Class I Medical Device Recall: Roche Diagnostics Operations, Inc., Elecsys Troponin I and Elecsys Troponin I STAT Immunoassays

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: March 12, 2012

Product: Elecsys Troponin I and Elecsys Troponin I STAT Immunoassays

Lot numbers: 163176, 163177

Use: Elecsys Troponin I and Elecsys Troponin I STAT Immunoassays are used to determine heart damage as an aid in the diagnosis of a heart attack.

Distribution Dates: June 29, 2011 through January 13, 2012

Recalling Firm:
Roche Diagnostics Operations, Inc.
9115 Hague Road
Indianapolis, Indiana 46256-1025

Reason for Recall: With certain types of plasma samples, doctors may receive a falsely low result (up to a maximum of 50% lower than the actual concentration of Troponin I). These incorrect results may cause serious adverse health consequences, including death.

Public Contact: Customers with any questions about this recall should contact Roche Diagnostics Technical Support, 24 hours a day, seven days a week, at 1-800-428-2336.

FDA District: Detroit District Office

FDA Comments: On March 12, 2012, Roche Diagnostics Operations sent an "URGENT MEDICAL DEVICE REMOVAL" letter to all its customers who received the affected lots of Elecsys Troponin I or Elecsys Troponin I STAT. The letter described the product, problem, and actions to be taken. Customers were instructed to:

- **Immediately discontinue use of the affected products.**
- Discard the affected product from their inventory according to their site's local regulations.
- Contact other sites if their facility distributed the affected products and ensure that Roche Diagnostics Operations' letter reaches those sites.

- Complete and return the attached fax form at 1-888-912-8457.
- File this letter for future reference.
- Contact Roche Diagnostics Technical Support, 24 hours a day, seven days a week, at 1-800-428-2336 for any questions about the information contained in the letter.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the MedWatch FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail, by telephone, or by FAX.

SOURCE [2]

Links:
[1] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
[2] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm301461.htm