



Cholestech LDX[®] Multianalyte Control

CONTROL**L1|L2**

Package Insert

ENSRC26105B

PN: 26105 Rev. B

Intended Use

Assayed quality control material for use with the Alere Cholestech LDX[®] System.

Summary and Explanation

Alere Cholestech LDX[®] Multianalyte Control (hereafter referred to as Controls) enables users to monitor the performance of total cholesterol (TC), high density lipoprotein cholesterol (HDL), triglycerides (TRG), glucose (GLU), alanine aminotransferase (ALT), and aspartate aminotransferase (AST) test procedures on the Alere Cholestech LDX[®] System.

Reagents

The Controls are 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 the Controls past the expiration date printed on the vial labels.

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 Controls:

- If they are cloudy or have an odor
- If they have been shipped or stored improperly

Materials Provided

Alere Cholestech LDX[®] Multianalyte Control:

Level 1: 2 x 2 mL

Level 2: 2 x 2 mL

Materials Required but Not Provided

- Alere Cholestech LDX[®] System
- Alere Cholestech LDX[®] test cassettes for measuring TC, HDL, TRG, GLU, ALT, and/or AST
- Pipette for the required volume of Controls 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. Refer to the “Quality Control” section of the package insert for the test cassettes you will be using to determine when to run Controls. Quality control material should be used in accordance with local, state, and/or federal regulations or accreditation requirements.
2. Remove one vial each of Level 1 and Level 2 Controls from the refrigerator. Note the expiration date and the date opened on vial labels. Do not use expired Controls.
3. Set the sample type to SAMPLE = “Whole B.” in the analyzer’s configuration menu.
4. Allow vials to sit at room temperature for at least 10 minutes.
5. Test one level of Controls as follows:
 - Refer to the test procedure in the package insert for the test cassette you will be using
 - Mix the control vial by gently inverting at least 7 times
 - Use a pipette for the required volume of Controls specified in the test cassette package insert
 - Follow the procedure for running the test cassette in the package insert
 - Replace the cap on the control vial after use and store at 2–8°C (36–46°F)
 - Dispose of the pipette tip in a puncture resistant waste container
6. Repeat this procedure for the other level of Controls.

Use a new pipette tip for each level of Controls.

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 Controls 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 “Quality Control” and

"Limitations" sections 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 expected values for each analyte. Be sure that the lot numbers on the vials of the Controls correspond to the lot numbers 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 Controls.

If you prefer to set your own ranges, see the "Quality Control" section in the Alere Cholestech LDX® System Procedure Manual for instructions.

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.

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Glossary of Symbols

		
Catalog Number	Batch Code	<i>In Vitro</i> Diagnostics
		
Level 1, Level 2	Expected Values	Contents
		
Biological Risks	Control	Manufacturer
		
Consult Instructions For Use	Temperature Limitation	Use By
		
Authorized representative in the European Community		CE Mark



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