

MEDICA EASYCAL

REF 10653 6 X 1.0 mL BOTTLES

CHEMISTRY HDL CALIBRATOR

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

Note: The HDL cholesterol value is traceable to the Center for Disease Control (CDC) reference method for HDL.

INTENDED USE

For use as the HDL calibrator for the Medica HDL 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.

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 -70° C. Frozen HDL calibrator aliquots are stable for up to 4 weeks at -70° C.

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.**

VALUE ASSIGNMENT

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

Lot No. 23331 Expires: 2025-06-26

Analyte:	Assigned Value	Units
HDL Cholesterol	60	mg/dL



Medica Corporation, 5 Oak Park Drive
Bedford, MA 01730-1413 USA



Emergo Europe, Prinsessegracht 20
2514 AP The Hague, The Netherlands