PROGRAM SUPPORT CENTER
PSC
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEDICAL SUPPLY BULLETIN

HHS SUPPLY SERVICE CENTER
PERRY POINT, MD 21902

We Service the World

Steven Pearson, Director | John Diesel, Q.A. Specialist, Editor

BULLETIN NO. 1 March 14, 2013

Urgent Medical Device Recall

Dear Valued Customer:

Alere San Diego, Inc. has issued a voluntary recall for the following product:

Alere Cholestech LDX® Multianalyte Control, 2 vial set, Catalog Number 888769, Lot numbers, C2572, C2572A, C2593 and C2593A.

The above listed lot numbers were investigated and it was confirmed that these lots of the LDX Multianalyte Controls may yield results which are out of range high when tested with Alere Cholestech LDX HDL test.

Our inventory records have indicated that we stock the Multianalyte Control under NSN 6550-00-000-6569 and you may have received one or more of the aforementioned kits.

We ask your cooperation in taking the following action:

1. Please examine your inventory and discontinue use of these lots and dispose of them in accordance with your local regulations.

2. Please refer to the attached Alere Customer/ Distributor Verification Form below, this must be filled out and faxed back to Alere.

3. If you have any questions about this recall, please contact John Diesel, SSC Quality Assurance Specialist, at 1-800-642-0263 Ext: 1128 or Alere San Diego Inc. at 1-877-308-8289. We apologize for any inconvenience caused and thank you in advance for your prompt attention to this urgent request.

Steven Pearson

Please complete this form even if you do not have any involved product and
Fax Back to 1-858-805-8457.

Customer/Distributor Verification Form
URGENT MEDICAL DEVICE RECALL

1. We acknowledge receipt of the Alere San Diego, Inc. URGENT MEDICAL DEVICE RECALL dated, March 6, 2013 for the following product:
   - **Alere Cholestech LDX® Multianalyte Control, 2 vial set, Catalog Number 88769, Lots C2572, C2572A, C2593 and C2593A**
2. We confirm that all areas where the product could be located have been checked.
3. **SELECT ALL STATEMENTS THAT APPLY***
   The following has been verified:
   - ☐ We do not have any affected product. If so, indicate zero in the table below.
   - ☐ Product was redistributed to another facility; notice was forwarded.
   - ☐ We will discard the product and would like a replacement of the same configuration we received originally (2mL per vial, 2 vials per level, PN 88769) – Up to 4 week lead time
   - ☐ We will discard the product and would like a credit. (The credit will be processed through your distributor and may take several weeks)**

   Note: You can purchase the new configuration through your distributor (0.25mL per vial, 1 vial per level, PN 88773) – Currently Available with April 15, 2013 expiration

Product Name	Catalog Number	Lot Number	Quantity Discarded	Unit of Measure (EA or BX)	Date Discarded
Alere Cholestech LDX® Multianalyte Control, 2 vial set	88769	C2572			
		C2572A			
		C2593			
		C2593A			

Credits and replacements will be processed on **PO: ASD313MAC

I have read, understood and implemented the required actions.

DATE*: _____

AUTHORIZED SIGNATURE*: _____

PRINT NAME*: _____

TITLE: _____ DEPARTMENT: _____

INSTITUTION*: _____

ADDRESS*: _____

CITY*: _____ STATE*: _____ PHONE*: _____

POSTAL CODE*: _____ COUNTRY*: _____

EMAIL: _____

To satisfy global requirements for regulatory reporting, please complete and return this form within 10 business days of receipt to Technical Service at **Fax Number 1-858-805-8457**.

*** Mandatory field**