

REF 10655 6 X 1.0 mL BOTTLES

CHEMISTRY LDL CALIBRATOR

Vials each containing 1.0 mL of lyophilized, human serum containing lipoproteins from the various lipoprotein classes including low density lipoprotein.

Note: The LDL cholesterol value is traceable to the National Reference System for Cholesterol (NRS/CHOL).

INTENDED USE

For use as the LDL calibrator for the Medica LDL cholesterol test on the Medica EasyRA Chemistry Analyzer.

SAFETY PRECAUTIONS AND WARNINGS

The human source material from which this product has been derived has been tested at the single donor unit basis and found non-reactive for HBsAg, anti-HIV 1 / 2, anti-HCV and HIV-1 Ag.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled and disposed of as though they are capable of transmitting infectious diseases.

INSTRUCTIONS FOR HANDLING, STORAGE AND STABILITY

The dry calibrator is stable until the expiration date on the label if stored at 2-8°C. **DO NOT USE PAST THE EXPIRATION DATE.** After reconstitution, store the calibrator closed at 2° - 8°C. The reconstituted calibrator is stable for 14 days at 2° - 8°C. The reconstituted stability of the calibrator may be extended by aliquoting and freezing the reconstituted calibrator at less than -80° C. Frozen LDL calibrator aliquots are stable for up to 4 weeks at -80° C. **DISCARD ANY VIAL IF THERE IS EVIDENCE OF MICROBIAL CONTAMINATION OR TURBIDITY.**

INSTRUCTIONS FOR USE

1. Before reconstitution, allow the vial to warm to ambient temperature.
2. Carefully reconstitute each vial of lyophilized serum with exactly 1.0 mL of ambient temperature reagent-grade water.
3. Close the vial and allow it to stand for 20 minutes. Mix by gentle swirling or inversion. **Do not shake.**
4. The calibrator should be run before patient samples in accordance with instructions in the EasyRA operators manual and calibrator instructions for use. The calibration frequency is 30 days (maximum).

VALUE ASSIGNMENT

The Table below contains the assigned values for the LDL Calibrator:

Lot No. 25066 Expires: 2026-09-02

Analyte:	Assigned Value	Units
LDL Cholesterol	122	mg/dL

EXPECTED VALUES

The reference range for LDL in serum is as follows according to the National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III) guidelines

LDL Cholesterol – Primary Target of Therapy		
<100	mg/dL	Optimal
100-129	mg/dL	Near optimal/above optimal
130-159	mg/dL	Borderline high
160-189	mg/dL	High
>190	mg/dL	Very high