



## Product Information

Abbott Rapid Diagnostics  
Alere San Diego  
9940 Mesa Rim Road  
San Diego CA, 92121

**Date Issued** 30-OCT-2023

**Product** Cholestech LDX™ Analyzer

**Background** This letter is to inform you of an important product update as a follow-up to the product correction letter mailed in May 2022 regarding the Cholestech LDX™ System's bilirubin interference levels. Abbott is continuing to make product improvements to address the noted interference level changes. These improvements include publishing the new FDA-cleared interference level of 2.5 mg/dL for both conjugated and unconjugated bilirubin and new additional limitation statement in our package insert: "Cholestech LDX is not for use in children under the age of 2 years or patients with hyperbilirubinemia (elevated bilirubin levels)." The package insert is available on our eIFU website: [globalpointofcare.eifu.abbott](https://globalpointofcare.eifu.abbott)

In the coming months, Abbott will release a new version of the Cholestech LDX Analyzer software known as the "ROM Pack" (SKU 13184) which will include the new additional limitation statement in the footer of all Cholestech LDX test result printouts. New ROM Pack replacements will be available free of charge for all current analyzers. As a result of this continued improvement, Abbott also is launching a new, slightly longer printer label (SKU 26710) to accommodate this added statement on the printout. Abbott anticipates the new ROM Pack and longer printer roll will be available for shipment by first quarter of 2024.

In the interim, Abbott has created a preprinted label (SKU 21078) with the new limitation statement already printed on it which is compatible with your current Cholestech LDX System. This preprinted label is also available free of charge.

**Order Label Rolls and/or ROM Packs by either:**

- Filling out the online form available at:  
<https://webform.globalpointofcare.abbott/LDX>
- Filling out and returning the attached form (page 2)



**Questions/Concerns?**

Contact Technical Services  
at 877-441-7440 or email us at  
[USProductSupport@abbott.com](mailto:USProductSupport@abbott.com)

# Cholestech LDX™ Universal Printer and ROM Pack Order Form

- ☐ Please send me \_\_\_\_\_ preprinted label roll(s) (Product code: 21078).
- ☐ Please send me \_\_\_\_\_ (number) ROM packs (Product code: 13184) for my \_\_\_\_\_ (number) Cholestech LDX Analyzers — only one ROM pack per Cholestech LDX Analyzer will be shipped. Please note, if the ROM pack is ordered, a roll of labels will be sent.

**Please write the analyzer serial number(s) on the lines below:**

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_

**If you have more than five Cholestech LDX Analyzers, please contact the Abbott customer service team at 877-441-7440 option 1 or email us at [clientservices@abbott.com](mailto:clientservices@abbott.com).**

**Please send the label roll(s) and/or ROM pack(s) to the following address:**

Requested by: \_\_\_\_\_

Ship to: \_\_\_\_\_

Attention: \_\_\_\_\_

Department: \_\_\_\_\_

Phone: \_\_\_\_\_

Address 1: \_\_\_\_\_

Address 2: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

ZIP code: \_\_\_\_\_

**You may send this form in via email to [clientservices@abbott.com](mailto:clientservices@abbott.com).**

