Alere San Diego
9975 Summers Ridge Road
San Diego, California, 92121 USA

Single Registration Number (SRN): N/A

Field Safety Notice

Urgent - Immediate Action Required

Date Issued 29.07.2022
dd/mm/yyyy

Product

Product Description	Part Number (PN)
Cholestech LDX® Lipid Profile•GLU Cassette	10-991, 99021, 14-531
Cholestech LDX® TC•HDL•GLU Cassette	10-990
Cholestech LDX® Lipid Profile Cassette	10-989
Cholestech LDX® TC•HDL Cassette	10-987

Note : This product correction impacts all lots of Cholestech LDX® Cassettes.

Explanation

This letter is to inform you that Alere San Diego has identified that bilirubin, at concentrations greater than 2.0 mg/dL (conjugated) or 1.6 mg/dL (unconjugated), can impact the accuracy of Triglyceride (TRG) and High-Density Lipoproteins (HDL). The percent bias for the TRG and HDL analytes were found to be greater than 10%. The Limitations section of the Cholestech LDX® package insert states that a bilirubin concentration of 5 mg/dL resulted in less than 10% interference.

Clinical samples with an endogenous total bilirubin concentration of 5 mg/dL were tested and produced Cholestech LDX results that were lower than the standard clinical reference analyzer by 17.83% for TRG and 21.64% for HDL. Studies conducted by Abbott found that clinical samples spiked with bilirubin levels at 2.0 mg/dL (conjugated) or 1.6 mg/dL (unconjugated) when tested on Cholestech LDX, produced results that are less than 10% for all four analytes compared to results obtained from serum samples spiked with solvent only. Total Cholesterol (TC) and Glucose (GLU) assays are not impacted by 5 mg/dL of endogenous total bilirubin.

The Cholestech LDX® package insert (PI) will be updated with the new bilirubin interference information. Until the PI is updated, all Cholestech LDX® kits will include labeling with this revised information.

Impact on Donor/Patient Results

There is a potential for incorrect patient results:

- Low recovery of TRG and HDL can occur with patient samples containing bilirubin concentrations greater than 2.0 mg/dL (conjugated) or 1.6 mg/dL (unconjugated).

According to data from the 2017–2018 National Health and Nutrition Examination Survey, 43 of the 5,903 patients surveyed (0.728%) had bilirubin concentrations of >1.6 mg/dL. From the article published in Hepatology, Vol. 40, No. 4, 2004, Serum Bilirubin Levels in the U.S. Population: Gender Effect and Inverse Correlation with Colorectal Cancer, only a small percentage of the adult United States population have Bilirubin levels of greater than 2.0 mg/dL. The common causes of raised bilirubin include anemia, cirrhosis, reaction to a blood transfusion, Gilbert syndrome, viral hepatitis, drug reaction, alcoholic liver disease and gallstones. Invariably, all causes of newborn physiological and/or pathological hyperbilirubinemia are characterized by jaundice and other symptoms that are easily recognized and are investigated and run with tests in addition to lipid profile. In the presence of hyperbilirubinemia, the health care provider would not change the therapy, especially to increase the dose of medication, until such time as the bilirubin levels are brought down. In cases with hyperbilirubinemia is due to irreversible causes then the drugs using liver as the first pass are stopped or removed.

Necessary Actions

- Test results from patients with bilirubin levels above 2.0 mg/dL (conjugated) or 1.6 mg/dL (unconjugated) should be verified using another test method.
- 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.

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Customer Required Action

Urgent - Immediate Action Required

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
Urgent Medical Device Recall Notification

1. We acknowledge receipt of the Alere San Diego, Inc. notice dated, 29.07.2022 (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 potential interference presented by bilirubin concentrations greater than 1.6 mg/dL unconjugated and 2.0 mg/dL conjuaged. This change will be taken into consideration when utilizing the product.

DATE*:

AUTHORIZED SIGNATURE*:

PRINT NAME*:

TITLE: DEPARTMENT:

INSTITUTION*:

ADDRESS*:

CITY*: STATE*: PHONE*:

POSTAL CODE*: COUNTRY*:

EMAIL:

***Mandatory Field**