule to room (ambient) temperature for 30 minutes.

Procedure for Transferring Levels 1-5 to Cartridges

1. Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.

2. Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.

3.Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge. Note: Since aqueous based solutions such as controls lack

the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube
Plain capillary tubes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule.
Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule.
Once the the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe
Plain syringes (fresh 1 mL or 3 mL sterile syringe with 11/2 inch blunt 16 – 20 gauge needles) are recommended to transfer aqueous calibration verification solutions from the ampule to the cartridge. When using a syringe, slowly draw approximately 1 mL of solution from the bottom of the ampule.

4.. Immediately seal the cartridge – it is important not to expose the solution to room air since this will alter the results. (Follow procedure below for testing.)
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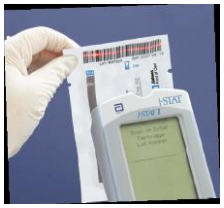
Procedure for Testing Levels 1-5 in Cartridges on Handheld Analyzer
Always remember to analyze the manufacturer's calibration verification standards in the Calibration Verification pathway under the Quality Tests option of the i-STAT Analyzer Administration Menu. Initiating Calibration Verification tests from the Quality Tests menu allows results to be stored in separate categories for the purpose of documentation and review.

- DO NOT insert cartridge to start test.
- Ensure calibration verification ampules, cartridges and handheld analyzers are at room temperature.
- Scan the cartridge barcode before opening cartridge pouch.
- Use a cartridge immediately after removing it from its protective pouch.
- Ensure that calibration verification testing is performed from the Quality Test Menu for the purpose of documentation and review.
- Measurement limits are not applied to results in the calibration verification test path. Results above and below the measurement ranges will be reported.

1. Press *ON* to turn on handheld.
2. Press *MENU*, *3* for *Quality Tests*, *3*, for *Cal Ver* Samples.
3. Follow handheld prompts.
4. Scan the lot number on the cartridge pouch.
    - Position barcode 3 - 9 inches from scanner window on the handheld.
    - Press and hold SCAN to activate the scanner.



    - Align the red laser light so it covers the entire barcode.
    - The handheld will beep when it reads the barcode successfully.

5. Continue normal procedures for preparing the sample, filling and sealing the cartridge.
6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.
Note: For Hct,testing, the handheld must remain on a level surface with the display facing up during testing. A level surface includes running the handheld in the downloader/recharger.
7. Review and record results.

Acceptable Criteria
Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT handhelds that have passed the Electronic Simulator test) are printed on a Value Assignment Sheet posted on the Abbott Point of Care website at www.pointofcare.abbott.

Calibration Verification Results
Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet. For hematocrit, the K2EDTA, not K3EDTA, acceptable ranges should be used.

TROUBLESHOOTING OUT-OF-RANGE CALIBRATION VERIFICATION RESULTS ON CARTRIDGES
Verify that the following conditions are met and then repeat the test:

- The correct expected values insert is being used and the correct cartridge type and lot number listing is being used.
- Expiration date printed on cartridge pouch and control ampule or vial have not been exceeded.
- Room temperature expiration date for cartridge and control have not been exceeded.
- Cartridge and control have been stored correctly.
- The control has been handled correctly.
- The analyzer being used passes the Electronic Simulator test.

If results are out of range despite meeting the above criteria, testing should be repeated by an experienced trained operator. If the problem persists, repeat the test using a new box of cartridges. If the problem persists, repeat the test using a new vial from a new Calibration Verification Set. If the problem persists, the manufacturer, Abbott Point of Care Technical Support, should be contacted for assistance. The Laboratory Director should be notified of any results that remain out of range. All corrective action should be documented.

Target values are specific to the i-STAT System. Results obtained when testing these aqueous controls with other methods may differ due to matrix effects.

AMR/Linearity Verification Results
When verifying the AMR, it is required that materials used are near the upper and lower limits of the AMR. Factors to consider in verifying the AMR are the expected analytic imprecision near the limits, the clinical impact of errors near the limits, and the availability of the test specimens near the limits. It may be difficult to obtain specimens with values near the limits for some analytes. In such cases, reasonable procedures should be adopted based on available specimen materials. The closeness of sample concentrations or activities to the upper and lower limits of the AMR are defined at the laboratory's director's discretion. The method manufacturer's instructions for verifying the AMR must be followed, when available. The laboratory director must define limits for accepting or rejecting verification tests of the AMR. For AMR verification, the comparability of the manufacturer's target values to BVHS data for each analyte is evaluated based on the acceptable difference defined by the manufacturer, Abbott, on the Value Assignment Sheet or 20%, whichever is greater.

Note: If the Calibration Verification Set is to be used to assess linearity, plot the BVHS analyte value against the mean value of the acceptable range. The concentrations of analytes in the Calibration Verification Set are not intended or prepared to be equally spaced. For hematocrit, the K2EDTA, not K3EDTA, mean values of the acceptable ranges should be used.

If results do not meet the acceptable difference, testing should be repeated by an experienced trained operator. If the problem persists, repeat the test using a new box of cartridges. If the problem persists, repeat the test using a new vial from a new Calibration Verification Set. If the problem persists, the manufacturer, Abbott Point of Care Technical Support, should be contacted for assistance. The Laboratory Director should be notified of any unresolved problem results. All corrective action should be documented.

Adjust the manufacturer's reportable range and/or BVHS reportable range for BVHS, if needed, according to the values obtained for the lowest and highest levels in the set, allowing for the BVHS acceptable difference between the current BVHS reportable range upper and lower limit numbers, and the test results obtained, 15% for the high end and 50% for the low end. The Laboratory Director at both Blanchard Valley Hospital and Bluffton Hospital will need to approve any change in the reportable range for an analyte. All corrective action should be documented.

AMR verification is not required for calculated test results as long as the Individual results contributing to the calculation have AMR verification.

Concerning TCO2, I-STAT CHEM8+ Level 1B material is available for purchase for customers who want to test lower levels of TCO2.

Concerning PO2, the upper limit of the reportable range for ***P***O2 is 800 mmHg. The highest ***P***O2 level in the i-STAT Calibration Verification set is just over 450 mmHg. Oxygen levels above 450 mmHg are so unstable in aqueous solutions that it would be impossible to make reliable measurements above 450 mmHg. Whole blood samples can be tonometered with 100% oxygen to create a sample around 700 mmHg at sea level.

Another alternative is to use CueSee Hyperbaric high pO2 control and CueSee Hypoxic low pO2 control to extend the reportable range. According to the manufacturer, Eurotrol, CueSee Hyperbaric is a high pO2 control that allows reporting of pO2 as high as 700-740 mmHg while CueSee Hypoxic is an extremely low pO2 control that allows reporting pO2 as low as 15 mmHg.

CueSee Hyperbaric

Storage and Stability
CueSee® Hyperbaric should be stored at a temperature of 2–30 °C (36–86 °F). Stored unopened at this temperature the product is stable as indicated until the expiration date on the ampules and the outer box. After opening an ampule of CueSee® Hyperbaric, the product is stable for 30 seconds.

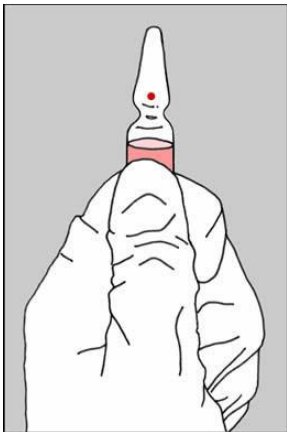
Procedure
1. Remove the ampule from box and tray. Equilibrate the ampule for a minimum of 1 hour to the room temperature where the testing will take place. Note the current room temperature.

2. Immediately before use, placing the ampule between the thumb and index finger, shake the ampule vigorously for at least fifteen seconds to re-equilibrate the gases with the solution.

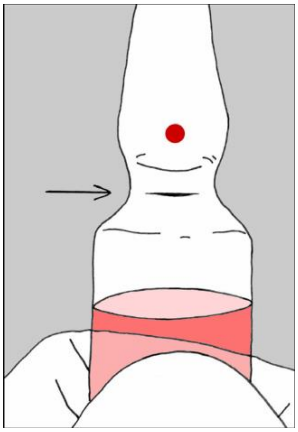
3. Swirl the ampule gently to return liquid to the bottom. Allow bubbles to rise to the surface before opening the ampule.

4. Protect fingers with gauze, tissue or gloves.

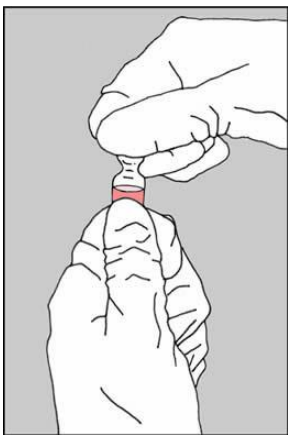
5. The One Point Cut (OPC) ampule must be opened as illustrated below.



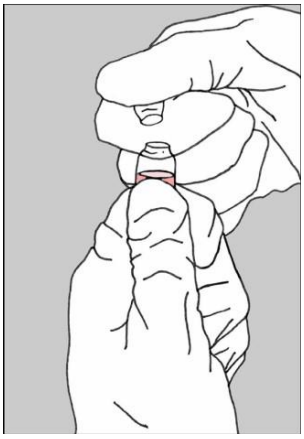
Hold the bottom of the ampule with thumb pointing to the red colored dot.



Cut located below the red dot is the breaking point of the ampule.



Grasp the top of the ampule with other hand, positioning thumb at the red dot.



Press back to break at the cut under the red dot.

6. Using techniques described in the instrument manufacturer's system manual, transfer the sample from the ampule to the cartridge within 30 seconds after opening of the ampule. Gently load the sample from the syringe to test cartridge following the sampling procedure of the instrument operating instructions. **Important: Use of the Quality Control or Calibration Verification Mode, depending on instrument manufacturer, may be needed to obtain high pO2 results.**

7. For i-STAT® instruments, read the pO2 target range from the Eurotrol Value Assignment Sheet according to the corresponding room temperature.

Expected values
The Eurotrol assigned values for the i-STAT® analyzer have been obtained after equilibration of randomly selected ampules from the applicable batch at 25 ± 1 °C before measurement and have been measured on multiple i-STAT® analyzers using multiple types of cartridges. The expected pO2 value for your applicable incubation temperature is shown in the value sheet which can be found on www.eurotrol.com/documents.

CuSee Hypoxic

Storage and Stability

CueSee® Hypoxic should be stored between 2-8 °C (35-46 °F) in the dark. Stored unopened at this temperature it is guaranteed stable until the expiration date as indicated on the outer box. After opening an ampule of CueSee® Hypoxic, it should be used within 10 minutes.

Procedure

1. Remove ampule from box. Equilibrate the ampule at room temperature for a minimum of 1 hour, but not more than 8 hours. Note: Do not put ampules back into refrigerator once exposed to room temperature.

2. Immediately before use, shake the ampule vigorously for at least fifteen seconds to re-equilibrate the gases with the solution.

3. Swirl the ampule gently to return liquid to bottom. Allow bubbles to rise to the surface before opening the ampule.

4. Protect fingers with an ampule snapper, gauze, tissue or gloves and carefully snap of the neck of the ampule following the illustration above (same as CueSee Hyperbaric).

5.The QC material should be analyzed within 10 minutes after opening the ampule. Follow the sampling procedure according to analyzer operating instructions.

Expected Values

Assigned values are established using the following measuring systems: Radiometer ABL835 FLEX blood gas analyzer, Abbott iSTAT® CG4+ system and epoc® Blood Analysis System. For this purpose, randomly selected ampules from the applicable batch of CueSee® Hypoxic have been equilibrated at 25 ± 1°C before measurement. Assigned values are available from http:/www.eurotrol.com/documents. Go to www.eurotrol.com to locate value sheet with acceptable result range corresponding to lot number and Abbott i-STAT SYSTEM CLEW.

Concerning hematocrit, calibration verification or a linearity check for hematocrit can also be performed by a manual method using blood collected in lithium heparin tubes and manipulated to create three levels of hematocrit. Target values for hematocrit for this manual method can be obtained from the bench top lab analyzer.

ALTERNATE VERIFICATION PROCEDURE FOR HEMATOCRIT

Preparation of Hematocrit Sample

1. Draw 4 lithium heparin green top tubes from a fasting person with abnormal hematocrit or MCHC. 7mL vacuum tubes are suggested. Label the tubes 1, 2, 3, and 4.
2. Centrifuge tubes 3 and 4 for 10 minutes at 3,000 rpm to pack the cells.
3. Remove two thirds the volume of whole blood from tube 1. This blood should be held in a clean plain tube in case it is needed to make adjustments later.
4. Transfer all of the plasma from tube 4 to tube 1.
5. Remove three fourths of the plasma from tube 3. This plasma should be held in a clean plain tube in case it is needed to make adjustments.
6. Gently invert tubes 1, 2 and 3 to resuspend the cells.

7. Measure the hematocrit of the blood in tubes 1, 2, and 3 using one cartridge for each tube. Adjust the hematocrit in tube 1 until it reads close to, but not less than, 15%. Adjust the hematocrit in tube 3 until it reads close to, but not more than, 75%.

Measurement
1. Gently invert tubes 1, 2, and 3 to resuspend the cells.
2. Measure the hematocrit of the blood in tubes 1, 2, and 3 three times each by the i-STAT and microcentrifuge methods.
3. Inspect the data for outliers. Repeat a measurement if necessary.
4. Calculate the mean of the three measurements of the three hematocrit levels for both methods.

Interpretation of Results
The i-STAT hematocrit method using blood anticoagulated with lithium heparin is calibrated to give results equivalent to the reference microhematocrit method using blood anticoagulated with K3EDTA. Since the blood used for the microhematocrit determination here is anticoagulated with lithium heparin, adjustment must be made to the observed i-STAT values to compensate for the anticoagulant difference.

1. To calculate the adjusted i-STAT hematocrit mean, multiply the mean of the observed i-STAT results by 1.0425.

2. The adjusted i-STAT hematocrit mean should be within ± 3% PCV of the microhematocrit mean.

For example: the microhematocrit method mean for the mid level sample is 36% PCV.
The i-STAT method mean is 34% PCV. 34 x 1.0425 = 35.445.
Acceptable range for the adjusted i-STAT mean: 33 - 39%PCV.

Note: If your analyzers are customized for K2EDTA/Heparin/None, the above calculation is unneccessary.

Notes on the Procedure
1. If a higher hematocrit value is needed in tube 1 or 3, packed cells can be obtained by centrifuging the whole blood retained from tube 1 in step 3. If a lower hematocrit value is needed, add plasma retained in step 5.
2. The highest hematocrit that should be tested on the i-STAT System is 75%. Whole blood samples with hematocrit values greater than 75% will be flagged as >75. The lowest hematocrit that should be tested on the i-STAT System is 15%. Whole blood samples with hematocrit values less than 15% will be flagged as <15.

Using Another Comparative Method
Methods other than the reference microhematocrit procedure may be used to verify calibration and reportable range of the i-STAT hematocrit. However, the following requirements apply:
• Blood should be drawn from a fasting donor with a normal hematocrit and a normal MCHC (calculated from hemoglobin and hematocrit values determined using reference methods) and be free of specific interferences which degrade the accuracy and/or precision of the alternative comparative method or the i-STAT method.
• Calculation of results must correct for any systematic bias between the reference microhematocrit method and the alternative comparative method selected.

Reference Method
CLSI recommends that the blood samples anticoagulated with Na2EDTA or K2EDTA be used for the microhematocrit method.* However, EDTA will interfere with the electrolyte measurements which are used in the calculation of hematocrit results on the i-STAT System.
* CLSI. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method;* Approved Standard–Third Edition. NCCLS document H7-A3 (ISBN 1-56238-413-9). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.

E. Biannual Procedure (Nonwaived Tests)

Patient Comparison

The BVHS Laboratory Point of Care Testing Coordinator and/or BVH Chemistry Coordinator and/or Bluffton i-STAT Coordinator will direct a patient result comparison study twice a year (spring & fall) to evaluate the comparability of patient nonwaived i-STAT results with results from other nonwaived instruments/methods accredited under a single CAP number. The comparability is evaluated based on the acceptable difference within CLIA limits (CAP Evaluation Criteria) and/or BVHS approved limits:

BUN +/- 2.0 mg/dL or 9%, whichever is greater

Calcium, Ionized +/- 0.24 mmol/L

Chloride +/- 5%

Creatinine +/- 0.3 mg/dL or 15%, whichever is greater

Glucose +/- 15 mg/dl or 20%, whichever is greater

Hematocrit +/- 6% or +/- 5.1, whichever is greater

Hemoglobin, Estimated +/- 7% or 1.7 g/dL whichever is greater

PCO2 +/- 5 mm Hg or 8%, whichever is greater

pH +/- 0.04

PO2 +/- 18 mmHg, or 15%, whichever is greater

Potassium +/- 0.5 mmol/L

Sodium +/- 4.0 mmol/L

Corrective action is taken when the criteria are not met. If results do not agree within the acceptable difference, testing should be repeated by an experienced trained operator. If the problem persists, repeat the test using a new box of cartridges. If results still do not agree within the acceptable difference, testing should be repeated with quality control materials for tests performed on the same instrument platform, with both control materials and reagents of the same manufacturer and lot number. If results still do not agree within the acceptable difference, the manufacturer, Abbott Point of Care Technical Support, should be contacted for assistance. The Laboratory Director should be notified of any unresolved test results that do not agree within the acceptable difference. All corrective action should be documented.

F. Three Times Per Year Procedure

Proficiency Testing

OVERVIEW
Proficiency, or external quality control, testing is the testing of unknown samples sent to a facility by an outside agency. After testing the unknown samples, the facility reports its results back to the agency. The agency grades the results and sends back scores that reflect how accurately the facility performed against its peers.

TESTING COMPLEXITY
• Moderate Complexity customers, refer to www.cms.gov for up-to-date information on CLIA Regulations Subpart H.
• Waived Complexity customers, refer to COLA at www.cola.org and/or CAP at www.cap.org for up-to-date guidelines.

NOTE: With the i-STAT 1 System, the FDA has categorized the tests included on the i-STAT G, and Crea cartridges as Waived when testing is performed using venous whole blood samples collected in lithium heparin evacuated tubes. Other venous whole blood samples, capillary, and/or arterial samples tested using these same cartridges on the i-STAT 1 System are categorized by the FDA as moderate complexity.

GENERAL PROCEDURE FOR TESTING
It is recommended that the Proficiency Test path be used on the i-STAT 1 analyzer when testing proficiency, or external quality control samples, especially those that include Hematocrit.

• The use of the Proficiency Test path will ensure that customization features enabled for patient testing are suspended. All analyzers will produce results using K3EDTA and CPB-Never for survey reporting purposes.

• The same CLEW is used for both the Patient and Proficiency Test path.

• If the Patient Sample Test path is used instead of the Proficiency Test path, do not select CPB, and if the analyzer is customized for K2EDTA, divide the Hematocrit results by 1.0425 before reporting.

Sample
Follow the agency's instructions for handling unknown samples.

Handling
Refer to the Quality Control section of the i-STAT 1 System Manual and follow the instructions for "Transfer with Capillary Tube" or "Transfer with Syringe" to ensure aqueous samples for blood gases and Ionized Calcium are not exposed to air.

Prerequisites
• Ensure that testing of unknown samples is performed from the Proficiency Test Menu for the purpose of documentation and review.
• Scan the cartridge barcode before opening the cartridge pouch.
• Ensure cartridges and handhelds are at the same room temperature.

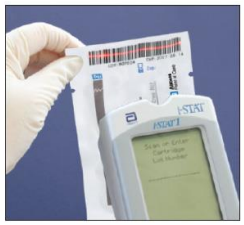
Procedure For Testing Proficiency Samples

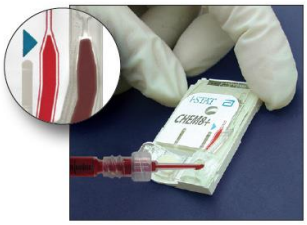
1. Press  to turn on handheld.

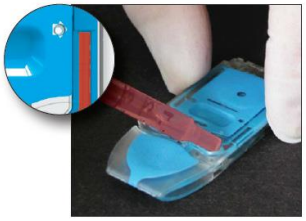
2.Press *MENU*, Press *3* for *Quality Tests*, Press *2* for *Proficiency* samples.

3.Follow handheld prompts. Be sure to scan or enter Proficiency Sample ID from official kit, if available.

4. Scan the lot number on the cartridge pouch.
    a. Position barcode 3–9 inches from scanner window on the handheld.
    b. Press and hold *SCAN* to activate the scanner.







    c. Align the red laser light so it covers the entire barcode.
    d. The handheld will beep when it reads the barcode successfully.

5. Continue normal procedures for filling and sealing the cartridge.
6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.

Note: For Hct, and immunoassay testing, the handheld must remain on a level surface with the display facing up during testing.

7. Review results.

REPORTING PROFICIENCY TEST RESULTS

It is important to record the cartridge type and lot numbers used to test samples. pH and ***P***CO2 results from EC8+ cartridge lots with prefix letters F, H, J and K will not agree with pH and ***P***CO2 results from other cartridges. When reporting results, select a separate peer group for these cartridge lot letters. For creatinine results, select IDMS-Traceable Calibration, if available. If not available, make your selection based upon the cartridge type and lot letter.

Ensure that the correct method and/or peer group are selected when reporting results.

To prevent transcription errors, review all selections and numeric entries.

• Ensure that testing of unknown samples is performed from the Proficiency Test Menu for the purpose of documentation and review.

• Scan the cartridge barcode before opening the cartridge pouch.

• Ensure cartridges and handhelds are at the same room temperature.

TROUBLESHOOTING AND PROFICIENCY TEST FAILURES

Samples

The i-STAT System is designed to measure fresh whole blood samples. Matrix effects and interfering substances can be expected when measuring non-whole blood samples. The following points should be considered when selecting and testing external quality control samples:

• Aqueous samples intended to assess blood gases will not be measured by the i-STAT System unless electrolytes, or at least sodium, are present.
• Fluorocarbon samples are not compatible.
• Preserved-cell samples are not compatible.
• Aged serum and lyophilized serum may contain degradation products or preservatives that interfere with the measurements.
• Matrix effects between aqueous-based and protein-based samples may cause results from the i-STAT System to differ from reference methods or other comparative methods.
• Aqueous samples that contain a resistive substance to allow assessment of conductometric hematocrit measurements will cause the i-STAT System to extrapolate ambient temperature results to 37 °C results for pH and ***P***CO2 as if the sample were whole blood. Since extrapolation coefficients for aqueous and whole blood samples differ, results on the i-STAT System for these samples may not agree with other methods.

While the various cartridges give the same results for whole blood samples, there may be substantial differences between types (e.g., 6+ vs CHEM8+) and generations (e.g., blue vs white) of cartridges for non-whole blood samples. Cartridge generations are identified by the prefix letter preceding the cartridge lot number. Abbott Point of Care will work with Proficiency testing providers to prevent i-STAT System users from being unfairly penalized for Proficiency testing failures that can be attributed to manufacturing changes. The CLEW software prevents manufacturing changes from affecting results when testing patient samples.

BVHS PROFICIENCY TEST PROVIDER

Select a Proficiency test for Hematocrit, which is formulated for a conductometric method. The BVHS Laboratories subscribe to CAP for i-STAT proficiency testing.

College of American Pathologists (CAP)

College of American
Pathologists (CAP)
325 Waukegan Road
Northfield, IL
60093-2750
800-323-4040 or
847-832-7000
www.cap.org

CAP AQIS (Critical Blood Gas, i-STAT) Surveys for blood gases, electrolytes and chemistries:
pH, ***P***CO2, ***P***O2, Cl, K, Na, iCa, Lactate, TCO2, Crea, Gluc, BUN, Urea, Hct, Hb

Both kits, SEQ#1 and SEQ#2 unknown samples are now indentical, as of January 2024.

G. Every June and December Procedure

Software Updates
The i-STAT System is designed to eliminate operator influence on delivered results. Due to continuous manufacturing process improvements to the i-STAT System, it is necessary to update standardization values from time to time to maintain long-term consistency of performance. These updates are equivalent to manually adjusting calibration on a traditional laboratory analyzer. New CLEW software -- delivered twice a year -- re-establishes these standardization values and incorporates refinements to the internal quality monitoring system. New JAMS application software allows the i-STAT Analyzer to recognize any newly launched cartridge types and to perform any newly launched features.

The BVHS Laboratory Point of Care Testing Coordinator and/or BVH Laboratory Administrative Director and/or Bluffton i-STAT Coordinator will direct software updates for the i-STAT Wireless handhelds before the deadlines set by Abbott, the manufacturer.

To access product software updates and related instructions, registration on the Abbott Point of Care website is required. Visit www.globalpointofcare.abbott to register and access content. Once logged in, select Support > i-STAT 1 and i-STAT Alinity Support > i-STAT 1 Resources login > Access Software (under i-STAT System Software Updates).

NETWORK OPTIONS FOR UPDATING THE i-STAT 1 ANALYER USING www.globalpointofcare.abbott

Preferred Method:

Using a Network Downloader, Downloader/Recharger, or DRC-300 and the JammLite process with TCP/IP

Alternate Method: (This is not recommended. It may require weekend work for network availability.)

Using the i-STAT/DE Customization Workspace and a Network Downloader, Downloader/ Recharger, or DRC-300

Before beginning, check the Analyzer Status page and verify that the i-STAT 1 handheld has enough battery power (7.5 volts or higher).

Preferred Method:

1. UPDATE PROCEDURE USING A NETWORK DOWNLOADER AND THE JammLite PROCESS WITH TCP/IP

1.1: Before starting the process, make sure all the required equipment / information is available.

- **Computer with:**
  - Windows 10 or 11
  - Access to www.globalpointofcare.abbott
- **i-STAT System Equipment**
  1. Network Downloader, Downloader / Recharger, or DRC-300
     - **Note: These instructions assume that the Network Downloader types used for the update process are already installed and in use on the customer's network.**
  2. i-STAT 1 Analyzer
  3. Electronic Simulator
- **List of the IP Address(es) for the network downloader(s) to be used for the software update process**

  BVHS IP ADDRESS LIST
  Special Care Nursery Downloader (Dock)
  DRC-92519 (Biomedical 06777)
  IP Address: 10.200.9.8

  Radiology/Imaging BVH Lab B Downloader (Dock) (preferred)
  DRC-100412 (Biomedical 07335)
  IP Address: 10.200.9.7

  Radiology/Imaging EWOC Downloader (Dock)
  DRC-10046 (Biomedical 07339)
  IP Address: 10.200.9.6

1.2: Close all open programs on the computer.

1.3: Navigate to www.globalpointofcare.abbott > Support > i-STAT 1 and i-STAT Alinity Support > i-STAT 1 Resources Login > Product Software > i-STAT System Software Updates > Access Software

1.4: Scroll to "Step 2: Download Software File".

Note: i-STAT/DE versions less than 2.8.0.1 are no longer supported. Use a Network Downloader, Downloader/Recharger, or DRC-300 and the JammLite process to perform the software update via its IP Address (TCP/IP) or Port (COM Port) for serially connected downloaders.

1.5: Navigate to saved zip file location. Right click on the zip file and select Extract All and Extract to the Desktop.

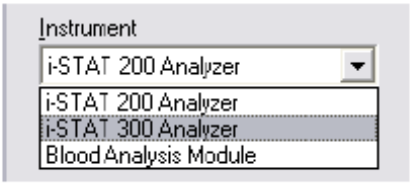
- Navigate to the Desktop and click on the folder SUXXXXXX to open.

1.6: Double click the software file "SUXXXXXX.exe" to run. If a Command window opens prompting to overwrite, answer "Y" and then press Enter. Continue answering "Y" to all prompts that appear until the Command window closes. From among the icons that appear, double click

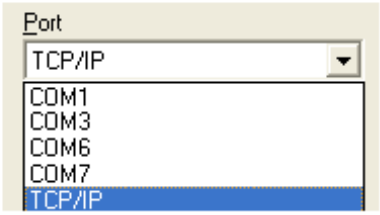

JAMMLITE.EXE to launch the JammLite Utility.

- If the JammLite program does not launch or you receive an error message, contact APOC Technical Support and tell the support specialist you are unable to launch the JammLite Utitlity.

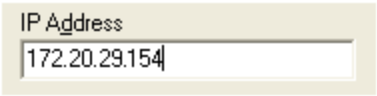
1.7: In the JammLite utility, select the **i-STAT 300 Analyzer** within the Instrument dropdown menu.



1.8: Select **TCP/IP** within the Port dropdown menu.



1.9: Type the IP Address of the Network Downloader being used for the software update in the **IP Address** box.

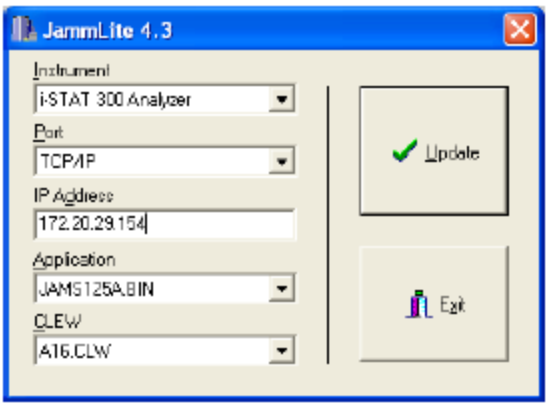


Note: the address used above is for example only.

Then connect one end of a cable to the i-STAT wall port and then the other end to the i-STAT downloader (dock).

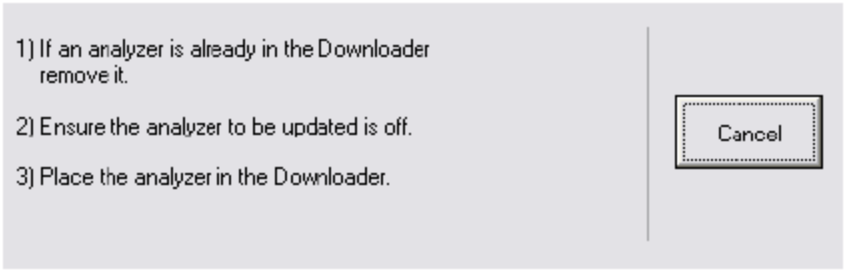
1.10: Check that the **Application** and **CLEW** listings match those in the Product Update.

Click the **Update** button.

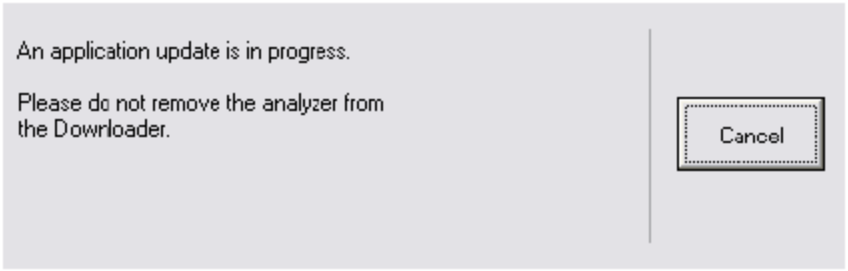


Note: Application and CLEW numbers are for example only.

1.11: Follow the onscreen instructions.

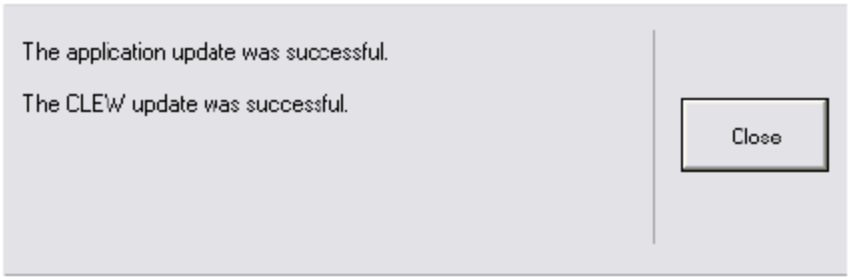


1.12: When the update is in progress, the following screen will appear:



The handheld will have 1's and 0's streaming across the screen signifying that it is receiving the software.

Do not move the handheld until the success screen is displayed.



1.13: Run the Electron Simulator in the analyzer. When the simulator finishes, PASS should be displayed.

Note: If PASS is not displayed, re-run the Electronic Simulator. If the repeated Electronic Simulator attempt fails, contact APOC Technical Support. For additional information on running the Electronic Simulator, see the i-STAT 1 System Manual.

Congratulations. **The process for updating the first i-STAT 1 Analyzer is complete.**

Review the options below for additional instructions.

If there are no additional analyzer to update, the process is complete.

- Click the X button in the upper right corner of the software screen.
- Close all other open boxes.
- Confirm all messages.

If there are additional analyzers to update via the same Network Downloader address:

- Click **Close**
- Repeat steps **1.10** through **1.13**

If there are additional analyzers to update via a different Network Downloader address:

- Click **Close**
- Repeat steps **1.9** through **1.13**

Alternate Method: (This is not recommended. It may require weekend work for network availability.)

UPDATING THE i-STAT 1 ANALYZER USING THE i-STAT/DE CUSTOMIZATION WORKSPACE AND A NETWORK DOWNLOADER, DOWNLOADER/ RECHARGER, or DRC-300

3.1: Before starting the process, make sure all the required equipment / information is available.

- Computer which can access the Customization Workspace
- Access to: www.globalpointofcare.abbott
- i-STAT System Equipment

  (1) i-STAT 1 Analyzer

  (2) Network Downloader, Downloader/Recharger, or DRC-300

  Note: These instructions assume that the Network Downloader types being used for the update process are already installed and in use on the customer's network.

  (3) Electronic Simulator

3.2: Update the CLEW and JAMS versions in the Customization Workspace.

a. Navigate to: www.globalpointofcare.abbott > Support > i-STAT 1 and i-STAT Afinity Support > i-STAT 1 Resources Login > Product Software > i-STAT System Software Updates > Access Software.

b. Scroll to "Step 2: Download Software Update File"

Note: i-STAT/DE versions less than 2.8.0.1 are no longer supported. Use a Network Downloader, Downloader/Recharger, or DRC-300 and the JammLite process to perform the software update via its IP Address (TCP/IP) or Port (COM Port) for serially connected downloaders.

c. Navigate to saved zip file location. Right click on the zip file and select Extract All and Extract to the Desktop.

d. Access the main Customization Workspace page.

e. Click **Update i-STAT/DE → Upload Update File**

f. Browse to Desktop, click on the SUXXXXXX folder to open. Select SUXXXXXX.exe and click upload.

(Note: the XXXXXX is the JAMS and CLEW version that you are updating.) Immediately after uploading the CLEW/JAMS to the i-STAT/DE server, i-STAT/DE will unpack the files and make them available for use in the analyzer's Customization Workspace.

3.3: Close Windows Explorer by clicking on the X in the upper right corner.

3.4: Access the Customization Workspace**.**

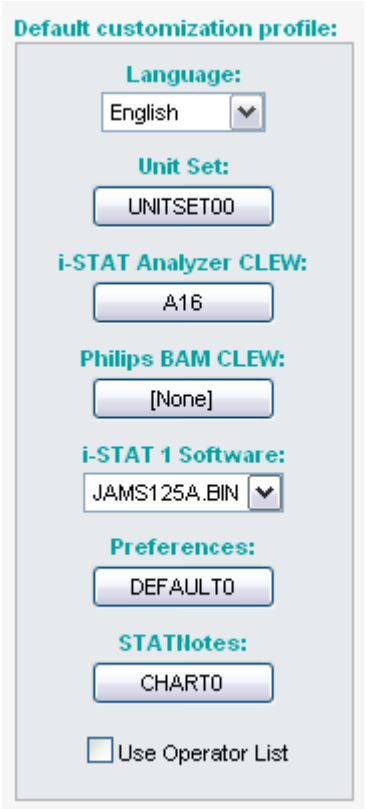
- RALS-Plus Users:
  - From the RALS-Plus Application, pick i-STAT from the drop-down menu.
  - Click on **Device Customization.**
- PrecisionWeb Users:

o Double click on the desktop shortcut or Internet Explorer Favorites for **i-STAT Customization**.

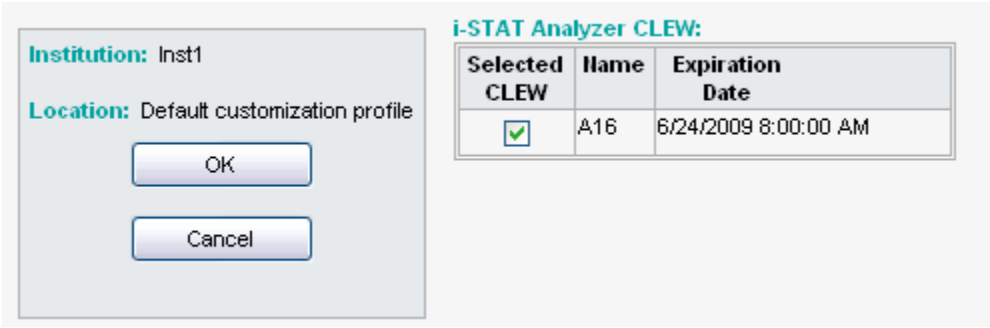
3.5: Update the CLEW and JAMS versions in the Customization Workspace.

- Under the "Default customization profile:" column, click on the "**i-STAT Analyzer CLEW**" button.

Note: Customization screens may vary depending upon i-STAT/DE version in use.

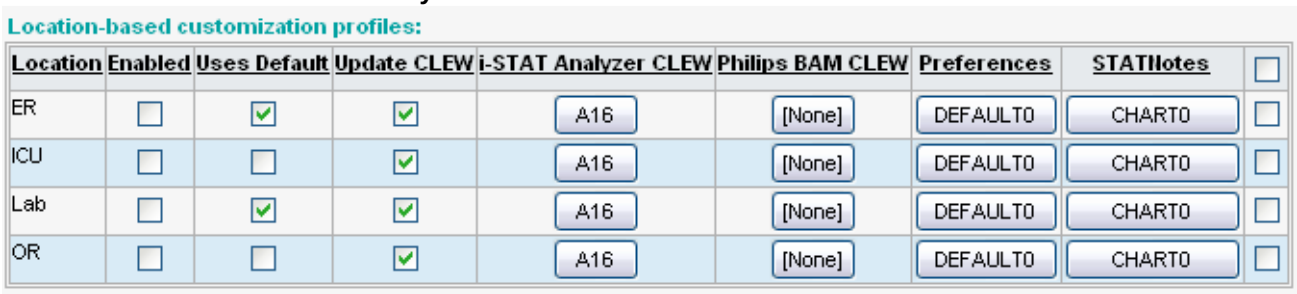


- Check the box next to the new version of **CLEW** and click **OK**.

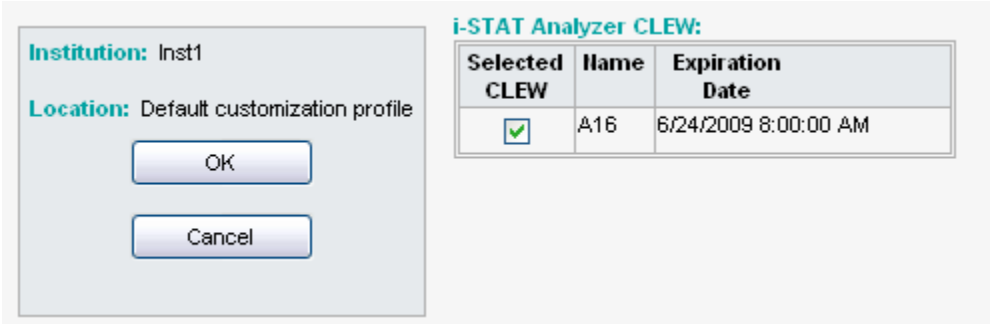


Answer **OK** to the question that appears.

- If “Uses Default” is not checked beside any Location-based customization profile, click the box under the “**i-STAT Analyzer CLEW**” column.

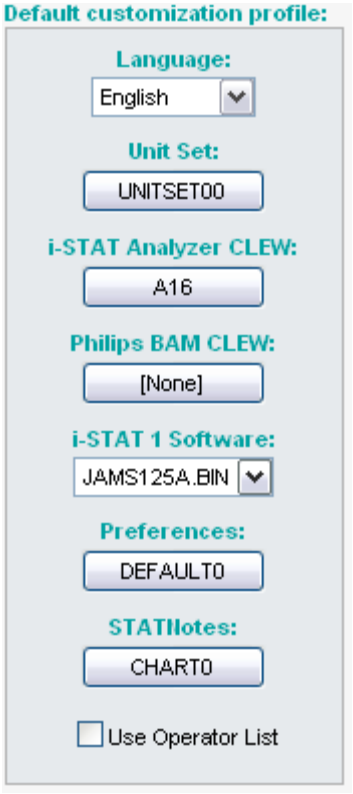


- Click the new version of **CLEW**, and then click **OK**.



Answer OK to the question that appears.

- Under the “Default Customization profile:” column, click on the **i-STAT 1 Software** drop-down list. Select the JAMS version that matches the Product Update and click **OK**.



3.6: Enable Customization.

- If the **Enable Customization** box is not already checked, click the box next to this listing.
- Under the "Location-based customization profile:" section, make sure **Enabled** is checked for every location from which you wish to perform software updates on your i-STAT 1 Analyzers.

3.7: Update the software in the i-STAT 1 Analyzer.

- Go to the location where the i-STAT 1 Analyzer(s) you wish to update are located or contact someone at that location who can assist in updating the analyzers(s).
- Press the **On/Off** button on the analyzer.
- Press the **Menu** key to bring up the Administration Menu.
- Press **7 – Utility**. When prompted for a password, press **ENT**. If that did not work, a password is needed. Enter the password defined by your facility and press **ENT**. Note: Abbott Point of Care Inc. recommends changing the default password.
- From the Utility menu, press **3 – Receive Software**. A "Waiting to Send" message will appear on the analyzer display.

- Place the analyzer in the downloader or downloader / recharger. **Do NOT move the analyzer until step 3.8.** A **Communication in Progress** message will appear on the screen. After this disappears, the analyzer display will stay blank for approximately 5-10 seconds.

- The analyzer will then display 1's and 0's streaming across the screen signifying that it is receiving the software. Once the 1's and 0's disappear, the analyzer display will again go blank for approximately 5-10 seconds.

- A **Waiting to Send** message following by a **Communication in Progress** message will then appear on the analyzer display. After these messages disappear, the analyzer display will go blank, and the update process is complete.

3.8: Run the external Electronic Simulator in the analyzer. When the simulator finishes, **PASS** should be displayed.

> **Note:** If **PASS** is not displayed, re-run the Electronic Simulator. If the repeated Electronic Simulator attempt fails, contact APOC (Abbott Point of Care) Technical Support. For additional information on running the Electronic Simulator, see the i-STAT 1 System Manual.

The process for updating the first i-STAT 1 analyzer is complete.

Review the options below for additional instructions.

- If there are no additional analyzers to update, the process is complete.

- If there are additional analyzers to update, return to step **3.7**

Using First i-STAT 1 Handheld Analyzer with Updated Software to Update More Handhelds:

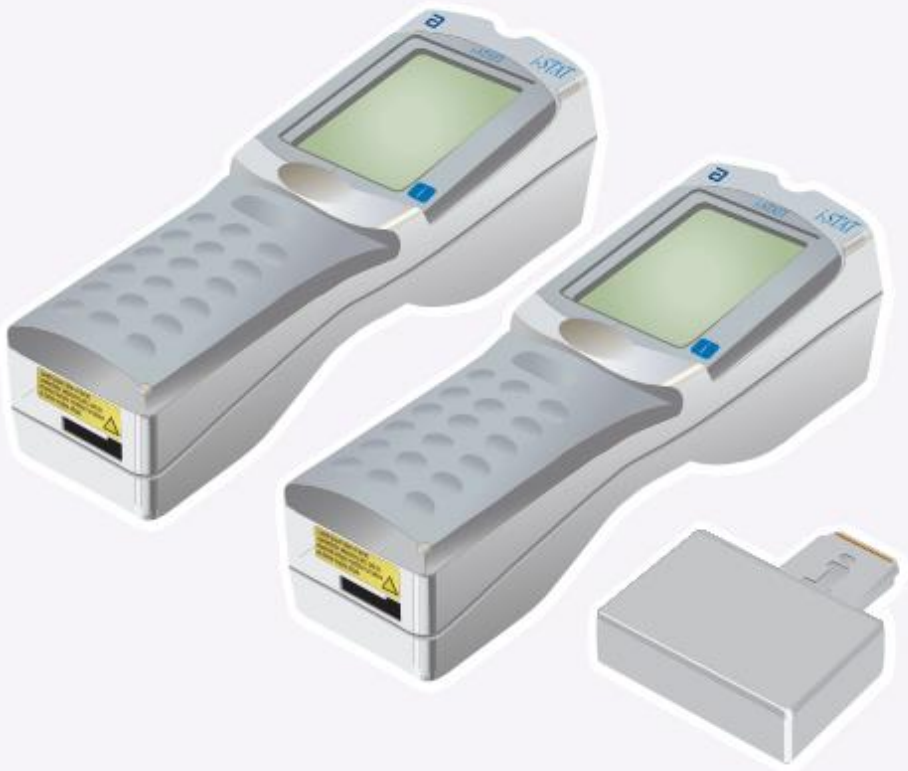
After updating the first i-STAT 1 Analyzer, follow these steps to update additional analyzers with the Analyzer-to-Analyzer Process:

Gathering All Equipment

Analyzer-to-Analyzer

2.1 Before starting the process make sure all the required equipment is available:

- Recently updated i-STAT 1 Analyzer (referred to in this section as the Sending Analyzer) charged to 7.5 volts or higher*
- The analyzer unit to be updated (referred to in this section as the Receiving Analyzer) charged to 7.5 volts or higher*
- Electronic Simulator

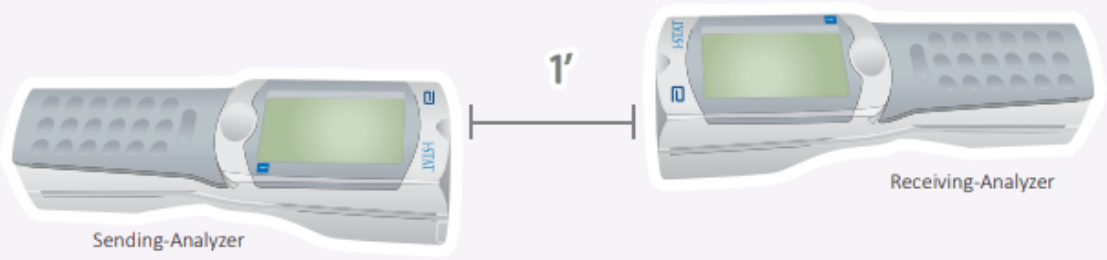


Connecting/Setting Up Equipment

Analyzer-to-Analyzer

2.2 Make sure the power is **off** on the Receiving Analyzer.

2.3 Place Sending and Receiving Analyzers on a flat surface with infrared (IR) windows aligned, approximately 1 foot apart.



2.4 Turn **on** the Sending Analyzer, press **MENU**, and select **7-Utility**.

2.5 When prompted for a password, press **ENT** and continue.

Note: Abbott Point of Care Inc. recommends changing the default password.

Updating your i-STAT 1 Analyzer

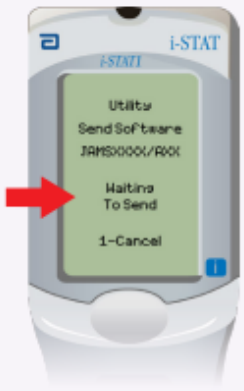
Analyzer-to-Analyzer

2.6 In the Utility Menu:

- Press **1-SEND SOFTWARE**
- Press **1-SEND**

Make sure the Receiving Analyzer's power is **off**.

2.7 When the Sending Analyzer displays **WAITING TO SEND**:



- Keep the infrared windows aligned
- Without lifting either analyzer off the flat surface move the Receiving Analyzer towards the Sending Analyzer until the Sending Analyzer displays **SENDING**.

Sending Analyzer

Receiving Analyzer

2.8 When the update is in progress, the Sending Analyzer will display **SENDING** along with a bar indicating that the software is being sent.

The Receiving Analyzer will have 1's and 0's streaming across the screen signifying that it is receiving the software.

Do not move the analyzers until the Sending Analyzer goes back to the Utility menu, and displays **Last Send Successful** The update is now complete.

Verfiying Software Update

Analyzer-to-Analyzer

2.9 **Run** the Electronic Simulator in the newly updated analyzer.

When the simulator finishes, PASS will be displayed..

If **PASS** is not displayed, re-run the Electronic Simulator.
If the repeated Electronic Simulator attempt fails, please contact APOC Technical Support.

For additional information on running the electronic simulator, please see:

- Section 14 of the i-STAT 1 System Manual, or
- The Introduction and Start-up section of the i-STAT System Manual for Waived Tests

Congratulations. The process for updating an additional i-STAT 1 Analyzer is complete.

If there are other i-STAT 1 Analyzers to update, repeat steps 2.2 through 2.9

If there are no other analyzers to update, the process is complete.

H. EVERY JUNE AND DECEMBER AND AS NEEDED

Electronic Value Assignment Sheets (eVAS)

Streamline and simplify the liquid quality control process by using the electronic Value Assignment Sheet (eVAS) for the *i-STAT System*. By downloading the eVAS file, your device can be automatically updated with the latest Value Assignment Sheet data. With this one download, you will have the most current information available for all of your test cartridges and handhelds. This is a required task every June and December after software updates are implemented.

eVAS DOWNLOAD INSTRUCTIONS

Choose the CLEW from the drop down menu.

Select the file for download. Save the file and **do not rename the file.**

Confirm "Save as type" is either:

- .VAS Document
- VAS File
- All Files

FOR DE CUSTOMERS:

- Save the file to any directory accessible to the i-STAT/DE. Click "Save".
- When download is complete, close the "Download Complete" window.
- Access the DE Customization workspace.
- To upload the eVAS file to i-STAT/DE, at the top of the Customization Workspace, click **Update i-STAT/DE** and select **Upload Update File**. When the "**Specify file for i-STAT/DE update**:" box opens, Click **Browse...**
- Navigate to the directory location of where the eVAS file was saved. Select the eVAS file and Click **Open**.
- Click **Upload**. If successful, a confirmation will appear that the file has been uploaded.

CLEW:

EVAS FILE FOR DOWNLOAD +

Are you seeing **Lot Not In eVAS** error on the i-STAT 1 analyzer when scanning your i-STAT 1 System cartridge or control fluid? The information

below can help you resolve the error.

Scenario 1

The *i-STAT 1* analyzer displays **Lot Not In eVAS** error when scanning an *i-STAT 1 System* cartridge or control fluid.

1. Check the eVAS file on the *i-STAT 1* analyzer to know if the current eVAS file is downloaded on it.

   On the analyzer keypad press the **Menu** key, under **Administration Menu -> 4-Customization –> 1-View –> 4-QC tests –> 2-Cartridge QC** –> press the right arrow key for next page to view the eVAS file.

   This eVAS file should match the current eVAS file on the Abbott Global Point of Care website.

   https://www.globalpointofcare.abbott/en/support/istat-brand/evas-i-stat.html

2. If the analyzer does not have the current eVAS file, compare the eVAS file in DE Customization Workspace to the current eVAS file on the Global Point of Care website.

3. If DE Customization Workspace does not have the current eVAS file, use the link provided above for instructions to upload current eVAS file.

4. Ensure customization is enabled in DE Customization Workspace.

5. To upload the current eVAS file from DE Customization Workspace, place/dock the analyzer in a downloader. The analyzer will communicate through the downloader's wired network connection or analyzer's wireless connection (if set up), to pick the latest eVAS file from the DE Customization Workspace.

6. Verify the eVAS file uploaded to the analyzer (see step 1 above).

Scenario 2

The analyzer has the current eVAS file, but **Lot Not In eVAS** error is still occurring.

1. Scan the product that corresponds to the prompt displayed on the analyzer. Do not scan the control barcode when prompted for the cartridge barcode and vice versa.
2. Scan the barcode on the appropriate control vial/ampule.
3. Next, scan the cartridge type that corresponds to the control product already scanned. For example: The **Lot Not In eVAS** error will occur if an *i-STAT cTnI* cartridge pouch barcode is scanned after scanning a *i-STAT TriControls* Control fluid ampule barcode. The *i-STAT cTnI* control vial barcode has to be scanned prior to scanning the *i-STAT cTnI* cartridge pouch barcode.

Scenario 3

This occurs during the JAMS/CLEW software update period. The analyzer has the eVAS file for the newest JAMS/CLEW software, however the analyzer has not yet been updated to the newest JAMS/CLEW software. The analyzer will show **Lot Not In eVAS** error when control product barcode is scanned.

- The DE Customization Workspace has been updated to the eVAS file that corresponds to the newest JAMS/CLEW software. **Note:** Once the eVAS file in DE Customization Workspace has been updated to a higher/newer version, this file cannot be switched back to an older eVAS file.

Resolution: In this scenario, the error occurs because the eVAS file version and the JAMS/CLEW software version in the analyzer are not compatible. Update the analyzer(s) to the new JAMS/CLEW and then test controls.

EXPECTED RESULTS:

Abbott Adult Reference Ranges, Reportable Ranges, and Test Unit Conversions

Reference range means the range of test values expected from 95% of fasting individuals presumed to be healthy. Reportable range means the range of test values throughout which the measurement system's results have been shown to be valid. The following table contains the manufacturer's Reference Ranges (for adults) and Reportable Ranges applicable to the i-STAT 1 System. Note that the manufacturer's table is all inclusive and may not reflect the actual patient testing done at BVHS.

ANALYTE	UNIT	REFERENCE RANGE (arterial) (venous)	REPORTABLE RANGE	UNIT CONVERSION
Sodium	mmol/L (mEq/L)	138 – 146 138 – 146	100 – 180	mmol/L x 1 = mEq/L Example: 140 mmol/L = 140 mEq/L

Potassium	mmol/L (mEq/L)	3.5 – 4.9	3.5 – 4.9	2.0 – 9.0	mmol/L x 1 = mEq/L
Chloride	mmol/L (mEq/L)	98 – 109	98 – 109	65 – 140	mmol/L x 1 = mEq/L
BUN	mg/dL	8 – 26	8 – 26	3 – 140	mg/dL BUN x 0.357 = mmol urea/L Example: 20 mg/dL BUN = 7.1 mmol urea/L
UREA	mmol/L	2.9 – 9.4	2.9 – 9.4	1 – 50	
Glucose	mg/dL	70 – 105	70 – 105	20 – 700	mg/dL x 0.055 = mmol/L Example: 100 mg/dL = 5.55 mmol/L
	g/L	0.70 – 1.05	0.70 – 1.05	0.20 – 7.00	g/L x 5.556 = mmol/L
	mmol/L	3.9 – 5.8	3.9 – 5.8	1.1 – 38.9	
Creatinine	mg/dL	0.6 – 1.3	0.6 – 1.3	0.2 – 20.0	mg/dL x 88.4 = µmol/L
	µmol/L	53 – 115	53 – 115	18 – 1768	
Ionized Calcium	mmol/L	1.12 – 1.32	1.12 – 1.32	0.25 – 2.50	mmol/L x 4 = mg/dL
	mg/dL	4.5 – 5.3	4.5 – 5.3	1.0 – 10.0	Example: 1.13 mmol/L x 4 = 4.52 mg/dL
pH		7.35 – 7.45	7.31 – 7.41	6.50 – 8.20	N/A
***P*CO$_2$**	mmHg	35 – 45	41 – 51	5 – 130	mmHg x 0.133 = kPa
	kPa	4.67 – 6.00	5.47 – 6.80	0.67 – 17.33	Example: 35 mmHg x 0.133 = 4.66 kPa
***P*O$_2$**	mmHg	80 – 105		5 – 800	mmHg x 0.133 = kPa
	kPa	10.7 – 14.0		0.7 – 106.6	Example: 83 mmHg x 0.133 = 11.04 kPa
TCO$_2$ (on the CHEM8+ cartridge only	mmol/L (mEq/L)	23 – 27	24 – 29	5 – 50	mmol/L x 1 = mEq/L

ANALYTE	UNIT	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)	REPORTABLE RANGE	UNIT CONVERSION
Hematocrit	% PCV	38 – 51	38 – 51	15 – 75	% PCV x 0.01 = Volume fraction
	Fraction	0.38 – 0.51	0.38 – 0.51	0.15 – 0.75	Example: 40% PCV = 0.40 PCV

Lactate	mmol/L mg/dL	0.36 –1.25 3.2 – 11.3	0.90 – 1.70 8.1–15.3	0.30 – 20.00 2.7 – 180.2	mmol/L x 9.01 = mg/dL
HCO_3*	mmol/L (mEq/L)	22 – 26	23 - 28	1.0 – 85.0	mmol/L x 1 = mEq/L
TCO_2* (on all cartridges but CHEM8+)	mmol/L (mEq/L)	23 – 27	24 – 29	5 – 50	mmol/L x 1= mEq/L
BE*	mmol/L (mEq/L)	(-2) – (+3)	(-2) – (+3)	(-30) – (+30)	
Anion Gap*	mmol/L (mEq/L)	10 – 20	10 – 20	(-10) – (+99)	
sO_2*	%	95 – 98		0 - 100	% x 0.01 = fraction saturated
Hb*	g/dL g/L mmol/L	12 – 17 120 – 170 7 – 11	12 – 17 120 – 170 7 – 11	5.1 – 25.5 51 – 255 3.2 – 15.8	g/dL x 10 = g/L
Celite ACT	sec	74 – 125 (PREWARM) 84 – 139 (NONWARM)	74 – 125 (PREWARM) 84 – 139 (NONWARM)	50 – 1000	
Kaolin ACT	sec	74 – 137 (PREWARM) 82 – 152 (NONWARM)	74 – 137 (PREWARM) 82 – 152 (NONWARM)	50 – 1000	
Prothrombin Time/PT	INR			0.9 – 8.0#	
Troponin I/cTnI	ng/mL (µg/L)		0.00 – 0.03** 0.00 – 0.08***	0.00 – 50.00##	ng/mL x 1 = µg/L
Creatine Kinase MB/CK-MB	ng/mL (µg/L)		0.0 – 3-5****	0.0 – 150.0	ng/mL x 1 = µg/L
B-Type Natriuretic Peptide/BNP	pg/mL (ng/L)		<15-50****	15 – 5000	pg/mL x 1 = ng/L
Total β-hCG	IU/L		<5.0	5.0 – 2000.0	

*Calculated values.

#Performance characteristics have not been established for INRs above 6.0.

**Represents the 0–97.5% range of results. Each facility should establish its own reference range using the i-STAT cTnI assay.

##Performance characteristics have not been established for cTnI values above 35.00 ng/mL.

***Represents the 0–99% range of results. Each facility should establish its own reference range using the i-STAT cTnI assay.

****Represents the 0–95% range of results. Each facility should establish its own reference range using the i-STAT assay

Abbott Critical Results

Critical results are test results that fall outside high and low critical limits that define the boundaries of life-threatening values for a test. Critical results represent an emergency condition and must be reported immediately to the patient's attending physician or nurse. Note that the manufacturer's table is all inclusive and may not reflect the actual patient testing done at BVHS.

ANALYTE (units)	ADULT		CHILDREN		NEONATES	
	low	high	low	high	low	high
Sodium (mmol/L)	120	158	121	156	121	156
Potassium (mmol/L)	2.8	6.2	2.8	6.4	2.8	6.5
Chloride (mmol/L)	75	126	77	121	77	121
TCO_2 (mmol/L)	11	40	11	39	–	–
Ionized Calcium (mmol/L)	0.78	1.58	0.74	1.57	–	–
pH	7.21	7.59	7.21	7.59	–	–
$\boldsymbol{P}CO_2$ (mmHg)	19	67	21	66	–	–
$\boldsymbol{P}O_2$ (mmHg)	43	–	45	124	37	92
BUN (mg/dL)	–	104	–	55	–	55
Glucose (mg/dL)	46	484	46	445	32	328
Creatinine	–	7.4	–	3.8	–	–
Lactate						
Hematocrit (% PCV)	18	61	20	62	33	71
Celite ACT						
Kaolin ACT						
PT/INR						
Troponin I/cTnI						
Creatine Kinase MB/ CK-MB						
B-Type Natriuretic Peptide/ BNP						
Total β-hCG						

BVHS Established Reference Ranges, Critical Values, and Reportable Ranges for i-STATs, including pediatric too:

BVHS Established Ranges:										
Assay Display	Age From	Age To	Sex	Units of Measure	Reference Low	Reference High	Critical Low	Critical High	Linear Low	Linear High
POC Anion Gap iStat Arterial	0 Minutes	150 Years	All	mmol/L	10	20			-10	99
POC Anion Gap iStat Venous	0 Minutes	150 Years	All	mmol/L	10	20			-10	99
POC BE iStat Arterial	0 Minutes	150 Years	All	mmol/L	-2	3			-30	30
POC BE iStat Capillary	0 Minutes	150 Years	All	mmol/L	-2	3			-30	30
POC BE iStat Cord Arterial	0 Minutes	150 Years	All	mmol/L	-2	3			-30	30
POC BE iStat Cord Venous	0 Minutes	150 Years	All	mmol/L	-2	3			-30	30
POC BE iStat Venous	0 Minutes	150 Years	All	mmol/L	-2	3			-30	30
POC BUN iStat Arterial	0 Minutes	150 Years	All	mg/dL	8	26			3	140
POC BUN iStat Venous	0 Minutes	150 Years	All	mg/dL	8	26			3	140
POC Chloride iStat Arterial	0 Minutes	150 Years	All	mmol/L	98	109			65	140
POC Chloride iStat Venous	0 Minutes	150 Years	All	mmol/L	98	109			65	140
POC Crea iStat Arterial	0 Minutes	150 Years	All	mg/dL	0.6	1.3		10	0.2	19
POC Crea iStat Venous	0 Minutes	150 Years	All	mg/dL	0.6	1.3		10	0.2	19
POC Glucose iStat Arterial	0 Minutes	4 Hours	All	mg/dL	41	60	25	250	25	600
POC Glucose iStat Arterial	4 Hours	1 Days	All	mg/dL	46	60	35	250	25	600
POC Glucose iStat Arterial	1 Days	2 Months	All	mg/dL	51	90	45	250	25	600
POC Glucose iStat Arterial	2 Months	16 Years	All	mg/dL	60	99	54	400	25	600
POC Glucose iStat Arterial	16 Years	150 Years	All	mg/dL	70	99	54	400	25	600
POC Glucose iStat Capillary	0 Minutes	4 Hours	All	mg/dL	41	60	25	250	25	600
POC Glucose iStat Capillary	4 Hours	1 Days	All	mg/dL	46	60	35	250	25	600
POC Glucose iStat Capillary	1 Days	2 Months	All	mg/dL	51	90	45	250	25	600
POC Glucose iStat Capillary	2 Months	16 Years	All	mg/dL	60	99	54	400	25	600
POC Glucose iStat Capillary	16 Years	150 Years	All	mg/dL	70	99	54	400	25	600
POC Glucose iStat Venous	0 Minutes	4 Hours	All	mg/dL	41	60	25	250	25	600
POC Glucose iStat Venous	4 Hours	1 Days	All	mg/dL	46	60	35	250	25	600
POC Glucose iStat Venous	1 Days	2 Months	All	mg/dL	51	90	45	250	25	600
POC Glucose iStat Venous	2 Months	16 Years	All	mg/dL	60	99	54	400	25	600
POC Glucose iStat Venous	16 Years	150 Years	All	mg/dL	70	99	54	400	25	600
POC HCO3 iStat Arterial	0 Minutes	150 Years	All	mmol/L	22	36			1	85

POC HCO3 iStat Capillary	0 Minutes	150 Years	All	mmol/L	22	36			1	85
POC HCO3 iStat Cord Arterial	0 Minutes	150 Years	All	mmol/L	22	36			1	85
POC HCO3 iStat Cord Venous	0 Minutes	150 Years	All	mmol/L	23	28			1	85
POC HCO3 iStat Venous	0 Minutes	150 Years	All	mmol/L	23	28			1	85
POC Hematocrit iStat Arterial	0 Minutes	3 Days	Male	%	45	67			15	75
POC Hematocrit iStat Arterial	3 Days	7 Days	Male	%	42	66			15	75
POC Hematocrit iStat Arterial	7 Days	14 Days	Male	%	39	63			15	75
POC Hematocrit iStat Arterial	14 Days	1 Months	Male	%	31	55			15	75
POC Hematocrit iStat Arterial	1 Months	2 Months	Male	%	28	42			15	75
POC Hematocrit iStat Arterial	2 Months	6 Months	Male	%	29	41			15	75
POC Hematocrit iStat Arterial	6 Months	2 Years	Male	%	33	39			15	75
POC Hematocrit iStat Arterial	2 Years	6 Years	Male	%	34	40			15	75
POC Hematocrit iStat Arterial	6 Years	12 Years	Male	%	35	45			15	75
POC Hematocrit iStat Arterial	12 Years	18 Years	Male	%	37	49			15	75
POC Hematocrit iStat Arterial	18 Years	150 Years	Male	%	41	53			15	75
POC Hematocrit iStat Arterial	0 Minutes	3 Days	Female	%	45	67			15	75
POC Hematocrit iStat Arterial	3 Days	7 Days	Female	%	42	66			15	75
POC Hematocrit iStat Arterial	7 Days	14 Days	Female	%	39	63			15	75
POC Hematocrit iStat Arterial	14 Days	1 Months	Female	%	31	55			15	75
POC Hematocrit iStat Arterial	1 Months	2 Months	Female	%	28	42			15	75
POC Hematocrit iStat Arterial	2 Months	6 Months	Female	%	29	41			15	75
POC Hematocrit iStat Arterial	6 Months	2 Years	Female	%	33	39			15	75
POC Hematocrit iStat Arterial	2 Years	6 Years	Female	%	34	40			15	75
POC Hematocrit iStat Arterial	6 Years	12 Years	Female	%	35	45			15	75
POC Hematocrit iStat Arterial	12 Years	18 Years	Female	%	36	48			15	75
POC Hematocrit iStat Arterial	18 Years	150 Years	Female	%	36	46			15	75
POC Hematocrit iStat Arterial	0 Minutes	150 Years	Unknown	%	28	67			15	75
POC Hematocrit iStat Capillary	0 Minutes	3 Days	Female	%	45	67			15	75
POC Hematocrit iStat Capillary	3 Days	7 Days	Female	%	42	66			15	75
POC Hematocrit iStat Capillary	7 Days	14 Days	Female	%	39	63			15	75
POC Hematocrit iStat Capillary	14 Days	1 Months	Female	%	31	55			15	75
POC Hematocrit iStat Capillary	1 Months	2 Months	Female	%	28	42			15	75
POC Hematocrit iStat Capillary	2 Months	6 Months	Female	%	29	41			15	75
POC Hematocrit iStat Capillary	6 Months	2 Years	Female	%	33	39			15	75
POC Hematocrit iStat Capillary	2 Years	6 Years	Female	%	34	40			15	75
POC Hematocrit iStat Capillary	6 Years	12 Years	Female	%	35	45			15	75
POC Hematocrit iStat Capillary	12 Years	18 Years	Female	%	36	48			15	75
POC Hematocrit iStat Capillary	18 Years	150 Years	Female	%	36	46			15	75
POC Hematocrit iStat Capillary	0 Minutes	3 Days	Male	%	45	67			15	75

POC Hematocrit iStat Capillary	3 Days	7 Days	Male	%	42	66			15	75
POC Hematocrit iStat Capillary	7 Days	14 Days	Male	%	39	63			15	75
POC Hematocrit iStat Capillary	14 Days	1 Months	Male	%	31	55			15	75
POC Hematocrit iStat Capillary	1 Months	2 Months	Male	%	28	42			15	75
POC Hematocrit iStat Capillary	2 Months	6 Months	Male	%	29	41			15	75
POC Hematocrit iStat Capillary	6 Months	2 Years	Male	%	33	39			15	75
POC Hematocrit iStat Capillary	2 Years	6 Years	Male	%	34	40			15	75
POC Hematocrit iStat Capillary	6 Years	12 Years	Male	%	35	45			15	75
POC Hematocrit iStat Capillary	12 Years	18 Years	Male	%	37	49			15	75
POC Hematocrit iStat Capillary	18 Years	150 Years	Male	%	41	53			15	75
POC Hematocrit iStat Capillary	0 Minutes	150 Years	Unknown	%	28	67			15	75
POC Hematocrit iStat Venous	0 Minutes	3 Days	Female	%	45	67			15	75
POC Hematocrit iStat Venous	3 Days	7 Days	Female	%	42	66			15	75
POC Hematocrit iStat Venous	7 Days	14 Days	Female	%	39	63			15	75
POC Hematocrit iStat Venous	14 Days	1 Months	Female	%	31	55			15	75
POC Hematocrit iStat Venous	1 Months	2 Months	Female	%	28	42			15	75
POC Hematocrit iStat Venous	2 Months	6 Months	Female	%	29	41			15	75
POC Hematocrit iStat Venous	6 Months	2 Years	Female	%	33	39			15	75
POC Hematocrit iStat Venous	2 Years	6 Years	Female	%	34	40			15	75
POC Hematocrit iStat Venous	6 Years	12 Years	Female	%	35	45			15	75
POC Hematocrit iStat Venous	12 Years	18 Years	Female	%	36	48			15	75
POC Hematocrit iStat Venous	18 Years	150 Years	Female	%	36	46			15	75
POC Hematocrit iStat Venous	0 Minutes	3 Days	Male	%	45	67			15	75
POC Hematocrit iStat Venous	3 Days	7 Days	Male	%	42	66			15	75
POC Hematocrit iStat Venous	7 Days	14 Days	Male	%	39	63			15	75
POC Hematocrit iStat Venous	14 Days	1 Months	Male	%	31	55			15	75
POC Hematocrit iStat Venous	1 Months	2 Months	Male	%	28	42			15	75
POC Hematocrit iStat Venous	2 Months	6 Months	Male	%	29	41			15	75
POC Hematocrit iStat Venous	6 Months	2 Years	Male	%	33	39			15	75
POC Hematocrit iStat Venous	2 Years	6 Years	Male	%	34	40			15	75
POC Hematocrit iStat Venous	6 Years	12 Years	Male	%	35	45			15	75
POC Hematocrit iStat Venous	12 Years	18 Years	Male	%	37	49			15	75
POC Hematocrit iStat Venous	18 Years	150 Years	Male	%	41	53			15	75
POC Hematocrit iStat Venous	0 Minutes	150 Years	Unknown	%	28	67			15	75
POC Hemoglobin iStat Arterial	0 Minutes	3 Days	Female	g/dL	14.5	22.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Arterial	3 Days	7 Days	Female	g/dL	13.5	21.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Arterial	7 Days	14 Days	Female	g/dL	12.5	20.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Arterial	14 Days	1 Months	Female	g/dL	10	18	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Arterial	1 Months	2 Months	Female	g/dL	9	14	6.9	20.8	5.1	25.5

POC Hemoglobin iStat Arterial	2 Months	6 Months	Female	g/dL	9.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Arterial	6 Months	2 Years	Female	g/dL	10.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Arterial	2 Years	6 Years	Female	g/dL	11.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Arterial	6 Years	12 Years	Female	g/dL	11.5	15.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Arterial	12 Years	18 Years	Female	g/dL	12	16	6.6	19.9	5.1	25.5
POC Hemoglobin iStat Arterial	18 Years	150 Years	Female	g/dL	12	16	6.6	19.9	5.1	25.5
POC Hemoglobin iStat Arterial	0 Minutes	3 Days	Male	g/dL	14.5	22.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Arterial	3 Days	7 Days	Male	g/dL	13.5	21.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Arterial	7 Days	14 Days	Male	g/dL	12.5	20.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Arterial	14 Days	1 Months	Male	g/dL	10	18	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Arterial	1 Months	2 Months	Male	g/dL	9	14	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Arterial	2 Months	6 Months	Male	g/dL	9.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Arterial	6 Months	2 Years	Male	g/dL	10.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Arterial	2 Years	6 Years	Male	g/dL	11.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Arterial	6 Years	12 Years	Male	g/dL	11.5	15.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Arterial	12 Years	18 Years	Male	g/dL	13	15	6.6	19.9	5.1	25.5
POC Hemoglobin iStat Arterial	18 Years	150 Years	Male	g/dL	13.5	17.5	6.6	19.9	5.1	25.5
POC Hemoglobin iStat Arterial	0 Years	150 Years	Unknown	g/dL	9	22.5	9.5	19.9	5.1	25.5
POC Hemoglobin iStat Capillary	0 Minutes	3 Days	Female	g/dL	14.5	22.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Capillary	3 Days	7 Days	Female	g/dL	13.5	21.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Capillary	7 Days	14 Days	Female	g/dL	12.5	20.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Capillary	14 Days	1 Months	Female	g/dL	10	18	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Capillary	1 Months	2 Months	Female	g/dL	9	14	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Capillary	2 Months	6 Months	Female	g/dL	9.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Capillary	6 Months	2 Years	Female	g/dL	10.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Capillary	2 Years	6 Years	Female	g/dL	11.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Capillary	6 Years	12 Years	Female	g/dL	11.5	15.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Capillary	12 Years	18 Years	Female	g/dL	12	16	6.6	19.9	5.1	25.5
POC Hemoglobin iStat Capillary	18 Years	150 Years	Female	g/dL	12	16	6.6	19.9	5.1	25.5
POC Hemoglobin iStat Capillary	0 Minutes	3 Days	Male	g/dL	14.5	22.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Capillary	3 Days	7 Days	Male	g/dL	13.5	21.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Capillary	7 Days	14 Days	Male	g/dL	12.5	20.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Capillary	14 Days	1 Months	Male	g/dL	10	18	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Capillary	1 Months	2 Months	Male	g/dL	9	14	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Capillary	2 Months	6 Months	Male	g/dL	9.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Capillary	6 Months	2 Years	Male	g/dL	10.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Capillary	2 Years	6 Years	Male	g/dL	11.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Capillary	6 Years	12 Years	Male	g/dL	11.5	15.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Capillary	12 Years	18 Years	Male	g/dL	13	15	6.6	19.9	5.1	25.5

POC Hemoglobin iStat Capillary	18 Years	150 Years	Male	g/dL	13.5	17.5	6.6	19.9	5.1	25.5
POC Hemoglobin iStat Capillary	0 Minutes	150 Years	Unknown	g/dL	9	22.5	9.5	19.9	5.1	25.5
POC Hemoglobin iStat Venous	0 Minutes	3 Days	Female	g/dL	14.5	22.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Venous	3 Days	7 Days	Female	g/dL	13.5	21.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Venous	7 Days	14 Days	Female	g/dL	12.5	20.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Venous	14 Days	1 Months	Female	g/dL	10	18	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Venous	1 Months	2 Months	Female	g/dL	9	14	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Venous	2 Months	6 Months	Female	g/dL	9.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Venous	6 Months	2 Years	Female	g/dL	10.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Venous	2 Years	6 Years	Female	g/dL	11.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Venous	6 Years	12 Years	Female	g/dL	11.5	15.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Venous	12 Years	18 Years	Female	g/dL	12	16	6.6	19.9	5.1	25.5
POC Hemoglobin iStat Venous	18 Years	150 Years	Female	g/dL	12	16	6.6	19.9	5.1	25.5
POC Hemoglobin iStat Venous	0 Minutes	3 Days	Male	g/dL	14.5	22.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Venous	3 Days	7 Days	Male	g/dL	13.5	21.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Venous	7 Days	14 Days	Male	g/dL	12.5	20.5	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Venous	14 Days	1 Months	Male	g/dL	10	18	9.5	22.5	5.1	25.5
POC Hemoglobin iStat Venous	1 Months	2 Months	Male	g/dL	9	14	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Venous	2 Months	6 Months	Male	g/dL	9.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Venous	6 Months	2 Years	Male	g/dL	10.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Venous	2 Years	6 Years	Male	g/dL	11.5	13.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Venous	6 Years	12 Years	Male	g/dL	11.5	15.5	6.9	20.8	5.1	25.5
POC Hemoglobin iStat Venous	12 Years	18 Years	Male	g/dL	13	15	6.6	19.9	5.1	25.5
POC Hemoglobin iStat Venous	18 Years	150 Years	Male	g/dL	13.5	17.5	6.6	19.9	5.1	25.5
POC Hemoglobin iStat Venous	0 Minutes	150 Years	Unknown	g/dL	9	22.5	9.5	19.9	5.1	25.5
POC Ionized Ca iStat Arterial	0 Minutes	6 Days	All	mmol/L	1.16	1.46			0.25	2.5
POC Ionized Ca iStat Arterial	6 Days	150 Years	All	mmol/L	1.22	1.35			0.25	2.5
POC Ionized Ca iStat Capillary	0 Minutes	6 Days	All	mmol/L	1.16	1.46			0.25	2.5
POC Ionized Ca iStat Capillary	6 Days	150 Years	All	mmol/L	1.22	1.35			0.25	2.5
POC Ionized Ca iStat Venous	0 Minutes	6 Days	All	mmol/L	1.16	1.46			0.25	2.5
POC Ionized Ca iStat Venous	6 Days	150 Years	All	mmol/L	1.22	1.35			0.25	2.5
POC pCO2 iStat Arterial	0 Minutes	2 Months	Female	mmHg	27	40			15	95
POC pCO2 iStat Arterial	2 Months	2 Years	Female	mmHg	26	41			15	95
POC pCO2 iStat Arterial	2 Years	150 Years	Female	mmHg	33	43			15	95
POC pCO2 iStat Arterial	0 Minutes	2 Months	Male	mmHg	27	40			15	95
POC pCO2 iStat Arterial	2 Months	2 Years	Male	mmHg	26	41			15	95
POC pCO2 iStat Arterial	2 Years	150 Years	Male	mmHg	36	46			15	95
POC pCO2 iStat Arterial	0 Minutes	150 Years	Unknown	mmHg	26	46			15	95
POC pCO2 iStat Capillary	0 Minutes	2 Months	Female	mmHg	27	40			15	95

POC pCO2 iStat Capillary	2 Months	2 Years	Female	mmHg	26	41			15	95
POC pCO2 iStat Capillary	2 Years	150 Years	Female	mmHg	33	43			15	95
POC pCO2 iStat Capillary	0 Minutes	2 Months	Male	mmHg	27	40			15	95
POC pCO2 iStat Capillary	2 Months	2 Years	Male	mmHg	26	41			15	95
POC pCO2 iStat Capillary	2 Years	150 Years	Male	mmHg	36	46			15	95
POC pCO2 iStat Capillary	0 Minutes	150 Years	Unknown	mmHg	26	46			15	95
POC pCO2 iStat Cord Arterial	0 Minutes	2 Months	Female	mmHg	27	40			15	95
POC pCO2 iStat Cord Arterial	2 Months	2 Years	Female	mmHg	26	41			15	95
POC pCO2 iStat Cord Arterial	2 Years	150 Years	Female	mmHg	33	43			15	95
POC pCO2 iStat Cord Arterial	0 Minutes	2 Months	Male	mmHg	27	40			15	95
POC pCO2 iStat Cord Arterial	2 Months	2 Years	Male	mmHg	26	41			15	95
POC pCO2 iStat Cord Arterial	2 Years	150 Years	Male	mmHg	36	46			15	95
POC pCO2 iStat Cord Arterial	0 Minutes	150 Years	Unknown	mmHg	26	46			15	95
POC pCO2 iStat Cord Venous	0 Minutes	150 Years	All	mmHg	40	50			15	95
POC pCO2 iStat Venous	0 Minutes	150 Years	All	mmHg	40	50			15	95
POC pH iStat Arterial	0 Minutes	1 Months	All		7.33	7.49			6.5	8.2
POC pH iStat Arterial	1 Months	2 Months	All		7.33	7.49	7.21	7.59	6.5	8.2
POC pH iStat Arterial	2 Months	2 Years	All		7.34	7.46	7.21	7.59	6.5	8.2
POC pH iStat Arterial	2 Years	150 Years	All		7.35	7.45	7.21	7.59	6.5	8.2
POC pH iStat Capillary	0 Minutes	1 Months	All		7.33	7.49			6.5	8.2
POC pH iStat Capillary	1 Months	2 Months	All		7.33	7.49	7.21	7.59	6.5	8.2
POC pH iStat Capillary	2 Months	2 Years	All		7.34	7.46	7.21	7.59	6.5	8.2
POC pH iStat Capillary	2 Years	150 Years	All		7.35	7.45	7.21	7.59	6.5	8.2
POC pH iStat Cord Arterial	0 Minutes	1 Months	All		7.33	7.49			6.5	8.2
POC pH iStat Cord Arterial	1 Months	2 Months	All		7.33	7.49	7.21	7.59	6.5	8.2
POC pH iStat Cord Arterial	2 Months	2 Years	All		7.34	7.46	7.21	7.59	6.5	8.2
POC pH iStat Cord Arterial	2 Years	150 Years	All		7.35	7.45	7.21	7.59	6.5	8.2
POC pH iStat Cord Venous	0 Minutes	1 Months	All		7.32	7.42			6.5	8.2
POC pH iStat Cord Venous	1 Months	150 Years	All		7.32	7.42	7.21	7.59	6.5	8.2
POC pH iStat Venous	0 Minutes	1 Months	All		7.33	7.42			6.5	8.2
POC pH iStat Venous	1 Months	150 Years	All		7.33	7.42	7.21	7.59	6.5	8.2
POC pO2 iStat Arterial	0 Minutes	2 Months	All	mmHg	60	76			15	600
POC pO2 iStat Arterial	2 Months	150 Years	All	mmHg	80	105			15	600
POC pO2 iStat Capillary	0 Minutes	2 Months	All	mmHg	60	76			15	600
POC pO2 iStat Capillary	2 Months	150 Years	All	mmHg	80	105			15	600
POC pO2 iStat Cord Arterial	0 Minutes	2 Months	All	mmHg	60	76			15	600
POC pO2 iStat Cord Arterial	2 Months	150 Years	All	mmHg	80	105			15	600
POC pO2 iStat Cord Venous	0 Minutes	150 Years	All	mmHg	25	47			15	600
POC pO2 iStat Venous	0 Minutes	150 Years	All	mmHg	25	47			15	600

POC Potassium iStat Arterial	0 Minutes	14 Days	All	mmol/L	4.5	6.8	2.5	6.5	2	8.5
POC Potassium iStat Arterial	14 Days	3 Months	All	mmol/L	4	6.4	2.5	6.5	2	8.5
POC Potassium iStat Arterial	3 Months	1 Years	All	mmol/L	4	5.9	2.5	6.5	2	8.5
POC Potassium iStat Arterial	1 Years	16 Years	All	mmol/L	3.7	5.6	2.5	6.0	2	8.5
POC Potassium iStat Arterial	16 Years	150 Years	All	mmol/L	3.7	5.3	2.5	6.0	2	8.5
POC Potassium iStat Capillary	0 Minutes	14 Days	All	mmol/L	4.5	6.8	2.5	6.5	2	8.5
POC Potassium iStat Capillary	14 Days	3 Months	All	mmol/L	4	6.4	2.5	6.5	2	8.5
POC Potassium iStat Capillary	3 Months	1 Years	All	mmol/L	4	5.9	2.5	6.5	2	8.5
POC Potassium iStat Capillary	1 Years	16 Years	All	mmol/L	3.7	5.6	2.5	6.0	2	8.5
POC Potassium iStat Capillary	16 Years	150 Years	All	mmol/L	3.7	5.3	2.5	6.0	2	8.5
POC Potassium iStat Venous	0 Minutes	14 Days	All	mmol/L	4.5	6.8	2.5	6.5	2	8.5
POC Potassium iStat Venous	14 Days	3 Months	All	mmol/L	4	6.4	2.5	6.5	2	8.5
POC Potassium iStat Venous	3 Months	1 Years	All	mmol/L	4	5.9	2.5	6.5	2	8.5
POC Potassium iStat Venous	1 Years	16 Years	All	mmol/L	3.7	5.6	2.5	6.0	2	8.5
POC Potassium iStat Venous	16 Years	150 Years	All	mmol/L	3.7	5.3	2.5	6.0	2	8.5
POC sO2 iStat Arterial	0 Minutes	150 Years	All	%	94	100			0	100
POC sO2 iStat Capillary	0 Minutes	150 Years	All	%	94	100			0	100
POC sO2 iStat Cord Arterial	0 Minutes	150 Years	All	%	94	100			0	100
POC sO2 iStat Cord Venous	0 Minutes	150 Years	All	%	60	85			0	100
POC sO2 iStat Venous	0 Minutes	150 Years	All	%	60	85			0	100
POC Sodium iStat Arterial	0 Minutes	2 Months	All	mmol/L	132	142	120	160	100	180
POC Sodium iStat Arterial	2 Months	150 Years	All	mmol/L	135	145	120	160	100	180
POC Sodium iStat Capillary	0 Minutes	2 Months	All	mmol/L	132	142	120	160	100	180
POC Sodium iStat Capillary	2 Months	150 Years	All	mmol/L	135	145	120	160	100	180
POC Sodium iStat Venous	0 Minutes	2 Months	All	mmol/L	132	142	120	160	100	180
POC Sodium iStat Venous	2 Months	150 Years	All	mmol/L	135	145	120	160	100	180
POC tCO2 iStat Arterial	0 Minutes	2 Months	Female	mmol/L	17	24	10	40	5	50
POC tCO2 iStat Arterial	2 Months	2 Years	Female	mmol/L	16	24	10	40	5	50
POC tCO2 iStat Arterial	2 Years	150 Years	Female	mmol/L	19	29	10	40	5	50
POC tCO2 iStat Arterial	0 Minutes	2 Months	Male	mmol/L	17	24	10	40	5	50
POC tCO2 iStat Arterial	2 Months	2 Years	Male	mmol/L	16	24	10	40	5	50
POC tCO2 iStat Arterial	2 Years	150 Years	Male	mmol/L	19	29	10	40	5	50
POC tCO2 iStat Arterial	0 Minutes	150 Years	Unknow n	mmol/L	16	29	10	40	5	50
POC tCO2 iStat Capillary	0 Minutes	2 Months	Female	mmol/L	17	24	10	40	5	50
POC tCO2 iStat Capillary	2 Months	2 Years	Female	mmol/L	16	24	10	40	5	50
POC tCO2 iStat Capillary	2 Years	150 Years	Female	mmol/L	19	29	10	40	5	50
POC tCO2 iStat Capillary	0 Minutes	2 Months	Male	mmol/L	17	24	10	40	5	50
POC tCO2 iStat Capillary	2 Months	2 Years	Male	mmol/L	16	24	10	40	5	50
POC tCO2 iStat Capillary	2 Years	150 Years	Male	mmol/L	19	29	10	40	5	50

POC tCO2 iStat Capillary	0 Minutes	150 Years	Unknown	mmol/L	16	29	10	40	5	50
POC tCO2 iStat Cord Arterial	0 Minutes	2 Months	Female	mmol/L	17	24			5	50
POC tCO2 iStat Cord Arterial	2 Months	2 Years	Female	mmol/L	16	24			5	50
POC tCO2 iStat Cord Arterial	2 Years	150 Years	Female	mmol/L	19	29			5	50
POC tCO2 iStat Cord Arterial	0 Minutes	2 Months	Male	mmol/L	17	24			5	50
POC tCO2 iStat Cord Arterial	2 Months	2 Years	Male	mmol/L	16	24			5	50
POC tCO2 iStat Cord Arterial	2 Years	150 Years	Male	mmol/L	19	29			5	50
POC tCO2 iStat Cord Arterial	0 Minutes	150 Years	Unknown	mmol/L	16	29			5	50
POC tCO2 iStat Cord Venous	0 Minutes	18 Years	All	mmol/L	18	27			5	50
POC tCO2 iStat Cord Venous	18 Years	150 Years	All	mmol/L	24	35			5	50
POC tCO2 iStat Venous	0 Minutes	18 Years	All	mmol/L	18	27	10	40	5	50
POC tCO2 iStat Venous	18 Years	150 Years	All	mmol/L	24	35	10	40	5	50

PROCEDURAL NOTES:

A. BACKUP FOR INOPERABLE SYSTEM: Should the i-STAT 1 System become inoperable for any reason, specimens should be collected and submitted to the Laboratory and/or Respiratory.

B. REFERRAL OF SPECIMENS: Not needed.

C. SUBMISSION/HANDLING OF REFERRAL SPECIMENS: Not needed.

LIMITATIONS AND INTERFERING SUBSTANCES:

An interferent is a substance which, if present at significant levels in the blood specimen being analyzed, will produce an error in the result of the analyte being measured. Note that the manufacturer's table is all inclusive and may not reflect the actual patient testing done at BVHS.

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Sodium	Bromide	37.5 mmol/L	Use Another Method.
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Increase (↑) Na
Potassium	Bromide	37.5 mmol/L	Use Another Method.
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease (↓) K
Chloride	Acetylcysteine	10.2 mmol/L	Increase (↑) Cl
	Bromide	37.5 mmol/L	Use Another Method.
	Bromide (therapeutic)	2.5 mmol/L	Increase (↑) Cl

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
	Iodide	2.99 mmol/L	Increase (↑) Cl
	Salicylate	4.34 mmol/L	Increase (↑) Cl
	Thiocyanate	6.9 mmol/L	Increase (↑) Cl
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Increase (↑) Cl
Ionized Calcium	Acetominophen	1.32 mmol/L	Decrease (↓) iCa
	Magnesium	1.0 mmol/L	Increase (↑) iCa by up to 0.04 mmol/L
	Acetylcysteine	10.2 mmol/L	Decrease (↓) iCa
	Bromide	37.5 mmol/L	Use Another Method.
	Lactate	6.6 mmol/L	Decrease (↓) iCa by up to 0.07 mmol/L
	Salicylate (therapeutic)	0.5 mmol/L	Decrease (↓) iCa by up to 0.03 mmol/L
	Salicylate	4.34 mmol/L	Decrease (↓) iCa
	Leflunomide	0.03 mmol/L	Decrease (↓) iCa
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease (↓) iCa
	Thiocyanate	6.9 mmol/L	Decrease (↓) iCa Use Another Method.
Glucose	Acetominophen	1.32 mmol/L	Increase (↑) glucose
	Acetylcysteine	10.2 mmol/L	Decrease (↓) glucose
	Bromide	37.5 mmol/L	Use Another Method.
	Bromide (therapeutic)	2.5 mmol/L	Decrease (↓) glucose

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Glucose (cont.)	pH	pH: per 0.1 pH units below 7.4 @ 37 °C	Decrease (↓) glucose by 0.9 mg/dL (0.05 mmol/L)
		pH: per 0.1 pH units above 7.4 @ 37 °C	Increase (↑) glucose by 0.8 mg/dL (0.04 mmol/L)
	Oxygen	***P*O₂** less than 20 mmHg @ 37 °C	May decrease (↓) glucose
	Hydroxyurea	0.92 mmol/L	Increase (↑) glucose Use Another Method.
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease (↓) glucose
	Thiocyanate	6.9 mmol/L	Decrease (↓) glucose
Lactate	Bromide	37.5 mmol/L	Use Another Method.
	Hydroxyurea	0.92 mmol/L	Increase (↑) lactate Use Another Method.
	Glycolic Acid	10.0 mmol/L	Increase (↑) lactate Use Another Method.
BUN/Urea	Bromide	37.5 mmol/L	Use Another Method.
	Hydroxyurea	0.92 mmol/L	Increase (↑) BUN/Urea results
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Decrease (↓) BUN/Urea results
Creatinine	Acetaminophen	1.32 mmol/L	Increase (↑) creatinine
	Ascorbate	0.34 mmol/L	Increase (↑) creatinine by up to 0.3 mg/dL
	Bromide (therapeutic)	2.5 mmol/L	Increase (↑) creatinine
	Hydroxyurea	0.92 mmol/L	Increase (↑) creatinine Use Another Method
	Acetylcysteine	10.2 mmol/L	Increase (↑) creatinine
	Creatine	0.382 mmol/L	Increase (↑) creatinine by up to 0.3 mg/dL
	Glycolic Acid	10.0 mmol/L	Decrease (↓) creatinine Use Another Method
	Nithiodote (sodium thiosulfate)	16.7 mmol/L	Increase (↑) creatinine
>2.0 mg/dL	***P*CO₂**	$Crea_{corr} = Crea * (1+0.0025 * (PCO_2 - 40))$	

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Hematocrit	White Blood Count (WBC)	Greater than 50,000 WBC/µL	May Increase (↑) hematocrit
	Total Protein	<u>For measured Hct<40%</u> For each g/dL below 6.5 For each g/dL above 8.0	 Decrease (↓) Hct by 1% PCV Increase (↑) Hct by 1% PCV
		<u>For measured Hct≥40%</u> For each g/dL below 6.5 For each g/dL above 8.0	Decrease (↓) Hct by 0.75% PCV Increase (↑) Hct by 0.75% PCV
	Lipids	Abnormally high	Increase (↑) Hct
	Bromide	37.5 mmol/L	Increased rate of star (***) outs
Celite ACT	Aprotinin		Falsely extends Celite ACT times
Kaolin ACT	Aprotinin (therapeutic)	200−280 KIU/mL	The i-STAT ^{Kaolin}ACT test is not significantly prolonged in the presence of a therapeutic level (200−280 KIU/mL) of aprotinin (Trasylol). If a patient has been administered the maximum aprotinin dosage of 400 KIU/ mL, APOC recommends that the first blood sample post administration be taken after 15 min to ensure the full distribution of the drug and to achieve a therapeutic plasma concentration.
***P*CO$_2$**	Propofol (Diprovan®) Thiopental Sodium		For patients administered propofol or thiopental sodium, APOC recommends the use of G3+, CG4+, CG8+, EG6+, and EG7+ cartridges, which are free from clinically significant interference at all relevant therapeutic doses. APOC does not recommend the use of EC8+ cartridges for patients receiving propofol or thiopental sodium.
PT/INR	Cubicin® (daptomycin for injection) Chlorhexidine Gluconate		Falsely extends prothrombin time (PT) and INR May falsely extend prothrombin time (PT) and INR

i-STAT 1 Sample Type Customization

The following describes the functionality of the i-STAT 1 Sample Type Customization feature.

With the release of CLEWA40/JAMS149A software, the Sample Type Customization feature of the i-STAT 1 analyzer provides the ability to choose between two options for the sample-type selection list displayed during a patient test.

Option 1, Cart Based: the analyzer will display only those sample types for the cartridge scanned. Information on i-STAT Cartridges may be found in the *Instructions for Use* (IFU), located at www.globalpointofcare.abbott.

Option 2, Custom: the analyzer will display the sample-type selection list provided by i-STAT/DE or CDS, or the following analyzer default selection list if none is provided: ART, VEN, MXVN, CAP, CORD, OTHR.

Minimum Analyzer Software Requirements

i-STAT Analyzer Software	Version
Application Software	JAMS149A

Perform the following steps on the analyzer keypad to verify the version of the application software:

1. Press **I** to turn on the analyzer.
2. Press **MENU** to go to the Administration Menu.
3. Press **1** to access the Analyzer Status screen.
4. **Version:** will display the application software

(JAMS) in the analyzer.

Details regarding other items within the Analyzer Status screen may be found in the *i-STAT 1 System Manual, i-STAT 1 Analyzer*.

Follow the instructions in “Abbott Technical Bulletin: Sample Type Customization on the i-STAT Analyzer” to set the sample type choice to appear on the analyzer before the cartridge test is run.

***SAMPLE TYPE CUSTOMIZATION FOR NEW** AND **REPLACEMENT** ANALYZERS*

Prior to placing the analyzers into use, ensure preferred customization of the sample-type selection list.

TROUBLESHOOTING

Problem	Resolution
The analyzer does not display the preferred sample-type selection list during patient test.	The analyzer may not have been customized for the preferred cartridge sample-type selection list. Customize the analyzer for a Cart Based or Custom sample-type selection list according to “Customization Using the Analyzer Keypad”. If using i-STAT/DE or CDS, place the analyzer in the downloader; this action will apply the preferred customization preference to the analyzer.

Problem	Resolution
The analyzer does not display (during patient test) the sample-type selection list provided by i-STAT/DE or CDS.	The analyzer may not have been customized for the preferred cartridge sample-type selection list. Customize the analyzer for a Custom sample-type selection list according to “Customization Using the Analyzer Keypad”. Verify that customization is enabled for the analyzer location within i-STAT/DE or CDS and place the analyzer in the downloader; this action will upload the customization.and apply the preferred customization preference to the analyzer.

Resolution

METHOD VALIDATION:

A. VERIFICATION OF ADDITIONAL NEW OR REPLACEMENT HANDHELDS

Repaired and newly purchased analyzers are received with factory calibration. The Electronic Simulator can better assure that the analyzer’s most important function is within factory specifications than calibration verification or control solutions.

Testing calibration verification samples or comparing patient sample results on a new or repaired analyzer with an older analyzer will assess cartridge performance only. Any variations in analyzer performance will not be statistically discernable above the performance of the cartridges. When multiple analyzers are to be used at a facility, Abbott Point of Care Inc. recommends including at least two analyzers in any performance verification studies so that statistics reflect the “system.”

Each new or replacement handheld must be verified before being put into use for nonwaived testing. The following minimum data be collected:

External Electronic Simulator
Run the external Electronic Simulator and record passing result.

Thermal Probe Check
Check the thermal probes on the i-STAT 1 Analyzer. Document acceptable result.

Reportable Range
Test the lowest level, the mid level and the highest level of calibration verification samples available for each test that will be performed on a new or replacement handheld. Results must be within the acceptable range(s) on the Value Assignment Sheet(s). Store the Value Assignment Sheet(s) with the data as evidence that results were within acceptable limits. The closeness of sample concentrations or activities to the upper and lower limits of the AMR are defined at the laboratory's director's discretion. For AMR verification, the comparability of the manufacturer's target values to BVHS data for each analyte is evaluated based on the acceptable difference defined by the manufacturer, Abbott, on the Value Assignment Sheet or 20%, whichever is greater.

Adjust the manufacturer's reportable range and/or BVHS reportable range for BVHS, if needed, according to the values obtained for the lowest and highest levels in the set, allowing for the BVHS acceptable difference between the current BVHS reportable range upper and lower limit numbers, and the test results obtained, 15% for the high end and 50% for the low end. The Laboratory Director at both Blanchard Valley Hospital and Bluffton Hospital will need to approve any change in the reportable range for an analyte. All corrective action should be documented.

Accuracy
Use the data from the above *Reportable Range* study to assess accuracy. In addition, test one or more patient samples on the new or replacement handheld and a comparative method or a previously verified handheld. Record results. The difference(s) between the new or replacement handheld and the comparative method or previously verified handheld should not exceed the laboratory's required level of agreement between systems. This could be the agreement required for the initial method comparison or the agreement required for the CLIA-required twice yearly Comparison of Test Results.

Precision
Test two levels of the appropriate controls in duplicate on each of two days on each new or replacement handheld. Each analyte that will be measured using a new or replacement handheld must be included in the *Precision* study. This study can be combined with the validation of IQCP. Record results.

Precision Study Results:
The additive used in the aqueous-based TriControls to simulate the effect of hematocrit in blood samples results in reduced precision in repeat measurement of electrolytes relative to the precision obtained when assaying with either standard control/calibration verification materials or whole blood. The imprecision is related to the concentration of additive. The increase is pronounced at higher levels of indicated hematocrit. Internal testing of non-Abbott aqueous control materials on the i-STAT System which have hematocrit, blood gas and chemistry functionalities exhibit similar precision to that observed for TriControls.
The acceptance limits which have been established for these control solutions are wider than analogous limits established for the current i-STAT control and calibration verification solutions, reflecting the precision effect highlighted above.

The situation where better precision will be obtained in clinical samples than in control solutions is not unusual. A similar effect is observed in control solutions for the i−STAT measurement of PO_2.
The precision data shown below, including results for TriControls solutions, were collected during studies at an Abbott Point of Care facility. SD and %CV are typical of performance; current Value Assignment

Sheets should be referenced for applicable mean data. Refer to the value assignment sheets posted on the APOC website at www.globalpointofcare.abbott.

Analyte	Level 1 Mean	SD	%CV	Level 3 Mean	SD	%CV
Na (mmol/L)	120	0.46	0.4%	158	1.39	0.9%
K (mmol/L)	2.85	0.038	1.3%	6.15	0.058	0.9%
Cl (mmol/L)	72.9	0.63	0.9%	113.6	2.30	2.0%
Glu (mg/dL)	289	2.4	0.8%	41.8	0.68	1.6%
Urea (mg/dL)	69.7	0.94	1.3%	5.5	0.45	8.2%
iCa (mmol/L)	0.84	0.012	1.4%	1.51	0.030	2.0%
Crea (mg/dL)	4.16	0.123	3.0%	0.50	0.046	9.1%
PCO_2 (mmHg)	63.8	1.57	2.5%	19.6	0.40	2.0%
PO_2 (mmHg)	65.1	3.12	4.8%	146.5	6.00	4.1%
pH	7.165	0.005	0.07%	7.674	0.003	0.04%
Hct (%)	17.6	0.40	2.3%	57.1	1.00	1.75%
TCO_2 (mmHg)	17.4	0.62	3.6%	30.4	0.70	2.3%

Before patient testing, new handheld information must be entered in the device column of TELCOR QML. The device processing rule should be set to “Enter”.

Prior to going live, the device should be purged of all results:
Administration Menu
7 Utility
2 Clear Memory
IT staff member may need to redirect the downloader to DE.
Dock meter again to connect to DE.
Run a simulator and dock to verify connectivity to Production QML.

B. VERIFICATION OF ADDITIONAL TEST ANALYTES

Each new test analyte on a cartridge must be verified before being put into use. The following minimum data be collected:

External Electronic Simulator

Run the external Electronic Simulator and record passing result.

Thermal Probe Check
Check the thermal probes on the i-STAT 1 Analyzer. Document acceptable result.

Reportable Range
Test the lowest level, the mid level and the highest level of calibration verification samples available for each new test analyte that will be performed on a handheld. Results must be within the acceptable range(s) on the Value Assignment Sheet(s). Store the Value Assignment Sheet(s) with the data as evidence that results were within acceptable limits. . The closeness of sample concentrations or activities to the upper and lower limits of the AMR are defined at the laboratory's director's discretion. For AMR verification, the comparability of the manufacturer's target values to BVHS data for each analyte is evaluated based on the acceptable difference defined by the manufacturer, Abbott, on the Value Assignment Sheet or 20%, whichever is greater.

Adjust the manufacturer's reportable range and/or BVHS reportable range for BVHS, if needed, according to the values obtained for the lowest and highest levels in the set, allowing for the BVHS acceptable difference between the current BVHS reportable range upper and lower limit numbers, and the test results obtained, 15% for the high end and 50% for the low end. The Laboratory Director at both Blanchard Valley Hospital and Bluffton Hospital will need to approve any change in the reportable range for an analyte. All corrective action should be documented.

Accuracy
Use the data from the above *Reportable Range* study to assess accuracy. In addition, test thirty or more patient samples in duplicate on two handhelds, as required by the manufacturer, and a comparative method (reference analyzer). Duplicate testing is recommended for accuracy verification to differentiate between an outlier and an interfering substance. Record results. The difference(s) between the new test analyte results on the handheld and the comparative method or previously verified test analyte cartridge should not exceed the laboratory's required level of agreement between systems. This could be the agreement required for the initial method comparison or the agreement required for the CLIA-required twice yearly Comparison of Test Results.

Precision
Test two levels of the appropriate controls 10 times on each of two days (5 + 5, 5 + 5) on the handheld(s). Each analyte that will be measured using a handheld must be included in the *Precision* study. This study can be combined with the validation of IQCP. Record results.

C. VERIFICATION OF ADDITIONAL TEST ANALYTE CARTRIDGE CONFIGURATIONS ON PREVIOUSLY VERIFIED TEST ANALYTES

Each new test analyte cartridge configuration must be verified before being put into use. The following minimum data be collected:

External Electronic Simulator
Run the external Electronic Simulator and record passing result.

Thermal Probe Check
Check the thermal probes on the i-STAT 1 Analyzer. Document acceptable result.

Reportable Range
Test the lowest level, the mid level and the highest level of calibration verification samples available for each test analyte that will be performed on a handheld. Results must be within the acceptable range(s) on the Value

Assignment Sheet(s). Store the Value Assignment Sheet(s) with the data as evidence that results were within acceptable limits. The closeness of sample concentrations or activities to the upper and lower limits of the AMR are defined at the laboratory's director's discretion. For AMR verification, the comparability of the manufacturer's target values to BVHS data for each analyte is evaluated based on the acceptable difference defined by the manufacturer, Abbott, on the Value Assignment Sheet or 20%, whichever is greater.

Adjust the manufacturer's reportable range and/or BVHS reportable range for BVHS, if needed, according to the values obtained for the lowest and highest levels in the set, allowing for the BVHS acceptable difference between the current BVHS reportable range upper and lower limit numbers, and the test results obtained, 15% for the high end and 50% for the low end. The Laboratory Director at both Blanchard Valley Hospital and Bluffton Hospital will need to approve any change in the reportable range for an analyte. All corrective action should be documented.

Accuracy
Use the data from the above *Reportable Range* study to assess accuracy. In addition, test one or more patient samples on the new test analyte cartridge configuration on the handheld and a comparative method (reference analyzer) or a previously verified cartridge on a handheld. Record results. The difference(s) between the new test analyte cartridge configuration results on the handheld and the comparative method or previously verified test analyte cartridge should not exceed the laboratory's required level of agreement between systems. This could be the agreement required for the initial method comparison or the agreement required for the CLIA-required six-month Comparison of Test Results.

Precision
Test two levels of the appropriate controls in duplicate on each of two days on each new test analyte cartridge configuration on the handheld. Each analyte that will be measured using a handheld must be included in the *Precision* study. This study can be combined with the validation of IQCP. Record results.

TECHNICAL SUPPORT

Abbott Point of Care Technical Support
1-800-366-8020, Option 1
www.globalpointofcare.abbott

SAFETY INCLUDING INFECTION CONTROL / PREVENTION:

All associates and providers are to follow the BVHS safety policies and procedures when performing point of care testing. The POCT program's goal is to assure the safety of patients and health care personnel commensurate with the scope of its activities, particularly those concerning infection control, hazardous waste, and chemical hygiene.

Standard precautions are used for point of care testing by testing personnel. Gloves must be worn during testing events, hand hygiene performed, and gloves changed between patients, according to Standard Precautions. Hands must be cleaned using an effective antimicrobial method. All waste sharps are to be discarded in puncture resistant containers that are easily accessible, located in areas where needles are commonly used, and properly labeled to warn handlers of the potential hazard.

The BVHS Infection Control/Prevention Policy is in effect to prevent transmission of infection. Compliance with the manufacturer's guidelines (when provided) is required. POCT handheld or portable testing devices must be disinfected after each patient use. Devices and materials designed for single use must not be disinfected and reused.

REQUIRED TRAINING AND COMPETENCY ASSESSMENTS:

Refer to the Point of Care Testing Policy for more information concerning required records of training and competency assessments, as directed by the BVHS Laboratory Point of Care Testing Coordinator.

REQUIRED EDUCATIONAL RECORDS:

Refer to the Point of Care Testing Policy for more information concerning required copies of college degrees / transcripts / diplomas, as directed by the BVHS Laboratory Point of Care Testing Coordinator.

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