

LDL CALIBRATOR

LDL CAL

IVD *in vitro* Diagnostic Kit

Lyophilized calibration serum

REF	Pack Size	Kit Components	Quantity
2011	1x1 mL	Calibrator	1 bottle

Intended use

LDL Calibrator is calibration serum intended for calibration of Direct LDL assay and calibrator is suitable for manual procedure and automated analyzers.

Principle

LDL Calibrator is intended for the calibration of LDL Cholesterol assays using Direct LDL cholesterol reagent.

Composition

This calibrator is a preparation of lyophilized containing LDL lipoproteins and sodium azide.

The LDL calibrator concentration is lot specific.

Preparation

Carefully open the vial, avoiding the loss of lyophilizes, and pipette in exactly 1 mL of distilled/deionized water. Carefully close the vial and dissolve the content by successive swirling. Wait for around 5 minutes until the complete dissolution and homogenize again. Do not shake strongly to avoid formation of foam.

Stability and Storage

Prior to reconstitution: When stored at 2-8°C and protected from light, the calibrator is stable until the expiry date stated on the label.

After reconstitution:

- * Reconstituted calibrator is stable for 14 days at 2-8°C
- * Reconstituted calibrator may be stored frozen at less than -80°C and up to 4 weeks (frozen only once)
- * after opening, the vials should be kept correctly and tightly capped to prevent contamination and evaporation.

Precautions

The calibrator is prepared from plasma donor units tested individually and found to be negative for HbsAg, anti-HCV antibody and anti-HIV 1&2 antibodies. Respect the normal precautions and good laboratory practice. All human material should be considered as potentially infectious. Harmful to aquatic life with long lasting toxic gas. Avoid release to the environment.

Contact with acids liberates very toxic gas.

Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these calibrators always flush with copious amounts of water to prevent azide buildup.

Use clean or single use laboratory equipment only to avoid contaminations.

Waste management

Disposal of all waste material should be in accordance with local and legal requirements.

Procedure

To calibrate with LDL calibrator follow procedure described in Autopak Liquid Direct LDL IFU.

Lot Number	Expiry Date	Value mg/dL

Symbols used on labels


IVD *in vitro* diagnostic medical device


REF Product Code


LOT Lot Number

 Precaution

 Instruction for use

 Manufacturer's address

 Temperature limitation

 Date of Manufacture

 Date of Expiry

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For your queries/suggestions/complaints, please contact the Product Manager at the mentioned details.