TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	10/26/2016
Department:	Core	**Due Date:**	11/16/2016
		Implementation:	**11/16/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

B-type Natriuretic Peptide (BNP) by TRIAGE Meter SGAH.H10 v3

Note: this has been converted to a system SOP

Description of change(s):

Minor formatting changes, no impact on test performance

Section	Reason
Header	Add WAH
4,5,6	Remove individual section labeling instructions and add general one
10.5	Review data moved from section 6
15	Update to new standard wording
17	Update PI revision dates

This revised SOP will be implemented on November 16, 2016

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

Technical SOP

Title	**B-type Natriuretic Peptide (BNP) by TRIAGE Meter**
Prepared by	Ashkan Chini Date: 3/21/2012
Owner	Robert SanLuis Date: 8/12/2014

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
B-type Natriuretic Peptide	Fluorescence Immunoassay TRIAGE® Meter / TRIAGE® Meter Plus	BNP

Synonyms/Abbreviations
BNP

Department
Hematology

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

The Triage® BNP Test is a fluorescence immunoassay for the quantitative determination of BNP in whole blood and plasma specimens in which EDTA is the anticoagulant.

After addition of a blood sample to the sample port of the test device, the red blood cells are separated from the plasma via a filter. A predetermined quantity of plasma moves by capillary action into a reaction chamber and is allowed to react with fluorescent antibody conjugates within the reaction chamber to form a reaction mixture. After an incubation period, the reaction mixture flows through the device detection lane. Complexes of the analyte and fluorescent antibody conjugates are captured on discrete zones in the detection lane. Excess plasma sample washes the unbound fluorescent antibody conjugates from the detection lane into a waste reservoir. The concentration of the analyte in the specimen is proportional to the fluorescence bound to the detection lane.

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 and plasma may be used for samples to be analyzed by this method.
Special Collection Procedures	N/A
Other	None

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	EDTA whole blood EDTA plasma
Collection Container	Purple top EDTA tube
Volume - Optimum **- Minimum**	5.0 mL 1.0 mL
Transport Container and Temperature	Collection container for whole blood, at room temperature or refrigerated Plastic vial for separated plasma, at room temperature or refrigerated Note: Avoid extreme temperatures
Stability & Storage Requirements	Room Temperature: 7 hours (Whole blood or Plasma)
	Refrigerated: 24 hours (Plasma only)
	Frozen (-20°C): Plasma – 6 months (Plasma only)

Form revised 2/02/2007

Criteria	
Timing Considerations	If testing cannot be completed within 24 hours, the plasma should be separated and stored at -20°C until it can be tested.
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	Severely hemolyzed specimens should not be used. Reject sample and request a recollection. Credit the test with appropriate LIS English text code. Document the request for recollection in the LIS.
Other Considerations	Frozen plasma and refrigerated whole blood or plasma specimen must be allowed to reach room temperature and be mixed thoroughly prior to testing.

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

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.

4.1 Reagent Summary

Reagent Kit	Supplier & Catalog Number
Triage® BNP Test Kit	Alere (Biosite Diagnostics) Cat #: 98000XR

4.2 Reagent Preparation and Storage

Reagent	BNP
Storage	Store at 2 - 8°C
Content	Murine monoclonal and polyclonal antibodies against BNP labeled with a fluorescent dye and immobilized on the solid phase, and stabilizers.

Stability	• Once removed from refrigeration, the Triage® Cardiac Panel is stable for fourteen days, but not beyond the expiration date printed on the pouch. If not used on the same day of removal from refrigeration, gently write the date of removal from the refrigerator and the date to discard on the foil pouch and/or or the kit box (use a soft, felt tip marker). • Once removed from refrigeration, allow a minimum of 15 minutes for the device to reach room temperature (20-24°C) while in the sealed pouch. Once equilibrated to room temperature, do not return the Test Device to refrigeration. • Do not remove the device from the pouch until ready to use.
Preparation	Reagents are supplied ready for use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
Reagent Code chip (included with each box of reagent)	Alere (Biosite Diagnostics) Cat #: 98000XR

5.2 Calibrator Preparation and Storage

Calibrator	**Reagent Code Chip** (included in BNP Test kit) **Note**: With each new lot number of reagent, QC device, and external QC there is an electronic code chip that contains calibration information. This chip MUST be inserted into the meter before each new lot is used. These chips are included in the Reagent test kits, External QC kits and the QC Device.
Preparation	None
Storage/Stability	N/A

5.3 Calibration Procedure – Download the Code Chip

Criteria	Special Notations
Frequency	The Reagent Code Chip must be inserted into the meter to transfer the calibration data before each new lot is used.
Procedure	**Download the calibration data onto the device from the Reagent Code Chip.**

	a. From the main screen of the instrument press INSTALL NEW REAGENT CODE CHIP. b. Press ENTER. c. Insert the chip in the chip slot located on left-hand side of the meter towards the front. d. Follow the prompts on the screen e. Remove the chip when the process is completed.

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
BNP QC Device (Electronic QC Simulator)	Electronic QC Simulator device **Notes**: • Prior to initial use each QC simulator contains a QC Device Code Chip. This must be entered into the meter prior to the first use of the QC Device. • Each QC Simulator device is paired to the individual meter by serial number and can only be run on that meter.
BNP control Level 1	Alere (Biosite Diagnostics) Cat #: 98013XR
BNP control Level 2	Alere (Biosite Diagnostics) Cat #: 98014XR
Calibration Verification Controls	Alere (Biosite Diagnostics) Cat #: 98015XR

6.2 Control Preparation and Storage

External Control	BNP control Levels 1 & 2 and Calibration Verification Controls
Preparation	Refer to the control insert sheet for preparation, storage, and handling instructions. Allow the control to thaw at room temperature (19-25° C) for at least 30 minutes. Do not use a warming device. Controls should be used within one hour of being removed from frozen storage. Mix the controls by vortexing or inversion prior to testing. Once thawed the controls should not be re-frozen or used at a later date. The BNP test device should remain in the sealed pouch until control is ready for use.
Storage/Stability	Unopened materials are stable until the expiration date at -20^{o}C.

6.3 Frequency

- The Electronic QC Simulator (QC Device) will be run once every 24 hours.
- The external liquid QC will be run with every new lot and shipment.
- The external liquid QC will be run at least once a month.
- Calibration Verification controls at least every 6 months.

Each Triage® BNP Test device contains two internal positive controls that satisfy routine quality control requirements. These controls indicate that sufficient sample was applied to the panel, that the unbound fluorescent label washed sufficiently from the detection zone, and that the panel was inserted and read properly by the Triage® Meter. An unacceptable result from either control causes a warning message on the Triage® Meter indicating that the test should be repeated.

6.4 QC Procedures

QC Type	Procedure
Electronic QC Simulator	The electronic control (QC Simulator Device) • From the main screen of the instrument select Run Test and press Enter. • Select QC Device and press Enter. • Insert the QC Simulator, with the arrowhead towards the Instrument, to the first click. Press Enter. • The instrument will pull the simulator into the instrument, and will release it when the testing is completed. Record the results on the maintenance log. **DO NOT THROW THE QC DEVICE AWAY.** **Place it in the special black QC Device Box.**
External QC BNP Level 1 & 2	The External Liquid Controls (BNP Levels 1 & 2) • See preparation instructions section 6.2. • Insert the Control Chip into the meter. The code chip module is LOT specific. **Note**: Each box of controls has a specific Control Chip included. • Select QC sample from the meter menu • Enter the QC sample (Control) Lot number. • Test the controls as a patient samples
Calibration Verification	External Calibration Verification controls • Follow the steps for patient testing in section 8.

6.5 Tolerance Limits and Criteria for Acceptable QC

The values on the Expected Values card (which is included with the package inserts) represent the results that should be obtained using the Triage BNP test. Document result on the Triage BNP Maintenance Log.

IF the result is …	THEN…
not acceptable	• Verify it is the correct control/reagent. • Verify the control/reagent has not expired. • Check for technical/clerical errors. • Visually inspect the condition of the control/reagent. • Inspect the instrument status, do maintenance and troubleshoot. • Repeat the QC test. • Notify the Supervisor if these results are not acceptable. • No patient results are to be reported until acceptable QC results are obtained.

6.6 Documentation

- 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 reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Triage® Meter

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining -10 to -20°C.
- Centrifuge

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.

	Testing Procedure
1.	**Add Sample** – • Open the pouch. • Label the test device with the patient accession number. • Using the transfer pipette provided, squeeze the larger (top) bulb completely and insert the tip into the specimen. • Release the bulb slowly. The transfer barrel should fill completely with some fluid flowing into the smaller (lower) bulb. • Place the tip of the transfer pipette into the sample port of the test device and squeeze the larger bulb completely • The entire contents of sample in the transfer pipette barrel must flow into the sample port. • The sample in the smaller (lower) bulb will not be expelled. • Remove the tip from the sample port and then release the bulb. • Discard the transfer pipette. **After sample addition, the device should be inserted into the meter within 30 minutes.** **Note: 6 samples are the maximum number of samples that should be set up at one time.**
2.	**Insert the test device into the Triage® Meter** • From the main screen of the instrument select Run Test and press Enter. • Select Patient Sample and press Enter. • Enter the patient accession number and press Enter. • Confirm that the number was entered correctly by selecting Confirm Patient ID and pressing enter. If the number was not entered correctly select Correct Patient ID, press Enter and repeat the previous step. • Insert the test device, with the arrowhead towards the instrument, to the first click and Enter. The instrument will pull the test device into the instrument, and will release it when the testing is completed.
	Note: The first results will take approximately 15 minutes after addition of the sample to the test device.

	Testing Procedure
3.	**Read Results** – • Read the assay results from the display screen, or the printer. • A blocked out result indicates the result was invalid and the test should be repeated. Discard the used test device in a biohazard waste container

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

The results are calculated automatically by the Triage® Meter.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

Instrument reports to one decimal point. Round patient results to a whole number for reporting in the LIS.

10.3 Units of Measure

pg/mL

10.4 Clinically Reportable Range (CRR)

5 – 5000 pg/mL

10.5 Review Patient Data

Technologist must review patient results print out for error messages, unusual patterns, trends or distributions in patient results, such as an unusually high percentage of abnormal results before releasing results.

10.6 Repeat Criteria and Resulting

- A blocked out result indicates that the result was invalid, and the test should be repeated

- Values that fall within the AMR or CRR may be reported without repeat. Values that fall outside these ranges must be repeated. If the test repeats as less than 5 or greater than 5000, enter that result into the LIS.

- Manually enter result in the LIS:
  1. Function: **MEM**
  2. Worksheet: **SCH1** (SGMC) or **WHE1** (WAH)
  3. Test: **BNP**
  4. Modify: **M**
  5. BNPT: CS1 (SGMC) or CW1 (WAH) will appear as default method
  6. Type: **BTRGS** (SGMC) or **BTRGW** (WAH)
  7. Accept
  8. Acc #
  9. Enter result.

11. EXPECTED VALUES

11.1 Reference Ranges

≤ 100 pg/mL

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Blood concentrations of BNP may be elevated in patients who are suspected of having a cardiac event, who may be candidates for renal dialysis, and who have had renal dialysis.

Higher BNP concentrations, measured in the first 72 hours after an acute coronary syndrome, are associated with an increased risk of death, myocardial infarction, and CHF.

Higher BNP concentrations or the lack of a decrease in the BNP concentration from hospital admission to discharge indicate an increased risk of hospitalization or death in patients with heart failure.

13. PROCEDURE NOTES

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

The results of Triage® BNP Test should be evaluated in the context of all the clinical and laboratory data available. If Triage® BNP Test results do not agree with the clinical evaluation, additional tests should be performed.

Some patients may have circulating BNP concentrations that are higher than the measurable range of the Triage® BNP Test (>5000 pg/mL).

This test has been evaluated with whole blood and plasma using EDTA as the anticoagulant. Serum and blood or plasma specimens obtained using other anticoagulants (e.g. heparin or citrate) have not been evaluated and should not be used.

If results from multiple specimens from the same patient will be compared, it is recommended to maintain a consistent sample type (whole blood or plasma).

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

5 – 5000 pg/mL

14.2 Precision

Mean (pg/mL)	SD (pg/mL)	CV (%)
71.3	7.0	9.9
629.9	75.5	12.0
4087.9	500.1	12.2

14.3 Interfering Substances

The presence of up to 1000 mg/dL of hemoglobin, cholesterol, and triglycerides or up to 20mg/dL of bilirubin did not interfere with the recovery of BNP. The hematocrit may vary between 27% and 51% without a significant effect on the recovery of BNP.

14.4 Clinical Sensitivity/Specificity/Predictive Values

Males	Age <45	Age 45-54	Age 55-64	Age 65-74	Age 75+
Sensitivity 95% Confidence Interval	81.6%	76.0%	75.6%	79.3%	82.4%
	70.8-92.5%	67.5-84.6%	68.2-82.9%	72.6-86%	76.1-88.7%
Specificity 95% Confidence Interval	98.9%	99.5%	98.3%	98.9%	95.8%
	97.4-100.0%	98.5-100.0%	97.7-98.9%	98.4-99.4%	94.7-96.9%

Females	Age <45	Age 45-54	Age 55-64	Age 65-74	Age 75+
Sensitivity 95% Confidence Interval	82.1%	69.0%	82.4%	97.9%	91.9%
	68.0-96.3%	57.1-80.9%	71.9-92.8%	93.7-100.0%	85.2-98.7%
Specificity 95% Confidence Interval	100.0%	98.9%	96.4%	95.0%	75.7%
	100.0-100.0%	97.5-100.0%	95.5-97.4%	93.4-96.7%	72.2-79.2%

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Safety Data Sheets (SDS)
4. Quest Diagnostics Records Management Procedure
5. Triage BNP Maintenance Log (AG.F169)
6. BNP QC Simulator Log (AG.F170)
7. Current package insert Triage BNP Test Product

17. REFERENCES

1. Current Package Insert of Triage BNP Test Product Insert, revised 04/2015.
2. Triage BNP Calibration Verification Product Insert, PN 26174, Rev 03/2015
3. Triage BNP Control Product Insert, PN 26148, Rev 03/2015

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes H017.001		
000	7/27/2012		Add instrument name to title	L. Barrett	J. Buss, RSL
000	7/27/2012	8	Add testing patients in duplicate	J. Buss	J. Buss, RSL
000	7/27/2012	10.5	Edit instructions for reporting duplicate testing, add steps for LIS entry at SGAH/WAH	J. Buss	J. Buss, RSL
001	8/12/2014		Update owner	H Genser	R SanLuis
001	8/12/2014	4.2	Add not to return to refrigeration	H Genser	R SanLuis
001	8/12/2014	7.2	Add centrifuge	H Genser	R SanLuis
001	8/12/2014	10.2	Add rounding to whole number	H Genser	R SanLuis
001	8/12/2014	10.5	Updated LIS resulting (worksheet, repeat criteria RE: CRR / AMR)	H Genser	R SanLuis

Version	Date	Section	Reason	Reviser	Approval
001	8/12/2014	13	Add to maintain sample type when comparing results	H Genser	R SanLuis
001	8/12/2014	14.4	Added Clinical Sensitivity / Specificity	H Genser	R SanLuis
001	8/12/2014	16	Move forms from section 19	L Barrett	R SanLuis
001	8/12/2014	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis
2	10/5/2016	Header	Add WAH	L Barrett	R SanLuis
2	10/5/2016	4, 5, 6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
2	10/5/2016	10.5	Review data moved from section 6	L Barrett	R SanLuis
2	10/5/2016	15	Update to new standard wording	L Barrett	R SanLuis
2	10/5/2016	17	Update PI revision dates	L Barrett	R SanLuis

19. ADDENDA

None