Company Name and Logo

Alere Triage Cardiac Panel

Effective Date:	SOP No.	Version No.
Author:	Approval Signature:	
Date:	Date:	

A. PRINCIPLE

The Alere Triage® Cardiac Panel is a single use fluorescence immunoassay device designed to determine the concentration of CK-MB, myoglobin and troponin I in EDTA anticoagulated whole blood or plasma specimens.

The test procedure involves the addition of several drops of an EDTA anticoagulated whole blood or plasma specimen to the sample port on the Test Device. After addition of the specimen, the whole blood cells are separated from the plasma using a filter contained in the Test Device. The specimen reacts with fluorescent antibody conjugates and flows through the Test Device by capillary action. Complexes of each fluorescent antibody conjugate are captured on discrete zones specific for each analyte.

B. SPECIMEN

A venous whole blood or plasma specimen using EDTA as the anticoagulant is required for testing with this product. Whole blood samples must be tested within 4 hours of collection. If testing cannot be completed within 4 hours, separate out plasma and freeze at -20*C until it can be testing. No more than a single freeze/thaw cycle is recommended. Avoid using severely hemolyzed specimens whenever possible. If a specimen appears to be severely hemolyzed, another specimen should be obtained and tested.

Frozen plasma and refrigerated whole blood or plasma specimens must be allowed to reach room temperature and be mixed thoroughly before testing. Mix whole blood specimens by gently inverting the tube several times. Mix plasma specimens by vortexing or inverting the tube several times.

C. REAGENTS, SUPPLIES AND EQUIPMENT

REAGENTS - Test devices are stored in a refrigerator at 2-8*C and must reach operating temperature of 22-24*C prior to use. Allow 15 minutes for individual foil pouches and 1 hour for a full kit to reach room temperature. Thawed Test Devices are stable up to 14 days at room temperature or expiration date of pouch, whichever is soonest. Test Devices cannot be returned to refrigeration after thawing.

SUPPLIES - Use transfer pipette provided in the kit. Do not use a non-Triage transfer pipette.

EQUIPMENT - Triage Meter Pro.

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D. PRECAUTIONS

- Do not use the kit beyond the expiration date printed on the outside of the box.
- Perform test between 20-24*C (68-75*C).
- Keep the Test Device in the sealed pouch until ready for immediate use.
- Test Device is for single use only. Discard in biohazard container.
- Do not test diluted samples.
- Do not use non-Alere controls or calibrations.
- Follow laboratory safety guidelines.

E. PROCEDURE

STEP 1 – Add Patient Specimen

1. Open the pouch and label the Test Device with the patient identification number. *NOTE: Do not use fluorescent or brightly colored ink, or write outside of the blank area as this may interfere with the test.* Place the Test Device on a level, horizontal surface.
2. Using the transfer pipette, squeeze the larger (top) bulb completely and insert the tip into the specimen.
3. Release the bulb slowly. The transfer pipette barrel should fill completely with some fluid flowing into the smaller (lower) bulb. *NOTE: Ensure that the pipette is not under filled or overfilled. An under filled pipette is one where the barrel is not filled completely with sample and there is no sample in the lower bulb. An overfilled pipette is one where there is some sample in the top bulb. Ideally the lower bulb should contain a small amount of sample (less than one quarter the volume of the lower bulb).*
4. Place the tip of the transfer pipette into the sample port of the Test Device and squeeze the larger bulb completely. The entire volume of fluid in the transfer pipette barrel must ow into the sample port. The specimen in the smaller (lower) bulb should not be expelled. *NOTE: Too much sample has been added to the device if the sample has migrated outside of the sample port and on to the label.*
5. Remove the transfer pipette tip from the sample port and then release the larger (top) bulb.
6. Discard the transfer pipette.
7. Allow specimen to absorb completely before moving the Test Device. At a minimum the sample should be below the sample port opening to be considered fully absorbed. Otherwise, blood will contaminate the equipment or insufficient sample quantity may invalidate the results.

STEP 2 – Run Test

1. From the main screen, select **Run Test** and press **Enter.**
2. Select **Patient Sample** and press **Enter**.
3. Enter the patient's MRN and press **Enter**.
4. 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.
5. Holding the Test Device by the edges, insert the Test Device into the Meter and press **Enter**. The results will be displayed when the analysis is complete. *NOTE: The Test Device must be inserted into the Meter within 30 minutes from the time the patient specimen was added. A delay longer than 30 minutes may cause the results to be invalid and blocked out on the printout.*

STEP 3 – Read the Results

1. Results may be printed by pressing the **Print** button.
2. Discard the Test Device after release from the Meter.
3. A blocked out result indicates the result was invalid and the test should be repeated.

F. INTERPRETATION OF RESULTS

The Meter measures the target analyte(s) automatically. The results are displayed on the screen. The operator has the option to print the results.

Temporal elevations of CK-MB, myoglobin and troponin I are observed in patients diagnosed with myocardial infarction. However, CK-MB and myoglobin, but not cardiac troponin I, may be elevated in renal disease and skeletal muscle injury. Cardiac troponin I appears to be elevated only in those diseases that directly involve the heart. Collectively, the diagnosis of myocardial infarction should include measurement of these cardiac related proteins and other clinical information including patient history and electrocardiographic data. Other conditions that may result in elevated cardiac proteins are: cardiac contusions, myocarditis, invasive examination of the heart, coronary artery bypass surgery, congestive heart failure and unstable angina. Therefore, these data must be considered when interpreting the results.

G. REFERENCE RANGE

CK-MB: 0.0 – 4.3 ng/mL

Myoglobin: 0.0 -107 ng/mL

Troponin I: 0.00 – 0.40 ng/mL

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H. CRITICAL VALUES

CK-MB: ≥ 8.0 ng/mL

Myoglobin: ≥ 170 ng/mL

CK-MB: ≥ 0.4 ng/mL

I. QUALITY CONTROL

Use the QC Device to ensure proper function of the Meter. Perform QC Device testing for the following conditions: upon initial setup of the Meter, each day of patient testing, when the meter has been transported or moved, whenever there is uncertainty about the performance of the Meter and when the laboratory's quality control guidelines requires it.

Do not discard the Alere Triage QC Device and associated CODE CHIP module. Store them in the QC Device Box.

Installing the CODE CHIP for a new QC Device.

1. The first time a new QC Device is run in the meter, install the QC Device CODE CHIP module. The QC Device CODE CHIP module data is stored in the Meter memory.

    a. From the main screen, select Install New Code Chip and press Enter.
    b. Place the QC Device CODE CHIP module into the lower left front corner of the Meter. Follow the prompts on the screen.
    c. Remove the QC Device CODE CHIP module from the meter when data transfer is complete.
    d. Place the QC Device CODE CHIP module back into the QC Device box for storage.
2. From the main screen, select **Run Test** and press **Enter.**
3. Select **QC Device** and press **Enter.**
4. Insert QC Device into the Meter and press **Enter.**
5. A Pass or Fail result will be displayed when complete. Each parameter should pass before patient testing is performed.
6. Remove the QC Device from the Meter and place in the QC Device Box. **DO NOT DISCARD THE QC DEVICE.**

NOTE: If the QC Device or external controls do not perform as expected, review the above instructions to see if the test was performed correctly and repeat the test. Contact Alere or your local Alere representative (refer to Contact Alere section). Inform the laboratory supervisor whenever the device is not working within specifications.

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J. LIMITATIONS OF PROCEDURE

- Test results should not be used as absolute evidence of myocardial infarction and should be evaluated in the context of all the clinical and laboratory data available. In those instances where the test results do not agree with the clinical evaluation, additional tests should be performed accordingly.
- Patients with skeletal muscle injury may have elevated CK-MB and myoglobin. Patients with renal failure may have elevated CK-MB and myoglobin.
- Failure to display or report troponin I results invalidates the use of the test as an aid in the diagnosis of myocardial infarction (injury).
- This test has been evaluated with venous whole blood and plasma using EDTA as the anticoagulant. Other specimen types, draw methods, or anticoagulants have not been evaluated.
- As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the sample. The test has been formulated to minimize this interference; however, specimens from patients who have been routinely exposed to animals or to animal serum products may contain heterophile antibodies which may cause erroneous results.
- There is the possibility that factors such as technical or procedural errors, as well as additional substances in blood specimens that are not listed below, may interfere with the test and cause erroneous results.

K. 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 EDTA anticoagulated plasma containing the three analytes did not interfere with the recovery of the analytes. Hemolyzed, lipemic and icteric samples did yield a false positive result on any of the three analytes. However, severely hemolyzed samples should be recollected.

Certain drugs were tested for cross-reactivity and interference in the Alere Triage Cardiac panel. None of the drugs interfered with the recovery of CKMB, myoglobin or troponin I. For the full list, refer to the Alere Triage Meter User manual.

L. FORMS/TEMPLATES TO BE USED

Cardiac Panel and D-Dimer record result form.

Cardiac Panel Test Result form for downtime use.

Biosite Triage MeterPro Daily Electronic QC Worksheet.

Alere Triage control record form.

Where Forms/Templates are referenced in the text, the numbers and titles are listed under this section.

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M. REFERENCES

Alere Triage Cardiac Panel Product Insert (2014). Rapid Quantitative Test for Creatinine Kinase (CK-MB), Myoglobin and Troponin I.

This section is used to list all controlled internal references (e.g. SOPs) and external references referred to within the text of the SOP only.

N. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.