



Field Safety Notice

Urgent - Immediate Action Required

Date Issued March 25, 2024

Product

Product Description	Part Number (PN)
Cholestech LDX™ Battery Kit	55170

Note : This product correction impacts all lots of the Cholestech LDX™ Battery Kit received prior to December 1, 2023.

Explanation

This letter is to inform you that Alere San Diego has recently revised the Cholestech LDX™ Battery label warning to include the following important precautionary statement: “Inspect battery for swelling prior to use, do not use if battery appears swollen.” This statement has been added due to the reported presence of swelling in some battery kits. There have been four (4) complaints reported with no adverse events associated with the event. This issue can occur with lithium ion rechargeable batteries.

Swelling may be identified by inspecting the black plastic casing enclosing the battery for bulging or malformation which would cause it to teeter or wobble when placed on a flat, level surface. The potential harms related to exposure to an overheated, warped, and/or broken/opened battery pack casing include burns, mild electric shock, cuts, or abrasions. The charging and use of swollen batteries can lead to further degradation of the product.

The analyzer is able to function without the use of the rechargeable battery when connected directly to A/C power. Therefore, the utilization of the system to perform patient testing is not impacted.

For best performance and longest product life, keep the battery at 40%~60% charge state before storage (less than 3 months).

Impact on Patient Results or Operator Safety

- There is no impact to the test results obtained from the Cholestech LDX™ Analyzer used with swollen batteries.
- Use of swollen batteries may result in burns, mild electric shock, cuts, or abrasions.

**Necessary
Actions**

- Inspect all Cholestech LDX™ Battery Kits for any signs of swelling. DO NOT CONTINUE USE OF BATTERIES THAT APPEAR SWOLLEN.
If your battery pack exhibits any signs of swelling, report the issue to Technical Services to request replacement. The swollen battery should not be used, and should be discarded per local regulations. If the battery appears normal, then it can continue to be used.
- To ensure that the product performs as expected and has the best product life, keep the battery charged at 40-60% prior to storing.
- Complete and return the Customer Reply Form.
- If you have forwarded the products listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
- Please retain this letter for your laboratory records.

**Contact
Information**

If you or any of the health care providers you serve have questions regarding this information, U.S. Customers please contact Technical Service at 877-308-8289. Customers outside the U.S., please contact your local area Technical Service.

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Technical Service.



Customer Required Action

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Please complete this form, even if you do not have any involved product and Fax to +35391680102 or e-mail to Field.Safety.Notifications@abbott.com

Customer Verification Form Field Safety Notification

1. We acknowledge receipt of the Alere San Diego, Inc. notice dated, 25.03.2024 (dd/mm/yyyy).

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.
- Affected product was redistributed to another facility. The contact information for that facility is:
_____.
- We have affected product. We acknowledge that we were made aware of the need to inspect the Cholestech LDX™ Battery Kit for signs of swelling prior to use. Do not use if the batteries appear swollen.

DATE*:

AUTHORIZED SIGNATURE*:

PRINT NAME*:

TITLE:

DEPARTMENT:

INSTITUTION*:

ADDRESS*:

CITY*:

STATE*:

PHONE*:

POSTAL CODE*:

COUNTRY*:

EMAIL:

***Mandatory Field**