Cholestech LDX® Calibration Verification

CAL VER L1 L2 L3 L4

Package Insert

ENSRC26111B
PN: 26111 Rev. B

Intended Use

Assayed calibration verification material is designed to be used for verifying the reportable range of tests on the Alere Cholestech LDX® System. This material is intended for use with any Alere Cholestech LDX® cassette type that includes total cholesterol, HDL cholesterol, triglycerides and glucose. Each set consists of four vials with 2 mL of liquid material.

Summary and Explanation

Alere Cholestech LDX® Calibration Verification (hereafter referred to as Calibration Verification Material) enables users to monitor the performance of total cholesterol (TC), high density lipoprotein cholesterol (HDL), triglycerides (TRG), and glucose (GLU) test procedures on the Alere Cholestech LDX® System.

Calibration verification is optional for CLIA waived systems, such as the Alere Cholestech LDX® System, under CLIA regulations. However local or state regulations may require that calibration verification is run at regular intervals. Using calibration verification material can be an important quality improvement tool.

The results obtained for each level are compared with the expected values given on the Expected Values Card accompanying the package insert to verify calibration of each analyte.

Reagents

Calibration Verification Material is prepared from human and animal constituents in an aqueous preservative medium containing antimicrobial agents.

Warnings and Precautions

For *in vitro* diagnostic use.

Human and animal source material. Treat as potentially infectious.

The human source material used to produce this product has been tested using FDA-accepted methods and found nonreactive for hepatitis B surface antigen (HBsAg), and for antibodies to hepatitis C (HCV) and human immunodeficiency viruses (HIV-1 and HIV-2). Because no test can offer complete assurance that infectious agents are not present, this product should be considered potentially infectious and handled with the same precautions used with patient specimens.

***Note: Do not use** Calibration Verification Material past the expiration date printed on the vial labels.*

***Note:** This material is not to be used for instrument calibration.*

Storage and Stability

Store upright and refrigerated at 2–8°C (36–46°F). Stored under this condition, unopened vials can be expected to give stable results through the expiration date listed on the box. Opened vials are stable for 30 days refrigerated at 2–8°C (36–46°F). Minimize exposure to strong light.

Do not use the Calibration Verification Material:

- If it is cloudy or has an odor
- If it has been shipped or stored improperly

Materials Provided

Alere Cholestech LDX® Calibration Verification:

Level 1: .....1 x 2 mL
Level 2: .....1 x 2 mL
Level 3: .....1 x 2 mL
Level 4: .....1 x 2 mL

Materials Required but Not Provided

- Alere Cholestech LDX® System
- Alere Cholestech LDX® test cassettes for measuring TC, HDL, TRG, and/or GLU
- Pipette for the required volume of Calibration Verification Material and pipette tips
- Gloves
- Puncture resistant waste container

***Note:** Alere™ pipettes for the required volume are available, but any appropriately calibrated pipette may be used.*

Test Procedure

1. Remove one vial each of Level 1, Level 2, Level 3, and Level 4 Calibration Verification Material from the refrigerator. Note the expiration date and the date opened on vial labels. Do not use expired material.
2. Set the sample type to SAMPLE = "Serum" in the analyzer's configuration menu.
3. Allow vials to sit at room temperature for at least 10 minutes.
4. Test one level of calibration verification material as follows:
   - Refer to the test procedure in the package insert for the test cassette you will be using
   - Mix the Calibration Verification Material vial by gently inverting at least 7 times
   - Use a pipette for the required volume of Calibration Verification Material specified in the test cassette package insert
   - Follow the procedure for running the test cassette in the package insert
   - Replace the cap on the Calibration Verification Material vial after use and store at 2–8°C (36–46°F)
   - Dispose of the pipette tip in a puncture resistant waste container
5. Run two cassettes using each level of Calibration Verification Material. Record both results for each analyte. Calculate the average value of the two results.
6. Record all relevant information as needed, e.g. Alere Cholestech LDX® Analyzer serial number, cassette lot number, Calibration Verification Material lot number, operator name, and date.
7. Repeat this procedure for each of the other three levels of Calibration Verification Material. Use a new pipette tip for each level of calibration verification material.

***Note:** Before you test patient samples, if necessary, reset the sample type in the Alere Cholestech LDX® Analyzer Configuration Menu to the patient sample type you will be using.*

Limitations

The results obtained using the Calibration Verification Material are dependent upon several factors. Erroneous results can occur from improper storage, inadequate mixing, and technique errors associated with the test. For more information, refer to the "Limitations" section of the package insert for the test cassette you will be using and the "Storage And Stability" section above.

Expected Values

Refer to the Expected Values Card for the expected values for each analyte. Be sure that the lot number on the vial of calibration verification material corresponds to the lot number on the Expected Values Card. The average value for each analyte should fall within the ranges on the Expected Values Card.

The target value and expected values for each analyte and each level are derived from data using multiple Alere Cholestech LDX® Analyzers and cassette lots. The expected values apply only to this lot of Calibration Verification Material.

Limited Warranty

For the applicable warranty period, Alere warrants that each product shall be (I) of good quality and free of material defects, (II) function in accordance with the material specifications referenced in the product manual, and (III) approved by the proper governmental agencies required for the sale of products for their intended use (the "Limited Warranty"). If the product fails to meet the requirement of the limited warranty, then as a customer's sole remedy, Alere shall either repair or replace, at Alere's discretion, the product. Except for the limited warranty stated in this section, Alere disclaims any and all warranties, express or implied, including but not limited to, any warranty of merchantability, fitness for a particular purpose and non-infringement regarding the product. Alere's maximum liability with any customer claim shall not exceed the net product price paid by customer. Neither party shall be liable to the other party for special, incidental or consequential damages, including, without limitation, loss of business, profits, data or revenue, even if a party receives notice in advance that these kinds of damages might result.

The Limited Warranty above shall not apply if the Customer has subjected the Product to physical abuse, misuse, abnormal use, use inconsistent with the Product Manual or Insert, fraud, tampering, unusual physical stress, negligence or accidents. Any warranty claim by Customer pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.

Contact Alere

Alere™ Product Support

Contact one of the following Alere™ Product Support Care Centers or your local distributor if you have any questions regarding the use of your Alere™ product. You may also contact us at www.alere.com.

Europe & Middle East
+ (44) 161 483 9032 EMEproductsupport@alere.com

Asia Pacific
+ (61) 7 3363 7711 APproductsupport@alere.com

Africa, Russia, & CIS
+ (972) 8 9429 683 ARCISproductsupport@alere.com

Latin America
+ (57) 01800 094 9393 LAproductsupport@alere.com

Canada
+ (1) 613 271 1144 CANproductsupport@alere.com

US
+ (1) 877 308 8289 USproductsupport@alere.com

Alere™ Customer Service

Contact the following Alere™ Service Care Center or your local distributor for order and billing assistance. You may also contact us at www.alere.com.

Phone	E Mail Address
+ (1) 877 441 7440	clientservices@alere.com

Glossary of Symbols

REF Catalog Number	LOT Batch Code	IVD *In Vitro* Diagnostics
L1 L2 L3 L4 Level 1, Level 2, Level 3 and Level 4	EV Expected Values	CONT Contents
Biological Risks	CAL VER Calibration Verification	Manufacturer
Consult Instructions For Use	Temperature Limitation	YYYYMMDD Use By
EC REP Authorized representative in the European Community		CE Mark

Alere San Diego, Inc.
9975 Summers Ridge Road
San Diego, CA 92121 USA
www.alere.com

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

2011/03