

Storage and Stability

Cholestech LDX Controls are to be stored upright and refrigerated at 2–8°C (36–46°F). Stored under this condition, unopened vials can be expected to give stable results until 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 FREEZE.**



Indications of Product Deterioration

Inability to obtain expected values may indicate product deterioration. Do not use a vial of control if there is evidence of a crack in the vial or microbial growth (cloudiness or odor). If the recovered values are not within the expected ranges:

1. Check expiration date on control vial. Discard outdated products.
2. Review control product package insert and the operating procedure for the Cholestech LDX Analyzer and test cassette, then run a test on a new vial of control.
3. If the values are still outside of the expected ranges, call Cholestech Technical Service at 1.800.733.0404 or 510.732.7200.

Limitations of Procedures

- When pipetting control material remove the pipette tip from the sample well before releasing the plunger or control material may be removed from the sample well causing erroneous results.
- Check the control assay sheet for the correct sample setting for running controls.
- Verify that the lot number on the control vial and the assay sheet are the same. Each control lot has different control ranges.
- Erroneous control results may occur if the control material is not stored according to the storage instructions or if controls are used past the closed or open vial expiration date.
- Discard any vial if there is evidence of product deterioration such as cloudiness or odor.
- This control material is not to be used as a standard or for instrument calibration.
- For more information, refer to the "Limitations" section of the package insert for the test cassette being used or the "Precautions and Warnings" section of the Cholestech LDX System User Manual.

Expected Results

Refer to the assay sheet for expected results. Be sure that the lot number on the vial of control corresponds to the lot number on the assay sheet.

The value and expected range for each analyte are derived from data using several Cholestech LDX Analyzers and cassette lots. The expected range established applies only to this lot of control. If a laboratory prefers to set its own ranges, see the Cholestech LDX System Procedure Manual section "Quality Control" for instructions.

Technical assistance may be obtained by contacting Cholestech Technical Service at 1.800.733.0404 or 510.732.7200.
U.S. Patents 5,614,414 and 5,770,451

Cholestech LDX

Lipid Control

L1 L2

Exp: 2010-03-04

L1 (Red Cap)

L2 (Black Cap)

LOT 9063

LOT 90630506

LOT 90630506

Constituent	Expected Range		Expected Range	
For all Lipid Cassettes				
Total Cholesterol	136-191 mg/dL	3.52-4.94 mmol/L	210-296 mg/dL	5.43-7.66 mmol/L
HDL Cholesterol	25-40 mg/dL	0.65-1.03 mmol/L	51-80 mg/dL	1.32-2.07 mmol/L
Triglycerides	103-152 mg/dL	1.16-1.72 mmol/L	213-313 mg/dL	2.41-3.54 mmol/L
Glucose	100-147 mg/dL	5.55-8.16 mmol/L	223-329 mg/dL	12.38-18.26 mmol/L

Sample Setting

Set the sample type to SAMPLE = "Whole B." in the Cholestech LDX configuration menu.



IVD • For In Vitro Diagnostic Use	REF • Catalog Number	L1 L2 • Level 1 and Level 2	Consult instructions for use	Temperature Limitation
Biological Risks	LOT • Lot Number	Professional Use Only • Professional Use Only	Manufacturer	Use By