



URGENT RECALL NOTIFICATION UPDATE

March 6, 2012

Re: Alere Cholestech LDX® System Recall Notification

Dear Valued Customer:

The purpose of this letter is to update the recall notification that has been previously provided on the Alere Cholestech LDX device and the potential humidity related impact on results for certain analytes tested on the Cholestech LDX® System. As indicated in the previous recall notification, we have identified that a bias may exist due to humidity variability as outlined below. The bias is observed in patient samples and it may not be detected by running quality control material. To adjust for this bias, a humidity sensor was incorporated into ROM pack v3.40 that enables the Alere Cholestech LDX® analyzer to make adjustments for humidity. However, if your Alere Cholestech LDX® Analyzer was not upgraded with a ROM pack v3.40 or higher, then a bias may exist as described in the table below and you must operate your device in a controlled environment that maintains humidity within 40% and 60%. In order to ensure that your environment is controlled, you must monitor the humidity as required in the customer action below.

Analyte	Observed Bias @ 20% Relative Humidity*	Observed Bias @ 80% Relative Humidity*
Glucose (GLU)	4 to 8%	-5 to -8%
Triglycerides (TRG)	5 to 9%	-8 to -11%
Total Cholesterol (TC)	4 to 8%	-4 to -9%
HDL Cholesterol (HDL)	3 to 10%	-9 to -10%
LDL	8%	-8%
ALT	-10 to -21%	10 to 43%
AST	-12 to -16%	13 to 42%

*As compared to 50% Relative Humidity

You can determine the ROM pack version by pressing, and holding, the STOP button for at least 3 seconds when the analyzer is plugged in.

Firmware Version	3.40
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If you received a new Alere Cholestech LDX® analyzer after November 2010, it contains ROM pack v3.40.

CustomerLetter-2879 Revision B



CUSTOMER REQUIRED ACTION

- If your LDX was not upgraded with the ROM pack v3.40 or higher, you must operate your device in a controlled environment that maintains humidity within 40% and 60%. If you are unable to monitor and maintain a controlled environment for humidity between 40% and 60%, the test system is no longer CLIA waived.
 - Contact Alere if you need assistance in following these instructions.
- If you are currently using ROM pack v3.40 or higher, you may continue to use the LDX System per your normal practices.
- Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation.
- If you have forwarded the product listed above to another laboratory, please provide a copy of this letter to them.
- Complete and FAX the enclosed Verification Form within 10 days to confirm your receipt of this notice.

At this point, we are asking that you be aware of the bias and take the required customer actions above. We sincerely regret any inconvenience this may have caused.

Should you have any questions about the information contained in this notification, please contact:

Alere San Diego, Inc.
9975 Summers Ridge Road
San Diego, CA 92121
U.S.A.
Phone: 877 308 8289
FAX: 858 805 8457

Sincerely,

Robert Di Tullio
Vice President
Global Regulatory & Clinical Affairs
Alere, Inc.

CustomerLetter-2879 Revision B



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

**Customer Verification Form
Urgent Recall Notification**

We acknowledge receipt of the Alere San Diego, Inc. notice dated, March 6, 2012 for the **Alere Cholestech LDX[®] System Recall Notification**

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**