TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	1/5/2015
Department:	Core	**Due Date:**	1/31/2015
		Implementation:	**2/1/2015**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

i-STAT System for Arterial and Venous Blood Gas GEC.C35 v1

B-Type Natriuretic Peptide (BNP) by i-STAT 1 System GEC.C39 v1

Description of change(s):

Most significant change is documenting QC in Unity instead of SQ

Section	Reason
6.3	Replace QC entry instruction for LIS with Unity Real Time
6.6	Replace LIS with Unity Real Time, add QC review process
16	Add forms

These revised SOPs will be implemented on February 1, 2015

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training (version 1)

Technical SOP

Title	**i-STAT System for Arterial and Venous Blood Gas**
Prepared by	Judy Codling/Cynthia Reidenauer Date: 3/25/2012
Owner	Robert SanLuis Date: 3/25/2012

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Blood Gas, Arterial or Venous	i-STAT 1 System	GBG (arterial) GBGV (venous)
Synonyms/Abbreviations		
ABG, VBG		

Department
GEC Lab Only

2. ANALYTICAL PRINCIPLE

The i-STAT 1 Analyzer is intended for use with i-STAT cartridges for in vitro quantification of various analytes in whole blood. The i-STAT System incorporates comprehensive components to perform blood analysis at the point of care. The System consists of a hand-held analyzer and single-use disposable cartridges. The analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration, and continuous quality monitoring. Analyzers with thermal control capability for testing at 37°C and cartridges requiring thermal control are labeled with a 37° symbol.

Blood Gas
PH and PCO2 are measured by ion-selective potentiometry. Concentrations are calculated from the measured potential through the Nernst equation.
PO2 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.
sO2 is calculated from measured PO2 and pH and from HCO3 calculated from measured PCO2 and pH.
When the cartridge includes sensors for both pH and PCO2, bicarbonate (HCO3), total carbon dioxide (TCO2) and base excess (BE) are calculated.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Specimens are collected via routine arterial puncture or venipuncture. When filling a blood gas syringe with arterial blood, avoid bubbles; exposure to air may increase PCO2.
Special Collection Procedures	**Heel/Fingerstick**: do not use the first drop of blood (may cause false increase in potassium while decreasing other tests results). Obtain and fill a 150ul balanced heparin capillary tube. **In-dwelling lines**: it is recommended to withdraw three to six times the volume of the catheter, connectors, and needle to remove intravenous solutions, heparin, and or medications that may contaminate the sample. Avoid drawing specimens from extremity with I.V. Avoid prolonged tourniquet use and clenching and unclenching the fist.

Component	Special Notations
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	Arterial or Venous blood Heel/Fingerstick	
Collection Container	**Arterial:** Plain syringe, heparinized syringe **Venous:** Lithium or sodium heparin collection tube (green top, any size)	
Volume - Optimum **- Minimum**	**Arterial**: 2 ml in a syringe **Venous**: ¾ to full tube 2ml	
Transport Container and Temperature	Capped syringe or collection tube at room temperature	
Stability & Storage Requirements	Room Temperature:	10 minutes
	Refrigerated:	Not established
	Frozen:	Unacceptable
Timing Considerations	N/A	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Additional Criteria for Specimen Rejection: 1. Evidence of clotting 2. The sample is under-filled for ionized calcium analysis. 3. Syringe for pH, PCO2, and PO2 with air bubbles in the sample Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.	
Compromising Physical Characteristics	Hemodilution and Hemolysis	
Other Considerations	N/A	

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Blood Gas Cartridge (G3)	Abbott 03P78-25

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Assay Kit	
Reagent	iSTAT cartridge for Blood Gas
Storage	Store at 2-8ºC Working supply is stored at room temperature (18-30°C)
Stability	Refrigerated - until expiration date printed on box Room Temperature - 14 days, re-date with new expiration date when removed from refrigerator
Preparation	A cartridge should not be removed from its protective pouch until it is at room temperature (18-30°C). Allow a single cartridge to warm at room temperature for 5 minutes and a box for 1 hour. Use a cartridge immediately after removing from the protective pouch, prolong exposure may cause a cartridge to fail Quality Control

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
G3 calibrator	Abbott 06F15-01

5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech (6) any special storage instructions; check for visible signs of degradation.

Calibrator	**G3 calibrator**
Preparation	Allow the **blood gas** ampule to equilibrate for 4 hours at room temperature before testing.
Storage/Stability	2-8ºC, until manufacturer's expiration date

5.3 Calibration Verification Procedure

Criteria	Special Notations
Frequency	Every 6 months
Tolerance Limits	Each result must be within the acceptable ranges printed on the value assignment sheet for that analyte.
Procedure	1. Program all calibrators using the quality test menu, select calibrator, and follow prompts. 2. Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phase. 3. Snap off the top of the ampule. Using a plain syringe or pipette transfer the solution into a cartridge. 4. Immediately seal the cartridge and insert it into the analyzer.
Dilutions	N/A
-Graph Type **- Point of Origin** **- Type of Paper**	N/A

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
G3 control level 1	Abbott 06F12-01
G3 control level 2	Abbott 06F14-01

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	**G3 controls**
Preparation	Allow the **blood gas** ampule to equilibrate for 4 hours at room temperature before testing.

Storage/Stability	2-8ºC. Controls may be stored at room temperature (18-30°C) for 5 days. Do not use after expiration date on box and ampules.

6.3 Frequency

- The instrument is programmed to run the internal Electronic stimulator every 8 hours when there is a Patient.
- The external Electronic Simulator is run once a day.
- The liquid controls are run once a week and with each new shipment of cartridges.

To enter QC results in Unity Real Time:

1. Log into Unity Real Time
2. Select Lab "544235 GEC X-pand 1"
3. Select "iSTAT"
4. QC Level 1 results are entered as Level 1
5. QC Level 3 results are entered as Level 2
6. SAVE

6.4 Tolerance Limits

Each result must be within the acceptable ranges printed on the **value assignment sheet for that analyte.**

Step	Action
1	**Run Rejection Criteria** • Anytime the established parameters are exceeded, the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
2	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.

"*" Instead of results**
Stars appear in place of results if the analyzer detects that the sensor's signal is uncharacteristic. Cartridges that have been stored improperly may show "***" instead of results. Check the supply of cartridges in use with a control solution. If the control results are starred, discontinue use of this supply of cartridges. Aged specimens may contain products of metabolism that can interfere with the test(s). A fresh sample should be tested. If the stars reappear there may be an interferent present. When flags occur, the specimen must be tested on a different iSTAT in order to obtain results. **Contact the Tech in Charge at SGAH for a replacement iSTAT.**

6.5 Review Patient Data

Review patient results for unusual patterns, trends or distributions in patient results, such as an unusually high percentage of abnormal results. Computer aided tools should be used when available.

6.6 Documentation

- QC tolerance limits are programmed into Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.7 Quality Assurance Program

- Each new lot number of cartridges and each subsequent shipment of the same lot of cartridges must be tested with external control material and all values must be within the acceptable range before patient testing is done.
- Training must be successfully completed and documented prior to performing this testing.
- The Laboratory participates in CAP proficiency testing.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

iSTAT analyzer

7.2 Equipment

Electronic Simulator
Martel Printer
Downloader

7.3 Supplies

N/A

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

8.1	Instrument Set-up Protocol
1.	Press the On/Off key to turn analyzer on.
2.	Press 2 for i-STAT Cartridge from the Test Menu.
3.	Scan or Enter Operator ID. Repeat if prompted.
4.	Scan or Enter Patient ID. Repeat if prompted.
5.	Scan Cartridge Lot number from the cartridge portion pack, or box.

8.2	Specimen Preparation
1.	Mix specimen well before testing.

8.3	Test Run
1.	Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
2.	Discard 1 drop of sample from the delivery device to clear unseen bubbles. Direct the dispensing tip or capillary tube containing the blood into the sample well.
3.	Dispense the sample until it reaches the FILL TO mark on the cartridge. Leave some sample in the well.
4.	Close the cover over the sample well until it snaps into place. (Do not press over the sample well.)
5.	Insert the cartridge into the cartridge door until it clicks into place.
6.	The Time to Results countdown bar will then be displayed. Once time has elapsed, view results on analyzer's display.
7.	Remove cartridge after Cartridge Locked message disappears. The analyzer is ready for the next test immediately.
8.	Dock the analyzer for result printing and uploading to occur.

8.4	Special Handling
1.	Do not attempt to remove the cartridge while the Cartridge Locked message is displayed
2.	The analyzer must remain on a level surface with the display facing up during testing.

8.4	Special Handling
3.	Motion of the analyzer during testing can increase the frequency of suppressed results quality check codes

9. CALCULATIONS

The Analyzer contains a microprocessor that performs all calculations required for reporting results.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

There are three conditions under which the I-STAT system will not display results:

1. Results outside the system's 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.
   Action: Repeat analysis and if results still have flags indicating the result is above or below the reportable range, report accordingly.

2. Results which are un-reportable based on internal QC rejection criteria are flagged with "****".
   Action: Repeat analysis using another cartridge. The results not suppressed should be reported in the usual manner. If the result is suppressed again, perform testing on a different iSTAT. **Contact the Tech in Charge at SGAH for a replacement iSTAT.**

3. Results will not be reported if a test cycle has a problem with the sample, calibrant solution, and sensors, mechanical or electrical functions of the analyzer.
   Action: Refer to the I-stat System Manual's Troubleshooting section if necessary.

10.1.1 Base Excess vs Base Deficit for Arterial and Venous Blood Gas:

On the iSTAT printout you will see a result for BEecf. If this is a negative number you will result this in the BD test result space as the Base Deficit. If this is a positive number you will result the value in the BE space for Base Excess.
If you answer the Base Deficit then "hide" the Base Excess.
If you answer the Base Excess then "hide" the Base Deficit.

10.2 Rounding

N/A

10.3 Units of Measure

Refer to Addendum 1

10.4 Clinically Reportable Range (CRR)

Refer to Addendum 1

10.5 Repeat Criteria and Resulting

Repeat testing is only performed if requested by the medical staff.

11. EXPECTED VALUES

11.1 Reference Ranges

Refer to Addendum 1

11.2 Critical Values

Refer to Addendum 1

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
pH	Exposing the sample to air	Prolonged tourniquet application and forearm exercise
PCO2	Airway obstruction, sedatives, anesthetics, respiratory distress syndrome, and chronic obstructive pulmonary disease	Hypoxia due to chronic heart failure, edema and neurologic disorders and mechanical hyperventilation
PO2		Airway obstruction, trauma to the brain, bronchitis, emphysema, pulmonary edema, and congenital defects in the heart

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved
- **Validated Test Modifications:** None

Hemodilution by more than 20% may cause clinically significant error on ionized calcium.
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14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

Refer to Addendum 1

14.2 Precision

N/A

14.3 Interfering Substances

Refer to Addendum 2

14.4 Clinical Sensitivity/Specificity/Predictive Values

N/A

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Critical Values (Lab policy)
3. Abbott iSTAT 1 System Manual
4. Current package insert for iSTAT cartridges

5. Shady Grove Adventist Dept of Respiratory Therapy Reference Ranges, Reportable Ranges and Critical Ranges
6. i-STAT 1 System Maintenance Log (AG.F213)
7. i-STAT Daily QC Simulator Log (AG.F214)

17. REFERENCES

1. iSTAT 1 System Manual, Abbott Point of Care, 08/14/06

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes GEC C052.001		
000	10/14/14	6.3	Replace QC entry instruction for LIS with Unity Real Time	A Chini	R SanLuis
000	10/14/14	6.6	Replace LIS with Unity Real Time, add QC review process	A Chini	R SanLuis
000	10/14/14	16	Add forms	L Barrett	R SanLuis
000	10/14/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis

19. ADDENDA

Addendum	Title
1	Reference / Critical / Reportable Range
2	Interferences

Addendum 1

REFERENCE / CRITICAL / REPORTABLE RANGES

ANALYTE	UNIT	REFERENCE RANGE	CRITICAL RANGE	REPORTABLE RANGE (AMR)
pH Arterial		0-30D 7.30-7.42 31D-17y 7.37-7.44 > 18y 7.35-7.45	All ages <7.21, >7.59	6.852-8.106
PCO2 Arterial	mmHg	0-30D 35.0-50.0 31D-17y 40.0-52.0 > 18y 41.0-51.0	Pediatric 31D-17yr <21.0, >66.0 Adult <19.0, >67.0	17.5-91.0
PO2 Arterial	mmHg	0-30D 54-62 31D-17y 80-100 > 18y 80-105	0-30D <37, >92 31D-17y <45,>124 > 18y <43	5-800
%02 Arterial	%	None defined	None defined	48.2-99.6
Base excess/ Base deficit Arterial	mmol/L	0-30D -3 to -7 31D-17y -2 to +2 > 18y -2 to +3	None defined	-30 to +30
HCO3 Arterial	mmol/L	0-30D 17.6-22.8 31D-17y 22.0-26.0 > 18y 22.0-26.0	None defined	1.0-85.0
pH Venous		0-30D 7.320-7.460 31D-17y 7.31-7.41 > 18y 7.31-7.41	None defined	6.852-8.106
PCO2 Venous	mmHg	0-30D 35.0-50.0 31D-17y 40.0-52.0 > 18y 41.0-51.0	None defined	17.5-91.0
PO2 Venous	mmHg	0-30D 30-60 31D-17y 30-50 > 18y 40	None defined	5-800
%02 Venous	%	None defined	None defined	48.2-99.6
Base excess/ Base deficit Venous	mmol/L	31D-17y -2 to +2 > 18y -2 to +3	None defined	-30 to +30
HCO3 Venous	mmol/L	0-30D 20.0-26.0 31D-17y 22.0-28.0 > 18y 23.0-28.0	None defined	1.0-85.0

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Addendum 2

INTERFERENCES

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
pH	Standing anaerobically at RT		Decrease (↓)by 0.03 pH units / hr
PCO2	Standing anaerobically at RT		Increase (↑) by 4 mmHg / hr
PO2	Exposure to air Standing anaerobically at RT Cold samples	Values <150mmHg Values > 150mmHg	Increase (↑) Decrease (↓) Decrease (↓)by 2-6 mmHg / hr Falsely elevated

Approved draft for training (version 1)

Technical SOP

Title	**B-Type Natriuretic Peptide (BNP) by i-STAT 1 System**
Prepared by	Judy Codling/Cynthia Reidenauer Date: 1/28/2013
Owner	Robert SanLuis Date: 1/28/2013

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

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TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
B-Type Natriuretic Peptide	i-STAT 1 System	BNP

Synonyms/Abbreviations
BNP

Department
Germantown Emergency Center

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2. ANALYTICAL PRINCIPLE

The i-STAT BNP test is an in vitro diagnostic test for the quantitative measurement of B-type natriuretic peptide (BNP) in whole blood using EDTA as the anticoagulant. BNP measurements can be used as an aid in the diagnosis and assessment of the severity of congestive heart failure.

The i-STAT BNP test cartridge uses a two-site enzyme-linked immunosorbant assay (ELISA) method. Antibodies specific for BNP are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the BNP molecule. The whole blood is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The BNP within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample is washed off the sensors, as well as excess enzyme conjugate. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of BNP within the sample.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing whole blood may be used for samples to be analyzed by this method.
Special Collection Procedures	In a situation of In-Dwelling Line, back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample.
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	EDTA whole blood None
Collection Container	Lavender Top Tube
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL
Transport Container and Temperature	Collection container or plastic vial at room temperature

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Criteria		
Stability & Storage Requirements	Room Temperature:	30 minutes
	Refrigerated:	Not recommended
	Frozen:	Not recommended
Timing Considerations	N/A	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.	
Compromising Physical Characteristics	Reject clotted specimens. Request a recollection and credit the test with the appropriate LIS English text code	
Other Considerations	Mix blood and anticoagulant by inverting a tube gently at least ten times.	

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
iSTAT BNP Cartridge	Abbott Point of Care Cat. No. 03P9325

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Reagent	iSTAT BNP Cartridge
Container	Each cartridge is packed in an aluminum foil
Storage	Stored at 2 - 8°C

Stability	• Unopened cartridges are stable until the expiration date printed on the label when stored at 2 - 8°C. • Unopened cartridges are stable for 14 days at room temperature. • All cartridges should be used immediately after opening.
Preparation	Individual cartridges may be used after standing five minutes at room temperature.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
iSTAT BNP Calibrator Verification Levels 1, 2 and 3	Abbott Point of Care Cat. No. 06F1221

5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech (6) any special storage instructions; check for visible signs of degradation.

Calibrator	iSTAT BNP Calibration Verification
Preparation	• Remove vial from freezer and thaw at room temperature (18 - 30°C) for 15 minutes. • Gently invert the vial 10 times, then swirl the vial 10 times. Inspect the sides of the vial to ensure that no particulate matter is clinging to the sides of the vial. If solids are observed in the control fluid or on the vial wall, repeat the mixing procedure. If further mixing does not homogenize the sample, discard the vial and thaw a fresh vial.
Storage/Stability	Stored at -18°C or colder. After thaw, use immediately. If short term storage (<4 hours) is desired, tightly recap the bottle immediately after all sampling is complete, and store at 2 - 8°C.

5.3 Calibration Procedure

Criteria	Special Notations
Frequency	Every 6 months
Tolerance Limits	Each result must be within the acceptable ranges printed on the value assignment sheet.

Procedure	• Turn the iSTAT on • Press Menu to change screen to administration menu. • Press 3 for Quality Test menu • Press 3 for Cal Ver (Calibration Verification) • Enter operator ID number using number keys • Scan or manually enter the lot number of the Cal Ver box • Scan the lot number in the cartridge pouch • Open the vial and transfer a drop of solution directly from the vial in the BNP cartridge and seal the cartridge. • Push the sealed cartridge into the cartridge port until it clicks into place

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
iSTAT BNP Control Levels 1 and 3	Abbott Point of Care Cat. No. 06F12

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	iSTAT BNP Control Levels 1 and 3
Preparation	• Remove vial from freezer and thaw at room temperature (18 - 30°C) for 15 minutes. • Gently invert the vial 10 times, then swirl the vial 10 times. Inspect the sides of the vial to ensure that no particulate matter is clinging to the sides of the vial. If solids are observed in the control fluid or on the vial wall, repeat the mixing procedure. If further mixing does not homogenize the sample, discard the vial and thaw a fresh vial.
Storage/Stability	Stored at -18°C or colder. After thaw, use immediately. If short term storage (<4 hours) is desired, tightly recap the bottle immediately after all sampling is complete, and store at 2 - 8°C.

Procedure	• Turn the iSTAT on • Press Menu to change screen to administration menu. • Press 3 for Quality Test menu • Press 1 for Control • Enter operator ID number using number keys • Scan or manually enter the lot number of the Control box • Scan the lot number in the cartridge pouch • Open the vial and transfer a drop of solution directly from the vial in the BNP cartridge and seal the cartridge. • Push the sealed cartridge into the cartridge port until it clicks into place.

6.3 Frequency

- The external Electronic Simulator is run once a day.
- The liquid controls are run once a week and with arrival of a new lot number or new shipment of the same lot number.

To enter QC results in Unity Real Time:

1. Log into Unity Real Time
2. Select Lab "544235 GEC X-pand 1"
3. Select "iSTAT"
4. QC Level 1 results are entered as Level 1
5. QC Level 3 results are entered as Level 2
6. SAVE

6.4 Tolerance Limits

Each result must be within the acceptable ranges printed on the **value assignment sheet.**

Step	Action
1	**Run Rejection Criteria** • Anytime the established parameters are exceeded, the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
2	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the

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Step	Action
	Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.

"*" Instead of results**
Stars appear in place of results if the analyzer detects that the sensor's signal is uncharacteristic. Cartridges that have been stored improperly may show "***" instead of results. Check the supply of cartridges in use with a control solution. If the control results are starred, discontinue use of this supply of cartridges. Aged specimens may contain products of metabolism that can interfere with the test(s). A fresh sample should be tested. If the stars reappear there may be an interferent present. When flags occur, the specimen must be tested on a different iSTAT in order to obtain results. **Contact the Tech in Charge at SGAH for a replacement iSTAT.**

6.5 Review Patient Data

Check for unusual patterns, trends, or distributions in patient results (such as an unusually high percentage of abnormal results). Resolve any problems noted before issuing patient reports.

6.6 Documentation

- QC tolerance limits are programmed into Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.7 Quality Assurance Program

- Each new lot number of cartridges and each subsequent shipment of the same lot of cartridges must be tested with external control material and all values must be within the acceptable range before patient testing is done.
- Training must be successfully completed and documented prior to performing this testing.
- The Laboratory participates in CAP proficiency testing.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

iSTAT 1 System

7.2 Equipment

Electronic Simulator
Martel Printer
Downloader

7.3 Supplies

Transfer Pipettes
Gauze

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

8.1	Instrument Set-up Protocol
1.	Press the On/Off key to turn analyzer on.
2.	Press 2 for i-STAT Cartridge from the Test Menu.
3.	Scan or Enter Operator ID. Repeat if prompted.
4.	Scan or Enter Patient ID. Repeat if prompted.
5.	Scan Cartridge Lot number from the cartridge portion pack, or box.

8.2	Test Run
1.	Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
2.	Discard 1 drop of sample from the delivery device to clear unseen bubbles. Direct the dispensing tip or capillary tube containing the blood into the sample well.
3.	Dispense the sample until it reaches the FILL TO mark on the cartridge. Leave some sample in the well.
4.	Close the cover over the sample well until it snaps into place. (Do not press over the sample well.)
5.	Insert the cartridge into the cartridge door until it clicks into place.
6.	The Time to Results countdown bar will then be displayed. Once time has elapsed, view results on analyzer's display.
7.	Remove cartridge after Cartridge Locked message disappears. The analyzer is ready for the next test immediately.

8.2	Test Run
8.	Dock the analyzer for result printing and uploading to occur.

8.3	Special Handling
1.	Do not attempt to remove the cartridge while the Cartridge Locked message is displayed
2.	The analyzer must remain on a level surface with the display facing up during testing.
3.	Motion of the analyzer during testing can increase the frequency of suppressed results quality check codes

9. CALCULATIONS

None

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

There are three conditions under which the I-STAT system will not display results:

1. Results outside the system's 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.
   Action: Repeat analysis and if results still have flags indicating the result is above or below the reportable range, report accordingly.

2. Results which are un-reportable based on internal QC rejection criteria are flagged with "****".
   Action: Repeat analysis using another cartridge. The results not suppressed should be reported in the usual manner. If the result is suppressed again, perform testing on a different iSTAT. **Contact the Tech in Charge at SGAH for a replacement iSTAT.**

3. Results will not be reported if a test cycle has a problem with the sample, calibrant solution, and sensors, mechanical or electrical functions of the analyzer.
   Action: Refer to the I-stat System Manual's Troubleshooting section if necessary.

10.2 Rounding

No rounding is necessary. Instrument reports results in whole numbers.

10.3 Units of Measure

pg/mL

10.4 Clinically Reportable Range (CRR)

15 – 5000 pg/mL

10.5 Repeat Criteria and Resulting

To enter patient results in the LIS, use function MEM and worksheet **GCH1**.

IF the result is …	THEN…
< 15 pg/mL	Assure the integrity of the sample. Report as: < 15 pg/mL
Flagged with "****"	Check the sample for any clots. Mix the sample according to instructions in section 3.2 and repeat sample using a new cartridge. If repeat gives a normal numerical value then release the result. If the same flag appears notify supervisor and contact the company tech support for further troubleshooting.
> 5000 pg/mL	Assure the integrity of the sample. Repeat using a new cartridge. If the same result is obtained, report as " > 5000 pg/mL-REP".

11. EXPECTED VALUES

11.1 Reference Ranges

0 – 100 pg/mL

11.2 Critical Values

None established.

11.3 Priority 3 Limit(s)

None established.

12. CLINICAL SIGNIFICANCE

Congestive heart failure (CHF) is a complex clinical syndrome resulting in decreased cardiac output that is insufficient to meet the body's metabolic needs. It may result from dysfunction of either ventricle in systole (contraction), diastole (relaxation) or both. The most common underlying cause of CHF is coronary artery disease. Other causes include: hypertension, myocarditis, valvular heart disease and idiopathic.

13. PROCEDURE NOTES

- **FDA Status:** Approved / Cleared
- **Validated Test Modifications:** None

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

15 – 5000 pg/mL

14.2 Precision

Aqueous Control	Mean	%CV (within run)	% CV (total)
Level 1	126	9.0	11.1
Level 2	1551	6.6	8.1
Level 3	3337	8.0	9.8

14.3 Interfering Substances

Samples from patients who have been exposed to animals or who have received therapeutic or diagnostic procedures employing immunoglobulins or reagents derived from immunoglobulins may contain antibodies, which may interfere with immunoassays and produce erroneous results.

14.4 Clinical Sensitivity/Specificity/Predictive Values

The frequency of suppressed results is affected by atmospheric pressure. Suppressed result rates may increase with higher elevations (decreased barometric pressure) and may become persistent if testing is performed at more than 7500 feet above sea level.

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.

- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Material Safety Data Sheets (MSDS)
4. Quest Diagnostics Records Management Procedure
5. Current package insert for iSTAT BNP Cartridge
6. i-STAT 1 System Maintenance Log (AG.F213)
7. i-STAT Daily QC Simulator Log (AG.F214)

17. REFERENCES

1. Package Insert for iSTAT BNP Control Levels 1, 2 and 3. Abbott Point of Care. Revised 06/02/2009
2. Package Insert for iSTAT Calibrator Verification. Abbott Point of Care. Revised 06/02/2009
3. iSTAT Manual Guide. Abbott Point of Care. Revised 08/04/2011

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	10/14/14	6.3	Replace QC entry instruction for LIS with Unity Real Time	A Chini	R SanLuis
000	10/14/14	6.6	Replace LIS with Unity Real Time, add QC review process	A Chini	R SanLuis
000	10/14/14	16	Add forms	L Barrett	R SanLuis
000	10/14/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis

19. ADDENDA

None