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**Manual: Chemistry Manual I**

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**TRIAGE BNP TEST**

1. **PRINCIPLE/PURPOSE**

## The Triage® BNP Test is a rapid, point of care fluorescence immunoassay to be used with the Triage Meters for the quantitative measurement of B-type natriuretic peptide (BNP) in EDTA anticoagulated whole blood or plasma specimens. The test is intended to be used as an aid in the diagnosis and assessment of severity of congestive heart failure. The test also is used for the risk stratification of patients with acute coronary syndromes and for the risk stratification of patients with heart failure.

## The test procedure involves the addition of EDTA whole blood or plasma specimen to the sample port on the Test Device. After the addition of the sample, the cells are automatically separated from the plasma via a filter contained in the Test Device. The sample reacts with fluorescent antibody conjugates within the reaction chamber and flows down the Test Device detection lane by capillary action. Complexes of each fluorescent antibody conjugate are captured on discrete zones resulting in binding assays that are specific for each biomarker

1. **SPECIMEN REQUIREMENTS**
   1. **PATIENT PREPARATION**

N/A

* 1. **SPECIMEN TYPE**

A venous whole blood or plasma specimen using EDTA as the anticoagulant is required for testing with this product. Other blood specimen types have not been evaluated.

* 1. **SPECIMEN VOLUME**

A minimum volume of 1.0ml is needed in order to perform this test.

* 1. **SPECIMEN HANDLING and STORAGE**

### Test whole blood specimens on the Test Device immediately or within 7 hours of collection. If testing cannot be completed within 7 hours, the plasma should be separated and stored at -20°C until it can be tested.

### Specimens should be transported at room temperature or chilled and avoid extreme temperatures.

## SPECIMEN REJECTION CRITERIA

## Severely hemolyzed specimens are reason for rejection and another specimen should be obtained.

# EQUIPMENT/REAGENTS/SUPPLIES

## EQUIPMENT

### Triage Meter with Reagent Code Chip Module®

## REAGENTS

### Test Device

#### Unopened Test Devices are stable up to the expiration date when stored refrigerated at 2ºC to 8ºC (35ºF to 46ºF) or for a total of 14 days at room temperature.

#### Once a Test Device is removed from refrigeration it must be marked with the date of removal as well as the 14 day expiration date.

### Controls

#### Triage Control 5, Level 1

#### Triage Control 5, Level 2

## SPECIAL SUPPLIES

### Reagent Code Chip

#### The calibration and expiration data for each new lot of Test Devices is stored on a chip.

#### The Reagent Code Chip is inserted into the Triage® Meter and the information is transferred and stored until a new lot is placed into service.

##### This procedure is performed only once for each new lot of Test Devices.

##### From the main screen, select <Install New Code Chip>. Press Enter.

##### Place the Reagent Code Chip module into the lower left side corner of the Meter and follow the prompts on the screen.

##### Remove the Reagent Code Chip module from the Meter when the data transfer is complete.

##### Refer to the Triage® Meter User Manual for complete instructions describing the Installation of Code Chip modules.

# CALIBRATION/VERIFICATION

## CALIBRATORS

### Triage® Total Calibration Verification 5 samples

## FREQUENCY

### Every 6 months.

### Or whenever it is necessary to test system performance.

## CALIBRATION PROCEDURE

### Triage® Total Calibration Verification 5 samples are tested in the same manner as the patient samples. (See VII.B below)

## ACCEPTABLE LIMITS

### Results must be within +2 SD of expected values unless otherwise specified by the manufacturer.

# INTERNAL QUALITY CONTROL

## QC MATERIALS

### QC device individualized for each instrument.

## FREQUENCY

### To be run daily, before any testing, as a regular maintenance routine.

## ACCEPTABLE LIMITS

### If an error is obtained, refer to the Operator’s Manual for further instruction.

# EXTERNAL QUALITY CONTROL

## QC MATERIALS

### The Triage® Total Controls 5 are assayed materials to be used with the Triage BNP, and the Triage Meter.

### Triage Level 1 and corresponding Control Code Chip™ module

### Triage Level 2 and corresponding Control Code Chip™ module

## FREQUENCY

### Each time a new lot or shipment of Triage Devices is received.

### Every 30 days.

### Whenever it is necessary to test the performance of the user or system.

## HANDLING AND STORAGE

### The Triage® Total Controls are shipped frozen and to be stored at -20°C until use.

### As long as the proper storage requirements are met, the controls will be stable until the date on the box.

### Control materials should not be refrozen once thawed.

## PREPARATION

### Remove only the tubes to be used from the box. Return the remaining tubes to the freezer immediately.

### Thaw at room temperature (19°C - 25°C) for at least 30 minutes.

### Use within 1 hour of removal from the freezer.

### Mix thoroughly by vortexing or inversion prior to testing.

### The Test Device should remain in the sealed pouch until the materials are thawed and ready for use.

## PROCEDURE

### Mix the materials thoroughly before use.

### Test the controls in the same manner as patient specimens are tested.

#### Hold the tube with the tip facing upward ensuring that all material is at the bottom of the tube.

#### Snap off the tab.

#### Turn the tube over and dispense entire contents into the sample port of the Test Device.

#### Discard the empty tube.

### Program the QC sample to run.

#### From the main screen, select <Run Test> and press Enter.

#### Select <QC Sample> and press Enter.

#### The screen will read Enter high or low vial LN. Enter the number located in the crimp at the bottom of the vial.

#### If it is a different lot number than already programmed in the Meter then the Meter will ask for the new QC code chip to be inserted.

##### *Note: Follow the procedure on Installing New Code Chips in the manual or III.C.b from above for further assistance.*

### Insert the Test Device into the Meter and press **<Enter>**.

### The results should print when testing is completed. If the analyte is out of range then it will be outlined in black and should be repeated.

### Repeat the steps for the next level of QC.

## ACCEPTABLE LIMITS

### Results must be within +2 SD of expected values unless otherwise specified by the manufacturer.

# ASSAY PROCEDURE

## ADD SAMPLE

### Open the pouch and label the Test Device with the patient specimen number.

### Using the transfer pipette, squeeze the larger (top) bulb completely and insert the tip into the specimen.

### Release the bulb slowly. The transfer pipette 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 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.

## RUN TEST

### From the main screen, select **<Run Test>** and press **Enter**.

### Select **<Patient Sample>** and press **Enter**.

### Scan or manually type your Operator ID and press **Enter**.

### Scan the Patient ID barcode and press **Enter**.

### Confirm that the ID number is correct and select **<Confirm Patient ID>** and press **Enter**.

#### *If the ID number was not correct, select <Correct Patient ID>, press Enter then repeat the previous step.*

### Insert the Test Device into the Meter and press **Enter**. The amount of the analyte present in the sample will be displayed when the analysis is complete. *Note: The Test Device should be entered into the Meter within 30 minutes from the time the sample was added.*

## READ RESULT

### The results should print automatically but can also be printed by pushing the **Print** button.

### Discard the Test Device after release from the Meter in appropriate biohazard container.

### A blocked out result indicates the result was invalid and the test should be repeated.

# REPORTING RESULTS

## EXPECTED VALUES

### BNP results less than or equal to 100 pg/mL are representative of normal values in patients without CHF.

### BNP results greater than 100pg/mL are considered abnormal and suggestive of patients with CHF.

## REPORTING FORMAT

## Triage BNP has been standardized using a purified protein preparation of BNP based on the mass of the analyte present in EDTA anticoagulated plasma and is reported in pg/mL.

## LINEARITY

The BNP range reported by the test system is 5pg/mL to 5000pg/mL. A BNP result of >5000pg/mL are considered very high values for BNP and exceed the upper limits of the BNP test.

## INTERFERING SUBSTANCES

### Hemoglobin (up to 1,000 mg/dL), lipids (cholesterol up to 1,000 mg/dL and triglycerides (up to 1,000 mg/dL) or bilirubin (up to 20 mg/dL) added to plasma specimens containing BNP did not interfere with the recovery of BNP.

### The hematocrit was varied between 27% and 51% with no significant effect on the recovery of BNP.

## TURNAROUND TIME

STAT – 1 hour

# PROCEDURE NOTES

## CLINICAL INTERPRETATION

### 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 indicates an increased risk of hospitalization or death in patients with heart failure.

# LIMITATIONS of METHOD

## The results of the Triage® BNP should be evaluated in the context of the clinical and laboratory data available. In those instances where laboratory results do not agree with the clinical evaluation of the patient, then additional testing should be performed.

## The test has been evaluated with EDTA whole blood and plasma. Serum and blood or plasma with other anticoagulants have not been evaluated and therefore should not be used.

## There is a possibility that factors such as technical or procedural errors, as well as additional substances in blood specimens may interfere with the test and cause erroneous results.

# ACTION TO BE TAKEN IF METHOD BECOMES INOPERABLE

## If all three Triage® Meters become inoperable or the Triage® BNP Test Devices are not performing correctly, all testing will be done on the laboratory’s Chemistry analyzers.

# REFERENCES

## Triage® BNP Product insert, Alere, 2011.

## Triage® Calibration Verification 5 Product insert, Alere, 2011.

## Triage® Total Control 5 Product insert, current edition

## CLSI Procedure Manual,CLSI Document GP2-A2.

***Signature Page***

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**XI. APPROVAL SIGNATURES**

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