

## **Biosite Incorporated Issues Voluntary, Nationwide Recall for Cardiac Marker Test**

### **Contact:**

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**FOR IMMEDIATE RELEASE** – SAN DIEGO, CA, May 5<sup>th</sup> – Biosite Incorporated has initiated a voluntary, nationwide recall of one lot of Triage<sup>®</sup> Cardiac Panel. The test is used by healthcare professionals as an aid in the diagnosis of myocardial infarction (heart attack). The product has been recalled due to reports of low recovery of quality control samples containing Creatine Kinase MB (CK-MB), troponin I and myoglobin on the affected lot. Although there have been no reported issues of patient misdiagnosis associated with this lot to date, low recovery may lead to reporting of falsely low values for CK-MB, troponin I and myoglobin. A root cause investigation has been initiated.

The recall is limited to the Triage<sup>®</sup> Cardiac Panel, Catalog No. 97000HS, Lot #W44467B. Biosite Incorporated has notified its customers via overnight mail and has instructed them to discontinue use of the affected lot and discard any remaining product from the lot that is on hand. The identified lot was distributed to clinical labs in the United States between January and February 2009. Replacement product will be provided to clinical labs with remaining inventory of this affected product lot.

Biosite Incorporated has reported the action to the U.S. Food and Drug Administration.

As is noted in the package insert, the results of the Triage Cardiac Panel 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.

Customers with questions may contact the company at 1-877-441-7440, option 2 (24 hours a day, 7 days a week)

Any adverse reactions experienced with the use of this product, and/or quality problems can also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).