**CHEM.TRIAGE.1.0 TRIAGE CARDIAC PANEL TEST FOR EDTA WHOLE BLOOD AND PLASMA**

**PRINCIPLE**

The Triage® Cardiac Panel is a fluorescence immunoassay for the quantitative determination of the cardiac proteins, CK-MB, myoglobin and troponin I in whole blood and plasma specimens using EDTA as the anticoagulant. After addition of the sample to the sample port, the cells are separated from the plasma via a filter contained in the device. A predetermined quantity of plasma is allowed to react with fluorescent antibody conjugates within the reaction chamber. After sufficient incubation has occurred, the reaction mixture flows down the device detection lane. Complexes of the analytes and fluorescent antibody conjugates are captured on discrete zones resulting in binding assays that are specific for each analyte. The concentration of the analyte in the specimen is directly proportional to the fluorescence detected.

The testing is used as an aid in the diagnosis of myocardial infarction. The Triage® Cardiac System is unique in that its greatest benefits lies in the ability to measure up to 3 cardiac markers simultaneously and enables the use of accelerated algorithms to monitor changes to the markers over time. Several landmark studies have demonstrated the exceptional clinical value of this strategy versus single marker testing.



**SCOPE**

All MACL laboratories performing the Triage Cardiac Panel Test.

**OWNERS**

Manager, MACL Community Hospital South Laboratory

Chemistry Best Practice Team

**SPECIMEN**

A. Patient preparation:

1. No special preparation needed.

B. Specimen type:

1. Whole blood or plasma using only EDTA as the anticoagulant, 3-7 ml tubes.

2. Unacceptable specimens are grossly hemolyzed, clotted specimens, tubes less than half full.

C. Specimen stability:

1. If testing cannot be accomplished within 4 hours after receipt, the separated plasma should be stored at -20° C until tested. Those specimens that are stored frozen should reach room temperature and be mixed prior to testing.

**REAGENTS**

A. Triage® Cardiac Panel Test Device contains all the reagents necessary for the simultaneous quantification of the cardiac proteins CK-MB, myoglobin and troponin I in plasma and whole blood.

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| Test Device:  | Murine monoclonal and polyclonal antibodies against CK-MB, murine monoclonal and polyclonal antibodies against myoglobin, and murine monoclonal and goat polyclonal antibodies against troponin I labeled with a fluorescent dye and immobilized on the solid phase and stabilizers. |

1. The Triage® Cardiac Panel Test Device should be stored at refrigerator temperature (2°-8°C or 35°-46°F) and is stable until the date stamped on the box or on the foil pouch.

2. The Triage® Cardiac Panel Test Device (once removed from the refrigerator) is stable for 14 days when stored in the foil pouch at room temperature. Do not exceed the printed expiration date on the package.

3. Gently write the date the test device is taken out of the refrigerator along with the discard date on the foil pouch and/or the kit box using a soft, felt tip marker if the test device is not to be used the same day.

4. Allow a minimum of 15 minutes for the test device to reach room temperature before use for individual foil pouches. If entire kit box is removed from refrigeration, allow box to reach room temperature a minimum of 1 hour.

5. Do not remove the test device from the foil pouch until ready to use.

**EQUIPMENT**

A. Biosite Diagnostics Triage® Cardiac Panel Test Kit

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| **Kit Contains** | **25 Test Kit** |
| Test Device | 25 each |
| Transfer Pipettes | 25 each |
| Reagent Code Chip | 1 each |
| Printer Paper | 1 roll |

B. Triage® MeterPro

C. Triage® Census Plus Data Management System, optional

**CALIBRATION/CALIBRATION VERIFICATION**

A. Reagent Code Chip:

1. The Reagent Code Chip contains calibration data that is specific for the test kit lot number. Each box of test kits includes a Reagent Code chip.

2. Enter the corresponding Reagent Code Chip into the analyzer with each change in kit lot number.

3. Analyze both levels of external QC after a new Reagent Code Chip has been entered and prior to patient testing. See Quality Control section.

B. Total Calibration Verification is used to verify the calibration of the test devices throughout the measureable range.

Alere recommends running Calibration Verification samples every 6 months.

The order number for the Total Calibration Verification set is 88755. The Total Calibration set contain 2 vials of 5 levels X 0.25mls. The Total Calibration Verification Set is stored at -20oC or colder in a non defrosting freezer. Do not store near the door and do not refreeze material.

**FOR EACH DEVICE TYPE:**

1. Remove 1 set of 5 levels of Calibration Verification samples from freezer.
2. Thaw at room temperature (19oC to 25oC) for 30 minutes. Use within one hour of removal from frozen storage.
3. Mix the control thoroughly by vortexing or inversion prior to testing.
4. Open a device and label device with the vial lot number (can be obtained from the expected values card or the vial).
5. Hold tube with tip facing upward. Make sure all the liquid is at bottom of the vial.
6. Open vial by twisting the tab at the top. Turn the tube over and dispense entire contents into sample port of the test device. Discard the empty tube.
7. Allow the fluid to absorb into the filter.
8. To run in meter: Highlight **Run Test** on the display panel. Press **Enter** to select.
9. Enter your ID number and press **Enter** (if applicable).
10. Use the arrow key to highlight **Patient Sample**. Press **Enter**.
11. Type in the lot number of the calibration verification vial. Enter 1 for the first sample. Press **ENTER** until you see the message ***Measurement in Progress*** on the meter screen.
12. You may apply the second Calibration Verification sample to a test device a few minutes after the first test device is put into the meter.
13. Review the results printed out by the meter to make sure all the test results are within + 2 SD of the mean.
14. Run the rest of the Calibration Verification samples following the same instructions.
15. **METER-TO-METER VERIFICATION:** If multiple meters are used, take the device from the first meter and run it on the second meter and so on. The first reading should take approximately 15 minutes. Subsequent reading should take approximately 2 minutes each. Once inoculated, each device may be read for up to 30 minutes.
16. If the Cal Ver results are > + 2 SD, remove a 2nd vial, thaw 30 minutes and rerun. If it fails again, call Alere technical service. 1-877-308-8287.
17. Enter all data and information, including all meter serial numbers, device, control and cal ver lot numbers, into the form and email to: William.sbai@alere.com.

**QUALITY CONTROL**

A. QC Simulator:

1. The QC Simulator mimics a test device and checks the following instrument functions:

a. Optics/Calibration

b. Laser stability

c. Carrier alignment

2. The QC Simulator provided with the Triage® Meter must be tested daily to verify instrument performance.

B. External Quality Controls:

Triage® Total Control 5 Level 1 (5 x 0.25 ml) with control chip

Triage® Total Control 5 Level 2 (5 x 0.25 ml) with control chip

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| ***Warning:*** The human source material used to produce this product has been tested for hepatitis B antigen, antibodies to hepatitis C, HIV-1 and 2 and found to be non-reactive when using licensed reagents. Inasmuch as no known test method can offer complete assurance that infectious agents are not present, the reagents and patient samples should be handled as though they are capable of transmitting disease. |

1. External Quality Controls are to be analyzed with each new shipment or lot of product, and at least every thirty days. Controls may be run to verify test performance as needed.

2. Controls are stable until the expiration date on the box when stored at < -20°C in a non-defrosting freezer where possible.

3. Thaw controls until room temperature and mix well by inversion prior to use.

4. Controls should be used within 1 hour of thawing.

5. Do not refreeze control material. Each vial should be used once and then discarded.

C. Internal Quality Controls:

1. Each Triage® Cardiac Panel contains two internal positive controls that satisfy routine quality control requirements. These controls indicate that sufficient sample was applied to the panel, the unbound fluorescent label washed sufficiently from the detection zone, and the panel was inserted and read properly by the meter.

2. An unacceptable result from either control displays a warning message on the Triage® Meter indicating that the test should be repeated. Lack of sample results will be indicated by dashes.

a. If a whole blood sample results in an error message, “Warning: Internal QC Out of Range,” spin the sample down and test the plasma. If the plasma does not result in an error message, the results are reportable.

b. If the error message “Measurement Failure” is displayed, insufficient sample was added to the device. This could be due to:

i. Improper use of the Biosite provided pipette

ii. Clot or fibrin strands present in sample

**PROCEDURE**

A. QC Simulator

1. Upon initial receipt of a QC Simulator, the Simulator data must be loaded into the meter by installing the QC Simulator Code Chip.

a. Switch the Triage® Meter on.

b. Select “Install Code Chip” using up/down keys from the Main Menu.

c. Press <Enter>

d. Install selected code chip in port reader.

e. Press <Enter>

f. Code chip information is automatically installed into meter memory.

g. Remove code chip from port.

h. If installation is unsuccessful, call Biosite Technical Service.

2. Perform Simulator test.

a. At MAIN MENU select RUN TEST and <ENTER>. Type in Sunquest user ID if prompted. Select QC Simulator and <ENTER>.

b. At the prompt, insert QC Simulator into meter until it clicks and press <ENTER>.

c. The device will be drawn into the meter.

d. PASS or FAIL results will appear on the screen and the meter will release the QC Simulator upon test completion. Results will automatically print.

e. Remove the QC Simulator from the meter and return it to the black storage box.

***Note:*** The QC Simulator is light sensitive and must be stored in the black box provided.

f. Record the Simulator results on the Triage Meter® Daily Maintenance Log.

g. If any of the tested functions fail, clean the QC Simulator with canned air or a lint free cloth and repeat the test. If the failure continues, contact Biosite Technical Service. If any of the QC Simulator checks fail, no patient QC samples can be tested.

B. QC Sample

1. Install Reagent Code Chip if necessary.

2. Remove Reagent Code Chip from meter port. Once any chip is loaded into the meter memory the chip does not need to remain in the port.

3. Install QC Code Chip.

4. Remove QC Code Chip from meter port and store with remaining frozen controls.

5. Log the QC sample into the appropriate log sheet if applicable.

6. Open the pouch, remove the test device and label with an identifier.

7. Vortex thawed QC material for approximately 30 seconds.

8. Dispensing contents from the tube

a. Hold the tube with the tip facing upward. Ensure that all material is at bottom of the tube.

b. Snap off the tab

c. Turn the tube over and dispense entire contents into the sample port of the test device.

d. Discard empty tube

9. At MAIN MENU, select RUN TEST and <ENTER>. Type in Sunquest user ID if prompted.

10. Select QC SAMPLE and <ENTER>.

11. Enter QC lot number from the label on the side of the vial, not from the side of the box, using numbers only. To correct if necessary, press DELETE and retype correct numbers. Press <ENTER>.

a. External QC Samples must be run in pairs. Both Level 1 and Level 2 are to be run consecutively. The meter will not recognize that QC is valid if only one level is run and the NUMBER OF CONTROLS setting is set to 2.

b. Do not re-insert the reagent code chip after QC has been run. Inserting the reagent code chip resets the QC Sample timer and QC samples will need to be repeated.

c. If the NUMBER OF CONTROLS setting is 2 and the 2nd level is rerun, the meter resets the counter and both levels must be run again. Example: Level 1 passes, Level 2 passes but the technician decides to run Level 2 again, the meter will reset the counter with the 2nd run and require Level 1 to be run again.

12. Insert the test device gently into the Triage® Meter until a click is heard.

**Note:** Once sample has been pipetted into a device, the device must be inserted into the meter within 30 minutes. If for any reason there is a delay, the test must be set up again using a new test device.

13. The results will be available in approximately 15 minutes.

14. The test device will be released from the analyzer upon test completion. Discard the test device appropriately. Up to four additional devices may be set up within the first 15 minutes of the initial device insertion.

15. Results may be read on the display screen or from meter printout. Document appropriately.

16. If results are blacklit on screen or printout then QC sample is greater than +/-2 SD and must be repeated. If External QC continues to fail, contact Biosite Technical Service.

17. Reagent Lots – QC

a. A list of Reagent Code Chips in memory, along with corresponding expiration dates for QC sample can be recalled from memory. The list will contain the Lot number, Panel type and expiration date (if the reagent lot expires prior to the QC sample, the reagent lot expiration date will be displayed).

i. If the QC expiration date has passed, the date will be in reverse video.

ii. If the QC for the lot has failed, “FAILED” will appear in reverse video.

iii. If a Code Chip has been installed for a new lot but QC has yet to be established, the words “NOT RUN” will appear in place of this expiration date.

iv. To access the information at MAIN MENU, select recall results, QC results, Reagent Lots – QC.

C. Patient Sample

1. Log patient information onto the appropriate log sheet, if applicable.

2. Open pouch, remove test device and label with a patient identifier.

3. Add well-mixed EDTA whole blood or plasma into the sample chamber using the transfer pipette provided. To pipette, depress the larger (top) bulb completely and insert the tip into the specimen. Release the bulb slowly. The tube should fill completely with some fluid overflowing into the smaller overflow bulb.

4. Place the tip of the pipette into the smaller port of the device and depress the larger bulb completely. The entire amount of sample in the pipette tube must be dispensed. The sample in the smaller overflow bulb will not be expelled.

5. Discard the transfer pipette into the biohazard trash.

6. At MAIN MENU, select RUN TEST and <ENTER>. Type in Sunquest user ID if prompted.

7. Select PATIENT SAMPLE and <ENTER>. Either scan Sunquest barcode with scanner or type in accession number and press <ENTER>.

8. Confirmation of the correct entry is required. If correct, press <ENTER>. If incorrect, select correct patient ID and press <ENTER>. Then press DELETE and retype the numbers. Press <ENTER>.

9. Insert the test device gently into the Triage® Meter until a click is heard.

***Note:*** Once sample has been pipetted into a device, the device must be inserted into the meter within 30 minutes. If for any reason there is a delay, the test must be set up again using a new test device.

10. The results will be available in approximately 15 minutes.

11. The test device will be released from the analyzer upon test completion. Discard the test device appropriately. Up to four additional devices may be set up within the first 15 minutes of the initial device’s insertion.

12. Results may be read on the display screen or from the meter printout. Document appropriately.

13. If the device’s Internal QC results are unacceptable, the patient result will not be displayed. A warning will appear on the display and printout. To troubleshoot, see QUALITY CONTROL, Section C.

**CALCULATIONS**

The results of the Triage® Cardiac Panel are calculated automatically by the Triage® Meter.

**REPORTING RESULTS**

A. Reference Range:

|  |  |
| --- | --- |
| CKMB | 1.0-4.3 ng/mL |
| MYOGLOBIN | 5.0-107.0 ng/mL |
| TROPONIN I | < 0.05 ng/ml |
|  | Indeterminate range 0.05-0.40 ng/nl |

B. AMR:

|  |  |
| --- | --- |
| TROPONIN I | 0.05 – 24.00ng/mL |
| CK-MB | 1.0-80.0 ng/mL |
| MYOGLOBIN | 5.0-500.0 ng/mL |

C. Critical Range: Not applicable

D. Entering results in

|  |  |  |
| --- | --- | --- |
|  | **Misys** | **QLS** |
| **Function/ Pathway** | MEM | 3,3,1 |
| **Worklist** | Specific to site | Specific to site |
| **Method** | Specific to site | N/A |
| **Test Code** | MYOGL | 51072 CTM |
|  | TROPN | 34693 Troponin I |
|  | CKMB | 51070 CKMB |

E. SVCR Back-up Result Reporting

1. Credit MASMB and TROPI.

2. Using Function REH, order test TROMB, (which is a panel for TROPN, CKMB), making sure to enter correct date and time of collection from the specimen.

F. Report patient results to the tenth for CKMB and Myoglobin results. Report patient results to the hundredth for Troponin results.

G. Report Values:

1. Troponin I result less than 0.05 ng/mL, report as < 0.05, if greater than 24.00 ng/mL, report as >24.00 ng/mL.

2. CK-MB result less than 1.0 ng/mL, report as < 1.0, if greater than 80 ng/mL, report as >80.0 ng/mL.

3. Myoglobin result less than 5.0 ng/mL, report as < 5.0, if greater than 500.0 ng/mL, report as >500.0 ng/mL.

H. If HIS or LIS systems are not functional, see Laboratory Downtime Policy (QA.LIS.10.0).

**PROCEDURE NOTES**

A. When testing cannot be performed, follow appropriate backup policy.

B. Notification of instrument downtime should be made to MACL Client Response, the nursing unit and the backup laboratory receiving specimens.

**LIMITATIONS**

A. The results of Triage® Cardiac Panel, like all other cardiac marker tests, do not provide a definitive diagnosis of myocardial infarction. As with all in vitro diagnostic tests, the results should be interpreted by the physician in conjunction with other laboratory test results and patient clinical findings.

B. 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 have not been evaluated and should not be used.

C. Hemoglobin (up to 10 mg/dL), lipids (cholesterol up to 1000 mg/dL and triglycerides up to 1400 mg/dL) or bilirubin (up to 20 mg/dL) added to heparinized plasma containing the three analytes did not interfere with the recovery of the analytes. However, severely hemolyzed specimens should be avoided whenever possible.

D. There is the possibility that factors such as technical or procedural errors, as well as additional substances in blood specimens that are not listed in the Cardiac Panel product insert, may interfere with the test and cause erroneous results.

**REFERENCES**

A. Biosite Diagnostics, Triage® Cardiac Panel package insert, 22369 Rev D, Biosite Incorporated, 2008/03/26.

B. Triage® Census Plus User’s Guide.

C. Triage® MeterPro Users Guide, 22719 Rev C, 2007/02/09.

D. Triage® Total Controls 5 Product Insert; Rev E, 2009.