Instructions for Use
For *in vitro* diagnostic use

TOPKAL HDL/LDL – CALIBRADOR

TopKal HDL/LDL - Calibrator

Anvisa 80115310095

ORDER INFORMATION

Cat. No.	Kit size
6290002KC	1 x 2 mL
6290004KC	2 x 2 mL

INTENDED USE

Calibrator for use in tests for quantitative in vitro determination of lipids on photometric systems

SUMMARY

TopKal HDL/LDL is a lyophilized calibrator based on human blood material (plasma) with additives of purified material of human origin.

STORAGE AND STABILITY

Unopened, TopKal HDL/LDL is stable until the end of the indicated expiry month if stored at a temperature of 2 – 8 °C.
Once reconstituted, TopKal HDL/LDL calibrator can be used within the period reported in the table below if stored tightly closed at the indicated temperature and bacterial contamination is avoided.
Shelf life of components after reconstitution:

	- 20 °C *	+ 4 °C	+ 25 °C
All analytes	30 days	5 days	8 hours

* Freeze only once!

The established stability criteria is recovery within ± 5% of the initial value.

WARNINGS AND PRECAUTIONS

1. Only blood donations of European origin were used for the production of TopKal HDL/LDL which were found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV. Moreover, HCV and HIV were additionally tested by PCR. As there is no possibility to exclude definitely that products derived from human blood components transmit infectious agents, it is recommended to handle the calibrator with the same precautions used for patient specimens.
2. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
3. For professional use only!

PREPARATION

The lyophilisate is vacuum sealed; therefore, the vial should be opened very carefully to avoid loss of dried material. For reconstitution add exactly 2 mL of distilled water. Close the vial carefully and allow the calibrator to stand for 30 minutes swirling occasionally.
Avoid foaming! Do not shake! Transfer the corresponding quantity needed for calibration into a clean sample cup and treat it the same way as patient samples. Leave frozen aliquots of the reconstituted TopKal HDL/LDL in the dark at room temperature (18 – 25°C) until they are completely unfrozen. To homogenize after complete defrosting, slightly swivel aliquots and use them immediately afterwards for calibration according to the freshly reconstituted TopKal HDL/LDL.

PROCEDURE

Please refer to the reagent package inserts for instructions for use.

WASTE MANAGEMENT

Follow the requirements of the current guidelines about technical regulation for the management of healthcare service waste, as well as other equivalent biosafety practices.

WARRANTY

These instructions for use should be read carefully before using the product and the information contained therein should be strictly adhered to. The reliability of the test results cannot be guaranteed if the instructions are not followed.,

CALIBRATOR VALUES

The concentrations of the calibrator analytes are lot-specific and stated in the value sheet of the corresponding lot. The values were determined by using the specified method and reagents. Determinations were performed according to standardized protocols using Kovalent reagents and TopKal HDL/LDL master calibrator or reference materials. The value sheet contains information regarding the traceability.

*Each laboratory must establish corrective actions in the event of deviations in the recovery of control.

**Changes in the analyte values defined in this calibrator may occur due to restandardization of the reference material.

LITERATURE

1. Myers GL, Cooper GR, Henderson LO, Hassemer DJ, Kimberly MM. Standardization of lipid and lipoprotein measurements. In: Rifai N, Warnick GR, Dominiczak MH, editors. Handbook of lipoprotein testing. Washington: AACC Press; 1997.p. 223-50.
2. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395)

CONSUMER INFORMATION

Symbols used:

	Manufacturer
	Temperature limit
	*In vitro* diagnostic device
	Caution
	Operating instructions
	Recycling material
	Do not discard directly into the environment
	Batch code
	Date of manufacture
	Use by date
	Biological hazards
	Highly toxic
	Corrosive
	Harmful

Manufacturer:

Kovalent do Brasil Ltda.
Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro
São Gonçalo – RJ – CEP 24722-414 - Brasil
www.kovalent.com.br
CNPJ: 04.842.199/0001-56

Customer service: sac@kovalent.com.br - (21) 3907-2534 / 0800 015 1414

Expiration date and Lot no.: See label