Quest Diagnostics

TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	2/8/2013
Department:	Core	**Due Date:**	2/28/2013

DESCRIPTION OF PROCEDURE

Name of procedure:
B-Type Natriuretic Peptide (BNP) by i-STAT 1 System GEC.C39.000
Description:
New SOP for BNP testing performed on iSTAT cartridges - to be implemented 2/12/13

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

Approved draft for training (version 000)

Technical SOP

Title	**B-Type Natriuretic Peptide (BNP) by i-STAT 1 System**
Prepared by	Ashkan Chini 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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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
Stability & Storage	Room Temperature: 30 minutes

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Criteria		
Requirements	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.

6.4 Tolerance Limits

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

To enter QC results in the LIS, use function MEM, worksheet **GCH1** and QC codes:
BNP1G (iSTAT BNP QC Level 1)
BNP3G (iSTAT BNP QC Level 3)

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.

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"*" 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 will be documented in the computer and all values must be within acceptable range before patient testing is done.

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.	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

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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

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 Calibraton 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

19. ADDENDA

None